



# Which Frozen Elephant Trunk Offers the Optimal Solution? Reflections From Essen Group

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Frozen Elephant Trunk (FET) combines the advantages of open and endovascular surgery for the treatment of complex aortic arch pathologies extending into the descending aorta. At University Hospital Essen, operative skills were developed to make FET surgery safer including guidance and control of FET deployment into the descending aorta by angioscopy and facilitation of arch repair by moving the distal anastomosis to Zone 2 and more proximally. Selective whole body perfusion during the arch repair was used to improve organ protection under moderate hypothermia. Our results demonstrate acceptable mortality in this high risk patient population and reduction of post-operative morbidity in the last years. With regard to the rate of exclusion of aneurysms in the distal arch and the false lumen in acute aortic dissection, FET should be the treatment of choice in both. In chronic aortic dissection and extensive descending aortic aneurysms, FET represents a safe first stage procedure and provides an ideal docking place in the mid-descending aorta for a second endovascular or open thoracoabdominal aortic repair, if required.

**Semin Thoracic Surg 31:679–685** © 2019 Published by Elsevier Inc.

**Keywords:** Frozen elephant trunk, FET

Frozen elephant trunk (FET) represents an evolution of the treatment of extensive aortic arch disease in the last 2 decades.<sup>1</sup> The combination of a self-expandable nitinol supported stent graft for the endovascular treatment of the descending aorta with a vascular graft for the aortic arch replacement allowed: first, the extension of the arch replacement into the descending aorta and second, the performance of this treatment with a single (combined) graft. Thus, the treatment of the descending aorta became possible in one stage through a median sternotomy without resection of the descending aorta pathology and without a surgical suture in the anatomically challenging left upper thoracic cavity.<sup>2</sup> In contrast to the endovascular treatment by a classic stent graft, the fixation of FET proximally is achieved by a surgical circumferential hemostatic suture, which eliminates the risk of proximal endoleak without sealing- and landing zone-related restrictions.

The Essen experience with extended thoracic aortic repair beyond the arch started in June 2001 by following the later called

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Funding: None.

Conflicts of Interest: Heinz Jakob is consultant to CryoLife/JOTEC GmbH.

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E-vita open facilitates the treatment of all 3 thoracic aortic segments in 1 step.

## Central Message

FET combines the advantages of surgical and endovascular treatment and should be the treatment of choice for a one- or facilitated two-stage approach for any kind of distal aortic arch pathology.

FET principle and using a classic aortic arch surgical replacement in combination with antegrade delivery of a separate stent graft (Talent, Medtronic) downstream.<sup>3</sup> This first experience was limited to 14 patients with degenerative aortic aneurysm or dissection and revealed severe shortcomings of the procedure with regard to safety of antegrade stent graft deployment and proximal sealing. The incidence of stent graft-related complications was 50% encompassing endoleak, stent graft migration, and aortic rupture postoperatively and during the follow-up, and the incidence of secondary open or endovascular intervention was 21%. Consequently, this pioneering program was stopped in 2004. The lessons learned by this experience promoted and influenced the development of the first commercially available FET graft, the so-called E-vita open (Jotec, CryoLife).<sup>4</sup>

## E-VITA OPEN AND E-VITA OPEN PLUS

The first E-vita open as well as the following E-vita open plus were designed to combine the advantages of the modified

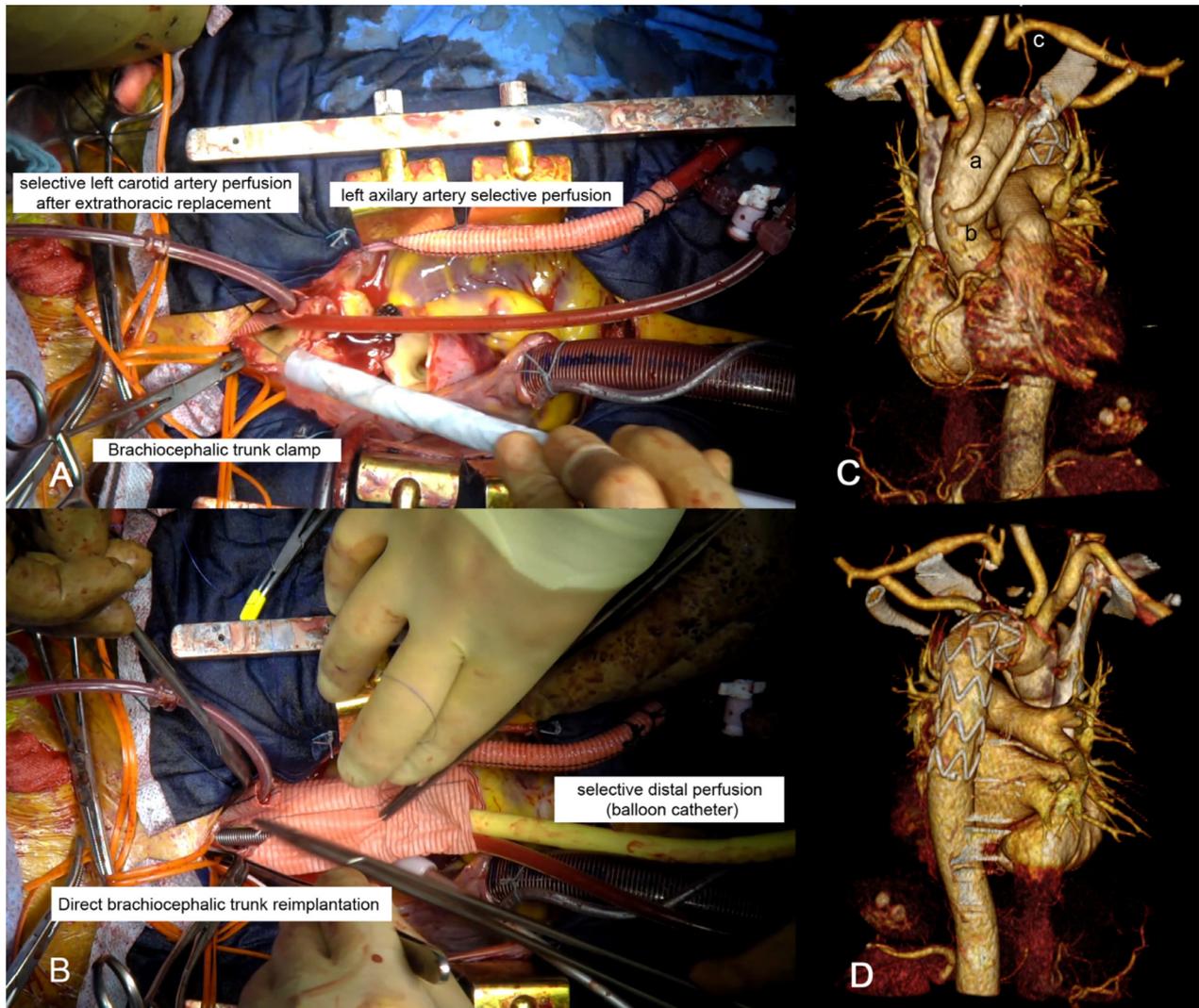
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elephant trunk technique with endovascular technology. This in one piece constructed hybrid prosthesis is consisting of a polyester vascular graft as a tube, which is intussuscepted into the lumen of a stent graft with a Z-shaped nitinol skeleton. At the junction between the grafts, a polyester collar enables the fixation of the graft to the rim of the distal aortic arch by a continuous surgical suture. Both segments of the graft are crimped and placed within a flexible endovascular introducer with an inflatable balloon at the tip for atraumatic delivery downstream

through the opened arch in over the wire technique (Fig. 1A). The advantages of this design are listed below:

### FET Placement

The guidance of the flexible endovascular introducer into the descending aorta over a stiff guide wire 0.035 inches (E-wire, Jotec/CryoLife) in a through-and-through wire technique enables the passive advancement of the FET downstream by pulling the distal end of the wire through a 6–8F sheath at



**Figure 1.** Zone 1 E-vita open treatment in acute type I aortic dissection complicated from cerebral malperfusion by left carotid artery occlusion. (A) Hypothermic circulatory arrest was initiated under bilateral selective cerebral perfusion after replacement of the left carotid artery (8-mm graft) distal to artery occlusion via neck incision and over the right axillary artery after clamping of the brachiocephalic trunk. The left subclavian artery was debranched and selectively perfused over an 8-mm graft at the left axillary artery. The arch was resected in Zone 1 and the E-vita open plus was introduced over the wire downstream. (B) Direct implantation of the brachiocephalic trunk was followed after FET fixation and retrieval and fenestration of the arch graft. The anastomosis is performed under additional selective distal body perfusion using a balloon catheter (yellow) as endoclamp and sump sucker within the arch graft lumen. The figure demonstrates the high flexibility of the arch prosthesis using this setup, which enables undisturbed access to the supra-aortic arteries facilitating the anastomosis. (C) Postoperative CT imaging demonstrates the position of the left carotid artery graft (a) and the left axillary artery graft (b) after implantation at the ascending prosthesis. The proximal left subclavian artery (c) and vertebral artery are retrogradely perfused after debranching. (D) No residual dissection after exclusion of the re-entry in the descending aorta.

the femoral artery. Thus, the introducer follows passively the determined route of the wire downstream to the distal landing zone without friction between the delivery system and the aortic wall. The avoidance of blind pushing of the FET downstream, the guidance over the wire, and the atraumatic balloon tip of the delivery system do increase the safety of FET placement by avoiding landing within a false lumen in aortic dissection (AD) or the sheering off debris in shaggy aortas. In AD, the position of the stiff guide wire within the true lumen of the descending aorta can be easily controlled by TEE or angiography. In addition, in our institution, the distal landing zone for stent graft placement is inspected prior to insertion and controlled thereafter by angioscopy to avoid any malpositioning.<sup>5</sup>

### FET Deployment

The intussuscepted position of the arch prosthesis and the graft configuration as a tube allows deployment of the E-vita open in each part of the thoracic aorta between Zones 0–4 according to Ishimaru classification. This variability enables a patient-tailored treatment according to the characteristics of the arch pathology. In the first years, the E-vita open was deployed initially in Zone 3 following the principle of classic ET taking into account a difficult and time-consuming distal anastomosis as well as a laryngeal nerve jeopardy. In 2009, we introduced the Zone 2 arch repair concept by moving the FET anastomotic site proximally in combination with left subclavian artery debranching.<sup>6</sup> Thus, the surgical treatment zone was moved closer to the surgeon and direct en block reimplantation of the supra-aortic arteries was limited to the brachiocephalic trunk and left carotid artery. Debranching of the left subclavian artery by an 8-mm vascular graft prior to extracorporeal circulation allowed the selective perfusion of all cerebral arteries during the open arch repair. In addition, the selective left subclavia artery perfusion may improve the spinal cord protection via collateral arteries during the period of hypothermic circulatory arrest distally. Arch repair became significantly faster leaving the laryngeal nerve region untouched and the supra-aortic island or isolated head vessels became easier accessible in case of bleeding. Thus, the E-vita open can be deployed more proximal in Zones 0–1 according to the intraoperative findings in combination with additional head vessels debranching<sup>7</sup> (Fig. 1A). On the other hand, the graft can also be deployed more distal toward Zone 4 without extensive resection of the proximal descending aorta. In such a scenario, the intussuscepted arch graft is pulled back into the arch to cover the gap between the aortic rim and the proximal stent graft end. The fixation of the graft is then performed by an in-and-out suture-line between the arch graft and the aorta, supported by balloon placement within the unsupported arch graft in order to avoid malalignment and collapse.

### FET Fixation and Head Vessels Reimplantation

The modified elephant trunk implantation technique by Svensson facilitated the anastomosis in distal aortic arch significantly.<sup>8</sup> Similarly, the intussuscepted position of the arch graft

after FET deployment provides an undisturbed access to the anastomosis for fast surgical fixation. The hemostatic suture is supported inside by the stent graft itself and outside by additional Teflon felt. Thus, bleeding complications at the anastomotic site have become very rare. Thereafter, the arch graft is pulled back into the arch position. After thorough deairing, circulatory arrest of the lower body is terminated by cannulation of the E-vita open stent graft with a 30F Foley catheter, and distal perfusion is started using a second pump with the balloon inflated as endoclamp<sup>9</sup> (Fig. 1B). This setup leaves the arch graft flexible within the operative field and facilitates the access to the supra-aortic arteries for en block or direct selective reimplantation. In case of severe atherosclerosis of the brachiocephalic trunk or the left carotid artery, an interposition graft or debranching of the carotid arteries can be used, if required (Fig. 1C).

### FET Sizing

The Z-shaped nitinol stent skeleton of the E-vita open stent graft has identical characteristics as conventional endovascular devices. The proximal surgical fixation enables the exclusion of the descending aorta pathology without extensive oversizing.<sup>10</sup> In our practice, the stent graft size is chosen according to the nature of the disease and the aortic diameter at the estimated distal landing zone as following: no oversizing in acute AD, no oversizing or one-size less in chronic AD and up to 10% oversizing in aortic aneurysm. In AD, the maximal true lumen diameter is used for sizing. By placing the proximal FET anastomosis in arch position Zone 2 and using a stent graft length of 130 mm, the stented portion of the FET usually ends at descending aorta level Th5–7. However, the definitive distal landing zone is determined intraoperatively by angioscopic findings in order to exclude re-entries or thrombus formations.

### OPERATIVE SETUP

Operative details are listed in Table 1. The right axillary artery is the favorite artery for cannulation over an 8-mm graft in our institution.<sup>11</sup> In addition, the left axillary artery and its collaterals to the brain and spinal cord are also perfused via an 8-mm graft, which is anastomosed to the artery and pulled through the first intercostal space into the mediastinum (Fig. 1A–D). This graft is connected over a Y-line to a second pump, which perfusion is started after ligation of the left subclavian artery origin. Distal hypothermic circulatory arrest is initiated at 28°C bladder temperature under bilateral selective cerebral perfusion at 22°C blood temperature and a mean perfusion pressure of 50–60 mm Hg, controlled by near infrared spectroscopy. Thus, the FET procedure is performed under perfusion of all supra-aortic arteries. Selective distal perfusion is initiated directly after FET fixation through the inserted balloon cannula and endoclampping of the stent graft as mentioned above. Completion of arch replacement is achieved during stepwise rewarming. Whole body perfusion via the right axillary artery is restarted after clamping of the arch graft. Thereafter, proximal aortic repair is completed by anastomosing the

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**Table 1.** Operative Setup for E-Vita Open Surgery in Essen

Operative Tools	Specification
<b>Monitoring</b>	
Three arterial lines	Both radial arteries, one femoral artery over an 8F sheath
Near infrared spectroscopy	Bilateral cerebral saturation monitoring
TEE	Heart and descending aorta imaging
LiquoGuard (Möller Medical GmbH)	Monitoring and adjustment of cerebrospinal fluid pressure <10 mm Hg in elective cases
<b>Wire tools</b>	
8F sheath	8F sheath in femoral artery for artery pressure measurement and pigtail catheter placement in the descending aorta in Seldinger technique under TEE or/and angiography control.
Pigtail catheter 6F	
J wire	The stiff guide wire is placed within the pigtail catheter. The pigtail catheter is used as a sheath for endovascular procedures through the arch in over the wire technique
Stiff wire 0.035'	
8-mm polyester woven graft	Cannulation of both axillary arteries after end-to-side anastomosis and debranching of the left subclavian artery by proximal LSA ligation and aortoaxillary extra-anatomic bypass
<b>Extracorporeal circulation</b>	
Centrifugal pump	Main artery pump, right axillary artery
Roller pump	Selective perfusion of left subclavian artery and distal aorta
Foley catheter	Endoclamp within the stent graft for distal selective perfusion
Angioscope (Olympus®, BF type Q180-AC)	Imaging of the descending aorta, choice of landing zone, control of endovascular procedures
Endovascular balloon (E-xpand, Jotec GmbH)	Stent graft relining, if required

arch graft to the ascending aorta graft and finally, the left axillary artery bypass graft is anastomosed to the ascending or arch prosthesis as an extra-anatomic bypass (Fig. 1C).

## ESSEN EXPERIENCE—RESULTS

Between January 2005 and October 2018, 307 patients underwent FET treatment in our institution using the E-vita open or E-vita open plus prosthesis. Patients' characteristics are presented in Table 2. Twenty percent of the patients were >70 years. Emergency surgery within 24 hours after the onset of symptoms was performed in 175 (57%) due to acute AD or imminent aortic rupture. The clinical status of acute AD patients was at the time of presentation Penn<sup>12</sup> Class A in 50 (30%), Class B in 75 (44%), Class C in 17 (10%), and Class BC in 27 (16%). In all patients, the dissection extended into the aortic arch and the descending aorta as DeBakey Type I or non-A to non-B AD. Fifty-seven (19%) of all patients and 42/71 (59%) with a chronic AD have had previous sternotomy for aortic or cardiac surgery.

Arch repair in Zone 3 was performed in 103 (34%) and in Zone 2 or proximally in 204 (66%). Zone 2 repair was combined with intraoperative debranching of the left subclavian artery with an 8-mm graft as aorto-subclavian (59/204, 29%), aortoaxillary (141/204, 69%), or carotid-subclavian bypass (4/204, 2%) and was associated with significant decrease of cardiopulmonary, selective cerebral perfusion, and visceral ischemia time. In total, 282 concomitant aortic root and

**Table 2.** Patients' Data

N (%)	N = 307	
Age	59 ± 12	
Male	211 (69)	
<b>Aortic disease</b>		
Acute aortic dissection	169 (55)	
Chronic aortic dissection	71 (23)	
Aneurysm	67 (22)	
<b>Additional surgery to arch repair</b>		
Ascending aorta repair	286 (93)	
Bentall procedure	38 (12)	
David procedure	7 (2)	
Partial root replacement	70 (23)	
AV replacement isolated	22 (7)	
MV repair/replacement	12 (4)	
CABG	72 (24)	
Other	18 (6)	
<b>Arch repair</b>		
	Zone 3	Zone ≤2
	103 (34)	204 (66)
<b>Operative time, min mean ± SD</b>		
Cardiopulmonary bypass time	250 ± 61	231 ± 51*
Cardioplegic arrest	147 ± 34	125 ± 38†
Selective cerebral perfusion	68 ± 18	56 ± 14†
Visceral ischemia	70 ± 24	39 ± 16†

\*P = 0.006.

†P < 0.001.

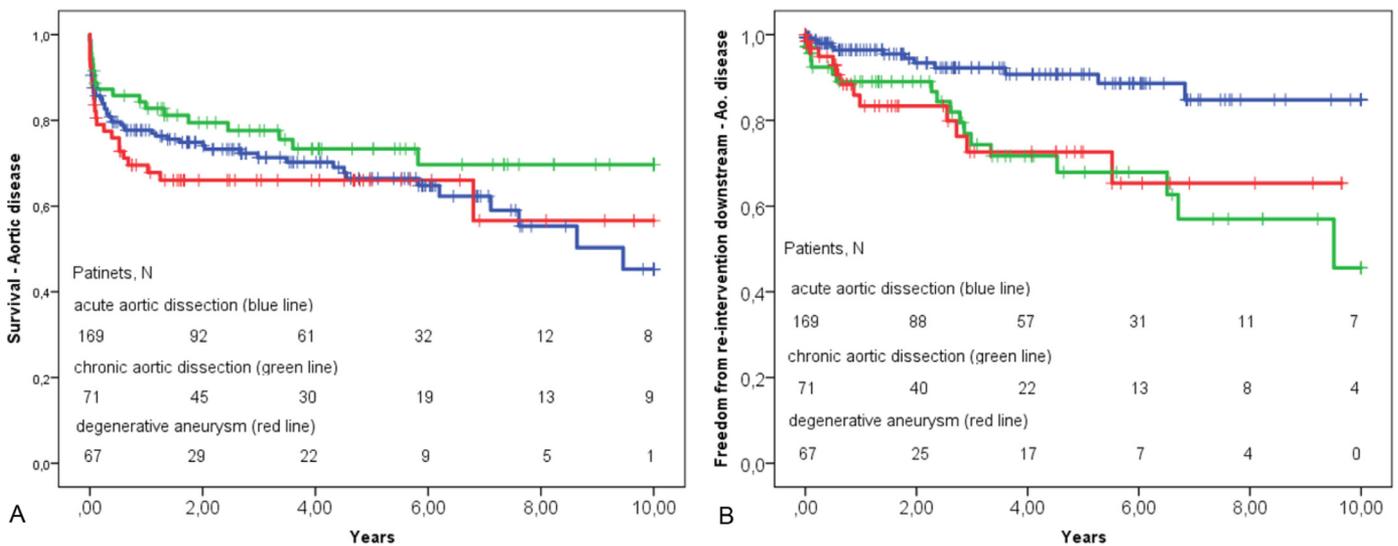
**Table 3.** Postoperative Results

N (%)	Total N = 307	Arch Replacement Technique		P Value
		Zone 3 N = 103	Zone ≤ 2 N = 204	
30-day mortality	36 (11.7)	12 (11.7)	24 (11.8)	1.000
In-hospital mortality	41 (13.4)	16 (15.5)	25 (12.3)	0.478
Cerebral neurologic deficit	26 (8.5)	12 (11.7)	14 (6.9)	0.192
Permanent	22 (7.2)	9 (8.7)	13 (6.4)	0.485
Transient	4 (1.3)	3 (2.9)	1 (0.5)	0.112
Spinal cord neurologic deficit	15 (4.9)	7 (6.8)	8 (3.9)	0.275
Permanent	9 (2.9)	5 (4.9)	4 (2.0)	0.169
Transient	6 (2.0)	2 (1.9)	4 (2.0)	1.000
Temporary renal replacement	94 (30.6)	41 (39.8)	53 (26.0)	0.018
Re-exploration for bleeding	32 (10.4)	15 (14.6)	17 (8.3)	0.113
Intubation time >72 h	112 (36.5)	54 (52.4)	58 (28.4)	<0.001

cardiac surgical procedures were performed in 189 patients (62%). Overall, 30-day mortality was 11.7% (Table 3). Permanent cerebral and spinal cord deficit occurred in 7.2% and 2.9%, respectively. Incidence of cerebral or spinal cord ischemia was less in patients with Zone ≤ 2 vs Zone 3 arch treatment without reaching statistical significance yet. Arch treatment in Zone ≤ 2 was associated with significantly less incidence of postoperative renal replacement therapy ( $P = 0.018$ ) or prolonged intubation ( $P < 0.001$ ) as well as with less incidence of re-exploration for bleeding ( $P = 0.013$ ) compared to Zone 3. Eight years' overall survival was 60% with no significant difference between the aortic diseases (Fig. 2A). Forty-two patients (13.7%) underwent 44 open (14/44) or endovascular (30/44) reinterventions downstream. Freedom from reintervention at 8 years was overall 73% and significantly better in acute AD (84.8%) compared to chronic AD (57.0%,  $P < 0.001$ ) and degenerative aneurysm (65.4%,  $P = 0.003$ ; Fig. 2B). In

degenerative aneurysmal aortic disease, reintervention was performed in 1/33 and 11/34 patients after FET for isolated distal arch/proximal descending aorta pathology and Crawford Type I/II thoracoabdominal aneurysm, respectively.

Clinical follow-up was 100% (mean ± SD  $3.8 \pm 3.2$  years). In acute and chronic AD patients, postoperative and follow-up computed tomography was available in 232/240. Complete exclusion of the dissection or complete spontaneous resolve of the residual dissection down to the diaphragm was achieved in 29% after acute AD and in 15% after chronic AD. Along the stent-grafted aortic segment, the false lumen resolved completely or remained thrombosed after acute AD in 90% and after chronic AD in 78%. Distal to the stent graft complete false lumen perfusion remained after acute AD in 54% and after chronic AD in 66%. In patients with degenerative aneurysm, CT examination was available in 63/67. Isolated aneurysmal cavities at the distal arch were excluded in 100%.



**Figure 2.** Kaplan-Meier analysis for survival (A) and freedom from aortic reintervention downstream (B).

## DISCUSSION

Open surgery and endovascular aortic repair represent the treatment of choice for aortic arch and descending thoracic aorta disease, respectively.<sup>13</sup> However, the interim zone of the distal arch represents a challenge for both approaches. Both techniques require an appropriate aortic segment for surgical suture or stent graft fixation.<sup>14</sup> Thus, more than one intervention is required for definitive exclusion of the distal arch/proximal descending aorta pathology, like classic elephant trunk first and secondary descending aortic treatment, or debranching of the supra-aortic arteries and secondary endovascular arch repair.<sup>15,16</sup> The FET technique overcomes these limitations by combining the advantages of both surgical and endovascular methods with durable results from the arch down to the midthoracic level. From the surgical point of view, the stented component of FET stabilizes the aortic wall at the level of the anastomosis and minimizes the risks of bleeding, pseudoaneurysm formation, and rupture.<sup>17</sup> From the endovascular point of view, the circumferential hemostatic surgical fixation diminishes the risk of proximal endoleakage without need for extensive stent graft oversizing.<sup>18</sup> In addition, the stent-grafted portion represents an ideal docking place for endovascular or surgical extension of the treatment downstream, if required.

The E-vita open prosthesis combines exact both surgical and endovascular requirements and is used routinely in our institution. This principle in combination with the angiography tool offers the flexibility to adjust the treatment in each intraoperative finding in the arch and the descending aorta. Additional debranching of at least the left subclavian artery prior to extracorporeal circulation (the Zone 2 concept) reduces the duration of hypothermic circulatory arrest and isolated cerebral perfusion time significantly, so that nowadays arch repair by FET does not exceed the operative times of classic total arch replacement without FET. Furthermore, the Zone 2 arch treatment is associated with less postoperative complications. These achievements in combination with the reliable option of an almost 100% durable exclusion of the proximal descending aorta pathology by the stent graft make FET probably the best technique for the treatment of a distal aortic arch aneurysm. In acute AD, the exclusion of the false lumen at least down to the distal stent graft end is achieved in 90% of the patients and results in 85% freedom from reintervention downstream at 8 years. FET induces positive aortic remodeling and an eliminated residual dissection in the arch and descending aorta dramatically reduces the risk of aortic rupture and aneurysm formation.<sup>19,20</sup> Especially in young patients, the elimination of residual AD may be beneficial for the daily and work-life. In addition, the improved perfusion of the true lumen makes FET an important operative armamentarium to overcome a true lumen collapse and malperfusion.<sup>21,22</sup> In chronic AD and in thoracoabdominal degenerative aortic aneurysm, FET treatment is less curative but offers the option for a less complicated secondary extension of the treatment downstream by moving the following intervention or reoperation far away from the distal arch.

FET treatment using the E-vita open prosthesis is a safe procedure considering the increased risks of the addressed aortic pathology and the comorbidities of the patients. However, the presented experience is the result of several intraoperative adjunct tools to FET including angiography and proximalization of the arch replacement in Zone  $\leq 2$ . In our opinion, FET should be the treatment of choice for a one- or facilitated two-stage approach to treat any kind of distal aortic arch pathology.<sup>23</sup> Experience with open and endovascular thoracic aortic surgery, however, is a prerequisite to perform optimal FET treatment.

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