Endovascular Repair of Thoracic Aortic Injury: Current Thoughts and Technical Considerations

W. Darrin Clouse, M.D., F.A.C.S.^{1,2,3}

ABSTRACT

Thoracic aortic traumatic injury is a highly morbid event. Mortality and paraplegia rates after emergent open repair remain high. Now, however, thoracic aortic endografting for trauma (TAET) is commonly used. It is appealing due to reduction of operative stress for the multiply injured trauma victim. This minimizing of stress and risk is secondary to avoidance of thoracotomy, single-lung ventilation, aortic cross-clamping, and the more complex anesthetic techniques required. Early and midterm results from TAET delineate improved outcomes, yet access and aortic constraints continue to challenge TAET. Questions regarding longer-term durability of endografts in younger patients remain unanswered. Broader application of TAET within endovascular programs is challenged by appropriate imaging, operating suite inventories, and the logistics and personnel required for TAET. Currently developed thoracic endograft devices are not ideal for TAET due to platform size and graft diameter. This is changing, however, as new modifications have been developed and trials are ongoing. In light of these collective factors, the management paradigm for traumatic aortic injury is beginning to favor TAET.

KEYWORDS: Aortic trauma, thoracic aortic repair, endovascular repair, thoracic endografts

Objectives: Upon completion of this article, the reader should be able to recall the pathological spectrum of thoracic aortic injury, contemporary data regarding repair outcomes utilizing both standard open surgical and endovascular modalities, and, finally, technical aspects and challenges confronting endovascular repair.

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Thoracic aortic injury is one of the most formidable injuries encountered. Although aortic trauma

accounts for less than 0.5% of all trauma admissions, it constitutes the second leading cause of trauma-related

¹David Grant USAF Medical Center, Travis AFB, California;
²University of California Davis, Division of Vascular and Endovascular Surgery, Sacramento, California; ³The Norman M. Rich Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, Maryland.

Address for correspondence and reprint requests: Lt. Col. W. Darrin Clouse, M.D., F.A.C.S., Associate Professor of Surgery, USUHS/UCD, UC Davis Vascular Center, 4860 Y Street, Suite

3400, Sacramento, CA 95817-2307 (e-mail: william.clouse@us.af.mil).
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Figure 1 Zones of thoracic aortic injury by anatomic location according to Schumacher et al.¹⁰

death, second only to head injury.¹ Fully 75 to 90% of those sustaining blunt aortic injury (BAI) expire in the prehospital setting, and only half of those surviving transport to a hospital will live more than 24 hours.²⁻⁸ The observed natural history shows that, once in the hospital, the majority of those who will succumb do so in the first several hours after admission unless treatment is initiated. In this group, two-thirds of deaths are directly attributable to aortic rupture.⁷

The typical mechanism causing these injuries is blunt deceleration, usually from motor vehicle collisions, falls, and crushes with significant amounts of force applied to the torso.⁹ For descriptive purposes, the anatomic site of thoracic aortic injury has been categorized by Schumacher et al (Fig. 1).¹⁰ Shear, torsion, and hyperflexion lead to a tearing phenomenon at the aortic isthmus where the relatively mobile arch becomes fixed to the posterior mediastinum and pleura. The majority of aortic injury occurs at the isthmus (IIC; 70 to 90%), with the ascending aorta/proximal arch (I to IIB; 10 to 15%) and mid-descending aorta (IIIA to IIIB; 5 to 10%)

Table 1 Thoracic Aortic Injury Pathological Classification of Parmley et al²

Grade	Pathology
1	Intimal hemorrhage
2	Intimal hemorrhage plus intimal laceration
3	Laceration into the aortic media
4	Complete aortic laceration (transection)
5	Pseudoaneurysm
6	Complete aortic laceration with active hemorrhage

representing secondary sites. The pathological findings in BAI occur along a spectrum described by Parmley et al in 1958 (Table 1).² Penetrating injuries occur less frequently.

With such significant force necessary to create these injuries, it is not surprising the associated injuries sustained, such as head injuries, solid organ injuries, pulmonary contusions, and long-bone fractures, along with their accompanying abnormal physiology, dominate patient outcomes. Adding thoracotomy, thoracic aortic clamping, with or without left-heart bypass, and the attendant hemodynamic and coagulation fluctuations creates a less than ideal milieu in this population during open repair. Indeed, open repair is associated with mortality in 15 to 30%, spinal cord ischemic complications in 5 to 20%, stroke rates of 3 to 8%, vocal cord paralysis in 10 to 15%, and pulmonary complications in 10 to 25%.^{7,11} It is no wonder an alternative solution is sought.

Traditionally, the early morbidity and mortality of BAI established rapid diagnosis along with emergent open aortic repair as standard to prevent rupture and death. Yet, the considerable perioperative problems mentioned have led to some important modifications to this approach. Institution of antihypertensive therapy for shear stress reduction is now advocated in stable patients to prevent rupture.^{9,12} This may allow for treatment and stabilization of other injuries and possibly reduce the ramifications of open repair. Delay, to a point where the patient is physiologically better prepared to undergo repair, may last several days after injury and benefits of delay have been suggested.¹³⁻¹⁷ However, the risk of aortic rupture appears to increase after about 1 week, so repair must still be timely.¹⁰ Absolute evidence of improvements in outcome based on this select approach have remained elusive, but delay may be preferable when repair is entertained.

Since its introduction, now over 16 years ago, less invasive endovascular grafting has become more mainstream, if not standard of care, for many aortic disease processes. The development of endograft devices specifically for use in the thoracic aorta continues to mature, and, as the evolution of endovascular techniques

continues to progress, it is only natural these therapies are applied to thoracic aortic injury. Similar to other vascular disorders, the question at hand currently is: Can endovascular repair be a better solution in thoracic aortic injury? Thus, the purpose of this article is to reflect on where thoracic aortic endografting for trauma (TAET) is in its evolution and describe technical considerations for successful endovascular treatment. Finally, we present the status in the United States of current commercially available thoracic endoprostheses within the context of how they may have a role in TAET.

TAET

The Evolution of TAET Data

The era of thoracic aortic endografting began in the United States in 1994. Dake and colleagues described their use of stent grafts for multiple pathologies.¹⁸ An account of their experience with endografting for 10 patients with traumatic lesions of the thoracic aorta was described in 1997.¹⁹ Since then, a plethora of experiential descriptions and cases have been reported. TAET is very attractive. It obviates the need for thoracotomy, aortic cross-clamping, and single-lung ventilation and avoids any potential need for complex distal perfusion or arrest techniques. Should the patient's injuries mandate, TAET can be performed without any procedural anticoagulation, but even when used, lower doses are required compared with open repair. Further, in most communications TAET can be accomplished in an hour or less, as opposed to the several hours for an open posterolateral thoracotomy with reconstruction and adjuncts. It can be performed under less complicated anesthetic methods and possibly even local anesthetic with sedation. The debate regarding delay of treatment in those with other significant injuries is dampened by endografting. TAET can be performed just before or immediately after other necessary procedures with minimal compounded stress. Still, should delay seem prudent because of other critical needs, TAET can be accomplished on a delayed basis as well.^{17,20} These are clearly key advantages given the drawbacks of open repair.

Institutional evaluations comparing traditional open repair to TAET for BAI continue to be published as experiences mature.^{21–36} All show similarly robust morbidity and mortality in those undergoing open repair, although endovascular repair appears to provide considerable attenuation, particularly in operative mortality and spinal cord ischemia. In a representative experience, Rousseau et al reviewed 35 patients undergoing open repair and 29 having endograft repair after BAI. In the open group, operative mortality was 21% and paraplegia occurred in 7%.²⁷ No mortality or para-

plegia was experienced in those undergoing TAET. This group recently described their continuing experience with endografting for trauma. Although there continued to be no perioperative deaths, one temporary paraparesis was noted. At a mean follow-up of nearly 3 years, no aortic reinterventions were required.²⁸ In a compilation of the literature involving series of TAET from the first part of this decade, Starnes and Arthurs found 235 patients who had undergone endovascular repair for BAI.³⁷ There were no noted spinal cord ischemic events, and perioperative mortality was just under 7%.

Similarly, a combination of the EUROSTAR and the UK Thoracic Endograft registries reported on 50 patients undergoing TAET.³⁸ The 30-day mortality was 6% with neurological complications occurring in three patients. One of these was a stroke and the other two were undefined. Over 80% of patients had adequate results both clinically and radiographically at 1 year. No endoleaks, migrations, or aortic-related deaths were noted in the midterm. Continued aortic expansion was found in two patients. In another extensive European experience, the Talent Thoracic Retrospective Registry noted use of this particular endograft in 85 traumatic injury victims with no procedural mortality and no paraplegia.³⁹

In 1997, the American Association for the Surgery of Trauma study group published a 50-center prospective registry of BAI. This communication provided significant information pertaining to open repair.⁷ In 2008, this group provided an update since the inception of TAET.⁴⁰ One hundred ninety-three patients (125 TAET; 68 open) injured in the period 2005 to 2007 were compared. They found no differences in the systemic complication rate but a significant reduction in gross mortality (odds ratio [OR] 3.97; $P = 0.001$) with TAET compared with open repair. After adjusting for the degree of injury (Glasgow Coma Score, hypotension, and extrathoracic injury), TAET provided clear attenuations in the mortality (open versus TAET; OR 8.4; $P < 0.0001$) and transfusion requirements (open versus TAET; OR 4.98; $P = 0.046$) accompanying open repair. In those with major extrathoracic injury, mortality (OR 5.68; $P = 0.04$) and pneumonia (OR 3.49; $P = 0.03$) were significantly higher with open repair. Overall, endoleak occurred in 14% of the TAET cases. Of note, no significant difference in paraplegia was discovered (2.9% open versus 0.8% TAET; $P = 0.28$).

A second communication compared this recent evaluation with the original 1997 open repair group.⁴¹ Diagnostic shift away from initial aortography (87% versus 8.3%; $P < 0.001$) to CT (34.8% versus 93.3%; $P < 0.001$) was evident. Nearly two-thirds of repairs were done with the endovascular method (64.8% versus 35.2%). Significantly more site-related complications occurred in the contemporary group owing to TAET access. Paraplegia occurred less frequently in the most

recent open repairs compared with the historical cohort (2.9% versus 8.7%; $P < 0.001$). Overall, mortality was significantly less in the recent cohort (13% versus 22%; $P = 0.02$), and the time from injury to repair was longer, thus indicating the acceptance of delayed repair (16.5 hours versus 54.6 hours; $P < 0.001$). Indeed, this same study group recently communicated on this cohort specifically regarding delayed repair.¹⁷ Regardless of repair method, delay beyond 24 hours after injury appeared advantageous (early versus delay; OR 7.8; $P = 0.008$). So, in total, improvements in surgical methods, critical care, shear stress reduction, delay when feasible, newer, noninvasive diagnostic modalities, and implementation of TAET appear to have had positive impact on mortality from thoracic aortic injury.

Further broadening our understanding of TAET's place in injury therapy, several recent meta-analyses have been published. Tang and colleagues evaluated 33 communications between 2001 and 2006.⁴² Three hundred twenty-nine patients were found who underwent open repair and 370 who were managed with TAET. There were no differences in age, injury severity score, or technical success between the two strategies. Follow-up averaged 4 years in those with open repair but only ~2 years in those having endovascular repair. However, perioperative mortality (7.6% versus 15.2%), spinal cord ischemia (0% versus 5.6%) and stroke (0.85% versus 5.3%) were all statistically less frequent in the endografting group. Similar findings have been reported by Xenos et al combining 17 studies from 2003 to 2007.⁴³ Another systematic review by Hoffer and coworkers again revealed similar reductions in mortality and paraplegia when comparing TAET with open repair.⁴⁴ Interestingly, they also compiled 667 reported TAET procedures regardless of open comparison and identified an early endoleak rate of 4.2% and late endoleak in 0.9%. Migration was negligible. Although seemingly quite adequate, almost 1 in 10 early deaths were related to endoleak and, essentially, treatment failure. In these meta-analyses, the technical success of TAET was estimated at over 96%, thus establishing its applicability as a reasonable treatment option. Without prospective data to lead us, these collective evaluations are perhaps the most compelling discussion in favor of TAET to date. This developing body of literature is captivating, and a paradigm shift toward endovascular repair is occurring.

TAET Disadvantages

TAET is not without its shortcomings. For one, it cannot be emphasized enough just how critical the endovascular operating team and procedure facility are to quality outcomes.³ Appropriate endovascular inventories, imaging, and around the clock accessibility are crucial in making this unique trauma therapy available.

Current thoracic endografts are really designed for use in degenerative disease, and, as most traumatic injuries occur in younger patients, existing graft diameters may not be appropriate for smaller aortas. Further, delivery platforms are 20- to 26-French, and iliac access may be difficult in this population. Indeed, access is perhaps the most challenging and complicating aspect of TAET. Currently, trials are in place to evaluate modifications in approved devices, consisting of smaller diameter grafts mounted on reduced-sized delivery systems, to address these shortcomings.

Even in the traumatic injury population, there is always the potential for stent fracture, migration, fistula formation, aortic expansion, and, as mentioned, endoleak. All have been described. Overall, the current literature would suggest these risks are less compared with treatment for degenerative aortic diseases, yet this is far from definitively clear. Although a distinct reduction in spinal cord ischemic events after TAET compared with open repair is suggested, cases of paraplegia following endografting for traumatic lesions are recorded.^{28,37,41-43} Thus, the risk is not completely negated. Finally, some may argue that the long-term durability of endografting is unproven, and resilient young trauma patients may well be a population tolerant of the stresses accompanying open repair.

TECHNICAL ASPECTS OF TAET

Preprocedural Imaging

Today, the sensitivity and positive predictive value of computed tomography (CT) for the diagnosis of traumatic thoracic aortic injury is unquestioned.^{9,12} Particularly as technical improvements have led to highly resolute, multichannel, multislice CT with volumetric reconstruction. Many of those with BAI have contained injuries and arrive at the trauma center relatively stable and are able to undergo CT. Endograft planning is straightforwardly expedited with the implementation of aortic protocol contrast-enhanced CT from thoracic inlet through the midthigh, which has become routine in many trauma practices. Should CT be equivocal, diagnostic aortography immediately followed by endovascular repair can be performed, and this single sitting is advantageous.

Endovascular Operating Theater

Despite the fact that thoracic aortic endografting can potentially be accomplished in an interventional radiology suite, we believe victims of multiple system trauma belong in an operating room where any potential emergency therapeutic maneuver is possible. Should open aortic repair or an open access adjunct be required, it can be accomplished in this adaptable environment

Figure 2 Operating room setup for thoracic endografting. 1, primary surgeon; 2, assisting surgeon; A, anesthesiologist; N, operating room nurse; T, operating room/endovascular technician; IVUS, Intravascular ultrasound; TEE, transesophageal echocardiography.

without patient movement. Appropriate instruments are easily available, sterile technique is at its best, and ease of anesthetic is unmatched. Today, with the growing contribution of endovascular therapies to the therapeutic arsenal, many facilities have a fixed, high-quality imaging system in an operating room, thus facilitating TAET. Although less favorable, thoracic endografting can also be done in the operating theater with a portable C-arm utilizing a vascular software package containing digital subtraction angiography and cine-loop capture, a power injector, and a fluoroscopy table.

Intravascular ultrasound (IVUS) and transesophageal echocardiography (TEE) capabilities enhance aortic imaging and reduce overall intravenous contrast load. IVUS not only assists injury visualization but also can accurately delineate the distance needed for sufficient endografting. It can also evaluate the expansion and aortic apposition of the endograft postdeployment. We have also found that IVUS is extremely helpful in confirmation of aortic size. Undersizing may occur when planning is performed on the initial CT evaluation, prior to adequate resuscitation and establishment of proper intravascular volume. Others have also noted the discrepancy in sizing between IVUS and CT, particularly at the isthmus where injury is most frequent.⁴⁵ The ability to perform TAET in the operating room, an endosuite in particular, is an asset not only to the endovascular program but to the trauma program as well.

Moreover, a dedicated operating room for endovascular procedures allows for development of an inventory of grafts and accessories. Aside from adequate imaging, procedure locale, and proper inventory, a dedicated, reliable team of endovascular-trained staff should be available. This includes nurses and technicians, as well as anesthesiologists and endovascular specialists. A committed team approach wherein all understand and appreciate the necessity, complexity, and expected outcome of endovascular repair greatly aids in TAET execution. Again, procedural efficacy and likely patient safety are enhanced as this is centralized in the operating room.

Procedural setup for TAET is straightforward (Fig. 2). The patient should be placed on a carbon, floating fluoroscopic table. There are two options for patient positioning. One is to place the left arm over the chest onto padding covering the right arm, after appropriate monitoring access is obtained. The back should be supported with radiolucent rolls. This allows both left chest and abdominal surgical access should either emergent thoracotomy or laparotomy become necessary. Further, this patient position minimizes C-arm rotational need. If aortic tortuosity, angulation, or injury anatomy make it clear left or right brachial access will be needed, then the patient is placed supine to allow accessibility to these sites. The primary surgeon stands on the patient's right; the assistant on the left. Imaging monitors are

Figure 3 Thoracic aortic endografting for trauma using infrarenal device cuffs. Note the short length of the cuffs, thus requiring multiple cuffs. Also observe the short length and poor conformability of the cuffs at the posterior arch genu along the inner curve.

placed on the left near the foot, and IVUS is positioned cephalad to them. The power injector is placed caudal to the monitors. The endovascular technician and table are stationed on the primary surgeon's right. TEE is located in easy proximity to the cardiovascular anesthesiologist. This overall positioning scheme allows for maximal table excursion, complete patient access, and visualization for all.

Access

As most thoracic aortic injury occurs in younger individuals, open arterial access via the iliofemoral system may come with its own unique challenges compared with those associated with the older population undergoing endografting for aneurysm and dissection. In TAET, the femoral and iliac vessels usually do not have significant calcification or thrombus burden. Instead, they are smaller and they taper, with a higher risk of iatrogenic injury such as perforation, tearing, and rupture. Also, the risk of thromboembolism is not negligible. When iliofemoral size allows, we continue to prefer an open right femoral approach for device access, along with percutaneous left femoral access for imaging purposes at the onset of these cases.

Access involving the iliac vessels is the most problematic feature of TAET and has been documented as the most frequent source of procedural complications. In the recent meta-analysis by Tang and colleagues, iliac access was the most common source of complication associated with TAET.⁴² Access difficulties associated with thoracic endografting in the trauma population are also apparent in most device-specific discussions where this particular patient subset sustains more access complications and requires more adjunctive maneuvers, such as conduits, than those with degenerative diseases.^{6,38,39,46-48} Thoracic endografts on the commercial market or in trials currently require 20- to 26-French inner diameter (7.6- to 9.1-mm outer diameter) delivery sheaths for access. Thus, realistically, a continuous iliac

system at least 8 mm in diameter throughout is necessary in most individuals.

Access concerns, in conjunction with market availability of thoracic endografts, have led some to utilize smaller profile, yet shorter length, infrarenal devices such as cuffs (Fig. 3).^{49,50} Unfortunately, the durability of multiple shorter pieces, usually necessary for adequate treatment, has been questioned.¹⁰ Overlap is possibly insufficient in this location, and graft compliance can be a problem with these pieces in this segment of the aorta, leading to poor wall apposition along the distal arch. Further, in tall individuals, most of the infrarenal platforms are not of satisfactory length to treat the aortic isthmus. At this time, the most appropriate role of these devices may be as a bridge to more definitive, open repair in pediatric patients, in whom TAET may otherwise be unsuitable due to problems with iliofemoral access alone.

Experience with endovascular repair of infrarenal aneurysms has aided in maturing adjunctive access methods. Graft conduits can be placed along the iliac arterial system, usually the common iliac, or the terminal aorta if no iliac site is reasonable.^{10,51} These are easily accomplished with relatively small, retroperitoneal incisions. The graft can be amputated postprocedure and the stump oversewn in a straightforward manner. Using the graft conduit instead of direct arterial puncture theoretically reduces arterial damage and diminishes the potential for luminal compromise as with repair by primary means. Conversely, in those where the iliofemoral system is very adequate for endograft access, some have reported reasonable results performing TAET with a totally percutaneous approach utilizing a preclose technique.^{52,53} Left brachial access can be helpful for visualization of the left subclavian artery and for allowing arteriography without hindrance of endograft deployment. Brachial access has also been purported to minimize intravenous contrast utilized for the procedure. Other benefits of brachial access are discussed below.

Figure 4 Infolding of a thoracic endograft due to size mismatch distally. (Courtesy S. O'Donnell.³)

Aortic Constraints

Another important limitation to thoracic endografting in the trauma population is aortic anatomy. As most vehicular crash victims, and those sustaining traumatic aortic injury in general, are young, the size of their aortas requiring treatment are relatively small. A significant proportion have aortas adjacent to the injury that are smaller than 20 mm.^{54–56} This is problematic. Perhaps more so than in the abdominal aorta, oversizing of thoracic endografts has unmasked serious troubles with graft infolding, graft collapse, aortic thrombosis, and failure.^{55,57,58} Thoracic endografts should, therefore, only be oversized by roughly 10% of the aortic diameter. However, the smallest diameter thoracic endografts available are 22 mm; so many aortas with a traumatic

lesion are not of an appropriate size for current thoracic devices.

Many normal thoracic aortas taper in the descending segment, and distal size mismatch may also cause incomplete deployment and graft infolding, requiring adjunctive measures such as secondary endograft placement or bare stenting (Fig. 4).⁵⁷ Aortic injury at the isthmus usually occurs 20 to 30 mm beyond the origin of the left subclavian artery.^{37,55,59} This may not always be the case though, and in some evaluations, the inner aortic curve from the subclavian to the injury has averaged less than 10 mm.⁵⁶ Ideally, today's thoracic endovascular devices should have a proximal seal zone length of at least 20 mm (Fig. 5).^{46–48} This may not be an issue in some traumatic injuries, but is a critical feature for TAET success and must be recognized and addressed.

Also, it is common in degenerative thoracic aortic diseases to require a modular configuration using more than one device for complete treatment. This may be less likely with focal traumatic injuries. When modular grafts are necessary, more overlap of components better minimizes the potential for later modular separation.

In addition to luminal diameter, other aortic morphology critical to proper endograft placement is the arch configuration. The posterior aortic arch genu creates an angulation along the inner aortic curvature such that the proximal edge of the endograft may not conform to the aortic wall at this position and may project into the lumen. This in and of itself can lead to graft collapse, migration, endoleak, thrombosis, stroke, and graft failure in this extremely high-flow and shear-force location. When graft protrusion takes place in

Figure 5 Thoracic endograft placement to repair an injury at the aortic isthmus. Note the 20 mm of proximal neck for proper placement without need to cover the left subclavian artery. Graft used is Medtronic Talent (Medtronic Vascular, Santa Rosa, CA).

conjunction with infolding secondary to graft oversizing, it portends poor durability. As humans age, the arch enlarges and elongates, leading to more acuteness in the posterior angle. This has clearly been identified in experiences with endovascular treatment of degenerative aortic diseases and may then confound TAET as well if the patient is older.

When angulation causes difficulties in accomplishing thoracic endografting, brachial access, either right or left depending on morphology and desired proximal placement, can help in a couple of aspects. It can assist in visualization and landmarking without hindering deployment. Also, when a long, stiff guide wire is snared and traverses from the brachial to the iliofemoral access, it straightens the angulation somewhat and may aid in device tracking and pushability. The need to endograft caudally to the level of the aortic hiatus is rare in trauma. However, a distal neck of 20 to 30 mm is usually required. If there is concern regarding the location of the celiac origin, a visceral selective catheter can be inserted into the celiac artery from a femoral access for marking purposes.

To circumvent these collective adversities of the proximal aorta, gaining more proximal seal length along a less angulated zone by intentionally placing the endograft across the left subclavian origin with or without adjunctive revascularization has been utilized.^{55,60} Most trauma patients do not have significant left arm ischemic complications with this approach, and it is now widely viewed as benign. Even rarer are hemodynamically significant vertebrobasilar insufficiency or acute posterior fossa stroke, but attention to the status of the vertebral arteries is important to avoid these. The risk of stroke is roughly 5% with surgical ligation of the vertebral artery, and this must be remembered.⁶¹ Revascularization of the left subclavian artery, with its individual inherent risks, can be performed secondarily should it be necessary for either arm or vertebrobasilar insufficiency.

A cautionary note, however. Recent data by the EUROSTAR investigators showed intentional coverage of the left subclavian without revascularization during endovascular repair of thoracic aortic pathologies to be the most significant independent predictor of spinal cord ischemia.⁶² Cooper and colleagues communicated a newly completed meta-analysis of left subclavian artery coverage during thoracic aortic endografting. Coverage of the left subclavian artery predicted stroke, regardless of pre-endograft revascularization, and spinal cord ischemia if no pre-endograft revascularization was performed.⁶³ Furthermore, open extra-anatomic brachiocephalic debranching, with varying degrees of ascending, arch, and proximal descending endograft coverage, are gaining visibility in the treatment of degenerative diseases.^{64,65} Few reports of these even more advanced hybrid-type procedures for

traumatic injury exist, and their place is undefined currently.

Blood Pressure Manipulation

Once appropriate arch aortography has been performed from a left anterior oblique view, stiff guide wires have been placed, and appropriate sheaths positioned, the graft is delivered and unsheathed. Prior to deployment in this high-pressure, high-flow area, the blood pressure should be lowered to a mean arterial pressure of 50 to 70 mm Hg.^{3,6,11} This allows for deployment without a billowing effect on the flowering, expanding graft and more accurate placement. Early in thoracic endografting, many found this to be a significant problem in achieving successful treatment. Poor graft expansion and movement were seen with disastrous consequences. Reported means to accomplish this include mechanical and pharmacological manipulations. Pharmacological methods utilize rapid-onset antihypertensive medications and adenosine administration. Adenosine is attractive as it allows for short-term asystole and no fluctuations in pressure occur at all during deployment. This induced cardiac arrest seems relatively harmless both from a systemic and neurological standpoint.⁶⁶

Placement of a transvenous pacemaker with tachycardic, hypotensive manipulation is also being used to achieve reduced mean arterial pressure on a mechanical basis, but this must be used with good judgment in those with significant coronary artery disease or heart failure.⁶⁷ Another described method of mechanically inducing hypotension for accurate thoracic endograft placement is temporary caval occlusion.⁶⁸ Regardless of the method chosen, it appears thus far that induction of hypotension to aid in deployment is safe and useful.

Current Commercial Devices

In the United States, the first FDA-approved endovascular graft that was widely used in the thoracic aorta is the Gore TAG Thoracic Endoprosthesis (W.L. Gore and Associates, Flagstaff AZ; Fig. 6A). The pivotal studies for this device only included use in degenerative thoracic aortic aneurysms.^{46,69,70} However, successful utilization of the TAG device for traumatic injuries has been illustrated throughout the herein cited literature since its U.S. introduction in 2005.

The device consists of nitinol stents affixed to the graft with thin expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) sheets. The current graft is formed by three adherent ePTFE layers including a low permeability layer. There are covered scallops at each end, which flare to aid in apposition, as well as seal cuffs consisting of thicker ePTFE just at the base of each end. Gold band markers are incorporated into the ePTFE layers as radiopaque

Figure 6 (A) Current TAG by W.L. Gore and Associates (Flagstaff AZ). (B) Next generation C-TAG.

markers. TAG comes in select 100-, 150-, and 200-mm lengths. The graft is constrained to the delivery system by a sleeve of ePTFE/FEP. Deployment occurs via a rip cord-type mechanism, first releasing the graft in the middle of the constraining sleeve, to avoid billowing due to blood pressure as much as possible, and progressing to each end of the graft. It has a similar profile to other thoracic devices developed thus far with 26- and 28 mm grafts delivered via a 20-French sheath. Midsized grafts can traverse a 22-French sheath and up to a 40-mm graft may be placed using a 24-French system. The sheath is required for appropriate delivery. A recently initiated trial using the next generation C-TAG endograft in aortic injury has begun and should provide valuable information. The modified, new endografts have an improved delivery system tip, as well as improved radial force and conformability (Fig. 6B). This is mainly due to the removal of the proximal and distal flares and newer nitinol stent technology. This new graft will expand the therapeutic range to aortas as small as 16 mm with obvious advantages in TAET.

Since June 2008, the Talent thoracic stent graft (Medtronic Vascular, Santa Rosa, CA) has been available in the United States, based upon data from the VALOR trial.^{47,71} We have had favorable experience with this graft in aortic injury, particularly with the addition of the Xcelarent delivery system (Figs. 5, 7A). Currently available grafts include 22-mm diameter devices. A trial evaluating, in a prospective fashion, use of Talent in aortic transection is being organized and should be underway in the near future. The Talent device has now evolved into its third generation, the Medtronic Valiant thoracic endograft (Fig. 7B).

This latest version of the Valiant device adds several modifications to the Dacron (monofilament polyester) graft with external nitinol self-expanding stents sewn in place. The stents at the attachment zones, both proximally and distally, have been altered so there are now eight apices, as opposed to five. This distributes force more evenly, and the graft side of the stent is incorporated into the material for more efficient stent deployment. Grafts with these proximal and distal

Figure 7 Medtronic Talent (Medtronic Vascular, Santa Rosa, CA) thoracic stent graft with Xcelarent delivery system (A) and the newer-generation Valiant graft (B).

stents fully incorporated into the Dacron in closed web are also available, which may be preferable in certain pathologies such as traumatic injury. Lengths from 100 mm up to 227 mm are now available. Graft diameters encompass 22 mm to 46 mm. Both straight and tapered endografts are made. Similar to other device evolutions, the longitudinal strut has been removed. The delivery platform is also the Medtronic Xcelerator system, and deployment occurs via proximal flowering proceeding distally. The length of the delivery tip has been decreased to aid in trackability in the aortic arch and tortuous areas. All platforms are 22-French or larger.

The VALOR II trial has now started in the United States evaluating the Valiant endograft. Of distinct interest to this discussion, there are treatment groups undergoing surveillance outside of the pivotal cohort. Both acute and stable, chronic traumatic injuries are included in these registries. Although the overall numbers of trauma patients treated will likely be small, some prospective information about use of the Valiant device for aortic trauma is forthcoming. This, in addition to the Talent aortic transection trial, will add important data to the TAET deliberation. As mentioned, a retrospective European registry including 85 trauma victims has been described.³⁹

Another recently reported U.S. clinical trial with phase II pivotal data, STARZ-TX2, opened in 2004 using the Zenith TX2 (Cook, Inc., Bloomington, IN) thoracic endograft (Fig. 8).^{48,72} Recent U.S. approval in May, 2008, added Zenith TX2 to the thoracic

endograft armamentarium. Thirty-day and 1-year trial data appear comparable to other thoracic devices. No device-specific cohorts involve traumatic injury, and little is reported regarding this graft's use in trauma. Yet, it has been part of experiential reports.⁷³ TX2 is a two-piece modular woven Dacron graft sewn to stainless steel, self-expanding Gianturco Z-stents with proximal and distal components. The proximal component has graft material along its full extent with barbs at the most proximal attachment area. The most proximal and distal stents on this component are internal so graft material is external in the overlap and seal zones. A bare stent with barbs secures the second, inferior piece at its caudal margin, similar to the proximal design of the infrarenal Zenith device. The overlap zone of the TX2 distal piece has two stents covered by the graft. Together, the two pieces can cover between 160 and 360 mm and still maintain a 30-mm overlap zone. Cook also produces TX1, which is a one-piece thoracic endograft with proximal fixation similar to the cephalic TX2 component and distal fixation with the bare stent; however, this device is not part of U.S. trial evaluation. For the great majority of traumatic injuries, a single proximal component repair seems prudent. TX2 comes in 28-mm to 42-mm diameters, which are packaged on 20-French to 22-French introducer sheath delivery systems. These platforms come with curved dilator tips to assist negotiation of arch and tortuous areas. Other grafts being made commercially and in various states of development include the Relay Thoracic stent graft (Bolton Medical, Barcelona, Spain), which is now in phase II U.S. trials, and the EndoFit Thoracic stent graft (LeMaitre Vascular, Inc., Burlington, MA). Their role and applicability in TAET remain unclear.

Figure 8 Zenith TX2 by Cook, Inc. (Bloomington, IN).

CONCLUSION

The last two decades have witnessed rapid development in endovascular therapies for the aorta. Specific use of endovascular grafts in thoracic aortic injury has significantly decreased the difficulties associated with aortic repair in multitrauma victims sustaining such injuries. Early and midterm results document a high degree of procedural success, improved procedural mortality, and a reduction in neurological complications. Later-term probabilities of graft migration, endoleak, continued aortic expansion, and subsequent aortic events are starting to appear acceptable. The management paradigm for thoracic aortic injury is, thus, beginning to change in favor endovascular repair.

However, the technical limitations of graft diameter and delivery profiles make currently available products less than ideal. Both access vessel and aortic constraints continue to challenge all who perform thoracic endografting for trauma. Hopefully, as we anticipate

newer-generation endografts, as well as late-term, dedicated appraisal of use in traumatic injury, these hurdles will be further minimized.

At best, TAET will declare itself an adequate definitive procedure for aortic injury. If found less favorable, however, this technology may serve as a temporizing measure in anticipation of later open repair, thus allowing patients to be better prepared physiologically. It cannot be overemphasized just how critical an endovascular operating team, appropriate endovascular inventories, and imaging in conjunction with strategic planning are to quality outcomes in these procedures. TAET has indeed made noteworthy progress. We eagerly await further maturation, in anticipation of improved care for these complex patients.

DISCLOSURE

The views expressed in this report are those of the authors and do not reflect the official policy of the Department of Defense or other departments of the U.S. Government.

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