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REVIEW

# The Landscape of TEVAR Today and Where It's Headed

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## Abstract

Thoracic endovascular aortic repair has been revolutionary within vascular surgery for the management of descending thoracic aortic diseases. Dating back to the first described series of implantation of thoracic aortic stent grafts by Dake et al in 1994, the ability to treat thoracic aortic pathology in patients otherwise deemed not to be surgical candidates has continued to expand.[1] Open repair of the descending thoracic aorta is a physiologically demanding procedure, with a relatively high rate of perioperative morbidity (55%) and mortality (22%) in elective repairs in the United States.[2] Endovascular repair of the descending thoracic aorta carries much lower early morbidity and mortality risk when compared with open repair, particularly in the setting of a ruptured thoracic aortic aneurysm (TAA).[3,4] Thoracic endovascular aortic repair is currently used for both acute and chronic pathologies; indications for use include aortic aneurysm, Stanford type B aortic dissection (AD), intramural hematoma, penetrating aortic ulcer, and traumatic and iatrogenic aortic injury.

## Introduction and Historical Perspective

Thoracic endovascular aortic repair (TEVAR) has been revolutionary within vascular surgery for the management of descending thoracic aortic diseases. Dating back to the first described series of thoracic aortic stent graft implantations by Dake et al in 1994, the ability to treat thoracic aortic pathology in patients otherwise deemed not to be surgical candidates has continued to expand.[1] Open repair of the descending thoracic aorta is a physiologically demanding procedure, with a relatively high rate of perioperative morbidity (55%) and mortality (22%) in elective repairs in the United States.[2] Endovascular repair of the descending thoracic aorta carries much lower early morbidity and mortality risk when compared with open repair, particularly in the setting of a ruptured TAA.[3,4] TEVAR is currently used for both acute and chronic pathologies; indications for use include aortic aneurysm, Stanford type B AD, intramural hematoma, penetrating aortic ulcer, and traumatic and iatrogenic aortic injury.

## Indications

### *Descending Thoracic Aortic Aneurysm*

Descending TAAs (DTAAs) occur considerably less frequently than infrarenal abdominal aortic aneurysms and ascending TAAs, with about 10 cases per 100,000 person-years in the United States.[5] This is generally a disease of older adults with an average age at diagnosis of 65; however, DTAAs can be seen in younger individuals, particularly patients with connective tissue disorders.[6] As is the case for all aneurysmal disease, the risk of rupture for individual patients generally guides decision-making regarding repair. DTAA rupture is usually life-threatening, if not life-ending, with only 41% of patients surviving the prehospital phase and even fewer surviving repair.[7] A demonstrated decrease in mortality from ruptured aortic aneurysms has been seen since 1999, but overall it remains a highly fatal disease process.[8] The current Society of Vascular Surgery guidelines recommend repair of TAA with TEVAR at a diameter threshold of 5.5 cm in low-risk patients with favorable aortic anatomy.[9] TEVAR should be considered first-line surgical therapy in patients with appropriate anatomy. It is also indicated as an initial temporizing measure in infected TAA, although data for this is lacking and confined to case reports and series.[10]

### *Aortic Dissection*

The estimated incidence of acute AD is 3 to 10 cases per 100,000 person-years, with men and older adults more frequently affected.[11] Given that there is a high prevalence of hypertension in patients with acute AD, initial medical therapy is focused on reducing blood pressure and the resultant shear stress, thus limiting the propagation of dissection and associated complications.[12] The indications for TEVAR for hyperacute and acute AD include aneurysm-associated dissection, treatment of malperfusion syndrome, and rupture.

### *Intramural Hematoma*

Intramural hematoma (IMH) is defined as crescentic thickening of the aorta in the absence of an intimal flap, with the resulting hematoma confined to the media. It occurs in approximately 5% to 20% of patients who present with signs and symptoms concerning for AD, with an associated mortality rate of 20% to 30%.[13,14] As with AD, management is mainly medical, involving blood pressure control. Indications for TEVAR include recurring or refractory pain, rapidly increasing size of the IMH, or progression to AD with potential for rupture. An operative concern for proceeding with TEVAR in these patients is causing an iatrogenic transformation of IMH into AD. This is due to the leading edge of the stent graft penetrating through the aorta at either the proximal or distal landing zones. To prevent this, the point of maximal thickness of the IMH should be excluded and at an appropriate distance from the endograft edge.[13]

### *Penetrating Aortic Ulcer*

Penetrating aortic ulcers (PAU), defined as focal intimal defects with a small area of flow outside the lumen, are much less common than AD; however, they also tend to affect older men, albeit at an advanced age. Most are localized to the descending thoracic aorta, making them amenable to endovascular therapy. TEVAR is indicated as first-line treatment for symptomatic PAU, recurrent or refractory pain, signs of impending rupture (rapid growth, periaortic hematoma, hemothorax, pleural effusion, pseudoaneurysm), and rupture.[15]

### *Traumatic Aortic Injury*

Traumatic aortic injury can occur in patients who have experienced high-energy blunt trauma with rapid deceleration mechanisms (such as high-speed motor vehicle crash). Blunt traumatic aortic injury (BTAI) most frequently occurs at fixed points along the aorta; the most common site of injury is at the aortic isthmus, just distal to the left subclavian artery at the ligamentum arteriosum. With the advent of high-resolution computed tomography scanning, BTAI is detected more frequently, earlier, and at lesser-grade injuries. BTAI is divided into 4 categories depending on degree of severity: grade I (mild intimal injury); grade II (development of IMH); grade III (development of pseudoaneurysm); and grade IV (free rupture).[16]

Initial medical therapy for BTAI is similar to management of AD, with a focus on aggressively controlling blood pressure with IV beta blockade. Medical therapy is considered definitive therapy for grade I injuries. Grade II-IV injuries should have strong consideration for repair, with TEVAR utilized as the first-line option over traditional open repair. When comparing a modern series of patients treated with TEVAR to a historical series of patients treated with traditional open repair, there is a clear benefit demonstrated in patients undergoing TEVAR in terms of morbidity and mortality.[17] Traditional open repair is now largely reserved for patients with unfavorable anatomy, and in centers without the capability to perform TEVAR.[18]

The timing for endovascular repair in BTAI is dependent on the grade of injury, as well as other sustained injuries and comorbidities. It is generally appreciated that treatment in a delayed fashion (>24 hours after injury) after medical optimization is preferred and associated with improved survival in cases where immediate operation would carry high mortality risk due to other life-threatening injuries.[18]

## Commercially Available Devices

### *C-TAG*

The C-TAG stent graft (Gore) is constructed with expanded polytetrafluoroethylene (ePTFE) on the luminal and abluminal sides over a nitinol stent frame. The stent is attached to the external surface of the graft using ePTFE/fluorinated ethylene propylene bonding tape, with the proximal end of the stent graft consisting of a partial bare stent and the distal stent ring completely covered. The original TAG device underwent an update with the addition of controlled conformability, as well as a staged deployment system (active control). The device is constrained within 2 sleeves that allow for 2-stage deployment. The deployment system reduces the risk of the windsock effect by deploying only 50% from leading to trailing end initially, which allows flow through and around the stent, aiding in accurate

placement. After initial deployment to the intermediate sleeve diameter, the delivery system and graft can be angulated prior to deployment to full diameter, if desired. Angulation may also be performed at full diameter prior to release from the deployment mechanism.[19]

### *Zenith TX2 and Zenith Alpha*

The Zenith TX2 (Cook Medical) is a 2-piece modular system consisting of woven polyester sewn to self-expanding Z-stents made of stainless steel with braided polyester and monofilament polypropylene suture. Seal and fixation are achieved without the use of barbs through an internal sealing stent proximally and distally. The accompanying bare dissection stent is a 1-piece cylinder constructed from nitinol Z-stents sewn together with polyester suture. The pro-form modification utilizes a diameter-reducing tie after the first stent ring, allowing the first stent ring to maintain its trifold shape as well as intussuscept into the second ring; this improves the ability to accommodate a proximal angulated landing zone and lessen the windsock effect, allowing for accurate deployment.[20]

The Zenith Alpha (Cook Medical) is a lower-profile 2-piece modular system constructed with woven polyester fabric sewn to self-expanding nitinol stents with braided polyester and monofilament polypropylene suture. The proximal component has an uncovered stent as well as a proximal internal sealing stent with fixation barbs. The distal component also has proximal and distal Z-stents on the inner surface to enhance seal, as well as a distal uncovered stent with associated fixation barbs. The Zenith Alpha is indicated for thoracic aneurysms and penetrating ulcers.[21]

### *Valiant Captiva*

The Valiant Captivia thoracic stent graft (Medtronic) is constructed using woven polyester sewn to sinusoidal-shaped nitinol springs on the outside of the graft using braided polyester suture. It utilizes the FreeFlo bare stent (Medtronic) at the proximal end of the proximal component and a closed web at the distal end of the proximal component. The distal component utilizes closed web configuration at the proximal margin and either a distal bare spring or closed web at the distal aspect.[22]

### *RelayPro*

The RelayPro (Terumo Aortic) is constructed using woven polyester sewn to sinusoidal, self-expanding nitinol stents using braided polyester suture. There is also a spiraled longitudinal curved nitinol support strut sewn to the proximal section of the graft fabric. The proximal component of the RelayPro stent graft comes in 2 configurations, including a bare stent configuration and a non-bare stent configuration. In the non-bare stent configuration, the proximal stent (crown stent) is fully covered. The delivery mechanism is unique, consisting of an outer hydrophilic sheath and an inner fabric sheath housing the stent graft. The outer sheath is positioned distal to the intended treatment area and the inner sheath is advanced from the outer sheath proximally to the intended target.[23]

### *TAG Thoracic Branch Endoprosthesis*

Recently approved by the U.S. Food and Drug Administration (FDA), the TAG Thoracic Branch Endoprosthesis (Gore) offers an off-the-shelf solution to avoid left carotid to left subclavian artery bypass, allowing for zone 2 deployment of TEVAR. It is a modular system consisting of an aortic component, optional aortic extender, and a side branch component that provides antegrade flow to the left subclavian artery. It is constructed in a similar manner to the current TAG device. Deployment of the aortic component initiates from the portal opening and simultaneously proceeds proximally and distally in 1 step. The side branch is advanced and deployed in a second step over a previously placed guidewire in the left subclavian artery (SCA).[24]

## Adjuncts and Advancements to Address Challenges Encountered in TEVAR

### *Debranching*

Approximately 40% of patients will require some form of debranching of the great vessels of the aortic arch during TEVAR, with the goal of providing a proximal seal zone when it would otherwise be inadequate with zone 3 deployment.[25,26] The most frequently performed cervical (extra-thoracic) debranching technique is left common carotid artery (CCA) to left SCA bypass (or left SCA transposition to the left CCA) to allow for zone 2 deployment.[26,27] Other methods for cervical debranching include right CCA to left SCA bypass with left CCA transposition to the intervening bypass, or right CCA to left CCA bypass in addition to left SCA debranching.[28]

Debranching may also be performed in the chest via sternotomy in a hybrid procedure. This allows for complete debranching of the great vessels and can be combined with cervical debranching (most often left CCA to left SCA bypass). These hybrid procedures are often used to provide a landing in zone 0 for TEVAR.[28]

### *Parallel Graft Technique*

Parallel graft technique, including snorkel or periscope configurations, allows for antegrade flow through arch vessels with or without extra-anatomic revascularization via debranching, while allowing for deployment of TEVAR devices in zones 0, 1, or 2.[29,30] Complications specific to this technique include stent thrombosis, stent fracture, and gutter endoleak,[31,32] as well as high rates of stroke (5% to 10%).[33,35]

### *In-situ Fenestration*

There is growing experience reported in the literature surrounding in-situ fenestration during TEVAR as a method of revascularization of the great vessels of the arch when planning for deployment within the aortic arch proximal to zone 3. Fenestration is usually performed in a retrograde fashion from access of the target vessel and can be performed with needle, laser, or radiofrequency. After the fenestration is completed, a bridging stent between the aortic stent graft and the target vessel is placed to facilitate stability and reduce the risk of endoleak. Data collected thus far on this method of revascularization has been promising and suggests that it is a relatively safe and durable option.[35,36]

### *Physician Modification*

Similar to in-situ fenestration, back-table modification of stent grafts may be performed to accommodate aortic arch disease. Various methods have been described including inner-branch modification, outer-branch modification, and creation of fenestrations. These are all off-label methods and should be limited to centers and surgeons with expertise in graft modification.[37]

### *Frozen Elephant Trunk*

Initially described in 1983, the elephant trunk technique for aortic arch replacement allows for and facilitates staged repair of the descending thoracic aorta.[38] A modification of this technique incorporates the placement of a TEVAR piece in the proximal descending thoracic aorta at the same time as open arch repair.[39] Recently, the Thoraflex device (Terumo Aortic) has been approved for use for this indication. It is a hybrid graft combining a woven polyester graft with a nitinol frame stent graft that extends into the proximal descending thoracic aorta, facilitating staged repair of the thoracic aorta by providing a landing zone for TEVAR or open repair.[40]

## Challenges and Issues

### *Access Complications*

With early TEVAR implementation, complications related to access occurred frequently, as the relatively large size of thoracic endografts necessitated large diameter delivery systems hindered by small diameter or heavily calcified vessels.[41] There has since been a trend toward lower profile device delivery systems with hydrophilic sheaths, allowing for use in smaller caliber, more tortuous arteries. However, access complications still exist and remain a challenge. Other adjunctive techniques have evolved to allow us to deliver these stent grafts, including creation of surgical conduits, angioplasty of the access vessels, intravascular lithotripsy, covered stent placement (crack and pave technique), transcaval access using intravascular ultrasound (IVUS), percutaneous transapical access, and the use of other access sites including the CCA and the SCA.[42,43] Discussion of the technical points of these alternative methods of delivery are beyond the scope of this review.

### *Endoleaks*

Endoleaks are defined as the persistence of blood flow within the diseased aortic segment, indicating incomplete exclusion by the endograft.[44] There are 4 types of endoleaks: type IA/B, indicating seal failure at either the proximal or distal attachment site of the graft to the vessel; type II, indicating retrograde through collateral vessels (usually lumbar arteries); type III, indicating device failure secondary to the endograft fabric or at areas of graft overlap; and type IV, indicating graft wall porosity. Type II endoleaks are most common. Type I and III endoleaks require reintervention, usually with placement of additional stent grafts. Novel techniques have emerged, involving the use of EndoAnchors (Medtronic), both as prophylaxis in patients at risk for device complications and as revision treatment in patients experiencing postprocedure endoleak with high rates of sac regression.[45,46]

### *Spinal Cord Ischemia*

Spinal cord ischemia is relatively less likely to occur with an endovascular approach when compared with open repair. However, it remains a complication, occurring in approximately 4% of patients who undergo TEVAR.[47,48] Adjunctive techniques to avoid spinal cord ischemia include limiting coverage of

the aorta, preoperative placement of a spinal drain, and postoperative blood pressure augmentation. Controversy still exists with regards to timing of placement, indications for placement, and management of spinal drains.

## Management of Aortic Arch Pathology

The adjunctive techniques described the above section are in service of treating the aortic arch. The difficulty remains in addressing complications associated with endovascular treatment of the arch including AD, stroke, stent graft migration, hostile anatomy not amenable to endovascular repair, and damage to the aortic valve. However, as technology continues to advance and the boundaries of TEVAR are expanded, it is not hard to see a future in which we are able to treat the aorta starting from the aortic valve.

## On the Horizon

### *Investigational Devices*

Current devices being investigated include those used in conjunction with open arch repair after AD, branched devices for treatment of the aortic arch and zone 0 landing, novel stents, and novel uses of bare metal stents. None of these devices are currently approved by the FDA for use in the United States.

### *Streamliner Multilayer Flow Modulator*

The Streamliner Multilayer Flow Modulator (Cardiatis) is a multilayered cobalt alloy bare metal stent device. The layers are interlocked and braided to create a mesh with goal of altering blood flow from turbulent to laminar and inducing positive shear stresses along the aortic wall to promote endothelialization along the luminal surface of the device, thus excluding flow into the aneurysmal aorta. Given the porosity of the device, it has been deployed with coverage of side branch vessels without ceasing flow through the side branches, and relatively low rates of target organ ischemia reported. It has been used to treat aneurysms throughout the aorta, AD, and PAU.[49]

### *Valiant Mona LSA*

The Valiant Mona LSA (Medtronic) stent graft system is currently under investigation as an off-the-shelf system for treatment of DTA in patients that would require left SCA revascularization if treated with a traditional TEVAR device. It is a modular branched stent graft. The main stent graft component is of the same composition as the Valiant stent graft. The branch stent graft utilizes a helical lattice of nitinol stents mounted to woven polyester and interfaces with the main stent graft through a high-density polyester fabric cuff serving as the seal between the 2 components. Results of the early feasibility study have been reported in 9 patients in the United States and United Kingdom with promising results.[50]

### *Nexus*

The Nexus aortic arch graft system (Endospan) is a unique single-branch device intended to treat aortic arch pathology in an off-the-shelf manner with the proximal extent landing in zone 0. It is a modular stent graft composed of 2 components, with a main component that conforms to the aortic arch and brachiocephalic artery via an integrated side branch and a second component that extends from the main component into the sinotubular junction of the ascending aorta. To utilize the Nexus, the great vessels need to be debranched prior to implanting the device, most often through a right CCA to left SCA bypass with left CCA transposition to the bypass. After repair with the Nexus device, the cerebral circulation is totally dependent on the brachiocephalic artery. Early results demonstrate a high success rate with excellent 1-year safety and performance.[51]

### *Zenith*

The Zenith double inner branched arch graft (Cook Medical) is an investigational device intended to exclude aortic arch pathology using a custom-made endograft with 2 inner branches that provide perfusion to the great vessels. The use of this device requires left SCA revascularization prior to aortic arch repair either through left CCA to left SCA bypass or left SCA transposition to the left CCA. The inner branches are cannulated and bridged using a special component for the brachiocephalic artery and an off-the-shelf covered stent for the left CCA. Experience with the device in multiple centers has been reported with favorable early outcomes.[52,53]

### *Ascending Aortic Stent Graft*

An exciting prospect on the horizon for endovascular aortic repair is the ascending stent graft being investigated for use in patients with type A dissection deemed to be high surgical risk with an entry tear ≥2 cm from the coronary orifices. The device is tailored to the ascending aorta allowing for

conformability to the lesser curve of the ascending aorta. Investigators have recently published promising data from the early feasibility study (ARISE trial) including 19 patients.[54]

### *Three-dimensional (3D) Printing*

While not widely available currently, the introduction of 3D printing has allowed researchers to entertain the use of this technology in the relatively rapid manufacture of custom-made stent grafts for complex aortic pathology. Tang et al have published their experience in rapid fabrication of customized thoracic aortic stent grafts around 3D-printed soluble core aortic models and their subsequent implantation in pigs.[55] While stent grafts are not able to be manufactured from printers yet, 3D printing offers the opportunity to create models of complex aortic anatomy allowing for preoperative planning in a 3D environment, as well as the ability to improve training for aortic interventionalists. ■

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