ENDOVASCULAR REPAIR OF THE THORACIC AORTA

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Contents

Summary

Thoracic endografts have evolved from endovascular aortic repair of abdominal aortic aneurysms. Although originally designed for the treatment of thoracic aneurysms, their use has been rapidly extended to treat a wide variety of aortic pathology. This chapter describes the initial trials and outcomes of thoracic endovascular grafting, the use of endovascular grafting for specific aortic pathologies, the management of complications secondary to endovascular thoracic grafting, and the outcomes of thoracic endovascular grafting as compared to open surgery.

1. Introduction

The first devices were handmade and individually tailored for specific patient use. Commercial devices now provide the surgeon with a wide variety of options which are readily available off the shelf. As surgeons have gained experience with the devices, the original limitations have been overcome, and now more complex pathology can be treated. Currently surgeons are adapting strategies and using hybrid techniques to treat pathology, which was not at first amenable to simple endovascular grafting.

As with any new technique, new complications were discovered, and management strategies were developed to overcome and limit these complications. Endoleaks and graft collapse are examples of such complications. Other complications associated with repair of aortic pathology such as paraplegia or respiratory failures have been demonstrated to be less than traditional open techniques.

Despite the initial enthusiasm for thoracic endovascular aortic repair (TEVAR), critics are focused on long term efficacy and costs to the patient and to society.

2. Evolution of Endovascular Technology

2.1. Early Trials

The first reported use of the thoracic endograft for the treatment of a descending thoracic aneurysm was by Dake, et al, (1994). The authors implanted the devices in patients who were believed to be at excessive risk for conventional open surgery. They showed that endovascular stent graft implantation could be performed successfully with relatively low morbidity. The initial feasibility trial of the W.L. Gore TAG endoprosthesis was completed in the United States in 1998. There was a subsequent voluntary withdrawal of the device during Phase II pivotal trial by the manufacturer in 2001 due to the discovery fractures involving the longitudinal deployment of the stent. A modified device was reintroduced and testing began in 2003. In 2005 the Food and Drug Administration (FDA) approved the first commercially available thoracic stent graft, the W. L. Gore TAG endograft system (Cho et al, 2005).

Clinical data for the Medtronic Talent and Valiant endografts was obtained from The Talent Thoracic Retrospective Registry. Data was collected from 1996 to 2004 in seven European referral centers. 427 patients (113 emergency and 340 elective) underwent thoracic endovascular aortic repair (TEVAR). Aortic pathologies included degenerative aneurysms (30%), dissection (40%), traumatic aneurysms (18%), as well as patients with penetrating ulcers and intramural hematomas (2%). Technical success was achieved in 98% of the procedures. Technical failure was secondary to inadequate caliber of the femoral or iliac vessels or problems with device deployment. The mortality rate was 7.9% for emergency cases, and 4% for elective cases. The incidence of stroke was 3.7%, and the incidence of paraplegia was 1.8%. In their analysis, stroke was associated with occlusion of the left subclavian artery without revascularization and paraplegia or paraparesis was associated with coverage of the aorta longer than 20 cm. Late mortality was 8.5% at a mean follow-up of 24 months. One third of the late deaths were related to the aortic disease.

The VALOR trial was a prospective multicenter non-randomized investigation of the safety and efficacy of the Talent thoracic stent graft system used for patients for the treatment of thoracic aortic aneurysms. The study included 40 institutions and United States and consisted of patients with either a fusiform or saccular aneurysms. The 30-day VALOR results included perioperative mortality of 2.1%, major adverse advents 41%, incidence of paraplegia 1.5%; paraparesis, 7.2%; and stroke, 3.6%. The 12-month VALOR results included all-cause mortality, 16.1%; aneurysm-related mortality, 3.1%; conversion to open surgery, 0.5%; target aneurysm rupture, 0.5%; stent graft migration >10 mm, 3.9%; endoleak (12.2%), stent graft patency, 100%; stable or decreasing aneurysm diameter, 91.5%. No deployment-related events or perforation of the aorta by a graft component occurred. The Talent Thoracic Stent Graft showed statistically superior performance with respect to acute procedural outcomes ($P < .001$), 30-day major adverse events (41% vs. 84.4%, $P < .001$), perioperative mortality (2% vs. 8%, $P < .01$), and 12-month aneurysm-related mortality (3.1% vs. 11.6%, $P < .002$) vs. open

surgery. The pivotal VALOR 12-month trial results demonstrate that the Medtronic Talent Thoracic Stent Graft System is a safe and effective endovascular therapy as an alternative to open surgery in patients with TAA who were considered candidates for open surgical repair (Fairman et al, 2008).

The VALOR II trial reported the three-day mortality of 3.1% paraplegia rate of 0.6% per recess rate of 1.9% and stroke rate of 2.5%. At 12 months, aneurysm related mortality was 4%, stent graft migration 2.9%, and endoleak rate was 13%. There were no ruptures, conversion to open surgery, or secondary procedures due to endoleak after 30 days. The authors concluded that the valley and thoracic stent graft is a safe and effective treatment for patients with descending thoracic aneurysms of degenerative etiology (Fairman et al, 2012).

In 2005, Greenberg reported the results of 100 patients treated with the Zenith TX1 and TX2 endovascular graft. Patient population consisted of 81 patients who had degenerative aneurysms, and 15 patients who had aneurysms secondary to aortic dissections. Two patients had aorto-esophageal or aorto-bronchial fistulas, and 29% of the patients required additional open procedures (hybrid procedures) to create an adequate landing zone. The hybrid procedures included an elephant trunk/arch reconstruction (14%), carotid subclavian bypass (18%), and visceral bypass (4%). Of these, 55% of the patients had undergone previous aneurysm repair. Iliac conduits were required in 19% of the cases. The overall one year mortality was 17%. Aneurysm related mortality was 14% at one year. Spinal cord ischemia and strokes were reported and 6% and 3% of the patients respectively. Endoleaks were detected an 8.5% patient's at 30 days and 6% at 12 months (Greenberg et al, 2005).

In 2008, the results for the intermediate and long-term outcomes Zenith TX1 and TX2 devices were published. A total of 160 patients were treated; 103 patients had thoracic aneurysms, 25 patients had aortic dissections with aneurysm, there were 2 patients with fistulas, and 3 patients who had symptomatic aneurysms or aortic ruptures. Of these, 47% of the patient's had previous aortic surgery, and 33% of the patient's required hybrid procedures to create adequate landing zones. The 30-day mortality was 6.9%. Mortality at one year was 16%. Endoleak rate was 9.4% at 30 days, and 7.5% after 30 days. Of these, 26% of the patients required re-intervention (Morales et al, 2008).

The FDA granted approval of the Cook Zenith TX2 and the Medtronic Talent thoracic endograft systems in 2008. All 3 systems were approved for the treatment of thoracic aneurysms; however the Medtronic Talent system and the Cook Zenith TX2 were also approved for the treatment of penetrating aortic ulcers.

2.2. Commercial Devices

All current commercial devices systems rely on a covered collapsible stent system, which provides radial force against the aortic wall to seal off blood flow from the pathology being treated. The devices are mounted on a delivery system to be delivered into the thoracic aorta. Access to the aorta is usually via a cut down of the femoral or iliac arteries. A temporary side graft is usually anastomosed to the iliac artery or distal aorta to aid in obtaining vascular access. Sheathed (WL Gore and Cook) and sheathless

systems (Medtronic) are available. Sheathed systems have the advantage of minimizing trauma to the arteries when multiple devices are being deployed. Sheathless systems tend to be smaller and may be used in patients with smaller peripheral vessels. Each has its own advantages and disadvantages. Current systems allow for stacking of the grafts to be used to treat either long segments and/or variations an aortic diameter. Current commercial devices can be used interchangeably in the same patient to achieve satisfactory results.

2.2.1. W.L. Gore TAG

The Gore TAG endoprosthesis was approved by the FDA in March of 2005, after the Pivotal trial demonstrated a decrease in morbidity and mortality as compared to conventional open repair. The Gore TAG device is designed as a self-expanding polytetrafluoroethylene endograft with a Nitinol support. The device is delivered via a sheath delivery system. Deployment of the device is from the center to the periphery. Precise placement on either the proximal or distal landing zone can sometimes be challenging. The original devices were prone to collapse when oversized are placed in the aortic arch. Improvements and device development and improvements in preoperative planning have limited these complications. The current modular system can be used for aortas with landing zones from 22-40 mm. They are available in lengths of 10-20 cm. The FDA has approved these devices to be used for the treatment of descending thoracic aneurysms.

2.2.2. Medtronic Talent and Valiant Thoracic Endoprostheses

Medtronic Talent and Valiant endoprostheses (Figure 1) are composed of a self-expanding nitinol, which are covered with a polyester graft. This modular system contains grafts were from 22-46 mm. This flexibility allows the treatment of aortic pathology with landing zones between 18 and 40 mm. This system is unique because the proximal grafts are available with tapered configurations. The proximal devices also have bare metal stents at the leading edge. They allow the device to be placed across the orifice of the left subclavian or common carotid artery while allowing antegrade blood flow through the vessel. Distal components also have similar configurations. The devices are deployed from a proximal to distal fashion, which allows for precise placement of the graft in the proximal landing zone. The Valiant device is more flexible than the Talent and also has a greater number of bare wires.

2.2.3. Cook Zenith TX2 Endoprosthesis

Zenith TX2 stent graft is a two-piece modular system of Dacron and stainless steel Z stents (Figure 2). The proximal end of the device contains stainless steel barbs, which protrude through the graft fabric and anchor the graft directly to the aortic wall. This may help prevent graft migration. The proximal components are available in diameter is 28-42 mm. The distal component has an uncovered bare metal stent, which allows for placement over the visceral vessels without causing obstruction of blood flow.

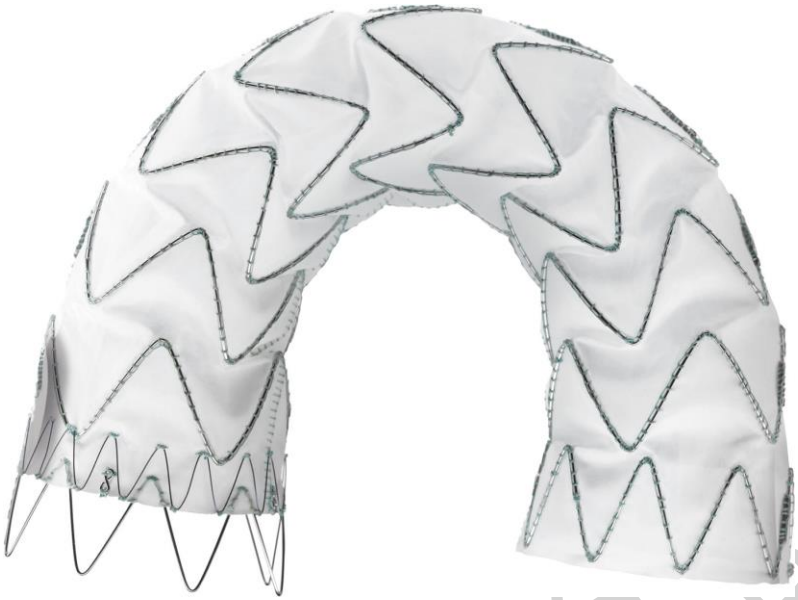

Figure 1. Medtronic Valiant Thoracic Endoprosthesis, Courtesy of Medtronic Corporation

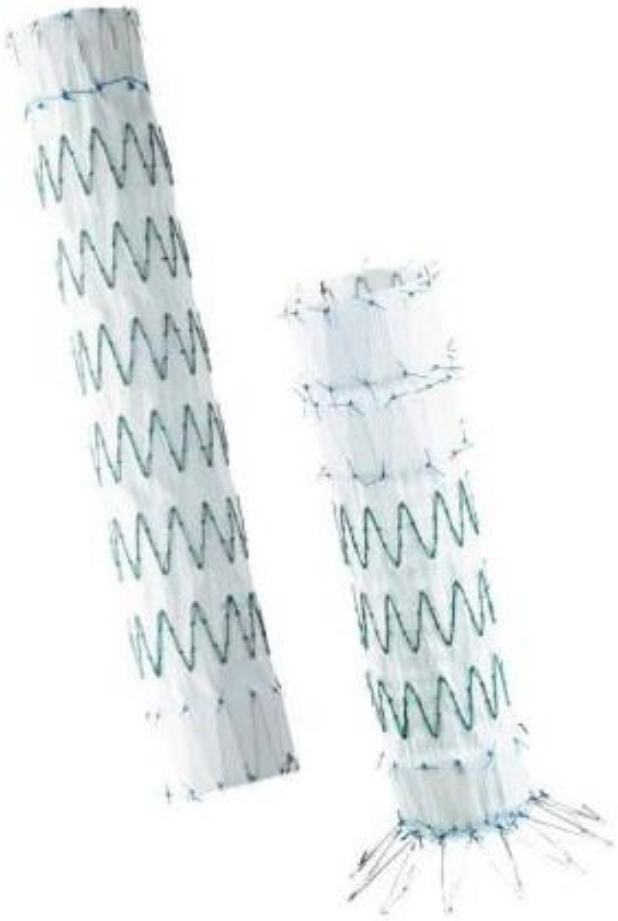

Figure 2. Cook TX2 Endoprosthesis, Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana.

2.3. Emerging Technologies

New devices are being developed to address the current limitations and endovascular technology. Uncovered stents are being evaluated for the treatment of aortic dissections without aneurysms. These devices are designed to allow the intima to be re-suspended against the adventitia. The bare-metal configuration allows the stent to be placed over branch vessels such as the left subclavian artery and celiac artery without impeding blood flow. Other devices are being developed with preformed perforations to allow side branches to be placed in the main body of the device to bypass vessels which normally would be occluded by the covered graft.

2.4. Indications for Use

The original FDA approval of the Gore TAG thoracic endografts was for the management of descending thoracic aneurysms located distal to the left subclavian artery and proximal to the celiac artery. An adequate proximal and distal landing zone 2 cm was recommended for placement of the thoracic and the grafts was needed to properly seat the device. The Medtronic and the Cook devices were also approved for the management of penetrating ulcers and pseudo aneurysms. Current published data has shown only 50% of the device is used as approved by the FDA (Hughes et al, 2008).

Currently, thoracic endografts are being used to treat a wide range of aortic pathology, and are often combined with concomitant bypass procedures to extend the use of these devices in high risk patients.

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Biographical Sketch

Frank Manetta received his BS in Nutritional Biochemistry from Cornell University in Ithaca, New York in 1989 and his M.D. from the Medical College of Pennsylvania in Philadelphia, Pennsylvania in 1994. He completed his General Surgery Residency training at the Albany Medical Center in Albany, New York in 1999. During that time, he was inducted into the Alpha Omega Alpha Medical Honor Society. He also received the Silver Scalpel Ward for his dedication to medical student teaching. He completed his Thoracic Surgery residency at the Long Island Jewish Medical Center in New Hyde Park New York in 2001. Dr. Manetta is currently an attending cardiothoracic surgeon at the Hofstra North Shore-LIJ School of Medicine and holds the academic title of Associate Professor of Surgery. He is certified by the American Board of Surgery, and the American Board of Thoracic Surgery. He is currently

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