Journal Pre-proof

REINTERVENTION RATE AFTER TREATMENT WITH THE INCRAFT AAA ULTRA-LOW-PROFILE STENT GRAFT SYSTEM

Dimitrios David Papazoglou, MD, Mathieu Béguin, MD, Mario Ricchiuto, Master of Medicine, Silvan Jungi, MD, Salome Weiss, MD, Fabrice Helfenstein, PhD, Michel Joseph Bosiers, MD, Drosos Kotelis, MD, Vladimir Makaloski, MD

PII: S0890-5096(24)00405-9

DOI: https://doi.org/10.1016/j.avsg.2024.05.023

Reference: AVSG 7252

To appear in: *Annals of Vascular Surgery*

Received Date: 19 February 2024

Revised Date: 9 May 2024

Accepted Date: 12 May 2024

Please cite this article as: Papazoglou DD, Béguin M, Ricchiuto M, Jungi S, Weiss S, Helfenstein F, Bosiers MJ, Kotelis D, Makaloski V, REINTERVENTION RATE AFTER TREATMENT WITH THE INCRAFT AAA ULTRA-LOW-PROFILE STENT GRAFT SYSTEM, *Annals of Vascular Surgery* (2024), doi: https://doi.org/10.1016/j.avsg.2024.05.023.

Original Article

REINTERVENTION RATE AFTER TREATMENT WITH THE INCRAFT AAA ULTRA-LOW-PROFILE STENT GRAFT SYSTEM

Short Title

Outcome of the INCRAFT stent graft system

Authors

Dimitrios David Papazoglou MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: papazoglou2019@gmail.com

Mathieu Béguin MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: mathieu.beguin@insel.ch

Mario Ricchiuto Master of Medicine

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: mario.ricchiuto@students.unibe.ch

Silvan Jungi MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: silvan.jungi@insel.ch

Salome Weiss MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: salome.weiss@insel.ch

Fabrice Helfenstein PhD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Department of Angiology, Bern University Hospital, University of Bern, Bern, Switzerland

Department of Clinical Research, University of Bern, Bern, Switzerland

Email: fabrice.helfenstein@unibe.ch

Michel Joseph Bosiers MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: michel.bosiers@insel.ch

Drosos Kotelis MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: drosos.kotelis@insel.ch

Vladimir Makaloski MD

Department of Vascular Surgery, Bern University Hospital, University of Bern, Bern, Switzerland

Email: vladimir.makaloski@insel.ch

Corresponding Author

Dimitrios David Papazoglou MD
Department of Vascular Surgery
Bern University Hospital
University of Bern
3010 Bern, Switzerland
E-mail: papazoglou2019@gmail.com

Word count manuscript: 3126 Words
Word count abstract: 302 Words
(Keywords: INCRAFT, ultra-low-profile, endovascular aortic repair, aortic aneurysm, EVAR)

Abstract

Objective: The INCRAFT stent graft system is an ultra-low profile endograft for the exclusion of infrarenal aortic aneurysms. In the market approval studies, an increased rate of device-related complications was observed and the endograft was approved with mandated postmarketing investigations. Our aim was to analyze midterm outcomes of a real-world patient cohort treated with the INCRAFT endograft.

Methods: Consecutive patients treated with the INCRAFT endograft between February 2015 and December 2022 at a single institution were included. In accordance with the Society for Vascular Surgery reporting standards, safety endpoints were reported and outcome endpoints included reinterventions, technical success, aortic-related and overall-mortality, endoleak, stent fracture, and endograft migration >5 mm.

Results: Eighty patients (85% male) with a mean age of 76 ± 7 years were included. Fifty-two patients (65%) were treated within the endograft's instruction for use (IFU). Mean aortic diameter was 59 ± 10 mm and 91% of the procedures were performed percutaneously. Mean follow-up was 37 ± 25 months and there was no aortic- or procedure-related mortality. Reinterventions occurred in 25 patients (31%) with a freedom from reintervention at 1, 3 and 5 years of 84%, 66% and 55%. The most frequent reinterventions were limb graft stenting (23%) and type II endoleak embolization (14%). Limb occlusion rate was 9% and in three patients (4%) distal endograft migrations >5 mm occurred. Persisting type II endoleaks were observed in 29% and aneurysm diameter was stable in 41% and had shrunk in 38%. Three type III endoleaks (4%) developed during follow-up and four open conversions (5%) were necessary. No known risk factors, including treatment outside IFU, were predictive for reinterventions.

Conclusion: Treatment of infrarenal aortic aneurysms with the INCRAFT stent graft system was safe and successful. Nevertheless, a substantial rate of reinterventions was necessary during follow-up to maintain endograft patency and prevent aneurysm growth.

Introduction

Although endovascular aortic repair (EVAR) has become a widely used treatment for abdominal aortic aneurysms (AAA), its long-term results heavily depend on anatomical factors, and reinterventions remain a concern.[1] In the early days, severe access vessel

anatomy was a major obstacle for EVAR due to the large-bore delivery systems. Therefore, low- and ultralow-profile devices have been developed to increase applicability. The INCRAFT AAA Stent Graft system (Cordis Corp, Miami Lakes, FL) is an ultra-low-profile device for the exclusion of infrarenal AAA, which has shown excellent short- and midterm results.[2-5] The European and US market approval study showed an excellent technical success rate and met its composite safety endpoints, while longer follow-up showed an increased rate of device-related adverse events of 30% at 3 years and 46% at 5 years.[4-7] Higher than anticipated rates of stent fractures, endoleaks and aneurysm expansion were observed at 5 years follow-up.[7] While these risks were acknowledged, the benefits of the ultra-low profile endograft were considered to outweigh the risks and the device was approved, while underlining the need for postmarketing studies to monitor its performance.[8] The aim of the present study is to report early- and mid-term outcomes of a real-world patient cohort treated with the INCRAFT AAA stent graft system.

Methods

A retrospective analysis of consecutive patients treated with the INCRAFT endograft between February 2015 and December 2022 at a single institution was performed. The study was approved by the local ethics committee (2023-00251) and included only patients who had provided written informed consent for the further use of their health-related data for research.

Data collection. All data were extracted from medical records and available imaging studies. All preoperative computed tomography angiographies (CTA) were reviewed and anatomic measurements were made by two vascular surgeons (D.D.P and M.B) using multiplanar reconstructions (SECTRA PACS, Sectra AB, Linköping, Sweden). Follow-up CTA scans were assessed by two investigators (D.D.P and M.B) independently, and in case of differing results measurements were confirmed by the senior author (V.M).

Patient selection. During the study period 228 EVARs and 462 open repairs for infrarenal abdominal aortic aneurysms were performed at our institution. Two EVAR devices were used during the study period and use of devices were selected at the discretion of the responsible surgeon considering the patient's anatomy and access vessel morphology. We aimed for 15-20% oversizing proximally and 10-15% distally in elective cases. Oversizing until 30% was occasionally accepted in emergent cases due to limited stent graft off-the-shelf availability. All patients treated with the INCRAFT endograft at our institution were included in the present study.

Device details. The INCRAFT AAA Stent Graft System is a trimodular, bifurcated ultra-low-profile endograft, with a 14-16 French (F) outer diameter (OD) integrated delivery system, which improves introduction in narrow and tortuous access vessels. The endograft consists of seamless, low-porosity, woven polyester fabric, which is supported from the inside by self-expanding nitinol z-stents. The main body has a short infrarenal sealing endoskeleton and suprarenal bare stents with barbs at the apex for better fixation. The endograft diameter at the bifurcation is 11 mm. The iliac limbs have a 12-13 F OD delivery system without an integrated sheath and proximal limb graft diameter is 13 mm in all models. Radiopaque maximum and minimum overlap markers at the iliac limbs allow for in situ limb length adjustment. Instructions for use include proximal neck length ≥10 mm with supra-renal and infra-renal angulations ≤60° and aortic neck diameters ≥17 mm and ≤31 mm. The minimum iliac landing zone length is 15 mm, iliac diameters of 7 mm to 22 mm as well as an aortic bifurcation >18 mm in diameter and minimum access vessel size of ≥5 mm is required.[6] A more detailed description of the endograft has been published previously.[7]

Primary and secondary endpoints. Primary endpoint was reintervention. Secondary endpoints included technical success of device implantation and absence of surgical conversion, mortality as well as endograft patency, with absence of type I and III endoleaks at

the time of procedure completion as confirmed by angiography, aortic-related and overall-mortality, endoleak, stent fracture, and mainbody and limb migration >5 mm.

Safety endpoint. The safety endpoint was in accordance with Society for Vascular Surgery reporting standards, including death, stroke, myocardial infarction, renal failure, respiratory failure, paraplegia, bowel ischemia, blood loss of more than 1,000 ml, and thromboembolic events (including limb occlusions and distal embolic events) within 30 days of the procedure.[9]

Treatment and follow-up protocol. Preoperative CTA with a slice thickness of 1mm was available for all patients. Postoperatively, standardized follow-up was performed at one, six, and twelve months and yearly thereafter. At one month follow-up CTA and contrast-enhanced ultrasonography (CEUS) were performed. Subsequent follow-ups were performed using CEUS, while CTA was performed only in case of endoleak or aneurysm growth.

Statistical analysis. Statistical analysis was performed using R, version 4.3. Continuous variables are presented as mean ± standard deviation or median (interquartile range), where appropriate, and categorical data as frequencies and proportions. The survival-, complication-free and reintervention-free probabilities were calculated using Kaplan-Meier curves. Univariable logistic regression models were used to identify the association between the presence of severe anatomic factors and reintervention. A p-value ≤.05 was considered statistically significant for all analyses.

Results

A total of 80 patients (85% male) were treated and included in the analysis. Mean age was 76 ± 7 years and 93% were ASA ≥3. The patients' risk factors are listed in Table 1. Mean aortic diameter was 59 ± 10 mm, 89% had an infrarenal AAA, 9% an iliac aneurysm, 3% a penetrating ulcer and 1% an aorto-caval fistula. Most patients presented asymptomatically (82%), 8% were symptomatic and 10% were ruptured. Implantation outside instruction for

use (IFU) was performed in 28 patients (35%). IFU violation were mostly related to the proximal landing zone (Table 2). The minimum access vessel diameter was 9 ± 2 mm, and 93% of patients had access vessels >6 mm. Further anatomic characteristics are shown in Table 2.

Procedural details. The majority of patients had total percutaneous access (91%) and median procedure time was 114 [92; 149] minutes. Adjunctive procedures were five iliac side branch devices for exclusion of iliac artery aneurysms, one inferior mesenteric artery embolization, one common femoral artery endarterectomy and chimney stents in unintentionally covered renal artery in two patients (Table S1). There were 10 reinterventions within 30 days, of which three (4%) were stent-graft related. These were surgical thrombectomy with limb graft stenting due to limb graft occlusion in two patients and coiling due to a persistent type Ia endoleak in one patient. Further interventions included access-site surgical revisions in four patients due to one femoral and one brachial pseudoaneurysm and groin lymphoceles in two patients. One patient had common femoral artery endarterectomy and two patients who had presented with ruptured aneurysm needed decompressive laparotomy.

Primary and secondary endpoints. Reinterventions occurred overall in 25 patients (31%) and device-related complications and freedom from reintervention at 1, 3 and 5 years was 20% and 84%, 31% and 66%, and 40% and 55%, respectively (Figure 2). Most reinterventions involved limb graft stenting in 18 patients (23%), catheter directed thrombolysis in 12 patients (13%) and open thrombectomy in 8 patients (10%) (Table 2). Type II endoleak coiling was a similarly frequent cause of reintervention, performed in 11 patients (14%). At the latest available follow-up 38% had aneurysm shrinkage ≥5 mm, 41% stable diameter and 15% growth ≥5 mm. There was one distal main body migration ≥5 mm, two distal limb migrations ≥ 5mm and no stent fractures.

Technical success was achieved overall in 71 patients (89%). For elective operations technical success was 90% (60/66) and in the emergent setting 79% (11/14). Technical failure occurred

in all nine patients due to low-flow type Ia endoleak at the end of the procedure. In seven of these patients the type Ia endoleak was spontaneously resolved at the discharge CTA or at first follow-up CTA; one patient had the abovementioned endoleak coiling within 30 days; and the other patient needed proximal extension with fenestrated EVAR (FEVAR). Of the nine patients with low-flow type Ia endoleak, there were three with an infrarenal angulation >60° and one patient with a ruptured aneurysm and a short neck <10mm, who were treated outside of IFU. One patient each had a tapered and a reverse-tapered neck, two patients had aortic neck calcification >50% and in one patient proximal oversizing of 30% could have been the reason for low-flow type Ia endoleak.

Proximal extension due to type Ia endoleak was performed in four patients (5%) after a mean of 41 ± 27 months with a proximal cuff in one case and FEVAR in three cases. In three of these patients dilatation of the proximal landing zone was the cause of newly developed type Ia endoleak and one patient had persisting low-flow type Ia endoleak after the index procedure, as aforementioned. Another four patients (5%) had to be converted to open repair. Indication for conversion were chronic limb occlusion in one limb and thrombus-associated stenosis in the other limb in one patient and late rupture due to endoleak type III in three patients after a mean of 37 ± 14 months (fabric tears in two, and disconnection of the EVAR with an iliac side branch device in one patient). No other type III endoleaks or type Ib occurred in our cohort. No single severe anatomic risk factor, including treatment outside IFU was predictive for reintervention in the regression analysis (Table S3).

Of the 80 patients, 75 (94%) had >30 days of follow-up (FU) data available. Mean FU was 37 ± 25 months and CTA was performed in 58% of FUs. During FU 23 patients (29%) died, none due to aorta- or procedure-related causes. Estimated overall survival at 1, 3 and 5 years was 92%, 81% and 61%, respectively (Figure 1).

Safety Endpoint. The safety endpoint occurred in eight patients (10%), of which five had a ruptured aneurysm. Two patients died within 30 days; one was an 86-year old man with a

ruptured aneurysm, who died on the 18th postoperative day due to pneumonia, which had also an limb occlusion as mentioned above and the other one was an 80-year old woman with a ruptured aneurysm, who died on the 28th postoperative day due to suspected cardiac arrhythmia. Three patients had prolonged (>48h) mechanical ventilation, three had renal failure and five had blood loss >1000 ml with one of them experiencing an iliac limb occlusion. The safety endpoint in the three patients without rupture were all blood loss >1000 ml due to one adjunctive common femoral artery endarterectomy and two cut-downs in case of closure-device failure.

Discussion

In this single-center retrospective observational study we analyzed all implanted INCRAFT endografts in elective and emergency cases. Although the INCRAFT approval studies had shown increased device-related complications, the few yet published postmarketing studies have reported remarkably lower rates. Our experience is consistent with the results from the approval studies, confirming its results in a real-world patient cohort.

In every third patient, the INCRAFT device was used outside IFU, mostly due to severe anatomical aortic neck characteristics. This may be one cause for the high rate of low-flow type Ia endoleak at the end of the initial treatment in 9 patients (11%) and subsequent low technical success rate of 89%. Technical success rates from the approval studies were between 90-100%. Most of these type Ia endoleaks resolved spontaneously until discharge or first follow-up, did not reoccur during FU and only two of these patients required reintervention due to persisting type Ia endoleak. Overall, type Ia endoleaks occurred in four patients during FU (5%) which is equal to previous studies reporting type Ia endoleaks in 3.3% and 5.3% of patients treated within the INCRAFT's IFU.[5, 10] Therefore it can be conluded that the INCRAFT's proximal landing zone IFU seems reasonable and that treatment within IFU probably leads to higher techincal success rate.

The 5% rate of open conversion after a mean of 36.8 ± 13.7 months compares unfavorably to the 1% in other reports of the INCRAFT device.[3, 11] The indication was limb occlusion in one and secondary ruptures in three patients with type III endoleaks due to fabric tears in two patients and disconnection between a stent graft limb and an IBD in one patient. Other fabric tears or stent graft fractures were not observed. The INCRAFT's endograft has a very thin woven polyethylene terephthalate fabric to achieve an ultra-low-profile, which could be prone to late type III endoleaks.[3] There has been reports about increased type III endoleaks with a specific low-profile device with a thin polytetrafluoroethylene fabric.[12] However, the INCRAFT's fabric is different and does not seem to behave in a similar way with previously low reported type III endoleak rate of 0-1.6%.[10, 12, 13] Further investigation with long-term results is necessary to ensure long-term endograft integrity.

In the 80 patients treated with the INCRAFT endograft, we have reported device-related complications of 20%, 31% and 40% and freedom from reintervention of 84%, 66% and 55% at 1, 3 and 5 years, respectively, which is comparable to the INSPIRATION US approval trial, with 10%, 30% and 46% device-related complications at 1, 3 and 5 years.[6] Most reinterventions were to maintain limb graft patency and included in our study catheter-directed thrombolysis or open thrombectomy and limb graft stenting, despite favourable distal landing zone anatomy. Only 9 patients (12%) had distal landing zone anatomy outside IFU. This finding is unexpected as the INCRAFT ultra-low profile endograft is approved for patients with severe access vessel anatomy. Midterm-outcome of another low-profile endograft have reported similar estimates of freedom from reeintervention at four years of 66%, mainly due to limb graft stenosis or occlusion and endoleaks.[14] In our patient cohort limb graft occlusion occurred in 9% of all patients, which is comparable to previous reports from other low-profile endografts.[15-17] Zavatta and collegues report a freedom from reintervention of 92.1% after 18.5 +/- 13.2 months FU with only five limb occlusions (2.4%)

in 190 patients treated with the INCRAFT endograft, despite smaller access vessel diameter and more severe access vessel anatomy. In their analysis the presence of two or more severe access vessel anatomic factors was significantly associated with increased reintervention rate. In our study previously reported severe access vessel anatomy was not associated with higher reintervention rate, neiter was treatment outside IFU.

Low-profile endografts seem to display higher limb graft occlusion rates (6-12%) than standard EVAR devices (1-3%).[15-18] Differences in fabric and endograft diameters, especially endograft bifurcation diameter, to achieve low-profile may play a crucial role.[19, 20] The INCRAFT's bifurcation diameter of 11 mm is 20-30% smaller than other EVAR devices with 13-14 mm bifurcation diameters. Thinner fabric to achieve low-profile may be less resistent to kinking and turtuous access vessels. Katsargyris and colleagues showed a very low rate of limb graft occlusion of 1%, mainly with the Cook Zenith and Gore Excluder, with a low threshold of preventive limb graft relining during the index procedure in case of severe access vessel anatomy, where the limbs of 10% of patients were preventively stented with bare metal stents.[21] This approach may have reduced limb graft occlusion rates, especially in an ultra-low-profile device like the INCRAFT stent graft, which is approved primarily for patients with severe access vessel anatomy.[8]

Today in our practice the INCRAFT endograft is occassionally used in selected patients with severe access vessel anatomy, where introduction of a standard EVAR endograft seems not feasible despite endovascular access vessel improvement. In case of narrow or turtous access vessels or narrow aortic bifuraction we have lowered our threshold for primary limb graft relinining with balloon-expandable stents to prevent limb graft complications with the INCRAFT endograft.

Limitations. Besides the limitations of a retrospective study, the absence of a comparison group does not permit the direct comparison of outcomes with other endografts. Our report

includes a real-world patient cohort with mixed pathologies and acuity presentation, limiting comparison with previous reports. Furthermore, as mentioned above, our patient selection for the INCRAFT endograft include a high proportion of old and comorbid patients, which may limit generalizability. The detection of some outcomes like stent graft fractures and migration may be underestimated due to our FU protocol with use of CEUS, which was used in 42% of FU's, and may not detect these complications reliably.

Conclusions

The treatment of infrarenal abdominal aortic aneurysms with the INCRAFT AAA stent graft system provide acceptable midterm results. Nevertheless, the use of the INCRAFT endograft may be limited to patients with complex access anatomies due to a substantial rate of reinterventions, maintaining endograft patency and preventing aneurysm growth. Further investigation is necessary to detect the primary cause of increased reintervention rate.

Authors contribution

Conception and design: DDP, VM

Analysis and interpretation: DDP, FH, VM

Data collection: DDP, MB, MR

Writing the article: DDP, VM

Critical revision of the article: DDP, MB, MR, SJ, SW, FH, MJB, DK, VM

Final approval of the article: DDP, MB, MR, SJ, SW, FH, MJB, DK, VM

Conflicts of Interest

VM and SJ are proctor and consultant to Cordis. The other authors have no conflicts of interest.

Funding

There was no funding for this research.

Citations

1. de la Motte L, Falkenberg M, Koelemay MJ, Lönn L. Is EVAR a durable solution? Indications for reinterventions. The Journal of cardiovascular surgery. 2018;59(2):201-12.
2. Scheinert D, Pratesi C, Chiesa R, Coppi G, Brunkwall JS, Klarenbeek G, et al. First-in-human study of the INCRAFT endograft in patients with infrarenal abdominal aortic aneurysms in the INNOVATION trial. J Vasc Surg. 2013;57(4):906-14.
3. Georgiadis GS, Chatzigakis PK, Kouvelos G, Argyriou C, Kopadis GC, Georgakarakos EI, et al. Multicenter Mid-term Results After Endovascular Aortic Aneurysm Repair with the Incraft® Device. Ann Vasc Surg. 2021;72:464-78.
4. Liang NL, Ohki T, Ouriel K, Teigen C, Fry D, Henretta J, et al. Five-year results of the INSPIRATION study for the INCRAFT low-profile endovascular aortic stent graft system. J Vasc Surg. 2021;73(3):867-73.e2.
5. Torsello G, Pratesi G, van der Meulen S, Ouriel K. Aortoiliac remodeling and 5-year outcome of an ultralow-profile endograft. J Vasc Surg. 2019;69(6):1747-57.
6. (NIH) NIoH. A Multicenter, Open Label, Prospective, Non-randomized Study of the InCraft® Stent Graft System in Subjects With Abdominal Aortic Aneurysms (INSPIRATION) (INSPIRATION): Clinical rials.gov; 2020 [Available from: https://clinicaltrials.gov/study/NCT01664078?tab=results.
7. Torsello G, Scheinert D, Brunkwall JS, Chiesa R, Coppi G, Pratesi C. Safety and effectiveness of the INCRAFT AAA Stent Graft for endovascular repair of abdominal aortic aneurysms. J Vasc Surg. 2015;61(1):1-8.
8. Iantorno M, Buchanan KD, Bernardo NL, Torguson R, Waksman R. Overview of the 2018 US Food and Drug Administration Circulatory System Devices Panel meeting on the INCRAFT AAA Stent Graft System. Cardiovasc Revasc Med. 2019;20(5):403-8.
9. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg. 2002;35(5):1048-60.
10. Torsello G, Bertoglio L, Kellersmann R, Wever JJ, van Overhagen H, Stavroulakis K. Three-Year Safety and Efficacy of the INCRAFT Endograft for Treatment of Abdominal Aortic Aneurysms: Results of the INSIGHT Study. J Endovasc Ther. 2023:15266028231214162.
11. Seike Y, Matsuda H, Shimizu H, Ishimaru S, Hoshina K, Michihata N, et al. Nationwide Analysis of Persistent Type II Endoleak and Late Outcomes of Endovascular Abdominal Aortic Aneurysm Repair in Japan: A Propensity-Matched Analysis. Circulation. 2022;145(14):1056-66.
12. Zavatta M, Squizzato F, Balestriero G, Bonvini S, Perkmann R, Milite D, et al. Early and midterm outcomes of endovascular aneurysm repair with an ultra-low-profile endograft from the Triveneto Incraft Registry. J Vasc Surg. 2021;73(6):1950-7.e2.
13. Gill HL, Doonan RJ, Altoijry A, Obrand DI, Mackenzie KS, Steinmetz OK. Early North American experience with the INCRAFT device. J Vasc Surg. 2019;70(1):102-6.
14. Broda M, Eiberg J, Vogt K, Ohlander JT, Lawaetz M, Sillesen H, et al. Midterm outcomes of aneurysm repair with the Cook Zenith Alpha abdominal endovascular graft. Journal of Vascular Surgery. 2022;76(4):942-50.e1.
15. Bogdanovic M, Stackelberg O, Lindström D, Ersryd S, Andersson M, Roos H, et al. Limb Graft Occlusion Following Endovascular Aneurysm Repair for Infrarenal Abdominal Aortic Aneurysm with the Zenith Alpha, Excluder, and Endurant Devices: a Multicentre Cohort Study. Eur J Vasc Endovasc Surg. 2021;62(4):532-9.
16. Broda M, Eiberg J, Taudorf M, Resch T. Limb graft occlusion after endovascular aneurysm repair with the Cook Zenith Alpha abdominal graft. Journal of Vascular Surgery. 2023;77(3):770-7.e2.

17. Ulsaker H, Lam M, Herje ML, Seternes A, Manstad-Hulaas F. A Retrospective Evaluation of Intra-Prosthetic Thrombus Formation After Endovascular Aortic Repair in Cook Zenith Alpha and Medtronic Endurant II Patients. Eur J Vasc Endovasc Surg. 2023;66(5):644-51.
18. Mangialardi N, Ronchey S, Kasemi H, Alberti V, Fazzini S, Serrao E. Percutaneous endovascular aneurysm repair with the ultra-low profile Ovation Abdominal Stent-Graft System. J Cardiovasc Surg (Torino). 2013;54(5):581-7.
19. Carroccio A, Faries PL, Morrissey NJ, Teodorescu V, Burks JA, Gravereaux EC, et al. Predicting iliac limb occlusions after bifurcated aortic stent grafting: anatomic and device-related causes. J Vasc Surg. 2002;36(4):679-84.
20. Wu IH, Liang PC, Huang SC, Chi NS, Lin FY, Wang SS. The significance of endograft geometry on the incidence of intraprosthetic thrombus deposits after abdominal endovascular grafting. Eur J Vasc Endovasc Surg. 2009;38(6):741-7.
21. Marques de Marino P, Ibraheem A, Gafur N, Mufty H, Schubert N, Verhoeven EL, et al. Limb Occlusion Rate after EVAR With Individualized Graft Limb Selection and a Liberal Protocol of Primary Relining. Annals of Vascular Surgery. 2021;75:445-54.

Figure legends

Figure 1. Kaplan-Meier curve for overall survival 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Figure 2. Kaplan-Meier curve for freedom of device-related complications and reinterventions 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Table 1. Demographic and preoperative characteristics of 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Variable	Mean ± SD or No. (%)
Age, years	76 ± 7
Male	68 (85)
BMI, kg/m2	27 ± 6
Medical history	
Hypertension	64 (80)
Diabetes	15 (19)
Active smoker	20 (25)
CAD	24 (30)
Atrial fibrilliation	25 (31)
COPD	19 (24)
Stroke/TIA	6 (8)
GFR ≤60ml/min	27 (34)
PAD	33 (41)
ASA class ≥3	74 (93)
Previous medication	
Antiplateled therapy	70 (88)
Anticoagulation therapy	27 (34)
Statin	73 (91)
ACE-inhibitors	56 (70)

BMI = body mass index; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; TIA = transient ischemic attack; GFR = glomerular filtration rate; PAD = peripheral artery disease ASA = American Society of Anesthesiology; ACE = angiotensin converting enzyme.

Table 2. Pathology characteristics and anatomic findings from preoperative computed tomography angiography of 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Variable	Mean ± SD or No. (%)
Degenerative aneurysm	76 (95)
Penetrating aortic ulcer	2 (3)
AV-Fistula	1 (1)
Juxtarenal AAA	2 (3)
Infrarenal AAA	71 (89)
Iliac aneurysm	7 (9)
Asymptomatic	66 (82)
Symptomatic	6 (8)
Ruptured	8 (10)
Anatomic measurements	
Aneurysm diameter*, mm	59 ± 10
Proximal neck diameter, mm	23 ± 2
Proximal neck length, mm	35 ± 17
Distal landing zone diameter, mm	14 ± 4
Distal landing zone lenght, mm	54 ± 19
IFU violations	
Neck diameter <17mm	2 (3)
Neck diameter >31mm	1 (1)
Neck length <10mm	2 (3)
Suprarenal angle >60°	2 (3)
Infrarenal angle >60°	12 (15)
Tapered neck	6 (8)
Reverse tapered neck	7 (9)
Aortic bifurcation ≤18 mm	6 (8)
Iliac landing zone length <15mm	1 (1)
Access vessel diameter <5 mm	2 (3)
≥1 IFU violation	28 (35)
Further severe anatomic characteristics	
Neck calcification ≥50%	6 (8)
Neck thrombus ≥50%	8 (10)
EIA landing zone	4 (5)
Turtuous iliac artery	26 (33)
Distal landing zone calcification or thrombus ≥50%	32 (40)
IIA occluded	13 (16)

*only abdominal aortic aneurysm
AAA = abdominal aortic aneurysm; AV = arterio-venous; IFU = instruction for use; EIA = external iliac artery; IIA = internal iliac artery.

Supplementary Table 1. Intraoperative data of 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Variable	Median [IQR] or No. (%)
Technical success	71 (89)
Percutaneous access	73 (91)
Additional brachial access	7 (9)
Total Operation Time, minutes	114 [92;149]
Volume of Contrast, ml	27 [13;39]
Fluoroscopy time, minutes	26 [20;37]
Dose area product, mGy/cm2	41 [21;60]
Blood loss, ml	100 [0;300]
Hospitalization days	4 [2; 6]
Intraoperative complications	
Type Ia endoleak	9 (11)
Type II endoleak	19 (24)
Partial renal artery coverage	2 (3)
Adjunctive procedures	
IMA embolization	1 (1)
Renal artery rescue chimney	2 (3)
Iliac side branch device	5 (6)
CFA endarterectomy	1 (1)

Gy = Grey; IMA = inferior mesenteric artery; CFA = common femoral artery.

Table 3. Long-term graft-related complications and reinterventions of 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Variable	Mean ± SD or No. (%)
Follow-up, months	37 ± 25
Mortality, overall	23 (29)
Mortality, aneurysm-related	0 (0)
Complications	
Limb occlusion	7 (9)
Distal embolization	12 (15)
Main body migration ≥ 5mm	1 (1)
Limb migration ≥ 5mm	2 (3)
Stent fracture	0 (0)
Stent graft related reinterventions	*N=25 (31)*
Access-site surgical revision	4 (5)
Open thrombectomy	8 (10)
Catheter-directed thrombolysis	12 (15)
Limb graft stenting	18 (23)
CFA endarterectomy	1 (1)
Type Ia endoleak coiling	1 (1)
Type II endoleak coiling	11 (14)
Proximal cuff/FEVAR	4 (5)
Open conversion	4 (5)
Fem-Fem crossover bypass	1 (1)
Endoleak at last FU	
Type Ia	1 (1)
Type II	23 (29)
Type III	3 (4)
Aneurysm change at last FU	
Growth ≥5mm	12 (15)
Stable	33 (41)
Shrinkage ≥5mm	30 (38)

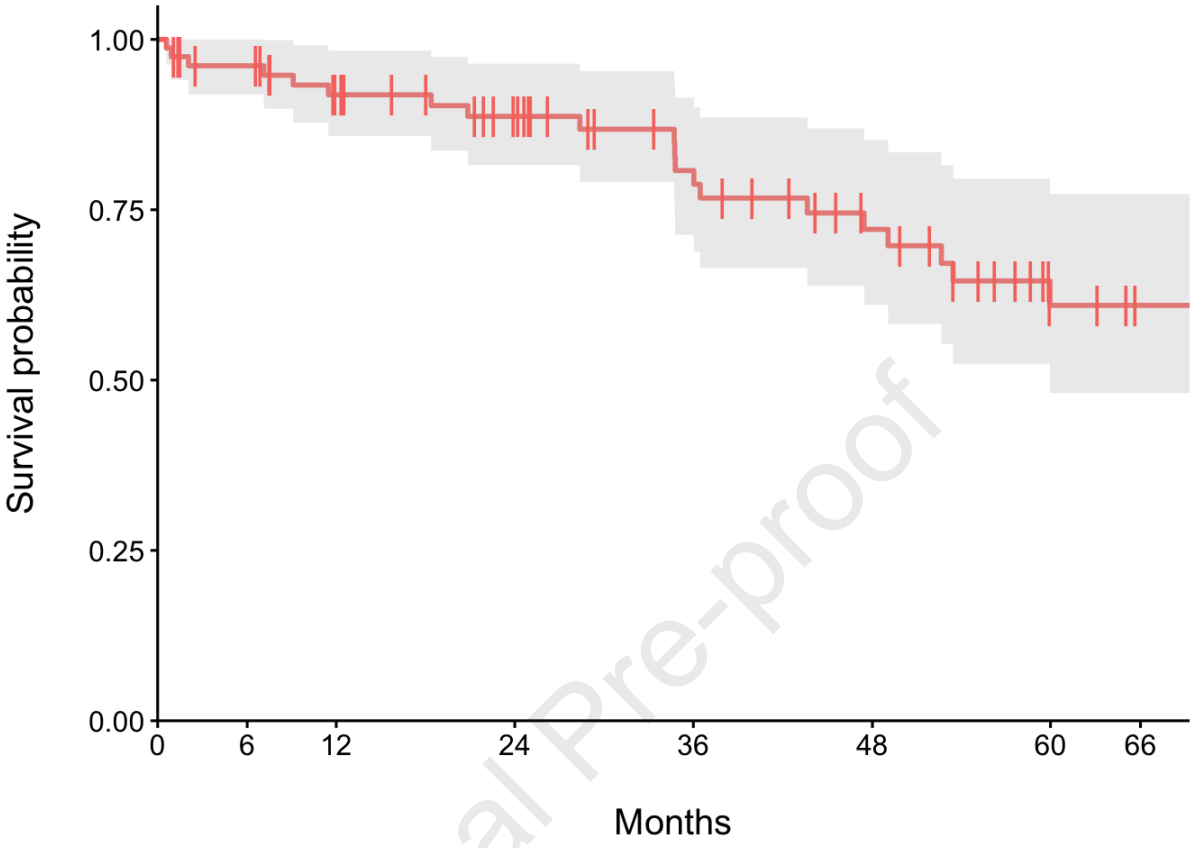
CFA = common femoral artery; FEVAR = fenestrated endovascular aortic repair; FU = Follow-up.

Supplementary Table 2. Univariable logistic regression analysis of correlation between severe anatomic characteristics and reinterventions of 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system

Risk factor	Odds ratio with 95% CI	p-value
Peripheral artery disease	0.89 (0.35 – 2.25)	0.79
Minimum access vessel diameter <10 mm	0.48 (0.17 – 1.34)	0.16
Turtuous access vessels	2.03 (0.77 – 5.36)	0.15
Calcification/thrombus >50% at distal landing zone	0.47 (0.17 – 1.25)	0.13
Treatment outside IFU	0.69 (0.24 – 1.93)	0.48

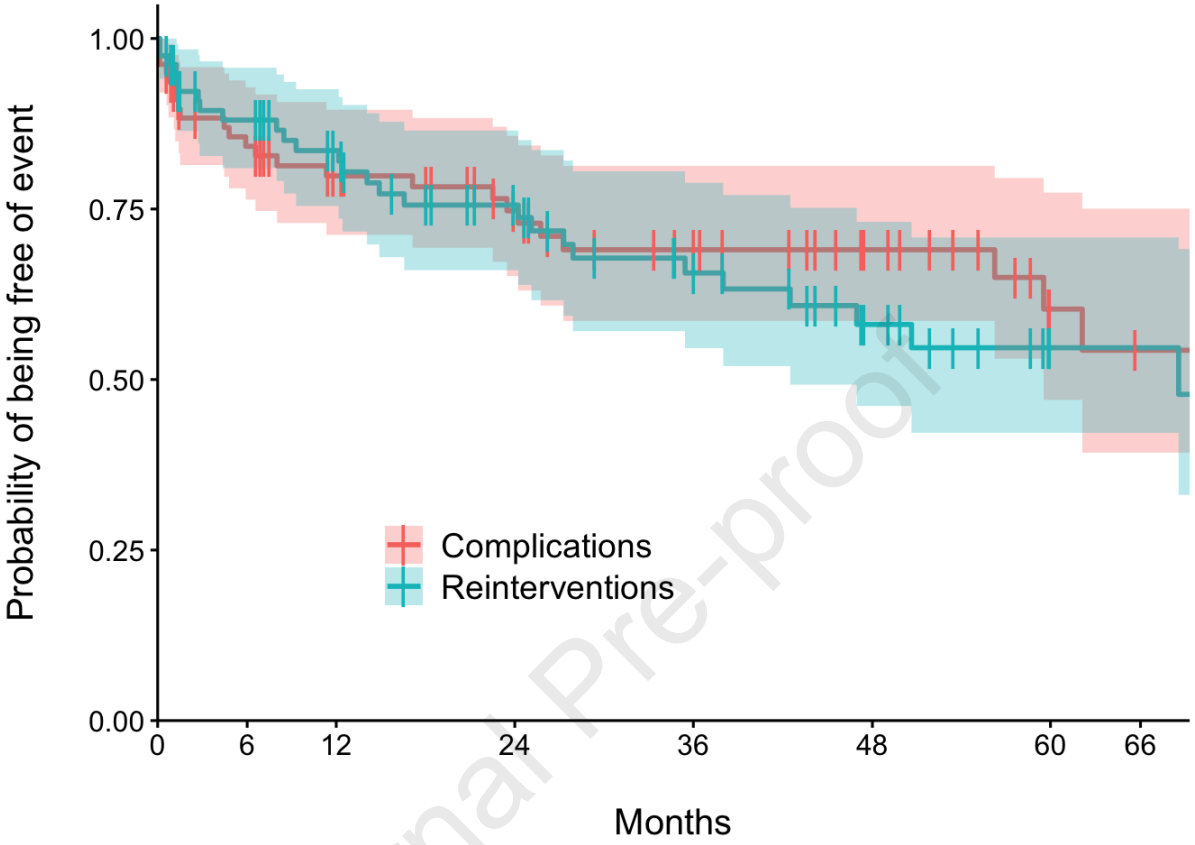
CI = confidence interval; IFU = instructions for use.

Figure 1. Kaplan-Meier curve for overall survival 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system



Months	0	12	24	36	60
Surv. prob.	1	0.92	0.89	0.81	0.61
95% CI	1;1	0.86;0.98	0.82;0.96	0.71;0.91	0.48;0.77
N° at risk	80	62	52	40	16

Figure 2. Kaplan-Meier curve for freedom of device-related complications and reinterventions 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft system



Freedom from device-related complications

Months	**0**	**12**	**24**	**36**	**60**
Surv. prob.	1	0.80	0.75	0.69	0.60
95% CI	1;1	0.71;0.90	0.65;0.86	0.59;0.81	0.47;0.77
N° at risk	80	52	41	32	10

Freedom from reinterventions

Months	**0**	**12**	**24**	**36**	**60**
Surv. prob.	1	0.88	0.76	0.66	0.55
95% CI	1;1	0.75;0.93	0.66;0.87	0.55;0.79	0.42;0.71
N° at risk	80	54	41	30	8