Precision and accuracy in treating hostile anatomy: limitations and on-going needs

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Disclosures

W.L. Gore
Consulting, Research, PI

Medtronic
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Boston Scientific
Consulting, Research
EXCELLENCE IN BKLYN
Outcome and “Durability” Measures for EVAR....mostly related to neck sealing

- Death/Rupture
- Endoleak
- Neck Integrity
- Migration
EVAR at its best: *when the neck is ideal*
Five-year report of a multicenter controlled clinical trial of open versus endovascular treatment of abdominal aortic aneurysms.

Peterson BG, Matsumura JS, Brewster DC, Makaroun MS; Excluder Bifurcated Endoprosthesis Investigators.

Abstract


METHODS: 334 subjects were treated with standard open repair (test, n = 235). Five-year clinical evaluations and corelab radiographic results are analyzed.

RESULTS: Overall and aneurysm-related survival are similar. There have been ten open conversions, most recently for enlarging sacs without endoleak. Two patients died after conversion. Including reinterventions and complications of reinterventions as adverse events, there is significant, persistent long-term reduction in major adverse events. At 5 years, corelab reported 0% limb narrowing, 0% trunk migration, 0% component (contralateral leg, aortic extender, and iliac extender) migration, 0% fracture, endoleak in 3% (2 type II/68), and aneurysm growth (>5 mm compared to baseline) in 38% (30/78) of the test group. There are no aneurysm ruptures in either test or control group.

CONCLUSIONS: After 5 years follow-up, endovascular repair is a safer and effective treatment compared with open surgical repair for abdominal aortic aneurysms. Major adverse events are less frequent with the endograft despite the need for late reinterventions. Aneurysm expansion is observed in nearly two-fifths of patients but is not associated with endoleak or aneurysm rupture. Multicenter clinical trials are evaluating a newer version of this device designed to avoid this high rate of sac expansion.

0% main body migration at 5 years
Zenith abdominal aortic aneurysm endovascular graft

Roy K. Greenberg, MD, a Timothy A. M. Chuter, MD, b Richard P. Cambria, MD, c
W. Charles Sternbergh III, MD, d and Neal E. Fearnott, PhD, e Cleveland, Ohio; San Francisco, Calif; Boston,
Mass; New Orleans, La; and West Lafayette, Ind

Purpose: The safety and efficacy of the Zenith (Cook Inc, Bloomington, Ind) endovascular graft was assessed based on the
United States multicenter trial through 5 years of follow-up.

Methods: Between 2000 and 2003, the pivotal study enrolled patients to open surgery (control) or the Zenith endovascular
graft (endovascular). A separate continued access study arm enrolled endovascular patients using the same inclusion/exclusion
criteria. Both studies were designed for 2-year follow-up, and the pivotal endovascular patients had the option of extending the
study follow-up through 5 years. Suboptimal endovascular patients were followed up through 3 years. All patients were classified into high-risk
and standard-risk groups to assess overall survival, freedom from aneurysm-related death, freedom from aneurysm-related migration.
The entire endovascular cohort was followed up through 5 years, with the exception of 158 patients who were censored at 2 years. Survival
Statistics analyses included Kaplan-Meier estimations and Cox regression to assess factors contributing to sac enlargement and SER.
Results: The study enrolled 739 endovascular patients (252 pivotal, 387 continued access); 158 patients in the pivotal study
reconsented to be followed up for 5 years. For the patients at standard and high risk at 5 years, the respective survival estimate
was 83% and 61%, aneurysm-related death was 2% and 4%, and freedom from rupture was 100% and 99.6%, respectively.
Cumulative risk of conversion, limb occlusion, migration >10 mm, or component separation was ≤3% at 5 years. Cumulative
risk of late endoleak was 12% to 15%, representing the primary indication for secondary interventions which occurred in 20%
of standard-risk patients and 25% of high-risk patients through 5 years. Sac enlargement was very rare and associated with
advanced age and larger aneurysms. SER was predicted by advanced age and internal iliac artery occlusion.
Conclusion: These middle- and long-term data support long-term durability of the Zenith endovascular graft. Risk of
aneurysm-related death or rupture was exceptionally low, and complications of migration, limb occlusion, and device
integrity issues were uncommon. Incidence of late endoleaks and association of endoleaks with sac growth underscore the
need for long-term follow-up of patients treated with endovascular grafts, although the sequelae of such events are

2.5 % (19/739) migration at 5 yrs
Hostile Infrarenal AAA necks
Predictors of EVAR FAILURE

Reverse taper
Severe neck angulation
Short
60% of EVAR procedures in USA do not meet IFU criteria!
Fenestrated? Chimney?
How to treat hostile neck infrarenal or juxtarenal AAA in the future?

branched EVAR? Maybe....not today
Reality

Even in most large volume tertiary care centers.... ~80% of all AAA treated patients have at least a 10 mm infrarenal neck
The Question Today

How can we optimize the coverage of the infrarenal sealing zone
How to keep the endograft sealed at the infrarenal neck
Why Active Fixation

1. Deployment accuracy
   Ability to place the sealing portion of the endograft below the renal arteries

2. Long Term Migration Prevention
   Allows the endograft stay where it originally deployed
Fixation **Type** Does Affect Migration Rates

<table>
<thead>
<tr>
<th></th>
<th>Medtronic ANEURX Device</th>
<th>EVT / ANCURE® Device</th>
<th>GORE® EXCLUDER® Device</th>
<th>STENTOR® Device</th>
<th>Medtronic TALENT® Device</th>
<th>VANGUARD® Device</th>
<th>COOK® ZENITH® Device</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-Related Endoleak</td>
<td>5.2%</td>
<td>8.6%</td>
<td>5.0%</td>
<td>9.6%</td>
<td>6.6%</td>
<td>7.2%</td>
<td>4.1%</td>
<td>6.2%</td>
</tr>
<tr>
<td>Type II Endoleak</td>
<td>4.5%</td>
<td>5.0%</td>
<td>10.5%</td>
<td>0.3%</td>
<td>4.6%</td>
<td>3.7%</td>
<td>7.0%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Growth</td>
<td>2.7%</td>
<td>2.2%</td>
<td>4.2%</td>
<td>2.7%</td>
<td>4.3%</td>
<td>2.7%</td>
<td>4.0%</td>
<td>3.3%</td>
</tr>
<tr>
<td>Shrinkage</td>
<td>20.3%</td>
<td>26.4%</td>
<td>20.9%</td>
<td>6.6%</td>
<td>30.0%</td>
<td>17.1%</td>
<td>35.0%</td>
<td>22.7%</td>
</tr>
<tr>
<td>Migration</td>
<td>4.3%</td>
<td>0.5%</td>
<td>1.1%</td>
<td>3.1%</td>
<td>2.4%</td>
<td>5.0%</td>
<td>0.7%</td>
<td>2.8%</td>
</tr>
<tr>
<td>Kinking</td>
<td>1.1%</td>
<td>2.2%</td>
<td>0.6%</td>
<td>3.9%</td>
<td>1.0%</td>
<td>5.0%</td>
<td>1.2%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Occlusion</td>
<td>1.9%</td>
<td>3.3%</td>
<td>1.1%</td>
<td>3.7%</td>
<td>2.3%</td>
<td>5.3%</td>
<td>3.5%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Conversion</td>
<td>1.9%</td>
<td>5.4%</td>
<td>0.8%</td>
<td>3.3%</td>
<td>2.1%</td>
<td>2.2%</td>
<td>0.6%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Secondary Intervention</td>
<td>6.3%</td>
<td>9.6%</td>
<td>3.5%</td>
<td>9.4%</td>
<td>6.6%</td>
<td>10.7%</td>
<td>5.3%</td>
<td>7.3%</td>
</tr>
<tr>
<td>Rupture</td>
<td>0.4%</td>
<td>0.0%</td>
<td>0.1%</td>
<td>0.8%</td>
<td>0.5%</td>
<td>0.8%</td>
<td>0.2%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Death</td>
<td>6.7%</td>
<td>4.7%</td>
<td>4.8%</td>
<td>5.8%</td>
<td>7.1%</td>
<td>7.5%</td>
<td>7.5%</td>
<td>6.8%</td>
</tr>
</tbody>
</table>

Data presented as annual incidence rate (number of patients). Number of patients ranges from 0–636.

**Fixation Location** Does Not Affect Type I Endoleaks

**Infrarenal (IRF) vs. Suprarenal (SRF)**

<table>
<thead>
<tr>
<th>Complications</th>
<th>Total Cohort %</th>
<th>IRF Group %</th>
<th>SRF Group %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal Type I Endoleak</td>
<td>7.3</td>
<td>7.4</td>
<td>7.1</td>
</tr>
<tr>
<td>Primary</td>
<td>3.5</td>
<td>2.8</td>
<td>4.8</td>
</tr>
<tr>
<td>Secondary</td>
<td>3.9</td>
<td>4.7</td>
<td>2.3</td>
</tr>
<tr>
<td>Conversion to Open</td>
<td>5.3</td>
<td>5.3</td>
<td>5.4</td>
</tr>
<tr>
<td>Early Conversion (30 days)</td>
<td>0.9</td>
<td>0.9</td>
<td>0.8</td>
</tr>
<tr>
<td>Post-EVAR Rupture</td>
<td>0.6</td>
<td>0.6</td>
<td>0.6</td>
</tr>
</tbody>
</table>


Endografts with suprarenal fixation do not perform better than those with infrarenal fixation in the treatment of patients with short straight proximal aortic necks

Eric S. Hager, MD, Jae S. Cho, MD, Michel S. Makaroun, MD, Sun Cheol Park, MD, Rabih Chaer, MD, Luke Marone, MD, and Robert Y. Rhee, MD, Pittsburgh, Pa; and Seoul, Korea

6 year study (2002-2008)
84 patients identified: 2yr f/u

1379 Patients

IF Group: 60 patients
SF Group: 24 patients

IF = Infrarenal fixation
SF = Suprarenal fixation
## Aneurysm Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Infra renal Fixation (n=60)</th>
<th>Supra renal fixation (n=24)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average proximal aortic neck</td>
<td>11.3 mm</td>
<td>11.1 mm</td>
<td>NS</td>
</tr>
<tr>
<td>Aneurysm size (post at 2 year)</td>
<td>5.8 cm (4.6 cm)</td>
<td>5.9 cm (4.9 cm)</td>
<td>NS</td>
</tr>
</tbody>
</table>
### Graft Migration at 24 months: > 3 mm

<table>
<thead>
<tr>
<th></th>
<th>Infrarenal Fixation (n=60)</th>
<th>Suprarenal Fixation (n=24)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graft migration</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>
Type 1 Endoleak

Follow-up:

- OR date
- 6 month
- 12 month
- 24 month

Percentage:

- IF
- SF
Angled Necks?

Challenges

- Graft tracking
- Deployment issues
  - “Jumping”
  - “Wind-socking” from loss of axial support
- Graft kinking

FLEXIBLE, COMFORMABLE system
Patient Selection is KEY!

- No more than ONE hostile factor?
- Consider fenestrated/chimney when reverse taper is more than 5 mm
- Evaluate the quality of the neck
  - Short good quality necks may be better than longer calcified or thrombus laden necks
  - Smaller diameter necks clearly do better than necks larger than 30mm
SR graft migration
2 years, 32mm neck treated with 36mm device
IR device migration
new type 1 endoleak at 1 year
(severe tapered (26-30mm) neck 1 year prior)
Too Late!
Deployment Precision

Seal every mm of available neck

*Limitation of Current endografts
Should we be treating patients with hostile necks?

Short: 10-15mm

Angulation: greater than 60 degrees

Reverse taper: more than 5 mm

YES! but.......*NOT if TWO or more* of these characteristics are present with the current endograft systems for infrarenal sealing
Tomorrow?

What are the qualities of an ideal infrarenal device?

- Deployment Accuracy
- Repositionability
- Active Fixation
- Flexibility
- Durability
- Low Profile
- Ease of Use
Product under development. This product is not commercially available and will only be available on the market when the CE mark can be applied by W. L. Gore & Associates.
Location, Location, Location
(of the EVAR device)

**C3 and the CEXC: Differences**

1. CTAG type nested stent design for max flexibility

2. Conformability to utilize every mm of the greater and lesser curve of the infrarenal neck

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**Clinical Challenge**: Maintaining wall apposition and seal in complex anatomy

**Abdominal Conformable Stent-Graft to incorporate the following design inputs**

- 16 Fr for most trunks
- Ability to conform to proximal neck angles up to 90°
- Achieve seal in short (≥ 10 mm) proximal necks
- Ability to reposition the device
- Mechanism to control device angulation
  - Fully constrained and partially deployed
  - Orthogonal positioning
Conformable AAA Endograft: An Evolution

• Multi-component Design
  – *Trunk-Ipsilateral Leg (conformable)*
  – *Aortic Extender (conformable)*
  – Contralateral Leg
  – Iliac Extender

• Trunk and Aortic Extender Stent-graft Design
  – Conformability
    • Leveraging GORE® Core Technology from the CTAG design
  – Reduced Profile
    • Leveraging ePTFE GORE® Core Technology

• Same Ipsilateral Stent-graft Design
  – Proven EXCLUDER® clinical performance
  – Proven EXCLUDER® durability

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Conclusions

optimizing success for hostile necks

Hostile necks are best handled with a “flexible endograft” with high quality imaging during deployment to maximize infrarenal sealing.

No significant difference in migration rates between IR and SR.

Fixation is required.
Optimal Infrarenal Sealing Endograft
“the future”

1. Deployment Accuracy
2. Repositionability
3. Active Fixation
4. Flexibility
5. Durability
6. Low Profile
7. Ease of Use

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Gore Clinical trial

- 50 U.S. sites
- 6 Japan sites
- Trial enrollment in Q2 of 2015
- Trial Design (2 parallel substudies)
  - Standard
  - High Angulation

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Thank you!
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