

Trusted Performance

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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.¹ 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.^{2,3}

Four devices have been approved in the United States for thoracic endografting, including the Relay[®]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

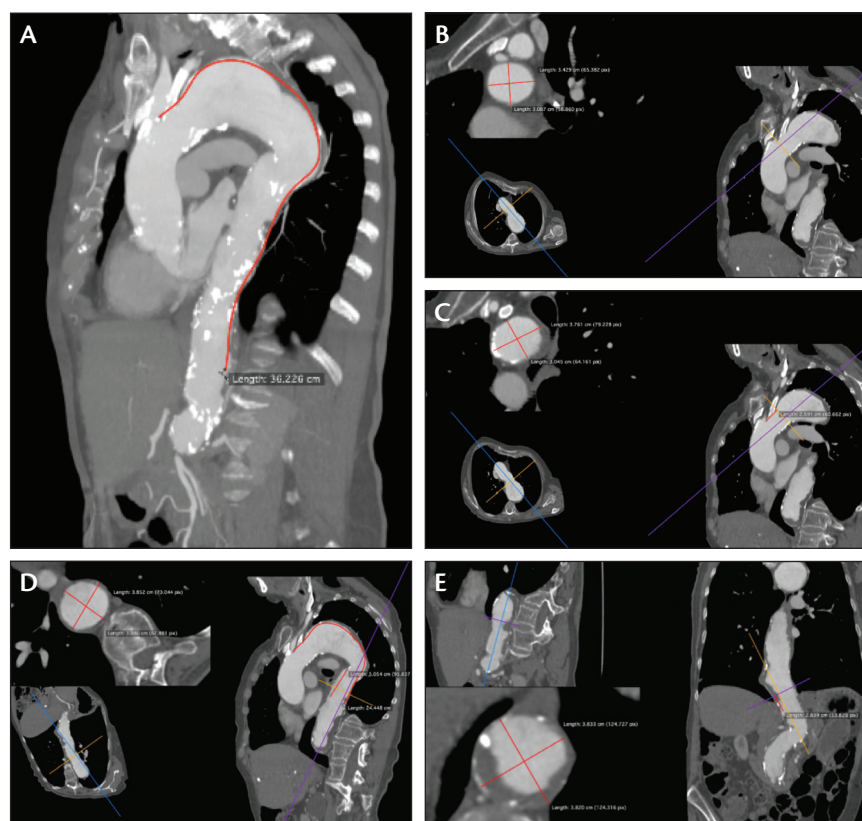


Figure 1. Preoperative imaging highlighting a large thoracic aortic aneurysm and the technical anatomical challenges of treating this patient. The superior edge of the proximal landing zone (A, B). The inferior edge of the proximal landing zone (C). Panels D and E show the distal landing zones.

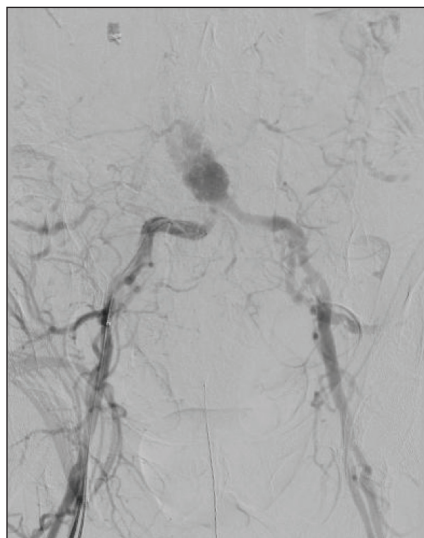


Figure 2. The access vessels.

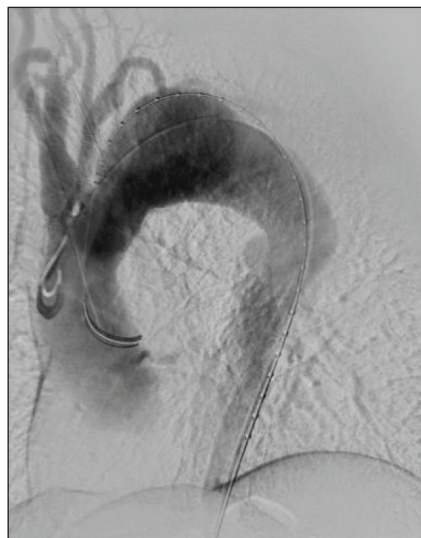


Figure 3. The patient had a type III arch with severe tortuosity.

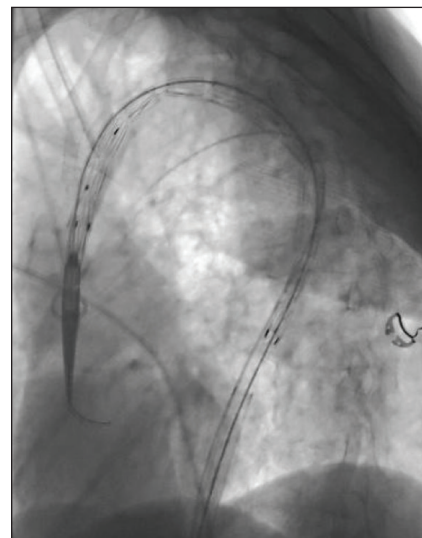


Figure 4. The graft has deployed.

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.² 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

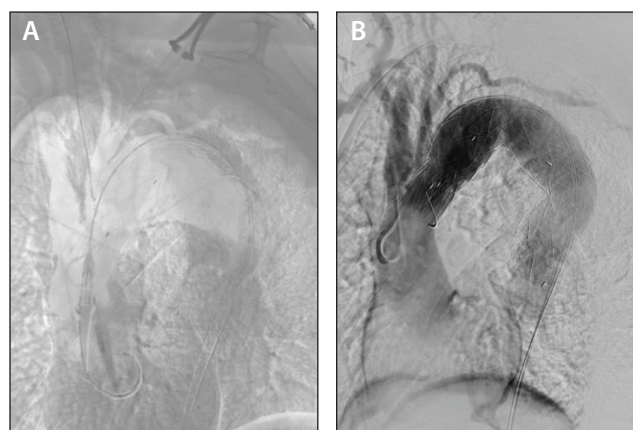


Figure 5. Controlled deployment and accurate positioning of the device (A, B).

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.⁴ 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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4. Bolton RelayPlus US pivotal trial data. Data on file.

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