Quantification of the Force Applied by Operators During Minimally Invasive Surgical Procedures

(Technical Paper)

The Impact of New Medical Devices on Role Boundaries Between Different Healthcare Occupations

(STS Paper)

A Thesis Prospectus Submitted to the

Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements of the Degree

Bachelor of Science, School of Engineering

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Fall, 2020

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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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Introduction

According to an interhospital study, 53% of surgical errors are due to inexperience with a procedure (Gawande et al., 2003). Minimally invasive (MI) surgeries require operators to be highly experienced in haptically judging whether or not they are using a safe level of force. To prevent patient injury due to incorrect force application my team and I will design a force measurement device that offers numerical feedback, maintains the surgeon's autonomy, and is compatible with more than one existing MI tool. In device design, the success of an instrument relies heavily on the potential users' receptions of it. With each medical technology comes additional training that can alter an operator's job requirements and the boundaries that separate different healthcare roles. Serious changes to an employee's responsibilities could result in a negative response to the device thus hindering its clinical success. Through the use of Actor-Network Theory (ANT), I will investigate the actants affected by the implementation of medical technology and how the borders of the network are altered in response to the device. Additionally, to address ANT's limited consideration of cultural values and preexisting practices, healthcare workers' reactions to the introduction of a new technology will be analyzed to see how their values guide their response to network changes. Lastly, I will provide recommendations for hospitals and medical device companies on how to effectively employ a new tool into a network without compromising the values of the existing actors.

Technical Topic

During minimally invasive (MI) surgeries, rather than making a large incision, surgeons use guidewires and catheters to travel through a patient's vasculature and perform the necessary procedures. While MI operations are beneficial in that they only require a small incision, they leave surgeons blind to abnormal patient anatomies, such as vascular stenosis, that could lead to vessel rupture (Figure 1). When conducting MI procedures, surgeons rely solely on the resistance they feel in the MI tools to judge whether or not they are using a safe amount of force. One study found that 47% of MI surgeons reported significant errors in their surgery practices (White et al., 2015). Additionally, this study cited the detachment between visual and haptic feedback in MI surgeries as a prominent source of surgical error. In order to mitigate the risks associated with improper force application in MI procedures, my team and I, in collaboration with Dr. John Angle, are developing a force measurement device that will provide numerical force feedback, preserve operator autonomy, and attach to more than one medical device. In addition to its function in a clinical setting, our device will also be used to teach medical students and residents how to apply a safe amount of force without the high stakes' environment of the operating room.

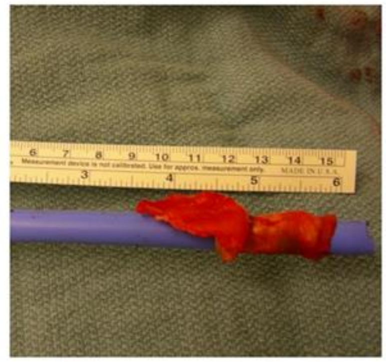

Figure 1: Aortic debris from an abdominal aortic endograft placement procedure. Courtesy of Dr. John Angle, Interventional Radiology, UVA.

Currently, no force measurement device for MI surgeries has been approved for clinical use. However, developments have been made in a research capacity to measure unsafe force levels. An external actuation system for cardiac ablation procedures used a fiber Bragg grating, which is a type of fiber optic sensor, to measure force (Aranda-Michel et al., 2018). Our device will build off of this study by using fiber optics as a sensing component to quantify force at the tip of the instrument. Additionally, our force measurement device will include a guidewire deflection sensing apparatus that is similar to the one created by researchers studying coil embolization of intracranial aneurysms (Haraguchi et al., 2013). Detecting guidewire deflection outside of the body will allow us to see how external forces translate to potentially dangerous forces in the vasculature.

MI surgeries require the operator to have a highly refined haptic perception of force application. This perception can be easily distorted by excess forces such as non-relevant frictional forces (Zhou et al., 2008). To address this problem, research has gone into developing automated systems that provide external actuation to MI tools in procedures such as cardiac ablation (Aranda-Michel et al., 2018). These systems cause the operator to lose partial control of the MI instrument and can lead to the presentation of new technical errors. Rather than limiting operator autonomy, our device aims to inform and potentially correct operator action.

Because different vascular surgeries require specific guidewires and catheters, existing measurement devices tend to be highly specialized for one MI tool or procedure. Having a multi-tool compatible force measurement device can improve procedure efficiency by reducing the number of instruments required for the surgery. A previous study developed a force measurement tool that could be attached to the forceps used during pig laparoscopic surgery (Yamanaka et al., 2015). Similarly, our device will also attach to the medical device itself rather than the operator. However, we will advance this study's technology by creating an attachable device that is compatible with more than one surgical instrument. For the sake of this project, we will be constructing a device that can be attached to both aortic endograft placement and inferior vena cava (IVC) filter removal tools.

To test our preliminary device, two phantoms will be constructed from materials that faithfully mimic the composition and anatomical structure of the aorta and IVC. Using existing measurement tools, we will compare the force and strain values that we obtain from the phantoms to true physiological values found in the literature to confirm that our phantoms reliably represent the anatomical properties of the aorta and IVC. These phantoms will then be used to test our numerical force measurement device.

STS Topic

In 2020, the U.S. medical device market was valued at 176 billion dollars. This market is expected to grow at a rate of 5% annually until 2025. (Grand View Research, 2019). As the number of new medical devices entering clinical settings increases at a rapid rate, the social impact of these devices on medical professionals requires careful consideration because this new technology is capable of altering the division of labor that exists between different healthcare occupations (Petrakaki & Kornelakis, 2016). This redistribution of tasks has the potential to blur the boundaries that have previously delineated occupational roles in the hospital and calls into question who should be trained on which devices. One group of healthcare workers that have experienced a large influx of medical technologies into their field are pharmacists. Using a personal case study of how pharmacists have been affected by new medical devices, I will apply ANT to see how the pharmacists' roles and network changed because of the incorporation of these new technical actors. Additionally, I will investigate which factors lead to a positive reception of a new device and offer guidance on the best ways to implement medical technology into a new network.

This past summer, the hospital in my hometown switched to a new intravenous (IV) pump system. Though IV pumps are primarily operated by nurses, the hospital's pharmacists, who have a highly specialized understanding of drug interactions and pharmacokinetics, were tasked with inputting all of the drugs and infusion limits into these new pumps. Despite being the ones to prepare the IV infusion bags, pharmacists rarely interact directly with the IV pumps. The pharmacy team's lack of familiarity with IV pump interfaces hindered their ability to input the necessary drug information and test that the pumps were programmed accurately. The addition of the IV pump as a direct actor in the pharmacists' network changed the responsibilities associated with their job and led to an increase in collaboration between the nursing and pharmacy staff. Expanding the IV pump's sociotechnical network to include pharmacists as a prominent group of actors could lead to improvements in the device itself and could change the limits of pharmacists' roles in the broader hospital network.

In this case study, where pharmacists and a medical device are interacting in a novel way, it seems fitting to apply ANT, which views human and non-humans as equal actors that can unite to form networks, to understand how each actor's actions impacted preexisting networks (Sismondo, 2011). According to ANT, the interests of actors, which drive their actions, require consideration and can be employed and altered to form a "stable" network that has a common aim (Sismondo, 2011). Analyzing how the pharmacists expanded their network to confer agency onto the IV pumps, will reveal which steps united the actors' forces to further the creation of a new network. The primary actors from the case study that will be examined using ANT are the pharmacists, the IV pump, the IV pump manual, the nurses, the medical device company representatives, and the hospital directors who decided to enact the IV pump project. While ANT is an advantageous framing tool because it uniformly weighs the actions of human and inanimate actors, it neglects the influence of culture and issues of trust between actors.

To address the shortcomings of ANT, the effects of actor values and practices on network structuring will be investigated by looking at the responses of the pharmacists from the case study as well as common reactions that a group of medical professionals had when an electronic patient record system was implemented (Petrakaki & Kornelakis, 2016). According to Petrakaki et al.'s analysis of healthcare workers' sentiments toward new technology, two prominent values that if compromised led to a poor reception of the device were autonomy and maintaining a strong patient relationship. Both of these values signify instances where a technology altered occupational boundaries in ways that ANT may not have accounted for. Additionally, conflicting values between actors could strain and modify the network (Novek, 2000). For instance, the hospital directors may view the IV pumps as a way to portray the hospital as technologically advanced and innovative whereas the pharmacists and nurses, who are on the ground working with the pumps, might see the technology's flaws and the potential for patient injury.

This exploration of the actors, values, and conflicts involved in the changing pharmacy network borders, will be followed by an analysis of what steps should be taken to ensure that a successful new network is produced. Three key components of positive technology implementation are having employees opt-in to learn about the new device, providing numerous opportunities for them to practice with the device, and encouraging these operators to reflect on and discuss possible improvements for the device (Edmondson et al., 2001). How the technology is initially presented to a group also plays a critical role in whether or not the prospect of learning how to use this new device evokes enthusiasm or fear in the future operators (Edmondson et al., 2001). With an understanding of how to use ANT to determine the actors that could be affected by the incorporation of new medical technology, baseline knowledge of the values that healthcare providers may have, and advice on what steps to take when bringing in a new device, hospitals will be prepared to successfully adjust occupational networks.

Next Steps

Thus far in my thesis research, I have looked primarily at how new technology affects healthcare workers. In future sections of my thesis, I will investigate the impact of these medical professionals on the technology itself. Using the Consensual View of Science, which advocates for a diverse community of inquiry to be involved in reaching scientific consensus, will reveal how changing occupational boundaries to include more healthcare workers' viewpoints during medical device design and improvement could better the outcomes of device use and acceptance. To see the implications of these role alterations on technology, I will examine how technology is evaluated in a hospital setting, how current research and development is conducted at medical device companies, and how the Food and Drug Administration (FDA) makes approval decisions for medical instruments.

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