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Original Article

Mid-Term Results of Frozen Elephant Trunk Technique for Chronic Aortic Dissection

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Objective: In this study, we report our experience using the frozen elephant trunk (FET) technique for chronic aortic dissection.

Methods: Between January 2011 and December 2017, 15 patients underwent total arch replacement (TAR) with the FET technique for chronic aortic dissection (CAD).

Results: Hospital mortality was 6.7% (n=1). No patients experienced spinal cord injury. Distal stent-induced new entry (dSINE) occurred in the early postoperative period in one patient. There were four unplanned additional operations to manage dSINE. Five patients suffered from dSINE, and aortoesophageal fistula developed in three of them. Short insertion length of the FET and large angle between the distal edge of the FET and the descending aorta were significantly more common in the dSINE group than in the non-dSINE group. The cumulative survival rates at 1, 3, and 5 years were 93.3%, 93.3%, and 66.4%, respectively. The cumulative aortic event-free rates at 1, 2, and 3 years were 85.7%, 77.1%, and 52.9%, respectively.

Conclusion: The FET technique for CAD provided good early results. Short insertion length of the FET, however, can induce dSINE, which requires an additional operation at mid-term. Thus, surgical indication of the FET technique for CAD must be discussed.

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Introduction

Many patients who have undergone previous aortic surgeries, including ascending aortic replacement, hemiarch replacement, or total arch replacement (TAR) for acute type A aortic dissection, later present with residual chronic aortic dissection (CAD) with patent false lumen. Such patients typically exhibit aneurysmal changes in the aortic arch or proximal descending aorta. In spite of recent improvements in devices for treating aortic dissection, the optimal methods for managing such conditions remain unclear.

Traditionally, patients with aneurysmal degeneration of the aorta due to chronic type B aortic dissection have been treated through open surgical repair. It is worth noting, however, that graft replacement approaching through the left thoracotomy is still challenging for aortic surgeons.[1)] More recently, thoracic endovascular aortic repair (TEVAR) has emerged as a less invasive alternative to open surgery for the treatment of aortic disease. TEVAR is also commonly used for chronic type B aortic dissection.[2)]

The frozen elephant trunk (FET) technique combines some aspects of open surgery with aspects of endovascular aortic repair. A device intended for the FET technique (Frozenix, Japan Lifeline, Tokyo, Japan) has been available since 2014[3)] in Japan, and several surgical strategies for aortic dissection have been developed based on this device. We previously reported the usefulness of the FET technique for acute type A aortic dissection.[4)] With regard to CAD, however, the literature to date has not clearly supported the usefulness of FET. To address this, we report here the mid-term results of our FET technique for the treatment of CAD, which we have used since 2011.

Materials and Methods

Patient characteristics

Between January 2011 and December 2017, we treated

15 patients using the TAR with FET technique. All 15 patients were indicated for surgery due to CAD with patent false lumen extending to the terminal aorta and aneurysmal degeneration in the distal portion of the aortic arch or the proximal portion of the descending aorta. Preoperative characteristics are shown in **Table 1**.

Table 1 Patient characteristics (N=15)

Preoperative characteristics	
Age, y	62.0±12.4
Male	12 (80.0%)
Hypertension	11 (73.3%)
Hyperlipidemia	6 (40.0%)
Diabetes mellitus	0 (0%)
Creatinine >1.2 mg/dL	3 (20.0%)
COPD	0 (0%)
Smoker	5(33.3%)
History of cerebrovascular event	1 (6.7%)
History of abdominal aortic surgery	1 (6.7%)
Marfan syndrome	1 (6.7%)
Right sided aortic arch	2 (13.3%)
History of thoracic aortic surgery for acute type A aortic dissection	12 (80.0%)
Ascending aortic replacement	11
Aortic root replacement	1
Months from onset to surgery	62.2±43.8
Operative variables	
Surgical time	499.3±98.8
Cardiopulmonary bypass time	268.4±59.2
Cardiac arrest time	142.8±49.2
Antegrade selective cerebral perfusion time	131.9±33.2
Lower body ischemia time	48.8±14.3
Lower body ischemia time >50 min	6 (40.0%)
Rectal temperature (°C)	27.1±0.8
Rectal temperature <25°C	0 (0%)
Concomitant surgery	2
CABG (SVG-RCA)	1
MVP+TAP	1
Frozen elephant trunk type	
Handmade	4 (26.7%)
J Graft Frozenix	11 (73.3%)
Insertion length of the FET (mm)	101±19.9
Distal landing position of the FET	
Th 5	2
Th 6	8
Th 7	4
Th 8	1
Th 9	0
mean	Th 6.3±0.8
Oversizing rate of the FET	11.2±1.0%
Angle between FET and Des Ao, °	15.2±15.9

COPD: chronic obstructive pulmonary disease; CABG: coronary artery bypass grafting; SVG: saphenous vein graft; RCA: right coronary artery; MVP: mitral valve plasty; TAP: tricuspid annulus plasty; FET: frozen elephant trunk; Des Ao: descending aorta

The mean age of this study population was 62.0±12.4 years. Twelve (80.0%) patients were male. All 12 (80.0%) had previously received graft replacements, including ascending aortic replacement or aortic root replacement for acute type A aortic dissection, and residual dissections were dilated more than 50 mm in the distal portion of the aortic arch or the proximal portion of the descending aorta. Two patients had chronic type A aortic dissection and one patient had chronic type B aortic dissection with ascending aortic aneurysm.

The mean duration between onset of acute aortic dissection and TAR with FET was 62.2±43.8 months (range, 13–151 months); all patients were observed more than 12-month period from the onset of aortic dissection.

The mean largest diameter of the aortic arch or the proximal descending aorta was 57±8.1 mm, the mean diameter of the descending aorta at the aortic valve level was 42.6±7.9 mm, and the mean diameter of the descending aorta at the diaphragm level was 35.3±6.9 mm.

Surgical techniques

The FET technique has been described in our previous report.[4] Briefly, a median sternotomy is performed under general anesthesia. An arterial perfusion cannula is inserted into the femoral or right axillary artery. A cannula for venous draining is inserted in both the superior and inferior vena cava from the right atrium, and total extracorporeal circulation is established. A left ventricular vent tube is inserted from the right superior pulmonary vein. After the rectal temperature has decreased to 28°C, antegrade selective cerebral perfusion (ASCP) is established (10–15 ml/kg/min). The origin of the left subclavian artery is dissected at the proximal end and the proximal stump is closed. The ascending aorta is then incised longitudinally to the origin of the left common carotid artery. After this incision is complete, the aortic arch is dissected transversely. Before inducing circulatory arrest, we perform transesophageal echocardiography (TEE) using the long-axis view of the proximal descending aorta. We then prepare the FET, selected in advance according to preoperative measurements, and insert it, confirming both visually and through TEE that it is in the true lumen. We then deploy the graft. Lower body perfusion (300–500 ml/min) for organ protection is performed via the femoral artery with an occlusion balloon catheter (Cook Medical, Bloomington, IN, USA) placed into the stented part of the FET. The adventitia of the aortic stump is covered with a felt strip, and the stump is reinforced with continuous 4-0 polypropylene sutures. A synthetic graft with four branches is anastomosed end-to-end at the stump of the distal aortic arch, and antegrade systemic perfusion is

started. The patient is re-warmed through extracorporeal circulation. The third branch is then anastomosed to the left subclavian artery. The left common carotid artery and the brachiocephalic artery are anastomosed to the respective branches of the graft. Finally, the proximal graft is anastomosed to the stump of the ascending aorta to complete the procedure.

Graft selection

Since 2014, we have used the J Graft Frozenix (Japan Lifeline Co., Ltd., Tokyo, Japan) for the FET technique; prior to that, we used handmade grafts. For each patient, we select an FET with a diameter of about 110–120% of the true lumen diameter, which we calculate from the circumference of the true lumen at the level of the descending aorta, where we have chosen as the distal landing position. We measured along the center line of the aorta from the origin of the left subclavian artery to the descending aorta at the level of T5 to T7 (mainly at level 2–3 cm proximal to the aortic valve) using preoperative computed tomography (CT) and selected the length of the stented part of the Frozenix.

Follow-up

One patient died within 30 days after the operation; the remaining 14 patients were followed up after surgery. The mean follow-up duration was 41.6 months (range, 15–72 months). Enhanced CT was routinely performed at 1, 6, and 12 months postoperatively and at yearly intervals thereafter to evaluate changes in aortic diameter, the degree of false lumen thrombosis, and presence of aortic events. In each CT scan, we measured the diameters of the aorta, the true lumen, and the false lumen at the level of the aortic valve and the level of the diaphragm of the descending aorta. Aortic events were defined as aortic disease causing death or necessitating further intervention or graft-related complications including distal stent-induced new entry (dSINE), infection, pseudoaneurysm, or branch occlusion.

Statistical analysis

Data are expressed as means ± SD. Continuous variables were analyzed using Student's t-test. Categorical variables were analyzed using a χ^2 univariate test. Calculated p values <0.05 were considered significant. Overall survival rate and aortic event-free rate were estimated using the Kaplan–Meier method. All statistical analyses were performed using JMP 14.0 statistical software (SAS Institute, Cary, NC, USA).

Ethics

This study complied with the standards of the Declaration of Helsinki and current ethical guidelines. It was approved by the institutional ethics board at the Hiroshima University Hospital (E-1847).

Results

Operative data

The operative variables are listed in **Table 1**. All patients received TAR with FET using ASCP and moderate hypothermia (28°C) to protect the brain and spinal cord. Mean surgical time was 499.3 ± 98.8 min, mean cardiopulmonary bypass time was 268.4 ± 59.2 min, mean cardiac arrest time was 142.8 ± 49.2 min, mean ASCP time was 131.9 ± 33.2 min, mean lower body ischemia time was 48.8 ± 14.3 min, and mean rectal temperature was 27.1 ± 0.8°C. We performed concomitant surgery in two patients: coronary artery bypass grafting in one case and mitral valve plasty with tricuspid annuloplasty in the other. We used the J Graft Frozenix device for 11 (73.3%) patients and a handmade FET for 4 (26.7%) patients. The mean insertion length of the FET was 101 ± 19.9 mm, the overall average outer diameter of the FET used in this study was 27.3 ± 2.3 mm (range, 23–31 mm), and the oversizing rate of the FET was 11.2 ± 1.0%. The average position of the distal edge of the FET was T6.3 ± 0.8.

Early and mid-term results

Postoperative variables are shown in **Table 2**. Hospital mortality was 6.7% (n = 1) and the cause of death was stroke; this was the only incidence of stroke (6.7%). No patients experienced spinal cord injury. Respiratory complications were seen in three patients (20.0%). One patient (6.7%) required additional TEVAR due to kinking of the non-stented part of the FET on the day following the operation. dSINE occurred in the early postoperative period in one patient with Marfan syndrome; this patient underwent additional TEVAR. Enhanced CT after surgery showed complete thrombosis of the false lumen in all patients at the FET level. Mid-term results were obtained in 14 patients, and the mean follow-up period was 40 months (range, 15–72 months). There were three (21.4%) mid-term deaths: one due to aortoesophageal fistula (AEF) in a patient who could not undergo surgery for AEF because of his bad general condition, one due to heart failure, and one due to lung hemorrhage after descending aortic replacement for AEF. The cumulative survival rates at 1, 3, and 5 years were 93.3%, 93.3%, and 66.4%, respectively (**Fig. 1A**). The cumulative aortic event-free rates at 1, 2, and 3 years were 85.7%, 77.1%, and 52.9%, respectively (**Fig. 1B**).

There were seven additional operations after TAR with FET. Three of these were planned surgeries: one additional TEVAR to close reentry, one descending aortic replacement due to dilatation of the descending aorta, and one false lumen occlusion to control false lumen flow.

Table 2 Early and mid-term results (N=15)

Follow-up duration, mo	40 (15–72)
Early mortality	1 (6.7%)
Operative death	0
Stroke	1
Early morbidities	
Cerebrovascular event	1 (6.7%)
Stroke	1 (6.7%)
TIA	0
Spinal cord injury	0
Lower limb ischemia	1 (6.7%)
Cardiac event (LOS)	0
Respiratory complication	3 (20.0%)
Mediastinitis	0
Sepsis	0
Intestinal ischemia	0
Kinking of FET	1 (6.7%)
dSINE	1 (6.7%)
Mid-term mortality	3 (21.4%)
Heart failure	1 (7.1%)
Aorto-esophageal fistula	1 (7.1%)
Lung hemorrhage	1 (7.1%)
Mid-term morbidities	
Cerebrovascular event	0
Spinal cord injury	0
dSINE	4 (28.5%)
Aorto-esophageal fistula	3 (21.4%)
Re-operation	7 (50.0%)
Planned operation	3 (21.4%)
Re-entry closure	1 (7.1%)
False lumen occlusion	1 (7.1%)
Descending aortic replacement	1 (7.1%)
Unplanned operation	4 (28.5%)
TEVAR due to dSINE	4 (28.5%)

TIA: transient ischemic attack; LOS: low output syndrome; FET: frozen elephant trunk; dSINE: distal stent induced new entry; TEVAR: thoracic endovascular aortic repair

The remaining four additional operations consisted of unplanned additional TEVAR to manage dSINE, which occurred in these four (28.5%) patients at 21.3 (10–31) months after leaving hospital.

Of the five patients (one in early period and others in mid-term period) with dSINE, two experienced false lumen rupture when dSINE occurred, and emergency TEVAR procedures were performed. The other three, including two patients with false lumen rupture, developed AEF. Of the three patients with AEF, two underwent staged surgery consisting of esophagectomy followed by graft replacement using a rifampicin-soaked Dacron graft and esophageal reconstruction. The remaining patient, who developed AEF 7 years after surgery, could not undergo staged surgery due to his bad general condition.

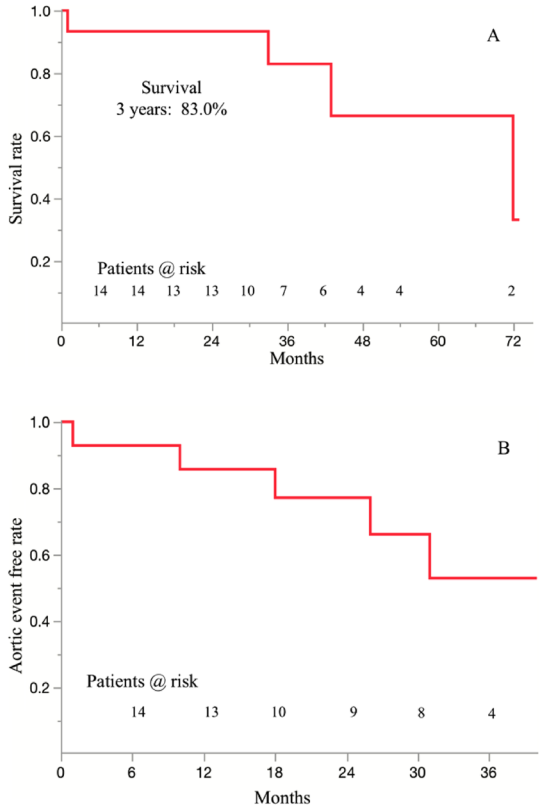

Fig. 1 (**A**) Kaplan–Meier estimate of overall survival. (**B**) Kaplan–Meier estimate of aortic event-free rate.

dSINE

The dSINE group (n=5) and non-dSINE group (n=9) are compared in **Table 3**. There was no significant difference between the groups in the cumulative oversizing rate of the FET or in the diameter ratio between the true and false lumen at the distal edge of the FET. There were significant differences, however, in the insertion length of the FET and in the angle between the distal edge of the FET and the descending aorta: short insertion length and large angle between the distal edge of the FET and the descending aorta were more common in the dSINE group (**Figs. 2A** and **2B**).

There was no significant difference in the occurrence of dSINE between the handmade FET group and the Frozenix group.

Aortic remodeling

The nine patients who did not develop dSINE were examined by enhanced CT for 2 years following surgery to assess aortic remodeling. The five patients who did develop dSINE were excluded from this portion of the study.

At the FET level of the aorta, enhanced CT at 12 months after surgery showed complete thrombosis in all nine patients. At the aortic valve level of the descending aorta, in contrast, complete thrombosis was seen in only seven (77.8%) patients; at the diaphragm level, it was seen in only

Table 3 dSINE group vs. non dSINE group

	dSINE n=5	Non-dSINE n=9	P value
J Graft Frozenix	3 (60%)	7 (77.8%)	0.34
Over size (circ, %)	8.8±10.7	14.5±11.8	0.41
Over size >20% (circ)	1 (20%)	2 (22.2%)	0.92
Diameter ratio of TL and FL at distal edge of the FET	2.5±0.5	3.6±0.4	0.42
FET insertion length (mm)	84.0±8.9	112±16.7	0.005
Angle between FET and Ao (°)	29.0±17.8	8.5±8.3	0.015

dSINE: distal stent induced new entry; TL: true lumen; FL: false lumen; FET: frozen elephant trunk; Ao: aorta

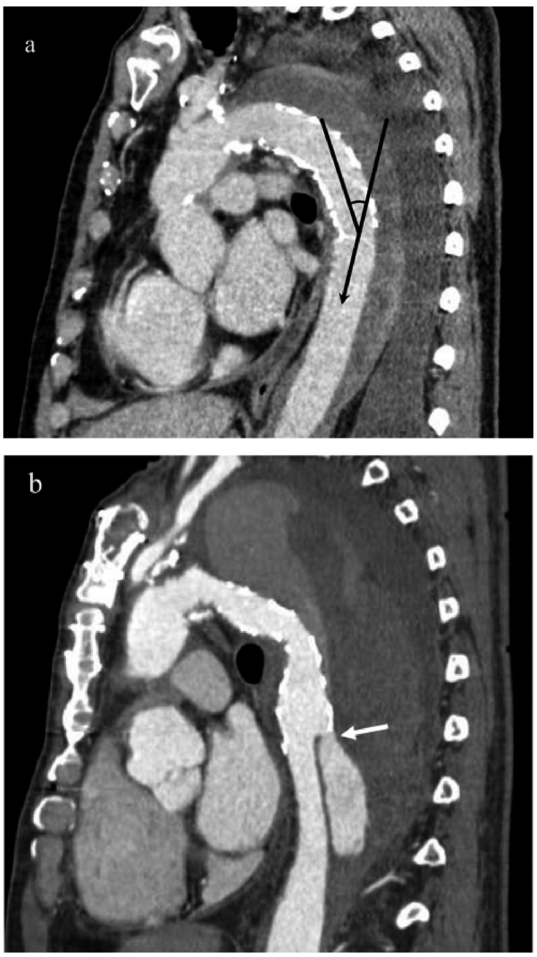

Fig. 2 Enhanced CT after TAR with FET. Short insertion length tends to result in a large angle between the distal edges of the FET (**a**) and is associated with dSINE (**b**: white arrow). CT: computed tomography; TAR: total arch replacement; FET: frozen elephant trunk; dSINE: distal stent induceld new entry

four (44.4%). The maximum diameter of the aorta, which was located at the FET level in all cases, decreased significantly from 56.5 ± 8.6 mm before surgery to 44.2 ± 9.1 mm 2 years later. At the aortic valve and diaphragm levels of the descending aorta, the aortic diameter did not decrease, although the diameter of the true lumen increased over time while the diameter of the false lumen decreased.

Discussion

Although open surgery including descending or thoracoabdominal aortic replacement is the "gold standard" method of treating CAD with aneurysmal change, the hospital mortality and morbidity rates for these procedures are still high.[2,5] The latest annual survey of thoracic and cardiovascular surgery in Japan revealed that the hospital mortality rate of descending aortic replacement was 7.6% in chronic type B aortic dissection.[5]

In recent years, TEVAR has emerged as a safer option for treating a multitude of aortic diseases including CAD. Conway et al.[1] have reported good outcomes of TEVAR for CAD. In that study, the mortality rate of TEVAR was 2.4% and the stroke and paraplegia rates were 0.8% and 2.4%, respectively.

There are also many reports suggesting aortic remodeling after TEVAR for CAD.[6–8] By occluding the primary entry tear, aortic remodeling with expansion of the true lumen (TL) and shrinkage of the false lumen (FL) at the thoracic aorta can be achieved. FL thrombosis rates range from 55% to 80% and are usually greater at the level of the thoracic stent graft than they are below the diaphragm level. Many studies have concluded that TEVAR for CAD has acceptable perioperative morbidity and mortality rates and that TEVAR is a useful alternative procedure for CAD.

In some cases, however, TEVAR cannot be performed for anatomical reasons. As reported here, we have performed the FET technique, which combines surgical and endovascular techniques, for patients with residual CAD with aneurysmal change at the distal aortic arch or the proximal descending aorta after graft replacement for acute type A aortic dissection or chronic type A aortic dissection.

To treat patients with previous graft replacements, we suggest TAR with descending aortic replacement via the antero-lateral partial sternotomy (ALPS) approach or the left thoracotomy approach, because most cases in this study had residual chronic dissection with aneurysmal change at the aortic arch and the proximal descending aorta. We have performed TAR with FET only through median sternotomy, and we expect expansion of the true lumen and shrinkage of the false lumen after this procedure. Thus, we infer that this procedure could be less

invasive than the graft replacement through the ALPS approach or the left thoracotomy approach.

To date, there have been few reports about the mid-term or long-term outcomes of the FET technique for CAD.[9–13] Di Eusanio et al.[9] reported short- and mid-term results after treatment of CAD with FET using the E-vita Open and E-vita Open plus (JOTEC® GmBH, Hechingen, Germany) devices. In their 49 patients, the hospital mortality rate was 10.2%, the neurological morbidity rate was 6.1%, and the spinal cord injury (SCI) rate was 10.2%. In our study, the hospital mortality rate was 6.7% (n = 1), the neurological morbidity rate was 6.7% (n = 1), and no SCI occurred. We conclude that our early results with this technique are acceptable.

Katayama et al.[14] reported that the cause of SCI after the FET technique is multifactorial and that placing the distal edge of the stent graft below T9 was one important contributing factor. In our study, no SCI occurred, presumably because the position of the distal edge of the FET was T6.3 on average and above T9 in all cases. This short insertion might have contributed to the absence of SCI in our patients.

In our study, there were three deaths during follow-up and a 5-year survival rate of 66.4%. We performed three planned additional surgeries: one false lumen occlusion, one reentry closure, and one descending aortic replacement. Unfortunately, dSINE occurred in five patients (33.3%) during follow-up (1–72 months), and two of these caused false lumen rupture. All five patients with dSINE underwent additional TEVAR, and all emergency surgeries in our patients were related to dSINE.

Kreibich et al.[13] performed the FET technique on 116 patients including 40 CAD patients. In their study, 20% of the CAD patients developed dSINE after FET, and 37.5% required re-intervention. They proposed that the incidence of dSINE was higher after FET than after conventional TEVAR.

Several factors have been considered as causes for dSINE,[13,15–19] and we propose that various factors among these contributed to the incidence of dSINE after TAR with FET in our series. First of all, when the FET device is passively bent at the aortic arch, self-expanding stent grafts including Frozenix have the inherent tendency to spring back to their initial straight position. This tendency could put stress on the greater curve of the aorta.[15] Moreover, this spring-back force may be particularly concentrated on the distal edge of the FET in the TAR with FET technique because the proximal edge of the FET is anastomosed.

Second, during the TAR with FET procedure, the distal position of the FET was determined only through TEE guidance without radiography. Thus, we could not deploy the FET exactly in the straight portion of the descending aorta, and the FET tended to be positioned in the distal portion of the aortic arch in our cases. In the dSINE group, the FET had a shorter mean insertion length and the angle between the distal edge of the FET and the descending aorta was larger compared to the non-dSINE group. This indicated that we were not able to insert the FET device in the straight position of the descending aorta in the dSINE group.

Li et al.,[16] who performed TEVAR in 579 patients with type B aortic dissection, concluded that stent grafts ≦145 mm in length and TEVAR done in the chronic phase were among the risk factors for dSINE.

Compared to previous reports on TAR with FET for CAD, the rate of dSINE in our series was high.[9] In studies with lower dSINE rates, the distal position of the FET was at T8–9 in 52.2% of cases and >T10 in 45.7% of cases; this indicates that the FET devices in these cases were successfully located in the straight portion of the descending aorta. These reports suggest that short insertion length could promote dSINE, while long insertion length could prevent it. Thus, additional TEVAR should be considered when the FET is not positioned in the straight portion of the descending aorta after surgery.

Finally, in patients with CAD, an FET device deployed at the narrowed true lumen with a thickened intimal flap cannot fully expand soon after deployment. Although the FET gradually expands over the long term, the intimal flap may not be able to withstand the radial force and dSINE may occur as a result. Several reports have concluded that distal oversizing of the stent graft is an independent predictor of the development of dSINE, and a significantly higher dSINE rate is seen in patients with distal stent graft oversizing >20%.[17] We selected grafts that were 10–20% oversized, calculated based on the circumference of the true lumen at the presumed distal landing zone, and our mean oversizing ratio was 11.2 ± 1.0%. Although we did not select excessively oversized grafts, a combination of spring-back force, short insertion length of the FET, large angle between the distal edge of the FET and the descending aorta, and radial force on the FET may have played a role in our relatively high rate of dSINE.

dSINE occurred at the proximal descending aorta, where the diameter of the false lumen was large. We speculate that the development of dSINE resulted in rapid loading on the large false lumen, leading to false lumen rupture in some cases. In our series, 60% of the dSINE patients experienced false lumen rupture. Meanwhile, AEF could develop due to mechanical compression by large hematomas or areas of inflammation around resorbed hematomas caused by rupture of the false lumen. Considering from the mid-term results, including this life-threatening AEF, surgical indication of the FET technique for CAD must be discussed. And, if the patient's condition permitted, open surgical graft replacement through the

ALPS approach or the left thoracotomy approach should be considered seriously.

This study was a retrospective review and there was no control group. Moreover, we are not able to provide a control group of patients with similar aortic diseases treated with other procedures. The follow-up period was too short and the number of patients was too small to conclude that the FET technique is an acceptable treatment method for CAD.

Conclusion

We report our early and mid-term results for TAR with FET for CAD. Short insertion length of the FET prevented SCI and provided acceptable short-term results but may have led to dSINE in the mid-term. Surgical indication of the FET technique for CAD must be discussed because half of our dSINE cases experienced false lumen rupture or AEF. If we performed FET technique for CAD, great care should be taken in determining the insertion length and graft diameter of the FET device. To prevent this critical complication, additional TEVAR should be considered when the FET is not positioned in the straight portion of the descending aorta after surgery. Close follow-up of all FET patients is required.

Disclosure Statement

Conflict of interest: none declared.

Additional Note

Written informed consent was obtained from the patient for publication of this report.

Author Contributions

Study conception: YY
Data collection: YY, TF
Analysis: YY, ST
Writing: YY
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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