Expert Consensus Document on the Treatment of Descending Thoracic Aortic Disease Using Endovascular Stent-Grafts*

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Between 43,000 and 47,000 people die annually in the United States from diseases of the aorta and its branches and continues to increase. For the thoracic aorta, these diseases are increasingly treated by stent-grafting. No prospective randomized study exists comparing stent-grafting and open surgical treatment, including for disease subgroups. Currently, one stent-graft device is approved by the Food and Drug Administration for descending thoracic aortic aneurysms although two new devices are expected to obtain FDA approval in 2008. Stent-graft devices are used "off label" or under physician Investigational Device Exemption studies for other indications such as traumatic rupture of the aorta and aortic dissection. Early first-generation devices suffered from problems such as stroke with insertion, ascending aortic dissection or aortic penetration from struts, vascular injury, graft collapse, endovascular leaks, graft mate-

See Appendix for authors' financial relationships with industry.

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Abbreviations and Acronyms

AAA	= abdominal aortic aneurysms
CT	= computed tomography
EVAR	= endovascular aneurysm repair
HRQL	= health-related quality of life
IDE	= Investigational Device Exemption
IMH	= intramural hematoma
INSTEAD	= INvestigation of STEnt grafts in patients with type B Aortic Dissection study
PAU	= penetrating aortic ulcers
SC	= surgical controls

rial failure, continued aneurysm expansion or rupture, and migration or kinking; however, the newer iterations coming to market have been considerably improved. Although the devices have been tested in pulse duplicators out to 10 years, long-term durability is not known, particularly in young patients. The long-term consequences of repeated computed tomography scans for checking device integrity and positioning on the risk of irradiation-induced cancer remains of concern in young patients. This document (1) reviews the natural history of aortic disease, indications for repair, outcomes after conventional open surgery, currently available devices, and insights from outcomes of randomized studies using stent-grafts for abdominal aortic aneurysm surgery, the latter having been treated for a longer time by stent-grafts; and (2) offers suggestions for treatment.

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Any decision to offer a patient with an aneurysm of the descending thoracic aorta a procedure, either open or endovascular, must balance the patient's expected prognosis and life expectancy without intervention against the risk of undergoing the procedure. At present, for descending thoracic aorta repairs, there is no level A or B evidence (results from prospective, randomized trials) to compare medical therapy with surgical intervention. Furthermore, there is no level A or B evidence comparing the results of open procedures with endovascular stent-graft procedures. The purpose of this document is to present a consensus expert opinion of cardiothoracic, cardiovascular, and vascular specialists who treat patients with thoracic aortic disease. The writing committee is well aware that these are general recommendations and that the final decision about when an intervention is justified and what type of intervention should be used must, of necessity, rest with the primary treating physician.

Natural History of Descending Thoracic Aortic Aneurysms

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To determine appropriate criteria for surgical intervention and type of surgical therapy, it is important to understand the natural history of untreated aneurysmal thoracic aorta. For the descending thoracic aorta, a significant aneurysmal dilatation is usually defined as an aorta twice the diameter of the patient's contiguous normal aortic caliber. Thus, in an average-height older man with an expected distal aortic arch diameter of 2.8 cm, a proximal descending aortic dilatation measuring 5.6 cm or greater is defined as aneurysmal [1]. Thus, for most patients, the descending thoracic aorta should have a diameter greater than 5.5 cm to be considered for surgery, as discussed later.

Specific aspects of the natural behavior of the human diseased aorta are examined next [2–6].

Growth Rate of Aortic Aneurysms

In adults, the normal aorta grows very slowly. Published reports note that in older populations, the ascending aorta grows at a rate of about 0.07 cm per year and the descending and thoracoabdominal aorta at a rate of about 0.19 cm per year [4]. Thus, when aneurysmal disease is present, growth of the aneurysm tends to follow an indolent course. Indeed, many reports of rapid growth of aneurysms in individual patients are related to measurement errors; that is, they either compare nonidentical segments of the aorta in sequential studies or measure an oblong aortic axis where the aorta courses transversely in the thorax. Clearly, symptomatic patients, for example those with acute aortic dissection, leak, or rupture, require immediate treatment, if feasible. Bona fide acute, rapid aortic growth is most often seen in the case of an aortic dissection or contained rupture, or with mycotic aneurysms that have developed in the interval between measurements.

Once aortic dissection has occurred, the aorta grows more rapidly—consistent with the concept that its restraining outer wall is now thinner than it was originally, containing only a fraction of the original number of lamellae. In the ascending and descending segments, the nondissected aorta grows at a rate of 0.09 cm per year and the dissected aorta grows at a rate of 0.14 cm per year [4]. The dissected descending and thoracoabdominal aorta may grow as rapidly as 0.28 cm per year [1, 2]. The larger the aorta, the faster it grows, as seen in Figure 1 [2].

It is important to note that the method used to measure aortic size can influence recorded diameter. Aortography can overestimate the luminal diameter. Echocardiography, magnetic resonance angiography, and computed tomography (CT) angiography measure intraluminal diameter, whereas CT measures external diameter. For the purpose of this review, external aortic CT measurement

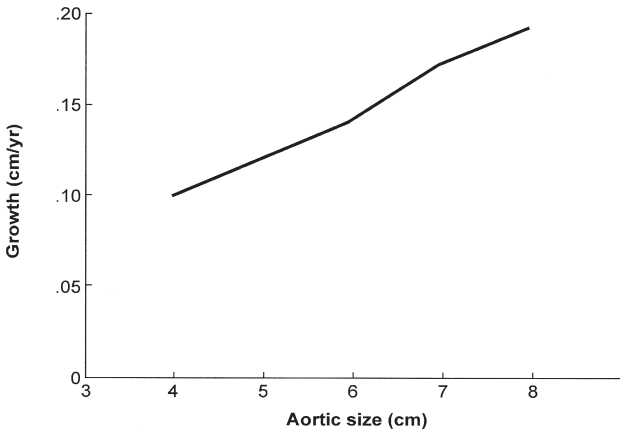

Fig 1. Growth rate as a function of aortic diameter. (Reprinted from J Thorac Cardiovasc Surg, 113, Coady MA et al, What is the appropriate size criterion for resection of thoracic aortic aneurysms? 476–91, Copyright (1997), with permission from Elsevier [2].)

of the external aorta diameter perpendicular to flow is used because this is usually the first study, and it is used most often for serial measurements.

Several important corollaries for assessing the effectiveness of endovascular stent-grafting are suggested by the growth rate data:

1. *The slow rate of growth of the aorta implies that, to be meaningful, longitudinal studies of the effectiveness of endovascular stent therapy must include long-term radiologic follow-up.* Even 3-year follow-up data may be inadequate, because measured dimensions may vary by several millimeters from scan to scan. Five-year follow-up would appear to be the shortest interval that permits accurate assessment of any true impact of stent-graft therapy on the natural growth of aortic aneurysms. Computer-calculated quantitative three-dimensional aneurysm volume measurements may be more precise.
2. *Endovascular stent-grafts must halt the process of aneurysm growth to maintain long-term effectiveness.* Otherwise, growth begets faster growth.
3. *The accelerating rate of growth of aortic aneurysms with increasing size introduces the potential for progressive outward traction on the proximal and distal "landing zones" for stent-graft fixation.* Follow-up studies beyond 3 to 5 years must include careful examination for endoleak and stent dislodgment or migration. Furthermore, aneurysms increase not only in diameter but also in length, increasing the risk of stent-graft kinking or foreshortening of the original landing zones.

Rates of Rupture, Dissection, and Death

One method of analysis examines rates of rupture or dissection according to maximum diameter as determined by CT. This lifetime risk is shown in Figure 2 [2].

In asymptomatic patients with aneurysms, there are sharp "hinge points" for both the ascending and descending aorta that demarcate the highly dangerous aortic diameter thresholds. For the ascending aorta, the hinge point occurs at 6 cm, with a 34% risk of rupture or dissection by the time the aorta reaches this dimension. For the descending aorta, the hinge point is 7 cm, with a 43% risk of rupture or dissection. Suggested *conservative* criteria for surgical intervention have been developed using these hinge points. Intervention at a diameter of 5.5 cm for the ascending aorta and 6.5 cm for the descending aorta will preempt most ruptures and dissections. Smaller size criteria are applied to patients with Marfan syndrome and those with a positive family history for aortic rupture or dissection. For example, in patients with Marfan syndrome or a bicuspid aortic valve, 15% of ascending aortic dissections occur when the ascending aorta diameter is less than 5.0 cm. Hence, dividing the ascending aortic maximal cross-sectional area (in square centimeters) by the patient's height (in meters) and using a cut-off threshold of 10 has been suggested as an indication for operation [5, 6]. This calculation also takes into account the more rapid increase in size for larger aneurysms and the greater risk of rupture or dissection in shorter patients.

Designation of a size criterion at which intervention is indicated and justified depends on balancing the risks of the procedure against its potential benefit. At centers with very low surgical mortality and vast experience, intervention may, on occasion, be justified for asymptomatic patients with smaller aortic sizes (ie, $<$ 5 cm for the ascending aorta and $<$ 6 cm for the descending and thoracoabdominal aorta in patients who have connective tissue disorders or chronic aortic dissection, particularly with evidence of an increased growth rate).

These criteria apply only to asymptomatic patients. *Symptomatic aneurysms should be treated regardless of size if there are no other contraindications, because symptoms often portend rupture.* Aneurysms may cause symptoms such as

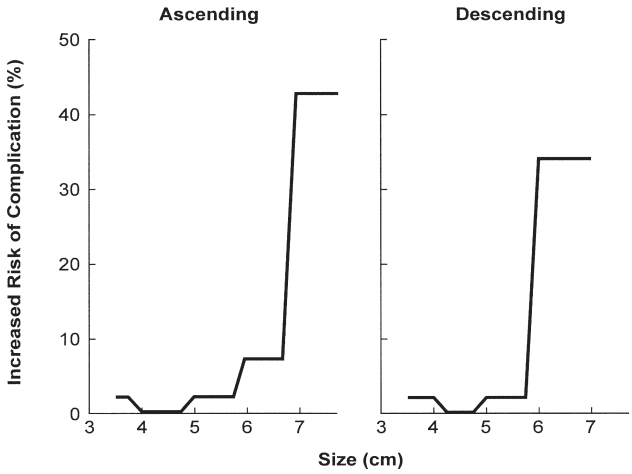

Fig 2. Risk of rupture or dissection over lifetime according to ascending (left) or descending (right) aortic size. Note hinge points at which natural complications rise sharply. (Reprinted from J Thorac Cardiovasc Surg, 113, Coady MA et al, What is the appropriate size criterion for resection of thoracic aortic aneurysms? 476–91, Copyright (1997), with permission from Elsevier [2].)

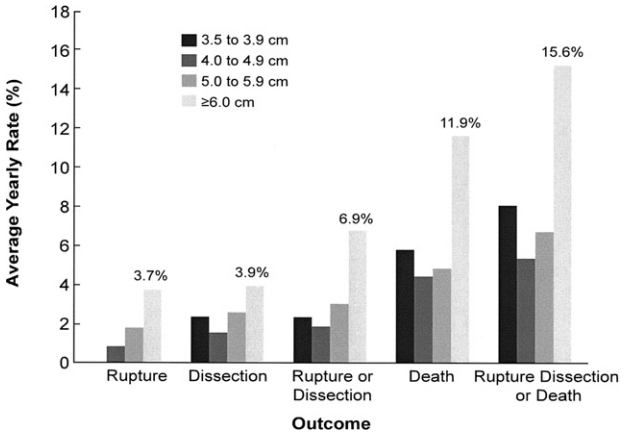

Fig 3. Yearly rates of rupture, dissection, or death based on aortic size. (Black bars = 3.5 to 3.9 cm; dark gray bars = 4.0 to 4.9 cm; medium gray bars = 5.0 to 5.9 cm; light gray bars = 6.0 cm or more.) (This article was published in Ann Thorac Surg, 73, Davies RR et al, Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size, 17–28, Copyright (2002), with permission from Elsevier [4].)

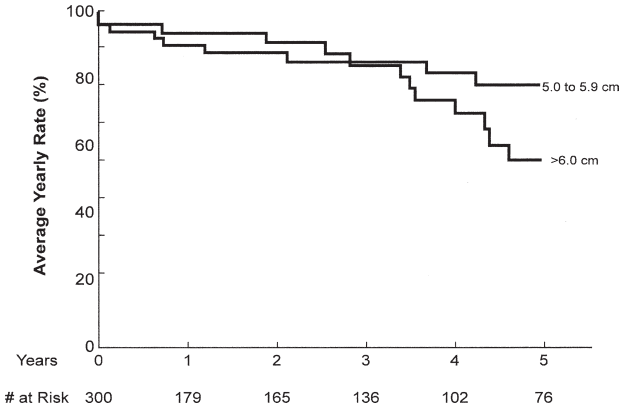

Fig 5. Survival (y-axis) before operative repairs as a function of initial aortic size. (This article was published in Ann Thorac Surg, 73, Davies RR et al, Yearly rupture or dissection rates for thoracic aortic aneurysms: simple prediction based on size, 17–28, Copyright (2002), with permission from Elsevier [4].)

back pain, hoarseness, dysphagia, dyspnea, and arrhythmia, but by the time these symptoms occur, the aortic diameter will usually be greater than 5 cm.

Another method used to determine appropriate criteria for intervention involves analyzing yearly rupture rates [4]. Such analysis requires extremely robust data, with a sufficient number of hard endpoints (rupture, dissection, death). Results indicate that risks of rupture, dissection, and death increase at a roughly exponential rate after the aorta reaches a diameter of 6 cm (Fig 3).

Events occur more commonly after the aorta exceeds 6 cm in diameter: The rates of rupture and of dissection are both approximately 4% annually. The annual rate of death (mostly, but not entirely, aorta related) is approximately 12% per year. The combined rate of rupture, dissection, and death is approximately 16% annually. Thus, these risks should be weighed against an institution's operative outcomes and discussed honestly with the patient. There is, however, no evidence that asymptomatic aneurysms smaller than 5.5 cm benefit from surgical repair unless other indications apply, as previously noted.

Aortic size varies with body size. Adjustment of criteria for intervention can be made on the basis of clinical judgment (intervene at a smaller aortic size for a small woman, at a larger size for a large man) or using nomograms adjusted for body surface area or height (Fig 4). Using the simple "2*x*" rule mentioned above takes into account the patient's most likely aortic size, equivalent to an internal barometer. It should be remembered, though, that in some patients (eg, those with chronic aortic dissection and diffuse aortic ectasia or "mega-aorta syndrome"), no truly normal aorta exists for comparison.

It is instructive to look at population survival curves for patients with thoracic aortic aneurysm. As seen in Figure 5

	Aortic Size (cm)									
BSA	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0	7.5	8.0
1.30	2.69	3.08	3.46	3.85	4.23	4.62	5.00	5.38	5.77	6.15
1.40	2.50	2.86	3.21	3.57	3.93	4.29	4.64	5.00	5.36	5.71
1.50	2.33	2.67	3.00	3.33	3.67	4.00	4.33	4.67	5.00	5.33
1.60	2.19	2.50	2.80	3.13	3.44	3.75	4.06	4.38	4.69	5.00
1.70	2.05	2.35	2.65	2.94	3.24	3.53	3.82	4.12	4.41	4.71
1.80	1.94	2.22	2.50	2.78	3.06	3.33	3.61	3.89	4.17	4.44
1.90	1.84	2.11	2.37	2.63	2.89	3.16	3.42	3.68	3.95	4.22
2.00	1.75	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
2.10	1.67	1.90	2.14	2.38	2.62	2.86	3.10	3.33	3.57	3.80
2.20	1.59	1.82	2.05	2.27	2.50	2.72	2.95	3.18	3.41	3.64
2.30	1.52	1.74	1.96	2.17	2.39	2.61	2.83	3.04	3.26	3.48
2.40	1.46	1.67	1.88	2.08	2.29	2.50	2.71	2.92	3.13	3.33
2.50	1.40	1.60	1.80	2.00	2.20	2.40	2.60	2.80	3.00	3.20

= low risk (~4% per yr) = moderate risk (~8% per yr) = severe risk (~20% per yr)

Fig 4. Risk of aortic complications by aortic diameter and body surface area (BSA), with aortic size index given within chart. (Unshaded area = low risk [approximately 4% per year]; light gray area = moderate risk [approximately 8% per year]; dark gray area = severe risk [approximately 20% per year].) (This article was published in Ann Thorac Surg, 81, Davies RR et al, Novel measurement of relative aortic size predicts rupture of thoracic aortic aneurysms, 169–77, Copyright (2006), with permission from Elsevier [268].)

[2], even for large aneurysms, the cumulative risk of death does not rise substantially until patients have been followed for several years. A thoracic aortic aneurysm is a serious, but relatively indolent, disease.

Corollaries of the information presented about aneurysms and relating to endovascular stent-grafts are as follows:

1. *Simple identification of a small aneurysm does not necessarily indicate that endovascular stent-grafting should be performed.* Rates of rupture, dissection, and death for small descending thoracic aortic aneurysms (< 5 cm) are very low except in patients with postcoarctation aneurysms and those who are symptomatic.
2. *Long-term follow-up is essential to determine whether endovascular stent-grafts have any impact on the natural history of aneurysmal disease.*

Natural History of Acute Descending Aortic Dissection

In contrast to uncomplicated acute ascending (Stanford type A) aortic dissection, uncomplicated acute descending (Stanford type B) aortic dissection has a relatively favorable early prognosis without surgical intervention. Of approximately 85% to 90% of patients who are discharged from the hospital after medical therapy, nearly two thirds are in good condition, with no complications after anti-impulse medical therapy alone. The remainder may require elective intervention. Conversely, patients with *complicated* acute type B aortic dissections have a very high (greater than 50%) likelihood of dying and require emergency open surgical or stent-graft treatment.

Corollaries of this information vis-à-vis stent-graft treatment of acute descending dissection are as follows:

1. *Acute descending (type B) aortic dissection is not as life-threatening as acute type A aortic dissection. Early survival is satisfactory using medical management alone, unless distal ischemic complications ("malperfusion") or aortic rupture occurs. In patients with uncomplicated acute type B aortic dissection, this constitutes a benchmark that will be difficult to surpass, or even to match, by endovascular stent-graft treatment.*
2. Patients with life-threatening complications of acute type B aortic dissection are at very high risk and require emergency treatment using thoracic aortic stent-grafting, open surgical aortic graft replacement, interventional or surgical flap fenestration, or catheter reperfusion or extra-anatomic surgical bypass, or both.

Natural History of Chronic Aortic Dissection

DEFINITION. Once a patient survives 14 days after initial onset of an acute aortic dissection, it is defined as chronic. This definition is based on autopsy studies demonstrating that 74% of patients who die from dissections die within the first 2 weeks [7]. The group of chronic dissection patients comprises those surviving surgery for acute indications and those initially treated with medical therapy alone. Additionally, there is a small cohort of fortunate persons who either never sought medical care or go undiagnosed and untreated during the acute phase and survive despite a lack of therapy [3, 7–43].

CHRONIC DISSECTION AFTER PROXIMAL REPAIR. Patients whose proximal dissection is limited to the ascending aorta (DeBakey type II) may be cured after emergency operation, but such morphology represents only one third of cases [39–42]. Most type A (DeBakey type I) dissections extend distally beyond the left subclavian artery and frequently to the abdominal aorta and iliac arteries. In a review of 208 patients undergoing repair of proximal dissection (135 acute, 73 chronic) between 1978 and 1995 at Cleveland Clinic, Sabik and colleagues [10] demonstrated 30-day, 5-year, and 10-year survival of 87%, 68%, and 52%, respectively. A residual distal dissected aorta with flow in the false lumen was detected in 63% of patients and, interestingly, was not predictive of late survival [10]. Once the proximal aorta is repaired, patients who are left with a distal dissection have similar survival to those who initially present with type B dissection [39–42]. Thus, management and indications for surgery in these patients are similar to those for chronic type B patients.

CHRONIC TYPE B DISSECTION. Although primary medical therapy for uncomplicated type B dissection may improve hospital survival, it has not changed long-term survival [11]. Most deaths are related to comorbid conditions, but late complications from *distal aortic dissection* are estimated to occur in 20% to 50% of patients [7, 12–15]. These sequelae include new dissection, with associated new complications, rupture of a weak false channel, and, most commonly, saccular or fusiform *aneurysmal degeneration* of the thinned walls of the false channel, which can lead to rupture and exsanguination [16–18].

GROWTH. Growth rate of the chronically dissected distal aorta is estimated to be anywhere from 0.1 cm to 0.74 cm per year [12, 16], but is strongly dependent on initial aortic diameter after dissection and control of hypertension. Choice of medical therapy and adherence to the regimen may play a significant role in determining late outcomes of uncomplicated dissections [43]. Genoni [14] found that freedom from aortic events at a mean of 4.2 years was 80% in those treated with beta-blocker therapy versus 47% in those treated with other antihypertensive regimens. Therefore, choice of anti-impulse therapy during the chronic phase may affect the rate of growth [39–42].

SIZE. During the chronic phase of either proximal or distal dissection, medical therapy with regularly scheduled imaging is continued until the risk of late aortic complications necessitates intervention. What constitutes the threshold of aneurysmal degeneration (maximum diameter) at which intervention is warranted is ambiguous. Some suggest that patients with chronic dissection should be treated when the aorta reaches 6 cm in diameter, similar to those with arteriosclerotic descending thoracic aortic aneurysms [3]. Crawford [7], however, found that in 23% of patients presenting with rupture of

a chronically dissected descending aorta, the aorta was between 5 and 6 cm in diameter. Similarly, the Mt. Sinai group [19] found that the last median diameter before rupture was 5.4 cm (range, 3.2 to 6.7 cm). During surveillance of patients with acute type B dissection, two groups found that an initial maximum diameter of greater than 4 cm was predictive of an aortic event and recommended earlier intervention [13, 20]. Of course, patients with aortic dissection also include those with inherited connective tissue disorders, who are at higher risk of aortic rupture at a smaller size than those without such a condition.

Morphologic substrates for developing aortic dissection represent risk factors for its occurrence. These include *medial degeneration* of greater degree than normal for patient age (20% of dissections) [21]; *Marfan syndrome* [22, 23] and related disorders; *bicuspid aortic valve*, which is frequently associated with dissection [24]; *coarctation of the aorta and right-sided arch*; *steroid and cocaine use*; *polycystic kidney disease*; *chronic pulmonary disease; penetrating ulcers; organ transplantation*; *prior aortic surgery; prior aortic valve replacement; prior cardiac surgery, including congenital surgery; Marfanoid patients;* and *dilated aorta and arteriosclerosis* [21, 25–27]. The most important risk factor is probably systemic arterial hypertension. Most patients are aged 60 years or older, although patients with type A dissections tend to be younger than those with type B dissection confined to the descending and abdominal aorta, as is true also of patients with specific predisposing syndromes [15]. All these factors must be considered when performing a risk–benefit analysis to determine when therapeutic intervention is justified for chronic dissection.

FALSE LUMEN PATENCY. Presence of distal fenestrations connecting true and false lumens may allow persistent flow into the false lumen in the aortic segment at risk. Yet, controversy exists about the importance of a patent versus a thrombosed false lumen. Juvonen [17] showed that false lumen patency was not associated with higher risk of rupture in medically treated patients, whereas others have shown that thrombosis may be associated with a slower rate of aortic growth [17, 28, 29, 44].

OPEN SURGICAL REPAIR VERSUS ENDOVASCULAR STENT-GRAFT THROMBOEXCLUSION. Treatment goals for both open surgical and endovascular approaches are the same: (1) reduce the risk of dissection-related death, and (2) limit the extent of aorta repaired to minimize associated morbidity. Thus, the principles are (1) exclude the proximal primary intimal tear, (2) remove or exclude all aneurysmal disease, and (3) maintain perfusion to all distal organs and major aortic side branches. The methods for achieving these goals vary, however, because of inherent differences in the approaches.

In the open approach, the proximal end of the repair is started at a segment of normal-caliber aorta, while the dissection tear, if present in this area, is resected *or* repaired. The degenerated aneurysmal false lumen portion of aorta is resected. At the distal end of the repair, the aortic graft is anastomosed to relatively normal caliber aorta, which may or may not be involved by persistent downstream dissection. If dissection is present, the dissection membrane is fenestrated or resected to maintain flow into both the true and the false lumens and ensure adequate perfusion of the distal branch arteries. This technique allows removal of the portion of aorta at risk for rupture, but does not eliminate risk of subsequent aneurysmal degeneration of the residual distal aortic false lumen.

Successful stent-grafting of patients with acute type B aortic dissection was first reported by Dake and colleagues [30] from Stanford in 1999; Nienaber and colleagues [31] simultaneously reported their results in patients with subacute and chronic type B dissection. Since then, many reports on stent-graft treatment of patients with *chronic* type B dissection have been published, but none provides long-term (more than 3 years) results. The rationale behind endovascular therapy is that covering the area of the primary intimal tear with a stent-graft promotes false lumen thrombosis and subsequent aortic remodeling by eliminating antegrade (or occasionally retrograde) flow into the false lumen. Preliminary success with this technique has been demonstrated, but the probability of eliminating all flow into the false lumen over time is much lower than that seen after stent-grafting of *acute* type B dissection. Partial thrombosis of the false lumen may be associated with a reduction in aortic diameter [35]. Stent-grafting of acute and subacute dissections is discussed in detail in text that follows. Currently, based on the INSTEAD (INvestigation of STEnt grafts in patients with type B Aortic Dissection) study, it appears that stent-graft treatment of patients with chronic aortic dissection offers no benefit in terms of reducing the risk of aortic rupture or enhancing life expectancy.

Regardless of the approach used, as long as patients have residual dissected aorta, they remain at risk for late aneurysmal degeneration and rupture of the false lumen and require indefinite serial imaging surveillance, close blood pressure monitoring, and negative inotropic medical therapy.

In summary, patients with chronic aortic dissection should always be considered susceptible to the late sequelae of the disease regardless of therapy chosen during the acute phase. Regularly scheduled imaging should be performed to monitor development of late complications, which are estimated to occur in one third to one half of patients. Aortic growth rates are variable, and predisposing conditions as well as choice of antihypertensive therapy may play a role in progression of aneurysmal false lumen degeneration. Both open surgical and endovascular stent-graft treatment may slow the disease, but neither reverses its natural history unless the entire extent of dissection is either resected or excluded, and that can be achieved only by surgical intervention.

Intramural Hematoma

Approximately 5% of patients admitted to the hospital with a diagnosis of acute aortic dissection have an intramural hematoma (IMH) without intimal disruption [45–

48]. This entity, compared with classic aortic dissection where blood flows in two aortic lumens, is observed far more often in the descending rather than ascending aorta [47] and typically occurs in older patients [42, 49]. Malperfusion and pulse deficit are rare, although progression to frank aortic dissection occurs in 16% to 36% of patients, including retrograde into the ascending aorta, depending on site of origin [11, 30, 45–78].

The characteristic finding of aortic IMH on axial imaging studies is a hyperdense, crescentic or circumferential thickening of the wall, with a smooth wall distinguishing it from intraluminal thrombus or arteriosclerotic disease. However, accurately discriminating between IMH and acute dissection with thrombosis of the false lumen may be difficult [62]. Intimal displacement of calcium, if present, helps distinguish intramural thickening from intraluminal clot, although this, too, may present a diagnostic challenge. Another distinguishing feature is that intramural hematomas often have a more linear tangential intraluminal filling defect, whereas intraluminal clots tend to be more curvilinear. Also, in IMH, the outer aortic wall is typically not well defined, and surrounding mediastinal fluid is often present. The distance between the esophagus and aorta is often increased as well, particularly early after the event. This is because the intimal dissection tear (class II) extends to the plane of the hematoma that is frequently between the adventitia and medial layers rather than in the medial layer, as with acute class I classical dissection [42]. Hence, pleural effusions are also more common.

Clinically, IMH involving the descending thoracic aorta (type B IMH, DeBakey type III) is less fatal than type A (DeBakey type I) acute aortic dissection [47, 55, 58, 61]. Accordingly, patients with type B IMH are most often managed like those with type B acute dissection, whereas most patients with acute type A IMH should be considered for urgent operation [55]. Indications for surgical intervention in patients with type B IMH include recurring or refractory chest pain, evidence of increasing size of the hematoma, and aortic leak. The role of endovascular stent-grafts in repair of IMH is debatable unless associated with a causal penetrating aortic ulcer, discrete leakage site, or progression to aortic dissection [30, 64].

Penetrating Aortic Ulcer

A penetrating ulcer may appear as an "ulcerlike projection" (termed "ULP" in the Japanese literature) into the media of the aorta with or without associated IMH or pseudoaneurysm [62]. Extensive arteriosclerosis of the thoracic aorta is often present, with the penetrating ulcer itself appearing as a craterlike ulcer with jagged edges, analogous to a mushroom cap. This occurs typically at the site of soft plaque that ruptures. Like IMH, penetrating ulcers are more frequently observed in the descending thoracic aorta. They are often multiple and range in size from 2 to 25 mm in diameter and 4 to 30 mm in depth [69].

There is considerable controversy about the natural history of penetrating ulcers, and, accordingly, about the indications for open surgical or endovascular treatment. Penetrating ulcers often evolve to become an IMH. For example, in the Mayo Clinic series, approximately 80% of patients with penetrating ulcers had an associated IMH [51]. Although the penetrating ulcer itself may appear ideal for endovascular stent-graft treatment because of its localized pathology [70–73], those affected often harbor extensive arteriosclerotic disease. This includes peripheral occlusive disease that may make suitable sheath/dilator access challenging, and laminated thrombus, which is not ideal for a stent-graft landing zone. Unfortunately, it is unclear whether surgical therapy will affect the long-term survival of these commonly very ill patients, who frequently have substantial pulmonary disease and many other comorbidities that markedly limit their life expectancy [11].

Contemporary Results of Open Surgical Graft Replacement of the Thoracic Aorta

Nicholas T. Kouchoukos, MD, Bruce W. Lytle, MD, Lars G. Svensson, MD, PhD, Hazim J. Safi, MD, and Joseph S. Coselli, MD

Because there are no prospective, randomized studies comparing outcomes of patients treated with open versus endovascular procedures, results of open operations based on reports from single centers and nonrandomized comparisons from Investigational Device Exemption (IDE) studies of open versus endovascular stent-graft procedures provide the only useful information (this is discussed in more detail in text that follows). Unfortunately, the endovascular literature is replete with examples of comparisons of endovascular procedures with either remote older open surgical procedures or open procedures with considerably greater extents of repair (eg, thoracoabdominal aneurysm or aortic arch repairs) [79–85].

Table 1 summarizes pertinent, recent results of open surgical repair of the descending thoracic aorta. Although there is debate about the best methods for arterial perfusion or whether distal perfusion is even necessary, these studies document the contemporary expected surgical results. Additionally, it must be recognized that because of pathoanatomic factors, not all these patients would be suitable candidates for endovascular stent-graft repair. Prevalence of stroke is included in the table because it is the most serious and commonly experienced complication after endovascular stent-grafting. In the early Stanford experience, it was 10%, and in the VALOR (Evaluation of Talent Thoracic Stent Graft System for Treatment of Thoracic Aneurysms) high-risk (Talent) study, it was 8%. On the basis of 1,898 reported cases (Table 1), in the hands of well-trained and experienced surgeons, an average lower extremity paralysis rate of 3.4%, stroke rate of 2.7% (43 of 1,584 reported stroke cases), and mortality rate of 4.8% can be expected for open surgical procedures today. Five- and 10-year survival estimates are 60% and 38%, respectively. Current results from individual large series are summarized in the text that follows.

For spinal cord protection, it is now widely, although not universally, accepted that distal perfusion should be em-

Table 1. Results of Open Descending Aortic Repair According to Etiology and Urgency: Patient Factors

Author	No. of Patients	Mean Age (years)	Male (%)	Acute Dissection No. (%)	Chronic Dissection No. (%)	Degen No. (%)	Other No. (%)	CAD No. (%)	COPD No. (%)	Renal Dys No. (%)	Perf, Rupt No. (%)
Estrera [139]	300	67	66	18 (6)	117 (39)	165 (55)		74 (25)	70 (23)	38 (13)	0 (0)
Coselli [82]	387	63	68	48 (12)	87 (22)	252 (65)	12 (3)	100 (26)	102 (26)	40 (10)	17 (4)
Borst [174]	132	48		5 (4)	60 (45)	22 (17)	45 (34)				14 (11)
Svensson [81]	832	65	70	50 (6)	204 (25)			210 (25)	320 (38)	94 (11)	34 (4)
Verdant [255]	267	55	65	33 (12)	24 (9)	122 (46)	88 (33)				45 (17)
Kouchoukos [256]	65	61	60	4 (6)	9 (14)	42 (65)	10 (15)	29%	30%	12%	5 (8)
Fehrenbacher (in press)	63	66	67	3%	30%	66%	1%	21%	24%	9%	

Results of Open Descending Aortic Repair According to Etiology and Urgency: Protective Measures

Author	No. of Patients	Distal Perfusion No. (%)	Hypothermia	CSF Dr No. (%)	IC Implant No. (%)
Estrera [139]	300	238 (79)	Mild	250 (83)	90 (32)
Coselli [82]	387	46 (12)	Mild	24 (6)	18 (5)
Borst [174]	132	132 (100)		20 (15)	Below T_8
Svensson [81]	832	275 (33)	Mild	No	Below T_8
Verdant [255]	267	267 (100)		No	
Kouchoukos [256]	65	65 (100)	Profound	No	Yes
Fehrenbacher (in press)	63	63 (100)	Profound	No	Yes

Results of Open Descending Aortic Repair According to Etiology and Urgency: Outcomes

		Mortality		Spinal Cord Event							Survival		
Author	No. of Patients	30-Day No. (%)	Hospital No. (%)	Paralysis	Paraplegia	Paresis	Immediate	Delayed	Stroke	Renal Failure No. (%)	3-Year (%)	5-Year (%)	10-Year (%)
Estrera [139]	300	22 (7.3)	24 (8.0)	7 (2.3)			5 (1.6)	2 (0.7)	6 (2.1)	12 (4.2)		66	35
Coselli [82]	387	11 (2.8)	11 (4.4)		10 (2.6)					29 (7.5)			
Borst [174]	132	4 (3)	4 (3)	6 (4.5)	4 (3)	2 (1.5)	2 (1.5)	2 (1.5)		2 (1.3)			
Svensson [81]	832	63 (8)[a]	63 (8)[a]	45 (5)	19 (2.3)	26 (3.1)			29 (3.5)	58 (6.9)	72	60	38
Verdant [255]	267		39 (15)	0 (0)	0 (0)					1 (0.4)			
Kouchoukos [256]	65		2 (3)	1 (1.5)	0 (0)	1 (1.5)	1 (1.5)	1 (1.5)	1 (1.5)	0 (0)			
Fehrenbacher (in press)	63		2 (3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)		0 (0)			

[a] After 1986, 98% survival.

Degen = degenerative; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; CSF Dr = cerebrospinal fluid drainage; Dys = dysfunction; IC = intercostal implantation; Perf, Rupt = perforation, rupture.

ployed in all patients having excision of more than a very limited section of the descending thoracic aorta. Cerebrospinal fluid drainage is another commonly used adjunct.

Since 1991, the Humana Hospital group in Houston has used a combination of distal aortic perfusion and cerebrospinal fluid drainage for repairs of the descending and thoracoabdominal aorta. They reported that between February 1991 and September 2004, 355 patients underwent repair of descending thoracic aortic aneurysms; 55 were excluded from analysis because of aortic rupture or need for hypothermic circulatory arrest as a result of transverse arch involvement. This left 300 patients for whom outcomes were analyzed. Adjunct distal aortic perfusion and cerebrospinal fluid drainage were used in 238 (79%) of the repairs, compared with 62 patients (21%) who underwent simple aortic clamping with or without a single adjunct. Proximal descending thoracic aortic aneurysms (left subclavian artery to T_6) were repaired in 99 patients (33%), distal descending (T_6 to the diaphragm) in 41 patients (14%), and entire descending (left subclavian artery to the diaphragm) in 160 patients (53%). Occurrence of stroke was 2.1% and of renal failure, 4.2%. Overall occurrence of neurological deficit was 2.3% to 1.3% for the adjunct group and 6.5% for the nonadjunct group ($p < 0.02$). All cases of neurologic deficit occurred in patients with aneurysmal involvement of the entire descending thoracic aorta. Thirty-day mortality was 7.3%, with an in-hospital mortality of 8%. Overall long-term survival estimates were 79%, 76%, 64%, and 35% at 1, 2, 5, and 10 years, respectively. Freedom from aortic-related reoperation was 96%. Of note, however, freedom from reoperation for distal aortic–related problems was 96% at 13 years, confirming that open repair for descending thoracic aortic aneurysm remains durable over the long term and does not require multiple reinterventions [79–85].

Kieffer and colleagues [86] reported a series of patients in whom they compared outcomes after stent-grafts and open procedures. Seventy-seven were good open surgical repair candidates, 44 were not good stent candidates and underwent open repair, and 52 received stents. The respective mortalities and morbidities for open procedures versus stent-grafts were mortality, 5% versus 15% ($p < 0.02$); spinal cord injury, 7.4% versus 0% ($p = 0.04$); stroke, 15% versus 4.1% ($p = 0.04$); respiratory failure, 57% versus 29% ($p = 0.002$); and renal failure, 20% versus 7.7% ($p = 0.05$) [86].

Between January 2001 and July 2006 at Cleveland Clinic, 683 patients with descending or thoracoabdominal disease underwent operation [87]. There was no difference in mortality or spinal cord injury. The only independent predictor of outcome was extent of repair. One-year mortality was similar in both groups. For the 284 descending aorta repairs, overall early mortality was 4.5% [87].

Indications for Interventions

Indications for Operative Intervention

Lars G. Svensson, MD, PhD

Criteria for operative intervention in asymptomatic patients with aneurysms of the descending thoracic aorta can be categorized according to either size or etiology of the aneurysm. In individual patients, presence of comorbid conditions also must be carefully considered for both open and endovascular procedures. No level A or B scientific evidence from prospective, randomized studies exists related to the timing of operative intervention according to aneurysm size, as is the case for abdominal aortic aneurysms (see text that follows).

Currently accepted size indicators justifying operation, unless modified by underlying etiologies, are an aortic diameter of 5.5 cm or twice the diameter of the normal contiguous aorta, for example, in the aortic arch [88]. For 5′6″ to 5′10″ older adults, the normal proximal arch size is 3.2 cm, the proximal descending aorta 2.8 cm (5.6 cm diameter), the mid descending 2.7 cm, and the distal descending 2.6 cm. Of note, 0.6 cm can be added to or subtracted from these figures for adults more than 6 feet or less than 5 feet in height [89–91].

In addition to fusiform aneurysms meeting the above size threshold, accepted indications for surgical treatment according to etiology are traumatic rupture of the aorta; acute type B aortic dissection with associated distal ischemia, rupture, or leak; false aneurysm or pseudoaneurysm; mycotic aneurysms; coarctation of the aorta; bronchial compression or aortobronchial or aortoesophageal fistulae; and large saccular aneurysms. The size at which operation is indicated for eccentric saccular aneurysms has not been determined. Nonetheless, either a saccular width of 2 cm or total aortic size of 5 cm is an acceptable indication for intervention.

Indications for Endovascular Stent-Grafting

Thomas G. Gleason, MD, and Joseph E. Barvaria, MD

The feasibility of stent-grafting descending thoracic aortic aneurysms is now firmly established for various pathologies [2, 4, 31, 32, 49, 51, 52, 56, 70, 74, 82, 89, 91–178] (Table 2), but the indications for intervention remain to be fully defined. In part, this discrepancy results from the lack of long-term follow-up data after stent-grafting and, consequently, a lack of understanding of the relative risk and benefit of stent-grafting versus either medical management or open surgical graft replacement of the descending aorta. Recently, with applications of stent-grafts across a broad range of clinical indications and clinical settings, the risks of thoracic aortic stent-grafting have been more clearly established. Several recent studies have demonstrated that operative mortality is between 2% and 26% and depends largely on urgency, the extent of comorbid conditions and operator experience [32, 92, 102, 104, 109, 110, 117–121]. Analysis of the midterm results of thoracic aortic stent-grafting demonstrates 3- to 8-year survival of 25% to 90% across a wide range of operative indications [93, 94, 99, 101, 106, 109, 120, 122, 123]. Results are summarized in Table 2.

Despite reasonably low early operative morbidity and mortality, late complications, including endoleaks, graft migration, stent fractures, and aneurysm-related death, are much more common than those reported for the gold standard procedure, namely, open aortic surgery. For

Table 2. Compiled Data From Published Series of Thoracic Aortic Endografting for Predominantly Aneurysmal Disease: Preoperative Data

Author	No. of Patients	Predominent Devices[a]	Aortic Pathology Treated (%)					Ao Diameter Range in mm (mean)
			Degen Aneurysm	Dissecting Aneurysm	Pseudoaneurysm	Penetrating Ao Ulcer	Other	
Bavaria [182]	140	Gore	100					20–110 (63.7)
Wheatley [257]	156	Gore	48	23	6.4	9.6	13	N/A
Ricco [118]	166	Gore/Talent	53	20	11	14	2	N/A
Glade [93]	42	Gore/Talent	100					40–80 (61)
Greenberg [32]	100	Zenith	81	15			4	(62.8)
Riesenman [92]	50	Talent	48	4	22	4	22	(60.5)
Bortone [121]	110	Gore/Talent	34	17	22		27	N/A
Czerny [101]	54	Gore/Talent	100					61–93 (73)
Neuhauser [94]	31	Gore/Talent	100					25–110 (65)
Bell [110]	67	Gore/Talent	54	12			34	50–100 (70)
Bergeron [97]	33	Gore/Talent	30	23	6	6	34	N/A
Chabbert [109]	47	Gore/Talent						N/A
Marin [106]	94	Gore/Talent						N/A
Orend [528][b]	74	Gore/Talent	46	19	8		27	43–107
Schoder [103]	28	Gore	100					43–107 (69)
Criado [259]	47	Talent	66	34				48–107 (68)
Mitchell [99][c]	103	Homemade	62	8		10	22	40–110 (62)

Compiled Data From Published Series of Thoracic Aortic Endografting for Predominantly Aneurysmal Disease: Postoperative Data

Author	No. of Patients	Operative Mortality No. (%)	CVA No. (%)	Paraplegia No. (%)	Endoleaks[d]		1-Year Survival
					Early	Late	
Bavaria [182]	140	3 (2.1)	5 (3.6)	4 (2.9)	10%	0%	N/A
Wheatley [257]	156	6 (3.8)	7 (4.5)	1 (0.6)	11.5%	N/A	76.6%
Ricco [118]	166	17 (10.2)	2 (1.2)	6 (3.6)	16.2%	N/A	N/A
Glade [93]	42	2 (5)	0 (0)	1 (2)	N/A	N/A	N/A
Greenberg [32]	100	7 (7)	3 (3)	2 (1)	10.3%	6%	83%
Riesenman [92]	50	4 (8)	2 (4)	0 (0)	10%	10%	79.4%
Bortone [121]	110	4 (3.6)	1 (1)	0 (0)	N/A	N/A	N/A
Czerny [101]	54	2 (3.7)	0 (0)	0 (0)	5.6%	8.9%	75%
Neuhauser [94]	31	6 (19)	1 (3.2)	2 (6)	29%	28%	61.1%
Bell [110]	67	1 (2)	3 (4)	3 (4)	N/A	3 (4.8)	89%
Bergeron [97]	33	3 (9)	1 (3.1)	0 (0)	0%	0%	N/A
Chabbert [109]	47	3 (6.4)	3 (6)	0 (0)	25.5%	N/A	91.5%
Marin [105]	94	N/A	6 (0.7)	N/A	25%	N/A	N/A
Orend [258][b]	74	7 (9.5)	0 (0)	0 (0)	20.3%	N/A	N/A
Schoder [103]	28	0 (0)	0 (0)	0 (0)	21.4%	N/A	96.1%
Criado [259]	47	1 (2.1)	0 (0)	0 (0)	8.7%	N/A	N/A
Mitchell [99][c]	103	9 (9)	7 (6.8)	3 (2)	24%	2%	81%
Totals	1,425	81 (5.7)	42 (2.9)	22 (1.5)			

[a] Gore denotes W.L. Gore & Associates (Flagstaff, Arizona) Excluder or TAG endoprosthesis. Talent denotes Medtronic Vascular (Santa Rosa, California) Talent device. Zenith denotes Cook (Bloomington, Indiana) Zenith TX2 device. Homemade denotes devices made by the surgeons implanting them at time of use. [b] Additional data/analysis based off of the same series from Sunder-Plassman et al [123]. [c] Additional data/analysis based off of the same series from Demers et al [120]. [d] Endoleaks were not consistently reported among the published series. Some authors reported only type I or type III leaks or none at all, and consequently, endoleak reporting is incomplete.

Note: All published series with more than 25 cases and adequate follow-up are included.

Ao = aortic; CVA = cerebrovascular accident; Degen = degenerative; N/A = not available.

example, in a single series in which the indication for stent-grafting was strictly applied to those deemed unsuitable candidates for conventional open surgical repair, 1- and 5-year survivals were 74% and 31% after stent-grafting compared with 93% and 78% ($p < 0.001$) after stent-grafting in patients who were reasonable candi-

dates for conventional open aortic replacement [120]. Driven primarily by the relative ease of descending thoracic aortic stent-grafting, it has been more liberally applied to patients with various descending thoracic aortic pathology, including traumatic transections, aortic dissections, penetrating ulcers, intramural hematomas, arch aneurysms, and descending thoracic aortic aneurysms smaller than the diameter at which open operation has conventionally been deemed necessary or indicated. It is not clear at this time whether the trend toward more aggressive endovascular stent-graft management will influence prognosis or offer improved long-term survival or freedom from aortic complications compared with conventional open surgical repair or medical management alone for these conditions.

The indication for stent-grafting of a descending thoracic aortic aneurysm at the present time should be based on a predicted operative risk that is clearly lower than the risk of either conventional open repair or optimal medical management. This is particularly important because stent-grafting necessitates frequent post-procedure surveillance CT scans and aortic reintervention at a later date. The fairly extensive follow-up for stent-grafting adds to the cumulative escalation of overall health care costs. Consideration of patient age, comorbidity, symptomatology, expected life expectancy, likely quality of life (if asymptomatic), aortic diameter, aneurysm morphology, aneurysm extent, suitability of landing zones, and operator experience are all distinctly relevant. Furthermore, stents have been designed to have a durability of 10 years based on ISO (International Standardization Organization) stress testing. Long-term durability is unknown.

AGE. Clear understanding of the natural history of thoracic aortic aneurysms is limited by lack of large, multiinstitutional databases and by interventions that usually occur before serious aortic-related events. Nonetheless, there are several comprehensive studies of single-institution databases on which current management paradigms for thoracic aorta disease are based [4, 124–134]. Ruptured thoracic aneurysms are more common in older patients, and advanced age correlates with higher operative risk after conventional open repair [125, 135–137]. In a Swedish population study, incidence of ruptured thoracic aneurysms in persons over age 80 was 530 per 100,000, compared with 100 per 100,000 among persons aged 60 to 69 [135, 179]. Indeed, the risk of aortic dissection is increasing in older patients [179]. The Mount Sinai group demonstrated that the risk of descending thoracic aortic disruption increased by a factor of 2.6 for every decade of life [125].

Currently, there are no studies comparing morbidity and mortality of descending thoracic aortic stent-grafting in older versus younger patients. Because the morbidity of conventional open surgical repair of descending aortic replacements in the elderly is substantial and greater than for stent-grafting of the descending thoracic aorta alone, there has been a recent predilection for treating elderly patients who have descending thoracic aneurysms with stent-grafts. This bias is not entirely justified by the current literature, because no prospective, randomized comparison of open conventional repair with stent-graft repair of the descending thoracic aorta exists. Moreover, no trial comparing open or stent-graft repair with medical management has been conducted. A note of caution is that stent-grafting should be employed with circumspection in young patients because the long-term durability of most stent-grafts is unknown; testing is simulated out to 10 years based on engineering design and mechanical fatigue factors.

The best available comparative information on the results of open surgical versus stent-grafting in patients with descending thoracic aortic aneurysms was provided by the Gore TAG phase II, nonrandomized trial, presented in 2005 (W.L. Gore & Associates, Flagstaff, Arizona) [117]. The TAG devices were placed in 137 low-risk patients and results compared with 44 concurrent and 50 historical open surgical control patients. Demographics were similar, with patient age averaging about 70 years for both groups. Operative mortality and occurrence of paraplegia were significantly lower in the TAG group compared with the open surgical group, 2.1% versus 12% ($p < 0.001$) and 3% versus 14% ($p < 0.003$), respectively [117]. There was no difference in 2-year survival (78% for TAG group versus 76% for open repair). Unfortunately, follow-up was not complete (86% for TAG group and 77% for open repair). Limitations of this trial included low-risk entry criteria, lack of complete follow-up, lack of randomization, and lack of a standard surgical technique (discussed in more detail in text that follows). Furthermore, emergency and urgent cases were more likely to be assigned to open repair, a strong predictor of greater risk of poorer outcome.

Another, small retrospective case–control comparison from a single institution demonstrated lower morbidity and lower hospital cost, but equivalent mortality, for stent-grafting versus open repair [93]. It is well documented that isolated open replacement of the supradiaphragmatic descending aorta can be safely accomplished in experienced centers, with mortality below 4% and prevalence of paraplegia of 2% to 4% across a wide range of patient ages. Despite these conflicting data, when considering age alone, it appears reasonable to conclude that for patients older than age 75, stent-grafting, when feasible, is associated with lower morbidity and mortality risk than open surgical repair.

PULMONARY DISEASE. Obstructive pulmonary disease is a strong predictor of thoracic aortic aneurysm disruption and is a significant operative risk factor for those undergoing open surgical repair [124, 125, 140–142, 180]. The subset of patients with degenerative descending thoracic aneurysms and severe lung disease are probably the most likely to benefit from avoidance of a thoracotomy and its attendant morbidity, because stent-grafting is well tolerated by this group [92, 94, 119, 120]. The life expectancy of patients with severe pulmonary disease is often less than 5 years [143]; therefore, concerns about

potential late complications of stent-grafting are not as compelling as for healthier patients.

PAIN. Chest or back pain in the presence of a thoracic aortic aneurysm is also predictive of aortic rupture [125, 126, 130, 132]. Historically, surgeons have recognized this correlation and generally recommend that any patient with a symptomatic aneurysm consider operative repair. Even patients with a thoracic aneurysm who have vague, uncharacteristic, or atypical pain at presentation have a higher risk of rupture over time [125]. Consequently, medical management of patients with symptomatic descending thoracic aortic aneurysms is unwarranted unless their life expectancy and quality of life are markedly impaired. Stent-grafting can often be performed more expeditiously than conventional open surgical repair. Pain on presentation in a patient with a descending thoracic aortic aneurysm should generally prompt consideration of intervention, but the decision regarding endovascular versus open repair should still be based primarily on technical and pathoanatomic factors, patient age, operative risks, general health, and individual circumstances.

AORTIC DIMENSIONS. Aneurysm diameter is a major criterion for operative intervention in asymptomatic patients, as discussed earlier. Growth rate of aneurysms is also important, and regression formulae have been developed to predict growth rate and identify patients with accelerated growth rates who are at increased risk [2, 124, 125, 127, 146, 148, 149]. It is important to note that all of the predicted growth rates and equations in use have been generated from relatively small numbers of patients in single-institution databases. Indeed, most databases have few patients with diameters in the 5.0 to 5.5 cm size, which is the area of particular interest.

An important caveat to note amid the development and advances in endovascular treatment of descending thoracic aortic aneurysms is that some practices have applied more liberal size criteria for intervening in patients with asymptomatic descending thoracic aneurysms, despite the lack of objective data to support such a therapeutic strategy. Strikingly, a recently published study of a nationwide registry demonstrated that 17% of 166 patients who underwent descending thoracic aortic stent-grafting had aneurysms smaller than 5.0 cm, and among these cases, operative mortality was 5% [118]. This raises a justifiable concern, because natural history studies demonstrate that the risk of disruption of descending thoracic aortic aneurysms less than 5 cm in diameter is extremely low and likely less than the 5% mortality for stent-grafting [125, 126, 128, 130, 132]. No asymptomatic patients with aortic degenerative aneurysms of less than 5 cm should undergo thoracic aortic stent-grafting until other indications apply.

AORTIC MORPHOLOGY AND HISTOPATHOLOGY. The morphology of descending thoracic aortic aneurysms may affect the likelihood of rupture and thereby modulate the decision to intervene surgically. Fusiform aneurysms are more common and appear to behave in a relatively predictable manner. Aortic dimensions can be used in this setting with reasonable certainty to prevent rupture. Saccular or eccentric aortic aneurysms may be associated with a greater risk of leak or disruption than fusiform aneurysms, but there are few data in the literature to substantiate this clinical suspicion. This deficiency is related, in part, to the relative rarity of saccular aneurysms [150–152], many of which actually are pseudoaneurysms resulting from a penetrating ulcer or previous trauma. Others are mycotic in origin. Regardless of etiology, saccular aneurysms often involve a focal disruption or weakening of the intima and media of the aorta and even sometimes of the adventitia [153, 154]. Consequently, it would seem intuitive that saccular or false aneurysms would be at greater risk of rupture than fusiform aneurysms. The short-term results of stent-grafting of saccular aneurysms are encouraging in several small series [92, 106, 155–157], and it may be ideally suited for these localized aneurysms because the aorta above and below the aneurysm is often relatively normal and a good landing zone for the stent-graft. Thrombin injection into saccular aneurysms has also been reported [181].

The role of endovascular stent-grafts for managing patients with mycotic aneurysms is unknown, although many reports have described successful short-term results in small numbers of patients. The concept of endovascular repair of an infected artery violates the principle of wide debridement of infected tissues and good drainage of all suppuration that is paramount to successful open operative management of infected aortic false aneurysms. Currently, endovascular repair of mycotic aneurysms is not recommended and should be used only in patients who have a prohibitively high operative risk for open surgical repair.

Patients with Marfan syndrome or other connective tissue disorders deserve special consideration. There are a few reports of short-term success after endovascular stent-grafting of the descending thoracic aorta in patients with Marfan syndrome [158–161]; however, there is limited information regarding the impact of persistent radial forces of a stent-graft in the abnormal and weak aorta of patients with this condition. Consequently, stent-grafting in patients with Marfan syndrome or any other known connective tissue disorder is not recommended unless operative intervention is clearly indicated and the risk of conventional open surgical repair is deemed prohibitive by a cardiovascular surgeon. To date, presence of Marfan syndrome or a connective tissue disorder has been a strict exclusion criterion in all commercial thoracic aortic stent-graft trials. Furthermore, these patients are usually young, and because the current long-term durability of available stent-grafts is unknown, stent-grafting is not prudent and should be avoided. In experienced centers, open thoracoabdominal aortic replacement can be achieved safely in such patients, with low morbidity and mortality [162]. Indeed, patients with Ehlers-Danlos syndrome or polycystic kidney disease appear to be at substantial risk for aortic dissection after insertion of stent-grafts.

PENETRATING AORTIC ULCER. Penetrating ulcers of the descending thoracic aorta are often associated with localized false or degenerative aneurysms and should prompt consideration of repair, especially giant arteriosclerotic penetrating ulcers [52, 74, 163]. Occurrence of rupture of aortic ulcers associated with intramural hematomas may be as high as 45% at initial presentation [49, 132]. In the absence of associated intramural hematomas or repair, many of these lesions can be managed medically with successful outcome [51, 56, 117]. However, if a conservative approach is elected, strict monitoring and frequent surveillance imaging are required, and enlarging ulcers warrant consideration for urgent intervention. Early and midterm results of stent-grafting for penetrating ulcers are encouraging [70, 94, 101, 103, 165, 166] (see text that follows), primarily because they represent localized aortic pathology.

ANEURYSM EXTENT. The extent of descending thoracic aorta involved by degenerative aneurysms is not a limiting factor in determining suitability of stent-grafting, beyond the need for acceptable proximal and distal landing zones. The necessary length and diameter of the landing zones depend on the specific stent-graft device employed.

As more experience is gained with concomitant or preemptive arch and pararenal abdominal aortic debranching procedures, the ability to exclude longer segments of the thoracic and abdominal aorta will be expanded. Currently, the most extensive experience with branch-vessel coverage is the left subclavian artery in treatment of proximal descending thoracic aortic aneurysms. This has been demonstrated to be safe when combined with left subclavian revascularization (carotid–subclavian bypass plus proximal left subclavian artery ligation, thrombosis, or transposition) and is associated with low morbidity [169, 170]. Left subclavian coverage without revascularization can be accomplished with relative safety provided the cerebellum and posterior cerebrum are not dependent on left vertebral arterial flow [171, 172]. Concerns about late left upper-extremity claudication have recently surfaced after covering the left subclavian artery with a stent-graft, but this is not life-threatening and can subsequently be treated by open surgical carotid–subclavian revascularization. Some suggest that as many as 70% of patients will tolerate coverage of the left subclavian artery without serious neurologic complications if the right vertebral artery is dominant. Clearly, if the left internal thoracic artery has been used (or might be used in the future) for coronary artery bypass grafting, then surgical revascularization of the left subclavian artery is mandatory before stent-grafting.

Extent of thoracic aortic replacement or coverage with a stent-graft does affect the risk of paraplegia or paraparesis. Descending thoracic aortic stent-grafting may be associated with a lower risk of spinal cord injury than replacement of an equivalent aortic segment with open surgical techniques. Retrospective stent-graft experiences and the phase II TAG trial suggested that the risk of lower limb neurologic injury is less with stent-grafting than with open surgical repair [31, 93, 99, 100, 102, 110, 111, 117, 118, 173]. These reports, however, have not controlled for extent of coverage, nor do they reflect contemporary occurrence of spinal cord injury in centers with a large open surgical experience, where paraplegia risk, particularly for isolated descending thoracic aortic replacement, is low (2% to 5%) [82, 174–178]. Extent of thoracic aorta involvement should not significantly influence the risk of paralysis unless the distal descending thoracic aorta is involved, the patient has had previous abdominal aortic surgery, substantial atheroma or laminated thrombus is present, the entire descending aorta is repaired, or the internal iliac (hypogastric) arterial system is compromised.

STROKE. While risk of spinal cord injury has been low after stent-grafting, risk of stroke has historically been relatively high. Indeed, in the early Stanford experience, among 103 cases, occurrence of stroke was 7% ± 3% [100]. Similarly, in the VALOR high-risk (Medtronic Talent) thoracic stent-graft trial, stroke occurrence was 8% [89, 120]. In both of these studies, the high stroke risk was probably secondary to use of older (and now obsolete) large, stiff sheath/dilator stent-graft delivery systems that required excessive manipulation of extensive hardware across the diseased arch of these elderly patients; newer stent-graft deployment systems, such as the Gore TAG device, no longer require anything except a guidewire to pass through the arch and thus require much less manipulation. Stroke occurrence in the more recent Gore TAG phase II trial was 4% in both the TAG stent-graft group and the open surgical repair group, consistent with other more contemporary reports [89].

RISK ASSESSMENT. It is prudent to consider all major factors that influence the risk of descending thoracic aortic rupture in the context of operative risk to determine when it is more appropriate to treat the patient conservatively, with expectant medical management, rather than with open operative or stent-graft intervention. The Mount Sinai group formulated an equation that calculates the probability of aortic rupture based on both demographic and dimensional data, including age, presence of pain or obstructive lung disease, and aortic diameter [125, 130]. This prediction equation was applied retrospectively and confirmed that the majority of patients who underwent operative repair had a probability of rupture exceeding 8%, which is higher than the risk of operation in their hands and lends further credence to the model.

Costs

The cost of thoracic stent-grafts is still to be determined, but is influenced by both device company contracts and the number of stent-grafts inserted. Costs of between $15,000 and $20,000 for descending thoracic aortic stent-grafts can be expected. The costs of fenestrated and branched grafts will be higher.

CONCLUSION. Based on the accumulated knowledge to date regarding the natural history of patients with descending thoracic aortic aneurysms and contemporary open surgical operative risks, it is reasonable to recommend elective operative intervention when the maximal orthogonal aortic diameter exceeds 5.5 cm in an asymptomatic patient. Careful consideration must also be given to patient age, comorbidity, and individual surgeon experience and results. Symptomatic aneurysms and penetrating ulcers with or without associated intramural hematoma also usually mandate consideration of operative intervention, provided the operative risk is not prohibitive, or stent-grafting.

Patients with degenerative aneurysms can be treated with either open conventional surgical graft replacement or endovascular stent-grafting, with expected equivalent midterm results in experienced hands. Results and durability of stent-grafting beyond 5 years, however, are still unknown. It is likely, however, that the lower initial mortality advantage of endovascular stent-grafting will be lost over time as further procedures or risk of rupture contribute to late deaths in this group, as was demonstrated in the Gore TAG phase II trial, where there was no difference in 2-year mortality [182]. This finding has been further reinforced by the comparative study from Cleveland Clinic, in which 1-year mortality was lower in the open surgical group than in the stent-graft group [87]. Of interest, although early mortality was the same, within 3 years in the prospective, randomized studies of abdominal aortic aneurysm management using either stent-grafts or open procedures, mortality was higher in the stent-graft group (see text that follows). In the Stanford follow-up study of their initial 103 stent-grafted patients, 30% ± 6% needed reintervention by 8 years [120]. Most of these interventions occurred within 5 years with use of first-generation devices [118, 120].

Management of Specific Pathologic Entities by Stent-Grafting

Penetrating Aortic Ulcers

D. Craig Miller, MD

The Stanford group realized early on that the most suitable pathologic target for successful thoracic aortic stent-grafting was lesions that were relatively localized, including penetrating aortic ulcers (PAU), anastomotic pseudoaneurysms, mycotic aneurysms, and false aneurysms due to chronic aortic transections. In most of these pathologic situations, relatively normal aortic necks exist on either side of the lesion that can be used as landing zones for stent-grafts.

Between 1993 and 2000, 26 *symptomatic* patients with a PAU involving the descending thoracic aorta were treated at Stanford with either a first-generation homemade (n = 19) or W.L. Gore Excluder (n = 7) stent-graft [70]. Twenty-three percent presented with aortic rupture, 54% had refractory, persistent pain, and 23% demonstrated pathologic progression of the ulcer to an intramural hematoma. Overall, 54% were judged by a cardiovascular surgeon to have a prohibitively high risk for open thoracotomy and surgical repair. Average age was 70 ± 8 (± 1 SD) years. Average interval from time of symptomatic presentation to stent-grafting was 17 ± 17 days (range, 6 hours to 60 days). Mean length of aorta covered by the stent-graft was 12.3 ± 0.7 cm, and average stent-graft diameter was 33 mm, reflecting the relatively normal-size descending thoracic aortas of these patients. Primary technical success was 92%, and secondary success was 96% after deployment of an additional stent-graft 90 days later. Operative mortality was 12% ± 7% (± 70% confidence limits [CLs]); the 3 deaths were caused by hemorrhagic stroke, retroperitoneal hemorrhage, and sepsis with secondary multiorgan failure. Five other patients had some complication, including two early type I endoleaks, but no cases of paraplegia or embolic stroke occurred.

Follow-up was 100% complete and averaged 51 ± 37 months, so midterm assessment of stent-graft treatment efficacy was possible. Maximum follow-up was 9.5 years. Actuarial survival estimates at 1 and 5 years were 85% ± 8% and 70% ± 10%, respectively (± 95% CLs). Causes of death were rupture due to a late type I endoleak in 1 patient, lung cancer, sudden/unexplained death in 1, and pneumonia in 2. The only multivariable predictors of early and late death were previous stroke and female sex.

Stanford comprehensive composite endpoint of *treatment failure* to assess overall effectiveness was used, defined as including (1) early death, (2) early or late endoleak, (3) stent-graft mechanical fault, (4) aortic reintervention, or (5) aortic-related or any sudden, unexplained late death.

In the absence of universal autopsy information on all patients who die, this latter criterion is important because it will detect any death that might be due to aortic rupture. This stringent definition of treatment failure probably overestimates the occurrence of late events due to stent-graft (or open surgical repair) failure, but it neutralizes reporting biases if applied to all series from all institutions.

Actuarial estimates of freedom from treatment failure at 1 and 5 years were 81% ± 8% and 65% ± 10%, respectively. Events judged to constitute treatment failure included early death (n = 3), early type I endoleak (n = 1), secondary intervention for early type I endoleak (n = 1), late aortic rupture due to untreated late type I endoleak 7 years later (n = 1), late wire fracture (Gore Excluder) without clinical sequelae (n = 1), and late, sudden, unexplained death (n = 2). Multivariable predictors of treatment failure were larger aortic diameter and female sex.

Because stent-graft complications can occur long after the procedure, annual serial surveillance imaging is mandatory on an indefinite basis to detect problems.

The clinical debate concerning whether patients with PAUs have a malignant or relatively benign natural history [45] has been outlined above. Perhaps the chief reason for this continuing controversy relates to which particular patient population is being studied, namely, a sample of acutely symptomatic in-patients versus pa-

tients drawn from a radiology imaging database, in which the majority are asymptomatic out-patients. Nonetheless, patients with PAUs treated with stent-grafts at Stanford (described above) were acutely symptomatic, which portended a prognosis equivalent to or even worse than that of acute type B aortic dissection reported by the Yale group [49]. Considering that more than half these patients were deemed inoperable or carried a prohibitively high open surgical operative risk, average age was 70 years, and most had other serious medical problems, these results after stent-graft treatment out to and beyond 5 years were satisfactory.

Conversely, the Michigan group recently observed in 73 patients that stent-grafting for a penetrating ulcer or pseudoaneurysm portended higher early and late mortality compared with stent-grafting for other aneurysms [183]. The Stanford group continues to believe that patients with symptomatic PAUs of the descending thoracic aorta who are not good surgical candidates (most are not) are excellent candidates for urgent stent-grafting. These patients usually are elderly and their life expectancy does not exceed about 10 years. Further, the results described above (1993 to 2000) represented the early Stanford learning curve; more refined patient selection—which remains of cardinal importance—and newer technical improvements in commercial stent-grafts and deployment systems should provide better results in the future in patients with PAUs who are not good surgical candidates.

Chronic Traumatic Aortic False Aneurysms

D. Craig Miller, MD

Another form of localized descending thoracic aortic pathology is chronic false aneurysms discovered long after a traumatic tear. The localized nature of these false aneurysms makes endovascular stent-graft treatment attractive, but stent-grafting has not been associated with satisfactory midterm durability in these cases, unlike when used for PAUs. These patients are fortunate in having survived the initial injury either undiagnosed or untreated and present many years, if not decades, later; their aneurysms are frequently detected as incidental findings in the absence of symptoms.

Traumatic false aneurysms at the aortic isthmus commonly are densely calcified. Between 1993 and 2000, 15 such patients at Stanford were treated with stent-grafts (homemade in 7 cases, Gore Excluder in 8) [184]. Average age was 54 ± 13 years, and mean time between discernible deceleration injury and treatment was 18 ± 14 years. Based on a cardiovascular surgical opinion, 27% were thought to have a prohibitively high surgical risk for left thoracotomy and open surgical graft replacement. Three had previously undergone some sort of attempted open surgical repair. Aneurysm diameter averaged 6.2 ± 1.5 cm, with the proximal and distal landing zone diameters being 2.7 ± 0.3 cm and 2.6, respectively; mean false aneurysm length was 5.9 ± 2.5 cm, all indicative of localized aortic pathology in what was otherwise a fairly normal aorta. One patient had a cascade of multiple complications and ultimately died 6 months later in the hospital, for an operative mortality of 7% ± 6%. Primary technical success was 87%; proximity of the false aneurysm to the lesser curve of the transverse aortic arch and left subclavian artery are major pathoanatomic problems in these cases. No stroke or paraplegia occurred.

Actuarial survival estimates at 1 and 6 years were 93% ± 6% and 85% ± 10%, respectively. The actuarial estimate of freedom from reintervention was only 70% ± 15% at 6 years. On the other hand, the actuarial estimate of freedom from treatment failure (using the Stanford definition, as described above) was 51% ± 15% at 6 years. Causes of treatment failure included early death (n = 1), early endoleak (n = 2), late endoleak (n = 1), sac enlargement (probably due to fluid weeping through the interstices of the thin expanded polytetrafluoroethylene covering of a Gore Excluder stent-graft (n = 2), Excluder wire fracture (n = 1), and sudden, unexplained death (n = 1). Looking at the incidence of treatment failure in the *actual* framework (also termed cumulative incidence or observed cumulative frequency) [185], which is more meaningful for an individual patient (because actuarial methods are population based and assume everyone is at risk indefinitely, for example, for looking at survival, all patients are immortal, which thereby overestimates the real risk when there are competing hazards for death and other nonfatal complications), the freedom from treatment failure estimates were higher: 87% ± 8% and 67% ± 12% at 1 and 6 years, respectively.

On the basis of these results, the Stanford Cardiovascular Surgery and Interventional Radiology group continues to use stent-grafts to treat patients with chronic traumatic false aneurysms, but *only* if they are judged unsuitable candidates for open thoracotomy. The limited durability of endovascular stent-grafting for this indication in their midterm (5-year) assessment [184] urged that a cautious approach be taken, unlike that voiced in two other reports of small numbers of patients followed for only 1 to 3 years [186, 187].

The anatomic suitability of the proximal aortic neck for stent-grafting in these chronic cases is problematic; today, this technical problem can be overcome by revascularizing the left subclavian artery and occluding it proximally or by moving and revascularizing multiple arch branches. Conversely, if the patient has a reasonable life expectancy otherwise and is a reasonable open surgical candidate, then left thoracotomy and surgical graft replacement using profound hypothermic circulatory arrest is the most dependable and durable therapeutic option. Contemporary mortality and morbidity risks associated with these open surgical procedures, even if requiring hypothermic circulatory arrest for an open proximal anastomosis in the distal arch, are low, as outlined above. The worrisome development of late stent-graft complications again underscores the vital importance of serial surveillance imaging to detect such problems early.

Acute Type B or Retro-A Aortic Dissection

D. Craig Miller, MD

In October 1996, 4 years after implanting their first thoracic aortic stent-graft, the Stanford group embarked on a trial of emergency stent-grafting for patients with acute type B (or "retro-A") aortic dissections who presented with life-threatening complications, including lower body malperfusion due to true lumen collapse, aortic rupture or impending rupture, refractory chest pain or uncontrollable severe hypertension, or both. Because these patients were desperately ill and faced a high risk of death whether treated surgically or medically, the rationale was that a stent-graft covering the primary intimal tear might alleviate the acute symptoms of malperfusion or threatened rupture, or both, and thereby allow the patient to be resuscitated, thus minimizing early mortality, and then to be followed closely when more definitive surgical intervention could be carried out, if necessary, under more optimal clinical conditions. This thinking was based on the original Duke–Stanford database report published in *Circulation* in 1990 [188], which showed how the clinical presentation of patients with acute type B aortic dissection and their general medical condition were the chief determinants of early outcome, regardless of whether they were treated medically or surgically. This notion was affirmed by the Stanford 36-year experience with patients with acute type B dissections [189], where the long-term prognosis was poor—but similar—for those treated medically versus those undergoing early open operation to replace the proximal descending thoracic aorta. This latter analysis was undertaken to examine which patients, if any, might have fared better if emergency stent-grafting had been available. The European multicenter study of 168 patients also showed that late outcome was better in patients with a thrombosed false lumen than in those with a perfused false lumen [190].

The initial 2-year Stanford and Mei University stent-graft experience for patients with complicated acute aortic dissections was published in 1999 [30]. Between October 1996 and October 1998, 19 selected patients were treated by emergency stent-grafting using primitive homemade stent-grafts or the first generation of commercial thoracic aortic stent-grafts (Gore Excluder). Average time between symptom onset and treatment was 3.9 ± 3.6 days (± 1 SD). Indications for emergency stent-grafting included rupture (n = 3), severe lower body malperfusion, or persistent, refractory back pain. Fifteen patients (79%) had a typical acute type B dissection, and 4 had a retro-A dissection (or Reul-Cooley-DeBakey type III-d) due to a primary intimal tear located in the descending thoracic aorta. The amount of descending thoracic aorta covered by the stent-graft was kept to a minimum (average length, 6.9 ± 1.5 cm), with the intent just to cover the primary intimal tear. The primary intimal tear was completely covered in 16 of the 19 patients; of the remaining 3, 2 had no flow into the false lumen near the primary intimal tear 1 month later, but 1 patient with a proximal type I endoleak required surgical graft replacement 1 year later.

Complete thrombosis of the false lumen in the descending thoracic aorta was achieved in 79% of patients and partial thrombosis in the remainder. As hoped, the diameter of the compressed true lumen in the descending aorta and abdominal aorta returned to normal size on follow-up imaging, whereas the overall (true and false lumen) aortic diameter did not change significantly after the procedure, except in the proximal descending aortic segment (near the location of the primary intimal tear and stent-graft), where is became smaller.

In the 4 retro-A dissection patients, the ascending aortic diameter decreased from 4.1 to 3.4 cm, associated with total thrombosis of the retrograde false lumen within 1 to 2 years. Jeopardized end-organ perfusion in all 22 major aortic branch vessels due to "dynamic" obstruction resolved spontaneously after the primary intimal tear was covered by the stent-graft. Adjunctive interventional procedures required distally included descending thoracic aortic true lumen "paving" with bare metal stents in 1 (owing to retrograde flow into the false lumen from a large fenestration at the level of the sheared-off celiac axis), abdominal aortic or iliac true lumen stents or both in 2 (due to nonreentering, thrombosed distal false lumen compromising true lumen flow), and true lumen stenting of the origin of 5 major aortic tributaries with persistent "static" compromise in 4 patients.

Three patients died, yielding an operative mortality of 16% (95% CL: 0% to 32%), 2 of distal aortic false lumen rupture and 1 secondary to ongoing gut and leg infarction. Serious complications developed in 2 other patients (colon ischemia requiring colectomy and renal failure requiring temporary hemodialysis). No patient sustained stroke or paraplegia (excluding 1 patient with preoperative paraplegia).

This early preliminary experience was promising enough that the Stanford group and some others [191, 192] around the world continued to explore the applicability of emergency stent-grafting for acute complicated aortic dissections, but most clinicians in Europe and Japan rigorously avoided patients who were less than 14 days from acute presentation.

Careful reading of the details of published reports is necessary because various authors have redefined what the term acute dissection means: The Mei University group in Japan [35] categorizes a dissection as "acute" if it is between 14 and 30 days old, a radical departure from the decades-old conventional demarcation of less than 14 days. Despite this major limitation that complicates interpretation of report results, the Mei group has been very active in this field. They have clearly demonstrated that the likelihood of false lumen thrombosis is inversely related to the age of the dissection [35]; in cases of chronic (more than 30 days) dissection, the likelihood that the false lumen will thrombose and subsequently fibrose and shrink after stent-grafting is low.

These observations and the experience of others has led most authorities to believe that thoracic aortic stent-

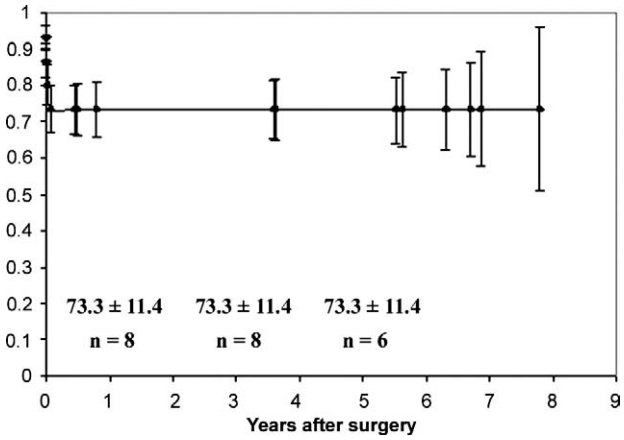

Fig 6. Kaplan-Meier actuarial patient survival estimates for 16 patients with complicated acute type B or retro-A aortic dissections (Stanford 1991 to 2004).

grafting for *chronic* aortic dissection is relatively futile, if not contraindicated altogether (the current Stanford posture), but there are dissenting views [193–197]. The Stanford group postulates that stent-grafting for chronic aortic dissection will eventually fail and represents self-delusion on behalf of treating physicians, despite the hundreds of reported cases treated using this technique. In chronic dissection, the clinical problem is not distal malperfusion but false lumen aneurysmal enlargement. Simply too many fenestrations exist between the true and the false channels throughout the length of the thoracoabdominal aorta, which allows the false lumen to remain pressurized ("endotension"), even if large primary or secondary intimal tears are successfully covered with a stent-graft and most of the false lumen clots. Many of these so-called fenestrations are indeed the sites of torn off intercostal arteries.

Hence, it is unlikely that stent-grafting can reliably prevent aortic rupture in cases of chronic aortic dissection over a 5- to 10-year time span. Furthermore, the small, compressed true lumen and chronically scarred, thick, and immobile dissection flap/septum are no longer amenable to being molded back into their predissection dimensions, and downstream tributaries can occasionally be supplied only by false lumen flow, such that sealing off the false lumen with a stent-graft above could infarct an important distal end organ.

Whether patients with uncomplicated subacute or chronic (2 weeks to 1 year) type B dissections should be stent-grafted prophylactically is a highly controversial topic. Thankfully, results from the European randomized, prospective INSTEAD trial engineered by Dr Christoph Nienaber, comparing best medical therapy with stent-grafting, has shed some light on this important topic, as discussed below.

To gain a firmer perspective on the long-term durability of stent-grafting for *acute* aortic dissection, the Stanford results in 16 patients with life-threatening complications (rupture, hemothorax, refractory chest pain or severe visceral or lower limb ischemia, or both) treated with a stent-graft within 48 hours between October 1996 and June 2004 were recently updated by Dr Jean Phillipe Verhoye [198]. Follow-up (average, 36 ± 36 months) was 100% complete. Early mortality was 23% ± 8% (± 70% CL), with no late deaths. No new neurologic complications (either strokes or spinal cord injury) occurred. Based on the latest scan, 4 patients (25%) had complete thrombosis of the false lumen, and 6 had partial thrombosis (38%). Aortic diameter increased in 1 patient. Actuarial survival was 73% ± 11% at both 1-year and 5-year intervals (Fig 6). The actuarial estimate of freedom from treatment failure (defined as aortic rupture, device mechanical fault, reintervention, aortic death, or sudden, unexplained late death) was 67% ± 14% at 5 years (Fig 7) [198].

As experience has been gained in stent-grafting patients with other types of thoracic aortic pathology, it has become clear that the keys to better results after endovascular repair of complicated acute aortic dissection will depend more on refined patient selection criteria and enhanced physician judgment than on the evolution of more sophisticated, smaller, and more flexible commercial stent-graft devices and deployment systems.

The Stanford Cardiovascular Surgery and Interventional Radiology group continues to believe that emergency stent-grafting for patients with life-threatening complications of acute type B (or retro-A) aortic dissection may save many lives and that this could well become the most clinically valuable application of thoracic aortic stent-grafting in the future. The goal is not to eliminate all flow from the false lumen, but simply to cover the primary intimal tear and relieve the lower body malperfusion and prevent rupture such that the patient can be resuscitated and then followed closely indefinitely. Caution should, however, be exercised if there is a large hematoma in the aortic arch area or mediastinum, because this may indicate leakage in the aortic arch, and the latter would not be covered with a stent-graft. Emergency stent-grafting for acute complicated aortic dissection should not be considered a "curative" intervention (as some believe it is in patients with thoracic aortic aneu-

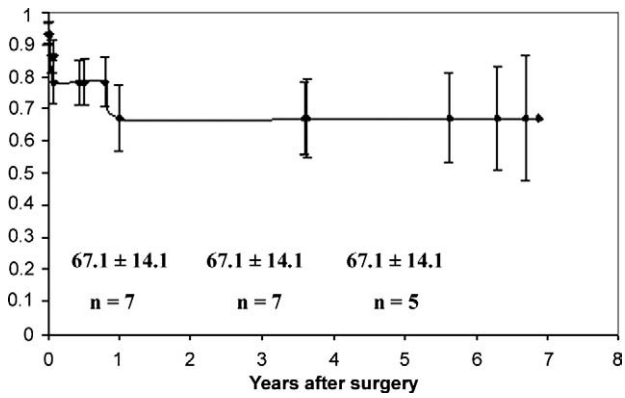

Fig 7. Actuarial freedom from treatment failure (including aortic rupture, device mechanical fault, reintervention, late aortic-related death, or sudden, unexplained late death) for 16 patients with complicated acute type B or retro-A aortic dissection (Stanford 1991 to 2004).

rysmal pathology), but it will save lives if applied judiciously and quickly to salvage patients who otherwise are doomed.

Subacute and Chronic Aortic Dissection

Holger Eggebrecht, MD, Christoph A. Nienaber, MD, and Raimund Erbel, MD

Given the perioperative morbidity and mortality associated with open surgical repair of aortic dissection, there is consensus that patients with chronic type B aortic dissection should primarily be treated medically with blood pressure control, while reserving operation for those with evolving complications (eg, unrelenting pain, progressive aortic dilatation, malperfusion syndromes, or [imminent] rupture) [199]. Both intermediate and long-term prognoses of patients with type B aortic dissection remain suboptimal, however, despite intensive medical and surgical therapy [189].

First reported in 1999 [30, 31], endovascular stent-grafting emerged as a novel, minimally invasive treatment option for patients with both acute and subacute aortic dissection who previously were considered candidates for open operation. The concept of stent-grafting was to facilitate aortic remodeling by sealing the proximal primary intimal tear and scaffolding the true lumen, which potentially would be associated with a lower risk than open surgical repair [196, 200]. This rationale was originally based on the observation that patients with spontaneous thrombosis of the false lumen may have a better long-term prognosis than those with a perfused false lumen [190]. Spontaneous thrombosis of the false lumen occurs only rarely (≤ 4% of patients) with classic aortic dissection [190]. Conversely, persistent perfusion of the false lumen may be a predictor of progressive aortic enlargement and adverse long-term outcome [20, 201–203].

CURRENT EVIDENCE. In their initial 1999 publication, Nienaber and associates [31] provided the only comparison, albeit not randomized, of stent-grafting with conventional open operation in 24 consecutive patients with subacute or chronic aortic type B dissection. Stent-grafting was successfully performed in 12 patients with no morbidity or mortality, whereas open operation in 12 other patients was associated with 4 deaths (33%, $p = 0.09$) and 5 serious adverse events (42%, $p = 0.04$) within 12 months. These preliminary results suggested that stent-graft placement might be a safer procedure in selected patients with subacute/chronic dissection and were the impetus for the INSTEAD randomized study discussed below.

Follow-up data on stent-graft placement in patients with aortic dissection are primarily derived from two retrospective analyses of single-center experiences, which have been summarized in a recent meta-analysis [194]. Furthermore, there are only two publications reporting on observational data from multicenter registries [204]. The only randomized study comparing stent-grafting with optimal medical treatment in patients with uncomplicated subacute/chronic dissection is the INSTEAD trial, which just completed patient enrollment, and the 1-year results are currently being analyzed [205].

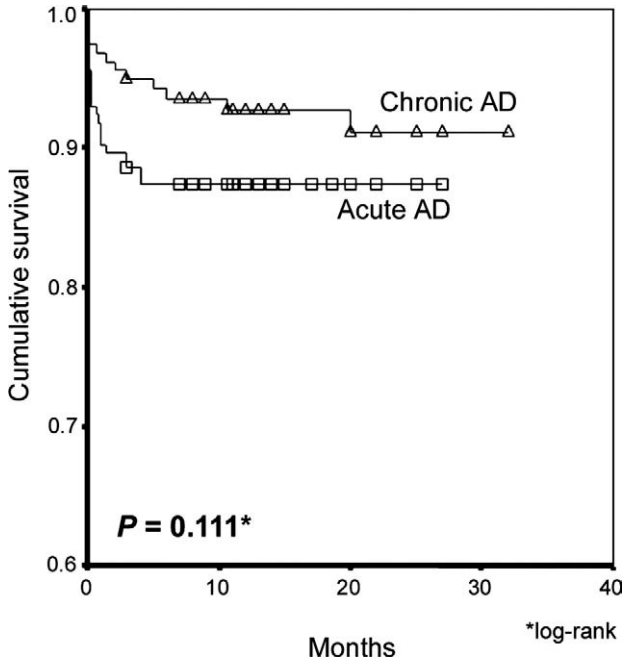

Fig 8. Cumulative survival of patients undergoing stent-graft insertion for acute type B aortic dissection (squares) compared with patients with chronic type B dissection (triangles).

A recent compendium summarized the results of 39 published studies of endovascular stent-grafting in 609 patients with aortic dissection [20, 30, 31, 189, 190, 194, 196, 199–203]. Of these, more than 42% had a subacute or chronic dissection, but the actual fraction of patients with acute (≤ 14 days) dissections could not be determined accurately because of ambiguity in terminology used by various authors. Procedural success was achieved in 96%, with only 2.3% of patients requiring in-hospital surgical conversion. Overall, complications occurred less frequently in patients with chronic dissections than in those undergoing stent-graft placement for acute dissection (9% ± 2% versus 22% ± 3%, $p = 0.005$). Prevalence of neurologic complications was remarkably low: stroke, 1.2% and paraplegia, 0.5%. Operative mortality was significantly lower for those with chronic versus acute dissection (3% ± 1% versus 10% ± 2%, $p = 0.015$; Fig 8), with a trend toward better 1-year survival (93% ± 2% versus 87% ± 2%, $p = 0.088$). Overall p value, however, was 0.111.

In 2004, Leurs and associates [204] published data gathered from 443 patients undergoing stent-graft placement for thoracic aortic diseases collected within the EUROSTAR (European Collaborators Registry) and United Kingdom Thoracic Endograft multicenter registries. Of these, 131 underwent stent-graft placement for type B aortic dissection, but acuity of dissection was not reported; nonetheless, 47% of patients underwent elective stent-graft placement, and the procedure was suc-

cessful in 86%. Although paraplegia did not occur in any patient in the elective group, 2 patients (3.2%) sustained a periprocedural stroke. Operative mortality was lower in patients treated electively than in those undergoing emergency stent-grafting (6.5% versus 12%, $p = 0.55$).

The recent Talent Thoracic Registry (TTR) retrospective study contained 457 consecutive patients (113 emergency, 344 elective) who underwent aortic stent-graft repair with the Medtronic Talent device; 38% (n = 180) had an aortic dissection, and 37 (8%) had an acute type B dissection. Technical success was 98%, and 0.7% of patients required direct surgical conversion. Occurrence of stroke was 4% (n = 17), and of paraplegia, 1.7% (n = 8). In-hospital mortality, including the 113 emergency cases, was 5%, and late mortality was 8.5% within the mean follow-up interval of 24 ± 19 months. Kaplan-Meier survival estimates were 91% at 1 year, 85% at 3 years, and 78% at 5 years. Estimates of freedom from a second procedure were 92%, 81%, and 70% at these time intervals, respectively. These data suggested that stent-grafting had relatively low mortality and morbidity risk [193].

Preliminary INSTEAD results show that 1-year mortality for medically treated patients was 3% versus 10% for stent-grafted patients. Of those treated medically, 11% crossed over to stent-graft or surgical treatment. Thus, elective, prophylactic stent-grafting does not appear to be justified in asymptomatic medically controlled patients with subacute or chronic type B aortic dissection [205, 206]. The issue now is to identify patients who needed later intervention and also to compare long-term outcomes in patients who underwent stent-grafting with those who required open aortic repair. A larger trial is now planned.

In summary, observational data suggest that endovascular stent-graft placement in patients with subacute or chronic aortic dissection can be performed with high technical success, and the prevalence of complications appears to be lower than in patients undergoing stent-graft placement for acute dissection. This may be because segmental arteries arising from the false lumen are usually not excluded from retrograde blood flow up the false lumen. The long-term outcomes provided by future randomized studies will be of interest regarding the role of stent-grafting in these patients.

Thus, despite the absence of controlled efficacy data, stent-grafting as a therapeutic option for high surgical risk patients with subacute or chronic aortic dissection may be considered for those who have a patent false lumen and an identifiable, proximal entry tear that can be covered by stent-graft implantation [11, 193, 199] in association with (1) a maximal thoracic aorta diameter greater than 5.5 cm, (2) documented increase of aortic diameter of more than 1.0 cm within 1 year, (3) resistant hypertension despite antihypertensive combination therapy associated with a small true lumen or renal malperfusion, or (4) recurrent episodes of chest/back pain that cannot be attributed to other causes. In younger, healthier patients, open surgical repair should be considered. The role of stent-grafting for patients with *chronic* dissections present for more than 8 weeks after the acute event (when the septum has begun to form scar tissue and is no longer elastic or pliable) is still uncertain; open surgical graft replacement is likely to be a better option particularly in young, good-risk patients.

Acute Traumatic Aortic Transection

Grayson H. Wheatley III, MD, and Lars G. Svensson, MD, PhD

Emergency surgical repair of traumatic ruptures of the aorta is associated with substantial morbidity and mortality. Thirty-day mortality for emergency and nonemergency standard surgical repair is reported to vary from 6% to 23% [132, 207, 208]. An endovascular approach to repair of these thoracic aortic injuries, pioneered by Kato and colleagues [209], may confer advantages in perioperative mortality and morbidity over traditional open repair [208, 210, 211].

In a multicenter study, 30 patients with chest trauma and multiple injuries (mean severity score = 62) underwent endovascular stent-grafting, with 100% successful implantation [210]. Two patients (6.7%) later died, 1 patient suffered a stroke (3.3%), and 1 (3.3%) had partial stent collapse. During a follow-up mean of 11.6 months, no endoleaks, migrations, or late pseudoaneurysms were observed.

Between September 2000 and April 2005, 7 patients underwent emergent stent-grafting with the Gore TAG endoprosthesis for aortic ruptures under a protocol approved by the Institutional Review Board of the Arizona Heart Institute and within the confines of an IDE. All patients were screened by a staff surgeon and underwent preoperative CT before being accepted for device deployment. Most were transferred from outside institutions and were stabilized before transfer. Aortic measurements were made from preoperative studies for planning the device diameter and length to allow for a minimum oversizing of 7% to 18% and 2-cm overlaps of healthy aortic tissue in the proximal and distal landing zones, as recommended by the manufacturer.

It is important to note that it is frequently necessary to cover the left subclavian artery to achieve an adequate proximal seal. In addition, device oversizing by more than 20% is contraindicated because the stent-graft may fold on itself and obstruct the aorta. This may also lead to detrimental increased radial force on the aorta. In addition, because patients are mostly young, the aorta has not typically enlarged and unfolded; thus, the arch acute angulation can be difficult to accommodate. If the proximal extent of the stent-graft is not opposed to the aortic wall on the lesser curve of the arch ("bird beak deformity"), the graft may become compressed by the pulse pressure under the proximal lip of the stent-graft, resulting in a proximal type I endoleak. Even worse, the graft may collapse and obstruct the aorta.

In summary, the long-term durability of current stent-graft technology is unknown, particularly in younger patients. In addition, little information is available re-

garding the long-term consequences of placing a stent-graft in a young person who has not yet reached full maturity. Further investigations are required to address these issues. Clearly, new devices are needed that are smaller and have built-in angulation capability that can be passed atraumatically into the smaller arteries and the angulated aorta seen in young persons.

Hybrid Stent-Graft and Open Surgical Procedures

Lars G. Svensson, MD, PhD

Hybrid procedures for descending thoracic aortic endovascular grafting include the elephant trunk procedure, to allow proximal anchorage of stent-grafts, or subclavian artery transfers, either left or right (for an aberrant subclavian artery), to allow safe placement of stent-grafts in the distal aortic arch.

Insertion of a descending thoracic endograft aorta anchored to an elephant trunk was first described by the Stanford group [212]. The advantages are several. During insertion of the elephant trunk graft as the first procedure, cardiac pathology, such as coronary artery or valvular disease, as well as aneurysmal disease of the ascending aorta and aortic arch, can be concomitantly treated. Patients who would otherwise be poor risks for an open second-stage procedure because of comorbid disease, lung pathology, or adhesions can thus undergo a safer operation. The lower thoracic or upper abdominal aorta can be wrapped to convert a thoracoabdominal aneurysm to a thoracic one, thus permitting descending thoracic aortic stent-graft repair. Second-stage procedures using a thoracic endograft can be done earlier after the first stage than open operation because of lower morbidity.

Key points are that the elephant trunk graft should be no longer than 15 cm, the end of the graft is marked with metal clips to permit easy identification, and a loop of wire is placed 1 cm proximal to the end of the graft at the initial operation to allow for straightening the graft if, during the second-stage stenting procedure, it becomes buckled within the aorta [213].

Aneurysms Involving The Aortic Arch

Lars G. Svensson, MD, PhD

As discussed above, the hybrid elephant trunk procedure is a suitable option for patients with aneurysmal disease involving the aortic arch, because the first stage can be done with 98% survival [213]. Similarly, the open clamshell bilateral thoracotomy procedure has excellent results when the ascending aorta, arch, and proximal descending aorta require replacement [214]. Thus, at this time, based on current results, stenting of the aortic arch is not often required or justified. In approximately 4% of patients, only the arch and descending aorta are involved. In this small group of patients, if high-risk comorbid factors such as aortic ruptures, reoperation, complications from previous descending aortic stents, cirrhosis or home oxygen use for chronic pulmonary disease are present, they can undergo minimally invasive off-pump ascending aorta to greater vessel bypasses before arch and descending aortic stent-grafting using a "J" incision [215]. This approach is not recommended for patients with chronic aortic dissection, either after previous ascending aorta repairs or because of chronic dissections beyond the left subclavian artery.

Treatment of Descending Thoracic Aortic Disease with Fenestrated and Branch Devices

Eric E. Roselli, MD, and Lars G. Svensson, MD, PhD

INDICATIONS. Durable endovascular repair of the descending thoracic aorta requires fixation and seal in a parallel walled and normal segment of aorta. In some patients, achieving this goal requires extending aortic coverage into the aortic arch or visceral segment using custom-designed fenestrated or branched devices. Use of these devices creates the dilemma of defining the extent of pathology in these patients, because once the endovascular aortic coverage extends into these territories, the risk approximates that of open aortic arch or thoracoabdominal aneurysm repair. In general, the definition for extent of disease is based on the planned extent of aortic coverage, and therefore, fenestrated or branched devices by definition are not indicated in the treatment of isolated descending thoracic aortic disease.

Fenestrated stent-graft devices are currently CE (European Certification Mark)-approved for treatment of juxtarenal aneurysms in Europe. More than 100 physicians have implanted more than 1,000 devices worldwide. This technology has been expanded to devices used to treat thoracic aneurysms requiring fixation within the aortic arch or visceral segment of the aorta. In the United States, these devices are currently available only as part of a physician-investigator–sponsored IDE study. Additionally, several case reports of homemade devices similar in design concept have been published. As such, all of these recommendations are class IIb with level of evidence C, at best. Current indications for use are for those patients with thoracic aneurysmal disease who would be at high risk for open surgical repair (usually owing to comorbid conditions) and whose anatomy is unsuitable for currently available commercial devices [216].

TECHNIQUES AND DEVICE DESIGN. The proximal and distal extent of aneurysmal disease, fixation and sealing zones, luminal diameters, and precise relationships between the arch or visceral vessels are determined using three-dimensional CT imaging techniques to plan the device design. Devices are modular in design. The Zenith endograft system currently forms the basis of these devices. Fenestrations mated with bare stents or branches mated with covered stents are added to a tubular component that encroaches on the arch or visceral segment. Two types of fenestrations are used, scalloped or rounded; and two types of branches are inserted, reinforced fenestrated or helical directional. These are constructed depending on location of the aortic prosthesis

within the aorta. The main body of the device is then mated with a balloon expandable stent (fenestrated), balloon expandable stent-graft (reinforced fenestrated branch), or a self-expanding stent-graft (directional helical branch). A given device may incorporate a combination of types of fenestrations and branches based on patient anatomy.

PROCEDURE. Procedures include bilateral femoral artery access (open or percutaneous), anticoagulation to maintain activated clotting times greater than 300 s, and selective exposure of brachial access sites. The primary device is delivered over a stiff wire that terminates in the ascending aorta. Each additional component is introduced through the contralateral femoral artery (visceral vessel) or brachial artery (arch or visceral vessels) [216].

Longitudinal positioning of the aortic component is assisted by small injections of contrast from a flush catheter positioned above the celiac artery or within the aortic arch. The sheath is then withdrawn to partially expand the device. A posterior tethering wire partially constrains the graft, allowing fine positioning adjustments during and after selective cannulation of accessory vessels from within the aortic prosthesis.

After access into each vessel, the aortic component is completely expanded by removal of the posterior tethering wire. Additional stents or stent-grafts are then delivered and mated with the main device. Finally, the aortic delivery system is removed and proximal or distal thoracic or abdominal components are added, as needed.

Perioperative care is critical to success. Regional anesthesia can be used in patients with significant comorbid pulmonary disease. Patients are followed in an intensive care unit for a minimum of 12 hours. Spinal fluid drainage is routinely used to keep the intrathecal pressure less than 10 cm H_2O and continued for 72 hours, or until CT scan confirms aneurysm exclusion.

Imaging and clinical evaluations occur at 1, 6, and 12 months postoperatively and annually thereafter. Studies include serum creatinine and blood urea nitrogen, CT with three-dimensional evaluation, visceral duplex ultrasonography, and plain chest and abdominal radiography.

OUTCOMES. Outcomes for these investigational devices used to treat high-risk, complex descending aortic aneurysms have not been published, but the Cleveland Clinic experience with 73 patients has been reported [216]. Information may be extrapolated regarding the safety of these devices based on the experiences with fenestrated devices to treat juxtarenal aneurysms and branched devices to treat thoracoabdominal aneurysms. In a recently reported series of 119 patients receiving fenestrated abdominal devices, successful deployment was achieved in all, with no acute vessel loss [217]. There was 1 death within 30 days, and actuarial survival was 92%, 83%, and 79% at 12, 24, and 36 months, respectively. There were no ruptures or conversions, and a single aneurysm growth secondary to a type II endoleak was later successfully treated. At 24 months, aneurysm size had decreased by more than 5 mm in 77% of patients.

Treatment of thoracoabdominal aortic aneurysms in a select high-risk group of patients using branched grafts has recently been presented in 73 patients, with promising results [216]. The first 9 of these have been included as part of a recently published report on the use of branched graft devices for treating suprarenal, aortoiliac, and thoracoabdominal aneurysmal disease [218].

Current Thoracic Endovascular Stent-Grafts

The Gore TAG Thoracic Endograft

R. Scott Mitchell, MD

The W.L. Gore TAG thoracic nitinol endograft was presented to a Food and Drug Administration panel in January 2005 and received approval in March 2005, making it the first commercially available thoracic endograft in the United States. An important unique feature of the Gore stent-graft system is that deployment requires passage of only a guidewire above the level of the diaphragm, meaning that the sheath/dilator assemblies inherent in the older stent-graft devices, which had to traverse the entire descending thoracic aorta and transverse arch, are no longer necessary. This markedly reduces aortic trauma and minimizes the risk of arterioembolic embolization during stent-graft deployment, which should lower the risk of stroke. Gore TAG approval was based on a multicenter, nonrandomized prospective trial comparing results of stent-graft repair of descending thoracic aortic aneurysms with those of open surgical graft replacement (control group) in low-risk patients [182, 219]. Seventeen test sites in the United States contributed both stent-graft and open surgical control patients. All stent-grafts were implanted between 1999 and 2001, and 85% of the open surgical control patients were treated during the same interval. A small number of additional open surgical control patients were retrospectively enrolled. In total, there were 140 stent-graft patients and 94 open repair patients.

Fairly rigid inclusion and exclusion criteria defined patient suitability for the trial. Inclusion criteria required aneurysms greater than 5 cm in diameter or requiring surgical treatment, as defined by the operating surgeon, in patients with a life expectancy greater than 2 years who were suitable candidates for open operation. Specifically excluded were patients with aneurysms of mycotic origin, hemodynamically unstable patients, patients having a myocardial infarction or stroke within the prior 6 weeks, a creatinine level of more than 2.0 mg/dL, and patients with Marfan syndrome or other connective tissue disorder. Inclusion criteria specific to the stent-graft group involved an aortic landing-zone diameter measuring between 23 and 37 mm, as available devices ranged from 26 to 40 mm. Also, the proximal and distal landing zones had to be greater than 2 cm in length and without substantial laminated thrombus or circumferential calcification. For the open, control patients, clampable aortic segments distal to the left carotid artery and proximal to the celiac axis were necessary for inclusion.

All patients in this study met all applicable inclusion and exclusion criteria. Because this was a nonrandomized study, reasons for patient exclusion from the stent-graft group included inadequate size of access vessels, symptoms upon presentation that made the surgeon unwilling to wait until a stent-graft became available, urgent and emergency patients, and patient unwillingness to receive an experimental device. An extensive array of preoperative variables was evaluated to ensure comparability of groups. The only one that was significantly different was presence of symptomatic aneurysm, which was more common in the surgical control cohort. It should be noted that symptomatic patients with aneurysms have higher morbidity (particularly neurologic and renal) and mortality risk historically after open surgery, and thus this group was at greater risk for morbidity and death. Not all these patients presented with pain, however; other symptoms included difficulty swallowing and hoarseness.

All patients had on-site data collection, with prospectively identified adverse events. At 1 year, it was determined that open surgical control patients were approximately twice as likely to experience a major adverse event. Adverse events that occurred with lower frequency in the stent-graft population included bleeding and pulmonary, renal, wound, and neurologic complications. Only vascular complications were significantly more common in the endovascular stent-graft group. Compared with surgical controls, stent-graft patients were less likely to sustain paraplegia or paraparesis (14% versus 3%) and early death (10% versus 2%). Surgical control patients spent approximately twice as long in intensive care, twice as long in the hospital, and required approximately twice as much time to return to normal activity. It should be stressed that more open surgical patients underwent emergency or urgent surgery, which is a strong predictor of adverse outcome. The benefit of stent-graft repair as assessed by aneurysm-related mortality persisted to 2 years. Despite the initial higher early mortality for the open surgical patients, however, by 2 years, there was no difference in all-cause mortality (approximately 80% survival in both groups).

At 2-year follow-up, there was a 4% occurrence of proximal migration of the graft and a 6% occurrence of migration of the graft components. Twenty-one of 140 patients (15%) had experienced an endoleak sometime during the first 2 years. Among 64 patients evaluated at 2 years, the aneurysm sac had enlarged by more than 5 mm in 11 (17%); 3 (5%) of these patients had associated endoleaks, 2 of which were revised using endovascular techniques, and 1 required open surgical revision. There were no instances of aneurysm rupture.

The stent-graft used in this study was subsequently redesigned because of fracture of the longitudinal support wire in 20 patients. That wire was eliminated, and the column strength of the stent-graft was enhanced by adding an additional fabric layer to the expanded polytetrafluoroethylene graft. This revision also provided the additional benefit of minimizing transgraft porosity, thereby eliminating type IV endoleaks commonly seen with the early Gore EXCLUDER thoracic and abdominal stent-grafts.

After FDA approval, W.L. Gore established special training programs based on paradigms learned from prior abdominal or thoracic endograft experience to certify physician competency in thoracic stent-graft technology and use. Only after satisfying these recommendations will physicians and hospitals be allowed to purchase and stock stent-graft devices. Additionally, the FDA mandated specific postmarketing surveillance for patients undergoing thoracic aortic stent-grafting, as well as long-term patient monitoring.

Medtronic Endografts

Joseph E. Bavaria, MD, and Wilson Y. Szeto, MD

Since 1996, Medtronic Vascular (Santa Rosa, California) has sold more than 20,000 thoracic endografts worldwide. The first-generation device was implanted in humans in 1996 by Dr Michael Denton in Australia. Because of difficulty with "trackability" of the device in a tortuous thoracic aorta, modifications were made to the original design. The Talent device with the CoilTrac delivery system was introduced in 1999 and offered a deployment system with improved trackability and pushability. With approximately 18,000 of these devices implanted worldwide, the Talent graft was the device used in the pivotal trial for FDA approval in the United States (VALOR high-risk clinical trial). One-year data for the VALOR trial are expected to be updated. The Valiant device, first introduced in Europe in 2005, is the third-generation Medtronic stent-graft device. It builds on the experience of the Talent device. Issues with lengths of the devices, conformability, and ease of deployment were addressed in the redesigned Valiant device with the Xcelerant delivery system. The availability of the Valiant device in the United States is anticipated in 2008.

THE TALENT DEVICE. The Talent device is a preloaded stent-graft incorporated into a CoilTrac delivery system. It is composed of a polyester graft (Dacron; C.R. Bard, Haverhill, Pennsylvania) sewn to a self-expanding nitinol wire frame skeleton. Radiopaque "figure-of-8" markers are sewn to the graft material to aid in visualization during fluoroscopy. The CoilTrac delivery system is sheathless and push rod based. Preloaded onto an inner catheter, the Talent device is deployed by pulling back an outer catheter, allowing the device to self-expand and contour to the aorta. A balloon may be used to ensure proper apposition of the graft to the aneurysmal aorta after deployment.

The Talent device is a modular system; 47 different configurations are available, ranging from a diameter of 22 to 46 mm and covering lengths from 112 to 116 mm. To accommodate the size differences often found between the proximal and distal portions of the aorta in thoracic aneurysms, tapered grafts are available for better aneurysmal conformability and prevention of junctional endoleaks. Four configuration categories are available: proximal main, proximal extension, distal main, and

Table 3. Comparison of Talent and Valiant Devices

Characteristic	Talent	Valiant
Diameter range	22–46 mm	24–46 mm
Length range (total length)	8–13 cm	10–23 cm
Delivery system	CoilTrac	Xcelerant
Location of stent springs	Inside of graft material	Outside of graft material
Connecting bar	Yes	No
MRI conditions	Tested safely at 1.5 Tesla	Tested safely at 3 Tesla
Number of peaks on end springs	5	8
Number of peaks on body springs	5	Same
Access profile (OD)	22F to 25F	Same
Graft material	Dacron (polyester)	Same
Stent material	Nitinol	Same
Tapered configurations	Yes	Same

MRI = magnetic resonance imaging; OD = outside diameter.

distal extension. The proximal configurations and the distal extension are offered with a bare-spring design (FreeFlo), which allows placement of the device across the origins of the arch vessels proximally and the celiac artery distally for suprasubclavian and infraceliac fixation, respectively.

THE VALIANT DEVICE. The Valiant device is designed based on the experience with the Talent device. Like its predecessor, the Valiant device is also a preloaded stent-graft made of the same polyester graft built onto a self-expanding nitinol skeleton. Modifications have been made to improve trackability, conformability, and deployment. First, device lengths have been increased to a maximum of 230 mm (130 mm for Talent). Because the device is a sheathless system, each piece requires individual deployment through the access vessel, resulting in repeated catheter exchanges in the artery. Longer lengths have been designed to minimize device exchange during deployment. Second, the connecting bar has been removed in the Valiant device for improved conformability, especially in the arch. Third, the number of bare springs at the proximal and distal ends of the device has been increased from 5 to 8 to improve circumferential force distribution and fixation along the aortic wall. Finally, the device is introduced in a new delivery system: Xcelerant.

DELIVERY SYSTEM. First available to physicians in the United States for use with the AneuRx abdominal aortic aneurysm device, the Xcelerant delivery system has been modified for the Valiant device to provide a more comfortable deployment mechanism, especially when there is tortuosity in the distal arch and thoracic aorta. As opposed to a simple pullback unsheathing mechanism, deployment of the Xcelerant delivery system includes a gearing, ratchetlike mechanism in the handle to allow easy deployment. The amount of force required to deploy the device is reduced significantly without compromising the precision of the deployment.

Like the Talent device, the Valiant device is a modular design. Eighty-eight different configurations are available, ranging from a diameter of 24 to 46 mm and covering lengths from 100 mm to 230 mm. Four configuration categories are available: proximal FreeFlo straight component, proximal closed-web straight component, proximal closed-web tapered component, and distal bare-spring straight component. The proximal FreeFlo straight component is designed for the most proximal deployment zone, as the bare springs are designed to allow precise and crossing deployment of the arch vessels. In addition, it is designed as the first piece to be deployed.

SUMMARY. Approximately 20,000 Medtronic Talent and Valiant devices have been implanted worldwide. The Valiant device is an improved design based on the previous experience with the Talent device. The similarity and differences of the devices are summarized in Table 3. An FDA-sponsored trial using the Valiant device in descending thoracic aortic aneurysms has commenced.

EARLY AND MIDTERM OUTCOMES. Originally manufactured by the World Medical Corporation and subsequently acquired by Medtronic Corporation (Santa Rosa, California), the Talent thoracic endovascular device has been used throughout the world to treat thoracic aortic pathology. The clinical experience with the Talent device worldwide, the VALOR trial, as well as other devices, is summarized in Table 4.

The Medtronic VALOR trial is a prospective, multicenter, nonrandomized, observational trial evaluating use of the Medtronic Talent thoracic stent-graft system in the treatment of thoracic aortic pathology. The trial consists of three groups: (1) the test arm, (2) the registry arm, and (3) the high-risk arm. The test arm contains patients with thoracic aortic aneurysms who are considered candidates for traditional open repair with low to moderate risk (based on SVS/ISCVS criteria). At least 20 mm of normal aorta at the proximal and distal landing zones is required. Enrollment of 195 patients is complete, and 1-year follow-up data (mortality and successful an-

Table 4. Results With Predominantly Medtronic Talent Device

Author	No. of Patients	Mean Follow-Up (mo)	Talent Device No. (%)	Procedural Success (%)	Stroke (%)	Paraplegia (%)	Endoleak (%)	Reintervention (%)	30-Day Mortality (%)	Survival (%)
VALOR (high-risk group)	150	12	150 (100)	98	8.1	5.5	10 at 6 mo	2.8 at 6 mo	8.4	—
TTR	457	24	457 (100)	98	0.7	1.7	9.6	8 at 1 y 19 at 3 y	5	91 at 1 y 85 at 3 y 77 at 5 y
Zipfel [220]	172	—	123 (72)	92	4.6	1	—	—	9.7	—
Appoo [221]	99	—	63 (64)	100	?	2	23	10	5	85 at 1 y 71 at 3 y 52 at 5 y
Criado [119]	186	40	186 (100)	96.7	?	4.3	15 at 30 d	15	4.7	62.5 at 40 mo
Farber [225]	22	12.5	19 (86)	100	?	9	4	—	4.5	—
Riesenman [92]	50	9	45 (90)	96	4	0	20	14	8	79.4 at 3 y
Scheinhert [223]	31	15	29 (94)	100	6	0	0	0	9.7	90 at 17 mo
Fattori [108]	70	25	67 (96)	97	1.5	0	7	4	8	91 at 25 mo
Ellozy [222]	84	15	62 (74)	90	4	4	5	—	6	67 at 40 mo
Herold [224]	34	8	33 (97)	100	?	0	0	—	2.9	88.7 at 8 mo

d = days; mo = months; TTR = Talent Thoracic Registry; y = years; ? = data not reported.

eurysm treatment) are accruing. The registry arm (27 patients) includes patients considered open surgical candidates with low to moderate risk, but with proximal or distal landing zones less than 20 mm, chronic pseudoaneurysm, or chronic dissection.

Results of the high-risk arm were reported at the Society of Vascular Surgery meeting in 2005, but not published. High-risk patients were not considered candidates for open operation and had degenerative aneurysms (82%), chronic dissection with aneurysmal formation (9%), pseudoaneurysm (9%), traumatic injury (6%), and complicated type B dissection (4%). A total of 150 patients were enrolled in this arm, with mean age of 73 years. Procedural success was 98%, and 30-day mortality was 8.4%. Prevalence of neurologic complications was 8% for stroke and 5.5% for paraplegia. At 1- and 6-month follow-up, prevalence of endoleak was 12% and 10%, respectively, with secondary reintervention of 2.8% at 6 months. In this arm, 15% of patients required an arterial graft, through which the device was deployed.

The European experience with this graft was recently reported in the Talent Thoracic Retrospective Registry [193]. This registry involved seven major European referral centers that enrolled patients over an 8-year period. Follow-up data were obtained for 457 patients (113 emergent and 344 elective procedures). Aortic pathology included aortic dissection (n = 180, 39%), arteriosclerotic aneurysm (n = 137, 29%), pseudoaneurysm, (n = 14, 3%), penetrating ulcer (n = 29, 6.3%), intramural hematoma (n = 12, 2.6%), and posttraumatic aneurysm (n = 85, 18%). Mean age was 60 years. Procedural success was 98%. Immediate conversion to open surgical repair was required in 3 patients (0.7%). Prevalence of early endoleak was 21% (98 patients); 26 of these resolved during follow-up with no further treatment, 18 resolved with endovascular adjunctive treatment with graft extension, and 10 resulted in aneurysm expansion requiring open surgical repair. In-hospital mortality was 5% (emergent, 7.9%; elective, 4%). Mean duration of follow-up was 24 months. Late mortality was 8.5% (n = 36); 7 of these patients presented with aortic rupture. All had persistent endoleaks. Prevalence of stroke and paraplegia was 3.7% (n = 17) and 1.7% (n = 8), respectively. In 70% of cases, only one stent was deployed, with a mean length of coverage of 131.5 mm (range, 28 to 380 mm). Kaplan-Meier overall survival estimates were 91%, 85%, and 77% at 1, 3, and 5 years, respectively. Freedom from a second procedure (open or endovascular) was 92%, 81%, and 70% at 1, 3, and 5 years, respectively [193].

Several single-institution series using the Medtronic Talent device have been reported, with similar results to the VALOR trial and the Talent Thoracic Retrospective Registry [92, 108, 119, 220–224]. The largest series, reported by Criado and associates [119], consisted of 186 patients (aneurysm, 111; dissection, 75) treated during a 92-month period. Procedural success was 96.7%. Thirty-day mortality was 4.7%, and prevalence of paraplegia was 4.3%; prevalence of stroke was not reported. Seventeen patients in the aneurysm group (15% of the total) were found to have angiographic evidence of endoleak within 30 days. At an average follow-up of 40 months, mortality in the aneurysm and dissection groups was 62.5% and 58.1%, respectively [119].

At The Society of Thoracic Surgery's 42nd annual meeting (Chicago, 2006), Zipfel and associates [220] reported a series of 172 patients who underwent endovascular treatment of descending thoracic aortic pathology, predominantly with the Medtronic Talent device (n = 123). Emergent operations were performed in 112 patients (57%). The indication for operation in 24 patients

(12%) was reintervention for endoleak from previous endovascular repair. Primary and secondary technical success was 85% and 92%, respectively, with 6 conversions to open repair. Neurologic complications included stroke (4.6%) and paraplegia (1.0%). Overall 30-day mortality was 9.7% [220].

In a series reported by Riesenman and associates [92], 50 patients underwent endovascular stent-graft treatment of descending thoracic aortic pathology, predominantly using the Medtronic Talent device (n = 45). Elective stent-graft deployment was performed in 39 patients and emergent deployment in 11. In the elective group, pathology included degenerative aneurysms (n = 24), pseudoaneurysms (n = 11), aortic dissection (n = 2), and penetrating ulcers (n = 2). Procedural success was 96%, with an overall endoleak prevalence of 20% (n = 10) and endovascular reintervention prevalence of 14% (n = 7).

In a smaller series looking at endovascular stent-graft for rupture and dissection, Farber and associates [225] reported a series of 22 patients with a diagnosis of ruptured thoracic aneurysm and dissection, treated predominately with the Medtronic Talent device (n = 19, 86.4%). All patients undergoing elective repair of aneurysm or dissection were excluded. Procedural success was 100%, with a 30-day mortality of 45.5% (aneurysm 27%, dissection 64%). Spinal cord ischemia was seen in 2 patients (9%). Unfortunately, stroke prevalence was not reported [225].

Improved results were reported by Scheinert and associates [223] in a series of 31 consecutive patients undergoing endovascular stent-graft repair of acute perforating lesions of the descending aorta, predominantly using the Medtronic Talent device (n = 29). In 21, the aortic perforation was due to rupture of a descending thoracic aneurysm or dissection, and in 10, the diagnosis was traumatic transection. Procedural success was 100%, with an overall 30-day mortality of 9.7%. At a mean follow-up of 17 months, there was no paraplegia and no death; however, the prevalence of stroke was 6% (n = 2) [223].

SUMMARY. Preliminary data demonstrate that short-term and midterm outcomes with the Medtronic Talent device compare favorably with conventional open repair. Procedural success is greater than 95% in most reported series, with prevalence of paraplegia ranging from 0% to 9% and 30-day mortality ranging from 2.9% to 9.7%. Risk of stroke has been high, ranging from 3.7% to 8.1%.

Cook Zenith Endografts

Lars G. Svensson, MD, PhD

The Cook Zenith TX1 and TX2 thoracic endovascular grafts (Cook Inc, Bloomington, Indiana) were developed in the context of a worldwide collaborative effort based on open and endovascular experience [32, 82, 118, 120, 139, 174, 177, 212, 213, 226–231]. The devices, commercially available in Australia since 2001 and in Europe and Canada since 2004, are founded on the platform of the Zenith abdominal aortic aneurysm graft [82, 174]. The design has been previously described [226], but fundamentally, it consists of stainless steel Z-stents and full-thickness polyester fabric. The Zenith endograft is introduced through a preloaded catheter with triggers. The two stent-grafts used for descending aortic repairs consist of a proximal stent with proximal engraved bare metal "V" wires with terminal barbs. After the first internal Z-stent, the remaining stents are external except for the last one of the proximal component. The second component has a proximal internal Z-stent, and the remaining intervening Z-stents are all external except the terminal one, which is internal and has external barbs attached to it.

The stents are attached to the fabric with large gaps (6-mm, 8-mm, or 10-mm, depending on device diameter) to provide flexibility of the device; diameter ranges from 22 to 42 mm. Unique to the Zenith system is that after introducing the proximal component to the site of choice, it is released out of the delivery catheter; however, the bare metal barbs are not released until positioning is certain, at which point a trigger allows for release of the barbed component. Before triggering the barbs, positioning can be adjusted, but this should be avoided. The second component is then seated in the first. If components are correctly chosen, balloon fixation is usually not required. Because the proximal barbs and stent are released by a trigger, hypotension and bradycardia are not needed for seating the stent-graft.

Several design variations exist, and the justification for each component is as follows:

1. *Proximal fixation system:* Barbs were added to mimic a surgical anastomosis and discourage migration. Uncovered proximal stents are not used because of concern about unequal proximal stent apposition with subsequent erosion of the aortic wall or potential for creating retrograde proximal dissection.
2. *Distal fixation systems:* Two distal fixation systems exist. For large fusiform aneurysms, a desire to incorporate barbs intended to prevent proximal migration of the distal stent prompted the addition of an uncovered distal stent with cranially oriented barbs. Such a design is not intended for use with dissections or in the setting of marked distal tortuosity. Therefore, the option to have a distal component without an uncovered stent or barbs exists and is used in those circumstances.
3. *TX1 design:* This is a single-piece, proximal and distal fixation system. The design incorporates proximal barbs and a distal uncovered stent with barbs and is intended for use in relatively short (< 12 cm in length) aneurysms of the descending thoracic aorta. Length of the device can be up to 202 mm.
4. *TX2 design:* This is a two-piece design whereby the proximal and distal fixation systems are on separate components, each with a variable length. It is intended to be used for longer (> 12 cm) thoracic aneurysms. The first component (proximal or TX2P) is sized from the proximal sealing segment to the distal end of the aneurysm, while the distal com-

ponent (TX2D) is sized from the proximal aneurysm to the distal seal, with an optional uncovered distal stent with cranial barbs used for supplemental fixation. The entire length of the aneurysm serves as an overlap zone to discourage component movement. Lengths range from 120 to 207 mm.

5. *Variations:* Given that thoracic aneurysms come in different shapes, sizes, lengths, and morphologies, many device combinations have been used for different circumstances. For example, in the setting of distal pathology, the TX2D device has been used in the absence of a TX2P device. In addition, for more isolated pathologies such as aortic diverticulum, extensions have been used in isolation. Extensions that currently exist are described as follows: (a) TBE is intended to be a proximal extension; thus, it is short (77 to 80 mm), but has a proximal fixation system incorporating barbs as described above. (b) ESBE is intended to extend the distal end or a joint between the joints; there are no barbs on this extension.

The delivery system is also relatively unique and has undergone several redesigns. The design currently used in the US trial has a sheath with a hydrophilic coating made of flexor material (to prevent kinking). Sheath size is from 18F to 22F, depending on the maximal stent diameter. The devices are attached to the delivery system using trigger wires. This is done so that deployments can occur in a controlled manner (without inducing hypotension or asystole). After sheath withdrawal, the trigger wires are removed to allow engagement of the fixation systems with the arterial wall.

IMPLANT RESULTS. The prospective US FDA trial has accumulated data on patients treated with TX1 and TX2 devices. The trial design was similar to that of other endovascular grafts and has been published [229]. It involved comparison with a mixed control group consisting of retrospective and prospective patients treated with open surgery. Given the commercial availability of the device in other countries and single-center trials within the United States, a plethora of data has been collected that helps to reassure us that the device is safe and efficacious. Table 5 summarizes studies that have included use of Zenith stent-grafts.

Overall, the results with this device seem satisfactory. There is evidence, analogous to the Zenith infrarenal graft, that aneurysms shrink in approximately 50% to 60% of patients, and thus, the natural history of the disease is reversed [32]. Techniques and modifications of the implant and delivery system have allowed for iterative improvements. There are some upcoming changes to the overall system and several areas of ongoing development:

1. *Delivery system:* Additional flexibility has been achieved by conversion of the stainless steel delivery system components to nitinol-based designs and incorporating more flexible sheaths and dilators. This has provided a new delivery system that has been used in the setting of extreme tortuosity and very proximal disease (such as ascending aortic aneurysms); it will likely be released in the near future.
2. *Distal fenestrations:* Thoracic aneurysms that abut the mesenteric vessels have been excluded from endovascular repair unless one is willing to sacrifice the vessel or perform a mesenteric bypass procedure preoperatively. Fenestrations, similar to the designs for juxtarenal aneurysms, have been used in more than 30 patients.
3. *Proximal fenestrations:* Extensive aneurysms that involve the arch and descending thoracic aorta require a staged approach involving an elephant trunk graft with a completion procedure (as described in the section on hybrid procedures). An endovascular device with fenestrations capable of accommodating the brachiocephalic vessels has been developed and used in about 20 patients. Results are promising and forthcoming soon.
4. *Branched devices for thoracoabdominal aneurysms:* These devices are extensions of thoracic, abdominal, and fenestrated technologies to allow for treatment of very complex aneurysms. This technology is promising and was published [218] and recently presented at the American Association for Thoracic Surgeons annual meeting. Both devices demonstrated good short-term results.

The FDA multicenter trial results were presented at the Society for Vascular Surgery Meeting in Baltimore, 2007. Of note, overall composite morbidity and outcome at 1 year was better in the descending aortic stent-graft group ($p < 0.05$). There are, however, certain caveats and interesting findings. The open surgical group included patients with type I thoracoabdominal aneurysm repairs, more patients with previous aortic surgery, and who had deep hypothermia with circulatory arrest for open distal aortic arch repairs. Of note, the incidence of death, lower limb paralysis, and stroke was equivalent. At 1 year, there was no difference in the need for reintervention or death. Food and Drug Administration review and approval are likely in 2008 for the Cook Zenith Device.

First-Generation Thoracic Aortic Stent-Grafts

D. Craig Miller, MD

The first thoracic aortic stent-graft procedure was performed at Stanford University Medical School in July 1992, soon after Parodi's pioneering work with stent-grafts for abdominal aortic aneurysms [232]. The patient had an enlarging pseudoaneurysm at the site of a coarctation patch repair performed when he was a child.

Since the inception of our Stanford thoracic aortic stent-graft experience 15 years ago, which now totals more than 400 thoracic aortic stent-grafts implanted, we at Stanford have worked as an integrated, cohesive team between interventional radiology and cardiovascular surgery [100, 120]. Regardless of who handles the referral, we jointly decide whether any intervention (open surgical or endovascular) is indicated and prudent; disagree-

Table 5. Results With Predominantly Cook Devices

Author	No. of Patients	Mean Follow-Up (mo)	Zenith Device No.	Procedural Success (%)	Paraplegia (%)	Stroke (%)	Endoleak (%)	Reintervention (%)	30-Day Mortality (%)	Survival (%)
Greenberg [32][a]	100	14	100	88	2.0	3 (3)	6.2 at 12 mo	14	7.0	83 at 12 mo 77 at 24 mo
Melissano [260][a]	45	7.3	45	97.8	2.2	?	2.2	—	0.0	-(2 patient deaths)
Stanley [261][a]	4	9.6	4	100	0.0	?	—	25	0.0	75 at 10 mo
Mossop [262]	Case study	12	1	100	0.0	?	—	—	0.0	100
Lawrence-Brown [263][a]	2	36	2	100	0.0	?	0	—	0.0	100 at 3 y
EUROSTAR[a]	40	—	40	82.5	0.0	?	5.6 at 1 mo 0.0 at 12 mo	—	—	90
Bergeron [264]	25	15	6	—	0.0	1 (3)	12	—	8.0	88 at 15 mo
Bortone [265]	110	20.8	9	96.4	0.0	1 (1)	1.8	—	—	93.7
Matsumura [266]	1,180	—	136	—	2.5	?	10.5	—	4.1 (degenerative aneurysm group)	—
Orford [267]	9	21	8	—	0.0	?	—	11	11	—
Riesenman [92]	50	8.9	1	96	0.0	2 (4)	20 at 12 mo	—	8.0	79.4 at 12 mo 79.4 at 36 mo

[a] Data (Zenith only) derived from the EUROSTAR (European Collaborators Registry) database as of 5/11/2006.

Note: Outcomes with Zenith devices. Shaded data refer to series reported exclusively with the Zenith device. The remaining portions of the table refer to data that have been extrapolated from mixed reports.
mo = months; y = years; ? = data not reported.

ments have arisen, but over time mutual respect and trust have grown and made this collaborative team approach function seamlessly and without friction. If an endovascular procedure is thought to be the best alternative, we do the stent-graft procedures together. If open surgical repair is deemed best, radiologists frequently look at the pathology in the operating room. Working together promotes the best medical decisions for the patient. Cardiovascular surgeons usually have the veto vote regarding the decision on whether any procedure is necessary versus continued medical management and watchful waiting.

The most vexing cases to resolve have been elderly *asymptomatic* patients with a limited life expectancy who already are disabled due to the ravages of other medical problems and who are not suitable open surgical candidates. Until 2003 we did offer these patients the stent-graft option, but candid self-reassessment of 5-year survival in this "inoperable" patient cohort (*vide infra*) forced us to admit that we were not helping them live satisfying, independent lives, nor were we relieving any pain or other symptoms [120]. We were simply mollifying their understandable fear and catering to pressure generated by children and grandchildren who hoped that something could be done.

We admitted making a judgment error in 2004 [120], and no longer offer these patients a stent-graft, because all that potentially can be accomplished is prolonging the preexistent poor quality of life they already faced. They may live longer, but they remain disabled and in pain owing to lung, cardiac, cerebrovascular, or renal disease, on dialysis, and nonambulatory due to arthritis or other medical problems.

This quality of life is not acceptable to many elderly patients, the majority of whom accept that they are nearing the end of their lives. Just because something can be done does not mean it should be done, and seasoned physician judgment is imperative. Gentle counseling of family members can usually dissuade them from the notion that anything technically possible must be performed. All we can strive to achieve as caring and compassionate physicians is to allow patients to die comfortably and with dignity, hopefully at home; prolonging patient suffering by preventing aneurysm rupture after stent-grafting is not what medicine is all about.

After 2 years, 13 cases of thoracic aortic stent-grafting had been accumulated and we published our first preliminary feasibility report in December 1994 [232]. Most candidates had contraindications to open surgical repair. Primitive homemade stent-grafts consisting of Gianturco stainless steel Z-stents covered by woven polyester (Dacron) graft material were custom constructed for each patient. These first-generation devices were large and cumbersome. The stent-graft delivery systems were equally primitive, incorporating a large (24F) sheath-dilator system that had to be advanced into the aortic arch, with the obvious potential for cerebral arterioemboli resulting potentially in stroke. Despite the technical limitations of these early devices and delivery systems, early and 1-year results were satisfactory in these 13 selected patients, with no deaths and no major complications (including stroke or paraplegia). Thus, the feasibility and periprocedural safety of thoracic aortic stent-grafting had been established.

Between 1992 and 1997, the Stanford series of patients receiving first-generation homemade thoracic aortic stent-grafts had reached 103 patients and was subjected to a comprehensive analysis of safety and efficacy out to 5 years [100]. Average patient age was 76 $\pm$ 12 years (range, 34 to 89). Importantly, based on a surgeon's opinion, 62 of 103 patients (60%) were deemed not to be reasonable open surgical repair candidates. The pathology treated was arteriosclerotic degenerative aneurysm in 62%, aortic dissection in 8%, traumatic false aneurysm in 8%, penetrating aortic ulcer in 10%, and other/miscellaneous conditions (mycotic pseudoaneurysm, intramural hematoma, anastomotic pseudoaneurysm) in 13%. Emergency procedures were carried out in 16% of cases. There was 1 emergency conversion to open surgical repair when the sheath-dilator ruptured the proximal descending aneurysm adjacent to an elephant trunk graft, which was the stent-graft proximal landing-zone target; this patient died.

Despite the technical limitations imposed by the primitive first-generation stent-grafts and delivery systems and the fact that this experience represented the Stanford initial learning curve era, early mortality was 9% $\pm$ 3%. Multivariable analysis revealed that prior myocardial infarction raised the risk of death by eightfold and prior stroke by ninefold. Risk of early death was highest in the "other/miscellaneous" category of aortic diseases treated. Postoperative complications occurred frequently, including stroke in 7%, paraplegia/paraparesis in 3%, myocardial infarction in 2%, respiratory insufficiency in 12%, and early endoleak in 24%. The admittedly high prevalence of stroke was probably due to extensive manipulations of the stiff, bulky sheath-dilator system in the diseased aortic arch.

Conversely, prevalence of spinal cord injury was low, even though many lower descending thoracic aortic intercostal arteries were covered. One factor did emerge related to paraplegia: prevalence of paraplegia/paraparesis was higher in the 19 patients who underwent concomitant abdominal aortic aneurysm repair and thoracic aortic stent-grafting than in 84 who underwent isolated thoracic aortic stent-grafting (11% $\pm$ 7% versus 1% $\pm$ 1%, respectively). Early technical success was only 73% in this early experience, but ultimately the aneurysm sac was completely thrombosed in 84% of cases. Overall actuarial survival estimate was 73% $\pm$ 5% at 2 years; most of the deaths occurred among patients in the subgroup judged not to be open surgical candidates (odds ratio = 5.2).

The actuarial estimate of freedom from treatment failure, according to the Stanford definition (given previously), was only 65% $\pm$ 5% at 1 year and 53% $\pm$ 10% at 3.7 years. These unsatisfactory results can be attributed to the early learning curve experience and to the fact that in the early years, bland-appearing endoleaks were followed and not aggressively treated. Indeed, one of the multivariable determinants of treatment failure was ear-

lier operative year, reflecting that this group learned from their mistakes, and patient selection criteria became more stringent over time. It was soon recognized that no patient should leave the hospital if any type I endoleak was detected.

Numerous stent-graft–related complications also occurred as follow-up progressed, and these were treated either interventionally or with open surgical repair [100]. Prevalence of endoleaks was highest in patients in whom the distal landing zone was located in the proximal descending aorta, indicative of the landing zone problems created by the distal arch anatomy. Aneurysm size was assessed in 23 selected patients who had a 1-year follow-up CT scan available: aneurysm diameter increased in 26% by 3 mm or more, usually associated with an endoleak, remained similar in 26%, and decreased by 3 mm or more in 48%.

These results from the early 1990s using crude first-generation devices were considered to be acceptable, but there obviously was much room for improvement. This aspiration materialized with the subsequent clinical introduction of more sophisticated, smaller, more flexible commercial thoracic aortic stent-grafts and elegant delivery systems by W.L. Gore. These required a guidewire to be passed only across the arch, obviating the need to manipulate the sheath-dilator delivery system into the descending thoracic aorta or transverse arch. Results using these newer commercial stent-grafts, described previously, are notable for a marked reduction in risk of stroke and death and far fewer early type I endoleaks. Of course, patient selection criteria and physician decision making also evolved over time, so these improved results cannot be entirely attributed to the new commercial stent-grafts.

The key unanswered question remained, however: just how durable would thoracic stent-graft repair be over the long term? The Stanford group followed their original 103 patients out further and in 2004 reported their 5- to 10-year results, focusing specifically on predictors of adverse late outcome [120]. Follow-up averaged 4.5 ± 2.5 years (range, 5 to 10), was 100% complete in the July to December 2003 closing interval, and included a total of 422 patient-years of data. Forty-eight patients remained alive and at risk at 5 years, such that meaningful inferences could be drawn about 5-year outcome.

As shown in Figure 9, panel A, overall survival was substantially inferior to an age- and sex-matched US population. Panel B demonstrates that survival was dismal in the 60% of stent-graft patients who had been judged not to be reasonable open surgical repair candidates; 5- and 8-year actuarial survival estimates for this cohort were 31% ± 6% and 28% ± 6%, respectively, compared with 78% ± 6% and 38% ± 12% for those who were open surgical candidates.

Causes of late death associated with descending thoracic aorta repair included aortoesophageal or aortobronchial fistula in 3 and thoracic aortic rupture in 3. Additionally, 7 late, sudden unexplained deaths occurred, which might have been related to the thoracic aorta

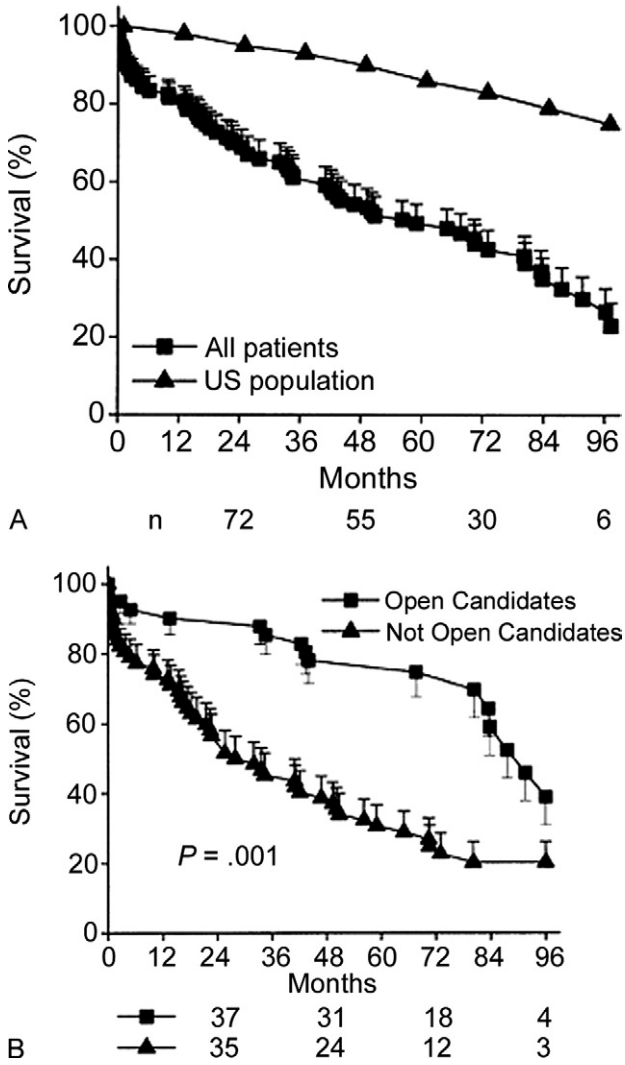

Fig 9. (A) Overall actuarial survival estimates for all 103 patients (1 SE). For perspective, this graph also portrays survival curve for age- and sex-matched US population. (Squares = all patients; triangles = US population.) (B) Actuarial survival according to whether patient was judged not to be a reasonable surgical candidate for open repair (1 SE). (Squares = open candidates; triangles = not open candidates.) (Reprinted from J Thorac Cardiovasc Surg, 127, Demers et al, Midterm results of endovascular repair of descending thoracic aortic aneurysms with first-generation stent grafts, 664–73, Copyright (2004), with permission from Elsevier [120].)

repair. The remaining 40 deaths (75%) could not be blamed on the thoracic aortic stent-graft repair.

Turning to stent-graft complications, the actuarial estimate of freedom from reintervention was 70% ± 6% at 8 years; using the cumulative incidence (or *actual, vide supra*) conceptual framework, *actual* freedom from reintervention was 78% ± 4% at 8 years. Eleven patients sustained rupture of the treated aortic segment, which was fatal in 10. Actuarial freedom from aortic rupture was 80% ± 8% at 8 years, and the *actual* estimate was 91% ± 3%. Actuarial and actual estimates of freedom from early or late endoleak were 50% ± 9% and 67 ± 5% at 8 years,

respectively. For the comprehensive composite clinical endpoint of treatment failure, as defined by the Stanford group, the actuarial freedom estimate was only 39% ± 8% at 8 years; in *actual* terms, this estimate was 52% ± 5% at that time.

These observations were the first long-term results to be published after endovascular stent-graft repair of descending thoracic aortic pathology and raised concern about suboptimal patient survival, freedom from aortic rupture, and the worrisome prevalence of early and late stent-graft–related complications. Specifically, the 5-year outlook in the 60% of patients who were not surgical candidates was poor, suggesting that if these patients were asymptomatic, they might best be managed conservatively, avoiding stent-grafting. As mentioned previously, these elderly patients also had multiple additional medical conditions that handicapped their quality of life; because stent-grafting does not improve quality of life in asymptomatic patients, the logic of proceeding with an invasive intervention to prevent aneurysm rupture in patients who are approaching the end of their expected biological lifespan is not persuasive.

Late aortic complications occur in a substantial proportion of stent-graft patients, emphasizing the importance of strict serial imaging surveillance indefinitely. This risk has been reduced by introduction of second-generation commercial stent-graft devices and better patient selection criteria, but still represents the leading drawback to endovascular stent-graft treatment. Only decades of follow-up in larger cohorts of patients will reveal the true long-term durability of stent-graft repair.

Finally, stent-graft repair of thoracic aortic dissections must remain in the domain of surgeons with expertise to deal with open thoracic aorta operations, because they have the global training, expertise, and experience to understand fully the natural history of the disease, the clinical judgment to decide prudently when an intervention is necessary, and the surgical skills necessary to deal with severe life-threatening complications when they do occur using conventional open surgical techniques after interventional "bailout" maneuvers are unsuccessful. Cardiovascular surgeons should work together collectively with interventional radiology, interventional cardiology, and vascular surgical colleagues in the endovascular care of patients with thoracic aortic problems; this team approach will put patients' welfare first and foremost, where it belongs, and ahead of personal egos and local political turf battles.

Abdominal Aortic Aneurysm Treatment

Michael A. Curi, MD, MPA, and Gregorio A. Sicard, MD

With the exception of the INSTEAD trial, no prospective randomized studies have compared the natural history of descending thoracic disease with either open surgery or stent-graft treatment, nor have any compared open surgery and stent-grafting. Thus, an examination of published randomized studies on infrarenal aneurysmal disease is informative to the discussion of the best treatment of thoracic aortic disease.

Randomized Controlled Trials and Long-Term Results

According to the Centers for Disease Control, between 43,000 and 47,000 patients die in the United States each year from diseases of the aorta and its branches; it is a major killer, causing more death than motor vehicles, homicides, colorectal cancer, or breast cancer [233]. Yet little is known of its causes, epidemiology, or best treatments. Abdominal aortic aneurysms (AAA), however, have been the best studied for indication and methods of treatment. These studies, discussed in the text that follows, illuminate the treatment of descending thoracic aneurysms.

Abdominal aortic aneurysms result in approximately 12,000 to 15,000 deaths per year in the United States and is a leading cause of death in men over the age of 65 [234, 235]. Thus, it might be assumed that if a patient is found to have AAA, it should be treated to avoid the risk of sudden death. However, while AAA is present in 3% of the male population over age 60 and in as many as 12% of elderly, hypertensive smokers [236, 237], the majority of these patients will die from a cause other than AAA. Add to this that AAA repair has classically been associated with high morbidity and mortality while nonruptured aneurysms are asymptomatic, and the result is a difficult dilemma as to the best treatment for both patients and treating physicians. These are the factors that led to an international debate to determine which types of AAA should be treated.

To address this question, the natural history of AAA must be characterized. Originally, the presence of an AAA was an indication for treatment, until risk of rupture was linked to diameter of AAA, presence of symptoms, and rate of expansion. Larger aneurysms were clearly associated with high prevalence of rupture and mortality, while many patients with smaller AAAs would die from other causes. Clearly, randomized controlled studies were necessary to determine just how small aneurysms needed to be to warrant postponement of surgery.

In 1990, a survey of members of the Society of Vascular Surgery identified surgery for small AAA as one of the areas of vascular surgery most in need of a randomized trial. Shortly thereafter, vascular surgeons in the United Kingdom, Canada, and the United States initiated trials to test the hypothesis that early, prophylactic elective surgery decreases long-term mortality in patients with small AAA. The Canadian trial ended early because of inadequate recruitment. The UK and US trials were completed and resulted in a significant change in the general practice with regard to treating small AAA. No similar studies have been done for descending thoracic aneurysms.

United Kingdom: Small Aneurysm Trial

This study was designed to test the hypothesis that early prophylactic, elective repair resulted in decreased mortality in patients with small infrarenal AAAs [238, 239]. It was a multicentered trial in which 1,090 patients aged 60

Table 6. Summary of United Kingdom Small Abdominal Aortic Aneurysm (AAA) Trial

Outcome	Operated (%)	Surveillance (%)
Six-year survival	64	64
Nine-year survival	53	45
AAA-related mortality	6.2	6.1
Perioperative 30-day mortality	5.8	7.1

to 76 years with small aneurysms (4 to 5.5 cm) and no medical contraindication to surgical repair were randomly allocated to one of two groups: (1) early surgery or (2) surveillance with ultrasound, with surgical repair if the aneurysm reached 5.5 cm or growth exceeded more than 1 cm per year. Surveillance was every 6 months for 4- to 5-cm AAAs and every 3 months for 5- to 5.4-cm AAAs. The *primary endpoint* was all-cause mortality; aneurysm rupture and death from surgical repair of AAAs were *secondary endpoints.* Initial results with 6-year follow-up were published in *Lancet* in 1998 [238], and a second report was published in *The New England Journal of Medicine* in 2002 [239], including 9 years of follow-up.

The two groups were similar, and the study is generally regarded as a valid well-conducted, randomized controlled trial (Table 6). By 6 years, approximately one third of all patients had died. There was no difference in all-cause mortality between groups for all patients or for any subgroup of patients at 6 years. In the early surgery group, perioperative mortality was 5.8%. About three fourths (74%) of patients in the surveillance group eventually underwent surgical repair over 8 years of follow-up, and their repair was associated with 7.1% perioperative mortality (compared with 5.8% in the early surgery group). Of all deaths in the surveillance group, 8% were due to aneurysm rupture, with the majority of these being in small aneurysms that ruptured while under surveillance. By 9 years, only 39 of the original 527 patients in the surveillance groups were alive or had not undergone surgical repair. Furthermore, at 9 years, there appeared a small but statistically significant survival advantage for early repair patients (53% versus 45%).

The authors of this study concluded that surveillance of small aneurysms was safe and resulted in survival similar to that of early surgery. Due to the relatively high perioperative mortality of 5.8% in the early repair group, this study was criticized by many who believed that if AAA repair could be performed with lower prevalence of perioperative mortality, there would be a survival benefit for early repair of small AAAs. Despite this controversy, results of the subsequent report detailing the 9-year follow-up demonstrated a survival advantage for early repair. This finding is difficult to interpret, and the authors have suggested that it may be attributable to changes in lifestyle adopted by members of the early repair group. Nevertheless, this study was the first good evidence supporting safety of surveillance of small AAAs.

Aneurysm Detection and Management (ADAM) Study

In 1992, the Veterans Administration's medical system commenced the Aneurysm Detection and Management (ADAM) Study. The results were published in *The New England Journal of Medicine* in May 2002 (Table 7) [240].

This study was designed to determine which of two strategies was superior for managing an AAA of 4 to 5.4 cm in diameter: "immediate repair" or "selective repair." Selective repair refers to the observation of aneurysms with follow-up imaging at 6-month intervals, reserving surgery for those that enlarged to 5.5 cm, enlarged rapidly, or became symptomatic [241].

This study analyzed 1,136 patients aged 50 to 79 years with small aneurysms (4 to 5.4 cm) and no medical contraindication to surgical repair. Patients were randomly assigned to one of two groups: (1) immediate open repair or (2) surveillance with ultrasonography or CT scans at 6-month intervals, with surgical repair if the aneurysm reached 5.5 cm or growth exceeded more than 1 cm per year or 0.7 cm in 6 months. The primary endpoint was all-cause mortality, and the secondary endpoint was prevalence of aneurysm-related death.

The two groups were similar. Mean duration of follow-up was 5 years. At the end of the study, there was no difference in all-cause mortality between groups for all patients or for any subgroup of patients. Approximately 25% of the immediate repair group and 22% of the surveillance group had died, resulting in a relative risk of death of 1.2, with a 95% confidence interval of 0.95 to 1.5. The prevalence of aneurysm-related death also did not differ between treatment strategies. In the immediate repair group, perioperative mortality was 2.7%. Of the patients in the surveillance group, 62% eventually underwent surgical repair, and their operative repair was associated with a 2.1% perioperative mortality. Only 27% of patients remained alive and were still undergoing ultrasonographic surveillance of aneurysms of 5.5 cm or less at the end of the trial.

In a second report published in the *Journal of Vascular Surgery* in October 2003 [242], the health-related quality of life (HRQL) of the two groups was compared. There were no significant differences between the immediate repair and surveillance groups [242].

The authors of this study conclude that a strategy of immediate repair does not improve survival among patients with low surgical risk and small AAAs. These results confirmed those of the UK Small Aneurysm Trial and put to rest the issue of whether low perioperative mortality would result in differences in survival. The

Table 7. Summary of Aneurysm Detection and Management (ADAM) Trial

Outcome	Operated (%)	Surveillance (%)
Five-year survival	75	78
AAA-related mortality	3	2.6
Perioperative 30-day mortality	2.7	2.1

AAA = abdominal aortic aneurysm.

Table 8. Summary of Dutch Randomized Endovascular Aneurysm Management (DREAM) Study

Outcome	EVAR (%)	Operated (%)
Thirty-day mortality	1.2	4.6
Two-year survival	89.7	89.6
AAA-related mortality	2.1	5.7
Complication-free survival	65.6	65.9

AAA = abdominal aortic aneurysm; EVAR = endovascular aneurysm repair.

question raised was whether these two trials, with vigorous follow-up and surveillance, could be applied to practice settings with less rigorous surveillance programs. Also, this study was limited in that participants were essentially all men, and because women have higher risks of rupture and higher mortality associated with rupture or elective repair, this study's conclusion may not be applicable to women.

Endovascular Aneurysm Repair Studies

With the advent of new endovascular approaches to repair of AAA, the debate over which aneurysms to repair has taken on another dimension. Initially, endovascular aneurysm repair (EVAR) was used only for higher risk patients, and early nonrandomized studies showed shorter hospital stay and less morbidity than with open surgery. But, as this technology has been applied to a greater proportion of patients with AAA, a few critical questions are brought into the equation. Is endovascular repair equivalent to open repair? If it is equivalent, does this change the threshold for who should have aneurysm repair? Do patients, previously too sick to undergo open repair, receive any benefit from endovascular repair? These are the questions being addressed by randomized studies, which have been conducted in Europe and are currently in progress in the United States.

Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial

The DREAM trial was conducted at 24 sites in the Netherlands and four centers in Belgium from November 2000 through December 2003 (Table 8) [243]. A total of 351 patients with AAAs greater than 4.9 cm and fit for open and endovascular repair were randomized to either standard surgical repair or endovascular repair. The perioperative results were published in October 2004, and the primary endpoint was a composite of operative mortality and moderate or severe complications. The 2-year results were published in June 2005, with survival as the primary endpoint and AAA-related death and complication-free survival as secondary endpoints. The types of endografts used were 33% Zenith, 27% Talent, 22% EXCLUDER, and 17% other [243].

This study demonstrated a clear advantage for endovascular repair in terms of operative morbidity and mortality. Operative mortality was 4.6% in the open repair group and 1.2% in the endovascular repair group, resulting in a risk ratio of 3.9. However, by 2 years, survival did not differ between groups (90%). Complication-free survival was also similar between the two groups (66%).

This study clearly showed the early perioperative advantage of EVAR over open repair. It also demonstrated that this survival advantage was *not* sustained at 2 years. The commonly proposed explanation is that the survival advantage offered by EVAR may be due to postponement of death among higher risk patients who would have died if subjected to the stress of a large open operation. Clearly, not all "eligible" patients are the same in their ability to withstand a major operation. Alternatively, comorbid disease may have been better addressed or managed in the open repair group, for example, detecting and treating coronary artery disease.

EVAR-1 Trial

The purpose of this study was to compare treatment of AAA using endovascular repair with open surgery in patients judged fit for open AAA repair (Table 9). The primary endpoint was all-cause mortality; secondary endpoints were aneurysm-related mortality, HRQL, postoperative complications, and hospital costs. Analyses were by intention to treat [244].

Between 1999 and 2003, 1,082 patients with AAAs greater than 5.5 cm and older than age 60 years were randomly assigned to either open repair or EVAR at 34 hospitals throughout the United Kingdom. The two groups were similar with regard to baseline characteristics. After a mean follow-up of 3.3 years, there was a clear benefit in terms of aneurysm-related mortality for EVAR (4% EVAR versus 7% open) that closely matches results of the DREAM trial [243]. Despite a much higher prevalence of late complications and reinterventions, AAA-related mortality remained lower for EVAR at 4 years postrandomization. Yet, this benefit came with significantly higher costs (33% more) over this period and did not translate into either a clinically significant improvement in HRQL or overall survival (74% EVAR versus 71% open). There was a persistent difference in AAA-related mortality in favor of EVAR. However, complications were significantly higher for EVAR (41%) versus open (9%) patients. Early reinterventions were similar between the two groups (6% EVAR versus 9% open). There were no clinically significant differences in HRQL.

Table 9. Summary of EVAR-1

Outcome	EVAR (%)	Operated (%)
Thirty-day mortality	1.6	4.6
Four-year mortality	26	29
AAA-related mortality	4	7
Postoperative complications	41	9
Late complications	42	20
Hospital costs (UK £)	13,257	9,946

AAA = abdominal aortic aneurysm; EVAR = endovascular aneurysm repair; UK = United Kingdom.

Table 10. Summary of EVAR-2

Outcome	EVAR (%)	No Intervention (%)
Thirty-day mortality	9	—
Four-year mortality	66	62
AAA-related mortality	14	19
Complications	43	18
Hospital costs (UK £)	13,632	4,983

AAA = abdominal aortic aneurysm; EVAR = endovascular aneurysm repair; UK = United Kingdom.

Based on these data, the authors concluded that EVAR offered no advantage with respect to all-cause mortality and HRQL over open operative repair, EVAR is more expensive than open repair, EVAR was associated with a greater number of complications and reinterventions, and EVAR resulted in a 3% better aneurysm-related mortality [245].

EVAR-2 Trial

The purpose of this study was to compare EVAR and best medical therapy versus best medical therapy alone with no intervention among patients deemed *not* fit for open surgery (Table 10). A total of 388 patients with AAAs greater than 5.5 cm and older than age 60 years and who had significant comorbid conditions precluding open repair were randomly assigned to EVAR (n = 166) or no intervention (n = 172) [246]. The primary endpoint was all-cause mortality, and secondary endpoints were AAA-related mortality, prevalence of complications, HRQL, and hospital costs [247].

Patients in EVAR-2 were older than in EVAR-1, with more cardiopulmonary comorbidities. This translated into a high 30-day operative EVAR mortality of 9% and a 4-year survival of only 34%. Despite more deaths from aneurysm rupture in the nonintervention group, the initial high operative mortality in the EVAR group resulted in no late difference in aneurysm-related mortality and no difference in overall survival. Thus, the authors concluded that EVAR offers no advantage to no intervention in this subgroup of patients with AAA and high levels of comorbidity [247].

Several questions have been raised about the applicability of these conclusions because of some unexpected results that stirred substantial debate. The AAA-related mortality in the EVAR group was reported as 14%, significantly higher than many previously reported series in "high-risk" patients. This 14% included 9 ruptured aneurysms during the time between randomization and EVAR. These ruptures accounted for nearly half the total of 20 aneurysm-related deaths in the EVAR group. The EVAR was not done until a median of 57 days after randomization despite a mean aneurysm diameter of 6.7 cm, a situation that does not coincide with general practice.

After randomization to the nonintervention group, 20% of patients subsequently underwent elective repair of their aneurysm in violation of the protocol. When only 1 (3%) of these patients died as a result of operation or an aneurysm complication during follow-up, it raised questions about the selection "unfit for surgery" criteria. Taken together, however, these effects biased the study against EVAR and reduced the power for a conclusive analysis. Nonetheless, the take-home message of EVAR-2 is clear and not surprising. Prophylactic operations designed to decrease all-cause mortality are not effective in patients with short life expectancy. It also points out the need to develop objective criteria to truly identify patients with large aneurysms (≥ 5.5 cm) who will not benefit from repair. The EVAR-2 trial results differ significantly from results published by the Society for Vascular Surgery Outcomes Committee in high-risk patients gathered from the database that included five multicenter IDE clinical trials that led to FDA approval (see below) [248].

Lifeline Registry

In an effort to evaluate long-term safety and effectiveness of endovascular treatment for infrarenal AAA, the Society for Vascular Surgery established the Lifeline Registry of Endovascular Aneurysm Repair in 1998 (Table 11). The registry uses a standardized reporting format that allows data from patients treated with endovascular grafts from different manufacturers to be pooled to determine the overall effectiveness of EVAR. Each patient within the registry was originally part of a multicenter controlled IDE clinical trial comparing endograft with open surgical repair (surgical controls [SC]). Each IDE clinical trial was sponsored by the manufacturer of the device, and the protocol, inclusion and exclusion criteria, and clinical results have been individually published [233, 249–253]. The compilation of data yielded cohorts of 2,664 endograft patients and 334 open SCs. Primary outcomes were all operative mortality, all-cause mortality, AAA-related mortality, aneurysm rupture, and conversion to open surgery [254]. Although not randomized, these highly audited data represent the best and longest follow-up available in the United States for evaluating long-term outcomes of EVAR.

Table 11. Summary of Lifeline Registry

	Data Related to 2,664 Endografts					
Outcome	1 Year (%)	2 Years (%)	3 Years (%)	4 Years (%)	5 Years (%)	6 Years (%)
Mortality	8	15	20	26	34	48
AAA-related mortality	2	2	2	2	2	2
Rupture	3	3	3	4	5	5

AAA = abdominal aortic aneurysm.

Thirty-day operative mortality was similar between the EVAR and SC groups (1.7% versus 1.4%), even though EVAR patients were significantly older and sicker than the SC patients and included patients at high risk for open surgery. During the first year of follow-up, no aneurysm ruptures were reported among SC patients (0%); 18 ruptures occurred among EVAR patients (0.2%). The ruptures included 3 early ruptures (< 30 days) and 15 late ruptures (> 30 days) and were reported from three of the four IDE clinical trials in the registry. Late aneurysm rupture prevalence for EVAR was 5% at 6 years, but this information was not available for SC patients. Overall mortality was high in both groups, as expected, and there was no difference at 4 years between SC (29%) and EVAR (26%; $p = 0.49$).

From this same database, the Society for Vascular Surgery Outcomes Committee evaluated the results of EVAR in high-risk patients [248]. Using a similar method, the same classification of the EVAR-2 trial for high-risk patients, 565 of 2,216 EVAR patients and 61 of 342 SC patients met high-risk criteria. The primary endpoints of AAA-related death, all-cause mortality, and aneurysm rupture were compared. Secondary endpoints included endoleak, AAA sac enlargement, and migration. Thirty-day operative mortality was 2.9% in EVAR versus 5.1% open ($p = 0.32$). The AAA-related mortality after EVAR was 3.0% at 1 year and 4.2% at 4 years, compared with 5.1% at both time points after open surgery ($p = 0.58$). Overall survival 4 years after EVAR was 56% versus 66% open ($p = 0.23$). After treatment, EVAR successfully prevented rupture in 99.5% at 1 year and 97.2% at 4 years. Despite these small differences, the conclusions of this study were that EVAR was safe in high-risk patients and provided excellent protection from AAA-related mortality [248]. No comparison was made with medical treatment.

The Lifeline Registry represents high-quality, closely monitored data for both high- and normal-risk patient populations. Although the data come from early experience with endovascular grafting, with some devices already out of date, results from current experiences with current devices would likely be even better. These data clearly show that EVAR is a safe and effective treatment for selected patients with infrarenal AAA and that it appears to be durable to 6 years of follow-up. EVAR, however, does not have significant advantages over open repair in terms of survival.

SUMMARY. Treatment of AAA continues to evolve with the development of new technologies and management strategies. EVAR has had a substantial impact in the treatment of AAA. Randomized trials of EVAR have altered treatment strategies and continue to incite further debate on their widespread application. Ongoing trials and evaluation of highly audited registry data sets will continue to shed light on the questions raised by these landmark studies. In the end, as physicians, we are obliged to apply the principles of evidence-based medicine in our practices as well as we can to each individual patient.

Table 12. Summary of Recommendation Classifications and Level of Evidence for Thoracic Stent-Graft Insertion

Entity/Subgroup	Classification	Level
Penetrating ulcer/IMH		
Asymptomatic	III	C
Symptomatic	IIa	C
Chronic traumatic	IIa	C
Acute type B dissection		
Ischemia	I	A
No ischemia	IIb	C
Subacute dissection	IIb	B
Chronic dissection	IIb	B
Degenerative descending		
> 5.5 cm, comorbidity	IIa	B
> 5.5 cm, no comorbidity	IIb	C
< 5.5 cm	III	C
Arch		
Reasonable open risk	III	A
Severe comorbidity	IIb	C
Thoracoabdominal/severe comorbidity	IIb	C

IMH = intramural hematoma.

In applying some lessons from AAA trials to descending thoracic aortic aneurysm repairs, it should be noted that for the abdominal aorta, despite it being smaller when not diseased, there is little evidence indicating repair of an asymptomatic aorta in men before 5.5 cm, either by EVAR or open repair. Furthermore, it should be noted that the late ratio of all-cause mortality to aortic aneurysm or surgery deaths is 4:1 to 5:1. This highlights how important it is to fully evaluate a patient for all comorbid disease at the time of intervention. The recommendations based on this review are summarized in Table 12.

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Appendix

Authors' Financial Relationships With Industry

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L.G. Svensson	Yes	Cook	
N.T. Kouchoukos	No		
D.C. Miller	Yes	Medtronic Heart Valve Division, Edwards Lifesciences, St. Jude Medical	R01 research grant, National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH) HL29589 (1982–2008), and R01 research grant, NHLBI, NIH HL67025 (2001– 2010)
J.E. Bavaria	Yes	W.L. Gore TAG, Medtronic Valiant	
J.S. Coselli	Yes	Cook, Medtronic, Vascutek Terumo	
M.A. Curi	No		
H. Eggebrecht	No		
J.A. Elefteriades	No		
R. Erbel	No		
T.G. Gleason	No		
B.W. Lytle	No		
R.S. Mitchell	Yes	W.L. Gore TAG Endograft	
C.A. Nienaber	No		
E.E. Roselli	Yes	Medtronic	
H.J. Safi	No		
R.J. Shemin	No		
G.A. Sicard	No		
T.M. Sundt	Yes	Atricute, Bolton Medical, Jarvik Heart, Medtronic, Sorin Group/Carbomedics, St. Jude Medical, Thoratec Corporation, W.L. Gore & Associates, Boston Scientific	
W.Y. Szeto	No		
G.H. Wheatley	Yes	W.L. Gore & Associates, Medtronic	