

# 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.<sup>1</sup> 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](mailto:t.koelbel@uke.de).*

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*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.*

1. Dake MD, Miller DC, Semba CP, et al. Transluminal placement of endovascular stent-grafts for the treatment of descending thoracic aortic aneurysms. *N Engl J Med*. 1994;331:1729-1734.