Ultra-Low-Profile in Practice

Discussing performance, durability, and the latest data for the INCRAFT® AAA stent graft.

WITH PROF. GIOVANNI TORSELLO, MD

As an experienced, high-volume center, you likely have access to most of the currently available stent graft systems. Do you believe there is a need for yet another endograft?

In our daily practice, we receive a lot of referral patients with moderate to challenging anatomy—highly angulated and conical aortic necks, small and calcified distal aortas, and/or tortuous and narrow access vessels. These more complex cases amount to 70% of the patients we treat on a daily basis.[1] To properly fit the right device for each patient and safely treat every case we face, we need a variety of tools and grafts. An ultra-low-profile device that is very precise in deployment is often the right one.

Are ultra-low-profile and precise placement the key features you look for in a device?

Among others, these two are indeed very important features. We have noted that with the newer devices released on the market, we keep pushing the limits of treating patients with shorter necks and narrower access. Having a device like the INCRAFT® System (Cordis Corporation) with a 14-F outer diameter delivery system* has allowed us to safely push the limits and open up treatment to candidates who previously couldn't be treated. Our second postmarket case with the device, for example, was an older woman waiting for the product to be CE Marked. She had bilateral 2-mm access vessels and was successfully treated without any complications (Figure 1).

As a teaching center, it is also important for us to have access to an easy-to-use yet precise delivery system. Thanks to its design, this stent graft system allows for perpendicular deployment of the main body so every millimeter of available neck length can be used. The ≤ 3 cm in-situ length adjustment of the limbs helps to provide distal accuracy.[2] These results were also demonstrated in the early feasibility study with outstanding data on precise placement.[3]

Cordis just released the 5-year clinical results of their INNOVATION study at the LINC congress earlier this year. Are these results encouraging, and how do they compare to your personal experience?

Our center was part of the INNOVATION first-in-human feasibility study supporting CE Mark approval that was started in 2010, and we enrolled 17 of the 60 patients. From the early follow-up results, we have seen outstanding results with only a single type Ia endoleak on final angiography for a patient with a significant calcification in the neck.[3] This trend has continued through 5 years of follow-up with a single type Ib endoleak secondary to an iliac dilatation, but 100% freedom of type Ia endoleaks at the last follow-up time point (Table 1). At up to 5 years of follow-up, the core laboratory results did not reveal any migrations, and we saw a 97.4% freedom from occlusions.

These results mimic our personal experience with the device very well. Between 2010 and 2015, we have treated 41 patients with the device without significant issues and have had promising outcomes. These results were recently published in the *Annals of Vascular Surgery*.[4]

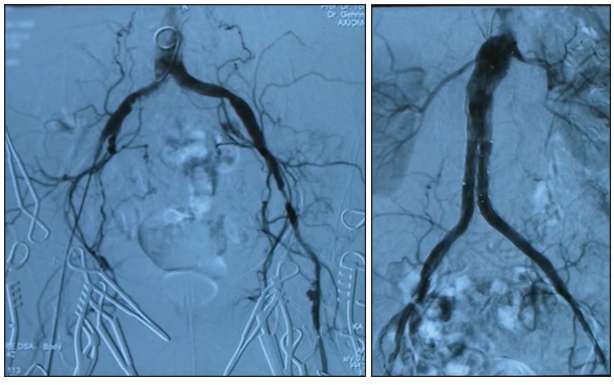

Figure 1. Successful treatment with the INCRAFT® System despite 2-mm access vessels.

*For the 34-mm diameter prostheses, the inner diameter of the integrated sheath introducer is 15 F (outer diameter, 16 F).

TABLE 1. INCRAFT® SYSTEM: 5-YEAR CLINICAL OUTCOMES

	Operative	30 Days	1 Year	2 Years	3 Years	4 Years	5 Years
Successful deployment at desired location	98.3% (59/60)	–	–	–	–	–	–
Freedom from endoleak							
Type Ia	98.3%* (59/60)	96.6%† (56/58)	100%† (53/53)	100% (50/50)	100% (45/45)	100% (39/39)	100% (38/38)
Type Ib	100% (60/60)	100% (58/58)	100% (53/53)	100% (50/50)	95.6% (43/45)	97.4% (38/39)	97.4% (37/38)
Type III	100% (60/60)	100% (58/58)	100% (53/53)	100% (50/50)	100% (45/45)	100% (39/39)	100% (38/38)
Stent graft patency	100% (60/60)	100% (58/58)	100% (53/53)	100%‡ (45/45)	97.8% (44/45)	97.6% (40/41)	97.4%§ (38/39)
Freedom from migrations	NA	NA	100% (53/53)	100% (50/50)	100% (44/44)	100% (38/38)	100% (37/37)
Freedom from fracture	NA	100% (54/54)	100% (52/52)	100% (46/46)	97.7% (42/43)	97.5% (39/40)	97.4%¶ (38/39)
Freedom from sac enlargement	NA	NA	100% (53/53)	100% (50/50)	95.6% (43/45)	89.7% (35/39)	92.1%‖ (35/38)
Freedom from MAE (death, QMI, CVA, renal failure)	100% (60/60)	100% (58/58)	98.2% (55/56)	88.9% (46/52)	87.3%** (48/55)	82.4% (42/51)	76%†† (38/50)

Abbreviations: CVA, cerebrovascular accident; MAE, major adverse events; NA, not available; QMI, Q-wave myocardial infarction.

*Type I endoleak due to severe calcification in aortic neck, resolved after additional endovascular intervention on day 61.

†Two patients underwent reintervention for the correction of a type Ia endoleak at day 61 and 278.

‡One patient developed a late right graft limb occlusion at day 666 treated with thrombectomy and bypass.

§Endoleg non-patency occurred in one subject at 3-year follow-up and is ongoing at 5-year follow-up.

¶Stent graft fracture is defined as stent skeleton fracture and barb separation and identified through x-ray. Fracture occurred in one subject at 3-year follow-up and is ongoing at 5-year follow-up. For seven subjects, x-rays were missing; however, no fractures were reported through other site imaging.

‖Both aneurysm enlargement and main body stent graft migration are defined as being compared to the 30-day baseline CT assessment. One subject did not have 30-day CT and therefore could not be evaluated.

**One death occurred within up to 1 year, five deaths within 2 years, and one within the 3 year time frame, all non-AAA related.

††One death occurred within up to 1 year, five within 2 years, one within 3 years, two within 4 years, three within 5 years, all non-AAA related.

Durability has become a hot topic and was always a point of concern with smaller devices—do you share the same concerns?

To better understand the potential drawbacks of an ultra-low-profile endograft, one should try to look at the technologies and modifications used to constrain the device in a lower-profile delivery system. As already demonstrated by some unsuccessful projects, the balance between performance and profile is not easy. Additional complexity comes from the fact that low-profile devices allow treatment of smaller and more diseased access. These conditions result in inferior hemodynamic flow and are associated with an increased rate of early limb occlusions and thrombosis.[5] As an example, clinical experience has reported a limb occlusion rate of other grafts to be 4.3% and 7.7% at 12 months, respectively.[6,7]

Does your experience with the ultra-low-profile INCRAFT® System confirm this trend?

The INCRAFT® System was designed to allow for increased packing efficiency without compromising on durability. It does so by combining the braided shaft of the integrated introducer sheath and proprietary stent design and crimping profile, which allows for a high compacting factor during the loading process.[8]

These features were not only confirmed by extensive benchtop testing but are also reflected in the recent 5-year results. Despite a high percentage of hostile anatomy both

TABLE 2. HOSTILE ANATOMY DISTRIBUTION*

	Hostile Anatomy Attribute	Categorization*	Absent	Mild	Moderate	Severe
PROXIMAL	Neck length (mm)	(> 25; 25–15; 15–10; < 10)	60%	23%	8%	8%
	Infrarenal angle (°)	(< 20; 20–40; 40–60; > 60)	13%	57%	25%	5%
	Suprarenal angle (°)	(< 20; 20–40; 40–60; > 60)	85%	13%	2%	0%
	Aortic thrombus	(Subjective analysis)	5%	73%	17%	5%
	Aortic calcification	(Subjective analysis)	7%	82%	12%	0%
DISTAL	Minimal aortic bifurcation ø	(> 22; 22–20; 20–18; < 18)	38%	10%	18%	33%
	Left iliac sealing length (mm)	(> 30; 30–20; 20–10; < 10)	15%	12%	33%	40%
	Right iliac sealing length (mm)	(> 30; 30–20; 20–10; < 10)	18%	20%	30%	32%
	Left minimal access ø (mm)	(> 10; 10–8; 8–7; < 7)	2%	29%	24%	46%
	Right minimal access ø (mm)	(> 10; 10–8; 8–7; < 7)	2%	30%	24%	44%
	Iliac tortuosity (τ)	(< 1.25; 1.25–1.5; 1.5–1.6; > 1.6)	85%	12%	0%	2%

*Based on core lab assessments.

in the proximal and distal segment (Table 2), there has been no report of type III endoleaks or migration.

At 3-year follow-up, only one nonclinical fracture was reported by the core laboratory, which was in the transrenal crown. A single patient developed limb occlusion at that same time point.

Compared to our early highly selected patients recruited for the INNOVATION trial, the patients treated after the CE Mark approval had significantly more challenging access routes confirming the difficulties of real-world conditions. Those patients required adjunctive procedures more frequently (33%).

In our experience, however, the remarkable radial force and flexibility of the INCRAFT® System, with a persistence in low rate of secondary procedures, does not yet suggest any concerns in durability.

In your practice, is percutaneous access with local/spinal anesthesia a routine practice? Have you changed your approach with the release of newer ultra-low-profile endografts?

In Munster, we have been using the percutaneous access technique for many years, and our team has experience with multiple closure devices. In the INNOVATION study, which started enrolling in 2010, all of our patients were treated through percutaneous access. In general, 60% of the total study population underwent percutaneous access with the Perclose® devices (Abbott Vascular), with successful delivery in all cases.[3] Concerning the modes of anesthesia with a percutaneous endovascular aneurysm repair approach, most of our procedures are performed under regional anesthesia with general anesthesia in a select group of patients. In general, we believe that lower-profile devices have the potential to reduce the necessity of more invasive surgical access, which in turn is connected to higher morbidity and mortality rates.

Where do you see the INCRAFT® System on the market?

The INCRAFT® System has all features to be used as a workhorse device. It allows treatment of standard anatomies, while safely expanding to more challenging aortas and access vessels. It could even be considered in emergency settings, as was confirmed to us the first week after the device was released on the market. We were presented with an urgent case with a ruptured AAA and extremely challenging access. This patient was successfully treated with the INCRAFT® system in a setting where alternative options were very limited.

Additional real-life experience will need to assist these initial findings and help this competitive endograft achieve the place it deserves on the market. ■

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