

Which is superior, the frozen elephant trunk technique alone or the classical elephant trunk technique followed by second-stage thoracic endovascular aortic repair for extensive aortic arch repair?

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ABSTRACT

Paraplegia is one of the most devastating complications during extensive aortic arch repair. We retrospectively analyzed our results by comparing primary repair using the frozen elephant trunk technique (FET) and the classical elephant trunk technique (CET) followed by second-stage thoracic endovascular aortic repair (TEVAR), which has been performed since 2009.

Between March 1997 and September 2015, 91 patients (the mean age: 70 ± 8.6 years old, 73 men and 18 women) underwent total aortic arch replacement with either the FET (54 cases) or CET (37 cases). The CET was followed by second-stage TEVAR with a median duration of 36 days. The number of in-hospital deaths was 2 (3.7%) in FET and none in CET. The overall survival was 73% in FET and 83% in CET at 5 years with no significant difference ($p=0.73$). Aortic events occurred in 12 cases (22%) in FET and 3 (8%) in CET. The rate of freedom from aortic events was 77% in FET and 91% in CET at 5 years with no significant difference ($p=0.45$). Five neurologic events (9%) occurred after the FET, and 3 events (8%) occurred after the CET ($p=0.85$). No patients in the CET group experienced paraplegia, while the FET group showed a relatively high paraplegia rate (17%, $p=0.014$). The FET with primary repair for extensive aortic arch repair had an acceptable hospital mortality rate and aortic events but was associated with a high incidence of paraplegia. The CET followed by second-stage TEVAR achieved better early results with a low risk of paraplegia and may produce a favorable mid-term surgical outcome for extensive aortic arch repair.

Keywords: elephant trunk, frozen elephant trunk, spinal cord injury

Abbreviations:

FET: frozen elephant trunk technique
CET: classical elephant trunk technique
TEVAR: thoracic endovascular aortic repair
CT: computed tomography
SD: standard deviation
SCI: spinal cord injury

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INTRODUCTION

The classical elephant trunk technique (CET) for extended aortic arch repair was first introduced by Borst et al in 1983.¹ This technique was initially designed to prepare for complex arch pathology, including descending or thoracoabdominal mega-aortic aneurysm repair, to reduce the risk of complications with single-stage repair. However, the interval morbidity and mortality of this procedure were major concerns. In 1995, a novel second-stage technique using thoracic endovascular aortic repair (TEVAR) for the treatment of descending aortic aneurysms was introduced, in which a stent graft is placed during the CET as a good landing zone.² The advantage of this technique is a decreased interval between the stages and complete aortic repair rather than a conventional surgical operation.

Another novel technique using the frozen elephant trunk (FET) was introduced by Kato in 1996.³ The main features of this single-stage technique are the elimination of additional surgery and a reduction in the interval morbidity and mortality. The present compared the clinical outcomes between the FET and the CET followed by second-stage TEVAR.

MATERIAL AND METHODS

Patients

From March 1997 to September 2015, a total of 91 patients underwent total arch replacement with the FET alone (group A, n=54) or CET followed by second-stage TEVAR (group B, n=37). The strategy for CET with second-stage repair was started in 2009 in our institution. There were 73 men and 18 women, with an average age of 70 ± 8.6 years old. The primary indications for the FET were true aortic aneurysms and aortic dissection (aneurysms: n=32, dissection: n=22). The indications for the CET with TEVAR were predominantly true aneurysms rather than dissection (aneurysms: n=35, dissection: n=2). More extended thoraco-abdominal aneurysms cases that underwent the CET followed by surgical completion extending to the diaphragm were excluded from this study. The preoperative demographic patients' characteristics are reported in Table 1.

Table 1 Pre-operative patient characteristics

Variable	Group A (n=54)	Group B (n=37)	p Value
Age	68.5 \pm 9.6	68.5 \pm 9.6	0.015
Gender (Male)	41 (76%)	32 (86%)	0.214
True/Dissection	32/22	35/2	<0.0001
Smoking	24 (44%)	30 (81%)	<0.0001
Diabetes mellitus	5 (9%)	7 (19%)	0.181
Hyperlipidemia	9 (17%)	17 (46%)	0.002
Hypertension	45 (83%)	29 (78%)	0.551
Renal Failure	5 (9%)	7 (19%)	0.181
COPD	2 (4%)	5 (14%)	0.085
History of CVD	6 (11%)	4 (11%)	0.964
Additional procedure	10 (19%)	8 (22%)	0.667
Emergent Op.	5 (9%)	1 (3%)	0.227

COPD: Chronic obstructive pulmonary disease

Emergent Op: emergent operation

CVD: cardiovascular disease

Surgical technique

1) FET

The original FET was used with a double-linked 10-bend Z-stent (50 mm length and 20% larger than the diameter of the descending aorta) and Ube graft[®], an ultra-thin woven Dacron graft (10% larger than the diameter of the descending aorta; Ubekosan, Ube, Japan). The graft and Z-stent were sutured together at each bend. A minor modification was made using another graft (Ube graft[®], 19; Triplex[®] [Terumo, Tokyo, Japan], 18; Gelweave[®] [Terumo], 1; J-graft[®] [Lifeline, Tokyo, Japan], 1). The precise details of the insertion technique were described in our previous reports.⁴

The “J graft Frozenix[®]” (Lifeline) is a relatively new device that has been commercially available since 2014 in Japan. The product information was recently summarized in a multicenter report.⁵ In brief, the Frozenix[®] consists of two parts: the graft part and the stent part. The graft part is a polyester woven graft. The stent part has a woven structure made of Nitinol wire, a superelastic/shape-memory alloy. The stent part is fixed to the inside of the graft to protect the stent part from coming in direct contact with the vessel wall. As for the stent part, the following 3 lengths are available: 60, 90 and 120 mm. The optimal length for each lesion is easy for surgeons to determine. The outer diameter of the stent graft ranges from 17 to 39 mm in increments of 2 mm. To implant the stent graft, the string fixed to the device is first removed, and the distal tip including the stent part is appropriately bent so that the configuration of the stent graft matches that of the lesion. The stent graft part is then inserted into the artery to be replaced. Next, the cover is removed to cause the stent graft part to expand, which fixes the stent graft to the target site. Similar to conventional vascular prosthesis implantation, the proximal end of the stent graft is sutured to the vessel.⁵

2) CET with second stage TEVAR

The CET was performed using a tubular graft inserted into the descending aorta according to Svensson’s modification,⁶ and the double-layered head was then sutured onto the descending aortic wall with another graft for arch reconstruction. Generally, the two segments of the graft are used to connect the arch segment and descending segment. However, suturing between these two parts of the graft is time-consuming. Recently, the CET was performed with the “Eaves” technique,⁷ for distal anastomosis to reduce the number of sutures and decrease bleeding from the suture site. In brief, an appropriate graft length is invaginated, and four horizontal mattress sutures are circumferentially placed along the line approximately 1 cm from the “new edge” circumferentially. The invaginated portion of the graft is then withdrawn, thereby creating 1-cm-wide eaves that become the site of anastomosis.

3) Technique for total arch replacement using the FET or CET

After standard median sternotomy, a cardiopulmonary bypass was initiated with direct cannulation of the aorta and the right atrium. The left subclavian artery was exposed and anastomosed with 8-mm-diameter synthetic grafts as outflow cannulation. The left heart was vented through the right superior pulmonary vein. The heart was arrested with antegrade cardioplegia, which was repeated every 20–30 minutes during the procedure. Cerebral protection was achieved by moderate hypothermic circulatory arrest at 25°C with direct cannulation into bilateral selective antegrade cerebral perfusion. After reaching the desired temperature, the systemic circulation was arrested, and the aortic wall was transected, either between the left carotid artery or between the left subclavian artery. The CET or FET was deployed into the proximal descending aorta using the guidewire on the cable technique via the femoral access.⁸ After distal anastomosis, the proximal of the CET or FET was sutured with the 4-branched graft (not necessary for the Eaves

technique), and perfusion to the lower part of the body was started, with rewarming also initiated at the same time. The proximal end of the graft was then anastomosed to the native ascending aorta, and each cerebral branch was anastomosed to the brachiocephalic and left carotid arteries. The left subclavian artery was finally anastomosed to the third branch of the graft.

Statistical analyses

Data were collected and analyzed retrospectively. Statistical analyses were performed using the SPSS 22.0 statistical software package for Macintosh (SPSS Inc., Chicago, IL, USA). Quantitative variables approximating a normal distribution are presented as the means \pm standard deviation (S.D.). Differences between the groups were evaluated by Student's t-test or the Mann-Whitney U-test for continuous data, according to the normality of the data; the χ^2 test or Fisher's exact test was used to compare categorical variables. Kaplan-Meier analyses were used to analyze the survival. Statistical differences in the Kaplan-Meier survival curves were determined with the log-rank test. Two-tailed P values <0.05 were considered significant.

RESULTS

The intraoperative and postoperative data are shown in Tables 2 and 3. Two in-hospital deaths occurred in group A (3.7%), while there was no in-hospital death in group B. One of the patients died because of multiple organ failure due to ischemic colitis, while the other died from distal aortic rupture. The operative time, cardiopulmonary bypass and aortic cross clamp time were longer in group A than in group B ($p=0.03$, 0.012 and 0.144, respectively). The lower body ischemic time was almost the same following FET and CET.

A significantly longer stay in the hospital and intensive-care unit was observed in group A than in group B ($p=0.028$ and 0.039, respectively). The duration of second-stage admission for TEVAR was <2 weeks (mean 11 days). There were 8 paraplegia cases (15%) and 1 paraparesis case (2%) in group A, while no paraplegia occurred during the first operation in group B. However, paraparesis was complicated at second-stage TEVAR. The rate of spinal cord injury (SCI) was 17% in group A and 5% in group B with no significant differences. The use of a handmade graft using the Z-stent was associated with a significantly higher rate of paraplegia than the commercially available graft (Z-stent: 8/39 20.5%, Frozenix[®]: 1/15 6.6%, $p=0.003$). Most of the SCI cases with handmade FET occurred in cases of true aneurysm; three of these cases had a deep landing zone below the Th9. Only one SCI case treated using the Frozenix[®] graft had recovered by the time of discharge. Almost 25% of the patients had a prolonged ventilation time (>72 h) in both groups. Stroke occurred in 9% of the patients in group A and 8% of those in group B.

The Kaplan-Meier curves for the survival and aortic events are shown in Figures 1A and 1B. No significant differences were found in the survival between the groups ($p=0.733$). Aortic events also occurred at similar rates with no significant difference between the groups ($p=0.452$).

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Table 2 Operative Data

Variable	Group A (n=54)	Group B (n=37)	p Value
Operation time(min)	501 ± 137	436 ± 122	0.03
CPB time(min)	254 ± 75	214 ± 56	0.012
ACC time(min)	122 ± 52	106 ± 41	0.144
Lower Body ischemic time	65 ± 27	60 ± 19	0.411
Lowest nasopharyngeal temperature(°C)	21.9 ± 3.2	25.6 ± 1.7	<0.001

CPB: cardiopulmonary bypass time

ACC: aortic cross clamp

Table 3 Post-Operative Data

Variable	Group A (n=54)	Group B (n=37)	p Value
Hospital death	2 (3.7%)	0	0.487
Hospital Stay (Day)	45 ± 26	34 ± 11	0.028
ICU Stay (Day)	6.7 ± 8.3	3.6 ± 3.6	0.039
Re-exploration	3	4	0.335
Stroke	5 (9%)	3 (8%)	0.849
Paraplegia	8 (15%)	0	0.014
Paraparesis	1 (2%)	2 (5%)	0.351
SCI	9 (17%)	2 (5%)	0.106
Renal failure	4 (7%)	1 (3%)	0.348
Af	13 (24%)	13 (35%)	0.217
Prolonged ventilation	14 (26%)	9 (24%)	0.798

ICU: intensive care unit

SCI: spinal cord injury

Af: atrial fibrillation

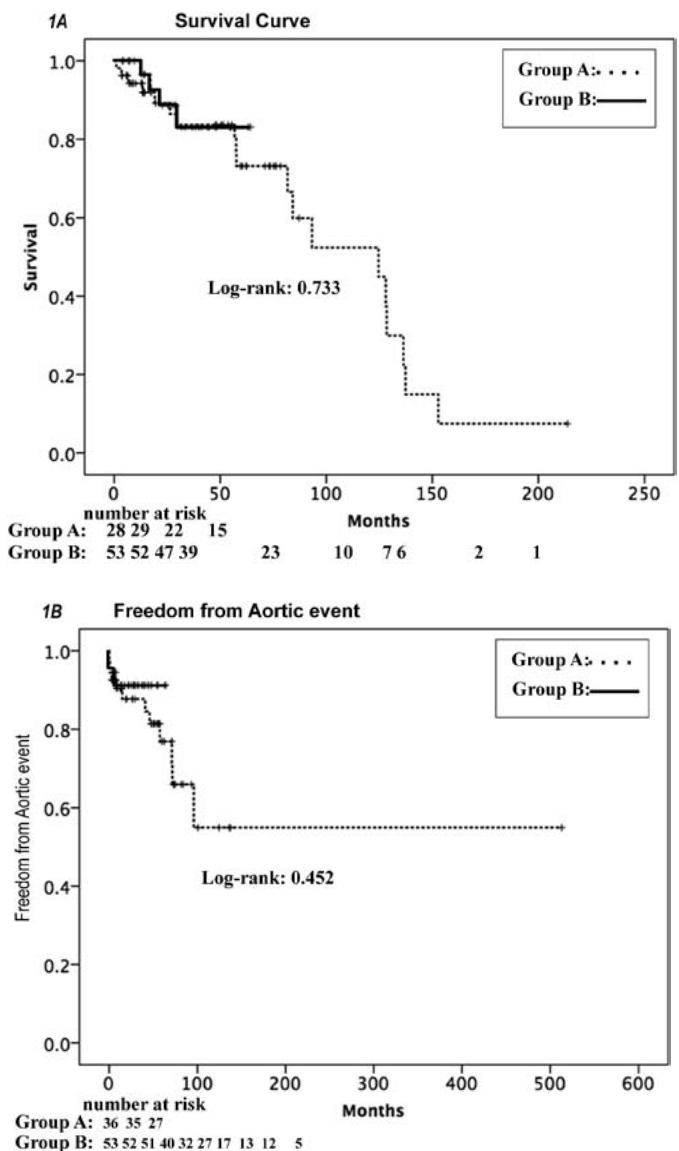


Fig. 1 Post-operative late outcome

Fig. 1A: Kaplan-Meier survival curves for each group patients was shown. Group A: FET
Group B: CET with TEVAR.

Fig. 1B: Kaplan-Meier survival curves of freedom from aortic event was shown. FET, frozen elephant trunk;
CET, classical elephant trunk

COMMENT

The current study showed that the FET technique with primary repair for extensive aortic arch repair had an acceptable hospital mortality rate and aortic events but a higher incidence of paraplegia than the CET. Therefore, the CET followed by second-stage TEVAR may produce favorable mid-term surgical outcomes with a low risk of paraplegia.

The CET technique was originally introduced to simplify second-stage operations. The initial problem with this technique was the high risk of early and midterm rupture at the untreated segment of the aneurysm. Major reports concerning the CET.⁸⁻¹¹ were reviewed by Miyamoto,¹² and the mortality rates for the initial operation ranged from 2%–12% (mean 6.9%), with a relatively high interval mortality, ranging from 3%–25% (mean 10%). The rate of reaching second-stage completion among CET patients ranged from 45%–56%. The mortality rate due to the second-stage operation ranged from 4%–10% (mean 7.5%). However, the precise reason for patients not undergoing the second-stage operation was not clear according to these reports.

The first long-term results¹³ of the CET from a single institution by Castrovinci showed that only 45% of patients underwent the second-stage operation, as insufficient recovery from the first-stage operation made them hesitant to undergo additional operations. However, the conclusion of this report was that the long-term survival is increased when the first and second stages are completed. This indicates that the second-stage operations should be completed if possible.

In our series, there was no hospital mortality or interval mortality in the CET group because the median interval was set to be as brief as possible; indeed, the median duration between first and second stages was approximately one month. There was no second-stage mortality. All of the patients in the CET group completed second-stage TEVAR. The concept of this strategy may also help select an adequate trunk length. There was no need to place a longer trunk in the first stage. In fact, no cases of spinal cord injury (SCI) were noted among the patients in the CET group after the first stage; however, 5% (2 patients) presented with paraparesis after second-stage TEVAR. Both cases recovered within a few days. Previous reports¹⁴⁻¹⁸ of the first-stage elephant trunk graft placement followed by second-stage TEVAR reviewed by Miyamoto¹² showed an acceptable complication rate, including a mortality rate of 6.1%, SCI rate of 4.6% and a stroke rate of 0%. The author concluded that the greatest disadvantage of this method is the risk of late endoleaks (7.4%). Our strategy to use an adequate length for the CET and shorten the duration between the first and second stages helped reduce the SCI rates.

The FET technique was first introduced by Kato,³ and its use has become widespread. The comparison study between the CET and FET conducted by the Hannover group¹⁹ included the largest patient cohort from a single institution. That study demonstrated a significantly better survival for patients who underwent the FET than those who underwent the CET. The survival was also significantly better in acute dissection cases. The reduced survival in the CET group may have been due to incomplete stabilization of the dissecting membrane or sealing of the false lumen. In the Hannover study, only 24% of the CET group underwent the second-stage procedure, of which 19% underwent open surgery and 5% underwent endovascular techniques. The remaining 76% of the cases did not complete repair of the remaining part of the descending aorta, which might have contributed to the significantly lower survival. Similar to the conclusion of Castrovinci's¹³ study, the second-stage procedure should be completed whenever possible, regardless of whether a surgical or endovascular technique is used. In our series, all of the cases underwent endovascular completion, and there was no significant difference in the survival between the FET and the CET with TEVAR.

A review from previous reports using a large-volume series^{12,20-26} demonstrated an average mortality rate of 6.4% with the FET compared to 10.7% with the CET. However, the most severe disadvantage regarding the FET appears to be the increased risk of temporary or permanent SCI (average: 3.7%, range: 2.8%–7.5%). Our series also had a high SCI rate of 16.6%, with the use of a handmade stent resulting in a particularly increased incidence rate of SCI (20.5% [8/39] compared to Frozenix[®] at 6.7% [1/15]). The single SCI case due to the use of a commercially available device (Frozenix[®]) recovered before discharge.

The mechanism underlying the high SCI rates in the FET group is multifactorial, with risk

factors including age >75 years old, a history of abdominal aortic aneurysm and a deep landing zone below the Th7 vertebral level.²⁷⁻²⁹ The incidence of SCI might be associated with single-stage repair involving a cardiopulmonary bypass with deep hypothermia, extensive open reconstruction and extensive coverage of the descending aorta.³⁰ In our series, the FET was initiated with a handmade Z-stent, and the indications for the FET were both true aneurysm and dissection. Most of the SCI cases with the handmade FET occurred in cases of true aneurysms, with three of these cases having a deep landing zone below the Th9 level. According to our previous reports,⁴ SCI frequently occurs in fusiform-type aneurysms, a finding that may support the notion of embolization as an etiology due to the large space between the aneurysm wall and the handmade endovascular graft in these cases.

The stability of the distal part of the FET with a Z-stent graft, which is a partially covered stent, compared to that with a “whole” stent graft (Frozenix®) is another issue. The previous multicenter early study of Frozenix® by Uchida et al⁵ described the differences between the devices prepared using the Z-stent graft and Frozenix®, with Frozenix® showing favorable trackability with a curved aortic arch. Furthermore, the authors noted good outcomes with a 5% hospital mortality rate and 6.7% SCI occurrence rate, 1 case of paraplegia and 3 cases of paraparesis.⁵ Our results with Frozenix® were similar to those of the multicenter study. Our primary indications for the FET with Frozenix® are acute and chronic aortic dissection, because of its better trackability than true aneurysm. Extended aortic aneurysms are indicated for the CET following by planned TEVAR. Since the Frozenix® became available in Japan in 2014, the indications for the FET have changed in our institution; thus, the FET was applied only for aortic dissection cases in the present study, not for true aortic aneurysms, due to the increased incidence of SCI. The distal side of the open stent should be landed above the Th8 level or more proximally in order to prevent SCI events. Further investigations will be necessary to clarify the mechanism underlying this complication.

The study limitations include the small number of patients, the varied aortic pathology among patients and the retrospective observational design. A randomized controlled study may be needed to compare the effectiveness of both techniques for aneurysms and dissection.

In conclusion, we performed the FET and CET for both true aortic aneurysms and dissection and compared the outcomes of the techniques, with similar results being found for the rates of survival and aortic events. However, the FET had inferior results to the CET regarding the incidence of paraplegia. The CET followed by second-stage TEVAR with two-stage repair achieved better early results than the FET with a low risk of paraplegia and may produce favorable mid-term outcomes for extensive aortic arch repair.

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CONFLICT OF INTEREST

There was no conflict of interest.

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