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The Aortic Team as a High-Tech Specialty Area

Industry innovations drive the emergence of the clinical aortic team.

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Despite being a niche not so long ago, aortic medicine has developed into a subspecialty of cardiovascular medicine in which the aortic team—much like the heart team in the treatment of structural heart valve disease—combines knowledge and experience from several disciplines to identify and apply the right treatments to appropriate patients, aiming to raise standards, improve quality and outcomes, and enhance durability of repair.

Traditionally, cardiac and vascular surgeons manage aortic cases, masterminding the entire course from diagnosis to treatment to follow-up, but several other specialties, such as anesthesiology, radiology, and cardiology, contribute to the bigger picture and provide invaluable insights.

Aortic medicine has developed from a classical surgical discipline to a high-tech specialty where highly developed surgical expertise and interventional skills create the platform for all options in both acute and chronic clinical scenarios.

Where indication seeks technology, the right industrial partners respond to the respective indications and surgical needs; the development of aortic medicine in the last 15 years is perfectly mirrored in the evolution of Terumo Aortic, which arose from Vascutek—a traditional aortic surgery company, instrumental in many major innovations in the surgical field—and Bolton Medical, which was known for several innovations in the endovascular field. The fusion of these two companies as Terumo Aortic created a manufacturer that complements and encourages the emergence of the clinical aortic team, not only by providing a range of treatment options but also by refocusing those options on the patient and pathology, not the technology or technique. This article focuses on three prostheses—one surgical, one endovascular, and another bridging both worlds: the Gelweave™ Siena graft (Terumo Aortic), the Relay®Plus stent graft (Terumo Aortic), and, finally, the Thoraflex™ Hybrid device (Terumo Aortic).

THE GELWEAVE SIENA GRAFT

The Gelweave Siena prosthesis was designed and developed as the modern prosthesis for the classic elephant trunk technique. It is particularly suited for use in patients with mega-aortic syndromes where the sewing collar allows tailoring to address size discrepancies in the native distal aortic arch (Figure 1). This original

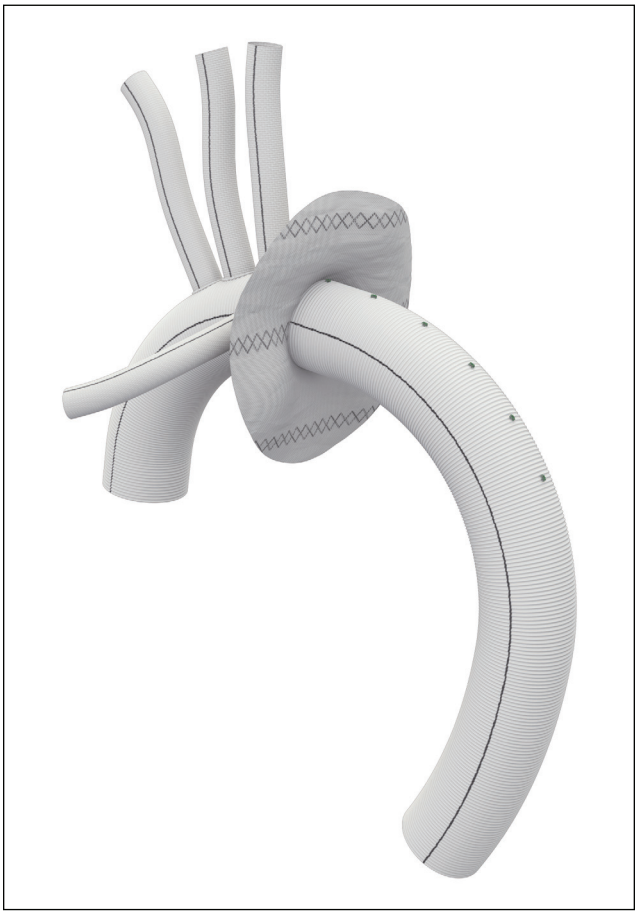

Figure 1. The Gelweave Siena graft with sewing collar for addressing size discrepancies in the native distal aortic arch.

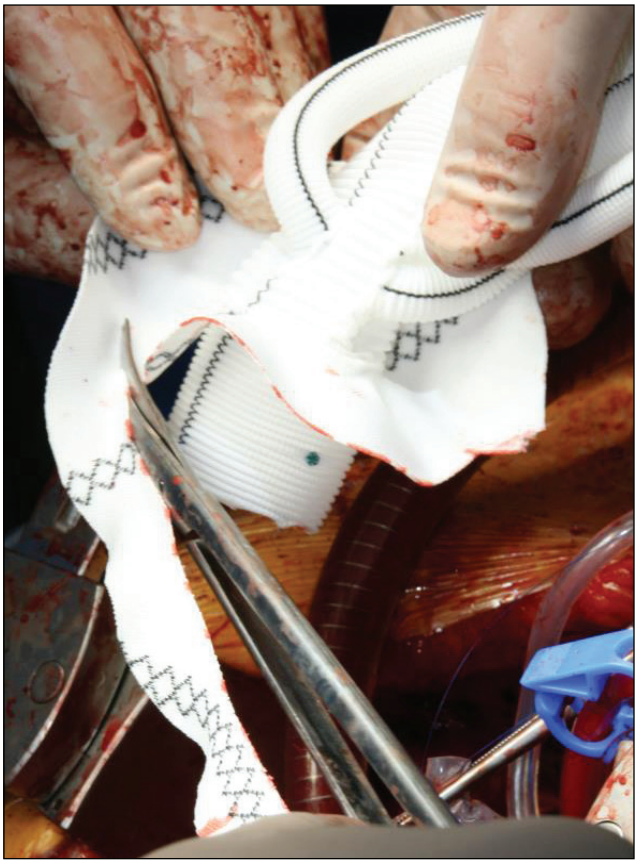

Figure 2. The Gelweave Siena collar is trimmed to fit to the proximal end of the stent graft.

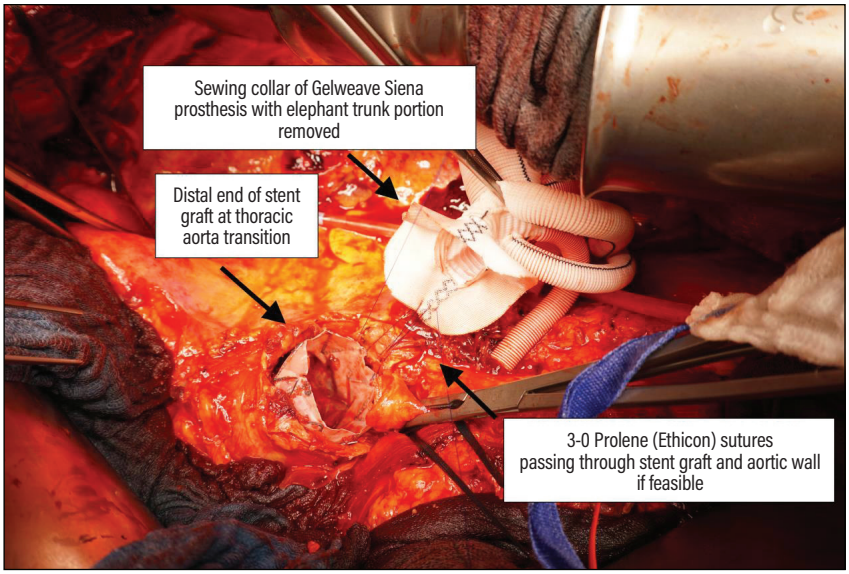

Figure 3. Use of the Gelweave Siena prosthesis for surgical distal TEVAR extension. Reprinted from The Annals of Thoracic Surgery, 105/2, Jasser A, Kreibich M, Morlack J, et al, Aortic replacement after TEVAR—diameter correction with modified use of the Siena prosthesis, 587-591, 2018, with permission from Elsevier.

concept has worked well for some time, and the concept has allowed for further innovation, such as tailoring to address size discrepancies in patients with previous aortic operations. For example, these new applications allow treatment of patients with previous thoracic endovascular aortic repair (TEVAR) and disease progression either proximally or distally or with persisting or newly developing type I endoleaks.

The largest available classic Dacron prostheses have a size of 34 mm, which is sufficient to adjust to native aortic diameters in most cases. However, if a patient has undergone TEVAR with, for example, a 46-mm stent graft and now needs proximal repair for a type Ia endoleak, then bridging this size discrepancy from 34 to 46 mm will be more challenging. The sewing collar of the Gelweave Siena graft is an ideal means to resolve this situation. The elephant trunk component is cut, and the collar is trimmed to the size of the proximal end of the stent graft (Figure 2). The remaining aortic wall can be incorporated into the anastomosis, but this is not mandatory if there is no remaining endoleak component or graft detachment.

The same concept works distally in patients with type Ia endoleaks or in patients with postdissection aneurysmal formation (Figure 3). In this case, the side branches—originally designed for the supra-aortic branches and perfusion—are used for the visceral and renal arteries.[1]

THE RELAY PLATFORM

The RelayPlus device (Figure 4) is a stent graft designed with challenging anatomies in mind. It has a dual-sheath delivery system—an outer sheath for support during advancement through access vessels and a soft, flexible inner sheath that reduces vessel trauma. Radial force varies from proximal to distal, with radial force maximized for zones of fixation and minimized for zones requiring conformability. The tip capture design holds the proximal end of the prosthesis safely in place during deployment of the main body and was the first of its kind on the market to ensure exact deployment. Finally, the RelayNBS non-bare-stent version of the stent graft has support wires that ensure perpendicular alignment of the prosthesis irrespective of the angulation of the intended landing zone (Figure 5). This add-on was a spinoff of the company's

ascending aortic work, which was an example of the symbiosis between physicians and industry in which an indication sought out technology and the solution came from bench to bedside. Many studies have confirmed the unique performance of the RelayPlus and RelayNBS Plus devices in several acute and chronic thoracic aortic pathologies.[2-4] A low-profile version of the standard device (RelayPro) with a 3- to 4-F profile reduction is now available.[5]

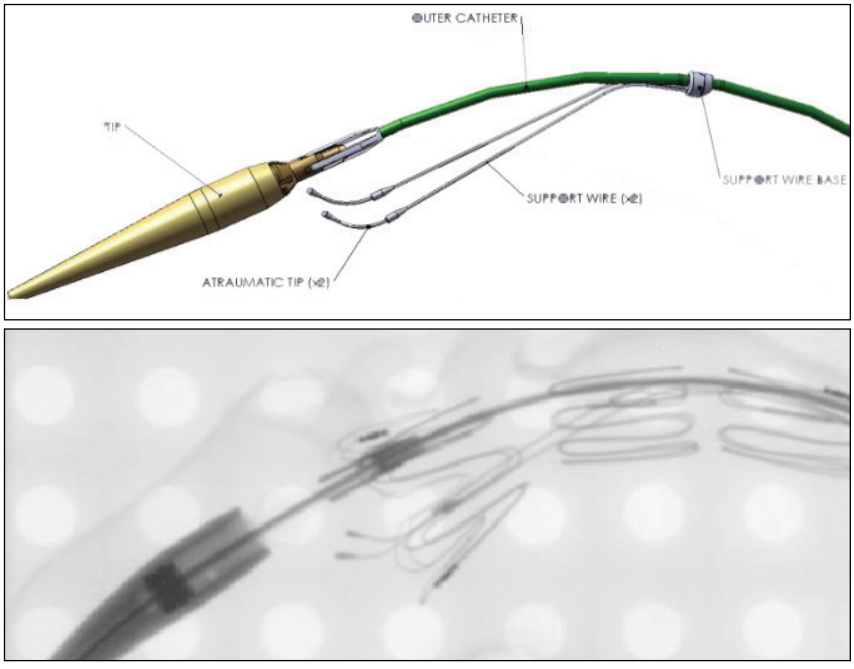

Figure 5. Support wire concept for perpendicular alignment during deployment.

THE THORAFLEX HYBRID

The Thoraflex Hybrid device bridges both worlds of classic surgery and endovascular therapy (Figure 6). Once again, clinical need triggered the development of this device and the result was a product that—within relatively little time—became an indispensable tool for the treatment of many acute and chronic thoracic aortic pathologies. Even today, many patients undergo partial solutions; the ascending aorta is replaced in a one-size-fits-all philosophy without analyzing in detail the underlying pathology and assessing long-term sequelae and without anticipating the need for further repair in the years to come. As a consequence, several patients after previous ascending aortic replacement—either for acute type A aortic dissection or aneurysmal formation—will experience disease progression and need secondary procedures. It is no coincidence that the aortic community is moving toward a "proximal full fix," which translates as a full proximal thoracic aortic repair, including the root, ascending aorta, and arch and ideally providing a platform for secondary endovascular or open surgical distal extension.

Figure 4. RelayNBS Plus stent graft.

The Thoraflex Hybrid meets these needs and has several features that make the operation safe and reproducible, irrespective of the underlying pathology. The supra-aortic branches enable

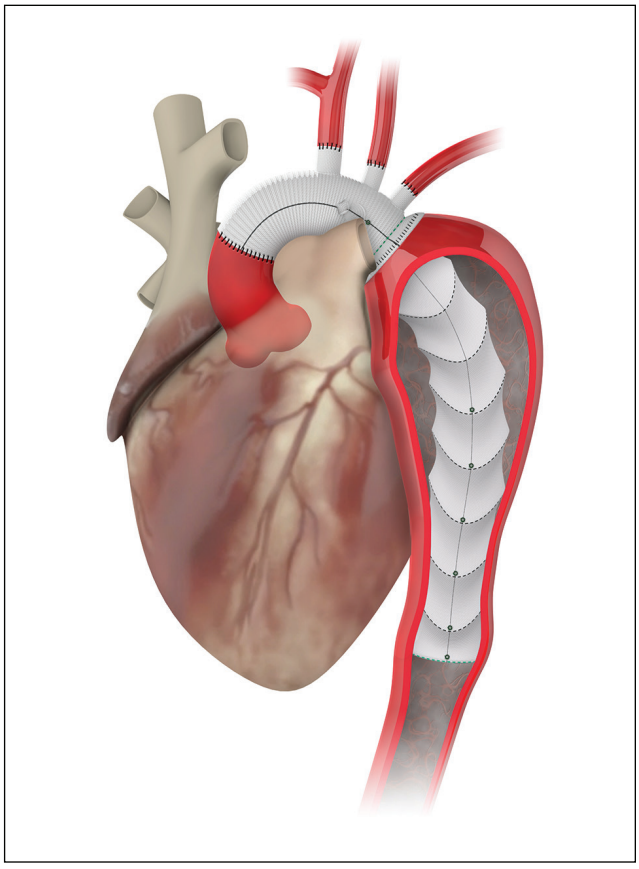

Figure 6. Thoraflex Hybrid device.

proximalization of the descending anastomosis into landing zone 2. (The European Association for Cardio-Thoracic Surgery and European Society for Vascular Surgery consensus document recommended unifying reporting and extent of repair or exclusion from circulation respectively, according to the Ishimaru landing zones.) This is a small technical detail but a big leap forward with regard to safety, ease of accomplishment, and accessibility for subsequent hemostasis.[6] We exclusively use the 10-cm stent component length to further minimize the remaining risk of symptomatic spinal cord injury. There are many factors contributing to this risk, and stent length is one of them.[7] We have not observed a single case of symptomatic spinal cord injury in > 150 Thoraflex Hybrid implantations to date.

In cases of secondary distal extension, our policy is to start with a RelayNBS Plus stent graft extension down to the level of the thoracoabdominal transition and metachronously adding type IV open distal repair. This concept converts a Crawford type II thoracoabdominal aneurysm into a Crawford type IV scenario, which has several advantages, primarily preconditioning the collateral network for spinal cord protection and a less extensive open thoracoabdominal repair.

For this type of open repair, the surgical Gelweave Siena graft is ideal to attach to the endovascular device and the remaining aortic wall. The three stages reflect a complete and comprehensive approach to the aorta and a combined effort of the aortic team: Thoraflex Hybrid for proximal full fix, RelayNBS Plus for distal extension, and, finally, Gelweave Siena for open distal completion.[8]

CONCLUSION

The recent history of aortic medicine and the solutions offered by Terumo Aortic demonstrate an excellent interplay between indication and technology, clinical specialties, and the mutual benefit when physicians and industry collaborate to provide better care for patients.

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