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Downstream thoracic endovascular aortic repair following zone 2, 100-mm stent graft frozen elephant trunk implantation

Maximilian Kreibich *, Matthias Siepe , Tim Berger, Stoyan Kondov , Julia Morlock, Clarence Pingpoh, Friedhelm Beyersdorf , Bartosz Rylski and Martin Czerny

Department of Cardiovascular Surgery, University Heart Centre Freiburg, Faculty of Medicine, Albert-Ludwigs-University of Freiburg, Freiburg, Germany

* Corresponding author. University Heart Centre Freiburg, Hugstetter Str. 55, 79106 Freiburg, Germany. Tel: +49-761-270-28180; fax: +49-761-270-25500; e-mail: maximilian.kreibich@uniklinik-freiburg.de (M. Kreibich).

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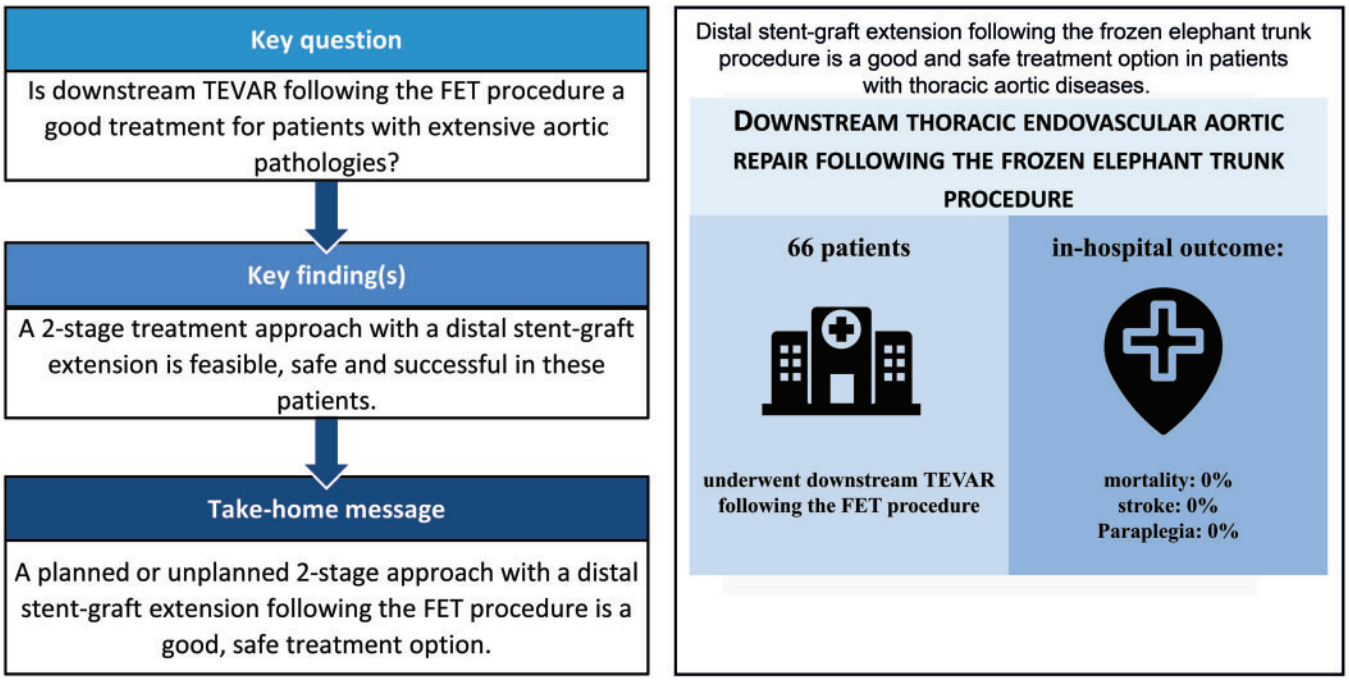

Abstract

OBJECTIVES: The aim of this study was to analyse outcomes of downstream thoracic endovascular aortic repair (TEVAR) following the frozen elephant trunk (FET) procedure.

METHODS: Sixty-six patients underwent downstream TEVAR following the FET procedure to treat thoracic aortic dissections ($n = 42$, 64%), aneurysms ($n = 19$, 29%) or penetrating aortic ulcers involving the aortic arch ($n = 5$, 8%). Patient and outcome characteristics were analysed.

RESULTS: Downstream TEVAR was performed 7 [interquartile range: 2–18] months after the FET procedure in 39 male (59%) and 27 female (41%) patients aged 68 [interquartile range: 56, 75] years, including 11 patients (17%) with a connective tissue disease. Before TEVAR,

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cerebrospinal fluid drainage was put in place in 61 patients (92%). Patients were treated with 1 stent graft ($n = 28$, 42%), 2 stent grafts ($n = 37$, 56%) or 3 stent grafts ($n = 1$, 2%). The femoral artery was accessed through surgical cut-down ($n = 15$, 23%) or percutaneously ($n = 49$, 74%). One patient (2%) developed a temporary spinal cord injury that resolved spontaneously. No case of permanent spinal cord injury, stroke or death was observed. After 12 [interquartile range: 2–23] months, 15 patients required an additional aortic reintervention (endovascular: $n = 6$; surgical: $n = 9$).

CONCLUSIONS: Downstream TEVAR following the FET procedure is associated with excellent clinical outcomes. We thus maintain that staging thoracic aortic repair—FET and secondary TEVAR—is a very successful and safe strategy. Certain patients might need a tertiary procedure to fix their entire aortic pathology; therefore, they will require long-term continuous follow-up, ideally in a dedicated aortic clinic.

Keywords: Frozen elephant trunk • Aortic dissection • Aortic aneurysm • Reintervention • Thoracic endovascular aortic repair

ABBREVIATIONS

CSF	Cerebrospinal fluid
dSINE	Distal stent graft-induced new entry
FET	Frozen elephant trunk
TEVAR	Thoracic endovascular aortic repair

INTRODUCTION

The frozen elephant trunk (FET) technique has become a well-established treatment option for patients presenting all thoracic aortic pathologies including acute and chronic dissection, aortic aneurysms and even penetrating aortic ulcers involving the aortic arch and descending aorta [1–4]. Wider and growing use of FET devices has been accompanied by 2 surgical developments. The first is a trend towards more proximal implantation of the grafts in zone 2 rather than zone 3 because of easier surgical exposure [1, 5, 6]. In fact, some authors have even reported that FET devices routinely implanted in zone 1 or 0 [7, 8]. The second is that shorter stent grafts are being implanted more liberally to lower the risk for spinal cord ischaemia [1, 9, 10].

However, both surgical developments cause 'proximalization' of the FET stent graft, which has been associated with a higher rate for secondary aortic re-interventions following the FET [6]. In fact, a high risk for secondary aortic re-interventions following the FET procedure has been described [10, 11]. It was this study's aim to analyse outcomes of downstream thoracic endovascular aortic repair (TEVAR) following the FET procedure.

PATIENTS AND METHODS

Ethics statement

Our institutional review committee (University Hospital Freiburg) approved this retrospective study (IRB number: 20-1302), and the need for informed consent was waived because of the retrospective nature of the study.

Patients and follow-up protocol

Our study population consisted of 66 patients who underwent endovascular distal stent graft extension 7 [3, 18] months after the FET procedure to treat thoracic aortic dissections ($n = 42$, 64%), aneurysms ($n = 19$, 29%), or penetrating aortic ulcers involving the aortic arch ($n = 5$, 8%) between November 2012 and July 2020 in a large aortic centre currently performing >60 total aortic arch procedures *per annum* (as of 2020). No patients were excluded from this study. We currently have a cumulative experience of >300 FET implantations in our centre. All patients were followed up for a total of 108 patient-years, with a median follow-up of 13 [3, 32] months; patients were routinely followed up after 6 months, 12 months and yearly thereafter. Computed tomography angiography scans were performed preoperatively, before discharge, during every follow-up visit, and whenever clinically warranted.

Surgical and endovascular approach

Our technique for FET implantation has been described [12–14]. In short, all patients routinely undergo a complete sternotomy with cannulation of the right axillary artery to enable arterial inflow for cardiopulmonary bypass. Concomitant cardiac, valve or root procedures are routinely carried out while the patient is cooled down to a 25°C core body temperature, and we apply cold-blood cardioplegia or the beating-heart technique using 300 ml normothermic myocardial perfusion for myocardial protection via the cardioplegia cannula during aortic arch replacement [14]. Bilateral cerebral perfusion is our standard method for cerebral protection (via the right axillary and the left common carotid artery). We routinely perform preoperative imaging of the supra-aortic vessels including the Circle of Willis and liberally perform trilateral antegrade cerebral perfusion (additional cannulation of the left subclavian artery) when needed. Our FET anastomosis is routinely performed in zone 2, and we use the short version (100 mm) of the Thoraflex (Terumo Aortic, Inchinnan, UK) hybrid-graft exclusively. Two of the 66 patients (3%) were treated following implantation of a Thoraflex and an E-vita Open (Jotec GmbH, Hechingen, Germany) graft in outside hospitals.

To lower the risk of spinal cord ischaemia, we avoid simultaneous FET und TEVAR implantation. TEVAR for distal stent graft extension is routinely performed after implantation of a cerebrospinal fluid (CSF) drainage the previous day to maximize spinal cord protection. Nowadays, we routinely access the vessel percutaneously to enable access to the common femoral artery using pre-closure techniques (Proglide, Abbott Medical, Chicago, IL, USA), and we usually extend TEVAR down to the level of the thoraco-abdominal transition in close proximity to the coeliac trunk offspring. We routinely employ proximal oversizing of 2 mm (most proximal stent graft diameter to the stent graft diameter of the Thoraflex hybrid prosthesis). In case of classical aneurysm formation, we aim for 10% oversizing at the distal landing zone; in case of chronic dissections, we routinely use tapered stent grafts and size the distal end according to institutional standards to avoid oversizing [15, 16].

Table 1: Patient characteristics

	N = 66
Age (years)	68 [56, 75]
Male	39 (59)
History of smoking	26 (39)
Hyperlipidaemia	21 (32)
Arterial hypertension	52 (79)
Insulin-dependent diabetes mellitus type 2	3 (5)
History of stroke	5 (8)
History of renal failure	5 (8)
COPD	8 (12)
Coronary artery disease	13 (20)
Connective tissue disease	11 (17)

Values are *n* (%) or median [fist quartile, third quartile].
COPD: chronic obstructive pulmonary disease.

Following TEVAR extension, patients are routinely monitored for 24 h in our intensive care unit, which entails invasive blood pressure measurements and continuous CSF pressure monitoring. Usually, the drains are removed the next day and patients are transferred to a normal ward.

Data collection and definition of parameters

Data were collected retrospectively using our centre's prospectively maintained aortic databases. Baseline and aortic characteristics, previous aortic procedures, intraoperative details, clinical outcomes and follow-up data were evaluated. Diameter progression was defined as an increase in total aortic diameter of >5 mm within 6 months or an increase to an aortic diameter exceeding 55 mm. A distal stent graft-induced new entry (dSINE) was defined as a new tear caused by the stent graft of the FET prosthesis, excluding tears created by natural disease progression. Acute aortic dissections were diagnosed when the onset occurred <14 days before clinical presentation; the rest we classified as chronic.

Statistical analysis

Data are presented as absolute and relative frequency or as median [first quartile, third quartile]. The Kaplan–Meier method was applied to analyse late survival. Statistical analysis was performed using IBM SPSS 21.0 (SPSS Software, IBM Corp., Armonk, NY, USA).

RESULTS

Patient characteristics

Patient characteristics are summarized in Table 1. The median age of the 39 male (59%) and 27 female (41%) patients was 68 [56, 75] years, including 11 patients (17%) with a connective tissue disease.

Aortic characteristics

Downstream TEVAR was performed 7 [3, 18] months following the FET procedure. The most common underlying pathology was an acute (*n* = 11, 17%) or chronic/residual (*n* = 31, 47%) aortic dissection. The most common indications for downstream TEVAR were diameter progression in 31 patients (47%), followed by a planned completion in 17 patients (26%), and a newly diagnosed dSINE in 12 patients (18%; Fig. 1). All aortic details are illustrated in Table 2.

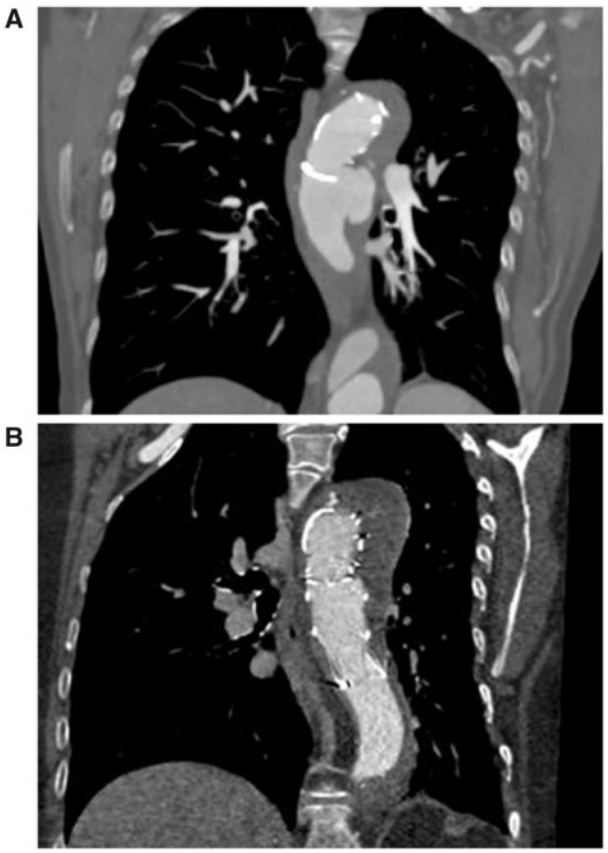

Figure 1: Representative computed tomography angiography scans of a patient who developed a large distal stent graft-induced new entry accompanied by significant diameter progression of the descending aorta following frozen elephant trunk implantation the year before (**A**). The new entry was closed through downstream endovascular stent graft extension with a short stent graft (**B**).

Periprocedural details

No preoperative CSF drainage was implanted in 5 patients (8%). The reasons were incomplete usage in the early study period (before 2016; *n* = 3), an urgent procedure following distal true lumen collapse and malperfusion during the FET procedure (*n* = 1), and an acute rupture following a type Ib endoleak (*n* = 1). A total of 105 stent grafts were implanted. Most patients (*n* = 37, 56%) were treated with 2 stent grafts. The Relay NBS Plus stent graft (Terumo Aortic, Inchinnan, UK) was the most commonly used one (88 implanted stent grafts).

During the early study period, a surgical cut-down was performed to access the common femoral artery in 15 patients (23%). During the last few years, percutaneous treatment become routine practice in 49 patients (74%). In 2 patients, the abdominal aorta had to function as the access vessel as the last viable option: in a 10-year-old boy with Marfan's syndrome and in a 67-year-old female whose all the other access vessels were severely calcified. All periprocedural details are summarized in Table 3.

Table 2: Aortic details

	N = 66
Underlying pathology	
Aortic dissection	42 (64)
Aortic aneurysm	19 (29)
Penetrating aortic ulcer	5 (8)
Time from FET implantation to endovascular extension (months)	7 [3, 18]
Indications for endovascular extension	
Diameter progression	31 (47)
Planned completion	17 (26)
dSINE	12 (18)
Distal true lumen collapse	2 (3)
Type 3 endoleak	1 (2)
Rupture following type 1b endoleak	1 (2)
Kinking of the FET stent graft	1 (2)
Thrombi at the distal end of the FET stent graft	1 (2)

Values are *n* (%) or median [fist quartile, third quartile].
dSINE: distal stent graft-induced new entries; FET: frozen elephant trunk.

Table 3: Periprocedural details

	N = 66
Preoperative cerebrospinal fluid drainage	61 (92)
Number of stent grafts	
1 stent graft	28 (42)
2 stent grafts	37 (56)
3 stent grafts	1 (2)
Most proximal stent graft diameter (mm)	32 [29, 38]
Most distal stent graft diameter (mm)	30 [28, 38]
Types of stent grafts used	
Relay NBS Plus[b]	88 (84)[a]
Valiant[c]	14 (13)[a]
Endurant II[c]	1 (1)[a]
Eucatech TAA stent graft uncovered[d]	2 (2)[a]
Vessel access	
Femoral artery: percutaneous	49 (74)
Femoral artery: cut-down	15 (23)
Abdominal aorta: cut-down	2 (3)
Procedure time (min)	68 [57, 82]
X-ray time (min)	9 [7, 14]

Values are *n* (%) or median [fist quartile, third quartile].
[a]Out of 105 implanted stent grafts.
[b]Terumo Aortic, Inchinnan, UK.
[c]Medtronic, Santa Rosa, CA, USA.
[d]Eucatech AG, Rheinfelden, Germany.

Outcome and follow-up characteristics

Outcome characteristics are summarized in Table 4. One patient (2%) developed a temporary spinal cord injury that resolved spontaneously. We observed no case of permanent spinal cord injury, acute kidney injury, stroke or death. Surgical site revision because of bleeding and a femoral artery stenosis was necessary in 2 patients (3%). Overall survival is depicted in Fig. 2. After 12 [2, 23] months, 15 patients had to undergo an additional aortic reintervention (23%; endovascular: $n = 6$ [9%]; surgical: $n = 9$ [14%]). Indications for additional re-interventions were as follows: distal completion with a fenestrated stent graft ($n = 1$) or open surgery ($n = 6$), endovascular treatment of a proximal endoleak type III of the FET stent graft ($n = 2$), treatment of an infrarenal abdominal aortic aneurysm by open surgery ($n = 2$), endovascular treatment of a newly developed dSINE ($n = 1$) and of a large penetrating aortic ulcer ($n = 1$), clinically relevant stent graft kinking ($n = 1$) and 1 patient had to undergo complete removal and orthotopic aortic reconstruction using self-made bovine tube grafts for stent graft infection ($n = 1$). Of the 15 patients, 4 patients have a connective tissue disease and underwent thoraco-abdominal completion.

DISCUSSION

This study's most important findings are that: (i) downstream TEVAR following the FET procedure is associated with excellent clinical outcomes and low perioperative risk; (ii) a delayed two-stage treatment approach involving distal stent graft extension is feasible, safe and successful, particularly in patients with shorter aortic stent graft coverage due to the use of shorter stent graft lengths of the FET prosthesis (i.e. 10 mm) or in case of a zone 2 arch anastomosis; but (iii) certain patients might eventually require a tertiary procedure to fix their entire aortic pathology, resulting in long-term need for continuous follow-up of all patients, ideally in a dedicated aortic clinic.

The FET procedure has become an excellent treatment option for patients with aortic pathologies involving the aortic arch and proximal descending thoracic aorta. It has the potential to be a genuine single-stage treatment option [1–4, 11, 17]. Nevertheless, there is evidence of frequent subsequent planned and unplanned secondary aortic re-interventions [11, 17]. While some of these re-interventions are related to unexpected aortic behaviour or device-related problems, the FET prosthesis also creates an ideal platform for secondary TEVAR and the concomitant treatment of downstream aortic segments, particularly in patients carrying a high risk of negative aortic remodelling (i.e. greater enlargement than expected) [10, 11]. For this reason, we follow recently published European consensus statements and the FET procedure has become our routine strategy for aortic arch replacement [1]. We perform the conventional elephant trunk procedure only in rare cases. This anticipatory strategy is well reflected by the high incidence of patients suffering connective tissue diseases in this study in whom the use of stent grafts is controversial in the absence of an artificial landing zone [1]. Note that when we perform distal stent graft extension in these patients, we anticipate a third, open thoraco-abdominal completion for the treatment of the entire aorta.

In fact, a quarter of all TEVAR procedures in this study were actually planned completions. Hence, in these patients, it was obvious that the FET stent graft would be unable to exclude the aorta's diseased portion during the index procedure. In addition, almost half of all patients underwent stent graft extension because of aortic diameter progression. In patients whose descending aorta's diameter is strongly suspect of enlarging, and/or in those whose downstream aortic diameter thresholds for treatment have not yet been reached, the FET procedure provides an ideal platform for an anticipated or probable later intervention. Nevertheless, note that 29% of all our patients' distal stent graft extensions were genuinely unexpected interventions. The most common underlying pathology was dSINE formation—a complication associated with the FET procedure more often than with TEVAR procedures, even though no specific risk factors for the development of dSINE after FET implantation have been identified [10].

Table 4: Outcome characteristics

	N = 66
Temporary spinal cord ischaemia	1 (2)
Permanent spinal cord ischaemia	0 (0)
Postoperative stroke	0 (0)
Acute kidney failure	0 (0)
Surgical site revision	2 (3)
In-hospital death	0 (0)
Intensive care unit stay (days)	1 [1, 2]
In-hospital stay (days)	6 [5, 9]

Values are *n* (%) or median [fist quartile, third quartile].

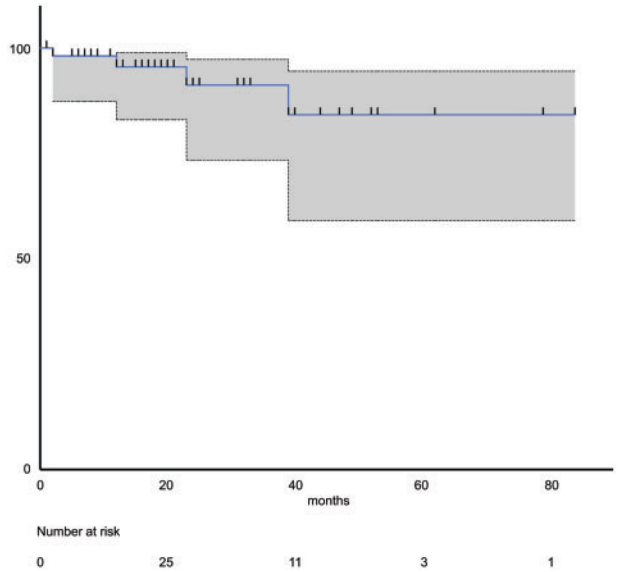

Figure 2: Kaplan–Meier curve showing our cohort's overall survival. Four patients expired during follow-up from visceral malperfusion (*n* = 1), following open thoraco-abdominal aortic replacement (*n* = 1), following graft infection (*n* = 1) and pneumonia (*n* = 1).

In our centre, we implant the short version of the FET stent grafts (100 mm) exclusively and routinely place our anastomosis in zone 2 to minimize the risk of spinal cord ischaemia, since the extent of stent graft coverage has been associated with impairing segmental spinal artery inflow [1, 9]. Because of this preventive strategy, we do not routinely employ CSF drainage during the FET procedure. Through this approach, we have in over 240 patients observed just 1 case of postoperative permanent spinal cord ischaemia following FET implantation, which compares well to the overall 4.7% incidence reported in a recent review addressing neurological outcomes following the FET procedure [9]. Nevertheless, during distal stent graft extension, it is a common policy in our centre to insert CSF drainage preoperatively in an elective setting, as described here. Additional preventative measurements to prevent spinal cord ischaemia routinely include ensuring a sufficiently high arterial blood pressure postoperatively, assuring an adequate haemoglobin level, fast-track concept and serial postoperative neurological examination.

While isolated pathologies such as dSINE may be managed with 1 stent graft exclusively, we usually extend down to the level of the thoraco-abdominal transition when performing secondary TEVAR frequently requiring >1 stent graft, as is evident in our periprocedural details. Through this approach, we believe we can lower the risk for type Ib endoleaks. In addition, should an open thoraco-abdominal replacement become necessary, and the necessary anastomosis (or its location) can have been moved further in distal direction during the previous TEVAR intervention. In so doing, the disease process is transformed into a Crawford-Type 4 process beginning at the level of the diaphragm, and the time needed for surgery is shortened during the thoraco-abdominal replacement. Also, we need not interrupt left-lung ventilation—a key factor to improve postoperative outcome in these cases [18]. Of note, while open thoraco-abdominal aortic replacement is feasible following the FET procedure without distal stent graft extension [19], we have learned that performing a surgical anastomosis to the Relay Plus stent graft is easier than an anastomosis to the Thoraflex FET stent graft portion with a rigid ring at the distal end. Because the Relay Plus stent graft is more flexible at the distal end and has thicker Dacron coverage, we routinely use this stent graft for distal TEVAR extension nowadays. Conversely, 2 uncovered stent grafts (Eucatech AG, Rheinfelden, Germany) for true-lumen expansion had been implanted in 1 patient during the very early study period in 2012—a approach we did not pursue, and which eventually failed, as this patient required fenestrated TEVAR and ultimately open thoraco-abdominal aortic replacement in 2019. In 1 patient, we inserted a Relay Plus stent graft into the FET stent graft while an endovascular extension down to the thoraco-abdominal transition necessitated implantation of an Endurant II (Medtronic, Santa Rosa, CA, USA) stent graft because of the patient's small residual true lumen diameter.

This study also reflects our gradual transition from surgical cut-down exposure of the femoral artery to routine percutaneous access, revealing a very low incidence of access site revisions today and highlighting the well-documented safety of full percutaneous endovascular procedures [20]. However, our work also shows that in exceptional scenarios as described in this study, certain other access sites such as the abdominal aorta may be needed, which is why we encourage an interdisciplinary team consisting at least of cardio-(thoracic) and vascular surgeons to treat aortic pathologies.

Lastly, we demonstrate excellent outcomes following planned, anticipated, unexpected, and even emergent TEVAR with no case of postoperative permanent spinal cord ischaemia, acute kidney failure, or in-hospital death. These encouraging data clearly supports our two-stage treatment strategy for combined pathologies of the aortic arch and descending aorta with the aim of minimizing surgical invasiveness during the FET implantation (through zone 2 implantation) and maximizing spinal cord protection (by using short FET stent grafts) by the timely development of collateral pathways for spinal cord perfusion. Hence, these benefits have to be weighed against a potentially higher risk of secondary aortic re-interventions that are—as shown in this study—associated with very low perioperative risk [6, 11].

Lastly, we also show that even after a second-step treatment, an additional third-step aortic reintervention might become necessary, underlying the value of stringent aortic follow-up ideally in a specialized interdisciplinary aortic clinic. Note that these additional re-interventions may also become necessary because of a progressive independent downstream aortic pathology.

Limitations and strengths

Our study is limited by its sample size, retrospective nature, the relatively brief follow-up period and the fact that no comparison arm is available. However, this investigation contributes valuable

knowledge on positive outcomes after downstream TEVAR following the FET procedure and highlights the need for continuous aortic follow-up.

CONCLUSIONS

This single-centre study indicates very good outcome following downstream TEVAR after the FET procedure with low perioperative risk. Hence, a delayed two-stage treatment approach with distal stent graft extension seems to be feasible, safe and successful, particularly in patients with shorter aortic stent graft coverage after employing the FET prosthesis' shorter stent graft lengths (i.e. 10 mm), or in case of a zone 2 arch anastomosis. However, as certain patients might later require a tertiary procedure to fix their entire aortic pathology, they will also need long-term, continuous follow-up, ideally in a specialized aortic clinic.

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Conflict of interest: Martin Czerny is a consultant for Terumo Aortic and Medtronic, received speaking honoraria from Cryolife and is a shareholder of TEVAR Ltd. Bartosz Rylski is a consultant to Terumo Aortic. Maximilian Kreibich received speaking honoraria from Terumo Aortic. All other authors report no conflict of interests/disclosures.

Data Availability Statement

Access to the data that support the findings of this study is available from the corresponding author, Maximilian Kreibich, upon reasonable request. Access is limited by privacy and ethical restrictions.

Author contributions

Maximilian Kreibich: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Project administration; Resources; Validation; Visualization; Writing—original draft. **Matthias Siepe:** Conceptualization; Formal analysis; Funding acquisition; Methodology; Project administration; Resources; Supervision; Validation; Writing—review & editing. **Tim Berger:** Conceptualization; Data curation; Formal analysis; Methodology; Software; Validation; Writing—review & editing. **Stoyan Kondov:** Data curation; Formal analysis; Investigation; Methodology; Software; Visualization; Writing—review & editing. **Julia Morlock:** Conceptualization; Data curation; Formal analysis; Methodology; Project administration; Validation; Visualization; Writing—review & editing. **Clarence Pingpoh:** Data curation; Formal analysis; Funding acquisition; Methodology; Validation; Writing—review & editing. **Friedhelm Beyersdorf:** Funding acquisition; Project administration; Resources; Writing—review & editing. **Bartosz Rylski:** Conceptualization; Data curation; Formal analysis; Methodology; Project administration; Resources; Supervision; Writing—review & editing. **Martin Czerny:** Conceptualization; Data curation; Funding acquisition; Methodology; Project administration; Resources; Supervision; Validation; Writing—review & editing.

Reviewer information

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