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Original Article

Preliminary and Intermediate-Term Results of the Novel Modification of Frozen Elephant Trunk: A Single-Center Study

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Objectives: We evaluate the preliminary and intermediate-term results of Viet Duc modification of the frozen elephant trunk (FET) technique.
Methods: During December 2019 and May 2023, 47 patients underwent surgery using our modification of the FET at Viet Duc University Hospital. The mean age of the patients was 56.8 years (±9.4, range 31–72). In all, 34 (72.3%) of the patients were men.
Results: There were 5 (10.6%) perioperative deaths. The duration of cardiopulmonary bypass, cross-clamping, circulatory arrest, and total operation were 165 (±49.1 range 94–330), 100 (±37, range 46–205), 32.6 (±8, range 20–58), and 366 (±60.6, range 270–540) minutes, respectively. In complications, tracheotomy, temporal hemodialysis, cerebral shock, and type 1A endoleak were noted in 3 (6.4%), 4 (8.5%), 4 (8.5%), and 3 (6.4%) patients, respectively. The mean follow-up time was 25.8 months (±11.7, range 3–42). One case was dead in the follow-up period. Three patients (6.3%) had successful reoperation for type 1A endoleak, and 4 patients (8.5%) underwent a second intervention. One (2.1%) patient had a second intervention and an infrarenal abdominal aortic replacement.
Conclusions: Our modification of the FET technique was feasible, effective, and safe, with good early and intermediate-term outcomes.

Keywords: frozen elephant trunk, Viet Duc University Hospital, intermediate-term results

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Introduction

Bost and College introduced the elephant trunk technique in 1983 to treat multisegmented thoracic aortic diseases.[1)] Over the years, this technique has undergone changes and improvements to become easier to apply in practice with a low rate of complications.[2,3)] In 2003, a new modification of the elephant trunk technique was published by Karck et al.,[4)] and this technique was called frozen elephant trunk (FET). Using a combination of Dacron vascular prostheses and stent grafts in FET simplifies the procedure and provides positive results. Over the past 2 decades, the FET technique has become more popular as the new standard for the treatment of complex thoracic aortic diseases.[2,3,5,6)] Many modifications of the FET technique have been introduced,[4,7,8)] and different customized devices for FET procedures are available on the market, such as Thoraflex, Evita Open Neo, etc. Therefore, these devices are relatively expensive and not always available in developing countries. Based on Roselli's publication,[9)] we conducted our modification of FET (Viet Duc modification) using an extended Medtronic stent graft and Dacron vascular prosthesis (Uni Graft—B. Braun and Gelweave, Terumo). Our technique and preliminary results of using this technique have been published.[10)] In this article, we evaluate the intermediate-term outcomes, specific complications, and possible ways to address them.

Patients and Methods

Patients

All patients who underwent the Viet Duc modification FET procedure at the Cardiovascular and Thoracic Center of Viet Duc University Hospital, Hanoi, Vietnam, from December 2019 to July 2023 were included in this study. Patients who received the Thoraflex, Evita Open Neo, or hybrid procedures were excluded from this study. The end date of data collection was 30 October 2023. There were 47 patients included in the study, and the mean follow-up time was 25.8 months (±11.7, range 3–42).

Endpoints
The primary endpoint was the mortality analysis in the group as a whole, and the secondary endpoint included morbidity in the cohort as a whole, with special attention to the specific technique-related complications.

Data collection
All clinical data were collected retrospectively through a review of the medical records.

Statistics
Analysis was performed using SPSS 20.0 (IBM Corp., Chicago, IL, USA) software. Research results are presented in the form of tables or graphs. Quantitative variables are presented as mean ± standard deviation (SD) and compared; qualitative variables are presented as % and compared, tested by test when squared, and statistically significant when P <0.05. Survival, freedom from reoperation, and reintervention are presented using Kaplan–Meier graphs.

Surgical technique
The surgical technique has been described in a previous publication.[10] Briefly, the operation is performed through a median sternotomy with moderate hypothermia (28°C) and bilateral antegrade cerebral perfusion. After sternotomy, cardiopulmonary bypass (CPB) was performed. To better expose the left subclavian artery (LSA), the left common carotid artery was initially dissected and ligated. After that, it was then cut and perfused with a retrograde coronary cannula and fixed to the skin incision. In the next step, the LSA is dissected, ligated, and cut out. The distal end of LCA will be anastomosed with an 8-mm Dacron graft. Myocardial protection is provided by a single dose of antegrade Custodiol-HTK cardioplegia. After the completion of the distal FET anastomosis, lower body perfusion was re-established, and the patient started warming up. The next steps are proximal anastomosis and aorta declamping. Upon heart beating, the 8-mm Dacron graft anastomosed with LSA was then anastomosed with the ascending aorta graft in place of the hold of aortic drainage. The left common carotid artery was anastomosed with the 8-mm Dacron graft in an end-to-side fashion. Using this order of steps allows for a shorter cross-clamp time. All patients in this study were treated by the same cardiac surgeon.

Results

Preoperative data
Preoperative characteristics are shown in **Table 1**. The median age was 56.8 ± 9.4 years, with a range from 31 to 72 years old, and the male gender predominated in the study group (72.3%). The most common comorbidity was hypertension (83%). Most patients had acute aortic syndrome, including 26 (55.3%) patients with acute type A aortic dissection, 2 (4.3%) patients with acute type A intramural hematoma, and 6 (12.8%) patients with type B aortic dissection. The thoracic aortic aneurysm was seen in 13 (27.7%) patients. Eight patients had a history of thoracic aorta surgery. Patients with type B dissections were selected for FET when their ascending aorta was larger than 4 cm and/or their aortic arch was dissected.

Table 1 Preoperative characteristics of patients (N = 47)

Preoperative parameters	Patients (n)	%
Age		
Mean ± standard deviation—years	56.8 ± 9.4	
Range—years	31–72	
Sex		
Male	34	72.3
Female	13	27.7
Hypertension	39	83
Type 2 diabetes mellitus	5	10.6
Chronic kidney disease	4	8.5
Marfan syndrome	4	8.5
Previous operation on thoracic aorta	8	17
Recurrent laryngeal nerve compression	2	4.3
Limb malperfusion	4	8.5
Indications for FET		
Acute type A aortic dissection	26	55.3
Acute type A intramural hematoma	2	4.3
Aortic dissection type B	6	12.8
Thoracic aortic aneurysm	13	27.7

FET: frozen elephant trunk

Intraoperative data
Intraoperative characteristics are shown in **Table 2**. In all, 27 (57.4%) patients underwent an emergency operation. Axillary artery cannulation was performed in 57.4% of patients. Common sizes of the vascular prosthesis and stent grafts were 26, 28, 30, and 28, 30, and 32, respectively.

Postoperative data
Postoperative data and complications are shown in **Table 3**. The mean follow-up time was 25.8 ± 11.7 months, with ranging from 3 to 43. In-hospital mortality was 10.6%. One patient died after 2 days of surgery from a deep coma. One patient had a cerebral shock and died after 90 days of multiorgan failure. One died after extubation due to a late-diagnosed pneumothorax. One patient died suddenly 2 days after extubation from unknown causes, and another patient died of multiorgan failure.

Mortality within the follow-up
During follow-up, 1 patient died 6 months after surgery due to cerebral shock. Others survived and underwent follow-up until this study (**Fig. 1**).

Table 2 Intraoperative characteristics (N = 47)

Intraoperative parameters	Patients (n = 47)	(%)
Emergency operation	27	57.4
Location of the arterial cannula		
Brachiocephalic trunk	12	25.5
Axillary artery	27	57.4
Femoral artery	6	12.8
Axillary and femoral artery	2	4.3
Operative time		
Mean ± standard deviation—hour	6.1 ± 1.1	
Range—hour	(4.5–9)	
Cardiopulmonary bypass time		
Mean ± standard deviation—min	165.3 ± 49.1	
Range—min	(94–330)	
Cross-clamping time		
Mean ± standard deviation—min	100 ± 37	
Range—min	(46–205)	
Body's temperature (°C)	28	
Circulatory arrest time		
Mean ± standard deviation—min	32.6 ± 8.8	
Range—min	(18–58)	
Size of vascular prosthesis (mm)		
22	1	2.1
24	2	4.3
26	15	31.9
28	16	34
30	13	27.7
Size of stent graft (mm)		
22	1	2.1
24	1	2.1
26	1	2.1
28	7	14.9
30	21	44.7
32	12	25.5
34	4	8.5
Length of stent graft (mm)		
150	14	29.8
185	8	17
200	21	44.7
205	2	4.3
280	1	2.1
Concomitant surgery		
Bentall procedure	3	6.4
Right coronary artery bypass grafting	1	2.1
Aortic valve replacement and mitral valve repair surgery	1	2.1
The sinus of Valsalva (noncoronary) repair surgery	1	2.1

Complications

In our series, there was no case of spinal cord ischemia (SCI); reoperation for bleeding, and malperfusion requiring intervention or surgery. Cerebral shock was in 4 (8.5%); half of them died and others survived with residual hemiplegia. One patient had recurrent nerve palsy after surgery but regained normal voice after 3 months. Acute kidney failure required temporal hemodialysis in 6 patients (12.8%), and renal function in all of these patients recovered completely. Three patients had prolonged mechanical ventilation and required a tracheotomy.

Table 3 Postoperative parameters, complications, and follow-up

Postoperative parameters	Patients	(%)
In-hospital mortality	5	10.6
Cerebral infarction	4	8.5
Spinal cord ischemia	0	0
Recurrent nerve palsy	1	2.1
Bleeding required reoperation	0	0
Red blood cell transfusion above 5 units	8	17
Malperfusion requires intervention or surgery	0	0
Hemodialysis	4	8.5
Tracheostomy	3	6.4
Mechanical ventilation time		
Mean ± standard deviation—day	7.5 ± 10.2	
Range—day	(1–59)	
Intensive care unit time		
Mean ± standard deviation—day	15.9 ± 15.4	
Range—day	(2–90)	
Length of hospital stay		
Mean ± standard deviation—day	26.7 ± 14.3	
Range—day	(2–91)	
The postoperative follow-up times (months) (N = 42)	25.8 ± 11.7 (3–43)	
Second-stage TEVAR (N = 42)	4	9.5
Second-stage TEVAR + open infrarenal abdominal aortic replacement (N = 42)	1	2.4
Late reoperation (N = 42)	3	7.1
Late death (N = 42)	1	2.4

TEVAR: thoracic endovascular aortic repair

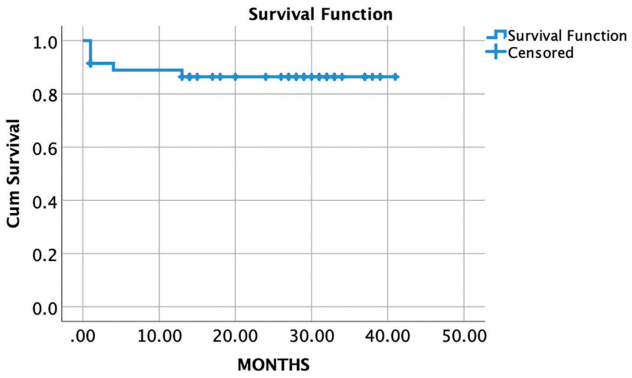

Fig. 1 The Kaplan–Meier survival curve for the overall surgical patients.

Reintervention during follow-up

Five patients (11.9%) underwent a second elective procedure, 4 (9.5%) of them had a second intervention only,

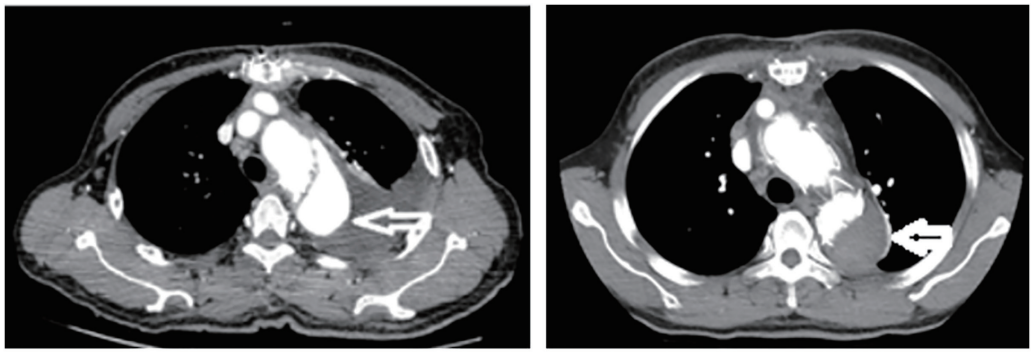

Fig. 2 Endoleak type 1A before (**A**) and after (**B**) surgery.

and 1 (2.4%) underwent a second intervention and open infrarenal abdominal aortic replacement.

Specific complications for modification

The type 1A endoleak occurred in 2 patients immediately after surgery (**Fig. 2A**) and in 1 patient 6 months after surgery. All of them were successfully reoperated on (**Fig. 2B**). Two endoleaks were closed by plication grafts to the aortic wall using "U" pleaded sutures; 1 brachiocephalic trunk was dissected, dilated, and replaced using a 9-mm Dacron prosthesis and closed the endoleak.

Distal stent graft-induced new entry (dSINE) was documented in 2 patients, who were treated successfully with an additional stent graft in the descending aorta.

Discussion

The indications for FET in our series were accorded the consensus document of the European Association for Cardio-Thoracic Surgery and the European Society for Vascular Surgery for the treatment of thoracic aortic pathologies involving the aortic arch.[5] Acute aortic syndrome, which includes acute type A aortic dissection, acute type A intramural hematoma, and type B aortic dissection with an ascending aortic diameter higher than 40 mm and/or aortic arch dissection (non-A non-B dissection), accounted for the majority of cases. During the acute phase of dissection, we performed FET for patients under 70 years old.

The hospital mortality in our series was 10.6%, and it is comparable with other studies.[5,11,12] Of the first 30 cases, there were no hospital deaths. By analyzing the causes of hospital deaths, we found that the technique-related death was in 2 patients. Both suffered cerebral infarction following surgery; 1 died of a deep coma because of thrombosis of the innominate artery. The cause of this complication may be that, when we performed selective brain perfusion for a patient with acute aortic dissection and dissected the innominate artery, we clamped the innominate artery and damaged its intima. After ending CPB, the blood flow went from the aorta to the innominate artery and inverted the damaged intima, which may be the cause of innominate artery thrombosis. After this case, in acute dissection, we do not occlude the innominate artery with a hard clamp; we try to use a soft silicon band. The other patient died of multiple organ failure after a long period of intensive care. In this case, the patient had atherosclerosis, aortic aneurysm, and atherosclerosis of the innominate artery, so we tried to cannulate it. This manipulation may cause embolism and right-side brain infarction. From this time on, in the same cases, we always cannulate the axillary artery. SCI is well known as an early feature of FET complications and accounts for approximately 0%–21%.[5,11,13] Many studies show a relationship between the SCI and the stent graft length; longer stent grafts increase the risk of SCI. We used an extended Medtronic stent graft for our patients with a length of 150–280 mm, which was longer than the stent graft in Thoraflex (100 and 150 mm) or Evita Open Plus (120–180 mm), so there were no cases with SCI. It can be explained that, in cases with fabric-made devices, the proximal landing zone of the stent graft is located behind the LSA, so in our technique, the proximal landing zone of the stent graft stays behind the innominate artery, and the distal end of the stent graft stays higher (30–40 mm) than in the classic FET technique when using the same length of stent graft. Another fact is that the number of patients in our study is limited, and in a larger sample size, this complication may appear. Recurrent palsy, which was in 1 patient (2.1%) affected only one side of the body. Using our method to expose the LSA has been introduced as a simplified procedure and may reduce the risk of recurrent injury.

Because hemostasis is always crucial following arch surgery, 2.5%–30% of cases of hemorrhage necessitating a second procedure have been reported.[5,8,11,14] There were very few instances of red blood transfusions and no bleeding-related reoperations in our group (**Table 3**). It can

explant the distal anastomosis located at zone 0, where it is easier to perform anastomosis and control hemostasis; another factor could be that the stent graft compresses against the aortic wall and blood flow only goes inside the stent graft, unlike conventional elephant trunks, in which blood flow goes retrogradely into the space between the vascular prosthesis and aortic wall. Intraoperative red blood transfusions were avoided in almost all patients. Following arch surgery, a major early consequence is a cerebral shock. The rate of this consequence was approximately 2%–25%, despite significant advances in brain perfusion, protection, and monitoring.[5,11–14] Two of the 4 (8.8%) cerebral shocks that occurred in our series were fatal.

Acute kidney injury (AKI), requiring temporary hemodialysis, accounted for 8.5% in our study. Previous studies have shown that age, gender, body mass index, hypertension, left ventricular ejection fraction, preoperative serum creatinine, CPB time, perioperative sepsis, thoracotomy exploration, and coronary involvement are predictors of AKI[15] and the incidence of AKI following a FET procedure ranged from 4.8% to 34.8%.[5] Analyzing our cases with AKI, we found the fact that, all of them had postoperative sepsis, 3 of them had blood transfusions of more than 5 units, 1 patient had a long CPB time and hypertension was presented in 3 of them. We think in these cases, the main causes of AKI were postoperative sepsis and blood transfusion, we did not find any technique-relative factor for AKI in our series.

In the follow-up period, the specific complication for our modification was type 1A endoleak. For the first cases, we did not plicate the graft to the aortic wall in the part of the brachiocephalic trunk (BCT). After surgery as well as during the follow-up period, we found 3 cases with type A endoleak. This complication was in Roselli's modification and required development.[9] All type A endoleak cases were successfully reoperated. We solved this problem by placing 2 additional pledged interrupted U-sutures to plicate the graft to the aortic wall just behind the BCT and to date no more cases of type A endoleak have occurred.

The second stage thoracic endovascular aortic repair (TEVAR) was performed in 6 patients, and 2 of them were caused by dSINE. According to a study by Nomura et al.,[16] dSINE occurs in 15.8%–18% of cases and may lead to a mortality rate of up to 25% without treatment. Many causes of dSINE have been reported, such as the phase of dissection (more frequently in chronic dissection)[17]; distal stent graft oversized >20%[18]; spring back force, expansion force, and length <145mm stent graft; the angle between the distal end of the stent graft end and the continuation of the aorta[19]; aortic remodeling mismatch.[16] We followed the rule that the size of the selected FET was less than 80% of the total aortic diameter of the planned implantation site in acute dissection and 100%–110% of the true lumen diameter in chronic dissection. As we know, the diameter of the proximal aorta is normally bigger than the distal part of the aorta. Therefore, some authors recommend using a tapered stent graft to avoid dSINE.[19] So, these stent grafts were produced to be implanted retrogradely from the femoral artery under digital subtraction angiography (DSA). In our technique, we deliver stent graft antegrade via an open aortic arch without DSA, and we cannot use tapered stent graft. We think that, in cases with a larger difference between the proximal and distal aorta or true lumen (higher taper ratio), the stent graft should be shorter (we can do it by cutting the stent graft before implantation); if the lesion requires a longer stent graft, it could be prolonged by adding a tapered stent graft in the second intervention.

During the follow-up period, 1 patient died of cerebral infarction. No late deaths related to the technique were noted. After 1 and 3 years, the survival rate was 88.9% and 86.4%, respectively. The mid-term results in our series may be comparable with the results of other studies.[13,14,20,21]

Conclusion

Our novel modification of the FET technique is safe and feasible. Short-term and mid-term outcomes are comparable with other studies, but long-term outcomes require further investigation.

Limitation of our study

This study was a retrospective study with a small sample size and no control group from a single center. The follow-up period was short after discharge. However, we will continue to apply our technique to a larger number of patients. Long-term results will be reported later.

Declarations

Ethics statement

Our institution does not require ethical approval for reporting individual cases or case series.

Author contributions

Study conception: SDHP, UHN
Data collection: LHP, TNV
Analysis: SDHP
Investigation: SDHP, HDD and UHN
Manuscript preparation: SDHP
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors.

Disclosure statement

The authors and co-authors have no conflicts of interest to declare.

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