Going the distance: Conformable Gore TAG device demonstrates durable outcomes over the long term.

D. Böckler
University Hospital Heidelberg, Germany
Disclosures

• Speaker name: Dittmar Böckler
• I have the following potential conflicts of interest to report:
  • Consulting
  • Employment in industry
  • Stockholder of a healthcare company
  • Owner of a healthcare company
  • Research Grant
• I do not have any potential conflict of interest
Launch: October 2009

- 100,000 Implants worldwide
Concept of CTAG

FDA-approved to treat various thoracic aortic pathologies
## Concept: Device Modifications

### Design – Size - Configurations

<table>
<thead>
<tr>
<th>Labeled Diameter (mm)</th>
<th>Intended Aortic Diameter (mm)</th>
<th>Device Length (cm)</th>
<th>Device Profile (Fr)</th>
<th>Oversizing Range (%)</th>
<th>Bare Stent Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td>16 – 19.5</td>
<td>10</td>
<td>18</td>
<td>8 – 31</td>
<td>3</td>
</tr>
<tr>
<td>26</td>
<td>19.5 – 24</td>
<td>10</td>
<td>20</td>
<td>8 – 33</td>
<td>4</td>
</tr>
<tr>
<td>28</td>
<td>22 – 26</td>
<td>10, 15</td>
<td>20</td>
<td>8 – 27</td>
<td>4</td>
</tr>
<tr>
<td>31</td>
<td>24 – 29</td>
<td>10, 15</td>
<td>22</td>
<td>7 – 29</td>
<td>4</td>
</tr>
<tr>
<td>34</td>
<td>27 – 32</td>
<td>10, 15, 20</td>
<td>22</td>
<td>6 – 26</td>
<td>5</td>
</tr>
<tr>
<td>37</td>
<td>29 – 34</td>
<td>10, 15, 20</td>
<td>24</td>
<td>9 – 28</td>
<td>5</td>
</tr>
<tr>
<td>40</td>
<td>31 – 37</td>
<td>10, 15, 20</td>
<td>24</td>
<td>8 – 29</td>
<td>6</td>
</tr>
<tr>
<td>45</td>
<td>34 – 42</td>
<td>10, 15, 20</td>
<td>24</td>
<td>7 – 32</td>
<td>6.5</td>
</tr>
<tr>
<td><strong>26 x 21</strong></td>
<td><strong>19.5 – 24 / 16 – 19.5</strong></td>
<td>10</td>
<td>20</td>
<td>8 – 33</td>
<td><strong>4</strong></td>
</tr>
<tr>
<td><strong>31 x 26</strong></td>
<td><strong>24 – 29 / 19.5 – 24</strong></td>
<td>10</td>
<td>22</td>
<td>7 – 33</td>
<td><strong>4</strong></td>
</tr>
</tbody>
</table>
Concept - Oversizing windows for different pathologies

CTAG - engineered for 6-33% oversizing conditions

IMH with 31 mm > CTAG 34 mm = 10 % Oversizing
TAA with 31 mm > CTAG 37 mm = 20 % Oversizing
4-5 Years – Results with CTAG (mean 2 yrs.)

- Prospective Multicentre Regulatory US- Study ¹
- Prospective Multicentre Europen Registry ²
- GREAT Registry unpublished
- Single Center Experience ²
- Heidelberg Experience (407 devices/163 pat.) unpublished

CLINICAL RESEARCH STUDIES

Results of a prospective multicenter trial of CTAG thoracic endograft

William D. Jordan Jr, MD; Toshiya Mori, MD; Jack Weisert, MD; Joseph Truncale, MD; Richard Cunefare, MD; Mark Hillmann, MD; William McMillan, MD; and Jon S. Pantazis, MD.

Aim: The thoracic aortic aneurysm (TAA) occurs frequently being treated with endografts, the treatment challenges are the thoracic aorta, where it is difficult to design modifications of endografts. The Conformable GORE TAG (CTAG) device (W.L. Gore & Associates, Flagstaff, AZ) was specifically designed to be a more conformable in various anatomy, more continuous to compression, and more accommodating to natural aortic dimensions compared to the original GORE TAG device. This prospective, multicenter study evaluated the safety and effectiveness of the CTAG device in the routine repair of descending TAAA with up to a 2-year follow-up. The study included 100 patients (97% male; mean age 70 yrs; mean BMI 29.5 kg/m²), of whom 36 were treated with CTAG device. The median follow-up period was 24 months. The primary outcome was freedom from aneurysm-related death or target lesion revascularization at 2 years. The study was stopped early because of recruiting difficulties. Key findings: Of the patients, 12 patients died during follow-up. Twenty-nine patients (29%) died within 90 days of the procedure. The aneurysm-related survival at 2 years was 84%, with a 95% confidence interval of 67% to 94%. This study shows that the CTAG device has excellent aneurysm-related survival, freedom from target lesion revascularization, and freedom from aneurysm-related death at 2 years. The study was stopped early because of recruiting difficulties. The results show that the CTAG device is safe and effective in the treatment of descending TAAA. However, further studies are needed to evaluate the long-term outcomes.

Device Conformability and Morphological Assessment After TEVAR for Aortic Type B Dissection: A Single-Centre Experience with a Conformable Thoracic Stent-Graft Design

WHAT THE PAPER ADDS
The conformable CTAG device was specifically designed for aortic arch pathologies showing high conformity with a low rate of major device-related events. Endovascular therapy of aortic arch pathologies is technically challenging and associated with significant device-related risks. The Conformable GORE TAG (CTAG) device (W.L. Gore & Associates, Flagstaff, AZ) was designed to be more conformable in various anatomy, continuous to compression, and more accommodating to the natural aortic dimensions compared to the original GORE TAG device. This prospective, multicenter study evaluated the safety and effectiveness of the CTAG device in the repair of descending thoracic aortic aneurysms (TAA) with up to a 2-year follow-up. The study included 100 patients (97% male; mean age 70 yrs; mean BMI 29.5 kg/m²), of whom 36 were treated with CTAG device. The median follow-up period was 24 months. The primary outcome was freedom from aneurysm-related death or target lesion revascularization at 2 years. The study was stopped early because of recruiting difficulties. Key findings: Of the patients, 12 patients died during follow-up. Twenty-nine patients (29%) died within 90 days of the procedure. The aneurysm-related survival at 2 years was 84%, with a 95% confidence interval of 67% to 94%. This study shows that the CTAG device has excellent aneurysm-related survival, freedom from target lesion revascularization, and freedom from aneurysm-related death at 2 years. The study was stopped early because of recruiting difficulties. The results show that the CTAG device is safe and effective in the treatment of descending TAAA. However, further studies are needed to evaluate the long-term outcomes.

CONFORMABILITY IN AORTIC TYPE B DISSECTION
Clinical experience with the Conformable GORE TAG (CTAG) Thoracic Devices

CTAG 08-03 Aneurysm Study (USA)

Clinical Research Studies

From the Society for Clinical Vascular Surgery

Results of a prospective multicenter trial of CTAG thoracic endograft

William D. Jordan Jr, MD,1 Joshua Rovin, MD,6 Sina Mosainie, MD,7 Joseph Bavaria, MD,8 Richard Cambria, MD,9 Mark Fillinger, MD,4 William McMillan, MD,6 and Jon S. Matsumura, MD,8

Birmingham, Ala; Clearwater, Fla; Indianapolis, Ind; Philadelphia, Pa; Boston, Mass; Lebanon, NH; Robbinsdale, Minn, and Madison, Wisc

Objective: As thoracic aortic aneurysms (TAs) are more frequently being treated with endografts, the anatomic challenges of the thoracic aorta have led to design modifications of endografts. The Conformable Gore TAG (CTAG) device (W. L. Gore & Associates, Flagstaff, Ariz) was specifically designed to be more conformable in tortuous anatomy, more resistant to compression, and more accommodating to various aortic diameters compared with the original GORE TAG device. This prospective, multicenter study evaluated the safety and effectiveness of the CTAG endograft in the repair of descending TAA.

Method: This was a prospective, multicenter regulatory study with a primary end point of freedom from major device event through 1 month after treatment. Two-year outcomes included aneurysm-related morbidity (endoleaks and morphology changes), aneurysm-related mortality, and all-cause mortality.

Results: Fifty-one patients were enrolled between October 2009 and October 2010, with at least one endograft implanted in 50 patients. After the regulatory study successfully completed its primary end point and expanded to a continued access phase, 15 additional patients were enrolled in the continued-access arm of the study from February 2011 until September 2011, for a total treatment group of 66 patients for the early results and 65 patients for the long-term clinical results with imaging evaluation. There was one 30-day death (1.5%), two patients (3%) with spinal cord ischemia, and two central strokes (3%) ≤ 30 days. Five patients (7.6%) died ≤ 1 year; 1 of ascending aortic aneurysm rupture, 2 of cardiac disease, and 2 of respiratory failure. The core laboratory adjudicated 1-month imaging in 60 patients (92.3%), where nine endoleaks (15.0%) were identified (1 type Ia, 4 type II, and 4 indeterminate). Forty-five patients (69.2%) had 2-year imaging with five endoleaks (11.1%, two type II and three indeterminate), and one patient had a distal aortic dilatation that required a secondary intervention. At 2 years, 20 of 38 imaged patients (52.6%) had aneurysm shrinkage ≥ 5 mm, 15 (39.5%) had no change in diameter, and three patients (7.9%) had an increase in aneurysm diameter of ≥ 5 mm. There were no conversions, fractures, compressions, or aneurysm ruptures of the treated segment through 2 years.

Conclusions: This next-generation thoracic endograft has a low rate of major device events through 2 years, with no graft compressions or device failures. The data for this new endograft demonstrate favorable outcomes and confirm low risks for treatment for patients with TAA. Follow-up will be continued for 5 years. (J Vasc Surg 2015;61:589-95.)

8 sites: 66 patients
all aneurysms (DTAA)

Oct 2009- Sept. 2011

30 d results:

Mortality 1.5 %
Any SAE 23 %
Paraplegia 2 %
Stroke 2 %

2 yrs. results

Type Ia Endoleak 3.2 %
TAA rupture 0 %
5 mm decrease 86 %

1 Jordan W et al., JVS 2015:61:589-95
Aneurysm Related Survival: 97% (n=2)

1 rupture of ascending aneurysm
1 arterial access rupture for secondary intervention
both separate from procedure

1 Jordan W et al., JVS 2015:61:589-95
Thoracic Endovascular Aortic Repair of Aortic Arch Pathologies with the Conformable Thoracic Aortic Graft: Early and 2 year Results from a Europe Multicentre Registry

D. Böckler 1, J. Brunkwall 1, P.R. Taylor 1, N. Mangialardi 1, J. Hüsing 1, T. Larzon 1, on behalf of the CTAG registry investigators

1Department of Vascular and Endovascular Surgery, University Hospital Heidelberg, Germany
2Department of Vascular and Endovascular Surgery, University Clinic Cologne, Germany
3Department of Vascular Surgery, Guy's & St Thomas' NHS Foundation Trust and King's College London, UK
4Department of Vascular Surgery, San Filippo Neri Hospital, Rome, Italy
5Coordination Centre for Clinical Trials (KETO) of the Heidelberg Medical Department, Germany
6Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Örebro, Sweden

WHAT THIS PAPER ADDS
The conformable TAG is a next generation device specifically designed for aortic arch pathologies showing high conformability with a low rate of major device related events. Endovascular therapy of aortic arch pathologies is technically demanding and associated with significant stroke risk.

Objective: To assess safety, effectiveness and clinical outcome of the conformable thoracic aortic endograft (CTAG) in the treatment of aortic arch pathologies.

Methods: Between October 2009 and December 2010, 100 consecutive patients (86 men, mean age 65 years) with aortic arch pathologies were treated with the CTAG device in five European centres. Indications were thoracic aortic aneurysm (n = 57), type B dissecting aneurysm (n = 30), intramural haematoma (n = 4), penetrating aortic ulcer (n = 9), and traumatic aortic transection (n = 6). Emergency procedures were performed in 33%. The proximal landing zone (L2) was L2 0 in 7%, L2 1 in 14%, L2 2 in 43%, and L2 3 in 36%. Data were collected prospectively and analysed for technical and clinical success. Conformability and deployment accuracy were analysed on intra-operative angiography and post-operative computed tomography. Mean follow up was 24 ± 19 months (range, 0.1–36 months).

Results: The 30 day, 1 and 2 year survival rates were 90%, 81% and 74% respectively. Two year survival was 80% in the elective and 62% in the emergency groups (p = .02). The major 30 day complication rate was 34%; primary Type la endoleak affected 1%, retrograde dissection in 1%, and the combined total stroke rate at 30 days were 4% and 11%. Age > 75 years was an independent predictor for mortality and complications. The primary technical success rate was 99%; deployment was successful in 100% and accurate in 99%. Conformability to the aortic arch was achieved in 95%.

Conclusion: The CTAG stent graft shows high deployment accuracy, good conformability, and clinical effectiveness in the treatment of aortic arch pathologies. However, thoracic endovascular aortic repair in the arch is associated with a relatively high stroke rate. Further studies with more patients and longer follow up are needed to evaluate the long-term results.

© 2016 European Society for Vascular Surgery. Published by Elsevier Ltd. All rights reserved.
Article history: Received 17 January 2014, Accepted 5 February 2015, Available online 20 April 2016
Keywords: Aorta, Aneurysm, TEVAR, Saphenous graft, Stroke

5 sites: 100 patients
56 TAA, 32 B-Diss., 4 Trauma
30 day Results

Technical success 92%
Mortality 3.3%
Complication rate 34%
Stroke rate 11%
2 yr. Results
Overall survival 74%
- Elective 80%
- Emergency 62%
Technical Results

- Device deployment 100%
- Accuracy deployment 99%
- Conformability 95%
## Predicting Risk Factors for Death and SAE

<table>
<thead>
<tr>
<th>Variables (30 day outcome)</th>
<th>$p$</th>
<th>HR</th>
<th>CI (95%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Death</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aneurysm</td>
<td>.29</td>
<td>0.499</td>
<td>0.135–1.887</td>
</tr>
<tr>
<td>Traumatic transection</td>
<td>.91</td>
<td>0.887</td>
<td>0.045–6.035</td>
</tr>
<tr>
<td>Other pathologies</td>
<td>.48</td>
<td>0.627</td>
<td>0.163–2.341</td>
</tr>
<tr>
<td>Urgency</td>
<td>.15</td>
<td>0.506</td>
<td>0.206–1.325</td>
</tr>
<tr>
<td>Gender</td>
<td>.79</td>
<td>0.892</td>
<td>0.361–2.027</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>.007</td>
<td>1.071</td>
<td>1.022–1.131</td>
</tr>
<tr>
<td><strong>SAE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aneurysm</td>
<td>.46</td>
<td>0.622</td>
<td>0.177–2.260</td>
</tr>
<tr>
<td>Traumatic transection</td>
<td>.84</td>
<td>0.796</td>
<td>0.040–5.394</td>
</tr>
<tr>
<td>Dissections, IMH and PAU</td>
<td>.59</td>
<td>0.705</td>
<td>0.187–2.584</td>
</tr>
<tr>
<td>Urgency</td>
<td>.14</td>
<td>0.503</td>
<td>0.206–1.315</td>
</tr>
<tr>
<td>Male gender</td>
<td>.98</td>
<td>0.991</td>
<td>0.419–2.189</td>
</tr>
<tr>
<td>Age</td>
<td>.01</td>
<td>1.058</td>
<td>1.013–1.113</td>
</tr>
</tbody>
</table>

SAE = serious adverse event; HR = hazard ratio.

Böckler, Brunkwall, Taylor, Mangilardi, Larzon *EJVES*. 2016;51: 791-800
GREAT - Real World Registry

Conformable GORE® TAG® Thoracic Device Designed to Provide Optimal Outcomes in a Wide Range of Pathologies

**Thoracic Pathologies Treated in GREAT**

- Aortic Aneurysm and Rupture: 32%
- Type B Aortic Dissection: 44%
- Penetrating Aortic Ulcer and Intramural Hematoma: 11%
- Traumatic Aortic Transection: 6%
- Other: Coarctation, Fistula: 7%

**Treatment Performance in All Lesions of the DTA**

<table>
<thead>
<tr>
<th></th>
<th>Procedure N = 580</th>
<th>One Month N = 269</th>
<th>One Year N = 131</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type IA</td>
<td>0.2%</td>
<td>0.4%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Migration</td>
<td>0%</td>
<td>0.4%</td>
<td>0%</td>
</tr>
<tr>
<td>Compression</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Two Year Cumulative Results in the DTA**

- 1.7% stroke / TIA
- 1.2% paraplegia, paraparesis, spinal cord ischemia
- 0.5% retrograde Type A dissection
# GREAT - Real World Registry

<table>
<thead>
<tr>
<th>Zone 2</th>
<th>Zone 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 179</td>
<td>N = 246</td>
</tr>
</tbody>
</table>

## Occurrence of Type 1 Endoleaks
- 1.3%  
- 0.9%

## Occurrence of Device Migration
- 0%  
- 0%

## Freedom from Device-Related Reintervention**
- 98.3%  
- 98.8%

---

* For outcome data, GREAT only collects site-reported serious adverse events. Based on one-month follow-up data (0–59 days), all pathologies.

** Device-related reinterventions include any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.
GREAT - Real World Registry
(n=133 through 2 years follow up)

- 2 Type Ia endoleaks
- 4 Type Ib endoleaks
- 2 type II endoleaks
- 1 migration
- 3% device related re-intervention through 2 yr. FU
- 8% death rate though 2 year follow up
Device – Conformability

- Apposition to inner wall 100%
- No association between apposition and arch type
- Less apposition in LZ 2 versus 3 (p=0.03)

# TEVAR – Heidelberg (n=487)

<table>
<thead>
<tr>
<th>Thoracic aortic aneurysm (TAA)</th>
<th>Total</th>
<th>elektiv</th>
<th>Notfall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80</td>
<td>61 (76.3)</td>
<td>19 (23.7)</td>
</tr>
</tbody>
</table>

- 163 patients (male 58%, mean age 66 yrs.)
- 407 CTAG devices (average 2.5 / patients)
- Mean 2.5 devices p.p.
- 83 % Arch involvement (Zone 0-3)
# Indications for TEVAR with CTAG

**Sept. 2010 – Sept. 2016**

<table>
<thead>
<tr>
<th>Indication</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute type B-Dissection</td>
<td>35</td>
</tr>
<tr>
<td>PAU</td>
<td>27</td>
</tr>
<tr>
<td>TAA*</td>
<td>19</td>
</tr>
<tr>
<td>TAAA</td>
<td>18</td>
</tr>
<tr>
<td>IMH</td>
<td>17</td>
</tr>
<tr>
<td>Traumatic rupture</td>
<td>10</td>
</tr>
<tr>
<td>CEAD**</td>
<td>10</td>
</tr>
<tr>
<td>rTAA</td>
<td>7</td>
</tr>
<tr>
<td>ABF</td>
<td>5</td>
</tr>
<tr>
<td>Anastomotic Aneurysm</td>
<td>5</td>
</tr>
<tr>
<td>Acute Type A Dissection</td>
<td>3</td>
</tr>
<tr>
<td>Posttraumatic TAA</td>
<td>2</td>
</tr>
<tr>
<td>Patchaneurysm</td>
<td>2</td>
</tr>
<tr>
<td>Patchrupture</td>
<td>1</td>
</tr>
<tr>
<td>Corpus alienum (Palakossporn)</td>
<td>1</td>
</tr>
<tr>
<td>Symptomatic Aortic Thrombus</td>
<td>1</td>
</tr>
</tbody>
</table>
Heidelberg Single Center 6 yr Experience

30 day Results:
Technical success 97.5%
Mortality 3.3%

Follow up Results:
Reintervention rate 21%
Overall mortality (43/166) 26%
Aortic related mortality (8/166) 5%
Advantages - Personal Opinion

- Oversizing windows for each pathology
- Unsheated device
  - very flexible for arch and tortuous anatomy
  - easy access for multiple devices
- Highly conformable in the arch
- Fast or slow deployment

Example of Complex Arch Morphology
Future Refinements of the CTAG

- Branched technology
- Steering delivery system to enhance control and vessel wall Partial deployment
- Partial deployment

All products are under development and not available or approved for sale in any market.
Conclusions

- Concept is proven in the long run
- Modifications of CTAG increased conformability
- CTAG shows very favorable results at mean 2 years
- No device failures, low major device events
- CTAG is our preferred device for aortic arch pathologies
- Continued FU over the next 5 yrs. will be important
Going the distance:
Conformable Gore TAG device demonstrates durable outcomes over the long

D. Böckler
University Hospital Heidelberg, Germany