The Inspiration Behind the Low-Profile, Durable, and Customizable INCRAFT® AAA Stent Graft System

The application of state-of-the-art technologies to develop an ultra-low-profile, customizable, and highly accurately placeable endograft without sacrificing durable AAA repair, anatomy coverage, or procedural complexity.

BY JAMES GROSS, MS, MBA; DAVID C. MAJERCAK, MS; AND STEFAAN VAN DER MEULEN, MS

For over a decade, Cordis Corporation has worked to reengineer and refine the conventional stent graft used for the endovascular treatment of abdominal aortic aneurysms (AAAs). This development time was necessary to achieve a stent graft design that can offer the benefits of a highly deliverable ultra-low-profile device and customization without compromising durable long-term AAA repair, broad anatomical coverage, or ease of use.

INCRAFT® CRITICAL-TO-QUALITY FEATURES

The development of the INCRAFT® AAA Stent Graft System (Cordis Corporation) focused on five critical-to-quality features:

- Long-term durability (the system completed 400 million cycles of fatigue testing under conditions representing actual clinical and physiological conditions)[1]
- Deliverability
- Proximal and distal placement accuracy
- Broad anatomy coverage
- Ease of use

Device development was not considered complete until each and every feature was achieved.

DESIGNING AN ULTRA-LOW-PROFILE DEVICE WITH LONG-TERM DURABILITY

As with the evolution of all interventional products, reducing the delivery profile is a key driver that enables higher rates of usage in a more minimally invasive fashion; a wider range of anatomies are treatable through the increased ability to reach the intended implant site. The same need holds true for AAA stent grafts, primarily due to tortuous, small, and/or highly calcified iliac arteries, but with the added need to reduce access site complications that may arise with larger-bore delivery systems.[2] The development of the INCRAFT® System sought to make a leap forward in the delivery profile of a traditional AAA endograft.

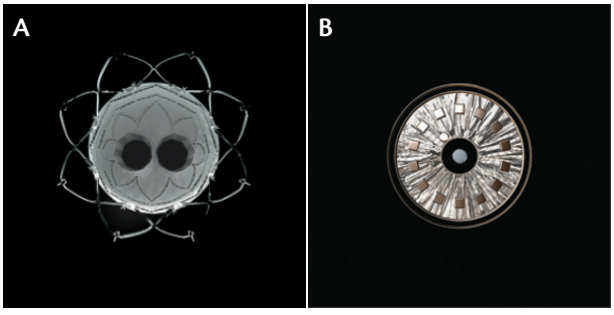

Figure 1. Fully deployed aortic bifurcate (A). Cross-sectional view illustrating the high packing efficiency of the stent graft in the ultra-low profile sheath (B).

In order to reduce the profile as significantly as possible with the INCRAFT® System, a very careful approach had to be devised that did not compromise acute performance or lead to the long-term durability issues that were observed with earlier generations of AAA endografts.[3] The key to this approach was a design that would allow the implant to be packed with high efficiency. The two main components driving this efficiency were a design that allowed an even distribution of the implant within the delivery sheath when compressed and a means to compress the materials very tightly. As was the case for most previous commercialized devices, the delivery profile was limited by localized bottlenecks, where portions of the implant were overlapped and inefficiently compressed. One key technology to overcome this

Durability and long-term data of the INCRAFT® AAA Stent Graft System are based on 2-year clinical follow-up and benchtop data.

limitation is the use of laser-cut nitinol stents that pack more efficiently than more typical wire-formed stents (Figure 1).

By far, the largest investment in time and effort in the development of the INCRAFT® System was to provide long-term device durability while lowering delivery profile. This effort entailed in-depth studies into the biomechanics of the aneurysmal environment (which has not been exhausted with the first-generation devices), careful study of the second-generation devices on the market that had promising durability, and development of a very rigorous fatigue test approach that would place devices in the most severe of environments while testing to failure. Validation of this regimen, which consisted of a battery of tests, was the replication of second-generation competitive design flaws that were addressed with subsequent iterations.

Through many rounds of this multitest, high-amplitude, mega-million-cycle testing regimen, durability was gained with seemingly small design changes. A select few areas were "durability critical" and needed the most painstaking engineering optimization and manufacturing care.[4]

A substantial portion of the profile gain was the implementation of a highly engineered catheter that is ultra-thin, yet extremely stretch-resistant in both the axial and circumferential directions. The engineering team used a variety of techniques, analytical tools, and simulations to balance the requirements of maintaining both radial and tensile force in the catheter sheath while minimizing frictional and deployment forces in the inner and outer diameter for optimal trackability through femoral access vessels.

CUSTOMIZATION AND PLACEMENT ACCURACY

Beyond the access and deliverability benefits of an ultra-low-profile delivery system, the INCRAFT® System sought to include bilateral real-time customization features that made it highly accurate to place both proximally and distally. Doing so allows the surgeon to apply control and individualize aneurysm exclusion in a wide range of vessels and associated anatomies.

Proximally, this is achieved through the ability to partially reposition the aortic main body of the stent graft during its quick, but highly controlled deployment. The barbs that offer migration resistance are held constrained against the tip of the delivery system during the initial deployment, allowing the operator to adjust positioning before using the secondary release to deploy the barbs and affix the main body within the aortic neck (Figure 2). Furthermore, the proximal sealing length of the aortic main body is maximized by a suprarenal stent design that deploys in a perpendicular fashion even in angulated vessels.

In the distal iliac vessels, the INCRAFT® System offers an in situ length customization capability that allows the operator to adjust the most caudal position of the limbs bilaterally by 2 to 3 cm during deployment by adjusting the overlap of the aortic bifurcate legs and the iliac limbs (Figure 3).

These two placement-accuracy features offer a variety of benefits to EVAR patients, their surgeons, and the institutions that provide and pay for the procedure.

Reduced Acute and Chronic Complications

Acute placement accuracy decreases the likelihood of unintentionally covering a patient's renal or internal iliac side branch vessels. Longer term, the placement accuracy offers longer seal zones, which reduce the possibility of endoleaks or device migration.

Reduced Need for Proximal or Distal Extensions

A high degree of placement accuracy significantly reduces the need for unintended extensions in the aorta and iliac vessels. When required due to an inaccurate deployment, these accessory devices result in unnecessary operative time, contrast exposure, and cost.

Few-Fits-Most Endograft Sizing

In situ length customization of the distal elements of the endograft results in far fewer device sizes and codes for the hospital to stock and manage in its inventory, without sacrificing broad anatomical coverage. The entire INCRAFT® System portfolio consists of 23 device codes to treat a wide anatomical range. There are four aortic bifurcates, all with the same length, that can treat aortic neck diameters between 17 and 31 mm. The iliac limbs are designed in five different diameters, which allow treatment of 7- to 22-mm iliac diameter distal landing zones. They are available in lengths of 80 to 140 mm, creating up to 212 mm of treatment length without the need for extensions (Figure 4).

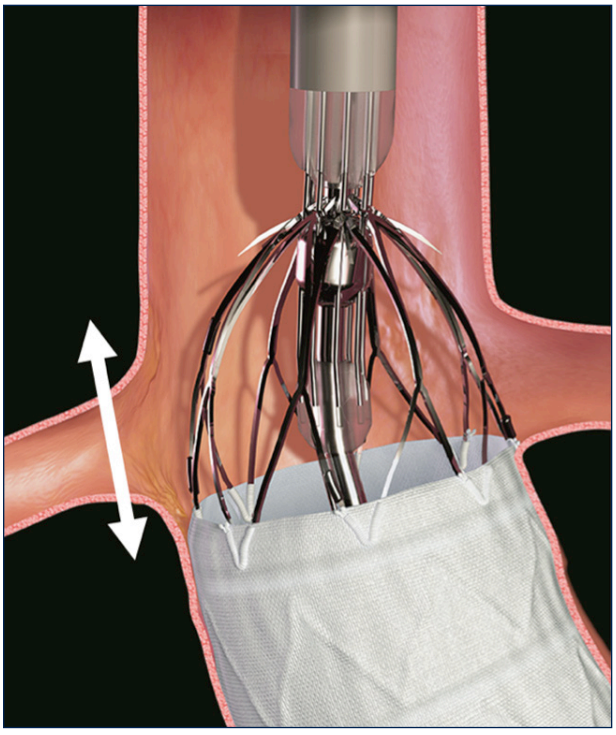

Figure 2. Proximal repositioning and perpendicular deployment.

CASE 1

MEDICAL HISTORY

An 82-year-old woman who was ASA grade III presented at the hospital with an AAA and a family history of AAA. She was elected for treatment 8 days after the initial screening.

ANATOMY

- Aortic neck diameter: 20 mm
- Neck length: 18 mm
- Neck angle: 58.6°
- AAA sac diameter: 59 mm
- Distal aorta diameter: 11 mm
- Right iliac access diameter: 5.5 mm
- Left iliac access diameter: 5.6 mm

PROCEDURE AND FOLLOW-UP

Despite very challenging access vessels and a highly calcified* and narrow distal aorta, the procedure was completed without any complications. There was very precise placement of the stent graft system in the highly angulated neck.

At 1-year follow-up, there were still no signs of migration, fractures, or graft occlusion, and the patient did not experience any aneurysm sac enlargement.

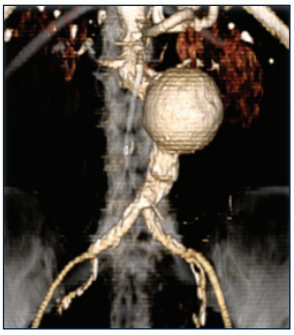

Figure 1. Preoperative image showing the highly calcified and narrow distal aorta.

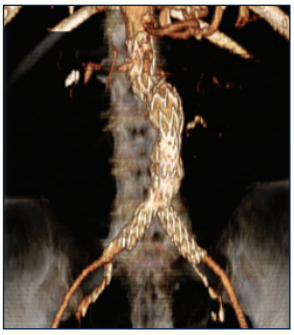

Figure 2. Postoperative image showing successful placement of the stent graft.

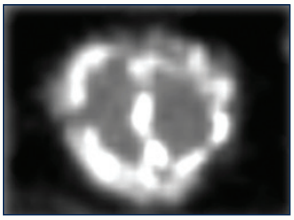

Figure 3. At the level of the distal aorta, the limbs maintain their so-called double-D configuration.

*Exercise caution in patients with irregular calcification and/or plaque as it may compromise the fixation and sealing of the implant, especially at the cranial and caudal sealing zones.

Of particular note, during the first-in-man INNOVATION study, only seven devices (two aortic bifurcates and five iliac limbs) were available, and even then, around 77% of the screened patients could be treated without any problem or need for additional device codes.[5]

Easier Preprocedural Planning

The intraoperative adjustability of the INCRAFT® System makes for an easier and more streamlined preoperative planning process because the operator can take advantage of the intraprocedural adjustability between the aortic main body and the iliac limbs.

BROAD ANATOMY COVERAGE

So far, more than 250 patients have been treated with the INCRAFT® System, most of whom were part of the INNOVATION European first-in-man trial and the INSPIRATION investigational device exemption trial, for United States and Japan approvals. Five patients have been treated through compassionate use programs in the United States and Canada, clearly demonstrating that a highly flexible, ultra-low-profile device does not just serve the current AAA population treated with endovascular repair, but can also safely expand the potentially treated population to patients who are currently in need.

During the clinical studies, patient selection and enrollment was based on the qualification of anatomical criteria as well as an independent reviewer's assessment. Core laboratory analysis of the preoperative patient's anatomy was graded using the Society for Vascular Surgery classification for challenging anatomy and demonstrates that up to 50% of the patients had multiple attributes meeting the severe hostile anatomy definition.[6] Almost half of the patients presented with access vessels smaller than 7 mm, with 5% of them smaller than 5 mm (Case 1). In addition to smaller access vessels, tortuous iliac arteries and tight distal aortas also contribute to potentially worsened patient outcomes. However, despite one-third of the first-in-man patient population having an aortic bifurcation diameter smaller than 18 mm—even as small as 11 mm in some cases—and tortuosity indices (τ) up to 2.41 (Case 2), there were no incidents in which the operator experienced difficulty gaining access during deployment, and there was only one occlusion at the 2-year follow-up time point.

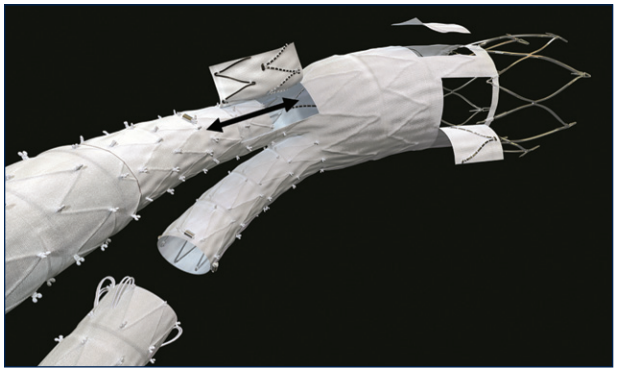

Figure 3. In situ length adjustment.

CASE 2

MEDICAL HISTORY

A 94-year-old man presented at the hospital with a symptomatic AAA. Due to his age and the size of the aneurysm, the patient was treated on the day of hospitalization.

ANATOMY

- Aortic neck diameter: 23 mm
- Neck length: 19 mm
- Neck angle: 52°
- AAA sac diameter: 101 mm
- Distal aorta diameter: 24 mm
- Right iliac tortuosity index: 1.43
- Left iliac tortuosity index: 2.41
- Right iliac access diameter: 7.9 mm
- Left iliac access diameter: 9 mm

PROCEDURE AND FOLLOW-UP

Because this was an unforeseen fourth patient treated at the study site on the same day with the INCRAFT® System, the procedure was started in the late afternoon with local anesthesia and a bilateral percutaneous approach.

Despite the extremely tortuous iliacs, the INCRAFT® System tracked very well, and the prosthesis was deployed at the desired location with nice conformability and without any adverse events or complications.

The final angiogram showed no device-related endoleaks, and the patient was discharged 3 days after the index procedure.

At 1-year follow-up, the core lab confirmed that there were no signs of migration, fractures, or graft occlusion, and the patient did not experience any aneurysm sac enlargement. The patient passed away in the second year of follow-up due to non-AAA-related events.

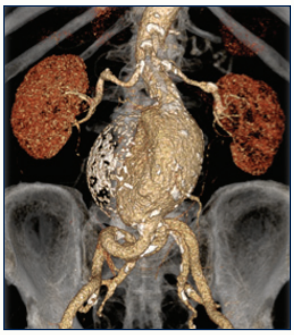

Figure 1. Preoperative image of the symptomatic AAA.

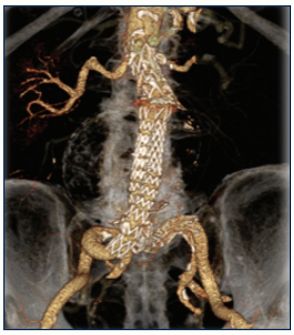

Figure 2. Postoperative image showing no device-related endoleaks.

EASE OF USE

The INCRAFT® System offers a variety of easy-to-use features above and beyond those already discussed intended to reduce the risk for adverse patient outcomes, including[4]:

- A limited number of intuitive steps without the possible allergic reaction and/or anaphylactoid response to polymers.
- An easy-to-use handle to facilitate a quick and controlled deployment.
- A built-in sheath introducer for the aortic bifurcate to eliminate the need for unnecessary sheath exchanges.
- A deployment mechanism that eliminates the need for transrenal nose cone recapturing.

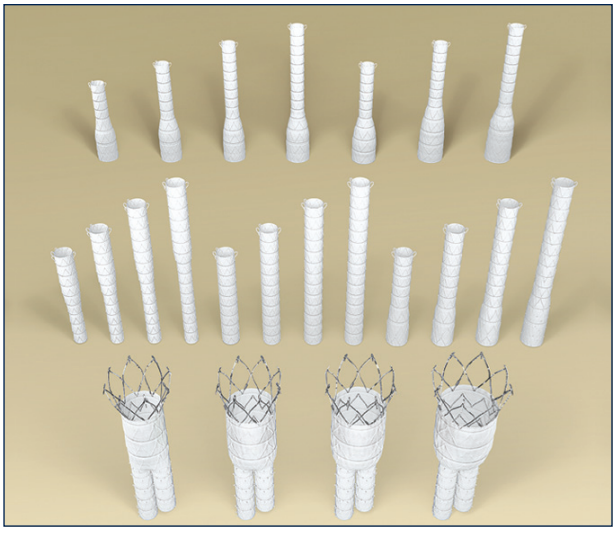

Figure 4. The INCRAFT® System portfolio of 23 codes.

CONCLUSION

The innovations and technologies embedded in the INCRAFT® System fulfill the ambitious goal set over a decade ago to evolve stent graft technology with a combination of critical-to-quality features to minimize the tradeoffs or compromises that have to be made in order to successfully treat patients with AAAs. ■

James Gross, MS, MBA, is a Director of R&D at Cordis Corporation. Mr. Gross may be reached at jgross10@its.jnj.com.

David C. Majercak, MS, is an Engineering Fellow in Advanced Engineering at Cordis Corporation. Mr. Majercak may be reached at dmajerc1@its.jnj.com.

Stefaan Van der Meulen, MS, is a Consultant Clinical Development Manager for Cordis Corporation. Mr. Van der Meulen may be reached at svanderm@its.jnj.com.

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