

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE  
CONTROVERSIES & UPDATES  
IN VASCULAR SURGERY



JANUARY 23-25 2014

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER PARIS, FRANCE

# Low profile TEVAR: is it an added value?

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[www.cacvs.org](http://www.cacvs.org)



## Disclosure

Speaker name:

.....Michel Bosiers.....

- ☐ I have the following potential conflicts of interest to report:
- ☐ Consulting
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☒ I do not have any potential conflict of interest

# Reason for unsuitability

- Access issues: 20-30% -



# Size of introduction system for current thoracic devices is 20-25 French

Company	Device	Metal	Covering	Tapered	Free flow	Outer diameter of delivery system (Fr)
Medtronic	Valiant	Nitinol	Polyester	Yes	Proximal	20 – 25
Gore	TAG	Nitinol	ePTFE	No	No	NA*
Cook	ZenithTX 2	Stainless steel	Polyester	Yes	Distal	23 - 25
Duke Vascular	TAArget	Nitinol	ePTFE	Yes	Proximal	22 - 24
Jotec	Evita	Nitinol	Polyester	Yes	Prox-Distal	20 - 24
Bolton	Relay	Nitinol	Polyester	Yes	Proximal	22 - 25

\*18 – 24 ID; Sheath required.





# Zenith Alpha

## Low Profile TAA Endovascular Graft

Zenith Alpha was designed to:

- Address vascular access issues associated with larger profile devices
- Enable magnetic resonance compatibility
- Improve conformability in tortuous anatomy
- Increase TEVAR applicability

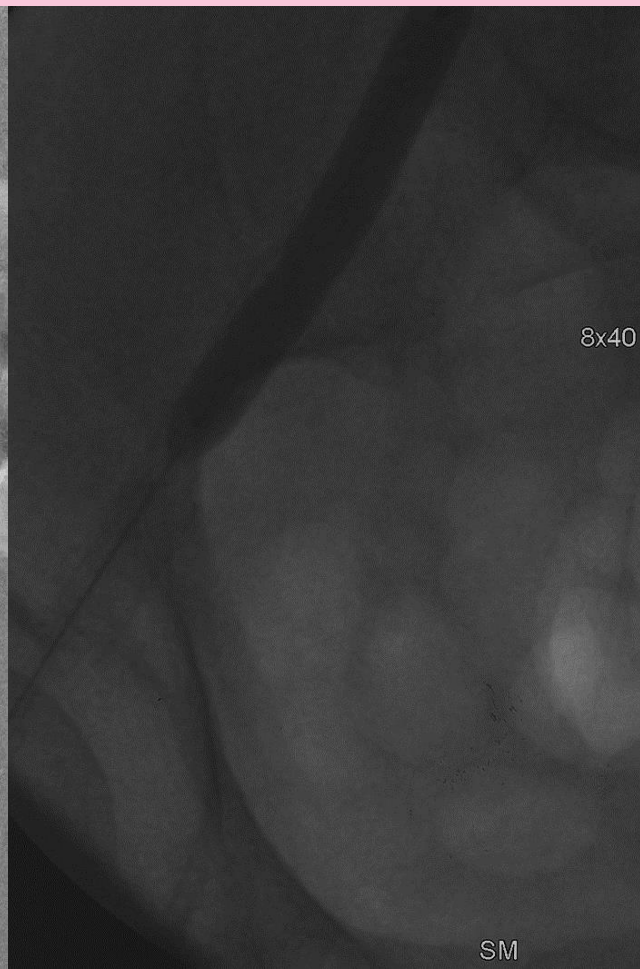
# Comparison to Zenith® TX2

Zenith TX2® TAA Endovascular Graft	Zenith® TX2® Low Profile TAA Endovascular Graft
Stainless steel Z-stents	Nitinol Z-stents
Standard Dacron	Thinner, more tightly woven Dacron
Covered proximal stent	Bare rounded proximal stent
20-24 Fr Z-Trak Plus® Introduction System	16-20 Fr Z-Trak Plus® Introduction System
22-42 mm diameter devices	18-46 mm diameter devices
-	MR compatible



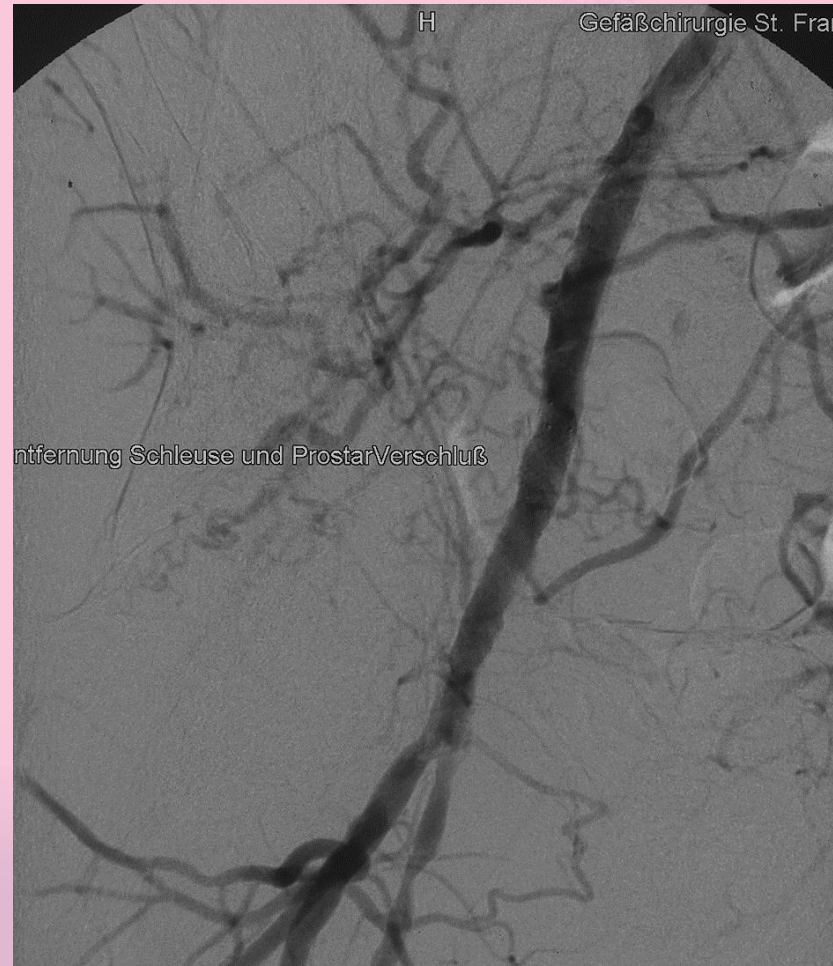
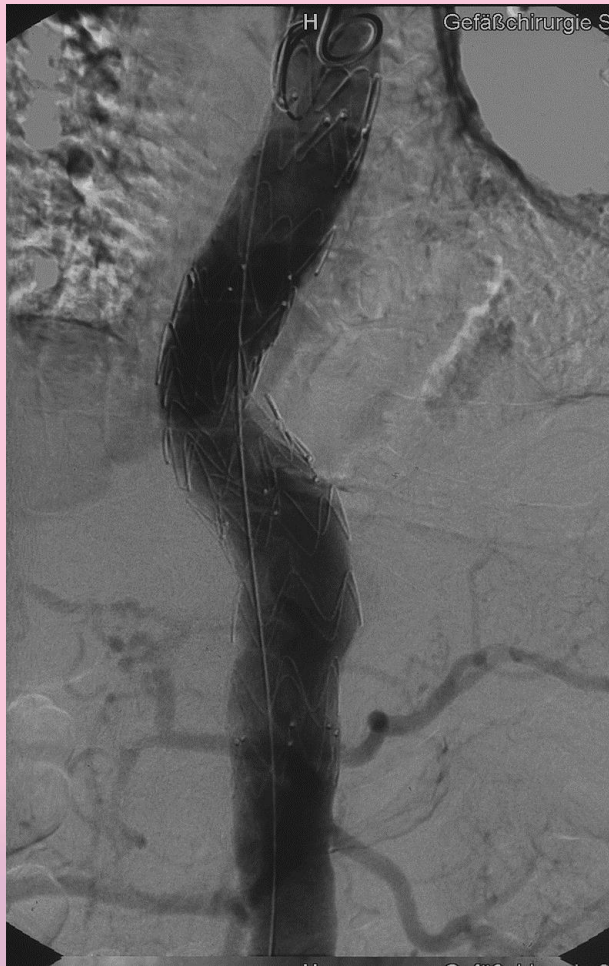
# TEVAR attempted with other graft

Stenosis of the right iliac /wound problem left groin





# Angiography after TEVAR and PTA of the right iliac artery



WHL30127/11/470 255

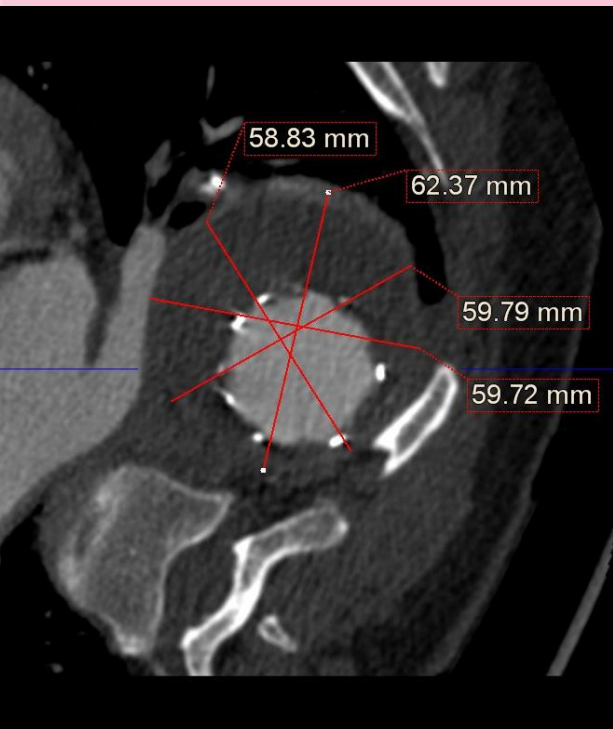
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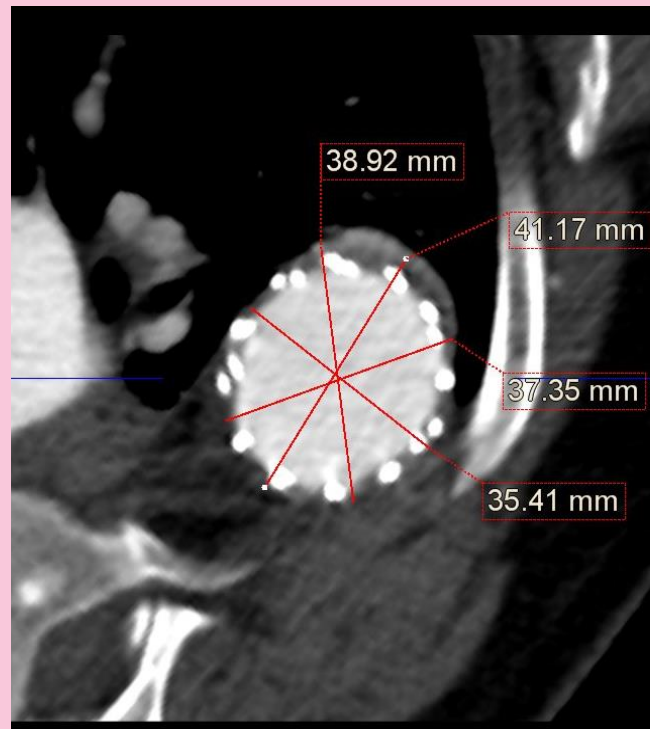
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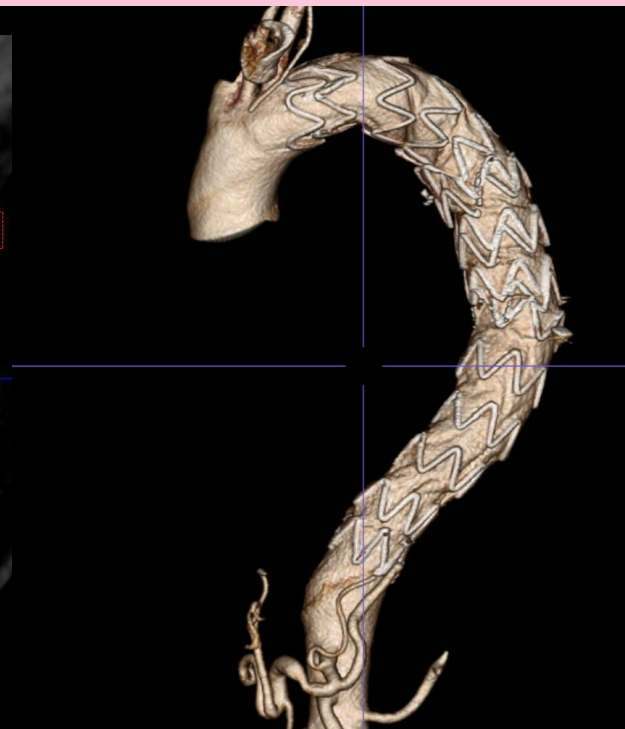
# Aneurysm Exclusion with TX2-LP



1-month CT

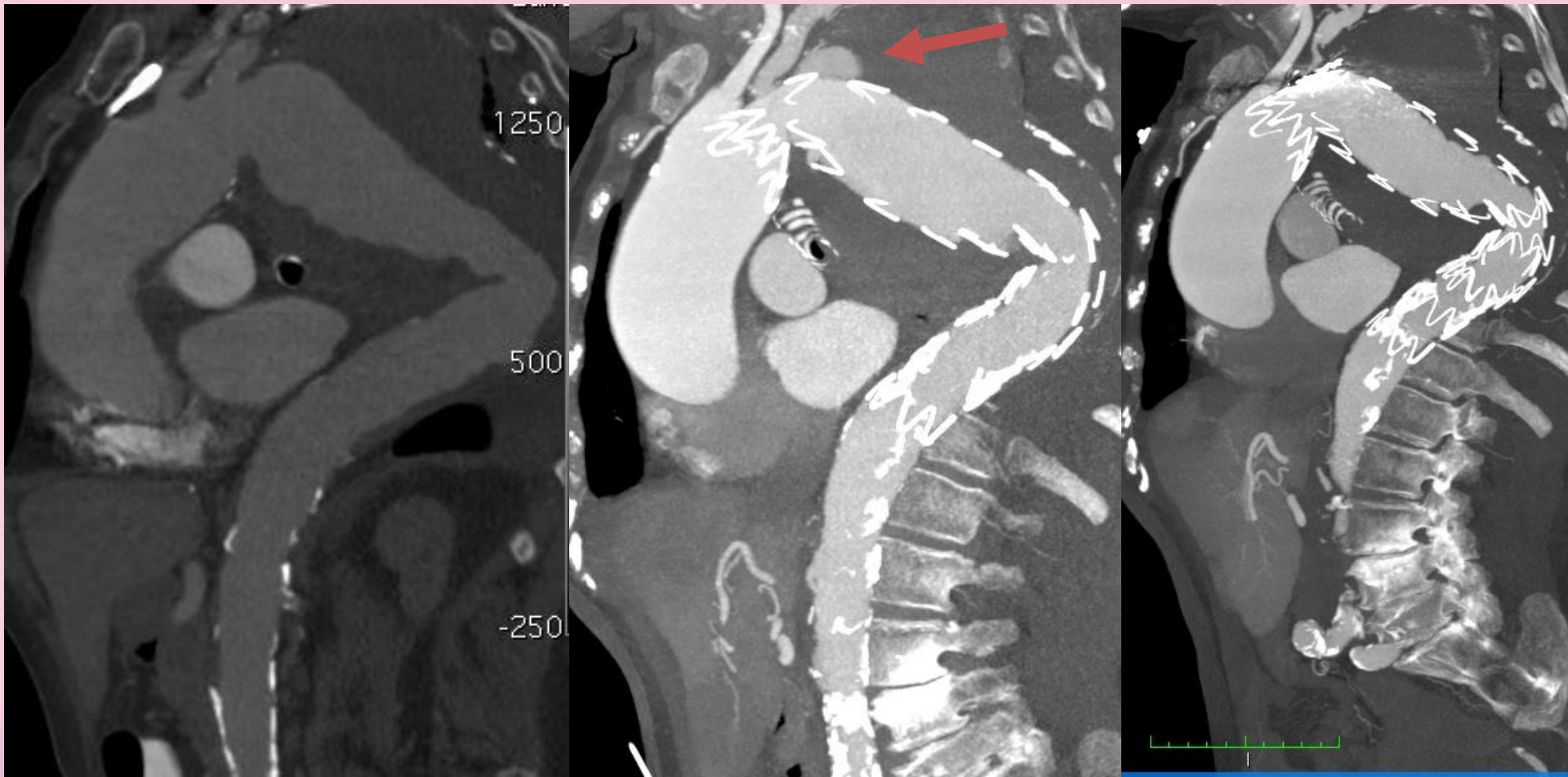


24-month CT





# Type I endoleak after treatment of ruptured TAA with Zenith Alpha





# Videoscopic view of the Zenith LP Endograft after coil embolization



# Study Overview

- Prospective, non-randomized, multicenter study in Europe, Japan, and the U.S.
- Target enrollment of 110 patients was completed in January 2013
- Patients will be followed for 5 years
- Results up to 1 year for the first 35 patients are presented

# Demographics

Result (n = 35)	
Age (years)	71 ± 11 (42-87)
Gender	
Male	57% (20/35)
Female	43% (15/35)
Ethnicity	
Asian	31% (11/35)
Black/African-American	9% (3/35)
White/Caucasian	60% (21/35)

43% female patients compared to 27% in the Zenith TX2 pivotal study (Matsumura et al. J Vasc Surg 2008;47:247-57)

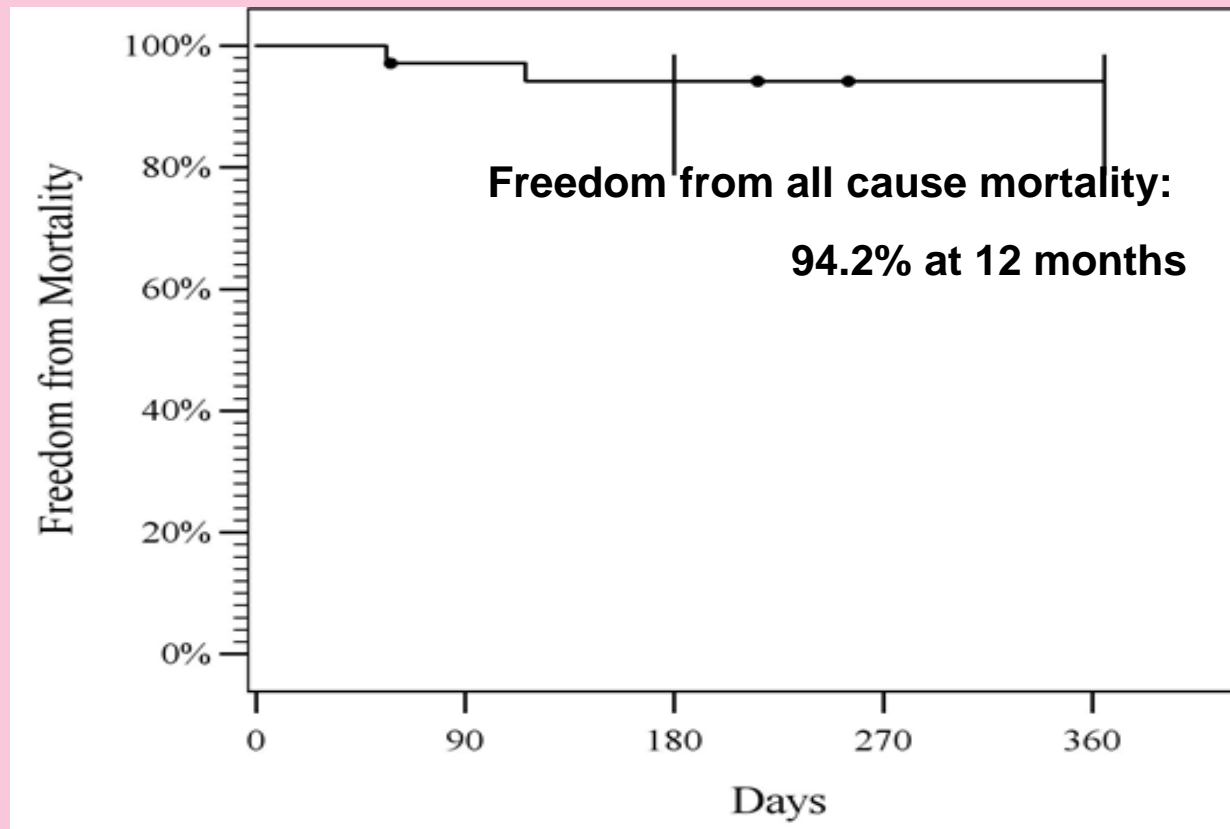
# Procedural Measures

Access method for TX2-LP	
Percutaneous	31% (11/35)
Cutdown	69% (24/35)
Procedure time (min) (n = 35)	97 ± 63
Anesthesia time (min) (n = 35)	167 ± 78

31% of patients had percutaneous access, compared to 2.5% in the Zenith TX2 pivotal study (J VS 2008)



# Mortality



# Preliminary Outcomes

Item	12-month
Rupture	0
Conversion to open repair	0
Paraplegia	0
Paraparesis	0
Stent fracture*	0
Barb separation*	0
Migration*	0

\*Based on core lab analysis

# 1-year outcomes

- Distal type I endoleak: 2 patients
  - aneurysm size decreased or stable
  - no treatment performed to date
- Aneurysm size decreased or stayed stable in most patients evaluated
  - Aneurysm growth in 1 patient at 12 months
    - no observed endoleak
    - secondary intervention with distal extension

# Summary

- Preliminary device performance is promising
  - No TAA-related mortality, rupture, or conversion
  - No paraplegia or paraparesis
  - One secondary intervention to date
  - No device migration or integrity issues
- Results indicate expanded applicability with increased female population
- Follow-up is ongoing



# MCQ

Do you think LP will decrease the durability?

A: yes

B: no

C: no idea





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homepage: [www.gefaesschirurgie-muenster.de](http://www.gefaesschirurgie-muenster.de)

# Thank you !



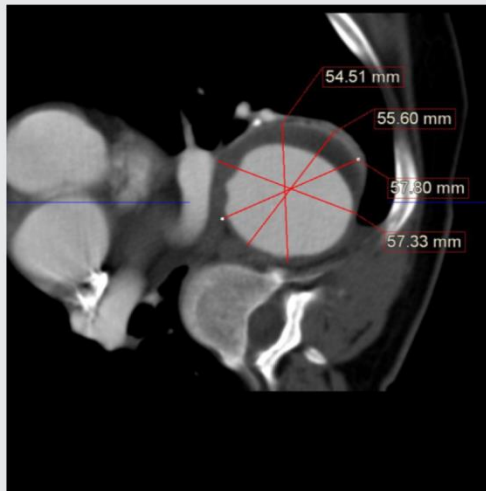
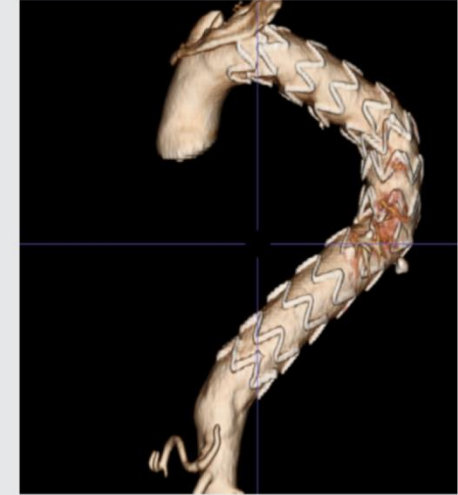
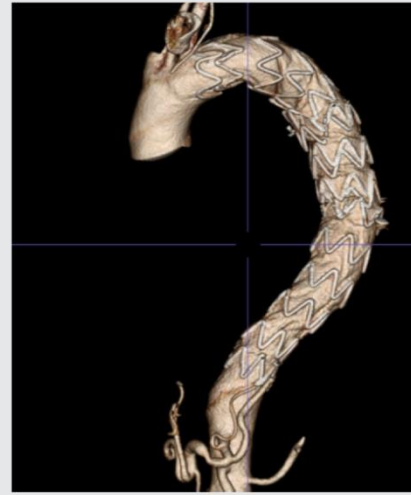
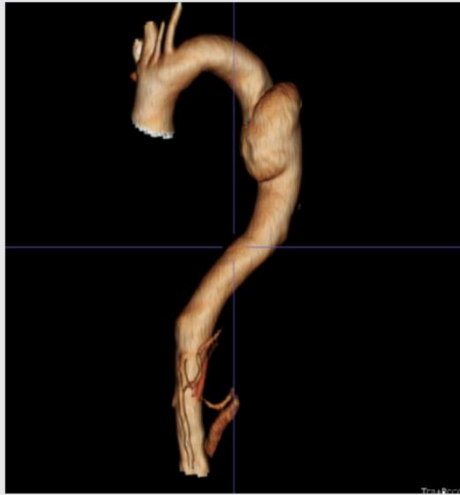
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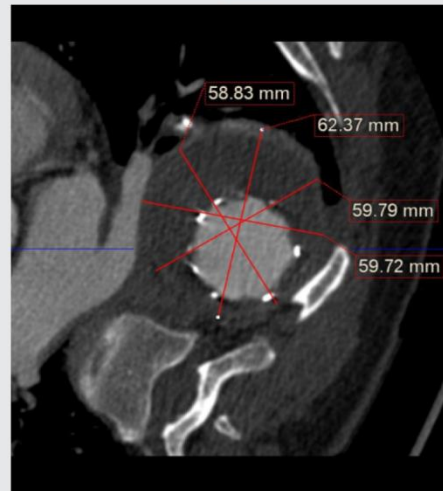
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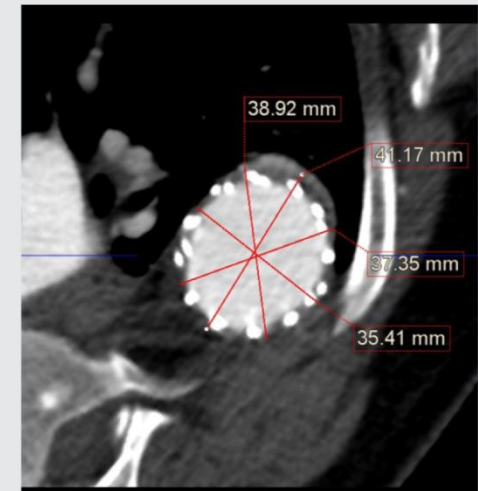
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Pre-procedure CT



1-month CT



24-month CT

Maximum aneurysm size decreased from 62 mm at 1 month to 41 mm at 24 months. [www.vvs.org](http://www.vvs.org)