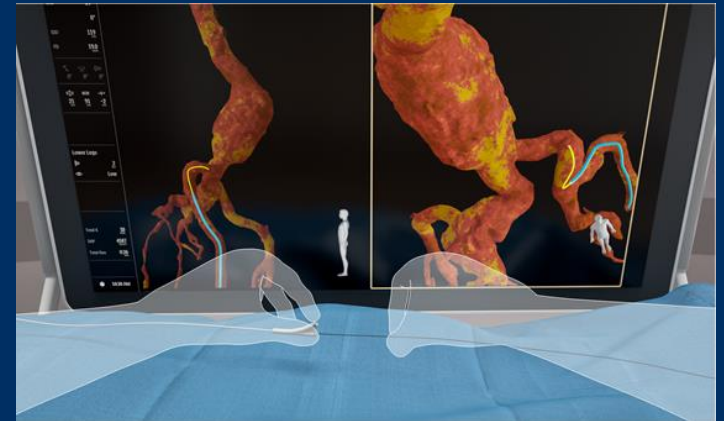


Innovation in 3D navigation: Results from the FORS - Fiber Optic RealShape first-in-human clinical study



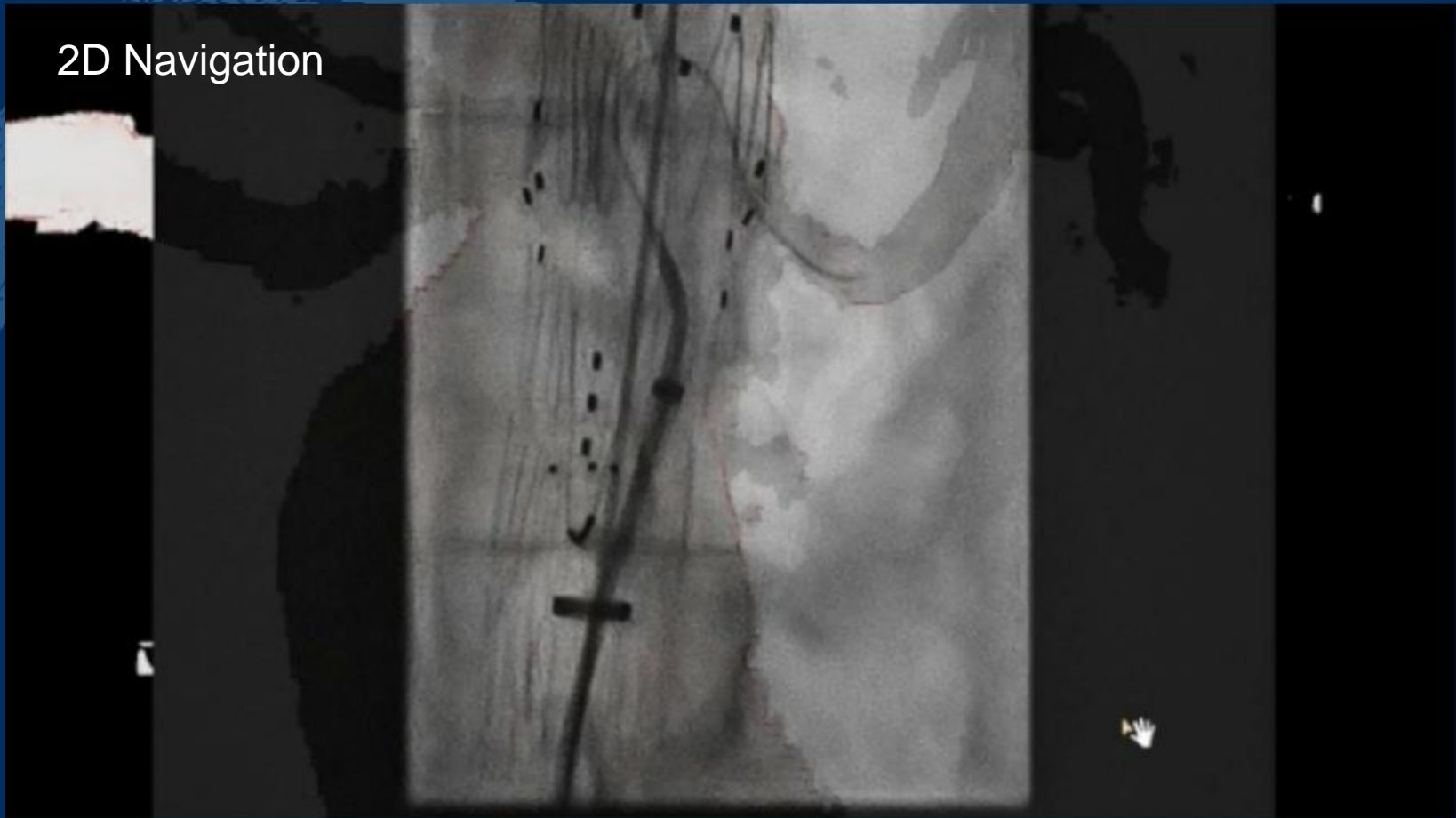
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Disclosure

- Consulting: Terumo Aortic, Cook Medical, Gore Medical
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s): Research collaboration with Philips

Drawback of Endovascular procedures with Fluoroscopy

2D Navigation



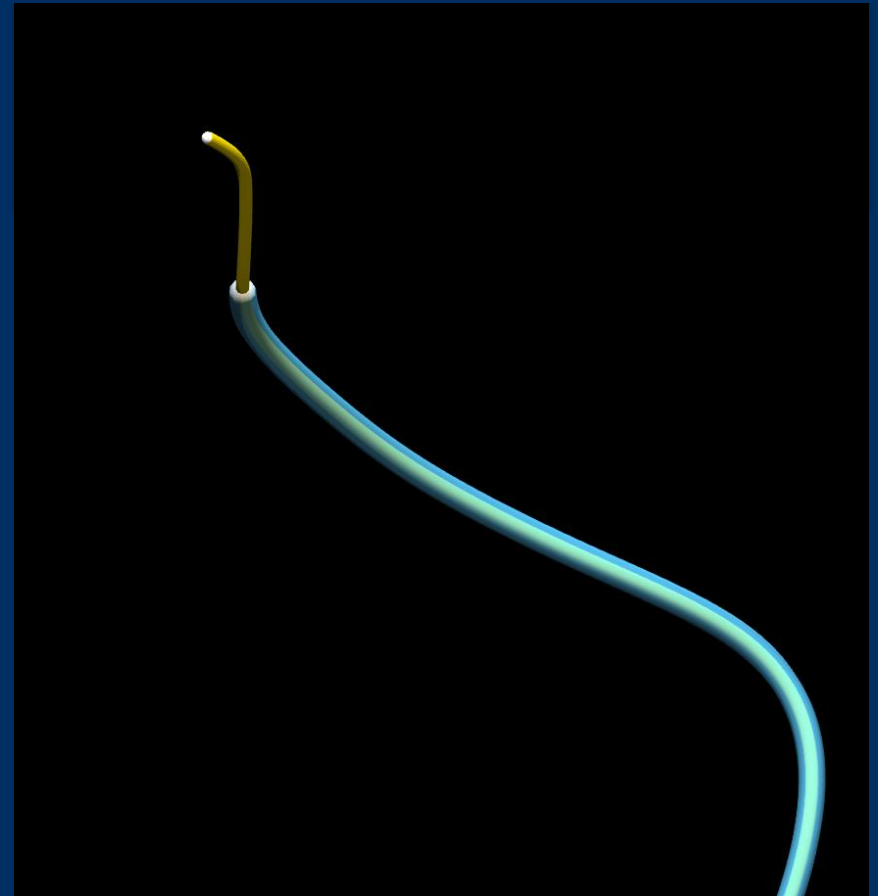
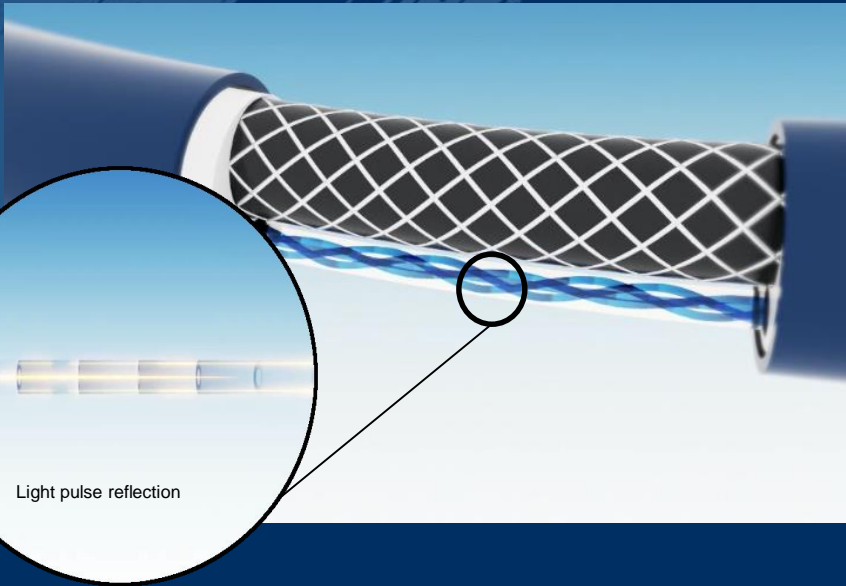
Drawback of Endovascular procedures with Fluoroscopy



LINC

Fiber Optic RealShape (FORS) technology

Real-time 3D visualization, using light



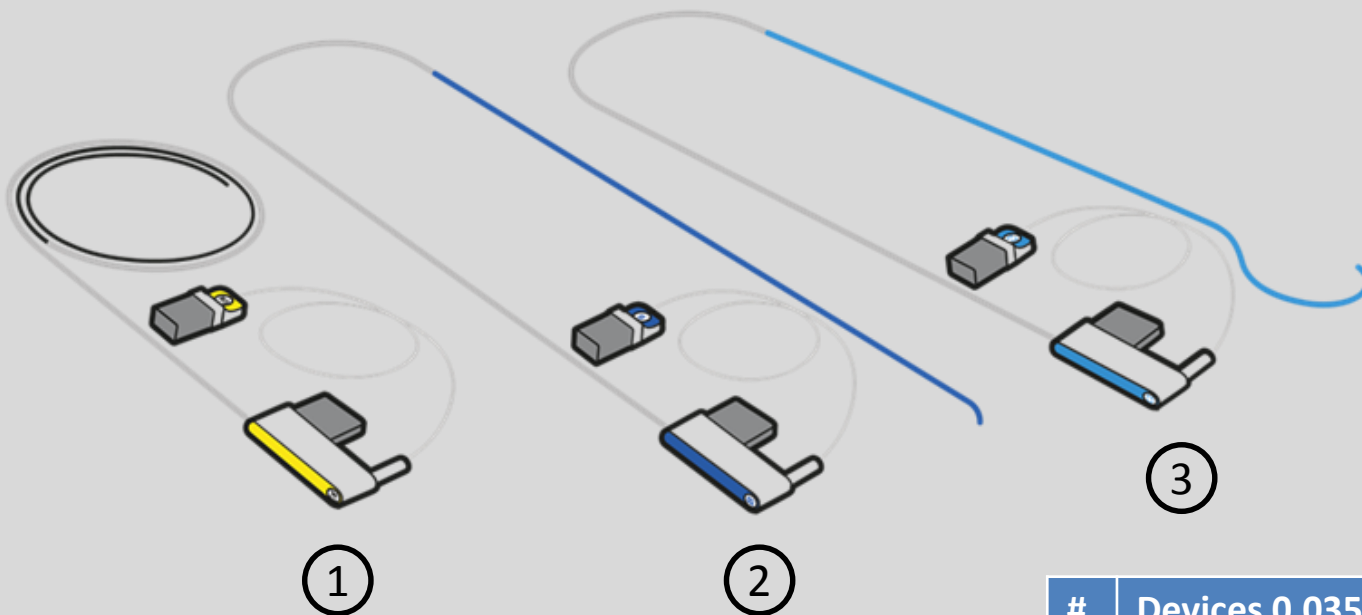
LINC

Fiber Optic RealShape (FORS) technology



FORS enabled angiographic devices

Investigational, not commercially available



#	Devices 0.035"
1	FORS guide wire
2	FORS Berenstein catheter
3	FORS Cobra catheter

First-in-human: FORS FIRST clinical study

Objectives:

Feasibility study for using the FORS technology in endovascular aortic and peripheral procedures

Inclusion:

Consecutive patients scheduled for standard or complex (fenestrated/ branched) EVAR or for iliac or SFA PTA (until 60 cannulations tasks)

Enrollment: July - December 2018

Study results shared today for the first time

First-in-human: FORS FIRST clinical study

Results

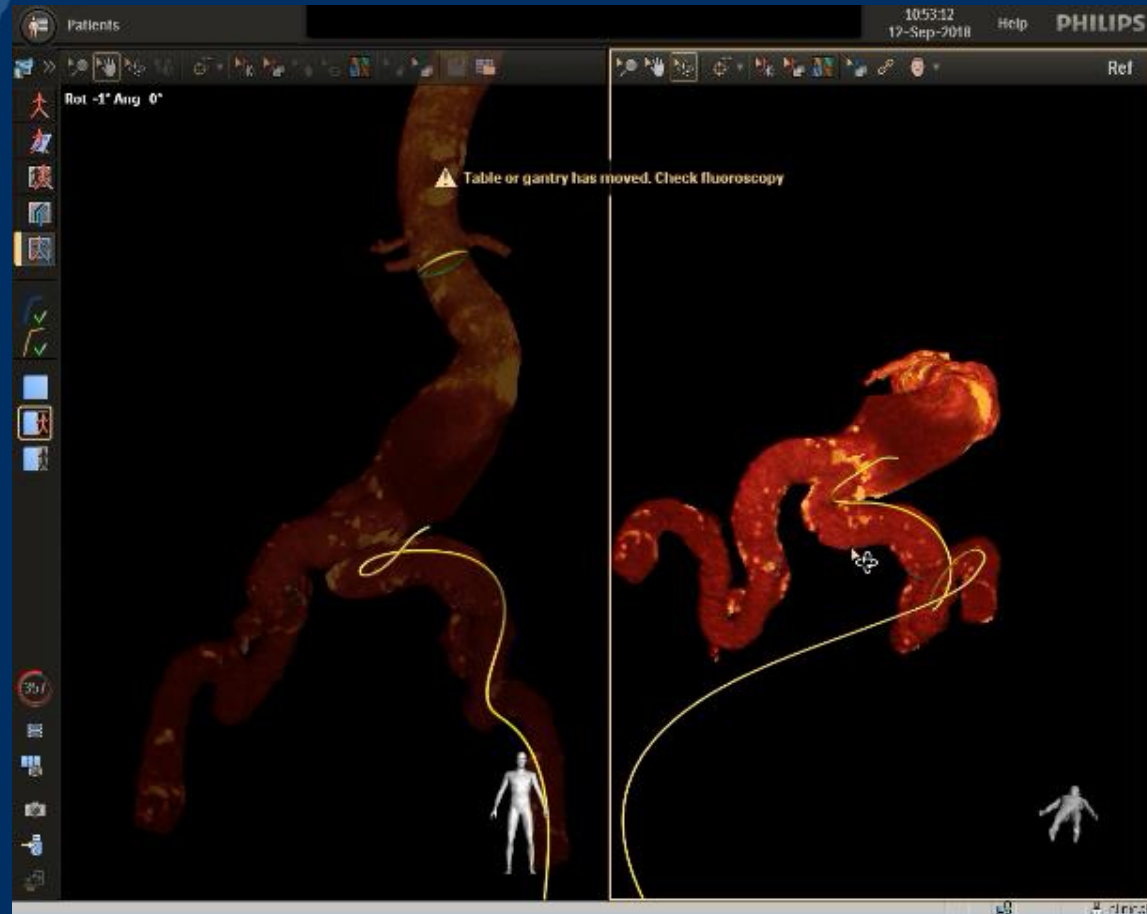
- 21 patients: 13 endovascular Aortic repair (AR)
8 peripheral endovascular intervention (PLT)
- 60/67 navigation tasks completed successfully using a FORS enabled Guidewire and/or a FORS enabled Catheter (91%)
- 7 tasks not completed successfully because different catheter shapes were needed
- Investigators rated the performance of FORS image based guidance (qualitative evaluation) as:
 - “better than standard guidance” in 16 (76%) cases
 - “at par with standard guidance” in 5 (24%) cases

Remarkable moments of the study #1

Challenge: Difficult move to the aorta through tortuous iliac artery

Observation:

- Navigate without fluoroscopy
- Multiple unrestricted viewing angles through huge caudo-cranial rotation of the anatomy, impossible to reach with a C-arm



Remarkable moments of the study #2

Challenge: Cannulation contralateral limb within deployed stentgraft

Observations:

- Navigate without fluoroscopy
- Biplane visualization: simultaneously use of two single shots in different angles as roadmap
- FORS usable within deployed stentgraft

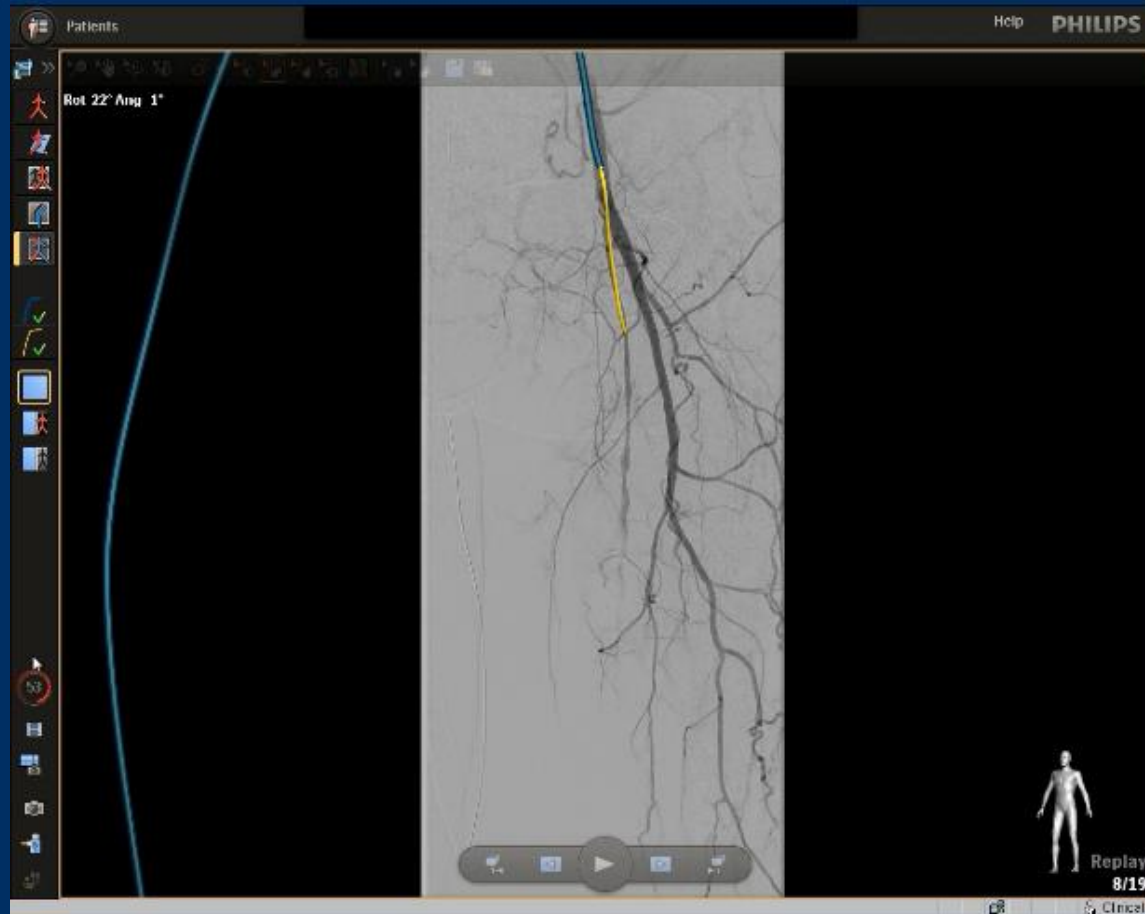


Remarkable moments of the study #3

Challenge: Navigation through stenotic vessels

Observations:

- Navigate without fluoroscopy
- Due to the great visibility of wire and catheter in distinctive colours, DSA is usable as roadmap
- Benefit from the angiographic details



Endovascular procedures using FORS technology are feasible

- Navigation possible without fluoroscopy
- Clear (3D) visualization of wire and catheters
- Multiple, unrestricted viewing angles and Biplane visualization
- CTA, regular angiogram or any other X-ray image can be used as roadmap

Conclusion:

- FORS appears to be a very promising, revolutionary new technology that has huge potential to improve endovascular procedures
- Expansion of the FORS-platform and further research to prove the benefits are needed

Acknowledgements

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- Advisory board: Barry Katzen and Frans Moll
- Thanks to Philips and the UMC-Utrecht FORS team for their innovative spirit to develop such ground breaking technology

