Treatment of complex thoracic cases
Focus on the new Gore Active Control TAG device

Professor Christoph A. Nienaber
The Royal Brompton and Harefield NHS Trust
Cardiology and Aortic Centre

C.Nienaber@rbht.nhs.uk
Built on the Established Success of the Conformable GORE® TAG® Device

A Legacy of Firsts

1998
First thoracic stent graft to receive CE Mark in Europe

2005
First thoracic stent graft approved in the U.S.

2008
First thoracic stent graft approved in Japan

2009
Next-generation thoracic stent graft receives CE Mark*

2011
Approved by FDA for treatment of aneurysms*

2012
First thoracic stent graft approved in the U.S. for isolated lesions including traumatic transections*

2013
First stent graft approved in the U.S. for acute and chronic Type B Dissections*

2016
First thoracic stent graft to reach 100,000 devices distributed

2017
First thoracic stent graft to feature a new delivery system that offers controlled, staged deployment


Most Studied TEVAR Device

- Ten clinical studies
- Global Registry for Endovascular Aortic Treatment (GREAT)
- Twenty years of clinical experience

Designed for multiple etiologies with proven results
Speaker Resource
Fully Supported Graft Material for Low Spring-Back Force
Partially uncovered stents are designed to allow maximum seal zone on the inner curve with no compromise to aortic blood flow or to seal.
Customized Oversizing Based on Patient Anatomy

3. Customized oversizing based on patient anatomy

RADIAL FORCE

directly related to oversizing percentage

- 31 mm
  GORE® TAG® Conformable
  Thoracic Stent Graft
  29 mm vessel

- 34 mm
  GORE® TAG® Conformable
  Thoracic Stent Graft
  29 mm vessel

- 37 mm
  GORE® TAG® Conformable
  Thoracic Stent Graft
  29 mm vessel

© 2017 W. L. Gore & Associates, Inc.
The GORE® TAG® Conformable Stent Graft with ACTIVE CONTROL System is specifically engineered to treat compromised thoracic aortas.

- No barbs or bare springs
- Low spring-back force
- Optimized graft construct to maximize device durability and conformability
- Provides the greatest options for oversizing of any commercially available device
Device Design Impacts Clinical Outcomes

The Angulation Control mechanism is designed to enhance the innate conformability of the GORE® TAG® Conformable Stent Graft.

- Single sinusoidal stent wire design provides exceptional flexibility and stent nesting, while maintaining an open lumen even through tortuous anatomies
- Improved orthogonal device placement and wall apposition in tight arches
- The device adapts to natural anatomy as opposed to the anatomy adapting to the device
Proven Long-Term Outcomes — Aneurysm

Real-World* Treatment of Aneurysms

97% FREEDOM
from device-related reintervention

 Serious device events:
• 2 Type IA serious endoleaks**
• 4 Type IB serious endoleaks**
• 2 Type II serious endoleaks**
• 1 Migration reported

* The GREAT Registry is a prospective, observational, multicenter registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up.
** Endoleak requiring intervention

© 2017 W. L. Gore & Associates, Inc.

Images courtesy of William Jordan, MD
Proven Long-Term Outcomes — Transection

Real-World* Treatment of Transection

ZERO

through 5-year follow-up

No Type II endoleaks reported at any time.

* The GREAT Registry is a prospective, observational, multicenter registry to actively track Gore commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up.

** Endoleak requiring intervention. No endoleaks persisted past one month or required intervention.

© 2017 W. L. Gore & Associates, Inc.

Pre-intervention

Post-intervention

© 2017 W. L. Gore & Associates, Inc.
Proven Long-Term Outcomes — Type B Dissection

Real-World* Treatment of Dissection

100% SURVIVAL
97% Dissection-related survival

Adverse events:
- .07 Retrograde Type A Dissection
- 1.4 Stroke
- 1.4 Type IA endoleaks*
- 0 Device compression
- 2 Paraparesis / Paralysis
- .07 Conversion

* The GREAT Registry is a prospective, observational, multicenter registry to actively track GORE commercial aortic endovascular device performance and associated patient outcomes in global markets with 10 years of follow-up
** Includes Acute Type B dissections, events occurring within 12 months post-procedure

© 2017 W. L. Gore & Associates, Inc.

Images courtesy of Nimesh Desai, MD
Proven Long-Term Outcomes Across All Etiologies

**Aneurysm**

<table>
<thead>
<tr>
<th>Freedom</th>
<th>from device-related reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>89%</td>
<td>through 5-year follow-up in Aneurysm of the Descending Thoracic Aorta clinical study (TAG 08-03)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Freedom</th>
<th>from device-related reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>97%</td>
<td>through 2-year follow-up in GREAT</td>
</tr>
</tbody>
</table>

**Traumatic Transection**

<table>
<thead>
<tr>
<th>Freedom</th>
<th>from device-related reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>through 5-year follow-up in Traumatic Transection clinical study (TAG 08-02)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Freedom</th>
<th>from device-related reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>98%</td>
<td>through 2-year follow-up in GREAT</td>
</tr>
</tbody>
</table>

**Type B Dissection**

<table>
<thead>
<tr>
<th>Survival</th>
<th>dissection-related survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>90%</td>
<td>through 1-year follow-up in Acute Complicated Type B Dissection clinical study (TAG 08-01)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Survival</th>
<th>acute dissection-related survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>97%</td>
<td>through 1-year follow-up in GREAT</td>
</tr>
</tbody>
</table>
Case 1 (day 1)

- 64 y/r male
- One episode of chest pain at rest, asymptomatic since then
- Exclusion of coronary artery disease and ACS

- Subclinical hypothyroidism
- Partial thyroidectomy – 20yrs ago
- Current smoker, 20/day
- No family history of dissection
- Multi-nodular thyroid goitre
- BP well controlled - ~100-110 sys

Initial CT on November 5, 2017
Case 1 (day 1)

Initial CT recon on November 5, 2017

IMH, no visible communications, ulcers or dissection
Case 1 (day 9)

- IMH progressing to type B aortic dissection with penetrating ulcers resulting in pseudoaneurysm
- Strategy: medical management (anti-impulse)
  - Amlodipine 5mg
  - valsartan 160mg BD
  - hydralazine 25mg TDS
  - metoprolol 75mg BD

2nd CT on November 14th 2017
Case 1 (day 9)

Progression to ulcers and initiation of dissection

2\textsuperscript{nd} CT on November 14\textsuperscript{th} 2017
Case 1 (day 30)

- Localized ulcers progressing to type B aortic dissection with formation of a pseudoaneurysm; IMH at distal arch has resolved.

- Strategy changed: Intervention under continued anti-impulse medication.

Localized distal type B dissection with entry close to CT

3rd CT on December 5th 2017
Case 1 (day 30)

Localized distal type B dissection with entry close to CT

3rd CT recon on December 5th 2017
Case 1 – Progression over 30 days

**Intervention:**
Precise placement
Vicinity to CT
Fragile aorta
Progressive lesion

**Choice:**
Gore Active Control TAG (31x100mm)
Fully Covered Distal End

4. Designed to decrease risk of septum perforation

Fully covered distal end provides a transition between the stent frame and the septum, decreasing the risk of septum perforation in the treatment of Type B dissection.
Case 1 (day 33/Intervention)
Case 1 (Day 5 post Intervention; day 38)

4<sup>rd</sup> CT recon on December 13<sup>th</sup> 2017
Case 1 (Progressive pathology & Intervention)
The case of progressive AAS showed...

- a highly conformable stentgraft with limited radial force is instrumental in a rapidly changing pathology.

- With the lesion close to a vital sidebranch of the aorta precise navigation and placement of SG is essential.
Case 2 (PMH and comorbidities)

PMH:
- 82 y/o male
- Saccular aneurysm in the inferior aspect of distal arch that was found during investigation for vocal cord palsy

Diagnoses:
- Coronary artery disease (PCI to LAD - 2014, PCI without stent to RCA - 2/2017)
- Arterial Hypertension
- Bilateral hip replacement
- Left knee replacement (2)
- COPD (TLCO=26%)
Case 2 (medication and management)

**History:**
Ongoing progression in the size of the saccular aneurysm arising in the sub aortic fossa, which now measures up to 60mm in the sagittal plane from previously 56mm.

The maximal diameter of the non thrombosed portion of the aneurysm as measured on the 3D reconstructed views has also slightly increased in size to 52mm from previously 43mm.

**Medication:**
- aspirin 75mg od
- atorvastatin 20 mg od
- bisoprolol 2.5mg od
- clopidogrel 75mg od
- salbutamol 100microgram SERETIDE 250 EVOHALER inhaler

**Plan:**
Endovascular management of arch aneurysm (EuroScore 2 = 31)
Case 2 (expanding arch aneurysm)

**Issues:**
Expansion with phrenic nerve palsy; unfit for surgery (Euroscore II = 31); tortuosity of the thoracic aorta; not suitable for inner branch technology.
GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

- Combines the proven conformability of the Conformable GORE® TAG® Device with an enhanced deployment system that offers users new levels of control
- Features advanced technology to improve deployment predictability through accuracy and control
Case 2 (expanding arch aneurysm)

Fully percutaneous exclusion of arch aneurysm with coiling of aneurysmal space (Nov. 17th 2017)

*Confida* wire in ascending aorta via LFA; TOE in place.
RCA cath via LRA in aneurysm for delivery of coils.
Positioning of AC Tag (Gore) at a sealing zone of 10mm; 31x100x31mm.
Semi-opening and fine-tuning position of SG; Active control to bend the SG before launch.
Case 2 (expanding arch aneurysm)

Fully percutaneous exclusion of arch aneurysm and coiling of the aneurysmal space

Precise launch of AC Tag device without rapid pacing
With stentgraft in place coils are being delivered to promote thrombosis
Safe delivery of multiple big and small spiral coils via radial catheter
Result after precise launch & coiling with complete exclusion of aneurysm
Conclusion and Insights

With the Gore Active Control TAG...

- Precise positioning and launching is feasible even without RP
- Short landing zones may be acceptable
- Tortuous access can be overcome and is not a limiting factor
- Active bending of stentgraft while in position (by AC mechanism) may be essential in difficult arch pathology to optimize conformability and avoid endoleak.
Unparalleled device conformability

for long-term durability in all anatomies

1. Low spring-back force
2. Wall apposition in highly angulated anatomy
3. Customized oversizing based on patient anatomy
4. Designed to decrease risk of septum perforation
Treatment of complex thoracic cases
Focus on the new Gore Active Control TAG device

Professor Christoph A. Nienaber
The Royal Brompton and Harefield NHS Trust
Cardiology and Aortic Centre

C.Nienaber@rbht.nhs.uk