DESIGN OF SENSOR-ENABLED TESTING DEVICE FOR ARTERIAL OCCLUSION PRESSURE STUDY OF TRUECLOT TOURNIQUET APPLICATION TRAINER

510(K) APPLICATIONS AND THE RISKS ASSOCIATED WITH THE REGULATORY PATHWAY

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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

Countless companies and startups submit an application for medical devices each year with the hopes that their respective medical devices will be approved by the Food and Drug Administration (FDA). As these medical devices interface with the body, strict regulatory standards must be upheld to keep users safe. The FDA has classifications for medical devices, such as Class I, II, and III. Class I devices are the lowest hazard and Class III devices are high risk devices that pose a significant risk of illness or injury (FDA, 2020). Depending on the device's classification, a company must submit a Premarket Notification (510(k)) or a Premarket Approval (PMA). A 510(k) application is "a premarket submission made to the FDA to demonstrate that the device to be marketed is safe and effective, that is, substantially equivalent, to a legally marketed device" (FDA.gov, 2020). This system allows for companies to reach commercialization faster by using products in the market as a substantial equivalent. However, if the prior art had caused serious patient harm, this would lower the strict regulatory standards, thus allowing for lower quality medical devices to be released onto the market.

My technical project is the design of a sensor-enabled testing device for arterial occlusion pressure stuy of the TrueClot™ Tourniquet Application trainer made by Luna Innovations. The Tourniquet Application trainer is a device that trains personnel on applying a tourniquet correctly and the right amount of pressure necessary to occlude an artery. In the current design, the user is only able to know if the bleeding has stopped if blood has stopped leaking down the tubing. The use of the sensor will allow the team to create an additional validation method and increase the efficacy of tourniquet application training. The application trainer does not have to undergo a medical device regulatory pathway because it does not fit the medical device definition, so it is loosely coupled to the STS project.

Using the framework of risk and standards, this study investigates the thesis surrounding the 510(k) application used to expedite the approval of medical devices based on prior innovation. This framework will assess the risks of using prior art with multiple recalls and the bodies that subjectively enforce the regulatory pathways. These inconsistencies should be reviewed and regulated by the FDA which will hopefully increase the safety of medical devices released onto the market.

Technical Topic

Tourniquets are commonly used in the field and are defined as any limb constrictive device used in an attempt to stop extremity bleeding (J. F. J. Kragh et al., 2009). The use of a tourniquet before hospital care has a strong association to lifesaving with minor morbidity, and as a result, the US Army has implemented a policy that all military personnel carry tourniquets. (J. F. Kragh et al., 2011; J. F. J. Kragh et al., 2009). The need for a tourniquet trainer has become evident for two reasons. First, *appropriate* tourniquet application is a painful process. Pain is a crucial factor to consider when it comes to tourniquet application. Furthermore, pain is not an accurate indicator for confirming if total arterial occlusion has occurred (Alterie et al., 2018). A tourniquet trainer would eliminate this pain factor when training EMTs and military personnel on how to properly apply a tourniquet. Second, when training how to apply a tourniquet without a trainer, there is no visual feedback of blood flowing and then stopping when the tourniquet is applied. The introduction of a trainer provides feedback to more realistically simulate real world scenarios.

The TrueClot® Tourniquet Application Trainer by Luna Innovations improves the quality of tourniquet application training. The trainer is a heavily-padded cuff with a simulated wound

and blood vessel that can be secured around the left shoulder and upper left arm. The blood vessel is constructed with flexible tubing and mimics the brachial artery. To use this product during training, an individual wears the trainer while synthetic blood flows through the tubing. The tourniquet is then applied around the cuff on the upper arm ("Tourniquet Application Trainer," 2017). The padding beneath the flexible tubing provides the proper resistance required to recreate the environment needed for complete brachial artery occlusion, and allows for training to occur without the pain of completely cutting off circulation to the individual. Currently, the only indication of accurate tourniquet use is the stop of the synthetic blood flow. The goal of this project is to design a sensor-enabled testing device to be used as another feedback mechanism to indicate the proper application of a tourniquet with the TrueClot® Tourniquet Application Trainer. The team has no clearly defined individual responsibilities and are collectively responsible for the project. This sensor will be placed within the trainer to determine if the tourniquet being applied to the trainer is exerting enough circumferential pressure to occlude the brachial artery.

Aim 1: Select a pressure sensor to implement with the TrueClot® Tourniquet Application Trainer

(A) Perform literature searches and product reviews in order to research various pressure sensor options.

(B) Verify the circumferential target pressure for total arterial occlusion of the brachial artery using literature review. As of now, the target pressure is considered to be in the 100g to 5kg or 0.2lbs to 10lbs range.

(C) Conduct literature review to determine how the arterial occlusion pressures are measured and create experiments to test the arterial occlusion pressures. Experimental design will include research of various testing methods.

Aim 2: Design a testing apparatus and test a wide range of tourniquet devices

(A) Determine the mathematical relationship between the voltage measured by the pressure sensor during tourniquet application and pressure to conclude average pressure with the desired units. Test the RapidStop® Tourniquet from AeroHealthcare with the sensor in order to design a sensor for the trainer that accommodates a wide range of tourniquets.

(B) Determine optimal sensor placement within the tourniquet application trainer through user feedback and design housing for the sensor to increase durability.

By designing a sensor-enabled testing device to indicate the proper application of a tourniquet with the Application Trainer, Emergency Medical Technicians (EMTs) and military personnel will be better equipped to properly apply a tourniquet both to themselves and to others. As a result, this will lead to better care for victims in need of hemorrhage control.

STS Topic

"He said I shouldn't feel anything" Ana Fuentes, Essure user.

The next day, Ms. Fuentes started experiencing heavy bleeding and stabbing pains, therefore decreasing her quality of life after her Essure implantation procedure (Francini et al., 2021). Essure is a permanent birth control method where a set of 4 cm coils would be placed into the fallopian tubes of a patient's uterus (*Essure FDA Application*, n.d.). The coils would cause an inflammatory response in the tubes, causing scar tissue generation, and the scar tissue obstruct

the fallopian tubes permanently (Francini et al., 2021). One of the most marketable features of Essure was that it was non-surgical and a quick procedure as opposed to other more invasive, surgical methods of sterilization. Although the procedure seemed efficient and simple, patients started to develop postoperative complications such as heavy bleeding and constant fevers. “The Bleeding Edge” is a Netflix documentary that encapsulates an important controversy in the FDA’S regulatory pathways and the profitable desire for innovation by using Essure as the main case study for medical devices that can decrease a user’s quality of life (Dick, n.d.). Essure had been approved through a premarket notification, an expedited FDA application process to approve medical devices, and resulted in more than 60,000 recalls leading up to December of 2020 (Health, 2021). The movement to reform the expedited regulatory pathway for a medical device application is an ongoing conversation with others about the role that the FDA plays in ensuring the lives and safety of patients as well as improvements to the current expedited regulatory approval processes.

Using the risks and standards framework from Hess and Sovacool, I will be exploring the consequences of subjective governance in the approval of medical devices. Hess and Sovacool believe that “risks and standards are developed through processes of social negotiation that create formal and translocal definitions to guide policy and practices” and that standards are “...practices that reinterpret risk based on citizen science or that reshape standards through implementation” (Hess & Sovacool, 2020). The main governing body for medical devices is the FDA. The FDA has determined that the standards for a 510(k) application are that it is a premarket submission which proves that a device is marketed as safe and effective and also known as “substantially equivalent”, to a legally marketed device (Health, 2020). Substantial equivalence is also known as the new device being as safe and effective as the predicate device is

in a legal sense. The requirements for determining if a device is substantially equivalent to a predicate is if the

- New device has the same intended use and same technological characteristics as the predicate or has the same intended use as the predicate
- Has different technological characteristics
- Does not raise different questions of safety and effectiveness
- Information submitted to the FDA demonstrates that the device is as safe and effective as the legally marketed device (Health, 2020).

This new modification to the regulatory pathway was created to "enable newer versions of existing devices to enter the market" and reduced the amount of time a product was released to a market (Kahan, 1984).

The introduction of a new regulatory pathway was also intended to accelerate the application reader's approval process, which was beneficial for FDA employees. This expedited application process also encouraged businesses to streamline their product onto the market and would encourage innovation amongst startups and new inventors. Lobbyists representing device manufacturers desired to streamline the lengthy FDA approval process because they believed the United States would lose its ability to compete globally against other medical devices due to the excessive costs and delays in getting the FDA's approval (Fargen et al., 2013). Although this may seem beneficial for businesses and the application reviewers who would spend less time on the 510(k) applications, this system also increased the chance for low quality medical devices to be approved for consumers and patients. As regulations for medical devices had not been classified

before the Medical Device Amendments in 1976, previous medical devices that had been approved before 1976 could serve as predicate devices for modern devices.

Devices approved before the Medical Device amendments had a lower standard to uphold because there were less regulations in place. If an older device was used as a predicate for a modern device developed now, the standards for a new device would also have low standards to be approved. Not only could the predicate device cause problems, but there have also been several cases where device failures were linked to patient harm because the 510(k) application does not require a randomized controlled trial evidence that demonstrates safety and effectiveness prior to approval (Fargen et al., 2013). In a standardized application process, the trials would have shown evidence that a device was failing on a safety level. In the example of Essure, initial clinical trials had shown success of the device with the proper technique to insert the Essure implant. However, as surgeons implanted the device in different ways, this led to many postoperative complications. The lower standards could allow for less safe devices to be released onto the market even though they could contain defects and faulty features based on the predicate.

More recently, the Institute of Medicine (IOM) Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process conducted a workshop on medical devices. The IOM committee had decided that "changes in the 510(k) process potentially would better foster innovation and ensure confidence that the process results in safe and effective medical devices (Medicine et al., 2010). The committee also recommended that the Class II medical device approvals should not reference preamendment products and should be based on objective performance criteria that ensure safe and effective use (Medicine et al., 2010). Multiple modifications to the 510(k) process were also recommended by the US FDA's January 2011

510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision making team to improve the 510(k) program and use of sciencere(*FDA 510(k) Recommendations Overview of Comments and Next Steps - ProQuest*, n.d.). These reforms would decrease the probability of patients developing postoperative complications as a result of the implant or other invasive medical devices.

Next Steps

Both the Technical Capstone project and the STS research project will be completed by May 2022. Currently, we have met with the team advisor on several occasions to discuss what the pressure study will entail, and what instrumentation would be necessary to run the experiments. We researched various pressure sensors and ordered ones that seemed the most promising.

Month	STS Topic	Technical Topic
September	● Created specific aims draft	● Introduced to STS frameworks from Hess and Sovacool
October	● Developed design specifications for device ● Researched various pressure sensors ● Conducted landscape analysis on other tourniquets used in the field and in hospitals	● Developed 3 theses to be the thesis for draft Prospectus ● Chose thesis and framework for Prospectus ● Edited draft Prospectus
November	● Create circuit to measure force of a mass and write software to measure the force ● Will conduct pressure study using Instron testing instrument ● Specific Aims Proposal due	● Turn in final Prospectus on November 1st ● Create presentation on Prospectus
December	● Create presentation of overall progress	

In terms of the STS research, I will also research the politics of standardization and how the FDA came up with an expedited process for medical devices. I would also want to include incidents where medical devices that were approved by the FDA using a 510(k)-application and explore whether or not the predicate device had flaws or if the medical device itself had multiple recall reports. To gain a more holistic understanding of the stakeholders involved in the regulatory process, I would include more results from the IOM committee meeting, mainly delving into the other recommendations that the IOM committee had created and researching the insight of other professionals. I will also discuss the proposed reforms that other experts have suggested as well as consumer advocate groups who want to revise the FDA regulatory pathway.

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