Challenges with Complex Anatomies
Advancing Care in Endovascular Aortic Treatment

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Endovascular Aortic Therapy

If the device diverting flow away from the diseased aortic wall is placed exactly as planned, the outcomes are excellent long term!

The main challenge is actually accomplishing this!
How can we achieve this during EVAR & TEVAR?

CONTROL

CONFORMABILITY
The First EVAR Frontier...

<table>
<thead>
<tr>
<th>Devices</th>
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<tbody>
<tr>
<td>Medtronic AneuRx, Guidant Ancure, GORE original EXCLUDER, Cook Zenith</td>
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<table>
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<tr>
<th>Design</th>
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<tbody>
<tr>
<td>More rigid stent-grafts</td>
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<tr>
<td>Indicated for 60° aortic necks and 15mm neck length</td>
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<table>
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<tr>
<th>Limitations</th>
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<tr>
<td>Not intended for challenging anatomy presentations</td>
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<tr>
<td>EVAR learning curve</td>
</tr>
<tr>
<td>Higher % conversion to open repair in primary procedure¹</td>
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<tr>
<td>Lower freedom from late reinterventions and late conversions¹</td>
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<tr>
<td>Higher incidence of endoleaks¹</td>
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<td>Increased risk of rupture¹</td>
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<th>Control</th>
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<td>Able to deploy, but still deployment failures</td>
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<td>Clinical outcomes not ideal</td>
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The First TEVAR Frontier...

Devices
- GORE® TAG® Thoracic Device, Medtronic Talent, Cook Zenith

Design
- Intended for the DTA only
- Indicated for aneurysm only

Limitations
- Incomplete wall apposition and birdbeaking
- Device compression when excessively oversized

Control: Technique dependent
Conformability: Rigid devices lead to suboptimal apposition and seal

The EVAR Landscape Today...

Devices
• Medtronic Endurant, Cook Zenith Flex, GORE EXCLUDER C3, Endologix Powerlink, Ovation, Lombard Aorfix, Cordis Incraft

Design
• More conformable...the concept of a RIGID device is OUT
• Reduced profile

Limitations
• Improved clinical outcomes
• But... even more hostile anatomy is now being treated...

Control
• Yes, better!
• Constrainability (example: GORE EXCLUDER C3)
• Improved deployment accuracy (due to EVAR learning curve?)
• Unpredictability and limited control in challenging anatomic presentations

Conformability
• Yes, better!
• Still... endoleaks, reinterventions
• Limitations in true conformability from renals to iliac bifurcation
Active Control & Conformability

*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.
TEVAR challenges......

*neck & angle*
The TEVAR Landscape Today...

**Devices**
- Conformable GORE® TAG® Device, Medtronic Valiant with Captivia, Cook Alpha, Bolton Relay

**Design**
- Engineered for younger TEVAR patient population
- Expanded indications including traumatic transection and Type B dissection depending on device

**Limitations**
- Arch applications, treatment zones, complex anatomy

**Control:** Challenging aortic dynamic forces and physician technique dependent

**Conformability:** Challenges with device apposition to inner aortic curvature in challenging anatomy
Clinical Needs of a TEVAR Device for the DTA

- Approved for broad indications
- Durability
- Conforms to the anatomy
- Designed with radial force characteristics safe for diverse pathologies
- Controlled deployment
- Post-deployment modification of device placement

Unmet clinical needs
Unmet Clinical Need: Controlled Deployment

• Deployment – Process of releasing the device from its delivery profile into its final diameter.

• Operator control needed to offset dynamic forces:
  – Wind-socking risk
  – Cardiac & respiratory forces
  – Discrepancy between wire travel vs. device deployment against outer curves of the aorta

• Remaining needs:
  – Multiple-stage deployment ideal for fine adjustment.
  – Free-flow through device during deployment step is critical.
Unmet Clinical Need:
Post-Deployment Modification of Device Placement

• Additional maneuvers post-deployment to improve device apposition to the inner aortic curvature.
  – Eliminate bird-beaking
  – Maximize seal zone

• Current options
  – Post-deployment angioplasty using a compliant balloon
  – Endostaples
  – Aggressive ballooning
  – Use of additional stent grafts to extend seal zone

• Remaining need: Device features to facilitate orthogonal placement of proximal end of device and improve wall apposition.
Acute Dissection
62 yo with severe HTN, rupture
Acute Rupture, unstable patient
Post TEVAR
GORE® TAG® Conformable Thoracic Device with Active Control System

- Same trusted GORE® TAG® Conformable Device
- New advanced deployment system
GORE® TAG® Conformable Thoracic Device with Active Control System

- Combines the current Conformable GORE® TAG® Thoracic device with an enhanced deployment system that offers users new levels of control.
- The Active Control System introduces new mechanisms to improve predictability through accuracy and control throughout the deployment process.
Staged Deployment in Action

- Continuous blood flow ensures hemodynamic stability
- Opportunity to visualize & refine
  - C-arm angle parallax correction
  - Device placement
Clinical Impact: Benefits of Staged Deployment

- Maximize seal length
- Ability to refine device placement
- Adjust parallax
- Fewer device extensions
- Reduced risk of reinterventions and/or adjunctive procedures

Table II. Effect of gantry angle correction on seal zone

<table>
<thead>
<tr>
<th></th>
<th>Overall cohort</th>
<th>Zone 2</th>
<th>Zone 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal gantry angle, °</td>
<td>50 ± 15 (16-86)</td>
<td>43 ± 13 (16-62)</td>
<td>62 ± 12 (29-86)</td>
</tr>
<tr>
<td>Mean centerline length, mm</td>
<td>26 ± 9 (12-49)</td>
<td>24 ± 7 (12-38)</td>
<td>28 ± 12 (12-49)</td>
</tr>
<tr>
<td>Absolute difference at 10°, °</td>
<td>2.4 ± 1.1 (0.7-6.3)</td>
<td>2.3 ± 0.9 (0.7-4.4)</td>
<td>2.6 ± 1.3 (1-6.3)</td>
</tr>
<tr>
<td>Percentage difference at 10°, %</td>
<td>10 ± 6 (2-26)</td>
<td>10 ± 5 (2-25)</td>
<td>11 ± 7 (3-26)</td>
</tr>
<tr>
<td>Absolute difference at 20°, °</td>
<td>6.1 ± 2.3 (2.4-12.9)</td>
<td>6.3 ± 2.3 (2.7-12.9)</td>
<td>5.9 ± 2.3 (2.4-11.8)</td>
</tr>
<tr>
<td>Percentage difference at 20°, %</td>
<td>25 ± 13 (5-58)</td>
<td>26 ± 12 (5-48)</td>
<td>24 ± 16 (6-58)</td>
</tr>
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Clinical Impact:
Benefits of Enhanced Conformability

- Improved wall apposition
- Reduced risk of endoleak
- Reduced need for adjunctive procedures
- Reduced need for explants
LS: 17 year old Female / Car accident

Multiple Injuries: Pelvic and facial fractures / Bladder and Liver injuries / Intracranial injuries

TAG 26 x 10
Conversion for dynamic obstruction of LCCA

27 month Follow-up Amaurosis and Light headedness (TIA)
To and Fro motion in Left CCA on Duplex
Pressure measurement in LCCA shows reversal of flow
Overview of Angulation Control

Angulation control refines orthogonal placement of the proximal end of device to improve wall apposition

Post-deployment modification of device placement

Improve apposition and seal along inner aortic curve
Angulation in Action: enhance wall apposition
Impact of such devices...

Control and conformability are built into the EVAR and TEVAR endovascular systems

What would this achieve?

– Entire use of landing zones
– Ability to make refinements to optimize the placement of the endograft, even in challenging anatomy
– Stabilization of device and delivery system during deployment
– Conforming of the endovascular device to the native aortic and iliac anatomy
Impact of such devices...

What would this achieve?

– Mitigate procedural risks with less manipulation and delivery sequences
– Mitigate risk of complications associated with inadequate inner curve apposition and device rigidity
  • Type I endoleaks & bird beaking
  • Device related RTAD
  • Stent graft-induced new entry tears
The New Frontier is...

Control + Conformability Throughout the Aorta

*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.
The New Frontier in Aortic Stentgrafts: *Active Control*

- **Conformability**
  - Fit the anatomy rather than alter it
- **Durability**
  - Based on proven Excluder and TAG design
- **Deliverability**
  - Adjustable endograft systems for more precise EVAR and TEVAR
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