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Achieving an **AORTIC TEAM APPROACH**



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The Aortic Team as a High-Tech Specialty Area

Industry innovations drive the emergence of the clinical aortic team.

BY MARTIN CZERNY, MD, MBA, AND BARTOSZ RYLSKI, MD

Despite being a niche not so long ago, aortic medicine has developed into a subspecialty of cardiovascular medicine in which the aortic team—much like the heart team in the treatment of structural heart valve disease—combines knowledge and experience from several disciplines to identify and apply the right treatments to appropriate patients, aiming to raise standards, improve quality and outcomes, and enhance durability of repair.

Traditionally, cardiac and vascular surgeons manage aortic cases, masterminding the entire course from diagnosis to treatment to follow-up, but several other specialties, such as anesthesiology, radiology, and cardiology, contribute to the bigger picture and provide invaluable insights.

Aortic medicine has developed from a classical surgical discipline to a high-tech specialty where highly developed surgical expertise and interventional skills create the platform for all options in both acute and chronic clinical scenarios.

Where indication seeks technology, the right industrial partners respond to the respective indications and surgical needs; the development of aortic medicine in the last 15 years is perfectly mirrored in the evolution of Terumo Aortic, which arose from Vascutek—a traditional aortic surgery company, instrumental in many major innovations in the surgical field—and Bolton Medical, which was known for several innovations in the endovascular field. The fusion of these two companies as Terumo Aortic created a manufacturer that complements and encourages the emergence of the clinical aortic team, not only by providing a range of treatment options but also by refocusing those options on the patient and pathology, not the technology or technique. This article focuses on three prostheses—one surgical, one endovascular, and another bridging both worlds: the Gelweave™ Siena graft (Terumo Aortic), the Relay®Plus stent graft (Terumo Aortic), and, finally, the Thoraflex™ Hybrid device (Terumo Aortic).

THE GELWEAVE SIENA GRAFT

The Gelweave Siena prosthesis was designed and developed as the modern prosthesis for the classic elephant trunk technique. It is particularly suited for use in patients with mega-aortic syndromes where the sewing collar allows tailoring to address size discrepancies in the native distal aortic arch (Figure 1). This original

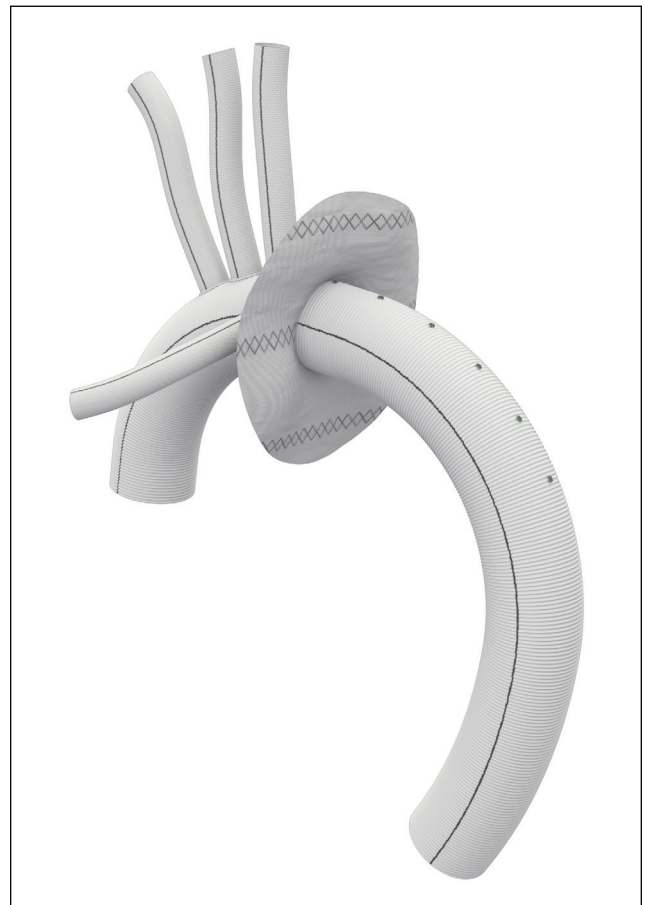


Figure 1. The Gelweave Siena graft with sewing collar for addressing size discrepancies in the native distal aortic arch.



Figure 2. The Gelweave Siena collar is trimmed to fit to the proximal end of the stent graft.

concept has worked well for some time, and the concept has allowed for further innovation, such as tailoring to address size discrepancies in patients with previous aortic operations. For example, these new applications allow treatment of patients with previous thoracic endovascular aortic repair (TEVAR) and disease progression either proximally or distally or with persisting or newly developing type I endoleaks.

The largest available classic Dacron prostheses have a size of 34 mm, which is sufficient to adjust to native aortic diameters in most cases. However, if a patient has undergone TEVAR with, for example, a 46-mm stent graft and now needs proximal repair for a type Ia endoleak, then bridging this size discrepancy from 34 to 46 mm will be more challenging. The sewing collar of the Gelweave Siena graft is an ideal means to resolve this situation. The elephant trunk component is cut, and the collar is trimmed to the size of the proximal end of the stent graft (Figure 2). The remaining aortic wall can be incorporated into the anastomosis, but this is not mandatory if there is no remaining endoleak component or graft detachment.

The same concept works distally in patients with type Ia endoleaks or in patients with postdissection aneurysmal formation (Figure 3). In this case, the side branches—originally designed for the supra-aortic branches and perfusion—are used for the visceral and renal arteries.¹

THE RELAY PLATFORM

The RelayPlus device (Figure 4) is a stent graft

designed with challenging anatomies in mind. It has a dual-sheath delivery system—an outer sheath for support during advancement through access vessels and a soft, flexible inner sheath that reduces vessel trauma. Radial force varies from proximal to distal, with radial force maximized for zones of fixation and minimized for zones requiring conformability. The tip capture design holds the proximal end of the prosthesis safely in place during deployment of the main body and was the first of its kind on the market to ensure exact deployment. Finally, the RelayNBS non-bare-stent version of the stent graft has support wires that ensure perpendicular alignment of the prosthesis irrespective of the angulation of the intended landing zone (Figure 5). This add-on was a spinoff of the company's

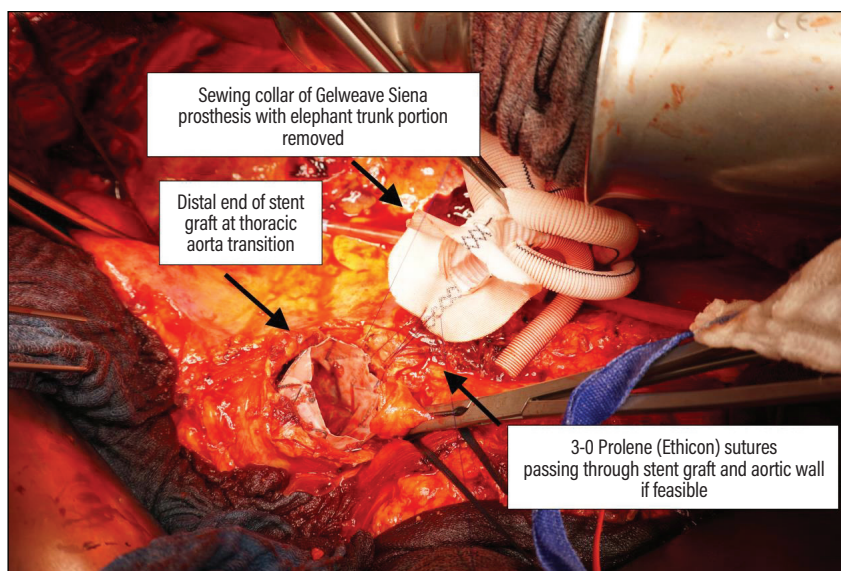


Figure 3. Use of the Gelweave Siena prosthesis for surgical distal TEVAR extension. Reprinted from *The Annals of Thoracic Surgery*, 105/2, Jasser A, Kreibich M, Morlack J, et al, Aortic replacement after TEVAR—diameter correction with modified use of the Siena prosthesis, 587-591, 2018, with permission from Elsevier.

ascending aortic work, which was an example of the symbiosis between physicians and industry in which an indication sought out technology and the solution came from bench to bedside. Many studies have confirmed the unique performance of the RelayPlus and RelayNBS Plus devices in several acute and chronic thoracic aortic pathologies.²⁻⁴ A low-profile version of the standard device (RelayPro) with a 3- to 4-F profile reduction is now available.⁵

THE THORAFLEX HYBRID

The Thoraflex Hybrid device bridges both worlds of classic surgery and endovascular therapy (Figure 6). Once again, clinical need triggered the development of this device and the result was a product that—within relatively little time—became an indispensable tool for the treatment of many acute and chronic thoracic aortic pathologies. Even today, many patients undergo partial solutions; the ascending aorta is replaced in a one-size-fits-all philosophy without analyzing in detail the underlying pathology and assessing long-term sequelae and without anticipating the need for further repair in the years to come. As a consequence, several patients after previous ascending aortic replacement—either for acute type A aortic dissection or aneurysmal formation—will experience disease progression and need secondary procedures. It is no coincidence that the aortic community is moving toward a “proximal full fix,” which translates as a full proximal thoracic aortic repair, including the root, ascending aorta, and arch and ideally providing a platform for secondary endovascular or open surgical distal extension.

The Thoraflex Hybrid meets these needs and has several features that make the operation safe and reproducible, irrespective of the underlying pathology. The supra-aortic branches enable

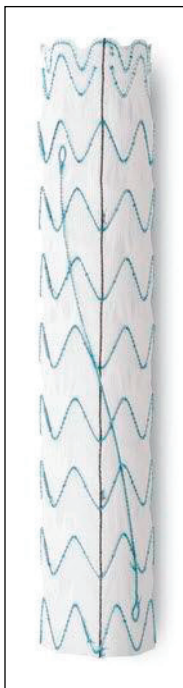


Figure 4.
RelayNBS Plus
stent graft.

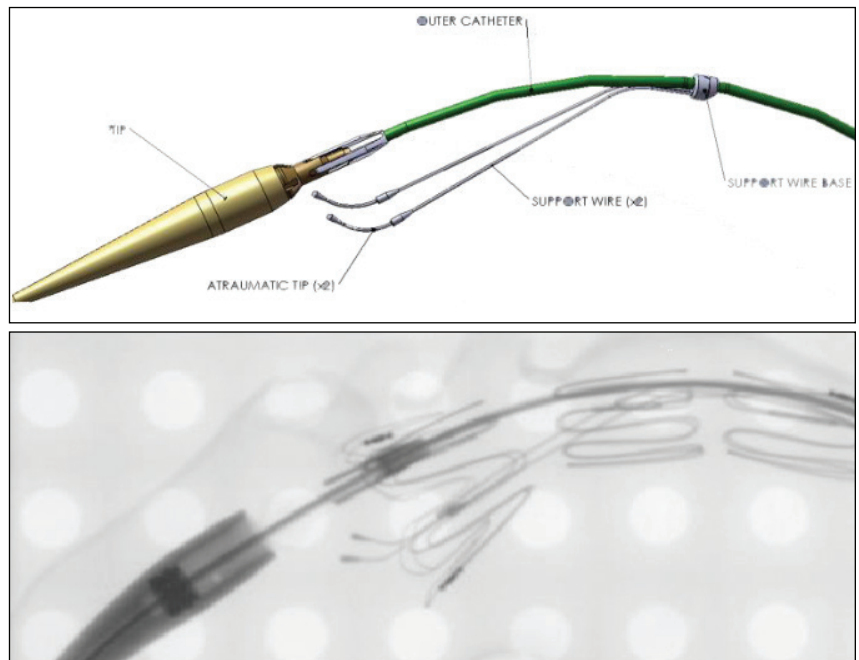


Figure 5. Support wire concept for perpendicular alignment during deployment.

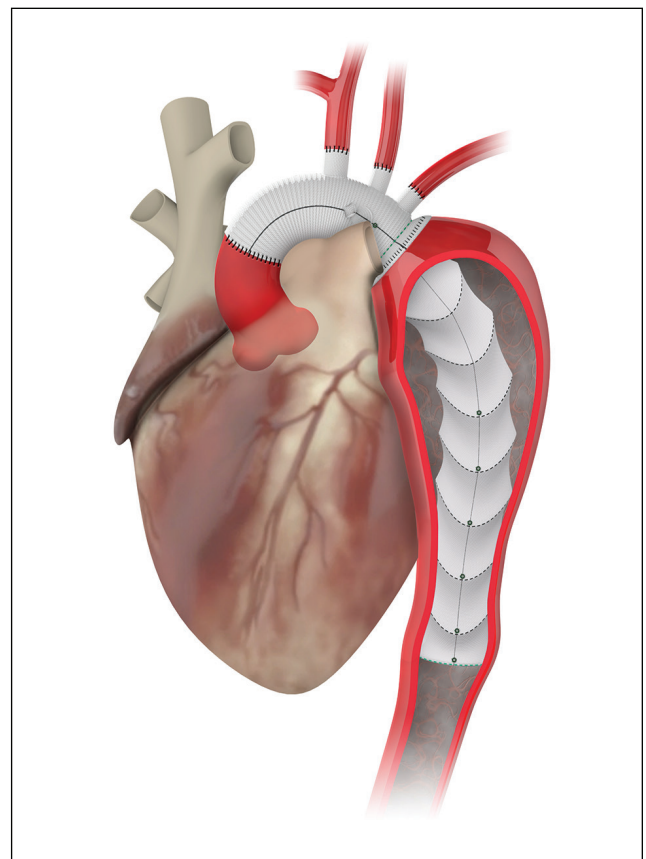


Figure 6. Thoraflex Hybrid device.

proximalization of the descending anastomosis into landing zone 2. (The European Association for Cardio-Thoracic Surgery and European Society for Vascular Surgery consensus document recommended unifying reporting and extent of repair or exclusion from circulation respectively, according to the Ishimaru landing zones.) This is a small technical detail but a big leap forward with regard to safety, ease of accomplishment, and accessibility for subsequent hemostasis.⁶ We exclusively use the 10-cm stent component length to further minimize the remaining risk of symptomatic spinal cord injury. There are many factors contributing to this risk, and stent length is one of them.⁷ We have not observed a single case of symptomatic spinal cord injury in > 150 Thoraflex Hybrid implantations to date.

In cases of secondary distal extension, our policy is to start with a RelayNBS Plus stent graft extension down to the level of the thoracoabdominal transition and metachronously adding type IV open distal repair. This concept converts a Crawford type II thoracoabdominal aneurysm into a Crawford type IV scenario, which has several advantages, primarily preconditioning the collateral network for spinal cord protection and a less extensive open thoracoabdominal repair.

For this type of open repair, the surgical Gelweave Siena graft is ideal to attach to the endovascular device and the remaining aortic wall. The three stages reflect a complete and comprehensive approach to the aorta and a combined effort of the aortic team: Thoraflex Hybrid for proximal full fix, RelayNBS Plus for distal extension, and, finally, Gelweave Siena for open distal completion.⁸

CONCLUSION

The recent history of aortic medicine and the solutions offered by Terumo Aortic demonstrate an excellent interplay between indication and technology, clinical

specialties, and the mutual benefit when physicians and industry collaborate to provide better care for patients. ■

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Arch Disease: Pathology and Treatment Strategies

A review of the Gelweave™ Siena vascular graft, Thoraflex™ Hybrid device, Relay®Plus and Relay®Branch stent grafts used to treat total and distal arch pathology.

BY ROBIN H. HEIJMEN, MD, PhD, AND HECTOR W.L. DE BEAUFORT, MD, PhD

Open surgical repair of aortic arch pathology remains a challenge due to the anatomy with limited exposure of the distal region through median sternotomy, as well as the need for temporary cardiac, cerebral, and systemic circulatory arrest. Additionally, the left recurrent nerve encircles the distal arch and its injury may lead to troublesome hoarseness. Therefore, preoperative planning as well as surgical expertise are of utmost importance to achieve good surgical outcomes.

Hypothermia is routinely used to reduce the detrimental effects of ischemia during arrest but has its own associated risks. Deep hypothermic circulatory arrest ($\leq 20^{\circ}\text{C}$) provides a safe duration of cerebral arrest for approximately 30 minutes; however, this is usually too short for complex repairs. As an alternative, most surgeons apply antegrade selective cerebral perfusion (either unilateral or bilateral) at moderate systemic hypothermia ($\leq 28^{\circ}\text{C}$), providing a safe duration of systemic arrest for > 1 hour, which is long enough for most extensive arch reconstructions. However, the latter approach requires direct manipulation of the cerebral vessels, risking embolic stroke. Nonetheless,

following a strict protocol for heart, brain, and systemic protection, aortic arch surgery can be performed at a very acceptable risk.^{1,2}

OPEN SURGICAL REPAIR

The extensive range of standard polyester vascular grafts enables surgeons to individualize their approach to the respective arch pathology to be treated. All specifications of the Gelweave Siena vascular graft (Terumo Aortic) can be selected upon ordering (Figure 1). For instance, the side branch (Gelweave Siena Ante-Flo) permits antegrade perfusion to minimize circulatory arrest time. The four-branch design (Gelweave Siena Plexus) with complimentary diameters facilitates individual arch vessel reimplantation as an alternative to the “island technique,” as well as antegrade perfusion. The Gelweave Siena collar compensates for diameter mismatch between the distal aorta and graft and allows the surgeon to leave a short segment of graft floating in the residual downstream aorta (ie, elephant trunk) for staged extension. The radiopaque markers define the proximal safe landing zone in case of endovascular completion. However, completion of the elephant trunk by either staged open or endovascular means is necessary to fully exclude the pathology. Aside from the cumulative risk of both procedures, interval mortality up to 4% has been observed.³

HYBRID REPAIR

As an alternative specification, the polyester segment distal to the collar is also available in a stented configuration (ie, frozen elephant trunk).⁴ The Thoraflex Hybrid device (Terumo Aortic) comprises a proximal single- or multibranched surgical graft and distal stent (Figure 2). The diameter varies between the polyester graft proximally and the stent distally, which has a covered length of either 10 or 15 cm. In cases where the arch pathology extends into the proximal descending aorta, the patient can be treated in a single stage only using this midsternal hybrid approach (Figure 3). To reduce

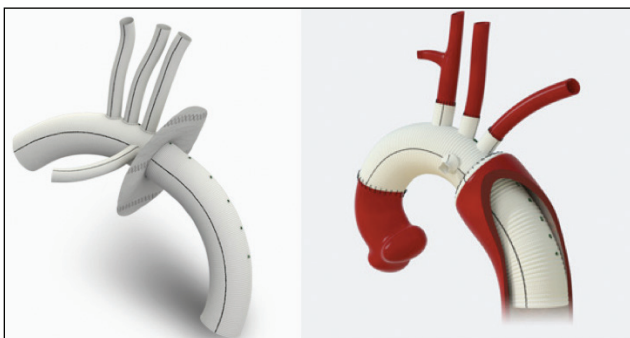


Figure 1. Gelweave Siena graft. A comprehensive range of product designs catering to a variety of both surgical techniques and patient needs for use during aortic arch and first-stage elephant trunk procedures.

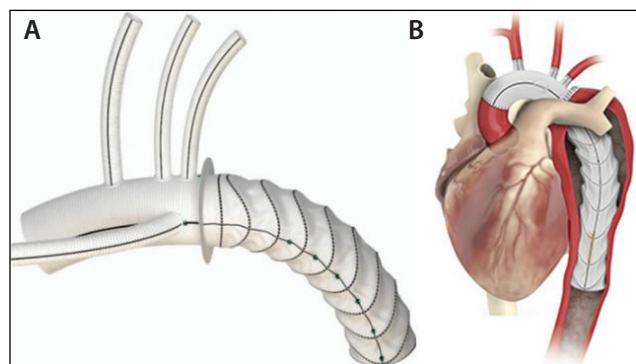


Figure 2. Thoraflex Hybrid device (A). Multibranched hybrid device that enables single-stage repair of extended arch pathology by combining endovascular treatment with conventional surgery (B). Reprinted from Di Marco L, Pacini D, Murana G, et al. Total aortic arch replacement with frozen elephant trunk (Thoraflex). *Ann Cardiothorac Surg.* 2018;7:451-453.

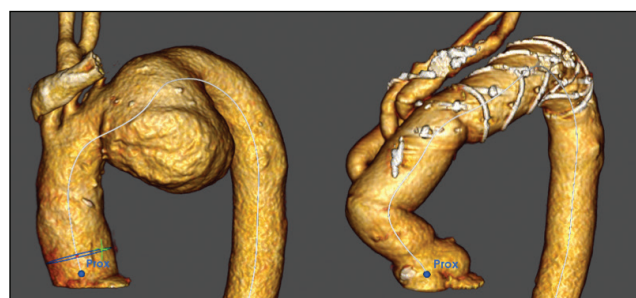


Figure 3. A 76-year-old man with concomitant two-vessel coronary artery disease and a moderately dilated ascending aorta presenting with hoarseness due to a large distal arch aneurysm. In the absence of other comorbidities, he was considered a good candidate for open surgical repair using the Thoraflex Hybrid device.

intraoperative complexity and thus the duration of systemic arrest risking spinal cord ischemia, the Plexus configuration enables proximalization of the distal suture line and also avoids the recurrent nerve. The anastomosis to the deep-lying left subclavian artery (LSA) can be managed with either single-stage or staged revascularization in the neck.

In addition to using this hybrid prosthesis for single-stage procedures, it is widely applied in more extensive downstream pathology. Using an endovascular trans-femoral approach, a RelayPlus stent graft (Terumo Aortic) can be used to complete the stented segment of the Thoraflex Hybrid device. The RelayPlus stent graft is designed with a spiral support strut (ie, S-bar), which provides longitudinal support; a precurved inner catheter;

and a dual-sheath system, consisting of a hydrophilic-coated reinforced outer sheath and flexible inner sheath for optimal aortic navigation. Proximal clamping allows for precise and perpendicular deployment.

In addition to its use in degenerative aneurysmal disease, the Thoraflex Hybrid device is also widely applied in acute and chronic dissections. The stented segment may act as a scaffold, inducing false lumen thrombosis and eventual aortic remodeling.⁵ However, the frozen elephant trunk technique may add to the complexity in this already complex subset of emergent patients. Attention should be paid to the potential increased incidence of spinal cord ischemia, and a careful comparative assessment is indicated in contrast to routine use. Nevertheless, in many selected patients at our center, the use of the Thoraflex Hybrid device in postdissection aneurysmal disease (ie, post-type A dissection repair by limited hemi-arch replacement only) has resulted in exclusion of the downstream false lumen and its remodeling and has avoided the otherwise-indicated second-stage repair of the descending aorta after conventional elephant trunk.

Because of all the necessary invasive adjunctive procedures, open surgery of aortic arch pathology may not be the best treatment option for all patients. Older patients with comorbidities may benefit from a less invasive approach that allows for quicker recovery.

ENDOVASCULAR REPAIR

Although most patients with descending thoracic aortic pathology can be easily and safely treated using a non-customized RelayPlus stent graft,⁶ the involvement of the arch vessels in arch pathology requires additional measures. Fortunately, there is a broad range of standard sizes and tapers that can be customized to the precise needs of the individual patient. Multiple designs are available with respect to diameter, taper, length, and body, requiring 3 weeks' delivery time. As an alternative to surgical revascularization of the LSA (or more complex endovascular alternatives such as in-situ laser or chimney grafts), a scalloped gate on the main body can proximally ensure blood flow while at the same time lengthening the landing zone (Figure 4).⁷ When combined with surgical debranching, a single scallop can be used to accommodate the left common carotid artery or the innominate artery more proximally. The pathology to be treated should be opposite the scallop to lower the risk of proximal endoleak. The maximum width of the scallop is limited by the stent graft diameter. In wide arch vessels, a fenestration on the main body can be an alternative if the anatomy allows proximal seating of the stent graft in the ascending aorta (Figure 5). A mechanical aortic valve may exclude its use due to interference with the nose

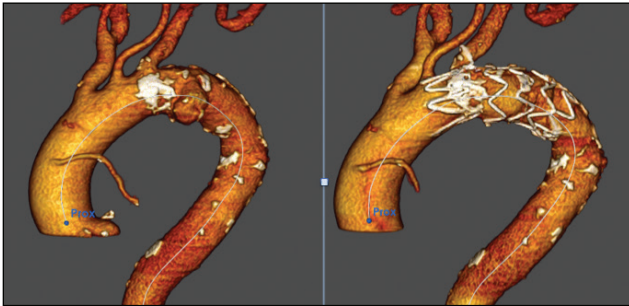


Figure 4. A 76-year-old man presented with a progressive distal arch saccular aneurysm. He had previously undergone endovascular aneurysm repair and coronary artery bypass grafting with a patent left internal mammary artery graft and had moderate left ventricular function. Given the medical history and aneurysm anatomy, he was considered a good candidate for a customized RelayPlus with a proximal scallop accommodating the LSA.



Figure 5. An 80-year-old man with severe chronic obstructive pulmonary disease and symptomatic severe aortic valve stenosis presented with a large arch aneurysm. Wide bovine trunk, excluding the use of a proximal scalloped RelayPlus. The patient was considered a good candidate for staged transfemoral transcatheter aortic valve implantation and fenestrated RelayPlus with concomitant surgical LSA revascularization.

cone. A moderately dilated ascending aorta (≥ 40 mm) may increase the risk of retrograde aortic dissection, and the presence of proximal anastomoses of aorta-coronary bypasses are also considered a contraindication for zone 0 seating.

More recently, the RelayBranch thoracic stent graft system (Terumo Aortic) was introduced as an alternative to open surgical repair in inoperable or high-risk patients.⁸ It consists of a main body graft that includes a large covered window with two internal tunnels designed to mate with branches that provide perfusion to the innominate and left carotid arteries. Usually, the LSA is surgically revascularized in this setting. Its use may be

limited by the anatomic requirements of a nondilated, lengthy proximal landing zone in the ascending aorta and nondilated, nondiseased supra-aortic vessels, together with adequate iliac access for the large-bore introducer sheath. Initial results are promising and demonstrate its effectiveness in excluding aortic pathology. Due to the required manipulations, the risk of neurologic injury is present. Careful patient selection and procedural handling are of the utmost importance, and its introduction should be carefully monitored.

CONCLUSION

The wide variety of standard surgical grafts, including graft (Gelweave Siena) and hybrid (Thoraflex Hybrid) devices together with the RelayPlus stent graft and its extensive custom-made program with scallops, fenestrations, and branches offer physicians the necessary range of options to solve a substantial amount of the challenges encountered in total and distal arch pathology. Thanks to currently available technology, the optimal mode of repair can be individually chosen after carefully weighing all available treatment options, preferably in a multidisciplinary setting at an aortic center of expertise.⁹

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Endovascular Treatment of Arch and Descending Aortic Pathologies

Addressing the challenging anatomies of the arch and descending aorta with custom-made options from the Relay® platform.

BY PIOTR SZOPINSKI, MD, PhD; ELIZA PLEBAN, MD, PhD; AND JAROSŁAW IWANOWSKI, MD, PhD

The widespread acceptance of thoracic endovascular aortic repair (TEVAR) for descending aortic pathologies has led to its application in off-label situations. The recent shift in thinking around the treatment of Stanford type B aortic dissections—from predominantly conservative to invasive strategies anticipating long-term remodeling and better outcomes—contributed to an expanding indication spectrum.^{1,2} Now, very ill patients with disease of the descending thoracic or thoracoabdominal aorta with a landing zone in the aortic arch who are not candidates for open surgery may be treated by wholly endovascular or hybrid repair.³ This expanded use of TEVAR means stenting the arch with or without open great vessel debranching.

Hybrid aortic arch reconstructions require surgical revascularization of at least one supra-aortic trunk (SAT) vessel to extend the proximal landing zone of the stent graft into the arch. Although open surgical repair remains the gold standard of care for complete aortic arch replacement, it is associated with the use of complex circulatory management and adjunct cerebral protection strategies and may be associated with significant morbidity and mortality from both neurologic and cardiovascular complications. Less invasive endovascular procedures with or without SAT debranching show promising results in the aortic arch in terms of decreased surgical morbidity and mortality. Advantages include that no sternotomy (or mini-sternotomy) is needed and the procedure is performed under general anesthesia without hypothermic circulatory arrest or cardiopulmonary bypass.

Patients with chronic aortic dissection can benefit from the hybrid approach as they often require repeat interventions to occlude entry tears due to enlargement of the pressurized false lumen or disseminated intravascular coagulation. Residual false lumen perfusion can persist even after performing the candy plug technique or branched stent graft repair in some cases.

We have performed more than 1,200 endovascular procedures in our center for different pathologies of abdominal, thoracic, thoracoabdominal aorta, and the arch. In addition to the different types of commercially available endovascular grafts, we have experience with the use of fenestrated, branched, custom-made, and physician-modified grafts and more complex procedures with parallel grafts and hybrid procedures. Before we started endovascular repair of the arch, we performed many implantations of Terumo Aortic stent grafts in thoracic and abdominal aorta with very good results. This article describes the features of the Relay stent graft (Terumo Aortic) platform and presents four examples, using custom-made RelayPlus devices in challenging anatomies of the arch and descending aorta.

THE RELAY PLATFORM FEATURES

The RelayPlus stent graft is indicated for the treatment of thoracic aortic pathologies including aneurysms, pseudoaneurysms, dissections, penetrating aortic ulcers, and intramural hematomas. The device consists of polyester vascular graft fabric sutured to a self-expanding scaffold created by nitinol stents. Each zone of the graft is designed to optimize conformability and seal with optimal radial load distribution. Two proximal seal stents overlap, providing multiple fixation points and equal distribution of seal radial load. Variable bare stent lengths and a proximal clasp allow for accurate alignment and controlled deployment. A flexible zone to the next stent allows for independent operation of the primary seal and fixation from the rest of the graft. A curved nitinol S-bar provides column strength and longitudinal support for the endograft and enhances “pushability” as well as conformability, even in small arch diameters. The delivery system consists of a precurved nitinol inner catheter and dual (inner and outer) sheaths. The flexible inner sheath allows for atraumatic advancement and staged graft expansion for better control, while the outer sheath



Figure 1. Preoperative CTA (A). The RelayBranch device (B). Intraoperative control angiograms (C, D). CT images 6 months postimplantation (E).

provides support during delivery and protects access vessels by acting as a conduit for the inner sheath.

The RelayNBS Plus (non-bare stent) is the covered proximal end configuration of Terumo Aortic's thoracic technology and was designed to avoid the gap and prevent retroflex deployment. Two asymmetrical clasping points located on the outer curve allow repositioning of the device and minimize any bird beak effect.

The Relay platform has a broad range of standard sizes and tapers and is complemented by the ability to customize to the precise needs of each individual patient. Standard diameters are from 22 and 46 mm and lengths from 100 to 250 mm. Tapering is possible on 150-, 200-, and 250-mm lengths with proximal diameters ranging from 28 to 46 mm, decreasing incrementally by 4 mm over the length of the stent graft.

Both RelayPlus and RelayNBS Plus are offered in custom-made configurations: individualized designs include fenestration and/or scallop, a bare distal stent, tapering (including reverse), and varying lengths. The latest configurations include arch branch designs (mostly single and double but some triple have been presented) based on RelayNBS and intended for zone 0 deployment. They have internal tunnels located in a window deployed under the ostia of target vessels (usually the brachiocephalic trunk [BCT] and left common carotid artery [LCCA]), which are connected to the main stent graft with covered, self-expandable bridging stents. Both configurations require creation

of extra-anatomic bypass or transposition of the left subclavian artery (LSA). Custom manufacturing and delivery take 3 weeks.

CASE 1

A 61-year-old man with hypertension, coronary artery disease, and chronic renal insufficiency on dialysis was diagnosed with thoracic aortic aneurysm with dissection (originating at the level of the LSA) and a maximum diameter of 83 mm. A type III arch and BCT and LCCA tortuosity presented additional challenges (Figure 1A). We elected to use a Relay double-branch device (Figure 1B) measuring 36/26 X 270 mm with

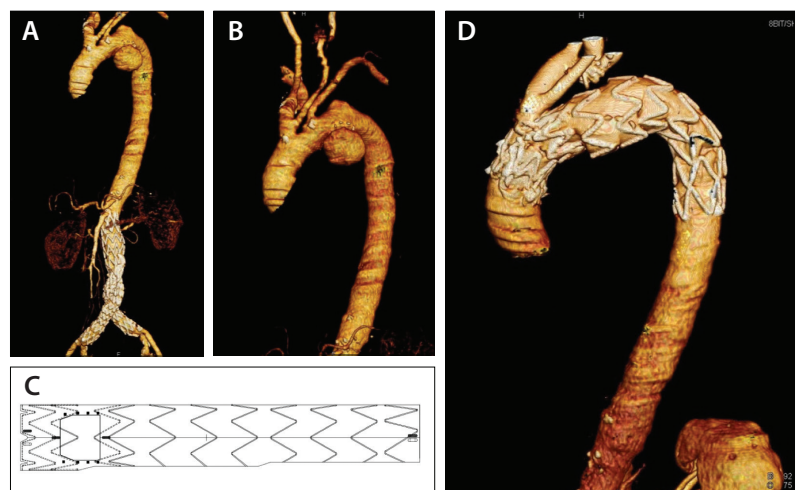


Figure 2. Preoperative CT showing pseudoaneurysm dilatation of the arch with coexisting dilatation (A, B). Case planning with specifications of the custom-made fenestrated RelayNBS Plus device (C). One-year follow-up CT showing complete seal, patent branches, and no endoleaks (D).

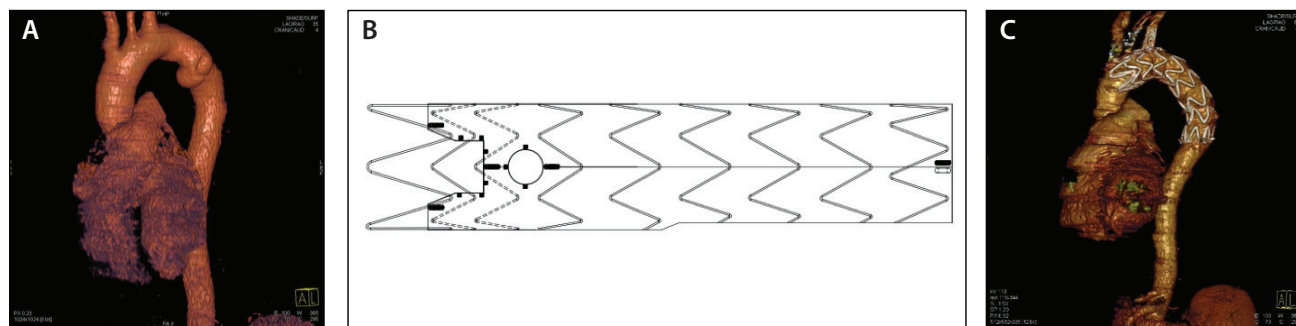


Figure 3. Preoperative CTA (A). Stent graft design with a scallop for the LCCA and fenestration for the LSA (B). CT at 1-month follow-up showing good seal and branch patency (C).

a window with two internal tunnels located 60 mm from the proximal end of the graft with two internal tunnels of 12-mm diameter each, extended distally with standard Relay stent grafts—a 28/24- X 200-mm RelayNBS Plus and a 26/26- X 100-mm RelayNBS Plus in the descending aorta. This configuration enabled tapering of the diameters from 36 to 26 mm. The LSA was occluded with an Amplatzer vascular plug (Abbott) to prevent endoleak. Intraoperative control angiograms showed successful implantations of all stent grafts with no endoleak (Figures 1C and 1D). Follow-up at 6 months showed patent vessels and no endoleak (Figure 1E).

CASE 2

An 80-year-old woman with prior endovascular repair of an abdominal aortic aneurysm (an Incraft device [Cordis, a Cardinal Health company] with “double ballerina” configuration of the legs caused by improper implantation of the stent graft) was diagnosed with a large pseudoaneurysm of the aortic arch with maximum diameter of 73 mm on the inner curvature and aneurysmatic dilatation on the opposite wall (Figures 2A and 2B). Her case was further complicated by a type III bovine arch. A tapered 34- X 30- X 200-mm fenestrated RelayNBS Plus device was implanted to zone 0 of the arch (Figure 2C). The flexibility of the Relay delivery system meant that there were no difficulties passing the primary sheath of the delivery system through the tortuous legs of the abdominal endograft nor crossing the arch with the flexible

inner sheath. The LSA was occluded with an Amplatzer vascular plug to prevent endoleak. The postoperative course was uneventful with no complications. Follow-up at 1 year showed complete aneurysm seal, patent branches, and no endoleaks or migration (Figure 2D).

CASE 3

A 45-year-old man with no significant comorbidities but a history of work-related chronic bronchitis was diagnosed with two pseudoaneurysms of the descending aorta located close to the LSA (Figure 3A). Open surgical repair was our first option, but the patient refused thoracotomy. We therefore turned to endovascular options and designed a custom-made, tapered 30/28- X 150-mm RelayPlus device with a scallop for the LCCA and fenestration for the LSA

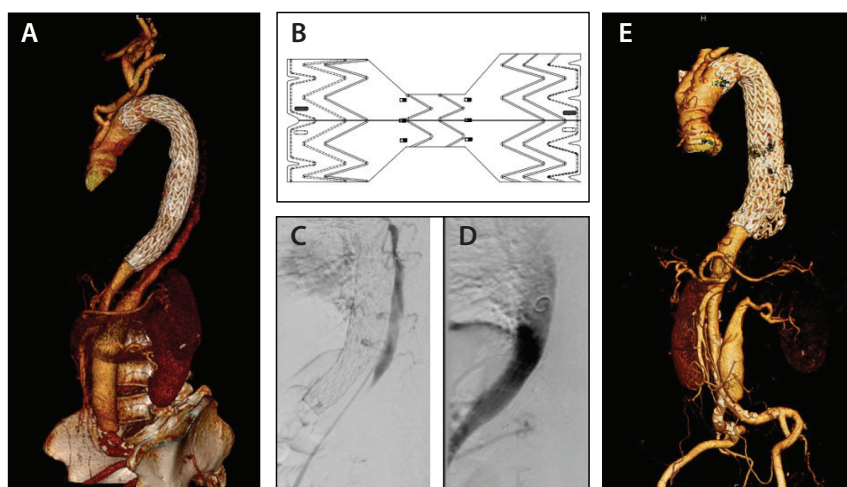


Figure 4. Preoperative CTA (A). Design of the custom-made candy plug Relay device (B). Intraoperative image showing type Ib endoleak to the false lumen (C). Intraoperative image showing complete exclusion after implant of the candy plug Relay device (D). CT at 1 year showed no false lumen perfusion (E).

(Figure 3B). The postoperative course was uneventful with no complications. Imaging at 30 days showed a patent LCCA and LSA and no endoleak (Figure 3C).

CASE 4

A 49-year-old woman presented after a Bentall procedure with hypertension and New York Heart Association class II heart failure. She had a history of endovascular repair for dissection of the descending aorta and persistent type Ib endoleak leading to enlargement of the false lumen originating at the level of the celiac trunk and superior mesenteric artery (Figure 4A). We planned a custom-made 30- X 16- X 32-mm candy plug Relay device (Figure 4B). The false lumen was closed successfully with the candy plug Relay device and an Amplatzer vascular occluder placed in the middle (Figures 4C and 4D). The postoperative course was uneventful with no complications. Imaging at 1 year showed no false lumen perfusion (Figure 4E).

CONCLUSION

Treatment of aortic arch pathologies continues to be a challenge and involves a creative combination of open and endovascular procedures requiring a multidisciplinary team evaluating risk and benefit case by case. The range of different configurations offered by Terumo Aortic's custom-made stent grafts based on the Relay platform offers the possibility to choose the most individualized product for each complex anatomy. The main potential benefit is extension of the proximal sealing zone in the inner curvature of the arch while preserving SAT flow. The recent CE Mark of a low-profile version of the standard device (RelayPro) with a 3- to 4-F profile reduction to treat patients with smaller anatomies⁴ is another important

step in establishing Relay as the thoracic endograft of choice. Experience with standard devices from Terumo Aortic is important to take full advantage of the platform's features as is familiarity with different endovascular techniques, including scallops, fenestrations, CHIMPS (chimney, periscope, or sandwich), and open surgical SAT reconstructions. ■

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CASE REPORT

Treatment of a Juxtarenal Aortic Aneurysm With a Relay[®]Plus Stent Graft and a Fenestrated Anaconda[™] Device

A RelayPlus stent graft was used to create a proximal landing zone for a Fenestrated Anaconda device in a patient with a juxtarenal AAA, penetrating aortic ulcer, and dilatation of the descending thoracic aorta.

**BY PROF. JÜRGEN FALKENSAMMER, MD, FEBVS; MARKUS PLIMON, MD;
AND AFSHIN ASSADIAN, MD**

In some cases of juxtarenal abdominal aortic aneurysm (AAA), the paravisceral segment is not suitable for a branched endograft due to space restrictions. The creation of a proximal landing zone using a thoracic tube graft in combination with a Fenestrated Anaconda device (Terumo Aortic) implanted distally may represent a feasible treatment option. This article describes a patient with a juxtarenal AAA with a narrow visceral aortic segment but no adequate landing zone for a fenestrated endograft proximal to the celiac artery.

DIAGNOSTIC EVALUATION

A 72-year-old man presented with an asymptomatic, progressive juxtarenal AAA (maximum diameter, 82 mm), a penetrating aortic ulcer at the level of the superior mesenteric artery (SMA), and a dilatation of the descending thoracic aorta (maximum diameter, 29 mm) (Figure 1). Because of a thrombus at the level of the celiac artery, the anatomy did not allow for anchoring of a Fenestrated Anaconda device at or immediately above the visceral level. The minimum diameter of the visceral segment at the level of the SMA was 23 mm and was deemed inappropriate for construction of a branched device.

TREATMENT APPROACH

The decision was made to implant a custom-made RelayPlus device (Terumo Aortic) in the distal descending aorta that was 65 mm in length and tapered from 34 to 24 mm (Figure 2A). This was to serve as a proximal landing zone for a Fenestrated Anaconda device (Figure 2B). The operation was performed under general anesthesia after insertion of a spinal catheter to monitor fluid pressure during surgery. Surgical access was gained via an oblique mini-incision in the right groin and percutaneous puncture of the left common iliac artery. The thoracic graft was delivered via the right groin and released immediately proximal to the celiac artery in a 90° left



Figure 1. Preoperative CTA showed a juxtarenal AAA (maximum diameter, 82 mm), a penetrating aortic ulcer at the level of the SMA, and dilatation of the descending thoracic aorta (maximum diameter, 29 mm). Due to aortic wall thrombus, the supraceliac segment of the aorta was not an adequate landing zone.

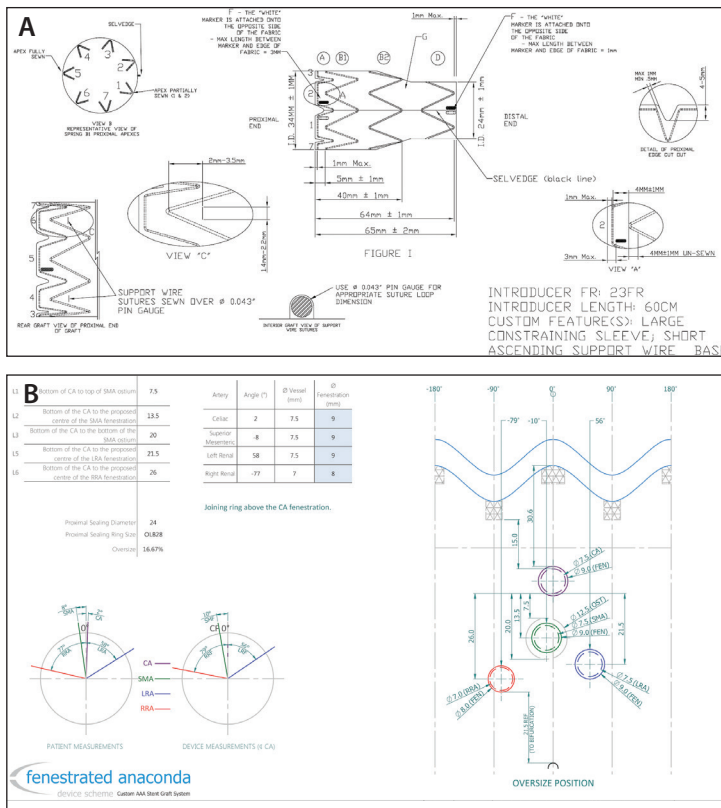


Figure 2. A custom-made RelayPlus device, tapering from 34 to 24 mm at a length of 65 mm (A) served as a proximal landing zone for a bifurcated Anaconda device with four fenestrations (B).

anterior oblique (LAO) position of the C-arm after angiographic identification of the vessel and insertion of a catheter to mark the position (Figure 3A). Then, the Fenestrated Anaconda device was inserted. After correcting for parallax of the distal end of the thoracic endograft, the renal arteries were identified by angiography in a 2° LAO position (Figure 3B) and the fenestrated device was released (Figure 3C). Sequential cannulation of the target vessels was performed using a steerable sheath (TourGuide, Medtronic), and a connection was achieved using covered peripheral balloon-expandable stent grafts (Advanta V12, Getinge). Connecting stents were oversized by 0.5 to 1.0 mm (7%–14%) compared to the target vessels and flared with 20-mm percutaneous transluminal angioplasty (PTA) balloons oversized 3 to 4 mm compared to the fenestration (25%–33%; Powerflex Pro, Cordis, a Cardinal Health company). After connecting the iliac limbs, PTA of the iliac axis was performed using 12-mm PTA balloons in a kissing balloon fashion. Completion angiography showed good perfusion of the target vessels with no sign of a type I or type III endoleak. This was confirmed by CTA on postoperative day 7 (Figure 4). The patient was discharged on day 10, and follow-up CTA 3 months after surgery demonstrated a good surgical result with no endoleaks and no graft migration.

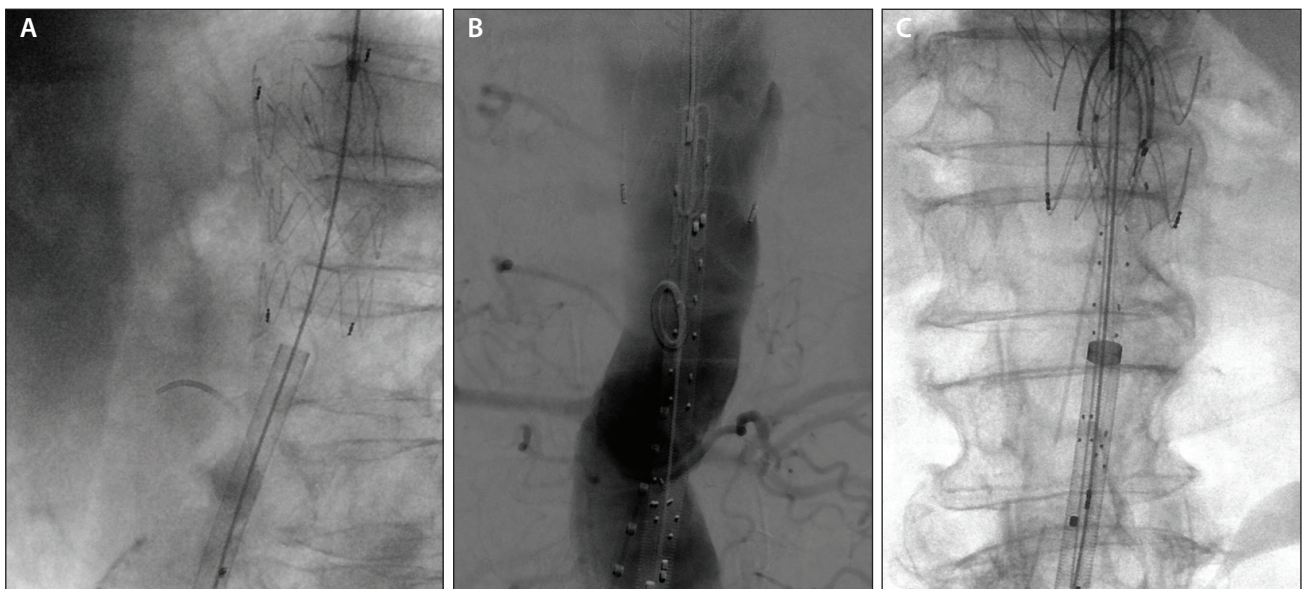


Figure 3. The position of the celiac trunk was marked with an angiographic catheter (A) and the thoracic tube graft was delivered at the cranial rim of the vessel ostium. After correcting the parallax of the distal end of the thoracic endograft, the renal arteries were identified by angiography in a 2° LAO position (B) and the fenestrated device was released (C).



Figure 4. CTA performed on day 10 after surgery confirmed complete exclusion of the aneurysm and unimpaired flow to the target vessels.

DISCUSSION

Recent developments and improvements of endovascular techniques have made endovascular aneurysm repair the most common treatment option for AAAs.^{1,2} Clinical results after complex endovascular procedures, such as branched and fenestrated endovascular repair, have been encouraging.³ As a result, custom-made devices have become widely popular over the last decade.⁴⁻⁷

However, anatomic restrictions apply, even for custom-made devices. Some juxtarenal AAAs lack a landing zone proximal to the celiac trunk, making isolated treatment with a Fenestrated Anaconda graft unfeasible. For many of these cases, the use of a branched graft may not be indicated due to a narrow paravisceral segment. The creation of a proximal landing zone using a RelayPlus stent graft with a Fenestrated Anaconda device implanted distally to provide an adequate paravisceral landing zone while preserving blood flow to the visceral and renal arteries can be considered as a treatment option in some of these anatomic situations. ■

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The Relevance of Abdominal Aortic Aneurysm Sac Shrinkage After Endovascular Repair

Clinical implications of AAA sac shrinkage, evaluation of sac shrinkage by device, and preliminary single-center results evaluating sac reduction after EVAR with the TREO® Stent Graft System.

BY VINCENT RIAMBAU, MD, PhD; CARLA BLANCO, MD; AND EFREM GÓMEZ JABALERA, MD

Aneurysmal sac shrinkage may not be the objective of endovascular aneurysm repair (EVAR), but it does indicate successful exclusion of the aneurysm from arterial pressure. It has been shown to be a predictor of low risk of EVAR failure during the first 5 postoperative years and has been proposed as a surrogate marker for clinical success.¹⁻⁴ However, evidence for sac shrinkage as a predictor of long-term survival is of variable quality because it is a continuous variable that has been dichotomized and assessed in various ways in the literature, which makes comparison difficult.

Because variations in size occur in three dimensions (spatial variability), both sac volume and diameter are relevant parameters for defining changes in aneurysm size. Relatively small diameter shifts of 1 to 2 mm, which may otherwise be difficult to accurately measure with conventional imaging techniques, may be correlated with a significant change in aneurysm volume.^{5,6}

It has been recently suggested that lesions display maximum growth away from maximum diameter and that a more accurate method of assessing abdominal aortic aneurysm (AAA) growth needs to be established in clinical practice that takes into account local surface growth.⁶ However, typically, only sac maximum diameter is used. Society for Vascular Surgery (SVS) EVAR reporting standards note that the intra- and interobserver variability of diameter measurements range between 2 mm and 5 mm or 5% and 15%; thus, a diameter change ≥ 5 mm is considered significant. A variable that complicates the analysis of AAA sac shrinkage is at what time point regression occurs, specifically if we are interested in analyzing what stent graft characteristics might contribute to it.

CLINICAL IMPLICATIONS OF ANEURYSMAL SAC SHRINKAGE

Significant sac shrinkage has been defined by some groups as a minimum 75% reduction between the baseline and any postoperative CT scans, with a reported 98.9% positive predictive value of significant sac shrinkage for treatment success.⁷ However, this was at the expense of a low negative predictive value (34%); that is, 66% of patients who did not experience significant sac shrinkage still experienced treatment success. Sac regression $> 75\%$ was also associated with significantly lower rates of endoleak and reintervention and absence of late aneurysm rupture.

In contrast, other authors have defined major aneurysmal shrinkage as a reduction in aneurysmal sac diameter ≥ 10 mm compared with preoperative measurements and showed significantly reduced rates of secondary procedures and AAA rupture.⁸ However, even after a significant diameter reduction, the development of late type I endoleaks did occur and resulted in rapid AAA growth with the risk of rupture.

Following SVS guidelines, recent data from the Vascular Study Group of New England registry involving 1,802 EVARs showed that sac shrinkage predicted a decrease in late mortality (hazard ratio [HR], 0.6; 95% confidence interval, 0.5–0.8; $P < .001$) and that the 5-year survival rate was markedly lower among patients with sac expansion (68% vs 83%). The investigators concluded that the simultaneous observation of risk-adjusted lower survival in patients with sac expansion and higher survival associated with sac shrinkage suggests that sac behavior is likely a surrogate for aneurysm-related mortality.⁷

More evidence is available from 14,817 EVAR patients enrolled in the Vascular Quality Initiative. After 1-year follow-up, 40% of AAA sacs regressed, 35% remained

stable, and 25% expanded. Sac stability and expansion were associated with higher long-term mortality compared with patients with sac shrinkage, suggesting that failure of the AAA sac regression after EVAR is associated with higher long-term mortality.⁹

IS SAC REDUCTION A DEVICE-RELATED PHENOMENON?

Previous results from the RATIONALE registry following 202 patients treated with Treovance® (the previous configuration of the TREO Stent Graft System [Terumo Aortic]) showed that mean (standard deviation) absolute change of aneurysm size was $-6.8 (\pm 8.4)$ mm and mean relative change was -11.2% . Absolute and relative reductions in aneurysm size were statistically significant ($P < .0001$); 106 (54.1%) had at least 5-mm reduction and 191 (97.4%) patients had decreased or stable aneurysm sac size at last follow-up.¹⁰ Aneurysm expansion-free survival was 97.4% at 1 year. Five (2.6%) patients had an increase ≥ 5 mm.

In the Eurostar registry, 10% of patients had sac enlargement,^{11,12} whereas 4.2% of patients had sac enlargement in the Zenith p-Branch pivotal study ($n = 739$) (Cook Medical).¹³ The 1-year results of the ENGAGE registry ($n = 500$) evaluating the Endurant AAA stent graft system (Medtronic) showed aneurysm size increased by ≥ 5 mm in 2.8% of cases, was stable in 55.9% of cases, and decreased by ≥ 5 mm in 41.3% of cases.¹⁴ In the 1-year results evaluating the Ovation abdominal stent graft system (Endologix) ($n = 161$), there was a 0.6% AAA enlargement rate, but baseline aneurysm diameter was $54 (\pm 9)$ mm (vs $58.6 [\pm 10.8]$ mm in the RATIONALE study) and only 32% had a decrease in aneurysm diameter (vs 54.1% in the RATIONALE study, 41.3% in the ENGAGE registry, 36% in the GREAT study).¹⁴⁻¹⁶ Finally, in a small series of 22 patients treated with Treovance, there was no AAA sac increase during follow-up and mean sac diameter regression of $-8.3 (\pm 6.4)$ mm.¹⁷

With this in mind, aneurysms can continue to change after 1 year. A recent Canadian single-center, retrospective cohort study analyzing 1,060 EVAR patients between 1999 and 2015 found that most sac regression occurred within a 2-year period. Other predictors were identified, including age < 75 years (HR, 1.4), female sex (HR, 1.4), and aneurysm diameter > 70 mm (HR, 1.6), with statistically significant device-specific variability even in the absence of endoleak (HR for Zenith, 2.0; HR for Endurant, 1.7).⁴ Furthermore, although sac shrinkage may plateau 2 years after EVAR at around 60%, shrinkage in the mid to longer terms has been noted.¹⁸ Five-year outcomes from the ENGAGE registry reported 61.4% long-term sac regression with Endurant, and a single Finnish center reported 16-year follow-up with 61% regression (mean decrease, 18 mm [range, 5–41 mm]) with the Zenith device.^{19,20}

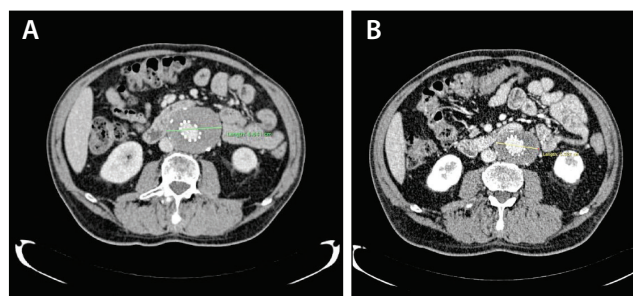


Figure 1. Baseline CT scan (A) and first-year follow-up (B) after performing a standard EVAR with the TREO device in a patient with AAA. Baseline CT scan was performed at 1 month after the intervention, showing an aneurysm sac transverse diameter of 6.64 cm. At 1-year follow-up, the CT scan showed a clear reduction of the aneurysm sac transverse diameter of 1.12 cm.

SAC REDUCTION EXPERIENCE WITH TREO

We are currently analyzing data on sac shrinkage from patients at our center and can share some preliminary results. In a retrospective analysis of a prospectively maintained database, we identified 37 patients treated with the TREO device between May 2014 and February 2019 (until July 2018 for the analyzed subgroup); six patients were excluded (three concomitant chimney procedures, one fenestrated device, and two patients without imaging follow-up), leaving 31 patients followed for analysis. Mean maximum AAA diameter at baseline was 58.1 mm.

At this preliminary stage, data are available for 26 patients with 1-year follow-up (mean, 356 days post-EVAR) and 18 patients with 2-year follow-up (mean, 795 days post-EVAR). Mean sac diameter at 1 year was 52.4 mm (a rate reduction of 0.49 mm per month) and at 2 years was 48.2 mm (a rate reduction of 0.41 mm per month). Figures 1 and 2 show illustrative cases from this series.

According to our findings, these sac shrinkage rates are similar to those reported by a single United States center comparing six patients treated with TREO and 16 patients treated with other devices: the $0.484 (\pm 0.107)$ mm per month shrinkage rate for TREO was significantly greater than in the non-TREO group ($0.018 (\pm 0.112)$; $P = .033$).²¹

There are a number of hypotheses to explain the sac shrinkage rates reported with TREO. In the first instance, the device is available in three main body lengths (80, 100, and 120 mm), and by occupying more of the aneurysm sac, it may favor remodeling. The combination of both suprarenal and infrarenal fixation proximally (proper sealing avoids the need for EndoAnchors [Medtronic]) and the lock stents, which attach the legs to the main body (the rounded barbs prevent migration and are dulled for compatibility with balloons), result in low endoleak rates. Low porosity of the graft material has also been reported in bench testing.

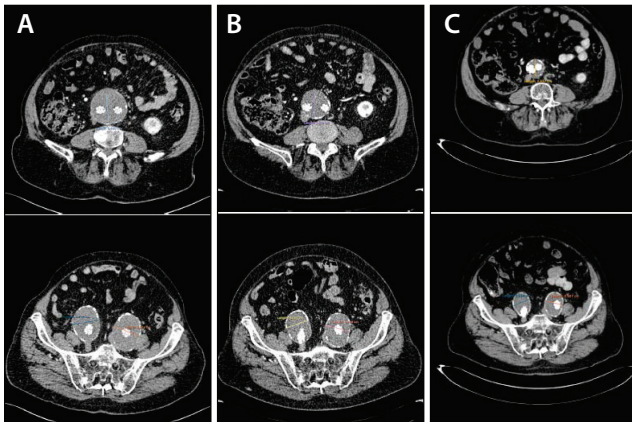


Figure 2. The second case treated with a TREO device showed a 6.66-cm aneurysm sac transverse diameter and 4.82-cm and 5.02-cm right and left common iliac transverse diameter, respectively, in the baseline CT scan (A). At the 1-year follow-up, the CT scan revealed sac shrinkage with a reduction of the aneurysm sac transverse diameter of 1.4 cm, a diameter reduction on the right common iliac aneurysm of 0.52 cm, and aneurysm reduction of 0.54 cm on the left common iliac (B). Third-year follow-up CT scan revealed progressive shrinkage with a reduction of the aneurysm sac transverse diameter of 2.96 cm, a diameter reduction on the right common iliac aneurysm of 1.27 cm, and a left common iliac aneurysm reduction of 1.21 cm when compared with baseline CT scan (C).

Finally, it has been suggested that inflammatory responses may vary depending on endograft materials, thus affecting aortic wall activity and stiffness and subsequent sac regression.^{22,23}

Other advantages of the TREO device are a proximal clasp that does not snag on the bare stent when recapturing the tip, a leave-behind sheath that reduces access vessel trauma, and adjustable zones between main body and leg sizes that allow for in situ sizing during implantation.

CONCLUSION

- Sac shrinkage during follow-up indicates successful exclusion of AAA and has been shown to be a predictor of low risk of EVAR failure.
- Sac expansion is related to endoleaks, reinterventions, and higher mortality rates.
- Sac shrinkage over time is a primary indicator of success after EVAR.
- Device-specific factors contributing to sac shrinkage still need to be fully understood.

The TREO device has a high regression rate at 1-year follow-up and represents a new-generation device to improve our trust in EVAR. ■

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Disclosures: None.





Freedom to find your fit.

Every patient has a different story. Each aorta, a unique challenge. Terumo Aortic empowers your team to collaborate with patient-driven solutions based on your preferred approach. With your expertise and our comprehensive portfolio, we help you find the right fit for your patient – and their aorta.

