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

Joost van Herwaarden, M. Jansen, T. Bloemert-Tuin, GJ. de Borst, EJ. Vonken, CEV. Hazenberg

Dept. of Vascular Surgery, University Medical Center Utrecht
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
Fiber Optic RealShape (FORS) technology
Real-time 3D visualization, using light
Fiber Optic RealShape (FORS) technology
FORS enabled angiographic devices

*Investigational, not commercially available*

<table>
<thead>
<tr>
<th>#</th>
<th>Devices 0.035”</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FORS guide wire</td>
</tr>
<tr>
<td>2</td>
<td>FORS Berenstein catheter</td>
</tr>
<tr>
<td>3</td>
<td>FORS Cobra catheter</td>
</tr>
</tbody>
</table>
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
Summary

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

• International partners: Frederic Cochennec, Hicham Kobeiter, Tilo Kölbel and Giuseppe Panuccio
• 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