

◆ CLINICAL INVESTIGATION ◆

Endovascular Repair of Thoracic Aortic Disease With the EndoFit Stent-Graft: Short and Midterm Results From a Single Center

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Purpose: To analyze the outcomes of endovascular treatment of thoracic aortic pathologies performed at a single center with the EndoFit thoracic stent-graft system.

Methods: From January 2002 to January 2007, 41 patients (33 men; mean age 69.3 ± 9.7 years, range 48–84) were treated for thoracic aortic disease with the EndoFit stent-graft system. Patient data were retrieved from a retrospective review of hospital records. Indications for treatment were progression of aneurysm size in atherosclerotic aneurysms ($n=24$, mean aneurysm diameter 7.19 ± 1.48 cm), acute contained aortic rupture ($n=5$), aortic dissection ($n=6$), penetrating atherosclerotic ulcers ($n=4$), post-traumatic pseudoaneurysm ($n=1$), and post coarctation repair aneurysm ($n=1$).

Results: The EndoFit stent-graft was successfully deployed in all 41 patients. The in-hospital and 30-day mortality rate was 7.3% (3 patients). Three (7.3%) postoperative endoleaks were recorded: a proximal type Ia and a distal Ib both resolved spontaneously at 1 and 3 months, respectively. The third patient had a persistent type Ia endoleak; conversion was necessary after 1 year. There was only 1 case of spinal ischemia, with consequent lower extremity weakness; no paraplegia was observed. During a mean 24.8-month follow-up, 2 secondary type Ia endoleaks were treated with additional stent-grafts. There were 7 (17%) deaths during follow-up. At 2 years, overall patient survival by Kaplan-Meier analysis was 70%; aneurysm-related survival was 89%.

Conclusion: Endovascular treatment of vascular disease involving the descending thoracic aorta can be safely performed with the EndoFit thoracic stent-graft system.

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Key words: endovascular aneurysm repair, thoracic aortic disease, thoracic aortic aneurysm, thoracic aortic dissection

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The incidence of thoracic aortic aneurysm (TAA) is growing universally due to the aging population and the increased use of diagnostic procedures in other aortic pathologies.^{1,2} For specific pathologies such as atheroscle-

rotic aneurysm, dissection, intramural hematoma, penetrating ulcer, or post-traumatic pseudoaneurysm, open surgical repair of thoracic aorta has been considered the gold standard treatment strategy.^{3,4} However, in

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comparison to open surgery, endovascular repair of thoracic aortic disease has proven to reduce perioperative mortality, operative time, intensive care unit (ICU) stay, and major complications, especially spinal cord ischemia with resultant paraplegia.^{5,6} The risks of open surgery of the thoracic aorta are prohibitive in an elderly population (>75 years), many of whom have multiple comorbidities (cardiac, pulmonary, and/or renal).^{7,8} For selected patients with suitable aortic anatomy, endovascular treatment of thoracic aortic disease may offer both short- and midterm advantages to open surgery, as it avoids a thoracotomy and aortic clamping.^{9–11}

Over more than 7 years, our institution has treated nearly 100 patients with thoracic endografts, acquiring experience and analyzing the characteristics of the different and most commonly used endografts (Talent, Excluder, and Zenith). In 2002, we began using the EndoFit thoracic stent-graft, which has a flexible introducer for navigating sharply curved aortic anatomies without kinking and a tapered stent-graft design, for chronic type B aortic dissection. The aim of this study was to report the early and midterm results from our experience with this device.

METHODS

The EndoFit Stent-Graft system (LeMaitre Vascular, Burlington, MA, USA) is composed of self-expanding nitinol stents that are encapsulated in 2 layers of expanded polytetrafluoroethylene fabric using a thermal process that avoids the need for fixation sutures (Fig. 1A). The EndoFit thoracic stent-graft is currently available in proximal and distal graft diameters of 30 to 42 mm and a graft length of 12 to 24 cm. Proximal extenders and cuffs with and without external fixation are also available, as is a true tapered stent-graft in sizes ranging from 42 mm at the proximal end down to 24 mm distally over a length of 24 cm.

The stent-graft introducer is a 22-F or 24-F hydrophilic sheath with a tapered conical dilator over a 0.035-inch stiff guidewire. Stent-graft-loaded cartridges (Fig. 1B) are also available, which can be deployed through the hydrophilic introducer sheath.

From October of 2006, the Flexi-Tip introducer tip was available with a shorter, more flexible tip designed to reduce trauma during passage above the aortic arch. Deployment is effected using the push-and-pull technique.

Patient Population

In a retrospective review of our hospital's records from January 2002 to January 2007, 41 consecutive patients (33 men; mean age 69.3 ± 9.7 years, range 48–84) were identified as undergoing endovascular repair of thoracic aortic disease using the EndoFit stent-graft. Informed consent and institutional review board approval had been obtained for all patients.

Many patients had several risk factors and so were judged to have high open surgical risk (Table 1). The indications for treatment were progression of aneurysm size in 24 (58.5%) atherosclerotic aneurysms with a mean aneurysm diameter of 7.19 ± 1.48 cm; acute contained aortic rupture in 5 (12.2%) patients (2 presented aorto-esophageal fistula as a complicating factor); recurrent pain and persistent hypertension or progression of aneurysm size despite maximal medical therapy in 6 (14.6%) patients with aortic dissection; recurrent pain in 4 (9.8%) patients with penetrating atherosclerotic ulcers, 1 (2.4%) post-traumatic pseudoaneurysm, and 1 (2.4%) patient with post coarctation repair aneurysm.

Patient Evaluation

All patients underwent preoperative helical computed tomographic angiography (CTA) of the chest, abdomen, and pelvis, with 3- or 5-mm increments and 3-dimensional reconstruction to determine the location, length, and diameter of the diseased aortic segment and the adequacy of distal vascular access. The anatomical suitability for endovascular grafting was determined by a proximal neck ≥ 1.5 cm long and a distal aortic neck ≥ 2 cm in length. Stent-graft dimensions were calculated from CTA images, with 10% to 20% oversizing of the landing zone diameter; in cases of aortic dissection, oversizing did not

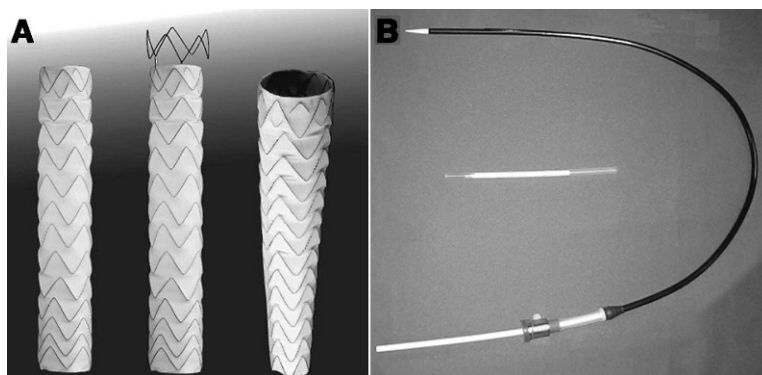


Figure 1 ♦ (A) Different configurations of the EndoFit thoracic stent-graft, from left: without external fixation, with fixation, and tapered. (B) Cartridge-loaded graft (center) and the Endomed Introducer System.

exceed 10%. In patients with a short proximal neck, a careful examination of the extra- and intracranial circulation was performed to determine if there was a need for a pre- or perioperative carotid-subclavian bypass.

Technique

After surgical exposure, the common femoral artery was the most common site for insertion, but a retroperitoneal or a right subclavian approach was used as necessary if this access was inadequate. All patients received systemic heparin (70 U/kg). A 6-F pigtail was placed through the contralateral femoral artery to perform angiography. Intraoperative transesophageal echocardiography was routinely used in aortic dissection patients to position the stent-graft into the true lumen and to monitor the efficacy of the procedure. Pharmacological hypotension (systolic blood pressure 80 mmHg) was induced with nitroglycerine at the time of graft deployment. In the event of an endoleak, additional balloon dilations with a special trilobe balloon (W.L. Gore & Associates, Flagstaff, AZ, USA) were performed or an additional stent-graft was placed.

Follow-up

In all patients, a CT scan was routinely performed at 1, 6, and 12 months and annually thereafter; in patients with a perioperative endoleak, a CT scan was also obtained at

3 months. All significant events and deaths were recorded. Aneurysm-related mortality referred to a death that occurred within 30 days of the procedure or a death due to aneurysm rupture at any time.

Statistical Analysis

Categorical data are described as the number and percentage of patients. Continuous variables are presented as mean \pm standard deviation. Kaplan-Meier survival analyses were used to plot rates for freedom from death, aneurysm-related death, and secondary interventions. Statistical analysis was performed with SPSS statistical software (version 13.0; SPSS, Chicago, IL, USA).

RESULTS

Stent-graft deployment was successful in all patients. General anesthesia was used in 14 (34.1%) patients and spinal or epidural anesthesia in 27 (65.8%). Proximal stent-graft diameters ranged from 28 to 42 mm; only 3 grafts were implanted without free-flow external fixation. Nineteen (46%) patients had more than 1 graft implanted, with overlaps of at least 2 to 4 cm. The stent-grafts covered the origin of left subclavian artery in 3 patients with a short proximal neck, but no one developed ischemic posterior circulation symptoms or left arm ischemia.

There were 2 access complications: a femoral artery dissection and an iliac artery

Table 1

Demographics and Characteristics of 41 Patients Treated With the EndoFit Stent-Graft

Age, y	69.3±9.7
Male	33 (80.5%)
Hypertension	41 (100.0%)
Hyperlipidemia	15 (37.0%)
Coronary artery disease	13 (31.7%)
Chronic obstructive pulmonary disease	21 (51.2%)
Peripheral vascular disease	3 (7.3%)
Renal failure	17 (41.5%)
Smoking	29 (70.7%)
Diabetes mellitus	5 (12.2%)
Abdominal aortic aneurysm	8 (19.5%)
Previous stroke	8 (19.5%)

Continuous data are presented as means ± standard deviation; categorical data are given as counts (percentages).

rupture; both were surgically repaired without any consequence.

There were 3 (7.3%) in-hospital deaths. The first patient was a 76-year-old man with a 7-cm thoracic aneurysm and a history of previous myocardial infarction (MI) and low left ventricular ejection fraction. He did not tolerate hypotension during graft deployment and developed cardiogenic shock; he died of cardiac arrest in multiorgan system failure after 2 weeks. The other 2 patients were a 65-year-old man with hypertension, severe chronic obstructive disease, and previous stroke and an 82-year-old woman with hypertension, severe chronic obstructive disease, dyslipidemia, abdominal aortic aneurysm (AAA), coronary artery disease, and peripheral artery disease. The man was treated for an 8-cm thoracic aneurysm and the woman for contained rupture of a 10-cm aneurysm in an emergent procedure. Both patients developed fatal stroke 1 and 2 days after the procedure, respectively.

There were no cases of acute MI, dialysis, respiratory failure, graft migration, infection, or fracture (Table 2). There was, however, 1 instance of spinal ischemia, with consequent lower extremity weakness, but no paraplegia was observed in our population.

At discharge, 2 proximal type I endoleaks existed, 1 resolved spontaneously 30 days post graft deployment, but the other eventu-

Table 2

Thirty-day Postoperative Complications and Mortality

Stroke	2 (4.8%)
Acute myocardial infarction	0
Dialysis	0
Respiratory failure	0
Spinal ischemia with lower extremity weakness	1 (2.4%)
Paraplegia	0
Graft migration or fracture	0
Intraoperative arterial injury	2 (4.8%)
Type I endoleak	3 (7.3%)
Type II endoleak	0
Type III endoleak	0
Mortality	3 (7.3%)

ally required open conversion after 1 year. One distal type Ib endoleak resolved spontaneously after 3 months. Over a mean 24.8±18-month follow-up (range 1–60), 2 new type Ia endoleaks were found at 20 months and after 4 years. The endoleaks were treated with additional stent-grafts, and both patients are in good health.

One other patient developed a retrograde type A dissection 15 months post procedure and underwent emergent replacement of the aortic valve and ascending aorta with an uneventful postoperative course.

There were 7 (17%) deaths during the follow-up period (Table 3). The mean age was 76 years, and all had multiple, severe comorbidities, including coronary artery disease (n=3), previous stroke (n=2), severe chronic obstructive disease (n=5), history of cancer (n=2), and concomitant AAA repair (n=1). However, only 1 of these deaths was aneurysm-related. The 73-year-old man had a 7-cm aneurysm excluded with an EndoFit stent-graft. Seventeen months after the procedure, the patient complained of sudden chest pain; CT in an outlying hospital showed sac enlargement, even though the CT scan 7 months prior had shown no endoleak or aneurysm expansion, and his blood pressure was under control. The patient was immediately transferred to our hospital, but he died 10 minutes after arrival. Rates for freedom from all mortality and from aneurysm-related mortality (Fig. 2) at 2 years were 70% and 89%, respectively. The Kaplan-Meier

Table 3

Midterm Outcomes in 41 Patients Treated With the EndoFit Stent-Graft

Follow up, mo	24.8±18
Range, mo	1 to 60
Late deaths (>30 days)	7 (17%)
Secondary endoleaks (>30 days)	2 (4.8%)
All reinterventions	4 (9.7%)

curve for freedom from secondary endovascular or open interventions is shown in Figure 3.

DISCUSSION

Endovascular stent-graft treatment of patients with thoracic aortic disease was introduced in 1992 at Stanford University, and in 1994 Dake and colleagues¹² reported the results of their initial experience. It was initially indicated for the treatment of descending TAA using custom-made devices for high surgical risk patients, subsequently also in patients with aortic dissection and penetrating atherosclerotic ulcers.^{13,14}

In comparison to open surgery, stent-graft repair is a less invasive alternative in the treatment of thoracic aortic disease, especially in elderly patients who very often have significant comorbidities, including coronary and cerebrovascular disease, renal failure, and chronic obstructive pulmonary disease. In fact, among these patients, respiratory complications and severe renal failure represent the most frequent cause of morbidity and mortality, ranging from 5.3% to 33% and 2.5% to 13.3%, respectively.¹⁵ Okita et al.¹⁶ showed that the most severe complication after thoracic aortic surgery in septuagenarians and octogenarians was postoperative stroke, which represented a strong incremental risk factor for both early and late death.

Another major complication of open surgery in the descending aorta is spinal cord ischemia, which has been associated with perioperative hypotension, prior history of infrarenal AAA repair, and long segment coverage of the thoracic aorta compromising the intercostal arteries to the spinal cord. In fact, despite advances in surgical technique such as reimplantation of intercostal arteries and shortened cross-clamping times, this

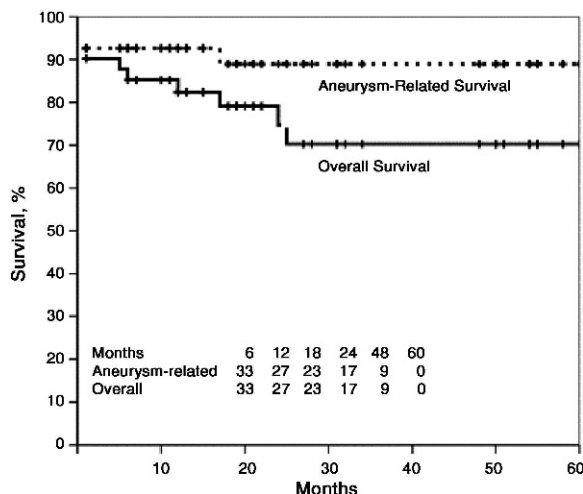


Figure 2 ◆ Kaplan-Meier survival curves.

complication occurs in ~7% to 17% of cases.⁶ However, in our series of 41 patients in whom no protective maneuvers (spinal fluid drainage) were used, we encountered no paraplegia and only 1 case of paraparesis in a 65-year-old man with hypertension, dyslipidemia, diabetes, coronary artery disease, and severe chronic obstructive disease. His 8-cm thoracic aneurysm was excluded with 2 EndoFit devices (40×220 and 42×130 mm). This is an interesting result, particularly if we compare this data to the spinal neurological events in other endovascular studies.^{17,18} In our experience, reducing the duration of hypotension during device deployment and then restoring blood pressure to ≥120/80 mmHg soon after may reduce ischemic time to the spinal cord.

The EndoFit device has a 22- or 24-F hydrophilic introducer sheath to limit vascular complications, so one femoral artery has to have a diameter of >7 mm. In our study, the common femoral artery was the most common site for access, but 3 patients required a retroperitoneal approach due to an inadequate femoral artery. Another patient had a right subclavian approach due to the occlusion of the abdominal aorta. Our 4.8% rate of vascular complications was less than the 10% to 15% reported.^{19,20}

Three patients with a short proximal neck had the origin of the left subclavian artery covered, which typically causes few complications.²¹ It is our practice to reserve pre- or

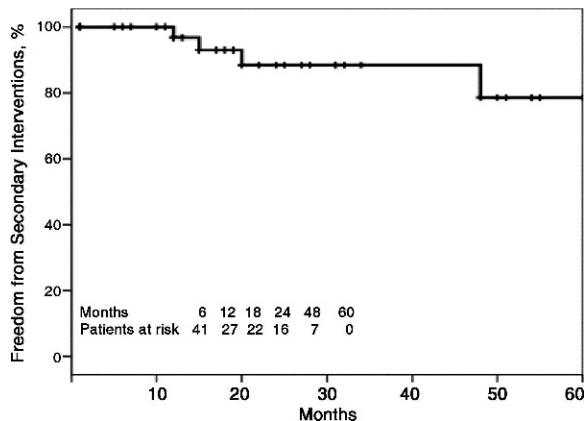


Figure 3 ♦ Freedom from secondary endovascular or open surgical intervention.

perioperative carotid-subclavian bypass for those in whom it is necessary to preserve the left internal mammary artery and/or left vertebral artery due to critical posterior cerebral circulation (left dominant vertebral artery; aberrant, occluded, or critically stenosed right vertebral artery).

In-hospital and 30-day mortality for emergent and non-emergent cases treated by open surgical repair have ranged from 5.5% to 22.6% and up to 39% in patients with ruptured TAA and acute aortic dissection.^{22–24} The EUROSTAR and UK Thoracic Endograft registry reported a 30-day mortality of 9.3%,²⁵ which was higher than ours (7.3%).

We had a low incidence (7.3%) of endoleaks compared to other studies.^{26–29} While 2 of the type I endoleaks resolved, the third persisted at discharge and eventually led to conversion after 1 year. This patient had a type A aortic dissection and underwent open surgical repair of the arch and ascending aorta with reimplantation of the left carotid artery during the same hospital admission in which the EndoFit device was implanted in the descending aorta. Our strategy in patients with type B aortic dissection is to cover the proximal entry point and to stent the entire dissected descending aorta because aortic remodeling is induced by thrombosis of the false lumen.^{30,31}

Our low rate of late endoleaks (4.8%, both type I) is, in our opinion, a result of the EndoFit stent-graft's flexibility and tapered design, which enable customized seating of the graft in the thoracic aorta. Moreover, we



Figure 4 ♦ Large (8.5 cm) aneurysm of thoracic aorta excluded with 2 Endofit stent-grafts that adapted very well to the native aortic tortuosity.

believe that the flexibility of the introducer system minimizes vascular complications compared to the other devices.^{18,19} The flexible introducer can be navigated through sharply curved aortic anatomies without kinking (Fig. 4). We also saw no stent fractures or collapse in our 41 patients.

Our data are similar to those of Saratzis et al.³² but differ from those reported by Melissano et al.³³ In our opinion, the disappointing results of the Melissano group were the consequence of the small, heterogeneous group of patients and treatment of patients with very critical anatomies in their learning curve (their previous experience with endovascular exclusion of thoracic aortic disease comprised 31 patients treated with 29 Excluder and 2 Talent stent-grafts). As in the Saratzis study, we did not select patients (they were at high surgical risk with aortic dissection, penetrating atherosclerotic ulcers, and acute contained rupture), and we also used the EndoFit device to treat very difficult anatomies.

The natural course of untreated TAA is correlated to aneurysm size.³⁴ A recent study reported a 3-year survival of 50% to 70% after surgery for TAA and aortic dissection.³⁵ In our cohort, the 17% late mortality rate was owing largely to underlying pathologies. In fact, we saw only 1 aneurysm-related death in a mean 2-year follow-up.

Conclusion

Our results suggest that the EndoFit stent-graft system offers the potential to treat even

high surgical risk patients with confidence and overall good results. This is largely due to the technical features of this device, availability of a wide range of stent-grafts for specific anatomies, and the flexibility of the EndoFit introducer sheath. With all variables considered, we can conclude that positive results have been obtained with the EndoFit stent-graft. Longer follow-up is needed to confirm these short and midterm results.

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