Modern imaging systems will revolutionize EVAR techniques

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Disclosure

My Name: Joost van Herwaarden

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
Introduction

1980

Vascular Surgery

from open...

2020

...to endovascular
Disadvantages of X-ray navigation


CONCLUSIONS: This is the first study to detect an acute DNA damage response in operators performing fluoroscopically guided aortic procedures and highlights the protective effect of leg shielding. Defining the relationship between this response and cancer risk may better inform safe levels of chronic low-dose radiation exposure.
Disadvantages of X-ray navigation

2D Navigation
Grayscale images
Disadvantages of X-ray navigation
Alternative technologies for navigation??
Alternative technologies for navigation??

- IVUS
- TrackCath System
- Electro Magnetic tracking
- Optical Fiber technology
Alternative technologies for navigation??

- IVUS
- TrackCath System
- Electro Magnetic tracking
- **Optical Fiber technology**
Fiber Optic RealShape (FORS)
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With FORS it is possible to show catheter and guidewire

- in real-time
- in 3D
- in distinctive colors
- using light instead of X-ray
Fiber Optic RealShape (FORS)
Phantom Experiment

Gold standard

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

with FORS

Cannulation time: 2:20 min
Fluoro time: 0 min
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
Fiber Optic RealShape (FORS)

<table>
<thead>
<tr>
<th>#</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FORS guide wire</td>
</tr>
<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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</table>
First-in-human: clinical study

Results

• 21 patients:  13 endovascular Aortic repair
  8 peripheral endovascular procedures

• 66 navigation tasks (e.g. passing stenotic lesion, catherization of contralateral limb or target vessels)
Results

- 21 patients: 13 endovascular Aortic repair
  8 peripheral endovascular procedures
- 66 navigation tasks (e.g. passing stenotic lesion, catherization of contralateral limb or target vessels)
- 60/66 navigation tasks completed successfully using a FORS catheter and/or FORS guidewire (91%)
- 5/66 tasks could not be completed successfully with FORS because different catheter shapes were needed
- 1/66 task failed, both with FORS and with regular devices

First-in-human: clinical study
Clinical Case #1

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

Task: Navigation through tortuous iliac artery

Observations:
- Biplane mode
- Unrestricted viewing angles
- Extreme caudo-cranial viewing angle, 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
Case 2:
- 66 yrs old pt
- 6 cm AAA
- juxtarenal: custom made FEVAR
Clinical Case #2

Task: Cannulation LRA

Observations:
• Image fusion with pre-op CTA with X-ray of the deployed fenestrated stentgraft
• Fusion with different available images & 3-D visualization of guidewire and catheter are ideal for cannulation of target vessels
• Navigation without fluoroscopy
Clinical Case #3

Case #3
• Female patient, 71 yrs old
• Max walking distance <50 mtrs
• Stenosis in left Superficial Femoral Artery (SFA)
Clinical Case #3

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
Clinical Case #4

Case 4
- 59 yrs old patient
- Severe Claudication left leg
- Occlusion stent Left Iliac artery
- Jehova whitness
Clinical Case #4

Task: Recanalization of occluded stent

Observations:
• Two X-rays are used as overlay (Biplane)
• Great visibility of guidewire & catheter
• Navigation without fluoroscopy
Summary

• New Imaging systems are being developed
  – to improve visualization
  – to reduce X-ray dose and contrast volume

• FORS appears to be a very promising new technology
  – Navigation possible without fluoroscopy
  – Wire and catheters are visible in color & 3-D
  – Multiple, unrestricted viewing angles (Bi-plane possible)
  – CTA, regular angiogram or any other X-ray image can be used for image fusion

• Expansion of the FORS-platform and further clinical research are needed to prove the benefits
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