New ThoracoAbdominal Aortic Aneurysm Stent Graft System

Patrick W. Kelly, MD FACS
Disclosures
Patrick Kelly

- US Patent Applications Pending/Awarded on Devices Presented
- Licensed Intellectual Property to Medtronic
Disclaimer

- This presentation discusses off-label and no-label use of devices
- This presentation discusses the use of physician-modified endografts (PMEGs) under PSIDE G140207
Current Endo Solutions Either Approved or Under Industry Sponsored Study

- **T-Branch**
  Approved in Europe and undergoing clinical trial in the U.S.

- **Z-Fem**
  4 fenestrations currently undergoing clinical trial in the U.S.

- **Tambe**
  Currently going through EFS with 3 clinical implants.
The Real World
Design Requirements

- Durable exclude the aneurysm with fixation and seal
- Handle virtually any anatomy
- Provide favorable flow characteristics
- Provide unimpeded flow to vital organs throughout the surgery
- Stageable
- Be a fully OFF THE SHELF product
The Valiant ThoracoAbdominal Aortic Aneurysm Stent Graft System In Partnership With Medtronic
Paradigm Shift

• Proximal Deployment
• Endo-Bypasses
• Delayed Distal Seal
ThoracoAbdominal Aortic Aneurysm Repair
Proximal Deployment

Place the Thoracic Bifurcated Graft and Visceral Manifold above the “branch vessels.”

This allows for continued perfusion throughout the procedure.
ThoracoAbdominal Aortic Aneurysm

Proximal Deployment Of Thoracic Bifurcated Graft
Thoracic Bifurcated Graft

Valiant Main Component
Diameter Size Match
32, 36, 40, 46

Endurant Extension
20mm Limb
16mm Limb
ThoracoAbdominal Aortic Aneurysm

Proximal Deployment Of Visceral Manifold
Visceral Manifold Graft

- 24mm Main Body
- 14mm Proximal Limbs
- 8mm Individual Limbs
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.
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass
ThoracoAbdominal Aortic Aneurysm

Endo-Bypass
Delayed Distal Seal

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.
ThoracoAbdominal Aortic Aneurysm

Delayed Distal Seal
ThoracoAbdominal Aortic Aneurysm

Delayed Distal Seal
ThoracoAbdominal Aortic Aneurysm
Velocity Streamlines
Examination of near-wall hemodynamic parameters in the renal bridging stent of various stent graft configurations for repairing visceral branched aortic aneurysms

Taylor Suess, MS, Joseph Anderson, BS, Laura Danielson, MD, Katie Pohlson, BS, Tyler Remund, PhD, Elizabeth Blears, MD, Stephen Gent, PhD, and Patrick Kelly, MD, Brookings and Sioux Falls, SDak

Objective: This study examined the flow behavior of four stent graft configurations for endovascular repair of complex aneurysms of the descending aorta.

Methods: Computational fluid dynamics models with transient boundary conditions and rigid wall simplifying assumptions were developed and used with four distinct geometries to compare various near-wall hemodynamic parameters.

Results: Graphic plots for time-averaged wall shear stress, oscillating shear index, and relative residence time were presented and compared among the four stent graft configurations of interest.

Conclusions: Abrupt 90° and 180° changes in stent geometry (particularly in the side branches) cause a high momentum change and thus increased flow separation and mixing, which has significant implications in blood flow characteristics near the wall. By comparison, longer bridging stents provide more gradual changes in momentum, thus allowing blood flow to develop before reaching the target vessel. (J Vasc Surg 2015;1:1-9.)
29 Patients Treated (March 2012 to Present)

Gender:
16 males
13 females

Mean Age:
72.1 (58-87)
I & II
8/29
5.5-7.1cm

III
6/29
5.2-8.2cm

IV
8/29
5.3-7.2cm
36.3-44.7mm
At the Renals

V
7/29
5.2-5.7cm
Intra-Op

- Total Length of Surgery: 297min (238-489)
- Fluoro Time: 95min (57-238)
- Total Contrast Used: 102ml (43-137)
- Target Vessels Debranched: 108/111*

*3 Vessel we unsuccessfully debranched secondary to previously placed superenal fixated Stent Grafts
In Hospital Post-Op Results

- Mortality rate: 0/29
- MI: 0/29
- Renal Failure: 2/29
- CVA: 0/29
- Paraplegia: 2/29
- LOS: 7.5 days (3-21)
- Discharged to Home: 23/29 w/ LOS 6.1 days
<table>
<thead>
<tr>
<th>Condition</th>
<th>Status</th>
</tr>
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<tbody>
<tr>
<td>Meeting 1yr Followup</td>
<td>22/29</td>
</tr>
<tr>
<td>Aneurysm Related Deaths</td>
<td>0/29</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0 new cases</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>0 new cases</td>
</tr>
<tr>
<td>EndoLeaks</td>
<td>2- Type 3 0-Type 1</td>
</tr>
<tr>
<td>No Evidence of Sack Growth Nor Graft Migration</td>
<td></td>
</tr>
<tr>
<td>Branch Graft Patency</td>
<td>80/81 99% &gt; 1yr</td>
</tr>
</tbody>
</table>
I & II
8/29
5.5-7.1cm

III
6/29
5.2-8.2cm

IV
8/29
5.3-7.2cm
36.3-44.7mm
At the Renals

V
7/29
5.2-5.7cm
Clinical Results Summary

- In Hospital Mortality: 0/29
- 30 Day Mortality: 0/29
- Aneurysm Related Mortality: 0/29
- All Cause Mortality: 4/22
- Renal Failure: 2/29 Requiring Dialysis
- Paraplegia: 2/29
- EndoBypasses Placed: 108/111
- Patency Rates: 107/108
- Secondary Interventions: 0/107 EndoBypasses
- Type 3 EndoLeaks: 2/248 Joints
From the Midwestern Vascular Surgical Society

A novel endovascular debranching technique using physician-assembled endografts for repair of thoracoabdominal aneurysms

Joe Anderson, a Madeline Nykamp, b Laura Danielson, a Tyler Remund, PhD, b and Patrick W. Kelly, MD, c
Sioux Falls, SD, SDak

Objective: The objective of this study was to demonstrate a technique that uses physician-assembled endografts to make use of the benefits of parallel grafts while also providing for circumferential seal and fixation in repair of thoracoabdominal aneurysms in inoperable patients.

Methods: A single-center all-comers retrospective analysis of 14 patients was performed that looked at the early outcomes of patients treated for thoracoabdominal aneurysms. Three Crawford type II, four type III, four type IV, and three type V thoracoabdominal aneurysms were treated. Contrast material, fluoroscopy time, length of stay, clinical success, and technical success were measured.

Results: There was no in-hospital, 30-day, or 6-month mortality. We found two type III endoleaks in the early design. One required coil embolization. Average volume of contrast material and average fluoroscopy time were 76.9 mL and 119.1 minutes, respectively. Average length of stay was 10.5 days, and average procedure time was 251.2 minutes. Clinical success was observed in 78.6% of patients to date, and technical success was observed in 85.7% of patients.

Conclusions: Short-term results show that this approach is safe. The device can be safely implanted, is off-the-shelf, and can treat each of the Crawford thoracoabdominal aneurysm types. Finally, the assembly of off-the-shelf components may shorten the regulatory path for this physician-assembled endograft. (J Vasc Surg 2014;1:1-8.)
Conclusions
Design Requirements

- Durable exclude the aneurysm with fixation and seal
- Handle virtually any anatomy
- Provide favorable flow characteristics
- Provide unimpeded flow to vital organs throughout the surgery
- Stageable
- Be a fully OFF THE SHELF product
With very reasonable but certainly not perfect results
Thank you!

Vascular Innovations
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