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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

ANZHSN

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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**

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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

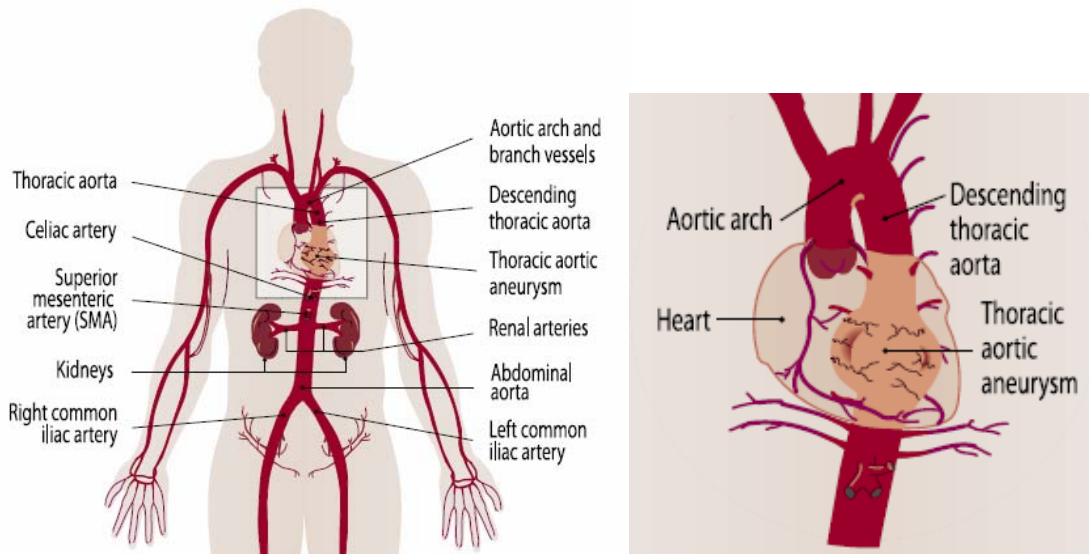
The GORE TAG® Thoracic Endoprosthesis (W.L. Gore & Associates, Inc., Flagstaff, AZ, USA) provides a minimally invasive option for managing patients with pathologies of the descending thoracic aorta as opposed to open surgical repair. The function of the endoprosthesis is to internally reline the thoracic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

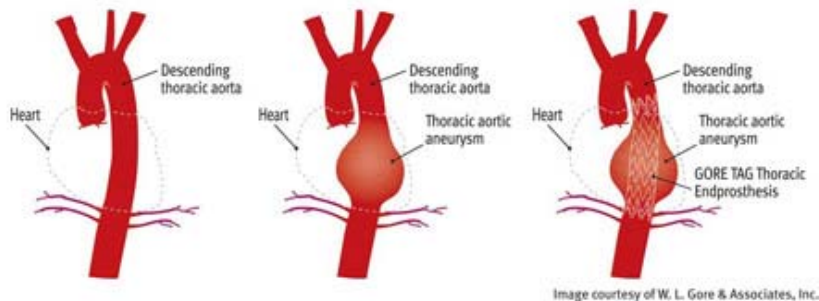
Traditional surgical repair involves general anaesthesia and left heart bypass. An incision is made through the length of the sternum to reveal the dilated portion of the aorta. Clamps are applied across the aorta to prevent blood flow into the aneurysm. The aneurysm is opened and the diseased section 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 ≥ 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 ≥ 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

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SEARCH CRITERIA TO BE USED

GORE TAG

Aortic Aneurysm, Thoracic/surgery*