

The Trimodular, Tailored Approach to EVAR

The benefits of incorporating proven surgical design concepts into the INCRAFT® AAA Stent Graft System design.

BY GIOVANNI TORSELLO, MD

There are two primary advantages to open surgical repair of abdominal aortic aneurysms (AAA) that result in long-term, durable outcomes: the ability to tailor-make the exclusion length based on the individual anatomical situation found during the procedure and the creation of a proximal attachment that mimics a sewn anastomosis with respect to fixation and sealing. Endovascular repair (EVAR) offers a less invasive alternative, but historically, most stent graft options have had limited anatomic applicability and can only be used in a finite range of access vessels and aortic necks. To mimic the benefits of open repair, an intuitive, low-profile endovascular system that allows introduction in a variety of iliac vessel diameters and the possibility of percutaneous introduction in some cases is crucial.

The novel INCRAFT® AAA Stent Graft System (Cordis Corporation) (Figure 1) was designed to solve the limitations of previous-generation endovascular AAA devices, particularly in regards to durability and customizability. The ultra-low-profile delivery system of the INCRAFT® System is able to navigate narrow, diseased iliac vessels and has the capability of percutaneous delivery.

In this article, the unique trimodular structure of this device will be highlighted, as well as some of the key benefits associated with this design:

- Real-time customization
- Treatment of a broad spectrum of anatomies with few units
- Enduring modular junction strength
- Placement accuracy

REAL-TIME CUSTOMIZATION

The modular components of the INCRAFT® System are designed to allow bilateral in situ length adjustment of the limb prostheses by 2 to 3 cm during implantation. This substantially improves placement accuracy, which is intended to reduce the risk of inadvertent side-branch coverage of the hypogastric and renal arteries.^{1,2} With traditional systems, there is little opportunity to accommodate any needed changes after delivery system introduction, particularly with regard to potentially inaccurately measured

preoperative aortoiliac dimensions. The INCRAFT® System design will fit most diameters and lengths of vessels due to the real-time customization capabilities, providing a tailored approach to EVAR.

TREAT A BROAD SPECTRUM OF ANATOMIES WITH FEW UNITS

Another key to accommodating a wide range of aortic diameters lies in the stent structure design, which distributes the appropriate level of radial force, while maintaining conformability.

There are four aortic bifurcate sizes to treat 17- to 31-mm aortic diameters and 19 iliac limb diameters available in the INCRAFT® System portfolio, all of which are designed for in-procedure customization for coverage ranging anywhere from 10% to even 30% of oversizing.

Each iliac limb is supplied in four lengths ranging from 8 to 14 cm, allowing a total aortoiliac coverage length of between 13 and 21 cm. The combination of 23 different modular components provides the operator with highly customizable options and eases the standard complexity of device selection. Thus, fewer units create streamlined pre-operative planning and inventory management and act as a benefit in both elective and emergent EVAR.

INTERLOCKING MODULAR COMPONENTS

The stent graft uses durable, biopolymer-free sealing technology, which helps to reduce modular disconnection and type III endoleaks.^{1,3} There are interlocking suture knots on the limb prosthesis connecting to the Z-stents on the inside of the aortic bifurcate legs. This acts as an additional safety feature and provides a hook-and-loop-like connection between the endoskeleton stent struts of the bifurcate and the suture knots (Figure 2).

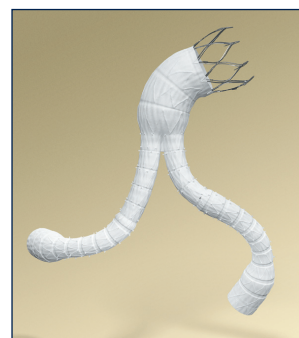


Figure 1. The INCRAFT® System provides custom deployment, optimized accuracy, and durable repair.

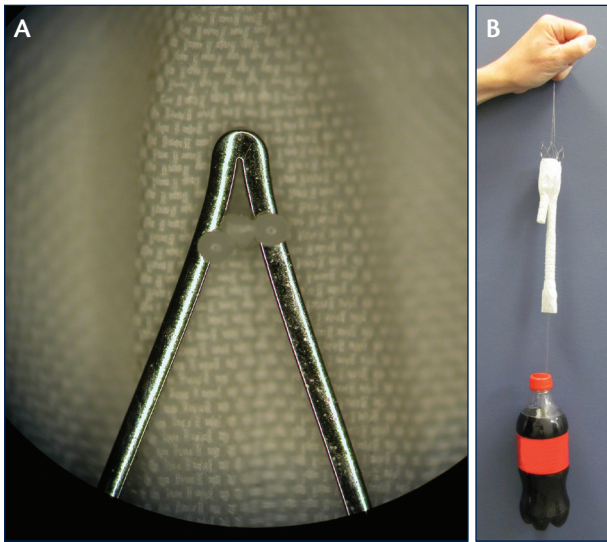


Figure 2. Increased modular junction force in the overlap zones are demonstrated by suspending a full 20 oz (591 ml) soda bottle from the iliac limb ex vivo (at room temperature) (A). The modular design is enhanced by the suture knots on the exterior of the iliac limb grafts interlocking with the Z-stents on the inside of the aortic bifurcate legs (B) to reduce disconnection.

Additionally, the seamless low-porosity polyester of the graft is kink-resistant to help mitigate perfusion of the AAA sac, and the laser-cut nitinol stents combine radial force with stent fracture resistance and are sutured to the graft in a unique way to minimize micromotion. The stent graft's stability is increased by the suprarenal fixation mechanism, composed of the laser-cut transrenal stent and integrated sharpened barbs that anchor the system.

PLACEMENT ACCURACY

Optimized proximal placement accuracy is achieved through the perpendicularly deployed aortic bifurcate and the partial repositioning of the bifurcate before full deployment, which is aided by distinctive radiopaque proximal markers (Figure 3) on the transrenal stent struts.

As noted, in-procedure bilateral in-situ adjustments of limb prostheses substantially improve distal placement accuracy and reduce the risk of inadvertent side-branch coverage.

INITIAL CLINICAL EXPERIENCE

The INNOVATION Trial is a 60-subject first-in-human trial, performed at six clinical centers in Germany and Italy. The objective of this multicenter, open-label, prospective, nonrandomized trial is to provide evidence regarding the effectiveness and safety of the INCRAFT® System in subjects with AAAs. After 2 years, no type I or III endoleaks, endograft migrations, stent fractures, or aneurysm enlargements were detected.² No aneurysm- or procedure-related death occurred. An average decrease of 11.4% (6 mm) was observed with ≥ 5 mm sac regression in 22 of 49 patients (45%) at 2 years. Although not statistically powered, aneu-

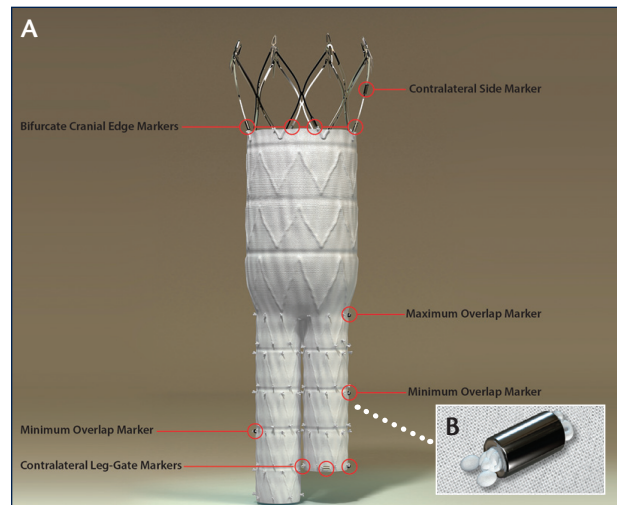


Figure 3. The locations of all the radiopaque markers on the bifurcate implant (A). Close up showing how each marker is sutured into the graft material (B).

rysm regression seemed to be consistent regardless of the aneurysm size. Three secondary procedures were performed: two for type I endoleak and one for limb occlusion. Three-year follow-up is still being collected.

The initial experience at Munster University Hospital showed excellent procedural results not only in straight-forward anatomy, but also in patients with challenging aortoiliac anatomy, including short proximal aortic neck, neck angulation, tight distal aortic bifurcation, small access arteries, and highly tortuous iliac vessels.¹ Sac regression was 7%, 12%, and 28% after 1, 2, and 3 years, respectively. Preliminary experience confirmed the in-situ sizing ability to telescope the limb prosthesis into the sockets of the bifurcated graft, adjusting the length of the overlap between the graft components.

CONCLUSION

The INCRAFT® AAA Stent Graft System is designed to incorporate lessons learned from previous generations of endovascular technologies and mimic familiar and proven open surgical principles. The end result is a highly versatile device that offers a more individualized endovascular option to a greater number of patients with AAAs. ■

Giovanni Torsello, MD, is Professor and Chief of the Department of Vascular Surgery, St. Franziskus-Hospital, and Head of the Center of Vascular and Endovascular Surgery, Munster University Hospital, Munster, Germany. He has disclosed that he has no financial interests related to this article. Dr. Torsello may be reached at giovanni.torsello@ukmuenster.de.

1. Torsello G, Brunkwall J, Scheinert D. Cordis INCRAFT™ ultra-low profile AAA stent-graft system. *J Cardiovasc Surg (Torino)*. 2011;52:661-667.
2. Torsello G, Scheinert D, Brunkwall JS, et al. Safety and effectiveness of the INCRAFT AAA Stent Graft for endovascular repair of abdominal aortic aneurysms. *J Vasc Surg*. 2014 July 19. [Epub ahead of print]
3. Chaikof EL, Fillinger MF, Matsumura JS. Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair. *J Vasc Surg*. 2002;35:1061-1066.