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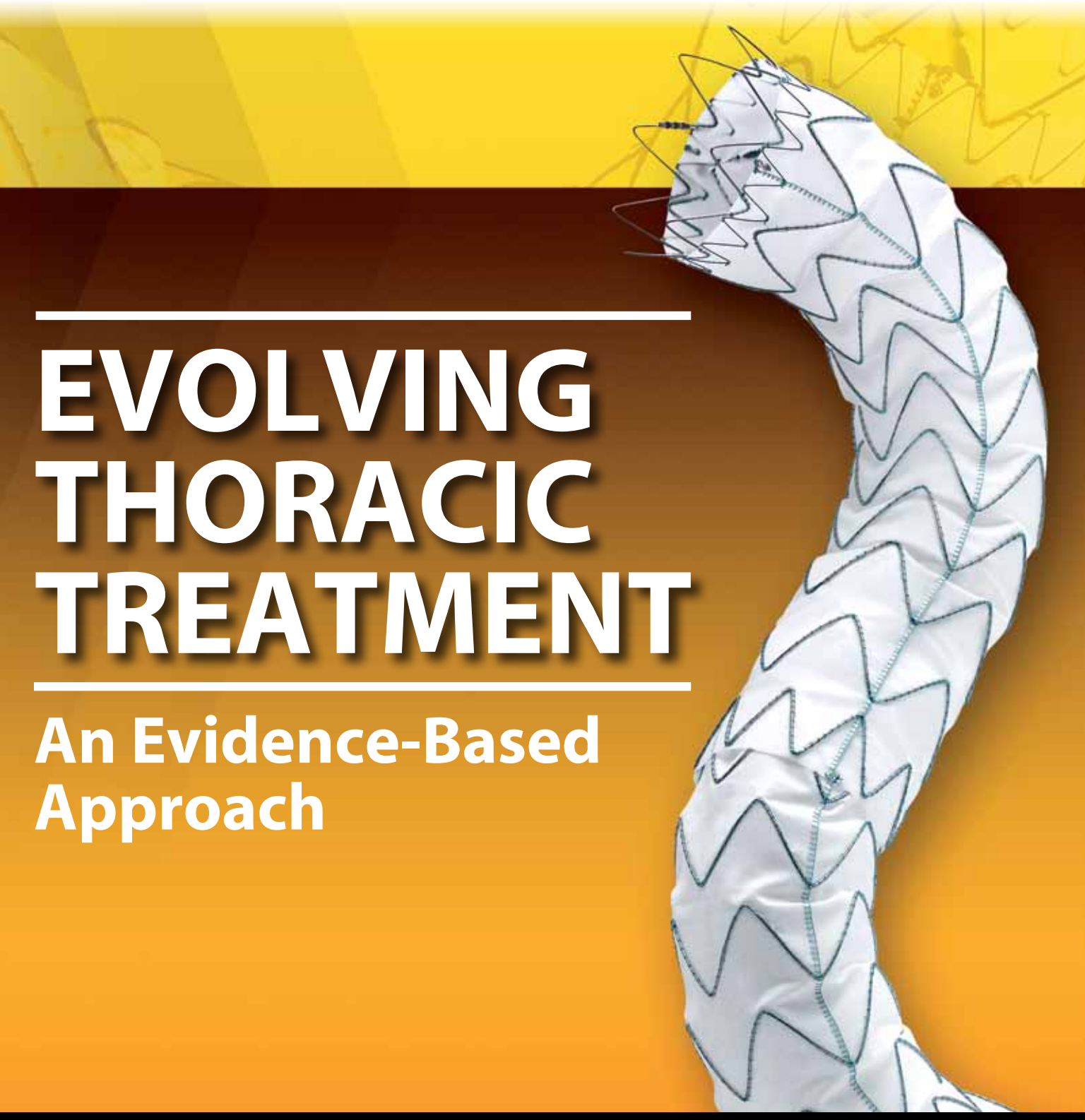

# EVOLVING THORACIC TREATMENT

## An Evidence-Based Approach

# Contents


Medtronic

# Innovation Spotlight: Expanding Indications to Treat More Thoracic Patients

How a branch graft for the left subclavian artery may extend the benefits of endovascular repair.

**BY FRANK R. ARKO, III, MD**

The Valiant® thoracic stent graft (Medtronic, Inc., Minneapolis, MN) (Figure 1) is a monofilament polyester fabric graft with nitinol springs that is indicated for the endovascular repair of isolated lesions (excluding dissections) of the descending thoracic aorta. The design consists of an eight-peak proximal self-expanding FreeFlo stent design that distributes radial force evenly across the aortic wall. There is no connecting bar between stents, which makes the graft highly conformable. Advantages of the delivery system include its tip capture for enhanced control and simplified operation with back-end design changes for tip-capture release and a hydrophilic coating to allow for improved delivery through difficult access vessels.

Multiple publications have addressed the use of the Valiant® stent graft in the treatment of thoracic aortic pathology, including the TRAVIATA registry, the VIRTUE registry, the Valiant® Captivia® registry, and the pivotal results of the VALOR II trial.[1-4] The VALOR II trial reported the 30-day and 12-month results of the Valiant® stent graft in patients with thoracic aortic aneurysms. This was a prospective nonrandomized pivotal trial at 24 sites in the United States. A total of 160 patients were enrolled in this trial. Technical success was achieved in 96.3% of patients being treated. Perioperative mortality was 3.1%, with a 0.6% paraplegia, 1.9% paraparesis, and 2.5% stroke rate. Aneurysm-related mortality at 1 year was 4%, with no ruptures or conversions to open surgery. These results demonstrate that the Valiant® stent graft is safe and effective in the treatment of descending thoracic aortic aneurysms.[4] This information corresponds to the currently approved version of the Valiant® thoracic stent graft; however, the following discussion pertains to a device that is currently under development and is unavailable globally.

Left subclavian artery (LSA) coverage during thoracic endovascular aortic repair (TEVAR) is often necessary due to anatomic factors and is performed in up to 40% of procedures.[5] Controversy still exists as to the appropriate management of the LSA when it requires coverage. Society for Vascular Surgery practice guidelines recommend that in patients who need elective TEVAR in which proximal seal necessitates coverage of the LSA, preoperative revascularization should be performed. Furthermore, in selected patients who have anatomy that compromises perfusion to critical organs, routine preoperative LSA revascularization is strongly recommended. However, in patients who need urgent TEVAR where LSA coverage is necessary, revascularization should be individualized and addressed expectantly.[6]

**Figure 1. The Valiant® Captivia® device.**

Data to date are inconclusive as to the appropriate management of the LSA during TEVAR. There is literature that suggests that LSA coverage is associated with an increased risk of arm ischemia, vertebrobasilar ischemia, and possibly spinal cord ischemia and anterior circulation stroke, and that left subclavian revascularization should be performed before coverage based on two different meta-analyses.[7,8] Single-center data have found that the use of selective revascularization is safe and does not appear to increase the risk of neurologic events;[9,10]

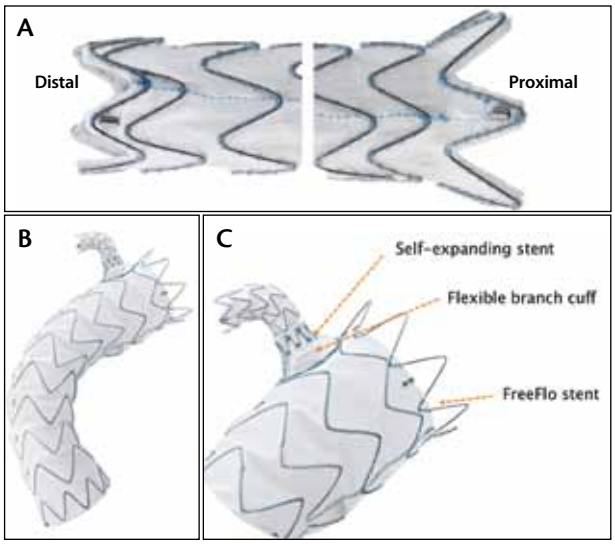


**Figure 2. The Valiant® Mona LSA thoracic branch stent graft is currently under development and is unavailable globally. The LSA branch stent graft (A). Main and branch stent graft system (B). Detail of the main stent graft and the cuff component (C).**

the data also suggest that LSA revascularization will clearly benefit some patients in the management of thoracic aortic disease that requires endovascular stent grafts. Clearly, if a procedure were simple, safe, and effective, and it avoided the need for surgical bypass for LSA revascularization, most physicians would utilize it.

## THE MONA LSA THORACIC BRANCH STENT GRAFT

The Valiant® Mona LSA thoracic branch stent graft currently in development is based on a modified Valiant® thoracic stent graft (Medtronic, Inc.) with a single-branch stent graft designed to perfuse the LSA. It is intended to be an "off-the-shelf" device. It is not yet available anywhere in the world. It will utilize the same stent graft platform as Valiant®, which has proven clinical performance since its first commercial introduction in 2005. The main body of the graft has the same eight-peak self-expanding FreeFlo proximal design as the Valiant® thoracic stent graft. The first two proximal covered stents have been modified to include space to accommodate a flexible cuff, which serves as a conduit between the main stent graft and the LSA branch stent graft. The cuff is radiopaque to aid visualization while positioning at the LSA. It also acts as a guide to ensure adequate overlap of the LSA branch stent graft with the cuff. There is a self-expanding stent at the top of the cuff to ensure fixation and seal of the LSA branch stent graft and the cuff (Figure 2).

The main stent graft delivery system is also modified from the current Captivia® delivery system. It has a dual-wire lumen with the main wire supporting the main stent graft and a second wire for LSA access. It maintains the tip capture feature of Valiant® Captivia® for controlled and accurate deployment (Figure 3). The second lumen is cannulated with a hydrophilic wire. The proximal nosecone has been modified to accommodate passage of two wires.

The left subclavian branch stent graft is composed of a nitinol stent and a polyester graft material with a proximal flare to provide a seal between components. The branch stent graft will come in a range of sizes specifically designed to treat the LSA. It is delivered from a femoral approach through a hydrophilic delivery system.

## STENT GRAFT DEPLOYMENT AND DELIVERY

A 5-F sheath is inserted for access, and a pigtail catheter is placed in the contralateral groin. Placement of a stiff wire up over the arch through the ipsilateral femoral artery will be required. After the main delivery system is flushed, a hydrophilic wire is sent up the second lumen to the end of the sheath. Once left brachial access is achieved, a 7-F sheath is placed, and utilizing standard catheter techniques, a large snare is placed just within the aortic arch from the left subclavian orifice. The main stent graft is then advanced over the stiff wire to a location just proximal from the left subclavian orifice. Care is taken to keep the orientation of the cuff toward the greater curvature.

The second wire is then advanced out of its lumen and is snared through the brachial access. Aortography is performed to allow for adjustment and alignment of the cuff with the orifice of the LSA.

The main stent graft is then slowly deployed to the level of the left carotid artery and the cuff engages in the orifice of the LSA. The main stent graft is then deployed with subsequent release of the tip-capture mechanism. The delivery system is resheathed after recapture of the tip and then removed. The proximal stent graft is then

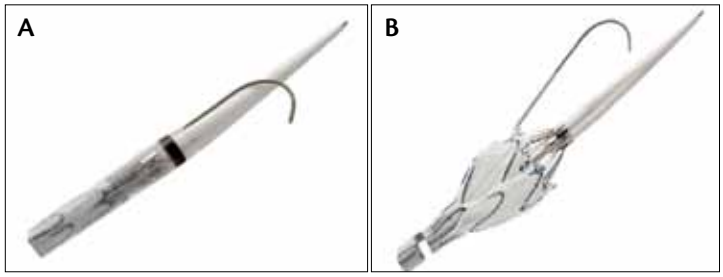


**Figure 3. The second lumen allows for rapid cannulation of the LSA. The wire can be advanced easily through this inner lumen in both constrained (A) and semiconstrained (B) form.**

modeled with a Reliant® balloon (Medtronic, Inc.). The LSA branch stent graft is advanced over the second wire and deployed with the proximal portion inside of the branch cuff. Standard percutaneous transluminal angioplasty is performed between the components, and completion aortography is used to assess the patency of the arch vessels and the left subclavian branch graft. Assessment for endoleaks is also performed at this time.

## DISCUSSION

Conventional repair of aortic arch pathology is associated with significant mortality and stroke rates of 6% to 20% and 2% to 18%, respectively.[11,12] Aneurysms involving the aortic arch have been treated with open surgical techniques that require cardiopulmonary bypass with hypothermic circulatory arrest. The use of endovascular stent grafts has clearly allowed for the application of interventions in the descending aorta as well as the visceral aorta.

The extension of these techniques has been utilized in the aortic arch given the current results of open surgical repair. Techniques have included in situ fenestrations using different tools, branch grafts, and chimney grafts placed parallel to the thoracic graft with varying results in small numbers of patients.[11,12] Utilization of a hybrid approach will typically be performed in stages, with the first surgical stage often being a carotid-carotid bypass and/or a carotid-subclavian revascularization. This is followed by thoracic stent graft repair with placement of the graft to the innominate or left carotid artery, respectively.[11,12]

Chimney grafts parallel to the main thoracic graft, typically in the carotid or subclavian arteries, have been used with varying results in the aortic arch. Concerns regarding this technique are the unknown and untested durability and the continued risk of type I endoleaks between components through the curvature of the arch.[13] The use of in situ techniques to create fenestrations within the graft after deployment across the supra-aortic vessels has been reported. As first reported by Murphy et al, good results have been shown with the use of a laser for in situ techniques.[14,15] As is seen in other series evaluating endovascular repair of aortic arch pathology, the number of patients treated is small with limited follow-up.

There have been case reports utilizing homemade branch grafts with favorable outcomes as well.[16,17] Any method that requires treatment of the arch should be performed with careful preoperative planning (preoperative imaging, ease of device use and durability, and should be devoid of access issues), high endovascular skills, and appropriate imaging equipment, as they are imperative for a successful result.

The Valiant® Mona LSA branch graft developed by Medtronic was selected by the US Food and Drug Administration (FDA) for participation in the FDA's early feasibility pilot program. This program allows for early clinical evaluation to provide proof of principle and initial clinical safety data. The device is one of nine devices selected by the FDA after its draft guidance document to encourage and facilitate early feasibility studies of innovative medical devices in the United States. This follows multiple benchtop testing, computer-simulated flow modeling, fatigue testing, and multiple animal studies evaluating proof of concept. If successful, the Valiant® Mona LSA system could potentially obviate the need for LSA bypass, extend the benefits of endovascular repair without surgery to more patients with thoracic aortic aneurysms, and quell the controversy that is related to whether the LSA needs to be, should be, or can be covered. ■

*Frank R. Arko, III, MD, is with the Department of Vascular and Endovascular Surgery, Sanger Heart and Vascular Institute in Charlotte, North Carolina. He has disclosed that he is a paid consultant to Medtronic. Dr. Arko may be reached at farkomd@gmail.com.*

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# Single-Center IDE Experience Treating Acute Traumatic Aortic Transection

Single-center data demonstrating the utility and midterm stability of thoracic endografts for traumatic aortic transection.

**BY RODNEY A. WHITE, MD; CARLOS E. DONAYRE, MD; IRWIN WALOT, MD; GEORGE KOPCHOK, BS; ALI KHOYNEZHAD, MD, PHD, FACS, FACC**

The use of thoracic aortic endografts to treat patients with acute traumatic transection of the descending aorta has dramatically affected the outcomes of these critically injured patients. Current literature and expanding clinical use of thoracic endografts for this indication has near-uniform consensus regarding utility of this procedure. In the United States, expanded clinical indications for thoracic endografts to include traumatic transections are actively being pursued by several manufacturers, with Medtronic's Valiant® thoracic stent graft (Medtronic, Inc., Minneapolis, MN) recently approved for this indication.

During the evolution of this indication, we have prospectively treated 41 patients enrolled in either an FDA-approved single-center IDE or as part of a commercial IDE. The Harbor/UCLA single-center IDE began in 2003, with patients being treated with three different devices as the technology evolved. The devices were provided by Medtronic, Inc. and included 23 Talent® thoracic, 11 Valiant® thoracic, and one Valiant® Captivia® thoracic stent graft. An additional five Valiant® Captivia® stent grafts were implanted as part of the Medtronic RESCUE trial.

One patient in the single-center IDE died before the procedure could be initiated. All patients in the IDE were enrolled in a lifetime surveillance protocol to observe the immediate and long-term impact of the thoracic endografts on severe descending thoracic aortic disruptions in a predominately younger patient population. Serial computed tomographic (CT) scans have been stored with M2S (West Lebanon, NH) with quantitative three-dimensional centerline measurement reconstructions providing aortic morphologic data, device stability, and adjacent aortic accommodation to the devices.

During the interval of the study, there has been 100% technical success in being able to deploy the device and exclude the injury, with the entry criteria being consistent across all of the studies. The length of the proximal landing zone was 15 to 20 mm, with individual patient considerations regarding coverage of the left subclavian artery being consistent with the SVS guidelines for treatment of acute, blunt descending thoracic aortic disruption. The data not only provide long-term surveillance regarding the performance of these devices but also demonstrate the utility of newer-design devices to better accommodate the arch anatomy in acutely injured patients.

## CASE REPORTS

A 21-year-old man was treated 7 years ago with a Talent® thoracic endograft to exclude a descending thoracic traumatic injury (Figure 1). The patient sustained disability for several months related to his asso-

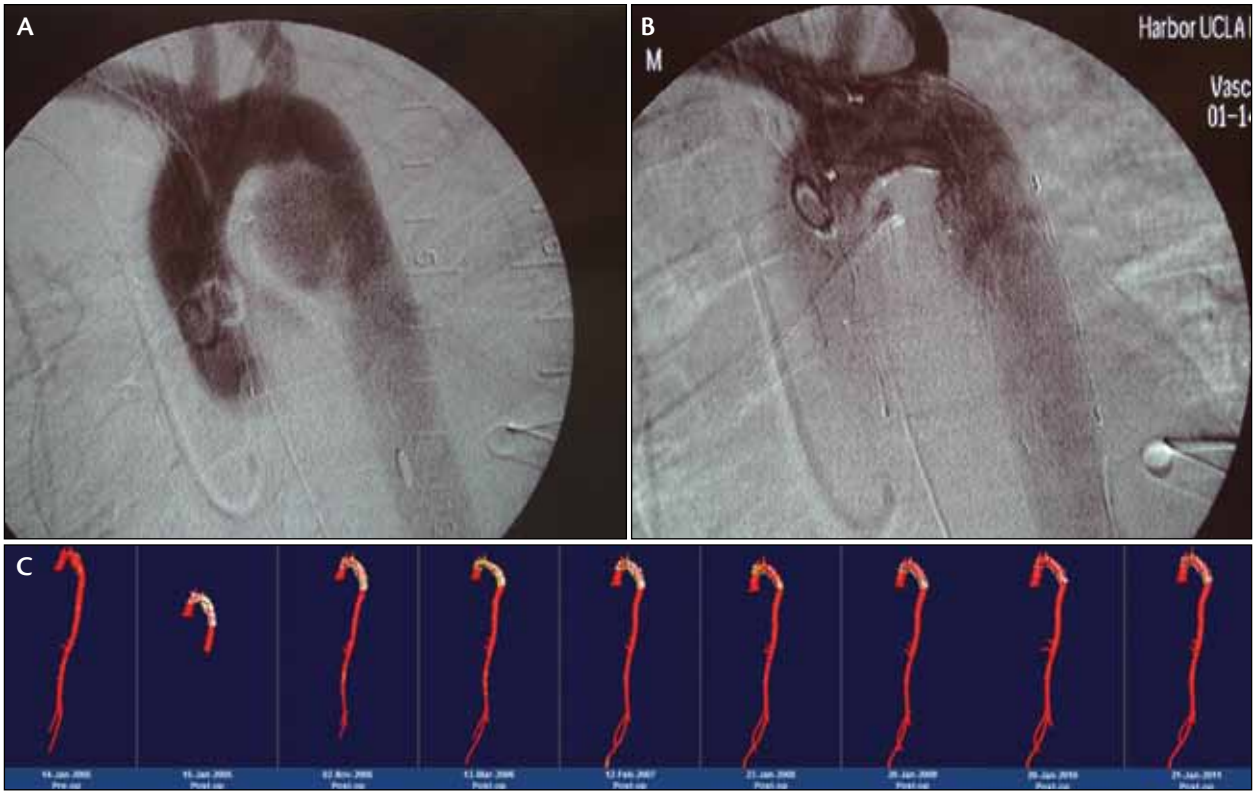


**Figure 1. Angiography of a thoracic aortic injury prior to and following device deployment (A, B). Sequential M2S images of the aortic anatomy and device stability at yearly surveillance intervals (C).**

ciated severe multiple organ injuries and head trauma. Yearly CT surveillance of the device has demonstrated continued stability of the endograft with no changes in the adjacent aortic anatomy.

With the development of improved iterations of the device, the IDE studies have included the evaluation of the Valiant® Captivia® thoracic endograft for this indication. We have found that the proximal portion of the device accommodates particularly well to acutely angled aortic anatomy, which is seen more frequently in younger patients and is easily deployed with controlled accuracy.

A recent patient treated with a Valiant® Captivia® stent graft was a 47-year-old man who sustained severe multisystem trauma. A CT scan before the intervention revealed an aortic hematoma with a severely disrupted aorta below the left subclavian artery. Additional injuries included blunt chest trauma with multiple rib fractures (first through ninth on the left and first and second on the right), bilateral pulmonary contusions, left hemothorax requiring a tube thoracostomy, complex pelvic fractures, a left acetabular fracture, and gross hematuria with bilateral renal contusions. The patient had a closed head injury with a CGS trauma score of 6 and a CT showing small punctuate hemorrhages but no cerebral swelling and normal-size ventricles. A ventriculostomy revealed normal intracranial pressures in the range of 6 to 7 mm Hg.

The preintervention aortic CT scan, angiography from the procedure, and accompanying intravascular ultrasound (IVUS) images of the proximal landing zone, site of the injury, and distal aortic anatomy emphasize the importance of IVUS an as integral part of the procedure (Figure 2A). By obtaining expedient access and wire passage through the injured segment, IVUS enhances rapid identification of the landing zones and aortic diameters, enabling rapid deployment. In approximately 25% of our patients, this technique allowed performance of the procedure without systemic heparin administration. Although the need for anticoagulation is determined for each individual patient based on the severity of injuries and concern for hemorrhagic complications, we have been able to deploy the devices with only heparin irrigation of the access sheaths and have not experienced any thrombotic complications.

An additional utility of IVUS is that the CT scan acquired at the time of patient admission is frequently performed when the patient is hypovolemic. In a signif-

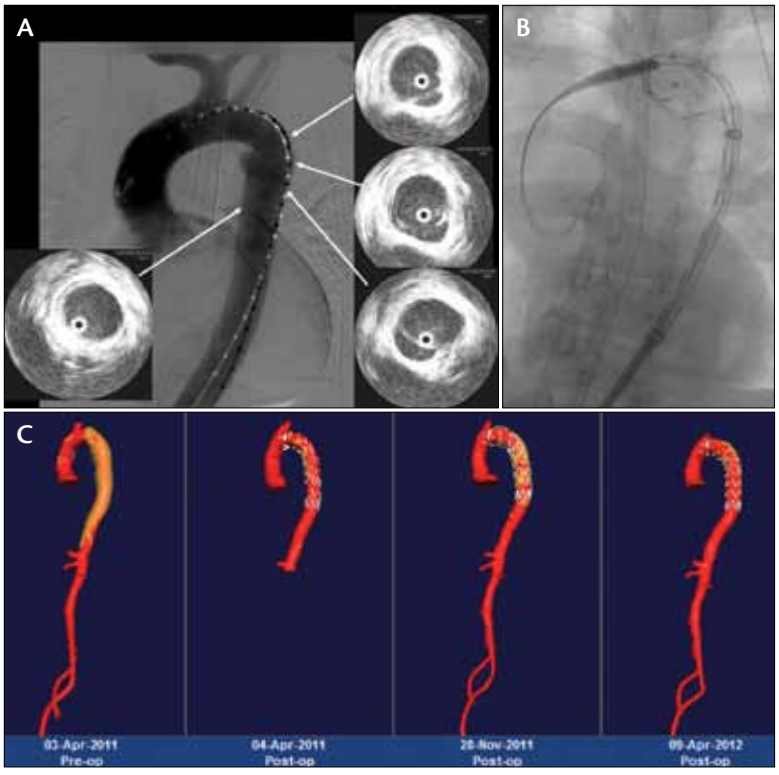


**Figure 2. Angiography at the time of device deployment with corresponding IVUS images of the aortic injury (A). Controlled device delivery provided by the Captivia® device (B). Sequential M2S images after device deployment (C).**

icant number of the cases, we have observed that once the patient has been transported to the endovascular suite and fluid resuscitation is performed, the aortic diameters are significantly larger in this predominately younger patient population with a compliant aorta. For this reason, we use IVUS to not only expediently identify the appropriate landing zones but also to determine the diameter. In a significant number of cases, we have used a larger device than would have been suggested from the initial CT.

Figure 2B shows the conformity of the device to the acute aortic anatomy and the controlled release provided by the Captivia® design. The Captivia® delivery system enables accurate positioning of the proximal fixation without requiring induced hypotension or asystole, a technique we used for many years to ensure accurate placement before the current design. Figure 2C shows the sequential follow-up CT images and demonstrates accurate deployment and accommodation of the device to the aortic anatomy.

## DISCUSSION

Our 9-year experience with evolving thoracic endograft technology for treatment of patients with acute traumatic aortic transection demonstrates the utility and midterm stability of the device for this indication. ■

*Rodney A. White, MD, is Vascular Surgery Division Chief, Vascular Surgery Fellowship Program Director, and Vice Chairman of Research, Harbor-UCLA Medical Center, and Professor of Surgery, David Geffen School of Medicine at UCLA in Torrance, California. He has disclosed that he is a paid consultant to and receives research support from Abbott Vascular, Cordis Corporation, Endologix, Inc., Medtronic, Inc., Volcano Corporation, and W. L. Gore & Associates. Dr. White may be reached at (310) 222-2704; rawhite@ucla.edu.*

*Carlos E. Donayre, MD, is a vascular surgeon with the Department of Surgery, Harbor-UCLA Medical Center in Torrance, California. He has disclosed that he is a paid consultant to and receives research support from Endologix, Inc., Medtronic, Inc., and Volcano Corporation. Dr. Donayre may be reached at cdonayre@cox.net.*

*Irwin Walot, MD, is a radiologist with the Department of Radiology, Harbor-UCLA Medical Center in Torrance, California. He has disclosed that he is a paid consultant to and receives research support from Abbott Vascular, Cordis Corporation, Endologix, Inc., Medtronic, Inc., Volcano Corporation, and W. L. Gore & Associates. Dr. Walot may be reached at drwalot@cox.net.*

*George Kopchok, BS, is a research associate at Harbor-UCLA Medical Center in Torrance, California. He has disclosed that he is a paid consultant to and receives research support from Medtronic, Inc., Endologix, Inc., and Volcano Corporation. Mr. Kopchok may be reached at gkopchok@labiomed.org.*

*Ali Khoynezhad, MD, PhD, FACS, FACC, is Director, Thoracic Aortic Surgery, and Associate Professor of Surgery at Cedars-Sinai Medical Center, Division of Cardiothoracic Surgery in Los Angeles, California. He has disclosed that he is a consultant and physician trainer for Medtronic, Inc., Cook, and Sorin. Dr. Khoynezhad may be reached at akhoy@cshs.org.*

# The MOTHER Multicenter Registry

An overview and discussion of a registry that may help us understand how and to what degree various factors influence the risk of complications after TEVAR.

**BY BENJAMIN O. PATTERSON, BSc, MRCS, AND MATT M. THOMPSON, MD, FRCS**

Endovascular repair of the thoracic aorta (TEVAR) has broadened the therapeutic options available for conditions affecting the aortic arch and descending thoracic aorta. The number of thoracic endovascular procedures performed has risen steadily over recent years, whereas the number of open surgical operations has remained stable (Figure 1).[1] This suggests that rather than replacing traditional techniques, TEVAR complements open surgery and allows more patients to be definitively managed than was previously possible.[2] Some patients are deemed unfit for open surgery due to poor physiological reserve, and although the risk of aortic-related death is abolished, they are subject to an increased risk of death from all other causes in comparison with matched controls.

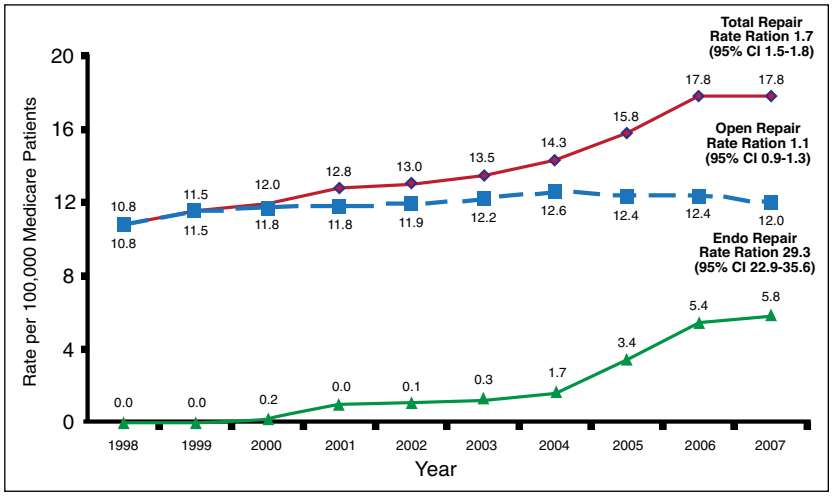


**Figure 1. The rates of thoracic and thoracoabdominal repair (triangles), open repair (squares), and endovascular repair in the Medicare population from 1998 to 2007. Note the increase in total repairs but the stability of the open figures. Reprinted from the *Journal of Vascular Surgery,* Vol. 53/6, Scali S, et al. National trends and regional variation of open and endovascular repair of thoracic and thoracoabdominal aneurysms in contemporary practice. 1499–1505, Copyright (2011), with permission from Elsevier.**

Understanding which patients will gain maximum benefit from TEVAR requires additional well-validated clinical evidence that describes perioperative events and midterm follow-up. Unfortunately, many series fail to discriminate between different aortic pathologies when reporting outcomes, making the results hard to assess and pooled analysis difficult. This is partly due to a lack of globally accepted reporting standards. One potential way to improve this situation could be by combining data obtained from high-quality trials at a raw data level.

## THE MEDTRONIC OUTCOMES OF THORACIC ENDOVASCULAR REPAIR (MOTHER) REGISTRY

The Medtronic Outcomes of Thoracic Endovascular Repair (MOTHER) registry comprises five prospective trials conducted by Medtronic, Inc. (Minneapolis, MN) with the addition of institutional data from a single UK center, St. George's Vascular Institute. The sponsored trials include pre-market investigational trials (52% of patients, all arms of VALOR[3] and VALOR II) and post-market registries (27% of patients, INSTEAD,[4] Valiant Captivia registry, and the VIRTUE registry[5]). The institutional data series was a prospectively collected dataset


**Figure 2. The improved conformability of the Valiant® thoracic device afforded by the sinusoidal springs located on the outside of the graft fabric. The eight-peaked FreeFlo springs are also displayed.**

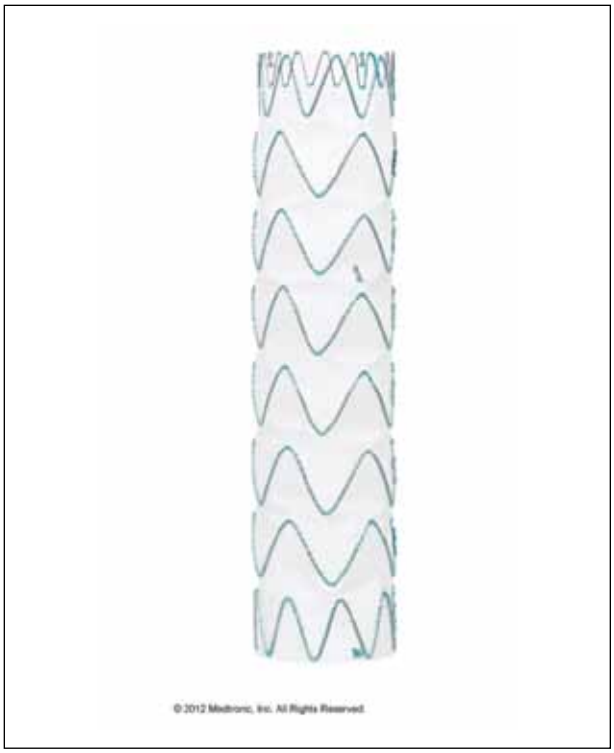


**Figure 3. The distal component of the Valiant® thoracic graft.**

that included all thoracic endovascular aortic repairs performed over a period of 8 years that used either the Talent® thoracic or Valiant® thoracic stent graft systems (Medtronic, Inc.) that were not entered into any of the aforementioned trials (Table 1).

There were stringent protocols for collection and validation of data, and for more than half of the patients, independent adjudication was used for any adverse events that occurred. The institutional series was prospectively maintained, and follow-up was assessed by computed tomography according to local protocol. The patient cohort was stratified into three groups determined by presenting pathology: thoracic aortic aneurysm (TAA), acute type B aortic dissection (A-BD) (< 2 weeks after symptom onset) , and chronic type B aortic dissection (C-BD) (> 2 weeks after symptom onset). There was an insufficient number of patients with other pathologies (eg, transection, mycotic aneurysm) for individual subgroup analysis.

TAA diameter > 5.5 cm, rapid expansion, symptoms attributable to the aneurysm, and aneurysm rupture were considered indications to treat TAA patients. All patients with acute type B dissection were treated if they presented with malperfusion of an arterial territory, rupture or impending rupture of the false lumen, uncontrollable blood pressure, unremitting pain, a rapidly expanding aorta, or a diameter of > 4.5 cm. In the chronic type B dissection group, there were some patients with stable type B dissections that were treated as part of the INSTEAD trial. Indications for reintervention in all cases were assessed on an individual case-by-case basis at each center.

The primary outcomes of interest were death, stroke (including transient ischemic attack), acute spinal cord injury (paraplegia and paraparesis combined), and endograft-related events, specifically those that required aortic reintervention. Deaths were classified as aortic- or nonaortic-related and were classified as specifically as possible. Aortic-related deaths were defined as any death occurring that was directly attributable to the index procedure, any subsequent reintervention, aortic rupture, or other aortic complication.

All patients in the MOTHER registry had either the Medtronic Talent® thoracic or Valiant® thoracic stent graft systems implanted. Both are modular stent graft systems that feature sinusoidal nitinol rings and springs for radial force and increased conformability, with a woven polyester fabric covering to exclude the diseased section of aorta. Developments from the Talent® design in the Valiant® thoracic stent graft include an eight-peaked proximal bare-spring (FreeFlo) configuration

that distributes radial force evenly. The relocation of the springs to the outside of the graft improves graft apposition and provides enhanced graft stability (Figures 2 and 3). In order to enhance the three-dimensional conformability of the graft, the longitudinal connecting bar that was present in the Talent® model has been removed.

The Captivia® delivery system has been designed to facilitate simple, accurate deployment. The ergonomic delivery system provides an option to deliver the graft gradually, using a gradual "unscrewing" action or, alternatively, by depressing a button and using one smooth withdrawing action (Figure 4). The tip capture mechanism is then recaptured to complete the process, and the delivery system can then be safely removed.

## SPECIFIC AIMS OF THE MOTHER REGISTRY

TEVAR has demonstrated an early mortality advantage over open surgical treatment of the thoracic aorta, which appears greater comparatively than that observed in the abdominal aorta.[6,7] Serious morbidity and other adverse events are also less common, and many clinicians now consider TEVAR as a first-line therapy for most conditions affecting the thoracic aorta. The applicability of endovascular and hybrid techniques continues to expand with emerging device technology and refined indications for use.[1,5]

Despite the obvious benefits, TEVAR is not altogether without risk. Neurological complications have been dreaded by surgeons since the early days of open aortic operations, and recent cohort studies report a 5% to 7% risk of stroke and a 2% to 3% risk of paraplegia following TEVAR.[8,9] These are serious complications and can cause long-term disability. The optimum strategy for preventing these events has not yet been defined but is likely to be multifactorial, making use of a tailored combination of measures.

The length of aortic coverage necessary to seal an aneurysm or exclude a dissection has been shown by some to increase the risk of paraplegia and stroke, as has coverage of the left subclavian artery.[10] The MOTHER registry represents an exciting opportunity to try to understand how—and to what degree—these factors influence the risk of neurological complications. Regression analysis will allow quantification of this risk and the construction of risk-prediction models that may eventually help to protect patients from serious complications.

Mid- to long-term follow-up of the patients enrolled in the EVAR trial suggested that the early mortality benefit derived from endovascular repair of abdominal aortic aneurysms may be lost eventually due to an excess of aortic-related deaths,[11] although important limitations to this study exist, such as the failure to include incisional hernias as a related reintervention after open repair. The observation regarding aortic-related deaths may have overshadowed the importance of the high nonaortic death rate observed in aneurysm patients, which is potentially an opportunity for increasing life expectancy. Some large administrative datasets have confirmed a high rate of all-cause mortality in TAA patients at follow-up, but there is a lack of good-quality data available at the individual patient level. The MOTHER database will make use of the rigorous follow-up of patients in the component trials to allow analysis of many factors that may influence midterm follow-up. Defining the cause and frequency of deaths in a large series of patients will help to determine if TEVAR is being offered appropriately to high-risk patients, as there have been concerns that

> The MOTHER registry will not resolve all contentious areas of practice, but it will certainly contribute in several important ways to the existing literature.


**Figure 4. The Captivia® delivery system. The graft is shown mid-deployment with the first few springs emerging from the sheath. The blue handle is either turned for maximum control during delivery or can be withdrawn quickly if the gray lever is depressed. Until the operator is satisfied with the position of the graft, the proximal bare stents remain constrained.**

the all-cause death rate is higher than in open surgical patients, despite risk adjustment.[2]

The frequency of aortic reintervention is considered to be the Achilles' heel of endovascular aortic repair in all anatomical locations.[11] To prevent late aortic death, resource-intensive surveillance programs and secondary procedures are necessary. Predicting those patients who are most at risk for these problems would be of great utility and could help with surgical planning and gauging the intensity of subsequent surveillance. Gaining a greater understanding of

**TABLE 1. THE MOTHER REGISTRY**

| Registry | No. | NCT Identifier | Stent | Indication | Purpose/ Endpoint | Duration |
|---|---|---|---|---|---|---|
| VALOR[3] | 359 | 00604799 | Talent® | Test: TAA with low/moderate risk (comparator with OSR); registry: as for test but not for comparison; high-risk: not suitable for OSR or high risk (TAA = 333, C-BD = 13, A-BD = 8) | Phase II/III study to determine success of aneurysm treatment at 1 year | 5-year follow-up (2003–2011) |
| VALOR II | 160 | 00413231 | Valiant® | TAA only in patients who are a candidates for OSR with low/moderate risk | Phase II/III study to determine success of aneurysm treatment at 1 year | 5-year follow-up (2006–2014) |
| CAPTIVIA | 68 | 01181947 | Valiant® Captivia® | All indications (included TAA = 49, C-BD = 23, A-BD = 19, other = 8) | Postmarket surveillance to evaluate mid-term clinical performance | 3-year follow-up (2010–2013) |
| VIRTUE[4] | 100 | 01213589 | Valiant® Xcelerant® | Acute (50) and chronic type B dissection (50) | Collection of safety, performance, and health economic data | 3-year follow-up (2006–2012) |
| INSTEAD[5] | 100 | 00525356 | Talent® | Chronic type B dissection | Phase III comparison of stent vs medical therapy in chronic dissection | 5-year follow-up (2002–2007) |
| St. George's Vascular Institute | 223 | N/A | Talent®/Valiant® | All indications (included TAA = 128, A-BD = 37, C-BD = 41, other = 17) | Institutional series of TEVAR with Medtronic stent grafts | Variable follow-up (2002–2010) |

*Abbreviations: OSR, open surgical repair.*

the effect of individual preoperative aneurysm morphology will almost certainly play a part in achieving this goal. There is emerging evidence that morphology affects the outcome of infrarenal aneurysm repair,[12] but unfortunately, there is no protocol for assessing the thoracic aorta as there is for infrarenal abdominal aortic aneurysms.[13,14] The MOTHER registry contains anatomical information from many of the patients entered into individual registries, measured by an independent core lab. This will allow detailed analysis of the morphological risk factors for midterm technical failure of TEVAR and may help allow the formulation of some guidelines for endograft planning.

TEVAR successfully prevents aortic death in TAA patients, but there is less quality prospective data that confirm these findings in those with dissection. The MOTHER registry will enable comparison of mid- to long-term survival in all groups of patients and allow an indirect comparison with equivalent open surgical series. This will be especially valuable in the chronic dissection group. The treatment of aortic dissection has different indications and objectives from that of aneurysmal disease, and some experts feel that endovascular procedures may not provide a robust long-term solution, despite reports of excellent early results for acute, subacute, and chronic presentations.[4,5,15]

Despite this, a contemporary series detailing midterm results of open surgical procedures demonstrated a high incidence of complications.[16] Although stent graft placement is associated with favorable aortic remodeling and false lumen thrombosis, the place of TEVAR in the treatment of chronic dissection will require demonstration of an ability to prevent aortic death in the medium-term. The MOTHER registry will help to determine the midterm death rate in dissection patients and the cause of these deaths in comparison to TAA. It is also possible that more complex morphological analysis may be undertaken to determine the effect of stenting on the false lumen in the midterm and to correlate this with clinical outcomes.

## CONCLUSION

As more evidence supporting the practice of TEVAR emerges, there will be a greater understanding of which patients are most likely to benefit from this approach. A barrier to this has been the relative few number of procedures that are performed, meaning that randomized control trials on the scale of those performed for infrarenal aortic aneurysm have not yet been feasible. The existing literature has aided expert consensus, but even guidelines commissioned by bodies such as the North American Society for Vascular Surgery can often only base recommendations on weak evidence. To develop a more usable core of literature, it is vital that universally acceptable reporting standards are defined and adhered to.

The MOTHER registry will not resolve all contentious areas of practice, but it will certainly contribute in several important ways to the existing literature. Specific aims include determining the influence of presenting pathology on short- and midterm outcomes, identifying risk factors for neurological complications, and describing the influence of aortic morphology on patient survival and endograft durability. The ultimate goal will be a fully validated risk stratification system for use in clinical practice, which will help to improve the safety of TEVAR. ■

*Benjamin O. Patterson, BSc, MRCS, is with St. George's Vascular Institute in London, United Kingdom. He has disclosed that he serves on the speakers bureau for Medtronic. Dr. Patterson may be reached at bop@doctors.org.uk.*

*Matt M. Thompson, MD, FRCS, is Professor of Vascular Surgery at St. George's Vascular Institute in London, United Kingdom. He has disclosed that he receives research grants from Cook and Medtronic and serves on the speakers bureau for Medtronic, Cook, Endologix, and GE. Professor Thompson may be reached at matt.thompson@stgeorges.nhs.uk.*

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# The Best Practice for Type B Aortic Dissection

Future refinements of stent graft technology, growing technical skill, and long-term outcome data are needed to determine the potential long-term benefit of endovascular repair.

**BY ROSSELLA FATTORI, MD; LUCIA MARINUCCI, MD; LUCIA UGUCCIONI, MD; ROSARIO PARISI, MD; AND GIOEL GABRIO SECCO, MD**

Aortic diseases have progressively gained increasing clinical importance in the last decades, both for their emerging epidemiology, characterized by a growing yearly incidence,[1] and for the severity of disease prognosis. Among them, acute aortic dissection is one of the most serious cardiovascular events. The estimated mortality rate of untreated aortic dissection is 1% to 2% per hour in the first 24 hours after onset and 80% within 2 weeks.

Although general consensus exists regarding the need of immediate surgical repair for patients with acute ascending aortic dissection (type A dissection), the optimal treatment of type B dissection is still a matter of debate. It has been generally recommended that patients who have type B aortic dissection without complications are treated with medical therapy in an intensive care unit. Usually, with aggressive antihypertensive therapy, up to 85% of patients may survive their initial hospital stay. In addition, keeping the heart rate below 60 bpm significantly decreases secondary adverse events (aortic expansion, recurrent aortic dissection, aortic rupture) compared to a conventional rate of > 60 bpm.[2] Unfortunately, approximately 30% to 42% of acute type B aortic dissections at clinical presentation are complicated by peripheral vascular ischemia or hemodynamic instability and have a highly unpredictable outcome, thus necessitating percutaneous or open surgical intervention. Despite substantial surgical, anesthesiologic, and postoperative care advances, emergent traditional open surgical repair of acute complicated dissection still has high mortality (25%–50%) and morbidity rates,[3-7] resulting in prolonged hospitalization and high costs. The advent of endovascular treatment of the thoracic aorta has revolutionized the clinical approach to type B aortic dissection, representing a new minimally invasive alternative to traditional surgery for the management of acute thoracic aortic pathologies, even in high-risk patients who could not be considered operative candidates. The emerging role of endovascular strategies has gained wide acceptance considering the unsatisfactory results of open repair. Encouraging initial reports of clinical outcomes achieved by endovascular repair and stent graft implantation to treat type B aortic dissection have also accelerated the adoption of TEVAR.[8,9]

Closure of the entry tear of dissection may promote both depressurization and shrinkage of the false lumen, with subsequent thrombosis, fibrous transformation, remodeling, and stabilization of the aorta, but also resolution of dynamic malperfusion. However, accurate anatomic selections of candidates, a thorough knowledge of imaging methods, as well as a wide endovascular experience are mandatory for achieving optimal results.

## RESULTS OF ENDOVASCULAR TREATMENT OF ACUTE TYPE B AORTIC DISSECTION

Endovascular treatment is advocated when a patient with acute type B aortic dissection presents with signs of aortic rupture at imaging and clinical evaluation shows evidence of severely impaired visceral/peripheral perfusion or symptoms of clinical instability, such as uncontrolled hypertension, severe hypotension, and recurrent or refractory pain. One or more covered stents are placed through femoral access over the intimal tear, and additional stents are often used to hold open the true lumen, cover additional entry sites, and promote thrombosis of the false lumen, thus protecting the aortic wall from rupture. Moreover, in the majority of cases, stent graft occlusion of the entry site in the descending thoracic aorta also leads to re-expansion of the true lumen, when compressed,

normalizing distal vessel perfusion and restoring branch vessel patency. This approach is being increasingly used in patients with type B dissection.[10-15] Results from clinical trials and meta-analysis of case series reported overall outcomes with in-hospital mortality rates ranging from 5% to 9%, 2% to 6% for stroke, and 1% to 3% for paraplegia.

The IRAD registry provides an analysis of the different management options for type B aortic dissection, with data comparing the impact on survival of different treatment strategies in 571 patients with acute type B aortic dissection:[16] 390 patients (68.3%) with uncomplicated aortic dissection were treated medically, whereas among complicated cases, 59 (10.3%) underwent standard open surgery and 66 (11.6%) underwent endovascular repair. TEVAR provided better outcomes, with 9.3% mortality in patients treated with a stent graft and 33.9% mortality in patients who underwent open surgery. In patients discharged to home, long-term results[17] seem to confirm the benefit of stent graft repair with respect to medical therapy alone. On the basis of several reports showing improved survival rates, endovascular repair is becoming the standard treatment for patients with acute complicated type B dissection.

## RESULTS OF ENDOVASCULAR TREATMENT FOR CHRONIC TYPE B DISSECTION

The "14 days after symptoms onset" has been designated as an acute phase of aortic dissection, owing to the highest rates of mortality and morbidity that occur in this period. Usually after that period, blood pressure has been stabilized and symptom relief achieved, and type B dissection is considered chronic. The patient could also be discharged, and clinical and imaging follow-up could be performed at 3 and 6 months and then yearly. TEVAR is considered a life-saving treatment for complicated acute type B dissection, but its role in stable type B dissection is still unknown.

Even if medical therapy is currently considered the best option for uncomplicated dissection, the effect of medical therapy may delay expansion of the descending aorta but does not promote the remodelling process. Subsequent interventions are often performed in chronic type B dissection for the development of complications, such as aneurysm expansion, progressive dissection, and other related adverse events from the unresolved dissection process. Recurrence of symptoms, aneurysmal dilation (> 55 mm), or a yearly aortic increase > 4 mm are all indicative of "complicated chronic dissections" and have a worse prognosis without treatment. However, aortic remodeling seems to be less effective in chronic dissection with a dilated false lumen, with late aneurysmal degeneration of the thrombosed false lumen reported in 7.8% of cases,[16,18,19] suggesting the need for earlier treatment before aortic dilation may occur.

## THE INSTEAD TRIAL

The Investigation of Stent Grafts in Aortic Dissection (INSTEAD) trial[20] enrolled 140 patients (72 with additional endovascular treatment) and had all-cause of death at 2 years as the primary endpoint; aortic-related death, aortic remodeling, and disease progression (need for conversion or reintervention with stent graft or open surgery) were secondary endpoints. The results did not show any significant advantage of endovascular treatment in comparison with optimal medical therapy at 2-year follow-up, with no difference in all-cause deaths and a 2-year cumulative survival rate of 95.6% ± 2.5% with medical treatment and 88.9% ± 3.7% with adjunctive TEVAR. No differences were found between the two groups for aortic-related death and disease progression. The INSTEAD study at 2 years does confirm the effectiveness of endovascular therapy for false lumen thrombosis (achieved in 90% of cases) and strengthens the role of a tight blood pressure control and close surveillance. Together with the nonsignificant procedure-related complications highlighted, these results support a complication-specific approach instead of endovascular therapy for all stable type B dissections. According to this approach, all patients who do not respond to medical treatment showing progressive false lumen expansion could be treated with a stent graft because even deferred endovascular therapy is feasible.

The INSTEAD study is limited by a short observation period (only 2 years). Some of the positive and promising aspects related to endovascular therapy, such as false lumen thrombosis and remodeling, need longer follow-up periods to be confirmed and demonstrate a potential advantage versus medical treatment. Waiting for long-term follow-up of randomized trials, which could modify our decision strategy, continuous progress in stent graft technology, and improving morphology and flexibility, may lead to more suitable stent graft configuration for aortic dissection and thus improve clinical results. ■

*Rossella Fattori, MD, is with the Interventional Cardiology Department, San Salvatore Hospital in Pesaro, Italy. She has disclosed that she has no financial interests related to this article. Dr. Fattori may be reached at rossella.fattori@unibo.it.*

*Lucia Marinucci, MD, is with the Interventional Cardiology Department, San Salvatore Hospital in Pesaro, Italy. She has disclosed that she has no financial interests related to this article.*

*Lucia Uguccioni, MD, is with the Interventional Cardiology Department, San Salvatore Hospital in Pesaro, Italy. She has disclosed that she has no financial interests related to this article.*

*Rosario Parisi, MD, is with the Interventional Cardiology Department, San Salvatore Hospital in Pesaro, Italy. She has disclosed that she has no financial interests related to this article.*

*Gioel Gabrio Secco, MD, is with the Interventional Cardiology Department, San Salvatore Hospital in Pesaro, Italy. He has disclosed that he has no financial interests related to this article.*

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# Retrograde Type A Aortic Dissection

A review of the available literature on this rare but potentially catastrophic complication.

**BY GABRIELE PIFFARETTI, MD, PHD; SANTI TRIMARCHI, MD, PHD; AND PATRIZIO CASTELLI, MD, FACS**

The definition of *acute thoracic aortic syndrome* has usually included ruptured thoracic aneurysm, acute type B dissection, traumatic blunt aortic injury, and symptomatic penetrating aortic ulcer. Retrograde type A aortic dissection (RTAD) is defined as a dissection that originates distally to the ascending aorta with retrograde flap progression into the ascending aorta.[1] It was a known complication during conventional cardiac surgery, but recently, it has been described as one of the most alarming complications after thoracic aortic endovascular repair (TEVAR).[2] It is potentially lethal and in all respects deserves to be included in acute thoracic aortic syndrome.

## INCIDENCE

The true incidence of RTAD has not yet been established, but it is an increasingly observed phenomenon, with an estimated overall incidence of 1% to 4%.[3-6] In their recent systematic meta-analysis, Luebke and Brunkwall[7] calculated a weighted event rate of 7% for RTAD. This figure significantly exceeds the 0% to 7.5% incidence rate reported in even the most extensive series, but it should be pointed out that their review analyzed only acute RTAD after complicated type B aortic dissections, whereas the others presented mixed entities of RTADs. Therefore, the real incidence for RTAD reported in the literature could be underestimated.

Aortic specialists must be aware that RTAD may have an acute or delayed presentation, potentially occurring acutely during either the indexed TEVAR procedure or in the postoperative period. Dong et al[4] detected an acute presentation in 27.3% of their first 11 cases, with a mean onset time of 11 ± 16 months in a recently updated analysis of 23 cases.[8] An insight analysis from the European registry on endovascular aortic repair complications revealed that RTAD occurred during the indexed procedure in 35.4% of the cases and in 64.6% within the first 30 days.[5] Most importantly, even though it is rare, RTAD has been detected as an incidental finding during a follow-up control, although with an asymptomatic clinical profile.

## PREDISPOSING FACTORS

The limited experience compiled on RTAD raises concerns regarding whether or not it is the consequence of a single independent event, because the available data seem to support the hypothesis of a combination of different causes. RTAD etiopathogenesis could be distinguished as:

- Disease related, due to the natural progression of the underlying disease
- Procedure related, when caused by ballooning or wire and sheath manipulation, typically in an acute aortic arch
- Endograft related, also defined as a stent graft–induced new entry site (SINE), which refers to wall injury that seems potentially related to the use of endografts. This type of aortic lesion has frequently been identified intraoperatively during open conversion.

Most cases have been detected after TEVAR for type B dissections or its variants. It is suggested to consider the fragility of the aortic wall (meaning the predominant presence of dissection, intramural hematoma, or connective tissue disorders like Marfan syndrome) as the pathological background and TEVAR maneuvers as the provoking trigger. Out of the 71 cases piled up from two of the most extensive series reported on RTAD, the presence of a connective tissue disorder accounted for 8.4% of the underlying disease.[4,5] In particular, the proportion of new SINE among Marfan syndrome patients was 33.33% in the study by Dong et al,[8] which was significantly higher than the 3.26% among non-Marfan patients.

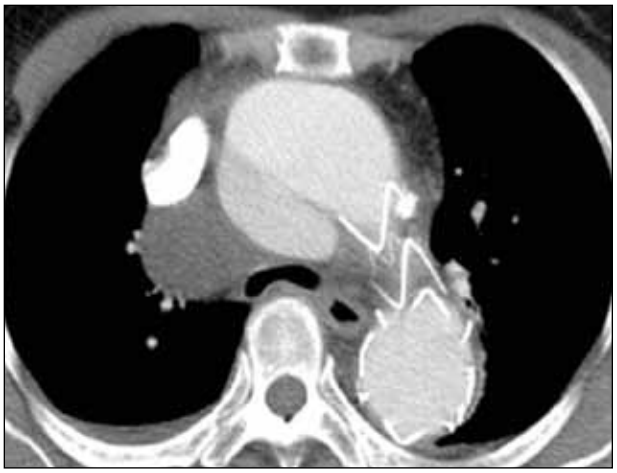

**Figure 1. RTAD following TEVAR in an acute arch. The proximal SINE was located near the endograft (proximal bare spring).**

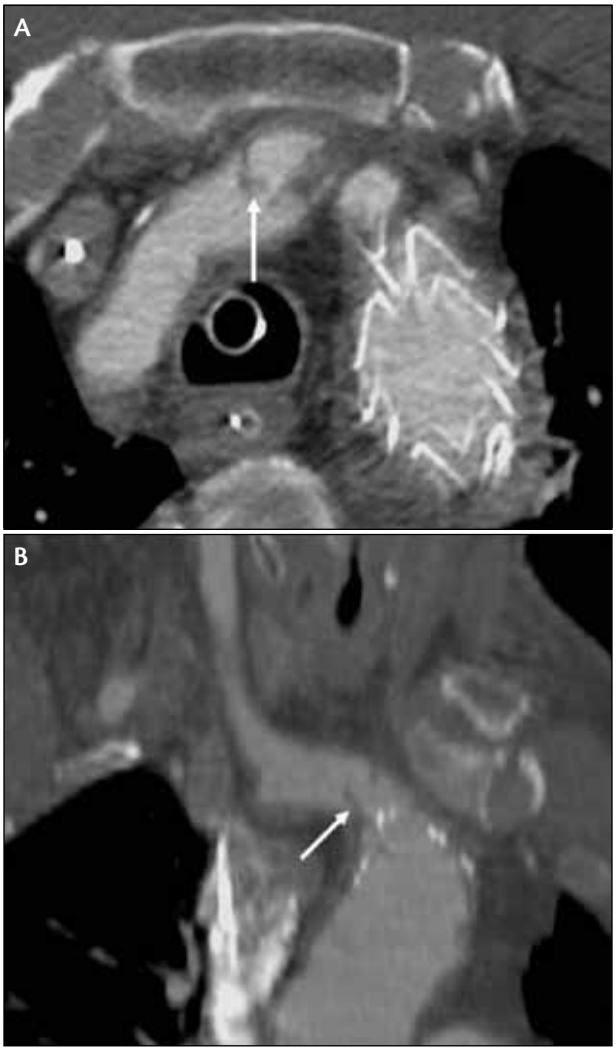


**Figure 2. A case of RTAD following TEVAR for an aortic arch aneurysm. SINE involved the supra-aortic trunks (A, arrow) and was located at the proximal edge (B, arrow) of the endograft (no bare spring).**

Recently, Williams et al[9] identified an ascending aorta diameter of > 40 mm as another potential predictor of RTAD and reported a higher incidence of this complication in such patients (4.8% vs 0.9%; $P = .047$). The incidence of RTAD increased markedly with combinations of higher-risk scenarios, such as the association of dissection plus an ascending aortic diameter ≥ 40 mm, which further increased to 25% using the native "zone 0" as a proximal landing zone for the endograft. A dilated ascending aorta or similar condition—such as a bicuspid aortic valve—are likely markers of diffuse aortic disease and is an inherent weakness of the diseased aortic wall, thus predisposing patients to this complication. Other anatomic conditions at the proximal neck may play a primary role in determining RTAD after TEVAR, such as the presence of an angulated (> 60°) "gothic" arch and the absence of a regular neck for safe deployment, which is frequently detected in acute B dissection and may be associated with retrograde dissection.[10]

Several authors have reported that reiterative balloon remodeling of the endograft may cause RTAD.[2] The ballooning was judged to be necessary because the endograft did not adapt perfectly to the inner curve of an angulated aortic arch. However, it should be observed that in most of these reported instances, a "fragile" aorta was the indication for TEVAR intervention.

Further procedure-related RTAD-provoking factors were recently described to be strictly linked to the debranching technique.[11,12] The risk of wall injury during aortic side-clamping under pulsatile flow has been documented during off-pump coronary artery bypass surgery, especially in the presence of a dilated ascending aorta. The risk of developing RTAD after total arch debranching could be amplified by the large anastomosis required to complete the rerouting of the supra-aortic vessels. In support of this hypothesis, an incremental risk of RTAD was observed for the "zone 0" proximal landing zone and a dilated (≥ 4 cm) ascending aorta.[9] The combination of these scenarios associated with use of endografts with proximal barbs showed an overall 10.7% incidence of RTAD.[6,9] This finding is of particular importance in light of data published by van Prehn et al,[13] who illustrated the significant pulsatility of the ascending aorta. This might further be evaluated as a concurrent mechanism for the increased incidence of RTAD that is seen with the "zone 0" proximal landing zone.

One of the most debated predisposing factors of RTAD has been the configuration of the endograft. Currently, we do not have a definitive indication that a specific configuration may significantly increase the risk of developing RTAD. Injury from endografts featuring a proximal bare spring (Figure 1) was considered first because this configuration was designed to strengthen proximal fixation. However, proximal SINE has also been observed in patients treated with endografts without the bare spring. In the experience of Kpodonu et al,[3] the RTAD incidence among endografts without bare springs (Figure 2) was 2.4%, which was fairly similar to the 2.5% incidence reported in a Chinese study using endografts with bare springs.[4,8] In a European registry, the evidence that RTAD tended to occur using many different endografts suggested that the semirigid design of the endograft might be responsible for the aortic tear rather than the proximal bare springs.[5] Therefore, we can speculate that the majority of endograft-related RTADs could be ascribed to the lack of pathology-specific devices, especially for those cases involving a "fragile" aorta.[7]

It has been suggested that the radial force of the endograft, which also depends on its oversizing, in combination with the inherent tendency of the endograft to spring back to its initial straight status, generates stress on the aortic curvature and may provoke the intimal injury. If oversizing is part of the dynamic effect that contributed to the development of RTAD, it could be speculated that excessive endograft oversizing (> 20%) should be frequently detected in RTAD cases, regardless of the primary aortic disease. Kpodonu et al[3] reported a mean 21.4% oversizing as the causative factor in 28% of their RTADs, but a mean of only 9.6% was observed in the acute cases. However, RTADs have been reported with increased frequency, even with low oversizing rates, so oversizing as a determining factor for RTAD does not seem to be considered as playing a primary role.

## OUTCOMES AND RESULTS OF SURGICAL REPAIR

Mortality rates after RTAD have been reported up to 42%, including sudden deaths, and have shown to be higher than the rate for spontaneously occurring acute type A aortic dissection.[2,5,7] Analysis of subgroups showed that patients in whom RTAD occurred during the TEVAR procedure, especially those with a proximal SINE, had the worst outcomes compared with patients in whom RTAD occurred during follow-up.[8] Hence, subsequent open conversion should be the treatment of choice in an effort to avert these life-threatening complications. In the report from the Duke group, 66% of RTADs occurred intraoperatively, 75% of which were initially detected by transesophageal echocardiography or intravascular ultrasound.[6,9] These data suggest that rapid diagnosis is of paramount importance and that intraoperative diagnostic tools may play a key role in facilitating early detection of RTAD.

RTADs ascribed to wire/sheath manipulation seem to be limited to the distal ascending aortic arch or proximal aortic arch in half of patients.[5] In addition, proximal SINE was more frequently located at the greater curve and involved the entire ascending aorta in the majority (83%) of cases.[8] Therefore, the presumed cause and location of RTAD may have a significant influence on treatment strategy. The substitution of the entire aortic arch with suturing of the vascular graft directly to the endograft was the preferred type of surgical repair.[2,14] The complete removal of the endograft and Dacron graft replacement using the modified "elephant trunk" technique was rarely performed as an alternative strategy.[1,2] Conservative treatment was used in selected cases, especially for those with wire-induced wall injury or in the presence of focal and asymptomatic lesions.[2]

## RECOMMENDATIONS

RTAD after TEVAR is a serious potential complication that may occur either intraoperatively or during follow-up. Due to the substantial mortality of RTAD, larger registries are needed to provide the necessary information to better define a treatment strategy. Similarly, further studies are needed to clarify the role and incidence of spontaneous retrograde extension of type B dissection in patients both with and without previous TEVAR. Nevertheless, RTAD during or after TEVAR may be considered a new acute aortic syndrome based on its recent description, anatomical involvement, and clinical characteristics.

Definitive risk factors have not yet been identified, although it seems reasonable to note the potential of some conditions in predisposing RTAD, such as the presence of connective tissue disorders in patients affected by type B dissection. A predictive score might help physicians lessen the risk of RTAD, especially during TEVAR.

Efforts to minimize the occurrence of this complication may focus on several strategic elements:

*Careful patient selection.* Close attention to specific etiologies of the underlying aortic disease is extremely important. A "fragile aorta" looks more susceptible to developing RTAD, especially in patients with aortic dissection or those who are affected by connective tissue disorders.

## CASE REPORT

As reported in the *Journal of Vascular Surgery* in April 2010,[1] a 76-year-old man was referred to our department and presented with an asymptomatic penetrating thoracic aortic ulcer (PAU) that had developed from a previous acute aortic syndrome caused by a type B intramural hematoma that was managed medically. The preliminary thoracoabdominal computed tomographic (CT) scan showed an acute (60°) aortic arch with an enlarged (maximum diameter, 47 mm) ascending aorta and the presence of a PAU (Figure 1A). Under general anesthesia, the right common femoral artery was exposed in a standard fashion, and a single endograft (36-mm X 15-cm TAG, Gore & Associates, Flagstaff, AZ) was deployed during controlled hypotension (< 90 mm Hg), with planned partial overstenting of the origin of the left subclavian artery. To better adapt the endograft to the inner curve of the aortic arch, gentle ballooning was performed once inside the proximal extremity of the endograft. Final control imaging confirmed complete exclusion of the ulcer and adequate endograft adherence to the aortic curvature.

Four hours later, while the patient was being extubated, profound and persistent hypotension and a disparity of the pupils were noted. Immediately, CT angiography was performed, showing exclusion of the PAU but the development of an RTAD due to a proximal SINE with a retrograde extension to the ascending aorta and causing hemopericardium. Both the origin of the brachiocephalic trunk and the left common carotid artery were dissected, and the true lumen was compressed by the false lumen (Figure 1B).

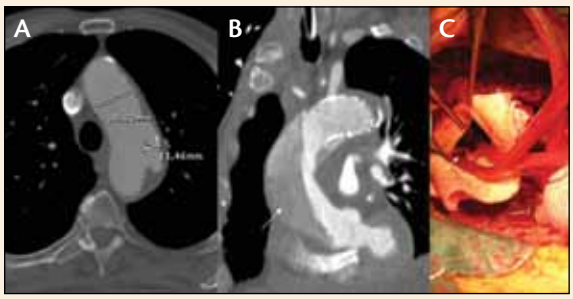


**Figure 1. A case of RTAD. Preoperative CT angiography scan before TEVAR for a penetrating aortic ulcer of the distal arch (A). Postoperative maximum intensity projection CT angiography (B) showing the RTAD involving the ascending aorta (arrow). Intraoperative view (C) showing the proximal SINE at the proximal edge of the endograft on the outer curve of the distal arch (arrow).**

Immediate surgical repair was performed of the total ascending/arch using hypothermic circulatory arrest. The ascending aorta and the proximal ventral part of the aortic arch were replaced with a 30-mm woven graft (Uni-Graft, B. Braun Interventional Systems, Inc., Bethlehem, PA) with epiaortic vessel reimplantation. The distal part of the graft was sutured to the proximal end of the endograft with a polypropylene suture. Intraoperatively, we confirmed the proximal SINE in correspondence to the proximal end of the endograft (Figure 1C).

1. Piffaretti G, Mariscalco G, Tozzi M, et al. Acute iatrogenic type A aortic dissection following thoracic aortic endografting. J Vasc Surg. 2010;51:993-999.

*Technical aspects.* Avoid excessive catheter and guidewire manipulations, landing zones in a severe angulation ("gothic arch") or in a dilated ascending aorta, and balloon dilatation when not absolutely required; oversizing of the endograft should be restricted to 10% in acute cases or "fragile aortas."

*Device options.* RTAD has been reported in all device configurations, either with or without bare springs. Many authors have urged manufacturers to provide an endograft designed specifically for use in difficult anatomies or delicate etiologies. This has led multiple manufacturers to address device implications and improve their platforms in this regard, particularly in terms of conformability to the aortic anatomy. Technology continues to develop, and additional endograft refinements may further decrease RTAD-related morbidity and mortality. ■

*Gabriele Piffaretti, MD, PhD, is a specialist staff surgeon with the Department of Surgery and Morphological Sciences, Circolo University Hospital, University of Insubria School of Medicine in Varese, Italy. He has disclosed that he has no financial interests related to this article. Dr. Piffaretti may be reached at +39-0332-393-259; gabriele.piffaretti@uninsubria.it.*

*Santi Trimarchi, MD, PhD, is an internal consultant of vascular surgery and Director of the Thoracic Aortic Research Center at the IRCCS Policlinico San Donato–San Donato Milanese in Milan, Italy. He has disclosed that he has no financial interests related to this article. Dr. Trimarchi may be reached at +39-02-5277-44-34; santi.trimarchi@unimi.it.*

*Patrizio Castelli, MD, FACS, is Chief of Vascular Surgery, Department of Surgery and Morphological Sciences, Circolo University Teaching Hospital, University of Insubria School of Medicine in Varese, Italy. He has disclosed that he has no financial interests related to this article. Prof. Castelli may be reached at +39-0332-393-575; patrizio.castelli@uninsubria.it.*

## THE VALIANT® THORACIC STENT GRAFT WITH THE CAPTIVIA® DELIVERY SYSTEM

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**Indications**
The Valiant® Thoracic Stent Graft with the Captivia® Delivery System is intended for the endovascular repair of isolated lesions (excluding dissections) of the descending thoracic aorta in patients having appropriate anatomy, including:

- iliac/femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- nonaneurysmal aortic diameter in the range of 18 – 42 mm (fusiform and saccular aneurysms/penetrating ulcers) or 18 mm to 44 mm (blunt traumatic aortic injuries); and
- nonaneurysmal aortic proximal and distal neck lengths ≥ 20 mm

**Contraindications**
The Valiant Thoracic Stent Graft with the Captivia Delivery System is contraindicated in:

- Patients who have a condition that threatens to infect the graft.
- Patients with known sensitivities or allergies to the device materials.

**Warnings and Precautions**
The long-term safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been established. All patients should be advised that endovascular treatment requires lifelong, regular follow-up to assess the integrity and performance of the implanted endovascular stent graft. Patients with specific clinical findings (for example, enlarging aneurysm, endoleaks, migration, or inadequate seal zone) should receive enhanced follow-up. Specific follow-up guidelines are described in the *Instructions for Use.* The Valiant Thoracic Stent Graft with the Captivia Delivery System is not recommended in patients who cannot undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures as described in the *Instructions for Use*. Strict adherence to the Valiant Thoracic Stent Graft sizing guidelines as described in the *Instructions for Use* is expected when selecting the device size. Sizing outside of this range can potentially result in endoleak, fracture, migration, infolding, or graft wear. The safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System has not been evaluated in some patient populations. Please refer to the product *Instructions for Use* for details.

**MRI Safety and Compatibility**
Nonclinical testing has demonstrated that the Valiant Thoracic Stent Graft is MR Conditional. It can be scanned safely in both 1.5T & 3.0T MR systems under certain conditions as described in the product *Instructions for Use*. For additional information regarding MRI please refer to the product *Instructions for Use*.

**Adverse Events**
Potential adverse events include, but are not limited to access failure, access site complications (e.g. spasm, trauma, bleeding, rupture, dissection), adynamic ileus, allergic reaction (to contrast, antiplatelet therapy, stent graft material), amputation, anaesthetic complications, aneurysm expansion, aneurysm rupture, angina, arrhythmia, arterial stenosis, atelectasis, blindness, bowel ischemia/infarction, bowel necrosis, bowel obstruction, branch vessel occlusion, buttock claudication, cardiac tamponade, catheter breakage, cerebrovascular accident (CVA) / stroke, change in mental status, coagulopathy, congestive heart failure, contrast toxicity, conversion to surgical repair, death, deployment difficulties / failures, dissection / perforation / rupture of the aortic vessel and/or surrounding vasculature, embolism, endoleak(s), excessive or inappropriate radiation exposure, extrusion / erosion, failure to deliver stent graft, femoral neuropathy, fistula (including aortobronchial, aortoenteric, aortoesophageal, arteriovenous, and lymph), gastrointestinal bleeding / complications, genitourinary complications, hematoma, hemorrhage / bleeding, hypotension / hypertension, infection and/or fever, insertion and removal difficulties, intercostal pain, intramural hematoma, leg /foot edema, lymphocele, myocardial infarction, neuropathy, occlusion – venous or arterial, pain / reaction at catheter insertion site, paralysis, paraparesis, paraplegia, paresthesia, peripheral ischemia, peripheral nerve injury, pneumonia, post-implant syndrome, procedural / postprocedural bleeding, prosthesis dilatation / infection / rupture / thrombosis, pseudoaneurysms, pulmonary edema, pulmonary embolism, reaction to anaesthesia, renal failure, renal insufficiency, reoperation, respiratory depression / failure, sepsis, seroma, shock, spinal neurological deficit, stent graft material failure (including breakage of the metal portion of the device / migration / misplacement / occlusion / twisting / kinking, transient ischemic attack (TIA), thrombosis, tissue necrosis, vascular ischemia, vascular trauma, wound dehiscence, wound healing complications, and/or wound infection.

Please reference product *Instructions for Use* for more information regarding indications, warnings, precautions, contraindications and adverse events.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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