A new 3D device guidance technology within the vascular tree
Fiber Optic RealShape (FORS) technology
How does it work and initial clinical results

Joost van Herwaarden
Dept. of Vascular Surgery
University Medical Center Utrecht
The Netherlands

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

Introduction

1980 Vascular Surgery 2020
from open... ...to endovascular

Disadvantages of X-ray navigation

2D Navigation
Grayscale images

Alternative technologies for navigation??

Fiber Optic RealShape (FORS)
**Fiber Optic RealShape (FORS) technology**

With FORS it is possible to show catheter and guidewire
- in real-time
- in 3D
- in distinctive colors
- using light instead of X-ray

**First-in-human: 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

**Enrollment:** July-Dec 2018

**Results**
- 21 patients: 13 endovascular Aortic repair 8 peripheral endovascular procedures
- 67 navigation task (e.g. passing stenotic lesion, catheterization of contralateral limb or target vessels)
- 60/67 navigation tasks completed successfully using a FORS Guidewire and/or FORS Catheter (91%)
- 7 tasks could not be completed successfully with FORS because different catheter shapes were needed
Clinical Case #1

Case #1 AAA
• 88 yrs old man
• Vital and active person
• Rapidly growing AAA 61 mm
• Tortuous iliac access

Task: Navigation through tortuous iliac artery
Observations:
• Multiple unrestricted viewing angles
• Extreme caudo-cranial viewing angle helped, impossible to reach with a C-arm
• Navigation without fluoroscopy

Clinical Case #1

Task: Cannulation contralateral limb
Observations:
• Two X-rays are used as overlay (Biplane)
• 3-D visualization of guidewire and catheter is ideal for cannulation of contralateral limb
• Navigation without fluoroscopy

Clinical Case #2

Case #2
• Female patient, 71 yrs old
• Max walking distance <50 mtrs
• Stenosis in left Superficial Femoral Artery (SFA)

Task: Navigation through stenotic vessels
Observations:
• Due to the great visibility of wire and catheter in distinctive colors, DSA is usable as roadmap
• Benefit from the angiographic details
• Navigation without fluoroscopy

Summary
• FORS appears to be a very promising new technology
  – Navigation possible without fluoroscopy
  – Wire and catheters are visible in 3D (Bi-plane possible)
  – Multiple, unrestricted viewing angles
  – CTA, regular angiogram or any other X-ray image can be used as roadmap
• Expansion of the FORS-platform and further research to prove the benefits are needed
Acknowledgements

Thanks to Philips and UMC-Utrecht FORS team

Thank you for your attention !!