

# 20<sup>th</sup>

## Annual Fall Scientific Meeting of SMSNA

November 20 - 23, 2014

Eden Roc Miami Beach,  
Miami, FL



# PROGRAM

## Contact Details

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# Welcome Message

Greetings to all! As President of the Sexual Medicine Society of North America, I am delighted to welcome you all for the 20th Annual Fall Scientific Meeting of our Society. This meeting continues to gain prominence with every passing year with its defined objective to advance the scientific knowledge and practice of sexual medicine in all areas of male and female sexual health.

This fall's meeting continues this unwavering mission. Our scientific program chair, Dr. Tobias Köhler, working collaboratively with the Scientific Program Committee, has assembled an outstanding program of master lecturers, panels, point- counterpoint debates, and poster sessions that provide a wealth of information in diverse topical areas encompassing exciting and timely advances in our field. The program will be of interest to specialists in all disciplines of sexual medicine whether you are a physician, mental health clinician, scientific researcher, non-physician practitioner, or health professional of any kind.

An outstanding social program has been assembled that incorporates several festive events that will delight you, as one would expect from a visit to Miami, with its abundant culture, cuisine, and history. This includes "Fun in the Sun", with plenty of exciting activities for the entire family on our beautiful white sand beaches at the wonderful Eden Roc Resort, and many other highlights that South Florida has to offer. In addition, there are several optional 'family friendly' activities, as well as tours of famous sites in and around the area. The Welcome Reception on Thursday evening will feature cocktails and hors d'oeuvres specially prepared by the master chefs at the Eden Roc Hotel. Our traditional "Taste of Miami" on Friday evening, showcasing our local culture and cuisine, will be an event not to be missed! (Those of you who attended our last "Taste of Miami" know what I mean!).

The success of our meeting could not be experienced if it were not for the significant time commitment and efforts of Tessa Benitez, Vivian Gies and David Casalod, from our outstanding Management Group, Status Plus. I also want to recognize and thank my wife, Lisa, for all of her time and input in helping us to assemble a world-class event. The society has gained a rich tradition of inclusiveness, scholarship, and camaraderie that is well displayed with its every year's scientific meetings. This year's fall meeting is no exception. Thank you for your energy and commitment towards making our Society special and the premier organization in North America devoted to preserving the sexual health of men and women.



**Lawrence S. Hakim, MD, FACS**

Chairman, Department of Urology  
Cleveland Clinic Florida

# Committees

## SMSNA Board of Directors

### **President**

Lawrence S. Hakim, MD, FACS

### **President-Elect**

Run Wang, MD, FACS

### **Secretary**

Hossein Sadeghi-Nejad, MD, FACS

### **Treasurer**

Serge Carrier, MD

### **Past President**

Arthur L. Burnett II, MD

### **Member at Large**

Nelson Bennett Jr., MD

Trinity J. Bivalacqua, MD, PhD

Brian S. Christine, MD

Andrew C. Kramer, MD

Christian Nelson, PhD

Alan W. Shindel, MD

### **Website Committee Chair**

Mohit Khera, MD

### **Meeting Committee Chair**

Tobias S. Kohler, MD, MPH

### **Surgical Committee Chair**

Brian S. Christine, MD

## Past Presidents

**2012-2013** Arthur L. Burnett II, MD

**2011** John P. Mulhall, MD

**2010** Ronald W. Lewis, MD

**2009** Ajay Nehra, MD

**2008** Craig F. Donatucci, MD

**2007** Laurence A. Levine, MD

**2006** Tom F. Lue, MD

**2005** Gregory Broderick, MD

**2004** Wayne J.G. Hellstrom, MD

**2003** Culley C. Carson, III, MD

**2002** Ira D. Sharlip, MD

**2001** Robert P. Nelson, Jr., MD \*

**2000** John J. Mulcahy, MD

**1999** Irwin Goldstein, MD

**1998** Arnold Melman, MD

**1997** Alvaro Morales, MD

**1996** Drogo K. Montague, MD

**1995** William F. Furlow, MD

\* deceased

# CME Infomation

## Activity Overview and Description

The 2014 SMSNA Annual Fall Scientific meeting will promote, encourage, and support the highest standards of practice, research, education, and ethics in the study of the anatomy, physiology, pathology, diagnosis, and treatment of human sexual function and dysfunction and provide a forum for the free exchange and discussion of new ideas, thoughts, and concepts in this field.

The SMSNA seeks to identify existing and emerging issues in the field of human sexual function and dysfunction, provide accurate and credible information to medical professionals, develop standards and guidelines for sexual medicine research and practice, and produce educational programs that bring leading-edge concepts of research, clinical practice, ethics, and politics to health care professionals interested in sexual medicine and related matters.

## Target Audience

This educational activity will be of interest to urologists, primary care physicians, internists, cardiologists, endocrinologists, gynecologists, psychiatrists, psychologists, therapists, physician assistants, nurse practitioners, residents, fellows, medical students, and researchers interested in sexual medicine.

## Learning Objectives

Upon completion of this activity, participants should be better able to:

- Identify medication and treatments commonly advertised that have been debunked as successful treatments.
- Describe both biochemical and clinical effects of smoking and smoking cessation, poor and healthy dietary choices, body weight, and exercise on

erectile and prostate function.

- Identify the link between erectile dysfunction and cardiovascular disease.
- List key questions to ask in medical histories for patients with sexual dysfunction.
- Describe psychiatric medications commonly used and how they both negatively and positively affect patients with sexual dysfunction.
- List the key personality components that correlate with patient satisfaction for surgery and/or treatment in patients with sexual dysfunction.
- Interpret the current state-of-the-art knowledge in epidemiology, physiology and pathophysiology of female sexual function and dysfunction.
- Understand the risk and benefits of both testosterone replacement to eugonadal and supra-gonadal levels. Explain the relationship between testosterone, estrogen and sex hormone binding globulin and their physiologic effects. Describe the impact Testosterone on development and physiology of sexual organs.
- Understand common and uncommon complications of Peyronie's disease surgery and genitourinary reconstruction. Know the risks and benefits of treatment pathways as pertains to simultaneous implant and incontinence procedures, complex incontinence where an artificial sphincter is not always the answer, ESWL and collagen fleece for the treatment of Peyronie's disease, choice of grafting materials, and treatment of penile fractures.
- Explain the evidence supporting and refuting post prostatectomy penile rehabilitation strategies.
- Understand common and uncommon complications of penile implant surgery. Know the risks and benefits of treatment pathways as pertains to sizing of cylinders, the use of malleable implants

# Accreditation



only for washout procedures, intentionally leaving reservoirs in situ for non-infected implant removal and routine placement of ectopic reservoirs after robot prostatectomy. Understand the basic science, pathophysiology and best strategies for prevention of penile implant infection.

- Identify challenges and opportunities in sexual medicine education. Summarize techniques to become a better educator, use simulation and the internet in teaching programs and improve feedback.

## **Method of Participation**

In order to meet the learning objectives and receive continuing education credits, participants are expected to check in at the registration desk each day of the program, attend the program and complete an on-line evaluation and credit request form at the conclusion of the activity. A letter certifying your attendance and credit verification will be mailed to you within 30 days following the completion of the online evaluation and credit request form.

## **Physicians**

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Rutgers, The State University of New Jersey and the Sexual medicine Society of North America. Rutgers, The State University of New Jersey is accredited by the ACCME to provide continuing medical education for physicians.

Rutgers, The State University of New Jersey designates this live activity for a maximum of 19.5 *AMA PRA Category 1 Credits*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity\*.

\* subject to change

# Faculty Information

Michael A. Adams, PhD  
*Queen's University*

Maarten Albersen, MD  
*University Hospital Leuven*

Richard Balon, MD  
*Department of Psychiatry*

Nelson Bennett Jr., MD  
*Lahey Clinic Medical Center*

William O. Brant, MD  
*University of Utah*

Arthur L. Burnett II, MD  
*Johns Hopkins Hospital*

Rafael E. Carrion, MD  
*USF Urology*

Selim Celtek, MD, PhD  
*Cranfield University*

William P. Conners, MD  
*Men's Health Boston*

Michael E. DiSanto, PhD  
*Rowan University*

Michael P. Finkelstein, MD  
*Urology Specialists of Nevada*

Andrew T. Goldstein, MD, FACOG  
*Center For Vulvovaginal Disorders*

Nestor Gonzalez-Cadavid, PhD  
*Harbor-UCLA Medical Center*

Lawrence S. Hakim, MD, FACS  
*Cleveland Clinic Florida*

Georgios Hatzichristodoulou, MD, FEBU, FECSM  
*TU Munich, Klinikum rechts der Isar*

Gerard D. Henry, MD  
*Regional Urology LLC*

Edward Karpman, MD  
*El Camino Urology Medical Group*

Tobias S. Köhler, MD, MPH  
*Southern Illinois University - School of Medicine*

Justin D. La Favor, PhD  
*Johns Hopkins University*

Laurence A. Levine, MD  
*Urology Specialists, SC*

Kurt McCammon, MD  
*Urology of Virginia*

Chris McMahon, MD  
*Australian Centre for Sexual Health*

Douglas F. Milam, MD  
*Vanderbilt University Medical Center*

Kenneth Mitchell, MPAS, PA-C  
*Metro Urology*

John J. Mulcahy, MD, PhD  
*University of Alabama*

Ricardo M. Munarriz, MD  
*Boston Medical Center*

Joseph B. Narus, DNP, APRN, NP-BC  
*Memorial Sloan-Kettering Cancer Center*

Sijo J. Parekattil, MD  
*South Lake Hospital, in partnership with Orlando Health*

Carol A. Podlasek, PhD  
*University of Illinois at Chicago*

David Ralph, MS, FRCS  
*St. Peter's Andrology*

Bonnie R. Saks, MD  
*University of South Florida*

Alan W. Shindel, MD  
*University of California at Davis*

Doron S. Stember, MD  
*Beth Israel Medical Center*

Ryan Terlecki, MD  
*Wake Forest University*

Landon W. Trost, MD  
*Mayo Clinic*

Steven K. Wilson, MD  
*Institute for Urologic Excellence*



# Peer Review

In order to help ensure content objectivity, independence, and fair balance, and to ensure that the content is aligned with the interest of the public, CCOE has resolved all potential and real conflicts of interest through content review by a non-conflicted, qualified reviewer. This activity was peer-reviewed for relevance, accuracy of content, and balance of presentation by:

Alan W. Shindel, MD  
*University of California, Davis*

Landon W. Trost, MD  
*Mayo Clinic - Department of Urology*

# Disclosure Declarations

In accordance with the disclosure policies of Rutgers and to conform with ACCME and FDA guidelines, individuals in a position to control the content of this educational activity are required to disclose to the activity participants: 1) the existence of any relevant financial relationship with any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients, with the exemption of non-profit or government organizations and non-health care related companies, within the past 12 months; and 2) the identification of a commercial product/device that is unlabeled for use or an investigational use of a product/device not yet approved.

## Faculty

Published in a separate booklet.

## Peer Reviewers

Alan W. Shindel, MD and Landon W. Trost, MD have no relevant financial relationships to disclose.

## Rutgers Staff

Elizabeth Ward, MSJ, Executive Director and Tristan Nelsen, MNM, CMP, Senior Program Manager, have no relevant financial relationships to disclose.

## Sexual Medicine Society of North America Staff

David Casalod, Executive Director, Tessa Benitez, Association Manager, Vivian Gies, Meeting Manager and Kate Ray, Director of Education have no relevant financial relationships to disclose.

## Off-Label/Investigational Use

This activity contains information on commercial products/devices that are unlabeled for use or investigational uses of products not yet approved. Faculty will disclose off-label/investigational uses within their presentations.

## Disclaimer

The views expressed in this activity are those of the faculty. It should not be inferred or assumed that they are expressing the views of any manufacturer of pharmaceuticals or devices, Rutgers or Sexual Medicine Society of North America.

It should be noted that the recommendations made herein with regard to the use of therapeutic agents, varying disease states, and assessments of risk, are based upon a combination of clinical trials, current guidelines, and the clinical practice experience of the participating presenters. The drug selection and dosage information presented in this activity are believed to be accurate. However, participants are urged to consult all available data on products or procedures before using them in clinical practice.

Rutgers and the Sexual Medicine Society of North America reserve the right to modify the activity content and faculty if necessary.

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For questions or concerns regarding this activity, please call the SMSNA Executive Office: (910) 667 2457.

# General Meeting Information


## Meeting Date and Venue

Thursday November 20 - Sunday November 23, 2014  
Eden Roc Miami  
4525 Collins Ave  
Miami Beach, FL 33140

## Registration/Information Desk Hours

Thursday November 20, 2014: 08:00 a.m. - 08:00 p.m.  
Friday November 21, 2014: 06:00 a.m. - 06:15 p.m.  
Saturday November 22, 2014: 06:00 a.m. - 06:15 p.m.  
Sunday November 23, 2014: 07:00 a.m. - 10:15 a.m.

## Speaker Center

 *Location: Promenade A*

Thursday November 20, 2014: 08:00 a.m. - 08:00 p.m.  
Friday November 21, 2014: 06:00 a.m. - 06:15 p.m.  
Saturday November 22, 2014: 06:00 a.m. - 06:15 p.m.  
Sunday November 23, 2014: 07:00 a.m. - 10:15 a.m.

## Exhibit Hall Hours

Thursday November 20, 2014: 12:00 p.m. - 08:00 p.m.  
Friday November 21, 2014: 08:30 a.m. - 04:30 p.m.  
Saturday November 22, 2014: 08:30 a.m. - 04:30 p.m.

## Mobile App

The complete program of the 20th Annual Fall Scientific Meeting of SMSNA is available on an app for your mobile device (Android and iOS).

Download the app in the App Store (Apple) or Google Play Store (Android) or manually by searching for “statusplus”. Once downloaded and installed, you can find our event in the “Available Events” section. Simply tap the “Install Event” button to download all event content into the app. Now, all content is contained locally on your device and you can use the app without having to be connected to the Internet.

## Syllabus/presentations

The syllabus/presentations will be available on a password-secured part of the SMSNA website after the CME activity.

Log in details:

Username: smsna2014

Password: presentnow

## Evening Functions

### Welcome Reception

**Date:** Thursday November 20, 2014

**Time:** 06:30 p.m. - 08:00 p.m.

**Location:** Ocean Tower I

**Attire:** Business casual

Welcome to the 20th Annual Fall Scientific Meeting of SMSNA! Catch up with friends and colleagues, and meet with exhibitors following the first day of the scientific program.

### Taste of Miami

**Date:** Friday November 21, 2014

**Time:** 07:00 p.m. - 11:00 p.m.

**Location:** Ocean Garden, Eden Roc Miami Beach

**Attire:** Business casual

**Cost:** \$75

Tickets available at Registration/Information Desk

- Great food
- Cocktails
- Live Latin music of Cachet Music Band
- Authentic cigar rolling

# Scientific Program » Thursday November 20, 2014

\* = not CME-certified

09:00 a.m. - 10:45 a.m.

## ⚡ APN-PA symposium - part 1

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📍 Pompeii Ballroom

👤 Moderator: Kenneth Mitchell, MPAS, PA-C

09:00 a.m. - 09:05 a.m.

### Welcome/Program overview

Kenneth Mitchell, MPAS, PA-C

09:05 a.m. - 09:30 a.m.

### Post pelvic surgery/Radiation penile rehab/ Injection program

Joseph B. Narus, DNP, APRN, NP-BC &

Landon W. Trost, MD

09:30 a.m. - 09:55 a.m.

### Controversy with Testosterone Replacement Therapy (TRT)

Kevin Flinn, RN

09:55 a.m. - 10:20 a.m.

### Chronic orchialgia

Sijo J. Parekattil, MD

10:20 a.m. - 10:45 a.m.

### Penile implant - perioperative management

Brian S. Christine, MD

10:45 a.m. - 11:00 a.m.

## ⚡ Break

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📍 Ocean Tower I Foyer

11:00 a.m. - 12:15 p.m.

## ⚡ APN-PA symposium - part 2

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📍 Pompeii Ballroom

👤 Moderator: Kenneth Mitchell, MPAS, PA-C

11:00 a.m. - 11:25 a.m.

### Female sexual dysfunction

Brooke Faught, MSN, WHNP-BC

11:25 a.m. - 11:50 a.m.

### Genital piercings/mutilation

Jorge Caso, MD

11:50 a.m. - 12:15 p.m.

### Imaging in sexual medicine

Douglas F. Milam, MD

12:30 p.m. - 02:00 p.m.

## ⚡ Sponsored lunch symposium

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📍 Ocean Tower II B/C

02:00 p.m. - 02:05 p.m.

## ⚡ Welcome

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📍 Pompeii Ballroom

Lawrence S. Hakim, MD, FACS

02:05 p.m. - 02:10 p.m.

## ⚡ Meeting overview

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📍 Pompeii Ballroom

Tobias S. Köhler, MD, MPH

02:10 p.m. - 03:55 p.m.

## ⚡ Lifestyle changes and sexual medicine: What should we really be telling our patients?

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📍 Pompeii Ballroom

👤 Moderators: Kenneth Mitchell, MPAS, PA-C &  
Christopher J. Wingard, PhD, MS

02:10 p.m. - 02:25 p.m.

### Introduction & basic science overview

Christopher J. Wingard, PhD, MS

# Scientific Program

\* = not CME-certified

02:25 p.m. - 02:40 p.m.

## **Cigarette smoking is a definitive risk factor for ED**

*Arthur L. Burnett II, MD & Hossein Sadeghi-Nejad, MD, FACS*

02:40 p.m. - 02:55 p.m.

## **Diet & exercise effect on sexual med ED, low T**

*Jason M. Greenfield, MD*

02:55 p.m. - 03:10 p.m.

## **The basic science of western diet & ED**

*Michael A. Adams, PhD*

03:10 p.m. - 03:25 p.m.

## **Prostate and diet/lifestyle**

*Aaron Spitz, MD*

03:25 p.m. - 03:40 p.m.

## **Biochemical and physiological basis of improvement in body composition & sexual function with lifestyle change and pharmacotherapy**

*Abdulmageed Traish, PhD*

03:40 p.m. - 03:55 p.m.

## **Recent non sexual medicine landmark findings all sexual medicine providers must know**

*Martin Miner, MD*

03:55 p.m. - 04:15 p.m.

## **ⓘ Break**

📍 *Ocean Tower I*

04:15 p.m. - 05:30 p.m.

## **ⓘ ED & BPH treatments: New strategies, new snake-oils**

📍 *Pompeii Ballroom*

👤 *Moderators: Eric L. Laborde, MD & Hossein Sadeghi-Nejad, MD, FACS*

04:15 p.m. - 04:30 p.m.

## **New BPH treatment paradigms**

*Kevin T. McVary, MD*

04:30 p.m. - 04:45 p.m.

## **ED & SM supplements & internet drugs**

*William P. Conners, MD*

04:45 p.m. - 05:00 p.m.

## **ESWL and ED**

*Trinity J. Bivalacqua, MD, PhD*

05:00 p.m. - 05:10 p.m.



## **Podium presentation: 001.**

**Impact on sexual function and two year durability of the prostatic urethral lift: A multi-center, prospective, randomized**

## **study**

*Butcher, M.J.<sup>1</sup>; Roehrborn, C.G.<sup>2</sup>; Gange, S.N.<sup>3</sup>; Bolton, D.M.<sup>4</sup>; Te, A.E.<sup>5</sup>; Shore, N.D.<sup>6</sup>; Chin, P.T.<sup>7</sup>; Rashid, P.<sup>8</sup>; Rukstalis, D.B.<sup>9</sup>; McVary, K.T.<sup>10</sup>*

*1: Southern Illinois University, USA; 2: University of Texas Southwestern Medical Center, USA; 3: Western Urological Clinic, USA; 4: Austin Hospital, Australia; 5: Weill Cornell Medical College, USA; 6: Carolina Urological Research Center, USA; 7: Figtree Private Hospital, Australia; 8: Port Macquarie Private Hospital, Australia; 9: Wake Forest Baptist Health, USA; 10: Southern Illinois University School of Medicine, USA*

05:10 p.m. - 05:30 p.m.

## **Discussion**

05:30 p.m. - 06:30 p.m.

## **ⓘ Female sexual medicine: New frontier**

📍 *Pompeii Ballroom*

👤 *Moderators: Lawrence S. Hakim, MD, FACS & Johanna Hannan, PhD*

# Scientific Program

\* = not CME-certified

05:30 p.m. - 05:50 p.m.

**1st Dr. Robert J. Krane annual lecture**

*Irwin Goldstein, MD*

05:50 p.m. - 06:05 p.m.

**Female sexual dysfunction & CAG repeats**

*Andrew T. Goldstein, MD, FACOG*

06:05 p.m. - 06:20 p.m.

**Basic science in FSD**

*Johanna Hannan, PhD*

06:20 p.m. - 06:30 p.m.



**Podium presentation: 002.**

**5 alpha reductase enzyme  
deficiency: A new  
pathophysiology of female sexual  
dysfunction**

*Cohen, S.D.<sup>1</sup>; Gonzalez, J.R.<sup>1</sup>; Gagnon, C.<sup>1</sup>; Minton,  
J.N.<sup>1</sup>; Espenschied, C.<sup>2</sup>; Goldstein, I.<sup>3</sup>*

*1: San Diego Sexual Medicine, USA; 2: San Diego Sexual  
Medicine, United States; 3: Alvarado Hospital, USA*

06:30 p.m. - 08:00 p.m.

**! Welcome reception**

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 *Ocean Tower I*

# Scientific Program » Friday November 21, 2014

\* = not CME-certified

06:45 a.m. - 07:45 a.m.

## **Sponsored breakfast symposium**

**📍** Ocean Tower II B/C

07:45 a.m. - 08:00 a.m.

## **Day introduction and recap of Thursday**

**📍** Pompeii Ballroom

Tobias S. Köhler, MD, MPH

08:00 a.m. - 09:00 a.m.

## **Psychology and sexual dysfunction**

**📍** Pompeii Ballroom

**👤** Moderators: Stanley Althof, PhD, IF &  
Christian Nelson, PhD

08:00 a.m. - 08:15 a.m.

### **Psychiatric drugs in sexual medicine: The good, the bad and the ugly**

Bonnie R. Saks, MD

08:15 a.m. - 08:30 a.m.

### **The cursed penis: Optimizing surgical patient selection**

Landon W. Trost, MD

08:30 a.m. - 08:45 a.m.

### **Key concepts & questions to optimize diagnosis & treatment of sexual dysfunction**

Michael A. Perelman, PhD

08:45 a.m. - 08:55 a.m.



**Podium presentation: 003.**  
**Effect of testosterone solution**  
**2% for the treatment of**  
**ejaculatory dysfunction in**  
**androgen-deficient men\***

*Paduch, D.A.<sup>1</sup>; Polzer, P.<sup>2</sup>; Ni, X.<sup>2</sup>; Basaria, S.<sup>3</sup>*

1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA

08:45 a.m. - 08:55 a.m.



### **Podium presentation: 004.**

**Prevalence of ejaculatory**  
**dysfunctions as a function of**  
**testosterone\***

*Paduch, D.A.<sup>1</sup>; Polzer, P.<sup>2</sup>; Morgentaler, A.<sup>3</sup>; Althof, S.E.<sup>4</sup>; Ni, X.<sup>2</sup>; Patel, A.B.<sup>2</sup>; Basaria, S.<sup>3</sup>*

1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA; 4: Center for Marital and Sexual Health of South Florida, USA

08:45 a.m. - 08:55 a.m.



### **Podium presentation: 005.**

**Perceived sexual dissatisfaction**  
**with ejaculatory dysfunctions\***

*Paduch, D.A.<sup>1</sup>; Polzer, P.<sup>2</sup>; Morgentaler, A.<sup>3</sup>; Althof, S.E.<sup>4</sup>; Ni, X.<sup>2</sup>; Patel, A.B.<sup>2</sup>; Basaria, S.<sup>3</sup>*

1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA; 4: Center for Marital and Sexual Health of South Florida, USA

09:00 a.m. - 10:30 a.m.

## **Truths in testosterone**

**📍** Pompeii Ballroom

**👤** Moderators: Mohit Khera, MD &  
Tobias S. Köhler, MD, MPH

09:00 a.m. - 09:20 a.m.

### **Testosterone replacement and CV risks**

Abraham Morgentaler, MD

09:20 a.m. - 09:40 a.m.

### **The role of estrogen and SHBG**

Michael P. Finkelstein, MD

09:40 a.m. - 10:10 a.m.

### **The realities and secrets of anabolic steroid abuse**

Chad Schaive

# Scientific Program

\* = not CME-certified

10:10 a.m. - 10:20 a.m.



**Podium presentation: 006.**  
**A descriptive analysis to compare the occurrence of myocardial infarction in testosterone-treated and untreated hypogonadal males and PDE5-inhibitor users\***

Li, H.<sup>1</sup>; Benoit, K.<sup>1</sup>; Michael, J.<sup>1</sup>; Motsko, S.<sup>1</sup>

1: Eli Lilly and Company, USA

10:20 a.m. - 10:30 a.m.



**Podium presentation: 007.**  
**Clomiphene citrate is superior to anastrozole in raising testosterone in hypogonadal infertile men: A prospective**

**randomized double blind comparison trial**

Helo, S.<sup>1</sup>; Mechlin, C.<sup>2</sup>; Alkaram, A.<sup>3</sup>; McCullough, A.<sup>3</sup>

1: Albany Medical Center, USA; 2: Urology Associates of Central Missouri, USA; 3: The Urologic Institute of Northeastern New York, USA

10:30 a.m. - 10:55 a.m.

**Break & poster viewing time**

**Ocean Tower I**

10:55 a.m. - 11:55 a.m.

**Moderated posters 1 – Androgens & Hypogonadism 1**

» Concurrent session

**Ocean Tower II A**

**Moderators: Andrew R. McCullough, MD & Abraham Morgentaler, MD**



**030. Change in hematocrit during treatment of hypogonadism via implantable testosterone pellets**

Hayden, R.<sup>1</sup>; Bennett, N.<sup>2</sup>; Tanrikut, C.<sup>1</sup>

1: MGH, USA; 2: Lahey Clinic, USA



**031. Daily dose and costs associated with maintenance therapy of topical testosterone agents among hypogonadal men\***

Kaltenboeck, A.<sup>1</sup>; Boytssov, N.<sup>2</sup>;

Hayes-Larson, E.<sup>1</sup>; San Roman, A.M.<sup>1</sup>; Ivanova, J.<sup>1</sup>; Birnbaum, H.G.<sup>1</sup>; Foster, S.A.<sup>2</sup>; Vazquez, J.A.<sup>2</sup>; Muram, D.<sup>2</sup>; Swindle, R.W.<sup>2</sup>

1: Analysis Group, Inc, USA; 2: Eli Lilly and Co, USA



**032. Hypogonadism in the infertile population: Different or the same?**

Levey, H.R.<sup>1</sup>; Kukreja, J.<sup>1</sup>; Kucherov, V.<sup>1</sup>; Smith, A.<sup>1</sup>; Ramasamy, R.<sup>2</sup>;

Gentile, D.<sup>1</sup>; Fung, C.<sup>1</sup>; Obrien, J.<sup>1</sup>

1: University of Rochester, Rochester, NY, USA; 2: Baylor College of Medicine, Houston TX, USA



**033. Pharmacokinetics and efficacy of a new SEDDS formulation of oral Testosterone Undecanoate (TU) in hypogonadal men: Data from two phase 3 trials**

**with different dose-titration algorithms\***

Swerdlhoff, R.S.<sup>1</sup>; Salameh, W.<sup>2</sup>; Dobs, A.<sup>3</sup>; Longstreth, J.<sup>4</sup>; Faulkner, S.<sup>2</sup>; Dudley, R.<sup>2</sup>; Flippo, G.<sup>5</sup>; Kaminetsky, J.<sup>6</sup>; Amory, J.<sup>7</sup>; Danoff, T.<sup>2</sup>; Honig, S.H.<sup>8</sup>; Wang, C.<sup>9</sup>

1: UCLA, USA; 2: Clarus Therapeutics, USA; 3: Johns Hopkins, USA; 4: Longstreth and Assoc, USA; 5: Alabama Clinical Therapeutics, USA; 6: University Urology Assoc, USA; 7: University of Washington, USA; 8: Yale University; 9: UCLA, USA



**034. Low testosterone at time of transplant independently predicts poor patient and graft survival in male renal transplant recipients**

Shoskes, D.<sup>1</sup>; Kerr, H.<sup>1</sup>; Askar, M.<sup>1</sup>;

Goldfarb, D.<sup>1</sup>; Schold, J.<sup>1</sup>

1: Cleveland Clinic, USA



# Scientific Program

\* = not CME-certified



**035. Application of the Endocrine Society clinical guidelines on testosterone therapy in men with androgen deficiency syndromes in clinical practice\***

Muram, D.<sup>1</sup>; Matsumoto, A.<sup>2</sup>; Zhang, X.<sup>1</sup>; Cui, Z.<sup>1</sup>

1: Lilly Research Laboratories, USA; 2: Geriatric Research, Education and Clinical Center, VA Puget Sound Health Care System, USA



**036. HCG can assist with recovery of spermatogenesis after testosterone use**

Wenker, E.P.<sup>1</sup>; Dupree, J.M.<sup>1</sup>; Langille, G.M.<sup>1</sup>; Kovac, J.<sup>1</sup>;

Ramasamy, R.<sup>1</sup>; Lamb, D.<sup>1</sup>; Mills, J.N.<sup>2</sup>; Lipshultz, L.I.<sup>1</sup>

1: Baylor College of Medicine, USA; 2: The Urology Center of Colorado, USA



**037. Androgen receptor CAG repeat length polymorphism is associated with risk of metabolic syndrome in a Korean male**

Kim, J.W.<sup>1</sup>; Bae, Y.D.<sup>1</sup>; Yoon, C.Y.<sup>1</sup>;

Kim, J.J.<sup>1</sup>; Moon, D.G.<sup>1</sup>

1: Korea University College of Medicine, Korea, South



**038. The effect of testosterone restorative therapy (TRES) on testicular volume. Results from a double blind randomized 12 week trial of clomiphene citrate**

**vs anastrozole**

McCullough, A.<sup>1</sup>; Xu, R.<sup>2</sup>; Helo, S.<sup>2</sup>; Elebyjian, L.<sup>2</sup>; Feustel, P.<sup>2</sup>

1: Albany Medical College, USA; 2: Albany Medical College



**039. Association between testosterone therapy and thrombotic events in elderly men**

Ramasamy, R.<sup>1</sup>; Scovell, J.<sup>2</sup>; Mederos, M.<sup>2</sup>; Mai, C.<sup>1</sup>; Cross, R.<sup>1</sup>;

Ran, R.<sup>1</sup>; Besada, S.<sup>1</sup>; Lipshultz, L.<sup>1</sup>

1: Baylor College of Medicine, USA; 2: Baylor College of Medicine, USA



**040. Effect of testosterone supplementation on symptoms in men with hypogonadism**

Wilken, N.<sup>1</sup>; Scovell, J.<sup>1</sup>; Ramasamy, R.<sup>1</sup>; Lipshultz, L.<sup>1</sup>

1: Baylor College of Medicine, USA

10:55 a.m. - 11:55 a.m.

## ⓘ Moderated posters 2 – BPH & Ejaculation

» Concurrent session

📍 Mona Lisa

👤 Moderators: Eric L. Laborde, MD & Alan W. Shindel, MD



**041. Delayed ejaculation remains a recalcitrant condition: Results of a SMSNA survey**

Butcher, M.<sup>1</sup>; Sadowski, D.<sup>1</sup>;

Botchway, A.<sup>1</sup>; Welliver, C.<sup>1</sup>; Kohler, T.<sup>1</sup>

1: Southern Illinois University SOM, USA



**042. Sexual function associated with lower urinary tract symptoms in men with benign prostatic hyperplasia: MTOPS cohort of cross-sectional and**

**longitudinal data**

Butcher, M.<sup>1</sup>; Fwu, C.<sup>2</sup>; Kirkali, Z.<sup>3</sup>; Kohler, T.<sup>4</sup>;

Burrows, P.<sup>5</sup>; Eggers, P.<sup>3</sup>; Kusek, J.<sup>3</sup>; McVary, K.<sup>4</sup>

# Scientific Program

\* = not CME-certified

1: Southern Illinois University, USA; 2: Social & Scientific Systems, Inc., Silver Spring, MD, USA; 3: Division of Kidney, Urologic, and Hematologic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, MD, USA; 4: Department of Urology, Southern Illinois University, Springfield, IL, USA; 5: The George Washington University Biostatistics Center, Rockville, MD, USA



## 043. Acceptance of a pre-operative educational seminar about recovery from side-effects after prostate cancer surgery

Paich, K.<sup>1</sup>; Dunn, R.<sup>1</sup>; Skolarus, T.<sup>1</sup>;

Montie, J.<sup>1</sup>; Palapattu, G.<sup>1</sup>; Wood, D.<sup>2</sup>; Mitchell, S.<sup>1</sup>; Hola, V.<sup>1</sup>; Erickson, K.<sup>1</sup>; Shifferd, J.<sup>1</sup>; Wittmann, D.<sup>1</sup>

1: University of Michigan, USA; 2: Beaumont Health System, USA



## 044. Crossover study of the prostatic urethral lift: Analysis of lower urinary tract symptoms

Gange, S.N.<sup>1</sup>; Cantwell, A.L.<sup>2</sup>; Shore, N.D.<sup>3</sup>; Fagelson, J.E.<sup>4</sup>; Woo, H.H.<sup>5</sup>;

Barkin, J.<sup>6</sup>; Dowling, W.T.<sup>7</sup>; Chin, P.T.<sup>8</sup>

1: Western Urological Clinic, USA; 2: Atlantic Urological Associates, USA; 3: Carolina Urological Research Center, USA; 4: Urology Associates of Denver, USA; 5: University of Sydney, Australia; 6: University of Toronto, Canada; 7: Chesapeake Urology, USA; 8: Figtree Private Hospital, Australia



## 045. Effects of tamsulosin on premature ejaculation in men with LUTS/BPH

Hyun, J.S.<sup>1</sup>; Kam, S.C.<sup>1</sup>; Jae, S.W.<sup>1</sup>; Yun, S.<sup>1</sup>

1: Gyeongsang National University Hospital



## 046. Screening for low testosterone during urology office visits without referral for hypogonadism

Sauer, A.<sup>1</sup>; Omarbasha, B.<sup>2</sup>; Mouraviev, V.<sup>3</sup>

1: Binghamton University, USA; 2: Upstate University, USA; 3: AMP Urology, USA



## 047. Non-medicinal components are an important factor in drug delivery in topical therapies: A study of topical lidocaine therapy for premature ejaculation

Garcia, F.<sup>1</sup>; Capomacchia, A.<sup>2</sup>; Kongkeo, S.<sup>3</sup>; Brock, G.<sup>4</sup>

1: University of Saskatchewan, Cypress Health Region, Canada; 2: University of Georgia, College of Pharmacy, Athens, GA, U.S.A.; 3: Absorption Pharmaceutical, Huntington Beach, CA, U.S.A.; 4: Western University, St. Joseph's Health Care, London, ON, Canada



## 048. Low T predicts worse LUTS: Final results of the CUPPID study

Kottwitz, M.<sup>1</sup>; Koenig, J.<sup>1</sup>; Stevenson, B.<sup>1</sup>; Sulaver, R.<sup>1</sup>; Bednarchik, C.<sup>1</sup>; Welliver Jr, C.<sup>2</sup>;

McVary, K.<sup>1</sup>; Kohler, T.S.<sup>1</sup>

1: Southern Illinois University SOM, USA; 2: Albany Medical Center



## 049. Buspirone in the treatment of chronic orchalgia

Liaw, A.<sup>1</sup>; Lowe, G.<sup>1</sup>

1: Ohio State University, USA



## 050. Trigger point injections: A new treatment strategy for sexual pain

Bahlani, S.<sup>1</sup>; Moldwin, R.<sup>1</sup>; King, A.<sup>1</sup>

1: North Shore-LIJ, USA

# Scientific Program

\* = not CME-certified



## 051. Characterization of voiding dysfunction in adults with sickle cell disease

Anele, U.<sup>1</sup>; Morrison, B.F.<sup>2</sup>; Burnett, A.L.<sup>1</sup>

1: Brady Urological Institute, The Johns Hopkins School of Medicine, USA; 2: University of the West Indies, Jamaica

12:00 p.m. - 01:30 p.m.

### ! SMSNA lunch and learn symposium -

#### Contemporary management of Peyronie's disease: An interactive case-based lunch and learn symposium

📍 Ocean Tower II B/C

👤 Moderator: John P. Mulhall, MD

The CME-certified symposium will consist of three case presentations, the use of audience response system (ARS) and open questions and answers

Wayne J.G. Hellstrom, MD, David Ralph, MS, FRCS & Landon W. Trost, MD

01:30 p.m. - 03:50 p.m.

### ! Translational perspective on the role of testosterone in sexual function and dysfunction (white paper session)

» Concurrent session

📍 Pompeii Ballroom

👤 Moderators: Michael E. DiSanto, PhD & Carol A. Podlasek, PhD

01:30 p.m. - 01:40 p.m.

#### Introduction and clinical role of testosterone

John P. Mulhall, MD

01:40 p.m. - 01:55 p.m.

#### Physiological role of testosterone

Kelvin Davies, BSc, MSc, PhD &

John P. Mulhall, MD

01:55 p.m. - 02:10 p.m.

#### Development & penile morphology on testosterone

Carol A. Podlasek, PhD &

Christopher J. Wingard, PhD, MS

02:10 p.m. - 02:25 p.m.

#### Autonomic input and testosterone

Trinity J. Bivalacqua, MD, PhD &

Johanna Hannan, PhD

02:25 p.m. - 02:40 p.m.

#### Testosterone impact/association RRP, diabetes and aging

Mohit Khera, MD &

Biljana Musicki, PhD

02:40 p.m. - 02:55 p.m.

#### PDE5i and testosterone

Michael E. DiSanto, PhD &

Nestor Gonzalez-Cadavid, PhD

02:55 p.m. - 03:10 p.m.

#### Summary and clinical integration

Arthur L. Burnett II, MD

03:10 p.m. - 03:20 p.m.



#### Podium presentation: 008. Low osteocalcin levels are associated with androgen deficiency

Le, B.<sup>1</sup>; Billups, K.<sup>2</sup>; Anele, U.<sup>2</sup>;

Burnett, A.L.<sup>2</sup>

1: Meriter Medical Group, USA; 2: Brady Urological Institute, Johns Hopkins Hospital, USA

# Scientific Program

\* = not CME-certified

03:10 p.m. - 03:20 p.m.



**Podium presentation: 009.**  
**Determining serum levels of osteocalcin in a rat model of hypogonadism**

*Le, B.<sup>1</sup>; Chen, H.<sup>2</sup>; Burnett, A.L.<sup>3</sup>;*

*Zirkin, B.<sup>2</sup>*

*1: Meriter Medical Group, USA; 2: Bloomberg School of Public Health, Johns Hopkins University, USA; 3: Brady Urological Institute, Johns Hopkins Hospital, USA*

03:20 p.m. - 03:30 p.m.



**Podium presentation: 010.**  
**Comparison of the effects of testosterone gels, injections and pellets on serum hormones, erythrocytosis, lipids, and**

**prostate specific antigen**

*Pastuszak, A.W.<sup>1</sup>; Gomez, L.P.<sup>1</sup>; Scovell, J.M.<sup>1</sup>; Khera, M.<sup>1</sup>; Lipshultz, L.I.<sup>1</sup>*

*1: Baylor College of Medicine, USA*

03:30 p.m. - 03:50 p.m.

**Q&A**

01:30 p.m. - 03:50 p.m.

**APN/PA hands on session**

» Concurrent session

📍 Key Biscayne

👤 Moderator: Kenneth Mitchell, MPAS, PA-C

**Injections/Priapism**

*Joseph B. Narus, DNP, APRN, NP-BC*

**Xiaflex®**

*Kenneth Mitchell, MPAS, PA-C*

**Male genital examination**

*Jeffrey Albaugh, PhD, APRN, CUCNS*

**Implant training**

*Brian S. Christine, MD*

**VED**

*Tim Irizarry, PA-C*

03:50 p.m. - 04:00 p.m.

**Journal of Sexual Medicine update\***

📍 Pompeii Ballroom

*John P. Mulhall, MD*

04:00 p.m. - 05:00 p.m.

**Sponsored afternoon symposium**

📍 Ocean Tower II B/C

05:00 p.m. - 05:15 p.m.

**Poster viewing time\***

📍 Mona Lisa & Ocean Tower II A

05:15 p.m. - 06:15 p.m.

**Moderated posters 3 – Androgens & Hypogonadism 2**

» Concurrent session

📍 Ocean Tower II A

👤 Moderators: Michael P. Finkelstein, MD & Mohit Khera, MD



**052. Testosterone therapy after radiation therapy for low, intermediate, and high risk prostate cancer**

*Pastuszak, A.W.<sup>1</sup>; Khanna, A.<sup>2</sup>;*

*Badhiwala, N.<sup>3</sup>; Morgentaler, A.<sup>4</sup>; Hulth, M.<sup>5</sup>; Connors, W.P.<sup>5</sup>; Sarosdy, M.<sup>6</sup>; Carrion, R.<sup>7</sup>; Lipshultz, L.I.<sup>1</sup>; Khera, M.<sup>1</sup>*

*1: Baylor College of Medicine, USA; 2: Cleveland Clinic Foundation, USA; 3: Washington University in St. Louis, USA; 4: Harvard Medical School, USA; 5: Men's Health Boston, USA; 6: South Texas Urology, USA; 7: University of South Florida, USA*

# Scientific Program

\* = not CME-certified



**053. Testosterone replacement therapy in opioid-induced hypogonadal men: A prospective analysis**

Sisul, D.<sup>1</sup>; Acevedo, J.<sup>1</sup>; Raheem,

O.<sup>1</sup>; Hsieh, T.<sup>1</sup>

1: UCSD Health System, USA



**058. The effect of testosterone topical solution in hypogonadal men with suboptimal response to a topical testosterone gel\***

Seftel, A.<sup>1</sup>; Kim, E.<sup>2</sup>; Ruff,

D.<sup>3</sup>; Burns, P.<sup>3</sup>

1: Cooper Medical School of Rowan University, USA; 2:

Department of Urology and Urologic Surgery, University of

Tennessee Graduate School of Medicine, USA; 3: Eli Lilly and

Company, USA



**054. Effect of testosterone replacement therapy on lipid profile in the patients with testosterone deficiency syndrome**

Han, K.<sup>1</sup>; Ahn, T.<sup>2</sup>

1: Asan medical center, Korea, South; 2: Asan Medical Center,

Korea, South



**059. Identifying factors affecting the variability of testosterone levels post therapy**

Chakrabarty, A.<sup>1</sup>; Panda,

S.<sup>2</sup>; Nicholas, J.<sup>3</sup>

1: Urologic Clinics of North Alabama, United States; 2: SCB

Medical College; 3: Urologic Clinic of North Alabama



**055. Influence of altitude on the rise hematocrit on patients receiving testosterone therapy: The low T experience**

Schmidhuber, J.<sup>1</sup>; Tan, R.<sup>1</sup>

1: Low T Center, USA



**060. Early experience with testosterone replacement therapy after radiation therapy for prostate cancer**

Berookhim, B.<sup>1</sup>; Krishnan, R.<sup>2</sup>;

Nelson, C.J.<sup>2</sup>; Mulhall, J.P.<sup>2</sup>

1: Lenox Hill Hospital, USA; 2: Memorial Sloan Kettering Cancer

Center, USA



**056. Factors that influence hypogonadal men to initiate testosterone replacement therapy\***

Rosen, R.C.<sup>1</sup>; Seftel, A.D.<sup>2</sup>; Ruff,

D.D.<sup>3</sup>; Muram, D.<sup>3</sup>

1: New England Research Institute, USA; 2: Cooper University

Hospital, USA; 3: Eli Lilly and Company, USA



**061. Efficacy and compliance with Anastrozole for the treatment of late onset hypogonadism**

Le, S.<sup>1</sup>; Feustel, P.; McCullough, A.

1: Albany Medical College, USA



**057. Testosterone restorative therapy in a urologic practice**

Ellen, J.<sup>1</sup>; McCullough, A.<sup>1</sup>

1: Albany Medical Center, USA



**062. Utilization patterns of parenteral testosterone preparations in hypogonadal men\***

Donatucci, C.<sup>1</sup>; Cui, Z.<sup>1</sup>; Zhu, Y.<sup>1</sup>;

Fang, Y.<sup>2</sup>; Muram, D.<sup>1</sup>

1: Eli Lilly and Company, USA; 2: InVentiv Health Clinical, USA

# Scientific Program

\* = not CME-certified



## 063. Enclomiphene citrate raises testosterone in hypogonadal men and lowers LDL cholesterol\*

Fontenot, G.<sup>1</sup>; Wiehle, R.<sup>1</sup>;  
Thompson, J.<sup>1</sup>; Sandel, M.<sup>1</sup>; Nydell,  
J.<sup>1</sup>; Cunningham, G.<sup>2</sup>; Podolski, J.<sup>1</sup>

1: Repros Therapeutics Inc., USA; 2: Baylor College of Medicine



## 066. Selection criteria used to guide surgical approach for management of Peyronie's disease: A single institution experience

Papagiannopoulos, D.<sup>1</sup>; Yura, E.<sup>1</sup>;

Levine, L.<sup>1</sup>

1: Rush University Medical Center, USA

05:15 p.m. - 06:15 p.m.

### ⓘ Moderated posters 4 – Peyronie's disease

» Concurrent session

📍 Mona Lisa

👤 Moderators: William O. Brant, MD &  
Joshua A. Broghammer, MD



## 064. Changes in the effects of Peyronie's disease after treatment with collagenase clostridium histolyticum according to men with Peyronie's

disease and their female sexual partners\*

Goldstein, I.<sup>1</sup>; Knoll, D.<sup>2</sup>; Lipshultz, L.I.<sup>3</sup>; Tursi, J.P.<sup>4</sup>;  
Smith, T.M.<sup>4</sup>; Kaufman, G.J.<sup>4</sup>; Gilbert, K.<sup>4</sup>; Rosen,  
R.C.<sup>5</sup>; McMahon, C.G.<sup>6</sup>

1: San Diego Sexual Medicine, San Diego, CA, USA; 2: Center  
for Urological Treatment, Nashville, TN, USA; 3: Baylor College  
of Medicine, Houston, TX, USA; 4: Auxilium Pharmaceuticals,  
Chesterbrook, PA, USA; 5: New England Research Institutes, Inc.,  
Watertown, MA, USA; 6: Australian Centre for Sexual Health, St.  
Leonards, NSW, Australia



## 067. The effect of urethroplasty on Peyronie's disease

Austenfeld, M.<sup>1</sup>; Broghammer, J.<sup>1</sup>

1: University of Kansas, USA



## 068. The Modified Sliding Technique (MoST) for penile lengthening with penile prosthesis insertion

Valenzuela, R.<sup>1</sup>; Weinberg,

A.<sup>1</sup>; Deibert, C.<sup>1</sup>; Hernandez, K.<sup>1</sup>; Egydio, P.<sup>2</sup>

1: Columbia University Medical Center, USA; 2: University of Sao  
Paulo, Brazil



## 069. Meaningful change in Peyronie's disease following treatment with collagenase clostridium histolyticum: Results from two large double-blind,

randomized, placebo-controlled phase 3 studies\*

Carson III, C.<sup>1</sup>; Gittelman, M.<sup>2</sup>; Tan, R.<sup>3</sup>; Tursi, J.P.<sup>4</sup>;  
Smith, T.M.<sup>4</sup>; Kaufman, G.J.<sup>4</sup>; Jones, N.A.<sup>5</sup>; Hellstrom,  
W.J.G.<sup>3</sup>

1: University of North Carolina School of Medicine, USA; 2: South  
Florida Medical Research, Aventura, USA; 3: Tulane University  
Health Sciences Center, USA; 4: Auxilium Pharmaceuticals, Inc.,  
USA; 5: Auxilium Pharmaceuticals, Inc, UK



## 065. Qualitative analysis of Peyronie's disease partner burden

Nelson, C.<sup>1</sup>; Hardin, C.<sup>2</sup>; Hardin,  
S.<sup>2</sup>; Bauler, V.<sup>2</sup>; Baum, V.<sup>2</sup>; Buehler,

S.<sup>3</sup>; Gutterman, R.<sup>2</sup>; Mulhall, J.<sup>1</sup>

1: Memorial Sloan Kettering Cancer Center, USA; 2: Association of  
Peyronie's Disease Advocates, USA; 3: The Buehler Institute, USA

# Scientific Program

\* = not CME-certified



**070. Intralesional interferon  $\alpha$ -2b therapy for Peyronie's disease: Penile duplex findings and clinical observations**

Tapscott, A.<sup>1</sup>; Hakim, L.<sup>2</sup>

1: Carolina Urology Partners, USA; 2: Cleveland Clinic Florida, USA



**071. Biomaterial grafting with penile prosthetic insertion in the management of Peyronie's disease: Efficacy and safety**

Knoll, L.D.<sup>1</sup>

1: USA



**072. Surgical therapy of Peyronie's disease by partial plaque excision and grafting with collagen fleece: long-term results**

Hatzichristodoulou, G.<sup>1</sup>; Fiechter,

S.<sup>1</sup>; Gschwend, J.E.<sup>1</sup>; Lahme, S.<sup>2</sup>

1: Department of Urology, Technical University of Munich, Klinikum rechts der Isar, Munich, Germany; 2: Department of Urology, Siloah St. Trudert Hospital, Pforzheim, Germany



**073. Peyronie's disease (PD) and penile hemodynamics: Color duplex doppler ultrasound analysis of PD patients**

Pathak, R.<sup>1</sup>; Chavers, R.<sup>1</sup>; Broderick,

G.<sup>2</sup>

1: Mayo Clinic, USA; 2: Mayo Clinic, USA



**074. Ventral intralesional verapamil injections for Peyronie's disease: Feasibility and safety**

Berookhim, B.<sup>1</sup>; Chevinsky, M.<sup>2</sup>;

Jakubowski, C.<sup>2</sup>; Larish, Y.<sup>1</sup>; Nelson, C.J.<sup>2</sup>; Mulhall, J.P.<sup>2</sup>

1: Lenox Hill Hospital, USA; 2: Memorial Sloan Kettering Cancer Center, USA



**075. Peyronie's disease symptom bother reduction is related to penile curvature improvement in response to treatment With collagenase clostridium**

**histolyticum: Results from two large double-blind, randomized, placebo-controlled phase 3 studies\***

Lipshultz, L.I.<sup>1</sup>; Sadeghi-Nejad, H.<sup>2</sup>; Mills, J.<sup>3</sup>; Tursi, J.P.<sup>4</sup>; Smith, T.M.<sup>4</sup>; Kaufman, G.J.<sup>4</sup>; Liu, G.<sup>4</sup>; Honig, S.<sup>5</sup>

1: Baylor College of Medicine, Houston, TX, USA; 2: Center for Male Reproductive Medicine, Hackensack, NJ, USA; 3: The Urology Center of Colorado, Denver, CO, USA; 4: Auxilium Pharmaceuticals, Chesterbrook, PA, USA; 5: Yale University School of Medicine, New Haven, CT, USA

07:00 p.m. - 11:00 p.m.

‡ Taste of Miami (ticket not included in registration fee)

# Scientific Program » Saturday November 22, 2014

\* = not CME-certified

06:45 a.m. - 07:45 a.m.

## **Sponsored breakfast symposium**

**📍** Ocean Tower II B/C

07:45 a.m. - 08:00 a.m.

## **Day introduction and recap of Friday**

**📍** Pompeii Ballroom

*Tobias S. Köhler, MD, MPH*

08:00 a.m. - 09:40 a.m.

## **Peyronie's/Reconstruction/Post RRP - part 1**

**📍** Pompeii Ballroom

**👤** Moderators: *Anthony J. Bella, MD & William O. Brant, MD*

08:00 a.m. - 08:50 a.m.

### **3 Worst complications of my career & what I would have done differently**

*Sean Elliott, MD, MS, Laurence A. Levine, MD & Kurt McCammon, MD*

08:50 a.m. - 09:40 a.m.

### **Controversial point/counterpoint: Simultaneous sling/aus IPP placement: Should be the default choice?**

*Brian S. Christine, MD*

### **Controversial point/counterpoint: Complex continence: conventional AUS is not always the answer**

*Joshua A. Broghammer, MD*

### **Controversial point/counterpoint: Alternative Peyronie's treatments – Are ESWL & collagen fleece ready for “prime time”?**

*Georgios Hatzichristodoulou, MD, FEBU, FECSM*

### **Controversial point/counterpoint: Grafting**

### **materials: have we found the perfect material?**

*Nelson Bennett Jr., MD*

09:40 a.m. - 10:05 a.m.

## **ESSM sponsored debate - Targeted therapy for rehabilitation: Is this the future**

**📍** Pompeii Ballroom

**👤** Moderators: *Serge Carrier, MD & David Ralph, MS, FRCS*

### **Nerve side**

*Maarten Albersen, MD*

### **Endothelium side**

*John P. Mulhall, MD*

10:05 a.m. - 10:50 a.m.

## **Peyronie's/Reconstruction/Post RRP - part 2**

**📍** Pompeii Ballroom

**👤** Moderators: *Anthony J. Bella, MD & William O. Brant, MD*

10:05 a.m. - 10:15 a.m.



**Podium presentation: 011. TNF-alpha is increased in major pelvic ganglion of rats following bilateral cavernous nerve injury and impairs neurite outgrowth ex vivo**

*Matsui, H.<sup>1</sup>; Hannan, J.L.<sup>1</sup>; Liu, X.<sup>1</sup>; Bivalacqua, T.J.<sup>1</sup>*

*1: The James Buchanan Brady Urological Institute and Department of Urology, The Johns Hopkins School of Medicine*



# Scientific Program

\* = not CME-certified

10:15 a.m. - 10:25 a.m.



**Podium presentation: 012.**  
**Frequency of Intracavernosal Injections (ICI) improves Erectile Function Recovery (EFR) following Radical Prostatectomy (RP)**

Nelson, C.<sup>1</sup>; Pessin, H.<sup>1</sup>; Mulhall, J.<sup>1</sup>

1: Memorial Sloan Kettering Cancer Center, USA

10:25 a.m. - 10:40 a.m.

**ISSM sponsored lecture - Strategies for penile prosthesis placement in PD and corporal fibrosis**

Wayne J.G. Hellstrom, MD

10:40 a.m. - 10:50 a.m.



**Podium presentation: 013.**  
**A new non invasive approach for the treatment of acute phase Peyronie's disease – A prospective, randomized, double-blind, placebo-**

**controlled study evaluating the safety and efficacy of topically applied gel H-100 which combines**

**Nicardipine, Superoxide Dismutase and Emu Oil**

Twidwell, J.<sup>1</sup>; Levine, L.<sup>2</sup>

1: Urology Associates LTD, USA; 2: Rush University

10:50 a.m. - 11:10 a.m.

**Break & poster viewing time**

Ocean Tower I

11:10 a.m. - 12:10 p.m.

**Moderated posters 5 – ED diagnosis & Medical treatment**

» Concurrent session

Ocean Tower II A

Moderators: Nelson Bennett Jr., MD & Run Wang, MD



**076. The efficacy of Avanafil in subjects with intercourse attempts within 15 minutes after dosing\***

Belkoff, L.H.<sup>1</sup>; Tursi, J.P.<sup>2</sup>; Uy, J.<sup>2</sup>;

Smith, T.M.<sup>2</sup>; Nejat, R.J.<sup>3</sup>

1: Urologic Consultants of SE PA, Bala Cynwyd, PA, USA; 2:

Auxilium Pharmaceuticals, Inc., Chesterbrook, PA, USA; 3: School of Medicine at the State University of New York, Stony Brook, NY, USA



**077. A comparison of baseline erectile function after on-demand 20 mg tadalafil vs. daily 5 mg tadalafil in men with erectile dysfunction and diabetes: A**

**prospective, observational 2-year study**

Park, H.J.<sup>1</sup>; Park, N.C.<sup>1</sup>

1: Pusan National University Hospital, Korea, South



**078. Cavernous Venous Occlusive Disease (CVOD) and Color Doppler Duplex Ultrasound (CDDU) analysis: What CDDU parameters are associated with CVOD**

Pathak, R.<sup>1</sup>; Chavers, R.<sup>1</sup>; Broderick, G.<sup>1</sup>

1: Mayo Clinic, USA



**079. Successful intercourse in men with erectile dysfunction within the first three doses of Avanafil\***

Goldstein, I.<sup>1</sup>; Karlin, G.S.<sup>2</sup>; Tursi,

J.P.<sup>3</sup>; Uy, J.<sup>3</sup>; Smith, T.M.<sup>3</sup>; Kaminetsky, J.<sup>4</sup>

1: San Diego Sexual Medicine, San Diego, CA, USA; 2: Urology

Care Alliance/Advanced Research, Lawrenceville, NJ, USA;

3: Auxilium Pharmaceuticals, Inc., Chesterbrook, PA, USA; 4:

University Urology Associates, New York, NY, USA

# Scientific Program

\* = not CME-certified



**080. Couples' treatment satisfaction following switch from on-demand phosphodiesterase type 5 inhibitor therapy to tadalafil 5 mg once daily\***

*Burns, P.R.<sup>1</sup>; Rosen, R.C.<sup>2</sup>; Dunn, M.<sup>3</sup>; Baygani, S.K.<sup>1</sup>; Perelman, M.A.<sup>4</sup>*

1: Eli Lilly and Company, USA; 2: New England Research Institutes, Inc., USA; 3: SUNY - Brooklyn Downstate Medical Center, USA; 4: NY Weill Cornell Medical Center, USA



**081. Erectile dysfunction, testosterone, and C-reactive protein are associated with progression of metabolic syndrome over time**

*Escolin, N.<sup>1</sup>; Iyengar, R.L.<sup>1</sup>; Maceda, C.<sup>1</sup>; O'Boyle, K.<sup>1</sup>; Thapi, S.<sup>1</sup>; Woodward, M.<sup>2</sup>; Crowley, L.<sup>1</sup>; Bar-Chama, N.<sup>1</sup>; McLaughlin, M.A.<sup>1</sup>*

1: Ichan School of Medicine at Mount Sinai, USA; 2: University of Oxford



**082. Predictors of erectile response in patients with arterial disease on penile doppler ultrasound**

*McCraw, C.<sup>1</sup>; Fox, P.<sup>1</sup>; Cutler, C.<sup>1</sup>; Ostrowski, A.<sup>1</sup>; Li, Q.<sup>1</sup>; Klaassen, Z.<sup>1</sup>; Lewis, R.W.<sup>1</sup>*

1: Georgia Regents University, USA



**083. Factors correlating with sexual interest and function in long-term colorectal cancer survivors**

*Westney, O.L.<sup>1</sup>; Ayoub, H.<sup>1</sup>; You, Y.<sup>1</sup>; Tran Cao, H.S.<sup>1</sup>; Hu, C.Y.<sup>1</sup>; Chang, G.<sup>1</sup>; Feig, B.<sup>1</sup>; Rodriguez-Bigas, M.<sup>1</sup>; Skibber, J.<sup>1</sup>*

1: MD Anderson Cancer Center, USA



**084. Udenafil for the treatment of erectile dysfunction: Results from two pivotal studies\***

*Mills, J.<sup>1</sup>; Bernstein, A.<sup>2</sup>; Thomas, H.<sup>3</sup>; Platt, C.<sup>2</sup>; Sniukiene, V.<sup>2</sup>; Hoel, G.<sup>3</sup>*

1: Center for Men's Health at The Urology Center of Colorado; 2: Actavis plc; 3: Actavis Inc



**085. Pre-treatment counseling on quality of life issues before management of prostate malignancy**

*Rankin-Wagenaar, R.<sup>1</sup>; Durbin-Johnson, B.<sup>1</sup>; Dall'era, M.<sup>1</sup>; Valicenti, R.<sup>1</sup>; Shindel, A.<sup>1</sup>*

1: University of California, Davis, USA



**086. The efficacy of long-term daily dosage of alfuzosin 10 mg upon sexual function of BPH patients: 2-year prospective observational**

*Hyun, J.S.<sup>1</sup>; Kam, S.C.<sup>1</sup>; Choi, S.M.<sup>1</sup>; Yun, S.<sup>1</sup>*

1: Gyeongsang National University Hospital

11:10 a.m. - 12:10 p.m.

## ⓘ Moderated posters 6 – Implant 1

» Concurrent session

📍 Mona Lisa

👤 Moderators: David Ralph, MS, FRCS & Doron S. Stember, MD



**087. Implant length – Baseline characteristic correlations**

*Bennett, N.E.<sup>1</sup>; Bella, A.J.<sup>2</sup>; Karpman, E.<sup>3</sup>; Brant, W.O.<sup>4</sup>; Jones, L.<sup>5</sup>; Kansas, B.<sup>6</sup>; Kohler, T.<sup>7</sup>; Khera, M.<sup>8</sup>*

1: Lahey Hospital and Medical Center, USA; 2: University of Ottawa; 3: El Camino Urology; 4: University of Utah; 5: Urology San Antonio; 6: The Urology Team; 7: Southern Illinois University; 8: Baylor College of Medicine

# Scientific Program

\* = not CME-certified



## 088. Validation of a prediction model for penile prosthesis implantation for erectile dysfunction management

Anele, U.<sup>1</sup>; Segal, R.L.<sup>1</sup>; Le, B.V.<sup>1</sup>;

Burnett, A.L.<sup>1</sup>

1: Brady Urological Institute, The Johns Hopkins School of Medicine, USA



## 089. Use of magnetic induction to activate a shape memory alloy penile prosthesis

Colombo, A.<sup>1</sup>; Le, B.<sup>2</sup>; McVary, K.<sup>1</sup>

1: SIU, USA; 2: MERITER Health services



## 090. The Carrion Cast: An update on the usage of the intracorporal antimicrobial doped spacer for the treatment of penile implant infection

Martinez, D.<sup>1</sup>; Alhammali, E.<sup>1</sup>; Emtage, J.<sup>1</sup>; Perito, P.<sup>2</sup>; Parker, J.<sup>1</sup>; Carrion, R.<sup>1</sup>

1: University of South Florida, USA; 2: Perito Urology, USA



## 091. The Medtronic Zotarolimus-ELuting Peripheral Stent System for the treatment of ED in males with sub-optimal response to PDE5 inhibitor - 3 year results\*

Kohler, T.<sup>1</sup>; Goldstein, I.<sup>2</sup>

1: Southern Illinois University SOM, USA; 2: Institute for Sexual Medicine, USA



## 092. Observation of local clinical penile prostheses infections instead of immediate salvage rescue/removal: Ten center study with surprising results

Henry, G.<sup>1</sup>; Price, G.<sup>2</sup>; Pryor, M.<sup>3</sup>; Greenfield, J.<sup>4</sup>; Jones, L.<sup>5</sup>; Perito, P.<sup>6</sup>; Morey, A.<sup>7</sup>; Goldstein, I.<sup>8</sup>; Bella, A.<sup>9</sup>; Kohler, T.<sup>10</sup>; Land, S.<sup>11</sup>; Berger, A.<sup>12</sup>; Cohen, S.<sup>13</sup>

1: Regional Urology, USA; 2: American Medical Systems, USA;

3: Urology Center of Spartanburg; 4: Urology Associates of North

Texas, USA; 5: Urology San Antonio, USA; 6: Perito Urology, USA; 7:

University of Texas Southwestern, USA; 8: San Diego Sexual Medicine,

USA; 9: Ottawa Hospital Research Institute, USA; 10: SIU School

of Medicine, USA; 11: Lake Shore Urology, USA; 12: Associated

Urological Specialists, USA; 13: Advanced Urological Care P.C., USA



## 093. Wound complications in inflatable penile prosthesis with scrotoplasty

Sulaver, R.<sup>1</sup>; Butcher, M.<sup>1</sup>; Kottwitz, M.<sup>1</sup>; Frederick, L.<sup>1</sup>; Welliver, C.<sup>1</sup>;

Kohler, T.<sup>1</sup>

1: Southern Illinois University SOM, USA



## 094. Long acting bupivacaine decreases peri-operative narcotic requirements in men undergoing penile prosthesis implantation

Hanerhoff, B.<sup>1</sup>; Welliver Jr, R.C.<sup>2</sup>; Brahmamdam, A.<sup>3</sup>; Cummins, C.<sup>4</sup>; Bednarchik, C.L.<sup>1</sup>; Mueller, G.<sup>1</sup>; Dynda, D.<sup>1</sup>; Kohler, T.S.<sup>1</sup>

1: Southern Illinois University SOM, USA; 2: Albany Medical

Center, USA; 3: St Andrews Hospital, USA; 4: Saint Johns

Hospital, USA



## 095. Is risk of AUS cuff erosion higher in patients with penile prosthesis?

French, D.C.<sup>1</sup>; Siegel, J.A.<sup>1</sup>; Tausch, T.J.<sup>1</sup>; Klein, A.<sup>1</sup>; Roehrborn, C.G.<sup>1</sup>;

Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA

# Scientific Program

\* = not CME-certified



## 096. Increased penile length after inflatable penile prosthesis replacement

Chung, P.H.<sup>1</sup>; Siegel, J.A.<sup>1</sup>; Mason, R.<sup>2</sup>; Tausch, T.J.<sup>1</sup>; Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA; 2: Methodist Dallas Medical Center

John J. Mulcahy, MD, PhD, David Ralph, MS, FRCS & Steven K. Wilson, MD

02:35 p.m. - 03:20 p.m.

## Controversial point/counterpoint: Cylinders should be upsized

Gerard D. Henry, MD



## 097. The ED care pathway for patients considering penile implants\*

Nelson, C.<sup>1</sup>; Hill, R.<sup>2</sup>; Burnett, A.<sup>3</sup>; Hakim, L.<sup>4</sup>; Mulhall, J.<sup>1</sup>

1: Memorial Sloan Kettering Cancer Center, USA; 2: American Medical Systems, USA; 3: Johns Hopkins Medical Institutions, USA; 4: Cleveland Clinic, USA

## Controversial point/counterpoint: Malleable only for washout

Ricardo M. Munarriz, MD

## Controversial point/counterpoint: Drain & retain vs removal in non-infected setting

Joshua A. Broghammer, MD



## 098. Inflatable penile prosthesis implantation is possible under local anesthesia with conscious sedation: Technique and results

Park, S.S.H.<sup>1</sup>; Wilson, S.K.<sup>2</sup>; Morey, A.F.<sup>3</sup>

1: Sewum Prosthetic Urology Clinic, Korea, South; 2: Editor in Chief ISSM Video Journal of Prosthetic Urology, USA; 3: UT Southwestern Medical Center, Department of Urology, USA

## Controversial point/counterpoint: Ectopic reservoir placement should always be used after robot RRP

Edward Karpman, MD

03:20 p.m. - 03:30 p.m.

## Update on Penile Fracture Repair

Anthony J. Bella, MD

12:15 p.m. - 01:45 p.m.

## 📌 Sponsored lunch symposium

📍 Ocean Tower II B/C

01:45 p.m. - 04:10 p.m.

## 📌 Penile implants

» Concurrent session

📍 Ocean Tower II A

👤 Moderators: Rafael E. Carrion, MD & Run Wang, MD

01:45 p.m. - 02:35 p.m.

## The 3 worst cases of my career & What I would have done differently

03:30 p.m. - 03:40 p.m.



## Podium presentation: 014.

“Unexpected” corporal fibrosis should be “expected”: the prevalence of significant corporal fibrosis encountered

## during penile prosthetics

Brant, W.<sup>1</sup>; Kohler, T.<sup>2</sup>; Henry, G.<sup>3</sup>; Karpman, E.<sup>4</sup>; Kansas, B.<sup>5</sup>; Jones, L.<sup>6</sup>; Christine, B.<sup>7</sup>; Bennett, N.<sup>8</sup>; Khera, M.<sup>9</sup>; Bella, A.<sup>10</sup>

1: University of Utah, USA; 2: Southern Illinois University, USA; 3: Regional Urology, USA; 4: El Camino Urology Medical Group, USA; 5: The Urology Team, USA; 6: Urology San Antonio, USA; 7: Urology Centers of Alabama, USA; 8: Lahey Clinic, USA; 9: Baylor College, USA; 10: University of Ottawa, Canada

# Scientific Program

\* = not CME-certified

03:40 p.m. - 03:50 p.m.



**Podium presentation: 015.**  
**Outcomes of IPP placement by surgical approach, penoscrotal vs infrapubic, results from a prospective multicenter study\***

*Karpman, E.<sup>1</sup>; Bella, A.<sup>2</sup>; Brant, W.<sup>3</sup>; Kansas, B.<sup>4</sup>; Jones, L.<sup>5</sup>; Kohler, T.<sup>6</sup>; Christine, B.<sup>7</sup>; Bennett, N.<sup>8</sup>; Khera, M.<sup>9</sup>; Henry, G.<sup>10</sup>*

*1: El Camino Urology Medical Group, Inc, USA; 2: University of Ottawa; 3: University of Utah; 4: The Urology Team; 5: Urology San Antonio; 6: SIU School of Medicine; 7: St. Vincent's Birmingham; 8: Lahey Clinic; 9: Baylor College of Medicine; 10: Regional Urology*

03:50 p.m. - 04:00 p.m.



**Podium presentation: 016.**  
**MRI analysis of architectural changes of the retropubic space and relevant structures post radical prostatectomy:**

**Implications for penile prosthesis reservoir placement**

*Sullivan, J.<sup>1</sup>; Foran, P.<sup>1</sup>; Nelson, C.<sup>1</sup>; Akin, O.<sup>1</sup>; Mulhall, J.<sup>1</sup>*

*1: MSKCC, USA*

04:00 p.m. - 04:10 p.m.



**Podium presentation: 017.**  
**Reoperation of penile prothetic surgery: A longitudinal analysis of California population database**

*Mirheydar, H.<sup>1</sup>; Hsieh, T.C.<sup>1</sup>*

*1: University of California San Diego Department of Urology, USA*

01:45 p.m. - 02:15 p.m.

**Basic science research forum**

» Concurrent session

📍 Pompeii Ballroom

👤 Moderator: Carol A. Podlasek, PhD

01:45 p.m. - 02:00 p.m.

**ISSM sponsored – Is there an genetic basis to lifelong premature ejaculation?**

*Chris McMahon, MD*

02:00 p.m. - 02:15 p.m.

**ESSM sponsored – Does microvascular dysfunction explain the pathophysiology of both ED and BPH-LUTS**

*Selim Cellek, MD, PhD*

02:15 p.m. - 04:10 p.m.

**Basic science abstracts**

» Concurrent session

📍 Pompeii Ballroom

👤 Moderators: Trinity J. Bivalacqua, MD, PhD & Carol A. Podlasek, PhD



**Podium presentation: 018.**  
**eNOS uncoupling contributes to earlier erectile dysfunction and endothelial dysfunction in the penis than in the carotid artery in a rat model of type 2 diabetes mellitus**

*Musicki, B.<sup>1</sup>; Hannan, J.<sup>1</sup>; Lagoda, G.<sup>1</sup>; La Favor, J.<sup>1</sup>; Bivalacqua, T.<sup>1</sup>; Burnett, A.<sup>1</sup>*

*1: Johns Hopkins University, USA*



**Podium presentation: 019.**  
**Sonic hedgehog regulation of collagen in the penis**

*Podlasek, C.<sup>1</sup>; Bond, C.<sup>2</sup>; McVary, K.<sup>3</sup>*

# Scientific Program

\* = not CME-certified

1: University of Illinois at Chicago, USA; 2: Northwestern University; 3: SIU



**Podium presentation: 020.**  
Effects of a selective alpha-1a adrenoceptor antagonist, silodosin treatment on erectile dysfunction of rats with partial bladder outlet obstruction

Gur, S.<sup>1</sup>; Kaya, E.<sup>1</sup>; Bastaskin, T.<sup>1</sup>; Onal, E.<sup>1</sup>; Yilmaz, D.<sup>1</sup>; Bayatli, N.<sup>1</sup>

1: Ankara University School of Pharmacy, Turkey



**Podium presentation: 021.**  
Nanotechnology improved stem cell therapy in erectile

Lin, H.<sup>1</sup>; Dhanani, N.; Tseng, H.; Souza, G.; Wang, R.<sup>2</sup>

1: University of Texas Medical School at Houston, USA; 2: University of Texas Medical School at Houston and MD Anderson Cancer Center, USA



**Podium presentation: 022.**  
Skeletal muscle derived stem cells (MDSC) ameliorate erectile dysfunction in a rat model of type 2 diabetes, but their repair

ability is severely impaired when isolated from long-term diabetic milieu

Kovanecz, I.<sup>1</sup>; Vernet, D.<sup>2</sup>; Masouminia, M.<sup>2</sup>; Tsao, J.<sup>3</sup>; Loni, L.<sup>2</sup>; Victorino, J.<sup>2</sup>; De Lang, I.<sup>2</sup>; Rajfer, J.<sup>4</sup>; Gonzalez-Cadavid, N.F.<sup>5</sup>

1: LABioMed Research Institute at Harbor-UCLA and UCLA School of Medicine, USA; 2: LABioMed Research Institute at Harbor-UCLA, USA; 3: Charles Drew University of Medicine and Science, USA; 4: LABioMed Research Institution at Harbor-UCLA, USA and UCLA School of Medicine, USA; 5: LABioMed Research Institute at Harbor-UCLA and UCLA School of Medicine, USA



**Podium presentation: 023.**

The cyclic AMP-binding protein kinase A (cAK), vasoactive intestinal polypeptide (VIP) and cyclic AMP phosphodiesterase type 4 (PDE4) are expressed in the human vagina

Ückert, S.<sup>1</sup>; Albrecht, K.<sup>2</sup>; Kuczyk, M.A.<sup>1</sup>; Bannowsky, A.<sup>3</sup>; Hedlund, P.<sup>4</sup>

1: Hannover Medical School, Dept. of Urology & Urological Oncology, Hannover, Germany; 2: Hannover Medical School, Institute for Legal & Forensic Medicine, Hannover, Germany; 3: Osnabrück Municipal Hospital, Dept. of Urology, Osnabrück, Germany; 4: Linköping University, Dept. of Clinical Pharmacology, Linköping, Sweden



**Podium presentation: 024.**

A role for CTDSPL in fibrosis and plaque calcification in Peyronie's disease

Pastuszak, A.W.<sup>1</sup>; Bournat, J.<sup>1</sup>;

Lamb, D.J.<sup>1</sup>; Lipshultz, L.I.<sup>1</sup>

1: Baylor College of Medicine, USA



**Podium presentation: 025.**

NADPH oxidase inhibition and sepiapterin supplementation fail to ameliorate age-related erectile dysfunction in Lewis rats

Becak, D.P.<sup>1</sup>; Jones, E.D.<sup>1</sup>; Lust, R.M.<sup>1</sup>; Wingard, C.J.<sup>1</sup>

1: East Carolina University, USA



**Podium presentation: 026.**

Differential effects of sildenafil and tadalafil on human penile smooth muscle cells: New insights for old mechanisms

Rezk, B.<sup>1</sup>; Moustafa, A.A.<sup>2</sup>; Sangkum, P.<sup>2</sup>; Abd Elmageed, Z.Y.<sup>2</sup>; Sikka, S.<sup>2</sup>; Abdel Mageed, A.B.<sup>2</sup>; Hellstrom, W.J.G.<sup>2</sup>

1: Southern University of New Orleans, USA; 2: Tulane University School of Medicine, USA

# Scientific Program

\* = not CME-certified



**Podium presentation: 027.**  
**Absence of S-nitrosoglutathione reductase alters erectile function through oxidative stress**  
*Lagoda, G.<sup>1</sup>; Anele, U.<sup>1</sup>; Goetz, T.<sup>1</sup>;*

*Burnett, A.L.<sup>1</sup>*  
*1: Johns Hopkins University, USA*



**Podium presentation: 028.**  
**NELL1: A genetic factor predisposing to fibrosis associated with Peyronie's disease**  
*Pastuszak, A.W.<sup>1</sup>; Bournat, J.<sup>1</sup>; Lamb, D.J.<sup>1</sup>; Lipshultz, L.I.<sup>1</sup>*

*1: Baylor College of Medicine, USA*



**Podium presentation: 029.**  
**Plasmid-based transient luciferase gene transfer in the major pelvic ganglion assessed with real time live animal imaging\***  
*Sopko, N.A.<sup>1</sup>; Cooper, J.<sup>1</sup>; Woda, J.<sup>2</sup>; Matsui, H.<sup>1</sup>; Liu, X.<sup>1</sup>; Hannan, J.L.<sup>1</sup>; Bivalacqua, T.J.<sup>1</sup>*

*1: Johns Hopkins School of Medicine, USA; 2: Juventas Therapeutics, Inc*

04:10 p.m. - 04:30 p.m.

## ⓘ Break & poster viewing time

📍 Ocean Tower I

04:30 p.m. - 05:30 p.m.

## ⓘ Podium presentations by past SMSNA grant awardees

» Concurrent session

📍 Pompeii Ballroom

👤 Moderators: Michael E. DiSanto, PhD & Johanna Hannan, PhD

04:30 p.m. - 04:45 p.m.

**The role of rho-kinase in peripheral nerve injury induced female sexual dysfunction**  
*Johanna Hannan, PhD*

04:45 p.m. - 05:00 p.m.

**Development of ED and CVD: Effects of a Western diet and exercise**  
*Justin D. La Favor, PhD*

05:00 p.m. - 05:15 p.m.

**Arousal incontinence in men following radical prostatectomy**  
*Christian Nelson, PhD*

05:15 p.m. - 05:30 p.m.

**The benefits of climbing the Matterhorn daily: Normobaric interval hypoxia preserves erectile function and benefits pulse pressure in the aging male SHR**  
*Cynthia M. Pruss, MD*

04:30 p.m. - 05:30 p.m.

## ⓘ Moderated posters 7 – Implant 2

» Concurrent session

📍 Ocean Tower II A

👤 Moderators: Andrew C. Kramer, MD & Ryan Terlecki, MD



**099. Factors associated with treatment satisfaction following penile prosthesis implantation**  
*Khurgin, J.L.<sup>1</sup>; Anele, U.<sup>1</sup>; Burnett, A.L.<sup>1</sup>*

*1: Johns Hopkins Hospital, USA*

# Scientific Program

\* = not CME-certified



**100. Maria Stitch: A novel technique to prevent pump migration in inflatable penile prosthesis**

Ramos, L.<sup>1</sup>; Maria, P.<sup>2</sup>

1: Montefiore Medical Center, USA; 2: Montefiore Medical Center



**101. "Distal Corporal Anchoring Stitch" a technique to address Distal corporal crossovers and impending lateral extrusions of a penile prosthesis**

Rafiei, A.<sup>1</sup>; Martinez, D.<sup>1</sup>; Suarez Sarimiento, A.<sup>2</sup>; Bianco, F.<sup>3</sup>; Antonini, G.<sup>4</sup>; Gheiler, E.<sup>3</sup>; Carrion, R.<sup>5</sup>; Perito, P.<sup>6</sup>

1: University of South Florida, USA; 2: Department of Urology, Coral Gables Hospital, USA; 3: Miami Urology Specialists, USA; 4: Department of Urology, "Sapienza" Rome University, Italy; 5: University of South Florida, USA; 6: Department of Urology, Coral Gables Hospital, USA



**102. Penile prosthesis insertion after radial forearm free flap neophallus**

Pariser, J.J.<sup>1</sup>; Malik, R.D.<sup>1</sup>; Gottlieb, L.J.<sup>1</sup>; Bales, G.T.<sup>1</sup>

1: University of Chicago, USA



**103. Inflatable penile prosthesis implantation in men under 30: Long-term outcomes regarding patient satisfaction**

Gross, M.<sup>1</sup>; Munarriz, R.<sup>1</sup>

1: Boston University Medical Center, USA



**104. Maximizing "rigidity factor" of inflatable penile prosthesis (IPP) results in better artificial erection**

Cordon, B.H.<sup>1</sup>; Eid, J.F.<sup>1</sup>

1: Lenox Hill Hospital, USA



**105. "Sticky pump" syndrome: Trending towards non-operative treatment of patients with difficult AMS 700-Series IPP inflation**

Tausch, T.J.<sup>1</sup>; Siegel, J.A.<sup>1</sup>; Klein, A.<sup>1</sup>; Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA



**106. Use of rear tip extenders does not affect penile implant satisfaction or outcomes**

Kohler, T.<sup>1</sup>; Brant, W.<sup>2</sup>; Karpman, E.<sup>3</sup>; Kansas, B.<sup>4</sup>; Jones, L.<sup>5</sup>;

Christine, B.<sup>6</sup>; Bennett, N.<sup>7</sup>; Khera, M.<sup>8</sup>; Bella, A.<sup>9</sup>; Henry, G.<sup>10</sup>

1: Southern Illinois University SOM, USA; 2: University of Utah; 3: El Camino Urology Medical Group; 4: The Urology Team; 5: Urology San Antonio; 6: Urology Centers of Alabama; 7: Lahey Clinic; 8: Baylor College; 9: University of Ottawa, Canada; 10: Regional Urology, USA



**107. Penile prosthesis placement in patients with a history of total phallic construction**

Zuckerman, J.<sup>1</sup>; Smentkowski, K.<sup>1</sup>; Gilbert, D.<sup>1</sup>; Virasoro, R.<sup>1</sup>; Tonkin, J.<sup>1</sup>; Jordan, G.<sup>1</sup>; McCammon, K.<sup>1</sup>

1: Eastern Virginia Medical School, USA



**108. Simultaneous inflatable penile prosthesis and quadratic transobturator male sling procedure**

Weinberg, A.<sup>1</sup>; Deibert, C.<sup>1</sup>;

Hernandez, K.<sup>1</sup>; Valenzuela, R.<sup>1</sup>

1: Columbia University Medical Center, USA



# Scientific Program

\* = not CME-certified



**109. Utilization of pre-operative penile stretch test as predictor of erection and total implant length**  
Ayoub, H.<sup>1</sup>; Westney, O.L.<sup>1</sup>; Perito, P.E.<sup>2</sup>

1: MD Anderson Cancer Center, Houston, USA; 2: Perito Urology, Florida, USA



**110. Key factors and influencers impacting the penile implant decision\***  
Nelson, C.<sup>1</sup>; Hill, R.<sup>2</sup>; Burnett, A.<sup>3</sup>; Hakim, L.<sup>4</sup>; Mulhall, J.<sup>1</sup>

1: Memorial Sloan Kettering Cancer Center, USA; 2: American Medical Systems, USA; 3: Johns Hopkins Medical Institutions, USA; 4: Cleveland Clinic, USA

04:30 p.m. - 05:30 p.m.

## ⓘ Moderated posters 8 – Priapism, Reconstruction & FSD

» Concurrent session

📍 Mona Lisa

👤 Moderators: Anthony J. Bella, MD & Andrew T. Goldstein, MD, FACOG



**111. How combined serotonin-1A receptor agonist and 2A-receptor antagonist can heal hypoactive sexual desire disorder (HSDD)**

Holstege, G.<sup>1</sup>  
1: The University of Queensland Australia, Netherlands



**112. A randomized, single center, single-blind, crossover thermographic study to evaluate the effect of 1000 mcg of topical alprostadil cream compared to an over-the-counter marketed lubricant**

Goldstein, I.<sup>1</sup>; Gonzalez, J.R.<sup>2</sup>; Gagnon, C.<sup>2</sup>; Minton, J.N.<sup>2</sup>; Morris, D.<sup>3</sup>; Goldstein, S.W.<sup>2</sup>

1: Alvarado Hospital, USA; 2: San Diego Sexual Medicine, USA; 3: Webbwrites, USA



**113. Symptomatic and asymptomatic Bartholin cyst formation after complete vestibulectomy for congenital or acquired neurolproliferative vestibulodynia**

Cohen, S.D.<sup>1</sup>; Gonzalez, J.R.<sup>1</sup>; Gagnon, C.<sup>1</sup>; Minton, J.N.<sup>1</sup>; Espenschied, C.<sup>2</sup>; Goldstein, I.<sup>3</sup>

1: San Diego Sexual Medicine, USA; 2: San Diego Sexual Medicine, United States; 3: Alvarado Hospital, USA



**114. Artificial urinary sphincter for treatment of incontinence in the elderly**

Raup, V.T.<sup>1</sup>; Eswara, J.R.<sup>2</sup>; Geminiani, J.<sup>1</sup>; Brandes, S.B.<sup>1</sup>

1: Washington University in St. Louis, USA; 2: Brigham and Women's Hospital, Harvard University, USA



**115. Location of AUS pressure regulating balloon: Functional outcomes of high submuscular position are equivalent to space of retzius**

Singla, N.<sup>1</sup>; Simhan, J.<sup>1</sup>; Siegel, J.<sup>1</sup>; Tausch, T.<sup>1</sup>; Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA



**116. Operative management for priapism: A contemporary experience at a single institution**  
Kappa, S.F.<sup>1</sup>; Green, E.A.<sup>1</sup>; Joshi, S.<sup>1</sup>; Kaufman, M.R.<sup>1</sup>; Milam, D.F.<sup>1</sup>

1: Vanderbilt University Medical Center, USA

# Scientific Program

\* = not CME-certified



## 117. Efficacy and sedation-related safety of Flibanserin in premenopausal women\*

Natarajan, K.<sup>1</sup>; Sicard, E.<sup>2</sup>; Kay, G.G.<sup>3</sup>; Kim, N.N.<sup>4</sup>

1: Sprout Pharmaceuticals, Raleigh, NC; 2: Algorithme Pharma, Montreal, Quebec, Canada; 3: Cognitive Research Corp., Saint Petersburg, FL; 4: Institute for Sexual Medicine, San Diego, CA



## 118. Persistent Genital Arousal Disorder (PGAD): Experience with management in 35 consecutive cases

Cohen, S.D.<sup>1</sup>; Gonzalez, J.R.<sup>1</sup>;

Gagnon, C.<sup>1</sup>; Minton, J.N.<sup>1</sup>; Espenschied, C.<sup>2</sup>; Goldstein, I.<sup>3</sup>

1: San Diego Sexual Medicine, USA; 2: San Diego Sexual Medicine, United States; 3: Alvarado Hospital, USA



## 119. Penile fracture outcomes: Faux pas du coit at high risk for urethral injury, ED & Peyronies

Butcher, M.<sup>1</sup>; Swanson, D.<sup>2</sup>; Polackwich, A.S.<sup>3</sup>; Helfand, B.T.<sup>4</sup>;

Masson, P.<sup>5</sup>; Dugi III, D.<sup>3</sup>; Hedges, J.<sup>3</sup>; Kohler, T.<sup>1</sup>; McVary, K.<sup>1</sup>

1: Division of Urology, Southern Illinois University, Springfield, IL, USA; 2: Department of Urology, Oregon health & Science University, Portland, OR, USA; 3: Department of Urology, Oregon health & Science University, Portland, OR, USA; 4: Division of Urology, Department of Surgery, NorthShore University Health; 5: Department of Urology, Feinberg School of medicine, Northeastern Univeristy, Chicago, IL



## 120. Priapism Impact Profile (PIP) questionnaire: Development and evaluation

Anele, U.<sup>1</sup>; Burnett, A.L.<sup>1</sup>; Derogatis, L.R.<sup>2</sup>

1: The Brady Urological Institute, The Johns Hopkins School of Medicine, USA; 2: Maryland Center for Sexual Health, USA



## 121. The association between sex hormones and female sexual dysfunction

Chung, W.S.<sup>1</sup>; Yoon, H.<sup>1</sup>

1: Ewha Womans University School of Medicine, Korea, South



## 122. Reconstructive armamentarium for correction of adult buried penis syndrome

Tausch, T.J.<sup>1</sup>; Westerman, M.E.<sup>1</sup>; Hoxworth, R.<sup>1</sup>; Klein, A.<sup>1</sup>; Siegel, J.A.<sup>1</sup>; Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA

05:30 p.m. - 06:00 p.m.

### ⚡ SMSNA business meeting

📍 Pompeii Ballroom

06:00 p.m. - 06:15 p.m.

### ⚡ SUPS business meeting

📍 Pompeii Ballroom

06:00 p.m. - 07:00 p.m.

### ⚡ Young clinicians mixer (on invitation only - more information at registration desk)

📍 Ocean Tower II Foyer

# Scientific Program » Sunday November 23, 2014

\* = not CME-certified

07:45 a.m. - 08:00 a.m.

## **Day introduction and recap of Saturday**

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 *Pompeii Ballroom*


*Tobias S. Köhler, MD, MPH*

08:00 a.m. - 09:15 a.m.

## **Andrologists as educators session**

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 *Pompeii Ballroom*

 *Moderators: Brian S. Christine, MD &  
Alan W. Shindel, MD*

08:00 a.m. - 08:10 a.m.

### **Medical student education**

*Alan W. Shindel, MD*

08:10 a.m. - 08:20 a.m.

### **Becoming a better educator**

*Kurt McCammon, MD*

08:20 a.m. - 08:30 a.m.

### **Evolving methods of resident education**

*Andrew C. Kramer, MD*

08:30 a.m. - 08:40 a.m.

### **The role of cyber technology in education**

*Brian S. Christine, MD*

08:40 a.m. - 08:50 a.m.

### **Andrology OPRS & giving feedback**

*Tobias S. Köhler, MD, MPH*

08:50 a.m. - 09:15 a.m.


### **Panel discussion**

09:15 a.m. - 10:15 a.m.

## **Awards & take home messages**

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 *Pompeii Ballroom*

 *Moderator: Tobias S. Köhler, MD, MPH*

09:15 a.m. - 09:25 a.m.

### **Awards recap\***

*William O. Brant, MD*

09:25 a.m. - 09:35 a.m.

### **Psych/Life style/Female**

*William P. Conners, MD*

09:35 a.m. - 09:45 a.m.

### **Basic science**

*Carol A. Podlasek, PhD*

09:45 a.m. - 09:55 a.m.

### **Implant**

*Gregory J. Lowe, MD*

09:55 a.m. - 10:05 a.m.

### **Peyronie's/Reconstruction**

*Brian S. Christine, MD*

10:05 a.m. - 10:15 a.m.

### **Hypogonadism**

*Ashley H. Tapscott, DO*

# Unmoderated Posters



## 123. Outcomes associated with Peyronie's disease by duration of disease

Levine, L.A.<sup>1</sup>; Gelbard, M.K.<sup>2</sup>; Tursi, J.P.<sup>3</sup>; Smith, T.M.<sup>3</sup>; Kaufman, G.J.<sup>3</sup>;

Gilbert, K.<sup>3</sup>; Kaminetsky, J.<sup>4</sup>; Mulhall, J.P.<sup>5</sup>

1: Rush University, Chicago, IL, USA; 2: Urology Associates Medical Group, Burbank, CA; 3: Auxilium Pharmaceuticals, Chesterbrook, PA; 4: University Urology Associates, New York, NY, USA; 5: Memorial Sloan-Kettering Cancer Center, New York, NY, USA



## 124. The efficacy of once-daily administration of Udenafil for 24 weeks on erectile dysfunction and lower urinary tract symptoms; results from a

randomized multicenter placebo-controlled clinical trial

Ko, Y.H.<sup>1</sup>; Moon, K.H.<sup>1</sup>; Kim, S.W.<sup>2</sup>; Moon, D.G.<sup>3</sup>; Kim, J.J.<sup>3</sup>; Park, N.C.<sup>4</sup>; Lee, S.W.<sup>5</sup>; Pacik, J.S.<sup>6</sup>; Ahn, T.Y.<sup>7</sup>; Chung, W.S.<sup>8</sup>; Min, K.S.<sup>9</sup>; Park, J.K.<sup>10</sup>; Yang, D.<sup>11</sup>; Park, K.S.<sup>12</sup>

1: Yeungnam University, Korea, South; 2: The Catholic University of Korea, Korea, South; 3: Korea University, Korea, South; 4: Pusan National University, Korea, South; 5: Samsung Medical Center, Korea, South; 6: Seoul National University, Korea, South; 7: Asan Medical Center, Korea, South; 8: Ewha Womans University, Korea, South; 9: Inje University, Korea, South; 10: Chonbuk National University, Korea, South; 11: Hallym University, Korea, South; 12: Chonnam National University, Korea, South



## 125. Functional outcomes and follow-up care after priapism treatment: A contemporary experience at a single institution

Kappa, S.F.<sup>1</sup>; Green, E.A.<sup>1</sup>; Joshi,

S.<sup>1</sup>; Kaufman, M.R.<sup>1</sup>; Milam, D.F.<sup>1</sup>

1: Vanderbilt University Medical Center, USA



## 126. Bulbocavernosus muscle area as a surrogate marker of hypogonadism in a symptomatic male population

Gupta, N.G.<sup>1</sup>; Herati, A.<sup>1</sup>;

Yamashita, Y.Y.<sup>2</sup>; Gilbert, B.R.<sup>1</sup>

1: North Shore-LIJ Smith Institute for Urology, USA; 2: Hofstra University, USA



## 127. Association of free testosterone with hypogonadal symptoms in men with near normal total testosterone levels

Wilken, N.<sup>1</sup>; Scovell, J.<sup>1</sup>;

Ramasamy, R.<sup>1</sup>; Lipshultz, L.<sup>1</sup>

1: Baylor College of Medicine, USA



## 128. The impact of vasectomy on sexual frequency

Guo, D.<sup>1</sup>; Eisenberg, M.<sup>1</sup>

1: Stanford University, USA



## 129. Subcutaneous (SC) testosterone enanthate (TE) 50 mg and 100 mg administered with a novel, auto-injector (AI) provides effective testosterone

(T) replacement

Kaminetsky, J.<sup>1</sup>; Jaffe, J.<sup>2</sup>; Swerdloff, R.<sup>3</sup>

1: NYU Langone Medical Center, New York, NY, USA; 2: Antares Pharma, Inc., Ewing, NJ, USA; 3: University of California Los Angeles Medical School, Los Angeles, CA, USA



## 130. Testosterone replacement therapy in hypogonadal men undergoing active surveillance for prostate cancer

Berookhim, B.<sup>1</sup>; Krishnan, R.<sup>2</sup>;

# Unmoderated Posters

Nelson, C.J.<sup>2</sup>; Mulhall, J.P.<sup>2</sup>

1: Lenox Hill Hospital, USA; 2: Memorial Sloan Kettering Cancer Center, USA



## 131. Outcomes of for cause prostate biopsy in men with hypogonadism

Shoskes, D.<sup>1</sup>; Barazani, Y.<sup>1</sup>; Fareed, K.<sup>1</sup>; Sabanegh, E.<sup>1</sup>

1: Cleveland Clinic, USA



## 132. Testosterone replacement therapy following androgen deprivation therapy among men with high risk prostate cancer

Krakowsky, Y.<sup>1</sup>; Hollingsworth, J.<sup>1</sup>;

Bristow, R.G.<sup>1</sup>; Berlin, A.<sup>1</sup>; Grober, E.D.<sup>1</sup>

1: University of Toronto, Canada



## 133. A review of the robotic microsurgical varicocele experience at Albany Medical Center

Ellen, J.<sup>1</sup>; Alkaram, A.<sup>1</sup>; Mechlin,

C.<sup>1</sup>; McCullough, A.<sup>1</sup>

1: Albany Medical Center, USA



## 134. Increased prevalence of hypoprolactinemia in men on testosterone supplementation therapy

Chandrashekar, A.<sup>1</sup>; Scovell, J.<sup>1</sup>;

Hakky, T.<sup>1</sup>; Pastuszak, A.<sup>1</sup>; Lipshultz, L.<sup>1</sup>

1: Baylor College of Medicine, USA



## 135. Consistency of serum testosterone levels in patients using Axiron

Muram, D.<sup>1</sup>; Baygani, S.K.<sup>1</sup>

1: Lilly Research Laboratories, USA



## 136. Safety of a new SEDDS formulation of oral Testosterone Undecanoate (TU) in hypogonadal men: Data from two phase 3 trials with different dose-titration algorithms

Swerdlow, R.S.<sup>1</sup>; Salameh, W.<sup>2</sup>; Dobs, A.<sup>3</sup>; Faulkner, S.<sup>2</sup>; Dudley, R.<sup>2</sup>; Flippo, G.<sup>4</sup>; Kaminetsky, J.<sup>5</sup>; Armory, J.<sup>6</sup>; Honig, S.H.<sup>7</sup>; Danoff, T.<sup>2</sup>; Wang, C.<sup>8</sup>

1: UCLA, USA; 2: Clarus Therapeutics, USA; 3: Johns Hopkins, USA; 4: Alabama Clinical Therapeutics, USA; 5: University Urology Assoc, USA; 6: University of Washington, USA; 7: Yale University; 8: Ucla, USA



## 137. Combination therapy of Tadalafil and Pentoxifylline in severe erectile dysfunction: A prospective randomized trial

Kumar, S.<sup>1</sup>; Kumar, R.<sup>1</sup>; Agrawal,

S.<sup>1</sup>; Jayant, K.<sup>1</sup>; Parmar, K.<sup>1</sup>; Sriharsha, A.<sup>1</sup>; Mavuduru, R.<sup>1</sup>; Singh, S.<sup>1</sup>

1: Postgraduate Institute of Medical Education and Research Chandigarh, India. PIN 160012, India



## 138. "Early" administration of low-dose tadalafil increases nocturnal penile tumescence in the acute phase after nerve-sparing radical prostatectomy

Bannowsky, A.<sup>1</sup>; Ückert, S.<sup>2</sup>; Samuel, C.<sup>1</sup>; van Ahlen, H.<sup>1</sup>

1: Klinikum Osnabrueck, Germany; 2: Hannover Medical School, Germany



## 139. Variation in penile vascular parameters according to location of cavernosal artery imaging

Pagano, M.<sup>1</sup>; Stahl, P.<sup>1</sup>

1: Columbia University College of Physicians and Surgeons, USA

# Unmoderated Posters



**140. Effects of daily dosing strategy of phosphodiesterase 5 inhibitors on prescription pattern**  
Yoo, D.S.<sup>1</sup>; Kim, B.<sup>2</sup>; Lim, J.<sup>3</sup>; Kim, D.<sup>1</sup>; Kim, E.<sup>1</sup>; Park, J.<sup>1</sup>; Woo, S.<sup>1</sup>

1: Department of Urology, Eulji University School of Medicine, Daejeon, Korea; 2: Daejeon Veterans Hospital, Daejeon, Korea; 3: Gangneung Asan Hospital, University of Ulsan College of Medicine, Gangneung, Korea



**141. An evaluation of semen characteristics in men after daily dosing of Udenafil**  
Sikka, S.S.<sup>1</sup>; Carlyon, T.C.<sup>2</sup>; Cardinali, L.<sup>2</sup>; Sniukiene, V.<sup>2</sup>

1: Tulane University Health Sciences Center; 2: Actavis plc



**142. The effect of Levitra on sustenance of erection (EROS): An open-label, prospective, multicenter, single-arm study to investigate the change of erection duration measured by stopwatch with flexible dose vardenafil administered for 8 weeks in subjects with erectile dysfunction**

Park, J.K.<sup>1</sup>; Lee, S.W.<sup>2</sup>; Park, K.<sup>3</sup>; Chung, W.S.<sup>4</sup>; Kim, S.W.<sup>5</sup>; Hyun, J.S.<sup>6</sup>; Moon, D.G.<sup>7</sup>; Yang, S.K.<sup>8</sup>; Ryu, J.K.<sup>9</sup>; Yang, D.<sup>10</sup>; Moon, K.H.<sup>11</sup>; Min, K.S.<sup>12</sup>; Shin, Y.<sup>13</sup>  
 1: Chonbuk National Univ. of Medical School and Biomedical Research Inst. and Clinical Trial Center for Medical Devices of Chonbuk National Univ. Hospital, Jeonju, Korea, South; 2: Sungkyunkwan Univ., Seoul, Korea.; 3: Chonnam National Univ. Gwangju, Korea; 4: Ihwa Univ., Seoul, Korea; 5: Catholic Univ., Seoul, Korea; 6: Kyungsang National Univ., Jinju, Korea; 7: Korea Univ., Seoul, Korea; 8: Chungju Hospital, Konkuk University, Chungju, Korea; 9: Inha Univ., Incheon, Korea; 10: Hallym Univ., Seoul, Korea; 11: Youngnam Univ., Daegu, Korea; 12: Inje Univ., Busan, Korea; 13: Chonbuk National Univ. of Medical School and Biomedical Research Inst. and Clinical Trial Center for Medical Devices of Chonbuk National Univ. Hospital, Jeonju, Korea



**143. Long-term efficacy, safety and satisfaction of intracavernosal injection therapy for radical prostatectomy patients**  
Phillips, E.A.<sup>1</sup>; Gross, M.<sup>1</sup>; Munarriz, R.<sup>1</sup>

1: Boston Medical Center, USA



**144. Prevalence and predictors of erectile dysfunction in Afro-Caribbean males with Type 2 Diabetes Mellitus: Is the glycosylated hemoglobin level predictive?**

Morrison, B.<sup>1</sup>; Balachandar, B.<sup>1</sup>; Wright-Pascoe, R.<sup>1</sup>; Reid, M.<sup>1</sup>

1: University of the West Indies, Jamaica



**145. Testosterone supplementation improves sexual function in hypogonadal men**  
Hakky, T.S.<sup>1</sup>; Pham, B.<sup>1</sup>; Wilken, N.<sup>1</sup>; Ramasamy, R.<sup>1</sup>; Chandrashekar, A.<sup>1</sup>;

Pastuszak, A.<sup>1</sup>; Lipshultz, L.I.<sup>1</sup>

1: Baylor College of Medicine, USA



**146. Identifying obstructive sleep apnea risk using a single-item question**

O'Boyle, K.<sup>1</sup>; Iyengar, R.L.<sup>1</sup>; Saeed, R.<sup>1</sup>; Maceda, C.<sup>1</sup>; Beebe, H.<sup>1</sup>;

Crowley, L.<sup>1</sup>; Bar-Chama, N.<sup>1</sup>; McLaughlin, M.A.<sup>1</sup>

1: Ichan School of Medicine at Mount Sinai, USA



**147. Preliminary assessment on the treatment of erectile dysfunction with Trimix gel**

Martinez, D.<sup>1</sup>; Chechik, J.<sup>2</sup>; Frasca, C.<sup>2</sup>; Munarriz, R.<sup>3</sup>; Parker, J.<sup>1</sup>; Carrion, R.<sup>1</sup>

1: University of South Florida, USA; 2: MenMD, USA; 3: Boston University School of Medicine, USA

# Unmoderated Posters



**148. Changes of sexual function after photoselective vaporization of the prostate by 120W greenLight high performance system laser: Long-term follow-up**

*Park, J.<sup>1</sup>; Cho, S.Y.<sup>2</sup>; Lee, S.B.<sup>1</sup>; Son, H.<sup>1</sup>; Kim, S.W.<sup>3</sup>; Paick, J.S.<sup>3</sup>*

*1: SMG-SNU Boramae Medical Center, Korea, South; 2: MG-SNU Boramae Medical Center, Korea, South; 3: Seoul National University Hospital, Korea, South*



**149. The relationship between carotid artery disease and erectile dysfunction**

*Lee, J.H.<sup>1</sup>*

*1: National Police Hospital, Korea, South*



**150. Inflatable penile prosthesis after quadratic transobturator male sling procedure**

*Weinberg, A.<sup>1</sup>; Deibert, C.<sup>1</sup>; Hernandez, K.<sup>1</sup>; Valenzuela, R.<sup>1</sup>*

*1: Columbia University Medical Center, USA*



**151. Deep glansplasty for impending medial distal extrusion of penile prosthesis cylinders**

*Chung, P.H.<sup>1</sup>; Tausch, T.J.<sup>1</sup>; Siegel, J.<sup>1</sup>; Morey, A.F.<sup>1</sup>*

*1: University of Texas Southwestern Medical Center, USA*



**152. Penile to scrotal length ratio and its influence on male attractiveness**

*Sanchez, P.<sup>1</sup>; Salgado, C.<sup>1</sup>; Gasgarth, R.<sup>1</sup>; Sinha, V.<sup>1</sup>; Flores, B.<sup>1</sup>*

*1: University of Miami Miller School of Medicine, USA*



**153. A retrospective analysis of health and socioeconomic factors of IPP patients: Active substance abuse concurrent with surgery as a newly-identified infection risk factor**

*Gross, M.<sup>1</sup>; Munarriz, R.<sup>1</sup>*

*1: Boston University Medical Center, USA*



**154. Preoperative penile measurements guide size selection of penile prosthetic implant**

*Sharma, N.<sup>1</sup>; Cordon, B.H.<sup>1</sup>; Eid, J.F.<sup>1</sup>*

*J.F.<sup>1</sup>*

*1: North Shore LIJ-Lenox Hill Hospital, New York, NY, USA*



**155. Effect of hypogonadism on the management plan of severe vasculogenic erectile dysfunction (ED)**

*Saleh, F.<sup>1</sup>; Bianco, F.<sup>1</sup>; Perito, P.<sup>1</sup>; Gheiler, E.<sup>1</sup>*

*1: USA*



**156. The minimally invasive infrapubic inflatable penile prosthesis: Our most recent 1000**

*Perito, P.<sup>1</sup>; Guerra, J.; Moscowitz, A.*

*1: Perito Urology, USA*



**157. "Just the Tip": Closed suction drain cultures after penile implant surgery with prolonged drains**

*Martinez, D.R.<sup>1</sup>; Wallen, J.<sup>1</sup>; Emtage, J.<sup>1</sup>; Rafiei, A.<sup>1</sup>; Parker, J.<sup>1</sup>; Carrion, R.<sup>1</sup>*

*1: University of South Florida, USA*

# Unmoderated Posters



## 158. Ventral or dorsal penoplasty for hypermobile floppy glans after penile prosthesis

Yang, C.<sup>1</sup>; Martinez, D.<sup>1</sup>; Baumgarten, A.S.<sup>1</sup>; Parker, J.<sup>1</sup>;

Carrion, R.<sup>1</sup>

1: University of South Florida, USA



## 163. Erectile dysfunction caused by a retropubic ganglion cyst - a rare tumor entity in the lesser pelvis

Bannowsky, A.<sup>1</sup>; Raileanu, A.<sup>1</sup>; Ückert, S.<sup>2</sup>; van Ahlen, H.<sup>1</sup>

1: Klinikum Osnabrueck, Germany; 2: Hannover Medical School, Germany



## 159. Glans fixation for floating glans (supersonic transporter deformity) during penile prosthesis placement, without additional incisions

Valenzuela, R.<sup>1</sup>; Weinberg, A.<sup>1</sup>; Deibert, C.<sup>1</sup>; Hernandez, K.<sup>1</sup>; Egydio, P.<sup>2</sup>

1: Columbia University Medical Center, USA; 2: University of Sao Paulo, Brazil



## 164. Are some US academic centers regulating themselves out of multicenter studies: The proper registry experience with IRB and contract approval

Henry, G.<sup>1</sup>; Karpman, E.<sup>2</sup>; Kansas, B.<sup>3</sup>; Brant, W.<sup>4</sup>; Jones, L.<sup>5</sup>; Bennett, N.<sup>6</sup>; Khera, M.<sup>7</sup>; Kohler, T.<sup>8</sup>; Kramer, A.<sup>9</sup>; Christine, B.<sup>10</sup>; Rhee, E.<sup>11</sup>; Carrion, R.<sup>12</sup>; Bella, A.<sup>13</sup>

1: Regional Urology, USA; 2: El Camino Urology, USA; 3: The Urology Team, USA; 4: University of Utah, USA; 5: Urology San Antonio, USA; 6: Lahey Clinic, Urology; 7: Baylor College of Medicine, USA; 8: SIU School of Medicine, USA; 9: University of Maryland, USA; 10: Urology Alabama, USA; 11: Kaiser San Diego, USA; 12: University of South Florida, USA; 13: Ottawa Hospital Research Institute, USA



## 160. Concomitant IPP and Virtue® male sling placement utilizing a single incision

Ayoub, H.<sup>1</sup>; Wang, R.<sup>1</sup>; Westney, O.L.<sup>1</sup>

1: MD Anderson Cancer Center, Houston, USA



## 161. Delayed post-operative hematoma formation after inflatable penile prosthesis insertion

Bickell, M.<sup>1</sup>; Garber, B.<sup>2</sup>

1: Hahnemann University Hospital, USA; 2: Hahnemann University Hospital



## 165. The effect on blood flow rate of prostate in daily administration of mirodenafil 50mg for benign prostatic hyperplasia patients: randomized

controlled, double blinded trial

Lee, S.W.<sup>1</sup>; Chung, J.H.<sup>2</sup>; Kim, K.S.<sup>1</sup>; Park, H.Y.<sup>1</sup>

1: Hanyang University Hospital, Korea, South; 2: Sokcho health care center, Korea, South



## 162. A series utilizing the “Molly Brown” stitch during inflatable penile prosthesis placement

Martinez, D.<sup>1</sup>; Mennie, P.<sup>1</sup>; Wallen, J.<sup>1</sup>; Parker, J.<sup>1</sup>; Dineen, M.<sup>2</sup>; Carrion, R.<sup>1</sup>

1: University of South Florida, USA; 2: Atlanta Urology Associates



# Unmoderated Posters



## 166. Prospective study of patient experience following prostatic urethral lift

Bogache, W.K.<sup>1</sup>; Freedman, S.J.<sup>2</sup>; Gange, S.N.<sup>3</sup>; Moseley, W.G.<sup>4</sup>;

Heron, S.P.<sup>5</sup>; Tutrone, R.F.<sup>6</sup>; Cantwell, A.L.<sup>7</sup>

1: Atlantic Urology Clinics, USA; 2: Sheldon J. Freedman, MD, LTD, USA; 3: Western Urological Clinic, USA; 4: Genesis Healthcare Partners, USA; 5: Pinellas Urology, Inc., USA; 6: Chesapeake Urology Research Associates, USA; 7: Atlantic Urological Associates, USA



## 167. Preserving sexual function with the Rezûm System: Using steam therapy to treat LUTS/BPH

Butcher, M.J.<sup>1</sup>; Dixon, C.<sup>2</sup>; Wagrell, L.<sup>3</sup>; Tornblom, M.<sup>3</sup>; Pacik, D.<sup>4</sup>;

Cedano, E.<sup>5</sup>; Kohler, T.<sup>1</sup>; McVary, K.<sup>1</sup>

1: Division of Urology, Southern Illinois University, USA; 2: Lennox Hill Hospital, New York, New York, USA; 3: Urologcentrum, Stockholm, Sweden; 4: Fakultni Nemocnice Brno University Hospital, Brno, Czech Republic; 5: Clinica Canela, Department of Urology, La Romana, Dominican Republic



## 168. Contemporary outcomes for targeted denervation of the spermatic cord for chronic scrotal content pain

Parekattil, S.<sup>1</sup>; Tojuola, B.<sup>1</sup>; Kartal, I.<sup>1</sup>; Brahmbhatt, J.<sup>1</sup>

1: South Lake Hospital, USA



## 169. Are negative preoperative urine cultures necessary for artificial urinary sphincter placement?

Siegel, J.A.<sup>1</sup>; Tellman, M.W.<sup>2</sup>;

Tausch, T.J.<sup>1</sup>; Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA; 2: Indiana University-Purdue University Indianapolis, USA



## 170. Survey on the impact of sexual health issues on overall health, happiness, and quality of life

Arrindell, D.<sup>1</sup>; Battaglino, E.<sup>2</sup>; Fadich, A.<sup>3</sup>; Leonard, B.<sup>3</sup>

1: American Sexual Health Association, USA; 2: Healthy Women; 3: Men's Health Network



## 171. Expression and distribution of fatty acid amide hydrolase (FAAH) in the human seminal vesicles and vas deferens

la Croce, G.<sup>1</sup>; Miscretta, F.<sup>1</sup>;

Bettiga, A.<sup>1</sup>; Colciago, G.<sup>1</sup>; Kuczyk, M.A.<sup>2</sup>; Ückert, S.<sup>2</sup>; Montorsi, F.<sup>1</sup>; Hedlund, P.<sup>3</sup>

1: University Vita Salute San Raffaele, Urological Research Institute, Milan, Italy; 2: Hannover Medical School, Dept. of Urology, Hannover, Germany; 3: Linköping University, Dept. of Clinical Pharmacology, Linköping, Sweden



## 172. Reduction of "unnecessary" radiation exposition for the patient and medical staff – Can transrectal ultrasound replace cystography in the evaluation of the vesicourethral anastomosis after radical prostatectomy?

Bannowsky, A.<sup>1</sup>; Ückert, S.<sup>2</sup>; Jünemann, K.<sup>3</sup>; van Ahlen, H.<sup>1</sup>

1: Klinikum Osnabrueck, Germany; 2: Hannover Medical School, Germany; 3: University Hospital Schleswig-Holstein, Campus Kiel, Germany



## 173. A survey on the sexual behavior of elderly people in South Korea

Kim, J.W.<sup>1</sup>; Lee, S.W.<sup>2</sup>; Min, K.S.<sup>3</sup>; Kim, J.J.<sup>1</sup>; Moon, D.G.<sup>1</sup>

1: Korea University College of Medicine, Korea, South; 2: Sungkyunkwan University School of Medicine, Korea, South; 3: Department of Urology, Inje University Busan Paik Hospital, Busan, Korea

# Unmoderated Posters



**174. Intraoperative findings influence decision-making in vasectomy reversal procedures - survey of fellowship-trained, high-volume surgeons**

Chandrashekar, A.<sup>1</sup>; Dupree, J.<sup>2</sup>; Ramasamy, R.<sup>1</sup>; Craig, M.<sup>1</sup>; Scovell, J.<sup>1</sup>; Hakky, T.<sup>1</sup>; Pastuszek, A.<sup>1</sup>

1: Baylor College of Medicine, USA; 2: University of Michigan, USA



**175. The concordance of preoperative core testis needle biopsies with surgical diagnoses among azoospermic infertile men**

Hollingsworth, J.<sup>1</sup>; Mullen, B.J.<sup>2</sup>; Jarvi, K.A.<sup>2</sup>; Lo, K.<sup>2</sup>; Grober, E.D.<sup>2</sup>

1: Queen's University, Canada; 2: Mount Sinai Hospital, Canada



**176. Human sperm miRNA profile in patients with normozoospermia and teratozoospermia**

Herati, A.<sup>1</sup>; Mielnik, A.<sup>2</sup>; Feliciano, M.<sup>2</sup>; Schlegel, P.<sup>2</sup>; Paduch, D.<sup>2</sup>

1: NS-LIJ, USA; 2: Weill Cornell Medical College, USA



**177. Ameliorating effects of modified Ojayeonjonghwan on cryptorchidism-induced oxidative stress and decline of semen quality in rats**

Bae, W.J.<sup>1</sup>; Kim, K.S.<sup>1</sup>; Kim, S.J.<sup>1</sup>; Cho, H.J.<sup>1</sup>; Hong, S.<sup>1</sup>; Lee, J.Y.<sup>1</sup>; Hwang, T.K.<sup>1</sup>; Kim, S.W.<sup>1</sup>

1: Seoul St. Mary's Hospital, Korea, South



**178. Comparison of Biocompatibility between PDMS and PMMA as packaging materials for the Intravesical Implantable Device**

Bae, W.J.<sup>1</sup>; Kim, K.S.<sup>1</sup>; Kim, S.J.<sup>1</sup>; Cho, H.J.<sup>1</sup>; Hong, S.<sup>1</sup>; Lee, J.Y.<sup>1</sup>; Hwang, T.K.<sup>1</sup>; Kim, S.W.<sup>1</sup>

1: Seoul St. Mary's Hospital, Korea, South



**179. Effects of Schisandra chinensis extract on the relaxation of isolated human prostate tissue and smooth muscle cell**

Lee, S.W.<sup>1</sup>; Kim, J.J.<sup>1</sup>; Chae, M.R.<sup>1</sup>; Kang, S.J.<sup>1</sup>; Choo, S.H.<sup>2</sup>; Park, J.K.<sup>3</sup>

1: Samsung Medical Center, Sungkyunkwan University, Korea, South; 2: Department of Urology, Ajou University School of Medicine, Suwon, Korea; 3: Department of Urology, Chonbuk National University School of Medicine, Jeonju, Korea



**180. Outcomes of intralesional interferon-α2B for the treatment of ventral plaques in Peyronie's disease**

Stewart, C.S.<sup>1</sup>; Trost, L.<sup>2</sup>; Mandava, S.<sup>1</sup>; Knoedler, M.<sup>1</sup>; Sikka, S.<sup>1</sup>; Hellstrom, W.<sup>1</sup>

1: Tulane University Medical Center, USA; 2: Mayo Clinic, USA



**181. Versatile algorithmic approach for definitive straightening without modeling during penile prosthesis surgery**

Tausch, T.J.<sup>1</sup>; Chung, P.<sup>1</sup>; Siegel, J.<sup>1</sup>; Klein, A.<sup>1</sup>; Morey, A.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA

# Unmoderated Posters



## 182. Subcoronal exposure through a modified no touch technique for penile reconstructive surgery

Valenzuela, R.<sup>1</sup>; Weinberg,

A.<sup>1</sup>; Deibert, C.<sup>1</sup>; Hernandez, K.<sup>1</sup>; Egydio, P.<sup>2</sup>

1: Columbia University Medical Center, USA; 2: University of Sao Paulo, Brazil



## 183. Usage of the Carrion Curettage for the management of corporal fibrosis during penile implantation

Martinez, D.<sup>1</sup>; Carrion, R.<sup>1</sup>; Yang,

C.<sup>1</sup>; Parker, J.<sup>1</sup>; Carrion, H.<sup>2</sup>

1: University of South Florida, USA; 2: Carrion Urological Center, USA



## 184. Heavy calcification on duplex ultrasound for Peyronies negatively predicts functionality after 2nd intervention: A retrospective review at a single centre

Garcia, F.<sup>1</sup>; Violette, P.<sup>2</sup>; DeYoung, L.<sup>3</sup>; Brock, G.<sup>4</sup>

1: University of Saskatchewan, Cypress Health Region, Canada; 2: Western University, St. Joseph's Health Care, London, ON, Canada; 3: St. Joseph's Health Care, Lawson Health Research Institute, London, ON, Canada; 4: Western University, St. Joseph's Health Care, London, ON, Canada



## 185. Penile curvature secondary to Peyronie's disease with penile prosthesis and relaxing incisions without loss of length

Valenzuela, R.<sup>1</sup>; Weinberg,

A.<sup>1</sup>; Deibert, C.<sup>1</sup>; Egydio, P.<sup>2</sup>

1: Columbia University Medical Center, USA; 2: University of Sao Paulo Medical School, Brazil



## 186. Efficacy of extended intralesional verapamil therapy for Peyronie's disease in early responders

Berookhim, B.<sup>1</sup>; Larish, Y.<sup>1</sup>;

Chevinsky, M.<sup>2</sup>; Jakubowski, C.<sup>2</sup>; Jamzadeh, A.<sup>2</sup>;

Nelson, C.<sup>2</sup>; Mulhall, J.<sup>2</sup>

1: Lenox Hill Hospital, USA; 2: Memorial Sloan Kettering Cancer Center, USA



## 187. Relationship of factors associated with Peyronie's disease (PD) that affect PD bother and erectile function

Serefoglu, E.C.<sup>1</sup>; Berktaş, M.<sup>2</sup>;

Smith, T.M.<sup>3</sup>; Kaufman, G.J.<sup>3</sup>; Liu, G.<sup>3</sup>; Hellstrom,

W.J.G.<sup>4</sup>

1: Bagcilar Training & Research Hospital, Turkey; 2: Yeditepe University Pharmacoeconomics and Pharmacoepidemiology Research Center (PEPIRC), Istanbul, Turkey; 3: Auxilium Pharmaceuticals, Inc., Chesterbrook, PA, USA; 4: Tulane University Health Sciences Center, New Orleans, LA, USA



## 188. A novel technique for Peyronie's plaque excision and grafting using a lateral incision: The 'Window' technique

Emtage, J.B.<sup>1</sup>; Yang, C.<sup>1</sup>; Lue, K.<sup>1</sup>;

Martinez, D.<sup>1</sup>; Carrion, R.<sup>1</sup>

1: University of South Florida, USA



## 189. Long term outcome of intralesional triamcinolone acetonide (Kenalog) with Verapamil injection for Peyronie's disease

Golan, R.<sup>1</sup>; Ryan, C.<sup>1</sup>; Funaro, M.<sup>1</sup>; Miller, B.<sup>1</sup>;

Paduch, D.A.<sup>1</sup>

1: Weill Cornell Medical Center, USA

# Unmoderated Posters



**190. Lingual mucosal graft in treatment of Peyronie's disease**  
Salem, E.<sup>1</sup>; Elkady, E.<sup>1</sup>; Sakr, A.<sup>1</sup>; Maarouf, A.<sup>1</sup>; Bendary, L.<sup>1</sup>; Khalil, S.<sup>1</sup>; Shahin, A.<sup>1</sup>; Kamel, H.<sup>1</sup>

1: Egypt



**191. Pilot survey on prevalence of Peyronie's like symptoms in men with dupuytren's contracture**  
Shindel, A.<sup>1</sup>; Rankin-Wagenaar, R.<sup>1</sup>;

Thieu, W.<sup>1</sup>; Szabo, R.<sup>1</sup>

1: University of California, Davis, USA



**192. Utilization of the "Carrion Cast" for the management of refractory priapism**  
Martinez, D.<sup>1</sup>; Emtage, J.<sup>1</sup>; Parker, J.<sup>1</sup>; Carrion, R.<sup>1</sup>

1: University of South Florida, USA



**193. Treatment of priapism in the emergency department prior to urologic surgery consultation: A contemporary experience at a single institution**

Green, E.A.<sup>1</sup>; Kappa, S.F.<sup>1</sup>; Joshi, S.<sup>1</sup>; Kaufman, M.R.<sup>1</sup>; Milam, D.F.<sup>1</sup>

1: Vanderbilt University Medical Center, USA



**194. Alterations in vaginal pain sensitivity in women with dyspareunia independent of psychological factors**  
Padavil, N.<sup>1</sup>; Tu, F.<sup>2</sup>; Hellman, K.<sup>2</sup>

1: University of Chicago Pritzker School of Medicine, USA; 2: NorthShore University HealthSystem, University of Chicago Pritzker School of Medicine, USA



**195. Quality of life and sexual health function in bladder cancer surgery patients who underwent cystectomy**  
Umarji, R.<sup>1</sup>; Lee, C.<sup>1</sup>; Goltz, H.<sup>2</sup>;

Latini, D.<sup>3</sup>; Wittmann, D.<sup>1</sup>

1: University of Michigan, USA; 2: University of Houston-Downtown, USA and Baylor College of Medicine, USA; 3: Baylor College of Medicine, USA



**196. Smaller urethral caliber in prostatectomy versus non-prostatectomy patients: Comparison of AUS cuff sizes**  
Chung, P.H.<sup>1</sup>; Siegel, J.A.<sup>1</sup>; Tausch, T.J.<sup>1</sup>;

Mulhall, J.P.<sup>2</sup>; Morey, A.F.<sup>1</sup>

1: University of Texas Southwestern Medical Center, USA; 2: Memorial Sloan Kettering Cancer Center, USA



**197. Buccal mucosal graft urethroplasty for the treatment of urethral stricture in the neophallus**  
Pariser, J.J.<sup>1</sup>; Cohn, J.A.<sup>1</sup>; Gottlieb, L.J.<sup>1</sup>; Bales, G.T.<sup>1</sup>

1: University of Chicago, USA



**198. Transitioning transgender**  
Fein, L.A.<sup>1</sup>; Salgado, C.J.<sup>2</sup>; Estes, C.<sup>3</sup>

1: University of Miami Miller School of Medicine, USA; 2: University of Miami Miller School of Medicine, Division of Plastic Surgery, USA; 3: Planned Parenthood of South Florida and the Treasure Coast, USA



**199. Erectile dysfunction after recurrent ischemic priapism in patients with and without sickle cell disease: Comparative analysis of risk factors**

Anele, U.<sup>1</sup>; Burnett, A.L.<sup>1</sup>

1: Brady Urological Institute, The Johns Hopkins School of Medicine, USA

# Unmoderated Posters



**200. The early use of phenylephrine in the prophylaxis of iatrogenic priapism in Peyronie's patients undergoing penile duplex doppler ultrasonography**

*Sadeghi-Nejad, H.<sup>1</sup>; Jiang, P.<sup>2</sup>; Christakos, A.<sup>2</sup>*

*1: Rutgers-New Jersey Medical School, Hackensack University Medical Center, VA NJ Health Care System, USA; 2: Rutgers-New Jersey Medical School, USA*



**201. Perineal body lengthening in females with displeasure of distorted perineum**

*Salgado, C.J.<sup>1</sup>; Fein, L.A.<sup>2</sup>; Gasgarth, R.<sup>1</sup>; Aponte, Y.<sup>1</sup>; Estes, C.M.<sup>3</sup>*

*1: Division of Plastic, Aesthetic, and Reconstructive Surgery, University of Miami Miller School of Medicine, USA; 2: University of Miami Miller School of Medicine, USA; 3: Planned Parenthood of South Florida and the Treasure Coast*



**202. Complications of genital piercings**

*Fein, L.A.<sup>1</sup>; Dalke, K.A.<sup>2</sup>; Jenkins, L.C.<sup>3</sup>; Caso, J.R.<sup>3</sup>; Salgado, C.J.<sup>4</sup>*

*1: University of Miami Miller School of*

*Medicine, USA; 2: Department of Obstetrics and Gynecology, University of Miami Miller School of Medicine, USA; 3: Department of Urology, University of Miami Miller School of Medicine, USA; 4: Division of Plastic, Aesthetic, and Reconstructive Surgery, University of Miami Miller School of Medicine, USA*



**203. Ligasure vessel sealing system facilitates rapid excision of massive genital lymphedema: A multi-institutional experience**

*Siegel, J.A.<sup>1</sup>; Zhao, L.C.<sup>2</sup>; Simham,*

*J.<sup>1</sup>; Belsante, M.J.<sup>1</sup>; Tausch, T.J.<sup>1</sup>; Vanni, A.J.<sup>3</sup>; Morey, A.F.<sup>1</sup>*

*1: University of Texas Southwestern Medical Center, USA; 2: New York University Langone Medical Center, USA; 3: Lahey Hospital & Medical Center*



**204. Dutasteride for recurrent priapism: A novel therapy**

*Tausch, T.J.<sup>1</sup>; Klein, A.K.<sup>1</sup>; Ashorobi, O.<sup>1</sup>; Siegel, J.<sup>1</sup>; Morey, A.F.<sup>1</sup>; Roehrborn, C.G.<sup>1</sup>*

*1: University of Texas Southwestern Medical Center, USA*



**205. The reduction corporoplasty: The answer to the unlikely question, "Can you make my penis smaller?"**

*Martinez, D.R.<sup>1</sup>; Manimala, N.<sup>1</sup>;*

*Rafiei, A.<sup>1</sup>; Emtage, J.<sup>1</sup>; Parker, J.<sup>1</sup>*

*1: University of South Florida, USA*



**206. Non-grafted vaginal depth augmentation for transgender atresia, our experience and survey of other procedures**

*Reed, H.<sup>1</sup>; Yanes, R.<sup>2</sup>; Delto, J.<sup>2</sup>;*

*Omarzai, Y.<sup>2</sup>; Imperatore, K.<sup>2</sup>*

*1: Reed Centre for Ambulatory Urological Surgery, Bay Harbor Islands, FL, USA; 2: Mount Sinai Medical Center Miami Beach, USA*



**207. High-flow priapism due to penile malignant peripheral nerve sheath tumor in a patient with Von Recklinghausen disease**

*Taylor, A.<sup>1</sup>; Broderick, G.<sup>1</sup>*

*1: Mayo Clinic Florida, USA*



**208. Efficacy and safety of polylactic acid microsphere as an injectable bulking agent for penile enhancement: 6-months follow-up**

*Lee, W.K.<sup>1</sup>; Kim, J.Y.<sup>2</sup>; Yang, S.K.<sup>3</sup>; Moon,*

*D.G.<sup>4</sup>; Yang, D.<sup>5</sup>*

# Unmoderated Posters

1: Hallym University Chuncheon Sacred Heart Hospital, Korea, South; 2: Seroi Clinic, Korea, South; 3: College of Medicine, Konkuk University, Korea, South; 4: College of Medicine, Korea University, Korea, South; 5: College of Medicine, Hallym University, Korea, South



## 209. Efficacy and safety of newly developed glandular injection of cross-linked dextran gel on glans penis augmentation

Lee, W.K.<sup>1</sup>; Kim, J.W.<sup>2</sup>; Yang, S.K.<sup>3</sup>;

Moon, D.G.<sup>4</sup>; Yang, D.<sup>5</sup>

1: Hallym University Chuncheon Sacred Heart Hospital, Korea, South; 2: College of Medicine, Joong Ang University, Korea, South; 3: College of Medicine, Konkuk University, Korea, South; 4: College of Medicine, Korea University, Korea, South; 5: College of Medicine, Hallym University



## 210. Spontaneous cavernosal hematoma mimicking malignant priapism

Phillips, E.<sup>1</sup>; Mendoza, P.<sup>2</sup>;  
Munarriz, R.<sup>1</sup>

1: Boston Medical Center, USA; 2: Jersey Shore University Medical Center



## 211. Functional outcomes and followup care for rare priapism cases: Spinal cord injury and baclofen pump malfunction

Green, E.A.<sup>1</sup>; Kappa, S.F.<sup>1</sup>; Joshi,

S.<sup>1</sup>; Kaufman, M.R.<sup>1</sup>; Milam, D.F.<sup>1</sup>

1: Vanderbilt University Medical Center, USA



## 212. Intracavernosal prostaglandin injection prior to circumcision allows more precise removal of foreskin

Sharma, N.<sup>1</sup>; Cordon, B.H.<sup>1</sup>; Eid, J.F.<sup>1</sup>

1: North Shore LIJ-Lenox Hill Hospital, USA



## 213. Mechanism of hypogonadism in the transgenic sickle cell mouse

Musicki, B.<sup>1</sup>; Chen, H.<sup>1</sup>; Zhang, Y.<sup>1</sup>;  
Brown, T.<sup>1</sup>; Zirkin, B.<sup>1</sup>; Burnett, A.<sup>1</sup>

1: Johns Hopkins University, USA



## 214. Mechanism of Sonic hedgehog induced cavernous nerve regeneration

Podlasek, C.<sup>1</sup>; Bond, C.<sup>2</sup>

1: University of Illinois at Chicago, USA; 2: Northwestern University



## 215. Topically applied NO-releasing nanoparticles can increase intracorporal pressure and elicit spontaneous erections in a rat model of radical prostatectomy.

Davies, K.P.<sup>1</sup>; Tar, M.<sup>1</sup>; Cabrales, P.<sup>2</sup>; Mahantesh, N.<sup>1</sup>;  
Friedman, A.<sup>1</sup>; Friedman, J.<sup>1</sup>

1: Albert Einstein College of Medicine, USA; 2: University of California, San Diego



## 216. eNOS uncoupling in the diabetic human penis

Musicki, B.<sup>1</sup>; Burnett, A.<sup>1</sup>

1: Johns Hopkins University, USA



## 217. Induced pluripotent stem cells (iPS) ameliorate corporal veno-occlusive dysfunction (CVD) in a rat model of bilateral cavernosal nerve resection

(BCNR), possibly through cross-talk with penile stem cells

# Unmoderated Posters

Vernet, D.<sup>1</sup>; Kovanecz, I.<sup>2</sup>; Masouminia, M.<sup>1</sup>; Loni, L.<sup>1</sup>; Aboagye, J.<sup>1</sup>; Rajfer, J.<sup>3</sup>; Izpisua Belmonte, J.C.<sup>4</sup>; Gonzalez-Cadavid, N.F.<sup>5</sup>

1: LABioMed Research Institute at Harbor-UCLA, USA; 2: LABioMed Research Institute at Harbor-UCLA, USA and UCLA School of Medicine, USA; 3: UCLA School of Medicine, USA and LABioMed Research Institute at Harbor-UCLA, USA; 4: Salk Institute, USA; 5: LABioMed Research Institution at Harbor-UCLA, USA and UCLA School of Medicine, USA



**218. Radioprotection of erectile function using novel anti-oxidant in the rat**

Granieri, M.<sup>1</sup>; Tovmasyan, A.<sup>1</sup>; Yan, H.<sup>1</sup>; Lu, X.<sup>1</sup>; Mao, L.<sup>1</sup>; Macias, E.<sup>1</sup>;

Spasojevic, I.<sup>1</sup>; Batinic-Haberle, I.<sup>1</sup>; Peterson, A.C.<sup>1</sup>; Koontz, B.F.<sup>1</sup>

1: Duke University, USA



**219. Efficacy of human bone marrow derived stem cells in type 2 DM rats (ZFDM) with erectile dysfunction: According to dose of transplantation**

Song, G.<sup>1</sup>; You, D.<sup>2</sup>; Kim, C.S.<sup>2</sup>; Ahn, T.Y.<sup>2</sup>

1: Kangwon national hospital, Korea, South; 2: Department of Urology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea



**220. Effects of chronic administration of PDE5 inhibitor combined with glycemic control on erectile function in streptozotocin-induced diabetic rats**

**rats**

Park, J.<sup>1</sup>; Kim, S.W.<sup>1</sup>; Paick, J.S.<sup>2</sup>

1: Seoul National University, Korea, South; 2: Eoul National University, Korea, South



**221. Western diet increases penile in vivo reactive oxygen species independent of fibrotic signaling**

La Favor, J.D.<sup>1</sup>; Luke, N.A.<sup>1</sup>;

Hannan, J.L.<sup>1</sup>; Burnett, A.L.<sup>1</sup>

1: Johns Hopkins University, USA



**222. A study on the effect of injection frequency of human bone marrow derived stem cells in type 2 DM rats (ZFDM) with erectile dysfunction**

Song, G.<sup>1</sup>; You, D.<sup>2</sup>; Kim, C.S.<sup>2</sup>; Ahn, T.Y.<sup>2</sup>

1: Kangwon national hospital, Korea, South; 2: Department of Urology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea



**223. Reduced equilibrative nucleoside transporter type 2 in pathophysiology of priapism**

Zhao, C.<sup>1</sup>; Wen, J.M.<sup>2</sup>; Ning, C.<sup>3</sup>;

Zhang, Y.<sup>1</sup>; Song, A.<sup>1</sup>; Wu, H.<sup>1</sup>;

Blackburn, M.R.<sup>1</sup>; Kellems, R.E.<sup>1</sup>; Xia, Y.<sup>1</sup>

1: University of Texas Health Science Center at Houston, USA; 2: Zhejiang University, China; 3: Capital Medical University, China



**224. Toll-like receptor 1/2 heterodimer mediates increased contractile responses in rat corpus cavernosum: A novel mechanism contributing to**

**erectile dysfunction**

Stallmann-Jorgensen, I.<sup>1</sup>; Ogbi, S.<sup>1</sup>; Webb, R.C.<sup>1</sup>

1: Georgia Regents University, USA

# Unmoderated Posters



## 225. The different patterns of TRPC subtypes expression in the disease- related erectile dysfunction

Lee, S.W.<sup>1</sup>; Kim, J.J.<sup>1</sup>; Chae, M.R.<sup>1</sup>;

Kang, S.J.<sup>1</sup>; Park, J.K.<sup>2</sup>

1: Samsung Medical Center, Sungkyunkwan University, Korea, South; 2: Department of Urology, Chonbuk National University Medical School, Jeonju, Korea



## 229. Prevalence of ejaculatory dysfunctions as a function of testosterone

Paduch, D.A.<sup>1</sup>; Polzer, P.<sup>2</sup>; Morgentaler, A.<sup>3</sup>; Althof, S.E.<sup>4</sup>;

Ni, X.<sup>2</sup>; Patel, A.B.<sup>2</sup>; Basaria, S.<sup>3</sup>

1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA; 4: Center for Marital and Sexual Health of South Florida, USA



## 226. Pioglitazone enhances survival and regeneration of rat pelvic ganglia nuerons after cavernosal nerve crush

Katz, E.<sup>1</sup>; Heidenberg, D.<sup>1</sup>; Haney,

N.<sup>1</sup>; Peak, T.<sup>1</sup>; Knoedler, M.<sup>1</sup>; Rittenberg, D.<sup>1</sup>; Rezk, B.<sup>2</sup>; Moustafa, A.<sup>3</sup>; Abd Elmageed, Z.<sup>1</sup>; Sikka, S.<sup>3</sup>; Abdel Mageed, A.<sup>3</sup>; Hellstrom, W.<sup>3</sup>

1: Tulane University School of Medicine, New Orleans, LA, USA; 2: Southern University of New Orleans, Department of Biology, New Orleans, LA, USA; 3: Department of Urology, Tulane University School of Medicine, New Orleans, LA, USA



## 230. Perceived sexual dissatisfaction with ejaculatory dysfunctions

Paduch, D.A.<sup>1</sup>; Polzer, P.<sup>2</sup>; Morgentaler, A.<sup>3</sup>; Althof, S.E.<sup>4</sup>; Ni,

X.<sup>2</sup>; Patel, A.B.<sup>2</sup>; Basaria, S.<sup>3</sup>

1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA; 4: Center for Marital and Sexual Health of South Florida, USA



## 227. NO dysregulation: A common mechanism of priapism and voiding dysfunction in sickle cell disease mice?

Anele, U.<sup>1</sup>; Lagoda, G.<sup>1</sup>; Hannan,

J.L.<sup>1</sup>; Bivalacqua, T.J.<sup>1</sup>; Burnett, A.L.<sup>1</sup>

1: Brady Urological Institute, The Johns Hopkins School of Medicine, USA



## 228. Effect of testosterone solution 2% for the treatment of ejaculatory dysfunction in androgen-deficient men

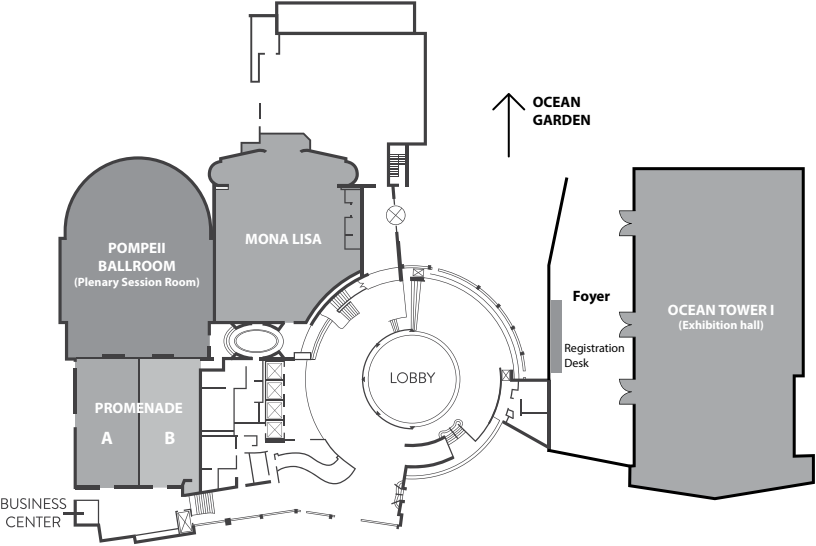
Paduch, D.A.<sup>1</sup>; Polzer, P.<sup>2</sup>; Ni, X.<sup>2</sup>;

Basaria, S.<sup>3</sup>

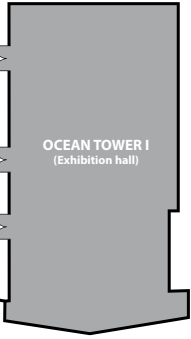
1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA



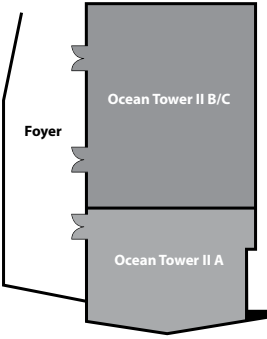
# Floor Plan



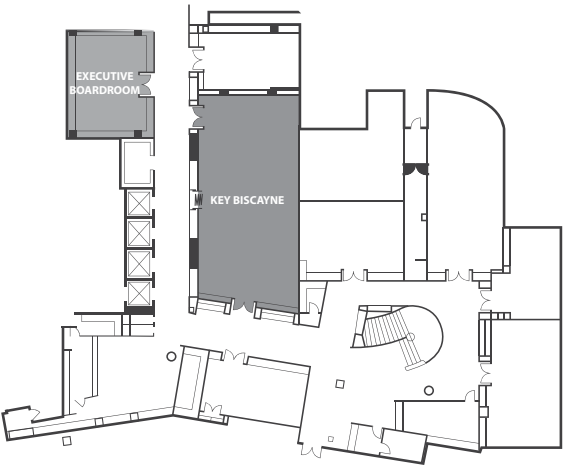
LEGENDARY TOWER  
LOBBY LEVEL



OCEAN TOWER  
LOBBY LEVEL



OCEAN TOWER  
UPPER LEVEL



LEGENDARY TOWER  
LOWER LOBBY LEVEL

# Abstracts

001

## **Impact on sexual function and two year durability of the prostatic urethral lift: A multi-center, prospective, randomized study**

*Butcher, MJ<sup>1</sup>; Roehrborn, CG<sup>2</sup>; Gange, SN<sup>3</sup>; Bolton, DM<sup>4</sup>; Te, AE<sup>5</sup>; Shore, ND<sup>6</sup>; Chin, PT<sup>7</sup>; Rashid, P<sup>8</sup>; Rukstalis, DB<sup>9</sup>; McVary, KT<sup>10</sup>*

1: Southern Illinois University, USA; 2: University of Texas Southwestern Medical Center, USA; 3: Western Urological Clinic, USA; 4: Austin Hospital, Australia; 5: Weill Cornell Medical College, USA; 6: Carolina Urological Research Center, USA; 7: Figtree Private Hospital, Australia; 8: Port Macquarie Private Hospital, Australia; 9: Wake Forest Baptist Health, USA; 10: Southern Illinois University School of Medicine, USA

**Objective:** To assess the preservation of sexual function of the Prostatic Urethral Lift (PUL) for men with BPH related LUTS utilizing the 2 year durability from a multi-center, randomized, sham controlled study.

**Material and Methods:** Subjects were  $\geq 50$  years with International Prostate Symptom Score (IPSS)  $\geq 13$ , peak flow rate (Qmax)  $\leq 12$  mL/s with a prostate volume between 30 and 80 cc. For those subjects in the PUL treatment arm, permanent transprostatic implants were placed via transurethral access to hold the obstructive lateral lobes apart and establish an open urethra. PUL subjects were followed to two years with validated instruments including IPSS, quality of life score, Qmax, Sexual Health Inventory for Men (SHIM), and Male Sexual Health Questionnaire - Ejaculatory Dysfunction (MSHQ-EJD).

**Results:** 206 men were randomized 2:1 and treated with PUL (n=140) or control (n=66) at 19 multi-national centers. Adverse events were typically mild and transient, with the most frequently experienced events being transient episodes of hematuria, dysuria, pelvic pain, urgency and urge incontinence. Subjects experienced symptom relief by 2 weeks that continued to improve to 3 months and was largely sustained through 2 years. At 2 years, the cumulative rate of additional treatment for LUTS was 7.5%. Sexual function was preserved with no reported incidence of de novo, sustained erectile or ejaculatory dysfunction. SHIM scores remained stable through 2 years. MSHQ-EJD function and bother scores improved significantly by 1 month and remained improved through 2 years ( $p < 0.0001$ ). Erectile function was significantly correlated with both ejaculatory function and bother score throughout follow up, with the magnitude of the correlation coefficient greater than 0.4 at 1 and 2 years for both ejaculatory function and bother ( $p$  value  $< 0.0001$ ).

**Conclusions:** The PUL procedure offers clinically meaningful improvement in LUTS and flow rate that can be sustained to two years. Ejaculatory function is not only preserved but improved and erectile function is not disturbed. Subjects will be studied on this protocol through 5 years.

### **Disclosure:**

Work supported by industry: yes, by NeoTract, Inc. (industry

initiated, executed and funded study). The presenter or any of the authors act as a consultant or shareholder of an industry.

002

## **5 alpha reductase enzyme deficiency: A new pathophysiology of female sexual dysfunction**

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**Objectives:** Women with testosterone deficiency syndrome (TDS) have persistent symptoms in mood, libido, and fatigue in the presence of low free testosterone and adequate estrogen. Treating HSDD with testosterone (T) pre-supposes that cytoplasmic enzyme 5 alpha reductase functions and converts free T to androgen dihydrotestosterone (DHT). A subgroup of women with TDS and FSD underwent 6-12 months of T treatment, that resulted in increases in total and calculated free T values to the mid to upper tertile. These women, however, continued to have symptoms of TDS, with persistent bothersome FSD, and failed to have any adverse events related to the increased T, such as acne facial hair or scalp hair loss. We measured DHT values before and after testosterone treatment.

**Material and Methods:** An IRB approved retrospective chart review was performed in 31 women examined between 2007-2014 presenting with persistent sexual side effects despite T therapy. Data collected included DHT, T, sex hormone binding globulin, and calculated free T values. Duration of use and of persistent side effects were recorded, as well as psychometrically validated questionnaires.

**Results:** The mean age was 47 +/- 16 years. The mean pre-treated T values were 18 +/- 6 ng/dl (range 6 – 82 ng/dl), mean free T values 0.2 +/- 0.1 ng/dl (ideal value 0.8 ng/dl) and mean DHT values of <5 ng/dl (range 4 – 22 ng/dl). After initial treatments with T, sexual dysfunction persisted with mean treated T values increased to 78 +/- 17 ng/dl, mean free T values were 0.9 +/- 0.2 ng/dl but the mean DHT values remained low 8 +/- 4 ng/dl.

**Conclusions:** Persistent FSD in woman on T treatment with normal or elevated total and free T values and low DHT values have been identified in a small subset of patients. The mechanistic hypotheses include persistent endocrine and epigenetic gene expression alterations of the 5AR enzyme. Symptoms were improved by increasing serum DHT levels to the upper tertile of the normal range using low dose topical DHT (andractim).

### **Disclosure:**

Work supported by industry: no.

# Abstracts

003

## Effect of testosterone solution 2% for the treatment of ejaculatory dysfunction in androgen-deficient men

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1: Weill Cornell Medical College, USA; 2: Eli Lilly and Company, USA; 3: Harvard Medical School, USA

**Objective-** Cross-sectional data suggests that hypogonadism doubles the relative risk of delayed ejaculation (DE), anejaculation (ANE) and decreased ejaculate volume (DEV); however, randomized control trials (RCT) have not been undertaken. This double-blind, placebo-controlled, proof-of-concept study explored the efficacy and safety of testosterone 2% solution for these ejaculatory dysfunctions in hypogonadal men.

**Material and Methods-** 76 hypogonadal men with serum testosterone (T) levels <300 ng/dL on two occasions, mean age 51 years old presenting with self-reported either DE, ANE, DEV or decreased force of ejaculation were randomized to placebo or testosterone 2% solution for a 16-week period. Testosterone 2% solution titration was allowed at Week 8 based on serum testosterone levels at Week 4. Primary outcomes were measured using the Male Sexual Health Questionnaire-Short Form (MSHQ-SF). Secondary measures were assessed with the International Index of Erectile Function – Orgasmic Function Domain (IIEF-OF), a Sexual Activity Log (SAL) and an objective measure of ejaculate volume. Change from baseline to 16 weeks in the primary and secondary outcomes was tested (at a pre-specified alpha level of 0.10) for a treatment group difference of testosterone solution versus placebo by a mixed model repeated measures analysis.

**Results-** At Week 16, 67% of men became eugonadal ( $T \geq 300$  ng/dL) in the testosterone 2% solution group and 17% in the placebo group. Testosterone solution 2% improved ejaculatory dysfunction as measured by the MSHQ-SF score change from baseline to endpoint (mean score change: +3.1) but this effect was not different relative to placebo (mean score change: +2.5;  $p=0.596$ ). Post-hoc analysis based on T levels (300 ng/dL cut-off) showed a statistically significant MSHQ-SF score change between patients with T levels  $\geq 300$  ng/dL and <300 ng/dL during treatment with testosterone 2% solution ( $p=0.002$ ). No significant differences were detected in measured ejaculate volume, IIEF-OF or SAL scores between placebo and testosterone 2% solution groups.

**Conclusions-** Testosterone replacement in hypogonadal men was not associated with an improvement in ejaculatory dysfunction when comparing testosterone 2% solution and placebo treatment arms. However, post-hoc analysis that factored T levels did show a T-dependent improvement in ejaculatory function among patients of the testosterone 2% solution arm; this warrants further study.

### Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter

or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

004

## Prevalence of ejaculatory dysfunctions as a function of testosterone

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**Objectives:** Evidence suggests that low levels of testosterone (T) are associated with ejaculatory disorders (EjDs); however, this has not been determined systematically with state-of-the-art testosterone assays. We determined T levels in men with delayed ejaculation (DE), anejaculation (AE), decreased ejaculate volume (DEV) and/or decreased force of ejaculation (DFE).

**Materials and Methods:** The sample was comprised of 901 men from the US, Canada and Mexico who self-reported ejaculatory dysfunction and screened for a clinical trial of testosterone therapy for EjD. During screening, 207 men had total T levels <300 ng/dL while 694 men had T levels  $\geq 300$  ng/dL. Prevalence of EjD symptoms were assessed across 6 T categories (<300, 300-350, 350-400, 400-600, 600-800, >800). Total T was measured using liquid chromatography mass spectrometry (LC-MS/MS). Participants completed an investigator-developed Ejaculatory Function Screening Questionnaire (EFSQ) that assessed history of ejaculatory dysfunction. Age, body mass index (BMI), race, ethnicity, and geographic location were also recorded. Baseline characteristics were compared across T categories using F-test.

**Results:-** Average age of the participants was 52 years ( $\pm 11$ ). Arithmetic mean T levels of participants experiencing EjDs was 437.1 ng/dL (95% Confidence Interval: 423.9 to 450.3 ng/dL). EjDs occurred over a spectrum of T levels. DFE and DEV were the most prevalent EjD symptoms (81% and 89% overall) across the T-categories, while AE was the least prevalent (37%). Prevalence of DE was 62% overall. For participants reporting at least one of these EjDs, age and BMI differed among the T categories (Age:  $p<0.01$ ; BMI:  $p<0.001$ ).

**Conclusions:** This study highlights that EjDs are prevalent across a broad range of T levels with some dysfunctions showing overall higher prevalence.

### Disclosure:

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# Abstracts

005

## Perceived sexual dissatisfaction with ejaculatory dysfunctions

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**Objectives:** Little is known about bother and sexual satisfaction across the subtypes of ejaculatory dysfunction (EjD) in the general population. This exploratory study assessed bother and sexual satisfaction among men experiencing anejaculation (AE), delayed ejaculation (DE), decreased ejaculate volume (DEV) and/or decreased force of ejaculation (DFE).

**Material and Methods:** The study population consisted of 884 men from the US, Canada and Mexico who self-reported ejaculatory dysfunction, screened for a clinical trial assessing testosterone therapy for EjD in hypogonadal men and completed the Male Sexual Health Questionnaire-Bother (MSHQ-Bother) item, "If you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?" (N=820), the International Index of Erectile Function (IIEF) question 7, "When you attempted sexual intercourse, how often was it satisfactory for you?" (N=884) and question 8, "How much have you enjoyed sexual intercourse?" (N=881). Subjects with premature ejaculation were excluded from this study. Participants with MSHQ-Bother scores of  $\geq 3$  were classified as "bothered". Sexual intercourse satisfaction and intercourse enjoyment scores of  $\geq 3$  were classified as "satisfied" and "enjoyed," respectively. Participants with scores of 0 (no intercourse) were excluded.

**Results:** Mean (SD) age of the participants was 52 years ( $\pm 11$ ). Overall, 68% of participants reported their EjD as bothersome. Participants with AE and DE were most bothered by their symptoms (84% and 76%, respectively). DEV and DFE were bothersome for 69% and 69% of participants, respectively. Ejaculatory dysfunctions contributed to sexual intercourse dissatisfaction (33%) and reduced intercourse enjoyment (19%). For participants with AE and DE, intercourse dissatisfaction was experienced in 39% and 39%, respectively. For participants with DEV and DFE, intercourse dissatisfaction was experienced in 34% and 33%, respectively.

**Conclusions:** More than half of all men experiencing delayed ejaculation, anejaculation, decreased ejaculate volume and/or decreased force of ejaculation were bothered by their symptoms. A substantial proportion also reported negative impact on intercourse satisfaction and intercourse enjoyment.

### Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

006

## A descriptive analysis to compare the occurrence of myocardial infarction in testosterone-treated and untreated hypogonadal males and PDE5-inhibitor users

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**Objective:** Finkle et al. 2014, using the Truven Health MarketScan® database, concluded that the risk of myocardial infarction (MI) increased after patients received a prescription for testosterone replacement therapy (TRT). The study did not compare the MI risk between TRT patients and untreated hypogonadal (HG) men, but rather used PDE-5 inhibitor (PDE5i) patients as the comparator. Therefore, our objective was to investigate the risk of MI among adult men receiving TRT prescriptions (w/o PDE5i) vs. HG men not receiving TRT and patients receiving PDE5i.

**Materials and Methods:** The study used the 2006 to 2010 US-based Truven Health MarketScan databases. The index date was the first prescription or first randomly assigned HG diagnosis date. The pre-index period was 12 months. The MI event rate (inpatient ICD-9 410) was calculated during the pre-index period, and during 90, 180, 365 post-index days, using mean and conditional probability divided into 30-day time-windows for 365 days. Analyses were stratified by age.

**Results:** 142,358 TRT patients ( $\pm$  PDE5i users), 86,643 untreated HG men and 359,321 PDE5i patients (without TRT prescriptions) were identified. Compared to untreated men (aged  $51.5 \pm 12.96$ ), the TRT patients (aged  $53.0 \pm 11.45$ ), and PDE5i patients (aged  $54.9 \pm 10.82$ ) were, on average, slightly older. Among TRT patients, an increase in the MI incidence rate was found during the 90-day post-index period (5.61, 95%CI: 4.76 - 6.45 per 1,000 PY) as compared to the pre-index period (4.59, 4.24 - 4.95), especially among elderly patients ( $> 65$  years). This increase trend was not found among PDE5i patients, consistent with Finkle. Among untreated HG men, a similar increase was observed during the 90-day post-index period (6.57, 5.40- 7.73), compared to the pre-index period (4.48, 4.03-4.92). A similar increase in MI incidence rate was also observed when compared to PDE5i patients.

**Conclusion:** As literature indicates, HG is a risk factor for CV events. This unadjusted analysis suggests that hypogonadism, rather than TRT, may contribute to the increased MI risk in this population. Future adjusted studies are warranted to further understand MI risk in treated and untreated HG patients.

### Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

# Abstracts

007

## Clomiphene citrate is superior to anastrozole in raising testosterone in hypogonadal infertile men: A prospective randomized double blind comparison trial

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**Objective:** The selective estrogen receptor modulator clomiphene citrate (CC), and the aromatase inhibitor anastrozole (AZ) have been used off label to raise testosterone levels in hypogonadal infertile men (HIM). CC increases T and estradiol (E2), whereas AZ increases T and decreases E2 thereby increasing T/E2 ratios. A randomized double blind study comparing the effects of CC and AZ in HIM desiring fertility has never been performed. In this prospective double-blinded randomized trial we set out to show non inferiority of AZ to CC with the objectives of raising T and improving T/E2 ratio in HIM.

**Material and Methods:** Our cohort consisted of 23 men presenting with infertility and hypogonadotropic hypogonadism defined as serum T less than 300 ng/dL and normal gonadotropins. Patients were randomized to either AZ (1 mg/day) or CC (25 mg/day) for 12 weeks. Hormones assayed were total and free T, E2, luteinizing hormone (LH), follicle stimulating hormone (FSH), and sex hormone binding globulin (SHBG). Safety labs included complete blood count and hepatic profile. Patient reported measures were quantified using the International Index of Erectile Function, Erection Hardness Scale, and the Androgen Deficiency in the Aging Male questionnaires. Blood tests and questionnaires were recorded at baseline, 6 and 12 weeks. Semen analyses were performed at baseline and 12 weeks.

**Results:** The mean age was 34 years. The baseline T increased significantly from baseline (AZ 251 ng/dL, CC 250 ng/dL) to 12 weeks (AZ 418 ng/dL, CC 575 ng/dL) in both groups ( $p < 0.005$ ). Mean increase from baseline total T at 12 weeks was less in the AZ group (69%) than the CC group (130%) ( $p = 0.02$ ). The T/E2 ratio increased from baseline (AZ 9.9, CC 9.1) to 12 weeks (AZ 16.7, CC 11.9) ( $p < 0.005$ ). LH increased in both groups (AZ 4.5 mIU/mL, CC 3.9 mIU/mL) to (AZ 6.7 mIU/mL, CC 7.6 mIU/mL) ( $p = 0.003$ ) at 12 weeks. Neither group demonstrated a significant change in safety measures, seminal parameters or patient reported measures.

**Conclusions:** While mean T levels increased in both groups at 6 and 12 weeks, CC demonstrated clear superiority. Although both drugs resulted in a T/E2 ratio greater than 10, AZ was superior in increasing the T/E2 ratio. Superiority in seminal parameters was not demonstrated.

### Disclosure:

Work supported by industry: no.

008

## Low osteocalcin levels are associated with androgen deficiency

*Le, B<sup>1</sup>; Billups, K<sup>2</sup>; Anele, U<sup>2</sup>; Burnett, AL<sup>2</sup>*

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**Introduction:** Recent studies have identified a novel regulatory relationship between bone turnover marker osteocalcin and testosterone (T) production and fertility through a previously orphaned G-protein coupled receptor. Osteocalcin may be an important regulator of testosterone production in humans as well. However, studies to characterize this relationship in humans have been limited to retrospective analyses of stored serum samples, and it is unclear if men identified from such studies had symptomatic hypogonadism. In this study, we sought examine the relationship between testosterone and osteocalcin in a prospective and survey validated cohort of hypogonadal and eugonadal men.

**Methods:** We prospectively enrolled men who presented to the Johns Hopkins Men's Health Clinic who warranted work-up for hypogonadism based on responses to the Androgen Deficiency in Aging Male (ADAM) survey. Serum T, free T, SHBG, bioavailable T, and osteocalcin were obtained from blood samples and assayed using commercial laboratory techniques. Additionally, men filled out IPSS and IIEF-5 questionnaires. Men were excluded if on ADT, TRT, or bone medications. The study design was approved by the IRB. Data were analyzed using Pearson's correlation, fisher's transformation and t-tests.

**Results:** Ninety-two men were enrolled to participate in this prospective longitudinal cohort study. Total T and osteocalcin demonstrated a positive linear relationship with a correlation coefficient of  $R = 0.45$  (95% CI 0.22-0.60). Free T and osteocalcin were also correlated at  $R = 0.31$  (95% CI 0.10-0.52). Men with total T 350 ng/dl or less had significantly lower osteocalcin levels than eugonadal men (11.4 vs. 21.9  $p < 0.01$ ). There were no significant differences in total IPSS and IIEF-5 scores between the hypogonadal and eugonadal cohort.

**Conclusions:** Androgen deficiency, and in particular lower free T, is associated with lower osteocalcin levels. Though this study does not determine causality, this supports a relationship between bone health and testosterone steroidogenesis. Further studies should be conducted to evaluate the nature of this relationship and effects of modulating osteocalcin levels as a potential avenue for the treatment of hypogonadism.

### Disclosure:

Work supported by industry: no.

009

## Determining serum levels of osteocalcin in a rat model of hypogonadism

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**Introduction:** Osteocalcin is a bone turnover marker that is produced exclusively by osteoblasts, and has recently been found to be a novel regulator of testosterone production that does not function through the LH-receptor. To elucidate osteocalcin's role in age-related decreases in testosterone production, we examined serum osteocalcin levels in rat models of aging and hypogonadism.

**Methods:** We used an animal model of hypogonadism to study serum osteocalcin and testosterone levels. Brown-Norway (BN) rats, like humans, have an age-related decline in testosterone production. We hypothesized that in our rat model of age-related hypogonadism osteocalcin levels would be lower in older rats (22 weeks old vs. 6 weeks old). We then altered serum testosterone levels acutely to examine its effects on serum osteocalcin.

**Results:** Similar to humans, in aged rats serum testosterone was lower compared to young rats (4.19 vs. 1.15 ng/ml  $p < 0.01$ ). Serum osteocalcin levels were also lower in aged rats (1.81 vs. 0.97 ng/ml  $P < 0.01$ ). In old rats treated with a transporter protein (TSPO) ligand, serum testosterone increased 43%, while serum osteocalcin levels remained unchanged (0.93 vs. 0.90  $p = 0.93$ ). In young rats treated with silastic T implants, serum osteocalcin levels decreased (2.19 vs 1.70  $p = 0.06$ ).

**Conclusions:** In our rat models of age-related hypogonadism, lower osteocalcin levels were associated with decreased testosterone levels. Acute increases in endogenous and exogenous testosterone levels did not lead to direct increases in osteocalcin suggesting that osteocalcin may indeed be an independent regulator of testosterone.

## Disclosure:

Work supported by industry: no.

010

## Comparison of the effects of testosterone gels, injections and pellets on serum hormones, erythrocytosis, lipids, and prostate specific antigen

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**Objectives:** Numerous testosterone (T) formulations for the treatment of hypogonadism are available, each with variable side effects. We present single-institution data on the long-term effects of T gels, injections and pellets on hormone levels, erythrocytosis, lipid profile and prostate specific antigen (PSA).

**Materials and Methods:** Retrospective review of hypogonadal men treated with a single T formulation was performed and 47 men treated with T gels, 57 with injectable T, and 74 with subcutaneous T pellets identified. Demographics, total T, free T

(FT), estradiol (E), hemoglobin (Hgb), hematocrit (Hct), PSA, total cholesterol (Tchol), triglycerides (TG), LDL, and HDL cholesterol were evaluated at baseline and every 3- 6 months for 3 years. Serum parameters were compared between each group using a mixed model linear regression for repeated measures.

**Results:** At baseline all 3 groups were similar except men in the injectable T group were younger, and FT, Hgb and Hct were higher in this group, while E was higher in the T pellet group. Significant increases in T and FT were seen at 3 months and persisted throughout in all groups. A significant increase in E was observed only in the injectable group at 3 months and persisting throughout. Erythrocytosis ( $Hct > 53\%$ ) was observed earlier and was significantly more common ( $p = 0.006$ ) in the injectable group (3 months, 22.8%) than in the gel (9 months, 4.3%) and T pellet (6 months, 8.1%) groups. Transient decreases ( $p < 0.05$ ) in Tchol were observed in the gel and pellet groups, and a transient decrease in LDL ( $p < 0.05$ ) and TG ( $p = 0.019$ ) was also seen in the pellet group at 36 months. No significant changes in PSA and HDL were observed in any group.

**Conclusions:** All T formulations resulted in a rise in Hct, with injectable T causing the greatest increase, and being the only formulation to cause an increase in E. While the gel and pellet formulations caused decreases in Tchol, LDL, and TG (pellets only), these changes were transient and inconsistent. These findings should be considered in selection of T formulations.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

011

## TNF-alpha is increased in major pelvic ganglion of rats following bilateral cavernous nerve injury and impairs neurite outgrowth ex vivo

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**Objectives:** Neuroinflammation after radical prostatectomy (RP) impairs cavernous nerve regeneration and leads to post-operative erectile dysfunction (ED). We hypothesize that an increase in tumor necrosis factor alpha (TNF- $\alpha$ ) in the major pelvic ganglion (MPG) after cavernous nerve injury (CNI) contributes to autonomic neuropathy. This study examines the temporal transcriptional and translational changes of TNF- $\alpha$  in MPGs after bilateral CNI (BCNI). We also tested the effect of exogenous TNF- $\alpha$  on neurite outgrowth from MPGs cultured in Matrigel.

**Materials and Methods:** Two groups of rats were used 1) Sham and 2) BCNI. MPGs were harvested 48 hours, 7, 14, 21, 30 and 60 days after BCNI to determine gene expression of TNF- $\alpha$  with qPCR. TNF- $\alpha$  protein expression in MPGs was

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assessed by western blot at 48 hours and 7 days after surgery. Whole MPGs were harvested from control rats and cultured in Matrigel with serum free media with or without TNF- $\alpha$  (20 ng/mL). Neurite outgrowth length was measured 48 and 72 hours after culture. We measured longest neurites in each area (25-40 neurites/MPG) and compared the averages to evaluate the effect of exogenous TNF- $\alpha$  on neurite outgrowth.

**Results:** TNF- $\alpha$  had increased gene expression ( $p < 0.05$ ) at all of the time points studied after BCNI in MPGs. The greatest increase in gene expression occurred from 48 hours to 14 days after BCNI with a decline to sham levels by 30-60 days. Following BCNI, TNF- $\alpha$  protein amounts were increased at 48 hours and 7 days. Average neurite lengths of MPGs incubated with TNF- $\alpha$  at 48 and 72 hours were significantly shorter than of the control group ( $329 \pm 12.2 \mu\text{m}$  and  $384 \pm 13.1 \mu\text{m}$ ,  $p < 0.01$  at 48 hours;  $369 \pm 14.5$  and  $462 \pm 20.0 \mu\text{m}$ ,  $p < 0.01$  at 72 hours).

**Conclusions:** This study demonstrates a temporal increase of TNF- $\alpha$  in MPGs after BCNI. Furthermore, exogenous TNF- $\alpha$  treatment inhibits neurite outgrowth from MPGs. These results suggest that increased expression of TNF- $\alpha$  delays cavernous nerve regeneration and its inhibition may be a future therapeutic target to prevent post-operative ED following RP.

## Disclosure:

Work supported by industry: no.

012

## Frequency of Intracavernosal Injections (ICI) improves Erectile Function Recovery (EFR) following Radical Prostatectomy (RP)

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**Objective(s):** Penile rehabilitation (PR) is frequently used following RP and intracavernosal injections play an important role at many centers. While there is data suggesting participation in a PR program improves long term EFR post-RP, there is little research investigating if frequency of ICI is associated with EFR.

**Material and Method(s):** Patients included in this analysis started PR using ICI  $\leq 6$  months (m) post-RP, had ICI frequency recorded and had erectile function (EF) data available for 12-30m post-RP. ICI frequency was assessed by patient self-report. Nerve sparing was surgeon graded for each nerve on a validated 1-4 point scale: 1-complete preservation, 2-near complete preservation, 3-partial resection, 4-complete resection (score 2-8). Pre-RP EF was graded on a validated 5-point patient-reported scale: 1 (fully rigid) to 5 (no tumescence). EF post-RP was graded on a percentage patient-reported scale (100% = fully rigid, 60% = adequate for penetration, 0% = no rigidity). Post-RP response to ICI, PDE5i, and spontaneous erectile rigidity (SER) was assessed. Very poor ICI responders (rigidity  $\leq 40\%$ ) and excellent PDE5i responders (rigidity  $\geq 80\%$ ) were excluded.

**Result(s):** 99 men with a mean age of  $59 \pm 7$  years met eligibility. The mean number of ICI/week was  $1.6 \pm 0.8$ . On average, men started ICI 4 $\pm$ 2m post-RP. Men reported good EF pre-RP (mean =  $1.6 \pm 1$ ). Mean follow-up time post-RP EF was  $22 \pm 5$ m. At follow-up, mean PDE5i EF was  $50 \pm 26\%$  and mean SER was  $31 \pm 24\%$ . On univariate analysis, PDE5i EF was related to age ( $r = -0.33$ ,  $p = 0.001$ ) and ICI/week ( $r = 0.39$ ,  $p = 0.001$ ). SER was related to age ( $r = -0.24$ ,  $p = 0.02$ ), NSS ( $r = -0.28$ ,  $p = 0.01$ ) and ICI injections/week ( $r = 0.24$ ,  $p = 0.02$ ). On multivariable analysis, ICI/week was a strong predictor of PDE5i EF ( $\beta = 0.48$ ,  $p = 0.001$ ). For an increase of 1 injection/week, PDE5i EF increased by 16 percentage points. ICI/week was also a strong predictor of SER ( $\beta = 0.31$ ,  $p = 0.01$ ). For an increase in 1 injection/week, SER increased by 11 percentage points.

**Conclusion(s):** In those patients pursuing PR, frequency of ICI was a significant predictor of EF recovery. Men in a PR program should be encouraged to inject as frequently as possible.

## Disclosure:

Work supported by industry: no.

013

## A new non invasive approach for the treatment of acute phase Peyronie's disease – A prospective, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of topically applied gel H-100 which combines Nicardipine, Superoxide Dismutase and Emu Oil

Twidwell, J<sup>1</sup>; Levine, L<sup>2</sup>

1: Urology Associates LTD, USA; 2: Rush University

**Objectives:** The objective of our study is to evaluate the safety and efficacy of a novel, topically applied gel (H-100<sup>TM</sup>) for treatment of acute phase Peyronie's Disease.

**Material and Methods:** Safety and efficacy of H-100<sup>TM</sup> was studied. H-100<sup>TM</sup> is a topically applied gel consisting of emu oil, nicardipine and superoxide dismutase. This 22 patient prospective, randomized, double blind, placebo-controlled study was conducted between May 2013 and December 2013. All patients had documented Peyronie's Disease of less than 12 months duration. Patients were sequentially selected and randomized to a treatment arm (H-100<sup>TM</sup>, 11 patients) or a placebo arm (11 patients) for 3 months. After 3 months, all study patients received 3 additional months of H-100<sup>TM</sup> treatment. Patients were evaluated monthly for medication side effects. Patients were also evaluated monthly for objective and subjective changes of their Peyronie's Disease.

The subjects were assessed with measurement of flaccid stretched penile length, degree of penile curvature, and pain level related to their Peyronie's Disease. Curvature was documented by photograph of the fully erect penis after medically induced erection. Pain was measured on a visual analogue scale.

**Results:** H-100<sup>TM</sup> showed significant improvement in all objective PD parameters at 6 months: mean flaccid stretched

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penile length increase (22.6%, mean=2.40cm, range=0.7 to 4.3cm,  $p=0.0002$ ), mean curvature reduction (40.8%, mean=20.2 degrees, range=3 to 55 degrees,  $p=0.0014$ ), mean pain level reduction (85.71%, mean=3.00, range=0 to 8,  $p=0.004$ ). Crossover patients from placebo to H-100™ showed significant improvement in all objective PD parameters tested: mean flaccid stretched penile length increase (17.54%, mean=2.16cm, range=0.9 to 3.2cm,  $p=0.000007$ ), mean curvature reduction (37.09%, mean=17.4 degrees, range=0 to 59 degrees,  $p=0.006$ ), mean pain level reduction (40%, mean=0.18, range=0 to 1,  $p=0.17$ ). Placebo group showed no significant improvement except for mean flaccid stretched penile length increase (6.77%, mean=0.78cm, range=-0.8 to 1.9cm,  $p=0.009$ ). The only medication related side effect was a self-limited skin rash in 3 patients.

**Conclusions:** This initial study suggests that H-100™ is a safe and possibly effective non-invasive, topically applied treatment for acute phase Peyronie's Disease. There were statistically significant improvements in flaccid stretched penile length and curvature and pain reduction. A larger study is warranted to confirm these initial encouraging results.

## Disclosure:

Work supported by industry: no.

014

## "Unexpected" corporal fibrosis should be "expected": the prevalence of significant corporal fibrosis encountered during penile prosthetics

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During penile prosthetic surgery, a surgeon will often prepare for difficult dissection when they anticipate fibrosis either due to patient history (e.g., a previous explant due to infection, history of priapism) or physical examination (e.g., the presence of peyronies disease). However, there are occasions where a surgeon finds themselves in need of performing adjunctive maneuvers due to fibrosis when that fibrosis is unexpected.

**Objective:** The goal of this study was to examine the prevalence of significant fibrosis in situations in which fibrosis would not be anticipated. To avoid subjective interpretation, fibrosis was defined specifically as a case in which adjunctive measures were required for corporal dilation (e.g., uramix or Rosselli cavernotomes, distal counterincisions). "Difficult" dissections not requiring such maneuvers were not considered significant.

**Material and Method:** A total of 759 IPP patients from the PROPPER database were included in this analysis regarding etiology of ED and intraoperative presence of significant

fibrosis.

**Result:** Within the group in which fibrosis was expected (history of previous explantation or infection, history of priapism, peyronies disease), approximately half of the patients (45/94) were found to have significant fibrosis. Within the rest of the patients, 28% (186/664) were found to have significant fibrosis. Within the most common etiologies of ED, diabetics were found to have the highest rates of significant fibrosis (35.0%), followed by radical prostatectomy (30.5%) with other etiologies showing much lower rates.

**Conclusion:** Even if a penile prosthetic case is anticipated to be straightforward, up to 1/3 of cases in common scenarios such as history of radical prostatectomy or diabetes may have significant fibrosis. Prosthetic surgeons should always be prepared for this inevitability both in terms of equipment and surgical skills.

Primary ED etiology	N	Significant corporal fibrosis or scoring noted - N (%)
Radical prostatectomy (RP)	223	68 (30.5%)
Diabetes	152	53 (35.0%)
Cardiovascular disease	163	36 (22.1%)
Other organic, please specify	53	5 (17.0%)
Neurologic disorder	5	2 (35.3%)
Peyronie's disease	71	28 (39.4%)
Radical pelvic surgery other than RP	12	1 (8.3%)
Pelvic radiation therapy	12	4 (33.3%)
Pelvic trauma or injury	4	1 (25.0%)
Spinal cord injury	5	1 (16.7%)
Phimosis	10	10 (100.0%)
Venous leak	25	5 (20.0%)
Other etiology, please specify	15	10 (66.7%)
Unknown	2	2 (100.0%)
Total	759	232 (30.6%)

## Disclosure:

Work supported by industry: yes, by American Medical Systems (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant or shareholder of an industry.

015

## Outcomes of IPP placement by surgical approach, penoscrotal vs infrapubic, results from a prospective multicenter study

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**Objective(s):** Pundits have lauded and criticized the nuances of penoscrotal (PS) and infrapubic (IP) approaches for IPP surgery despite the fact that there has never been a prospective comparison of both techniques. Criticisms such as dorsal nerve injury and high riding pumps for IP approach and difficulty with reservoir placement with PS approach are based on dogma and not science.

**Material and Method(s):** The PROPPER registry was evaluated



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for IPP outcomes stratified by surgical approach (PS vs IP). Patient demographics, surgery parameters, complications, device survival and patient satisfaction were recorded and evaluated. Statistical analysis was done to compare variables between the two groups.

**Result(s):** Through June 16, 2014, 759 men were enrolled and implanted with a penile prosthesis at a total of 12 sites with a PS (n=611, 81%) or IP (n=147, 19%) approach. Original surgery was done in 84.8% of PS and 89.8% of IP patients. Operative time was 48 +/- 29 and 33 +/-14 min in PS and IP patients, respectively. Cylinder size of 18 cm was the most commonly used in both groups. Zero to one RTEs were used in 86% of PS and 97.9% of IP patients ( $p < 0.001$ ). Pre-op stretched and post-op inflated penile length was 11.9 and 14.6 cm in PS and 12.3 and 13.5 cm in IP patients. A separate incision was required in 3.6% of PS and 0% of IP patients. Device related complications occurred in 17 pts with no reports of glans hypoesthesia. There were 3 device related infections and one herniation in PS and zero infections and 3 reservoir herniations in IP patients. One patient in the PS group required revision for pump malposition. Patient satisfaction (satisfied or very satisfied) at one-year f/u was 80.6% in PS and 97.6% in IP patients with one-year satisfaction data.

**Conclusion(s):** Our study shows no increased risk of dorsal nerve injury or high riding pumps requiring surgical revision in IP patients. Penoscrotal patients had a higher rate of requiring separate surgical incision for reservoir placement, but risk of herniation was not higher in PS patients.

## Disclosure:

Work supported by industry: yes, by American Medical Systems (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant or shareholder of an industry.

016

## MRI analysis of architectural changes of the retropubic space and relevant structures post radical prostatectomy: Implications for penile prosthesis reservoir placement

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**Objective:** Insertion of a three-piece inflatable penile prosthesis (IPP) is commonly performed in men post radical prostatectomy (RP). The traditional reservoir placement in the space of retzius can result in damage to bladder, bowel and femoral vessels. In this study using pre and post operative magnetic resonance imaging (MRI) we aimed to assess the effects of RP on pertinent retropubic anatomy with respect to IPP placement.

**Methods and Materials:** Endorectal MRI studies in men with prostate cancer were reviewed. Inclusion criteria: (i) availability of pre and post operative MRI from single institution, (ii) post RP MRI (>6 months), (iii) no pre or post RP pelvic surgery or radiation. All scans were performed on a 3 Tesla system

with T1 and T2 weighted images reviewed using axial and sagittal planes. Pertinent landmarks were evaluated by 2 independent readers, blinded to clinical and pathological data. All measurements were defined by an experienced radiologist. Measurements included (i) distance from external inguinal ring (EIR) to external iliac vein (EIV) (ii) superior aspect of pubic symphysis (PS) at midline to bladder and (iii) EIR to nearest bladder point. Correlation was measured between bladder volume and (iii). For distances (i) and (iii) bilateral measurements were obtained and data averaged as no significant differences were observed. Maximal post operative scar thickness in the retropubic space was quantified. Repeated measure t-test was used to assess differences in pre and post operative values.

**Results:** 22 patients were included in the analysis. Operative approach: open retropubic 64%, laparoscopic / robotic 36%. Both pre and post operative scans were reviewed. Mean pre and post operative measurements are reported (cm): (i) EIR to EIV: pre op 3.00 (1.94-3.83); post 2.95 (1.94-3.76), (ii) EIR to the nearest point of the bladder: pre op 2.62 (1.47-3.92); post 2.75 (2.10-4.10), superior aspect of PS to nearest point of bladder (midline): pre op 1.05 (0.56-1.82); post 1.09 (0.69-1.62). No significant differences were observed. Post operative midline retropubic scar thickness range 0.55-1.01cm. A significant difference was observed in mean scar thickness in open 0.55cm vs laparoscopic 0.28cm approaches ( $p=0.04$ )

**Conclusions:** In this study we have attempted to highlight the changes in the architecture of the retropubic space post RP. Patients undergoing a laparoscopic procedure have significantly less post operative scarring in this region. Although not currently routine, reviewing MRI prior to IPP placement may aid in pre operative planning, selection of appropriate prostheses and reservoir placement location.

## Disclosure:

Work supported by industry: no.

017

## Reoperation of penile prothetic surgery: A longitudinal analysis of California population database

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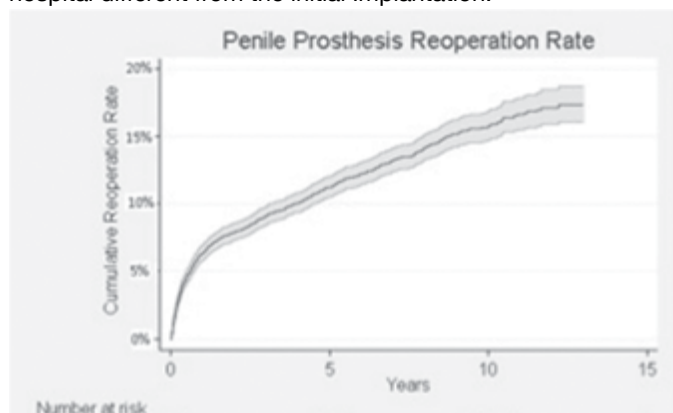
**Objectives:** The true reoperation rate of penile prosthetic surgery is unknown due limited data from retrospective, single institution studies. This study aims to evaluate the reoperation rate after virgin penile prosthetic surgery using a large population database

**Materials and Methods:** A longitudinal analysis of California Office of Statewide Health Planning and Development database from 1995 to 2010 was performed. Inclusion criteria were men who underwent their first penile prosthetic surgery. Patients were excluded if they had an explant of a prior prosthesis at the time of their first recorded surgery. Primary outcome was

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reoperation, specified as the removal or replacement of the prosthesis. Censoring events included penile amputation, surgeries of the genitalia or pelvis, and cancer involving the genitourinary organs. Statistical analysis was performed via Kaplan-Meier plot, hazard curve, and multivariate analysis adjusting for age, race, gender, comorbidities, insurance status, hospital volume and teaching status

**Results:** 7,666 patients (40,932 patient years) were included in the study. The 5 and 10-year cumulative reoperation rates were 11.2% (CI: 10.5-12.0%) and 15.7% (CI: 14.7-16.8%) respectively. Malfunction and infection accounted for 57% and 27% of reoperations. Reoperation rate was highest at 1 year post-operatively (3.4% per year), and steadily declined until 2 years postoperatively, after which it remained at roughly 1.25% per year. Multivariate analysis showed higher rates of reoperation among younger patients (HR=1.51, CI: 1.12-2.05 for <50yo compared to >75yo), African American patients (HR=1.30, CI: 1.05-1.62), and Hispanic patients (HR=1.32, CI: 1.12-1.57). 22.9% of the reoperations were performed at a hospital different from the initial Implantation.



**Conclusions:** Reoperation rate for penile prosthetic surgery is highest in the first year postoperatively. The patients with highest risk for reoperation are African American, Hispanics, and younger age for unclear reasons that warrant further study. Nearly a quarter of reoperations occur at a hospital different from the initial surgery, suggesting that existing literature does not reflect the true prevalence of penile prosthetic complications.

**Disclosure:**

Work supported by industry: no.

018

**eNOS uncoupling contributes to earlier erectile dysfunction and endothelial dysfunction in the penis than in the carotid artery in a rat model of type 2 diabetes mellitus**

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**Objectives:** Men with type 2 diabetes mellitus (T2DM) and erectile dysfunction (ED) have greater risk of cardiovascular events than T2DM men without ED, suggesting ED as a predictor of cardiovascular events in diabetic men. However, molecular mechanisms underlying endothelial dysfunction in the diabetic penis explaining these clinical observations are not known. We evaluated whether the temporal relationship between ED and endothelial dysfunction in the systemic vasculature in T2DM involves earlier redox imbalance and eNOS dysfunction in the penis than in the systemic vasculature, such as the carotid artery.

**Methods:** Rats were rendered T2DM by high-fat diet for 2 weeks, followed by ip injection of streptozotocin. After 3 weeks, erectile function (intracavernosal pressure) was measured and penes and carotid arteries were collected for molecular analyses of eNOS uncoupling, protein S-glutathionylation, eNOS S-glutathionylation, oxidative stress (4-HNE), protein expression of NADPH oxidase subunit gp91phox, and endothelium-dependent vasodilation in the carotid artery.

**Results:** Erectile response to electrical stimulation of the cavernous nerve was decreased ( $p < 0.05$ ) in diabetic rats, while relaxation response of the carotid artery to acetylcholine was not impaired. eNOS monomerization, protein S-glutathionylation, eNOS S-glutathionylation, and protein expressions of 4-HNE and gp91phox were increased ( $p < 0.05$ ) in the penis, but not in the carotid artery, of diabetic compared to nondiabetic rats.

**Conclusion:** Redox imbalance, increased oxidative stress by NADPH oxidase, and eNOS uncoupling by S-glutathionylation, occur early in T2DM in the penis, but not in the carotid artery. These molecular changes contribute to diabetic ED, while endothelial function in the systemic vasculature remains preserved, at this early point of T2DM development.

**Disclosure:**

Work supported by industry: no.

019

**Sonic hedgehog regulation of collagen in the penis**

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**Objectives:** Cavernous nerve (CN) injury, which occurs during prostatectomy, decreases penile smooth muscle through an apoptotic mechanism, leading to erectile dysfunction (ED). As smooth muscle is lost, collagen production increases and there is a change in subtypes. This occurs in ED patients by a largely undefined mechanism. We've shown in previous studies that the sonic hedgehog (SHH) pathway is critical for the response of the penis to denervation. It has recently been suggested that SHH may play a role in renal and pulmonary fibrosis and collagen production during lung embryogenesis. Our preliminary studies suggest that collagen production is responsive to SHH signalling, and we hypothesize that SHH may be a regulator of

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collagen in the penis.

**Materials and Methods:** Collagen abundance was quantified by trichrome stain and Image J analysis in corpora cavernosal tissue of prostatectomy, diabetic and control (Peyronie's) patients, and in rat penis from: 1) CN crushed, 2) SHH inhibited, 3) SHH treated control and CN injured penis, and 4) Postnatal development time points.

**Results:** Our results show that collagen was increased 16% in prostatectomy and 20% in diabetic patients. SHH treatment of the penis at the time of CN injury prevented collagen induction by 20% at 2 days and 7% at 4 days after injury, as SHH became depleted from the delivery vehicle. During the first week after birth smooth muscle is abundant with minimal collagen synthesis. Collagen abundance increased significantly between postnatal day 7 and 13 and disruption of innervation with L-NAME treatment at P4 alters collagen deposition at P12.

**Conclusions:** These results show that SHH suppresses collagen induction in response to CN injury. This is an innovative idea with significant potential for intervention and suggests that the SHH pathway sits at the nexus of several key pathways which regulate erectile function.

## Disclosure:

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020

## Effects of a selective alpha-1a adrenoceptor antagonism, silodosin treatment on erectile dysfunction of rats with partial bladder outlet obstruction

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**Objective:** Patients with benign prostatic hyperplasia (BPH), apply to the clinic with lower urinary tract symptoms (LUTS) because of partial bladder outlet obstruction (PBOO) and the severity of LUTS is related to erectile dysfunction (ED). Silodosin is a novel, highly selective alpha-1A adrenoceptor antagonist and has been approved for the treatment of BPH. In this study, we aimed to determine whether an alpha-1A adrenoceptor subtype-selective antagonist, silodosin (Rapaflo™, Watson Pharmaceuticals, Inc., NYSE) attenuates any ED.

**Material and Method(s):** Adult male Sprague-Dawley rats (n= 60) were randomized into four groups: 1) sham-operated control; 2) silodosin-treated control; 3) PBOO; and 4) silodosin-treated with PBOO. Groups 3 and 4 were subjected to PBOO for 6 weeks by ligation of the urethra, while groups 2 and 4 rats received daily oral silodosin (3mg/kg/day) for 6 weeks. PBOO created by binding of urethra in laboratory was used as an experimental animal model for LUTS linked BPH. Erectile response was measured using cavernosal nerve stimulation by evaluating ratios of intracavernosal pressure (ICP)/mean arterial pressure (MAP). The relaxant and contractile properties of corpus cavernosum smooth muscle (CCSM) strips were

evaluated in tissue baths, and then, the penises were resected, stained with Masson's trichrome, and observed microscopically. Bonferroni's multiple t-test was used for statistical analysis.

**Result(s):** The ratio of maximum ICP-to-MAP was significantly decreased in rats with PBOO ( $0.26 \pm 0.043$ ) compared to sham-control rats ( $0.64 \pm 0.10$ ,  $p < 0.05$ ). Silodosin treatment restored erectile function of PBOO rats ( $0.59 \pm 0.14$ ) compared with sham-control rats. Maximum electrical field stimulation (EFS)-mediated and endothelium-dependent acetylcholine-induced relaxation and direct neurogenic and phenylephrine contractile responses were significantly reduced in CCSM strips from the PBOO group. Silodosin treatment restored EFS-induced relaxant and contractile responses, but not endothelium-dependent relaxation response. Smooth muscle/collagen ratios in the PBOO group were significantly lower than in the sham-control group, while ratios in the silodosin treated group were significantly higher than in the obstructed group.

**Conclusion(s):** Silodosin administration improves erectile function by altering sympathetic tone, enhancing nitric oxide-induced neuronal relaxation and augmenting blood flow in a rat model of PBOO. Silodosin by relieving bladder storage function and benign prostatic obstruction in patients with ED may have an advantage with dual effect. The current results support the possible use of silodosin as a new treatment option for ED. Further evaluation is required to identify potential mechanisms of action and assess its clinical usefulness.

## Disclosure:

Work supported by industry: yes, by TUBITAK (industry funding only - investigator initiated and executed study).

021

## Nanotechnology improved stem cell therapy in erectile

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**Objectives:** Recently, intracavernous injection (ICI) of stem cells has shown some promise for erectile dysfunction (ED). However, most stem cells were washed out immediately due to the communication between corpus cavernosum (CC) and the blood circulation. Keeping stem cells in CC after ICI maybe the key step for successful stem cell therapy for ED. We investigate a novel nanotechnology to improve stem cell therapy in an animal model.

**Material and Methods:** Adipose-derived stem cells (ADSCs) were isolated from paratesticular fat tissue of adult male Sprague-Dawley (SD) rats and cultured in DMED/F12 medium. Magnetic nanoparticles were added to ADSCs. CellTracker™ Green CMFDA (5-Chloromethylfluorescein Diacetate) was used to track ADSCs present in CC. ED animal models were created by bilateral cavernous nerve crush (BCNC) injury and randomly assigned into three groups. Group A: ADSCs ICI.

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Group B: ADSCs with nanoparticle ICI. Group C: ADSCs with nanoparticle ICI + magnet probes. Rats were sacrificed at day 1, 3, 5 and 9 after ICI, respectively. Rat penis was harvested for tracking ADSCs by immunofluorescence.

**Results:** Our in vitro study showed that ADSCs with nanoparticles promoted cell aggregation with the use of a magnet probe. In vivo study with the immunofluorescence confirmed that ADSCs with nanoparticles were successfully maintained in CC with the use of magnet probes for up to 9 days; while most ADSCs were washed out in other groups in day 1 and 3 after ICI.

**Conclusions:** Magnetic nanoparticle is a novel technology to improve ADSCs therapy for ED in animal model.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

022

**Skeletal muscle derived stem cells (MDSC) ameliorate erectile dysfunction in a rat model of type 2 diabetes, but their repair ability is severely impaired when isolated from long-term diabetic milieu**

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1: LABioMed Research Institute at Harbor-UCLA and UCLA School of Medicine, USA; 2: LABioMed Research Institute at Harbor-UCLA, USA; 3: Charles Drew University of Medicine and Science, USA; 4: LABioMed Research Institution at Harbor-UCLA, USA and UCLA School of Medicine, USA; 5: LABioMed Research Institute at Harbor-UCLA and UCLA School of Medicine, USA

**Objectives:** MDSC implanted into the corpora cavernosa ameliorate erectile dysfunction in rat models of aging and cavernosal nerve damage, presumably by replenishing the lost corporal smooth muscle cells (SMC). Other stem cells are effective in these models and also in diabetic rats. In this work we studied whether: a) MDSC counteract corporal veno-occlusive dysfunction (CVOD) in a congenital rat model of type 2 diabetes (T2D); b) MDSC isolation from long-term T2D donors reduces their tissue repair capacity.

**Methods:** MDSC from prediabetic Zucker obese (PDZO) male rats were exposed to normo-glycemic-like medium (PDN cells) or hyperglycemic-like medium (PDH cells), and assayed by western blot for: a) phenotype changes, +/- azacytidine (ACT) for stem cell reprogramming, and paracrine crosstalk with rat penile stem cells (PSC); b) differentiation into various cell types. MDSC from late diabetes (LDZO) rats were only exposed to hyperglycemic-like medium (LDH cells). PDN, PDH, and LDH cells were separately implanted (10<sup>6</sup> cells) into the corpora cavernosa of LDZO rats (n=8/group), with another group left untreated (UT). Zucker lean (ZL) rats (untreated) were non-

diabetic controls. At 2 months, CVOD was determined by cavernosometry. The underlying corporal histopathology was defined by histochemistry, western blot and ad-hoc assays.

**Results:** PDH versus PDN cells had increased Acta2/calponin ratio (myofibroblasts) and decreased VEGF levels, but not when ACT was present which reduced stem cell gene expression (Oct-4a, nanog). PDN cells upregulated Oct 4a and nanog in PSC cells by paracrine crosstalk. Treatment of LDZO rats with PDN cells normalized erectile function by increasing the papaverine response and reducing drop rate, presumably by the increase in the corporal smooth muscle/collagen (Masson) ratio, calponin/Acta2 ratio, and eNOS and nNOS levels and the reduction of collagen (hydroxyproline) and fat infiltration (Oil red O). PDH cells acted similarly, but did not improve the drop rate and calponin/ACTA2 ratio. LDH cells were ineffective, except for nNOS and eNOS.

**Conclusions:** MDSC from prediabetic donors implanted in the corpora of T2D rats improve CVOD and the underlying histopathology, in part by crosstalk with PSC. MDSC from long-term T2D donors have reduced tissue repair capacity and may not be efficacious as autografts unless subjected to in vitro reprogramming

## Disclosure:

Work supported by industry: no.

023

**The cyclic AMP-binding protein kinase A (cAK), vasoactive intestinal polypeptide (VIP) and cyclic AMP phosphodiesterase type 4 (PDE4) are expressed in the human vagina**

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**Objectives:** The vagina contributes to the normal female sexual response cycle. There are hints from experimental studies that this mechanism is under the control of the nitric oxide (NO)/cyclic GMP pathway and related proteins. Up until today, only a few studies have investigated the significance of the cyclic AMP signalling in maintaining the function of vascular and non-vascular female genital smooth muscle. The present study aimed to evaluate in the human vagina by means of immunohistochemistry the expression and distribution of the protein kinase A (cAK), known as a major intracellular target for cyclic AMP, the cyclic AMP-specific phosphodiesterase type 4 (PDE4), vasoactive intestinal polypeptide (VIP), and protein gene product 9.5 (PGP 9.5).

**Material and Methods:** Human vaginal wall (full wall specimens)

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was obtained post mortem from female cadavers (age at time of death: 19 years to 42 years) who had been subjected to forensic examination. Immunohistochemical methods (double-labelling technique, laser fluorescence microscopy) were applied to sections of the human vaginal wall in order to evaluate the expression and distribution of cAK, PDE4, VIP, and PGP 9.5

**Results:** A dense meshwork of varicose nerve fibers, characterized by the expression of the neuronal marker protein PGP 9.5, was identified in the subepithelial layer of the vagina. Some of these nerves also presented staining for VIP. Immunoreactivity specific for cAK was observed in non-vascular smooth muscle and the entire wall of small arteries interspersing the tissue. These arteries also expressed PDE4. Blood vessels were found innervated by VIP- and also CGRP- (calcitonin gene-related peptide) positive slender varicose nerve fibers.

**Conclusions:** Our results indicate that the cyclic AMP pathway is involved in the perception of sensory signals and the control of local vascular events in the human vagina.

#### Disclosure:

Work supported by industry: no.

024

#### A role for CTDSPL in fibrosis and plaque calcification in Peyronie's disease

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*<sup>1</sup>: Baylor College of Medicine, USA*

**Objectives:** Calcification is a frequent complication of penile plaque development in Peyronie's disease (PyD). The causes of plaque calcification are poorly understood, although it may be regulated by osteoblast and myofibroblast differentiation. We sought to identify genes involved in PyD plaque calcification and pathogenesis, and herein present data implicating *CTDSPL* in that process.

**Methods:** Gene copy number variations (CNVs) were identified in genomic DNA from 14 men with both PyD and Dupuytren's Disease (DD) and 4 controls using microarray-based comparative genomic hybridization (aCGH). Gene copy numbers were validated using gene-specific Taqman qPCR and DNA sequencing used to identify mutations in genes of interest. Fibroblasts were isolated from the TA of a patient with PyD and *CTDSPL* transfected and overexpressed to determine effects on osteoblast and myofibroblast differentiation pathways using qPCR.

**Results:** Using aCGH, a 4.3kb microdeletion at chromosome 3p22.2 encompassing the *CTDSPL* gene was identified and validated in 1/14 (7.1%) patients with PyD. In contrast, CNV frequencies in *CTDSPL* were 0.008% and 0.012% in 2 databases of ~40,000 patients not selected for specific conditions. No deleterious mutations were identified during sequencing. Overexpression of *CTDSPL* in TA fibroblasts derived from a patient with PyD resulted in downregulation

of myofibroblast differentiation (*ACTA2*) and fibrosis (*CTGF*) pathway markers, and upregulation of osteoblast differentiation (*BMP2*, *BMPR1B*) pathway markers.

**Conclusions:** A microdeletion in *CTDSPL* was identified in men with PyD and DD. *CTDSPL* overexpression in TA fibroblasts from men with PyD induces osteoblast pathway marker expression and represses myofibroblast pathway markers, consistent with a possible role for *CTDSPL* in plaque calcification and fibrosis in PyD.

#### Disclosure:

Work supported by industry: no.

025

#### NADPH oxidase inhibition and sepiapterin supplementation fail to ameliorate age-related erectile dysfunction in Lewis rats

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**Objectives:** Aging is a major risk factor for the development of erectile dysfunction. The pathology may be driven in part by increases in reactive oxygen species (ROS) from overactivity of the NADPH oxidase enzyme complex. The increased oxidative burden can lead to vasculopathies through the oxidation of the nitric oxide synthase (NOS) cofactor, tetrahydrobiopterin (BH<sub>4</sub>) and subsequent uncoupling of the NOS complex. We hypothesized that increasing the bioavailability of BH<sub>4</sub> and inhibition of NADPH oxidase activity would ameliorate the age-related erectile dysfunction in male Lewis rats.

**Materials and Methods:** Erectile function in anesthetized young (14 weeks old; n=12) and aged (74 weeks old; n=6) male Lewis rats was assessed *in situ* by measuring the maximum intracavernosal pressure (ICP) and mean arterial pressure (MAP) in response to electrical field stimulation (EFS, 0- 6 volts) of the cavernosal nerve. We assessed the erectile responses before and after intracavernosal injection of 100  $\mu$ M VAS-2870, an NADPH oxidase inhibitor, or 10  $\mu$ M sepiapterin, a BH<sub>4</sub> precursor.

**Results:** The maximum ICP response to EFS was significantly decreased ( $P < 0.05$ ) in the aged control compared to that of the young control at 4V ( $35.8 \pm 4.6$  mmHg;  $50.8 \pm 3.6$  mmHg), 5V ( $36.2 \pm 3.7$  mmHg;  $52.6 \pm 3.9$  mmHg) and 6V ( $36.3 \pm 3.4$  mmHg;  $51.6 \pm 3.7$  mmHg). The MAP response to EFS was also significantly reduced ( $P < 0.05$ ) in the aged control compared to that of the young control at 4V ( $62.8 \pm 4.3$  mmHg;  $77.3 \pm 3.8$  mmHg), 5V ( $61.8 \pm 4.3$  mmHg;  $80.2 \pm 4.2$  mmHg) and 6V ( $63.9 \pm 4.3$  mmHg;  $81.5 \pm 4.5$  mmHg). The normalized ICP/MAP ratio showed no significant difference between the aged and young controls. Neither VAS-2870 nor sepiapterin restored the age associated impairment in voltage-dependent ICP levels.

**Conclusions:** Lewis rats exhibit age associated ED that is not recovered by increasing NO bioavailability through presumed stabilization of eNOS or through the reduction in ROS via

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inhibition of NADPH oxidase. Based on these data, alternate etiologies of age-related ED in the Lewis rat may include: a veno-occlusive dysfunction due to morphologic changes in the corpus cavernosum, or deranged inflow from the vascular beds that supply the penis.

## Disclosure:

Work supported by industry: no. Supported in part by a Sexual Medicine Society of North America fellowship to D.P.B., Department of Physiology and NIH U19 ES 019525.

026

## Differential effects of sildenafil and tadalafil on human penile smooth muscle cells: New insights for old mechanisms

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**Objective:** Normal penile smooth muscle structure and function are necessary for the initiation and maintenance of erection. Improved relaxation of the cavernosal smooth muscle via phosphodiesterase 5 inhibitors (PDE5i) is attributed to the inhibition of PDE5 enzyme resulting in accumulation of cGMP and reduction of cytosolic calcium. This study investigates the additional mechanism(s) of the effects of sildenafil and tadalafil on human penile smooth muscle cells.

**Materials and Methods:** Primary human corpora cavernosa smooth muscle cells (HCCSMC) were isolated from penile tissues. HCCSM cells (passages: 3-7) were seeded in petri dishes (1 x 10<sup>6</sup>/ml) for 24 hr. The cells were then treated with 100  $\mu$ M of sildenafil or 100  $\mu$ M tadalafil for 4 h and 24 h. **Results:** HCCSMC showed an elevation of mRNA expression of nNOS with 100  $\mu$ M of sildenafil (19.4  $\pm$  7.4, p = 0.035) compared to tadalafil (8.5  $\pm$  7.4, p = 0.19). However, the mRNA expression of endothelial eNOS was slightly downregulated with sildenafil (0.64  $\pm$  0.22, p = 0.17) while tadalafil induced insignificant increase in the mRNA expression of eNOS (2.8  $\pm$  1.6, p = 0.19). Although both sildenafil and tadalafil are phosphodiesterase 5 inhibitors, the PDE5 mRNA expression increased after treatment with sildenafil (2.15  $\pm$  0.53, p = 0.20) but decreased with tadalafil (0.37  $\pm$  0.2, p = 0.12). On the other hand, levels of cGMP were significantly elevated with sildenafil (1.82  $\pm$  0.23 pM/mg protein compared to control 1.28  $\pm$  0.15 pM/mg protein with p value of 0.04). However, tadalafil showed no effect on the cGMP levels compared to control. PKG mRNA expression levels were increased 6.88 $\pm$ 3.41 fold with sildenafil (p = 0.08), and 2.3  $\pm$  1.07 fold with tadalafil (p = 0.2).

**Conclusion:** These findings suggest differential effects of sildenafil and tadalafil on HCCSMC. Sildenafil elevates mRNA levels of nNOS and PKG and cGMP protein levels. However, tadalafil enhances eNOS mRNA expression while downregulating PDE5 mRNA. These need further investigation, possibly using *in vivo* approaches.

## Disclosure:

Work supported by industry: no.

027

## Absence of S-nitrosoglutathione reductase alters erectile function through oxidative stress

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**Objectives:** S-nitrosoglutathione reductase (GSNOR) plays an important role in the regulation of S-nitrosylation and in protection against oxidative/nitrosative stress through denitrosylation of S-nitrosoglutathione (GSNO). Previous studies show that increased oxidative stress is associated with decreased endothelial function and erectile function (EF). This study examines physiologic oxidative/nitrosative stress and vascular cell adhesion molecule, (V-CAM)-1 expression, in the penis of mice with a targeted gene deletion of GSNOR (<sup>-/-</sup>).

**Materials and Methods:** Adult male GSNOR <sup>-/-</sup> mice (3-7 months) and age-matched wild type (WT) controls were used. EF was assessed by electrically stimulating the cavernous nerve (CN) at 1, 2, 3 and 4 volts and recording maximal intracavernosal pressure (ICP) above baseline. A separate group of mouse penes were collected at baseline for western blot analysis of the oxidative/nitrosative stress markers; nitrotyrosine (NT), 4-hydroxynonenal (4-HNE) and Malondialdehyde (MDA) and a biomarker of endothelial dysfunction (V-CAM)-1.

**Results:** Following electrical stimulation of the CN GSNOR <sup>-/-</sup> mice had significantly decreased maximal ICP values compared to WT mice at 1, 2 and 4 volts (p<0.05). At baseline, NT, 4-HNE, MDA and (VCAM)-1 expressions were all significantly increased in GSNOR <sup>-/-</sup> mice compared to WT mice (p<0.05).

**Conclusions:** The altered EF in GSNOR <sup>-/-</sup> mice suggests the functional importance of GSNOR as an active denitrosylation mechanism in the penis as evidenced by increased oxidative/nitrosative stress. Increased oxidative/nitrosative stress may be a mechanism by which endothelial dysfunction and thus decreased EF occur.

## Disclosure:

Work supported by industry: no.

028

## NELL1: A genetic factor predisposing to fibrosis associated with Peyronie's disease

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**Objectives:** Peyronie's disease (PyD) is characterized by development of fibrotic plaques in the penile tunica albuginea (TA), triggered by an abnormal inflammatory process

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involving myofibroblasts and osteoblasts. The genetic factors predisposing to PyD are unknown. We sought to identify genes involved in PyD, and herein present data implicating *NELL1*, a gene involved in osteogenesis and inflammation.

**Materials and Methods:** Genomic DNA from 14 men with both PyD and Dupuytren's Disease (DD) and 4 controls was used for microarray-based comparative genomic hybridization (aCGH). Copy number variations (CNVs) were identified and candidate PyD genes were selected. Gene copy numbers were validated using gene-specific Taqman qPCR and DNA sequencing used to identify mutations in genes of interest. Fibroblasts from the TA of a patient with PyD were treated with human recombinant *NELL1* (hrNELL1) protein to determine effects on myofibroblast and osteoblast differentiation pathways using qPCR.

**Results:** Using aCGH, 23.1kb and 16.0kb microdeletions at chromosome 11p15.1 encompassing the *NELL1* gene were identified and validated in 2/14 (14.3%) patients. In contrast, in 2 databases of ~40,000 patients not selected for specific conditions, CNV frequencies in *NELL1* were 0.022% and 0.015%. Sequencing of *NELL1* in 14 men with PyD identified a missense mutation, R82Q, in exon 3 in 12 patients, predicted to negatively affect protein function and associated with Crohn's disease and ankylosing spondylitis. *NELL1* was highly expressed in TA fibroblasts derived from a PyD patient, and addition of hrNELL1 protein to TA fibroblasts induced expression of myofibroblast /myoblast (*ACTA2*, *SMTN*) and osteoblast (*BMP2*) differentiation pathway markers.

**Conclusions:** Microdeletions in *NELL1*, as well as a missense mutation linked to inflammatory conditions, were identified in men with PyD. *NELL1* is highly expressed in TA fibroblasts from men with PyD, and treatment with exogenous *NELL1* induces expression of myofibroblast and osteoblast pathway markers. These results suggest that *NELL1* may play a role in inflammatory pathway activation and pathogenesis in men with PyD.

## Disclosure:

Work supported by industry: no.

## 029

### Plasmid-based transient luciferase gene transfer in the major pelvic ganglion assessed with real time live animal imaging

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**Objective:** To assess the success and feasibility of directed plasmid-based transient luciferase gene transfer into the major pelvic ganglion (MPG) using real-time live animal imaging. This technique was developed to validate and monitor gene delivery to the MPG for treatment following cavernous nerve injury.

**Material and Methods:** Male Sprague Dawley rats (350g, n=12)

were anesthetized and their MPGs were exposed. A 30 gauge needle was inserted underneath the fascial plane overlying the MPG and 75µl of plasmid expressing firefly luciferase driven by an enhanced CMV promoter (1µg/ml) was injected. Intramuscular injections into lower limbs with the same plasmid were used as a positive control in each animal. Plasmid vehicle and luciferin vehicle served as negative controls. At 2, 3, 7, 14, 21, 35 days post MPG injection, luciferin (intraperitoneal 150 mg/kg) was administered and allowed to incubate for 10 minutes. Animals were imaged under inhaled anesthesia using the Xenogen In Vivo Imaging System. Following imaging animals were sacrificed, MPGs collected and luciferase mRNA expression was assessed using quantitative PCR.

**Results:** Positive control luciferase luminescence was detected less than 2 days post-injection in all animals. MPG luminescence was detected through the skin by 3 days post-injection with continued expression 3 weeks post-injection in all 3 animals evaluated at that time point. No luminescence was detected by 5 weeks post-injection in positive control sites and MPGs in all 3 animals evaluated at that time point. Luminescence was not detected in vehicle control animals or animals injected with plasmid that were not administered luciferin. Quantitative PCR of luciferase mRNA demonstrated expression in MPGs from animals injected with the luciferase plasmid but not in vehicle control animals with detectable amplification by 30 cycles.

**Conclusions:** MPG directed plasmid-based gene transfer therapy is feasible and durable expression is achievable. Expression of plasmids can be monitored serially in real-time with non-invasive imaging. This study supports the investigation of non-viral gene therapies for ED.

## Disclosure:

Work supported by industry: yes, by Juventas Therapeutics (industry funding only - investigator initiated and executed study).

## 030

### Change in hematocrit during treatment of hypogonadism via implantable testosterone pellets

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**Objectives:** All forms of androgen replacement involve stimulation of erythropoiesis. Unexpected and large elevations of hematocrit can increase blood viscosity, portending risk of thrombosis. Little is known regarding the impact of subcutaneous testosterone pellets on hematocrit. The aim of this study is to quantify the rise of hematocrit during treatment with implantable testosterone pellets.

**Materials and Methods:** This multi-center, retrospective database analysis evaluated men treated with testosterone replacement therapy at two tertiary referral centers between 2009 and 2014. Inclusion criteria consisted of adult, hypogonadal males who underwent treatment with implantable

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pellets. A Wilcoxon signed-rank test was subsequently used to calculate the significance of any change in hematocrit or testosterone level after initiation of pellet therapy.

**Results:** 97 patients constitute the study population. The average age of the cohort was 52, with a range of 24 to 80. Co-morbidities included DM (12%), HTN (43%), hyperlipidemia (45%), and obesity (29%). Mean pre- and post-pellet hematocrits were found to be 43.9% and 46.1%, respectively, corresponding to a statistically significant rise of 2.2% (CI=1.4 – 2.9;  $p < 0.001$ ). The average increase in testosterone level was 145.3 ng/dL (CI=105.7 – 184.9 ng/dL;  $p < 0.001$ ). Subgroup analysis revealed a trend towards an increase of hematocrit in those with comorbid conditions, although this was not statistically significant.

**Conclusions:** Although the data demonstrated a statistically significant increase in hematocrit, an increment of 2.2% is not likely to translate into a clinically significant result. Thus, for this cohort of patients treated with implantable testosterone pellets, there appears to be no significant risk of erythrocytosis.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

031

## Daily dose and costs associated with maintenance therapy of topical testosterone agents among hypogonadal men

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**Objective:** Topical testosterone agents (TTAs) are commonly used to raise low serum levels of testosterone in men. After initiating at a recommended starting dose (RSD), patients may undergo dose titration to achieve an appropriate maintenance dose. The objective of this study was to compare daily maintenance doses and costs of treatment with TTAs from US payer perspective in adult men diagnosed with Hypogonadism (HG).

**Materials & Methods:** Adult men with a HG-associated diagnoses initiated at the RSD with Axiron® (Lilly USA, LLC; RSD 60mg per day; N=209), AndroGel® 1% (AbbVie Inc.; 50mg per day; N=614), AndroGel® 1.62% (AbbVie Inc.; 40.5mg per day; N=235), or Testim® (Auxilium Pharmaceuticals, Inc.; 50mg per day; N=558) between January 1, 2011 and March 31, 2012 were identified in a database of commercially insured beneficiaries. Patients were required to have continuous eligibility and no claims of the index therapy in 12 months prior to and at least 1 month of continuous eligibility following initiation. Baseline demographic characteristics, Charlson Comorbidity Index (CCI), comorbidities, and testosterone use were compared using chi-squared test for categorical variables

and Wilcoxon rank-sum test for continuous variables. Mean dose was estimated per-person per-day (PPPD). Risk-adjusted dose and payer costs PPPD were estimated with a generalized linear model.

**Results:** Maintenance dose was attained at month 4. Mean dose PPPD in month 4 was 68.45mg, 56.68 mg, 51.18mg, and 59.24mg and risk-adjusted dose PPPD was 113.3%, 113.5%, 126.3%, and 118.7% of RSD for Axiron, AndroGel 1% (non-significant vs. Axiron), AndroGel 1.62% ( $P < 0.001$  vs. Axiron), and Testim ( $P = 0.047$  vs. Axiron), respectively. Risk-adjusted third-party payer costs PPPD were \$7.49, \$9.49, \$10.39, and \$9.59 (all  $P < 0.001$  vs. Axiron), respectively.

**Conclusions:** Maintenance dose as a proportion of RSD was the least among Axiron and AndroGel 1% patients, while third-party payer costs for the maintenance dose were lowest among Axiron patients

## Disclosure:

Work supported by industry: yes, by Eli Lilly and Co, USA (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

032

## Hypogonadism in the infertile population: Different or the same?

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**Objective:** Few studies have quantified sexual, psychological and physical symptoms associated with hypogonadism in infertile men. Our study examined the threshold of total testosterone (TT) level at which prevalence of hypogonadal symptoms in infertile men is increased.

**Material and Methods:** We performed a retrospective study of infertile men (n=418) between October 2004 to June 2013 who have complete data for TT and Androgen Deficiency in the Aging Male (ADAM) surveys. We evaluated testosterone levels that were drawn on the same day in the AM that men filled out the questionnaires.

**Result(s):** The mean age of the study cohort was 35 years and the mean TT was 366. Compared to infertile men with a TT  $\geq 250$ , those with TT  $< 250$  were more likely to experience decreased libido (n=28 [30%] vs n= 58 [18%];  $p = 0.01$ ) and lack of energy (n=36 [38%] vs n=75 [23%];  $p = 0.003$ ). Univariate analysis showed that men with TT  $< 250$  had 1.92 and 2.06 times significantly higher odds of experiencing decreased libido (95% CI = 1.14-3.25,  $p = 0.01$ ) and lack of energy (95% CI = 1.26-3.36,  $p = 0.004$ ) than those with TT  $\geq 250$ , respectively. Lack of energy remained statistically significant in the multivariate analysis (OR = 2.07, 95% CI = 1.06-4.03,  $p = 0.03$ ).

**Conclusion:** A TT level of  $< 250$  ng/dL appears to be the



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threshold at which decreased libido and lack of energy develop in infertile men, as many of these symptoms improved for patients with TT>300. Among the hypogonadal symptoms evaluated in men with infertility, lack of energy and decreased libido appear to be associated with a TT level of <250ng/dL. The uniform threshold of 300ng/dL cannot be uniformly applied to all men presenting with infertility and hypogonadism.

## Disclosure:

Work supported by industry: no.

033

### Pharmacokinetics and efficacy of a new SEDDS formulation of oral Testosterone Undecanoate (TU) in hypogonadal men: Data from two phase 3 trials with different dose-titration algorithms

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1: UCLA, USA; 2: Clarus Therapeutics, USA; 3: Johns Hopkins, USA; 4: Longstreth and Assoc, USA; 5: Alabama Clinical Therapeutics, USA; 6: University Urology Assoc, USA; 7: University of Washington, USA; 8: Yale University; 9: UCLA, USA

**Introduction :** An oral route of administration for a testosterone (T) replacement therapy (TRT) has potential convenience, compliance and safety advantages over current therapies for hypogonadism marketed in the US that are delivered by oral, transdermal or injectable routes. A novel formulation of oral TU that utilizes a SEDDS (Self-Emulsifying Drug Delivery System) and that offers the possibility of better efficacy was evaluated in two Phase 3 trials.

**Subject and Methods:** Both trials recruited hypogonadal men (serum T ≤ 300 ng/dL) age 18-75 years old into open-label, multicenter, dose-titration trials. Trial I was a randomized, active-controlled, 2-arm, 12-month study

in 325 hypogonadal men. Participants were randomized to either oral TU (n=162) or 1% AndroGel® (n=163), a commonly prescribed TRT. Trial II was a single-arm 114-day study with oral TU (n=144). The starting dose of oral TU (as T equivalents) in both studies was 200 mg BID dosed with food. There were up to 2 dose-titration opportunities, but the trials differed in: 1) Timing of the post-dose sample used for dose titration (Trial I: 4-6 h, Trial II: 3-5 h); 2) T concentration thresholds for dose adjustment (Trial I: 250-1100 ng/dL, Trial II 250-700 ng/dL); and 3) size of the dose adjustment (Trial I 100 mg, Trial II 50 mg T equivalent). Efficacy was assessed on Day 90 in Trial I and Day 114 in Trial II based on T Cavg from serial serum samples collected over 24 hours

for T assayed by LC-MS/MS.

**Results :** In Trial I, T Cavg value was 628 ± 342 ng/dL (mean ± SD) with oral TU and 485 ± 220 ng/dL with T-gel with 84% and 79% of oral TU and T-gel subjects, respectively, in the eugonadal range (defined as 300-1000 ng/dL). In Trial II the

T Cavg was 422 ± 171 ng/dL with 75% of subjects in the eugonadal range. Serum T peak (Cmax) excursions occurred in both trials but with the revised dose-titration algorithm used in Trial II only 6% of subjects had a Cmax between 1800-2500 ng/dL and only 3% >2500 ng/dL. These Cmax excursions were infrequent, transient and inconsistent for any given subject.

**Conclusions:** Both trials demonstrated effective T replacement and with the revised dose-titration algorithm the Cmax was comparable to other TRTs. This novel SEDDS formulation of TU fulfills an unmet need for an effective oral T replacement therapy in hypogonadal men.

## Disclosure:

Work supported by industry: yes, by Clarus Therapeutics (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

034

### Low testosterone at time of transplant independently predicts poor patient and graft survival in male renal transplant recipients

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**Introduction:** Low testosterone (T) is common in men with end stage renal disease and has been associated with death on dialysis. While successful kidney transplant improves T in many men, it doesn't in all. Low T has been correlated with chronic rejection in heart transplant recipients but has never been studied in kidney recipients. Our objective was to study serum T at time of transplant and correlate with patient and graft outcomes.

**Methods:** We identified serum samples collected and frozen at time of transplant for immunologic testing in male dialysis dependent recipients of primary kidney transplants done between 6 and 10 years ago at our institution. In 197 recipients there was sufficient serum to run a total T. Low T was defined as <220 ng/dL. Contingency outcomes were analyzed by Fischer's exact test, continuous values by student T test and survival curves by Gehan-Breslow-Wilcoxon tests.

**Results:** Patients ranged in age from 14 to 75 years (mean 48.9). There were 100 living and 97 deceased donors and 53 (27%) recipients were diabetic. Serum T ranged from 48-2013 ng/dL (mean 477±251.3). There was no significant difference in age between those with low and normal T (48.5 vs 49.0 years). The low T group had worse outcomes compared to normal T in 1 year patient survival (75% vs 95%, p=0.003), 3 year patient survival (62.5% vs 86.1%, p=0.008), 1 year graft survival (62.5% vs 92.4%), and 3 year graft survival (50% vs 76.3%, p=0.01). Comparison of Kaplan Meier survival curves showed significantly worse patient survival (Hazard ratio 2.53, p=0.004) and graft survival (death not censored) (Hazard ratio

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1.62,  $p=0.02$ ). In multivariable analysis adjusted for age, donor type, and pre-op dialysis, low T independently predicted patient death (Hazard ratio 2.27, 95% CI 1.19-4.32) and graft loss (Hazard ratio 2.045 95% CI 1.16-3.62)

**Conclusions:** These retrospective results show that low T is not uncommon in transplant recipients and correlates with early patient death and graft loss. If causality is present, T replacement therapy may improve survival. If there is association without causality, then low T may still be a useful marker for post transplant risk stratification, issues which should now be addressed in prospective studies.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

035

## Application of the Endocrine Society clinical guidelines on testosterone therapy in men with androgen deficiency syndromes in clinical practice

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**Objectives:** The 2010 Endocrine Society guidelines on testosterone therapy in androgen deficient men were based on the best scientific evidence available. However, little is known about application of the guidelines in clinical practice. The purpose of this study was to evaluate application of the guidelines related to the use of serum testosterone (T) for the diagnosis of hypogonadism (HGN) and monitoring of testosterone replacement therapy (TRT).

**Materials and Methods:** Using the Truven MarketScan® Database, we identified men 18 years or older who received transdermal TRT in 2011 and had a diagnostic code for HGN. Patients who received TRT within 6 months prior to the index date (initial testosterone prescription) were excluded. Patients were required to have continuous pharmacy and medical benefit enrollment for 1 year prior to and 6 months after the index date. 27,758 men met criteria for analysis.

**Results:** Out of the 27,758 men, 18-95 (mean  $52.8 \pm 10.8$ ) years with a HGN diagnosis and who received TRT, 22,107 (79.6%) had at least 1 T measurement performed in the year prior to initiation of therapy; 8091 (29.1%) had 1 and 14,016 (50.5%) had 2 or more testosterone determinations. During the 6 months following TRT, 11,742 (42.3%) had no follow up T measurements performed; 6176 (22.2%) had 1 T measurement and 9840 (35.4%) had 2 or more. 2572 (9.3%) patients had dose adjustment within 6 months, 1921 (6.9%) and 651 (2.4%) men had a dose escalation and reduction, respectively. Follow-up T levels were not measured in 1282 (49.8%) men who had a dose adjustment.

**Conclusions:** The 2010 Endocrine Society recommendation to measure 2 or more T levels for diagnosis of HGN was followed in about 50% of patients. The recommendation to monitor T measurements in patients on TRT was followed in only about 60% of men within 6 months after initiation of transdermal TRT. In the patients who had their dose of transdermal testosterone adjusted, about half had T determinations following adjustment. Only 40-50% of practitioners who prescribe testosterone adhere to evidence-based guidelines for use of T levels in the diagnosis of HGN and monitoring of TRT, suggesting a need for further investigation into reasons for non-adherence to guidelines and for practitioner-based educational efforts.

## Disclosure:

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036

## HCG can assist with recovery of spermatogenesis after testosterone use

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**Objective:** About 3 million men take testosterone in the US, including up to 6% of high school males, with many reproductive-age men unaware of the negative impact of testosterone supplementation on fertility. Addressing this population, we investigated the use of human chorionic gonadotropin to assist recovery of spermatogenesis in a case series of men with testosterone-related infertility.

**Materials and Methods:** We retrospectively reviewed charts from two tertiary care infertility clinics to identify men with azoospermia or severe oligospermia ( $<1$  million sperm/mL) due to exogenous testosterone use. All were placed on 3,000 units hCG subcutaneously every other day and supplemented with clomiphene citrate, tamoxifen, anastrozole, or recombinant follicle-stimulating hormone (or combination) according to physician preference. Clinical outcomes, including hormone values, semen analyses, and clinical pregnancies were tracked.

**Results:** 49 men were included in this case series. Return of spermatogenesis was documented in 47 men (95.9%) with one additional man (2.1%) having a documented pregnancy without follow-up semen analysis. The average time to return of spermatogenesis was 4.6 months with a mean first density of 22.6 million/mL. There was no significant difference by type of testosterone administered or supplemental therapy. No men stopped hCG due to adverse events.

**Conclusions:** We demonstrated the feasibility of using hCG and supplemental therapy to assist recovery from testosterone

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supplementation therapy (TST)-related infertility. Furthermore, patients treated with hCG remained minimally symptomatic after testosterone withdrawal. Future studies are needed to refine this therapeutic approach and document the presumed improved tolerability and speed of recovery compared to unaided withdrawal of exogenous testosterone.

## Disclosure:

Work supported by industry: no.

037

## Androgen receptor CAG repeat length polymorphism is associated with risk of metabolic syndrome in a Korean male

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**Objective:** The metabolic syndrome (MS) includes a clustering of metabolic derangements and low testosterone levels have been shown to be associated with both components of MS and MS per se. In this study we explored the relationship between androgen receptor (AR) CAG repeat length polymorphism and MS in a Korean male population.

**Material and method:** The association between AR CAG repeat length polymorphism and metabolic syndrome was analyzed in 144 Korean men (40-80 years old). MS was diagnosed according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP) criteria (any three or more of the following components were present: abdominal obesity (WC > 102 cm), triglycerides > 150 mg/dL (> 1.7 mmol/L), HDL cholesterol < 40 mg/dL (< 1.04 mmol/L), fasting glucose > 110 mg/dL (> 6.1 mmol/L), or blood pressure of > 130/85 mmHg). AR CAG repeat length polymorphism was determined by microsatellite fragment sizing and association with clinical factors (MS, age, height, weight, BMI, waist circumference, FBS, total cholesterol, HDL, LDL, triglyceride, HbA1c, sex hormone binding globulin) were analyzed.

**Results:** Mean age was 56.6±8.4 years. Mean AR CAG repeat length and serum testosterone levels were 20.74±12.5 and 5.5±1.7ng/ml respectively. Twelve men with hypogonadism (serum testosterone level lower than 3.5ng/ml) showed relatively short AR CAG repeat length compared with men with normal serum testosterone level (18.33 vs 20.95, p=0.48). Long AR CAG repeat length is associated with an increase in LDL, triglyceride, and HbA1c while showing negative correlation with HDL and total cholesterol. Total 113 men had at least 1 component of MS and 27 men were diagnosed with MS (more than 3 components). Men with MS showed relatively longer AR CAG repeat length compared with men without MS (23.3 vs 19.7, p = 0.14). Hypogonadal men showed relatively high risk of MS (OD: 1.656, CI: 0.409-6.709) compared with eugonadal men and in cross-sectional analyses, men with AR CAG repeat length less than 21 combined with hypogonadism showed more increased risk of MS (OR: 2.074, CI: 0.872-4.931).

**Conclusion:** In conclusion, AR CAG repeat length and hypogonadism seem to be associated with increased risk of MS in Korean male.

## Disclosure:

Work supported by industry: no.

038

## The effect of testosterone restorative therapy (TRES) on testicular volume. Results from a double blind randomized 12 week trial of clomiphene citrate vs anastrozole

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**Introduction:** The use of TRES in hypogonadal infertile men is widely accepted. Both the selective estrogen receptor modulators (SERMS) and Aromatase inhibitors (AI) have been used.

**Methods:** 18/25 hypogonadal infertile men undergoing a 12 week randomized double blind therapeutic trial of clomiphene citrate (CC) 25 mgs a day vs. anastrozole (AZ) 1 mg a day had pre and post treatment testicular doppler ultrasounds with testicular volume determinations. All ultrasounds were performed by the same ultrasonographer

**Results:** All hormone levels were comparable at baseline. Testosterone and free testosterone are shown to be significantly elevated post AZ and CC treatments. At 12 weeks, CC treatment when compared to AZ resulted in higher hormone levels except FSH. Post treatment testicular volumes increased over baseline in both treatment groups. % change in volume from baseline was greater in the AZ group p< 0.05. 66% of men had varicoceles (55% bil). Varicoceles did not affect testosterone increase or % change in volume. % change in testicular volume did not correlate with % change testosterone. No significant changes in seminal parameters were seen. Intra-observer variability of measurements had been previously established at 4%.

**Conclusions:** TRES results in significant increases in free and total testosterone levels. During a 12 week course of TRES testicular volume increased. The presence of varicoceles did not affect the testosterone response.

	Testosterone	FT	LH	FSH	SHBG	Total	% Change
Baseline	207 (84)	6.4 (3.3)	4 (1.4)	6.6 (3)	27 (3.3)	50.8 (14)	
Baseline AZ	204 (87)	6.6 (3)	4.2 (2)	7.2 (3.6)	26.8 (1.6)	33 (14)	
12 Weeks AZ	156 (92)*	11.4 (7.2)*	5.5 (2)	11 (7)	31 (1.5)	58.5 (15)	16.6 (13.5)*
Baseline CC	200 (86)	6.3 (2.5)	4 (1.1)	6.3 (3.4)	26 (1.8)	42.8 (12)	
12 Weeks CC	354 (232)*†	15.7 (5.4)*†	7.9 (3.3)*†	11 (10)	50 (2.1)*†	65.5 (14.3)	7.36 (5)

\*p<0.05 over baseline, † p<0.05 between treatment groups

## Disclosure:

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039

## Association between testosterone therapy and thrombotic events in elderly men

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**Objective:** The association between testosterone therapy and thrombotic risk in elderly men remains controversial. We evaluated mortality, the prevalence of cardiovascular and atherosclerotic events in men older than 65 years with symptomatic hypogonadism treated with testosterone therapy. We compared men treated with testosterone to an age and comorbidity matched cohort of hypogonadal men who were not on testosterone therapy.

**Methods:** After IRB approval, we retrospectively reviewed the charts of 932 men older than 65 years. Of the 932 men, 432 men were on testosterone therapy and 500 hypogonadal men (testosterone < 300ng/dL) did not take testosterone supplementation. We evaluated age and Charlson Comorbidity Index.

**Results:** Mean age and Charlson Comorbidity Index of men on testosterone therapy (72y; 1.9) was similar to men without hypogonadism (73y, p=0.82; 1.5, p=0.11). The mean duration of testosterone therapy was 4.4 ± 4.3 years. The prevalence of MI (8% vs. 13%, p=0.23), TIA/CVA (8% vs. 3%, p=0.37), and PE (0% vs. 2%, p=0.26) were similar between men treated with testosterone and men not on testosterone therapy. Serum testosterone (524 ng/dL vs. 338, p=0.005), fT (15.7 ng/dL vs. 5.7, p=0.01), and DHT (448 ng/dL vs. 269, p=0.01) were greater in men on testosterone therapy compared to men not on testosterone therapy. There was an insignificant trend for a greater hemoglobin (15.04 g/dL vs. 14.5, p=0.09), and a lower PSA (1.52 ng/mL vs. 3.02, p=0.06) for men on TST compared to men not on testosterone therapy. There was no difference in SHBG, E, and lipid parameters in men on testosterone therapy and men not on testosterone therapy.

**Conclusion:** Testosterone supplementation appears to be a safe and effective therapy for symptomatic hypogonadism in elderly men. There was no difference in prevalence of MI, TIA/CVA, or PE between patients who were treated with testosterone and men not treated with testosterone. Despite reassuring data from our cohort study, testosterone should be used with caution in elderly men with co-morbidities until larger randomized trials are performed.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

040

## Effect of testosterone supplementation on symptoms in men with hypogonadism

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**Objectives:** We sought to compare satisfaction and treatment efficacy in men (age range 35 to 75) with symptomatic hypogonadism (total testosterone < 300ng/dL and ≥ 3 (+) symptoms on the Androgen Decline in Aging Male - ADAM questionnaire) before and after receiving testosterone supplementation.

**Materials and Methods:** We prospectively followed a total of 42 men on T injections and T gels (n=21 in each group) from 2013 - 2014. These men were then age-matched to 42 eugonadal men (T > 300ng/dL and < 3 (+) symptoms on ADAM) with a similar comorbidity profile who were not on TST (controls) followed during the same time period. We then compared the hormone parameters and symptom characteristics in men who responded symptomatically to TST with men who did not respond to TST.

**Results:** Median serum total and free testosterone increased from pre-treatment levels in all men, regardless of therapy type (T injections= 294 to 693 ng/dL, 6.0 to 19.5 pg/mL, T gels= 263 to 412 ng/dL, 6.0 to 9.2 pg/mL, p<0.05). Men taking TST reported fewer ADAM symptoms after treatment (5.0 to 3.1, p < 0.05) and a higher qADAM score (26.1 to 30.5, p<0.05). When the types of hypogonadal symptoms were evaluated, both sexual (libido and erectile function), and psychological (decreased enjoyment in life, sad / grumpy, lack of energy, decreased ability to play sports) symptoms responded to TST. However, physical symptoms did not appear to improve with TST. Men who responded to TST (n =17, ≥ 3 symptoms improvement on ADAM) were younger (48.9 vs. 58.3 y), had a larger increase in serum total (368.9 v. 205.3 ng/dL) and free testosterone (13.1 v. 4.8 pg/mL) compared to men who did not respond to TST (n = 14, ≤ 1 symptom improvement on ADAM). On univariate and multivariable analysis, only younger age was positively associated with response to TST (OR = 0.926, p = 0.03).

**Conclusions:** Testosterone supplementation improves both sexual and psychological symptoms in hypogonadal men. Clearly, younger men appear to respond better to symptom improvement following testosterone therapy.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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041

## **Delayed ejaculation remains a recalcitrant condition: Results of a SMSNA survey**

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**Objectives:** Delayed ejaculation (DE) is a disorder that lacks defined treatment outside of consensus and expert opinion. A survey was administered to the members of the Sexual Medicine Society of North America (SMSNA) to evaluate members' perceptions of DE significance, frequency, etiology, and treatment.

**Methods:** Members of the SMSNA were invited by email to participate in a web based survey. The questionnaire consisted of 8 questions pertaining to DE. Questions addressed the number of patients the practitioner sees per month with DE, a qualification of how bothersome the problem is to patients, ranking of common etiologies, perceived success of common treatments, which common treatments are used by the practitioner, a quantification of symptom resolution and a broad characterization of the practitioner's current work position. The final question allowed practitioners to add in any additional comments.

**Results:** A total of 94 respondents completed the survey with 73% of those being urologists. Thirty-eight percent of the respondents saw >2 patients a month with DE and 89% of practitioners felt that DE was moderately (61%) and severely bothersome (28%) to the patients. Etiology of DE was felt to be primarily from medication effects. Psychological factors were seldom thought to be an underlying etiology, however; psychological counseling was often offered after primary treatment attempts failed. Independent of modality, 60% of patients had a poor response to treatment (seldom 49%, never 11%). Carbergoline was the most commonly selected first line medication treatment (36%) followed by Bupropion (28%), Oxytocin (15%), Cyproheptadine (13%) and others. Normalization of hypogonadism "never" or "seldom" corrected DE for high volume practitioners ( $p=0.047$ ).

**Conclusion:** Delayed ejaculation remains a poorly understood, bothersome disorder without clear practice patterns found among members of the SMSNA. For most, DE is seen greater than twice pre month, is highly discrepant in etiology and treatment, and is rarely treated successfully.

### **Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

042

## **Sexual function associated with lower urinary tract symptoms in men with benign prostatic hyperplasia: MTOPS cohort of cross-sectional and longitudinal data**

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**Objective:** To examine the cross-sectional associations between baseline characteristics and sexual function and the longitudinal associations between change in lower urinary tract symptoms (LUTS) and change in sexual function among men with benign prostatic hyperplasia (BPH).

**Materials and Methods:** We studied LUTS assessed by the American Urological Association Symptom Index and sexual function determined by the Brief Male Sexual Function Inventory (BMSFI) in men enrolled in the Medical Therapy of Prostatic Symptoms (MTOPS) Study. The cross-sectional cohort included 2,916 men who completed the BMSFI at baseline. The longitudinal cohort included 672 men who were randomized to placebo and had completed the BMSFI at baseline and at least once during a four year follow-up. Multiple adjusted linear modeling for each domain of the BMSFI was performed to assess associations of sexual function with LUTS.

**Results:** After adjustment for baseline demographic and clinical characteristics; increased age, less education, obesity, and severe LUTS were each significantly associated with worse sexual drive, erectile function, ejaculatory function, sexual problem assessment, and overall sexual dissatisfaction in the cross-sectional BPH cohort. However, none of these baseline characteristics predicted change in sexual function in the longitudinal cohort. A small negative change in all sexual function domains was associated with worsening of LUTS in this group.

**Conclusions:** Increased age, less education, obesity, and more severe LUTS were individually associated cross-sectionally, but not longitudinally, with poorer sexual function in men with LUTS/BPH. The decline in sexual function associated with worsening of LUTS in men assigned to placebo was small.

### **Disclosure:**

Work supported by industry: no.

043

## **Acceptance of a pre-operative educational seminar about recovery from side-effects after prostate cancer surgery**

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**Objectives:** Education before radical prostatectomy (RP) helps patients set appropriate expectations for functional recovery. We evaluated the acceptance of and knowledge attained in a pre-operative psychoeducational group seminar for patients and partners. We hypothesized that the seminar would be acceptable and facilitate learning.

**Materials and Methods:** Men scheduled for RP were eligible, partners were invited. The 2.5-hour interactive seminar included multidisciplinary presentations about surgery-related urinary and sexual outcomes, rehabilitation, and couples' work towards recovering sexual intimacy. A *Satisfaction and Knowledge* survey was administered immediately afterwards. Demographic and satisfaction data were analyzed with descriptive statistics. Congruence of patients' and partners' *Knowledge* responses was analyzed using non-parametric statistics.

**Results:** Of 618 patients scheduled, 426 patients, 342 partners attended; 323 couples provided complete data. Over 90% of participants found the seminar informative, 74% found a group setting acceptable, 84% found travel to the seminar burdensome. Most patients and partners (84%, 90%, respectively) expected some urinary incontinence and understood rehabilitation strategies to regain bladder control; 84% patients/78% partners expected post-surgery sexual activity to be different, 73% patients/65% partners expected surgery to make erections worse, 63% patients/58% partners expected a 2 year erection recovery timeline. The majority of couples were congruent in their expectations; 19% - 39% couples were incongruent, varying by question.

**Conclusions:** A pre-operative psychoeducational group seminar on the recovery from RP side-effects promotes realistic expectations, and is acceptable to patients and partners. Incongruent couples may need further instruction after surgery. Web-based methodology could improve access and should be studied in future research.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

044

## Crossover study of the prostatic urethral lift: Analysis of lower urinary tract symptoms

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**Objective:** To assess the clinical effects of the Prostatic Urethral Lift (PUL) when delivered after sham procedure using a self-controlled paired data set through a crossover study

**Material and Methods:** Subjects underwent a sham procedure through a prospective, randomized, blinded study conducted at 19 centers in the USA, Canada and Australia. The sham procedure involved rigid cystoscopy with simulated active treatment sounds. After unblinding at 3 months, 80% (53/66) of the sham subjects elected to undergo PUL. PUL is a mechanical approach to treating the prostate's lateral lobes and employs transurethrally placed permanent UroLift® implants that enlarge the urethral lumen. Comparisons were made between sham and PUL using paired statistical analysis for symptom relief, quality of life, flow rate, sexual function, and adverse events. Erectile function was assessed through the Sexual Health Inventory in Men (SHIM) and ejaculatory function through the Male Sexual Health Questionnaire - Ejaculatory Dysfunction (MSHQ-EjD).

**Results:** Lower urinary tract symptoms (LUTS) as measured by IPSS, quality of life, and flow rate in the crossover subjects improved from baseline and were similar to results from other published studies. Response after PUL was markedly greater than sham and durable to 12 months for most parameters. Adverse events were typically mild to moderate with 2% of crossover subjects requiring additional intervention for LUTS within the first year. There were no occurrences of de novo, sustained erectile or ejaculatory dysfunction. Ejaculatory function dropped 2.1 points in MSHQ-EjD after sham procedure. In contrast, sexual function measures in the erectile, ejaculatory, and ejaculatory bother domains improved after crossover PUL at every time point.

**Conclusions:** The Prostatic Urethral Lift reduces urinary symptoms more than rigid cystoscopy and can provide rapid, durable symptom improvement with low perioperative morbidity. Increase in ejaculatory function after PUL compared to the functional compromise after the sham procedure suggests that PUL may be uniquely suited to treating LUTS while preserving sexual function, utilizing a quick, minimally-invasive outpatient procedure.

## Disclosure:

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045

## Effects of tamsulosin on premature ejaculation in men with LUTS/BPH

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**Objective:** Previous studies have revealed that tamsulosin is not only effective on improving Lower Urinary Tract Symptoms (LUTS), but also effective on erectile functions. However, from the evaluation of its effect on ejaculatory function, there were some negative effects including decreased amount

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of ejaculation. But the effects of tamsulosin on premature ejaculation (PE) are hard to find. Therefore, this study was conducted to understand the effect of tamsulosin on PE of benign prostatic hyperplasia.

**Material and methods:** 29 patients who visited with LUTS were categorized into 2 groups of LUTS-only patients group (n=12) and LUTS combined with PE patients group (n=17), and 0.4mg of tamsulosin was administered for 12 weeks. And comparative analyses of before and after the treatment were conducted for IPSS (International Prostate Symptom Score), IIEF (International Index of Erectile Function), IELT (Intravaginal Ejaculation Latency Time), PEDT (Premature Ejaculation Diagnostic Tool) and PEP (Premature Ejaculation Profile). The patients with IPSS score at or higher than 8 were determined as LUTS patients, and the patients with less than 2 minutes of IELT and at or higher than 9 of PEDT score were determined as PE patients.

**Result:** IPSS of LUTS group after tamsulosin treatment showed a significant decrease (from  $19.6 \pm 10.03$  to  $15.4 \pm 7.76$ ,  $p=0.044$ ), and IPSS of the group of patients with LUTS combined with PE also showed a significant decrease (from  $25.4 \pm 8.94$  to  $20.4 \pm 10.34$ ,  $p=0.03$ ). There was no statistically significant change of PEDT for LUTS group, but there was a significant decrease of PEDT (from  $12.1 \pm 3.31$  to  $8.4 \pm 4.49$ ,  $p=0.012$ ) in the group of patient with LUTS combined with PE.

**Conclusion:** Tamsulosin has not only treatment effect for LUTS but also it improves PE of LUTS/BPH patients combined with premature ejaculation. Further large scale studies are needed in LUTS/BPH with PE to fully elaborate the effects of tamsulosin on premature ejaculation

## Disclosure:

Work supported by industry: no.

046

## Screening for low testosterone during urology office visits without referral for hypogonadism

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**Objectives:** Male hypogonadism can cause diminished quality of life as well as a number of physiological problems. Screening all men for low testosterone could detect a significant number of patients who can benefit from treatment.

**Materials and Methods:** We screened all male office visits over the last 18 months for testosterone levels. These are patients who came to the office for a variety of urological complaints not related to hypogonadism. The first baseline testosterone levels were recorded to determine whether those patients were testosterone deficient, using  $<300\text{ng/dl}$  as a cutoff value. Patients who were found to be testosterone deficient were asked to answer the ADAM questionnaire to determine if they were clinically suffering from hypogonadism. Patients were also

stratified based on treatment outcome.

**Results;** 320 patients were screened for PSA and testosterone. 141 patients (44%) were found to have subtherapeutic level of testosterone ( $<300\text{ng/dl}$ ). Out of this group, after counseling, 69 patients (49%) proceeded with treatment. The remaining 72 patients (51%) refused treatment, had a contraindication for treatment (CVD, prostate cancer, etc.) or were not symptomatic enough to treat.

**Conclusion;** Screening for hypogonadism at least at the initial office visit may lead to a significant number of symptomatic hypogonadal men who may benefit from treatment. Due to the fact that most patients are unable to recognize the symptoms of hypogonadism, this inexpensive screening test will identify those patients. As a result of the screening, 22% of the patients were treated with excellent outcome.

## Disclosure:

Work supported by industry: no.

047

## Non-medicinal components are an important factor in drug delivery in topical therapies: A study of topical lidocaine therapy for premature ejaculation

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**Objectives:** To evaluate the effect of topical lidocaine preparations for the treatment of premature ejaculation using standard dosing and objective outcome variables.

**Materials and Methods:** After ethics approval four commercially available topical lidocaine preparations (Endurance Rx, Epic, Promescent and Stud100) were selected and a standard dose of 30.0mg of lidocaine was applied to a freshly harvested square (3cm) of human cadaveric skin placed on a Frantz cell apparatus. Buffer solution containing lidocaine was drawn from the receptor cell at multiple time points to measure permeation. After permeation testing the tissue was then processed. A separate single product study using synthetic Strat-M membranes predictive of diffusion in human skin stratum corneum was used to measure Promescent permeation.

**Results:** Tissue retention for Promescent derived lidocaine applied to skin squares was greater ( $2.274\text{ mg/mL}$ ) as compared to the other lidocaine preparations ( $0.392 - 0.630\text{ mg/mL}$ ). More lidocaine was retained as determined by extraction analysis of the skin at 80 minutes. This result was corroborated due to less lidocaine passing through the tissue into the receptor cell from the Promescent sample which was one quarter the concentration of the competitors ( $0.366\text{ mg/mL}$  vs  $1.354-1.816\text{ mg/mL}$ ). The skin permeation study using synthetic Strat-M membranes demonstrated rapid permeation of lidocaine with Promescent.

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**Conclusions:** Non-medicinal components of drug delivery in the Promescent formulation significantly promote lidocaine dermis fixation and rapid permeation through the stratum corneum in a tightly controlled laboratory analysis. This preliminary laboratory analysis seems to support the assertions that Promescent lidocaine passes through the stratum corneum rapidly, yet is retained in the tissue more effectively than all sampled products. These parameters would be in keeping with the goals of clinical, topical therapy - quicker onset of action, and a longer duration of effect. This study demonstrates the importance of non-medicinal components of specific proprietary formulations may have on the potential clinical efficacy of a therapeutic option. Potential clinical benefits of Promescent over the sampled products may include improved erection control, higher patient and partner satisfaction and improved quality of life. Further laboratory and clinical work is required to support and prove these hypotheses with larger cohorts.

**Disclosure:**

Work supported by industry: yes, by Absorption Pharmaceuticals (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

048

**Low T predicts worse LUTS: Final results of the CUPPID study**

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1: Southern Illinois University SOM, USA; 2: Albany Medical Center

**Objective:** Previous data from this trial have demonstrated the increased prevalence of low testosterone (T) in male cardiology patients. Here we sought to assess patient factors that might predict low T, erectile dysfunction (ED), and lower urinary tract symptoms (LUTS) as well as patient outcomes that are related to low T.

**Methods:** We assessed a cohort of consecutive men within a cardiology clinic via IIEF-15, IPSS, ADAM, and previous ED treatment questionnaires, serum total testosterone (T), estradiol (E), and sex hormone binding globulin (SHBG). Data were collected on patient age, BMI, cardiac history and comorbidities. We utilized the online ISSM calculator to determine calculated free testosterone (CFT) values. A CFT of 6.5 or greater was considered normal. Multivariate logistic and linear regression were performed analyzing various end points and predictive factors.

**Results:** 200 patients were included in the study (mean age 67). Mean CFT and T:E were 5.4ng/dl and 8.2 respectively. Prevalence of low CFT was 79% while low total T was only 55%. Prevalence of moderate to severe ED and LUTS was 69% and 62% respectively. 68% of those with moderate to severe ED had received no treatment. Comparative risk of moderate

to severe ED by age group compared to the general population (NHANES) was 3.2, 1.4, and 1.2 for those aged 40-59, 60-69, and 70 and older respectively.

Decreasing CFT predicted worse LUTS ( $p = 0.02$ ). Increasing age and BMI were significantly associated with decreased CFT.

**Conclusion:** Male cardiac patients are 7 times more likely to be hypogonadal than the general population. One third of hypogonadal patients would have been missed using total testosterone instead of calculated free testosterone. Male cardiac patients are at increased risk of ED and undertreated. Hypogonadism was associated with worse LUTS challenging current dogma.

**Disclosure:**

Work supported by industry: yes, by Abbvie (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant or shareholder of an industry.

049

**Buspirone in the treatment of chronic orchalgia**

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1: Ohio State University, USA

**Objectives:** Chronic pelvic and testicular pain in males is frequently treated initially with NSAIDs and local anaesthesia, moving to surgical management thereafter. Other chronic pain syndromes are however being treated as bodily distress syndromes, with multidisciplinary treatment including anxiolytics and behavioural therapy. We investigate the possible effect of buspirone on chronic testicular pain in males.

**Materials and Methods:** Male patients seen at our clinic with diagnoses of chronic testicular pain, scrotal pain or pelvic pain were evaluated for the proximate cause, treatments and results of treatment. All patients were reviewed for buspirone use, as well as other treatments, and their progress notes reviewed for subjective improvement. The endpoint was subjective improvement after buspirone.

**Result:** Buspirone showed a subjective improvement rate of 43%. This increased to 50% when it was used as a second line treatment after failure of another treatment modality. This was compared to subjective improvement rates of 28% and 9% for NSAIDs/scrotal support and neurontin respectively.

**Conclusions:** Patients show subjective improvement with buspirone with similar or greater efficacy to other nonsurgical treatments. Further investigation into multimodal nonsurgical treatments is warranted.

**Disclosure:**

Work supported by industry: no.



# Abstracts

050

## Trigger point injections: A new treatment strategy for sexual pain

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**Introduction:** Sexual pain is found in up to 42% of patients with pelvic floor dysfunction (PFD). The etiology of sexual pain in these patients is often musculoskeletal with the frequent finding of hyperirritable, tender muscular foci termed "trigger points" (TrP) within the pelvis. The objective of this study was to evaluate the efficacy of anesthetic trigger point injections for treatment of sexual pain associated with PFD.

**Materials/Methods:** 48 patients with PFD who received trigger point injections were identified through medical record review. Trigger point injections were performed using a 25 gauge spinal needle through a transvaginal, paravaginal, or pararectal approach. Medical record review and direct patient questioning were used to evaluate post procedural symptomatology. Categorical data were compared with the chi-square test; binary data were compared with McNemar's test. No data was considered censored. All analyses were performed using SPSS version 22.0.

**Results:** 48 patients with PFD were included. Median age of patients was 47 years [43.1-52.5]. 36 (75%) of these patients are female and 12 (25%) patients are male. Total average volume injected was 4.3ml, with a range of 2-10 mL per session in 0.25-0.5 mL increments. 31 patients (64.6%) that received trigger point injections reported improvement in urinary hesitancy ( $p<0.0001$ ), nocturia ( $p<0.0001$ ), and constipation ( $p<0.0001$ ). 17 patients (35.4%) were unresponsive to treatment. In total, 22 of 48 (45.8%) patients reported sexual pain. 12 of 19 (63.2%) female patients with sexual pain reported a decrease in dyspareunia ( $p<0.0001$ ). Three of three male patients (100 %) with ejaculatory pain felt improvement in symptoms ( $p=.25$ ). In total, 15 of 22 (68.1%) patients reported improvement in sexual pain including dyspareunia and ejaculatory pain ( $p<0.0001$ ) after trigger point injections. No adverse events were noted.

**Conclusions:** The identification of TrPs of the pelvic floor and surrounding musculature is important to the care of patients with sexual pain secondary to PFD. 70% of patients with PFD reported symptom improvement after receiving trigger point injections. The use of trigger point injections for treatment of sexual pain yields impressive clinical results and can be easily performed in the office setting with small anesthetic doses and very low morbidity.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

051

## Characterization of voiding dysfunction in adults with sickle cell disease

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**Objective:** Recent discoveries regarding nitric oxide (NO) dysregulation underlying priapism may apply to other aspects of lower genitourinary system functions such as voiding. Voiding dysfunction has become increasingly recognized in patients with sickle cell disease (SCD), yet it remains understudied. We investigated characteristics of voiding dysfunction in a large group of young adult SCD patients.

**Material and Methods:** We performed a single-center, cross-sectional study of SCD patients, aged  $\geq 17$  yrs, from Oct 2012 to Feb 2014, using the validated Overactive Bladder short form questionnaire (OAB-q SF) and voiding histories. Patients scoring  $\geq 12$  were classified as potentially having OAB. Patient responses and scores were compared to controls having normal (AA) or sickle cell trait (AS) hemoglobin genotypes.

**Results:** A group of 239 patients (116 males, 123 females) with SCD (mean age  $32.0 \pm 10.0$  yrs) were compared with 104 normal and 57 sickle cell trait patients (mean ages  $30.2 \pm 12.1$  yrs and  $33.0 \pm 7.6$  yrs, respectively). Seven of 239 (2.9%) SCD patients compared to none of the 161 patients without SCD ( $p = 0.03$ ) reported current nocturnal enuresis. The mean age of enuresis cessation was higher in SCD patients ( $12.5 \pm 4.9$  yrs) compared to both normal ( $8.5 \pm 4.0$  yrs) and sickle cell trait ( $7.6 \pm 2.2$  yrs) groups ( $p < 0.0001$ ). Ninety-two of 238 (38.7%) SCD patients compared to both normal (16.3%) and sickle cell trait (19.3%) groups were classified as potentially having OAB ( $p < 0.0001$ ). Mean OAB symptom severity score was also higher in SCD patients ( $19.4 \pm 19.5$ ) compared to both normal ( $9.6 \pm 12.5$ ) and sickle cell trait ( $10.3 \pm 15.4$ ) groups ( $p < 0.0001$ ). Fifty-six (48.3%) of the 116 SCD males reported histories of priapism. Twenty-two (39.3%) of the 56 reporting priapism vs 14 (23.3%) of the 60 denying priapism were identified as having OAB ( $p = 0.06$ ).

**Conclusion:** We demonstrate that the rate of nocturnal enuresis remains elevated in the adult population with SCD compared to that in individuals without SCD. More generally, OAB symptoms appear quite common and increasingly severe in patients with SCD, and therefore may be an under-recognized complication of SCD that may continue well into adulthood. Our data are also suggestive of an association between priapism history and OAB. A more generalized lower genitourinary system dysfunction in the SCD population, mediated by NO dysregulation, may exist that extends beyond erection disorders.

### Disclosure:

Work supported by industry: no.

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052

## Testosterone therapy after radiation therapy for low, intermediate, and high risk prostate cancer

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**Objectives:** Testosterone therapy (TTh) in the setting of prostate cancer (CaP) is controversial, although a limited literature has described its relative safety. Here we present our multi-institutional data examining the effects of TTh in hypogonadal men with CaP treated with radiation therapy (XRT).

**Materials and Methods:** A retrospective review of 98 men with hypogonadism treated with TTh after XRT for CaP between 1999-2013 at four institutions was performed. Serum testosterone (T), free testosterone (FT), estradiol (E), sex hormone-binding globulin (SHBG), and prostate specific antigen (PSA) values were assessed before and at 3-6 month intervals following TTh initiation. PSA velocity and improvement in hypogonadal symptoms were also evaluated.

**Results:** Median (IQR) age at TRT initiation was 66.5 (61.0–72.0) years, and median baseline hormone levels were: T 209.0 (153.8–262.0) ng/dL, FT 5.9 (4.4–9.0) ng/dL, E 31.1 (22.8–56.6) pg/mL, SHBG 35.0 (28.3–48.0) nmol/L, and PSA 0.08 (0.0–0.31) ng/mL. Prostate biopsy pathology showed 5 men (3.1%) with Gleason (GI) 5, 44 (44.9%) with GI 6, 28 (28.6%) with GI 7, 7 (7.1%) with GI 8, and 4 (4.1%) with GI 9 tumors. Follow-up after TRT initiation was 40.8 (range 1.5–147.4) months, at which point serum T increased to 420.0 (233.3–707.3) ng/dL ( $p < 0.001$ ) and FT increased to 10.7 (4.9–29.2) ng/dL ( $p = 0.03$ ). No significant increase in median serum PSA was observed (0.09 (0.0–0.60) ng/mL ( $p = 0.37$ )) among all patients, including within the high-risk subgroup ( $p = 0.07$ ). Median serum E and SHBG did not rise significantly ( $p = 0.72$ ). Subjective improvement in hypogonadal symptoms was assessed in 40 (40.8%) men, and improvements seen in libido in 34 (85.0%) men, erections in 18 (45.0%) and energy in 35 (87.5%).

**Conclusions:** TTh provides symptomatic and biochemical benefit and does not appear to increase risk of CaP progression or recurrence in hypogonadal men treated with XRT, regardless of primary tumor grade, over the short to medium term.

### Disclosure:

Work supported by industry: no.

053

## Testosterone replacement therapy in opioid-induced hypogonadal men: A prospective analysis

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**Objectives:** To identify the effect of testosterone replacement therapy (TRT) in men with chronic pain undergoing opiate therapy. We hypothesize that treatment of opiate-induced hypogonadism can reduce the opiate requirement in men suffering from chronic pain

**Material and Methods:** A prospective study of men on chronic opioids with hypogonadism at a single institution (University of California-San Diego Health Systems) was conducted. Signs and symptoms of hypogonadism were assessed using the Androgen Deficiency in Ageing Males and International Index of Erectile Function questionnaires. Patient pain type, level of pain control based on the Visual Analog Scale and opiate requirements in the form of morphine equivalent dose (MED) were recorded. Patients were screened for hypogonadism by the following blood work: total testosterone (TT), follicle-stimulating hormone (FSH), luteinizing hormone (LH), and estradiol (E<sub>2</sub>). Men with symptomatic hypogonadism (TT <300 ng/dL) were offered TRT. All patients were followed longitudinally at physicians follow-up and phone interview.

**Results:** Twenty-seven men have now been enrolled with mean follow-up of 6 months (see Table 1). Mean patient age is 54.4. Mean BMI is 30.5. The most common etiology of pain include lumbar spine (63%), cervical spine (22.2%) and groin (14.8%). Mean FSH is 5.94 mIU/mL. Mean LH is 3.87 mIU/mL. Mean E<sub>2</sub> is 22.2 pg/mL. Mean TT is 262.8 ng/dL. 65.4% are hypogonadal. 44.4% are undergoing TRT. A total of 18.2% of men have had a decrease in their MED since starting TRT (see Table 2).

**Conclusions:** At this preliminary stage of our prospective study, it appears that TRT may benefit men on chronic opioid therapy by reducing their MED requirements. As more patients are enrolled and the follow-up period increases, we can validate our initial findings.

Table 1									
Age	BMI	Pain Type	FSH	LH	E <sub>2</sub>	TT	TRT	Follow-up (mo)	Δ MED
54.4	30.5	Lumbar spine	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Cervical spine	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Groin	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Other	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Lumbar spine	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Cervical spine	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Groin	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Other	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Lumbar spine	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Cervical spine	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Groin	5.94	3.87	22.2	262.8	44.4%	6	18.2%
54.4	30.5	Other	5.94	3.87	22.2	262.8	44.4%	6	18.2%

### Disclosure:

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## Effect of testosterone replacement therapy on lipid profile in the patients with testosterone deficiency syndrome

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**Objective:** As testosterone replacement therapy (TRT) use increases, its role on cardiovascular health must be explored. However, the effect of testosterone in cardiovascular health remains unclear. We evaluated the lipid profile changes with TRT in the population with testosterone deficiency syndrome.

**Material and Methods:** We performed a retrospective observational study in 230 male patients (mean age 60.1) with testosterone deficiency syndrome between 2007 and 2012 at the Asan Medical Center. Testosterone was replaced in hypogonadal patients by regular intramuscular injection (long acting testosterone undecanoate, 1000 mg) every 3 month at least for 1 year. The parameters estimated at the time of diagnosis, 6 months and 12 months after TRT were: total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), triglycerides (TGs), low-density lipoprotein cholesterol (LDL-C).

**Results:** Total cholesterol was significantly decreased after 6 months by TRT compared to before TRT (183.7±33.9, 175.5±33.1, p=0.001). Triglycerides was also significantly decreased after 6 months (147.2±84.1, 131.2±62.7, p=0.009). TC and TGs were decreased after 12 months. However, there were no changes in LDL-C at 6 months (114.2±27.7, 110.2±30.1, p=0.44) and 12 months (114.2±27.7, 110.8±25.7, p=0.159) after TRT. The change was not found in HDL-C at 6 months and 12 months (50.2±13.7, 50.1±14.6, 49.5±13.9). There was no increase in PSA with treatment at 6 months, however the increase was found at 12 months (0.85±0.58, 1.17±1.2, p=0.002).

**Conclusions:** TRT has the efficacy to reduce total cholesterol and triglycerides. But LDL-C and HDL-C were not changed at 6 months and 12 months after TRT.

	Baseline	6months	P value
Hb (g/dl)	14.7±1.3	15.4±1.6	<0.001
PSA (ng/ml)	0.85±0.58	1.7±1.4	0.165
LDL (mg/dl)	114.2±27.7	110.2±30.1	0.44
HDL (mg/dl)	50.2±13.7	50.1±14.6	0.85
Triglycerides (mg/dl)	147.2±84.1	131.2±62.7	0.009
Cholesterol (mg/dl)	183.7±33.9	175.5±33.1	0.001
Total Testosterone (ng/ml)	2.1±0.9	4.8±1.8	<0.001

	Baseline	12months	P value
Hb (g/dl)	14.7±1.3	15.4±1.6	<0.001
PSA (ng/ml)	0.85±0.58	1.17±1.2	0.002
LDL (mg/dl)	114.2±27.7	110.8±25.7	0.159
HDL (mg/dl)	50.2±13.7	49.5±13.9	0.804
Triglycerides (mg/dl)	147.2±84.1	134.3±68.8	0.005
Cholesterol (mg/dl)	183.7±33.9	173.8±29.1	0.001
Total Testosterone (ng/ml)	2.1±0.9	4.8±1.8	<0.001

### Disclosure:

Work supported by industry: no.

055

## Influence of altitude on the rise hematocrit on patients receiving testosterone therapy: The low T experience

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1: Low T Center, USA

**Objectives:** We hypothesize varying responses of total testosterone (TT) and hematocrit (Hct) to similar doses of injectable testosterone cypionate based on altitude. The 50 Low T Centers are at various altitudes but have identical treatment protocols.

**Methods:** In the pilot, 3 centers in Colorado (>5000ft) were compared to 4 centers (Plano, Houston, Nashville, Las Vegas) in lower altitudes (<5000ft). After IRB approval, data was mined from the EMR with patient information deidentified. Randomization was by selection of last name by fixed alphabetical order. Data was entered into Excel, and statistical analysis performed using Graphpad QuickCalcs.

**Results:** 160 patients were analyzed, equally distributed to >5000 ft (n=80) and <5000 ft (n=80). Of those >5000 ft mean initial TT= 230ng/dl and mean initial Hct=46. After 6 months of treatment, mean TT=644ng/dl and Hct =50.4. Of those < 5000 ft mean initial TT= 250ng/dl and mean initial Hct=44.5. After 6 months treatment, mean TT=649ng/dl and Hct =48. Unpaired t test was applied to mean change of TT and Hct for both groups. The difference in change in Hct was statistically significant, p =0.01, C.I. -1.75 to -0.23. However, the difference in the change in total T was insignificant.

**Conclusion:** Under standard protocols, equivalent doses of testosterone raise TT to the same extent in different altitudes. However, the impact on Hct differs based on altitude. The implication may be more frequent phlebotomies in higher altitude patients. In Colorado, one in 18 of our patients requires phlebotomy on a regular basis compared to about 1 in 30 patients in lower latitudes. A larger study is needed to confirm our preliminary findings.

### Disclosure:

Work supported by industry: no.

056

## Factors that influence hypogonadal men to initiate testosterone replacement therapy

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**Introduction:** We identified trends in patient characteristics and perceptions in men diagnosed with hypogonadism (HG) who initiated TRT (TRT+), compared to a matched sample of men who were diagnosed with HG but did not initiate TRT (TRT-).

**Materials and Methods:** A market research-based survey was

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conducted in a large, diverse sample of men with HG (N=742). The dataset included five distinct populations of HG men; our analysis was comprised of men who were diagnosed and elected to receive TRT (TRT+; n=155) and those who were diagnosed but declined TRT (TRT-; n=157). Patient demographics, clinical characteristics, and attitudes toward low testosterone (lowT) and TRT were examined as potential correlates with treatment initiation, and p-values were calculated (Fisher's exact test at the 0.10 level).

**Results:** Significant trends were observed between men with HG in TRT+ and TRT- groups: most bothersome were lack of energy (91% vs 81%, p=.075), decreased strength and endurance (86% vs. 76%, p=.077), and deterioration in work performance (52% vs. 31%, p=.004). A high percentage of men (TRT+ vs TRT-) reported erectile dysfunction (83% vs 70%, p=.050), lowT (68% vs 57%, p=.062), and benign prostatic hyperplasia (62% vs. 29%, p=.059) as very/extremely bothersome male disorders. A significantly higher percentage of men (48%;TRT+) were more knowledgeable of lowT as compared with TRT- men (14%, p<.001); regardless, most obtained their information from healthcare professionals (89% vs. 82%, p=.074). A high percentage of men (TRT+ [93%];TRT- [71%, p<.001]) viewed lowT as a medical condition requiring treatment; 29% of untreated men viewed lowT treatments as similar to steroids with safety issues (compared to 18% of treated men, p=.034). Most (TRT+ [82%];TRT- [66%, p=.002]) were comfortable bringing up personal topics with their doctor and believed that their doctor was knowledgeable about treating lowT (79% vs. 53%, p<.001).

**Conclusions:** Our analysis identified significant differences in demographics, clinical characteristics, and perceptions toward low T and TRT between men being actively treated for HG compared to those who declined treatment.

## Disclosure:

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057

## Testosterone restorative therapy in a urologic practice

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**Objectives:** Currently the only FDA approved treatments for hypogonadism involve testosterone replacement. (TREP). The use of testosterone restorative (TRES) treatment with aromatase inhibitors (AI) and selective estrogen receptor modulators (SERM) is common in the treatment of hypogonadal infertile men but not for late onset hypogonadism. Currently there are no FDA approved TRES drugs. The mechanism of action of TRES is to increase LH secretion by reducing the negative feedback of estradiol. Because EMAS data revealed

that 85% of hypogonadal men (T <302.5 ng/dl) were classified as secondary, most should respond to increased LH with normalization of endogenous testosterone secretion. TRES is appealing as a first line modality due to easy use, favorable side effect profile and low cost. We have been treating all men with symptomatic hypogonadism with either SERMS (clomiphene citrate (CC) 25mg daily) or AIs (anastrozole (AZ) 1 mg daily) as primary treatment and report our baseline and post treatment findings on sex hormones.

**Materials & Methods:** Retrospective analysis of labs on 132 consecutive hypogonadal men treated with CC or AZ as primary therapy since January 2014. All labs were analyzed by Labcorp and drawn after 5 weeks.

**Results:** 90% of men in both groups normalized T (>350 ng/dl). Estradiol increased in both groups. 50% had been on previous replacement therapy, and of those who responded, none returned to replacement therapy. Nonresponders were placed on exogenous replacement. Three men on CC developed T>1000 vs none on AZ.

**Conclusion:** Most men with hypogonadism will respond to treatments aimed at increasing their LH levels (AI or SERMS) which is consistent with the diagnosis of secondary hypogonadism. Long term trials of TRES vs TREP should be undertaken to ascertain the duration of response and long term safety of TRES in men.

Hormone Levels in Men on TRES Therapies (\*p<0.05 over baseline, †p <0.05 over other treatment)

	Age	Testosterone	Free Testosterone	Estradiol	Free Estradiol	T/E	FT/FE
Baseline		230 (60)	5.3 (2)	14 (6)	0.66 (3.77)	36 (77)	22 (31)
SERM	45 (11)	640† (263)	14 (3)	34† (16)	1.51† (0.58)	66 (100)	38 (100)
AI	44 (11)	484† (146)	11 (3)	9† (5)	0.23† (0.14)	128† (306)	66† (85)

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

058

## The effect of testosterone topical solution in hypogonadal men with suboptimal response to a topical testosterone gel

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**Objectives:** Hypogonadism is associated with decreased energy, libido and sexual function. In the United States, topical testosterone replacement therapy (TTRT) is a commonly prescribed treatment, however, research suggests that approximately 20% of patients fail to reach a normal testosterone (TT) level. Furthermore, up to 27% of men who switched topical

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gel formulations remained resistant to treatment. Given the anatomical and physiologic differences between the approved application sites for Axiron (axilla) versus those of other topical formulations (abdomen, shoulder, upper arm and thigh) we hypothesized that Axiron would increase TT levels in individuals who had suboptimal responses to a previous trial of TTRT.

**Material and Methods:** In this phase IV, multicenter, open-label, single-arm study, 78 men who failed to reach a normal TT level with either Androgel 1.62% (48.7%), Androgel 1% (32.1%), Testim 1% (34.6%), or Fortesta 2% (7.7%), and had a TT level below 300 ng/dL were treated with Axiron until TT reached a normal range ( $\geq 300$  and  $\leq 1050$  ng/dL) or for up to 9 weeks. On average, the study participants were 57 years old with a body mass index of 31.9 and a baseline TT level of 180.9 ng/dL.

**Results:** In 69% of men receiving Axiron, TT reached normal levels within the first two weeks of treatment. At the conclusion of the study, 94.7% of men had achieved a mean TT level of 535.6 ng/dL, representing an average 3 fold increase over baseline ( $P < 0.001$ , Wilcoxon signed rank test). Prior to starting treatment, over 61% of the study participants reported impairment in either energy or sexual drive. After treatment, energy and sexual drive improved in subjects (75.3% and 70.1%, respectively). No deaths or serious adverse events were reported.

**Conclusion:** In conclusion, Axiron is a safe and effective TTRT for hypogonadal men that had a suboptimal response to treatment with topical testosterone gel formulations.

## Disclosure:

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059

## Identifying factors affecting the variability of testosterone levels post therapy

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**Objective:** Late onset hypogonadism (LOH) and its association with aging males remains a debated issue. Testosterone replacement therapy (TRT) is the cornerstone of treatment. Various testosterone preparations are available in the market each having distinct pharmacokinetic profile. Subcutaneous testosterone pellet implants (Testopel®) recently have gained popularity because of better patient compliance, longer duration of action, and maintenance of steady testosterone levels. Limited data is available regarding optimal dose, frequency of pellet implantation and incidence of side effects. This prospective study seeks to evaluate the variability of testosterone levels in men and to identify factors affecting it,

in an effort to accurately assess the dosage and frequency of such implantations.

**Material and methods:** From January 2013 onwards, a total of 111 patients undergoing Testopel® implantation for LOH were evaluated prospectively. All received a total of 12 pellets inserted subcutaneously in the gluteal region in the prescribed sterile manner. Serum total testosterone (TT), free testosterone (FT), serum estradiol were measured before implantation and repeated at 2 weeks and 3 months post implantation. Rate of decay of TT levels was assessed using linear regression analysis as a function of time. A subgroup analysis based on BMI, number of pellets implanted was carried out.

**Results:** Mean patient age  $\pm$  SD was  $54 \pm 11.77$  years. Mean BMI  $\pm$  SD was  $30.79 \pm 4.78$  kg/m<sup>2</sup>. 53(43.6%) patients had BMI  $\leq 30$ kg/m<sup>2</sup> and 58(56.4%) patients had BMI  $> 30$  kg/m<sup>2</sup>, respectively. Testopel® implantation resulted in an increase of serum TT levels followed by exponential decay. At 3 months post implantation, men with BMI  $\leq 30$  kg/m<sup>2</sup> had significantly higher mean TT levels (499ng/dl) compared to men having BMI  $> 30$ kg/m<sup>2</sup> (397ng/dl). Adverse reactions were noted only in 5(4.5%) patients and were all Grade 1 as per Clavien-Dindo classification.

**Conclusion:** Our study suggests that the rate of decay in level of testosterone is greater in obese patients. Further studies may be warranted to determine the significance of body mass index on testosterone metabolism in order to optimize treatment regimens with Testopel. The findings from this study suggest that people with BMI  $> 30$  kg/m<sup>2</sup> may need more Testopel implanted in order to maintain a normal testosterone level. Several factors may determine the metabolism rate of Testopel, but if further studies determine that BMI is a major predictor of patient testosterone levels at 3 months, tailored therapy for patients based on BMI might be possible instead of a standardized dose for all men. We are studying other factors that might affect testosterone metabolism.

## Disclosure:

Work supported by industry: no.

060

## Early experience with testosterone replacement therapy after radiation therapy for prostate cancer

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**Objective:** As the use of testosterone replacement therapy (TRT) in men continues to increase, the role of TRT in patients with prostate cancer (CaP) is becoming better elucidated. We report our experience with TRT in patients with prostate cancer treated with radiation therapy (RT).

**Material and Methods:** An IRB approved retrospective review was performed on all patients with a prior diagnosis of CaP treated with RT and presenting with signs and symptoms consistent

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with hypogonadism (HG) to a single urologist specializing in andrology. All patients had final surgical pathology reports available for review and had baseline testosterone (TT) labs performed before 11 A.M., with repeat lab testing performed to confirm initial results. Patients with low or borderline TT levels (<300 ng/dL) and the presence of symptoms of hypogonadism were offered TRT (either clomiphene citrate, transdermal or intramuscular testosterone) after extensive counseling. Repeat hormonal evaluation, PSA, hemoglobin and hematocrit values were obtained at 6 weeks after initiation of therapy, and TRT doses were titrated as needed. Biochemical recurrence (BCR) was defined as a 2.0 ng/mL increase from nadir PSA according to Phoenix criteria. Labs were monitored every 3 months for the 1<sup>st</sup> year, 6 month for 2 years and then annually.

**Results:** A total of 13 patients met inclusion criteria. Mean age at end of RT was 63 years. Mean PSA prior to RT was 5.6 ng/mL (range 1.2-10.6). 8 patients had Gleason 6, 4 Gleason 3+4 and one Gleason 4+5 CaP. 3 patients received external beam or intensity modulated radiation therapy (EBRT) and brachytherapy (BT), 7 EBRT and 3 BT. 5 patients received neoadjuvant androgen deprivation therapy (ADT). Mean interval between end of RT and initiation of TRT was 7.7 years (range 1.2-17.2). Mean TT prior to initiating TRT, and while on treatment, was 211 ng/dL (range 22-462) and 591 ng/dL (range 353-1056), respectively. Mean nadir PSA after RT was 0.2 ng/mL (range 0.05-1.5). Mean follow up on TRT was 20 months (range 1-70), and mean PSA at last follow up was 0.4 ng/mL (range 0.05-1.7). No patients had a BCR, and none discontinued TRT.

**Conclusion:** In a small population of selected patients, TRT is safe in patients following RT for CaP, with no evidence of BCR or discontinuation of TRT at 20 month follow up. Longer term follow up will be crucial to determine the safety of TRT in this patient population.

## Disclosure:

Work supported by industry: no.

061

## Efficacy and compliance with Anastrozole for the treatment of late onset hypogonadism

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**Introduction:** Late onset hypogonadism is predominantly secondary. The pharmacokinetics of anastrozole (AZ), a reversible inhibitor of the aromatase p450 enzyme, make it an ideal treatment for secondary hypogonadism. Despite its proven efficacy in normalization of testosterone, there are no reports of patient compliance outside of sponsored clinical trials.

**Objective:** Review the efficacy and compliance with aromatase inhibitor therapy for the treatment of late onset hypogonadism in a urological practice.

**Materials and Methods:** The records of 85 men (age 53 +/-

13) with at least a 12 month follow-up (June 2011-July 2013), treated with AZ therapy 1mg daily for late onset hypogonadism were evaluated. Inclusion criteria were symptomatic hypogonadism and serum testosterone levels (TT)  $\leq$  350ng/dL. Outcome measures were the percentage of patients who normalized TT > 350ng/dL and compliance to medication at 12 months. Patients were seen at 7 weeks, 18 weeks, 42 weeks, and 66 weeks. Adverse events were recorded.

**Results:** Mean TT prior to therapy was 233 +/- 73ng/dL. Mean TT post therapy was 542 +/- 183 ng/dL. The highest TT measured in patients on AZ therapy alone was 939ng/dL. At a median of 46 days, 76 out of 85 patients normalized TT > 350 ng/dL (89% success rate).

Treatment compliance at 7 weeks was (0.94, 95% CI [0.81-0.99]) with a mean testosterone of (462 +/- 176ng/dL). At a mean of 12 months, compliance was (0.65, 95% CI [0.75-0.55]), with a mean testosterone of (495 +/- 196ng/dL). Patients lost to follow-up were considered noncompliant. An adverse-event profile for 103 patients showed the most common side effects to be joint pain (6), headache (3), loss of libido (1), and diarrhea (1). 17 patients gave nonspecific symptoms, categorized as "other".

**Conclusions:** Anastrozole is well tolerated and clinically efficacious for the normalization of serum testosterone, with an 89% success rate. No patients demonstrated supraphysiologic levels of testosterone. Adherence to medication (65%) is superior to that of transdermal gels (15% in another adherence study).

## Disclosure:

Work supported by industry: no.

062

## Utilization patterns of parenteral testosterone preparations in hypogonadal men

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**Objective:** Testosterone replacement therapy (TRT) is prescribed to treat hypogonadism (HG). However, most patients only use TRT for a short time, with nearly half discontinuing after 3 months. The aim of this study was to assess whether the use of parenteral TRT (defined as short-acting injectable, P-TRT) in men with HG has similar utilization pattern.

**Material and Methods:** 517 men  $\geq$ 18 years-old from the Truven MarketScan® Database with HG and P-TRT initiated in 2009 were followed for 12-30 months. Treatment discontinuation was defined as a medication gap of >30 days. A restart was defined as a P-TRT refill after a medication gap. Patients with one medication gap only were classified as continuous users. Patients with >2 medication gaps were classified as cyclic users.

**Results:** For continuous users, only 58 patients (31.2%) continued P-TRT 3 months after initiation. With time, the number of treated patients declined: 23 (12.4%) at 6 months,



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9 (4.8%) at 12 months, and 0 (0%) at 30 months. Duration of P-TRT was longer for many of the intermittent users. 3 months after initiation of therapy, 131 patients (39.6%) received P-TRT. With time, the number of treated patients declined: 95 (28.7%) at 6 months, 84 (25.4%) at 12 months, and 48 (14.5%) at 30 months. Some intermittent users had multiple medication gaps followed by a restart. The mean duration of P-TRT was 2-3 months (median 1 month) followed by a mean gap in P-TRT of about 2-5 months (median 2-3 months). At each of the pre-specified time points, some intermittent patients were off P-TRT, but restarted P-TRT at a later date. When considering these patients as being in active therapy, 330 (99.7%), 301 (90.9%) and 257 (77.6%) patients received P-TRT at 3, 6 and 12 months, respectively. After the first discontinuation, 59 patients (11.4%) switched to topical testosterone and were removed from this study.

**Conclusions:** The results suggest that high discontinuation rates may be due to the disease state rather than cost, dosing, daily use, or application method. Looking beyond adherence, many men who discontinued P-TRT displayed episodic use. We hypothesize that patients use P-TRT when they are symptomatic and discontinue therapy when symptoms abate. After discontinuation, it's our assumption that patients who remain asymptomatic stay off P-TRT whereas those whose symptoms recur reinitiate P-TRT.

## Disclosure:

Work supported by industry: yes, by Eli Lilly and Company (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

063

## Enclomiphene citrate raises testosterone in hypogonadal men and lowers LDL cholesterol

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Secondary hypogonadism is common in men with metabolic syndrome (MS). Increased waist circumference, dyslipidemia, hypertension and insulin resistance are hallmarks of MS. Enclomiphene citrate is an isomer of clomiphene citrate, increases serum testosterone levels in many men with idiopathic acquired secondary hypogonadism (IAH). Typically, enclomid increases serum testosterone (TT) into the normal range (300-1040 ng/dL) in about 85% of men with IAH. A six-month Phase III safety trial with enclomiphene citrate, (ZA-300), enrolled 499 men with IAH. Subjects initiated treatment at 12.5 mg/day and uptitrated to 25 mg/day of enclomid if their morning TT was <450 ng/dL. At baseline, men were 48.6±8.1 (Mean±SD) y.o., and they had a BMI of 33.0±4.6. After 6 and 26 weeks of enclomid, 83.7% and 86.6% of men had serum TT in the normal range. Serum TT in the 12.5 mg and 25 mg dose groups

after 26 weeks were 512 ng/dL and 417 ng/dL, respectively. Remarkably, 24.5% were in the normal range four weeks after discontinuation and 17% had normal TT levels after 8 weeks. The men on 12.5 mg responded better, with persistence of normal TT in 36.0% and 27.3% of the men at four and eight weeks, respectively. In this study, 35% of the men entering the study demonstrated total cholesterol (TC) in the high range, i.e., >200 mg/dL (201-372 mg/dL). Those subjects experienced a 35.7 mg/dL (14.9%) decrease after 6 months (p<0.0001). The changes were most dramatic for LDL Cholesterol (LDL-C) with a 29.8 mg/dL (21.2%) decrease and matched by only a 3.5 mg/dL (5.4%) decrease in HDL-Cholesterol. After 6 months of treatment, 61% of the subjects were in the optimal range (<200 mg/dL) for TC and 79% were out of the very high range (<190 mg/dL) for LDL-C (compared to 39% at baseline). Mean TC value for men who started with elevated TC was 196 mg/dL at 6 months. Enclomiphene citrate improved the LDL/HDL ratio over 6 months from 2.11 to 1.95 (p<0.0001). The results seen in LDL-C were not repeated with other components of metabolic syndrome. These results are from a study of men with IAH and a more detailed look with men specifically with metabolic syndrome is warranted. Raising TT into the optimal range plus the effects on LDL-C should be beneficial to an obese population of men at risk for cardiovascular disease.

## Disclosure:

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064

## Changes in the effects of Peyronie's disease after treatment with collagenase clostridium histolyticum according to men with Peyronie's disease and their female sexual partners

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**Objective:** To evaluate the effects of collagenase clostridium histolyticum (CCH) treatment in men with Peyronie's disease (PD) and to evaluate the men's PD symptoms and female bother reported by the men's female sexual partners (FSPs). CCH is approved as intralesional therapy for treatment of adult men with PD with a palpable plaque and curvature deformity of ≥30 degrees at the start of therapy, and has demonstrated efficacy for the treatment of PD in the double blind, placebo-

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controlled studies IMPRESS I/II.

**Materials and Methods:** Men with PD who had previously received placebo in IMPRESS I/II received up to 8 injections of CCH 0.58 mg/injection over 24 weeks in this phase 3, open-label study. Assessments included penile curvature deformity measures and the PD questionnaire (PDQ). FSPs who chose to participate in the study completed the female sexual function index (FSFI) and the PDQ for FSPs (PDQ-FSP), a 12-item, investigational questionnaire adapted from the men's PDQ.

**Results:** A total of 189 men were enrolled in the study. From baseline to Week 52, a 36.3% (95% CI 30.9%, 41.6%) improvement in penile curvature deformity and a 2.4 point (95% CI 1.8, 3.0) improvement in PDQ bother score was observed in the male subjects. The most common AEs reported were penile hematoma, penile pain, and penile swelling; no serious treatment-related AEs were reported. A total of 30 FSPs participated in the study. Following CCH treatment of their male partners with PD, FSPs reported improvement (using the PDQ-FSP) in both their male partner's PD symptoms and female bother by their partner's PD (mean score reductions of 4.8 and 2.0, respectively). Improvement was also observed on the FSFI scales of desire, arousal, lubrication, orgasm, satisfaction, and pain, as well as the full scale total scores. The proportion of FSPs who reported sexual dysfunction (FSFI total score of <26.55) decreased from 75% at baseline to 33.3% after partner treatment.

**Conclusions:** The efficacy of CCH for the treatment of men with PD observed in this study was consistent with results of previous studies. Exploratory analyses of FSP responses demonstrated decreases in FSP assessments of their partner's PD symptoms as well as female bother by their partner's PD symptoms after their partner's CCH treatment. Improvement in female sexual function was observed as measured by all 6 domains of the FSFI score, and FSP sexual dysfunction decreased.

## Disclosure:

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065

## Qualitative analysis of Peyronie's disease partner burden

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**Objective(s):** The limited literature exploring the psychosocial impact of Peyronie's Disease (PD) is almost exclusively focused on the patient. The purpose of this study is to explore the extent to which committed and empathic partners suffer because of the patient's affliction and day-to-day life with PD. This study is

one of the first to better understand how partners are affected by the PD experience.

**Material and Method(s):** This qualitative study collected data from 42 female partners of men with PD. These data were both written comments and transcribed telephone conversations collected from the Association of Peyronie's Disease Advocates (APDA) website archive forum, APDA online community active forum, PD-specific partner forums on the internet, and personal testimonies via interviews with partners of men with PD. These data cover over 5 years of partner comments. Five coders used thematic analysis of de-identified comments and transcripts to highlight primary themes related to these written comments. All coders agreed that thematic saturation had been reached.

**Result(s):** Four predominant PD partner themes were identified: 1) emotional alienation/isolation/loneliness; 2) detached and difficult communication; 3) grief over lack of physical sex, emotional intimacy and affection; and 4) finally, partners seek education and value being a self-advocate. Partner ultimate burden is to realize PD is not a temporary life change, but a permanent life alteration where the couple needs to alter and adapt the way they communicate and interact with each other.

**Conclusion(s):** PD is a couple's condition that is shared in equal measure between PD patients and partners. Many couples seemed like they could not form an alliance in fighting or coping with PD. The men were in a silent battle or they gave up, and their partners were burdened without any hope. In the final analysis, the condition underscores the extent to which PD strikes at the very core of a partner's place within the relationship and the decision to continue sharing their life journey with a man afflicted with PD.

## Disclosure:

Work supported by industry: no.

066

## Selection criteria used to guide surgical approach for management of Peyronie's disease: A single institution experience

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1: Rush University Medical Center, USA

**Objective:** Peyronie's disease (PD) is manifest by a fibrotic plaque within the tunica albuginea of the penis. For select patients, several surgical techniques are available. In an attempt to guide operative selection, we report our series of penile straightening procedures for PD spanning six years, with the following selection criteria. Patients with satisfactory erections and curvature < 60 degrees and no hinge effect were treated with tunica albuginea plication (TAP). Those with satisfactory erections and curvature > 60 degrees and/or hinge effect were treated with partial plaque excision and grafting (PEG). Patients with unsatisfactory erections were treated with placement of inflatable penile prosthesis (IPP).

**Methods:** We retrospectively reviewed all patients who



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underwent penile straightening procedures for PD between 2007 and 2013. Work-up involved a history, physical exam, and a duplex ultrasound. When possible, the Peyronie's Disease Questionnaire (PDQ) was employed to assess bother and distress associated with PD. Objective outcomes and patient satisfaction were assessed post-operatively

**Results:** A total of 389 patients underwent penile straightening procedures for correction of PD by one surgeon between 2007 and 2013. Of these patients, 29%, (n=114) received primary TAP, 40% (n=158) primary PEG, and 30% (N=114) IPP. Mean follow-up was 17 months. The PDQ showed no difference in emotional status or bothersome score between groups. There was a significantly higher incidence of DM within the IPP group ( $P<0.01$ ). Patients with less satisfactory erectile function were also more likely to undergo IPP placement ( $p<0.01$ ). Those with superior erectile function, a hinge effect, an extensive calcified plaque, or severe curvature were more likely to undergo PEG ( $p<0.01$ ). There were no significant differences in satisfactory rigidity, residual bothersome curve, or ability to engage in intercourse after surgery. At most recent post-operative visit, change in stretch penile length was improved in PEGs (+0.96 cm) compared to TAPs (+0.44 cm), ( $p<0.01$ ).

**Conclusion:** Patient experience with post-surgical rigidity, ability to engage in intercourse, and residual bothersome curve was not statistically different across the three groups. These results support the use of our selection criteria, even in the face of patient preference. The primary factors that compromised patient adherence to our treatment algorithm were fear of length loss or hesitance to pursue IPP placement.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

067

## The effect of urethroplasty on Peyronie's disease

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**Objective:** To determine the effects of urethroplasty on Peyronie's disease.

**Methods:** Retrospective billing data were collected for those patients at our institution with ICD-9 diagnosis codes for urethral stricture, Peyronie's disease, and Dupuytren's contracture and had undergone urethroplasty of any type in the last six years. Each chart was then examined for those patients who had pre- or post-operative Peyronie's disease, their disease progression, operative complications, and preexisting Dupuytren's contracture.

**Results:** We separated our patients into two groups: those with preoperative Peyronie's disease and those which developed it after urethroplasty. Overall stricture length in both groups ranged from 1.8 to 8 centimeters. Of the postoperative patients,

two had dorsal onlay urethroplasty and two had anastomotic urethroplasty. Two had postoperative hematomas. Three of the four had history of Dupuytren's contracture. Curvature and pain improved in one anastomotic patient with vacuum device therapy. One dorsal onlay patient stabilized with medical therapy.

The three patients with preoperative Peyronie's disease had either anastomotic urethroplasty or dorsal onlay urethroplasty; none reported worsening of their curvature or penile scar, and none reported preoperative Dupuytren's contracture. All had longstanding, non-active phase disease prior to surgery.

**Conclusion:** Peyronie's disease can develop as a rare complication of urethroplasty, but not all patients with Peyronie's necessarily have worsening disease after urethroplasty. Further study is needed to better characterize those patients who are at risk for developing a mass and curvature after surgery, but those patients with preoperative Dupuytren's contractures should be counseled about their risk of postoperative complications. Stable preoperative Peyronie's disease does not appear to preclude patients from undergoing urethroplasty.

## Disclosure:

Work supported by industry: no.

068

## The Modified Sliding Technique (MoST) for penile lengthening with penile prosthesis insertion

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**Objective:** Penile curvature caused by Peyronie's disease (PD) and the subsequent difficulty with penetration are extremely distressing to men. While standard incision and plication may work for small abnormalities, grafts are the preferred method for correcting large deviations or multiple abnormalities. Mobilization of the neurovascular bundle (NVB) has been described to maintain length during PD treatment, but this is often only temporary. Following inflatable penile prosthesis placement (IPP), NVB can be mobilized and PD treated as the IPP acts as a scaffold for penile reconstruction. We describe our experience in correcting PD following NVB mobilization and IPP placement without the use of a graft though a subcoronal incision.

**Patients and methods:** 13 men presented with PD and ED refractory to medical management. All patients had dorsal and midline plaque(s) identified by Doppler US. NVB release, incision of penile plaque, penile modelling and inflatable prosthesis placement was performed using our Modified Sliding Technique (MoST) for Penile Lengthening with Penile Prosthesis Insertion.

**Results:** Preoperatively, patients demonstrated an average curvature of 12-30 degrees. The penis was degloved through

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our subcoronal modified no touch technique, and an artificial erection was created. PD plaque and penile deformity was identified and marked. NVB mobilization was initiated lateral to the urethra, using a modified "sliding technique" (Rolle, et al. J Sex Med 2012). Following IPP placement any residual curvature was noted. Using relaxing incisions with cautery into the corpora, penile modeling or plicating stitches, the curvature was addressed. No grafting material was used in any patients. Curvature improved by 90-95% for men.

**Conclusions:** PD and the subsequent penile curvature and ED that results can be very concerning to men, our subcoronal surgical approach to IPP and the MoST procedure allow for simultaneous correction of penile deformities caused by Peyronie's plaques and IPP placement through a single incision. Men improved by 95% in this cohort.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

069

## Meaningful change in Peyronie's disease following treatment with collagenase clostridium histolyticum: Results from two large double-blind, randomized, placebo-controlled phase 3 studies

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1: University of North Carolina School of Medicine, USA; 2: South Florida Medical Research, Aventura, USA; 3: Tulane University Health Sciences Center, USA; 4: Auxilium Pharmaceuticals, Inc, USA; 5: Auxilium Pharmaceuticals, Inc, UK

**Objective:** The clinical efficacy of collagenase clostridium histolyticum (CCH) in subjects with Peyronie's disease (PD) was shown in The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies (IMPRESS) I and II, two large identical phase 3 randomized, double-blind, placebo-controlled studies. The degree of penile curvature improvement associated with subject-report of meaningful change has not yet been reported. Using the Global Assessment of PD (GAPD), we present subject-reported change in symptoms and effects of PD and penile curvature improvement following CCH treatment in the combined IMPRESS I and II studies.

**Materials and Methods:** CCH-treated subjects in the identical IMPRESS I and II (N=545) phase 3 studies received a maximum of 4 treatment cycles, each separated by a 6-week period. Subjects received up to 8 injections of 0.58 mg CCH, two injections per cycle separated by approximately 24-72 hours, with the second injection in each followed 24-72 hours later by plaque modeling. CCH-treated subjects who completed the GAPD and underwent goniometer penile curvature evaluation at baseline and at least once following CCH injection were included in the current analyses. The GAPD asks a subject to

assess the overall change in the symptoms and effects of PD on his life. Possible responses range from -3 (much worse) to 3 (much improved).

**Results:** At Week 52, 25% and 75% of CCH-treated subjects achieved penile curvature  $\leq 20^\circ$  and  $< 45^\circ$ , respectively. These men also reported a meaningful change (GAPD rating  $\geq 1$ ) in PD symptoms and effects, with mean percent improvements in penile curvature of 25.5%, 42.7%, and 69.8% for penile curvature deformity at Week 52 of  $30^\circ$ - $< 45^\circ$ ,  $21^\circ$ - $< 30^\circ$ , and  $\leq 20^\circ$ , respectively.

**Conclusions:** Seventy-five percent of men with PD reported meaningful change in PD symptoms and effects of PD on their life following CCH treatment that resulted in 25% or greater improvement in penile curvature deformity.

## Disclosure:

Work supported by industry: yes, by Auxilium Pharmaceuticals, Inc. (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

070

## Intralesional interferon $\alpha$ -2b therapy for Peyronie's disease: Penile duplex findings and clinical observations

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**Objective:** Intralesional interferon  $\alpha$ -2b (IFN) is a safe and effective therapeutic option for the management of Peyronie's disease (PD), with an exact regimen and length of treatment for efficacy yet to be determined. We report our clinical experience with IFN, in a large, multi-series injection program for PD, including penile duplex Doppler study (PDDS) results, objective penile curvature progression measurements and patient satisfaction data.

**Methods and Materials:** A retrospective analysis was performed on 143 consecutive patients undergoing intralesional IFN therapy for PD. All patients had an initial pre-treatment PDDS performed, documenting degree of penile curvature, plaque size, penile pain, erectile function and hemodynamic measurements. Therapy regimen consisted of 3 series of 6 biweekly injections of 3 million Units of IFN, performed by a single urologist. After each series of injections, follow-up PDDS data, penile curvature and plaque measurements were recorded. Results were documented after 6, 12, and 18 injections. Patients were followed up to 12 months post therapy.

**Results:** Pretreatment median penile curvature of these patients was 95 degrees (range: 35-150D). Median penile curvature after six injections was 65 degrees (range: 20-95D), with an average improvement of 30 degrees. After 12 injections, there was an overall median curvature improvement to 40 degrees (range: 10-80D), with an average improvement of an additional 25 degrees in penile curvature. After 18 injections, there was

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an overall median curvature improvement to 25 degrees (range: 5-40D) with an average improvement of an additional 15 degrees in penile curvature. Overall median improvement in penile curvature after three series of injections was 74%. All patients completing the treatment series demonstrated a decrease in penile pain and plaque size, improved erectile pliability and ability to have more comfortable intercourse with or without oral meds; with no decrease in erectile function or hemodynamic parameters. 30/143 (20%) patients reported occasional flu symptoms following therapy, resolving in less than 8 hours. No adverse side effects required delay or cessation of treatment.

**Conclusions:** Intralesional interferon  $\alpha$ -2b therapy for PD results in a significant decrease in penile curvature and discomfort that continues to improve with each course of a multi-series treatment regimen.

**Disclosure:**

Work supported by industry: no.

071

**Biomaterial grafting with penile prosthetic insertion in the management of Peyronie's disease: Efficacy and safety**

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1: USA

**Objective(s):** To report the technique(s) and long term followup of the use of biomaterial grafting after penile prosthetic insertion and plaque incision for Peyronie's disease.

**Material and Method(s):** A total of 72 patients with at least a 6 month followup were evaluated. Patient age ranged from 53-72 years (mean 65). All patients underwent the implantation of a 3 piece inflatable prosthesis via an infrapubic approach. All patients required a straightening procedure via a subcoronal approach with incision of the plaque with biomaterial grafting.

**Result(s):** Surgical correction of penile curvature was achieved in all patients. At a mean followup of 24 months (range 6-60) 68 of 72 patients (94%) have a functioning prosthesis. Four patients were explanted, 3 (4.2%) due to infection (2 within 6 weeks and 1 12 months postop) and 1 due to erosion. No reports of permanent hypoaesthesia, recurrent curvature, long term pain or bulging at the graft site have been noted.

**Conclusion(s):** Biomaterial grafting for the coverage of tunical defects after prosthetic insertion with plaque incision allow for satisfactory clinical results in long term followup.

**Disclosure:**

Work supported by industry: no.

072

**Surgical therapy of Peyronie's disease by partial plaque excision and grafting with collagen fleece: long-term**

**results**

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**Objectives:** Grafting procedures are preferred for surgery in advanced Peyronie's disease (PD) to avoid penile shortening. Today, non-autologous grafts are widely used to reduce morbidity. We report long-term results of a prospective study analyzing the outcomes after partial plaque excision and grafting with a self-adhesive collagen fleece.

**Materials and Methods:** PD patients with deviation in stable disease and unable to fulfil coitus were included. After partial plaque excision, grafting was performed in all cases with a ready-to-use collagen fleece coated with tissue sealant (TachoSil®, Takeda, Berlin, Germany). Results of correction were documented intraoperatively by artificial erection. Pre- and postoperative evaluation consisted of IIEF-5, penile length, sonography and artificial erection.

**Results:** From December 2004 to July 2013 n=290 patients underwent surgery. Mean patient age was 57.0 years (33-73). 87.6% of patients had dorsal deviation and 12.4% lateral or ventral deviation. In 244/290 patients (84.1%) a partial plaque excision with collagen fleece grafting was performed. 46/290 patients (15.9%) underwent a Nesbit-procedure. Mean operating time was 80.8 minutes (60-165). A totally straight penis was achieved in 97.5% of patients. After a mean long-term follow-up of 36.8 months (3-100), erectile function improved in 23.3%, remained unchanged in 66.0%, and worsened in 10.7% of patients. Mean penile length before and after surgery was 14.3 cm (6-21) and 15.0 cm (8-22), respectively. 273/290 patients (94.1%) had normal glans sensibility.

**Conclusions:** Grafting by a ready-to-use collagen fleece following partial plaque excision in PD is safe and successful. Long-term results are encouraging. A major advantage of the collagen fleece is reduced operating time and its easy application. Moreover an additional haemostatic effect is provided. The collagen fleece represents a feasible alternative to other grafts for PD reconstructive surgery.

**Disclosure:**

Work supported by industry: no.

073

**Peyronie's disease (PD) and penile hemodynamics: Color duplex doppler ultrasound analysis of PD patients**

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1: Mayo Clinic, USA; 2: Mayo Clinic, USA

**Introduction:** Peyronie's Disease (PD) can be diagnosed by patient history and physical findings. Beyond diagnosis, the triage of patients to appropriate interventions (intralesional

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therapies, reconstruction or penile implant) requires the assistance of Color Duplex Doppler Ultrasound (CDDU). The aim of our study is to define ultrasonographic characteristics of PD plaques and non-invasively assess penile vascular integrity.

**Materials and Method:** A retrospective review was completed of all patients who underwent office testing with intracavernous pharmacologic erection augmented by visual sexual stimulation and CDDU from January 2010 to June 2013 by one Urologist (IRB# 14-005781). Patients were further characterized by age, BMI, degree of penile curvature, cardiovascular risk factors, comorbid diagnosis of Dupuytren's contracture or hypogonadism, tunical plaque characteristics (acoustic shadowing, scattered microcalcifications, focal microcalcifications and heterotopic bone formation), Sexual Health Inventory for Men score (SHIM), and prior prostatic surgery. CDDU characteristics including pre and post- intracavernous injection peak systolic velocities (PSV) and resistive indices (RI) were also identified.

**Results:** 298 patients were identified, with a mean age of 62 years (26-88), mean BMI of 27.2 (18.1-46.1), and mean duration of PD of 41.2 months. Dupuytren's palmar contractures were evident in 13% (40/298); 12% of patients had prior prostate surgery (37/298). 41%, 11%, 40%, and 13% of patients reported HTN, DM, HLD, HD, respectively. 27.5% (82/298), 17.8% (53/298), 15.8% (47/298), and 12.8% (38/298) of patients had 30-45, 45-60, 60-90, and greater than 90 degrees curvature, respectively. 96/298 (32%) of men claimed ED non-responsive to PDE-5 inhibitors. CDDU parameters suggest 10% of PD patients had arterial insufficiency (PSV<35cm/s), 27% of men had cavernous venous occlusive disease (PSV>35cm/s, RI<1.0), 24% had mixed vascular ED, and 39% had normal vascular erectile response to Alprostadil.

**Conclusion:** In our series one-third of men complained of ED refractory to PDE-5 inhibitors. An evidence based assessment with CDDU suggests that only forty percent of PD patients have normal vascular integrity. Further multi-variable analysis is pending to correlate plaque characteristics (acoustic shadowing, microcalcifications and heterotopic bone formation) with degrees of penile deformity and duration of PD.

## Disclosure:

Work supported by industry: no.

074

## Ventral intralesional verapamil injections for Peyronie's disease: Feasibility and safety

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**Objective:** To report our initial experience with ventral intralesional verapamil injections (ILI) for Peyronie's Disease (PD).

**Methods:** We analyzed prospectively gathered data from

an institutional database pertaining to PD patients. For the purposes of this analysis, inclusion criteria included men (i) with uniplanar curvature (ii) who had curvature assessment (CA) with the assistance of intracavernosal injection and developed at least an 80% rigid erection (iii) who underwent 6 ILI (10mg verapamil in 5ml saline) and (iv) had an end of treatment CA at least 3 months after treatment completion. Ventrally located plaques were treated similarly to dorsal, with special attention paid to avoid midline injection directly into the urethra.

**Results:** 154 men met all criteria. 144 (93%) had dorsal ILI and 10 (7%) underwent ventral ILI. Mean duration of PD was 8±18 months and 3±2 months (p=0.46) while mean age was 55±8 and 59±7 years (p=0.16) respectively. Comorbidity profiles were similar in both groups. Mean baseline curvature was 38±15 degrees and 39±11 degrees (p=0.96) respectively. No significant difference existed in change in curvature between groups (see Table, p=0.33). Those who improved in the ventral ILI group had higher mean baseline curvature (51±7 degrees) compared to those who remained stable or worsened (30±7 degrees, p=0.04). Ventral ILI patients reported rare self-limiting hematuria and occasional blood at the urethral meatus at procedure completion, with a penile ecchymosis rate identical to dorsal ILI patients. There were no reports of urinary clot retention, penile hematoma or delayed urinary symptoms suggestive of urethral stricture.

**Conclusions:** Ventral ILI is a safe procedure. Changes in curvature with ventral injections are similar to those seen with those administered dorsally, with 40% demonstrating clinical improvement. Given our initial data, ILI should be considered in men with ventral plaques.

	Improvement in curvature >10 degrees	Stable curvature	Worsening curvature >10 degrees
Dorsal ILI	20%	44%	31%
Ventral ILI	40%	50%	10%

## Disclosure:

Work supported by industry: no.

075

## Peyronie's disease symptom bother reduction is related to penile curvature improvement in response to treatment With collagenase clostridium histolyticum: Results from two large double-blind, randomized, placebo-controlled phase 3 studies

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**Objective:** Collagenase clostridium histolyticum (CCH) intralesional injection was shown to statistically significantly improve penile curvature deformity (PCD) and Peyronie's

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Disease Questionnaire PD Symptom Bother from baseline to Week 52, the co-primary efficacy outcome measures for the large randomized, double-blind, placebo-controlled phase 3 studies IMPRESS I and II. The current analysis examines whether reduced PD Symptom Bother is associated with improvement in PCD in CCH-treated subjects from the IMPRESS studies.

**Materials and Methods:** IMPRESS I/II combined data included CCH-treated modified ITT subjects (N=401) with PCD and PD Symptom Bother assessment at baseline and  $\geq 1$  subsequent time point. The current study examined baseline and week 52 or last observation carried forward (LOCF) for all outcomes. Subjects were further characterized using final PCD  $\leq 45^\circ$  (N=314) to identify CCH-treated subjects whose final PCD was  $\leq$  that of the lowest 50% of PCD among subjects at baseline (mITT population median PCD at baseline =  $48^\circ$ ). 3 groups were created using final PCD: final PCD  $\leq 15^\circ$  (N=72), final PCD  $>15^\circ$  to  $\leq 30^\circ$  (N=120), and final PCD  $>30^\circ$  to  $\leq 45^\circ$  (N=122). Percent change in PCD and change in PD Symptom Bother were examined.

**Results:** The final PCD  $\leq 15^\circ$  group showed the greatest percent reduction in PCD from baseline (mean reduction 74.1%; mean baseline/week 52-PCD  $40.0^\circ$  to  $9.9^\circ$ ) and the greatest improvement in PD Symptom Bother (mean improvement 5.2 points; mean baseline to week 52, 7.2 to 2.1 points). The final PCD  $>15^\circ$  to  $\leq 30^\circ$  group showed mean PCD reduction of 43% (mean baseline to week 52, PCD  $45.8^\circ$  to  $24.7^\circ$ ) and mean PD Symptom Bother improvement of 3.3 points (mean baseline to week 52, 7.0 to 3.7 points). The final PCD  $>30^\circ$  to  $\leq 45^\circ$  group showed 22% mean PCD reduction (mean baseline to week 52, PCD  $51.8^\circ$  to  $38.2^\circ$ ) and mean PD Symptom Bother improvement 2.2 points (mean baseline to week 52, 7.7 to 5.5 points). The mean improvements in all 3 groups showed meaningful responses in PCD ( $>20\%$ ) and PD Symptom Bother ( $>2$  points) following CCH therapy.

**Conclusions:** Greater improvement in PCD was associated with greater reduction in PD Symptom Bother in CCH-treated subjects. Clinically meaningful mean responses in PCD and PD Symptom Bother were shown in CCH-treated subjects with final PCD  $\leq 45^\circ$ .

## Disclosure:

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076

## The efficacy of Avanafil in subjects with intercourse attempts within 15 minutes after dosing

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**Objective:** To examine the efficacy of avanafil in the subset of subjects from a randomized, double-blind study who reported at least 1 attempt at intercourse within approximately 15 minutes after dosing.

**Materials and Methods:** This was a post hoc analysis of data from a controlled, phase 4 study that randomized men aged  $\geq 18$  years with a history of mild to severe erectile dysfunction (ED) of  $\geq 6$  months' duration to placebo (n=145), avanafil 100 mg (n=147), or avanafil 200 mg (n=147). Subjects took 1 dose of their assigned treatment when they and their partner developed a desire to engage in sexual activity, and were encouraged to attempt intercourse approximately 15 minutes after dosing. Subjects started a stopwatch upon dosing, stopped it when an erection sufficient for vaginal penetration was achieved, and then continued with sexual activity. After each attempt at sexual activity, patients recorded the stopwatch time and their responses to questions about the sexual experience. The primary end point of the study was the per-subject proportion of sexual attempts during the treatment period in which subjects maintained an erection within approximately 15 minutes of dosing ( $\leq 17$  minutes 59 seconds) of sufficient duration to have successful intercourse (mean success rate).

**Results:** In the 100 mg and 200 mg avanafil dose groups, 92 (62.5%) and 99 (67.3%) subjects reported  $\geq 1$  attempt at intercourse within 15 minutes after dosing, respectively, and the mean success rates for these attempts within 15 minutes were 73.3% and 71.5%, respectively. Mean success rates for all attempts by these same subjects regardless of time after dosing were 38.8% and 40.9%. For all subjects, the mean per-subject percentages of sexual attempts resulting in successful intercourse within 15 minutes of dosing were 25.9% and 29.1%. In the study overall, most treatment-emergent adverse events reported were mild or moderate in severity, and the 3 most common were headache, upper respiratory tract infection, and nasal congestion.

**Conclusions:** The subset of subjects who reported at least 1 intercourse attempt within 15 minutes after dosing experienced higher mean success rates than the overall study population, as well as higher success rates when evaluated regardless of time. These findings support the idea that men who experience an erection sufficient for vaginal intercourse within 15 minutes may also be more likely to have successful intercourse with avanafil treatment, particularly within an approximately 15 minute time period after dosing.

## Disclosure:

Work supported by industry: yes, by VIVUS, Inc., and Auxilium Pharmaceuticals, Inc. (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## A comparison of baseline erectile function after on-demand 20 mg tadalafil vs. daily 5 mg tadalafil in men with erectile

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## dysfunction and diabetes: A prospective, observational 2-year study

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**Objectives:** We studied whether long-term use of 5 mg tadalafil once daily improved baseline erectile function or prevented erectile dysfunction (ED) in men with diabetes.

**Material and Methods:** Men with ED and diabetes who were naïve to PDE5 inhibitors were assigned to 20 mg tadalafil on-demand or 5 mg tadalafil once daily and asked to provide information about erectile function at the start of treatment and after 2 years. When men completed the questionnaire after 2 years of treatment, they also stopped the medication for 4 weeks to check their baseline erectile function. The primary efficacy variable was the IIEF-EF score. Secondary efficacy variables included a change in the scores IIEF Q3 and Q4 from baseline, changes in all domain scores on the IIEF from baseline, SEP2 and SEP3, and the GAQ. Rigiscan® measurements of nocturnal penile tumescence and rigidity (NPTR) were also carried out 2 years after treatment.

**Results:** The study enrolled 118 men (mean age: 56.2yrs) and most had mild to moderate ED (57.6%): 65 patients (55.1%) were prescribed 20 mg tadalafil on demand and 53 patients (44.9%) took 5 mg tadalafil once daily. After 2 years of treatment, the daily treatment group had a significantly greater change in the IIEF-EF domain score from baseline compared with the on-demand group (7.3 vs. 2.4,  $P < 0.0001$ ). The changes in IIEF from baseline on Q3 (1.4 vs. 0.4,  $P < 0.0001$ ) and Q4 (1.4 vs. 0.3,  $P < 0.0001$ ) were higher in the daily group. Differences between the daily and on-demand groups were significant for SEP2 (53.8% vs. 32.3%,  $P = 0.0003$ ) and SEP3 (56.6% vs. 15.4%,  $P < 0.0001$ ). Normal EF domain scores ( $\geq 26$ ) at the end of the study were achieved by 20.7% and 6.2% in the daily and on-demand groups, respectively ( $P = 0.0031$ ). Normal patterns of NPTR at the end of the study were achieved by 13.2% only in the daily group. Most treatment-associated adverse events were mild and resolved spontaneously.

**Conclusion:** Long-term use of 5 mg tadalafil once daily was more beneficial for improving baseline erectile function or preventing ED than the on-demand pattern in men with ED and diabetes

### Disclosure:

Work supported by industry: no.

078

## Cavernous Venous Occlusive Disease (CVOD) and Color Doppler Duplex Ultrasound (CDDU) analysis: What CDDU parameters are associated with CVOD

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1: Mayo Clinic, USA

**Objective:** Cavernous venous occlusive disease (CVOD) is

defined as a failure to maintain adequate erections despite appropriate arterial inflow and can be non-invasively diagnosed by Color Duplex Doppler Ultrasound (CDDU) analysis. The aim of our research is to evaluate the relationship between arteriogenic risk factors of Erectile Dysfunction (ED) and CVOD, as well as determine the severity of CVOD via CDDU analysis.

**Material and Methods:** A retrospective review was performed to identify patients who underwent CDDU from January 2010 to June 2013 (IRB# 14-005540). Patients were diagnosed with pure CVOD, defined by persistent diastolic flows yielding resistive indices (RI) less than 1.00, given a peak systolic velocity greater than 35cm/s. Arteriogenic risk factors of hypertension, diabetes, hyperlipidemia, heart disease and smoking were noted. Further subgroup analysis was performed in (a) patients refractory to PDE-5 inhibitor therapy, (b) primary ED, (c) concomitant Peyronie's Disease (PD), and (d) history of prostatic surgery.

**Results:** 156 patients, who had a mean age of 60 (19-87) and a mean BMI of 27.9 (18.9-46.0), were diagnosed with CVOD. 49%, 16%, 41%, and 12% of patients reported hypertension, Diabetes, hyperlipidemia, and heart disease, respectively. The mean age of ED was 51. Based on calculated RI, we propose an evidence based classification of CVOD as mild, moderate or severe.

	A (104/156)	B (51/156)	C (65/156)	D (33/156)
Mean BMI	27.8	27.7	27.1	27.4
Mean Age	62.7	62.9	61.2	67.2
SDMA	8.9	9.3	11.2	7.1
RI R	73.8	74.2	74.6	71.7
RI L	73.0	73.3	74.0	73.9

**Conclusions:** Our data suggest that arteriogenic risk factors do not correlate well with CVOD. Subgroup analysis illustrates that history of prostate surgery negatively impacts Doppler characteristics. Moreover, PD patients represent 41% of this population. Unlike arteriogenic ED, the etiology and risk factors for CVOD remain indeterminate and further research into this field is critical.

### Disclosure:

Work supported by industry: no.

079

## Successful intercourse in men with erectile dysfunction within the first three doses of Avanafil

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**Objective:** To examine the proportion of men with erectile dysfunction (ED) who reported successful intercourse within the first 3 doses of avanafil received in a randomized, double blind, phase 4 study.

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**Materials and Methods:** This was a post hoc analysis of data from a double-blind, 12-week study that randomized subjects  $\geq 18$  years old with a history of mild to severe ED of  $\geq 6$  months duration to placebo (n=145), avanafil 100 mg (n=147), or avanafil 200 mg (n=148). Subjects were instructed to take 1 dose of their assigned treatment when they and their partner developed a desire to engage in sexual activity but to take no more than 1 dose in any 24-hour period. Sexual function was assessed at baseline and at all follow-up visits using patient diaries, which included questions from the Sexual Encounter Profile (SEP). Successful intercourse was determined by response to SEP3 ("Did your erection last long enough for you to have successful intercourse?").

**Results:** A total of 136, 138, and 139 subjects were randomized to placebo, avanafil 100 mg, or avanafil 200 mg, respectively, took  $\geq 1$  dose of study medication (as reported in a diary entry) and had  $\geq 1$  post-dose efficacy assessment with diary data. Of these subjects, 26.5%, 44.2%, and 46.8%, respectively, reported successful intercourse after taking their first dose. The percentages of subjects who reported successful intercourse within their first two doses taken were 34.6%, 50.0%, and 59.0%, respectively. The percentages who reported successful intercourse within their first 3 doses were 41.9%, 58.7%, and 64.0%, respectively. Overall, the percentages of subjects who had successful intercourse after any dose were 55.9%, 73.9%, and 76.3% for placebo, avanafil 100 mg, and avanafil 200 mg, respectively. Most treatment-emergent adverse events reported were mild or moderate in severity. The 3 most common treatment-emergent adverse events in the study overall were headache, upper respiratory tract infection, and nasal congestion.

**Conclusions:** Greater than 60% of subjects treated with avanafil reported success after 3 doses. A slightly higher percentage reported success after any dose. This indicates that the effect of avanafil treatment is likely to be apparent within the first 3 doses and may have implications in a clinical setting where 3 pill sampling is common practice.

## Disclosure:

Work supported by industry: yes, by VIVUS, Inc., and Auxilium Pharmaceuticals, Inc. (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Couples' treatment satisfaction following switch from on-demand phosphodiesterase type 5 inhibitor therapy to tadalafil 5 mg once daily

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1: Eli Lilly and Company, USA; 2: New England Research Institutes, Inc., USA; 3: SUNY - Brooklyn Downstate Medical Center, USA; 4: NY Weill Cornell Medical Center, USA

**Objective(s):** The treatment satisfaction of men and their partners with therapies for erectile dysfunction (ED) is essential to successful long-term therapy. We assessed treatment satisfaction of men with a partial response to prior on-demand (PRN) PDE5is, and of their female partners, following tadalafil 5 mg once daily or placebo in a randomized, double-blind, parallel, placebo-controlled study.

**Material and Method(s):** Men were  $\geq 18$  years old, with an IIEF-EF score  $\geq 17$  and  $< 26$  at screening. Treatment satisfaction was assessed following a 4-week maximum dose PRN lead-in, 4-week non-drug washout, and treatment with tadalafil once daily (2.5 mg titrated to 5 mg, or 5 mg, pooled for analyses) or placebo through 12 weeks. Satisfaction was assessed using the Treatment Satisfaction Scale (TSS); TSS domain scores range from 0 to 100, with higher values indicating greater satisfaction. Statistical comparisons were made using ANCOVA.

**Results:** Mean age was 58 years and ED severity was mild-moderate in most men. Treatment satisfaction was significantly greater with tadalafil once daily (randomized N=414) versus placebo (N=209) across all six TSS domains for both patients and their partners (all  $p < 0.001$ ). For the Confidence to Complete Sexual Activity domain, mean patient scores for the tadalafil and placebo groups, respectively, were 54.8 and 53.7 after PRN treatment; 26.7 and 29.2 after washout; and 55.4 for tadalafil and 32.6 for placebo following double-blind treatment. For the Ease of Erection domain, scores for tadalafil and placebo, respectively, were 56.4 and 56.3 after PRN treatment; 35.6 and 35.0 after washout; and 59.7 and 39.6 following double-blind treatment. For partners, Confidence to Complete Sexual Activity scores for tadalafil and placebo, respectively, were 58.0 and 60.3 after PRN treatment; 28.4 and 31.1 after washout; and 54.6 and 32.2 following double-blind treatment. For Ease of Erection, partner scores for tadalafil and placebo, respectively, were 59.4 and 58.6 after PRN treatment; 34.6 and 36.2 after washout; and 58.6 and 36.1 following double-blind treatment. Results were comparable for other TSS domains for both patients and partners.

**Conclusion(s):** Treatment satisfaction for tadalafil 5 mg once daily was superior to placebo and comparable to maximum dose PRN PDE5 inhibitors for both patients and female partners. This finding suggests that tadalafil once daily is a viable therapy option for men with ED who had a partial response to PRN PDE5i therapy.

## Disclosure:

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081

## Erectile dysfunction, testosterone, and C-reactive protein are associated with progression of metabolic syndrome over time



# Abstracts

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**Introduction:** Metabolic Syndrome (MetS) is a condition encompassing a group of risk factors defined by the WHO. It has been used as a predictor of cardiovascular disease (CVD). It is known that risk factors of cardiovascular disease can affect erectile dysfunction. Metabolic Syndrome has also been found to be associated with C-reactive protein. Our clinical observations suggest that progression of Metabolic Syndrome is associated with erectile dysfunction (ED), testosterone levels (TT), and high sensitive C-reactive protein (hs-CRP).

**Material and Methods:** We evaluated 2,497 subjects who were enrolled in the World Trade Center-Law Enforcement Cardiac Screening (WTC-LECS) program between 2008-2010 and 992 participants were re-evaluated again for the WTC-CHEST program from 2012-2014. In both screenings programs, anthropometric measurements, laboratory analysis (cholesterol panel, TT, and hs-CRP) and multiple screening questionnaires including the International Index of Erectile Function (IIEF) survey were completed. MetS criteria was defined by the ATP III Clinical Identification of the Metabolic Syndrome and MetS was divided into four groups, never met MetS criteria, only met criteria in LECS, only met criteria in CHEST and met criteria in both LECS and CHEST. We ran independent t-test, ANOVA and Chi-squared to analyzed the data.

**Results:** We found those who MetS criteria in 2008 – 2010 (LECS only) had significant decrease in ED from 26.9% diagnosis of ED in 2008-2010 vs 18.4% 2012-2014 (CHEST) ( $p = 0.040$ ). In addition those who only met MetS criteria in 2008-2010 had a significant increase mean TT from 319.68 ng/dL in LECS to 353.83 in CHEST ( $p = 0.001$ ) where as those who were diagnosed in 2012-2014 TT decreased significantly from 363.83 ng/dL to 296.70 ng/dL ( $p = 0.001$ ). We also observed a significant decrease in hsCRP from 4.73 mg/dL in LECS to 2.17 mg/dL in CHEST ( $p = 0.001$ ).

**Conclusions:** Meeting criteria for MetS has a significant impact on all health outcomes such as low total testosterone, erectile dysfunction, hsCRP, and CVD risk. Identifying these participants allowed us to advise them on how to improve their risks for MetS. Appropriate treatment and counseling have positive benefits on improving health outcome.

## Disclosure:

Work supported by industry: no.

082

## Predictors of erectile response in patients with arterial disease on penile doppler ultrasound

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**Objectives:** Erectile Dysfunction (ED) is the inability to attain and maintain an erection for satisfactory sexual performance, and is a common worldwide condition affecting men both physically and psychologically. Penile Doppler (PD) ultrasound provides an objective measure of a patient's erectile hemodynamic status and is a baseline diagnostic modality for ED evaluation and treatment. The objective of this study was to determine the characteristics that predict a response to intercavernosal injection (ICI) in patients with arterial disease using PD ultrasound.

**Methods:** Between July 2008 and February 2013, 472 consecutive patients were evaluated for ED with a PD ultrasound of which 462 patients had complete data. Among this cohort, 254 patients (55.0%) had arterial disease, defined as peak systolic velocity (PSV) <30 cm/s. These patients were then divided into responders to ICI (>45 degree erection) (Group 1: n=56, 22.0%) and non-responders to ICI (<45 degree erection) (Group 2: n=198, 78.0%). Demographic and PD ultrasound parameters between the groups were compared using t-test for continuous variables and Fisher Exact test or Chi-square analysis for categorical variables. The odds ratios (OR) of clinical response associated with demographics and PD ultrasound variables were determined using a multivariable logistic regression model.

**Results:** The mean age for Group 1 was 57.6 years and 58.8 years for Group 2 ( $p=0.54$ ). Patients in Group 1 had a higher BMI compared to Group 2 (32.0 vs 29.6,  $p=0.04$ ). There was no difference between the groups for race, marital status and smoking status. Patients in Group 1 had a greater mean PSV (26.9 vs 21.6,  $p=0.001$ ), end diastolic velocity (EDV) (3.0 vs 1.4,  $p=0.004$ ) and post-injection cavernosal artery diameter (CAD) (0.74 vs 0.62,  $p<0.001$ ) compared to Group 2. After adjusting for age, race, BMI, marital status, smoking status, PSV, EDV, and post-injection CAD, the predictors of clinical response to ICI in patients with ED and arterial disease were BMI (OR 1.09; 95% CI 1.01-1.16,  $p<0.01$ ), PSV (OR 1.05; 95% CI 1.01-1.09,  $p<0.01$ ) and EDV (OR 1.11; 95% CI 1.01-1.25,  $p<0.03$ ).

**Conclusion:** This study shows that a higher BMI, PSV and EDV independently predict adequate erectile response to ICI on PD ultrasound when arterial disease is the underlying cause of ED.

## Disclosure:

Work supported by industry: no.

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## Factors correlating with sexual interest and function in long-term colorectal cancer survivors

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**Purpose:** Long-term sexual dysfunction after multimodality treatment of rectal cancer occurs in roughly 40% of patients,



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irrespective of gender. We sought to evaluate the factors influencing the quality of sexual function as reported on a colorectal cancer specific quality of life instrument.

**Materials and Methods:** Colorectal Cancer (CRC) patients alive > 5 years from their diagnosis were identified from our Tumor Registry. Demographics, tumor characteristics and treatment details were extracted. Patients were mailed a standardized survey - European Organization for Research and Treatment of Cancer (EORTC) CRC disease specific module (CR29). Responses to items in the CR29, generic sexual interest and gender specific sexual function (impotence and dyspareunia), were extracted and analyzed. Univariate and multivariate analysis (logistic and linear) was performed to examine the relationship between clinical treatment factors [extent/location of surgical resection (abdominal, distal rectal or anus), lifetime chemotherapy, lifetime XRT and presence of an ostomy] and sexual interest/function. A two tailed  $p < 0.05$  was considered statistically significant.

**Results:** Of 830 responders, 671 (81%) completed the sexual items. The mean age was 55.9 (SD, 11.6) years with a mean time from diagnosis of greater than 10 years. In males, decreased sexual interest correlated with younger age ( $p < 0.001$ ). Impotence was associated with a permanent ostomy ( $p = 0.0045$ ), radiation ( $p = 0.0003$ ), current cancer ( $p = 0.0103$ ) and younger age at cancer diagnosis ( $p < 0.001$ ). In female survivors, sexual interest was negatively impacted by permanent ostomy, radiation and younger age of diagnosis but positively related to marriage (0.0001). In univariate analysis, dyspareunia was associated with surgery type (0.0012), permanent ostomy (0.0025), history of radiation therapy (0.0025), prior chemotherapy (0.0061), older age (0.0405) and marital status ( $< 0.0001$ ). Marriage was predictive of dyspareunia ( $p = 0.001$ ).

**Conclusion:** Both permanent ostomy and radiation correlated with impotence and dyspareunia. Determinants of sexual interest varied tremendously based on gender. Younger patients had more complaints regarding level of sexual interest. Due to the cross-sectional nature of this study, we cannot determine the relationship to baseline. Additionally, historical and present frequency of sexual activity is unknown.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Udenafil for the treatment of erectile dysfunction: Results from two pivotal studies

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1: Center for Men's Health at The Urology Center of Colorado;

2: Actavis plc; 3: Actavis Inc

**Objectives:** The purpose was to prospectively assess the

efficacy and safety of three doses of the investigational phosphodiesterase 5 (PDE5) inhibitor udenafil to treat erectile dysfunction (ED) as needed before sexual intercourse.

**Materials and Methods:** Two Phase 3 studies (Study PR-01209 and Study PR-01309) were identical in design. Both were multicenter, double-blind, placebo-controlled studies in men with mild to severe ED. Patients were randomized in a 1:1:1:1 ratio to receive placebo, udenafil 50 mg, 100 mg, or 150 mg. A 4-week, treatment-free run-in period was followed by a 12-week treatment period with an on-demand dosing regimen. Coprimary efficacy endpoints assessed changes in International Index of Erectile Function (IIEF) erectile function domain (EF) score, percentage of sexual attempts in which men were able to insert the penis into the partner's vagina (Sexual Encounter Profile [SEP] 2), and the percentage of sexual attempts in which men were able to maintain an erection of sufficient duration to have successful intercourse (SEP 3).

**Results:** 1219 patients were randomized between September 28, 2009 and June 3, 2010. Compared to placebo, least-squares mean change from baseline to final visit in IIEF-EF, SEP 2, and SEP 3 were statistically, significantly improved for all three udenafil groups ( $p < 0.0001$ ) in both studies. Improvements in the scores of all 3 coprimary endpoints appear to be dose-related, with the greatest improvements occurring in the 150 mg udenafil groups of both studies. Adverse events most commonly reported with udenafil were headache, flushing, and nasal congestion.

**Conclusions:** The two studies demonstrate that udenafil is safe and effective for treating men with mild to severe ED.

The adverse events seen with udenafil were similar to those seen with other PDE5 inhibitors.

*Trial Registration: NCT01037244 (Study PR-01209) and NCT01037218 (Study PR-01309)*

## Disclosure:

Work supported by industry: yes, by Actavis (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

085

## Pre-treatment counseling on quality of life issues before management of prostate malignancy

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**Objective:** Patients frequently complain of not being informed about long term risks of radiation and surgical management of prostate cancer. We have instituted an optional program of supplemental pre-treatment counseling on sexuality and urinary issues for patients contemplating management of prostate malignancy.

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**Materials and Methods:** Men diagnosed with prostate cancer and planning definitive treatment (radical prostatectomy or radiation based therapy) were eligible. Men were offered the option of meeting with a fellowship trained andrologist before treatment; men who accepted were classified as group A and men who declined were classified as group B. All participants supplied demographic information and completed the EPIC-26 before treatment and at 3, 6, and 12 months post-treatment. Subjects also completed the SHIM and the AUASS as well as a questionnaire on treatment satisfaction (quality of care score, QOC) and whether their clinical outcomes have been in line with their expectations. In this analysis we focus on data from the 3 month post-treatment time point. Linear regression was used to assess the relationship between QOC and other metrics

**Results:** 39 patients have data at baseline and 3 months; of these 30 are in group A and 9 in group B. Two patients in group A had radiation, all others had prostatectomy. Men in group A had lower urinary EPIC urinary incontinence domain scores (86.5 vs 100) and urinary irritation scores (80.5 vs. 87.5) at baseline. 23 men in group A and 4 in group B had complete data for EPIC-26 Sexual Domain (E26-SD); mean domain score was 62.4 in group A and 69.5 in group B. At 3 months 24 respondents in group A and 6 in group B had E26-SD data, mean score was 22.3 versus 26.9, respectively. QOC was high in both groups with no significant differences between groups at 3 months (n=20 for group A and 6 for group B). Multivariable analysis revealed a trend towards worse QOC in men with lower 3 month urinary incontinence and irritative EPIC domain scores.

**Conclusions:** Preliminary data do not suggest a major benefit of pre-operative consultation with close follow up compared to close follow up alone in patient's perception of quality of care/quality of life outcomes at 3 months.

## Disclosure:

Work supported by industry: no.

086

## The efficacy of long-term daily dosage of alfuzosin 10 mg upon sexual function of BPH patients: 2-year prospective observational

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**Objective:** This study was conducted to identify the consequential sexual function improvement from the continuous daily dosage of alfuzosin 10 mg for 2 years.

**Materials and methods:** This study enrolled 30 men with Lower urinary tract symptom / benign prostate hyperplasia (LUTS/BPH) who visit our urologic clinics between 2010 and 2012. At the first visit, urin analysis, prostate specific antigen (PSA), transrectal ultrasound (TRUS), and uroflowmetry were performed. and questionnaires upon International prostate symptom score (IPSS), quality of life (QoL), International

Index of Erectile Function (IIEF), and Male Sexual Health Questionnaire Ejaculation Function Domain (MSHQ-EjFD) were assessed. Then follow up the above questionnaires at 1 month, 6 months, 1 year, and 2 years.

**Results:** The mean age was 59.30 years, the mean prostate volume was 33.76 ml, and the mean PSA was 2.07 ng/ml. After administration of alfuzosin, the mean IPSS at the first visit, 1 month, 6 months, 1 year, and 2 years were 19.20, 17.17, 14.24, 12.35 and 12.08, respectively, and were continuously improved ( $p < 0.05$ ). The mean QoL at the same time points were 4.20, 3.80, 3.07, 3.05, and 2.50, respectively, and were also improved ( $p < 0.05$ ). The mean IIEF at the same time points were 40.63, 43.20, 49.66, 49.00, 50.00, and were also showed the continuous improvement ( $p < 0.05$ ). The mean MSHQ-EjFD at the same time points were 21.13, 23.77, 26.76, 27.70, 27.00, respectively, and were also improved ( $p < 0.05$ ).

**Conclusion:** After the long term administration of alfuzosin 10 mg for 2 years, IPSS, QoL, IIEF and MSHQ-EjFD were all improved significantly. This results means that long-term administration of alfuzosin 10 mg daily would be effective not only on LUTS but also on the erectile and ejaculation functions.

## Disclosure:

Work supported by industry: no.

087

## Implant length – Baseline characteristic correlations

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**Objectives:** The "Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration" (PROPPER) is a large, multi-institutional, prospective clinical study. There is a paucity of data regarding the factors that contribute to penile prosthesis size. co-morbid conditions and demographic data with implanted penile prosthesis size were correlated. **Methods:** The PROPPER registry prospectively evaluates outcomes in men undergoing penile prosthesis implantation. Men completed baseline questionnaires prior to prosthesis implantation and at 12 months. Demographic, etiology of ED, duration of ED, co-morbid conditions, and pre-operative penile length (flaccid and stretched), operative technique, implant type and length, duration of surgery were complied. Pearson correlation coefficient was generated for length of implanted penile prosthesis vs. comorbid conditions /demographic data.

**Results:** 791 men underwent implantation of IPP at 13 study sites. 14 of patients with missing implant length were excluded. All AMS IPP types were included in the analysis. comorbidities were CV disease (32.7%), DM (14.4%), and PD (12.8%). Primary etiology of ED: RP (28.9%), CV Disease (21.5%), DM

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(20.9%), Other (16.0%), PD (9.3%), and Priapism (1.4%). Mean duration of ED is  $6.8 \pm 4.6$  years. Pearson Correlation was weakly negatively correlated with White/Caucasian ( $r = -0.14$ ;  $p \leq 0.0005$ ), h/o RP ( $r = -0.13$ ;  $p \leq 0.0005$ ), concomitant presence of PD ( $r = -0.08$ ;  $p \leq 0.05$ ), venous leak ( $r = -0.07$ ;  $p = 0.05$ ), and SUI ( $r = -0.16$ ;  $p \leq 0.0005$ ). Implant length was weakly positively correlated with Black/AA men ( $r = 0.27$ ;  $p \leq 0.0005$ ), CV disease ( $r = 0.13$ ;  $p \leq 0.0005$ ) and stretched penile length ( $r = 0.18$ ;  $p \leq 0.0005$ ) There is a moderate positive correlation with flaccid penile length ( $r = 0.35$ ;  $p \leq 0.0005$ ).

**Conclusions:** Implanted penile cylindrical length is significantly negatively correlated with White/Caucasian ethnicity. History of RP and presence of SUI are also strongly negatively correlated with implant length. Positive correlates include Black/AA ethnicity, CV disease, preoperative stretched penile length, and flaccid penile length. There does not appear to be a significant correlation with diabetes or duration of ED.

## Disclosure:

Work supported by industry: yes, by American Medical Systems (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant or shareholder of an industry.

088

## Validation of a prediction model for penile prosthesis implantation for erectile dysfunction management

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**Introduction:** No validated clinical instruments exist for quantifying the physical and emotional impact of experiencing priapism.

**Materials and Methods:** We created a 12-item questionnaire to survey priapism impact in 3 domains: quality of life (QoL), sexual function (SF), and physical impact (PI), which was self-administered to adult patients with priapism histories presenting in the urology and sickle cell disease clinics of a single institution from Jan 2011 to April 2014. Higher scores indicate inferior experience in respective domains. Scores were stratified according to various factors including priapism duration, erectile dysfunction (ED), and disease activity (remote activity defined as  $\geq 1$  year without priapism episodes). The PIP was assessed for internal consistency and construct validity using priapism history, IIEF and SHIM scores. Participants were also asked to assess the clarity and importance of each question on the PIP.

**Results:** Each domain and the total scale demonstrated high degrees of internal consistency (Cronbach's alpha values  $\geq 0.75$  and  $0.90$ , respectively). Fifty-three patients (mean age  $31.6 \pm 11.5$  years) completed the questionnaire. Patients with an active priapism history ( $n=41$ ) had higher QoL, SF, PI, and total scores than those with a remote history ( $n=8$ ) ( $p=0.008$ ,

$0.08$ ,  $0.0003$ ,  $0.005$ , respectively). Patients with a history of episodes  $>2$  hours had higher QoL, SF, PI, and total scores than those with shorter episodes ( $\leq 2$  hours) ( $p=0.002$ ,  $0.03$ ,  $0.0006$ ,  $0.002$ , respectively). Patients with "Mild to Moderate" to "Severe" ED (SHIM  $<17$ , IIEF  $<19$ ) had higher QoL, SF, PI, and total scores than those with no ED or "Mild ED" ( $p=0.11$ ,  $0.0002$ ,  $0.11$ ,  $0.007$ ). An average of 93% and 78% of patients rated questions as being clear and important, respectively.

**Conclusion:** The PIP questionnaire is a psychometrically sound instrument that appears to perform rigorously across several clinical variables. It may serve as a valuable tool in clinical practice and for future research purposes such as evaluating responses to priapism interventions.

## Disclosure:

Work supported by industry: no.

089

## Use of magnetic induction to activate a shape memory alloy penile prosthesis

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1: SIU, USA; 2: MERITER Health services

**Introduction:** A common challenge with the use of inflatable penile prostheses is difficulty manipulating the scrotal pump. We developed then tested a novel "pump-free" and "touchless" method of activating a shape memory alloy (SMA) based penile prosthesis. Using a handheld external magnetic induction generator, we repeatedly activated SMA penile prostheses evaluating time to activation, temperature and force generated.

**Methods:** Previously fabricated SMA penile prostheses of 22 cm in length with an activation temperature of  $42^{\circ}\text{C}$  were placed in a vertical holder at 1/3 of their length with a preset deviation of 30 degrees. Using a mini-ductor II (Induction Innovations, Inc) of 1000 watts we induced a magnetic field through the prosthesis. Once the prosthesis reached the erect configuration, we measured the temperature and time to activation. We then measured the recovery force generated during activation using a force measuring device (Dillon, Inc).

**Results:** Using a handheld magnetic inductor, we were able to successfully activate the SMA penile prosthesis with no direct contact. The time necessary to reach a straight/erect conformation using a 1000 watt magnetic inductor was  $100 \pm 5$  seconds. The force generated as it transitioned from the flaccid to erect configuration was  $0.3 \pm 0.015$  kgf. The final temperature reached by the prosthesis was  $50 \pm 3^{\circ}\text{C}$ .

**Conclusion:** Magnetic induction is a valid method to activate a SMA penile prosthesis. This method circumvents many of the challenges associated with placement and manipulation of the pump. Further tests will be necessary to optimize the response of the SMA prosthesis to the magnetic field.

## Disclosure:

Work supported by industry: yes, by American Medical System

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(industry funding only - investigator initiated and executed study).

090

## The Carrion Cast: An update on the usage of the intracorporal antimicrobial doped spacer for the treatment of penile implant infection

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**Objectives:** Since the inception of the penile prosthesis, infection has always been a significant risk. With the advent of antibiotic coated implants the rate has decreased to 1-3%, and with the “no touch technique”, 0.7%. Despite this, infection is still a reality, and a devastating complication; resulting in a decrease in penile size, increase in pain, and loss of sexual function. We present our updated series of the “Carrion Cast”, antimicrobial spacer that maintains size while treating infection, bridging the gap between explantation and reimplantation.

**Materials and Methods:** From May 2012 to February 2014, 9 cases have been performed using high purity CaSO<sub>4</sub> mixed with antimicrobials for the management of infected penile prosthesis in patients who are not candidates for immediate salvage. All cases had either already failed an immediate salvage and/or presented with bacteremia/septicaemia. 5 were Coloplast Genesis Semirigid Penile Prosthesis (SRPP), 2 were Coloplast Titan Inflatable Penile Prosthesis (IPP), and 2 were narrow SRPP's, sizes ranging from 17cm to 23cm. All cases underwent complete removal of prosthetic material and modified “Mulcahy Salvage” wash. The amount of CaSO<sub>4</sub> used varied, depending on the volume of corpora (20-30cc, split between the two corpora). Serum calcium, vancomycin and tobramycin levels remained stable while the cast was palpable within the corpora.

**Results:** Time to reimplantation varied (6-18 weeks), but most at 6 weeks, the time it takes for the cast to dissolve. All patients were able to have a prosthesis replaced: 1 SRPP, 3 IPP's, 2 narrow SRPP's, and 1 narrow IPP, with sizes ranging from 17cm to 20cm; 2 cases are still pending reimplantation. The mean loss of penile prosthesis length was only 1.1cm, meaning the average percent of penile length maintenance was 95%.

**Conclusions:** Penile prosthesis infection is devastating. Thanks to the “Mulcahy Salvage Protocol”, most cases can be immediately reimplanted. These cases, however, can be technically challenging, carry a higher rate of reinfection, and some patients are too sick for an immediate salvage. Thus, many infected implants undergo explantation and are left with a scarred, severely shortened penis, and inability to perform coitus. Thanks to the “Carrion Cast”, our small, yet growing series shows that they can be bridged with this antimicrobial-doped spacer, and reimplanted at 6 weeks, maintaining their penile length by 95%. Albeit a small series at this time, the “Carrion Cast” provides hope to this subset of patients that

would otherwise be left in a terrible predicament.

### Disclosure:

Work supported by industry: no.

091

## The Medtronic Zotarolimus-ELuting Peripheral Stent System for the treatment of ED in males with sub-optimal response to PDE5 inhibitor - 3 year results

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**Objective:** We report 3 year safety, feasibility and outcomes of zotarolimus-eluting stent implantation in focal atherosclerotic lesions of the internal pudendal arteries (IPAs) among men with erectile dysfunction (ED) and a suboptimal response to phosphodiesterase-5 inhibitors.

**Methods:** We performed a prospective, multicenter, single armed safety and feasibility trial of 30 male subjects >18 years with atherosclerotic ED and a suboptimal response to phosphodiesterase-5 inhibitors. A novel combination of clinical, duplex ultrasound, and invasive angiographic factors were used to determine eligibility for stent therapy.

**Results:** Forty-five lesions were treated with stents in 30 subjects. Procedural success was 100% with no major adverse events through follow-up. The primary feasibility end point (IIEF-6 >4) was achieved by 59.3% (16/27) of intention to treat subjects at 3 and 6 months, 81% of subjects (17/21) at 1 year, 57.9% (11/19) at 2 years and 38.5% (5/13) at three years (3 year data still accruing). Mean peak systolic velocity on penile Doppler increased from 16.4 cm/s at baseline to 28.8 cm/sec at 3 months, 42 cm/sec at 6 months, and 32.4 cm/sec at 1 year. 5 patients were stented outside the pudendal artery. Restenosis occurred in 11/32 lesions (34.4%).

**Conclusions:** Among patients with ED and limited response with pharmacologic therapy, percutaneous stent revascularization of the internal pudendal artery is safe and appears promising. However, significant challenges remain in determining and screening for the appropriate patient treatment population, optimizing procedural techniques for placement, and preventing stent restenosis.

### Disclosure:

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## Observation of local clinical penile prostheses infections instead of immediate salvage rescue/removal: Ten center study with surprising results

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1: Regional Urology, USA; 2: American Medical Systems, USA; 3: Urology Center of Spartanburg; 4: Urology Associates of North Texas, USA; 5: Urology San Antonio, USA; 6: Perito Urology, USA; 7: University of Texas Southwestern, USA; 8: San Diego Sexual Medicine, USA; 9: Ottawa Hospital Research Institute, USA; 10: SIU School of Medicine, USA; 11: Lake Shore Urology, USA; 12: Associated Urological Specialists, USA; 13: Advanced Urological Care P.C., USA

**Introduction and Objectives:** Traditionally, post-operative Inflatable Penile Prosthesis (IPP) patients with culture positive wound drainage and/or greatly increasing erythema / tenderness / swelling or skin fixation of the device several days to months post implantation underwent immediate surgical removal or salvage rescue of their IPP. IPP infection has been markedly reduced in the era of infection retardant coatings. Medico-legally, many prosthetic urologists were sued for delayed surgical treatment of IPP infections and it has been proposed at scientific meetings that this delay in definitive treatment was the number one reason to be sued for IPP infections. However, the published literature shows that most IPPs have bacteria present at the time of revision / replacement of clinically uninfected IPPs indicating that the body can heal over infected devices. We evaluated patients with local clinical infections of their wounds / IPPs with observation instead of surgical therapy.

**Methods:** At ten centers a total of nineteen patients with locally positive, but no systemic signs and symptoms of wound / IPP infection were reviewed. If the patient had systemic / septic symptoms, immediate surgical treatment was performed. Patient demographics acquired included age, race, primary etiology, diabetic or not, IPP type, presence of infection retardant coating, primary (virgin) or replacement with revision number and whether washout was done. Post-operative data gathered were time to signs/symptoms, primary symptom, drainage, swelling, erythema, device fixation to the skin, increasing pain / tenderness, drainage organism cultured, antibiotic sensitivity, antibiotic given (if any), time to return to sexual activity / resolution of symptoms.

**Results:** Fifteen patients were retrospectively reviewed. Demographics reveal age of 47 to 80 (mean 59.7), 14 Titans / 3 700s / 1 Genesis / 1 Ambicor with only the Ambicor not having an infection retardant coating on the IPP and 14 (74%) were primary implantation with 4 (21%) being replacements and 1 (5.3%) into previous infected IPP scarred corporal bodies. Time to local wound infection after implantation was 7 to 40 days (mean 19.1 days), 18 (94.7 %) had incisional wound drainage with some described as large quality of fluid, 5 (26.3%) had

significant swelling, 6 (31.7%) had localized erythema, 1 (5.3%) had device skin fixation and 5 (26.3%) of the 19 patients had significant increase in IPP pain / tenderness. 11 different bacteria isolates were cultured out of the incisional drainage of 9 patients with 3 Staph Epi, 2 pseudomonas, 1 enterococcus, 2 E. coli, 1 staph aureus, 1 alpha streptococcus and 1 proteus growths. Time to total resolution of symptoms was 3 to 141 (mean 58.4) days with 17 patients having total resolution of symptoms and two currently under observation.

**Conclusions:** Observation maybe an option for patients with local signs / symptoms of IPP infection, even with incisional drainage of culture positive bacteria, that traditionally indicated immediate surgical intervention. The authors strongly feel that from a medical legal issue this information is important to get into the literature.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Wound complications in inflatable penile prosthesis with scrotoplasty

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1: Southern Illinois University SOM, USA

**Objectives:** Scrotoplasty has become a common practice among experienced implanters. While this practice does not actually change the penile length, data has shown that the practice improves patient perception of penile length. Previous reports on scrotoplasty outcomes have only focused on the perceived benefits. In our practice we have noted increased tension on these closures. We sought to review our outcomes and complications of this procedure.

**Methods:** This IRB approved retrospective review of single surgeon series included 100 patients who underwent scrotoplasty between the dates of 2/1/2009 and 2/1/2014. We reviewed charts for complications of scrotoplasty along with patient information including basic demographics and medical co-morbidities. Factors surrounding surgical outcomes including surgical time and complication rates during follow-up were also collected from charts.

**Results:** Of the 100 scrotoplasties performed during the study period, a total of 15 had varying degrees of wound dehiscence. Of these 15 cases, 9 were minor and healed secondarily without incident (60%). Five cases healed after a single stitch placed in clinic that reinforced the closure. Only 1 patient required a return to the operating room. He required a washout with exchange of inflatable prosthesis to malleable and subsequently did well. Upon examination of medical co-morbidities that may have influenced wound dehiscence, the odds ratio for dehiscence was 10.2 (p < .001) fold higher in diabetics. Other examined

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co-morbidities including patient age, Peyronie's disease, hypertension, intra-operative penile modeling, and surgeon experience did not reach statistical significance.

**Conclusion:** Although scrotoplasty can improve patient satisfaction with IPP, it can lead to increased patient morbidity, particularly in diabetics. Patient age and other medical co-morbidities did not appear to effect rates of wound dehiscence in this cohort.

**Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

094

**Long acting bupivacaine decreases peri-operative narcotic requirements in men undergoing penile prosthesis implantation**

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1: Southern Illinois University SOM, USA; 2: Albany Medical Center, USA; 3: St Andrews Hospital, USA; 4: Saint Johns Hospital, USA

**Objective:** The inflatable penile prosthesis (IPP) remains the gold standard for the treatment of severe erectile dysfunction (ED). Men undergoing penoscrotal implantation will generally have pain in the areas of incision and pump placement. A new extended release suspension bupivacaine (ERSB) delivers 3 days of local anesthetic and has been shown to reduce pain and narcotic usage in patients undergoing non-urologic surgeries but is largely unstudied in use during urologic surgery. **Material & Methods:** We performed a single surgeon retrospective chart review of patients who underwent implantation of an IPP at our institution within a 6 month period. The control group received either no local anesthetic or standard bupivacaine. Pain scores and standardized morphine equivalent (ME) dose data were collected over subjects' 23 hour observation period.

**Results:** A total of 37 patients were compared with 13:24 receiving ERSB and not receiving ERSB, respectively. Groups were comparable with a mean age of 63 and no statistical difference in co-morbidities. Mean ME used was 5.56 for ERSB vs. 18 for non-ERSB ( $p=.04$ ). Mean overall pain scores were 3.8/10 ERSB and 3.9/10 non-ERSB ( $P=NS$ ). The per patient medication cost for the control group was \$5.16 and \$285.54 for the ERSB group, which was \$285 per dose.

**Conclusion:** The use of a new ERSB in IPP implantation lead to reduced narcotic consumption with comparable post-operative pain control to the non-ERSB group. Future cost benefit analysis is required given the large cost discrepancy between ERSB and traditional analgesic regimens.

**Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

095

**Is risk of AUS cuff erosion higher in patients with penile prosthesis?**

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**Objectives:** We hypothesized that concomitant penile prosthesis (PP) may promote artificial urinary sphincter (AUS) cuff erosion by impaired corporal blood flow and/or direct pressure on the cuff. We sought to analyze the rate of AUS erosion in patients with and without PP.

**Methods:** We performed a retrospective review of our PP and AUS institutional databases from 2007-2014. We identified patients who had both an AUS and PP, placed simultaneously or sequentially by a single surgeon during that time period. Data was then compared to a cohort of patients who only had an AUS. AUS cuff erosions were identified cystoscopically and time to erosion was defined as the time from the most recent AUS surgery.

**Results:** Among 221 men with an AUS, 138 patients had an AUS alone (138/221, 62%), while 83 patients had PP/AUS (83/221, 38%). AUS cuff erosion occurred slightly more often in PP/AUS patients (10/83, 12%) versus the AUS only patients (9/138, 6.5%,  $p=0.154^*$ ). There was no difference in the rate of AUS cuff erosion in those who had their AUS and PP placed simultaneously (7/53, 13%) versus those who had their procedures done in different surgeries (3/30, 10%,  $p=0.65^*$ ). Five patients had an AUS combined with a malleable PP (5/83, 6%), with one patient experiencing AUS cuff erosion. In patients with erosion, prior history of radiation therapy was present in 8 PP/AUS patients (8/10, 80%) and in 8 AUS alone patients (8/9, 89%).

**Conclusion:** Although there is a numerical trend showing a higher rate of AUS cuff erosion with concomitant PP, the patient numbers needed to reach a statistically sound conclusion are lacking. If the current proportions are maintained, we would need roughly three times the patient volume to achieve statistical significance. Thus, we encourage the development of a multi institutional dataset to answer this important question.

\* Calculated with two-tailed Student's t-test

**Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Increased penile length after inflatable penile prosthesis replacement

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**Objective:** Although reduced penile length is a common complaint among patients having inflatable penile prosthesis (IPP) surgery, the IPP has also been advocated as a tissue expander which may enhance penile length with regular use over time. We sought to evaluate penile length changes over time among patients having IPP replacement in a nationwide cohort.

**Materials & Methods:** The nationwide American Medical Systems (AMS) Patient Information Form (PIF) database was queried to identify patients who underwent two AMS 700 LGX or CX implants between 2004 and 2013. All patients with documented age, time between implants, and complete cylinder length data were included in the final analysis. IPP length was calculated as the average total length of cylinders plus rear tip extenders from both sides. Patients were grouped by prosthesis replacement <2 or ≥2 years to separate those who may have sustained erosion or infection, and to assess the change of length over time.

**Results:** During the ten-year study period, 1532 LGX and 717 CX patients met the study criteria for study inclusion. Mean age at first placement was 60 years for both groups. Mean time between first and second implant was 8.0 and 8.7 months for LGX and CX patients who underwent replacement at <2 years and 55.4 and 60.1 months for LGX and CX patients who underwent replacement at ≥2 years. Penile length increased by 1.10 cm for LGX patients who underwent revision surgery at ≥2 years compared to -0.11 cm for patients <2 years ( $p<0.001$ ). Similarly, penile length increased by 1.17 cm for CX patients who underwent revision surgery ≥2 years compared to 0.03 cm for patients <2 years ( $p<0.001$ ). At ≥2 years, LGX and CX patients experienced similar mean change in penile length ( $p=0.619$ ) as well as distribution of change in penile length ( $p=0.481$ ): 42.0% of LGX and 37.7% of CX patients had >1 cm increases in penile length. Age was not a significant factor for change in penile length.

**Conclusions:** Penile length appears to increase among patients who have had an IPP for more than 2 years. Length increase was similar in both LGX and CX patients.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## The ED care pathway for patients considering penile implants

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**Objectives:** The typical treatment algorithm for erectile dysfunction (ED) starts with a trial of phosphodiesterase type 5 inhibitors (PDE5i), followed by one or more “second line” therapy options such as Vacuum Erection Devices (VED) and/or injection therapy. Often it is only after all of these options fail that penile implants are given serious consideration. We conducted two patient research studies, in part, to explore the typical care pathway of patients exploring the option of a penile implant.

**Material and Methods:** Two separate IRB approved patient research studies were conducted. The first study was a quantitative survey of 257 men who had attended American Medical System (AMS) sponsored Patient Education Seminars on ED. The research assessed men at three time points: 1-2 months post-seminar ( $n=43$ ), 3-6 months post-seminar ( $n=80$ ), and 12-16 months post-seminar ( $n=134$ ). Survey length was approximately 30 min. Respondents answered questions on their ED history, the seminar itself, activities since the seminar, therapies tried and relative satisfaction, and potential barriers to penile implants. The second study was also a quantitative survey of approximately 30 min in length. This study sample ( $n=61$ ) consisted of men who had a recommendation from a urologist to receive a penile implant. Half of this sample ( $n=31$ ) had implant surgery, while the other half ( $n=30$ ) decided not to receive an implant. The primary purpose of the study was to better understand the differences between these two groups.

**Results:** On average, patients receiving a penile implant had been suffering from ED for 6-7 years. Similarly, those patients considering an implant but not yet receiving one had been suffering for 5-6 years. The vast majority of men had tried a PDE5i (95%) and a second line treatment (65%), while reporting significant dissatisfaction with both a PDE5i (55%) and a second line treatment (75%). Those men who had not received an implant tended to utilize more second line therapies. In the group of men in the second study who had implant surgery ( $n=31$ ), 42% stated that they should have had the implant surgery earlier.

**Conclusions:** The ED care pathway can be a long and frustrating journey for patients and their partners. It is important for physicians to recognize the risk of treatment fatigue as patients move through a series of less than satisfying options before deciding on the more permanent and invasive implant solution.

### Disclosure:

Work supported by industry: yes, by American Medical Systems (industry initiated, executed and funded study). The presenter

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or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## **Inflatable penile prosthesis implantation is possible under local anesthesia with conscious sedation: Technique and results**

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**Objective:** To report our results using local anesthesia with conscious sedation for inflatable penile prosthesis (IPP) procedure

**Material & Methods:** Retrospective review of 40 patients who had inflatable penile prosthesis (IPP) procedure under local anesthesia with conscious sedation. Patient age was  $56.25 \pm 10.43$  (Mean  $\pm$  SD) and all had medical clearance for conscious sedation. Patients were followed up to 6 months.

**Technique:** Conscious sedation was induced by careful and continuous infusion of propofol (DiprivanR). Nursing professionals monitored airway, vital signs and pulse oximeter. Local anesthesia was obtained by injection of 20cc of 1:1 mixture of 2% lidocaine and bupivacaine. The local was injected in scrotal skin, base of the penis and the external inguinal ring. A high transverse scrotal incision was used and reservoir placement was either in the retroperitoneal space (60%) or the high submuscular location (40%). Closed suction drainage and compressive scrotal dressing were utilized.

**Results:** Mean procedure time was  $41.02 \pm 18.97$  min (Mean  $\pm$  SD). Some patients evidenced discomfort during reservoir placement but none remembered the experience. 19.5% of patients (n=8) had transient saturation drop under 90%, which was easily corrected with oral suction or jaw retraction. One scrotal hematoma was experienced which healed spontaneously.

**Conclusion:** IPP on uncomplicated subjects can be accomplished safely under local anesthesia with conscious sedation.

### **Disclosure:**

Work supported by industry: no.

099

## **Factors associated with treatment satisfaction following penile prosthesis implantation**

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**Objective:** High treatment satisfaction rates have been associated with penile prosthesis implantation (PPI). The

potential association of underlying patient characteristics and satisfaction rates has not been fully elucidated. We analyzed patient characteristics to identify potential factors contributing to satisfaction with PPI.

**Material and Methods:** 20 patients with a history of PPI were evaluated in our institution between January and December 2012. Demographics, duration of erectile dysfunction (ED), prior ED treatments, body mass index (BMI), comorbidities, social history and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) questionnaire scores were compiled. Nonparametric (Spearman) correlation analysis was performed.

**Results:** Overall PPI satisfaction was 85%, as determined by the first EDITS question, which is comparable to historical data. All EDITS questions scored a mean of 50 or higher (on a 0 to 100 scale), indicating satisfaction with PPI. No statistically significant correlation was noted between satisfaction rates and factors that were assessed, including: age, duration of ED, prior ED treatments, BMI, marital status, smoking or alcohol abuse history, prior ED treatments (phosphodiesterase 5 inhibitors, intracavernosal injections, intraurethral suppositories, vacuum erection devices), the presence of medical comorbidities (diabetes mellitus, atherosclerosis, hypertension, dyslipidemia, obstructive sleep apnea, renal failure, spinal cord injury, depression, anxiety, coronary bypass surgery) or the presence of urological conditions (prostate cancer, prostatectomy history, Peyronie's disease, pelvic radiation or trauma, priapism history, hypogonadism, psychogenic ED).

**Conclusion:** Patients who underwent PPI have high satisfaction rates. Correlation between patient characteristics and satisfaction rates was not identified. Larger studies and questionnaires focusing on patients who underwent PPI may be of benefit in the future.

### **Disclosure:**

Work supported by industry: no.

100

## **Maria Stitch: A novel technique to prevent pump migration in inflatable penile prosthesis**

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**Objective:** Retrospective cohort study that introduces the Maria Stitch as a novel technique to prevent pump migration in patients undergoing inflatable penile prosthesis

**Materials and Methods:** We retrospectively analyzed 120 patients that underwent inflatable penile prosthesis at single institution by the same surgeon. We compared the rate of pump migration with historical controls in the primary literature.

**Description of the Maria Stitch:** When the pump is to be placed in the scrotum, the dartos fascia is grasped at the most inferior position in the scrotum with an Allis clamp and brought up through the incision. A 3-0 chromic suture is then placed



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through the fascia, ensuring no placement through the skin . Subsequently, the suture is then wrapped around the pump and tied down . The pump is then brought down into the scrotum into the dependent position. The remainder of the operation is completed as normal.

**Results:** After 2 years of follow up there has not been any evidence of pump migration in our patients nor there has been any evidence of infection related to skin breakdown at stitch site.

**Conclusion:** The Maria Stitch offers an opportunity to reduce pump migration, a rare complication that may cause morbidity for the patient. The national average of pump migration is noted to be as high as 3.5% in some series which compares favorably with this approach. Longer term follow up is a valid criticism that will be addressed in future studies.

## Disclosure:

Work supported by industry: no.

101

### **“Distal Corporal Anchoring Stitch” a technique to address Distal corporal crossovers and impending lateral extrusions of a penile prosthesis**

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**Objectives:** Distal corporal crossover and impending lateral extrusion of a penile prosthesis may cause pain and place the patient at risk for erosion. Distal fixation of an inflatable penile prosthesis is a useful surgical adjunct to treating patients with previously unidentified distal crossovers, delayed distal crossovers and impending lateral extrusion. As prosthetic surgeons our armamentarium should be equipped with techniques used for problem solving. We provide another method for its management, the “Distal Corporal Anchoring Stitch”.

**Materials and Methods:** A lateral, subcoronal incision is utilized on the side where the crossed over or laterally extruding cylinder should be positioned. Dissection is carried through Bucks fascia, followed by a transverse incision of the Tunica Albuginea where the distal aspect of the affected cylinder is delivered. A 4-0 PDS suture is threaded through the distal cylinder ring of the implant after the original suture is removed. A new, properly positioned intracorporal channel is created using scissors and Hegar dilators. Using a Keith needle and Furlow device, the 4-0 PDS is passed through the distal end of this channel. Once the suture is through the glans and the cylinder is in the correct position, a small cruciate incision is made on the glans, at the location of the anchor stitch. The suture is tied

with the knot buried in the glans tissue. The cruciate incision is then closed with Dermabond. The corporoplasty incision is closed in standard fashion and routine postoperative care is followed.

**Results:** A total of 52 patients have undergone treatment of their distal penile implant crossover with a distal corporoplasty utilizing the “Distal Corporal Anchoring Stitch” from Jan 2009 – May 2014 (38 lateral extrusions, 9 unidentified crossovers and 5 delayed crossovers). This technique ensures that the cylinder remains in the newly created, appropriately positioned channel. No patients have experienced any infections, glandular hypoesthesia, anesthesia or pain in the glans related to the suture and only one patient reported recurrence of a lateral herniation not requiring further treatment.

**Conclusions:** Albeit relatively rare, distal corporal crossover and impending lateral extrusion of a penile implant can be devastating if untreated. Previous modalities for managing these complications carried the risk of recurrence secondary to tenuous or absent tunica. The “Distal Corporal Anchoring Stitch” is a safe and efficacious technique in securing distal fixation of the inflatable penile implant.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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### **Penile prosthesis insertion after radial forearm free flap neophallus**

*Pariser, JJ<sup>1</sup>; Malik, RD<sup>1</sup>; Gottlieb, LJ<sup>1</sup>; Bales, GT<sup>1</sup>*

*1: University of Chicago, USA*

**Objective:** Patient often undergo neophallus creation as a result of gender dysphoria or surgical or traumatic loss of the phallus. Our preferred method is a radial forearm free flap using microsurgical anastomoses. Patients often desire erectile function, and penile prosthesis offers the potential for adequate rigidity. We present our experience of inflatable penis prosthesis insertion in patients with prior neophallus construction.

**Material and Methods:** Patients with a history of prior neophallus construction who underwent penile prosthesis insertion were identified. All patients underwent previous radial forearm free flaps at our institution as a separate procedure before prosthesis insertion. A single inflatable cylinder was used in all procedures, and except for the first procedure, a bone drill was used to create a fixation chamber in the symphysis pubis to anchor the proximal rear tip.

**Results:** Eight consecutive patients underwent inflatable penis prosthesis insertion from December 2006 to September 2013. Mean age at neophallus construction was 40 years old. Neophallus was performed for gender reassignment in six patients and for penile loss in two patients. Mean age at prosthesis insertion was 41 years old. The mean cylinder size

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was 17.3 cm with mean rear tip size of 1.9 cm. Median follow-up was 20.6 months (range 1-85 months). Three patients required reoperation (37.5%) One patient required additional proximal bony fixation, and two required replacement for mechanical malfunction.

**Conclusion:** Inflatable penile prosthesis is feasible, safe and effective for achieving erectile function after neophallus construction. We recommend proximal anchoring into the symphysis pubis with a bone drill, using a single inflatable cylinder, and standard prosthetic infectious precautions to obtain optimal surgical outcomes.

**Disclosure:**

Work supported by industry: no.

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**Inflatable penile prosthesis implantation in men under 30: Long-term outcomes regarding patient satisfaction**

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**Objective:** Although refractory erectile dysfunction is most common in older men, there exists a population of young men with conditions that cause significant ED. Vasoactive medications and microarterial bypass surgery are the primary treatments for this small cohort. Implantation of an inflatable penile prosthesis is a valuable and definitive treatment option, but there is a dearth of information regarding long-term outcomes in young patients. This study reports long-term outcome data using validated instruments and a non-validated questionnaire in a sample of men younger than 30 years old who underwent IPP implantation.

**Material and Methods:** This is a single-institution, retrospective IRB-approved study of 22 men under 30 who underwent IPP implantation between 2005 and 2013. All patients had failed conservative management with PDE-5 inhibitors and intercavernosal injection therapy. All patients underwent extensive hemodynamic testing with Duplex Doppler Ultrasound and Dynamic Infusion Cavernosometry and Cavernosography and had results consistent with either severe corporo-occlusive or veno-occlusive erectile dysfunction.

**Results:** Between 2005 and 2013, 22 patients under 30 underwent IPP implantation. Average patient age was 24.6, ranging from 18 to 29 years old. After surgery, SHIM scores showed significant improvement when compared to scores from before surgery. Satisfaction scores by modified EDITS assessment were high. Additionally, the non-validated questionnaire documented high satisfaction rates in this sample. Most patients reported that they would undergo the procedure again and that they would recommend it to other patients.

**Conclusions:** IPP implantation is a valuable option for young men under 30 who desire definitive management for erectile dysfunction. Data on young patients with severe ED are limited,

but validated instruments and a non-validated questionnaire in this sample show that young men who undergo IPP implantation report high satisfaction after the procedure.

**Disclosure:**

Work supported by industry: no.

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**Maximizing “rigidity factor” of inflatable penile prosthesis (IPP) results in better artificial erection**

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**Objective:** It is well established that the inflatable penile prosthesis (IPP) more closely mimics expansion of the corporal bodies during erection compared to the malleable. Classic teaching regarding placement of IPP supports the notion of using rear tip extenders (RTE) to improve mechanical survival by allowing tubing to come through the corpora more directly to the pump. This disregards the benefits of providing the crus with inflatable cylinders. To highlight this hypothesis, we propose a novel concept “Rigidity Factor,” (RF) and argue that avoidance of RTEs is preferred when possible with an expectation of higher long-term patient satisfaction.

**Material and Methods:** The 3-piece Coloplast Titan® (CT) IPP was analyzed. We defined RF for a given cylinder as a ratio between the live (inflatable) portion of cylinder over the total length.

**Results:** Current IPP cylinder design is a hybrid of rigid and inflatable implant. A CT cylinder has a 5cm rigid non-inflatable portion. Adding RTEs increase the non-inflatable portion of implant, figure 1. For a given cylinder length there is a maximum RF. Use of RTEs decrease the RF, table 1. Maximizing the RF leads to high quality artificial erection, figure 2.

**Conclusions:** In normal erection, full expansion of the cavernosum produces an erection well buttressed to the pelvic ramus. Over time loosening of the pseudocapsule over the rigid portion of implant leads to instability, droop and wobble of the erection. Use of RTEs in our experience will with time lead to diminished erection quality. Despite lack of objective data proving this observation, which would be difficult and impractical, contrary to prior teaching, RTEs should be avoided in order to maximize penile implant support. Maximizing inflatable length leads to higher RF and may improve durability of high quality artificial erection and subsequently patient satisfaction.

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Figure 1.

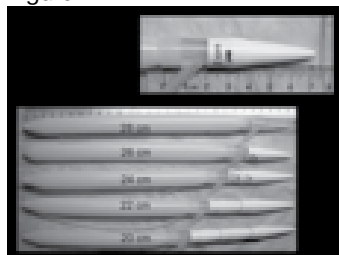


Table 1.

Total Cylinder Length	Live Cylinder Length	Maximum Rigidity Factor	1 cm RTE	2 cm RTE	3cm RTE
28 cm	23cm	0.82	0.78	0.75	0.71
26 cm	21cm	0.81	0.77	0.73	0.61
24cm	19cm	0.79	0.75	0.71	0.67
22cm	17cm	0.77	0.73	0.68	0.64
20cm	15cm	0.75	0.7	0.65	0.6

Figure 2. Titan XL 26cm Cylinders:



## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## “Sticky pump” syndrome: Trending towards non-operative treatment of patients with difficult AMS 700-Series IPP inflation

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**Objectives:** Patients presenting for inflatable penile prosthesis (IPP) activation following implantation occasionally report that the AMS Momentary Squeeze (MS) pump “sticks” and is rigid or it does not re-inflate when depressed. We present our experience in managing patients with difficult inflation of the MS pump.

**Methods:** We queried our IRB-approved, institutional database of patients undergoing IPP surgery and identified those who

had experienced difficulty with pump activation. We then performed a chart review and identified presenting complaints, management, and outcomes.

**Results:** Of 306 patients receiving AMS 700-series IPPs at our institution from 2007-2014, 4 (1.3%) presented with difficulty activating the MS pump (from 2011-2014). Four additional patients were referred from outside institutions with the same complaint. All patients (8/8, 100%) presented after a period of inactivity during which the IPP was not cycled and remained stagnant. The initial 3 patients (38%) underwent surgical exploration, with pump mobilization and replacement. Intraoperatively, after complete pump mobilization, the device cycled without difficulty but was replaced due to concern about recurrence. The next patient (13%) underwent pump replacement for malfunction, and eventually required complete device replacement after multiple revisions of the pump. The four most recent patients (50%) were treated non-operatively by “forced deflation” maneuver in the office-- firm compression on the cylinders and depression of the release button resulted in a fluid shift and the device began to cycle normally.

**Conclusion:** Patients receiving the AMS 700-series IPP rarely have difficult inflation initially or following periods of inactivity. The forced deflation maneuver in the clinic appears to obviate the need for surgical intervention, and patients should be instructed in daily cycling to keep the system functioning properly.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Use of rear tip extenders does not affect penile implant satisfaction or outcomes

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1: Southern Illinois University SOM, USA; 2: University of Utah; 3: El Camino Urology Medical Group; 4: The Urology Team; 5: Urology San Antonio; 6: Urology Centers of Alabama; 7: Lahey Clinic; 8: Baylor College; 9: University of Ottawa, Canada; 10: Regional Urology, USA

**Objective:** Experts disagree on the clinical impact of number and length of rear tip extenders (RTE) utilized with inflatable penile prosthesis (IPP) insertion. Although the column strength of an implant is maximized with less RTE, operative technical factors such as the ratio of distal to proximal corporal measurements and satisfactory pump position often require the use of RTE. We sought to assess if the cylinder to RTE ratio affected IPP device satisfaction or outcomes.

**Material & Methods:** Ad hoc analysis of prospectively collected data as part of the PROPPER IPP patient registry with at least 1 year of patient satisfaction data follow-up. Descriptive

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statistics were used to summarize the Cylinder to RTE ratio and satisfaction data; categorical variables were compared using Chi-Square test with  $p < .05$  considered statistically significant.

**Results:** A total of 758 subjects had evaluable cylinder length or cylinder to RTE ratio data with a mean ratio of  $9.4 \pm 5.8$  (~ 18 cm cylinder with 2cm RTE). Among these, satisfaction data was available in 334 patients. 277 patients were satisfied or very satisfied with an average cylinder length (cm), RTE length (cm) and ratio of 19.3, 2.5 and 9.9 respectively. Similar findings were seen in 19 patients whom where neither satisfied or dissatisfied (18.9, 2.5, 9.7) and 38 patients whom were very dissatisfied or dissatisfied (19.3, 2.6, 9.5). Subjects were stratified into groups with no RTE ( $n=18$ ), Ratio  $> 10.5$  ( $n=115$ ), Ratio 5.25-10.5 ( $n=146$ ), & Ratio  $< 5.25$  ( $n=55$ ). No statistically significant differences were found in regard to 1 year patient satisfaction ( $p = .71$ ), or patient dissatisfaction at 1 year ( $p = .398$ ). This finding was consistent even when comparing the no RTE only group to RTE ratio  $< 5.25$  group (most rear tips used).

**Conclusion:** Our data indicate the use of rear tip extenders does not significantly affect device satisfaction, dissatisfaction or utilization. Given these findings and the fact that patients rarely inflate their device maximally, surgeons need not minimize rear tip use at the expense of appropriate pump position.

## Disclosure:

Work supported by industry: yes, by AMS (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Penile prosthesis placement in patients with a history of total phallic construction

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*1: Eastern Virginia Medical School, USA*

**Introduction:** Outcomes following penile prosthesis placement in patients with a history of total phallic construction are not well described.

**Methods:** Retrospective review penile prosthesis placement in patients with prior total phallic construction. Gortex sleeve corporal construction was utilized in all patients.

**Results:** Twenty-five patients underwent neophallus prosthesis placement at a mean 34.4 years of age. Prosthesis placement occurred an average 42 months following phallic construction and follow-up was a mean of 60 months. Malleable prostheses were placed in 17 patients and inflatable in 8; implants were bilateral in 92%. Eight percent experienced operative complications including a bladder injury (1) and phallic flap arterial injury (1). Post-operative complications occurred in 24% at a median 5.9 months following placement. Four prostheses (16%) were explanted secondary to infection or erosion and two additional required revisions. Of the explanted prosthesis one was later replaced without further complication. Seventy-

six percent of patients were sexually active following prosthesis placement.

**Conclusions:** Penile prosthesis placement is possible in patients with prior phallic construction. Although complications rates appear to be increased in this population compared to historic controls of normal anatomic males, the majority in this series were sexually active following prosthesis placement. This demonstrates the utility of prosthesis implantation in these difficult patients.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Simultaneous inflatable penile prosthesis and quadratic transobturator male sling procedure

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*1: Columbia University Medical Center, USA*

**Objective:** Following radical prostatectomy (RP) stress urinary incontinence (SUI) and erectile dysfunction (ED) are two major complications. After medical treatment fails, penile prosthesis implant and transobturator male sling are both validated options to manage ED and SUI. Our goal was to assess the feasibility and results of the combination of these two devices.

**Material and Methods:** Ten patients were treated for SUI and ED following RP in our institution by simultaneous quadratic transobturator sling and inflatable penile prosthesis, following failure of medical management. Each patient was preoperatively evaluated by age, complete medical history, ASA score, cystoscopy, pad-test, and urodynamics. All patients had both procedures performed in the same outpatient operative setting, the sling via a perineal approach and the penile prosthesis via an infrapubic approach. Post-operative follow-up was focused on complications and efficacy.

**Results:** No perioperative complication occurred. After a minimum of 18 month follow-up, all patients were considered socially continent, pad-free with none or minimal leakage reported, all had returned to sexual activity. All patients were fully satisfied.

**Conclusions:** According to our initial experience, surgery combining the quadratic transobturator male sling and an infrapubic penile prosthesis is feasible, and leads to excellent functional results with no complications in men following RP.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Utilization of pre-operative penile stretch test as predictor of erection and total implant length

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**Objectives:** Prediction of the erection and total corporal length prior to inflatable penile prosthesis (IPP) surgery is of great benefit to both the surgeon and the patient. For the patient, estimation of the post-operative result is helpful in creating realistic expectations. The ability to accurately calculate the range of the total implant length utilizing a penile stretch test could focus the amount of inventory shipped for an individual procedure. Thus, we sought to determine whether a formula based on the pre-operative stretch length could reliably predict the total corporal length.

**Methods:** Fifty-three consecutive virgin IPP patients were performed by a single surgeon over 30 days. All patients received a Coloplast Titan® IPP through an infrapubic approach. In all patients, a pre-operative stretch test was performed using Furlow along the dorsal aspect of the penis from the mons pubis to the tip of the glans. Intraoperatively, the same measurements were repeated after induction of normal saline artificial erection and after implantation and inflation of the device. Formulas based on the stretch test were constructed to predict the total device length [stretch test + (x%) stretch test]. Descriptive statistics, paired significance testing and linear regression were performed using Stata 13.

**Results:** In comparing the three penile measurements, the stretch test and the post-implant measurement were not statistically different (p-value=0.3878). The artificial erection length was statistically different from both penile stretch and post-implant lengths (p< 0.0001). On linear regression, all measurements demonstrated a significant linear relationship with the overall implant length with inflated post-implant length having the highest correlation. The linear formula, stretch test + (0.35) stretch test, predicted the total device length within the range [stretch test (cm) to calculated value (cm)] in 96% of cases. (Table I) Rear tip extenders, primarily 1 cm, were utilized in 25 cases (47.2%). No total implant length was less than the pre-operative stretch test.

**Conclusion:** The preoperative stretch test demonstrated a high correlation with post-implant erection length and total IPP device length in this pilot dataset. The formula for estimating total device length will need to be verified prospectively to determine its reproducibility.

**Table I: Correlation between predictive formulas and final implant length**

Formula	% correct prediction of implant length within the range (stretch test to calculated value)
Stretch + (.15) Stretch (cm)	43%
Stretch + (.20) Stretch (cm)	71%
Stretch + (.30) Stretch (cm)	94%
Stretch + (.35) Stretch (cm)	96%

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Key factors and influencers impacting the penile implant decision

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**Objectives:** For men with erectile dysfunction (ED), the decision to have penile implant surgery can be a difficult one. However, little is known about how men make this decision. We conducted two quantitative studies to explore the primary factors and relative influencers in the decision to move forward (or not move forward) with a penile implant.

**Material and Methods:** Two separate IRB approved patient research studies were conducted. The first study was a quantitative survey of 257 men who had attended American Medical System (AMS) sponsored Patient Education Seminars on ED. The research assessed men at three time points: 1-2 months post-seminar (n=43), 3-6 months post-seminar (n=80), and 12-16 months post-seminar (n=134). Survey length was approximately 30 min. Respondents answered questions on their ED history, the seminar itself, activities since the seminar, therapies tried and relative satisfaction, and potential barriers to penile implants. The second study was also a quantitative survey of approximately 30 min in length. This study sample (n=61) consisted of men who had a recommendation from a urologist to receive a penile implant. Half of this sample (n=31) had implant surgery, while the other half (n=30) decided not to receive an implant. The primary purpose of the study was to better understand the differences between these two groups.

**Results:** The primary factors across both study which lead to an implant were: 1) belief that it is the best solution for them, 2) trust and confidence in their urologist, and 3) a supportive spouse/partner. Factors deterring patients from an implant included: 1) hope that a better solution exists, 2) concern about pain and other surgical side effects, and 3) concern about the reaction of their partner. Interestingly, the relative influence of key players in the decision was similar when comparing implanters vs. non-implanters: urologist (36% vs. 29%), the spouse/partner (23% vs. 27%), and the patient himself (34% vs. 29%).

**Conclusions:** It is important for physicians treating ED to understand the dynamics behind a patient's decision related to a penile implant. Both the urologist and the spouse/partner hold about the same relative influence as patient in this decision.

## Disclosure:

Work supported by industry: yes, by American Medical Systems

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(industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## How combined serotonin-1A receptor agonist and 2A-receptor antagonist can heal hypoactive sexual desire disorder (HSDD)

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**Introduction:** Hypo-active sexual desire disorder (HSDD) is a sexual dysfunction in men and women. More than 20% of all women, and probably also men, between 20 and 49 years of age suffer from it.

**Materials and Methods:** Using PET-scanning we studied differences in brain function between women with no sexual disorder (NHSD) and HSDD women. They watched neutral, and "women friendly" low and high erotic film clips.

**Results:** In NHSD women, but much less in HSDD women, watching low, but especially high erotic movies resulted in a strong activation involving the parietal, temporal and to a lesser extent prefrontal cortex of the right brain. In contrast, in the NHSD volunteers watching high, but especially low-erotic movies strong de-activation was found in the left temporal and prefrontal cortex. Remarkably, this large area of deactivation did not extend into the medial orbitofrontal cortex (medial Brodmann's area 11). However, this same area was strongly de-activated on both sides in HSDD women, who showed only very small other areas of de-activation. The left hemisphere is rational, processing established information. The right hemisphere is intuitive and spontaneous. Both hemispheres receive strong information from the medial orbitofrontal cortex.

**Conclusions:** In NHSD women the medial orbitofrontal cortex, after receiving and assessing the erotic visual information, activates specific regions in the right temporal and frontal lobe and de-activates large areas in the left temporal and frontal lobes. Since the same erotic visual information de-activates the medial orbitofrontal cortex in HSDD women, de-activation in their left temporal and frontal lobes and activation in their right temporal lobe is inhibited, leading to HSDD.

It has been reported that an inverse association exists between the desire for social relationships and 5HT<sub>2A</sub> binding in medial orbitofrontal cortex. In animals the highest receptor density for 5-HT<sub>2A</sub> and 5-HT<sub>1A</sub> receptors was found in the frontal cortex. In isolation-reared rats in this same frontal cortex the 5-HT<sub>2A</sub> receptor binding site densities were significantly increased, while 5-HT<sub>1A</sub> receptor binding site densities were significantly reduced.

A similar situation might exist in HSDD men and women, increased 5-HT<sub>2A</sub> and decreased 5-HT<sub>1A</sub> receptor binding site density. It would explain why flibanserin, a serotonin-1A receptor agonist and 2A-receptor antagonist, restores the activation level of the medial orbitofrontal cortex in the HSDD

men and women by reducing the 5-HT<sub>2A</sub> receptor binding sites and increasing the 5-HT<sub>1A</sub> receptor binding sites, solving their sexual and possibly other emotional problems.

### Disclosure:

Work supported by industry: yes, by Boehringer-Ingelheim (industry funding only - investigator initiated and executed study).

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## A randomized, single center, single-blind, crossover thermographic study to evaluate the effect of 1000 mcg of topical alprostadil cream compared to an over-the-counter marketed lubricant

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**Objectives:** There are no FDA-approved drugs for women with bothersome FSAD. Study drug efficacy for the treatment of peripheral genital arousal may be assessed by measuring improvement in genital blood inflow using a non-invasive technique, Forward Looking InfraRed (FLIR) thermography. A prospective, randomized, single center, single-blind, crossover thermographic study was performed to evaluate the effect on peripheral genital arousal of 1000 mcg of topical alprostadil cream (Femprox) compared to OTC lubricant.

**Material and Methods:** Healthy premenopausal women (mean age 32 +/- 12 years, n = 10) were topically administered study drug to their clitoris and anterior vaginal wall by a designated NP. Continuous temperature monitoring of the vestibule, clitoris and vulva was conducted for 30 minutes before and 60 minutes post-application in subjects watching a non-sexual film. After each application subjects completed questionnaires assessing genital sensations and maximum intensity and duration of effect; adverse events were recorded.

**Results:** In all subjects topical alprostadil cream induced a statistically significant increase in temperature of the vestibule, clitoris and vulva relative to the OTC lubricant. Sustained statistically significant treatment differences occurred at 11 minutes post-application for the vestibule, 19 minutes for the clitoris and 9 minutes for the vulva and maintained for the duration of the assessment. Six of the ten women reported being aware/conscious of genital sensations with the topical alprostadil cream and not the OTC lubricant, consistent with concordance of physiological and subjective assessments. Discordance was noted in 30% who reported being aware/conscious of genital sensations with both treatments and 10% who reported not being aware/conscious of genital sensations with either. No adverse events were reported.

**Conclusion:** Topical alprostadil cream administered to healthy premenopausal women induced statistically significant sustained increases in genital temperatures of the vestibule,



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clitoris and vulva within 20 minutes relative to OTC lubricant. Further studies are planned.

## Disclosure:

Work supported by industry: yes, by Apricus Biosciences (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Symptomatic and asymptomatic Bartholin cyst formation after complete vestibulectomy for congenital or acquired neuroproliferative vestibulodynia

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**Objectives:** During physiologic sexual arousal, mucous lubrication is released into the vestibule for pain-free introital penetration from the right and left Bartholin's glands whose ducts enter the introitus at 5:00 and 7:00. Women with sexual pain secondary to congenital or acquired neuroproliferative vestibulodynia, who fail conservative treatment options and who have a positive Vestibular Anesthesia Test (VAT), may be managed by complete vestibulectomy with vaginal advancement flap. In such cases the right and left Bartholin's ducts may become transected/obstructed. The objective of this study was to analyze, in women who underwent complete vestibulectomy for the treatment of neuroproliferative vestibulodynia, the prevalence of post-operative symptomatic and asymptomatic post-operative Bartholin's cyst formation.

**Material and Methods:** At a single site 28 women who underwent complete vestibulectomy with vaginal advancement flap for congenital or acquired neuroproliferative vestibulodynia were available for at least one post-operative history and physical examination including at least one post-operative perineal ultrasound study. An IRB approved retrospective chart review was performed using post-operative history and physical examination and perineal ultrasonography data regarding the presence or absence of symptomatic and asymptomatic Bartholin's cysts.

**Results:** Of the 28 charts reviewed, 3 (11%) patients had symptomatic Bartholin cysts with complaints of: discomfort after sexual arousal (1), tenderness during sexual arousal (1) or mass-effect after arousal (1). Three women with Bartholin cysts had unilateral symptomatic cysts >10 mm, present on physical examination and on post-operative perineal ultrasonography; all were successfully managed with out-patient surgical marsupialization. A total of 20 (80%) women had asymptomatic Bartholin cysts, undetectable by physical examination, but documented on postoperative ultrasound, 18 (90%) women had very small cysts, less than 4 mm, and were seen bilaterally. As there were no associated symptoms, management has thus far been conservative and none have yet progressed to symptomatic cysts.

**Conclusion:** Symptomatic post-vestibulectomy Bartholin cysts that are identified both on physical examination and on post-operative perineal ultrasonography are managed with marsupialization. Asymptomatic small Bartholin cysts are heretofore unrecognized but very common sequella after complete vestibulectomy surgery. Continued observation is recommended. It remains unclear why some patients develop larger symptomatic Bartholin cysts, but this is a rare outcome.

## Disclosure:

Work supported by industry: no.

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## Artificial urinary sphincter for treatment of incontinence in the elderly

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**Objectives:** Manipulation of an artificial urinary sphincter (AUS) can be difficult for many patients. Here, we examine the role of advanced age (defined as >70 years old), impaired cognitive function, and decreased manual dexterity in the rates of re-operation (revision or replacement) of AUS.

**Materials and Methods:** From 1988-2012, 213 men underwent virgin AUS placements at a single institution. Sparse medical records prevented the determination of cognitive/dexterity function in 83 cases. Failure was defined as a revision performed for recurrent/persistent SUI and replacement or exploration performed for urethral erosion/infection or mechanical failure. Failure was further sub-classified into erosion/infection failure, recurrent or persistent incontinence, and mechanical failure.

**Results:** Mean age at time of surgery was 67.0 years, with 84 patients being over the age of 70. Median follow-up was 47 months overall and 40 months in the advanced age group. Median times to failure after initial AUS placement was 30 months overall and 29 months in the advanced age group. Advanced age was not shown to be associated with overall failure ( $p=0.48$ ), erosion/infection failure ( $p=0.65$ ), recurrent/persistent incontinence failure ( $p=0.08$ ), or mechanical failure ( $p=0.36$ ). There were 5 patients identified with cognitive dysfunction and 6 patients with decreased manual dexterity at or near the time of surgery. Controlling for age, patients with cognitive dysfunction or decreased manual dexterity showed a higher rate of overall failure ( $p=0.01$ ).

**Conclusions:** AUS placement is an excellent option to treat urinary incontinence caused by intrinsic sphincter deficiency in elderly patients with intact cognition. AUS placement should be performed with caution in patients with impaired cognitive function or decreased manual dexterity. Further studies are needed to examine the role of cognition and manual dexterity in the successful functioning of an AUS.

## Disclosure:

Work supported by industry: no.

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## Location of AUS pressure regulating balloon: Functional outcomes of high submuscular position are equivalent to space of retzius

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**Objectives:** Traditional placement of artificial urinary sphincter (AUS) pressure regulating balloons (PRB) within the space of Retzius (SOR) may be challenging and subject to troublesome complications. We report our longitudinal experience utilizing a novel high submuscular (HSM) PRB placement technique and compare functional outcomes to traditional SOR placement of the PRB.

**Materials & Methods:** We reviewed a prospectively maintained database of AUS patients between July 2007 and January 2014. Only 61-70 cm H<sub>2</sub>O PRBs were placed through a trans-scrotal approach via an HSM tunnel (2011-2014) or within the SOR (2007-2010). Our HSM technique consisted of uniform placement of the PRB beneath the rectus abdominis muscle while SOR placement involved perforation of the transversalis fascia at the pubic tubercle, beneath the external inguinal ring. Demographics, patient data, cuff durability, and functional outcomes were compared between groups.

**Results:** 232 consecutive patients underwent AUS placement with a mean follow up of 38 months. SOR placement was performed in 139 (60%) patients while HSM placement was performed in 93 (40%). Functional outcomes including continence (defined as 0-1 pads/day) rates (88% vs. 81%,  $p=0.15$ ), erosion rates (9% vs. 5%,  $p=0.32$ ), and explantation rates (12% vs. 10%,  $p=0.83$ ) were similar between groups. Fewer AUS revisions for persistent incontinence were required in patients undergoing HSM PRB placement (6.5% vs. 18%,  $p=0.01$ ). Although mean follow-up was longer for patients undergoing SOR placement (51 vs. 20 months,  $p<0.001$ ), Kaplan-Meier analysis revealed no difference between groups with regards to rates of explantation ( $p=0.71$ ) or revision ( $p=0.36$ ).

**Conclusions:** High submuscular placement of the PRB at the time of AUS surgery offers a safe and effective alternative with equivalent functional outcomes to traditional SOR.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Operative management for priapism: A contemporary experience at a single institution

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**Objective:** To review a contemporary cohort of priapism patients who failed initial management strategies requiring operative intervention for the treatment of priapism.

**Materials and Methods:** Retrospective review of consecutive priapism cases at a single institution from January 2005 to June 2014 was performed utilizing an inpatient Urologic Surgery consultation database. Baseline characteristics including age, race, prescription and illicit drug use, and medical comorbidities were gathered. Patients were grouped by priapism etiology, initial management, and surgical management. Fisher's exact test and Student's t test for categorical and continuous variables were employed to compare patients who ultimately required an operation for persistent priapism versus those who did not require operative management.

**Results:** Of 62 total patients, median age was 34 years (IQR, 26-42). Median duration of erection was 8 hours (4.0-17.5). Seventeen patients (27.4%) had repeat presentations, resulting in a total of 102 uniquely presenting cases. Sickle cell disease was the most common etiology (33 cases, 32.4%), while 22 cases (21.6%) were attributed to psychotropic medications, 21 (20.6%) were idiopathic, and 15 (14.7%) were secondary to injection therapy for erectile dysfunction. A majority of the cases—77 (77.5%)—were initially treated with irrigation/aspiration and/or phenylephrine injections, while 7 patients (6.9%) were definitively treated with medication only. Thirteen patients (12.7%) required surgical shunts, 6 of whom required at least two operations. Patients who required operative management were more likely to present with a longer duration of erection (54 vs. 13.2 hours,  $p<0.001$ ) and idiopathic etiology (46.1% vs. 16.9% of cases,  $p<0.05$ ) compared to patients who did not require operative management.

**Conclusions:** In this large contemporary case series, the most common causes of priapism were sickle cell disease, psychotropic medications, and idiopathic. For men who failed nonoperative management, surgical shunt procedures were effective, although nearly half of these men required two or more operations. Patients who required operative management were more likely to present with a significantly longer duration of erection than were men who did not require operative management, underlining the importance of prompt evaluation and treatment of these patients.

### Disclosure:

Work supported by industry: no.

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## Efficacy and sedation-related safety of Flibanserin in premenopausal women

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**Objectives:** Flibanserin is a centrally-acting, multifunctional



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serotonin agonist/antagonist and is being developed for the indication of hypoactive sexual desire disorder (HSDD) in premenopausal women. Chronic bedtime oral dosing is necessary to achieve therapeutic efficacy and to minimize the most commonly reported adverse events (AEs) that include dizziness, somnolence, nausea and fatigue. Due to this dosing regimen and AE profile, it is important to determine the extent of next-day impairment in cognition or alertness.

**Methods:** Efficacy was evaluated in 3 separate multicenter, randomized, placebo-controlled, pivotal phase 3 trials in North America in premenopausal women diagnosed with acquired HSDD. Potential next-day residual effects were evaluated the next morning after bedtime dosing in a preliminary analysis of a randomized, double-blind, placebo-controlled, four-way crossover study with validated assessments including simulated driving performance and symbol digit coding substitution test in healthy premenopausal women.

**Results:** Compared to women on placebo (n=1238) at 24 weeks of treatment, women with HSDD treated with flibanserin 100 mg qhs (n=1227) had significantly increased desire, increased sexually satisfying events and decreased distress (p<0.0001 for key endpoint assessments). During assessment of potential next-day impairment, healthy women (n=72) completed a cumulative total of 57,600 km of simulated driving. Driving and cognitive assessment scores indicated that flibanserin 100 mg was no worse than placebo for both acute and chronic dosing. Flibanserin 200 mg was similar to the 100 mg dose for cognitive testing and driving performance, although commonly reported AEs were predictably increased in a dose-dependent manner.

**Conclusions:** Flibanserin is efficacious in ameliorating symptoms of HSDD. Consistent with the low prevalence of accidental injury in phase 3 clinical trials, preliminary safety study data suggest that bedtime dosing of flibanserin 100 mg does not impair next day cognitive function or driving performance.

## Disclosure:

Work supported by industry: yes, by Sprout Pharmaceuticals, Inc.

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## Persistent Genital Arousal Disorder (PGAD): Experience with management in 35 consecutive cases

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**Objectives:** Persistent genital arousal disorder (PGAD) is a rare, unwanted and intrusive sexual dysfunction associated with excessive and unrelenting genital arousal and engorgement without sexual interest, with no recognized safe and effective evidence-based treatment. Characteristics of women with PGAD were assessed.

**Methods:** A retrospective clinical chart review was performed on the last 35 women assessed for PGAD.

**Results:** Women (age 46+/-18) had symptoms of PGAD for 17+/-16 years, appearing secondary to increased peripheral sensory afferent input and an under inhibited central sexual arousal reflex center falsely interpreting excess peripheral sensory information as sexual arousal, leading to spontaneous arousal, orgasm and a short refractory period post-orgasm. Conditions resulting in increased peripheral sensory afferent input: altered pre-menopausal hormone integrity, hormonally mediated provoked vestibulodynia; altered menopausal hormone integrity, genitourinary syndrome of menopause; increased nerve fiber density, genetic susceptibility with elevated levels of nerve growth factor substances; injury to or irritation of pudendal nerves transmitting pain and other sensations; abnormal response of tissues to Candida infection, recognized or non-specific allergies; lichen sclerosus or lichen planus; vulvar granuloma fissuratum; peri-urethral glans pathology; clitorodynia; pelvic congestion syndrome; S2 Tarlov cyst; high tone pelvic floor dysfunction. Reducing excess peripheral sensory input with sex therapy/counseling, pelvic floor, pharmacologic, device and surgical treatments, and increasing inhibitory regulation of the uninhibited central sexual reflex center kept the PGAD manageable.

**Conclusions:** An estimated 20% of healthcare providers have cared for individuals with PGAD. Afflicted women can have normal life quality without suicidal ideation or distress after treatment(s). PGAD seems to be caused by a combination of excess peripheral afferent stimulation along the spinothalamic tract from irritated genital, pudendal nerve, pelvic floor tissues or sacral nerve roots and a central sexual reflex with limited central inhibition. PGAD may be lifelong or acquired. The arousal usually does not resolve with orgasm.

## Disclosure:

Work supported by industry: no.

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## Penile fracture outcomes: Faux pas du coit at high risk for urethral injury, ED & Peyronies

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**Objective:** We report the largest penile fracture study in the United States describing preoperative evaluation, surgical repair, and long term outcomes.

**Methods:** Medical records from Northwestern Memorial

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Hospital and Oregon Health & Science University from 2002 to 2011 were reviewed. Clinical presentation, preoperative evaluation, time from injury, mechanism and site of injury, and presence of urethral injury were assessed. Outcomes including erectile dysfunction (ED), penile curvature, and voiding symptoms were evaluated using IPSS and IIEF scores.

**Results:** Twenty-nine patients with 30 separate episodes of penile fractures presenting to the emergency room were identified. Mean patient age was 43 yo ( $\pm$  9.6). The mean time from injury was 13.9 hours ( $\pm$  14.6). Mechanism of injury was intercourse in 26/30 fractures with 4/30 attributed to masturbation, "rolling over" and "routine penile stretching." Immediate surgical repair was offered to all patients and when performed occurred 5.5 hours ( $\pm$  4.4) after injury. Two patients were treated conservatively. The 27 repairs included cystourethroscopy and surgical exploration. The site of fracture was at the proximal shaft in 13, mid shaft in 13, and distal shaft in 4 patients. The mean follow up period was 14.3 weeks ( $\pm$ 15.8). Urethral injury was noted in 5/27 (18%). Eight patients (33%) reported new mild ED and 4 (17%) reported mild penile curvature. Overall IIEF score at follow-up was a mean of 26.8 ( $\pm$  3.7). One patient reported new irritative voiding symptoms. Erectile dysfunction occurred in half of men treated conservatively.

**Conclusions:** Unlike previously reported series from the Middle East, the most common mechanism of penile fracture in the United States was from sexual intercourse. Concomitant urethral injury occurred in 20% of men. Even with gold standard immediate surgical repair, 1/5 of men developed new curvature and 1/3 of men developed new ED.

## Disclosure:

Work supported by industry: no.

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## Priapism Impact Profile (PIP) questionnaire: Development and evaluation

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**Introduction:** No validated clinical instruments exist for quantifying the physical and emotional impact of experiencing priapism.

**Materials and Methods:** We created a 12-item questionnaire to survey priapism impact in 3 domains: quality of life (QoL), sexual function (SF), and physical impact (PI), which was self-administered to adult patients with priapism histories presenting in the urology and sickle cell disease clinics of a single institution from Jan 2011 to April 2014. Higher scores indicate inferior experience in respective domains. Scores were stratified according to various factors including priapism duration, erectile dysfunction (ED), and disease activity (remote activity defined as  $\geq$ 1 year without priapism episodes). The PIP

was assessed for internal consistency and construct validity using priapism history, IIEF and SHIM scores. Participants were also asked to assess the clarity and importance of each question on the PIP.

**Results:** Each domain and the total scale demonstrated high degrees of internal consistency (Cronbach's alpha values  $\geq$ 0.75 and 0.90, respectively). Fifty-three patients (mean age 31.6  $\pm$  11.5 years) completed the questionnaire. Patients with an active priapism history (n=41) had higher QoL, SF, PI, and total scores than those with a remote history (n=8) (p=0.008, 0.08, 0.0003, 0.005, respectively). Patients with a history of episodes  $>$ 2 hours had higher QoL, SF, PI, and total scores than those with shorter episodes ( $\leq$ 2 hours) (p=0.002, 0.03, 0.0006, 0.002, respectively). Patients with "Mild to Moderate" to "Severe" ED (SHIM  $<$ 17, IIEF  $<$ 19) had higher QoL, SF, PI, and total scores than those with no ED or "Mild ED" (p=0.11, 0.0002, 0.11, 0.007). An average of 93% and 78% of patients rated questions as being clear and important, respectively.

**Conclusion:** The PIP questionnaire is a psychometrically sound instrument that appears to perform rigorously across several clinical variables. It may serve as a valuable tool in clinical practice and for future research purposes such as evaluating responses to priapism interventions.

## Disclosure:

Work supported by industry: no.

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## The association between sex hormones and female sexual dysfunction

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**Objectives;** A role of adrenal androgens has been suggested in female sexual behavior. Low sexual desire and sexual dysfunctions in females have been associated with decreased androgen levels. By affecting the entire sexual response cycle, sex hormones might induce significant changes in sexual desire, arousal, orgasm, and satisfaction. To examine the relationship of sex hormones and sex hormone-binding globulin (SHBG) with sexual dysfunction.

**Material and Methods;** We evaluated 74 consecutive women with sexual dysfunction by obtaining their medical and personal history, performing physical examination, and administering a self-reporting questionnaire, which enquired about sexual problems and satisfaction rates. We measured the levels of total, free, and bio-available testosterone, LH, FSH, estradiol, DHEAS and SHBG and calculated the free androgen index. Using Wilcoxon rank-sum test, the hormone levels were compared between the sexual dysfunction and control groups. And we treated 9 patients by testosterone replacement using gel-type androgen.

**Results;** The mean levels of LH, FSH, DHEA and DHEAS were lower in women with lack of sexual desire. The levels of DHEA

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was lower in the arousal disorder group ( $p<.05$ ) and lower in the orgasmic disorder group ( $p<.01$ ) than the control group. Sexual pain disorder groups showed lower estradiol level ( $p<.05$ ). Among 9 patients receiving testosterone replacement therapy, 4 patients reported that symptoms were improved subjectively, 4 patients had not significant change, and 1 patient stopped the therapy due to side effect.

**Conclusion;** These findings support the concept that sex hormones significantly affect sexual response in women with sexual dysfunction. An androgenic hormone profile is associated with lack of libido, orgasmic disorder, and estrogen with pain disorder.

## Disclosure:

Work supported by industry: no.

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## Reconstructive armamentarium for correction of adult buried penis syndrome

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**Objective:** Adult buried penis syndrome (ABPS) involves a spectrum of different anatomic components, thus requiring a flexible yet comprehensive reconstructive approach for effective management. We present our institutional experience with various reconstructive strategies for ABPS.

**Methods:** We reviewed all patients who underwent reconstruction of ABPS at our institution between 2007 and 2014. We stratified patients by primary procedures, and reviewed demographics, comorbidities, and clinical outcomes. If the preputial skin was viable, a ventral slit with scrotal flap (VSSF) was performed. In cases of significant fibrosis, the penile skin was completely excised and replaced with a split-thickness skin graft (STSG). In patients with severe abdominal lipodystrophy, a panniculectomy was performed. When necessary, phalloplasties were performed with anchoring of the penoscrotal junction. Depending on intraoperative findings, more conservative measures were utilized if deemed clinically appropriate. We defined success as stable symptoms with no requirement for other interventions.

**Results:** Fifty patients underwent reconstruction of buried penis during the study interval. VSSF was performed for 19/50 men (38%). Eighteen (36%) underwent complete foreskin resection with STSG, and 5/18 (28%) required panniculectomy. In 10/50 patients (20%), panniculectomy with a phalloplasty was performed. Three patients (6%) were treated with phalloplasty alone. Etiology was lymphedema in 18/50 (36%), lichen sclerosis in 18/50 (36%), obesity in 12/50 (24%), and trauma in 2/50 (4%). Mean age was 53 (range 26-73), and mean BMI was 37.4 kg/m<sup>2</sup> (range 22.4-56.1). Five patients (10%) required additional procedures, for an overall success rate of 90%.

**Conclusions:** Successful correction of adult buried penis

often necessitates a multi-modality approach, and excellent outcomes are possible with appropriate patient selection.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant or shareholder of an industry.

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## Outcomes associated with Peyronie's disease by duration of disease

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**Objective:** Intralesional injection therapy with collagenase clostridium histolyticum (CCH) is FDA-approved for the treatment of adult men with Peyronie's disease (PD) with a palpable plaque and penile curvature deformity (PCD) of at least 30° at the start of therapy. This posthoc analysis examines improvements in PCD and bother related to PD following treatment with CCH or placebo in subjects with PD duration of 6 to <12 months or ≥12 months.

**Material and Method:** 147 subjects with PD were enrolled in a double-blind, randomized, placebo-controlled phase 2 study at 12 US sites. Males >18 years of age were eligible if they had PCD between 30°-90°. Subjects received intralesional injections of 2 doses of either CCH (0.58 mg/dose) or placebo 24-72 hours apart in 3 treatment cycles, separated by 6 weeks. Subjects were assessed for 36 weeks (last observation carried forward; LOCF) using PCD measurements, responses to a PD-specific patient reported outcome (PRO) measure, and adverse event (AE) reports.

**Results:** In subjects with PD duration of 6 to <12 months (n=22, CCH; n=12, placebo), a 38% mean improvement (mean change -19.4°) in PCD was observed following CCH treatment vs. a 19.8% mean improvement (mean change -8.9°) for placebo ( $p=0.08$ ). For PD duration of ≥12 months (n=78, CCH; n=22, placebo), a 27.6% mean improvement (mean change -15.2°) in PCD was observed following CCH treatment vs. a 7.3% mean improvement (mean change -3.9°) for placebo ( $p=0.004$ ). For the bother domain of the PD-specific PRO, similar magnitudes of score improvements were observed for subjects with PD duration of 6 to <12 months (2.4 reduction, CCH vs 0.5 reduction, placebo;  $p=0.24$ ) or ≥12 months (2.6 reduction, CCH vs 0.9 reduction, placebo;  $p=0.12$ ). Most AEs in the CCH group occurred at the injection site (penile bruising, pain, edema, contusion) and were mild/moderate in severity; AE profiles were comparable regardless of PD duration.

**Conclusions:** Improvement of PCD was comparable or better

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for PD duration of 6 to <12 months compared with  $\geq 12$  months, although the observed differences were not statistically significant in this dataset. An increased placebo effect was also observed in subjects with a PD duration of 6 to <12 months. Further study of CCH treatment in the early months of PD should be considered.

## Disclosure:

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## The efficacy of once-daily administration of Udenafil for 24 weeks on erectile dysfunction and lower urinary tract symptoms; results from a randomized multicenter placebo-controlled clinical trial

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**Objective:** Erectile dysfunction (ED) and lower urinary tract symptoms (LUTS) are prevalent diseases in aging men and have similar pathophysiology. The aim of this study was to evaluate the efficacy and safety of Udenafil as a treatment for ED and LUTS.

**Material and Methods:** This multicenter, randomized, double-blind clinical trial included 346 ED patients (placebo, Udenafil 50 mg, Udenafil 75 mg). Subjects were treated with each medication once daily for 24 weeks. Subjects were asked to complete the International Index of Erectile Function (IIEF)-EF domain and international prostate symptom score (IPSS) at baseline, 12, and 24 weeks.

**Results:** Both dosages of Udenafil induced a significant increase in IIEF-EF compared with placebo at both 12 and 24 weeks. When patients were divided according to the severity of baseline EF score, significant improvement was observed only with Udenafil 75 mg regardless of the degree of ED. At 24 weeks, the proportions of patients who reported a return to normal EF (IIEF-EF over 26) were 35% for Udenafil 50 mg and 47.1% for Udenafil 75 mg. Regarding LUTS, significant decrease of IPSS within the group was observed only for Udenafil 75 mg ( $p=0.048$ ), particularly in men with severe baseline symptoms (mean decrease of 7.0,  $p=0.005$ ).

In terms of safety, adverse drug reactions (ADRs) were observed in 6.1%, 12.9%, and 17.7% for placebo, Udenafil 50 mg, and 75 mg, respectively. Although a statistically higher rate of ADRs was observed in the Udenafil 75 mg group ( $p=0.002$ ), the majority were mild and recovered without treatment.

**Conclusions:** Once daily administration of Udenafil 50 mg and 75 mg for 24 weeks resulted in improvement of EF, with an acceptable rate of ADRs. In particular, Udenafil 75 mg improves EF regardless of the baseline degree of ED together with relief of symptoms in patients with severe LUTS.

## Disclosure:

Work supported by industry: yes, by Dong-A pharmaceutical (industry funding only - investigator initiated and executed study).

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## Functional outcomes and follow-up care after priapism treatment: A contemporary experience at a single institution

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**Objective:** To assess functional outcomes and follow-up care after priapism treatment in a contemporary cohort of patients.

**Materials and Methods:** Retrospective review of consecutive priapism cases at a single institution from January 2005 to June 2014 was performed utilizing an inpatient Urologic Surgery consultation database. Institutional Review Board (IRB) approval was obtained. Patients were contacted by telephone. After providing informed consent, patients completed a survey consisting of the International Index of Erectile Function (IIEF)-15, Erection Hardness Score (EHS), and follow-up care since their last priapism episode.

**Results:** There were 102 uniquely presenting cases of priapism during the study period from a total of 62 patients. Survey data was collected on 30 priapism cases (29.4% of total cases) from 13 patients (21.0% of total patients). Mean follow-up time from last priapism case was 30.1 +/- 25.6 months. Mean IIEF-15 was 37.9 +/- 21.3, with erection function domain score of 13.9 +/- 11.5. Mean EHS was 3.7 +/- 0.7, with 2 patients reporting no erections during the followup period. The surveyed cohort was young (mean age 31.9 +/- 11.2 years) with sickle cell disease as the most common etiology (17 cases, 56% of cohort). Sickle cell patients reported similar functional outcomes (mean IIEF-15 of +/- 37.1 +/- 21.5, with erection function domain score of 13.9 +/- 11.5) compared to patients with other priapism etiologies (mean IIEF-15 of +/- 38.8 +/- 22.7, with erection function domain score of 13.9 +/- 11.8). Only two patients experienced additional episodes of priapism. Hematoma was reported after 16.7% of cases. Less than half of patients (36.7%) ultimately saw a urologic surgeon in follow-up.

**Conclusions:** Long-term functional outcomes and follow-up from this large priapism case series reveals mild to moderate erectile dysfunction in a relatively young surveyed cohort

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with sickle cell disease as the predominant priapism etiology. Patients reported rare subsequent priapism episodes, relatively few complications after treatment, and poor urologic follow-up. While this study is limited in numbers and biased towards young patients with sickle cell disease, it demonstrates the feasibility of obtaining long-term follow-up data on priapism patients and provides a framework for further studies.

## Disclosure:

Work supported by industry: no.

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## Bulbocavernosus muscle area as a surrogate marker of hypogonadism in a symptomatic male population

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**Objectives:** Male hypogonadism is difficult to diagnose. Traditionally the combination of symptomatology and testosterone assays is evaluated to establish the diagnosis of hypogonadism. Studies have shown that the Bulbocavernosus Muscle area (BCM) is androgen sensitive. Dabaja et al (Asian J Uol, 16:1-5, 2014) recently demonstrated that the BCM area is inversely related to the number of CAG repeats. Others have found that castration reduces the BCM area and androgen replacement increases BCM area. This study investigates whether a relationship exists between BCM area and serum testosterone level in a symptomatic male population and whether BCM area may be useful as a surrogate marker for hypogonadism.

**Materials and Methods:** Men presenting with symptoms of hypogonadism underwent standard evaluation including a measurement of BCM area using B-mode perineal ultrasonography. Morning serum testosterone levels were compared to investigate a correlation between testosterone and BCM area and BCM area normalized for body mass index (BMI).

**Results:** Forty-three men presenting for erectile dysfunction, hypogonadism symptoms or infertility had both BCM area on ultrasound and a morning serum testosterone level. A correlation was found between both BCM area and BCM normalized for BMI and serum testosterone level with a testosterone cutoff of 400 ng/dL. Below a serum testosterone level of 400 ng/dL BCM area was below 0.72 cm, while above a serum testosterone level of 400 ng/dL BCM area was at or above 0.72cm. No difference was found using other testosterone cutoffs.

	T < 400	T > 400	p
Age	54.3	54.1	0.98
BMI	29.6	25.8	0.03
BCM	0.54	0.72	0.017
Normalized BCM	0.019	0.029	0.006

**Conclusion:** Normal and low BCM area as measured by ultrasound correlates with serum testosterone levels. Serum testosterone < 400 ng/dl correlate with a decreased BCM while serum testosterone >400 ng/dl correlates with a more normal BCM area. Thus, BCM area may be useful as a surrogate marker for male hypogonadism.

## Disclosure:

Work supported by industry: no.

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## Accociation of free testosterone with hypogonadal symptoms in men with near normal total testosterone levels

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**Objectives:** To investigate the association between hypogonadal symptoms and calculated free testosterone levels in men with near normal total testosterone levels (250 – 350ng/dL). We also attempted to determine whether there exists a clear-cut discriminatory threshold of free testosterone below which hypogonadal symptoms become more prevalent.

**Patients and Methods:** We retrospectively reviewed the charts of 137 men who presented to an outpatient men's health clinic with chief complaint of "low testosterone". We evaluated hypogonadal symptoms using the Androgen deficiency in Aging Male (ADAM) questionnaire and quantitative ADAM questionnaire. Serum levels of total testosterone, sex-hormone binding globulin (SHBG) were collected on the same day that men completed their questionnaires. We subsequently performed univariate (t test, chi-square) and multivariate analyses (ordinal logistic regression) to evaluate factors that predicted a low free testosterone level.

**Results:** The probability of hypogonadal symptoms increased at a calculated free testosterone level of 6 ng/mL. A cluster of symptoms: two psychological (decreased energy, sadness), and three physical (decreased strength and endurance, falling asleep after dinner, and deterioration in work performance) were most strongly associated with free serum testosterone levels of <6ng/mL. Of note, sexual symptoms (libido and poor erectile function) were not associated with free testosterone. On multivariable analysis, only younger age was positively associated with a free testosterone of more than 6ng/mL.

**Conclusion:** Hypogonadal symptoms in men with near normal total testosterone levels can be associated with a free testosterone level of less than 6ng/mL. Symptom-specific free testosterone thresholds could not be defined, as age remains an important confounder.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## The impact of vasectomy on sexual frequency

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**Objective:** Men who are considering vasectomy as a means of contraception may harbor significant anxiety regarding their future sexual potency. As a result, couples may choose other forms of contraception with lower efficacy. We sought to determine the impact of vasectomy on the frequency of sexual intercourse.

**Materials and Methods:** We analyzed data from cycles 6 (2002) to 7 (2006-2008) of the National Survey of Family Growth (NSFG) to compare the frequency of sexual intercourse (within the prior 4 weeks) for men who had undergone vasectomy versus those who had not. We excluded men who had never had sex, as well as men under the age of 30, since vasectomy prior to this age is less common. We then constructed a multivariate logistic regression model to adjust for age, marital status, race, education, health, BMI, children and income.

**Results:** A total number of 3798 men met the criteria for our study; 317 had vasectomies performed. For men who had undergone vasectomy, the average frequency of sexual intercourse was 5.8 times per month compared to 4.8 times for non-vasectomized men. Only 6% of vasectomized men did not have sexual intercourse in the prior 4 weeks, compared to 16% of non-vasectomized men. In addition, 66% of vasectomized men and 53% of non-vasectomized men had sexual intercourse at least once a week. After adjusting for demographic, socioeconomic, reproductive, and health factors, men utilizing vasectomy had a 77% higher odds (95% CI 2-205%) of having sexual intercourse at least once a week versus less than once a week.

**Conclusion:** Vasectomy does not adversely impact sexual frequency. This finding may be helpful to couples as they consider contraceptive options.

### Disclosure:

Work supported by industry: no.

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## Subcutaneous (SC) testosterone enanthate (TE) 50 mg and 100 mg administered with a novel, auto-injector (AI) provides effective testosterone (T) replacement

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**Objectives:** Topical treatments for hypogonadal men restore physiologic T but require daily dosing, titration, and risk transfer. Transfer is not a risk with T for IM injection (IMT), but it may be painful, inconvenient, not easily self-administered, and may be

associated with peaks and troughs leading to mood swings. The PK profile of a novel, prefilled SC TE auto-injector (AI) was studied.

**Material and Methods:** Twenty-nine HGM, ages 31-69 with T <300 mg/dL at 2 screening visits, were randomized to 50 mg (n=14) or 100 mg (n=15) AI weekly for 6 weeks. AI TE was administered by clinic staff. Ten IM TE pts at steady-state at time of screening were enrolled in a reference arm and continued to receive IM TE at their prescribed dose until study day 1, when they received one dose of 200 mg IM TE and then had PK sampling for 4 weeks. Mean baseline total T was 244 ng/dL for pts in the 50 mg group and 243 ng/dL in the 100 mg group. IM arm mean TT was 466.1. At week 1, both AI doses produced normal mean TT concentrations in 24 h (433 ng/dL in the 50 mg group [range 197-821 ng/dL] and 545 ng/dL in the 100 mg group [range 388-833 ng/dL]). In the 50 mg group, T C<sub>min</sub> was generally unchanged and increased through week 5 in the 100 mg group.

**Results:** Steady state C<sub>avg(0-168h)</sub> T levels at week 6 were 895.5 ng/dL for the 100 mg group vs. 422.4 ng/dL for 50 mg; 2.12-fold higher. Among 50mg pts, week 6 C<sub>max</sub> was 622.4 ng/dL (range 388-825) and T<sub>max</sub> was 45.4 h; C<sub>min</sub> was 272.3 ng/dL (range 211-372). Among 100 mg pts week 6, C<sub>max</sub> was 1345.6 ng/dL (range 624-2120) and T<sub>max</sub> was 35.54 h; C<sub>min</sub> was 568 ng/dL (range 236-860). Mean AUC(0-168h) at week 6 was 70955.7 and 150445.2 ng\*h/ml for the 50 and 100 mg doses, respectively. Serum estradiol and dihydrotestosterone rose proportionately with T. AI took 3-4 secs and consistently provided precise doses. 200 mg IM group C<sub>max</sub> was 2261.9, range 787 – 4840 ng/dL. C<sub>avg</sub>[0-168h] was 1658.7 ng/dL; Mean AUC(0-168h) was 19668.6 ng\*h/ml.

**Conclusions:** AI rapidly restored and maintained physiologic levels of T with attenuated peak-to-trough fluctuations relative to higher dose IM TE given 1-2 times/mo. This may reduce mood swings and hematocrit elevations associated with IM TE. Improved dose frequency, ameliorated transference risk, and convenience suggest AI may represent an option to topical or IMT treatments for hypogonadism.

### Disclosure:

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## Testosterone replacement therapy in hypogonadal men undergoing active surveillance for prostate cancer

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**Objective:** With increasing experience with testosterone replacement therapy (TRT) for men undergoing prostatectomy

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for prostate cancer (CaP), attention has turned to TRT in patients undergoing active surveillance (AS). We report our experience with TRT in patients on AS.

**Material and Methods:** An IRB approved retrospective review was performed on all patients with a prior diagnosis of CaP opting for AS and presenting with signs and symptoms consistent with hypogonadism (HG) to a single urologist specializing in andrology. All patients had final surgical pathology reports available for review and had baseline testosterone (TT) labs performed before 11 A.M., with repeat lab testing performed to confirm initial results. Patients with low or borderline TT levels (<300 ng/dL) and the presence of symptoms of hypogonadism were offered TRT after extensive counseling. Patients with LH levels in the normal laboratory range were offered clomiphene citrate (CC). Those who failed to achieve therapeutic TT levels (goal 600 to 800 ng/dL) on CC, or who opted against CC were offered transdermal testosterone (TDT) or intramuscular testosterone (IMT). Repeat hormonal evaluation, PSA, hemoglobin and hematocrit values were obtained at 6 weeks after initiation of therapy, and TRT doses were titrated as needed. Labs were monitored every 3 months for the 1<sup>st</sup> year, 6 month for 2 years and then annually.

**Results:** A total of 11 patients met inclusion criteria. Mean age at start of TRT was 66 years. Mean PSA at baseline was 3.7 ng/mL (range 0.4-8.2). All patients had Gleason 6 CaP. CaP stage was cT1c in 10 patients and cT2c in 1. Mean TT prior to initiating TRT, and while on treatment, was 237 ng/dL (range 93-396) and 603 ng/dL (range 463-807), respectively. 2 patients were on CC, 8 on TDT, and 1 on IMT. Mean follow up on TRT was 26 months (range 6-101). Mean PSA at last follow-up was 5.6 ng/mL (range 1.1-11.4). No patient had grade or stage progression of CaP on TRT. 2 patients discontinued TRT, either on advice of outside physician or due to anxiety.

**Conclusion:** In a small population of patients, TRT is safe in patients on AS for CaP, with no evidence of grade or stage progression noted on approximately 2 year follow up. Further study with longer follow up is necessary to confirm safety of TRT in selected men with untreated CaP.

## Disclosure:

Work supported by industry: no.

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## Outcomes of for cause prostate biopsy in men with hypogonadism

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**Introduction:** The relationship between Testosterone Replacement Therapy (TRT) and prostate cancer is controversial. Recent data suggests TRT to be safe following prostate cancer therapy however a black box warning remains for the drug. Most studies of TRT show that mean prostate specific antigen (PSA) values remain stable during therapy but

some men do have PSA rise or develop an abnormal digital rectal exam (aDRE) during therapy. The purpose of this study was to examine the biopsy results of men with hypogonadism before or during therapy.

**Methods:** Data was extracted from our electronic medical record on men with a diagnosis of hypogonadism who had a prostate biopsy within the past 4 years done by 3 Urologists with similar practice patterns. Men were divided into three groups: 1) diagnosis of low testosterone, not started on therapy at time of biopsy 2) on TRT < 2 years and 3) on TRT 2 or more years.

**Results:** Overall 96 men were identified. Mean age at time of biopsy was 63 +/- 9 years (range 40-85) and median PSA of 3.78ng/dl (0.5-662). Of the 61 men not on TRT, mean age was 64, median PSA 4.34 (0.5 to 662) and mean total testosterone 276 (191-341). There were 9 men with PSA < 2.5 with aDRE. There were 29 (47.5%) prostate cancers found (6 Gleason 6, 13 Gleason 7, 10 Gleason 8 or 9). Two men had metastatic disease at presentation. Of the 35 men on TRT, mean age was 60 years and median PSA was 3.27 (0.5 to 13.7). Nine had PSA < 2.5 but an aDRE. The % increase PSA compared to the prior value ranged from 2 to 251% (mean 93.5%). Mean total testosterone was 383 (146-792). Of the 14 men treated < 2 years, none had cancer. Of the 21 men treated 2 or more years there were 5 cancers (2 Gleason 6, 3 Gleason 7).

**conclusions:** Men with hypogonadism and aDRE or abnormal PSA often have prostate cancer on biopsy which may be aggressive. No men with an early PSA rise on TRT had cancer. Men on long term TRT should be monitored with PSA and DRE per guidelines similar to the general population.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Testosterone replacement therapy following androgen deprivation therapy among men with high risk prostate cancer

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**Objective:** The role of testosterone replacement therapy (TRT) among men with prostate cancer continues to evolve. Androgen deprivation therapy (ADT) combined with other treatments is frequently part of the management of men with high-risk prostate cancer. Following ADT, many men do not restore normal physiologic levels of testosterone and manifest the symptomatic and metabolic consequences of testosterone deficiency. As part of a pilot initiative, the objective of the current investigation was to evaluate the influence of TRT among symptomatic hypogonadal men with prostate cancer



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treated with ADT.

**Methods:** As part of a quality and safety pilot initiative, a prospective series of men with high-risk prostate cancer previously treated with surgery or radiation plus ADT who remained symptomatic and biochemically hypogonadal were offered TRT. Prior to TRT, all patients were off ADT for at least 1 year, free of biochemical cancer recurrence and documented to be hypogonadal (total testosterone < 10 nmol/L). Patients were evaluated at 3-month intervals for symptomatic response and changes in PSA and testosterone (mean follow up 8 months).

**Results:** 13 patients were treated (9 with radiation/ADT, 4 with surgery/ADT) with a mean age of 73 years (64-88 years). Pre-treatment mean PSA and Gleason scores were 9.8 ng/ml (4.5-29) and Gleason 8 (7-9). PSA was undetectable in 62% of patients after cancer treatment. Mean post-treatment PSA was 0.2 ng/ml among men with a measurable PSA. Prior to initiating TRT, mean total testosterone was 5.4 nmol/L (0.2-8). Mean Sexual Health Inventory for Men (SHIM) scores were 2.4. On average patients reported 6 hypogonadal symptoms on the Androgen Deficiency in the Aging Male (ADAM) questionnaire. Following TRT, mean total testosterone increased to 16 nmol/L (11-33) with symptomatic improvement in 11/14 (79%) patients. All but one patient with an undetectable PSA prior to TRT remained undetectable. Among men with measurable PSA, the mean change in PSA was 0.27 ng/ml. No clinical or biochemical cancer recurrence or progression was observed.

**Conclusions:** Many men with prostate cancer treated with ADT remain biochemically hypogonadal following treatment. TRT may offer symptomatic and metabolic benefits to these patients. Results from this preliminary investigation suggests that TRT has the potential to ameliorate hypogonadal symptoms without early and overt PSA progression. Larger and longer series are needed.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## A review of the robotic microsurgical varicocele experience at Albany Medical Center

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**Objective:** The use of the operating microscope for varicocelectomy is widely accepted. With the introduction of the DaVinci in Urology, its use in microsurgery has increasingly been reported. The robot platform is common to other areas of Urology. Since August of 2012 we have utilized the robot to perform all microsurgical repairs. We are reporting our experience through April 2014.

**Material and Methods:** An IRB approved retrospective review of our experience. The indications for repair were infertility,

hypogonadism (HGD), pain. All men had baseline hormone labs and pre op testicular dopplers to measure testicular volume. At three months post op repeat testicular dopplers were performed as well as hormone labs. Infertility patients were evaluated with pre and post op semen analyses.

**Results:** We performed 140 repairs on 253 testicular units. Mean age was 34.5. The primary diagnosis was infertility, infertility and HGD, HGD and pain in 13%, 56%, 9%, 21% respectively. Total testis volume, testosterone and sperm concentrations increased. There was persistent flow in 18/253 (7%). Complications were transient pain, hematoma and hydrocele in 12%, 3% and 0.7%. 62% did not require post op pain medication.

**Conclusion:** The robotic for microsurgical varicocelectomy yields comparable results to the standard microscope. In training programs that have the robot, consideration should be given to adopting this technique.

	Infertility (22)	Infertility & HGD (76)	HGD (19)	Pain (22)
Surgery type (B+/I-)	18/4	66/10	16/3	17/5
Test Test vol (pre op/post op)	35.6 (8/38.9 (8)	34 (17/40 (14)	43 (12/51 (17)	45 (12/52 (12)
Pre-op Testosterone	409 (126)	341 (173)	308 (100)	408 (100)
Pre-op/Post Diam (L/R mm)	3.6/2.8	3.6/2.8	3.3/2.8	4.4/2.8
Sperm conc (mil) (pre/post)	18.8 (21/35 (87)	15 (22/19 (28)	-	-
Post-op T	604 (146)	456 (207)	440 (94)	601 (96)
No of arteries (1/2/3)	6/7/2	26/14/1	7/3/0	9/6/1
Pain Meds (16/1/16)	50/50	65/35	50/50	62/38

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Increased prevalence of hypoprolactinemia in men on testosterone supplementation therapy

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**Objective:** The purpose of this study is to determine whether there is a difference in the prevalence of hypoprolactinemia in patients on testosterone supplementation therapy (TST) when compared to men not on TST.

**Methods and Patients:** We performed a retrospective analysis of men who presented to an academic urology clinic and had available medication usage and prolactin level data. Patient who were taking any form of exogenous testosterone were included in the testosterone supplementation cohort. Patients who were taking cabergoline were excluded from the study. We compared the prevalence of hypoprolactinemia at different cut-points (<1, <3, and <6 ng/ml) using a Pearson Chi-Square test with a significance of p<0.05.

**Results:** 4,551 men were included for analysis with a mean age of 45.5 years (Range: 15-96, Std.Dev: 13.197). 49% (n=2242) of men were on TST and 51% (n=2,309) were not. There was a greater prevalence of hypoprolactinemia in men on TST than



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in men not on TST for prolactin cut-points of <6 ng/mL (40.4% vs. 29.6%,  $p=0.001$ ) and <3 ng/mL (3.4% vs. 1.8%,  $p=0.001$ ). There was no statistical difference in the prevalence of profound hypoprolactinemia (<1 ng/mL) between men on TST and not on TST (0.4% vs. 0.1%,  $p=0.074$ ).

**Conclusions:** Prolactin appears to be involved in the central control of sexual function through modulation of dopaminergic and serotonergic systems. Hypoprolactinemia has also been associated with metabolic syndrome, arteriogenic erectile dysfunction, premature ejaculation, and anxiety. Our study demonstrated that there is a greater prevalence of hypoprolactinemia in men taking testosterone supplementation therapy when compared to men not taking exogenous testosterone. Given this finding, patients on TST may need to be monitored for development of signs and symptoms related to low prolactin levels.

## Disclosure:

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## Consistency of serum testosterone levels in patients using Axiron

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**Objectives:** The 2010 Endocrine Society guidelines on testosterone therapy in androgen deficient men were based on the best scientific evidence available. However, little is known about application of the guidelines in clinical practice. The purpose of this study was to evaluate application of the guidelines related to the use of serum testosterone (T) for the diagnosis of hypogonadism (HGN) and monitoring of testosterone replacement therapy (TRT).

**Materials and Methods:** Using the Truven MarketScan® Database, we identified men 18 years or older who received transdermal TRT in 2011 and had a diagnostic code for HGN. Patients who received TRT within 6 months prior to the index date (initial testosterone prescription) were excluded. Patients were required to have continuous pharmacy and medical benefit enrollment for 1 year prior to and 6 months after the index date. 27,758 men met criteria for analysis.

**Results:** Out of the 27,758 men, 18-95 (mean  $52.8 \pm 10.8$ ) years with a HGN diagnosis and who received TRT, 22,107 (79.6%) had at least 1 T measurement performed in the year prior to initiation of therapy; 8091 (29.1%) had 1 and 14,016 (50.5%) had 2 or more testosterone determinations. During the 6 months following TRT, 11,742 (42.3%) had no follow up T measurements performed; 6176 (22.2%) had 1 T measurement and 9840 (35.4%) had 2 or more. 2572 (9.3%) patients had dose adjustment within 6 months, 1921 (6.9%) and 651 (2.4%) men had a dose escalation and reduction, respectively. Follow-up T levels were not measured in 1282 (49.8%) men who had a dose adjustment.

**Conclusions:** The 2010 Endocrine Society recommendation to measure 2 or more T levels for diagnosis of HGN was followed in about 50% of patients. The recommendation to monitor T measurements in patients on TRT was followed in only about 60% of men within 6 months after initiation of transdermal TRT. In the patients who had their dose of transdermal testosterone adjusted, about half had T determinations following adjustment. Only 40-50% of practitioners who prescribe testosterone adhere to evidence-based guidelines for use of T levels in the diagnosis of HGN and monitoring of TRT, suggesting a need for further investigation into reasons for non-adherence to guidelines and for practitioner-based educational efforts.

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## Safety of a new SEDDS formulation of oral Testosterone Undecanoate (TU) in hypogonadal men: Data from two phase 3 trials with different dose-titration algorithms

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**Introduction:** TRT approved in the US is methyl-T which has hepatotoxicity concerns. The safety of a novel oral TU formulation utilizing a Self-Emulsifying Drug Delivery System (SEDDS) with improved T replacement characteristics was evaluated in two Phase 3 trials.

**Subject and Methods:** Both were open-label, multicenter, dose-titration trials in hypogonadal men (serum T  $\leq 300$  ng/dL) age 18-75. Trial I was a randomized, active-controlled, 2-arm, 12-month study. Participants were randomized to either oral TU (n=162) or 1% AndroGelR (n=163), which was included for safety comparison. Trial II was a single-arm 114-day study with oral TU (n=144). The trials differed in their dose-titration algorithms for oral TU that resulted in a lower T Cavg in Trial II (422 ng/dL) v. Trial I: (628 ng/dL) and fewer high Cmax excursions in Trial II. Safety was assessed through adverse event (AE) reporting, routine clinical laboratory and dihydrotestosterone (DHT) measurements.

**Results :** No deaths occurred. In Trial I, the incidence of AEs was similar between T-gel (62%) and oral TU (68%) groups, while serious AEs were 4% and 7% (only 1% in oral TU deemed treatment related), respectively. A single case of prostate cancer occurred in the T-gel group. The most frequently reported classes of AEs for all subjects were infection, GI,

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reproductive system, breast, musculoskeletal and connective tissue disorders.

In Trial II the incidence of AEs was 49% with 1% considered serious but not treatment-related, and the pattern was similar to Trial I. LFT elevations were rare and inconsequential in both trials. In Trial I, total and LDL cholesterol, triglycerides and PSA were not statistically significantly different between the two groups. The HDL-C reduction from baseline (associated with all TRT to some degree) was greater in Trial I (T-gel 12% and oral TU 22%) than Trial II (oral TU only; 9%). HCT increased in TU subjects by 3% but mean values remained within the normal range. DHT and DHT/T ratio rose in both groups but were greater with oral TU v. T-gel. The observed effect of oral TU on DHT and DHT/T ratio was deemed clinically neutral as it was less than reported with other TRTs.

**Conclusion:** These two Phase 3 trials demonstrate that this novel SEDDS formulation of oral TU has a safety profile consistent with other TRTs and is well tolerated in hypogonadal

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**Combination therapy of Tadalafil and Pentoxifylline in severe erectile dysfunction: A prospective randomized trial**  
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**Objective:** To assess efficacy of tadalafil alone versus tadalafil plus pentoxifylline in the treatment of erectile dysfunction by using self administered IIEF-5 questionnaire.

**Materials and methods :** Two hundred and thirty seven patients presenting with ED at andrology OPD were evaluated for ED by a self administered IIEF (International Index of Erectile Function) questionnaire. Patients were systematically randomized by computer generated random table into two groups groups namely, Group A : Tadalafil only group, Group B: combination of Tadalafil + Pentoxifylline. All the patients were re-assessed by IIEF-5 questionnaire after 8 weeks of medical therapy. Statistical analysis was performed using student's unpaired t-test, paired t-test, chi square test. p- value < 0.05 was considered statistically significant.

**Results:** Two hundred and thirty seven patients were included in the present study, in group A: 92 patients(78.6%) showed improvement in their IIEF score after 8 weeks of tadalafil treatment. While in group B, overall 104 patients(86.6%) showed improvement after combination of tadalafil and pentoxifylline. There was a statistically significant difference of percentage change in IIEF score was seen in group B. (group A

90.7±15.2%, group B 95.6±13.4%; p value - 0.014). We found this difference even more statistically significant in patients with severe ED. (group A 72.7±47.2%, group B 132.3±54.3%; p value - 0.000). There was no significant difference in between the two groups with regards to occurrence of side effects.

**Conclusion:** Both tadalafil and combination of tadalafil + pentoxifylline improve erectile function in patients of ED. Particularly patients with severe ED in Group B got much significant improvement in there erectile function with combination therapy.

## Disclosure:

Work supported by industry: no.

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**“Early” administration of low-dose tadalafil increases nocturnal penile tumescence in the acute phase after nerve-sparing radical prostatectomy**

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**Objectives:** Several pathophysiologies are postulated for postoperative erectile function rehabilitation. In previous prospective studies we showed nocturnal penile tumescence and rigidity (NPTR) in the acute phase during the first night after catheter removal in 93% of the patients after nerve-sparing radical prostatectomy (nsRP) and the improvement of erectile function by using daily low dose PDE5-inhibitors. The “optimal” time to initiate a rehabilitation program with PDE5-inhibitors is still unknown.

**Material and Methods:** 20 sexual active patients were operated by nerve-sparing retropubic radical prostatectomy. All patients completed an IIEF-5 questionnaire concerning erectile function preoperatively. To maintain and support recovery of spontaneous erectile function 10 patients received tadalafil 5mg/d at night starting at the 3<sup>rd</sup> night after surgery (group 1). A control of 10 patients received tadalafil 5mg/d at night beginning one day after catheter removal (group 2). 8 days after surgery the transurethral catheter was removed and an erectometer measurement of NPTR (Rigi-Scan®) was carried out on each patient at the following night.

**Results:** Baseline IIEF-5 as well as nerve-sparing status was comparable in both groups. In the “early” tadalafil group (group 1) 2-5 erections were recorded (mean 3.4 erections/night) during the first night after catheter removal. The “delayed” tadalafil group (group 2) showed 1-4 erections (mean 2.5 erections/night) within this acute phase after nsRP (p<0.05).

**Conclusions:** “Early” low dose tadalafil beginning at the 3<sup>rd</sup> night after surgery leads to a significant increase of nocturnal penile tumescence in the acute phase after nsRP compared to a “delayed” administration of PDE5-inhibitors after catheter removal. If “early” PDE5-inhibitors also lead to significant improvement to further erectile function rehabilitation, further

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follow-up is needed.

## Disclosure:

Work supported by industry: no.

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## Variation in penile vascular parameters according to location of cavernosal artery imaging

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**Objective:** Standard operating procedures (SOP) for penile color duplex doppler ultrasound (CDDU) were recently published in 2013 to promote standardization of vascular assessment of erectile dysfunction (ED). However, neither recent nor prior SOP specify a standard anatomic location along the cavernosal artery (CA). Our objective was to determine the effects of anatomic location on measured penile vascular hemodynamics.

**Materials and Methods:** CDDU was performed by a single urologist in men with ED and/or Peyronie's disease (PD) using an 18 MHz linear array transducer after pharmacologic induction of an erection using vasoactive agent mix (papaverine, phentolamine, PGE1). CA peak systolic velocity (PSV), end diastolic velocity (EDV), and resistive index (RI) were measured at three points: the origin of the CA just distal to its take-off from the dorsal penile artery within the crus, the proximal penile shaft, and the mid-shaft. Differences in vascular parameters based on anatomic location were assessed for statistical significance using Friedman's test for continuous nonparametric data and Dunn's multiple comparisons test. Penile vascular status was classified at each point of measurement according to the 2013 ISSM SOP for CDDU into one of 9 categories: nonvascular (PSV $\geq$ 30, EDV <3), arteriogenic (PSV<25, EDV <3), arteriogenic/partial venous (PSV<25, EDV 3-6), mixed (PSV<25, EDV  $\geq$ 6), partial arteriogenic (PSV 25-30, EDV <3), borderline mixed (PSV 25-30, EDV 3-6), partial arteriogenic/venous (PSV 25-30, EDV  $\geq$ 6), partial venous (PSV $\geq$ 30, EDV 3-6), and venous (PSV $\geq$ 30, EDV  $\geq$ 6).

**Results:** A total of 66 CAs were imaged in 33 men. Mean PSV was 54.3, 31.2, and 24.5 cm/s and mean EDV was 1.6, 3.4, and 3.5 cm/s as measured at the crus, proximal, and mid-shaft, respectively. Both PSV ( $p<0.0001$ ) and EDV ( $p<0.05$ ) varied significantly by anatomic location imaged. Post hoc analysis showed significant differences in PSV between all three imaging locations, while for EDV only crus and mid-shaft were significantly different. Based on the ISSM 2013 SOP, only 20% of the CAs assessed would have been classified consistently regardless of imaging location. The remaining 80% exhibited different vascular diagnoses that varied based on the location of imaging.

**Conclusion:** There is large variability in measured CA PSV and EDV on CDDU depending on the selected site, which can often sway diagnosis. Future operating procedures should attempt to

standardize this assessment.

## Disclosure:

Work supported by industry: no.

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## Effects of daily dosing strategy of phosphodiesterase 5 inhibitors on prescription pattern

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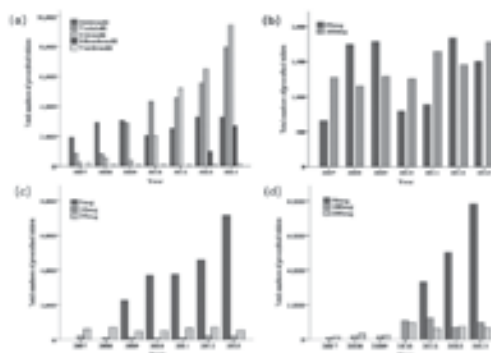
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**Objective** Recently, daily dosing of phosphodiesterase 5 inhibitors (PDE5Is) has been popular as a new treatment strategy for erectile dysfunction. We analyzed the prescriptions pattern of PDE5Is in a general hospital.

**Material and Methods** We investigated does and frequency of prescription of PDE5Is from a general hospitals in Korea from January 1, 2007 to December 31, 2013. Data were collected from patients to whom PDE5Is were prescribed by the urology department and by other departments. PDE5Is were classified into sildenafil, tadalafil, udenafil, vardenafil, and mirodenafil. We analyzed the data according to year, ingredient and does

**Results** PDE5Is were prescribed to 1,578 patients in total over 7 years (M 1,535, 97.3% and F 43, 2.7%). Mean age of patients was 52.83 (range 0 - 98) years. The total frequency of prescriptions was 6,461, and total number of prescribed PDE5Is was 75,231. Since 2007, prescriptions of PDE5Is has shown rapid growth. In 2007, total number of prescribed PDE5Is was 3,251, but it was 23,594 in 2013. Most frequently prescribed PDE5I was tadalafil (35.9%), and followed by udenafil (32.4%), sildenafil (25.4%), mirodenafil (4.9%) and vardenafil (1.4%). Most frequently prescribed tadalafil was 5mg (79.8%) and followed by 20mg (16.0%) and 10mg (4.2%). In udenafil, 50mg (66.6%) was most frequently prescribed does and followed by 100mg (18.1%) and 200mg (15.3%).

**Conclusions** Present study showed that PDE5Is prescription has been increased stiffly since introducing daily dosing. Increment of tadalafil 5mg and udenafil 50mg, which are prescribed for daily dosing, was a major cause of the increment.



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Figure 1 Total numbers of annually prescribed tablets of (a) PDE5 inhibitors stratified by ingredients; (b) Sildenafil stratified by does; (c) Tadalafil stratified by does; (d) Udenafil stratified by does

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## An evaluation of semen characteristics in men after daily dosing of Udenafil

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**Objective:** To compare the effects of 26 weeks of daily dosing with 150 mg udenafil vs. placebo on spermatogenesis, as assessed by the percentage of subjects who experienced a  $\geq 50\%$  decrease in sperm concentration.

**Methods:** This was a multicenter, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the effects of a daily oral dose of udenafil (150 mg) for 26 weeks on semen characteristics and reproductive hormone concentrations in healthy volunteers. Subjects were stratified by sperm concentration (20 to 50 million per mL or  $>50$  million per mL) at baseline.

**Results:** A total of 239 subjects were randomized ( $n=117$  placebo;  $n=122$  udenafil). At week 26, 8 (8.99%) placebo and 13 (14.29%) udenafil subjects had a  $\geq 50\%$  decrease in primary endpoint, ie, sperm concentration (5.30% difference, 14.62% upper limit of 97.5% CI) ( $p=0.2112$ ). The upper bound of the 97.5% confidence interval of the difference in the percentage of subjects with at least a 50% decrease in sperm concentration did not exceed the predefined non-inferiority margin of 20%; therefore, udenafil was considered to be non-inferior to placebo. Also there were no significant differences between placebo and treatment groups in secondary end points (% motility and morphology). The most frequently reported adverse events (AEs) reported with udenafil compared to placebo were headache (14 subjects), dyspepsia (9 subjects), and flushing (7 subjects). Nine subjects on udenafil and 2 subjects on placebo withdrew from the study due to AEs.

**Conclusions:** There were no adverse effects of udenafil on sperm count, morphology, motility or reproductive hormone concentration. Once daily oral administration of 150-mg udenafil for 26 weeks was well-tolerated.

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## The effect of Levitra on sustenance of erection (EROS): An open-label, prospective, multicenter, single-arm study to investigate the change of erection duration measured by stopwatch with flexible dose vardenafil administered for 8 weeks in subjects with erectile dysfunction

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**Objective:** To investigate the change of erection duration measured by stopwatch with flexible dose vardenafil administered for 8 weeks in subjects with erectile dysfunction (ED).

**Materials and Methods;** The EROS was an open-label, prospective, multicenter, single-arm study designed to measure the duration of erection in men with ED receiving flexible dose of vardenafil over 8 weeks treatment period. Patients were instructed to take the vardenafil 10 mg, 60 min prior to attempting intercourse. Vardenafil could be increased to 20mg or decreased to 5mg by patients' efficacy and safety. Following initial screening, patients entered a 4 weeks treatment-free run-in phase and entered 8 weeks treatment period, during which they were instructed to make at least six attempts of intercourse on six separate days.

**Results;** 95 men were enrolled in 10 centers. During the 8 weeks treatment period, the mean duration of erection leading to successful intercourse was statistically superior when patients were treated with vardenafil. There were significant benefits with vardenafil in all domains of International Index of Erectile Function. Secondary efficacy end-points included success rate of penetration, maintaining, ejaculation, satisfaction were superior when patients were treated with vardenafil. There was significant correlation between duration of erection with other sexual factors. Also partner's sexual satisfaction increased with vardenafil. Most adverse events were mild or moderate in severity.

**Conclusion;** Vardenafil was safe and well tolerated. Vardenafil therapy provided a statistically superior duration of erection leading to successful intercourse in men with ED with partner.

## Disclosure:

Work supported by industry: no.

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## Long-term efficacy, safety and satisfaction of intracavernosal injection therapy for radical prostatectomy patients

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**Objective(s):** Determine long-term efficacy, safety and satisfaction of intracavernosal injection therapy (ICI) for patients status-post radical prostatectomy.

**Material and Method(s):** A 12-page questionnaire was sent to 999 patients on ICI, 262 patients returned the questionnaire. Of these patients, 28 were status-post radical prostatectomy (RP). Using validated indexes, patients were evaluated for changes in penile rigidity, IIEF and satisfaction with ICI. Results were compared to ICI patients who had not undergone radical prostatectomy.

**Result(s):** Length of ICI treatment for post-RP patients averaged 5.6 years (range 0.3 – 16 years). Pre and post-treatment IIEF was 28.96 and 54.57, respectively, for these patients. This was not significantly different when compared to non-RP patients (32.76 and 59.05) ( $p=0.25$ ). Patients post-RP had lower Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) scores as compared to non-RP patients ( $p=0.05$ ). Interestingly, subjective satisfaction was similar between the two groups. ( $p=0.47$ ).

**Conclusion(s):** Patient status-post RP can be successfully treated with ICI and expected results may be similar to non-RP patients with regard to IIEF and subjective satisfaction with treatment.

### Disclosure:

Work supported by industry: no.

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## Prevalence and predictors of erectile dysfunction in Afro-Caribbean males with Type 2 Diabetes Mellitus: Is the glycosylated hemoglobin level predictive?

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**Objective:** Diabetes Mellitus (DM) is seen in 6.4% of the male population in Jamaica. We sought to determine the prevalence and predictors of erectile dysfunction (ED) in a population of Jamaican males with Type 2 DM, as well as evaluate the association of level of glycosylated hemoglobin (HbA1c) and severity of ED in these patients.

**Materials and Methods:** A cross-sectional survey was conducted of consecutive sexually active adult men (>18 years) with Type 2 DM attending ambulatory diabetic clinics in Kingston, Jamaica between February 1 and June 30, 2013. The International Index of Erectile Function (IIEF) - 5, International Prostate Symptom Score (IPSS) and Overactive Bladder- short

form and quality of life (OABq-SF and QOL) questionnaires were administered by interviewers. Questionnaires related to DM, its complications and treatment and other risk factors were completed. Weight (kg), height (m) and body mass index (BMI) ( $\text{kg/m}^2$ ) were measured. Serum HbA1c levels were tested in all patients.

**Results:** 185 men of mean age  $56.3 \pm 14.7$  (range 19.4-83.3) years were recruited. The overall prevalence of ED was 81.6 % (mild- 18.9%, moderate- 24.3%, severe- 38.4%). Using stepwise multiple linear regression analyses, the main predictors of erectile dysfunction were increasing age (CI: -0.37 to -0.15) and elevated systolic blood pressure (CI: 10.17 to -0.02). There was no significant correlation between HbA1c levels and erectile dysfunction. However, men with severe ED had lower HbA1c levels than other groups,  $p<0.05$ . Duration of DM was longer in the more severe ED categories. There was a negative relationship between OAB symptoms and ED and a positive relationship between OAB-QOL scores and ED ( $p<0.001$ ).

**Conclusions:** ED is very common in Jamaican diabetic males, with increasing age and elevated blood pressure being major predictors. Surprisingly, HbA1c does not appear to be predictive of severity of ED in these men.

### Disclosure:

Work supported by industry: yes, by Pfizer (industry funding only - investigator initiated and executed study).

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## Testosterone supplementation improves sexual function in hypogonadal men

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**Objectives:** Testosterone supplementation therapy is commonly used to treat men with hypogonadism. However, it is unclear whether testosterone supplementation improves symptoms in men with moderate erectile dysfunction. In this study we examined the effect of testosterone supplementation on sexual symptoms in hypogonadal men. We also compared the change in erectile function in patients with and without the use of phosphodiesterase 5 inhibitors (PDE5).

**Material and Methods:** We prospectively followed hypogonadal men with total serum testosterone  $< 300\text{ng/dL}$  and at least 3 (+) symptoms on Androgen Deficiency in Aging Male (ADAM) questionnaire. Men filled both the Sexual Health Inventory for Men (SHIM) and the ADAM questionnaire at an initial visit prior to starting testosterone supplementation and during follow-up. Patients were started on PDE5 therapy if they had severe ED (SHIM  $> 17$ ). We excluded men who used intracavernosal injections. An unpaired test was used to analyze the patient's changes in testosterone and SHIM scores.

**Results:** A total of 38 hypogonadal men were included in the

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study and were followed for median of 6.5 months and mean age of 49.5 years. Serum testosterone increased from a median of 320 ng/dl to 650 ng/dl. Erectile function improved following testosterone supplementation. SHIM score increased from  $16.4 \pm \text{SD}$  to  $18.9 \pm \text{SD}$  after testosterone supplementation ( $p = 0.044$ ). Of the 38 men, 22 patients were placed on injectable testosterone supplementation and 16 were placed on topical testosterone gels. SHIM scores improved regardless of the modality of testosterone supplementation ( $p = 0.02$ ). SHIM scores improved in both men who were not on PDE5 inhibitors ( $n=24$ ) and 14 men who were on PDE5 inhibitors ( $p < 0.05$ ).

**Conclusions:** Testosterone supplementation in hypogonadal men improves erectile function. Testosterone therapy appears to improve erectile function in hypogonadal men regardless of whether PDE5 inhibitors were used. Further studies are needed to elucidate the role of TRT and its role in the penile erectile axis.

**Disclosure:**

Work supported by industry: no.

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**Identifying obstructive sleep apnea risk using a single-item question**

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**Introduction:** Erectile dysfunction (ED) has numerous underlying etiologies and risk factors. Recently obstructive sleep apnea (OSA) has been shown to be an independent risk factor for ED. Patient's with OSA have increase daytime somnolence but often deny poor sleep quality. In this abstract we aim to examine the relationship between suboptimal quality of sleep and OSA in middle-aged men using a single-item question from the Patient Health Questionnaire-9 (PHQ-9).

**Material and Method:** We analyzed 826 male participants in the WTC-CHEST Program from January 2011 to September 2013. The PHQ-9 is a screening tool for depression and anxiety. Question 3 of the PHQ-9 asks whether the patient has "trouble falling or staying asleep, or sleeping too much" A dichotomous analysis of the PHQ-9 question 3 was performed where sleep disturbance was classified as either 1) none to occasional (not at all and several days) or 2) often to always (more than half the days and nearly every day). The Berlin Questionnaire (BQ) is used to indicate risk for OSA, and has a sensitivity of 86% and specificity of 87%. High risk for OSA was defined as 2 or more positive categories on the BQ.

**Results:** The mean age of this group was  $51.36 \pm 6.07$  years. Those with high risk for OSA had significantly greater sleep disturbance, 60.3% vs. those with low risk for OSA, 39.7% ( $p < 0.001$ ). When adjusted for age, hypertension, and diabetes the results remained significant ( $p < 0.001$ ).

**Conclusion:** In our analysis, a significant association between

high risk for OSA and suboptimal quality of sleep exists. Using a single-item question can be an effective and timely way to assess for OSA risk. Further analysis using a validation sample is warranted. Assessing for suboptimal quality of sleep is necessary not only as a risk factor for ED but also for adequately assessing men's health.

**Disclosure:**

Work supported by industry: no.

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**Preliminary assessment on the treatment of erectile dysfunction with Trimix gel**

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**Objective:** Combinations of papaverine, phentolamine and prostaglandin ("Bimix"/"Trimix") have been used for intracavernosal injections (ICI) for 30+ years. These medications can also be prepared in a stable gel form, Intraurethral Trimix Gel (TMG), which provides an easy, needle-free application. This data provides an early review of TMG outcomes for erectile dysfunction (ED).

**Material and Methods:** Over two-months (5/2014 – 7/2014)  $n = 8$  patients were prescribed TMG for the needle-free convenience as a substitute to ICI for the treatment of ED. Three (38%) had diabetes, 5 (63%) were post-radical prostatectomy and all (100%) had other comorbidities (i.e. hypertension, hyperlipidemia). Mean age was 66 (range 46-78). Formulation of TMG was 30mcg papaverine, 4mcg phentolamine and 1000mcg PGE1 (per ml). Patients received 10-12 prefilled syringes containing 1mL of gel per syringe. Patients were instructed how to properly insert the gel to promote absorption and maximize outcomes at doses from 0.25-1.0mL.

**Results:** Comparing pre-TMG and post-TMG Sexual Health Inventory For Men (SHIM) scores, the average was 6.2 (range 1-16) and 19.7 (range 14-25), respectively. The pre-TMG scores represent patients being off all forms of ED therapy. Three patients did not provide post-TMG SHIM scores and were excluded from the calculations. Patients responded favorably regarding the medication's efficacy. They reported an average rigidity post gel administration of 90%, and all choose to abandon ICI in favor of TMG. None of the patients decided to return to ICI. All patients reported being "very excited" about needle-free drug delivery. No adverse events were reported.

**Conclusions:** Trimix Gel may have several advantages over both phosphodiesterase inhibitors (PDE5-I) and traditional, ICI. This needle-free option for Trimix is an important addition in sexual medicine, as patients require alternatives for ED care. Preliminary results with TMG are favorable, yet further clinical data will help determine its place in urologists' armamentarium.

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## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Changes of sexual function after photoselective vaporization of the prostate by 120W greenLight high performance system laser: Long-term follow-up

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**Objective:** To evaluate the impact of 120W GreenLight High Performancer System photoselective vaporization of the prostate (HPS-PVP) on erectile function at long-term follow-up in men with LUTS due to benign prostatic hyperplasia (BPH)

**Material & Methods:** Three hundred and fifty-one consecutive patients who underwent HPS-PVP during 2008-2012 were analyzed retrospectively. We divided all patients into three groups: group I (International Index of Erectile Function (IIEF-5)  $\leq 7$ , n = 202), group II (8  $\leq$  IIEF-5  $\leq 16$ , n = 90) and group III (IIEF-5  $\geq 17$ , n = 59) according to the preoperative IIEF-5. The patients were assessed before surgery and at 3, 12 and 24 months after HPS-PVP. We measured IPSS, QoL, Qmax, post void residual volume and IIEF-5 at each visit. The risk factors were evaluated for over three IIEF-5 points decrease at postoperative 3 months.

**Results:** The mean age, presence of hypertension, prostate volume, IPSS and QoL were significantly different among three groups. Perioperative parameters such as operative time, applied energy, catheterization time and postoperative complication rates showed no statistical differences. In all groups, main parameters following operation such as IPSS, QoL, Qmax, and post void residual volume had significant improved compared to baseline. Whereas, the IIEF-5 was significant decrease in group II and group III. On the contrary, Group I was increased. In group II and III, multivariate analysis showed that the age, BMI, and prostate volume were significantly related to a diminution of erectile function after HPS-PVP.

**Conclusion:** Sexual function was significantly deceased after HPS-PVP except patients with preoperative severe erectile dysfunction (IIEF-5  $\leq 7$ ). The age, BMI, and prostate volume were the independent risk factors for erectile function decline after HPS-PVP.

Table 1. Changes in IIEF-5 scores from baseline to long-term follow up

Group	IIEF-5	Initial (n=202)	3mo (n=90)	1yr (n=80)	2yr (n=70)
Group I	IIEF-5	2.3 $\pm$ 1.7	3.7 $\pm$ 4.4	4.9 $\pm$ 5.8	3.8 $\pm$ 5.3
	P value	-	0.008	0.043	0.181
Group II	IIEF-5	11.2 $\pm$ 2.5	9.8 $\pm$ 6.9	9.8 $\pm$ 7.0	9.4 $\pm$ 7.8
	P value	-	0.019	0.012	0.044
Group III	IIEF-5	20.8 $\pm$ 2.4	17.8 $\pm$ 6.1	17.0 $\pm$ 6.8	16.3 $\pm$ 7.1
	P value	-	0.008	0.002	0.012
All Patients	IIEF-5	7.8 $\pm$ 7.3	8.0 $\pm$ 7.6	7.9 $\pm$ 7.6	7.6 $\pm$ 7.8
	P value	-	0.308	0.292	0.088

## Disclosure:

Work supported by industry: no.

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## The relationship between carotid artery disease and erectile dysfunction

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**Objective:** Erectile dysfunction (ED) and carotid artery disease are known predictors of cardiovascular disease. However, little is known regarding the relationship of carotid artery disease with ED. Elucidation of the relationship of ED with carotid plaque would be helpful in comprehensive and detailed management in ED patients. Therefore, we evaluated the relationship of carotid artery disease with and ED.

**Material and Methods:** We enrolled 799 men who had participated in a health examination. During this examination, they received an international index of erectile function-5 (IIEF), a carotid duplex ultrasound, and a full metabolic work-up. The plaques were classified into three groups according to the severity of plaque size (absence:  $\leq 1$  mm, mild: 1.1–2.0 mm, and moderate to severe:  $\geq 2.1$  mm). Additionally, we classified ED as normal, mild, mild to moderate, moderate, and severe for IIEFs of  $> 21$ , 16–21, 11–16, 7–11, and  $\leq 7$ , respectively. We investigated the relationship between carotid artery plaque with ED using the Spearman correlation test, the Mantel-Haenszel Extension test, and logistic regression analyses.

**Results:** The median age was 57 years, and the median IIEF were 15. The IIEF showed a significant negative linear correlation with maximum intima-media thickness (max IMT) (correlation coefficient = -0.132,  $P < 0.001$ ). Additionally, there was a significant increase in the severity of ED with increased the severity of plaque size ( $P$  trend  $< 0.001$ ). There was a greater likelihood of having moderate ED in the moderate and severe plaque size groups when compared to the absence of plaque group, after adjusting for age and components of metabolic syndrome (odds ratio [OR] = 1.672,  $P = 0.021$ ).

**Conclusions:** In this study, the IIEF were significantly correlated with increased plaque size. Our data indicates the potential role of ED as predictors of carotid artery plaque.

## Disclosure:

Work supported by industry: no.

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## Inflatable penile prosthesis after quadratic transobturator male sling procedure

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**Objective:** Following radical prostatectomy (RP), the



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development of stress urinary incontinence (SUI) and erectile dysfunction (ED) are known complications. After medical treatment fails, inflatable penile prosthesis (IPP) and transobturator male sling validated surgical options. Our goal was to assess the feasibility of IPP following sling placement.

**Material and Methods:** Eight patients who were initially treated for SUI at our institution by the quadratic transobturator sling were found to have subsequent ED. All patients were socially continent; 3 patients complained of leakage of urine with sexual activity or orgasm. All men failed medical management for ED and were offered IPP, via our subcoronal approach. Each patient was preoperatively evaluated by age, complete medical history, ASA score, cystoscopy, pad-test, and urodynamics. All patients had both procedures performed separately in the outpatient operative setting. Post-operative follow-up was focused on complications and efficacy.

**Results:** After a minimum of 6 month follow-up, no perioperative complication occurred. All patients remained pad-free with no leakage reported. All patients remain sexually active. Three patients experienced transient bladder outlet obstruction requiring catheterization. 2 patients had spontaneous resolution of urinary retention after two weeks and the third patient experienced high residuals for up to three months. Currently all 3 patients are doing well and are fully satisfied.

**Conclusions:** Placement of inflatable penile prosthesis after quadratic male sling may increase the tension of the prepubic arms across the urethra. This may explain the transient urinary retention and improved continence in this cohort of patients. Our initial experience has demonstrated that, IPP surgery is not complicated in patients who had previous quadratic transobturator male sling. A penile prosthesis is feasible and continues to lead to excellent functional results and may improve continence without complications.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Deep glansplasty for impending medial distal extrusion of penile prosthesis cylinders

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**Objective:** Medial distal extrusion of a penile prosthesis (PP) cylinder is a rare but potentially devastating complication. We describe a novel "deep glansplasty" reconstructive technique for managing impending medial distal extrusion using natural tissue support without the need for device replacement.

**Materials & Methods:** We reviewed patients who underwent deep glansplasty procedures for impending medial PP cylinder extrusions. A distal, semi-circular incision was made just proximal to the coronal sulcus on the involved side. The tip

of the cylinder was then exposed, reflected laterally, allowing access to the medial pseudocapsule tissue, which was then plicated to itself using several 2-0 braided, non-absorbable sutures, recreating a stable backing for the tip of the cylinder in the previously weakened medial tissue. If the cylinder was too long, a second penoscrotal incision was made, the cylinder removed, and the rear-tip extenders downsized. The device was then replaced and the lateral corporotomies were closed.

**Results:** Four patients underwent a total of 5 deep glansplasty procedures (one bilateral). With a mean of 6 months follow-up (range 4-10), all patients report excellent function and no patient has required a further procedure. One patient with previous severe priapism underwent deep glansplasty of his left cylinder, and subsequently developed an impending medial extrusion of the right cylinder, which was successfully repaired.

**Conclusion:** Deep glansplasty via medial pseudocapsule plication offers a safe and effective minimally-invasive solution for impending medial distal cylinder extrusion.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Penile to scrotal length ratio and its influence on male attractiveness

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**Objective(s):** Determine through an anonymous online survey individual's appreciation of male attractiveness with regards to penile to scrotal length ratio to give both the patient and genital surgeon basic guidelines on what is considered attractive when performing surgery of the genitalia.

**Material and Methods:** A five-question survey for individuals greater than 18 years old was administered during the period of May 30, 2014 to July 1, 2014. Questions asked were: 1. Age range, 2. Geographic location, 3. Gender identity, 4. Sexual orientation, 5. Preference among figures demonstrating three different scrotal lengths to flaccid penile length ratios viewed anteriorly deemed attractive in the male pelvic region. The link to the survey was sent through e-mail addresses, SMS messaging and social media to the study authors' contacts.

**Result(s):** There were 504 respondents, most of them between the ages of 25 and 34 (n=270), followed by 30% between 35 and 44 years of age (n=104). Overall, more respondents were female (60%) than were male (40%). The prominent sexual preference was heterosexual (93%), homosexual 4%, and 3% as bisexual. Nearly two-thirds of respondents (67%) preferred option A, the average penis size with scrotal length above the level of the glans penis. Slightly less than one-third (29%) option B, the average penis size with scrotal length at the level of the glans of the penis. The remaining 4% option C, the average penis



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size with scrotal length below the glans of the penis. Option A was favored by all age groups, except for respondents over the age of 75 ( $p < 0.001$ ). The majority of respondents that selected option C (62%) were between the ages of 25 and 34.

**Conclusion:** We found that the ideal position of the scrotum is above the glans of the flaccid penis. This study provides a foundation for surgeons to suggest against patients desiring excessively large scrotal implants which will lead to a C ratio and supports patients desire for scrotal lift surgeries for aesthetic or hygienic reasons. Our limitations were the nature of the study design and the lack of obligatory response to all of our five questions.

**Disclosure:**

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**A retrospective analysis of health and socioeconomic factors of IPP patients: Active substance abuse concurrent with surgery as a newly-identified infection risk factor**

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**Objective:** In the past 10 years a single surgeon has implanted 590 IPPs at our institution. In that same period, we have noted an infection rate of approximately 2% of new IPPs. Surgical technique has remained consistent, with the addition of innovations as they arise, but without substantive change in the infection rate. A retrospective analysis was performed to examine potential patient health and socioeconomic factors that influence our IPP infection rate. Our investigation revealed that patients engaging in substance abuse at the time of implantation are more likely to have infection after IPP placement.

**Material and Methods:** This is a retrospective single-institution study of 590 patients who underwent IPP placement. Relevant elements of patients' operative notes and charts were extensively reviewed to compile study data. Rigorous statistical analysis was performed.

**Results:** Between 2002 and 2014, 590 patients underwent IPP placement. Age, operative data, and rates of hypertension, hyperlipidemia, diabetes, HIV status, and MRSA infection were established. Also documented were HbA1c, preoperative blood glucose, CD4 count, active and historical substance abuse, former and current smoking, insurance status, employment status, homelessness, and ethnicity. Post-operative infection occurred in 12 patients. Of these, 5 (42%) were engaged in substance abuse at the time of infection. The rate of documented concurrent substance abuse in the 590 total implants was approximately 5%. No other patient socioeconomic or health factors approached statistical significance.

**Conclusions:** Active substance abuse at the time of implantation appears to be a newly-identified risk factor for IPP infection in our population of IPP patients over the past

10 years. Other health and socioeconomic factors were not relevant to IPP infection risk. Further correlation with data pools from other providers is needed to verify this highly preventable risk factor.

**Disclosure:**

Work supported by industry: no.

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**Preoperative penile measurements guide size selection of penile prosthetic implant**

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**Objective:** The selection of penile prosthetic size used at the time of surgery is typically based on multiple intraoperative measurements of the crus to corporotomy and corporotomy to glans. Size modifications of the implant can be performed to better approximate the implant and often require multiple manipulations of the implant. We aimed to evaluate the selection of penile prosthetic size used during virgin inflatable penile prosthetic surgery and whether preoperative penile length measurements can help guide implant size selection.

**Materials and Methods:** From January 2013 to June 2013, the charts of 91 patients who underwent placement of virgin penile prostheses were reviewed. All patients underwent implantation of a 3-piece inflatable Coloplast Titan® penile prosthesis by a single surgeon. Prior to surgery, all patients had measurements taken of the stretched penis and the erect penis following intracavernosal injection of alprostadil. These measurements were then compared to the size of the prosthetic implanted on the day of surgery. A successful implant size was one that required less than 2 cm in size adjustment.

**Results:** Median lengths (in cm) of the stretched penis and penis following pharmacologically-induced erection were 16 and 14, respectively (Range 8-18). Median length of prosthetic implant used during surgery was 20 cm (Range 18-26). On average, the difference between preoperative penile length and prosthetic implant was 6 cm for the stretched penis and 7 cm for the pharmacologically-erect penis. The accuracy of prediction for the stretched penis using 5, 6, and 7 cm was 58%, 65%, and 45% respectively. The accuracy of prediction for the erect penis using 6, 7, and 8 cm was 63%, 79%, and 36% respectively.

**Conclusions:** An estimate of implant size based on preoperative penile measurements can serve as an adjunctive metric for the Urologist in implant size selection. Adding 6 cm to the stretched penis or 7 cm to the erect penis provides the highest accuracy of prediction in selecting prosthetic size. This information can help guide the Urologist in preoperative prosthetic size selection and may minimize intraoperative manipulations of the implant.

**Disclosure:**

Work supported by industry: no. The presenter or any of the

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authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Effect of hypogonadism on the management plan of severe vasculogenic erectile dysfunction (ED)

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1: USA

**Objectives:** Approximately 30 million men are affected by erectile dysfunction (ED) in the United States. Men with ED suffer from depression and decreased quality of life (QOL). The guidelines set for treatment of ED excluded the patients with endocrinopathies.

Our study is meant to look at the patients diagnosed with severe vasculogenic ED with concomitant hypogonadism. Is there a significant delay in their treatment plan compared to the eugonadal ED patients?

**Materials and Methods:** All penile implant surgeries done consecutively by a single surgeon from January to September, 2013 were reviewed. Severe vasculogenic ED was documented. Patients with hypogonadism together with patients who had ED and prostate cancers were sorted in two groups to be compared to the rest of the patients who will serve as the control group. We looked at the time elapsed from the date the patients had their penile Doppler study done until they had their surgery as a definite treatment to their ED.

**Results:** 164 ED patients were divided into 3 groups. Group A: 20 patients who were diagnosed with hypogonadism, Group B: 29 patients who had ED and prostate cancer. Group C: 115 patients who will serve as the control group. All 164 Patients eventually underwent a penile implant placement surgery after they weren't satisfied by any other treatment option to solve their ED problem. Group A patients had to undergo Testosterone replacement trial before surgery. The average time lag between the penile Doppler studies and penile implant surgery was 6.5, 3.8 and 2.9 months for group A, B and C respectively. The time lag was significantly higher in Group A compared to Group C (p-value < 0.01).

**Conclusion:** In patients with vasculogenic ED and hypogonadism, TRT alone did not resolve their ED; it only delayed their eventual penile implant allowing these patients to suffer the emotional stress of ED for a longer period of time.

### Disclosure:

Work supported by industry: no.

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## The minimally invasive infrapubic inflatable penile prosthesis: Our most recent 1000

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**Objective:** Analysis of a simplified approach for infra-pubic IPP and review of efficacy, post-operative morbidity, and patient return to function.

**Methods:** Retrospective review of N = 1032 IPPs (Jan 2010- May 2012) from one surgeon. All cases were Coloplast Titan 3-piece IPP's. 823 patients were original implants (80%), 185 revisions (18%) and 29 reimplants (2%). Patients received similar pre/intra-operative antibiotic prophylaxis (flouroquinolone/hibiclen 24-hours before the procedure and Vancomycin/Gentamycin pre-op). The Minimally Invasive approach was presented (SMS 12/07), modifications include: no catheter, no dilation unless the "Scratch" technique was utilized, only 125cc reservoirs are utilized. All patients receive a #7 JP drain (removed the following day). Patients were reviewed post-op for six-weeks. All complications were reported.

**Results:** The Minimally Invasive (Perito Penile Implant) technique was easily reproduced in 574(70%) virgin cases. The remaining 247(30%) virgin cases required ancillary techniques (i.e. Modeling/Scratch). All revision cases were conducted via infra-pubic technique regardless of initial approach. 11 infections (.94%) occurred and 10 (90%) were successfully salvaged. Two mid urethral injuries occurred and were aborted. Two patients showed significant scrotal hematoma and required drainage. No patients experienced glandular anesthesia or hypoesthesia after six-weeks. (90%) of patients were instructed to resume sexual function at four-weeks and balance of patients by six-weeks.

**Conclusion:** The Minimally Invasive infra-pubic IPP is safe, efficacious and offers patients a rapid return to sexual function. Post-op outcomes mirror clinical literature of other approaches.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## "Just the Tip": Closed suction drain cultures after penile implant surgery with prolonged drains

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**Objectives:** Closed suction drains have been used in penile prosthetic surgery for some time to prevent hematoma formation. There does exist the concern that these foreign bodies may actually increase the risk of infection, by allowing bacteria found on the skin to migrate in a retrograde fashion into the wound. We present the culture results of these drains at different distances from the skin to assess for bacterial colonization.

**Materials and Methods:** In the past, we have presented our series of drains status post placement of an inflatable penile prosthesis. It consisted of approximately 100 drains left in for

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72 hours, and none have experienced an infection to date. The last 10 drains removed have had two portions sent for anaerobic and aerobic culture, the distal tip and a section 1cm from the skin. An alcohol pad was first used to sterilize the skin, and all drains were removed in standard fashion.

**Results:** All 10 patients had their drains in place for 72 hours. None had any evidence of a hematoma at the time of drain removal. All 10 distal drain tips showed no evidence of bacterial growth. Only one of the ten distal drain sections, 1cm from the skin, showed 2 colony forming units (CFU) of *Staphylococcus* (coagulase negative). The other nine, at 1cm from the skin, showed no growth after 48 hours.

**Conclusions:** Hematoma formation after penile prosthetic surgery can cause patient discomfort, prolonged postoperative recovery time, and may even act as a medium for potential bacterial proliferation. Postoperative drain placement has been shown to decrease the rate of hematoma formation while not increasing the risk of infection. In our series of prolonged drainage, of at least 72 hours, none have developed infections. Opponents of drain placement endorse the argument that there exists a hypothetical risk that the longer the drain is left in place, the higher the likelihood that bacteria may contaminate the surgical site possibly compromising the implant. We now present our initial series of drain sections, at different distances from the skin, sent for culture. Even after a prolonged period of time, the drain portions within the surgical site, in close contact with the prosthetic, do not show any evidence of bacterial colonization, even the sections close to the skin. While drain placement is still a surgeon preference, these results further supports the safe usage of closed suction drains in penile prosthetic surgery for the prevention of hematoma formation.

## Disclosure:

Work supported by industry: no.

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## Ventral or dorsal penoplasty for hypermobile floppy glans after penile prosthesis

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**Objectives:** After treatment of erectile dysfunction with penile prosthesis, a small portion of patients have a hypermobile floppy glans that can make intercourse painful or difficult. Ventral floppy glans has been described as SST deformity, but dorsal floppy glans can also occur. After confirming accurate prosthesis sizing, previously described techniques for surgical repair of SST deformity have involved dissecting the glans off of the tips of the corpus cavernosa and fixating the glanular Buck's fascia further proximally on the tunica albuginea of the cavernosa. We present a novel surgical technique for penoplasty of either dorsal or ventral hypermobile floppy glans.

**Material and Methods:** With the penile prosthesis fully erect, clamps are used to imbricate the skin and dartos fascia on the

side opposite of the direction of the floppy glans until the glans is in line with the penile shaft. The skin and dartos fascia within these clamps are excised in an elliptical fashion. Then the cut edges of the dartos fascia are reapproximated using simple interrupted absorbable sutures, and the same is done for the skin. This holds sufficient tension opposite the direction of the hypermobile glans, resulting in a functionally straight glans.

**Results:** A total of 10 penoplasties have been performed at our institution, including 6 for ventral floppy glans and 4 for dorsal floppy glans. All patients have been satisfied with their surgical outcomes, and none have required additional surgical correction of their floppy glans.

**Conclusions:** Penoplasty is a safe and effective technique for correction of ventral or dorsal hypermobile floppy glans after penile prosthesis.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Glans fixation for floating glans (supersonic transporter deformity) during penile prosthesis placement, without additional incisions

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**Objective:** Supersonic transporter (SST) deformity is a known complication following inflatable penile prosthesis (IPP) surgery and occurs when the glans penis does not assume its normal anatomic position atop the penile shaft after IPP placement. SST deformity may lead to buckling of the glans and therefore poor ability to penetrate during intercourse, causing dissatisfaction for men and their partners. Our goal was to assess the feasibility of SST repair through the original IPP surgical incision.

**Materials and methods:** Eighteen patients who intraoperatively were found to have SST deformity following IPP placement through a subcoronal surgical incision, underwent glanulopexy using absorbable suture prior to skin closure.

**Results:** The subcoronal incision allowed for easy access to both the ventral and lateral aspects of the glans and permitted simple fixation to allow the glans to be evenly reapproximated onto the corporal bodies providing a more natural fit. At 6 month post-operative follow-up, none of these 18 men displayed recurrent SST deformity when fully inflated.

**Conclusions:** SST deformity is a known complication following IPP placement and can result in poor patient and partner sexual satisfaction. We demonstrate a surgical technique for correcting this at the time of prosthesis placement. Using the subcoronal approach for prosthesis placement allows for the repair of SST deformity without an additional incision.

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## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Concomitant IPP and Virtue® male sling placement utilizing a single incision

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**Purpose:** We sought to describe an alternative technique for placement of an inflatable penile prosthesis (IPP) and a quadratic male bulbourethral sling (Virtue®) through single perineal incision. Our group previously reported on concomitant implantation of an IPP and two-arm transobturator male sling through a single perineal incision. We herein report on a technique adapted to the Virtue® male sling for the treatment of post prostatectomy incontinence and erectile dysfunction.

**Methods:** IPP insertion proceeds through a 4cm perineal incision with dissection of the perineal-scrotal fat until both corpora cavernosa are identified and Buck's fascia is uncovered bilaterally. A 1.5 cm vertical corporotomy is performed between four 2-0 PDS pre-placed stay sutures in each corporal body. Proximal and distal dilation followed by corporal measurements are completed in the standard fashion and the corresponding cylinders are implanted. After closure of the corporotomies, the transversalis fascia at the external inguinal ring is perforated inferior and medial to the spermatic cord with Metzenbaum scissors through the same perineal incision, which can be further extended should the external ring prove difficult to reach. The reservoir is then placed with a rubber-coated ring forceps in the space of Retzius which is developed bluntly with an index finger with the aid of a baby Dever retractor. The pump is then placed in the left dependent scrotal dartos pouch, with standard tube connecting.

The Virtue® sling placement then follows after adequate exposure of the bulbospongiosus muscle is completed. While preserving the muscle, dissection is carried bilaterally to identify the inferior rami. 2-0 Prolene figure-of-eight afferent limb anchoring stitches are placed into the periosteum of the inferior rami bilaterally. The transobturator arms are passed using a J hook introducer to a previously marked location 2 cm inferior to the adductor longus tendon. The pre-pubic arms are brought through skin 2 cm above the symphysis pubis and lateral to the midline bilaterally. The afferent limb sutures are brought through the mesh just superior to the intersection of the mesh body and afferent limbs. The sling is then tensioned under cystoscopic guidance providing both direct compression and urethral elevation.

**Conclusions:** Concomitant placement of an IPP and virtue male bulbourethral sling is an efficient and safe for the simultaneous treatment of post prostatectomy incontinence and impotence. The utilization of a single incision is a novel approach for dual

implantation of these devices and may decrease the recovery time by eliminating the penoscrotal incision.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Delayed post-operative hematoma formation after inflatable penile prosthesis insertion

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**Objective:** Infrequent but serious post-operative complications following Inflatable Penile Prosthesis (IPP) insertion include infection, malfunction, and bleeding. Bleeding complications may occur immediately after surgery or may be delayed several days to weeks. Prior publications report methods to reduce immediate post-operative bleeding, but there is little in the literature concerning the etiology, diagnosis, and management of delayed bleeding following IPP insertion. The aim of the study is to review the incidence and management of patients who developed a delayed (defined as greater than five days post-operative) hematoma.

**Material and Methods:** A retrospective chart review was performed on 600 consecutive patients who were implanted with an IPP by a single surgeon. The data was analyzed to determine the incidence, etiology, and treatment of a delayed post-operative hematoma.

**Results:** Three out of 600 consecutive patients (0.5%) developed a delayed post-operative hematoma following IPP insertion. These patients were managed with intravenous antibiotics, wound exploration, hematoma evacuation, and antibiotic washout. All three patients' IPPs were successfully salvaged and none developed peri-prosthetic infection. The two etiologies of delayed hematoma formation that were identified included excessive post-operative physical activity and premature use of anticoagulants.

**Conclusions:** The incidence of delayed post-operative hematoma following IPP insertion is a rare occurrence. If the surgical incision remained intact, then conservative management was attempted. If the incision was open and draining blood, we were able to successfully salvage the IPP with surgical exploration. Based on our findings we recommend avoiding anticoagulants for at least five days post-operatively and avoiding vigorous physical activity for at least three weeks following IPP insertion.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## **A series utilizing the “Molly Brown” stitch during inflatable penile prosthesis placement**

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**Objectives:** The inflatable penile prosthesis (IPP) carries the highest rate of patient and partner satisfaction for all modalities of erectile dysfunction treatment. There are however, a number of complications that can alter this, one being the abnormality known as the “Maserati Tail Pipes”, where the IPP cylinder exit tubing is palpable, sitting on the proximal shaft. This can cause discomfort to the patient and partner during intercourse, and can be unsightly. This may also be associated with IPP pump migration. Proper cylinder sizing, and proximally made corporotomies will help prevent this deformity, but we have added an additional step, a deep dartos stitch utilized to bury the exit tubing and fix the pump at the most dependent position of the scrotum, what we have coined the “Molly Brown” stitch.

**Materials and Methods:** From 2011 to 2014, over 500 IPP's have been placed utilizing the “Molly Brown” stitch. The IPP's were placed following our standard protocol. After system assembly and placement of the pump in the dartos pouch, a 2-0 Vicryl is used to reapproximate the deep dartos tissue over the tubing. The procedure is then completed with an additional two-layer closure and standard postoperative management.

**Results:** Over 500 “Molly Brown” stitches have currently been placed at our institution. At this time, no patients have complained of palpable exit tubing, and no “Maserati Tail Pipes” have been noted on routine postoperative visits. None of the patients have complained of pump migration and none have had difficulty manipulating the pump.

**Conclusions:** Ensuring the highest rate of patient and partner satisfaction is the most important aspect when treating erectile dysfunction. Although the IPP carries the highest rate, there are certain situations that can alter this, and lead to patient and partner dissatisfaction. We have shown that a small additional step, during IPP placement, utilizing the “Molly Brown” stitch, allows for burying of the exit tubing and prevention of the “Maserati Tail Pipes” and migration of the tubing and pump caudally. Alone, this modification is not enough. One must ensure proper cylinder sizing and corporotomies as proximal as possible in order to prevent palpable tubing on the proximal shaft and appropriate pump placement. It is the small details that help the patient achieve the highest rate of satisfaction possible, and the “Molly Brown” stitch helps obtain this goal.

### **Disclosure:**

Work supported by industry: no.

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## **Erectile dysfunction caused by a retropubic ganglion cyst - a rare tumor entity in the lesser pelvis**

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**Objectives:** Retropubic tumors without contact to bones or surrounding tissues are extremely rare with only 22 cases reported in the literature. The majority of tumors described within these reports are osteochondroma in 17 cases, 2 cases of leiomyoma and one case of each fibroma, fibrosarcoma and nodular fasciitis.

**Material and Methods:** We report a case of a 52 year-old-man who complained about symptoms of chronic prostatitis / LUTS with decreased erectile function since the last 6 months. The physical examination and the digital transrectal examination showed a slightly enlarged prostate without any other abnormalities. The urine culture were negative, PSA, hormones as well as serum blood levels were within normal limits. Transrectal ultrasound showed a 2cm retropubic mass between the pubic symphysis and prostate. CT-Scan and MRI revealed a tumor with cystic elements without contact to the surrounding tissue or bone.

**Results:** The tumor was resected “in toto” by laparoscopy. No complications occurred within the intra- and postoperative days and the patient was discharged from the hospital at the 4<sup>th</sup> day after surgery without any complaints. Histopathology showed a fibrous tumor with mucoid degeneration and pseudocystic elements without any malignant criteria, which confirmed the diagnosis of a retropubic ganglion cyst. No symptoms of prostatitis reoccurred in the follow-up of 12 months. The sexual function esp. erectile function recovered 4 weeks after surgery.

**Conclusions:** Retropubic isolated tumors are extremely rare and might cause voiding and/or sexual problems. Our case demonstrates the first laparoscopic resection of one of these “symptomatic” tumors with favorable clinical outcome, good cosmetic results and excellent erectile function recovery.

### **Disclosure:**

Work supported by industry: no.

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## **Are some US academic centers regulating themselves out of multicenter studies: The propper registry experience with IRB and contract approval**

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**Introduction and Objectives:** The “Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration” (PROPPER) study is a multi-center clinical registry collecting real-world outcomes for patients with penile implants. PROPPER is designed to document outcomes for American Medical Systems (AMS) 700 and Ambicor inflatable penile prostheses (IPPs), and Spectra penile implants. Validated patient questionnaires and electronic data collection are used to record baseline patient characteristics and surgical implantation details, and to prospectively measure response to treatment annually to five years post-implantation including durability, complications, and effectiveness (functional, satisfaction and quality of life) outcomes. There is no experimental treatments or randomization of patients. We evaluate IRB and contract approval timing and rates at 14 diverse centers.

**Methods:** After 2 years of expert review, discussion, evaluation, and approval, the PROPPER registry first patients were enrolled June 9, 2011. 7 sites are academic, 7 sites are private practice with 1 Canadian academic site and the 13 US sites spread across the country geographically. The private practice sites vary from small to large single specialty groups and large multi-specialty groups. The academic sites vary in size, number of urology residents, and academic / veteran administration hospitals utilized. We evaluated the length of days for contract approval, IRB approval time, and enrollment / activation date for each site. Group 1 consists of the 6 US academic sites while Group 2 consists of the 7 US private practice and the 1 Canadian academic site.

**Results:** The time from the start of contract negotiation to contract approval date for the US academic sites (Group 1) was 16 to 892 (average 295.5) days while group 2 was 3-420 (126) days ( $p = 0.204$ ). The time from the start of IRB submission to approval date for the US academic sites (Group 1) was 25 – 90 (53) while Group 2 was 4 -190 (41.4) days ( $p = 0.709$ ). Enrollment / activation date has occurred at all the US private practice / Canadian academic sites (Group 2) while 5 of the 6 Group 1 sites have occurred.

**Conclusions:** For this large multicenter prospective registry US academic centers have longer contract approval and IRB approval time in terms of length of days, but the difference is not statistically significant based on t test.

## Disclosure:

Work supported by industry: yes, by American Medical Systems / Endo (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## The effect on blood flow rate of prostate in daily administration of mirodenafil 50mg for benign prostatic hyperplasia patients: randomized controlled, double blinded trial

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**Introduction & objectives:** Erectile dysfunction (ED) and lower urinary tract symptom/ benign prostatic hyperplasia (LUTS/ BPH) has common pathophysiology. And phosphodiesterase type 5 inhibitor (PDE5-I) partially reverses the prostatic tissue contraction, and increases cyclic guanosine monophosphate to show antiproliferative effects in the prostatic smooth muscle cells and consequently, voiding symptoms were suggested to be improved. However, there was no definite mechanism of the effectiveness of PDE5-I on LUTS/BPH. Some previous study has reported the hypothesis which is PDE5-I improve the blood flow rate of prostate and it may improve the LUTS. In present study, by transrectal ultrasonography (TRUS), evaluated the change of blood flow rate of prostate after PDE5-I administration.

**Patients and Methods:** Total 16 patients were included in this study. Among enrolled patients, 9 patients had once daily administrated mirodenafil (MVIX<sup>®</sup>, SK chemical, Korea) 50mg for 1week, other 9 patients had administrated placebo daily. Peak systolic velocity (PSV) and end diastolic velocity (EDV) were estimated by TRUS at before medication and a day after last administration.

**Results:** Baseline characteristics were no significant difference between two groups. In mirodenafil group showed 4.82 cm/sec increase of PSV and placebo group showed 0.29 cm/sec increase of PSV ( $p=0.029$ ). Moreover, mirodenafil group showed 0.38 cm/sec increase of EDV and placebo group showed 0.19 cm/sec decrease of EDV ( $p=0.543$ ).

**Conclusion:** Once daily administration of mirodenafil 50mg showed improvement of blood flow rate of prostate.

Table 1. Baseline characteristics

	Mirodenafil group (n=9)	Placebo group (n=7)	p-value
Age, yrs	61.22±12.43	63.66±16.32	0.709
Prostate volume, mL	30.46±11.01	27.41±8.57	0.557
PSA, ng/mL	1.66±1.67	1.42±1.14	0.704
EDV, ng/mL	24.16±3.89	23.66±3.25	0.78
IPSS	15.22±16.85	16.86±10.67	0.781
IIEF-5	12.22±4.66	13.57±6.48	0.633

IPSS: international prostate symptom score, IIEF: international index of erectile function.

## Disclosure:

Work supported by industry: yes, by SK Chemical (industry funding only - investigator initiated and executed study).

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## Prospective study of patient experience following prostatic urethral lift

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**Objective:** To report the results of a prospective, non-randomized study designed to characterize the perioperative subject experience with the Prostatic Urethral Lift (PUL) procedure

**Material and Methods:** Subjects were  $\geq 50$  years old with IPSS  $\geq 12$ , peak flow rates  $\leq 12$  ml/s, and prostate volume between 30 and 80 cc. During the PUL procedure, permanent implants were positioned to mechanically pull the prostatic lateral lobes apart and enlarge the urethral lumen. Subject experience during the procedure was captured at specific points through a pelvic pain visual analog scale and through 1 month by validated instruments designed to assess quality of recovery, work productivity, activity impairment, symptom response, quality of life, flow rate and sexual function.

**Results:** 51 subjects were treated under local anaesthesia without any serious adverse events. No case was abandoned or postponed due to subject discomfort. Adverse events related to PUL were typically mild to moderate and resolved by 2 weeks. By one month, 86% of subjects were recovered ( $>80$  QOR), 90% reported improvement through PGI-I, 96% had returned to pre-operative activity, 100% of employed subjects had returned to work, and 75% of subjects would recommend the procedure to a friend. Average erectile function scores did not change significantly ( $17.9 \pm 6.4$  at baseline to  $18.2 \pm 7.3$  at one month;  $p=0.7$ ), and both ejaculatory function and bother were improved ( $p$  values  $< 0.01$ ).

**Conclusions:** PUL was tolerated under local anaesthesia and rarely required post-operative catheterization. Many patients quickly returned to pre-operative activity level while experiencing significant symptom and flow improvements. Sexual function was not adversely affected by the procedure; ejaculatory function may have improved. This study assists urologists in advising patients regarding post-procedural expectations and side effects of the PUL procedure.

### Disclosure:

Work supported by industry: yes, by NeoTract, Inc. (industry initiated, executed and funded study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Preserving sexual function with the Rezūm System: Using steam therapy to treat LUTS/BPH

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**Objectives:** The Rezūm® System is a novel transurethral device being developed for office-based treatment of LUTS/BPH. It is fundamentally different than earlier devices because it is based on the principle of controlled, phase-change, convective heating using steam to ablate tissue. This principle allows rapid tissue treatment, very short procedure times and “compartmentalization” of the vapor to the transition zone. Due to the convective transfer of stored thermal energy, it is hypothesized the energy and the procedure would not negatively affect erectile or ejaculatory function. The objective was to determine the effect of the Rezūm System on sexual function.

**Methods:** The Rezūm procedure was performed in 50 men aged 65.5 years ( $\pm 7.1$ ) under the REZUM I Pilot Study. Primary inclusion criteria included IPSS  $\geq 15$ , Qmax Peak flow rate  $\leq 15$  mL/sec with prostate volume 20 -120 gm and post-void residual  $< 300$  ml. Men were evaluated at baseline, 1 day, 1 week, 1, 3, 6 months, 1 year post procedure using the IIEF and IPSS questionnaire. PSA was also followed at a year.

**Results:** Baseline IPSS was  $20.9 \pm 5.0$  ( $n=50$ ) and changed to  $9.8 \pm 7.2$  ( $n=21$ ) at one year. There were no inclusion criteria for sexual function but at baseline 4/50 (8%) of participants had retrograde ejaculation and 24/50 (48%) had erectile dysfunction. Baseline IIEF-EF score was  $10.1 \pm 10.9$  ( $n=21$ ) and at 1 year had changed to  $10.5 \pm 11.1$  ( $n=21$ ). The SHIM score and PSA values showed no significant change in a year. No patient reported retrograde ejaculation at any follow-up visit.

**Conclusions:** Rezūm technology for minimally invasive treatment of LUTS/BPH demonstrated success rates with lowering the IPSS from severe symptoms to low moderate symptoms. Likewise, this success is augmented by the finding that sexual function is preserved through follow-up to a year with stable erectile function compared to baseline. Additional studies are warranted to validate the Rezūm System as an alternative treatment option for LUTS secondary to BPH.

### Disclosure:

Work supported by industry: yes, by NxTherma (industry funding only - investigator initiated and executed study). The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Contemporary outcomes for targeted denervation of the spermatic cord for chronic scrotal content pain

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**Objectives** Previous groups have shown microsurgical denervation of the spermatic cord (MDSC) as a possible treatment option for chronic orchialgia. Pathology and anatomical studies have identified specific nerve bundles within the spermatic cord that may be responsible for chronic pain in these men. This study presents contemporary outcomes for a robotic assisted targeted MDSC approach (RMDSC) utilizing a mapped nerve protocol to maximize preservation of vessels and lymphatics.

**Materials and Methods** This study is a retrospective case series review. 625 cases were performed from October 2008 to August 2014 by two surgeons. Technique modifications have occurred during this course of time including use of hydro-dissection to ligate small nerves on the vas deferens (while preserving the vasa vasorum) and use of a bio-wrap at the completion of the denervation to protect the cord (to decrease potential inflammation, scarring and neuroma formation). A detailed outcomes review of all 59 cases performed from December 2013 to August 2014 was performed to assess contemporary outcomes (using all the new technique modifications). Selection criteria for RMDSC were: chronic testicular pain (>3 months), failed all other standard pain management treatments and negative urologic workup. Pre and post-operative pain was assessed utilizing a standardized externally validated pain assessment tool: PIQ-6 (QualityMetric Inc., Lincoln, RI). Pain scores were recorded preoperatively and then postoperatively at 1, 3 and 6 months. Subjective patient reported response to the procedure was also recorded.

**Results** 64% of the patients had a significant decrease in their pain based on the validated objective PIQ-6 assessment tool. Subjective patient reported outcomes reported a significant reduction in pain in 81% (complete elimination of pain in 40% and a partial reduction in pain in 41%) by 6 months post-op. Complications were: 1 hydrocele, 3 hematomas, 2 seromas and 1 wound infection. Median f/u was 3 months (1-7).

**Conclusion** Targeted robotic assisted microsurgical denervation of the spermatic cord is safe and effective. Longer follow up and further evaluation is on-going.

### Disclosure:

Work supported by industry: no.

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## Are negative preoperative urine cultures necessary for artificial urinary sphincter placement?

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**Objectives:** Although patients undergoing artificial urinary sphincter (AUS) placement commonly have preoperative urine cultures performed, little evidence exists to support this practice in the published literature. In a tertiary referral setting, preoperative urine testing and treatment of asymptomatic positive cultures can be a costly, inefficient practice since many patients live remotely and culture results are often unavailable prior to surgery. We sought to evaluate the relationship of preoperative urine cultures with AUS infection or erosion rates.

**Methods:** We identified patients in our institutional database who underwent AUS placement by a single surgeon from 2007-2014. All patients received standard perioperative antibiotics with cephazolin (vancomycin if allergic) and gentamicin as well as three days of post-operative rifampin and ciprofloxacin. Positive preoperative urine cultures were treated only in symptomatic patients and these patients were excluded from this review. Three groups were identified: Group A (positive urine culture and no treatment), Group B (negative urine culture), Group C (no urine culture). Infection was defined by clinical diagnosis (fever, elevated white blood count, and/or gross pus at explantation) or a positive culture from the explanted device. A device was considered infected only in the absence of urethral erosion, which was determined cystoscopically.

**Results:** Over the study period, 277 AUS devices were implanted in 249 patients. AUS infection rates were similar in all 3 groups regardless of urine culture presence or results [Group A (positive urine culture and no treatment, 2/66, 3.0%); Group B (negative urine culture, 1/112, 0.9%, p=0.28); Group C (no urine culture, 2/88, 2.2%, p=0.77). Likewise, erosion rates compared to Group A (9.1%) were not significantly different in Group B (7.1%, p=0.62) or Group C (10.2%, p=0.82).

**Conclusions:** Pre-operative urine cultures in asymptomatic patients appear to be unnecessary. Routine perioperative antibiotics appear to prevent AUS device infection in patients with asymptomatic bacteriuria.

### Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Survey on the impact of sexual health issues on overall health, happiness, and quality of life

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1: American Sexual Health Association, USA; 2: Healthy Women; 3: Men's Health Network

**Objective(s):** To assess the impact of sexual health issues on the overall health, happiness, and quality of life of sexually active Americans in committed relationships.

**Material and Method(s):** An online survey was conducted



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between July 16<sup>th</sup> and July 29<sup>th</sup>, 2014 of 3,015 Americans aged 40-74 who are sexually active, in committed relationships, and either have at least one sexual health issue or have a partner with at least one sexual health issue; 1,503 respondents were male and 1,512 respondents were female. The male sexual health issues identified were: erectile dysfunction, premature ejaculation, prostate issues, low testosterone, decreased sexual desire or interest in sexual activity, inability or difficulty in achieving orgasm, and painful erections. The female sexual health issues identified were: overactive bladder, vaginal dryness or atrophy, painful sexual intercourse, inability or difficulty in achieving orgasm, decreased sexual desire or interest in sexual activity, and hormonal changes due to menopause.

**Result(s):** Forty-two percent of respondents believe that their sex life has an impact on their overall health, yet only 31% have talked to a healthcare professional about their problems and 26% say that embarrassment about talking to a doctor about sexual health issues would prevent them from seeking advice or treatment. Couples with sexual health issues currently have sex five times a month but would prefer to have intercourse nine times per month and only 24% are always able to communicate honestly with their partners about their sex lives. Overall 64% of respondents believe that their sex life impacts their overall satisfaction with their lives.

**Conclusion(s):** Despite understanding the impact to overall health, embarrassment remains a barrier to addressing sexual health problems. These findings suggest that individuals facing sexual health issues may benefit from professional support and/or medical attention, as well as more open and honest communication with their partners to establish a healthier relationship, a more fulfilling sex life and improved overall health and enhanced quality of life.

## Disclosure:

Work supported by industry: yes, by Pfizer (industry initiated, executed and funded study).

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## Expression and distribution of fatty acid amide hydrolase (FAAH) in the human seminal vesicles and vas deferens

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1: University Vita Salute San Raffaele, Urological Research Institute, Milan, Italy; 2: Hannover Medical School, Dept. of Urology, Hannover, Germany; 3: Linköping University, Dept. of Clinical Pharmacology, Linköping, Sweden

**Objectives:** The endocannabinoid system (ECS), comprising of the cannabinoid receptors (CB), their ligands and enzymes controlling the endocannabinoid turn-over, has been proposed to be involved in the regulation of sperm function. Altered levels of components of the ECS have been reported in sperm of infertile men, CB (anandamide)-mediated signals have been suggested to modulate neurotransmission in the vas

deferens. The present study aimed to investigate in the human seminal vesicles (SV) and vas deferens (VD) the expression and distribution of fatty acid amide hydrolase (FAAH, isoforms FAAH1 and 2), an enzyme known to hydrolyse anandamide into arachidonic acid and ethanolamine

**Material and Methods:** Macroscopically normal tissue of the SV and VD was obtained from 4 patients who underwent radical prostatectomy. Specimens were processed for PCR and immunohistochemistry (immunofluorescence, Western blot analysis, DAPI stainings). Total RNA was extracted with an RNAeasy kit, retrotranscribed with an Immprom-II Transcriptase kit and amplified by GoTaq. For immuno-histochemistry, sections were incubated with antibodies directed against FAAH1 and FAAH2.

**Results:** PCR products of 260, 387 and 137 bp, corresponding to FAAH1, FAAH2 and alpha-actin, respectively, were detected in all specimens. By immunohistochemistry, high intensity expression of FAAH1 and FAAH2 was located to the pseudo-stratified columnar epithelium of both the SV and VD. Cytosolic staining was dense in cells of all layers of the epithelium. No immunoreactivity was detected in relation to the smooth musculature or nerve fibers/varicosities in the epithelial or subepithelial (mural) region. In the Western Blot experiments, signals for FAAH1 were more pronounced in the VD than the SV, whereas almost equal amounts of FAAH2 were registered in both tissues.

**Conclusions:** FAAH1 and FAAH2 mRNA and protein is expressed in the human SV and VD. Immunoreactivity for both FAAH isoforms is exclusively located in the epithelial multilayer. Considering their location, the ECS may be involved in epithelial homeostasis and secretory functions.

## Disclosure:

Work supported by industry: no.

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## Reduction of “unnecessary” radiation exposition for the patient and medical staff – Can transrectal ultrasound replace cystography in the evaluation of the vesicourethral anastomosis after radical prostatectomy?

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**Objectives:** Evaluation of the vesicourethral anastomosis after radical prostatectomy is usually performed by cystography. The transrectal ultrasound of the prostate (TRUS) is mainly utilized to get anatomical information like volume determination, tumor detection and extension. In a prospective, two-institutional study we compared TRUS with cystography after radical prostatectomy in the evaluation of the vesicourethral anastomosis.

**Material and Methods:** In 212 patients the vesicourethral

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anastomosis was evaluated by TRUS (7 MHz) followed immediately by cystography on day 7-14 after radical prostatectomy. Sonographically all patients were evaluated for hematomas, lymphoceles and leakages of the anastomosis, controlled by irrigation (100 - 120 ml 0.9% saline solution) during real time TRUS examination. All TRUS and "x-ray" findings, duration of the examination and dose of radiation were separately documented and compared. Leakages and hematomas were compared with the ultrasound findings and statistically evaluated.

**Results:** 52 of the 212 patients (24.5%) showed an extravasation. In 39 cases (18.4%) this was seen by cystography and TRUS. 9 patients (4.2%) with leakage were identified only by TRUS without radiographic correlation. The topographic localisation of the leakage was in 94% the dorsal part of the anastomosis. In 12 cases (5.6%) hematomas were identified only by TRUS without any correlation in the cystogram, 5 in continuity with the anastomosis were responsible for a persisting hematuria and 2 were the cause for temporary bladder outlet obstruction. The source for bladder impressions due to paravesical lymphoceles could be identified by TRUS in 10 cases (4.7%). The duration of examination differed significantly with 5.4 minutes for TRUS vs. 8.7 minutes for cystogram. No significant differences existed between the two institutions.

**Conclusions:** In the evaluation of the anastomosis after radical prostatectomy TRUS shows the same efficiency as the usually performed cystography. It allows an online assessment of postoperative topography, like hematomas or lymphoceles, and dynamic evaluation (exact localisation and dimension) of inefficient anastomosis omitting the cystography. The radiation exposition for the medical staff and patient can be reduced by using TRUS. Treatment costs e.g. x-ray and contrast medium are decreased. Due to the good results the transrectal ultrasound replaced the cystogram at the two institutions participated in this study.

## Disclosure:

Work supported by industry: no.

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## A survey on the sexual behavior of elderly people in South Korea

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**Objectives:** With the aging of society and extension of life expectancy, the education and management of sexually transmitted infections (STIs) in elderly people has become important. This study aimed to improve the sexual health of Korean elderly people and to prepare adequate education programs by investigating their sexual behavior.

**Material and Methods:** From September 2013 to November 2013, we surveyed elderly people in senior welfare centers or public parks. Participants filled out a self-administered questionnaire, which elicited information concerning: demographic information, information on their sexual behavior, purchase of sexual services, experience of STIs, and experience of sex education.

**Results:** A total of 403 men participated in the study. Occupations of the respondents were: white-collar job, 18.4%; self-employed, 16.9%; blue-collar workers, including part-time guards, 17.6%; and unemployed, 46.7%. In total, 70.2% of the respondents had a fixed sexual partner, and the mean number of sexual partners was 1.1. The number of sexual partners was higher in blue-collar workers than in men with other occupations, in men with a spouse than those without one. Of the respondents, 15.9% had had a sexual experience with a prostitute (client group). The proportion of people with a spouse, of a lower age, of middle socioeconomic status, and blue-collar workers was higher in the client group. The prevalence of STIs based on this study was 6.0% and 83% of the people with STIs sought medical treatment. Of the STIs, 57.3% were transmitted from a casual sex partner, the prevalence of which was higher in the client group than in the non-client group (18.8% vs. 3.5%). Only 8% of the respondents had received sex education in the past year. The most desired education topics were symptoms of STIs (37.7%), followed by sexual conflicts after middle age (33.7%), and treatment of erectile dysfunction (22.3%).

**Conclusions:** Elderly people are a new group vulnerable to STIs. To control these infections, powerful policies containing sex education and medical services will be needed.

## Disclosure:

Work supported by industry: no.

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## Intraoperative findings influence decision-making in vasectomy reversal procedures - survey of fellowship-trained, high-volume surgeons

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**Objectives:** Intraoperative decision-making regarding the need for epididymovasostomy versus vasovasostomy during vasectomy reversal is based on preoperative factors and intraoperative findings. The purpose of this study is to identify the opinion and practice trends of fellowship-trained, high-volume vasectomy reversal surgeons focusing on intraoperative decision-making based on vasal fluid characteristics.

**Material and Methods:** We composed a survey consisting of eleven questions regarding practice characteristics and intraoperative decision-making based on vasal fluid characteristics. The questionnaire was distributed to fellowship-

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trained, high-volume vasectomy reversal surgeons, and surveys were collected between April and May 2014.

**Results:** 89 surveys were distributed and 53 (60%) responses were collected. The mean number of vasectomy reversals performed annually by respondents was 37.7 (standard deviation 32.0). 82% reported that microscopic evaluation of vasal fluid was the “most important” factor in determining whether to perform a vasovasostomy or an epididymovasostomy. 20% of surgeons reported that obstructive interval was “not important” in intraoperative decision-making. When sperm heads with short tails are found on microscopic examination, 81.1% of respondents routinely perform a vasovasostomy, while 49.1% routinely perform a vasovasostomy when only sperm heads are found. 40.7% of respondents stated that the type of reversal performed on the first side affects intraoperative decision-making on the contralateral side.

**Conclusions:** The majority of fellowship-trained vasectomy reversal surgeons consider microscopic examination of vasal fluid to be the most important factor in intraoperative decision-making when choosing between performing a vasovasostomy versus an epididymovasostomy. A significant portion of survey respondents (40.7%) consider the type of reversal performed on the first side when making a decision on which technique to utilize on the contralateral side. Moreover, when faced with ambiguous findings on the second side, most surgeons choose to perform the opposite procedure on the contralateral side.

## Disclosure:

Work supported by industry: no.

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## The concordance of preoperative core testis needle biopsies with surgical diagnoses among azoospermic infertile men

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**Objectives:** Among men with azoospermia, establishing a clinical and/or histological diagnosis (obstructive-OA, non-obstructive-NOA) is essential for patient counselling, prognostication, operative planning and offering strategies for sperm retrieval. The primary objective of the current initiative was to establish the safety, utility and surgical diagnostic accuracy of a pre-operative core-needle testis biopsy among azoospermic men.

**Materials and Methods:** Between 2000 -2014, azoospermic men with diagnostic uncertainty (OA vs. NOA) following clinical evaluation (history, physical exam, laboratory testing and diagnostic imaging) were offered a core needle testis biopsy under local anesthetic. A single tissue core obtained from the “healthiest” testis and preserved in Bouin's fixative was evaluated by an experienced reproductive pathologist. Biopsy specimens were classified as active spermatogenesis, hypospermatogenesis, maturation arrest or Sertoli cell only.

Among patients electing for surgery, the concordance of the core biopsy findings were compared with operative diagnostic findings. Biopsy tissue specimen quality, complications and clinic predictors of testis histology were analysed.

**Results:** Among 367 core testis needle biopsies, 359 (97%) yielded tissue of adequate quality for histologic interpretation. 134 of these azoospermic men subsequently underwent surgical intervention (reconstruction, microTESE). Of these men, the concordance of the needle biopsy diagnosis with surgical findings was 98.4% (63/64 patients) among men with OA (active spermatogenesis on biopsy) and 100% (52/52 patients) among men with NOA (Sertoli cell only, maturation arrest). Patients with a biopsy diagnosis of hypospermatogenesis (n=18) were equally classified as OA and NOA. Among men with OA, FSH was  $\leq 10$  in 95% of cases. LH, testosterone and testis size were not diagnostically discriminating between NOA and OA. Among all patients, 3 (0.8%) complications, including 2 hematomas and one epididymitis, as a result of a needle biopsy were identified.

**Conclusions:** Core-needle testis biopsy to resolve diagnostic uncertainty among azoospermic men is well tolerated and yields adequate tissue samples for histological classification that is highly concordant with intra-operative diagnoses. Hypospermatogenesis on biopsy is the exception, with no discrimination between OA and NOA. Histological classification offered by core needle testis biopsy can optimize patient counselling, surgical planning and strategies for sperm retrieval with minimal increased risk of complication.

## Disclosure:

Work supported by industry: no.

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## Human sperm miRNA profile in patients with normozoospermia and teratozoospermia

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**Objectives:** MicroRNA (miRNA) are small noncoding RNA's (18-25 nt) that regulate the level of messenger RNA expression by repression of translation or transcription. Data is lacking on the differences in the miRNA expression profiles of patients with teratozoospermia compared to the expression profiles of men with normozoospermia. The objective of this study was therefore to identify miRNA's that are essential for the development of morphologically normal spermatozoa.

**Methods:** RNA was extracted from the spermatozoa of men with normozoospermia and teratozoospermia using the swim-up technique to isolate the clean motile sperm fraction of the semen. Semen from a patient with non-obstructive azoospermia was used as a control. RNA was isolated using the Exiqon miRCURY RNA Isolation Kit® (Vedbaek, Denmark). MiRNA profiling was performed using quantitative real-time PCR (qPCR) and miRCURY LNA Universal RT microRNA PCR system (Exiqon, Vedbaek, Denmark) on human plate panels

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V1+V2. Expression was considered significant if the miRNA expression was different by two fold for both normozoospermia and teratozoospermia. The expression profiles were compared using the student two tailed t-test and principal component analysis. miRNA expression analysis was performed with GenEx Professional Software version 6.0 (MultiD, Göteborg, Sweden).

**Results:** Of the 742 miRNA's assayed, 26 (3.5%) had at least two fold increased expression in the normozoospermia over the teratozoospermia. Conversely, the expression level of nine miRNA's were significantly increased with respect to the normozoospermic group (in order of decreasing difference hsa-let-7b-5p, hsa-miR-548c-5p, hsa-miR-16-1-3p, hsa-miR-490-3p, hsa-miR-320d, hsa-miR-151a-3p, hsa-miR-18a-3p, hsa-miR-377-3p, and hsa-miR-196a-5p). The top five miRNA's underexpressed in the teratozoospermic group were hsa-miR-449a, hsa-miR-19b-3p, hsa-miR-28-5p, hsa-miR-148b-3p, and hsa-miR-106b-5p.

**Conclusion:** Results of this study have identified several over and under-expressed miRNA's associated with spermatozoa with abnormal morphology. These miRNA's might be useful noninvasive markers for human male infertility. Examination of their mRNA targets may elucidate molecular mechanisms for the development of abnormal sperm morphology and male infertility.

## Disclosure:

Work supported by industry: no.

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## Ameliorating effects of modified Ojayeonjonghwan on cryptorchidism-induced oxidative stress and decline of semen quality in rats

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**Objective(s):** Idiopathic infertility is a significant number of causes of male infertility. Empirical treatments are used for idiopathic male infertility, and antioxidant supplementation is a kind of management of oxidative stress related infertility. We investigated the antioxidant effects of the modified Ojayeonjonghwan (KH-204) in a rat model of cryptorchidism.

**Material and Method(s):** Male rats were divided into four groups (n=8 in each): a normal control group, a cryptorchidism-induced control group and two cryptorchidism-induced groups treated p.o. with either 200 or 400 mg/kg, KH-204 for 4 weeks. The testes and epididymides from rats in all groups were removed, weighed and subjected to histological examination and semen analysis after surgery. Oxidative stress was assessed by measuring 8-OHdG, SOD and heat shock protein (HSP) levels. Apoptosis was determined using a TUNEL assay.

**Result(s):** Treatment with the multi-herbal medicine KH-204 (1) increased the mean weight of the cryptorchid testes; (2) restored

sperm counts, motility and germinal cell layer thickness; (3) decreased levels of 8-OHdG and increased levels of SOD; and (4) decreased HSP70 levels and apoptosis.

**Conclusion(s):** It suggests that KH-204 may be beneficial for regaining testicular function via the reduction of oxidative stress and apoptosis.

## Disclosure:

Work supported by industry: no.

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## Comparison of Biocompatibility between PDMS and PMMA as packaging materials for the Intravesical Implantable Device

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**Objective(s):** Several attempts to invent implantable devices have done, and it is also necessary to develop biocompatible packaging materials for implantable devices. Thus, we evaluated the biocompatibility of polydimethylsiloxane (PDMS) and polymethyl methacrylate (PMMA) by analyzing of the changes of macrophage, macrophage migratory inhibitory factor (MIF) and inflammatory cytokines of the bladder.

**Material and Method(s):** A 2 mm-sized, ball-shaped lead was made and coated with PDMS or PMMA. After 1-, 2-, and, 4- week intravesical implantation with each lead balls in the bladder of the rats, the inflammatory changes by foreign body reaction were evaluated.

**Result(s):** At 1 week, the increased activity of macrophages and increased expression of MIF in the urothelium was observed except control group, however the significantly decreased activity of macrophages and MIF expression in rats implanted with PDMS- or PMMA-coated lead were noted at 2 and 4 weeks. In addition, significant decreased levels of inflammatory cytokines such as IL-1 $\beta$ , IL-6, and TNF- $\alpha$  were observed with time.

**Conclusion(s):** In this study, we noticed the expression of MIF in the urothelium and presented the changes of MIF as well as macrophages and other inflammatory cytokines. After the intravesical implantation with PDMS or PMMA, the lower inflammatory response was observed in the bladder. Therefore, PDMS or PMMA are suggested for the biocompatible polymers in the bladder.

## Disclosure:

Work supported by industry: no.

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## Effects of Schisandra chinensis extract on the relaxation of isolated human prostate tissue and smooth muscle cell

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**Objective(s):** Schisandra chinensis has been commonly used as a traditional herbal medicine to treat various diseases including body weakness, dysentery, impotence, enuresis and frequent urination in many countries including Korea, China and Russia. Benign prostate hyperplasia is a common disease for the elderly men and it induces lower urinary tract symptoms which hinder general activity and quality of life. We evaluated the therapeutic potential of Schisandra chinensis extract (SCE) in benign prostate hyperplasia using human prostate tissue.

**Materials and method(s):** S. chinensis fruit was collected and extracted with ethanol. Human prostate tissues were obtained from 14 prostate cancer patients. Macroscopically normal tissue was excised from the transition zone and the periurethral regions. Isolated prostate tissue strips were mounted in an organ-bath system, and the relaxation effect of SCE was evaluated by cumulative addition to the pre-contracted prostate strips with 10–5 M norepinephrine. The effect of tamsulosin was compared, and the additive effect was evaluated. Electrophysiological studies using cultured human prostate smooth muscle cells (HPrSMC) were conducted.

**Results:** Cumulative dosing of SCE induced concentration-dependent relaxation in contracted prostate tissue:  $3.9 \pm 2.3\%$  at 0.1 mg/mL,  $13.9 \pm 4.0\%$  at 0.5 mg/mL,  $26.7 \pm 4.6\%$  at 1.0 mg/mL, and  $40.7 \pm 5.9\%$  at 2.0 mg/mL ( $n = 18$ ,  $P < 0.05$ ). Simultaneous dosing of SCE and tamsulosin showed an additive relaxation effect:  $68.9 \pm 8.7\%$  at 1.0 mg/mL SCE and 10-8M tamsulosin. The relaxation effect of SCE was abolished by inhibition of K<sup>+</sup> channels by pre-treatment with tetraethylammonium. In HPrSMC, extracellular application of 100 µg/mL SCE significantly increased outward currents, and this effect was significantly attenuated by treatment with 100 nM Iberiotoxin.

**Conclusions:** SCE showed a dose dependent relaxation effect on human prostate tissue as well as an additive effect with tamsulosin. The relaxation effects of SCE on HPrSMC were, in part, due to the activation of K<sup>+</sup> channels.

### Disclosure:

Work supported by industry: no.

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## Outcomes of intralesional interferon-α2B for the treatment of ventral plaques in Peyronie's disease

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**Objective:** Currently, clostridium collagenase histolyticum is the only therapy approved to treat Peyronie's disease (PD); however, its use is contraindicated in men with ventral plaques. Given these limitations and the paucity of literature on ventral plaque outcomes, we sought to comparatively analyze results of PD men undergoing intralesional interferon-α2b (ILI IFN) to assess for differences based on plaque location.

**Materials and Methods:** A retrospective analysis was performed on men undergoing ILI of IFN at one institution from 2001-2014. Patients received 2 million units of IFN injected every 2 weeks for 6-12 treatments. All men underwent pre- and post-penile duplex Doppler ultrasounds (PDDU). Demographic information, disease characteristics, PDDU, and objective measurements were reviewed. Patients were stratified into ventral and dorsal plaque cohorts, with response defined as a 20% or greater improvement in curvature.

**Results:** 129 patients with a mean age of 53 (range 25-75) underwent a median 12 ILI of IFN injections (range 6-12). Mean duration of PD was 3 years and was similar between ventral and dorsal groups. Mean pretreatment curvatures were  $44.7^\circ \pm 21.8^\circ$  (ventral;  $n=18$ ) and  $45.2^\circ \pm 18.5^\circ$  (dorsal;  $n=111$ ). Overall, 69.8% of patients responded to therapy. No significant differences were noted between the ventral and dorsal groups in regards to response rates (77.8% vs. 68.5%) or absolute changes in curvature ( $13.1^\circ \pm 20.3^\circ$  vs.  $7.8^\circ \pm 13.4^\circ$ ), respectively ( $p=0.058$ ). Other factors, including disease duration, age, pretreatment curvature, PDDU flow measurements, and IIEF scores failed to predict response to therapy.

**Conclusions:** Treatment with ILI of IFN improves curvature in +69% of men with PD. The extent of improvement is independent of plaque location, pretreatment curvature, and disease duration.

### Disclosure:

Work supported by industry: no.

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## Versatile algorithmic approach for definitive straightening without modeling during penile prosthesis surgery

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**Objectives:** We present a novel algorithm for definitive reconstruction of penile curvature in men undergoing concomitant inflatable penile prosthesis (IPP) surgery as an alternative to penile modeling.

**Methods:** Patients receiving IPP placement who also had penile curvature were divided into two treatment groups based on when the deformity was recognized: group A) when the penile deformity was known preoperatively, the patient underwent penile plication immediately prior to IPP insertion via the same

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penoscrotal incision; group B) patients whose penile curvature was recognized after inflation of the newly inserted IPP were treated with a Yachia (Heineke-Mikulicz) corporoplasty over the intact cylinders. A qualitative survey assessing penile curvature, adequacy for intercourse and overall patient satisfaction after surgery was administered.

**Results:** Among 405 men receiving IPP at our institution from 2007-2014, 30 patients received synchronous reconstruction for penile curvature (7%). Group A included 23/30 (77%) patients, and 7/30 (23%) were in group B. Mean pre-op curvature overall was 37° corrected to <10°. A median of 4 sutures (range 3-6) were used for plication with each suture providing correction of approximately 8°. Average operative times were only 24 minutes longer compared to patients who underwent IPP placement only (88 vs 64 minutes,  $p < 0.05$ ). At an average 8 months of follow-up, 17/18 (94%) patients who completed surveys reported no residual curvature, erections adequate for sexual intercourse and an improved overall condition. One patient (7%) who underwent a complex biplanar plication reported minor residual curvature. No patient reported chronic pain or recurrent deformity.

**Conclusion:** Penile curvature can be safely and reliably reconstructed at the time of IPP placement in a definitive manner, regardless of whether or not the deformity was identified preoperatively.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Subcoronal exposure through a modified no touch technique for penile reconstructive surgery

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## Objective:

The surgical treatment for disorders of male sexual function requires specific exposure to safely and efficiently correct the underlying problem. Subcoronal exposure is utilized for treatment of phimosis, Peyronie's plaque and semi-rigid penile prosthesis insertion; infrapubic or scrotal incisions are used for inflatable penile prosthesis (IPP) placement. Men who present with several disorders may require multiple procedures and surgical incisions. A single subcoronal incision allows for access to the entire corporal shaft many male reconstructive procedures.

**Material and Methods:** 61 men had IPPs placed through our modified no touch technique, via a subcoronal incision. The penis was degloved to the level of the penoscrotal junction and the cremaster muscle was everted and secured to the

drapes. This allowed scrotal and penile skin exclusion from the operative field. Following IPP sizing the patients corpora were inspected for Peyronie's plaques and other abnormalities; and subsequently repaired.

**Results:** Of the 61 men who had IPP placement, 22 had Peyronie's plaques which were treated by incision, plication or relaxing incisions, 35 uncircumcised men requested circumcision and 18 men who were found to have supersonic transporter deformities after IPP placement and received glanulopexies. Mean operative time was 54 minutes. Three complications, specifically one man had partial necrosis of a suture line and two had contracture of a Peyronie's plaque which required release; specifically none of the complications were infectious.

**Conclusions:** Specialists in the surgical treatment of disorders of male sexual function can perform multiple procedures safely and easily through a modified no touch single subcoronal incision. Inflatable penile prosthesis, circumcision, glanulopexy, urethral reconstruction and the surgical management of Peyronie's disease can be accomplished through this exposure. This approach allows for access to the entire corporal shaft providing excellent visibility and allowing the surgeon to perform multiple penile reconstructive surgeries through a single incision.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Usage of the Carrion Curettage for the management of corporal fibrosis during penile implantation

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**Objectives:** The reported prevalence of Peyronie's disease is up to 10%. This disease is managed with a variety of treatment modalities, including surgical. Recently, minimally invasive options have improved, but many patients still require either plication or plaque manipulation/grafting. Semi rigid or inflatable penile prosthesis (SRPP or IPP) are also employed, especially in the setting of impotence. Simple placement may not be sufficient and simultaneous molding or manipulation of the plaque using different techniques may be warranted. We present our series utilizing the Heaney curette for intracorporal disruption of a Peyronie's plaque prior to placement of an SRPP or IPP, deemed the "Carrion Curettage".

**Materials and Methods:** From 2000 to 2014 a single surgeon at a single site has utilized the "Carrion Curettage" during placement of IPP's for the management of mild to moderate Peyronie's (<60 degrees) with a palpable plaque. A peno-scrotal approach was used in all cases and dilation of the corpora was

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performed prior to plaque scratching with the Heaney curette. **Results:** After proximal and distal dilation, the penis was held in stretch position and the Heaney curette was inserted intracorporally where the plaque was scratched vigorously. Placement of the IPP was then completed in standard fashion. Occasionally, if a curvature >30 degrees was still present continued molding or repeat scratching of the plaque was performed. All curvatures improved to <30 degrees, and no patients had worsening of their bend. No complications occurred during the "Carrion Curettage" portion or postoperatively.

**Conclusions:** The Heaney curette, normally used for dilation and curettage of the uterus is an ideal tool for the management of a Peyronie's plaque or intracorporal fibrosis during placement of prosthesis. The small size of the head and neck, and long body and handle allows for the surgeon to reach the plaque intracorporally through any incisional approach. The ridges/teeth along the border of the head helps break up the scar when scratched vigorously, in a controlled and safe manner. This tool and technique further expands the lists of treatment modalities available for the management of Peyronie's disease. As we have shown, during the placement of an IPP or SRPP, the "Carrion Curettage" is a safe and effective adjunct for the management of Peyronie's disease.

## Disclosure:

Work supported by industry: no.

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## Heavy calcification on duplex ultrasound for Peyronies negatively predicts functionality after 2nd intervention: A retrospective review at a single centre

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**Objectives:** To evaluate the clinical and radiographic aspects of peyronie's disease (PD) presentation for identification of predictors of treatment success.

**Materials and Methods:** Ethics approval was obtained. Retrospective review of 266 duplex ultrasounds with vasoactive injections from 2007 at a single institution performed by a single clinician (GBB). Exclusions included no PD on history or ultrasound and age less than 18. All images reviewed by a single independent assessor (FJG). Data was collected on demographics, clinical factors, sonographic factors, treatment selection and functional outcomes. Treatment options included no treatment, traction therapy, chronic PDE5-Inhibitors, intralesional verapamil, peyronie's reconstruction and inflatable implant. Complications from index treatment were also collected. Appropriate univariate analysis and multivariate logistic regression was performed to identify predictors of

functional success after an initial treatment and a second treatment if necessary.

**Results:** After exclusions 137 ultrasounds and clinical information were available for review. Several radiographic patterns were observed and used to describe the peyronie's plaques. 68.6% of patients reported dorsal curvature, and there was an even distribution of curves less than 31 degrees (36.5%), between 31 degrees and 59 degrees (32.1%), and greater than 59 degrees (31.4%). Charlson Comorbidity Index (CCI), Smoking status, heavy calcification and plaque volume were not independent predictors of functionality on multivariate logistic regression. After a 2<sup>nd</sup> intervention, heavy calcification was negatively associated with functionality (p<0.001). Re-analysis of those who failed the first PD intervention demonstrated that after the 2<sup>nd</sup> intervention they achieved 50% functionality if a non-surgical option was selected, and a 90.1% functionality if a surgical option was selected (p=0.017).

**Conclusion:** This is an exploratory analysis for hypothesis generation. We did not identify any independent predictors of functionality after the 1<sup>st</sup> intervention. Heavy calcification was identified as a poor prognostic indicator of functionality after the 2<sup>nd</sup> intervention. Those who fail their first intervention have 50% functionality with non-surgical treatments as compared to those who select surgical options and have 91% functionality. Larger numbers and further analysis are required to support these observations.

## Disclosure:

Work supported by industry: no.

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## Penile curvature secondary to Peyronie's disease with penile prosthesis and relaxing incisions without loss of length

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**Purpose:** Erectile dysfunction (ED) treated with an inflatable penile prosthesis (IPP) and Peyronie's disease (PD) managed by incision and plication both are thought to decrease penile length postoperatively. Pathologically the tunica scarring or fibrosis of this disease severely limits the elasticity of the tunica albuginea. Even high volume implanters have noted that they often identify undiagnosed PD during IPP placement. These men often don't have their PD treated because surgeons are concerned about damaging the prosthesis. A subcoronal incision for IPP placement allows access to the entire corporal shaft for correction of penile angulation, incision of plaques in PD and other penile reconstructive procedures.

**Patients and methods:** 61 men who had ED and failed medical management presented for IPP. 36 men were found to have Peyronie's plaque(s) identified by Doppler US. IPP was performed via our no touch subcoronal approach, whereby the

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penis was degloved to the level of the penoscrotal junction. The cremaster muscle was everted and secured to the drapes. This allowed scrotal and penile skin exclusion from the operative field. Following IPP sizing the patients corpora were inspected and plaques were evaluated and treated by a combination of penile modeling, Peyronie's plaque relaxing incisions with cautery and/or plication stitches during the same operation.

**Results:** Preoperatively, patients demonstrated an average curvature of 46 (12-78) degrees. Following subcoronal placement of the prosthesis, it was fully inflated, and any residual curvature noted. Using relaxing incisions with cautery into the corpora, penile modeling, or plicating stitches, the curvature was addressed. No grafting material was used in any patients. 12 men required neurovascular bundle mobilization to fully incise the plaque. Curvature improved by 90-95% (range) for men.

**Conclusions:** In patients with ED and PD the subcoronal approach to inflatable penile prosthesis allows for simultaneous correction of Peyronie's plaques through the same incision. Men improved by over 90% in this cohort.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Efficacy of extended intralesional verapamil therapy for Peyronie's disease in early responders

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**Objective:** To report our experience using a total of 12 intralesional verapamil injections (ILVi), among men with a good response following the initial 6 ILVi for treatment of Peyronie's disease.

**Methods:** The study population consists of men (i) with palpable penile plaque (ii) uniplanar penile curvature and (iii) who underwent 6 ILVi (10 mg verapamil in 5 ml saline) every 2 weeks. All patients were evaluated with a penile injection assisted deformity assessment (DA) at baseline. Those reporting improvement after 6 ILVi had a repeat DA within 2 weeks, and when clinical improvement was documented were offered an additional course of 6 ILVi. ILVi 7-12 were administered identically to the first 6 ILVi. A final end of treatment DA was conducted 3 months after last ILVi (number 12).

**Results:** 123 men had 6 ILVi. Mean duration of PD was 4±3 months. There was a non-significant mean 2.1 degree increase in curvature from baseline (35.0±18.3) to 6 injections (37.2±20.1, p=0.19). 30 (24%) had a >10 degree decrease, 53 (43%) were unchanged (<10 degrees increase/decrease), 40 (33%) >10 degree increase.

17 patients (10%) had documentable improvement after 6 injections and proceeded to 12 ILVi. Mean age = 51±12 years and the mean number of months with PD at the time ILVi was commenced = 4±4 (range 2-14) months. Following 6 ILVi, there was a significant reduction in mean degree curvature (41 to 30.0, p=0.05). 9 (53%) had a >10 degree decrease, 5 (29%) were unchanged (<10 degrees increase/decrease), 3 (18%) >10 degree increase. There was a mean reduction in curvature between 6 and 12 treatments of 3.8 degrees (30 to 26.2, p=0.28). 6 (35%) had a >10 degrees decrease, 7 (41%) were unchanged (<10 degrees increase/decrease), 4 (24%) >10 degree increase. Overall, among those patients who opted for 12 ILVi, there was a significant reduction in curvature from baseline to 12 injections (41 to 26.2, p=0.01, mean reduction=14.7). 9 (53%) had a >10 degree decrease, 4 (24%) were unchanged (<10 degrees increase/decrease), 4 (24%) >10 degree increase.

**Conclusions:** Among patients with demonstrated improvement following an initial course of 6 ILVi, one third will appear to experience further improvement with an additional 6 ILVi. Consideration should be given to a longer course of treatment for those men considered early responders to ILVi.

## Disclosure:

Work supported by industry: no.

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## Relationship of factors associated with Peyronie's disease (PD) that affect PD bother and erectile function

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**Objective:** Despite the known association between Peyronie's disease (PD) and erectile dysfunction (ED), the underlying pathophysiologic mechanisms of ED in men with PD remain unknown. The aim of this posthoc analysis is to elucidate factors that have an impact on PD bother and erectile function in subjects with PD.

**Materials and Methods:** Data from collagenase clostridium histolyticum (CCH) phase 3 studies (IMPRESS I and II), which included 832 men over 18 years old with PD symptoms >12 months and penile curvature deformity of 30-90° were analyzed. Scores from the international index of erectile function, erectile function domain (IIEF-EF), and the Peyronie's disease questionnaire (PDQ) were used in the analysis. A covariance analysis and linear structural equations (CALIS) procedure to estimate relationships of selected variables on bother and ED associated with PD was performed.

**Results:** The CALIS procedure using data of subjects (mean age 57.3±8.3 years and mean penile curvature deformity

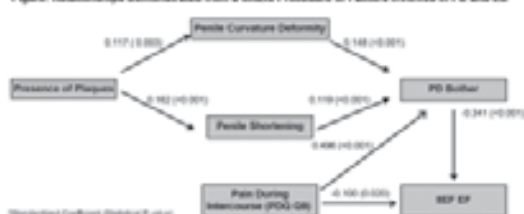


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49.8°±14.2°) revealed relationships between penile curvature deformity, perceived penile shortening, pain during intercourse, the presence of plaques, PD bother, and erectile function (Figure).

**Conclusions:** The results of this posthoc analysis suggest that PD bother can come from several different sources: penile curvature deformity, perceived penile shortening, and especially pain during intercourse. Also, PD bother and pain during intercourse both appear to have a direct impact on erectile function. Additional prospective studies are warranted to further investigate these relationships.

Figure: Relationships Demonstrated from a CALIS Procedure of Factors Involved in PD and ED



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## A novel technique for Peyronie's plaque excision and grafting using a lateral incision: The 'Window' technique

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**Objectives:** Peyronie's disease (PD) is a debilitating disorder in which plaque formation in the corporal tunica albuginea leads to penile curvature, shortening and pain. The standard management for severe curvatures is plaque incision or excision and grafting (PIEG), which has classically been performed through a circumcising incision with penile degloving. This can be associated with a number of complications such as penile lymphedema, decrease in glans sensitivity, paraphimosis, distal skin necrosis and excessive post-operative pain. Additionally, very proximal plaques can be difficult to access with this approach and maintenance of a circumcised foreskin is not possible. In order to minimize these issues we have developed a novel approach to PIEG via a longitudinal 'window' incision for the correction of PD. We report our pilot experience.

**Materials and Methods:** Our patient presented with a 90-degree leftward curvature necessitating PIEG for repair. In contrast with the standard circumcising incision and penile degloving, a 4 cm longitudinal incision was made on the left lateral aspect of the penile shaft overlying the point of maximal curvature. This allowed for direct access to the left corpus cavernosum and the associated plaque. The entire procedure

was performed using only this incision.

**Results:** The length of the left lateral skin incision was 4 cm. The excised plaque measured 2.5 x 5.5 cm and a 3 x 6 cm graft was used. Total operative time was 106 minutes and estimated blood loss was 35 ml. There were no major peri- or post-operative complications. The patient experienced rigid erections by post-operative day 3 with minimal penile edema. At six months after surgery, he had good cosmetic and functional outcome with spontaneous unassisted erections and no curvature.

**Conclusions:** A lateral longitudinal incision for PIEG is a feasible and efficacious technique for the management of severe PD. This approach may reduce the many complications associated with the traditional circumcising incision with penile degloving. Additionally, it obviates much of the needed dissection, allows for access to proximal plaques and allows for maintenance of an uncircumcised foreskin. Larger comparative studies are necessary for further evaluation.

## Disclosure:

Work supported by industry: no.

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## Long term outcome of intralesional triamcinolone acetonide (Kenalog) with Verapamil injection for Peyronie's disease

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**Objective:** To evaluate the long-term outcomes of multi-visit intralesional verapamil (VER) and triamcinolone acetonide (Kenalog; KEN) injections in men with Peyronie's disease (PD) who failed therapy with oral colchicine.

**Material and Methods:** A retrospective chart review was first performed. Men were included if they had clinically significant PD deformity (>25 degree curvature with palpable plaque, with or without pain), had failed six months of oral colchicine (1.2 mg daily), and received multiple injections of VER (10mg) + KEN (10mg) between 2008 and 2013. Patients were then contacted by telephone and asked to participate in a seven-question survey about their treatment outcomes. Men were only included if they had undergone no additional treatment between cessation of treatment and survey.

**Results:** A total of 70 patients were identified as candidates for inclusion. 32 patients agreed to participate in the survey. Median age of patients was 51 ± 12.8 years, mean duration of treatment was 212.2 ± 256.7 days, median number of injections was 6 ± 2.56, and median length of follow-up was 3.25 ± 2.18 years.

As compared to their pre-treatment scores, patients reported a 1.38 point increase in their ability to engage in vaginal intercourse (0-10; p<0.005), a 0.83 point increase in their ability to maintain an erection (0-10; p<0.05), 0.79 point increase in their ability to masturbate following treatment (0-10; p=0.13), and a -1.03 point decrease in aesthetic bother (0-5 scale; p<0.005). There

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were no hematomas or penile fractures requiring intervention during treatment.

**Conclusions:** Adding 10 mg of triamcinolone acetonide to verapamil injections in men with Peyronie's disease provides meaningful improvement in patient symptoms and sexual satisfaction when used over multiple sessions. Considering the low cost and successful outcomes of Kenalog and verapamil injections, this treatment regimen may be offered as initial or alternative treatment options.

**Disclosure:**

Work supported by industry: no.

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**Lingual mucosal graft in treatment of Peyronie's disease**

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*1: Egypt*

**Objectives:** Peyronie's disease (PD) is a fibrotic disorder of the tunica albuginea. Plaque excision and tunical grafting is used to correct the resulted penile curvature. This study evaluates the use of lingual mucosal graft (LMG) as a substitute for tunica albuginea in treatment of PD.

**Materials & Methods:** Seventeen patients, reporting normal erectile function, with PD interfering with sexual function were operated upon by plaque excision and grafting with LMG. Preoperative assessment included: International index of erectile function (IIEF-5), penile duplex and penile curvature angle measurement. Post operative erectile function and penile deformity were assessed every 3 mo for 9 -18 months.

**Results:** Mean patients age was 52 ( $\pm 4.7$ ) years and mean angle of deformity 60° ( $\pm 5.1$ ). Donor site complications occurred in the form of mild transient swelling, numbness and pain. Post operative (PO) assessment showed complete penile straightening in 15 patients with mild curvature recurrence ( $< 20^\circ$ ) in 2 patients at the 3rd month. De novo mild erectile dysfunction was reported by 1 patient who responded to low dose PDE-5I. Patients and partners' satisfaction were reported in 16 (94%) patients. These results remained stable until the end of the follow-up period.

**Conclusions:** LMG seems to be a valuable substitute for tunica albuginea in cases of PD, It is readily available and shows early graft take. It also proved safety, reliability, feasibility and satisfactory short term outcome for treatment of PD.

**Disclosure:**

Work supported by industry: no.

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**Pilot survey on prevalence of Peyronie's like symptoms in men with Dupuytren's contracture**

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**Objective:** Peyronie's Disease (PD) is known to be associated with Dupuytren's Contractures (DC) of the hand. It is estimated that 22% of men with PD have DC; to our knowledge there are no data on the prevalence of PD in men with DC. To ascertain the prevalence of PD-like symptoms in men to an orthopedic-hand clinic presenting with DC. We hypothesized that approximately 22% of men with DC would have evidence of PD.

**Materials and Methods:** A customized survey was developed which included demographic questions and items adapted from the Erection Hardness Scale (EHS), a sexual satisfaction question from the International index of Erectile Function (IIEF), and questions on bother and decline in sexual activity from penile deformity from the Peyronie's Disease Questionnaire (PDQ). Subjects were also asked about their willingness to pursue various theoretical treatment options. All adult men presenting to the orthopedic hand service at our institution who were diagnosed with DC were invited to participate. They were given a copy of the survey which was returned in a postage paid envelope. IRB approval was obtained and all data were kept anonymous. Descriptive statistics were obtained.

**Results:** 33 men were invited to participate; of these, 12 surveys (36%) were returned. Three men (25%) reported changes in their penis since puberty and two of these answered follow up questions. There were no significant differences in age or mean erection hardness between men with or without penile changes. Both of the men who endorsed penile changes reported penile curvature and loss of length. One man with changes reported EHS 2 erections and was very bothered by his deformity. The other man reported EHS 3 erections and was a little bothered by his deformity. Both men were interested in oral therapies. One was amenable to clinic based procedures for treatment. Neither man reported nodularity of his feet or scarring of his inner ear.

**Conclusions:** Our sample size is too small to derive meaningful conclusions about the prevalence of PD in DC; however, our early data suggest that PD may be a problem in a significant minority of men presenting with DC.

**Disclosure:**

Work supported by industry: no.

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**Utilization of the "Carrion Cast" for the management of refractory priapism**

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**Objectives:** Priapism can, at times, be difficult to manage, requiring multiple therapeutic interventions with different treatment modalities. The corporal "snake" procedure ("snake") is very successful at treating this condition, but carries a high

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rate of impotence and phallic scarring. In combination with immediate semi rigid penile prosthesis (SRPP) placement, this can be prevented, but at a high risk of infection, especially when previously manipulated. New treatment modalities are needed to help manage this difficult subset of patients, and we present the first case utilizing an intracorporal cast of calcium sulfate with antimicrobials ("Carrion Cast") after a "snake" for the management of surgically refractory priapism.

**Materials and Methods:** A gentleman was transferred in from an outside hospital with stuttering priapism lasting greater than 24 hours. At that facility, he underwent irrigation twice and a distal surgical shunt, but remained refractory. The decision was made to proceed with a "snake" and utilization of the "Carrion Cast" rather than an SRPP, due to the increased risk of infection, high risk of erectile dysfunction and the patient's desire to maintain penile length/girth.

**Results:** A subcoronal incision was made; corpora exposed, stay sutures placed, corporotomies made and dilation with 8mm Hegar, bilaterally, with subsequent successful detumescence. The "Carrion Cast" was mixed with vancomycin and tobramycin, and 20mL injected intracorporally. Immediate closure of the corporotomies and maintenance of the penis in a stretched position until the cast hardened. The incision was closed in standard fashion, and the patient discharged, with plan to place prosthesis after the cast dissolves (6 weeks).

**Conclusions:** Irrigation and injection with phenylephrine is the mainstay, but not always successful, especially in the setting of prolonged/stuttering priapism. Often, these patients require distal and proximal shunts, but may still remain refractory. In this setting a "snake" with concomitant placement of SRPP tends to be successful, but may carry a high risk of infection. We present a different option for managing this difficult situation, one that helps maintain phallic size, while exposing the tissues to antimicrobials. Eventually, the patient will likely require placement of prosthesis, either semi rigid or inflatable, but in a more controlled setting. We present the first case of a refractory priapism managed with a "snake" and concomitant placement of the "Carrion Cast".

## Disclosure:

Work supported by industry: no.

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## Treatment of priapism in the emergency department prior to urologic surgery consultation: A contemporary Experience at a single institution

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**Objective:** To review the medical management of priapism patients by the Emergency Department (ED) prior to Urologic Surgery consultation in a contemporary cohort of patients.

**Materials and Methods:** Retrospective review of consecutive priapism cases at a single institution from March 2004 to

June 2014 was performed utilizing an inpatient Urologic Surgery consultation database. Treatments administered in the Emergency Department were gathered from a review of treatment orders placed in the ED as well as medical records obtained from outside hospitals for patients who received care prior to transfer to our medical center. Patients were determined to have been treated successfully prior to Urologic Surgery consultation if they experienced detumescence without Urologic intervention.

**Results:** Of the 102 cases of priapism treated at our center, 50 patients (49.0%) were treated with oral or IV medications ordered in the ED. Thirty-eight cases (37.3%) were treated with terbutaline, of which 27 received the medication subcutaneously (median dose 0.25mg) and 12 received the medication administered orally (median dose 10 mg). Twenty patients (19.6%) were treated with oral pseudoephedrine (median dose 60 mg), 9 (8.8%) received diphenhydramine, 6 (5.9%) were treated with topical nitroglycerin paste applied to the penis, and 3 (2.9%) patients were treated with IV sodium bicarbonate. Of the 50 cases treated with medication in the ED, 7 cases (6.9% of all cases, 14% of cases treated medically in the ED) experienced detumescence without further intervention. All 7 of these patients received terbutaline (5 patients received median dose 0.5 mg subcutaneously, 3 patients received median 10 mg po, 1 patient received both). Four of these patients received a median dose of 90 mg pseudoephedrine, 3 received topical nitroglycerin paste, and 1 received IV sodium bicarbonate. Of the 7 successfully treated cases, 3 resulted from sickle cell disease, 1 from a psychotropic medication, 1 from cocaine, and 1 case was defined as idiopathic.

**Conclusions:** In this contemporary case series of patients treated for priapism, nearly half of all patients received medications in the ED intended to treat their priapism, of which 14% experienced detumescence without further intervention. All patients treated successfully with medications alone received terbutaline, with additional medications including pseudoephedrine, topical nitroglycerin paste, and sodium bicarbonate.

## Disclosure:

Work supported by industry: no.

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## Alterations in vaginal pain sensitivity in women with dyspareunia independent of psychological factors

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**Objective:** Pain sensitivity, oral contraceptive use, psychological factors, and age are postulated to be contributing factors for dyspareunia. To determine the role of these factors, we performed a secondary analysis on a dataset containing sexual history variables and measures of pressure pain threshold

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(PPT), a quantitative sensory testing method routinely employed in pain medicine.

**Materials and Methods:** To focus on mechanisms involved in dyspareunia, we evaluated sexually active women (n=36) who had no other forms of chronic pelvic pain aside from dyspareunia. Dyspareunia was self-evaluated at two independent sessions on a 0-10 visual analog scale (VAS). Women were further subdivided into women with dyspareunia (VAS >0.5; n=7) and without dyspareunia (VAS <0.5; n=29). The STAI and CES-D were used to evaluate anxiety and depression. Self-reported numeric rating scale (0-10) pain scores were recorded during palpation of vaginal and external sites during a standardized physical exam. Vaginal PPTs were measured bilaterally on iliococcygeus sites, at the bladder interface, and the rectal interface. External PPTs were measured on the hip, knee, scapula, and forehead. Medians [25th - 75th percentile] are reported because the data was not normally distributed. Wilcoxon Rank Sum tests were performed to compare differences between groups. Linear regression was used to evaluate the relationship between age and vaginal PPTs.

**Results:** Women with isolated dyspareunia reported almost no pain during clinical exam (0.0 [0.0-0.1]) similar to controls (0.0 [0.0-0.0], p=0.2), but significantly lower pelvic PPTs (1.1 kg/cm<sup>2</sup> [1.0-1.4] vs. 1.6 [1.2-1.9]; p<0.05). Differences in external PPTs were not significant (3.4 [2.9-3.6] vs. 3.9 [3.1-4.5]; p=0.08). There were no significant differences in depression (p=0.15) or anxiety (p=0.17). Women with dyspareunia were more likely to report use of oral contraceptives (4/7 vs. 3/29; p<0.05). Younger ages in women with dyspareunia (p=0.08) and among oral contraceptive users (p<0.01) may have contributed to effects on vaginal pain sensitivity. Lower vaginal PPTs were correlated with younger age (r=0.53, p<0.001).

**Conclusions:** Independent of psychological factors, increased vaginal pain sensitivity is associated with self-reported dyspareunia isolated from other forms of chronic pelvic pain. Further studies will be required to dissociate the additional potential contributions of age and oral contraceptive use on dyspareunia.

## Disclosure:

Work supported by industry: no.

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## Quality of life and sexual health function in bladder cancer surgery patients who underwent cystectomy

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**Objective(s):** Bladder cancer (BICa) currently affects 563,640 people in the United States. Patients' decline in sexual function after surgical treatment for BICa has been documented. Studies with female patients have shown mixed results, varying by

surgical techniques such as nerve-sparing. The purpose of this study is to assess the impact of cystectomy on sexual function in a large cohort of patients with muscle invasive BICa.

**Material and Method(s):** Sexual function of BICa patients who underwent cystectomy at a Midwestern Cancer Center from 2008 to present (n=414) was assessed pre-surgery and 6 months post-surgery using the Bladder Cancer Index, which measures several disease-specific quality of life domains. Data on demographics and nerve-sparing surgery were also collected.

**Result(s):** Subgroup analyses show that, while sexual function at baseline was similar for males and females, males (n=320) experienced significant decrease in sexual function between pre-surgery and post-surgery time points (mean difference=11.58; p<0.01) while women (n=94) experienced slight, non-significant decrease on average. Age was significantly and negatively correlated with sexual function at baseline for males (r=-0.44; p<0.01); females showed a small non-significant negative correlation. We expect that controlling for demographic and clinical variables may reveal a positive relationship between nerve-sparing surgeries and overall sexual function; however, gender-based differences are likely to remain.

**Conclusion(s):** While both men and women should be counselled about sexual function recovery after cystectomy, loss and grief may be greater for men and necessary to address in counselling because of significant functional decline. For women, whose sexual function remained unchanged, interest in sexual recovery, not loss and grief may be more appropriately addressed. In contributing to the limited literature on female sexual function in BICa research, we hope to increase support for targeted sexual health interventions in clinical care for BICa patients.

## Disclosure:

Work supported by industry: no.

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## Smaller urethral caliber in prostatectomy versus non-prostatectomy patients: Comparison of AUS cuff sizes

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**Objective:** Prior studies have shown decreases in penile length and circumference in patients following radical prostatectomy. Our experience is that patients who have undergone prostatectomy seem to have smaller urethral circumferences than non-prostatectomy patients. Using artificial urinary sphincter (AUS) cuff size, we compared urethral caliber between prostatectomy and non-prostatectomy patients in a nationwide cohort.

**Methods:** American Medical Systems (AMS) Patient Information Form (PIF) data was used to identify all patients who underwent AUS placement between 2004 and 2013.

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Patients were divided by prostatectomy status and era of AUS placement (before or after 3.5 cm cuff release in 2009). Mean cuff length and distribution of cuff sizes were compared between prostatectomy and non-prostatectomy patients. Regression analyses were used to identify associations between patient age and prostatectomy status with cuff length.

**Results:** 17,038 (86%) prostatectomy and 2,862 (14%) non-prostatectomy patients underwent AUS placement between 2004 and 2013. Prostatectomy patients underwent AUS placement at an older age compared to non-prostatectomy patients (mean 68.3 years versus 65.3,  $p<0.001$ ). Mean cuff size over the 10-year study period was 4.2 cm for prostatectomy patients and 4.3 cm for non-prostatectomy patients ( $p<0.001$ ). After the release of the 3.5 cm cuff, mean cuff size was 4.1 cm for prostatectomy patients and 4.3 cm for non-prostatectomy patients ( $p<0.001$ ). Prostatectomy patients underwent 3.5 cm cuff placement more frequently compared to non-prostatectomy patients (17.7% versus 13.5%,  $p<0.001$ ). Patient age and history of prostatectomy were both negatively associated with cuff length ( $p<0.0001$ ).

**Conclusions:** In a nationwide cohort, prostatectomy patients had smaller urethral calibers and received 3.5 cm cuffs more frequently than non-prostatectomy patients.

## Disclosure:

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## Buccal mucosal graft urethroplasty for the treatment of urethral stricture in the neophallus

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**Objective:** There are multiple techniques described for neophallus reconstruction for gender reassignment or after traumatic or surgical loss of the phallus. At our institution, the preferred method is radial forearm free flap. Urethral strictures are common following neophallus creation, and management is challenging as most are refractory to endoscopic management. We present our approach to and outcomes with mucosal graft urethroplasty for refractory strictures in the radial forearm flap neophallus.

**Material and Methods:** All patients who underwent buccal mucosal graft urethroplasty by a single surgeon for urethral stricture in a neophallus between March 1998 and June 2013 were identified. All urethroplasties were performed using one-stage ventral onlay buccal mucosal graft following incision of the stricture.

**Results:** The study population consisted of 10 patients. One patient underwent creation of neophallus following traumatic injury while all others were performed in association with gender reassignment. In all patients, strictures were located

at the anastomosis between the native and neourethra. Mean age at urethroplasty was 39 years (range 26-56). Mean stricture length was 3.6 cm (range 2-6). Median follow-up was 236 days (range 20-2555). At last follow-up, each of our first 3 patients had stricture recurrence, whereas, 5 of the next 7 patients were free of stricture (overall success rate 50%). 11 total follow-up stricture procedures were performed in these five patients, including 8 internal urethrotomies, one suprapubic tube and two re-do buccal graft urethroplasties. The only perioperative complication was one case of mild rhabdomyolysis, which resolved quickly with fluid support.

**Conclusions:** Experience with urethral strictures in the neophallus is limited, and management is challenging. Buccal mucosal graft urethroplasty may be more effective than endoscopic management, but failure is common. Modifications in surgical approach and increased experience may improve outcomes.

## Disclosure:

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## Transitioning transgender

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**Objectives:** Transitioning, the process undertaken by transgender persons to align their gender expression with their gender identity, is highly individualized and complex, but generally results in improved quality of life. Health professionals are vital to the transition by providing mental health, medical, and surgical interventions. However, transgender persons report mistreatment in healthcare contexts, and physicians have identified barriers to their care of trans patients, including discomfort in influencing decision-making relating to surgical or medical procedures. With the intention of reducing this barrier, a survey was developed asking transgender persons to identify elements of the transition they considered to be most important for "feeling like" and "passing as" their identified gender. "Feeling like" and "passing as" represent internal and external manifestations of gender identity, respectively. The purpose of this study is to better understand the transition process and establish a basis for providing transition-related medical and surgical advice to optimize care for transgender patients.

**Methods:** IRB approval was obtained to conduct an online survey within our network of transgender patients.

**Results:** Of 126 people that logged on to the survey, 84 completed it ( $n=46$  Male-to-Female (MtF) and  $n=38$  Female-to-Male (FtM)). The following percentages represent the proportion of respondents who identified that they had undergone a procedure and ranked it as "Very Important" to their transition.

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Among MtF respondents, most important to feeling like their identified gender were hormone therapy (96%), name change (94%), and top surgery/breast augmentation (88%), and most important for passing as their identified gender were hormone therapy (89%), name change (88%), and frontal bone setback (82%). For FtM respondents, most important for feeling like their identified gender were top surgery/chest reconstruction (100%), voice therapy (100%), and hormone therapy (96%), and most important for passing as their identified gender were hormone therapy (93%), top surgery/chest reconstruction (83%), and legal gender change (82%).

**Conclusions:** The need for transgender-health knowledgeable healthcare providers is unequivocal. Physicians will be able to use the results of this survey to better counsel transgender patients who seek guidance for treatment during the transition process.

**Disclosure:**

Work supported by industry: no.

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**Erectile dysfunction after recurrent ischemic priapism in patients with and without sickle cell disease: Comparative analysis of risk factors**

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**Objectives:** Erectile Dysfunction (ED) is a known complication of recurrent ischemic priapism (RIP) with a documented high risk in sickle cell disease (SCD) patients. However, the risk factors associated with this complication are incompletely defined. For this analysis, we focused on "minor" RIP, since major episodes are characterized to produce irreversible cavernosal tissue damage.

**Materials and Methods:** We performed a retrospective study of RIP patients seen in our clinic from June 2004 to March 2014 using priapism-specific, IIEF and SHIM questionnaires. We defined RIP as having  $\geq 2$  episodes of ischemic priapism within the past 6 months, with the majority ( $>75\%$ ) of episodes lasting  $<5$  hrs. Patients with incomplete questionnaires or priapism histories were excluded.

**Results:** Of 124 patients reviewed, 63 were deemed eligible [41 SCD (mean age  $28.0 \pm 8.9$  yrs) and 22 non-SCD (mean age  $33.3 \pm 12.8$  yrs) (17-idiopathic, 5-drug-related)]. SCD patients had a mean RIP duration of  $9.1 \pm 6.9$  yrs vs  $4.8 \pm 4.9$  yrs in non-SCD patients ( $p=0.006$ ). Thirty-two of 41 (78.0%) SCD patients vs 11 of 22 (50%) non-SCD patients ( $p=0.02$ ) had episodes regularly lasting  $\leq 2$  hrs ("very minor"). Twenty-seven of 41 (65.9%) SCD patients vs 15 of 22 (68.2%) non-SCD patients had weekly or more frequent episodes ( $p=0.85$ ). Twenty of 41 (48.8%) SCD vs 6 of 22 (27.3%) non-SCD patients had ED (IIEF $<25$  or SHIM $<22$ ) ( $p=0.10$ ). Among patients with ED, 16 of 20 (80%) SCD vs 1 of 6 (16.7%) non-SCD had episodes lasting  $\leq 2$  hrs ( $p=0.004$ ). Also

among patients with ED, 12 of 20 (60%) SCD vs 3 of 6 (50%) non-SCD had weekly or more frequent episodes ( $p=0.66$ ).

**Conclusion:** ED is associated with RIP, occurring in approximately 30-50% of affected individuals. SCD patients are more likely to experience RIP episodes regularly lasting  $\leq 2$  hrs compared to non-SCD patients although both groups have similar episode frequencies. The likelihood of experiencing ED in SCD RIP appears to be related to RIP duration despite very minor episode durations ( $\leq 2$  hrs).

**Disclosure:**

Work supported by industry: no.

200

**The early use of phenylephrine in the prophylaxis of iatrogenic priapism in Peyronie's patients undergoing penile duplex doppler ultrasonography**

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**Objective(s):** Characterize incidence of prolonged erection after intracavernosal injection (ICI) of alprostadil using Peyronie's disease patients as a model population and characterize efficacy of prophylactic phenylephrine in preventing iatrogenic priapism in these patients after ICI during in-office Peyronie's evaluation.

**Material and Method(s):** A retrospective review of patients with Peyronie's disease in a specialized practice ( $n=78$ ) was used to evaluate the efficacy of phenylephrine prophylaxis on prolonged erections after alprostadil ICI during Peyronie's disease workup with penile duplex Doppler ultrasonography (PDDU). Patients received 10\_g alprostadil to achieve tumescence, with an additional 10\_g for complete response. Grade of penile rigidity (1 to 5) and direction of penile curvature were noted, along with PDDU-recorded peak systolic (PSV) and end diastolic velocity (EDV). Patients with prolonged rigidity after 1 hour received 200\_g phenylephrine with 5 minutes of firm pressure. Systemic symptoms were recorded. Patients with neurogenic causes of erectile dysfunction were excluded ( $n=0$ ). A database based on patient data objects and results of in-office evaluation were compiled. The patients were divided into 2 groups based on penile rigidity of 1-3 (minimal) and 4-5 (full tumescence). One patient was excluded for immediate phenylephrine reversal.

**Result(s):** The 4-5 rigidity group and the 1-3 group had no significant differences in demographics and comorbidities. 44/77 (57%) patients had persistent tumescence (4-5) after one hour and received phenylephrine. All patients achieved detumescence after injection. No patients reported priapism ( $n=0$ ). The 44 patients were subdivided into reported erectile dysfunction history, with 26/44 (59%) reporting no ED symptoms (PD only) and 18/44 (41%) with a history of ED (PD+ED). On PDDU, ESV in the PD+ED group was  $20.94 \pm 5.71$  and in the

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PD only was  $25.92 \pm 7.30$  ( $p=0.02$ ).

**Conclusion(s):** Phenylephrine prophylaxis in patients with prolonged erections after alprostadil intracavernosal injection is effective in preventing iatrogenic priapism, especially in patients who are at high risk. This can prevent unnecessary patient stress and save healthcare dollars in the form of decreased ER visits for emergent priapism management. More patients may be receiving workup for Peyronie's with increased awareness of the disease from new FDA approval of minimally invasive collagenase therapy.

**Disclosure:**

Work supported by industry: no.

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**Perineal body lengthening in females with displeasure of distorted perineum**

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**Objectives:** The female perineal body is an important anatomical structure that has a role in supporting the pelvic floor, in maintaining fecal and urinary continence, and in sexual function. The average perineal body length is between 3.1 and 3.9 cm. A short perineum, 2.5 cm or less, is associated with increased risk of perineal trauma, particularly during childbirth, which can lead to significant postpartum morbidity. A short perineal body can also be considered by a woman to be aesthetically displeasing and can be a cause of dyspareunia, which can both lead to reduced quality of life and sexual dysfunction. The purpose of this case series is to demonstrate that perineoplasty can be utilized to lengthen the perineal body in order to improve aesthetic appearance, enhance sexual function, and reduce dyspareunia and other sequelae of perineal trauma such as incontinence.

**Methods:** At the University of Miami Hospital, three female patients with short perineal body (2.5 cm or less) underwent perineoplasty with perineal body lengthening. A diamond-shaped perineoplasty incision technique was used.

**Results:** The perineal bodies were lengthened by 1.4cm, 1.1cm, and 1.5cm, respectively. A paired samples *t* test revealed a statistically reliable difference between the mean pre-operative perineal body length ( $M = 2.20$ ,  $s = 0.26$ ) and post-operative perineal body length ( $M = 3.53$ ,  $s = 0.06$ ),  $t(2) = -11.1$ ,  $p = 0.01$ ,  $\alpha = .05$ . Additionally, each patient reported a decrease in her dyspareunia after surgery, demonstrated by decreased of report pain on the Visual Analog Scale. Patients' reported improved quality of life and sexual functioning, resolution of incontinence, and satisfaction with aesthetic appearance as early as six weeks postoperatively.

**Conclusions:** This case series demonstrates a surgical

technique that can be successfully performed to lengthen the perineal body. Because of the improvement of quality of life, particularly related to sexual functioning and continence, in each of these patients, the benefit and importance of the lengthening perineoplasty are clearly demonstrated, making this surgery a valuable therapeutic and potentially prophylactic option for women with short perineal bodies.

**Disclosure:**

Work supported by industry: no.

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**Complications of genital piercings**

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**Objectives:** Genital piercing has become a social reality in our present day culture. Its practice is not limited by sexual preference, gender, age, or background. There are a variety of complications related to the piercing of both male and female genitalia that can affect the individual and his or her sexual partner. Currently, men and women with genital piercings report feeling uncomfortable discussing piercing care or treatment of complications with their healthcare provider and instead seek advice from nonmedical sources. It is therefore imperative for healthcare providers to be more aware of genital piercing practices. The purpose of this review is to familiarize healthcare providers with genital piercings, including common jewelry, motivations for getting genital piercings, and potential complications, so that they are better able to care for genitally pierced patients.

**Methods:** A Pubmed search of existing literature using the terms genital piercing, complications of genital piercing, clitoral piercing, penile piercing, and Prince Albert along with references from bibliographies of papers from the literature search until September 2013 were used to in this review.

**Results:** The most common genital piercing for men and women are the Prince Albert and vertical clitoral hood respectively. Most people who seek genital piercings do so to enhance sexual expression and improve sexual pleasure. The most common rings used are the barbell, the curved barbell, and the captive ring. In studies that surveyed men and women with genital piercings, over 50% of respondents report suffering from complications. Reported structural complications of genital piercings, more common in men than women, include bleeding, site tears, strictures, fistulas, keloids, scars, urethral damage, and genital swelling. Other complications include infection, injury to sexual partner, and interference with barrier contraception. Potential complications of genital piercings are

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tearing during childbirth or during sexual intercourse, difficulty inserting a foley catheter, and fibrosis or numbness at the piercing site.

**Conclusions:** Genital piercing is an increasingly common trend. This review provides a guide for providers to increase awareness of genital piercings in order to better offer appropriate counseling and treatment, which can lead to better care for their patients with genital piercings.

**Disclosure:**

Work supported by industry: no.

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**Ligasure vessel sealing system facilitates rapid excision of massive genital lymphedema: A multi-institutional experience**

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**Introduction:** We present a multi-institutional series of patients who underwent surgical treatment for massive genital lymphedema and explore the utility of the LigaSure™ hemostatic vessel sealing system for resection of advanced cases.

**Methods:** A chart review of all patients who underwent surgical treatment of massive genital lymphedema from 2008-2014 was performed. The LigaSure™ hemostatic vessel sealing system was used in cases of extensive disease to mitigate bleeding and improve operative times. Results were compared to cases resected with Bovie® electrocautery alone. Reconstruction was then performed using adjacent tissue transfer (ATT), split-thickness skin grafting (STSG), or both. Preoperative characteristics and technical considerations were analyzed.

**Results:** Thirteen patients (mean age 48 years, range 24-64) underwent 17 procedures (mean specimen weight 1782g, 100-9528g) for the treatment of massive genital lymphedema during the study period (mean follow-up 37 months). Surgical technique included excision using Bovie® electrocautery alone in 11/17 (65%) and LigaSure™ in 6/17 (35%). The LigaSure™ allowed for lymphedema resection to be performed over three times the rate of patients undergoing surgery with Bovie® electrocautery alone (17.7 g/min vs. 5.3 g/min,  $p < 0.05$ ). Therapy consisted of excision of affected tissue with ATT (7/17, 41%), STSG (4/17, 24%), or both (6/17, 35%). Surgical sites included scrotal (4/17, 24%), penile (1/17, 6%), penoscrotal (7/17, 41%), abdominopenoscrotal (4/17, 24%), and suprapubic (1/17, 6%). Specimen weights for patients treated with the LigaSure™ were far greater than patients treated with Bovie® electrocautery only (3646 g vs. 765 g,  $p < 0.001$ ). Of the 13 patients, 2 patients receiving Bovie® electrocautery alone recurred (15%) and required a total of 5 procedures for lymphedema treatment.

**Conclusions:** Resection of genital lymphedema using the LigaSure™ device offers promising results in management of advanced disease with the potential for faster resections and a low rate of recurrence.

**Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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**Dutasteride for recurrent priapism: A novel therapy**

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**Objective:** Several small series have reported efficacy of finasteride in treating patients with recurrent priapism. Recent laboratory studies demonstrate a decrease in erectile response to cavernosal nerve stimulation among animals treated with 5 $\alpha$ -reductase inhibitors. We present our results of prescribing dutasteride as prevention of recurrent ischemic priapism.

**Materials & Methods:** We performed a retrospective review of all outpatient visits for priapism seen by a single provider from 2011-2014. We identified patients with recurrent priapism who were treated with dutasteride (0.5 mg daily, reduced to twice per week after one month if patient is responding). We recorded demographic and clinical information, as well as adverse events. Success was defined as no further episodes of priapism, and all patients were questioned about side-effects at follow-up.

**Results:** We treated 7 men with recurrent priapism using dutasteride, which prevented recurrence in 6/7 for an overall success rate of 86%. Mean age was 41 years (30-56), and 2/7 (29%) had sickle cell disease while 5/7 (71%) were idiopathic. Mean follow-up was 19 months (6-38). One patient (14%) has a successful result, but developed gynecomastia, and was successfully changed to finasteride 5 mg daily. The one failure (14%) was a patient who recurred after he began using recreational marijuana after starting treatment and was then also started on bicalutamide briefly; at 6 months he remains on dutasteride without recurrent priapistic episodes. No patient reported any sexual side effects.

**Conclusion:** Dutasteride appears to be safe and efficacious in treating patients with recurrent priapism, though larger, prospective studies are needed to confirm our results.

**Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.



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## **The reduction corporoplasty: The answer to the unlikely question, "Can you make my penis smaller?"**

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**Objectives:** Large and/or deformed phalluses secondary to hyperplastic/aneurysmal corpora can occur as a result of different pathological states. This is most commonly seen in recurrent priapism, and is secondary to blood pooling in the cavernous sinusoids with resultant hypoxemia, acidemia, and eventual cavernous smooth muscle necrosis with fibroblast proliferation, plaque formation, and collagen deposition. We present a surgical technique for the management of this morphologic deformity, the reduction corporoplasty.

**Materials and Methods:** A 17-year-old male with a history of sickle cell disease presented with a phallus that was "too large for intercourse". The patient reported normal erectile function with masturbation, but inability to penetrate his partner due to the size and shape of his phallus. He had a history of three priapismic episodes since 10 years of age, each treated with irrigations in the emergency department. These episodes progressively led to the aneurysmal deformity of his phallus. Further evaluation included an MRI, which revealed true aneurysmal dilatation of bilateral corpora cavernosa distally, with diffusely hyperplastic tunica.

**Results:** The patient was taken to the operating room, and the penis was degloved via a circumferential incision. Elliptical cuts were then made over the lateral aspects of both corpora, incising a longitudinal ellipse of the aneurysmal corpora. These elliptical wedges of aneurysmal corpora were then removed, and healthy bleeding smooth muscle surrounded by a thick collagen rind was noted. The edges of the elliptical incisions were transversely closed, with 3-0 vicryl sutures in an interrupted, watertight fashion, with the aid of Allis clamps. The phallus was inspected for symmetry, cosmesis, and adequate reduction. The circumcision incision was closed and drains left in place. At the latest follow up of 6 months the patient reports normal erections and successful coitus.

**Conclusions:** Reduction corporoplasty was performed, and the patient reported intact erectile function without aneurysmal recurrence at 6 months postoperatively. We present this case, the subsequent successful treatment of this debilitating pathology with the surgical technique, reduction corporoplasty. The literature is currently scarce in providing a protocol for managing patients with corporal enlargement. Reduction corporoplasty can optimize sexual function while improving the cosmetic appearance of a deformed phallus such as the one discussed here.

### **Disclosure:**

Work supported by industry: no.

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## **Non-grafted vaginal depth augmentation for transgender atresia, our experience and survey of other procedures**

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**Objective:** To follow the outcome of male to female (MTF) transsexuals undergoing secondary depth enhancement without use of graft or flap.

**Material and Methods:** Eighteen patients were evaluated with a non-grafted approach for a vaginal depth enhancement. The fascial plane of Denonvilliers was reopened and packed for 7 days to facilitate maintenance of a pelvic space. Patients were requested to perform serial self-dilations with a stent set indefinitely to maintain patency and procure additional depth. Immunohistochemistry staining was performed to demonstrate estrogen receptor (ER) presence in male genital skin. Estrogen cream may be utilized to facilitate wound healing.

**Results:** Following revision of the pelvic space, static depths increased two-fold on average from 2.44 inches (6.2 cm) to 5.0 inches (12.7 cm). The FSFI domain scores (of desire, arousal, lubrication, orgasm, satisfaction, and pain) were all mid-range or above. Full scale FSFI score (compilation score) averaged 23.4 (range limits 2-36). Histologic staining showed presence of ER in genital skin of all genetic males tested regardless of estrogen usage and perceived gender.

**Conclusions:** Given adequate development of the rectal-vesical space and preservation of that space with serial self-dilation, epithelialization will ensue providing sexual gratification for patient and partner (as per patient).

### **Disclosure:**

Work supported by industry: no.

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## **High-flow priapism due to penile malignant peripheral nerve sheath tumor in a patient with Von Recklinghausen disease**

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**Objective:** Most commonly, non-ischemic, high flow, arterial priapism arises from post-traumatic vascular injury leading to fistula formation. Although much less common, tumors located near or within the corpus cavernosum can also be a cause. We have identified the first reported case of high-flow priapism secondary to a malignant peripheral nerve sheath tumor at the base of the penis in a patient with Von Recklinghausen's disease. The goal of this case is to review causes, diagnosis and treatment for high-flow priapism.

**Methods:** A case of biopsy-proven malignant peripheral nerve sheath tumor arising circumferentially around the base of

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the penis in a 60 year old white male with a known history of Neurofibromatosis, type I who presented to the urology clinic with a 4 week history of a continuous erection. MRI and Penile Doppler US was performed, ultimately leading to biopsy of the mass and subsequent treatment.

**Results:** MRI demonstrated heterogeneity and enlargement of the penile cavernosa, with disruption of the tunica at the level of the penoscrotal junction, suggestive of a 2.4cm plexiform neurofibroma of the penile corpora cavernosa. Penile Color Doppler US was performed establishing high flow priapism with peak systolic velocities of 62 cm/sec on the right, 53 cm/sec on the left, elevated end diastolic velocities throughout the examination, and no evidence of an arterial sinusoidal fistula or trauma. Under general anesthesia, cystoscopy and transcutaneous biopsy of the mass was performed. Final pathology revealed a grade 2 sarcoma, representing a malignant peripheral nerve sheath tumor. PET scan was negative. After review from our institutional tri-site sarcoma conference, it was determined that the patient would undergo preoperative radiation therapy, followed by total penectomy. After receiving neoadjuvant RT 500cGy, MRI of the pelvis demonstrated progression of the penile tumor to 3.8 cm with evidence of regional metastasis to right acetabulum and pubic symphysis. CT of chest revealed evidence of multiple pulmonary metastases, largest measuring 1.2 cm. He is currently undergoing chemotherapy with AIM (adriamycin, ifosfamide, mesna), with no plans for surgical intervention.

**Conclusion:** Clinical presentation, MRI and color Doppler US are important in appropriately diagnosing high-flow priapism. Although rare, non-ischemic, high-flow priapism secondary to tumor has been reported, though this is the first case reported a malignant, peripheral nerve sheath tumor as the source of high-flow priapism.

## Disclosure:

Work supported by industry: no.

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## Efficacy and safety of polylactic acid microsphere as an injectable bulking agent for penile enhancement: 6-months follow-up

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**Objectives:** Polylactic acid (poly-D,L-lactide; PLA) has been widely used as an injectable bulking agent for cosmetic volume enhancement, such as a correction of facial lipoatrophy. We first evaluated the efficacy and safety of injectable PLA filler for penile enhancement.

**Materials and Methods:** 23 healthy adult males were included

in this study. PLA filler was injected into the subcutaneous tissue of the penile shaft, between Colles' fascia and Buck's fascia by the fanning technique using a syringe with 18-gauge needle. The penile girth was measured in flaccid state, at baseline, and at 3 and 6 months after the injection. Subject's satisfaction was measured using a visual analogue scale (VAS; 0-100 point), at baseline, and at 3 and 6 months. Adverse events were evaluated immediately after injection, and at 3 and 6 months.

**Results:** Mean injected volume was 10.0 ml. The circumference of penile girth increased by mean  $2.4 \pm 1.1$  cm at 3 months ( $p < 0.001$ ). There was no significant difference in the girth circumference between 3 and 6 months post-procedure ( $p = 0.511$ ). VAS points increased steadily from  $51.6 \pm 14.7$  at baseline to  $65.0 \pm 19.3$  at 3 months, and a further  $74.3 \pm 14.6$  at 6 months ( $p < 0.001$ ). The procedure-related adverse events were 5 cases, including 3 cases of injection site induration, one of penile curvature, and one of painful erection. All adverse events were mild, and improved within follow-up period. There were no clinically significant adverse events in all subjects.

**Conclusions:** Penile injection of PLA filler led to a significant increase in penile size, and was well-tolerated and safe without serious adverse events. These results suggest that penile injection of PLA filler may be a new effective method for penile enhancement.

## Disclosure:

Work supported by industry: no.

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## Efficacy and safety of newly developed glandular injection of cross-linked dextran gel on glans penis augmentation

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**Objective:** Glans penis augmentation has been performed in real practice, although it is not an established procedure. Cross-linked dextran gel is a newly developed filler for glans penis augmentation. We evaluated the efficacy and safety of injectable cross-linked dextran gel for glans penis augmentation.

**Materials and Methods:** 18 healthy adult males were included in our study. Gel was injected into the lamina propria layer of the glans penis by the fanning technique. The glandular size was measured, at baseline and at 6 months after injection. Subject's satisfaction was measured at 6 months. Adverse events were evaluated immediately after injection, and at 1 and 6 months.

**Results:** Mean injected volume was 6.4 ml. The mean glandular sizes before injection and at 6 months were  $20.0 \pm 3.5$  and  $33.6 \pm 5.4$  cm<sup>2</sup> (68.7% increases,  $p < 0.001$ ), respectively. In all subjects, there was a size increase of more than 45%.

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16 subjects (88.8%) were satisfied, whereas only two (11.1%) were dissatisfied. All subjects experienced mild and transient penile pain and edema immediately after injection. However, in almost all subjects, these spontaneously subsided within two weeks, and there was only one case lasting for 6 months. At 1 month, there were 3 cases of ecchymosis, 3 of erythema, 1 of paresthesia, and 1 of surface irregularity, respectively. However, all of them spontaneously subsided within 6 months. There were no serious adverse events in all subjects.

**Conclusions:** Glandular injection of cross-linked dextran gel led to a significant increase in glandular size, and was well-tolerated and safe without serious adverse events. Our study suggests that glandular injection of cross-linked dextran gel may be a new effective method for glans penis augmentation.

**Disclosure:**

Work supported by industry: no.

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### Spontaneous cavernosal hematoma mimicking malignant priapism

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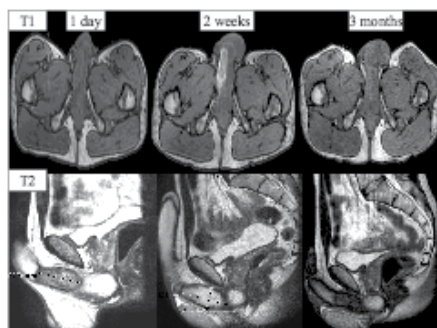
1: Boston Medical Center, USA; 2: Jersey Shore University Medical Center

**Objective(s):** Identification of spontaneous cavernosal hematoma mimicking malignant priapism

**Material and Method(s):** 42 year old man presented with partial erection and penile pain of 72 hour duration following long-distance bike riding. Evaluation included physical exam, penile ultrasound (US) and magnetic resonance imaging (MRI).

**Result(s):** Penile ultrasound revealed a heterogeneous, non-vascular corporal mass. MRI demonstrated a 2.2 x 7.3cm lesion occupying the right proximal corpus. Underlying malignancy could not be ruled out. Clinical evaluation failed to identify source of presumed malignancy. Expectant management resulted in spontaneous resolution of cavernosal hematoma as documented on serial MRI. There were no short or long-term complications.

**Conclusion(s):** Spontaneous cavernosal hematoma is rare. Few cases have previously been reported. Malignancy should be ruled out. MRI is beneficial in diagnosis and confirmation of resolution of hematoma.



**Disclosure:**

Work supported by industry: no.

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### Functional outcomes and followup care for rare priapism cases: Spinal cord injury and baclofen pump malfunction

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**Objective:** To assess functional outcomes and followup care for rare priapism cases.

**Materials and Methods:** Retrospective review of consecutive priapism cases at a single institution from January 2005 to June 2014 was performed. Patients were grouped by priapism etiology to identify rare cases. After providing informed consent, patients completed a survey consisting of the International Index of Erectile Function (IIEF)-15, Erection Hardness Score (EHS), and followup care since their last priapism episode.

**Results:** There were 102 uniquely presenting cases of priapism from a total of 62 patients. Two rare priapism etiologies associated with spinal cord pathology were identified: spinal cord injury (3) and baclofen pump malfunction (1). Case #1: Patient with C5-7 subluxation fractures from a 25-foot fall. On exam 3 hours post-injury, the penis was engorged but not rigid. Priapism was managed conservatively and complete detumescence occurred by the next morning (9 hours later). At 4.5-month followup, his IIEF-15 was 14 and EHS 5. Case #2: Patient with C5-6 fracture dislocation from motor vehicle collision (MVC) resulting in incomplete quadriplegia. Nine hours after the accident, priapism was noted at the scene. On exam in the ED, penis was engorged but not completely rigid. Patient was managed with observation. At 28-month followup, the patient reported spontaneous erections with full rigidity, but no erections to sexual stimulation. His IIEF-15 was 33 and EHS 5. Case #3: Patient with C6-7 fracture from MVC resulting in incomplete quadriplegia. Priapism was first noted at the scene, and persisted on arrival to the ED. Spontaneous detumescence occurred 5 hours after the injury. At 2-month followup, his IIEF-15 was 6 and EHS 0. Case #4: Patient with cerebral palsy was admitted for malfunction of his intrathecal baclofen pump. Patient reported a penile burning sensation and intermittent painful erections lasting 2 hours. He underwent baclofen pump revision and Urology was consulted on postoperative day 1 for priapism. However, penis was flaccid on exam. Patient was managed expectantly.

**Conclusions:** Two rare priapism etiologies were identified in this large case series: spinal cord injury and baclofen pump malfunction. All cases were observed with spontaneous detumescence. Followup IIEF-15 revealed poor erectile function although scores ranged from 0-33 while EHS varied from 0-5.

**Disclosure:**

Work supported by industry: no.

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## **Intracavernosal prostaglandin injection prior to circumcision allows more precise removal of foreskin**

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**Objective:** To evaluate the outcomes of circumcision with the use of intracavernosal injection (ICI) of prostaglandin to induce an erection at time of operation.

**Materials and Methods:** 20 patients undergoing circumcision received ICI of prostaglandin prior to surgery. Demographics of all patients along with outcomes and complications at 2-week follow up were recorded.

**Results:** No complications were evident at 2-week follow up. All 20 patients were satisfied with cosmetic result.

**Conclusions:** Circumcisions performed with ICI of prostaglandin is a novel technique that allows accurate removal of foreskin and can be safely applied to current surgical technique for improved cosmetic results.

### **Disclosure:**

Work supported by industry: no. The presenter or any of the authors act as a consultant, employee (part time or full time) or shareholder of an industry.

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## **Mechanism of hypogonadism in the transgenic sickle cell mouse**

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**Objectives:** Priapism is common in patients with sickle cell disease (SCD). Because hypogonadism occurs in SCD patients and may contribute to priapism, we investigated the mechanism of testosterone (T) deficiency in a mouse model of human SCD.

**Methods:** 7 month old homozygote SCD (Sickle) mice were used. Age-matched heterozygote SCD (Hemi) and WT mice served as controls. Blood was obtained for measurements of T and LH by RIA. Testes were collected for measurement of protein expressions of steroidogenic acute regulatory protein (StAR), cholesterol side-chain cleavage enzyme (P450scc), reactive oxygen species-generating NADPH oxidase subunit gp91phox, oxidative stress (4-HNE) by Western blot, intratesticular T by RIA, and Leydig cell isolation. Isolated Leydig cells were treated with LH (2.5 and 20 ng/ml), dbcAMP (1 mM), cholesterol (12.5  $\mu$ M), and pregnenolone (12.5  $\mu$ M) and T produced into the media was measured by RIA.

**Results:** Plasma and intratesticular testosterone levels were reduced significantly ( $P < 0.05$ ), while serum LH was not significantly decreased ( $P > 0.05$ ) in Sickle compared to WT mice. Testosterone production from isolated Leydig cells in response to LH, dbcAMP, cholesterol, and pregnenolone

was not significantly decreased ( $P > 0.05$ ) in Sickle compared to Hemi mice. Protein expression of StAR, but not P450scc, was significantly ( $P < 0.05$ ) reduced in the testis of Sickle compared to that of WT and hemi mice. Protein expression of NADPH oxidase catalytic subunit gp91phox and 4-HNE were significantly ( $P < 0.05$ ) increased in the testis of Sickle compared to that of WT and Hemi mice.

**Conclusion:** Hypogonadism in a mouse model of SCD is due to NADPH oxidase-derived oxidative stress and testicular damage.

### **Disclosure:**

Work supported by industry: no.

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## **Mechanism of Sonic hedgehog induced cavernous nerve regeneration**

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**Objectives:** During prostatectomy, the cavernous nerve (CN) is injured in up to 80% of patients, resulting in morphology changes in the penis that lead to erectile dysfunction (ED). In previous studies we've shown that the Sonic hedgehog (SHH) pathway is critical to maintain CN morphology and function. When the CN is injured (prostatectomy model), SHH treatment by peptide amphiphile (PA) nanofiber hydrogel is neuroprotective and speeds CN regeneration. The mechanism of how CN regeneration is enhanced by SHH is unknown. In this study we examine the mechanism of how SHH treatment promotes CN regeneration after crush injury.

**Materials and Methods:** Immunohistochemical analysis for SHH pathway members was performed on pelvic ganglia (PG) and CN of control, sham, CN crushed, CN crushed with SHH treatment, CN crushed with BSA treatment and CN cut (n=24) adult (P120) Sprague Dawley rats.

**Results:** Our results show that SHH and its receptors patched (PTCH1) and smoothened (SMO) are localized in normal PG neurons, and SMO undergoes anterograde transport by the CN to signal to down stream targets. When the CN is crushed, PG neurons die, SHH protein is decreased in neurons but not the associated glia, SMO localization changes to the neuronal cell surface and is not transported by the CN. With SHH PA treatment, PG neurons remain intact with normal SHH pathway signaling. SHH is taken up at the injury site and undergoes retrograde transport to PG neurons, allowing SMO transport to occur as under normal conditions.

**Conclusions:** These results show that SHH is neuroprotective and promotes CN regeneration by preventing neuronal death in the PG and maintaining normal signaling mechanisms to down stream targets. This study is significant because understanding how regeneration occurs can provide novel avenues to further enhance regeneration and to prevent ED.

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## Disclosure:

Work supported by industry: no. Sources of Funding: NIH/ NIDDK DK079184, DK101536

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### Topically applied NO-releasing nanoparticles can increase intracorporal pressure and elicit spontaneous erections in a rat model of radical prostatectomy.

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**Objective(s):** Patients undergoing radical prostatectomy (RP) suffer from erectile dysfunction (ED) refractory to PDE5 inhibitors, which act downstream of CN-mediated release of NO. We previously demonstrated topically applied NO-releasing nanoparticles (NO-np) result in spontaneous erections in an aging rat model of ED. The aim of the present study was to determine if topically applied NO-np could elicit erections in a rat model of RP and demonstrate that the mechanism is through increased blood flow.

**Material and Method(s):** Sprague-Dawley rats underwent bilateral transection of the CN. One week later NO-np were applied topically to the penile shaft in DMSO-gel or coconut oil. Erectile function was determined through the intracorporal pressure/ blood pressure ratio (ICP/BP) which was used to assess spontaneous erections, onset and duration of erectile response and basal ICP/BP ratio. The effect of the NO-np on blood flow was determined using a hamster dorsal window chamber where microcirculatory blood-flow was determined through arteriolar and venular diameter.

**Result(s):** Eight out of ten animals treated with NO-np suspended in DMSO-gel had a significant increase in basal ICP/ BP, and six out of the ten animals demonstrated spontaneous erections represented by ICP/BP peaks >0.6 of approximately one minute duration. Onset of spontaneous erections ranged from 5-37 minutes and occurred for at least 45 minutes. No erectile response was observed in six control animal models treated with "empty" np. Similar results were observed with NO-np applied in coconut oil. The hamster dorsal window chamber demonstrated NO-np applied as a suspension in coconut oil caused a significant increase in the microcirculatory blood flow, sustained over 90 minutes.

**Conclusion(s):** Topically applied NO-np result in spontaneous erections and increased basal ICP in an animal model of RP. These effects are most likely due to increased microcirculatory blood flow. These characteristics suggest that the NO-np would be useful in penile rehabilitation of patients following RP.

## Disclosure:

Work supported by industry: no.

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### eNOS uncoupling in the diabetic human penis

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**Objectives:** Erectile dysfunction (ED) associated with type 2 diabetes mellitus (T2DM) is characterized by impaired vasorelaxation and increased oxidative stress in the penis; however, the underlying mechanisms of diabetic ED, and specifically human diabetic ED, are not fully defined. We evaluated whether NADPH oxidase-derived oxidative stress and eNOS dysfunction occur in the penis of men with advanced T2DM and ED.

**Methods:** Human penile specimens (erectile tissue) were retrieved from proximal aspects of the penis from ED patients with advanced T2DM during penile prosthesis surgery (n=4). A control group included penile specimens from patients without ED or diabetes histories who underwent penectomy for penile cancer (n=3). Tissue was analyzed for eNOS uncoupling, oxidative stress (4-HNE and nitrotyrosine), and protein expression of NADPH oxidase catalytic subunit gp91phox.

**Results:** The ratio of eNOS functional dimers / non-functional monomers was decreased (P<0.05) in the erectile tissue of diabetic men with ED compared to that of nondiabetic control men without ED. Protein expressions of 4-HNE, nitrotyrosine, and gp91phox were increased (P<0.05) in the erectile tissue of diabetic compared to that of nondiabetic control men.

**Conclusion:** eNOS uncoupling and NADPH oxidase upregulation occur in the penis of men with advanced T2DM, suggesting increased oxidative stress that conceivably contributes to diabetic ED in this patient's population.

## Disclosure:

Work supported by industry: no.

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### Induced pluripotent stem cells (iPS) ameliorate corporal veno-occlusive dysfunction (CVOD) in a rat model of bilateral cavernosal nerve resection (BCNR), possibly through cross-talk with penile stem cells

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**Objectives:** Adult stem cells prevent and correct erectile dysfunction and the underlying histopathology when implanted into the corpora cavernosa in animal models. Clinical therapeutic translation may still be affected by the invasive

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procedures required for their isolation, impairment of their repair ability by the noxious environment of donor tissues, risk of immunorejection, and inefficient cell lineage commitment. We studied whether: a) induced pluripotent stem cells (iPS) can counteract neuropraxia-induced CVD and the underlying corporal smooth muscle (SM) and neural histopathology in a rat model of bilateral cavernosal nerve resection (BCNR); b) iPS may cross talk with penile stem cells (PSC) and stimulate their differentiation.

**Methods:** Mouse fibroblasts generated the mfiPS clone by transfection with a polycistronic plasmid for Oct4, Sox2, Klf4, and c-myc, without transgene genomic insertion (inconsequential myc risks). mfiPS were cultured on mouse embryonic feeder layer (FL) in KO-DMEM and tested in dual culture for paracrine crosstalk (dual culture in DMEM or KO-DMEM, + or - FL) with rat PSC and differentiation of PSC into various cell types, by immunocytochemistry and western blot. Rats subjected to BCNR were immunosuppressed, implanted into the corpora cavernosa with FL/KO-DMEM mfiPS ( $10^6$  cells) (BCNR-iPS), and compared at 2 months with untreated controls (BCNR-UT) (n=8/group). CVD was determined by cavernosometry. The underlying corporal histopathology was defined by histochemistry, western blot and ad-hoc assays

**Results:** The mfiPS (- FL/DMEM) cross-talked with PSC, upregulating Oct-4 (stem cells) and the calponin/ ACTA2 ratio (SM/myofibroblasts ratio), but down-regulating nanog (stem cells), the individual ACTA2 and calponin, and CD31 (endothelium). Erectile function in BCNR-iPS, versus BCNR-UT, was normalized via increasing the papaverine response and reducing the drop rate, presumably by the increase in the corporal calponin/Acta2 ratio, and eNOS (endothelium) and the reduction of collagen (hydroxyproline). Neurogenesis markers, such as NF70, nNOS and PnNOS, were up-regulated.

**Conclusions:** iPS implanted into the corpora of BCNR rats improve CVD, the corporal SM/endothelium, and the expression of neural markers. iPS may be less impaired by the original donor cell environment and be easier to generate than adult stem cells, and may crosstalk with PSC, but further work needs to compare efficacy.

## Disclosure:

Work supported by industry: no.

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## Radioprotection of erectile function using novel antioxidant in the rat

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**Objectives:** To evaluate whether systemic treatment with the potent free radical scavenger and superoxide dismutase mimetic Mn (III) meso-tetrakis(N-n-butoxyethylpyridinium-2-

yl) porphyrin, or MnBuOE, would protect erectile function (EF) after prostate-confined radiotherapy (RT).

**Materials and Methods:** Twenty-two 12 week old male rats were divided into control (n=4), RT alone (n=7), MnBuOE alone (n=4), or MnBuOE + RT (n=7) groups. RT was administered in a single 20Gy dose. MnBuOE was given at a dose of 0.5mg/kg SC daily two days before RT and continued for 28 days after RT and then twice weekly until sacrifice at nine weeks. Measurement of EF was performed at four and nine weeks by counting the number of erectile events (EE) and yawns (Y) after injection of 0.1mg/kg apomorphine. Intra-cavernosal pressure (ICP) measurements with left cavernosal nerve stimulation were performed at week 9. Statistical analysis was performed using Student's t-test between pairs for apomorphine and Student's t-test between pairs and Pearson Chi Square for entire cohort for ICP.

**Results:** MnBuOE was tolerated well with no measurable toxicity. There were no differences in EE or Y between groups at four weeks. There was a significant decrease in EE in the RT group when compared to control (control mean EE  $2.5 \pm 0.6$ , RT mean EE  $0.7 \pm 0.5$ ,  $p=0.01$ ). There was no statistical difference in EE between control and MnBuOE (MnBuOE mean EE  $2.5 \pm 1.3$ ,  $p=1.0$ ), MnBuOE+RT and control (MnBuOE+RT mean EE  $3.4 \pm 1.4$ ,  $p=0.17$ ), or MnBuOE and MnBuOE+RT ( $p=0.17$ ). Small numbers limited ICP analysis with a non-significant trend for worse ICP/basal ratio between control and RT groups ( $p=0.27$ ) but no difference among all groups ( $p=0.14$ ).

**Conclusions:** MnBuOE is a novel potent antioxidant which provided substantial radioprotection to erectile function. Experiments are underway to confirm that MnBuOE is not protective of human prostate tumor prior to advancement of this compound into clinical study.

## Disclosure:

Work supported by industry: no.

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## Efficacy of human bone marrow derived stem cells in type 2 DM rats (ZFD) with erectile dysfunction: According to dose of transplantation

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**Objective:** The aim of this study is to investigate whether injection of human bone marrow derived stem cells (BMSCs) according to the range of cellular doses can ameliorate diabetes mellitus (DM) associated erectile dysfunction (ED).

**Materials and Methods:** Forty 8 week old male type 2 diabetic fa/fa Zucker Fatty Diabetes Mellitus (ZFD) rats (DM group) and ten fa/+ ZFD rats (normal control group) underwent weight and blood glucose measurement every one week. At age 22 weeks, diabetic rats were randomly divided into four groups:

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rats that underwent intracavernous injection with PBS (n=10, DM + PBS (60µL)), low dose human BMSCs (n=10, 0.5X10<sup>6</sup> cells/60µL, DM+IBMSC), medium dose human BMSCs (n=10, 1X10<sup>6</sup> cells/60µL, DM+mBMSC), and high dose human BMSCs (n=10, 2X10<sup>6</sup> cells/60µL, DM+hBMSCs). Human BMSCs were labeled with PKH-26, and then transplanted into corporal cavernosum of diabetic rats. Four weeks after transplantation, all rats were analyzed for erectile function (the ratio between intracavernous pressure (ICP) and mean arterial pressure (MAP)) and immunohistochemistry (α-smooth muscle actine marker, von Willebrand factor marker and eNOS in corpus cavernosum and nNOS in dorsal nerve).

**Results:** After human BMSCs transplantation, the ICP/MAP ratio of IBMSC, mBMSC and hBMSC groups were increased significantly compared with diabetic controls, but there were no significant differences among the groups of human BMSCs transplantation (0.59±0.13 vs. 0.59±0.09 vs. 0.62±0.21, p=0.12). Content of smooth muscle and endothelium in corporal cavernosum of human BMSCs transplanted rats was significantly increased compared to diabetic controls. However, the α-smooth muscle actine marker and eNOS were not significant differences among the groups of human BMSCs transplantation. The nNOS marker of dorsal nerve in penis was also significantly increased in mBMSC and hBMSC groups compared with diabetic group. However, the nNOS marker did not increase in IBMSC group compared with diabetic controls. At days of 28, a few human BMSCs were visualized in corporal cavernosum.

**Conclusions:** Intracavernous transplantation of human BMSCs had beneficial effects on erectile function and histopathology of diabetic rats but the different doses maybe needed to restore destructed nerve, smooth muscle and endothelium. The more work is needed to define the optimal stem cell doses.

## Disclosure:

Work supported by industry: yes, by Ministry for Health, Welfare and Family Affairs, Republic of Korea (industry funding only - investigator initiated and executed study).

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### Effects of chronic administration of PDE5 inhibitor combined with glycemic control on erectile function in streptozotocin-induced diabetic rats

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**Objective:** Chronic treatment with type 5 phosphodiesterase inhibitors (PDE5I) is effective in an animal model of diabetes-induced erectile dysfunction (DMED). In addition, recent research indicates that glycemic control can restore DMED. We evaluated the effect of chronic administration of PDE5I combined with glycemic control on DMED.

**Material and Methods:** Sprague-Dawley rats (8-weeks-old)

were divided into five groups (n=10 each): normal control (C), diabetes (DM), DM treated with insulin (DM-I), DM treated with PDE5I (DM-P), and DM treated with insulin and PDE5I (DM-I+P). Rats in the diabetic groups received an injection of streptozotocin (45 mg/kg). After 10 weeks of induced diabetes, the DM-I group was treated with a daily injection of neutral protamine Hagedorn, and the DM-P group was treated with a daily dosage of 20 mg/kg PDE5I (DA-8159) for 4 weeks. The DM-I+P group was treated with both treatments simultaneously. After 14 weeks of induced diabetes, an evaluation of erectile function and histological and biochemical markers of corporal tissue was performed.

**Results:** Rats in the DM group showed markedly lower erectile parameters than those in the C group, whereas rats in the DM-I and DM-P groups showed intermediate erectile function between the DM and C groups. Rats in the DM-I+P group showed restored erectile function, comparable to group C. A comparison of apoptotic index, expression of the endothelial marker, and phosphorylation of eNOS and Akt displayed a similar pattern with the results from cavernosometry (DM < DM-I = DM-P < DM-I+P = C, p<0.05). The distribution of phosphorylated MYPT was in the reverse order.

**Conclusions:** Chronic administration of PDE5I or glycemic control with insulin resulted in restoration of overt DMED. The combination of both treatments was superior to monotherapy with insulin or PDE5I.

## Disclosure:

Work supported by industry: no.

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### Western diet increases penile in vivo reactive oxygen species independent of fibrotic signaling

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**Objectives:** Oxidative stress, caused by excessive production of reactive oxygen species (ROS), is implicated as a cause of erectile dysfunction (ED) in several disease states. Excessive ROS production is suggested to stimulate fibrosis, which is known to promote ED. PGC-1α is a major regulator of mitochondrial content which can be adversely affected by chronic oxidative stress to promote insulin resistance in cardiac and skeletal muscle. The objective of this study was to determine if *in vivo* penile ROS production is increased in Western diet (WD)-induced ED, and if WD induces fibrosis and changes in penile mitochondrial content.

**Materials and Methods:** Young male Sprague-Dawley rats were fed a control diet (n = 6) or WD (n = 6) for 12 weeks. *In vivo* ROS production was measured in the penis following the dietary intervention utilizing a novel microdialysis approach. Microdialysis probes were inserted into the penis of anesthetized rats and perfused with saline containing 100 uM Amplex Ultrared, 1 U/ml horseradish peroxidase, and 10

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U/ml superoxide dismutase, and dialysate fluorescence was measured at the outlet. Following microdialysis, penes were harvested for protein expression analysis of the NADPH oxidase subunits p22phox and p67phox, PGC-1alpha, mitochondrial complexes I-V, and the fibrotic signaling molecules fibronectin, TGF-beta, SMAD3, and phosphorylated SMAD3. Masson's trichrome staining was performed to assess collagen deposition.

**Results:** *In vivo* penile production of hydrogen peroxide (1.31 vs. 1.96;  $p = 0.014$ ) and superoxide (1.86 vs. 2.39;  $p = 0.029$ ) were elevated in response to the WD. The NADPH oxidase subunit p22phox was increased in WD penes (0.36 vs. 0.51;  $p = 0.038$ ), while a trend toward increased p67phox (0.45 vs. 0.63;  $p = 0.079$ ) was observed in WD penes. There were no diet induced differences in PGC-1alpha ( $p = 0.32$ ) or complexes of the mitochondrial electron transport chain (CI:  $p = 0.48$ , CII:  $p = 0.46$ , CIII:  $p = 0.96$ , CIV:  $p = 0.46$ , CV:  $p = 0.78$ ). There were no diet induced differences in fibronectin ( $p = 0.59$ ), TGF-beta ( $p = 0.72$ ), SMAD3 ( $p = 0.56$ ), p-SMAD3:SMAD3 ( $p = 0.85$ ), or penile collagen content ( $p = 0.51$ ).

**Conclusions:** NADPH oxidase is a probable source of increased ROS in the penis in WD-induced ED. Although ROS was elevated, there were no evident changes in mitochondrial content or induction of fibrosis or fibrotic signaling in response to the WD.

## Disclosure:

Work supported by industry: no.

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## A study on the effect of injection frequency of human bone marrow derived stem cells in type 2 DM rats (ZFDM) with erectile dysfunction

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**Objective:** In this study, we investigated effect of injection frequency of human bone marrow-derived stem cells (BMSCs) on functional and histological properties in diabetic erectile dysfunction (ED)

**Materials and Methods:** Forty 8-week old male type 2 diabetic fa/fa Zucker Fatty Diabetes Mellitus (ZFDM) rats (DM group) and ten fa/+ ZFDM rats (normal control group) underwent weight and blood glucose measurement every one week. At age 22 weeks, diabetic rats were randomly divided into three groups: rats that underwent intracavernous injection with PBS ( $n=10$ , DM+PBS (60 $\mu$ L)), single injection group ( $n=15$ ,  $1 \times 10^6$  cells/60 $\mu$ L, DM+sBMSC) and multiple injections group ( $n=15$ ,  $1 \times 10^6$  cells/60 $\mu$ L X 2, DM+mBMSCs). Human BMSCs were injected at age 22weeks in single injection group, and human BMSCs were injected at age of 22 weeks and 24weeks in multiple injection group. Human BMSCs were labeled with PKH-26, and then transplanted into corporal cavernosum of

diabetic rats. Four weeks ( $n=10$  in each group) and 8 weeks ( $n=5$  in each group) after last transplantation, all rats were analyzed for erectile function (the ratio between intracavernous pressure (ICP) and mean arterial pressure (MAP)) and immunohistochemistry.

**Results:** Differences in non-fasting blood glucose level between fa/fa and fa/+ rats were evident as early as 11 weeks of age and were maintained until 22 weeks of age (fa/fa  $361 \pm 102.2$  mg/dl vs. fa/+  $123.0 \pm 12.9$  mg/dl,  $p = 0.015$ ). After human BMSCs transplantation, the ICP/MAP ratio of sBMSC and mBMSC groups were increased significantly compared with diabetic controls, but there was no significant differences of the ratio between sBMSC and mBMSC groups at 4 weeks and 8 weeks after last injection of human BMSCs ( $0.79 \pm 0.07$  vs.  $0.82 \pm 0.11$ ,  $p=0.15$ , 4 week;  $0.78 \pm 0.05$  vs.  $0.84 \pm 0.10$ ,  $p=0.12$ , 8 week). In immunohistochemistry analysis, the content of smooth muscle and endothelium in corporal cavernosum and nNOS in dorsal nerve of human BMSCs transplanted rats were significantly increased compared to diabetic controls and maintained the regenerated histological properties at 8 weeks after last injection of human BMSCs in two groups. At days of 28 and 56, a few human BMSCs were visualized in corporal cavernosum in all groups

**Conclusions:** Intracavernous transplantation of human BMSCs had beneficial effects on erectile function and histopathology of diabetic rats. The multiple injection of human BMSCs were not shown benefit compared with single injection during short-term follow-up period but more work is needed to define the optimal stem cell injection frequency and intervals.

## Disclosure:

Work supported by industry: yes, by Ministry for Health, Welfare and Family Affairs, Republic of Korea (industry funding only - investigator initiated and executed study).

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## Reduced equilibrative nucleoside transporter type 2 in pathophysiology of priapism

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**Objective:** Priapism is highly prevalent in sickle cell disease (SCD) patients and defined as painful prolonged penile erection. Recent studies have demonstrated that excess adenosine accumulation in the penis contributes to priapism in SCD. However, molecular basis for increased penile adenosine in priapism in SCD remains unclear.

**Methods and Results:** To assess the molecular basis underlying elevated penile adenosine, we conducted RT-PCR screening purinergic signaling components. We found that equilibrative nucleoside transporter type 2 (ENT2), a surface transporter



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controlling extracellular adenosine, was most reduced in the penile tissues of SCD mice. We further discovered that genetic deletion of *ENT2* but not *ENT1* led to priapism features including increased intracavernosal pressure (ICP) in response to cavernosal nerve stimulation (CNS). Next, lower penile adenosine by adenosine deaminase (ADA) therapy or interfering ADORA2B activation significantly reduced priapism features in *ENT2*<sup>-/-</sup> mice. Follow-up studies transplanting SCD mouse bone marrow to wild type mice and *ENT2*<sup>-/-</sup> mice demonstrated that SCD/*ENT2*<sup>-/-</sup> chimeras displayed enhanced priapic features compared to SCD/WT chimeras. Besides reduction of *ENT2*, we found that HIF-1a levels were significantly increased in the penile tissues of SCD mice implicating that elevated HIF-1a may contribute to decreased *ENT2* gene expression in SCD mice. To test this possibility, we transplanted SCD mouse bone marrow to WT mice and endothelial HIF-1a specific knockouts (HIF-1a<sup>fl/v</sup>-Cad-Cre). We found that reduced penile *ENT2* gene expression was significantly attenuated in SCD/HIF-1a<sup>fl/v</sup>-Cad-Cre chimeras and thereby priapic features were significantly reduced in these chimeras compared to SCD/WT chimeras. Finally, we revealed that excess adenosine directly reduced *ENT2* gene expression in cultured human microvascular endothelial cells in a HIF-1a dependent manner.

**Conclusion:** In conclusion, we have demonstrated that 1) *ENT2*<sup>-/-</sup> mouse is a novel animal model of priapism with elevated penile adenosine; 2) Lowering adenosine by ADA or interfering ADORA2B activation corrected priapic features in *ENT2*<sup>-/-</sup> mice; 3) HIF-1a-mediated down regulation of *ENT2* gene expression is a previously unrecognized signaling network contributing to priapism in SCD. Altogether, our studies revealed new insight to pathogenesis of priapism and novel therapeutic targets for the disease.

## Disclosure:

Work supported by industry: no.

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## Toll-like receptor 1/2 heterodimer mediates increased contractile responses in rat corpus cavernosum: A novel mechanism contributing to erectile dysfunction

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**Objectives:** Toll-like receptor (TLR) family members sense molecular patterns from pathogens and injured cells that warn of danger, and respond with inflammatory signaling. The heterodimer TLR2/1 has been implicated in vascular disease and diabetes in which erectile dysfunction (ED) is a common co-morbidity, but a role for TLR2/1 in penile vascular function is not established. We hypothesized that the TLR2/1 complex has a functional role in the penis, that receptor activation increases contraction to an adrenergic agonist in corpus cavernosum (CC), and that inhibiting TLR2/1 dimer formation will prevent such an increase.

**Materials and Methods:** Isolated CC from adult male Sprague Dawley rats was cleaned of adherent tissue and halved lengthwise. Tissues were incubated 6 h in media containing vehicle (CON), a TLR2/1 agonist Pam<sub>3</sub>CSK<sub>4</sub> (100ng/mL, Pam3), or pre-treated for 20 min with a selective TLR2/1 dimerization inhibitor, CU-CPT22 (5 uM, CURx+Pam3) before adding Pam3 (n=6/group) and mounted in a myograph for measurement of isometric force generation to phenylephrine (PE). Maximal contraction to KCl was set as 100% and used to normalize data. Statistical analyses: One and Two-Way ANOVA based on means±SE, alpha-level was set at 0.05.

Results: Pam3 compared to CON showed increased contraction across the 0.03-10.0 uM PE range, p<0.05, whereas in CURx+Pam3, augmented responses were abolished, normalizing them to CON levels, p>0.05. Maximal contraction (E<sub>max</sub>) to PE was higher in Pam3 (190.7±6.5 %KCl) compared to CON (158.2±4.8 %KCl), p<0.05, while in CURx+Pam3 (175.4±5.8 %KCl) the Pam3-induced increase in E<sub>max</sub> was attenuated and not different from E<sub>max</sub> of CON, p>0.05. Sensitivity to PE (pD<sub>2</sub> value) was enhanced in Pam3 (6.35±0.4) compared to CON (5.47±0.2), p<0.05, while in CURx+Pam3 the pD<sub>2</sub> value was reduced to level of CON (5.34±0.1, p>0.05).

Conclusion: Short-term TLR2/1 activation increases contraction to PE in CC, whereas blocking dimerization of these receptors using CURx abolishes this increase. Vascular disease and diabetes are linked with inflammation and ED, a hallmark of which is increased contractile responses. Thus, TLR2/1 inhibition may be a useful approach for treating vasculogenic ED in inflammatory conditions.

## Disclosure:

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## The different patterns of TRPC subtypes expression in the disease- related erectile dysfunction

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**Objective(s):** Transient receptor potential canonical (TRPC) proteins have been known as Ca<sup>2+</sup>- permeable cation channels, which play important roles in the regulation of smooth muscle function. Recently, emerging evidence suggests a significant contribution of TRPC proteins to pathophysiological mechanism of various diseases. However, to date, there are few data regarding the potential role of TRPC channel in the pathogenesis of ED. The aim of current study was to evaluate the potential pathophysiological relevance of TRPC in the ED development caused by various diseases complications.

**Materials and Method(s):** Real-time PCR and Western blots performed to evaluate the expression level of TRPC mRNA and protein in the each penile tissue of diabetes mellitus and

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hypercholesterolemia rats. To examine the cellular localization and changes in the expression levels of TRPC channels, immunohistochemical (IHC) experiments were also performed.

**Result(s):** The relative expression levels of TRPC3, TRPC4 and TRPC6 mRNA were significantly increased in the diabetic rats than normal controls. The TRPC4 mRNA was showed dramatic changes than any other subtype of TRPC (TRPC3:  $1.4 \pm 0.15$  fold, TRPC4:  $1.8 \pm 0.29$  fold, TRPC6:  $1.5 \pm 0.2$  fold,  $n=8$ ,  $p < 0.05$  vs. normal control). Also the protein level of TRPC4 was three times higher than in normal controls. However in the hypercholesterolemia rats, the mRNA expression of TRPC6 was significantly up-regulated than normal controls (TRPC4:  $1.4 \pm 0.29$  fold, TRPC6:  $2.2 \pm 0.27$  fold  $\square p < 0.05$ ,  $n=8$ ). TRPC6 protein showed the same trends as the mRNA. IHC study could confirm the expression of TRPC1, TRPC4, and TRPC6 in the penile tissue of every experimental animal group. Consistently, the TRPC4 and TRPC6 expressed much higher in the each diabetes and hypercholesterolemia rats in IHC. The increasing of these proteins were mostly located in smooth muscle cells.

**Conclusion(s):** This study showed that the TRPC subtype expression was changed in disease dependently. The alteration of TRPC channel expression or/and function might contributed to the pathogenesis of ED and could be a target for drug development for disease-specific ED

## Disclosure:

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## Pioglitazone enhances survival and regeneration of rat pelvic ganglia nuerons after cavernosal nerve crush

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**Objective:** Pioglitazone, a thiazolidinedione approved for treatment of Type II Diabetes Mellitus (DMII), has neuroprotective effects in models of sciatic nerve ischemia and crush injury, optic nerve crush injury, and traumatic brain injury. In this study, we assessed the neuroregenerative/neuroprotective effects of pioglitazone on the rat pelvic ganglia after cavernosal nerve (CN) injury, thereby evaluating its utility for prevention of post-prostatectomy neurogenic ED.

**Materials and Methods:** Sprague-Dawley rats ( $n=32$ ) aged 12 weeks were divided into four groups ( $n=8$  each). Groups A, B, and C underwent bilateral CN crush injury. Group D underwent sham operations. Group A received pre-surgical and post-surgical treatment with oral pioglitazone (6.5 mg/kg body weight), while Group B only received post-surgical treatment. Pre-surgical treatment of pioglitazone was for four days and

post-surgical treatment was for two weeks following CN crush injury. Groups C and D received oral phosphate-buffered-saline (PBS) as a control.

Pelvic ganglia were resected from all rats after two weeks and processed for reverse transcription polymerase chain reaction (RT-PCR) and immunohistochemistry (IHC) for the expression of neuronal nitric oxide synthase (nNOS), tyrosine hydroxylase (TH), beta-III tubulin, neurturin (NTN), and GDNF family receptor alpha-2 (GFR alpha-2).

**Results:** Both RT-PCR and IHC data demonstrated that treatment with pioglitazone (Groups A and B) induced higher expression of nNOS, beta-III tubulin, and TH in the pelvic ganglia compared to that in Group C rats. The sham group (Group D) showed moderate expression of nNOS, beta-III tubulin, and TH, but not to the same level of rats in Groups A and B.

**Conclusions:** This study indicates that pioglitazone has neuroprotective/neuroregenerative effects on the cavernosal nerves; this may signify a novel therapeutic avenue for preventing ED in patients who experience CN injury, such as in radical prostatectomy. More mechanistic investigations are underway.

## Disclosure:

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## NO dysregulation: A common mechanism of priapism and voiding dysfunction in sickle cell disease mice?

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**Objectives:** Voiding dysfunction has become increasingly recognized in patients with sickle cell disease (SCD), yet it remains significantly understudied. Recent investigations into the pathophysiology of SCD-related priapism have identified aberrations in the nitric oxide (NO) regulatory signaling pathway and oxidative stress as principal underlying molecular mechanisms. Based on these findings, we propose that these derangements may apply commonly to the lower urinary tract.

**Materials and Methods:** Whole bladder tissue samples were obtained from adult male SCD mice (a previously established model of the priapism phenotype) and heterozygous littermates as controls (age 13-15 months), and processed by Western blot analyses of protein expressions of p-eNOS (Serine 1177) and p-nNOS (Serine 1412). Voiding filter paper assays to assess voiding patterns and volume estimates were conducted in male SCD and hetero control mice (age 4-6 months).

**Results:** The ratio of p-eNOS/total eNOS was decreased by 33% ( $p < 0.0001$ ) but unchanged for p-nNOS/total nNOS ( $p=0.40$ ) in whole bladder samples of male SCD mice compared to controls. Mean estimated urine volume per body weight trended towards an increase in male SCD mice ( $n=5$ )

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compared to controls (n=4) (SCD  $7.2 \pm 1.2$  vs control  $4.2 \pm 1.7\mu\text{L/g}$ ,  $p=0.16$ ). There was no significant difference in spot number between SCD mice and age-matched controls.

**Conclusion:** SCD mice may offer a viable model for future study of SCD-associated voiding dysfunction. The mechanism of voiding dysfunction in SCD may involve derangements in the NO signaling pathway as evidenced by decreased p-eNOS expression. Thus, the priapism-associated NO dysregulation previously demonstrated in SCD mice may also apply to other lower genitourinary tract organs such as the bladder.

## Disclosure:

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## Effect of testosterone solution 2% for the treatment of ejaculatory dysfunction in androgen-deficient men

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**Objective-** Cross-sectional data suggests that hypogonadism doubles the relative risk of delayed ejaculation (DE), anejaculation (ANE) and decreased ejaculate volume (DEV); however, randomized control trials (RCT) have not been undertaken. This double-blind, placebo-controlled, proof-of-concept study explored the efficacy and safety of testosterone 2% solution for these ejaculatory dysfunctions in hypogonadal men.

**Material and Methods-** 76 hypogonadal men with serum testosterone (T) levels  $<300$  ng/dL on two occasions, mean age 51 years old presenting with self-reported either DE, ANE, DEV or decreased force of ejaculation were randomized to placebo or testosterone 2% solution for a 16-week period. Testosterone 2% solution titration was allowed at Week 8 based on serum testosterone levels at Week 4. Primary outcomes were measured using the Male Sexual Health Questionnaire-Short Form (MSHQ-SF). Secondary measures were assessed with the International Index of Erectile Function – Orgasmic Function Domain (IIEF-OF), a Sexual Activity Log (SAL) and an objective measure of ejaculate volume. Change from baseline to 16 weeks in the primary and secondary outcomes was tested (at a pre-specified alpha level of 0.10) for a treatment group difference of testosterone solution versus placebo by a mixed model repeated measures analysis.

**Results-** At Week 16, 67% of men became eugonadal ( $T \geq 300$  ng/dL) in the testosterone 2% solution group and 17% in the placebo group. Testosterone solution 2% improved ejaculatory dysfunction as measured by the MSHQ-SF score change from baseline to endpoint (mean score change: +3.1) but this effect was not different relative to placebo (mean score change: +2.5;  $p=0.596$ ). Post-hoc analysis based on T levels (300 ng/dL cut-off) showed a statistically significant MSHQ-SF score change between patients with T levels  $\geq 300$  ng/dL and  $<300$  ng/dL during treatment with testosterone 2% solution ( $p=0.002$ ). No

significant differences were detected in measured ejaculate volume, IIEF-OF or SAL scores between placebo and testosterone 2% solution groups.

**Conclusions-** Testosterone replacement in hypogonadal men was not associated with an improvement in ejaculatory dysfunction when comparing testosterone 2% solution and placebo treatment arms. However, post-hoc analysis that factored T levels did show a T-dependent improvement in ejaculatory function among patients of the testosterone 2% solution arm; this warrants further study.

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## Prevalence of ejaculatory dysfunctions as a function of testosterone

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**Objectives-** Evidence suggests that low levels of testosterone (T) are associated with ejaculatory disorders (EjDs); however, this has not been determined systematically with state-of-the-art testosterone assays. We determined T levels in men with delayed ejaculation (DE), anejaculation (AE), decreased ejaculate volume (DEV) and/or decreased force of ejaculation (DFE).

**Materials and Methods-** The sample was comprised of 901 men from the US, Canada and Mexico who self-reported ejaculatory dysfunction and screened for a clinical trial of testosterone therapy for EjD. During screening, 207 men had total T levels  $<300$  ng/dL while 694 men had T levels  $\geq 300$  ng/dL. Prevalence of EjD symptoms were assessed across 6 T categories ( $<300$ , 300-350, 350-400, 400-600, 600-800,  $>800$ ). Total T was measured using liquid chromatography mass spectrometry (LC-MS/MS). Participants completed an investigator-developed Ejaculatory Function Screening Questionnaire (EFSQ) that assessed history of ejaculatory dysfunction. Age, body mass index (BMI), race, ethnicity, and geographic location were also recorded. Baseline characteristics were compared across T categories using F-test.

**Results-** Average age of the participants was 52 years ( $\pm 11$ ). Arithmetic mean T levels of participants experiencing EjDs was 437.1 ng/dL (95% Confidence Interval: 423.9 to 450.3 ng/dL). EjDs occurred over a spectrum of T levels. DFE and DEV were the most prevalent EjD symptoms (81% and 89% overall) across the T-categories, while AE was the least prevalent (37%). Prevalence of DE was 62% overall. For participants reporting

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at least one of these EjDs, age and BMI differed among the T categories (Age:  $p < 0.01$ ; BMI:  $p < 0.001$ ).

**Conclusions-** This study highlights that EjDs are prevalent across a broad range of T levels with some dysfunctions showing overall higher prevalence.

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ejaculation, anejaculation, decreased ejaculate volume and/or decreased force of ejaculation were bothered by their symptoms. A substantial proportion also reported negative impact on intercourse satisfaction and intercourse enjoyment.

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**Perceived sexual dissatisfaction with ejaculatory dysfunctions**

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**Objectives:** Little is known about bother and sexual satisfaction across the subtypes of ejaculatory dysfunction (EjD) in the general population. This exploratory study assessed bother and sexual satisfaction among men experiencing anejaculation (AE), delayed ejaculation (DE), decreased ejaculate volume (DEV) and/or decreased force of ejaculation (DFE).

**Material and Methods:** The study population consisted of 884 men from the US, Canada and Mexico who self-reported ejaculatory dysfunction, screened for a clinical trial assessing testosterone therapy for EjD in hypogonadal men and completed the Male Sexual Health Questionnaire-Bother (MSHQ-Bother) item, "If you have had any ejaculation difficulties or have been unable to ejaculate, have you been bothered by this?" (N=820), the International Index of Erectile Function (IIEF) question 7, "When you attempted sexual intercourse, how often was it satisfactory for you?" (N=884) and question 8, "How much have you enjoyed sexual intercourse?" (N=881). Subjects with premature ejaculation were excluded from this study. Participants with MSHQ-Bother scores of  $\geq 3$  were classified as "bothered". Sexual intercourse satisfaction and intercourse enjoyment scores of  $\geq 3$  were classified as "satisfied" and "enjoyed," respectively. Participants with scores of 0 (no intercourse) were excluded.

**Results:** Mean (SD) age of the participants was 52 years ( $\pm 11$ ). Overall, 68% of participants reported their EjD as bothersome. Participants with AE and DE were most bothered by their symptoms (84% and 76%, respectively). DEV and DFE were bothersome for 69% and 69% of participants, respectively. Ejaculatory dysfunctions contributed to sexual intercourse dissatisfaction (33%) and reduced intercourse enjoyment (19%). For participants with AE and DE, intercourse dissatisfaction was experienced in 39% and 39%, respectively. For participants with DEV and DFE, intercourse dissatisfaction was experienced in 34% and 33%, respectively.

**Conclusions:** More than half of all men experiencing delayed

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