Experiences With the Valiant Thoracic Endograft

Evolved from the Talent, this new device design improves trackability and enables a lower force of deployment.

BY MATT THOMPSON, MD, AND ROB MORGAN, MD

n the United Kingdom, endovascular treatment of the thoracic aorta is becoming established as a firstline treatment for pathological conditions affecting the distal arch and descending thoracic aorta. The

pathology affecting the thoracic aorta is complex and adds to the challenges that must be faced with thoracic endografting. Common conditions now treated with endovascular techniques include thoracic aneurysms, dissections, and transections. As experience with thoracic endografting grows, the case mix has become increasingly complex, with the indications for thoracic endovascular procedures expanding. It is now common to treat pathological lesions affecting the mid arch, to use hybrid approaches to treat thoracoabdominal aneurysms, to treat patients with a ruptured thoracic aorta, and to attempt repair of lesions with unfavorable anatomy.

In general, it is true to say that endograft design and manufacture has not kept pace with clinical ambition in the thoracic aorta, particularly as many thoracic endografts have been modified from infrarenal devices in which the anatomical challenges are different. This has often resulted in considerable techni-

cal difficulty when attempting to treat complex thoracic diseases with first-generation thoracic endografts. Common problems include:

• The ability of relatively rigid thoracic endografts to

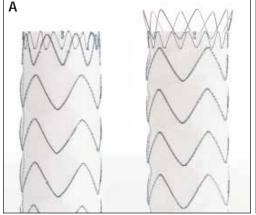




Figure 1. The Valiant (Medtronic, Inc., Santa Rosa, CA) stent graft's closed-web and open-web designs (A). These may be used in different pathologies, with some clinicians using the closed-web design preferentially for acute dissections and the open-web for aneurysms. Note the open web design is an eight-peaked proximal stent that allows for radial force to be distributed over more apices than the Talent graft and with less flare. The removal of the connecting bar has led to increased graft flexibility (B).

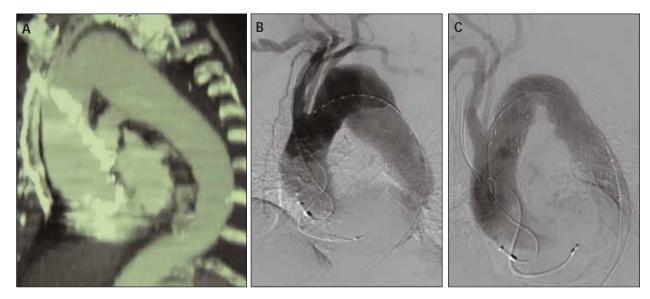


Figure 2. A thoracic aneurysm in a patient with a steeply angled arch (A). The Valiant graft conforms well to this configuration (B-C).

conform to the anatomy of the aortic arch. Graft nonconformity may lead to a graft sitting proudly in the aortic arch with subsequent instability and graft failure.

- The ability of long delivery systems to track through tortuous, calcified vessels.
- The ability of current stents to provide secure fixation and long-term graft durability.
- Inaccurate deployment leading to great vessel occlusion or a proximal endoleak.
- High forces of deployment resulting in inaccurate positioning or the necessity for repeated manipulation and brachial wires.

• The same graft type being used for both thoracic aneurysms and dissections despite the grossly different pathologies and desired outcomes.

MEDTRONIC VALIANT ENDOGRAFT

In response to the challenges of the thoracic aorta, Medtronic introduced the Valiant thoracic endograft into clinical practice outside the US in 2005. The Valiant is an evolution from the Talent thoracic endograft and contains improved design features including modifications to stent design, delivery sheath, graft configuration, deployment methodology, and markers.

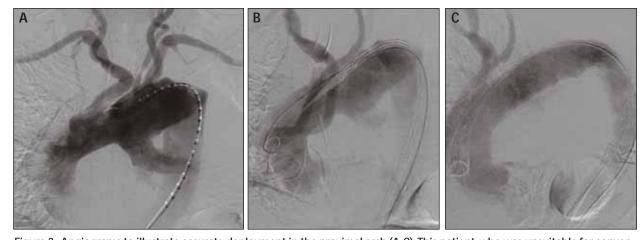


Figure 3. Angiograms to illustrate accurate deployment in the proximal arch (A-C). This patient, who was unsuitable for conventional repair, had a large aneurysm of the arch of the aorta. An ascending aorta to innominate and L carotid bypass was performed followed by endovascular exclusion of the arch aneurysm.

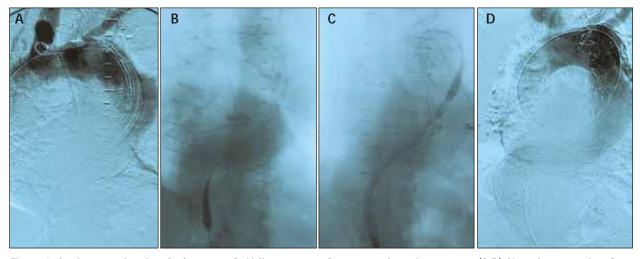


Figure 4. Angiograms showing deployment of a Valiant stent graft to treat a thoracic aneurysm (A-D). Note the tortuosity of the vessel, which is navigated by the delivery system.

Some of the most significant changes to the Valiant graft include:

- An eight-peak spring to provide proximal fixation.
 This allows better apposition to the vessel and distributes the radial force over more apices.
- Both closed-web and open-web options may be tailored to the particular thoracic pathology (Figure 1A).
- No connecting bar allows greater flexibility of the main endograft (Figure 1B).
- More choices in graft selection and longer lengths available (up to 227 mm).
- Improved graft cover design leading to less stretching, improved trackability, and lower force of deployment.
- Integrated handle for deployment (same platform as the Talent AAA stent graft) provides a mechanical advantage and a lower user-experienced deployment force.

The Valiant stent graft is available in lengths ranging from 100 mm to 227 mm, and in diameters ranging from 24 mm to 46 mm. Both straight and tapered grafts are available.

CLINICAL EXPERIENCE

The first cases using this device were performed at St. George's Hospital in London. Since then, the Valiant graft has been introduced across Europe, and more than 1,000 grafts have been implanted in 700 patients. The St. George's experience includes 58 grafts in 32 patients. The technical success in our personal series is 100%, but midterm data are not yet available. Currently, a retrospective study is underway to define the early and midterm results of the Valiant graft. A prospective reg-

istry is planned to define technical success in placement and midterm outcome.

Initial clinical observations have confirmed the promise of the Valiant graft in the treatment of thoracic aortic pathology. The delivery system allows tracking of the device through tortuous vessels and enables placement in the proximal arch without impacting on the aortic valve. The deployment has been made significantly easier with the integrated mechanical handle such that the user-experienced force is significantly reduced and accurate deployment is possible in most situations. Removal of the connecting bar allows conformation to acutely angled aortic arches (Figures 2 through 4). The closedweb system allows different proximal configurations to be trialled in different disease states. Several centers have used the closed-web design to preferentially treat Type B dissections. This has proved possible in the descending thoracic aorta, but the closed web should not presently be utilized in the arch due to the hemodynamic forces involved.

Early experience suggests that technical success of the Valiant graft is high and that there are significant advantages to this design. Clearly, carefully documented prospective evidence of efficacy is now needed.

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