

Evolution and Future Direction of Fenestrated and Branched Aortic Endografts for Complex Abdominal Aortic Aneurysms and Thoracoabdominal Aortic Aneurysms

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Abstract: Technological advances over the last 2 decades have provided an evolution in endovascular devices, further expanding the range of complex aortic disease treated by endovascular techniques. Expanding endovascular repair into the visceral segment of the aorta required extension of the proximal landing zone, which led to the development of fenestrated and branched endovascular aortic repair. Initially, physician-modified procedures such as chimney/snorkel techniques and physician-modified endografts were utilized to overcome barriers to the treatment of pararenal aortic and thoracoabdominal aortic aneurysms. These devices helped pioneer the next generation of endografts, including physician and manufactured custom-made endografts and off-the-shelf fenestrated/branched devices. This article provides a contemporary appraisal of the literature regarding the evolution of endovascular therapy for complex aortic disease and future directions.

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Key words: branched aortic endografts, endovascular repair of aortic aneurysms, EVAR, fenestrated aortic endografts

Introduction

Endovascular repair of aortic aneurysms (EVAR) was first introduced by Parodi and colleagues in 1991 as an alternative to open surgical repair for abdominal aortic aneurysms (AAAs) in high-risk vascular patients.¹ Over time, this technique has demonstrated superior perioperative outcomes regarding early mortality, length of hospital stay, and in-hospital complications.² Due to these outcome measures, EVAR now accounts for more than 75% of all elective AAA repairs and over 55% of ruptured AAAs.²⁻⁴ Despite the success of endoluminal repair, standard infrarenal EVAR is not without limitations.

Approximately 40% of patients with aortic aneurysms have anatomy unsuitable for standard EVAR secondary to short proximal neck length, severe aortic angulation, or involvement of renal or visceral vessels.⁵ Additionally, 10% of aortic aneurysms are thoracoabdominal aortic aneurysms (TAAA) with extensive involvement of the descending thoracic aorta and visceral/renal segments.⁶ Due to the anatomic constraints provided by these complex aortic pathologies, open surgical repair has long been referred to as the gold standard.⁷ However, patients with complex aortic aneurysmal disease are a highly comorbid patient population and are generally considered high-risk surgical candidates.^{6,7} Open repair of complex AAAs and TAAAs in these patients can cause a devastating physiological insult with high perioperative morbidity and mortality.^{7,8} These outcomes highlight the need

for less invasive and durable techniques for the repair of complex AAAs and TAAAs.

The outcomes of open aortic repair have prompted revolutionary device development, including fenestrated and branched endovascular aortic aneurysm repair (F/BEVAR). The first FEVAR was successfully implemented by Browne and colleagues in 1998.⁹ The primary utility in F/BEVAR is the proximalization of the device landing zone into healthy tissue above the visceral segment to allow minimally invasive treatment of complex AAAs and TAAAs while preserving end-organ perfusion.⁶

Technological advances over the last 20 years have provided an evolution in endovascular devices for the successful treatment of complex AAAs and TAAAs. Several endovascular methods have been developed, including parallel stent (chimney/periscope/snorkel techniques), physician-modified branch/fenestrated endografts (PMEGs), off-the-shelf devices (including the Zenith t-Branch [Cook Medical], ThoracoAbdoMinal Branch Endoprostheses [TAMBE] device [Gore], and Visceral Manifold [Medtronic]), and custom-made, patient-specific devices (CMDs). Some off-the-shelf devices have been approved for use in Europe and are considered first-line therapy for paravisceral AAAs and TAAAs.¹⁰ In the United States, there are no current devices approved by the FDA for the treatment of TAAAs. Currently, 10 institutions across the United States have been approved for utilizing CMDs through individual physician-sponsored investigational device

exemption (PS-IDE) studies, with other market approval clinical trials still in process.¹¹ A number of other institutions have PS-IDE studies approved by the FDA for use of physician-modified devices, or other branch device constructs, such as the Visceral Manifold device invented by Dr. Patrick Kelly, which is being investigated at multiple individual sites. In this manuscript, we aim to provide a review of CMDs as well as other F/BEVAR endografts currently under investigation and the future trajectory of this technology.

Snorkel/Chimney Technique

Chimney, periscope, and snorkel techniques (ChEVAR, also known as parallel stents) for complex AAAs were originally described as methods to reestablish perfusion to incidentally covered visceral/renal arteries during EVAR.^{12,13} They were adapted as a modality to treat aneurysms involving the visceral/renal aortic segments while preserving renal/visceral arterial flow and have been extensively studied within the international performance of the chimney technique for the treatment of complex aortic pathologies (PERICLES) registry.¹⁴ There are various strategies in the successful deployment of the main aortic graft and parallel stent grafts. Generally, bilateral femoral artery access is required for delivery of the main graft body with unilateral or bilateral brachial/axillary artery access for branch vessel stent graft deployment.¹⁵

Advantages of ChEVAR include utilizing readily available, off-the-shelf devices with intraoperative modulation, and sometimes smaller delivery systems compared with FEVAR. Also, an IDE has not typically been obtained for performing ChEVAR,^{13,15,16} although one might argue that operators should pursue these pathways given the off-label nature of these procedures. Studies have demonstrated comparable early results between FEVAR and ChEVAR regarding overall survival and graft patency.^{15,17} Other studies using the PERICLES registry consisting of 517 patients and 898 chimney grafts demonstrated primary patency of 94% at 17 months and 90% at 5 years, with overall survival of 79% at 17 months and 66.1% at 5 years.^{15,18}

Although early outcomes have been respectable, multiple disadvantages and challenges have been identified with these techniques. ChEVAR simply violates both main principles of endovascular aortic repair: the necessity of seal and fixation. Multiple studies from the PERICLES registry have demonstrated that ChEVAR is prone to early type IA endoleaks (often referred to as “gutter” leaks) and significantly increased mortality and limb occlusion events when more than 2 parallel stents are deployed.^{12,13,15,16} Additionally, for optimal results, current recommendations are to ensure 20 mm of healthy proximal neck seal zone and utilization of balloon expandable covered stents,^{12,13} which is likely an indication that additional coverage of normal aorta is needed to accommodate for the loss of circumferential seal/fixation by the main aortic graft. Due to the known complications and limitations of ChEVAR, the most recent European Society of Vascular Surgery guidelines approve the use of ChEVAR with several stipulations, including limiting it to patients who are not candidates for FEVAR or if FEVAR

is not available, emergent circumstances, and avoiding deploying more than 2 parallel stents.¹⁰

Fenestrated and Branched Aortic Endografts (F/BEVAR)

The last 2 decades of technological advancement have produced a revolution in endovascular techniques and devices in the treatment of complex AAAs and TAAAs. F/BEVAR has expanded the ability to combine multiple fenestrations and branches to incorporate multiple visceral and renal vessels while eliminating the risk of a gutter/type IA endoleak in ChEVAR.¹³ There are several main categories of branched/fenestrated devices, including PMEGs, CMDs, and off-the-shelf endografts. Over the last decade, multiple devices have been investigated and approved in European studies.^{6,19,20} However, in the United States, the Zenith fenestrated AAA endovascular graft (Cook Medical) has remained the only device approved by the FDA for complex AAAs.²¹ This device allows for 3 graft modifications to incorporate the visceral/renal vessels, with other important sizing constraints.⁶ Unfortunately, this limits the utility of the device to short proximal neck and juxtarenal AAAs and prohibits on-label use in TAAAs.¹⁹

Physician-Modified Endografts (PMEGs)

The first described utilization of PMEGs was described by Uflacker and colleagues in the early 2000s.²² PMEGs fill a void of anatomical constraints to available infrarenal endografts and extend the proximal landing zone beyond the renal and visceral segments.²⁰ A number of institutions have existing FDA-approved PS-IDE studies for the modification and deployment of these devices, and they are also being widely utilized across the United States by other operators without PS-IDE studies. Although aortic device selection for PMEGs is variable, studies have primarily utilized the commercially available Zenith TX2 TAA endovascular graft (Cook Medical), Zenith Alpha thoracic endovascular graft (Cook Medical), Zenith fenestrated AAA endovascular graft, Zenith Flex AAA endovascular graft (Cook Medical), and Treovance abdominal stent graft (Terumo Aortic).^{19,20,23-25}

Extensive preoperative planning is critical in these cases and requires advanced imaging software (eg, TeraRecon) to generate 3-dimensional (3D) centerline reconstruction for precise measurements and branch vessel angulation evaluation (**Figure 1**). Similar to planning for CMD devices, the proximal and distal landing zones are determined and measured. The spine or another reference location (eg, the middle of the superior mesenteric artery [SMA] ostium) can be used to specify the 12 o'clock position, with orientation of the remaining branch vessels recorded in reference to 12 o'clock (**Figure 1**).²⁰ All measurements are recorded to create a procedure map for the modification of the endograft at time of surgery for PMEG devices, or used to communicate with the company for CMD development.

Institutions have developed various iterations of modifying off-the-shelf endografts in use for complex AAAs and TAAAs. Generally, the endograft is constructed preoperatively on a sterile back table. In urgent or emergent scenarios, this can be performed as the patient is being positioned and anesthesia is induced. The graft

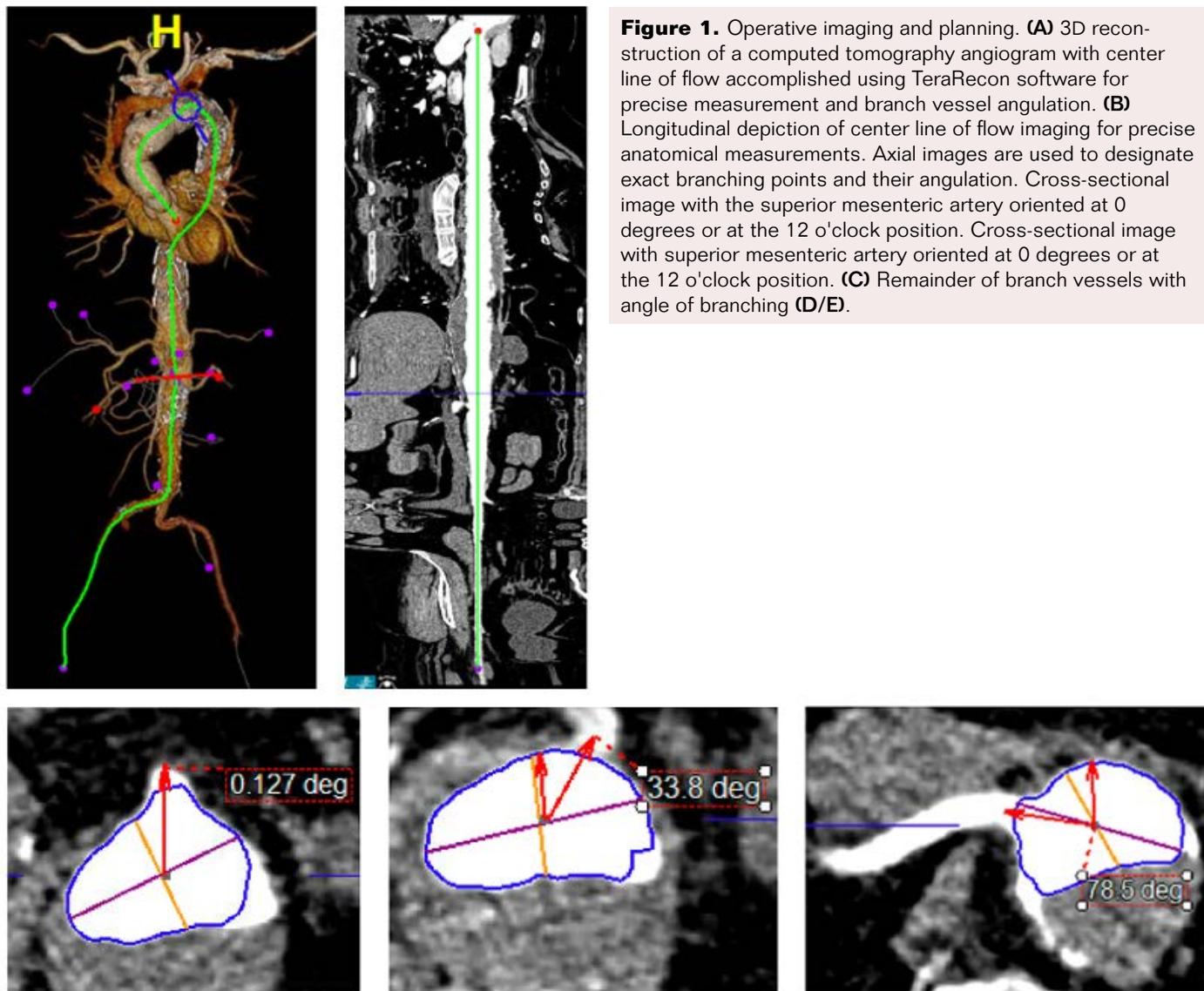


Figure 1. Operative imaging and planning. **(A)** 3D reconstruction of a computed tomography angiogram with center line of flow accomplished using TeraRecon software for precise measurement and branch vessel angulation. **(B)** Longitudinal depiction of center line of flow imaging for precise anatomical measurements. Axial images are used to designate exact branching points and their angulation. Cross-sectional image with the superior mesenteric artery oriented at 0 degrees or at the 12 o'clock position. Cross-sectional image with superior mesenteric artery oriented at 0 degrees or at the 12 o'clock position. **(C)** Remainder of branch vessels with angle of branching **(D/E)**.

is unsheathed, and diameter reducing sutures and fixation wires are removed. Once deployed, the fenestrations are marked and precisely measured using a previously designed procedure map. Low-energy heat cautery is used to create the fenestrations, which are then reinforced by circumferentially suturing a radiopaque wire to each fenestration. If creating branched fenestrations, 6-mm or 8-mm Viabahn stent grafts (Gore) can be sutured at the sight of fenestrations to form 1-cm to 2-cm branch arm cuffs.^{19,20} The modification and resheathing techniques used at our institution are detailed in **Figure 2** and **Figure 3**.²⁰

Multiple studies utilizing single institution as well as database-derived data have been conducted describing the outcomes of PMEG in complex AAAs and TAAAs.^{19,24-27} The overall technical success rate when used in the elective setting is excellent, ranging from 90% to 100%.^{26,27} Starnes and colleagues reported excellent short- and mid-term results of PMEGs with 69% freedom from reintervention, 94% freedom from aneurysm-related mortality, and 70% freedom from all-cause mortality at 4 years. Overall rate

of adverse events at 30 days was 11.9% and 30-day mortality was 5.1%. They reported an average graft construction time of over 1 hour, average procedure time of 156 minutes, and technical success of 95%.²⁴ Other single-institution studies have demonstrated similar results.^{19,28}

A large study investigating the use of FEVAR (PMEG = 256) within the Vascular Quality Initiative (VQI) revealed that PMEGs are typically utilized in larger and more complex AAAs that involve more branch vessels when compared with commercial FEVAR devices in the United States or ChEVAR.²⁷ Additionally, PMEGs demonstrate a trend toward superior perioperative mortality: 2.7% vs 3.4% in FEVAR and 6.1% in ChEVAR ($P = .16$).²⁷ Patients undergoing ChEVAR experienced significantly more major cardiac and cerebrovascular events when compared with PMEGs or FEVAR.²⁷ Lastly, in a meta-analysis of 20 studies investigating outcomes following PMEG, Melo and colleagues demonstrated perioperative mortality of 3.0% in elective cases, with a major complication rate of 11%. They also demonstrated

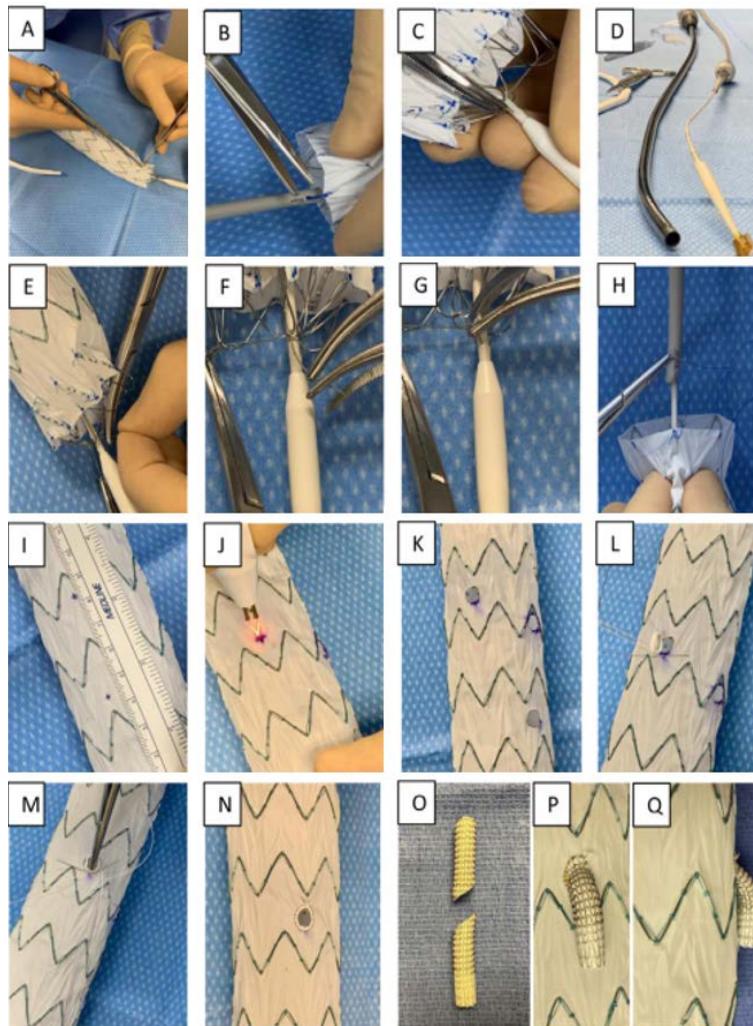


Figure 2. Construction of physician-modified endograft device. **(A)** After the graft is unsheathed, cut the diameter-reducing ties from the proximal end of the graft (only present on Cook graft sizes 38 and greater). **(B)** Cut the distal graft fixation stitch from the distal graft fixation wire. **(C)** Remove the proximal fixation wires from the proximal bare metal stent and release the graft. **(D)** Remove the delivery system from the sheath. **(E, F)** Place the graft back over the delivery system and carefully pull the distal fixation wires back through the bare metal stents (1 wire should cross 3 to 4 stent loops). **(G)** Replace the distal fixation wires back into the holes in the delivery system. **(H)** Re-fix the distal graft to the distal fixation wire by suturing around the stent and the wire twice with a 4-0 Prolene suture. **(I)** Measure and mark level of fenestrations from the proximal fabric. **(J)** Moisten the graft with saline and use eye cautery to burn a hole in the graft for the appropriately sized fenestration (6 to 8 mm). **(K)** Endograft with fenestrations at 2:45 (top), 12:00 (middle), and 12:15 (bottom). **(L, M, N)** The radiopaque distal tip of an 0.014" Thruway wire (Boston Scientific) is sutured circumferentially around each fenestration, incorporating a 1-mm ring of 7-mm polytetrafluoroethylene graft to complete the fenestration. **(O)** When creating branched fenestrations, a 50-mm Viabahn stent (Gore) can be cut in half at a 45-degree angle to create a conduit for 2 branched fenestrations. **(P)** Branched fenestrations are sutured to the graft in similar fashion with a Thruway wire circumferentially. **(Q)** The distal Viabahn stent is sutured to the endograft with a single Gore-Tex suture to keep orientation and reduce profile for resheathing.

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a reintervention rate of 8.7% across studies, with a trend toward improved technical success and decreased complications over time. Overall, these studies demonstrate the feasibility and versatility of PMEGs in complex AAA and TAAA repair.

The implementation of PMEGs has also been expanded to patients presenting with symptomatic or ruptured TAAAs and pararenal/paravisceral AAAs.^{5,12,20,23,29} Current literature regarding use of PMEGs in the case of symptomatic or ruptured complex AAAs or TAAAs is limited primarily due to the time constraints of preparing PMEGs and the overall complexity of these cases.²⁰ Scali and associates reported outcomes of 37 patients undergoing PMEG FEVAR for pararenal AAA (17%) and TAAA (65%) for acute aortic pathology. They demonstrated a respectable 1- and 4-year mortality for this highly lethal presentation at 70% and 67%, respectively.³⁰ They demonstrated a 1-year branch vessel patency of 98% with a reintervention rate of 30%. Juszczak and colleagues reported comparable results for similar patient groups (n=54) with 2-year survival at 73% and a reintervention rate of 20%. This study also provided insight

into the critical importance of the learning curve of PMEGs as well as the benefits of improved imaging technology over the period of 2009 to 2018. The authors demonstrated that the 30-day mortality decreased significantly from 29% in the first group of patients treated to 3.7%.²⁹ Lastly, patients successfully treated with PMEGs at acute presentation are more likely to be discharged to home when compared with open repair.²⁰

An additional technique in developing PMEGs is in situ mechanical or laser fenestrations to reestablish perfusion to branched vessels. This technique was originally introduced in maintaining perfusion to the left subclavian artery after coverage and extending proximal seal zone during thoracic endovascular aortic repair (TEVAR).³¹ Both antegrade and retrograde techniques for in situ fenestrations have been described.³¹⁻³⁴ This method has been expanded as a potential option for endovascular management of complex AAAs and TAAAs. Reports regarding in situ fenestrations within the abdominal aorta have largely been limited to case reports and series from single institutions.³¹⁻³⁴

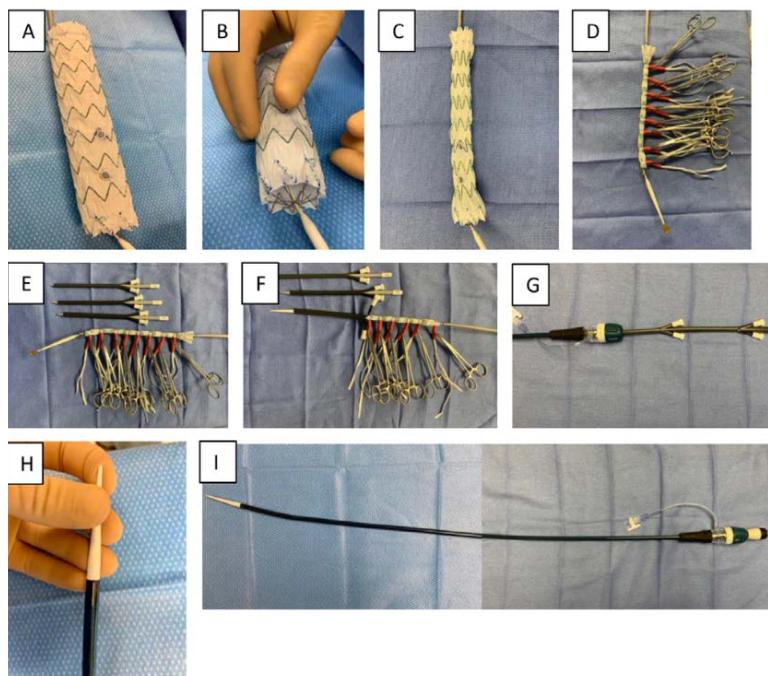


Figure 3. Physician-modified endograft resheathing. **(A)** Once fenestrations are completed, the graft is examined to determine the lie of the fenestrations. **(B, C)** Diameter-reducing sutures of 5-0 chromic are then placed around each stent of the endograft and tied down to crimp the graft to approximately 20 mm in diameter. **(D)** Umbilical tapes and red rubber catheters are cut to create a series of small Rommel tourniquets, which are then placed around each stent to shrink the graft for resheathing. **(E, F, G)** The graft is then carefully loaded into peel away sheaths 24 Fr, 22 Fr, and 20 Fr, and then the delivery sheath. **(H)** The graft is advanced to expose the notch in the distal cone of the delivery system. **(I)** The graft is now ready for flushing with rifampin (60 mg/mL) and loading onto a stiff wire for deployment.

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Utilization of in situ FEVAR has primarily been applied to patients unsuitable for other endovascular modalities of repair, or who present with symptomatic or ruptured complex AAAs.^{33,34} These procedures require extensive planning with high-quality preoperative computed tomography (CT) imaging and 3D reconstruction as described previously (**Figure 1**). Endografts described in the literature have included the Endurant II (Medtronic), Valiant Captivia (Medtronic), and Zenith Alpha.³³ The technique can be performed with preliminary stenting of all planned branch vessels to facilitate visualization and accurate laser fenestration, with subsequent full deployment of the main body endograft, although the senior author of this manuscript tends not to pre-stent prior to deployment, opting for diligent use of 3D overlay instead. After aortic graft deployment, a laser catheter is inserted through the contralateral femoral artery. Fenestrations are created starting with the SMA followed by the renal arteries and the celiac axis to minimize mesenteric and renal ischemic time. Fenestrations can be serially balloon dilated followed by deployment of appropriately sized covered stents³³ (**Figure 4**), although serial dilation is not entirely necessary.

Advantages of in situ FEVAR include off-the-shelf availability, rapid aneurysm exclusion in the setting of rupture, and no time lost with back-table graft modification. Disadvantages relative to other techniques include nonreinforced fenestrations that can disconnect due to hemodynamic stress, visceral/renal ischemic time during laser fenestration, and concern for stent migration.^{32,33} Literature examining outcomes after in situ FEVAR is limited. One prospective study observed 16 patients undergoing in situ laser FEVAR. The authors reported promising results with no deaths at 17 months and primary patency of 97%.³³ They reported a 5% failed fenestration rate and a 25% reintervention rate. The long-term durability of this method has not been described.

Patient-Specific Custom-Made (or Company Manufactured) Devices

The use of ChEVAR and PMEGs has evolved into the development of CMDs. These devices are manufactured to accommodate patient-specific anatomy in the treatment of complex AAAs and TAAAs that are not amenable to commercially available devices or are prohibitive high-risk open surgical candidates.

As previously mentioned, CMDs are currently limited in the United States to sites with FDA-approved individual PS-IDE studies. The CMD platform provides the advantage to design an endograft tailored specifically to the patient's anatomy. These endografts primarily follow the Zenith model and can incorporate multiple branches, various sizes of fenestrations or scallops, multidirectional branches, and variations in graft diameter to accommodate changes in luminal size (**Figure 5**). Additionally, these grafts are delivered ready for implantation without the need for further modification. The primary disadvantages to CMDs are the expense and the waiting period for design and construction, largely limiting their use to the elective setting.^{3,6}

Operative planning for CMDs requires advanced skills with the use of 3D CT reconstruction to determine precise measurements for preparation of the endograft (**Figure 1**). The measurements required regarding the aorta are proximal/distal neck lengths, aortic angulation, and inner aortic luminal diameter at the origin of the visceral and renal arteries. The required measurements for branch vessels include the radial positioning of each vessel (by clock position or 0 to 360 degrees), the size and length to bifurcation of any target vessels, and the luminal diameter. Additionally, the general condition of atherosclerotic aortic disease and branch vessel patency, as well as the condition and size of potential access vessels (femoral, iliac, brachial). These measurements are recorded on a designated measurements form specific to the patient. This allows for the consulted company to prepare the endograft to the exact specifications requested by the surgeon.⁶

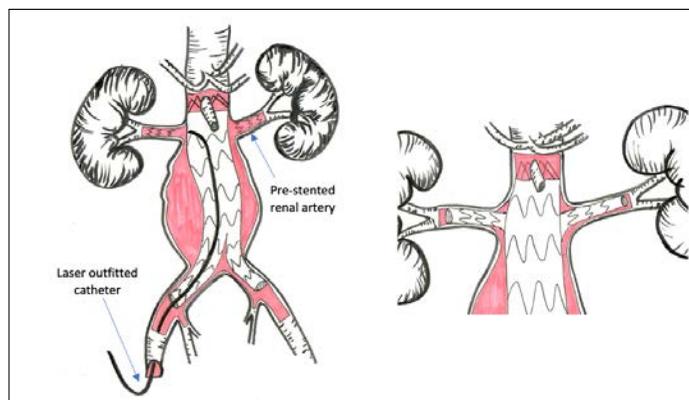


Figure 4. Antegrade laser fenestration technique.

(A) Temporary coverage of pre-stented renal arteries with in situ laser fenestration creation. (B) Completion of fenestration and covered stent deployment.

Illustration by Julia Banks. Adapted from Le Houérou T, Fabre D, Alonso CG, et al. In situ antegrade laser fenestrations during endovascular aortic repair. *Eur J Vasc Endovasc Surg.* 2018;56(3):356-362, Fig 1.

At our institution, for all F/BEVAR procedures, we utilize the VesselNavigator 3D overlay imaging system (Philips) along with Fiber Optic RealShape (Philips) technology using preoperatively obtained CT angiographic 3D reconstruction imaging. The endograft fenestrations are aligned with branch vessels and confirmed using radiopaque markers and the 3D overlay system. The distal aspect of the endograft is typically cannulated from the contralateral side with a 14 Fr sheath (12 Fr can be used for 2 or less branch vessels). Each fenestration is then cannulated, and separate wire access is established. After deploying the main aortic device, the vessels are serially revascularized using balloon-expandable stent grafts. Stents are balloon-dilated to match the branch vessel diameter distally, flared at the fenestration. If directional graft branches are utilized, they are typically revascularized after completing the entirety of the main aortic grafts and iliac limbs, with cannulation of the branches from the femoral access using a Nagare deformable sheath (Terumo). Prior to case conclusion, a cone beam noncontrasted intraoperative CT scan is done to ensure that the branch stents are not deformed and are at the proper distance into each branch vessel. Some centers perform completion CT angiography, which can help determine if significant endoleaks are present prior to case completion, although this is not typically done at our institution.

As mentioned previously, studies reporting CMD outcomes are primarily limited to single centers with FDA-approved PS-IDE studies,^{3,25,35-37} but the recently developed US Aortic Research Consortium (US-ARC) has developed a combined registry of 10 independent PS-IDE sites, which has allowed for powerful analyses including large numbers of patients who have been treated with patient-specific devices. A study utilizing the US-ARC data revealed excellent short-term and mid-term outcomes following FEVAR.³⁸ The authors stratified results by octogenarians and nonoctogenarians to determine the feasibility of FEVAR in an

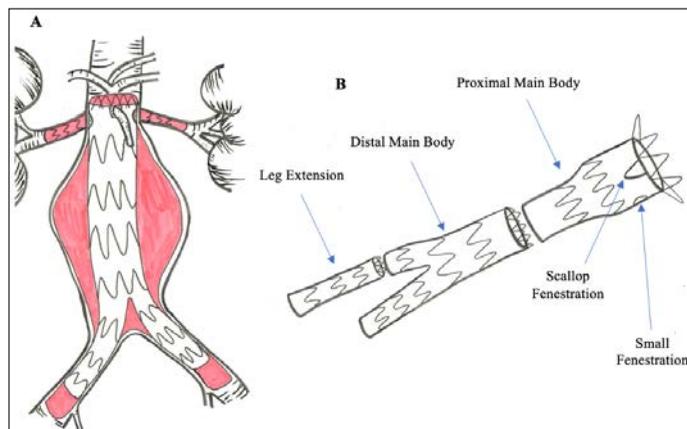


Figure 5. Artistic reproduction of Zenith Fenestrated Endograft (Cook Medical) (A) in situ and (B) external configuration.

Illustration by Julia Banks. Adapted from Greenberg RK, Sternbergh WC 3rd, Makaroun M, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. *J Vasc Surg.* Oct 2009;50(4):730-737 e731.

older patient population. In the nonoctogenarian group, patients experienced a 30-day mortality of 1.3% and adverse event rate of 9.7%. At 3 years, 73% of nonoctogenarians were alive, with a freedom from secondary intervention of 69.7%. Octogenarians demonstrated similar results with 30-day mortality of 0.5%, 30-day adverse event rate of 9.2%, and 3-year survival of 66%.³⁸ Another study investigating sex-related outcomes after FEVAR did not demonstrate sex as an independent risk factor for poor outcomes, with similar 1-year survival and freedom from reintervention in men and women at 89.9% vs 91.6% and 82.8% vs 85.5%, respectively.³⁹ Additionally, CMDs have demonstrated efficacy in patients who failed initial treatment with standard EVAR.⁴⁰ In their study, Schanzer and colleagues demonstrated a comparable technical success rate (97% vs 97.9%; $P=.15$), 30-day mortality (2.5% vs 1.1%; $P=.25$), and 1-year freedom from reintervention (84.7% vs 88.7%; $P=.10$) between failed EVAR and no prior EVAR groups, respectively. The failed EVAR group experienced worse survival at 1 year at 86.3% vs 91.9% in the no-EVAR group ($P=.02$). When adjusted for other variables, however, the difference in survival dissipated.⁴⁰ Other studies have demonstrated similar outcomes in using FEVAR to treat chronic post-dissection aneurysmal degeneration when compared with primary, degenerative TAAAs or complex AAAs.⁴¹ Overall, F/BEVAR has been proven to serve as a versatile treatment modality for multiple complex aortic pathologies.

Additional platforms for the manufacturing of CMDs that are only available in European countries include the Ex-tra Design Engineering endografts with inner branches (Jotec) and the Anaconda endograft (Terumo Aortic) (Figure 6). The Anaconda CMD is outfitted with 2 nitinol rings at the superior aspect and multiple hooks for supraceliac fixation. Unique aspects of this device are the ability to constrain and reposition the main body for precision alignment, a nonreinforced mid-aspect (no wireform

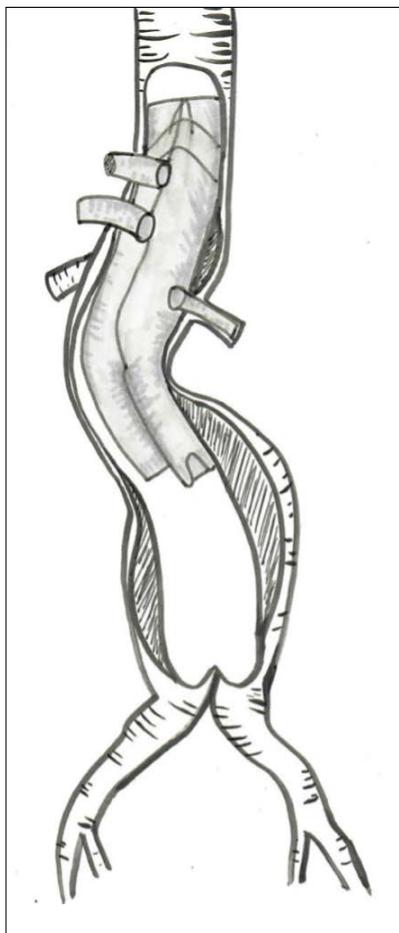


Figure 6. Anaconda graft (Terumo Aortic) in situ illustration.

Illustration by Julia Banks; adapted from Terumo Aortic, <https://terumoortic.com/custom-solutions/fenestrated-anaconda>.

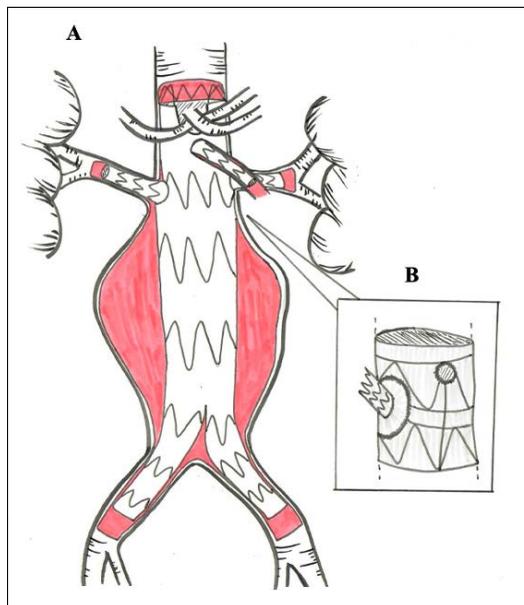


Figure 7. Zenith p-Branch device schematic (A) in situ illustration. (B) Demonstration of pivot branches to accommodate cephalad or caudal angled renal arteries.

Illustration by Julia Banks; adapted from Farber MA, Parodi FE. New devices on the frontier for off-the-shelf repair of TAAAs. *Endovascular Today*. 2019;18(11):77-79, Fig. 2; Fillinger M. Managing branches during endovascular aortic aneurysm repair. *Technique*. Chapter 91. *Thoracic Key*. 2016. <https://thoracickey.com/technique-4>; Fig 91.5.

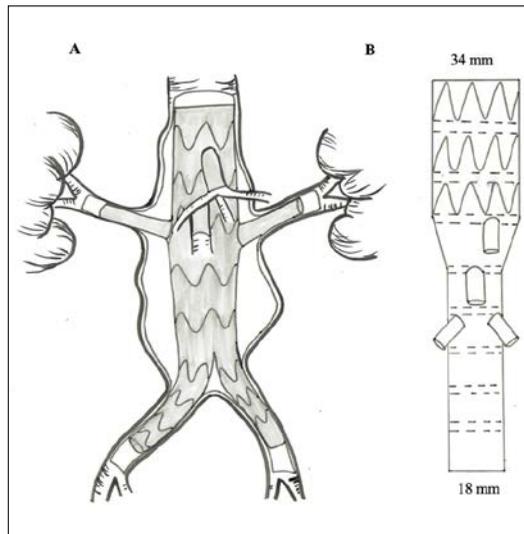


Figure 8. Cook Medical t-Branch system (A) in situ illustration. (B) Schematic demonstrating branch vessels and size measurements of distal and proximal components.

Illustration by Julia Banks; adapted from Farber MA, Parodi FE. New devices on the frontier for off-the-shelf repair of TAAAs. *Endovascular Today*. 2019;18(11):77-79, Fig. 3; Bertoglio L, Grandi A, Carta N, et al. Comparison of anatomic feasibility of three different multibranched off-the-shelf stent-grafts designed for thoracoabdominal aortic aneurysms. *J Vasc Surg*. 2021;74(5):1472-1482.e4

structure) that allows ease of fenestration location, and the ability to accommodate neck angulation up to 90 degrees due to device flexibility.^{42,43} Technical success has been reported to range from 88% to 94% with 30-day mortality of 4.2%, 1-year survival of 91%, reintervention rate ranging from 9% to 19% at 1 year, and target vessel patency of 98%.^{42,43}

The Jotec CMD incorporates an inner branch design allowing for increased maneuverability within the aortic lumen, minimized suprarenal coverage (in comparison with devices with internal-external branches), and reportedly improved ability to cannulate fenestrations/branch cuffs. The inner branches also theoretically provide improved ability to tolerate sharp aortic neck angulation.⁴⁴ In one study, technical success was 100%, 30-day mortality was 0%, and freedom from reintervention at 1 year was 98%.⁴⁴

Off-the-Shelf Endografts

Off-the-shelf aortic endografts for the treatment of complex AAAs and TAAAs are an attractive potential for the treatment of

aneurysms near/in the visceral segment, given that many patients present in nonelective scenarios. Multiple off-the-shelf devices have been evaluated in both physician-sponsored and company-sponsored investigational device exemption studies, as well as outside of the United States.^{45,46} The Zenith p-Branch device (Cook Medical) was studied in a company-sponsored study but has yet to be introduced to the market. The device construct included renal and SMA fenestrations and a celiac scallop in 2 device configurations, and was felt to accommodate approximately 70% of juxtarenal aneurysm anatomy (Figure 7).⁴⁷ The procedure is similar to that described for other juxtarenal devices above. One study reviewed 206 CT scans of ruptured pararenal and short-neck infrarenal AAAs and determined that the Zenith p-Branch could accommodate 40% to 60% of cases based on graft characteristics and measurements.⁴⁸

Another off-the-shelf device that has been utilized outside of the United States but is only available at select U.S. centers with PS-IDE studies is the Zenith t-Branch system (Figure 8). The t-Branch endograft measures 202 mm in length with a 34-mm

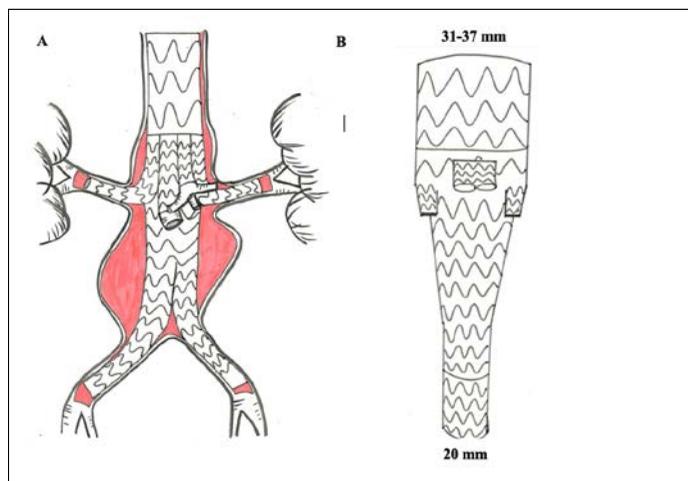


Figure 9. The Gore ThoracoAbdoMinal Branch Endoprosthesis (TAMBE) (A) in situ illustration. (B) Schematic representation with proximal and distal component measurements.

Illustration by Julia Banks; adapted from Farber MA, Parodi FE. New devices on the frontier for off-the-shelf repair of TAAAs. *Endovascular Today*. 2019;18(11):77-79, Fig. 1; Bertoglio L, Grandi A, Carta N, et al. Comparison of anatomic feasibility of three different multibranched off-the-shelf stent-grafts designed for thoracoabdominal aortic aneurysms. *J Vasc Surg*. 2021;74(5):1472-1482.e4

proximal component and a tapered distal diameter of 18 mm. The graft consists of polyester fabric supported by circumferential stainless-steel Z-stents. There are 8-mm diameter branches for the celiac artery and SMA and 6-mm diameter renal branches (Figure 8). A large study investigating outcomes in 562 patients treated with the Zenith t-Branch for urgent or elective pathology revealed 30-day mortality of 8.5% in elective and 30% in rupture presentation, stent graft-related reintervention rate of 5.7%, primary patency of 99%, and renal injury rate of 13%.⁴⁶ A meta-analysis evaluating seven studies demonstrated midterm mortality ranging from 2% to 12% reintervention rate ranging from 2.7% to 11.4% at 15 months.⁴⁹ Other studies have yielded similar results.^{23,50}

The TAMBE is currently being investigated at select US centers for the treatment of Crawford Extent I-IV TAAAs (Figure 9). TAMBE is a modular system consisting of the visceral branching main body with a bifurcated abdominal segment and iliac limbs.⁵¹ The device is manufactured in a 215-mm length and 160-mm length depending on the orientation of the renal portals (retrograde vs antegrade). The proximal diameter ranges from 26 mm to 37 mm, and the distal diameter is fixed at 20 mm. The main device is usually delivered using a 22 Fr system with a 12 Fr system required for delivering branch vessel stent grafts antegrade. Balloon-expandable Viabahn VBX stent grafts (Gore) are used to extend branches into the renal and visceral arteries. The device has preloaded guidewire tubes and catheters within the branch portals to assist successful cannulation. The full description of deployment of the TAMBE has been described previously.⁵¹ The 30-day outcomes from the prospective pivotal trial of 13 patients demonstrated 92% technical success, no mortality or spinal cord

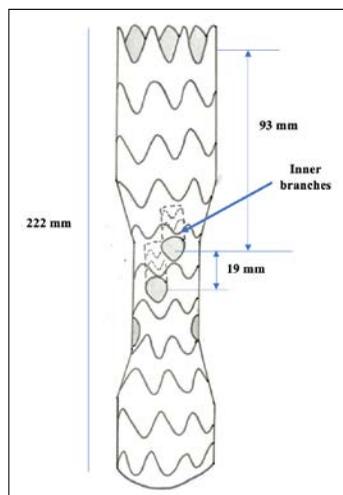


Figure 10. The E-nside endograft (Jotec) schematic illustration with measurements.

Illustration by Julia Banks; adapted from Abisi S, Zymvragoudakis V, Gkoutzios P, et al. Early outcomes of Jotec inner-branched endografts in complex endovascular aortic aneurysm repair. *J Vasc Surg*. 2021;74(3):871-879.

ischemia (SCI), and 100% target vessel patency.⁵¹ The overall anatomical feasibility of the TAMBE based on instructions for use is 43% to 49%.^{50,52}

The E-nside endograft (Jotec) is a novel endovascular technique that employs precannulated inner branch technology in the treatment of complex AAAs⁵³ and has only been used outside of the United States thus far. The device is 222 mm in length with available 33-mm and 38-mm proximal diameters and 26-mm and 30-mm distal diameters. The innovative structure provides the advantages of both a branched and fenestrated endograft. The polyester fabric is supported by nitinol Z-stents with 6-mm branches for renal arteries and 8 mm for the SMA and celiac artery. The device requires a 24 Fr delivery system. The graft reportedly can accommodate supraceliac angulation up to 70 degrees and infrarenal angulation up to 30 degrees. Additionally, the graft can accommodate up to 45 degrees of longitudinal angulation of target vessels (Figure 10).⁵³ The overall deployment of the E-nside endograft has been described previously.⁵³ Early outcomes using the E-nside endograft for multiple aortic pathologies have recently been described. At 30-days, technical success was 95%, mortality was 5%, SCI occurred in 6%, and target vessel reinterventions were required in 2%.⁵⁴ The overall anatomical feasibility of E-nside endografts is approximately 43%.⁵⁰ The Valiant TAAA endograft (Medtronic) has been approved for investigational studies, but no outcomes data are currently available.

Overall Outcomes/Complications

Comparing outcomes after open surgical repair and F/BEVAR for complex AAAs or TAAAs is difficult because patients undergoing F/BEVAR tend to have significantly more risk factors (especially cardiopulmonary) and are approximately 10 years older across studies.^{6,55} Several systemic reviews and meta-analyses have been conducted to compare open surgical outcomes and F/BEVAR in complex AAA or TAAA repair.^{27,55,56} In their meta-analysis including 71 studies, Rocha et al demonstrated a similar perioperative mortality (7.4% F/BEVAR vs 8.9% open repair; $P=.21$) with lower rates of cerebrovascular events and renal failure

in F/BEVAR. In a similar study, Patel et al reported perioperative mortality of 3.1% in F/BEVAR compared with 4.4% in open repair with associated significant risk reduction of perioperative mortality and cardiac events in FEVAR (RR 0.62 95% CI 0.32–0.95 and RR 0.37, 95% CI 0.16–0.62). Sequential retrospective multicenter European studies demonstrated similar perioperative and 2-year mortality between 2 techniques at 6.7% F/BEVAR vs 5.4% open and 14.9% vs 11.8%, respectively.^{57,58} This study also demonstrated higher perioperative mortality in F/BEVAR when compared with open repair in infra-diaphragmatic TA-AAs (11.6% vs 4%; $P=.01$). The early mortality advantage to F/BEVAR demonstrated in these studies seems to dissipate at midterm follow-up.^{56,58}

These comparable and in some cases superior outcomes after F/BEVAR in a more highly comorbid population are a testament to the utility of this technique, but durability is certainly still in question in younger patients. Thus, risk for reinterventions remains a critical challenge in F/BEVAR. In a meta-analysis comparing open repair and F/BEVAR, the authors reported a higher risk of midterm reintervention in the F/BEVAR group (HR 1.65, 95% CI 1.04–2.66).⁵⁶ These results were echoed by an additional systematic review with increased risk for reintervention in F/BEVAR (HR 2.11, 95% CI 1.39–3.98).⁵⁹ The overall reintervention rate at midterm follow-up has been reported at 24% at 2 years with a freedom from reintervention at 1 and 3 years of 80% and 64%, respectively.⁶⁰ Incidence of reintervention is correlated with extent of aortic disease with increased reintervention rates in type I–III TAAAs.^{60,61} However, reinterventions do not appear to affect overall survival.⁶⁰ Report from the largest cohort of open TAAA repairs demonstrated freedom from aortic-related reinterventions at 94%.⁷ Long-term freedom from reintervention or death after F/BEVAR at 5 years ranges from 66% to 78%, with primary patency of 94.2%.^{62,63} The primary limitations of F/BEVAR are the reintervention rates, overall cost, anatomical constraints, and required long-term imaging surveillance.

The most devastating complication after complex AAA or TAAA repair remains SCI and ranges from 2% to 10% across studies.⁶⁴ The risk of SCI increases with the extent of aortic disease and extent of aortic coverage during F/BEVAR.^{61,64,65} F/BEVAR is limited in the ability to preserve collateral flow from intercostal arteries and lumbar arteries, requiring other modalities for SCI prevention. Additionally, in some off-the-shelf F/BEVAR devices, a greater extent of healthy aorta is sacrificed compared with open repair, which may increase the risk for SCI.⁶⁶ Recommended measures for SCI include staged aortic procedures when possible, preservation of subclavian and hypogastric arteries, and some advocate for sequential pre-emptive intercostal embolization.⁶⁴ Postoperative measures recommended by the US-ARC also include prophylactic spinal drainage in high-risk patients, maintaining MAP >90 mm Hg intraoperatively, and increasing the hemoglobin goal to 10 intraoperatively.⁶⁴ Over time, the risk of SCI has decreased in high-volume centers with the implementation of these strategies.

Finally, the learning curve for these newly developed devices is steep and must be considered in early outcomes. Over time,

as experience with these endografts has increased, outcomes have improved.⁶ Importantly, endovascular treatment of complex AAA and TAAA currently have better outcomes at high-volume aortic centers.⁶⁷

Conclusion

In this article, we have described the evolution of aortic repair of the branched visceral aorta including CMDs and off-the-shelf devices, in addition to more widely available methods such as ChEVAR and physician-modified constructs. Early results from these techniques are generally excellent, and the future of minimally invasive complex aortic repair is certainly bright as more sophisticated devices become more widely available. Challenges certainly remain regarding anatomical feasibility, durability/reinterventions, especially in younger and healthier patients, as well as prevention of SCI. ■

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