

Fenestrated Options for Aortic Arch Applications

The great vessels of the aortic arch require uniquely tailored therapeutic options.

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The thoracic aorta has a three-dimensional angulation between the aortic arch and the descending thoracic aorta, and also the anatomical peculiarity of three vessels branching off at narrow intervals along the greater curvature of the arch. The first-generation thoracic endografts, consisting of a straight Z-stent skeleton, were relatively rigid. They did not appose the curvature of the arch and were prone to migration, collapse, or stenosis.

Earlier attempts to improve trackability along the aortic curvature have consisted of widening the connection interval between stent elements or eliminating the longitudinal wire strut to increase device flexibility. However, it is difficult to completely appose these endografts to a curving aorta because contact with the aortic wall is determined by the linear length of each stent unit.

A second-generation device, the Gore TAG (Gore & Associates, Flagstaff, AZ), has achieved flexibility by connecting stent elements of short length with the device's polytetrafluoroethylene (PTFE) film.¹ A ring-type stent such as the one used in the home-made Inoue stent graft² or a stent with a braided skeleton, such as the Matsui-Kitamura stent graft (Kitagawa, Kanazawa, Japan),³ may also be more flexible and morphologically adaptable. However, flexible devices with no longitudinal struts tend to bend into the aneurysmal sac, due to pulsatile blood flow change and wall shear stress, which can result in endograft migration when graft fixation on the landing zone is insufficient.

DEVICE DEMANDS OF THE AORTIC ARCH

In a large-caliber aortic arch, high blood flow from cardiac output will cause a windsock effect on the endograft before it is affixed to the aortic wall and lead to endograft migration. There are some methods to minimize this adverse motion, including pharmacological transient cardiac arrest, hypotension, electrical ventricular fibrillation, or inflow occlusion by balloon inflation. As far as the endograft system itself is concerned, the Gore TAG adopts a mechanism to expand the middle of the graft first, which is followed by an expansion of both ends of the endografts. This deployment mechanism is thought to be accurate; however, its performance when used in severely angulated necks has not yet been proven.

There are some drawbacks in endografts equipped with scallop-shaped proximal fixation elements, such as the loss of a sufficient landing zone with no measures to enable blood supply to the arch vessels. Moreover, bare stents at the proximal end of an endograft can damage the aortic arch. The Zenith TX2 (Cook Medical, Bloomington, IN) has a promising stabilization mechanism to expand the graft body first on the aorta while both the proximal and distal ends of the graft are kept closed and attached to the delivery system with trigger wires.⁴

Although each device has advantages and disadvantages, the application of any endograft may be limited in aneurysms that are adjacent to the arch vessels (distal arch aneurysms). This is especially true where three vessels branch



Figure 1. The Najuta tailor-made endograft, individually designed for fitting to the aorta configuration (A). Fenestrations are created along the greater curvature of the Najuta endograft to secure blood supply via the arch vessels (B).

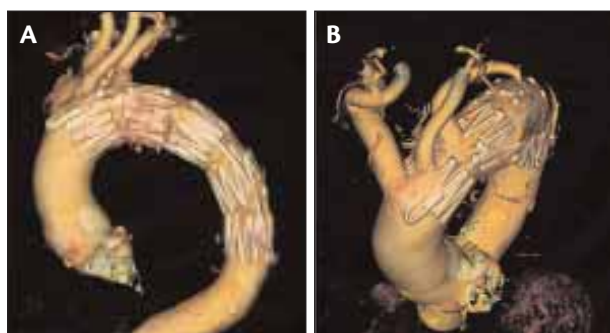


Figure 2. The proximal end of the Najuta endograft is placed in zone 1 (A). The left common carotid artery and the left subclavian artery are clearly patent (B).

and take off at narrow intervals. In this anatomy, high deployment accuracy is required to gain an effective landing zone without any cerebral blood flow interruption. To preserve the blood supply to the supra-aortic arch vessels, there are great expectations for the invention of a branched endograft, such as the Inoue graft, as well as a modular multibranched endograft, which was reported by Chuter et al.⁵ Because there is a concern over thromboembolism associated with the delivery technique, indications for these types of endografts are still limited, and it may be necessary to simplify the system to make it adaptable to any anatomical conditions in the future.

ARCHITECTURE OF THE NAJUTA THORACIC DEVICE

The Najuta endograft system is designed for thoracic aortic aneurysm repair and has been developed based on our 10-year clinical experiences in Tokyo Medical University. The primary concept is to design a tailor-made endograft suitable for the aorta of each unique patient. The basic architecture of the Najuta system includes a rigid graft column structure that apposes the curvature of the aorta to prevent endograft migration as well as post-operative endoleaks. Z-stent elements are connected with longitudinal support struts and covered with PTFE. The strategic locations of these struts are designed to allow the stent position alignment to adjust with the straight portion of the aorta. Because the PTFE graft material is sutured to the stent framework at both ends of the endograft only, even if the stent is deformed or kinked due to tortuous anatomy, the PTFE will be able to expand to its diameter thereby maintaining the luminal area.

The proximal end of the Najuta device is designed to be placed between zones 0 and 2 (indicated by the anatomical landing zone map),⁶ which constitutes the highly critical region involved with the aortic arch. Each

Najuta device is individually designed using three-dimensional CT for fitting to the aorta configuration. There are single or multiple fenestrations created along its greater curvature to secure blood supply via the arch vessels (Figure 1).

DEPLOYMENT CONSIDERATIONS

Even with these considerations regarding device design, precise deployment of the endograft in the aortic arch is necessary to adjust the fenestrations corresponding to each ostium of the arch vessels. The device's stent framework, supportive structures, proximal endograft stabilizer, and a curved delivery sheath are designed to enable pinpoint deployment. Deployment methodology, such as the use of brachial-femoral traction wire or the "tug-of-wire" technique, is a technical adjunct to assist in precise endograft placement. It has been shown that fixation of the endograft will be successful without endoleak if there is at least 15 mm of healthy aorta from the left carotid or subclavian arteries to the margin of the aneurysm (Figure 2).

The Najuta fenestrated endograft system is a promising device for the aortic arch application, and a multicenter clinical trial is scheduled to start in Japan in early 2008. ■

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