A New Option for a Wider Range of Anatomies

Early EU experience with the new Zenith Alpha Thoracic Endovascular Graft.

BY PIERGIORGIO CAO, MD, FRCS, AND CIRO FERRER, MD

The technology of thoracic endovascular aortic repair (TEVAR) has rapidly improved after the early use of first-generation devices. However, not all patients with thoracic aortic disease are eligible for endovascular treatment, and selection of the patients with morphological suitability is the key to the success of the procedure. Despite the improvements in graft design and the larger availability of devices for different pathologies, critical issues with endovascular grafts remain. These include delivery system profile, graft adaptability to vessel angulation (including the aortic arch), and adequate fixation of modular components to avoid possible early or late complications such as misdeployment, collapse, or migration. Current limitations in thoracic stent grafting have recently been addressed with a new design of highly individualized, low-profile thoracic endografts.

DEVICE SPECIFICS

In 2013, Cook Medical launched a new model of thoracic stent graft in Europe, the Zenith Alpha Thoracic Endovascular Graft (Figure 1). This device offers significant improvements, such as lower profile and ease of use, and it is emerging as an optimal solution for patients presenting with challenging anatomies (eg, tortuosity of the thoracic aorta and difficult access vessels).

The Zenith Alpha Thoracic follows the Zenith TX2 Pro-Form in the Zenith Thoracic product line. Several changes were introduced in the Zenith Alpha Thoracic with respect to the previous model. The choice of a nitinol frame combined with a thinner and more tightly woven polyester fabric has resulted in a significant device profile reduction, without compromising the durability of the stent graft in terms of frame integrity and fabric porosity. It was extensively tested against the high standards of the previous generations, including material fatigue and device stability in terms of radial force, fixation, and kink resistance. These important innovations actually make the Zenith Alpha Thoracic the thoracic endograft with the lowest profile (16–20 F, depending on graft sizes) available on the market. Other notable features were also introduced: the precurved introduction system has a "candy cane" shape that hugs the inner curve of aortic arch, the more flexible stent graft accommodates a tighter inner curvature of the aortic arch (20 mm, as compared to 35 mm with the TX2 Pro-Form), the proximal bare stent improves graft conformability and provides better wall apposition, and the new delivery system adds control and precision in the deployment process, minimizing the force needed to release the stent graft.

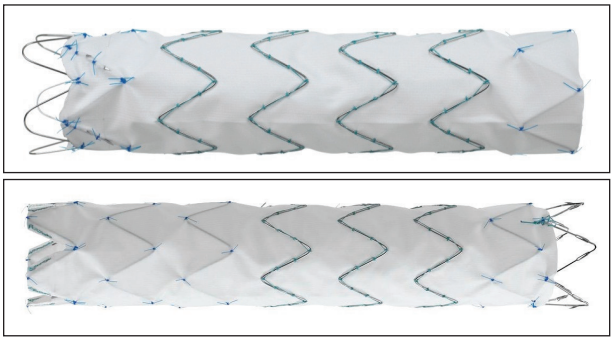

Figure 1. The proximal and distal components of the Zenith Alpha Thoracic Endovascular Graft.

FIRST EXPERIENCE

From December 2013 to August 2014 at San Camillo-Forlanini Hospital in Rome, Italy, 50 TEVAR procedures

TABLE 1. BASELINE CHARACTERISTICS

Patients	N = 22
Male	13 (59%)
Female	9 (41%)
Mean age	69.8 (49–80)
Hypertension	20/22 (91%)
CAD	7/22 (32%)
COPD	8/22 (36%)
Diabetes	2/22 (9%)
Hyperlipemia	15/22 (68%)
Previous aortic surgery • Surgery on ascending aorta + elephant trunk • Surgery on abdominal aorta • TEVAR	9/22 (41%) • 5 • 3 • 1

Abbreviations: CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease.

were performed for thoracic aortic diseases, including 14 aortic arch, 24 descending, and 12 thoracoabdominal aneurysms or dissections. Twenty-two patients in this series were treated with the Zenith Alpha Thoracic device. The baseline characteristics of these 22 patients are shown in Table 1. In four cases, Zenith Alpha Thoracic was deployed in combination with a T-branch or custom-made thoracoabdominal stent graft (Figure 2). Among the other 18 patients, half underwent a concurrent supra-aortic hybrid procedure for disease that extended to the aortic arch involving the supra-aortic trunks. All procedures were performed electively. Indications for treatment and the extent of diseases are explained in detail in Table 2.

In five cases (22.7%), a percutaneous approach was used. A catheter for cerebrospinal fluid drainage was positioned in seven patients (31.8%) according to the length of coverage of the thoracic aorta. The technical success rate was 100%. No patients died perioperatively. One case (4.5%) of transient spinal cord ischemia occurred early in a patient with a type 2 thoracoabdominal aneurysm (TAAA). No other neurological complications were recorded. In two cases (9%), the presence of narrow, highly calcified iliofemoral vessels resulted in an early iliac occlusion, which was treated with a femorofemoral crossover bypass in one case and external iliac artery stenting in the other (Figure 3).

All patients underwent a 1-month postprocedure CT scan, showing complete exclusion of the aneurysm in all but one patient, who was at high risk of spinal cord

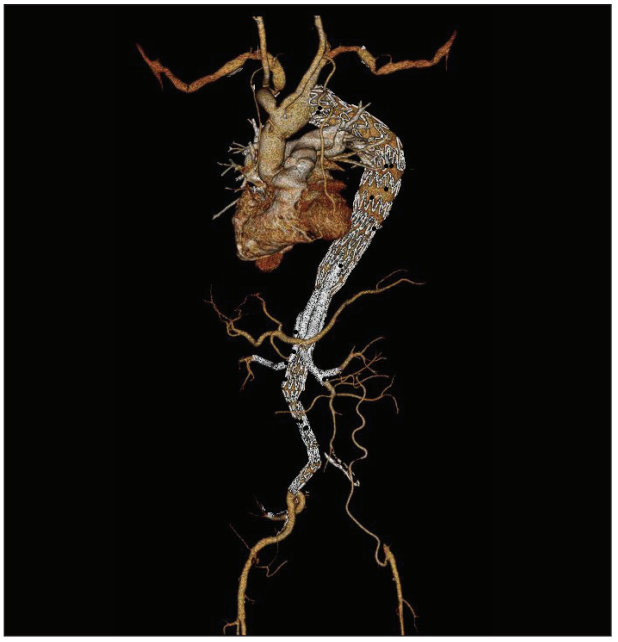

Figure 2. Two proximal segments of the Zenith Alpha Thoracic combined with a T-branch thoracoabdominal device and an aorto-uni-iliac stent graft in the treatment of a type 2 TAAA associated with an asymptomatic chronic occlusion of the left iliac axis.

ischemia with a type 2 thoracoabdominal endovascular repair, where a type 3 endoleak was intentionally created and a second stage procedure was planned. No retrograde aortic dissection was observed.

DISCUSSION

Despite the successful introduction of TEVAR as a minimally invasive option for treating thoracic aortic diseases, this approach is still associated with multiple challenges. Chief among them are access vessel complications and difficulty in conforming to tortuous aortic anatomy. The passage of large-caliber devices precludes safe transfemoral TEVAR in up to 30% of patients.[1] Modifications of the delivery systems and sheaths, including tapered tips, hydrophilic coating, device diameter reduction, and improved trackability, were made in order to overcome anatomic limitations. Published series report a 9% to 22% incidence of access complications, contributing to perioperative morbidity in patients who are often elderly and fragile.[2-4]

A recent study by Jackson et al suggested significant anatomic constraints limiting the applicability of TEVAR. In their group of 126 patients screened for TEVAR in the pivotal clinical trials of the Gore TAG (Gore & Associates) and Medtronic Talent (Medtronic, Inc.) stent grafts, 33 were rejected on the basis of

TABLE 2. INDICATIONS FOR TREATMENT AND DISEASE EXTENSION	
Indication	
Aneurysm	17/22 (77%)
Dissection (elephant trunk completion)	3/22 (13%)
Penetrating aortic ulcer	2/22 (9%)
Extent of disease	
Arch • Supra-aortic revascularization • Elephant trunk completion	9/22 (41%) • 5 (1 left subclavian artery, chimney) • 4
Descending thoracic aortic aneurysm	9/22 (41%)
TAAA (associated with a branched/fenestrated stent graft)	4/22 (18%)

morphological suitability, 10 of which (30.3%) were due to inadequate access vessels. It should be noted that in these studies, the use of conduits was allowed, implying that the rejection rate for TEVAR would have been substantially higher if only the transfemoral approach was considered.[5] Vandy and colleagues observed, in their series of 126 patients, a 12% incidence of access vessel–related complications. In a multivariate analysis, the difference between iliac diameter and sheath size, morphology score (calculated by combining tortuosity, calcification, and vessel diameter), and ankle-brachial index were identified as independent predictors of iliofemoral complications ($P = .014$, $P = .033$, and $P = .012$, respectively), with consequent higher perioperative mortality (13.3% vs 1.8%; $P = .069$).[6]

Arnaoutakis et al recently reported the outcomes of TEVAR procedures from the American College of Surgeons National Surgical Quality Improvement Program database. A total of 649 patients were evaluated in this report. The 279 women who were included were more likely to require iliac artery access when compared with men (18% vs 7%; $P < .001$), and this alternative approach was identified as an independent predictor of 30-day mortality (relative risk, 4.42; 95% confidence interval, 2.07–9.44; $P < .001$).[7] In a series of 164 patients, as reported by Lee et al, an iliac conduit resulted in a 2.6-fold increase in blood loss, 82% longer procedure time, 1.5 additional hospitalization days, and a 1.8-fold higher rate of perioperative complications.[8] In our first experience with the Zenith Alpha Thoracic device, all procedures were performed through a femoral access, with only two access-related complications, both immediately treated without further complications. The Zenith Alpha Thoracic device has proven to navigate well through complex anatomies, extending the applicability of TEVAR to patients who were previously denied from endovascular treatment.

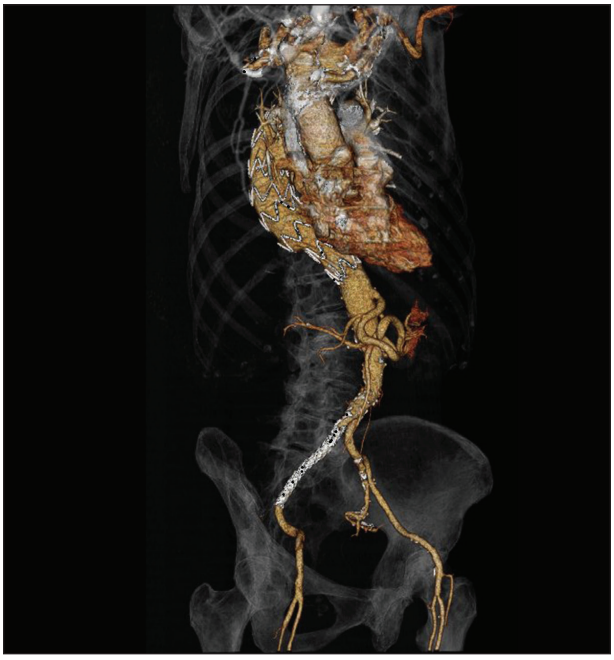

Figure 3. External iliac artery stenting after TEVAR in a patient with TAA and a right-sided arch.

Another critical issue in thoracic endografting is to ensure proximal sealing and stent graft conformability to the aortic wall, especially when the disease includes angulated and tortuous aortic segments. Several authors investigated the incidence and the possible factors associated with graft-to-wall malapposition. Melissano and colleagues, in their experience with the Zenith TX2 Pro-Form, defined a significant malapposition (so-called bird-beak sign) as the protrusion of the proximal edge of the stent graft 5 mm into the aortic lumen. In their

series of 27 patients, the bird-beak sign was observed in only one case, in which an inadequate apposition of stent graft to the inner curvature of the arch was recorded in an acutely angulated aorta.[9] The bird-beak phenomenon may be responsible for major complications after TEVAR, such as type I endoleak and stent graft collapse.[10,11] Factors proposed to be associated with an increased risk for the bird-beak sign include anatomical features of the aortic arch, as well as characteristics of thoracic stent grafts.

Current developments in thoracic endografting follow the concept that better stent graft conformability is important for a correct graft-to-wall apposition. The force generated by a straight stent graft in seeking to return to its original configuration may contribute to the bird-beak effect in angulated anatomies. As a consequence, the use of less-rigid devices with a lower reset force would result in better proximal graft apposition, which can be further improved with the use of a proximal bare stent. This configuration is less frequently associated with a significant bird-beak phenomenon and stent-graft collapse, although potentially lethal complications (eg, retrograde dissection and aortic perforation) were described.[12,13] In Zenith Alpha Thoracic, the rounded apices of the proximal bare stent help to reduce the load and redistribute it uniformly on the aortic wall, thus minimizing the risk of aortic trauma.

The Zenith Alpha Thoracic Endovascular Graft combines the successful features of the previous model with the newest innovations in terms of fixation and conformability. The radial force of the frame associated with anchoring barbs provides an optimal graft-to-wall apposition. The self-expanding nitinol stents and the proximal bare stent are shorter than the previous model, providing the stent graft with a remarkable flexibility that mimics the natural anatomy of the thoracic aorta. Furthermore, an internal releasing wire system controlled by a rotating handle makes the deployment extremely precise. The proximal bare stent is able to open in an ideal position, requiring the Pro-Form technology only in the largest graft diameters. In our experience with Zenith Alpha Thoracic, no type I endoleaks were detected, and no bird-beak signs were observed on postoperative CT scans.

CONCLUSION

Technological innovation is crucial for successful TEVAR and further expansion of the indications already achieved with previous stent graft generations. The small caliber and low profile of the Zenith Alpha Thoracic Endovascular Graft allows ease of progression and precise deployment in difficult native anatomies, potentially decreasing the occurrence of perioperative adverse events. ■

Piergiorgio Cao, MD, FRCS, is Chief of Vascular Surgery, Azienda Ospedaliera S. Camillo-Forlanini in Rome, Italy; and Professor of Vascular Surgery, University of Perugia. He has disclosed that he receives speaker fees, research grants, or consulting fees from Bolton, Cook Medical, Gore & Associates, and Medtronic. Dr. Cao may be reached at piergiorgio.cao@gmail.com.

Ciro Ferrer, MD, is with the Unit of Vascular Surgery, Azienda Ospedaliera S. Camillo-Forlanini in Rome, Italy. He has disclosed that he has no financial interests related to this article.

Disclaimer: The Zenith Alpha Thoracic Endovascular Graft is an investigational device in the United States and is limited by United States law to investigational use. It is CE Mark approved only for the indication of endovascular treatment of patients with aneurysms and ulcers in the descending thoracic aorta having vascular morphology suitable for endovascular repair.

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