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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).[1] 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 clasping 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.

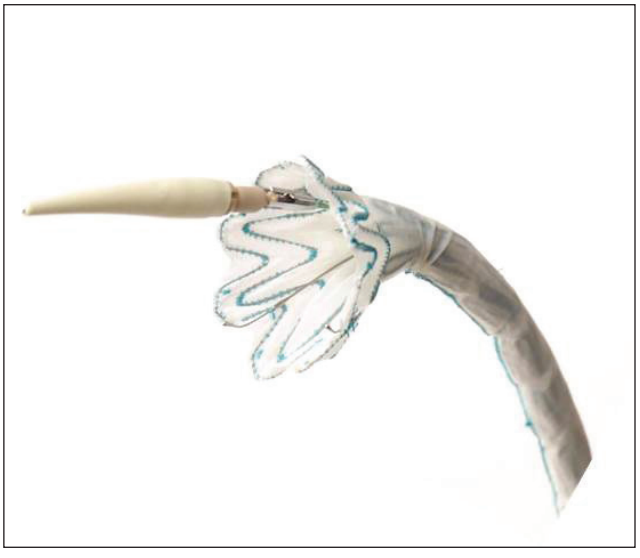

Figure 1. The NBS proximal configuration.

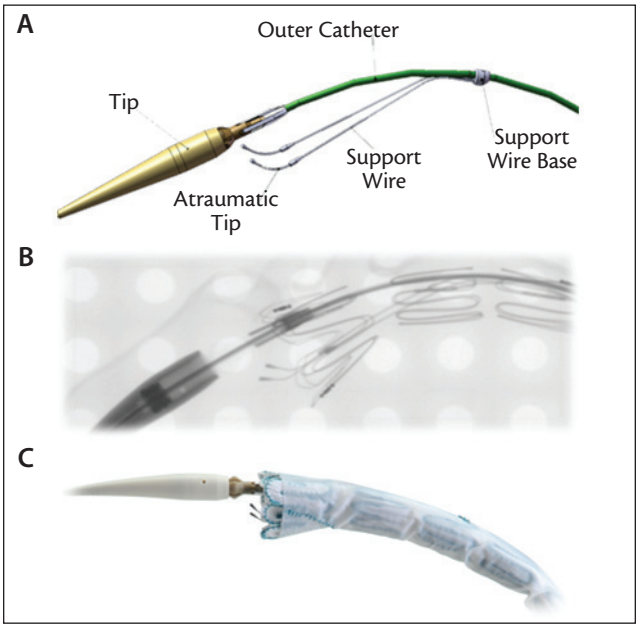

Figure 2. Illustration of the RelayNBS clasp and support wires (A). The RelayNBS under simulated fluoroscopy (B). The RelayNBS dual sheath (C).

INTO THE ARCH

The RelayNBS technology was designed to deliver a covered proximal configuration in a controlled and accurate manner utilizing the novel proximal clasping 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), 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."[2]

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.

Figure 3. The RelayBranch endograft.

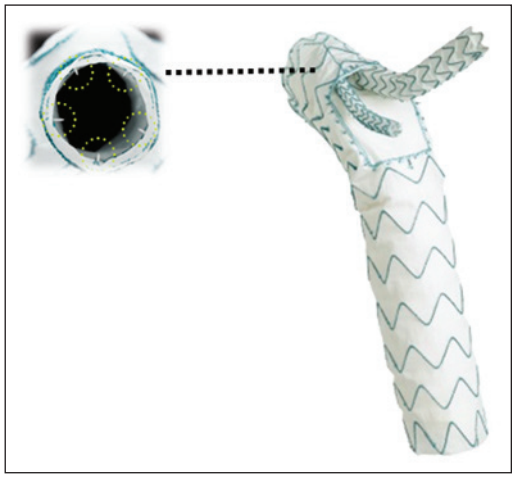

Figure 4. The Lock Stent in the RelayBranch endograft.

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 successful 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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