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.



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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-

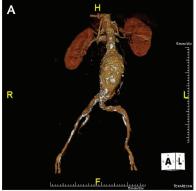






Figure 1. CTA showing an aortic neck with a 4-cm length (A). Axial CTA showing narrow-caliber EIAs measuring 5 to 6 mm bilaterally (B). CTA showing heavily calcified CFA (C).

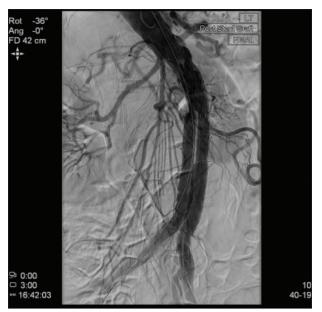


Figure 2. Final digital subtraction angiogram showing the stent graft in situ and good flow of contrast through the stent graft and into bilateral iliac systems.

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

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

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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^{*}The third-party trademarks used herein are trademarks of their respective owners.



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



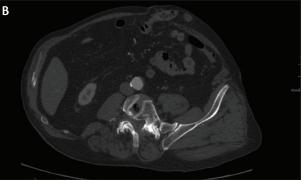


Figure 5. Sagittal CT showing abnormal aneurysm neck morphology in detail. At the level of the renal arteries, the aorta measured 26 mm, narrowed to 24 mm, and then flared out to 26 mm (A). Axial CT image of the distal aorta showing the narrowest point measuring 16 mm (B).

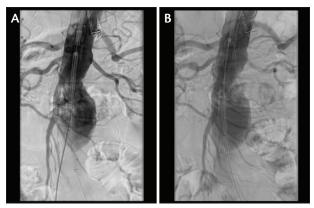


Figure 6. Digital subtraction angiogram showing the stent graft in situ prior to deployment into the hourglass-shaped neck (A) and the main body partially deployed and top end markers visible at the level of the renal arteries (B).



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

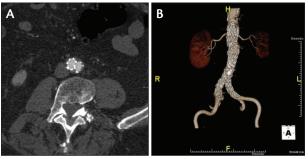


Figure 9. CTA at 30 days postintervention showing a satisfactory appearance of the distal aorta. Stent graft limbs are widely patent and not compressed (A). CTA at 30 days postintervention showing satisfactory appearance of the stent graft (B).

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 pat-

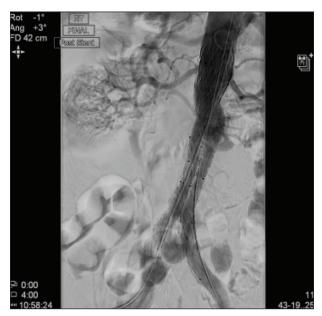


Figure 8. Final angiogram showing satisfactory exclusion of the aneurysm and good flow of contrast into bilateral iliac systems with maintenance of the internal iliac artery flow.

ent with the bilateral limbs in a satisfactory position (Figure 9). No complications were seen in the bilateral CFA.

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.