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Midterm Follow-up of Fenestrated and Scalloped Physician-Modified Endovascular Grafts for Zone 2 TEVAR

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Abstract

Purpose: To investigate the midterm outcomes of scalloped or fenestrated physician-modified endovascular grafts (PMEGs) for zone 2 thoracic endovascular aortic repairs (TEVAR). **Materials and Methods:** Between November 2013 and May 2019, 54 consecutive patients (mean age 63 years; 41 men) were treated with thoracic PMEGs modified with 7 scallops or 47 fenestrations for the left subclavian artery (LSA). Indications for aortic repair were acute complicated type B aortic dissection (17, 31%), degenerative aneurysm (13, 24%), acute traumatic rupture of the aortic isthmus (9, 16%), post chronic dissection aneurysmal evolution (8, 15%), penetrating aortic ulcer (3, 6%), intramural hematoma (2, 4%), and floating thrombus (2, 4%). **Results:** Technical success was 94%; 3 (6%) LSAs were unintentionally covered. An intraoperative type Ia endoleak was treated during the index procedure. One (2%) patient suffered spinal cord ischemia, with irreversible bilateral paraplegia. Three (6%) patients experience postoperative minor strokes with full neurological recovery. Four (7%) patients died in the perioperative period; 2 (2%) were due to aneurysm rupture. Mean follow-up was 26±16 months; 15 (28%) patients had at least 3 years of follow-up. Two (4%) type II endoleaks were identified and successfully treated (4% reintervention rate); no other endoleaks were identified. All the LSAs remained clinically and radiologically patent. There were no conversions to open repair, ruptures, retrograde dissection, stent fracture, migrations, or other aortic complications. **Conclusion:** Scalloped or single-fenestrated PMEGs for the LSA appear to be durable and safe in the midterm. Combined with low periprocedural morbidity and mortality, these results suggest that this approach can be considered as an off-label alternative to extend proximal seal to zone 2 for TEVAR. Further studies with a larger number of patients and long-term outcomes are needed to fully validate this approach.

Keywords

aortic arch, endograft, fenestrated stent-graft, left subclavian artery, physician-modified endovascular grafts, scallop, stent-graft, supra-aortic branches, thoracic aorta, thoracic endovascular aortic repair

Introduction

Thoracic endovascular aortic repair (TEVAR) has become the preferred strategy for the management of multiple acute and chronic pathologies of the descending thoracic aorta, often enabling the treatment of patients with complex comorbidities who could not tolerate open repair. The outcome of TEVAR is directly related to adequacy of stent-graft apposition to healthy aorta proximally and distally. To avoid coverage of any supra-aortic trunk, conventional TEVAR is limited to zone 3 pathologies [distal to the origin of the left subclavian artery (LSA)]. However, real world experience has demonstrated that 40% to 50% of TEVAR procedures require coverage of the LSA (zone 2) to reach healthy proximal aorta.[1–6]

The role of LSA revascularization in TEVAR remains controversial. Some authors recommend prophylactic LSA transposition or bypass prior to intentional coverage.[2,4] Conversely, others suggest that routine LSA revascularization offers no significant benefit and may even increase the

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Table 1. Anatomic Criteria Guiding Patient Selection for Zone 2 TEVAR Using PMEGs With Fenestrations or a Scallop.

Aortic fusiform and saccular aneurysm / penetrating ulcers / dissection / traumatic isthmic rupture that require a seal in zone 2 with:
• A minimum of 5 mm between the LCCA and LSA for fenestrations
• At least 15 mm of healthy proximal aorta between the LCCA and the proximal part of the lesion
• Diameters of the proximal and distal aorta <40 mm
• Left brachial access suitable to accommodate 7-F sheaths
• Iliac access suitable to accommodate 24-F sheaths

Abbreviations: LCCA, left common carotid artery; LSA, left subclavian artery; PMEG, physician-modified endovascular grafts; TEVAR, thoracic endovascular aortic repair.

procedure risk.[7] The European Society for Vascular Surgery (ESVS) recommends preoperative LSA revascularization in electively treated patients requiring coverage for seal; in the acute setting, patients with left internal mammary to coronary bypass or dominant cerebral blood supply from the left vertebral artery require revascularization.[8] The Society for Vascular Surgery (SVS) further includes termination of the vertebral artery into the posterior inferior cerebellar artery, patent left arm arteriovenous fistula or graft, prior infrarenal aortic repair, planned extensive coverage (>20 cm) of the descending thoracic aorta, and occlusion of the internal iliac arteries.[9] The literature demonstrates the outcomes of combining open distal aortic arch debranching with TEVAR in patients having a variety of thoracic aortic pathologies, with stroke and death rates ranging between 3% and 8%.[10,11]

In addition to open LSA revascularization, novel endovascular technologies, such as branched or fenestrated endografts, chimneys, snorkels, in situ fenestration, and physician-modified endovascular grafts (PMEGs) have been developed for revascularization of aortic arch vessels during TEVAR. The world experience with these strategies is both limited and without long-term follow-up. We have reported our experience[12–15] in the use of PMEGs for TEVAR with proximal landing in zones 0, 1, and 2. This retrospective analysis reviews the midterm outcomes of those TEVAR patients treated with PMEGs in zone 2.

Materials and Methods

Study Design and Patient Sample

Between November 2013 and May 2019, 103 patients were treated with PMEGs, 49 of whom received a common fenestration for the innominate and left common carotid artery (LCCA) with a second fenestration for the LSA for zone 0 TEVAR. The other 54 patients (mean age 63±13 years; 41 men) treated at 2 centers [47 at Arnaud de Villeneuve Hospital (Montpellier, France) and 7 at Santa Helena Hospital (Florianopolis, Brazil)] with zone 2 TEVAR using fenestrated/scalloped PMEGs form the patient sample for this retrospective analysis. This clinical work was supported by an experimental feasibility study in human cadaveric aortas implanted with PMEGS to extend the proximal landing zone to the aortic arch while preserving flow in the supra-aortic vessels.[16]

Patients with zone 2 aortic lesions were considered candidates for TEVAR using a scalloped or fenestrated PMEG if the proximal and distal aortic neck diameters were <40 mm and the landing zones at least 15 mm in length. The minimal acceptable length of healthy proximal aorta between the LCCA and the proximal edge of the lesion was 15 mm; otherwise, the lesion was considered to be in zone 1. Anatomic criteria for selection of patients suitable for scalloped/fenestrated PMEGs in zone 2 are summarized in Table 1.

Indications for zone 2 TEVAR in the 54-patient cohort were complicated type B aortic dissection in 17 (31%) patients, degenerative aneurysm in 13 (24%), acute traumatic rupture of the aortic isthmus in 9 (16%), post chronic dissection aneurysmal evolution in 8 (15%), penetrating aortic ulcer in 3 (6%), intramural hematoma in 2 (4%), and floating thrombus in 2 (4%). More than half of the procedures were performed urgently (32, 59%). All patients underwent high-resolution computed tomography angiography (CTA) preoperatively. The mean proximal aortic diameter was 32±3 mm with a mean proximal sealing length of 23±4 mm.

The protocol and informed consent for the clinical study were approved by the institutional review boards of both centers. All patients gave written consent. Demographic, anatomical, intraoperative, and postoperative data (Table 2) were recorded into a prospectively maintained database.

Planning, Sizing, and Device Preparation

These aspects have already been described in detail for both scalloped and fenestrated TEVAR in our previous publications.[12–15] In summary, procedure planning and device sizing were performed using a dedicated 3-dimensional vascular imaging workstation [either Aquarius WS (Terarecon Inc., San Mateo, CA, USA) or OsiriX Imaging Software (OsiriX, Geneva, Switzerland) until 2017, when the EndoSize 3D vascular imaging workstation (Therenva, Nanjing, France) became available. Center lumen line reconstruction was used to determine aortic diameter at the landing zones and measure lengths. The stent-graft oversizing was <10% for

Table 2. Demographics, Clinical Characteristics, and Operative Details of 54 Patients Who Underwent Zone 2 TEVAR Using Fenestrated/Scalloped PMEGs.[a]

Age, y	63±13 (20–87)
Men	41 (76)
Comorbid conditions	
Hypertension	40 (74)
Smoking	28 (52)
Dyslipidemia	18 (33)
Coronary disease	10 (19)
Diabetes mellitus	8 (15)
Arrhythmia	5 (9)
Peripheral artery disease	5 (9)
Renal Insufficiency	5 (9)
COPD	3 (6)
Congestive heart failure	3 (6)
ASA	
II	20 (37)
III	31 (57)
IV	3 (6)
Operative details	
Urgent surgery	32 (59)
Elective surgery	22 (41)
Proximal landing in zone 2	54 (100)
Distal landing in zone 4	32 (59)
Distal landing in zone 5	22 (41)
Proximal aortic diameter, mm	32±3
Proximal stent-graft diameters,[b] mm	24–42
Proximal sealing neck length, mm	23±4
Fenestration with LSA bridging stent	43 (80)
Scallop without LSA bridging stent	7 (13)
Fenestration without LSA bridging stent	4 (7)
Bridging covered stent diameters,[b] mm	8–10
Fenestration preparation time, min	16±2
Operative time, min	76±22
Technical success	51 (94)

Abbreviations: ASA, American Society of Anesthesiologists score; COPD, chronic obstructive pulmonary disease; LSA, left subclavian artery; PMEG, physician-modified endovascular grafts; TEVAR, thoracic endovascular aortic repair.
[a]Continuous data are presented as the mean ± standard deviation (range) unless otherwise noted; categorical data are given as the number (percentage).
[b]Range of sizes.

acute aortic dissection and between 10% and 15% for other aortic arch pathologies. Volume-rendering associated with centerline of flow reconstructions were used to determine the optimal position of the C-arm and to evaluate aortic arch tortuosity.

The Valiant Captivia stent-graft (Medtronic, Santa Rosa, CA, USA) was used in all procedures. Modification of the stent-graft was performed on a back table, beginning before the start of anesthesia. A portion of the aortic stent-graft was unsheathed. In our early experience, a blade was used to cut a scallop 5-mm larger than the size of the LSA orifice. In 2017 scallops were replaced by fenestrations opened with a cautery between the stent-graft stent struts; they were sized 2 mm smaller than the diameter of the covered stent intended for the LSA. A radiopaque nitinol wire was sewn onto the edge of the scallop or fenestration, acting as a marker and reinforcing sealing between the LSA covered stent and aortic stent-graft in fenestrated cases (Figure 1).

Technique

All procedures were performed with the patient under general anesthesia in an operating room equipped with a C-arm or in a hybrid room (available since 2017). A surgical cut down of the common femoral artery was performed, and heparin was administered (100 U/kg) with a target activated coagulation time of 300 seconds. The specific approach to the fenestrated cases with stenting of the subclavian is detailed in Figure 2. A pigtail catheter was introduced retrograde via a left brachial artery access or a contralateral femoral artery access for angiography. Mean blood pressure was lowered to ~80 mm Hg at stent-graft deployment to optimize accuracy. The stent-graft marker was positioned on the outer curve of the descending thoracic aorta, and the device was then advanced proximally. If adjustment was required due to misalignment with the LSA, the stent-graft was withdrawn into the descending aorta before reintroduction. No ventricular rapid pacing was used.

For fenestrated stent-grafts, a 7-F long sheath was placed through the retrograde left brachial artery into the ostium of the LSA, and the stent-graft was partially unsheathed. A 0.035-inch guidewire from the brachial access was advanced through the fenestration, followed by the long sheath into the stent-graft lumen. The thoracic stent-graft was fully deployed. An 8- to 10-mm-diameter, 38- or 59-mm-long balloon-expandable covered stent (Advanta V12; Getinge, Gothenburg, Sweden) was deployed and flared.

Follow-up

Follow-up CTA was performed at 1 week, 3 and 6 months, and annually thereafter. A duplex scan was performed in case of clinical or CT abnormality.

Results

Zone 2 TEVAR using PMEGs customized with a homemade scallop (7, 13%) or fenestration (47, 87%) for LSA revascularization was technically successful in 51 (94%) patients. Three (6%) LSAs were unintentionally covered. One was treated during the same procedure with a chimney for the LSA; the remaining 2 LSAs were left untreated. Operative details are summarized in Table 2. Four of the LSA fenestrations were unstented; the 43 bridging covered stents ranged in diameter from 8 to 10 mm and from 38 to 58 mm in

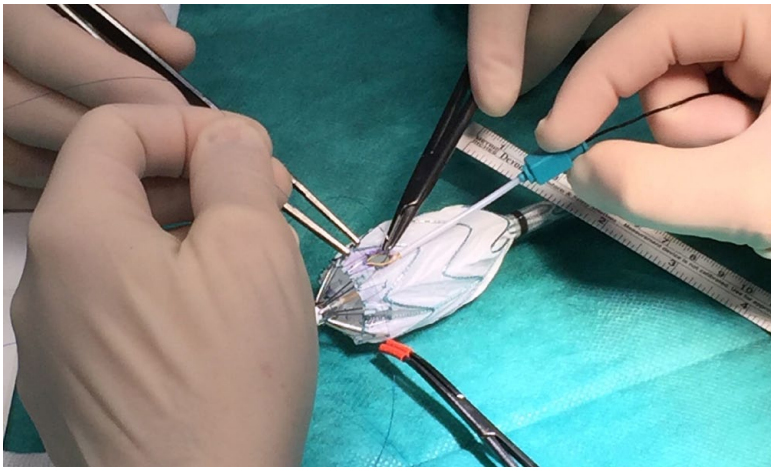

Figure 1. Custom fenestration preparation on the back table prior to the start of anesthesia. Note the radiopaque nitinol wire sewn onto the edge of the left subclavian artery fenestration, with a polypropylene suture reinforcing the fenestration and acting as a marker.

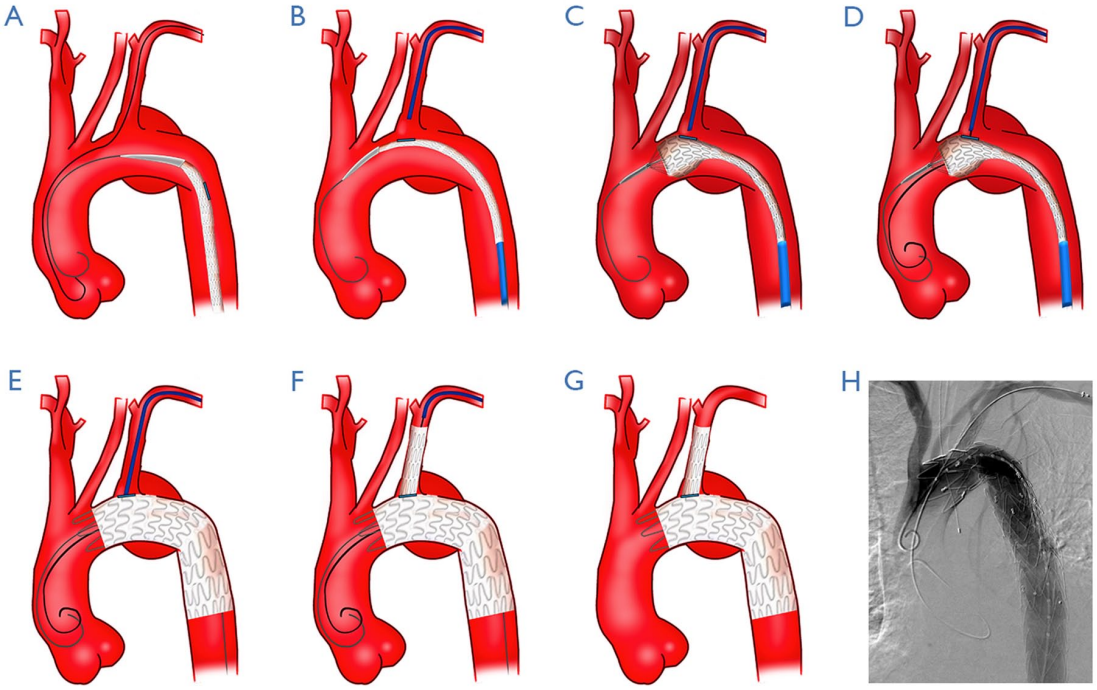

Figure 2. The technical approach to deploy a custom fenestrated stent-graft in a zone 2 thoracic endovascular aortic repair. (A) A hydrophilic guidewire is advanced into the ascending aorta via a left brachial access. The stent-graft is advanced over an extra stiff guidewire from a femoral access. In the descending thoracic aorta, the stent-graft is adjusted to be correctly positioned with the fenestration marker pointing to the outer curve of the aorta. (B) A long sheath is advanced from the left brachial access up to the left subclavian artery (LSA) ostium. The stent-graft is advanced proximally with the fenestration marker pointing to the LSA ostium. (C) The first 2 stents of the endograft are deployed. (D) The left brachial hydrophilic wire is advanced to cannulate the fenestration. (E) The brachial long sheath is advanced over the hydrophilic wire into the stent-graft, which is then completely deployed. (F) A balloon-expandable covered stent is deployed into the LSA fenestration. (G) Final schematic result with complete exclusion of the aortic lesion. (H) Completion aortography demonstrating successful exclusion of a saccular aneurysm at the LSA ostium.

Table 3. Adjunctive Procedures in 54 Patients Who Underwent Zone 2 TEVAR Using Fenestrated/Scalloped PMEGs.

Adjunctive Procedure	Comment
LSA chimney	One patient required an LSA chimney because of unintentional LSA coverage.
Deployment of a second proximal stent-graft	One patient required deployment of a second proximal stent-graft to the distal edge of the LSA to successfully treat a type Ia endoleak.
Second stent for LSA	One patient required an additional bare stent to treat kinking of the LSA distal to the bridging covered stent.
Iliac conduit	One patient required an iliac conduit with a 10-mm Dacron tube.
CFA access repair	Two patients required a prosthetic bypass and suture repair, respectively.
Endovascular fenestration of the false lumen	A patient with complicated acute type B dissection with preoperative bilateral paraplegia.
EVAR	One patient with an infrarenal aneurysm treated during the same procedure.

Abbreviations: CFA, common femoral artery; EVAR, endovascular aneurysm repair; LSA, left subclavian artery; PMEG, physician-modified endovascular grafts; TEVAR, thoracic endovascular aortic repair.

length. Twenty (37%) patients required a second distal aortic stent-graft, and 3 (6%) patients required an extension with a third stent-graft. An intraoperative type Ia endoleak was treated by deployment of an additional stent-graft at the distal border of the LSA scallop during the index procedure. Adjunctive procedures are summarized in Table 3. Mean time for stent-graft modifications on the back table was 16±2 minutes, and mean duration of the endovascular procedure was 76±22 minutes. The range of hospital stay was 3 to 29 days (mean 6±6).

Mortality and Morbidity

Four (7%) patients died in the perioperative period despite successful sealing of the aortic lesion. Two patients with traumatic rupture of the thoracic aorta died from other injuries on postoperative days 1 and 5. One patient with a ruptured aortic aneurysm died on the first postoperative day from secondary refractory shock. One patient with a symptomatic aortic aneurysm died on postoperative day 6 secondary to decompensated hepatic encephalopathy. No mortality was observed in the elective procedure group.

Complications are outlined in Table 4. In addition to the accidental coverage of 3 LSAs noted above, 2 patients developed a type II endoleak on the 9th postoperative day and at 14 months, respectively. Both were successfully treated by distal extension of the LSA covered stent (4% reintervention rate). No other endoleak was detected in follow-up.

One (2%) patient suffered spinal cord ischemia at the T10 level, with irreversible bilateral paraplegia. Three (6%) patients presented with postoperative minor stroke[17]; medical treatment resulted in full recovery prior to discharge. No major stroke was observed.

The mean follow-up was 26±16 months (range 3–69). No patients were lost to follow-up, and no further deaths occurred. Of the 50 patients surviving the perioperative period, follow-up was available in 10 at ≤6 months, 16 at 1 year, 9 at 2 years, and 15 at ≥3 years. All the LSAs remain clinically and radiologically patent (Video 1; available in the online version of the article). There has been no stroke, aortic rupture, retrograde dissection, stent migration or fracture, type I/III endoleak, reintervention, or conversion to open surgical repair in follow-up.

Discussion

Our group has previously demonstrated the technical feasibility and short-term safety of TEVAR with either a scallop or fenestration for the LSA.[12–15] Although our fenestration technique cuts only the stent-graft fabric leaving the struts intact, in our earlier reports we expressed concern about the long-term durability of this approach. Metal fatigue and material deterioration are known complications of stent-grafting,[18] and it has been hypothesized that custom-modified stent-grafts in the arch may be particularly vulnerable due to the asymmetric force distribution.[19,20] This study demonstrates that these PMEGs continue to perform well at least in the midterm; no cases of stent fracture have been detected in follow-up.

There were no prespecified criteria to choose between a scallop and a fenestration in this series. Scallops were used in our early experience because it was the simplest modification, but as our skills developed, a shift was made to stented LSA fenestrations for zone 2 diseases. Although no migration or misalignment has been observed with either of these approaches (the patients with scalloped PMEGs have the longest follow-up), a covered stent provides a better seal in the proximal landing zone and maintains the alignment of the PMEG with the LSA despite remodeling of the aorta.

The risk of left upper limb ischemia is significantly reduced by maintaining perfusion of the LSA.[21] The largest endovascular LSA revascularization series in the occlusive disease literature reports a 5-year primary patency of 80.5% and secondary patency of 97.7%.[22] In our cohort of patients with radiologically normal LSAs, no clinical or radiological evidence of restenosis and no upper limb ischemia have been observed.

Table 4. Complications in the 54 Patients Who Underwent Zone 2 TEVAR Using Fenestrated/Scalloped PMEGs.

Complications	Comment
Death (n=4, 7%)	Two patients died on POD1 and POD5 as a result of trauma sustained in a road traffic accident. One patient with a ruptured thoracic aneurysm died on POD1 as a result refractory shock. One patient died on POD6 as a result of hepatic encephalopathy decompensation.
Stroke (n=3, 6%)	Two patients had minor strokes after the procedure with full recovery. One patient experienced a left cerebral infarction after unintentional LSA coverage.
Spinal cord ischemia (n=1, 2%)	One patient with PMEGs + 2 distal stent-graft extensions relining the thoracic aorta developed ischemia at the T10, with bilateral paraplegia of and sphincter incontinence.
Type I endoleak	One successfully treated during the initial procedure; none seen during follow-up.
Type II endoleak (n=2, 4%)	One developed on POD 9 and the other at 14 months; both were successfully treated with an additional LSA covered stent.
Unintentional LSA coverage (n=3, 6%)	Three patients had unintentional LSA coverage; one required a LSA chimney.
Access-related events (n=2, 4%)	One patient needed a prosthetic bypass graft for a lacerated CFA and the other had a CFA laceration sutured.

Abbreviations: CFA, common femoral artery; LSA, left subclavian artery; PMEG, physician-modified endovascular grafts; POD, postoperative day; TEVAR, thoracic endovascular aortic repair.

It is important for the bridging covered stent to extend sufficiently into the supra-aortic trunk to avoid type III endoleak; if necessary, self-expanding stent extensions should be used to smooth out any kinks created in the native vessel by the bridging covered stent. Similarly, to avoid potential kinks or strain of the bridging covered stent at the reinforced fenestration, the diameter of the fenestration is normally 2 mm smaller than the covered stent selected for the LSA. This 2-mm size difference produces a nonhemodynamically significant cincture in the stent-graft, diminishing the risk of migration.

Two (4%) of the 54 patients developed an endoleak during follow-up, the rate comparing favorably with the 24.8% reported in the VALOR II trial of the unmodified Valiant stent-graft.[23] Of note the majority of endoleaks in that study were type II, as were those in our series, but ours arose from inadequate extension of the covered stent into the LSA, producing retrograde flow to the aortic arch. These 2 patients were successfully treated with a distal covered stent sized to the LSA diameter, extending to the origin of the vertebral artery and overlapped a minimum of 3 cm.

No postoperative type Ia endoleaks have occurred because we are strict about the adequacy of the seal zone for the stent-graft. Proximally, the aortic diameter must be <40 mm, and there must be at least 15 mm of healthy aorta for the landing zone. With the fenestrated approach, at least 5 mm is required between the distal edge of the LCCA and proximal LSA edge to accommodate the mini support spring located in the proximal 5 mm of the textile of the Valiant Captiva stent-graft. The diameter and morphology of the aorta at the level of the fenestrated segment must permit good seal between the aortic stent-graft adjacent to the large fenestration and the aortic wall around the LCA origin. In patients with aneurysm involving the greater part of the arch or when the stent-graft would not be able to appose the aortic wall at the level of the LSA, a branched covered stent would be more suitable. The approach used in this series is ideally suited for aneurysms arising close to the LSA and involving the descending thoracic aorta.

Despite the recommendations of the SVS historically,[9] the ESVS[8] more recently, and the theoretical benefits of LSA revascularization in certain groups, the issue of who does and does not benefit is unresolved. No randomized evidence is available. Though 2 meta-analyses[21,24] of observational studies involving heterogeneous pathologies have failed to demonstrate a statistically significant reduction in either stroke or spinal cord ischemia between the 2 strategies, more recent studies have reported associations between both complications and lack of LSA revascularization after coverage during TEVAR.[25,26]

The pathophysiology of stroke after TEVAR is multifactorial. It should be noted, however, that both carotid-subclavian bypass and transposition involve manipulations of the LCCA, which are absent from the endovascular approach in this study. In our cohort 3 (6%) patients had a minor stroke with full neurological recovery. The perioperative stroke rate in patients undergoing surgical LSA revascularization prior to LSA coverage during TEVAR was lower than for occlusive disease (8.9% vs 15.8%) but was still a cause of significant morbidity in a retrospective study of 139 patients.[10]

Given the controversy surrounding LSA revascularization in TEVAR, the custom fenestrated approach would appear to be a good compromise. The approach has similar technical and midterm outcomes as TEVAR alone. Patency of the vessel is preserved while avoiding the morbidity of open surgical revascularization, which includes thoracic duct, phrenic nerve, and brachial plexus injuries as well as stroke. The total endovascular approach is also quicker and

therefore more realistically usable in an emergent setting or an unstable patient.

Other off-the-shelf branch devices (Medtronic's Valiant Mona LSA[27] and the Gore thoracic single-branch endoprosthesis[28]) consist of a main stent-graft and a branch stent-graft designed to maintain LSA patency while diverting circulation through the encroaching aneurysm. This approach preserves the patency of the LSA during emergent TEVAR. However, these devices are not currently available on the market. Availability of branched stent-grafts may limit the indications for PMEGs. The use of branched (off-the-shelf) stent-grafts would allow treatment of a larger number of patients; however, deployment of branched devices is more challenging.

Conclusion

PMEGs with fenestrations or scallops for the LSA enable extension of the proximal landing to zone 2 during TEVAR. It is a simple, effective, and reproducible option for LSA revascularization, especially in the urgent or emergent setting. In the midterm, it appears to be a durable, though long-term clinical follow-up is required to fully assess the stability of PMEGs in zone 2.

Declaration of Conflicting Interests

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Supplemental Material

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