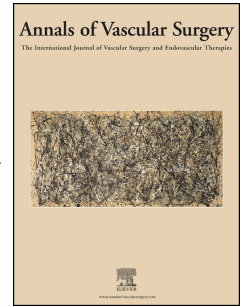


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REINTERVENTION RATE AFTER TREATMENT WITH THE INCRAFT AAA ULTRA-LOW-PROFILE STENT GRAFT SYSTEM

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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

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69

70

71 **Abstract**

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

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

82 **Results:** Eighty patients (85% male) with a mean age of 76 ± 7 years were included. Fifty-
83 two patients (65%) were treated within the endograft's instruction for use (IFU). Mean aortic
84 diameter was 59 ± 10 mm and 91% of the procedures were performed percutaneously. Mean
85 follow-up was 37 ± 25 months and there was no aortic- or procedure-related mortality.

86 Reinterventions occurred in 25 patients (31%) with a freedom from reintervention at 1, 3 and
87 5 years of 84%, 66% and 55%. The most frequent reinterventions were limb graft stenting
88 (23%) and type II endoleak embolization (14%). Limb occlusion rate was 9% and in three
89 patients (4%) distal endograft migrations >5 mm occurred. Persisting type II endoleaks were
90 observed in 29% and aneurysm diameter was stable in 41% and had shrunk in 38%. Three
91 type III endoleaks (4%) developed during follow-up and four open conversions (5%) were
92 necessary. No known risk factors, including treatment outside IFU, were predictive for
93 reinterventions.

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

97

98 **Introduction**

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

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

115

116 **Methods**

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

121 **Data collection.** All data were extracted from medical records and available imaging studies.

122 All preoperative computed tomography angiographies (CTA) were reviewed and anatomic
123 measurements were made by two vascular surgeons (D.D.P and M.B) using multiplanar
124 reconstructions (SECTRA PACS, Sectra AB, Linköping, Sweden). Follow-up CTA scans
125 were assessed by two investigators (D.D.P and M.B) independently, and in case of differing
126 results measurements were confirmed by the senior author (V.M).

127 **Patient selection.** During the study period 228 EVARs and 462 open repairs for infrarenal
128 abdominal aortic aneurysms were performed at our institution. Two EVAR devices were used
129 during the study period and use of devices were selected at the discretion of the responsible
130 surgeon considering the patient's anatomy and access vessel morphology. We aimed for 15-
131 20% oversizing proximally and 10-15% distally in elective cases. Oversizing until 30% was
132 occasionally accepted in emergent cases due to limited stent graft off-the-shelf availability.
133 All patients treated with the INCRAFT endograft at our institution were included in the
134 present study.

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

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

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

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

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

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

171

172 **Results**

173 A total of 80 patients (85% male) were treated and included in the analysis. Mean age was 76
174 \pm 7 years and 93% were ASA \geq 3. The patients' risk factors are listed in Table 1. Mean aortic
175 diameter was 59 \pm 10 mm, 89% had an infrarenal AAA, 9% an iliac aneurysm, 3% a
176 penetrating ulcer and 1% an aorto-caval fistula. Most patients presented asymptotically
177 (82%), 8% were symptomatic and 10% were ruptured. Implantation outside instruction for

178 use (IFU) was performed in 28 patients (35%). IFU violation were mostly related to the
179 proximal landing zone (Table 2). The minimum access vessel diameter was 9 ± 2 mm, and
180 93% of patients had access vessels >6 mm. Further anatomic characteristics are shown in
181 Table 2.

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

193 **Primary and secondary endpoints.** Reinterventions occurred overall in 25 patients (31%)
194 and device-related complications and freedom from reintervention at 1, 3 and 5 years was
195 20% and 84%, 31% and 66%, and 40% and 55%, respectively (Figure 2). Most
196 reinterventions involved limb graft stenting in 18 patients (23%), catheter directed
197 thrombolysis in 12 patients (13%) and open thrombectomy in 8 patients (10%) (Table 2).
198 Type II endoleak coiling was a similarly frequent cause of reintervention, performed in 11
199 patients (14%). At the latest available follow-up 38% had aneurysm shrinkage ≥ 5 mm, 41%
200 stable diameter and 15% growth ≥ 5 mm. There was one distal main body migration ≥ 5 mm,
201 two distal limb migrations ≥ 5 mm and no stent fractures.

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

204 in all nine patients due to low-flow type Ia endoleak at the end of the procedure. In seven of
205 these patients the type Ia endoleak was spontaneously resolved at the discharge CTA or at
206 first follow-up CTA; one patient had the abovementioned endoleak coiling within 30 days;
207 and the other patient needed proximal extension with fenestrated EVAR (FEVAR). Of the
208 nine patients with low-flow type Ia endoleak, there were three with an infrarenal angulation
209 $>60^\circ$ and one patient with a ruptured aneurysm and a short neck $<10\text{mm}$, who were treated
210 outside of IFU. One patient each had a tapered and a reverse-tapered neck, two patients had
211 aortic neck calcification $>50\%$ and in one patient proximal oversizing of 30% could have
212 been the reason for low-flow type Ia endoleak.

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

224 Of the 80 patients, 75 (94%) had >30 days of follow-up (FU) data available. Mean FU was 37
225 ± 25 months and CTA was performed in 58% of FUs. During FU 23 patients (29%) died,
226 none due to aorta- or procedure-related causes. Estimated overall survival at 1, 3 and 5 years
227 was 92%, 81% and 61%, respectively (Figure 1).

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

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

238

239 **Discussion**

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

245 In every third patient, the INCRAFT device was used outside IFU, mostly due to severe
246 anatomical aortic neck characteristics. This may be one cause for the high rate of low-flow
247 type Ia endoleak at the end of the initial treatment in 9 patients (11%) and subsequent low
248 technical success rate of 89%. Technical success rates from the approval studies were
249 between 90-100%. Most of these type Ia endoleaks resolved spontaneously until discharge or
250 first follow-up, did not reoccur during FU and only two of these patients required
251 reintervention due to persisting type Ia endoleak. Overall, type Ia endoleaks occurred in four
252 patients during FU (5%) which is equal to previous studies reporting type Ia endoleaks in
253 3.3% and 5.3% of patients treated within the INCRAFT's IFU.[5, 10] Therefore it can be
254 concluded that the INCRAFT's proximal landing zone IFU seems reasonable and that
255 treatment within IFU probably leads to higher technical success rate.

256

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

268 In the 80 patients treated with the INCRAFT endograft, we have reported device-related
269 complications of 20%, 31% and 40% and freedom from reintervention of 84%, 66% and 55%
270 at 1, 3 and 5 years, respectively, which is comparable to the INSPIRATION US approval trial,
271 with 10%, 30% and 46% device-related complications at 1, 3 and 5 years.[6] Most
272 reinterventions were to maintain limb graft patency and included in our study catheter-
273 directed thrombolysis or open thrombectomy and limb graft stenting, despite favourable distal
274 landing zone anatomy. Only 9 patients (12%) had distal landing zone anatomy outside IFU.
275 This finding is unexpected as the INCRAFT ultra-low profile endograft is approved for
276 patients with severe access vessel anatomy. Midterm-outcome of another low-profile
277 endograft have reported similar estimates of freedom from reintervention at four years of
278 66%, mainly due to limb graft stenosis or occlusion and endoleaks.[14] In our patient cohort
279 limb graft occlusion occurred in 9% of all patients, which is comparable to previous reports
280 from other low-profile endografts.[15-17] Zavatta and colleagues report a freedom from
281 reintervention of 92.1% after 18.5 ± 13.2 months FU with only five limb occlusions (2.4%)

282 in 190 patients treated with the INCRAFT endograft, despite smaller access vessel diameter
283 and more severe access vessel anatomy. In their analysis the presence of two or more severe
284 access vessel anatomic factors was significantly associated with increased reintervention rate.
285 In our study previously reported severe access vessel anatomy was not associated with higher
286 reintervention rate, neither was treatment outside IFU.

287 Low-profile endografts seem to display higher limb graft occlusion rates (6-12%) than
288 standard EVAR devices (1-3%).[15-18] Differences in fabric and endograft diameters,
289 especially endograft bifurcation diameter, to achieve low-profile may play a crucial role.[19,
290 20] The INCRAFT's bifurcation diameter of 11 mm is 20-30% smaller than other EVAR
291 devices with 13-14 mm bifurcation diameters. Thinner fabric to achieve low-profile may be
292 less resistant to kinking and tortuous access vessels. Katsargyris and colleagues showed a
293 very low rate of limb graft occlusion of 1%, mainly with the Cook Zenith and Gore Excluder,
294 with a low threshold of preventive limb graft relining during the index procedure in case of
295 severe access vessel anatomy, where the limbs of 10% of patients were preventively stented
296 with bare metal stents.[21] This approach may have reduced limb graft occlusion rates,
297 especially in an ultra-low-profile device like the INCRAFT stent graft, which is approved
298 primarily for patients with severe access vessel anatomy.[8]

299 Today in our practice the INCRAFT endograft is occasionally used in selected patients with
300 severe access vessel anatomy, where introduction of a standard EVAR endograft seems not
301 feasible despite endovascular access vessel improvement. In case of narrow or tortuous access
302 vessels or narrow aortic bifurcation we have lowered our threshold for primary limb graft
303 relining with balloon-expandable stents to prevent limb graft complications with the
304 INCRAFT endograft.

305

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

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

314

315 **Conclusions**

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

321

322 **Authors contribution**

323 Conception and design: DDP, VM

324 Analysis and interpretation: DDP, FH, VM

325 Data collection: DDP, MB, MR

326 Writing the article: DDP, VM

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

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

329 **Conflicts of Interest**

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

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334 Citations

- 335 1. de la Motte L, Falkenberg M, Koelemay MJ, Lönn L. Is EVAR a durable solution?
336 Indications for reinterventions. *The Journal of cardiovascular surgery*. 2018;59(2):201-12.
- 337 2. Scheinert D, Pratesi C, Chiesa R, Coppi G, Brunkwall JS, Klarenbeek G, et al. First-
338 in-human study of the INCRAFT endograft in patients with infrarenal abdominal aortic
339 aneurysms in the INNOVATION trial. *J Vasc Surg*. 2013;57(4):906-14.
- 340 3. Georgiadis GS, Chatzigakis PK, Kouvelos G, Argyriou C, Kopadis GC,
341 Georgakarakos EI, et al. Multicenter Mid-term Results After Endovascular Aortic Aneurysm
342 Repair with the Incraft® Device. *Ann Vasc Surg*. 2021;72:464-78.
- 343 4. Liang NL, Ohki T, Ouriel K, Teigen C, Fry D, Henretta J, et al. Five-year results of
344 the INSPIRATION study for the INCRAFT low-profile endovascular aortic stent graft
345 system. *J Vasc Surg*. 2021;73(3):867-73.e2.
- 346 5. Torsello G, Pratesi G, van der Meulen S, Ouriel K. Aortoiliac remodeling and 5-year
347 outcome of an ultralow-profile endograft. *J Vasc Surg*. 2019;69(6):1747-57.
- 348 6. (NIH) NIOH. A Multicenter, Open Label, Prospective, Non-randomized Study of the
349 InCRAFT® Stent Graft System in Subjects With Abdominal Aortic Aneurysms
350 (INSPIRATION) (INSPIRATION): Clinical trials.gov; 2020 [Available from:
351 <https://clinicaltrials.gov/study/NCT01664078?tab=results>.
- 352 7. Torsello G, Scheinert D, Brunkwall JS, Chiesa R, Coppi G, Pratesi C. Safety and
353 effectiveness of the INCRAFT AAA Stent Graft for endovascular repair of abdominal aortic
354 aneurysms. *J Vasc Surg*. 2015;61(1):1-8.
- 355 8. Iantorno M, Buchanan KD, Bernardo NL, Torguson R, Waksman R. Overview of the
356 2018 US Food and Drug Administration Circulatory System Devices Panel meeting on the
357 INCRAFT AAA Stent Graft System. *Cardiovasc Revasc Med*. 2019;20(5):403-8.
- 358 9. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al.
359 Reporting standards for endovascular aortic aneurysm repair. *J Vasc Surg*. 2002;35(5):1048-
360 60.
- 361 10. Torsello G, Bertoglio L, Kellersmann R, Wever JJ, van Overhagen H, Stavroulakis K.
362 Three-Year Safety and Efficacy of the INCRAFT Endograft for Treatment of Abdominal
363 Aortic Aneurysms: Results of the INSIGHT Study. *J Endovasc Ther*.
364 2023;15266028231214162.
- 365 11. Seike Y, Matsuda H, Shimizu H, Ishimaru S, Hoshina K, Michihata N, et al.
366 Nationwide Analysis of Persistent Type II Endoleak and Late Outcomes of Endovascular
367 Abdominal Aortic Aneurysm Repair in Japan: A Propensity-Matched Analysis. *Circulation*.
368 2022;145(14):1056-66.
- 369 12. Zavatta M, Squizzato F, Balestriero G, Bonvini S, Perkmann R, Milite D, et al. Early
370 and midterm outcomes of endovascular aneurysm repair with an ultra-low-profile endograft
371 from the Triveneto Incraft Registry. *J Vasc Surg*. 2021;73(6):1950-7.e2.
- 372 13. Gill HL, Doonan RJ, Altoijry A, Obrand DI, Mackenzie KS, Steinmetz OK. Early
373 North American experience with the INCRAFT device. *J Vasc Surg*. 2019;70(1):102-6.
- 374 14. Broda M, Eiberg J, Vogt K, Ohlander JT, Lawaetz M, Sillesen H, et al. Midterm
375 outcomes of aneurysm repair with the Cook Zenith Alpha abdominal endovascular graft.
376 *Journal of Vascular Surgery*. 2022;76(4):942-50.e1.
- 377 15. Bogdanovic M, Stackelberg O, Lindström D, Ersryd S, Andersson M, Roos H, et al.
378 Limb Graft Occlusion Following Endovascular Aneurysm Repair for Infrarenal Abdominal
379 Aortic Aneurysm with the Zenith Alpha, Excluder, and Endurant Devices: a Multicentre
380 Cohort Study. *Eur J Vasc Endovasc Surg*. 2021;62(4):532-9.
- 381 16. Broda M, Eiberg J, Taudorf M, Resch T. Limb graft occlusion after endovascular
382 aneurysm repair with the Cook Zenith Alpha abdominal graft. *Journal of Vascular Surgery*.
383 2023;77(3):770-7.e2.

- 384 17. Ulsaker H, Lam M, Herje ML, Seternes A, Manstad-Hulaas F. A Retrospective
385 Evaluation of Intra-Prosthetic Thrombus Formation After Endovascular Aortic Repair in
386 Cook Zenith Alpha and Medtronic Endurant II Patients. *Eur J Vasc Endovasc Surg.*
387 2023;66(5):644-51.
- 388 18. Mangialardi N, Ronchey S, Kasemi H, Alberti V, Fazzini S, Serrao E. Percutaneous
389 endovascular aneurysm repair with the ultra-low profile Ovation Abdominal Stent-Graft
390 System. *J Cardiovasc Surg (Torino).* 2013;54(5):581-7.
- 391 19. Carroccio A, Faries PL, Morrissey NJ, Teodorescu V, Burks JA, Gravereaux EC, et al.
392 Predicting iliac limb occlusions after bifurcated aortic stent grafting: anatomic and device-
393 related causes. *J Vasc Surg.* 2002;36(4):679-84.
- 394 20. Wu IH, Liang PC, Huang SC, Chi NS, Lin FY, Wang SS. The significance of
395 endograft geometry on the incidence of intraprosthetic thrombus deposits after abdominal
396 endovascular grafting. *Eur J Vasc Endovasc Surg.* 2009;38(6):741-7.
- 397 21. Marques de Marino P, Ibraheem A, Gafur N, Mufty H, Schubert N, Verhoeven EL, et
398 al. Limb Occlusion Rate after EVAR With Individualized Graft Limb Selection and a Liberal
399 Protocol of Primary Relining. *Annals of Vascular Surgery.* 2021;75:445-54.

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402 **Figure legends**

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

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406 Figure 2. Kaplan-Meier curve for freedom of device-related complications and reinterventions
407 80 patients who underwent endovascular aneurysm repair using the INCRAFT stent graft
408 system

409

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

Variable	Mean \pm SD or No. (%)
Age, years	76 \pm 7
Male	68 (85)
BMI, kg/m ²	27 \pm 6
<i>Medical history</i>	
Hypertension	64 (80)
Diabetes	15 (19)
Active smoker	20 (25)
CAD	24 (30)
Atrial fibrillation	25 (31)
COPD	19 (24)
Stroke/TIA	6 (8)
GFR \leq 60ml/min	27 (34)
PAD	33 (41)
ASA class \geq 3	74 (93)
<i>Previous medication</i>	
Antiplatelet 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 \pm 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)
<i>Anatomic measurements</i>	
Aneurysm diameter*, mm	59 \pm 10
Proximal neck diameter, mm	23 \pm 2
Proximal neck length, mm	35 \pm 17
Distal landing zone diameter, mm	14 \pm 4
Distal landing zone length, mm	54 \pm 19
<i>IFU violations</i>	
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 \leq 18 mm	6 (8)
Iliac landing zone length <15mm	1 (1)
Access vessel diameter <5 mm	2 (3)
\geq 1 IFU violation	28 (35)
<i>Further severe anatomic characteristics</i>	
Neck calcification \geq 50%	6 (8)
Neck thrombus \geq 50%	8 (10)
EIA landing zone	4 (5)
Turtuous iliac artery	26 (33)
Distal landing zone calcification or thrombus \geq 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/cm ²	41 [21;60]
Blood loss, ml	100 [0;300]
Hospitalization days	4 [2; 6]
<i>Intraoperative complications</i>	
Type Ia endoleak	9 (11)
Type II endoleak	19 (24)
Partial renal artery coverage	2 (3)
<i>Adjunctive procedures</i>	
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 \pm SD or No. (%)
Follow-up, months	37 \pm 25
Mortality, overall	23 (29)
Mortality, aneurysm-related	0 (0)
<i>Complications</i>	
Limb occlusion	7 (9)
Distal embolization	12 (15)
Main body migration \geq 5mm	1 (1)
Limb migration \geq 5mm	2 (3)
Stent fracture	0 (0)
<i>Stent graft related reinterventions</i>	
<i>N=25 (31)</i>	
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)
<i>Endoleak at last FU</i>	
Type Ia	1 (1)
Type II	23 (29)
Type III	3 (4)
<i>Aneurysm change at last FU</i>	
Growth \geq 5mm	12 (15)
Stable	33 (41)
Shrinkage \geq 5mm	30 (38)

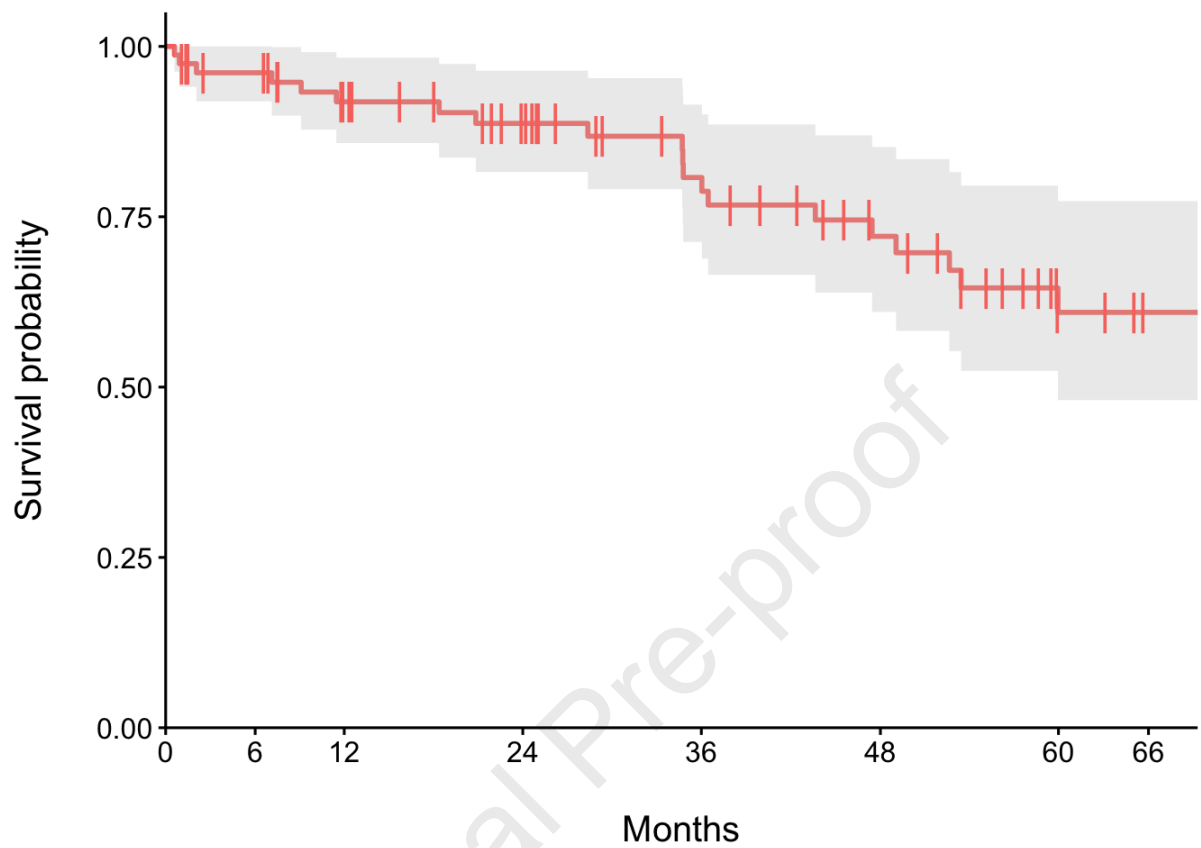
CFA = common femoral artery; FEVAR = fenestrated endovascular aortic repair; FU = Follow-up.

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

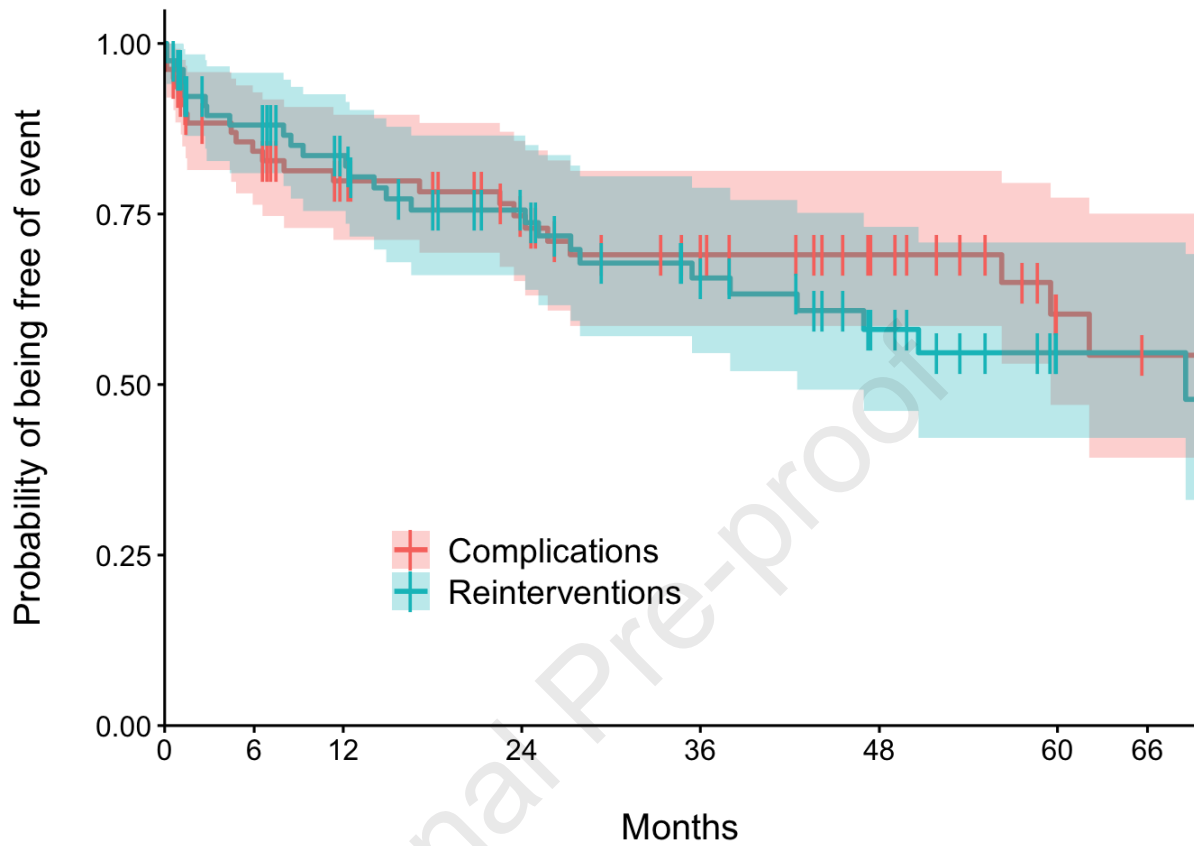
CI = confidence interval; IFU = instructions for use.

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