The Current State of Branched Stent Grafts for the Aortic Arch

A review of five devices with investigational device exemptions in the United States.

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As the general population ages, physicians will continue to encounter more advanced and complex aortic disease and comorbidities. In many cases, these comorbidities prohibit open repair of thoracic aortic disease, whereas complex aortic anatomy is prohibitive against standard endovascular repair of both aneurysms and dissection of the thoracic aorta, particularly when the arch is involved.

Traditional open repair of aortic pathology of the arch and great vessels involves a sternotomy, some degree of extracorporeal circulation with selective perfusion of the great vessels, and replacement of some or all of the aortic arch with a synthetic graft. Morbidity and mortality rates vary based on etiology and patient presentation, as well as the extent of surgical repair required. In a meta-analysis, Settepani and colleagues showed that overall operative mortality in total arch repair is 5.3%, and permanent and transient neurologic deficits occurred at rates of 3.4% and 5.2%, respectively.[1] However, when elective and emergent cases were separately analyzed, operative mortality was shown to be 2.9% and 8.8%, respectively—a nearly three-fold difference. A similar difference was seen in rates of permanent neurologic deficit (2.2% for elective and 6.5% for emergent cases).

The ability to address pathology of the aortic arch with endovascular techniques has the potential to reduce operative and disease-specific morbidity and mortality. However, several challenges should be addressed in order to be successful with less invasive techniques. Maurel and colleagues defined six challenges specific to endovascular repair of aortic arch pathology: (1) the shape of the arch, (2) angulation of the great vessels, (3) dynamics of blood flow, (4) shear force, (5) variability during the cardiac and respiratory cycles, and (6) position of the coronary vessels and aortic valve.[2] New iterations of endovascular devices attempt to meet these challenges with designs that have an adequate proximal seal zone, will not buckle or "bird-beak" within the arch, and do not require much manipulation, thereby decreasing the embolic stroke risk.

Although fenestrated stent grafts are an option, they are expensive, time consuming, and require custom design and construction. Chimney or snorkel grafting has also been explored, such as in abdominal aortic aneurysms, but this carries an increased stroke risk within the arch.[3] Data are also lacking on the interaction between parallel-placed aortic stent grafts and stents to the great vessels, which may pose serious risk to the patient.

Branched stent grafts are a potential solution to these problems. At present, there are no branched stent grafts approved by the US Food and Drug Administration; however, several are in clinical use overseas and are used in the United States as part of an investigational device exemption (IDE). This article discusses five branched stent graft devices in use via IDEs in the United States: the Zenith arch branched device (Cook Medical), the TAG thoracic branch endoprosthesis (Gore & Associates), the Valiant Mona LSA device (Medtronic), the Nexus aortic arch system (Endospan), and the Ascending Thoracic Device based on the Relay NBS Plus (Bolton Medical).

ZENITH ARCH BRANCHED DEVICE

The Zenith arch branched device is one of the longest-standing devices on the market (outside of the United States), as an off-the-shelf device for treatment of

Courtesy of Cook Medical.

Figure 1. Zenith arch branched device. Curved main component (A), internal side branches (B), external view of internal side branches along outer curve of main component (C).

aortic arch disease. It has a curved main body with two side branches that are contained internally prior to their deployment (Figure 1).

Much like other stent grafts available in the Zenith platform, the Zenith arch branched device seals proximally in the ascending aorta, but it requires a larger delivery system (22- or 24-F sheath). To reduce the need for multiple manipulations when in the aortic arch, it has features to help with stabilization and alignment once it is introduced. Additionally, to address the risk to the aortic valve and left ventricle, it features a soft, tapered tip, which allows for safe placement proximally, enhancing the seal in the ascending arch (zone 0).

The technique for implementation requires groin access for the main body of the stent graft and left axillary artery and right common carotid artery access to cannulate the left common carotid artery (LCCA) and innominate artery (IA), respectively. A right internal jugular vein ventricular pacing wire is also placed for rapid pacing during graft deployment.

In 2014, results from the first 38 patients were reported.[4] Technical success was demonstrated in 32 patients (84.2%), and technical failures included three deaths in the first 24 hours postoperatively: one type Ia endoleak, one femoral-to-right carotid bypass (due to inability to cannulate the IA), and one conversion to the chimney technique. Four patients required additional procedures to treat subsequent endoleaks. Six patients sustained cerebrovascular events (four transient ischemic attacks, one stroke, and one subarachnoid hemorrhage), although all recovered.

In a follow-up study that included 27 patients, technical success was 100%, and there were no deaths at 30 days.[5] Four patients (14.8%) required early reinterventions, three patients (11.1%) sustained cerebrovascular events (two major strokes and one minor stroke), and two patients experienced transient spinal cord ischemia (SCI).

TAG THORACIC BRANCH ENDOPROSTHESIS

The TAG thoracic branch endoprosthesis has a structure very similar to the Conformable TAG thoracic endoprosthesis and includes a nitinol stent frame with a polytetrafluoroethylene graft and exposed stents at the proximal extent to assist with the proximal seal zone. As the proximal stents are uncovered by graft material, it can also be advanced to cover up to 50% of the opening of the LCCA. The TAG thoracic branch endoprosthesis is designed for use in the arch and features a single side branch. The device can land in zones 0 to 2 with the single side branch in the brachiocephalic, left common carotid, or left subclavian artery (LSA). When used in zone 2, it is intended to eliminate the need for LSA debranching procedures. It consists of up to three components: the main body with an internal portal for the side branch; a tapered, heparin-coated side branch stent graft; and an optional proximal aortic extender (Figures 2 and 3). Deployment requires placement of guidewires from the groin into the aorta as well as the LSA (Figure 2D). Through-and-through wire placement to a left upper extremity artery is optional.

Preliminary feasibility data published in 2016 demonstrated successful device deployment and patency of the side branch in all 22 included patients at the conclusion of the procedure.[6] There were two (9%) access-related complications that required additional procedures but no residual deficits. There were no deaths or strokes at 30 days, but one patient (4.5%) experienced right lower extremity paraparesis that resolved within 2 days, with cerebrospinal fluid drainage and permissive hypertension. Four patients (18.2%) had a type I endoleak post-procedure that resolved within 30 days, two patients (9%) had a type II endoleak that persisted at 6 months with no aneurysm enlargement, and one patient (4.5%) had a type III endoleak that resolved by the 30-day CT scan. There was one death (4.5%) reported in the 6-month follow-up period.

Courtesy of Gore & Associates.

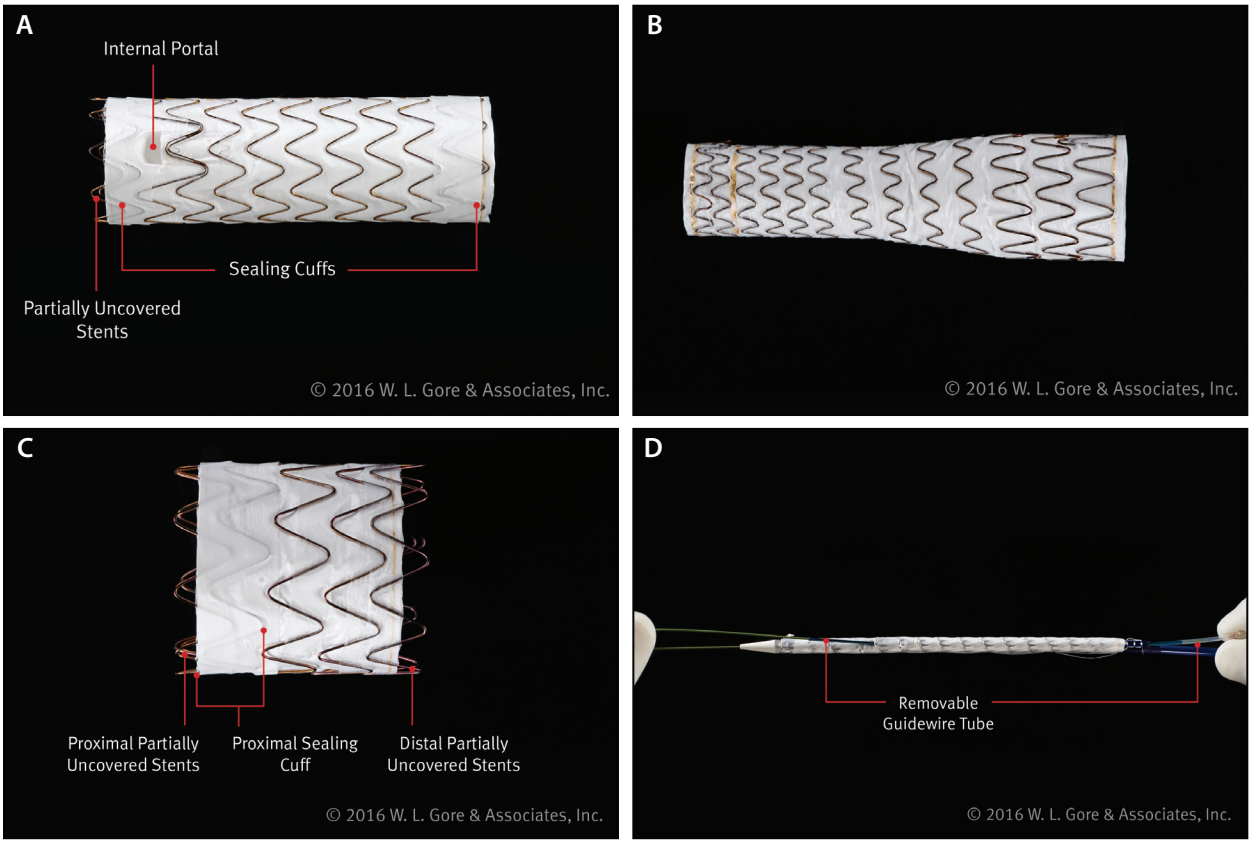


Figure 2. TAG thoracic branch endoprosthesis and delivery system. Main body (A), side branch (B), proximal aortic extender cuff (C), and delivery system with two guidewires (D).

Courtesy of Gore & Associates.

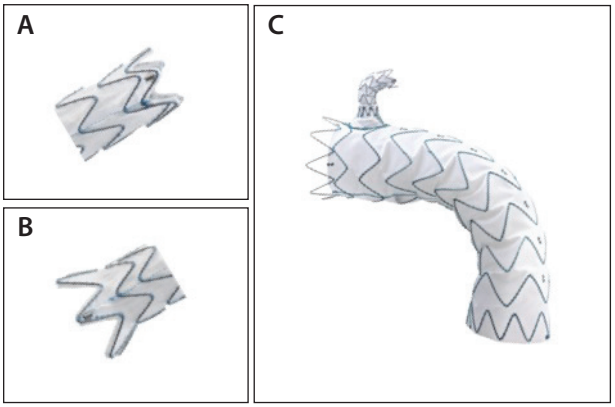
Figure 3. TAG thoracic branch endoprosthesis.

VALIANT MONA LSA

The Valiant Mona LSA thoracic stent graft system is used to extend the proximal seal zone of a repair of the descending thoracic aorta by placing a stent in the LSA rather than covering its opening and potentially performing a debranching procedure. It is intended to be placed into zone 2 of the aortic arch. The device is composed of two stent grafts. The main stent graft is made of nitinol stents and polyester graft material. It requires a 20-mm proximal seal zone, which includes 10 mm between the LCCA and LSA and the cuff for the LSA branch stent and 5 mm between the LSA and the start of the aneurysm. Similar to the main stent graft, the branch stent graft is also made of nitinol stents and polyester graft material (Figure 4).

Valiant Mona LSA uses a two-wire delivery system. The first is the main aortic tracking wire and the second is a wire precannulated into the LSA cuff. Through-and-through access from the groin to either the left brachial or left axillary artery is required for deployment of both components.

Early feasibility data on the Valiant Mona LSA included nine patients.[7] All nine cases were considered treatment successes, as defined by successful delivery and deployment of the stent graft in the planned location, exclusion of the (descending thoracic aneurysm), and maintained patency of the main and branched stent grafts at 30 days. The safety endpoints included aneurysm-related mortality, stroke, paraplegia, and left arm/hand ischemia. Although there



Courtesy of Medtronic.

Figure 4. Valiant Mona LSA: distal (A), proximal (B), and top (C).

were no major strokes at 30 days, there were four nondisabling strokes. Four patients had endoleaks at discharge (although none had endoleaks at the end of the procedure), and two resolved by 30-day follow-up. At 6-month follow-up, among seven of the nine patients (two are behind schedule by 4 months), there have been no deaths or major strokes. There have been no structural or anatomic complications with the device itself and no conversions to open procedures or repeat endovascular procedures. Follow-up will continue to 5 years postprocedure.

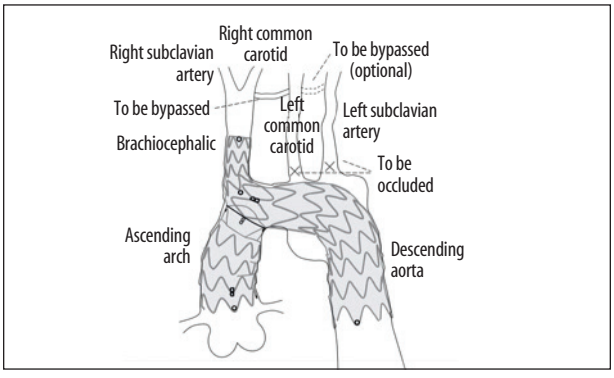
NEXUS AORTIC ARCH SYSTEM

The single-branch Nexus is a two-component stent graft system deliverable through a 20-F sheath. The double-branch Nexus is a three-component stent graft system, deliverable through the same sheath. In contrast to the previously described devices, the single-branch Nexus is meant to be deployed as an adjunct to debranching procedures, as a way to safely treat arch disease extending to its most proximal extent (just distal to the aortic root). Use of the single-branch device requires either a carotid-carotid bypass or an LCCA-LSA bypass (Figure 5) and a periscope graft to the LSA. Alternatively, use of the double-branch device involves an additional polytetrafluoroethylene-covered stent placed between an additional superior-facing fenestration on the outer curve of the main device and the LCCA.

For both devices, the main component is deployed via a through-and-through technique using a brachiofemoral wire proximally into the IA cranially, with the wider distal aspect deployed in the descending thoracic aorta. It has one large self-projecting sleeve (SPS), which is directed proximally toward the ascending aorta (Figure 6A). A second optional fenestration is on the outer curve in the double-branch design.

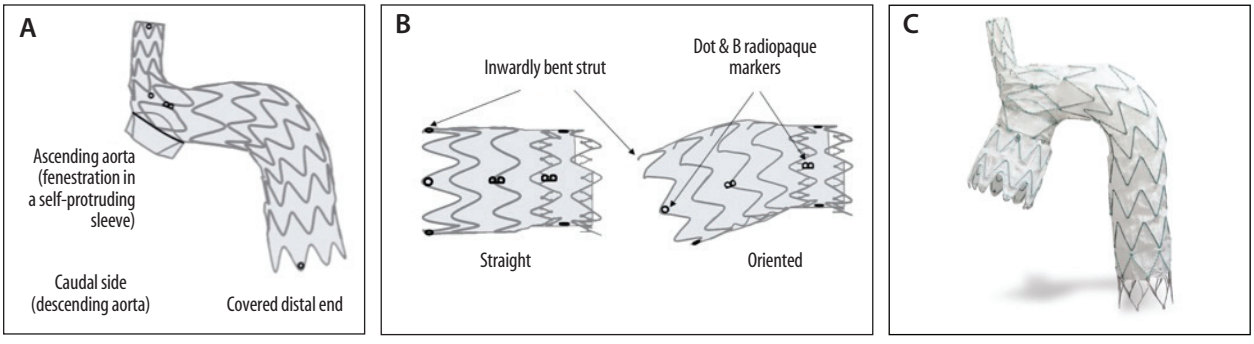
The ascending component of both single- and double-branch devices is a "precurved" module with a supportive "spine" on the outer curve and compressive springs on the inner curve to prevent bird-beaking (Figure 6B). It is positioned proximally in the ascending aorta, just distal to the coronary arteries and sinotubular junction. The ascending component then distally interlocks at the SPS of the main component, ensuring a secure connection and hemostatic endoanastomosis (Figure 6C). Deployment of the two components in this order cuts down on manipulation within the native arch, as crossing the arch will only be realized inside the first main component, thereby decreasing the risk of stroke and other procedure-related complications.

Endospan has reported 100% technical success in initial studies of both the single- and double-branch designs.



Courtesy of Endospan.

Figure 5. Single-branch Nexus Aortic Arch System placed within the anatomy.



Courtesy of Endospan.

Figure 6. Single-branch Nexus. Main component (A), ascending aorta component (B), and ascending aorta component locked within the main component (C).


Courtesy of Bolton Medical.

Figure 7. Double-branch Ascending Thoracic Device.

Initial cases were divided into two groups: the Nexus first-in-man (FIM) study (n = 7) and compassionate use cases (n = 13). The FIM study began in 2014 with planned 5-year follow-up and is taking place at centers in Switzerland, Czech Republic, and Italy. In this group, there was one death due to respiratory failure and multisystem organ failure in the first 30 days after using the double-branch design. There were two strokes reported in the FIM group in the first 30 days. One stroke presented as right-sided weakness on postoperative day 2 after use of the single-branch design and resolved with urgent LSA bypass. The other stroke presented as left-sided weakness after use of the double-branch design and resolved within 2 days without intervention. There have been no reports to date of SCI or type Ia or III endoleaks in the FIM group.

The Nexus device is also being evaluated in the compassionate/special access pathway study in seven centers in Switzerland, Italy, Canada, and India. In this group, there were two deaths in the first 30 days postimplantation: one using the single-branch design due to an unknown cause and one due to myocardial infarction using the double-branch design. Device failure is not suspected as a cause of death in either of these cases. There were two cases of stroke, both in patients who received the double-branch design. The first presented as right hemiparesis, and the second presented as right arm paresis, both of which resolved without additional intervention. There was one case of SCI in a patient with extended coverage of the descending aorta, which completely resolved with a spinal drain in 72 hours. There was also one minor type III endoleak in a previous design of the endoanastomosis unit.

ASCENDING THORACIC DEVICE

The Ascending Thoracic Device, like the Zenith arch device and Nexus, should be deployed in zone 0 of the aortic arch in conjunction with a debranching procedure. Also similar to the Nexus device, the Ascending Thoracic Device is offered as a single- or double-branch design. The single-branch graft is designed for placement in the IA, and the double-branch graft is designed for deployment in the IA and LCCA (Figure 7).

The delivery technology is based on the Relay NBS Plus platform and employs a self-orienting guidewire lumen to reduce manipulation within the arch. It also features a double-sheath deployment design that facilitates advancement into zone 0.

There are currently 11 reported uses of the single-branch design and 61 reported uses of the double-branch design. In early-use studies of 26 patients, there were two type I endoleaks and four intraoperative complications, including coverage of the right subclavian artery, dissection of the LCCA, left ventricular perforation, and one death. Overall, there were two deaths in this group.[8] Clinical studies are ongoing.

CONCLUSION

Branched stent graft devices provide an acceptable off-the-shelf alternative for addressing pathology in the aortic arch. Although studies are ongoing, early data show reasonable complication rates, given the alternative of open repair. Once approved by the FDA, these devices will provide an excellent option in situations when a fenestrated device is not feasible. They will also provide an FDA-approved alternative to chimney grafts in the setting of difficult anatomy. ■

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