# DEVELOPMENT OF A DEVICE TO RETAIN MEMORY IN ULTRASOUND CATHETERS

# ROBOTIC SURGERY AND ITS INTEGRATION IN SOCIETY

A Thesis Prospectus
In STS 4500
Presented to
The Faculty of the
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Bachelor of Science in Biomedical Engineering

By
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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Approved: C. Atherine D. Baritaud Date: Dec. 9, 2019
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Approved: ______________________ Date: 11/12/19.
Dr. Nishaki Mehta, M.D., Department of Medicine

According to the American Heart Association, atrial fibrillation (AF) is one of the most common heart arrhythmias affecting the lives of at least 2.7 million Americans (American, 2016). As seen in Figure 1, atrial fibrillation is the chaotic and irregular beating of the heart, causing the heart's two upper chambers to be out of sync with the two bottom chambers. Left untreated, atrial fibrillation can weakened the heart muscles and increase the risk of strokes, heart failure, and many other heart-related complications (Mayo Clinic, 2019). Catheter-based procedures are performed to treat atrial fibrillation and eradicate the origin of the arrythmia. As more advanced catheters began emerging, physicians in electrophysiology (EP) started to rely more heavily on them for guidance and treatment during therapeutic procedures. A common catheter used during electrophysiology procedures is the ultrasound imaging catheter, a device that uses measurements from pulse-echo signals to create images. This imaging modality is often used in conjunction with other catheters to perform cardiac ablations, a procedure that can correct arrhythmias such as atrial fibrillation. Ultrasound catheters have been adopted for their "low cost, high accessibility, and lack of ionizing radiation"

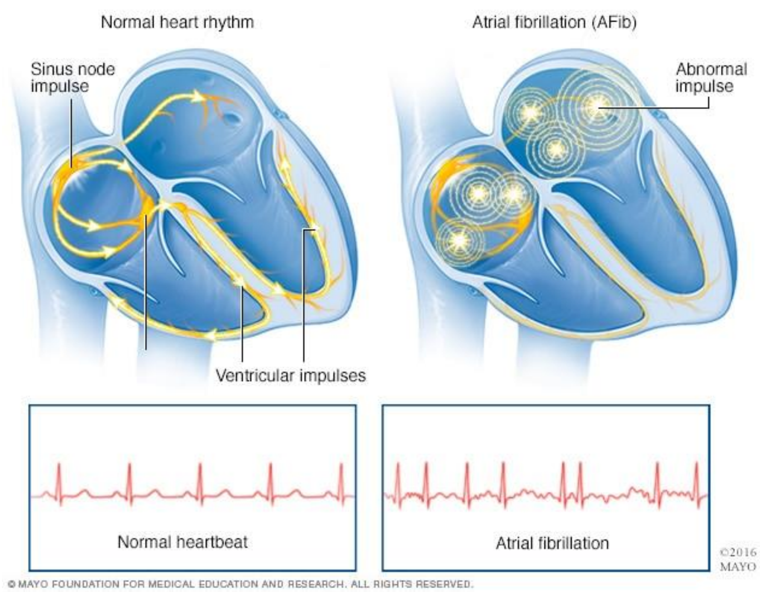


Figure 1. Atrial Fibrillation. In a normal heart (left), electrical signals are sent from the sinus node in the atrium and travel down to the ventricles, causing them to contract and pump blood regularly. In a heart experiencing atrial fibrillation (right), electrical signals are being fired from multiple areas in the atria. These chaotic and irregular signals travel to the ventricles, causing them to contract irregularly and beat faster than normal. Atrial fibrillation can be diagnosed by its recognizable appearance on a rhythm strip (bottom) (Mayo Clinic, 2019).

(Cikes, Tong, Sutherland, & D’hooge, 2014), providing invaluable guidance when maneuvering multiple catheters inside the heart by producing cardiac structural and functional images in detail (Ren, Marchlinski, Callans, & Herrmann, 2002) and “real-time, direct observations” (Stephens et al., 2008, p. 1570) of the heart’s interior. Ultrasound imaging catheters allow for the continuous monitoring of catheter location within the heart, a reduced need for extended X-ray exposure, and the use of local anesthesia rather than general anesthesia which reduces procedure time and patient risks.

Although it is a tool pertinent to cardiac procedures with numerous advantages, an issue regarding the maneuverability and stability of the ultrasound catheter can significantly impact the overall effectiveness of the treatment. As laid out in the Gantt chart in Figure 2, under the guidance of Assistant Professor of Medicine Nishaki Mehta, M.D. and Biomedical Engineering graduate student Katerina Morgaenko, Biomedical Engineers Avinaash Pavuloori and I will conduct technical research over the duration of two semesters to resolve the issues with the current design of ultrasound imaging catheters by developing a device that will hold the

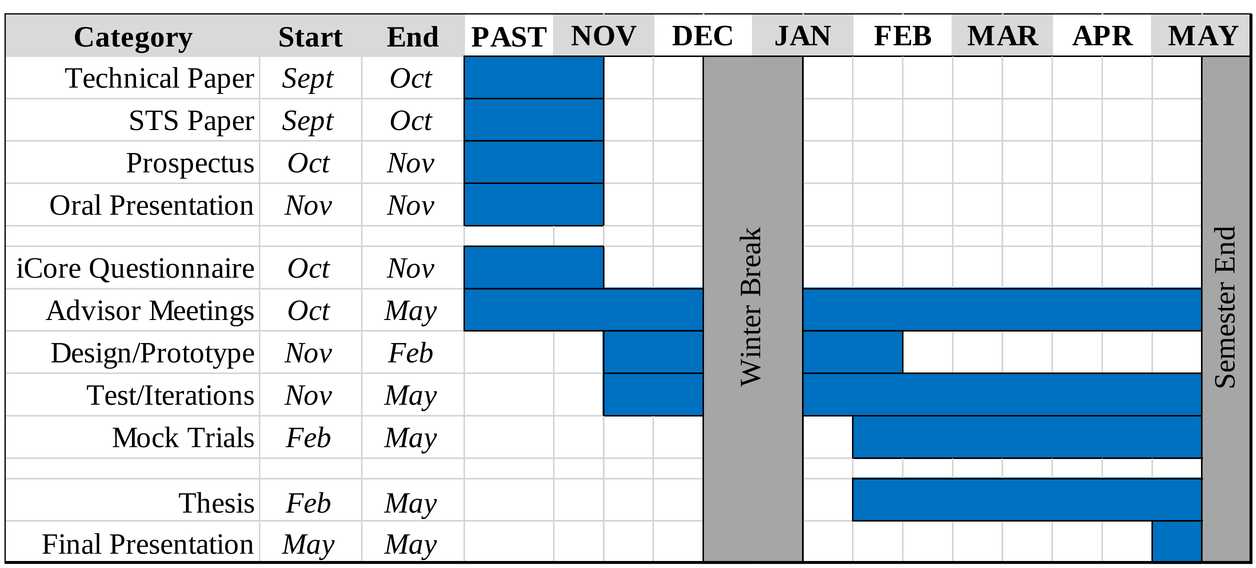

Figure 2. Gantt Chart. The breakdown of work, in months, that have been and will be carried out over the next two semesters, until May 1. Durations of time in December, January, and May were blocked out for Winter Break and the end of the semester (Lam, 2019).

ultrasound catheter in place. This will ultimately improve the ergonomics and efficiency of the procedure room, decrease risks of complications, and reduce medical bills. Loosely coupled with our technical project, my STS research focuses on the risks and benefits of robotic surgery and society's current view regarding deeper integration of technology in medicine. The STS topic will be discussed with the Social Construction of Technology (SCOT) model where the impact of advancements in medical technology will be mapped out. Together, my technical and STS research will be submitted as a conference-style paper written for a biomedical journal.

## RETAINING MEMORY

My team's technical project seeks to address an issue that is prevalent during invasive electrophysiology (EP) procedures: ultrasound catheters' inability to remain in a set position which can result in the loss of valuable time and efficiency within the procedure room and a higher risk of procedural complications. Our team will investigate the current ergonomics surrounding the use of ultrasound catheters in electrophysiology procedures.

Over the years, many improvements have been made to the tip of the catheter such as adding different sensors and electrodes to better image quality and understand the position of the catheter inside of the heart (Hijazi, Shivkumar, & Sahn, 2009). Image quality and spatial awareness are pertinent aspects of ultrasound catheters that contribute to a successful procedure. There is, however, a flaw in the fundamental design of the catheters that has not yet been addressed: ultrasound catheters do not remain in the position that the physician placed them in. As seen in Figure 3, the view that the ultrasound catheter provides is achieved by adjusting two control knobs and torqueing, or rotating clockwise or counterclockwise, and advancing the catheter handle (Loschack, Tenzer, & Degirmenci, 2015). The control knobs allow the catheter tip inside of the heart to flex, while torqueing and advancing the catheter handle changes the

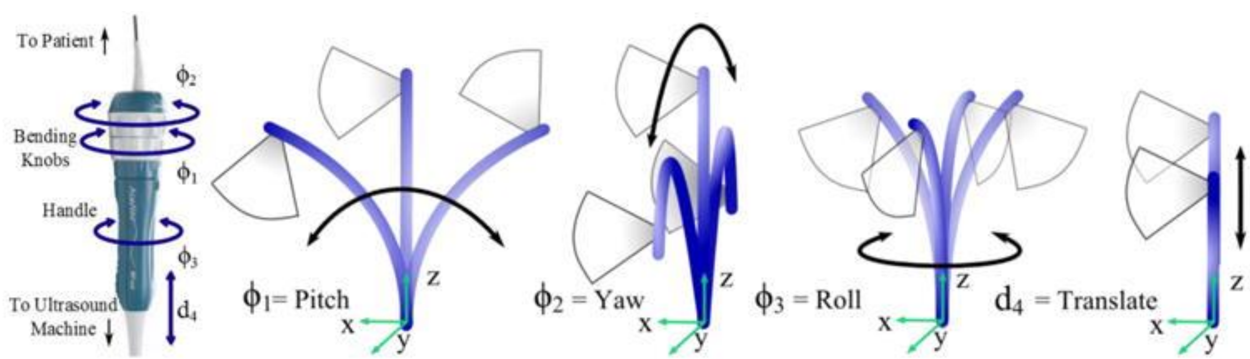


Figure 3: Ultrasound catheter handle degrees of freedom and corresponding catheter tip motions: The four ways to maneuver an ultrasound catheter are illustrated with the plane and direction it can move in (Loschack et al., 2015).

entire position of the catheter. Unlike the two knobs that have a built-in locking mechanism, when the catheter handle is torqued or advanced, it has a tendency to reset back to its natural position, throwing off the intended view. Steering the ultrasound catheter and finding the view of interest only to have it move out of place when physicians let go of the handle is frustrating, challenging, and time-consuming.

Current methods physicians have taken to overcome this challenge, which my team has termed “retaining memory,” include holding the catheter handle in place themselves, requiring an assistant, or placing a heavy, wet towel over the handle. These methods can reduce workflow efficiency, increase staffing in the procedure rooms, and lengthen procedure duration, ultimately leading to greater medical costs. Some physicians do not perform any of the previously mentioned methods and instead resort to re-orienting the catheter handle throughout the procedure. Naturally, this presents greater risks of complications because the physician is constantly distracted and will need to temporarily let go of other equipment to make adjustments to the ultrasound catheter that fell out of view.

The goal of my technical project is to design a device that will maintain the ultrasound catheter’s set position, leading to improved ergonomics in the procedure room while also reducing risks of complication and procedural costs. The technical project will span the duration of two semesters and require many iterations of designing and prototyping before any applications in animal or human studies. My team has not received any funding to help with our research, however we will implement various approaches towards the addressing the issue that will be then evaluated in electrophysiology procedure labs, prototyped with 3D-rendering software, followed by 3D-printing at supporting facilities around the University of Virginia.

In designing a device that can be subtly integrated within the current workflow yet significantly improve multiple aspects of an invasive medical procedure, my team and I will be able to better understand the variety of factors that can contribute to medical procedural costs. In a conference-style paper written for a biomedical journal, my team and I will present our technical project containing our research and innovation on improving interactions with ultrasound catheters during electrophysiology procedures. As engineers integrating into the ever-changing and demanding world of technology and medicine, we hope to become more cost- and efficiency-conscious and better understand the social impact of medical technology and workflow efficiency.

## THE ROBOT CURE

The term “medical technology” broadly refers to procedures, equipment, and processes that help deliver medical care. Since the birth of medical devices in the 1800s, technology has brought upon many significant improvements to people’s health including greater life expectancy and better quality of life (Hajar, 2015). From simple inventions, such as adhesive bandages, to more significant innovations such as prosthetic limbs, technology has played a large role in medicine.

Advances in medical science have opened up doors to ways of treatment that were not previously seen as possible. The growing integration of technology and medicine has allowed physicians to treat patients in more depth and to better results. A report from the Congressional Budget Office (2008) pointed to technology-related changes as a significant contributor to the increase of service utilization which inflates health expenditures.

As reported by Debt.org, America’s Debt Help Organization, Americans spent approximately $3.5 trillion in 2017 on healthcare-related expenses and about 32% of that amount, or $1.1 trillion, was spent on hospital services. In a sample of consumer credit reports from one National Consumer Reporting Association (NCRA), about one in five consumers reported one or more collections tradelines, or records of extended credit to borrowers, originating with a medical provider (Consumer Financial Protection Bureau, 2014). Looking across all collection tradelines, more than half of them are associated with medical providers, as depicted by Figure 4 on Page 8.

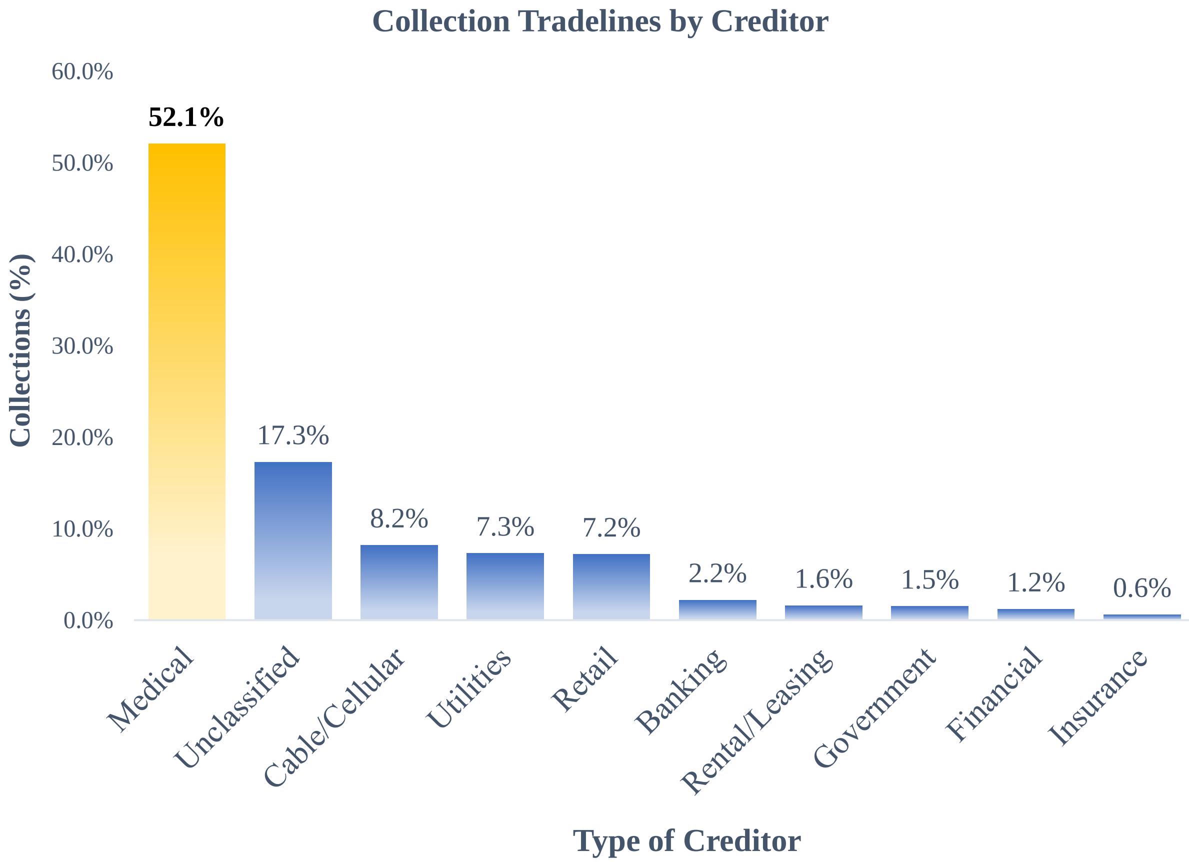


Figure 4: Break down of composite collections tradelines on credit reports by the type of creditor: More than half are associated with medical providers (Consumer Financial Protection Bureau, 2014).

According to Centers for Medicare and Medicaid Services, national health expenditures are expected to reach $6.0 trillion by 2027 (n.d.). While major contributing factors to large medical bills include the growing aging population and government policies, one of the largest contributing factors is medical technology.

A rising field in medical technology is the development of robotic surgery. Topics of discussion critics often argue regarding robotic surgery include the benefits and limitations of robotic surgery, scientific evidence establishing that robotic surgery can replace traditional surgeons, and financial restrictions. What society will need to accept if robotic surgery were to be continually integrated within healthcare systems is that much of the decision-making will not be performed by the surgeon they visited and developed a treatment plan with. Because decision making is such “an important […] component of surgical expertise” (Jacklin, Sevdalis, Darzi, & Vincent, 2008, p. 693), incorporating robotic surgery will significantly change the nature of how procedures are performed. Although unorthodox, the ergonomic benefits of robotic surgery are tempting for surgeons: reduced levels of physical stress and mental fatigue. With various advantages to the wider use of robots during surgeries, a large decision-maker for the inclusion of this technology is the financial stress that it would add to patients’ medical bills. An email exchange between a doctor from University of Ulsan College of Medicine in South Korea and Reuters Health expressed concerns about the rapid increase in robotic surgery and its integration in healthcare systems. The doctor expressed concern for the burden that a huge increase in the cost of medical care can inflict on the healthcare system (Boggs, 2017).

A complication exists due to the entanglement of desire for potentially more consistent patient outcomes, reduced physical and mental stress in surgeons, trust and reliance on technology to treat human diseases, and the overwhelming impact on surgical costs and medical bills. To analyze the incorporation of robotic surgery, one must also analyze a Social Construction of Technology (SCOT) model as seen in Figure 5. In the center of the SCOT model is the engineer; in this case, robotic surgery is at the center of the social construction and responsible for all the changes and impacts it would make on other parties in the system. Parties directly related to the center piece of the SCOT model include doctors, people, government, healthcare systems, and medical device companies. Doctors, who act as a gatekeeper in this system, have the utmost impact on how robotic surgery will be interpreted by society, businesses, and the government. They are also most apparently impacted by robotic surgery for

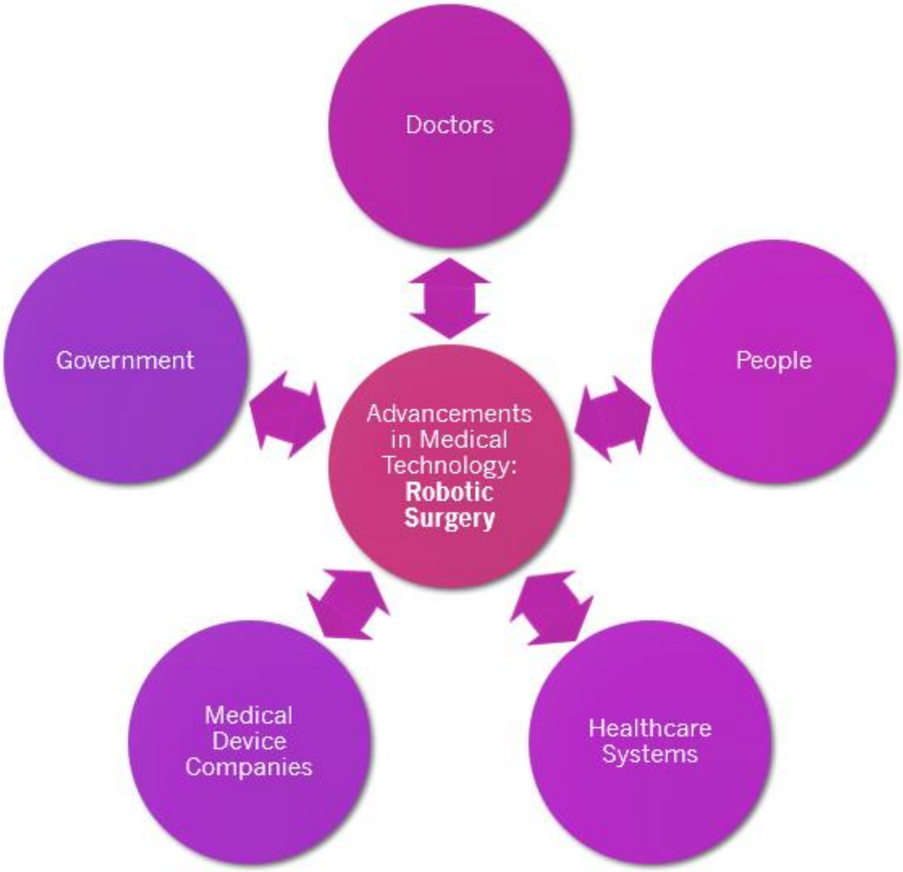


Figure 5: SCOT model: Schematic showing the relationships between robotic surgery, the center of the social construction, and groups directly impacted by the integration of the technology (Lam, 2019).

robots will change the nature of how doctors will be needed for medical procedures. As doctors are responsible for overlooking the technology, the robots can help reduce physical and mental stress in surgeons. With this, doctors are responsible for protecting the privacy and upholding the safety of patients, making sure to achieve the best patient outcomes with greater technology. The people are directly impacted because they are the patients who the robots are operating on. People have a strong say in whether robotic surgery should or should not exist since their top concerns are their safety, trust, and privacy. The government may fear the negative impact of having robots taking on responsibilities as large as treating or harming individuals in society. High numbers of complication rates in a nation's hospitals could impact how politics and government operate, and at the same time, the government is essentially putting considerable amount of trust into machines to help save their people. Similarly, healthcare systems also fear the responsibilities that come with robotic surgery and potential toll they might have to take since their business is in the hands of a machine. Lastly, medical device companies are essentially the creators of this technology. They are the ones responsible for producing reliable technology that will not only better patient outcomes, but ultimately help reduce medical bills in the long run.

Engineers in medical device companies are the deciding factor for how robotic surgery can be developed and understood. The aspect of interpretive flexibility of robotic surgery is the responsibility of engineers to convey properly. Although in this SCOT model, the center of the social construction is robotic surgery, engineers are responsible for creating this center piece and thus responsible for tackling the fears and uncertainties of all the related parties in the system.

My STS research project will be in the form of a scholarly article addressing the costs and benefits of robotic surgery and how engineers are in control of the future of medical technology and innovation. Although loosely coupled with my technical project, robotic surgery, as discussed in my STS research project, can potentially be more widely implemented during surgeries without considerable amounts of medical bills due to the implementation of a device that can improve the ergonomics of procedures and reduce procedural costs holistically. In other words, the device that our team is working on designing to better the operation of ultrasound catheters in procedures can lead to considerations for implementing robots into surgery. These changes can lead to improvements in not only annual medical expenditures, but also consistency patient outcomes of medical procedures. Small changes in the procedure room can lead to great changes outside of the procedure room.

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