



Early and mid-term results of frozen elephant trunk procedure for acute type A aortic dissection

Akut tip A aort diseksiyonu için frozen elephant trunk işleminin erken ve orta dönem sonuçları

Mustafa Akbulut¹, Adnan Ak¹, Özgür Arslan¹, Davut Çekmecelioğlu¹, Serpil Taş¹, Arzu Antal Dönmez¹, Mesut Şişmanoğlu¹, Mehmet Altuğ Tuncer¹

Department of Cardiovascular Surgery, Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital, İstanbul, Turkey

ABSTRACT

Background: This study aims to investigate the early and mid-term results of total thoracic aorta repair with E-vita OPEN PLUS stent graft, which we used to remove the residual false lumen and prevent late-term complications in patients with acute type A aortic dissections.

Methods: The study included 41 patients (29 males, 12 females; mean age 51.9±10.4 years; range, 30 to 77 years) who underwent total thoracic aorta repair with frozen elephant trunk stent graft for acute type A aortic dissection between November 2013 and November 2017. The reduction in false lumen size and thrombosis were evaluated by repeated computed tomography-angiography on 10th day and third, sixth, and 12th months.

Results: Six patients (14.6%) were lost during hospital stay and one patient (2.4%) was lost during the follow-up period. Frozen elephant trunk stent graft's distal end at descending aorta ended at T₆, T₇, and T₈ levels in 15 (36.6%), 21 (51.2%), and five (12.2%) patients, respectively. The supra-aortic vessels were re-implanted separately in 21 (51.2%) or as island in 20 (48.8%) patients. Transient paraparesis (spinal cord ischemia) was observed in only one patient (2.4%), while permanent neurologic deficit (stroke or coma) was observed in two patients (4.9%). Mean duration of follow-up was 26.5±20.5 months. Computed tomography-angiography at first month showed that false lumen became thrombosed at rates of 93.9% and 54.5% at pulmonary trunk and diaphragmatic level, respectively.

Conclusion: We believe that total arcus repair in acute type A aortic dissection treatment with single-session frozen elephant trunk technique by ensuring early false lumen thrombosis is safe and successful.

Keywords: Aortic zones, false lumen, frozen elephant trunk, type A aortic dissection.

ÖZ

Amaç: Bu çalışmada akut tip A aort diseksiyonlu hastalarda rezidüel sahte lümeni çıkarmak ve geç dönem komplikasyonları önlemek için kullandığımız E-vita OPEN PLUS stent grefti ile total torasik aort onarımının erken ve orta dönem sonuçları araştırıldı.

Çalışma planı: Çalışmaya Kasım 2013 - Kasım 2017 tarihleri arasında akut tip A aort diseksiyonu nedeniyle frozen elephant trunk stent grefti ile total torasik aort onarımı geçiren 41 hasta (29 erkek, 12 kadın; ort. yaş 51.9±10.4 yıl; dağılım, 30-77 yıl) dahil edildi. Sahte lümen boyutundaki azalma ve tromboz 10. günde ve üçüncü, altıncı ve 12. aylarda tekrarlanan bilgisayarlı tomografi-anjiyografi ile değerlendirildi.

Bulgular: Altı hasta (%14.6) hastanede kalış süresinde ve bir hasta (%2.4) takip süresinde kaybedildi. Frozen elephant trunk stent greftin distal ucu inen aortta T₆, T₇ ve T₈ düzeylerinde sırasıyla 15 (%36.6), 21 (%51.2) ve beş (%12.2) hastada sonlandı. Supra-aortik damarlar 21 hastada (%51.2) ayrı şekilde veya 20 hastada (%48.8) adacık olarak yeniden implante edildi. Geçici paraparezi (spinal kord iskemisi) sadece bir hastada (%2.4) gözlenirken iki hastada (%4.9) kalıcı nörolojik defisit (inme veya koma) gözlemlendi. Ortalama takip süresi 26.5±20.5 ay idi. Birinci aydaki bilgisayarlı tomografi-anjiyografi sahte lümenin pulmoner gövde ve diyafragmatik düzeyde sırasıyla %93.9 ve %54.5 oranında tromboze olduğunu gösterdi.

Sonuç: Erken dönem sahte lümen trombozunu sağlayarak tek aşamalı frozen elephant trunk tekniği ile akut tip A aort diseksiyonu tedavisinde total arkus onarımının güvenli ve başarılı olduğunu düşünüyoruz.

Anahtar sözcükler: Aort bölgeleri, sahte lümen, frozen elephant trunk, tip A aort diseksiyonu.

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Correspondence: Mustafa Akbulut, MD, Kartal Koşuyolu Yüksek İhtisas Eğitim ve Araştırma Hastanesi, Kalp ve Damar Cerrahisi Kliniği, 34865 Kartal, İstanbul, Turkey. Tel: +90 506 - 351 33 34 e-mail: dr_mustafa_akbulut@yahoo.com

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In acute type A aortic dissections (ATAADs), the primary aim of the surgical intervention is to ensure the survival of patient by preventing aortic rupture. The principal of conventional treatment via ascending aorta replacement is to allow the distal flow by protecting the unity of aortic wall and the resection of the segment, where intimal rupture is located. Although it is a treatment protocol having successful results with acceptable mortality rates in short-term,^[1-5] extension of residual false lumen towards distal in late period affects the prognosis. In patients surviving during acute period, the patent false lumen mostly leads to aneurysm in distal aorta.^[4] Particularly, the development of aneurysm-caused rupture is the main reason of late-period deaths.^[5] As long as false lumen stays patent, the risk of death continues in long-term, and re-operations will be inevitable.^[6-8] In this study, we aimed to investigate the early and mid-term results of total thoracic aorta repair with E-vita OPEN PLUS (JOTEC™ GmbH, Hechingen, Germany) stent graft, which we used to remove the residual false lumen and prevent late-term complications in patients with ATAADs.

PATIENTS AND METHODS

This retrospective study included 41 patients (29 males, 12 females; mean age 51.9±10.4 years;

range, 30 to 77 years) who were diagnosed with ATAAD and underwent total thoracic aorta repair with frozen elephant trunk (FET) stent graft (E-vita OPEN PLUS, JOTEC™ GmbH, Hechingen, Germany) in Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital between November 2013 and November 2017. Demographic characteristics of patients were presented in Table 1. The study protocol was approved by the Kartal Koşuyolu Yüksek İhtisas Training and Research Hospital Ethics Committee. A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All patients were diagnosed by computed tomography (CT) angiography and examined for cardiac function and valve pathologies with echocardiography. In all patients, the primary rupture started from ascending aorta while additional secondary rupture was observed in 13 patients (31.7%). Radiological and anatomic characteristics of the dissection were presented in Table 2.

Six patients (14.6%) developed renal malperfusion-caused acute renal dysfunction. Mesenteric ischemia or visceral malperfusion was not observed in any patient. Two patients (4.9%) applied for paraplegia caused by spinal cord ischemia. One patient (2.4%) developed right hemiplegia due to occlusion of left carotid artery

Table 1. Patients' demographic characteristics

	n	%	Mean±SD	Limits
Age (year)			51.9±10.4	30-77
Gender				
Male	29	70.7		
Coronary artery disease	4	9.7		
Body mass index			27.4±4.9	18.5-39.1
Diabetes mellitus	5	12.2		
Chronic obstructive pulmonary disease	4	9.7		
Acute renal failure	6	14.6		
Hypertension	34	82.9		
Cerebrovascular accident	3	7.3		
Spinal cord ischemia	2	4.9		
Visceral malperfusion	0	0		
Lower extremity ischemia	1	2.4		
Ejection fraction <%35	4	9.7		
Marfan syndrome	3	7.3		
Previous operation	3	7.3		
Aortic valve replacement	1	2.4		
Coronary artery bypass grafting	1	2.4		
MVR + TDVA	1	2.4		

SD: Standard deviation; MVR: Mitral valve replacement; TDVA: Tricuspid De Vega annuloplasty.

Table 2. Radiological and anatomic features of aortic dissections

	n	%	Mean±SD	Limits
Diameters (mm)				
Ascending aorta			49.7±7.9	31-66
Arcus aorta			40.2±9.1	30-82
Descending aorta			37.6±8.8	20-65
Abdominal aorta			31±5.5	19-47
Visceral branches with dissections				
Celiac artery	14	34.1		
Superior mesenteric artery	6	14.6		
Right renal artery	8	19.5		
Left renal artery	16	39		
Right iliac artery	16	39		
Left iliac artery	15	36.6		

SD: Standard deviation.

by dissection flap. But his neurologic deficit recovered during the transfer from neurology clinic to our hospital.

In one patient, ATAAD was detected via CT angiography performed due to the suspicion of dissection flap in echocardiography which was performed because of deterioration of medical status on second postoperative day after mitral valve replacement and tricuspid De Vega procedure. The patient underwent an urgent operation after resuscitation.

The reduction in false lumen size and thrombosis were evaluated by repeating the CT angiography on 10th day and third, sixth, and 12th months. Evaluation was performed using lumen and pseudo-lumen diameters and measurements performed at two different levels of descending aorta. Levels were determined as descending aorta at pulmonary bifurcation level^[1] and the descending aorta at diaphragmatic level.^[2] Thrombosis evaluation was classified in accordance with false lumen contrasting. False lumen reduction was assessed by comparison with preoperative CT angiography.

Patients underwent operation within the first 14 days from the start of back pain and other symptoms of acute dissection. Early mortality was defined as mortality within the first 30 days. Contrast thoraco-abdominal CT was utilized in diagnosis and follow-up of aortic pathologies. Acute renal dysfunction was defined as the increase in serum creatinine level higher than 1.8 mg/dL without known previous renal dysfunction. Cerebral vascular disease definition was defined as having a cerebrovascular event before 72 hours. Patients considered as

suspicious by intensive care unit team for neurological deficit during physical examination were consulted by a neurologist.

In our study, the E-vita OPEN PLUS prostheses were used in all patients. Central catheter, arterial monitorization via left arm, cerebral pulse oximeter, and cerebrospinal fluid pressure catheter were used routinely in all patients. Arcus repair was performed in moderate hypothermia using unilateral selective antegrade cerebral perfusion (flow rate=10-15 mL/kg/min). However, when significant decrease in saturation was detected via cerebral pulse oximeter, bilateral antegrade selective cerebral perfusion was performed.

Median sternotomy was applied to all patients. While right subclavian artery was used for arterial cannulation, venous drainage was provided by using right atrium. Vent cannula was placed from upper-right pulmonary vein. Myocardial protection was ensured with blood cardioplegia. Proximal aorta repair was performed in cooling phase. When nasopharyngeal temperature was 26°C, aortic clamp was removed, and selective antegrade cerebral perfusion was started. E-vita OPEN PLUS prosthesis was fixed to aorta wall via single U sutures at 1 cm distal of left subclavian artery. The stent graft size was calculated by considering the real lumen diameter of aorta measured in tomography preoperatively. When the arcus elements were anastomosed with separate grafts, proximal suture line of FET graft was shifted to between left carotid artery and left subclavian artery and a fourth branch was added to provide distal perfusion. In all patients, FET prosthesis placement

Table 3. Intraoperative values

	n	%	Mean±SD
Left subclavian artery coverage	5	12.2	
Additional procedures			
Aortic valve reconstruction	4	9.7	
Aortic valve repairment	1	2.4	
Coronary artery bypass grafting	3	7.3	
Bentall procedure	4	9.7	
Mitral valve replacement	1	2.4	
Mean nasopharyngeal temperature (°C)			25.8±1.9
Mean operation duration (min)			
Total perfusion duration			205.3±48.7
Anterograde selective cerebral perfusion			74.2±27.7
Visceral ischemia			64.9±22.4

SD: Standard deviation.

into the true lumen was confirmed with the guidance of trans-esophageal echocardiography. Then, the E-vita OPEN PLUS prosthesis was anastomosed to pre-implanted proximal Dacron graft. Because no dissection was detected in arcus components in islet-shape arcus aorta replacement cases, arcus aorta was repaired by resecting only the small curvature of arcus aorta and protecting the unity of descending aorta and islet including the components of aortic arch as we described previously.^[9]

Statistical analysis

The IBM SPSS version 22.0 (IBM Corp., Armonk, NY, USA) software was used in statistical analyses.

In analyzing the study data, besides the definitive statistical methods (mean, standard deviation, and frequency), paired sample t-test was utilized in preoperative-postoperative comparison of quantitative data. A *p* value <0.05 was considered as statistically significant.

RESULTS

The supra-aortic vessels were re-implanted separately in 21 (51.5%) or as island in 20 patients (48.5%). In all patients, right subclavian artery was utilized for arterial cannulation, and bilateral anterograde selective cerebral perfusion was used.

Table 4. Postoperative values

	n	%	Mean±SD
In hospital mortality	6	14.6	
Total mortality	7	17.1	
Secondary re-intervention to distal aorta	5	12.2	
Pulmonary complications	7	17.1	
Dialysis			
Temporary	6	14.6	
Permanent	1	2.4	
Stroke	2	4.9	
Transient paraparesis	1	2.4	
Duration of intensive care unit stay (day)			7.2±4.9
Duration of hospital stay (day)			12.8±13.2
Re-sternotomy			
Tamponade	5	12.2	
Bleeding	6	14.6	

SD: Standard deviation; Pulmonary complications: Ventilator support for >3 days or tracheostomy; Renal failure: Postoperatively developed serum creatinine level of >2.5 and transient or permanent dialysis.

Table 5. Computed tomography-angiography findings at follow-up (n=33)

False lumen status in follow-up CT angiography	n	%	Mean±SD
At pulmonary artery level			
Total thrombosed	31	93.9	
Partial thrombosed	1	3	
Patent	1	3	
Diaphragmatic level			
Total thrombosed	18	54.5	
Partial thrombosed	10	30.3	
Patent	5	15.2	
Descending aorta diameter			
Preoperative			37.3±9.2
Postoperative			31.2±4.7

SD: Standard deviation; CT: Computed tomography

Operative data and the distribution of operations by pathologies were presented in Table 3.

Hospital mortality rate was 17.1% (n=6). The causes of death were aortic complications (n=3), multiple organ failure (n=1), stroke (n=1), and low cardiac output syndrome (n=1). One patient had Marfan syndrome and died on second postoperative day due to bleeding diathesis.

Second patient who had Marfan syndrome applied to our clinic with complaint of difficulty in breathing one month postoperatively. No aortic pathology could be detected in the patient, but he was intubated due to pulmonary regurgitation, and died in 66th postoperative day due to multiple organ failure. Third patient was 76 years old and applied to another center with complaint of dyspnea. No aortic complication

was detected in controls and he was diagnosed with pneumonia, but died due to pulmonary failure.

Frozen elephant trunk stent graft's distal end at descending aorta ended at T₆, T₇, and T₈ levels in 15 (36.6%), 21 (51.2%), and five (12.2%) patients, respectively. While paraparesis (spinal cord ischemia) was observed in only one patient (2.4%), permanent neurologic deficit (stroke or coma) was observed in two patients (4.9%). The patient having paraparesis had no neurologic deficit when discharged. Other postoperative complications were presented in Table 4.

Data of 24 patients were compiled for follow-up until January 2018 and only one patient died during follow-up. Mean duration of follow-up was 26.5±20.5 months. Besides the decrease in aorta diameters, false lumen was thrombosed in short-term. Postoperative CT findings were presented in Table 5.

Pre- and postoperative aortic diameters were compared with t-test in dependent groups. There was a statistically significant difference between pre- (37.4±8.9) and postoperative (31.8±4.9, p<0.001) aortic diameters. The mean difference between the two groups was 5.60 mm (95% confidence interval [8.10-3.09]) (Figure 1).

DISCUSSION

In ATAAD, which has high mortality and morbidity rates and courses noisily, the main aim is to save the life of patient.^[10-12] Immediate, simple, and effective repair of proximal aorta or hemi arcus aorta has successful results in short-term.^[13-15] However, the development of late complications in long-term and the remarkably high reoperation rates have effects on mortality and the quality of life of patient.^[11,16]

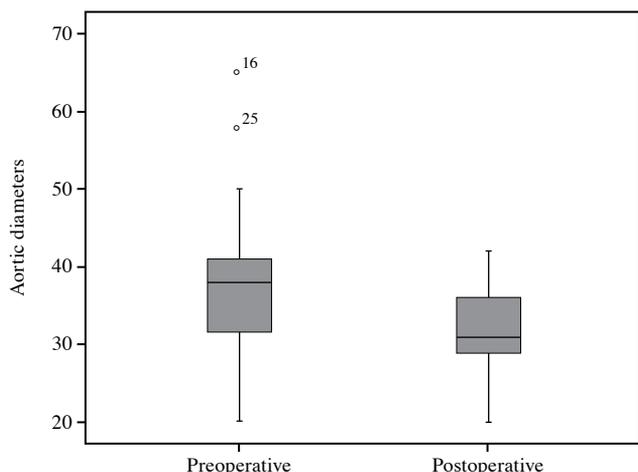


Figure 1. Comparison of pre- and postoperative aortic diameters.

The first 30-day mortality rate of conventional type A aortic dissection surgery has been reported to be between 9% and 21%.^[13,14] In a systematic examination and meta-analysis of Tian et al.^[17] on FET-implemented patients, the first 30-day mortality in ATAAD has been reported to be 7.7% (0-18.2%). The mortality rates represented in our study are compatible with the literature.

While Uchida et al.^[18] reported 2.5% for stroke, 3.8% for transient renal failure, 7.5% for lung failure, and 5% for bleeding revision in postoperative follow-up, Roselli et al.^[19] reported the stroke rate as 12%, lung failure as 12%, and renal failure as 19%. Both teams have reported the percentage of paraplegia as 0%. In our study, the percentage of stroke was observed to be 6.9%, pulmonary complications 7%, and newly developed renal failure 14.6%, while no paraplegia was observed.

The most feared complication that can develop even though measures are taken for FET is the newly developed neurologic deficit.^[20] In a multi-center study of Tsakagis et al.,^[21] the percentage of stroke development has been reported to be 10%, while the percentage of paraparesis has been observed to be 1%. Moreover, in a meta-analysis of their study of FET implementation in ATAAD, Tian et al.^[17] have reported stroke between 0% and 11.8% and spinal cord damage between 0% and 8.3%. Even if advanced age is considered to be a risk factor for stroke,^[22] aortic dissection involving acute pathology forms an operation-independent risk factor. However, the stent graft ends below T₈ and the occlusion of the intercostal arteries due to the closure of the left subclavian artery by the graft are accepted to be particular predisposing risk factors for spinal cord damage. Our study produced similar results with the literature.

Supra-coronary graft replacement is a simple and classical treatment method of ATAAD. Residual dissection due to patent false lumen may develop complications that consequently necessitate reoperation in long-term and increase mortality. The reoperation risk of aorta in distal residual dissection segment after conventional dissection surgery is at a remarkable level of 30%.^[6-8] There are three important factors here: segmented diameters of aorta, non-thrombosed false lumen, and uncontrollable hypertension.^[23] With FET technique, false lumen decreases and becomes totally thrombosed at the level of graft even in short-term. In segment at distal of the graft, false lumen has been determined to be highly thrombosed.^[24-25] In our study, CT angiography performed in the follow-up

showed that false lumen became fully thrombosed at rates of 93.9% and 54.5% at pulmonary trunk and diaphragmatic level, respectively.

The limited number of retrospective data and cases limits our study; however, the study could represent the advantages and success of single-phase distal aorta treatment of ATAAD in mid-term. Long-term follow-up is required to compare the results of FET technique with residual-dissection-caused complications observed in long-term.

In conclusion, to prevent complications such as rupture and malperfusion that can develop due to false lumen gap, we believe that performing total arcus repair in acute type A aortic dissection treatment with single-session frozen elephant trunk technique by ensuring early false lumen thrombosis is safe and successful.

Declaration of conflicting interests

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EDITORIAL COMMENT

Anil Z. Apaydin

Type A acute aortic dissection (TAAAD) is the most catastrophic disease of the aorta. Patients with TAAAD may present with a wide variety of symptoms and the clinical picture may vary from a very stable one to a state of shock due to tamponade or severe malperfusion. The primary goal of the operation for this lethal disease is the survival of the

patient. There are number of surgical alternatives ranging from a simple ascending aortic replacement to valve preserving root replacement and total arch replacement. The secondary goal is to provide the surviving patient with a life eliminating future risks of possible distal aortic rupture or intervention/operation.

According to the authors of this article, total arch replacement with frozen elephant trunk (FET) is a procedure which can achieve the aforementioned goals.^[1] However, I have concerns about the efficacy and the safety of this operation.

The idea of elephant trunk operation emerged as a two-stage solution in patients with mega-aortic pathologies to facilitate the second stage. It received criticism due to high combined mortality of the two stages and the interval between them. With the introduction of endovascular techniques, the second stage could have been completed by a thoracic endovascular aortic repair (TEVAR) procedure. The technique of FET with the use of hybrid grafts facilitated the second stage even further by providing a convenient landing zone. The FET has been used in TAAAD to obliterate the false lumen in the descending aorta with the expectation that it would prevent the dilatation of the distal aorta in long-term and it would relieve the malperfusion in short-term.

In their retrospective analysis of 41 patients with TAAAD who underwent total arch replacement with FET, the authors reported that the false lumen of the descending aorta became thrombosed, particularly at the proximal part.^[1] The authors also reported that this technique decreased the size of the descending aortic diameter, compared to the preoperative values. The overall mortality and morbidity rates in this series compare favorably with those in previous similar reports. However, the rate of malperfusion (particularly the visceral malperfusion which was not seen in the series) is less than the usual reports regarding acute dissection. It is well-known that malperfusion syndrome which is seen in about 30% of the TAAAD significantly increases the operative mortality.^[2] The difference between the pre- and postoperative diameters of the descending aorta could be explained by the pressure drop in the false channel by the closure/exclusion of the intimal tear during the proximal repair, not because of the implementation of FET. The rate of temporary neurological dysfunction (i.e., lethargy and agitation) and left diaphragm paralysis due to a trauma to the recurrent laryngeal nerve should have been also mentioned, since they are common complications of prolonged brain protection and total arch replacement, respectively.

The FET is a technically difficult operation, particularly in patients with TAAAD considering the inherited risks of this disease such as friable aorta, coagulation problems, and metabolic changes due to malperfusion. The reported bleeding and tamponade

rate in this series seems to be slightly high. It may not be easy to place a stented graft into a dissected descending aorta in every patient and stent-induced new entry is another potential problem.

This technique can not overcome the impact of distal reentries below the bottom of the FET which can cause the dilatation of those segments. The rate of distal reinterventions was significant in a report of 94 TAAAD patients who underwent FET.^[3] In a report by Zierer,^[4] in which the follow-up was 100% complete, only 15 distal aortic reoperations were required in 168 operative survivors of TAAAD within a mean period of 60±50 months postoperatively. Therefore, every patient does not need a prophylaxis. The factors which influence the natural history of the residual aorta still remain incompletely understood and the effect of the patent false lumen on the prognosis is debatable.

To expose an acutely ill patient to a longer period of brain and lower body ischemia for a prophylactic application of FET should be only justified by a very solid evidence. To the best of my knowledge, it is not available yet. Currently, this approach should be used in clinically stable patients with a tear or reentry tear in the distal aortic arch or proximal descending aorta.

Despite all the criticism I have made for this technique, I do appreciate the current work and also, the ongoing efforts of this group for pioneering FET technique in Turkey in an attempt to provide dissection patients with an improved quality of life without secondary interventions.

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Correspondence: Anil Z. Apaydın, MD. Ege Üniversitesi Tıp Fakültesi Kalp ve Damar Cerrahisi Anabilim Dalı, 35100 Bornova, İzmir, Turkey. Tel: +90 232 - 388 10 23 e-mail: anil.apaydin@ege.edu.tr