Branched versus fenestrated thoracic endovascular aortic repair in the aortic arch: A multicenter comparison

Sven R. Hauck, MD,[a] Alexander Kupferthaler, MD,[a,b,c] Maximilian Kern, MD,[d] Hervé Rousseau, MD,[e] Ciro Ferrer, MD,[f] Shinichi Iwakoshi, MD,[g] Shoji Sakaguchi, MD,[h] Marie-Elisabeth Stelzmüller, MD,[i] Marek Ehrlich, MD,[i] Christian Loewe, MD,[a] and Martin A. Funovics, MD[a]

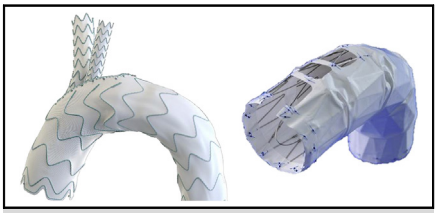
ABSTRACT

Objective: For thoracic endovascular aortic repair of the arch, branched and fenestrated endografts are available with different limitations regarding anatomy and extent of the pathology. Comparisons are lacking in the literature. The aim of this study was to compare the results of 2 currently commercially available devices for branched thoracic endovascular aortic repair and fenestrated thoracic endovascular aortic repair.

Methods: In a retrospective, multicenter cohort study, a consecutive patient series treated with branched thoracic endovascular aortic repair or fenestrated thoracic endovascular aortic repair for aortic arch pathologies was assessed. Baseline characteristics, procedural fenestrated thoracic endovascular aortic repair, and outcome were analyzed. Furthermore, the potential anatomic feasibility of the respective alternate device was assessed on the preoperative computed tomography scans.

Results: The branched thoracic endovascular aortic repair and fenestrated thoracic endovascular aortic repair cohorts consisted of 20 and 34 patients, respectively, with similar comorbidities; indication was aneurysm in 65% and 79%, penetrating aortic ulcer in 20% and 9%, and dissection in the remaining procedures, respectively. Technical success was achieved in all but 1 patient. Perioperative mortality and major stroke rate were both 10% in branched thoracic endovascular aortic repair and 0% and 3% in fenestrated thoracic endovascular aortic repair, respectively. During follow-up of 31 and 40 months, 1 branch occlusion occurred in the branched thoracic endovascular aortic repair cohort, and 2 late endoleaks occurred in the fenestrated thoracic endovascular aortic repair group. One aortic death occurred. Although 35% of patients undergoing branched thoracic endovascular aortic repair were anatomically suitable for fenestrated thoracic endovascular aortic repair, 91% of those undergoing fenestrated thoracic endovascular aortic repair were suitable for branched thoracic endovascular aortic repair.

Conclusions: Both branched thoracic endovascular aortic repair and fenestrated thoracic endovascular aortic repair show excellent technical success and acceptable complication rates, whereas branched thoracic endovascular aortic repair tends toward higher morbidity, especially stroke rates. By offering fenestrated thoracic endovascular aortic repair along with branched thoracic endovascular aortic repair, aortic centers could potentially lower complication rates and simultaneously still treat a wide range of anatomies. (J Thorac Cardiovasc Surg 2022;164:1379-89)



Branched (*left*) and fenestrated (*right*) SGs for endovascular aortic arch treatment.

CENTRAL MESSAGE

bTEVAR and fTEVAR are complementary: The broader applicability of bTEVAR is associated with higher morbidity. If anatomically suitable, fTEVAR could provide a less-invasive alternative.

PERSPECTIVE

In the aortic arch, bTEVAR is technically effective but suffers from a relatively high stroke rate. This study compares bTEVAR and fTEVAR and shows that fTEVAR, although equally effective, carries a lower stroke rate and may be anatomically applicable to one-third of patients undergoing bTEVAR.

ADULT

From the [a]Division of Cardiovascular and Interventional Radiology, Department of Bio-medical Imaging and Image-Guided Therapy, Medical University of Vienna, Vienna, Austria; [b]Department of Diagnostic and Interventional Radiology, Ordensklinikum Linz, Linz, Austria; [c]Johannes Kepler University Linz, Medical Faculty, Linz, Austria; [d]Department of Radiology, Klinik Floridsdorf, Vienna, Austria; [e]Department of Radiology CHU Rangueil, Toulouse, France; [f]Vascular and Endovascular Surgery Unit, San Giovanni Addolorata Hospital, Rome, Italy; [g]Department of Radiology, Nara Medical University, Nara, Japan; [h]Department of Radiology, Matsubara Tokushukai Hospital, Matsubara, Japan; and [i]Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria.

Institutional Review Board Approval: Patient consent was waived because of the retrospective nature of the study (1786/2021, 23.09.2021).

Received for publication Dec 16, 2021; revisions received Feb 15, 2022; accepted for publication March 24, 2022; available ahead of print April 6, 2022.

Address for reprints: Martin A. Funovics, MD, Cardiovascular and Interventional Radiology, Medical University of Vienna, AKH Wien, Währinger Gürtel 18-20, 1090 Vienna, Austria (E-mail: martin.funovics@meduniwien.ac.at).

0022-5223

https://doi.org/10.1016/j.jtcvs.2022.03.023

Abbreviations and Acronyms

BCA = brachiocephalic artery
BSG = bridging stent graft
bTEVAR = branched thoracic endovascular aortic repair
EL = endoleak
fTEVAR = fenestrated thoracic endovascular aortic repair
LCCA = left common carotid artery
LSA = left subclavian artery
LZ = landing zone
SG = stent graft
TEVAR = thoracic endovascular aortic repair

Scanning this QR code will take you to the table of contents to access supplementary information.

Pathologic processes in the ascending aorta and the aortic arch are traditionally treated with open repair involving cardiopulmonary bypass, deep hypothermia, and adequate cerebral perfusion, with their associated morbidity and mortality.[1] Consequently, these procedures are unavailable to a substantial proportion of patient subgroups with relevant comorbidity, older age, and prior open aortic surgery.[2] Procedures that involve less operative trauma, such as frozen elephant trunk, still carry mortality and stroke rates of up to 14% and 10%, respectively.[3]

A combination of supra-aortic vascular debranching with thoracic endovascular aortic repair (TEVAR), termed "hybrid procedures," is increasingly advocated for patients with high operative risks, but with similar stroke and mortality rates, especially in proximal landing zones (LZs).[4]

Since 2003, ideas and implementations for branched and fenestrated arch endografts were developed and have been under constant development ever since.[5,6] Currently, 2 principal directions in device design are being pursued.[7,8] In one method, 2 inner antegrade branches are connected to the brachiocephalic artery (BCA) and left common carotid artery (LCCA) with a tubular aortic device using bridging stent grafts (BSGs) from a cranial approach. In another method, the aortic stent graft (SG) carries fenestrations designed to align with the ostia of the supra-aortic vessels. The former option allows the exclusion of pathologies close to the supra-aortic ostia but requires additional manipulation of the cerebral vessels, and stroke rates are a concern regardless of manufacturer.[9,10] The latter option is less invasive, but requires a larger sealing zone between the fenestration and the aortic pathology and is thus limited to processes at the inner curvature or more distal in the arch.[7] Although both options have been advocated by the European Association for Cardio-Thoracic Surgery and the European Society for Vascular Surgery as a means to treat patients unfit for surgical aortic arch repair, there are only a few single-arm studies with limited patient numbers and mostly short-term follow-up. A comparison between the fenestrated thoracic endovascular aortic repair (fTEVAR) and branched thoracic endovascular aortic repair (bTEVAR) has, to date, been made only for the Cook devices in a single-center cohort study.[8,11] Two other frequently used devices, namely, the fenestrated Najuta (Kawasumi Laboratories Inc) device and the branched Terumo Aortic device, have not yet been compared.

The purpose of the present article is to report outcomes and compare these 2 devices in a multicenter study.

MATERIALS AND METHODS

Study Design

This was a retrospective, multicenter cohort study of a consecutive series of patients treated with bTEVAR or fTEVAR for various aortic pathologies. The study was approved by the institutional ethics committee, and the need for patient consent was waived because of the retrospective nature of the study (1786/2021, 23.09.2021).

Technical success was defined as successful deployment of the SG in the intended position without conversion to open repair, subsequent exclusion of the pathology, and the absence of a type I or III endoleak (EL), confirmed via completion angiography or computed tomography angiography.

The stability of success was defined as the absence of branch occlusion, SG migration, occurrence of a type I or III EL, progression of original disease, or development of related new pathology, such as retrograde dissection and adhering reinterventions.

Patients

Patients who were treated with bTEVAR or fTEVAR due to aortic arch diseases between 2008 and June 2021 were recruited from 4 tertiary aortic referral centers across Europe and Japan. Patients were preoperatively discussed in an interdisciplinary vascular board, consisting mostly of vascular and cardiothoracic surgeons, as well as interventional radiologists, and were deemed unfit for open surgery or they had opted for endovascular treatment. Computed tomography angiography and a clinical visit were scheduled before discharge, at 3 to 6 months and 1 year postoperatively, and annually thereafter.

Device

The SG used for bTEVAR was the Relay Branch system (Terumo Aortic, Sunrise, Fla), and the SG used for fTEVAR was the Najuta Thoracic Stent Graft System (Figure 1). Both SGs, as well as the general deployment procedure, have been described in detail.[9,12] Briefly, the Terumo Aortic device consists of a tubular aortic main body based on the Relay NBS Thoracic Stent Graft and is designed for retrograde deployment through a femoral approach. On the outer curvature, the SG carries a large rectangular fenestration that funnels into 2 retrograde (ie, proximally oriented) parallel tunnels of 12 mm in diameter for connection of the BCA and the LCCA with BSGs.

The Najuta device is a fenestrated endograft for the aortic arch and obtained Japanese regulatory approval in 2013 and CE mark in 2017 (for aneurysm). It consists of an inner-skeleton graft, available in a permutation of 64 patterns of stent frame, 21 patterns of graft size, and 7 patterns of fenestration configuration. The total length is 175 mm. Application over a pull-through wire from a brachial puncture is

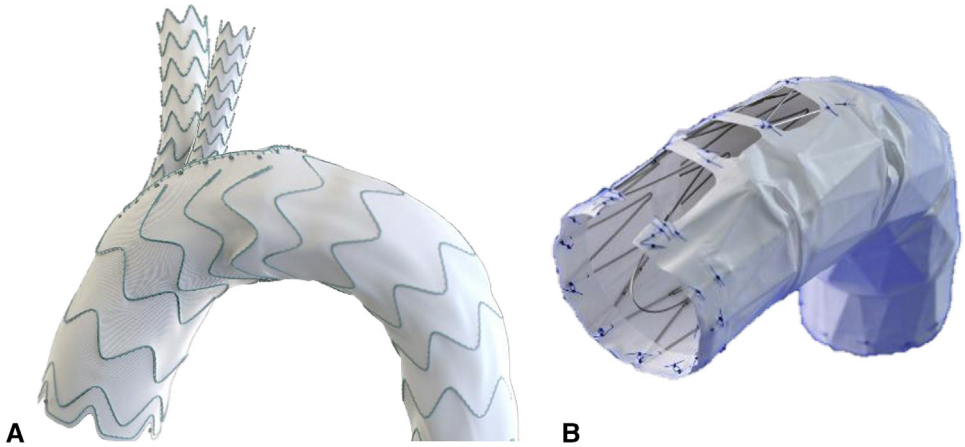


FIGURE 1. Terumo double-branched device (A) for bTEVAR and Najuta fenestrated device for fTEVAR (B). *bTEVAR*, Branched thoracic endovascular aortic repair; *fTEVAR*, fenestrated thoracic endovascular repair.

recommended. Before delivery, the SG is tested in a patient specific 3-dimensional aortic model.

Access

Both devices are deployed through an inguinal approach (surgical cut-down or suture-mediated percutaneous access). Although the Najuta device requires only a brachial puncture for the pull-through wire, the Terumo Aortic device requires BSG implantation, which in this study was performed through a surgical cut-down of the left and right common carotid arteries, with brief clamping of the internal carotid artery during BSG deployment.

Indications for Branched Thoracic Endovascular Aortic Repair and Fenestrated Thoracic Endovascular Aortic Repair

Treatment allocation was decided on with regard to anatomic requirements for each SG, extent of disease, comorbidities, and age, as shown in Table 1, by a multidisciplinary vascular board at an institutional basis. Generally, fTEVAR was used to extend the LZ more proximally into the arch, if the necessary sealing distance of 20 mm between the edges of the fenestrations and the pathology could be maintained, whereas bTEVAR was used in patients where the pathology came close to or involved the origins of the supra-aortic vessels. Overstenting of the left subclavian artery (LSA) without revascularization was considered after evaluation of the vertebral arteries if both arteries were of sufficient caliber and confluent.

TABLE 1. Anatomic instructions for use of the Terumo and Najuta stent grafts

Terumo	Ascending aortic landing zone 29-43 mm diameter, 30 mm length Sinotubular junction to BCA length >65 mm Proximal BCA to distal LCCA <45 mm BCA landing zone 7-20 diameter, 25 mm length LCCA landing zone 7-20 mm diameter, 30 mm length Descending aorta landing zone, 19-43 diameter, 25 mm length
Najuta	Ascending aortic diameter 20-42 mm Proximal sealing zone >20 mm length, 20-38 mm diameter between target vessels distal ostium and proximal edge of pathology Distal landing zone 20-38 mm diameter, >25 mm length

BCA, Brachiocephalic artery; *LCCA*, left common carotid artery.

Data

Patient data were collected at each center individually and combined into an anonymized electronic database. Demographics, preoperative baseline characteristics, procedural details, and outcome modalities, such as morbidity and mortality, were recorded and presented according to TEVAR reporting standards.[13]

Statistical Analysis

Continuous data are presented as mean ± standard deviation, and categorical data are portrayed in absolute values and percent (%). Normal distribution and equality of variances were analyzed with the Shapiro–Wilk test and Levene's test, respectively. The groups were compared with a 2-sided independent samples *t* test with a 95% confidence interval or the Mann—Whitney *U* test if prerequisites could not be met. The Fisher exact test was used to assess binary variables. Data were analyzed using SPSS 27.0 (IBM).

RESULTS

Patients

The bTEVAR cohort consisted of 20 patients, and the fTEVAR cohort consisted of 34 patients (Figure E1). Demographics and comorbidities are outlined in Table 2. The bTEVAR cohort had a higher prevalence of previous endovascular aortic procedures. Other than that, no relevant difference was noted between cohorts in demographics and comorbidities. All patients were treated electively. No patients with connective tissue disease were included. The main indication was aneurysm, predominantly fusiform (13 in the bTEVAR, 27 in the fTEVAR group), with a mean diameter of 61 mm, and similar morphology in the 2 cohorts. Penetrating aortic ulcers were the indication in 4 bTEVAR and 3 fTEVAR patients. The remaining procedures were performed for chronic dissections.

TABLE 2. Baseline characteristics, indication, and treatment allocation of patients

Characteristic	All TEVAR n = 54 no. %	Terumo n = 20 no. %	Najuta n = 34 no. %	*P* (CI) Terumo vs Najuta
Demographics				
Male sex	44 (81.5%)	18 (90%)	26 (76.5%)	.2912
Age, y	77.4 (±8.1)	77.0 (±7.0)	77.6 (±8.8)	.7803 (−5.3; 4.0)
Comorbidities				
Prior MI	7 (13%)	4 (20%)	3 (8,8%)	.4030
Hypertension	44 (81.5%)	20 (100%)	24 (70.6%)	.0087
Hyperlipidemia	29 (53.7%)	13 (65%)	16 (47.1%)	.2628
Coronary artery disease	14 (25.9%)	7 (35%)	7 (20.6%)	.3368
COPD	13 (24.1%)	9 (45%)	4 (11.8%)	.0090
Smoking	20 (37%)	10 (50%)	10 (29.4%)	.1543
Renal insufficiency	5 (9.3%)	2 (10%)	3 (8.8%)	1.0000
Diabetes II	5 (9.3%)	0 (0%)	5 (14.7%)	.1450
Previous aortic procedures				
Surgery	12 (22.2%)	4 (20%)	8 (23.5%)	1.0000
Endovascular	9 (16.7%)	7 (35%)	2 (5.9%)	.0090
Indication				
Aneurysm	40 (74.1%)	13 (65%)	27 (79.4%)	.3368
Mean aneurysm ø, mm	61.2 (±10.6)	66.8 (±12.0)	58.8 (±9.5)	.0387
Dissection	7 (13%)	3 (15%)	4 (11.8%)	1.0000
Penetrating aortic ulcer	7 (13%)	4 (20%)	3 (8.8%)	.4030

TEVAR, Thoracic endovascular aortic repair; *CI*, confidence interval; *MI*, myocardial infarction; *COPD*, chronic obstructive lung disease; *ASA*, American Society of Anesthesiologists.

ADULT

Procedures

Revascularization of the LSA was performed in 17 bTEVAR patients and 16 fTEVAR patients with an LCCA-LSA bypass, an axillo-axillary bypass, or LSA transposition. The LSA was overstented without revascularization in 3 patients in the bTEVAR group and 8 patients in the fTEVAR group. In all bTEVAR patients, 2 branch vessels were targeted (BCA in 19, right common carotid artery in 1, LCCA 20 cases). In the fTEVAR patients, the fenestrations were targeted at the BCA in 31, the right common carotid artery in 2, the LCCA in 27, and the LSA in 10 cases. Deployment was under rapid pacing in 17 bTEVAR patients and under pharmacologic blood pressure control in the remaining patients. The LZ for bTEVAR was always zone 0; for fTEVAR, it was zone 0 in 33 and zone 1 in 1 case. Endovascular procedure time was significantly shorter in fTEVAR, with 48 minutes versus 132 minutes in bTEVAR (Table 3).

Early Outcome

Technical success was achieved in all patients in the bTEVAR cohort and in 33 of 34 patients in the fTEVAR cohort (examples shown in Figure 2). Two perioperative mortalities occurred in the bTEVAR group (1 major stroke, 1 retrograde type A dissection). One further major stroke and 1 minor stroke occurred in the bTEVAR group, and 1 major stroke and 1 spinal ischemia (in a case with previously occluded LSA) in the fTEVAR group. Two minor surgical revisions were required at the puncture site, 2 patients had minor respiratory complications, and no myocardial infarction, kidney injuries, or other organ failures occurred. Although hospital stay was similar between cohorts, the significant longer intensive care unit stay in the bTEVAR group may be attributed to 2 outliers with prolonged weaning due to pneumonia and pulmonary dysfunction. Further details are shown in Table 3.

Follow-up

Mean follow-up was 31 months in the bTEVAR group and 40 months in the fTEVAR group. Seven late mortalities occurred in the bTEVAR group, 1 of which was due to a late infratentorial stroke without evidence of in-stent thrombus. Twelve late mortalities occurred in the fTEVAR group, one of which was due to an aortic-esophageal fistula (unrelated to the original SG). Mortalities are shown in Figure E2. Technical success was stable in 19 bTEVAR (95%) and 28 fTEVAR (82%) patients. One branch occlusion of an LCCA BSG was detected without clinical or neurologic symptoms in the bTEVAR group, whereas no late (high pressure) EL occurred. However, 1 type II EL required embolization. In the fTEVAR group, technical success was unstable in 6 (18%) cases. Two high-pressure ELs and 1 type IV EL, required insertion of an additional tubular thoracic SG. One patient was operated for device-unrelated aorto-esophageal fistula. One further patient underwent total arch replacement due to device

TABLE 3. Procedural details of stent graft deployment, 30-day and midterm outcome parameters of patients

Characteristic	All TEVAR n = 54 no. %	Terumo n = 20 no. %	Najuta n = 34 no. %	*P* (CI) Terumo vs Najuta
Anatomic details				
Beginning of lesion				<.0001
Zone 0	1 (1.9%)	1 (5%)	0 (0%)	.3704
Zone 1	17 (31.5%)	10 (50%)	7 (20.6%)	.0352
Zone 2	17 (31.5%)	9 (45%)	8 (23.5%)	.1335
Zone 3	19 (35.2)	0 (0%)	19 (55.9%)	<.0001
End of lesion				.0462
Zone 3	30 (55.6%)	15 (75%)	15 (44.1%)	.0462
Zone 4	24 (44.4%)	5 (25%)	19 (55.9%)	.0462
Bovine arch	6 (11.1%)	1 (5%)	5 (14.7%)	.3947
Procedure time				
Endovascular	121.2 (±47.9)	132.2 (±40.7)	47.7 (±12.3)	.0021 (34.5; 134.6)
Fluoroscopy	39.3 (±21.4)	42.6 (±21.2)	19.0 (±6.6)	.0052
Revascularization procedure	34 (63%)	18 (90%)	16 (47.1%)	.0029
Planned execution				<.0001
Staged	11 (32.4%)	11 (61.1%)	0 (0%)	<.0001
Simultaneously	23 (67.6%)	7 (38.9%)	16 (100%)	<.0001
Bypass				
LCCA-LSA	20 (58.8%)	16 (88.9%)	4 (25%)	<.0001
Axillo-axillary	14 (25.9%)	0 (0%)	14 (87.5%)	<.0001
Transposition				
LSA-LCCA	1 (1.9%)	1 (5.6%)	0 (0%)	1.0000
LVA-LCCA	2 (3.7%)	2 (11.1%)	0 (0%)	.4866
TV in branch/fenestration				
BCA	50 (92.6%)	19 (95%)	31 (91.2%)	1.0000
RCCA	3 (5.6%)	1 (5%)	2 (5.9%)	1.0000
LCCA	47 (87%)	20 (100%)	27 (79.4%)	.0383
LSA	10 (18.5%)	0 (0%)	10 (29.4%)	.0087
Intentional LSA Overstenting*	11 (20.4%)	3 (15%)	8 (23.5%)	.5099
Deployment under				
Rapid pacing	17 (31.5%)	17 (85%)	0 (0%)	<.0001
Heparin bolus	33 (61.1%)	5 (25%)	28 (82.4%)	<.0001
ACT monitoring and heparin bolus	21 (38.9%)	15 (75%)	6 (17.6%)	<.0001
Surgical vascular access†				
Groin	48 (88.9%)	14 (70%)	34 (100%)	.0015
RCCA	15 (27.8%)	15 (75%)	0 (0%)	<.0001
RSA	5 (9.3%)	5 (25%)	0 (0%)	.0049
LCCA	14 (25.9%)	14 (70%)	0 (0%)	<.0001
LSA	6 (11.1%)	6 (30%)	0 (0%)	.0015
Bridging stent grafts‡	40 branches	40 branches		
Gore Excluder Limb	4 (10%)	4 (10%)		
Bard Fluency	4 (10%)	4 (10%)		
Gore Viabahn	8 (20%)	8 (20%)		
Terumo Limb	24 (60%)	24 (60%)		
Bentley Begraft	1 (2.5%)	1 (2.5%)		
ICU stay, d	2.7 (±8.3)	6.2 (±13.0)	0.6 (±1.2)	<.0001
Hospital stay, d	15.1 (±13)	14.8 (±17.3)	15.4 (±10)	.0110
Postoperative medication				<.0001
Single antiplatelet	15 (27.8%)	6 (30%)	9 (26.5%)	.7494
Dual antiplatelet	17 (31.5%)	12 (60%)	5 (14.7%)	.0009
Anticoagulation	1 (3.1%)	0 (0%)	1 (2.9%)	1.0000

(Continued)

TABLE 3. Continued

Characteristic	All TEVAR n = 54 no. %	Terumo n = 20 no. %	Najuta n = 34 no. %	*P* (CI) Terumo vs Najuta
AC + AP	2 (1.9%)	2 (10%)	0 (0%)	.1328
None	19 (35.2%)	0 (0%)	19 (55.9%)	<.0001
Technical success	53 (98.1%)	20 (100%)	33 (97.1%)	1.0000
Major complications 30 d	8 (14.8%)	6 (30%)	2 (5.90%)	.0410
Mortality§	2 (6.3%)	2 (10%)	0 (0%)	.1328
Major stroke	3 (5.6%)	2 (10%)	1 (2.9%)	.5476
Minor stroke	1 (1.9%)	1 (5%)	0 (0%)	.3703
Other‖	3 (5.6%)	2 (10%)	1 (2.9%)	.5477
Minor complication 30 d¶	3 (5.6%)	3 (15%)	0 (0%)	.0460
Follow-up, mo	35.8 (±38.2)	30.7 (±21.0)	40.3 (±42.6)	1.0000
Late mortality				
Unrelated	18 (33.3%)	7 (35%)	11 (32.4%)	1.0000
Aortic#	1 (1.9%)	0 (0%)	1 (2.9%)	1.0000
Stability of success	47 (87%)	19 (95%)	28 (82.4%)	.2393
Late EL**	2 (3.7%)	0 (0%)	2 (5.9%)	.5248
Branch occlusion	1 (1.9%)	1 (5%)	0 (0%)	.3704
Stent migration	0 (0%)	0 (0%)	0 (0%)	
Aortic reintervention	6 (11.1%)	1 (5%)	5 (14.7%)	.3947

TEVAR, Thoracic endovascular aortic repair; *CI*, confidence interval; *LCCA*, left common carotid artery; *LSA*, left subclavian artery; *LVA*, left vertebral artery; *BCA*, brachiocephalic artery; *RCCA*, right common carotid artery; *ACT*, activated clotting time; *RSA*, right subclavian artery; *ICU*, intensive care unit; *AC*, anticoagulation; *AP*, antiplatelet. *Without revascularization procedure. †Used for stent graft deployment. ‡Once, 2 BSGs were used for 1 branch. §Includes 1 major stroke and 1 retrograde type A dissection. ‖Patient with prolonged weaning due to COPD, 1 patient who developed pneumonia, and 1 patient with spinal ischemia. ¶Pseudoaneurysm of the LSA, 1 cervical bleeding after left vertebral artery transposition and 1 temporary hyposthenia of the left arm. #Due to aortic-esophageal fistula. **High-pressure EL (type I or III)

infolding. One patient had sac enlargement without detectable EL (Type V EL). Aortic reintervention rates were similar, with 5% for bTEVAR and 14.7% for fTEVAR ($P = .3947$).

Feasibility of the Other Device

There was a significant difference regarding the anatomic suitability of the other respective device. Although more than 91% of fTEVAR patients would have been able to

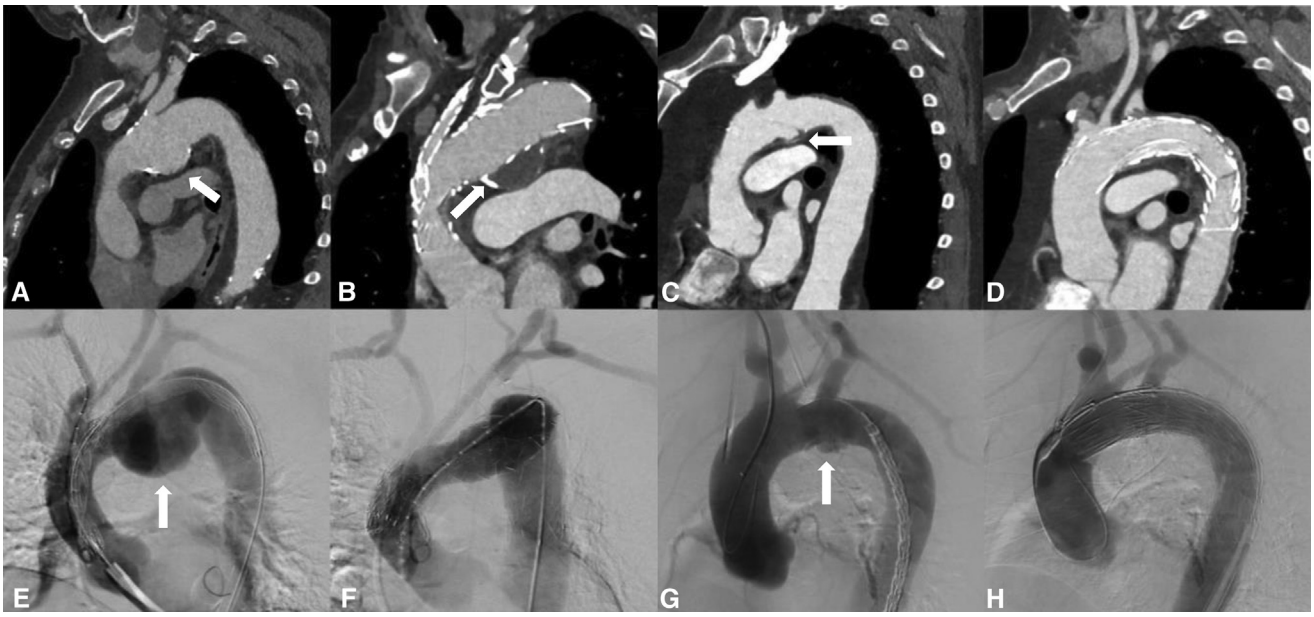


FIGURE 2. Aortic computed tomography angiography and angiography scans of arch pathologies before treatment with bTEVAR (A, E) and fTEVAR (C, G), and afterward with excluded pathologies (*white arrows*, B, D, F, H). *bTEVAR*, Branched thoracic endovascular aortic repair; *fTEVAR*, fenestrated thoracic endovascular repair.

receive a Terumo Aortic device, 35% of bTEVAR patients were suitable for the Najuta device. The main reasons for unsuitability of the Najuta device were an insufficient proximal sealing zone in 12 patients and an unfitting distal LZ in 5 patients. Regarding the Terumo Aortic device, the distance between the BCA and LCCA was too far in 2 patients and in 1 patient no sufficient LZ was available in the descending aorta (Table 4).

TABLE 4. Feasibility of Terumo or Najuta device in the other patient cohort

Characteristic	All TEVAR n = 54 N. %
Feasibility of respective other device	38 (70.4%)
	$P < .0001$
Najuta in Terumo patients	7 (35%)
Terumo in Najuta patients	31 (91.2%)
Exclusion of feasibility for Najuta*	13/20 patients
Unsuitable ascending aortic ø, mm	3 (15%)
Mean ascending aortic ø, mm	35.9 (±6)
Insufficient proximal sealing zone	12 (60%)
Mean proximal sealing zone length, mm	24.7 (±6.4)
Mean proximal sealing zone ø, mm	28.2 (±5)
Unsuitable distal landing zone	5 (25%)
Mean distal landing zone ø, mm	32.57 (±6.6)
Exclusion of feasibility for Terumo*	3/34 patients
Unsuitable ascending aortic landing zone	0 (0%)
Ascending aortic LZ mean ø, mm	32.7 (±2.1)
Ascending aortic LZ mean length, mm	93.7 (±4.9)
Insufficient STJ to BCA distance	0 (0%)
Mean STJ to BCA distance, mm	90.3 (±4.9)
Unsuitable BCA to LCCA distance	2 (5.9%)
Mean BCA to LCCA distance, mm	31.3 (±3)
Unsuitable BCA LZ	0 (0%)
Mean BCAT LZ ø, mm	12.3 (±0.6)
Mean BCA LZ length, mm	40.7 (±20.6)
Unsuitable LCCA LZ	0 (0%)
Unsuitable descending aorta LZ	1 (2.9%)
Mean descending aorta LZ ø, mm	27 (±2.7)

TEVAR, Thoracic endovascular aortic repair; *LZ*, landing zone; *STJ*, sinotubular junction; *BCA*, brachiocephalic artery; *LCCA*, left common carotid artery. *More than 1 reason may apply.

DISCUSSION

The present study showed, for the first time, a multicentric comparison between bTEVAR with the Terumo Aortic device and fTEVAR with the Najuta device.

Because both devices have been available for years, it could be shown that the technical success rate for both approaches in experienced hands is excellent. All target vessels in both cohorts could be safely engaged with branches or fenestrations with no unintentional occlusion. Recent concerns about the safety of the fenestrated approach could not be confirmed.[14]

When comparing both cohorts, the complication rate was significantly higher and perioperative mortality tended to be higher for bTEVAR over fTEVAR, whereas the mortality and complication rates are well within the range of previously published single-arm experiences with the respective devices (Table 5).[15-28] The 2 perioperative deaths in the bTEVAR cohort occurred very early (2013 and 2014) and may be due to a learning curve.

Patient cohorts treated with bTEVAR or fTEVAR usually have several different underlying disease mechanisms, and the present study was no exception.[2,29] There is consensus among most researchers that stroke rate is determined rather by the location and amount of atherosclerotic disease than by device selection.[9,30] It can be expected that proximal penetrating aortic ulcers and patients with a heavy plaque burden are at higher risk than patients with aortic dissections, for example.[30] Yet, there exists no scoring system comparable to the European System for Cardiac Operative Risk Evaluation or the Society of Thoracic Surgeons score with which to preoperatively assess bTEVAR and fTEVAR risks, and such a system would have to place more emphasis on atherosclerotic disease manifestations.

Although patient selection may be the most relevant risk factor, device and implantation parameters may also contribute to complication risk. The recommendations concerning the BSGs for bTEVAR have changed over time: Originally, infrarenal iliac SGs were used; since 2015, modified devices, similar to the iliac platform, are available, and recently, heparin-coated self-expandable SGs (WL Gore & Associates, Newark, Del) are recommended. Different opinions exist for the access vessel. Some authors (including this study) prefer an approach through the common carotid arteries with clamping of the internal carotid artery during deployment. Others prefer a brachial/subclavian approach through the BCA or the LSA-LCCA bypass. Data about BSGs or operative approaches are currently lacking.

An exhaustive overview of the currently available literature regarding bTEVAR and fTEVAR devices (excluding case reports and physician-modified approaches) is given in Table 5. For devices with anterior inner branches (Terumo & Cook, Sunrise, Fla), stroke rates remain a concern,[9,10] whereas fTEVAR carries a lower morbidity. Stroke rates in endovascular procedures must be benchmarked against open aortic arch replacement and frozen elephant trunk technique, which still has to be regarded as the gold standard. Open surgery carries similar event rates regarding disabling stroke and lower rates regarding nondisabling stroke.[3] In the light of recent studies that identified gas bubbles as significant sources of cerebral embolism during TEVAR, rigorous de-gassing protocols (eg, preoperative carbon dioxide flushing followed by saline irrigation of the SG in the sheath) may lower stroke rates. Currently, there is no consensus about intentional LSA overstenting versus revascularization. In the present study, LSA

ADULT

TABLE 5. Literature overview of branched and fenestrated TEVAR in the aortic arch

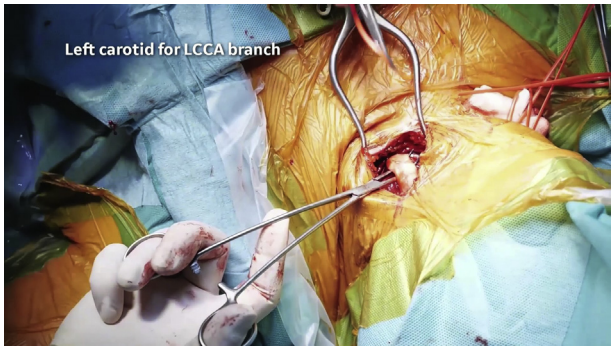
Device and author	Indication	Patient/ center	Follow-up, mo	Technical success	Mortality* no. (%)	Disabling stroke + nondisabling stroke† no. (%)	Journal	Year
Terumo bTEVAR								
Ferrer[15]	Aneurysm	7/1	24	100%	2 (28%)	1 (14%)	*JCVS*	18
Czerny[16]	Multiple (eg, aneurysm, penetrating aortic ulcer, dissection)	15/4	9		1 (6.7%)	1 (6.7%) + 2 (13.3%)	*EJCTS*	18
Ferrer[17]	Multiple	24/9	18	95.8%	4 (17%)	3 (12.5%)	*JVS*	19
Weijde[18]	Aneurysm	11/5	17	100%	2 (18%)	2 (18%) + 2 (18%)	*ATS*	19
Kudo[19]	Multiple	24/1	48	100%	0 (0%)	2 (7%) + 2 (7%)	*JTCVS T*	20
Czerny[9]	Multiple	43/10	16		4 (9%)	3 (7%) + 8 (19%)	*EJCTS*	21
Najuta fTEVAR								
Iwakoshi[12]	Aneurysm	32/3	30	91%	0 (0%)	1 (3.1%)	*JVS*	15
Kurimoto[31]	Multiple	37	17		0 (0%)	2 (5.4%)	*ATS*	15
Toya[32]	Aneurysm	8/1	12	100%	0 (0%)	0 (0%)	*CVIR*	18
Fukushima[33]	TBD	13/2	14	100%	0 (0%)	0 (0%)	*JVS*	19
Sato[20]	Aneurysm	37/2	35	97%	0 (0%)	6 (16.7%)	*AVD*	20
Cook fTEVAR								
Tsilimparis[21]	Multiple	44/1	18	95%	4 (9%)	3 (7%) + 1 (2%)	*JVS*	20
Cook bTEVAR								
Haulon[22]	Aneurysm	38/10	12	84%	5 (13%)	1 (2.6%)	*JTCS*	14
Spear[23]	Aneurysm	27/3	12	100%	0 (0%)	2 (7.4%) + 1 (3.7%)	*EJVES*	16
Clough[24]	Multiple	30/1	12	90%	3 (10%)	1 (3.3%)	*BJS*	18
Tsilimparis[25]	TAD	20/1	17	95%	1 (5%)	1 (5%)	*EJCTS*	18
Law[26]	Multiple	11/1	6	100%	1 (9%)	1 (9%)	*ATS*	19
Tsilimparis[10]	Multiple	54/1	12	98%	5 (7.4%)	3 (5.5%) + 3 (5.5%)	*JVS*	19
Verscheure[30]	CTAD	70/14	10	94.3%	2 (2.8%)	1 (1.4%) + 1 (1.4%)	*AOS*	21
Cook b- vs fTEVAR								
Tsilimparis[7]	Multiple	15f v	8	93.3%	3 (20%)	2 (14%)	*JVS*	16
		14b/1	10	100%	0 (0%)	1 (7%)		
Inoue bTEVAR								
Tazaki[27]	Aneurysm	89/1	45	100%	4 (4.5%)	14 (16%)	*JVS*	17
Kawatou[28]	Multiple	68/1	43	100%	3 (4.4%)	4 (5.9%)	*ICTS*	17
Terumo vs Najuta								
Hauck	Multiple	54/5	36	100%	2 (6.3%)	2 (6.3%) + 1 (3.1%)		21
		20b	31	100%	2 (10%)	2 (10%) + 1 (5%)		
		34f	44	100%	0 (0%)	0 (0%)		

bTEVAR, Branched thoracic endovascular aortic repair; *fTEVAR*, fenestrated thoracic endovascular repair; *TBD*, type B dissection; *TAD*, type A dissection; *CTAD*, chronic type A dissection. *Perioperative. †When only 1 number is mentioned, only a general stroke rate was given.

overstenting was accepted in the presence of sufficient vertebral artery caliber and regular vertebral confluence. One of these 11 patients had a minor stroke (in the anterior territory), whereas all major stroke events occurred after LSA revascularization. The only case of spinal ischemia in this series occurred in a patient with preexisting atherosclerotic LSA occlusion. Thus, the results of this study do not suggest a potential to reduce complication rates by routinely revascularizing the LSA.

As of yet, no uniform protocols for anticoagulation and antiaggregation have been established. Although tubular TEVAR usually does not require antiplatelet therapy, experience from carotid stenting suggests a double antiplatelet regimen for patients with stents in the supra-aortic vessels. The heterogeneity in the antiplatelet regimen is also reflected in our series. Although 60% of patients undergoing bTEVAR received double antiplatelet therapy, 56% of patients undergoing fTEVAR received no antiplatelet therapy, with fTEVAR still showing a trend to lower stroke rates.

Obviously, bTEVAR and fTEVAR are not interchangeably applicable for all anatomies. Although bTEVAR requires a sealing zone only at the proximal edge of the stent graft and at the ends of the BSGs, fTEVAR requires an individual sealing zone for each fenestration. Patients in this study were allocated to fTEVAR if a minimal distance of 20 mm could be maintained between the proximal



VIDEO 1. Short summary of the study and its participants, the necessary and optional procedures for both SGs, and the implications of our results. Video available at: https://www.jtcvs.org/article/S0022-5223(22)00374-9/fulltext.

edge of the pathology and the respective nearest edge of a fenestration. Because both longitudinal and circumferential distances were counted, localized pathologies such as penetrating ulcers at the inner curvature could be treated with fTEVAR even if they were located more proximally in the arch than aneurysms that affected the whole circumference of the aorta. Pathologies closer than 20 mm to a fenestration were allocated to bTEVAR, if the anatomic preconditions were met. Because the treatment decision was made in the individual centers, and based on operator experience and device availability, allocation algorithms were not uniform across the centers. This is reflected in a potential interchangeability of treatment options in the cohorts. Although 91% of Najuta patients in our cohort would have been anatomically suitable to be treated with the Terumo Aortic device, approximately one-third of the Terumo Aortic patients would have also fit Najuta's anatomic criteria.

Given the availability of both devices on a custom-made basis throughout Europe in 2021, it seems advisable to consider patients primarily for the less-invasive option. Crossing over anatomically suitable bTEVAR patients to fTEVAR might independently lower stroke rates. This notion is supported not only by the findings in our study but also by most single-arm studies previously published.[12,31-33] A single other article that compared bTEVAR and fTEVAR showed a trend toward higher mortality and stroke rate in fTEVAR; however, this study investigated Cook devices in both groups, and anchoring BSGs were placed not only in bTEVAR but also in all

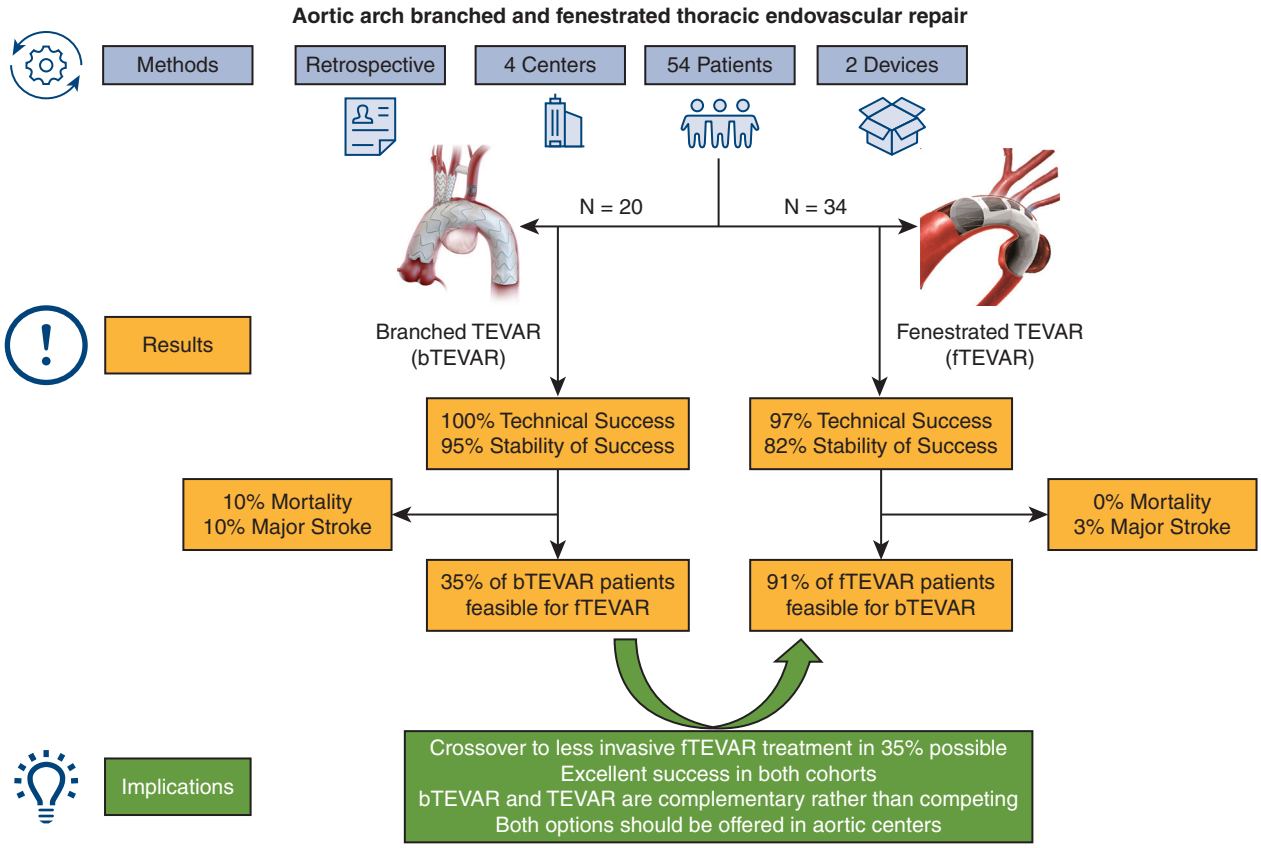


FIGURE 3. Graphical abstract presenting the topic TEVAR in the aortic arch methods, results, and implications of the study. *TEVAR*, Thoracic endovascular aortic repair; *bTEVAR*, branched thoracic endovascular aortic repair; *fTEVAR*, fenestrated thoracic endovascular repair.

fTEVAR fenestrations.[7] Potentially, the added supra-aortic vessel manipulation has contributed to the higher mortality and stroke rate in fTEVAR compared with bTEVAR in that study.

Study Limitations

These implications must be regarded in the context of the study limitations. First, treatment allocation of the patients was not randomized because of the different anatomic selection criteria of the devices. Second, the study was retrospective and potential confounding parameters (eg, calcium or atherosclerotic load in the arch) may have been differently distributed between these cohorts. Although comorbidities between cohorts were similar, the bTEVAR group had more proximal disease extension, currently not approachable with the Najuta device. This may partly account for higher perioperative complication rates in the bTEVAR group. Larger studies are needed to better define the differences between techniques in defined pathologies. Third, the devices used are still under constant development. In bTEVAR, the previously recommended infrarenal legs have been replaced by heparin-coated BSGs. In fTEVAR, anatomic criteria have been relaxed over time and the treatment indication has been expanded toward dissections. Fourth, no control group comprising high-risk patients with open surgical repair was included, which makes predictions about this alternative approach difficult. Because of the limited event rates, the effect of a potential learning curve could not be determined. Therefore, it cannot be predicted how many cases per center should be performed to provide sufficient competence. Finally, few centers offered both bTEVAR and fTEVAR to all patients, which may have biased the patient acceptance rate based on anatomic criteria. The strengths of this study include the multicentric approach, the feasibility evaluation of the alternative device, and the relatively long midterm follow-up data.

Future studies will undoubtedly see a high proportion of triple-branched bTEVAR with a third retrograde branch to engage the LSA from an inguinal approach, reducing the necessity for LSA revascularization procedures.[34] According to recent data, LSA preservation can attenuate cerebral and spinal neurologic injury.[35] Triple branched and fenestrated TEVAR allows for LSA preservation with minimal effort and operative trauma. Upcoming larger multicentric registries will facilitate the differential investigation of the main indications, namely, aneurysms, obliterative diseases such as penetrating aortic ulcers with their high atherosclerotic burden, and residual dissections after open ascending replacement, which have recently shown encouraging results.[30]

CONCLUSIONS

Our multicentric comparison of bTEVAR and fTEVAR has confirmed the excellent technical success and the stability of technical success in both cohorts. However, the broader anatomic suitability of bTEVAR comes at the cost of increased mortality and morbidity, namely, stroke rates. Approximately one-third of patients undergoing bTEVAR would have been anatomically suitable for fTEVAR treatment. The key message is that bTEVAR and fTEVAR are more complementary than competing, and aortic centers should have both options available (Video 1 and Figure 3).

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.

References

1. Urbanski PP, Luehr M, Di Bartolomeo R, Diegeler A, De Paulis R, Esposito G, et al. Multicentre analysis of current strategies and outcomes in open aortic arch surgery: heterogeneity is still an issue. *Eur J Cardiothorac Surg*. 2016;50:249-55.
2. Baikoussis NG, Antonopoulos CN, Papakonstantinou NA, Argiriou M, Geroulakos G. Endovascular stent grafting for ascending aorta diseases. *J Vasc Surg*. 2017;66:1587-601.
3. Weiss G, Tsagakis K, Jakob H, Di Bartolomeo R, Pacini D, Barberio G, et al. The frozen elephant trunk technique for the treatment of complicated type B aortic dissection with involvement of the aortic arch: multicentre early experience. *Eur J Cardiothorac Surg*. 2015;47:106-14; discussion 114.
4. Cazavet A, Alacoque X, Marcheix B, Chaufour X, Rousseau H, Glock Y, et al. Aortic arch aneurysm: short- and mid-term results comparing open arch surgery and the hybrid procedure. *Eur J Cardiothorac Surg*. 2016;49:134-40.
5. Chuter TAM, Buck DG, Schneider DB, Reilly LM, Messina LM. Development of a branched stent-graft for endovascular repair of aortic arch aneurysms. *J Endovasc Ther*. 2003;10:940-5.
6. Chuter TA, Schneider DB. Endovascular repair of the aortic arch. *Perspect Vasc Surg Endovasc Ther*. 2007;19:188-92.
7. Tsilimparis N, Debus ES, von Kodolitsch Y, Wipper S, Rohlffs F, Detter C, et al. Branched versus fenestrated endografts for endovascular repair of aortic arch lesions. *J Vasc Surg*. 2016;64:592-9.
8. Czerny M, Schmidli J, Adler S, van den Berg JC, Bertoglio L, Carrel T, et al. Current options and recommendations for the treatment of thoracic aortic pathologies involving the aortic arch: an expert consensus document of the European Association for Cardio-Thoracic surgery (EACTS) and the European Society for Vascular Surgery (ESVS). *Eur J Cardiothorac Surg*. 2019;55:133-62.
9. Czerny M, Berger T, Kondov S, Siepe M, Saint Lebes B, Mokrane F, et al. Results of endovascular aortic arch repair using the Relay Branch system. *Eur J Cardiothorac Surg*. 2021;60:662-8.
10. Tsilimparis N, Detter C, Law Y, Rohlffs F, Heidemann F, Brickwedel J, et al. Single-center experience with an inner branched arch endograft. *J Vasc Surg*. 2019;69:977-85. e971.
11. Blanco Amil CL, Mestres Alomar G, Guarnaccia G, Luoni G, Yugueros Castellnou X, Vigliotti RC, et al. The initial experience on branched and fenestrated endografts in the aortic arch. a systematic review. *Ann Vasc Surg*. 2021;75:29-44.
12. Iwakoshi S, Ichihashi S, Itoh H, Tabayashi N, Sakaguchi S, Yoshida T, et al. Clinical outcomes of thoracic endovascular aneurysm repair using commercially available fenestrated stent graft (Najuta endograft). *J Vasc Surg*. 2015;62:1473-8.
13. Fillinger MF, Greenberg RK, McKinsey JF, Chaikof EL. Reporting standards for thoracic endovascular aortic repair (TEVAR). *J Vasc Surg*. 2010;52:1022-33. 1033.e1015.
14. Zhang L, Lu Q, Zhu H, Jing Z. Branch stent-grafting for endovascular repair of chronic aortic arch dissection. *J Thorac Cardiovasc Surg*. 2021;162:12-22. e11.
15. Ferrer C, Coscarella C, Cao P. Endovascular repair of aortic arch disease with double inner branched thoracic stent graft: the Bolton perspective. *J Cardiovasc Surg (Torino)*. 2018;59:547-53.

16. Czerny M, Rylski B, Morlock J, Schröfel H, Beyersdorf F, Saint Lebes B, et al. Orthotopic branched endovascular aortic arch repair in patients who cannot undergo classical surgery. *Eur J Cardiothorac Surg*. 2018;53:1007-12.
17. Ferrer C, Cao P, Coscarella C, Ferri M, Lovato L, Camparini S, et al. iTalian RegIStry of doUble inner branch stent graft for arch PatHology (the TRIUmPH Registry). *J Vasc Surg*. 2019;70:672-82.e1.
18. van der Weijde E, Heijmen RH, van Schaik PM, Hazenberg C, van Herwaarden JA. Total endovascular repair of the aortic arch: initial experience in The Netherlands. *Ann Thorac Surg*. 2020;109:1858-63.
19. Kudo T, Kuratani T, Shimamura K, Sawa Y. Early and midterm results of thoracic endovascular aortic repair using a branched endograft for aortic arch pathologies: a retrospective single-center study. *JTCVS Tech*. 2020;4:17-25.
20. Sato H, Fukada J, Tamiya Y, Mikami T, Sibata T, Harada R, et al. Long-term clinical outcomes of thoracic endovascular aortic repair for arch aneurysms with the Najuta Thoracic Stent-Graft System. *Ann Vasc Dis*. 2020;13:384-9.
21. Tsilimparis N, Law Y, Rohlffs F, Spanos K, Debus ES, Kölbel T. Fenestrated endovascular repair for diseases involving the aortic arch. *J Vasc Surg*. 2020;71:1464-71.
22. Haulon S, Greenberg RK, Spear R, Eagleton M, Abraham C, Lioupis C, et al. Global experience with an inner branched arch endograft. *J Thorac Cardiovasc Surg*. 2014;148:1709-16.
23. Spear R, Haulon S, Ohki T, Tsilimparis N, Kanaoka Y, Milne CP, et al. Editor's Choice - subsequent results for arch aneurysm repair with inner branched endografts. *Eur J Vasc Endovasc Surg*. 2016;51:380-5.
24. Clough RE, Spear R, Van Calster K, Hertault A, Azzaoui R, Sobocinski J, et al. Case series of aortic arch disease treated with branched stent-grafts. *Br J Surg*. 2018;105:358-65.
25. Tsilimparis N, Detter C, Heidemann F, Spanos K, Rohlffs F, von Kodolitsch Y, et al. Branched endografts in the aortic arch following open repair for DeBakey type I aortic dissection. *Eur J Cardiothorac Surg*. 2018;54:517-23.
26. Law Y, Kölbel T, Detter C, Rohlffs F, von Kodolitsch Y, Makaloski V, et al. Emergency use of branched thoracic endovascular repair in the treatment of aortic arch pathologies. *Ann Thorac Surg*. 2019;107:1799-806.
27. Tazaki J, Inoue K, Higami H, Higashitani N, Toma M, Saito N, et al. Thoracic endovascular aortic repair with branched Inoue Stent Graft for arch aortic aneurysms. *J Vasc Surg*. 2017;66:1340-8. e1345.
28. Kawatou M, Minakata K, Sakamoto K, Nakatsu T, Tazaki J, Higami H, et al. Comparison of endovascular repair with branched stent graft and open repair for aortic arch aneurysm. *Interact Cardiovasc Thorac Surg*. 2017;25:246-53.
29. Brown JA, Arnaoutakis GJ, Szeto WY, Serna-Gallegos D, Sultan I. Endovascular repair of the aortic arch: State of the art. *J Card Surg*. 2021;36:4292-300.
30. Verscheure D, Haulon S, Tsilimparis N, Resch T, Wanhainen A, Mani K, et al. Endovascular treatment of post type A chronic aortic arch dissection with a branched endograft: early results from a retrospective international multicenter study. *Ann Surg*. 2021;273:997-1003.
31. Kurimoto Y, Maruyama R, Ujihira K, Nishioka N, Hasegawa K, Iba Y, et al. Thoracic endovascular aortic repair for challenging aortic arch diseases using fenestrated stent grafts from zone 0. *Ann Thorac Surg*. 2015;100:24-32; discussion 32-3.
32. Toya N, Ohki T, Fukushima S, Shukuzawa K, Ito E, Murakami Y, et al. Case series of aortic arch aneurysm in patients with bovine arch treated with proximal scalloped and fenestrated stent graft. *Cardiovasc Intervent Radiol*. 2018;41:1648-53.
33. Fukushima S, Ohki T, Toya N, Shukuzawa K, Ito E, Murakami Y, et al. Initial results of thoracic endovascular repair for uncomplicated type B aortic dissection involving the arch vessels using a semicustom-made thoracic fenestrated stent graft. *J Vasc Surg*. 2019;69:1694-703.
34. Negmadjanov U, Motta JC, Lee WA. Total endovascular aortic arch repair using the Terumo Aortic triple-branch arch endograft. *Ann Vasc Surg*. 2021;77:351.e7-14.
35. Huang Q, Chen XM, Yang H, Lin QN, Qin X. Effect of left subclavian artery revascularisation in thoracic endovascular aortic repair: a systematic review and meta-analysis. *Eur J Vasc Endovasc Surg*. 2018;56:644-51.

Key Words: aneurysm, aortic arch, branched stent graft, endovascular aortic arch repair, fenestrated stent graft, stent graft

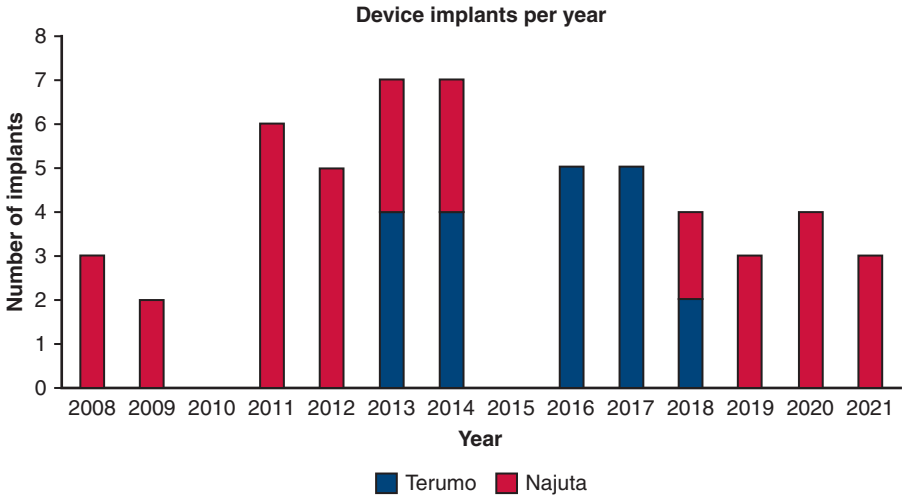


FIGURE E1. Bar graph showing the number of device implants per year.

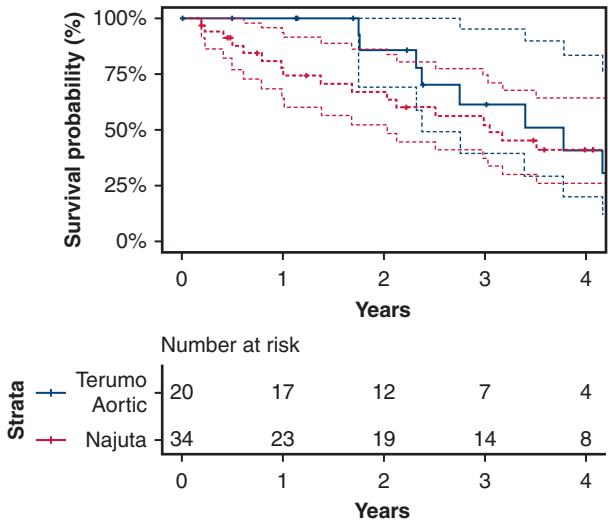


FIGURE E2. Cumulative overall survival throughout the follow-up of bTEVAR (*blue lines*) and fTEVAR (*red lines*) cohorts with 95% confidence intervals (*thin dotted lines*).