Endovascular Repair of the Thoracic Aorta

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KEYWORDS

• Aorta • Endovascular • Stent graft • Aneurysm
• Penetrating ulcer • Aortic dissection

Since first reported more than 50 years ago, surgical repair of the descending thoracic aorta with resection and graft interposition has become the standard treatment strategy for patients with aneurysmal disease.[1] Despite significant clinical advances, which have allowed operative mortality to decrease to as low as 3% in specialized centers,[2] open surgical repair is generally associated with substantial morbidity and mortality in a patient population that is often aged and frail secondary to multiple medical comorbidities.

Endovascular exclusion of aortic aneurysms with covered stent grafts represents a less invasive alternative therapy to patients who might not survive open surgical repair. In addition, either as part of a trial or in an off-label manner, endovascular repair has been applied with increased frequency to other thoracic aortic pathologies such as pseudoaneurysms, type B aortic dissections, traumatic aortic disruptions, intramural hematomas, and treatment of patients with connective tissue disorders. The goals of this review are to: provide information on the 3 commercially available thoracic endografts that have been approved by the US Food and Drug Administration (FDA); detail the preoperative evaluation including imaging, device selection, and sizing; elaborate on certain anatomic considerations that guide therapy; and review the potential complications specific to endovascular repair. The extended use of this evolving technology to treat multiple thoracic aortic pathologies, albeit in an off-label manner, is also discussed.

HISTORY

It was in the early 1990s that treatment of thoracic aortic aneurysms entered the endovascular era. The same guiding principles of complete aneurysm exclusion and subsequent decompression with covered stent grafts used to successfully treat abdominal aortic aneurysms by Parodi[3] were first applied to descending thoracic

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aneurysms in a high-risk population by Dake and colleagues[4] in 1994. The devices used in these patients consisted of self-expanding stainless steel Z-stents (Cook, Inc, Bloomington, Indiana) covered with woven polyester graft material, which was hand sewn to the stent body with 5-0 polypropylene sutures. Although complication rates were high with this first generation of devices,[5] the development of multiple commercially manufactured endografts with improved flexibility and durability significantly decreased the number of complications.

During the next decade, results steadily improved as device and delivery system designs evolved and as strict inclusion and exclusion criteria were employed to guide patient selection.[6–9] Currently, three devices have been approved by the FDA and are commercially available in the United States for the treatment of thoracic aneurysms, and two of those devices are also approved for treatment of complicated penetrating ulcers of the descending thoracic aorta. With commercial availability, thoracic endovascular aortic repair (TEVAR) of thoracic aortic pathology has significantly increased.[10,11] Many groups have since reported superior short- and mid-term results to those of conventional open surgery, including decreased operative time, shorter intensive care unit (ICU) and hospital stays, and lower perioperative morbidity and mortality rates.[12,13]

AVAILABLE DEVICES

In March of 2005, following publication of the phase 2 multicenter trial with the TAG endoprosthesis (W. L. Gore & Associates, Inc, Flagstaff, Arizona),[6] the first device approved by the FDA became commercially available in the United States to treat descending thoracic aneurysms. More recently, in 2008, the Zenith TX2 TAA Endovascular Graft (Cook, Inc) and the Talent Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, California) received FDA approval for descending thoracic aneurysms and penetrating aortic ulcers.

TAG Device

The TAG endoprosthesis is a tube composed of expanded polytetrafluoroethylene (ePTFE) externally reinforced with an additional layer of ePTFE and fluorinated ethylene propylene (FEP) and supported by a flexible nitinol exoskeleton available in diameters of 26 to 40 mm and in lengths of 10, 15, and 20 cm (**Fig. 1**). The exoskeleton is commercially bonded to the graft material without sutures and is constrained by an ePTFE-FEP sleeve. EPTFE-covered scalloped flares are present on both ends of the device to aid in fixation. A circumferential ePTFE sealing cuff is located on the external surface of the endoprosthesis at the base of each flared end to enhance sealing of the endoprosthesis to the wall of the aorta. The device profile depends on the size of the graft and requires a 20F to 24F sheath for delivery. Deployment is extremely rapid and occurs with the release of the constraining sleeve in a rip-cord fashion. The TAG expansion initiates from the middle of the endograft and simultaneously extends toward both ends to avoid the ''windsock effect'' from the high arterial flow that would occur in a standard proximal-to-distal deployment mode (see **Fig. 1**A). The device is then molded with a specially designed trilobed balloon that allows flow to continue during inflation (see **Fig. 1**C).

Multiple clinical trials were conducted leading to FDA approval of the TAG endoprosthesis in March 2005. The pivotal study, which enrolled patients from September 1999 to May 2001, was a nonrandomized multicenter study comparing open surgical repair (n = 94) to endovascular repair (n = 140) in patients with descending thoracic aneurysms. The primary end point compared the incidence of major adverse events