Check for updates

# Total arch replacement with extended branched stented anastomosis frozen elephant trunk repair for type A dissection improves operative outcome

Kenichi Hashizume, MD, PhD,<sup>a</sup> Tadashi Matsuoka, MD, PhD,<sup>a</sup> Mitsuharu Mori, MD, PhD,<sup>a</sup> Hidenobu Takaki, MD,<sup>a</sup> Kiyoshi Koizumi, MD, PhD,<sup>b</sup> Hiroaki Kaneyama, MD,<sup>b</sup> Koji Funaishi, MD,<sup>a</sup> Kento Kuroo, MD,<sup>a</sup> and Hideyuki Shimizu, MD, PhD<sup>c</sup>

# ABSTRACT

**Objective:** Emergency surgical repair is the standard treatment for acute aortic dissection type A. However, the surgical risk of total arch replacement remains high. The Viabahn Open Revascularization TEChnique has been used for supraaortic reconstruction during total arch replacement. This Cleveland Clinic technique is called "branched stented anastomosis frozen elephant trunk repair." Our total arch replacement with reconstructed extended branched stented anastomosis frozen elephant trunk repair. We compared the outcomes of extended branched stented anastomosis frozen elephant trunk repair and conventional total arch replacement in acute aortic dissection type A.



Total arch repair with sutureless revascularization for dissected supra-aortic vessels.

#### CENTRAL MESSAGE

Sutureless revascularization of dissected supra-aortic vessels is an effective maneuver to simplify aortic arch repair with FET for the treatment of acute type A aortic dissection.

#### PERSPECTIVE

TAR for type A acute aortic dissection is associated with a high rate of complications. This study describes a TAR with EB-SAFER. This technique improves true lumen flow by sutureless anastomoses and dilation of the cervical branch with a self-expanding stent-graft without dissection. Further investigation is needed to determine the long-term outcomes.

**Methods:** We compared the clinical course of patients undergoing total arch replacement using sutureless direct branch vessel stent grafting with frozen elephant trunk (extended branched stented anastomosis frozen elephant trunk repair) for acute aortic dissection type A with patients undergoing conventional total arch replacement. For the procedure, the aortic arch was transected circumferentially distal to the brachiocephalic artery origin. Frozen elephant trunk was fenestrated by heating with a cautery, and the self-expandable stent graft was delivered into the branch vessels through the fenestration.

**Results:** Of 58 cases, 21 and 37 were classified in the extended branched stented anastomosis frozen elephant trunk repair and conventional total arch replacement groups, respectively. The times (minutes) of selective antegrade cerebral perfusion (75  $\pm$  24, 118  $\pm$  47), total operation (313  $\pm$  83, 470  $\pm$  151), and cardiopulmonary bypass (195  $\pm$  46, 277  $\pm$  96) were significantly better in the extended branched stented anastomosis frozen elephant trunk repair group (P < .001). Six surgical deaths occurred: 2 (9%) in the extended branched stented anastomosis frozen elephant trunk repair group. In all cases, only 1 patient (2%) in the conventional total arch replacement group had a branch artery-related complication during the postoperative follow-up period. In the extended branched stented anastomosis frozen elephant trunk repair group, blood product use significantly decreased (P < .05).

**Conclusions:** Extended branched stented anastomosis frozen elephant trunk repair has shown comparable safety and efficacy to conventional total arch replacement and can be used for acute aortic dissection type A emergency repair. It optimizes true lumen perfusion and facilitates supra-aortic artery remodeling. (JTCVS Techniques 2023;17:1-9)

From the <sup>a</sup>Department of Cardiovascular Surgery, Saiseikai Utsunomiya Hospital, Tochigi, Japan; <sup>b</sup>Department of Cardiovascular Surgery, Ashikaga Red Cross Hospital, Tochigi, Japan; and <sup>c</sup>Department of Cardiovascular Surgery, Keio University School of Medicine, Tokyo, Japan.

Institutional Review Board number 2020-48; date of approval September 24, 2020. Informed written consent for the publication of the study data was obtained from the patients.

Received for publication July 31, 2022; revisions received Sept 25, 2022; accepted for publication Oct 6, 2022; available ahead of print Nov 3, 2022.

Address for reprints: Kenichi Hashizume, MD, PhD, Department of Cardiovascular Surgery, Saiseikai Utsunomiya Hospital, Tokyo, Japan, 911-1 Takebayashicho, Utsunomiya, Tochigi 321-0974, Japan (E-mail: kenichihszm@mac.com). 2666-2507

Copyright © 2022 The Author(s). Published by Elsevier Inc. on behalf of The American Association for Thoracic Surgery. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/). https://doi.org/10.1016/j.xjtc.2022.10.011

Abbreviations and	Acronyms
-------------------	----------

AADA	= acute aortic dissection type A
<b>B-SAFER</b>	= branched stented anastomosis frozen
	elephant trunk repair
CT	= computed tomography
CTAR	= conventional total arch replacement
EAVR	= estimated arch vessel reconstruction
EB-SAFER	= extended branched stented
	anastomosis frozen elephant trunk
	repair
FET	= frozen elephant trunk
FFP	= fresh-frozen plasma
HCA	= hypothermic circulatory arrest
LSCA	= left subclavian artery
RBC	= red blood cells
SACP	= selective antegrade cerebral perfusion
SAVSTEB	= supra-aortic vessel anastomosis stent
	bridging
TAR	= total arch replacement

► Video clip is available online.

Emergency surgical repair is the standard treatment for Stanford acute aortic dissection type A (AADA); however, it carries a high morbidity. The primary goal of emergency surgical repair is to save the patient and minimize surgical risk.<sup>1-3</sup> To achieve this primary goal, the conventional approach has been conservative operation, typically limiting repair to include ascending and hemiarch replacement.<sup>1-5</sup> During intermediate-term follow-up, a large percentage of patients are at risk for degeneration of the downstream aorta and have an associated risk of death.<sup>6,7</sup>

In recent years, refinement of surgical techniques and availability of endovascular devices have made it feasible to perform an extended initial open surgery repair with acceptable risk.<sup>8-14</sup> The Cleveland Clinic has indicated that branched stented anastomosis frozen elephant trunk repair (B-SAFER), a simplified hybrid approach consisting of stented anastomosis frozen elephant trunk (FET) repair, has been developed and used for the extended emergency repair of acute DeBakey type I aortic dissections.<sup>8-10</sup>

We have also actively used the total arch replacement (TAR) with the Viabahn Open Revascularization TEChnique and successfully reconstructed the vertebral artery, which is a direct branch of the aortic arch.<sup>15</sup> Since then, extended B-SAFER (EB-SAFER) has been refined to improve its effectiveness and more easily disseminate its In the present study, we aimed to evaluate the safety and efficacy of EB-SAFER in the short term to the middle term and to focus on the advantages of the simple creation of a safe anastomosis. Our deliberate focus for this investigation was the clinical outcome of the arch procedure. The surgical results showed that EB-SAFER does not require exposing the cervical artery compared with CTAR in AADA.

# PATIENTS AND METHODS

# Patients

From 2016 to 2021, 58 patients underwent emergency repair of type A aortic dissection with a patent false lumen using TAR. EB-SAFER was performed in 21 of the 58 patients (36%) without exposing the cervical artery. The mean age of patients was  $58.7 \pm 13.8$  years, and there were 17 male patients (80.9%) (Table 1). The study was approved by the Institutional Review Board (Institutional Review Board Number: 2020-50; approval date: September 25, 2020) of our hospital. Informed written consent for the publication of the study data was obtained from the patients. Data were collected from the electronic medical records and computed tomography (CT) imaging studies. We have started using EB-SAFER from January 2020.

# Presentation

Once a definitive diagnosis was confirmed and the CT imaging revealed a proximal dissection, the patient was transferred to the operating room for emergency repair. The approach to repair was surgeon-specific. However, when the dissection was extensive, the latest version of EB-SAFER was preferentially adopted by several surgeons in our hospital.

Regarding the preoperative demographic characteristics of both groups (Table 1), one group with 21 patients underwent EB-SAFER and a second group with 37 patients underwent CTAR. For the EB-SAFER group and CTAR group, 7 patients (33.3%) and 7 patients (18.9%) presented with end-organ malperfusion, 1 (4.8%) and 5 (13.5%) with tamponade, and 1 (4.8%) and 1 (2.7%) with coma, respectively. Coexisting aortic pathology included rupture in 2 patients (9.5%) and 2 patients (5.4%), and thrombosis type (partial thrombosis in the false lumen) in 5 patients (23.8%) and 7 patients (18.9%), respectively. Preoperative CT scans were available for review in all patients (100%). Extension of the dissection into the branch vessels was found in 12 patients (57%) and 9 patients (24%), respectively. Only 1 patient in the CTAR group in our cohort study had a history of cardiac surgery, and emergency repair of the dissection was performed as a reoperation (Table 2).

# **Preparation and Operative Details**

**Device selection.** Three-dimensional CT imaging was reviewed to evaluate surgical anatomy and guide device selection. The sizing of stent grafts was based on the aortic diameter measured in cross-section to the centerline of blood flow at the Zone 1 level. We did not oversize the device as oversizing was not necessary for fixation because the device was sutured directly to the surgical graft.

An 11-mm or 13-mm diameter self-expandable stent graft was mostly commonly selected for the subclavian artery based on the CT measurements with minimal oversizing (Table 2). The length of the left subclavian artery (LSCA) was measured to the left vertebral artery. The preferred insertion length for branch vessel stent grafting was up to approximately 2.0 cm to avoid obstruction of the vertebral artery and vessel wall injury during direct placement into this often tortuous, decompressed subclavian artery.

If a patient has an abnormality in the left vertebral artery that originates directly from the aortic arch, a branched stent graft is used, one in the left

TABLE 1.	<b>Demographics and</b>	characteristic	details of the 58	patients who	underwent total	arch replacement

Variable	EB-SAFER	CTAR	P value
Patients (n)	21	37	
Age (y) Mean $\pm$ SEM	$58.7 \pm 13.8$	$58.8 \pm 14.2$	.975
Gender (male) No (%)	17 (80.9)	29 (78.4)	.751
Comorbidities No (%)			
Diabetes mellitus	2 (9.5)	0 (0)	.127
Dyslipidemia	5 (23.8)	7 (18.9)	.741
Coronary artery disease	0 (0)	1 (2.7)	1.000
Cerebrovascular disease	3 (14.3)	2 (5.4)	.341
COPD	2 (9.5)	3 (8.1)	1.000
Hypertension	13 (61.9)	29 (78.4)	.226
Hemodialysis	0 (0)	0 (0)	NA
Marfan syndrome	0 (0)	2 (5.4)	.530
Smoking	13 (61.9)	17 (45.9)	.284
Dissection state No (%)			
Rupture	2 (9.5)	2 (5.4)	.620
Malperfusion	7 (33.3)	7 (18.9)	.338
Tamponade	1 (4.8)	5 (13.5)	.402
Thrombosis	5 (23.8)	7 (18.9)	.748
Severity			
Euro score	2.4 (1.9-4.1)	2.7 (1.5-5.0)	.993
Japan score	10.9 (9.3-17.6)	7.7 (3.7-12.4)	.002
Entry tear site			.035
Ascending	1 (4.8)	13 (35.1)	
Arch	12 (57.1)	10 (27.0)	
Descending	7 (33.3)	11 (29.7)	
Unknown	1 (4.8)	3 (8.1)	

*EB-SAFER*, Extended branched stented anastomosis frozen elephant trunk repair; *CTAR*, conventional total arch replacement; *SEM*, standard error of the mean; *COPD*, chronic obstructive disease; *NA*, not available.

vertebral artery and one in the cervical branch. These were not performed in the current target group. Aortic morphologic features were assessed using 3-dimensional reconstruction imaging software (Endosize vascular; Therenva SAS).

**Operation.** The operation was performed under general anesthesia through a median sternotomy. Then, central aortic cannulation was used. Cardiopulmonary bypass was initiated and cooling was started. To achieve hypothermic circulatory arrest (HCA), the target blood and core temperature should be less than 20 °C, with a bladder temperature of less than 28 °C. Near-infrared spectroscopy was used to monitor the brain.

After reaching the desired level of cooling, selective antegrade cerebral perfusion (SACP) was instituted at a rate of  $10 \text{ cm}^3 \cdot \text{kg} \cdot \text{min}$  at a perfusate temperature of less than 18 °C. The mean circulatory arrest times were 55.0  $\pm$  19.9 minutes and 67.7  $\pm$  33.9 minutes for the EB-SAFER and CTAR groups, respectively. The proximal arch was transected at Zone 1 along the lesser curvature of the arch similarly to the conventional partial aortic arch repair. The open stent graft was delivered antegradely into the true lumen. We used the J Graft FROZENIX (Lifeline Co, Ltd) commercially available in Japan as FET. The device is positioned such that it lies proximally within the arch, covering the LSCA.

After deployment, the position of the branches of the aortic arch relative to the stent graft was inspected, and a hole approximately 80% of the diameter of the branched graft was burned into the stent graft to accommodate that vessel. The branch vessel graft (5.0-cm–long Viabahn; Gore Medical) was then placed directly through the hole into the target vessel and deployed into the target vessel with approximately 15 mm extending into the aortic arch lumen. The branching device was then dilated with an angle clamp, and a selective cerebral perfusion catheter was inserted and crimped into the stent graft by balloon dilation. The proximal end of the branched

stent graft was secured to the greater curvature of the aortic arch centrally with a mattress 5-0 polypropylene suture (Table 3).

The surgical graft was then beveled such that the shorter edge was aligned with the lesser curve of the aortic arch. For distal anastomosis, the proximal end of the inserted open stent graft was secured with a circumferential horizontal mattress suture after cutting the aortic wall at Zone 1 or 2. After the surgical graft was sutured in an end-to-end anastomosis, the proximal anastomosis of the surgical graft to the aortic root was then completed in the standard fashion (Figure 1, A-C).

We reconstructed the ascending aorta and brachiocephalic artery with a 2-branched arch graft (J Graft SHIELD; Japan Lifeline Co, Ltd), which is a woven gelatin-coated vascular prosthesis. An associated operative procedure is shown in the Video 1 and Video Abstract.

#### **Statistical Analysis**

Categorical variables were summarized using frequencies and percentages; continuous variables were summarized using median or mean  $\pm$  standard error of the mean. Estimated survival and freedom from reintervention were determined using the Kaplan–Meier method. All data were analyzed using SPSS 25.0 statistical software (SPSS Inc).

# RESULTS

# **Early Outcomes**

All the 58 patients underwent TAR for AADA. Technical success was achieved in all the EB-SAFER cases. The 30-day operative mortality was 9.5% (n = 2 of 21) in the EB-SAFER group and 10.8% (n = 4 of 37) in the CTAR

	EB-SAFER	CTAR	P value
Subjects	21	37	
Distal anastomosis level No. (%)			<.001
Zone 0	1 (4.8)	3 (8.1)	
Zone 1	11 (52.4)	5 (13.5)	
Zone 2	9 (42.9)	11 (29.7)	
Zone 3	0 (0)	16 (43.2)	
Diameter of the cervical branch (mm)			
Diameter of the self-expandable stent (mm)			
CCA Mean $\pm$ SEM, range	$9.0 \pm 1.2$ (7-10)	-	
	$10.1 \pm 1.1$ (8-11)		
LSCA	$10.7 \pm 1.0 \ (8.5-12)$	-	
	$12.1 \pm 1.2 \ (9-13)$		
Concomitant procedure No. (%)			
AVR	1 (4.8)	0 (0)	.362
CABG	1 (4.8)	1 (2.7)	1.000
ARR	0 (0)	1 (2.7)	1.000

TABLE 2. Operative characteristic details of the 58 patients who underwent total arch replacement

*EB-SAFER*, Extended branched stented anastomosis frozen elephant trunk repair; *CTAR*, conventional total arch replacement; *CCA*, common carotid artery; *SEM*, standard error of the mean; *LSCA*, left subclavian artery; *AVR*, aortic valve replacement; *CABG*, coronary artery bypass grafting; *ARR*, aortic root replacement.

group. Two patients presented with myocardial infarction of the left anterior descending artery and aortic root rupture in the EB-SAFER group, and 2 of the 4 patients presented with shock due to rupture and the other 2 presented with disseminated intravascular coagulation due to postoperative infection in the CTAR group.

There was no significant difference in the ventilator-free days (30) (26 [18-29] and 27 [5-28] days [P = .898]) and in the intensive care unit-free days (30) (24 [14-26] and 20 [3-23] days [P = .106]) between the EB-SAFER group and the CTAR group, respectively. Only 1 case of branch artery-related complication was found in the CTAR group (n = 1 of 37, 2.7%) (Table 4). No patients (0%) in the EB-SAFER group and 1 patient (2.7%) in CTAR group were deemed to be at a high risk of rupture due to the very rapid growth on CT before discharge. The patient underwent unexpected thoracic endovascular aortic repair

extension of the descending aorta during the same hospitalization. The additional procedures were well tolerated.

# **Surgical Outcome**

The potential benefit of the routine use of EB-SAFER in TAR may be estimated by looking at HCA, SACP, and estimated arch vessel reconstruction (EAVR) times as surrogate markers. The HCA times were 55.0  $\pm$  19.9 minutes and 67.7  $\pm$  33.9 minutes, and the SACP times were 75.6  $\pm$  24.6 minutes and 118.7  $\pm$  47.8 minutes for acute aortic dissections in the EB-SAFER and CTAR groups, respectively. Regarding the distal anastomosis procedure, The EAVR times were 26.8  $\pm$  14.5 minutes in the EB-SAFER group compared with 63.3  $\pm$  28.8 minutes in the CTAR group (P < .001). The outcomes of the total operation (313  $\pm$  83 and 470  $\pm$  151), cardiopulmonary bypass (195  $\pm$  46 and 277  $\pm$  96), and SACP (75.6  $\pm$  24.6 and

#### TABLE 3. Highlights of the procedure steps

1.	There is no oversizing
2.	Leave the stent from 15 to 20 mm into the lumen
3.	Caution with the left vertebral artery to limit the left subclavian stent to 2 cm
4.	Management of origin of the vertebral artery from the aortic arch
5.	Eye cautery to create a hole of 80% diameter
6.	If the subclavian artery is tortuous, insert the subclavian artery stent over the wire into the true lumen and deploy it.

7. Crimp the subclavian artery stent through the lumen with an angle clamp to prevent leakage at the junction of the stent and the FET, and then insert a selective cerebral perfusion catheter and crimp into the stent graft by balloon dilation.

8. Fix the subclavian artery stent to the greater curvature with a 5-0 monofilament suture, proximal to the lumen if the overhang is long.

FET, Frozen elephant trunk.



FIGURE 1. Making the fenestration stent-graft. The performance of EB-SAFER is shown. The FROZENIX (Lifeline Co, Ltd) was used for the FET. A, Opening of the fenestrated FET inserted after complete dissection of the aortic arch in Zone 1. B, Subsequent insertion of a device that will be a cervical branch using a small self-expanding covered stent. C, Demonstration of a completed repair with anastomosis in the proximal arch Zone 1 with the sutureless self-expandable covered stent in the supra-aortic arteries penetrating the FET and establishing a direct anastomosis to the innominate artery.

118.7  $\pm$  47.8) were significantly better in the EB-SAFER group than in the CTAR group, respectively (P < .001). There was no significant difference in complication occurrence between the 2 groups (Table 4).

# **Blood Products**

Comparison of the use of blood products showed a significant difference in the red blood cells (RBCs) (2 [0-7] and 10 [8-14] units; P < .001), fresh-frozen plasma (FFP) (6 [4-10] and 10 [8-14] units; P = .002), and platelets (20 [20-20] and 20 [20-40] units [P = .002]) between the EB-SAFER and CTAR groups for acute aortic dissections, respectively (Table 4).

# Survival and Freedom From Unanticipated Reintervention

For the results according to the status of the supra-aortic branches, estimated mortality and unanticipated intervention from Kaplan–Meier were examined for each comparison. There was no significant difference in the estimated mortality and unanticipated intervention between the EB-SAFER



**VIDEO 1.** The operative procedure and early and midterm results after EB-SAFER. Video available at: https://www.jtcvs.org/article/S2666-2507(22)00537-5/fulltext.

(P = .557) and CTAR (P = .554) groups. However, the EB-SAFER group tended to have less of both (Figure 2, *A* and *B*).

Stent patency was found in all 21 cases in the EB-SAFER group. There was no occurrence of negative factors due to the use of self-expanding stent grafts. There was no junction endoleak (Type 3), and the number of new-onset vessel dissections was low (Figure 3). One patient was additionally treated for type 1B endoleak of the subclavian artery. The additional treatment involved the use of a covered stent, and the endoleak disappeared. Consequently, there were no EB-SAFER–induced neurological complications. Only 1 patient (2.7%) in the CTAR group with dissection extending to the distal LSCA without symptoms had branch artery–related complications.

When inserting the FET, there was no dissection or pseudoaneurysm at the anastomosis. The cervical branch also had no dissection, anastomotic pseudoaneurysm, or leakage at the junction of the FET and the self-expanding stent-graft. The arch vessels healed to the distal arch with staged thoracic endovascular aortic repair.

### **Neurological Complications**

Three patients (10%) had postoperative radiographic evidence of stroke: 1 patient (3%) in the EB-SAFER group and 2 patients (5%) in the CTAR group. In the 1 patient in the CTAR group, there was an extension of the dissection into the branch vessels resulting in the dissection of the LSCA and vertebral artery with associated posterior stroke. One patient in the EB-SAFER group in whom encephalopathy occurred immediately after surgery eventually recovered.

# **Distal Aorta Remodeling**

All patients were evaluated by CT before and after 1 month postsurgery. To evaluate the morphology of the

	EB-SAFER	CTAR	
Subjects	n = 21	n = 37	P value
Time	Mean $\pm$ SEM		
Estimated arch vessels reconstruction	$26.8\pm14.5$	$63.3\pm28.8$	<.001
Total operation	$313.3\pm83.5$	$470.1 \pm 151.1$	<.001
Cardiopulmonary bypass	$195.2 \pm 46.4$	$277.5 \pm 96.2$	<.001
Cardiac arrest	$134.0 \pm 34.7$	$184.4 \pm 52.7$	<.001
Cerebral perfusion	$75.6 \pm 24.6$	$118.7 \pm 47.8$	<.001
Circulatory arrest	$55.0\pm19.9$	$67.7 \pm 33.9$	.126
Blood products	Units		
Red blood cells	2 (0-7)	10 (8-14)	<.001
Fresh-frozen plasma	6 (4-10)	10 (8-14)	.002
Platelets	20 (20-20)	20 (20-40)	.002
Ventilator-free d (30)	26 (18-29)	27 (5-28)	.898
ICU-free d (30)	24 (14-26)	20 (3-23)	.106
Mortality No (%)			
30 d	2 (9.5)	4 (10.8)	1.000
In-hospital	2 (9.5)	6 (16.2)	.696
Stroke	0 (0)	2 (5.4)	
Branch artery-related			
Complication No. (%)	0 (0)	1 (2.7)	1.000

TABLE 4. Surgical outcomes of the 58 patients who underwent total arch replacement

Short-term: 30-day mortality. Midterm: mortality in patients followed for more than 6 months. Ventilator-free days are the number of days within the first 28 days after enrollment during which a patient was able to breathe without a ventilator. Ventilator-free days in patients who died during the study period was assigned as 0. Intensive care unit–free days were calculated in the same manner. *EB-SAFER*, Extended branched stented anastomosis frozen elephant trunk repair; *CTAR*, conventional total arch replacement; *SEM*, standard error of the mean; *ICU*, intensive care unit.

dissected thoracic aorta, the aorta at the pulmonary artery level was analyzed based on the CT scan findings. The true and false lumen diameters were measured perpendicular to the contour of the intimal flap at the same level. To account for the aortic diameter, we calculated the true lumen index, defined as the ratio of the true lumen diameter to the total aortic diameter. The ratios of the true lumen index at follow-up visit to that at baseline were evaluated. There was no significant difference in the true lumen index (00 [18-29] and 27 [5-28] [P = .000]) between the EB-SAFER group and the CTAR group before and after surgery, respectively.



**FIGURE 2.** Estimated mortality and unanticipated intervention from Kaplan–Meier. Estimated mortality (A) and unanticipated intervention (B) from Kaplan–Meier were examined for each comparison; there was no significant difference between the EB-SAFER and CTAR groups (P = .557 and P = .554, respectively). The average and median follow-up times for EB-SAFER were 383 ± 252 and 365 days, ranging from 14 days up to 925 days, respectively. The average and median follow-up times for CTAR were 968 ± 968 and 721 days, ranging from 1 day up to 2286 days, respectively. *EB-SAFER*, Extended branched stented anastomosis frozen elephant trunk repair; *TAR*, total arch replacement.



Extended Branched Stented Anastomosis Frozen Elephant Trunk Repair (EB-SAFER) to the supra aortic vessels for type A acute aortic dissection: Early to midterm results

**FIGURE 3.** Summary of the TAR by EB-SAFER for AADA. Confirmation of retrograde blood flow after deploying of self-expanding stent grafts and postoperative 3-dimensional CT showed blood flow patency in the cervical branch. *CTAR*, Conventional total arch replacement; *FET*, frozen elephant trunk; *3D*, 3-dimensional.

# DISCUSSION

Whether an extended initial aortic repair for AADA should be performed remains the subject of active debate. Our experience shows that aortic replacement using a simplified FET operation is a safe and effective option for emergency extended repair of type A aortic dissection. FET repair can be performed with mortality comparable to that of the conventional hemiarch repair strategy even in patients with ischemia.<sup>8,11,13</sup>

The use of our EB-SAFER strategy has kept the cardiac arrest and SACP times relatively shorter. It eases management of complications in the chronic phase of dissection by facilitating later endovascular repair. The original B-SAFER technique is used to create the junction between the FET and the supra-aortic vessel and has been shown to be safe and efficacious. In this admitted patient cohort, it has been possible to secure perfusion of every cervical artery anatomically.<sup>16</sup>

The anatomic reconstruction of the supra-aortic vessels is particularly challenging if the distal anastomosis of the arch graft is moved distal to the LSA. The proximal transfer of anastomosis simplifies the distal sewing, thus reducing circulatory arrest and cerebral perfusion times and decreasing complications (eg, recurrent laryngeal nerve injury) as shown here and in other studies.<sup>17,18</sup> In such cases, the LSA is often managed by rerouting or complete debranching of all supra-aortic vessels.

In contrast, EB-SAFER allows an orthotopic reconstruction even if the distal anastomosis is moved to Zone 1. This is considered useful, particularly in young patients with acute aortic dissection, and clearly reduces the rate of abandoned subclavian arteries in this setting. However, in the present study, EB-SAFER significantly reduced the cardiac arrest and SACP times at 55 and 67 minutes compared with CTAR at 75 and 118 minutes, respectively, proving the superiority of EB-SAFER. The EAVR time was also significantly shorter.

With these improved technical aspects, the frequency of bleeding complications from the supra-aortic vessels decreased even in patients with acute dissection and have not been recently observed. The supra-aortic vessel anastomosis stent bridging (SAVSTEB) technique for reconstructing the arch branch using the Viabahn has been reported. The authors indicated that SAVSTEB causes residual extravasation from the anastomosis, whereas our EB-SAFER causes no extravasation.<sup>19</sup>

There are also differences between our EB-SAFER and the original B-SAFER. EB-SAFER is based on dissecting the aorta in Zone 1 and inserting self-expandable stentgrafts in the common carotid artery and LSCA, reinforced internally with FET and externally with felt. As a result, EB-SAFER is thought to make the anastomotic procedure easier. Moreover, EB-SAFER, which can use transection, does not cause suture dissection of the suture line. Additionally, because 80% fenestration is used and the SACP catheter is crimped intraoperatively after Viabahn deployment, the patient cannot experience persistent flow in the false lumen as reported by Guo and colleagues.<sup>20</sup>

On the other hand, B-SAFER, which reconstructs the brachiocephalic artery and common carotid artery in the form of islands, leaves the aortic tissue intact. Therefore, it is necessary to level the anastomosis along the aortic arch axis or dissection at Zone 2. EB-SAFER has the advantage of sutureless enlargement of the true lumen without bleeding even if the dissection extends into the cervical branches. Transfusion volume significantly decreased from 10 RBCs, 10 FFP, and 20 (20-40) platelet units in the CTAR group to 2 RBCs, 6 FFP, and 20 (20-20) platelet units in the EB-SAFER group, which may reflect a decrease in blood loss. There have been almost no specific problems associated with branched stent grafts during follow-up. There was no case observed in which a stented side branch of the arch graft showed obstruction and kinking or progressive narrowing.

EB-SAFER expectedly has some potential pitfalls. There is an inherent danger if the vertebral artery is overstented, particularly if the take-off from the LSCA is low. Here, some practice and experience in estimating the permissible depth of insertion of the stent into the recipient vessel are required. If the subclavian artery is extremely tortuous or dissected, careful Viabahn insertion is necessary.

At the beginning of the procedure, a guidewire was inserted from the left radial artery into the aortic arch via the LSCA. After the circulation was stopped, a pullthrough method was established and the Viabahn was inserted in a progressive manner. However, in this method, the subclavian artery was extended excessively by the pull-through method, causing difficulty in adjusting the length of the Viabahn insertion and complication of the procedure. Therefore, we now insert the top of the Viabahn directly into the origin of the subclavian artery through a homemade hole. If the device can be inserted 2 cm without resistance, it is deployed there. However, if there is resistance to the top, the device is inserted in an over-the-wire fashion to prevent complications.

However, compared with SAVSTEB, which requires the subclavian artery to be transected from the arch, EB-SAFER with its longer effective length of available vessels has fewer complications and less bleeding. There were no patients in our series who experienced accidental vertebral artery overstenting. In CTAR, although there were no complications related to the vertebral artery, the difficulty of distal anastomosis caused a significantly longer operative time in the present series of dissection.

Regarding the evolution of the suitable procedure and management of LSCA, Roselli and colleagues<sup>21</sup> reported that there are no commercially available hybrid stent-graft devices specifically designed to perform FET repair in the United States. In 2006, Roselli and colleagues<sup>21</sup> used a commercially available stent graft for antegrade delivery and started performing modified FET repair to treat complex thoracic aortic disease. Because EB-SAFER was first used at our institution, a series of refinements have been made to improve its efficacy. In Japan, the FROZENIX has been commercially available as FET since 2014. Although the importance of TAR for AADA remains high, many centers perform only ascending aortic replacement due to TAR's invasiveness. In contrast, the ratio of TAR using the FROZENIX as FET has been reported to be 12%.<sup>22</sup> In a recent meta-analysis, Takagi and colleagues<sup>14</sup> analyzed data from 15 studies involving 1297 patients who underwent FET operations for acute type A dissection. They reported a mortality rate of 9.2% and a spinal injury risk of 3.5%. Despite the encouraging results, their technique has not been widely adopted by centers in other countries, with only 2 studies in the United States. The slow adoption of their technique in Japan is partly due to the lack of available commercial devices.

Two other devices are now commercially available in Europe: the E-vita OPEN PLUS prosthesis (JOTEC GmBH) and the Thoraflex hybrid prosthesis (Vascutek). Both devices have been described using a more complex technique involving multiple anastomoses in the arch. Therefore, we introduced EB-SAFER as a simplified procedure and for further minimally invasive surgery using the FROZENIX. EB-SAFER is safe and effective for the emergency extended repair of AADA. This technique optimizes true lumen perfusion and promotes remodeling of the aorta. Thus, EB-SAFER may facilitate the management of late complications in the chronic phase of disease. Finally, the present study included EB-SAFER in 10 patients (47.7%) with dissection in the cervical branches. Among them, there was only 1 case of stroke complication in the acute phase. This may be due to the advantage of self-expanding stent grafts, which enlarge the lumen more distally.

# **Study Limitations**

This research was a retrospective study with the inherent limitations of such analysis. The analysis was also limited by the comparatively short follow-up of the characteristics of the patient cohort.

# CONCLUSIONS

EB-SAFER is a comparatively simple, safe, and efficacious technique for creating an anastomosis between the branched FROZENIX and the supra-aortic arteries compared with CTAR in the short and intermediate terms. EB-SAFER can be used for the emergency extended repair of AADA. It was successful in nearly all cases, and no subclavian artery had to be abandoned or reattached by extra anatomic means. However, a few procedure-related complications occurred in the earlier versions of SAVSTEB, where the cervical branch was exposed and the Viabahn was inserted. Particular attention should be paid to low dissection from the LSA, overstenting into the vertebral artery, and stent misplacement into the false lumen. Stent-related complications are extremely rare if the self-expandable stentgraft insertion procedure and its length are correct. It optimizes true lumen perfusion and facilitates remodeling of the aorta and supra-aortic artery if EB-SAFER anastomosis is properly performed. EB-SAFER anastomoses meet the technical requirement to move the FET technique forward to simplify this surgical procedure.

### **Conflict of Interest Statement**

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

The authors thank Dr Edward Barroga (https://orcid.org/0000-0002-8920-2607), Medical Editor and Professor of Academic Writing at St Luke's International University, for editing the manuscript.

#### References

- Sabik JF, Lytle BW, Blackstone EH, McCarthy PM, Loop FD, Cosgrove DM. Long-term effectiveness of operations for ascending aortic dissections. *J Thorac Cardiovasc Surg.* 2000;119:946-62.
- Westaby S, Saito S, Katsumata T. Acute type A dissection: conservative methods provide consistently low mortality. *Ann Thorac Surg.* 2002;73:707-13.
- Rice RD, Sandhu HK, Leake SS, Afifi RO, Azizzadeh A, Charlton-Ouw KM, et al. Is total arch replacement associated with worse outcomes during repair of acute type A aortic dissection? *Ann Thorac Surg.* 2015;100:2159-65; discussion 2165-6.
- 4. Nienaber CA, Powell JT. Management of acute aortic syndromes. *Eur Heart J*. 2012;33:26-35.
- Omura A, Miyahara S, Yamanaka K, Sakamoto T, Matsumori M, Okada K, et al. Early and late outcomes of repaired acute DeBakey type I aortic dissection after graft replacement. *J Thorac Cardiovasc Surg.* 2016;151:341-8.

- **6**. Olsson C, Hillebrant CG, Liska J, Lockowandt U, Eriksson P, Franco-Cereceda A. Mortality in acute type A aortic dissection: validation of the Penn classification. *Ann Thorac Surg.* 2011;92:1376-82.
- Hagan PG, Nienaber CA, Isselbacher EM, Bruckman D, Karavite DJ, Russman PL, et al. The International Registry of Acute Aortic Dissection (IRAD): new insights into an old disease. *JAMA*. 2000;283:897-903.
- Roselli EE, Rafael A, Soltesz EG, Canale L, Lytle BW. Simplified frozen elephant trunk repair for acute DeBakey type I dissection. *J Thorac Cardiovasc Surg.* 2013;145(3 Suppl):S197-201.
- 9. Roselli EE. Clearing the next hurdles in the treatment of acute ascending aortic syndrome. *Eur J Cardio Thorac Surg.* 2015;47:205-8.
- Roselli EE, Tong MZ, Bakaeen FG. Frozen elephant trunk for DeBakey type I dissection: the Cleveland Clinic technique. Ann Cardiothorac Surg. 2016;5: 251-5.
- Murzi M, Tiwari KK, Farneti PA, Glauber M. Might type A acute dissection repair with the addition of a frozen elephant trunk improve long-term survival compared to standard repair? *Interact Cardiovasc Thorac Surg.* 2010;11:98-102.
- 12. Vallabhajosyula P, Szeto WY, Pulsipher A, Desai N, Menon R, Moeller P, et al. Antegrade thoracic stent grafting during repair of acute DeBakey type I dissection promotes distal aortic remodeling and reduces late open distal reoperation rate. J Thorac Cardiovasc Surg. 2014;147:942-8.
- 13. Ma WG, Zheng J, Zhang W, Sun K, Ziganshin BA, Wang LF, et al. Frozen elephant trunk with total arch replacement for type A aortic dissections: does acuity affect operative mortality? *J Thorac Cardiovasc Surg*. 2014;148:963-70; discussion 970-2.
- Takagi H, Umemoto T, ALICE Group. A meta-analysis of total arch replacement with frozen elephant trunk in acute type A aortic dissection. *Vasc Endovasc Surg.* 2016;50:33-46.
- Takaki h, Hashizume K, Mori M. Less invasive redo total arch replacement with isolated left vertebral artery. *Ann Thorac Surg.* 2022;113:e403.
- Roselli EE, Idrees JJ, Bakaeen FG, Tong MZ, Soltesz EG, Mick S, et al. Evolution of simplified frozen elephant trunk repair for acute DeBakey type I dissection: midterm outcomes. *Ann Thorac Surg.* 2018;105:749-56.
- 17. Leone A, Di Marco L, Coppola G, Amodio C, Berardi M, Mariani C, et al. Open distal anastomosis in the frozen elephant trunk technique: initial experiences and preliminary results of arch zone 2 versus arch zone 3. *Eur J Cardio Thorac Surg.* 2019;56:564-71.
- Detter C, Demal TJ, Bax L, Tsilimparis N, Kölbel T, von Kodolitsch Y, et al. Simplified frozen elephant trunk technique for combined open and endovascular treatment of extensive aortic diseases. *Eur J Cardio Thorac Surg.* 2019;56: 738-45.
- Pichlmaier M, Buech J, Tsilimparis N, Fabry TG, Joskowiak D, Rustum S, et al. Routine stent bridging to the supraaortic vessels in aortic arch replacement: 10year experience. *Ann Thorac Surg.* 2022;113:1491-8.
- 20. Guo M, Naeem A, Yang B, Arbar A. The challenges of novel interventions in complex aortic disease. *JTCVS Tech*. 2020;4:57-60.
- Roselli EE, Soltesz EG, Mastracci T, Svensson LG, Lytle BW. Antegrade delivery of stent grafts to treat complex thoracic aortic disease. *Ann Thorac Surg.* 2010;90:539-46.
- Okita Y, Kumamaru H, Motomura N, Miyata H, Takamoto S. Current status of open surgery for acute type A aortic dissection in Japan. *J Thorac Cardiovasc Surg.* 2020;160:1-10.

**Key Words:** acute aortic dissection type A, EB-SAFER, frozen elephant trunk, total arch replacement