Mechanical Malfunction Profiles in Men Undergoing 3 Piece Inflatable Penile Implants

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Introduction

• Penile Implants are gold standard treatment for medication-refractory ED

• Inflatable penile implants were introduced in 1973

• Mechanical failure is the most common non-infectious complication
Introduction

• Considerable improvements in modern implants
  - Kink-resistant tubing
  - Lock-out valve
  - Increased durability of core material
  - Reinforcement of cylinder material (Parylene)
  - Controlled expansion (silicone)
Introduction

• Repair rates of 15% @ 5 years and 30-40% @ 10 years
  

• Reoperation rates @ 5 and 10 year follow up of 11% and 16%; 57% secondary operations due to mechanical failure
  
  Mirheyday et al. JSM 2016

• Apparently not related to surgeon expertise or volume
  
  Onyeji et al. J Urol 2016

• Expert opinion: replace all the components after 1 year
  
  Mulcalhy. JSM 2015
Study Objective

To define the rate and causes of mechanical malfunction after penile implant surgery
Methods

• Study population consisted of men who:
  - Underwent primary 3-piece inflatable penile implant
  - Presented with mechanical malfunction
  - Wanted to resume sexual intercourse

• Patient demographic, comorbidity and operative data were recorded.
Methods

• Multivariable analysis was performed to determine predictors of mechanical malfunction:
  - Type of cylinder (Alpha-1 vs Titan)
  - Type of reservoir (LO vs NLO)
  - Type of pump (Genesis vs OTR)
  - Degree of reservoir filling (partial vs complete),
  - Patient age
  - Duration since primary implant surgery
  - Activation frequency
Results

• N=543 (99% Alpha-1, Titan)

• 76 (14%) patients experienced mechanical malfunction
  - Mean age at presentation = 64 ±12 years
  - Mean partner age = 59 ±14 years.
  - Mean age at IPP = 52 ±11 years

• 89% were partnered

• All patients had used their implant within the 12 months prior to presentation

• Mean self-reported number of implant activations per month = 4 ± 7 (2-22)
Results

• Mean duration to initial malfunction = 7.4 ± 6.2 (0.75-22) years

• Time between initial identification of an issue and complete failure of the implant = 3 ± 2 months
Results

• The mechanical problems included:
  - Cylinder tubing fracture at pump junction 76%
  - Blow out in reservoir-pump tubing 12%
  - Reservoir tear 2.5%
  - Cylinder tear 1%

• No case of malfunction of more than one component

• At time of re-operation:
  - Pumps assessed
  - Reservoir filled and emptied to assess integrity
  - Cylinders filled and emptied to assess integrity
Results

- Pump-related issues: only pump replaced
- Reservoir tears: reservoir alone replaced
- Cylinder tears: Cylinder/pump replaced, reservoir left in place
- All devices were functioning well @ 17±6 (9-34) months after repair surgery
## Multivariable Analysis

### Predictors of Mechanical Malfunction

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age (&lt;50y @ implant surgery)</td>
<td>1.45</td>
<td>1.1-4.1</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Duration &gt;5y since implant surgery</td>
<td>3.4</td>
<td>2.2-7.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Activation ≥4/month</td>
<td>2.4</td>
<td>1.8-6.5</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Strengths/Limitations

• Strengths
  - Large number of patients with long-term follow-up
  - Single center

• Limitations
  - Retrospective design
  - Did not compare different models/companies
Conclusions

• The implant malfunction rate is distinct but low at 10 years after implant surgery date

• The majority of implant malfunctions are pump-related and pump replacement is a viable option for these patients

• Younger age, duration post-implant surgery and frequent activation were predictors of malfunction