



DEUTSCHES HERZZENTRUM
DER CHARITÉ

EINSTEIN
CENTER
Digital Future



L. Goubergrits

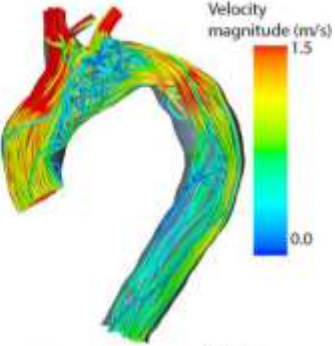
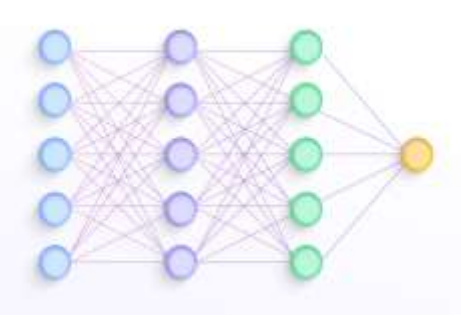
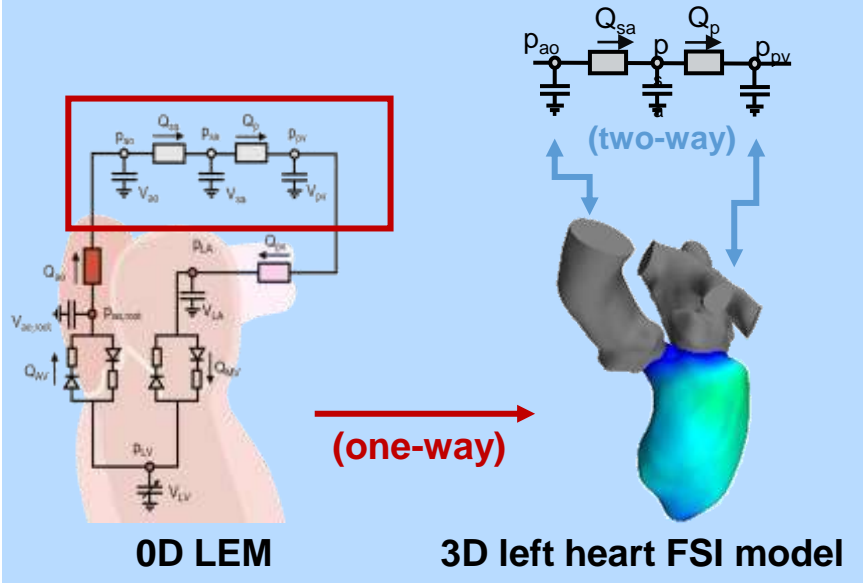
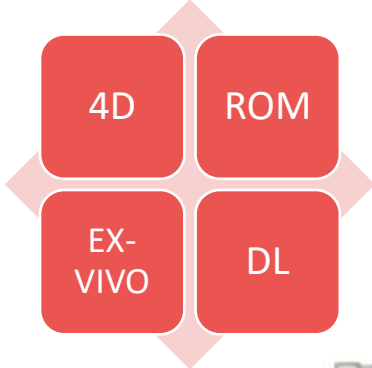
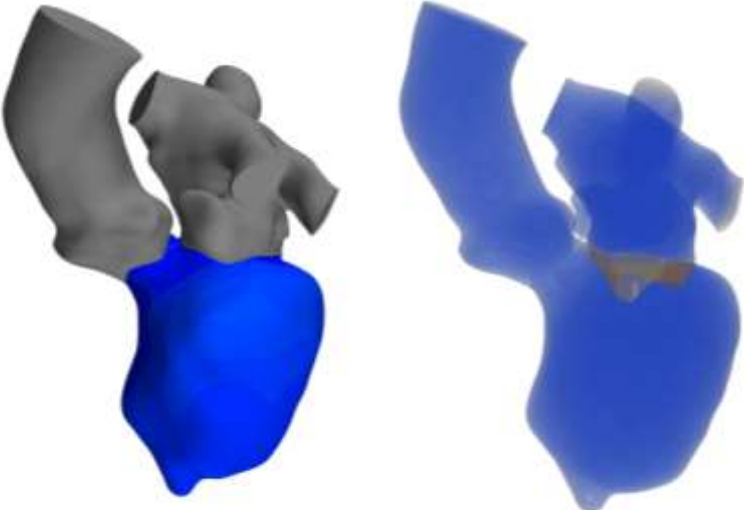
Institute of Computer-assisted Cardiovascular Medicine



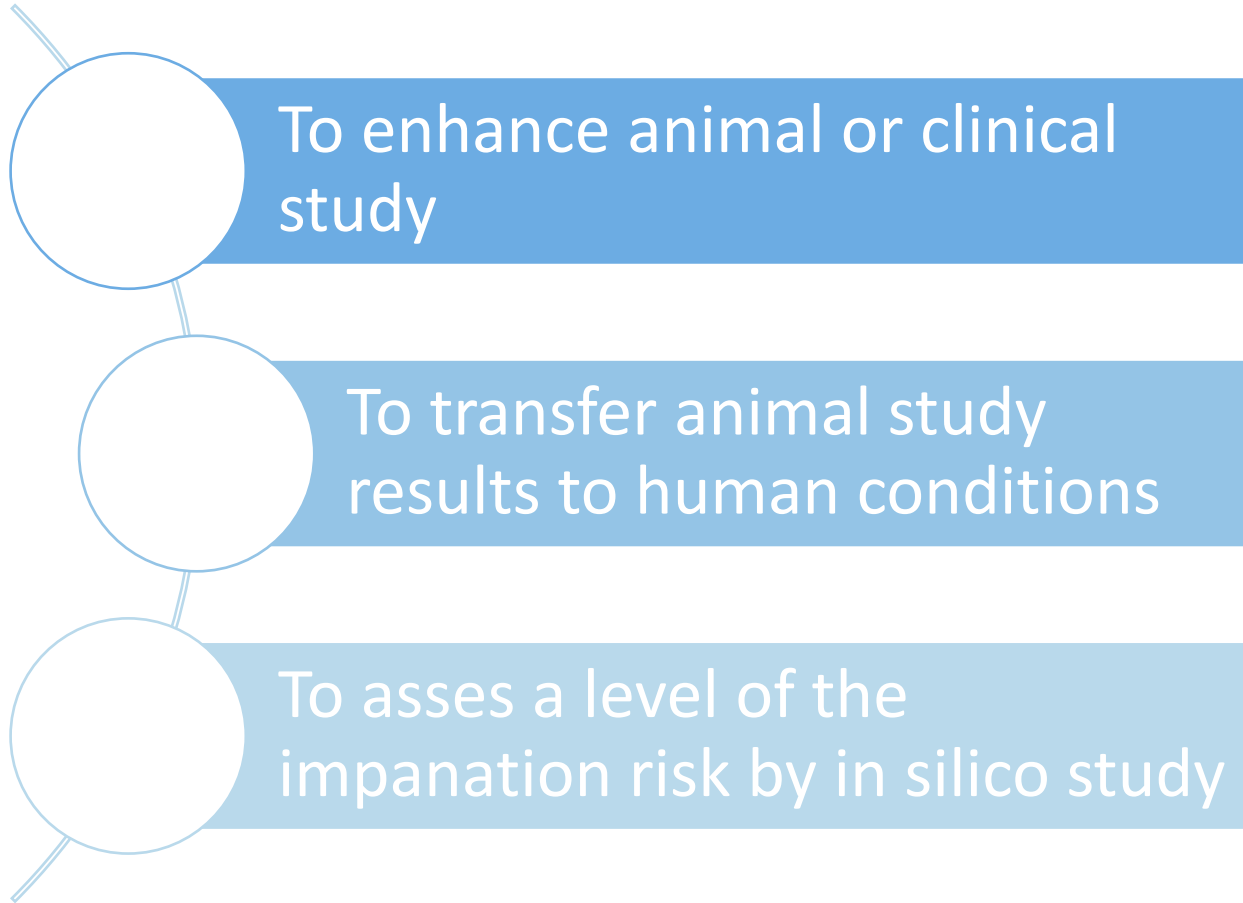
*Modelling approaches to accelerate
development and certification of medical
devices*

06.06.2024

Digital Health: Modelling approaches



To accelerate Development and Certification of a novel Medical Device: Pulmonary Artery Pressure Sensor (PAPS)



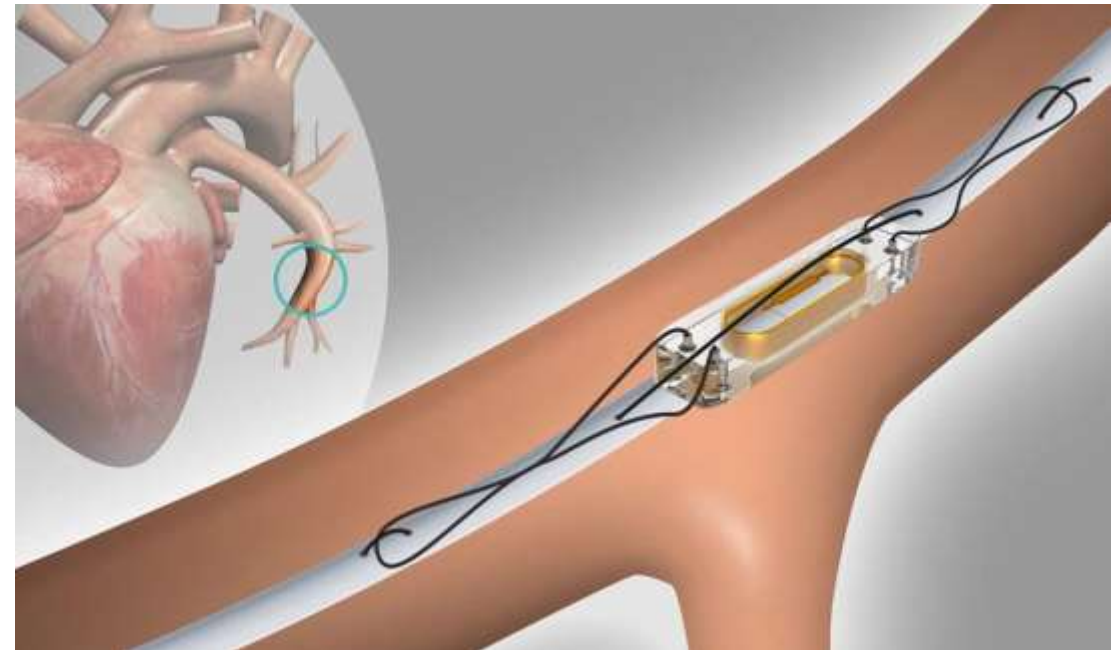
SIMCor

www.simcor-h2020.eu

PAPS Introduction

Prevent Heart Failure Hospitalizations by Remotely Managing Pulmonary Artery Pressure

- aid physicians in preventing worsening heart failure
- lower mortality rates
- improve quality of life
- catheter-based implantation
- fixation by wires



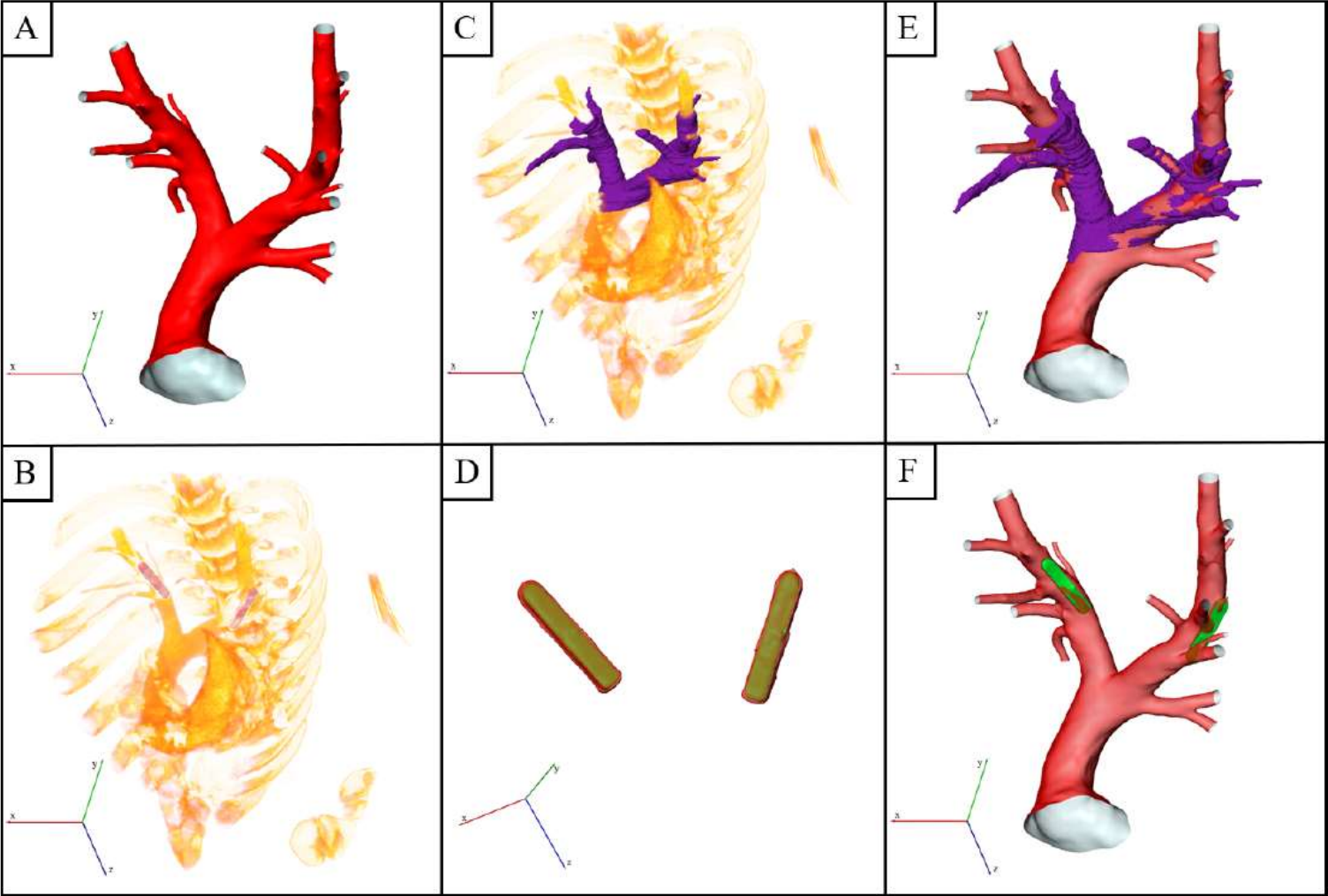
Center for Advanced Cardiac and Vascular Interventions (cacvi.org)

EXAMPLE I: To Enhance Animal Study

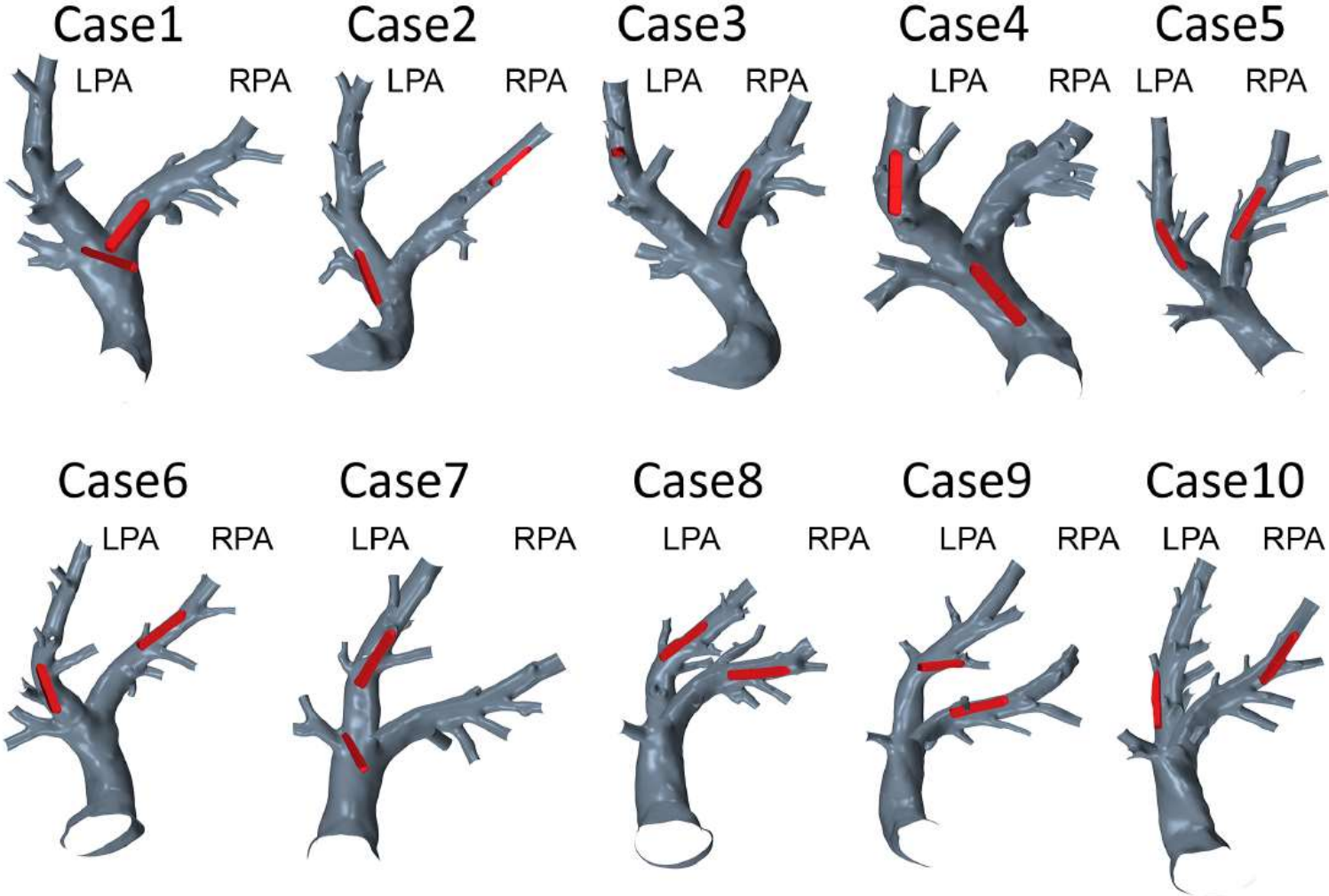
- Chronic animal study with 10 pigs
- Study duration: 3 months
- 2 PAPS implanted in each animal
- CT imaging: pre/post



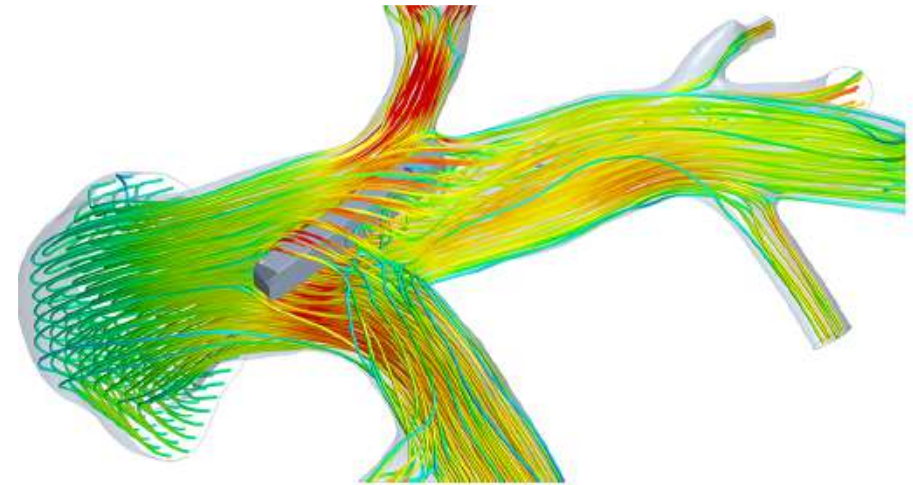
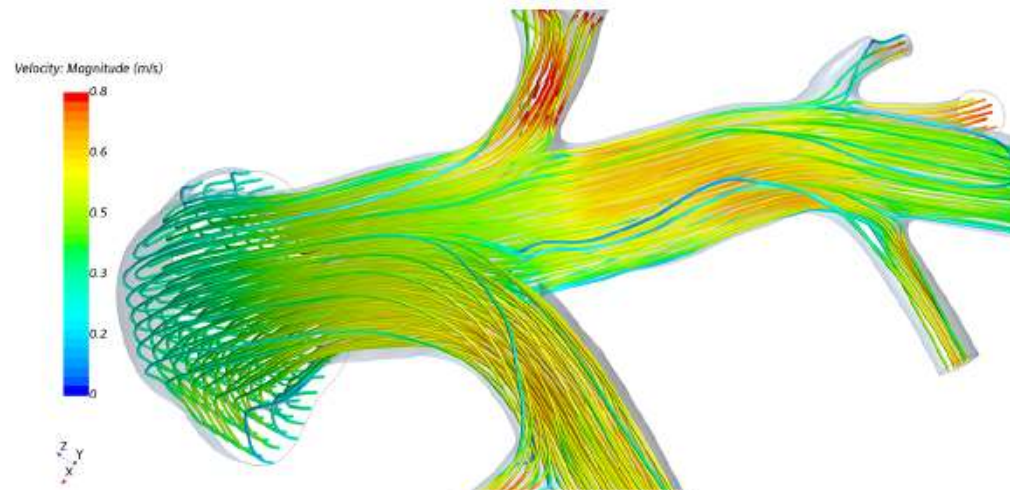
To Enhance Animal Study: virtual PAPS implantation



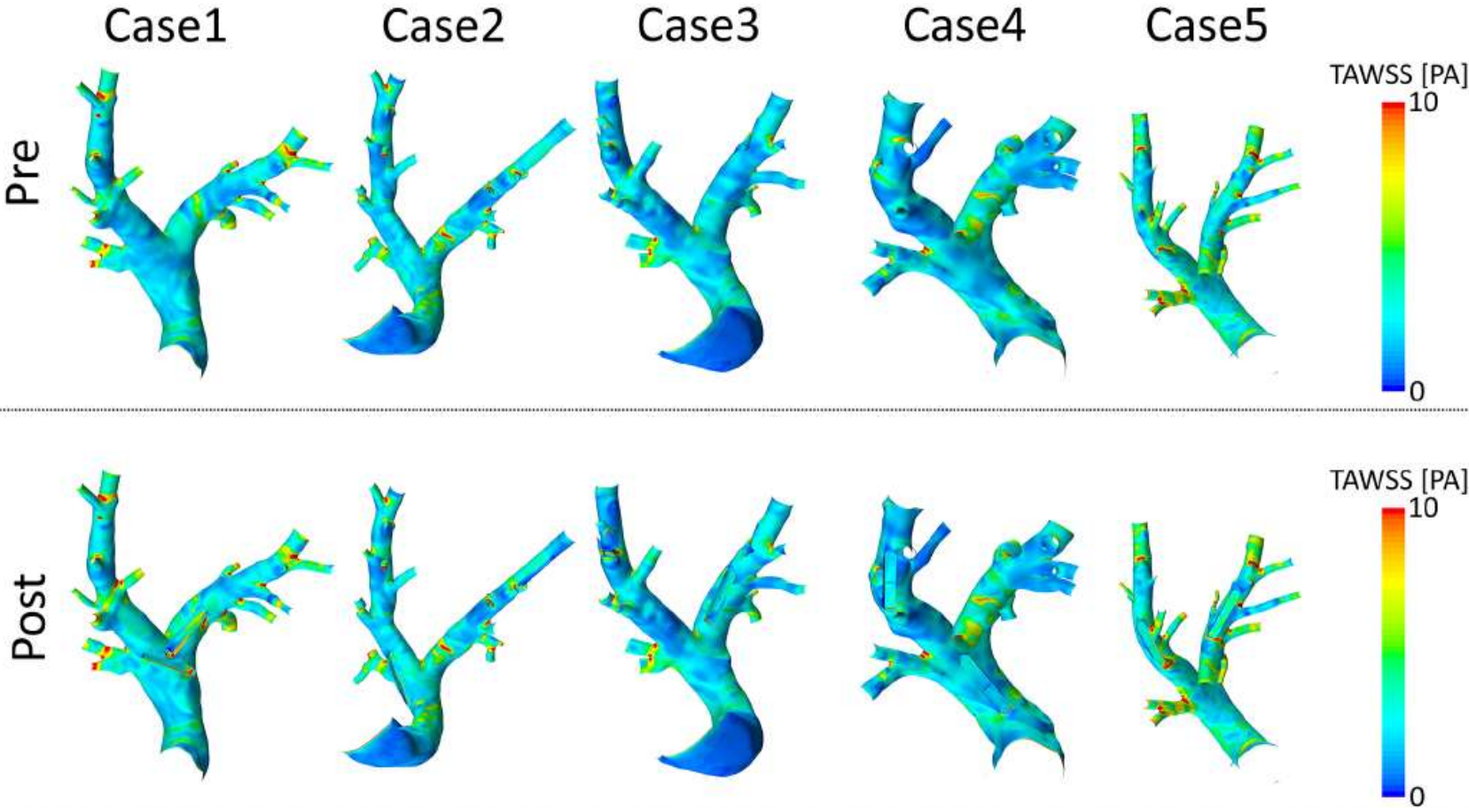
To Enhance Animal Study: virtual PAPS implantation



To Enhance Animal Study: CFD based analysis of hemodynamics



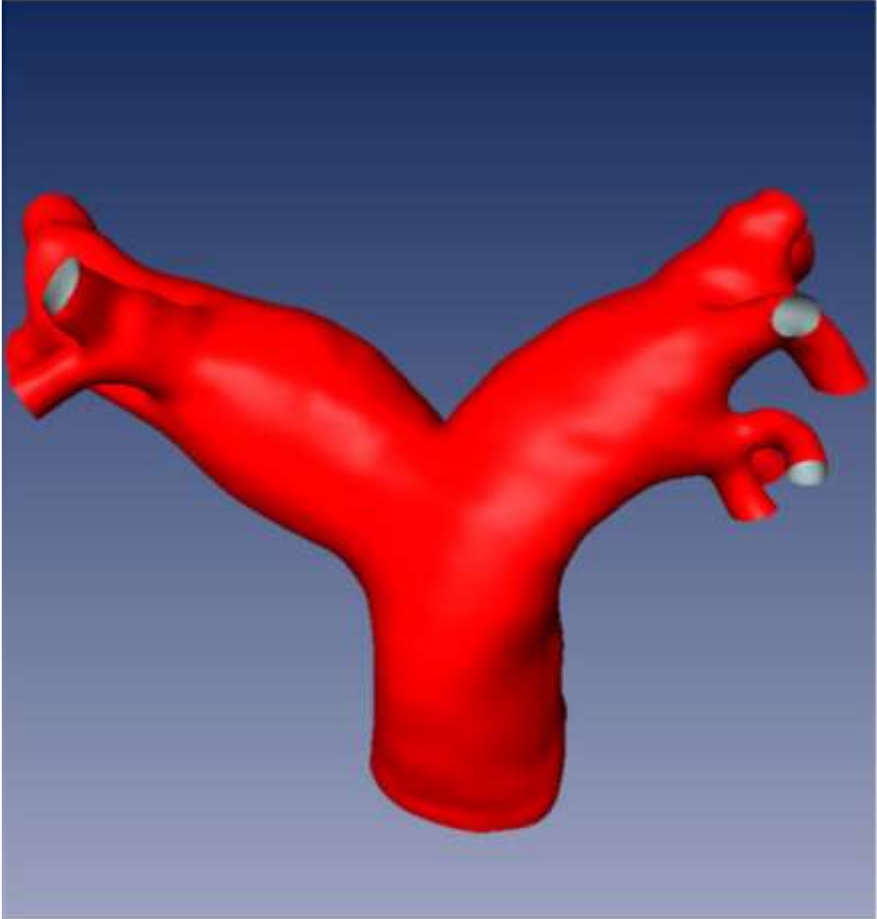
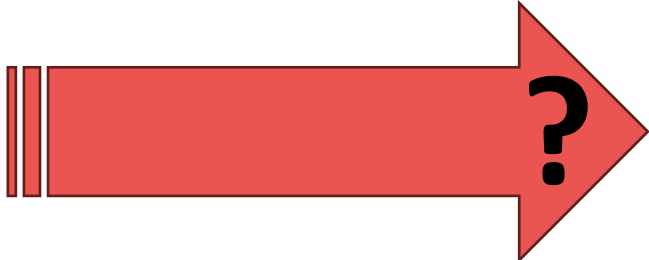
To Enhance Animal Study: CFD Results



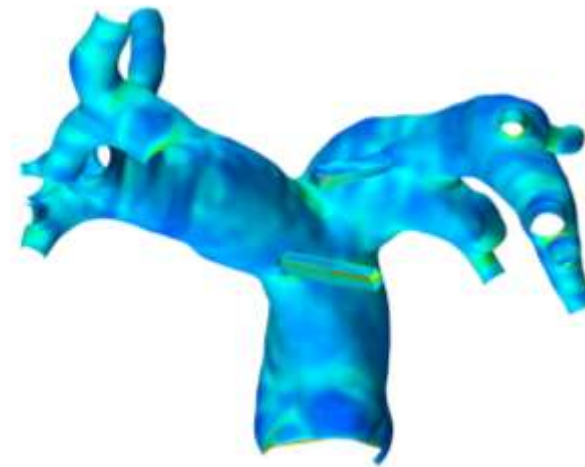
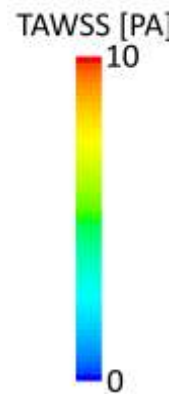
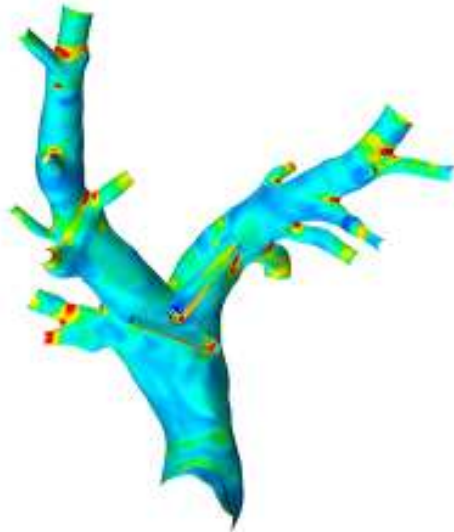
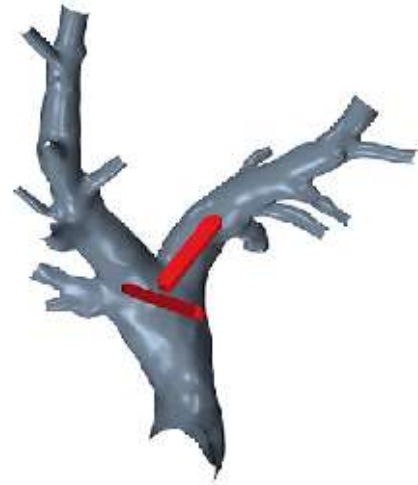
To Enhance Animal Study: CONCLUSION I

- PAPS does not affect clinically relevant PA hemodynamics
- No clinically relevant significant differences were found between optimal and non-optimal PAPS implantations

EXAMPLE II: To Transfer Animal to Human Conditions



To Transfer Animal to Human Conditions: mimicking porcine PAPS study



To Transfer Animal to Human Conditions: CFD based analysis



TAWSS
OSI
Pressure drop

Pre	Post
2.4±0.5 Pa	2.5±0.5 Pa
0.08±0.17 -	0.08±0.16 -
	0.7±1.1 mmHg

TAWSS
OSI

Optimal	Non-optimal
2.6±0.6 Pa	3.9±0.7 Pa
0.12±0.08 -	0.09±0.03 -



TAWSS
OSI
Pressure drop

Pre	Post
1.38[1.11] Pa	1.4[1.2] Pa
0.16[0.07] -	0.15[0.07] -
	0.8±0.8 mmHg

TAWSS
OSI

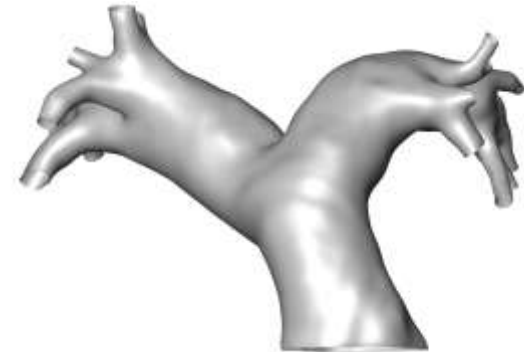
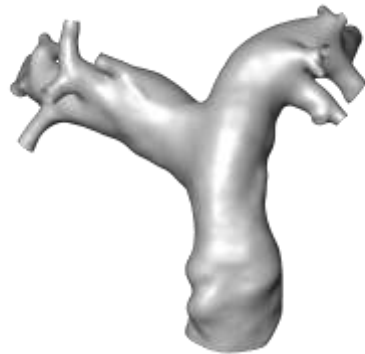
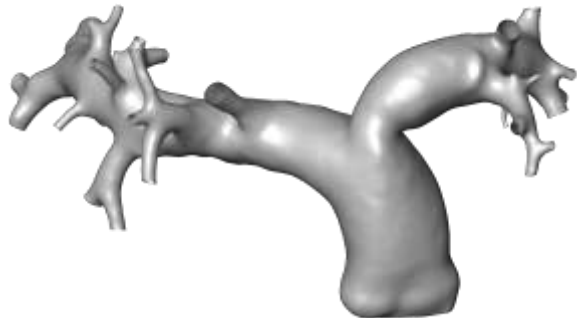
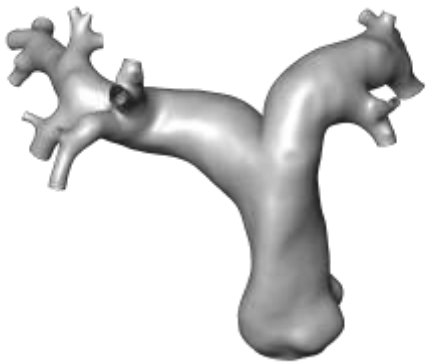
Optimal	Non-optimal
1.7±0.9 Pa	2.8±1.7 Pa
0.19[0.14] -	0.15[0.07] -

To Transfer Animal to Human Conditions: CONCLUSION II

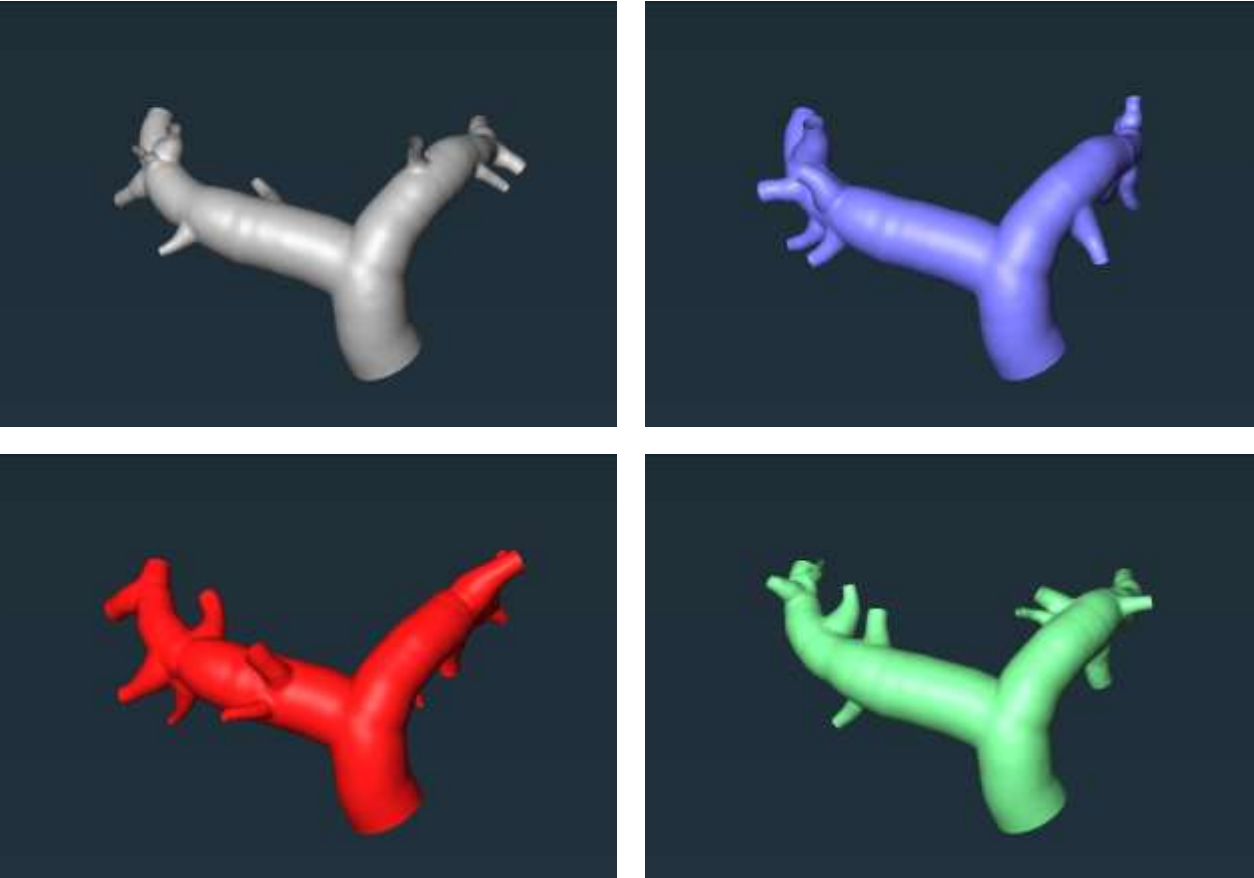
- There are significant differences in hemodynamics between porcine and human PA.
- Both in silico studies of PAPS implanted in porcine or human PA found no higher risk of thrombus formation due to PAPS implantation.
- Both in silico studies of PAPS implanted in porcine or human PA found no higher risk of thrombus formation in non-optimally implanted PAPS.

EXAMPLE III: In Silico Study - Impact of Implantation Site

Is there an increased risk of thrombosis if the device is (partly) covering a side branch?



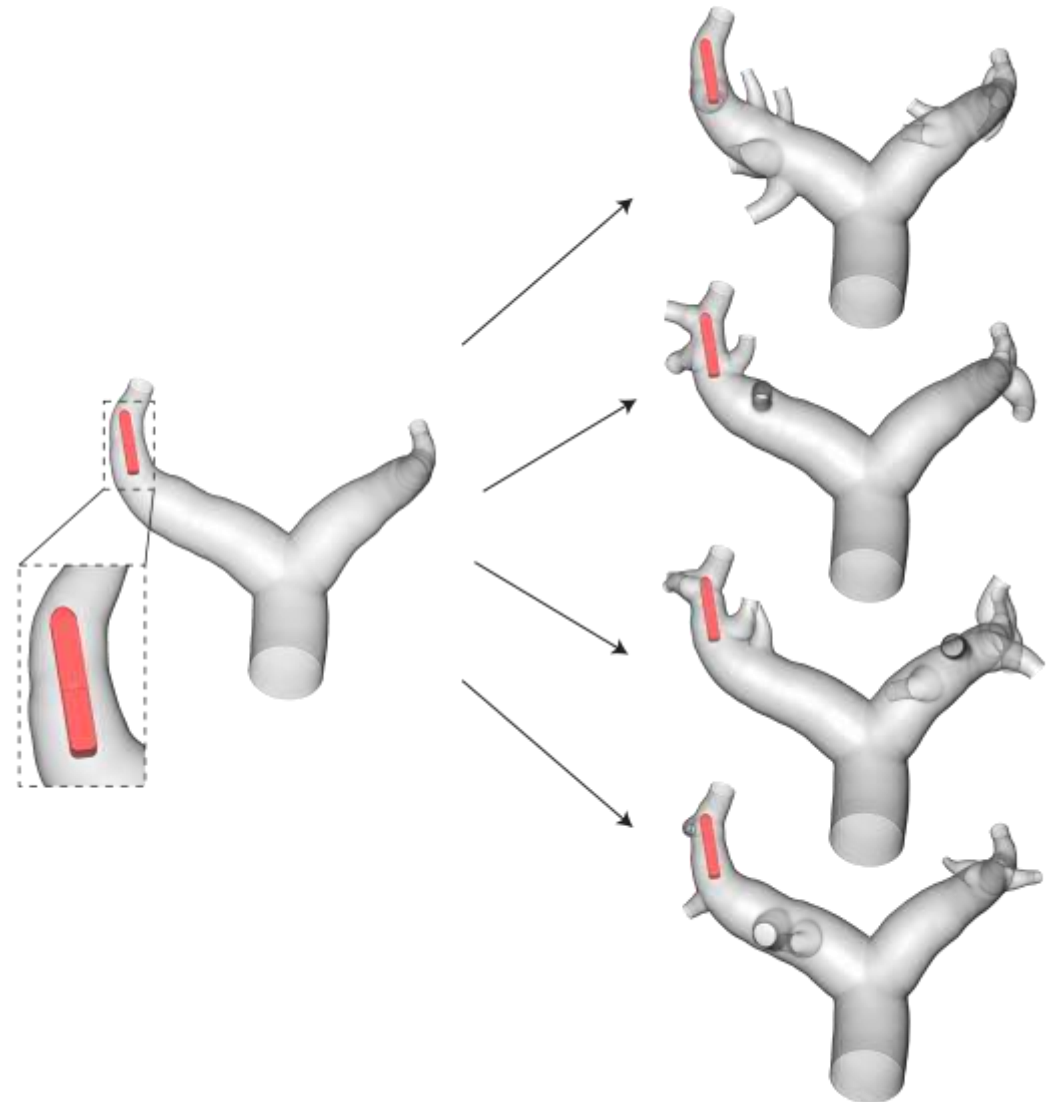
In Silico Clinical Study: Generate Synthetic Shapes using Statistical Shape Model approach



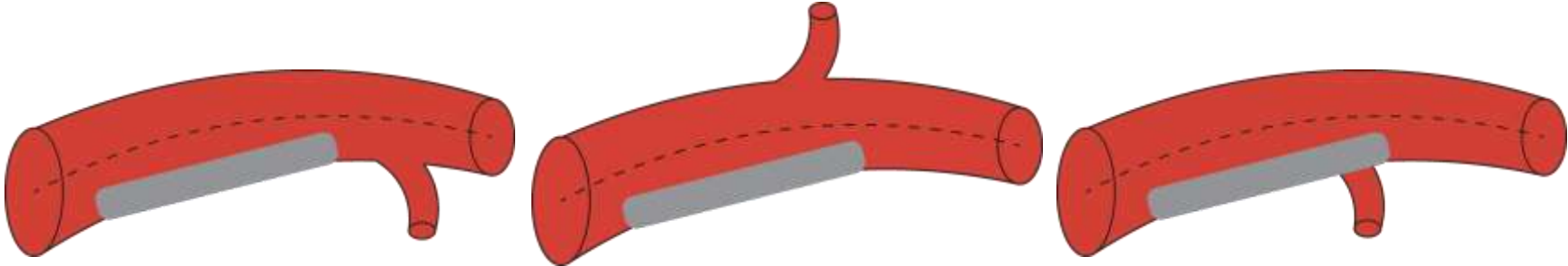
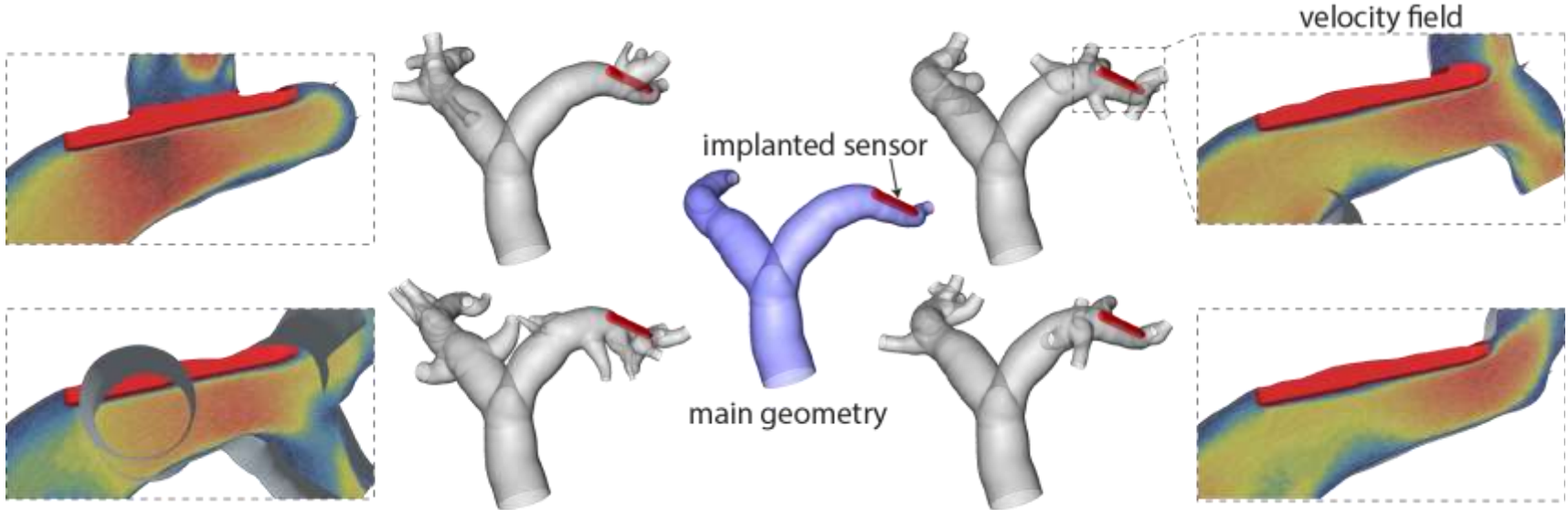
- **Step 1:** Generation of 500 main bifurcation geometries without side branches
 - mimicking real PA with respect to length, diameter, curvature of PA
- **Step 2:** Generate ≥ 4 different side branch configurations
 - mimicking real PA with respect to number, position, orientation and size of side branches

In Silico Clinical Study: Virtual Implantation

- random selection of
 - 50 main branch geometries
 - Sensor position along the centerline within the manufacturer's diameter specification
 - 4 side branch configurations per main branch
- Virtual device implantation in all side branch configurations, resulting in 200 implantations



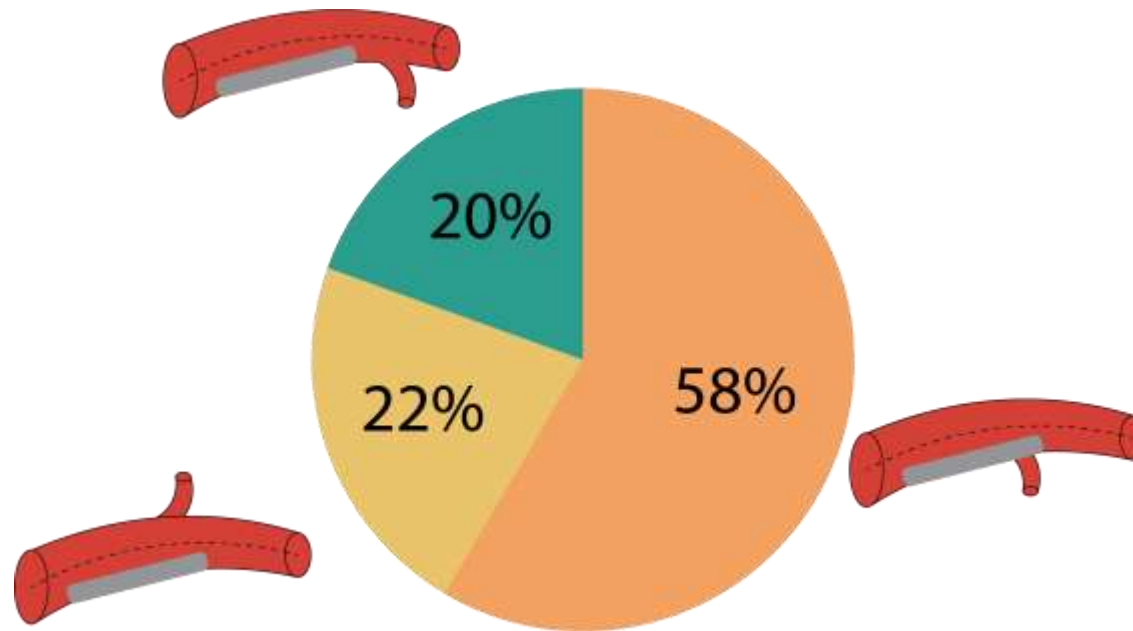
In Silico Clinical Study: CFD Analysis



- **Configuration 1:** No side branches within the implantation segment
- **Configuration 2:** Side branch within the implantation segment but not covered by device
- **Configuration 3:** Side branch (partly) covered by device

In Silico Clinical Study: CONCLUSION III

- PA side branches/PAPS configuration does not affect clinically relevant PA hemodynamics
- High probability of non-favorable side branch configuration in non-controlled implantation procedure





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Thank you for your attention.

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