

Endovascular

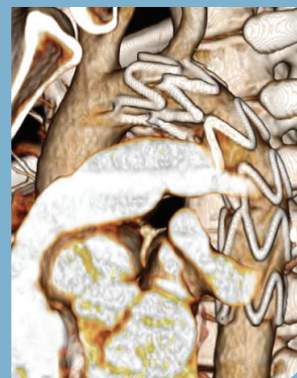
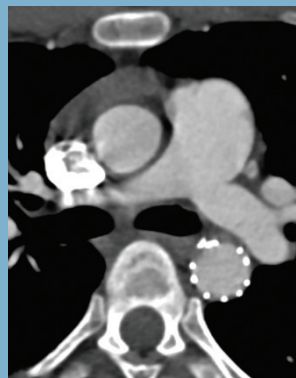
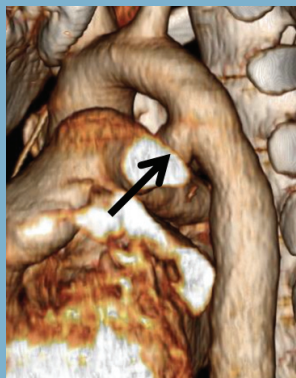
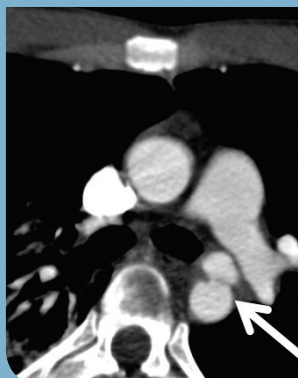
EUROPE

TODAY

Volume 2, No. 6

THE NEXT CHAPTER IN TEVAR

MOVING TECHNOLOGY TOWARD PATIENT NEEDS



Tilo Kölbel, MD



Eric E. Roselli, MD



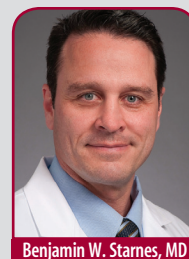
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The Next Chapter in TEVAR

An introduction by Nicky James, Vice President and Global Business Unit Leader of Aortic Intervention at Cook Medical, and a discussion with Tilo Kölbel, MD, PhD, from Hamburg, Germany, about his vast experience with TEVAR and the challenges we face today.

We've come a long way since the first thoracic endovascular aortic repair (TEVAR) procedure in 1992.¹ Gone are the days of questioning whether open surgery is a more viable option for etiologies like aneurysms, ulcers, and transections. Equipped with a better understanding of the progressive nature of aortic disease, our approach to endovascular repair (and specifically TEVAR for this issue) must continue to evolve in order to meet the clinical needs of the patients.

We continue to ask ourselves how the technology can deliver a more durable repair to more patients. Can we improve outcomes with a smaller-bore delivery system? How do we treat emergent cases with TEVAR? How do we lower the incidence of stroke/ischemia? What do we do with patients who present with smaller access vessels and tortuosity?

In this supplement, we explore some of these key TEVAR questions, the factors that need to be considered, and the decisions that need to be made to provide the most durable repair possible. To bring these issues to light, we have asked a group of experienced cardiovascular surgeons to share their thoughts and experiences to help further our understanding of the treatment options. Eric E. Roselli, MD, lays the groundwork in "Why Do TEVAR Grafts Fail?" by discussing where and when thoracic grafts fail, as well as the causes. Next, Piergiorgio Cao, MD, and Ciro Ferrer, MD, highlight the challenges of tortuosity and smaller access vessels and how the new Zenith Alpha thoracic device (Cook Medical) has addressed those issues in "A New Option for a Wider Range of Anatomies." Michael C. Moon, MD, then discusses "The Benefits of Utilizing a Low-Profile TAA Device." And finally, in "Treating Trauma," Benjamin W. Starnes, MD, presents case studies in which patients with blunt force injuries are treated via TEVAR.

As an introduction to this supplement, we wanted to hear the perspective of Professor Tilo Kölbel, whose extensive experience sets the context for today's challenges with TEVAR.



Tilo Kölbel,
MD, PhD

Professor Kölbel, with the availability of thoracic stent grafts, more aortic etiologies are being treated by TEVAR. Where do you think TEVAR has shown the most benefit over open repair?

In recent years, TEVAR has become the unquestioned gold standard for the treatment of aortic pathologies

of the descending thoracic aorta, including aneurysm, dissection, and trauma. The advantages of TEVAR—less invasiveness, instant availability, and rapidity—take fullest effect in the treatment of ruptured aortic pathologies such as transection or ruptured aneurysms. With the quick procedure time, the option of local anesthesia, and no need for cardiopulmonary bypass (with necessary but potentially disastrous heparinization) have substantially decreased morbidity and mortality and enabled treatment in a group of patients who would not have survived open surgical techniques. Patients of older age

and with comorbidities now have a realistic chance to survive a procedure with the use of thoracic endografts.

Another group of patients with a specific advantage are those who have undergone previous surgery; these patients combine the advantage of avoiding repeat sternotomy or thoracotomy, which multiplies open surgical risks, with the fundamental advantage of achieving a safe landing zone in the preexisting surgical graft. This becomes even more distinct in patients after previous surgery with genetic connective tissue disorders like Marfan syndrome or Loeys-Dietz syndrome. The role of endovascular repair in these high-risk patients with fragile aortic tissue is not yet defined, and I am convinced that we will see an increased utilization of endovascular techniques in the future.

What excites you most about the technology (ie, thoracic stent grafts), and what realities do you still find sobering?

Endovascular techniques for the treatment of aortic pathologies are still in their early infancy, and I am

extremely excited to know that we will see substantial changes in techniques and device technology during the coming years. The materials and techniques we use today to produce endovascular grafts could essentially have been used 60 years ago. Basically, metal springs are hand-sewn onto polyester tubes and loaded into delivery sheaths. Of course, there is a lot more technology in today's grafts and their delivery systems, but this might not be obvious at first sight and is sometimes difficult to appreciate as a user. All the changes to the endografts, delivery systems, and loading techniques have massively improved their performance during the 25 years of commercial endograft development. Still, the basic appearance and principles remain the same in current-generation endografts, with few exceptions including the polymer technologies used in recently launched endografts.

These new technologies will need to prove their safety and effectiveness in the long-term and have not yet been explored in the thoracic aorta at all. To get a glimpse into the future, we can take out our smartphones and look at the technology put into these little high-tech boxes. There is so much more to come in device technology and operating techniques in the coming years.

The most sobering fact about stent graft technology for me is the limited availability of proven devices around the world. The European Union appears as a land of bliss with regard to device availability, and we tend to forget when presenting at overseas meetings that the majority of vascular specialists and their patients around the world lack access to endografts and the adjuncts needed for their implantation.

Are we, as clinicians and industry, addressing the needs of the world's thoracic aortic disease patients? What do you see as unmet needs?

Almost all approved thoracic endografts have been certified for aneurysmal disease only. It is a clear necessity in the future to address the needs of other thoracic pathologies besides descending thoracic aortic aneurysm and to include these pathologies in the regulatory process. The practice of physicians using endografts has developed far beyond the intended use with current approval. The treatment of aortic dissection and transection with aortic endografts has become daily practice and should not be considered off-label use going forward. The different requirements of pathologies treated and the increasing utilization of endografts should grant the development of disease-specific devices incorporating these demands.

The most important unmet need in TEVAR, from my perspective, is the unchanged high rate of cerebrovascular

complications in up to 10% of patients treated with some devices. This significantly restricts endovascular treatment success despite all of the obvious advantages of endografts and should be addressed with the highest priority by interventionists and industry!

Once you've decided on a course of therapy, are you always able to get your device into place?

With all the access techniques that we have in our armamentarium today, like conduits, endoconduits, through-wires and alternative access routes, we hardly fail to get a device into place, even if it requires, for example, a 24-F access as in large fenestrated arch grafts with preloaded catheters. The reduced device profile and improved trackability of newer-generation endografts and modern imaging systems have further contributed to the fact that we rarely need to reject patients from treatment, even when they have very tortuous aortas. I expect devices of the next generation to improve the trackability further with new materials for the delivery components that allow for a better balanced allocation of stiffness throughout the length of the device.

However, this doesn't imply that we are always successful with our treatment, as there are a number of potential difficulties, especially with positioning fenestrated and branched devices and getting access to target vessels. There has been significant advancement in the planning of procedures based on the experience of interventionists worldwide and of the company specialists. The body of knowledge about what anatomy is best treated by which technique is constantly increasing and is a great example of fruitful collaboration of industry and physicians for the benefit of our patients.

What do you think TEVAR devices will look like in 5 years? 10 years?

TEVAR has proven to be a treatment option for all segments of the aorta. With branched and fenestrated techniques in the aortic arch, as well as debranching operations, TEVAR has conquered significant territory but is still considered inferior to open surgery in the aortic arch and the ascending aorta and therefore is reserved for high-risk patients. I predict that this will change within the coming 10 years for aortic arch pathologies, as we already have devices that allow endovascular treatments starting from the sinotubular junction in the ascending aorta.

However, outcomes of endovascular treatments of the complete aortic arch are still limited by adverse events.

Morbidity and mortality need to be significantly reduced to allow further enforcement of these techniques. Safety is the key issue, and I am convinced that we can reduce the adverse event rate for these complex treatments of the aortic arch to under the 5% margin. Device modifications, deployment steps, and changes in the operating and monitoring techniques will allow us to overcome current limitations, and I am strongly convinced that this can only work in an environment of interdisciplinary collaboration with cardiovascular surgery and anesthesia.

With what is known today, what would you consider to be durable repair in the thoracic aorta?

A durable solution needs to be determined on an individualized basis, as the requirements for durability differ greatly among our patients. A 25-year-old patient with Marfan syndrome requires durability for a lifetime, whereas some of our older patients are well-treated with an endovascular solution that lasts until another life-limiting disease or event strikes. Sometimes, an endovascular solution may only need to last for weeks or months to get the patient out of an acute situation and provide a treatment bridge to a more durable repair. This is the case, for example, in patients with aortic ruptures or type A aortic dissection. So, the question of durability cannot be

answered collectively because of the variety of patients and diseases that we treat in the thoracic aorta. We have learned over the past 20 years that the key to a durable repair is generally the presence of a parallel-walled and nondilated landing zone, as this indicates healthy aortic wall. Given the progressive nature of aneurysmal disease, durability can only have a relative meaning because this healthy-looking aortic segment, in which we ideally choose for our endograft to land, will become diseased at a later stage. So, given this progressive nature, the best durability we can achieve is a treatment that allows for future options in extending the repair further proximal and distal into less-diseased aortic segments. Durability emerges if we calculate the natural progression of the disease in our patients and ensure a “next-step” option for treatment.

Thank you very much, Professor Kölbel for sharing your insightful thoughts on the technology.

Tilo Kölbel, MD, PhD, is with the Department of Vascular Medicine, University Heart Center in Hamburg, Germany. He has disclosed that he is an intellectual property holder of Cook Medical and has also received research and travel grants. Prof. Kölbel may be reached at t.koelbel@uke.de.

In the articles to follow, I think you will find some commonalities with Professor Kölbel's response. In considering the next chapter of TEVAR, as an industry, we must continue to challenge ourselves to deliver the best possible patient outcomes. We still have a lot to learn, and we'd like to talk about it.

The intent of this Endovascular Today supplement is to engage you in what's relevant in today's TEVAR conversation. At Cook Medical, we acknowledge the progressive nature of aortic disease and are working hard to find solutions that help you deliver durable repairs. We will always strive to be the responsible partner that you expect. We hope you find this supplement both useful and informative. ■

*Thank you,
Nicky James
Vice President, Cook Medical
Global Business Unit Leader, Aortic Intervention*

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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Why Do TEVAR Grafts Fail?

The Cleveland Clinic experience in treating serious complications that can occur after TEVAR.

BY ERIC E. ROSELLI, MD



In the 15 years since stent grafting has been applied to the treatment of thoracic aortic disease, devices have improved, and indications for use have expanded. Thoracic endovascular aortic repair (TEVAR) has become the preferred treatment option

for most descending disease, including aortic dissection. However, it is more common for thoracic aortic disease to involve the proximal aorta or multiple segments of the aorta than to be isolated to the descending aorta. Without disease-specific devices for treating the proximal aorta, operators have increasingly pushed the limits of use with commercially available devices.

The expanded use of TEVAR has also led to a greater appreciation for late complications. Some of the most serious complications, including retrograde aortic dissection and type I endoleak, can be life threatening and often require urgent conversion to open repair. Although technically feasible, TEVAR for chronic aortic dissection falls short of achieving the intended reverse aortic

remodeling in up to one-third of patients. Usually, this is due to persistent retrograde false lumen flow from distal entry tears. Both endovascular and open solutions have been successfully used to address these late failures. Finally, all patients with prosthetic endovascular devices are at risk for device infection. Depending on the source and severity of infection, this dreaded complication might require open surgical conversion with stent graft explantation.

The multidisciplinary aortic surgical team at the Cleveland Clinic has substantial experience in treating all of these very serious complications following TEVAR, many of which have required conversion to open repair.¹ This article reviews that experience, including outcomes and important lessons learned.

STENT GRAFT INFECTIONS

Severe graft infection represents the most complex indication for conversion to open repair after TEVAR. In our published experience with six of these patients, half of them died from intermediate complications. If

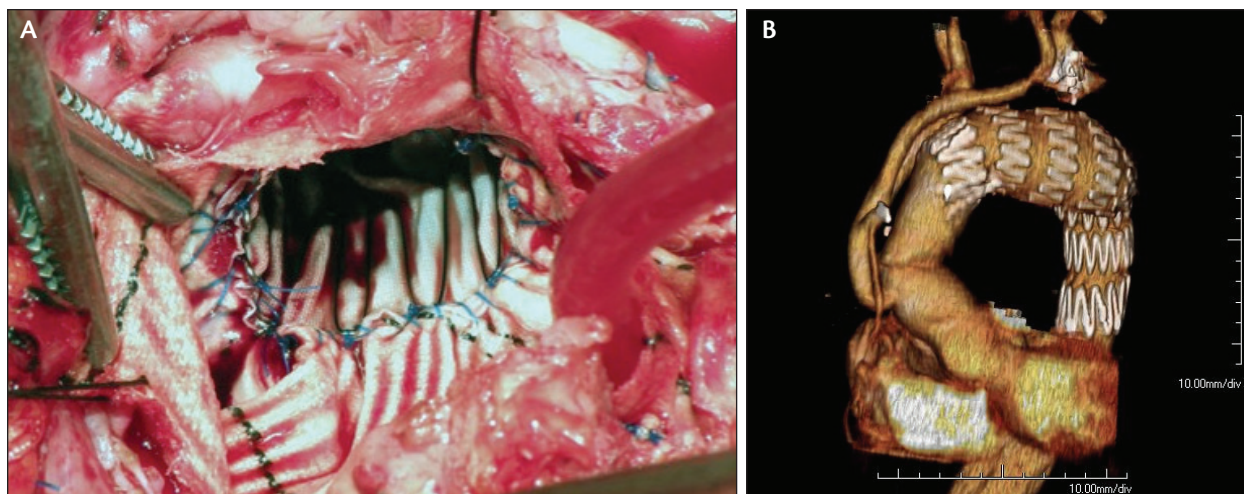


Figure 1. Proximal open thoracic aortic repair after TEVAR using a “reverse frozen elephant trunk” approach. An intraoperative photo (A) showing the stent graft in the arch being sutured to the surgical graft proximally, as well as a postoperative volume-rendered CT reconstruction (B).

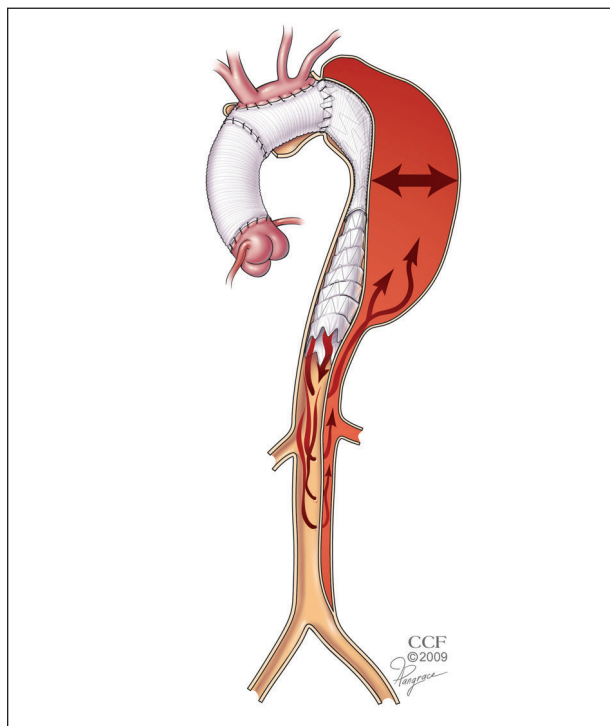


Figure 2. An illustration depicting retrograde false lumen perfusion after TEVAR for chronic dissection. Reprinted from *The Annals of Thoracic Surgery*, 92, Roselli EE, Sepulveda E, Pujara AC, et al, Distal landing zone open fenestration facilitates endovascular elephant trunk completion and false lumen thrombosis, 2078-2084, Copyright (2011), with permission from Elsevier.

the infection has not compromised the integrity of the aorta and the imaging does not demonstrate obvious air around the device, we first try to manage these patients medically. If the infection is due to a process occurring in the periphery of the lung, it can usually be treated with the placement of additional stent grafts to control hemoptysis and prolonged organism-specific intravenous antibiotics followed by oral antibiotics, sometimes for life. If the esophagus or more central airways are involved, then the infected devices must be removed to control the infection, and this usually needs to be done urgently. If the patient is young and can tolerate a multistaged repair, then they may stand a chance at survival with a clear plan for extra-anatomic bypass, debridement of the infected field (which may include esophagectomy and diversion), and later, reconstruction.²

TYPE I ENDOLEAKS

Type I endoleak is one of the most common indications for secondary surgical intervention after TEVAR. In our series of 50 open reoperations after

TEVAR, 19 (38%) were for type I endoleaks. These may be proximal (14 of 19 in our series) or distal type I endoleaks (5 of 19 in our series). In a retrospective review of the imaging at the Cleveland Clinic, all of these patients had shorter-than-recommended landing zones or another use of the stent graft that was considered off-label.

Proximal type I endoleaks are often treatable with proximal endograft extension. This usually requires coverage of the left subclavian artery with pre-emptive left subclavian artery revascularization. If this approach does not provide an adequate landing zone, we have also used an open conversion strategy.

One option for patients with proximal endoleak is to transpose or debranch the arch by creating bypasses originating from the ascending aorta, extending the endovascular repair more proximally into the arch or distal ascending aorta. The stent graft may be delivered in a retrograde or an antegrade fashion.³ Although we have performed this procedure in select patients, several authors have demonstrated that this is still a high-risk procedure, with a significant risk of persistent endoleak or retrograde dissection in up to 11% of patients.⁴

More often, we have chosen to convert these patients by using the “reverse frozen elephant trunk” operation (Figure 1). This is performed using cardiopulmonary bypass, hypothermic arrest, and selective antegrade brain perfusion via cannulation of the right axillary artery with a side graft.⁵ Once the distal circulation is arrested, the arch is opened, and the previously placed stent graft may be directly sutured into the aortic arch. If the old stent graft is too distal in the aorta for direct suturing, then an additional device may be added to bring the repair more proximal and facilitate direct suturing. Typically, the more proximal aorta is replaced with an interposition graft because patients with arch aneurysms usually have some underlying ascending aortopathy as well.

PERSISTENT FALSE LUMEN PERFUSION IN CHRONIC DISSECTION

The use of stent grafts to treat chronic dissections in the setting of an aneurysm is currently controversial because of the uncertainty of thromboexclusion of the false lumen (Figure 2).⁶ An increasing body of data suggests that the rate of false lumen thrombosis in the treated segment is approximately 70% and may be predicted by the extent of aorta dissected.^{7,8} If the endovascular therapy does not achieve the desired reverse remodeling, then the patients can safely be converted to a hybrid distal reconstruction.¹ This indication for open conversion represented one-third of the cases in our series. In that regard, TEVAR and open repair should be considered complementary options for the treatment of patients with chronic aortic dissection



Figure 3. A volume-rendered three-dimensional reconstruction CT scan demonstrating open repair post-TEVAR of a type 2 thoracoabdominal aortic aneurysm. Reprinted from *The Annals of Thoracic Surgery*, 97, Roselli EE, Abdel-Halim M, Johnston DR, et al, Open aortic repair after prior thoracic endovascular aortic repair, 750–757, Copyright (2014), with permission from Elsevier.¹

and aneurysm (Figure 3). As such, we will explain to our patients who are undergoing TEVAR for chronic dissection that the chances of them needing a later open repair may be as high as 25% to 30%.

RETROGRADE DISSECTION

This is an increasingly recognized and significant complication of TEVAR. In a large review, the incidence was nearly 2% and 3% to 8% in patients who were treated with TEVAR for chronic and acute aortic dissection, respectively.⁹ We reviewed our experience with retrograde dissection, and nearly all of the cases in this series occurred in patients with a history of previous aortic dissection. The key to saving these patients is timely diagnosis and transfer to a center where the techniques of hypothermic circulatory arrest are commonly practiced.

In our series of 15 patients, one died soon after arrival to the emergency department because she did not arrive in time to get to the operating room. The other 14 were treated with reverse frozen elephant trunk repair, with excellent

results (there were no deaths, two patients with respiratory failure, and no strokes, renal failure, or spinal cord injuries).¹⁰

CONCLUSION

The precise denominator is unclear because many of our patients who required conversion to open repair after TEVAR had their initial procedure at another institution. In our experience with more than 1,400 TEVAR procedures, a very small number (< 3%) have required conversion to open repair.

Although hospital survival has been good in our experience with open conversion after TEVAR, late survival was less than favorable, and 42% of patients required additional operations. Many of the late open and endovascular operations were performed for progression of aneurysmal degeneration either related to the presence of a chronic dissection or a known connective tissue disorder consistent with the progressive nature of extensive aortic aneurysmal disease.

Conversion to open repair after thoracic stent grafting may be indicated for type I endoleak, retrograde dissection, chronic aortic dissection with persistent false lumen perfusion and growth, or graft infection. These salvage operations are complex but can be completed safely with good early outcomes and preservation of the stent graft (hybrid repair) in most cases. Late outcomes are consistent with the chronic disease state of these patients. ■

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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

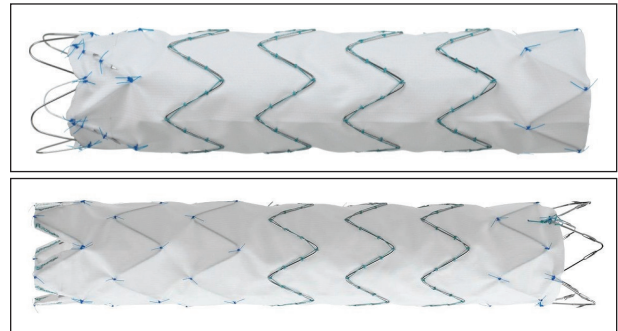


Figure 1. The proximal and distal components of the Zenith Alpha Thoracic Endovascular Graft.

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.

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	9/22 (41%)
<ul style="list-style-type: none"> • Surgery on ascending aorta + elephant trunk • Surgery on abdominal aorta • TEVAR 	<ul style="list-style-type: none"> • 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

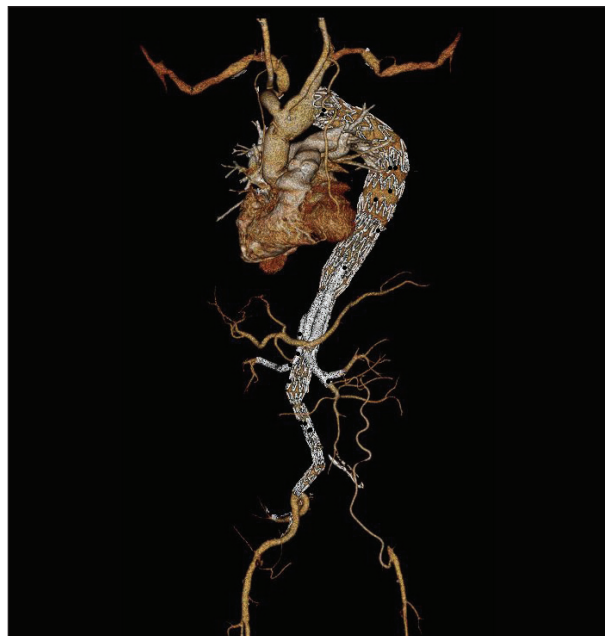


Figure 2. Two proximal segments of the Zenith Alpha Thoracic combined with a T-branch thoracoabdominal device and an aorto-uni-iliac stent graft in the treatment of a type 2 TAAA associated with an asymptomatic chronic occlusion of the left iliac axis.

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	9/22 (41%)
<ul style="list-style-type: none"> • Supra-aortic revascularization • Elephant trunk completion 	<ul style="list-style-type: none"> • 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



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

of TEVAR to patients who were previously denied from endovascular treatment.

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. ■

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The Benefits of Utilizing a Low-Profile TAA Device

Factors that make the low-profile Zenith Alpha Thoracic aortic aneurysm device more useful than a standard abdominal aortic aneurysm device.

BY MICHAEL C. MOON, MD



Advances in stent graft technology have permitted the treatment of an increasing number of aortic pathologies, both with off-the-shelf devices and with custom devices (fenestrated and branched devices). The regions of the aorta that

can currently be addressed in an endovascular manner extend proximally from the ascending aorta and the aortic arch (custom/special access devices), down through the thoracoabdominal aorta, to below the aortic bifurcation (custom/special access and off-the-shelf devices). Despite the availability of countless custom fenestrated and branched configurations, as well as the use of multiple separate stent graft pieces, the limiting factor in the ability to treat patients with aortic pathology is the size of their access vessels.

All manufacturers of endovascular technology are striving to reduce the external diameter of the delivery system, whether the aim is to treat peripheral arterial disease, aortic valve stenosis, or aortic pathology. The technological challenges of developing a low-profile system hinge on the ability to load a device into a small introducer while still yielding robust radial force for a durable seal and maintaining trackability and pushability at the same time.

BENEFITS OF A LOW-PROFILE TAA DEVICE

The aorta is largest proximally in the ascending segment and tapers as it approaches the aortic bifurcation. The inherent smaller size of the infrarenal abdominal aorta has required the delivery system of abdominal aortic aneurysm (AAA) devices to be small in diameter. The original Zenith infrarenal AAA stent graft (Cook Medical) had a delivery system between 18 to 22 F (outer diameters of 7.1–8.5 mm), and thus the minimal vessel size through which the standard Zenith stent graft could be delivered was 7.1 to 8.5 mm. Even with the smaller stent grafts used to treat infrarenal

AAAs, there is a need to reduce the size of the delivery system. The resulting Zenith LP Abdominal device (Cook Medical), with a 16- or 17-F delivery system, can now treat patients with access vessels as small as 6 to 6.5 mm in diameter.

Stent grafts aimed at treating thoracic aortic aneurysms (TAAs) require larger-diameter devices because of the inherent larger proximal and distal landing zones. In many cases, this poses technical challenges due to the size of the access vessels by requiring iliac conduits or access to the distal abdominal aorta. Similar to the driving forces resulting in smaller infrarenal stent grafts, the design of the low-profile Zenith Alpha Thoracic device (Cook Medical) allows for treatment of TAAs in patients with smaller access vessels. The Zenith Alpha Thoracic device, with a 16- to 20-F delivery system, can be delivered through vessels as small as 6 to 7.7 mm while permitting treatment of aortas with diameters ranging from 15 to 42 mm.

The new low-profile Zenith Alpha Thoracic device has the ability to be delivered through access vessels as small as 6 mm, yet maintains the same pushability as the standard Zenith TX2 device (Cook Medical) and with superior trackability. As illustrated in the following three cases (Figures 1 through 3), the Zenith Alpha Thoracic device permits the treatment of aortic pathology that the standard Zenith TX2 could not easily treat.

THE CASE FOR A LOW-PROFILE TAA DEVICE OVER A AAA DEVICE

The benefit of a low-profile TAA device is greater than a low-profile AAA device because of the inherent larger diameters of the thoracic aorta than the abdominal aorta. The larger-diameter landing zones of the thoracic aorta require larger stent grafts, and thus the larger delivery systems and larger femoral and iliac artery

CASE STUDIES

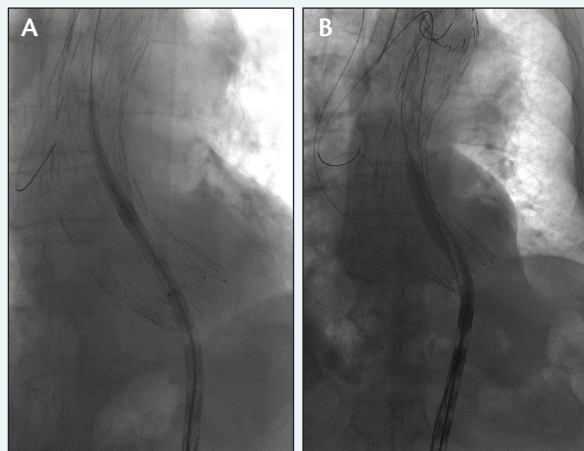


Figure 1. The Zenith Alpha Thoracic device (A) was able to negotiate a tortuous aorta that the Zenith TX2 (B) could not.

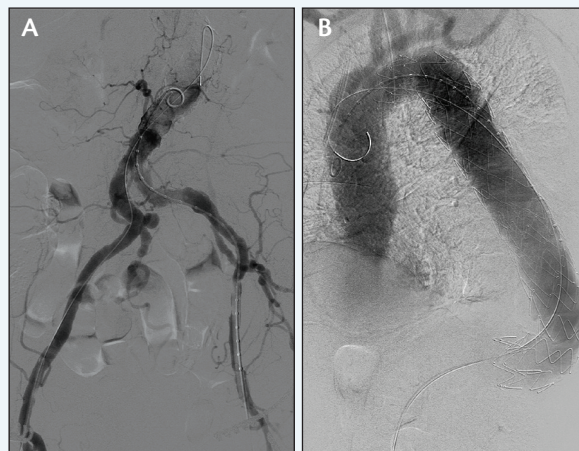


Figure 2. Vascular access (A) and deployment (B) of the Zenith Alpha Thoracic device in a patient who was unsuitable for a standard-profile device due to small access vessels.

CASE 1: TORTUOSITY

In a patient who had a TAA with significant tortuosity, a staged procedure was planned. The first Zenith Alpha Thoracic device was able to navigate the tortuous aorta easily, but we were unable to navigate the second standard-profile Zenith TX2 device around the angle (Figure 1). The second-stage procedure was to be completed at a later time.

CASE 2: SMALL ACCESS

In a patient who had small vascular access, the Zenith Alpha Thoracic device was able to negotiate easily and was successfully deployed (Figure 2).

CASE 3: TIGHT ARCH

In a patient who had a small-sized thoracic aorta with a tight arch, the Zenith Alpha Thoracic device was successfully deployed, with good conformance to the aorta (Figure 3).

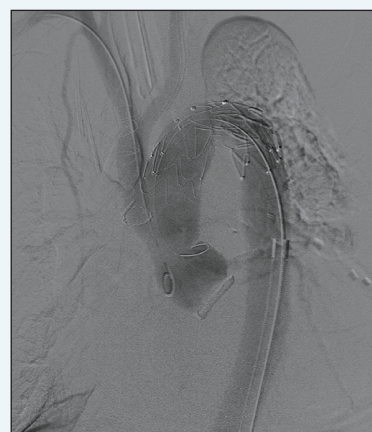


Figure 3. A Zenith Alpha Thoracic device was deployed in a small and tortuous thoracic aorta with good conformance.

diameters. In patients with small access vessels, this may mandate the need for an iliac artery conduit or access to the abdominal aorta in order to be able to deliver the stent graft. Additionally, in patients with adequate native iliac and femoral artery diameters but having atherosclerotic disease and/or calcification, the ability to deliver a standard-profile TAA device may not be possible.

The current smaller diameters of stent graft delivery systems meant for the treatment of AAA pathology can be used to navigate the femoral and iliac arteries in most patients, but the larger diameters of the delivery systems designed for TAA pathology will often preclude an

endovascular option. In these cases, balloon angioplasty or vessel dilation with the use of dilators may permit the use of a standard-profile device, but this is not always possible. Thus, a low-profile TAA device, such as the Zenith Alpha Thoracic device, will allow patients with thoracic aortic pathology and femoral and iliac arteries of smaller diameters to still be appropriate candidates for an endovascular intervention.

DISCUSSION

As demonstrated in the previous cases, the Zenith Alpha Thoracic device has maintained the characteristics of the standard-profile Zenith TX2 while being packaged

in a smaller delivery system. The delivery system continues to have great pushability, and with a lower profile, offers unparalleled trackability. The redesigned mechanism to release the trigger wires has eliminated the need for the application of high deployment forces. In highly tortuous aortas, the release of the original trigger wires often required a coordinated effort from two operators and the application of high forces. The new Zenith Alpha Thoracic trigger wire release is now a single-operator job that is effortless and allows for precise maintenance of the stent graft position.

With the low-profile delivery system, excellent pushability and trackability, and an improved trigger wire release, the new Zenith Alpha Thoracic device is ideal for the treatment of TAA pathology, particularly in patients with smaller access vessels. These features make the Zenith Alpha Thoracic an excellent device to consider

when treating women and patients of Asian descent, as both groups are noted to have difficulties with vascular access. ■

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Treating Trauma

Case studies and early experience with the Zenith Alpha Thoracic Endovascular Graft for treatment of blunt aortic injuries.

BY BENJAMIN W. STARNES, MD, FACS



Dramatic improvements have been made in the care of patients harboring vascular disease over the past 2 decades. Much of this progress has been made on the back of new device design. In 2008, the American Association for the Surgery of Trauma

published results on emerging trends in the management of blunt aortic injury (BAI) and stated that, "There is a major and urgent need for improvement of the available endovascular devices."¹ Industry responded to this call for better device design with improvements that have finally arrived. In 2010, I was invited by Cook Medical to serve as Principal Investigator for TRANSFIX, the national multicenter clinical trial evaluating the Zenith TX2 low-profile endovascular graft (now called Zenith Alpha Thoracic) for the management of patients presenting with BAI. The following is a description of a few cases using this device to manage severely injured patients with aortic injury.

DISCUSSION

The Zenith Alpha Thoracic device offers what amounts to a great breakthrough in managing patients with BAI. The low-profile, hydrophilic, braided sheath delivery system; precurved inner cannula (Figure 1); and nitinol-based stent design provide for unparalleled opportunity to treat a wide variety of patients. With the lowest treatable aortic diameter (15 mm), lowest arch radius indication (20 mm), and smallest-diameter

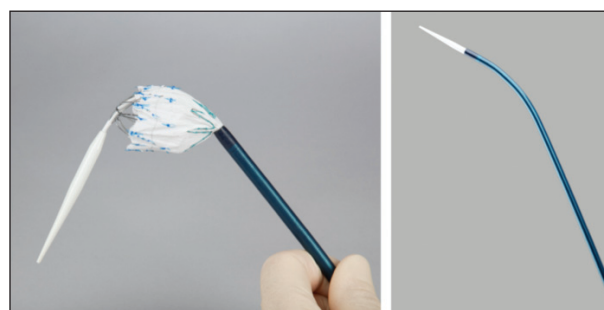


Figure 1. The precurved inner cannula.

delivery system (16 F), more patients can be treated with this newer-generation device. A comparison of Zenith Alpha Thoracic with its predecessor, Zenith TX2, is depicted in Table 1.

TRANSFIX TRIAL DESIGN AND SHORT-TERM RESULTS

Fifty patients were enrolled into the prospective, nonrandomized TRANSFIX trial between January 2013 and May 2014. Patients in the trial will be followed through 5 years. The primary safety endpoint is 30-day mortality, and the primary efficacy endpoint is 30-day device success. As presented at the 2014 annual meeting of the Society for Vascular Surgery, technical success was achieved in all patients (100%), and there were no intraoperative mortalities. Short-term results indicate that the Zenith Alpha Thoracic device appears safe and

TABLE 1. COMPARISON OF ZENITH ALPHA THORACIC VERSUS ZENITH TX2 CHARACTERISTICS

Characteristics	Zenith TX2	Zenith TX2-LP (Zenith Alpha Thoracic)
Introducer sheath size	20–24 F	16–20 F
Device diameter size	22–42 mm	18–46 mm
Aortic arch radius	> 35 mm	≥ 20 mm
Stent strut metal, shape	Stainless steel, Z	Nitinol, Z
Graft material	Standard Dacron	Thinner, more tightly woven Dacron
Fixation	Covered, proximal	Bare, rounded proximal

CASE STUDY

Figures 2 through 7 are a compilation of CT images obtained from six patients who were enrolled into this trial at the author's institution between June 2013 and May 2014. All of these patients experienced blunt force trauma to the thoracic aorta by way of differing mechanisms. The images are arranged such that the preoperative axial slice (panel A) and three-dimensional reconstruction (panel B) are paired and compared with the postoperative axial slice (panel C) and relevant three-dimensional reconstruction (panel D). In Figure 3, panel E represents an alternate obliquity demonstrating good apposition of the stent graft against the aortic arch.

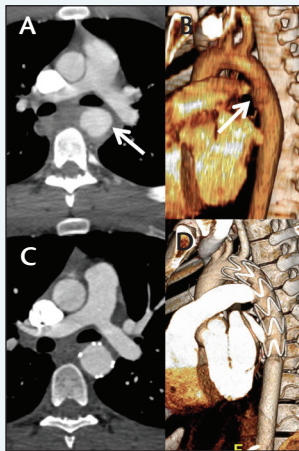


Figure 2.

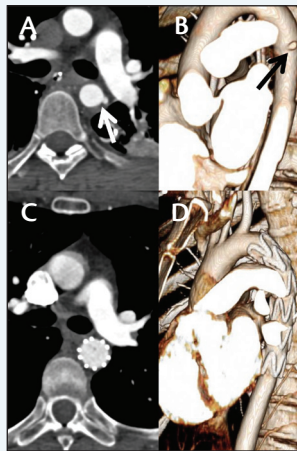


Figure 3.

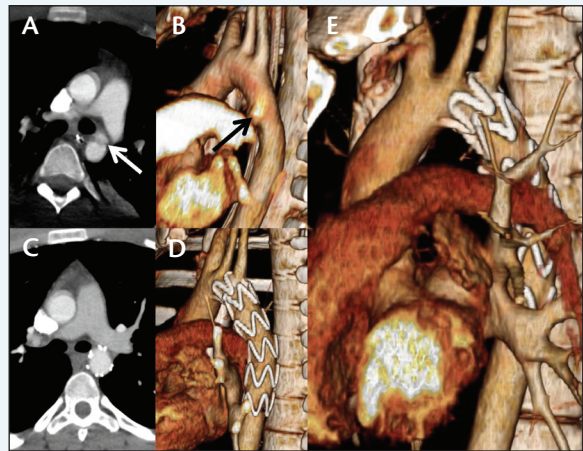


Figure 4.

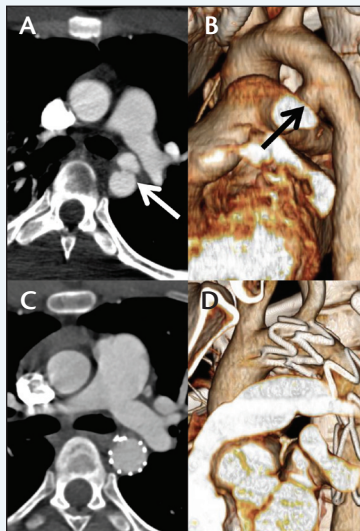


Figure 5.

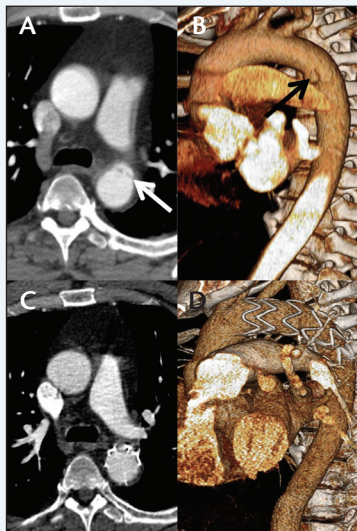


Figure 6.

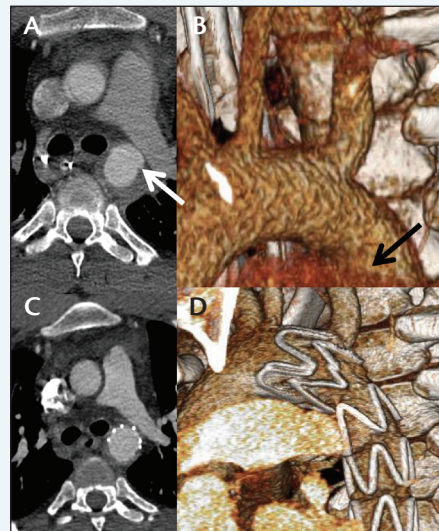


Figure 7.

effective for the management of patients with BAI. The results are currently under review by the US Food and Drug Administration and are the topic of a manuscript under preparation.

Other than access-related complications, the most feared complication of thoracic endovascular aortic repair for BAI is either stroke or paraplegia. Modern workup includes magnetic resonance (MR) imaging of the brain or spinal cord, respectively. In the past, the presence of ferrous stent graft designs in the thoracic aorta was a contraindication to MR imaging in these scenarios. The Zenith Alpha Thoracic device has improved compatibility with MR imaging, which allows for alternative imaging in challenging clinical scenarios.

CONCLUSION

Zenith Alpha Thoracic represents a powerful tool in our armamentarium for managing aortic pathology. The management of BAI has become a percutaneous, semielective procedure that can be performed in under

an hour. Thanks to better device design that includes a smaller, precurved delivery system and a nitinol frame, more patients with BAIs are candidates for this minimally invasive technology. ■

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