

Early period results for repair of complex thoracic aortic diseases with E-vita open stent graft

Mustafa Akbulut¹, Özgür Arslan¹, Adnan Ak¹, Serpil Taş¹, Davut Çekmecelioğlu¹,
A. Arzu Dönmez¹, Mesut Şişmanoğlu², Altuğ Tuncer³

¹⁾ Kosuyolu Kartal Heart Training and Research Hospital, Department of Cardiovascular Surgery, MD, Istanbul, Turkey

²⁾ Kosuyolu Kartal Heart Training and Research Hospital, Department of Cardiovascular Surgery, Prof. Dr., Istanbul, Turkey

³⁾ Kosuyolu Kartal Heart Training and Research Hospital, Department of Cardiovascular Surgery, Assoc. Prof., Istanbul, Turkey

Abstract

Aim: Nowadays, usage of hybrid techniques in complex aortic diseases, especially in the high risk patient group for conventional surgery, enables us to cope with the challenges posed in major surgery and reduce complications. In this study, we evaluate our early results in patients who underwent Frozen Elephant Trunk procedure using e-Vita Open stent grafts for complex aortic disease.

Methodology: A total of 61 patients (mean age 56 ±11.5, 50 patients (81.9%) were male) who underwent E-vita Open Plus repair between January 2013 and October 201, with the diagnosis of either acute / chronic type I aortic dissection, acute / chronic type III aortic dissection, or thoracic aortic aneurysm were analyzed retrospectively. 21 patients (34.4%) had acute / chronic type I aortic dissection, 22 (36.0%) had acute / chronic type III aortic dissection, 11 (18.0%) had thoracic aortic aneurysm and 7 (11.4%) had residual type I aortic dissection.

Results: Arterial cannulation sites were right subclavian artery in 57 patients (93.4%), brachiocephalic artery in 2 patients (3.2%) and ascending aorta in 2 patients (3.2%). The mean times for antegrade cerebral perfusion and cardiopulmonary bypass were 80 minutes (range 52-167) and 178 minutes (range 105-350) respectively. First 30-day mortality rate was 7 (11.4%). In terms of neurological deficit, 2 patients (3.2%) had paraplegia, 3 (4.9%) had major stroke/coma and one (1.6%) had right hemiplegia. Patients with paraplegia and hemiplegia recovered completely and were free of any neurological deficits during discharge.

Conclusion: Frozen elephant trunk procedure is a good alternative method which makes the techniques of surgical repair more feasible in the treatment of complex aortic diseases and enables us to use the combination of surgery and endovascular techniques to reduce complications.

Key words: Aortic dissection, complex repair, frozen elephant trunk, early results

Akbulut M., Arslan Ö., Ak A., et. al. Early period results for repair of complex thoracic aortic diseases with E-vita open stent graft
EJCM 2017; 05 (1): 01-06. Doi: 10.15511/ejcm.17.00101.

Introduction

Classic surgery procedure in complex thoracic aortic diseases has high rate ratio of mortality and morbidity as well as its difficulty.¹ For this reason, it was applied to hybrid methods in order to eliminate the risks of classic surgery and render it more feasible. The evolution process began with conventional Elephant Trunk Procedure and two-stage treatment protocols were formed by combining endovascular stent grafts. Nowadays this becomes one-stage applicable form by means of stent grafts implanted by antegrade route. Frozen elephant trunk technique, of which we have used open surgery with concomitant endovascular treatment is a hybrid treatment procedure that has acceptable and lower rate of mortality and morbidity when compared to classic surgery.²

In our clinic, the first implementation of FET procedure was begun with a patient diagnosed with thoracic aortic aneurysm in 2012. We began to use it widely in complex aortic diseases after gaining experience by expanding the field of application with Type I and Type III aortic dissections. In our study, we present the early period results of FET procedure performed on complex aortic diseases between the years of 2013 and 2015.

Materials and Methods

Patient profile

61 patients who underwent to Frozen elephant trunk stent graft implementation and thoracic aortic surgery between January 2013 and October 2015 were included in this study. Data were collected prospectively and examined retrospectively. Their average age was 56.0 ± 11.5 (between 25 to 81) and 50 patients were men (81.9%). The demographic properties of patients are shown in **Table 1**. The diagnoses of cases at the time of admission to hospital were pointed out in **Table 2**.

Definitions

Early mortality definition corresponds to the first 30-day mortality. Emergency surgery includes the patients who were operated within the first 24 hours of the beginning of symptoms and admission to the hospital. Preoperative and postoperative contrast enhanced thoracoabdominal computed tomography was used for the diagnosis of aortic pathology, preoperative planning

and follow-up of the patients. During the physical examination patients who had findings that might point out a possible neurological complication, were consulted and followed up by a neurologist. Patients who had a previous pulmonary disease diagnosis or pulmonary function tests with FEV1 <30% and FEV1/FVC <50% were accepted to have COPD. Serum creatinine

Table 1. The characteristics of the patients

	n (%)	Range
Age	56.09±11.5	25-81
Sex (Male)	50 (81.6%)	
CAD	9 (14.7%)	
BMI	25.8±2.7	
DM	7 (11.4%)	
COPD	17 (27,8%)	
Serum creatinine > 1.7mg/dL	3(4,9%)	
HT	55 (90,1%)	
CVE	3 (4,9%)	
EF<%35	5 (8,1%)	
Marfan Syndrome	4 (6,5%)	
ARSA	2 (3,2%)	
Emergency	23 (37,7%)	
Previous Operations	10 (16,3%)	
Valve	1 (3.8%)	
Dissection or aneurysm	7 (11.4%)	
TEVAR	2 (3.2%)	
Vascular	1 (1.6%)	
Aortic diameters (mean ± SD, mm)		
Ascending aorta	47.8±10.9	30-82
Aortic arch	41.5±8.2	30-80
Descending aorta	51.3±13.1	31-83

CAD: Coronary artery disease, **DM:** Diabetes mellitus, **COPD:** Chronic obstructive pulmonary disease, **HT:** Hypertension, **CVE:** Cerebrovascular event, **EF:** Ejection fraction, **ARSA:** Aberrant right subclavian artery, **TEVAR:** Thoracic Endovascular Aneurysm Repair, **SD:** Standart deviation

levels of 1.7 mg/dL or more were accepted as renal failure. Patients who had a history of coronary artery disease or were newly diagnosed during the preoperative diagnostic evaluation, were included in coronary artery disease group. Cerebrovascular events that occurred more than 72 hours ago correspond to cerebrovascular disease definition.

Operation technique

In our study, E-vita Open Plus prosthesis were used in all cases. Central catheter, arterial monitorization in left arm, cerebral pulse oximetry were routinely used in all patients. The drainage catheter of cerebrospinal fluid were implemented in cases with acute type I aortic dissection. Arcus repair was done at medium hypothermia with unilateral selective antegrade cerebral perfusion (flow rate 10-15 kg/min). In case of detecting a significant decrease at cerebral pulse oximetry we switched to bilateral selective antegrade cerebral perfusion by insertion of an additional arterial cannula in left carotid artery. Median sternotomy was implemented in all patients. To initiate cardiopulmonary bypass left subclavian artery, brachiocephalic artery or ascending aorta was used for arterial cannulation, whereas right atrial or bicaval cannulation was used for venous drainage. Venting cannula was placed in right superior pulmonary

vein. Myocardial protection was provided by blood cardioplegia. Proximal aorta repair was performed on cooling phases. When nasopharyngeal temperature was at 26 oC, it was switched to selective antegrade cerebral perfusion by removing aortic clamp. E-vita Open Plus prosthesis were fixed to the aortic wall with U sutures at Zone 2 and Zone 3 levels. FET prosthesis was verified to be in true lumen by transesophageal echocardiography guidance in patients with dissection. Afterwards, Dacron graft which was previously anastomosed to proximal aorta and E-vita Open Plus prosthesis were anastomosed to each other.

Graft Size Choice

In patients with aneurysm suitable stent graft size was arranged by oversizing (10-20%) the landing zone for descending aorta. Stent graft size in patients with dissection was determined by measuring actual lumen diameter and native descending aorta diameter at the level of left subclavian and it was not oversized. Seventh thoracic vertebra was determined as border level where distal edge of FET stent graft ended. However, this changed depending on height of patient and proximal anastomosis level.

Statistical Analysis

The statistical analysis were performed with the SPSS 22.0 statistical software. Data were analyzed by using descriptive statistical methods such as mean, standard deviation and frequency.

Intra Operative Results

Most commonly used surgical technique with FET procedure was the separated graft in the ascending aorta and the islet-shaped replacement of aortic arch in 34 patients (55.7%). Right subclavian artery was primarily chosen for arterial cannulation (n:57, 93.4%). Operation information and distribution of operation types were stated in **Table 3**.

Postoperative Results

On the first 30 days, 7 patients were lost in total of (11.4%). 2 of these patients (3.2%) had type I aortic dissection and 1 (1.6%) had ruptured aneurysm. These 3 patients (6.5%) were cases among ones applied to emergency department. It was found that the causes

Table 2. Admission diagnosis of aortic pathologies

	n (%)
Acute Type I Aortic Dissection	17(27.8%)
Chronic Type I Aortic Dissection	4(6.5%)
Acute Type III Aortic Dissection	3(4.9%)
Acute Type III Aortic Dissection + Ascending Aorta aneurysm	4(6.5%)
Chronic Type II Aortic Dissection	6(9.8%)
Chronic Type III Aortic Dissection + Ascending Aorta aneurysm	9(14.7%)
Descending aorta aneurysm	2(3.2%)
Diameter of thoracic Aorta > 55mm	7(11.4%)
Ruptured Thoracic Aorta	2(3.2%)
Residual Type I Aortic Dissection	7(11.4%)

of their death were aortic (n:3), multiple organ failure (n:3), neurologic (n:1).

In postoperative ICU follow-ups, patients who had suspicious findings during physical examinations were evaluated by neurologist. It was determined that 3 patients (4.9%) had permanent neurologic deficit (stroke and coma) and 4 patients had (6.5%) spinal cord ischemia (paraplegia and paraparesis) and 1 patient (1.6%)

Table 3. Distribution of operative parameters

	n (%)
AASGI + Aortic arch (island) + FET	34(%55,7)
AASGI + Debranching (Y graft) + FET	12(%19,6)
FET + Debranching	6(%9,8)
FET	7(%11,5)
FET + Antegrad Visceral Debranching	2(%3,3)
Additional interventions	
Benthall de Bono	6(%9,8)
Aortic suspension	2(%3,3)
CABG	1(%1,6)
Mitral valve	5(%8,2)
Endovascular	1(%1,6)
Cannulation	
Axillary	57(%93,4)
Brachiocephalic	2(%3,3)
Ascending aorta	2(%3,3)
Transesophageal temperature (oC) mean (±SD)	24.85±3.67
Operational values (min) mean(±SD)	
Total perfusion time (minutes)	178.57±49.71
ASCP (minutes)	80.08±25.29
Visceral ischemia (minutes)	72.49±23.67

FET: Frozen Elephant Trunk, AASGI: Ascending aorta separated graft interposition, CABG: Coronary Artery Bypass Grafting ASCP: Antegrade Selective Cerebral Perfusion

had hemiplegia. Neurologic deficit was not detected in physical examinations of 2 patients with paraplegia and a patient with hemiplegia during discharging from hospital. Most of the patients with stroke were observed in patients with type I aortic dissection (n:2, 66.7%) and spinal cord injury was observed to occur more frequently in patients with type III aortic dissection (n:2, 50%). The other postoperative complications were shown in **Table 4**.

Discussion

The description of new intervention models has been needed with the requirement of gross surgery in order to access descending aorta in treatment of complex aortic diseases.

After Borst and coworkers³ described the conventional elephant trunk technique; the combination of thoracic endovascular aortic repair technique (TEVAR) with this conventional technique inspired the two-stage treatment of complex aortic diseases.⁴⁻⁶ Afterwards, Kato and coworkers⁷ took first steps of one-stage treat-

Table 4. Distribution of post operative properties

	n (%)
30 day mortality	7(%11,5)
Stroke	3(%4,9)
Paraplegia	2(%3,3)
Paraparesis	2(%3,3)
Hemiplegia	1(%1,6)
Pulmonary Complications	5(%8,2)
Renal Failure (Permanent/Temporary)	7/2(%11,5/3,3)
Wound complications	5(%8,2)
Re-exploration: Tamponade	6(%9,8)
Re-exploration: Bleeding	5(%8,2)
Re-exploration: Sternal dehiscence	2(%3,3)
ICU duration days (mean±SD)	4.93±5.66
Discharge day (mean±SD)	14.11±14.96

ICU: Intensive Care Unit

ment by doing replacement of stent graft through antero-grade route and pioneered the improvement on antegrade implantation of stent grafts with increasing experience and development of technology until today.⁸⁻¹³

In our study, mortality was observed as 9.6% for first 30 days and this was found to conform to the literature. Mortality varied between 3.8% and 17.2% in conducted studies using FET technique without grouping complex aortic diseases.^{8,10,14,15,16} When the complex thoracic aortic diseases were arranged into groups, especially in type I aortic dissection, Pochettino and coworkers⁹ stated the conditions requiring emergency cardiac surgery as an independent risk factor for mortality and it was reported that mortality percentage was 13.9 for first 30 days. Likewise, as known, acute type I aortic dissection with mortality percentage varying between 7.8 and 18.2 in the literature was observed to be a predictive factor on mortality independently of operation.^{17,18} In our study, for acute type I aortic dissections, mortality was 11.7% for first 30 days.

In aortic arch surgery, the most important factor affecting mortality and life quality of patients is undoubtedly the development of neurologic complications. The prevalence of permanent neurologic deficit was higher in acute type I aortic dissections required immediate treatment since arcus components was affected easily by dynamics and mechanic changes caused by dissection flap.¹⁹ Similarly, in our study, the stroke development was found to be related with the acute type I aortic dissection.

Development of ischemic spinal cord injury is the most feared complication in cases with descending aorta pathologies requiring surgical intervention. Utilization of cerebrospinal fluid drainage, adjusting the distal landing zone above the level of T7, keeping the antero-grade perfusion time short, paying attention to the continuity of left subclavian artery are the precautions that can be taken for spinal cord protection. However, in spite of the protection methods of spinal cord, percentages of paraplegia as 21.7 and 24^{14,20} stated in the

literature are demoralizing, the presence of successful series stated as 8% and 9%^{13,21} is encouraging.

In our study, spinal cord injury was 5.7 % and patients with type III aortic dissection were majority and this was in accordance with the literature.²⁰ In cases with type I aortic dissection which required urgent surgical repair of proximal aorta, it is stated that the possibility of a re-intervention to the distal aorta will be markedly high within 10 years, with a ratio of 25-30%.²²

With our gaining experience from patients with these residual type I aortic dissections in our clinic, we have implemented a single stage arcus aorta replacement and FET technique in acute type I aortic dissection patients who are young in age or have Marfan syndrome or have descending aorta diameter of 40mm or more in order to prevent the late period of complications related to a secondary rupture or a patent false lumen in arcus and descending aorta. Also, complex thoracic diseases are progressing pathologies and therefore the stent will prevent enlargement and retrograde tear on the proximal suture line of the graft.

This proximal suture line contrary to the thoracic endovascular aneurysm repair (TEVAR) prevent both the formation of type Ia endoleak and reduce the risks of paraplegia without affecting the flow of left subclavian artery.^{23,24} In this study, there are restrictions due to the limited number of patient groups and the lacking of a long follow-up period. However, even with these data sufficient evidences showing treatment principles were presented and results reflecting literature were obtained. More accurate results will be obtained by enlargement of patient series and randomization of groups.

Frozen elephant trunk procedure, which makes the repair techniques of surgery more feasible in the treatment of complex aortic diseases and provides us to use the combination of surgical and endovascular techniques to reduce complications, is a good alternative method that has acceptable mortality and morbidity rates.

References

1. DeBakey ME, McCollum CH, Graham JM. Surgical treatment of aneurysms of the descending thoracic aorta. *J Cardiovasc Surg*. 1978;19:571-6.
2. Tian DH, Wan B, Di Eusanio M, Yan TD. Systematic review protocol: the frozen elephant trunk approach in aortic arch surgery. *Ann Cardiothorac Surg*. 2013 Jul;2(4):578.
3. Borst HG, Walterbusch G, Schaps D. Extensive aortic replacement using “elephant trunk” prosthesis. *Thorac Cardiovasc Surg*. 1983;31:37-40.
4. Safi HJ, Miller CC 3rd, Estrera AL, et al. Staged repair of extensive aortic aneurysms: morbidity and mortality in the elephant trunk technique. *Circulation* 2001;104:2938-42.
5. Etz CD, Plestis KA, Kari FA, et al. Staged repair of thoracic and thoracoabdominal aortic aneurysms using the elephant trunk technique: a consecutive series of 215 first stage and 120 complete repairs. *Eur J Cardiothorac Surg* 2008;34:605-14; discussion 614-5.
6. LeMaire SA, Carter SA, Coselli JS. The elephant trunk technique for staged repair of complex aneurysms of the entire thoracic aorta. *Ann Thorac Surg* 2006;81:1561-9; discussion 1569.
7. Kato M, Ohnishi K, Kaneko M, et al. New graft-implanting method for thoracic aortic aneurysm or dissection with a stented graft. *Circulation* 1996;94:II188-93
8. Shimamura K, Kuratani T, Matsumiya G, et al. Long-term results of the open stent-grafting technique for extended aortic arch disease. *J Thorac Cardiovasc Surg* 2008;135:1261-9
9. Pochettino A, Brinkman WT, Moeller P, et al. Antegrade thoracic stent grafting during repair of acute DeBakey I dissection prevents development of thoracoabdominal aortic aneurysms. *Ann Thorac Surg* 2009;88:482-9; 24. discussion 489-90.
10. Uchida N, Katayama A, Tamura K, et al. Long-term results of the frozen elephant trunk technique for extended aortic arch disease. *Eur J Cardiothorac Surg* 2010;37:1338-45.
11. Chen X, Huang F, Xu M, et al. The stented elephant trunk procedure combined total arch replacement for DeBakey I aortic dissection: operative result and follow-up. *Interact Cardiovasc Thorac Surg* 2010;11:594-8.
12. Sun L, Qi R, Zhu J, et al. Total arch replacement combined with stented elephant trunk implantation: a new “standard” therapy for type a dissection involving repair of the aortic arch? *Circulation* 2011;123:971-8.
13. Jakob H, Tsagakakis K, Pacini D, et al. The International 28. E-vita Open Registry: data sets of 274 patients. *J*
14. Leontyev S, Borger MA, Etz CD, et al. Experience with the conventional and frozen elephant trunk techniques: a single-centre study. *Eur J Card. Surg* 2013.
15. Ius F, Fleissner F, Pichlmaier M, et al. Total aortic arch replacement with the frozen elephant trunk technique: 10-year follow-up single-centre experience. *Eur J Cardiothorac Surg* 2013.
16. Di Eusanio M, Pantaleo A, Murana G, et al. Frozen elephant trunk—the Bologna’s experience. *Ann Cardiothorac Surg* 2013;2:597-605
17. Ma WG, Zheng J, Dong SB, et al. Sun’s procedure of total arch replacement using a tetrafurcated graft with stented elephant trunk implantation: analysis of early outcome in 398 patients with acute type A aortic dissection. *Ann Cardiothorac Surg* 2013;2:621-8
18. Xiao Z, Meng W, Zhu D, et al. Treatment strategies for left subclavian artery during total arch replacement combined with stented elephant trunk implantation. *J Thorac Cardiovasc Surg* 2013.
19. Conzelmann LO, Hoffmann I, Blettner M, Kallenbach K, Karck M, Dapunt O et al. Analysis of risk factors for neurological dysfunction in patients with acute aortic dissection type A: data from the German Registry for Acute Aortic Dissection Type A (GERAADA). *Eur J Cardiothorac Surg* 2012;42: 557-65.
20. Flores J, Kunihara T, Shiiya N, et al. Extensive deployment of the stented elephant trunk is associated with an 21. increased risk of spinal cord injury. *J Thorac Cardiovasc Surg* 2006;131:336-42
21. Pacini D, Tsagakakis K, Jakob H, Mestres CA, Armario A, Weiss G et al. The frozen elephant trunk for the treatment of chronic dissection of the thoracic aorta: a multicenter experience. *Ann Thorac Surg* 2011;92:1663-70.
22. Tsagakakis K1, Tossios P, Kamler M, Benedik J, Natour D, Eggebrecht H, Piotrowski J, Jakob H. The DeBakey classification exactly reflects late outcome and re-intervention probability in acute aortic dissection with a slightly modified type II definition. *Eur J Cardiothorac Surg*. 2011 Nov;40(5):1078-84.
23. Uchida N. How to prevent spinal cord injury during endovascular repair of thoracic aortic disease. *Gen Thorac Cardiovasc Surg*. 2014 Jul;62(7):391-7.
24. Czerny M1, Eggebrecht H, Sodeck G, Verzini F et al. Mechanisms of symptomatic spinal cord ischemia after TEVAR: insights from the European Registry of Endovascular Aortic Repair Complications (EuREC). *J Endovasc Ther*. 2012 Feb;19(1):37-43. doi: 10.1583/11-3578.1.

Received: 14/10/2016

Accepted: 17/02/2017

Published: 15/03/2017

Disclosure and conflicts of interest:

Conflicts of interest were not reported.

Corresponding author:

Dr. Davut Çekmecelioglu

Mail: d.cekmecelioglu@yahoo.com