

GORE PERIPHERAL VISION

PERFORMANCE through collaboration

COMMERCIAL LAUNCH OF CONFORMABLE GORE TAG® THORACIC ENDOPROSTHESIS IN EUROPE

Next Generation Device has Widest Treatment Range for Thoracic Aortas

W. L. Gore & Associates (Gore) announced the commercial release of the Next Generation Conformable GORE TAG® Device at the LINC Congress in Leipzig, Germany. The Conformable GORE TAG® Device is available in an expanded portfolio of sizes and is engineered to treat multiple etiologies including thoracic aortic aneurysms, traumatic aortic transections and acute thoracic aortic dissections.

Since receiving CE Mark in the summer of 2009, a limited number of hospitals have been implanting the Next Generation Conformable GORE TAG® Device. Professor Böckler at the University of Heidelberg in Heidelberg, Germany and Dr. Larzon at the Örebro University Hospital in Örebro, Sweden were the first European physicians to implant the device. Another early implanter, Professor Brunkwall, vascular surgeon at the University Hospital in Cologne said “I have had the opportunity to treat numerous patients with the Conformable GORE TAG® Device and am very pleased with its performance.”

The Next Generation Conformable GORE TAG® Device is designed to treat the widest range of thoracic aortic diameters ranging from 16 – 42 mm. The Conformable GORE TAG® Device will also be available in tapered configurations, intended to broaden its treatment capabilities.

The Conformable GORE TAG® Device offers clinicians a modified device delivery catheter. Modifications include a more radiopaque delivery catheter and a soft tipped olive.



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RUPTURED THORACIC ANEURYSM REPAIR WITH GORE TAG® THORACIC DEVICE (TAG 04-01)

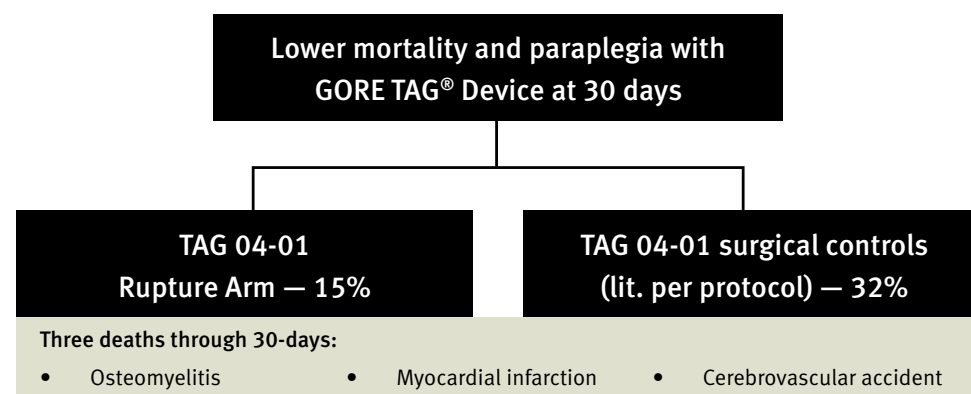
Clinical Data Now Available on Treatment of Ruptured Thoracic Aortic Aneurysm

Highlighting its commitment to clinical research and data, Gore recently announced that rupture data from the TAG 04-01 Study show that patients treated with a GORE TAG® Device for a ruptured aortic aneurysm resulted in lower mortality / better survival compared to patients treated for a ruptured aortic aneurysm with open surgical repair. These data support the use of the GORE TAG® Device as a treatment option for patients with ruptured aneurysms of the descending thoracic aorta (DTA).

Gore has supplemented the GORE TAG® Device *Instructions for Use* (IFU) in the US with clinical data from the ruptured thoracic aortic aneurysm arm of the GORE TAG® Device Complex Pathology Study (TAG 04-01). The TAG 04-01 Study was initiated in August 2005 to evaluate patients with ruptured thoracic aortic aneurysm of the DTA, acute complicated Type B dissection and traumatic aortic transection. Enrollment was completed in February 2007.

Patients treated with the GORE TAG® Device for a ruptured aneurysm of the DTA presented emergently, were more likely to be symptomatic, and were older compared to patients treated with a GORE TAG® Device for an intact aneurysm in the GORE TAG® Device Pivotal (TAG 99-01) and Confirmatory (TAG 03-03) studies. Additionally, ruptured aneurysm patients treated in the TAG 04-01 study did experience higher mortality, longer convalescence, and higher incidence of endoleak compared to intact aneurysm patients in the TAG 99-01 and TAG 03-03 studies. These results indicate that additional considerations may be warranted when treating ruptured aneurysm patients compared to intact aneurysm patients. The GORE TAG® Device IFU in the US has been updated to include one year outcomes from the rupture arm of the TAG 04-01 Study.

Patients in TAG 04-01 Rupture Arm had lower 30-day mortality and paraplegia than surgical controls (literature):



	TAG 99-01	TAG 03-03	TAG 04-01 Aneurysm Rupture
Age*	74 (31, 87)	72 (45, 86)	80 (51, 89)

*Median (Min., Max.)

HIGHLIGHTS FROM GORE TAG® DEVICE RUPTURE DATA

- Data support the use of the GORE TAG® Device as a treatment option for patients with ruptured aneurysms of the DTA.
- Patients treated with a ruptured aneurysm in TAG 04-01 Complex Pathology Study were more likely to be symptomatic and were older patients compared to previous studies.
- Ruptured aneurysm patients in the TAG 04-01 Study experienced higher mortality, longer convalescence, and higher incidence of endoleak compared to previous studies. Ruptured aneurysm patients may warrant additional radiological follow-up.

THE ULTIMATESAAAVE.COM

Gore is working to raise patient awareness of AAA and increase the screenings of at-risk individuals — and **we need your help.**

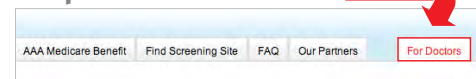
If you are a specialist who treats AAA patients, you are uniquely positioned to participate in developing the premier online resource for those who are concerned about AAA for themselves or their friends and family members. This new site, ultimatesaaave.com, will provide patient-centered information that includes:

- What is AAA?
- How someone is screened for AAA
- The Medicare screening benefit
- Common treatment options
- A national directory of screening physicians

Step 1: visit ultimatesaaave.com



Step 2: click **For Doctors** tab



Step 3: go to **Add Me to the AAA Screening Directory**



click here

Step 4: fill out AAA Screening Directory form

We will verify your information and include you in the screening directory.



GORE PROPATEN® VASCULAR GRAFT WITH INTEGRATED RINGS NOW AVAILABLE

In November 2009, Gore expanded the line of GORE PROPATEN® Vascular Grafts to include configurations having a unique, all ePTFE radial support. These new configurations will feature the same proprietary end-point covalently bonded Heparin Bioactive Surface in addition to integrated ePTFE radial support that resists kinking and compression. The GORE PROPATEN® Vascular Graft with Integrated Rings retains much of the longitudinal extensibility, feel and handling characteristics inherent to GORE-TEX® Stretch Vascular Grafts and can provide up to a 24% reduction in profile compared to an externally ringed or spiral graft.

Please contact your Gore Vascular Sales Associate for further details.

CLINICAL TRIALS

INITIATION OF US CLINICAL TRIALS FOR CONFORMABLE GORE TAG® DEVICE

Investigating Three Indications: Aneurysm, Traumatic Transection and Acute Type B Dissection with Next Generation Device

The launch of three separate clinical trials for three indications for the Next Generation Conformable GORE TAG® Device continues to highlight our commitment to physicians and pioneering heritage in aortic clinical research. The three separate trials include: TAG 08-01 Conformable GORE TAG® Device in acute Type B dissections, TAG 08-02 Conformable GORE TAG® Device in traumatic aortic transections and TAG 08-03 Conformable GORE TAG® Device in descending thoracic aortic aneurysms.

The commercially available GORE TAG® Device is indicated in the US for the treatment of descending thoracic aneurysms. The two new separate Conformable GORE TAG® Device trials for acute Type B dissection and traumatic transection are firsts of their kind.

Traumatic thoracic aortic transection is most frequently caused by motor vehicle accidents and often results in death, comprising up to 15 percent of all motor vehicle related deaths. Many transection victims die at the scene of the accident, but patients who survive to make it to the ER usually have smaller tears or partial-thickness tears of the aortic wall with pseudoaneurysm formation. These patients often have multiple, complex injuries that increase the risk of standard surgical repair of the aorta, but still require immediate treatment. “We hope to gain insight and knowledge from this trial that will not only illustrate the capabilities of the GORE TAG® Device, but will also help show that thoracic endografts can offer patients with traumatic aortic transection a less invasive alternative,” stated Mark Farber, MD, the national PI for the Gore TAG 08-02 Trial.

“The US clinical trials for the Conformable GORE TAG® Device exemplify Gore’s commitment to endovascular treatment of thoracic disease. With a next generation conformable thoracic device, we plan to play a major part in partnering with physicians to seek minimally invasive treatment options for patients well into the future.” said David Abeyta, Aortic Business Unit Leader at Gore. “These three trials, whose objectives are to evaluate a new and potentially more effective device designed to meet the unique anatomic and physiologic challenges associated with TAA patients, are being conducted at more than 120 sites across the US.”

With the first clinical implant occurring in 1997, the GORE TAG® Device has been studied in seven FDA approved clinical studies, one European clinical trial, and one European registry.

US CLINICAL TRIAL PRINCIPAL INVESTIGATORS:

Thoracic Aortic Aneurysm Study
William Jordan, MD, University of Alabama,
Birmingham

Traumatic Aortic Transection Study
Mark Farber, MD, University of North Carolina,
Chapel Hill

Acute Complicated Type B Dissection Study
Richard Cambria, MD, Massachusetts General
Hospital

OUTCOMES FOLLOWING ENDOVASCULAR VS OPEN REPAIR OF ABDOMINAL AORTIC ANEURYSM

A Randomized Trial (JAMA. 2009;302(14):1535-1542)

The Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study is a multi-center randomized clinical trial of 881 patients from 42 Veterans Affairs Medical Centers across the US. Patients underwent elective open (n = 437) or endovascular (n = 444) repair of abdominal aortic aneurysm (AAA) and this interim report analyzed patients at a mean follow-up of 1.8 years.

Patients who underwent endovascular repair of AAA had lower perioperative mortality, but there was no significant difference in mortality at two years. The GORE EXCLUDER® AAA Endoprosthesis showed a hazard ratio (HR) of 0.6, which favors use of the device compared to open surgery. In contrast, a HR of 1.7 for the Medtronic ANEURX Device actually favors open surgical repair of AAA. This study will continue follow-up through five to nine years, and will provide great insight into the benefits of endovascular repair of AAA.

CASE STUDY

COMMON FEMORAL ARTERY TO BELOW KNEE POPLITEAL ARTERY BYPASS WITH A RINGED *GORE PROPATEN*[®] VASCULAR GRAFT IN A PATIENT WITH FACTOR V LEIDEN

*Syed M. Hussain, MD, Jennifer L. Ash, MD
Division of Vascular and Endovascular Surgery, HeartCare Midwest
Department of Surgery,
University of Illinois College of Medicine – Peoria, Illinois*

Clinical Challenge

The patient was a 73-year-old female with a history of coronary disease, hypertension, diabetes mellitus, ex-smoker, and Factor V Leiden on chronic COUMADIN[®] Tablet Therapy who presented with claudication upon walking 100 feet. The patient had tried medical therapy for six months which failed to relieve her symptoms. Doppler study revealed a resting right ABI of 0.46 and a left ABI of 0.89.

Angiography of the right lower extremity revealed an occluded superficial femoral artery and above knee popliteal artery with reconstitution behind the knee and below knee popliteal artery. Runoff was via two vessels: the peroneal and posterior tibial artery.

Percutaneous therapy was not an option due to a long TASC D occlusion

Procedure

A right common femoral to below knee popliteal artery bypass was performed with an 8 mm ringed *GORE PROPATEN*[®] Vascular Graft in the standard fashion.

Post procedure the patient had a palpable posterior tibial pulse and was symptom free.

COUMADIN[®] Tablet Therapy was restarted with LOVENOX[®] Therapy on post-procedure day two and patient was discharged home on post-procedure day three.

Results

Three month follow-up revealed a widely patent graft on duplex exam with complete healing of the incisions and no peripheral edema.

One year follow-up revealed a widely patent graft on duplex ultrasonography and patient continues to be symptom free.

Physician Comments

The *GORE PROPATEN*[®] Vascular Graft is a viable option in patients with a history of hypercoagulable disorders. Furthermore, it serves as a good alternative to vein in patients who need below knee bypass surgery and vein is not available. Recovery time is quicker than for vein bypass and outcomes are equivalent thus far. Obviously, a higher number of bypasses to below knee arteries need to be done to assess for long-term patency and limb salvage.



ROUNDTABLE DISCUSSION

WHAT ARE THE ADVANTAGES OF THE GORE FLOW REVERSAL SYSTEM?

Carotid Embolic Protection Roundtable Discussion

August 17, 2009, New York, New York

DANIEL CLAIR, MD: One of the major advantages is in complex lesions, which would include ulcerative lesions. In a patient who has thrombus, I think it's hard to justify not using this system when treating them. Severe stenosis, such that you think placing a filter through the lesion is going to be difficult, mandates the use of this type of protection. And,

obviously, I think tortuosity in the vessel makes this an outstanding device.

Another advantage is that you get to choose the wire that's going to be best to cross the lesion, and you have protection beforehand. In fact, we have had situations, some of the patients enrolled in the EMPiRE trial, where I had trouble getting a .014-inch wire to cross the lesion and needed to actually put a micro catheter in with the wire in order to get across the lesion. I would never have tried that with a filter device. I believe it's just completely impossible to do that with a filter device.

This system provides a level of protection in those complex lesions that you can't match with anything else.

L. NELSON HOPKINS, MD: You can break it down into categories; the anatomical issues for which a proximal device is clearly a better choice with difficult perilesional anatomy, and then the symptomatic patients for whom we know there's a higher risk of a lesion having a large plaque burden that may be fractured, therefore posing a greater risk of embolization and a greater risk for overcoming a filter. Those are some of the patients for whom we think there may be an advantage to embolic protection proximally with the GORE Device.

As Dr. Clair mentioned, any complex anatomy in which you don't feel comfortable or you know there's a greater risk using a filter is the kind of patient where the GORE Device is a much better choice.

The downside, of course, is just that there is a real or perceived difference in terms of the ability to get a larger device that is used for proximal protection around a more difficult arch. I say "real or perceived" because I think that it's a lot easier to use than most people think it is. It is a 9 Fr device, so it's bigger, and it can be more difficult to navigate. It's a little more bulky at the tip, but I'm impressed with how flexible the distal end is.

A difficult arch comes with its own set of challenges, and there are a lot of people who, in my own shop, were using the CONCENTRIC® balloon catheter for any situation in which we wanted to occlude the common carotid until Gore came along. Now that we have the GORE Device, it's taken a lot of encouragement to get the guys away from the CONCENTRIC® device even though it is not nearly as good a device, and it doesn't have anywhere near the stability that the GORE Device has. Most of the difference is perception rather than reality. It's a pretty easy device to use, but we have to first get past people's natural concern about the fact that it's a bigger device and it has more paraphernalia on the end of it, and, therefore, it may be more of a challenge to get it around a difficult arch.

WILLIAM GRAY, MD: I don't think it's more difficult to place the sheath itself. I like the sheath design. I think the sheath is among the best I have used. Although a bit larger in terms of French size, it has a nicely graduated taper of the stiffness, such that the durometer of plastic is very nicely segmented and matches its placement in the aorta and common carotid anatomy. I find that it goes places I didn't think it would go, so I've been favorably impressed with that.

The only real challenge to the device is getting the external carotid balloon into place, when occasionally there are external lesions or a very proximal superior thyroidal artery, as well as hooking up everything in the back end to make sure it's all flushed and ready to go.

Once it's established, it's a very quick procedure, and it doesn't require the release and recapture of filters. Also, a wire specific to the patient's anatomy can be used. It's very helpful in those aspects.

For the full roundtable discussion, please see the *Endovascular Today* November Supplement, or visit evtoday.com.

2010 EVENTS

DATE	NAME	LOCATION
GORE EVENTS		
April 19 – 20	Advanced Thoracic Symposium	Chicago, Illinois
April 22 – 23	Advanced AAA Symposium	San Francisco, California
April 22 – 23	Endo and Surgical Technology Forum	Flagstaff, Arizona
April 29 – 30	Acute Symptomatic AAA Workshop	Houston, Texas
May 13 – 14	Aortic Technology Forum	Flagstaff, Arizona
June 24 – 25	Endo and Surgical Technology Forum	Flagstaff, Arizona
July 15 – 16	Aortic Technology Forum	Flagstaff, Arizona
August 26 – 27	Endo and Surgical Technology Forum	Flagstaff, Arizona
October 28 – 29	Endo and Surgical Technology Forum	Flagstaff, Arizona
November 4 – 5	Aortic Technology Forum	Flagstaff, Arizona
SUPPORTED CONGRESSES		
April 7 – 10	Society for Clinical Vascular Surgery	Scottsdale, Arizona
April 10 – 13	Charing Cross	London, United Kingdom
June 10 – 13	Society of Vascular Surgeons	Boston, Massachusetts
September 21 – 25	Transcatheter Cardiovascular Therapeutics	Washington, District of Columbia

LITERATURE RECOMMENDATIONS

AAA

Brown LC, Greenhalgh RM, Thompson SG, Powell JT; EVAR Trial Participants. Does EVAR alter the rate of cardiovascular events in patients with abdominal aortic aneurysm considered unfit for open repair? Results from the Randomised EVAR Trial 2. *European Journal of Vascular & Endovascular Surgery*. In press.

Lederle FA, Freischlag JA, Kyriakides TC, et al; Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study Group. Outcomes following endovascular vs open repair of abdominal aortic aneurysm. A randomized trial. *Journal of the American Medical Association* 2009;302(14):1535-1542.

Ohki T. EVAR takes root in Japan. *Endovascular Today* 2010;49(1):46-49

Subedi SK, Lee AM, Landis GS. Suprarenal fixation barbs can induce renal artery occlusion in endovascular aortic aneurysm repair. *Annals of Vascular Surgery* 2010; 24(1): 113.e7- 113.e10.

Torsello G, Troisi N, Tessarek J, et al. Endovascular aortic aneurysm repair with the Endurant Stent-graft: early and 1-year results from a European Multicenter Experience. *Journal of Vascular & Interventional Radiology* 2010; 21(1):73-80.

Young KC, Awad NA, Johansson M, Gillespie D, Singh MJ, Illig KA. Cost-effectiveness of abdominal aortic aneurysm repair based on aneurysm size. *Journal of Vascular Surgery* 2010;51(1):27-32.

PERIPHERAL VASCULAR TREATMENT

Farraj N, Srivastava A, Pershad A. One-year outcomes for recanalization of long superficial femoral artery chronic total occlusions with the Viabahn stent graft. *Journal of Invasive Cardiology* 2009;21(6):278-281.

McQuade K, Gable DR, Pearl GJ, Theune B. Four-year randomized prospective comparison of percutaneous expanded polytetrafluoroethylene/nitinol self-expanding stent graft vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease. Abstract presented at the Southern Association for Vascular Surgery (SAVS) 34th Annual Meeting; January 20-23, 2010; Paradise Island, Bahamas. *Journal of Vascular Surgery* 2009;50(6):1531.

Have a story idea or case study to share?

Send your suggestions to peripheralvision@wlgore.com

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INDICATIONS FOR USE IN THE US: The GORE TAG® Thoracic Endoprosthesis is intended for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy, including: Adequate iliac / femoral access; Aortic inner diameter in the range of 23-37 mm; ≥ 2 cm non-aneurysmal aorta proximal and distal to the aneurysm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials. Patients with a systemic infection who may be at risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. **Rx Only**

INDICATIONS FOR USE: Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac / femoral access; Infrarenal aortic neck treatment diameter range of 19 – 29 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; Iliac artery treatment diameter range of 8 – 18.5 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** There are no known contraindications for these devices. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. **Rx Only**

INDICATIONS FOR USE: The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for the patients diagnosed with carotid artery stenosis and who have appropriate anatomy as described in the *Instructions for Use*. Refer to the *Instructions for Use* at goremedical.com for contraindications, warnings and precautions. **Rx Only**

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