50 year outcome data in Venous Stenting

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What are our expectations

Arterial Patients

Venous Patients

Testing benchmarks started the same as they were for arterial
What happens when we walk?

Ligament crush

Flexion
Why does the standard fall short?

The deformation modes have precedent in other anatomical locations.

<table>
<thead>
<tr>
<th></th>
<th>Distal SFA</th>
<th>Paget-Schroetter</th>
<th>Venous Inguinal Ligament</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral Compression</td>
<td>---</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Axial Compression</td>
<td>✓</td>
<td>---</td>
<td>✓</td>
</tr>
<tr>
<td>Torsion</td>
<td>✓</td>
<td>---</td>
<td>✓</td>
</tr>
<tr>
<td>Bending</td>
<td>✓</td>
<td>---</td>
<td>✓</td>
</tr>
</tbody>
</table>

But, the **arterial precedent of a 10-year test is insufficient for venous applications.**

Young age of venous occlusion patients (typically 30+ years of age) may present additional considerations on duration of stent performance.¹

<table>
<thead>
<tr>
<th>Activity</th>
<th>Change in Hip Angle</th>
<th>95% Confidence Interval Upper Limit</th>
<th>Count Estimate per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>$34.3^\circ \pm 3.5^\circ$</td>
<td>$41.3^\circ$</td>
<td>1,000,000</td>
</tr>
<tr>
<td>Stair Climbing</td>
<td>$41.9^\circ \pm 9.9^\circ$</td>
<td>$61.7^\circ$</td>
<td>25,000</td>
</tr>
<tr>
<td>Sit-to-Stand*</td>
<td>$90^\circ$</td>
<td>N/A</td>
<td>48,000</td>
</tr>
</tbody>
</table>

*Assumed to be consistent among adult population.
BENCH TESTING APPROACH FOR VENOUS STENTS

- **Body Movements**:
  - Sit-to-Stand
  - Stair Climbing

- **Deformation Modes**:
  - Torsion
  - Bending
  - Lateral Compression
  - Axial Compression

- **Duration**:
  - 50 Years

Unique challenges of iliofemoral venous obstruction: Need for Venous Stents with 50 Year Durability

January 2020

*Worst case (bending) deformation mode was tested to 10 and to 50 years, all other deformation modes were tested to 10 years*
PRIMARY STENT LOADING MODES: NUMERICAL ANALYSIS

- Bending
- Axial
- Compression
- Torsion
PRIMARY STENT LOADING MODES: BENCH TESTING

- Bending
- Axial
- Compression
- Torsion

Testing not justified
## A NEW BENCH FOR VENOUS APPLICATION

<table>
<thead>
<tr>
<th>Sample Size</th>
<th>Deformation Mode</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Venous Stents</td>
<td>Bending (Worst case)</td>
<td>50 Years</td>
</tr>
</tbody>
</table>

### Results

0 Fractures
Conclusions

• This is a step toward setting a benchmark for testing of venous stents
• New failure modes need to be added as they are identified
• We need to provide assurance to both patients and ourselves that the stents will last for their lifetime
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