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Advanced Computer-Integrated Surgery Checkpoint: Bioelectric Guidewire

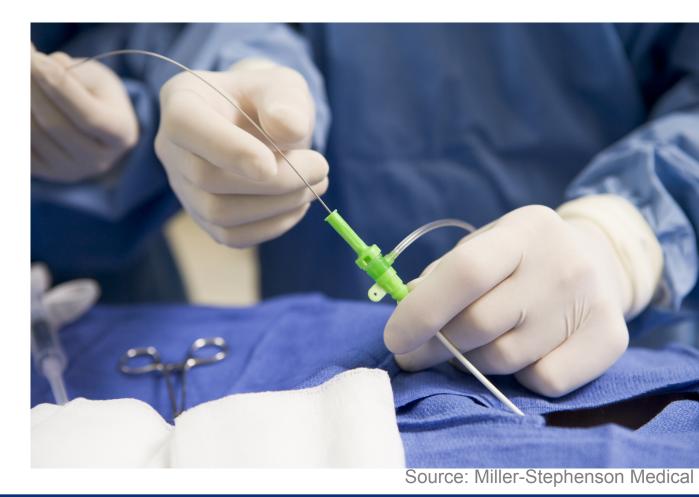
Erin Sutton April 11, 2017





Team

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- Nassir Navab
- Noah Cowan





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Clinical Need



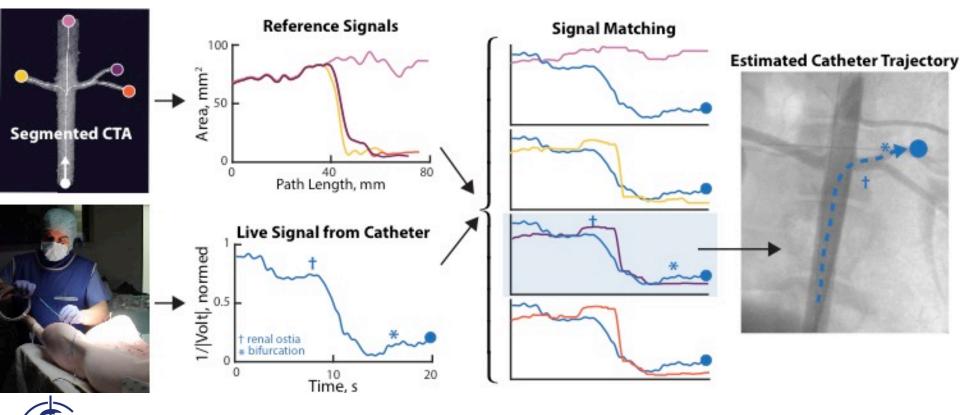
- 8 million intravascular
 procedures performed under
 fluoroscopy each year Schauer 2009
- Radiation dose equivalent to 250-3500 chest x-rays ^{CDRH 2010}
- Pediatric, pregnant patients especially vulnerable
- Technically challenging

Can we meet the technical challenges without radiation?

Bioelectric Navigation

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ABORATORY



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Project Goal

The state of the art for intravascular navigation is to first 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, nonirrigated 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.

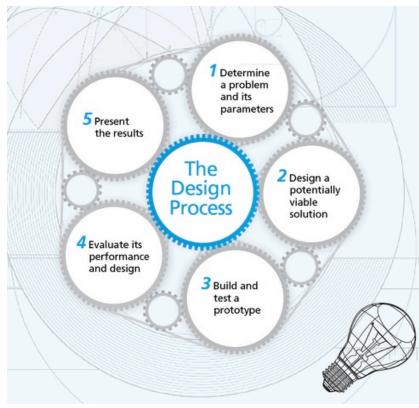


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Work Plan

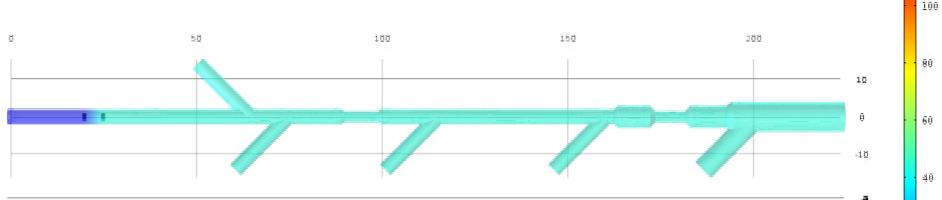
- Research guidewire construction
- Simulate 3-electrode guidewire
- Design guidewire
 - Define design constraints
 - Fully develop at least 3 designs
 - Perform decision analysis with mentors to pick design
 - Improve embodiment design
 - BOM
- Build guidewire
- Test guidewire in acrylic phantom
 - 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



Source: Assist Development

Volums: Electric potential (µV) Volume: 1

FEA Simulation



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



± 43.8

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Guidewire Designs



"Spring"Spring soldered to copper wire

Polyethlene tubing

"Cylinder"

 Copper wire soldered to Pt cylinders



"Braid"

- Copper braid wound around core
- Selectively exposed wire

0.014" guidewire core

Decision Analysis

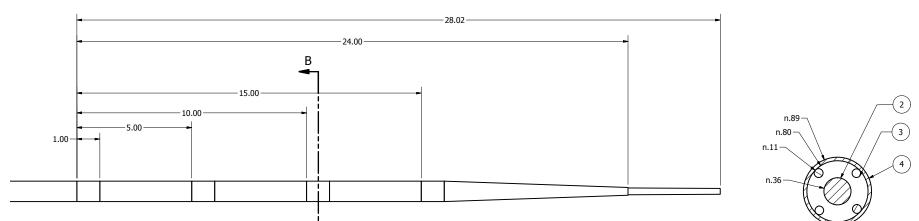
Patents, literature		Weight	С	ylinder		Spring	Braid	
			Raw	Weighted	Raw	Weighted	Raw	Weighted
Custom vs off-the-shelf, my skills, available tools	Evidence	5 10 5		50	7	35	3	15
	Ease of Manufacture	4	5	20	8	32	6	24
	Durability	4	8	32	4	16	3	12
Electrode/wire connection, corrosion	Flexibility	3	5	15	7	21	7	21
	Electrode Surface Area	5	10	50	6	30	3	15
,								
	Total			167		134		87
Repeated bends in / - tortuous paths								I



Embodiment Design

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- 0.014" guidewire core
- 0.035" Pt cylinders
- 34 AWG coated stainless steel wire





Dependencies

Dependency	Status						
How to solder steel to Pt?	Resolved – not difficult						
Difficult to source small diameter heat shrink	Resolved – 0.5 mm sufficient						
I'm not supposed to operate x-ray machine	Resolved – canceled gelatin experiment						

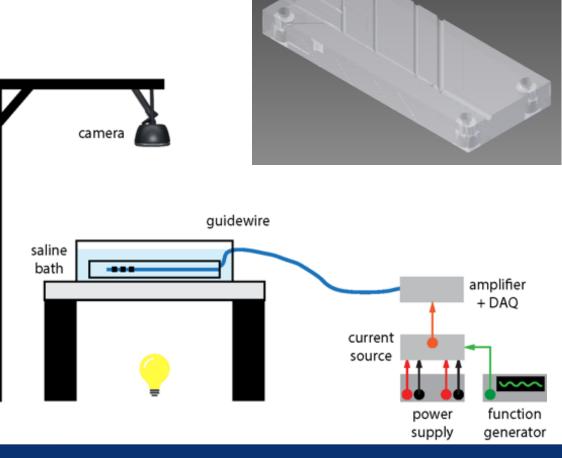
Other challenges:

- Constant current sources delayed at manufacturer, so I made a breadboard version
- Only 10 Pt cylinders, so I will make a 2-electrode guidewire to enable more prototypes



Experimental Plan

- phantom in 0.9% NaCI bath
- camera records guidewire trajectory as it is drawn through 6 paths at 1-2 mm/s
- signal to input electrode is ±5 mV at 730 Hz at constant 18 μA
- voltage between electrodes amplified and filtered
- DFT and matching in Matlab



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



Schedule

	17-Feb	24-Feb	3-Mar	10-Mar	17-Mar	24-Mar	31-Mar	7-Apr	14-Apr	21-Apr	28-Apr	5-May	12-May	19-May
write Project Plan	21-Feb													
read articles														
simulate guidewire														
make seminar presentation			2-Mar											
create 3 design alternatives														
write critical review														
source materials														
repair current sources														
build prototype														
write experiment design report								5-Apr						
write checkpoint presentation									11-Apr					
experiment, acrylic phantom														
analyze data														
make gelatin phantom														
experiment, gelatin phantom														
analyze data														
design in vivo test														
write final report														18-May
make poster														18-May
original plan														
new plan														
completed														

References

- B. Fuerst*, E.E. Sutton*, R. Ghotbi, N.J. Cowan, and N. Navab. Bioelectric navigation: A new paradigm for intravascular device guidance. In Sébastien Ourselin, William Wells, Mert R. Sabuncu, Gözde Unal, and Leo Joskowicz, editors, *Medical Image Computing and Computer-Assisted Intervention*, volume 9902 of LNCS. Springer, 2016.
- D.A. Schauer and O.W. Linton. 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*, 97(1):1–5, 2009.
- Center for Devices and Radiological Health. Initiative to reduce unnecessary radiation exposure from medical imaging. *US Food and Drug Administration*, Feb 2010.
- Stamper, S., Roth, E., Cowan, N., and Fortune, E. (2012). Active sensing via movement shapes spatiotemporal patterns of sensory feedback. *J Exp Biol*, 215(9):1567-1574.
- UK Endovascular Trainees. [UKETS]. (2013, June 26). Cardiac Catheterisation Part 1 Left Coronary. [video]. Retrieved from <u>https://youtu.be/zF8jk_F9Beo</u>.



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Advanced Computer-Integrated Surgery Thanks!



