Benefits of the Gore ® TAG® ACTIVE CONTROL System for achieving optimal outcomes in complex TEVAR

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Disclosures

- Consultant
  - Cook, Endologix, Gore, Medtronic
- Research Grant
  - Gore, Maquet, Medtronic, Siemens
- Advisory Board
  - Endologix, Gore, Maquet, Medtronic, Siemens
- Paid Speaker
  - Endologix, Gore, Maquet, Medtronic, Siemens
- Major Stakeholder
  - none
TEVAR is challenging – especially in the arch.
Influencing Factors of Outcome after TEVAR

Patient related Factors
- age & comorbidities
- underlying pathology
- arch morphology

Device related Factors
- flexibility
- radial force
- conformability

Procedure & operator related factors
- operator & center volume
- intraoperative imaging
- elective or emergency

Ref: Böckler et al., CX 2015 Book Chapter, Biba Medical
Current Limitations Performing TEVAR

- Profile (up to 24Fr.)
- Inner wall apposition in the arch (Zone 0 & 1)
- Control during deployment (hemodynamic forces)
- Preservation of aortic branches
- Longterm durability (migration)
- Clinical AE e.g. stroke, EL, Paraplegia
- etc.
19 Years of Stent Graft Evolution

TAG 1998

Conformable TAG 2009

CTAG with active control 2017
Current CTAG Deployment Sequence

- One step deployment
- Mid to both ends
Refinements for Device Accuracy

- Maintain conformability of Conformable GORE® TAG®
- Precurved olive for self orientation
- New delivery system to 1. enhanced control
  2. vessel wall apposition
Intuitive deployment system allows physicians to focus on the patient, not the deployment system.

- **Optional steps** can be skipped.

- **Lockwire keeps stent graft attached** to catheter throughout the procedure, **enhancing control** of the stent graft.
CTAG with **ACTIVE CONTROL** System

- **Staged deployment** enables adjustment of placement and angulation
- Continuous blood flow ensures **hemodynamic stability**
- Opportunities to visualize & **refine device placement**
  - C-arm parallax correction
  - Device placement
3 Important Steps for Deployment – not changed

1. (double) curved wire in the ascending
2. Push stiff wire = device to the outer curve
3. Eliminate stored energy by pulling the device back into intened landing zone
CTAG Experience Heidelberg
March 1997 - January 2019

589 TEVAR Procedures

399 Patients with CTAG

66 patients with n= 93
CTAG with Active Control
Benefits of the Device

1. Approved for aneurysms, isolated lesions, and type B aortic dissections
2. Radial force adapted to underlying disease
3. Highly conformable and therefore ideal for aortic arch pathologies
4. No significant bare stent lengths, which mitigates risk of retrograde dissections
5. Short precurved olive
6. Unsheathed device allows the use of multiple devices with one access
7. Staged deployment for parallax correction, with no rapid pacing necessary
8. Stent graft attached onto the catheter for total placement control
9. Deployment from trailing to leading ends allows for accurate landing at the celiac trunk level
10. There is time to optimize accuracy, angulation, and apposition
11. A good device for teaching new operators
# 1 Conformable TAG is FDA Approved
to treat various thoracic aortic pathologies

Aneurysm
70-year-old patient

Dissection
50-year-old patient

Trauma
25-year-old patient
# 2 Oversizing window 6-33%

adapting radial force to the underlying pathology

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**GORE TAG® Device**

- 26
- 28
- 31
- 34
- 37
- 40
- 45

**Next Generation Conformable GORE TAG® Device**

- 21
- 26
- 28
- 31
- 34
- 37
- 40
- 45

**Recommended Inflation Volume**

- GORE Tri-Lobe Balloon Catheter
  - BCM1634
  - BCL2645

**Aortic Diameter (mm)**

- 16
- 18
- 20
- 22
- 24
- 26
- 28
- 30
- 32
- 34
- 36
- 38
- 40
- 42
# 3 High Coformbaility
Ideal for aortic arch pathologies
# 4  no bare stents
important for patients with fragile wall conditions
e.g. trauma, dissections and IMH
# 5 short precurved olive
Ideal for Zone 0, ascending and self-orientation

- Arch Involvement 72% for all TEVAR (n=589)
- Arch Involvement 68.2% for CTAG active control
# 6 unsheathed device

ideal if multiple devices are needed (every 3rd pat) and if percutaneous access

- Every 3rd patient needs more than 1 device
# 7 staged deployment
paralaxis correction at intermediate deployment > accuracy
# 7 staged deployment

No rapid pacing > less invasive
more local anesthesia > time saving
# 8 Optional angulation

To actively accommodate to individual arch morphology
## Use of Active Control (n=51)

<table>
<thead>
<tr>
<th>Indications</th>
<th>When / Where</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optional angulation used</td>
<td>intermediate deployment alone</td>
<td>77 % (10)</td>
</tr>
<tr>
<td></td>
<td>intermediate and full deployment</td>
<td>33 % (4)</td>
</tr>
<tr>
<td></td>
<td>after full deployment alone</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Depending on Arch Type</th>
<th>Type I</th>
<th>15 % (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type II</td>
<td>54 % (7)</td>
</tr>
<tr>
<td></td>
<td>Type III</td>
<td>31 % (4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Underlying Pathology</th>
<th>Degenerative disease (TAA &amp; PAU)</th>
<th>54 % (7)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dissection (AoD &amp; IMH)</td>
<td>38 % (5)</td>
</tr>
<tr>
<td></td>
<td>Others</td>
<td>8 % (1)</td>
</tr>
</tbody>
</table>

![Staged Deployment and Angulation Control](image)
# 9 Stentgraft is fixed to the delivery system with lockwires.
Control during deployment > precise placement.
“Pull and Pray“ = times over for this rumor
# 10 New deployment sequence
Precise deployment at distal landing zones close to celiac trunk
# 11 Time for optimization

Ideal for teaching
# 12 NEW: lowered profile (minus 2 French)
To reduce/avoid access problems, percutaneous approach

- First low profile CTAG active Control Implants 21st January 2019
- Percutaneous in local anesthesia
Strategy Change with CTAG Active Control

Liberal overstenting of supraaortic branches with bares stents

Not with active control due to second sleeve
### Technical Results (n=51)

<table>
<thead>
<tr>
<th></th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical Success</strong></td>
<td>96 % (49)</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>Landing Zone 96 % (49)</td>
</tr>
<tr>
<td><strong>Conformability</strong></td>
<td>Bird beaking 96 % (49)</td>
</tr>
</tbody>
</table>

* Different patients Y> 4 in total

### Definitions:

- **Technical Results**: according to the reporting standards ¹
- **Accurate placement was deployment within the intended LZ** ²
- **Non-conformability**: gap of more than 2 mm between the proximal gold band and the inner aortic wall ²


² Böckler D et al. Thoracic Endovascular Aortic Repair of Aortic Arch Pathologies with the Conformable Thoracic Aortic Graft: Early and 2 year Results from a European Multicentre Registry, Eur J Vasc Endovasc Surg (2016) 51, 791-800
## Clinical Results (n=51)

<table>
<thead>
<tr>
<th>SAE</th>
<th>Specification</th>
<th>% (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endoleak</strong></td>
<td>Overall</td>
<td>17% (8)</td>
</tr>
<tr>
<td></td>
<td>Type la</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Type lb</td>
<td>4% (2)</td>
</tr>
<tr>
<td></td>
<td>Type II</td>
<td>12% (6)</td>
</tr>
<tr>
<td></td>
<td>Type III</td>
<td>0</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>Overall</td>
<td>4% (2)</td>
</tr>
<tr>
<td></td>
<td>Ischemia</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Bleeding</td>
<td>1</td>
</tr>
<tr>
<td><strong>Spinal Cord Ischemia</strong></td>
<td>Grading 3 b ¹</td>
<td>4% (2)</td>
</tr>
</tbody>
</table>

Summary

- New CTAG has additional features:
  - Staged deployment
  - New deployment sequence
  - Optional angulation
- Early experience is very convincing
- New CTAG is about to overcome existing limitations
- “Surpass Registry” started to gain more data
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