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Abstract: **OBJECTIVES:** To evaluate the feasibility and the outcomes of second-stage thoracoabdominal (TA) repair after previous frozen elephant trunk (FET) implantation. **METHODS:** Between 2005 and 2013, 41 patients underwent open TA aortic repair in our institution. Of these, 9 patients (78% male) underwent second-stage TA repair after previous FET implantation. Feasibility and outcomes were evaluated. **RESULTS:** The mean interval between FET implantation and second-stage TA repair was 423 days (19-1979 days). Indications for second-stage TA repair were progression in aortic diameter of atherosclerotic aneurysms in the downstream segments in 6 patients, diameter progression in post-dissection aneurysms in 2 patients and giant cell aortitis with aneurysm formation in another patient. There were no in-hospital deaths. The median intensive care unit stay was 3.5 days (range: 1-12 days) and median hospital stay was 22 days (range: 14-132 days). We did not observe symptomatic spinal cord ischaemia or stroke. One patient (11%) developed acute renal failure requiring haemodialysis. **CONCLUSION:** Second-stage TA aortic repair after previous frozen elephant implantation is a feasible and effective treatment modality for patients with various pathologies of downstream aortic segments. This approach adds additional value to the conventional elephant trunk technique by providing an excellent landing zone not only for additional stent graft procedures but also for subsequent open TA repair.

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Thoracoabdominal aortic aneurysm repair after frozen elephant trunk procedure[†]

Sandra Folkmann^{a,*}, Gabriel Weiss^a, Harald Pisarik^a, Martin Czerny^b and Martin Grabenwoger^a

^a Department of Cardiovascular Surgery, Hietzing Hospital, Vienna, Austria

^b University Hospital Zurich, Zurich, Switzerland

* Corresponding author. Department of Cardiovascular Surgery, Hietzing Hospital, Wolkersbergenstrasse 1, 1130 Vienna, Austria. Tel: +43-1-801102391; fax: +43-1-801102391; e-mail: s.folkmann@gmx.at (S. Folkmann).

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Abstract

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METHODS: Between 2005 and 2013, 41 patients underwent open TA aortic repair in our institution. Of these, 9 patients (78% male) underwent second-stage TA repair after previous FET implantation. Feasibility and outcomes were evaluated.

RESULTS: The mean interval between FET implantation and second-stage TA repair was 423 days (19–1979 days). Indications for second-stage TA repair were progression in aortic diameter of atherosclerotic aneurysms in the downstream segments in 6 patients, diameter progression in post-dissection aneurysms in 2 patients and giant cell aortitis with aneurysm formation in another patient. There were no in-hospital deaths. The median intensive care unit stay was 3.5 days (range: 1–12 days) and median hospital stay was 22 days (range: 14–132 days). We did not observe symptomatic spinal cord ischaemia or stroke. One patient (11%) developed acute renal failure requiring haemodialysis.

CONCLUSION: Second-stage TA aortic repair after previous frozen elephant implantation is a feasible and effective treatment modality for patients with various pathologies of downstream aortic segments. This approach adds additional value to the conventional elephant trunk technique by providing an excellent landing zone not only for additional stent graft procedures but also for subsequent open TA repair.

Keywords: Frozen elephant trunk implantation • Second stage • Thoracoabdominal aortic replacement

INTRODUCTION

Extensive thoracic aortic pathology of various origins might warrant extensive aortic replacement. Consequently, surgical approaches to facilitate second-stage thoracoabdominal (TA) aortic repair have been developed [1]. As thoracic endovascular aortic repair (EVAR) has been broadly embraced by the cardiovascular community for various thoracic aortic pathologies, the combination of both approaches—surgical and interventional—was obvious. Consequently, the frozen elephant trunk (FET) approach was developed and rapidly introduced into clinical routine [2, 3]. This technique was meant to treat the entire thoracic aortic disease in one step, which would have required a two-step approach by conventional surgery in previous days. However, the FET could also serve as a proximal platform for second-stage TA repair later on.

The aim of this study was to evaluate the feasibility and the outcomes of second-stage TA repair after previous FET implantation.

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METHODS

Patients

Between 2005 and 2013, 41 patients underwent open TA aortic repair in our institution. Of these, 9 patients (78% female) underwent second-stage TA repair after previous FET implantation.

Definition of clinical parameters and neurological injury

Mortality was defined as in-hospital death. Stroke and symptomatic spinal cord injury were defined as any new sensorimotor deficit (including those with subclinical manifestation) persisting at the time of discharge in combination with a morphological correlate in computed tomography or magnetic resonance imaging. Left laryngeal nerve palsy was defined as any new onset of hoarseness after surgery with confirmation of palsy by an otolaryngologist.

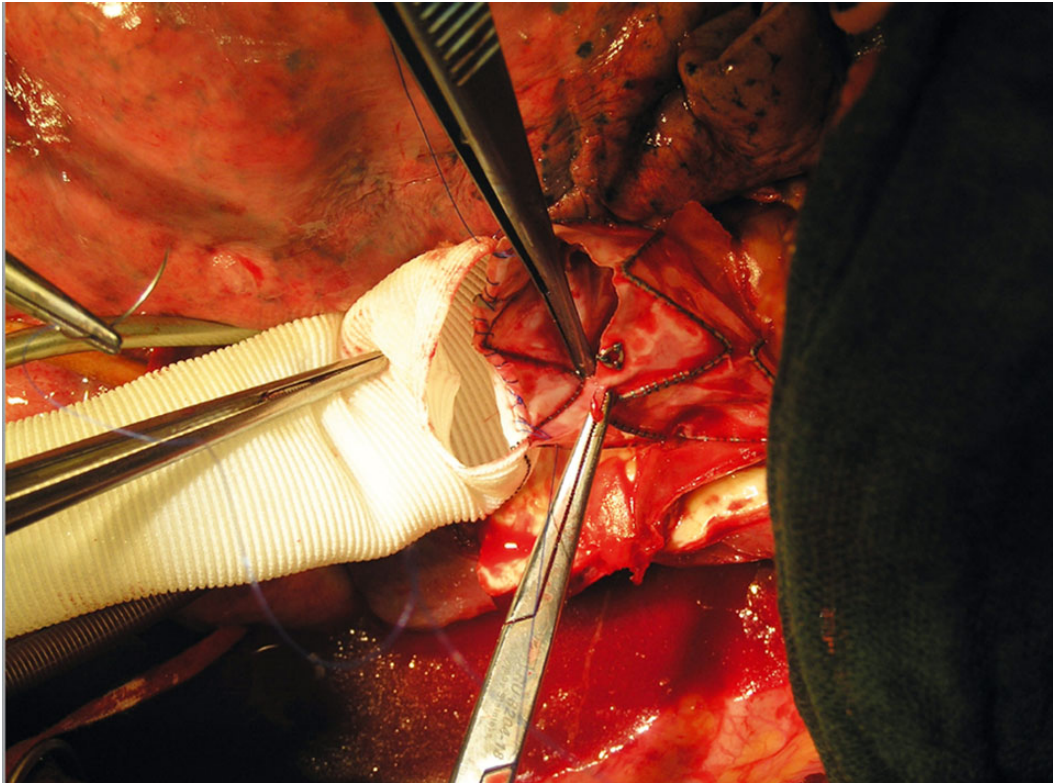


Figure 1: Proximal anastomosis of Dacron prosthesis to distal end of frozen elephant trunk–stent graft.

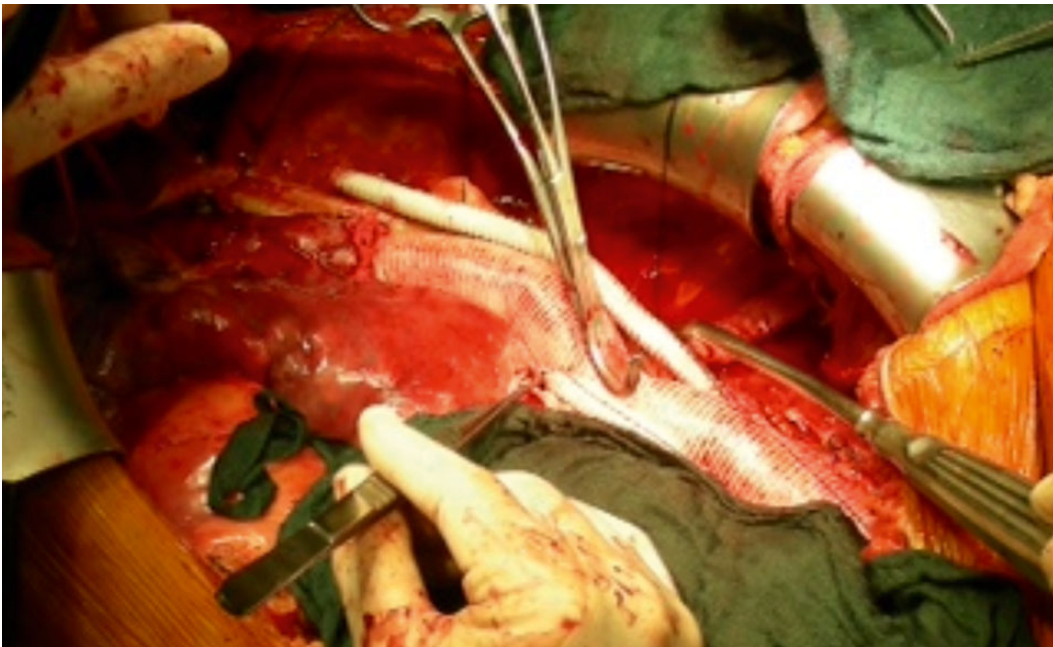


Figure 2: Thoracoabdominal aortic aneurysm repair: reimplantation of the graft of visceral arteries to the Dacron prosthesis.

Data collection and follow-up protocol

Data were prospectively collected. After surgery, patients were seen in our outpatient clinic on a regular basis. Consequently, follow-up was complete in all patients.

Operative strategy

Cerebrospinal fluid (CSF) drainage was routinely used for 72 h in all patients. After induction of anaesthesia and single-lung ventilation, TA aortic aneurysm repair was performed through a standard TA

incision, entering the chest through the sixth intercostal space. Left heart bypass (LHB) was instituted connecting the left inferior pulmonary vein and the distal aorta, and permissive hypothermia down to 32°C was accepted. Repair was performed from proximal to distal by sequential aortic cross clamping, primarily by cross clamping the stent graft. After having performed the proximal anastomosis between the stent graft and a conventional Dacron prosthesis (Fig. 1), selective reimplantation of intercostal and visceral arteries (Fig. 2) was performed. Selective visceral blood perfusion was done via perfusion catheters at a rate of 300 ml/min (Pruitt Cannula). For renal protection, a solution at 4°C (Ringer Lactate 900 ml with 100 ml Mannit 20% and 1 g Methylprednisolone) was used.

RESULTS

Demographics and clinical risk factors

Patient demographics and clinical risk factors are given in Table 1. The median age at second-stage TA–repair of these patients was 59 years (range: 34–73 years).

Time interval

The mean interval between FET implantation and second-stage TA repair in the cohort of 9 patients was 423 days (19–1979 days).

Indications and extent for second-stage thoracoabdominal repair

The indication for the second-stage TA repair was progression of the diameter of the downstream aorta in 6 patients (67%) due to atherosclerotic aneurysms, Marfan syndrome in 2 (22%) patients after previous aortic dissection and giant-cell aortitis in 1 patient (11%). Distal anastomosis of TA replacement was performed in all patients at the iliac bifurcation (Fig. 3).

Table 1: Baseline patient characteristics

	n = 9 (%)	
Demographics		
Age, median (range)	59 years	34–73 years
Female	7 (78)	
Chronic health conditions and risk factors		
Hypertension	8 (89)	
Chronic obstructive pulmonary disease	4 (44)	
Diabetes mellitus	2 (22)	
Serum creatinine >200 mmol/l	0	
Coronary artery disease	1 (11)	
Peripheral vascular disease	2 (22)	
Previous surgical approach (thoracic aorta)		
Frozen elephant trunk procedure	9 (100)	
Concomitant CABG	1 (11)	
Concomitant aortic valve replacement	2 (22)	
Concomitant mitral valve replacement	1 (11)	

CABG: coronary artery bypass grafting.



Figure 3: Computed tomography scan-3D reconstruction of an aortic replacement: thoracoabdominal aortic replacement after frozen elephant trunk technique.

Intraoperative data and left heart bypass data

The mean duration of surgery for second-stage TAAA replacement was 360 min (range: 275–440 min). The LHB technique was used on average for 27 min (range: 20–31 min). The mean aortic cross-clamping time was 110 min. The mean duration of single-lung ventilation was 238 min (193–276 min). Renal protection was performed via intermittent renal perfusion with the previously described crystalloid solution (4°C) with a mean duration of 39.8 min.

Additional surgical procedures and outcomes

The median intensive care unit (ICU) stay was 3.5 days (range: 1–12 days) and median hospital stay was 22 days (range: 14–132

days). There were no in-hospital deaths. We did not observe symptomatic spinal cord ischaemia or stroke.

One patient (11%) underwent concomitant splenectomy. Another patient (11%) sustained partial renal infarction and developed acute renal failure requiring haemodialysis. Furthermore, this patient experienced gastrointestinal bleeding due to a duodenal ulcer, which was treated by emergency clipping of the bleeding gastrointestinal vessel and additionally by a conventional laparotomy. This patient had to undergo a second stay at the ICU for 17 days. One patient (11%) postoperatively showed a coeliac trunk stenosis, and consecutively, a percutaneous transluminal angioplasty and stent implantation was performed on postoperative day 3.

DISCUSSION

Second-stage TA aortic repair after previous frozen elephant implantation is a feasible and effective treatment modality for patients with multisegmental aortic disease. This approach adds additional value to the conventional elephant trunk technique by providing an excellent landing zone not only for additional stent graft procedures but also for subsequent open TA repair.

In this series, indications for primary FET implantation were various and were accompanied by several additional surgical procedures such as coronary artery bypass grafting, root replacement or valve repair, thereby showing the variety of underlying thoracic aortic pathology and their accompanying cardiovascular disease patterns.

A specific focus should be reserved for patients undergoing surgery for acute type A aortic dissection. There is growing support in the literature that the routine use of FET in type A repair might well be associated with a reduced incidence for secondary TA replacement, and even if progression of the aortic disease distal to the FET prosthesis occurs, second-stage repair is facilitated by distal shifting of the disease to the distal part of the descending aorta [3–5]. In particular, patients with retrograde type A aortic dissection with a primary entry tear in the descending aorta, where closure is not feasible during conventional surgery, seem to benefit with regard to reduced need for second-stage TA repair [6].

In patients with multisegmental thoracic aortic pathology, where downstream aortic segments are already affected, but the threshold for repair is not yet reached, this technique might also prove its particular value as the platform for either endovascular completion or surgical repair is already prepared. The broad range of the time interval between FET implantation and second-stage TA replacement substantiates both approaches.

Our intraoperative data regarding LHB times and operative times are well in line with recent reports and do not need further discussion [7]. In this series, we did not observe any kind of symptomatic spinal cord injury, which is well attributed to our protocol of routinely using CSF-drainage as well as reimplantation of intercostal arteries at the known critical level. As we do not routinely use motor-evoked potentials to reconfirm segmental supply, we do follow a very conservative approach in this matter as opposed to more liberal approaches relying on the collateral network theory [8, 9]. One patient had a new onset of left laryngeal nerve palsy. This was unexpected as distal shifting of surgical manipulation away from the aortic arch by the FET technique should avoid this complication, which might potentially result in a prolonged hospital stay due to delayed respiratory recovery.

Zipfel *et al.* [10] have reported on the occurrence of spinal cord ischaemia after the insertion of an endovascular stent graft.

Extended coverage of the thoracic and TA aorta appears to be associated with a higher risk of spinal cord ischaemia. Pacini *et al.* [3] registered a slightly higher rate of spinal cord ischaemia in patients in whom the distal landing zone of the stent was at T10 or lower (14 vs 6%, respectively). Besides, none of the three patients who had stent coverage at or below T8 experienced paraparesis or paraplegia. Furthermore, the actuarial freedom from secondary endovascular repair of the distal aorta was $78 \pm 5\%$ and $69 \pm 8\%$ at 12 and 48 months, respectively, whereas the actuarial freedom from secondary open surgical repair was $96 \pm 3\%$ at 12 months as well as 48 months [3]. As shown in another study, the Dutch Randomized Endovascular Aneurysm Management trial, a late aneurysmal expansion and the need for reintervention are not ignorable following initially successful EVAR. The cluster of reinterventions appeared in the fifth year and beyond, which suggested inferior durability of EVAR when compared with open surgery [11]. It seems that the initial benefit of EVAR disappears in the intermediate and long term because of the need for frequent, meticulous and costly follow-up and the potential need for reinterventions, especially for patients who could tolerate open surgery [12].

We would like to share important surgical details with the readers concerning the ability to clamp the stent graft and to perform the anastomosis between the endovascular stent graft and the surgical prosthesis. Due to its self-expanding capability and due to its memory effect, nitinol resumes its natural shape after the clamping procedure. In case of severely atherosclerotic aneurysmal wall with massive thrombus formation in the aneurysmal sac, it might be necessary to use two clamps in parallel to achieve secure cross clamping of the aorta. Additionally, an anastomosis between the distal end of the stent graft and a conventional Dacron prosthesis is feasible without support of the native aortic wall (Fig. 1). Nevertheless, we would recommend to include surrounding native aortic tissue into the anastomosis to prevent tearing of the thin Dacron fabric of the endovascular prosthesis.

The median follow-up is 356 days to date (range: 131–2666 days). There was no death and no need for redo surgery in this period. However, these patients have to be subjected to routine follow-up protocols, clinically as well as radiologically in order to reconfirm success or to detect potential events at a very early time-point.

Limitations and strengths

Primarily, the patient number is low and indications are heterogeneous. However, this small study is the proof of concept that second-stage TA replacement after previous FET implantation is feasible. Furthermore, this approach is against the mainstream of what is currently followed by large parts of the surgical community, namely total endovascular TA repair. We feel that it remains important to report advances of conventional surgical approaches in such highly complex patients as presented here.

In summary, second-stage TA aortic repair after previous frozen elephant implantation is a feasible and effective treatment modality for patients with various pathology of downstream aortic segments. This approach adds additional value to the conventional elephant trunk technique by providing a more stable proximal segment as to the stent graft.

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Conflict of interest: none declared.

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APPENDIX. CONFERENCE DISCUSSION

Dr M. Karck (Heidelberg, Germany): Dr Folkmann and colleagues presented a cohort of nine patients with thoracoabdominal aortic replacement who survived without neurological complications. They had a frozen elephant trunk in place, and this is what makes these patients slightly different from those who had not had aortic surgery before, and those with a conventional elephant trunk. And the best argument for a specific treatment option is the achievement of excellent results such as yours. But still, and this is what this session is about to me, hasn't the world changed?

I, like many others of you, sit at least once a week with a bunch of progressive endovascular guys. And what I've learned is that they are particularly enthusiastic about custom-made, branched, next generation endografts, or hybrid repairs in patients with a frozen elephant trunk because of the good proximal landing zone. In view of at least six hours of 'skin to skin', the longest incision that you can think of, and nightmares that your patient might not move his legs the next morning, such an approach may appear attractive to many conventional surgeons, and this leads to my first question.

Now, in the light of your results, should we withstand the general endovascular movement in these patients and operate on all of them, or are there criteria you can suggest to us favouring a more endovascular approach in at least some of them?

And a second aspect that intrigues me has to do with Marfan syndrome. I get more and more enquiries from members of patient organizations who are irritated by inconsistent suggestions as to the use of a frozen elephant trunk in Marfan patients, and now I learned from your presentation that two out of nine

patients had Marfan syndrome. So, what is your perspective on the use of a frozen elephant trunk in these patients?

Dr Folkmann: In response to your first question, in our institution the interventional radiologists would really like to manage all of our patients with endovascular stent grafting treatment, but unfortunately we did not have good results after endovascular treatment. We do have better results with open repair. So that's why we choose this option of treatment.

And the second question on the Marfan syndrome patients, from my point of view, this frozen elephant trunk technique with this prosthesis has the advantage that you are sewing the stent graft to the aortic wall. So I think it's a good way to treat the aorta in Marfan syndrome.

Dr T. Sioris (Tampere, Finland): May I ask you, what was your method for controlling the frozen elephant trunk when you open the aorta? You have to close it in order for the patient not to bleed all their blood out. How do you control it? Did you clamp from the outside or did you exsanguinate and then just expose the frozen elephant and then you clamped it, or how did you do it?

Dr Folkmann: The control of what?

Dr K. Tsagakis (Essen, Germany): The elephant trunk, when you started the second procedure, how did you reach the elephant trunk? Did you clamp the aorta from outside, did you open the aorta?

Dr Folkmann: You mean if you do the proximal anastomosis?

Dr M. Grabenwöger (Vienna, Austria): I will answer it. It's easy. We clamp it from the outside, and in most cases if you have a huge aneurysm around the stent with a lot of thrombus, you need two clamps. So we do not open the aneurysm. I do not take out everything as in the conventional elephant trunk, and search for the stump; we are doing it from outside. And it's very wise to look in front of the operation versus the distal end of the stent graft. If you have a huge aneurysm, you do not feel the stent graft through the aortic wall. If you have a small aorta, this is also an advantage. Using a stent graft, you feel the bare springs through the aortic wall, and so you know at which height you can put the clamp on. This is very important. In one case I had the clamp on, I opened it, but the stent graft was above, so this was a very critical situation.

Also I like to use this stent on the Marfan patients, and knowing Marfan patients, a secondary operation (to Matthias Karck we answer) is obvious. I cannot heal a Marfan patient with a stent graft, but I can heal entries in a descending aorta in a dissection case. And one of these two Marfan patients had a very long interval between the first frozen elephant trunk operation and the next step. And then for me it's an advantage. It's easier to undertake the second operation to perform the anastomosis with a stent graft than looking for these tiny crimped Dacron prostheses from the conventional stent graft.

Dr J. Bachet (Paris, France): I do apologize to Dr Folkmann because my comment is not intended for this particular presentation, which was excellent, but to something that has really teased me for years and that we hear frequently.

You have assessed your results by using one criterion which is ICU stay duration. We should stop using this because this is one of the worst criteria. Let me give you an example. Take a department in which 50% of the patients die in ICU within 24 h. They will have an excellent ICU stay duration but we can't say it's a very good department. If you want to assess your results, tell us the rate of bleeding in the first 24 h, the time of extubation and awakening, et cetera, but please, don't use this criterion that is most probably based on financial considerations and insurance management.

Dr B. Zipfel (Berlin, Germany): I have an additional question. Is it your current policy to implant a frozen elephant trunk even if a conventional procedure is planned afterwards, or did you have some reasons not to proceed with endovascular procedures?

Dr Grabenwöger: The reason I explained before. If you look at the time interval, there was one patient with 19 days between the frozen elephant trunk and the thoracoabdominal, and I switch from the conventional elephant trunk to the frozen elephant trunk even in patients where I know I have to operate on them some weeks thereafter. It is easier to clamp the aorta more in the distal or the mid part of the descending aorta than to clamp an aorta in the distal part of the aortic arch. You have to go up, you have the recurrent nerve, and sometimes I struggled with conventional elephant trunks if the stump was very short; you are in the distal arch, you are very high up in the thorax.

So for me, I would recommend also the use of frozen elephant trunk in a procedure where it's clear that you have to undertake a conventional operation thereafter. But it's a personal opinion.

Dr Zipfel: Is this why a frozen elephant trunk cannot be compressed in comparison to a conventional one?

Dr Grabenwöger: The frozen cannot be compressed and the distal anastomosis is pushed more distally.