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.

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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.

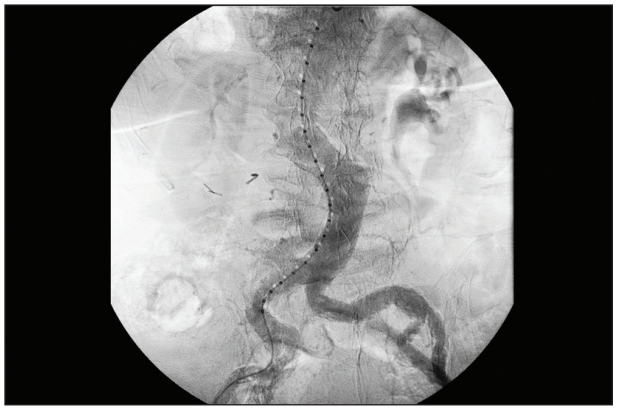

Figure 1. Initial angiogram demonstrating severely calcified, small, tortuous access vessels.

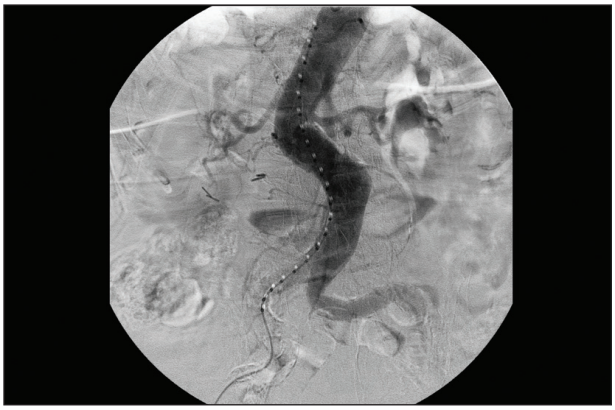

Figure 2. Initial angiogram representing a markedly angulated superior neck.

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.

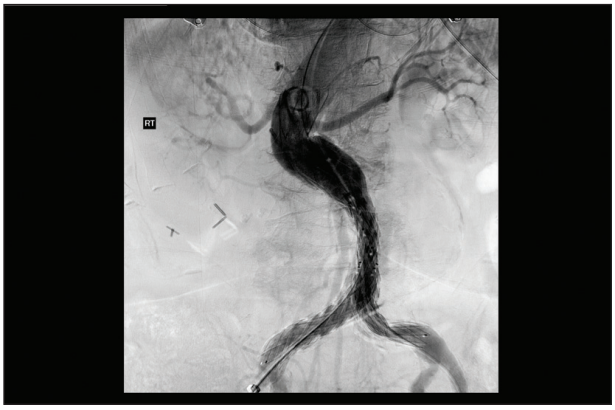

Figure 3. Final angiogram demonstrating successful exclusion of the aneurysm sac.

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. ■