FORS technology – clinical experience and data gathered so far

Tilo Köbel, Joost van Herwaarden, Geert Willem Schurink, Giuseppe Panuccio

German Aortic Center Hamburg
Dep. Of Vascular Diseases
University Heart & Vascular Center
University Medical Center Eppendorf

Leipzig, 6–9 June 2023
Disclosures

- Consultant: Cook Medical, Philips, Getinge, Terumo Aortic, Arterica
- Research-grants: Cook Medical, Philips, Terumo Aortic, Medtronic
- Travel-grants: Cook Medical, Getinge, Philips
- Speaking fees: Cook Medical, Philips, Getinge
- Shares: Mokita-Medical, Arterica
- IP: Cook Medical, Terumo Aortic, Mokita Medical
- Royalties: Cook Medical, Terumo Aortic
Trends in Endovascular procedures

Radiation Induced DNA Damage in Operators Performing Endovascular Aortic Repair

Running Title: Ei-Sayed and Patel et al.; Radiation Induced DNA Damage in EVAR

Brain and Neck Tumors Among Physicians Performing Interventional Procedures

Jarek Regan, MD, PhD**, Jodie Goldstein, MD*, Gabriel Bae, MD, and James A. Goldstein, MD**
What is FORS technology

**Fiber Optic RealShape technology**

- Displays the full shape of devices in 3D
- In real-time and in distinctive colors
- In multiple, user controlled, unrestricted projections
- In relation to the patient’s anatomy
- Using light instead of X-ray
FORS experience to date

FORS Clinical partners

Total of 770 FORS procedures to date

- FEVAR
- BEVAR
- EVAR
- PTA
- CERAB
- Deep venous
- IBD
Key Publications to date

- **FORS First (FIH)**
- **EVAR dose study** (UMCU, case-match)
- **FORS Experience** (UHZ, 1st 50)
- **FORS Learn Flow**
- **FORS Learn Registry** (Global, Multi-center, prospective, real-world data)
- **FORS Animal study**
- **Technical Accuracy**
- **FORS Experience** (MUMC, 1st 100)
- **FORS endovascular**
- **FORS aortic repair**
- **Historic case-match study - UMass**
- **Case study**
- **Technical 3D Hub**

Authors:
- J. van Herwaarden, C. Hazenberg, UMCU, EIVES
- G. Panuccio, T. Kölbel, UHZ, JVS
- M. Megens, Philips, Medical Physics
- E. Finnesgard, A. Schanzer, UMASS, Seminars VS
- M. Jansen, J. van Herwaarden, UMCU, EIVES
- G. Panuccio, T. Kölbel, UHZ, JET
- J. Klaassen, J. van Herwaarden, UMCU, MDPI
- E. Finnesgard, A. Schanzer, UMASS, ET
- J. van Herwaarden, C. Hazenberg, UMCU, EIVES
- F. Pavarino, C. Timaran, UTSW, JVS-CIT
- T. Bydlon, Philips, EIVES-VF
First in Human Clinical Feasibility Study of Endovascular Navigation with Fiber Optic RealShape (FORS) Technology

Joost A. van Herwaarden a, Marloes M. Jansen a, Evert-Jan P.A. Vonken b, Trijntje Bloemert-Tuin a, Roland W.M. Bullens c, Gert J. de Borst a, Constantijn E.V.B. Hazenberg a

- prospective, single center, single arm feasibility study
- 3 surgeons, 21 procedures, 22 subjects enrolled

Endpoints:
Technical success & Qualitative Performance
Table 4. Technical success rate with Fiber Optic RealShape (FORS) technology enabled devices in endovascular tasks during endovascular aorto-iliac or peripheral lesion repair in total 21 patients

<table>
<thead>
<tr>
<th>Procedure and endovascular task</th>
<th>Tasks — n</th>
<th>Technical success — n</th>
<th>Proportion (90% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Endovascular aorto-iliac repair</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheterisation of thoracic aorta from groin</td>
<td>21</td>
<td>21</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Catheterisation of abdominal aortal from left arm</td>
<td>1</td>
<td>1</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Catheterisation of coeliac trunk</td>
<td>3</td>
<td>2</td>
<td>0.67 (0.219–1.000)</td>
</tr>
<tr>
<td>Catheterisation of superior mesenteric artery</td>
<td>5</td>
<td>5</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Catheterisation of right renal artery</td>
<td>5</td>
<td>4</td>
<td>0.80 (0.506–1.000)</td>
</tr>
<tr>
<td>Catheterisation of left renal artery</td>
<td>5</td>
<td>5</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Catheterisation of fenestrated cuff (after partial deployment)</td>
<td>1</td>
<td>1</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Cross over aortic bifurcation</td>
<td>1</td>
<td>1</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Catheterisation of contralateral limb stent graft</td>
<td>9</td>
<td>7</td>
<td>0.78 (0.550–1.000)</td>
</tr>
<tr>
<td>Catheterisation of internal iliac artery</td>
<td>2</td>
<td>2</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>All</td>
<td>53</td>
<td>49</td>
<td>0.92 (0.865–0.984)</td>
</tr>
<tr>
<td><strong>Endovascular peripheral lesion repair</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cross over aortic bifurcation</td>
<td>2</td>
<td>1</td>
<td>0.50 (0–1.000)</td>
</tr>
<tr>
<td>Catheterisation of abdominal aorta from groin</td>
<td>2</td>
<td>2</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Recanalisation occluded (stent) in common iliac artery</td>
<td>1</td>
<td>1</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Crossing common iliac artery stenosis</td>
<td>3</td>
<td>3</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Recanalisation occluded internal iliac artery</td>
<td>1</td>
<td>0</td>
<td>0.00 (0–0)</td>
</tr>
<tr>
<td>Crossing superficial femoral artery stenosis</td>
<td>2</td>
<td>2</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Crossing popliteal artery stenosis</td>
<td>1</td>
<td>1</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>Crossing popliteal aneurysm</td>
<td>1</td>
<td>1</td>
<td>1.00 (1.000–1.000)</td>
</tr>
<tr>
<td>All</td>
<td>12</td>
<td>11</td>
<td>0.85 (0.687–1.000)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>66</td>
<td>60</td>
<td>0.91 (0.851–0.967)</td>
</tr>
</tbody>
</table>

CI = confidence interval.
Qualitative Assessment

- **Better** than standard guidance in 16 / 21 cases (76%)

- Usability **on par** with conventional (100%)
Single case study

79-year old, male, 3 navigation tasks in very tortuous anatomy

Medical history:
history of hypertension, CAD, atrial fibrillation
Better understanding of 3D position using multiple projections

3/3 (100%) cannulation success

Relatively **short procedure time** (overall 12 min) with 19 sec. of fluoroscopy
**Endovascular navigation with Fiber Optic RealShape technology**

Giuseppe Panuccio, MD, PhD, a Andres Schanzer, MD, b Fiona Rohlffs, MD, PhD, a Franziska Heidemann, MD, PhD, a Bart Wessels, PhD, c Geert W. Schurink, MD, PhD, d Joost A. van Herwaarden, MD, PhD, e and Tilo Kölbl, MD, PhD, a Hamburg, Germany; Worcester, MA; Best, Maastricht, and Utrecht, The Netherlands

- prospective, single center, ‘real-world’ data
- **50 subjects** enrolled, 201 navigation tasks

**Endpoints:** Technical success, catheterization time, and radiation dose

- FORS used in **186 (93%)** tasks
- **60% success** rate
- **No FORS-related complications**
Predictors of converting to fluoroscopy

- Challenging Target Vessel Angle
- Ostial stenosis
- Branch vs fenestration
- Renal arteries compared to CT / SMA

<table>
<thead>
<tr>
<th>No.</th>
<th>%</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheterization through</td>
<td></td>
<td>.01</td>
</tr>
<tr>
<td>Branch</td>
<td>33</td>
<td>52</td>
</tr>
<tr>
<td>Fenestration</td>
<td>44</td>
<td>59</td>
</tr>
<tr>
<td>None</td>
<td>39</td>
<td>80</td>
</tr>
<tr>
<td>TV with challenging catheterization angle</td>
<td></td>
<td>.007</td>
</tr>
<tr>
<td>TV with ostial stenosis &gt;50%</td>
<td></td>
<td>.001</td>
</tr>
</tbody>
</table>

TV type | .01 |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Celiac trunk</td>
<td>13</td>
</tr>
<tr>
<td>Superior mesenteric artery</td>
<td>26</td>
</tr>
<tr>
<td>Renal arteries</td>
<td>35</td>
</tr>
<tr>
<td>Accessory renal arteries</td>
<td>6</td>
</tr>
<tr>
<td>All</td>
<td>9</td>
</tr>
<tr>
<td>Contralateral gate</td>
<td>19</td>
</tr>
<tr>
<td>Others</td>
<td>8</td>
</tr>
</tbody>
</table>

TV, Target vessel.
Prospective observational data with retrospective matched cohort study (single center)

Endpoints:
1. Technical success
2. Procedure time and radiation
Initial single-center experience using Fiber Optic RealShape guidance in complex endovascular aortic repair

Matched Cohort

**FORS Guidance**

21 F/B-EVAR

**Matching**

BMI, extent, components

**Non-FORS**

61 F/B-EVAR

➢ 81/95 (85%) Technical success
FORS showed

- 37% shorter procedure time
- 41% shorter fluoroscopy time
- 56% lower dose area product

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall</th>
<th>Cohort</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases, No</td>
<td>82</td>
<td>21</td>
<td>61</td>
</tr>
<tr>
<td>Procedure time, minutes</td>
<td>209 (156-288)</td>
<td>140 (121-191)</td>
<td>222 (180-296)</td>
</tr>
<tr>
<td>Fluoroscopy time, minutes</td>
<td>56 (45-75)</td>
<td>37 (26-52)</td>
<td>63 (51-81)</td>
</tr>
<tr>
<td>DAP, Gy x cm²</td>
<td>299 (159-457)</td>
<td>160 (111-189)</td>
<td>363 (245-516)</td>
</tr>
<tr>
<td>Air kerma, Gy</td>
<td>3.3 (1.8-5.7)</td>
<td>1.2 (0.8-2)</td>
<td>3.8 (2.6-7.1)</td>
</tr>
<tr>
<td>Contrast, mL</td>
<td>81 (62-96)</td>
<td>93 (79.5-103)</td>
<td>80 (56-94)</td>
</tr>
</tbody>
</table>

DAP: Dose area product.
Data presented as median (interquartile range) for continuous variables, unless noted otherwise.
Conclusion

- >750 cases using FORS guidance in multiple centers across EU and USA
- Demonstrated advantages of 3D visualization with FORS technology
- Single center demonstration on procedure time reduction
- Radiation reduction shown in complex endovascular aortic repair
- 3D Hub technology introduced → expected to further reduce radiation
- New tools on the horizon: stiffness-profiles, lengths, profile, backloadability, …..
Thank You!

Hamburg
FORS technology – clinical experience and data gathered so far

Tilo Kölbl, Joost van Herwaarden, Geert Willem Schurink, Giuseppe Panuccio

German Aortic Center Hamburg
Dep. Of Vascular Diseases
University Heart & Vascular Center
University Medical Center Eppendorf

Leipzig, 6–9 June 2023