

# Thoracic endovascular aortic repair: Current evidence and challenges

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## ABSTRACT

In 1987 Nikolay Volodos performed the world's first endovascular treatment of aortic aneurysms. Endovascular technology has progressed significantly since then. There are now many thoracic endovascular aortic repair (TEVAR) systems commercially available. By applying them, we can treat many pathologies: aneurysms, dissections, aortic ruptures, and penetrating aortic ulcers. However, TEVAR technology still has its limitations, namely the risk of a retrograde type A dissection, the issue of precise landing in the distal landing zone, and the risk of air embolism and paraplegia. Furthermore, there are no appropriate stent grafts widely available to treat acute dissections. Those currently used are designed for aneurysms, not for dissections. As a result, there are several challenges facing the future TEVAR surgical community, such as the need to develop new and more precise systems with retrograde deployment for the distal landing zone, as well as to introduce flexible stent grafts to treat dissections. The endo-Bentall is being developed as an alternative treatment method for acute type-A aortic dissection.

**Key words:** thoracic aortic pathologies, thoracic endovascular repair

## INTRODUCTION

Nikolay Volodos carried out the first thoracic endovascular aortic repair (TEVAR) in the world in 1987 at the Vascular Surgery Department of the Kharkov Scientific Institute for Research in Ukraine [1]. The Z-shape stent design he invented had been patented already in 1984 in the Soviet Union, but Soviet patents had no international validity [2]. Other pioneering implantations in the abdominal aorta were reported by Parodi et al. [3] in 1991.

TEVAR is an important therapy option for various pathologies. Indications for this novel therapeutic method became increasingly broadly defined and applied to aortic lesions, chronic and acute type-B dissections, and penetrating atherosclerotic ulcers. However, the technology still has its limitations, such as the risk of occurrence of a retrograde type-A dissection, the issue of precise landing in the distal landing zone, and the risk of air embolism and paraplegia. Additionally, no specific stent grafts are widely available to treat acute dissections.

This review article aims to describe the latest evidence and challenges associated with TEVAR.

## IMAGING

The planning of every aortic treatment starts with an imaging examination. Computed tomographic angiography (CTA) enables accurate imaging of the entire aorta and nowadays is the diagnostic gold standard. Electrocardiography-gated techniques are also very helpful for accurately assessing the aorta [4].

## POST-INTERVENTIONAL FOLLOW-UP

Strict follow-up is mandatory to achieve good long-term results. Post-interventional CTA follow-up is recommended after 6 and 12 months, and then annually. Examinations should be carried out at these recommended intervals on an outpatient basis. Regular imaging helps detect late complications such as progression of aortic disease or endoleaks. The aortic disease may develop

further and affect new sections of the aorta. It is also very important to control excessive arterial hypertension in this context. The above recommendations are reflected in the European cardiological, cardiosurgical, and vascular guidelines [5, 6].

## THORACIC AORTIC PATHOLOGIES TREATED WITH TEVAR

### *Descending aortic aneurysms*

An intervention is recommended in aneurysms once they have reached the 55 mm cutoff point. This value can drop to 50–55 mm for women or patients with connective tissue disorders. Additionally, if the diameter increases rapidly (by over 10 mm annually), that qualifies as an indication for TEVAR [5].

### *Intramural hematomas and penetrating aortic ulcers*

TEVAR treatment should be considered in patients presenting complicated intramural hematomas and penetrating ulcers. Penetrating aortic ulcers with a diameter >20 mm and depth >10 mm are considered a treatment indication. Attention is called for when an aortic ulcer is associated with an intramural hematoma, which is associated with a high incidence of distal stent-graft-induced new entry tears (dSINE). These patients require lifelong, intensive follow-up [7].

### *Traumatic aortic injury*

TEVAR is the first-choice therapy for traumatic aortic lesions. The lesion proximal to the left subclavian artery can sometimes be managed surgically *via* a left common carotid artery-left subclavian artery bypass to avoid the drawbacks of subclavian coverage with the stent graft [5].

### *Acute aortic dissection*

Acute type-B aortic dissections are classified as uncomplicated or complicated. The latter characterizes malperfusion syndrome involving visceral, renal, or extremity ischemia, rupture or impending rupture, uncontrolled hypertension, persistent abdominal or chest pain, or evidence of rapid expansion on CTA imaging.

Immediate invasive treatment is required in patients presenting a complicated type-B dissection. The therapy of uncomplicated dissection has been investigated in clinical studies. The INvestigation of STEnt Grafts in Aortic Dissection (INSTEAD) was the first randomized trial; it showed that TEVAR failed to improve 2-year survival, and its adverse-event rates were high despite favorable aortic remodeling in the 140-patient cohort [8]. However, the 5-year follow-up findings in this cohort study (entitled INSTEAD-XL) showed that TEVAR supplemented by optimal medical treatment was associated with better 5-year aorta-specific survival and delayed disease progression [9]. In patients with

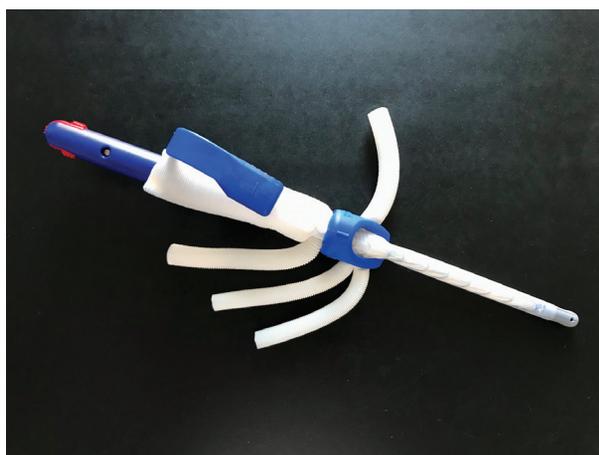
a stable type-B dissection and suitable anatomy, preemptive TEVAR is considered to improve late outcomes. Results from the randomized trial — Acute Dissection: Stent graft OR Best medical therapy (ADSORB) — also suggest a stronger benefit from TEVAR than with medical therapy alone regarding aortic-remodeling outcomes one year after dissection [10]. According to the current recommendations, any of the following factors should be considered an indication for performing TEVAR 15 to 90 days after the index event: (1) a most proximal communication between both lumens (primary entry tear) in the inner aortic curvature; (2) a primary entry tear exceeding 10 mm; (3) false lumen diameters larger than 25 mm and, finally; (4) initial total aortic diameters larger than 40 mm [6].

A non-A non-B dissection is defined as both descending-entry types with the entry distal to the left subclavian artery and dissection extending into the aortic arch, and the arch-entry type with the entry between the innominate and left subclavian arteries. Acute non-A non-B aortic dissections require emergency intervention in case of organ malperfusion or aortic rupture. Most patients undergo aortic repair within two weeks after the dissection onset. Endovascular treatment is usually TEVAR-based or performed without carotid-subclavian bypass or isolated stenting of dissected visceral vessels. In the case of non-A non-B aortic dissection with the entry in the aortic arch, the frozen elephant trunk technique, combining a descending aortic stent graft with a Dacron aortic arch prosthesis, is already a well-established treatment option enabling the elimination of the primary entry tear without the risk of retrograde aortic dissection of type A (Figures 1 and 2). This approach provides an ideal landing zone for secondary endovascular or open surgical interventions. TEVAR in non-A non-B dissection patients presenting the entry in the aortic arch is unsuitable due to the exceptionally high risk of retrograde aortic dissection of type A [6, 11–13].

In patients with an aortic dissection, TEVAR may lead to complications in the landing zones since in most of these patients, at least one landing zone is a dissected aortic segment. In the study by Berkarda et al. [14] in patients undergoing TEVAR for acute aortic dissection, the diameters of dissected distal landing zones had increased significantly already one year after the intervention. The risk of distal stent-graft-induced new entries and the increase of the aortic diameter at the distal landing zone make subsequent follow-up imaging monitoring in these patients mandatory.

Similarly, as the study by Yammine et al. [15] demonstrated, patients should be examined long-term, as patients may suffer type-A retrograde dissections even a year after TEVAR.

TEVAR results in the dissection setting have been very encouraging. The dissection trial was a prospective, non-randomized trial on TEVAR outcomes in type-B aortic dissection that included 50 patients. Thirty-day mortality was 8% (4 of 50) and 12-month mortality was 15%. In this trial,



**Figure 1.** Thoraflex hybrid prosthesis is the closed preimplantation setting (Terumo Medical, Tokyo, Japan)



**Figure 2.** Thoraflex hybrid prosthesis is the opened post-implantation setting (Terumo Medical, Tokyo, Japan)

the 5-year freedom from dissection-related mortality, secondary procedures related to the dissection, and endoleaks were 83%, 86%, and 85%, respectively. Those authors concluded that patients experienced positive and sustained degrees of aortic remodeling [16, 17]. A systematic review and meta-analysis of long-term survival by Wilson-Smith et al. [18] of 2565 patients showed survival at 2, 4, 6, and 10 years of 87.5%, 83.2%, 78.5%, and 69.7%, respectively.

TEVAR is not recommended for patients with genetic diseases except for bail-out situations, but it is a potential alternative in emergencies for patients with diseases involving the aorta. TEVAR can be used where there is a proximal landing zone made of artificial material. One such example is the implanted frozen elephant trunk. However, we need more long-term published data to support such an approach [19].

### CURRENT TEVAR PLATFORMS

The currently available stent graft systems are made of different materials. Mezzetto et al. [20] compared early and late results of an expanded polytetrafluoroethylene (ePTFE Gore TAG, Gore Medical, Flagstaff, AZ, US) mesh-structured



**Figure 3.** Relay Plus stent graft (Terumo Medical, Tokyo, Japan)

stent graft to a Dacron one (Relay Plus, Terumo Medical, Tokyo, Japan, **Figure 3**) for TEVAR in 129 consecutive patients in both elective and emergency settings. Technical success was achieved in 100%, of which 22.4% were emergency procedures. Early mortality and spinal-cord ischemia were documented in 8.5% and 2.3% of patients, without significant differences between stent graft types. The effectiveness of the TEVAR procedure with modern stent grafts was confirmed by the high rate of sac shrinkage and technical success and seemed to be independent of the specific material used when manufacturing the stent grafts.

The new delivery system of the Conformable TAG thoracic stent graft (Gore Medical, Flagstaff, Arizona, US) was introduced to enable a more precise graft deployment. This system has an angulation mechanism on the proximal stent-end and 2-stage deployment for more easily controllable device positioning. In the observational registry, 30-day and 12-month clinical success rates were impressive at 97.6% and 92.9%, respectively [21].

The Valiant Captivia thoracic stent graft system (Medtronic, Dublin, Ireland) is a third-generation endovascular stent graft that benefits from advancements in minimally invasive delivery and anatomic conformability. Lim et al. [22] reported on their 3-year outcomes in the type-B dissection setting. Freedom from all-cause and dissection-related mortality was 79.1% and 90.0%. The Valiant Captivia stent graft initially exhibited very good performance, safety, and results. Patients treated with the Val-



**Figure 4.** Zenith Alpha stent graft with distal base springs and distal component (Cook Medical, Bloomington, IN, US)

iant Navion stent graft system showed positive short-term outcomes in clinical trials; however, late structural failures including type IIIb endoleaks have been recently discovered. These are serious adverse events because they raise the risk of aortic rupture. In the study by Verzini et al. [23], 5 of their 83 patients developed such IIIb endoleaks. Due to this complication, Medtronic issued a global, voluntary recall of the Valiant Navion stent graft system.

A total of 50 patients who suffered a blunt aortic trauma were enrolled in a study to assess the Zenith Alpha thoracic endovascular graft (Cook Medical, Bloomington, IN, US, **Figure 4**). During a mean 21-month follow-up, a 30% incidence of in-graft thrombus resulted in the manufacturer's voluntary removal of the blunt-aortic-trauma indication for this device [23].

Burdess et al. [24] investigated in 16 patients a dissection-specific stent graft (DSSG) that was specifically designed to treat chronic type-B dissection and lower the risk of dSINE. The DSSG, derived from the Cook Zenith Alpha Thoracic stent graft (Cook Medical, Bloomington, IN, US), has no proximal barbs, and a customized longer body length with substantial taper. The second and third distal Z-stents are located internally to avoid any contact between the metal skeleton and dissection membrane and have reduced radial force, while the most distal stent was removed creating a distal 30 mm unsupported Dacron graft. Technical success was achieved in 96%. One patient died postoperatively from a retrograde type-A dissection. There were no strokes, spinal cord ischemia, or re-interventions observed. After a median imaging follow-up period lasting 17 months, one patient developed a dSINE. After median survival follow-up lasting 23 months, one late

death occurred from traumatic brain injury. Using a novel DSSG with low radial force for TEVAR in the dissection setting seems to be safe, feasible, and effective across a wide range of anatomies. These early data have shown promising effectiveness and very low rates of dSINE, re-interventions, and satisfactory aortic remodeling [24].

To treat pathologies involving the aortic arch, TEVAR is challenging due to the arch's inherent anatomic limitations. Factors such as the degree of aortic-arch angulation can affect the proximal landing zone's suitability [25]. An unfavorable landing zone can later influence the long-term durability of TEVAR's outcome in the arch. Hanna et al. [26] evaluated the Bolton Relay scallop endograft (Terumo Aortic, Sunrise, FL, US). This custom-made stent graft has a U-shaped gap (for the "scallop" approach) in the exterior of the stent graft fabric that is designed to extend the seal zone along the aorta's inner curvature, whereas the scallop maintains normal perfusion of the supraaortic branches from the greater aortic curvature. Although their technical success rate was very high, 8% of their patients suffered a minor stroke and 5% temporary spinal-cord ischemia.

Patel et al. [27] reported on a 5-year follow-up in their study evaluating TEVAR using the Valiant Captivia stent graft (Medtronic, Dublin, Ireland) for blunt thoracic aortic injury in a 50-patient cohort. Thirty-day mortality was 8%. No secondary endovascular procedures or conversion to open surgery were done during the follow-up period. Complete exclusion of the traumatic injury was achieved in all patients with no signs of stent graft kinking, fracture, loss of patency, or migration.

## TEVAR COMPLICATIONS

An overview of TEVAR complications is presented in **Table 1**.

### **Retrograde type-A aortic dissection**

One very serious TEVAR complication is a type-A retrograde dissection. Its pooled rate after TEVAR is reportedly 2.5%, and the mortality rate is very high (37.1%). This fatal complication's incidence is significantly higher in patients treated for dissection. There is evidence that oversizing is a potential risk factor for retrograde dissection [28].

### **Endoleaks**

Endoleaks are the most common TEVAR complications. An endoleak is a persistent flow of blood into the aneurysmal sac, usually visible on radiological imaging. Endoleaks lead to the sac's continuous pressurization, which can eventually cause expansion or rupture. Endoleaks are categorized by their cause and/or origin. Type I endoleaks are a subgroup that occur at graft ends (Ia at the proximal end, Ib at the distal end). The most common endoleak is a type II endoleak — caused by backflow from collateral arteries. Type II endoleaks usually do not resolve and are often treated interventionaly, i.e. *via* coil embolization [29].

**Table 1.** Overview of thoracic endovascular aortic repair (TEVAR) complications

Complication type	Mechanism	Prevalence	Risk factors	Source
Retrograde type-A aortic dissection	Natural progression of the underlying disease, ballooning or wire and introducing sheath manipulation, stent-graft-induced new entry site	2.5%	Stent graft oversizing, primary diagnosis of type B acute aortic dissection, ascending aortic aneurysm	[29]
Endoleaks	Leak at graft ends, backflow from collateral arteries	9.5% to 15.8%	Landing zone in curved aortic segment, landing zone with different proximal and distal diameters, left subclavian artery coverage, inappropriate oversizing, aneurysm diameter	[30]
Inaccurate stent graft deployment in the distal landing zone	Deployment mechanisms focusing only on an accurate proximal landing	25%	Aortic diameter, the length of the distal landing zone	[31]
Air embolism	Air embolisms during stent graft implantation	4%	Too small saline flushing volume	[32, 33]
Spinal cord ischemia	Coverage of arteries supplying the spinal cord, intraoperative hypotension	2.5% to 8%	Simultaneous closure of at least 2 vascular territories supplying the spinal cord, especially in combination with prolonged intraoperative hypotension, no use of cerebrospinal fluid drain	[34–38]
Negative cardiac remodeling, hypertension	Increased aortic stiffness after TEVAR and elimination of Windkessel effect	55%	Stent graft length	[39, 40]

### **Inaccurate stent graft deployment in the distal landing zone**

The most recent TEVAR technology focuses on accurate stent graft deployment in the proximal landing zone. However, implanting the stent graft in the distal landing zone is often very challenging. Inaccurate landing in this area is associated with a significantly higher endoleak Ib incidence, frequently requiring at least second stent graft implantation. That, in turn, can lead to the potential coverage of arteries whose off-spring is close to the landing zone. There is evidence that an inaccurate distal landing zone is a major TEVAR limitation. This results from deployment mechanisms focusing on an accurate proximal landing, but not on deploying the stent graft precisely in the distal landing zone. New stent graft deployment devices enabling implantation starting in the distal landing zone may solve this problem. Most patients usually require 2 stent grafts due to the extension of their aortic pathology. It would be advantageous to have 2 different deployment systems: one for the proximal and another for the distal landing zone [30].

### **Air embolism**

In the study by Kölbel et al. [31], stent grafts were flushed for 2 minutes with carbon dioxide to avoid an air embolism. Of their 36 patients, one suffered a minor stroke. Our group investigated how to minimize air embolisms during thoracic endovascular aortic repair *via* the Relay Pro stent graft system (Terumo Aortic, Inchinnan, UK). Stent grafts were de-aired *via* standard saline flushing of 40 ml, increased volume saline flushing of 120 ml, carbon dioxide followed by 40 ml saline flushing, and de-airing with 40 ml of saline in an ultrasound bath. We found that the most effective method to reduce the air volume was de-airing with an increased saline volume of 120 ml [32]. We have incorporated this effective approach into our daily routine. Nevertheless, the clinical relevance of air embolisms in

association with TEVAR is still not well documented and needs further investigation.

### **Spinal cord ischemia**

Spinal cord ischemia is a severe TEVAR complication. One method to reduce the consequences of spinal cord malperfusion after TEVAR is to put a cerebrospinal fluid drain in place before TEVAR to enable cerebrospinal fluid-pressure monitoring and regulation.

The preoperative prophylactic employment of a cerebrospinal fluid drain is somewhat controversial due to potential concerns regarding catheter-related complications.

Aucoin et al. [33] evaluated differences between patients who developed spinal cord ischemia despite preoperative cerebrospinal fluid drainage and those treated therapeutically during their postoperative course. The therapeutic group's outcome was significantly worse, as they suffered a 79% permanent paraplegia rate, whereas the prophylactic group's rate was 54%. Performing cerebrospinal fluid drainage is associated with a significantly lower incidence of spinal cord ischemia after TEVAR than when it is not done; the complication rate associated with cerebrospinal fluid drainage insertion or removal is very low. There were no major and 10% minor complications reported. Additionally, routine monitoring of evoked potentials helps to detect an arterial perfusion obstruction to the spinal cord immediately [34].

Clinicians' knowledge on the spinal collateral network's role in spinal cord perfusion is still growing. Anterior radiculomedullary arteries connect the dorsal segmental arteries to the spinal collateral network's intraspinal compartment. The number of these arteries varies widely. The impact of their pattern on spinal cord perfusion during thoracic aortic procedures is being investigated. A few anterior radiculomedullary arteries, or considerable variation in their distribution and offspring, may have a negative impact on spinal cord perfusion. The preoperative non-invasive

imaging of these arteries remains challenging in practice and unavailable for use in the daily clinical routine [35].

TEVAR starting in the aortic arch frequently requires strategies to preserve supraaortic perfusion by rerouting procedures in case the supraaortic vessels are covered. Left subclavian artery revascularization is necessary to prevent posterior cerebellar malperfusion, minimize the risk of spinal cord injury, and secure blood supply to the upper-left extremity whenever TEVAR was done in zone 2. Luehr et al. [36] reported that every 10<sup>th</sup> patient with a covered left subclavian artery and no revascularization experienced left-arm malperfusion. They concluded that patients should undergo left subclavian revascularization to prevent neurologic complications and upper-left extremity malperfusion [36]. We routinely carry out left common carotid artery-left subclavian artery bypass in this scenario. Alternatively, unibody single-branched stent grafts are available and may be used for TEVAR zone 2. They allow endovascular revascularization of the left subclavian artery [37].

### Left ventricular function changes after TEVAR

Vallerio et al. [38] evaluated 20 patients who underwent TEVAR for aortic trauma regarding aortic diameters and their left ventricular mass index. Median follow-up was  $5.0 \pm 3.5$  years. Interestingly, 55% of their patients developed hypertension. After more than 3 years, their patients revealed a higher left ventricular mass index and a dilated ascending aorta. TEVAR in this cohort modified their aortic functional properties, inducing hypertension and aortic and cardiac degeneration. Our study suggests that negative cardiac remodeling occurs in conjunction with impaired left and right ventricular function following TEVAR despite enhanced antihypertensive therapy [39]. More research is necessary to better understand the influence of chronically increasing aortic stiffness in association with TEVAR on left-ventricular function.

## THE ENDO-BENTALL APPROACH FOR TREATING ACUTE AORTIC DISSECTION OF TYPE A

There is evidence that up to 10% of acute Type A aortic dissections fail to qualify for open surgical repair because of their excessively high surgical risk [40]. TEVAR in patients with a type A aortic dissection is limited by the lack of appropriate landing zones. However, the endo-Bentall concept has been suggested for the endovascular treatment of a type A aortic dissection. The endo-Bentall device consists of a proximal transcatheter aortic valve connected to a covered stent graft's uncovered portion. The device provides three landing zones: the aortic valve annulus for stable anchorage of the device through the catheter valve, a proximal sealing zone at the level of the sinotubular junction, and a distal sealing zone at the level of the distal ascending aorta before the brachiocephalic trunk's takeoff. There are 2 clinical scenarios for endo-Bentall implantation: a one-stage concept to stabilize the ascending aorta in

patients without malperfusion but carrying a high perioperative risk; the second: endo-Bentall implantation may be appropriate as the first-step option to treat distal-organ malperfusion by re-expanding the true lumen and to achieve proximal stabilization of the aorta to stabilize the patient temporarily [41]. Clinical results of this approach have not been reported yet. According to the radiological evidence, the vast majority of patients with an acute aortic dissection are anatomically suitable for treatment with the endo-Bentall device [42].

## CONCLUSIONS

TEVAR is a surgical technique in which substantial progress has been made in recent years. We can now effectively treat almost all pathologies of the descending aorta by applying this method. The main unfortunate exception is, however, patients suffering from genetic aortic disease. We have many modern stent grafts at our disposal. However, there are still significant limiting factors: occurrence of a retrograde type-A dissection, the issue of precise landing in the distal landing zone, the risk of air embolism, and paraplegia. Since aortic pathologies are so complex, these patients tend to undergo treatment in aortic centers offering both classic and endovascular therapies. Outpatient postoperative care, with regularly scheduled imaging and hypertension control, enables the early detection of complications that can be later treated in an endovascular or open fashion.

### Article information

**Conflict of interest:** MC is a consultant to Terumo Aortic, Medtronic, Endospan and NEOS, received speaking honoraria from Bentley and Cryolife, and is a shareholder of TEVAR Ltd and Ascense Medical. BR is a consultant to Terumo Aortic and a shareholder of Ascense Medical.

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