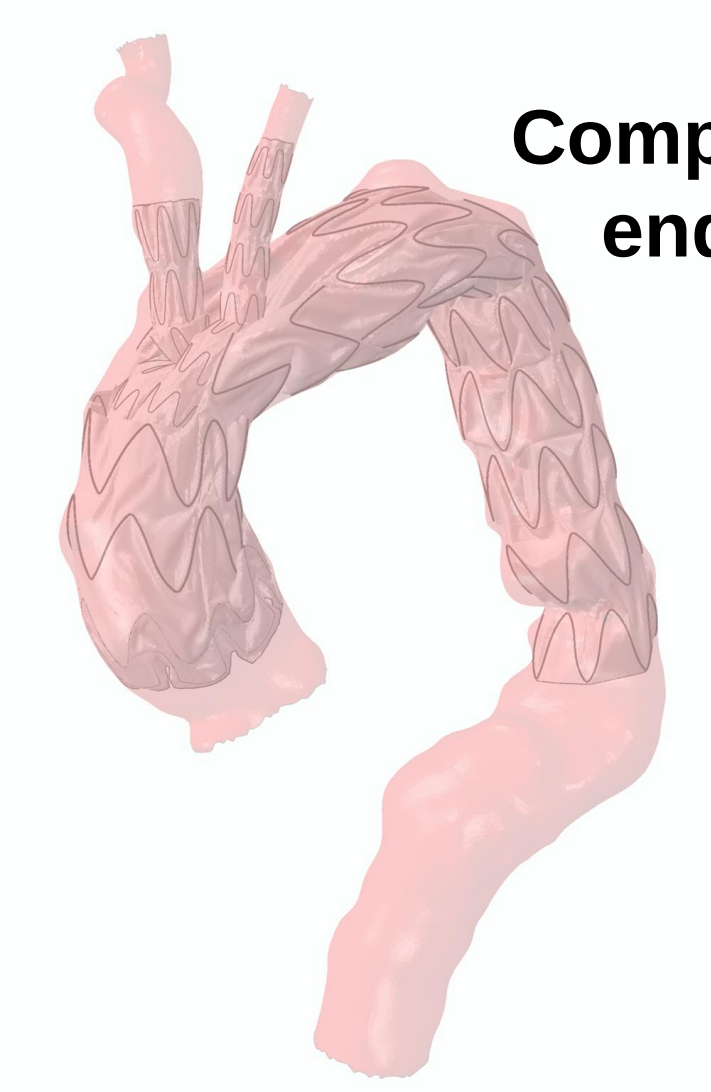
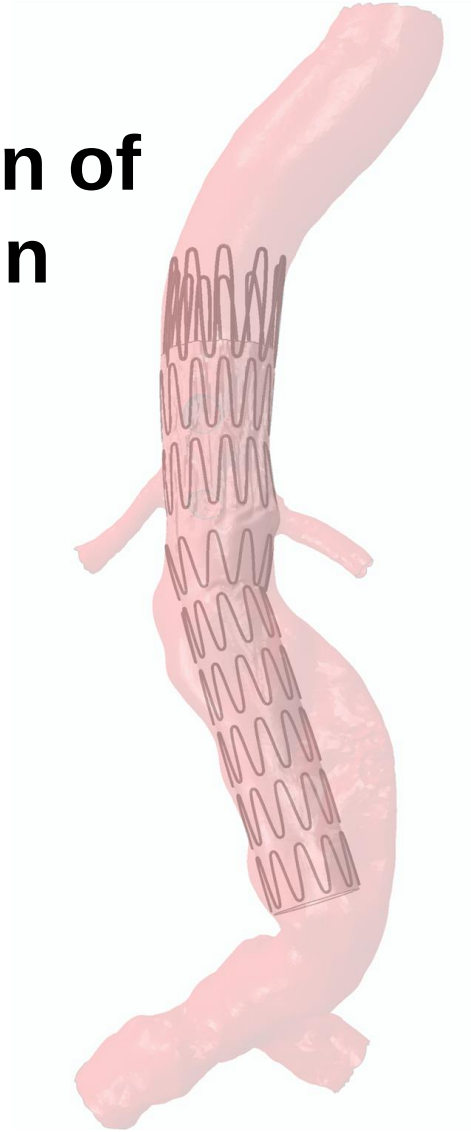


Computational prediction of endograft placement in complex aortic aneurysm repair



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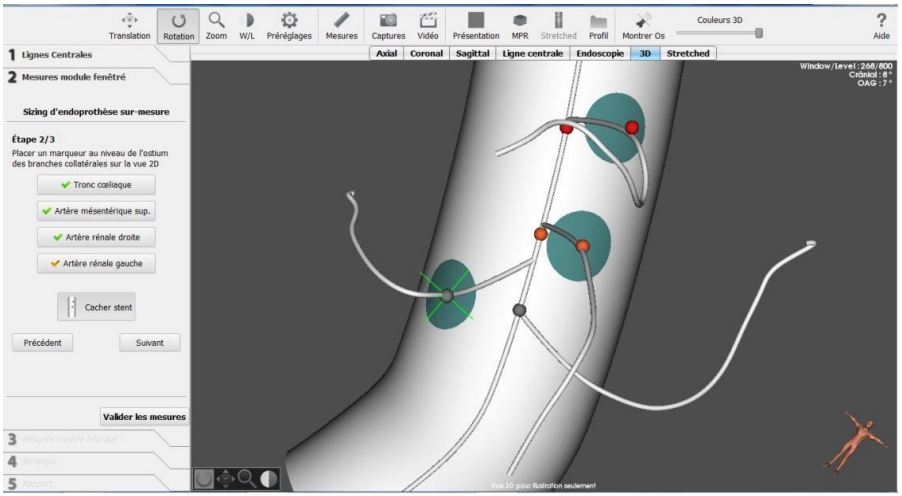
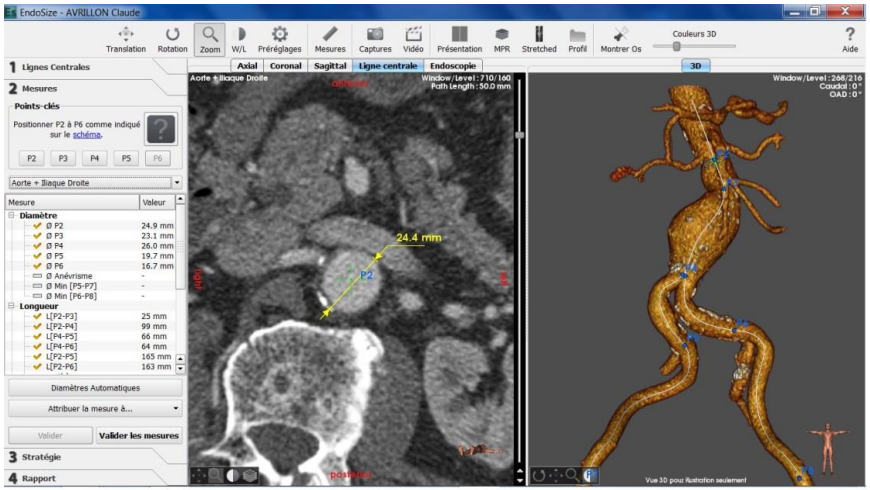
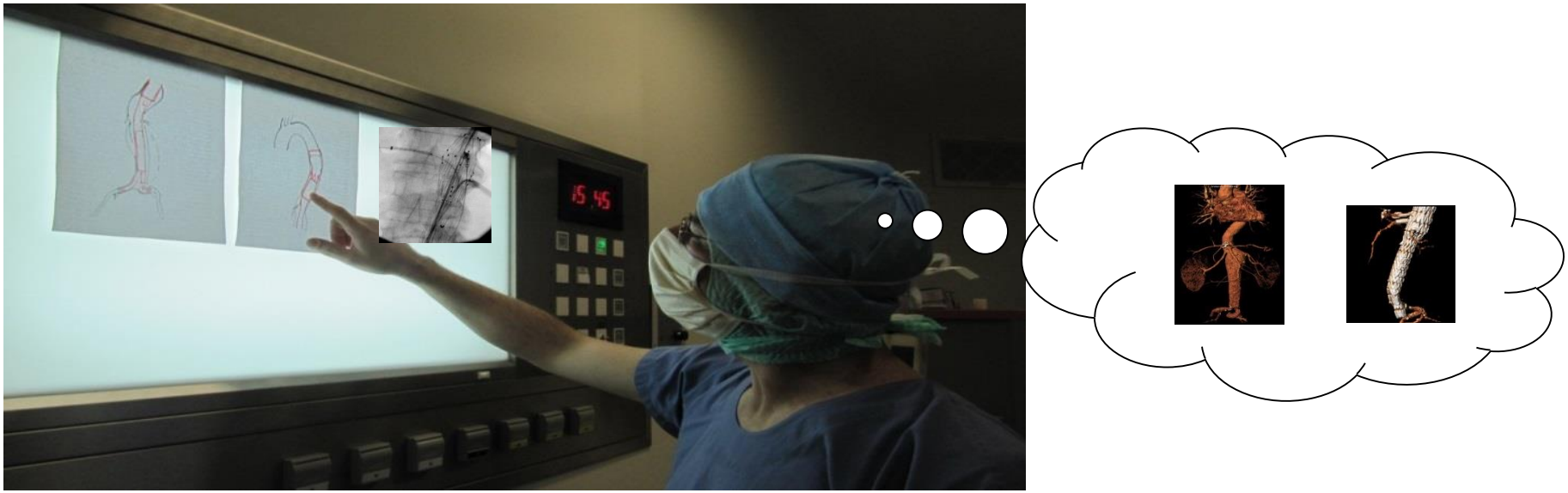
Disclosures

S. Avril is cofounder of the company Predisurge SAS.

Planification / sizing of fenestrated stent grafts in EVAR procedures







Current limitations of planification / sizing

- Intra-operative difficulties induced by inappropriate pre-operative planification.

- Variability of fenestration positions depending on operators.

- Extended delivery times.

- Use of in vitro validation test with plastic replica for Terumo Anaconda®.

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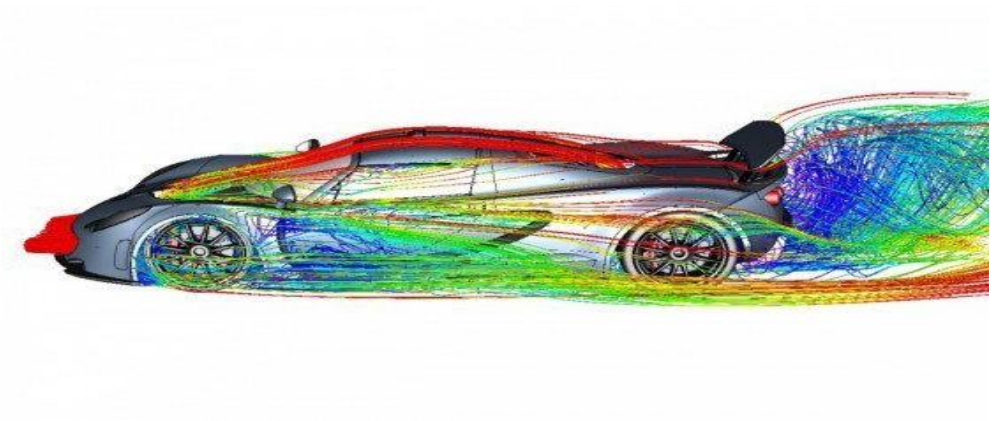
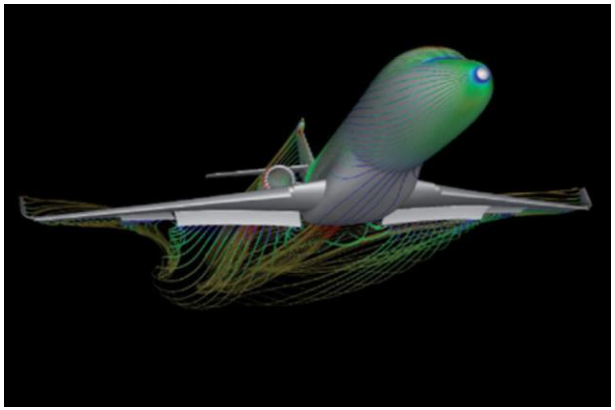
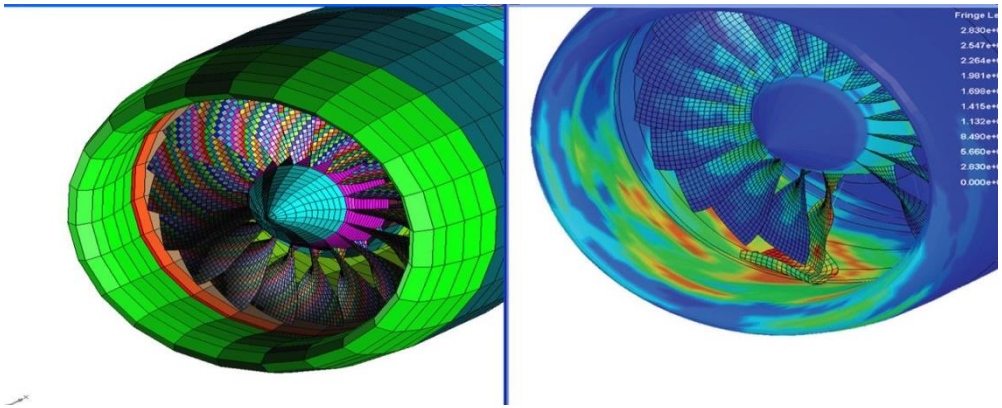
Numerical simulation is commonplace in automotive and aeronautics industry







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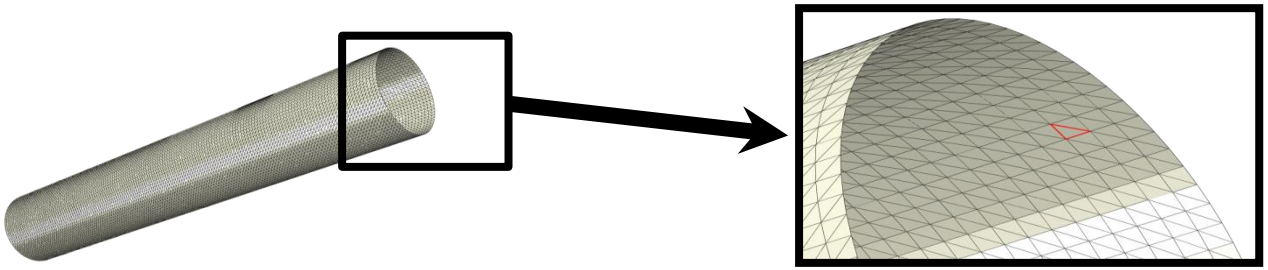
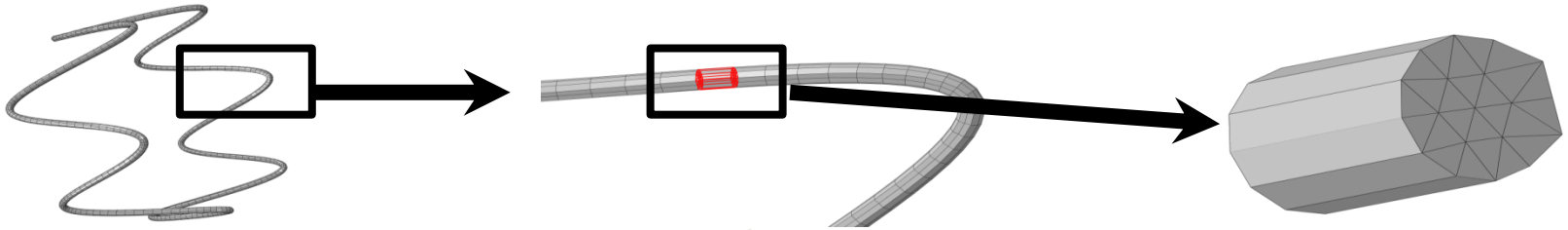
Finite element simulations of stent grafts



$$\begin{pmatrix} \varepsilon_{LL} \\ \varepsilon_{CC} \\ 2\varepsilon_{LC} \end{pmatrix} = \begin{pmatrix} 1/E_L & -\frac{\upsilon_{LC}}{E_L} & 0 \\ -\frac{\upsilon_{CL}}{E_C} & 1/E_C & 0 \\ 0 & 0 & 1/G_{LC} \end{pmatrix} \begin{pmatrix} \sigma_{LL} \\ \sigma_{CC} \\ \sigma_{LC} \end{pmatrix}$$



$$\frac{1}{E_\theta} = \frac{\cos^4\theta}{E_L} + \frac{\sin^4\theta}{E_C} + \frac{1}{4}\left(\frac{1}{G_{LC}} - \frac{2\upsilon_{LC}}{E_L}\right)\sin^2(2\theta).$$

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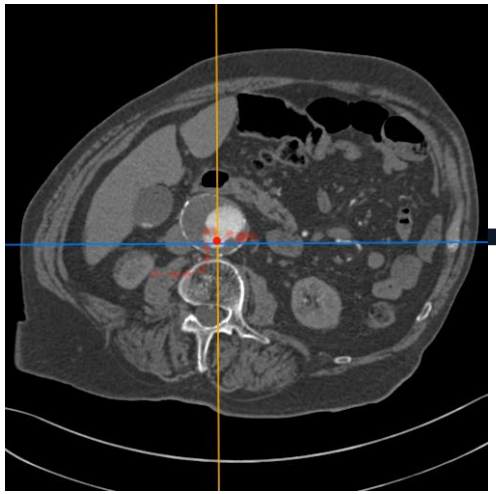
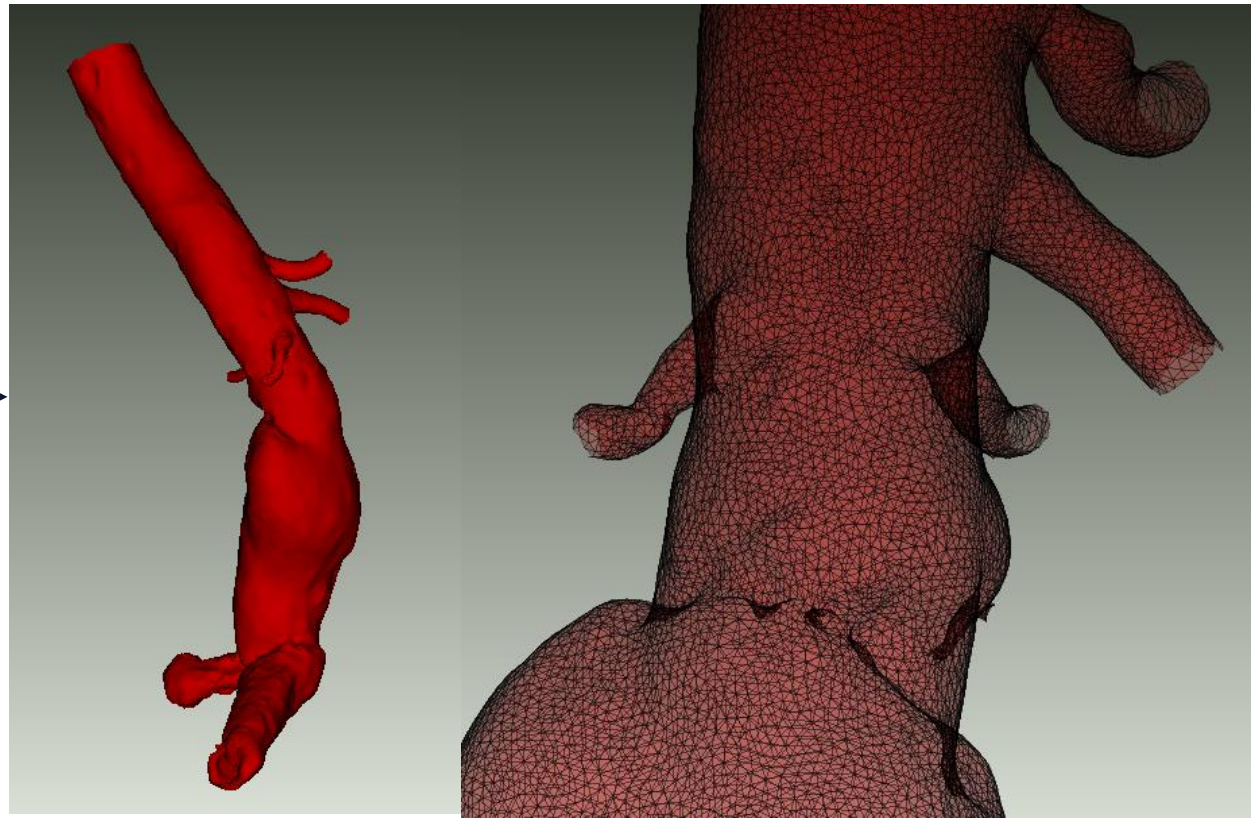
Patient-specific model of the aorta





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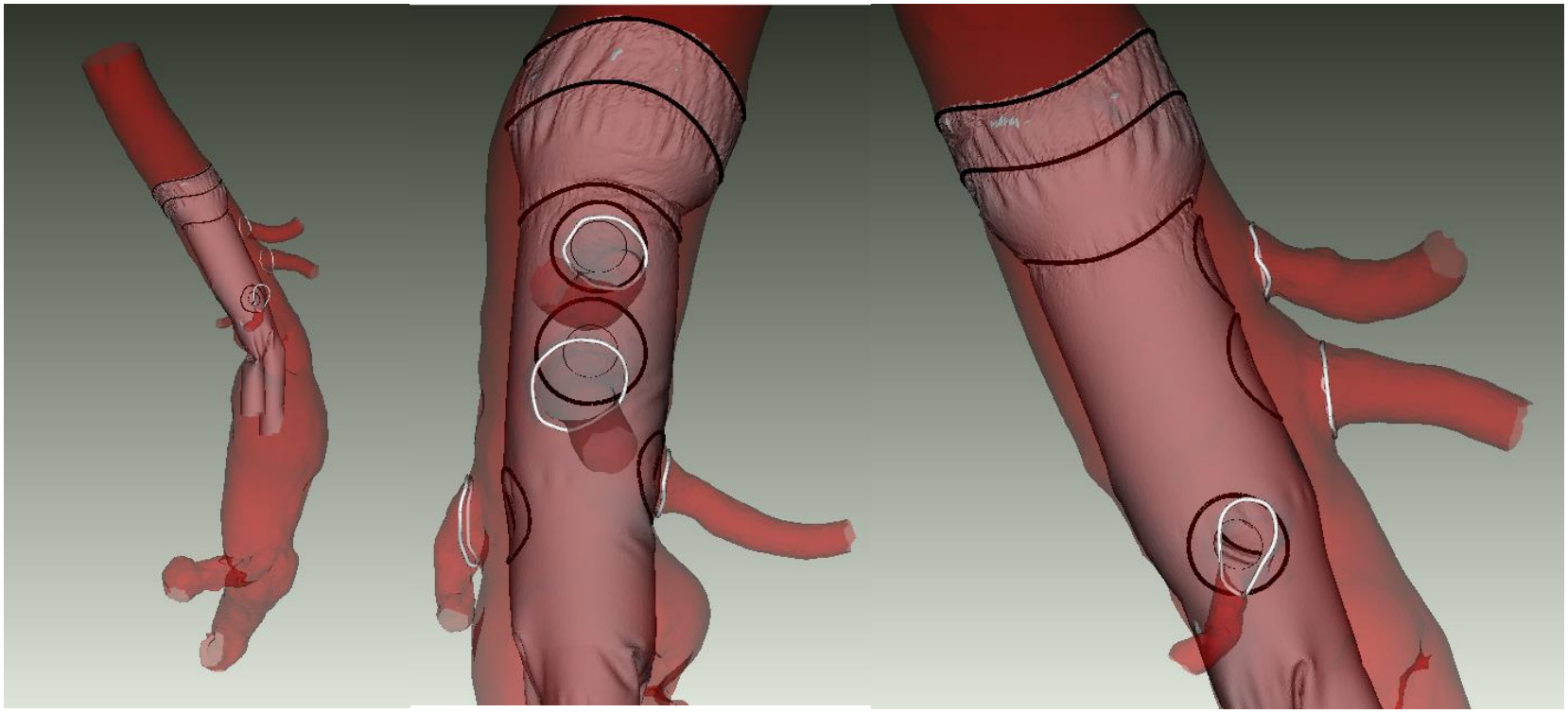
Patient-specific prediction of the deployed stent-graft in the aorta – Example with Terumo Anaconda®



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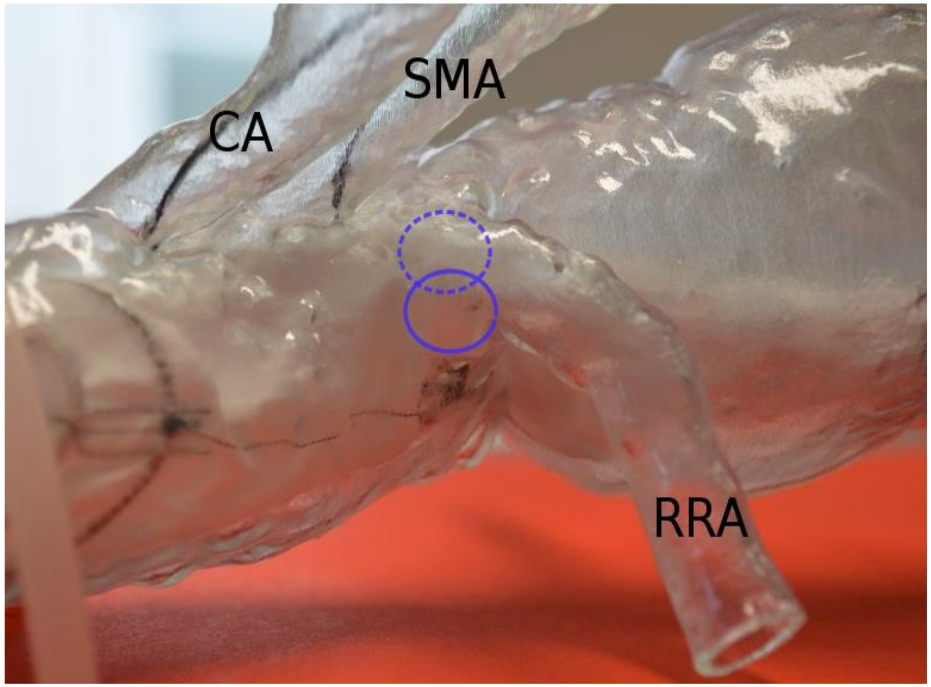
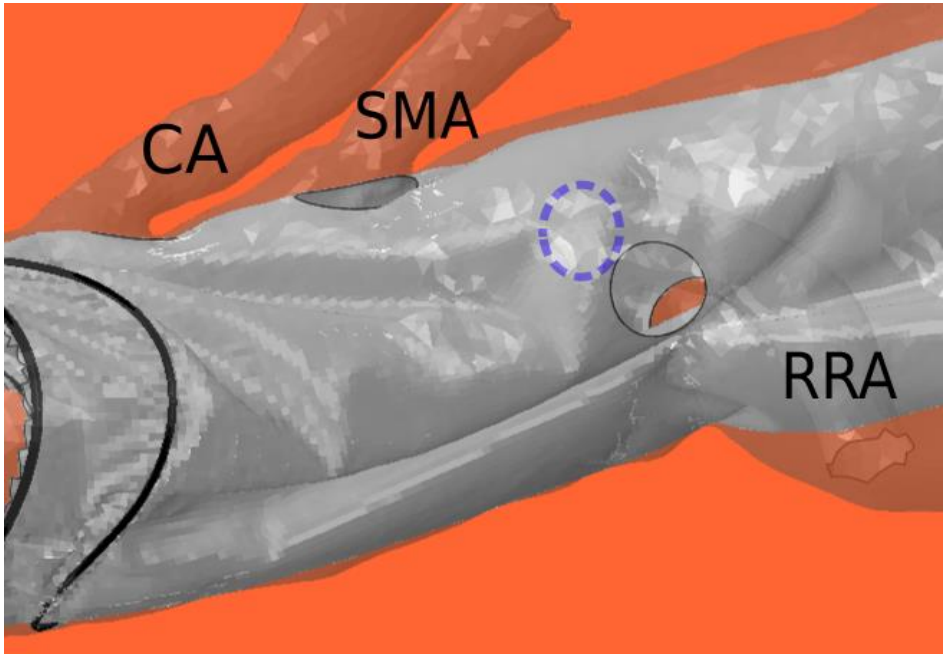
Digital model of in vitro validations for Terumo Anaconda® fenestrated stent-grafts





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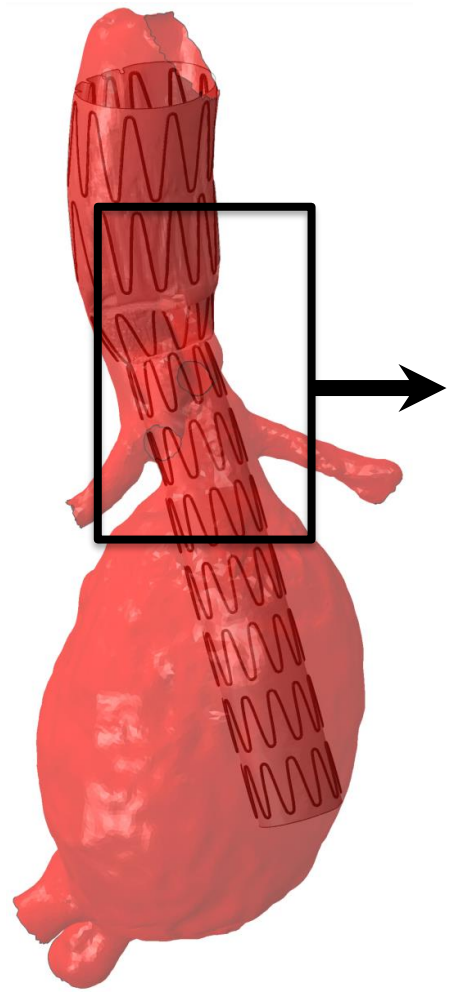
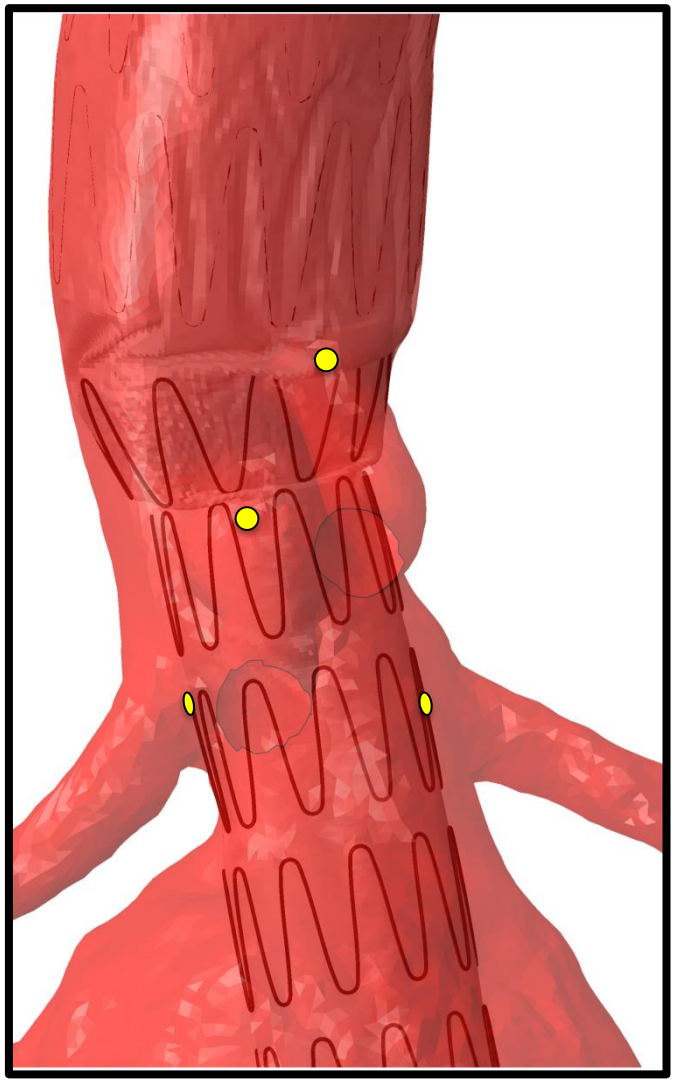
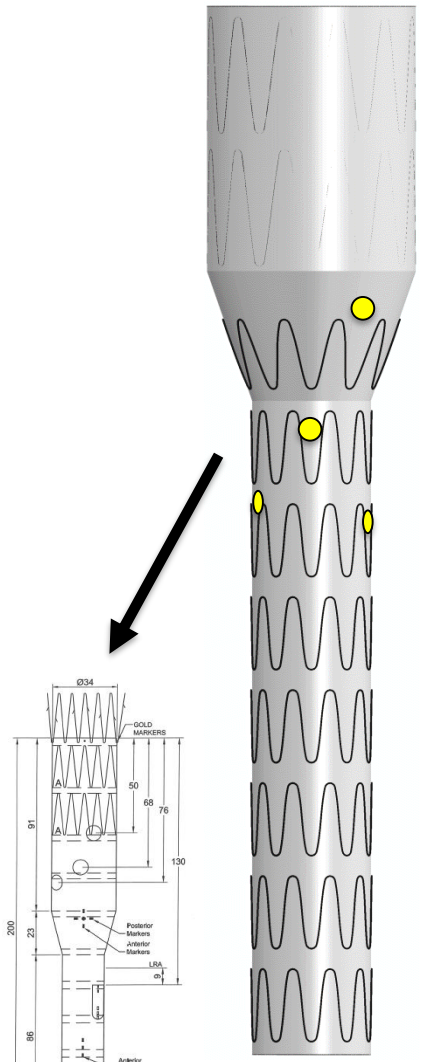
Fast and repeatable approach for FEVAR Zenith® Cook Medical

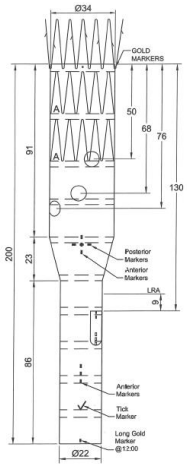


Position of ostias



Position of fenestrations





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Clinical validation for fenestrated Terumo Anaconda®
6 centers – 70 patients
Prospective study (on going)
PI: Bertrand Chavent (Saint-Etienne, France)

Prof Stéphane Avril
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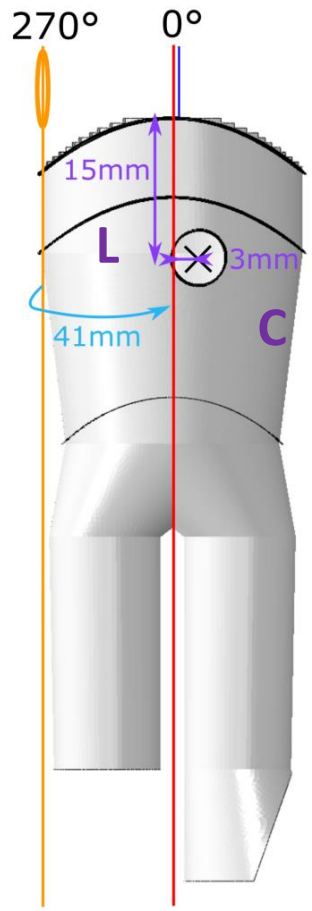
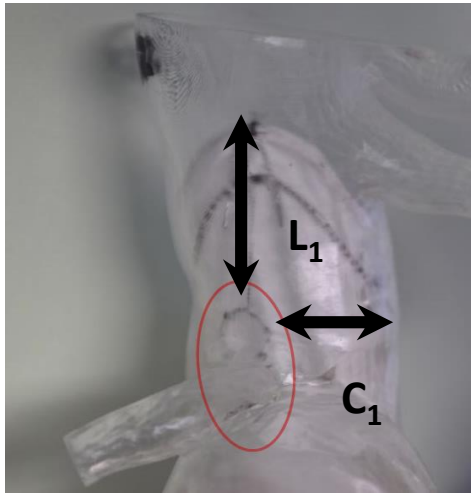
Assessment criteria

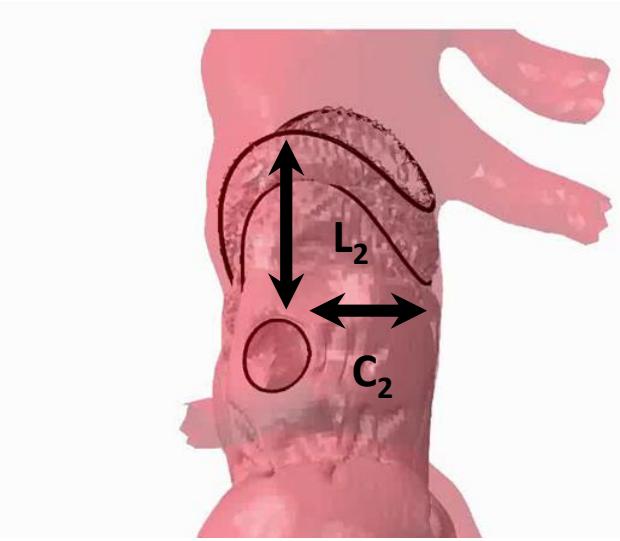
$\Delta L = |L1 - L2|$

$\Delta C = |C1 - C2|$

ΔL et $\Delta C \leq 2.5$ mm for more than 80%







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Results

Average difference:

- longitudinal **L1-L2** **1.5mm**
- circulferential **C1-C2** **1.2mm**

Position difference < 2.5mm

- **longitudinal** **96%**
- **circumferential** **97%**

Process duration:

- in vitro test 17 days
- numerical simulation 1.8 days

p<0.001

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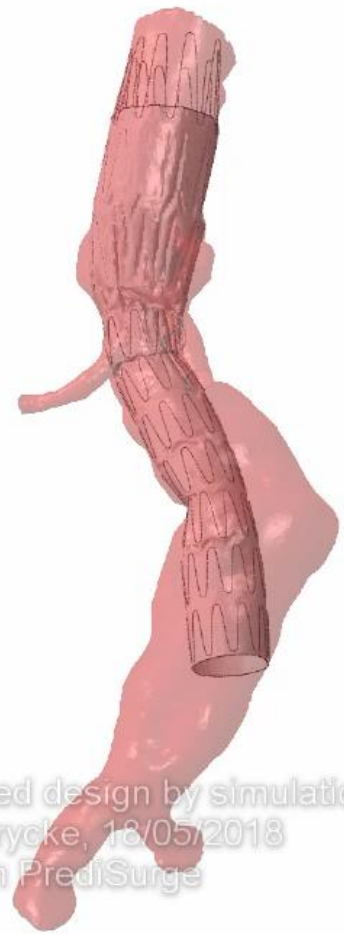
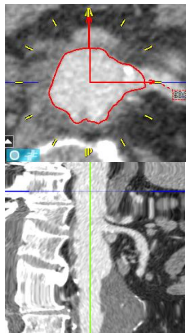
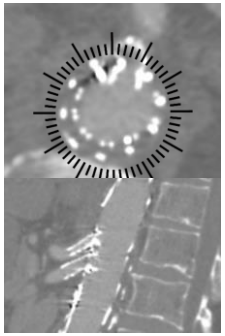
Clinical validation for FEVAR Zenith® Cook Medical
51patients- 180 fenestrations – 18 scallops
Retrospective study 2016-2018
PI: Stephan Haulon (Paris)



Results

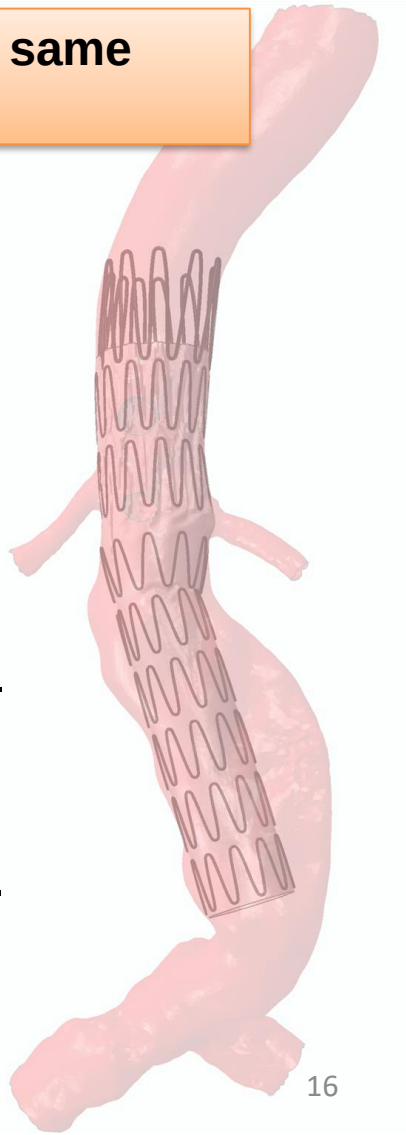
Measurements: longitudinal and circumferential				
Longitudinal position, mm				
	Pre-op sizing		**Post-op sizing**	
	Median ± SD [Min-Max]	**N ≤ 3 mm %**	**Median ± SD [Min-Max]**	**N ≤ 3 mm %**
Simulation	1.0 ± 1.1 [-5.9, 6.0]	95	0.96 ± 0.97 [-4.6, 5.0]	98
Pre-op sizing	0.8 ± 0.8 [-4.0, 4.0]	97		
Circonferential position, °				
	Pre-op sizing		**Post-op sizing**	
	Median ± SD [Min-Max]	**N ≤ 15 ° %**	**Median ± SD [Min-Max]**	**N ≤ 15 ° %**
Simulation	6.9 ± 6.1 [-44.3, 25.1]	96	4.8 ± 3.6 [-21.8, 19.3]	99
Pre-op sizing	5.1 ± 5.0 [-37.1, 18.4]	98		





Conclusions

Numerical simulation can position fenestrations with the same precision as the standard approach

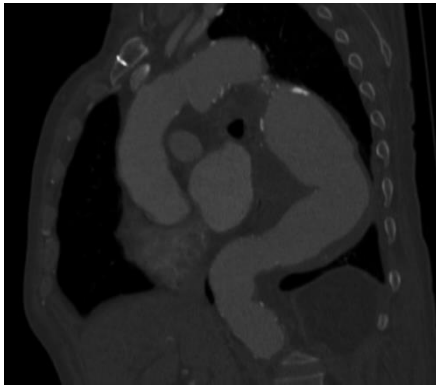


Potential advantages are:

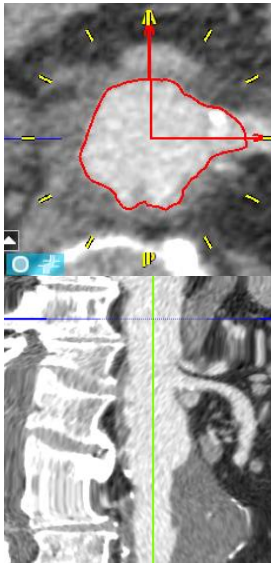
- Reduce inter- and intra-operator variability.
- Give quantitative information about the deployend stent-graft in the aorta (mechanics).
- Decrease the incidence of post-operative complications.

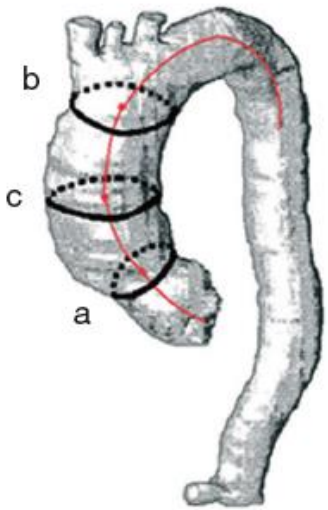
Current developments

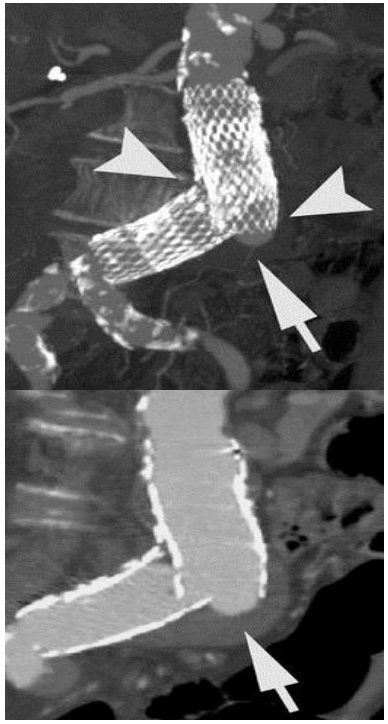
Patient specific FE model of double branch Bolton® device deployment in aortic arch aneurysm



Endovascular Aortic Arch Challenges







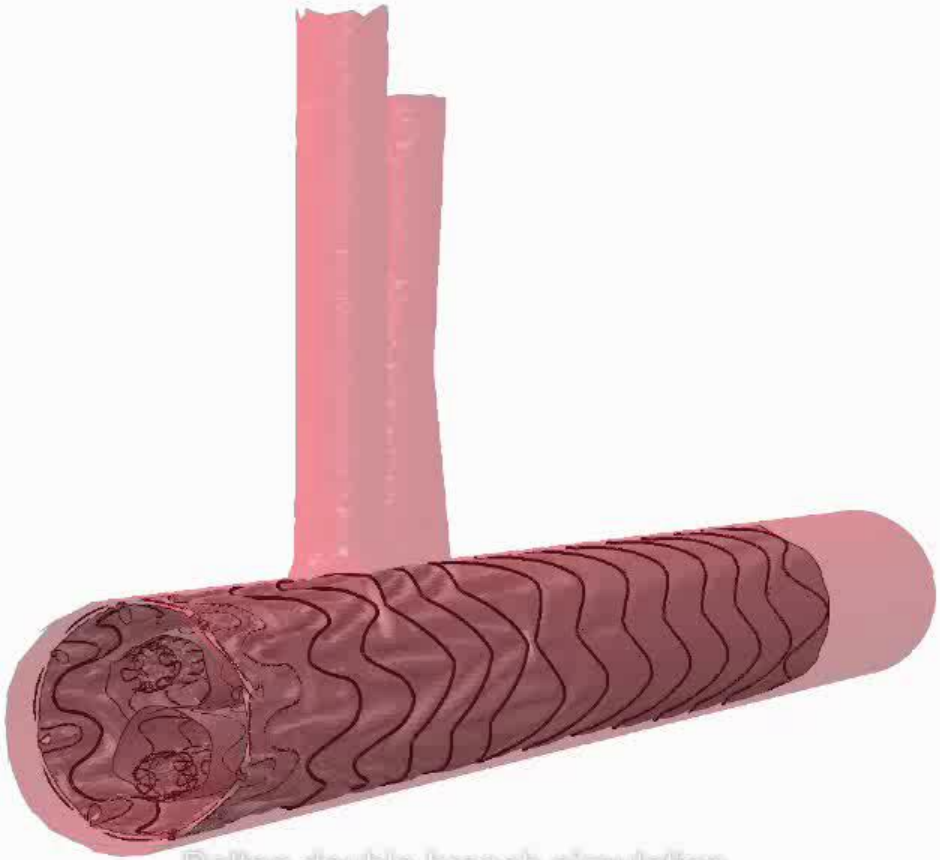
Custom-made device
Measures on preop CT

Device alignment
Secure device

Device durability
New set of physiological loads

Numerical simulation can assist at the planification stage and can be helpful to improve device properties

Current developments



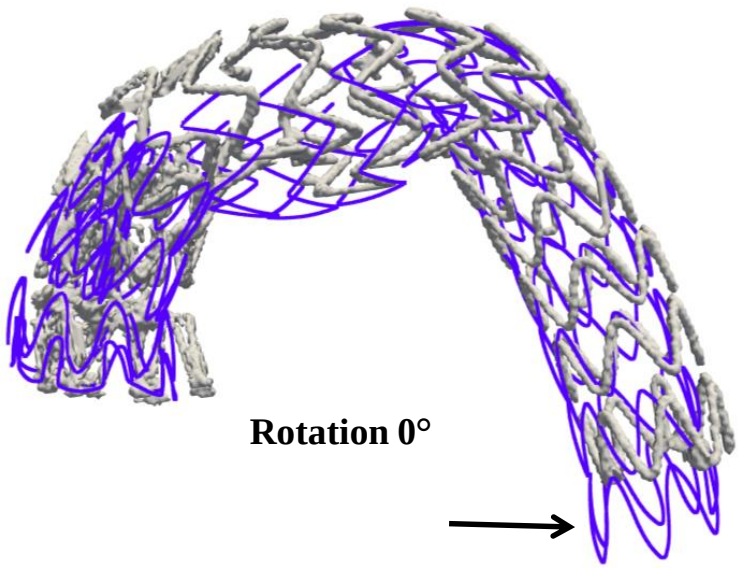
Bolton double branch simulation
03/09/2018
Lucie Derycke, with PrediSurge

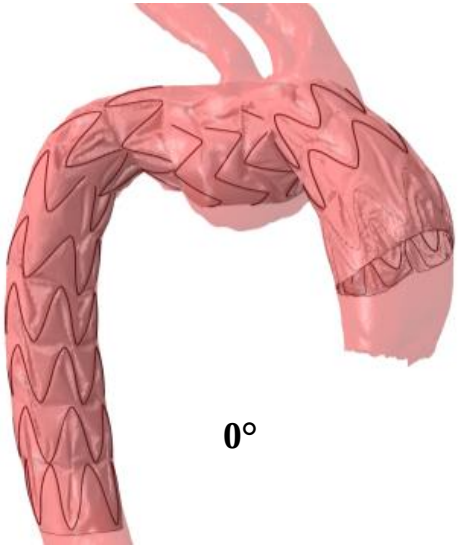
Current developments

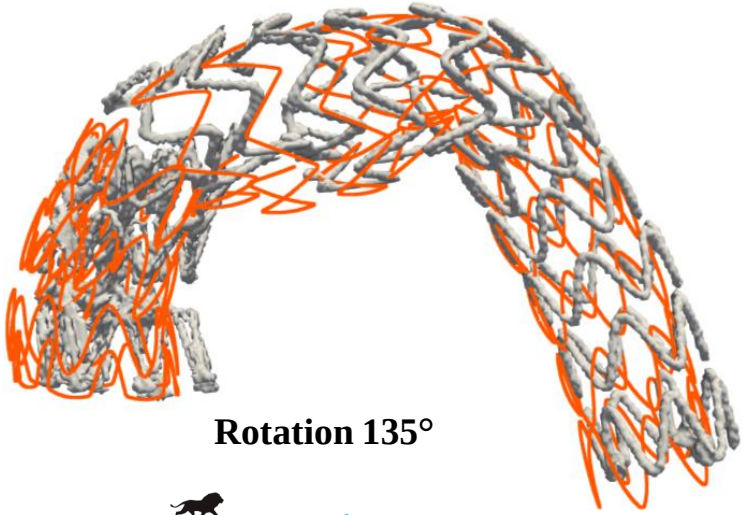
Bolton double branch simulation
03/09/2018
Lucie Derycke, with PrediSurge

Current developments

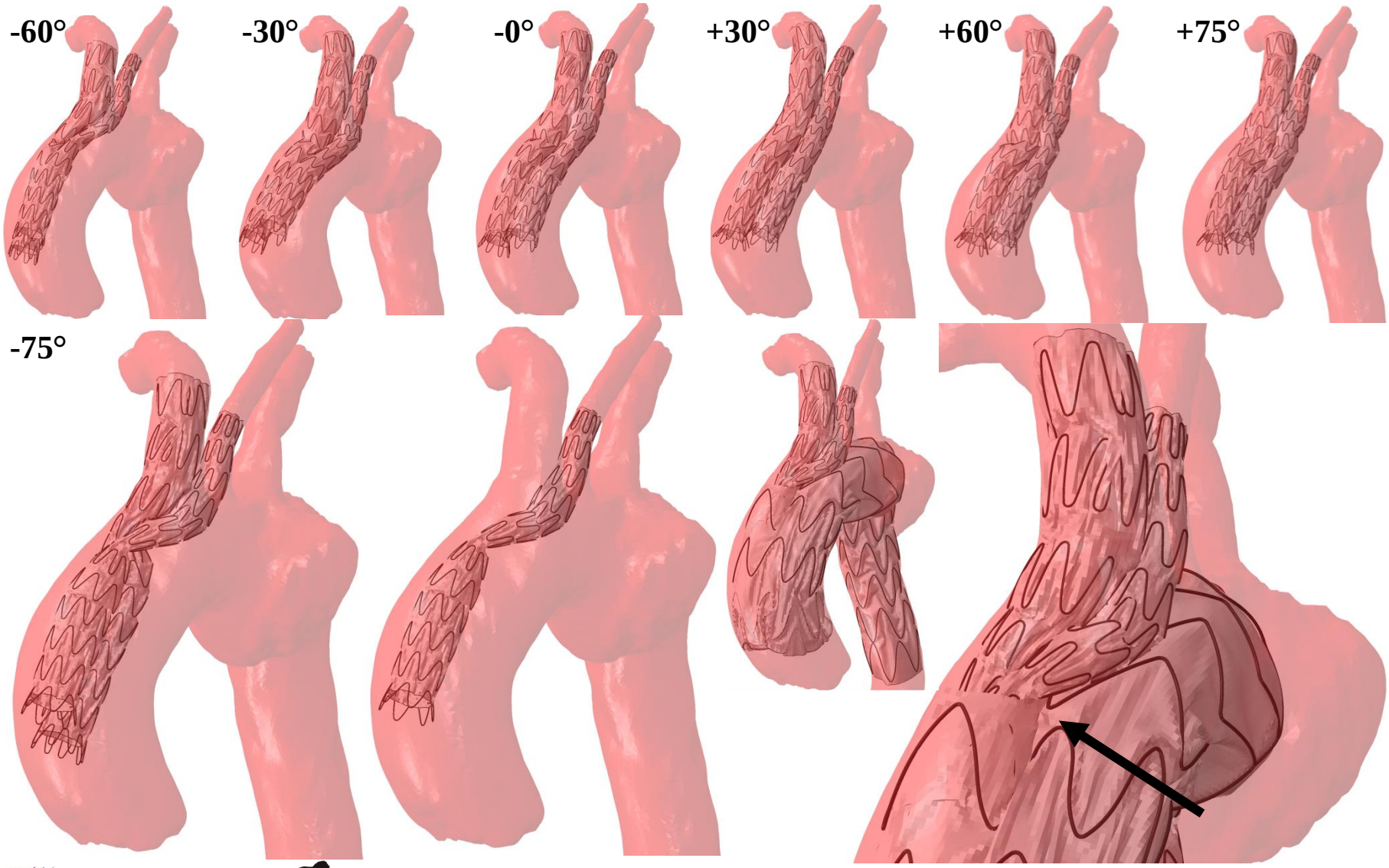
TORSION EFFECTS







Current developments



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Summary

www.predisurge.com

PrediSurge

Software solutions assisted by numerical simulation

Optimize design, preoperative planning and implantation of medical devices

- Company founded in May 2017
- Focus on endovascular repair (EVAR) of aortic aneurysms
- Graphical user interface
- On-going CE and FDA approval

GRAZIE!

B Chavent, A Millon, P Feugier, M Reijnen, JW Lardenoije, A Assadian, J Falkensammer, M Kliewer, N Frisch, C Muller, D Midy, F Cochennec, J Senemaud, JP Favre, L Derycke, D Perrin, JN Albertini, S Haulon

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