Design and Evaluation of a Bioelectric Guidewire

Erin Sutton
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Clinical Need

- 8 million intravascular procedures performed under fluoroscopy each year (Schauer 2009)
- Radiation dose equivalent to 250-3500 chest x-rays (CDRH 2010)
- Pediatric, pregnant patients especially vulnerable
- Technically challenging

Can we meet these challenges without radiation?
Inspiration

• electric fish use vision and electrosense to characterize and localize objects

• EOD creates electric field

• measure changes to electric field caused by objects of different impedance

Stamper 2009
In Vivo Catheter Test
Bioelectric Navigation

Segmented CTA

Reference Signals

<table>
<thead>
<tr>
<th>1/Area, mm²</th>
<th>Path Length, mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>0</td>
</tr>
<tr>
<td>0.05</td>
<td>40</td>
</tr>
<tr>
<td>0.025</td>
<td>80</td>
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</table>

Live Signal from Catheter

<table>
<thead>
<tr>
<th></th>
<th>Time, s</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0.5</td>
<td>10</td>
</tr>
<tr>
<td>1</td>
<td>20</td>
</tr>
</tbody>
</table>

Signal Matching

Estimated Catheter Trajectory

*bifurcation
† renal ostia
Project Goal

The state of the art for intravascular navigation is to navigate a guidewire under fluoroscopy to the area of interest then advance a catheter over the guidewire. The current BN prototype uses a commercially available, non-irrigated 6F catheter, too large to be used as a guidewire. The goal of this project is to create a guidewire based on the BN technology.
Team

- Erin Sutton
- Bernhard Fuerst
- Nassir Navab
- Noah Cowan

Source: Miller-Stephenson Medical
Work Plan

• *Research guidewire construction*

• Simulate 3-electrode guidewire in COMSOL

• Design guidewire
  ✤ Define design constraints
  ✤ Fully develop at least 3 designs
  ✤ Perform decision analysis with mentors to pick design
  ✤ Improve embodiment design
  ✤ BOM

• Build guidewire

• Test guidewire in acrylic phantom
  ✤ Measure voltage as guidewire passes through all paths
  ✤ Use video as ground truth
  ✤ Compare results with catheter’s performance
  ✤ Detect branches as small as 2 mm
FEA Simulation

- Comsol: Electric Currents Module, Parametric Study
- Spacing based on Kassab et al. *Ann Biomed Eng.* 2004
- Configurable electrodes
Design Alternatives

“Spring”
- Copper wire soldered to copper wire

“Cylinder”
- Copper wire soldered to Pt cylinders

“Braid”
- Copper braid wound around core
- Selectively exposed wire
## Decision Analysis

<table>
<thead>
<tr>
<th></th>
<th>Weight</th>
<th>Cylinder</th>
<th>Spring</th>
<th>Braid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Raw</td>
<td>Weighted</td>
<td>Raw</td>
<td>Weighted</td>
</tr>
<tr>
<td>Evidence</td>
<td>5</td>
<td>10</td>
<td>50</td>
<td>7</td>
</tr>
<tr>
<td>Ease of Manufacture</td>
<td>4</td>
<td>5</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Durability</td>
<td>4</td>
<td>8</td>
<td>32</td>
<td>4</td>
</tr>
<tr>
<td>Flexibility</td>
<td>3</td>
<td>5</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>Electrode Surface Area</td>
<td>5</td>
<td>10</td>
<td>50</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>167</td>
<td>134</td>
</tr>
</tbody>
</table>

- Patents, literature
- Custom vs off-the-shelf, my skills, available tools
- Electrode/wire connection, corrosion
- Repeated bends in tortuous paths
Embodiment Design

- 0.014” commercial guidewire core
- 0.035” Pt cylinders
- 34 AWG coated stainless steel wire
Experimental Setup

- phantom in 0.9% NaCl bath
- camera records guidewire trajectory as it is drawn through 6 paths at 1-2 mm/s
- signal to input electrode is $\pm 5 \text{ mV}$ at 730 Hz at constant $18 \mu \text{A}$
- voltage between electrodes amplified and filtered
- DFT and matching in Matlab
Results
<table>
<thead>
<tr>
<th>Minimum</th>
<th>Expected</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Plan report and presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>simulation with single stenosis</td>
<td>simulation in phantom's main path</td>
<td>simulation with configurable electrodes</td>
</tr>
<tr>
<td>repaired current sources</td>
<td>replacement current sources</td>
<td>design for new current sources</td>
</tr>
<tr>
<td>CAD design of a single guidewire</td>
<td>several CAD designs for guidewire</td>
<td></td>
</tr>
<tr>
<td>Checkpoint presentation</td>
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<tr>
<td>working guidewire prototype</td>
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<tr>
<td>experiment design report</td>
<td></td>
<td>ACUC submission for in vivo experiment</td>
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<tr>
<td>experimental results from acrylic phantom</td>
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<td>results from experiment in gelatin phantom</td>
</tr>
<tr>
<td>study</td>
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<tr>
<td>Final poster and report</td>
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Next Steps

• Guidewire
  ✤ professional prototype
  ✤ cadaver and *in vivo* studies

• Catheter
  ✤ *in vivo* study
  ✤ software: GUI and matching algorithm
  ✤ add direction detection
Let’s Graduate!

• CIS II final poster — May 18, 2:30-5
• catheter paper — May
• thesis — June
• defense — early July
• vacation — lolz
• have baby — August 10-ish
• thesis edits — October
• start job — November

Please come to grade!
References


