Early experience with the Incraft® device for endovascular abdominal aortic aneurysm repair

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Abstract:

Aim: To report our early series of patients treated with the INCRAFT and evaluate the technical and clinical success in patients with AAA requiring endovascular repair.

Methods: Consecutive patients undergoing INCRAFT implantation between January 2016 to December 2020 at a university teaching hospital were enrolled in a prospectively maintained database. End points included technical and clinical success and freedom from any secondary intervention, any type of endoleak, and aneurysm-related death.

Results: 33 patients were included. Patients had a distal aortic diameter of median 22 mm, (range 17-24 mm) and a mean access vessel size of 6+-1.6 mm (range, 4.0-9.7 mm). Primary technical success was achieved in all patients. The majority (75%) of the procedures were accomplished percutaneously. There were no 30-day mortality. Two patients had major complications during the procedure. The median postoperative stay was 1 day (range, 1-8 days). Follow-up was available for all patients. During a median follow-up of 22 months (range, 6-54 months) no reintervention was performed. No disconnection, type III endoleak, migration or type Ia endoleak was recorded. Additionally, no limb thrombosis occurred. Clinical success was achieved in all patients. Three patients were diagnosed with a type II endoleak during the follow-up period. During follow-up no sac enlargement was noted in any patient.

Conclusion: The use of the INCRAFT device in a real-world setting at a single center is relatively safe and effective, and is associated with a low rate of perioperative complications. Given the low-profile properties the device enables percutaneous access and treatment of patients with challenging access vessels. Further studies with longer follow-up are needed to confirm these results.

INTRODUCTION

Endovascular aneurysm repair (EVAR) has gained wide acceptance as the primary treatment choice in patients with favourable anatomy and has become the most common form of elective repair for infrarenal abdominal aortic aneurysm (AAA).[1,2] Over the past several years, there has been a significant increase in the number of patients eligible for EVAR. This increase is undoubtedly attributable to new generations of endografts and recent advances in endotherapies. However, EVAR applicability still remains limited in some patients by hostile anatomic characteristics such as small, calcified, or tortuous access vessels.

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Access issues are present in up to 20% of patients with AAA, and in a variable number of patients can involve the most distal part of the infrarenal aorta.[3] The INCRAFT AAA Stent Graft system (Cordis Corp, Bridgewater, NJ) was designed to deal with some of the limitations of preceding endografts. Especially, its ultralow-profile design and high flexibility enable extended applicability for smaller and more diseased iliac access vessels. The device has been approved based on the results of the INNOVATION trial, a prospective, multi-institutional study of 60 patients showing safety and efficacy.[4] Herein, we report our early series of patients treated with the INCRAFT and evaluate the technical and clinical success in patients with AAA requiring endovascular repair.

METHODS

We performed a retrospective analysis of data collected from patients who underwent endovascular treatment for AAA with the INCRAFT endograft from January 2016 to May 2020. The INCRAFT device was used according to surgeon preference and not only for difficult anatomic characteristics. However, in patients with challenging vessel access anatomy, including small, calcified, or tortuous access vessels, the INCRAFT device was used preferentially during the study period. The indi-

cations for use of the INCRAFT device include femoral access vessels adequate for delivery system, a proximal neck length of 10 mm, aortic neck diameters of 17 to 31 mm, an aortic neck suitable for suprarenal fixation, infrarenal and suprarenal neck angulation of 60 or less, iliac fixation length of 15 mm or greater, iliac diameters of 7 to 22 mm, a minimum overall treatment length of 128 mm or greater, and morphology suitable for aneurysm repair.

Percutaneous approach: Perclose ProGlide® (Abbott, Santa Clara, CA, USA) was used in all cases under duplex ultrasonography (DUS) guidance in order to achieve a safe insertion of the device. With the US probe in transverse position to the underlining femoral artery, the artery was visualized from the femoral bifurcation and upwards ending at the level of the inguinal ligament. Then, the most adequate point for puncture was chosen. The following criteria were assessed in each case where percutaneous approach was decided: absence of excessive arterial stenosis and anterior atherosclerotic plaque, large distance from the skin (>2cm) diameter of the artery (<9mm). Having the artery in the middle of the US image, direct puncture was then achieved with a large bore needle. After successful catheterization of the femoral artery, a standard J-shape guidewire was inserted and followed with the US up to the external iliac artery to ensure the uncomplicated, adequate position inside the artery. Afterwards a standard 6F sheath was inserted and finally local heparinization was performed. The sheath was withdrawn and one or two Proglide® devices inserted according to the instructions for use.

A dedicated database was established to prospectively collect patient data that included demographics, preoperative risk factors, operative time, blood loss, contrast media use, patient outcomes, length of stay and complications. Sizing and planning before EVAR were performed using computer-based software (3Mensio, Pie Medical Imaging B.V., Maastricht, The Netherlands). All procedures were performed in an adequately equipped operating room with the patient under general or regional anaesthesia. Access was accomplished percutaneous or after surgical cut down of both femoral arteries.

All patients underwent a postoperative surveillance protocol at 1, 6 and 12 months and yearly thereafter that included a physical examination, blood pressure measurement and computed tomography angiography or duplex ultrasound. To stratify patients according to their risk status for open repair, we used the well-validated Glasgow aneurysm score and chose a cut-off of 70 to characterize a patient as unfit for open repair.[5]

OUTCOME MEASUREMENTS

We used the reporting standards of the guidelines from the Society for Vascular Surgery/American Association for Vascular Surgery.[6] Technical success was defined as successful deployment of the endograft in the intended anatomical position, completion of the procedure with no type I or III endoleak and no need for a secondary intervention within the first 24 h. Clinical success was defined as freedom from aneurysm expansion >5 mm, type I or III endoleak, aneurysm rupture, conversion to open surgery, graft infection, migration, thrombosis and aneurysm-related death during the follow-up periods.

STATISTICAL ANALYSIS

Data are expressed as mean ± standard deviation except for non- Gaussian parameters that are presented as median and interquartile range. Categorical data are presented as absolute values and percentages (%). Differences in sac diameter changes during the follow-up period were compared using the paired Student's t-test. Statistical analyses were done using SPSS 20.0 software (IBM Corp, Armonk, NY, USA). A p-value of <.05 was considered statistically significant.

RESULTS

We included 33 patients with a median follow-up of 22 months (range, 6-54 months). The mean age of the included patients was 72.6+-7.3 years with all men. Patient demographic data and preoperative risk factors are presented in Table 1. Patients had a proximal aortic diameter of 23.6+-4.1 mm, neck length of 21.2±9.3mm and a distal aortic diameter of median 19 mm, (range 14-24 mm) (Figure 1).

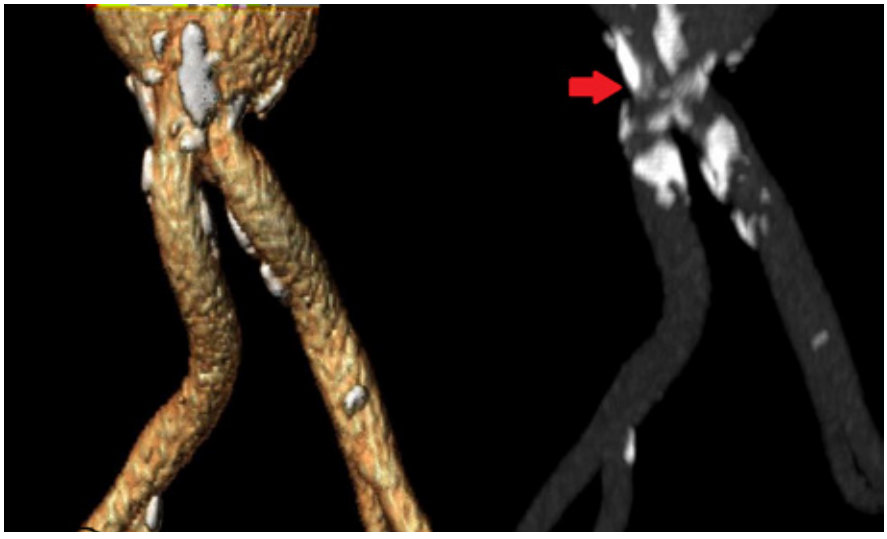

Figure 1. The low-profile of the device permits the adequate position of the endograft in patients with narrow aortic bifurcations. The median distal aortic diameter was estimated at 19 mm (range 14-24 mm) in this analysis.

Baseline characteristics	
Demographics	
Age (years)	72.6+-7.3
Male gender (N,%)	33 (100)
Preoperative risk factors (N,%)	
Hypertension	20 (60)
Coronary artery disease	13 (40)
COPD	9 (30)
Hyperlipidemia	23 (70)
Diabetes	3 (10)
Cardiac failure	3 (10)
Smoking	9 (30)
AAA anatomy	
Neck length, mm	23.6+-4.1
Aortic bifurcation,mm, median (range)	19 (14-24)
Suprarenal angle, degrees	7.5+-2.3
Infrarenal angle, degrees	15+-5.4
Maximum aneurysm diameter, mm	59+-3.6
Thrombus >30%, N (%)	3 (10)
Calcification >30%, N (%)	6 (20)

Table 1. Baseline characteristics

Perioperative data are summarized in Table 1. All patients were operated under general anaesthesia. In 8 (25%) patients access was accomplished with femoral cut-down, while in 25 (75%) patients the whole procedure was completed percutaneously under ultrasound guidance (Figure 2). Primary technical success was achieved in all patients. There were no 30-day deaths. Two patients had major complications during the procedure. In one patient, the contralateral limb was mistakenly deployed outside the main endograft and was successfully removed after a direct iliac artery cut-down through a retroperitoneal approach. The procedure was successfully accomplished endovascular after a new contralateral limb catheterization. In another patient there was a distal external iliac artery rupture during the initial catheterization that was successfully treated by open means. The same patient underwent open femoral artery repair (endarterectomy + bovine pericardium patch) to repair existing atherosclerotic stenotic pathology complicated by thrombosis after sheath removal and primary artery repair. One patient sustained a non-fatal acute myocardial infraction on the second postoperative day. The median hospital stay after the procedure was 1 day (range, 1-8 days).

Follow-up was available for all patients. During a median follow-up of 22 months (range, 6-54 months) no reintervention was performed. No disconnection, type III endoleak, migration or type Ia endoleak was recorded. Additionally, no limb thrombosis occurred. Clinical success was achieved in all patients. Three patients were diagnosed with a type II endoleak during the follow-up period. Two of these endoleaks resolved spontaneously, whereas 1 persisted but without any change in aneurysmal sac diameter at 1 year. During follow-up, in our series, no sac enlargement was noted in any patient.

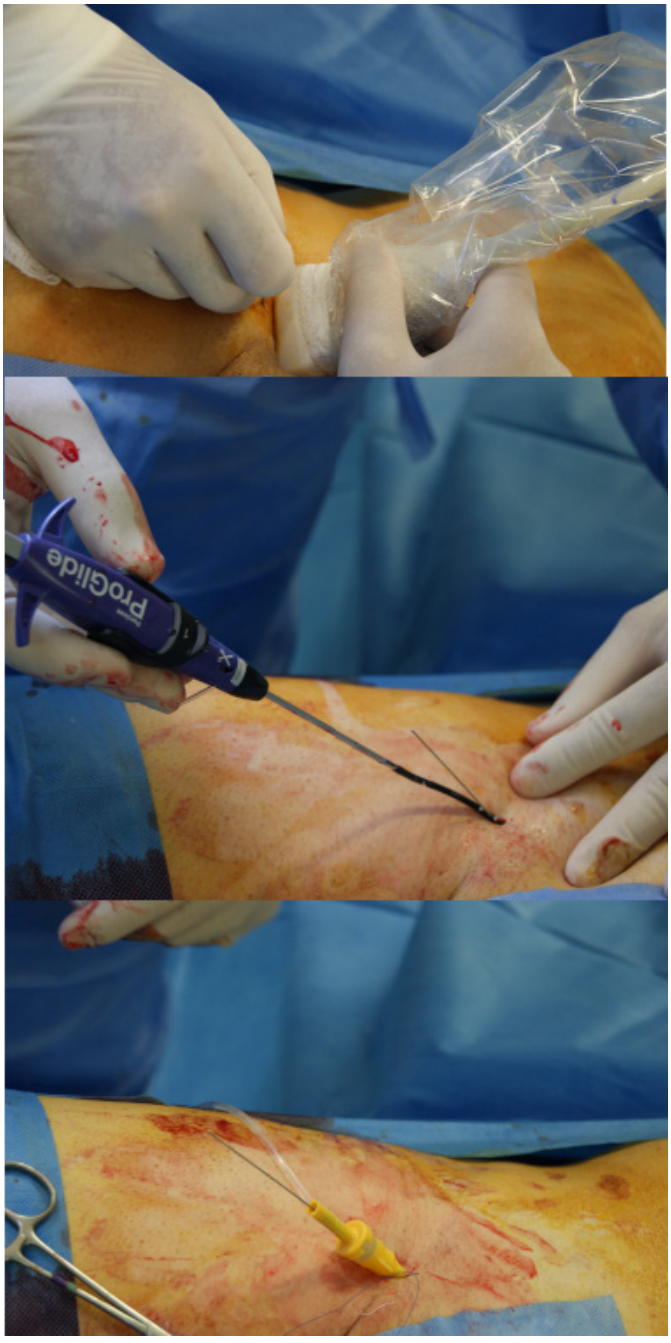

Figure 2. Twenty-five INCRAFT cases were treated percutaneously using Perclose under US guidance. Using US, the femoral artery was punctured and one or more Perclose device and the sheath were introduced.

DISCUSSION

Lower profile potentially provides various benefits such as easy delivery even through smaller, calcified, and tortuous iliac vessels (Figure 3), and results in less access injuries. In addition, lower profile devices have the potential to reduce the necessity of more invasive surgical access, which in turn is connected to higher morbidity and mortality rates. The INCRAFT device was introduced in an attempt to widen the availability of EVAR to patients with difficult access vessels, given its ultralow profile. In the present study patients had a mean

access vessel size of 6+-1.6 mm (range, 4.0-9.7 mm). These sizes are similar to other studies using the INCRAFT device.[7,8] In our series, nearly half of access was obtained percutaneously with a mean length of stay of 2 days, below the average length of stay reported in other trials from other endografts.[9]

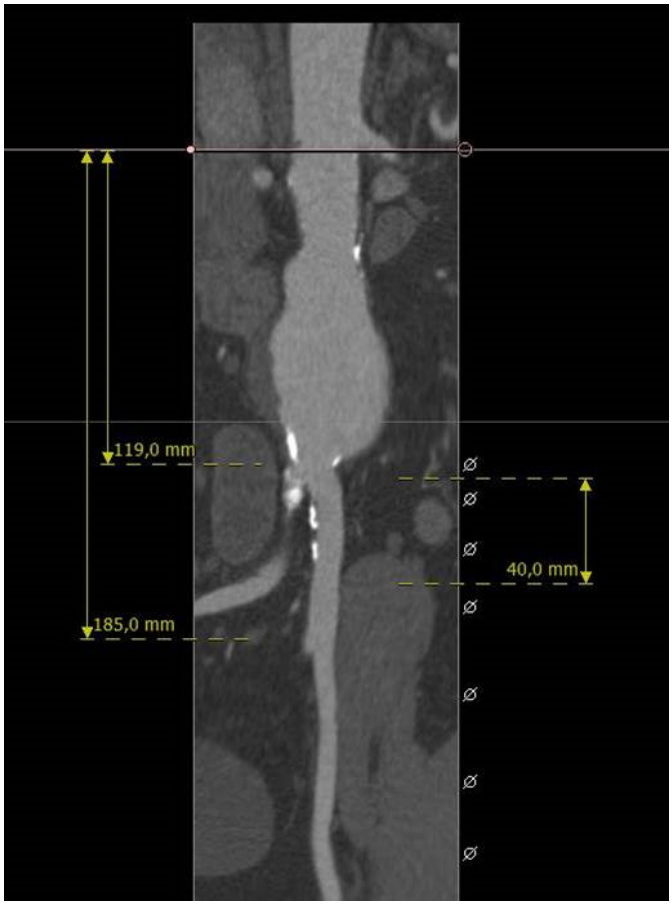

Figure 3. Narrow iliac access may be confronted using low profile endografts as INCRAFT. Patients with severe atheromatosis may also be candidates for this type of devices.

Several studies have also reported that smaller iliac arteries with stenotic lesions have a negative impact on the limb patency after EVAR, as a result from the compression of limbs.[10,11] Narrow aortic bifurcation (<16mm) has been associated with high thrombosis rates.[10-12] Graft limbs with smaller diameter are also reported to result in the higher rate of limb thrombosis in follow-up.[10] In the present study, we have both factors (challenging access vessels and low-profile endografts). However, no limb thrombosis occurred in 1 year mean follow-up (Figure 4). The limb occlusion rates of the Endurant and the Zenith AAA Low Profile (Medtronic, Santa Rosa, Cal. and Cook, Bloomington, Ind.) were reported to be 4.3% and 7.7% at 12 months respectively.[12,13]

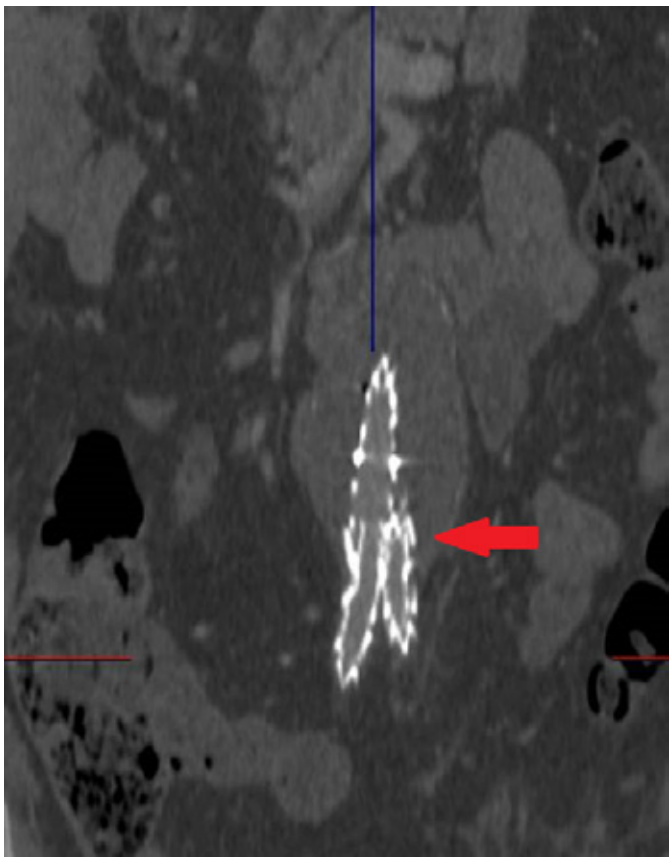

Figure 4. Narrow aortic bifurcation or iliac arteries may affect post-operative limb patency. Re-enforcement using bare metal stents may reline any underlying stenosis.

Through 1 year of follow-up, the INCRAFT AAA Stent Graft System provides a durable solution for patients with AAAs. Patients with demanding anatomy could also be successfully treated with a low frequency of device related events. The midterm results of the INNOVATION trial suggest that the INCRAFT System holds great potential as a novel endograft that expands the population of patients amenable to EVAR. The 23% proportion of patients with at least one access vessel <6 mm in diameter exceeds that of the most available stent grafts.[10-12]

The present study has several drawbacks. Sample size is small, and the median follow-up is relatively short (22 months). Most patients in the present series had small iliac arteries. After INCRAFT became available on the market, many patients with demanding iliac anatomy could be treated by EVAR even outside the IFU in our clinical practice. Our current algorithm is to select the INCRAFT as a first-line treatment in patients with challenging access (iliac diameter <7 mm, severe calcified, highly tortuous, narrow aortic bifurcation) and with peripheral arterial disease. Obviously, a main advantage of this device is the extension of EVAR applicability by overcoming more challenging access morphology.

CONCLUSION

The INCRAFT AAA Stent Graft System is a device with increased applicability over the broad spectrum of aortoiliac anatomic

configurations encountered in patients undergoing EVAR. Use of the INCRAFT device in a real-world single center setting is relatively safe and effective, and is associated with a low rate of perioperative complications. Given the low-profile properties, the device enables percutaneous access and treatment of patients with challenging access vessels. Further studies with longer follow-up are needed to confirm these results.

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