The New Frontier in Aortic Stent-Grafts: Combining Control and Conformability

Robert Y. Rhee, MD
Chief, Vascular and Endovascular Surgery
Director, Maimonides Aortic Center
Maimonides Medical Center
Brooklyn, New York
60% of EVAR procedures in USA do not meet IFU criteria!
Hostile Infrarenal AAA necks
Predictors of EVAR FAILURE

Reverse taper  Severe neck angulation  Short
Current Treatment Limitations: Challenging Anatomy

- 30–60% of patients may be excluded from EVAR treatment due to challenging proximal aortic necks\(^1,2\)

- Most common reasons for exclusion from EVAR\(^3\)
  1. Short infrarenal neck length
  2. Small iliac access (almost a non issue in 2016)
  3. Proximal neck angle

The First EVAR Frontier...

**Devices**
- Medtronic AneuRx, Guidant Ancure, Gore original EXCLUDER, Cook Zenith

**Design**
- More rigid stent-grafts
- Indicated for 60° aortic necks and 15mm neck length

**Limitations**
- Not intended for challenging anatomy presentations
- EVAR learning curve
- Higher % conversion to open repair in primary procedure
- Lower freedom from late reinterventions and late conversions
- Higher incidence of endoleaks
- Increased risk of rupture

**Control**
- Able to deploy, but still deployment failures
- Clinical outcomes not ideal

**Conformability**
- Increased endoleaks
- Clinical outcomes not ideal
Current Treatment Limitations: Challenging Anatomy

- Need for **adjunctive procedures** to achieve proximal seal\(^1\)
  - Use of aortic cuffs
  - Use of balloon expandable stents (i.e., PALMAZ® Balloon-Expandable Stent)
  - Use of endostaples
  - Snorkels

- Increased risk of:
  - Off-label techniques
  - Proximal Type I endoleaks\(^1,2\)
  - Device migration\(^2\)
  - Proximal neck dilatation\(^1,2\)
  - Aneurysm enlargement
  - Aneurysm-related mortality\(^1\)

---


Second generation...conformable...but
Solution

Need for an EVAR device that can be used within the IFU for majority of those 60%!
TEVAR challenges...neck and angle
The First TEVAR Frontier...

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

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

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

Control
- Technique dependent

Conformability
- Rigid devices lead to suboptimal apposition and seal

Stent graft-induced new entry after endovascular repair for Stanford type B aortic dissection

Stent-Graft Induced New Entry (SINE)
The TEVAR Landscape Today…

**Devices**

- Conformable GORE® TAG® Thoracic Endoprosthesis, Medtronic Valiant with Captivia, Cook Zenith with ProForm, Bolton Relay

**Design**

- Engineered for younger TEVAR patient population

- Expanded Indication including traumatic transection and Type B dissection depending in 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
Compensation for Procedural Control and Conformability

- EVAR Tips and Trick including “off-label techniques”
  - Bending guidewire
  - Endoanchors
  - Additional ballooning and/or stents or stent-grafts
  - Sheath-assisted controlled deployments
  - Endowedge
  - Chimney/Snorkel
  - Modifying device structure

- TEVAR Tips and Trick including “off-label techniques”
  - Bending guidewire
  - Pre-forming or conditioning device on catheter
  - Endoanchors
  - Aggressive ballooning
  - Using additional stents or stent-grafts
  - Chimney/Snorkel/ Fenestration

- Common Theme
  - Compensate for limitations in device conformability and/or delivery system design
Reality

Even in most large volume tertiary care centers.... ~80% of all EVAR and TEVAR treated patients have at least a 10 mm proximal neck
In a Perfect World...

- Control and conformability are built into the EVAR/TEVAR endovascular system (device and deployment)

**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
- 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
# GORE® EXCLUDER® Conformable AAA Endoprosthesis

<table>
<thead>
<tr>
<th>Current Treatment Limitations</th>
<th>Now Addressed by GORE® EXCLUDER® Conformable AAA Endoprosthesis</th>
</tr>
</thead>
</table>
| Short infrarenal neck length                  | Designed to conform and seal in both straightforward and challenging patient anatomy:  
  • Up to 90° proximal aortic neck  
  • ≥ 10 mm seal zone in proximal aortic neck |
| High neck angulation                          | Maximize the seal zone with the only device to offer an ACTIVE CONTROL System, featuring:  
  ▪ Angulation control  
  ▪ Enhanced repositionability  
  ▪ Conformable stent-graft |
| Adjunctive procedures to achieve proximal seal| Innovative delivery system combined with a conformable stent graft to achieve optimal seal. |
| Small iliac access                            | Delivery system at reduced profile (~16 Fr)                  |
| Treatment diameter range                      | Broadest treatment range of patients: 16–32 mm proximal neck diameter |

What is the ACTIVE CONTROL System?

- **Angulation control**
  - Angle adjustment with angulation wire within delivery catheter
  - Available when fully constrained or partially deployed

- **Enhanced repositionability**
  - Secondary sleeve over trunk body
  - GORE® C3® Delivery System functionality

- **Conformable stent-graft**
  - Individual stent rows
  - Temporary attachment fiber
Control + Conformability in EVAR = The NEW Frontier
Safety and effectiveness of the GORE® EXCLUDER® Conformable AAA Endoprosthesis for the treatment of infrarenal AAA
US IDE Study

Design:
Prospective, non-randomized, study with 2 parallel substudies

- 50 sites

- Substudy: Short Neck
  - Proximal neck angle: $\leq 60^\circ$
  - Proximal seal length: $\geq 10$ mm
  - 80 subjects

- Substudy: High Neck Angulation
  - Proximal neck angle: $> 60^\circ$ and $\leq 90^\circ$
  - Proximal seal length: $\geq 10$ mm
  - 110 subjects
USA Sites

- Baptist Cardiac and Vascular Institute
- Washington University School of Medicine – St. Louis
- Leland Stanford Junior University
- Vanderbilt University Medical Center
- University of Pittsburgh Medical Center
- Oschner Clinic Foundation
- University of Virginia
- University of Wisconsin System
- Cleveland Clinic Foundation
- Southern Illinois University
- Baylor Research Institute
- Greenville Hospital System
- Emory / St. Joseph’s
- The Methodist Hospital – Houston
- Mayo Clinic Arizona
- Health Research Association, Inc.
- University of Chicago Hospital
- Essentia Institute of Rural Health
- Florida Hospital
- Novant Medical Group
- Spectrum Health System
- Sanford Clinic – Clinic Research
- Research Foundation SUNY Buffalo
- The Rhode Island Hospital
- Mission Hospital
- The Hitchcock Foundation
- Mayo Clinic – Rochester
- University of Michigan
- Medical University of South Carolina
- University of Alabama at Birmingham
- AHA Hospital Corp.
- Good Samaritan Hospital – Cincinnati
- Staten Island University Hospital
- Maimonides Medical Center
- River City Clinical Research
- Duke University Medical Center
- CAMC Health Education and Research Institute, Inc.
- Aurora Health Care, Metro Inc.
- Ohio Health Research Institute
- Vascular Surgical Associates, PC
- Oklahoma Heart Hospital Research Foundation
- University of Tennessee
- Sentara Medical Group
- North Central Heart Institute, Ltd.
- University of California - Los Angeles
- Minneapolis Heart Institute Foundation – Abbott Northwestern Hospital
- Loyola University – Chicago
- Sarasota Vascular Specialists
- St. Anthony’s Medical Center

Control + Conformability in TEVAR = The New Frontier

- Staged deployment provides opportunities to visualize and refine stent graft placement throughout procedure.
  - Ideal for fine adjustment
  - Free-flow of blood throughout device during deployment
  - Provides opportunity to adjust parallax to confirm placement at intermediate stage
  - Visualize both proximal and distal landing zones

- 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
Control + Conformability in TEVAR
The New Frontier is...
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. Caution: Investigational Device. Limited by United States Law to Investigational Use Only.
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
Thank you!

EXCELLENCE IN

BKLYN
The New Frontier in Aortic Stent-Grafts: Combining Control and Conformability

Robert Y. Rhee, MD
Chief, Vascular and Endovascular Surgery
Director, Maimonides Aortic Center
Maimonides Medical Center
Brooklyn, New York