



Valiant Navion: what have we learned about this next Generation TEVAR device: 1-year results from the global clinical trial and new morphometry insights

Prof. Fabio Verzini

Associate Professor of Vascular Surgery

Department of Surgical Sciences

University of Turin, Italy

Disclosure

Speaker name:

.....Verzini.....

I have the following potential conflicts of interest to report:

- Consulting for Medtronic,
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

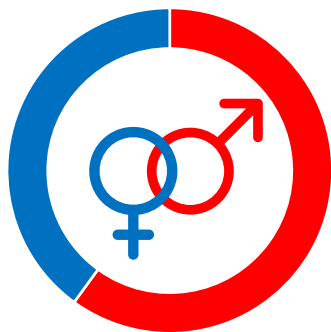
Valiant Navion Clinical Trial

- Prospective, multi-center, single-arm trials in North America & EU
- 100 subjects enrolled from 2016-2018
- 47% from 15 OUS centers
- 53% from 18 US centers



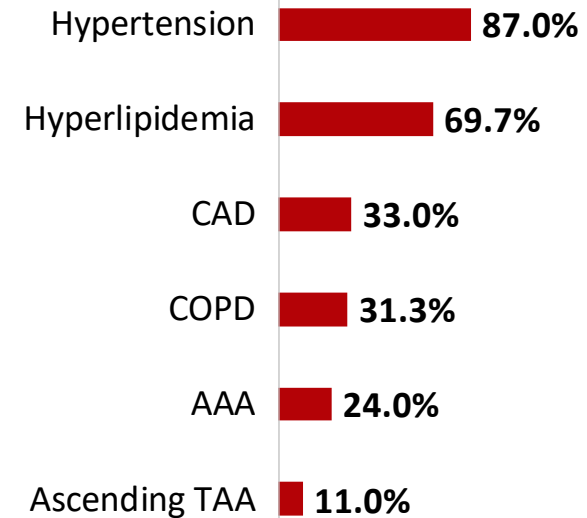
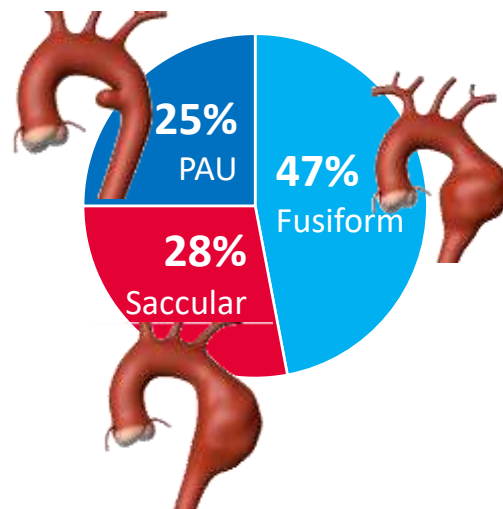
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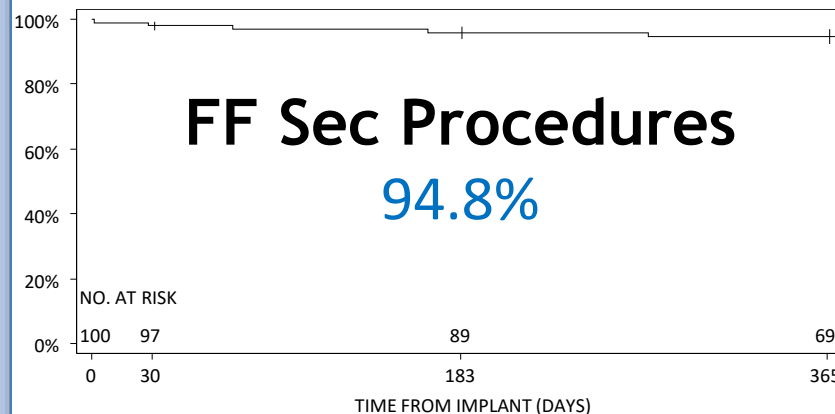
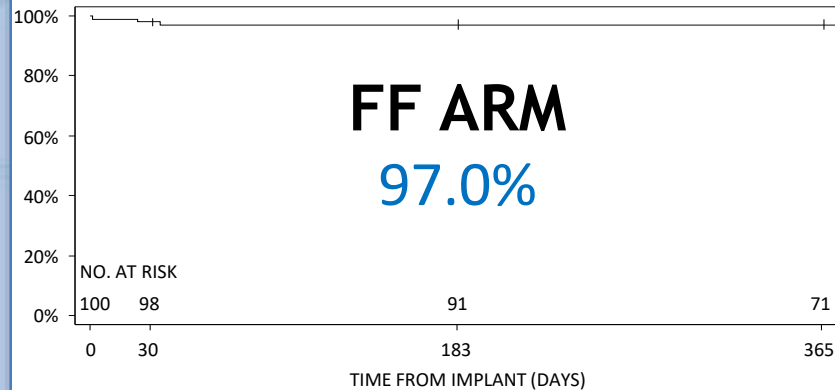
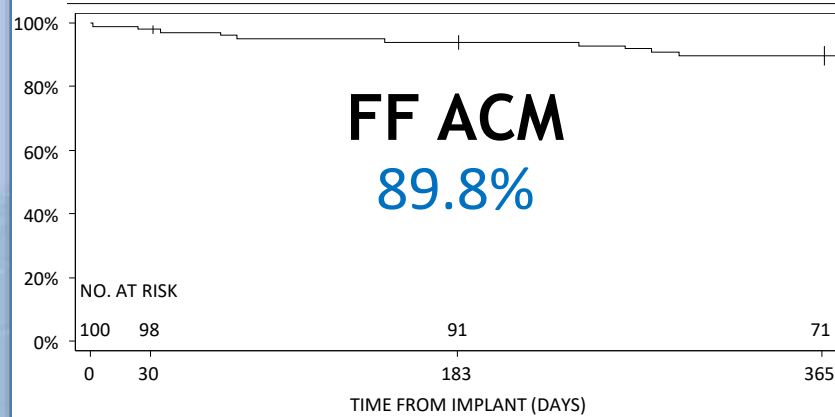


40% Female

70.8 ± 8.9 yrs old



One Year Trial Outcomes

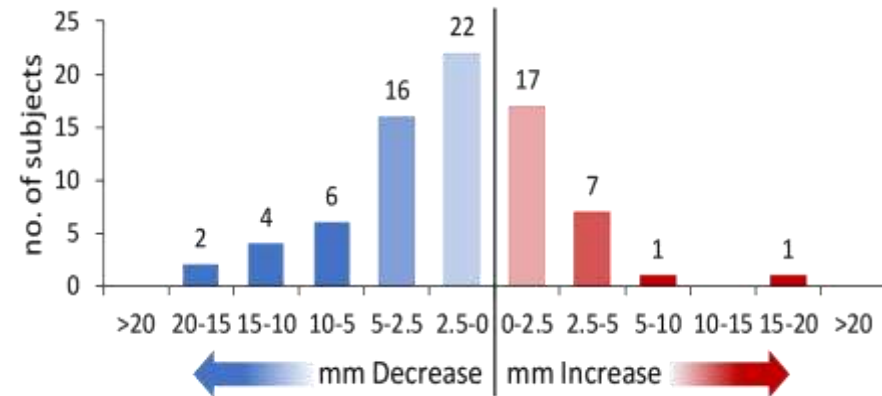


FF Type I EL **94.4%**

FF Type Ia EL **97.6%**

FF Type II EL **95.4%**

Increase: 2.6% (2/76) increase
Stable: 81.6% (62/76) stable
Decrease: 15.8% (12/76) decrease



Thoracic Aorta Morphometry

01

Pre-procedural to one month

Effect of the stent graft
implantation on native anatomy

02

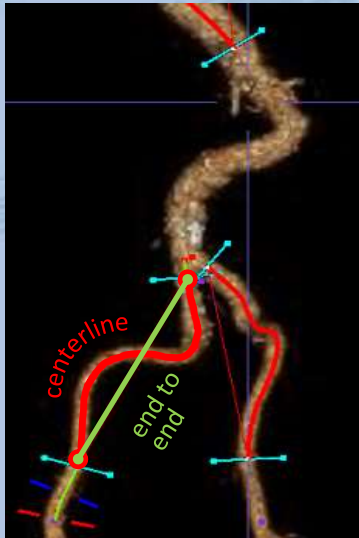
One month to one year

One-year changes in
morphology and effects on stent
graft



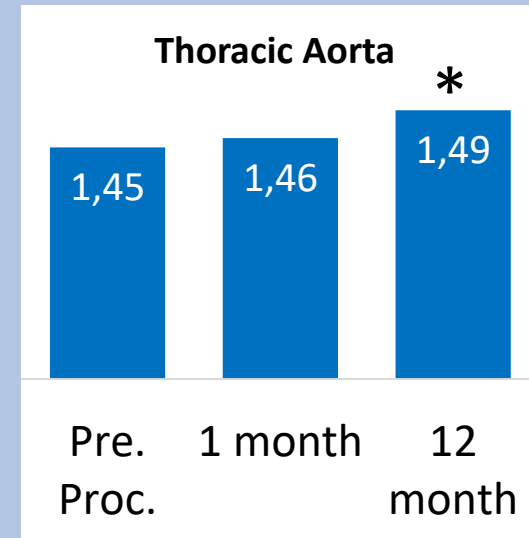
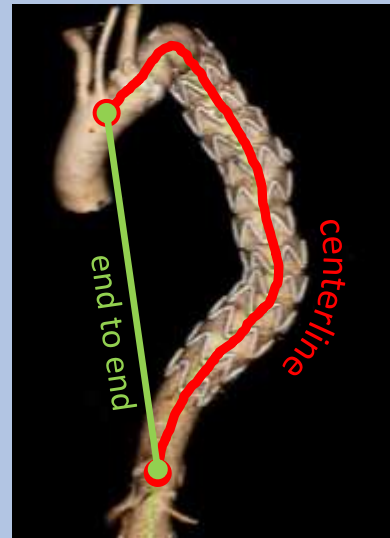
Effect of Stent Graft on Native Anatomy

$$\text{Tortuosity} = \frac{\text{centerline length}}{\text{end to end length}}$$



73.7% severe access artery tortuosity

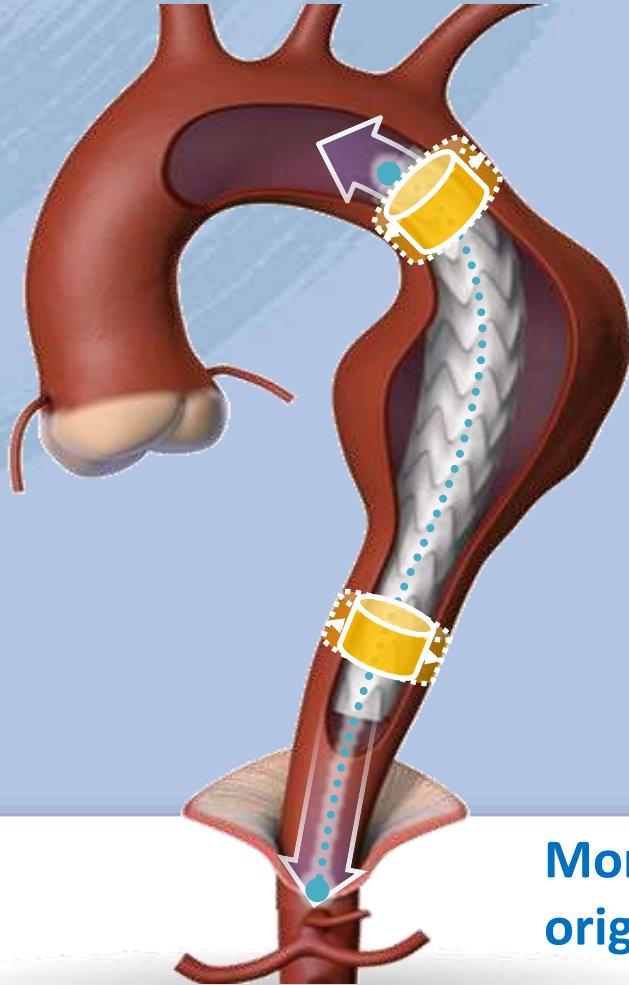
100% success in advancing and deploying graft



Stent graft conforms to the native anatomy during implant and did not inhibit natural tortuosity changes at 1yr

* indicates p<0.05 compared to tortuosity measurement at prior follow up

Morphological Changes at One Year



Aortic Elongation

- LSA to celiac: 272.6 to 279.8mm (+2.6%)
- LCC to proximal fabric: 57.4 to 58.6mm (+2.1%)
- Distal fabric to celiac: 72.4 to 76.6mm (+5.5%)

Aortic Dilation

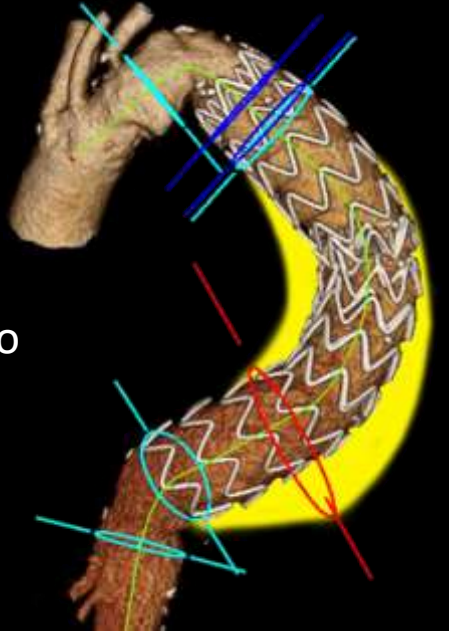
- Proximal attachment zone (+1.5mm, 4.8%)
- Distal attachment zone (+2.8mm, 8.5%)

Morphological changes could potentially compromise original seal zones particularly at the distal end

Valiant Navion Clinical Trial - Patient Case

One Month

Short proximal seal zone and no distal seal



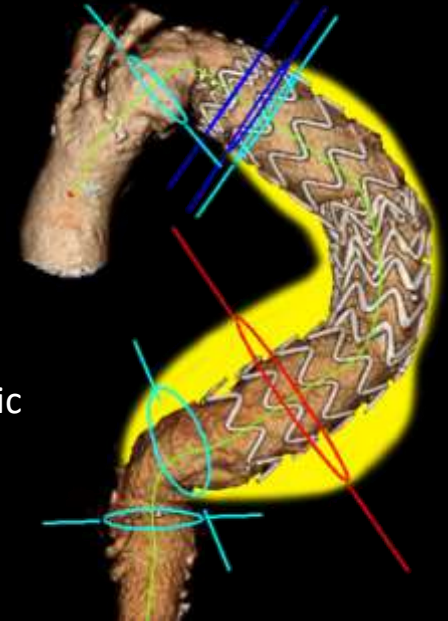
One Year

Day 379

- Type IB endoleak
- 16.9mm sac increase

Day 448

- Valiant Captivia, abdominal aortic coils, Jotec stent in SMA
- EL resolved at end of secondary procedures



One Year Navion Trial Conclusions

Positive patient outcomes

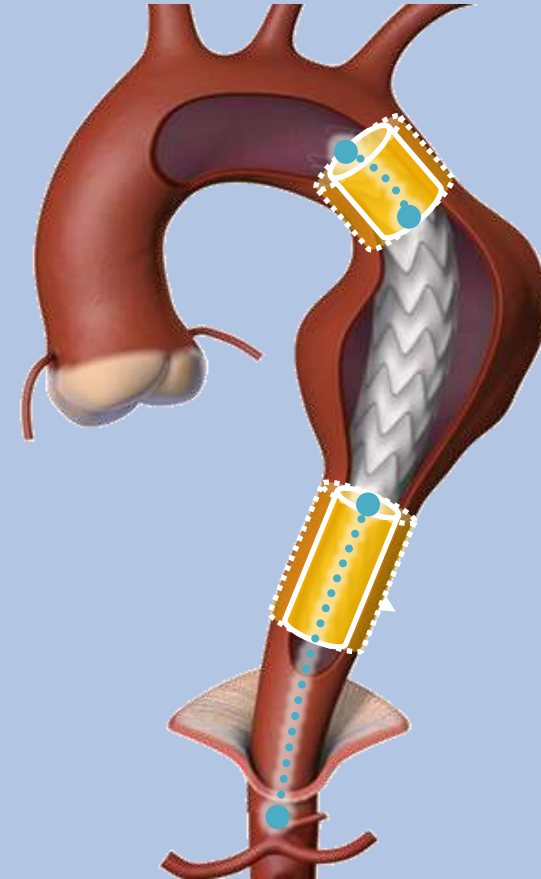
- Low ACM, ARM, and secondary procedures
- Stent graft conforms to native aorta tortuosity and maintains conformability over time

Morphological changes at one year

- Aortic elongation and dilation occur, particularly at the DISTAL end

Actionable Lessons

- Must consider distal attachment zone in pre-case planning as well as adjunctive procedures in short landing zones
- Good seal zones play a role in sac regression and reduced risk of endoleaks



Quantified Evidence of the Conformability of Valiant Navion



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