Assessment of Girth Expansion Restriction on Inflatable Penile Implant Length and Rigidity

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Disclosures

- Consultant – Boston Scientific
Inflatable Penile Prosthesis

- IPP is gold standard for management of erectile dysfunction refractory to medical pharmacotherapy

- Goals of intraoperative device selection are to maximize length, girth and rigidity

- "Right-sizing" or "up-sizing" are strategies to optimize these parameters

- AMS 700 LGX (Boston Scientific, USA) expands circumferentially and longitudinally
Question

• Unknown is whether restricting expansion in one axis (i.e. girth, or length restriction) may restrict expansion along the opposite axis
## IPP Biomechanics

<table>
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<tr>
<th>Study</th>
<th>Biomechanical variables</th>
<th>Results</th>
<th>Conclusions</th>
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</thead>
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<tr>
<td>Al Ansari et al.⁶</td>
<td>Axial rigidity</td>
<td>Mean axial pressure to bend the implanted penis was 984.8 ± 268.7 g.</td>
<td>Highest dissatisfaction with Ambicor. Patients who received 3-piece IPPs were more satisfied than those with a 2-piece or maleable prosthesis.</td>
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<td>Udelson et al⁷</td>
<td>Axial rigidity, Radial rigidity</td>
<td>Radial rigidity units and axial buckling force magnitudes increase with intracavernosal pressure.</td>
<td>Both axial and radial rigidity depend on intracavernosal pressure, but axial rigidity variables include cavernosal erectile tissue properties and penile geometry, whereas radial rigidity variables include tunical surface wall tension properties. Axial rigidity determines the ability of an erect penis to complete vaginal intromission and pelvic thrusting without buckling.</td>
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<td>Goldstein and Udelson⁸</td>
<td>Axial rigidity</td>
<td>Average axial force of 0.9 kg (2.0 lb.) needed for vaginal penetration. Only AMS LGX, at less than maximum inflation, was unable to consistently withstand the 0.9-kg (2.0-lb.) pressure required for intromission.</td>
<td>Axial rigidity is dependent on mechanical and geometric variables. Penile tissue mechanical properties: cavernosal maximum volume at low intracavernosal pressure and tunical distensibility. Penile geometric properties: penile aspect ratio and magnitude of flaccid penile diameter.</td>
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<td>Scovell et al⁹</td>
<td>Axial rigidity</td>
<td>Penetration testing showed that less force was required for the AMS device to kink vs the Coloplast implant in all 3 fill pressures. Coloplast Titan had a smaller angle of displacement in the modified cantilever test.</td>
<td>Coloplast Titan had greater resistance to penetration and gravity. The AMS device was more sensitive to fill pressures.</td>
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<td>Barboglio Romo et al¹⁰</td>
<td>Internal pressure Length Girth</td>
<td>Titan Touch had a girth of 17.8 mm at 22.0 mL vs 15.6 mm for AMS 700 LGX and 16.5 mm for CX. AMS 700 LGX increased in length by 13 mm from baseline. Rigidity curves during compression showed significant variability. Titan and AMS CXR had similar patterns needing a higher load to achieve 50% compression. The buckling experiment showed different patterns of deformity.</td>
<td>Prostheses have significant physical differences that should be considered when choosing the prosthesis.</td>
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<td>Chung et al11</td>
<td>Clinical outcomes</td>
<td>No statistically significant difference in device survival. AMS 700 CX</td>
<td>AMS 700 CX and Coloplast Titan IPP mechanical survival was 91% vs 87% in</td>
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<td>Post-prosthesis satisfaction rates</td>
<td>mechanical survival was 91% vs 87% in Titan, ( P &gt; .05 ). Both</td>
<td>permanent penile straightening and a high patient satisfaction rate without</td>
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<td>provided similar penile straightening without revision. 79% reported</td>
<td>increased risk of revision surgery.</td>
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<td>great satisfaction following CX or Titan implants, and 82% reported</td>
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<td></td>
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<td>that they would undergo the same operation again.</td>
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<td>Wallen et al12</td>
<td>Maximum axial load</td>
<td>At maximum inflation, all 3 implants had comparable performance, with</td>
<td>Circumferentially expanding penile prostheses had larger resistance in</td>
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<td>Kink formation</td>
<td>differences caused by lower pressures. Only AMS LGX at less than</td>
<td>biomechanical testing than longitudinal and circumferentially expanding</td>
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<td>Horizontal stiffness</td>
<td>maximum inflation could not resist 0.9-kg (2.0-lb.) pressure imitating</td>
<td>devices.</td>
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<td>Resistance to 3-point flexure testing</td>
<td>vaginal intromission. Coloplast Titan showed slightly better rigidity</td>
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<td>Ge et al13</td>
<td>Axial compression Cantilever data</td>
<td>RTE length for differences in slope, kinking, and IPP buckling was</td>
<td>Large implants (&gt;20 cm) did not</td>
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<td>Thirumavalavan et al14</td>
<td>Axial rigidity Angular deflection</td>
<td>linked to vaginal insertion strength, horizontal load strength, and</td>
<td>respond well in vivo; however, in shorter prostheses, RTE use may</td>
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<td>Rear tip extender</td>
<td>prosthesis rigidity.</td>
<td>maximize those variables.</td>
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Madiraju. *Sex Med Rev* 2018
Objectives

1. To determine maximal length expansion across various conditions of girth constraint and across various conditions of internal device pressurization

2. To validate a novel methodology for the reliable measurement of inflatable penile implant expansile parameters
Methods

- Custom IPP molds were 3D-printed (Autodesk Fusion 360) in polylactic acid (PLA)
- Varying girth constraints (13mm, 18mm)
Methods

- Unilateral deflated AMS 700 LGX and CX devices of varying lengths were inserted into molds
Methods

• Molds were closed to ensure no change in girth constraint
Methods
Methods

- Pump tubing attached to air pressure regulator which was used to supply air from 2 to 18 psi in 1 psi intervals
- Length expansion of the girth constrained cylinder was measured by distal tip rod displacement
- Girth expansion of the unrestrained cylinder was measured using laser micrometry
Results
21cm AMS 700 LGX

Growth Length (mm) and Unrestricted Diameter Expansion (mm), 21cm AMS LGX

Length (mm)

Diameter (mm)

Pressure (psi)
Max expansion (18psi) | 18cm LGX | 18cm CX
---|---|---
Length (mm) | 12.5 | 4.4
Diameter (mm) | 4.3 | 6.4
Max expansion (18psi) | 15cm LGX | 15cm CX
---|---|---
Length (mm) | 12.2 | 3.4
Diameter (mm) | 5.9 | 7.1
Conclusions

• In AMS 700 LGX device, length expansion is limited by girth constraint
• In AMS 700 CX device, length expansion is minimal, though not zero
• LGX length expansion requires high internal pressures
• This represents a novel methodology for the reliable measurement of inflatable implant expansile parameters

• Future directions:
  • Length constraint to determine limitations of concentric/girth expansion
  • Pressure testing/rigidity measurements
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Questions?
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