

Endoluminal stent graft repair for acute and chronic type B aortic dissection and atherosclerotic aneurysm of the thoracic aorta: an interdisciplinary task[☆]

Ulf Herold^{a,*}, Jarowitt Piotrowski^a, Dietrich Baumgart^b, Holger Eggebrecht^b,
Raimund Erbel^b, Heinz Jakob^a

^aDepartment of Thoracic and Cardiovascular Surgery, University of Essen, 45147 Essen, Germany

^bDepartment of Cardiology, University of Essen, 45147 Essen, Germany

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Abstract

Objective: Endoluminal thoracic aortic stenting is a new therapeutic tool in reducing the operative trauma of the patient. However, the inherent risks of aortic stent grafting are perivascular leakage, stent dislocation, blunt rupture of the aorta, side branch occlusion and neurological sequelae. To reduce these risks, in our institution all stent implantations were performed in close collaboration with our fellow cardiologists under biplane X-ray control supported by simultaneous intravascular and transoesophageal ultrasound imaging. **Methods:** Between August 1999 and August 2001, endovascular stent graft repair was performed in 34 patients (27 male, seven female) with a mean age of 68.6 ± 7 years (range 58–84). Indication for treatment was an acute Type B aortic dissection in six patients (18%), a symptomatic chronic Type B dissection in 12 patients (35%), a true aneurysm of the descending aorta in seven patients (21%) and an atherosclerotic contained rupture of the descending aorta in nine (26%) patients. Out of six acute type B dissections three patients (8.8%) and one patient (2.9%) out of the chronic dissection group were in severe haemorrhagic shock, ventilated and required high-dose adrenergic support. The others (30 patients, 88.3%) remained symptomatic despite maximum medical treatment. In a special case a combined surgical and endoluminal stent graft repair was performed. Individually manufactured Talent, Medtronic AVE (33), and Gore (1) stents were used. Follow-up examination was performed 1 week after implantation and repeated every 3 months (mean follow-up 8 months, range 1–24). **Results:** In all patients the aneurysm or the entry of the dissection could be excluded. The observed hospital mortality was 2.9% (one patient). No perivascular leakage, no stent dislocation, no neurological deficit or perfusion impairment was observed. All patients except four were extubated immediately after the procedure and discharged from hospital on postoperative day 2–3. The late procedure-related mortality was 5.8% (two patients) resulting in an overall mortality of 8.8% (three patients). **Conclusion:** Stent graft repair is a safe and feasible treatment option for selected patients, especially in emergency situations, if the aortic lesions can be clearly identified and localized. The use of biplane X-ray control combined with simultaneous intravascular and transoesophageal ultrasound imaging in an interdisciplinary approach enables a more precise targeting of the stent landing zone, resulting in low morbidity and mortality rates. © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Endoluminal stent graft; Stent graft repair; Thoracic aortic aneurysm; Thoracic aortic aneurysm repair; Aortic dissection

1. Introduction

Acute or chronic Type B dissection as well as an atherosclerotic aneurysm of the descending aorta often leads to life threatening situations requiring immediate therapy [1]. Besides the two standard treatment options as surgery and

medical therapy, over the last 8 years endoluminal stent grafting has emerged as an attractive alternative with a low periprocedural mortality and morbidity, especially in elderly patients with severe comorbid conditions, not suitable for surgery [2–5].

Despite the initially promising results this method has its own inherent risks, one has to be aware of. The reported incidence of endoleakage and perivascular leakage is up to 25% and blunt rupture of the aorta may occur during the implant procedure or later in 1–3% [6]. Side branch occlusion with unpredictable end organ ischemia results in 1–4%, associated with a high mortality [7]. Neurological sequelae

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* Corresponding author. Tel.: +49-201-723-3151; fax: +49-201-723-5931.

E-mail address: ulf.herold@uni-essen.de (U. Herold).

due to perfusion impairment of the spinal cord or atherosclerotic emboli are reported in 1–8%, equal to conventional surgery [8]. Dislocated stents penetrating the aortic wall represent a catastrophic and eventually lethal complication [7,9].

To reduce these risks and to assure a more precise and durable stent deployment, all stent graft implantations were performed by an interdisciplinary team of cardiac surgeons and cardiologists under biplane X-ray control supported by simultaneous intravascular and transoesophageal ultrasound imaging.

A new treatment modality emerges if surgical and endoluminal stent graft repair are combined and performed simultaneously. To date this approach was used in one case. This study reports our institutional experience and early clinical results in endovascular stent grafting.

2. Patients and methods

Between August 1999 and August 2001, 101 patients were admitted to our institution because of an aneurysm or dissection of the thoracic aorta. Out of these, 34 (33.6%) patients received an endovascular stent graft procedure of the descending aorta. There were seven women and 27 men with a mean age of 68.6 ± 7 years (range 58–84 years). Indication for treatment was an acute, complicated Type B aortic dissection in six patients (18%), a symptomatic chronic Type B dissection in 12 patients (35%), a true aneurysm of the descending aorta in seven patients (21%) and an atherosclerotic contained rupture of the descending aorta in nine (26%) patients. Out of six acute type B dissections, three patients (8.8%) and 1 patient (2.9%) out of the chronic dissection group were admitted as emergency cases (total four patients, 11.7%) under conditions of severe haemorrhagic shock requiring high-dose adrenergic support ($>0.5 \mu\text{g}$ adrenalin/noradrenalin/kg per min), mechanical ventilation and immediate red blood cell transfusion.

In the three other patients out of the acute Type B dissection group and in seven patients out of the symptomatic chronic Type B dissection group, transoesophageal ultrasound investigation revealed a true lumen collapse (total ten patients, 29.4%) with downstream perfusion impairment. The remaining five patients of the symptomatic chronic Type B dissection group presented incurable pain in two patients (5.8%) and enlargement of the false lumen of more than 2 cm in 3 months in three patients (8.8%) (see Table 1).

In our collaborative approach the potential treatment options were discussed for every patient between experienced cardiovascular surgeons and cardiologists. Thirty patients (88.3%) were judged to be inoperable in terms of conventional surgical repair. This was due to severe haemodynamic instability, multiorgan comorbidity as coronary heart disease, chronic obstructive pulmonary disease, diabetes, renal failure in combination with advanced age

and a poor general status of the patient. Four patients (11.7%) out of the contained rupture group were judged to be suitable candidates for surgery, but endovascular stent graft repair was considered to be feasible and therefore the modality of choice.

All patients, except the emergency cases, gave their informed consent according to the protocol approved by the institutional review board of the Essen University Hospital. Preoperatively all patients received a spiral computed tomography (CT), a transoesophageal and intravascular ultrasound investigation, an aortography and a coronary arteriogram. In case of stable conditions a magnetic resonance tomography (MRT) was performed additionally. The exact location, the diameter and the extension of the entry or aneurysm were determined for appropriate stent design beforehand. The precise anatomical analysis of the expected proximal and distal neck, as well as the stent landing zone itself was a prerequisite prior to stent graft implantation. Great care was taken to evaluate the true diameter of the femoral and iliac artery, the potential site of access for stent graft implantation (Table 2).

All procedures, except the combined surgical–stent graft repair, were performed under general anaesthesia in the catheter laboratory with the patient in supine position. Corresponding to the obtained diagnostic imaging results either the right or left femoral artery was accessed by a horizontal skin incision of the groin. In one case (2.9%) the left iliac artery

Table 1
Patient characteristics ($n = 34$)^a

Characteristic	Value	Percent
Sex		
Male	27	79.4
Female	7	20.6
Age (years)		
Mean \pm SD	68.6	
Range	58–84	
Preoperative status		
Emergency conditions	4	11.7
Non-emergency	30	88.3
Comorbid conditions		
CAD	11	32.3
Hypertension	30	88.2
COPD	14	41.1
Diabetes	4	11.7
Renal failure		
Moderate	9	26.4
Severe – no dialysis	3	8.8
Severe – dialysis	1	2.9
Preoperative organ ischemia		
Renal	6	17.6
Leg	2	5.8
Gut	2	5.8
Previous cardiac surgery	7	20.5
NYHA classification		
NYHA III	15	44.1
NYHA IV	19	55.9

^a CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association.

Table 2
Aneurysm and dissection characteristics

	<i>n</i>	Percent
Acute Type B dissection	6	18
Emergency conditions	3	8.8
Symptomatic chronic	12	35
Type B dissection		
Emergency conditions	1	2.9
True aneurysm	7	21
Contained aortic rupture	9	26
Aneurysm diameter		
Mean \pm SD (mm)	61.2 \pm 15	
Range (mm)	41–134	

had to be chosen, because the diameter of the femoral artery was too small due to atherosclerosis. After administration of 5000 U of heparin sodium a 7-F introducer sheath was inserted. A 5-F calibrated angiographic pigtail catheter was advanced to the ascending aorta to obtain an angiographic evaluation of the entry tear or aneurysm. Intravascular ultrasound imaging was used additionally to assure the exact distance between the entry or the beginning of the aneurysm and the left subclavian artery. Simultaneously a transoesophageal ultrasound probe was inserted and adjusted to the entry site or aneurysm. In addition the flow conditions in the false lumen or aneurysm sac were visualized. The imaging results were compared to each other to determine the ideal stent landing zone.

The Talent, Medtronic AVE, self expanding stent, mounted in a 21-F deployment catheter, contains a central lumen, so the stent was advanced to the entry site or aneurysm by an 'over the wire technique'. The stent consists of a polyester (Dacron) graft fixed to a nitinol wire stent with bare springs at the proximal and distal site of the covered portion. At the top and the end of the stent, markers are placed to determine the proper position and the margins of the covered part of the device. If the stent had to be placed close to the left subclavian artery, an angiographic catheter was inserted into the left radial artery and retrogradely advanced for exact localization of the origin of the subclavian artery.

After reassuring proper position of the stent in the landing zone, systolic arterial blood pressure was lowered with nitroprusside sodium to 60 mmHg. By pulling back the sheath of the introducer, the stent was deployed. After deployment an inflatable balloon was used to model the stent graft to the vessel wall. In atherosclerotic lesions and a case of massive calcified aorta, balloon inflation was abandoned. Nitroprusside sodium infusion was stopped and blood pressure raised to normal.

The complete delivery system was removed, and control angiography and intravascular ultrasound imaging was performed. To evaluate the decline of flow in the false lumen or the excluded aneurysm and to detect potential endoleakage, transoesophageal ultrasound imaging combined with Doppler flow examination was used. All

patients except the four emergency cases were extubated immediately after the procedure.

All patients received stent grafts with a length of 12 cm, whereas the length of the covered portion was 10 cm with the intention to keep the implanted device as short as possible avoiding unnecessary side branch occlusion. For safe and durable stent fixation an overlapping of the stent in the 'normal' aorta with a neck of at least 2 cm length at the distal and proximal site was chosen. Therefore, the left subclavian artery had to be overstented with the uncovered

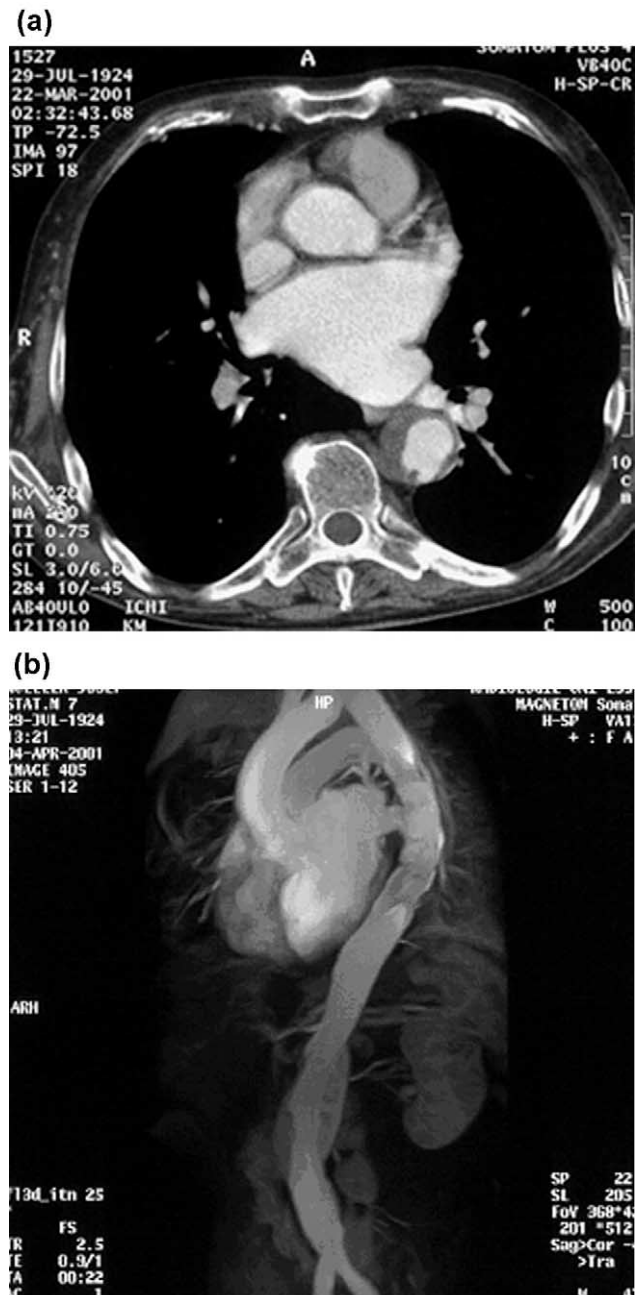


Fig. 1. Seventy-six-year-old symptomatic male patient with a ruptured aortic plaque shown on computed tomograph (CT) (a). Control magnetic resonance image shows a stable position of the stent graft and sealing of the aortic lesion (b).

part of the device in seven patients (21%), reassuring unimpaired perfusion directly after deployment and in the later course. Overstenting of the left subclavian artery with the covered part of the device was avoided in all cases.

To avoid unnecessary side branch occlusion and therefore intercostal artery perfusion impairment, we attempted to exclude the aneurysm or entry tear with one stent only, if at all possible. In three patients of the chronic Type B dissection group a second stent graft was required. In contrast to our intention, the second stent had to be implanted in one case during the initial procedure; in the other two patients follow-up investigations revealed, though the aneurysm was excluded successfully, that the resulting distal neck was too short (<2 cm) for durable stent graft position. They received a second stent graft 3 and 6 weeks after the initial procedure.

Before discharge, 1 week after implantation and every 3 months, CT scanning and magnetic resonance imaging (MRI) were performed for follow-up investigation to determine subsequent thrombosis of the false lumen or aneurysm sac and stable position of the stent graft device (Figs. 1 and 2).

In a special case of a 64 year-old woman, a combined surgical–endoluminal stent graft procedure was performed simultaneously. The patient had a status post emergency surgical repair of an acute Type A dissection with a valved conduit in 1989 elsewhere. She was admitted for large false aneurysm formation due to suture dehiscence compromising the coronary reimplantation sites. In addition, an atherosclerotic aneurysm of the arch with a diameter of 7 cm and a chronic Type B dissection originating 4 cm distal to the left subclavian artery was diagnosed preoperatively. Surgical therapy consisted in replacement of the valved conduit, a hemi-arch replacement with a 32-mm vascular Dacron prosthesis under continuous antegrade cerebral perfusion (37 min). After resection of the diseased part of the aortic arch, a special custom-made Talent Medtronic AVE prosthesis was deployed under direct vision control via the open distal arch in the descending aorta. The stent graft was mounted in reverse position on the delivery system to allow deployment with unfolding from the top to the bottom for better implant control.

3. Results

The 30-day mortality observed in the presented patient group was 2.9% (one patient). This patient out of the chronic Type B dissection group died 6 days after stent graft implantation due to an acute myocardial infarction. Preprocedural coronary angiography revealed a stenosis of the LAD (left anterior descending coronary artery) which was treated by percutaneous coronary angioplasty (PTCA) and stent graft implantation of the LAD prior to the aortic stent graft intervention.

All aneurysms and entries have been excluded successfully. This was achieved in 31 patients (91.2%) with a single

stent graft only; in three patients (8.8%) a second stent graft was required, all three patients belonging to the group of chronic Type B dissection. In one patient (2.9%) the second stent graft was implanted during the same procedure. In two patients (5.8%) the second graft was implanted 3 and 6 weeks after the initial procedure.

There were no neurological deficits or sequelae detectable in the periprocedural and postoperative observation period. All stents were in stable position, there was no stent graft dislocation found in this series. A perivascular leakage or persisting endoleak could not be observed. In all

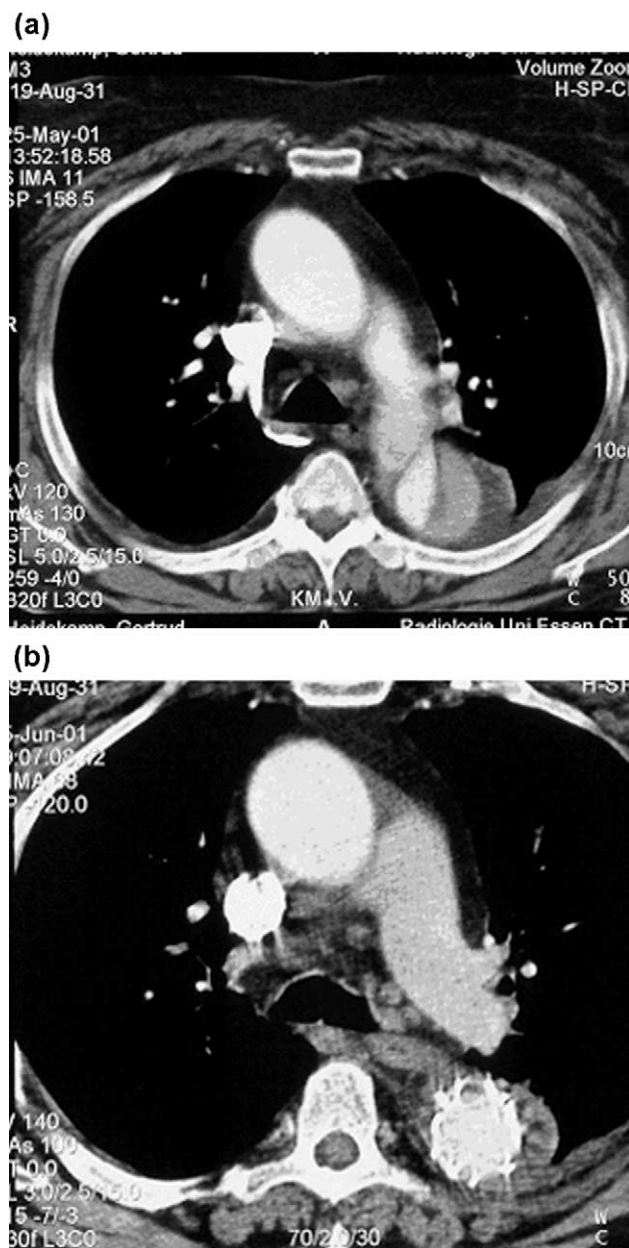


Fig. 2. Sixty-nine-year-old female patient with an acute type B dissection beginning directly after the left subclavian artery on CT (a). Control CT shows the restoration of the true lumen and subsequent thrombosis of the false lumen (b).

Table 3
Results

	<i>n</i>	Percent
Overall mortality	4	11.7
Hospital mortality (30 days)	1	2.9
Late death (>3 months)	3	8.8
Cause of death		
Myocardial infarction	1	2.9
Rupture of thoracic aneurysm	1	2.9
Suicide	1	2.9
Unknown	1	2.9
Procedure related mortality	3	8.8
Second stent graft	3	8.8
Perivascular leakage	0	
Stent dislocation	0	
Neurological deficit	0	
Organ ischemia/perfusion impairment	0	
Extubation immediately after procedure	30	88
Length of stay (days) (except four emergency cases)	2.8	

patients transoesophageal ultrasound imaging revealed subsequent thrombosis of the false lumen or aneurysm sac within 36–48 h (Table 3).

Minor intraoperative and early postoperative complications occurred in three patients (8.8%). A dissection of the femoral artery caused by the stent graft implantation device occurred in two patients (5.8%). In both patients the dissected part of the artery was replaced with a 10-mm Gore vascular graft with no perfusion impairment of the leg. One patient (2.9%) had postoperative bleeding at the site of retroperitoneal arterial access which had to be revised surgically.

All patients except the four patients admitted under emergency conditions were extubated immediately after the procedure (91%) and discharged from hospital at postoperative day 2–3, with a mean length of stay of 2.8 days.

Three late deaths (8.8%) occurred in the follow-up period. One patient treated for an acute Type B dissection as a ‘last chance’ procedure presented a Leriche syndrome with paraplegia for more than 24 h and was anuric. Although the flow in the abdominal aorta could be restored by interventional fenestration of the abdominal aorta, paraplegia persisted. The acute Type B dissection (13 cm in diameter) with impending rupture was treated with a stent graft implantation. The huge thromboembolic mass surrounding the stented thoracic aorta led to a fatal pressure-induced erosive rupture of the aneurysm sac into the oesophagus on the 62nd postoperative day. One patient with a successfully excluded chronic Type B dissection died of unknown causes 3 months postoperatively; late rupture of the entire diseased aorta cannot be ruled out. A third patient with a successfully excluded true aneurysm committed suicide due to other reasons. Thus, the procedure-related late mortality is 5.8% (two patients), resulting in an overall procedure-related mortality of 8.8% (three patients). The survival rate is 88.7% (30 patients) in this study.

The patient treated with a combined surgical endovascular procedure showed an uneventful postoperative course with no signs of neurological disorders. Follow-up examination revealed a stable stent position and restitution of the true lumen in the thoracic aorta; the false lumen thrombosed totally.

4. Discussion

In the 1990s endovascular stent grafting of abdominal aortic aneurysm emerged as a new and less invasive method [6]. It was only a short step from first case reports and feasibility studies to the introduction of this method as a treatment option for thoracic aortic aneurysm and dissection [8,12]. Although the first stent grafts used were pure ‘home-made’ devices, the initially reported results were promising with mortality rates of 10% [4,5]. Although to date only midterm results are available, the reported results indicate a more favourable outcome compared to conventional surgery [10]. Especially elderly patients presenting with acute and chronic Type B dissection or atherosclerotic aneurysm often show significant comorbidities such as pulmonary and renal insufficiency, coronary heart disease, hypertension and diabetes mellitus, resulting in higher morbidity and mortality rates in open surgical repair of up to 50% [1,6,14].

Despite the advantageous results given in numerous studies, endoluminal stent graft repair has its own inherent risks. Complications such as perivascular leakage, stent graft dislocation, acute and late rupture of the aorta, side branch occlusion and neurological sequelae still are the main causes of early and late morbidity and mortality, and therefore for failure of therapy [4,5]. Another major drawback is that most of the studies are fairly comparable. Due to the different types and generations of devices used in endovascular stent graft repair it is nearly impossible to identify whether the complications are device-, procedure- or patient-related. Furthermore, endovascular stent graft repair is performed by various specialities such as radiology, surgery, vascular surgery, cardiology and cardiothoracic surgery, each of them with their own specific criteria for indication and contraindication [2,5,10]. Therefore our approach is to perform endovascular stent graft repair in a close interdisciplinary collaboration with our fellow cardiologists, to combine diagnostic and interventional catheter expertise with the long-standing experience of aneurysm management and tissue handling by cardiothoracic surgeons.

Although there is an ongoing debate whether chronic or acute type B dissection should be treated surgically or by endovascular stent grafting, there is evidence that up to 20% of medically treated patients will suffer a rupture of the aneurysm or the dissected aorta [11–15]. Therefore in a consensus conference, indication and treatment options are discussed for each patient individually. Prerequisite is a

detailed analysis of the morphology and size of the aneurysm or dissection, to determine whether the patient is suitable for endovascular stent graft repair or not. The following criteria for endovascular stent graft repair have to be fulfilled. For durable stent localization a sufficient proximal and distal neck of at least 2 cm of normal aorta has to be preserved. Therefore, intravascular ultrasound imaging enables a detailed morphological analysis of the vascular pathology in the expected neck region allowing improved judgement of stable stent positioning. Kinking of the aorta near the predicted stent landing zone was not allowed to exceed more than 20° to prevent perivascular leakage, aortic rupture and stent graft retraction.

To date, no stent dislocation was observed in our series which supports this approach. In addition, the newer commercially available stent graft devices are less rigid and fit better to an atherosclerotic aorta, resulting in a tighter position to the vessel wall. Furthermore, the implanted self-expandable Talent stent graft prosthesis is provided with a special reinforced proximal bare spring for theoretically improved resistance against resulting dislodgement forces. This contributes to our results that no early or late endoleaks could be detected thus far and the false lumen or the remaining aneurysm sac of the thoracic aorta thrombosed subsequently in all patients.

To avoid peripheral neurological sequelae, the aneurysm or dissection should have to be excluded with a maximum length of 20 cm of coverage. Neither in the group of acute Type A dissection nor in the other treated patients could a neurological deficit be detected postoperatively. Our approach is supported by Dake et al., who reported that the incidence of peripheral neurological complications is directly related to the length of the excluded part of the aorta [6].

An underestimated problem represents the arterial site of access. Due to the large diameter (21–24 F) and rigid properties of the deployment devices, the femoral arteries have to be evaluated carefully. A corresponding diameter has to be assured and severe obliterating calcification of the pelvic axis and abdominal aorta excluded. Despite meticulous sizing a local dissection occurred in two patients (5.8%), requiring local graft replacement. Furthermore, the advancing of the rigid stent deployment device through an extremely atherosclerotic aorta in a retrograde way might result in embolic complications due to mechanically altered plaques, but this was not observed in this study [3,10].

In the presented study 30 patients were judged preoperatively not to be candidates for surgical repair. Although the maximum follow-up period only extends up to 24 months, our results demonstrate that endovascular stent graft repair is a safe and valid treatment option in selected patients, even in conventionally inoperable patients, with excellent short-term results.

Our interdisciplinary approach in combining cardiologic and surgical experience seems to further improve the results in the management of complicated thoracic aortic

disease. Thus, the addition of intravascular ultrasound imaging to the periprocedural visualization of the aortic lesion represents a major improvement because stent graft deployment can be achieved very precisely, even in close proximity to aortic side branches.

The introduced combined simultaneous surgical and endovascular procedure represents a new and promising treatment modality in management of aortic disease affecting the entire thoracic aorta. It allows for ischemic time shortening, since the deployment through the open aortic arch necessitates less than 3 min and this reduces operative trauma significantly. The value of this measure has to be proven carefully in a study of its own. However, whether these promising early results hold true in the long run has to be seen in the future.

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Appendix A. Conference discussion

Dr J. Bachet (Paris, France): I would like to have a technical answer, please, about the patient who had the open arch repair and the stenting of the descending aorta. We see now more and more case reports of this kind and there was a recent report from a Japanese group about this technique. Considering that it was a chronic Type B dissection, did you remove the flap between the two channels, before stenting? We know indeed from the surgical experience that if the false channel is closed, your patient may get into a lot of trouble due to malperfusion.

Dr Herold: Of course, before this procedure we determined that all the vessels originated from the true lumen. Otherwise you couldn't do that.

Dr Bachet: How do you do that?

Dr Herold: By angiogram and CT scan.

Dr Bachet: What about the spinal cord?

Dr Herold: We were very aware of problems regarding the spinal cord and therefore our policy was to implant the stent as short as possible, and therefore we had three redos where we had to implant a second stent, and in the chronic Type B dissection with this huge false lumen, we weren't afraid of spinal cord impairment because we thought that all the side branches were already occluded.

Dr L. von Segesser (Lausanne, Switzerland): I would like to know some more details about the procedures. We have a similar series, and in our hands not all procedures were straightforward, and we had also some worries with unloading, pressure control during the unloading procedure. I would also like to ask you how long was the mean duration and the maximum duration of your procedures, and how did you control the blood pressure prior to unloading of the grafts?

Dr Herold: The mean duration of the procedure was 35 min with a standard deviation of 22 min, and a maximum duration of a procedure was in a very calcified distal abdominal aorta with about 1 h 45 min. This was not really procedure-related but the problem had advanced to the thoracic aorta. The blood pressure is controlled in our study or in our patients with nitroprusside sodium, and we lower the arterial pressure to 60 mmHg and raise it up to normal values when the stent has been deployed.

Dr M. Turina (Zurich, Switzerland): Did I understand you correctly that the false lumen was thrombosed after these procedures, and does it really mean that the distal aorta was normal afterwards? If this is true, this would be a real breakthrough in the treatment of chronic dissection. When you operate on a chronic Type B dissection, it is very difficult to get rid of the very distal dissection, which, in my experience, practically always extends beyond visceral and renal arteries.

Dr Herold: This is for sure a very good question and I have to be, I think, more accurate. The false lumen in the excluded part of the aneurysm or in the excluded part of the chronic dissection thrombosed, not the whole false lumen and the entire length.

Dr Turina: And may I ask, how did the false lumen distal to your stent look like after 3 and 6 months? This is a crucial question, because the appearance of distal aorta will determine the future course of the disease.

Dr Herold: We found several flow patterns. Mostly we found beginning thrombosis with some islands of very low flow, and sometimes still the false lumen was really under pressure, and these were the patients where a second leak or a second aneurysm appeared in the abdominal aorta, but these patients were then scheduled for repair of their abdominal aortic aneurysm.

Dr Turina: So it is obvious that these patients will have to be followed exactly like the patients who had surgery on the proximal aorta?

Dr Herold: They have to be followed up very closely, I think.

Dr A. Haverich (Hannover, Germany): That brings me to the question about the cause of death and the site of rupture in the patient who died late from thoracic aortic rupture.

Dr Herold: But the patient I introduced had a huge chronic dissection with a diameter of more than 13 cm, and as a last resort we implanted a stent, and due to this huge thrombi formation around the aorta, the stent was set under pressure and was pressed against the oesophagus, and this led to a pressure-induced rupture of the false lumen into the esophagus.

Dr Haverich: A question regarding the logistics. You said you only use custom-made, individually fabricated stents. How does that work in the presence of shock and acute Type B aortic dissection?

Dr Herold: That is where we used the stent which was ordered for another patient but which fitted the size of the aorta, and we had always three to four patients in the planning, and so we had a little stock of prostheses of different sizes.