Proximal sealing in the aortic arch for inner curve disease using the custom Relay scalloped and fenestrated stent graft

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ABSTRACT

Objective: This study aimed to analyze early and midterm results of custom-made proximal scallop and fenestrated stent grafts for thoracic endovascular aortic repair (TEVAR) with a proximal landing zone (PLZ) in the aortic arch.

Methods: All consecutive patients treated with the custom made proximal scalloped and fenestrated Relay stent grafts (Terumo Aortic Bolton Medical Inc.) in 10 Italian centers between January 2014 and December 2022 were included. The primary end points were technical success, incidence of intraoperative major adverse events, deployment accuracy, and rate of early neurological complications, endoleaks (ELs) and retrograde aortic dissection.

Results: During the study period, 49 patients received TEVAR with Relay custom-made endograft in Italy were enrolled. The median patient age was 70.1 years (interquartile range, 23-86 years) and 65.3% were male. The indication for treatment was atherosclerotic aneurysms in 59.2% of cases and penetrating aortic ulcer in 22.4%. The endograft configuration was proximal fenestration in 55.1% and scallop in 44.9%. The proximal landing zone was zone 0 in 25 cases (51%), zone 1 in 14 cases (28.6%), and zone 2 in 10 cases (20.4%). The supra-aortic debranching procedures were 38 (77.5%). Technical success was 97.9% (48/49) owing to one case (2.0%) of inaccurate deployment. Intraoperatively, one (2.0%) type Ia and one (2.0%) type III EL were detected. There were no cases of in-hospital mortality, major adverse events, or retrograde dissection. Three minor strokes (6.1%) (National Institutes of Health Stroke Scale score of ≤4) were observed. At a mean follow-up time of 36.3 ± 21.3 months the rate of types I to III ELs and reintervention was 4.1%, respectively. Four patients (8.2%) died during the follow-up period, one (2.1%) from abdominal aortic rupture and three (6.1%) from nonaortic causes.

Conclusions: Our early and midterm outcomes suggest that scalloped and fenestrated TEVAR may provide an acceptable alternative treatment option for aortic arch pathologies. Large-scale studies are needed to assess the long-term durability of this technique. (J Vasc Surg 2024;80:1317-25.)

Keywords: Aortic arch; TEVAR; Custom-made; Scallop; Fenestrated; Stent graft; Multicenter study

Thoracic endovascular aortic repair (TEVAR) is now considered the gold standard for the treatment of pathologies of the distal aortic arch and descending thoracic aorta.[1] However, the feasibility of TEVAR is determined by several anatomic factors, in particular the availability of a proximal landing zone (PLZ) length of ≥2 cm according to the aortic arch type.[2] In case of inadequate PLZ, it is necessary to extend the coverage

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to the aortic arch in Ishimaru PLZs 0 to 2.[1] In the literature, it is reported that 38.8% to 59.5% of thoracic aortic diseases find a proximal sealing in zones 0, 1, and 2.[3]

During the previous decade, hybrid aortic repair combining TEVAR with surgical cervical debranching has been increasing.[4] It allows for the proximal extension of the landing zone, with preservation of blood flow to the supra-aortic trunks (SATs), avoiding the need for aortic arch replacement and cardiopulmonary bypass.

Moreover, the recent development of arch endografts with specific delivery systems, fenestration, and inner branches has allowed the treatment of thoracic aortic disease with a total endovascular solution.[1] Several devices for endovascular treatment of the aortic arch are available, using both branched and fenestrated TEVAR. However, in these cases the rate of stroke remains a major concern owing to the devices manipulation in the arch and SATs, air emboli released from the delivery system, and coverage of the target vessels.[5]

In case of a short PLZ during TEVAR in patients unfit for open surgery, the custom-made stent grafts with a proximal scallop or fenestration for the origin of a supra-aortic vessel represent an effective strategy to increase the PLZ in the inner curvature.[6-8]

The aim of this study was to analyze the early and midterm results of custom-made proximal scallop and fenestrated stent grafts for TEVAR with PLZ in the aortic arch.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective study of prospectively collected multicenter registry data
- **Key Findings:** In 49 patients undergoing endovascular thoracic aortic repair with custom scallop and fenestrated stent graft, the rate of in-hospital mortality, major stroke, and retrograde dissection was 0%. The indication for treatment was atherosclerotic aneurysms in 59.2% of cases. During a follow-up of 36 months, no patient died of stent graft-related causes and 8.1% required reintervention.
- **Take Home Message:** Thoracic endovascular aortic repair with a proximal landing zone in the aortic arch with custom-made proximal scallop and fenestrated stent grafts is feasible, and the results are acceptable.

METHODS

Study design. This single-arm, nonrandomized, retrospective multicenter study included all consecutive patients treated with the custom made proximal scalloped and fenestrated Relay stent grafts (Terumo Aortic Bolton Medical Inc., Sunrise, FL) in 10 Italian centers (Supplementary Table, online only) between January 2014 and December 2022. The study was performed in accordance with the Institutional Ethics Committee rules, and individual consent for intervention and retrospective analysis was obtained from all patients. Study data were prospectively collected using REDCap electronic data capture tools.[9] Institutional Review Board ID: 2992; International Clinical Trials: NCT05777460. The database included preoperative demographics, risk factors, anatomical features, procedural details, and follow-up outcomes (postoperative clinical events and imaging examinations).

Patient selection. The authors considered fenestrated and/or scallop grafts in cases of aortic pathologies along the inner curve of the arch distal to the origin of the brachiocephalic trunk and descending thoracic aorta requiring a PLZ into the aortic arch. A broad spectrum of aortic arch pathologies was treated, including degenerative aneurysmal disease, penetrating aortic ulcer, postdissection aneurysm, and type Ia endoleak (EL) on previous TEVAR. All patients were considered at high risk for open repair based on their anatomy, age, and comorbidities. The treatment strategy was decided for each case after multidisciplinary discussion.

Evaluation of the preoperative computed tomography angiography (CTA) images was performed for all patients with a dedicated workstation. Each case was analyzed and planned by an experienced operator. The Terumo Aortic Custom Solutions planning center also assessed aortic anatomical characteristics and feasibilities.

In case of PLZ 1-2 with adequate sealing length (≥15 mm for arch type I-II and ≥20 mm for arch type III), the decision was for a scalloped device with the possible association of SATs debranching (scallop TEVAR in PLZ 2, scallop TEVAR and carotid-subclavian bypass in PLZ 1). In case of inadequate sealing length in zones 1 and 2, it was necessarily a more proximal TEVAR with a fenestration configuration requiring a PLZ length of ≥25 mm in zones 0 and 1.

Patients who presented with a shaggy aorta, significant atheroma and thrombus (ulcer-like thrombus, thrombus thickness >5 mm, and mural thrombus occupying more than two-thirds of the circumference of the aortic diameter) in the aortic arch, were considered ineligible for endovascular repair because of the high cerebral embolic potential complication risk.[10] In case of fenestration, patients with prior mechanical aortic valve replacement and PLZ length of <15 mm distal to the coronaries were excluded. The maximum PLZ aortic diameter was 42 mm.

All patients receiving the custom-made proximal scalloped/fenestrated Relay stent graft at a participating center during the study period were included. Exclusion criteria were ineligibility for endovascular aortic repair and inability to provide consent.

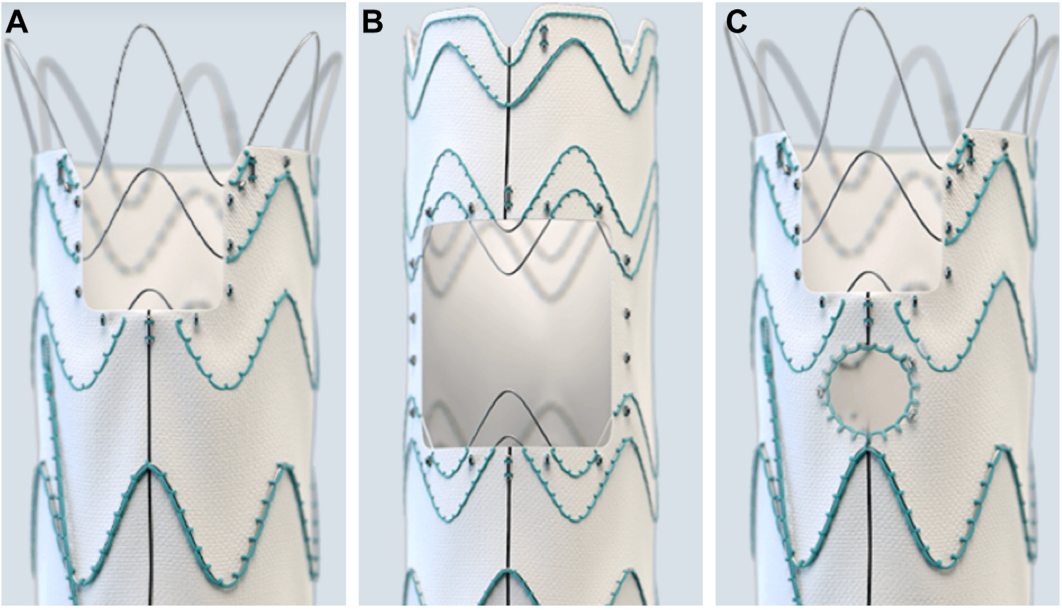

Fig 1. Appearance of the device with customized scallop **(A)**, fenestration **(B)**, or a fenestration and a scallop **(C)**.

Stent graft characteristics and procedural details. Custom-made fenestrated or scallop stent grafts are manufactured using the standard stent graft platform Relay Plus (2014-2019) and Relay Pro (2019-2023) Terumo Aortic (Bolton Medical Inc). The device may feature a customized scallop, fenestration, or a fenestration and a scallop (Fig 1). Although there is no limitation for scallop length, the width can be 13 to 22 mm and cannot be more than the distance between the two apexes. Fenestration width can be between 20 and 50 mm and can be tapered along the length of the graft.[6] Fenestration position, shape, and dimensions can be customized on both the bare stent and nonbare stent configurations (scallops can only be bare stent). The stent graft diameter ranges from 22 to 48 mm. The delivery system consists of a precurved nitinol inner catheter and dual (inner and outer) 22F to 26F (Relay Plus) and 19F to 23F (Relay Pro) sheaths, with a proximal capture mechanism.

All procedures were performed under general anesthesia, with common femoral artery percutaneous or surgical access. Angiographic runs were performed through a pigtail catheter, introduced percutaneously through the contralateral femoral or left brachial access and placed into the arch. The stent graft delivery system was inserted up to the mid descending thoracic aorta where the secondary sheath was further advanced into the arch. During the fenestrated device deployment, the distal apex clasp is rotated 30° posteriorly to help with the alignment of the fenestration. Owing to the dual sheath system and spiral support strut, the stent graft has the characteristic to self-align to the outer curvature of the aortic arch. The marker of the scallop and fenestration were aligned to the targeted SAT (Supplementary Fig, online only). Deployment was performed after angiogram control in anteroposterior and right anterior oblique projection, to confirm stable positioning of the markers. Prior to deployment, the systolic blood pressure was decreased to approximately 80 mm Hg to optimize deployment accuracy. The steps of stent graft deployment were followed according to manufacturer instructions, as already described.[7,11,12] Completion angiography were performed in anteroposterior and right anterior oblique projection in all cases (Fig 2).

In case of scallop and big fenestration, stenting of SATs was not performed. All SATs not perfused with a scallop/fenestration were revascularized with a cervical debranching procedure before the concomitant TEVAR (carotid-subclavian or carotid-carotid subclavian) bypass or subclavian transposition. All operations were performed in a hybrid operating room with a fixed imaging system.

Follow-up protocols. Patients were observed at regular postoperative appointments. CTA was performed 1 month and 6 months postoperatively, and yearly thereafter.

End points and definitions. Outcomes are defined according to the current TEVAR reporting standards.[13] The primary end points were technical success, intraoperative major adverse event (MAE) rate, deployment accuracy, and incidence of early neurological complications, ELs, and retrograde aortic dissection. Technical success was defined as successful deployment of the endovascular device at the intended location, with

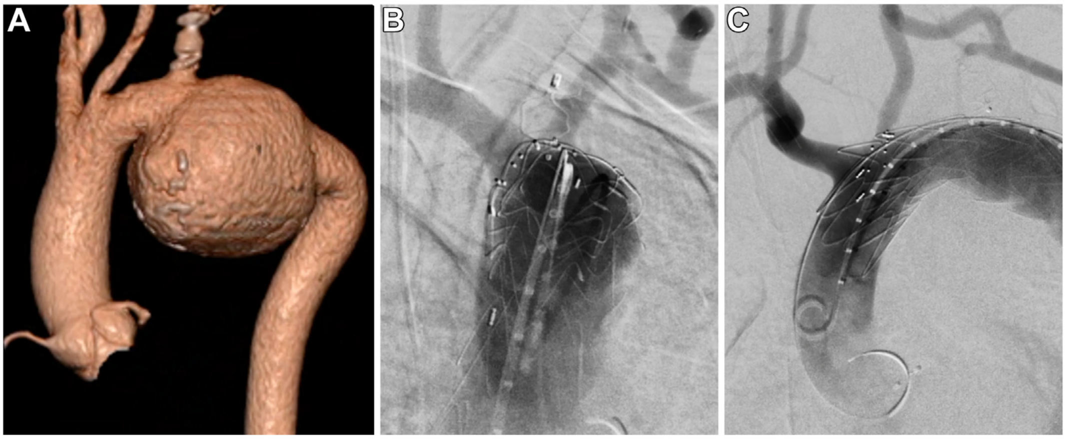

Fig 2. Preoperative three-dimensional volume rendering of post-traumatic chronic aortic isthmus pseudoaneurysm **(A)** treated with debranching and scallop thoracic endovascular aortic repair (TEVAR) in proximal landing zone (PLZ) 1 with final angiography showing the correct position of the stent graft and the patency of the supra-aortic trunks (SATs) without endoleaks (ELs) **(B** and **C)**.

evidence of no type I or III ELs and patency of the graft and all SATs at the intraoperative digital subtraction angiography. Intraoperative MAEs is a composite end point including any intraoperative mortality, conversion to open surgery, or aortic rupture. Deployment accuracy was defined as a proximal distance to the intended implantation site of ≤5 mm. Neurological complications included ischemic stroke and transient ischemic attack, defined as any new neurological deficits lasting >24 or <24 hours, respectively. Stroke is defined using the National Institutes of Health Stroke Scale (NIHSS) score: minor (NIHSS score ≤4), moderate to severe (NIHSS score 5-20), or major (NIHSS score ≥21). Early events were defined as within the first 30 days or in hospital. The secondary end points were overall mortality, aortic-related mortality, aortic-related reintervention rate, ELs rate, and endograft-related complications at 30 days and during follow-up.

Statistical analysis. Continuous data are reported as the mean ± standard deviation, or, in the case of Gaussian distribution, as the median with interquartile range. Categorical data are reported as the number and its accompanying percentage of the whole. Data analysis was performed using STATA 15.1 (StataCorp, College Station, TX).

RESULTS

Study population. Between January 2014 and December 2022, 49 patients with different thoracic aortic diseases who underwent TEVAR with scallop or fenestrated Terumo Relay stent graft were included in the analysis. The mean patient age was 70.1 ± 11.8 years, with 32 male patients (65.3%). Comorbidities were cardiovascular risk factors, including hypertension (77.5%), dyslipidemia (63.2%), smoking (22.4%), and coronary artery disease (18.4%). Twenty-one (42.8%) had undergone previous aortic surgery.

The indication for custom TEVAR was thoracic aortic aneurysm in 29 patients (59.2%) and penetrating aortic ulcer in 11 cases (22.4%). The type of arch was I in 23 patients (47%), II in 18 patients (36.7%), and III in 8 cases (16.3%). The baseline characteristics and aortic pathology of the patients are reported in Table I.

Procedural details. All procedural details and intraoperative results are described in Table II. The endograft configuration was proximal scallop in 22 cases (44.9%), and fenestration in 27 cases (55.1%). One case of proximal scallop for the left common carotid artery included a small fenestration for the left subclavian artery with PLZ 1 without any SAT debranching. Proximal deployment was zone 0 in 25 cases (51.0%), zone 1 in 14 cases (28.6%), and zone 2 in 10 cases (20.4%). Twenty-five cases (92.6%) of proximal fenestration were in zone 0 and two cases (7.4%) in zone 1. Twelve cases (54.5%) of proximal scallop were in zone 1 and 10 (45.5%) in zone 2. Associated SAT debranching procedure was performed in 38 cases (77.5%). Left brachial access was used in 39 cases (79.6%).

The systolic pressure during proximal graft release was <60 mm Hg in 15 patients (30.6%). The cardiac pacing was used in 26 cases (53.1%), in all PLZ 0 and one PLZ 1. No hemodynamic pressure control was used in five cases (10.25) of PLZ 2.

The technical success rate was 97.9%, with one case of inaccurate PLZ 0 deployment of a fenestrated stent graft, requiring left common carotid artery stenting owing to the partial coverture of the left carotid artery ostium. The proximal deployment accuracy rate was 97.9%. Two other cases required an intraoperative adjunctive procedure, consisting of deployment of an adjunctive distal graft for a type IB EL in one case and deployment of a balloon-expandable stent graft (BeGraft Bentley,

Table I. Baseline characteristics and indication for treatment (n = 49)

	Number or mean ± standard deviation	Percent or range
Baseline characteristics		
Male gender	32	65.3
Age, years	70.1 ± 11.8	range 23-86
Smoking	11	22.4
Hypertension	38	77.5
Diabetes mellitus	8	16.3
Dyslipidemia	31	63.2
CKD	6	12.2
Stage 1-3a (eGFR >44)	3	6.1
Stage 3b-4 (eGFR 15-44)	3	6.1
Stage 5 (eGFR <15)	0	0
COPD	10	20.4
Cerebral vessels disease	3	6.1
AMI	9	18.4
Previous CABG	1	2.0
Previous PCI	8	16.3
ASA score		
ASA II	12	24.5
ASA III	31	63.2
ASA IV	6	12.2
Previous aortic surgery	21	42.8
Open	16	32.6
Endovascular	5	10.2
Antiplatelet therapy	34	69.4
Anticoagulation therapy	5	10.2
Aortic pathology		
Thoracic aortic aneurysm	29	59.2
PAU	11	22.4
Aortic dissection	3	6.1
Relining of previous TEVAR	3	6.1
Pseudoaneurysm	2	4.1
Brachiocephalic trunk dissecting aneurysm	1	2.0

AMI, Acute myocardial infarction; *ASA score*, American Society of Anesthesiologists score; *CABG*, coronary aortic bypass graft; *CKD*, chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *eGFR*, estimated glomerular filtration rate calculated CKD-EPI Creatinine Equation (2009) and measured in ml/min/1.73 m^2; *PAU*, penetrating aortic ulcer; *PCI*, percutaneous coronary intervention; *TEVAR*, thoracic endovascular aortic repair.

Bentley Innomed GmbH, Hechingen, Germany) in left subclavian artery fenestration for a type III EL in one case. Intraoperatively, were detected one type Ia (2.0%) and two type Ib (4.1%) ELs. Proximal ballooning in the case of type Ia EL was performed. There were no intraoperative MAEs, including stroke and deaths.

Early outcomes. Three cerebrovascular complications (6.1%) were registered: all cases were embolic minor strokes, in two cases of fenestrated PLZ 0 and one case of a scallop zone 2 procedure. In these cases, complete resolution of the symptoms was observed. No cases of spinal cord ischemia occurred. There were two (4.1%) access-related complications of wound dehiscence in two patients with cutdown femoral access owing to lymphatic leaks. There were no cases of in-hospital mortality or retrograde dissection.

At the 1-month CTA, there was evidence of one case (2.0%) of type Ia ELs after zone 2 scallop TEVAR treated after 3 months with carotid-subclavian bypass and proximal relining in PLZ 1. The intraoperatively treated type III EL was present also at the first CTA, the patient refused any treatment and was followed in the time with no evidence of sac increase. Another type III EL was detected, and early reintervention was performed with the positioning of balloon expandable stent graft (BeGraft Bentley, Bentley Innomed GmbH, Hechingen, Germany) in the left common carotid artery. The two cases of type II intraoperative ELs were confirmed at the first postoperative CTA with stability of the aneurysm sac. Early results are summarized in Table III.

Midterm outcomes and overall follow-up. The mean follow-up time was 36.3 ± 21.3 months (range, 2-58 months). One type Ia EL (4.2%) requiring reintervention after 3 months from the procedure was observed. Four type II (8.2%) and one type III (2.1%) ELs were noted in late CTAs without sac growth and were followed in the time. The patency rate of supra-aortic debranching bypasses was 97.4% (37/38), with one case (2.1%) of carotid-subclavian asymptomatic occlusion observed during follow-up. Two reinterventions (4.1%) were performed: one case of proximal relining for a type Ia EL after left subclavian artery scalloped TEVAR and one case of acute left upper limb ischemia (brachial embolization with patent carotid-subclavian graft). Four patients (8.2%) died during the follow-up period, all for nonaortic reasons except for one case (2.1%) of abdominal aorta rupture. Estimated freedom from death and reintervention was 95.6% ± 3% and 96.6% ± 3% at postoperative at 1 year, 95.6% ± 3% and 92.2% ± 5% at 2 years, and 88.2% ± 2% and 87.8% ± 6% at 5 years, respectively (Fig 3).

DISCUSSION

The use of proximal scallop or fenestration for TEVAR represents a valid solution for aortic pathologies of the descending thoracic aortic diseases in zone 3 and for lesions of the aortic arch located at the inner curve. In patients with inadequate proximal seal zones, this

Table II. Procedural details and intraoperative results (n = 49)

	Number	Percent
Procedural details		
Endograft configuration		
Proximal scallop	22	44.9
Proximal fenestration	27	55.1
Ishimaru PLZ		
Zone 0	25	51.0
Zone 1	14	28.6
Zone 2	10	20.4
Supra-aortic debranching	38	77.5
Carotid-subclavian bypass	33	67.3
Carotid-carotid-subclavian bypass	3	6.1
Carotid-subclavian transposition	2	4.1
Left subclavian artery plug	36	73.4
Type of anesthesia		
General	46	93.9
Local	3	6.1
Femoral access approach		
Cut-down	29	59.2
Percutaneous	20	40.8
Systolic pressure during proximal graft release		
100-80 mm Hg	15	30.6
79-60 mm Hg	19	38.8
<60 mm Hg	15	30.6
Hemodynamic adjuncts during proximal deployment		
None	5	10.2
Pharmacological hypotension	18	36.7
Rapid cardiac pacing	26	53.1
Operating time, minutes	215.1 ± 140.9	33-660
Intraoperative results		
Technical success	48	97.9
Access failure	0	0
Deployment failure	0	0
Deployment accuracy in proximal target landing zone	48	97.9
Intraoperative EL		
Type Ia	1	2.0
Type Ib	2	4.1
Type II	2	4.1
Type III	1	2.0
Intraoperative adjunctive graft-related procedures	3	6.1
MAEs	0	0
Intraoperative stroke	0	0
Intraoperative death	0	0

EL, Endoleak; *MAE*, major adverse event; *PLZ*, proximal landing zone.

approach is a feasible alternative to extra-anatomic debranching such as carotid-subclavian bypass, and allows to gain a PLZ in the inner curve, while preserving the patency of the SATs on the outer curvature with possible less invasive maneuvers. Most of the lesions in our patients and in the published series[14] were aneurysms and penetrating aortic ulcers (81.6%) located along the inner curve of the arch, where the device showed the major applicability. Moreover, fenestrated devices were more frequently used in the proximal arch (92.6% in zone 0) compared with scalloped devices that were typically used for distal arch disease (54.5% in zone 1 and 45.45% in zone 2).

In TEVAR in the aortic arch, different anatomical challenges are posed by the aortic angulation and nonuniform caliber, the pulsatility of the ascending aorta and aortic arch, and the location and variation of the supra-aortic branch vessels.[15] Endovascular solutions for TEVAR in PLZs 0 to 2 are expanding rapidly. A recent review and meta-analysis on 571 patients requiring elective endovascular aortic treatment with a PLZ in the aortic arch showed that fenestrated and branched TEVAR are the most common used technique (38.4% and 54.1% cases, respectively).[16] In this review, 47 cases of scalloped graft and only 5 cases of fenestrated Terumo Relay stent graft are reported.[6,8] To our knowledge, the current paper, including a total of 49 patients (27 fenestration and 22 scallop), is the largest series in the literature on this graft outcomes.

In the endovascular treatment of the aortic arch, precise deployment of devices is crucial for the correct alignment of fenestration or scallop with supra-aortic branches. In our experience, technical success was 97.9%, with only one case of inaccurate PLZ 0 deployment of a fenestrated stent graft. The Terumo platform ensures self-alignment of the device on the natural curvature of the aortic arch thanks to a precurved internal introducer with a nitinol core. Additionally, it allows for preloading of the prosthesis with a specific offset in case of supra-aortic branches with an ostium angled >15° from 12 o'clock.

Minimizing the need for manipulation of the device once it is delivered into position is a key factor to decrease the potential risk of embolization. Avoiding the need to manipulate the SATs limits the risk of stroke compared to the more invasive branched device. The total rate of major or disabling strokes reported in the literature is 6.2% for fenestrated and branched TEVAR.[16] However, cerebrovascular events remain an open issue for the branched devices, with high perioperative rates of stroke ranging from 5% to 25%.[17-20] Isernia et al[21] reported rates of 1.31% for major stroke and 3.9% for cerebrovascular event after fenestrated Najuta endograft implantation. In a large series of Cook fenestrated stent

Table III. Early outcomes (n = 49)

Early results	Number or mean ± standard deviation	Percent or range
Cerebrovascular complications	3	6.1
Major stroke	0	0
Minor stroke	3	6.1
SCI	0	0
AMI	0	0
Acute renal failure	0	0
ARI	1	2.0
Access-related complications	2	4.1
EL		
Type Ia	1	2.0
Type Ib	1	2.0
Type II	2	4.1
Type III	2	4.1
Retrograde dissection	0	0
Early reintervention	1	2.1
In-hospital mortality	0	0
30-day mortality	0	0
Mean hospitalization time, days	12.2 ± 10.2	3-53
Mean ICU stay, days	2.4 ± 1.7	1-8

AMI, Acute myocardial infarction; *ARI*, acute respiratory infection; *EL*, endoleak; *ICU*, intensive care unit; *SCI*, spinal cord ischemia.

grafts for treatment of diseases involving the aortic arch, Tsilimparis et al[22] found that the technique was feasible, with a high technical success rate. However, rates of stroke in the perioperative period amounted to 9%.[22] Our series demonstrates excellent safety, with no cases of major strokes and a 6.1% rate of minor strokes with three neurological events occurring in two cases of fenestrated PLZ 0 and one case of scallop zone 2 procedure. These findings would in fact indicate that more proximal TEVAR interventions, which are potentially associated with more complex instrumentation within the aortic arch, may bear an increased risk for neurological complications. The technical features of the Terumo Relay that contribute to reducing the risk of stroke include the presence of a dual introducer system. The external introducer, which is more rigid, is not advanced into the arch, preventing the release of air bubbles during deployment. Meanwhile, the internal introducer, coated with Dacron and less rigid, is advanced into the arch, ensuring minimal trauma to the aortic wall.

One of the advantages of the fenestrated and scalloped endografts is to minimize the surgical insult and the complications of debranching procedures required to perfuse the SATs. Total arch debranching is described as an important independent predictor of 30-day mortality (odds ratio, 9.6; 95% confidence interval, 1.54-59.90; $P = .015$).[23] The major complication directly related to the carotid-carotid-subclavian bypass includes the transient unilateral recurrent laryngeal nerve deficit (7.7%).[12] Carotid-subclavian bypass seemed to be safe, with a reported 4.3% stroke incidence and 98.1% primary patency rate at 15 months follow-up. However, 11.4% rates of local bleeding, 10.4% rates of reinterventions, and 9.5% rates local peripheral neurological damage postoperatively are reported.[24,25] According to Madenci et al,[26] analyzing the largest series on cervical debranching procedures on 918 patients, the incidence of major stroke and mortality was 3.3% and 3.5%, respectively. In our experience, there were no complications related to the debranching procedure and 97.4% patency rate at 36 months follow-up with only one case of asymptomatic carotid-subclavian bypass occlusion.

Type Ia EL is a possible complication of TEVAR and is due to an inadequate seal at the proximal end of the endograft.[27] The mean reported incidence of type Ia EL after fenestrated TEVAR is 5% (range, 0%-21.4%).[28] Spath

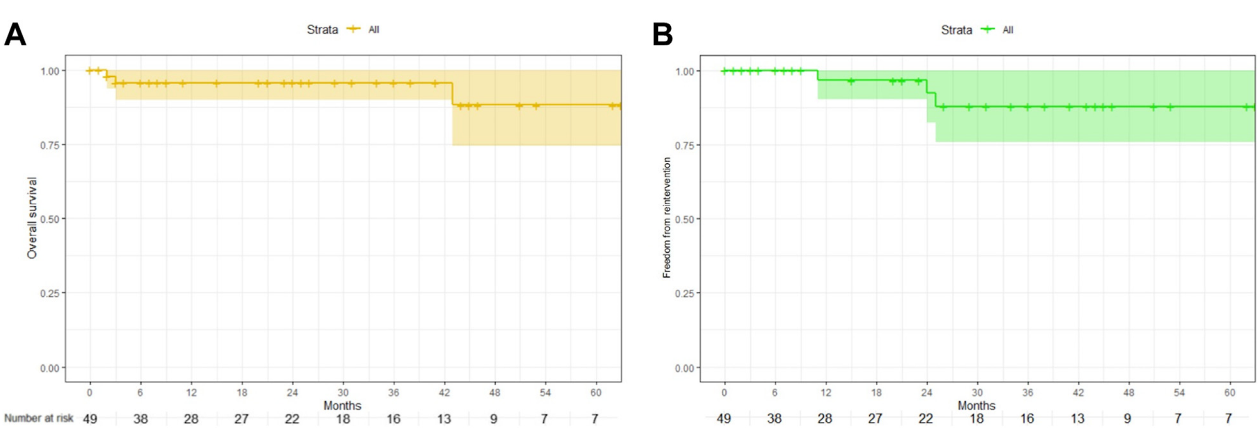

Fig 3. Kaplan-Meier curves for freedom from death **(A)** and reintervention **(B)**.

et al[16] compared fenestrated with branched TEVAR showed a significant higher rate of type I e III ELs in fenestrated endografts (9.8% vs 2.6%; $P = .034$). Isernia et al[21] reported 2.6% rate of type I EL after TEVAR with the fenestrated Najuta device. Our results are in line with the current literature, with 2.0% rate of type Ia ELs after scallop TEVAR in zone 2.

The implementation of endovascular approaches, associated or not with partial debranching, might be useful in avoiding arch manipulations and thereby decreasing the risk of perioperative MAEs, especially in patients requiring stent graft landing in zone 0.[23] Reported data suggest that the complications of arch interventions are most likely related to wire manipulation of the arch and the curvature of the landing zone, which are pertinent to disease extension into the proximal arch.[29] On the other hand, lesions involving the proximal descending aorta are associated with lower EL occurrence compared with the distal aorta (11.1% vs 51.9%; $P < .001$).[30] Even if a strict correlation cannot be demonstrated, our paper showed that neurological complications were more common in fenestrated zone 0 procedures because of the more proximal arch extent of the device, whereas type Ia ELs were more common in scallop zone 2 procedures, probably for the inadequate proximal sealing.

Study limitations. This study has some limitations. First, although it is one of the largest series regarding fenestrated and scalloped procedure with the Terumo device, the sample size is too small for drawing strong conclusions. In addition, the accuracy of our findings might be affected by the multicenter design of the study although this may also increase the generalizability. Last, all outcomes were self-reported by participating institutions and core laboratory adjudication of imaging data was not available.

CONCLUSIONS

Our early and midterm outcomes suggest that scalloped and fenestrated TEVAR may provide an acceptable alternative treatment option for aortic arch pathologies. Further studies, in particular long-term outcome data, are needed to establish the advantages and durability of custom-made scalloped and fenestrated thoracic endografts.

AUTHOR CONTRIBUTIONS

Conception and design: SS, GP, GR, MF, LL, PV, GF, MF, AR, MO, RM, YT, GT
Analysis and interpretation: SS, MF
Data collection: SS, GP, GR, MF, LL, PV, GF, MF, AR, MO, RM, YT, GT
Writing the article: SS, MF
Critical revision of the article: SS, GP, GR, MF, LL, PV, GF, MF, AR, MO, RM, YT, GT
Final approval of the article: SS, GP, GR, MF, LL, PV, GF, MF, AR, MO, RM, YT, GT
Statistical analysis: SS, MF
Obtained funding: Not applicable
Overall responsibility: GT

DISCLOSURES

None.

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OSCAR (prOximal Sealing aortiC ARch) Collaborative Study Group

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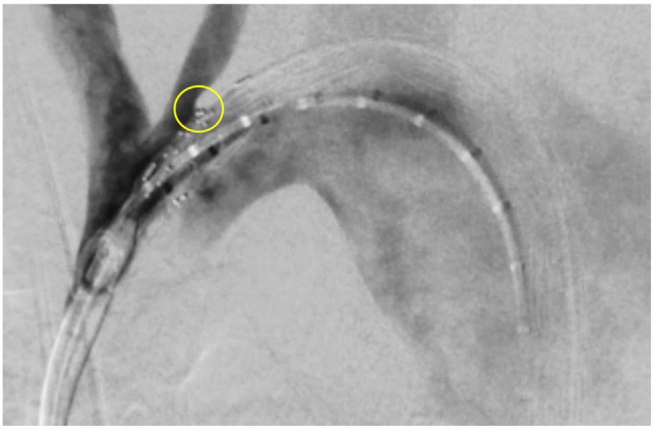
Supplementary Table (online only). Participating centers with number of performed cases

Center	No. of cases
Fondazione Policlinico Universitario A. Gemelli IRCCS (Rome)	8
San Martino Hospital (Genova)	8
Manzoni Hospital (Lecco)	7
S. Orsola Malpighi Hospital (Bologna)	7
Bianchi Melacrino Morelli Hospital (Reggio Calabria)	6
Ospedale San Francesco (Nuoro)	5
Mauriziano Umberto Hospital (Turin)	4
Fondazione Toscana G. Monasterio (Massa)	2
University Hospital of Trieste (Trieste)	1
Santa Maria Hospital (Terni)	1



Supplementary Fig (online only). Alignment of the scallop marker at the end of the left common carotid artery before stent graft deployment.