MORE OPTIONS & SOLUTIONS FOR TREATMENT OF COMPLEX AORTIC DISEASE

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Relay®Branch: A Review of the Technology and Early Results

The endovascular approach to aortic arch pathologies using the RelayBranch Thoracic Stent Graft System.

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When John Gibbon first carried out a successful open heart procedure on a human using the heart-lung machine in 1953 in Philadelphia,1 cardiac surgeons did not even dream about heart transplantation. Then, in 1967 in Cape Town, South Africa, Christiana Barnard performed the world’s first human-to-human heart transplant.2 The aortic endovascular era started exactly 30 years ago in 1987 when Nikolai Volodos implanted the first thoracic stent graft in a patient with thoracic aortic false aneurysm.3 At that time, nobody even thought about endovascular treatment of the aortic arch. Today, endovascular aortic arch repair has become reality. This article reviews our algorithm for treatment of aortic arch pathologies based on the patient’s specific aortic anatomy and condition and describes the RelayBranch Thoracic Arch System (Bolton Medical; Figure 1), including prosthesis design, anatomic requirements, and recently published results.

TREATMENT DEFINED BY AORTIC PATHOLOGY

The treatment approach is defined by aortic pathology and the patient’s condition, not the technology available at a hospital or the physician’s expertise. The decision-making process starts with a CTA of the entire aorta. Thoracic endovascular aortic repair (TEVAR) is chosen if the aortic arch pathology is more distal and subclavian-to-carotid or if a double transposition provides a sufficient proximal landing zone at least 2.5-cm long measured along the lesser curvature and the diameter is < 4 cm. In case of more proximal pathologies without an adequate landing zone in the aortic arch, we consider total aortic arch replacement with the frozen elephant trunk procedure, or we use the RelayBranch System in patients at increased risk for open surgery.

RelayBranch DESIGN

The RelayBranch System consists of three components: (1) the Main Body Graft, which is intended to be placed in the arch and spans from zones 0 to 4 and includes a large covered window with two internal tunnels designed to extend into the innominate and left carotid arteries; (2) the first branch graft that connects the posterior tunnel with the innominate artery; and (3) the second branch graft that connects the anterior tunnel with the left carotid artery (Figure 1). All three components are composed of self-expanding nitinol stents sutured to a polyester vascular graft fabric. The main body’s proximal end consists of sinusoidal nitinol stents and crown-shaped nitinol stents with no uncovered portions or bare springs, similar to the Relay non-bare stent (NBS) thoracic stent graft (Bolton Medical). The main body has two standard total length offerings: the 270 mm with an ascending section of 60 mm and the 255 mm with an ascending section of 45 mm. The main body’s proximal diameter ranges between 32 to 48 mm in 2-mm increments, and the distal diameter ranges between 22 and 48 mm in 2-mm increments. Multiple tapering configurations are available (eg, 48-mm proximal and 32-mm distal diameters in the same endoprosthesis).

The RelayBranch Main Body is delivered in two stages. First, the introducer with hydrophilic
coating is inserted over a stiff wire via transfemoral access into the thoracoabdominal aortic segment. Next, the primary sheath (the hydrophilic coated introducer) remains on the thoracoabdominal level and the arch graft, compressed in a very flexible secondary sheath, and is advanced into the aortic arch. The flexibility of stage two allows the most atraumatic access possible into the aortic arch. Correct orientation of the arch graft, with both internal tunnels oriented toward the larger curvature, is ensured by the outer primary sheath’s preformed tip and by radiopaque markers assisting orientation of the arch graft. To avoid the bird-beak phenomenon and guarantee optimal apposition of the proximal arch graft end in the curved ascending aorta, two heart-shaped nitinol wires (support wires) attached to the delivery system catheter actively guide the inferior portion of the graft toward the inner curvature.

The RelayBranch branch graft components are modified iliac branches of the TREO® device (Bolton Medical) with proximal clasping to the delivery system. The proximal apexes of the branch grafts are uncovered. Because the internal tunnels of the main body always measure 12 mm in diameter, the proximal diameter of both branch grafts is 13 mm. The distal diameter ranges between 8 and 24 mm, and the length spans from 70 to 140 mm.

**Anatomic Requirements**

The success of any aortic endovascular procedure is defined by accessing the appropriate landing zones. The main body of the RelayBranch requires a proximal landing zone at least 30-mm long with a diameter up to 43 mm. The anatomic prerequisites for the distal landing zone are the same as in standard TEVAR cases. Because the shorter ascending portion of the arch graft measures 45 mm in length and has an additional 10- to 15-mm distance to the coronary arteries, and because 10 mm between the arch graft window and innominate artery are necessary, the distance between the sinotubular junction and innominate artery should be at least 65 mm. Due to the main body window size, the distance between the proximal and distal edges of the innominate and left carotid arteries should not exceed 45 mm. The diameters of the innominate and left carotid arteries should range between 7 and 20 mm, and the landing zone lengths should measure at least 25 and 30 mm, respectively. In patients with a remaining dissection in the supra-aortic vessels after type A dissection repair, use of the RelayBranch System is inadvisable. The reasons for this are usually a very small true lumen in a chronically dissected aortic arch, dissected supra-aortic vessels with a compromised true lumen, and a short ascending graft or previous ascending replacement with two grafts anastomosed under a sharp angle. Figure 2 illustrates a penetrating aortic ulcer in the distal aortic arch in a patient with anatomy suitable for RelayBranch implantation.

**RESULTS**

The first published series on the RelayBranch includes 15 treated patients, 12 of whom underwent revascularization of the left subclavian artery. There was one in-hospital mortality due to myocardial infarction 2 weeks after the procedure. One patient had a disabling stroke due to a heavily calcified ascending aorta and supra-aortic vessels. No patients had symptomatic spinal cord ischemia. There were no type la or type III endoleaks, and there was a single type Ib endoleak that resolved spontaneously. During a median follow-up of 263 days, one patient developed an endoleak via the left subclavian artery, which was successfully treated by embolization. Aortic-related survival was 100%, and four patients died during follow-up of nonaortic-related causes. Figure 3 shows a postoperative 3D reconstructed CTA obtained after RelayBranch implantation in one patient in this study.

![Figure 2. CT and draft of aortic anatomy of a patient with a penetrating aortic ulcer in the distal aortic arch in which the proximal landing zone with carotid-subclavian bypass would have been 7 mm and only 13 mm in the case of double transposition. Due to severe comorbidities, open aortic arch surgery was too risky, and the patient underwent successful implantation of the RelayBranch with carotid-subclavian bypass on the left side.](image-url)
SUMMARY

The RelayBranch System enables the effective treatment of aortic arch pathologies with very low mortality and excellent aortic-related survival in patients anatomically suitable for TEVAR. The number of patients in the published report is quite low, and larger studies with longer follow-up are necessary to compare the RelayBranch with other endovascular and open approaches to aortic arch pathologies. The risk of neurologic injuries is omnipresent and should be carefully evaluated before planning treatment with the RelayBranch. A high degree of calcification in the ascending aorta, aortic arch, and supra-aortic vessels is a reason to favor open arch repair, because endovascular manipulation in this milieu can quickly lead to serious neurologic complications. Careful deairing of the delivery device, clamping the carotid arteries during branch graft implantation, and flushing the carotid arteries before declamping may reduce the risk of cerebral embolization. Frequently, aortic arch pathologies extend downward into the thoracic descending aorta, requiring distal extension with TEVAR. Preserving the flow via the left subclavian artery via transposition or carotid-subclavian bypass is necessary to keep the risks for spinal cord ischemia as low as possible. We prefer the carotid-subclavian bypass to transposition, because the anastomosis on the carotid artery may be placed more distally, eliminating the risk of covering the bypass offspring with a branch graft and avoiding passing the anastomosis with the branch graft’s delivery device.

Aortic arch repair requires careful assessment—first of the aortic anatomy and then choosing the treatment option according to the patient’s anatomy and condition, not the other way around. The RelayBranch System is a safe and feasible device, enriching our armamentarium and giving us another option to repair the aortic arch without sternotomy.


Figure 3. Three-dimensional reconstructed CTA of the aortic arch after implantation of the RelayBranch.

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