Valiant ThoracoAbdominal Aortic Aneurysm Stent Graft System

Patrick W. Kelly, MD, FACS
Disclosure

• The Devices and Technology presented here has been licensed to Medtronic Corporation
Paradigm Shift For Repair Of Complex Aneurysm

- Proximal Deployment
- Endo-Bypasses
- Delayed Distal Seal
Proximal Deployment

Placement of the Thoracic Bifurcated Graft and the Visceral Manifold above the “visceral vessels.”

Allows for continued perfusion throughout the procedure.
Endo-Bypass

Each of the branch vessels are stented individually from a position more proximally.

These bridging stents are slightly longer, but the favorable flow characteristics and conformability to anatomic variations mirror many of the lessons we’ve learned from open bypass.
Once flow has been secured to each of the involved branches, then the open limb of the proximal compartmentalizing graft can be extended distally, excluding the diseased segment of vessel.
Partnering With Industry To Solve This Problem
The Valiant ThoracoAbdominal Aortic Aneurysm Stent Graft System By Medtronic
VTAAA Device
Thoracic Bifurcated Graft TBG

Valiant Main Component
Diameter Size Match

Endurant Extension
20mm Limb
16mm Limb
Visceral Manifold (VM)

- 24mm Main Body
- 14mm Proximal Limbs
- 8mm Individual Limbs
Assembled System
Outflow Conditions of Each Configuration Under Steady State

- Fenestrated
- Antegrade branch
- Investigational retrograde branch
- Investigational Manifold
- Investigational Unitary
Velocity Streamlines (steady-state condition)

<table>
<thead>
<tr>
<th>Fenestrated</th>
<th>Antegrade branch</th>
<th>Investigational retrograde branch</th>
<th>Investigational Manifold</th>
<th>Investigational Unitary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Velocity: Magnitude (m/s)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.00000</td>
<td>0.11200</td>
<td>0.22400</td>
<td>0.33600</td>
<td>0.44800</td>
</tr>
</tbody>
</table>
Clinical Results of ThoracoaAbdominal Aortic Aneurysm Repair First 36 Patients
Clinical Results of 36 Visceral Manifold Patients

Gender
22 Males
14 Females

Mean Age
72.3 (58-89)

Previous Aortic Surgery
14/36
Clinical Results of 36 Visceral Manifold Patients

- 36 TAAA
  - 28 Non Emergent
  - 5 TAB
  - 3 Emergent Leaking
    - 1 TBG/VM
    - 2 Modified Configuration
Clinical Results of 36 Visceral Manifold Patients

Intra Op (All 36 Patients)

ASA Score 4 or greater: 18/36
Length of Surgery: 450 min (184-870)
Fluoro Time: 116 min (49-300)
Total Contrast Used: 166 ml (23-357)
Target Vessels Debranched: 132/135* 98%

*3 vessels were unsuccessfully debranched secondary to previously placed suprarenal fixated stent grafts
### Clinical Results of 36 Visceral Manifold Patients

In Hospital Post Op Results (VM)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality Rate</td>
<td>1/36</td>
</tr>
<tr>
<td>MI</td>
<td>1/36</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>3/36</td>
</tr>
<tr>
<td>CVA</td>
<td>0/36</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>3/36</td>
</tr>
<tr>
<td>LOS</td>
<td>9.6 Days (3-26)</td>
</tr>
<tr>
<td>Discharged to Home</td>
<td>20/36 w/ LOS 6.6 Days</td>
</tr>
</tbody>
</table>
Clinical 1 yr Summary

In Hospital Mortality 1/36
30 Day Mortality 1/36
One Year Device Related Mortality 0/36
Aneurysm Related Mortality 2/36
1yr All Cause Mortality 10/36
Renal Failure 4/36
Paraplegia 3/36
Patency Rates 65/67 97% => 1yr
Secondary Interventions 1/132 EndoBypasses
Type 3 EndoLeaks 2
<table>
<thead>
<tr>
<th>Region</th>
<th>Number</th>
<th>Length Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>I &amp; II</td>
<td>13/36</td>
<td>5.1-8.6 cm</td>
</tr>
<tr>
<td>III</td>
<td>12/36</td>
<td>5.2-9.6 cm</td>
</tr>
<tr>
<td>IV</td>
<td>10/36</td>
<td>5.1-12.1 cm</td>
</tr>
<tr>
<td>V</td>
<td>1/36</td>
<td>5.3 cm</td>
</tr>
</tbody>
</table>
Applying To Type IV and ParaVisceral Aneurysm
IDE
Unitary
Graft
Unitary Stent Graft System (PMEG)

- Fixation
- 25-36 mm Diameter Main Body
- 6-8 mm Visceral Limbs
- 13-14 mm InfraRenal Extension
Unitary (PMEG)

6-8mm Visceral Limbs

13-14mm InfraRenal Extension
Clinical Results of First 6 Patients Under IDE (PMEG)

Gender: 5 males, 1 female

Mean Age: 69.8 (57-80)

Previous Aortic Surgery: 3/6

Patients: 5 – non-emergent, 1 - emergent
Clinical Results of First 6 Patients Under IDE (PMEG)

**Intra-Op**

- ASA Score 4 or greater: 5/6
- Length of Surgery: 282 min (185-512)
- Implant Time (n=5): 163 min (136-231)
- Fluoro Time: 78.5 min (57-112)
- Total Contrast Used: 88 ml (37-133)
- Target Vessels Debranched: 23/23 (100%)
Clinical Results of First 6 Patients Under IDE (PMEG)

In Hospital Post-Op Results (Unitary)

- Mortality rate 0/6
- MI 0/6
- Renal Failure 0/6
- CVA 0/6
- Paraplegia 0/6
- LOS 8.6 days (5-18)
- Discharged to Home 5/6 w/ LOS 6.8 days
Clinical Results of First 6 Patients Under IDE (PMEG)

30-Day Follow-up (Unitary)

Aneurysm Related Deaths 0
30 Day All Cause Mortality 0
Device Related Death 0
Renal Failure 0
Paraplegia 0 new cases
EndoLeaks 2 - Type 2
No Evidence of Graft Migration
Secondary Interventions 2/23
EndoBypasses on 1 subject
Branch Graft Patency 22/23 96%
Conclusions
By Approaching This Problem From A Non-Anatomical Standpoint

Of

Proximal Deployment
Endo-Bypass
Delayed Distal Seal
Minimizing Aortic Coverage
We’ve Been Able To Perform In-Situ Customized Aneurysm Repairs
Handling Virtually Any Anatomy
With Very Reasonable Results