Annual Fall Scientific Meeting
SMSNA

Surgery as the Gold Standard for Peyronie’s Disease

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Jacksonville, Florida

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The Phoenician
Scottsdale, Az
Disclosures

• Consultant: Abbvie
Definition: Peyronie’s Disease

3rd International Consultation on Sexual Medicine

• An acquired penile abnormality characterized by fibrosis of the tunica albuginea, which may be accompanied by:
  • Pain
  • Deformity
  • ED
  • Penile shortening
  • Psychological distress

J Sex Med 2010;7:2359-74
Penile Ultra-Structure

- **Anatomy**
  - Inner circular layer sends off septal projections and oblique projections (pillars).
  - The strands of the septum give vertical rigidity to the penis.
  - Bending the penis out of the column stresses the septal and pillar strands.
PyD: Natural History

- Spontaneous resolution uncommon (3-13%).
- Most patients experience progression (30-50%).
- Pain is usually present in the early stage. Resolves in most men (90%).
Peyronie’s occurs most frequently in middle-aged men; with less rigidity and less elasticity. The lesion is typically on dorsum between the layers of the tunica albuginea.

Peyronie’s Disease
Septum
Peyronie’s Disease
Septum + Pillars
Scattered Micro-Calcifications in PYD: Is this early stage disease?

Asia J Androl 2010, Nov
Nat Rev Urol 2010, May
J Sex Med 2010, May
J Sex Med 2010, June
BJU Int. 2010, July
AUA Guideline (2015): Peyronie’s Disease

**HISTORY & PHYSICAL**
- **BASIC ASSESSMENT**
  - Penile deformity
  - Palpable abnormalities
  - Interference with intercourse
- **PATIENT COUNSELING**
  - Typical course of PD
  - Available treatment options based on phase
  - Benefits/risks of treatment options
  - Agree on realistic treatment goals

**PATIENT HAS STABLE DISEASE**
- Patient desires invasive treatment

**PATIENT HAS ACTIVE DISEASE**
- Patient desires treatment of pain

**EXPERT OPINION**
- Offer NSAIDS
- **CONDITIONAL RECOMMENDATION**
  - If inadequate pain control with oral medications, may offer ESWT (Grade B), BUT
  - Substantial patient burden
  - Rarely used in US
  - Does not reduce curvature or plaque

**EXPERT OPINION**
- Perform in-office intracavernosal injection (ICI) test with or without duplex ultrasound
  - Document curvature, other deformities, presence of plaque(s) and ED

**MODERATE RECOMMENDATIONS**
- Offer intracavernosal collagenase clostridium histolyticum with modeling by clinician and patient for curvature reduction (Grade B)
  - Appropriate for patients with curvature >30 and <90 degrees
  - Patient must have intact erectile function with or without use of medications
  - Offer intracavernosal injection α2b for curvature, plaque, and pain reduction (Grade C)

**CONDITIONAL RECOMMENDATION**
- Offer intracavernosal verapamil (Grade C)
  - Note: evidence for efficacy is weak

**CONDITIONAL RECOMMENDATION**
- Patient has stable disease and requires greater deformity correction than possible with intracavernosal treatments

**PATIENT HAS INTEGRITY OF ERECTILE FUNCTION**
- Patient has intact erectile function with or without pharmacotherapy and/or vacuum device therapy

**MODERATE RECOMMENDATION**
- Offer tunical plication or plaque incision/excision with or without grafting (Grade C)
  - Use inflatable penile prosthesis (Expert Opinion)

**PATIENT DOES NOT HAVE INTEGRITY OF ERECTILE FUNCTION**
- Patient does not have intact erectile function and/or has severe penile deformity and/or shortening

**THERAPIES THAT SHOULD NOT BE OFFERED:**
- Oral therapy with vitamin E, omega-3 fatty acids, vitamin E plus L-carnitine (Grade B), tamoxifen, procarbazine (Grade C)
- Electromotive verapamil (Grade C)
- Radiotherapy (Grade C)
- Intralesional Collagenase Clostridium Histolyticum followed by modeling in patients with stable disease, dorsal curvature > 30° and < 90° (Moderate Recommendation, Grade B)
  - Counsel on adverse events: ecchymosis, swelling, pain, corporal rupture.
- Intralesional Interferon α-2b (Moderate Recommendation, Grade C)
- Intralesional Verapamil (Moderate Recommendation, Grade C)
- Clinicians should not use ESWT for reduction of penile curvature or plaque size. (Moderate Recommendation, Grade C)
- Clinicians should not use radiotherapy (Moderate Recommendation, Grade C)
Intralesional Collagenase Clostridium Histolyticum

FDA approved indication:

The treatment of adult men with Peyronie’s disease with a palpable plaque and curvature deformity of at least 30 degrees.

Contraindication:

Peyronie’s plaques that involve the penile urethra.
IMPRESS Study Co-Primary Endpoint: Curvature Deformity Improvement at Week 52

**IMPRESS I**
*P* = .0005

- **Baseline**
  - CCH: 48.8
  - Placebo: 31.0

- **Week 52**
  - CCH: 37.6%
  - Placebo: 21.3%

**IMPRESS II**
*P* = .0059

- **Baseline**
  - CCH: 49.0
  - Placebo: 39.0

- **Week 52**
  - CCH: 30.5%
  - Placebo: 15.2%

*Week 52 last observation carried forward (LOCF).

Efficacy: Stepwise Intralesional Therapy with Xiaflex


<table>
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<th>Baseline curvature deformity</th>
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<td>Week 36 curvature deformity</td>
<td>28°</td>
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</table>

17° or 38% improvement
Xiaflex Intralesional Stepwise Therapy: 8 Treatments

Pre

August 2015

Post Xiaflex

January 2016
• Xiaflex Intralesional Therapy - Outcomes

Aug 2015

Aug 2015

Aug 2015

Aug 2015

Aug 2015

Feb 2016

Xiaflex 8 treatments
Xiaflex®: Best Candidates

• Dorsal or dorsolateral bends
• Solitary plaque / single area of bend
• Good passive elasticity
• Curvature < 60°
• Lack of severe indent / notching
• Lack of contiguous calcification

Courtesy: Dr. Martin Gelbard
Non-Industry Sponsored Studies of Collagenase Clostridium Histolyticum Outcomes in PyD

1. (PD45-02) Impact of Number of Cycles of CCH; WJG Hellstrom et al
   • Curvature improved from 58 degrees to 42 degrees post-treatment (-16 degrees)

2. (PD45-03) Survey of Patient and Partner Satisfaction Following CCH; WJG Hellstrom et al
   • 33% reported some degree of glans hypoesthesia

Non-Industry Sponsored Studies of Collagenase Clostridium Histolyticum Outcomes in PyD


- Adverse events: 65% ecchymosis, 31% penile erythema, 23% penile pain, 18% penile edema, 9% hematoma, 7% penile blister, 3.6% corporal rupture
Non-Industry Sponsored Studies of Collagenase Clostridium Histolyticum Outcomes in PyD

SMSNA, Nov 3, 2016:

• (029) Comparative Analysis of Tunica Plication vs Intralesional CCH for Ventral PyD
  • There was significantly better improvement in mean curvature with TP (46 degrees) vs. IIT (9 degrees).

• (002) Penile Traction Does not Improve Outcomes with CCH
  • Overall patients experienced significant improvement of penile curvature 20 degrees.
Non-Industry Sponsored Studies of Collagenase Clostridium Histolyticum Outcomes in PyD

SMSNA, Nov 3, 2016:

• (003) Safety and Efficacy of CCH in Combination with Vacuum Therapy
  • At week 36 mean improvement in penile curvature was 23.7 degrees in CCH + vacuum + modeling and 23 degrees in CCH + vacuum.

• (004) Safety and Effectiveness of CCH in Treatment of PyD Using a New Modified Protocol
  • Mean penile curvature improvement 18.5 degrees.
Non-Industry Sponsored Studies of Collagenase Clostridium Histolyticum Outcomes in PyD

SMSNA, Nov 3, 2016:

• (110) Correlation of Clinical Meaningfulness and Curvature Improvement in Men Undergoing CCH Injections for PyD
  • Median improvement was 25 degrees
Non-Industry Sponsored Studies of Collagenase Clostridium Histolyticum Outcomes in PyD

SMSNA, Nov 3, 2016:

- (116) Retrospective Review of Protocol Based Intralesional Injection Therapy at La Jolla VAMC, SA King and I Goldstein

- After Interferon injections 60% of men experienced a mean improvement of 18 degrees.
- After CCH injections 44% of men experienced mean improvement of 22 degrees.
In this study most of the joints (65%) were successfully treated with CCH. Three years after treatment, the overall recurrence rate was 35%.
Xiaflex® : Poor Candidates

• Ventral bend
• Palpable / Calcification
• Inelasticity / retraction
• Bending in the 90° range
• Marked notching or indent
• Pure lateral bend with significant indent

Courtesy: Dr. Martin Gelbard
Differences between CCH and placebo for non-contiguous stippling and contiguous calcification (that did interfere with injection) were not statistically significant.
Hourglass Deformities

**Patient A**
- Peyronie's plaque
- Vas L38
- RCA PRE 0.11 cm

**Patient B**
- Peyronie's plaque
- Vas L38
- 1.55 cm
PYD Plaque: Bone Formation
Consider CT Imaging before recommending Xiaflex if calcified is plaque suspected. There is no evidence that these patients respond to CCH.
Sono

DECT
Indications for Surgical Reconstruction

- Stable disease for at least 6 months
  - Duration of 12 – 18 months
- Painless deformity
- Unable to engage in coitus (2° to deformity and/or inadequate rigidity)
- Failed conservative therapy*
- Extensive plaque calcification
- Desire most rapid result

*Best practice recommendation

3rd ICSM Guidelines
J Sex Med 2010;7:2359-74
PYD – Surgical Algorithm

When rigidity adequate w/o pharmacotherapy

1) Tunica plication techniques
   - Simple curve < 60 degrees (30° - 45°)
   - No hourglass or hinge-effect
   - When change in length has been minimal
     - Or shaft is generous

2) Incision / Excision and Grafting
   - Curve > 60 degrees (> 45° with loss of length)
   - Destabilizing hourglass or hinge

3rd ICSM Guidelines
J Sex Med 2010;7:2359-74
PYD – Surgical Algorithm

When penile rigidity is inadequate

3) Penile Prosthesis Placement

- IPP alone
  - Coloplast Titan yes
  - AMS CX yes
  - AMS LGX no

- Or with
  - modeling (Wilson)
  - Internal modeling (Perito)
  - plication
  - incision and grafting
**Stable PYD**
- > 6 to 12 mo.
- No recent changes
- Pain free

**ED Testing**

- < 60 degrees
  - Adequate

- > 60 degrees
  - Shorter

**Angulation Penile Length**

**Penile Prosthesis**

**PLICATION**

**PRO:**
1. No post-op ED
2. No need for ED meds
3. No recurrence of deformity

**CON:**
1. Risk for infection
2. More post-op discomfort
3. Cost

**GRAFTING**

**PRO:**
1. Less shortening vs Plication
2. Correct complex deformity
3. Best for proximal curve
4. Calcified plaques

**CON:**
1. Greater risk post-op ED
2. Mobilization of NVB

No ED, or responds to PDE5-Inh
Outcome Measures Following Peyronie’s Surgery

- Penile straightening
- Erectile function
- Penile length
- PD recurrence
- Glans hyposensitivity
- Global satisfaction
- Partner satisfaction
Surgical Plication Techniques

‘Nip Tuck’

• Nesbit – Excision & closure
• Yachia – Incision & plication
• Lue 16 dot – No incision plication
• Duckett / Baskin / Levine TAP – Partial incision & plication
## Outcome of Tunical Shortening Procedures for Peyronie's Disease

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>First Author</th>
<th>Number of patients</th>
<th>Mean follow up duration (months)</th>
<th>Straight at latest follow-up (%)</th>
<th>Erectile Dysfunction (%)</th>
<th>Satisfaction Rates (%)</th>
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8-359 mos 12-89 mos 29-100% 2-60% 62-96%
Penile Plication Procedures

- There is no evidence that one surgical approach provides better outcomes over another.

- With plication curvature correction can be expected with low risk of de-novo ED.

4th ICSM: Clinical Principle / Expert Opinion
Advantages of PIG/PEG Procedure

• Best opportunity to correct severe curvature > 60°

• Only approach to restore girth & correct hinge

• Least likely to cause further length loss

• Most likely to enhance length with or without traction post-op
Recommendation – Grafts for PD

- Autologous grafts require more time and a second incision.
- Allograft and Xenograft procedures appear shorter in duration with no reported transmission of diseases.
- Synthetic grafts increase the risk of infection and are not recommended.
- There is no evidence that surgical outcomes are consistently better with one graft type.
• Step I: Degloving incision
• Step II: Artificial erection
• Step III: mark site of greatest curvature
• Step IV: excision of DDV
• Step V: mobilize Dorsal NVB
Peyronie’s Plaque Incision and Grafting

‘Looks easy.’

Paulo Egydio et al, BJUI 2004;94:1147-1157
Ultimate Disaster Distal Necrosis

‘But it’s not.’
Plaque Excision and Grafting

Calcified Plaque
Calcified Plaque Excision
Incision or Excision Grafting Complications

- Residual curvature
  - Improper sizing
  - Graft contraction
- Bulging of the graft
  - Consider aspirating the camel’s hump at 2 weeks post-op
- Worsening erectile function
- Penile numbness
- Shortening not improved
- Glans necrosis
## Graft Material

<table>
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<tr>
<th>First Author</th>
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### Outcomes for Plaque Excision/Incision and Grafting

- **Dermal Grafts**
- **Saphenous Vein Grafts**
- **Buccal Mucosa**
- **Proximal Crura**
- **Tunica Vaginalis**
- **Dura Mater**
- **Temporalis Fascia**
- **Fascia Lata**
- **Pericardial Graft**
- **Stratasis Grafts**
- **Small Intestinal Submucosa (SIS)**
- **Tutoplast Pericardial graft**
- **Acellular dermis**
- **Synthetic Materials**

### Graft Materials
- Dermal Grafts
- Saphenous Vein Grafts
- Buccal Mucosa
- Proximal Crura
- Tunica Vaginalis
- Dura Mater
- Temporalis Fascia
- Fascia Lata
- Pericardial Graft
- Stratasis Grafts
- Small Intestinal Submucosa (SIS)
- Tutoplast Pericardial graft
- Acellular dermis
- Synthetic Materials

5-162 6 – >60mos 55-100% 0-53% 60-100%
Peyronie’s Disease + Penile Prosthesis

- Can be treated with an inflatable IPP.
- “Modeling Procedure”, done over fully inflated cylinders.
  - The center of the curve is used as a fulcrum to fracture the plaque.
- PD may be present in patients undergoing IPP, undiagnosed prior to surgery!
  - Evident when device is first cycled in the OR.
Modeling Procedure For Peyronie’s Disease

Inflate IPP and shod the tubing.

Bend and hold for 90 seconds. Listen for cracking sound.
Wilson Fracture Technique

Coloplast Titan
PYD + Prosthesis / Manual Modeling

• Technique
1) Peno-scrotal or Infracubic
2) Titan or CX cylinders
3) Close corporotomies?
4) Protect pump – shod tubing
5) Bend & hold x 60 sec.
6) Repeat

• Complications
1. Urethral Injury at Meatus 4%
2. Corporal Rupture 1%
3. Re-Size Implant
Comparison between AMS 700™ CX and Coloplast™ Titan Inflatable Penile Prosthesis for Peyronie’s Disease Treatment and Remodeling: Clinical Outcomes and Patient Satisfaction

Eric Chung, FRACS,* † Matthew Solomon, MBBS,* Ling DeYoung, MD,* and Gerald B. Brock, FRCSC*

*Division of Urology, St Joseph’s Health Care, London, ON, Canada; †Department of Urology, Princess Alexandra Hospital, Brisbane, QLD, Australia

DOI: 10.1111/jsm.12009

Summary
Surgical Correction of Peyronie’s Disease

✓ Detailed consent imperative
✓ Follow published algorithms
✓ Plication for less severe deformity and when borderline ED
✓ Grafting reserved for severe deformity, +/- hinge, normal erectile function, & experienced surgical team
✓ Prosthesis placement with additional maneuvers for combined ED & PYD
Mayo Clinic Update in Urology 2017

February 20-24, 2017

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Course Directors
David D. Thiel, M.D.
Gregory A. Broderick, M.D.

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