The Two-Piece Prosthesis Has No Role in the Modern Era

Point/Counterpoint: CON

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## Disclosures

- Consultant/Speaker
  - American Medical Systems
  - Coloplast Corporation
Inflatable Penile Prostheses

- Over 40 years
  - Penile implants held major position in treatment algorithm for patients with ED

- Historically data reflects mostly self-administered vs validated questionnaires

- Studies now producing objective data

- No overt papers 2 piece vs 3 piece for same patient
Product Comparison

American Medical Systems, Minnetonka, MN, USA
Coloplast Corporation, Minneapolis, MN, USA
Product Comparison
Ambicor

- Introduced 1994, successor to Dynaflex (1 piece)

- 1998 redesign
  - RTEs: increased durability
  - Tubing insertion: stress protection at flex point
Two-Piece Prosthesis

2007, Levine & Morgentaler
- First objective and subjective report of performance of revised IPP, 146 patients
- Up to 6 years follow up

- High device viability
- Low reoperation and infection rates
  - No reported complications
- High patient and partner satisfaction
  - No removals due to dissatisfaction

Two-Piece Prosthesis

- 91% Ease of use
- 95% Little to no trouble learning to use device
- 95% Rigidity suitable for intercourse

Free from reoperation
- 1 year: 99.2%
- 3 years: 99.2%
- ≥ 4 years: 91%

Surgeon preferences play a role in device choice

- Penoscrotal
  - 2-piece
  - 3-Piece

- Infrapubic
  - 3-Piece
Decreasing infection rates: active area of design, protocol development

- Mechanical aspect of device (coating)
  - Reduced infections and colonization
  - Decreased incidence from 3-5%, to 1-2%
- Surgeon technique/experience
- Patient selection
- Other factors/quality measures

Infection

2-Piece, Wet within packaging, prefilled

- Precludes InhibiZone®
- 2007 study: 0.7% infection rate
Inflation and Deflation

Pump/Inflation

- No available data on “number of squeezes” for either device
- Patient dexterity
Inflation and Deflation

2-Piece: Easy deflation, inflation
Fewest pumps inherent in design
Penile Length

Complaint not unique to 2 piece design

- Overall 72% patients subjective decrease in penile length
  - Despite lack of significant difference in pre and post operative measurements

- Maximize cylinder length/perceived length
  - “Sellers Sizing”, preoperative VED
  - Henry, NLMT, aggressive corporal measurement
  - Wilson, Severe fibrosis: narrow expander upsizing
  - Carrion, ventral phalloplasty

Flaccidity/Concealment

2-piece

- Theoretical concern for inadequate concealment
- Ease of concealment when deflated
  - 92% patients
  - Some men enjoy appearance of partial penile fullness

Several factors are responsible for cylinder rigidity

- **FIXED**
  - Cylinder length
  - Cylinder girth
  - Cylinder pressure

- **NOT FIXED, dependent on patient**
  - Wall thickness - +/- presence of capsule
  - Scarring, +/- PD
  - Tissue elasticity
Mechanical Reliability

2-piece
- 146 implants
- Mean 38 month follow up: 0.7% failure

3 piece, Longest-term study, 2,000 implants
- 10 years: failure 21%
- 15 years: failure 29%

Reservoir Placement

- **2-piece**
  - “Hostile” abdomen
  - Independent of future abdominal surgeries
  - Surgeon preference to avoid reservoir placement

- **3-piece**
  - Reports of placement into surrounding structures +/- experience
  - Advances in surgical techniques and device modifications
Reservoir Placement

Inguinal ring, gateway to reservoir placement

- Henry et al, Cadaver Study, external inguinal ring
  - 2.5–4 cm from the external iliac vein
  - 5.3–8 cm from the decompressed bladder
  - 2–4 cm from the filled bladder

- Altered in location, distance in any abdominal/pelvic surgery without consideration for mesh, new organ, scarring, adhesions

Reservoir Removal

- Reported life-threatening bleeding with removal
- “Drain and retain” in uninfected cases
- Same vs different surgeon implanting/explanting


“Ectopic” Reservoir Placement

Alternative sites

- Anterior/Posterior to abdominal wall musculature
- Potentially safer location
- ? Worth risk of palpable or herniated reservoir/affect patient satisfaction
- ? Create new complications

“Ectopic” Reservoir Placement

Survey of high volume prosthetic surgeons

- 90% SMSNA members believe placing the reservoir in an “ectopic” location can be advantageous for patient safety
“Ectopic” Reservoir Placement

In some patients....... Safest??.. No reservoir
“Ectopic” Reservoir Placement
“Ectopic” Reservoir Placement

NOT A MAGICAL UNICORN
“Ectopic” Reservoir Placement

Ectopic reservoir placement is not the panacea for all implant patients

- DESPITE excellent described technique and safety advantages
- Not all surgeons will be comfortable or proficient
- Not all patients will be candidates
- Not all patients will be accepting

Rogue Reservoir Patients

Patient Anatomy

- “Hostile” pelvis
  - Multiple/Combined/Repeated ABD procedures
  - Bladder reconstruction
  - Bilateral hernia repair +/- mesh

- Organ transplant (kidney)
- Thin habitus
- Surgery on anticoagulation
- Reconstruction/plastics: Neophallus
Best Patient Outcome
Surgeon Comfort + Patient Comfort

Need the right implant for the right patient = options
Patient vs Patient
...for people like you.

Dr. Tapscott,
Feb. 28th marks the one year anniversary of my implant surgery. Tina and I are doing great and can’t tell you enough of how thankful we are to you. I turned 60 on Jan. 10th and feel like I’m in my 30’s. You are such a kind and caring person. We are so grateful to you.
Drinks&dinner
Hey, you know it will be a year this Thursday since YOU fixed Mr Johnson, We should celebrate! OK?
Dr. Tapscott,

Feb. 28th marks the anniversary of my injury. Tina and I are doing well and I can't tell you enough of our gratitude. Thankful we are to you.

Go on Jan. 10th and Feb. in my 30's. You are such a caring person. We are so thankful.

Drinks & dinner
Hey, you know it will be a year this Thursday since YOU fixed Mr Johnson, We should celebrate! OK?
• Goal of IPP placement is to improve quality of life by resumption of sexual activity
• Device/technique adjustment vs compromise for complications

• Preoperative counseling, assessment of all patient qualities, proper device selection = higher patient satisfaction
Two-Piece Prosthesis

- Safe
- Effective
- Mechanically reliable
- Low revision rate
- Low infection rate
- Good patient and partner satisfaction
- Cost
There continues to be a valuable role for the 2 piece

Do not underestimate the role of SIMPLICITY

- Placement, Performance, Use
- Especially in complicated patients
LONG LIVE THE 2-PIECE