Pre-clinical results of a 3D navigation Innovation: Fiber Optic RealShape (FORS) Technology

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UMC Utrecht

Disclosure

I have the following potential conflicts of interest to report:

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

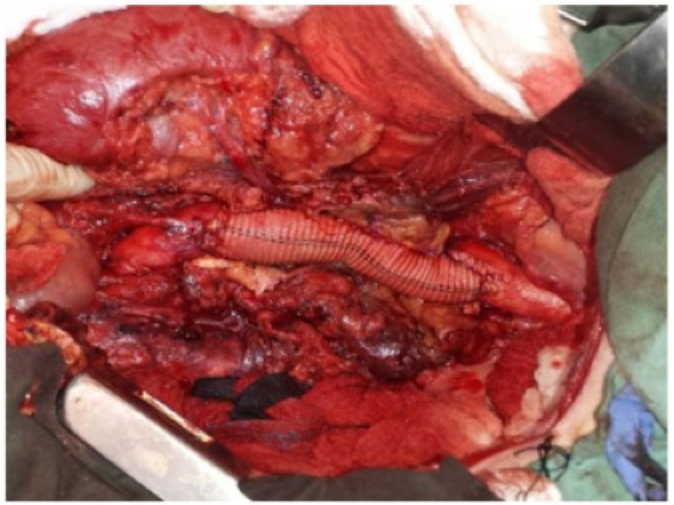
- [ ] I do not have any potential conflict of interest

Endovascular therapy has revolutionized medicine

1980 2010

Vascular Therapy

from open... ...to endovascular



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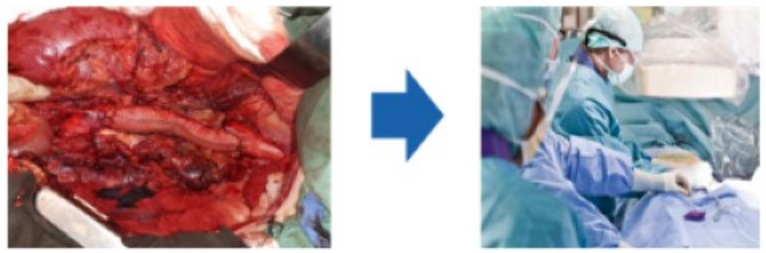
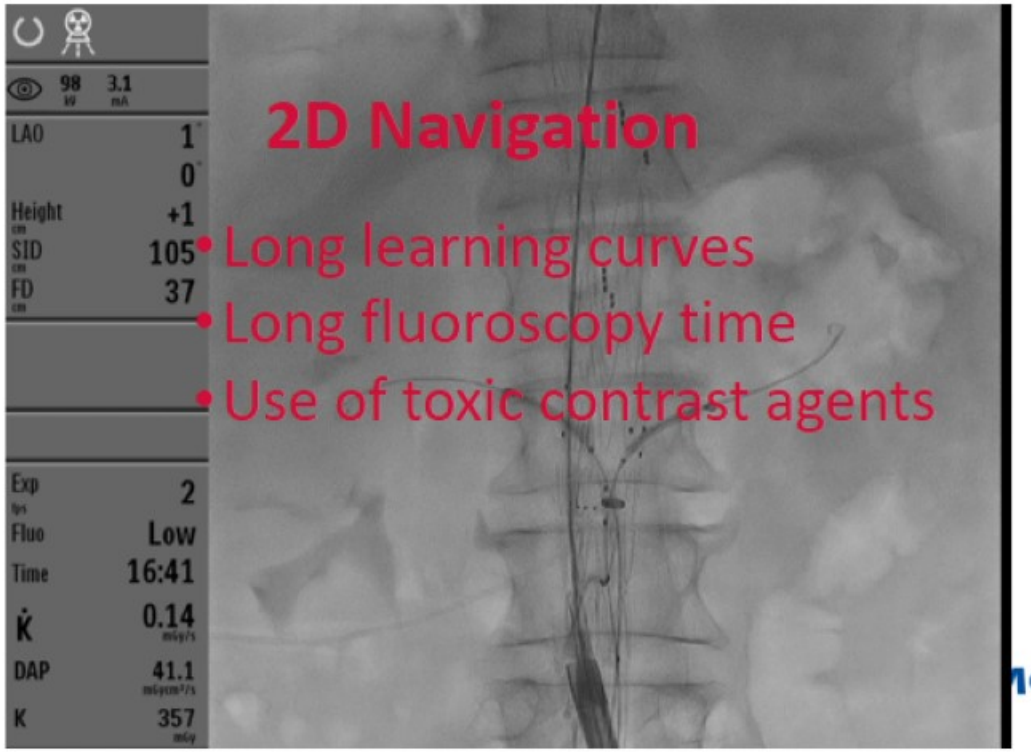
Drawback of Endovascular procedures with Fluoroscopy

1980 2010

Vascular Therapy

from open... ...to endovascular





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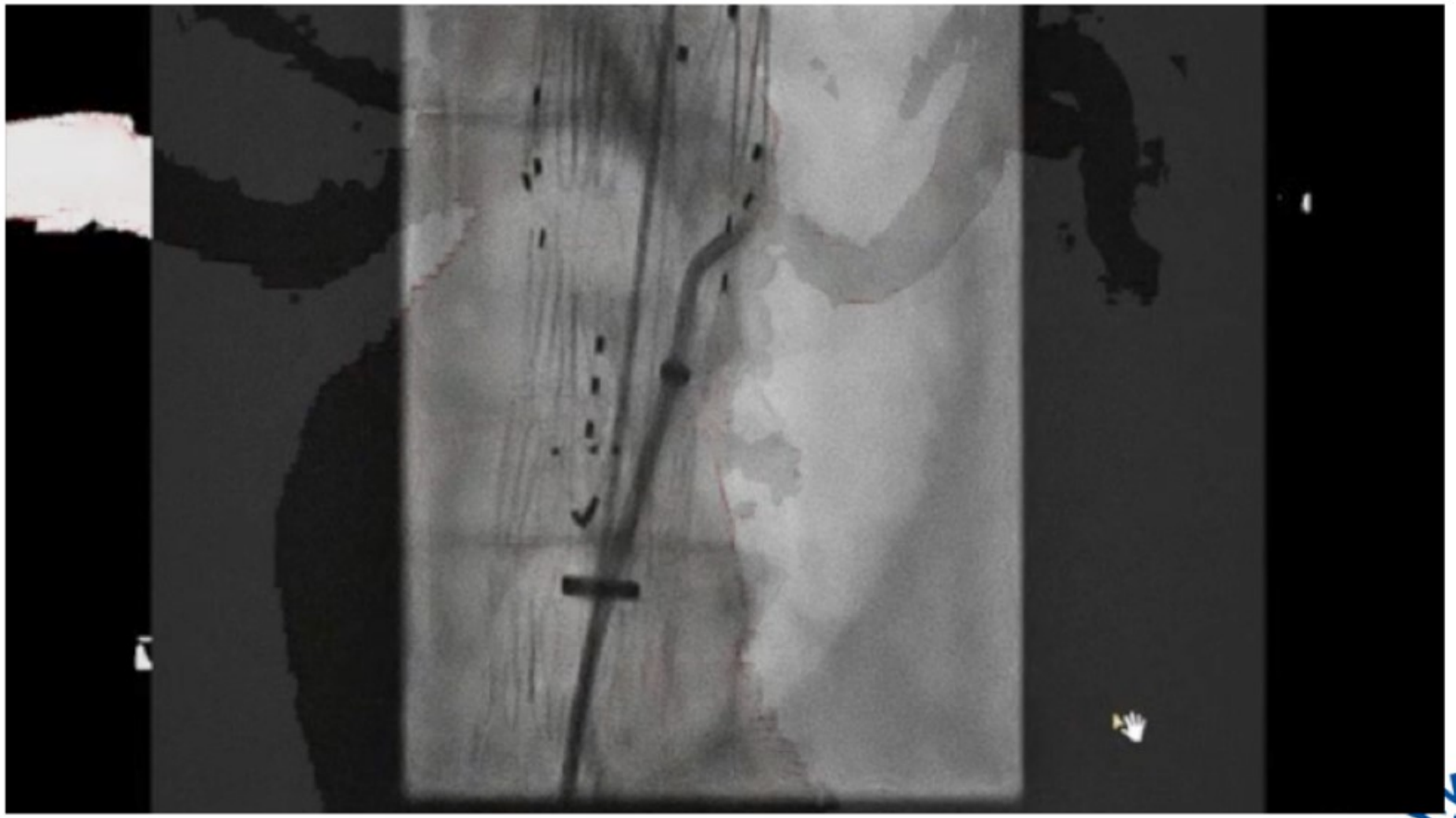
Drawback of Endovascular procedures with Fluoroscopy

2D Navigation



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UMCU-Philips collaboration in Image Guided Therapy has a long history and was intensified in 2012 for

- Development of FORS technology
- Development of FORS devices
- Validation Studies
- Pre-clinical feasibility studies

In collaboration with

Universitätsklinikum Hamburg Eppendorf (dr Tilo Kölbel)
Universitätsklinikum Münster (dr Giuseppe Panuccio)
Henri Mondor Hospital, Creteil (dr Hicham Kobeiter & dr Frederique Cochennec)

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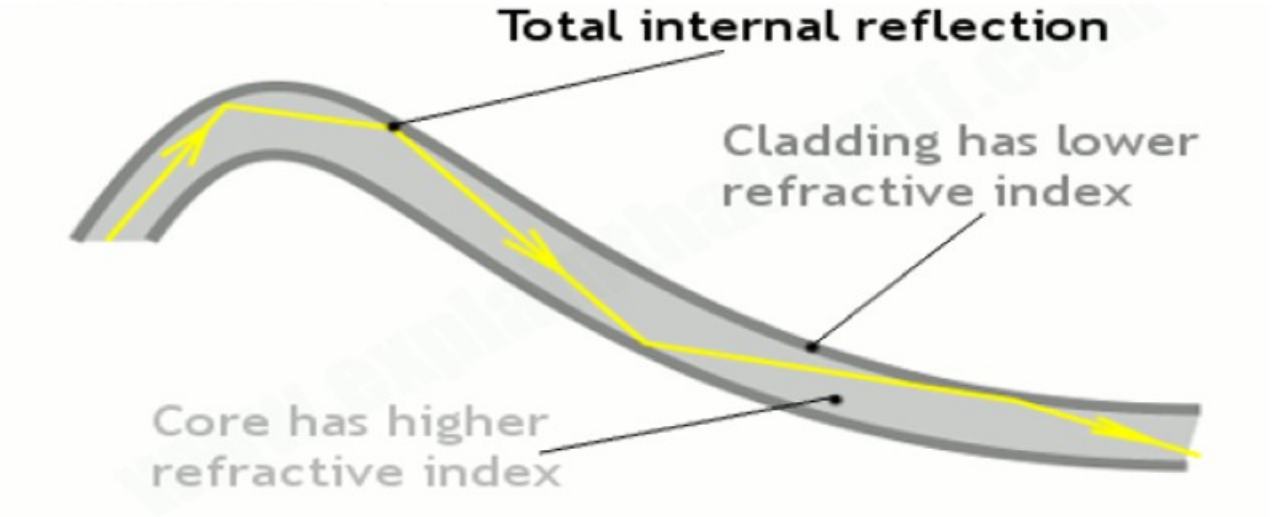
FORS technology allows for real-time 3D visualization, using light



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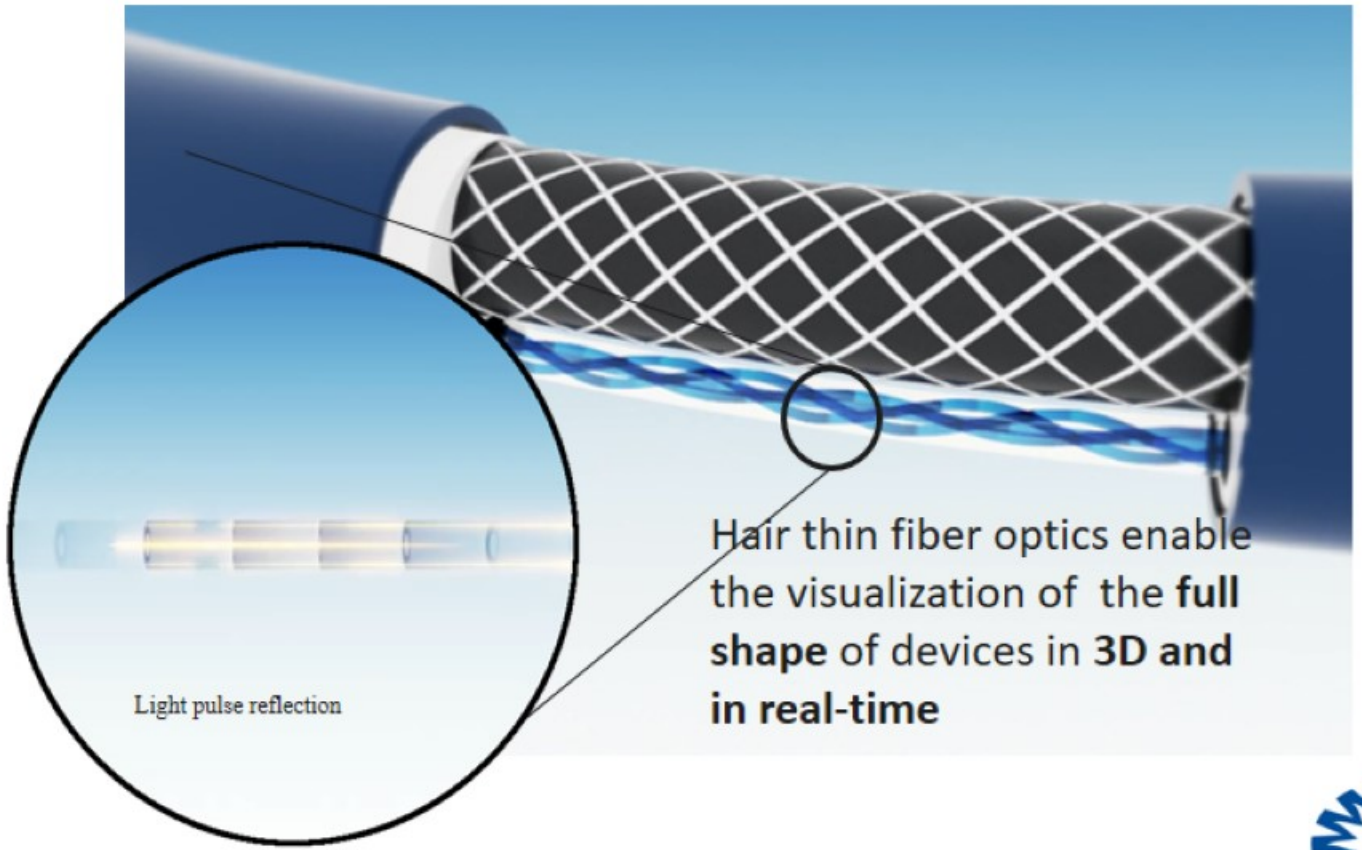
FORS technology allows for real-time 3D visualization, using light

The FORS technology & Medical devices



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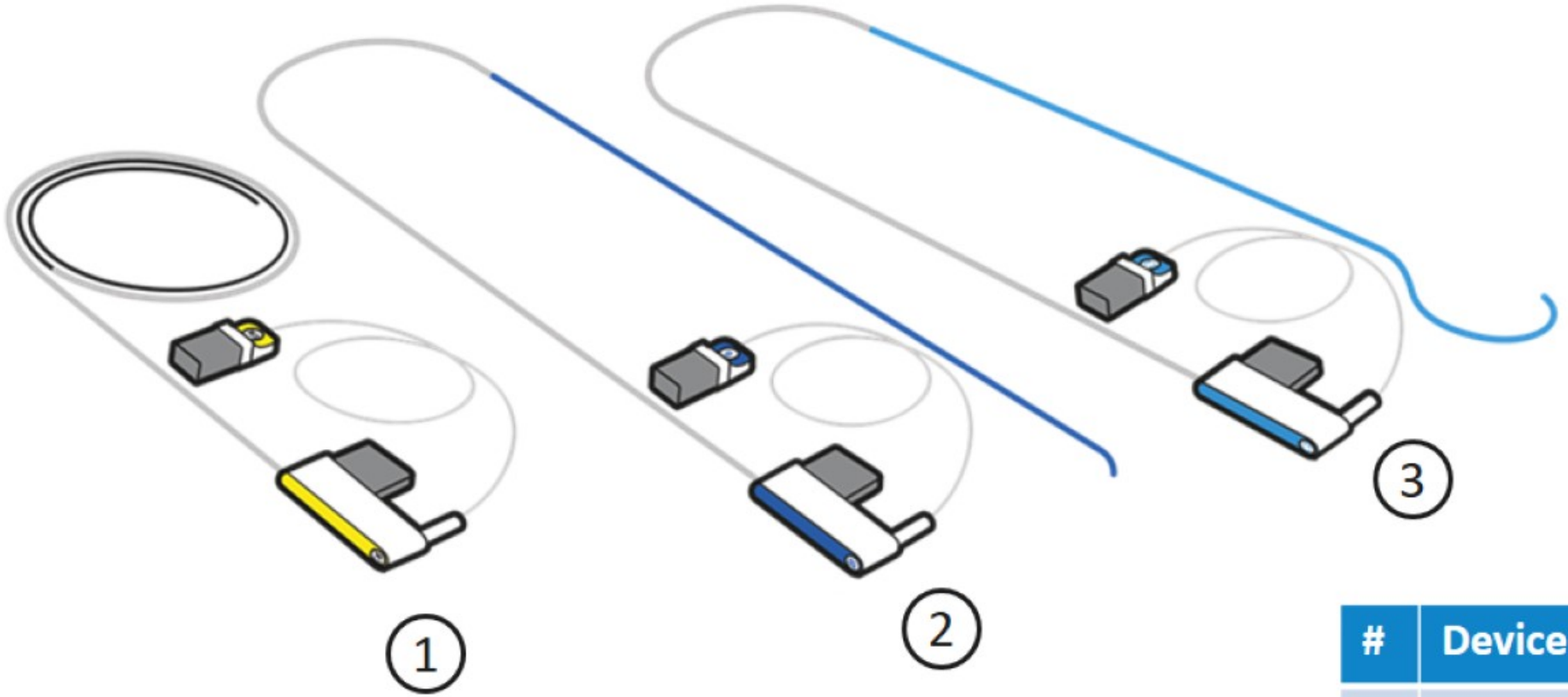
Lower Legs
2
Low

FORS enabled angiographic devices

Investigational, not commercially available

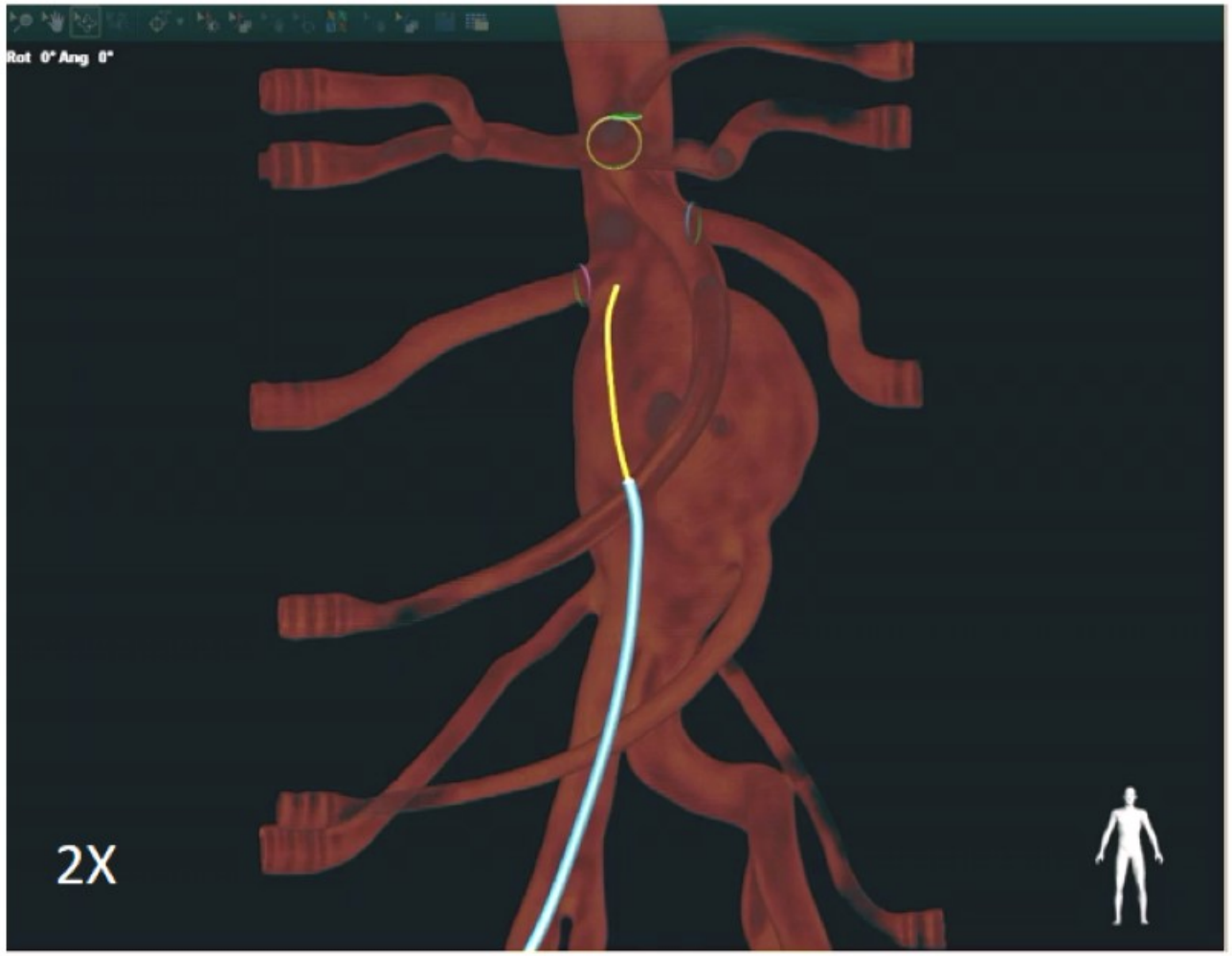


#	Devices
1	FORS guide wire
2	FORS Berenstein catheter
3	FORS Cobra catheter

Gold standard

Cannulation time: 5:45 min
Fluoro time: 5:45 min

with Fiber Optic RealShape (FORS)



Cannulation time: 2:20 min
Fluoro time: 0 min

Pre-clinical validation study *phantom & animal*

Objective

1. **Confirmation that the FORS technology aids the navigation and positioning** during endovascular interventions, in conjunction with fluoroscopy
2. **Qualitative assessment of performance** of the devices & equipment

Methods

- 6 Operators (Derbel, van Hattum, Hazenberg, Kobeiter, van Strijen, van Herwaarden)
- 72 Catheterizations of target vessels in phantom and 72 in swine
    - 60/72 catheterizations with FORS wire & catheter, 12 with FORS wire and commercially available catheter
- Questionnaire for assessment of qualitative performance

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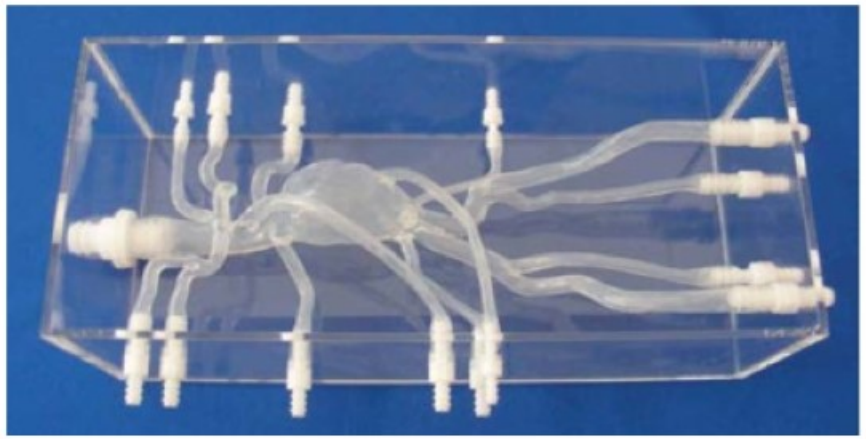
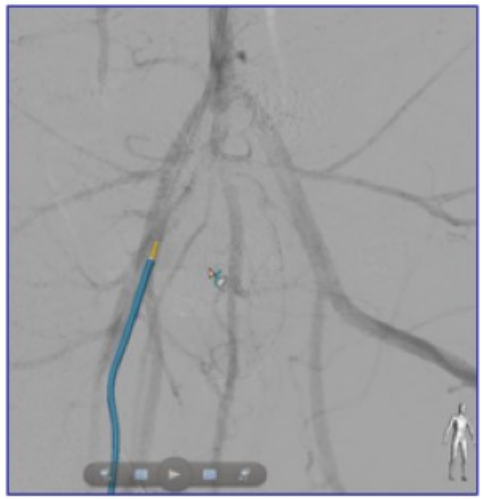
Pre-clinical validation study *phantom & animal*

Results

- Phantom: 72/72 successful catheterizations
- Animal: 70/72 (97%) successful catheterizations
- Questionnaire: Operators enthusiastic about qualitative performance





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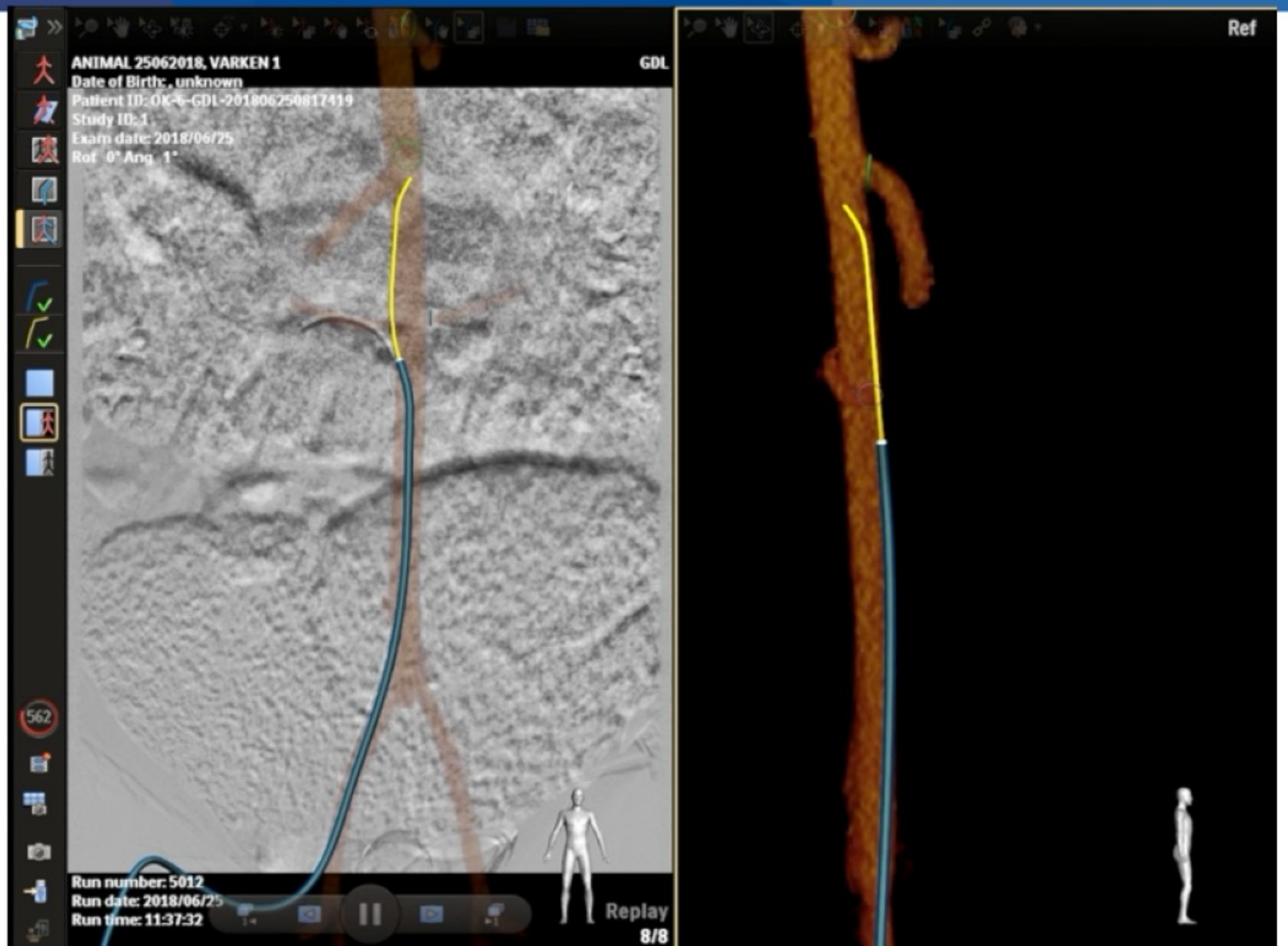
Iliac Cross-over

Right Renal Catheterization



SMA Catheterization

Conclusions from pre-clinical studies

- Endovascular procedures with FORS technology are feasible
- Due to Fiber Optic technology less fluoroscopy is needed
- 3D navigation and 3D visualization of devices is helpful

First-in-Human study

Inclusion:

- 10 consecutive Patients for simple and complex (F)EVAR's
- 10 consecutive patients for peripheral procedures in which hydrophilic floppy guidewire and Berenstein or Cobra catheter are usable

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First-in-Human study

Methods

- First patient treated on July 31 2018

Results expected @LINC 2019

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FORS PROJECT

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- Frederic Cochennec
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- Tilo Kölbel
- Giuseppe Panuccio
- Marco van Strijen

Thanks to **Philips** and **the UMC-Utrecht FORS team** for their innovative spirit to develop such ground breaking technology

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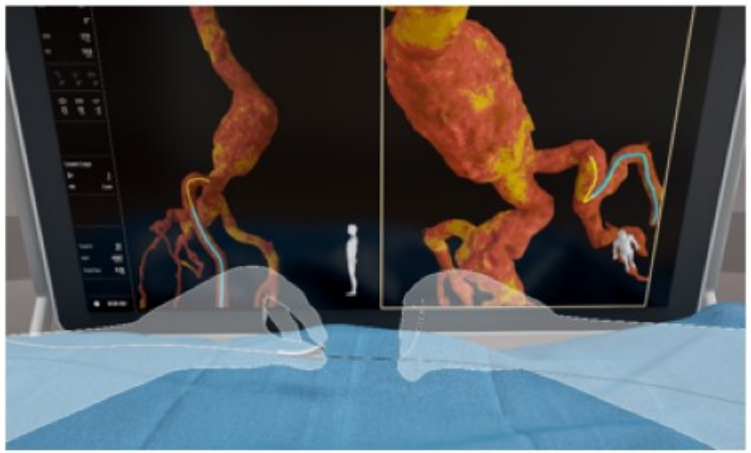

Thank you !

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