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Long-term results of treatment of infrarenal aortic aneurysms with low-profile stent grafts in a multicenter registry

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Abstract

Objective

In recent years, manufacturers have developed new stent grafts with lower profiles to increase the endovascular aneurysm repair applicability. As reported by the current European Society for Vascular Surgery guidelines, long-term evaluation of such low-profile platforms is strongly recommended. This study aims to report outcomes beyond 5 years from a multicenter registry, including a real-world cohort of patients electively treated with low-profile stent grafts.

Methods

A retrospective data collection of patients who had undergone elective implantation of low-profile endograft ≤16 Fr. (Zenith LP, Ovation, Incraft) was performed in nine centers. The primary endpoint was a long-term primary clinical success. Secondary endpoints were survival rate, freedom from abdominal aortic aneurysm (AAA)-related death, freedom from type I to III endoleak, limb patency, and freedom from all reinterventions. The Kaplan-Meier curves were stratified for investigative devices. A multivariate analysis evaluated predictors of primary clinical success and reintervention rate.

Results

A total of 619 patients were enrolled (Ovation, n = 373; Incraft, n = 111; and Zenith LP, n = 135), with a mean follow-up of 56.8 ± 22.8 months. The overall primary and the secondary clinical success rate at 8 years was 72.1% and 93.8%, respectively. At 8 years, overall survival was 53.2%, freedom from AAA-related death was 94.4%, freedom from reintervention was 74%, freedom from type I/III endoleak was 86.9%, and limb patency was 90.4%. A significantly worse primary clinical success of the Zenith LP was recorded as dependent on more limb-related events. No differences between platforms were registered in the rate of AAA-related deaths, open conversion, sac enlargement, and type I/III endoleaks (P = .26). Multivariate analysis identified iliac tortuosity (hazard ratio, 2.053) and Zenith LP (hazard ratio, 3.818) as significant independent predictors of clinical failure and reintervention.

Conclusions

Low-profile stent grafts have acceptable long-term outcomes. Overall survival and AAA-related death were in line with those reported for traditional devices. Long-term surveillance and reintervention, when necessary, remain crucial to guarantee durability.

Endovascular aneurysm repair (EVAR) has become the standard treatment for most patients with abdominal aortic aneurysm (AAA) and suitable anatomy, offering a reduced risk of early mortality and morbidity in comparison to open repair.[1,2]

In the beginning, a large number of patients were denied endovascular treatment due to challenging aortoiliac anatomy. In particular, short and angulated neck (so-called complex neck) and narrow access vessels were responsible for EVAR ineligibility in more than 50% of cases.[3]

In recent years, manufacturers have developed new stent grafts with the enhanced sealing capability and delivery systems with lower profiles to allow an endovascular approach even in patients with complex neck and small access vessels.[4,5]

Although favorable midterm outcomes have been reported for the latest generation low profile compared with standard profile stent grafts,[6] the current guidelines strictly recommend long-term outcome data collection to confirm these findings.[7,8]

In the last years, three low-profile (≤16 Fr) stent grafts have been specifically designed to address the applicability and durability of EVAR in patients with infrarenal AAA and small iliac access.

In Italy, these low-profile stent grafts have been commercially available for years: the Zenith Flex Low Profile [LP] endograft (Cook Medical Inc, Bloomington, Ind) since 2010; the Ovation stent graft (Endologix, Irvine, Calif) since 2011; and the Incraft endograft system (Cordis Corporation, Bridgewater, NJ) since 2014.

This study aims to report long-term outcomes (beyond 5 years) from a multicenter registry, including a daily practice cohort of patients electively treated for AAA with low-profile stent grafts. A multivariate analysis was carried out to evaluate the influence of anatomical factors and device materials on primary clinical success and reintervention rates.

Methods

Data collection

The paper was presented following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for observational studies.[9]

In June 2020, we completed a retrospective data collection of patients who had undergone elective implantation of low-profile endograft ≤16 Fr (Cook Zenith LP, Endologix Ovation Prime and iX, Cordis Incraft) for AAA at least 12 months previously. Patients with a mycotic aneurysm or prior aortic reconstructive surgery were excluded. The study followed the Declaration of Helsinki on medical protocol.

Patient informed consent for data collection was obtained, and the local institutional review board was informed of the descriptive, non-experimental, and retrospective nature of the study.

A total of nine centers in Italy were enrolled as participants in the Lo.Lo.Pro (Long Term of Low Profile endograft) study. Each participant center was asked to collect data of clinical status at preoperative and at last follow-up visits.

Data abstraction was performed at each participating center. One institution (University of Siena) was responsible for gathering the data from all the participating centers, evaluating the completion and the quality of the data, and performing the analysis. Audits between investigators were scheduled when needed to clarify data flow into the database.

Patient selection

All patients who underwent elective EVAR procedures with the implantation of a selected low-profile endograft were enrolled in the registry. The endograft selection was made by single operator's preference based on patients' anatomical features, endograft availability, and platform characteristics.

Indication to EVAR was AAA diameter of ≥5.5 cm in male and ≥5 cm in female, or if the aneurysm was rapidly increasing (≥0.5 cm in 6 months, or >1 cm in 12 months).

All patients treated in an urgent or emergent setting and all patients treated for other conditions than AAA (such as dissection and iliac aneurysm) were excluded.

Patients' demographics, intraoperative data, and postoperative outcomes were collected through hospital charts. Coronary artery disease, hypertension, diabetes mellitus, chronic obstructive pulmonary disease, renal disease (chronic renal insufficiency defined by serum creatinine >1.2 mg/dL), smoking history (any current or past regular use of tobacco), congestive heart failure, history of cerebrovascular events (stroke and/or transient ischemic attacks), history of cancer (any current or past incidence if malignancy), dyslipidemia, and atrial fibrillation were considered as comorbidities.

Treatment and follow-up protocols

Preoperative imaging was routinely performed with an angio-computed tomography scan of the abdominal aorta of 1 mm slice thickness. According to reporting standards, the evaluation of anatomic and morphologic characteristics (such as aortic neck angle >60°, aortic neck length, neck calcification ≥50%, neck thrombus ≥50%, iliac tortuosity index τ >1.5, iliac artery calcification ≥ 50%, and external iliac artery <6 mm) was recorded.[10] Follow-up included a clinic visit assessing serum creatinine level and computed tomographic angiography at 1 month. Color-flow duplex ultrasound (US) or contrast-enhanced ultrasound US was performed every 12 months to assess the stent graft, aneurysm size, and the presence of endoleaks. A computed tomographic angiography was rescheduled when the duplex US or contrast-enhanced US revealed significant endoleaks, sac enlargement >1 cm/year, or any suspicion of procedure-related complications.

Definitions

Reporting is according to the guidelines from the Society for Vascular Surgery/American Association of Vascular Surgery ad hoc Committee for Standardized Reporting Practices in Vascular Surgery.[11] Technical success, primary clinical success, primary assisted clinical success, and secondary clinical success is defined accordingly.

Technical success relates to periprocedural events that occur from the initiation of the procedure and extend through the first 24-hour postoperative period. Primary technical success is defined on an intent-to-treat basis. It requires the successful introduction and

deployment of the device in the absence of surgical conversion or mortality, type I or III endoleaks, or graft limb obstruction.

Clinical success is defined as successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion (diameter >5 mm, or volume >5%), aneurysm rupture, or conversion to open repair.

AAA-related adverse events are defined as a composite of the following: direct (type 1 or 3) or undetermined type endoleaks, aneurysm sac growth, migration, device integrity failure, AAA-related death, late post-implantation AAA rupture, or any AAA-related secondary intervention.

Secondary interventions are considered if performed to resolve or prevent a possible complication and included endovascular procedures (proximal cuff and stent implant, distal extension implant, catheter-based thrombolysis, iliac angioplasty, coil or glue embolization of aortic branch vessels) as well as surgical procedures (balloon thrombectomy, femoro-femoral crossover, conversion to open repair, open or laparoscopic ligation of collaterals).

Devices under investigation

The Cordis Incraft stent graft is made of a self-expanding nitinol hypotube covered by a seamless, low-porosity polyester graft. The system has a trimodular design with an aortic bifurcate main body with suprarenal fixation and two iliac limb endoprosthesis. The delivery system has a 14 Fr outer diameter for the 22- to 30-mm main bodies and a 16 Fr for the 34-mm main body, with an integrated and braided sheath introducer.

The Ovation (Prime and iX) abdominal stent graft system (Endologix) is a trimodular device. The aortic body is provided with a suprarenal nitinol stent with anchors that offer active fixation. A network of rings and channels inflated with a low-viscosity radiopaque polymer during stent graft deployment provides effective sealing. In the Ovation endograft platform, stent and fabric are not competing for the same space within the delivery system, and an ultra-low profile delivery can be achieved without compromise. It is delivered via a flexible, hydrophilic-coated, 14 Fr outer diameter (OD) catheter for the 20- to 29-mm main bodies, and 15 Fr for the 34-mm main body.

The design of Zenith flex LP (Cook Medical Inc) is based upon Cook Medical's original Zenith AAA endovascular graft. The graft modules are constructed of woven polyester fabric sewn to self-expanding nitinol stents with braided polyester and monofilament polypropylene suture. The Zenith LP and the 16 Fr (inner diameter) introduction system were constructed with innovative materials resulting in a lower-profile, magnetic resonance-conditional device that does not compromise the key performance features (active fixation, radial force, and columnar strength) critical to the success of Zenith.

Endpoints

This study aimed to analyze long-term primary clinical success (beyond 5 years from the implantation) of EVAR with a low-profile stent graft.

The secondary aims were survival rate, freedom from AAA-related death, freedom from type I and III endoleak, limb patency, and freedom from all reinterventions.

Statistical analysis

Continuous data were shown as mean values ± standard deviation. Categorical variables were expressed as fractions. Analysis of variance was used for independent tests to compare groups on continuous variables after demonstrating a normal distribution of the data.

Categorical variables were compared using a 2 × 3 contingency table tests for overall heterogeneity.

The Kaplan-Meier (KM) method was used to create survival curves to evaluate overall survival, primary clinical success, freedom from reintervention, freedom from type I/III endoleak, and limb patency. KM curves were presented for the whole study population and stratified for endograft implanted. A pairwise log-rank test analysis was used to compare life table curves.

Data sets were analyzed using univariate methods with two goals: (1) determining the risk factors correlated to primary clinical success; and (2) determining the risk factors associated with reintervention. The independent variables that were believed to have an impact on the two dependent variables were: age, AAA diameter, aortic neck length, aortic neck angle >60°, neck calcification ≥50%, neck thrombus ≥50%, iliac calcification, iliac tortuosity index >1.5, small access (<6 mm), endograft type (Ovation/Incraft/Zenith LP), operating center, and subgroup stratification for date of implantation per endograft type (tertiles). Notably, the random effect for anonymized center was included in the analysis.

A Cox proportional analysis was used to determine independent predictors for the two dependent (primary clinical success and reintervention); a probability of 0.10 was used to enter variables into the Cox model in a forward-stepwise manner. Independent predictor variables contributing to the final multivariate model were considered significant risk factors if $P < .05$.

All statistical analyses were performed with GraphPad Prism 9.0 (GraphPad Software Inc, San Diego, Calif) and StatPlus Build 7.1.1 (AnalysisSoft Inc, Walnut, Calif).

Results

Study population

A total of 642 patients were initially enrolled. Twenty-three patients (3.6%) were lost to follow-up. The final study population consisted of 619 patients. The three different endografts were implanted following this distribution: 373 Ovation (60.3%), 111 Incraft (17.9%), and 135 Zenith LP (21.8%).

The mean age was 75.3 ± 7.9 years, and most were male (549; 88.7%). Baseline demographics and anatomical features are listed in Table I.

The majority of cardiovascular risk factors were equally distributed among stent graft populations.

The mean AAA diameter was 56.9 ± 7.9 mm. Some features, considered as indicators of complex anatomy, were extensively prevalent in the population study: 37.2% of patients

had significant iliac calcifications, 32.5% had tortuous iliac arteries, and iliac vessels were <6 mm in 26% of cases.

Table I shows the distribution of anatomical characters between groups: short aortic neck was more frequent in the Ovation group (27.6% vs 6.3% for Incraft and 5.2% for Zenith LP; P < .0001), whereas angulated aortic neck (11.9% vs 20.9% for Ovation and 23.4% for Incraft; P = .005) and small iliac accesses (17% vs 26.5% for Ovation and 35.1% for Incraft; P = .005) were less frequent in the Zenith LP group.

Instruction for use (IFU) compliance was 76.1%. The reason for not respecting the IFU was neck length in 2.9% (4 Ovation, 7 Zenith LP, 7 Incraft), or angulation in 19.4% (78 Ovation, 16 Zenith LP, 26 Incraft).

Procedural characteristics and perioperative outcomes

Primary technical success was 98.1% (607/619). Causes of technical failure were: type Ia endoleak (n = 5), type Ib endoleak (n = 6), and acute femoral artery occlusion (n = 1). Assisted primary technical success was reached in 99.4%. In four cases, technical success was not achieved due to persistent type Ia endoleak (n = 2) or type Ib endoleak (n = 2). The two type Ia endoleaks disappeared spontaneously, and the type Ib endoleaks underwent reintervention at the 1-month follow-up.

The majority of procedures were performed under loco-regional anesthesia (562/619; 90.8%). Bilateral percutaneous access was chosen in 59% (365/619), bilateral surgical femoral exposures in 26.6% (165/619), and the rest of the procedures were performed using a percutaneous and a surgical femoral approach (89/619; 14.4%). The mean contrast medium used per procedure was 85 ± 21 mL.

The mean hospital stay was 3.6 ± 1.8 days.

The mortality rate at 30 days was 0.5% (3/619). None of them were AAA-related. Two patients died due to acute myocardial infarction, one of heart failure.

Clinical success and reinterventions

The mean follow-up was 56.8 ± 22.8 months (range, 1-105 months). Among study population patients, 96 (15.5%) completed >5 years of follow-up.

KM overall primary clinical success rates were 95.5% at 1 year, 90.9% at 3 years, 88.3% at 5 years, and 72.1% at 8 years. Subgroup comparison is shown in Table II: Ovation vs Incraft and Zenith LP vs Incraft did not significantly differ (log rankt P = .39 and P = .28, respectively). In contrast, Ovation vs Zenith LP was strongly different (P < .0001; Fig 1, A-B).

For those who did not reach clinical success, the failure in the first 3 years was 70.7%, in the first 3 to 5 years was 13.8%, and between 5 and 8 years was 15.5%.

Study population secondary clinical success rates were 99.2% at 1 year, 98.7% at 3 to 5 years, and 93.8% at 8 years. Subgroup analysis did not reveal any significant differences (log-rank P = .1).

During the entire follow-up, 65 reinterventions were performed. In the first 3 years after the index procedure, 50 reinterventions (76.9%) were performed, 7 (10.8%) occurred between 3 and 5 years after EVAR, and 8 (12.3%) between 5 and 8 years.

Reintervention was performed in 26 cases (40%) for high-flow type I to III endoleak, in 28 (43.1%) for a limb-related complication, and in 11 (16.9%) for type II endoleak determining AAA sac enlargement. A full list of reinterventions is shown in the Supplementary Table.

Overall freedom from reintervention was estimated at 96% at 1 year, 90.8% at 3 years, 88.6% at 5 years, and 74% at 8 years follow-up. Curves stratified for stent grafts were not statistically different for Ovation vs Incraft and Incraft vs Zenith LP (log-rank P = .33 and P = .69, respectively). Still, they were significant for Ovation vs Zenith LP (log-rank P = .0047) (Fig 1, C-D).

Freedom from type I/III endoleak was 98.2% at 1 year, 96.4% at 3 years, 96.1% at 5 years, and 86.9% at 8 years. Subgroup analysis did not reveal any significant differences (Fig 1, E-F).

Limb patency rates at 1, 3, 5, and 8 years were 98.2%, 96.4%, 94.8%, and 90.4%, respectively. The patency rates were significantly different for Ovations vs Incraft and Ovation vs Zenith LP (log-rank P = .0049 and P < .0001, respectively) (Fig 2, A-B).

Survival and AAA-related mortality

During the follow-up, 113 patients died. The cause of death was unknown in 39.8% of cases (n = 45). The known causes of death were neoplasia (24.8%; n = 28), myocardial infarction (15%; n = 17), cerebral ischemia (9.7%; n = 11), renal failure (5.3%; n = 6), and AAA-related (5.3%; n = 6).

Overall survival rates were 95.5% at 1 year, 89.8% at 3 years, 79% at 5 years, and 53.2% at 8 years. Endograft curve comparisons did not show significant differences (log rank P = .8) (Fig 2, C-D).

Freedom from AAA-related death rates were 99.83% at 1 year, 99.44% at 3 years, 99.1% at 5 years, and 94% at 8 years, with a nonsignificant difference between devices. (Fig 2, E-F).

Multivariable analysis

The uni- and multivariable stepwise analyses are shown in Table IV.

Iliac tortuosity (hazard ratio [HR], 2.053; 95% confidence interval [CI], 1.197-3.512; P = .008) and endograft Zenith LP (HR, 3.818; 95% CI, 2.128-6.9; P < .0001) were found as significant independent predictors of clinical failure.

Iliac tortuosity (HR, 1.761; 95% CI, 1.028-2.992; P = .003) and endograft Zenith LP (HR, 2.418; 95% CI, 1.332-4.362; P = .003) were found to be also independent predictors of reinterventions.

Discussion

Based on a Cochrane systematic review of randomized controlled trials with long-term survival and cost-effectiveness as the key outcomes, different AAA management recommendations have been published recently.[12]

The National Institute for Health and Care Excellence guidelines recommended offering open repair unless contraindicated for the repair of unruptured AAA.[13] They also suggest considering EVAR as the first option only if there is a hostile abdomen or in selected high-risk comorbid patients. On the other hand, the overall assessment of current evidence led the European Society for Vascular Surgery guidelines committee to suggest EVAR as the first approach in patients with reasonable life expectancy and remark on the importance of long-term data collection.

The committee recognized that a rapid technological and medical development has occurred since randomized controlled trials were conducted, with a shift to a percutaneous approach under local anesthesia, with a result of less aggressive follow-up and reintervention policies. They also strongly supported long-term follow-up and evaluation of the durability of stent grafts, particularly of newer generations of stent grafts based on existing platforms, such as those with low profiles, in prospective registries (recommendation #57). Unfortunately, no prospective registries have evaluated low-profile stent grafts results over a long period (>5 years).

Our investigation shows that elective treatment of AAA with low-profile stent graft is safe and effective, with acceptable durability outcomes as demonstrated by the primary clinical success at 8 years of 72.1%.

This clinical success is slightly better than that recently reported for a series of 277 patients treated within the IFU (60.1% at 7 years) with standard endografts.[14]

In our study, the overall survival rate of 79% and the freedom from aneurysm-related death of 99.1% at 5 years are also in line with available EVAR durability data of traditional stent grafts. The global, prospective, multicenter registry evaluating the Endurant stent graft (ENGAGE) reported an overall survival rate of 67.4% and the freedom from aneurysm-related mortality of 97.8% at the 5-year follow-up.[15] Data from the Global Registry for Endovascular Aortic Treatment with Gore Excluder endograft (GREAT), described an overall survival and freedom from reintervention at 5 years approximately equal to our 5-year results with a low-profile stent graft, despite the GREAT patients being younger and consisting of more American Society of Anesthesiologists (ASA) class I and II patients.

Long-term surveillance of low-profile stent grafts revealed an acceptable reintervention rate, in line with those reported for traditional stent grafts. In particular, complications related to main body device fatigue, which may be questionable for devices with a reduction in the profile, occurred rarely.

Other data on low-profile stent graft durability for up to 5 years have been published. A retrospective analysis of a cohort of patients undergoing EVAR with the Ovation platform (the ENCORE database) prospectively collected data from 1296 patients and reported freedom from all-cause mortality, aneurysm-related mortality, and type I and III endoleaks at 5 years of 78.9%, 99.3%, and 94%, respectively. Our investigation confirms the durability of such a device platform and offers significant 8-year data (54.1%, 99.1%, and 94.7% respectively). In particular, the low rate of neck-related events seems related to the

use of a polymer that does not apply outward radial force to the aneurysm neck, preserving it from enlargement and neck-related complications.[16,17]

Our investigation also offers a direct comparison of durability results between different device platforms. The significantly worse primary clinical success rate of the Zenith LP ($P < .0001$) seems dependent on more limb-related events. Of note, no difference with other stent grafts in the rate of AAA-related deaths, open conversion, sac enlargement, and type I/III endoleaks (log-rank $P = .26$) were registered.

Furthermore, multivariate analysis identified iliac tortuosity (HR, 2.053) and Zenith LP (HR, 3.818) as significant independent predictors of clinical failure and reintervention. These findings are not surprising, because iliac-related events were already reported as linked to the old design of isolated Z stainless steel stents with unsupported gaps in between.[18] The new design of Zenith Alpha stent graft, which was not investigated in this study, comprises Spiral Z-Stent limbs made of a continuous nitinol spiral stent. This innovative design offers good patency and required infrequent limb-related reinterventions, as demonstrated by a recent post-market registry.[19]

Limitations

We recognize that some selection bias may affect our investigation, because the choice of device was completely dependent on physician preference. Moreover, our research is subject to biases regarding the patients, lesions, and therapeutic strategies used because of its retrospective design.

As a multicenter study, different centers' practices could be associated with eventual unmeasured effects of patient selection that could be difficult to separate from treatment effects.

As a retrospective data collection, we cannot be sure that a few attempted cases without stent graft implantation remained unreported.

The good results reported may be related to operators' high familiarity with a low-profile stent graft and may not be reproduced in other centers.

Finally, the comparison of KM curves among the three investigative devices may be unfair due to the more recent availability on the market of the Incraft stent graft, which determined a shorter follow-up (standard error >10% at 5 years); additionally, more than 60% of patients received a single model of endograft, and some anatomical conditions were significantly different among study groups.

Conclusions

This retrospective study shows that patients treated with low-profile stent grafts have acceptable long-term outcomes. Overall survival and AAA-related deaths were in line with those reported for traditional devices. Long-term surveillance and reintervention, when necessary, remain crucial to guarantee durability. The design evolution toward low-profile platforms seems not to affect the type of complication during the follow-up.

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Table I. Baseline demographics and aortic anatomical features of the total study population (n = 619) and endograft subgroup comparison (Ovation, n = 373; Incraft, n = 111; Zenith LP, n = 135)

	All patients (n = 619)	Ovation (n = 373)	Incraft (n = 111)	Zenith LP (n = 135)	*P*-value
Clinical variables					
Age, *years*	75.3 ± 7.9	74.9 ± 8.1	75.3 ± 7.7	76.6 ± 7.7	.085
Male	549 (88.7)	329 (88.2)	95 (85.6)	125 (92.6)	.2
Hypertension	437 (70.6)	276 (74)	85 (76.6)	76 (56.2)	**.0002**
DM	76 (12.3)	42 (11.3)	15 (13.5)	19 (14.1)	.6
Dyslipidemia	141 (22.8)	83 (22.3)	27 (24.3)	31 (23)	.9
Smoking	109 (17.6)	72 (19.3)	17 (15.3)	20 (14.8)	.4
COPD	71 (11.5)	39 (10.4)	14 (12.6)	18 (13.3)	.6
CAD	159 (25.7)	86 (23.1)	32 (28.8)	41 (30.3)	.17
AF	49 (7.9)	21 (5.6)	13 (11.7)	15 (11.1)	**.03**
Chronic renal disease	70 (11.3)	37 (9.9)	15 (13.5)	18 (13.3)	.4
Smoking	181 (29.2)	109 (29.2)	29 (26.1)	43 (31.8)	.6
Congestive heart failure	93 (15)	57 (15.2)	15 (13.5)	21 (15.5)	.8
Cerebrovascular disease	66 (10.6)	34 (9.1)	15 (13.5)	17 (12.5)	.3
History of cancer	65 (10.5)	39 (10.4)	10 (9)	16 (11.8)	.7
ASA classification					
I-II	266 (42.9)	171 (45.8)	43 (38.7)	52 (38.5)	.2
II-IV	353 (57.1)	202 (54.2)	68 (61.2)	83 (61.4)	.2
Anatomical features					
AAA diameter, *mm*	56.9 ± 7.9	55.2 ± 8.2	57.5 ± 9.5	58.5 ± 9.2	**.0003**
Aortic neck angle >60°	120 (19.4)	78 (20.9)	26 (23.4)	16 (11.9)	**.007**
Short aortic neck (<10 mm)	117 (18.9)	103 (27.6)	7 (6.3)	7 (5.2)	**<.0001**
Neck calcification >50%	81 (13.1)	42 (11.3)	21 (18.9)	18 (13.3)	.1
Neck thrombus >50%	76 (12.2)	37 (9.9)	16 (14.4)	23 (17)	.07
Iliac calcifications	230 (37.2)	149 (39.9)	40 (36)	41 (30.4)	.13
Iliac tortuosity index >1.5	201 (32.5)	126 (33.8)	36 (32.4)	39 (28.9)	.5
Small iliac access <6 mm	161 (26)	99 (26.5)	39 (35.1)	23[17]	**.005**

AAA, Abdominal aortic aneurysm; AF, atrial fibrillation; ASA, American Society of Anesthesiologists; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus.

Data are presented as number (%) or mean ± standard deviation.

Boldface P values indicate statistical significance.

Table II. Overview of Kaplan-Meier analysis results on general study population (n = 619) and endograft subgroups (Ovation, n = 373; Incraft, n = 111; Zenith LP, n = 135)

Outcomes (no. patients at risk at time 0)	**1 year**	**3 years**	**5 years**	**8 years**
Overall survival (619)	95.5 (594)	89.8 (384)	78.9 (166)	53.3 (11)
Ovation (373)	94.6 (353)	89.1 (227)	79.7 (102)	54.1 (7)
Incraft (111)	97.3 (109)	94.5 (41)	[a]	[a]
Zenith LP (135)	96.3 (132)	88.7 (116)	75.2 (64)	49.3 (4)
AAA-related mortality (619)	99.8 (594)	99.4 (384)	99.1 (166)	94 (11)
Ovation (373)	99.7 (353)	99.7 (227)	99.1 (102)	99.1 (7)
Incraft (111)	100 (109)	100 (41)	[a]	[a]
Zenith LP (135)	100 (132)	98.4 (116)	98.4 (64)	84.4 (4)
Primary clinical success (619)	95.5 (560)	90.9 (344)	88.3 (151)	72.1 (9)
Ovation (373)	95.9 (333)	92.9 (204)	92.4 (96)	88.2 (6)
Incraft (111)	98.1 (106)	92.6 (38)	[a]	[a]
Zenith LP (135)	92.5 (121)	85.2 (102)	80.7 (55)	46.2 (3)
Freedom from type I/III endoleak (619)	98.2 (581)	96.4 (370)	96.1 (157)	86.9 (11)
Ovation (373)	97.7 (344)	95.9 (220)	95.9 (96)	94.7 (7)
Incraft (111)	100 (108)	100 (41)	[a]	[a]
Zenith LP (135)	99.2 (129)	96 (111)	96 (59)	75.5 (4)
Limb patency (619)	98.2 (579)	96.4 (368)	94.8 (162)	90.3 (10)
Ovation (373)	98.6 (345)	98.2 (220)	98.2 (100)	98.2 (7)
Incraft (111)	98.2 (107)	94 (39)	[a]	[a]
Zenith LP (135)	97 (127)	93.7 (109)	90.3 (62)	77.2 (3)
Freedom from reintervention (619)	96 (568)	90.8 (351)	88.7 (149)	74 (9)
Ovation (373)	96.2 (340)	92.2 (212)	91.3 (95)	87.1 (6)
Incraft (111)	97.3 (106)	91.8 (38)	[a]	[a]
Zenith LP (135)	93.9 (122)	86.6 (101)	84 (54)	52.1 (3)
Secondary clinical success (619)	99.2 (580)	98.7 (372)	98.7 (164)	93.8 (11)
Ovation (373)	98.8 (342)	98.8 (216)	98.8 (101)	98.8 (7)
Incraft (111)	100 (109)	100 (41)	[a]	[a]
Zenith LP (135)	99.2 (131)	97.3 (115)	97.7 (63)	84 (4)

AAA, Abdominal aortic aneurysm.
Outcomes are reported at 1, 3, 5, and 8 years as percentages (%) and patients at risk (n).
[a] Standard error >10%.

Table III. Clinical details of the five aneurysm-related deaths registered during follow-up

Patient number	Endograft implanted	The occurrence of index event after EVAR, months	Clinical description
1	Ovation	9	AAA rupture due to type IB endoleak; death occurred with no possibility of surgical intervention.
2	Zenith LP	73	AAA rupture due to endoleak IA, endograft explantation, and aorto-bifemoral reconstruction were performed. The death occurred 2 weeks after intervention.
3	Zenith LP	23	AAA rupture due to type IA endoleak; death happened during the emergency surgical open repair.
4	Zenith LP	19	Iliac artery aneurysm rupture secondary to type IB endoleak; the emergency endovascular repair was performed (coil embolization of hypogastric artery and distal extension in the external iliac artery). The death occurred 16 days after intervention due to acute mesenteric ischemia after severe shock condition.
5	Zenith LP	88	AAA rupture due to type IB endoleak; death happened during the emergency endovascular repair.
6	Ovation	46	AAA rupture due to type III (fabric hole) endoleak; endograft explantation and aorto-bifemoral reconstruction were performed. The death occurred 3 days after intervention for multi-organ failure.

AAA, Abdominal aortic aneurysm; *EVAR*, endovascular aneurysm repair.

Table IV. Stepwise analysis for predictors of clinical failure and reintervention in the total population (N = 619)

	Hazard ratio	95% CI	P-value
Variables for clinical failure			
All (univariate analysis)			
Age	0.981	0.948-1.133	.266
AAA diameter	1.024	0.994-1.015	**.10**
Aortic neck length <1 cm	1.388	0.619-3.545	.455
Aortic neck angle >60°	1.152	0.563-2.225	.683
Neck calcification >50%	1.34	0.789-2.561	.728
Neck thrombus >50%	1.283	0.365-3.691	.832
Iliac arteries calcifications	0.65	0.352-1.161	.155
Small iliac access (<6 mm)	0.883	0.443-2.323	.708
Iliac tortuosity (tortuosity index >1.5)	2.3	1.318-4.016	**.003**
Endograft type			
Incraft	1.056	0.443-2.323	.896
Zenith LP	3.643	1.951-6.886	**<.0001**
Treating center			
Center 2	0.922	0.443-3.984	.278
Center 3	0.782	0.692-2.274	.44
Center 4	0.899	0.582-1.375	.371
Center 5	1.286	0.762-3.374	.635
Center 6	0.857	0.619-2.961	.732
Center 7	1.178	0.631-3.767	.344
Center 8	1.386	0.736-1.732	.17
Center 9	0.698	0.383-1.969	.285
Ovation date of implantation (tertiles)			
Tertile 2	0.853	0.371-2.237	.361
Tertile 3	0.685	0.459-1.632	.293
Incraft date of implantation (tertiles)			
Tertile 2	1.059	0.405-1.936	.29
Tertile 3	1.045	0.571-1.852	.190
Zenith LP date of implantation (tertiles)			
Tertile 2	0.959	0.371-1.961	.459
Tertile 3	1.592	0.691-2.191	.275
Stepwise (multivariate analysis)			
AAA diameter	1.024	0.995-1.054	.099
Iliac tortuosity (tortuosity index >1.5)	2.053	1.197-3.512	**.008**
Endograft type			
Incraft	1.098	0.467-2.366	.819
Zenith LP	3.818	2.128-6.9	**<.0001**
Variables for reintervention			
All (univariate analysis)			
Age	0.973	0.941-1.007	.115
AAA diameter	1.025	0.995-1.054	**.093**
Aortic neck length	1.255	0.582-3.022	.584
Aortic neck angle >60°	1.394	0.709-2.618	.315
Neck calcification >50%	1.472	0.873-2.471	.451

Neck thrombus >50%	0.972	0.597-1.958	.691
Iliac arteries calcifications	0.626	0.23-1.114	.12
Small iliac access (<6 mm)	1.416	0.765-2.546	.253
Iliac tortuosity (tortuosity index >1.5)	1.942	1.113-3.373	**.018**
Endograft type			
Incraft	0.98	0.43-2.077	.96
Zenith LP	2.538	1.34-4.806	**.004**
Treating center			
Center 2	0.892	0.633-2.139	.34
Center 3	0.686	0.394-1.963	.293
Center 4	1.021	0.786-2.785	.364
Center 5	1.184	0.537-2.515	.164
Center 6	0.749	0.651-1.794	.35
Center 7	1.395	0.841-2.617	.156
Center 8	1.251	0.539-2.936	.254
Center 9	0.578	0.416-1.783	.391
Ovation date of implantation (tertiles)			
Tertile 2	0.718	0.426-1.651	.461
Tertile 3	0.685	0.335-2.159	.274
Incraft date of implantation (tertiles)			
Tertile 2	0.834	0.741-1.861	.26
Tertile 3	1.456	0.953-2.759	.391
Zenith LP date of implantation (tertiles)			
Tertile 2	1.149	0.571-2.174	.341
Tertile 3	1.052	0.426-2.027	.094
Stepwise (multivariate analysis)			
AAA diameter	1.026	0.996-1.055	.07
Iliac tortuosity (tortuosity index >1.5)	1.761	1.028-2.992	**.003**
Endograft type			
Incraft	1.061	0.473-2.201	.07
Zenith LP	2.418	1.332-4.362	**.003**

AAA, Abdominal aortic aneurysm; CI, confidence interval.

Boldface P values indicate statistical significance.

Figure 1. Kaplan-Meier (KM) curve analyses. In the left column, KM graphs of the entire study population (N = 619) for primary clinical success (A), freedom from reintervention (C), and freedom from type I/III endoleak (E). In the right column, KM graphs comparing the three investigative devices (Ovation, n = 373; Incraft, n = 111; Zenith LP, n = 135) for primary clinical success (B), freedom from reintervention (D), and freedom from type I/III endoleak (F).

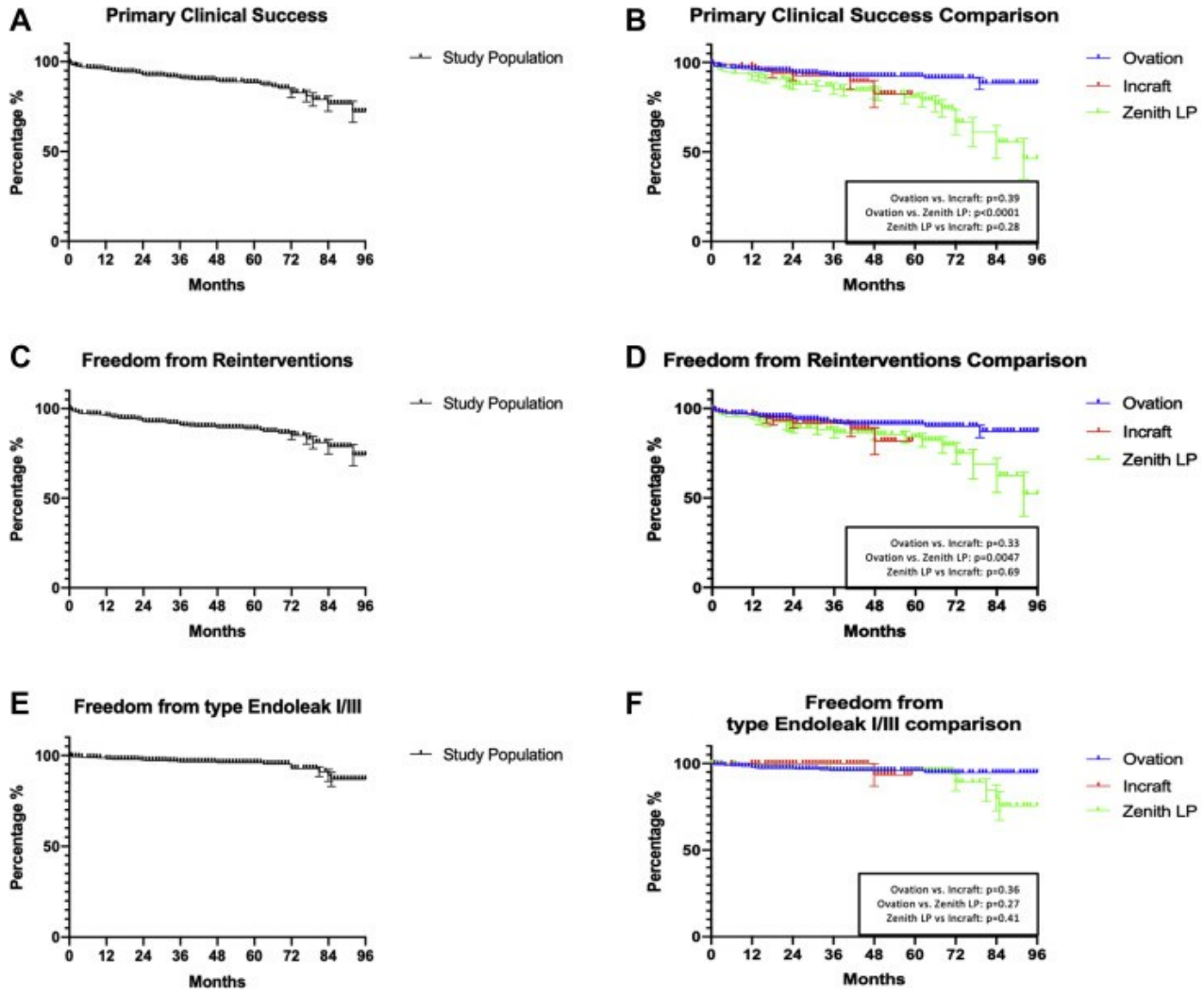
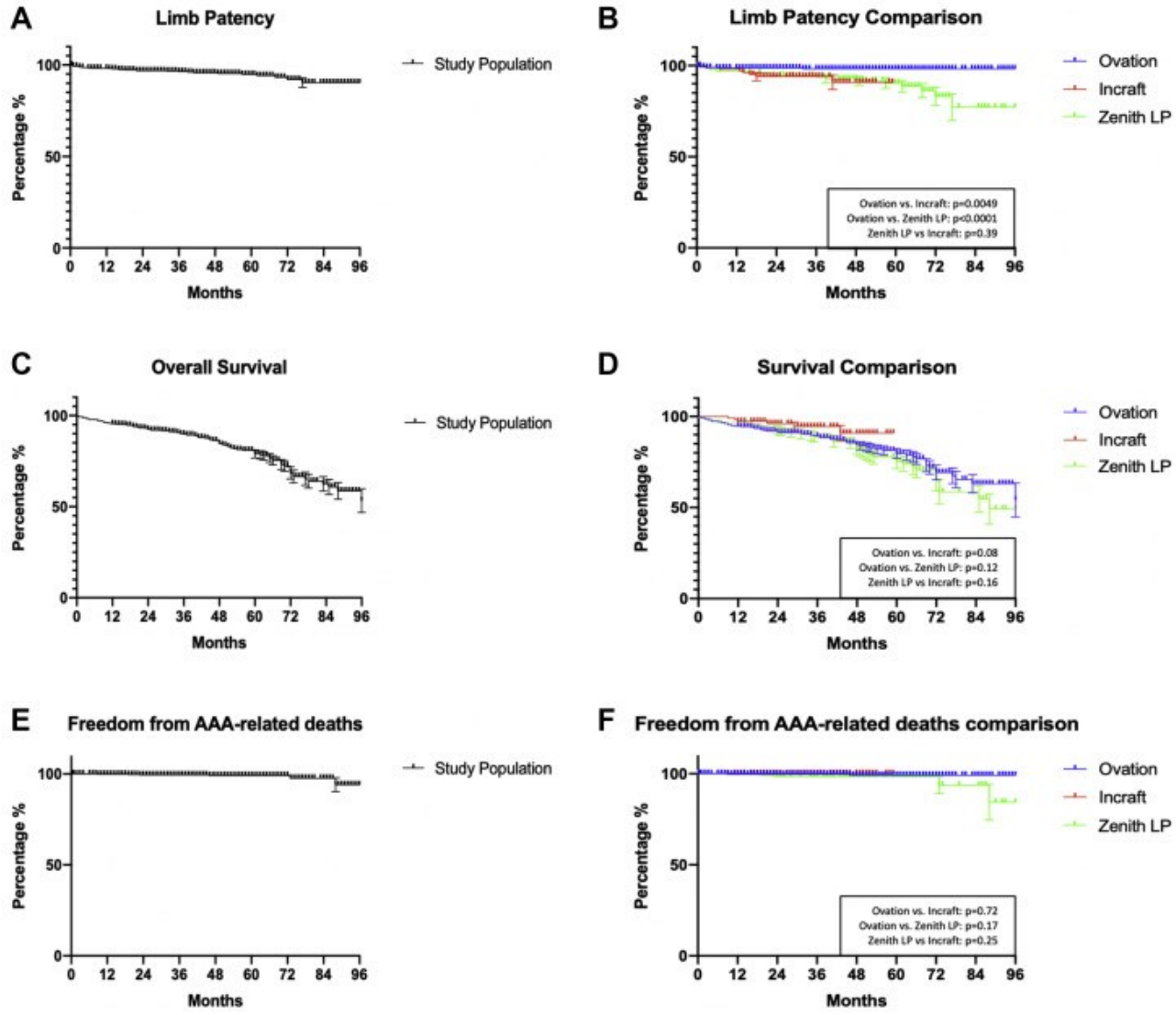


Figure 2. Kaplan-Meier (KM) curve analyses. In the left column, KM graphs of the entire study population (n = 619) for limb patency (A), overall survival (C), and freedom from abdominal aortic aneurysm (AAA)-related deaths (E). In the right column, KM graphs comparing the three investigative devices (Ovation, n = 373; Incraft, n = 111; Zenith LP, n = 135) for limb patency (B), overall survival (D), and freedom from AAA-related deaths (F).



Supplementary table. List of the 65 reinterventions, subgroup analysis for the three investigative devices (Ovation, Zenith LP, and Incraft), and list of corrective procedures undertaken

	Type I/III endoleak	**Type II endoleak**	**Limb-related complication**
Ovation	14	9	6
Zenith LP	10	2	15
Incraft	2		7
Total	26	11	28
Type of reintervention			
Ovation	Endoleak IA	Coil embolization (2)	
		Endograft relining (1)	
		Proximal extension and renal chimney (2)	
		Graft explantation (1)	
		No procedure completed (see Table III)	
	Endoleak IB	Distal extension (3)	
		Distal extension and iliac branch device implantation (2)	
	Endoleak II	Coil embolization (9)	
	Endoleak III	Endograft relining (1)	
		Endograft explantation and surgical reconstruction (1)	
	Iliac thrombosis	Femoro-femoral bypass (2)	
		Surgical recanalization (1)	
		Intra-arterial thrombolysis (2)	
	Iliac dissection	Endovascular stenting (1)	
Zenith LP	Endoleak IA	Proximal extension (2)	
		Graft explantation (2)	
	Endoleak IB	Distal extension (5)	
		Distal extension and hypogastric embolization (1)	
	Endoleak II	Coil embolization (2)	
	liac thrombosis	Intra-arterial thrombolysis (4)	
		Endovascular thromboaspiration (1)	
		Surgical correction and stenting (4)	
		Axillo-bifemoral bypass (1)	
		Endovascular recanalization (2)	
		Femoro-femoral bypass (2)	
		Graft explantation and surgical reconstruction (1)	
Incraft	Endoleak IA	Proximal extension (1)	
	Endoleak IB	Distal extension (1)	
	Endoleak II	Coil embolization (1)	
	Iliac thrombosis	Intra-arterial thrombolysis (1)	
		Femoro-femoral bypass (3)	
		Surgical recanalization (2)	
		Endovascular recanalization (1)	