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Project Plan: Design and Evaluation of a Bioelectric Guidewire

Mentors

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Summary of the Technology

Bioelectric navigation (BN) is a new technique for guiding intravascular devices without ionizing radiation. A set of electrodes on the tip of the device creates a small, weak electric field inside the blood vessel. Changes in the geometry of the vessel as the device moves cause measurable changes to the signal at the electrodes. That geometry-dependent signal can be mapped to a previously acquired 3D model of the vessel tree, enabling localization of the device.

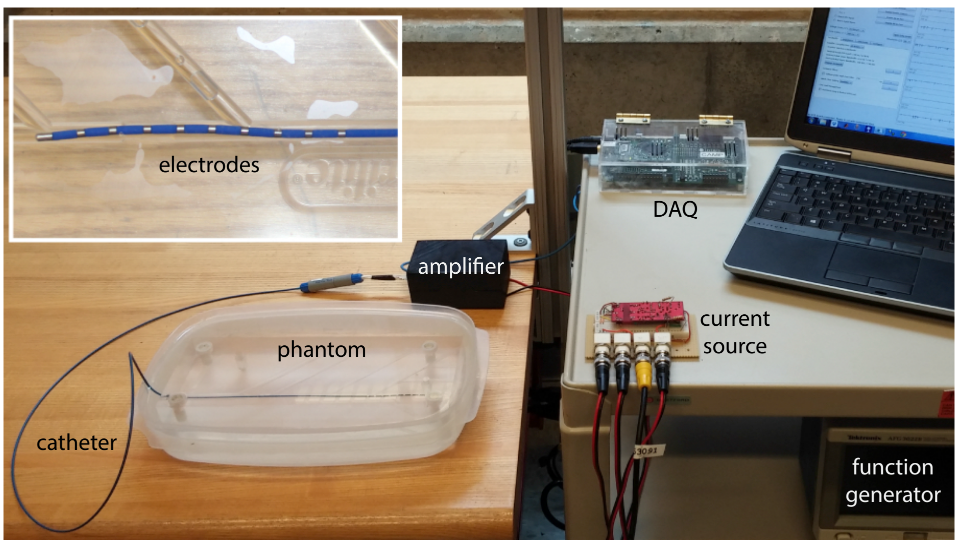

Figure: Experimental setup. For this project, I will design a guidewire to replace the catheter. Image from [1].

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. Guidewires are used for navigation because they are smaller, so there's less chance of puncturing a vessel or getting stuck in a small artery. The current BN prototype uses a commercially available, non-irrigated 6F catheter, too large to be used as a guide wire. The goal of this project is to create a guide wire based on the BN technology.

Relevance

If successful, the guidewire could have a significant impact on minimally invasive endovascular procedures. In the US, there are approximately 8 million endovascular procedures performed every year under fluoroscopic guidance [2]. Each procedure exposes the patient to the equivalent of 250-3500 chest x-rays [3], which means that pediatric and pregnant patients are usually unable to benefit from minimally invasive vascular surgery. While BN seems like a promising technology to reduce the dependence on x-ray guidance, its clinical utility is limited by the fact that our prototype is a catheter rather than a guidewire. Our clinical collaborator has specifically asked for a guide wire so that we can test the navigation capabilities of BN *in vivo*, and the success of this project is integral to the eventual adoption of the technology.

Deliverables

- Minimum
    - Project Plan report and presentation
    - Simulation of 3-electrode guidewire in single stenosis in COMSOL
    - Repaired current sources
    - Seminar presentation (article critique)
    - Single CAD design of guidewire, including Bill of Materials
    - Checkpoint presentation
    - Working guidewire prototype
    - Experiment design report prior to conducting experiments
    - Results from experiment in acrylic phantom
    - Final report
- Expected
    - Simulation of 3-electrode guidewire in a geometry that matches the acrylic phantom's main path
    - Replacement current sources
    - Several CAD designs of guidewire, with core based on 0.014" commercially available guidewire
- Maximum
    - Simulation of guidewire with several electrode configurations
    - New design for the constant current source in Eagle
    - Results from experiment in gelatin phantom
    - Experiment design for *in vivo* test, ready to submit to ACUC

Key Tasks & Dates

Please see attached chart.

Approach

First, I will research guidewire construction. I found an excellent article outlining how to construct custom guidewires [4]. Next, I'll simulate a three-electrode guidewire in COMSOL's electric currents module. I'm interested in how the wire's signal amplitude compares to the catheter's. Next, I will design the guidewire. Working with the mentors, I will define the design constraints. I will fully develop at least three designs. The mentors and I will perform a decision analysis to pick the best design. I will improve the embodiment design based on their comments and create the bill of materials. Then I'll order all of the parts and construct the prototype. Finally, I will test the guidewire in the acrylic phantom. I'll measure the voltage as the guidewire passes through all six paths of the phantom, using video recordings as ground truth for the guidewire position. I will compare the results to the catheter's performance in the same phantom. If time allows, I'll conduct a similar study in a gelatin phantom with x-ray fluoroscopy for ground truth position measurement.

List of Dependencies and Plans for Resolving

- Not sure how to solder stainless steel to platinum – ask Iulian and Noah
- May have trouble sourcing sufficiently small diameter heat shrink tubing – either don't coat wire for this experiment or look into specialty polymer manufacturers
- I'm not supposed to use the C-arm, which is necessary for the gelatin experiment – Ravi and Manu have offered to operate the C-arm for me during the experiment

Management Plan

I'm the only student working on this project, so I am responsible for all of the deliverables. I will attend a weekly meeting with the other students working on CAMP CIS II projects. Noah and I will meet once a week to discuss progress, and I will attend CAMP's weekly meeting.

Reading List

1. 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.
2. 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.
3. Center for Devices and Radiological Health. Initiative to reduce unnecessary radiation exposure from medical imaging. *US Food and Drug Administration*, Feb 2010.
4. Condino, S., Ferrari, V., Freschi, C., Alberti, A., Berchiolli, R., Mosca, F., and Ferrari, M. (2012). Electromagnetic navigation platform for endovascular surgery: how to develop sensorized catheters and guidewires. *J Med Robotics Comput Assist Surg*, 49(2):344-356.
5. 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.
6. UK Endovascular Trainees. [UKETS]. (2013, June 26). *Cardiac Catheterisation Part 1 – Left Coronary*. [video]. Retrieved from https://youtu.be/zF8jk_F9Beo.

	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														
create 3 design alternatives														
make seminar presentation				9-Mar										
source materials														
repair current sources														
write checkpoint presentation							30-Mar							
build prototype														
write experiment design report								5-Apr						
experiment, acyrlic phantom														
analyze data														
make gelatin phantom														
experiment, gelatin phantom														
analyze data														
design in vivo test														
write final report														18-May
make poster														18-May