Supplement to

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Endovascular TODAY

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# The Future of Aortic Therapy

## Key areas of ongoing global study regarding the expanding applicability of aortic endovascular repair.

- Next-Generation Devices for TEVAR
- Valiant Captivia Postmarket Registry
- The VIRTUE Registry
- Extending TEVAR Therapy
- Global TEVAR and EVAR Trials
- Breaking Barriers: Expanding the EVAR Population
- The ENGAGE Study
- Quality Imaging With 3D CTA for Aortic Endovascular Therapies

# Introduction

As global experience with the endovascular treatment of thoracic and abdominal aortic aneurysms continues to build, numerous clinical trials are underway evaluating stent graft use in a variety of other applications. Investigators are working to improve upon encouraging initial experiences and determine the degree to which endovascular repair can successfully treat challenging aortic indications such as type B dissection, traumatic injury, transection, and aneurysm rupture.

Research and further device development also continue in the arena of abdominal aortic aneurysm treatment. Next-generation endovascular systems feature advanced delivery system designs that allow for accurate stent graft placement and controlled deployment, and the stent grafts themselves are more flexible and better suited to treat patients with challenging anatomies.

The goal of these efforts is to expand the population of patients that can be treated. Due to emergent conditions, comorbid concerns, high risk for surgery, and difficult anatomies, many patients have insufficient options for treating their life-threatening aortic pathologies.

Accordingly, leading centers from around the world are enrolling patients in clinical trials and working with industry to develop devices that meet these challenging needs.

In this supplement to *Endovascular Today*, leading investigators provide overviews of their clinical endeavors, including the rationale for current trial designs and reports on available data. Also included are in-depth overviews of new thoracic and abdominal stent grafts and delivery systems, with experience-based discussions regarding how and when to best apply them.

Advanced imaging applications are also discussed, with an emphasis on preprocedural planning, accurate device sizing, precise stent graft placement, and efficient follow-up.

We hope this supplement is both helpful in your current endovascular practice and of interest regarding future applications and devices in the pipeline. ■

# Contents

# Next-Generation Devices for TEVAR

The Valiant Stent Graft: 30-day results from the VALOR II study.

BY RONALD M. FAIRMAN, MD

Originally modeled on devices for endovascular abdominal aortic repair (EVAR), devices for thoracic endovascular aortic repair (TEVAR) have evolved toward ever greater anatomic specificity, and the latest generation of thoracic stent grafts promises improved performance with respect to the unique characteristics of the aortic arch and descending thoracic aorta—extreme tortuosity, greater hemodynamic forces, remoteness from the sites of vascular access, and risk of iatrogenic injury.[1,2] The potential for complications (stent graft collapse, migration, fracture, endoleak, and retrograde type A aortic dissection) due to poor proximal alignment and apposition of the stent graft is better understood, and the risks for neurologic embolic complications and spinal cord ischemia with attendant paraplegia and paraparesis are better defined (along with the indications for adjunctive procedures such as left subclavian artery bypass and cerebrospinal fluid drainage).[3-7] Vascular access for large-diameter thoracic devices has remained a major challenge, particularly in elderly women with small, calcified, stenotic external iliac arteries.[3,8,9]

The Valiant Thoracic Stent Graft (Medtronic, Inc., Minneapolis, MN) (Figure 1) is an evolution of the Talent Thoracic Stent Graft (Medtronic, Inc.),[9] with new features specifically addressing TEVAR issues identified by earlier studies. Since 2005, when the device received Conformité Européenne (CE) Mark, the Valiant Thoracic Stent Graft has been employed for repair of thoracic aortic lesions in clinical practice outside the United States.[10-12] In the United States, the Valiant Thoracic Stent Graft is currently being investigated under an investigational device exemption (IDE) in the VALOR II prospective, multicenter, single-arm trial.

**Figure 1. The Valiant Thoracic Stent Graft.**

## THE VALIANT THORACIC STENT GRAFT SYSTEM

The Valiant is a modular device consisting of a woven monofilament polyester graft sutured to a self-expanding nitinol wire stent. The nitinol scaffolding of the stent graft is composed of a series of serpentine 5-peaked springs stacked in a tubular configuration and sewn to the outside (not the inside, as with the Talent Thoracic Stent Graft) of the graft material, the raised surface of the springs providing additional mechanical interference as the device is modeled into the vessel wall. The proximal and distal stents have an 8-peak configuration (as compared to the 5-peak configuration of the Talent device) that distributes radial force across more points of contact with less stress per point, allowing for excellent sealing characteristics while offering a softer interface with the

aortic wall. To increase graft flexibility and conformability, the longitudinal connecting bar of the Talent device has been eliminated in the Valiant, and the spring spacing has been redesigned to allow adjacent peaks to contact each other and provide the necessary column strength for deployment. To facilitate tailoring of the device to particular aortic pathologies, the proximal stent graft is available in FreeFlo configuration, and the distal grafts are available in closed-web, straight, tapered, and bare-spring configurations. The FreeFlo configuration has a bare proximal spring extending beyond the edge of the fabric, whereas the closed-web design does not have bare proximal springs.

The Valiant Thoracic Stent Graft has been evaluated most extensively in the real-world TRAVIATA (Thoracic Repair Analysis Using Valiant in Indications of the Thoracic Aorta) retrospective multicenter registry, from which 3-year results have been published.[12] In TRAVIATA, 92 patients underwent TEVAR for degenerative aneurysm (60.8%), aortic dissection (34.8%), and traumatic injury (4.4%) at four German centers between June 2005 and March 2008. The technical success rate was 86.9%. Periprocedural complications included endoleak (6.5%), systemic complications (6.5%), arterial rupture or dissection (6.5%), device-related complications (5.4%), retrograde aortic dissection (1.1%), aortic rupture (1.1%), spinal cord ischemia (1.1%), and stroke (1.1%). Through 30 days there were three deaths (3.3%). The rate of aneurysm-related mortality was 2.2%. Cumulative survival was 95.5% at 1 year, 87.4% at 2 years, and 76.4% at 3 years. No patients were converted to open surgery during the 3-year follow-up.

## VALOR II: PRELIMINARY 30-DAY RESULTS

VALOR II is a prospective, multicenter, single-arm IDE trial conducted in the United States to evaluate the safety and effectiveness of the Valiant Thoracic Stent Graft System for treating thoracic aortic aneurysms (TAAs) in the descending thoracic aorta. Enrollment of 160 patients occurred from December 2006 to September 2009 at 24 institutions across the United States. Eligible patients were considered candidates for open surgical repair of TAA with low to moderate risk (0, 1, and 2) per the modified Society for Vascular Surgery/American Association for Vascular Surgery criteria. Indications for inclusion in the trial were fusiform TAA $\geq$ 5 cm or $\geq$ 2 times the diameter of the nonaneurysmal thoracic aorta and/or focal saccular TAA (penetrating atherosclerotic ulcers). Anatomical eligibility criteria included TAA $\geq$ 20 mm distal to the origin of the left common carotid artery and $\geq$ 20 mm proximal to the celiac artery, proximal and distal nonaneurysmal aortic neck diameter of between 20 and 42 mm, and proximal and distal nonaneurysmal aortic neck lengths of $\geq$ 20 mm. VALOR II exclusion criteria included planned placement of the covered portion of the stent graft in zone 0 or 1 of the aortic arch, TAA with contained rupture, and connective tissue disease. Standard follow-up evaluations were performed at 1, 6, and 12 months, and annually thereafter. Follow-up visits included a computed tomography (CT) scan, chest radiograph, and physical examination.

The primary safety endpoint of VALOR II is 12-month all-cause mortality. The primary effectiveness endpoint is 12-month successful aneurysm treatment, defined as the absence of (1) > 5-mm aneurysm growth between 1 and 12 months and (2) type I and/or type III endoleak for which a secondary procedure was performed or recommended. The 30-day secondary endpoints included perioperative mortality, paraplegia, paraparesis, secondary procedures due to endoleak after discharge, and major adverse events.

The mean age of VALOR II patients at baseline was 72.2 ± 9.1 years, and 59.4% were men. The baseline risk profile of the VALOR II patients was similar to that for other TEVAR trials, including the VALOR trial of the Talent device[9] and the report on 443 TEVAR procedures in the EUROSTAR and United Kingdom Thoracic Endograft registries.[13] Concomitant vascular conditions included abdominal aortic aneurysms (AAAs) in 38.8%, previous AAA repair in 20.6%, ascending thoracic aneurysm in 8.1%, and peripheral vascular disease in 25%. At enrollment, 50 of the 160 patients (31.3%) had aneurysm-related symptoms. Core laboratory preimplant mean anatomical dimensions included maximum aneurysm diameter 57 ± 11.03 mm and aneurysm length 123.25 ± 73.02 mm. Vessel access was successful in 98.1% of patients, and device delivery and deployment in 96.3%. Three patients did not receive the study device because of access failure. There were two instances of misaligned deployment (bare spring flip). A mean number of 1.8 ± 0.8 stent graft devices (range, 1–4) were implanted per patient.

Through 30 days postimplantation, five of 160 VALOR II patients (3.1%) died; three of these deaths (1.9%) were adjudicated (by the clinical events committee) as aneurysm related. Causes of deaths included aortic rupture, aortic dissection, multiorgan failure, pneumonia, and respiratory failure. Through 30 days, there were no conversions to open surgery, and no patient experienced aneurysm rupture. One secondary procedure was performed at day 9 postimplantation to resolve a type I endoleak. One or more major adverse events occurred in 38.1% (61 of 160) of the VALOR II patients $\leq$ 30 days after implantation. Four VALOR II patients had a periprocedural stroke (2.5%). Postoperative paraplegia and para-

paresis ≤ 30 days occurred in one patient (0.6%) and three patients (1.9%), respectively. Through 30 days, the rates of site-reported endoleak were type I, 0.7%; type II, 3.4%; type III, 0.0%; and type IV, 0.0%.

## THE NEXT-GENERATION CAPTIVIA TEVAR DELIVERY SYSTEM

For both TRAVIATA and VALOR II, the Valiant Stent Graft was compressed and preloaded on the Xcelerant Delivery System (Medtronic, Inc.), consisting of a flexible single-use disposable catheter, compatible with a 0.035-inch guidewire, with an integrated handle intended to provide a mechanical advantage and lower user deployment force. The Valiant System is inserted through the femoral or iliac artery via surgical incision and advanced to the lesion site, where upon withdrawal of the delivery sheath, the stent graft self-expands to conform to the vessel morphology and exclude the aneurysm.

The next-generation Captivia Delivery System (Medtronic, Inc.) adds to the Xcelerant feature set a novel tip capture mechanism for more controlled deployment of the FreeFlo proximal stent grafts to avoid the windsock effect and to stabilize the graft at the targeted landing zone. With the tip capture mechanism, deployment occurs in two stages: (1) deployment of the stent graft with the FreeFlo stent still constrained, then (2) release of the FreeFlo stent. A hydrophilic coating has also been applied to the graft cover of the delivery system to facilitate vascular access and enhance stent graft delivery through tortuous iliac and aortic courses.

The Captivia Delivery System received CE Mark in October 2009 and is currently under investigation in two trials. In the United States, it has been evaluated with the Talent Thoracic Stent Graft in 20 high-risk patients as a continuation of the high-risk arm of the VALOR study, the pivotal trial of the Talent Thoracic Stent Graft as compared with retrospective surgical data.[9] The Talent Thoracic Stent Graft with the Captivia Delivery System has received FDA clearance and introduction to the US market is planned. Outside the United States, the Captivia Delivery System is being evaluated with the Valiant Thoracic Stent Graft in 100 patients in more than 20 sites across Europe. ■

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# Valiant Captivia Postmarket Registry

Preliminary results from the multicenter, postmarket, noninterventional, prospective study.

BY ROSSELLA FATTORI, MD

With improved graft performance and recent technical evolution, endovascular repair is becoming the first-line treatment for a broad range of thoracic aortic disease etiologies. Nevertheless, there are still some cases in which the native aortic anatomy is challenging or even prohibitive. In particular, native arch anatomy can be deemed unsuitable, as short neck lengths, tortuosity, and angulation may result in imprecise deployment and endoleak due to lack of stent graft conformability. The Valiant Thoracic Stent Graft on the Xcelerant Delivery System (Medtronic, Inc., Minneapolis, MN) has been broadly available outside the United States since 2005, with over 22,000 patients treated worldwide in just 5 years of clinical experience. It has emerged as a preferred thoracic stent graft mainly due to its hallmark feature of conformability, broad patient applicability, and ease of use.

## THE CAPTIVIA DELIVERY SYSTEM

The Captivia Delivery System, used in conjunction with the Valiant Thoracic Stent Graft (Figure 1), received CE Mark approval and was introduced in September 2009. The Captivia Delivery System has several key features that may contribute to the successful introduction, delivery, placement, and conformability of the stent graft in challenging thoracic aortic anatomies. First, the addition of hydrophilic coating on the graft cover of the delivery system facilitates vascular access and enhances stent graft delivery through tortuous iliac and aortic courses (Figure 2). Second, the dual control of the delivery system allows partial deployment with the opportunity to reposition for precise placement, which is especially important when accurate placement in short landing zones is critical (Figure 3). Third, the tip capture feature further enhances control during proximal stent graft deployment, avoiding the windsock effect and stabilizing the graft at the targeted landing zone (Figure 4). These new features associated with the Captivia Delivery System in combination with the Valiant Thoracic Stent Graft are designed to expand treatment to more patients with complex aortic disease and ultimately improve patient outcomes.

## REGISTRY DESIGN

A postmarket registry to collect and evaluate short- and midterm clinical performance of the Valiant Thoracic Stent Graft with the Captivia Delivery System is being conducted in Europe and Turkey. Sixteen centers have enrolled 100 patients with a variety of conditions such as thoracic aortic aneurysm, type B dissection, penetrating aortic ulcer, and blunt aortic injury. Patients are followed per standard of care at the investigational sites with imaging and clinical follow-up.

**Figure 1. The Valiant Thoracic Stent Graft with the Captivia Delivery System.**

**Figure 2. The system's hydrophilic coating spans 65 to 70 cm of the graft cover.**

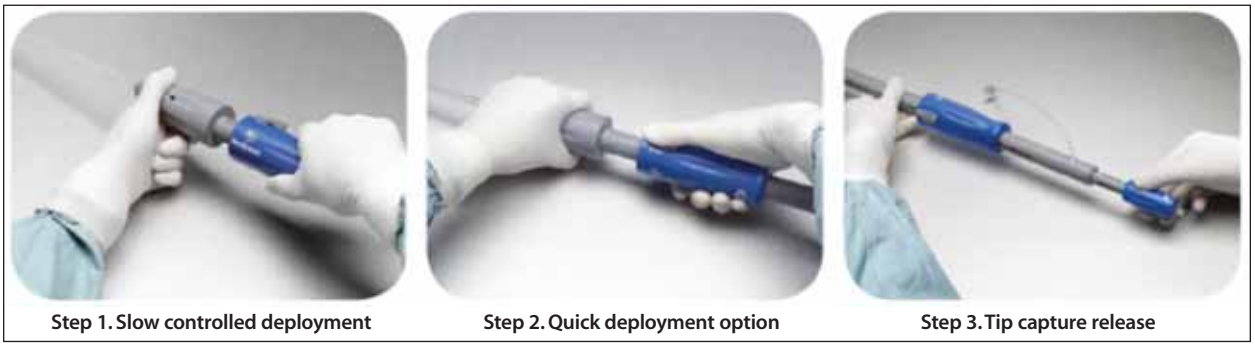


**Figure 3. The Captivia Delivery System's easy, three-step process allows for slow, controlled deployment but offers a quick deployment option as well.**

The primary endpoints of the registry are technical success at the time of implant and treatment success at 12 months. In addition, a 30-day analysis is being conducted to evaluate acute performance. Technical success is defined as successful delivery and deployment of the stent graft (assessed intraoperatively) in the planned location with no unintentional coverage of the left subclavian artery, left common carotid artery, and/or brachiocephalic artery and with the removal of the delivery system. The secondary endpoints for the 30-day analysis are procedural complications at the time of implant, including misaligned deployment and aortic perforation, and clinical outcomes within 30 days of implantation, including all-cause mortality, paraparesis/paraplegia, secondary endovascular procedures due to an endoleak after discharge, and one or more major adverse events.

## RESULTS

This report summarizes the 30-day analysis of the first 50 subjects enrolled. One hundred percent of this 30-day data has been monitored to ensure compliance with the clinical investigation plan and to assess the accuracy and completeness of submitted clinical data. Among the first 50 patients, there were 39 men and 11 women (mean age, 64. 2 ± 13). Aneurysm and dissection were the most common disease etiology, with 20% of acute type B dissection, but traumatic transection and pseudoaneurysm were also present. Comorbidities and preexisting conditions were present in more than 50% of patients, including hypertension, previous cerebrovascular accident, dyslipidemia, abdominal aneurysm, and Marfan syndrome. Anatomical characteristics showed a mean diameter of 53 mm (± 14.8 mm), a mean aneurysm extension of 109 mm (± 96 mm), and a mean proximal neck length of 34.8 mm (± 34.5 mm). Interestingly, in five patients, the proximal neck length was less than 10 mm, and two out of 50 patients had a diameter of the femoral/iliac arteries less than 7 mm.

Deployment was successful at the intended landing zone in all patients without migration or twisting. At 30-day follow-up, there were no observations of type I or type III endoleak. The left subclavian artery was covered in 25 of 50 patients (of which none were unintentional), 12 of whom had previous revascularization. Clinical outcome at 30 days showed a mortality rate of 6%, an incidence of stroke of 8%, and a paraplegia rate of 2%. These data are in line with previous reports, considering 20% of this patient cohort was treated for acute, complicated type B dissection.

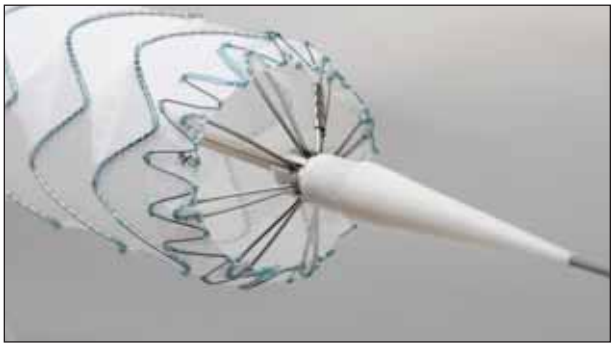

**Figure 4. The system's tip capture feature aids in graft stabilization for accurate placement.**

## CONCLUSION

The interim analysis of the first 50 patients treated with the Valiant Thoracic Stent Graft with the Captivia Delivery System confirms high device conformability that is able to adapt to a broad range of patient anatomies, with no incidence of misaligned deployment or twisting. Hydrophilic coating facilitated iliac access and stent graft delivery, which was exemplified in two patients who had ≤ 7-mm femoral arteries. Early outcomes confirm stent graft reliability with no incidence of endoleak or migration. ■

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# The VIRTUE Registry

The VIRTUE registry is designed to assess thoracic endografting with the Valiant Stent Graft System for the treatment of type B aortic dissections.

BY MATT THOMPSON, MD, FRCS

Despite the relative infancy of thoracic endografting, these procedures are now routinely used in the treatment of type B aortic dissection. The early results of endovascular treatment of acute complicated type B dissections are reasonably well characterized and suggest a substantial early mortality advantage over open surgical treatment. A recent report from the US inpatient sample has identified a considerable mortality advantage over conventional surgical repair. Less certain is the place of endovascular therapy for chronic type B dissections or in lesions that may be classified as subacute (between 2 and 6 weeks after the onset of dissection). There is relatively sparse literature reporting the outcomes of endovascular therapy in nonacute dissections.

The majority of contemporary reports detail the acute outcomes of endovascular therapy in type B aortic dissection, but the long-term outcomes are less well characterized. The incidence of graft-related complications has not been described in sufficient detail, and information regarding the long-term protection from aortic dilatation and rupture is lacking. One of the fundamental differences in the treatment of thoracic aneurysms as compared to the treatment of type B dissections is the ability of the aorta to remodel following endovascular repair. There have been some reports that suggest the aorta of acute type B dissection remodels more extensively than chronic dissections, but the remodeling of subacute dissections remains a matter of conjecture.

The VIRTUE registry was designed to evaluate the performance of one particular endograft, the Valiant Stent Graft System (Medtronic, Inc., Minneapolis, MN), in the treatment of type B aortic dissection. The registry will report the results of patients treated in the acute, subacute, and chronic phases of the disease process and will inform on both clinical and morphological outcomes. The registry aims to report outcomes to a follow-up of 3 years. The present report details the design of the VIRTUE registry. The early outcomes will be published in the *European Journal of Vascular and Endovascular Surgery* later this year.

## METHODS AND STUDY DESIGN

The VIRTUE registry is a prospective, nonrandomized, multicenter European Clinical Registry designed to inform on the clinical and morphological outcomes of 100 patients with type B aortic dissection treated with the Valiant Thoracic Stent Graft with the Xcelerant Delivery System (Medtronic, Inc.). The primary endpoint of the registry is all-cause mortality at 12 months post-procedure. Secondary endpoints include all-cause mortality, disease-, procedure-, or device-related mortality, major complications, technical success, procedural success, reintervention, and graft-related complications. Endpoints will be recorded at 30 days (or the end of inpatient stay if longer) 3, 6, 12, 24, and 36 months. Aortic morphology will be reported after analysis of cross-sectional imaging by a core laboratory.

Written informed consent will be obtained before enrollment. Patients will be considered for inclusion in the registry if they had a type B dissection amenable to endovascular treatment and were over 18 years of age. Specific indications for inclusion were documented by the duration of the disease and were at the investigators' clinical discretion. Examples of inclusion criteria include:

- Acute dissection (14 days from first dissection): aortic rupture, malperfusion syndromes (visceral, renal, lower limb), impending rupture (persistent pain), and refractory hypertension.
- Subacute dissection (15–92 days): complicated/symptomatic dissection, aortic expansion > 5.5 cm, and aortic diameter > 4 cm with true and false lumens both patent.
- Chronic dissection (> 92 days): complicated/symptomatic dissection, aortic diameter > 5.5 cm, or expanding > 0.5 cm/year.

Exclusion criteria included patients with a dissection involving the ascending aorta, penetrating ulcers and intramural hematoma in the absence of dissection, ongo-

ing infection, an estimated life expectancy < 12 months, documented connective tissue disease (eg, Marfan syndrome), and patients with a history of bleeding diathesis.

Patients were recruited from the following centers: St. Antonius Ziekenhuis, Nieuwegein, The Netherlands (Dr. R. Heijmen, 20 patients); Ospedale Sant'Orsola Malpighi, Bologna, Italy (Dr. R. Fattori, 19); St George's Vascular Institute, London, United Kingdom (Prof. M. Thompson [Principal Investigator],16); Universitätsspital Bern, Inselspital, Switzerland (Prof. Dai-Do Do, 9); Universitätsklinikum Essen, Germany (Dr. H. Eggebrecht, 7); Onze-Lieve-Vrouw Ziekenhuis, Aalst, Belgium (Dr. I. Degrieck, 7); University School of Medicine Rostock, Germany (Prof. C. Nienaber, 6); St. Mary's Hospital London, England (Prof. N. Cheshire, 5); Unità di Chirurgia Vasc, Ospedale R. Silvestrini, Perugia, Italy (Prof. P. Cao, 3); Herz-Kreislauf Zentrum der Universität Freiburg, Germany (Dr. Rylski, 2); Sahlgrenska University Hospital, Goteborg, Sweden (Prof. L. Lonn, 2); Azienda Osp Santa Maria della Misericordia, Udine, Italy (Dr. D. Gasparini, 2); Hospital Clínico Universitario San Cecilio, Granada, Spain (Prof. E. Ros Die, 1); Hospital Universitario La Paz, Madrid, Spain (Dr. G. Garzon, 1).

Cross-sectional imaging will be analyzed by a core laboratory (University of Utrecht, The Netherlands) at specified time points. Briefly, measurements will include the aortic diameter and area of both true and false lumen at four specified anatomical sites (ascending aorta, origin of the left subclavian artery, 10 cm distal to the origin of the left subclavian artery, and the origin of the celiac trunk). The true lumen index, the false lumen index, and the true/false lumen ratio will be calculated. The state of the false lumen in terms of thrombosis (patent, partially thrombosed, or thrombosed) will be documented.

## EARLY RESULTS

The early results of the study are now available and will be reported this year in the *European Journal of Vascular and Endovascular Surgery*. This registry, specific to dissections, will inform on the long-term durability of endovascular repair in this pathology. Interestingly, the rapid pace of device evolution is evidenced by the introduction of a new delivery system for the Valiant Stent Graft, the Captivia Delivery System, which incorporates a tip capture feature for enhanced control for precise stent graft placement. ■

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# Extending TEVAR Therapy

Two new trials for US indications for descending thoracic aortic dissections and traumatic transections.

BY RODNEY A. WHITE, MD

Treatment of thoracic aortic lesions using endografts has progressed rapidly, with three manufacturers in the United States having indications for aortic aneurysms in the descending thoracic aorta that have adequate proximal and distal landing zones. Depending on the studies that were performed, some of the devices also have an indication for exclusion of penetrating ulcers. Based on the demonstrated utility of the thoracic aortic device and supported by studies that have been performed inside the United States and in international sites, adaptation of this technology to descending thoracic aortic dissections and traumatic transections is developing rapidly. Currently, it is estimated that approximately 50% of thoracic device use in the United States is for treating lesions outside of the instructions for use (IFU) indications, with the majority of these procedures being for descending thoracic aortic dissections and traumatic transections.

Because of the rapid expansion of the use of this technology, several companies have responded to the need to expand the IFU to include indications for dissections and transections. The US Food and Drug Administration (FDA) has also recognized the potential utility of these technologies and is considering innovative study options that would appropriately expedite approval of these devices if data can be captured in appropriately designed trials. As an example of this collaboration, the FDA is willing to consider data from acute complicated dissection and traumatic aortic disruption patients treated with thoracic endovascular aortic repair (TEVAR) under multiple physician-sponsored Investigational Device Exemptions (PS-IDEs) as a control, supplemented by historical reference data. The PS-IDE data that are available were collected by a multidisciplinary group of physicians (including members of the Society of Thoracic Surgeons, Society of Interventional Radiology, and Society for Vascular Surgery [SVS]) and coordinated by the SVS Outcomes Committee. The SVS outcomes data have been submitted as a Master File to the FDA and have been made available to manufacturers as a point estimate for comparison to clinical study outcomes in patient populations in which randomized studies are not feasible.[1,2]

In response to the need to broaden the IFU indications for TEVAR devices, Medtronic, Inc. (Minneapolis, MN) has initiated two studies in the United States that are designed to address expansion of the IFU for the lat-

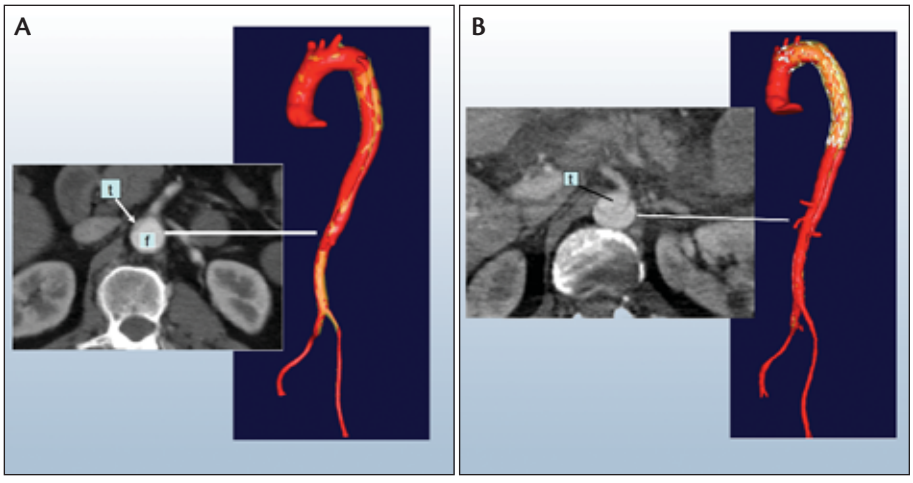


**Figure 1. M2S reconstruction (M2S, Inc., West Lebanon, NH) of the thoracoabdominal aorta showing the descending aortic dissection with near occlusion of the true lumen (t) in the visceral segment as shown on the centerline computed tomographic (CT) image at the level of the superior mesenteric artery, producing abdominal and peripheral ischemia (f, false lumen) (A). M2S reconstruction of the thoracoabdominal aorta 2 days after deployment of a Valiant Thoracic Stent Graft (Medtronic, Inc., Minneapolis, MN) showing partial expansion of the true lumen (t) with reperfusion of the visceral arteries and reconstitution of flow to the lower extremities (B).**

est-generation thoracic stent graft, the Valiant Thoracic Stent Graft with the Captivia Delivery System, to include treatment of patients with descending thoracic dissections and traumatic transections. The Valiant Thoracic Stent Graft's hallmark feature of high conformability meets the engineering and clinical design parameters for these new indications. The Captivia Delivery System has a deployment mechanism that controls release of the proximal FreeFlo stent until the entire length of the stent graft has been deployed. This tip-capture mechanism enhances precise positioning of the device and enables proximal device conformation to acutely angled thoracic aortic arch anatomy.

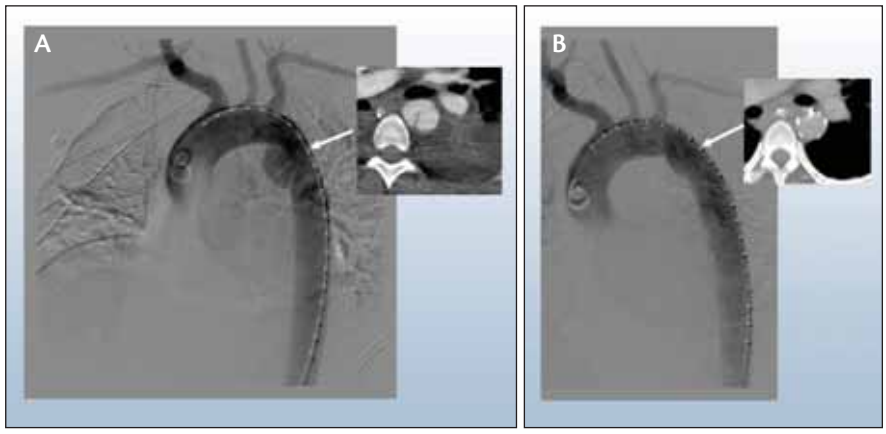


**Figure 2. Preintervention angiogram and CT of an acute aortic traumatic injury (A) and 2-week postprocedure angiogram and CT of the aorta after placement of the Valiant thoracic device (B).**

## MEDTRONIC DISSECTION TRIAL

This study was designed to evaluate the clinical safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the endovascular treatment of acute complicated type B dissections of the descending thoracic aorta.

The study is currently enrolling 50 to 84 subjects at up to 25 centers. The criteria for inclusion into the Medtronic Dissection Trial include patients with acute complicated descending thoracic aortic dissections admitted to the hospital within 14 days of symptom onset and treatment of the dissection within the index hospitalization. The type B Stanford classification dissections have an entry site originating in the descending thoracic aorta with the entry being at least 20 mm distal to the proposed proximal fixation site. Eligible patients must have a type B dissection that is complicated by either malperfusion as demonstrated by either visceral, renal, spinal cord, and/or lower limb ischemia, or by rupture.

The Premarket Approval Application (PMA-S) will be filed after all subjects reach 1-year postimplant, and all subjects will be followed for 5 years after the procedure.

Figure 1 shows a patient who presented with acute malperfusion treated with the Valiant Thoracic Stent Graft as part of a single-center IDE approved by the FDA.

## THE RESCUE TRIAL

The RESCUE trial was designed to evaluate the clinical safety and effectiveness of the Valiant Thoracic Stent Graft with the Captivia Delivery System in the endovascular treatment of blunt thoracic aortic injury in adult patients. The study is enrolling 50 patients in up to 25 sites. Patients will be followed to 5 years, but a PMA-S will be filed after all subjects have reached 30-day postimplant. The emphasis in this study is to evaluate what appears to be a clear trend indicating lower morbidity and mortality rates in patients with traumatic aortic injury treated with TEVAR. The intent is to obtain not only procedural success rates but also longer-term follow-up to record secondary complications related to the devices in a younger population of trauma victims. Figure 2 shows an acute traumatic aortic disruption that was treated using the Valiant Thoracic Stent Graft that was enrolled in a single-center IDE approved by the FDA. ■

*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 and/or receives grant/research funding from Medtronic, Inc., Abbott Vascular, Cordis Corporation, Endologix, Inc., Endomed, Inc., Nellix, Inc., Volcano Corporation, and W. L. Gore & Associates. Dr. White may be reached at rawhite@ucla.edu.*

1. White RA, Miller DC, Criado FJ, et al. Report of results of TEVAR for acute, complicated type B aortic dissection at 30 days and 1 year from IDE trials. From the Society for Vascular Surgery (SVS) Outcomes Committee. J Vasc Surg. In press.

2. Dake MD, White RA, Diethrich EB, et al. Report on endografts management of traumatic thoracic aortic transections at 30 days and 1 year from IDE trials. A report for the Society for Vascular Surgery (SVS) Outcomes Committee. J Vasc Surgery. In press.

# THORACIC AORTIC ENDOGRAFT TRIALS

| Sponsor | Trial Name |
|---|---|
| Azienda Opsedaliera Universitaria di Bologna Policlinico S. Orsola Malpighi | ATLANTIS: Extensive Type A Dissections and Thoracic/Thoracoabdominal Aneurysms Repair With Lupiae Hybrid Technique |
| Bolton Medical | Phase II Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent Graft in Patients With Thoracic Aortic Pathologies |
| Cleveland Clinic | Endovascular Exclusion of Thoracic Aortic Aneurysms |
| Cook Medical | Evaluation of the Safety and Effectiveness Performance of the Zenith Dissection Endovascular System in the Treatment of Patients With Aortic Dissection Involving the Descending Thoracic Aorta |
| | Zenith TX2 Low Profile TAA Endovascular Graft Clinical Study |
| | Zenith TX2 TAA Endovascular Graft Postapproval Study |
| | Zenith TX2 TAA Low-Profile Endovascular Graft Clinical Study |
| LeMaitre Vascular, Inc. | A Phase I Feasibility Study of the TAArget Thoracic Stent Graft for the Treatment of Aneurysms in the Descending Thoracic Aorta (ENTRUST) |
| Medtronic, Inc. | Valiant CAPTIVIA Postmarket Registry: Multicenter, Postmarket, Noninterventional, Prospective Study |
| | Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft with the Captivia Delivery System for the Endovascular Treatment of Blunt Thoracic Aortic Injuries (RESCUE) |
| | Valiant Thoracic Stent Graft With the Captivia Delivery System: Evaluation of the Clinical Performance of the Valiant Thoracic Stent Graft with the Captivia Delivery System (Valiant Captivia) for the Treatment of Acute, Complicated Type B Aortic Dissections |
| | Descending Thoracic Aortic Aneurysm Endovascular Repair Post-approval Study (THRIVE) |
| | VIRTUE Registry of Type B Thoracic Dissections |
| | VALOR II: Prospective, Controlled, Multicenter, Evaluation of Valiant with the Xcelerant Delivery System |
| TriVascular, Inc. | A Pilot Trial to Evaluate the Performance of the TriVascular Thoracic Stent Graft System |
| University of Arizona | A Phase II Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent Graft in Patients With Thoracic Aortic Pathologies |
| University of California, San Francisco | Endovascular Exclusion of Thoracoabdominal and/or Paravisceral Abdominal Aortic Aneurysm |
| W. L. Gore & Associates | Conformable Gore TAG Device in Acute Complicated Type B Dissections |
| | Conformable Gore TAG Device Traumatic Aortic Transection Trial |
| | Conformable Gore TAG Device in Thoracic Aortic Aneurysm Trial |

*Abbreviations: PAU, penetrating aortic ulcer; PVAAA, paravisceral abdominal aortic aneurysm; TAA, thoracic aortic aneurysm; TAAA, thoracoabdominal aortic aneurysm; TSX*

| | Endograft | Pathology | Identifier | Status | Location |
|---|---|---|---|---|---|
| | Arch reconstruction with thoracic endograft | Type A dissection, TAA | NCT01107366 | Pending | Azienda Opsedaliera Universitaria di Bologna Policlinico S. Orsola Malpighi, Italy |
| | Relay Thoracic Stent Graft | TAA | NCT00435942 | Recruiting | US |
| | Research device | Ascending and descending thoracic aorta | NCT00583817 | Recruiting | Cleveland Clinic (US) |
| | Zenith TX2 with Zenith Dissection Stent | Type B dissection | NCT00526487 | Recruiting | Europe |
| | Zenith TX2 LP | TAA, PAU | NCT01151020 | Recruiting | US |
| | Zenith TX2 | TAA, PAU | NCT00813358 | Recruiting | US |
| | Zenith TX2 | TAA, PAU | NCT00923754 | Recruiting | Europe |
| | TAArget | TAA | NCT01033214 | Recruiting | US |
| | Valiant with Captivia Delivery System | Descending thoracic aortic pathology | NCT01181947 | Enrollment completed | Europe |
| | Valiant with Captivia Delivery System | TSX | NCT01092767 | Recruiting | US |
| | Valiant with Captivia Delivery System | Type B dissection | NCT01114724 | Recruiting | US |
| | Talent Thoracic Stent Graft | TAA | NCT00805948 | Recruiting | US |
| | Valiant Thoracic Stent Graft | Type B dissection | NCT01213589 | Enrollment completed | Europe |
| | Valiant Thoracic Stent Graft | TAA in descending thoracic aorta | NCT00413231 | Enrollment completed | US |
| | TriVascular Thoracic Stent Graft | TAA | NCT01082172 | Recruiting | South America |
| | Relay Thoracic Endograft | TAA, PAU | NCT00998491 | Recruiting | University of Arizona (US) |
| | Branched endograft | TAAA, PVAAA | NCT00483249 | Recruiting | University of California, San Francisco (US) |
| | C-TAG | Type B dissection | Gore TAG 08-01 IDE | Recruiting | US |
| | C-TAG | TSX | Gore TAG 08-02 IDE | Recruiting | US |
| | C-TAG | TAA | Gore TAG 08-03 IDE | Recruiting | US |

*traumatic aortic transection.*

Courtesy of John A. Kaufman, MD, MS

## ABDOMINAL AORTIC ENDOGRAFT TRIALS

| Sponsor | Trial Name | Endograft |
|---|---|---|
| Aptus Endosystems | The Pivotal Study of the Aptus Endovascular AAA Repair System (STAPLE-2) | Aptus Repair System |
| CardioMEMS | Pressure and Imaging—Using the CardioMEMS EndoSure Sensor for Long-term Follow-up After Endovascular Aneurysm Repair (EVAR) (PRICELESS) | CardioMEMS |
| Cook Medical | Zenith Low Profile AAA Endovascular Graft Clinical Study | Zenith LP Endovascular Graft |
| | Acute Technical Outcomes of the Talent Abdominal Aortic Aneurysm (AAA) Stent Graft Versus Cook Zenith Stent Graft | Cook Zenith and Medtronic Talent Stent Grafts |
| Cordis Corporation | A Study Of Incraft In Subjects With Abdominal Aortic Aneurysms (INNOVATION) | Incraft System |
| Endologix | Percutaneous Endovascular Aneurysm Repair (PEVAR) Trial | PEVAR (ProGlide closure), SEVAR (IntuiTrak), PEVAR (Prostar XL closure |
| | 34-mm Cuff Study for Endovascular Repair of Abdominal Aortic Aneurysms | Endologix Powerlink stent graft |
| | Powerlink | PowerLink System |
| | Powerlink Bifurcated Stent Graft Long-Term Follow-up Study | PowerLink System |
| | PEVAR Trial | ProGlide/IntuiTrak/Prostar XL |
| Lombard | Prospective Aneurysm Trial: High Angle Aorfix Bifurcated Stent Graft (PYTHAGORAS) | Aorfix AAA bifurcated stent graft |
| Medtronic, Inc. | Endurant Bifurcated and AUI Stent Graft System | Endurant Stent Graft System |
| | Talent Abdominal Converter Stent Graft Postapproval Study | Talent AUI Stent Graft |
| | Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE) | Endurant Stent Graft |
| | Postapproval of Talent Abdominal Stent Graft to Treat AAA (VITALITY) | Talent Abdominal Stent Graft |
| Lawson Health Research Institute | Evaluation of the Endovascular Repair for Aortic Aneurysm (EVAR) Program at LHSC | Open repair vs EVAR |
| Imperial College London | Immediate Management of the Patient With Aneurysm Rupture: Open Versus Endovascular Repair (IMPROVE) | Open repair vs EVAR |
| UMC Utrecht | Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial | Open repair vs EVAR |
| Terumo CVS; Vascutek Ltd. | The Vascutek Anaconda Stent Graft System Phase II IDE Study | Anaconda Stent Graft System |
| TriVascular, Inc. | A Phase I Evaluation of the Safety of the TriVascular Stent Graft System in the Treatment of Abdominal Aortic Aneurysms (AAA IDE) | Ovation Abdominal Stent Graft System |
| | TriVascular European Union (EU) Abdominal Stent Graft Trial | TriVascular Aortic Stent Graft |
| | Clinical Study of the TriVascular Abdominal Stent Graft System | TriVascular AAA Stent Graft |

*Abbreviations: AAA, abdominal aortic aneurysm; AUI, aorto-uni-iliac.*

| | Pathology | Status | Location | Identifier |
|---|---|---|---|---|
| | AAA | Active, not recruiting | US | NCT00507559 |
| | AAA | Enrolling by invitation | N/A | NCT00831870 |
| | AAA | Recruiting | US | NCT00833924 |
| | AAA | Recruiting | US | NCT00922454 |
| | AAA | Recruiting | Europe | NCT01106391 |
| | AAA | Enrolling by invitation | US | NCT01070069 |
| | AAA | Active, not recruiting | N/A | NCT00706394 |
| | AAA | Completed | US | NCT00543270 |
| | AAA | Completed | N/A | NCT00543270 |
| | AAA | Enrolling by invitation | N/A | NCT01070069 |
| | AAA | Recruiting | N/A | NCT00522535 |
| | AAA | Bifurcated enrollment completed, AUI recruiting | US | NCT00705718 |
| | AAA | Recruiting | US | NCT01129609 |
| | AAA | Recruiting | World | NCT00870051 |
| | AAA | Enrollment completed | US | NCT0081602 |
| | AAA | Completed | N/A | NCT00226629 |
| | Ruptured AAA | Recruiting | Europe | NCT00746122 |
| | AAA | Ongoing, not recruiting | Netherlands | NCT00421330 |
| | AAA | Recruiting | US | NCT00612924 |
| | AAA | Completed | US and Europe | NCT00646048 |
| | AAA | Completed | Europe | NCT01097772 |
| | AAA | Recruiting | US | NCT01092117 |

# Breaking Barriers: Expanding the EVAR Population

The new technology and techniques that will allow operators to treat a higher-risk subset of patients.

BY GIOVANNI TORSELLO, MD, PHD, AND KONSTANTINOS DONAS, MD, PHD

The successful treatment of infrarenal aortic aneurysms via endovascular repair has been demonstrated, and a number of devices have been approved for this indication. However, the feasibility of this technique is limited in patients with short and/or angulated proximal aortic necks or access site challenges such as severe tortuosity or calcification of the iliac arteries. Unfortunately, patients with high surgical risk who are routinely screened for endovascular aneurysm repair (EVAR) often have this type of complex aortoiliac anatomy that makes the aneurysm unsuitable for endovascular repair. Aneurysms with so-called hostile necks are usually excluded from the endovascular treatment option because they are strongly associated with the risk of proximal type I endoleak. Alternative techniques and new devices have been introduced to overcome these limitations.

## NEW TECHNOLOGY

The most significant technical innovation in the endovascular treatment of abdominal aortic aneurysms is reflected in the advent of flexible stent grafts that more readily conform to the patient's native anatomy. This evolution makes the procedure feasible for patients with highly angulated necks. The Endurant Stent Graft (Medtronic, Inc., Minneapolis, MN) exhibits high flexibility due to M-shaped, nitinol stents on the main body of the graft and the absence of a longitudinal connecting bar. Endurant relies on active fixation with suprarenal anchoring pins that provide proximal fixation and reduce the risk of migration even in highly angulated anatomies.

An article describing the performance of the Endurant stent graft, published in 2010,[1] reported only one type I endoleak at 30 days (2.2%). Another prospective study that was conducted at our center reported 2-year freedom from type I endoleak at a rate of 97.3%.[2]

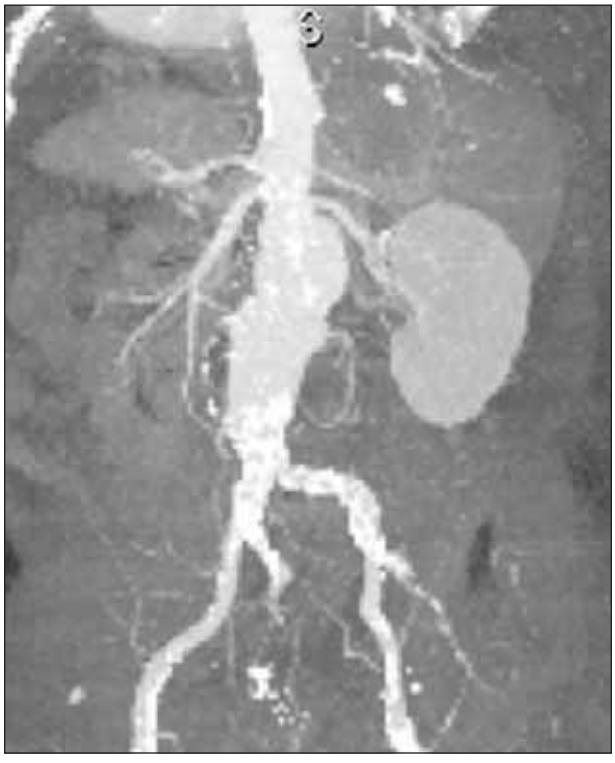

**Figure 1. A patient with previous nephrectomy and juxtarenal aortic aneurysm with short neck (≤ 5 mm) and origin of the superior mesenteric artery and renal artery at the same level.**

Additionally, we found that the performance of the Endurant Stent Graft in hostile, short, and angulated neck cases was promising. In this series, one-third of aneurysms had a neck length of < 10 mm, and approximately 40% of patients presented with a severely angulated neck (> 60°). Both early (1.3% type I endoleak at 30 days) and midterm outcomes (96.9% freedom from type I/III endoleak at 2 years) were excellent. In this series, it was also found that the key factor in long-term durability was proximal aortic neck length.

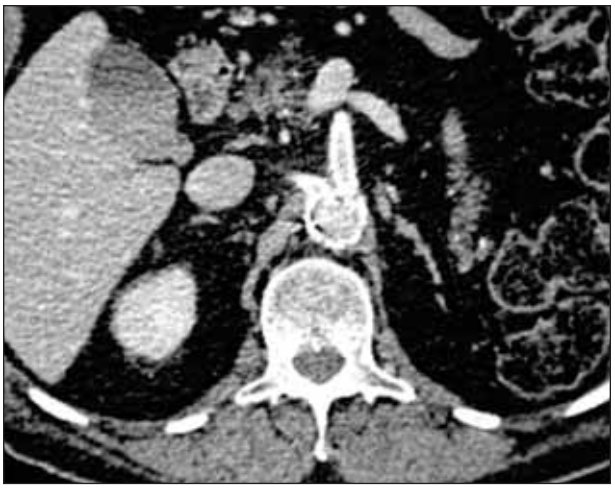

**Figure 2. Successful placement of Advanta stent grafts using the chimney technique in the superior mesenteric artery and renal artery.**

## ALTERNATIVE TECHNIQUES

Several strategies have been investigated to overcome the current limitations related to very short aortic neck anatomies. Fenestrated grafts have been used with good clinical success, but the procedure is technically demanding and is not feasible in patients with angulated necks. Hybrid open/endovascular repair including bypass surgery of the renal arteries followed by endovascular exclusion of the aneurysm is an option for pararenal aortic aneurysms. However, the reported early mortality for these procedures reflects the complexity of the hybrid technique and highlights the need for an effective alternative treatment.

Prophylactic use of the chimney technique[3] or vascular endostapling[4,5] have been proposed elsewhere. The chimney technique consists of placing covered stent(s) parallel to the main aortic stent graft to preserve or rescue flow to aortic branch vessels in the stent graft seal zone.

We have adopted the chimney technique at our institution and have used it in more than 26 cases (Figures 1 through 5). Outcomes have demonstrated acute technical success, even in necks shorter than 5 mm. Our preliminary results in 15 patients with juxtarenal aortic aneurysms has recently been published.[6] In this series, the acute technical success rate was 100%. A high 6-month patency rate also serves to justify this approach. Only one chimney graft was occluded postoperatively at day 45. The patient underwent open thrombectomy of the left renal artery and iliac-renal bypass. Additionally, one type II early endoleak was detected via retrograde flow from the inferior mesenteric artery and was treated conservatively with surveillance.

In contrast to other groups, we prefer to use balloon-expandable covered stents. We have a high level of experience with the Advanta V12 stent (Atrium Medical Corporation, Hudson, NH) and have used it in more than

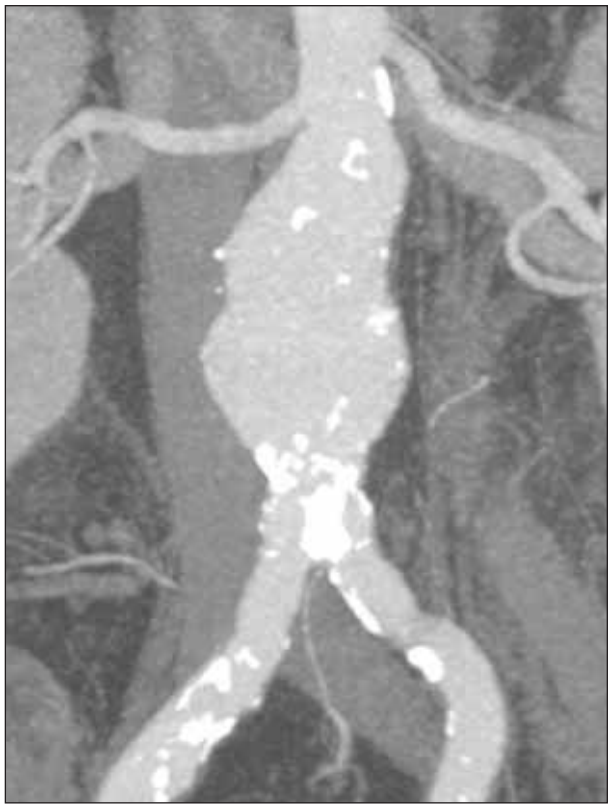

**Figure 3. Juxtarenal aortic aneurysm with insufficient neck length for conventional EVAR.**

64 aneurysms involving the iliac bifurcation[7] and more than 45 branched devices for thoracoabdominal aortic aneurysms. This covered stent provides accurate placement, good fluoroscopic visibility, and high radial force. The placement of the Advanta covered stent ensures preservation of flow in the stented-over renal artery and a synchronous extension of the proximal fixation zone of the abdominal aortic stent graft.

For the chimney technique, we prefer a flexible stent graft for the abdominal aorta to achieve suitable apposition of the two components. Up until now, this technique has shown acceptable periprocedural outcomes, although long-term effectiveness has yet to be established.

## OVERCOMING LIMITATIONS

Besides hostile proximal neck anatomy, difficulties in gaining access also pose a risk to EVAR success. Many patients are considered ineligible for endovascular treatment because of small vessel size, excessive tortuosity, and/or calcification of the iliac axis. For the graft to pass safely through the vasculature, the diameter and trackability of the delivery system is generally considered the main factor. Several strategies have been reported to overcome unfavorable access situations in high-risk patients. Iliac conduits, brachiofemoral through-and-through wires, arterial reconstruc-

**Figure 4. Successful endovascular treatment using the chimney technique for the right renal artery.**

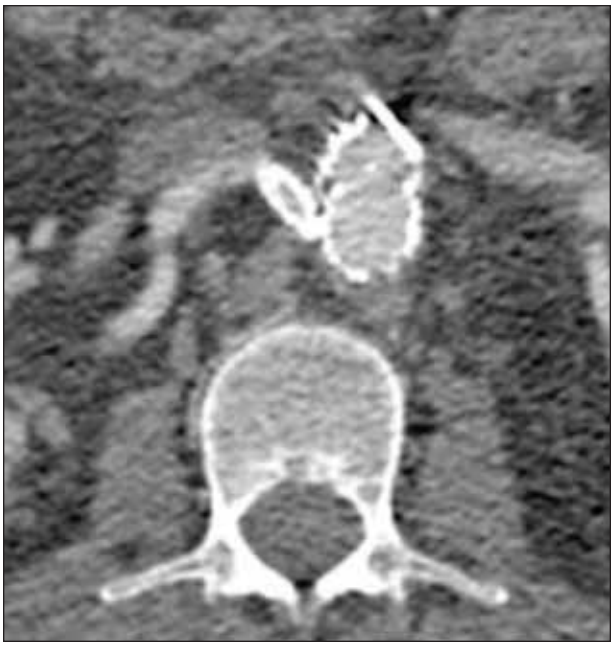

**Figure 5. Postoperative computed tomographic angiogram showing no evidence of endoleak and demonstrating patency of the chimney graft.**

tions, "paving and cracking" techniques, and direct aortic access are used to facilitate EVAR and prevent access-related issues. However, some of these techniques make EVAR fundamentally more invasive.

The hypothesis that low-profile delivery systems are associated with lower complication rates has been proven. Their benefit may be significant in female patients because their vessels are generally smaller. The use of highly flexible, low-profile stent grafts increases the applicability of EVAR, especially in challenging-access anatomies. These attributes also allow for treatment without the need for a conduit.

To this end, Endurant has an improved delivery system with a hydrophilic coating and tip capture to allow for smooth, accurate deployment. Its low profile allows safe access and tracking through small iliac arteries. In our experience, the low outer diameter of the Endurant Delivery System leads to favorable patient outcomes with the option of total percutaneous access. No iliac damage has been noted during the insertion or manipulation of the graft. At 30 days, we have noted only one graft thrombosis (2.2%),[1] which is similar to rates demonstrated with other commercially available stent grafts.

## CONCLUSION

Our preliminary experience shows that the application of the new Endurant Stent Graft appears to be feasible and safe in the endovascular exclusion of abdominal aortic aneurysms in patients with hostile anatomy of the proximal aortic neck and iliac arteries. New technologies and techniques allow a broader group of patients to be treated with EVAR, even though further studies are needed to evaluate their long-term outcomes. ■

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6. Donas KP, Torsello G, Austermann M, et al. Use of abdominal chimney grafts is feasible and safe: short-term results. J Endovasc Ther. 2010;17:589-593.
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# The ENGAGE Study

The 30-day results from the first 180 patients enrolled.

BY VINCENT RIAMBAU, MD, PHD, AND DITTMAR BÖCKLER, MD, PHD, ON BEHALF OF THE ENGAGE INVESTIGATORS

The latest-generation stent graft for the treatment of abdominal aortic aneurysms (AAAs), the Endurant Stent Graft (Medtronic, Inc., Minneapolis, MN), obtained CE Mark approval in July 2008 and was market released in over 88 countries based on previously collected clinical premarket data. The ENGAGE (Endurant Stent Graft Natural Selection Global Postmarket Registry) study has been initiated to prospectively collect global real-world safety and clinical performance data on the Endurant stent graft device and to create a database that can be pooled and compared with other available stent graft data.

## METHODS

ENGAGE is a multicenter, noninterventional, nonrandomized, single-arm prospective study. It aims to recruit approximately 1,200 patients with an indication for elective AAA repair on an intention-to-treat basis from 80 sites throughout Europe, Asia, South Africa, the Middle East, Latin America, and Canada and will follow these patients for 5 years postimplantation. Patients fulfilling the eligibility criteria are being consecutively enrolled. The primary endpoint is treatment success, which comprises freedom from stent graft technical observations (stent graft migration, patency or integrity issues, endoleaks, aneurysm expansion), freedom from (serious) adverse device effects, freedom from major adverse events, and aneurysm-related and all-cause mortality. These endpoints are to be evaluated annually.

An interim analysis was performed based on investigator-reported data for the first 180 patients that were enrolled. These patients were asymptomatic elderly men (92.1%) with considerable comorbidities. Of these patients, 47.3% were American Society of Anesthesiologists risk class III or IV. The Endurant stent graft was successfully deployed in 99.4% of patients for the elective treatment of AAAs.

## RESULTS

Through 30 days, the rate of all-cause mortality was 1.7% (n = 3), with all three deaths being classified as procedure-related but not device-related. The 30-day mortality rate of 1.7% in these initial results is in line with the range of 1% to 3% reported in the literature for other current-generation endografts.[1] The rate of secondary endovascular procedures was 1.1%, and the rate of conversion to open repair was 0.6%. At postprocedure and at 30-day follow-up, there were no type I or type III endoleaks and no instances of stent graft kinking, thrombosis, or occlusion. ENGAGE represents the largest real-world registry for any single stent graft for endovascular aneurysm repair.

> "ENGAGE, unprecedented in size, scope, and geographical involvement, will closely monitor the real-world performance of the Endurant Stent Graft System."

## CONCLUSION

The 30-day interim results of the first 180 patients enrolled in ENGAGE are promising. Longer-term follow-up for more ENGAGE patients will be reported. ENGAGE, unprecedented in size, scope, and geographical involvement, will closely monitor the real-world performance of the Endurant Stent Graft System. It will provide physicians with data that are intended to help optimize the minimally invasive treatment of AAA in the real-world setting of standard clinical practice. ■

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# Quality Imaging With 3D CTA for Aortic Endovascular Therapies

A look at why three-dimensional preprocedural imaging is important for managing complex aortic cases.

BY DOUGLAS MASSOP, MD, FACS

The evolution of aortic endovascular therapies has been dramatic in the past decade. Understanding this evolution requires examination of three critical components; these components depend on each other to obtain favorable results for endovascular treatment of the entire aorta and its major branches. The three components are (1) the ability to obtain and process detailed preprocedural imaging to clearly understand a particular anatomic situation, (2) improvements in intraprocedural imaging to clearly perform what is intended, and (3) development of the devices in terms of accuracy of position and achieving a durable seal. These components, which have progressed while successfully treating increasingly complex cases, are interwoven with the skill of the operator performing these cases.

The purpose of this article is to address the first component above, which considers the preprocedural imaging involved in complex cases. Further, this article offers a perspective as to how three-dimensional (3D) computed tomography angiography (CTA) contributes to a better understanding of what is being accomplished. The ultimate goal is accurate and durable control of life-threatening aortic disease. This is challenged by the fact that treatment is being performed in a minimally invasive fashion. The basis of this imaging has been the increase in the quality of fine-slice resolution (the raw CT axial slices) and the ability to postprocess virtual 3D models of a particular anatomic situation in terms of overall morphology and functional measurements applied to that model of a real case. When these models are appropriately studied, the actual execution of the case becomes a simpler, more predictable, faster, and safer exercise. This occurs because of the second and third components: better intraprocedural imaging and better products.

The time spent carefully planning a case is time spent well. Attempts to completely automate case planning have been problematic for a number of reasons. In a study by Wyss et al, the average time spent by a physician operator reviewing and planning a case was 17 min-

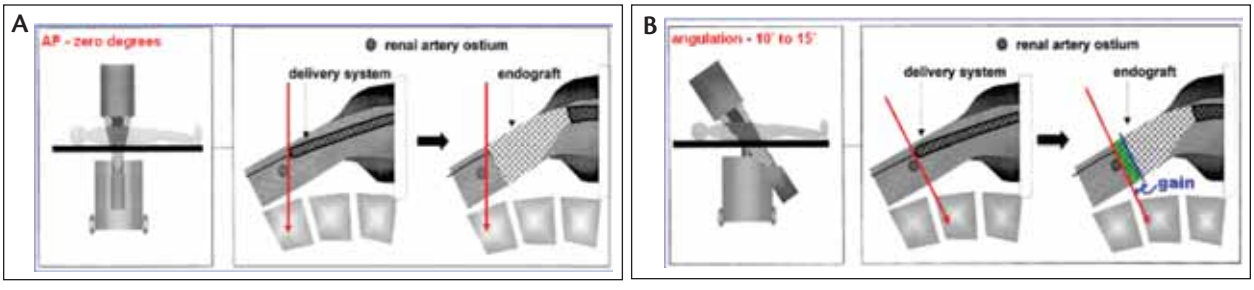


**Figure 1. Angulation of the proximal neck: anterior/posterior image underestimates the final position of the graft relative to the renal arteries (A); orthogonal image intensifier (II) angulation perpendicular to the aortic neck yields significant gain of functional neck seal (B). Reprinted from *Seminars in Vascular Surgery*, Vol 21. Murphy EH, Arko FR. Technical tips for abdominal aortic endografting. Pages 25-30, Copyright 2008, with permission from Elsevier.**

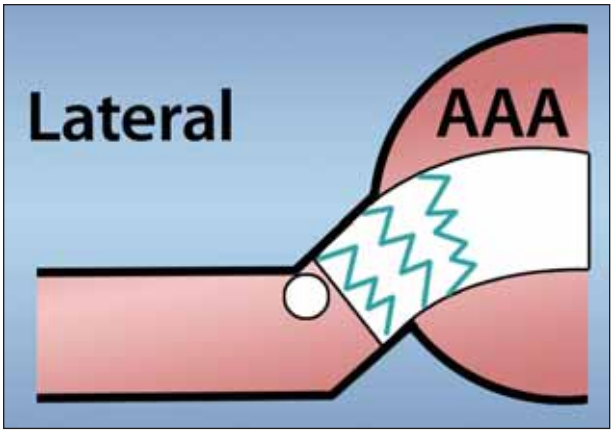


**Figure 2. Ventral takeoff of lowest renal artery leads to shorter proximal seal zone.**

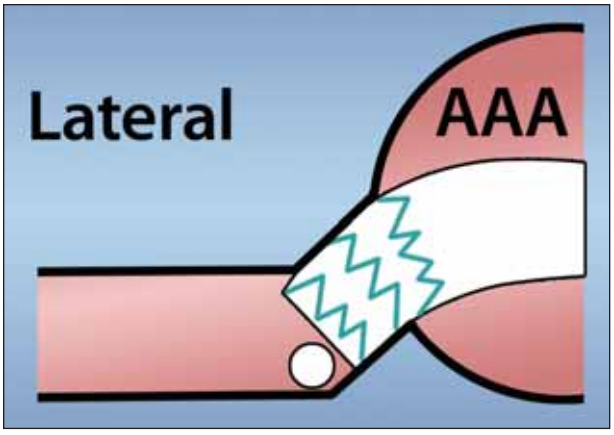


**Figure 3. Dorsal takeoff of the lowest renal artery can lead to improved functional length of proximal seal.**

utes.[1] They found that the intraobserver consistency was very good at planning with little variability. The interobserver error was a bit higher but still demonstrated excellent consistency when the interventionist was involved in the planning of a particular case.

The routine use of automation and set protocols is an excellent starting point for automated 3D software. The basis of most of these is the center lumen line (CLL). The CLL is an easily reproducible reference that extends along the entire length of the aorta, into the major branch vessels, and all the way to access points. However, the purpose of operator review is to take into account the variations necessary to carefully plan a particular case. These can include alterations of where the endograft will lie varying from the CLL. The situations in which this can be a major factor are if the aortic pathology is (1) particularly saccular, (2) very large aneurysms—especially if no thrombus is contained, (3) tortuous aortas, (4) complex thrombus in the aortic sac, and (5) abrupt angulation of the iliacs entering the aortic flow channel. Additional processing of the CLL needs consideration of how a guidewire and endograft delivery system will align in one of the above situations and vary from the CLL.

Standard 3D software is an excellent way of seeing the full axis of the aorta and its branch relationships. The importance of this will be discussed in this article with specific considerations for the abdominal and thoracic aorta.

## SPECIFIC ABDOMINAL CONSIDERATIONS

Endovascular treatment of abdominal aortic disease has several fundamental considerations; these mainly involve a keen understanding of (1) the adequacy of access anatomy, (2) the proximal neck quality and renal relationships, and (3) the distal landing zones.

The access anatomy must have adequate quality, caliber, and lack of tortuosity to safely introduce selected devices. Three-dimensional imaging allows a more thorough investigation of these variables to help determine which delivery systems could be safely used. If two out of the three previously mentioned variables are considered challenging, alternative methods should be considered. These possibilities would include percutaneous transluminal angioplasty/stenting, endoconduits, and formal surgical conduits.

The proximal neck quality is a very complex consideration of the actual quality of the aortic tissue at that level and the degree of thrombus/calcification, the shape of the neck (3D), the angle of the neck (3D), and the relationship of the renal arteries to each other and their position on the neck.[2] The quality of the neck is first determined in terms of whether the neck is concentric or irregular at the seal zone. Commonly, there is some degree of irregularity at the posterolateral quadrants due to the aorta lying on the spine, which, along with the degree of calcification/thrombus, must be carefully looked at when both sizing and positioning a particular case. Recall that the renal arteries have identifiable accessory vessels in 15% of kidneys. There is frequently linear offset, and one of the two renal arteries (left) is usually lower than the other. A clear understanding of the 3D takeoff of the renal arteries assists in optimal alignment of the II angle to be truly orthogonal to the takeoff the lowest renal. Frequently, the right renal artery will originate in the right anterior quadrant, and the left renal artery will originate in the left posterior quadrant of the transverse view of the aorta. Optimal visualization for endograft deployment occurs most often with some degree of a left anterior oblique (LAO) projection, usually in the range of 10° to 45°.

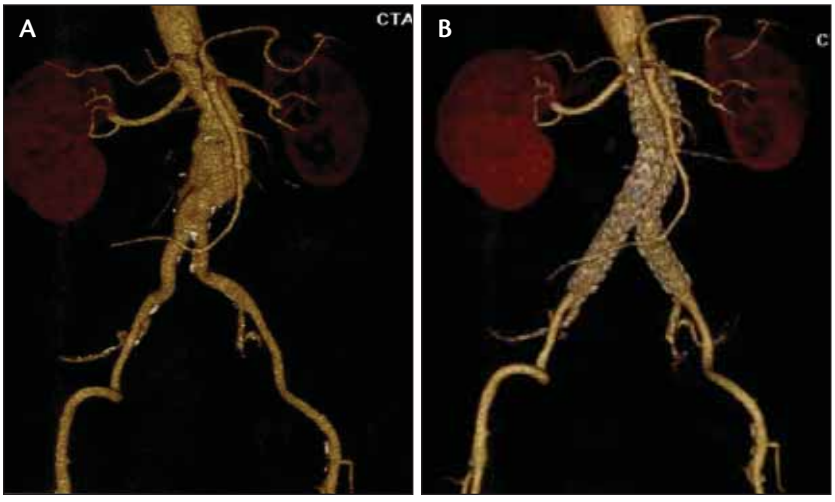


**Figure 4. Preoperative planning 3D CTA (A) and subsequent 2-year postimplantation 3D CTA (B) showing accurate position and function of an Endurant Stent Graft (Medtronic, Inc., Minneapolis, MN). Note precise landing of the ends of the device at the renal and distal iliac levels.**

The infrarenal aneurysm dilates, and as it does, the neck is lifted and angles anteriorly to a variable degree, mandating some cranial angulation of the II to get orthogonal to the neck itself.[3]

The complexity of this arrangement is often grossly underestimated when performing a particular case (Figure 1). For example, when the endograft is delivered to a 25-mm-diameter neck that is only 20 mm long and has an anterior angulation of 45°, presumed optimal visualization will only require the II to have minimal or no cranial angulation to appear orthogonal to the upper end of the constrained endograft. However, when the graft is deployed, it will foreshorten in the angulation of the neck and ultimately land several millimeters lower than intended. This concept is important in thoughtful 3D assessment of a particular case. This also argues for tip capture/control of grafts in more challenging anatomies to be able to fine-tune the exact position of an opened but not yet anchored endograft.

Further, the relationship of the renal arteries relative to how far ventral or dorsal they come off the aorta needs to be considered to assess the functional length of the aortic neck (Figures 2 and 3). In the same model as previously described, consider the following variation. If the renal artery appears to come off the more ventral portion of the aorta, there will be less neck available for a landing/seal zone than if it comes off more dorsal. Both of these renals will come off on the same axial CT slice and yet affect the case and its ultimate outcome very differently. These relationships are better understood with a virtual 3D model.

The functional positioning of the endograft relative to the abdominal aortic aneurysm sac and neck must be carefully considered.[4] The gait of the graft (in most systems) will land 8 cm below the top of the graft. The quality of the abdominal aortic aneurysm lumen can have a significant impact on the ability to cannulate the gait and the ultimate function of the gait to contralateral limb docking.

The orientation of the aortic bifurcation and the ostia of the common iliacs will also affect the alignment of the graft and the ease of performing the procedure. Frequently, the left iliac is more dorsal than the right. I will often use the left side for the ipsilateral access. The gait and the right iliac ostia can then be aligned for easier cannulation. However, more importantly, there seems to be better alignment of the endograft components and less twisting and abrupt angulation of devices.

The final consideration is the amount of dilatation of the common iliacs relative to the external iliacs. The more dilated the common iliacs, the more elongation and tortuosity present. When this occurs, the angle between the common and external iliac arteries will be more acute and can actually be < 90°. This can be a significant concern if a large common iliac limb (eg, 18 or 20 mm) encroaches the ostia of a standard size external iliac (eg, 7–9 mm). The ventral part of the limb will lie closer to the external iliac and potentially compromise a smooth flow channel. A clear understanding of this distal relationship before the case with the 3D software is important. During the procedure, appropriate obliquity for visualization needs to be understood ahead of time to maximize this fluoroscopic view. Careful preprocedural planning improves the efficacy of radiation and contrast doses and the accuracy of the procedure (Figure 4).

## SPECIFIC THORACIC CONSIDERATIONS

A complete discussion of the complexities of the thoracic aorta and the possibilities for dissections and deceleration injuries is beyond the scope of this article. However, there are several key relationships that first must be understood when dealing with descending thoracic aneurysms. The aortic arch itself has a predictable progression with age; the arch will dilate, elongate, and rotate. Normal relationships include the fact

that the innominate artery is typically more dorsal, the common carotid straight off the mid-apex, and the subclavian more ventral. With age, the arch dilates and then rotates from a typical LAO relationship to the body of 20° to 30° up to a full 75° or greater LAO angle over time. This angle for deployment of the graft is fundamental to the performance of thoracic endografting. The preoperative 3D images will assist in the positioning of the patient so that an optimal functional imaging angle can be obtained. The positioning on the table is very important with regard to not only how far the body is rotated but also for side-to-side positioning so that there is a clear fluoroscopic view free of side rails, arm boards, arms, and monitoring devices. An older patient frequently has a larger, more gradual radius of curvature for delivery of the graft, which leads to less infolding and kinking of the endograft. This concept is a primary problem with endografting younger patients with a tighter radius curvature in smaller-diameter aortas.

The distal aorta in particularly large aneurysms can fold laterally in the left chest because of relative fixation at the level of the diaphragm. This raises concern for delivery and/or kinking of the lower end of the endograft. This will also significantly affect the ability to land at the intended target relative to the celiac artery. The 3D images will clearly show the CLL, and the full consideration of length and angulation can be more clearly appreciated.

The distal landing at the celiac/superior mesenteric artery level is better understood with accurate imaging. The anterior wall of the visceral segment of the aorta is commonly of better quality because of the embryologic interlacing of fibers due to the takeoff of the ostia of the four visceral vessels, whereas the posterior wall is frequently more diseased (eccentric). An appreciation of this will assist particularly in the preoperative planning of size and landing site of devices.

## CONCLUSION

Aortic endograft therapy is a rapidly developing field in vascular medicine. A clear understanding of the vascular anatomic-to-graft relationships is fundamental to the success of the procedures. The description of relationships involved and the use of 3D imaging to understand them before the procedures should be a comfortable component in the abilities of an endovascular specialist who wishes to treat the aorta in this manner. Unfortunately, the ability to convey the advantages of a 3D platform is limited by the very fact that I am communicating this in a 2D format. I have tried to illuminate some of the key concepts that I have learned in doing these cases and thinking about them in a 3D perspective. I would encourage all operators to consider carefully working to understand the advantages of the 3D format. The best recommendation is to work with vendors who are supporting the spread of this technology and spend time with local representatives who want to share this knowledge with you to gain a stronger understanding for your individual practice. ■

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