

# Endovascular TODAY

November 2016



AHEAD OF THE  
**C U R V E**

**RELAY® PLUS**  
THORACIC STENT-GRAFT SYSTEM



**Bolton Medical**  
A WerfenLife Company



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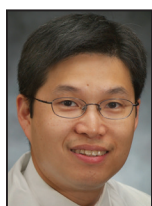
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# AHEAD OF THE CURVE

By Wilson Y. Szeto, MD



Early efforts in addressing endovascular solutions for the thoracic aorta focused on fundamentals learned from endovascular aneurism repair that included access, exclusion of the aneurysm, and durability. Through the evolution of thoracic endovascular aortic repair (TEVAR), physicians and

industry have been focused on improving device deliverability and conformability, while reducing the risk of endoleak. The Relay®Plus thoracic stent-graft system (Bolton Medical) was a later entrant into the TEVAR market, but this system embodies features that will help us address the challenges we face when treating our patients with thoracic aneurysms. The precurved dual-sheath delivery system is designed for access vessel stabilization, accurate deployment in the arch, and optimal conformance of the stent-graft upon deployment. The device is available in multiple diameters, lengths, and tapers to allow for a patient-specific treatment plan. I am convinced that the flexibility of this graft has the potential to allow us to treat patients with arch curvatures who would not have been candidates for treatment in the past because their anatomy was too challenging.

In the following supplement to *Endovascular Today*, a group of esteemed endovascular aortic specialists have shared their experiences with the RelayPlus system, highlighting the many benefits of this technology. To begin, Grayson H. Wheatley III, MD, FACS, discusses the combination of anatomic and hemodynamic challenges in the distal aortic arch and how device selection is critical to optimizing repair outcomes. Antonio Polanco, MD; Kyle W. Eudailey, MD; Michael Borger, MD; and Isaac George, MD, focus on challenging access conditions, and how the RelayPlus stabilizes access vessels in order to prevent the

excessive manipulation that can lead to rupture, dissection, or pseudoaneurysm. Venkatesh G. Ramaiah, MD, FACS, provides a challenging case in which the RelayPlus made it possible to navigate a type III aortic arch with severe tortuosity. Finally, Matthew Eagleton, MD, provides background and forward-looking insights on future developments in the Bolton family of stent-grafts.

RelayPlus has established itself as a workhorse device capable of treating patients with a wide range of thoracic anatomy. Bolton Medical continues to innovate with their next-generation RelayPro thoracic stent-graft system. This next-generation device builds upon the foundational technology of RelayPlus while reducing the profile of the delivery system. RelayPro has entered into pivotal trials in the United States with expected approvals in the coming years. ■

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# Achieving Accuracy in Challenging Arch Anatomies

BY GRAYSON H. WHEATLEY III, MD, FACS



Patients with aortic arch disease represent a significant treatment challenge due to the anatomic constraints associated with arch angulation and associated relationship of the aortic disease with the origins of the great vessels.

As such, intense case planning is needed when considering an endovascular solution in these patients. Advanced multidetector computed tomography angiographic (CTA) imaging, along with three-dimensional reconstructions with centerline measurements, are needed to optimally evaluate the arch anatomy and choose an endovascular solution. Furthermore, a healthy respect and understanding of the unique hemodynamic forces in the aortic arch are essential to appreciate the impact these factors have on aortic stent-graft deployment accuracy and achieving adequate seal in a hostile proximal landing zone.

For example, cardiac output is increased in the aortic arch compared to the descending thoracic aorta, which translates into increased distal migration forces at the time of aortic stent-graft deployment during the period of time when the aortic stent-graft is partially deployed and all of the cardiac output forces are being directed to push the aortic stent-graft distally. In addition to the distal migration forces associated with increased cardiac output, there is also increased aortic motion in the aortic arch as a result of the fluid dynamics of the cardiac output being ejected from the left ventricle and traversing the curved aortic arch. Finally, the angulation of the aortic arch varies by individual and the degree of angulation, relative to the origin of the great vessels, and greatly affects the decision of where to land the proximal extent of the aortic stent-graft.

As a result of the combination of anatomic and hemodynamic challenges in the aortic arch, the selection of the optimal aortic stent-graft is critical for achieving optimal outcomes in thoracic endovascular aortic repair (TEVAR) procedures for the aortic arch.<sup>1</sup> The RESTORE study, published in 2010, was a prospective European

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**The Relay<sup>®</sup>Plus stent-graft is engineered with a nitinol wire associated with a polyester vascular graft with an associated spiral support bar that provides column support and torque response.**

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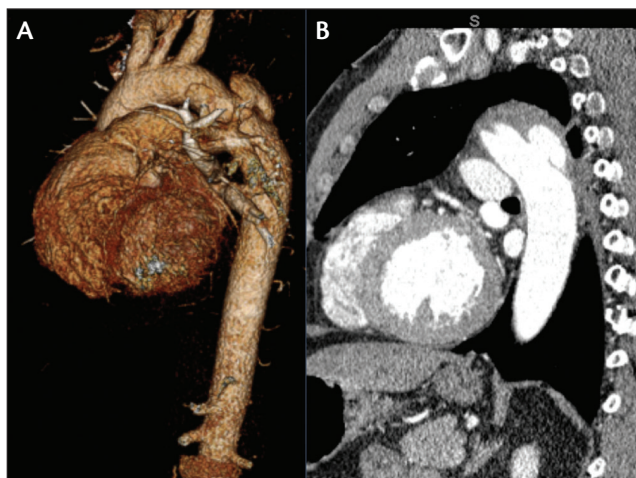
registry involving 22 centers that studied the outcomes of patients treated with the Relay<sup>®</sup>Plus (Bolton Medical) aortic stent-graft.<sup>2</sup> The Relay stent-graft is engineered with a nitinol wire associated with a polyester vascular graft and an associated spiral support bar that provides column support and torque response. The study consisted of 304 consecutive patients, with an average age of 64 years. Thoracic aortic aneurysms constituted 52.9% of the aortic pathologies. Overall technical success was 97.7%, while 80% of the proximal landing zones in this study were in the aortic arch. There was a 95.4% freedom from endoleak and 30-day mortality was 7.2%. Freedom from procedure- and device-related mortality at 2 years was 95.9%. There were no retrograde dissections in the study, and the stroke rate was 1.6%.

## CASE DISCUSSIONS

### Case 1

A 65-year-old woman presented with new-onset back pain. A detailed workup demonstrated a 5-cm penetrating aortic ulcer (PAU) of the proximal descending thoracic aorta with associated intramural hematoma extending retrograde to the distal aortic arch and abutting the origin





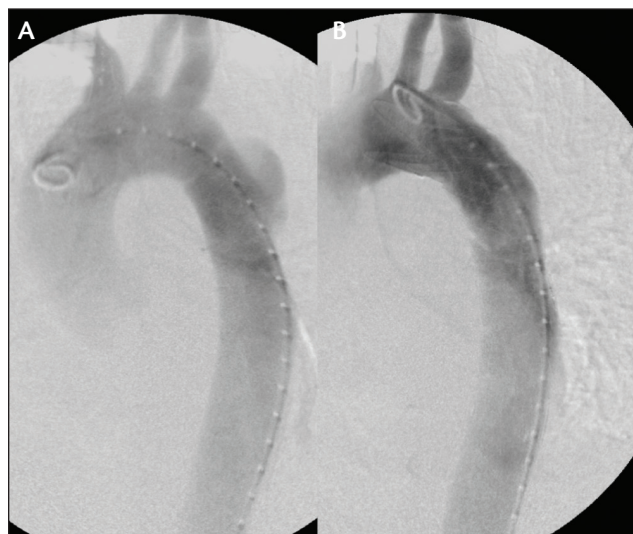
**Figure 1.** Three-dimensional reconstruction of a multidetector CTA of a patient with a 5-cm PAU of the proximal descending thoracic aorta extending retrograde into the distal aortic arch (A). Multidetector CTA of a 5-cm PAU of the distal aortic arch and proximal descending thoracic aorta (B).

of the left subclavian artery (LSCA) (Figure 1). The remainder of the aorta was normal. Due to the size of the PAU, a decision was made to treat the patient with an aortic stent-graft. A Relay aortic stent-graft was selected to align the maximal conformability of the aortic stent-graft in the distal aortic arch to the curvature of the arch in order to preserve the origin of the LSCA. The proximal sealing stent technology of the Relay device with the “Free-Flex Zone” is appealing in this patient’s anatomy because of the expected challenges associated with a proximal landing zone in the distal aortic arch. In addition, the precurved nitinol delivery catheter and inner delivery sheath of the Relay aortic stent-graft facilitates accuracy of deployment in this patient’s challenging anatomy.

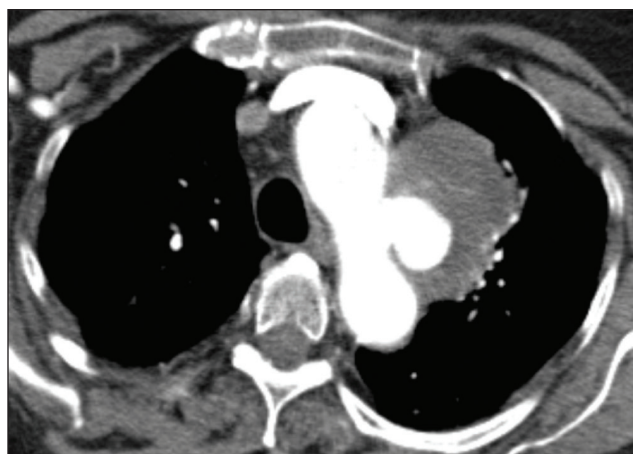
The patient was taken to the hybrid operating room, and right femoral access was obtained using general anesthesia. Aortography confirmed the landing zones (Figure 2A). The outer sheath of a 38-mm X 38-mm X 150-cm Bolton Relay aortic stent-graft was delivered into the lower descending thoracic aorta from a right common femoral artery access. The inner delivery sheath and aortic stent-graft were advanced out of the outer delivery sheath and maneuvered into the mid aortic arch. With transient hypotension, the aortic stent-graft was deployed, with the proximal aspect of the fabric landing just beyond the origin of the LSCA and the bare springs were subsequently released. A completion aortogram demonstrated a patent LSCA, no endoleak, and a successfully excluded PAU (Figure 2B).

## Case 2

A 69-year-old woman presented to the emergency room with new-onset back pain and shortness of breath.

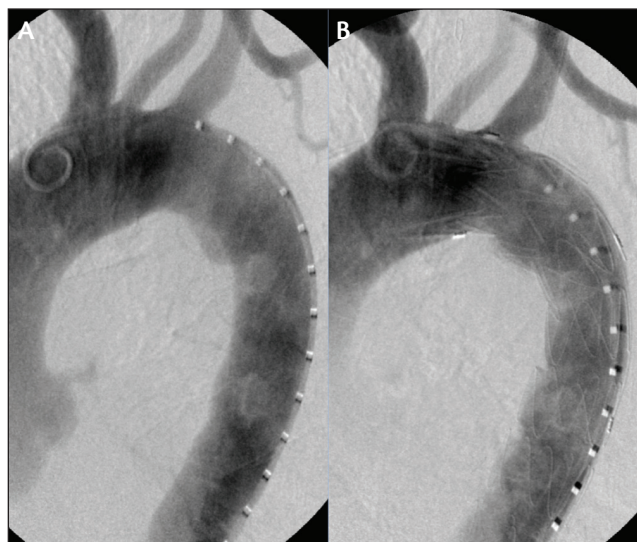


**Figure 2.** Intraoperative angiogram of a patient with a 5-cm PAU of the distal aortic arch with associated intramural hematoma (A). Completion angiogram after TEVAR for a 5-cm PAU of the distal aortic arch with a Bolton Relay aortic stent-graft distal to the LSCA (B).



**Figure 3.** Multidetector CTA of a 69-year-old patient with an 8-cm saccular aneurysm of the distal aortic arch.

A CTA revealed an 8-cm saccular aneurysm of the distal aortic arch (Figure 3). The distance between the origin of the LSCA and the aneurysm was 1.5 cm along the inner curve. With a short, angled proximal landing zone, we selected a Relay aortic stent-graft to take advantage of the minimum proximal seal zone of 15 mm (indicated in the indications for use). The patient underwent successful TEVAR with a Bolton Relay 42-mm X 42-mm X 150-mm aortic stent-graft. There were no endoleaks and even though the LSCA was partially covered with the fabric of the aortic stent-graft, there was adequate filling of the LSCA as determined by angiography, and there were no blood pressure differences between the left and right upper extremities (Figure 4).



**Figure 4.** Intraoperative angiogram of patient with an 8-cm saccular aneurysm of the distal aortic arch (A). Completion angiogram after TEVAR for an 8-cm saccular aneurysm of the distal aortic arch with a Bolton Relay aortic stent-graft with partial coverage of the LSCA (B).

## CONCLUSION

Endovascular repair of the distal aortic arch is a challenging process in any patient. The unique combination of aortic arch curvature, short proximal landing zone, rela-

tionship of the origins of the great vessels, and increased cardiac output forces all combine to challenge the accuracy of deployment and obtaining proximal seal of any aortic stent-graft. By understanding the different deployment mechanisms and aortic stent-graft designs, the astute clinician will optimize clinical outcomes of TEVAR procedures involving the aortic arch by aligning the notable design and functional attributes of a particular aortic stent-graft with the patient's anatomy.

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# Dual-Sheath Delivery System for Vessel Stabilization Using the Bolton Relay<sup>®</sup> Thoracic Stent-Graft

BY ANTONIO POLANCO, MD; KYLE W. EUDAILEY, MD; MICHAEL BORGER, MD;  
AND ISAAC GEORGE, MD



Endovascular intervention for complex aortic pathology is an evolving field,

and as a consequence, interventionists are confronted with patients who have challenging vascular access. The inherent large bore of thoracic endovascular aortic repair (TEVAR) delivery sheaths as well as the relative motion during stent-graft deployment pose additional risks in marginal vasculature. The following case illustrates the benefits of a sheath-in-sheath system in small, fragile, and highly calcified iliofemoral vessels in a patient requiring TEVAR.

## CASE DISCUSSION

A 71-year-old woman with a 59 pack-year smoking history presented with stabbing persistent retrosternal chest pain. She underwent a CT angiogram and was found to have a saccular aneurysm measuring 2.2 X 2.7 cm with an associated penetrating atherosclerotic ulcer (PAU) along the inner curve of the aorta at the level of the junction of the left common carotid artery and left subclavian artery, in addition to a 5-cm proximal descending aorta (Figure 1). Transthoracic echo (TTE) revealed a normal ventricular function (55%–60%) with no valvular disease. Finally, a left heart catheterization (LHC) revealed triple-vessel disease.

The preoperative plan was a total arch repair with resection of the aortic tissue involving the aneurysm and ulcer. The coronary bypass was completed first after cardioplegic arrest and cooling to 24°. Next, under circulatory arrest and perfusion to the individual head vessels, the aorta was opened and the ulcer was found to be extending deep into the descending aorta and full resection was not possible.

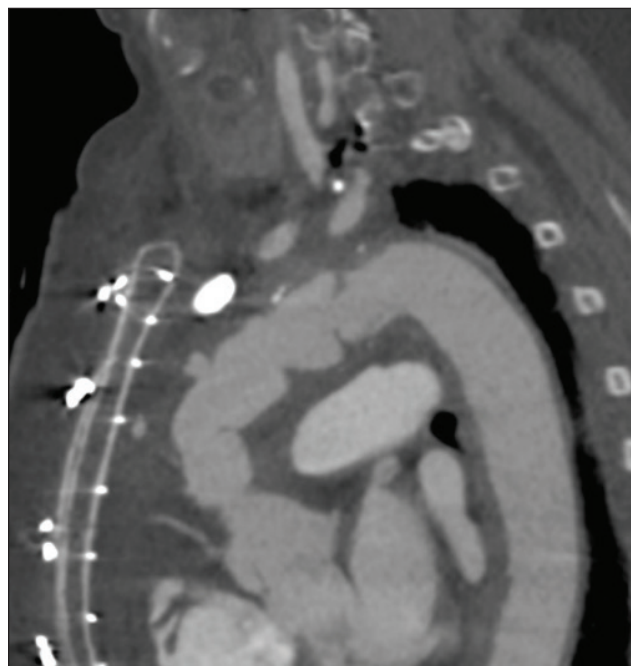


Figure 1. Sagittal CT scan of the thoracic aorta after total arch repair before TEVAR.

Therefore, an elephant trunk procedure was performed using a #26 Gelweave graft (Vascutek), with the distal anastomosis constructed just proximal to the ulcer and just distal to the left subclavian artery; 8 cm of graft was positioned in the descending aorta while under circulatory arrest. The arch vessels were then each sewn to side arms of the aortic graft after the distal anastomosis and after resuming full cardiopulmonary bypass. Given that the ulcer was not resected, a second stage procedure with TEVAR was needed to adequately seal off the lesion.



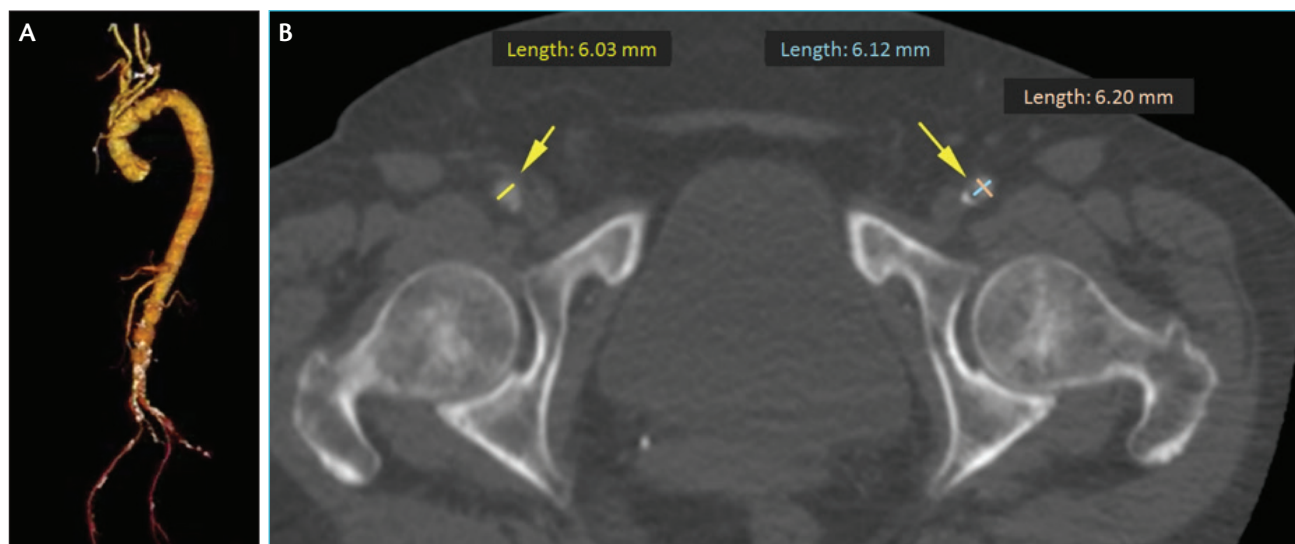


Figure 2. Reconstruction of the aorta as well as the iliofemoral vessels (A). CT scan highlighting access vessel size (B).

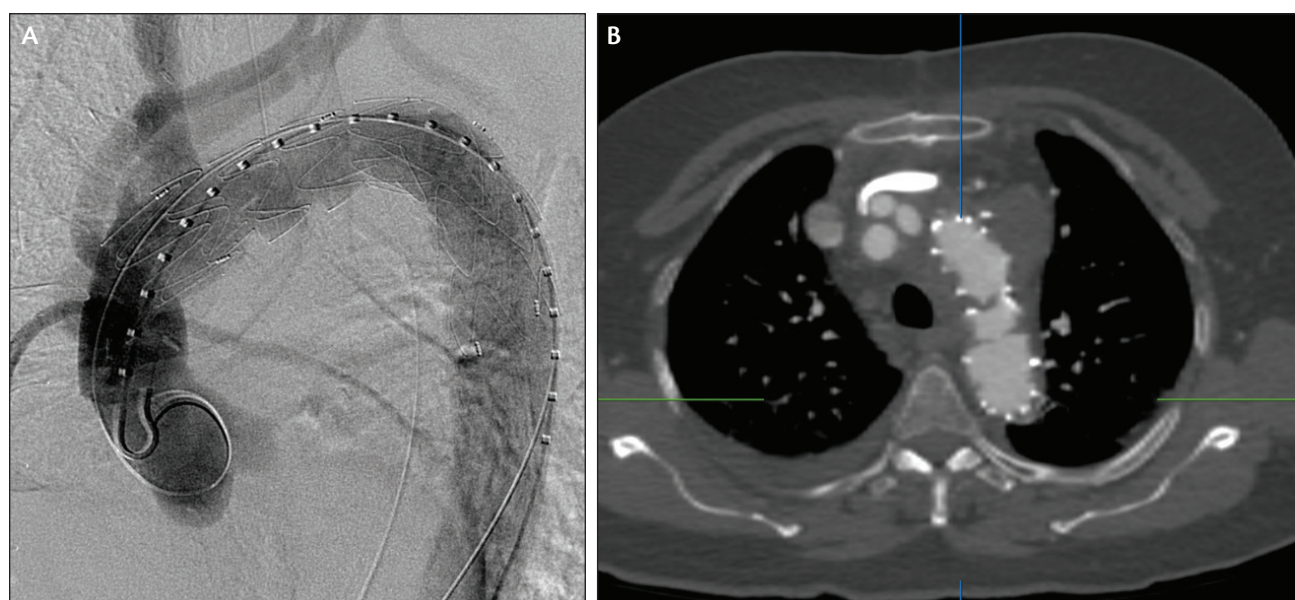


Figure 3. After stent-graft deployment. Complete angiogram (A) and CT scan (B) showing exclusion of the aneurysm by the stent-graft.

Ten days after the aortic arch procedure, the patient underwent TEVAR. During planning for this second operation, iliofemoral vessels were found to be small and highly calcified on CT angiography (Figure 2), with maximal right external iliac diameter of 6 mm and left external iliac diameter of 6.1 mm, and femoral diameters of 6.4 mm and 6.7 mm, respectively. The Relay<sup>®</sup>Plus system (Bolton Medical) was chosen due to its hydrophilic coating and dual-sheath design. The dual-sheath system allows for one sheath to maintain primary vascular access, and the other to be used as a working sheath for the procedure, thus limiting the movement within the access vessels. This

may serve to minimize trauma, particularly when vessel diameter is small and calcified. The LFA was accessed and preclosed, and a tapered 34- X 30- X 150-mm Bolton stent-graft was selected for the procedure.

The device was advanced into position after a diagnostic angiogram confirmed proximal and distal landing zones. Once positioning was confirmed, the graft was deployed using the left subclavian artery takeoff as the proximal marker. A completion angiogram revealed exclusion of the aneurysm and ulcerated areas without endoleak, with over 5 cm of graft-graft overlap. The delivery system was then removed without issue, the preclose



sutures were tied without incident, and a peripheral angiogram confirmed patency (Figure 3). The patient was extubated in the operating room and discharged in good condition 3 days postoperatively.

## CONCLUSION

The Bolton Relay's hydrophilic dual-sheath delivery system affords distinct advantages in challenging peripheral

access in TEVAR, namely by stabilizing the primary access vessel, straightening tortuosity, and minimizing sheath motion relative to the vessel. This in-line design also stabilizes the inner sheath that contains the stent-graft, and thus allows for extremely precise deployment. These features making it an attractive TEVAR option in situations with tight, tortuous access and in complex aortic arch anatomy that necessitate precise positioning. ■

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# Trusted Performance

BY VENKATESH G. RAMAIAH, MD, FACS



Thoracic endovascular aortic repair has become a preferred first-line intervention for complex aneurysms in the thoracic aorta and is considered a significant surgical advance in treatment of thoracic aortic disease.<sup>1</sup> Thoracic endografting

has improved over the past 20 years with technologic advances in device materials, graft sizes, conformability, access, and deployment. Patients with challenging and complex anatomy and those with conditions that place them at high risk for open surgery can be treated with thoracic endografting with less perioperative morbidity and mortality compared with open repair.<sup>2,3</sup>

Four devices have been approved in the United States for thoracic endografting, including the Relay<sup>®</sup>Plus (Bolton Medical), which has been available since 2012. The vast thoracic experience at the Arizona Heart Hospital has allowed me the opportunity to evaluate and assess a variety of endografts. Currently, the Bolton Relay thoracic stent-graft has become our device of choice for most thoracic pathology; the case report presented in this article highlights the aspects of this device that make it invaluable in my practice.

## PATIENT BACKGROUND

A 79-year-old woman with a history of back pain, interscapular pain, and occasional chest pain was referred to our institution. She was a chronic smoker with a 50-year history of smoking. The patient had severe chronic obstructive pulmonary disease requiring home oxygen and coronary artery disease with an ejection fraction of 35% to 40%.

Imaging workup revealed a large fusiform thoracic aortic aneurysm that measured 6.24 cm in diameter. There was diffused parietal thrombosis throughout the entire descending and abdominal aorta, ulcerated plaque 50 mm above the celiac trunk, and intercostal arteries that were mostly occluded by the

thrombosis (Figure 1A–1E). The patient had not received previous vascular graft implants.

Workup also revealed additional concerns for treating this patient. There were indications of osteoporosis, pulmonary emphysema, and calcific stenosis at the takeoff of the common iliac arteries. We had concerns about presence of a stent inside the proximal part of the left subclavian artery (6 X 30 mm; distance to the left vertebral artery, 15 mm).

## PROCEDURAL DESCRIPTION

The patient was clearly at prohibitive risk for open surgery, so the decision was made to treat her with a thoracic endograft due to her age and comorbidities. The access vessels were small (Figure 2), with the external iliac arteries

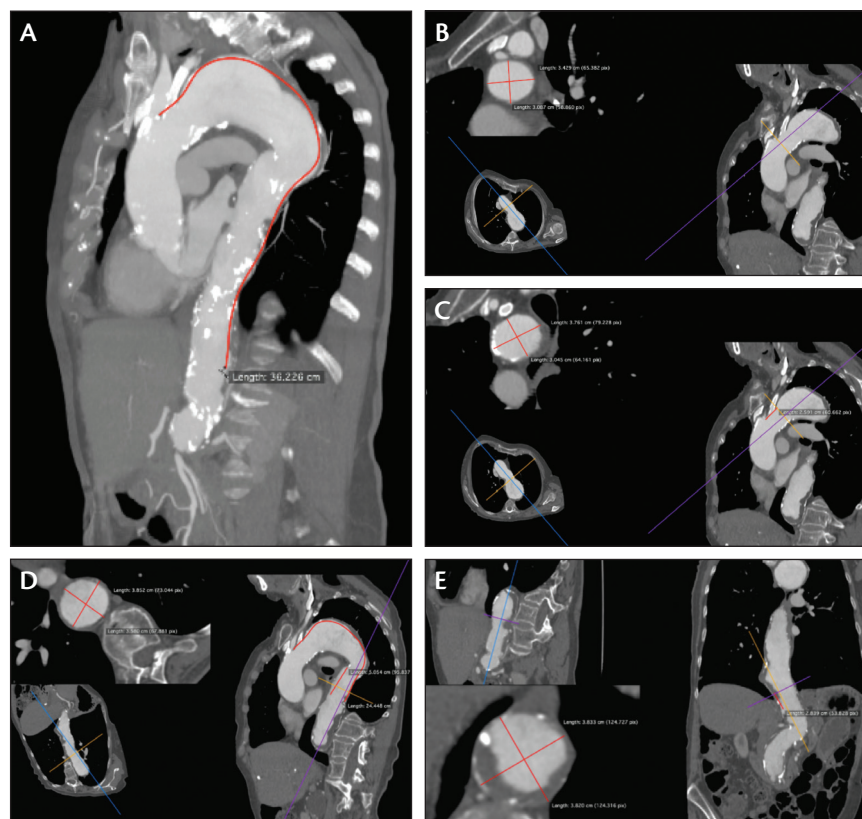


Figure 1. Preoperative imaging highlighting a large thoracic aortic aneurysm and the technical anatomical challenges of treating this patient. The superior edge of the proximal landing zone (A, B). The inferior edge of the proximal landing zone (C). Panels D and E show the distal landing zones.

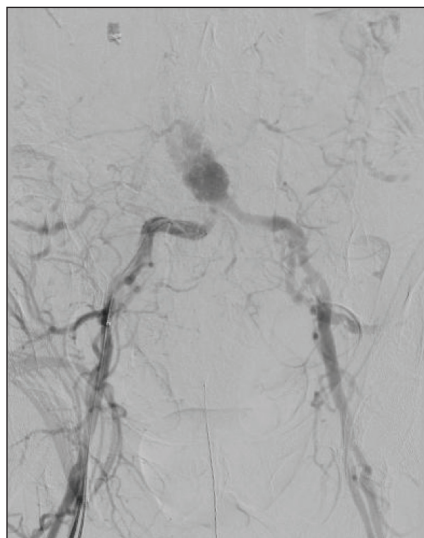


Figure 2. The access vessels.

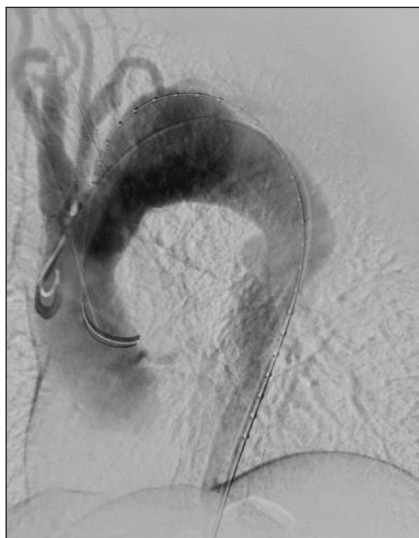


Figure 3. The patient had a type III arch with severe tortuosity.

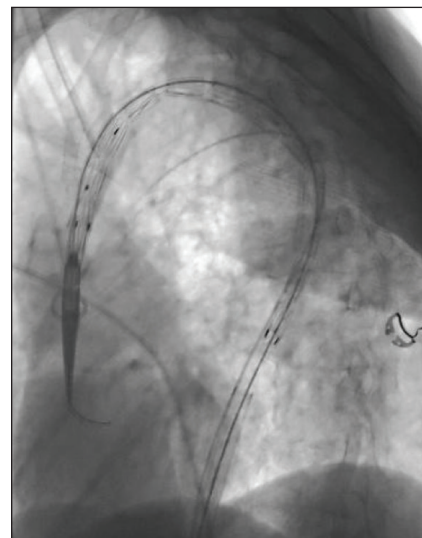


Figure 4. The graft has deployed.

measuring 5.8 mm in diameter, and they were soft with mild calcification. The iliac bifurcation also showed stenosis. The patient had a tight type III arch, so planning and device selection were critical for success.<sup>2</sup> We elected to use the Bolton RelayPlus device because we find that the design of the system enables easy access through the iliac arteries, provides excellent pushability, and protects the access vessels during the placement of the graft. We also believe that the staged delivery of the dual-sheath system is less traumatic while navigating the aortic arch and allows for precise placement in angulation.

The intended landing zone was just distal to the left subclavian to avoid catching the subclavian stent. The centerline measurement from the 3D reconstructed CT measured 32 mm, and the total length needing coverage was 200 mm, so we planned to use a 36-mm stent-graft. The delivery system is 24 F but tracked well through a tight access vessel. The access vessels were small but mostly free of disease and had no significant tortuosity, so access was planned for the right femoral artery. Minimizing manipulation of the access vessels was critical for this case, so the S-bar and dual-sheath design of the RelayPlus system allowed us to plan and predict the distal landing zone more accurately and stabilize the access vessels during graft delivery. We accessed the right femoral artery with a cutdown and introduced the system over a 260-cm Lunderquist wire (Cook Medical). The hydrophilic coating of the RelayPlus system, which extends to the tip, enhanced the ease of access, while the stiff outer sheath gave the pushability needed to navigate the tight vessels.

We were able to successfully reach the distal landing zone, which was well above the diaphragm. We parked the outer sheath and proceeded to deploy the inner sheath. As the soft inner sheath was deployed and advanced into

the arch, the precurved inner catheter enabled the system to track easily over the highly angulated arch.

With the staged deployment of the RelayPlus system, initial stored energy from the nitinol is released as the inner sheath is deployed. This was important for the stability and precise placement in this case. The integrated design of the RelayPlus stent-graft and delivery system allowed the graft to be successfully deployed and placed precisely where intended and perpendicular to the aorta while conforming nicely without bird-beaking. After successful removal of the system, the final angiogram showed complete exclusion of the aneurysm. The procedure was successful and the patient is doing well at 1-year follow-up.

#### KEY DEVICE CONSIDERATIONS

The patient had a type III arch with severe tortuosity that appeared as a C-curve, a configuration often found

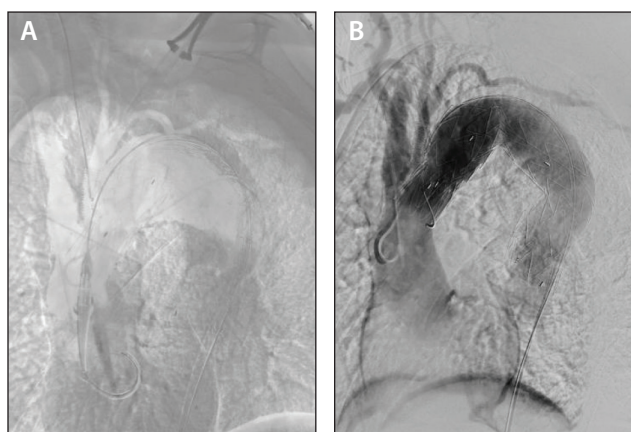


Figure 5. Controlled deployment and accurate positioning of the device (A, B).



in older patients (Figure 3). Her treatment required a conformable graft that deploys at a 90° angle; otherwise, a bird-beak configuration was likely to occur. We knew we needed a system that would be able to navigate to the deployment site and provided trackability, maneuverability, and pushability across a tight type III arch. The RelayPlus does not need the entire rigid delivery system to be advanced across the arch; instead, we can park the primary outer sheath in the descending thoracic aorta and advance the softer secondary sheath with a precurved inner cannula into the tight arch for more conformable navigation. These were all important considerations for this patient, as well as other patients with challenging anatomy.

One key aspect that made the RelayPlus the right system for this patient was the soft inner sheath that permits atraumatic advancement in the vessel. The partial expansion of the inner sheath provides for reduced deployment forces and helps to increase the accuracy of the system. Navigation is improved with the RelayPlus due to the smooth transition between the tip and sheath. Unlike other devices, once access is obtained through the iliac vessels, any subsequent advancement or repositioning does not impact the access vessels. The inner sheath travels into the aorta and, instead of pushing this entire delivery system across the rigid arch, only the inner sheath advances around the arch facilitated by the precurved inner catheter. The graft is then deployed from the system (Figure 4). It also features a controlled tip deployment that allows it to be repositioned accurately before opening the bare spring. It deploys exactly where positioned.

The dual-sheath system of the RelayPlus includes a longer braided outer sheath (60 cm), a nitinol inner catheter, and a reinforced inner liner. The design improves visualization because of the enhanced radiopacity and braided outer sheath, and the nitinol inner catheter aids in alignment. The graft remains encapsulated in the inner sheath so that it tracks very nicely across difficult arch configurations, as demonstrated in this case (Figure 5).

Controlled deployment and positioning of the stent-graft were important advantages of the RelayPlus for this patient. The dual-sheath design with proximal clasp allowed for accurate positioning and easier deployment, and it facilitated maneuvering the graft to achieve exact placement. Because the graft does not remain within a rigid outer sheath, as with other devices, the deployment and delivery of the stent-graft are accurate for this case.

The device's curved inner catheter self-aligns to properly place the S-bar, which is critical to successful endovascular treatment. This S-bar technology enhances the deployment accuracy and conformability of the device and enables more predictable distal placement.

The RelayPlus device has been shown to perform extremely well in difficult anatomy.<sup>4</sup> Results from the RelayPlus United States pivotal trial demonstrated a 1-year freedom from aneurysm-related mortality rate of 93% and freedom from all-cause mortality rate of 85%. There was 100% accurate deployment, and the technical success rate with the device (defined as successful delivery/deployment) was 96.7%.

## DISCUSSION

In our practice, we are seeing more patients with complicated anatomy, particularly in the arch. Type III arches with ≥ 90° angulation are becoming more common, so it is important to have a device available that can successfully treat this anatomy. The RelayPlus system has the trackability, pushability, and conformability to deliver successful outcomes in challenging anatomy. The integrated features in the RelayPlus system (dual-sheath, precurved cannula, S-bar, and proximal clasp) give me the control and confidence I need to treat the most challenging anatomy. ■

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# Emerging Aortic Technologies

BY MATTHEW EAGLETON, MD



This year, the field of endovascular aortic aneurysm repair (EVAR) celebrates the 25th anniversary of the procedure's first description by Dr. Juan Parodi and colleagues in five patients with abdominal aortic aneurysms (AAAs).<sup>1</sup>

From this remarkable accomplishment sprang a specialty that would further push the bounds of what was possible in treating patients with aortic disease by refining both device design and technique to allow for the broader application of endovascular repair as we know today. Bolton Medical is one of the companies emerging globally with a portfolio of products designed to address challenges and further expand aortic treatment options.

## BACKGROUND

Unique to the endovascular space, Bolton Medical entered the thoracic market first with receipt of CE Mark in 2005 for its Relay® thoracic stent-graft system. This change in paradigm and focus allowed Bolton to design around the challenges in thoracic endovascular aneurysm repair (TEVAR) and develop a solution specific for the thoracic aorta. The Relay system introduced the dual-sheath concept, precurved inner cannula, and proximal clasp technologies to the market, which were intended to optimize delivery and accuracy, especially in the arch.

After establishing their place in the thoracic market with both commercial products and a robust custom program, Bolton expanded into the abdominal market with the Treovance® abdominal stent-graft system, which received CE Mark in 2013, and the newest-generation TREO® AAA system, which received CE Mark in 2015 and is currently under US Food and Drug Administration (FDA) review. Bolton Medical has delivered a strong cadence of product innovation to the market by releasing new technology almost every year, either commercially or into their custom program, since 2005.

Currently in the United States, the Relay®Plus thoracic stent-graft system is Bolton's only FDA-approved device; however, with the completion of the Treovance/TREO phase 2 trial in early 2016, Bolton anticipates approval of

the TREO AAA system in the coming months. In 2016, Bolton Medical celebrated their 20,000th implant globally.

## FUTURE TEVAR

In an effort to continue to drive innovation, Bolton is pursuing approval of their RelayPro thoracic device in both Europe and the United States. With completion of the Regeneration trial in Europe earlier this year, the company anticipates approval of the system in early 2017 and is currently enrolling patients in the United States pivotal trial. The phase 2 trial will seek indications for aneurysms, dissections, and transections. The RelayPro device lowers the crossing profile of the RelayPlus' dual-sheath system by 4 F while maintaining the integrity of the stent design to preserve the durability of the stent-graft. The RelayPro system will offer both the bare-stent proximal configuration as well as the non-bare-stent (NBS) proximal configuration (Figure 1) upon launch, as well as the notable suite of tapers and lengths that are present on the approved RelayPlus system. RelayPro will serve as the platform technology as Bolton Medical continues to develop into the arch and ascending aorta.

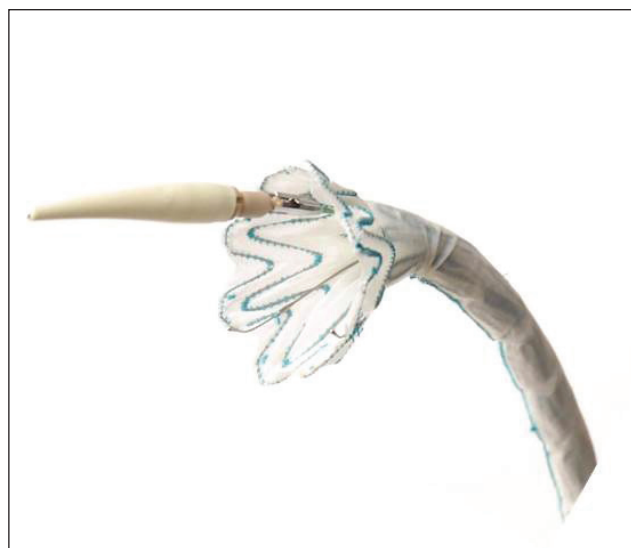
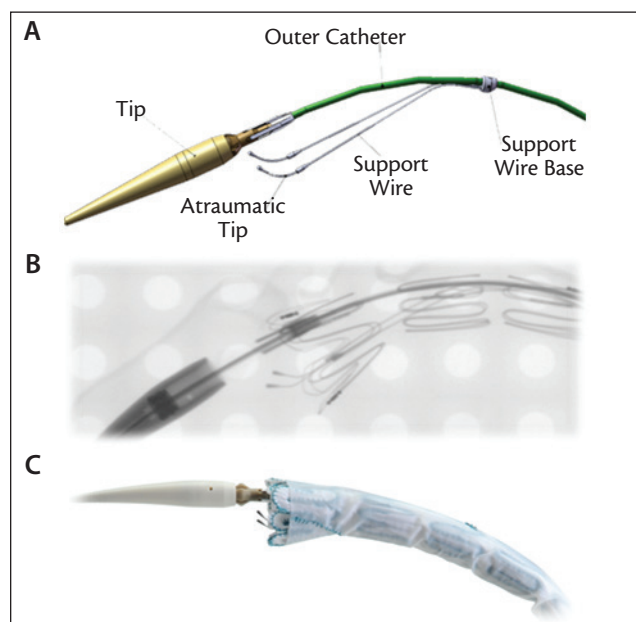


Figure 1. The NBS proximal configuration.



**Figure 2.** Illustration of the RelayNBS clasp and support wires (A). The RelayNBS under simulated fluoroscopy (B). The RelayNBS dual sheath (C).

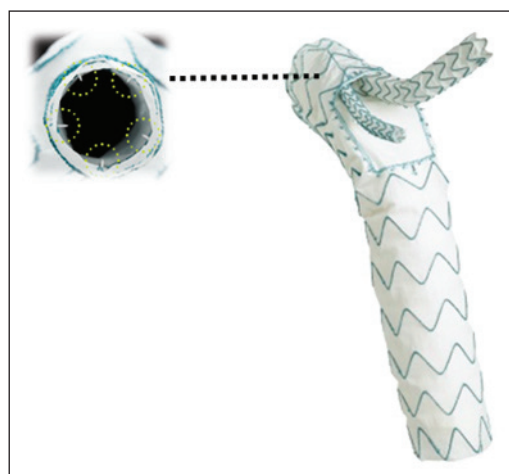
## INTO THE ARCH

The RelayNBS technology was designed to deliver a covered proximal configuration in a controlled and accurate manner utilizing the novel proximal clasp mechanism with support wires. The NBS technology eliminates the need to fixate in zone 0 with bare metal and allows for more proximal landing when necessary. In conjunction with the precurved dual-sheath delivery system, this is an optimal design to deliver a stent-graft over the arch (Figure 2).

Based on the established RelayNBS technology, Bolton Medical developed the RelayBranch endograft (Figure 3),



**Figure 3.** The RelayBranch endograft.



**Figure 4.** The Lock Stent in the RelayBranch endograft.

which is intended to seal in zone 0 and has been designed with two internal tunnels that support continuous blood flow to the target vessels (innominate and left common carotid artery) through branch grafts. The graft is designed with a large window that acts as a gateway to the tunnels and allows for easy cannulation and uninterrupted blood flow to the arch vessels during the procedure.

The branched stent deploys similarly to the RelayPlus system for precise deployment, which is crucial in the aortic arch because the device must be deployed near the sinotubular junction. Precision is also imperative to maintain patency to the coronary vessels in that region. This location is particularly difficult for stent-graft deployment because of the distinct hemodynamic forces in the region.

Due to the unique physiologic and hemodynamic demand on the stent-graft system deployed in zone 0, Bolton Medical has integrated its Lock Stent technology into the RelayBranch device (Figure 4). The Lock Stent is a dull barb located in the tunnel of the main graft that interlocks with the stent apices of the branch graft. This locking mechanism is intended to mitigate component separation.

## CLINICAL IMPACT

Current worldwide clinical experience with the RelayBranch System has reached 70 patients through the custom program and has been focused in Europe, Latin America, and Asia. The RelayBranch system is not currently available for use in the United States.

Although research is limited, a group of Italian investigators provided a detailed description of the endograft's application in aortic arch aneurysms in the *Journal of Vascular Surgery* in 2013. The investigators found that the branched endograft resulted in successful endovascular repair of a 61-mm aortic arch aneurysm in an 81-year-old man. They concluded that "multibranched technology is very attractive and represents the 'next step' in aortic arch endovascular repair."<sup>2</sup>

If approved, the dual-branch graft would be the first of its kind in the United States. Although its ultimate impact remains to be determined, the graft could potentially benefit thousands of patients if used to treat individuals with arch aneurysms and/or aortic dissections.

## ENHANCEMENTS IN ABDOMINAL ENDOGRAFTS

Utilizing facets of its thoracic stent-graft technology, Bolton Medical developed the TREO abdominal stent-graft system for the treatment of AAAs. This CE Mark–approved graft is distinguished from others on the market by its low-profile delivery system and dual-active fixation for migration resis-



tance within a single laser-cut stent. The two fixation points include a suprarenal barb for primary proximal fixation and an infrarenal barb for supplemental fixation in angulated anatomies. The delivery system operation for both the placement of the endograft and release of the proximal clasp is both intuitive and smooth. Experience with the Treovance, an earlier iteration of TREO, has allowed for improvements in ease of use and sheath design. The TREO platform is also a part of Bolton's custom-made program, providing patient-specific solutions in cases that required extreme tapers, fenestrations, and/or scallops.

### PRELIMINARY OUTCOMES

Results for the Treovance abdominal stent-graft in two early trials—the preliminary ADVANCE study in Europe and the phase 1 BENEFIT study in the United States—showed promise and led to the Bolton Treovance abdominal stent-graft system's phase 2 clinical trial (for which I serve as Principal Investigator). The multicenter, nonblinded, nonrandomized trial completed enrollment in February 2016. The final study population included 150 patients with AAAs from 30 hospitals in the United States.

Early outcomes indicated successful graft implantation with minimal perioperative risk. At 30 days, there was a low rate of morbidity and no deaths, and at 6 months, nearly half of the patients demonstrated aneurysm regression. More data on this trial will be available in early 2017, including the primary efficacy endpoint, defined as suc-

cessful aneurysm treatment 12 months after implantation using a performance goal of at least 88%.

### CONCLUSION

Improvements in design of both thoracic and abdominal endografts will allow a broader patient population to benefit from TEVAR and EVAR. Although Bolton Medical's RelayBranch technology and TREO abdominal stent-graft are in the early stages of investigation, initial results are encouraging. Additional research will be critical for determining the overall safety, efficacy, and durability of these new technologies. Bolton Medical demonstrates a commitment to the aortic market and is continuing to push development in all areas of the aorta. ■

1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Ann Vasc Surg.* 1991;5:491-499.

2. Piffaretti G, Rivolta N, Fontana F, et al. Aortic arch aneurysm repair with a new branched device. *J Vasc Surg.* 2013;57:1664-1667.

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