

DeBakey type I dissection: when hybrid stent-grafting is indicated?

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Aim. For avoidance of late downstream complications after classic DeBakey type I aortic dissection repair, replacement of the arch with simultaneous antegrade descending stent-grafting using a hybrid prosthesis was applied in acute and chronic aortic dissection. Indication and results were studied.

Methods. Between January 2001 and January 2010, 168 patients were operated for acute and chronic aortic dissection (AD). Forty-five patients received an E-vita open stent-graft prosthesis, 29 for acute aortic dissection (AAD) (28 for DeBakey type I, 1 for type III) and 16 for chronic aortic dissection (CAD) (13 type I, 3 type III). Indication was full circular arch dissection, an entry or re-entry tear distal to the left subclavian artery in AAD, and new abdominal malperfusion, rapid growth of the false lumen (FL), impending or contained rupture in CAD.

Results. Hospital mortality was 10% in AAD and 0 in CAD. Complications like new stroke occurred in 7% versus 6%, temporary dialysis in 55% versus 19%, and false lumen obliteration was observed in 93% versus 63% in AAD versus CAD, respectively. Follow-up was 100% at a mean of 19 months. Overall survival at four years was 72% in AAD versus 94% in CAD. FL thrombosis was stable in AAD (92%) and increased to 93% in CAD over time. Freedom from secondary aortic intervention was 90% in AAD and 75% in CAD.

Conclusion. This hybrid approach in patients with AAD and CAD type I is safe when indicated and renders stable results over time down to the stent-graft end. Secondary TEVAR can be easily performed downstream when necessary. The international E-vita open registry data supports this single center results.

Key words: Aortic diseases - Aorta, thoracic - Aortic diseases, surgery - Stents.

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Hospital mortality after surgical treatment of acute type A aortic dissection (AAAD) still ranges between 15-30% in the Western world, mainly correlating to the presence of malperfusion complications.¹⁻⁴ Currently, medical treatment does not present an alternative with its reported 58% mortality⁵ and interventional treatment options for this pathology is at its very beginning.⁶⁻⁸

Current surgical philosophy includes rapid operation and replacement of the ascending aorta with or without hemiarch/arch, leaving the downstream pathology of a persisting patent false lumen in the descending aorta untreated.⁹ This can lead to late complications like aneurysm formation, rupture, or distal malperfusion, and often requires redo surgery.¹⁰⁻¹³ However, reoperation after previous AAAD surgery poses another challenge to the surgeon, dealing either with a planned two stage operation and its inherent high cumulative mortality^{14,15} or a single midline surgical approach combining arch replacement with descending aortic stent-grafting, as demonstrated primarily by Japanese authors, followed by European authors.¹⁶⁻¹⁹

At Essen University Hospital, a program of simultaneous treatment of the ascending aorta/arch and descending stent-grafting started in June 2001 for chronic cases, and was extended to AAAD in December 2002.²⁰

More recently, the International E-vita open Registry (Figure 1) was started to compile data from several institutions applying this approach, which are studied

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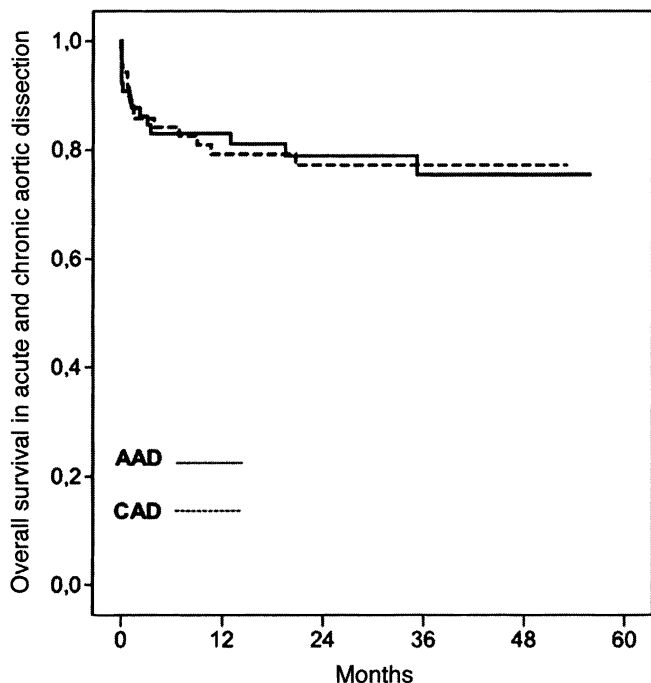


Figure 1.—Kaplan Meier Curve for survival in acute and chronic aortic dissection according to the International E-vita Open Registry. AAD: acute aortic dissection (type I); CAD: chronic aortic dissection (type I).

in regard to morbidity and mortality and development of thrombosis within the thoracic false lumen, at midterm follow-up (Appendix 1).

Materials and methods

From January 2001 to January 2010, a total of 764 consecutive patients underwent surgery of the thoracic aorta at the Department of Thoracic and Cardiovascular Surgery, West German Heart Center, University Hospital of Essen. Out of these, 168 patients were operated for acute (N.=115) or chronic AD (N.=53). Forty-two patients with DeBakey type II dissection were excluded from the study, leaving 73 patients for investigation. Out of these, 45 patients (62%) received an E-vita open Hybrid stent-graft prosthesis implanted, 29 for AAD (28 DeBakey type I, 1 DeBakey type III) and 16 for chronic aortic dissection (13 DeBakey type I, 3 DeBakey type III) combining classic proximal repair with antegrade stent-grafting of the descending aorta, the so-called hybrid approach (Table I).

TABLE I.—Prevalence of salivary gland tumors (benign and malignant) (1978-2009).

N. (%); mean±SD	Acute AD N.=29	Chronic AD N.=16
Age (y)	60±12	54±14
Age >70 y	7 (24)	3 (19)
Male	19 (66)	16 (100)
Emergency	27 (93)	2 (13)
Severe hemodynamic instability	15 (52)	1 (6)
Intubated prior to surgery	3 (10)	2 (13)
Blood pressure medication	20 (69)	16 (100)
Chronic obstructive lung disease	6 (21)	3 (19)
Renal insufficiency	8 (28)	2 (13)
Peripheral vascular disease	3 (10)	2 (13)
Previous cerebral insult	4 (14)	0
Previous cardiovascular surgery	1 (3)	9 (56)
Previous endovascular intervention	1 (3)	1 (6)

TABLE II.—Indications for E-vita open.

N.	Acute AD N.=29	Chronic AD N.=16
Entry/Re-entry in descending aorta	22 (76)	0
Contained rupture of descending aorta	2 (7)	3 (19)
Circular arch dissection	5 (17)	0
False lumen progression	0	13 (81)

Indication for hybrid stent-grafting in type I dissection

Besides classic repair consisting of ascending aortic replacement in acute type I aortic dissection, all patients, who demonstrated an entry or re-entry tear in the arch, had arch replacement, either as a hemi-arch or full arch replacement.

In case of a tear around the left subclavian artery or below, or full circular arch dissection, the indication for additional stent-grafting of the descending aorta was seen. In chronic type I AD, ongoing or new abdominal malperfusion, rapid growth of the persistently patent false lumen (more than 1 cm per annum) or aneurysm formation to a FL + TL combined diameter of 6 cm and beyond), impending or contained rupture, the indication for this approach was given (Table II).

This has been approved by the Ethics Committee of the University Hospital of Essen. In acute cases, the chairman of the Ethical Committee waived its need.

Choice of endograft

According to a somewhat dismal experience with a reversed version of the abdominal Talent stent-graft for antegrade application, a self designed hybrid stent-graft, later called E-vita open® (Jotec GmbH, Hechingen, Germany) was used.²¹ It consists of a polyester stent-graft-prosthesis, combining a 15 cm long nitinol stented portion with an integrated 7 cm long non-stented and non-preclotted portion for aortic arch/ascending aortic replacement. More recently, a blood impermeable version (E-vita open plus®) was used, obviating the need for presealing the graft with fibrin glue.²² The insertion into the descending aorta was achieved using a stiff backup Meier wire, which was previously placed into the true lumen of the descending aorta via the femoral artery using online TEE control or fluoroscopy to secure later safe landing of the stent-graft in the true lumen in the descending thoracic aorta.

Surgery

All patients were operated upon with three arterial pressure lines (2 radials, 1 femoral) in place for malperfusion control. Right axillary artery cannulation was the arterial cannulation site of choice. In case of CT-proven brachiocephalic trunc dissection, in CPR cases or extremely unstable patients, direct ascending aortic cannulation was performed more recently after primary venous exsanguination and direct sight cannulation of the true lumen, as reported previously.²³ Core cooling to 25 °C bladder temperature was begun. Aortic cross-clamping was done early with the administration of cold, crystalloid cardioplegia (1 500-2 000 mL Custodiol® solution) into the coronary ostia after transecting the ascending aorta. Then proximal repair was started while cooling continued. After reaching the target temperature, a brief period of hypothermic circulatory arrest was initiated with removal of the crossclamp and inspection of the arch. According to the principles of removing all reachable entry – or re-entry sites, the aortic arch was radically resected and the proximal descending aorta was transected just beneath the often encountered reentry tear at the origin of the left subclavian artery. Then selective antegrade cerebral perfusion was started *via* the right axillary artery cannula after crossclamping the proximal brachiocephalic trunc, and additional cannulation of the left common carotid artery was performed for bilateral perfusion, while the left subclavian artery was blocked proximally using a 6F

Fogarty catheter. In case of primary direct aortic cannulation, the brachiocephalic trunc was cannulated separately. The Perfusate temperature chosen was 18 °C, at a flow rate of approximately 15 mL/kg/min to maintain a line pressure between 50 and 60 mmHg.

Then the previously placed guidewire was picked up. Sizing of the true lumen of the descending aorta was performed with specially designed highly bendable nitinol obturators (Fehling Instruments GmbH&Co.KG, Karlstein, Germany) to measure the real diameter of the true lumen and to avoid oversizing. Thereafter, the endograft was placed over the stiff guide wire and deployed in the descending aorta. After retraction of the introducer, the unfolded stent-graft ended around 1 cm below the proximal end of the cut-off descending aortic stump. The Elephant trunk like inverted, non stented polyester tube was then pulled back approximately 5 mm for proximal suturing of the graft to the proximal descending aortic stump using a 3-0 polypropylene continuous sutureline, stabilized externally with a teflon felt. Then full retraction of the intussuscepted arch graft was done and a corresponding incision for creation of the cephalad island anastomosis, or for separate implantation of the head vessels to the arch graft took place. After finishing this anastomosis, an end to end anastomosis with the ascending aorta completed surgery. Five minutes prior to the expected finishing of the anastomosis, the brain perfusate was gradually rewarmed to 25 °C. Full body reperfusion was restarted either by using the axillary arterial cannula or direct cannulation of the arch prosthesis, after deairing of the arch vessels with the patient's head down 20 °C. While rewarming, proximal repair was completed if necessary. Finally, an end to end anastomosis between the ascending aortic graft and the arch prosthesis was performed. Additional procedures like coronary revascularization were done during rewarming (Table II). After reaching normothermia, extracorporeal circulation was discontinued under TEE control. While protamine was administered, the thrombosing process of the false lumen around the descending aortic stent-graft was observed and documented with TEE.

Follow-up protocol and data analysis

All surviving patients underwent early (postoperative day 6-10) CT angiography, as well as after 3, 6, 12 months, and annually thereafter. At these time inter-

TABLE I.—*E-vita Open, Essen results II 01/2005-01/2010.*

	AAD	CAD
Patients, N.	29	16
In-hospital mortality	3 (10)	0
Stroke	2 (7)	1 (6)
Spinal cord injury	0	0
Dialysis		
Permanent	0	1 (6)
Temporary	16 (55)	3 (19)
Secondary interventions in downstream aorta ⁺	3 (10)	4(25)
False lumen at stent graft level postop.		
Patients, n	29	16
Thrombosed	25/29 (86)	10/16 (63)
Partial thrombosed	4/29 (14)	5/16 (31)
Patent	0	1 (6)
False lumen thrombosis distal to stent graft postop.		
Patients, N.*	28	15
Thrombosed	4/28 (14)	0
Partial thrombosed	10/28 (36)	1 (7)
Patent	14 (50)	14 (93)
False lumen at stent graft at follow-up		
Patients, N.	25	15
Thrombosed	23/25 (92)	14/15 (93)
Partial thrombosed	2/25 (8)	1/15 (7)
Patent	0	0
False lumen distal to stent graft at follow-up		
Patients, N.*	24	14
Thrombosed	4/24 (17)	1/14 (7)
Partial thrombosed	13/24 (54)	6/14 (43)
Patent	7/24 (29)	7/14 (50)

Data are presented as mean±SD or number (%); AAD, Acute aortic dissection; CAD: chronic aortic dissection; ⁺6 secondary endovascular aortic repairs and 1 secondary surgery, * only patients with extension of the false lumen along the abdominal aorta.

vals, patients were also seen in our outpatient clinic.

Data were collected prospectively supported by our database for thoracic aortic surgery and studied retrospectively by team members. Follow-up was complete in all patients by January 2010. The PASW 18.0 package was used for analysis.

International E-vita open Registry

The International E-vita open Registry was founded September 2008 to collect data from several institutions applying the principle of simultaneous repair of the ascending aorta, the arch and stent-grafting of the descending aorta in complex thoracic aortic disease, encompassing acute and chronic dissection as well as extensive aneurysmal disease. Data from 186

patients form the basis of this study, where 50 cases with aneurysmal disease were excluded, leaving 66 cases with acute and 70 cases with chronic type I dissection for evaluation.

Results

Follow up was 100%. In-hospital mortality was 10% (3/29) in AAD and zero in CAD. Postoperative complications like new stroke occurred in 7% (2/29) *versus* 6% (1/16), temporary dialysis in 55% (16/29) *versus* 19% (3/16) in AAD *versus* CAD, respectively (Table III). Angio-CT follow-up scans demonstrated false lumen obliteration around the descending stent-graft in 93% (27/29) of AAD cases within days and remained stable over time (92%) at 19 months. In CAD, a 63% (10/16) thrombosis rate could be observed during the first hospital stay and improved to 93% at 19 months. Overall survival at four years was 72% in AAD and 94% in CAD. The need for secondary downstream intervention was 10% (3/29) in AAD *versus* 25% (4/16) in CAD.

In AAD three patients underwent secondary endovascular intervention at the distal stent graft end due to a primary (one type III endoleak) or a secondary Endoleak (one type Ib and one type II endoleak). In CAD three patients required TEVAR for stent graft extension due to type Ib (N.=2) or type III (N.=1) endoleak. In all cases the retrograde placement of the new graft and the landing within the distal E-vita open stent-graft was successful resulting in sealing of the endoleak. One CAD patient underwent descending aortic replacement 29 days after the first operation due to a persistently perfused third false lumen originating from the origin of the left subclavian artery (type II endoleak).

The registry follow-up data show similar results: Hospital mortality was 14%, both for AAD and CAD, new strokes 9% *versus* 1%, spinal cord injury 2% *versus* 5%. The fate of the false lumen demonstrated thrombosis in 88% *versus* 69% after days, and 93% *versus* 81% at follow up CT scan after 21 months in AAD *versus* CAD, respectively. Cumulative survival rate at four years was 78% (Figure 2).

Discussion

Classic surgical treatment of acute type I aortic dissection leaves the false lumen in the aortic arch and/or descending aorta untreated, sometimes causing sec-

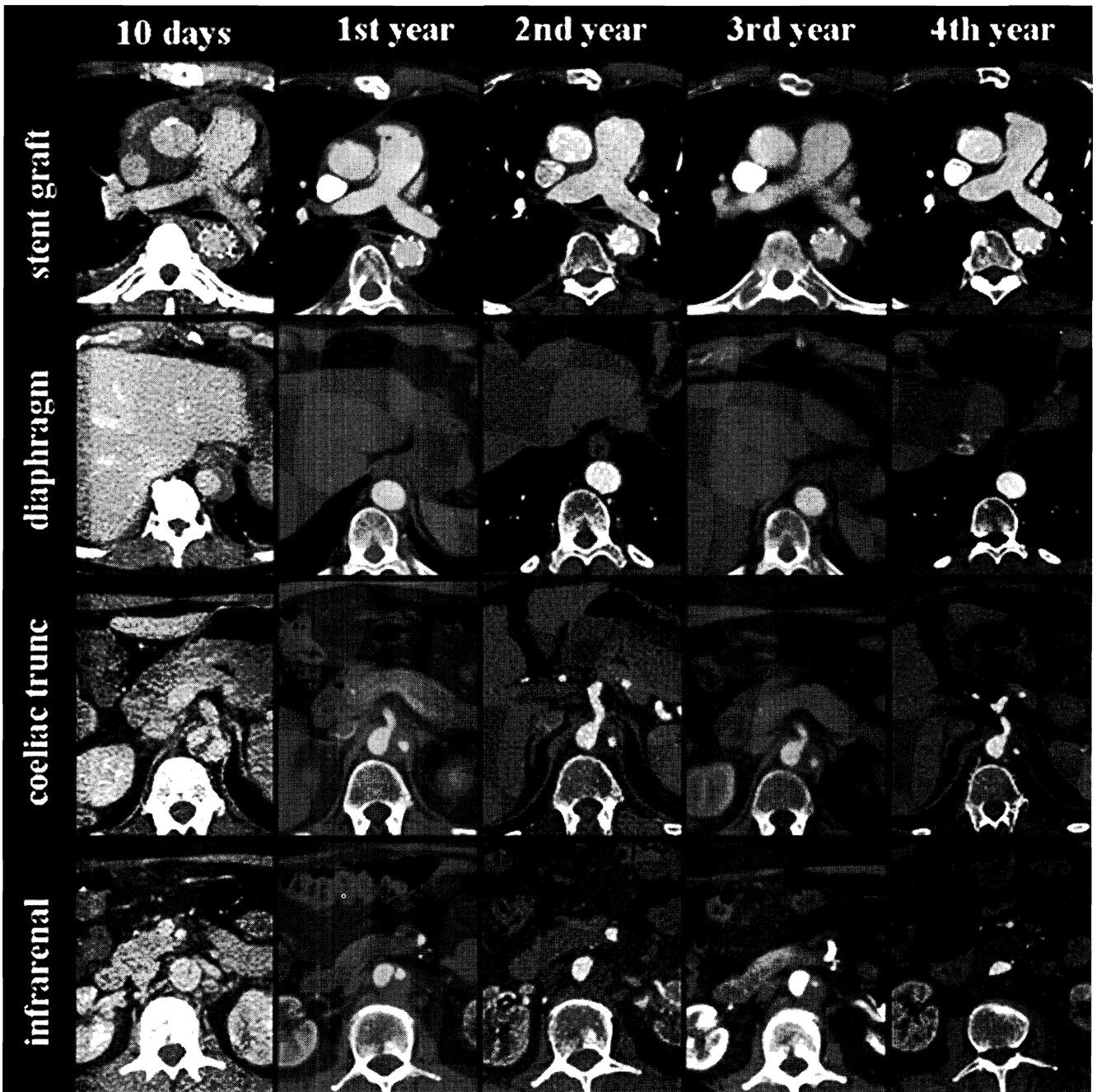


Figure 2.—Case computed tomography study of a 52-year-old male with acute type I AD: durable thrombosis and shrinkage of the false lumen is documented at stent-graft and diaphragmatic level, while the true lumen and the partially thrombotic false lumen in the abdominal aorta remains stable over a period of four years.

ondary problems like aneurysm formation aortic rupture or distal malperfusion.^{10-14, 24, 25} Due to the fact, that in the literature usually the Stanford classification is

used, no differentiation between the extension of the dissection process distally is made. This means, that probably one third or even more of the patients belong

into the DeBakey type II subgroup, where no distal dissection process exists, thus probably not causing distal aortic problems over time, as studied recently in our institution at late follow-up.²⁶ From this can be concluded, that the late downstream complication rate after DeBakey type I aortic repair probably is significantly underestimated in the literature and might exceed the estimated rate of 30% reoperations within 10 years after the primary operation.^{11, 25}

Even more, in case of evident late complications within the chronic type I situation like aneurysm formation in the distal ascending aorta/arch and the descending aorta, the surgical approach usually consists of a staged procedure starting with midline replacement of the distal ascending aorta/aortic arch, followed by replacement of the descending aorta *via* lateral thoracotomy. However, the trauma for the patient associated with this two-stage procedure is severe and the results achieved including the interval mortality is summing up to 30% even in the best hands.^{15, 27}

Credit has to be given to Japanese authors who propagated simultaneous stent-grafting of the descending aorta through a midline approach primarily for aneurysmal disease, followed by aortic dissection cases.^{16, 17, 28, 29}

Being confronted with several symptomatic patients presenting after previous ascending aortic replacement for DeBakey type I dissection, we began to adopt those techniques in 2001. The advent of our hybrid room in 2004 with its possibilities for immediate and online TEE, angiography, TEVAR and operation expanded this principle to all kinds of complex thoracic aortic pathologies. Due to the fact, that this is a safe but extensive surgical procedure, the indication to simultaneously splint the downstream aorta was reserved for patients with entry or re-entry tears at or below the left subclavian artery and/or full circular arch dissection in the AAD.³⁰ Thus, results of this procedure have to be compared to total arch replacement combined with the conventional elephant trunk procedure, where the overall mortality ranges from 13% and 36%.¹⁵

In contrast to the conventional elephant trunk procedure, stable thrombosis of the FL beyond 90% down to the mid-descending aortic level around the stent graft prosthesis can be achieved, which tends to shrink over time, leading to growth of the TL, eventually resulting in aortic remodelling of the complete aorta in up to 30% of the cases (Figure 2). Surprisingly, in

CAD, the expected lower rate in contrast to AAD of immediate thrombosis of the FL (63%) tends to increase to unexpected 93% within 19 months follow-up time, suggesting also a process of proximal healing down to the stent-graft end. Thus, the primary goal to possibly create a stable situation within the thoracic aorta not requiring another open surgery has been fully achieved. A close follow-up protocol (100% at Essen University Hospital) is mandatory and a potential unstable situation in the thoraco-abdominal or abdominal aorta can be easily detected using CT scanning or MRT, and can be usually treated by secondary TEVAR *via* the femoral artery access. Three (10%) cases after AAD surgery required TEVAR in contrast to three (19%) of CAD cases without procedural morbidity or mortality.

Landing within the distal E-vita open stent-graft is easily achieved with a very stable connection to a covered or non-covered new stent-graft, and sealing of distal endoleakage was successful in all cases. Proximal endoleakage is virtually impossible due to the nature of the E-vita open hybrid stent-graft prosthesis relying on a classic proximal sutureline and its seamless transition from the non-stented portion into the stented part. In one case, a proximal type II endoleak was detected originating from the subclavian artery, finally necessitating conventional replacement of the whole thoraco-abdominal aorta.³¹ These single center results are supported by the International E-vita open registry data. No additional open surgery was required to date for 136 AD patients being treated with this hybrid concept.

Conclusions

We believe that the demonstrated concept of simultaneous stent-grafting of the descending aorta after ascending aorta and arch replacement in complex thoracic aortic dissection is a promising step forward to create a stable false lumen thrombosis at least down to the stent-graft end which tends to heal over time. Owing to the nature of this extensive procedure the indication for its application is reserved for cases with additional entry/re-entry tears in the distal arch/proximal descending aorta and/or full circular arch dissection in acute aortic type I dissection. In complicated chronic type I or III aortic dissection, aneurysm formation in the arch and the descending aorta with impending or contained rupture or resulting in abdom-

inal malperfusion also suggests this approach. Follow-up studies demonstrate that the goal of shrinkage of the false lumen channel and expansion of the true lumen can be achieved in over 90% of the cases, surprisingly also in chronic aortic dissection. Hospital morbidity and mortality is at acceptable levels and less than in the classic two stage approaches. Upcoming procedural changes probably will decrease perioperative complications in the near future.

In case of secondary thoraco-abdominal problems like distal endoleakage, additional interventional treatment with TEVAR is possible with an ideal landing zone for the new stent-graft within the E-vita open hybrid stent-graft, obviating open surgery in most cases. Lifelong surveillance of those patients, however is warranted. The reported results are fully supported by the data from the International E-vita open registry.

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APPENDIX I

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