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THE CURRENT STATUS OF ENDOVASCULAR REPAIR OF THORACIC AORTIC ANEURYSMS (TEVAR)

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Abstract

Thoracic endovascular aortic repair (TEVAR) has been one of the most important advances in the management of thoracic aortic disease in the past two decades. The procedure was originally developed by Dake and colleagues in 1994 for the treatment of descending thoracic aortic aneurysm (DTAA), using the same principles as EVAR for the treatment of abdominal aortic aneurysm (AAA).[1] The first device approved for this indication was the TAG device (W.L. Gore & Associates, Inc., Flagstaff, AZ) in 2005. Since then there has been a plethora of changes and new developments related to thoracic endovascular aortic repair. This article will summarize the major updates related to TEVAR, focusing on three main aspects: what is new in device technology and future prospects; the expanding indications of TEVAR for the treatment of other pathologies and the newly developed techniques involved; and a glimpse at the expected future direction in the field.

Current Status of TEVAR Devices

Currently, there are three FDA-approved devices in the U.S. market for TEVAR. The first one is the Gore TAG device (W.L. Gore & Associates, Inc., Flagstaff, AZ), which was the first approved device in the country (Figure 1). It is a self-expanding endoprosthesis made of an expanded polytetrafluoroethylene (ePTFE) tube reinforced with ePTFE/fluorinated ethylene (FEP) film and an external nitinol self-expanding stent along the entire graft. A circumferential PTFE sealing cuff is located on the external surface of the endograft at the base of each flared scalloped end. The endoprosthesis size ranges from 26–45 mm in diameter and 10, 15, and 20 cm in length. The device needs a sheath for its introduction that ranges between 20 French (Fr) and 24 Fr depending on the device diameter. Since its original design, the device has had several modifications including removal of the longitudinal wire that had the tendency to fracture, addition of a low permeability film, and modifications of the sealing zone comorbidities and delivery system. Gore also developed a new sheath in 2010 with a pressurized balloon hemostatic valve to reduce blood loss (Figure 2). Currently, Gore is working on a conformable device (C-TAG) that provides better conformability to the arch area, and it received FDA approval to investigate this device in treating thoracic aortic aneurysms and other thoracic aortic pathology including traumatic aortic transection and acute aortic dissection.

The second approved device for TEVAR is the Zenith TX2 endovascular graft (Cook Medical, Inc., Bloomington, IN), a two-piece modular device that has full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z stents (Figure 3). For added fixation, the proximal component has caudally oriented barbs, and the distal component has distal bare stents with cranially oriented barbs. The device comes in diameters between 28–42 mm and lengths between 120–216 mm; it is loaded in its own sheath that is 20 Fr for sizes up to 36 mm and 22 Fr for larger sizes. Some new modifications on the device since its introduction include the creation of a new hemostatic valve that markedly reduces blood loss during the procedure and a modification to the sheath that reduces the risk of kinking

Figure 1. Conformable GORE TAG® Device (C-TAG®).
Image courtesy of W.L. Gore & Associates, Inc.

Figure 2. GORE® DrySeal Sheath. It is comprised of an introducer sheath with a GORE® DrySeal inflatable Valve attached, a dilator, and a 2.5 ml valve inflation syringe. When the valve is inflated, the sheath is completely hemostatic and multiple devices can be introduced through the sheath without compromising the seal.
Images courtesy of W.L. Gore & Associates, Inc.

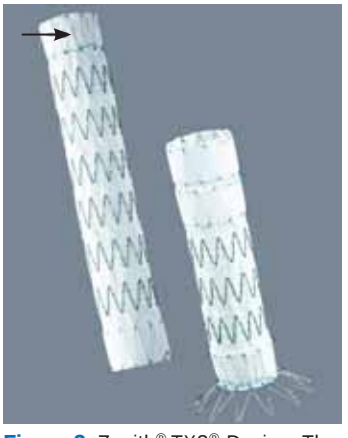

Figure 3. Zenith® TX2® Device. The black arrow points at the proximal caudally oriented barbs on the proximal main body component.
Image courtesy of Cook Medical, Inc.

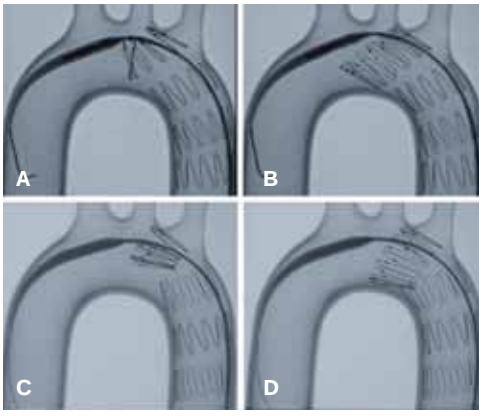

Figure 4. (A) and (B) show the original TX2® Device with "Bird's Beak Effect" in the aortic arch. (C) and (D) show the new TX2® Pro-Form™ Device addressing this problem.
Images courtesy of Cook Medical, Inc.

Figure 5. Talent™ thoracic stent graft device.
Image courtesy of Medtronic, Inc.

Figure 6. Talent™ thoracic stent graft with the Captivia® delivery system. The proximal bare metal stent is constrained in the delivery system to be released independent of device deployment. Image courtesy of Medtronic, Inc.

Graft Type	Graft Diameter (mm)	Access Diameter (mm)
Talent™	22–32	7.3
Gore TAG®	26, 28	7.6
Cook TX2®	28, 30, 32, 34	7.7
Talent™	34, 36, 38, 40	8.0
Talent™	42, 44, 46	8.3
Gore TAG®	31, 34	8.3
Cook TX2®	36, 38, 40, 42	8.7
Gore TAG®	37, 40, 45	9.2

Table 1. Comparison of device graft and access diameters. Device diameters are based on labeled diameters from device instructions for use.

during passage along tight curves, a risk that was present in the older sheath design. Also, the trigger wire conformation now allows the device to be constrained at the proximal stent, which results in better conformity to the aortic wall in the curvature of the arch (Figure 4).

The third device is the Talent Thoracic Stent Graft (Medtronic, Inc., Santa Rosa, CA) composed of a series of shaped, sinusoidal, self-expanding nitinol wire rings that act as springs (Figure 5). A full-length connecting bar connects the proximal and distal springs. The nitinol structure is covered by a monofilament polyester woven graft that is sewn securely to the nitinol structure. The device comes in four different components: proximal main, proximal extension, distal main, and distal extension. The proximal stent grafts and the distal extensions are equipped with a bare spring to improve fixation and allow deployment across the origins of the great vessels proximally and the celiac axis distally. The device comes in a wide range of diameters between 22–46 mm with 2 mm increments and lengths between 112–116 mm. Tapered grafts are available to accommodate the differences in diameter along the length of the aorta. The device comes preloaded in its Medtronic Xcelerant delivery system, which has a 22–25 Fr outer diameter (as opposed to the inner diameter in the TAG and TX2 devices) depending on the diameter of the device. The recently released Captivia delivery system offers complete control of device deployment, with minimal friction during the deployment process, and allows proximal device conformation to acutely angled thoracic aortic arch anatomy (Figure 6). There is currently a fourth device (Relay, Bolton Medical, Inc., Sunrise, FL) that is undergoing a phase II trial in the United States.

The sizing criteria for device choices differ, with the Gore TAG® trial using the inner aortic diameter and the Talent™ and TX2® trials using outer aortic diameter. Also, the access diameters of the devices are reported in different ways: the TX2® and TAG® devices report the sheath diameter needed (which means inner diameter of the delivery sheath required), while the Talent™ device reports the outer diameter size as it is already loaded into a delivery sheath. Which device has the smallest delivery system? It really depends on the graft diameter in its constrained condition within its delivery system (Table 1).[2] Table 2 summarizes a comparison of the three FDA-approved devices, and Table 3 summarizes the 30-day and 1-year outcomes of their regulatory trials.

All the device manufacturers are pursuing fenestrated and branched devices for both abdominal and thoracic cases to expand their use and versatility in dealing with aortic pathologies involving the great arch and visceral vessels. These are complex areas where the inherent curvature of the arch, the closely packed supra-aortic trunk vessels, and the potential for serious adverse consequences have delayed development.[2] (See "Fenestrated and Branched Endographs" in this issue, page 35.)

Table 2. Comparison of the three FDA-approved TAA devices. ePTFE: expanded polytetrafluoroethylene; OD: outer diameter.

Company	Product Name	Stent Material	Graft Material	Stent Expansion	Length (cm)	Diameter (mm)	Sheath required for delivery	Delivery sheath (Fr)	Proximal seal required (mm)
Cook Medical, Inc.	TX2® with Pro-Form™	Stainless Steel	Woven polyester	Self-expanding	Proximal: 12–21.6; Tapered proximal: 15.2–20.8; Distal: 13.6–20.7	Straight proximal: 28–42; Tapered proximal 32–42; Distal 28–42	No	20, 22	30
W.L. Gore & Associates, Inc.	Gore TAG® Thoracic Endoprosthesis	Nitinol	ePTFE	Self-expanding	10, 15, 20	26, 28, 31, 34, 37, 40, 45	Yes	20, 22, 24	20
Medtronic, Inc.	Talent™ Thoracic Captivia®	Nitinol	Dacron polyester	Self-expanding	11, 16, 20	22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46	No	22, 24, 25 (OD)	20

	Gore TAG	VALOR	STARZ
30-day results			
Mortality	1.5%	2.1%	1.9%
Paraplegia/Paraparesis	2.8%	8.7%	5.6%
Stroke	3.5%	3.6%	2.5%
Major adverse event	28%	30%	41.9%
Endoleak	3.6%	25.9%	4.8%
Access complications	14%	9.2%	22%
1-year follow up			
Endoleak	3.9%	12.2%	3.9%
Sac size increase >5 mm	9%	8.5%	7.1%
Migration >10 mm	0.7%	3.9%	2.8%
Ruptures	0%	0.5%	0%
Conversion	0.7%	0.5%	0%

Table 3. Results of the three FDA-approved thoracic devices according to their regulatory trials. STARZ: The study of Thoracic Aortic Aneurysm Repair with the Zenith® TX2® TAA Endovascular Graft; VALOR: Vascular Talent™ Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms

New Techniques and Treatment of Other Aortic Pathology

The introduction of TEVAR almost two decades ago was essentially targeted at the treatment of thoracic aortic aneurysm. Actually, all the current devices have been approved primarily for use in descending thoracic aortic aneurysm repair (DTAA). With the advancement of endovascular technology, those techniques have been applied to other challenging pathologies affecting the thoracic aorta. Acute aortic ulcer and intramural hematoma are now being primarily treated using thoracic endografting techniques. In fact, this is an approved indication for both the TX2 and the Talent devices. Other more complicated pathologies include acute and chronic aortic dissection, traumatic aortic transection, mycotic aneurysms, and aortoesophageal and aortobronchial fistula.

Surgical treatment of aortic dissection is indicated in all type A dissection and acute type B dissection with malperfusion, rupture, or impending rupture and in chronic dissection with progressive aneurysmal dilation. Historically, open aortic repair for aortic dissection has been associated with high morbidity and mortality. The International Registry of Acute Aortic Dissection (IRAD) investigators reported an in-hospital mortality of 34% for those undergoing open surgical intervention for complicated type B dissections. These patients also had a 40% in-hospital complication rate.[3] The use of endovascular techniques for the management of complicated type B dissection has been more promising: the IRAD investigators reported an 11% in-hospital mortality rate and 21% complication rate in patients who received endovascular therapy for complicated type B dissection.[3]

Aortic dissection is a complex pathology and there is no standard endovascular technique that is available for its management. Multiple different techniques have been developed to address aortic dissection including endovascular fenestration, with or without the use of bare metal aortic and branch vessel stenting, and the use of stent grafting to seal the proximal injury point of the aorta. The type of therapy selected depends on the pathologic criteria of the case, the presence of significant aortic occlusion, and the type of branch vessel occlusion whether static or dynamic. Whatever the technique used for endovascular therapy, intravascular ultrasound (IVUS) and high-quality flat plate fluoroscopy are mandatory for the safe and effective performance of the procedure. Compared to the earlier debate regarding the use of endografts for treating aortic dissection, the Society for Vascular Surgery guidelines currently recommend preoperative vascularization of patients whose anatomy requires covering the left subclavian artery with an endograft unless the procedure is done emergently, in which case selective revascularization of the left subclavian artery is suggested.[4] Covering the left subclavian artery without revascularization has been reported to have a four-fold increase in spinal cord ischemia that results in paraplegia, stroke, and upper extremity ischemia.[5]

Despite the lack of level I evidence, open repair is falling out of favor as the gold standard for the treatment of descending thoracic aortic injury (DTAI).[6] Recently, there has been more enthusiasm using TEVAR for the treatment of DTAI. For example, in a recent review by Jonker of all patients in the state of New York treated for DTAI from 2000 to 2007, the number of TEVAR cases exceeded the number of open procedures.[7] In the United States, however, there is no FDA-approved device for the treatment of DTAI. This has led to the off-label use of stent grafts that were not originally designed for this kind of pathology and in turn have had many limitations. As a result, device manufacturers have started designing endografts for that specific indication. A nonrandomized registry for the new C-TAG device (W.L. Gore & Associates, Inc., Flagstaff, AZ), is under way to evaluate the safety and efficacy of the device in DTAI.[6]

Other complicated thoracic aortic pathologies include mycotic and infected aortic aneurysm and aortoesophageal and aortobronchial fistula. These pathologies are all infected pathologies and carry an extremely high mortality rate if treated only medically.[8] The gold standard open surgery is also associated with unacceptably high mortality and morbidity rates.[9, 10] Compared to open surgery, the use of minimally invasive TEVAR to treat these pathologies in those often moribund patients has been reported to have early mortality as low as 0%.[11-13] The late results of the procedure remain poor, but the risk of late mortality is often related to the underlying comorbidities frequently present in this high-risk population. It appears that thoracic endovascular repair is considered a suitable but palliative therapeutic option in patients presenting with infected thoracic aortic pathology.[14]

Future Directions

The use of TEVAR in the treatment of thoracic aortic pathology is an active field that carries many promises for the future on multiple fronts. Devices will definitely become more developed and will be more suited to the specific pathology they are intended to treat. Improvement in the delivery platforms will allow safer and more accurate device deployments. Smaller device calibers will reduce both access-site complications and the use of surgical conduits currently needed in 9–21% of cases.[15] More flexible devices will conform better to the aorta, specifically in the hostile aortic arch environment as well as other tortuous areas. Also, the development of branched devices will expand the utility of the technology in covering more pathologies and treating them in a more effective manner. As a matter of fact, there are multiple attempts at developing such devices by all the major device manufacturing companies.

Imaging is an integral part of the success of TEVAR procedures, and the field is booming with new ideas and technologies. In addition to the liberal use of IVUS and high-quality fluoroscopy,

Figure 7. The modern hybrid suite at The Methodist Hospital. In addition to regular fluoro capabilities, the new Siemens fixed unit (DynaCT) located in the suite features rotational 3D angio/CT capabilities with fusion technology. The monitors can show the patient's vital data, real-time fluoro, IVUS images, previous CT and angio studies, and real-time road mapping.

other newer imaging modalities are being developed and refined to allow a safer and easier performance of complex endovascular procedures. Rotational angiography performed using motorized C-arms can create a three-dimensional (3D) image compared to the 2D image of conventional digital subtraction angiography. Some of the newer machines can also perform intraoperative 3D rotational CT scan. In the United States, three such fluoro CT systems are commercially available: DynaCT (Siemens Medical Solutions, Forchheim, Germany), XperCT (Philips Medical Systems, Eindhoven, The Netherlands), and Innova CT (GE Healthcare, Waukesha, WI) (Figure 7). Both rotational angiography and CT 3D technology allow the operator to have more confidence about vascular and soft tissue anatomy when performing complex endovascular procedures on the thoracic aorta.[16]

Another emerging technology is the ability to fuse past studies on current live fluoroscopically derived images. This is the basic concept behind the so-called roadmapping that can be performed using regular fluoroscopy machines. However, this technique is static in nature; if another fluoro projection is used, the roadmapping capability is lost. To overcome this limitation, a preoperative CT scan is fused over a non-contrast intraoperative rotational CT scan by registering anatomical landmarks in both scans (usually bony landmarks in different projections). Using this technology, the roadmapping becomes dynamic and the C-arm can be moved — maintaining the ability to navigate using the images from the preoperative CT scan fused with the live fluoro image. The data from the preoperative CT can be projected onto the live fluoro either as a full 3D image or in the form of a computer-generated graphic, which will then update in the correct projection depending on the arc-angle of the C-arm (Figure 8).[16] While the efficacy of these new technologies has yet to be determined, imaging technology development will prove to be an integral part of the future of TEVAR.

Another promising area has been the use of medical robotics. Currently, intravascular robots are being developed that may play an important role in the future of endovascular surgery. They can be used to assist endovascular devices in avoiding vascular wall contact with more precise navigation and in cannulation of side branches of the aorta in a more deliberate and predictable manner — which can be extremely helpful in cases of fenestrated and branched endograft.

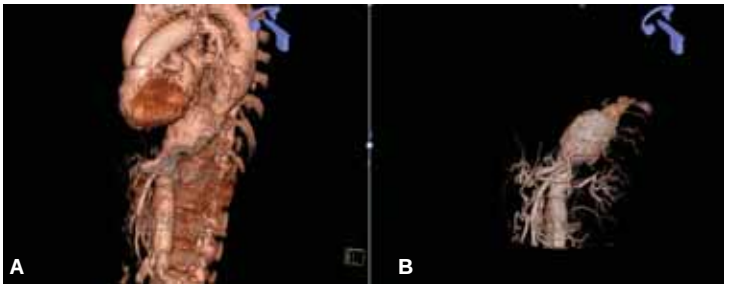

Figure 8. (A) shows a previous 3D CT study superimposed on (B) current 3D angiographic study, which can be fused into the current live fluoro to allow real-time continuous road mapping capability.

The combination of new devices, expanding robotics, and imaging technology development will lead to collective improvement and advancement of the TEVAR technology as a whole.

Summary

Endovascular management of thoracic aortic diseases has made long strides since its introduction in 1994. This modality of therapy has been an important addition in a field of surgery that has typically been associated with high morbidity and mortality. The future definitely carries promise, as there is ongoing development of endovascular devices, techniques, imaging, and technology that will ultimately improve outcomes for patients with aortic disease.

References

1. Dake MD, Miller DC, Semba CP, Mitchell RS, Walker PJ, Liddell RP. Transluminal placement of endovascular stent-grafts for the treatment of descending thoracic aortic aneurysms. N Engl J Med. 1994 Dec 29;331(26):1729-34.
2. Greenberg RK, Qureshi M. Fenestrated and branched devices in the pipeline. J Vasc Surg. 2010 Oct;52(4 Suppl):15S-21S.
3. Fattori R, Tsai TT, Myrmel T, Evangelista A, Cooper JV, Trimarchi S, et al. Complicated acute type B dissection: is surgery still the best option?: a report from the International Registry of Acute Aortic Dissection. JACC Cardiovasc Interv. 2008 Aug;1(4):395-402.
4. Matsumura JS, Lee WA, Mitchell RS, Farber MA, Murad MH, Lumsden AB, et al.; Society for Vascular Surgery. The Society for Vascular Surgery Practice Guidelines: management of the left subclavian artery with thoracic endovascular aortic repair. J Vasc Surg. 2009 Nov;50(5):1155-8.
5. Buth J, Harris PL, Hobo R, van Eps R, Cuypers P, Duijm L, et al. Neurologic complications associated with endovascular repair of thoracic aortic pathology: Incidence and risk factors. a study from the European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) registry. J Vasc Surg. 2007 Dec;46(6):1103-1110; discussion 1110-1.
6. Tefera G. Traumatic thoracic aortic injury and ruptures. J Vasc Surg. 2010 Oct;52(4 Suppl):41S-4S.
7. Jonker FH, Giacovelli JK, Muhs BE, Sosa JA, Indes JE. Trends and outcomes of endovascular and open treatment for traumatic thoracic aortic injury. J Vasc Surg. 2010 Mar;51(3):565-71.
8. Hsu RB, Lin FY. Infected aneurysm of the thoracic aorta. J Vasc Surg. 2008 Feb;47(2):270-6.
9. Muller BT, Wegener OR, Grabitz K, Pillny M, Thomas L, Sandmann W. Mycotic aneurysms of the thoracic and abdominal aorta and iliac arteries: experience with anatomic and extra-anatomic repair in 33 cases. J Vasc Surg. 2001 Jan;33(1):106-13.
10. von Segesser LK, Tkebuchava T, Niederhäuser U, Künzli A, Lachat M, Genoni M, et al. Aortobronchial and aortoesophageal fistulae as risk factors in surgery of descending thoracic aortic aneurysms. Eur J Cardiothorac Surg. 1997 Aug;12(2):195-201.
11. Wheatley GH 3rd, Nunez A, Preventza O, Ramajah VG, Rodriquez-Lopez JA, Williams J, et al. Have we gone too far? Endovascular stent-graft repair of aortobronchial fistulas. J Thorac Cardiovasc Surg. 2007 May;133(5):1277-85.
12. Ting AC, Cheng SW, Ho P, Poon JT. Endovascular stent graft repair for infected thoracic aortic pseudoaneurysms — a durable option? J Vasc Surg. 2006 Oct;44(4):701-5.
13. Riesenman PJ, Brooks JD, Farber MA, Thoracicendovascular aortic repair of aortobronchial fistulas. J Vasc Surg. 2009 Nov;50(5):992-8.
14. Patel HJ, Williams DM, Upchurch GR Jr, Dasika NL, Eliason JL, Deeb GM. Thoracic aortic endovascular repair for mycotic aneurysms and fistulas. J Vasc Surg. 2010 Oct;52(4 Suppl):37S-40S.
15. Garcia-Toca M, Eskandari MK. Regulatory TEVAR clinical trials. J Vasc Surg. 2010 Oct;52(4 Suppl):22S-5S.
16. Eagleton MJ. Intraprocedural imaging: flat panel detectors, rotational angiography, FluoroCT, IVUS, or still the portable C-arm? J Vasc Surg. 2010 Oct;52(4 Suppl):50S-9S.