Intraoperative Positioning System (IOPS-From Centerline Biomedical)
A non x-ray 3D imaging and navigation

Mark A. Farber, MD FACS
Chief, Division of Vascular Surgery
Director, Aortic Network
Professor of Surgery and Radiology
University of North Carolina
Chapel Hill, NC

Disclosures

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Cook Medical</th>
<th>WL Gore</th>
<th>Medtronic</th>
<th>Endologix</th>
<th>Centerline Biomedical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Support, Clinical Trials, Consulting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Consulting</td>
</tr>
<tr>
<td>Received</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grants, Honoraria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Honoraria</td>
</tr>
<tr>
<td>Honoraria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Honoraria</td>
</tr>
<tr>
<td>Honoraria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Stock Options</td>
</tr>
</tbody>
</table>

Caution: IOPS is an Investigational Device. Limited by United States law to investigation use only.

Current Imaging Technology

- Imaging is the key component to endovascular therapy

- Fluoroscopy is limited
  - 2 dimensional
  - Radiation exposure

Transition from Fluoroscopy

- Non-radiation generated real time image for operator to "visualize" the anatomy

- Ability to localize "tools" within a specified field

IOPS

- Intraoperative Positioning System

- What does it provide?
  - Interactive 3D Vascular Imaging
  - EM tracking of endovascular "tools" within the vascular tree

Developed a Mathematical Model for Vascular Image Construction

- Generated from DICOM CT data
  - The model was tested by assessing the relative geometry of the aortic branches
  - System was refined to "understand the geometry"
System was Further Developed so that it could “Understand” the Geometry

Commercial Overlay Methods (DICOM-DICOM Overlay)

Overlay Fusion of Mathematical Model

Overlay Fusion of Mathematical Model

Why use the Mathematical Model?

- Model can be discretized at any resolution
  - Mesh appears smooth even when zoomed in
- Can be rendered in wireframe
  - Transparent while also clearly demarcated
- Broken into components
  - Single arteries
  - Aorta

Computer “Anticipated” Deformations

- Can affect alterations at discrete sections of the vessel

Patient-mounted tracking pad maintains registration even in context of gross patient motion
Tracking system attaches to table quickly without tools

Single-use/disposable devices:
- Catheters, guidewire, guidewire, handle, tracking pad

Caution: IOPS is an Investigational Device. Limited by United States law to investigation use only.

- Starts with standard 4 viewports: sagittal, coronal, axial, perspective; can be customized and cut planes used to see “down the barrel”

- Catheter RRA - IOPS

- Catheter RRA - Angio verification

Caution: IOPS is an Investigational Device. Limited by United States law to investigation use only.

- Catheter RRA - Angio verification

Improved Intra-operative Guidance

Caution: IOPS is an Investigational Device. Limited by United States law to investigation use only.
System Usability Testing
- Evaluated usability in simulated OR environment at two sites
- X-ray techs tasked with deploying system
- Clinicians tasked with accessing branch vessels in 3D printed phantom

System Usability Results
- Acceptance criterion was a usability score of 68
  - Technologists:
    - Median score: 87.5
    - Mean score: 82.5
  - Clinicians:
    - Median score: 89
    - Mean score: 87.5
- Mean time required to cannulate: 59 seconds

Augmented Reality / Holographic Guidance
- Headset displays holograms overlaid on reality
- Allows "x-ray vision" - see anatomy inside patient directly
- Studied in porcine model

Guidance, Navigation, and Control
- Displays endograft within delivery system and provides real-time positioning feedback
  - Longitudinal position
  - Rotational / clock position

Head-mounted Displays
- Compact and portable, with true depth perception and superior display
- Can be worn by multiple operators simultaneously
- Holographic visualization is also being developed
• Virtual representation of endograft, with visual aids and alignment indicator for LRA fenestration

Conclusions

• Advancements in technology may help:
  • Reduce radiation exposure
  • Enhance implantation of devices

Fenestration Alignment

• Operator can read real time quantitative feedback without having to look away from work