IMPROVING THE ERGONOMICS OF OPERATING THE ENDOSCOPE

THE IMPACT OF WOMEN ON MEDICAL DESIGN

A Thesis Prospectus
In STS 4500
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In Partial Fulfillment of the Requirements for the Degree
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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Colorectal cancer is the second leading cause of cancer-related deaths in the United States (U.S.), and in the current standard of care, colonoscopy is the only procedure capable of screening for colorectal polyps and cancers (Marley & Nan, 2016). In the U.S. alone, approximately 19 million colonoscopies are conducted by gastroenterologists every year and serve as the primary diagnostic tool to identify these otherwise undetectable gastrointestinal pathologies (iData Research, 2018). Through a survey of 1,353 respondents, Cohen et al., (2006) found that gastroenterologists in the U.S. often must perform an average of 22.3 colonoscopies per week (p. 968-967). A high frequency of colonoscopies has often led to De Quervain's tenosynovitis of the practitioner's left thumb, among other related repetitive strain injuries, which is caused by frequent "abduction and extension of the thumb to manipulate the dials" of the endoscope (Harvin, 2014). As shown in Figure 1, characterization of this injury typically involves a painful inflammation of two tendons that run between the thumb and the wrist: the

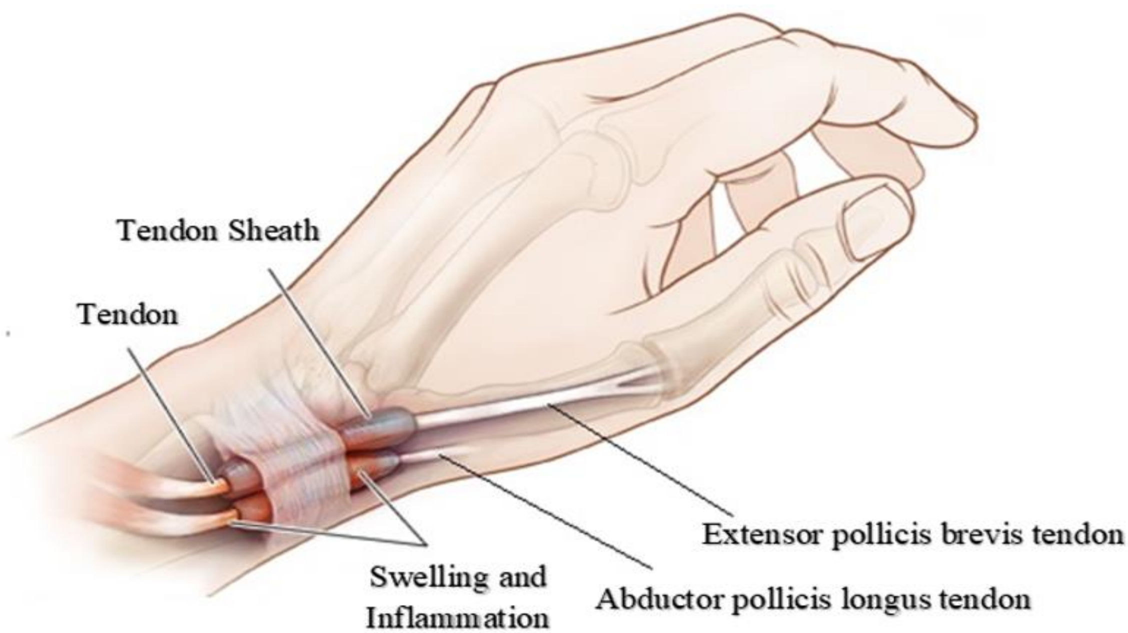

Figure 1: De Quervain's Tenosynovitis. This figure visualizes the swelling and inflammation of the extensor pollicis brevis and abductor pollicis longus tendons involved in De Quervain's tenosynovitis. (Adapted by Kevin Chang from Ryan Glover, 2018).

abductor pollicis longus (APL) and the extensor pollicis brevis (EPB) ("De Quervain's tenosynovitis," n.d.). Improving the endoscopy ergonomics of the modern scope not only reduces the risk for repetitive strain injuries, but also offers a solution to improve the quality of life for the physician.

The technical project and the STS thesis will be tightly coupled and will be completed over the course of two semesters by following the timeline described in the Gantt chart in Table 1. The primary goal of the technical project is to develop a device capable of reducing the

Table 1: Gantt chart for the technical project and STS thesis timeline.

TASK NAME	START DATE	END DATE	11/18 - 11/22	11/25 - 11/29	12/01 - 12/07	12/08 - 12/14	01/12 - 01/18	01/20 - 01/24	01/27 - 01/31	02/03 - 02/07	02/10 - 02/14	02/17 - 02/21	02/24 - 02/28	03/02 - 03/06	03/09 - 03/13	03/16 - 03/20	03/23 - 03/27	03/30 - 04/03	04/06 - 04/10	04/13 - 04/17	04/20 - 04/24	04/27 - 05/01
Ergonomics Clinical Study																						
Learn EMG	11/18	11/30																				
Acquire tactile force sensor	11/18	1/18																				
IRB approval	11/18	12/10																				
Increase pool of clinical candidates	11/25	2/14																				
Design and conduct EMG study using existing colonoscopes	11/18	1/18																				
Design and conduct force study using existing colonoscopes	12/1	1/19																				
Conduct national ergonomics survey	1/25	2/7																				
Clinical Likert scale assessments with device	1/12	2/28																				
Design and conduct EMG study with interventional solutions	2/24	4/10																				
Design and conduct force study with interventional solutions	2/24	4/10																				
Analyze statistical results from clinical study	3/16	4/24																				
Pursue intellectual property	4/20	5/1																				
Initiate process for FDA class II medical device certification	4/20	5/1																				
Interventional Strategy Development																						
Phase 1: SergoMask dial mating feature customization	11/18	1/31																				
Phase 1: Design outer casing	1/12	2/14																				
Phase 1: Incorporate simple rachet system design	1/23	2/14																				
Phase 1: Embedded force and torque testing sensors	2/10	2/21																				
Phase 1: Incorporate sensors for mechanical testing	2/10	2/21																				
Phase 1: Clinical Feedback	2/24	3/6																				
Phase 2: Adjust outer casing for preferable positioning styles	3/2	3/27																				
Phase 2: Incorporate bidirectional locking mechanism	3/2	4/6																				
Phase 2: Higher density polymer study	3/23	4/17																				
Phase 2: Clinical Feedback	3/9	5/1																				
STS Thesis Development																						
Finish Prospectus	11/18	12/7																				
Identify other potential medical technologies to apply SCOT	11/18	1/18																				
Identify relevant social groups for each medical technology	11/18	12/10																				
Explore way women succeeded/failed to influence design																						
Run SCOT analysis on relevant social groups	11/25	2/14																				
Design and outline thesis	11/18	1/18																				
Complete thesis	12/1	1/19																				

ergonomic hazards of operating the dials of the endoscope while the Science, Technology and Society (STS) thesis will seek to examine areas in which women have succeeded or failed to impact not only the design of the endoscope, but also the design of various medical technologies. Analysis will be conducted using Pacey's Triangle in order to categorize social groups relevant to each technology (Pacey, 1983); furthermore, these social groups will then be mapped onto a Social Construction of Technology (SCOT) framework as defined by Bijker, Bonig, & van Oost, (1970) in order to evaluate their impacts on the development of each technology. The two key social groups of this analysis will be the female physician and the female patient. The STS topic will begin with a study of the impact of women on the design of the endoscope to establish a foundational framework that will be used to explore a broad spectrum of medical innovations. Results from this study will illuminate the areas in medical design that fail to account for females as stakeholders and will serve to encourage engineers to begin putting forth solutions.

The technical advisor of this project will be Professor William H. Guilford from the University of Virginia (U.Va.) Department of Biomedical Engineering (BME), with Dr. Dushant Uppal from U.Va. Gastroenterology and Hepatology serving as a medical consultant for the project. Three biomedical engineering undergraduate students from the U.Va. School of Engineering and Applied Sciences (SEAS) spearheading the project are: Mr. Kevin Ly Chang, Mr. Vincent Sciortino, and Mr. Vikram Seshadri. The STS portion of the thesis will be advised by Professor Catherine D. Baritaud from the U.Va. Department of Engineering and Society.

IMPROVING THE ERGONOMICS OF OPERATING THE ENDOSCOPE

Gastroenterologists who frequently perform a high volume of colonoscopies risk musculoskeletal overuse injury due to the mechanical challenges posed by operating the scope. Current endoscopes often require the physician to use their left thumb and forearm muscles to exert and sustain forces on a system of dials to control and maintain its position of the scope during the procedure. The current design allows the physician to deflect the distal end of the scope so that the tortuous bends of the gastrointestinal tract can be navigated (K. Chang, personal communication, September 25, 2019). The repetitive abduction and extension of the left thumb often leads to De Quervain’s tenosynovitis which, in a study conducted by Byun et al., (2008), affected 49 out of the 55 (89.1%) endoscopists surveyed. Although various strategies have been proposed to address these issues, including self-propelling scopes (Vucelic et al., 2006), joystick controlled scopes (Woo, Choi, Seo, Kim, & Yi, 2017), and robotic systems (Lee & Chung, 2013), highly-skilled gastroenterologists are reluctant to exchange their years of experience and training operating the dials on the traditional endoscope for the sake of learning an entirely different system. To illustrate this reluctance, Gómez, & Wallace, (2013) estimated that most endoscopists typically achieve competency after an average of 275 colonoscopies which is a number that may take a couple years to acquire (p. 659).

Many studies that attempt to identify the root cause of these musculoskeletal injuries find that poor ergonomic design of the modern endoscope is a likely risk factor. There is a strong hypothesis that hand injuries resulting from the practice of colonoscopy are caused by some combination of the following three risk factors: prolonged strain on the thumb, repetitive action of the thumb, and high forces being exerted on the thumb to operate the dials (Harris-Adamson et al., 2015, p.33). A study conducted by Shergill, Harris-Adamson, Lee, McQuaid, & Rempel, (2016) found over a cohort of 12 endoscopists that while they were performing colon insertion, their hands exerted an average peak thumb force of 15 Newtons (N) on the left thumb and spent 17% of their procedure time exerting high pinch forces above 10 N. A separate study also found that those with occupations that require them to spend more than 11% of their work exerting high pinch forces increased their risk of overuse injury (Harris-Adamson et al., 2015). Therefore, this technical project aims to address this problem by reducing at least 2 out of the 3 identified risk factors that frequently lead to repetitive strain injuries.

UNDERSTANDING AND APPLYING ERGONOMICS TO ENDOSCOPY

The technical project will involve the design of an experiment and the design of a device solution. The experimental approach will prioritize validating the underlying cause of musculoskeletal injury in endoscopists by evaluating the left hand activation of the muscles associated with the abductor pollicis longus (APL) tendon and the extensor pollicis brevis (EPB) tendon as well as the forces exerted by the thumb while performing a colonoscopy. The study will compare data collected before and after the implementation of our proposed design. The experiment will require Institutional Review Board (IRB) approval to gather a cohort of endoscopists for the experiment. These endoscopists will be tasked to perform a simulated colonoscopy on a training model of the colon commonly used in gastroenterology fellowships. During the procedure, force sensors and electromyography (EMG) will be used to measure the force exerted by the thumb and the muscle activity in the hand, respectively. Insights gathered in this study regarding the cause of muscle injury in endoscopists will be used in the device design iteration phase. Figure 2 shows the current concept of the technical project which involves an attachable device capable of alleviating the strain on the left thumb while operating the dials of the endoscope. The functionality of this design will offer endoscopists the tactile familiarity of manipulating the dials so that they do not need to relearn an entirely new procedure of endoscopy. The device will alleviate the prolonged strain on the thumb by holding the dials in place after they are turned to a certain angle so that the hand will not be required to continuously exert a force to maintain a position. Additionally, to

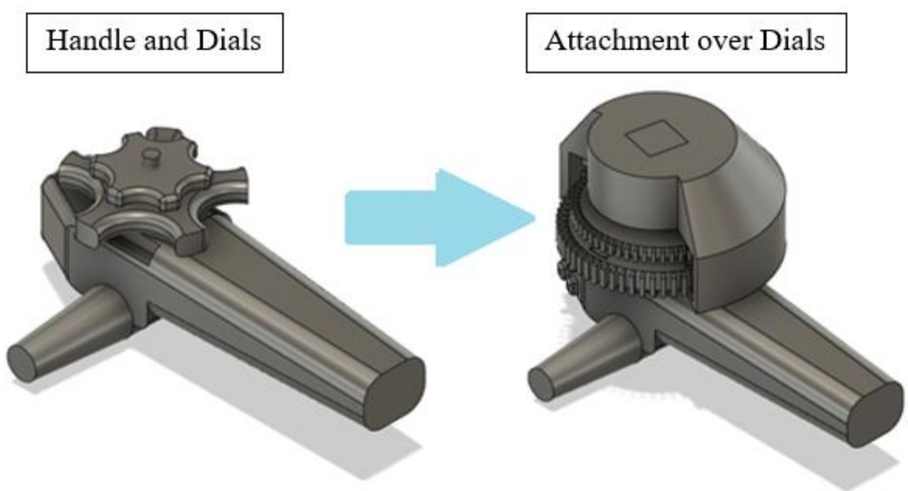

Figure 2: Ergonomic Endoscope Attachment Prototype. The three dimensional rendering of the handle of the endoscope before and after the attachment is secured on top of the dials is shown here. The exposed gears of the device represent the user interface of the device (Created by Kevin Chang and Vincent Sciortino, 2019).

address the root issue of high forces and repetitive strain, the device will provide a secondary system that will aid the physicians in turning the dials if their left thumb becomes fatigued. Having a secondary system in place will ensure that they are not required to supply the necessary forces to deflect the distal end of the scope while tired. By tackling the three fundamental risk factors for these injuries, this device solution provides an effective intervention for reducing the possibility of injury.

REMEMBERING THE PHYSICIAN

In the pursuit of patient-centered care, physicians are often inadvertently “subordinated, forgotten, or dismissed” (Shergill & McQuaid, 2019, p. 3). By putting the health of the physician first, the technical project turns the current standard of patient-centered care on its head and has the potential to benefit the clinical setting from the top down. One study in Korea found that out of 55 endoscopists surveyed, 16% of them reported modifying or reducing the number of procedures they conducted as a result of musculoskeletal pain (Byun et al., 2008). The results from this study suggests that De Quervain’s tenosynovitis can lead to a loss of productivity as well as a shortened career. Maintaining the health of a physician’s hands can potentially reverse the observed loss of productivity, allowing more patients to be seen in a day and streamlining the patient experience in the endoscopy suite.

The space used to conduct research on hand muscle activity and force exertion for the first phase of the technical project has yet to be determined, but will ideally take place in an endoscopy training suite that supplies a model colon capable of simulating a colonoscopy. Muscle activity will be measured using the BioRadio electromyogram (EMG), and the forces exerted by the thumb will be measured using a force sensor. The technical advisor, Professor William Guilford, has generously provided access to a three-dimensional (3D) printer, as well as an estimated budget of $6,000, so that prototypes from the second phase of the technical project may be produced and iterated. By the end of the year, the technical project team hopes to produce a working prototype that alleviates these musculoskeletal overuse injuries for the physicians, followed by a technical paper on the comparative study showing the efficacy of our proposed design.

THE IMPACT OF WOMEN ON MEDICAL DESIGN

In the study of this Science, Technology and Society (STS) topic, the impacts that women may have on medical design can be studied in two separate groups of the same demographic: the female physicians and the female patients. In recent history, the role of women in medicine has been steadily increasing, indicated by the 31% increase of women in the physician workforce from 5% at the end of the 19th century to approximately 36% by 2015 ("Women in medicine", 2015). This trend suggests that more women are entering the medical field as physicians, resulting in an increasing need for medical equipment designed with certain constraints in mind, such as the difference in average hand size between males and females. Furthermore, a significant gap in data collected between males and females can lead to lethal consequences. Data that has been skewed by gender due to a higher volume of male data pose the risk of treating females as anomalies. In terms of the patient population, this means that when a female presents with symptoms that are different than that of a male, there is a potential risk of misdiagnosis (Criado-Perez, 2019).

The first flexible video-endoscopes introduced to the field of gastroenterology in 1980 possessed a one size fits all design that did not cater to a spectrum of potential users. Forty years later, major endoscope companies have managed to ignore this issue and little about endoscope mechanical design has changed (Shergill & McQuaid, 2019). Women have been one of the major users affected by the lack of a human-centered design. Cohen, Naik, Tamariz, & Madanick, (2008) conducted a study on 227 gastroenterology fellows to determine the relationship between hand size and its effect on their training in endoscopy. Of these fellows, the median surgical glove size was 7.5. This study found that out of the 38 respondents with small hand sizes, indicated by a surgical glove size of 6.5 or smaller, 97.4% of them were female, and all of them were more likely to consider their hands too small to operate standard endoscopes. The results from this study suggest that hand sizes are an important design constraint for the endoscope. As displayed in Figure 3, the endoscopist is required to wrap the palm of their left hand around the dorsal side of the endoscope and their thumb and fingers must reach toward the ventral side in order to access the dials. Smaller hands would have a greater difficulty in maintaining this hand position around the handle of endoscope, thus making it even more difficult to operate the scope.

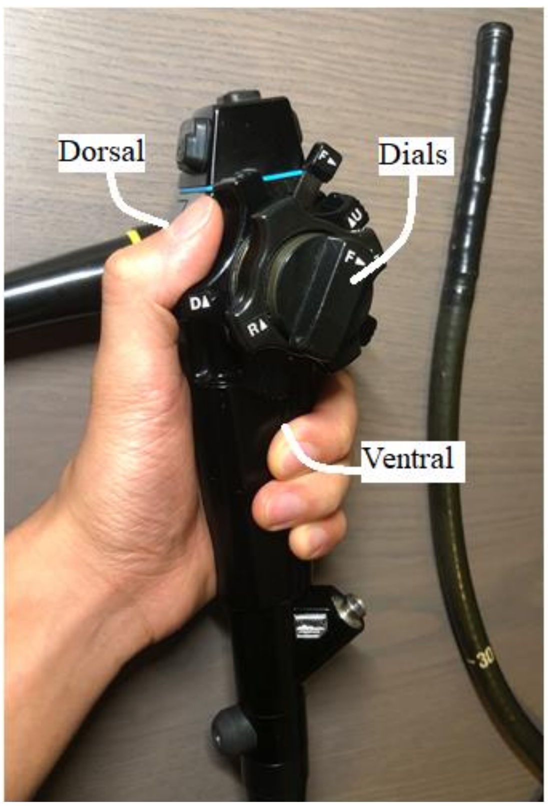

Figure 3: Operation of the Endoscope. The hand is required to wrap around the dorsal (back) side of the endoscope to access the dials on the ventral (front) side. (Created by Kevin Chang and Vincent Sciortino, 2019).

In another example, described by Caroline Criado-Perez in Chapter 8 of *Invisible Women*, a voice recognition notetaking software was designed to transcribe what attending emergency physicians were describing about their patients. One study found that when incorrect transcriptions were made by the software, 15% of the errors miscommunicated critical points of information regarding a patient's health; furthermore, another study reported that a significantly higher rate of transcription errors were caused when the software was transcribing the voice of a woman than that of a man. Criado-Perez attributes these design flaws to what she calls the gender data gap, or the misrepresentation of women in data. Speech recognition software is typically designed using a large database of voice recordings so that it can identify spoken words and phrases; however, the recordings compiled on most of these databases are dominated by male voices. As a result, the skewed data develops the software to recognize male voices more easily than female voices (Criado-Perez, 2019).

Although the importance of considering women in medical design is recognized by authors and activists like Criado-Perez, a number of medical technologies with gender associated drawbacks, such as the endoscope, continue to exist unchanged (Shergill & McQuaid, 2019). It is apparent that the drawbacks of some medical technologies are met with apathy when it comes to gender constraints; thus, more research must be conducted in order to understand what has been done to include women in medical design so that its framework may be used to encourage change in technologies that are resistant to the influence of women.

To begin the Science, Technology and Society (STS) analysis, Pacey's Triangle can be used to divide social groups into three categorical roles in the development of a medical design: the technical, the organizational and the cultural aspects of each group. By first identifying and separating each social group into their respective roles, the influence of each group can be examined on their impact on medical design using the Social Construction of Technology (SCOT) framework, as defined by Bijker et al., (1970). Furthermore, the STS analysis will involve a focused investigation of the role of women in medical design by evaluating areas in which innovations have succeeded or failed to account for women as stakeholders in the design process.

Analysis will be separated into two groups. For medical technologies that have identified women as stakeholders and have constrained their designs to match the needs of women, the STS thesis will evaluate to what degree women have made an impact and will seek to determine if these impacts have been sufficient to satisfy the social group. As for the designs that have disregarded women as stakeholders, the analysis will seek to describe the problems identified by women in each technology and will seek to explain why these issues have not been resolved. Using this structure of analysis, the STS thesis will begin with an investigation of the endoscope before moving on to other medical devices.

On page 11, Figure 4 organizes the relevant social groups involved in the design of the endoscope onto Pacey's Triangle. The cultural category on this diagram lists the people who suffer from the design of the endoscope, including: the physicians who suffer from De Quervain's tenosynovitis (Harvin, 2014), the subcategory of female physicians who on average have smaller hands than men (Byun et al., 2008), and the patients. Drawing from an informal interview conducted with gastroenterologist Dr. Dushant Uppal, patients are identified as potential sufferers of the endoscope design due to longer wait times (K. Chang, personal communication, November 13, 2019). Although long wait times are considered more as inconveniences to patients, the Cancer Treatment Options and Management (CTOAM) speculates that longer wait times between a patient's initial complaint about a potential cancer related symptom to their time of diagnosis can prolong their access to medical care; thus, allowing more time for the cancer to progress untreated ("Wait times for treatment," 2019). The organizational side of endoscope design involves the government, such as the Food and Drug Administration (FDA), which provides legal obstacles that need to be crossed before changes to the endoscope or how it is operated can be approved for commercial use (U.S. Food and Drug Administration, 2018). Once approved, the device must then be manufactured by an industry and then adopted into clinics or hospitals so that physicians may have access to these new technologies. Finally, it is up to the researchers and engineers to play the technical role in

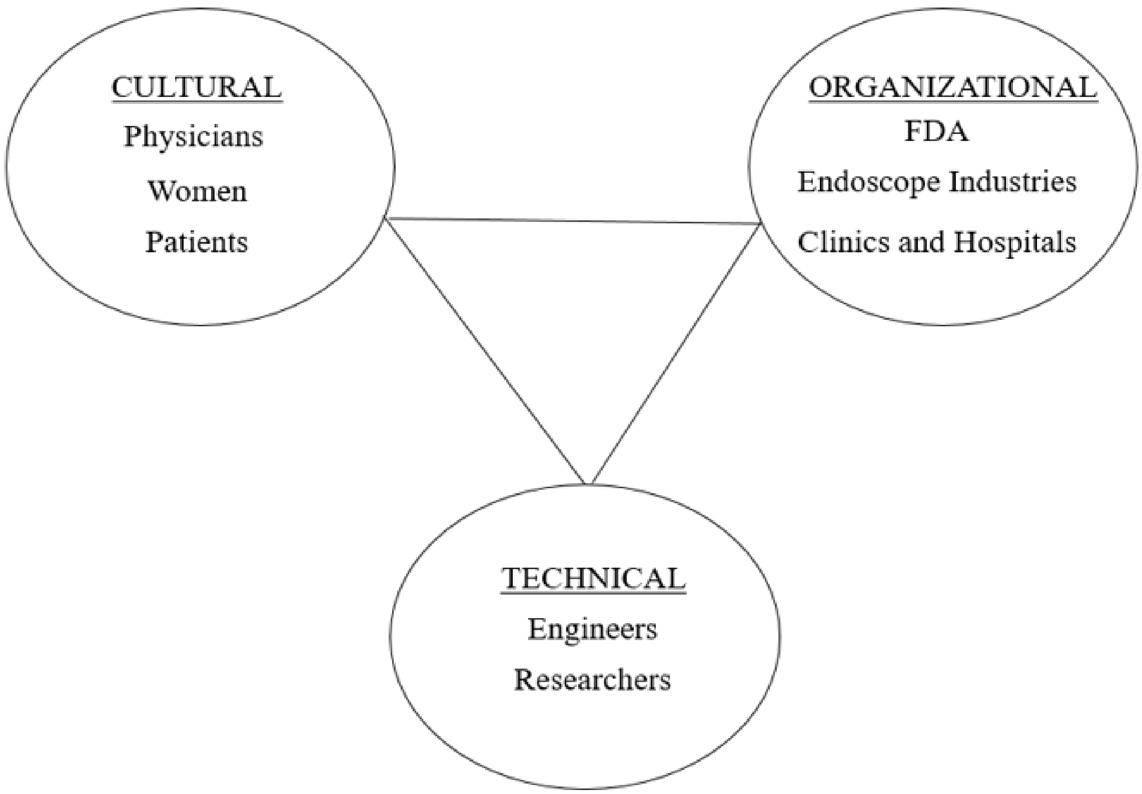

Figure 4: Pacey's Triangle of the Endoscope. This STS conceptual framework helps organize relevant social groups associated with the design of the endoscope into three main categories: the cultural, organizational and technical groups. (Adapted by Kevin Chang, 2019 from Arnold Pacey).

identifying problems with a design and then putting forth solutions. Given these various social groups, they can now be mapped onto a SCOT diagram for an analysis of their influence in the social construction of the endoscope.

On page 12, Figure 5 tells the story of the social construction of the endoscope by beginning with the overarching problem: colorectal cancer, which affects the health of many patients nationwide as the second most common and deadly cancer in the United States (U.S)

(Marley & Nan, 2016). Physicians needed a way to properly diagnose colorectal cancer patients, resulting in the introduction of the first endoscope in 1980; however, this initial design, as indicated in the SCOT diagram, created another set of problems for patients, women, and physicians, leaving it up to the engineers of the technical group to design better solutions. The concepts proposed to resolve these issues include smaller handled endoscopes, motor controlled endoscopes and joystick controlled endoscopes.

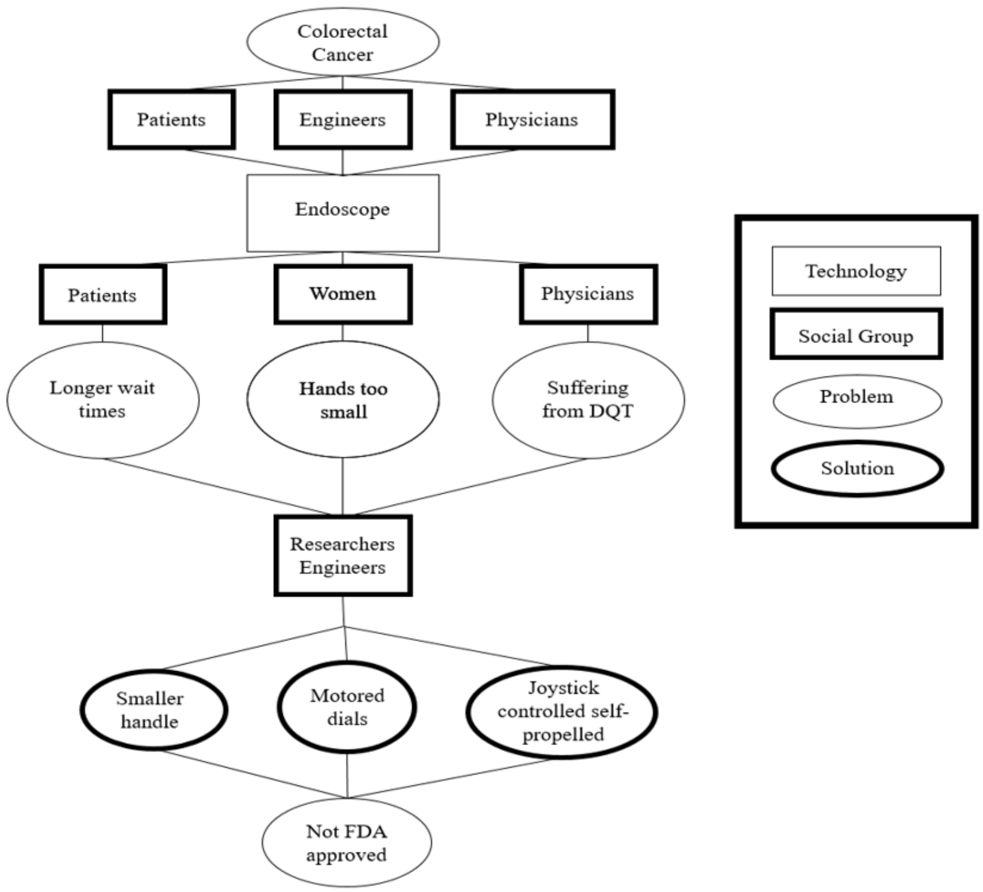

Figure 5: SCOT Diagram of the Endoscope. This diagram describes the progression of the social construction of the endoscope, starting from its initial design used to diagnose colorectal cancer, then to the problems that arose from this design, and then ending at the current state of innovations to address these issues. The SCOT framework will be used to analyze various medical technologies in a similar way (Created by Kevin Chang, 2019).

The three concepts produced by the engineers in Figure 5 all serve to potentially benefit women by making the endoscope more accessible. Female physicians that, on average, have difficulty operating the endoscope due to smaller sized hands would thus benefit from a specialized endoscope with a smaller handle, so that their hands could easily wrap around the device to access the dials. Furthermore, an endoscope with motorized dials would remove the need for the hands to manually operate the dials, entirely. As for the third concept, the Aer-O-Scope is a device currently under development that is ergonomically designed to be operated through joystick controls and is capable of propelling itself through the colon, eliminating the need for physical exertion from the physician (Gluck et al., 2015). Despite the advantages of these proposed designs, none are currently approved for sale in the U.S. by the FDA, although some devices, like the Aer-O-Scope, are currently undergoing clinical trials (Gluck, Melhem, Halpern, Mergener, & Santo, 2016).

Due to the lack of commercially available medical devices that address the problems presented by women, a great demand exists to bring forth solutions not only to women in endoscopy, but to women involved with various other medical technologies such as the voice recognition notetaking software. The current state of medical design necessitates engineers to recognize the importance of women as stakeholders so that they will reject the notion that ignoring the issue is in any way acceptable. By using Pacey's Triangle and SCOT as conceptual frameworks, the STS thesis seeks to illuminate drawbacks in the design of certain medical technologies as it pertains to women. The scope of research will involve the investigation of the social role women play in the development of the endoscope as well as various other technologies to construct a broad understanding of the impact women have on medical design. By doing so, the project will serve as a call to action for engineers to begin resolving gender based inadequacies in medical design so that aspects of each technology can be readjusted to fit the paradigm of the growing demand for gender equality.

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