



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon scanning technology Prioritising summary**

## **GORE TAG®**

### **August 2008**



**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**

© Commonwealth of Australia 2008

ISBN

Publications Approval Number:

This work is copyright. You may download, display, print and reproduce this material in unaltered form only (retaining this notice) for your personal, non-commercial use or use within your organisation. Apart from any use as permitted under the *Copyright Act 1968*, all other rights are reserved. Requests and inquiries concerning reproduction and rights should be addressed to Commonwealth Copyright Administration, Attorney General's Department, Robert Garran Offices, National Circuit, Canberra ACT 2600 or posted at <http://www.ag.gov.au/cca>

Electronic copies can be obtained from <http://www.horizonscanning.gov.au>

Enquiries about the content of the report should be directed to:

HealthPACT Secretariat  
Department of Health and Ageing  
MDP 106  
GPO Box 9848  
Canberra ACT 2606  
AUSTRALIA

**DISCLAIMER:** This report is based on information available at the time of research cannot be expected to cover any developments arising from subsequent improvements health technologies. This report is based on a limited literature search and is not a definitive statement on the safety, effectiveness or cost-effectiveness of the health technology covered.

The Commonwealth does not guarantee the accuracy, currency or completeness of the information in this report. This report is not intended to be used as medical advice or intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used therapeutic purposes or as a substitute for a health professional's advice. The Commonwealth does not accept any liability for any injury, loss or damage incurred by use of or reliance the information.

The production of this horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from departments in all states and territories, the Australia and New Zealand governments, and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This horizon scanning prioritising summary was prepared by Lana Sturm from the Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S).

# PRIORITISING SUMMARY

---

**REGISTER ID** S000080

**NAME OF TECHNOLOGY** GORE TAG® (W.L. GORE & ASSOCIATES, INC., FLAGSTAFF, AZ, USA)

**PURPOSE AND TARGET GROUP** ENDOVASCULAR TREATMENT FOR THORACIC AORTIC ANEURYSMS

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United States	✓	✓	
Japan	✓	✓	

## IMPACT SUMMARY

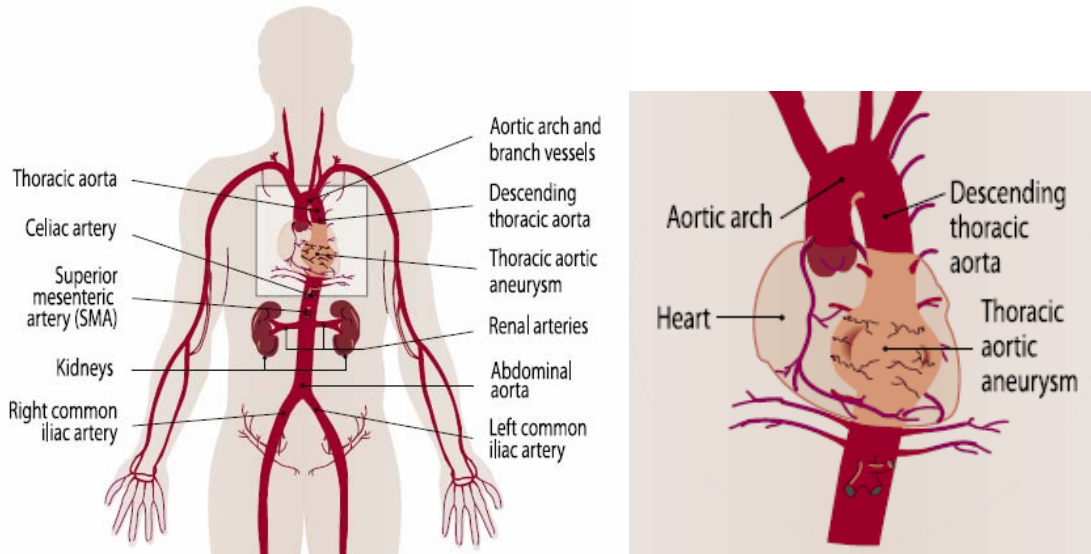
The GORE TAG® Thoracic Endoprosthesis (W.L. Gore & Associates, Inc., Flagstaff, AZ, USA) provides a minimally invasive option for managing patients with pathologies of the descending thoracic aorta as opposed to open surgical repair. The function of the endoprosthesis is to internally reline the thoracic aorta and isolate the defective segment from blood circulation.

## BACKGROUND

An aortic aneurysm is defined as a permanent localised dilation of the aortic wall resulting in a 50% or more increase in its normal diameter (Coselli 2003) (Figure 1). Aneurysms of the descending thoracic aorta tend to originate just below the origin of the left subclavian

artery and may be sac-like or spindle-shaped (Isselbacher 2008). The predominant causes of aneurysms of the descending thoracic aorta are atherosclerosis and degenerative changes in the aortic wall (Arko & Zarins 2003; Isselbacher 2008). If left untreated, aortic aneurysms become larger and can eventually rupture, resulting in massive haemorrhage and death (Arko & Zarins 2003). The presence of descending aortic aneurysms is often asymptomatic, and they are typically detected incidentally on routine chest X-rays or other diagnostic imaging studies (Isselbacher 2008). Occasionally they can be symptomatic if mechanical compression of adjacent structures is present or a blood clot (embolus) forms from the aneurysm and blocks other blood vessels (Arko & Zarins 2003).

**Figure 1: Anatomy of thoracic aortic aneurysms**



Source: GORE TAG website. Patient information <http://www.goremedical.com/en/file/AJ0083.pdf>

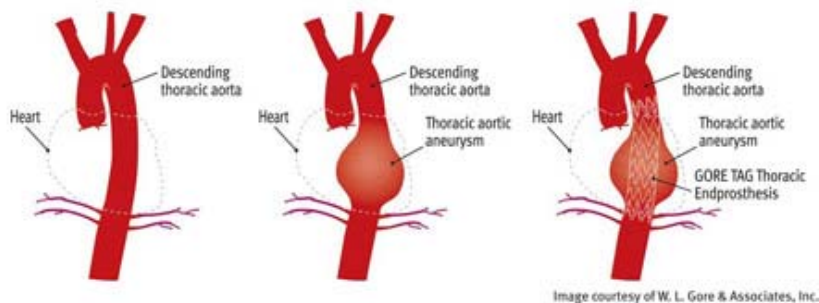
Traditional surgical repair involves general anaesthesia and left heart bypass. An incision is made through the length of the sternum to reveal the dilated portion of the aorta. Clamps are applied across the aorta to prevent blood flow into the aneurysm. The aneurysm is opened and the diseased section is removed and replaced with an artificial substitute. The decision to operate on a patient with an aortic aneurysm is based on the risk of aneurysm rupture versus the risk of aneurysm repair, within the context of the patient's overall life expectancy (Fillinger 2007). Open repair of descending thoracic aneurysms is often only offered to people who are good surgical candidates (Makaroun et al 2005). Surgical repair in large centres is associated with mortality rates of between 1.5% and 26% (Coselli et al 1996; Kouchoukos & Dougenis 1997; Lawrie et al 1994). Major complications of open repair include stroke and haemorrhage, as well as postoperative paraplegia secondary to interruption of the blood supply to the spinal cord (Isselbacher 2008).

Endovascular treatments for thoracic aneurysms, such as the GORE TAG device, offer an attractive alternative to open surgical repair for patients who are poor surgical candidates (Cho et al 2006b). The GORE TAG device originally comprised a symmetrical expanded polytetrafluoroethylene (ePTFE) tube reinforced with two longitudinal self-expanding nitinol spines, which provided support during deployment (Cho et al 2006b). However, longitudinal fractures were detected in the stent body of the device, which led to the

voluntary withdrawal of the device from distribution in May 2001. The device was subsequently altered; the longitudinal nitinol spines were removed and the device was reconfigured with three ePTFE layers (Cho et al 2006b; Wheatley et al 2006). The additional ePTFE layer, which is located between the two original layers, provides longitudinal stiffness and has low permeability (Cho et al 2006a). The GORE TAG device is available in diameters ranging from 26 to 40 mm that require from 20 to 24 French gauge introducer sheaths, depending on the size of the device (Cho et al 2006b). The modified device underwent a confirmatory trial in late 2003 to compare the incidence of major adverse events between the new and old device up to 30 days post-treatment (Gore & Associates 2007).

The GORE TAG device is introduced into the vasculature via the iliac or femoral artery under general anaesthesia. The device is constrained by a sleeve, which is in turn connected via a line to a deployment knob located at the control end of the delivery catheter (Cho et al 2006b). Turning and pulling the deployment knob detaches the line from the sleeve and deploys the device (Cho et al 2006a). Deployment is rapid and adjustment of the device during deployment is limited. A specially designed tri-lobed balloon, which allows continuous blood flow during inflation, is used to secure the device in position (Cho et al 2006a).

**Figure 2: Repair of descending thoracic aortic aneurysm using the GORE TAG endoprosthesis**



Source: Palomar Pomerado Health website 2006 <http://www.pph.org/default.aspx?nd=1425>

### **CLINICAL NEED AND BURDEN OF DISEASE**

Thoracic aortic aneurysms are estimated to affect 10 out of every 100,000 elderly patients, with 30% to 40% of these being descending thoracic aneurysms (Bavaria et al 2007). The patient population is typically male with an average age of 65 or over (Brooks et al 2000). In Australia there were 601 reported incidences of ruptured thoracic aortic aneurysm in 2004-5 (Australian Institute of Health and Welfare [AIHW] 2007). A similar number of incidences have been reported over the last 6 years. There were 426 reported incidences of thoracic aortic aneurysm without mention of rupture in 2004-5 (AIHW 2007). This represents more than a 150% increase from 1998-9 (269 cases) (AIHW 2007).

Thoracic aortic aneurysms typically occur in people who are heavy smokers and have hypertension, coronary heart disease and obstructive pulmonary disease (Rousseau et al 2005). Untreated patients with large thoracic aortic aneurysms have a 2-year mortality rate of >70%, and most deaths occur as a result of aneurysm rupture (Crawford & DeNatale 1986). Davies et al (2002) found that the mean yearly rate of rupture or dissection is 2%

for small aneurysms, 3% for aneurysms 5.0–5.9 cm, and 6.9% for aneurysms 6.0 cm or greater in size. The odds ratio for rupture is more than 25 times higher in patients with aneurysms of 6.0 cm or greater than in patients with aneurysms between 4.0 and 4.9 cm (Davies et al 2002).

### **DIFFUSION**

The GORE TAG Thoracic Endoprosthesis has been used in clinical trials in the United States. According to the manufacturer, (Gore and Associates, 2007), approximately 17,000 GORE TAG devices have been distributed up to January 2007. Two versions of this device exist (the original and the modified version), and it is estimated that 85% of the distributed devices are the newer modified version.

The US Food and Drug Administration approved commercial use of the modified GORE TAG device in March 2005 (US FDA, 2005). It is not currently approved for use in Australia.

### **COMPARATORS**

- Open surgical repair
- Other endovascular repair devices including:
  - TALENT™ Thoracic Stent Graft System, Medtronic Vascular, Santa Rosa, CA
  - Zenith TX2 TEVAR® Graft, Cook Medical, Bloomington, IN

### **SAFETY AND EFFICACY ISSUES**

Two studies on the use of GORE TAG for thoracic aortic pathology were identified by literature searches for inclusion in this summary: one non-randomised comparative study, the results of which were reported in two different articles (Cho et al 2006a; Makaroun et al 2008) and one case series study (Wheatley et al 2006). The primary focus of these articles was the original GORE TAG device, but they also included data on the newer modified device. Multiple publications were found on the same patient cohort, so only the most recent and most relevant articles were selected.

Makaroun et al (2008) described the results of a phase II multicentre, prospective trial comparing GORE TAG to surgical controls after 5 years of follow up. Patients with aortic dissections, ruptures, trauma or aneurysms caused by fungal infections were excluded from the study. Patients with descending thoracic aortic aneurysm of at least twice the diameter of the normal thoracic aorta and with 2 cm of nonaneurysmal neck of sealing distal to the left carotid artery and proximal to the celiac artery were eligible for endovascular treatment. One hundred and forty patients were enrolled in the GORE TAG arm. The surgical control arm (n = 94) comprised concurrent (n = 44) and historical (n = 50) controls. Open repair was performed according to local protocols at the participating institutions. The extent of open repair could not extend more proximally than the left carotid artery or more distally than the celiac axis. Follow-up exams, four-view chest X-rays and spinal computed tomography (CT) scans were obtained for all patients at 1, 6 and

12 months, and yearly thereafter. These assessments were also performed at 3 months if any blood leaked from the device (endoleak). The GORE TAG and control groups were not significantly different on perioperative comorbidities or presentation other than there being fewer symptomatic aneurysm patients in the GORE TAG group (21% versus 38%,  $P = 0.007$ ). During this trial, fractures were noted in the spine of the device and the device was subsequently altered. A further 51 patients were enrolled in the study to compare major adverse events using the old GORE TAG device to the new GORE TAG device 30 days after treatment. Results were compared with the open surgical control group from the original study.

Results for this study have been reported by both Makaroun et al (2008) and Cho et al (2006a). Makaroun et al (2008) reported that successful deployment was achieved in 98% (137/140) of patients. There were three access failures. Major adverse events primarily occurred in the immediate postoperative period, where 28% of GORE TAG patients and 70% of surgical controls had at least one major adverse event ( $P < 0.001$ ). At 12 months, the rate of major adverse events in the GORE TAG group was 77% compared with 42% in the control group ( $P < 0.001$ ). At 5 years, aneurysm-related mortality was lower for GORE TAG patients at 2.8% compared with open repair patients at 11.7% ( $P = 0.008$ ). There were no differences in all-cause mortality, with 68% of GORE TAG patients and 67% of open repair patients surviving to five years ( $P = 0.43$ ). In the GORE TAG group, there were 17 cases of cardiac arrest/ myocardial infarction compared with six cases in the control group ( $P$ -value not reported). At five years, patients in the GORE TAG group were significantly less likely to have experienced pulmonary, renal, wound or neurologic complications or bleeding ( $P$ -value not reported). GORE TAG patients were more likely to have had vascular complications than open repair patients ( $P = 0.004$ ). Among the GORE TAG patients, endoleaks occurred in 10.6% (14/137) during the five years of follow up. Five patients had additional thoracic reinterventions related to the specific aneurysm treated. Three patients required a total of five endovascular reinterventions for endoleaks. There was one case of device migration, but no ruptures or collapses occurred. Device fracture occurred in 13.9% (19/137) of patients. All of these occurred before the device was modified. The proportion of GORE TAG patients with at least one secondary procedure following, but not directly related to, the aneurysm repair was 15% (21/140) compared with 32% (30/94) in the control group ( $P = 0.011$ ). For GORE TAG patients, 19% of patients at 5 years had 5 mm or more sac enlargement compared with a 1 month baseline, and 50% had  $\geq 5$  mm of sac shrinkage.

Makaroun et al (2008) also reported results for the original device compared with the modified device. It was reported that no patients who received the modified device exhibited aneurysm enlargement at 1 year compared with the original GORE TAG device ( $P = 0.0548$ . Value for aneurysm enlargement at 1 year for original group not reported), and 2.9% exhibited  $\geq 5$  mm sac enlargement at 2 years ( $P = 0.11$ . Value for sac enlargement at 2 years for original group not reported). Cho et al (2006a) reported comparisons of major adverse events 30 days post-treatment for patients treated with the new device and the control group. At 30 days post-treatment, the incidence of major adverse events was 12% in the GORE TAG patients and 70% in the control group. The authors stated that this was a highly significant difference corresponding to an 83% risk reduction for those treated

with the GORE TAG device, but no P- value or confidence interval was reported. No early deaths were reported in the GORE TAG group. It was unclear how many early deaths occurred in the control group. The rate of vascular complications was not significantly different in this cohort compared with the surgical controls. Estimates of the probability of freedom from major adverse events up to 30 days after treatment showed a significant advantage for the GORE TAG group compared with the surgical control group ( $P < 0.001$ ). Hospital length of stay was shorter with the GORE TAG device compared with the control group (3 versus 10 days, respectively; P-value not reported). The time to return to normal activities was shorter in the GORE TAG group than for the control group (15 days versus 78 days; P-value not reported). No major device-related events were noted at the 30-day follow up, compared with a 4% major device-related complication rate reported for the original device.

Wheatley et al (2006) reviewed consecutive patients who received the GORE TAG prosthesis as part of an investigational single centre protocol for various descending thoracic aortic pathologies. Both versions of the GORE TAG prosthesis were used. Only results for the modified device are reported in this summary, as the study did not compare the two versions of the device and modification of the device may have affected its performance. Between February 2003 and July 2004, 101 patients received the modified GORE TAG prosthesis for various aortic pathologies (the number of patients for each pathologic indication was not reported). Enrolment was limited to patients who were deemed to be a high surgical risk. Physical examinations, CT scans and X-rays were performed at 1, 6 and 12 months, and yearly thereafter. Patients with an early endoleak also received a CT scan at the 3-month visit.

Data on anatomic indications, demographic variables, prosthesis size, and number of prostheses used per patient were reported collectively for all patients, but not specifically for the modified device. Delivery of the modified GORE TAG device was accomplished in 84.2% (85/101) patients. Two (2%) patients required subsequent bypass for left upper extremity ischaemia. An iliac artery conduit was necessary in 7 (6.9%) patients. A sheathless “bareback” delivery through the common femoral artery was used in 9 (8.9%) patients with small, noncalcified access vessels. Two (2%) patients experienced iliac artery perforation during introduction of the endoluminal graft through a common femoral artery approach. The 30-day mortality for the entire study population was 3.8% (6/156) of patients and 4% (4/101) for the modified GORE TAG device group. Endoleaks occurred in 11(10.9%) patients receiving the modified GORE TAG device. Of these, 7 patients with endoleaks received endoluminal grafts for descending thoracic aneurysms, and 4 patients were treated for aortic dissections. The number of spinal cord neurologic events, open surgical conversions and endovascular re-interventions were reported for all study patients, but not specifically for the modified GORE TAG device.

### **COST IMPACT**

The cost of the GORE TAG Thoracic Endoprosthesis was not detailed in the retrieved material. The price of the device is not on the company website. No cost-effectiveness studies were retrieved for this device.

## **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved materials.

## **OTHER ISSUES**

No issues were identified from the retrieved materials.

## **SUMMARY OF FINDINGS**

Endovascular treatments for thoracic aneurysms and other aortic pathologies offer an attractive alternative to open surgical repair. This prioritising summary is limited by the poor quality and paucity of the available evidence. The limited evidence from one non-randomised comparative study suggests that treatment with the GORE TAG endoprosthesis results in a decrease in major adverse events, lower aneurysm-related mortality and fewer secondary procedures when compared with open surgery. Although evidence suggests that the modified version of the GORE TAG device has a similar efficacy and better safety profile than the original device, the reporting of outcomes related to the new device was sparse and the results for both devices were often combined. To make any definitive conclusions regarding the efficacy of the modified GORE TAG device, it will be necessary to obtain longer term follow-up data. In addition to this, further studies comparing the modified GORE TAG device with an appropriate control group are needed to ascertain its safety.

## **HEALTHPACT ACTION**

Based on the evidence available, the GORE TAG thoracic endoprosthesis appears to be a potential alternative for selected patients with aneurysms or other pathologies of the descending aorta. The GORE TAG endoprosthesis will be monitored for 24 months to retrieve additional evidence on its safety and effectiveness.

## **NUMBER OF STUDIES INCLUDED**

Total number of studies	2
Level III-3 evidence	1
Level IV evidence	1

## REFERENCES

Arko FR, Zarins CK. Endovascular repair of thoracic aortic aneurysm. In: Ascher E, Haimovici H (Eds). *Haimovici's Vascular Surgery*. 5<sup>th</sup> Edn. Wiley-Blackwell, USA 2003. [http://books.google.com.au/books?id=--o\\_NnWEjzEC&pg=PA688&lpg=PA688&dq=descending+thoracic+aneurysm&source=web&ots=55CdizMQql&sig=nLHMSoDGRfZd\\_BUWb\\_Rc-3haFAM&hl=en#PPA688.M1](http://books.google.com.au/books?id=--o_NnWEjzEC&pg=PA688&lpg=PA688&dq=descending+thoracic+aneurysm&source=web&ots=55CdizMQql&sig=nLHMSoDGRfZd_BUWb_Rc-3haFAM&hl=en#PPA688.M1) [accessed 13 June 2008].

Australian Institute of Health and Welfare (AIHW). Separation, patient day and average length of stay statistics by principal diagnosis in ICD-10-AM, Australia, 1998-99 to 2004-05. Last updated 2007. <http://www.aihw.gov.au/cognos/cgi-bin/ppdscgi?DC=Q&E=/ahs/principaldiagnosis9899-0405> [accessed 19 June 2008].

Bavaria JE, Appoo JJ, Makaroun MS and Gore TAG Investigators. Endovascular stent grafting versus open surgical repair of descending thoracic-aortic aneurysms in low-risk patients; a multicenter comparative trial. *Journal of Vascular Surgery* 2007; 46(3): 609.

Brooks MJ, Kerle M, Cheshire NJ, et al. Thoracoabdominal aortic aneurysm: evaluation of pre-operative assessment in 257 elective repairs. *British Journal of Surgery* 2000; 87 (Supp 2): 1-92.

Cho JS, Haider S, Makaroun MS. Endovascular therapy of thoracic aneurysms: Gore TAG trial results. *Seminars in Vascular Surgery* 2006a; 19: 18-24.

Cho JS, Haider S, Makaroun MS. US multicenter trials of endoprotheses for the endovascular treatment of descending thoracic aneurysms. *Journal of Vascular Surgery* 2006b; 43 (2 Suppl 1): A12-A19.

Coselli JS. Thoracic aortic aneurysms. In: Ascher E, Haimovici H (Eds). *Haimovici's Vascular Surgery*. 5<sup>th</sup> Edn. Wiley-Blackwell, USA 2003. [http://books.google.com.au/books?id=--o\\_NnWEjzEC&pg=PA688&lpg=PA688&dq=descending+thoracic+aneurysm&source=web&ots=55CdizMQql&sig=nLHMSoDGRfZd\\_BUWb\\_Rc-3haFAM&hl=en#PPA663.M1](http://books.google.com.au/books?id=--o_NnWEjzEC&pg=PA688&lpg=PA688&dq=descending+thoracic+aneurysm&source=web&ots=55CdizMQql&sig=nLHMSoDGRfZd_BUWb_Rc-3haFAM&hl=en#PPA663.M1) [accessed 17 June 2008].

Coselli JS, Plestis KA, La Francesca S et al. Results of contemporary surgical treatment of descending thoracic aortic aneurysms: experience in 198 patients. *Annals of Vascular Surgery* 1996; 10: 131-137.

Crawford ES, DeNatale RW. Thoracoabdominal aortic aneurysm: observations regarding the natural cause of disease. *Journal of Vascular Surgery* 1986; 3: 579-582.

Davies RR, Goldstein LJ, Coady MA, et al: Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size. *Annals of Thoracic Surgery* 2002; 73:17-28.

Fillinger M. Who Should We Operate On and How Do We Decide: Predicting Rupture and Survival in Patients with Aortic Aneurysm. *Seminars in Vascular Surgery* 2007; 20(2):121-127.

Gore and Associates, Inc. GORE TAG Thoracic Endoprosthesis. Annual Clinical Update. April 2007 <http://www.goremedical.com/en/file/AK0314.pdf> [accessed 6 June 2008].

Gore and Associates, Inc. GORE TAG thoracic endoprosthesis instructions for use – relevant information. January 2006 <http://www.goremedical.com/en/ifu/AJ0076.pdf> [accessed 16 June 2008].

Isselbacher EM. Diseases of the Aorta. In: Libby P, Bonow RO, Mann DL, Zipes DP (Eds). *Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine*. 8<sup>th</sup> Edn. Saunders Elsevier, Philadelphia, USA, 2008.  
<http://www.mdconsult.com.ezproxy.surgeons.org/das/book/body/97321993-2/0/1549/380.html> [Accessed 17 June 2008].

Kouchoukos NT, Dougenis D. Surgery of the thoracic aorta. *New England Journal of Medicine* 1997; 336: 1876-1888.

Lawrie GM, Earle N, De Bakey ME. Evolution of surgical techniques for aneurysms of the descending thoracic aorta: twenty nine years experience with 659 patients. *Journal of Cardiovascular Surgery* 1994; 9: 648-661.

Makaroun MS, Dillavou ED, Kee ST, Sicard G, Chaikof E, Bavaria J, Williams D, Cambria RP, Mitchell RS. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicentre trial of the GORE TAG thoracic endoprosthesis. *Journal of Vascular Surgery* 2005; 41: 1-9.

Makaroun MS, Dillavou ED, Wheatley GH, Cambria RP. Five-year results of endovascular treatment with Gore TAG device compared with open repair of thoracic aortic aneurysms. *Journal of Vascular Surgery* 2008; 45(5): 912-918.

Rousseau H, Bolduc JP, Dambrin C, Marcheix B, Canevet G, Otal P. Stent-Graft Repair of Thoracic Aortic Aneurysms. *Techniques in Vascular and Interventional Radiology* 2005; 8:61-72.

US Food and Drug Administration (US FDA). New Device Approval. GORE TAG Thoracic Endoprosthesis - P040043. Updated 5 April 2005  
<http://www.fda.gov/cdrh/mda/docs/p040043.html> [Accessed 27 June 2008].

Wheatley GH, Gurbuz AT, Rodriguez-Lopez JA, Ramaiah VG, Olsen D, Williams J, Diethrich EB. Midterm outcome in 158 consecutive Gore TAG thoracic endoprostheses: single centre experience. *Annals of Thoracic Surgery* 2006; 81(5):1570-1577.

## **SOURCES OF FURTHER INFORMATION**

Ellozy SH, Carroccio A, Minor M, Jacobs T, Chae K, Cha A, Agarwal G, Goldstein B, Morrissey N, Spielvogel D, Lookstein RA, Teodorescu V, Hollier LH, Marin ML. Challenges of endovascular tube graft repair of thoracic aortic aneurysm: midterm follow-up and lessons learned. *Journal of Vascular Surgery* 2003; 38(4):676-683.

Jackson BM, Carpenter JP, Fairman RM, Moser GW, Pochettino A, Woo EY, Bavaria JE. Anatomic exclusion from endovascular repair of thoracic aortic aneurysm. *Journal of Vascular Surgery* 2007; 45(4): 662-666.

Heijmen RH, Deblie IG, Moll FL, Dossche KM, van den Berg JC, Overtoom TT, Ernst SM, Schepens MA. Endovascular stent-grafting for descending thoracic aortic aneurysms. *European Journal of Cardio-thoracic Surgery* 2002; 21: 5-9.

Nienaber CA, Kische , Ince H. Thoracic Aortic Stent-Graft Devices: Problems, Failure Modes, and Applicability. *Seminars in Vascular Surgery* 2007; 20(2): 81-89.

## **SEARCH CRITERIA TO BE USED**

GORE TAG

Aortic Aneurysm, Thoracic/surgery\*

# PRIORITISING SUMMARY (UPDATE 2010)

---

**NAME OF TECHNOLOGY**

**GORE TAG®**

**PURPOSE AND TARGET GROUP**

**ENDOVASCULAR TREATMENT FOR THORACIC AORTIC ANEURYSMS**

## **AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL**

- Yes ARTG no.: 157814  
 No  
 Not applicable

Since the completion of the original GORE TAG prioritising summary (August 2008), this device has been approved for use in Australia by the TGA in December 2008.

## **DIFFUSION**

In the United States, two other endovascular treatment systems have been approved by the FDA since the completion of the original prioritising summary. At the time of writing, the top three endovascular grafts utilised for the treatment of thoracic aortic aneurysms are the GORE TAG, Zenith TX2® endovascular graft (William Cook Europe, Denmark) and the Talent™ Thoracic Stent Graft System (Medtronic Vascular, USA).

## **2010 SAFETY AND EFFECTIVENESS ISSUES**

### *Study descriptions*

A search of the literature identified 18 new published papers on GORE TAG. From these, three retrospective comparative studies (Cambria et al 2009, Hughes et al 2008, Adams et al 2009) were selected for inclusion in this update based on study quality and sample size.

The comparative study by Cambria et al (2009) aimed to determine the effectiveness of GORE TAG for the treatment of challenging descending thoracic aorta (DTA) pathologies or ruptured degenerative aneurysm (RDA), traumatic tear (TT) and acute complicated Type B aortic dissections (cTBD). This trial was performed in 14 United States academic centres between August 2005 and February 2007, patients were compared to literature controls. Literature controls were derived from 19 manuscripts, each with a minimum sample size of 50 patients per pathology (total: 800 patients). Cambria et al (2009) enrolled a total of 59 patients (19 cTBD group, 20 TT group and 20 RDA group). Patients in the RDA group were significantly older ( $p=0.004$ ) than those in the cTBD and TT groups. In addition, the RDA group had significantly higher prevalence of coronary artery disease, chronic obstructive pulmonary disease, hypertension and smoking compared to the TT group. Summary Society of Vascular Surgery (SVS) risk score for the entire cohort was  $6.2\pm 6.1$  (range: 0-24) with significantly higher values for the RDA cohort. Follow up visits at 30

days, 6 months and annually for 5 years post-treatment included clinical and computed tomography (CT) scans. Actuarial survival was reported with Kaplan-Meier curves. Only the surgeon investigators (not sponsors' clinical study staff) had access to pre-procedural imaging. Anatomic inclusive criteria for all pathologies mandated that the proximal aortic seal zone should be between 23mm and 37mm, and >2cm in length. Primary end point measures were the 30-day composite of death and total paraplegia. Lower extremity motor function post-anaesthesia at hospital discharge and at 30 days was assessed utilising a standardised scale. Secondary end points include the incidence of adverse events, device efficacy, one year survival and graft performance data (Cambria et al 2009).

Adams et al (2009) conducted a retrospective comparative analysis on the use of GORE TAG to determine if the outcomes of this device have changed when FDA oversight no longer governed patient selection. The authors examined the first 50 patients (28 men, mean age: 64.8±14.9 years) who underwent GORE TAG implantation after FDA approval from March 2005 to September 2006. The investigators recorded length of stay, number of intensive care days, 30-day mortality, complications and overall survival. These results were then compared to the phase II multicentre trial of the GORE TAG endoprosthesis (Makaroun et al 2005) to determine if patient outcomes have changed substantially when the strict inclusion and exclusion criteria of clinical trials were no longer enforced. All patients underwent postoperative imaging, either CT or magnetic resonance angiography, at 1, 6 and 12 months, and yearly thereafter. A range of indications were treated with GORE TAG: ruptured aneurysm, type B aortic dissection, acute traumatic disruption, penetrating ulcer with or without intramural haematoma, thoracoabdominal aneurysm, aberrant right subclavian artery aneurysm and repair of a large type I endoleak after stent-graft placement. Overall, 19 (38%) of the patient cohort underwent GORE TAG implantation for a non-approved/off-label indication (Adams et al 2009).

Hughes et al (2008) examined their experience with the GORE TAG endoprosthesis 2 years after FDA approval to characterise “real world” use (including off-label use) and patient outcomes outside of clinical settings. A total of 83 patients received the GORE TAG device between 23 March 2005 and 23 March 2007. Several patients were selected as a comparator to the GORE TAG group (20 patients who underwent conventional open descending thoracic and thoracoabdominal repairs during the same time period). Open repair patients tended to be younger and were more likely to have a connective tissue disorder such as Marfan syndrome or anatomy deemed unfavourable for standard or hybrid endovascular repair. At 1, 6, and 12 months postoperatively and yearly thereafter, patients underwent a follow-up protocol that included clinical examination, 4-view chest roentgenogram and computed tomography angiography (CTA).

### *Safety and Effectiveness*

Cambria et al (2009) reported that prosthesis deployment was successful in all 59 patients. However, three patients (one in each group: RDA, TT, cTBD) required conversion to open surgery within 30 days due to rupture (cTBD group), aorto-oesophageal fistula (RDA group) and device compression (TT group). The authors noted that 48 patients (81%) had femoral cutdowns, of which 11 (19%) had percutaneous access for delivery. Procedure time

was significantly shorter for the TT group compared with the RDA group (85±25 vs. 133±28 minutes;  $p<0.05$ ). Procedural blood loss was similar between all groups. Hospital stay was significantly longer for the TT group compared to the RDA and cTBD groups (TT: 31±36.6 days; RDA: 7.5±5.1 days; cTBD: 9.1±7.1 days;  $p<0.05$ ). Combined 30-day mortality/paraplegia rates for the GORE TAG group was significantly less compared to literature controls (13.6%[8/59] vs. 29.6%[237/800];  $p=0.008$ ). Of the seven early deaths, three occurred in the cTBD group (two strokes, one aortic rupture), three in the RDA group (sepsis, stroke and myocardial infarction) and one in the TT group (acute respiratory distress syndrome). Analysis revealed that age (odds ratio: 1.05; 95% confidence interval [CI]: 1.01-1.09;  $p=0.008$ ) and chronic obstructive pulmonary disease (COPD) (odds ratio: 4.3; 95% CI: 1.3-14.4;  $p=0.02$ ) were predictors of death at one year post-implantation. Major adverse events occurred in 48 (81%) patients within 30 days after the procedure. Of these, 11 (18.6%) were classified as device-related events. Partial proximal endograft collapse occurred in two patients in the TT group. One was repaired with the placement of a second endograft and the other with open conversion. In addition, two RDA patients experienced other implant related complications. The first suffered from type 1a endoleak while the second had an aorto-esophageal fistula (prosthesis extrusion was noted during explantation) on day 28. Two cTBD patients suffered from major device related events (endoleaks) that led to procedural revisions. The overall occurrence of endoleaks (any degree) was 29% (17 patients: 7 cTBD, 2 TT, 8 RDA) throughout the 30 day period. Of these, 6 were considered major adverse events (2 cTBD, 1 TT, 3 RDA) as they resulted in conversion, rupture or death. Kaplan-Meier analysis of survival through to one year was 66% (range: 52-77%) for the entire cohort; 79% (range: 53-92%), 79% (range: 53-92%) and 37% (range: 16%-59%) for cTBD, RR, and RDA groups, respectively. RDA patients had significantly shorter survival times than cTBD or TT ( $p=0.03$ ), but this significance was eliminated when controlled for baseline co-morbidities (age, COPD). At one year, freedom from aortic-related death was 84.5% (95%CI: 72.3-91.6) (Cumbria et al 2009).

Adams et al (2009) reported that endovascular repair with the GORE TAG was successful in all 50 patients. Overall, there were no significant differences for the length of ICU stay, length of stay or 30-day mortality between the post-FDA approval patients and the phase II trial patients. At one year, overall survival in study patients was 92% compared to 82% in the phase II trial ( $p=0.16$ ). Comparisons of early complications (first 30 days) revealed that the occurrence of endoleak was significantly greater in the study cohort compared to the phase II trial (12 incidents [24%] vs. 5 incidents [5%];  $p<0.05$ ). All other complications (bleeding, vascular, spinal cord injury, cerebrovascular accidents, pulmonary, cardiac and death) were comparable between the study and phase II patients. Kaplan-Meier estimates of survival indicated that with a mean follow-up of 625.1 days, overall survival was 88% while freedom from stent-graft related death was 100%. Late complications, determined as those occurring greater than 30 days after the procedure, were similar between both groups with no significant differences for migration, endoleak or need for further intervention (conversion to open or endovascular revision) at 1 year post-treatment (Adams et al 2009).

Hughes et al (2008) reported that primary technical success<sup>1</sup> for GORE TAG implantation was achieved in 82 patients (98.8%) Operative mortality<sup>2</sup> occurred in 3 patients (3.6%) while cerebrovascular accident<sup>3</sup> was noted in 3 patients (3.6%). New permanent paraparesis or paraplegia occurred in 2 patients (2.4%). Meanwhile, the rate of vascular or device-related complications requiring additional endovascular or open procedures within 30 days was 7.2% (6 patients). Overall actuarial midterm survival was 75% at 28 months, with an aortic-specific actuarial survival rate of 94%. Late deaths consisted of one (1.2%) aortic-related event and 15 others due to co-morbid conditions. Type I or II endoleak occurred in 4 patients (5%) and all were detected on initial postoperative CT scan. One of these patients died before definitive repair, the remaining 3 were successfully treated. On follow-up imaging, an additional 5 patients (6%) presented with type II endoleak. At the latest follow-up, 45/73 patients (62%) had decreasing (>5mm) aortic dimensions, meanwhile aortic dimensions were stable in 27/73 patients (37%). Of the patients who had follow-up imaging at 6 months or greater, 45/51 (88%) had aortic dimensions that have decreased by at least 5 mm. There was one incidence of late conversion to open repair (1.2%) during midterm follow-up. Overall, 10 patients (12%) required late intervention during midterm follow up; of these, one failed and resulted in patient death from aortic rupture (Hughes et al 2008). Surprisingly, despite initial indications within the protocol that 20 open repair patients would be utilised as comparators, no comparative data was presented within the results section.

#### **COST IMPACT**

Walker et al (2010) compared hospital costs and physician relative value units (RVUs) between thoracic endovascular aortic repair (TEVAR; n=28) with GORE TAG and open repair (n=29) at a United States institution between January 2005 and December 2007. The authors noted that despite shorter surgical times for TEVAR(168 vs. 465 minutes; p<0.001) compared to open surgery, TEVAR operating room costs were 2.03 times greater than open repair (p<0.001). The greater operating room costs were secondary to TEVAR graft costs, which were 22.2 times higher than open repair. However, total hospitalisation costs were still greater (1.55 times) for open repair compared to TEVAR. This was mainly due to longer length of stay (p<0.01), anaesthesia costs (4.00 times greater vs. TEVAR; p<0.001), pharmacy costs (5.74 times greater vs. TEVAR; p=0.001), laboratory costs (4.94 times greater vs. TEVAR; p<0.001) and respiratory services (4.89 times greater vs. TEVAR; p=0.001).

#### **OTHER ISSUES**

One meta-analysis (Jonker et al 2010) of open surgery verses endovascular repair for ruptured descending thoracic aortic aneurysms indicated that endovascular repair is associated with significantly lower mortality, however TEVAR was associated with a considerable number of aneurysm-related deaths during follow-up (estimated aneurysm-related survival after 3 years: 70.6%). However, this meta-analysis was excluded from the

---

<sup>1</sup> Defined as successful endograft deployment with secure proximal and distal fixation with no type I or III endoleak and absence of open surgical conversion or mortality within the first 24 hours postoperatively.

<sup>2</sup> Death within 30 days of procedure or during the same hospital admission.

<sup>3</sup> New neurologic deficit lasting for than 24 hours

prioritising summary as only 12/143 (8.4%) patients were treated with the GORE TAG endoprosthesis. In addition, this meta-analysis included studies from 1995 onwards (which includes older devices that are less developed than those currently available).

The study by Cambria et al (2009) was funded by the manufacturers of GORE TAG. The investigators attempted to reduce potential bias by restricting pre-procedural imaging to investigator surgeons only.

## **2010 SUMMARY OF FINDINGS**

There is some evidence from the included studies that despite the expanded indications for GORE TAG, patient outcomes were comparable to the phase II trial for the device, at least at midterm follow-up. In addition, when compared to open surgery, patients treated with GORE TAG appear to have lower 30-day mortality rates. An assessment of in-hospital costs indicate that TEVAR may be more cost-effective compared to open surgery, at least in the short-term.

However, these studies do not provide any evidence to support the long-term durability of the GORE TAG endoprosthesis and are inherently exposed to potential bias due to their retrospective nature. Further studies are necessary to determine the optimum patient selection criteria and the long-term costs effectiveness of GORE TAG and TEVAR in general.

## **2010 HEALTHPACT ASSESSMENT**

TEVAR continues to diffuse rapidly and has gained widespread acceptance among clinicians in the United States, particularly for acute and potentially catastrophic conditions of the descending thoracic aorta. Nevertheless, there is still paucity of published evidence that shows the long-term durability and cost-effectiveness of GORE TAG. It is not known if high quality prospective comparative studies on TEVAR will be published in the near future due to the potential reluctance of clinicians to randomised patients to open surgery. GORE TAG and TEVAR in general have been noted by HealthPACT, but further assessment by HealthPACT is not necessary at this time.

## **2010 INCLUDED STUDIES**

Total number of studies	3
Level III-2 intervention evidence	2
Level IV intervention evidence	1

## **2010 REFERENCES**

Adams JD, Angle JF, Matsumoto AH, Peeler BB, Arslan B, Cherry KJ, Kern JA, Dake MD. Endovascular repair of the thoracic aorta in the post-FDA approval era. *J Thorac Cardiovasc Surg* 2009; 137(1):117-123.

Cambria RP, Crawford RS, Cho JS, Bavaria J, Farber M, Lee WA, Ramaiah V, Kwolek CJ; GORE TAG Investigators. A multicenter clinical trial of endovascular stent graft repair of acute catastrophes of the descending thoracic aorta. *J Vasc Surg* 2009; 50(6): 1255-1264.

Hughes GC, Daneshmand MA, Swaminathan M, Nienaber JJ, Bush EL, Husain AH, Wolfe WG, McCann RL. "Real world" thoracic endografting: results with the Gore TAG device 2 years after U.S. FDA approval. *Ann Thorac Surg* 2008; 86(5):1530-1537.

Jonker FH, Trimarchi S, Verhagen HJ, Moll FL, Sumpio BE, Muhs BE. Meta-analysis of open versus endovascular repair for ruptured descending thoracic aortic aneurysm. *J Vasc Surg* 2010; 51(4): 1026-1032.

Makaroun MS, Dillavou ED, Kee ST, Sicard G, Chaikof E, Bavaria J, Williams D, Cambria RP, Mitchell RS. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. *J Vasc Surg* 2005; 41(1): 1-9.

Walker KL, Lipori P, Lee WA, Beaver TM. Cost of thoracic endovascular aortic repair versus open repair and implications for the US health care system. *J Thorac Cardiovasc Surg* 2010; 139(1): 231-232.