

Homemade Fenestrated Stent-Grafts for Complete Endovascular Repair of Aortic Arch Dissections

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Abstract

Purpose: To evaluate outcomes of homemade fenestrated stent-grafts for complete endovascular aortic repair of aortic arch dissections. **Materials and Methods:** From July 2014 through September 2018, 35 patients (mean age 66 ± 11 years; 25 men) underwent homemade fenestrated stent-graft repair of acute ($n=16$) or chronic ($n=10$) complicated type B aortic dissections ($n=16$) and dissecting aortic arch aneurysms subsequent to surgical treatment of acute type A dissections ($n=9$). Nineteen (54%) procedures were emergent. **Results:** Zone 2 single-fenestrated stent-grafts were used in 25 cases; the remaining 10 were double-fenestrated stent-grafts deployed in zone 0. Median time for stent-graft modification was 18 minutes (range 16–20). Technical success was achieved in all cases. An immediate distal type I endoleak was treated intraoperatively. Among the double-fenestrated stent-graft cases, the left subclavian artery fenestration could not be cannulated in 2 patients and revascularization was required. Partial coverage of the left common carotid artery necessitated placement of a covered stent in 3 cases. One (3%) patient had a stroke without permanent sequelae. Two type II endoleaks required additional covered stent placement at 5 and 7 days postoperatively, respectively. The 30-day mortality was 6% (2 patients with ruptured aortic arch aneurysm). During a mean follow-up of 17.6 ± 13 months, there was no aortic rupture or retrograde dissection. One late type I endoleak was treated with additional proximal fenestrated stent-graft placement. One type II endoleak is currently under observation. One additional patient died (unrelated to the aorta); overall mortality was 9%. All supra-aortic trunks were patent. **Conclusion:** The use of homemade fenestrated stent-grafts for endovascular repair of aortic arch dissections is feasible and effective for total endovascular aortic arch repair. Durability concerns will need to be assessed in additional studies with long-term follow-up.

Keywords

aortic arch, dissection, endograft, endoleak, fenestrated stent-graft, physician-modified stent-graft, stroke, thoracic endovascular aortic repair, thoracic stent-graft

Introduction

Aneurysmal dilatation of the aortic arch is not uncommon after repair of an acute type A aortic dissection (incidence up to 30%).¹ A quarter of patients with type B aortic dissection (TBAD) have aneurysmal degeneration in the aortic arch.² Surgical treatments to address aortic arch pathology traditionally have involved open techniques of total arch replacement with circulatory arrest and reimplantation of the supra-aortic trunks. Even in a high-risk patient population, excellent results can be achieved, and many centers continue to advocate this open surgical approach as the standard of care.³ Despite advances in surgical techniques and postoperative management, the open procedure is still associated with both significant in-hospital mortality and a

higher incidence of cerebral and other end-organ injury compared with surgery on the more proximal ascending aorta and root.⁴

Thoracic endovascular aortic repair (TEVAR) offers a less invasive surgical procedure in the aortic arch, but it typically requires hybrid open surgical procedures, such as debranching of the cervical vessels, to provide an adequate

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landing zone.^{5,6} An alternative strategy is to use the chimney technique in conjunction with TEVAR,⁷ but the risk of type I endoleak arising from intergraft gutters is concerning. Branched stent-grafts permit completely percutaneous aortic arch repair,⁸ and contemporary series^{9,10} of inner branched endografts in the aortic arch demonstrate improved patient outcomes compared with the early experience published in 2014.¹¹

Another option is a physician-modified thoracic stent-graft. This involves deployment of a conventional stent-graft device modified with custom fenestrations and reconstrained in the delivery system. Our group has previously reported good short-term results for aortic arch aneurysms using a single fenestration combined or not with cervical debranching.¹² This study aims to review our experience with homemade single- and double-fenestrated stent-grafts for total endovascular repair of aortic arch dissections with preservation of the supra-aortic trunks.

Materials and Methods

Study Design and Patient Population

A retrospective review was conducted of 35 patients (mean age 66±11 years; 25 men) with aortic arch dissections treated using homemade single- and double-fenestrated stent-grafts in a tertiary referral center from July 2014 through September 2018. Demographic, anatomic, intraoperative, and postoperative data were extracted from a prospectively maintained database.

The indications were acute complicated TBAD (n=16), chronic complicated TBAD (n=10), and dissecting aortic arch aneurysms subsequent to surgical treatment of acute type A dissections (n=9). All patients were considered to be at high surgical risk owing to serious comorbidities (American Society of Anesthesiologists score ≥III) and/or emergent repair (19/35; Table 1). Treatment planning for all aortic arch lesions was discussed among vascular and cardiothoracic surgeons who were routinely involved with the endovascular procedure. The protocol for homemade fenestrated stent-graft implantation was approved by the Institutional Review Board of the Arnaud de Villeneuve Hospital, and the local authorities approved the study. All patients gave written consent to the procedure.

Planning, Sizing, and Device Preparation

A vascular imaging workstation (EndoSize Workstation; Therenva, Nanjing, France) was employed to reconstruct computed tomography angiography (CTA) datasets using the center lumen line technique. Aortic diameters at both the proximal and distal landing zones were measured. The proximal landing zone was always in nondissected aorta; for the distal landing zone a dissected aorta was considered

Table 1. Characteristics of the 35 Patients in the Study and Indications for Aortic Arch Repair.^a

Age, y	66 (43–83)
Men	25 (71)
Hypertension	33 (94)
Dyslipidemia	6 (17)
Diabetes mellitus	4 (11)
COPD	6 (17)
Coronary artery diseases	11 (31)
LVEF <40%	4 (18)
Prior thoracic aortic surgery	10 (28)
Maximum aortic diameter, mm	58 (45–73)
Emergent cases	18 (51)
Indications	
Postsurgical arch aneurysm ^b	9 (24)
Emergent	2
Ruptured	1
Aneurysm diameter, mm	53 (40–75)
TBAD	26 (77)
Chronic complicated TBAD	10 (29)
Emergent	1
Ruptured	1
Acute complicated TBAD	16 (46)
Emergent	16
Persistent pain	5
Refractory hypertension	4
Malperfusion	7

Abbreviations: COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; TBAD, type B aortic dissection.

^aContinuous data are presented as the mean (range); categorical data are given as the number (percentage).

^bSurgical treatment of acute type A dissections.

acceptable, though the final distal landing zone was often determined intraoperatively, aiming to cover the primary tear and obvious large tears to diminish or stop flow in the false lumen after endograft deployment. Expansion >45 mm of the true lumen in the arch and existence of a short surgical graft (<4 cm) were contraindications to the procedure.

Stent-grafts of sufficient length were selected to provide proximal and distal landing zones of at least 20 mm in healthy aorta. The proximal stent-graft oversizing was <5% for acute dissections and between 5% and 10% for chronic dissections. The distal stent-graft sizing was based on the true lumen and avoided oversizing >20%. Only Valiant stent-grafts (Medtronic, Santa Rosa, CA, USA) were used in this series.

Zone 2 aortic arch lesions were treated using a single-fenestrated stent-graft, with a balloon-expandable covered stent (iCAST; Atrium Medical Corp/Maquet Getinge Group, Hudson, NH, USA) securing the fenestration. Since the techniques to size, prepare, and deploy a single-fenestrated stent-graft have been reported,^{12,13} the remainder of this section will focus on the double-fenestrated stent-graft for treating dissections in zones 0 and 1.

The planning of a custom 2-fenestration thoracic stent-graft is similar to a fenestrated abdominal graft except that the greater curvature line rather than the centerline of flow is used to measure lengths including the distance between the aortic branches. The centerline of flow view is still used to measure aortic diameters as well as determine the “clock positions” for the origin of each supra-aortic trunk. The diameters of the innominate artery (IA), the left common carotid artery (LCCA), and left subclavian artery (LSA) were determined from axial images. Volume-rendering images were used to determine the optimal position of the C-arm and to evaluate the aortic arch tortuosity.

The double-fenestrated stent-graft had a proximal large fenestration for both the IA and LCCA; it was sized 2 mm larger laterally than the distance from the proximal edge of the IA ostium to the distal edge of the LCCA orifice. The distal fenestration for the LSA matched the diameter of the vessel. The distance between the 2 fenestrations equaled that between the LCCA and LSA as measured on the preoperative high-resolution CTA.

Modification of the stent-graft was performed on a back table before the start of anesthesia. A portion of the device was unsheathed; our preference is to expose the area to be modified plus one additional stent. Fenestrations are marked and fashioned on the main stent-graft according to the measurements obtained from the vascular workstation. For the double-fenestrated stent-graft, the proximal large fenestration for the IA and the LCCA is made without removing the stent-graft stent struts. The site of the LSA fenestration is chosen such that it will not be crossed by stent struts. Clock position is used to determine the position of the LSA relative to the position of the IA/LCCA island using the reconstructed images.

To avoid damage to the graft fabric, the proximal large fenestration is created using a size 11 blade. At least 5 mm of fabric seems to be required between the proximal fenestration and the proximal edge of the stent-graft fabric to avoid compromising the integrity and stability of the graft. A cautery device is used to carefully burn the Dacron fabric to create the LSA fenestration. To reinforce seal around the opening and mark its position, a radiopaque nitinol wire from the loop of a snare (Amplatz Goose Neck Snare; Medtronic) is sewn onto the edge of the LSA fenestration.

Deployment Technique

Placement of a double-fenestrated stent-graft is simplified because accurate positioning of the LSA fenestration, secured by a covered stent, should align the proximal fenestration over the IA and LCCA.

All procedures were performed under general anesthesia in either an operating room equipped with a C-arm or in a hybrid room. The optimal position of the C-arm was determined preoperatively on the CT reconstruction. After

surgical cut down of the common femoral artery (CFA), heparin (5000 units) was administered, and the thoracic stent-graft was introduced over an ultra-stiff guidewire under angiographic guidance performed through a pigtail catheter introduced percutaneously through the contralateral CFA.

As branch vessels originate from the superior aspect of the arch, it is necessary to position the delivery system such that the stent-graft fenestration(s) are oriented superiorly on entering the arch. The stent-graft fenestration marker was therefore positioned on the outer curve of the thoracic aorta. It is important to ascertain that the fenestration is oriented toward the LSA by aligning the radiopaque marker with the target vessel. If misaligned, the stent-graft is pulled back in the descending thoracic aorta, rotated to adjust the position of the fenestration, and reintroduced into the aortic arch. Large axial adjustments in the arch are ill-advised because of the risk of embolization and the poor torqueability of the stent-graft in this location.

A 7-F sheath was placed retrogradely through a left brachial artery access to the ostium of the LSA. After ascertaining that the fenestration was oriented toward the supra-aortic target vessel, the mean blood pressure was lowered to ~80 mm Hg and the stent-graft was partially deployed. (Rapid pacing was not used during stent-graft deployment as the time required to cannulate the LSA fenestration varied.) Only very minor adjustments are possible to rotate the stent-graft in order to adjust the position of fenestrations once the first stents are deployed. A 0.035-inch guidewire from the brachial access was advanced through the fenestration into the stent-graft lumen. The 7-F brachial sheath was then advanced through the fenestration into the stent-graft lumen. Then, the thoracic stent-graft was fully deployed. An 8- to 10-mm balloon-expandable iCAST covered stent (38 or 59 mm in length) was deployed protruding ~5 mm into the aortic stent-graft lumen, with the remaining length in the LSA. The intrastent-graft portion of the covered stent was flared using a 14- \times 20-mm balloon introduced from the brachial access. Completion angiography was performed.

Follow-up

Follow-up surveillance was performed with serial CT scans at 1 week, at 3, 6, and 12 months, and annually thereafter. A duplex scan was additionally performed in case of clinical or CT abnormality.

Definitions and Statistics

Acute complicated TBAD requiring urgent aortic repair was characterized by hemodynamic instability, organ malperfusion, intractable pain, refractory hypertension, increasing periaortic hematoma, and/or hemorrhagic pleural effusion on imaging. Chronic complicated TBADs were

indicated by recurrence of symptoms, aortic aneurysmal dilatation (>55 mm), or a yearly increase of >4 mm after the acute phase.¹⁴ Technical success was correct positioning of the fenestrated device without type I or III endoleak at the end of the procedure.

Categorical data are reported as the absolute number and percentage; continuous data are reported as the mean \pm standard deviation and/or range. Statistical analysis was performed in Excel (Microsoft, Redmond, WA, USA).

Results

Procedure Outcomes

A single-fenestrated stent-graft was deployed in zone 2 in 25 cases (Figure 1A); a double-fenestrated stent-graft was positioned in zone 0 in 10 cases (Figure 1B). Median time for stent-graft modification was 18 minutes (range 16–20). The mean proximal sealing length was 22 ± 4 mm. Mean length of the proximal fenestration was 21 mm (18–25). Mean length between the fenestrations was 5.3 mm (5–8).

Endovascular exclusion of the aortic arch was achieved in all the cases (Supplemental Video 1; available in the online version of the article) with deployment of 1 or 2 thoracic stent-grafts (mean 1.7). Associated endovascular procedures included preplanned transcatheter aortic valve replacement in 1 case and preplanned supra-aortic trunk reentry tear closure using a covered stent in 2 cases.

An intraoperative distal type I endoleak was treated with a distal stent-graft. In 2 double-fenestrated stent-grafts, LSA catheterization failed and surgical revascularization and stent-graft coverage of the fenestration was required (Table 2). Three patients with partial coverage of the LCCA required placement of a covered stent.

Outcomes at 30 Days

One (3%) patient with a single-fenestrated stent-graft repair had a stroke without permanent sequelae. Two type II endoleaks required distal extension of the covered stent in the LSA with a further covered stent (postoperative days 5 and 7). Two patients with ruptured dissected aortic arch aneurysms died despite successful endovascular exclusion, leading to a 30-day mortality of 6%.

Follow-up

During a mean follow-up of 17.6 ± 13 months (range 4–37), there were no conversions to open surgical repair, aortic rupture, or paraplegia, and all supra-aortic trunks were patent. One type II endoleak (from the LSA) without sac expansion is currently under observation. One late type I endoleak (8 months after initial aortic repair) in a patient treated using a single-fenestrated stent-graft was

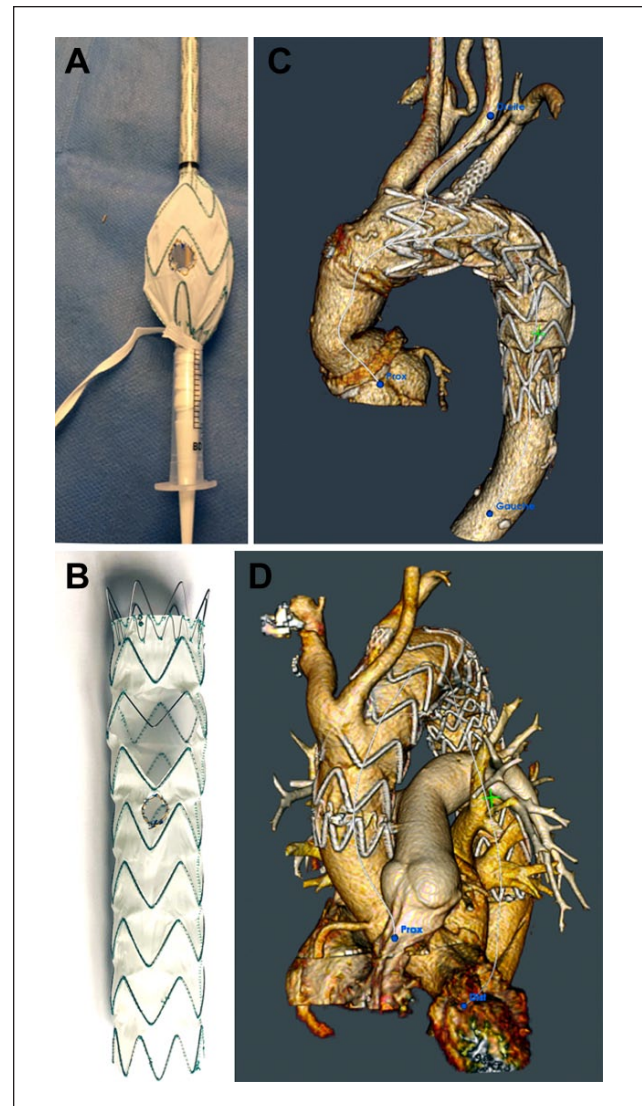


Figure 1. Homemade (A) single- and (B) double-fenestrated stent-grafts. (C, D) Volume rendered reconstructions demonstrating homemade (C) single- and (D) double-fenestrated stent-grafts and patency of the supra-aortic trunks.

treated by additional proximal fenestrated stent-graft placement, necessitating LSA coverage and surgical revascularization. An additional patient died 4 months after the endovascular procedure of a nonaortic cause. Overall mortality was 9%. All supra-aortic trunks were patent at the latest imaging studies.

Discussion

A complete repair of the aortic arch with or without the frozen elephant trunk procedure is a complex process with a relevant risk of postoperative morbidity and mortality.^{15,16} However, surgical outcomes have been improving lately.

Table 2. Procedure Results and Outcomes at 30 Days.^a

Operation duration, min	93 (38–164)
Contrast volume, mL	74 (60–120)
Dose area product, Gy·cm ²	42 (15–55)
ICU stay, d	1.2 (1–2)
Hospital stay, d	5.8 (3–7)
Early complications	
In-hospital death	2 (6)
Stroke	1 (3)
Retrograde type A dissection	0
SCI	0
Endoleak type I / II / III	1 / 1 / 2
Early secondary procedures	3 (9)
Late complications	
Death	3 (9)
Stroke	0
Endoleak type I / II	1 / 1
Retrograde type A dissection	0
Late secondary procedure	1 (3)

Abbreviations: ICU, intensive care unit; SCI, spinal cord ischemia.

^aContinuous data are presented as the mean (range); categorical data are given as the number (percentage).

Sundt et al¹⁷ reported that the 30-day mortality after aortic arch surgery in the standard risk population (renal failure 5%, diabetes 7%, prior stroke 9%, prior myocardial infarction 7%) ranges from 4% to 28.6%, varying with the cerebral protection method used (profound hypothermia and antegrade or retrograde cerebral perfusion) and mode of presentation (elective or emergency). Furthermore, many patients are deemed unsuitable owing to serious comorbidities. As a consequence, a less invasive approach is favored for a significant number of patients.

As all cases reported here used physician-modified systems, accurate preoperative planning is essential. Intraoperatively ascertaining that the fenestration is well oriented toward the supra-aortic target vessel is crucial. As a consequence of the homemade nature of these devices, graft rotation and misalignment of the fenestration-vessel ostium interface can nevertheless occur. In addition, the aorta may change configuration after insertion of the semirigid stent-graft. It may be necessary to manipulate a semiconstrained or partially deployed arch stent-graft to orient fenestrations correctly, which increases the risk of cerebral embolization.

The specific feature of the double-fenestrated device is its simple handling during the operation, with the proximal fenestrations being directed to the IA and LCCA orifices automatically when the LSA fenestration is catheterized and secured by covered stent placement. Furthermore, because the proximal fenestration is large enough to accommodate the 2 branches with low risk of branch occlusion, bare or covered stents are not needed in the branches. The

deployment algorithm actively steers the operator away from superfluous manipulations of the device within the arch and avoids guidewire manipulation in the IA and the LCCA. Compared with other endovascular techniques, we believe that this is likely to be the reason that patients treated with the homemade double-fenestrated stent-graft had no neurological complications.

This approach is an off-label use of the Valiant stent-graft. Our group has a large experience with complex thoracic endovascular repairs (over 800 TEVARs). The risk of technical failure with the double-fenestrated approach may be increased if performed by inexperienced teams. During the study period, 118 patients underwent repair of acute type A dissection. Selective antegrade cerebral perfusion through the right subclavian artery combined with mild systemic hypothermia was used in all these patients. Ten patients underwent open aortic arch replacement for a dissecting arch aneurysm. Two patients had zone 0 hybrid aortic arch repair for a dissecting arch aneurysm.

The challenge of fenestrated TEVAR intraoperatively is to ensure accurate alignment of the LSA fenestration with the vessel orifice. The deployment procedure includes several important components. First, the optimal position of the C-arm was determined preoperatively on the 3-dimensional CT reconstruction. Using this information an intraoperative angiogram strictly perpendicular to the LSA was obtained to achieve clock face alignment. Second, the stent-graft fenestration marker for the LSA was positioned on the outer curve of the thoracic aorta and aligned with the LSA. Despite these steps, there were 3 patients with LCCA partial coverage due to misalignment. We are currently working on incorporating and developing the use of an externalized through-and-through guidewire into our deployment sequence.¹⁸

The addition of reducing ties could be used to facilitate longitudinal and rotational movements of the stent-graft, allowing adjustment of the position of fenestrations to facilitate cannulation of target vessels. We would, however, be concerned that additional manipulation in the arch could increase the neurological morbidity.

The bailout strategies in case the larger fenestration is misaligned are firstly to pull back the partly unsheathed stent-graft in the descending thoracic aorta and deploy it. In this situation supra-aortic debranching is required to complete the TEVAR, thus treating the aortic arch lesion and covering the fenestration of the first graft. Alternatively, if the pullback attempt fails, LCCA and IA chimney grafts can be inserted after bilateral carotid artery exposures. Thirdly, if the chimney attempt fails, complete rerouting of the supra-aortic trunks via a median sternotomy would have to be performed.

One concern with the approach described is that the uncovered strut in the large fenestration can protrude into the IA ostium, increasing the theoretical risk of stroke. In an analogous situation, when performing hybrid zone 1

debranching combined with placement of a stent-graft with proximal free-flow configuration, the proximal bare stent often protrudes in the IA and to date has never been reported as a risk factor of stroke. Furthermore, long-term antiplatelet therapy was systematically used in our cohort of patients.

The fragility of homemade stent-grafts is a crucial problem. The question of fabric durability still needs to be evaluated. Metal fatigue and material deterioration are known complications of stent-grafting. These alterations might have an impact on general ring stability of the graft. In our series, no stent fractures were detected by routine radiologic follow-up examinations. In order to avoid type III endoleaks, the proximal large fenestration is cut into the graft beginning at least 5 mm from the proximal edge of the stent-graft to avoid compromise of graft integrity and stability. Additionally, the LSA fenestration is reinforced with wire. To avoid type I endoleak, stent-grafts must be long enough to guarantee at least 20 mm of healthy aorta for the proximal landing zone.

It is important that the diameter of the true lumen in zone 1 does not exceed 45 mm. This ensures good seal between the aortic graft around the large fenestration and the aortic wall around the IA/LCCA island. The long-term interactions between the stent-graft and the covered stent will need to be monitored closely over time because of the potential for stent collapse or fracture and the development of a late type III endoleak between the two components. Careful long-term monitoring of patients is required to avoid major complications resulting from material fatigue in these devices.

Endoleaks after TEVAR for aortic dissection are commonly described, with rates of 27%¹⁹ and 42%²⁰ reported in the literature. Our 14% endoleak rate coincides with this high incidence of this complication, although only 3 of 8 endoleaks required reintervention.

Retrograde type A aortic dissection is another potential complication of arch stent-grafting. The reported risk factors for this complication are oversizing $\geq 10\%$, a treatment indication of dissection, and the proximity of the proximal landing zone to the ascending aorta, with an increased risk in zones 0 and 2.²¹ Therefore, the choice of the appropriate diameter for the stent-graft would seem to be more crucial than the choice of a specific type of stent-graft.

The disadvantages of this technique are the necessity for the physician to spend time modifying the stent-graft, the lack of industrial quality control after device modification, and no sizeable body of evidence supporting its use. Modification of commercially available devices by physicians may void any guarantee of safety by the manufacturer, and systematic evaluation of such devices is best done within a protocol approved at the institutional and/or regulatory level.

There are several different alternatives to obtain an adequate proximal seal for thoracic stent-grafts. Debranching and the chimney technique have been proposed to allow

proximal extension of the stent-graft with preservation of supra-aortic branch flow. However, debranching requires an adjunctive invasive procedure. While the chimney technique can be performed in a less invasive manner, there are concerns about type I gutter endoleaks. Wang et al⁷ reported an 11% endoleak rate among 122 patients undergoing single or double chimney TEVAR for aortic arch pathologies.

Custom-made branched devices are currently available. The world experience with 38 branched arch devices was first published as a multicenter experience in 2014 by Haulon et al.¹¹ They reported a 13% mortality, a 16% stroke rate, a technical failure rate of 15.8%, and a secondary procedure rate of 19.6%. Factors such as the delay in device planning and manufacturing, anatomical and technical limitations, and expense hinder the widespread uptake of this technology, which is additionally unsuitable for emergency cases. Above all, the technical difficulty of side branch catheterization results in an inherently high risk of cerebral embolism.

The use of readily available “off-the-shelf” branched arch stent-grafts would decrease the cost of endovascular repair and broaden the availability of these minimally invasive techniques to a greater number of patients. Off-the-shelf branch devices (Valiant Mona LSA; Medtronic)²² and the Gore single-side branch (W.L. Gore & Associates, Flagstaff, AZ, USA) consist of a main stent-graft and a branch stent-graft designed to maintain patency of one of the supra-aortic trunks during emergent TEVAR. However, these devices are not currently available on the market and will not allow total endovascular repair for zones 0 and 1 aortic arch lesions.

Until an “off-the-shelf” device is available, patients who are poor surgical candidates and have acute dissections or rapidly expanding, symptomatic, or ruptured arch aneurysms have limited endovascular options other than immediate physician modification of stent-grafts. More data are required to confirm the general applicability of this approach and to establish durability. In the long-term strict surveillance of these stent-grafts and modifications will be necessary to monitor durability of repair because of the potential for stent collapse or fracture.

Conclusion

The use of homemade fenestrated stent-grafts for endovascular repair of aortic arch dissections is both feasible and effective for maintaining the patency of the supra-aortic trunks and allows total endovascular aortic arch repair. This technique is an especially attractive option for emergent cases. Durability concerns will need to be assessed in additional studies with long-term follow-up.

Declaration of Conflicting Interests

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Supplemental Material

The video is available at <http://journals.sagepub.com/doi/suppl/10.1177/1526602819858578>.

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