Original Article

One-stage hybrid aortic repair using the frozen elephant trunk in acute DeBakey type I aortic dissection

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Background: The extent of emergent surgery for acute DeBakey type I aortic dissection is discussed controversial. The frozen elephant trunk (FET) technique in addition to ascending and arch repair promotes aortic remodelling in the descending aorta and thus may provide superior long-term results in terms of less secondary re-interventions and reduced mortality linked to the downstream aorta.

Methods: Between October 2009 and December 2016, a total of 72 patients underwent emergent hybrid aortic repair using the FET for acute DeBakey type I aortic dissection at our centre. Data were analysed from our prospectively collected database and clinical and imaging mid-term follow-up was obtained.

Results: Implant success was 98.6% with an overall 30-day-mortality of 15.3%. New postoperative stroke was seen in 2.8%, new spinal cord injury in 4.2%. In follow-up (mean 37.8±21.2 months) cumulative survival was 75.0% with freedom from distal reintervention in 96.7% and aortic remodelling rate in the descending aorta in 96.5%.

Conclusions: Hybrid aortic repair using the FET in acute DeBakey type I aortic dissection does not elevate the perioperative risk of mortality and provides excellent aortic remodelling with low distal re-intervention rate in mid-term follow-up.

Keywords: Aortic dissection; total arch replacement; frozen elephant trunk technique (FET technique)

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Introduction

Surgery for acute aortic dissection was focused on the proximal repair to eliminate the entry site so far. But in DeBakey type I dissection subsequent follow-up revealed a high rate of mortality linked to the distal aorta (1-4). Therefore, aortic arch inspection for re-entries and repair, if needed, is already recommended and established in international guidelines (5). Moreover, the development of the frozen elephant trunk (FET) allows for one-stage hybrid treatment of the thoracic aorta by classic Dacron prosthetic arch replacement and integrated covered stentgrafting of the proximal descending aorta. The stentgraft portion re-establishes the true and decompresses the false lumen and thus promotes aortic remodelling by inducing false lumen thrombosis (6-12). This technique may reduce the rate of reintervention of the downstream aorta. In case of secondary distal aortic dilation or re-dissection endovascular repair is facilitated as well as open surgery due to the landing zone provided by the stentgraft portion of the hybrid prosthesis. But the high complexity of the procedure requires not only expertise by the performing surgeon but also prolonged operative and circulatory arrest times. The

Table 1 Preoperative patient characteristics

Patient characteristics	Values
Age (years)	59.4±12.0
Male sex	55 (76.4)
BMI (kg/m^2)	27.1±4.5
Logistic EuroSCORE I (%)	40.0±20.0
Hypertension	68 (94.4)
Diabetes	3 (4.2)
COPD	9 (12.5)
Chronic kidney disease	9 (12.5)
Reoperation (previous sternotomy)	4 (5.6)
Clinical presentation	
Preoperative CPR	2 (2.8)
Cardiogenic shock	15 (20.8)
Cardiac tamponade	11 (15.3)
Haemopericardium	33 (45.8)
Ventilated	7 (9.7)
Neurologic deficit	19 (26.4)
Malperfusion	19 (26.4)

Continuous variables are given as means ± standard deviation (SD), categorical variables as numbers (n) and percentages (%). BMI, body mass index; COPD, chronic obstructive pulmonary disease; CPR, cardiopulmonary resuscitation.

potentially increased rates of perioperative mortality and neurologic complications raised concerns about the use of the FET in the acute dissection despite the potential long-term benefit. Aim of the study was to assess the safety and efficacy of the hybrid aortic repair using the FET in acute aortic dissection. We therefore analysed our results including mid-term follow-up.

Methods

Patients

From our institutional prospective database, counting a total of 260 patients operated on aortic dissection, 72 patients were identified who underwent emergent FET procedure for acute aortic dissection DeBakey type I between October 2009 and December 2016. Indication for FET procedure in these patients was DeBakey type I dissection, including retrograde Stanford type B dissection in two cases, especially in presence of an intimal tear reaching into the descending aorta, and a suitable anatomy in preoperative imaging. That is a minimum aortic diameter of 20 mm according to the size of hybrid prosthesis available as oversizing is not recommended, and absence of multiple re-entries or extremely kinking in the descending aorta due to increased risk of false lumen placement and stentgraft-induced aortic injury. In case of preoperative paraparesis or paraplegia individual patient centred decision was made. If symptoms were most likely due to true lumen collapse FET procedure was favoured to restore distal body perfusion. Instead, if the spinal cord was supposed to depend from false lumen perfusion conventional aortic arch procedure was considered to be superior to allow for possibly communication between true and false lumen and prevent false lumen thrombosis for spinal cord perfusion. Accordingly, exclusion criteria were DeBakey type II dissection and anatomical reasons like small aortic diameter or presence of multiple re-entries or extreme kinking in the descending aorta. Not least, as it is emergency cases, final decision was left to the discretion of the attending surgeon. All but one senior surgeons of our department are familiar with the FET procedure.

Clinical presentation of patients at admission was cardiogenic shock in 20.8%, a neurologic deficit in 26.4%, and malperfusion in 26.4%. The critically ill condition of these patients is also reflected by a mean logistic EuroSCORE of 40.0%. Haemopericardium as "impending tamponade" was even existent in roughly half of the patients (n=33, 45.8%). Of note, no patient is declined surgery as long as he reaches our centre alive. Preoperative patient characteristics are summarized in *Table 1*.

Procedure

For FET procedure the E-vita Open Plus® (Jotec GmbH, Hechingen, Germany) hybrid prosthesis was used in all patients. It consists of a combined conventional polyester tube graft for arch replacement and an integrated covered stentgraft of self-expanding (Nitinol) zick-zack-shaped struts for deployment into the descending aorta. A sewing collar facilitates distal anastomosis to and sealing of the descending aorta. Detailed implantation technique was described earlier (13).

Standard surgical approach was median sternotomy and establishment of cardiopulmonary bypass (CPB) with preferred right axillary arterial cannulation (n=63, 87.5%). FET procedure was performed under moderate

Table 2 Intraoperative data

Intraoperative data	Values
Arterial cannulation for CPB, n (%)	
Axillary	63 (87.5)
Femoral	6 (8.3)
Aortic	3 (4.2)
Concomitant procedures, n (%)	
Valve-sparing aortic root repair (David procedure)	28 (38.9)
Bentall procedure	20 (27.8)
CABG	7 (9.7)
Intraoperative times (minutes), median [IQR]	
Skin-to-skin	339 [298–392]
CPB	220 [198–259]
Cross-clamp time	157 [134–180]
Circulatory arrest	69 [61–83]

CPB, cardiopulmonary bypass; CABG, coronary artery bypass grafting; IQR, interquartile ranges.

hypothermic circulatory arrest (28 ℃) with bilateral selective antegrade cerebral perfusion in all patients. In the last years, additional neuromonitoring using bifrontal near infrared spectroscopy (NIRS) was established. The left subclavian artery was blocked or perfused with a separate perfusion catheter. Distal anastomosis of the FET was created distal to the left subclavian artery in Ishimaru zone 3 (14), supraaortic vessels were reimplanted as island.

Concomitant procedures were as follows: in 77.8% (n=56) the aortic root was dissected and had to be addressed by surgery; in 11.1% (n=8) replacement of the noncoronary sinus was sufficient to restore aortic root stability, but in 38.9% (n=28) aortic root repair (David procedure) and in 27.8% (n=20) prosthetic aortic root replacement was added. Reconstruction of coronary ostia was necessary in 6.9% (n=5) and coronary artery bypass grafting (CABG) in 9.7% (n=7), when coronary ostia were completely destroyed by dissection. Complete intraoperative data are depicted in *Table 2*.

Follow-up

All patients received computed tomography (CT) or magnetic resonance (MR) angiography scan of the thoracic aorta prior to discharge expect in case of non-resolved acute kidney injury. At least one further follow-up imaging scan was obtained, preferably with the same imaging method. Aortic remodelling was assumed when there was progressive false lumen thrombosis not only at the level of the stent graft but also in the distal aorta and distal aortic diameters decreased or remained stable. Aortic diameters were taken of the descending aorta at the level of pulmonary artery bifurcation (covered by stentgraft, level 1), just below the end of the stentgraft (level 2) and at the level of the coeliac trunk (level 3). In case of stable aortic remodelling and diameters or denial of angiographic imaging clinical follow-up was collected.

Statistical analysis

For this retrospective analysis statistical calculations were performed using SPSS Version 22.0 (IBM SPSS Statistics for Windows, Armonk, NY, USA: IBM Corp.). Categorical data are reported as numbers and percentages, continuous data as means ± standard deviation (SD) if normally distributed, otherwise as medians and interquartile ranges (IQR). Assumption of normal distribution was tested with the Kolmogorov-Smirnov test. Univariate models were used for risk factor analysis, i.e., Fishers exact test for categorical variables and Mann-Whitney U test for continuous variables. A multivariate model was not appropriate due to sample size and event rate. Kaplan-Meier-analysis was assessed for actuarial survival and reintervention rate.

Results

Patients

We observed an overall 30-day-mortality of 15.3% which is equivalent to in-hospital mortality. Risk factors for early mortality in univariate analysis were preoperative cardiopulmonary resuscitation (P=0.02), preoperative cardiogenic shock (P=0.008), postoperative low cardiac output syndrome (P=0.0001) and length of intensive care unit (ICU) stay (P=0.005). Interestingly, preoperative malperfusion did not have an impact on postoperative survival (P=0.46).

Acute kidney injury requiring haemodialysis occurred in 25.0% (n=18) of patients, 5 of these were acute-on-pre-existent-chronic kidney injuries. The need for renal replacement therapy (RRT) was transient in all patients, no one needed permanent haemodialysis. Re-exploration was

Table 3 Postoperative data

Postoperative data	Values
30-day mortality, n (%)	11 (15.3)
New postoperative stroke, n (%)	2 (2.8)
New postoperative spinal cord injury, n (%)	3 (4.2)
Delirium, n (%)	18 (25.0)
Acute kidney injury (transient RRT), n (%)	18 (25.0)
Low cardiac output syndrome, n (%)	12 (16.7)
Transfusions, median [IQR]	
Packed red blood cells	9 [4–14]
Fresh frozen plasma	12 [8–16]
Thrombocyte concentrate	4 [2–5]
Recombinant factor VII	32 (44.4)
Re-exploration, n (%)	18 (25.0)
Postoperative ventilation <24 hours, n (%)	36 (50.0)
ICU length of stay (days), median [IQR]	5 [3–9]
Hospital length of stay (days), median [IQR]	19 [12–31]

RRT, renal replacement therapy; ICU, intensive care unit; IQR, interquartile ranges.

necessary in 25.0% (n=18), predominant indications were bleeding and tamponade. Half of the patients (50.0%) could be extubated within 24 hours, median ICU stay was 5 days (IQR 3–9 days), median hospital length of stay 19 days (IQR 12–31 days).

New postoperative stroke occurred in 2 patients (2.8%), new spinal cord injury in 3 (4.2%), one of these with delayed onset on postoperative day 2 after the patient had been extubated and mobilized without limitations on postoperative day 1. All 3 patients with paraparesis showed regressive symptoms in postoperative course and were able to walk again after accomplished rehabilitation.

Out of the 19 patients with preoperative neurologic deficit (26.4%) there were 4 in-hospital deaths, and only 7 patients with postoperative persistent neurologic deficit.

Postoperative data are summarized in *Table 3*.

Procedure

Procedural implant success was 98.6% (71/72). In one patient with multiple re-entries in the descending aorta, retrograde guidewire placement was not possible and

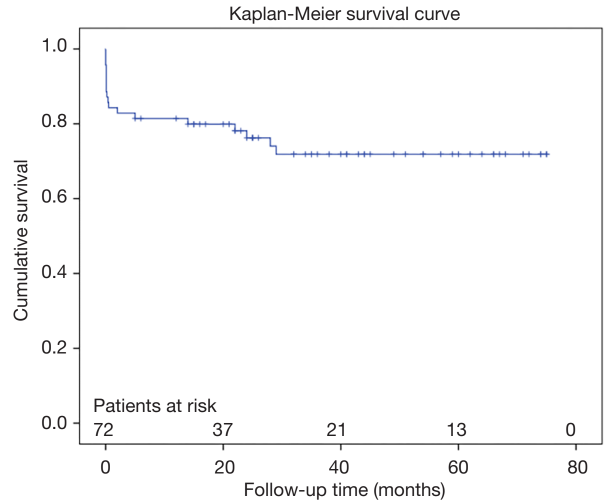

Figure 1 Kaplan-Meier overall survival estimate.

antegrade stenting resulted in false lumen placement, so that the FET had to be retrieved, which ended lethally. Most common FET sizes used were between 24 and 28 mm of diameter in 72.2% (n=52). Stentgraft length was 150 mm and later on during the study period 130 mm.

Follow-up

Clinical follow-up was 96.7% complete. In follow-up up to 4 years (mean 37.8±21.2 months) cumulative survival was 75.0%. Causes of late mortality were: in each two patients pneumonia and sepsis (after previous severe neurologic damage), one fatal bleeding from aorto-esophageal fistula, one cancer, one unknown. Most deaths occurred within 1 year after surgery resulting in a 1-year-survival rate of 80.6%, survival at 2 years of 76.4%, at 3 years 75%, and no late deaths beyond 3 years (*Figure 1*). CT-angiographic imaging showed positive aortic remodelling in the downstream aorta in terms of false lumen thrombosis at level 1 in 98.2%, at level 2 in 85.2%, and at level 3 in 18.9%, in terms of aortic diameter changes, i.e., decreased or stable diameter, at level 1 in 96.5%, at level 2 in 80.4%, and at level 3 in 82.1% (*Figure 2*). There was a significant decrease of median aortic diameter at level 1 (P<0.001), whereas aortic diameter kept stable at level 2 and increased significantly at level 3 (P=0.04, *Figure 3*). *Figure 4* gives an example of the aortic remodelling process over time, *Figure 5* a 3D reconstruction.

In survivors freedom from distal reintervention was

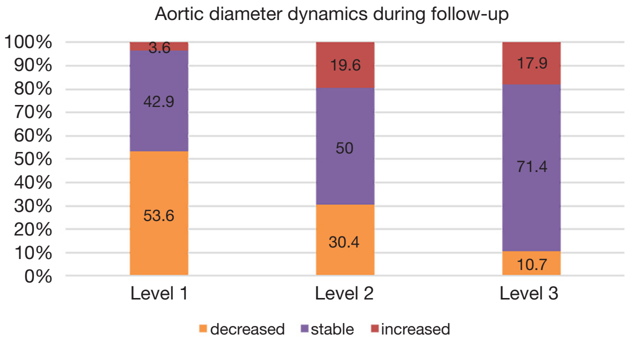

Figure 2 Aortic diameter dynamics in follow-up. Level 1: descending aorta at the level of pulmonary bifurcation (level of stentgraft); level 2: descending aorta distal of stentgraft; level 3: abdominal aorta at the level of celiac trunk.

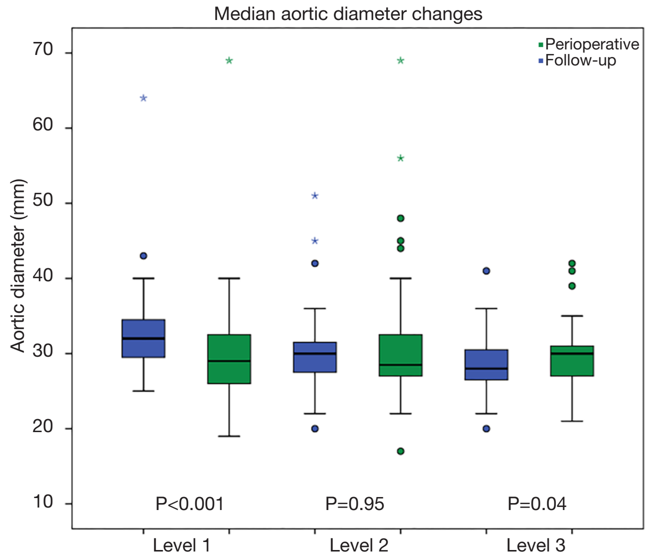

Figure 3 Median aortic diameter changes. Level 1: descending aorta at the level of pulmonary bifurcation (level of stentgraft); level 2: descending aorta distal of stentgraft; level 3: abdominal aorta at the level of celiac trunk. Asterixes and dots: outliers.

96.7% (*Figure 6*). Two patients required reintervention within 2 and 3 years after initial surgery, respectively. Both received open thoraco-abdominal surgery due to progressive aneurysm growth distal of stentgraft. One of these was turned out to be a Marfan.

Discussion

Acute aortic dissection Stanford type A is still affected with a considerable high-risk of pre- and perioperative mortality. Thus, surgical efforts are primarily aimed to save life and to avert damage. Several developments over the past years have helped to improve short-term outcomes like perfusion, hypothermia or surgical strategies. Contemporary series report short-term mortality and neurologic deficit rates of 2.8–25% and 3.4–11%, respectively (15-22). In general, these do not differentiate between dissections limited to the ascending aorta and those reaching beyond. But in the long-term this distinction is of paramount importance. In DeBakey type II dissection usually all diseased tissue can be resected and replaced. In contrast, in DeBakey type I dissection the residual downstream dissection after proximal repair carries the risk of dilation, re-dissection and rupture, with remarkable impact on long-term survival (3). It has been shown that a patent false lumen in the descending aorta is a predictor for both mortality and the need for reintervention due to aortic diameter growth (1,2,4). The FET implantation in the setting of acute aortic dissection effectively promotes aortic remodelling with thrombosis of the false lumen in over 90% of cases which could be confirmed by our results (7-9). Furthermore, it stabilizes the true lumen and decompresses the false lumen in the descending aorta. Not least, it gives a substrate or landing zone in case subsequent downstream reoperation or stentgrafting is necessary. The FET can effectively prevent the descending aorta from further growth and therefore reduce the risk of descending rupture.

But potential long-term benefits have to be weighed against periprocedural risks. Mortality rates are accused to be higher than in conventional, more limited surgery. Our data show that this is not the case. In our series we report a 30-day mortality rate of 15.3%, which is well comparable to contemporary results. The latest reports of the GERAADA and IRAD registries showed an overall 30-day mortality of 16.9% and 18% in all, mostly conventional operated, dissection patients (15,16). Specialized aortic centers do even report superior results with mortality rates between 8% and 12% with the use of the FET (6,23). And risk factor analysis reveals predominantly the status of preoperative presentation accounting for perioperative survival. Of note, we don't have any pre-selection other than death before hospital arrival due to our all-comers treatment policy, which is also reflected by the high percentage of patients with unfavourable clinical presentation. In addition, this rate is equivalent to hospital mortality without "hidden" deaths transferred to external clinics. As we have observed a

Figure 4 CT documentation of aortic remodelling over time in the same patient. (A) Preoperative CT scan; (B) postoperative CT scan one week after surgery; (C) follow-up CT scan after 3 years. CT, computed tomography.

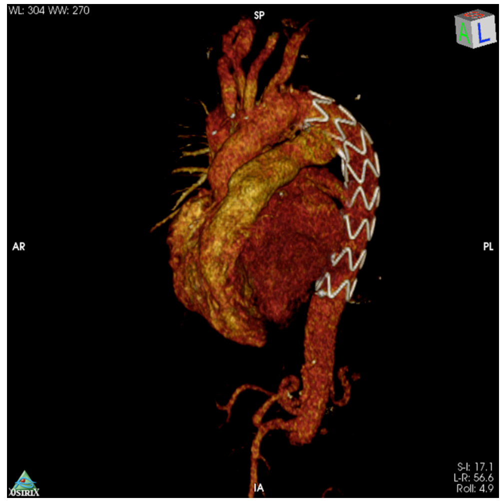

Figure 5 3D-CT reconstruction after FET implantation in acute aortic dissection. CT, computed tomography; FET, frozen elephant trunk.

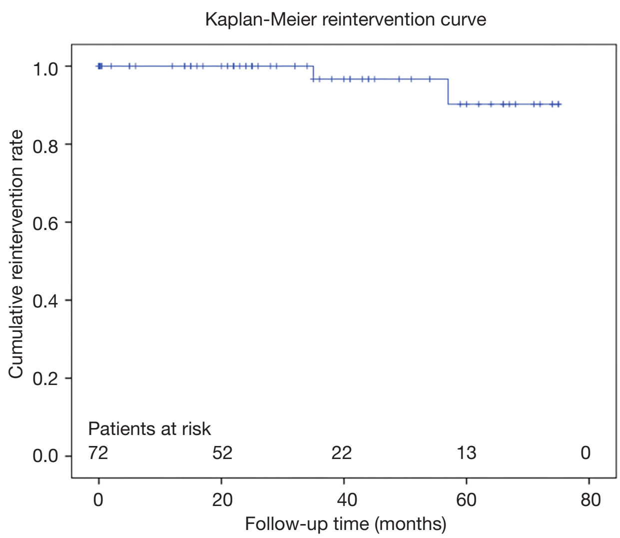

Figure 6 Kaplan-Meier freedom from distal reintervention estimate.

dismal outcome in our patients with preoperative CPR we changed our surgical strategy to a more limited approach in this condition.

Stroke rates in acute type A aortic dissection repair range from 3.4% to 15% and a more aggressive approach regarding replacement of the aortic arch and supraaortic vessels might be even protective (6,19-22). The rate of new-onset postoperative stroke in our series is as low as 2.8%. We think that it is not only dependent on the extent of arch surgery but also on perfusion and hypothermia management. Our strategy is the consequent use of selective antegrade cerebral perfusion monitored by near-infrared spectroscopy (NIRS) of cerebral oxygenation. With the right axillary arterial cannulation, we ensure a continuous cerebral perfusion throughout CPB and circulatory arrest times. Additional perfusion of the left common carotid and subclavian artery plus the lower body might further improve organ protection of spinal cord and viscera (24-27).

Selective cerebral perfusion ensures safe organ protection of the brain and allows for moderate systemic hypothermia (28 ℃) avoiding the negative side effects of deep hypothermia.

One major drawback of the FET technique is the elevated risk of spinal cord injury which has been reported to be from 2% to as high as 24% (24). In our series there were 3 patients (4.2%) with postoperative paraparesis, all showing regressive symptoms in follow-up. We also had six patients with a preoperative neurologic deficit who went out without persistent neurologic damage. And also, in limited proximal aortic repair for type I dissection spinal cord injury can be observed, but is, in our opinion, underreported. The genesis of spinal cord injury is multifactorial and false lumen thrombosis can also be seen after conventional aortic repair. We are moving somewhat between Scylla and Charybdis: on the one hand we want the false lumen in the descending aorta to thrombose for prevention of subsequent dilation and rupture. On the other hand, we want to have the spinal cord perfused, even if it is perfused from the false lumen. So, if we put the FET to facilitate false lumen thrombosis we have to face the risk of spinal cord injury when collaterals are not sufficient. One strategy to reduce the risk of spinal cord injury has been to shorten the stentgraft portion of the FET as a stentgraft below Th 7 has been identified as a risk factor for spinal cord injury. We have therefore switched to the shorter 13 mm stentgraft prosthesis. Other centers changed to a more proximal implantation, i.e., in Ishimaru zone 2. Other hypothesized spinal cord saving measures are lower body perfusion, either by a prosthetic sidegraft or by a Foley catheter placed in the stentgraft portion after completion of the distal anastomosis, cerebrospinal fluid drainage, which in our opinion is not an option in acute dissection due to coagulation disorder caused elevated risk of bleeding, and a permissive elevated postoperative blood pressure (24-27). The controversy remains to put or not a FET in a patient already presenting with paraparesis.

Bleeding is a relevant complication in acute aortic dissection surgery as displayed by our substantial transfusion and rethoracotomy (25%) rates, lying in the upper range compared to the literature (24,26). In most cases a severe coagulation disorder can be seen. From the surgical point of view, the FET itself is protective for bleeding from the distal anastomosis as the stentgraft portion depressurizes the false lumen and therefore reduces the risk of back-bleeding from the false lumen. In order to reduce our rethoracotomy and transfusion rates we have now implemented a systematic and early point-of-care diagnostic tool (ROTEM® thromboelastometry) and specific administration of clotting factors (28,29).

Although the rate of acute kidney injury requiring RRT is quite high with 25% in our series it is worth noting that all of these patients came out with restored renal function without the need for permanent haemodialysis (26).

During mid-term follow-up we observed a cumulative survival of 75% up to 4 years which is in line with contemporary data (6-8,10). The FET promotes excellent aortic remodelling of the descending thoracic aorta with a rate of 96.5% which is, in our opinion, the base for the high rate of freedom from distal reintervention (96.7%). Furthermore, one of our two patients requiring distal reintervention was diagnosed a Marfan after initial surgery. Nevertheless, further follow-up is needed to confirm the decreased need for distal reintervention in the long-term (3,26).

Conclusions

In conclusion, our data support the use of the FET in acute DeBakey type I aortic dissection as it provides excellent aortic remodelling with low distal re-intervention rate in mid-term follow-up. Long-term data are still needed to confirm these encouraging results.

Acknowledgements

None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: In line with our local ethics committee an ethics approval was not required as this was a retrospective analysis of already existing data after pseudonymization.

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