

THE 26<sup>TH</sup> INTERNATIONAL EXPERTS SYMPOSIUM  
**CRITICAL ISSUES**  
IN AORTIC ENDOGRAFTING

**MARCH 21 & 22 2024**  
COPENHAGEN/MALMÖ  
SCANDIC TRIANGELN, MALMÖ

Low profile devices make it all much easier  
but are they durable?

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# Low profile devices make it all much easier but are they durable?

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Speaker Name: **Prof Mauro Gargiulo**

I have the following potential conflicts of interest to report:

**X Consulting : Cook Medical, WL Gore & Associates, Medtronic**

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

**X Principal Invesigator Expand Registry VBX 17-04**



# How many patients with infrarenal aneurysms are candidates for endovascular repair? *The Northern California Experience*

Arko FR et al.

*J Endovasc Ther* 2004; 11: 33-40

98 / 220 pts (**45%**) anatomically unsuitable candidates for EVAR

## *Primary reason for endovascular repair ineligibility by gender*

	Men (n=68)	Women (n=30)	Totals (n=98)
Neck characteristics	49	24	73 (74%)
Proximal neck length <15 mm	25	16	43 (44%)
Proximal neck diameter >26 mm	18	7	25 (25%)
Tortuous/calcified neck	6	1	7 (7%)
Iliac artery characteristics	12	4	16 (16%)
Stenosis/occlusion/tortuosity	4	2	6 (6%)
Aneurysms	8	2	10 (10%)
Other anatomical characteristics	4	1	5 (5%)
Accessory renal arteries	1	0	1 (1%)
One kidney and accessory renal artery	1	0	1 (1%)
Small diameter of aortic bifurcation	2	1	3 (3%)
Poor quality CT scan	3	1	4 (4%)

CT: computed tomography.

# Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair

Elliot L. Chaikof, MD, PhD, Mark F. Fillinger, MD, Jon S. Matsumura, MD,  
Robert B. Rutherford, MD, Geoffrey H. White, MD, Jan D. Blankensteijn, MD,  
Victor M. Bernhard, MD, Peter L. Harris, MD, K. Craig Kent, MD, James May, MD,  
Frank J. Veith, MD, and Christopher K. Zarins, MD

*J Vasc Surg 2002;35:1061*

## Hostile Iliac Arteries

	<b>Absent = 0</b>	<b>Mild = 1</b>	<b>Moderate = 2</b>	<b>Severe = 3</b>
<b>CALCIFICATION</b>	none	< 25% vessel length	25-50% vessel length	> 50% vessel length
<b>DIAMETER</b>	>10 mm	8-10 mm	7-8 mm	< 7 mm
<b>Occlusive disease</b>	no	Stenosis > 7 mm or > 3 cm long	Focal stenosis < 7 mm and < 3 mm length	<b>Stenosis &lt; 7 mm and &gt; 3 mm length</b>
<b>ANGULATION AND TORTUOSITY</b>				
Iliac Tortuosity Index	$\tau < 1.25$	$\tau 1.25-1.5$	$\tau 1.5 - 1.6$	$\tau > 1.6$
Iliac Angle	160-180°	121-159°	90-120°	< 90°
<b>ILIAC ARTERY SEALING ZONE</b>				
Length	> 30 mm	20-30 mm	10-20 mm	< 10 mm
Diameter	< 12.5 mm	12.5-14.5 mm	14.5-17 mm	> 17 mm



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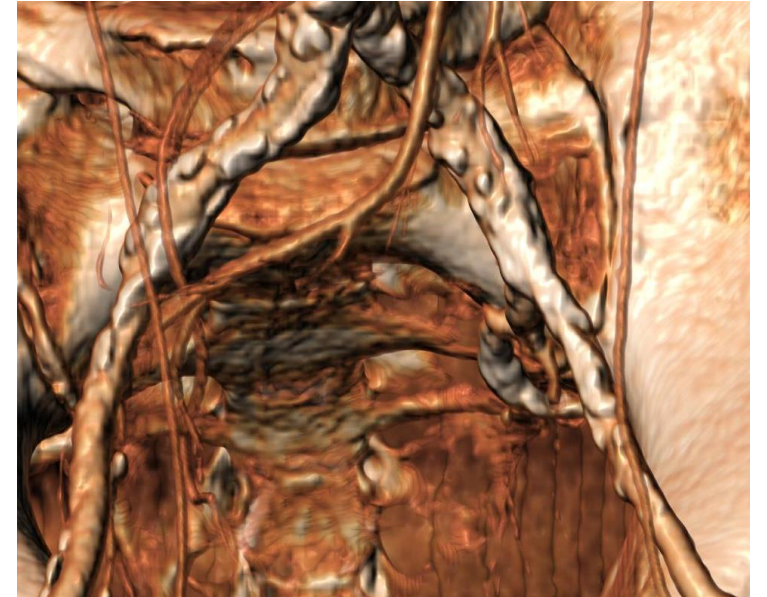
**Severe = 3**

- The key role in the exponential increase of EVAR's utilization rate is the continuous evolution of endovascular techniques, materials and especially of **stent-grafts** which increased the applicability of EVAR.
- 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 and small access vessels

# AAA – Bifurcated Endograft for EVAR

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- Stent graft
- Low-profile stent graft (main body 16 - 20 F OD)
- Ultra-low profile stent-graft (main body  $\leq$  16 F OD)



# EVAR : Main body graft available on the market

Company Name	Product Name	Main Body Delivery System Profile: Device OD (F)
Artivion, Inc.	E-tegra Stent Graft System	18 (<32 mm), 20 (≥32 mm)
Cook Medical	Zenith Alpha Abdominal	18 (22–32 mm grafts), 20 (36 mm)
Cook Medical	Zenith Flex with Z-Trak	21, 23, 26
Cordis	Incraft AAA Stent Graft System	14 (≤ 30 mm), 16 (34 mm)
Lombard –Medical	Aorfix	18
Lombard – Medical	Altura	14
Lombard - Medical	Minos	14 F (22-28 mm) ; 16 F (30-34 mm)
Endologix	Ovation	14 (≤ 29 mm),15 (34 mm)
Gore & Associates	Gore Excluder C3	16 (< 28.5 mm),18 (≥ 28.5 mm)
Gore & Associates	Gore Excluder Conformable	16 (≤ 28.5 mm),18 (> 28.5 mm)
Medtronic	Endurant II AAA Stent Graft System	18 (≤ 28 mm), 20 (>28 mm)
Medtronic	Endurant II AUI Stent Graft System	18 (≤ 28 mm), 20 (>28 mm)
Medtronic	Endurant IIs AAA Stent Graft System	18 (≤ 28 mm), 20 (>28 mm)
Terumo Aortic	Anaconda	20 (≤ 30.5-mm); 22 (≥ 32 mm)
Terumo Aortic	Treo	18, 19 (≥ 30 main )



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Artivion, Inc.	E-tegra Stent Graft System	18 (<32 mm), 20 ( $\geq$ 32 mm)
Cook Medical	Zenith Alpha Abdominal	18 (22–32 mm grafts), 20 (36 mm)
Cook Medical	Zenith Flex with Z-Trak	21, 23, 26
<b>Cordis</b>	<b>Incraft AAA Stent Graft System</b>	14 ( $\leq$ 30 mm), 16 (34 mm)
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Terumo Aortic	Treo	18, 19 (for 30, 33, 36 main bodies)



An aerial photograph of a city, likely Copenhagen, featuring a prominent, tall, white, twisting skyscraper (the COWI Tower) on the right side. The city is densely packed with multi-story residential buildings. In the foreground, there is a waterfront area with a stone breakwater and a small boat. The sky is a mix of blue and pinkish-purple, suggesting a sunset or sunrise. The text "Low profile devices make it all much easier but are they durable?" is overlaid in white, serif font across the center of the image.

Low profile devices make it all much easier  
but are they durable?

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

Gianmarco de Donato, MD, PhD,<sup>a</sup> Edoardo Pasqui, MD,<sup>a</sup> Giovanni Nano, MD, PhD,<sup>b</sup> Massimo Lenti, MD, PhD,<sup>c</sup> Nicola Mangialardi, MD, PhD,<sup>d</sup> Francesco Speziale, MD, PhD,<sup>e</sup> Mauro Ferrari, MD, PhD,<sup>f</sup> Stefano Michelagnoli, MD, PhD,<sup>g</sup> Matteo Tozzi, MD, PhD,<sup>h</sup> and Ciancarlo Palasciano, MD, PhD,<sup>a</sup> on behalf of the LoLopro Registry Collaborators,<sup>\*</sup> *Siena, Milan, Perugia, Rome, Pisa, Florence, Insubria, Italy*

(J Vasc Surg 2022;75:1242-52.)

- 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.

**Table 1.** 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
<b>Clinical variables</b>					
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)	<b>.0002</b>
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)	<b>.03</b>
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
<b>ASA classification</b>					
I-II	266 (42.9)	171 (45.8)	43 (38.7)	52 (38.5)	.2
III-IV	353 (57.1)	202 (54.2)	68 (61.2)	83 (61.4)	.2
<b>Anatomical features</b>					
AAA diameter, mm	56.9 ± 7.9	55.2 ± 8.2	57.5 ± 9.5	58.5 ± 9.2	<b>.0003</b>
Aortic neck angle >60°	120 (19.4)	78 (20.9)	26 (23.4)	16 (11.9)	<b>.007</b>
Short aortic neck (<10 mm)	117 (18.9)	103 (27.6)	7 (6.3)	7 (5.2)	<b>&lt;.0001</b>
Neck calcification >50%	81 (13.1)	42 (11.3)	21 (18.9)	18 (13.3)	.1
Neck thrombus >50%	76 (12.3)	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 <sup>17</sup>	<b>.005</b>

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.

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- Primary Technical Success 98.1%
- Assisted Primary Technical Success 99.4%
- 30 days Mortality rate 0.5%

**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

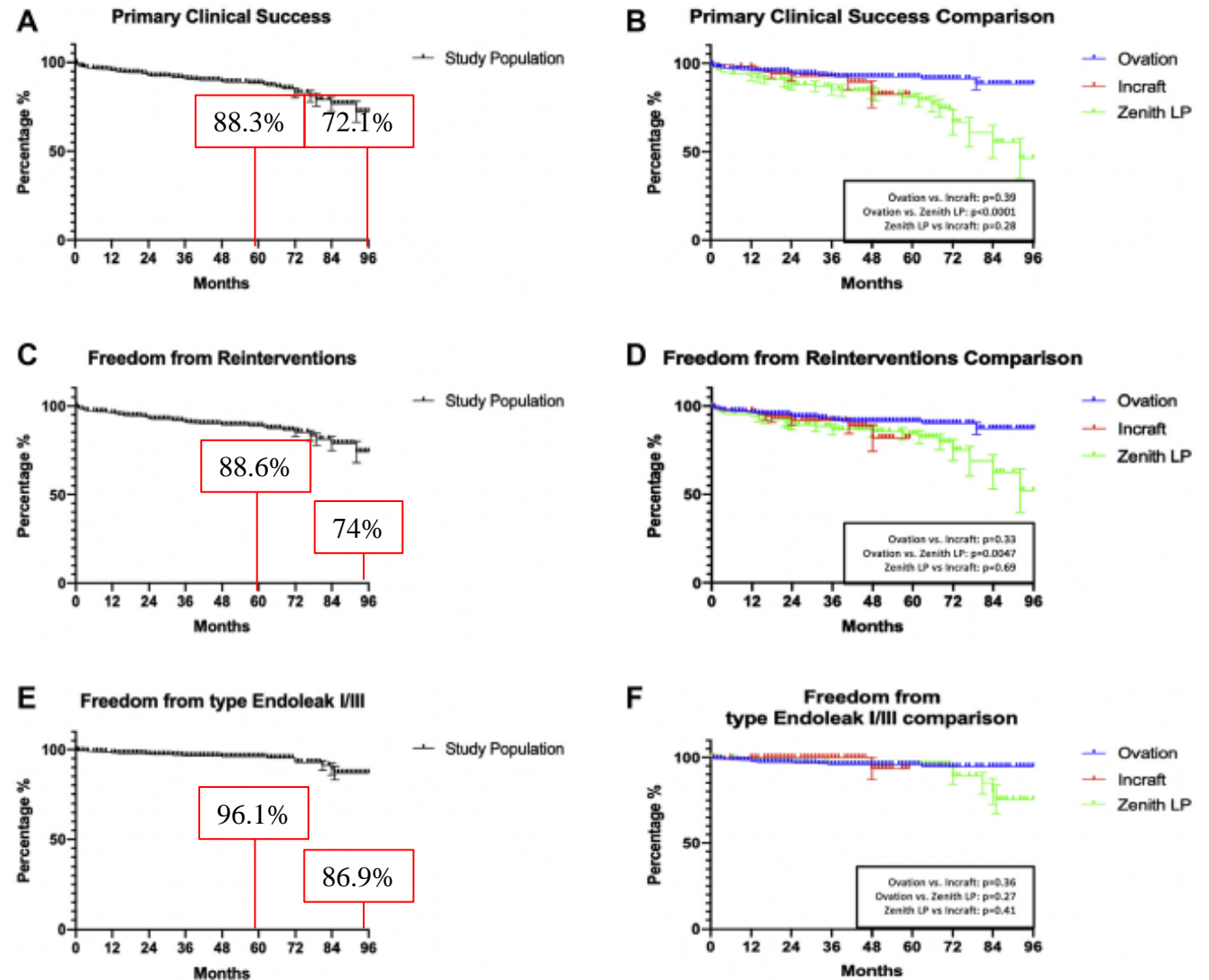
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Mean follow up :  $56.8 \pm 2.8$  months

**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.



**Fig 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).

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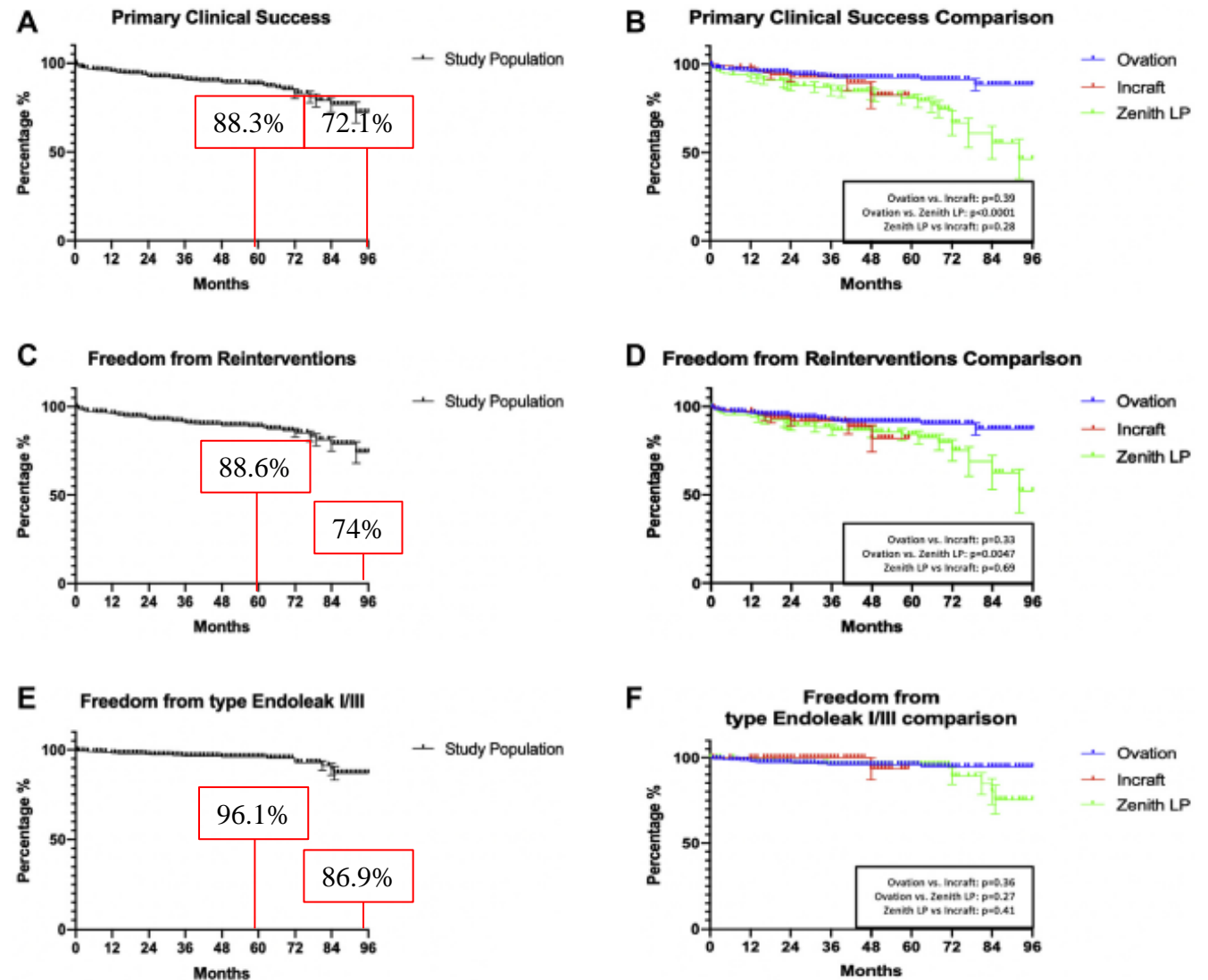
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## Multivariable analysis

- **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**.

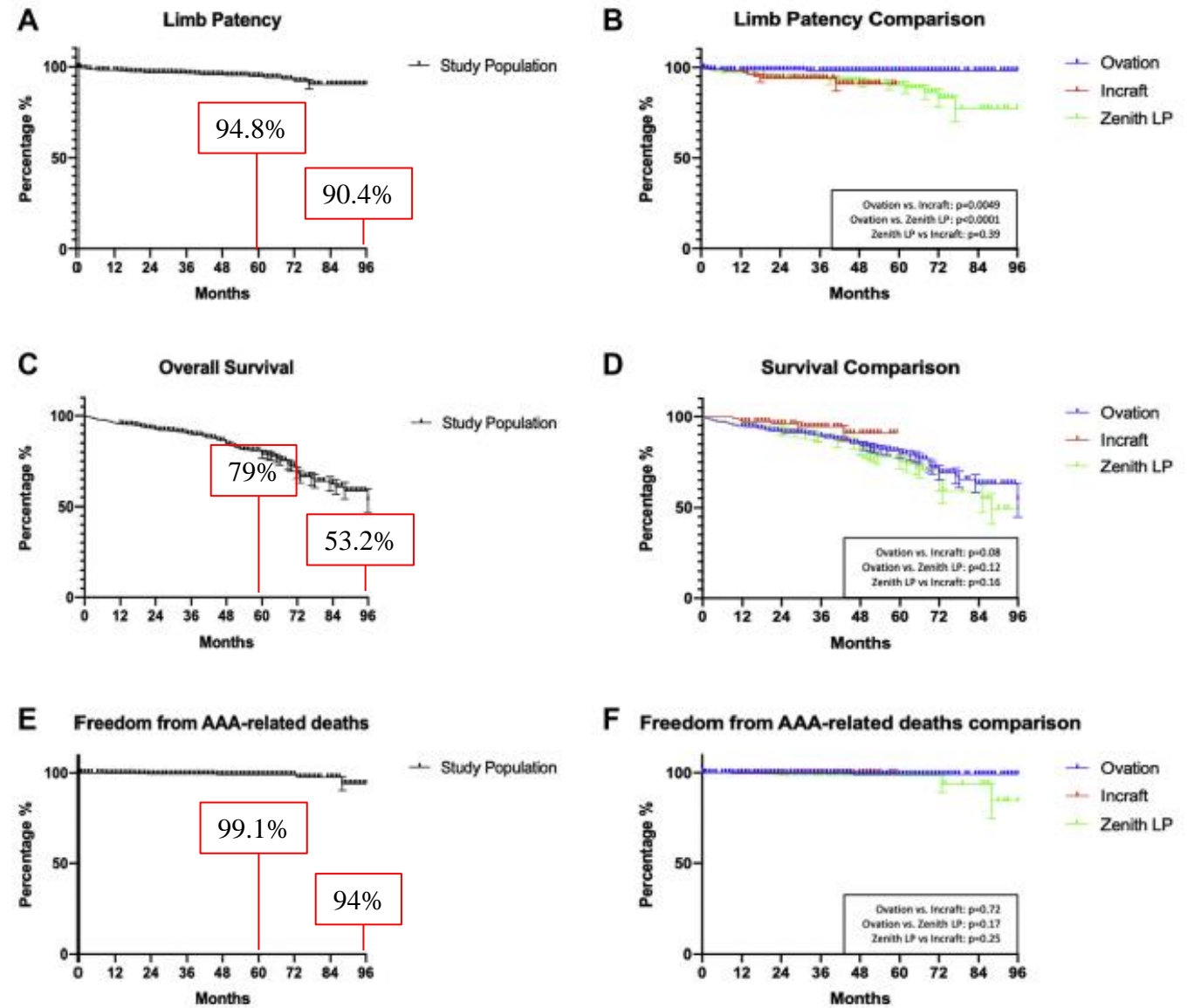


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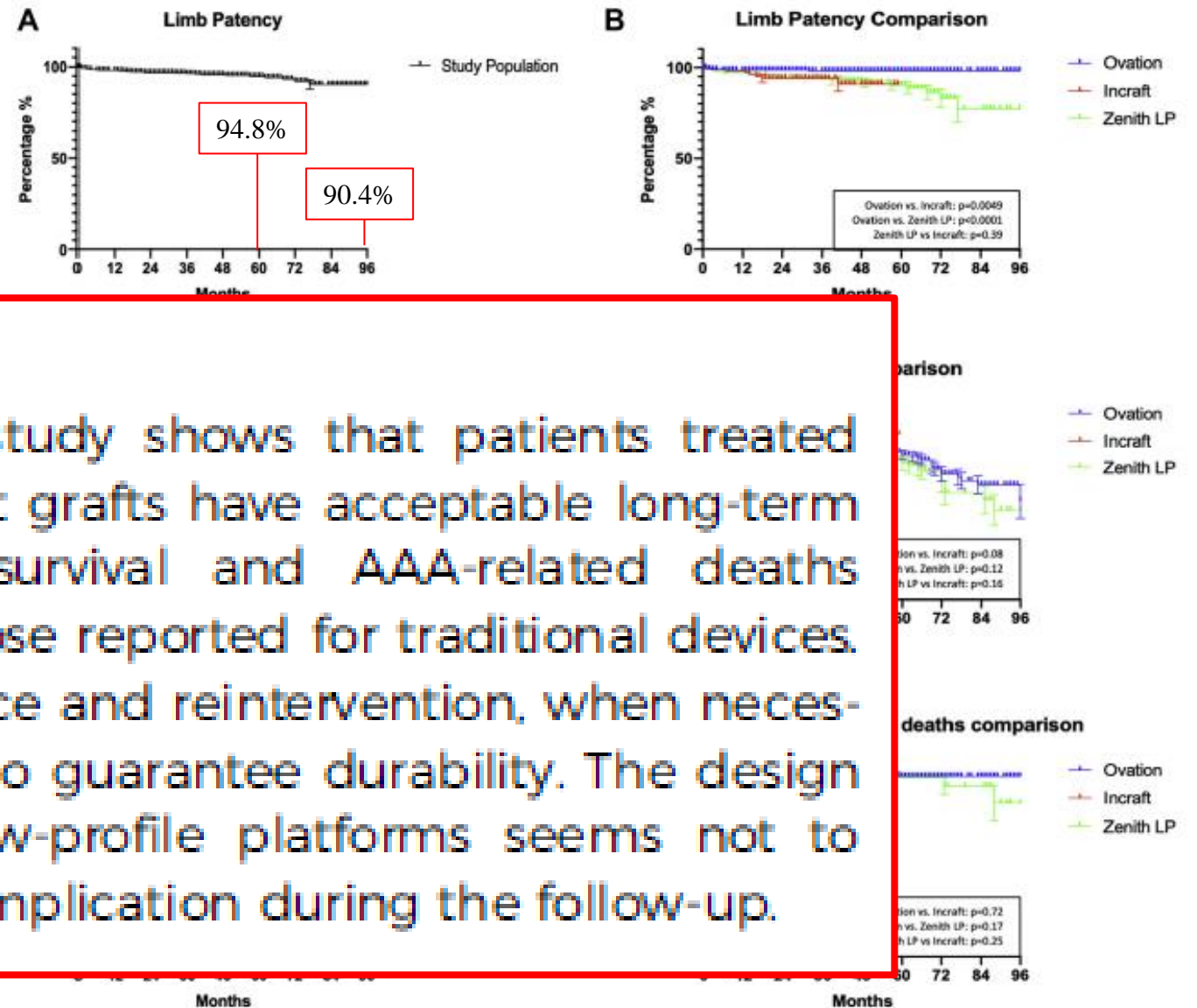
**Fig 2.** Kaplan-Meier (KM) curve analyses. In the left column, KM graphs of the entire study population (n = 619) for limb patency (A), overall survival (C), and freedom from abdominal aortic aneurysm (AAA)-related deaths (E). In the right column, KM graphs comparing the three investigative devices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



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## 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.

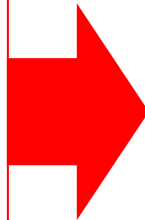
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Ten-year single-center outcomes following endovascular repair for abdominal aortic aneurysm using the INCRAFT device

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- 2012-2013
- Single center, retrospective study
- 30 pts with AAA
- INCRAFT device
- **Median Follow up: 125 months**
- Follow up rate:
  - 5 years 100%
  - 10 years 96.7%



Clinical Success	100%
MAE	0%
Periop. procedure-related complications	0%

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# 10-years Results

Table III. Follow-up outcomes

Variables	Value
Total follow-up duration, months	125 (98-131)
Clinical follow-up duration, months	119 (61-130)
<b>Aneurysm sac status</b>	
Shrinkage	11 (36.7)
Stable	8 (26.7)
Growth	11 (36.7)
<b>Reintervention</b>	
Individual number of cases	10 (33.3)
Cumulative number of cases	15
<b>Reasons for reintervention (cumulative number)</b>	
Type Ia endoleak	5
Type Ib endoleak	1
Type II endoleak	7
Type IIIb endoleak	1
Endotention	2
<b>Late open conversion</b>	6 (20.0)
Open aneurysmorrhaphy with stent graft preservation	5 (16.7)
Open surgical repair with stent graft explantation	1 (3.3)
<b>Limb occlusion</b>	0
<b>Significant proximal neck dilatation</b>	12 (40.0)
<b>Aneurysm-related death</b>	0 (0.0)
<b>All-cause death</b>	9 (30.0)

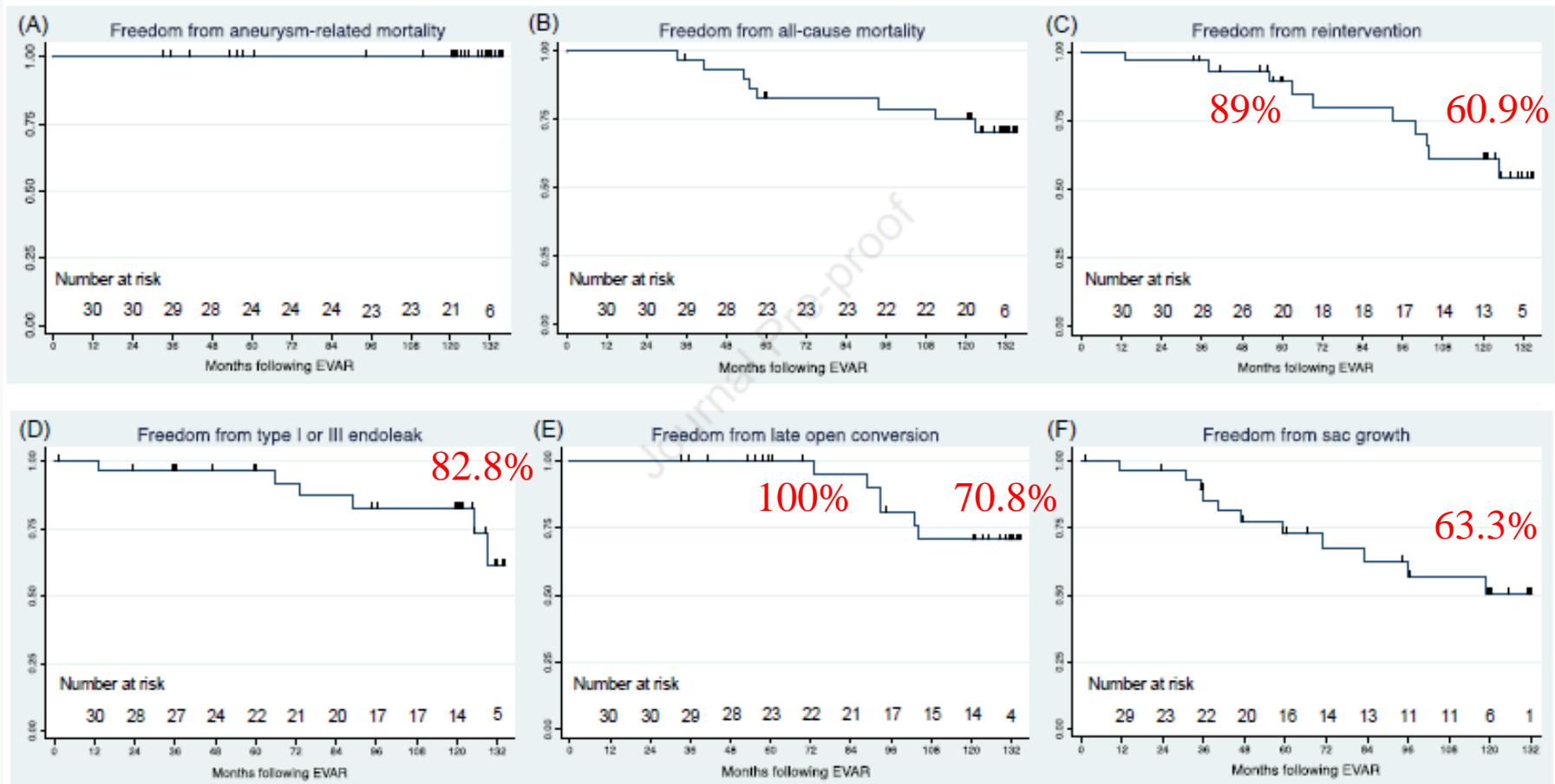


# 10-years Results

Ten-year single-center outcomes following endovascular repair for abdominal aortic aneurysm using the INCRAFT device

Hirotsugu Ozawa, MD, PhD, Takao Ohki, MD, PhD, Kota Shukuzawa, MD, PhD, Kentaro Kasa, MD, Yuta Yamada, MD, Hikaru Nakagawa, MD, Miyo Shirouzu, MD, Makiko Omori, MD, Soichiro Fukushima, MD, Hiromasa Tachihara, MD, PhD

Figure I.



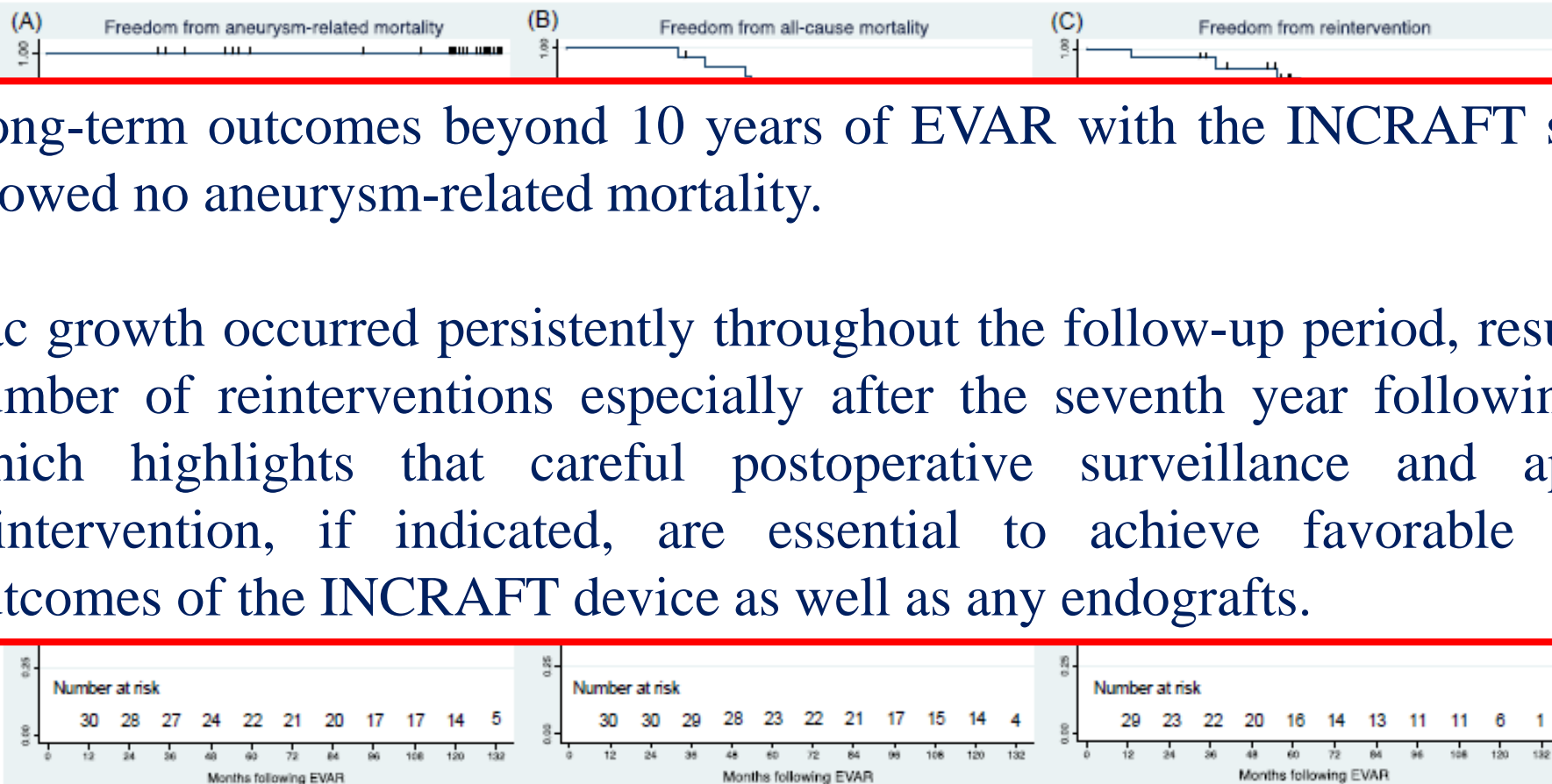
Ten-year single-center outcomes following endovascular repair for abdominal aortic aneurysm using the INCRAFT device

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# 10-years Results

Figure I.



- Long-term outcomes beyond 10 years of EVAR with the INCRAFT stent graft showed no aneurysm-related mortality.
- Sac growth occurred persistently throughout the follow-up period, resulting in a number of reinterventions especially after the seventh year following EVAR, which highlights that careful postoperative surveillance and appropriate reintervention, if indicated, are essential to achieve favorable long-term outcomes of the INCRAFT device as well as any endografts.

## Early Results of Elective Endovascular Repair of Infrarenal Abdominal Aortic Aneurysms With the Minos™ Stent-Graft System

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1–8

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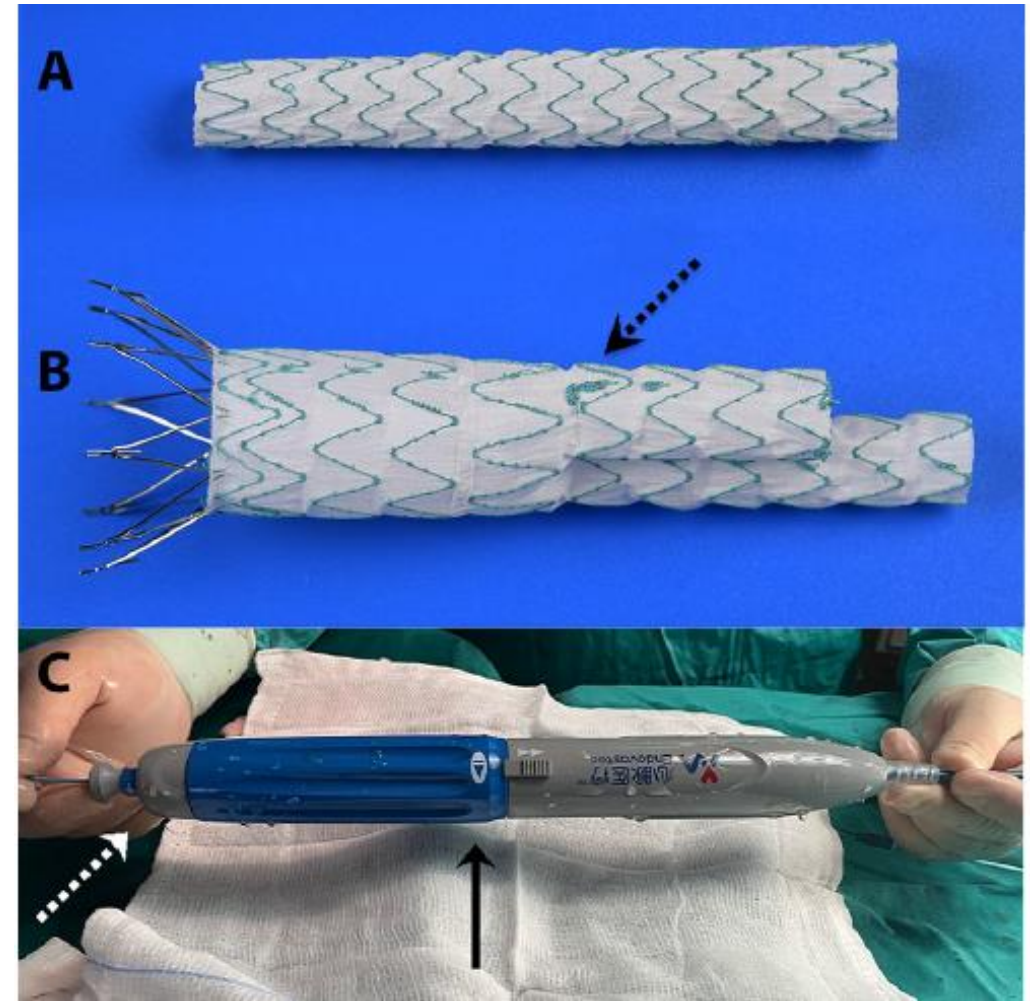
DOI: 10.1177/15266028231172379

www.jevt.org



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Dimitrios A. Chatzelas, MD, MSc<sup>1</sup>, Theodosia Zampaka, MD, MSc<sup>1</sup>,  
Charalampos Loutradis, MD, MSc<sup>1</sup>, Anastasios Potouridis, MD, MSc<sup>1</sup>,  
and Maria D. Tachtsi, MD, PhD<sup>1</sup>

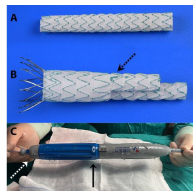
- Endograft first introduced in China in 2019
- Conformance Européenne (CE) mark in September 2019
- **Stent Graft System**
  - PN length no less than 15 mm.
  - hydrophilic delivery system with ultra-low (14F–16F) outer sheath profile,
  - three-piece design
  - suprarenal fixation with 8 laser-cut M-bare stents and integrated barbs
- 41 pts
- Hostile iliac arteries 26.8%
- Median clinical follow up 12.4 months





## Early Results of Elective Endovascular Repair of Infrarenal Abdominal Aortic Aneurysms With the Minos™ Stent-Graft System

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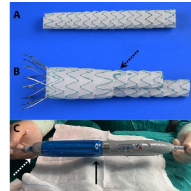


### Table 2. Outcomes.

	Mean±SD or Median—IQR (range) or N—%
<b>Follow-up</b>	
Clinical, months	12.4–12.0 (1.3–25.1)
CTA imaging, months	12.0–15.0 (1.0–24.0)
Maximum AAA's diameter <sup>a</sup>	50.8±7.2
Difference AAA's sac <sup>a</sup>	3.0±2.3
Absolute increase	0–0.0%
Stable <sup>b</sup>	27–65.9%
Sac regression ≥2.5 mm	14–34.1%
Notable regression ≥2.5 mm and <5 mm	8–19.5
Important regression ≥5 mm	6–14.6%
Graft-related endoleak/migration	0–0.0%
Graft-related morbidity/mortality	0–0.0%
Graft-related reinterventions	0–0.0%
Type II endoleak	4–9.8%
Clinical success, 30-day	41–100%
Clinical success, follow-up	41–100%
Clinical success out of IFU	22–100%

# Early Results of Elective Endovascular Repair of Infrarenal Abdominal Aortic Aneurysms With the Minos™ Stent-Graft System

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and Maria D. Tachtsi, MD, PhD<sup>1</sup>



## Conclusions

- The Minos abdominal aortic stent-graft presented easy navigation even through hostile iliac vessels and provided precise deployment, optimal proximal fixation, and powerful sealing even in short and angulated necks.
- The results of this preliminary experience in standard EVAR, within as well out of the stent-graft’s IFU, are promising with excellent feasibility, safety, and effectiveness at first year.
- The overall clinical performance appeared to be in very high standards.

**Table 2. Outcomes.**

	Mean±SD or Median—IQR (range) or N—%
Follow-up	
Clinical, months	12.4–12.0 (1.3–25.1)
CTA imaging, months	12.0–15.0 (1.0–24.0)
Maximum AAA’s diameter <sup>a</sup>	50.8±7.2
	±2.3
	0%
	9%
	1%
	9.5
	6%
	0%
	0%
	0%
	0%
	8%
	0%
Clinical success, follow-up	41–100%
Clinical success out of IFU	22–100%



# EVAR : Main body graft available on the market

- **Low-profile stent graft (main body 16 - 20 F OD)**

Company Name	Product Name	Main Body Delivery System Profile: Device OD (F)
Artivion, Inc.	E-tegra Stent Graft System	18 (<32 mm), 20 (>32 mm)
<b>Cook Medical</b>	<b>Zenith Alpha Abdominal</b>	18 (22–32 mm grafts), 20 (36 mm)
Cook Medical	Zenith Flex with Z-Trak	21, 23, 26
Cordis	Incraft AAA Stent Graft System	14 (≤ 30 mm), 16 (34 mm)
<b>Lombard –Medical</b>	<b>Aorfix</b>	18
Lombard – Medical	Altura	14
Lombard - Medical	Minos	14 F (22-28 mm) ; 16 F (30-34 mm)
Endologix	Ovation	14 (≤ 29 mm), 15 (34 mm)
<b>Gore &amp; Associates</b>	<b>Gore Excluder C3</b>	16 (< 28.5 mm), 18 (≥ 28.5 mm)
<b>Gore &amp; Associates</b>	<b>Gore Excluder Conformable</b>	16 (≤ 28.5 mm), 18 (> 28.5 mm)
<b>Medtronic</b>	<b>Endurant II AAA Stent Graft System</b>	18 (≤ 28 mm), 20 (>28 mm)
<b>Medtronic</b>	<b>Endurant II AUI Stent Graft System</b>	18 (≤ 28 mm), 20 (>28 mm)
<b>Medtronic</b>	<b>Endurant IIs AAA Stent Graft System</b>	18 (≤ 28 mm), 20 (>28 mm)
Terumo Aortic	Anaconda	20 (≤ 30.5-mm); 22 (≥ 32 mm)
<b>Terumo Aortic</b>	<b>Treo</b>	18, 19 (≥ 30 main )



# October 2015 - Zenith Alpha™ Abdominal



## Zenith® Alpha™ Abdominal Endovascular Graft

### Nitinol

Thin tightly woven dacron (~0.12 mm)

No top cap

### 16 Fr Flexor

6 mm O.D. (32 mm stent-graft)

Blue rotational handle with integrated releasing mechanism

4 radiopaque markers at the proximal edge of the graft, 1 tick marker at the distal edge of CL limb, 1 marker at the level of the flow-divider, 1 marker at the distal edge of IL limb

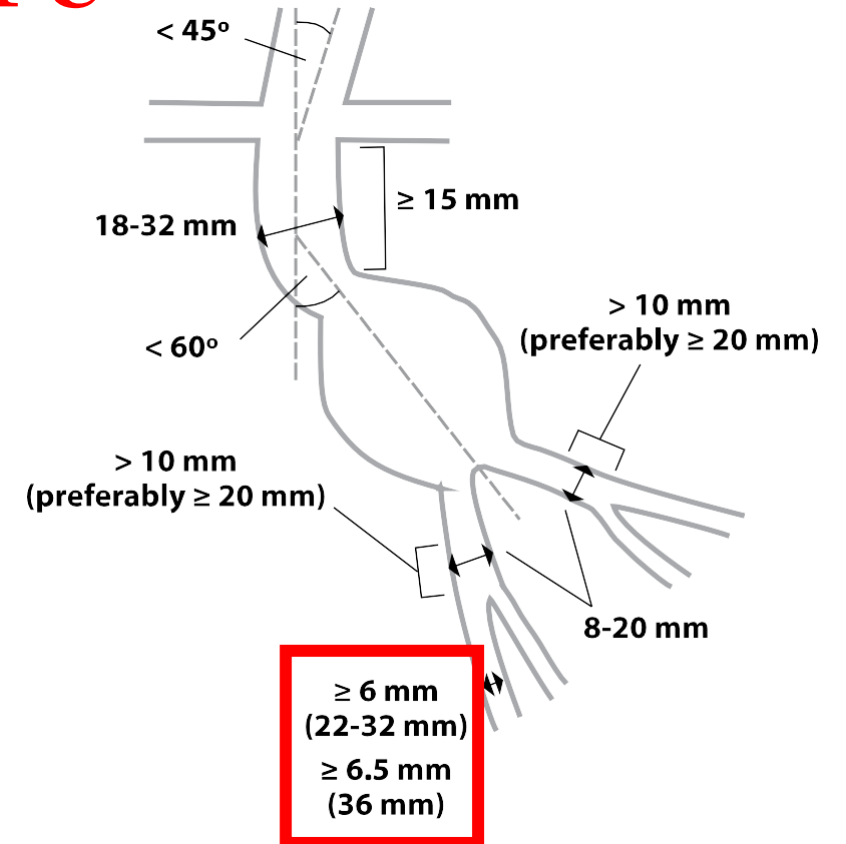
30 mm bare suprarenal stent length

20 mm proximal sealing stent length

## Low aortic bifurcation



## IFU



# Cook Zenith Alpha™ Abdominal

## *Endograft implantation – Bologna procedure*

- Step 1: main body introduction in the juxtarenal aorta ,
- Step 2; diagnostic angiography 1° stent deployment ,
- Step 3: parallax correction
- Step 4: angiographic control controlateral gate openin
- Step 5: angiographic control, free flow opening
- Step 6: controlateral gate cannulation, marked pig tail, retrograde angiography, iliac leg lenght evaluation
- Step 7: minimum overlap, AP projection**
- Step 8: projection for hypogastric visualization, iliac limb deployment
- Step 9: ipsilateral leg proximal landing zone at the same level of controlateral leg**
- Step 10: proximal main-body landing zone PTA (compliant balloon)
- Step 11: main body biforcation - kissing balloon (semicompliant balloons – 12 mm - 6 cm)**
- Step 12: distal landing zone PTA (compliant balloon if limb diameter  $\geq$  18 mm)
- Step 13: completion aortography with floppy guidewires (AP and LAO-RAO 45°),**
- Step 14: femoral retrograde angiography, iliac stenting if residual stenosis is detected**



# The Efficacy of a Protocol of Iliac Artery and Limb Treatment During EVAR in Minimising Early and Late Iliac Occlusion

Andrea Vacirca<sup>\*</sup>, Gianluca Faggioli, Rodolfo Pini, Paolo Spath, Enrico Gallitto, Chiara Mascoli, Mohammad Abualhin, Mauro Gargiulo

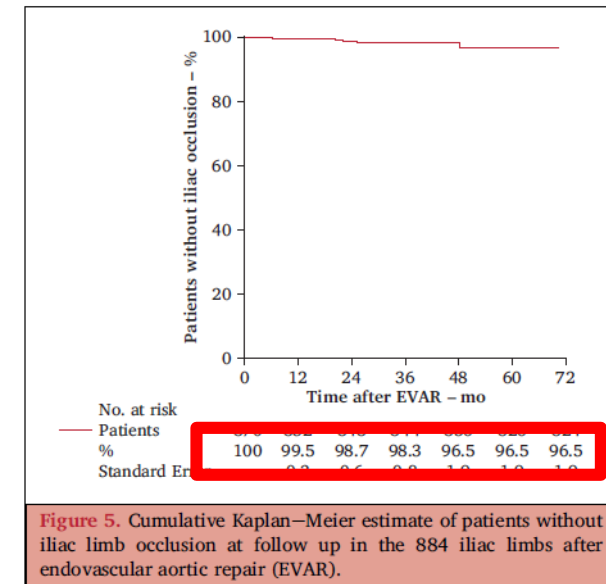
Vascular Surgery, Department of Experimental, Diagnostic and Specialty Medicine, University of Bologna, Policlinico Sant'Orsola-Malpighi, Bologna, Italy

## Results

- January 2012 - December 2017
- 442 pts, 884 iliac limbs treated
- Protocol of intraoperative iliac limb management

- for a stenosis morphologically >50% of the lumen of the CIA or EIA on the pre-operative CTA, a non-compliant balloon angioplasty of the stenosed vessel was performed before endograft implantation;
- the contralateral iliac limb was always deployed precisely at the level of the main body flow divider, even if the endograft IFU allowed its deployment more proximally;
- the implantation of the aortobi-iliac endograft was always performed over stiff guidewires; after the moulding ballooning of the proximal fixation of the endograft, a kissing non-compliant ballooning was performed at the level of the docking zone between the iliac limbs and the main body of the endograft;
- after the kissing ballooning of both iliac limbs, selective angiography with a floppy guidewire with different iliac axis angulations was performed. Both iliac limbs were ballooned along their entire length and, in case of flared iliac limb, the distal segment of the limb was dilated with a compliant balloon. For residual extrinsic compression of the iliac limb or kinking of the iliac endoprosthesis, a self expandable bare metal stent, such as Protégé or Everflex Medtronic, Luminexx Bard or Sinus Optimed, was deployed.<sup>13</sup>

- **30 days outcome:**
  - Perioperative mortality 1.6%
  - **ILO 0%**
- **Long-term outcome:**
  - Mean follow up 33± 12 months
  - **ILO: 0.8%**



# Zenith Alpha Abdominal

## *Bologna Experience*

- ✓ Study period: 2015 - 2022
- ✓ pts : 231
- ✓ Monocentric study
- ✓ Elective and urgent procedures
- ✓ Mean Follow-up: 33 + 24 months



# Zenith Alpha Abdominal

## *Bologna Experience*

### 30-day/in-hospital results

- ✓ Technical success: 98,7 % (228) of cases (228)
- ✓ Technical failure: 1,3% (3): 2 Endoleak type Ia; 1 Endoleak type Ib

Reinterventions: 8 (3.5 %) cases:

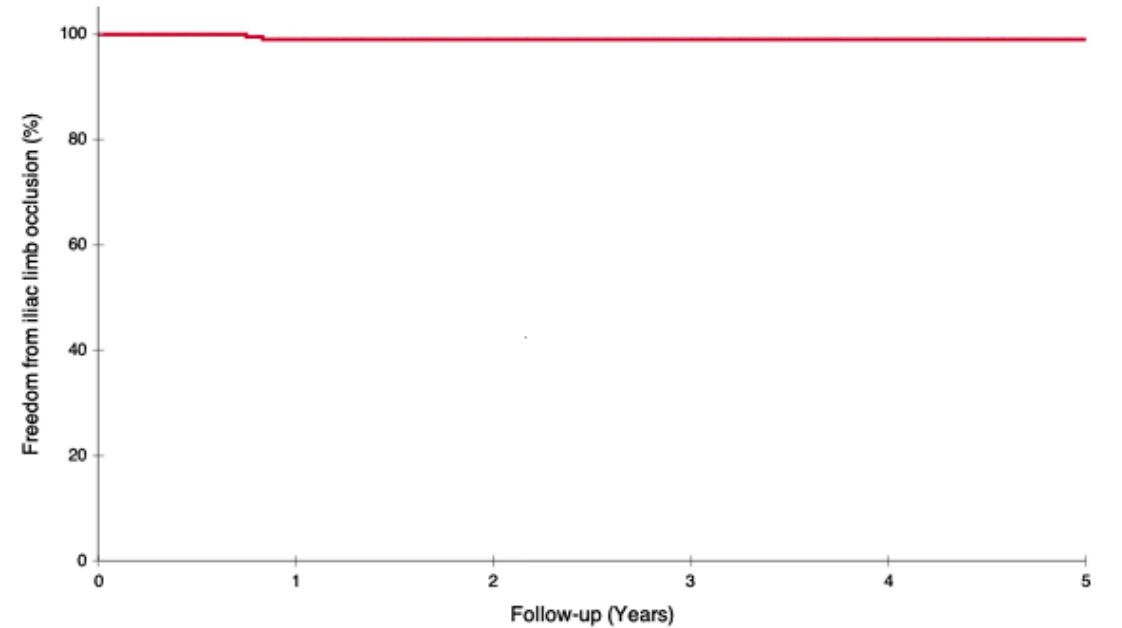
- 1 Endograft explantation due to Type Ia Endoleak;
- 2 Iliac leg relining due to a Type III Endoleak;
- 1 Iliac leg relining due to a Type Ib Endoleak;
- 2 Inguinal surgical debridement due to wound dehiscence;
- 1 Femoral artery patch angioplasty due to a femoral pseudoaneurysm;
- 1 Hemicolectomy due to acute bowel ischemia (embolization).



# Follow-up results: ILO

✓ Mean Follow-up: 33 + 24 months

- Iliac Limb Occlusion: 3 limbs (1,3%)
- Aortic Shrinkage: 52%



	0	1	2	3	4	5
Number at risk (n)	230	200	166	134	86	50
Estimate (%)	100	99	99	99	99	99
Standard error (%)	0	0.7	0.7	0.7	0.7	0.7

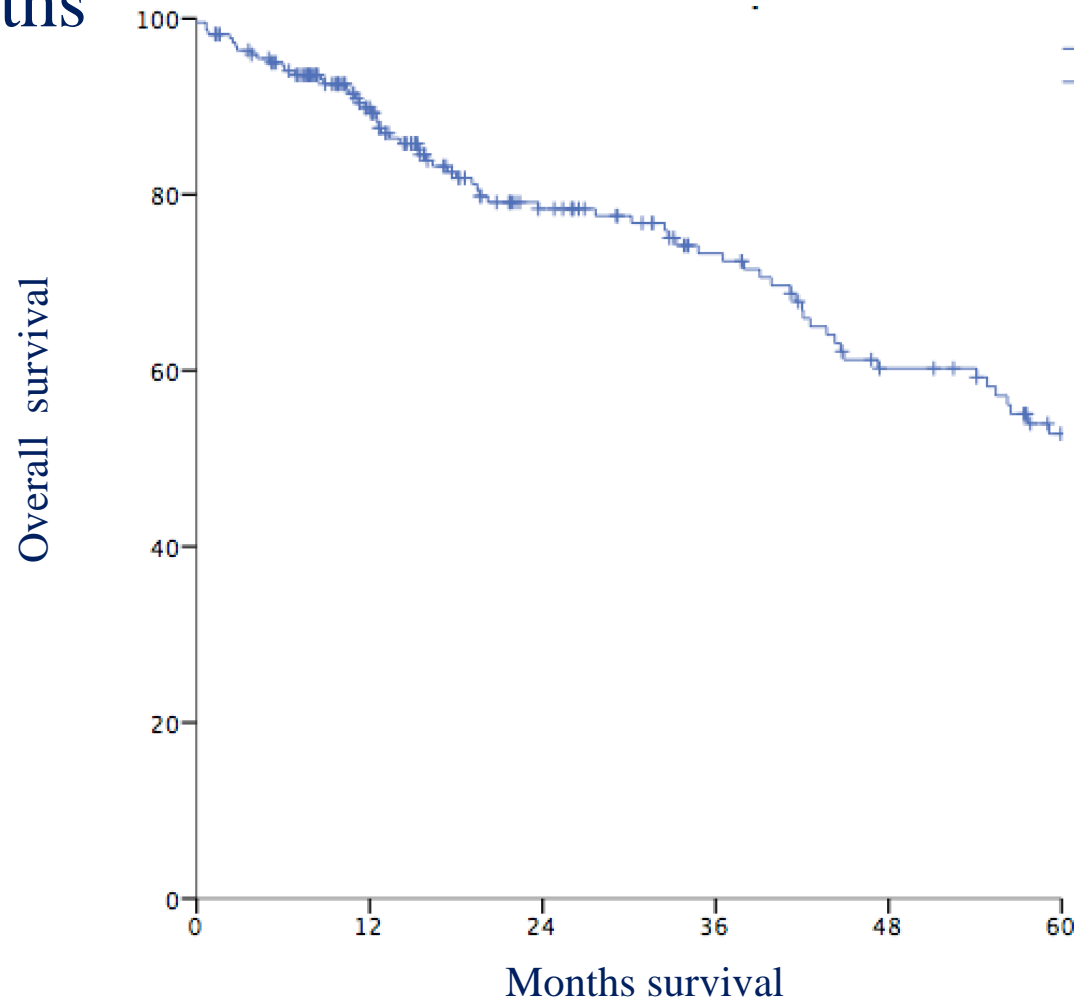


## Follow-up results: **Survival**

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✓ Mean Follow-up: 33 + 24 months

5-year Survival :  $53 \pm 4$  %

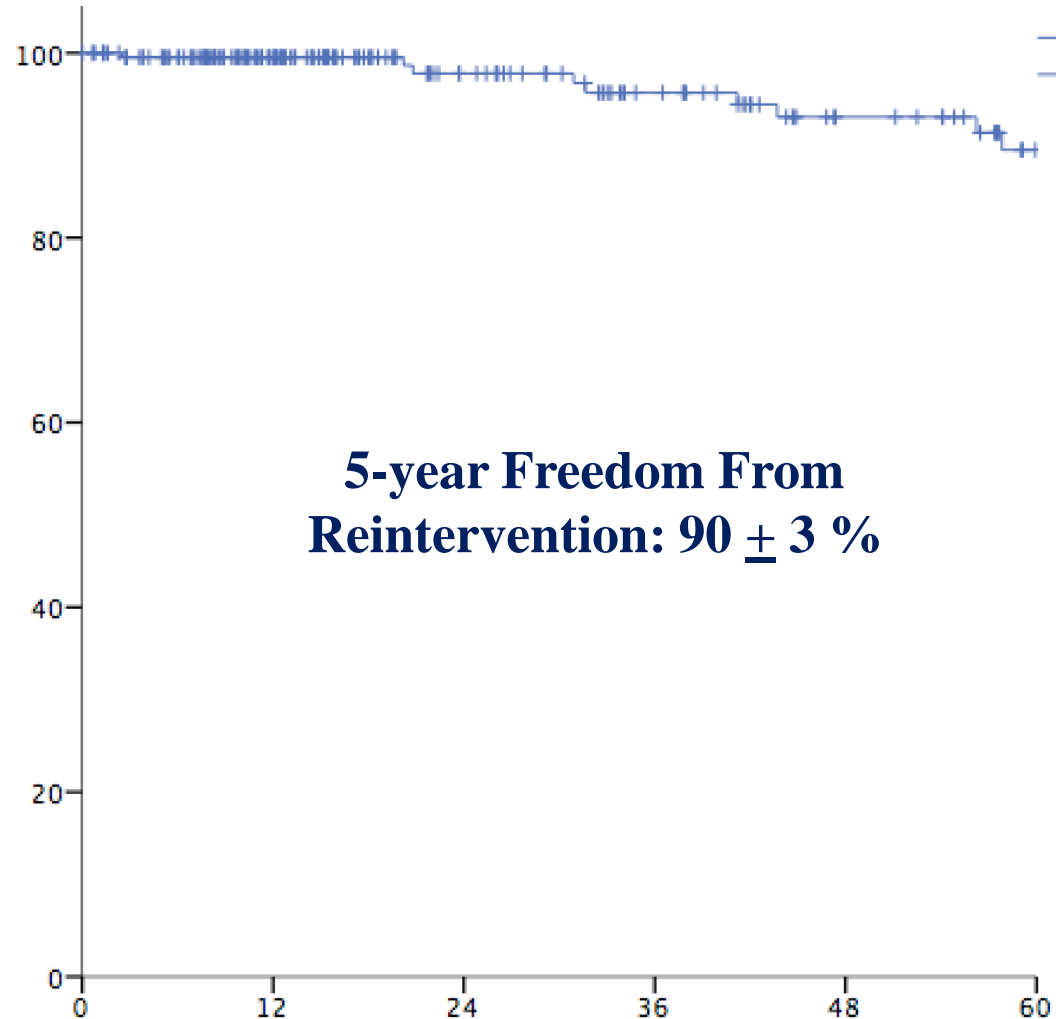




## Follow-up results: Reinterventions

13/231 - 5.6% reintervention during the follow-up

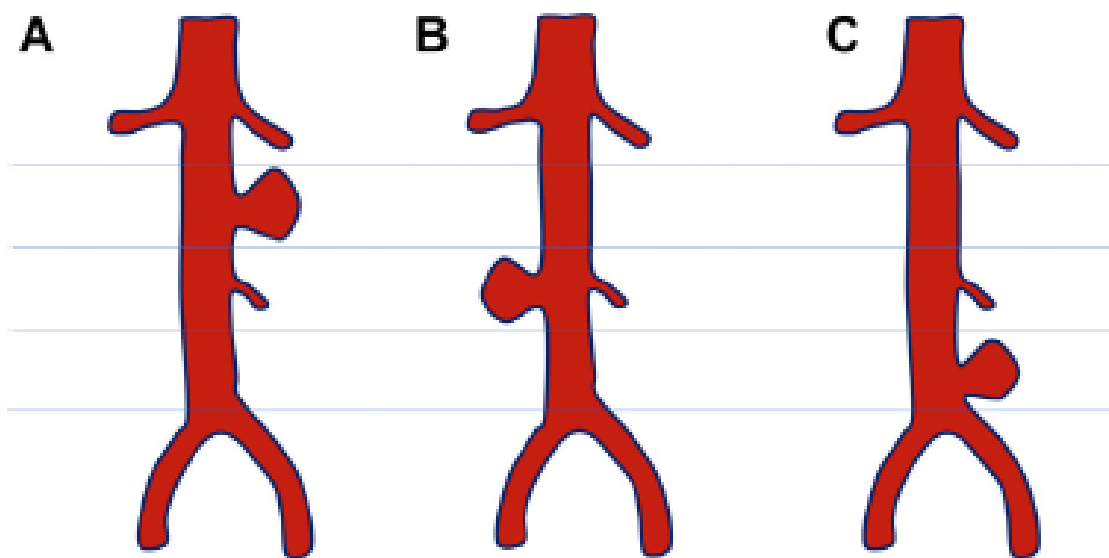
- 3 pts: type 1A endoleaks (surgical conversion)
- 2 pts: type 1B endoleak (iliac limb extension)
- 1 pt: type 3 endoleak (iliac limb relining)
- 3 pts: limb graft occlusion
- 3 pts : type 2 endoleaks (lumbar/sac embolization)
- 1 pt: groin revision



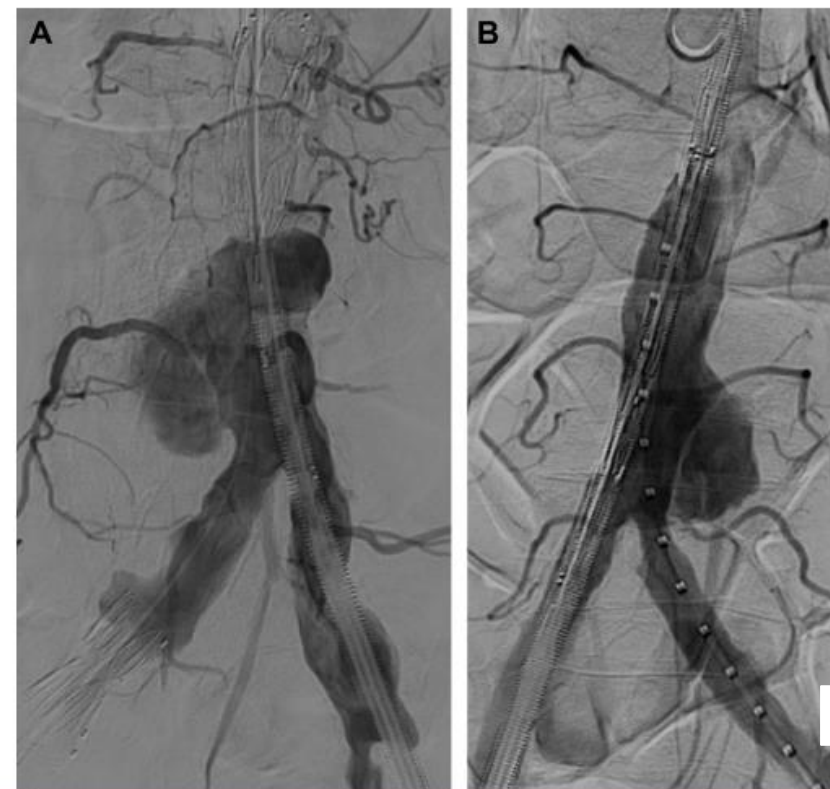
# Midterm results of complicated penetrating abdominal aortic ulcer treated by aortobi-iliac endograft and embolization

Enrico Gallitto, MD, PhD, Gianluca Faggioli, MD, Paolo Spath, MD, Stefano Ancetti, MD, Rodolfo Pini, MD, PhD, Antonino Loggiacco, MD, Sergio Palermo, MD, and Mauro Gargiulo, MD, *Bologna, Italy*

*J Vasc Surg* 2023;77:106-113



**Fig 2.** The infrarenal abdominal penetrating aortic ulcers (PAUs) were classified in type **A** (proximal infrarenal aorta), **B** (mid infrarenal aorta), or **C** (distal infrarenal aorta) according to its localization.



**Fig 1.** A and B, Angiographic images of contained aortic rupture associated with multiple patent afferent vessels.

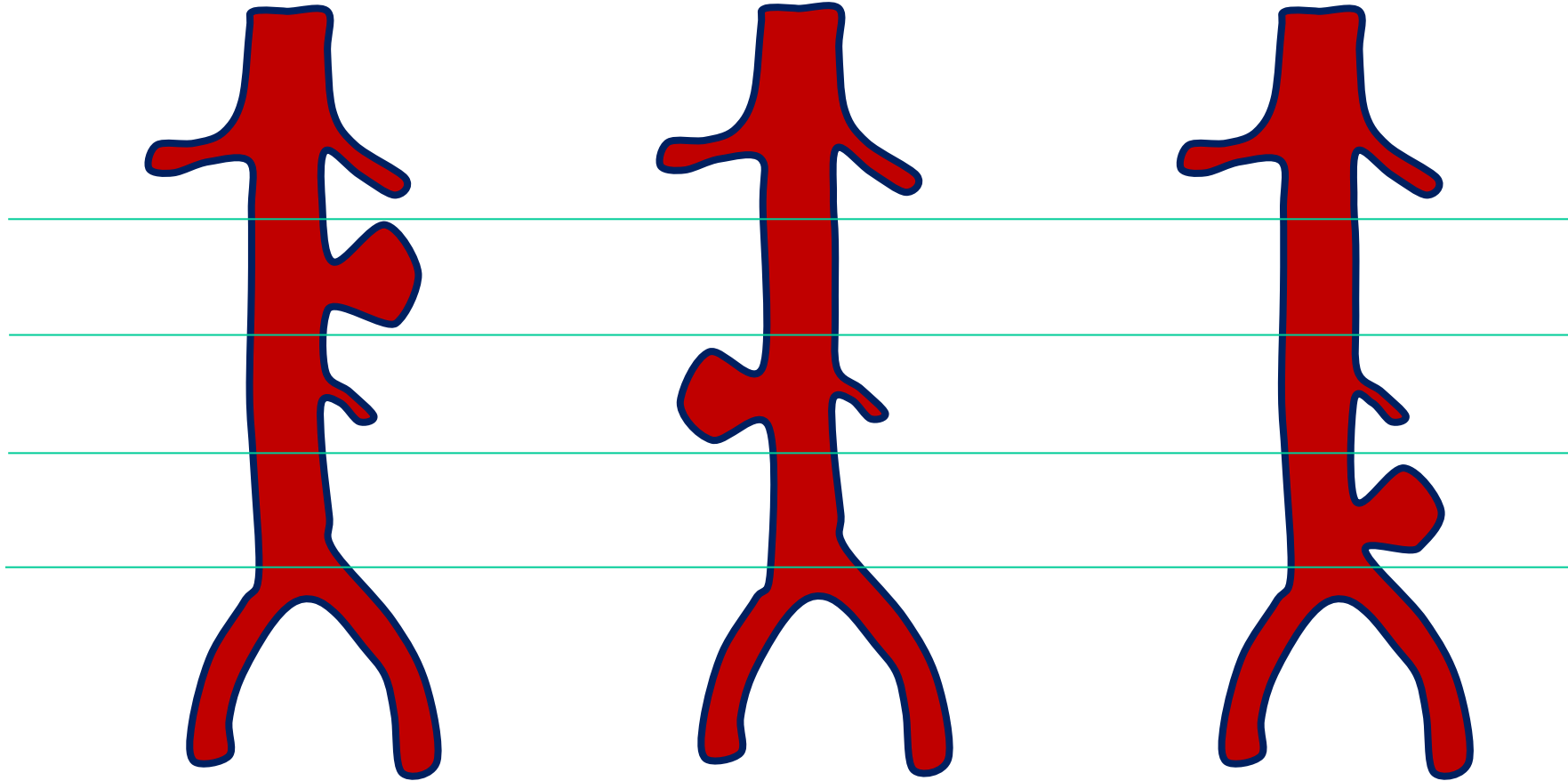
# Results

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- 45 pts
- Median maximum diameter at the level of PAU: 49 mm
- The median diameter of aortic bifurcation: 18 mm (IQR, 3 mm),
- Bilateral severe femoral or iliac access: 13 pts (29%)
- External iliac artery diameter of less than 7 mm: 7 pts (16%)



# Anatomical Details



**A** - 18%

**B** - 55%

**C** - 27%



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J Vasc Surg 2023;77:106-113

## Early Endpoints

@ 30-day	n	%
Technical Success	45	100
Morbidity		
Cardiac	1	2
Pulmonary	2	4
Renal	8	18
Reinterventions*	2	4
Mortality**	1	2

\*: femoral access related (Percutaneous 1; Surgical 1)

\*\* : Pulmonary complication in urgent patient with preoperative severe COPD



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J Vasc Surg 2023;77:106-113

## Follow up Endpoints

✓ Median: 24 (IQR:18) months

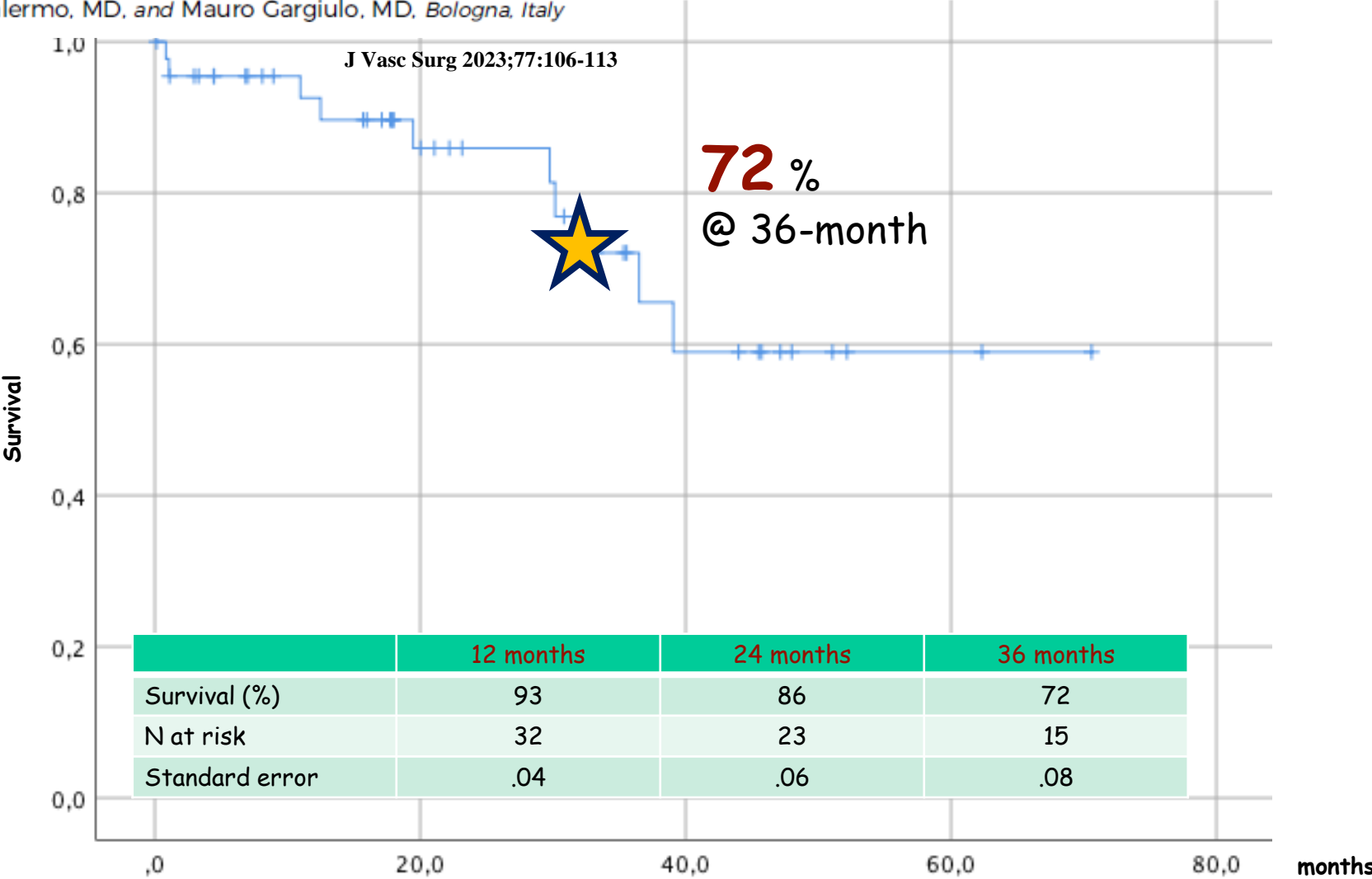
	n	%
EL I - III	0	-
Reinterventions	0	-
PAU enlargement	0	-
Infection	0	-
Iliac leg occlusion	0	-
PAU related mortality	0	-



# Midterm results of complicated penetrating abdominal aortic ulcer treated by aortobi-iliac endograft and embolization

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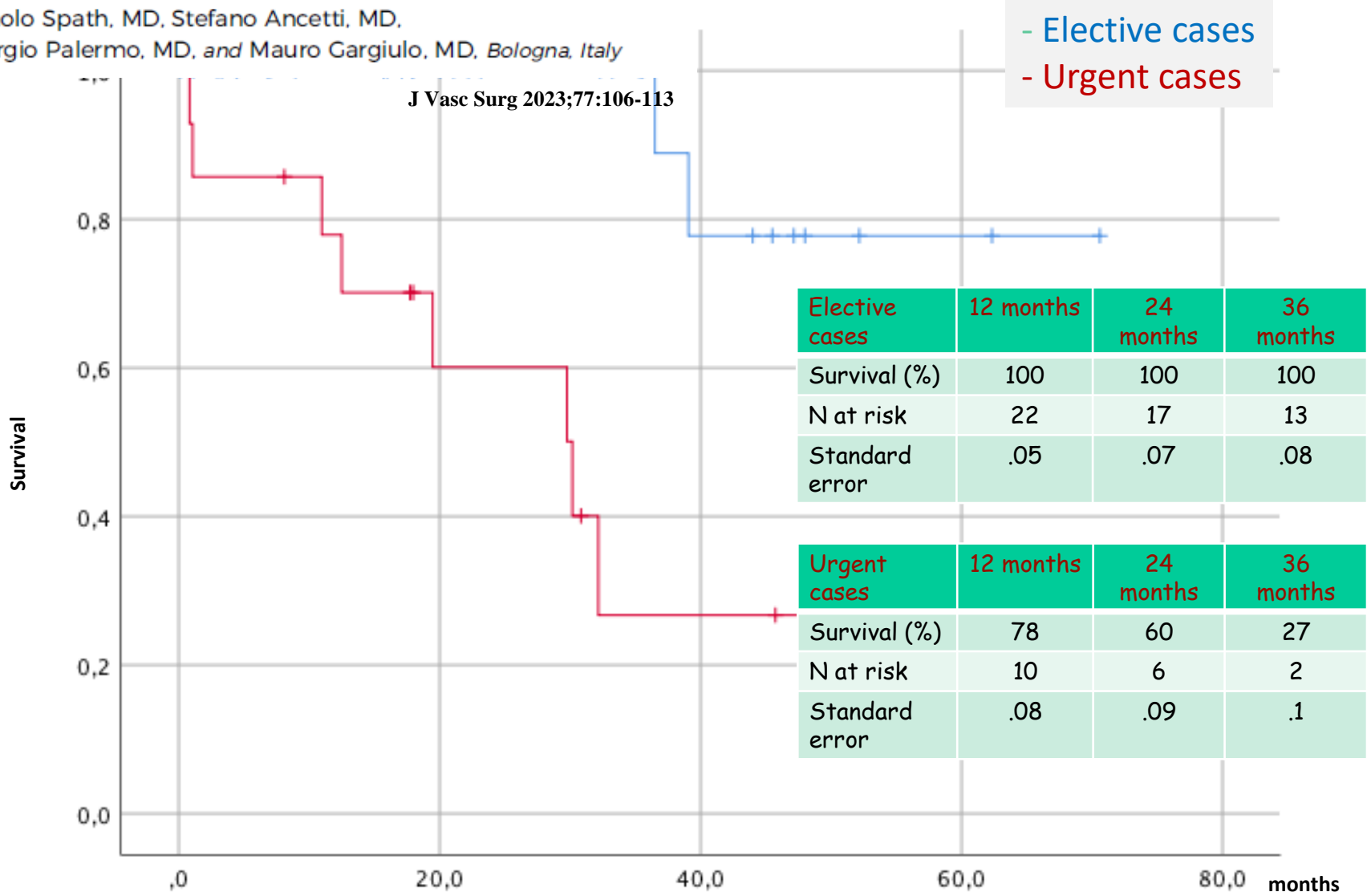
## Survival



# Midterm results of complicated penetrating abdominal aortic ulcer treated by aortobi-iliac endograft and embolization

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## Survival





### Low profile devices make it all much easier but are they durable?

- Yes
- This review shows that patients treated with low-profile stent grafts have acceptable mid and long-term outcomes.
- The design evolution toward low-profile platforms seems not to affect the type of complication during the follow-up.
- Long-term surveillance and reintervention, when necessary, remain crucial to guarantee durability.