Team #28 Electrically Controlled Steerable Catheter

BME @uiowa

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Initial Statement of Problem

Catheters are limited in precision and degrees of motion because of their reliance on mechanical movements. These limitations lead to extended procedure times.

Background & Motivation

- Atrial fibrillation is the most common arrhythmia in adults, effecting nearly 2 million people, requiring catheter ablation. [4]
- Manual and robotic catheterization procedures are emerging more in a clinical setting as they're able to minimize procedure time and improve patient outcomes. [5]
- Project aims at developing an electronically steerable catheter to be utilized in minimally invasive procedures to combat cardiac arrhythmias, a growing epidemic in the United States.

Population

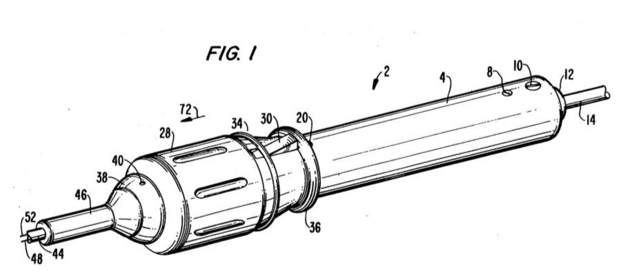
- Surgeons – decrease fatigue and increased precision
- Patients – improved outcomes through higher precision catheters and shorter procedural times

Insights about Problem

- Current cost of automated catheter systems in $1.2 - $1.5 million [1]
- Heart disease is the number one cause of death in the United States [2]
- Catheter design should have tactile feedback to avoid dissection of artery origins [3]
- Kinking catheters pose problems that increase procedure time [3]
- The catheter might be pulled out when the electronic motors pull the tendons of the catheter [3]
- No parts of current catheters are reusable for sterility reasons [3]

Prior Art

A wide range of steerable catheter designs exists on the market possessing numerous actuation mechanisms and feature sets. Although generally purpose-built for a single procedure type, mechanically actuated catheters will fall under one of the following types, each with its own advantages:



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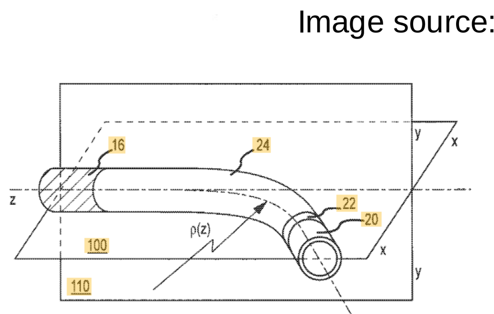

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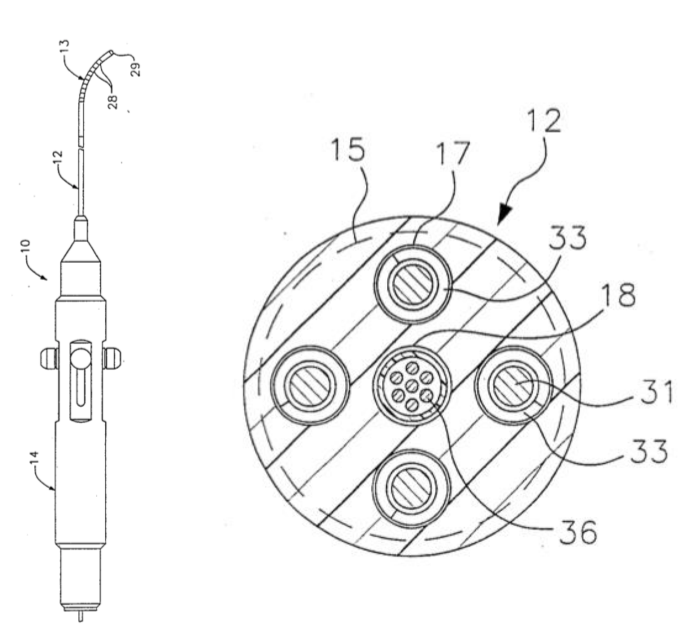
Unidirectional/Bi-directional catheter

- Uses 1-2 pull-wires to deflect tip
- Movement is limited to a fixed plane
- Fewer pull-wires allows for single single-handed operation
- Catheter must be rotated manually to achieve full range of motion, which increases procedure time and error.

4-way catheter

- Uses 4 pull-wires to deflect tip
- Wider range of motion afforded
- One-handed operation sacrificed as two actuation mechanisms are needed; assistance is often needed
- Range of motion still limited relative to electronic control



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Robotic catheter

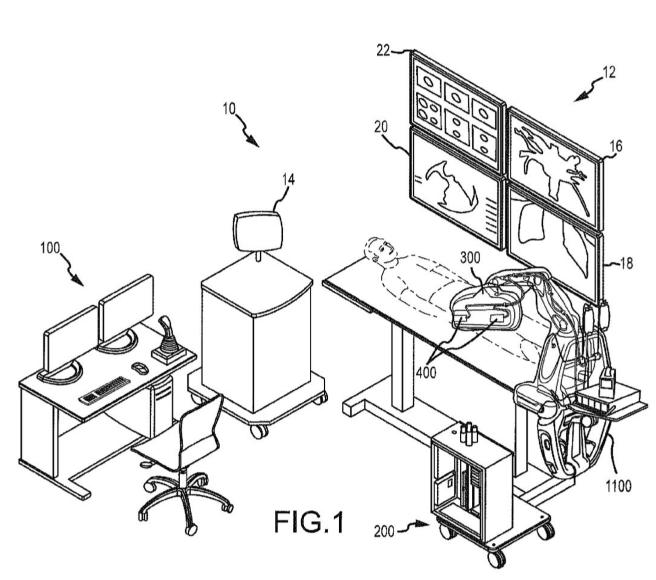

Image source:[6]

- Uses 4+ pull-wires to deflect tip
- Electronic control of a greater number of pull-wires allows for very accurate motion
- Remote control allows physician to avoid routine radiation exposure
- Cost is significantly higher

Need Statement

A way to improve the usability and actuation of steerable catheters controlled by surgeons to increase surgical accuracy and decrease procedural time.

Functional Requirements

Functional Requirements	Design Parameters	Analysis	References
Affordable	Ability to attach to existing catheters, low cost motors, low cost computer.	Attachment to other catheters eliminates need to produce more than just the handle. Cost of use per year, compare against competitors values and non-electronic catheters.	https://www.advisory.com/research/service-line-strategy-advisor/the-pipeline/2013/robotic-pci-is-it-worth-the-cost
Electronically Controlled	Arduino, motors, power source to pull tendons.	Requirement from the mentors and the company.	Interview with mentors.
Ability to attach to catheter	Use standardized attachments based on company, Easy modifiable catheter attachment design.	Test attachment with general catheters. Catheter design will be such that it can change slightly.	Trials using various existing catheters. Mentors Lexi Leggat, Jesse Haworth, Jessica Kloehn.
One-handed use	Multiple axis controller, ergonomic handle.	Overall consensus from surveys and physician's opinions.	Physicians
Contour catheter to different turns/angles with precision	Multiple axis control, current multiple tendon catheter designs.	Measure precision against angles with current designs.	Physicians specified what wires they currently use and angles they desire.
Waterproof	Sealed casing, mechanical input must not have an opening associated with it.	Testing in aqueous scenarios.	Cycle testing and team verification.
Sterile	Ability to attach to catheter with cover over it, Ability to sterilize between procedures.	Comply with ISO 11737-2:2009.	https://www.iso.org/obp/ui/#iso:std:iso:11737:-2:ed-2:v1:en

Anticipated Engineering Skills and Tools

- Electrical safety tests in aqueous conditions
- Fatigue testing on handle to catheter attachment
- Angle precision and repeatability experiments
- CAD Model for handle design (Creo)
- Arduino programming for motor movement

Milestones

	Week of:	Sep 09	Sep 16	Sep 23	Sep 30	Oct 07	Oct 14	Oct 21	Oct 28	Nov 04	Nov 11	Nov 18	Nov 25	Dec 02	Dec 09	Dec 16
Identify	Identify Problem															
	Develop Need Statement															
	Identify Functional Requirements															
Invent	Research/Develop Strategies															
	Select Best Strategy															
	Brainstorm/Develop Concepts															
	Select Top 3 Concepts															
	Prove Best Concept															
	Prove Concept to Mentors															
Implement	Determine Materials Needed for Prototype															
	Develop Prototype															
	Test Prototype															

Potential Needs/Wish List

- Several existing steerable catheters with varying designs to visualize its size in a clinical setting
- Arduino Nano
- Stepper motors
- Lithium-Ion battery
- Access Medical Murray R&D laboratory to validate test methods and develop new critical design intents

References

[1] Magellan is quick and good for complex ops. (2012, September 4). Retrieved from https://healthcare-in-europe.com/en/news/magellan-is-quick-good-for-complex-ops.html.
[2] Heron, M. (2018, July 26). Deaths: Leading Causes for 2016. *National Vital Statistics Reports*, *67*(6). Retrieved from https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm
[3] Interview with three surgeons from the Iowa Heart Center at Mercy Hospital
[4] Rojas, F., & Valderrábano, M. (2013). Effect of Age on Outcomes of Catheter Ablation of Atrial Fibrillation. *Journal of atrial fibrillation*, *6*(1), 886. doi:10.4022/jafib.886
[5] Ali, A., Plettenburg, D. H., & Breedveld, P. (2016, February 4). Steerable Catheters in Cardiology: Classifying Steerability and Assessing Future Challenges. Retrieved from https://ieeexplore.ieee.org/document/7399367.
[6] M. Kirschenman and T. Tegg, "Robotic Catheter Device Cartridge," U.S. Patent 0 132 950 A1, May 17, 2018
[7] Japanese Patent 4 194 691 B2, October 3, 2008
[8] R. Nitzsche, "Tip Deflectable Steerable Catheter," U.S. Patent 5 190 050 A, Mar. 02, 1993
[9] X. Guo et al., "Deflectable catheter with distal deflectable segment," WO Patent 2009/085470 A1, Jul. 9, 2009.