Since being approved in 2005 by the Food and Drug Administration (FDA) for commercial use as a treatment option for thoracic aortic aneurysms, the thoracic endograft device has broadened the therapeutic strategies in patients with thoracic aortic disease. Endovascular repair of thoracic aortic aneurysms offers many practical benefits and technical advantages compared to the conventional open thoracotomy. Deployment of a thoracic endograft in the descending aortic aneurysm, particularly in patients with adequate proximal and distal aortic neck landing zones, can be accomplished in a straightforward manner. In patients with suitable iliofemoral artery access, this procedure can be performed under local anesthesia without incurring significant cardiopulmonary stress. Frequently encountered physiologic insults associated with an open repair, such as thoracotomy, aortic cross-clamping, left-heart bypass, and single-lung ventilation, can be avoided by an endovascular thoracic aortic endografting procedure.

Exclusion of a descending aortic aneurysm with an endograft does not necessitate cross-clamping the thoracic aorta. As a result, the avoidance of aortic cross-clamping minimizes significant blood pressure shifts and coagulopathy, which also reduces operative blood loss, as well as ischemic events involving the spinal cord, viscera, and kidneys. Additional advantages of endovascular repair, which is in sharp contrast to an open operation, include a reduced systemic anticoagulation with heparin during the procedure. This is particularly beneficial in patients with traumatic aortic injuries who have concomitant intracranial or abdominal injuries. Last, patients who underwent endovascular thoracic procedures experienced a significantly shorter convalescent period compared to those who underwent open repair, which is a comparable and well-recognized benefit documented in studies of endovascular abdominal aortic aneurysm repair.

These perceived benefits of endovascular thoracic repair have generated enormous interest to develop the ideal device for thoracic aortic pathology. Many endovascular manufacturers have launched their own devices, as well as clinical investigations to validate the efficacy of their respective devices. This article provides a brief overview of the various endovascular thoracic endografts, as well as the available clinical studies supporting their utility. Devices that will be discussed herein include the Gore TAG Endoprosthesis (Gore & Associates, Flagstaff, AZ), the Zenith TX2 Stent Graft (Cook Incorporated, Bloomington, IN), the Talent Thoracic Stent Graft (Medtronic Vascular, Santa Rosa, CA), and the Relay Thoracic Stent Graft (Bolton Medical, Sunrise, FL).

THE GORE TAG ENDOPROSTHESIS

The initial feasibility trial of the Gore TAG endoprosthesis was completed in the US in 1998. After a voluntary withdrawal by the manufacturer in 2001 due to the discovery of fractures involving the longitudinal deployment stent, a modified device was reintroduced in 2003. It became the first commercially approved thoracic device in the US as the FDA granted its approval for clinical application in 2005.

Device Description
The Gore TAG endoprosthesis is composed of a symmetrical ePTFE (expanded polytetrafluoroethylene) tube externally reinforced with a layer of ePTFE/fluorinated ethylene propylene (FEP) (Figure 1). An exoskeleton consisting of nitinol stents is attached to the entire external surface of the graft with ePTFE/FEP bonding tape. Both proximal and distal segments of the endograft have scalloped flares to facilitate conformity of the endograft in a tortuous thoracic aorta. Two radiopaque gold bands are attached to the base of the flares, serving as a guide during deployment and in graft surveillance. A PTFE sealing cuff, which is affixed to the base of the flares, is attached on one end with FEP, while the other end is allowed to remain free. This designed enhances the attachment of the device to the aortic wall and potentially reduces type I endoleaks. [AU: PREVIOUS SENTENCE OK AS EDITED?]

The device contains a unique deployment mechanism in which the endograft is constrained by an ePTFE/FEP sleeve connected to a deployment knob located at the control end of the delivery catheter (Figure 2). Release of the endograft begins in the midgraft region to reduce distal displacement via a “wind-sock” effect. After device deployment, a unique tri-lobed balloon, which permits continuous antegrade aortic blood flow during balloon inflation, is used to ensure full device attachment to the aortic wall (Figure 3). The flexible catheter delivery system and the rapid deployment mechanism are potentially beneficial, particularly for deployment in curved segments of aorta within or close to the aortic arch. The delivery system and compatible introducer sheaths vary according to the diameter of the device and range from 20-F to 24-F sheaths. [AU: PREVIOUS SENTENCE OK AS EDITED?]

Grafts are available in diameters ranging from 26 mm to 40 mm, and in lengths of 10 cm, 15 cm, or 20 cm.

**Brief Clinical Results**

A phase 2 pivotal trial, which was a prospective, multicenter, nonrandomized study that evaluated the safety and efficacy of the Gore TAG endoprosthesis in 17 institutions for the treatment of descending thoracic aortic aneurysm as compared to an open surgical repair, was recently published.1 The primary safety endpoint was the percentage of patients with more than one major adverse event (MAEs) through 1 year after treatment. The primary efficacy endpoint was the percentage of patients free from major device-related events through 1-year follow-up for the TAG group. One hundred thirty-nine (98%) of 142 patients had a successful implantation of the device. Inadequate arterial access was responsible for the three failures. Operative mortality after a TAG repair, defined as death within 30 days of the procedure or dur-
ing the same hospitalization, occurred in three (2.1%) patients. Within 30 days of the operation, 45 (32%) patients had at least one major adverse event: five (4%) experienced a stroke, four (3%) demonstrated temporary or permanent paraplegia, 20 (14%) experienced vascular trauma or thrombosis, and two (1.5%) died. Mean follow-up was 24 months. Two-year all cause mortality was comparable between the TAG and open surgical groups, which were 24% and 26%, respectively. The incidence of MAEs at 1-year follow-up was significantly lower in the TAG group as compared to surgical controls, which were 42% versus 77%, respectively. The majority (70%) of MAEs were noted to have occurred within 30 days of the original procedure. This advantage to the TAG group persisted through 3-year follow-up. Kaplan-Meier estimates of the probability of freedom from MAEs at 3 years were 48% after TAG repair and 20% after open repair. Based on the findings of this study, the authors concluded that the Gore TAG endoprosthesis represents a safe alternative for the treatment of descending thoracic aneurysms, with remarkable 2-year freedom from aneurysm-related death.1-3

THE MEDTRONIC TALENT STENT GRAFT SYSTEM

The clinical feasibility trial of the Talent stent graft system was initiated in the US in 1998.4 This clinical study, also known as the VALOR Trial (Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms), recently completed the enrollment of three study arms. The Talent endograft system evaluated in the VALOR Trial has been used extensively outside the US for many years. The manufacturer is preparing to introduce the next generation of their thoracic endograft device, which is called the Valiant Stent Graft, into US clinical trial. The evolution of the Talent thoracic stent graft to the Valiant device is based in part on the accumulated clinical experience from device implantation worldwide.

Device Description

The Talent thoracic stent graft system is composed of a nitinol stent between layers of polyester graft. The Talent has a longitudinal support bar throughout the length of the endograft. Individual stents are secured to the graft with sutures (Figure 4). Between individual stents is an unsupported graft to allow for flexibility. The proximal end of this stent graft is made in two configurations, which include either a serrated (open web configuration) or an open bare stent segment (FreeFlo configuration). The bare stent FreeFlo configuration allows device implantation across the orifice of the left subclavian or common carotid artery while maintaining antegrade blood flow. Similar bare wire configuration is also available in the distal stent graft, which permits the uncovered device to anchor across the celiac artery. The delivery systems for Talent have profiles between 22 F and 25 F. The Talent system is composed of two device components. The proximal device is a straight tube stent graft with proximal FreeFlo configuration. The proximal device is available in diameters of 22 mm to 46 mm, in 2-mm increments.[AU: PREVIOUS SENTENCE OK AS EDITED?]

Covered lengths of the proximal device range from 112 mm (largest diameters) to 116 mm (smallest diameters). In contrast, the distal Talent device is a tapered tube endograft system with a 4-mm difference in diameter between the proximal and distal orifice. The proximal orifice of the distal Talent device has an open web configuration, whereas the distal orifice of the same component has a closed web configuration (Figure 5). The distal Talent device is available in diameters ranging from 22 mm to 44 mm, in 2-mm increments. Covered lengths of the distal Talent endograft range from 110 mm (largest diameters) to 114 mm (smallest diameters).

Precise deployment of the thoracic endograft in the vicinity of the aortic arch is of fundamental importance to prevent device-induced cerebral embolization. In an effort to improve the deployment accuracy and technical ease, the long con-

![Figure 4. The Medtronic Talent thoracic stent graft.](image-url)

![Figure 5. The Medtronic Talent stent graft system is composed of two components. The proximal stent graft device is a straight tubular endograft with proximal FreeFlo bare stent configuration. The distal stent graft component is a tapered tubular endograft with an open web proximal configuration and closed web distal configuration.](image-url)
necting bar of the Talent device, while columnar support has been optimized through stent spacing and the exoskeleton. The removal of the connecting bar enables the device to become more flexible. Additionally, the need to orient the device in the aorta has been eliminated due in part to its enhanced flexibility. The Valiant stent graft has a modified proximal FreeFlo configuration with eight bare peak wires compared to the five bare peak wires found in the Talent stent graft (Figure 6). This modification allows for same radial force as the Talent system with less stent flare, while distributing similar radial force across more points of contact with less force and stress per point of contact.

The Valiant device is available in lengths ranging from 100 mm to 227 mm, and its proximal neck diameters range from 24 mm to 46 mm, in 2-mm increments. Longer thoracic stent grafts are desirable in selected situations when treating thoracic aortic pathologies. The great majority of thoracic aortic conditions require stent graft coverage of up to 200 mm in length. Although shorter thoracic endografts are adequate when excluding focal disease processes, such as aortic transection, penetrating ulcers, or saccular aneurysms, longer thoracic coverage is typically necessary when treating atherosclerotic fusiform aortic aneurysm. Longer endografts may result in less modular junctional endoleaks. In addition, fewer passes of large delivery systems through diseased iliofemoral arteries may avoid the risk of device-induced arterial rupture and life-threatening hemorrhage. The Valiant distal device contains closed web configuration in both straight and tapered fashion.

Figure 6. The Valiant stent graft has a modified proximal FreeFlo configuration with eight bare peak wires (shown left) compared to the five bare peak wires found in the Talent stent graft (shown right).

Similar to the Talent device, distal bare spring device available in the Valiant component when implantation near the celiac artery is required. The delivery system in the Valiant device is 2 F smaller than the Talent device, and allows for controlled, ratcheted, precise deployment using the refined Xcelerant delivery system (Figure 7).

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**Brief Clinical Results**

The VALOR Trial is a prospective, multicenter, nonrandomized investigation of the safety and efficacy of the Talent Thoracic Stent Graft System when used in patients with thoracic aortic aneurysms. The primary test arm consists of patients diagnosed with thoracic aortic aneurysms who are considered candidates for open surgical repair and who are low to moderate risk. Additionally, two observational treatment group registries were conducted concurrently, serving to record descriptive information that may serve as the basis for future clinical investigations. The registry and high-risk arms include patients diagnosed with dissections, traumatic injury, pseudoaneurysms, as well as aneurysms without a distinct proximal or distal aneurysm neck >20 mm in length. The VALOR study includes 40 participating institutions in the US. The great majority of diseases treated throughout all arms of the study consisted of either fusiform or saccular thoracic aneurysms. In the high-risk arm, aneurysm comprised of 76% of the procedural indications among patients enrolled. Forty percent of the patients enrolled were female. With a relatively high percentage of
female patients compared to abdominal aortic aneurysmal disease, challenging issues relating to iliofemoral artery access becomes critically important. In the VALOR trial, surgically placed conduits were necessary in upward of 15% of patients, demonstrating the need for delivery systems smaller than 22 F to 24 F. The bare spring or FreeFlo proximal design, as well as the availability of stent graft devices with diameters as large as 46 mm, allowed for a greater suitability of endovascular treatment options for a broader range of patients in VALOR compared to any other thoracic device trials currently in clinical investigations.

**THE ZENITH TX2 STENT GRAFT SYSTEM**

The Zenith TX2 TAA Endovascular stent graft is designed as a two-piece modular system, although implantation of a single device may be sufficient for focal thoracic aortic lesions (Figure 8). The Zenith TX2 endograft is constructed of Dacron fabric covered by stainless steel z stents. In this device, the proximal end is covered and has stainless steel barbs protruding through the graft fabric (Figure 10), which anchor the graft directly to the aortic wall. This also protects against distal stent graft migration during high-velocity systolic blood flow. The device utilizes an active fixation mechanism, with external barbs oriented in opposing directions and designed to engage the aortic wall to decrease the risk of proximal and distal migration. Full deployment of the proximal stent is released by pulling a trigger wire once optimal graft position is confirmed. The stents are modified Gianturco z stents, with small gaps left between each stent to allow some flexibility. Each end of the graft is held within a cap; inadvertent release during positioning within the aorta is prevented by a safety catch. The full length of the graft material is stent supported to prevent distal endograft device (Figure 8). The product line of the Zenith TX2 stent has recently introduced a novel extension of the original endograft design to be used in conjunction with the proximal TX2 component and specially designed for the treatment of dissections, which is composed of stacked bare z stents (Figure 9). This is an investigational device and only available under an IDE in the US. [AU: PLEASE CLARIFY THE PREVIOUS SENTENCE; DO YOU MEAN THE “NOVEL EXTENSION” IS INVESTIGATIONAL?]

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The authors noted that 55% of these enrolled patients had undergone previous aortic aneurysm repair and 19% required iliac conduits. The Zenith TX2 pivotal trial has recently completed the enrollment of the test or endovascular arm. This was a prospective, nonrandomized, multinational, IDE clinical trial involving 47 centers studying the safety and efficacy of the TX2 stent graft system in the treatment of thoracic aortic aneurysms. Anatomic inclusion criteria included descending thoracic aortic aneurysms and penetrating ulcers with at least 3 cm of healthy, uninvolved aorta proximal and distal to the lesion. The study design involved 135 endovascular repairs and 70 contemporary (repairs performed within 12 months of enrollment) and prospective open surgical controls. The primary safety endpoint was 30-day, all-cause mortality as compared with the surgical controls and the primary efficacy endpoint was 30-day rupture-free survival. Secondary endpoints included procedural and treatment successes, adverse events, mortality, clinical utility measures, and quality-of-life assessment at 12 months. The findings of this study revealed the Zenith TX2 is a highly safe and efficacious device in the treatment of descending thoracic aortic aneurysm.

THE RELAY THORACIC STENT GRAFT SYSTEM
Device Description
The Relay Thoracic Stent-Graft is a new endovascular device for treating thoracic aortic pathologies (Figure 13). Clinical investigation is currently underway to assess its efficacy in treating descending thoracic aneurysms. The Relay device is composed of self-expanding nitinol stents that are sutured to a polyester fabric graft. The skeleton of the device is composed of a series of sinusoidal stents placed along the length of the graft fabric. To provide a longitudinal support for this device, a curved nitinol wire is attached to the outer curve of the endograft fabric by a series of sutures. This design provides moderate column strength while maintaining desirable flexibility and torque response. A series of radiopaque markers, composed of platinum and iridium, are attached to the endograft in various locations to enhance fluoroscopic visualization. The Relay device is available in various sizes and


graft torsion or compression. The placement of the stents relative to the fabric is varied along the length of the device. At the ends of the endograft, the stents are sewn inside the fabric, whereas in its mid-portion they are outside the fabric. The intent of this design is to optimize fabric apposition to the aortic lumen and fabric-fabric interstent junctions. The Zenith TX2 Proximal Component is available in diameters ranging from 28 mm to 42 mm, and in lengths ranging from 12 cm to 21.6 cm. The Z-Trak delivery systems for the Zenith TX2 device have profiles ranging from 20 F to 22 F. Device deployment is achieved by withdrawing an external sheath.

The Zenith TX2 Distal Component differs slightly in design configuration compared with the proximal component. The distal end of the device has an uncovered bare-metal stent similar to the proximal end of the Zenith AAA Endovascular Graft. The barbs are on this bare stent and are oriented in a retrograde manner opposite the direction of the proximal hooks (Figure 11). This bare stent configuration allows fixation of the device over the origins of the visceral vessels, where it may be relatively less diseased and the covered portion to extend right to the origin of the celiac artery. Similar to the Distal Component, the TX2 Proximal Component diameters range from 28 mm to 42 mm and lengths range from 12.7 cm to 20.7 cm. The stent component is constructed of stacked z stents joined by polypropylene sutures, which can be deployed through a 16-F sheath and inserted through the existing Zenith TX2 Proximal Component sheath. A single stent diameter accommodates aortic luminal diameters ranging from 24 mm to 38 mm and is available in lengths of 82 mm, 123 mm, and 164 mm. The z stents exert a minimal radial force that allows gradual opposition of the dissection septum and re-expansion of the true lumen.

Brief Clinical Results
Greenberg et al recently reported the mid-term results of their first 100 consecutive thoracic aortic repairs using the Zenith TX1 (first generation) and TX2 stent graft systems. The authors noted the majority of the experience was composed of aneurysms (81%) and dissections. All-cause mortality in this cohort was 17% at 1 year. Spinal cord ischemia occurred in 6% of patients, and strokes occurred in 3%. Other pertinent outcomes at 1 year included an endoleak (6%), secondary interventions (15%), and migration (6%).
configurations, both tapered and nontapered. Graft lengths up to 200 mm are available, with diameters ranging from 22 mm to 46 mm. The profile of the primary introducer sheath ranges from 22 F to 26 F, depending on graft diameter and length.

**Brief Clinical Results**

The feasibility or phase 1 study for the Relay thoracic stent graft in treating descending thoracic aortic aneurysms and penetrating ulcers was approved by the FDA in December 2004. The study was initially limited to 30 patients and five clinical sites. Regulatory approval to include two additional sites was granted in April 2005. Available information showed that more than 20 patients have been enrolled in the phase 1 study as of November 2005. Eighteen (90%) had thoracic aortic aneurysm and two (10%) had penetrating ulcers. Delivery and deployment of the device was deemed satisfactory in all instances, except in three cases (15%), all involving a tendency of distal device migration. This phenomenon occurred when the deployment sequence involved a “stop-and-go” maneuver with initial expansion of the first two to three stent segments before proceeding to full uncovering and expansion along its full length. These observations were similarly reproduced on bench testing, which led to a modification of the instruction for use involving the deployment technique. Since a modified deployment technique was instituted, no further occurrences relating to device migration were noted during the deployment process. Among all procedures that could be completed, there was a 100% technical success rate, with delivery and deployment of the device as intended, and with complete angiographic exclusion of the target lesion. There have been no 30-day mortalities. Two endoleaks have been reported on 6-month follow-up scans, while the precise cause of these endoleak remained undetermined. There have been no unanticipated device-related adverse events to date. Completion of the phase 1 study was achieved in 2006. It is anticipated the result of this trial will be published at a later date.

Peter H. Lin, MD, is Associate Professor of Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Chief of Vascular Surgery, Michael E. DeBakey VA Medical Center, Houston, Texas. [AU: PLEASE COMPLETE THE ATTACHED FINANCIAL DISCLOSURE FORM] Dr. Lin may be reached at (713) 794-7892; plin@bcm.tmc.edu.

Wei Zhou, MD, is Assistant Professor of Surgery, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, Texas. [AU: PLEASE COMPLETE THE ATTACHED FINANCIAL DISCLOSURE FORM] Dr. Zhou may be reached at (713) 794-7892; wzhou1@bcm.edu.