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The International E-vita Open Registry: data sets of 274 patients

H. JAKOB¹, K. TSAGAKIS¹, D. PACINI^{2*}, R. DI BARTOLOMEO^{2*}, C. A. MESTRES^{3*},
F. W. MOHR^{4*}, R. S. BONSER^{5*}, S. CERNY^{6*}, P. OBERWALDER^{8*}, M. GRABENWOGER^{3*}

Aim. After the introduction of the hybrid stent-graft “E-vita-open” by the Essen group in January 2005 for one stage repair of complex thoracic aortic disease, the International E-vita Open Registry was founded in 2008 to study the principles of this algorithm treatment and to control reported favorable single center results on a large patient data set basis up to six years after the first clinical implant.

Methods. Retrospective data work-up after prospective data acquisition was achieved by institution of the International E-vita Open Registry with anonymous registration and calculation at Essen University Hospital. From January 2005 to December 2010, 274 patients (mean age 60; 74% males) with complex aortic disease, 190 with aortic dissection (88 acute (AAD), 102 chronic aortic dissection (CAD), and 84 with complex thoracic aortic aneurysm (TAA) were included in the studied.

Results. Eighty-one out of 274 (30%) patients underwent emergency surgery. Stent-graft deployment and arch replacement (238 total, 36 subtotal) was performed under selective antegrade cerebral perfusion (75 min mean). Cardiopulmonary bypass (CPB) and cardiac arrest times were mean 235 and 134 minutes, respectively. In-hospital mortality was 15% (40/274), 18% for AAD, 13% for CAD, and 14% for TAA. New strokes were observed in 6% (16/274), spinal cord injury in 8% (22/274). The false lumen (FL) was evaluated throughout the first hospital stay and at a median follow-up time of 59 months after surgery. From the first follow-up CT-examination to the last, thoracic complete FL thrombosis increased from 83% to 93% in AAD, from 72% to 92% in CAD. Full exclusion of the aneurysmal disease was achieved in 77% (61/79) during the primary hospital stay.

*On behalf of the International Registry Group.

Corresponding author: H. Jakob, MD, PhD, Department of Thoracic and Cardiovascular Surgery, West-German Heart Center Essen, University Hospital Essen, Hufelandstr. 55, 45122 Essen, Germany.
E-mail: heinz.jakob@uk-essen.de

¹Department of Thoracic and Cardiovascular Surgery
West German Heart Center Essen
University Hospital Essen, Essen, Germany

²Department of Cardiac Surgery
S. Orsola-Malpighi Hospital
University of Bologna, Bologna, Italy

³Department of Cardiovascular Surgery
Hospital Hietzing, Vienna, Austria

⁴Department of Cardiovascular Surgery
Hospital Clínico

University of Barcelona, Barcelona, Spain

⁵Department of Cardiac Surgery
Leipzig Heart Center

University of Leipzig, Leipzig, Germany

⁶Department of Cardiothoracic Surgery
University Hospital Birmingham

NHS Foundation Trust, Birmingham, UK

⁷Department of Cardiac Surgery

Na Homolce Hospital, Prague, Czech Republic

⁸Department of Cardiac Surgery

University Hospital Graz, Graz, Austria

Conclusion. Favorable single center results could be confirmed by an international community of cardiac surgical centers in regard to hospital mortality and morbidity, as well as a low postoperative complication rate and exclusion of false lumen in aortic dissection.

KEY WORDS: Aorta, dissection, surgery - Aneurysm - Aortic arch syndromes.

Complex thoracic aortic disease encompasses acute (AAD) and chronic type A dissection (CAD), as well as aortic arch aneurysms (TAA) with or without involvement of the ascending and descending aorta. This constellation still represents a surgical challenge due to the complex surgical strategy to replace the aortic arch and the limited access to the descending

aorta. Thus, classically the compromise in the surgical treatment algorithm consists of a quick and often lifesaving ascending aortic replacement in acute Type A dissection leaving the downstream segments of the thoracic aorta untreated with a persisting false lumen >70%¹⁻⁵ or a two-stage approach in chronic AD or multiple aneurysms consisting of ascending aorta/arch repair *via* median sternotomy followed by a secondary distal aortic repair through left lateral thoracotomy with a time interval from weeks to months⁶ with its substantial morbidity and inherent cumulative mortality of a mean of 23% (up to 36%) and less than 50% of patients cohort who does return for the originally planned second stage operation.⁷ In addition, after successful primary proximal repair of AAD, there remains a subset of about 30% of patients who has to undergo a secondary surgical procedure for false lumen complications after proximal aortic replacement within 10 years.^{8,9} Cumulative mortality for planned two stage surgery in CAD or TAA, including adverse outcome between the stages observed in several cases sobers the good results of the first stage. Thus, a one-stage strategy may be preferable, which was initiated by Japanese colleagues using homemade stent-grafts constructed during the operation.^{10,11} After primary experience with a combined approach using the Talent stent-graft in antegrade fashion through the open aortic arch to splint the proximal descending aorta after conventional arch replacement, the hybrid E-vita open stent-graft was developed and applied first-in-man in January 2005 in Essen, Germany.¹² The principle of this hybrid graft concept combines conventional arch replacement with the antegrade endovascular treatment of the descending aorta using a covered stent-graft based on a proximal suture line to avoid Type I endoleakage. After primary use in CAD and TAA, AAD also became an indication in case of entry tears in the distal aortic arch and/or proximal descending aorta,^{13,14} aiming at obliteration of the false lumen down to the stent-graft end or beyond, as well as full aneurysm exclusion in TAA cases. After achieving favorable single center results, September 2008 the International E-vita Open Registry was started at Essen University Hospital compiling anonymously data from several European centers applying the E-vita open principle in the aforementioned indication. The present multicenter study evaluates early and midterm results in regard to morbidity and mortality, and the fate of the false lumen in dissection cases.

Materials and methods

Patients

Eight European referral centers (Barcelona, Birmingham, Bologna, Essen, Graz, Leipzig, Prague and Vienna-Hietzing) are currently participating in the International E-vita Open Registry (IEOR). From January 2005 to December 2010 a total of 274 patients with complex aortic disease underwent arch replacement combined with open antegrade stent-grafting using the E-vita open (JOTEC GmbH, Hechingen, Germany) hybrid stent-graft and have been enrolled to the IEO database. The mean±SD age was 60±12 years and 204 (74%) were males (Table I). Eighty-eight (32%) were operated for acute AD, 102 (37%) for chronic AD and 84 (31%) for extended aortic aneurysm. DeBakey Type I AD was documented in 162 (85%) patients and a type III AD involving the arch in 28 (15%). Twelve (5%) patients were operated for Marfan syndrome. In acute AD, 77 (88%) patients underwent emergency surgery within 24 hours after onset of symptoms. In chronic AD, 71 (70%) patients underwent redo surgery after proximal aortic repair. Computed tomography (CT) or magnet resonance imaging (MRI) were performed in 269 (98%) patients and in 5 (2%) emergency cases angiography or echocardiography alone was performed.

Hybrid stent-grafting

The E-vita open hybrid stent-graft (130-160 cm long, 24-40 mm diameter) consists of a nitinol covered stent-graft for descending aortic treatment with an integrated non-stented vascular prosthesis on the top for continuous arch replacement. No standard surgical protocol was used for the perioperative management including cannulation site, deep temperature for hypothermic circulatory arrest, cerebral and cardiac protection, stent-graft insertion and landing, arch replacement as well as reinsertion of the supraaortic vessels.¹⁵ However, bilateral antegrade cerebral perfusion was used in all cases.

Statistical analysis

Categorical variables are presented as frequencies. Continuous values are expressed as mean ± standard deviation or median and interquartile range (range from 25th to 75th percentile). Survival was analyzed with the Kaplan-Meier analysis and

TABLE I.—*Demographics.*

Mean ± SD, N. (%)	Total N.=274	AAD N.=88	CAD N.=102	TAA N.=84
Age, mean±SD	60±12	59±13	57±12	66±9
Male	204 (74)	68 (77)	82 (80)	54 (64)
Marfan	12 (4)	5 (6)	6 (6)	1 (1)
Emergency	81 (30)	77 (88)	4 (4)	5 (6)
Tamponade	21 (8)	20 (23)	—	1 (1)
Coronary artery disease	43 (16)	12 (14)	7 (7)	24 (29)
Aortic valve disease	128 (47)	57 (65)	45 (44)	26 (31)
Chronic pulmonary disease	51 (19)	21 (24)	112 (12)	18 (21)
Renal insufficiency	33 (12)	13 (15)	9 (9)	1 (13)
Peripheral vascular disease	51 (19)	8 (9)	10 (10)	33 (39)
Previous cardiovascular surgery	94 (34)	4 (5)	71 (70)	19 (23)
Previous stroke	14 (5)	5 (6)	3 (3)	6 (7)

was used for presentation of the survival and freedom of secondary interventions. Statistical analysis was performed using the 18.0 version SPSS software package (SPSS Inc, Chicago, IL, USA).

Results

Intraoperative management

The right subclavian artery (181/274, 66%) was used in most cases for artery access to the extracorporeal circulation in acute (51/88, 58%) as well as in chronic disease (dissection and aneurysm) (130/186, 70%), Table II. Arch surgery followed under selective cerebral perfusion (75±27 min) and hypothermic visceral ischemia (58±32 min). The hybrid stent-graft (mean diameter 31±5 mm) was placed antegradely into the descending aorta after resection of the arch; in over the wire technique in 208 (76%). Total arch replacement was performed in 238 (87%) and subtotally leaving a tissue bridge between the arch and the descending aorta in 36 (13%). Arch replacement was performed with the integrated E-vita open vascular prosthesis in 151 (55%) cases, with a branched prosthesis in 47 (17%) or with a simple tubular prosthesis in 76 (28%) cases. Reimplantation of the supra-aortic vessels was achieved with the island technique in 63% (173/274) or separately in 37% (101/274). Proximally, replacement of the supravalvular ascending aorta was undertaken in 80% (219/274), including the aortic root in 17% (46/274). Additional CABG was documented in 16% (43/274).

TABLE II.—*Operative procedures additional to E-vita open placement.*

Mean±SD, N. (%)	Total N.=274	AAD N.=88	CAD N.=102	TAA N.=84
Subclavian artery cannulation	181 (66)	51 (58)	68 (67)	62 (74)
Aortic valve intervention				
— Repair	14 (5)	10 (11)	1 (1)	3 (4)
— Resuspension	28 (10)	25 (28)	2 (2)	1 (1)
— Replacement isolated	23 (8)	4 (5)	11 (11)	8 (10)
— Bentall procedure	34 (12)	12 (14)	19 (19)	3 (4)
Thoracic aorta replacement				
— Sinus valsalvae	46 (17)	20 (23)	20 (20)	6 (7)
— Ascending aorta	219 (80)	87 (99)	64 (63)	58 (69)
— Aortic arch	274 (100)	88 (100)	102 (100)	84 (100)
Supra-aortic arteries				
— Island anastomosis	173 (63)	55 (63)	56 (55)	62 (74)
— Separate reinsertion	101 (37)	33 (37)	46 (45)	22 (26)
E-vita open diameter, mm	31±5	28±4	30±4	34±5
CABG	43 (16)	19 (22)	7 (7)	17 (20)
Cardiopulmonary bypass, min	235±64	243±65	246±69	215±53
Cardioplegic arrest, min	134±48	139±48	146±48	114±43
Selective cerebral perfusion, min	75±27	68±22	85±26	71±27
Visceral ischemia, min	58±32	48±36	64±30	61±25

The mean time of CPB and cardioplegic arrest was 235±64 and 134±48 minutes, respectively.

In-hospital outcome

Median hospital stay was 19 days (range 12-29). Thirty day mortality was 12% (33/274) and

TABLE III.—Postoperative results.

Median, N. (%)	Total N.=274	AAD N.=88	CAD N.=102	TAA N.=84
In-hospital stay, days (median)	19	23	17	18
In-hospital mortality	41 (15)	16 (18)	13 (13)	12 (14)
30 days mortality	33 (12)	11 (13)	10 (10)	12 (14)
Re-exploration for bleeding	38 (14)	16 (18)	13 (13)	9 (11)
Intubation >72 h	91 (33)	33 (38)	32 (31)	26 (31)
Stroke	16 (6)	5 (6)	3 (3)	8 (10)
Spinal cord injury	22 (8)	5 (6)	8 (8)	9 (11)
Dialysis				
— Permanent	10 (4)	1 (1)	4 (4)	5 (6)
— Temporary	60 (22)	31 (35)	14 (14)	15 (18)

TABLE IV.—Fate of the false lumen in acute and chronic dissection.

	Acute AD N. (%)	Chronic AD N. (%)
<i>First CT stent-graft level</i>	N.=75	N.=94
Complete thrombosis	62 (83)	68 (72)
Partial thrombosis	11 (15)	17 (18)
Patent	2 (3)	9 (10)
<i>Last CT stent-graft level</i>	N.=56	N.=67
Complete thrombosis	52 (93)	62 (92)
Partial thrombosis	4 (7)	4 (6)
Patent	—	1 (2)

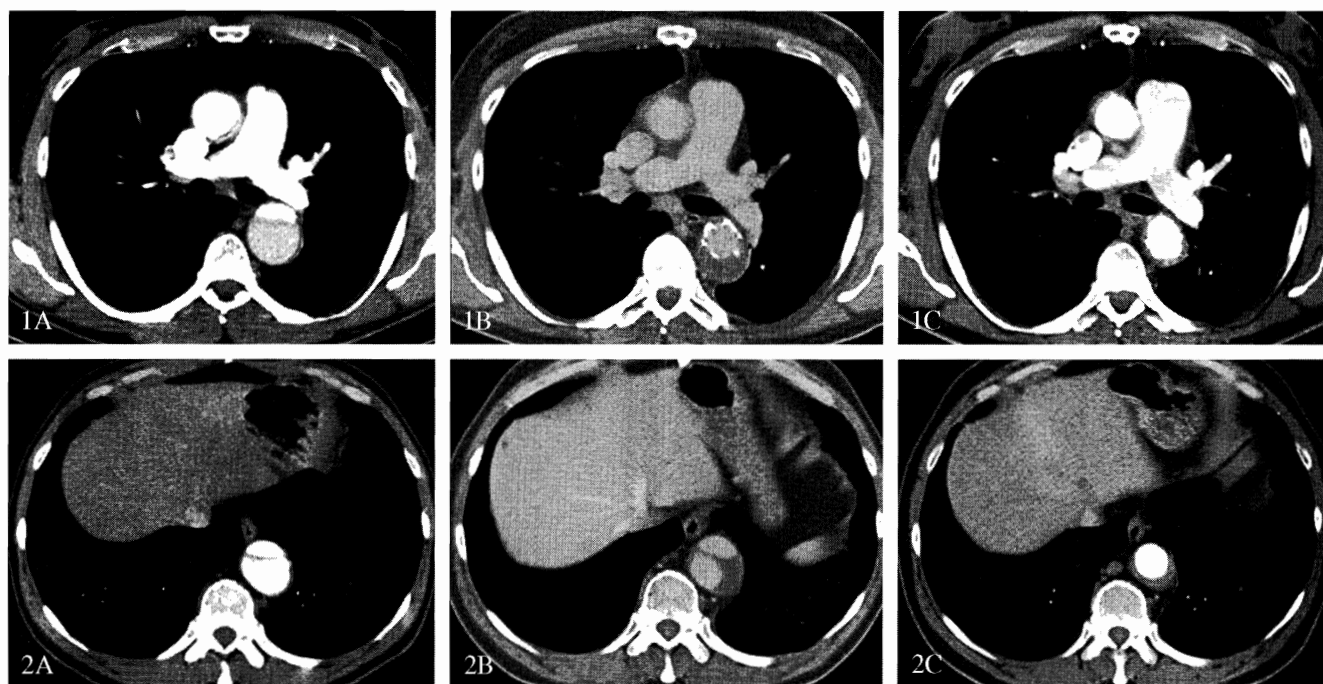


Figure 1.—Progressive false lumen thrombosis around the stent-graft level of descending aorta, at pulmonary bifurcation - and diaphragmatic level in chronic aortic dissection (status post proximal Type A repair) (1A, 2A) preoperatively, at six months (1B, 2B) and three years (1C, 2C) postoperatively. Shrinking of false lumen and aortic remodelling occurred.

in-hospital mortality was 15% (Table III). Surgical re-exploration was required 14% (38/274), more frequently in acute AD (16/88, 18%). In 16 (6%) patients, permanent or regressive stroke occurred postoperatively. The incidence of paraplegia or paraparesis was 8% (22/274), more commonly in chronic disease. Out of those, spinal cord injury fully resolved in two and partially in 10 cases. The rate of a permanent dialysis was 4% (10/274)

including six patients who died during the hospitalization.

Reinterventions and fate of the aortic disease

Postoperatively, the false lumen was evaluated by CT in 75 patients with acute, 94 with chronic aortic dissection and 79 with aneurysm (Table IV). Around the covered part of the descending aorta,

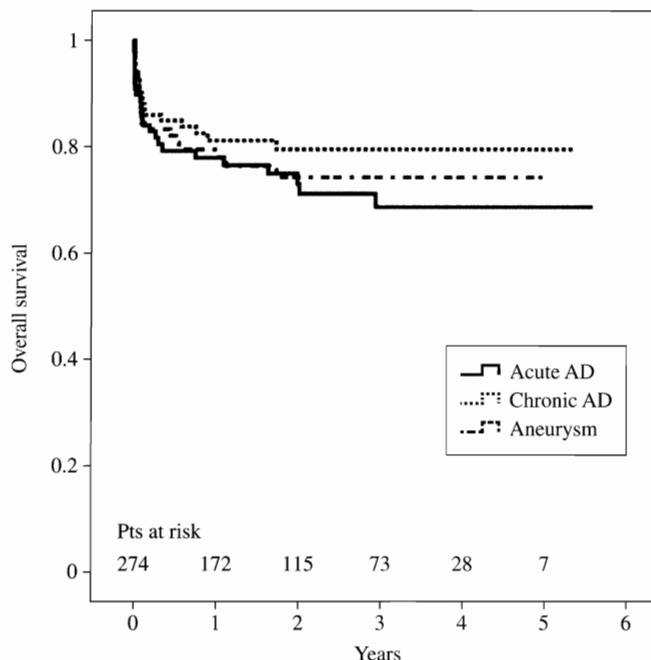


Figure 2.—Actuarial survival according to Kaplan Meier analysis in acute and chronic aortic dissection and in aneurysmal cases.

the false lumen thrombosed completely in 83% (62/75) AAD patients and in 72% (68/94) CAD cases. During a median follow-up of 59 months (range 28-99) the rate of complete thrombosis increased up to 93% in AAD and 92% in CAD (Figure 1). Among the aneurysmal cases complete exclusion of the aneurysm occurred in 77% (61/79) postoperatively. Actuarial survival rate after five years (all patients included) was 74% (Figure 2), freedom from secondary endovascular intervention and secondary surgery distally was 82% and 95%, respectively (Figure 3). Among survivors (233/274), the incidence of secondary endovascular intervention or surgery downstream was 13% (29/233) and 3% (6/233), respectively.

Discussion

The combination of surgical and endovascular techniques for the treatment of complex aortic disease enabled the development of new surgical hybrid concepts. Especially in aortic disease involv-

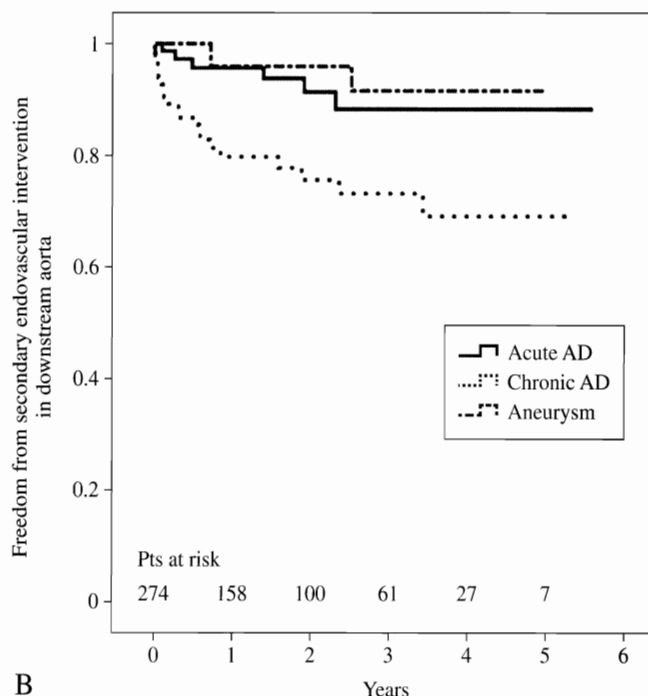
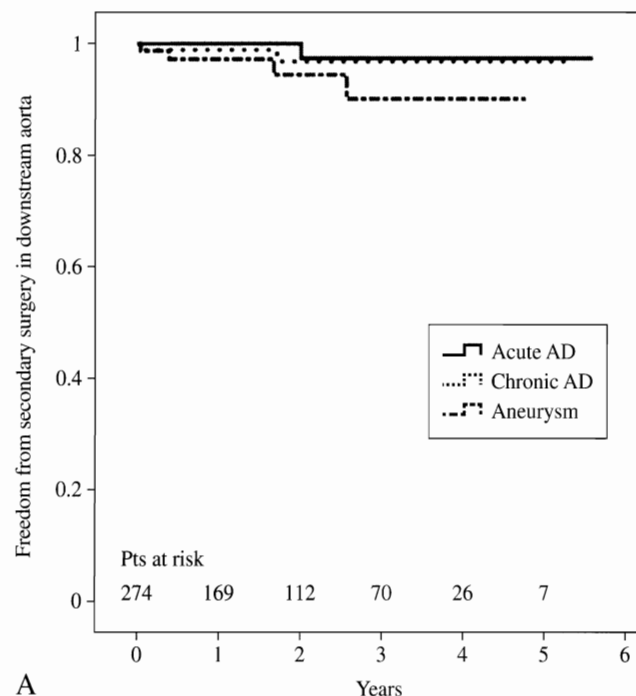


Figure 3.—Actuarial freedom of secondary surgery and endovascular intervention along the downstream aorta according to Kaplan Meier analysis in acute and chronic aortic dissection and aneurysmal disease.

ing the arch, the use of a stent-graft for extended covering of the disease offers the possibility to exclude the descending aorta pathology in one step aiming to reduce the surgical trauma by avoidance of a clamshell incision or of a secondary surgical procedure by left lateral thoracotomy.^{16, 17} The innovation to combine a vascular graft with a stent-graft for continuous arch replacement and stent-grafting of the descending aorta crossed from Japan to Europe in the last decade and led to the development of industrial made hybrid stent-grafts, the so called "frozen elephant trunk".¹⁸⁻²⁰ The International E-vita Open Registry represents the first database for evaluation of aortic disease after extensive aortic repair by a hybrid stent-graft and currently, a ninth center is joining a group of eight European cardiothoracic surgical centers. Beginning with the data collection in September 2008, the investigating surgeons aim for a detailed evaluation of the operative procedure based on the underlying extent of disease and the analysis of the aortic remodeling process during follow up. Thus, feasibility and efficiency of the treatment principle as well as outcome and complications of the procedure have been analyzed. The in-hospital mortality of 15% represents a promising result respecting a substantial learning curve with this kind of major surgery for complex aortic disease, and represents improved survival in contrast to the classic surgical two-stage concept with its cumulative mortality of 24.5%, inasmuch as the rate of emergency procedures encompasses 30% in the IEOR *versus* 9% in the series reported by Etz *et al.*⁷ The IEOR results also demonstrate an 8% incidence of spinal cord injury, especially seen after surgery for CAD or TAA. Though paraparesis and paraplegia have a trend to resolve at least partially in 40% of the patients, this complication is taken seriously. The pathophysiology of spinal cord injury after the frozen elephant trunk operation remains not fully understood and the intraoperative time interval of spinal cord ischemia, thromboembolism and weight gain during the operation have been suggested as risk factors.²¹ In addition, the extension of the covered portion of the descending aorta down to vertebral level Th 8-9 has been also suggested to correlate with spinal cord injury,²² and for this reason, the stented portion length of the E-vita open stent-graft has been reduced from 15 to 13 cm. However, Miyairi *et al.* reported cases with paraplegia after landing at the level of Th 6, indicating the multifac-

torial etiology of spinal cord injury perioperatively. A reduction of the spinal cord ischemic time, additional cannulation and perfusion of the left subclavian artery, and strict perioperative monitoring of the cerebrospinal fluid pressure combined with adjustment of the systemic blood pressure²³ should be considered and evaluated in the future. In addition and based on the IEOR data of chronic dissection, Pacini *et al.* reported an association between the ratio of the diameter of the true lumen to the descending aorta and the incidence of spinal cord injury.²⁴ Consequently, the characteristics of aortic dissection could lead to a preoperative selection of patients for the frozen elephant trunk operation and the timing of surgery according to the progression of the false lumen width.

One major goal of the E-vita open surgical principle has been almost fully achieved both in AAD and CAD: the exclusion of the false lumen at least down to the stent-graft end over time in 93% *versus* 92% of the cases, respectively (Table IV). Thus, a remodeling process of the thoracic aorta is initiated without the prize of one single instance of proximal endoleakage type I (Figure 1), which remains durable during the investigation period. The exclusion of aneurysmal disease, which is fully achieved in only 77% of the reported cases, currently is under investigation, since it contrasts to the 100% exclusion rate with successive shrinkage of the aneurysmal sac in some TAA patients at the University Hospital of Essen.

A close follow-up at six months, one year and annually thereafter, is essential to identify a potential progression of the disease distally using CT- or MRI technology besides clinical evaluation. In such a case, a secondary endovascular intervention can be easily performed by landing a second stent-graft within the distal portion of the E-vita open prosthesis. In case of rapid expansion of the distal false lumen or aneurysmal sac, secondary thoraco-abdominal open replacement is feasible by directly anastomosing the prosthesis to the end of the E-vita open stent-graft at midthoracic level. Freedom from secondary endovascular intervention was much less in chronic dissection patients and reflects the complexity of treatment of a chronic status after incomplete primary surgical treatment of AAD and delivers additional arguments to primarily trying to induce obliteration of the thoracic false lumen in AAD. The documented low incidence of required secondary

surgical intervention along the downstream aorta represents the durability of the E-vita open stent-graft technique at least during an up to six year follow-up period.

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