Endoluminal stent grafting of the thoracic aorta: Initial experience with the Gore Excluder

Charles S. Thompson, MD, Virginia D. Gaxotte, MD, Julio A. Rodriguez, MD, Venkatesh G. Ramaiah, MD, Mitar Vranic, DO, Rajagopalan Ravi, MD, Leanne DiMugno, MD, Shoaib Shafique, MD, Dawn Olsen, PA, and **Edward B. Diethrich, MD,** *Phoenix, Ariz*

Purpose: **The purpose of this study was to describe our experience with endoluminal graft repair of a variety of thoracic aorta pathologies with a commercially developed device currently under investigation. Our patient population included patients eligible for open surgical repair and those with prohibitive surgical risk.**

Methods: **From February 2000 to February 2001, endovascular stent-graft repair of the thoracic aorta was performed in 46 patients (mean age, 70 years; 29 male and 17 female patients) with the Gore Excluder. Twenty-three patients (50%) had atherosclerotic aneurysms, 14 patients (30%) had dissections, three patients (7%) had aortobronchial fistulas, three patients (7%) had pseudoaneurysms, two patients (4%) had traumatic ruptures, and one patient (2%) had a ruptured aortic ulcer. Patient characteristics, procedural variables, outcome, and complications were recorded. All patients were followed with chest computed tomographic scans at 1, 3, 6, and 12 months. Follow-up period ranged from 1 month to 15 months, with a mean of 8.5 months.**

Results: **All the procedures were technically successful. There were no conversions. Average duration of the procedure was 120 minutes. Average length of stay was 6 days, but most patients (64%) left the hospital within 4 days after endoluminal grafting. The overall morbidity rate was 23%. Two patients (4%) had endoleaks that necessitated a second procedure for successful repair. Two patients (4%) died in the immediate postoperative period. There were no cases of paraplegia. At follow-up examination, one patient had an endoleak found the day after the procedure and another patient had an endoleak 6 months after the procedure. Both cases were treated successfully with additional stent-grafts. There were no cases of migration. One patient died of a myocardial infarction 6 months after graft placement. In patients treated for aneurysm (n = 23), the aneurysm diameter ranged from 5.0 to 9.5 cm (mean, 6.8 cm). Residual sac measurements were obtained at 1, 6, and 12 months, with mean sac reductions of 0.59 cm, 0.77 cm, and 0.85 cm, respectively. In three cases, the sac remained unchanged, without evidence of endoleak.**

Conclusion: **Thoracic endoluminal grafting with the Gore Excluder is a safe and feasible alternative to open graft repair and can be performed successfully with good results. Early data suggest an endoluminal approach to these disease entities may be favorable over classical resection and graft replacement. (J Vasc Surg 2002;35:1163-70.)**

Thoracic aortic dissections, ruptures, fistulas, and aneurysms pose a unique surgical challenge. Traditional repair of thoracic aortic aneurysms involves thoracotomy with graft interposition. Despite advances in perioperative care and both total and partial cardiopulmonary bypass procedures, conventional surgery still carries a significant morbidity and mortality risk. Principal complications include bleeding, paraplegia, stroke, cardiac events, pulmonary insufficiency, and renal failure.[1-5] Recent enthusiasm for innovative endovascular therapies in the treatment of aortic disease has spurred many centers to investigate endoluminal grafting of the thoracic aorta. Early reports on endovascular repair with custom-made "first-generation devices" showed the technique to be feasible with a mortality and morbidity rate comparable with that of open repair.[6-11]

In February 2000, we initiated a single-center research protocol on the basis of an investigational device exception with a "second-generation" device. Improvement in the device design reflected in the Gore Excluder thoracic stent-graft (WL Gore, Flagstaff, Ariz) has allowed us to pursue complex thoracic surgical problems with endovascular approaches. Although previous studies of thoracic stent-grafts have only reported the use in patients at high risk, our population included those patients who would have otherwise been surgical candidates. We report our initial experience with this thoracic aortic endoluminal graft in the treatment of a variety diseases of the thoracic aorta.

From the Department of Cardiovascular and Endovascular Surgery, Arizona Heart Institute and Arizona Heart Hospital.

Competition of interest: nil.

Reprint requests: Edward B. Diethrich, MD, Arizona Heart Institute, 2632 N 20th St, Phoenix, AZ 85006.

0741-5214/2002/$35.00 + 0 **24/1/122885**
doi:10.1067/mva.2002.122885

METHODS

During 2000, 46 patients were admitted to the Arizona Heart Hospital for thoracic endoluminal grafting to treat thoracic aortic aneurysms, pseudoaneurysms, dissections, aortobronchial fistulas, acute traumatic ruptures, and aortic ulcers. All prospective patients were enrolled with the provisions of a Food and Drug Administration Investigational Devices Exemption for the Gore Excluder without exceptions during this period of time. The thoracic Gore Excluder protocol in our institution was in compliance with the Institutional Review Board of the Arizona Heart Hospital.

The Gore Excluder is a self-expandable endoprothesis of an expanded polytetrafluoroethylene tube and an exter-

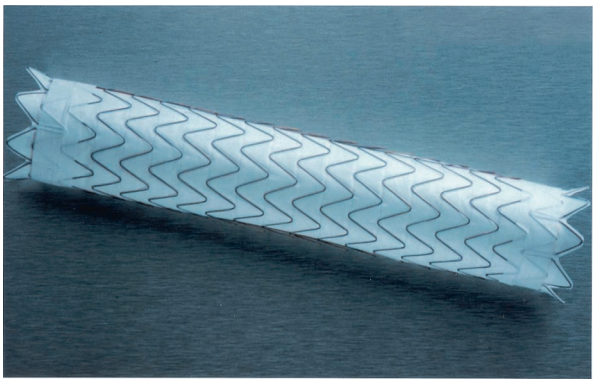

Fig 1. Gore Excluder, self-expandable endoprothesis for thoracic aorta. Device is made of expanded polytetrafluoroethylene inner tube and outer nitinol exoskeleton.

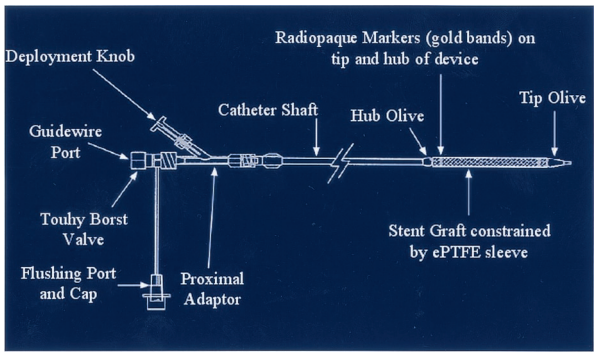

Fig 2. Device loaded on flexible over-wire delivery system with polytetrafluoroethylene sleeve. Wire is pulled for deployment.

nal nitinol wire support structure designed for the thoracic aorta (Fig 1). The graft is mounted on a flexible delivery system and surrounded by a sleeve of expanded polytetrafluoroethylene (Fig 2). A pull wire releases the corset, and deployment occurs first in the middle of the graft and then rapidly proceeds to the proximal and distal ends (Fig 3). A unique trilobed aortic balloon expands the graft for aortic apposition without complete aortic occlusion (Fig 4). The intended size specifications, graft diameters, graft length, and sheath sizes are given in Table I.

Each patient was evaluated by a staff surgeon and underwent chest roentgenography and contrast-enhanced computed tomographic (CT) scanning before the procedure. Angiography was performed with a calibrated catheter for the thoracic aortic component with studies of the abdominal and iliac vessels. Patients were chosen for endoluminal grafting according to presenting pathology and suitability of anatomy for device implantation. The aortic measurements were made from the preoperative studies for determination of device diameter and length. All stent-grafts were oversized 2 mm to 6 mm compared with the proximal neck diameter (Table I). Length of the device was chosen on the basis of the length of the lesion and at least 2 cm of both proximal and distal landing zones. For graft pseudoaneurysms and aortobronchial fistulas caused by previous interposition graft material, a length was chosen to transverse both anastomoses to ensure no further paraanastomotic leakage.

If the lesions were in close proximity to the subclavian artery with less than 2 cm of neck for the proximal landing zone, a standard carotid subclavian bypass procedure or transposition was performed before the endovascular procedure. Distal aortic arch and proximal descending thoracic lesions therefore were treated in our series. These cases were generally staged. However, in one instance, an unplanned procedure was performed immediately after a device was placed over the left subclavian artery. Concern existed not only for an ischemic process but for persistence of retrograde flow to the aneurysmal sac. The origin of the subclavian artery was either ligated or diverted with a transposition to the carotid artery.

All procedures were performed with general anesthesia in endovascular suites equipped with fluoroscopic and angiographic equipment. The artery for transluminal device placement was selected on the basis of the degree of obstructing atherosclerotic plaque. One femoral arery was surgically exposed for device delivery. Percutaneous access was obtained through the contralateral common femoral artery. Through the left brachial artery, a 4F or 5F pigtail catheter was placed to assist in accurate identification of the left subclavian artery.

In those patients with diseased iliac arteries, balloon angioplasty was performed to allow passage of the delivery system. If severe obstructing atherosclerotic plaque in the iliac vessels prohibited femoral artery delivery, an iliac artery delivery was performed through a retroperitoneal approach. The iliac artery was exposed through a transverse lower abdominal incision and retroperitoneal dissection. An end-to-side anastomosis was created between the common iliac artery and a 10-mm Hemashield graft conduit (Boston Scientific, Natick, Mass). The device was transluminally placed into the aorta through this conduit. At the completion of the procedure, this conduit was attached to the common femoral artery, creating an iliofemoral bypass.

Arteriography, transesophageal echocardiography (TEE), and intravascular ultrasound scanning (IVUS) were used to determine precise aortic landing zones. Aortic diameters also were confirmed during the procedure with IVUS. A shelf stock of devices allowed selection of the appropriate size on the basis of the preoperative CT scan measurements and the intraoperative measurements. TEE and IVUS precisely located pseudoaneurysms, fistulas, entry and exit points of dissections, and false lumens that are not easily or accurately detected with aortography or CT scans. A Keller-Tillerman introducer sheath (Cook, Inc, Bloomington, Ind) was inserted through the femoral or iliac artery over a 0.035-inch "superstiff" wire (Amplatz, Meditech, Boston Scientific, Boston, Mass; or Flex Finder, Microvena, White Bear Lake, Mich). The delivery system was loaded onto the wire and through the sheath to the level of the thoracic

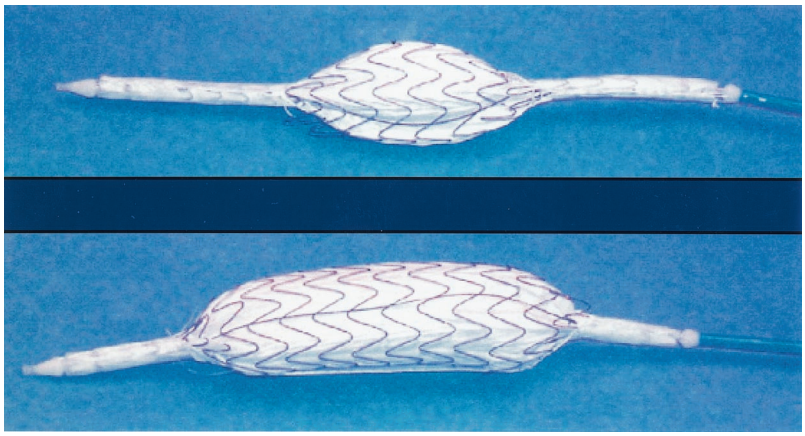

Fig 3. Graft deploys in middle first and then proceeds toward distal ends.

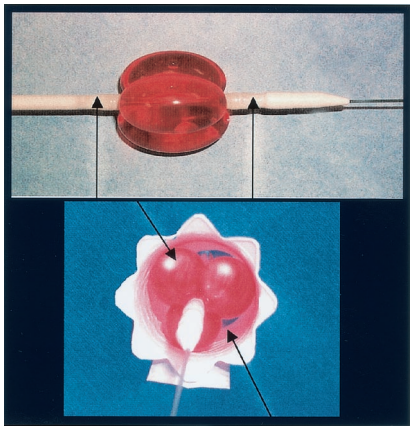

Fig 4. Aortic balloon has trilobed configuration for aortic apposition without impedance of aortic blood flow.

Table I. Gore Thoracic Excluder sizing guide

Intended aortic diameter (mm)	*Endoprothesis diameter (mm)*	*Overall endoprothesis lengths (cm)*	*Recommended sheath size*
23-24	26	7.5, 10, 12.5	22F
24-26	28	7.5, 10, 12.5, 15	22F
26-29	31	7.5, 10, 12.5, 15	22F
29-32	34	10, 12.5, 15, 20	24F
32-34	37	10, 12.5, 15, 20	24F
34-37	40	10, 12.5, 15, 20	24F

aorta. If the rigid sheath could not negotiate tortuous or diseased iliac arteries, then the device was placed "bareback" without the sheath. Arterial control then was managed with a Rummel tourniquet, and device exchange was more complicated. Once the delivery system was in place, arterial pressure was pharmacologically lowered to less than 100 mm Hg before deployment. The device was directed into place with arteriography, fluoroscopy, and TEE. Rapid graft deployment with a pull-wire system prevented significant graft migration. Completion arteriography was performed to confirm adequate placement and exclusion without endoleak. TEE and IVUS confirmed elimination of pulsatile flow in the false lumen of dissections, exclusion of fistulas, and exclusion of aneurysms.

The patients were monitored in the recovery room or intensive care unit overnight. A CT scan was obtained before discharge to confirm adequate placement and lack of endoleak. All postoperative care was directed by the surgical team. Contrast CT scans were repeated at 3 months, 6 months, and 1 year, with routine evaluation for aneurysmal sac measurements and presence of endoleak.

RESULTS

From February 2000 to February 2001, 46 patients at the Arizona Heart Hospital underwent treatment with thoracic stent-graft placement (Figs 5 and 6). The patients were operative and nonoperative candidates. All patients were of American Society of Anesthesiology classification III or IV, on the basis of their comorbid conditions (Table II). A total of 46 patients received 54 grafts during 48 operations for aneurysms, dissections, pseudoaneurysms, aortobronchial fistulas, and an aortic ulcer (Table III). Three patients (6.5%) had contained ruptures. No open conversions were necessary (Table IV). One patient had a significant endoleak after the procedure, which necessitated a return to the operative suite 2 days after the initial procedure. The leak was successfully excluded with a second graft on the second postoperative day. A second patient had an endoleak 5 months after the original graft placement. This also was successfully managed with another device placement.

Access played an important role in facilitating the operation. Iliac arteries with extensive occlusive disease required dilatation and balloon angioplasty to accommodate device placement into the aorta. However, six patients (13%) needed iliac access via a retroperitoneal approach

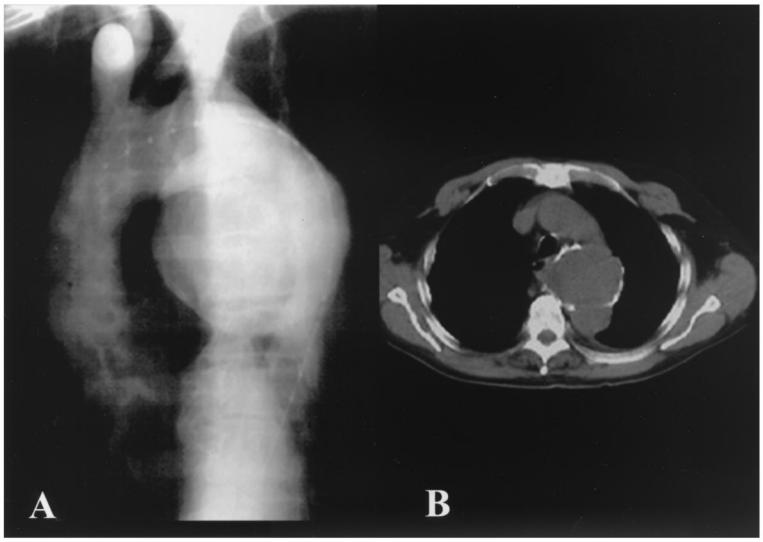

Fig 5. Preoperative angiogram **(A)** and CT scan **(B)** show 7-cm aneurysm in distal aortic arch and proximal descending thoracic aortic in 72-year-old patient.

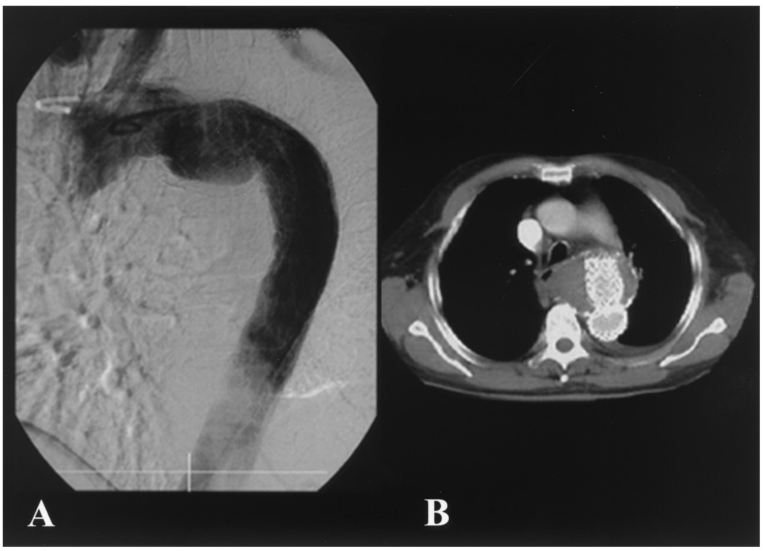

Fig 6. Postoperative angiogram **(A)** and CT scan **(B)** after deployment of Gore Excluder stent-graft show adequate exclusion of aneurysm described in Fig 5. Carotid subclavian bypass procedure was performed before stent placement to allow for adequate landing proximal landing zone.

because of tortuous or diseased iliac arteries, and an iliac-femoral bypass procedure was performed after deployment through an iliac graft conduit. Mean operative time was 120 minutes (Table IV), and the actual surgical time decreased as we became familiar with the operative technique. Mean estimated blood loss was 300 mL. Most patients (64%) left the hospital within 4 days after the stent-grafting. The average length of stay was 5 days, and all patients who stayed longer had second procedures during the same hospitalization (Table V). Seven patients needed carotid subclavian bypass procedure or transposition before stent placement.

Two patients died in the perioperative period, for an early mortality rate of 4% (Table VI). One patient died after an iliac artery rupture caused by a sheath perforation during device deployment. The second death occurred after the repair of a ruptured thoracic aortic aneurysm. An emergency repair was performed with successful device deployment. However, the patient died 24 hours after the procedure. Autopsy results found the cause of death to be diffuse

Table II. Patient characteristics and comorbidities

Patient characteristic/comorbidity	*No.*
Mean age (years; range)	70 (45-86)
Male/female ratio	29/17
Hypertension	34 (73%)
Coronary artery disease	23 (50%)
COPD	20 (44%)
AAA	14 (30%)
Previous thoracotomy	13 (28%)
Peripheral vascular disease	11 (23%)
Hyperlipidemia	9 (20%)
Congestive heart failure	6 (13%)
Renal insufficiency	6 (13%)
Diabetes mellitus	6 (13%)
Previous CVA	4 (9%)
Morbid obesity	3 (8%)
Oxygen dependence	2 (7%)
Steroid dependence	2 (7%)
Multitrauma	2 (7%)

COPD, Chronic obstructive pulmonary disease; *AAA*, abdominal aortic aneurysm; *CVA*, cerebrovascular accident.

Table III. Anatomic characteristics

Lesion	*No.*
Atherosclerotic aneurysm	23 (50%)
Dissection	14 (30%)
Aortobronchial fistula	3 (7%)
Pseudoaneurysm	3 (7%)
Traumatic rupture	2 (4%)
Aortic ulcer	1 (2%)

Table IV. Procedural characteristics

Variable	
Operating time (minutes)	120 (60-350)
Contrast (mL)	360 (106-860)
Blood loss (mL)	292 (100-1000)
Femoral access/iliac access	40/6
Endoleaks	2
Conversions	0
Length of stay (days)	5.6

Table V. Procedures on same admission

Procedure	*No.*
Carotid subclavian bypass or transposition	7
Abdominal aortic aneurysm repair	3
Thrombectomy of iliac conduit	1
Thrombectomy of lower extremity	1
Reexploration of hemorrhage from conduit	1

Table VI. Morbidity and mortality

Complication	*No. of Events*
Pneumonia/atelectasis/prolonged ventilation	5 (11%)
Renal insufficiency (not needing dialysis)	2 (4%)
Groin hematoma	1 (2%)
Iliac conduit hemorrhage	1 (2%)
Iliac conduit thrombosis	1 (2%)
Lower extremity thrombosis	1 (2%)
Mesenteric ischemia	1 (2%)
Stroke	1 (2%)
Early mortality	2 (4%)
Late morality	1 (2%)

Table VII. Changes in aneurysmal sac measurements

Measurements of aneurysms (n = 23; 50%)		*Follow-up interval (mean size/mean reduction)*		
No.	*Before surgery (mean; cm)*	*1 month*	*6 months*	*12 months*
16 (70%)	6.86	6.27 (0.59)	—	—
10 (43.4%)	6.74	—	5.97 (0.77)	—
2 (8.7%)	6.10	—	—	5.25 (0.85)

embolization and ischemia of the visceral organs. A third patient died of a myocardial infarction 6 months after the procedure.

The morbidity rate was 23%, including major and minor events (Table VI). Postoperative complications included pulmonary complications, such as atelectasis and pneumonia, renal insufficiency, mesenteric ischemia, local hemorrhage, iliac conduit, and lower extremity thrombosis. One patient (2%) had a left hemispheric cerebrovascular accident after the procedure. There were no cases of paraplegia. There were no cases of renal failure requiring dialysis.

The follow-up period ranged from 1 to 15 months, with a mean of 8.5 months. During the follow-up period, residual sac measurements were obtained in patients who underwent treatment for aneurysms or dissections with aneurysmal changes. Before surgery, the size of the sac ranged from 5.0 to 9.5 cm, with a mean of 6.8 cm. Sac measurements were available in 16 of the 23 patients with aneurysms (70%) (Table VII). At 1 month, the sac shrunk from a mean of 6.86 cm to 6.27 cm, for a mean reduction of 0.59 cm. At 6 months, 10 of 23 patients (43.4%) had sac measurements available. In seven of 10 patients (70%), the sac reduced from a preoperative mean of 6.74 cm to 5.97 cm, for a mean reduction of 0.77 cm. In the remaining three cases, the sac was unchanged. No symptoms or endoleaks were found in those patients.

At 12 months, two patients had sac measurements. Diameter decreased from 6.1 cm to a mean of 5.25 cm, for a mean reduction of 0.85 cm (Table VII). All grafts remained patent and properly positioned. There were no ruptures.

DISCUSSION

Conventional surgical treatment of thoracic aortic aneurysms, dissections, ulcers, aortobronchial fistulas, pseudoaneurysms, and traumatic ruptures involves open thoracotomy, aortic cross clamping, extracorporeal circulation, and

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.