Total Endovascular Repair of the Aortic Arch

An overview of branched arch devices on the horizon.

BY STÉPHAN HAULON, MD, PhD; JONATHAN SOBOCINSKI, MD, PhD; RAFAELLE SPEAR, MD; JARIN KRATZBERG, PhD; BLAYNE ROEDER, PhD; RICHARD AZZAOUÏ, MD; AND BLANDINE MAUREL, MD, PhD

Complete replacement of the aortic arch remains one of the most complex operative procedures of the vascular system and one of the last major hurdles in providing patients with an endovascular treatment option for the entire aortic tree. Despite tremendous advances in surgical techniques over the last 5 decades and the introduction of hybrid techniques, the repair continues to be plagued with significant morbidity and mortality rates in high-risk patients. This article discusses current challenges with open and endovascular repair of the arch, presents an endovascular device to treat the entire arch, and discusses its early clinical results.

OPEN REPAIR

Open surgery remains the gold standard in aortic arch repair for aneurysms or dissections. Although open surgery was first attempted over 6 decades ago, it was not until the introduction of cardiopulmonary bypass and hypothermic circulatory arrest in the 1960s and 1970s that successful aortic arch repair could be performed with lower morbidity and mortality rates. The major benefit from these procedures was increased neurological protection while operating in a relatively blood-free environment. Improved surgical techniques continued to be introduced throughout the late 20th century, including alternative cannulation techniques (femoral, direct ascending, axillary), cerebral perfusion methods (antegrade and retrograde), and improved surgical techniques for addressing anastomosis sites. Despite these improvements, open surgery continues to be associated with high rates of mortality (5%–20%) and neurological impairment (5%–18%). Other significant complications are not infrequent after open aortic arch repair, including renal impairment and cannulation-site injuries leading to secondary intervention. Due to these factors, alternative approaches to arch repair continue to be explored.

ENDOVASCULAR STRATEGIES

Although open repair remains the gold standard of care for patients with limited comorbidities, alternative procedures are showing promise in treating the aortic arch with similar morbidity and mortality compared to surgical repair, despite addressing a more complex patient population. Beginning in the early 1990s, several endovascular repair strategies have emerged in the treatment of aortic arch disease, including hybrid aortic repair, chimney graft techniques, and custom stent graft designs. Endovascular repair strategies offer advantages over open repair, as they are minimally invasive and do not require hypothermic circulatory arrest or rerouting of aortic blood flow. Several of these techniques have proven technically successful with promising early and midterm results, whereas others have been associated with long-term durability concerns. Each of these techniques is discussed further in the sections that follow.

Hybrid Arch Repair

Hybrid arch repair combines open and endovascular procedures to successfully treat aortic arch disease. This procedure requires an open sternotomy for debranching the supra-aortic trunks on the ascending aorta before stent grafting. The procedure has proven beneficial for patients with expansive aortic disease affecting both the aortic arch and descending thoracic aorta. The aim of the hybrid procedure is to simplify what would be a multistage open repair to a single open repair for debranching the supra-aortic trunks, followed by an endovascular procedure to repair the diseased arch and descending thoracic aorta. Single, double, or total great vessel transposition is performed, followed by thoracic endovascular aortic repair (TEVAR).

With the introduction of hybrid arch repair, mortality rates have at worst remained stable (6%–10%), despite treating a patient population with added comorbidities. As with any new surgical procedure, hybrid arch repair has introduced new complications postoperatively. Of note are those complications associated with traditional TEVAR
Chimney Repair

As endovascular technology has evolved, new approaches to the repair of the aortic arch have emerged. One of these techniques is the parallel graft or chimney graft technique. Standard branched or fenestrated endovascular grafts are designed such that the blood is directed through the main body of the aortic stent graft and then through the branched or connection stents. With the chimney graft technique, multiple stent grafts are deployed within the same seal site, such that the chimney graft(s) is sandwiched between the aortic wall and the main body stent graft. Thus, blood is simultaneously directed through the main body stent graft and the chimney graft to achieve both aortic and branch vessel perfusion.

The chimney graft technique was developed for patients presenting with emergent aortic complications, as it offers physicians an off-the-shelf treatment option. Essentially, a combination of thoracic endografts and any covered (or uncovered) peripheral vascular stent that is commercially available can be used in the procedure. However, several device- and procedure-related complications are inherent to the chimney repair approach, including endoleak, migration, device kink, and difficulty in performing secondary interventions. Type I endoleak rates for chimney repair range from 15% to 40% peripheratively and have been reported as high as 23% during early and midterm follow-up.

Additionally, the rate of chimney graft occlusion has been reported as high as 11%, and stroke rates remain significant at perioperative and short-term follow-up. Also, deformation applied by the chimney graft on the main body thoracic graft will affect its ability to conform to the aortic wall and resist migration, further adding to the likelihood of a compromised seal in the long run. Finally, long-term durability of the chimney technique remains a major concern. Each of the components utilized in a chimney repair is used outside of its intended indication, and long-term durability under such use has not been proven by the device manufacturers. With this in mind, we advocate that the chimney approach should be reserved as a bailout option for those patients with symptomatic or ruptured aneurysms.

Custom-Made Scalloped, Fenestrated, and Branched Grafts

Other endovascular approaches for treating aortic arch disease include options of custom-made scalloped or fenestrated grafts and branched grafts. However, most of these devices have limited use and lack large cohort studies with long-term follow-up, and early data suggest that these procedures are technically challenging and should be performed only at institutes of excellence.

In a custom stent graft with fenestrations and scallops, the use of a scallop at the proximal end of the stent graft allows for a single branch vessel (eg, left subclavian artery [LSA] or left common carotid artery [LCCA]) to be perfused while extending the seal more proximally. This is an option, for example, when descending thoracic aortic disease extends to the level of the LSA. Technical success with scalloped devices has been shown in small series, however, to date, large cohort studies demonstrating these successes are nonexistent.

Several concerns, including type I endoleaks, remain with this approach, as a large portion of the scalloped proximal sealing stent is uncovered. Also, the procedure is technically demanding, as precise deployment is required to ensure that the scallop does not cover the intended branch vessel. The technical challenges further escalate when fenestrations are included in combination with a scallop and alignment of multiple target vessels is required. Nonetheless, designs that incorporate multiple fenestrations or a combination of fenestrations and scallops have been used for arch treatment. These devices are custom made to fit each individual patient. Diligent planning and procedural execution is required, as minor offsets of the fenestrations can lead to perfusion concerns to the branch vessel. Additionally, because these devices are delivered through a femoral approach and require long delivery systems, the ability to precisely maneuver the device is limited, thus further complicating fenestration alignment.

Inoue et al reported the first use of a branched endovascular device for treatment of arch aneurysms in 1999. From 1995 to 2002, 48 total patients were treated with this design; however, only 13 patients were treated with a double- or triple-branched device. Technical feasibility of the procedure was demonstrated; however, the procedure-related mortality was 23% (3/13) for patients treated with a multibranched device. Additionally, severe complications were reported for 17% of the patients, including stroke, dissection, and persistent endoleak. The major challenges with the Inoue graft are branches that protrude external to the aortic component, thus complicating cannulation of the target vessels and proper placement of covered stents in each of the branches.

Chuter and colleagues first reported use of a modular branched stent graft for arch repair in 2003. With this system, carotid-carotid and LCCA-LSA bypasses are performed first. Next, a branched endovascular graft is delivered via right common carotid access, with the proximal
portion of the graft landing in the ascending aorta; a long branch extending in the innominate artery (IA); and a short, large branch remaining open to the aortic arch. A secondary component is then delivered via femoral access, bridging the distal end of the large branch of the branched device to the descending thoracic aorta, thus completing the repair.

Although case studies have demonstrated technical success with this approach, several challenges persisted. First, the procedure is technically challenging, requiring both carotid and femoral access routes and extreme precision in placement of the proximal component. Second, this device is delivered through a very large delivery sheath (22–24 F) relative to the carotid artery, thus greatly reducing the number of patients who could receive the device. Additionally, the risk of significant morbidity and mortality is increased with the use of such a large delivery system through carotid access.

**CHALLENGES OF ENDOVASCULAR REPAIR OF THE AORTIC ARCH**

Although an endovascular approach to arch repair may ultimately offer the least perioperative morbidity, challenges remain in device design and implantation technique to achieve optimal long-term results. Specific concerns for endovascular repair include adequate seal, long-term device durability, device alignment, stroke, aortic valve issues, and mortality. The sections that follow address each of these concerns in more detail.

**Seal Zone**

Over the last decade, outcomes from endovascular aneurysm repair studies have repeatedly demonstrated that an adequate seal zone must be present in order to achieve long-term device success.\(^2\)\(^2\)\(^3\) In the arch, an adequate seal zone is composed of neck diameters consistent with healthy tissue (< 38 mm), minimal tapering, a length of > 25 mm that is free of excess calcification and thrombus, and aortic angulation < 60°. Reports on chimney grafts, where type I endoleak rates > 20% have been depicted, is an illustration of what can occur when the seal zone is compromised.\(^2\)\(^4\)\(^5\) Treating patients within these anatomical constraints greatly reduces the chances for type I endoleak and graft migration and increases the likelihood of long-term performance. In the case of aortic arch treatment, landing the device within a healthy seal zone is challenged by the relatively short ascending aorta. Due to the catastrophic consequences that can occur due to loss of device seal and/or device migration in the aortic arch, maximizing the length of seal beyond the standard 25 mm may be warranted to account for aortic growth, remodeling, and potential disease progression.

**Device Durability**

Long-term stent graft durability remains a major concern with endovascular procedures. Although many durability concerns for stent grafting have been addressed with commercial abdominal, thoracic, and fenestrated devices, treatment of the aortic arch presents a new set of physiologic loads that will further challenge device durability. Of specific concern is the high pulsatility of the aortic arch, subjecting the stents to more significant fatigue loading conditions. Pulsatility of the vessels in this region has been reported to be two to three times higher than the pulsatility seen in the descending thoracic and abdominal aorta. Additionally, branch vessel motion relative to the aorta due to cardiac pulsation and respiration will have to be quantified to address long-term durability. These motions could lead to device complications such as graft wear, stent fracture, and stent kink, all of which could be detrimental to device performance. To ensure long-term device durability, these new boundary conditions need to be established through high-resolution imaging and tested by device manufacturers in the nonclinical setting.

**Device Alignment**

The ability to accurately align and deploy an arch stent graft is essential. Implementing designs with self-aligning features of the branches or fenestrations to the branch vessels will minimize the need for excessive manipulation of the device in the aortic arch, thus reducing the risk of stroke due to emboli. Due to the length of the delivery systems used for transfemoral access, the ability to precisely control the device end of the delivery system is limited, further highlighting the need for auto-aligning features. Additionally, a controlled release of the stent graft from the delivery system is warranted, with minimal motion of the device occurring. Motion of the device during release can lead to catastrophic events, including coronary artery coverage and/or misalignment of the branches or fenestrations with the great vessels.

**Aortic Valve**

Due to the relative proximity of the aortic valve to the aortic arch and branch vessels, it is of utmost importance to design endovascular devices and delivery systems that will limit valve interaction and be atraumatic to the valve when interactions do occur. Although in current transcatheter aortic valve repair procedures, wire guides, catheters, and sheaths are routinely placed across the valve, these procedures have been associated with stroke and valve damage. Additionally, current endovascular aneurysm repair (EVAR) systems are large in diameter, and delivery system tips are relatively stiff, potentially increasing the risk of valve damage, especially in cases where the system must be left across the aortic valve for extended periods of time. Finally, these
procedures are modular and may require crossing the aortic valve multiple times in order to place each component, which will further expose the valve to potential injury. It will be essential to valve health that endovascular repair options limit valve involvement and encompass atraumatic materials such that minimal damage occurs.

Stroke
Stroke remains a major concern after endovascular repair of the thoracic aorta. Stroke rates of > 6% have been reported for endovascular repair of the descending thoracic aorta and > 10% in chimney cases. Major contributing factors to stroke during these procedures include emboli due to device, delivery system, and/or wire manipulation; air emboli released from the delivery system; and coverage of branched vessels. As previously mentioned, the ability to properly align the device with minimal manipulation and maintain device alignment during release from the delivery system will be essential in decreasing stroke risk. Additionally, special care must be taken to ensure that the systems are entirely void of air upon sheath withdrawal to avoid any potential air emboli. Finally, it should be noted that for years, intentional coverage of the left subclavian artery was common practice in many TEVAR procedures. However, recent data have shown that an increased risk of stroke has been seen in those patients. Thus, devices must address treatment options for all of the aortic branch vessels or require partial debranching in order to minimize stroke risk.

Mortality
Perioperative and 30-day device-related mortality have been reported at significant rates for current endovascular repairs of the aortic arch. Chimney repairs, hybrid repairs, and standard endovascular procedures have seen mortality rates of 6% to 23%, and this remains a major concern. It should be noted that the vast majority of these patients have severe comorbidities and would not have tolerated an open procedure. In order to minimize mortality, endovascular arch repair should be performed at centers of excellence, where high volumes of open and complex EVAR procedures are traditionally performed. Additionally, device designs need to minimize trauma to the patient during delivery and as a long-term implant. Finally, careful surgical planning and attention to anatomic and comorbid conditions should be considered in order to further reduce device- and procedure-related mortality.

**CURRENT APPROACH TO ENDOVASCULAR REPAIR OF THE AORTIC ARCH**

The arch branch graft (Cook Medical), a third-generation arch branched endovascular graft for the aortic arch, was designed to address the previously described challenges and was based on the experience gained from previous strategies in endovascular arch repair. The design and delivery of the graft have been previously described but will be summarized here. The graft is designed to seal in the ascending aorta (Figure 1), with either one or two sealing stents and active fixation with barbs on the most proximal seal stent. As such, a healthy nondilated segment of aorta is required proximal to the IA and distal to the sinotubular junction to achieve a durable seal. The graft includes two internal branches for connection to the IA and LCCA (or LSA in a few instances). The graft is designed to conform to the curvature of the arch to achieve proximal seal with minimal “bird-beaking” and without kinking in “gothic” arches. There are two distal seal stents, but often, a distal extension is required to fully exclude an extensive aneurysm. A modified Zenith iliac limb component (Cook Medical) is used to connect the most proximal branch to the IA. A commercially available covered stent is used to bridge the second branch to the LCCA.

Also described previously, device deployment will be described in brief here. Three access sites are required for deployment. The most commonly used are femoral (for main body graft), left axillary (for the LCCA covered bridging stent), and either a conduit or direct puncture of the right axillary or direct puncture of the right common carotid (for the bridging limb for the IA). A means to control cardiac output during device deployment must also be employed. Most commonly, rapid ventricular pacing is used. A catheter or sheath is used to mark the ostia of the IA and LCCA to help position the graft during deployment. Fusion imaging is also very beneficial (Figure 2).

From femoral access, a Glidewire (Terumo Interventional Systems) is placed across the aortic valve and then exchanged for a stiff wire with the tip of the wire curled in the left ventricle. The tip of the stiff wire must be visualized at every step of the procedure to ensure that ventricular damage does not occur. The delivery system for the arch branch graft is tracked into place by advancing the tip of the delivery system through the aortic valve into the LV. Markers on the branches are used to align the device with the origin of the IA and LCCA (Figure 2). The delivery system is designed to automatically align the branches’ rotational orientation, so only longitudinal positioning of the delivery system is required. Once the device is in position, rapid pacing is initiated, and the graft is deployed by
first retracting the sheath and then removing various ties that hold the graft to the delivery system and constrain its diameter.

Upon completion of the branch graft deployment, ventricular pacing is stopped. Immediately after, the nose cone of the delivery system and the stiff wire are retrieved and positioned at the distal end of the endograft. The branches are cannulated from above, and bridging components are placed. An illustrative follow-up CT scan is shown in Figure 3.

**CLINICAL EXPERIENCE**

Clinical experience with the arch branch graft has been through use as a custom-made device, through use under special access, or through physician-sponsored investigations. The first clinical use of the device was reported by Lioupis et al in 2012. This initial case series included six patients treated at three separate hospitals in Canada between October 2009 and May 2011. Although the procedures occurred in separate hospitals, all of the surgical teams were led by the senior author of the study (C.Z. Abraham, MD). In the short series, 11 of 12 branches (91.6%) were successfully cannulated and preserved. In one patient, the IA branch could not be catheterized due to a planning error, and the patient had a femoral-axillary bypass to restore flow to the right carotid and right vertebral arteries. Unfortunately, this patient developed a right-sided stroke. Other major complications noted in this series included a type I endoleak in one patient due to a large ascending aortic diameter (39 mm), which was successfully managed, and a right cerebellar infarct in another patient. Regardless of the complications noted in this series, this initial work demonstrated the technical feasibility of total endovascular arch repair with the arch branch graft.

A retrospective, multicenter analysis of the first 38 patients treated with the arch branch graft was recently published by Haulon et al. It is important to note that this case series is inclusive of the entire learning curve with this device. It included all six patients in the initial learning experience presented by Liopis et al, as previously discussed. All patients were nonsurgical candidates and had an American Society of Anesthesiologists score of 3 or 4 in 34 of 38 patients (89.5%). Technical success was achieved in 32 of 38 patients (84.2%). Technical failures included three deaths within 24 hours of the procedure, one proximal type I endoleak, one failure to cannulate the IA branch, and one conversion to a chimney technique. Five patients (13.2%) died within 30 days of the procedure, and there were six cerebrovascular complications noted in follow-up (four transient ischemic attacks, one stroke, and one subarachnoid hemorrhage). Although the difference was not statistically significant, mortality was 30% and 7.1% in the first 10 and last 28 patients treated, respectively.

When combined together, the risk of early mortality or neurologic complications was statistically higher in the first 10 patients ($P = .019$) and patients with ascending aortic diameters > 38 mm ($P = .026$). This initial study demonstrated that with proper operator training and careful patient selection, aortic arch repair could be extended to patients who are not candidates for open surgical repair. This initial experience also stresses the need for strict inclusion criteria for endovascular arch repair. Specific inclusion criteria, as described by Haulon et al, are shown in the Anatomic and Physiologic Criteria for Endovascular Arch Repair sidebar.

In the aforementioned series by Haulon et al, 12 of 38 patients had previous ascending aortic surgery. The first case completed on a patient with previous aortic surgery was presented by Spear et al. The previous aortic repair pro-

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Figure 2. The tip of the delivery system is advanced through the aortic valve into the left ventricle. The same image is shown with (A) or without (B) fusion imaging performed in a Discovery IGS730 hybrid room (HeartVision, GE Healthcare). The fusion mask is very helpful in positioning the device and aligning branches to the target vessels, as well as in visualizing the true (yellow) and false (green) lumen in this chronic dissection with a previous TEVAR. From left to right, the rapid pacing probe is positioned into the right ventricle through a right jugular vein puncture, and catheters positioned into the ascending aorta from the right common carotid and left axillary arteries (through an LSA-to-LCCA bypass) are observed. They are also helpful markers of the ostia of the target vessels.

Figure 3. Preoperative (A) and postoperative CT angiographic scan (B) in a patient treated with the arch branch device.
vides a stable landing zone for the endovascular graft. These patients are ideal candidates for an endovascular approach, as a redo aortic arch procedure can be high risk. The first case presented by Spear et al and the 10 patients treated by Haulon et al demonstrate the feasibility of endovascular repair in these patients. Open operation to repair the arch distal to an ascending aortic graft is associated with a 13.8% in-hospital mortality rate. Silva et al compared in-hospital mortality of redo ascending aorta procedures (12.1%) with in-hospital mortality of primary procedures (6%). Although rates were nearly twice as high in the redo group, the finding was not statistically significant (P = .18). The in-hospital mortality of these surgical patients compares well with the 30-day mortality in the initial experience with endovascular repair in nonsurgical candidates. In patients requiring reintervention after open surgical repair for type A dissection, the anatomy distal to ascending repair can be very complex.

The previously presented approach requires the delivery system dilator to be placed through the aortic valve and in the left ventricle for a few moments during deployment of the endovascular graft. This precludes treatment of patients with a mechanical aortic valve, as there is a risk of damaging the aortic valve prosthesis. One patient in the series presented by Spear et al had a prosthetic aortic valve, which was managed by sewing a conduit on the ascending graft and placing the tip of the delivery system of the endograft in this conduit. Unfortunately, the endograft was implanted distal to the intended position, resulting in technical failure of the procedure, as two chimney grafts were required to maintain flow to the supra-aortic vessels.

Recent modifications to the delivery technique described in Spear et al allow treatment of patients with a previous aortic valve repair. In its current form, this system allows deployment of the proximal end of the aortic endograft to within approximately 30 mm of the aortic valve (15 mm of the coronary ostia). In short, deployment is accomplished by first placing a 100-cm-long sheath that is large enough to accommodate the arch branch graft and tracking it over a Lunderquist wire (Cook Medical) into the ascending aorta. The sheath allows tracking of the system with a very short dilator tip. Subsequent retraction of the delivery sheath and complete deployment of the arch branch graft is unchanged from the earlier description.

**DISCUSSION**

**Up to the Challenge**

Although still in its infancy, early results demonstrate the technical feasibility of complete arch repair via endovascular means. The arch branch graft has been selectively used at centers of high excellence since 2011. Despite a steep initial learning curve, 30-day mortality rates for the endovascular group were similar to the traditional open repair despite taking on a significantly more morbid patient population.

The device has potential to be used off the shelf, with two configurations treating the vast majority of patients. The design builds on the Zenith platform, which has a significant clinical history, and uses materials with proven performance history. Additionally, the arch branch graft offers a delivery system that allows for precise placement of the stent graft, an essential characteristic of devices intended for branch treatment. Finally, self-aligning features have been implemented in the delivery system design, such that minimal manipulation of the system is required once in the arch to achieve branch alignment. This feature is extremely important, as increased manipulation in the arch will inevitably be associated with increased stroke rates.

Type I endoleak issues have been addressed by using stents providing adequate seal forces while also harmonizing the graft and delivery system to optimize the conformance of the proximal end of the graft with the aortic wall. When
treatment within the device limits established by Haulon et al, the arch branch device has been associated with zero type I endoleaks through 12-month follow-up.

Device migration issues have also been addressed through the use of active fixation on the proximal stent seal of the graft. Unlike TEVAR or EVAR treatment, in which clinically significant migration is defined as movement ≥ 10 mm, even minor motion of an arch device can be catastrophic to the patient, as branch perfusion could be compromised. The arch branch graft uses fixation means similar to those of other Zenith devices, which have historically been associated with extremely low rates of migration. To date, the clinical evidence demonstrates similar migration resistance of the arch branch design.

Remaining Challenges

Early results demonstrate that repair should be limited to patients with ascending aortic diameters ≤ 38 mm. What should be done with patients with an ascending aortic diameter > 38 mm? The largest proximal graft diameter used in the series presented was 46 mm. Should a graft be designed and manufactured to treat larger-diameter ascending aortas? Although a proximal seal could most certainly be initially obtained, the long-term durability of the proximal seal in such a large-caliber aorta is unknown. The current data show that sealing in ascending aortas ≤ 38 mm is free from type I endoleak through 12-month mean follow-up.28 However, because the ascending aorta is the last location to seal proximally, and many of the patients presenting with arch disease show an ascending aorta > 38 mm, a treatment option must be explored to address this. Landing in an aorta > 38 mm in these patients will likely be associated with increased complications, as vessels of this size are typically indicative of disease.

Despite significant efforts to minimize the profile of the device by using low-profile graft fabric and stents, the sheath size for a 46-mm graft is 24 F (inner diameter), with the remainder of sizes utilizing a 22-F system. These larger-profile systems have typically been associated with increased access site complications due to an increase in the need for vascular cutdowns and conduits.

Finally, a bridging stent design must be revisited in order to ensure long-term durability. A custom-designed bridging stent has been developed for the IA, utilizing spiral leg technology. To date, the clinical outcomes have been promising with this design. However, specific designs for the remaining arch vessels are warranted to optimize durability and ensure that long-term vessel perfusion is achieved.

Stéphan Haulon, MD, PhD, is with the Aortic Centre, Hôpital Cardiologique-CHRU Lille in Lille, France. He has disclosed that he is a consultant to Cook Medical and GE Healthcare. Dr.

Haulon may be reached at stephan.haulon@chru-lille.fr.

Jonathan Sobocinski, MD, PhD, is with the Aortic Centre, Hôpital Cardiologique-CHRU Lille in Lille, France. He has stated that he has no financial interests related to this article.

Rafaelle Spear, MD, is with the Aortic Centre, Hôpital Cardiologique-CHRU Lille in Lille, France. She has stated that she has no financial interests related to this article.

Jarin Krazetberg, PhD, is a research engineer with Cook Medical in Bloomington, Indiana.

Blayne Roeder, PhD, is Director of Product Development, Aortic Intervention at Cook Medical in Bloomington, Indiana. Richard Azzouz, MD, is with the Aortic Centre, Hôpital Cardiologique-CHRU Lille in Lille, France. He has stated that he has no financial interests related to this article.

Blandine Maurel, MD, PhD, is with the Aortic Centre, Hôpital Cardiologique-CHRU Lille in Lille, France. She has stated that she has no financial interests related to this article.