Design and Evaluation of a Bioelectric Guidewire

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Endovascular Navigation

8 million endovascular procedures are performed under fluoroscopy each year in the US [1]:

- Patient radiation dose equivalent to 250-3500 chest x-rays [2]
- Pediatric, pregnant patients especially vulnerable
- Technically challenging
- Complex 3D structures and metallic components are difficult to image, so surgeons resort to "trial and error" to navigate through vessels

DSA: Aortic graft placement. This situation calls for many repeated scans, injections, catheters and guidewires to find the combination that enables the interventionalist to navigate to the area of interest and safely deploy the stent below the level of the renal arteries.

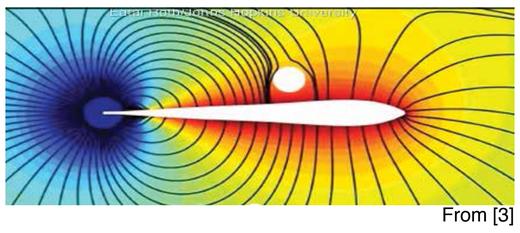
To navigate, clinicians primarily interested in device's current position in the vessel tree relative to surrounding bifurcations, stenses, aneurysms:

- Global position estimate is not required
- Sensor on the device could enable navigation from inside the vessel tree

Bioelectric Navigation

Bio-inspired sensing:

- Weakly electric fish produce a weak, local electric field
- Receptors on the skin detect nearby objects that disturb the voltage distribution in the field



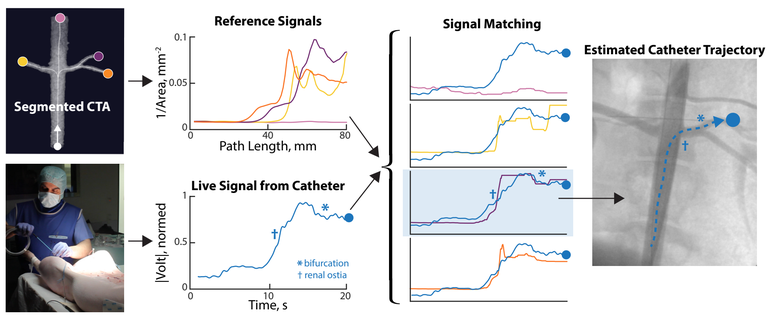
From [3]

We developed a catheter based on the same principle:

- Constant current source sends input signal to electrode on the catheter
- Neighboring electrodes measure the voltage
- Bifurcations, stenoses, and implants are detected based on voltage measurements

Navigation is enabled by [4]:

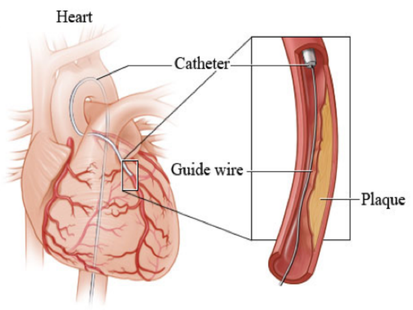
- **Simulation** of bioelectric signals based on a pre-interventional image, yielding a reference signal for each possible branch
- **Acquisition** of intravascular voltage measurements with the sensorized catheter
- **Matching** of the live measured signals from the catheter with the reference signals
- **Visualization** of the most likely position of the catheter in the vessel tree



Project Goal

Create a bioelectric guidewire:

- Navigation is done with a guidewire, not a catheter
- Clinical collaborator specifically requires a guidewire to test BN
- Integral to the eventual adoption of BN
- Test novel design against BN catheter

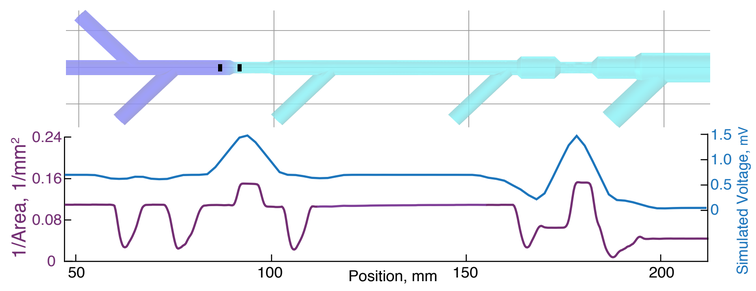


Guidewire Design

Simulation

FEA in COMSOL to determine electrode spacing:

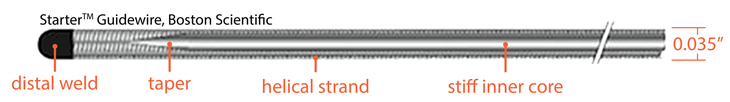
- Electric Currents Module
- Parametric Study: compute voltage distribution as electrodes move through path
- Configurable electrode spacing
- DC voltage, so single input only



Guidewire behaved as expected:

- Electrode spacing based on [5]
- Simulated voltage agrees with inverse CSA

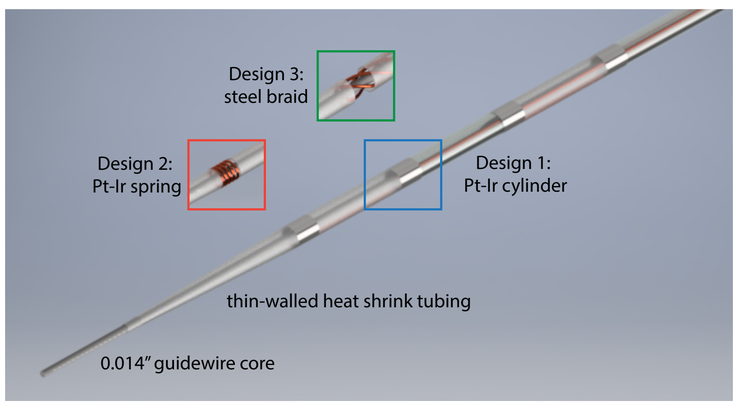
Clinical Guidewire Specifications



Novel design must meet clinical specifications for guidewires in addition to the electrical needs of BN:

- **Safety**: biocompatible materials (ASTM 316L, nitinol, Pt-Ir), atraumatic tip to avoid perforation and dissection
- **Durability**: strong electrode/wire connection, corrosion-resistant
- **Flexibility**: withstands repeated bends in tortuous paths
- **Size**: 0.035" outside diameter to fit into catheters

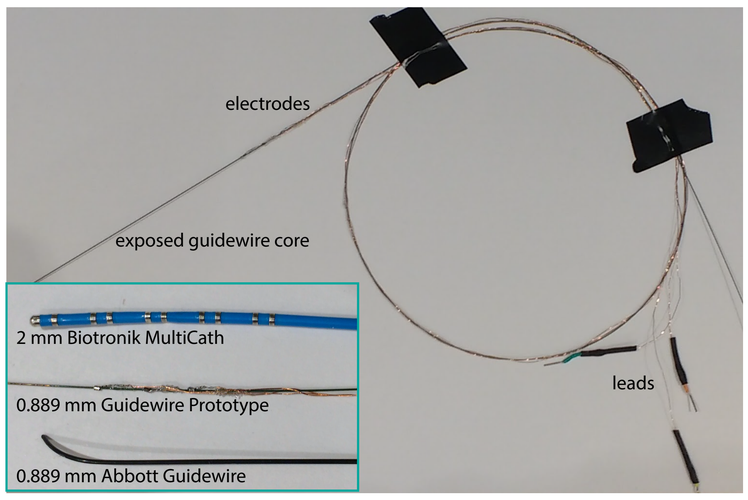
Design Alternatives



Decision Analysis

	Weight	Cylinder		Spring		Braid	
		Raw	**Weighted**	Raw	**Weighted**	Raw	**Weighted**
Safety	5	10	**50**	10	**50**	10	**50**
Evidence	5	10	**50**	7	**35**	3	**15**
Ease of Manufacture	4	5	**20**	8	**32**	6	**24**
Durability	4	8	**32**	4	**16**	3	**12**
Flexibility	3	5	**15**	7	**21**	7	**21**
Electrode Surface Area	5	10	**50**	6	**30**	3	**15**
Total			**217**		184		137

Prototype Construction



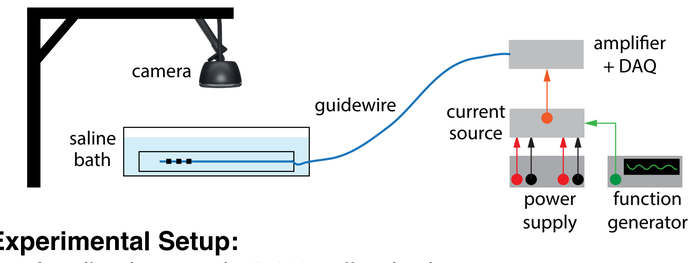
Features:

- 0.014" guidewire core
- 3 Pt-Ir electrodes with adjustable spacing
- 0.15 mm enameled Cu connecting wires

Compromises:

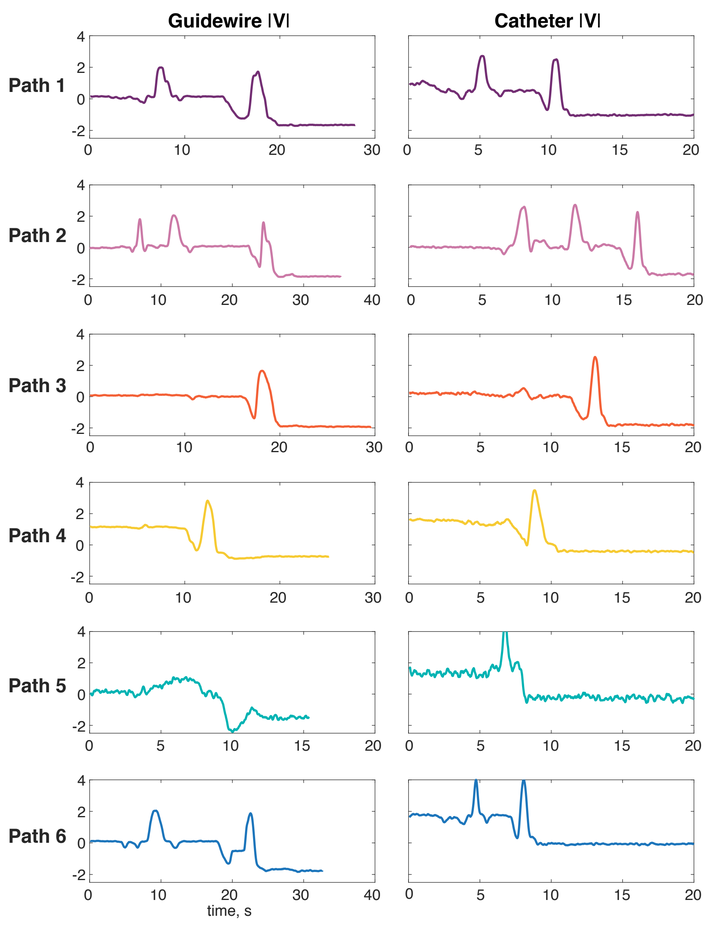
- Stiff distal tip
- No polymer coating -- not suitable for biological tissue
- Improvised leads

Experimental Validation



Experimental Setup:

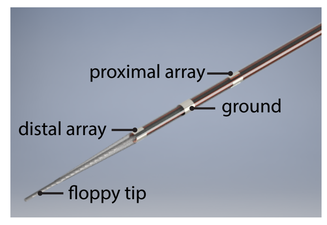
- Acrylic phantom in 0.9% saline bath
- Camera recorded guidewire trajectory as it was drawn through 6 paths at 1-2 mm/s
- Input signal is ±5 mV, 730 Hz, 18 μA
- Repeat with Biotronik MultiCath catheter



Discussion

Next Steps:

- Atraumatic, floppy tip
- Professional prototype with direction detection
- Mechanical tests for trackability and torqueability
- *Ex vivo* experiment



Deliverables

I met all of the minimum and expected deliverables on time. I decided to forego the gelatin experiment to give additional time to develop the prototype.

Minimum	Expected	Maximum
Project Plan report and presentation		
simulation with single stenosis	simulation in phantom's main path	simulation with configurable electrodes
repaired current sources	replacement current sources	~~design for new current sources~~
CAD design of a single guidewire	several CAD designs for guidewire	
Checkpoint presentation		
working guidewire prototype		
experiment design report		ACUC submission for *in vivo* experiment
experimental results from acrylic phantom study		~~results from experiment in gelatin phantom~~
Final poster and report		

References

1. Schauer DA, Linton OW. "NCRP Report No. 160, Ionizing radiation exposure of the population of the United States, medical exposure–are we doing less with more, and is there a role for health physicists?" *Health Phys.* 2009; 97(1):1–5.
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3. Stamper SA, Roth E, Cowan NJ, Fortune ES. "Active sensing via movement shapes spatiotemporal patterns of sensory feedback." *J Exp Biol.* 2012; 215(9):1567-1574.
4. Fuerst B*, Sutton EE*, Ghotbi R, Cowan NJ, Navab N. "Bioelectric navigation: A new paradigm for intravascular device guidance." *Medical Image Computing and Computer-Assisted Intervention.* 2016; 9902.
5. Kassab GS, Lontis ER, Gergersen H. "Measurement of coronary lumen area using an impedance catheter: Finite element model and in vitro validation." *Ann Biomed Eng.* 2004; 32(12):1642-1653.

US Patent: "System and Method for Bioelectric Localization and Navigation of Interventional Medical Devices". Nassir Navab, Noah Cowan, Bernhard Fuerst, Eric Fortune