Slide 1

VEITH SYMPOSIUM
Connecting The Vascular Community

Real-world ten-year experience
with a low profile thoracic endograft

Germano Melissano
"Vita-Salute" San Raffaele University, Milan, Italy
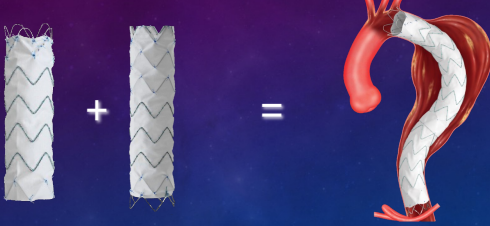
Slide 2

Disclosures

Speaker name: **Germano Melissano**

❑ I have the following potential conflicts of interest to report:

   ❑ Receipt of grants/research support

   ❑ Receipt of honoraria and travel support

   ❑ Participation in a company-sponsored speaker bureau

   ❑ Employment in industry

   ❑ Shareholder in a healthcare company
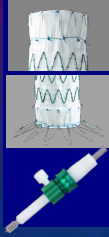
   ❑ Owner of a healthcare company

❑ I do not have any potential conflict of interest

Slide 3

2013 - ZENITH ALPHA: MODULAR DESIGN

Slide 4

DIFFERENCES BETWEEN TX2 AND ALPHA

1. Stainless steel -> Nitinol
2. No top bare stent -> bare stent
3. Dacron dense weave
4. Barbs location
5. Distal bare metal stent
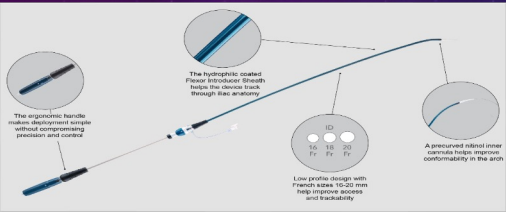6. Release trigger wires mechanism

TX2   Alpha

Slide 5

INTRODUCER FEATURES

The hydrophilic coated Flexor Introducer Sheath helps the device track through iliac anatomy

The ergonomic handle makes deployment simple without compromising precision and control

Low profile design with French sizes 16-20 mm help improve access and trackability

A precurved nitinol inner cannula helps improve conformability in the arch

16 Fr 18 Fr 20 Fr

Slide 6

INITIAL CLINICAL EXPERIENCE

Vascular Surgery

Initial clinical experience with a new low-profile thoracic endograft

Germano Melissano, MD, Yamume Tshomba, MD, Enrico Rinaldi, MD, and Roberto Chiesa, MD, Milan, Italy

November 2013 → October 2014

• 42 procedures

MID-TERM CLINICAL EXPERIENCE

Single-center mid-term results with the low profile Zenith Alpha Thoracic Endovascular stent-graft

Germano Melissano, MD, Enrico Rinaldi, MD, Daniele Mascia, MD, Niccolò Carta, MD, Victor Bilman, MD, Luca Bertoglio, MD, Andrea Kahlberg, MD, Monica De Luca, MD, Fabrizio Monaco, MD, Roberto Chiesa, MD
Milan, Italy

November 2013 → December 2019

• 270 procedures

Melissano G. et. al. J Vasc Surg 2021

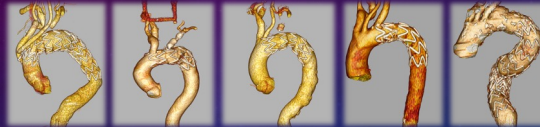## FIRST DECADE RESULTS

November 2013 → November 2023

• 463 procedures

• 455 patients

INDICATIONS

	N	(%)
TAA	138	(29.8)
Aortic Arch	77	(16.6)
TAAA (1 st step of F/B- EVAR)	123	(26.6)
Redo	48	(10.4)
Type B aortic dissection	37	(8.0)
PAU / IMH	24	(5.2)
Emergency	16	(3.5)
Total	463	(100.0)

STENT-GRAFT DELIVERY
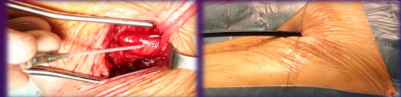
	Zone 0 N (%)	Zone 1 N (%)	Zone 2 N (%)	Zone 3 N (%)	Zone 4 N (%)
N (%)	23 (5.0)	22 (4.8)	151 (32.6)	184 (39.7)	83 (17.9)

Proximal deployment in the intended position in 99.8 %

STENT-GRAFT ARRANGEMENT IN 463 PROCEDURES

| 538 ZTA	N	(%)
Single proximal component	340	(63.2)
Two or more proximal components	141	(26.2)
One or more proximal components + distal component	39	(7.2)
Single distal component	18	(3.3)
Mean stent-graft / procedure		1.2

FEMORAL ARTERY ACCESS

Period	Surgical N(%)	Percutaneous N(%)	Total
2013-2015	82 (100)	0 (0)	82
2016-2019	30 (16.0)	158 (84.0)	188
2020-2023	3 (1.6)	190 (98.4)	193
Total	115 (24.8)	348 (75.2)	463

8 (1.7%) groin surgical conversions after percutaneous approach

ANCILLARY PROCEDURES

- Iliac a. PTA-stenting before TEVAR: 11 pts (2.4 %)

- Brachio-femoral wire: 18 pts (3.9 %)

- Iliac a. PTA-stenting after TEVAR : 17 pts (3.7 %)

- TEVAR advanced in a introducer: 4 pts (0.9 %)

Stent-grafts were introduced and released from the intended common femoral access in 99.8 % of cases
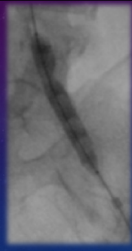
LOW-PROFILE ADVANTAGES

4 pts were treated with Zenith Alpha Thoracic after previous failed attempt with other thoracic stent graft

ANESTHESIOLOGIC MANAGEMENT

- General anaesthesia: 252 pts (54.4 %)

- Local anaesthesia: 211 pts (45.6 %)

- 73 (15.8 %) patients were admitted to the ICU after surgery

ZENITH ALPHA THORACIC IN 37 TBD

- 14 acute / subacute TBD*
- 23 chronic (9 with candy plug)

- Low radial force proximal bare stent
- High conformability
- One case of retrograde dissection (subacute)

* Off-label

30-DAY RESULTS – MAJOR OUTCOMES

Procedures: 463	N	(%)
Technical success	455	(98.3)
Clinical success	425	(91.8)
Mortality*	18 *	(3.9)*
Type IA Endoleaks	5	(1.1)
Type IB Endoleaks**	3 (/340)**	(0.9)**

* 11 pts. treated in urgent/emergent settings
** 123 first steps for F/B-EVAR not included

30-DAY RESULTS – SECONDARY OUTCOMES

Procedures: 463	N	(%)
Type II Endoleaks	8	(1.7)
AKI with dyalisis	2	(0.4)
Major stroke	7	(1.5)
Any SCI	16	(3.5)
Permanent SCI	3	(0.6)

FOLLOW-UP: 62.3 MONTHS (RANGE: 5-120)*

- 407 pts available at FU
- No stent fracture
- 1 new onset type IA
- 2 new onset type IB
- 1 stent-graft migration
- No intra-graft thrombosis

*Data under second revision

FOLLOW-UP: 62.3 MONTHS (RANGE: 5-120)*

- 31 deaths at FU, 3 aortic related**
- 1 open conversion with FET for persistent Type IA EL
- 2 TAAA open conversions for distal progression of disease
- 14 secondary unplanned endovascular procedures

*Data under second revision
* 3 Aortic rupture (2 Type II EL, 1 Type III EL)

CONCLUSIONS

- Zenith Alpha allowed extended indications and a safe navigation also through calcified and tortuous vessels
- It retained the precision and control of previous generation device with high conformability in a "real world" scenario
- Satisfactory long-term follow-up were obtained

DECEMBER 11th - 13th, 2024: SAVE THE DATE

I.R.C.C.S. Ospedale San Raffaele

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