Chapter 3

US multicenter trials of endoprostheses for the endovascular treatment of descending thoracic aneurysms

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Since the first report of endovascular therapy for descending thoracic aortic pathology in 1994 by Dake et al,[1] the advent of commercially available devices has been relatively slow. This is primarily due to the relatively lower volume of thoracic aortic aneurysms as compared with infrarenal aortic aneurysms. Technical and anatomic challenges in thoracic endografting, such as proximity of the great vessels and tortuosity around the arch, also pose a challenge. In addition, a larger device profile and hostile hemodynamic forces complicate the technical aspect of the deployment procedure.

With broadened applications for endovascular treatment of thoracic pathology worldwide,[2-4] including aortic dissections, aneurysmal degeneration of chronic dissections, traumatic ruptures, and penetrating ulcers, there has been an increased focus on the development of thoracic endoprostheses. As many as 12 thoracic endografts are currently available for commercial use in Europe.

In the United States, only one thoracic endoprosthesis, the Gore Thoracic Aortic Graft (TAG) device (W.L. Gore and Associates, Flagstaff, Ariz), has gained US Food and Drug Administration (FDA) approval for treatment of descending thoracic aortic aneurysms (DTAs) and is commercially available. Two other devices are undergoing US multicenter trials: the TX2 device (Cook, Bloomington, Ind) and the Talent stent graft (Medtronic AVE, Sunrise, Fla). This chapter provides an update on these three devices and the available data on the US trials.

GORE TAG THORACIC ENDOPROSTHESIS

The Gore Excluder thoracic endoprosthesis was the first thoracic endograft to enter clinical trials in the United States in 1998 with a feasibility trial. This was followed by the pivotal study in 1999. After the conclusion of the trial, the discovery of longitudinal deployment wire fractures led to the withdrawal of the device from distribution in May 2001. The device was modified with the removal of the wire and replacement by a stronger polytetrafluoroethylene (PTFE) with a new bonding of the sinusoidal wire. A confirmatory trial was instituted in late 2003 with the modified device. In March 2005, the FDA approved commercial use of the TAG device.

DEVICE DESIGN

The TAG endoprosthesis is a symmetrical expanded PTFE (ePTFE) tube reinforced with ePTFE/fluorinated ethylene propylene (FEP) film and an external nickel-titanium (nitinol) self-expanding stent along the entire surface of the graft (Fig 1). The stent is attached to the graft with ePTFE/FEP bonding tape. A circumferential PTFE sealing cuff is located on the external surface of the endograft at the base of each flared, scalloped end. Flares are designed to help with conforming to tortuous anatomy. Each cuff is circumferentially attached on one edge with FEP, thus allowing the other end to remain free to enhance sealing of the endoprosthesis to the aortic wall and help eliminate endoleaks.

The original TAG device graft material was constructed from 2 ePTFE layers with 2 longitudinal wires for support during deployment. The modified TAG device is constructed from 3 ePTFE layers. The additional layer, similar to that incorporated into the Excluder bifurcated endoprosthesis, is sandwiched between the two original layers and provides support that was formerly provided by the deployment wires. At the base of the flares are two radiopaque gold bands, which serve as a guide during implantation and in follow-up. The devices are available in 26- to 40-mm diameters and require 20F through 24F introducer sheaths, depending on the device size.

Deployment of the TAG device is unique. A sleeve made of ePTFE/FEP film is used to constrain the endograft. A deployment knob is located at the control end of the delivery catheter and has a deployment line that runs the entire length of the catheter connecting it to the sleeve. Turning and pulling the deployment knob removes the

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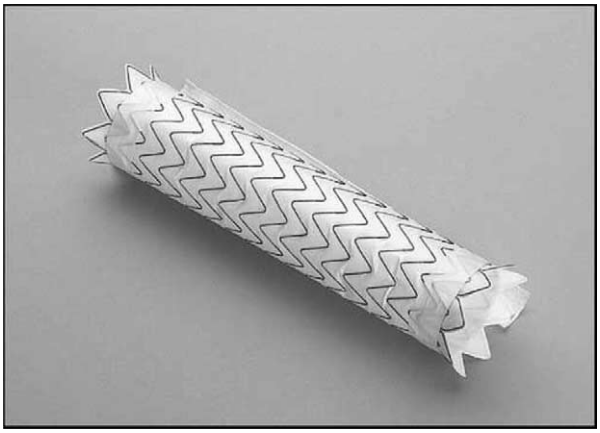

Fig 1. Gore TAG thoracic endoprosthesis.

deployment line from the endograft, thereby deploying it. The device is deployed rapidly from the middle of the endograft toward both ends of the prosthesis. The device is then secured in position with a specially designed trilobed balloon, which allows continuous blood flow during inflation.

FEASIBILITY STUDY

The first trial to be conducted in the United States was the feasibility study to establish preliminary device safety data. This study was performed at two sites in the United States and enrolled a total of 28 patients between 1998 and 1999. The 30-day mortality rate was 3.6% (n = 1). At 1 year, the mortality rate was 21% without any paraplegia or stroke. Renal failure and myocardial infarction were noted in one patient each (3.6%). Through a 5-year follow-up period, two additional adverse events were reported between 2 and 5 years. All-cause mortality at 5 years was 25%. Endoleaks were noted at any time in 21% of the patients, and aneurysm sac growth was noted in 18%. Stent fractures were noted in 32%. There was one conversion and there were two reinterventions over time to place additional devices. No aneurysm ruptures, device migration, extrusion, erosion, lumen obstruction, or branch vessel occlusions were reported.

PIVOTAL (PHASE II) TRIAL

Objectives and hypotheses

The objectives were to determine the safety and efficacy of the TAG endoprosthesis for the treatment of DTA as compared with open surgical repair controls. The primary safety hypothesis was that the percentage of subjects with one or more major adverse events (MAEs) through 1 year after treatment would be lower in the TAG group as compared with the surgical control group. The primary efficacy hypothesis was that freedom from any major device-related events through 1 year of follow-up for the TAG device group would be better than 80%. A predefined point estimate of 80% for the endovascular group was considered to be a reasonable efficacy outcome, because the device was expected to show a considerable improvement in safety profile. The efficacy for the surgical procedure was assumed to be 100%. The secondary hypotheses were that the procedural blood loss, intensive care unit (ICU) and hospital stay, and convalescence to normal activities would be lower in the TAG device group as compared with the surgical control group. The primary efficacy end point of this pivotal study was the percentage of subjects who were free from major device-related events through 1 year of follow-up for the TAG device group.

Study design

This study was a prospective, nonrandomized, controlled multicenter trial. The study enrolled 140 study patients and 94 control subjects between September 1999 and May 2001 through 17 clinical sites in the United States. The control group consisted of 44 patients acquired prospectively during the study and 50 historical patients acquired by selecting the most recent surgical patients in reverse chronological order. Inclusion and exclusion criteria are detailed in Tables I and II.

Follow-up

All patients are to be followed for 5 years. Computed tomography (CT) scans, plain radiographs, and physical examinations were obtained at 1-month, 6-month, and 12-month intervals and yearly thereafter. A 3-month visit with a CT scan was conducted for patients with early endoleaks. A core laboratory reviewed all imaging studies. Clinical data were reported by individual centers and monitored by sponsor representatives. MAEs were adjudicated by the Clinical Events Committee and defined as clinical events that required therapy or that resulted in an unintended increase in the level of care, prolonged hospitalization, permanent adversity, or death.[5] Minor adverse events were those that did not require any therapy or those with no consequences.

RESULTS OF THE PIVOTAL STUDY

Clinical material

The TAG group and the surgical group were very similar in all major demographic and clinical variables (Table III). The average age of the patients was 71 years in the TAG group and 68 years in the control group. Men accounted for 58% of the patients in the TAG group and 51% in the control group.

Baseline aortic morphology was also well matched between the groups, except for the smaller diameter of the proximal and distal necks in the TAG device group, which was expected because of the requirements for sealing. Baseline comorbidities were also quite similar between the TAG device group and the control group (Table IV). Although coronary artery disease seemed to be more prevalent among the TAG group, this difference was not significant. Symptomatic aneurysms, however,

Table I. Inclusion criteria

Criterion	*Medtronic Talent*	*Cook TX2*	*Gore TAG*
Age (y)	>18	>18	>21
Women	Negative pregnancy test 7 d before treatment	Negative pregnancy test 7 d before treatment	Must be infertile
Open-surgical candidate	Yes	Yes	Yes
Neck length	Minimal 2 cm proximal and distal	Minimal 3 cm proximal and distal	Minimal 2 cm proximal and distal
Aneurysm	Fusiform DTA at least twice the size of normal thoracic aorta; saccular	Fusiform DTA at least twice the size of normal thoracic aorta	Fusiform DTA at least twice the size of normal thoracic aorta; saccular
Penetrating ulcer	Yes	No	No
Proximal landing zone location	20 mm distal to left CCA	30 mm distal to left CCA	20 mm distal to left CCA
Distal landing zone location	20 mm proximal to celiac axis	20 mm proximal to celiac axis	20 mm proximal to celiac axis
Landing zone diameter (mm)	18-42	24-38	23-37

CCA, Common carotid artery; DTA, descending thoracic aortic aneurysm.

Table II. Exclusion criteria

Criterion	*Medtronic Talent*	*Cook TX2*	*Gore TAG*
Creatinine (mg/dL)			>2.0
Unstable rupture	N/A	Yes	Yes
Mycotic aneurysm	Yes	Yes	Yes
Connective tissue disease	Yes	Yes	Yes
Significant landing zone thrombus	Yes	Yes	Yes
Previous descending aortic surgery or endovascular repair of DTA or AAA	Yes	Yes	N/A
Aortic dissection	Yes	Yes	Yes
Coagulopathy	Yes	Yes	Yes
MI/CVA	<3 mo	<3 mo	<6 wk
Major operation within 30 d	Yes	Yes	Yes
Participation in another investigational study	<30 d	<30 d	<1 y

DTA, Descending thoracic aortic aneurysm; *AAA,* abdominal aortic aneurysm; *MI,* myocardial infarction; *CVA,* cerebrovascular accident; *N/A,* not applicable.

Table III. Patient demographics

Variable	*TAG group*	*Surgical control*
Male (%)	57	51
Age (y)	71	68
Ethnicity (%)		
White	87	86
Black	8	10
Other	5	4
Height (cm)	170	170
Weight (kg)	76	78

were significantly more prevalent in the control group than in the TAG group. The risk classifications performed on the basis of the standard American Society of Anesthesiologists classification and the SVS risk score showed no significant difference in either classification.

Table IV. Comparison of early complications between TAG and open surgical controls in the GORE pivotal trial

Variable	*TAG device (%)*	*Surgical control (%)*	P *value*
Coronary artery disease	49	36	.06
Cardiac arrhythmia	24	31	.23
Stroke	10	10	>.95
PVOD	16	11	.33
Prior vascular intervention	45	55	.14
Symptomatic aneurysm	21	38	<.01
Other concomitant aneurysms	28	28	>.95
COPD	40	38	.89
Smoking	84	82	.86
Renal dialysis	1	0	.52
Hepatic dysfunction	2	1	.65
Paraplegia	1	0	>.95
Cancer	19	13	.21

PVOD, Peripheral vascular occlusive disease; *COPD,* chronic obstructive pulmonary disease.

Operative data

Of 142 patients recruited (140 in the pivotal trial and 2 extended access), 139 (98%) underwent successful implantation of the TAG device. The three failures were all due to poor iliac access. A conduit was placed to facilitate access in 21 patients (15%). More than 1 device was used in 77 patients (55%); 61 patients (44%) received 2 devices, 11 patients (8%) received 3 devices, and 5 patients (4%) received 4 devices.

Prophylactic left carotid/subclavian bypass grafting was performed in 28 patients in preparation for planned left subclavian artery coverage with the device. Unplanned subclavian artery and visceral artery coverage occurred in one patient each. The latter underwent an open abdominal explantation of the device and redeployment of a new device without sequelae.

Table V. Operative complications

Variable	*TAG*	*Open surgical*
Death	2.1	11.7
Paraplegia/paraparesis	3	14
Stroke	4	4

Early adverse events

Mortality. Operative mortality, defined as death within 30 days of the procedure or on the same hospital admission, occurred in three patients (2.1%) after TAG implantation (Table V). One death was due to a postoperative stroke and another to a cardiac event that occurred on postoperative day 11. The third death occurred after 7 months of a protracted hospital course as a result of anoxic brain injury after a respiratory arrest. The patient died of septic complications from an aortoesophageal fistula. Six deaths (6.4%) occurred in the surgical control group.

Spinal cord ischemia. Spinal drainage was not routinely used in either group. In the TAG group, spinal cord ischemia (SCI) was noted in four patients. One was noted immediately after the procedure, and the deficit persisted despite all supportive measures. Three were delayed in onset, and all these regained motor function (one complete and two partial) and were ambulatory at last follow-up. It should be noted that multiple pieces of TAG endografts were used in three of four patients and that two of four patients had had previous infrarenal aortic aneurysm repair. The incidence of SCI did not differ between those with and without prior abdominal aortic aneurysm repair (4.7% vs 2%, respectively). The incidence of SCI in the control group was significantly higher (13.8%). Of 13 patients, 8 had paraplegia, of whom 6 died. One case of paraplegia resolved completely.

Cerebrovascular accidents. Perioperative stroke was noted in five patients (3.5%). One was fatal. Three were right-sided. Four of the five strokes occurred in patients who had proximal aneurysms requiring extension of the TAG to the left carotid and coverage of the subclavian artery; all four underwent carotid/subclavian bypass. Of the 28 patients with proximal aneurysms who had planned subclavian artery coverage, 4 (14%) had a stroke, compared with 1 (1%) of 114 with disease distal to the subclavian artery ($P < .001$). The overall incidence of cerebrovascular accident (4.3%) was similar in the two groups.

Endoleaks. Early endoleaks were seen in five patients. One patient had a proximal type I endoleak and was treated with endovascular revision and additional grafts. The remaining endoleaks were thought to be type II.

Other MAEs. The other most common MAEs were bleeding, cardiopulmonary events, and intraoperative vascular injury. Both bleeding and pulmonary events were significantly reduced in the TAG group compared with the surgical control group, due to a high percentage of procedural bleeding and respiratory failure in the latter.

The incidence of vascular injuries was 14% in the TAG group, which was significantly higher than in the control group (4%). This was related to the introduction of large introducer sheaths through the iliac system.

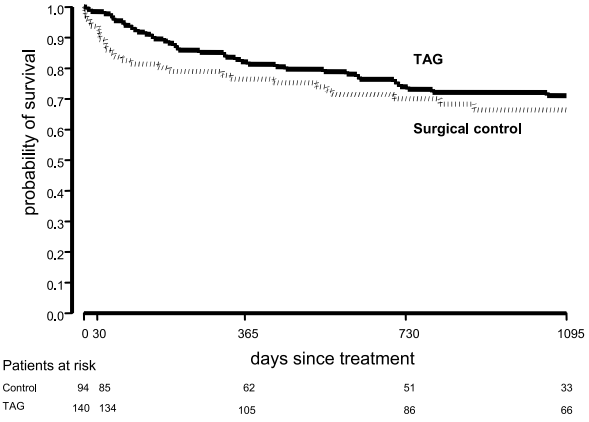

Fig 2. Comparison of Kaplan-Meier estimates for all-cause mortality through the 3-year follow-up between the Gore TAG and surgical control groups.

Hospital length of stay. The average ICU stay was significantly shorter in the TAG group compared with the control group (2.6 ± 14.6 days vs 5.2 ± 7.2 days; $P < .001$), as was total length of stay (7.4 ± 17.7 days vs 14.4 ± 12.8 days; $P < .001$).

Late outcome

Late survival. All-cause mortality through 3 years did not differ in the two groups (Fig 2). The causes of death were commensurate with associated comorbidities in this elderly population. No ruptures have been reported.

With respect to aneurysm-related mortality, defined as death before hospital discharge, death within 30 days of the primary procedure or within 30 days of any secondary procedure to treat the original aneurysm, or death due to aneurysm rupture, there was one late death in the TAG group. This patient had an aneurysm growth in the setting of graft infection at 2 months. The patient underwent an open conversion and was found to have an aortoesophageal fistula, which was treated by graft excision and an extra-anatomic bypass, only to experience a respiratory arrest on postoperative day 13 with resultant anoxic brain injury. The patient died 3 days later. In the open-surgical group, three additional deaths occurred during the first 6 months of follow-up. Freedom from aneurysm-related mortality through 3 years was 97% for the TAG device group and 90% for the open-surgical controls ($P = .024$). No mortalities were noted in either group after the first year (Fig 3).

Major adverse events. The Kaplan-Meier estimates of the probability of freedom from MAEs were significantly higher with TAG treatment (58%) than with open surgical controls: 48% vs 20% at 3 years, respectively (Fig 4). In fact, 70% of all MAEs occurred within 30 days of the original procedure. A similar observation was made in the feasibility study, in which 63% of all events over 5 years were noticed in the first 30 days.

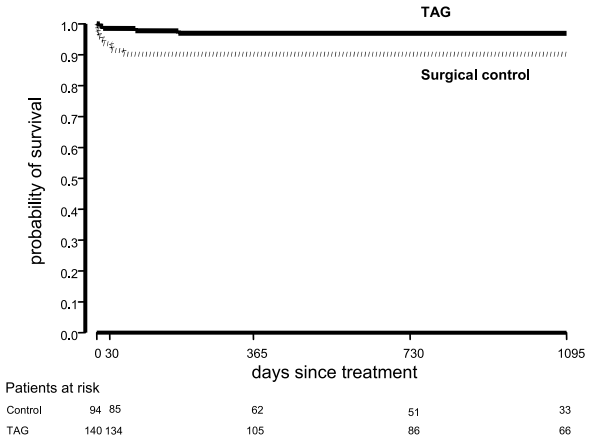

Fig 3. Comparison of Kaplan-Meier estimates for aneurysm-related mortality through 3-year follow-up between the Gore TAG and surgical control groups.

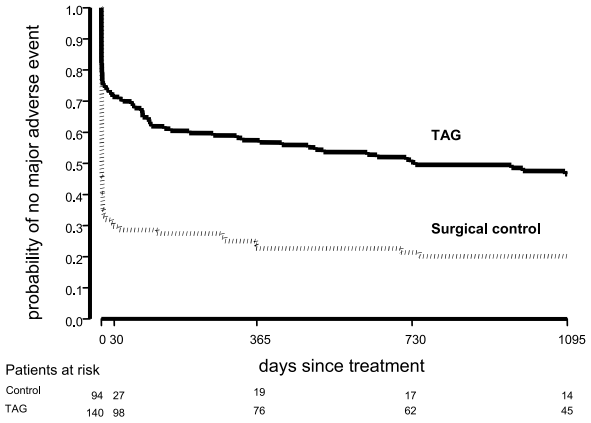

Fig 4. Comparison of Kaplan-Meier estimates for freedom from major adverse events through the 3-year follow-up between the Gore TAG and surgical control groups.

Device-related events. During a 3-year follow-up, five patients underwent endovascular revisions, and one patient underwent surgical conversion. Three of the revisions occurred after 24 months of follow-up. Device migrations, three proximal and four component, were noted without clinical compromise at the 2-year follow-up. Sac shrinkage of greater than 5 mm was observed in 38% (24/64) and sac expansion in 17% (11/64) of patients. Three of the 11 patients with sac enlargement had endoleaks at some point during follow-up. Twenty fractures were noted in 19 patients: 18 in the longitudinal spine and 2 in the apical nitinol support rings. Clinical sequelae developed in only one patient, who developed a type III endoleak that was treated with an endograft. No ruptures were noted at a follow-up extending to 2 years. No device-related deaths were noted through 3 years.

CONFIRMATORY STUDY

Objectives and hypotheses

The confirmatory study was launched to demonstrate that deployment and early results with the modified device are comparable to those with the original device. The safety and efficacy hypotheses were the same as in the pivotal trial except for using a 30-day end point. This earlier safety end point was chosen as an appropriate measure on the basis of the results of the pivotal study, in which most MAEs occurred within the 30-day period. Almost all major device-related events were also identified in the first 30 days during the pivotal trial. Although 30-day study end points were used, all patients are to be followed up to 5 years. Inclusion and exclusion criteria were identical to those used in the pivotal study.

Design

The confirmatory study was a prospective, nonrandomized trial with all test subjects treated with the modified TAG device. The study was performed at 11 sites, all but one of which had participated in the pivotal trial. Fifty-one patients were enrolled in this study, and their results were compared with the same 94 control subjects used in the pivotal study.

Results of the confirmatory study

Clinical materials. Baseline demographics and aortic morphology were quite similar in the TAG device group and the surgical control group. Comorbidities were also well matched. In this comparison, the symptomatic aneurysm difference did not reach statistical significance. However, there was a higher prevalence of cancer or a history of cancer in the TAG device group compared with the surgical control group. Risk classification according to the American Society of Anesthesiologists was very well matched between the TAG and the surgical control groups. The SVS risk score was slightly higher in the TAG device group, and this was significant.

Early MAEs. At 30 days, the incidence of MAEs was 12% in the TAG group and 70% in the controls, a highly significant difference corresponding to an 83% risk reduction for those treated with the TAG device. No early deaths were noted in the TAG group. The rate of vascular complications was not significantly different in this cohort compared with the surgical controls.

Kaplan-Meier estimates of the probability of freedom from MAEs through 30 days showed a significant advantage for the TAG device group compared with the surgical control group ($P < .001$).

Device-related events. No major device-related events were reported through the 30-day follow-up in the test subjects compared with six (4%) reported for the pivotal study test subjects.

Hospital length of stay. Hospital length of stay was shorter with the TAG device compared with the control group (3 vs 10 days, respectively). The time to return to

Fig 5. Medtronic Talent stent graft.

normal activities was shortened in the TAG group to 15 days vs 78 days for the control group.

MEDTRONIC TALENT THORACIC ENDOGRAFT AND THE VALOR TRIAL

Device design

The Talent Thoracic Stent Graft device is composed of a polyester graft fabric sewn to a self-expanding nitinol wire frame (Fig 5). It is a modular device that accommodates the use of additional main sections, as well as proximal and distal extensions. The proximal end of the device is usually a bare stent for better proximal fixation. The graft diameters are 18 through 42 mm, and the delivery catheter profile ranges from 22F to 25F. The stent grafts are selected on the basis of anatomic measurements. Deployment system modifications were introduced later in the trial, and a modified device, the Valiant system (Medtronic, Inc, Minneapolis, Minnesota), has been introduced in Europe recently.

The VALOR trial

The VALOR trial (Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms) is a prospective, multicenter study with 3 arms conducted at 35 sites in the United States. Enrollment for the study concluded in June 2005 with 394 patients total, and final VALOR trial results may be available by 2006. The test group (n = 144) consisted of patients who were diagnosed with DTA and were considered candidates for open surgical repair with low- to moderate-risk Society for Vascular Surgery/International Society for Cardiovascular Surgery criteria. The test group inclusion/exclusion criteria are listed in Tables I and II. No surgical control arm was included, and the comparative open control arm would be derived from the established literature. In addition to the test group, two additional observational treatment group registries were conducted concurrently. The registry group (n = 150) enrolled subjects who were open-surgical candidates with complicated type B thoracic aortic dissections, aneurysmal degeneration from dissection, pseudoaneurysms, and chronic, stable traumatic injuries. The last arm was a high-risk group (n = 100). Patient eligibility included patients considered at high risk for open surgery, nonsurgical candidates not associated with Society for Vascular Surgery scoring, and subjects with traumatic thoracic aortic injuries. Only the data from the test arm will be used in device safety and efficacy analysis. The information from the registries will be descriptive in nature and may serve as the basis for future phase III clinical investigations.

The primary objective of the study is to determine the safety and efficacy of the Talent device in the treatment of DTA in subjects who are otherwise eligible for standard open repair. The safety end point compares the all-cause mortality of DTA repair with the Talent endograft against the literature control for open surgical repair within 1 year of follow-up. The efficacy end point measures the proportion of subjects with successful aneurysm treatment at the 12-month follow-up.

The secondary safety and efficacy end points evaluate the technical success rate, the percentage of subjects with MAEs, device-related events, and aneurysm rupture rates at 30 days and at 12 months. Additional data analysis will include blood loss, blood product transfusion, operative time, ICU stay, and overall length of hospital stay. The VALOR trial reached its enrollment target in June 2005, and no results are yet available.

Subject screening required a minimum of a contrast-enhanced spiral CT scan of the chest, abdomen, and pelvis with optional three-dimensional reconstruction or contrast-enhanced magnetic resonance arteriography. History and physical, chest radiograph, and CT or magnetic resonance arteriography of the chest were obtained at 1, 6, and 12 months and yearly thereafter.

COOK ZENITH TX2 THORACIC ENDOGRAFT AND THE STARZ TRIAL

Device description

The Zenith endograft is a one-piece (TX1) or two-piece (TX2) modular endovascular graft (Fig 6). The TX2 is the endograft used in the US trials. The device composition is of Dacron (DuPont, Wilmington, Del) fabric sewn to self-expanding stainless steel Z-stents with braided polyester and monofilament polypropylene sutures. The graft is fully stented with an intention to provide columnar stability and expansile force. It consists of a proximal (TX2P) and a distal (TX2D) component, with a minimal overlap of 2 stents between them. The proximal part of the TX2P is covered and contains a series of 5-mm-long, staggered, caudally oriented barbs to prevent distal migration. Proximally, the distal TX2 component has a two-stent overlap zone in which the stents are sutured to the internal surface of the fabric. Distally, there is an uncovered Gianturco Z-stent with cranially oriented barbs to help prevent proximal migration. Four gold radiopaque markers are stationed near the edge of the graft material to enhance visualization of graft ends. The graft diameters range from 28 to 42 mm, and the graft profile ranges from 20F to 22F. The proximal components can either be tapered or nontapered. The device is deployed by manually retracting the

Fig 6. Cook Zenith TX2 thoracic endovascular graft.

outer sheath of the delivery system while holding the stent graft in position.

Additional ancillary endovascular components (proximal and distal main body extensions) are available. The TX2 ancillary components are cylindrical components constructed from the same polyester fabric and materials. At the distal and proximal graft margins, the Z-stents are attached to the inner surface. Elsewhere, the Z-stents are sutured on the external surface.

The STARZ trial

The STARZ-TX2 trial (Study of Thoracic Aortic Aneurysm Repair with the Zenith TX2 TAA Endovascular Graft) is a North American multicenter, nonrandomized, prospective clinical trial. It is seeking to enroll 270 patients at 35 sites in the United States and Canada. It includes a control group consisting of patients with concurrent and recent historical open surgical procedures. Subject selection will be based on the inclusion and exclusion criteria listed in Tables I and II. Control subjects are those who do not meet the anatomic inclusion criteria for the endovascular treatment group but otherwise fit the study criteria.

The primary safety hypothesis is that the subjects treated with the Zenith device will have 30-day survival rates equivalent to those of the surgical control group. The secondary hypothesis under investigation is that patients treated with the TX2 stent graft will have equivalent or fewer complications compared with the surgical arm up to 30 days after the procedure. Other outcome measures include 12-month survival, aneurysm-related survival, incidence of rupture and conversion, aneurysm size reduction, rates of MAEs, device-related events, and secondary intervention rates.

The screening process includes a thorough history and physical, an ankle/brachial index, and a preoperative Short Form-36 quality-of-life questionnaire, as well as a preoperative angiography or a contrast-enhanced CT scan. Follow-up physical examination, Short Form-36 quality of life, ankle/brachial index, chest radiograph, and a CT scan of the chest are obtained before discharge at 1, 6, and 12 months after implantation with annual follow-up thereafter up to 5 years. The study started enrolling patients in March 2004 and is nearing its enrollment targets. No results are yet available.

DISCUSSION

Endovascular technology is expected to result in more pronounced benefits in the treatment of aneurysmal disease in the chest than in the abdomen because of the higher morbidity of thoracic aortic procedures. The results of the Gore TAG trials have demonstrated not only the safety and efficacy of the device in the treatment of DTA, but also its unequivocal superiority as compared with open surgical repair.[6] Perioperative mortality and morbidity, particularly with respect to SCI and cardiopulmonary complications, have been noticeably lower than those observed in open surgical repairs. These results warranted the FDA approval of the Gore TAG device for the treatment of DTA.

Thoracic endografts have been commercially available in Europe and in other parts of the world for a few years, with nearly a dozen devices having been tested or currently in use. These endografts have been applied to a variety of clinical settings beyond aneurysmal disease, including aortic dissections, transections, and most other pathologies of the descending thoracic aorta. The US trials have so far resulted in one approved device, and two more are likely to be approved within the next year or two. As of now, the Gore TAG device is approved solely for the treatment of DTA. The upcoming two devices are likely to carry the same indication, because the current trials are similar in enrollment criteria and patient populations. The only difference has been the absence of a concurrently enrolled open surgical control group in the VALOR trial. A wider indication may ultimately be warranted, depending on the results of the high-risk registry group in the VALOR trial. A similar high-risk trial with the Gore TAG device is under way to expand the indications of the device to be more in line with worldwide usage.

No device-specific results are yet available. There are few differences in the design of the devices and their anatomic inclusion criteria worth noting. The TX2 device is the only device designed with an aggressive fixation mechanism and the only one requiring a 3-cm neck in the trials. The other 2 devices require 2-cm minimum landing zones.

The Talent device carries the largest grafts, which allow treatment of a neck as large as 42 mm with a 46-mm diameter graft, whereas the other two are limited to smaller aortic diameters (<37 mm). Early experience with all three is shaping future development. The Gore TAG device has already been modified, and the Talent device is undergoing modifications as of this writing. Additional modifications and improvements are to be expected from all three and future devices to be tested in the United States.

All devices tested to date carry a large profile, ranging from 20F to 25F, and require a large access vessel for introduction. Access to the thoracic aorta continues to be a main source of complications, accounting for all three technical failures in the Gore pivotal trial. In this study, 15% of the patients required access proximal to the femoral artery.[6] The increased prevalence of DTA in women compared with abdominal aneurysms clearly exacerbates this problem. The vascular complication rate with the TAG device was the only category of complications that was more frequently observed in the endovascular group. These high rates of access complication reflect those in the literature[7] and emphasize the need to use conduits as a preventative measure and not as a rescue procedure. It is interesting to note that the incidence of vascular complications in the confirmatory trial was only 6% and did not differ from the control group. This most likely reflects the increased awareness that iliac access represents a major source of complications for thoracic endografting unless a conduit to a more proximal vessel is used.

Although the incidence of spinal ischemic injury was low and less than that reported with open repair,[6-10] it does occur with thoracic endograft repair. Although previous aortic surgery and coverage of long segments of aorta have been reported to portend a higher risk of paraplegia with endovascular repair of DTA,[10-12] the association could not be documented in the TAG study.

Aneurysm sac shrinkage of 38% and an expansion rate of 17% at 2 years with the TAG device are noteworthy.[6] The rate of shrinkage is lower and that of expansion higher than the experience with other endografts.[8,13] These effects have been described with the Excluder abdominal endograft[14] and probably reflect the intrinsic porosity of the ePTFE material that was used in the TAG pivotal study. The commercially released product, however, has a markedly reduced porosity after the modification and is expected to have a different sac response to exclusion, thus avoiding the sac expansion noted previously.

CONCLUSION

In summary, the US trials have so far resulted in one approved device showing that endovascular repair of descending thoracic aneurysms has improved on short- and mid-term results of traditional surgical repair. Treatment may become more acceptable for higher-risk patients, and new trials are expected to expand indications of the technology.

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