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Background. **We evaluated endovascular stent-grafting as a new technique in aortic surgery.**

Methods. **One hundred ninety-six stent-grafts were implanted in the thoracic aorta in 172 patients. All procedures but one were performed in the operating room by a team of cardiothoracic surgeons; 112 operations (57%) were emergency procedures. Twenty-four procedures (12%) were reoperations for endoleaks. The left subclavian artery origin was covered in 46 cases and the left common carotid artery in 2 cases. Access was by femoral cut-down in 174 procedures, percutaneous femoral approach in 1, and by conduit to the iliac arteries or infrarenal aorta in 17. Surgical reconstruction of damaged access vessels became necessary in 10 cases.**

Results. **Thirty-day mortality was 9.7% (19 patients). Paraplegia occurred in 1.0% (2 patients). Primary technical success was 85.2%, secondary 91.8%. Six conversions to open repair were necessary, 3 during the procedures and 3 secondarily before discharge. Actuarial survival was 79% at 1 year, 67% at 3 years, and 55% at 5 years.**

Conclusions. **The results are excellent, taking into account the high incidence of emergency procedures and that open surgery is not promising in many patients. The cardiothoracic surgeon can perform the procedure after adequate training in endovascular techniques. Surgical skills are mandatory because of the potential need for extended surgical approach to the access vessels or immediate conversion to open surgery. Therefore, the operating room is the preferred site for this procedure.**

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Since Parodi and colleagues [1] implanted their first homemade endovascular stent-graft, endovascular repair has evolved into a routine procedure for abdominal aortic aneurysms. In thoracic aortic lesions, the potential benefit for the patient is more evident than in abdominal aortic aneurysms because of the more significant mortality and morbidity associated with the conventional procedure. Dake and associates [2] implanted the first stent-graft in the thoracic aorta in 1992, and that series was the stimulus to develop commercial stent-grafts.

As they possessed endovascular skills, vascular surgeons, cardiologists, and radiologists started to treat the thoracic aorta as well as the cardiothoracic surgeons, to whom traditionally patients with thoracic aortic disease were referred. There is growing interest in the whole cardiothoracic community [3] in this new minimally invasive modality. Since we started our endovascular program very early with abdominal aortic aneurysms, experience has accumulated [4], and the technique is now fully integrated into our operative spectrum.

Patients and Methods

Between September 1999 and the end of 2005, we performed 196 thoracic aortic stent-graft procedures in 172 patients (119 male and 53 female), aged 15 to 87 years (mean, 60). Twenty-four implantations were redo operations for secondary graft extension; 22 of these secondary procedures were performed in patients from our own series, 2 were referred from other institutions. Data were collected in a Microsoft Access database from the hospital and office charts, the operative reports, and the preoperative and postoperative measurements. Only stent-grafts approved in the European Community were implanted. Written informed consent for the operation was obtained in all cases according to the rules of regular elective or emergency surgery. This retrospective study was approved by

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Table 1. Patients' Demographics and Aortic Diseases as Indications for Stent Grafting

Aortic Pathology	n	Male	Age (Years)	Age (Mean)
Traumatic rupture	31	28 (90%)	15–81	37
Posttraumatic aneurysm	4	3 (75%)	37–65	52
Penetrating atherosclerotic ulcer	43	23 (54%)	55–87	70
True aneurysm	26	14 (54%)	57–85	72
Type-B dissection	57	43 (75%)	36–87	62
Suture aneurysm	8	6 (75%)	33–66	54
Others	3	1 (33%)	46–61	55
Total	172	119 (69%)	15–87	60

the Institutional Ethics Committee, which waived the need for additional patient consent to the study.

The indications for primary stent-graft implantation and patient demographics are summarized in Table 1.

One hundred twelve operations (57%) were emergency procedures with these preoperative conditions: active bleeding in 23, contained rupture in 55, malperfusion in type B dissections in 17, symptomatic aneurysm in 12, and 5 urgent procedures because of impending complications.

Diagnostic Evaluation

The elective cases were seen as outpatients, and optimal diagnostic evaluation was performed to plan the procedures and optimize risk factors. That included high-quality spiral computed tomography (CT) and coronarography combined with aortography. In 11 cases of impaired renal function, magnetic resonance imaging replaced CT. The appropriate stent-grafts were chosen in cooperation with the manufacturers; custom-made grafts were ordered if necessary. If coronary artery disease was detected, this was treated by percutaneous intervention or coronary bypass grafting some weeks before the procedure.

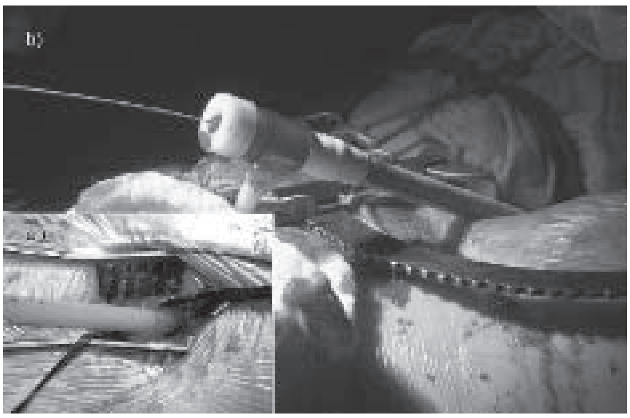

Fig 1. Endovascular access. a) Routine angioaccess consists of exposure of the common femoral artery with a small oblique incision. The delivery system of the stent-graft is advanced directly over the puncture site without arteriotomy guided by the ultrastiff guidewire. b) For the access conduit, a 10-mm Dacron graft has been sutured end to side to the distal abdominal aorta (Fig 3). A 24F sheath is passed through this graft into the suprarenal aorta.

Fig 2. Hybrid procedure for a thoracoabdominal aneurysm in a 72-year-old woman. The celiac axis ostium was covered by the stent-graft (E-vita). The 10-mm Dacron access graft to the distal abdominal aorta was used as a bypass for iliac artery reconstruction after deployment of the endograft. A second bypass (6-mm expanded polytetrafluoroethylene) to the common hepatic artery was anastomosed on top.

In most of the emergency procedures, however, measurements had to rely on the plain axial CT scans performed by the referring hospitals and simple graphical methods. These CT scans were often of inferior quality, with 5- to 10-mm slices. Usually no information concerning the iliac vessels was available from these external emergency evaluations. When in doubt, the correct diameters of the aorta were determined with intraoperative transesophageal echocardiography or intravascular ultrasonography. Stent-grafts were chosen from the in-hospital stock of Talent and, since 2004, E-vita grafts.

Devices and Implantation Technique

We used Talent (Medtronic Vascular, Santa Rosa, California) stent-grafts in 123 procedures, E-vita (Jotec, Hechingen, Germany) in 60, Zenith TX1 (William Cook Europe,

Fig 3. Endograft (E-vita in two long segments) of the entire descending thoracic aorta from the left common carotid artery down to the celiac trunk. The left subclavian artery has been transposed to the left common carotid artery preliminarily and is not excluded by the stent-graft.

Bjaeverskov, Denmark) in 5, Relay (Bolton Medical, Sunrise, Florida) in 4, Endofit (Endomed, Phoenix, Arizona) in 2, Valiant (Medtronic Vascular) in 1, and TAG (W.L. Gore Associates, Flagstaff, Arizona) in 1 procedure. All stent-grafts are self-expanding and are oversized by 10% to 20% related to the outer diameter of the aorta at the landing zone. They are packed in delivery catheters of 22F to 27F. The stent-grafts are described in detail elsewhere [5].

All procedures were performed in a standard operating room, except for one in the cardiology angio-suite. A surgical C-arm with angiography equipment (BV 300; Philips, Eindhoven, Netherlands) was used for intraoperative fluoroscopy and angiography. Additional transesophageal echocardiography was used in 54 procedures and intravascular ultrasonography in 1. General anesthesia was used in all cases, except for 1 in which local anesthesia was used.

The stent-grafts were advanced in retrograde manner from the femoral or iliac vessels and deployed as guided by the landmarks of a target angiogram. Angioaccess is shown in Figure 1. Access conduits were used if the femoral or external iliac arteries were not accessible for the 22F to 27F sheaths (Fig 1b). The conduit is ligated at the end of the procedure or used as an iliofemoral bypass if the artery has been damaged by earlier attempts to advance the stent-graft (Fig 2).

In aneurysm cases, the stent-graft was placed to cover the length of the aneurysm and to extend by a minimum of 20 mm proximally and distally. In many cases, we decided to use extensions ad hoc during the procedure; in longer or tortuous lesions, a modular stent-graft of two or more components was planned from the beginning (Fig 3). Our strategy for type B dissections consisted of endograft placement at least from the origin of the left subclavian artery to cover all entries of the descending thoracic aorta. Currently we use the longest E-vita (230 mm) as standard for type B dissections, and this ends usually just above the diaphragm.

Follow-up was obtained by office visits, hospital reports, telephone interviews with patients, families, and home physicians, and inquiries of local population registries. Actuarial survival was calculated by the Kaplan-Meier method.

Results

In 193 procedures, the stent-graft was successfully placed at the target zone in the thoracic aorta. Three procedures (1.5%) were aborted because of access failure. In 175 procedures, access was from the surgically exposed common femoral artery. Access conduits were necessary in 17 procedures. In an additional 10 patients, arterial reconstruction of the iliac artery had to be performed as the artery had been damaged by the

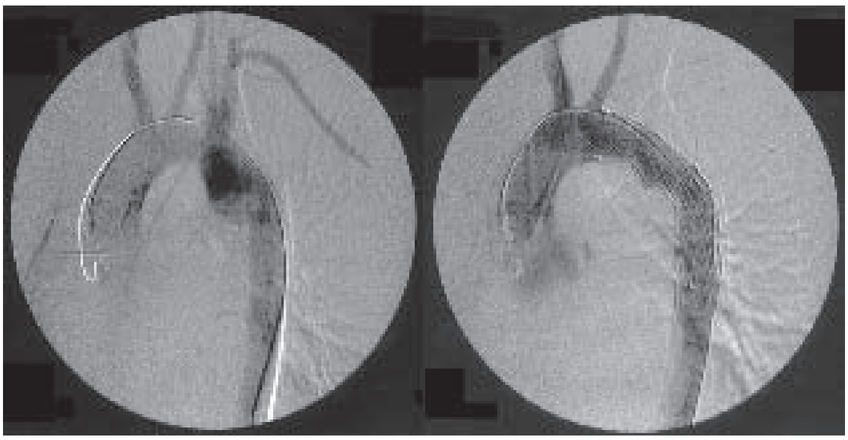

Fig 4. Intraoperative angiograms of a 19-year-old patient with blunt traumatic rupture. (Left) False aneurysm close to the left subclavian artery origin. The endograft delivery catheter is already in park position downstream. (Right) A Talent stent-graft is in place: the Dacron starts immediately downstream of the left common carotid artery; the bare springs are crossing it. The left subclavian artery is occluded. The stent-graft is oversized by 27% and expands to its full diameter at the spot of the rupture.

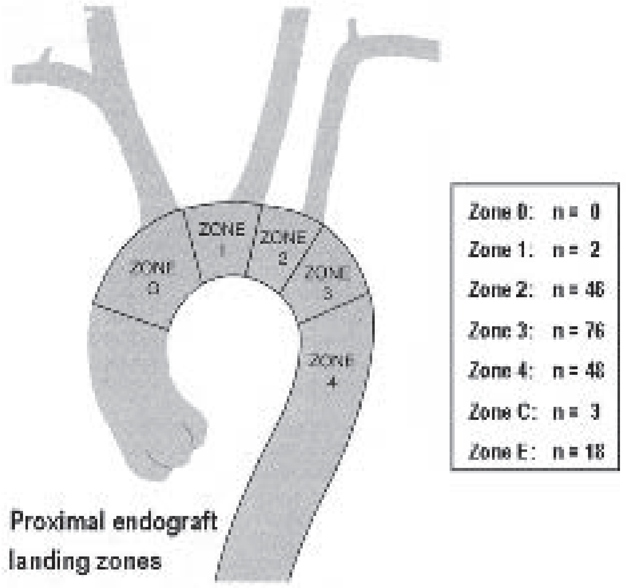

Fig 5. Distribution of proximal endograft attachments (full diameter graft material; bare springs may reach further in proximal direction). Modified from Criado et al [6]: zone C, inside a previously placed conventional surgical graft; zone E, inside a previously placed endograft.

stent-graft delivery system. Therefore, for 30 of 196 procedures (15.3%), access problems made more extensive surgery necessary.

Grafts with diameters of between 20 and 46 mm (average 35.2 mm) were used. The covered length of the segments ranged from 100 to 230 mm. In 150 procedures, one segment was used, in 28 two segments, and in 10 three or more segments. The average number of grafts was 1.26 per procedure (range, 1 to 5). The effective length of covered thoracic aorta per procedure was 155 mm (range, 30 to 394 mm).

Fixation of the stent-graft in the distal aortic arch was required in 122 procedures (63%; Fig 4). The distribution of the proximal landing zones is displayed in Figure 5. Twenty of 48 patients with stent-grafts in landing zone 0 to 2 (41%) had adjunctive extrathoracic transposition or bypass of the left subclavian artery or the left common carotid artery, or both—1 simultaneously, 12 before, and 7 after the endograft procedure.

Distal stent-graft attachment was at the level of the diaphragm or lower in 57 procedures (29.5%). Among these, the celiac trunk origin was crossed with the bare springs in 26 and covered by the endograft in 4. One of these patients required bypass surgery (Fig 2); the remaining 3 had sufficient collaterals verified in selective angiography after deployment. The entire descending aorta from the arch to below the diaphragm was covered in 22 patients, 17 primarily (Fig 3) and 5 step by step with secondary procedures.

The average procedure time was 140 minutes (range, 45 to 445), average fluoroscopy time 15 minutes (range, 4 to 655), and average amount of contrast medium 120 mL (range, 15 to 350 mL). Ninety-five patients (48%) were extubated directly after the procedure, 42 (21%) were ventilated for less than 12 hours, and 59 (31%) required ventilation for between 12 hours and 79 days. After 38 procedures (19%), patients were transferred to the ward directly; 89 (46%) remained in the intensive care unit for less than 24 hours, and 69 (35%) required intensive care for between 1 and 79 days.

Twenty-four procedures were reoperations for secondary graft extensions. Indications were 9 type I endoleaks in aneurysms, 4 type III endoleaks (classification in Chaikof and coworkers [7]), and perforation of the dissection membrane or progression of the disease in type B dissections in 11 cases. Nine redo procedures were performed in the early postoperative period owing to leaks detected in the first postoperative CT.

The Society for Vascular Surgery/American Association for Vascular Surgery 2002 reporting standards for endovascular aortic aneurysm repair [7] define the technical success in terms of (1) successful access, (2) success deployment, (3) absence of type I or III endoleak, (4) patent graft without obstruction, (5) absence of surgical conversion, and (6) absence of 24-hour mortality. According to these definitions, there was 85.7% primary success and 92.4% secondary success after further interventions (9 early secondary stent-graft extensions, 1 Palmaz stent, 1 stent-graft dilatation, 1 surgical endoleak closure) or spontaneous closure of type I endoleak (1 case).

A survey of the 15 technically nonsuccessful cases is given in Table 2. Conversion to open surgical repair was necessary in 6 cases, 3 during the original operation and 3 before discharge. The indications for primary conversion were retrograde type A dissection (patient no. 8, Table 2), access failure (patient no. 11), and rupture after deployment of the stent-graft (patient no. 15).

Patient no. 8 had a proximal type B dissection with a small retrograde intramural hematoma in the aortic arch and malperfusion of renal and visceral vessels, indicating stent-graft therapy. A stent-graft without bare springs (TAG) was chosen. However, opening of the graft caused retrograde dissection reaching into the ascending aorta. Immediate replacement of the ascending aorta was performed with extracorporeal circulation and deep hypothermia (18°C), and the distal anastomosis was performed in circulatory arrest with partial excision of the proximal end of the stent-graft.

In patient no. 11, access through a previously implanted 16/8-mm expanded polytetrafluorethylene (e-PTFE) aortobifemoral graft failed, and conventional throracoabdominal repair was performed during the same operation. The e-PTFE graft—in contrast to Dacron—showed no elastic enlargement when we tried to advance a 22F sheath as a test device.

Patient no. 15 had acute traumatic rupture with extensive mediastinal hematoma associated with multiple injuries after a motor vehicle accident. There was a diameter mismatch between the aortic arch (26 mm) and the descending aorta (20 mm). The 26-mm graft was probably undersized in the proximal portion, which resulted in

Table 2. Survey of Cases With Endograft Failure in Accordance With Reporting Guidelines [7]

No.	Age	Sex	Diagnosis	Localization	Indication	Date	Device	Failure	Intervention	POD	Outcome (30 Days)
1	41	m	Traumatic rupture	Isthmus	Contained rupture	1999-09-09	Talent	Bare spring penetration	Secondary conversion	14	Discharged
2	58	m	Suture aneurysm	Isthmus	Active bleeding	2000-11-15	Talent	Secondary rupture	—	1	Fatal
3	35	m	Suture aneurysm	Ascending	Elective	2002-09-09	Talent	Access failure	Secondary conversion	21	Discharged
4	76	f	PAU	Hiatus	Contained rupture	2003-09-09	Talent	Secondary rupture	—	1	Fatal
5	73	f	PAU	Infradiaphragmal	Symptomatic	2003-12-12	Talent	Secondary rupture	—	1	Fatal
6	80	f	PAU	Infradiaphragmal	Contained rupture	2004-04-23	E-vita	Iliac artery rupture	Iliac artery repair	Intraoperative	Fatal
7	70	f	PAU	Descending	Active bleeding	2004-09-10	Talent	Access failure	Secondary conversion	0	Discharged
8	38	f	Type-B dissection	Distal Arch	Symptomatic	2004-09-24	TAG	Retrograde type-A dissection	Primary conversion	Intraoperative	Further hospitalization Severe neurologic deficit
9	61	m	Type-B dissection Leriche's syndrome	Descending	Malperfusion	2004-11-12	Talent	Failure to restore distal perfusion	—	0	Fatal
10	46	f	Aortopulmonary collaterals (TOF)	Descending	Active bleeding	2005-02-15	Talent	Intraoperative migration Ongoing bleeding	Endograft as rescue procedure after surgery, no further interventions	Intraoperative	Fatal
11	70	m	TAAA	Hiatus	Elective	2005-04-19	Zenith	Access failure	Primary conversion	Intraoperative	Discharged
12	79	f	TAA	Descending	Symptomatic	2005-05-20	E-vita	Endoleak la	—	29	Fatal
13	69	m	TAA	Arch/Descending	Elective	2005-07-29	E-vita	Endoleak la	—	—	Discharged
14	19	m	Traumatic rupture	Isthmus	Contained rupture	2005-09-18	E-vita	Endoleak la	—	—	Further hospitalization
15	39	m	Traumatic rupture	Isthmus	Active bleeding	2005-11-17	E-vita	Endoleak la, immediate rupture	Primary conversion	Intraoperative	Fatal

Endoleak Ia = endoleak from proximal attachment site; Endoleak Ib = endoleak from distal attachment site.

f = female; m = male; PAU = penetrating atherosclerotic ulcer; POD = postoperative day; TAA = thoracic aortic aneurysm; TAAA = thoracoabdominal aortic aneurysm; TOF = tetralogy of Fallot.

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Table 3. Mortality and Severe Neurologic Complications

	All Procedures n = 196	Elective n = 84	Emergency n = 112
Death	19 (9.7%)	0	19 (16.9%)
Stroke	9 (4.6%)	2 (2.4%)	7 (6.3%)
Paraplegia	2 (1.0%)	0	2 (1.8%)
Combined (Death/ stroke/paraplegia)	27 (13.8%)	2 (2.4%)	25 (22.3%)

a type Ia endoleak leading to immediate free aortic rupture. Immediate sternotomy and graft replacement with extracorporeal circulation was performed. The patient died on the operating table owing to trauma and extracorporeal circulation–related abdominal bleeding.

The indications for secondary conversion to conventional surgery were access failure in 2 cases and bare spring penetration in 1. The latter (patient no. 1) was our very first case. The Talent graft was mishandled in that the partially opened stent-graft was advanced again for about 10 mm after it had slipped downstream during deployment. The false aneurysm was successfully excluded, but postoperative imaging demonstrated one of the bare springs situated in the aortic wall. For safety reasons, after 2 weeks a conventional Dacron graft was implanted with extracorporeal circulation and deep hypothermia. Two more cases required post–stent-graft adjunctive conventional surgery: 1 secondary arch replacement due to a penetrating ulcer remote from the stent-graft [8] and 1 endoleak closure in the aortic arch with beating heart surgery on extracorporeal circulation.

The overall 30-day mortality rate was 9.7% (n = 19); strokes occurred in 6 patients (4.6%). Paraplegia was seen in 2 patients (1.0%). A separate analysis (Table 3) for elective and emergency patients reveals that, except for two strokes, the severe complications occurred in the emergency group.

Actuarial survival is displayed in Figure 6. Cumulative survival was 79% at 1 year, 67% at 3 years, and 55% at 5 years. Mean follow-up was 1.92 years (range, 0 to 6.7), with 324 patient-years.

Comment

Our early results compare favorably with those of other studies on the endovascular treatment of thoracic aortic diseases [6, 9]. Thirty-day mortality of 9.7% is superior to the results of elective conventional surgery, even at a high-volume center [10]. The advantage is even more evident taking into account that, in our series, 60% of the endograft implantations were performed as emergency procedures and that the deaths occurred exclusively in the emergency group (Table 3). Long-term survival of 66.5% at 3 years offers hope to many patients who have previously been denied surgical treatment of thoracic aortic disease because of their advanced age and comorbidity. The 5-year survival rate of 55% is still a preliminary result, with only 11 patients at risk. Ongoing investigation will yield reliable results in the coming years (Fig 6).

The risk of spinal cord ischemia seems to be lower than after conventional surgery (1.0%), despite more extensive covering of the descending thoracic aorta. One of the 2 patients concerned was at extremely high risk for paraplegia, having recovered from paraplegia after previous conventional aortic repair.

Primary and secondary technical success is higher than in previously reported studies with homemade devices [2, 11]. The industrially fabricated grafts have some technical advantages in terms of the fixation mechanism and the delivery systems. The need for secondary graft extensions has been reduced over time owing to growing experience. In the beginning, short stent-grafts were preferred because of the fear of paraplegia. As we learned that covering of longer parts of the aorta or even of the entire descending aorta did not significantly increase the risk of paraplegia, the proximal and distal fixation zones were extended to improve fixation and sealing. The Talent graft, which was our standard graft in stock until 2002, was limited in length to 115 mm in the standard and 150 mm in custom-made configurations. Therefore, more segments had to be used in extensive disease, with connections that may be themselves at risk for secondary endoleak. That has improved with the new stent-grafts that are available in lengths of as long as 200 or 230 mm.

Precise preoperative evaluation for planning and sizing of the endografts and orientation in the three-dimensional space is the key for successful stent-graft therapy. Our method of choice is contrast-enhanced spiral CT with 1.5- to 3-mm slices. The axial CT scans in combination with three-dimensional and multiplane re-

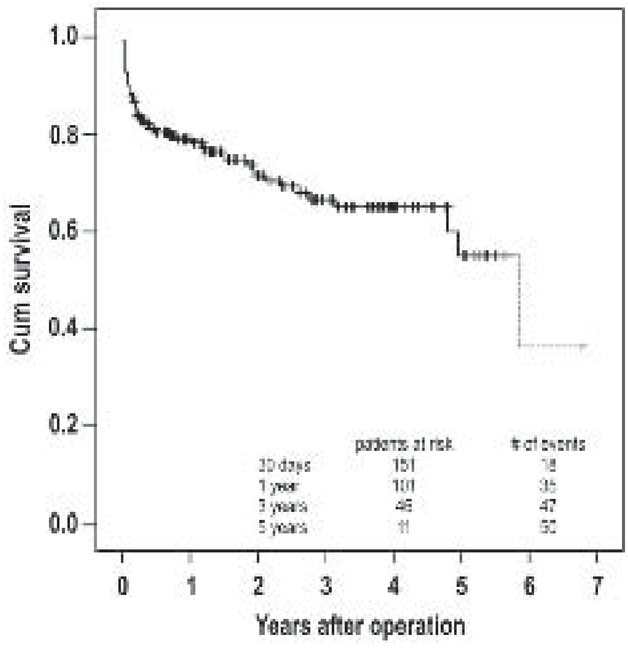

Fig 6. Actuarial survival for all patients.

constructions allow precise measurement of diameters and lengths (aneurysm, proximal and distal landing zone) [12]. In difficult cases with elongated arch or tortuous aorta, the surgeon together with the radiologist reconstruct the landing zones on the workstation of the CT to determine the precise diameter perpendicular to the axis at the landing zones. Moreover, CT provides important information for access of the delivery system on angulation, tortuosity, and calcification of the aorta and iliac vessels. Preoperative angiography is helpful but not absolutely necessary. Magnetic resonance imaging may replace CT if of good quality.

With such preoperative evaluation, intraoperative angiography can be limited to a few shots to identify the target zones and to check the final result. This is provided in sufficient quality by a surgical C-arm with angiography equipment. Endovascular treatment of side branches such as the renal arteries can be done as well. The imaging quality provided by a mobile C-arm has often been criticized versus fixed x-ray machines in the angiosuite [13]. Angiography has limitations in measuring and detecting endoleaks that cannot be overcome even with more sophisticated stationary angiography equipment. Transesophageal echocardiography has proved to be an excellent additional tool. For aneurysms, it is more sensitive in detecting small endoleaks. For dissections, it is essential to identify the endovascular instruments in the true lumen. The entry can be identified by the Doppler flow much more easily than in angiography, and in combination with fluoroscopy of the probe, the entry can be located precisely. The flow dynamic after deployment of the stent graft can be observed under direct echocardiographic vision.

However, with regard to the evolving side-branch technology [14, 15] and more complex aortic arch and throracoabdominal procedures, higher x-ray imaging resolution is desirable. Currently, we are planning a hybrid operating room with fixed high-performance x-ray equipment in our institution. This equipment will allow hybrid cardiac procedures, especially in congenital heart disease, as well as carotid stenting and more complex combined endovascular and surgical procedures. However, as our experience with the C-arm is good, it has to be stressed that this kind of sophisticated equipment is not a sine qua non for starting a thoracic endovascular program. Some authors are still in favor of mobile C-arms, as the imaging quality of the newer models is almost comparable with that of stationary x-ray machines, and this makes the endovascular setting more flexible [16].

This study shows that endovascular repair of the thoracic aorta can be performed by the cardiothoracic surgeon as stent-graft procedures for abdominal aortic aneurysms are performed by vascular surgeons. The procedure can be performed in a standard operating room setting. The same surgeon can carry out the surgical approach and the endovascular procedure. Especially in emergency procedures, the operating room provides a better and safer working environment than the catheterization laboratory or the radiology angio-suite. In every

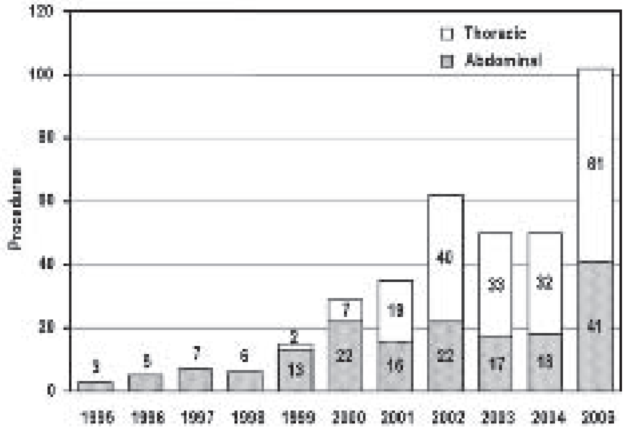

Fig 7. Development of endovascular stent-grafting at the Deutsches Herzzentrum Berlin.

procedure, there may be a need for extended surgery on the access vessels. That was the case for 15.3% of our procedures, and in most of them, the decision was made during the procedures after the simple femoral approach failed. Conversions to open repair are reported rarely, and most of them were performed secondarily [8, 17–20]. Therefore, it has been argued that remote stand-by of cardiovascular surgery might be sufficient back-up for thoracic endovascular procedures. Our experience, however, demonstrates that, albeit rarely, the need for immediate conversion with extracorporeal circulation may arise. Therefore, it is preferable that the procedure is performed by a surgeon who is able to manage all possible complications.

Technical strategies to expand stent-graft applicability in the aortic arch involve the cardiovascular operation field. Recently published techniques of antegrade stent-graft implantation from the ascending aorta may solve some of the technical problems in endografting of the aortic arch [21]. A new hybrid stent-graft can convert the classical staged repair of complex aortic disease into a one-step procedure through a sternotomy with stent-grafting of the descending thoracic aorta and surgical reconstruction of the aortic arch and ascending aorta [22].

For all these reasons, stent-grafting should be integrated into the thoracic surgeon's repertoire. Basic endovascular procedures using the "over the wire" technique are already part of the surgeon's practice for the insertion of intra-aortic balloon pumps and pacemakers, femoral arterial cannulation, and so forth. That will enable the thoracic surgeon to readily adopt the technique. Several opportunities to master endovascular techniques for thoracic surgeons willing to start an endovascular program have been outlined [23]. Surgeons may choose to partner with other endovascular specialists. The industry is offering workshops and small group mentoring arrangements. Proctors are available to assist with cases at the outset.

We gained our initial experience with abdominal aneurysms in 34 procedures starting in 1995 (Fig 7), for the first 2 years in cooperation with two interventional radiologists. From the beginning, we performed the procedures in the operating room. After we took over the program on our own, the first step was to acquire profound systematic knowledge of the interventional instrumentarium and to simplify it to a basic set with a small number of adjunctive wires, catheters, and balloons for troubleshooting and side-branch access. Fellow surgeons and residents have been trained by the first author (B.Z.) since then. The thoracic aortic endovascular program outlined in this paper started in 1999 and has been performed entirely by surgeons. It has grown steadily since then, and currently represents about two thirds of our entire endovascular program.

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DISCUSSION

DR JOSEPH E. BAVARIA (Philadelphia, PA): Thank you, Mr President. I wish to congratulate Dr Zipfel and his colleagues on their comprehensive single-institution series on thoracic aortic stent grafting. Doctor Zipfel highlights in his manuscript the fact that the procedures were exclusively performed by cardiothoracic surgeons, who also admitted these patients to their service, cared for them, and made decisions about eventual therapeutic options, because they are accomplished open and endovascular CT surgeons. This complete "skill set" paradigm is similar to vascular surgeons performing either open repair or endoabdominal aortic aneurysm (AAA) endografting. The series has reasonable results in a broad spectrum of thoracic aortic diseases, from the technically easier penetrating ulcers and saccular aneurysms to the more difficult "full pavement" extensive atherosclerotic fusiform aneurysms and complicated type B dissections. Additionally, for those surgeons and institutions in the audience without dedicated endovascular operating room suites, Dr Zipfel and colleagues "show us the way" in that all these cases were performed using a mobile C-arm in the operating room.

It should be pointed out that this series represents the early phase of this therapy with relatively early generation devices. More recent device generations, or iterations—especially in the past year with the introduction of the redesigned Gore TAG device, the next generation Medtronic Valiant system, and the Cook Zenith systems—are longer, more flexible at the arch, and simply better than the initial devices. We look forward to industry efforts to design devices specifically for the different thoracic aortic diseases that we confront.

Importantly, this study reinforces yet again that the operating room is the place to perform these procedures, as 17% of the cases required either extensive iliac artery surgery or conversions to open operations.

I have a few questions for Dr Zipfel. First, 25% of your cases covered the left subclavian artery. Approximately half of those had subclavian bypass procedures. Most importantly, 7 had the bypass procedures after the stent operation. Why did these patients need postprocedure restoration of subclavian blood flow, and what were the complications associated with subclavian coverage in your series?

Second, in 17, or approximately 10% of your series, you performed "full coverage or pavement" of the descending thoracic aorta. Additionally, only 26 of the 193 patients were for fusiform, classic atherosclerotic aneurysms. What were your outcomes regarding death, paraplegia, and cerebrovascular accident stroke in this very important subgroup?

Third, importantly, you point out that 23 of the 172 primary procedures, or nearly 13% of patients, needed a reoperation. Can you elaborate on why this reoperation rate was so high? And a follow-up question: Twelve (12) of these reoperations were for type B dissections. Why? Were they acute or chronic type B dissections?

Fourth, how important is it, in your opinion, and this is a bit of an editorial, to have AAA experience in order to perform thoracic aneurysm operations endovascularly, as I know you have significant AAA experience?

I thank The Society for Thoracic Surgeons for the opportunity to comment on this paper. I urge the membership to heed Dr Zipfel's example and acquire endovascular skills. I also urge our leadership and program directors to immediately push for significant endovascular skill sets in our residency programs. Thank you.

DR ZIPFEL: Thank you very much, Dr Bavaria, for your kind remarks. Let me answer the questions. The first question concerns the coverage of the left subclavian artery. The changes in management of the occluded left subclavian artery were a development during our program, because at the beginning we overstented the left subclavian artery quite liberally, as everybody did, and there was a common opinion that this does no harm. We had the experience that 7 of 30 patients, where the left subclavian artery had been covered without preliminary reconstruction, developed ischemia of the arm, 5 exercise induced and 2 at rest. These patients needed postprocedure restoration of subclavian blood flow. We also experienced 3 of the cerebellar strokes which I mentioned. In all, one third of the patients with unprotected coverage of the left subclavian artery experienced complications. This experience changed our policy. For the past year and a half, at least in elective cases, we have performed subclavian reconstruction before we implant the stent graft. In the emergency cases, depending on the situation, we still do the stent graft first and then we look at what has happened. But we are very open to restoring subclavian blood flow after the procedure, even with mild exercise-induced ischemia.

On the second question, in this series altogether, 17 patients had the entire descending thoracic aorta covered from the left subclavian artery or from the common carotid artery down to the celiac trunk. This is also part of the development during the years. First of all, this full coverage of the descending thoracic aorta has become possible only with the new stent grafts with longer segments like E-vita, which we used predominantly. This system allowed us to cover the whole aorta with just two segments and sufficient overlap. In the former Talent era of 10-cm grafts, it would have needed five to six segments to do this, with many connection sites prone to type III endoleaks.

It is astonishing, but we had no paraplegia in this subgroup of patients. The 2 cases of paraplegia I mentioned were the only hint of spinal cord ischemia. We had no reversible spinal cord ischemia. These 2 patients did not have extensive endografts implanted. One of them was at high risk; he had had conventional thoracoabdominal aortic replacement 10 years before he came in with acute bleeding from his proximal anastomosis. He had recovered from paraparesis after the first operation. The other patient was one of the women with a distal perforation of the aorta at the level of the diaphragm from an atherosclerotic ulcer. Remarkably, all intercostal arteries were patent in the intraoperative pre-deployment angiography, and about four pairs were covered by the stent graft. This patient had paraplegia 24 hours after the procedure.

On question number three, there was indeed quite a high incidence of secondary procedures, but this is again due to the first experience with the short stent grafts. At the beginning, everybody was afraid to cover long parts of the aorta, and we had only short stent grafts available. This led to the phenomenon that we had quite a lot of proximal and distal type I endoleaks in the beginning, which we closed with secondary extension grafts. Some of these secondary extension grafts were necessary because of another technical aspect. In the first version, the Talent grafts had bare springs distally and proximally, and we learned early on that these distal bare springs tended to perforate the dissection membrane in type B dissections. This kind of experience was one of the reasons that Medtronic abandoned these distal bare springs. We had 5 cases of this kind, which we managed by extensions with the second version of Talent or the new E-vita grafts without distal bare springs.

The experience in chronic type B dissection is miscellaneous. Some are really reduced in diameter, some stay as they are, but we had also 2 cases where obviously the dissection membrane was so stiff and so rigid that the self-expanding stent graft couldn't do its work. These patients had to be operated on later after a year or so, when we realized that this was unsuccessful.

Let me answer your last question concerning training in AAA. Of course, it is very useful to have training in AAA not only because you can do more cases but also because AAA is an excellent field to train endovascular skills. The endovascular technique itself may be more sophisticated than in thoracic stent grafting, for example, in targeting the contralateral limb or endovascular treatment of important side branches such as the renal arteries. But I think if there is a program that offers many cases for training in thoracic stent grafting, it is definitely not a must to start with AAA procedures before implanting the first thoracic endografts. In terms of setting rules for training programs that qualify for endovascular therapy of the thoracic aorta, there should be a certain number of cases performed as AAA or thoracic cases, with a minimum of, let us say, one third of thoracic cases. Thank you very much.