ADVANCES IN THE MANAGEMENT OF JUXTARENAL ABDOMINAL AORTIC ANEURYSMS

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Chief of Vascular Surgery
Centennial Medical Center
DISCLOSURES

• WL Gore and Associates
  • Research/Faculty

• Cardiovascular Systems Inc
  • Research/Education/Faculty

• Abbott
  • Research/Education/Faculty

• Cordis
  • Research/Education/Faculty
OBJECTIVES

• Understand how aneurysm management has changed in the past century.

• Demonstrate that endovascular treatment is intuitively safe.

• Where are we now with juxtarenal aneurysm repair?

• What’s next?
MILESTONES IN ANEURYSM REPAIR

Aortic Ligation (100-200)

Open repair with maintenance of continuity (Mid 1900's)

Endovascular Repair (Sept 1990)

Customized Fenestrated Endograft (1990's)

Off the Shelf Fenestrated (early 2000)
AORTIC LIGATION

• Antyllus
  • 126-216 AD
  • Midline laparotomy
  • Ligation of the aneurysm
  • Removal of grumus

• 1923, Matas performed the first successful complete ligation of the aorta for aneurysm.
  • Lived 1.5 years
  • Died of TB related complication

RUDOLPH MATAS (1860-1957)
WHY KEEP LIGATING?

• No other good answer

• Hope and a prayer

• Operating on the aorta
  • Different appreciation for its strength
  • Ascending/arch
GRAFTS

• Biological grafts
  • Carrel and Guthrie
  • Human/canine vascular transplantation
  • Dubost
    • Maintenance of arterial continuity
    • 51 year old man, received the aorta of a young girl harvested three weeks previously
    • Thrombosed and pt died

• Synthetic
  • Arthur Voorhees
    • Endothelialization of an errant suture
      • Why not take some cloth and replace a diseased blood vessel with it
  • Vinyon-N
    • proved robust
    • Voorhees, Jaretski and Blakemore.
  • 1952
    • First synthetic graft for ruptured AAA
  • Dacron, ePTFE, Teflon
STANDARD OPEN AAA
DON’T FORGET IMAGING

- ‘Investigation of Abdominal Masses by Pulsed Ultrasound,’

- The Multicentre Aneurysm Study showed that ultrasound screening resulted in a 42% reduction in mortality from ruptured AAAs over four years to 2002.

- Computed Topography
  - ABC
    - Airway, breathing, CT Scan

STARS ALIGNED

• Overall operative mortality from ruptured AAA fell by 3.5% per decade from 1954-1997

• Leap forward in surgical techniques (Juan Parodi et al)

• Drastically improved imaging modalities.
ENDOVASCULAR TREATMENT IS SAFE

- EVAR1

- DREAM

- Short term advantages
  - Blood loss
  - Operative time
  - Hospital stay
  - Morbidity/mortality


DEFINITION

- A juxtarenal aortic abdominal aneurysm (JRAAA) is an infrarenal aortic aneurysm extending to the renal arteries **without** involving them

- <15 mm neck

- Incidence has been estimated as approximately 16% of infrarenal aortic aneurysm

- The shorter the neck, the harder to seal
THAT SICK FEELING

Lowest renal
ENDURANT

• Endurant I
  • 2010 (US)
    • IFU neck >10mm (compared to 15)
    • Employs suprarenal fixation

• European pivotal trial of the Endurant stent graft
  • 30-day freedom from all cause mortality was noted in 97.5%
  • technical success rate was 91% when three periprocedural endoleaks (type I = 1, type III = 2), one graft thrombosis, and three secondary endovascular interventions were considered


Endurant stent-graft system: preliminary report on an innovative treatment for challenging abdominal aortic aneurysm

# ENDURANT RESULTS

## EVENT RATES AT 30 DAYS ACROSS 1400+ PATIENTS

<table>
<thead>
<tr>
<th>Trial Study Design</th>
<th>Technical / Deployment Success (%)</th>
<th>Type I Endoleak (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EU TRIAL (N = 80)</strong></td>
<td>Prospective, open-label, multicenter trial conducted at 10 sites across Europe</td>
<td>100</td>
</tr>
<tr>
<td><strong>US IDE (N = 150)</strong></td>
<td>Prospective, multicenter trial conducted at 26 sites across the United States, Reviewed by independent core lab</td>
<td>99.3</td>
</tr>
<tr>
<td><strong>ENGAGE REGISTRY (N = 1263)</strong></td>
<td>Post-market, real-world registry involving 1263 patients at 79 sites in 30 countries</td>
<td>99.4</td>
</tr>
</tbody>
</table>

### Intervention/Complication

<table>
<thead>
<tr>
<th>Intervention/Complication</th>
<th>Year 1, % (N=1263)</th>
<th>Year 2, % (N=500)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No reintervention</td>
<td>94.8</td>
<td>93.0</td>
</tr>
<tr>
<td>Any second procedure</td>
<td>5.6</td>
<td>1.6</td>
</tr>
<tr>
<td>Second procedure to correct Type I/III endoleak</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Endoleak (total)</td>
<td>9.7</td>
<td>9.1</td>
</tr>
<tr>
<td>Type I or III</td>
<td>0.6</td>
<td>1.1</td>
</tr>
<tr>
<td>Significant sac shrinkage</td>
<td>41.0</td>
<td>56.0</td>
</tr>
<tr>
<td>Sac enlargement</td>
<td>3.4</td>
<td>3.9</td>
</tr>
<tr>
<td>Migration</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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ENGAGE Registry:
Schimanski M. ENGAGE 30-day and 1-year results. VMA 2011.

2. EU Trial delivery success = successful vascular access and delivery of the device to the intended anatomic treatment sites; EU Trial deployment success = successful deployment of the device in the intended site and the successful removal of the delivery system. IDE IDE deployment success = "successful stent-graft implant.”
3. 30 Day EU Trial data represents follow-up on N = 79 patients. 30 Day IDE data represents follow-up on N = 106 patients.
4. 30-day ENGAGE data represents imaging follow-up on N=1163 patients.
<table>
<thead>
<tr>
<th></th>
<th>Enrolment, year</th>
<th>Primary devices</th>
<th>Secondary interventions, %</th>
<th>Conversions, %</th>
<th>Aneurysm-related mortality, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>DREAM</td>
<td>2000–2003</td>
<td>Zenith®, Talent®, Excluder®</td>
<td>12</td>
<td>1.7</td>
<td>2.1</td>
</tr>
<tr>
<td>OVER</td>
<td>2002–2008</td>
<td>Zenith®, Excluder®</td>
<td>13.7</td>
<td>&lt;1.5</td>
<td>2.1</td>
</tr>
<tr>
<td>ENDURANT® US IDE</td>
<td>2008–2009</td>
<td>Endurant®</td>
<td>FF 93.9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>ENGAGE</td>
<td>2009–2011</td>
<td>Endurant®</td>
<td>6.4</td>
<td>0.8</td>
<td>FF 98.1</td>
</tr>
</tbody>
</table>
## ENGAGE VS EVAR 1

<table>
<thead>
<tr>
<th>Outcomes Through 4Y</th>
<th>EVAR Arm of EVAR I Trial</th>
<th>Endurant in ENGAGE Registry</th>
<th>Relative Risk Reduction (RRR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARM</td>
<td>3.5% (19/543)</td>
<td>1.6% (20/1,263)</td>
<td>54%</td>
</tr>
<tr>
<td>Ruptures</td>
<td>0.9% (5/532)</td>
<td>0.5% (6/1263)</td>
<td>44%</td>
</tr>
<tr>
<td>Reinterventions</td>
<td>20%</td>
<td>13%</td>
<td>35%</td>
</tr>
</tbody>
</table>

Source: Dittmar Bockler, Charing Cross 2016
ENDURANT IIS

- New bifurcated component
- Expands the system's anatomical customization options
- 20% reduction in distal diameter
- Simplified inventory

Source: Medtronic
ENDOANCHORS

- Helical anchors 3 mm in diameter and 4.5 mm in length
- Deflectable guide sheath
- Engage the adventitia to provide durable fixation
- 4-6 anchors
- Compatibility
ANCHOR REGISTRY

- Proximal attachment site complications
  - Graft migration
  - Type IA endoleak

- Evaluate the potential benefit of endo-anchor treatment

- Primary and revision arm
  - EndoAnchor implantation at the same procedure as the initial EVAR procedure or Type IA at completion arteriogram
    - Judgement call

- Prior EVAR with Type IA or migration on presentation
## ANCHOR RESULTS

<table>
<thead>
<tr>
<th>Patients, No.</th>
<th>Technical success, a No. (%)</th>
<th>Procedural success, b No. (%)</th>
<th>No evidence of type Ia leak at completion angiography, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>319</td>
<td>303 (95.0)</td>
<td>279 (87.5)</td>
</tr>
<tr>
<td>Primary arm</td>
<td>242</td>
<td>233 (96.3)</td>
<td>217 (89.7)</td>
</tr>
<tr>
<td>Prophylaxis for hostile neck</td>
<td>186</td>
<td>180 (96.8)</td>
<td>172 (92.5)</td>
</tr>
<tr>
<td>Treatment of type Ia endoleak</td>
<td>52</td>
<td>51 (98.1)</td>
<td>43 (82.7)</td>
</tr>
<tr>
<td>Treatment of distal deployment</td>
<td>4</td>
<td>2 (50.0)</td>
<td>2 (50)</td>
</tr>
<tr>
<td>Revision arm</td>
<td>79</td>
<td>70 (90.9)</td>
<td>62 (80.5)</td>
</tr>
<tr>
<td>Treatment of type Ia endoleak</td>
<td>45</td>
<td>43 (95.6)</td>
<td>35 (77.8)</td>
</tr>
<tr>
<td>Treatment of migration</td>
<td>11</td>
<td>8 (72.7)</td>
<td>8 (72.7)</td>
</tr>
<tr>
<td>Treatment of endoleak and migration</td>
<td>21</td>
<td>19 (90.5)</td>
<td>19 (90.5)</td>
</tr>
</tbody>
</table>

Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy

Jordan, William D; Jordan, William D; et al.
Journal of Vascular Surgery, Volume 60, Issue 4, 885-892.e2
CLINICAL RESEARCH STUDIES
From the Society for Vascular Surgery

Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms

Gustavo S. Oderich, MD,1* Roy K. Greenberg, MD,2,4* Mark Farber, MD,† Sean Lyden, MD,‡
Luis Sanchez, MD,4 Ron Fairman, MD,3† FeiJi, PhD,§ and Priya Bharadwaj, PhD,‖ on behalf of the Zenith Fenestrated Study Investigators, Rochester, Minn; Cleveland, Ohio; Chapel Hill, NC; St. Louis, Mo; Philadelphia, Pa; and West Lafayette, Ind
THE DEVICE

- **Device**
  - one to three fenestrations
    - Small
    - Large
    - scallop fenestrations,
  - maximum of two fenestrations of the same type
  - Small fenestrations have dimensions of
    - 6 X 6 mm or 6 X 8 mm
    - Do not have struts crossing the middle of the fenestration,
    - Reinforced by a nitinol ring,
    - fashioned > 15 mm and < 36 mm (for 24- to 32-mm devices) or < 46 mm (for 34- to 36-mm devices) from the edge of the fabric.
  - Large fenestrations
    - not reinforced by a nitinol ring,
    - measure 8 to 12 mm in diameter
    - fashioned > 10 mm from the edge of the fabric.
    - Struts crossing at the edge or middle of the fenestration
      - Limit the ability to place alignment stents.
  - Scallops are openings in the upper edge of the fabric that are 10 X 6 to 12 mm.

- The most common design (2/3rd of pts) in the US multicenter pivotal trial includes two small fenestrations for the renal arteries and a scallop for the superior mesenteric artery.

Source: Cook Endovascular
10 STEPS

• Multisheath Femoral Access
• Precatheterization of Target Vessels
• Device Orientation and Deployment
• Fenestration and Target Vessel Catheterization and Sheath Advancement
• Deployment and Retrieval of the Top Cap
• Proximal Neck Balloon Dilatation
• Target Vessel Stenting
• The Distal Bifurcated Component
• Gate Catheterization and Contralateral Iliac Extension
• Balloon Dilatation of Attachment Sites and Distal Landing Zones
FINAL RESULT
SUMMARY

- 14 Centers
- 195 pts
  - 128 excluded
  - 67 patients
    - 42 pivotal
    - 25 extended

- Prep
  - High resolution CTA
  - Neck length
    - >4mm//<15mm

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**Supplementary Table III (online only). Reasons for anatomic exclusion from participation in the Cook Zenith Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft Trial**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal neck &lt;4 mm or &gt;15 mm in length</td>
<td>60</td>
</tr>
<tr>
<td>Proximal neck diameter change over the length of the proximal seal zone &gt;4 mm</td>
<td>37</td>
</tr>
<tr>
<td>Proximal neck &gt;31 mm or &lt;19 mm in diameter</td>
<td>34</td>
</tr>
<tr>
<td>Unsuitable arterial anatomy</td>
<td>33</td>
</tr>
<tr>
<td>Iliac artery diameter &lt;0.5 mm at any point along access length</td>
<td>32</td>
</tr>
<tr>
<td>Proximal neck angulation &gt;45 degrees relative to the long axis of the aneurysm</td>
<td>14</td>
</tr>
<tr>
<td>Significant occlusive disease, tortuosity, or calcification</td>
<td>12</td>
</tr>
<tr>
<td>Suprarenal neck angulation &gt;45 degrees relative to the immediate infrarenal neck</td>
<td>9</td>
</tr>
<tr>
<td>Nonfurburated segment of any artery to be stented &lt;15 mm in length</td>
<td>9</td>
</tr>
<tr>
<td>Renal artery stenosis &gt;50%</td>
<td>8</td>
</tr>
<tr>
<td>Ipsilateral iliac artery fixation site diameter &lt;9.0 mm</td>
<td>7</td>
</tr>
<tr>
<td>Proximal seal site with circumferential thrombus/atheroma above the renal arteries</td>
<td>6</td>
</tr>
<tr>
<td>Inability to maintain at least one patent hypogastric artery</td>
<td>6</td>
</tr>
<tr>
<td>Iliac artery distal fixation site &lt;30 mm in length</td>
<td>5</td>
</tr>
<tr>
<td>Aortic or aortoiliac aneurysm with diameter of ≥5 cm</td>
<td>4</td>
</tr>
<tr>
<td>Iliac artery diameter &gt;21 mm at distal fixation site</td>
<td>4</td>
</tr>
<tr>
<td>Artery to be stented with a maximum diameter &lt;3 mm or &gt;8 mm at the vessel ostium</td>
<td>2</td>
</tr>
<tr>
<td>Total number of patients excluded</td>
<td>128</td>
</tr>
</tbody>
</table>

*A patient may meet more than one exclusion criterion.*
RESULTS

• Greenberg et al 24 month
  • No proximal type I endoleaks or aneurysm ruptures during a period of 24 months
  • 8 renal complications
    • Renal artery stenosis (4)
    • Renal artery occlusion (2)
    • Renal infarct (2)
  • Type II Endoleak
    • 26% @ 1 year
    • 20% @ 2 years

• Verhoeven et al also did not identify any secondary proximal type I endoleaks in a group of 100 patients with juxtarenal AAAs treated with this device during a median follow-up of 24 months.

• Oderich et al through 2012
  • 67 patients
    • 1 perioperative death
      • Bowel ischemia
    • Major adverse events
      • 1 related to surgery
    • Renal arteries
      • Five-year primary renal artery patency was 81% (±5%)
      • secondary renal artery patency was 97% (±2%)
    • 1 stent migration
The Future...is Here
OTHER OPTIONS

• Ovation Prime system

  • Proximal aortic landing zone
    • inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery

  • aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm
CONCLUSION

• We’ve come along way with abdominal aortic aneurysm repair

• Neck anatomy will continues to be a challenge

• Off the shelf fenestrated devices are here and will continue to be refined

• Customized off the shelf fenestration has to be the future
REFERENCES


REFERENCES


• Cohn, I. and Deutsch, H.B. in: Rudolph Matas: a biography of one of the great pioneers in surgery. Doubleday & Company, Inc, Garden City (NY); 1960: 9–10 (201-15)
THANK YOU