

**Updated Results From The AFX 2-LIVE European Registry:
An Experience With The Outcomes Of >500 AFX EVAR Cases:
Benefits, Complications, Conversions And Technical Considerations**

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on behalf of the the AFX2-LIVE Collaborative Study Group

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Disclosures

Pasqualino Sirignano is consultant for

- Endologix
- Inspire MD
- Medtronic

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AFX 2 LIVE Registry

Unibody Endograft Using AFX 2 for Less Invasive and Faster Endovascular Aortic Repair: Protocol for a Multicenter Nonrandomized Study

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AFX 2 LIVE Registry

43 Italian and Spanish Centers

Enrolled 544pts

8 excluded because treated with a non-proprietary aortic extension, and 1 because of consent withdrawal

535pts analysed according to the protocol

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Baseline

87.1% AAA

	Mean±SD
Proximal Neck Diameter	21.8±3.6mm
Neck Length	33.6±15.9mm
Max AAA Diameter	46.4±13.1mm
Aortic Length	99.8±15.5mm

12.9% PAU & AD

20% patients had a narrowed bifurcation (<20mm)

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Procedural Details

- Elective Procedures 90.5%
- Total Percutaneous 52.3%
- Percutaneous + cutdown 36.6%
- Anaesthesia Local/Regional 71.6%

CM 76.8±48.9ml
→6 patients treated without CM

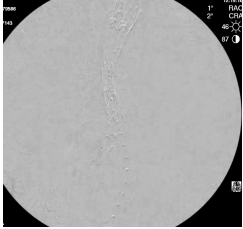
- Procedural Time 80.2±35.02min
- Proximal extension 48.0% (29.3% suprarenal)

Decrease of 6 ml CM for every additional 5 cases (coef 6.32, each 5 case-load decrease: 95%CI 1.3,65-9.81; p=0.001)

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Procedural Details



Planned Adjunctive procedures (39, 7.3%)

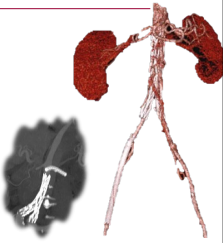
- 5 (0.9%) AAA sac embolization
- 9 (1.7%) feeding vessel embolization
- 19 (3.5%) monolateral iliac stenting
- 1 (0.2%) kissing stenting

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Immediate Results


Technical success 99.9%
1 Type1aEL → untreated

Primary technical success 97.7%
4 rescue chimney on renal artery
2 non Endologix proximal extension to treat Type1aEL
5 femoral cutdown for closure device failure



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@30-day Results

All enrolled patients completed the 30d FUP 

↓

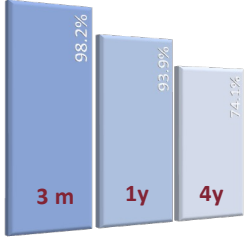
2 (0.4%) non-AAA related death
Acute myeloid leukemia, day 21
Cerebral hemorrhage, day 28

↓

9 (1.6%) reintervention
5 corrections for closure device failure,
3 embolectomies for ALI,
1 fibrinolysis+iliac stenting for thrombosis


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Clinical Success

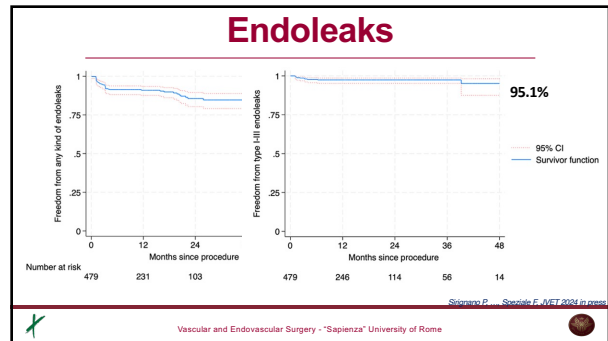
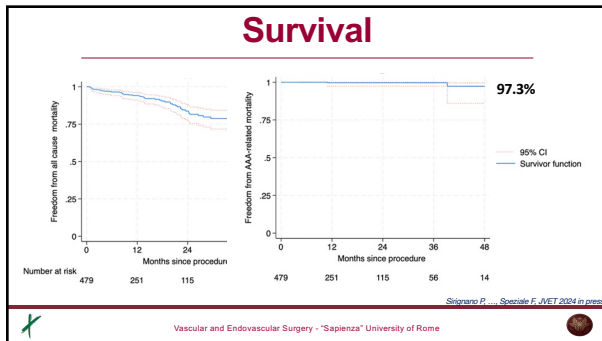


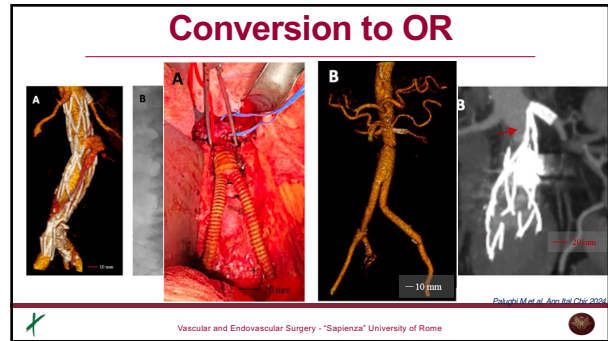
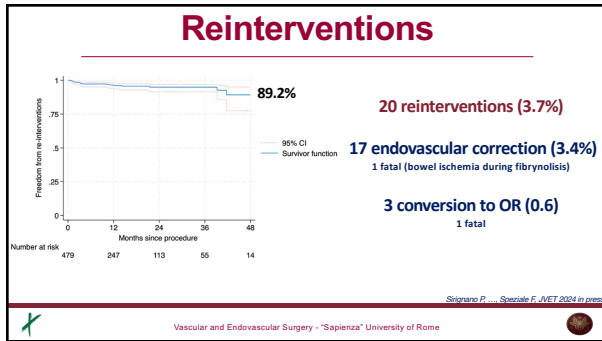
Mean follow-up 15.22±13.65

Data available for 479 patients (89.5%)



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Risk factor for procedural failure

	Univariable			Multivariable		
	HR	95% CI	p value	HR	95% CI	p value
Male Sex	0.71	0.25-2.02	0.5	-	-	-
Age at operation	1	0.96-1.04	0.6	-	-	-
BMI>30	0.88	0.37-2.11	0.7	-	-	-
ASA III and IV	0.92	0.56-1.51	0.7	-	-	-
General anesthesia	2.77	1.35-5.70	0.005	3.14	1.51-6.52	0.002
Center experience	1.23	1.01-1.51	0.038	1.22	1.00-1.49	0.05
Need for adjunctive procedures	2.53	1.27-5.06	0.008	2.96	1.46-6.03	0.003
Non-aneurysmatic disease	1.6	1.01-2.57	0.044	1.82	1.13-2.95	0.014

Schoenfeld residuals, global p=0.27

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Conclusions

- The AFX2-LIVE study demonstrated excellent clinical and technical success **up to 4-year FU**
- Center **experience** and adequate **indication** showed a great **influence on clinical success**
- **Limitations:** Non-comparative design, possible selection bias, short follow-up and heterogeneity limited the inference of data

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AXF2-LIVE Study Group

Infrarenal Aortic Treatment With AFX2 Endograft: Results From a Multicentric, International, Non-Randomized, Prospective Registry—the AFX2-LIVE Study

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