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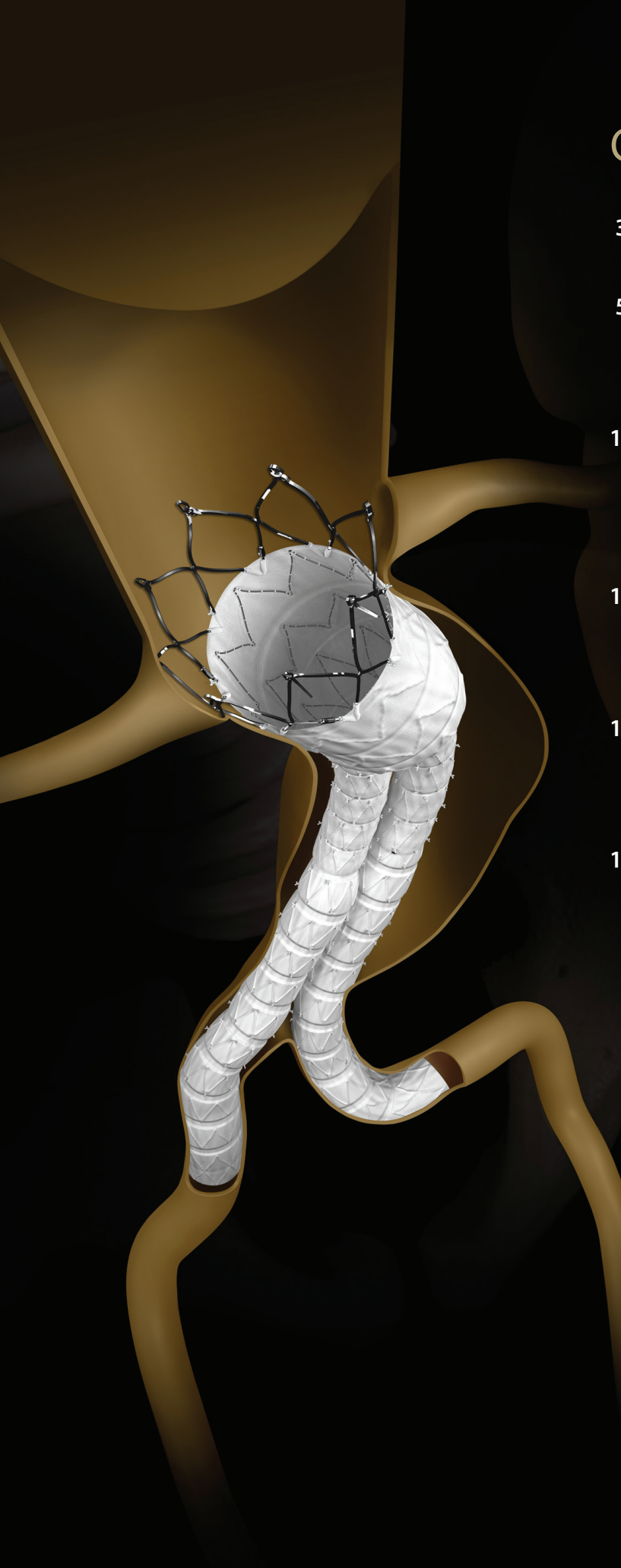
ADVANCING THE ART OF EVAR

One Year Later: How the INCRAFT® AAA Stent Graft System Is Realizing Its Design Promise



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Insights From David J. Wilson, President of Cordis Corporation

As Cordis Corporation joins Cardinal Health, the Cordis President reflects on the company's legacy of innovation and shares goals for the future.

David J. Wilson
Worldwide President of Cordis Corporation
Fremont, California

David, you started your career at the Johnson & Johnson Family of Companies with Cordis Corporation, followed by multiple leadership roles within the Johnson & Johnson Family of Companies. Now, you are leading Cordis Corporation, while becoming part of Cardinal Health. What do you think about this move to Cardinal Health?

After 20 years with the Johnson & Johnson Family of Companies, including over 11 years with Cordis Corporation, I'm tremendously excited to be leading Cordis at this moment in time. Cordis is known for delivering meaningful, innovative products to patients and customers, and I am proud to have spent the earlier part of my career in the Cordis Research & Development labs. Cordis is now joining a corporation, Cardinal Health, that deeply values our people and their work, our global capabilities, and our strong customer relationships. The Cordis business is a priority for Cardinal Health. Cardinal Health is looking forward to working with Cordis to continue building on our market reputation and expanding our growth.

Cordis has a long legacy of innovation and of bringing many firsts to the cardiovascular field. How do you envision Cordis innovating in the future?

Today, Cordis is a recognized leader in the development and manufacturing of interventional vascular technology with its more than 50-year history of delivering pioneering products to treat millions of patients worldwide. We will build on this rich history working together with Cardinal Health, utilizing their complementary skills and new expertise. Recognizing the important role we play across the cardiovascular market, Cardinal Health is eager and committed to investing in the Cordis business to drive growth and innovation, and in turn enhance patient care. Leveraging Cordis' deep experience in product innovation and Cardinal Health's business and operational expertise, we will be uniquely positioned to continue meeting the evolving needs of our customers and their patients.

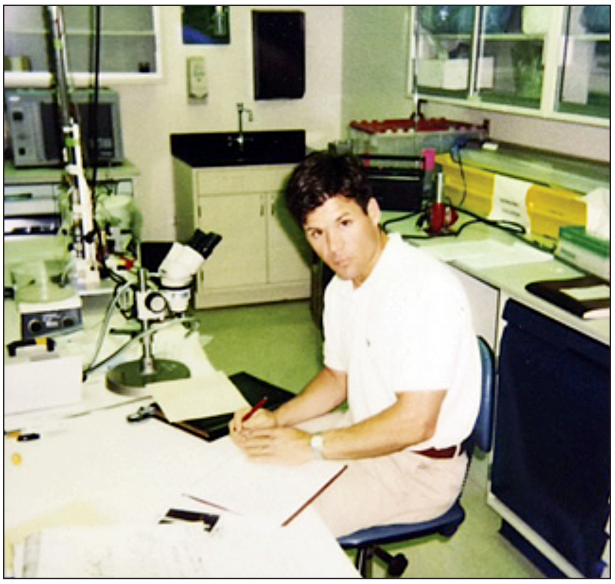
The health care industry has been going through significant changes over the past several years. Which of these changes has had the most profound impact on Cordis and its plans for the future?

Health care is changing faster today than at any time in the past. With an aging population and an increase in chronic illnesses, there's greater demand for innovative yet affordable solutions for quality health care. At the same time, in order to deliver better patient care, hospitals today need to provide more access to more patients while being operationally efficient.

For over 50 years, Cordis' mission has been to advance less-invasive therapies, leading to better experiences for patients by innovating across both products and education. This rich legacy of innovation will continue to strengthen the Cordis brand worldwide going forward. Cordis, with Cardinal Health, is committed to doing much more to help health care providers increase access by addressing delivery of care and operational efficiencies that will be critical in this evolving industry. This will also include expanding our high-quality training and service, as well as ensuring our strong clinical acumen.

What do the significant changes and consolidation across the health care industry mean to medical device companies like Cordis?

Integrating primary care physicians, specialists, and hospitals into consolidated health care delivery organizations is a strategy intended to help deliver better clinical outcomes at a greater value. Medical device companies are taking a similar approach, by bundling complementary products and services. There is more we can learn about the effectiveness of integrated health care delivery systems, as well as the alliance of medical device and insurance companies. At the core of these consolidations is the need for efficiency and coordination of care. It is clear this trend will continue.



David J. Wilson contributing to a specialized catheter design while working in Cordis R&D in 1996.

Cordis already has a solid reputation in the interventional cardiology and endovascular space, and we plan to continue delivering technology-driven innovation! With Cardinal Health, we also have a significant opportunity to focus on operational efficiencies with information-enabled systems (eg, RFID). Investment in the infrastructure of delivery systems will result in cost savings seen through inventory holding cost reduction, the decrease of inventory levels, and the elimination of costs associated with expired or lost products. This should allow Cordis to drive better patient care, while also helping our customers with efficiencies that support better access for more patients.

With products spanning aortic endografts to chronic total occlusion (CTO) devices, where do you see Cordis' growth opportunities?

While we believe the next phase of health care will focus on innovating both technology and services, in the short term, we have some promising technological advances in the treatment of both abdominal aortic aneurysms (AAAs) and CTOs resulting from peripheral artery disease.

An estimated 24 million people worldwide are afflicted with AAAs, and millions more suffer from CTO in peripheral arteries. The INCRAFT® AAA Stent Graft System, which has been cleared for use in Europe and Canada, brings an innovative advancement to the field of endovascular aneurysm repair, entering a growth segment that further diversifies Cordis' strong portfolio of products. The INNOVATION trial will complete its 5-year follow-up in 2016.

Our Crossing Portfolio for treatment of CTOs underscores Cordis' long-standing commitment to the treatment of patients with CTOs, which began in 2005 with the acquisition of LuMend, Inc. Our workhorse solutions, the FRONTRUNNER® XP CTO Catheter and the AQUATRACK® Nitinol Guidewire, are now supported with our most recent addition, the OUTBACK® Elite Re-Entry Catheter. We look forward to continuing the expansion of these new lines and coming up with new complementary products.

Significant technological strides have been made in the treatment of aortic aneurysms and CTOs, but more work needs to be done to provide the most comprehensive offering of products to help treat these conditions in patients.

With Cardinal Health's acquisition of Cordis complete, can you share with us what this means for the entire business?

I truly believe this is a very exciting time for Cordis and Cardinal Health. Cordis is a leader in interventional vascular technology and plans to continue building on our rich history as part of Cardinal Health. This transaction brings together two remarkable players in the health care industry to deliver greater access to quality products, creating an unmatched offering in the cardiovascular space.

From high-quality daily use products to reliable, trackable inventory and logistics with deep analytic capabilities, the Cordis and Cardinal Health venture will result in comprehensive offerings for the entire episode of care. As we move forward, our customers and the patients they serve remain our highest priority. We are excited and look forward to ensuring a continuation of our high-quality, innovative products and exceptional customer service. ■

The INCRAFT® AAA Stent Graft System: Clinical Results and Experience

Prof. Giovanni Pratesi outlines the effectiveness of a new-generation device in expanding EVAR applicability using clinical evidence from trials and real-world experience.

Prof. Giovanni Pratesi
University of Rome Tor Vergata
Rome, Italy
gpratesi@gmail.com
Financial disclosures: He has disclosed that he is a consultant for Cordis.

ADVANCED DESIGN AND TECHNOLOGY

The INCRAFT® AAA Stent Graft System (Cordis Corporation) is part of the latest generation in advanced endovascular aneurysm repair (EVAR) technology that combines and introduces unique features for the treatment of infrarenal abdominal aortic aneurysms (AAAs).[1]

The main body of the INCRAFT® Stent Graft is delivered through a flexible 14-F, ultra-low-profile delivery system,* allowing for proximal repositioning, and has a cap-free fixation release to assist with optimal placement accuracy. The iliac limb delivery system is equivalent to a 12-F sheath introducer.† Both the aortic bifurcation and the iliac limbs are constructed out of low-porosity polyester fabric with segmented endoskeletal nitinol stents. The stent graft design allows the highest amount of in situ sizing of all endografts currently on the market and, as such, provides a maximum level of customizability and conformability to address a wide range of AAA anatomies (Figure 1).

The current clinical data confirm excellent results with the INCRAFT® System, and a postmarket study is ongoing to verify the effectiveness of this system in the real-world setting.

INNOVATION TRIAL

The INNOVATION first-in-human feasibility study supporting the EU CE Mark approval was started in 2010 and enrolled 60 patients in two countries and six participating centers. With 14 patients treated, the Unit of Vascular Surgery, University of Florence (Florence, Italy) was among the highest enrollers in the study and built an extensive experience in the early developments of the device.

Based on the primary technical and safety endpoints at 1-month follow-up, the INCRAFT® Stent Graft System showed promising results despite a large number of patients with core lab–confirmed anatomic challenges. The most significant challenges were high infrarenal neck angulations (> 40° in 30% of patients), tight aortic bifurcations (< 18 mm in 33% of patients), and tight iliac access (< 7 mm in 45% of patients).[2]

The rate of technical success, defined as freedom from endoleaks, at 1 month was 97% (56/58 patients of the original 60 patients who were enrolled), with 100% of patients free from aneurysm enlargement and no type I or type III endoleaks in any patients at 2 years postprocedure.[3]

These favorable results were similar at 3-year follow-

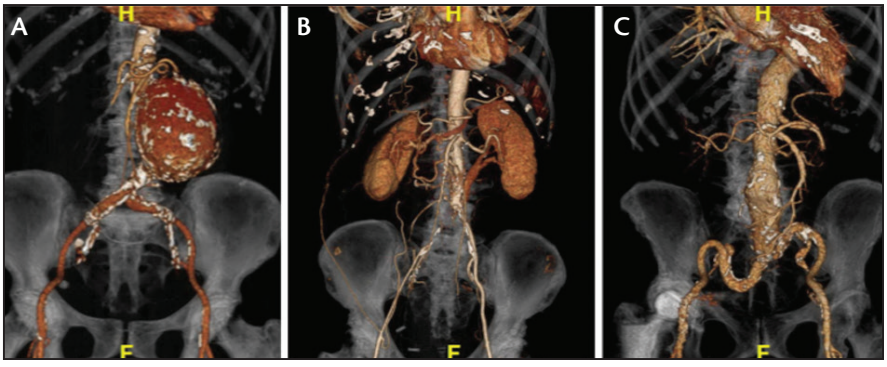


Figure 1. Examples of patients treated with the INCRAFT® System: small distal aorta and challenging neck (A), narrow or occluded iliac arteries and difficult access (B), and tortuous iliac arteries (C).

*For the prostheses diameter of 34 mm, the inner diameter of the integrated sheath introducer is 15 F (outer diameter of 16 F).
†The iliac limb delivery system has a 12-F outer diameter for prothesis diameters between 10 mm and 20 mm and the 13-F outer diameter for the 24-mm diameter prosthesis.

TABLE 1. PRIMARY TECHNICAL AND SAFETY ENDPOINTS OF THE INNOVATION TRIAL

Event	30 Days (N = 58)[a]	1 Year (N = 56)[a]	2 Years (N = 52)[a]	3 Years (N = 55)[a]
Freedom from endoleak (CEC adjudicated) Type Ia Type Ib Type III	 96.6%[b] 100% 100%	 100% 100% 100%	 100% 100% 100%	 100% 95.6% 100%
Stent graft patency	100%	100%	100%[c]	97.8%[d]
Freedom from migrations	N/A	100%	100%	100%[e]
Freedom from fracture	100%	100%	100%	97.7%[f]
Freedom from sac enlargement	N/A	100%	100%	95.6%
Freedom from MAE (death, QMI, CVA, renal failure)	100%	98.2%	88.5%	87.3%[g]

Abbreviations: CEC, Clinical Events Committee; CVA, cerebral vascular accident; MAE, major adverse event; N/A, not applicable; QMI, Q-wave myocardial infarction.
[a]Denominators vary based on the number of subjects who had imaging performed.
[b]Type I endoleak was present at 30-day follow-up and resolved after additional endovascular intervention on day 278.
[c]One patient developed a late graft thrombosis at day 666 due to sac contraction and limb and confirmation change.
[d]Endoleg nonpatency (ie, occlusion) occurred in one subject.
[e]Both aneurysm enlargement and 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.
[f]Stent graft fracture is defined as stent skeleton fracture and barb separation and identified through radiograph. Fracture occurred in one subject.
[g]One death occurred within 1 year, five within 2 years, and one within 3 years; they were not AAA-related.

up, and despite two distal sealing leaks (one of which was potentially caused by insufficient oversizing and another that was secondary to a type II endoleak) and one non-aneurysm–related death, there was no other incidence of device-related endoleaks, major adverse events (death, Q-wave myocardial infarction, cerebrovascular accident, renal failure), or stent graft migrations (Table 1). A single patient presented with a proximal strut fracture identified by the core lab but without clinical sequelae. Two patients experienced aneurysm enlargement following type II endoleaks; however, an average sac regression of 6.8 mm was reported for the overall cohort.[4]

Despite the high number of patients with severe distal morphologies, no early limb occlusions were seen within 1-year follow-up, and overall stent graft patency was 97.8% within the 3-year follow-up period.

One of the most important features of the INCRAFT® System is the proximal and distal precision by which it is deployed. During the study, the mean proximal placement accuracy was 2 mm from the lowest renal artery, and due to the in situ sizing capabilities, the average iliac artery coverage was 79%, which assists with better long-term outcomes.

Another important design characteristic is graft conformability. Analysis of neck dilatation showed that, just as in surgical treatment, the aortic neck seems to dilate over time, which is likely related to the progression of the disease. Although the aortic neck enlargement was limited at the level of the lowest renal artery (mean increase, 1.2 mm ± 1.15 mm over 3 years), the effect was more significant at 15 mm below the lowest renal artery (mean increase, 2.6 mm ± 1.77 mm over 3 years). A similar effect was seen in the distal sealing area of the common iliac artery (mean increase, 2 mm ± 1.48 mm over 3 years). According to a preliminary analysis, this effect could not be attributed to stent graft oversizing. The nitinol-based configuration did however allow the device to adjust to the changes in anatomy (Figure 2).

In summary, the INNOVATION study has demonstrated outstanding clinical results, with 95% freedom from reinterventions at 3-year follow-up. These results are to be confirmed as the initial study patients return for 4-year follow-up at our center.

INSPIRATION TRIAL

Following the European clinical study, the INSPIRATION trial, which was initiated in 2012, enrolled a total of 190 patients in approximately 1 year and was the first AAA clinical trial to be conducted in parallel in the United States and Japan via the Harmonization by Doing program.

The objective of this study is to evaluate the safety and effectiveness of INCRAFT® in subjects with AAAs requiring endovascular repair. The primary safety end-

Neck diameter increase (Lowest renal vs 1-month CT)	6 Month	1 Year	2 Year	3 Year
Diameter, mm (mean ± SD)	22.3 ± 2.13	22.4 ± 2.18	23.2 ± 2.28	23.2 ± 2.14
Variation, mm (mean ± SD)	0.2 ± 0.78	0.5 ± 0.96	1.0 ± 1.11	1.2 ± 1.15

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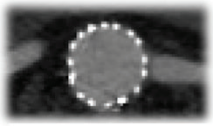
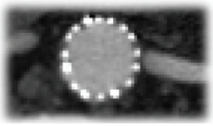
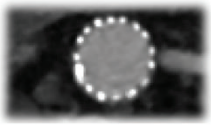


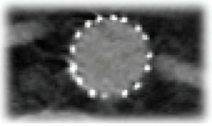
Aortic neck diameter (lowest renal): 6-mo FU = 19.4 mm



Aortic neck diameter (lowest renal): 1-y FU = 19.5 mm



Aortic neck diameter (lowest renal): 2-y FU = 19.5 mm



Aortic neck diameter (lowest renal): 3-y FU = 20 mm

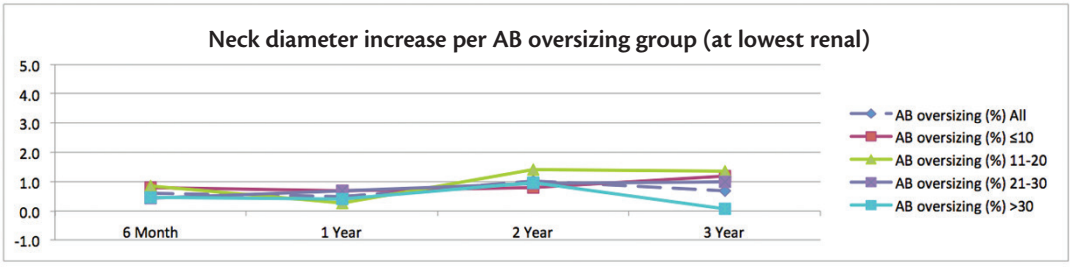


Figure 2. Neck compliance achieved in INNOVATION: 3-year evaluation of diameter increase at the lowest renal per oversizing group. Abbreviations: AB, aortic bifurcation; FU, follow-up.

point will look at a composite major adverse event rate at 30 days postprocedure, while the primary effectiveness endpoint will evaluate the acute technical success and absence of aneurysm enlargement, migrations, conversion to open surgery, sac rupture, type I/II endoleaks, or graft occlusions up to 1 year.

Results of the INSPIRATION study are currently under evaluation and are expected to be published in the very near future.

INSIGHT POSTMARKET STUDY

A postmarket study of the INCRAFT® Stent Graft System has recently commenced enrollment. The study will evaluate the safety and effectiveness of INCRAFT® System in patients with AAAs requiring endovascular repair in routine clinical practice. The first patient was enrolled on March 30, 2015, and the primary endpoint is the absence of major adverse events within 30 days postprocedure.

FROM CLINICAL TRIAL TO REAL WORLD

Based on the very promising results coming from international trials, the INCRAFT® Stent Graft System obtained CE Mark approval in August 2014. Since that time, we started to use the INCRAFT® Stent Graft System in our daily practice, and at present, 29 patients (24 males; mean age, 75 ± 5.7 years) have undergone elective EVAR with the INCRAFT® System at our institution. Case selection was mainly based on the innovative features of the INCRAFT® System, including ultra-low-profile delivery system, accuracy of placement, and in situ sizing customization to address more challenging anatomies[‡] in terms of access vessels and

TABLE 2. ANATOMIC CHARACTERISTICS OF PATIENTS WHO HAVE UNDERGONE EVAR WITH THE INCRAFT® SYSTEM IN OUR PRACTICE

	Mean	Range
Infrarenal angle	36.9°	5.9°–87.3°
Proximal neck diameter	23.1 mm	18.3–29.1 mm
Neck length	18.9 mm	8.7–35.5 mm
AAA maximum diameter	64.6 mm	48–93 mm
Minimum aortic bifurcation diameter	23.9 mm	12.3–50 mm
Right iliac seal zone diameter	14.9 mm	11.1–22.5 mm
Left iliac seal zone diameter	12.7 mm	8–19 mm
Right minimum access diameter	6.9 mm	2.1–10.3 mm
Left minimum access diameter	6.8 mm	5–10.8 mm

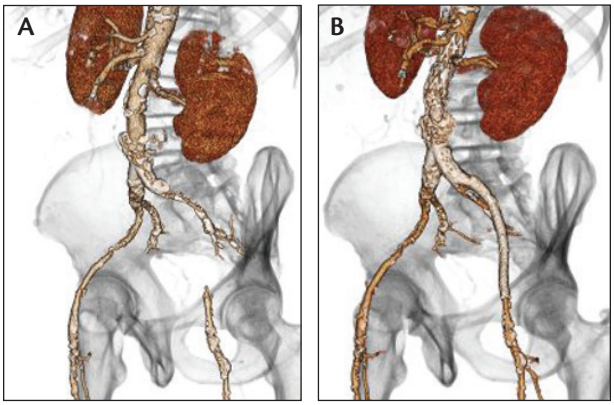


Figure 3. Pre- (A) and postoperative (B) CT angiograms of an AAA associated with extensive calcification and left external iliac artery occlusion treated with INCRAFT® Stent Graft System implantation and self-expanding stenting of the occluded vessel.

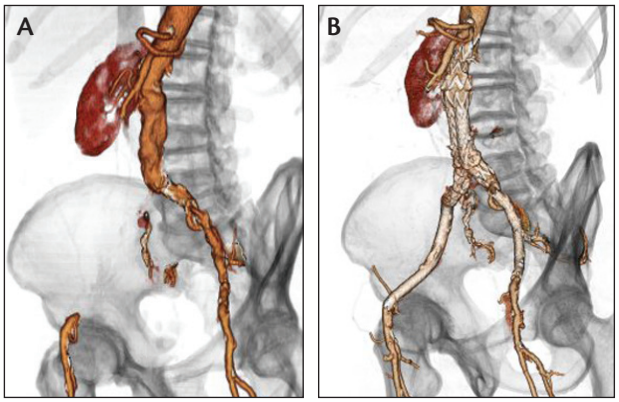


Figure 4. Pre- (A) and postoperative (B) CT angiograms of an AAA associated with right common and external iliac artery occlusion and severe stenosis of the left external iliac artery treated with INCRAFT® Stent Graft System implantation and self-expanding stenting of the access vessels.

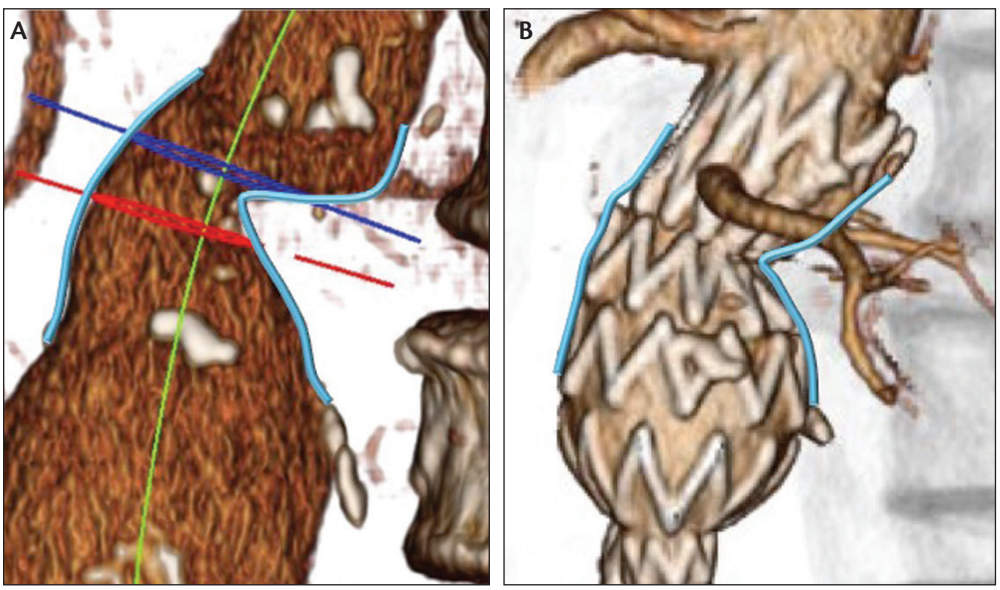


Figure 5. Preoperative CT angiogram of an AAA with an hourglass configuration of the proximal aortic neck (A); postoperative CT angiogram showing the excellent conformability of the INCRAFT® Stent Graft System to the native aorta anatomy (B).

proximal aortic neck and iliac arteries. In fact, when looking at the anatomic characteristics of our study group (Table 2), the median diameter of the access vessels was < 7 mm on both sites (range, 2.1–10.8 mm), the median neck length was 18.9 mm (range, 8.7–35.5 mm), median angulation was 36.9° (range, 5.9°–87.3°), and median aortic bifurcation diameter was 23.9 mm (range, 12.3–50 mm). Intraoperative technical success was obtained in 100% of the cases in absence of any major graft-related complications. Completion angiography showed the absence of endograft limb kinking and no reinforcing stenting was required. All operations were carried out under local anesthesia with bilateral percutaneous femoral access using only one Perclose ProGlide® (Abbott Vascular) either for the main body or the contralateral limb. Mean hospital stay was 3 ± 2.5 days. At 30 days, no type I or III endoleak, limb occlusion, or migration was observed. Four type II endoleaks were detected (13.8%), without aneurysm sac enlargement. One patient died of unrelated causes. Median follow-up was 4.3 ± 2.3 months (range, 1–6 months). During this time, there was one limb occlusion, which required a reintervention with thrombolysis and stenting, and no other graft-related complications in terms of type I and III endoleaks, migration, and aneurysm sac enlargement.

‡Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification, or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity, and/or angulation, which can affect successful initial treatment of the aneurysm.

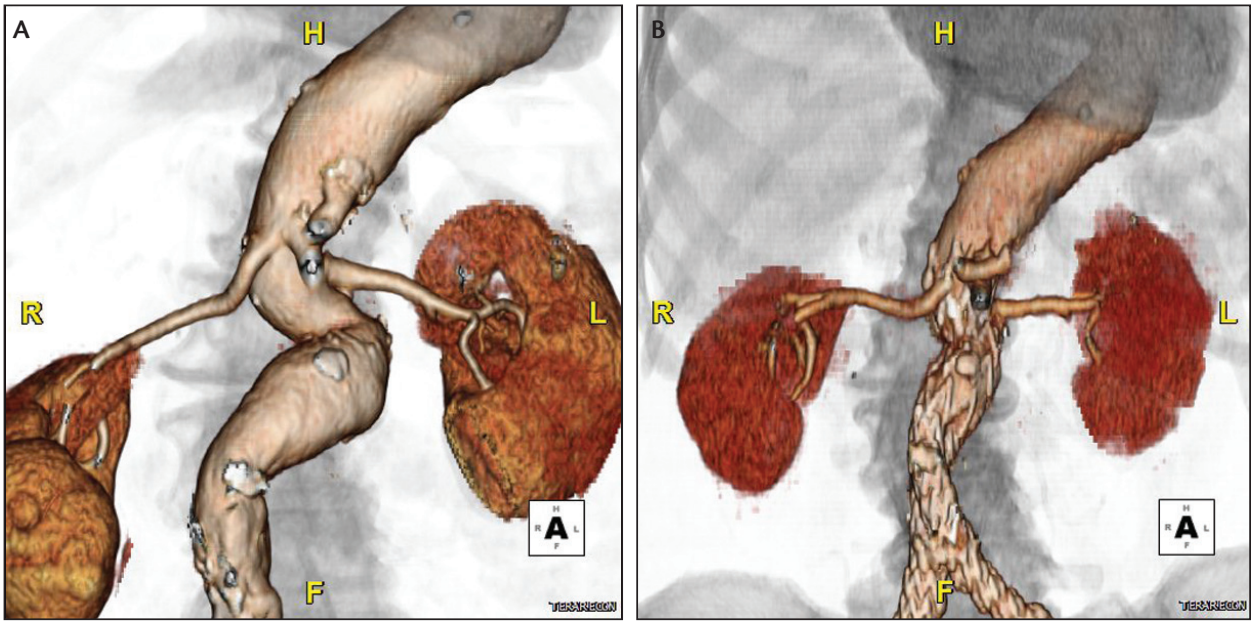


Figure 6. Preoperative CT angiogram of an AAA with a double severe angulation of the short proximal aortic neck (A); postoperative CT angiogram showing the precise deployment and the conformability of the INCRAFT® Stent Graft System to the tortuous anatomy (B).

The growing experience with the INCRAFT® System combined with its ease of use and clinical performance drove us to utilize it even in more challenging cases, additionally expanding the applicability of EVAR in our daily practice. Three patients in our practice presented with AAAs associated with iliac occlusion. In all of these cases, after recanalization of the occluded vessels (external iliac artery in two patients and common and external iliac artery in one patient), the graft was successfully advanced and deployed, and the procedure was concluded with stenting of the recanalized vessels (Figures 3 and 4). However, we did not focus only on challenging access vessels; we also addressed complex proximal aortic neck anatomy in terms of length, angulation, and shape. The INCRAFT® System confirmed its excellent precision in deployment and great conformability even in the presence of an hourglass proximal aortic neck configuration (Figure 5) and combination of severe supra- and infrarenal angulations (Figure 6).

This experience needs to be confirmed in a larger multicenter study with longer follow-up, but technical success in presence of such anatomies clearly represents a relevant step forward in the endovascular management of complex AAAs. ■

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The INCRAFT® AAA Stent Graft System: Remarkable Ease of Use in Practice for Patients With Complex Aortic Anatomies* to Repair Infrarenal AAAs

Corey L. Teigen, MD, summarizes his firsthand experience with the new ultra-low-profile INCRAFT® AAA Stent Graft System during his participation in the premarket INSPIRATION clinical trial.

Corey L. Teigen, MD
Fargo Sanford Health Interventional Radiology Department Chair
Sanford Health
Fargo, North Dakota
corey.teigen@sanfordhealth.org
Financial disclosures: Cordis Corporation supported the research study referenced in this article. He serves as a consultant for Cordis and has received payment for this service.

FIRSTHAND CLINICAL EXPERIENCE

As an interventional radiologist, I was aware of an unmet need for a stent graft that could safely and effectively treat a wide range of anatomies in a large, underserved population throughout the world. I was a consultant in the development of the INCRAFT® AAA Stent Graft System (Cordis Corporation) and had first knowledge of its development and the intended benefits.

I was selected to participate in the United States–based INSPIRATION study, a multicenter, open-label, prospective, nonrandomized study of the INCRAFT® Stent Graft System in patients with abdominal aortic aneurysms (AAAs). I successfully repaired 31 infrarenal AAAs between July 2012 and July 2013 with the INCRAFT® Stent Graft, including one compassionate-use patient, which is presented in detail in the case study. Despite my work in its development, it was not until I used the INCRAFT® Stent Graft in my first patient that I realized that it had all of the advantages of other available grafts in one easy-to-use device. Through my experience with the INCRAFT® Stent Graft, I anticipate it will be the most versatile graft on the market chiefly due to its ease of use, low profile, accurate placement, and the fact that the graft has the unique ability for in situ sizing to specific patient anatomy so it can be used in any type of patient. Patients with short, superior necks; small calcified or tortuous access vessels*; as well as small distal bifurcations will now be excellent candidates for endovascular repair—patients previously deemed poor candidates due to the deficiencies of the grafts currently available on the market. Because the INCRAFT® Stent Graft can be utilized in most patients, the need to stock several different endografts is reduced, and there is a limited need for a large inventory because a few INCRAFT® Stent Graft codes appropriately accommodate many different neck sizes and treatment lengths.

EASE OF USE OF THE INCRAFT® AAA STENT GRAFT SYSTEM

The INCRAFT® AAA Stent Graft System is considered an ultra-low-profile delivery system and is comprised of a straightforward delivery mechanism. Due to its industry-leading low profile, the INCRAFT® Stent Graft can be placed percutaneously, which allows for improved patient comfort and earlier discharge. The low profile also allows for treatment of patients with small and/or calcified access vessels, as well as in patients in whom access via the femoral artery is difficult, such as patients with previous vascular interventions or bypasses. The INCRAFT® AAA Stent Graft System consistently offers easy and accurate placement at

*Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification, or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity, and/or angulation, which can affect successful initial treatment of the aneurysm.

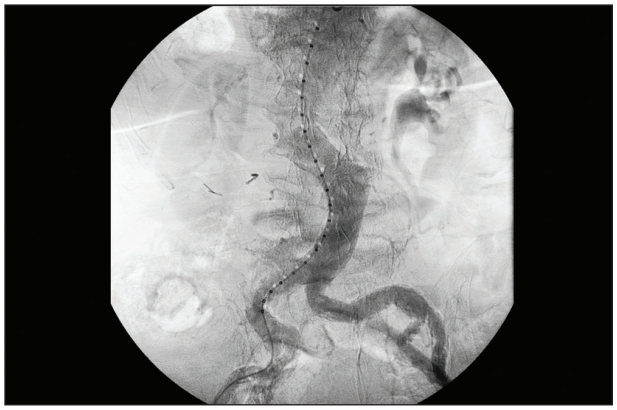

Figure 1. Initial angiogram demonstrating severely calcified, small, tortuous access vessels.

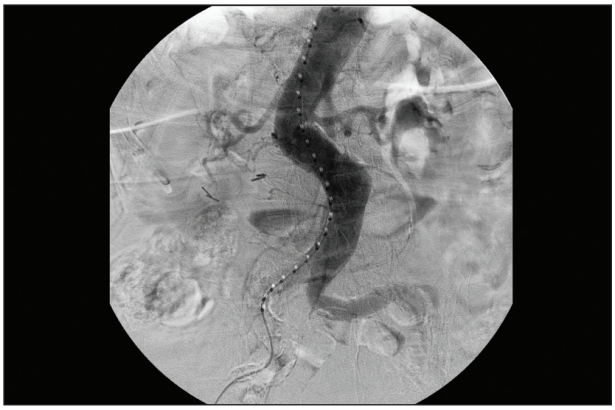

Figure 2. Initial angiogram representing a markedly angulated superior neck.

the level of the renal arteries as well as in situ adjustment of limb length. In doing this, the entire common iliac artery can be treated to the bifurcation. Because the clinician has absolute control with deployment of the graft, accurate placement can be achieved, both superiorly at the aortic neck as well as inferiorly at the iliac bifurcation. In my experience, the INCRAFT® AAA Stent Graft System surpasses the accuracy of placement and ease of delivery of any other graft on the market.

Design

The design of the INCRAFT® Stent Graft is intended for accurate placement in markedly tortuous anatomy. I have utilized this stent graft in patients with sharp, angulated necks (up to 60°); significant angulation of the aneurysm itself; as well as in marked angulation of the common and external iliac arteries. The device is made of nitinol stent and polyester graft technology. The straightforward delivery system not only allows accurate placement, but also allows for shorter procedure times. Blood loss is minimized, and there is noticeably improved patient comfort during and postprocedure.

CASE STUDY

A 91-year-old woman with severe peripheral vascular disease and severe heart and lung disease presented with a large, nearly 6-cm, infrarenal AAA. She was obviously not an open surgical candidate due to her multiple comorbidities, including underlying heart and lung disease, advanced age, as well as severely calcified and small access vessels. However, this patient was very active and lived by herself with no restrictions to her activities and day-to-day living.

The patient was brought to the operating room, and an attempt was made to place the commercially available grafts, including the smallest available Gore EXCLUDER® graft (Gore & Associates), but this was not possible due to her small access vessel size. The patient was not a surgical candidate for a cutdown to the common iliac artery to allow placement of any of the currently available grafts due to her severe underlying cardiac and pulmonary disease.

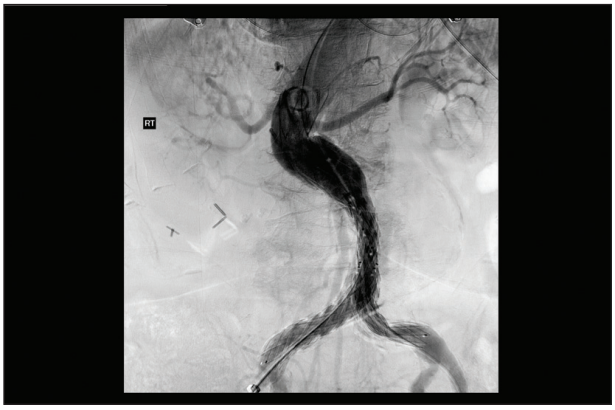

Figure 3. Final angiogram demonstrating successful exclusion of the aneurysm sac.

At this time, I was using the INCRAFT® AAA Stent Graft with great success in patients similar to this patient in the INSPIRATION clinical trial; however, this patient did not meet the US Food and Drug Administration study criteria due to her small, calcified, tortuous access vessels (Figure 1) and severely angulated superior neck (Figure 2). Upon petition for compassionate-use approval, this patient returned to the endovascular suite, and an INCRAFT® AAA Stent Graft was placed without complication. Because of the small size of the stent and deployment system used in the INCRAFT® AAA Stent Graft, not only was I able to accommodate this patient's very small access vessels, but I was also able to easily deploy the device, isolating the aneurysm sac (Figure 3), greatly reducing the risk of rupture and death. ■

The INCRAFT® AAA Stent Graft System: Novel Features Allow for Treatment of Challenging AAAs in Routine Clinical Practice

Stephen Goode, MBChB, MRCS, FRCR, PhD, explains how ease of use and ultra-low profile benefit his patients and his practice.

Stephen Goode, MBChB, MRCS(Eng), FRCR, PhD
Sheffield Vascular Institute
Northern General Hospital
Sheffield, United Kingdom
stephen.goode@sth.nhs.uk
Financial disclosures: He has disclosed that he is a proctor for Cordis.

FIRSTHAND CLINICAL EXPERIENCE

As a large endovascular center in Sheffield, United Kingdom, around 80% to 85% of endovascular aneurysm repair (EVAR) procedures are performed with percutaneous access and preferably under local anesthetic. Following the publication of the 1- and 2-year results of the INNOVATION trial, as a Consultant Vascular Interventional Radiologist, I was keen to try the INCRAFT® AAA Stent Graft System (Cordis Corporation). I was particularly interested in the novelty of the ultra-low-profile nature of the system, which would hopefully enable easy and safer percutaneous access, along with extending the use of EVAR to some more challenging anatomy. This article discusses how ease of use of the INCRAFT® device benefits patients with challenging aortic anatomy and presents two cases that demonstrate some of the novel features of this exciting and new stent graft system.

CASE 1: SMALL-CALIBER EXTERNAL ILIAC ARTERIES AND MODERATE FEMORAL ARTERY CALCIFICATION

An 83-year-old woman who had been in the aneurysm surveillance program for 3 years presented with abdominal pain. CT showed that the aneurysm had increased rapidly in size and now reached the size criteria for intervention at 5.5 cm. The preoperative CT angiogram (CTA) revealed an aneurysm with a reasonable length of aortic neck (Figure 1A) but with several adverse fea-

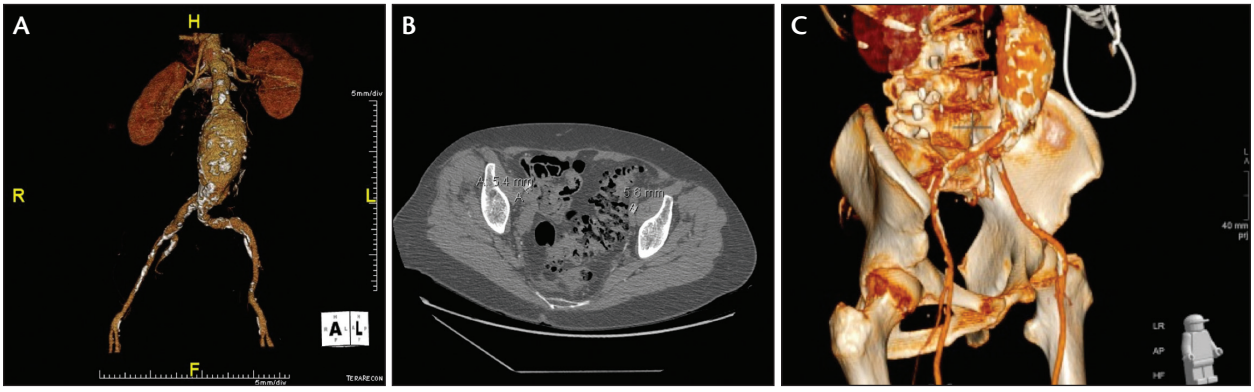

Figure 1. CTA showing an aortic neck with a 4-cm length (A). Axial CTA showing narrow-caliber EIAs measuring 5 to 6 mm bilaterally (B). CTA showing heavily calcified CFA (C).

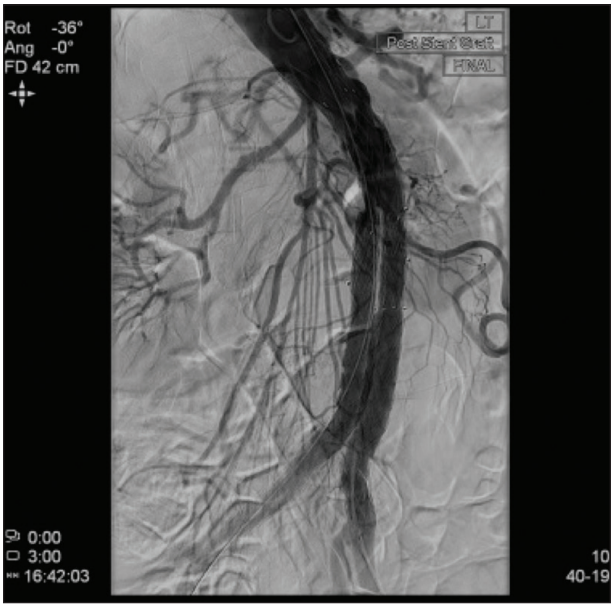

Figure 2. Final digital subtraction angiogram showing the stent graft in situ and good flow of contrast through the stent graft and into bilateral iliac systems.

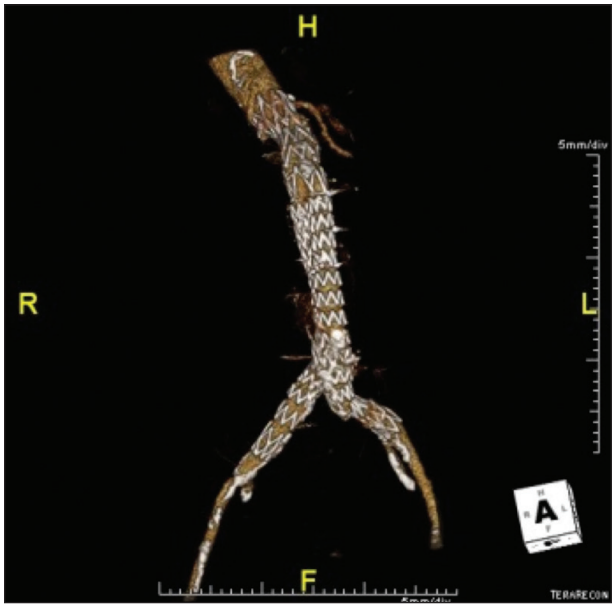

Figure 3. CTA at 30 days postintervention showing the INCRAFT® AAA Stent Graft System in situ.

tures, including small-caliber external iliac arteries (EIAs) bilaterally measuring between 5 and 6 mm (Figure 1B) and short and diseased common femoral arteries (CFAs) bilaterally with moderate posterior and side wall calcification (Figure 1C), which was more severe in the left CFA. Because of these features, we chose to use the INCRAFT® System to treat this aneurysm electively.

EVAR was performed under local anesthesia and was infiltrated under ultrasound (US) guidance into skin and onto and around both CFAs. Access was then gained under US via bilateral CFA, taking care to puncture the artery away from the calcific plaques in an optimum position for ProGlide® (Abbott Vascular)* deployment. Bilateral 8-F sheaths were inserted initially following the predeployment of two ProGlide devices. The main body of the INCRAFT® device was deployed from the right side after marking the renal arteries. There was no problem inserting the delivery system despite the diseased CFA and narrow-caliber EIA. The ipsilateral side was completed after marking the iliac bifurcation and confirming the limb length using a measuring pigtail catheter. After deployment of the ipsilateral limb, the delivery system was removed and replaced with a 10-F sheath, followed by securing both ProGlide sutures to ensure good hemostasis around the sheath. The contralateral limb was cannulated, and following the marking of the left iliac bifurcation and confirming the correct length of the contralateral limb, it was successfully deployed. The contralateral limb delivery system was then removed, and the access site was downsized to a 10-F sheath. Balloon molding of the top end, overlap zones, and the distal ends was completed with a Coda® balloon (Cook Medical).* The final angiographic result was good with satisfactory exclusion of the aneurysm and no evidence of any type I endoleak (Figure 2). Following the completion angiogram, both CFA access sites were closed utilizing the predeployed ProGlide sutures without complication, gaining satisfactory hemostasis immediately. The patient was comfortable throughout the procedure.

Postoperatively, the patient mobilized quickly, and there were no groin complications. The initial follow-up CTA showed a satisfactory appearance of the aneurysm repair with successful aneurysm exclusion (Figure 3). Only a small type II endoleak was seen, and there were no type I or III endoleaks. Bilateral CFAs were satisfactory in appearance with no complications seen on CTA.

CASE 2: CHALLENGING NECK ANATOMY AND NARROW DISTAL AORTA

An 88-year-old man had been in the US aneurysm surveillance program for 6 years. His latest US showed an increase in aneurysm size from 5.2 to 5.9 cm in 6 months. CTA showed an actual maximum diameter of 6.3 cm (Figure 4). His aneurysm had several adverse features, including a short and hourglass-shaped neck (Figure 5A) and a tight distal aorta measuring 16 mm at its narrow-

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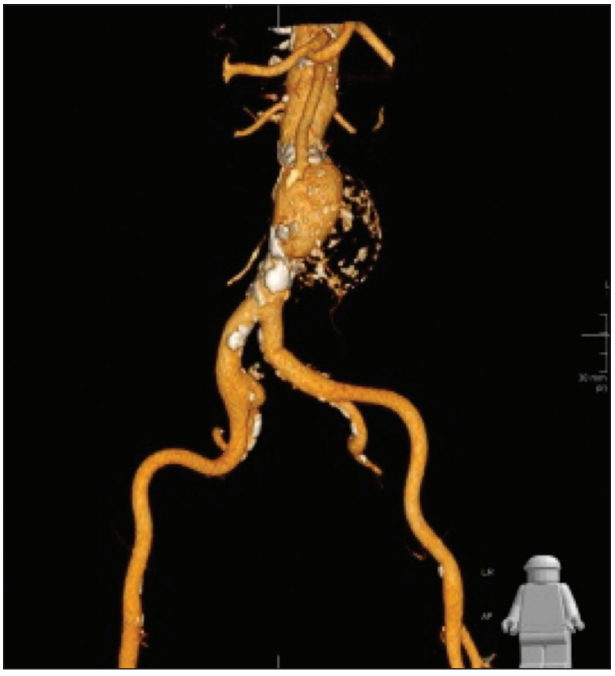

Figure 4. Reformatted CTA showing a 6.3-cm infrarenal AAA with a short, hourglass-shaped neck and narrow distal aorta. Bilateral CFAs are disease free, good caliber, and suitable for percutaneous access.

est point (Figure 5B). He had normal-appearing bilateral CFAs, which were suitable for percutaneous access.

EVAR was performed under local anesthesia using a marcaine and lidocaine mixture. Local anesthesia infiltration and CFA puncture were performed under US guidance. We predeployed double ProGlide devices in the CFA bilaterally prior to inserting 8-F sheaths. We planned to use the INCRAFT® device with a 34-mm main body, which was inserted from the left CFA; the imaging pigtail catheter was placed from the right side. After marking the renal arteries, the main body was deployed into an infrarenal location, with the top end markers easily visible and enabling accurate placement of the top end of the stent graft, which was especially important due to this patient's complex aneurysm neck morphology (Figure 6). The ipsilateral limb was then completed after marking the left iliac bifurcation and confirming the measurement of the required limb length with a marker pigtail catheter. After cannulation of the contralateral limb, the right side was completed after marking the right iliac bifurcation. The deployment systems were removed, and 12-F and 10-F sheaths were inserted on the left and right, respectively. Balloon molding of the top end, bilateral overlap zones, and distal ends was performed with a Coda balloon. Due to the tight aortic bifurcation, balloon angioplasty was performed with two 12-mm percutaneous transluminal

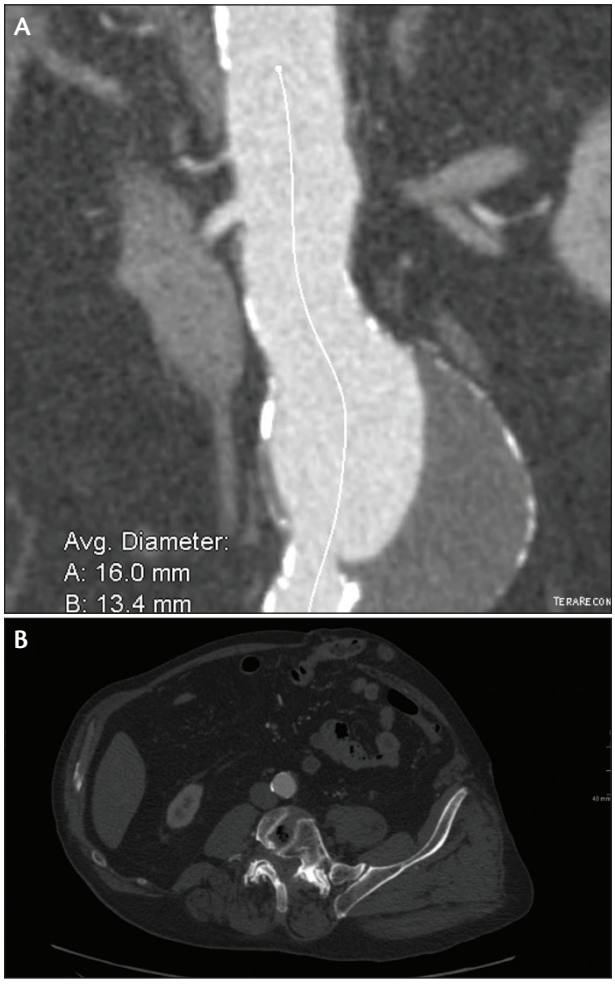

Figure 5. Sagittal CT showing abnormal aneurysm neck morphology in detail. At the level of the renal arteries, the aorta measured 26 mm, narrowed to 24 mm, and then flared out to 26 mm (A). Axial CT image of the distal aorta showing the narrowest point measuring 16 mm (B).

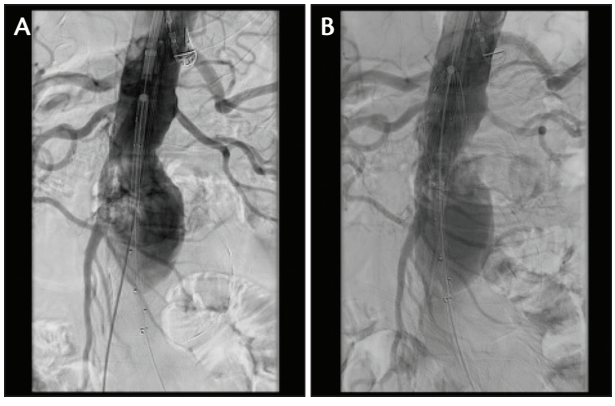

Figure 6. Digital subtraction angiogram showing the stent graft in situ prior to deployment into the hourglass-shaped neck (A) and the main body partially deployed and top end markers visible at the level of the renal arteries (B).

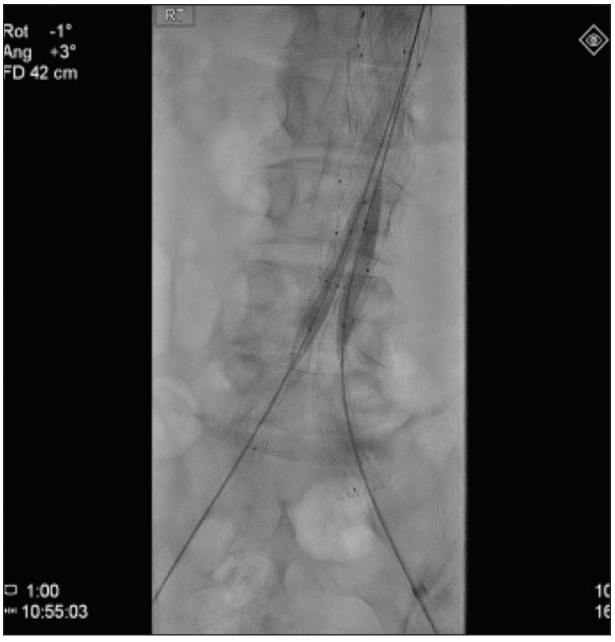

Figure 7. Fluoroscopy showing kissing balloon angioplasty of the distal aorta after deployment of the INCRAFT® AAA Stent Graft System.

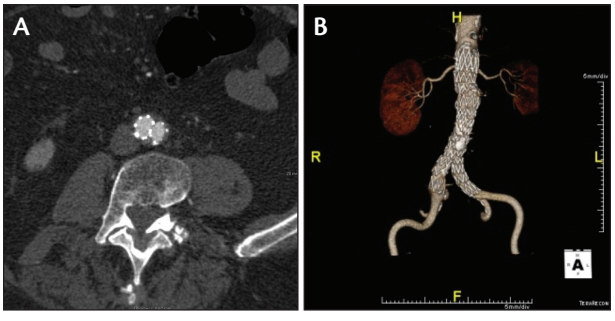

Figure 9. CTA at 30 days postintervention showing a satisfactory appearance of the distal aorta. Stent graft limbs are widely patent and not compressed (A). CTA at 30 days postintervention showing satisfactory appearance of the stent graft (B).

angioplasty balloons (Figure 7). There was a good angiographic result with satisfactory exclusion of the aneurysm and no endoleak (Figure 8). Successful closure of bilateral CFA access points using predeployed ProGlide devices was completed without complications. The patient was comfortable throughout the procedure under local anaesthesia, with no need for additional sedation or pain relief. The patient recovered well following the procedure and was discharged home after 24 hours.

Follow-up CTA at 30 days showed an excellent appearance with the stent graft in a good position, prompt flow of contrast through the stent graft, and no evidence of any endoleak. In addition, the aortic bifurcation was not compressed and widely patent with the bilateral limbs in a satisfactory position (Figure 9). No complications were seen in the bilateral CFA.

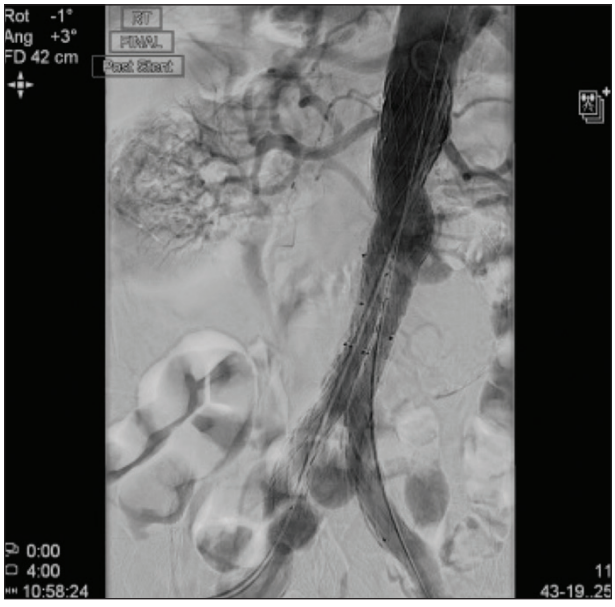

Figure 8. Final angiogram showing satisfactory exclusion of the aneurysm and good flow of contrast into bilateral iliac systems with maintenance of the internal iliac artery flow.

CASE DISCUSSION

These cases demonstrate some of the novel features of the INCRAFT® System. Case 1 illustrates the benefits of the smaller, low-profile delivery system, which was ideally suited for treating this aneurysm given its ability to work well in the narrow-caliber access vessels and provide only low-profile access to the CFA. The CFAs were markedly diseased and calcified, making the percutaneous access challenging. Using an ultra-low-profile system enabled safe and secure access with the patient under local anesthesia, despite the adverse features, and led to a comfortable experience for the patient. Case 2 illustrates that the INCRAFT® System manages well within adverse aortic neck morphology due to its easily identifiable top end and straightforward two-step delivery. During deployment, tactile feedback is good, and the markers are easily identified, enabling confident and straightforward stent graft delivery.

The INCRAFT® System has a number of novel features that allows the treatment of challenging AAAs. Due to the ultra-low-profile and hydrophilic delivery systems, it is ideally suited to percutaneous access and performing aneurysm repair under local anesthesia. This feature fits well into my practice for percutaneous EVAR; patients are comfortable during the endovascular procedure and have early ambulation and quick discharge postprocedure. ■

The INCRAFT® AAA Stent Graft System: PEVAR Utilizing the New Ultra-Low Profile in Infrarenal AAAs

Prof. Do and Dr. Makaloski discuss how a device with an ultra-low profile offers advantages to patients and the practice.

Prof. Dai-Do Do, MD
Director Peripheral Vascular Interventions and Vice Chairman
Department of Clinical and Interventional Angiology
University Hospital
Bern, Switzerland
dai-do.do@insel.ch
Financial disclosures: He has disclosed he is a paid consultant to Cordis.

Vladimir Makaloski, MD
Department of Cardiac and Vascular Surgery
University Hospital
Bern, Switzerland
vladimir.makaloski@insel.ch
Financial disclosures: He has disclosed he is a paid consultant to Cordis.

Minimally invasive treatment of abdominal aortic aneurysms (AAAs) was first introduced by Volodos and colleagues in the 1980s and then became popularized by Parodi in the early 1990s. Until recently, most stent grafts with rather large delivery system profiles required bilateral open surgical cutdown of the common femoral artery (CFA). Newer delivery systems with lower profiles, such as the INCRAFT® AAA Stent Graft System (Cordis Corporation), enable safe and effective percutaneous treatment of patients with AAAs on a much larger scale. Prof. Do and Dr. Makaloski discuss their firsthand experience with the INCRAFT® System and present a case that demonstrates use of the device in percutaneous endovascular aneurysm repair (PEVAR).

Why did you decide to first try the INCRAFT® AAA Stent Graft System? How have you adopted it in your practice?

Prof. Do: I started with the EVAR program 20 years ago. I was the interventional angiologist who convinced the vascular surgeon on our team to treat the first endovascular case at that time—successful implantation of the Stentor stent graft (MinTec, Inc.)* in a patient with an infrarenal AAA. Since that time, I am always looking for new technology, which was my reason for using the INCRAFT® Stent Graft System. We have adopted it very well into our practice.

Why is low profile important to you?

Prof. Do: Low-profile devices enable treatment of patients with challenging access vessels; these patients may otherwise be excluded from an EVAR program.

In your experience, how does the low profile of the INCRAFT® System compare to other devices?

Prof. Do: The INCRAFT® System performs as well or even better than other devices with a low profile. The ultra-low profile, the lowest outer diameter (OD) sheath for both the main body and contralateral limb (14 F and 12 F, respectively,[†,‡]) compared to other devices, improves flexibility, which in turn favors advancement of the stent graft through very tortuous access vessels.

What are the benefits of low profile in patients with small access vessels and in those with regular anatomy?

Prof. Do: As stated previously, patients with small access vessels may not be candidates for EVAR if not for a device with an ultra-low profile. Patients with regular anatomy

*The third-party trademarks used herein are trademarks of their respective owners.
†For the prostheses diameter of 34 mm, the inner diameter of the integrated sheath introducer is 15 F (outer diameter of 16 F).
‡For the iliac limb prosthesis with a 24-mm diameter, the outer diameter is 13 F.
For EMEA healthcare professionals only. Important information: Prior to use, refer to the Instructions for Use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings, and precautions. As part of the Cordis policy of continuous product development, we reserve the right to change product specifications without prior notification.
The use of the INCRAFT® AAA Stent-Graft System requires that physicians be specially trained in endovascular abdominal aortic aneurysm repair techniques, including experience with high-resolution fluoroscopy and radiation safety. Cordis Corporation will provide training specific to the INCRAFT® AAA Stent-Graft System.
Contact your Cordis sales representative for availability and ordering. As part of the Cordis policy of continuous product development, we reserve the right to change product specifications without prior notification.

get all of the benefits of a low-profile device: percutaneous implantation with local anesthesia and early discharge.

Does the low-profile feature of the INCRAFT® System provide specific benefits to any other patient groups?

Prof. Do: In our experience, a reduction in intervention time, blood loss, wound complications, and secondary interventions can be expected, even in patients with small access arteries. There is also a reduced need for closure devices. As a result, there is shorter hospitalization for inpatient treatment and outpatient treatment is a more feasible option; both options result in cost savings. ■

CASE PRESENTATION: PEVAR IN AN INFRARENAL AAA WITH A LONG PROXIMAL NECK

A 68-year-old man with an asymptomatic abdominal aortic aneurysm (AAA) was referred to our center for evaluation for EVAR. He was a former heavy smoker, but otherwise without a history of hypertension, hyperlipidemia, diabetes mellitus, and coronary artery disease. The preoperative CT scan confirmed the ultrasound findings of an infrarenal AAA of 5.5 cm in diameter with a long proximal neck (Figure 1). The patient was offered either open surgery or EVAR, and the decision was to proceed with PEVAR.

PERCUTANEOUS ENDOVASCULAR REPAIR

PEVAR took place in the hybrid operating room. Under local anesthesia, the preclosure technique was performed on both common femoral arteries (CFAs) using Perclose ProGlide devices (Abbott Vascular).* The anterior wall of the right CFA was first punctured at a 45° angle and at the appropriate site based on the preoperative CT findings. A stiff 0.035-inch Radifocus M stiff type guidewire (Terumo Interventional Systems)* was engaged. After predilatation of the subcutaneous tissue and vessel wall using the dilator of an 8-F sheath, the two ProGlide systems were deployed at 30° medially, lateral from the centerline (Figure 2). The two sutures with pretied knots of each device were secured with a covered clamp, and an 8-F sheath was inserted over the guidewire. Knowing the very low profile of the contralateral limb of the INCRAFT® Stent Graft (Cordis Corporation), only one ProGlide device was placed into the left CFA.

The Radifocus guidewire on the right side was then exchanged for a stiffer 0.035-inch guidewire (E-wire, JOTEC).* Next, the 8-F sheath was removed, and the delivery system of the INCRAFT® AAA Stent Graft System (14-F OD†) with the main body inside was lined up with the contralateral gate and advanced smoothly up to the level of the renal arteries. At this step, an initial angiogram using a graduated pigtail catheter from the left side was done, showing the position of the device and the lower location of the left renal artery as well as the two normal common iliac arteries (Figure 3). After adjusting the INCRAFT® Stent Graft just below the take-off of the left renal artery, the main body (26 mm in diameter and 94 mm in length) was deployed. The AAA was then successfully excluded after percutaneous placement of the contralateral and then ipsilateral limb. An iliac limb 13 mm in diameter and 120 mm in length was used for

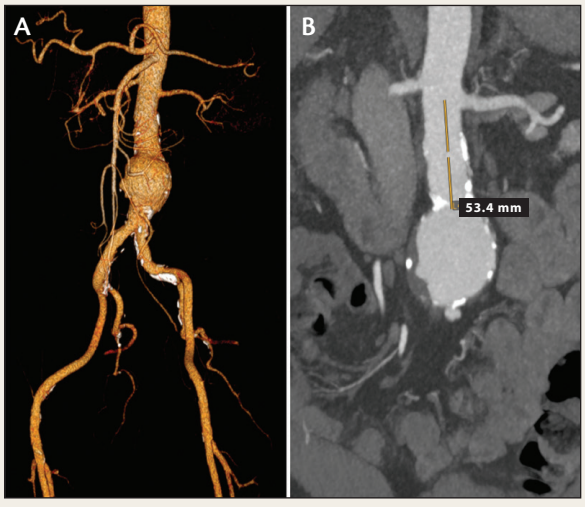

Figure 1. Preoperative CT scan showing the infrarenal AAA (A) with a rather long proximal neck (B).

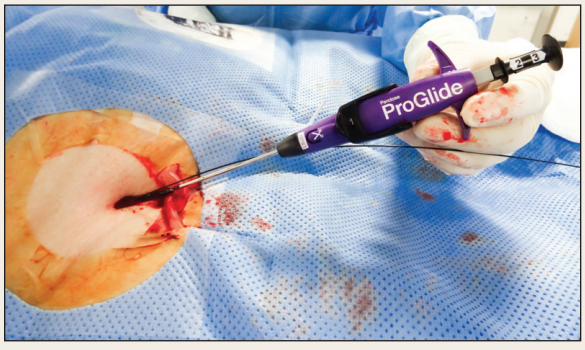

Figure 2. Preclosure of the access sites using ProGlide devices.

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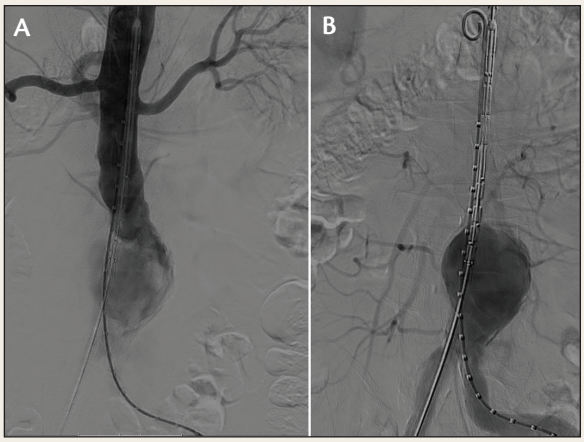

Figure 3. Initial angiogram using a graduated pigtail catheter showing the position of the ultra-low profile delivery system within the abdominal aorta with the still undeployed INCRAFT® main body. Note the lower take-off of the left renal artery (A) and the normal common iliac arteries (B).

the contralateral left side. An iliac limb 16 mm in diameter and 120 mm in length was placed into the right side common iliac artery (both delivery systems 12-F OD‡). The proximal and distal seal zones, as well as the stent graft component junctions, were subsequently ballooned using a Reliant stent graft balloon catheter (Medtronic, Inc.).* The final angiogram demonstrated an excellent result of PEVAR and good perfusion of the hypogastric arteries (Figure 4).

At the end of the PEVAR procedure, the access sites in both groins were sealed one after the other by withdrawing the delivery system, then advancing and tying the knots using the knot pusher of the ProGlide system. Immediate hemostasis was obtained so that the guidewires could be removed, and no compression bandage was needed. The whole procedure took 55 minutes, and just 57 mL of contrast media was administered.

MEDICAL THERAPY AND FOLLOW-UP

The patient was discharged with antiplatelet monotherapy (acetylsalicylic acid, 100 mg/day). A controlled CT angiogram performed at 1 month post-intervention confirmed the good initial result after PEVAR with complete exclusion of the aneurysm and no endoleak (Figure 5).

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‡For the iliac limb prosthesis with a 24-mm diameter, the outer diameter is 13 F.

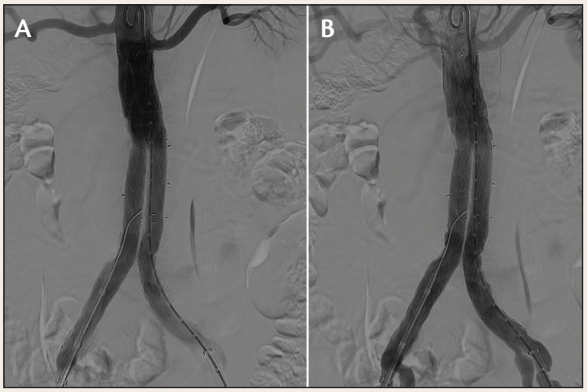

Figure 4. Final angiogram showing the complete exclusion of the AAA using the ultra-low-profile INCRAFT® AAA Stent Graft System (A, B).

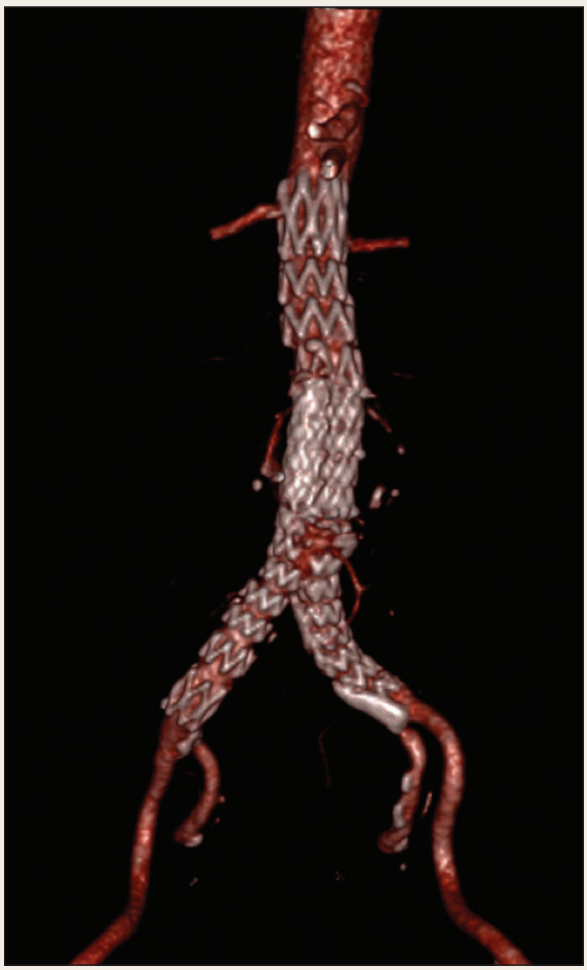

Figure 5. Follow-up CT scan confirmed the good result of PEVAR.

The INCRAFT® AAA Stent Graft System: Placement Accuracy and Customization

Prof. Jose M. Abadal, MD, PhD; Prof. Miguel Araujo, MD; and Prof. Esther Vazquez, MD, discuss their clinical experience using this innovative stent graft system.

Prof. Jose M. Abadal, MD, PhD
Department of Vascular and Interventional Radiology
Severo Ochoa University Hospital
Madrid, Spain
jmabadal@yahoo.es
Financial disclosures: None.

Prof. Miguel Araujo, MD
Department of Vascular and Endovascular Surgery
Severo Ochoa University Hospital
Madrid, Spain
miguelaraujopazos@gmail.com
Financial disclosures: None.

Prof. Esther Vazquez, MD
Department of Vascular and Endovascular Surgery
Severo Ochoa University Hospital
Madrid, Spain
esther.vazquezro@salud.madrid.org
Financial disclosures: None.

An essential feature of any endovascular device used to treat abdominal aortic aneurysms (AAAs) is the ability to accommodate any necessary changes after the delivery system has been introduced. The INCRAFT® AAA Stent Graft System (Cordis Corporation) was designed to solve the limitations of previous-generation endovascular devices, particularly with regard to versatility, accuracy, and real-time customization.

Profs. Abadal, Araujo, and Vazquez discuss two key attributes of the INCRAFT® AAA Stent Graft System—placement accuracy and in situ customization—and present several cases illustrating the device's benefits in real-world clinical practice.

Why did you decide to first try the INCRAFT® AAA Stent Graft System?

We have extensive experience in AAA endovascular treatment, but in working with other endografts over the years, we have encountered problems, such as difficulties with femoral and iliac access and navigation as well as a need for multiple device sizes and lengths to account for different anatomies. The launch of the INCRAFT® System has made our daily practice easier, not only because of the ultra-low profile and flexible delivery system, but also the trimodular design of the graft, which allows the procedure to be optimized using the fewest prostheses and covers a broad number of cases with simplified inventory management.

How have you adopted the INCRAFT® AAA Stent Graft System in your practice?

The INCRAFT® System has become a device that is routinely used in our practice. Specifically, it is our first choice to treat AAA patients with narrowed and diseased aortoiliac vessels and access. The main benefits of the INCRAFT® AAA Stent Graft System are the device's ultra-low profile and its in situ iliac extension customization.

Why is placement accuracy important to you?

Placement accuracy is one of the key goals of the AAA endovascular procedure and enables a great result, reducing any unexpected complications. Placement accuracy is also related to long-term clinical success. Device misplacement can result in endoleaks and persistence of aneurysmal sac enlargement, which increases endovascular and surgical complexity and risk of reintervention.

In your experience, how does the placement accuracy of the INCRAFT® System compare to other devices?

Placement accuracy of the INCRAFT® System is enhanced by the distinctive proximal and distal radiopaque markers that can be partially repositioned prior

to full deployment. Although every case is planned in advance with precise measurements, and the optimal graft is selected for each patient, there is always a minimal intraprocedural discrepancy. The INCRAFT® device is versatile and aids in intraprocedural graft adjustment, without requiring other unplanned grafts. That is an important difference from competitors and a very important issue in emergency cases.

What are the benefits of placement accuracy of the INCRAFT® System to the patient, physician, and institution?

The INCRAFT® endograft offers customized treatment to a broader range of patients. Moreover, it may allow patients with AAAs to be treated who otherwise would not be candidates for endovascular repair using other devices because of anatomic constraints, for example, narrowed iliac vessels (diameter < 7 mm) or tight aortoiliac bifurcation (10-mm limb diameter).

For the clinician, the easier the procedure, the better results in terms of surgery, access and placement complications, grafts needed, radiation exposure, etc. Our feeling is that the anatomic variations during the surgery do not have an important impact on your planning and resource management.

For the institution, we can stock less inventory using the INCRAFT® System compared with any other endoprostheses, because of its in situ length customization. In our experience, the flexibility of the INCRAFT® System allows placement in up to 90% of AAA procedures. Billing prediction per procedure has been simplified because fewer product codes are needed, and there is a low variation in the number of devices used in patients because of its trimodular design.

Does improved placement accuracy lead to a reduction in acute and chronic complications?

Data on placement accuracy from the INNOVATION study have demonstrated a 2-mm median distance from the lowest renal artery to the graft edge markers in 58 interventions, with no reports of stent migration in 50 cases at 2 years. Data on in situ limb adjustment also outline distal limb accuracy with a median 12-mm distance from the origin of the internal iliac artery. These technical data correlate with the excellent 1-year results and absence of complications: 0% type I or III endoleaks and no aneurysmal sac enlargement.[1]

Can you explain in situ length customization? How does this work? What are the benefits of this feature?

In situ length customization allows a clinician to adjust the graft in real time during the procedure. The limb length can be adjusted bilaterally, up to 3 cm ipsilaterally and 2 cm contralaterally. This substantially improves placement accuracy and reduces the risk of inadvertent side branch coverage.

The safety of variable limb overlapping is enhanced by suture knots in the outer surface of the limb stent, which provides more stability and firms up the modular junction.

The benefit is obvious, because you can use the same iliac extension for different lengths; as a result, a broad range of patients can be treated with a small stock. This issue is very important in ruptured AAAs. The device's versatility allows us to treat patients easily and quickly, even in emergency cases, when there is little time for planning and measurements.

What are the main benefits of the INCRAFT® System as compared to other devices you use in your practice?

First, the iliac limbs of the main graft have 11 mm in diameter; this feature is important in small and diseased aortic bifurcations. The very low profile system (equivalent to a 12-F catheter sheath introducer profile*) allows the device to be introduced through the superficial femoral artery in high and diseased femoral bifurcations. The delivery system is extremely easy and precise for suprarenal fixation and the aortic main body, and without a cap at the top, deployment and the retrieval of the graft is simplified. The learning curve is also reduced when compared to other devices. ■

*The iliac limb delivery system has a 12-F outer diameter for prothesis diameters between 10 mm and 20 mm and the 13-F outer diameter for the 24-mm diameter prosthesis.

1. 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. 2015;61:1-8.

CASE 1: NARROWED AORTIC BIFURCATION

An 80-year-old man with multiple risk factors, including hypertension, hyperlipidemia, and coronary heart disease, presented with a 60-mm AAA. CT showed a narrowed distal aorta (Figure 1). An angiogram demonstrated a narrowed distal aorta with nontortuous iliac arteries. The INCRAFT® device with a 22-mm main body device and 10-mm diameter iliac limbs was deployed (Figure 2). Kissing balloon angioplasty was performed to maintain patency without the need for stent reinforcement. AAA exclusion was successful without limb kinking or occlusion on follow-up.

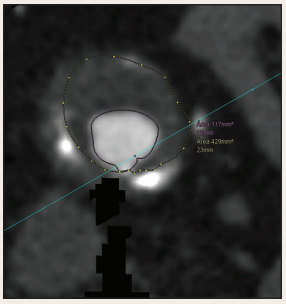

Figure 1. Axial image of a contrast-enhanced CT showing a narrowed aortic bifurcation of 23-mm diameter (adventitia-adventitia) and patent luminal diameter of 12 mm.

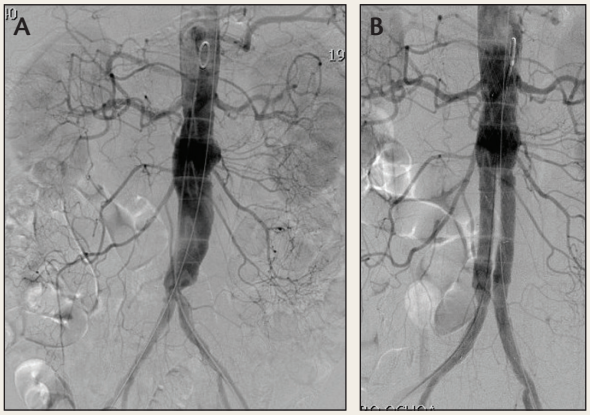

Figure 2. Angiogram demonstrating a narrowed distal aorta (A). Results after use of the INCRAFT® device demonstrating an open distal aorta, with widely patent graft limbs (B).

The INCRAFT® device may broaden the inclusion criteria in narrowed iliac bifurcation due to the ultra-low profile and iliac limbs of 10-mm in diameter. The use of an aorto-uni-iliac graft and femorofemoral bypass may also be avoided. Iliac graft radial force was sufficient to maintain patent bifurcation.

CASE 2: TORTUOUS AORTOILIAC ARTERIES†

A 73-year-old man presented with a 68-mm diameter AAA and renal insufficiency. CT showed tortuous and calcified iliac vessels and a long neck infrarenal AAA (Figure 1). Percutaneous endovascular aortic repair with the INCRAFT® device (22-mm main body) was performed. The device easily handled the patient's challenging anatomy. There was no need to force the stent graft delivery system, and a catheter-like navigation sensation was felt. There was no excessive rectification of the iliac vessels/aorta (Figure 2). The INCRAFT® AAA Stent Graft adapted to the anatomy successfully, excluding the aneurysm (Figure 3).

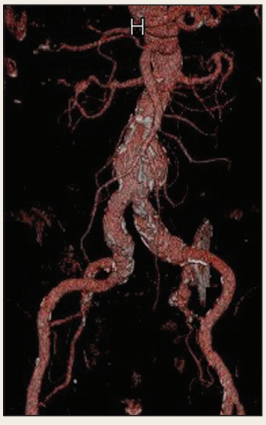

Figure 1. Three-dimensional CT showed an AAA with tortuous, angulated, dilated, and calcified iliac vessels.

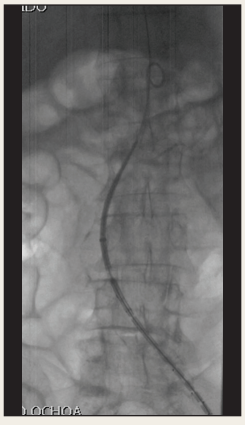

Figure 2. The main body graft delivery system, with flexible navigation that preserves vessel curves and angulation.

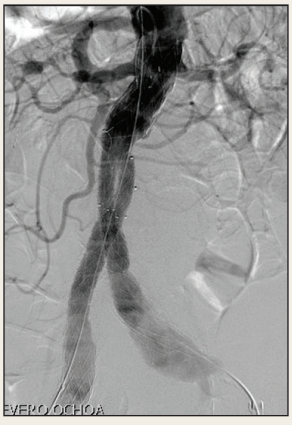

Figure 3. Excellent conformability of the INCRAFT® device in a "ballerina" position.

The INCRAFT® AAA endovascular device allowed a catheter-like, easy navigation, even in hostile iliofemoral vessels. The device design reduces trauma to the iliac artery access, avoiding potential complications (eg, rupture, dissection/thrombosis, embolism).

†Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity, and/or angulation, which can affect successful initial treatment of the aneurysm.

CASE 3: NARROWED ILIAC VESSELS†

A 75-year-old patient presented with an asymptomatic AAA of 60 mm in diameter. The patient had comorbid factors that increased surgical risk, including multiple drug allergies, renal failure, previous abdominal surgeries, and cardiovascular disease, as well as a vascular history of Rutherford stage 2 peripheral artery disease with bilateral femoropopliteal occlusion.

CT of the anatomy was favorable, as the aneurysm had a long infrarenal neck and no angulations. However, the iliac arteries were extensively diseased and narrowed in diameter (Figure 1). The peripheral arteries were also narrowed, and there was a bilateral femoropopliteal occlusion. At this point, the main concern was to choose a graft that could manage the extensively diseased iliac arteries and avoid graft component overlapping.

We decided to use the INCRAFT® AAA Stent Graft System because the ultra-low profile would facilitate iliac navigation through the tortuous, stenotic, and narrowed iliac vessels. Periprocedural customization of the iliac limbs would help enable accurate placement on a nondiseased landing zone. The main body graft was introduced and deployed through the right side, with an excellent navigation due to the ultra-low profile and catheter-like shaft flexibility. The contralateral left iliac stenosis was easily passed without the need of predilation because of the 12-F integrated delivery system.* In this case, it was mandatory to land the iliac extensions in the desired location to avoid any outflow problems (Figure 2). This is an advantage of the INCRAFT® device's limb flexibility, which allows for a 2- to 3-cm in situ adjustment.

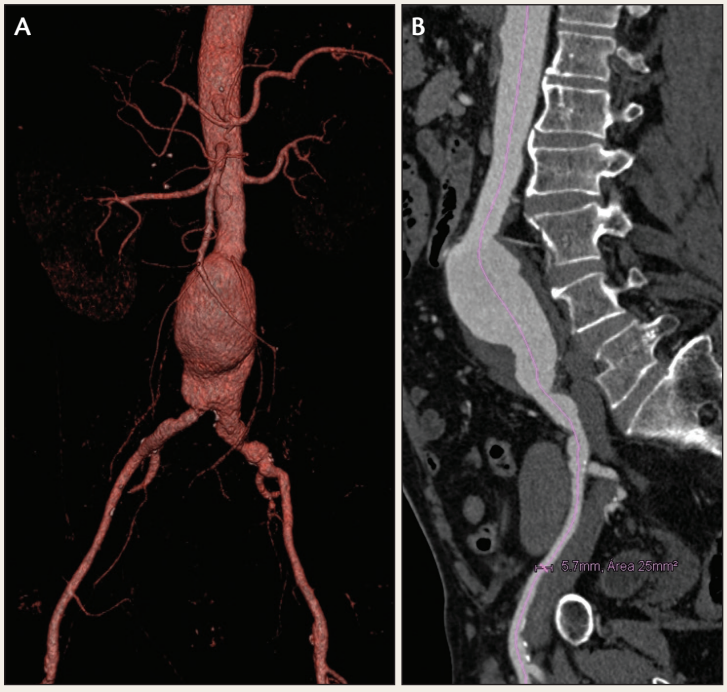

Figure 1. Three-dimensional volume rendering of an AAA with a long neck and without angulations (A). CT centerline reconstruction shows the small external iliac diameters (5.7 mm). Note the common iliac stenosis (3.5-mm lumen) (B).

At 6-month follow-up, contrast-enhanced ultrasound demonstrated a reduction of the aortic sac (56 mm), without leaks, and the patient's walking distance had improved as a result of the procedure (Figure 3).

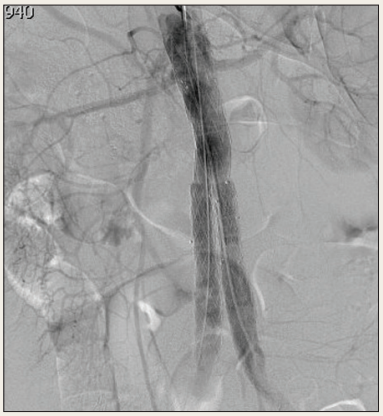

Figure 2. Final angiogram after EVAR.

Because of the combination of ultra-low profile and ease of navigation, the INCRAFT® AAA Stent Graft System may have an advantage over other devices in iliac vessels < 7 mm. This situation is more prevalent in women, Caucasian men of small stature, and Asian descendants.

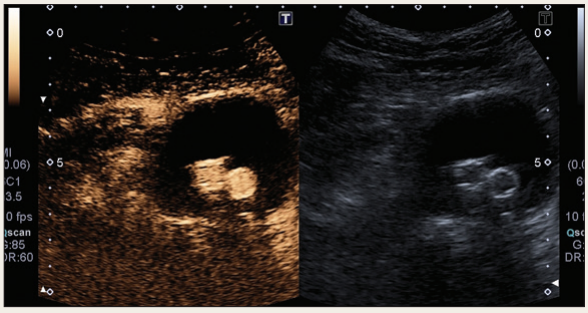

Figure 3. Axial view with contrast-enhanced ultrasound of the AAA with patent limbs and sac thrombosis at 6-month follow-up.

*The iliac limb delivery system has a 12-F outer diameter for prothesis diameters between 10 mm and 20 mm and the 13-F outer diameter for the 24-mm diameter prosthesis.

†Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification, or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity, and/or angulation, which can affect successful initial treatment of the aneurysm.

CASE 4: ISOLATED COMMON ILIAC ANEURYSM

A 73-year-old man presented with an isolated aneurysm of the right common iliac artery. CT showed a 35-mm aneurysm in the common iliac artery that had grown over the 2 last years (Figure 1). The aneurysm started at the short neck of proximal iliac artery and ended at the level of the internal iliac bifurcation. There was an important discrepancy between the proximal common iliac and external iliac diameter.

Percutaneous access with two Perclose ProGlide devices (Abbott Vascular)‡ was performed, and a 13/10-mm X 80-mm INCRAFT® limb graft was used to exclude the aneurysm. A 14-mm Amplatzer vascular plug (St. Jude Medical)‡ was placed in the origin of the hypogastric artery to prevent retrograde flow into the aneurysm.

Care was taken to spare the gluteal and hypogastric branches and to preserve pelvic blood flow from the contralateral artery.

The endograft was successfully advanced and deployed precisely to the intended position. Sizing of the limb graft adapted to proximal and distal iliac diameters with the use of only one stent. Radial force of the stent graft and the interlocking suture knot design resulted in an adequate fixation of the stent graft without migration or endoleak.

Follow-up CT scan at 6 months demonstrated exclusion of the aneurysm, no stent graft migration, and preservation of hypogastric arterial branches (Figure 2).

‡The third-party trademarks used herein are trademarks of their respective owners.

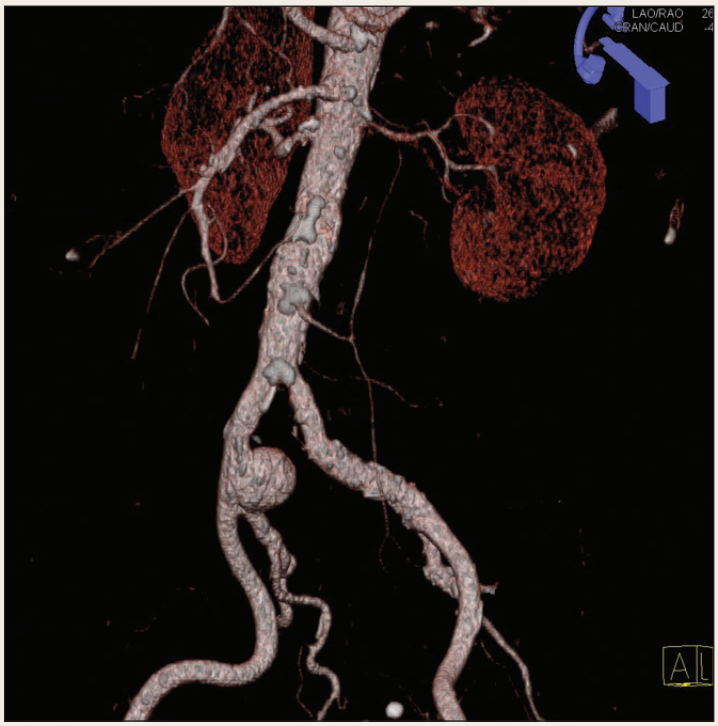

Figure 1. Three-dimensional CT reconstruction with volume rendering showed a right 35-mm aneurysm, with a 2-cm neck of 12-mm diameter that extended up to the iliac bifurcation. External iliac diameter ranged between 8.7 and 9.2 mm.

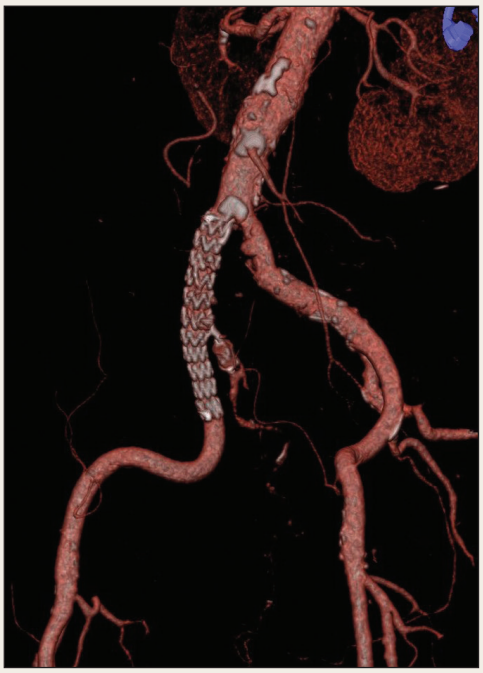

Figure 2. Postoperative three-dimensional CT reconstruction with volume rendering demonstrated placement of the INCRAFT® Stent Graft, a patent limb, and sac thrombosis. Note the Amplatzer occlusion plug at the origin of the internal iliac artery.

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