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Endovascular TODAY

Winter 2014

INNOVATING

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SOLUTIONS

Providing optimal therapy
with the Bolton Medical Relay®
Thoracic Stent-Graft.



Innovating Conformable Thoracic Solutions

Thoracic endografting technology has made remarkable improvements in the last decade, making it the first-choice therapy for many thoracic aorta pathologies. The Relay® thoracic stent-graft (Bolton Medical, Inc., Sunrise, FL) possesses many unique features that demonstrate the refinement of this technology, including proximal capture, a double-sheath system, and a spiral support strut, which fill the desired niche for apposition and conformability.

In this supplement to *Endovascular Today*, a variety of esteemed physicians share their first-hand experience with the Relay stent-graft in a series of six case reports. Francis P. Cuzzo, MD, and Jean M. Panneton, MD, FACS, FRCSC, share an endovascular repair of an isolated descending thoracic aneurysm. Daniel J. Torrent, MD, and Michael C. Stoner, MD, RVT, FACS, detail two cases from their practice: an elective repair of a saccular descending thoracic aortic aneurysm and a bilobed descending aortic aneurysm. Prashanth Vallabhajosyula, MD, MS, and Wilson Y. Szeto, MD, discuss stent-grafting in a patient with a rapidly enlarged aneurysm. Martyn Knowles, MD, and Carlos H. Timaran, MD, explain the benefits of using the Relay stent-graft in a patient with a tight thoracic arch. W. Anthony Lee, MD, presents a patient with a fusiform descending thoracic aneurysm. We hope you find this supplement to be a valuable tool in your practice.

Contents

- | | |
|---|--|
| 3 United States Data for the Bolton Relay® Thoracic Stent-Graft | 10 Utilizing the Relay® Thoracic Stent-Graft for Excellent Apposition in a Patient With Tight Thoracic Arch
By Martyn Knowles, MD, and Carlos H. Timaran, MD |
| 4 Endovascular Repair of an Isolated Descending Thoracic Aortic Aneurysm With the Relay® Thoracic Stent-Graft System
By Francis P. Cuzzo, MD, and Jean M. Panneton, MD, FACS, FRCSC | 12 Endovascular Repair of a Thoracic Aortic Aneurysm Using the Bolton Relay® Stent-Graft
By W. Anthony Lee, MD |
| 7 Elective Repair of a Saccular Descending Thoracic Aortic Aneurysm
By Daniel J. Torrent, MD, and Michael C. Stoner, MD, RVT, FACS | 14 Repair of a Bilobed Descending Aortic Aneurysm
By Daniel J. Torrent, MD, and Michael C. Stoner, MD, RVT, FACS |
| 8 Endovascular Stent-Grafting in a Patient With a Rapidly Enlarging Thoracic Aortic Aneurysm
By Prashanth Vallabhajosyula, MD, MS, and Wilson Y. Szeto, MD | |

United States Data for the Bolton Relay® Thoracic Stent-Graft

The Relay thoracic stent-graft with Plus delivery system (Bolton Medical, Inc., Sunrise, FL) received United States Food and Drug Administration approval in September 2012, but it has been used in Europe and other international markets since 2005. The United States pivotal study included 120 endovascular patients at 30 hospitals. The study was expanded to include a continued access arm. The clinical data presented here are updated through February 2013 and include both phase II and continued access figures.

DEMOGRAPHICS. There were 133 patients treated with Relay, including both the clinical trial and continued access data (Table 1). A surgical control arm was required in the clinical trial, consisting of 60 patients.

Most notable in the Relay arm was a very large percentage of older patients—46.6% of patients were over 75 and 26.3% were 80 years or older, which is double the 11.7% of octogenarians included in the surgical group. No surgical patients were over the age of 84. There was an approximately even amount of men and women, and the majority of patients were Caucasian.

CLINICAL UTILITIES. The procedure times were quite similar to surgical control groups in other clinical trials, with the endovascular arm being far superior in almost every metric (Table 2). The Relay arm had a mean and standard deviation (SD) of 2.3 ± 1.2 (range, 0.1–6.2 hours) versus the surgery arm's SD of 4.6 ± 2.3 (1.4–14.1 hours).

Blood loss, ICU time, and hospital stay were all more favorable in the Relay arm.

RELAY OPERATIVE DATA. Implants were successful in 96.7% of patients (128 of 132; one subject did not have a completed case report). Four subjects' procedures were aborted, all related to anatomical challenges. There were no operative conversions to open repair.

EARLY OUTCOMES. Mortality within 30 days was 5.3%. The surgical arm had higher rates of stroke, paralysis/paraplegia, myocardial infarction, procedural bleeding, renal failure, respiratory failure, wound complications, and mortality.

LATE OUTCOMES. Mean follow-up was 30 months and outcomes were CEC-adjudicated (Table 3). The Relay arm had substantially lower rates of procedural bleeding, renal failure, respiratory failure, wound complications, all-cause mortality, and aneurysm-related mortality than the surgical control.

EFFECTIVENESS. There was no site-reported incidence of stent-graft migration, lumen occlusion, or aneurysm rupture. One patient required conversion to open repair during follow up. Throughout all follow-ups, there was a 6.0% overall incidence of endoleak; type I endoleak was in 4.5% (6/133) and type III, 2.3% (3/133).

Table 1. Demographics

	Relay (n = 133)	Surgical (n = 60)
Mean Age (Range)	72.8 (28–91)	70.0 (35–84)
18–64	15.8% (21/133)	20% (12/60)
65–74	37.6% (50/133)	40% (24/60)
75–79	20.3% (27/133)	28.3% (17/60)
80–84	16.5% (22/133)	11.7% (7/60)
≥ 85	9.8% (13/133)	0% (0/60)
Gender		
Male	52.6% (70/133)	68.3% (41/60)
Female	47.4% (63/133)	31.7% (19/60)
Race		
Caucasian	85.7% (114/133)	83.3% (50/60)
African American	6.8% (9/133)	10% (6/60)
Other	7.5% (10/133)	6.7% (2/60)

Table 2. Clinical Utilities

Parameter	Relay (m±SD, range)	Surgical (m±SD, range)
n	132	56
Procedure Time (hours)	2.3 ± 1.2 (0.1–6.2)	4.6 ± 2.3 (1.4–14.1)
n	130	31
Blood Loss (ml)	2347 ± 377 (0–4000)	2347 ± 2647 (0–12,000)
n	127	42
ICU Time (hours)	56 ± 51 (0–257)	191 ± 190 (24–745)
n	127	56
Hospital Stay (days)	5.2 ± 4.1 (1–30)	13 ± 10 (3–45)

Table 3. Early and Overall Outcomes

Early safety outcomes		
Adverse Events	Relay (n = 133)	Surgical (n = 60)
Stroke	4.5% (6/133)	6.7% (4/60)
Paralysis/Paraplegia	1.5% (2/133)	3.3% (2/60)
MI	1.5% (2/133)	1.7% (1/60)
Procedural Bleeding	6.0% (8/133)	28.3% (17/60)
Renal Failure	1.5% (2/133)	5.0% (3/60)
Respiratory Failure	5.3% (7/133)	18.3% (11/60)
Wound Complications	5.3% (7/133)	6.7% (4/60)
Mortality	5.3% (7/133)	10.0% (6/60)
Overall effectiveness outcomes		
Major device-related adverse events	9/133 (6.8%)	
Any endoleak	8/133 (6.0%)	
Type I	6/133 (4.5%)	
Type III	3/133 (2.3%)	
Type IV	0/133 (0%)	
Stent migration	0/133 (0%)	
Lumen occlusion	0/133 (0%)	
Aneurysm rupture	0/133 (0%)	
Deployment failure/conversion to surgical repair	1/133 (0.8%)	

Endovascular Repair of an Isolated Descending Thoracic Aortic Aneurysm With the Relay[®] Thoracic Stent-Graft System

BY FRANCIS P. CUOZZO, MD, AND JEAN M. PANNETON, MD, FACS, FRCSC

The incidence of thoracic aneurysms has increased from 5.9 to 13.9 cases per 100,000 people in the last 20 years.¹ In elderly patients with increased medical comorbidities, endovascular repair has become a reliable alternative to open repair in the treatment of patients with isolated descending thoracic aortic aneurysms. Several studies have delineated decreasing perioperative morbidity and mortality when compared to open thoracic or thoracoabdominal approaches.²⁻⁷ Since the late 1990s, diverse thoracic stent-grafts have been approved outside the United States. Several medical device companies and independent physicians have evaluated these devices in United States clinical trials, and four commercial devices for thoracic endovascular aortic repair (TEVAR) are currently approved for use in the United States. Published early and midterm results regarding the use of these devices have been favorable and supportive of the therapy in comparison to standard surgical repair. We report a case of a patient presenting with a complex isolated descending thoracic aneurysm successfully treated with TEVAR using the Relay thoracic stent-graft system (Bolton Medical, Inc., Sunrise, FL) as part of our participation in the phase II clinical trials for this device. The phase II Clinical Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft in Patients with Thoracic Aortic Pathology recently led to the FDA approval of this new thoracic stent-graft.

CASE REPORT

A 79-year-old man with a significant history of hypertension and previous open infrarenal abdominal aortic

aneurysm tube graft repair had been followed at our clinic for an asymptomatic descending thoracic aneurysm. At his most recent visit, the thoracic aneurysm had expanded, and a computed tomography angiogram (CTA) revealed a 5.5 cm isolated descending thoracic aortic aneurysm with a severe angulation at its distal extent (Figure 1A). The descending aorta made an approximately 90° turn at its most posterior aspect with evidence of lumen compromise (Figure 1A). In addition to this severe aortic buckling, moderate bilateral iliac tortuosity added to the patient's anatomic complexities (Figure 1B). There was no history of aortic dissection. Because the aneurysm started approximately 4 cm from

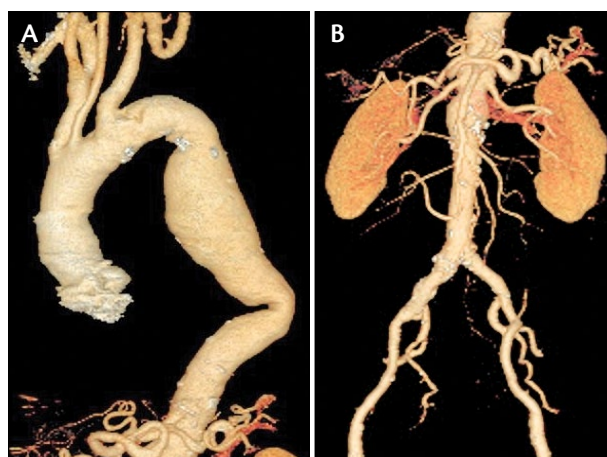


Figure 1. Preoperative 3D CTA revealing an isolated descending thoracic aortic aneurysm with severe aortic buckling (A) and moderate bilateral iliac tortuosity (B).

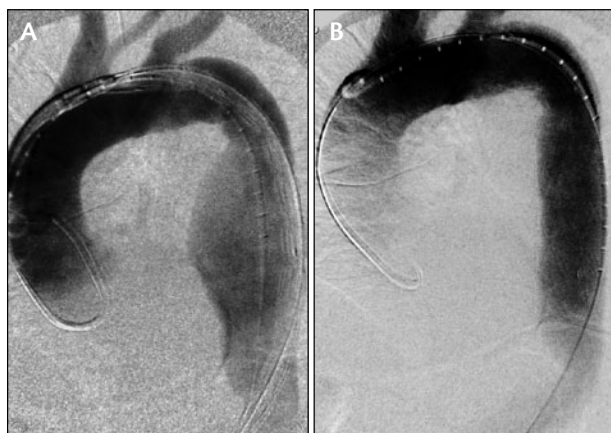


Figure 2. A predeployment aortogram shows the proximal extent of the descending thoracic aneurysm (A). The post-deployment aortogram shows repaired aneurysm with no endoleak (B).

the takeoff of the left subclavian artery and was limited to the thoracic aorta, we decided that the anatomy was well suited for TEVAR, and the patient was consented and enrolled in the Relay phase II trial. A 34 mm X 250 mm single-segment Relay endograft was advanced over a superstiff guidewire from the right common femoral artery and delivered into the aortic arch. The dual-sheath delivery system enabled the Relay endograft to track effortlessly through the iliac system and the aortic angulation in a smooth and controlled fashion. The takeoff of the left subclavian and left carotid arteries were then marked after an arch injection with a left anterior oblique view (Figure 2A). Partial opening of the Relay graft enabled us to accurately position the proximal bare stent across the left subclavian artery and the covered stent right at its ostium (Figure 3B). The endograft was then fully deployed with the distal extent well above the celiac artery. Completion aortogram showed absence of any endoleak and patent arch vessels (Figure 2B). Postoperatively, the patient had an uncomplicated course and was discharged to home on postoperative day 2. The initial postoperative CTA confirmed accurate positioning as well as excellent conformability of the Relay endograft at the level of the aortic arch and across the distal aortic angulation (Figure 3A and 3B). Significant aneurysm sac shrinkage was noted on a 2-year follow-up CTA (Figure 4). A 5-year follow-up CTA revealed a stable stent-graft without any migration and absence of residual aneurysmal sac in the descending thoracic aorta.

DISCUSSION

In the nearly 20 years that endovascular treatment of thoracic aortic pathologies has been performed, numer-

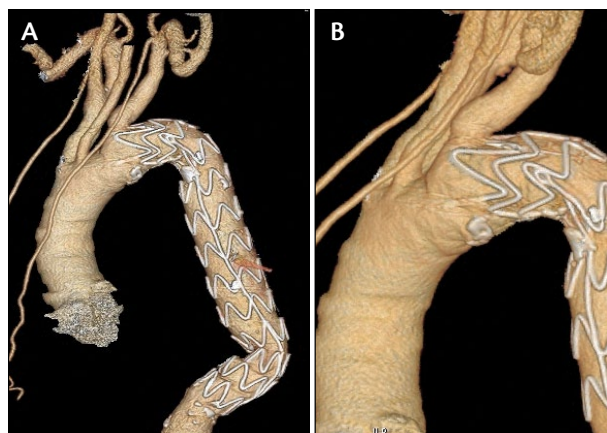


Figure 3. Postoperative 3D CTA shows excellent positioning of the stent-graft with total aneurysm sac exclusion (A). Note the precise positioning of the uncovered portion of the proximal stent at the left subclavian artery (B).

ous investigators have demonstrated its safety, efficacy, and comparable results to open surgical repair with less morbidity and mortality. Successful TEVAR requires complete endovascular sac exclusion, which relies upon exact positioning of the graft in order to achieve adequate fixation and sealing. Another important factor in the selection, planning, conduct, and outcome of endovascular aortic aneurysm repair is the degree of aortoiliac tortuosity. Excessive tortuosity may cause difficulty in gaining access to the aneurysm and in the deployment of the stent-graft, and it may result in unstable fixation.⁸ Tortuosity has been implicated as a cause of late complications and endograft failure through progressive distortion and limb retraction.⁹ Not all patient anatomy is suitable for endovascular repair, and device-related complications such as endoleaks, stent-graft collapse, and migration, could occur.

The optimal aortic stent-graft needs to be highly flexible and conform perfectly to the aortic wall and should also withstand aortic movement and blood flow. Reliable trackability of the delivery system is also crucial to achieve precise positioning.

In our preoperative assessment of this patient's anatomy, we believed he would be a good candidate for the phase II trial involving the Relay thoracic stent-graft system. This endograft is designed specifically for thoracic aorta disease repair and has the advantage of additional columnar support, achieved by a helical nitinol backbone wire that helps preserve torque response and flexibility. We have found that this design feature, combined with the dual-sheath delivery system, improves the device's ability to track through severe aortic angulations. In addition, the oblique backbone at the outer half of the

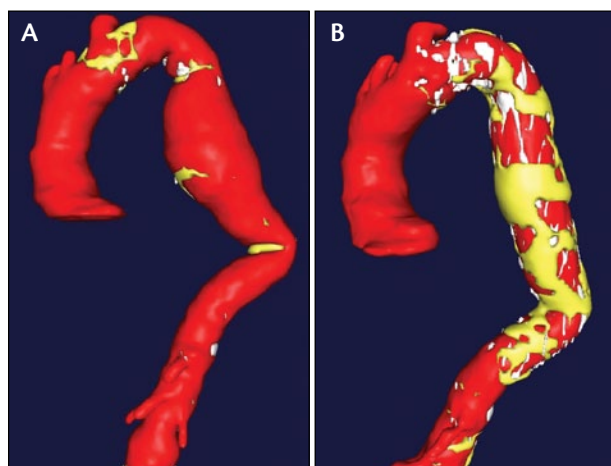


Figure 4. Three-dimensional M2S reconstructions (M2S Inc., West Lebanon, NH) of the preoperative thoracic aorta (A) and a 2-year follow-up image (B) displaying significant aneurysm sac (yellow) remodeling and relief of aortic buckling.

stent-graft tends to rotate toward its intended position during application, allowing for precise delivery to increase accuracy of positioning. The nitinol wire starts proximally below the second ring, which allows for relatively independent movement of the first and second stent-graft rings for optimal apposition in the aortic arch. The radial force of the stent-graft is also greatest at the proximal ring in order to provide the highest radial load for sealing and fixation.¹⁰ Seemingly, these attributes contributed to the successful outcome of our patient and will make this graft a safe and effective choice in the future for patients with challenging thoracic aortic anatomy.

In conclusion, we have demonstrated a successful TEVAR outcome in a patient with difficult anatomy using the Relay stent-graft system without perioperative complications. The device's durability is evidenced by a 5-year follow-up with complete aneurysm sac shrinkage and absence of migration. Anatomic aortoiliac complexities such as those illustrated in our patient can account for both technical and treatment failures in patients undergoing TEVAR. Structural and delivery design improvements in the Relay stent-graft system may have

the potential to increase the feasibility and success of endovascular repair in this cohort of patients with complex anatomy. ■

Francis P. Cuzzo, MD, is a vascular surgery fellow with the Division of Vascular Surgery, Eastern Virginia Medical School in Norfolk, Virginia. He has disclosed that he has no financial interests related to this article.

Acknowledgements: I am a military service member. This work was prepared as part of my official duties. Title 17, USC, §105 provides that 'Copyright protection under this title is not available for any work of the U.S. Government.' Title 17, USC, §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties.

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Elective Repair of a Saccular Descending Thoracic Aortic Aneurysm

BY DANIEL J. TORRENT, MD, AND MICHAEL C. STONER, MD, RVT, FACS

A 61-year-old man originally presented with a 5.8 cm abdominal aortic aneurysm, which was repaired with an endovascular modular bifurcated system. Upon imaging for this aneurysm, a 5.6 cm saccular descending thoracic aortic aneurysm was found (Figure 1). He presented 7 months after his abdominal aortic aneurysm repair for elective repair of the thoracic aortic aneurysm.

A right groin incision was made through the prior scar, and the femoral artery was exposed. Percutaneous access was achieved to the left femoral artery, and an 8 F sheath was placed. An 8.5 Volcano IVUS probe (Volcano Corporation, San Diego, California) was advanced to the aortic arch and brought distally to the distal extent of the aneurysm, measuring the proximal and distal diameter of the aneurysm. A 14 F sheath was then placed through the exposed right femoral artery, and a pigtail catheter was advanced to the aortic arch. Angiography was performed to show the aneurysm (Figure 2). A 40 to 36 mm taper X 140 mm length Relay graft (Bolton Medical, Inc., Sunrise, FL) was chosen.

A Lunderquist curved wire (Cook Medical, Bloomington, IN) was placed through the left groin to the aortic arch, and the pigtail catheter was removed. The deployment system was advanced to the proximal abdominal aorta and was unsheathed. The deployment device was then advanced to the beginning of the descending thoracic aorta. The proximal cap and bare metal stent were released. The delivery system was recaptured and removed. The IVUS probe was advanced through the graft and showed infolding in the distal portion. A Coda balloon catheter (Cook Medical) was advanced through the sheath, and ballooning of the distal graft was performed. Upon reimaging, the infolding had resolved. Angiography after placement of the stent showed exclusion of the aneurysm without endoleak (Figure 3). The sheaths and catheters were removed. A StarClose device (Abbott Vascular, Santa Clara, CA) was used for hemostasis of the left groin puncture site. The arteriotomy in the right femoral artery was closed, and the groin was closed in layers.

The patient did well postoperatively and was discharged to home on postoperative day 1. Repeat CT scans at

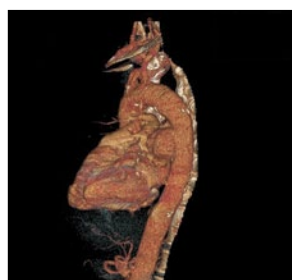


Figure 1. Computed tomography angiogram (CTA) of the saccular descending thoracic aortic aneurysm.

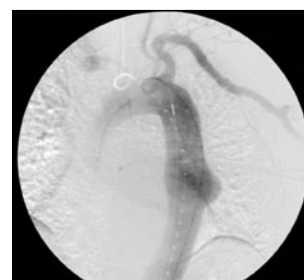


Figure 2. Intraoperative angiography of the thoracic aortic aneurysm.

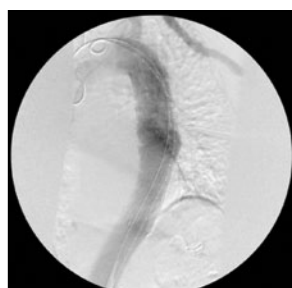


Figure 3. Intraoperative angiography after placement of the stent.



Figure 4. CTA at 2-year follow-up.

1 month and 2 years (Figure 4) after the repair showed the graft in place and patent without evidence of endoleak. ■

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Endovascular Stent-Grafting in a Patient With a Rapidly Enlarging Thoracic Aortic Aneurysm

BY PRASHANTH VALLABHAJOSYULA, MD, MS, AND WILSON Y. SZETO, MD

A 79-year-old woman with a history of Sjögren's syndrome, rheumatoid arthritis, hypertension, moderate to severe interstitial lung disease with pulmonary fibrosis, and a known descending thoracic aortic (DTA) aneurysm (4.5 cm) presented with rapid expansion of the aneurysm to a maximal diameter of 6.2 X 5.6 cm over 1-year follow-up. Given these findings, the patient was electively taken for endovascular surgical intervention. The aneurysm had a large mural thrombus burden along with marked tortuosity in the distal thoracic aorta, extending from the proximal DTA to the aortic hiatus. The aortic dimensions were 29 mm at the left subclavian artery takeoff and 28 mm at the celiac axis.

Intraoperatively, right common femoral arterial access was achieved via open groin exposure, along with percutaneous left common femoral artery access for diagnostic study. Upon heparinization, a guidewire was placed into the ascending aorta under fluoroscopic guidance and exchanged to a Lunderquist stiff wire (Cook Medical, Bloomington, IN). A pigtail catheter was advanced from the left femoral access 7 F sheath, and angiography delineated the aortic arch/DTA anatomy (Figure 1). A 34 to 30 mm taper X 200 mm Relay graft (Bolton Medical, Inc., Sunrise, FL) was maneuvered around a severely angulated DTA by the aortic hiatus and was deployed proximally by the left subclavian artery without occluding it (Figure 2A). Upon confirming good proximal seal with angiography, DTA anatomy by the aortic hiatus was delineated, with special attention given to the celiac axis takeoff and the severe angulation of the aorta. Next, a second 34 X 34 X 150 mm Relay graft was advanced in a retrograde fashion and parked inside the first stent with a 5 cm overlap. The graft was then deployed, ensuring that the distal land-

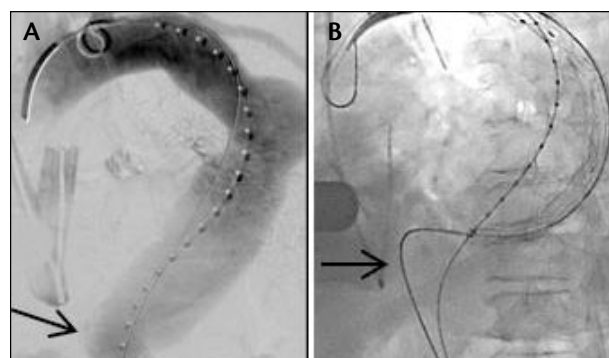


Figure 1. Angiography of the DTA aneurysm is shown, delineating the sharp angulation of the DTA by the diaphragmatic hiatus. DTA angiogram (A) and predeployment image (B) of the proximal Bolton Relay stent-graft are shown.

ing zone did not occlude the celiac axis (Figure 2B). A completion angiogram showed good proximal and distal seal, without any type I or III endoleaks (Figure 2C). The patient had an uneventful recovery and was discharged to home on postoperative day 6.

At her most recent 2-year follow-up, the patient continued to do well and remained asymptomatic. A CT scan at follow-up showed no endoleaks (Figure 3), with reduction of the DTA aneurysm to 5.2 cm.

The Bolton Relay graft was the ideal endograft choice in this case given the extreme tortuosity seen in the DTA by the diaphragmatic hiatus. The flexibility of this device, which was specifically designed to handle such tortuosity in the thoracic aorta, facilitated excellent coverage of the DTA aneurysm without any endoleak. The modular design of the system, along with multiple straight and tapered configurations and different lengths, enabled ease of coverage of the entire DTA aneurysm

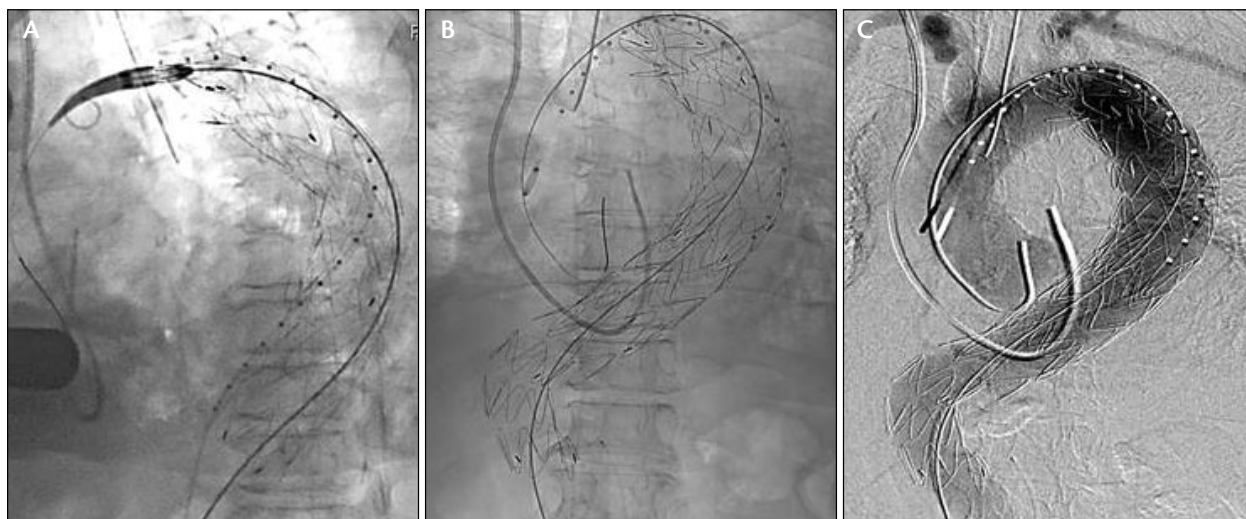


Figure 2. DTA aneurysm coverage with Bolton Relay stent-graft (A). For proximal DTA coverage, a 34 to 30 mm taper X 200 mm Bolton Relay uncovered stent-graft was deployed by the left subclavian artery takeoff. This enabled coverage of the DTA right up to the subclavian artery without occluding this vessel (B). For complete coverage of the DTA, and to handle the extreme tortuosity by the diaphragmatic hiatus, a 34 X 34 X 150 mm Bolton Relay graft was deployed with 5 cm stent-to-stent overlap (C). Completion angiography confirmed excellent coverage of the DTA aneurysm without any endoleak.

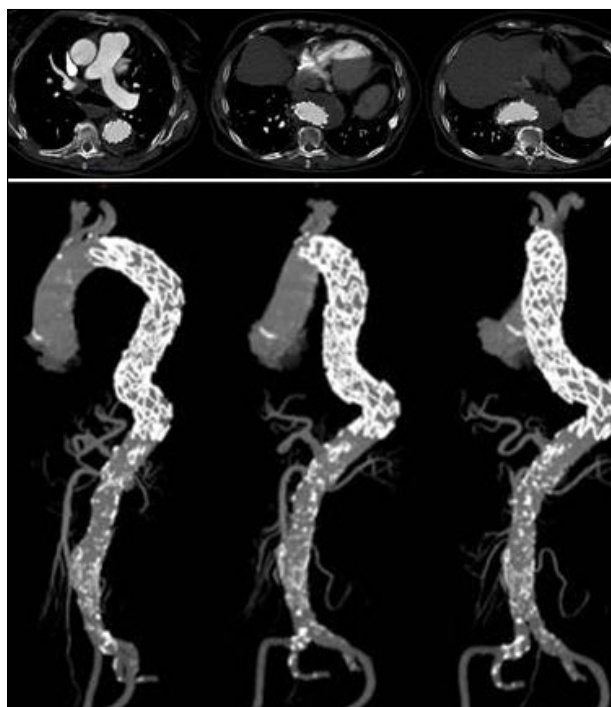


Figure 3. Two-year follow-up imaging showing a decrease in the size of the DTA aneurysm without any endoleaks or collapse or migration of the stent-grafts. Axial cuts and rotational images of the virtual aorta are shown to display the tortuosity of the DTA aneurysm and the severe angulation by the diaphragmatic hiatus that was successfully stented.

with two stent-graft segments. Proximal landing with a 34 X 30 mm tapered device enabled good proximal landing seal. The ability to place a 34 X 34 mm distal stent-graft piece with 5 cm stent overlap allowed excellent seal between the two stent-grafts to prevent type III endoleak and a good distal landing zone seal by the celiac axis (DTA measured 28 mm by the aortic hiatus). The S-bar technology of the Relay system enables conformability to handle severe angulation of the aorta and provides longitudinal support to prevent the stent-graft from collapsing at the site of a severely kinked aorta. In this case, the severe angulation of the DTA aneurysm by the diaphragmatic hiatus was handled with relative ease due to the excellent conformability of the Bolton Relay endoprosthesis. ■

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Utilizing the Relay® Thoracic Stent-Graft for Excellent Apposition in a Patient With Tight Thoracic Arch

BY MARTYN KNOWLES, MD, AND CARLOS H. TIMARAN, MD

The tortuous anatomy of the thoracic aorta, especially in the arch, can prove difficult when it comes to the repair of various pathologies via endovascular techniques. Challenges in patient anatomy, coupled with high strain and an acute curve in the aortic arch, can create difficulty in trying to get apposition with a stent-graft.

The Bolton Medical Relay thoracic graft (Bolton Medical, Inc., Sunrise, FL) received FDA approval in the United States a year ago and has had more than 9,000 implants worldwide. The device is designed to conform to difficult thoracic anatomy, preventing endoleaks and migration. With a wide variety of stents available (diameters of 22 to 46 mm, lengths of 100 to 250 mm, straight or tapered), a clinician is well prepared to treat a range of patient scenarios. The dual-sheath design and hydrophilic coating creates excellent pushability to navigate difficult anatomy, while the short tip allows easy proximal extension into the thoracic arch. The deployment technique and ability to adjust the stent allows precise placement, and the spiral support strut and proximal bare stents allow excellent apposition and conformability.

CASE REPORT

A 76-year-old man known to have a type II thoracoabdominal aneurysm, incidentally found on a computed tomography (CT) chest scan 3 years earlier, had an increase in aneurysm sac size to 6.2 cm. CT imaging showed the largest segment was paravisceral, however, there was aneurysmal involvement proximally to an area near the left subclavian artery (Figure 1). He was asymp-

tomatic and denied any back, chest, or abdominal pain. He had a significant history of hypertension, coronary artery disease, and had previous coronary artery bypass surgery. A staged endovascular repair was planned, with a thoracic aortic aneurysm repair (TEVAR) performed first to reduce the risk of paraplegia.

The patient was taken to the operating room, and

percutaneous bilateral femoral access was achieved. Thoracic angiography and intravascular ultrasound were performed to confirm an adequate proximal landing zone. The angiogram uncovered a short landing zone distal to the origin of the left subclavian artery and prior to an acute angle of the proximal descending thoracic aorta. After dilating the right femoral access with a 22 F sheath, we placed a 38 X 34 X 200 mm tapered stent-graft into the mid-descending thoracic aorta. Uncovering the inner sheath, we advanced into position using our previous

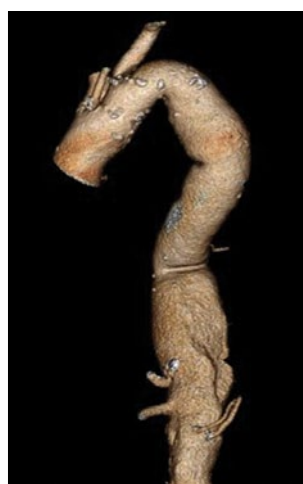


Figure 1. A CT angiogram 3D reconstruction showing the type II thoracoabdominal aortic aneurysm with a large paravisceral segment as well as an abnormal proximal aorta with an acute turn near the left subclavian artery.

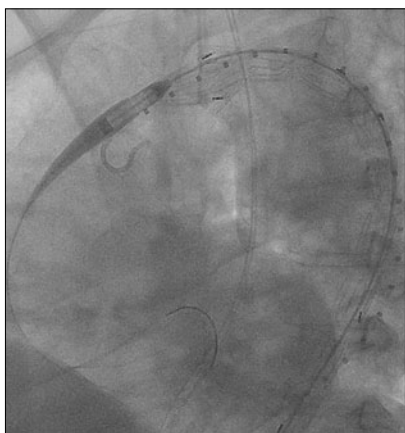


Figure 2. Intraoperative fluoroscopy showing sheath withdrawal after the first stent, allowing exact deployment and the ability to realign the graft if needed before complete deployment.

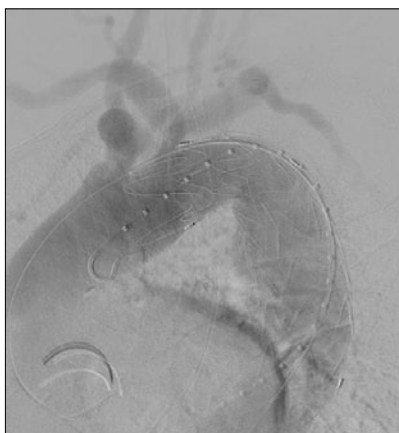


Figure 3. Intraoperative angiogram showing placement of the thoracic graft abutting the left subclavian artery without any bird-beaking and excellent apposition in a tight, short curve.



Figure 4. Postoperative CT angiogram 3D reconstruction showing no evidence of endoleak and exceptional conformability of the graft.

angiogram as a reference. The spiral support strut automatically took favor to the outer curve during sheath advancement. The device was partially unsheathed uncovering the first stent, and we obtained another angiogram for confirmation of location and placement (Figure 2). We were able to realign the device for accurate landing at the left subclavian artery, and once satisfied with positioning, released the remainder of the device. No additional maneuvers, such as significantly dragging or advancing the device, were necessary to obtain the desired placement after deployment. The bare stents were released, and the deployment device was resheathed and removed. We placed another device, 36 X 32 X 150 mm, distally after ensuring adequate overlap with similar precision. A completion angiogram was obtained, showing excellent apposition of the stent without bird-beaking proximally in the acute angle and no evidence of endoleak (Figure 3), which was confirmed on a postoperative CT angiogram (Figure 4). The patient did well and was discharged home on the third day after an uneventful postoperative course.

CONCLUSION

The Bolton Medical Relay Plus device impresses with excellent apposition and conformability in a tight thoracic arch. In addition, the deployment technique allows precise placement and the ability to adjust the stent. Moreover, the wide variety of sizes, lengths, and opportunity for tapered grafts allows inclusion for a wide variety of patients. ■

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Endovascular Repair of a Thoracic Aortic Aneurysm Using the Bolton Relay[®] Stent-Graft

BY W. ANTHONY LEE, MD

The Bolton Relay thoracic stent-graft (Bolton Medical, Inc., Sunrise, FL) is a self-expanding stent-graft constructed of nitinol stents and Dacron fabric material. The proximal end of the device has a bare-stent segment for fixation and coaxial alignment. It has a unique dual-stage delivery system, composed of an outer hydrophilic sheath that is advanced to the distal thoracic aorta and a highly flexible inner sheath constructed of a low-friction fabric that allows delivery of the endograft through the tortuosity of the arch to the intended proximal landing zone. The delivery system employs a staged deployment mechanism, which allows controlled release of the endograft. This case study describes an endovascular repair of a descending thoracic aneurysm using the Bolton Medical Relay stent-graft that illustrates some of its unique features.

CASE REPORT

An 80-year-old woman presented with a 6.6 cm fusiform descending thoracic aortic aneurysm. The proximal landing zone was 20 mm distal to the left subclavian aneurysm, and the distal landing zone extended to the origin of the celiac artery (Figure 1). The patient had a spinal drain placed preoperatively to reduce the risk of spinal cord ischemia. This is routinely performed in all cases in which more than 150 mm of the thoracic aorta will be covered.

The right femoral artery was exposed through a transverse oblique incision. The left femoral artery was percutaneously accessed, and a 5 F sheath was inserted, through which a marked pigtail angiographic catheter was advanced into the aortic arch. After adequate anticoagulation, a 32 mm (proximal diameter) X 28 mm (distal diameter) X 200 mm (length) Bolton Medical Relay device was introduced through the right femo-

ral artery. The proximal covered sealing stent was deployed in zone 4 just distal to the left subclavian artery (Figure 2).

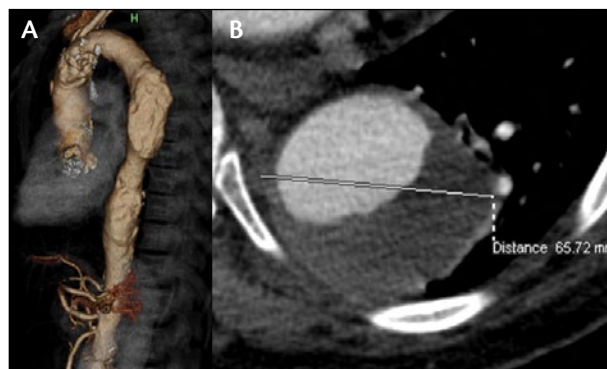


Figure 1. Three-dimensional volume rendering of the CT angiogram (A) and orthogonal multiplanar reconstruction of the maximum aneurysm diameter (B).

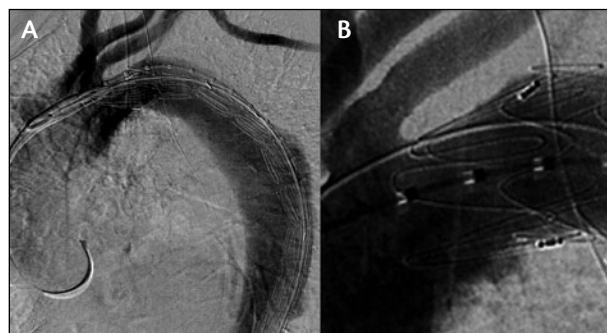


Figure 2. Deployment of the first Bolton Medical Relay stent-graft in the proximal landing zone. The proximal end of the stent-graft is partially deployed while the bare stent remains constrained (A). This facilitates accurate positioning. Note the close apposition of the covered sealing stent along the inner curve of the aorta without any bird-beaking (B).

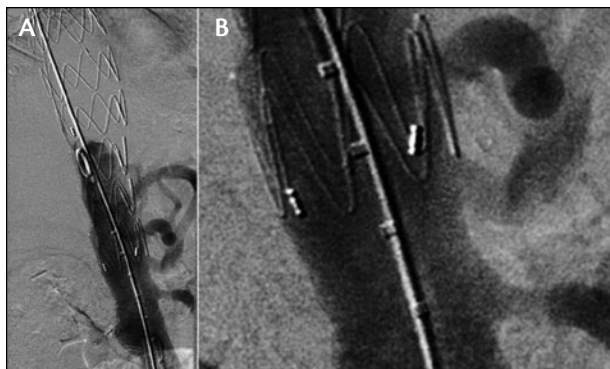


Figure 3. The distal end of the second Bolton Medical Relay stent-graft landed precisely just proximal to the origin of the celiac artery.

A second Bolton Medical Relay stent-graft measuring 32 X 32 X 200 mm was deployed distal to the first stent-graft with sufficient overlap. The C-arm gantry was rotated 90° to visualize the origin of the celiac artery. The distal end of the stent-graft was deployed just proximal to its origin (Figure 3). A completion angio-

gram showed no evidence of an endoleak. The right femoral artery and groin were closed routinely, and the left femoral access site was closed using an Angio-Seal closure device (St. Jude Medical, Inc., St. Paul, MN).

Postoperatively, the patient recovered in the cardiovascular intensive care unit. She remained neurologically intact without signs of stroke or spinal cord ischemia. The spinal drain was removed after 24 hours, and the patient was discharged to home on postoperative day 4.

CONCLUSION

The Bolton Medical Relay thoracic stent-graft is an effective device for endovascular repair of descending thoracic aortic aneurysms that can be deployed in a reliable and accurate manner. ■

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Repair of a Bilobed Descending Aortic Aneurysm

BY DANIEL J. TORRENT, MD, AND MICHAEL C. STONER, MD, RVT, FACS

An 80-year-old woman with multiple medical comorbidities, including chronic obstructive pulmonary disease requiring home oxygen, was being followed for a bilobed descending aortic aneurysm. The thoracic portion was saccular and increased in size on serial imaging to 6 cm. Her comorbidities prohibited open repair, and on CT scan, it was noted that her iliac arteries were very bilaterally tortuous, making access difficult.

The patient was admitted for elective repair and taken to the operating room. Percutaneous access was achieved through the right common femoral artery. A left common femoral artery cutdown was performed for access on that side. Catheters were advanced through the femoral arteries into the aortic arch, and systemic heparin was administered. Angiography was performed to show the saccular aneurysm (Figure 1). A 42 X 150 mm

Relay device (Bolton Medical, Inc., Sunrise, FL) was selected based on prior measurements. Initially, attempts were made to pass the graft up a Lunderquist wire through the left common femoral artery. Because of her very tortuous iliac artery (Figure 2), the graft could not be passed even after using an Amplatz buddy wire to help straighten the course.

A right femoral cutdown around the 5 F sheath was then performed, and the device was passed through the femoral artery and a very tortuous right iliac artery over a wire. With the device in place, a thoracic aortic angiogram showed that the graft was in a good location, and the stent was deployed. Completion angiography showed appropriate deployment and opposition against the aortic wall with exclusion of the aneurysm sac (Figure 3). The catheters, wires, and sheaths were removed with fluoro-



Figure 1. Intraoperative angiogram showing the aneurysm.



Figure 2. Preoperative CTA showing the tortuous course of the bilateral iliac arteries.



Figure 3. Completion intraoperative angiography after stent deployment.

scopic guidance. The arteriotomies were repaired, and the groins were closed in layers.

She was discharged to home on postoperative day 3 after weaning back to her home oxygen requirements.

At 1-year follow-up, the patient was doing well. She was eating and getting exercise. A CT of her chest showed that the stent was in position and patent without endoleak. The aneurysm shrank to 4.6 cm with a 37 mm neck proximally (46 mm distally).

The design of the Relay graft facilitates advancement through tortuous iliac arteries. Device trackability was key in facilitation of endovascular repair. ■

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