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# RESEARCH ARTICLE

Experience with Thoracic EndoVascular Aortic Repair (TEVAR) treatment of uncomplicated Stanford type B aortic dissection, 2022 Updates

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## ABSTRACT

There have been significant advances in the technique and application of endovascular repair of thoracic aortic pathology over the past 20 years. The Stanford type A and the complicated type B dissection patients require urgent/emergent intervention. In the last decade, earlier intervention has been pursued for uncomplicated type B dissections. The INvestigation of STent-grafts in Aortic Dissection (INSTEAD) Long term (XL) study showed that there was significant crossover from medical management to Thoracic EndoVascular Aortic Repair (TEVAR) at year 3, suggesting TEVAR might benefit this population long term.

Today, the application of TEVAR, which was initially designed to address aneurysmal disease, has become a standard and Food and Drug Administrative (FDA) approved management option in dissections.

Currently there are four FDA approved TEVAR devices in the United States for the treatment of the thoracic dissections, namely Gore, Medtronic, Cook, and Terumo. With each iteration, there are increased opportunities for customization and widespread use in individualized patient's pathology. As the technology improves and the feasibility of the grafts expands, the complication rates continue to decline cementing the safety and efficacy of these thoracic aortic grafts. Two rare but catastrophic complications in spinal ischemia and retrograde Stanford type A aortic dissection are further discussed. With the success of the TEVAR, a new frontier of hybrid aortic surgery has developed. The debranching of the aortic arch vessels in order to advance the TEVAR proximal landing zones has been aggressively pursued. With the widespread growth of TEVAR technology it is apparent that complex aortic pathology can be safely repaired endovascularly.

**Keywords:** Thoracic EndoVascular Aortic Repair (TEVAR), Uncomplicated Stanford type B aortic dissection, INvestigation of STent-grafts in Aortic Dissection (INSTEAD) Long term (XL) trial, GORE Comfort graft, Medtronic Valiant graft, Cook Zenith graft, Terumo Relay graft Medical Research Archives

#### **Continued Innovations**

The technique of thoracic endovascular aortic repair (TEVAR) continues to move forward today after more than three decades of innovation and evolution<sup>1</sup>. We have come a long way from the early success of "homemade" Dacron stents in the 1990s<sup>2-3</sup>. Today new generations of these well tested devices have allowed successful endovascular management of complex aortic pathology. Whereas the original indication for use of TEVAR was in aneurysmal disease, it is now well accepted and Food and Drug Administration (FDA) approved for management of Stanford Type B aortic dissections. The dreaded rates of complications which brought caution to their initial use are now low enough to incorporate into standard of care. The most current data has shown that if left to medical management alone, approximately 40% of uncomplicated type B aortic dissections will progress to aneurysmal disease within 5 years. Of these, 20-50% will go on to require aortic repair with rupture rates up to 30% once aortic diameter reaches 6cm<sup>4</sup>. This only solidifies the utility of early intervention in these patients

#### **Uncomplicated Stanford Type B Aortic Dissection**

The uncomplicated Stanford type B aortic dissection patients generally have a good short-term prognosis. Traditionally, about 90% of these patients are discharged from the hospital with antihypertensive medical therapy to reduce the dynamic stress on the aorta<sup>5</sup>. This is in contrast to the type A aortic dissection patients requiring the cardiopulmonary bypass for emergent ascending aortic repair and the complicated type B aortic dissection with distal malperfusion or rupture requiring emergent intervention. The latter group carries mortality rates reported as high as 50%.

Although most of the uncomplicated type B aortic dissection patients are discharged from the hospital. 50% of them will have sequelae including continuing dissection, unrelenting pain, malperfusion syndromes as well as aneurysm degeneration with possible rupture<sup>6</sup>. Those with risk factors or underlying diseases including Marfan syndrome, bicuspid aortic valve, aortic coarctation, drug abuse, and uncontrolled hypertension are especially prone to the development of these complication<sup>7</sup>. They require vigilant follow-up with serial imaging surveillance along with blood pressure monitoring and control as well as aggressive intervention. In the setting of a hypertensive patient with type B dissection that has developed an aneurysm, the threshold for intervention would be sooner than the 5.5cm compared to a patient with an atherosclerotic descending thoracic aneurysm.

The guiding principle in TEVAR for dissection is to exclude the primary intimal tear, to maintain perfusion to the major thoracic and abdominal branch vessels, and to enhance thrombus regression in the false lumen<sup>8-9</sup> (Figure 1.) Current studies recommend 1.5 to 2cm landing zone proximal to the entry tear to assure adequate exclusion of the dissection.

**Figure 1.** The guiding principle in TEVAR for dissection is to exclude the primary intimal tear, to maintain perfusion to the major thoracic and abdominal branch vessels, and to enhance thrombus regression in the false lumen. The initial CTA image/3D reconstruction of the dissection (top) and the post-TEVAR CTA image/3D reconstruction (bottom.)



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Dake et al first reported their TEVAR results in the acute dissection patients in 1999<sup>10</sup>. Early (30-day) mortality was 16% with no additional mortality out to 13 month for a cohort of 19 patients. Nienaber and colleagues concurrently reported their European results in the 24 consecutive chronic (>14 days) type B dissection patients who underwent either surgery or TEVAR<sup>11</sup>. No mortality or neurologic complications were reported in the 12 TEVAR patients. Open operation in the 12 surgical patients was associated with 4 deaths (33%) and 5 adverse events (42%). Despite the small numbers reported in these early studies, the chronic type B dissection patients had better outcome compared to patients with the complicated acute dissection. In the chronic setting, TEVAR outperformed the open surgical intervention. Since then, many groups have published their midterm data (3-5 years) but few have reported their long term results<sup>12</sup>.

440 patients from the EUROSTAR (The European Collaborator Registry) and the United Kingdom Thoracic endograft multicenter registries had 30% that underwent TEVAR due to type B aortic dissection<sup>13</sup>. 47% of them had TEVAR electively in the chronic phase. The elective versus emergent early mortality was 7% and 12% respectively. The one year survival rate was 90%. No paraplegia was noted in the elective group but one suffered paraplegia in the emergency group. Endoleaks were observed in 3% of patients. The elective TEVAR patients had better morbidity and mortality rates compared to the emergent patient populations.

A meta-analysis of 609 patients from 39 studies with 40% chronic type B aortic dissection patients quantified similar findings<sup>14</sup>. Acute vs. chronic dissection patient complication rates were respectively 22% vs. 9%, early 30-day mortality was 10% vs. 3%, and one year survival 87% vs. 93%. Neurological complications were approximately 3%. Stroke was more prevalent at 2% versus paraplegia at 1%. Again, the elective TEVAR patients outperformed their emergent cohorts.

The Talent Thoracic Retrospective Registry midterm results were reported in 2009 and consisted of 180 patients followed for 22 months. 143 (80%) chronic type B dissection with diameter > 5.5 cm, rapid progression > 1 cm/year, signs of impending rupture and 37 acute type B dissection were included in the study<sup>15</sup>. The early mortality rate was 5%. The in-house mortality was 13% versus 2% for the acute versus chronic dissection patients. American Society of Anesthesiologists (ASA) class > 3 and age > 75 years were independent predictors of death. Surgical conversion rate was 3%. 4% had a stroke and 3% had spinal cord ischemia. Late death rate was 7%. 30 (18%) patients required re-intervention (12 open, 20 TEVAR) for 6 endoleaks, 2 false lumen growth, and 2 retrograde type A dissection.

The INSTEAD (INvestigation of STEnt grafts in patients with type B Aortic Dissection) was the first prospective, randomized controlled trial that compared optimal medical therapy with TEVAR in patients with type B aortic dissection. The primary end point of the study was all cause mortality at 2 years. Secondary end points included aortic related mortality, aortic remodelling and disease progression. The results of the study initially failed to show survival benefit among the TEVAR arm<sup>16</sup>; however, critical analysis of the study revealed the lack of power in the study as well as relatively short follow up<sup>17</sup>. Conceptually, the trial substantiated

the management guidelines for uncomplicated type B aortic dissection. These patients require close blood pressure control unless the dissection progresses or becomes aneurysmal at which point intervention will become necessary.

The INSTEAD XL trial was published in 2013 and examined long term results of the study population. The long term analysis revealed that patients undergoing TEVAR did in fact have a reduced allcause mortality (11.1% vs. 19.3% medical management), reduced aortic specific mortality (6.9% vs. 19.3%), and increased disease free progression (95.9% vs. 71.9%)<sup>18</sup>. This 5-year data from the INSTEAD XL study showed improved survival and freedom from progression after 5 years due to thrombosis of the false lumen induced by the stent graft in over 90% of cases, thereby demonstrating superiority of TEVAR in Additionally, uncomplicated aortic dissections. morphologic evidence of aortic remodeling, a known factor for non-progression to aneurysmal disease, was present in almost 80% of patients undergoing TEVAR by year 5 whereas only 10% was noted in patients with optimal medical management.

A previous meta-analysis of 17 studies consisting of 567 patients looking at the use of TEVAR in the chronic type B dissection showed the mid-term mortality of 9%, the endoleak rate of 8%, the aneurysmal degeneration rate of 8%, the retrograde type A dissection rate of 0.7%, the paraplegia rate of 0.5% and the stroke rate at  $2\%^{19}$ . The authors concluded that the lack of natural history for the medically managed group and the absence of consensus in the indication for TEVAR make the standard treatment for this population uncertain.

More recently, the Acute Dissection Stent Grafting or Best Medical Treatment (ADSORB) compared uncomplicated type B aortic dissection patients to determine trends in aortic remodeling and growth after medical management vs TEVAR<sup>20</sup>. Overall, the trial demonstrated clear benefits to TEVAR in aortic remodeling at 1 year follow up. Kamman et al analyzed the ADSORB data to further analyze which patients were at risk of aortic growth and adverse outcomes thereby providing further insight into timing of optimal repair. They were able to extract that the number of vessels originating from the false lumen was an independent predictor of false lumen growth in uncomplicated type B aortic They further showed that stent dissections. placement provides a benefit in terms of aortic remodeling and improves rates of false lumen thrombosis when compared to optimal medical management alone.

Based on the findings of these studies, the chronic/uncomplicated type B dissection patients who underwent TEVAR outperformed their counterpart in the acute/complicated setting<sup>10-11, 13-</sup>  $^{15, 18-19}$ . The early mortality rates were below 10%for the uncomplicated group compared to greater than 10% in the complicated group. The stroke and paraplegia rates were in the range of 1-5%. In the same setting, the TEVAR patients also outperformed their surgical cohorts<sup>11</sup>. The data shows long term benefits for early TEVAR intervention. Not only is the procedure more commonly being employed, the impact of stenting on aortic remodeling is not to be overlooked. The data is clear on the utility of TEVAR in chronic uncomplicated type B Dissections. Further studies have examined patient specific factors that benefit from early intervention in uncomplicated type B dissections. Further studies are needed that continue to quantify patient specific factors that aid in early intervention.

Our retrospective internal review of 62 consecutive patients with 37% type B aortic dissection and 24% aortic transection showed 8% 30-day mortality, 3% retrograde dissection with (100% mortality) and 2% paraplegia.

# Historic and Current Thoracic Endovascular Aortic Repair (TEVAR) Design

In the United States, the FDA approved TEVAR devices were initially for the descending thoracic aortic aneurysm or for the thoracic aortic transection. Today, they are also FDA approved for use in dissections and there has been rapid improvement of available grafts/stents available. The first stent graft approved by the FDA for treatment of type B Aortic Dissections was the GORE TAG device. Since then, companies such as Medtronic, Cook, and Bolton/Terumo all have competing stent grafts which address thoracic aortic pathology.

It still remains that the endovascular surgeon must have an in-depth understanding of the stent graft basic design, appropriate sizing, and the steps in deployment. Indeed, TEVAR's versatility is embedded in the engineering which without a certain level of technical mastery would make procedural success impossible. Without the appropriately sized stent, the case will become problematic due to type I and III endoleaks. In the emergency setting, the availability of the appropriately sized stent may be an issue depending upon the shelf stock at the medical center or the availability of the manufacturer to deliver the graft in a timely fashion. A significant experience with one TEVAR device does not necessarily translate to another device given the differences in the design, the deployment techniques, and the graft behavior. It cannot be overemphasized that understanding the design and the pitfalls behind the TEVAR devices is paramount.

**Custom-Design Thoracic Endovascular Aortic Repair (TEVAR):** The Stanford group in 2004 reported their long term data from their initial 103 patients implanted with the" homemade" Dacron stents with their 24F delivery system with 8% reported in the series as aortic dissection patients<sup>21</sup>. The 5-year survival estimates were 78% and 31% for the surgical vs. the non-surgical candidates while the 8-year survivals were 48% and 28%. At 8 years, the freedom from reintervention was 78% and from late endoleak 67%. The intermediate 5year survival showed that the patient's comorbidities contribute to their survival in the initial years. The 8-year survival, results were more comparable in the two groups after accounting for those patients succumbing to the complications in the initial years. This is one of the few longer term data available in the literature and it was from the pioneer group using the homemade graft. There were limited chronic aortic dissection patients

**Commercial Thoracic Endovascular Aortic Repair** (TEVAR): The GORE (Flagstaff, Arizona) TAG thoracic nitinol graft was the first FDA approved (2005) commercial device (Figure 2). The approval was for the descending thoracic aortic aneurysm model comparing 140 stent grafts versus 94 open repairs<sup>22-23</sup>. The stent-graft group compared to the surgical patients had lower early death rate (2% vs. 10%) and paraplegia (3% to 14%.) These rates were comparable to previously noted chronic type B dissection studies above. In the stent graft arm, 6% had graft migration, and 15% had endoleaks. Design modifications were made to eliminate the type IV endoleaks associated with the graft material porosity with the addition of another polytetrafluoroethylene (PTFE) layer.

**Figure 2.** The **GORE** (Flagstaff, Arizona) TAG thoracic nitinol graft was the first FDA approved (2005) commercial device. The prosthesis opens from the middle toward the two ends. Reprinted J Vasc Surg 41, Makaroun et al. Endovascular treatment of thoracic aortic aneurysm, 1-9, 2005, permission from Elsevier.



Goretech's latest stent is the conformable TAG device which is made of expanded polytetrafluorethylene with nitinol exoskeleton and provides a wider range of diameters to address more tortuous aortic anatomy (Figure 3). The device diameter by design was expanded to 21-45mm and lengths of 10-, 15-, and 20cms. The device is currently FDA approved for the management of the descending thoracic aortic aneurysms, transections

and type B dissections. The stent itself is unchanged since 2009 however the smaller diameter delivery sleeve gives the device a lower profile across up to 10 different device sizes. The 2017 system has a two stage deployment which allows continuous blood flow throughout deployment and multiple opportunities to visualize and refine graft placement. There is also the added benefit of precision to customize angulation to allow a more appropriate stent placement.

**Figure 3.** GORE cTAG- The evolution of Gore's TEVAR device, from the original GORE TAG Device to the Conformable GORE TAG Endoprosthesis and more recently, the new GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System.



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The SURPASS registry was created to assess the performance of the conformable TAG stent graft with the Active Control system in patients undergoing TEVAR and showed the efficacy of this device<sup>24</sup>. Between 2017-2018, 127 patients were enrolled in the post market international study and treated with the dual system for a variety of aortic pathologies including 17 (13.4%) in complicated type B dissections, and 24 (18.9%) in uncomplicated type B dissections. Overall, technical success was reported as 97.6% with unintentional coverage of the supra-aortic branches in three cases. There were no reported device compression, bird-beak configuration, fracture or graft occlusion. Clinical success rates at 30 day and 12 months were 97.6% and 92.9% respectively. Three aortarelated deaths were reported at 30 days and three additionally at 12 months. These were due to retrograde type A dissection (0.8%), paraplegia,

bowel ischemia, sepsis in the setting of mycotic aneurysm, aneurysm rupture post aortoesophageal fistula, and multi system organ dysfunction.

As of 2022, Gore is introducing to the market first of its kind FDA approved TEVAR with left subclavian endo-debranching device after completing its investigational device evaluation<sup>25</sup>. There is much enthusiasm across all the endovascular interventionalists knowing more endo-debranching towards the aortic root is forthcoming. Overall, the Gore stents have stood the test of time and continues to be the most studied TEVAR device.

**Medtronic** (Santa Rosa, California) has had multiple generations of TEVAR stents with the second generation **Talent** (the CoilTrac delivery system) introduced in 1999 and the third generation **Valiant** (the Xcelerant delivery system) introduced in 2008 (Figure 4). The Talent device was used in the VALOR trial with 189 thoracic aortic aneurysm patients at one year having 2% early mortality, 0.5% rupture, and 4% endoleaks<sup>26</sup>. The FDA approved the Talent device for the treatment of the descending thoracic aneurysm/penetrating ulcer in 2008 and later for the thoracic aortic transection. The Valiant device was used in the VALOR II trial with 160 similar patients to VALOR but with higher cardiovascular risk factors yet still demonstrated non-inferior results<sup>27</sup>. The 12 month all-cause mortality was 13% vs. 16% (VALOR II vs. I). There was no aneurysm growth >5mm nor any additional intervention required for endoleaks at 97% vs. 80% (VALOR II vs. I)

**Figure 4.** Medtronics (Santa Rosa, California) has had multiple generations of TEVAR stent grafts with the secondgeneration **Talent** (the CoilTrac delivery system) introduced in 1999 and the third generation **Valiant** (the Xcelerant delivery system) introduced in 2008. Shown below is the Valiant endograft. Reprinted permission from Medtronic.



The Talent Thoracic Retrospective Registry was reported in 2009<sup>15</sup>. 143 chronic type B dissections and 37 acute type B dissections were included in the study. The early mortality rate was 5%. The in-house mortality was 13% versus 2% for the acute versus chronic dissection patients. 4% had a stroke and 3% had spinal cord ischemia. Other pertinent data have already been summarized above.

A retrospective study using the Talent device coming out of Baltimore Maryland had 186 patients (40% dissection patients) showing early 30 day mortality of 5% and paraplegia at 4%. At 3 year followup, the dissection group had all-cause mortality of  $58\%^{28}$ . Another study using the Talent device coming out of Berlin Germany had 172 patients with early 30-day mortality of 10%, paraplegia at 1%; 1/3/5 year survival at  $79\%/67\%/55\%^{29}$ . Overall, the early mortality and the neurologic complication rates between the two studies are comparable to the chronic type B dissection rates noted above. The Talent device is a Dacron graft sewn into a nitinol wire frame. The radiopaque "figure-of-8" markers are present for the ease of visualization during fluoroscopy. The diameters ranging from 18-44mm and the lengths of 130mm are available in forty plus configurations including proximal to distal tapering. The Valiant device builds on the operative experiences from the Talent devices. The maximum device length was extended to 230mm, and there are eighty plus different configurations. The longitudinal connecting bar was removed to improve the conformability to the aortic arch. The bare springs at the ends have also improved fixation to the aortic wall.

Medtronic has also made numerous updates to their initial Talent thoracic graft. The VALOR I and VALOR II studies have cemented the efficacy of the next generation Valiant device which is made of polyester graft with a nitinol exoskeleton with proximal bare stent modification. Using the modified Valient graft with the latest Captivia delivery system now allows for improved tip control and a more controlled deployment. The TRAVIATA registry assessed the performance of Medtronic's Valiant Stent graft in the treatment of thoracic aortic disease and found success rates of 86.9% with 1-year survival of 95.5%<sup>30</sup>. The high technical and clinical success coupled with low allcause mortality continue to reinforce the efficacy of TEVAR with each new iteration of device.

The Valiant Navion stent was the next generation Medtronic stent. This was unfortunately recalled from the market in 2021 due to risk of stent fracture (4 cases) and endoleaks (4 cases.). Two injuries and one death were also noted. The **Cook** (Bloomington, Indiana) **Zenith** thoracic graft has the TX1 and TX2 design (Figure 5) on the stainless steel Z stents sutured on the polyester fabric. The TX1 single-piece proximal-distal fixation system is intended for the short aortic pathology of less than 12cm. The TX2 two-piece design (TX2P, TX2D; Proximal, Distal grafts) has a diameter of 24-46mm, covers between 105-230mm and, has an overlap zone to discourage component migration. The device was FDA approved for thoracic aortic aneurysms/ulcers in 2009 and for dissection in 2019.

Figure 5. The Cook (Bloomington, Indiana) Zenith thoracic graft has the TX1 and TX2 design. Shown below is the TX2 the 2-piece Dacron modular graft.

Reprinted Sem in Vas Surg 19, Hassoun et al. The COOK TX2 thoracic stent graft, 32-9, permission from Elsevier.



A study examined the Zenith devices from the Cleveland clinic included 160 patients, 15% dissection, had 7% early mortality, 16% 1-year mortality, and 9% had endoleaks requiring intervention<sup>31</sup>. The STABLE trial examining the use of TX2/distal extension in 40 complicated dissection patients showed early mortality of 5%, 1-year mortality of 10%<sup>32</sup>. Paraplegia was noted at 3%. These morbidity and mortality are comparable to other device outcome data except the STABLE early

mortality seemed low for the complicated dissection patients.

The Cook Zenith TX2 device is a two piece system which utilizes a Dacron graft with a stainless steel z stent exoskeleton. Modifications to this system include the addition of Pro-Form which allows the surgeon to conform the graft to the aortic arch and limits 'bird beak 'effects. The same group has also developed a composite device, the Zenith Dissection Endovascular System which includes a proximal portion that allows for coverage of the entry tear and follows with an uncovered distal scaffold to compress a false lumen. Early studies examining this device is favorable, with improved aortic remodeling at 2 years and low risk of complications (STABLE trial).

**Terumo** has purchased Bolton (Sunrise, Florida) in 2017 and Bolton received the FDA approval for the

**RELAY** TEVAR device in 2012 (Figure 6). Straight or tapered, diameters of 22-46mm, and lengths of 100-250mm offered extensive choices in configuration. In the RESTORE registry using the Relay stents (91 patients, 84% dissections), patients had an early mortality of 8% but a 2-year mortality of 18%<sup>33</sup>.

Figure 6. Terumo/Bolton Medical (Sunrise, Florida) is the latest comer to the US market and in 2012 received the FDA approval for the RELAY TEVAR device.

Reprinted J Vasc Surg, 53, Riambau et al. Final operative and midterm results of the European experience in the RELAY Endovascular Registry for thoracic disease (RESTORE) study, 565-73, 2011, permission from Elsevier.



Most device specific outcome data do not separate out for chronic type B aortic dissection. The Talent Thoracic Retrospective Registry is one exception. Gore,

Medtronic, Cook, and Terumo were approved for the thoracic aortic aneurysm and dissection; Gore and Medtronic were approved for the thoracic aortic transection. The early mortality and the neurologic complication rates appeared to be comparable to the chronic type B dissection population.

## Thoracic Endovascular Aortic Repair (TEVAR) Related Complications

The uncomplicated type B dissection patients typically have lower complication rate than the complicated type B dissection patients after a TEVAR procedure. However, these complications, namely stroke, paraplegia, endoleaks, migration, and retrograde dissection are not negligible even in the stable type B dissection patients<sup>34-35</sup>. Two complications, however, deserve special attention. The spinal cord ischemia leading up to paraplegia is an apprehended complication. Nevertheless, we have the ability to intervene by placing a cerebrospinal fluid (CSF) drain and altering patients 'outcome. Retrograde type A dissection is another dreaded complication but our cumulative experience is finally reaching sufficient number for us to describe this rare complication more clearly. Usually. emergent suraical repair usina cardiopulmonary bypass is required which is significant given the comorbidities that are already involved in these patients.

#### **Spinal Cord Ischemia**

The most recent studies suggest that TEVAR is associated with a 3-5% incidence of spinal cord ischemia (SCI.) Most of these outcomes were based on studies from the thoracic aneurysm patients. The dissection patients 'outcome are comparable with the chronic patients on the lower end of the range while the acute patients on the opposite end. Previous abdominal aortic repair, the extended thoracic aortic coverage, any coverage involving the subclavian artery, and the sustained hypotension have all been implicated<sup>36-37</sup>. With the use of CSF drainage, however, the incidence of neurologic deficit is decreased by ten fold<sup>38</sup>. Now most thoracoabdominal cases with a CSF drain in place have a protocol to keep CSF pressure <10 mm Hg and to keep the mean arterial pressures (MAPs) greater than 90mm Hg with fluid bolus or vasopressors<sup>39-40</sup>.

The use of the CSF drainage is beneficial but its benefits come with certain risks<sup>41</sup>. Intracranial hemorrhage (ICH) with its associated 40% mortality<sup>42</sup> is due to the traction of the dural veins when the brain is displaced while the CSF is drained. In addition, the spinal headache is attributed to the sensory receptor traction in the dural sinuses during CSF drainage. CSF leak is usually treated conservatively. If it does not resolve, a blood patch is then performed. In one study, 55% of the patients with a CSF leak needed a blood patch<sup>40</sup>. In our retrospective 62 patients, 8% had spinal drain placed and 2% (one patient) had paraplegia due to hypotension from aortic rupture in the acute setting.

## **Retrograde Stanford Type A Dissection**

The retrograde dissection is an infrequent but potentially catastrophic complication. Although the true incidence is still being established, it is estimated to be around 1%. Some studies have quoted as high as  $4\%^{43}$ . 35% of the retrograde type A dissection occurred during surgery while 64% occurred during the first 30 days. The retrograde dissection rate in the chronic dissection patient is comparable with the few limited studies in the literature.



**Figure 7.** The Ishimaru's classification scheme defines the five TEVAR landing zones. Each zone is bordered by a tangential line aligned with the distal sides of each great vessel. Zone 0: involves the origin of the innominate artery Zone 1: the origin of the left common carotid artery (LCCA) Zone 2: the origin of the left subclavian artery (LSA) Zone 3: the proximal descending thoracic aorta down to the T4 vertebral body

Zone 4: the remainder of the thoracic aorta

Reprinted Sem Thorac Cardiovasc Surg, 21, Szeto et al. Hybrid repair of aortic arch aneurysm, 347-54, 2009, permission from Elsevier. Conceptually, the retrograde dissection seems natural given the combination of the diseased aorta and the multiple catheter/device manipulation at a tortuous segment of the aorta. More objectively, several variables have been examined. Patients whose ascending aorta is > 4 cm, a marker for the underlying disease, are five times more likely to have a retroarade dissection<sup>44</sup>. Additional underlying disease markers include the dissection itself, the bicuspid aortic valve, as well as the angulation related markers like using zone 0 as the proximal landing zone (Figure 7) and the angulated gothic arch have all been implicated<sup>45</sup>. Balloon dilation has also be shown to increase the risk of retrograde dissection. Finally, contributing to this phenomenon, the proximal bare spring for fixation has the tendency to spring to its final configuration and may become oversized, creating excessive radial force.

Mortality rates after retrograde type A dissection are reported at 42%. The dissection typically requires surgical conversion. Intraoperatively, the greater curve of the aorta and the ascending aorta are implicated in  $83\%^{46}$ . The replacement of the aortic arch anastomosing a surgically placed graft to the endovascularly placed endograft has been reported. The modified elephant trunk with the removal of the endograft is not recommended<sup>47</sup>. Again our internal review showed retrograde dissection rate at 3% with 100% mortality; the two patients were in telemetry beds then decompensated rapidly.

## The Frontier

The debate for earlier TEVAR intervention in the chronic type B dissection is most likely closed. If future studies indicate that the natural history of these patients will require intervention, the indication for endovascular repair will continue to expand. In the mean time, the hybrid surgery and the endograft into the ascending aorta are also expanding the indications for TEVAR

**Hybrid Surgery:** a new frontier to debranch the arch vessels in order to advance the proximal landing zone has been aggressively pursued<sup>48</sup> (Figure 8). Such approach has significantly lower morbidity and mortality compared to the two-stage surgery requiring the cardiopulmonary bypass and possibly the circulatory arrest<sup>49</sup>. The GORE TEVAR with endo-debranching option beginning with the left subclavian artery is also becoming available.

**Figure 8.** A new frontier to debranch the arch vessels in order to advance the proximal landing zone has been aggressively pursued. Note the different debranching grafts and the different aortic pathology shown below. Reprinted J Thorac Cardiovasc Surg, 140, Milewski et al. Have hybrid procedure replaced open aortic arch reconstruction in high risk patients? 590-7, 2010, permission from Elsevier.



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A retrospective European study<sup>50</sup> of 141 aortic arch patients (16% dissection) with the hybrid surgery had an early mortality rate of 10%/3%/3% (zone 0, 1, 2). 3 cases of retrograde dissection were noted. In the 47 thoracoabdominal aortic patients (17% dissection) with the hybrid surgery/visceral bypass had early mortality of 15%. As most other data have been small case series, a meta-analysis of 1886 patients from 50 studies showed in hybrid surgery with dissection patients, the peri-operative mortality was 10%, the stroke rate was 4%, and the spinal ischemia rate was  $6\%^{51}$ . Clearly, as the technique continues to be refined and the volume continues to accumulate, the outcome will continue to improve and further broaden the indication for TEVAR.

Thoracic Endovascular Aortic repair (TEVAR) in the Ascending Aorta: When the endograft was first placed into the thoracic aorta, it was a new era in the field of aortic intervention. In the last two decades, a new era has also begun as more endograft approaches the ascending aorta<sup>52</sup>. Current standard type A dissection repair is done with the cardiopulmonary bypass, leaving patients with significant morbidity and mortality (60-80%). Up to another 30% of patients are not surgical candidates due to their comorbidity<sup>53</sup>. TEVAR might offer the alternative going forward but it is not without its own technical challenges. The proximal TEVAR landing zone would be close to the aortic valve and the coronary arteries. The distal TEVAR landing zone would be close to the innominate artery. Similar trans-axillary or trans-carotid and transfemoral approach to the transcatheter aortic valve implantation (TAVI) would be necessary with the involved risks of valve disruption, and the need to manage cardiac output during deployment with rapid pacing.

Preliminary studies have shown that 30-40% of the patients are suitable for TEVAR placement given the current device specification and patients' anatomy<sup>54-55</sup>. Current literature regarding the use of TEVAR in ascending dissection is limited to single case report and small case series. In one report with

45 Stanford type A aortic dissection, the TEVAR success rate was 98%, the early mortality rate was 7% and the type I endoleak rate was  $22\%^{56}$ . In the decade ahead, this will be an area of continuing research and study.

## Summary

It has been thirty years of significant progress in the field of thoracic endovascular aortic repair (TEVAR)<sup>57</sup>. Uncomplicated type B aortic dissections are typically managed with TEVAR and this treatment paradigm was substantiated by the INSTEAD trial<sup>16-18</sup>. TEVAR are indicated when in the subacute setting the dissection continues to progresses and or become aneurysmal.

From the initial days of the custom-design stent when the descending thoracic aneurysm was the primary pathology for TEVAR three decades ago, we have made significant advances tackling the complicated type B aortic dissection involving malperfusion, the acute thoracic aneurysm rupture as well as the traumatic aortic transection with the several commercial devices available. Thus far, several groups have published their result. The area of the hybrid surgery involving the use of debranching when TEVAR is being landed ever more proximally in the aortic arch is also another area fueled with enthusiasm. Endo-debranching in the aortic arch is also progressing. The use of the TEVAR in the ascending aorta is also another active area of research.

The practice of TEVAR in the catheter laboratory or the hybrid operating room involving the vascular/endovascular surgeon, the interventional radiologist, and the cardiothoracic surgeon also have ramification for future practice. It will continue to evolve and move forward in the decade to come.

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