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

Joost van Herwaarden
I have the following potential conflicts of interest to report:

- 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

☐ I do not have any potential conflict of interest
Endovascular therapy has revolutionized medicine

1980
Vascular Therapy
from open...

2010
...to endovascular
Drawback of Endovascular procedures with Fluoroscopy

1980
Vascular Therapy from open...

2010
...to endovascular

2D Navigation
- Long learning curves
- Long fluoroscopy time
- Use of toxic contrast agents
Drawback of Endovascular procedures with Fluoroscopy

2D Navigation
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 Cochenneuc)
FORS technology allows for real-time 3D visualization, using light.

Diagram: Total internal reflection
- Cladding has lower refractive index
- Core has higher refractive index
FORS technology allows for real-time 3D visualization, using light.

The FORS technology & Medical devices

Hair thin fiber optics enable the visualization of the full shape of devices in 3D and in real-time.
FORS enabled angiographic devices

Investigational, not commercially available

<table>
<thead>
<tr>
<th>#</th>
<th>Devices</th>
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<tbody>
<tr>
<td>1</td>
<td>FORS guide wire</td>
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<tr>
<td>2</td>
<td>FORS Berenstein catheter</td>
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<tr>
<td>3</td>
<td>FORS Cobra catheter</td>
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Gold standard

with Fiber Optic RealShape (FORS)

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

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

• Phantom: 72/72 successful catheterizations
• Animal: 70/72 (97%) successful catheterizations
• Questionnaire: Operators enthusiastic about qualitative performance
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
First-in-Human study

Methods

- First patient treated on July 31 2018

Results expected @LINC 2019
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Thank you!