

Single Center Experience with a New Commercially Available Thoracic Endovascular Graft

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Purpose. To evaluate the intra-operative performance and clinical outcome of a new commercially available stent-graft for the treatment of thoracic aortic diseases.

Methods and patients. From January 2003 to October 2004, 45 consecutive patients received endovascular treatment with the Zenith TX1 device for diseases of the thoracic aorta at a single center in northern Italy. Indications included disease of the descending thoracic aorta in 26 cases, of the aortic arch in 17 cases and of the thoraco-abdominal aorta in two cases. We treated 38 atherosclerotic aneurysms, two post-traumatic aortic ruptures, two penetrating ulcers, two chronic dissections and one case was treated for aortic bleeding after voluntary acid ingestion for attempted suicide. General anesthesia was used in 20 cases. Combined or hybrid endovascular and open surgical repair was performed in 11 patients. Mean follow-up was 7 months (range 1–22 months).

Results. Technical success was obtained in 44 patients (98%). One primary type I endoleak occurred (2%). ICU was used in 12 cases with a mean stay of 1 day. The mean hospital stay was 6 days (range 4–13 days). There were no hospital deaths or strokes but one transient paraplegia (2%). A type II endoleak was observed in one case and resolved spontaneously 1 month later. No aneurysm enlargement, endograft migration or structural failures were observed during follow-up. Two late unrelated-deaths were observed.

Conclusions. This stent-graft does not fulfill all the characteristics of the ideal graft, however, it proved to be safe and allowed satisfactory short term results in this group of patients treated at a single center.

Keywords: Aortic aneurysm; Thoracic aorta; Stent-graft; Endovascular.

Introduction

Few mid and long term studies on the outcome of endovascular grafting of the thoracic aorta have been reported. However, this procedure is becoming more popular for the treatment of a wide range of diseases due to its reduced invasivity especially in patients at increased risk for open surgery.^{1–5} Several factors correlate with the final outcome of the procedure including the type of disease, its extension and anatomical characteristics, the age and co-morbidities of the patient,⁶ the type of endovascular graft and the experience of the individual and of the center performing the procedure.

Since, the introduction of endovascular grafting of the thoracic aorta by the Stanford group a decade ago,^{7,8} several custom made and commercially available grafts have been used and each showed its own

peculiar advantages and drawbacks. In spite of the technological improvements the currently available grafts are still relatively primitive since they require large introducer sheaths, they are stiff and navigate poorly through the iliac and aortic tortuosities;⁹ oversizing and radial force that are necessary for sealing may damage the aortic wall. Moreover, the durability over time of both the metal and the fabric components of the grafts is a major concern. The purpose of this study was to evaluate a new commercially available stent-graft for the treatment of thoracic aortic diseases. The intra-operative performance and clinical outcome were analyzed in a series of 45 patients treated in a single center in northern Italy during 2 years.

Materials and Methods

Patient population

From January 2003 to October 2004, 45 consecutive

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patients received endovascular treatment for diseases of the thoracic aorta at our institution. Written informed consent was obtained in all cases. This series included 40 males and five females with a mean age of 73 years (range 19–86 years). Indications for treatment included disease of the descending thoracic aorta in 26 cases, of the aortic arch in 17 cases and of thoraco-abdominal aorta in two cases. Atherosclerotic aneurysms were observed in 38 cases, penetrating ulcers in two cases, chronic dissections in two cases, post-traumatic aortic rupture in two cases and one patient had esophageal, gastric and aortic injuries after ingestion of muriatic acid (27% HCl), attempting suicide. Acute dissections were not treated with this device, as advised by the manufacturer, due to the presence of a distal bare stent and proximal and distal barbs for anchoring. One patient was treated emergently for traumatic rupture of the aortic isthmus after a motor vehicle accident; the other patients were treated electively.

Procedures

Graft oversizing 10–20% in diameter was based on pre-operative spiral-CT scans (slice thickness: 0.5–2 mm); aortogram with calibrated catheters were also obtained selectively (28 cases) in patients with complex pathology, severe aortic tortuosity or involvement of supra-aortic or visceral vessels. All the patients underwent pre-operative ilio-femoral and carotid artery duplex ultrasound.

The common femoral artery was used for device insertion in 40 cases (88.9%), a retroperitoneal iliac approach was used in two patients (Fig. 1) and three patients had the device inserted through an infra-renal aortic tube graft.

Spinal anesthesia was used in 22 cases, local

anesthesia in three cases and general anesthesia in 20 cases. All the procedures were performed in the operating room, using a portable digital C-arm image intensifier with subtraction angiography and road-mapping capabilities (SIMAD Medical Technology, Modena, Italy). Trans-esophageal echocardiography (TEE) was used in six selected cases (13.6%). The contrast agent used was ioprimide (Ultravist, 300 mg/ml, Berlin, Germany) and the mean volume given during procedure was 156 ± 58 ml (range 60–370 ml). The mean time of fluoroscopy utilized was 21 min (range 5–46 min) and procedures had a mean duration of 74 min (range 42–220 min). Three patients required packed red blood cells transfusion, and the mean volume of bleeding during the procedures was 170 ml (range 110–1150 ml).

Combined or hybrid endovascular and open surgical repair was performed in 11 patients, by means of staged or simultaneous procedures. In nine cases, surgical revascularization of the supra-aortic trunks or abdominal visceral arteries was performed to obtain a neck of suitable length (de-branching of the aorta). The other two underwent combined treatment of a descending aortic and infrarenal abdominal aortic aneurysms. The left subclavian artery was covered in nine cases with no additional revascularization procedure necessary. In another patient with previous myocardial revascularization by mean of a left internal thoracic artery to left anterior descending artery, a carotid to subclavian bypass was performed before covering the subclavian artery.

Follow-up ranged from 1 to 22 months (mean 7.3) and was obtained in all patients. This was achieved with CT and chest X-ray controls every 6 months for 1 year, and then yearly.

Endovascular prosthesis

All patients were treated with the Zenith TX1 device (William Cook Europe—Denmark), which obtained the CE marking in April 2001 and is available for clinical use in Europe. The endograft consists of self-expandable stainless steel Gianturco® Z-stents and woven polyester fabric (Dacron®). An uncovered Z-stent with hooks is located at the bottom of the graft body for fixation, contained in a capsule that protects the sheath from the cranially orientated hooks during sheath withdrawal. The first proximal covered stent also has hooks. These hooks will go through the wall of the aorta thus stabilizing the graft.¹⁰ The gaps between stents vary from 5 to 10 mm depending on the diameter of the graft. The graft has four proximal and distal radiopaque gold markings for better

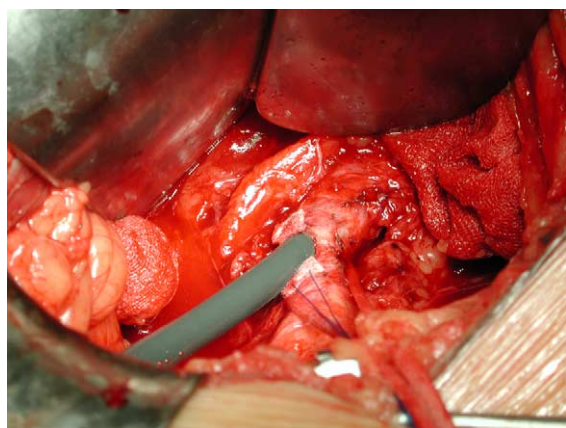


Fig. 1. Device insertion through common iliac artery by means of a retroperitoneal approach.

location in the vessel and an additional marker on each stent for visualization of twists during placement.

The introduction system has a long tapered tip that may be either straight for delivery in the descending thoracic aorta or curved for delivery in the aortic arch. The tapered tips may be 8 or 10 cm long. Shorter tips are available in custom-made devices. Endograft diameters available range from 22 to 42 mm, which need an 18–22 Fr diameter introduction system to be inserted. Deployment requires several steps: first the introducer sheath is withdrawn at this stage, however, the top of the proximal stent is still held closed by a wire, thus avoiding a parachute effect in the aortic bloodstream. The bottom-uncovered stent is also still closed, housed within a bottom cap that protects the sheath from the cranially orientated barbs during sheath withdrawal. The wires connected to the top and bottom stents need to be pulled out sequentially in order to release the stents and fully deploy the graft, the distal bare stent is released first and the proximal stent, last.

Technical details

Patients were placed in the dorsal decubitus position, and the operative field was prepared and draped permitting emergency laparotomy or thoracotomy. Cerebrospinal fluid drainage was used in six selected cases. All patients received prophylactic antibiotic therapy peri-operatively. In most cases, the common femoral artery was exposed through an inguinal incision. A bolus of heparin (70 IU/kg) was administered. The contra-lateral femoral artery was percutaneously punctured for diagnostic aortography. A stiff 260-cm-long, 0.035-inch guide wire (Lunderquist, William Cook Europe—Denmark or Amplatz, Boston Scientific Corporation, Miami, FL) or a 300-cm-long, 0.035-inch super-stiff guide wire (Back-up-Meier, Boston Scientific, Medi-Tech, Miami, USA) was advanced up to the aortic arch under fluoroscopic guidance. The stent-graft was then passed over the guide wire into the appropriate position within the descending thoracic aorta or aortic arch under fluoroscopic guidance. Additional left brachial arterial access was used in five cases. During deployment a mild systemic hypotension was induced pharmacologically by the anesthesiologist with a bolus of fast-acting venous or arterial vasodilators such nitrates or urapidil. Nitroprusside or adenosine-induced asystole were never used. After deployment of the endoprosthesis in the selected location a completion angiogram was performed. Ballooning of the stent graft proximally and distally was only required in one patient in this series.

Results

Technical success¹¹ was obtained in 44 cases (97.8%), with one (2.2%) primary endoleak discovered at the time of intra-operative completion aortography that was left untreated because the proximal aortic neck was inadequate for further endovascular procedures. Diameter of the grafts used ranged from 26 to 42 mm (mean 37 mm) and length from 100 to 230 mm (mean 143 mm). All the prosthesis were standard tubular endografts except for one custom-made endograft used to treat an aortic arch aneurysm.

ICU was required in 12 cases (patients that received a hybrid surgical-endovascular approach, one case of severe coronary artery disease) with a mean stay of 1 day. The mean hospital stay was 6 days (range 4–13 days). We recorded one case of transient paraplegia, no hospital deaths or strokes. Post-operative fever, leukocytosis, elevated CRP occurred in 14 cases and resolved in a mean of 2.5 ± 1 days. The patient undergoing complete aortic arch grafting experienced an asystolic cardiac arrest during surgery. Cardiac resuscitation was immediately performed by means of direct cardiac massage and intravenous administration of 2 mg of adrenaline. Spontaneous and effective cardiac activity was promptly restored and the procedure was completed uneventfully. The same patient experienced atrial fibrillation and pulmonary effusion, respectively, on post-operative days 2 and 3, which regressed after medical therapy. Neither arterial thromboembolism nor other cardiac, renal and major respiratory problems were recorded in the remaining patients in the early post-operative period. In the nine cases, in which the left subclavian artery was covered no clinically relevant adverse consequence was observed.

Post-operative CT scans were obtained in 44 patients and complete thrombosis was observed in all but one of the aneurysms. In one patient with renal failure post-operative thrombosis of the sac was ascertained by means of TEE. A type II endoleak was observed in one case and resolved spontaneously with aneurysmal sac thrombosis seen with CT scan 1 month later. Mean follow-up was 7.3 months (range 1–22) and two late unrelated-deaths were recorded. Aneurysm enlargement, endograft migration or structural failures were also not observed.

Discussion

Mortality and morbidity rates of thoracic aorta open repair are currently still significant in spite of the anesthesiological and technical progress made in this

field.¹² Endovascular repair has become widely accepted for treating a selected population of patients with thoracic aortic pathology, mainly due to its reduced invasiveness.^{8,13–16} Patients who require treatment are frequently elderly and have important associated co-morbidities (cardiac, respiratory, cerebro-vascular and renal diseases).¹⁷ An endovascular approach to the descending aorta can be performed under loco-regional anesthesia,¹⁸ and avoids aortic clamping and its well-known haemodynamic and ischemic complications.^{19,20}

On the other hand, in the long term, the safety and durability of the stent grafts are not clear, and also changes of aneurysm dimensions and morphology can happen. In particular, prospective studies in this field are still lacking.²¹ Several thoracic endografts are now available commercially, each with its own peculiarities, advantages and drawbacks. The Talent graft for instance is one of the most popular ones, however, ready-made grafts come in one length (115 mm) only. Due to the friction of the stents with the sheath, difficulties have been described when trying to release in angulated areas or in the arch.⁶ The endograft proximal stent is opened first during the deployment phase, which can cause a 'parachute effect'. The Excluder TAG graft has also been used worldwide with successful short-term results until November 2001; a new modified device without the longitudinal spines is now available for clinical use. This graft characteristically opens up almost instantly, the parachute effect is thus avoided, however, it cannot be positioned in an extremely precise fashion. Endofit graft was recently modified both in terms of the stent graft and the delivery system. We recently described

our experience with their first generation device for the treatment of thoracic aortic pathology.²²

Several literature reports have pointed out that serious and even fatal problems may arise from introduction of the device through the femoral artery. In particular, rupture or avulsion of the external iliac artery have been reported frequently.^{5,9,21,23} We, therefore, liberally switch to extraperitoneal surgical exposure of the common iliac artery or even the distal aorta if it is difficult to advance the device through the femoral arteries. We have found it unnecessary to anastomose a vascular graft on the vessel to facilitate introduction, as we did previously. A simple purse-string suture on Teflon pledgets is enough to guarantee hemostasis (Fig. 1). Tunneling of the sheath through the fascia and skin may avoid further tortuosity and kinks.

In this series, deployment at the intended position was possible in all cases. The endograft has very good visibility and trackability even considering the lower imaging quality that is obtained with a portable C-arm as compared with fixed equipments. Control during deployment is satisfactory since the graft is still held by the introduction system after withdrawal of the sheath. The graft system is highly flexible (Fig. 2), however, this is not the case with the introducer sheath which is relatively stiff and tends to kink in tortuous segments, therefore, sheath withdrawal may require a significant amount of force especially when the graft is delivered in the aortic arch or through an angled route. We have found that warming the tapered dilator tip with hot saline, just prior to insertion, makes it softer and helps the introducer navigate the tortuosities. The rationale for applying downward oriented hooks in the proximal stent and upwards oriented hooks in the distal one, is to avoid the proximal stent being pulled downwards and the distal stent being pulled upwards by the vector forces of the blood column flowing into the descending aorta.^{24,25} Earlier experimental experiences have shown that the displacement force needed to dislodge a graft from the aorta in the Zenith design with hooks that penetrate the aortic wall without damaging it, is significantly higher than with other stent-grafts (Talent, Vanguard, Ancure). A sutured graft-aorta anastomosis, however, was six times stronger.²⁶ Migration was never a problem in our series.

Guide wire and catheter manipulation as well as navigation of the introducer through diseased vessels, especially at the level of the supra-aortic trunks, may be responsible for distal embolization and cerebrovascular accidents.²⁷ They should be kept at a minimum and the technique should be meticulous. Earlier experience with trans-ostial placement of stainless

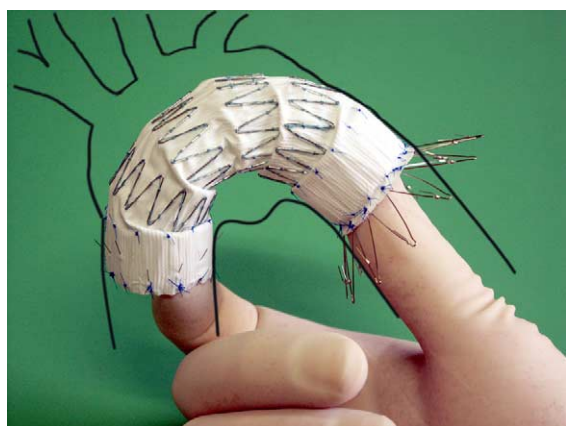


Fig. 2. The stent-graft system shows good flexibility and appears suitable to treat aortic arch pathologies. Of note the proximal covered stent with the hooks facing downwards, and the distal uncovered stent with the hooks facing upwards designed in order to prevent migration.



Fig. 3. (a) Schematic view of a complex TAAA with previous thoracic and infrarenal aortic tube-graft replacement. Note the retrograde bifurcated bypass to visceral arteries. (b) Intra-operative angiogram after endograft deployment showing patency of visceral branches. (c) Post-operative CT-scan evidencing complete thrombosis of the thoracoabdominal aneurysm.

steel wires over the renal arteries, allowed us to be fairly confident with placement of the bare stent at this level.^{28–34}

Hybrid approaches for arch and thoracoabdominal aortic aneurysms may extend the applicability of endovascular procedures in these delicate anatomical regions.^{35–37} We treated three very ill patients, unfit for traditional surgery, with hybrid endovascular procedures, avoiding more invasive open surgery approaches. Two cases of arch aneurysms were treated with previous supra-aortic trunk revascularization. In the first patient, a right common to left common carotid extra-thoracic bypass was performed. In the second one, after a median sternotomy, the ascending aorta was side-clamped, then a bifurcated bypass was performed to the innominate artery and left common carotid. The third patient submitted to the hybrid approach had a thoracoabdominal aortic aneurysm (TAAA), a frozen chest from previous thoracic aneurysm resection and a previous abdominal infrarenal aneurysm resection for rupture. A retrograde bifurcated bypass graft from the abdominal aortic graft to the visceral arteries (SMA and CT) was performed (Fig. 3). An endovascular exclusion of the TAAA extending from the mid-thoracic graft to the suprarenal aorta was then performed.

A single-stage open surgical repair for thoracic and abdominal aortic aneurysms is a subject of much controversy due to the increased surgical time and associated risks.³⁸ We treated two patients with combined open surgical and endovascular repair of infrarenal and a descending thoracic aneurysms. In both cases, the device was inserted through the infrarenal aortic graft, and the patients did well in the post-operative period.

Another topic of concern is precise endograft deployment, necessary when the proximal or distal aneurysm neck is near the supra-aortic vessels or abdominal visceral arteries. In one case, the celiac trunk was covered by the distal bare stent. Selective catheterization was used to identify the exact visceral artery location during deployment. The celiac trunk inflow was not affected by the partial ostial covering, as showed on the post-operative CT-scan. The bottom stent of this prosthesis may be very helpful for treating descending aortic pathology with short distal neck.

Two cases in this series were treated for acute post-traumatic thoracic aortic rupture. The current experience with endovascular treatment of traumatic lesions is increasing and a few cases have been described in the literature.^{39–43} More debatable⁴⁴ is the indication for another case of a young man that attempted suicide ingesting a large quantity of muriatic acid. He underwent two previous open procedures: a subtotal esophago-gastrectomy and total gastrectomy with

repair of aorto-esophageal fistula. He experienced recurrent aortic bleeding on 28th post-operative day, which was treated with endovascular deployment of the stent-graft into the supra-celiac aorta.

Endovascular thoracic stent-grafting avoids spinal cord ischemia due to aortic cross-clamping, but presents a risk of spinal cord injury due to occlusion of critical intercostal arteries covered by the endograft. In some cases, especially for lengthy aneurysms or in patients with previous aortic surgery, the blood supply to the spinal cord through collaterals may be severely affected, leading to ischemic complications.⁴⁵ Recommendations for routine prophylactic use of CSF drainage during thoracic or thoracoabdominal aortic reconstruction have been conflicting and procedure-related complication are described.⁴⁶ Nonetheless many other reports describe the benefits of CSF drainage, sometimes in combination with systemic or intrathecal drugs, and the outcome in our experience of endovascular TAA repair supports the potential therapeutic role of this manoeuvre.^{47,48} In conclusion, this stent graft proved to be safe and allowed satisfactory short term results in this group of patients treated at a single centre, including a number of cases with disease of the aortic arch.

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