A Hand-Held Device for Controlling a Mounted, Motor-Driven Colonoscope

A thesis presented to

the faculty of

the Russ College of Engineering and Technology of Ohio University

In partial fulfillment

of the requirements for the degree

Master of Science

Corey D. Sheerer

May 2015

©2015 Corey D. Sheerer. All Rights Reserved.
This thesis titled

A Hand-Held Device for Controlling a Mounted, Motor Driven Colonoscope

by

COREY D. SHEERER

has been approved for

the School of Electrical Engineering and Computer Science

and the Russ College of Engineering and Technology by

JungHun Choi

Assistant Professor of Mechanical Engineering

Dennis Irwin

Dean, Russ College of Engineering and Technology
ABSTRACT

SHEERER, COREY D., M.S., May 2015, Mechanical Engineering

A Hand-Held Device for Controlling a Mounted, Motor Driven Colonoscope

Director of Thesis: JungHun Choi

Colorectal cancer is a prevalent and deadly disease that is further emerging within our society. As knowledge about this disease becomes more widespread, an increasing demand for screening and high standards arises. This creates a need for a device which can be more easily mastered by physicians to achieve competency, as well as reduce injury risks from performing repetitive motions during a heavy load of colonoscopy procedures. This thesis focuses on the fabrication of a prototype colonoscope that incorporates a holding structure to support the colonoscope, and a hand-held device that actuates distal tip steering. Experimentation was performed to compare the fatigue and learning curve of the prototype scope to a conventional scope. Fatigue was measured as a reduction in force corresponding to the maximum voluntary contraction of the left thumb and forearm. Results show that subjects using the prototype scope did not experience any significant reduction in force in either the thumb or forearm, while the conventional scope resulted in a force reduction of 17% and 16% in the forearm and thumb respectively. Cecal intubation time and learning rate showed no significant decrease while using the prototype scope compared to a conventional scope.
DEDICATION

To my family, friends, and advisors

Nothing truly worth doing can be done alone
# TABLE OF CONTENTS

Abstract ........................................................................................................................................... 3

Dedication ......................................................................................................................................... 4

List of Tables ................................................................................................................................... 8

List of Figures ................................................................................................................................... 9

Chapter 1: Introduction .................................................................................................................. 12
  1.1 Colorectal Cancer and Colonoscopy ..................................................................................... 12
  1.2 The Endoscope and Colonoscope ......................................................................................... 13
  1.3 Quality in Colonoscopy .......................................................................................................... 16
  1.4 Relevant Work and Needs Statement ....................................................................................... 18

Chapter 2: Literature Review ......................................................................................................... 20
  2.1 Colonoscope Ergonomics ........................................................................................................ 20
  2.2 Learning Rate of Colonoscopy ............................................................................................... 25
  2.3 Capsule Endoscopy ................................................................................................................. 28
  2.4 Automated Colonoscopes and Colonoscope Mechanisms .................................................... 30
    2.4.1 Self-Intubation Scopes and Mechanisms ......................................................................... 31
    2.4.2 Distal Tip Centering Colonoscope .................................................................................. 34
    2.4.3 Automated Colonoscope Tip .......................................................................................... 35
  2.5 Improved Colonoscope Features .......................................................................................... 38
    2.5.1 Gesture Distal Tip Steering Colonoscope ......................................................................... 38
    2.5.2 Variable Stiffness Colonoscope ....................................................................................... 40
    2.5.3 Control Head Holder ........................................................................................................ 41
  2.6 Objectives ............................................................................................................................... 42

Chapter 3: Prototype ...................................................................................................................... 45
  3.1 Design Overview ....................................................................................................................... 45
  3.2 Motor Overview ......................................................................................................................... 47
  3.3 Belt System ............................................................................................................................... 49
  3.4 Stand Overview ........................................................................................................................ 51
    3.4.1 Stand Stabilizers and Scope Supports ............................................................................... 52
LIST OF TABLES

Table 1. Ergonomics study fatigue results [9] .................................................................. 21

Table 2. Ergonomics study fatigue results (continued) [8]............................................... 22

Table 3. Ergonomic risk factors for endoscopist [8].......................................................... 24

Table 4. Forearm average normalized force (ANF) results with t-test for each trial............ 74

Table 5. Thumb average normalized force results with t-test for each trial ..................... 76

Table 6. Intubation time t-test results between conventional and prototype scope .......... 80

Table 7. Average normalized intubation time t-test results .............................................. 81

Table 8. Fatigue data for conventional scope ................................................................... 109

Table 9. Fatigue data for prototype scope ...................................................................... 110

Table 10. Intubation time data for conventional scope and t-test results (disqualified subject excluded) ............................................................................................................ 111

Table 11. Intubation time data for prototype scope (disqualified subject excluded)...... 111
LIST OF FIGURES

Figure 1. Anatomy of a colon [4]......................................................................................... 13

Figure 2. The colonoscope [6].......................................................................................... 14

Figure 3. Distal tip components [6]. .................................................................................... 15

Figure 4. Distal tip maneuvering mechanism [6]. .............................................................. 16

Figure 5. Moving average competency curve [11]............................................................... 27

Figure 6. Capsule endoscopy pill [12]................................................................................ 28

Figure 7. PID controller step-response capsule position [17]. ......................................... 30

Figure 8. Invendoscope with (A) hand-held controller and (B) driving mechanism [14]. 32

Figure 9. (a) Earthworm-like robot and (b) spiral robot [20]............................................... 33

Figure 10. (Left) Distal end infrared attachment and (right) DC motor and controller
attachment on control head [21]. ......................................................................................... 35

Figure 11. Automated tip controlled by three pressure chambers [22]. ......................... 36

Figure 12. Time response for tip displacement [22]............................................................ 37

Figure 13. Sensor data for turn trial (y-axis: mm from tube wall, x-axis: mm inserted in
tube) [22].......................................................................................................................... 37

Figure 14. Intuitive grip with orientation steering and (1) air, (2) suction, and (3) water
buttons [15].......................................................................................................................... 39

Figure 15. Main components of colonoscope design.......................................................... 46

Figure 16. Force acquisition setup using dial, string, and a force sensor [27].............. 47

Figure 17. Experimental force results for A) small knob and B) large knob...................... 48

Figure 18. Pittman motor with encoder............................................................................. 49
Figure 19. (a) 2.037” pulley on colonoscope shaft and (b) 0.764” pulley on motors. .... 50

Figure 20. Belt system with two pulleys attached to the colonoscope shaft and held in place by a locknut piece. ................................................................. 51

Figure 21. Prototype stand for colonoscope. .......................................................... 52

Figure 22. (a) Cord support and (b) intubation support........................................ 53

Figure 23. Colonoscope stand clamps attached to table. .................................. 54

Figure 24. Motor mount for two Pittman DC motors........................................ 55

Figure 25. Linear slide with hex nut locking mechanism. ................................. 55

Figure 26. Circuit system with arduino, motor shield, bluetooth, current sensor, and motor with encoder. ................................................................................. 56

Figure 27. Electro-mechanical system block diagram. ...................................... 57

Figure 28. Android application user interface for colonoscope control. ............ 58

Figure 29. 120 VAC to DC circuit (iCircuit). ...................................................... 59

Figure 30. Strain gauge dynamometer (a) and Jamar dynamometer [29] (b) for collecting maximum voluntary contraction for thumb and forearms respectively .......... 61

Figure 31. Hand position for MVC strain gauge dynamometer. ....................... 62

Figure 32. a) Wheatstone bridge configuration. b) Fluke multimeter with USB capabilities. c) Precision strain gauge on delrin cylinder. ................................. 63

Figure 33. Typical data with three presses to determine MVC (top), and methodology for determining voltage magnitude of each press (bottom). ........................................... 64

Figure 34. Active Colonoscopy Training Model simulator with LabView for force measurements [30]. ................................................................. 68
Figure 35. Average normalized thumb MVC distribution. .............................................. 72

Figure 36. Average normalized forearm MVC results for prototype and conventional
scope. ................................................................................................................................ 73

Figure 37. Average normalized thumb MVC results for prototype and conventional
scope. ................................................................................................................................ 75

Figure 38. Prototype scope distribution of intubation time over the four trials. .......... 78

Figure 39. Conventional scope distribution of intubation times over the four trials....... 78

Figure 40. Average cecal intubation time for conventional and prototype scope......... 79

Figure 41. Average normalized cecal intubation time................................................. 81

Figure 42. Voltage drop (top) and current (bottom) across dc motor with PWM speed
control. .................................................................................................................................. 100

Figure 43. H-bridge with relay activation controlled by Arduino digital pin. .......... 101

Figure 44. Voltage drop (green) and current (red) across h-bridge with no PWM...... 101

Figure 45. Cord support model.................................................................................. 128

Figure 46. Cord support mechanical drawing ............................................................ 129

Figure 47. Intubation tube support model. ............................................................... 130

Figure 48. Intubation tube support mechanical drawing ........................................ 131

Figure 49. Motor mount model. ............................................................................... 132

Figure 50. Motor mount mechanical drawing......................................................... 133

Figure 51. Lock nut model. ..................................................................................... 134

Figure 52. Lock nut mechanical drawing ............................................................... 135
CHAPTER 1: INTRODUCTION

Colorectal cancer is the third most common and fourth most fatal cancer in the world [1]. It is estimated by The American Cancer Society that the United States will witness 96,000 new cases of colon cancer, 40,000 new cases of rectal cancer, and 50,000 deaths from these conditions this year alone (2014) [2]. Detection of pre-malignant adenomatous polyps, which can be removed before they become cancerous, plays a colossal role in the prevention of colorectal cancer [1]. Furthermore, detecting cancer cells during the early stage of the disease is a critical factor of whether the cancer is curable [2]. Colorectal cancer formation and mortality rate can be severely reduced by proper screening (up to 90% and 53% respectively) [3]. Therefore, screening is an important aspect in prevention and cure of colorectal cancer [2] [1].

1.1 Colorectal Cancer and Colonoscopy

A polyp is an abnormal formation of tissue mass that forms on the colon wall [1]. In many cases, a newly formed, or neoplastic, polyp has no symptoms occurring with its presence. However, the longer a polyp exists, the more chance it has of becoming cancerous. A non-new polyp formation, or nonneoplastic, accounts for 70% of all carcinoma polyps [4]. Formation of polyps as well as carcinoma has been strongly linked to diet, lifestyle, and genetics [1]. Furthermore, polyp formation is more common with increasing age [4].
Colonoscopy is the primary method for detecting polyps and cancerous cells within the rectum and colon [1]. A colonoscope is inserted into the anus and travels up through the rectum and colon (seen in Figure 1) [5]. For a colonoscopy to be considered complete, the scope must reach the cecum (end of the large intestine). As the colonoscope advances and retracts through the colon, a physician examines the colon by means of video being transmitted through a camera attached to the tip of the scope [4]. If a polyp or other suspicious entity is observed, immediate removal can be performed [2].

![Figure 1. Anatomy of a colon](image)

1.2 The Endoscope and Colonoscope

An endoscope is a medical device consisting of an insertion tube that enters the body to observe the digestive tract [6]. A colonoscope is a specialized endoscope that is inserted into the anus and observes the colon. The colonoscope is the main tool for detection and removal of polyps within the colon [1]. The colonoscope, seen in Figure 2,
consists of three main parts; the insertion tube, the control head, and the universal cord and plug. The insertion tube traverses the colon and is controlled by the control head. The whole device is connected via the universal cord and plug to a processing unit that provides power, water, air, and suction [4].

Figure 2. The colonoscope [6].

The insertion tube is a 130 cm long tube that brings visual imaging and medical tooling into the colon. Tension cables running from the control head down the insertion tube allow the distal end of the colonoscope to be maneuvered within the colon. Furthermore, multiple channels run through the insertion tube to provide air, water,
suction, and a tooling pathway to the distal tip of the device. Along with the channel openings, the distal tip, seen in Figure 3, contains a camera and light for video capture and transmission [4]. Insufflation and lens cleaning are the main purpose of the water and air channels, while the suction and instrument channel provide the means for applying biopsy tooling within the colon. The channels and connections to the distal tip as well as the steering cables are encased in a flexible sheath [6].

![Figure 3. Distal tip components [6].](image)

The control head is used to maneuver the distal tip of the insertion tube, interact with the channel controls, and inserts biopsy tooling. Maneuvering the distal end of the colonoscope is achieved with two knobs on the control head that can be seen in Figure 2. The up/down motion of the tip is controlled with the larger knob, while the left/right motion is accomplished with the smaller knob. The steering mechanism can be seen in Figure 4. The control head also contains push-valves that enable air, water, and suction
to be utilized at the distal tip to obtain better visualization of the colon. Furthermore, a biopsy channel opening is located on the control head allowing inserted tooling to reach the distal tip of the colonoscope. The tooling is commonly used for taking samples and removing polyps.

Figure 4. Distal tip maneuvering mechanism [6].

1.3 Quality in Colonoscopy

Successful administration of a colonoscopy is a result of training and procedural experience. A successful colonoscopy includes reaching the cecum, minimizing intubation time, minimizing pain, and avoiding complications [7]. Quality of the procedure can be compromised, however, when inexperienced physicians perform the colonoscopy procedure [7], or experienced physicians develop fatigue injuries from performing too many procedures [8]. These can lead to increase risks of complications and decreased effectiveness of screening.
Frequent muscle activity as well as awkward hand and arm positioning required to control the insertion tube and control head during a colonoscopy can lead to muscle fatigue and musculoskeletal related injuries for the performing physicians [8]. A physician usually holds the control head and manipulates the two knobs and the valves with the left hand, assisting with the right hand when needed. The right hand is primarily responsible for stabilizing and providing the intubation force for the intubation tube [4]. Risks on the left side of the body arise from stabilization of the control head with the left hand and wrist, as well as manipulating the steering knobs with the left thumb. The right hand and wrist are also at risk from the need to stabilize, drive, and twist the insertion tube [9]. Reduction in the physician’s ability to insert and control the scope due to these injuries can sacrifice the rate the endoscopist can insert the scope and view the colon.

Quality in colonoscopy can also be decreased when inexperienced physicians perform the colonoscopy before they reach competence. Competency for an endoscopist is most widely generalized as percentage, called the cecal intubation rate (CIR), of how often the physician reaches cecum with the colonoscope [7]. To be considered competent, an endoscopist must achieve a CIR of 90%, although an experienced physician may achieve up to a 98% success rate [7] [4]. Procedures that do not reach the cecum due to problems such as looping, intestinal fixations, or an inexperienced physician may leave potentially harmful areas unchecked for polyp formations [4].

A successful colonoscopy includes reaching the cecum as well as having a timely intubation, minimizing pain, and avoiding complications. Intubation rate is an important success factor because it correlates to completion rate as well as pain and discomfort of
the patient [7]. Furthermore, complications such as perforation, bleeding, and mortality (occurring at 0.1%, 0.2%, and 0.006% respectively) may arise even with experienced physicians [4] [10]. A successful colonoscopy will observe the whole colon while avoiding these unwanted conditions.

Incomplete colonoscopies as well as the risk associated with the procedure are more prominent in residents learning colonoscopy. While a 90% CIR is widely accepted as a competence level, the number of procedures a resident is required to undergo to reach that competence level is highly debated [7]. The American Board of Surgery requires 50 procedures before being considered competent, however, many studies show that more are necessary [11]. The largest and most recent study by Ward, S. et al, [11], concluded that residents must complete an average of 233 colonoscopies to reach a competency rate of 90%. Furthermore, before reaching a competent level, the resident is more inclined to cause pain and/or complications [7].

1.4 Relevant Work and Needs Statement

Many devices and procedures have been designed to improve the field of colonoscopy. Innovative ideas focus on reducing invasiveness, reducing risks such as perforation, decreasing learning time, and reducing and/or eliminating physician interactions with the colonoscope. Procedures such as capsule endoscopy, that use a swallowable capsule with a camera in it, observe the gastrointestinal tract, are being developed to decrease invasiveness of endoscopy and colonoscopy [12] [13]. Other adaptations such as self-propelling scopes are being created to eliminate human interaction
during intubation and, thereby, reducing learning time [14]. Furthermore, some mechanisms are being developed to increase the intuitiveness, effectiveness, and ease of the colonoscope. These include variable stiffness scopes and intuitive steering mechanisms [15].

While advancement in colonoscopy is occurring, it continues to be a complex procedure that involves extended training, experience, and focus in order to successfully and continually perform. Furthermore, with a growing awareness of the benefits screening has in the prevention and treatment of colorectal cancer, the magnitude of procedures being performed is rising. [7]. This constitutes a need for a colonoscope design that can reduce learning time and improve the ergonomics of the scope in order to maintain high screening standards for an increasing number of procedures while protecting the physician’s health.
CHAPTER 2: LITERATURE REVIEW

Colonoscopy is growing field with new research and devices being developed in order to improve this procedure. Many studies highlight the importance of a safe working environment for the physicians, as well as the amount of necessary experience a physician needs in order to perform successful colonoscopy. New devices are being developed to improve success rates of colonoscopies by simplifying and reducing physician interactions with said devices. This chapter will cover studies highlighting risks physicians face while performing colonoscopies, the amount of procedures a physician must perform to become competent, and new devices that are emerging in order to increase efficiency of the colonoscopy procedure.

2.1 Colonoscope Ergonomics

Ergonomics of the endoscope and colonoscope are being scrutinized as more studies reveal risks a physician faces while performing an increasing amount of procedures [8]. The colonoscope design requires exuberant and repetitive hand activity to perform a colonoscopy, leading to muscle pain and injuries. One study, performed by Shergil, Ak, et al, [8], compared multiple relevant ergonomic studies to conclude the importance of ergonomic impact on physicians. Shergil’s study found that 35-90% of all endoscopists have musculoskeletal pain or injury from performing endoscopy [8]. Table 1 and 2 shows the results of the multiple studies that indicate (through reported injury) endoscopy and colonoscopy cause injury to the physician.
Table 1. Ergonomics study fatigue results [9]

<table>
<thead>
<tr>
<th>Study</th>
<th>Type of study</th>
<th>Response rate (%)</th>
<th>Number of endoscopists</th>
<th>Age (y) Mean (SD)</th>
<th>Sex (% men)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buschbacher,¹ 1994</td>
<td>Survey of ASGE members</td>
<td>72</td>
<td>265</td>
<td>47.8 ± 8.6</td>
<td>95.1</td>
</tr>
<tr>
<td>O’Sullivan et al,² 2002</td>
<td>Survey of Canadian ERCP endoscopists</td>
<td>74</td>
<td>114</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Liberman et al,⁴ 2005</td>
<td>Survey of worldwide members of American Society for Colon and Rectal Surgery</td>
<td>28</td>
<td>608</td>
<td>48 ± 9.5</td>
<td>89.3</td>
</tr>
<tr>
<td>Keate,⁴ 2006</td>
<td>Online survey of ASGE members</td>
<td>N/A</td>
<td>237</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Hansel et al,³ 2007</td>
<td>E-mail survey, case-control study of Mayo Clinic gastroenterologists (GI group) and nonprocedure-oriented internists and subspecialists (non-GI group)</td>
<td>GI-group, 63</td>
<td>72</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td></td>
<td>non-GI group, 45</td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lee and Valiozis,⁵ 2007</td>
<td>Survey of members of Gastroenterological Society of Australia</td>
<td>12.4</td>
<td>94</td>
<td>88% between ages 31 and 60</td>
<td>84</td>
</tr>
<tr>
<td>Byun et al,² 2008</td>
<td>Endoscopists practicing in general hospitals or health promotion centers in Korea willing to participate</td>
<td>N/A</td>
<td>55</td>
<td>Median age 39</td>
<td>67</td>
</tr>
</tbody>
</table>

ASGE, American Society for Gastrointestinal Endoscopy; N/A, not applicable; CTS, carpal tunnel syndrome.

*The total of 12% reported missing work because of injury and/or requiring surgery for injury; surgery rate not specifically defined.
Table 2. Ergonomics study fatigue results (continued) [8]

<table>
<thead>
<tr>
<th>Years in practice</th>
<th>Mean (SD) time spent in endoscopy</th>
<th>% Reporting injury</th>
<th>Type of injury (%)</th>
<th>% Requiring surgery</th>
<th>% Time off work</th>
</tr>
</thead>
<tbody>
<tr>
<td>All &gt;0.5 y</td>
<td>12.4 h/wk</td>
<td>57</td>
<td>Low back (13), thumb (10), neck (10), elbow (8), CTS (4), shoulder (3), hand numbness (3), other (6)</td>
<td>3.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Mean (SD): injured, 14.7 (7) y; noninjured, 11.6 (5.9) y</td>
<td>2.4 (1.9) d/wk</td>
<td>39</td>
<td>Right foot (12.5), neck (10.7), right hand (8.7), back (8.6), right fingers (7.2), left fingers (6.4), left-hand pain (6.3), left thumb (5.3), right thumb (3.3), CTS (2)</td>
<td>2.7</td>
<td>1.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>78</td>
<td>Hand or CTS (43), back (29), neck (28), other (16)</td>
<td>(&lt;12%)*</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>74</td>
<td>Gl group: thumb (19), hand (17), back (12), neck (10)</td>
<td></td>
<td>13.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>37</td>
<td>Thumb (70)</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Median duration 3.25 y</td>
<td>19.5 (7.7) h/wk</td>
<td>89</td>
<td>Right shoulder (31), left shoulder (29), left finger (29), right wrist (26), neck (18), left wrist (18), right finger (16)</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
An important factor of deciding if an activity is potentially ergonomically harmful to the physician is the muscle force being applied to the scope. One study by Shergil, Ak, et al. [9], used hand activity level (HAL), which, defined by the American Conference of Industrial Hygienist (ACGIH), is a percentage of muscle force to maximum force that can be achieved, as a means of quantifying risk levels for muscle motions [8]. In this study, muscle activity of three endoscopists were acquired using electromyography and compared to two threshold standards (action limit and threshold limit) given by ACGIH. An activity exceeding the action limit (defined as ≥30% maximum muscle limit) is given a recommendation by ACGIH to vary the process in order to reduce chance of repetitive motion injury, while an activity exceeding the threshold limit (≥50 maximum muscle limit) is strongly recommended to change in or order to prevent high strain injury [9]. The results, shown in Figure 7, provide that the left and right hand as well as the left thumb are at risks for injury.

Shergil’s study resulted in the left and right wrist, the right hand, and the left thumb exceeding the action limit (at risk for repetitive injury) as well as the left wrist exceeding the threshold limit (at risk for high strain injury). The right wrist and right hand strain is a result of stabilizing and torqueing the intubation tube, while manipulating the control knobs on the control head provide strain for the thumb. High strain on the left wrist is caused by stabilizing the control head while allowing the fingers and thumb to interact with the valves and control knobs [9].
Table 3. Ergonomic risk factors for endoscopist [8]

<table>
<thead>
<tr>
<th>Muscle</th>
<th>Action</th>
<th>Subtask during colonoscopy</th>
<th>Potential injury</th>
<th>Study results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left APL</td>
<td>Abduction and extension of thumb</td>
<td>Manipulating dials of colonoscope</td>
<td>DeQuervain’s tenosynovitis</td>
<td>Yes</td>
</tr>
<tr>
<td>Left ECR</td>
<td>Wrist extension and abduction</td>
<td>Stabilizing control section of colonoscope</td>
<td>Second and third extensor compartment tenosynovitis at the wrist and epicondylitis (tennis elbow)</td>
<td>Yes</td>
</tr>
<tr>
<td>Left FDS</td>
<td>Flexion of the digits of the hand</td>
<td>Grasping control section of colonoscope</td>
<td>Carpal tunnel syndrome</td>
<td>No</td>
</tr>
<tr>
<td>Right ECR</td>
<td>Wrist extension and abduction</td>
<td>Torquing colonoscope insertion tube</td>
<td>Second and third extensor compartment tenosynovitis at the wrist and epicondylitis (tennis elbow)</td>
<td>Yes</td>
</tr>
<tr>
<td>Right FDS</td>
<td>Flexion of the digits of the hand</td>
<td>Grasping colonoscope insertion tube</td>
<td>Carpal tunnel syndrome</td>
<td>No</td>
</tr>
</tbody>
</table>

*Action limit, HAL: for colonoscopy, defined as APDF ≥ 30% maximum voluntary contraction; if forces exceed the action limit, then the task should be modified to reduce the risk of repetitive strain injury.

†Threshold limit, HAL: for colonoscopy, defined as APDF ≥ 50% maximum voluntary contraction; if forces exceed the threshold limit, then the task should be changed, given the high risk of repetitive strain injury.
It can be concluded that manipulating an endoscope or colonoscope is harmful for the practicing physician. Shegril’s studies provide data that many physicians performing endoscopy or colonoscopy are experiencing pain [8]. Furthermore, all physicians involved in these procedures are at risk for developing complications in both the left and right wrist, the right wrist, and the left thumb due to the repetitive nature of the procedure. The left thumb and both wrists exceed the action limit, putting them in danger of a repetitive motion injury, while the left wrist exceeds the threshold limit, indicating a high risk for a strain injury [9]. New methodology and instrumentation needs to be implemented in order to reduce the risks a physician faces while performing an increasing number of procedures.

2.2 Learning Rate of Colonoscopy

Learning colonoscopy incorporates many ethical and technical abilities to become competent as to provide a high standard of care. Learning colonoscopy is essential to perform complete colonoscopies within a reasonable time and entirely assess the colon. The American Board of Surgery requires a minimum of 50 procedures to be considered a competent endoscopist (most commonly defined as achieving a cecal intubation rate of $\geq 90\%$), however, many studies show more training is required [11]. One study, by Church, J. et al, [7], concluded that after 18 students performed 125 procedures each, the cecal intubation rate was only 75.1% when the intubation time was limited to below 19 minutes [7]. Another six-month study in Japan estimates a need for 325 to 350
procedures for residents to achieve competence: defined in the study as above a 90% cecal intubation rate with an insertion time of less than or equal to 15 minutes [16].

The most comprehensive study, Ward S. et al, [11], performed in the U.K., observed 297 trainees perform over 35,000 colonoscopies with database progress tracking. This study used two statistical strategies to assess cecal intubation rates: moving average method and learning curve cumulative summation (LC-CuSum). The moving average method calculated cecal intubation rates every 20 procedures performed by each resident. This resulted in an average of 233 procedures completed before a 90% cecal intubation rate was achieved. Progress of the residents can be seen in Figure 8. The LC-CuSum method observed competency in every procedure to determine if multiple predetermined competency thresholds were reached. As benchmarks were passed, parameters were adjusted in order to eliminate statistical bias arising from residents making mistakes earlier in their training. By the end of the study, only 36 of the 261 residents reached competency according to the LC-CuSum method. The residents who reached proficiency performed an average of 171 procedures to reach competency. This method was inconclusive because of the large number of residents who didn’t complete proficiency, however, it indicates a much higher number of procedures are required to reach competence than is currently required.
Many studies have been done to quantify the learning and competency rate achieved by residents. These studies indicate a relatively large number of procedures are required to become proficient at endoscopy and colonoscopy compared to the current standards. The American Board of Surgery’s standard of 50 procedures needed to be considered competent is over 100 procedures less than any of the studies concluded procedure requirements to become competent. This shows a need for more training, better training methodology, and/or more intuitive medical device.
2.3 Capsule Endoscopy

Capsule endoscopy is a non-invasive method for gastro intestinal observation where patients swallow a capsule containing camera equipment. Unlike conventional colonoscopy, the capsule, seen in Figure 9, provides a pain-free experience that can capture images from the stomach, small, and large intestine allowing a more complete detection area than a conventional endoscope or colonoscope. However, the quality of the video captured depends on orientation of the pill, lighting, and the degree of patient preparation. This leads to relatively high error in the detection of carcinomas (about 25% miss rate) as well as smaller polyps (under 6 mm). Furthermore, if detection does occur, there is no widely used method for pinpointing the location of the detected anomaly within the body [13]. Capsule endoscopy also suffers from the inability to manipulate the capsule’s position through the body. This leads to high procedure times as the capsule naturally moves through the body, as well as an inability to stop capsule movement for observational purposes [12].

Figure 6. Capsule endoscopy pill [12].
One proposed method for triangulating the anatomical location of the capsule within the body is real-time ultrasound tracking. This method emits sound waves through the patient that creates a 2 DOF image based on their deflection due to varying densities. The accuracy of the method was determined by placing the capsule within a gel solution that had human properties and measuring the start and finish position of the capsule after a displacement. The displacement, calculated by the ultrasound, was compared to a caliper (with 0.2 mm accuracy) to determine the error. This resulted in the determined error of the ultrasound to be under 2 mm [12]. This was concluded to be a sufficient triangulation precision and therefore a potentially viable method for use.

Another area of research that plays a role in the development of capsule endoscopy is magnetically driven capsule manipulation. This approach implants a permanent magnet into the capsule that is manipulated by magnet fields created outside the body. In one study, Hosseini, S. et al, [17], magnetic capsule steering was tested within a viscous fluid. The exterior magnets used a PID controller with multiple step responses in order to change the capsule location on the horizontal plane measured by laser position sensors. The position of the capsule using the PID controller can be seen in Figure 10. It can be seen that the first and second rise times are 0.9 and 1.2 seconds respectively with no discernable overshoot. This experiment showed a potential option for capsule position control within the body, however, lacks the ability to control the z-direction motion [17].
Capsule endoscopy is a promising field for gastrointestinal screening due its minimal invasiveness and discomfort for patients combined with its ability to traverse the stomach and both large and small intestine. Furthermore, a physician needs almost no training or interaction with capsule endoscopy in order to successfully administer it on a patient. However, drawbacks include high cost, with each capsule costing around 700 dollars, high error in detection, long procedure times, and the inability to triangulate position of the capsule [13]. New technology such as the magnetically driven capsule and ultrasound tracking are helping to bridge the gaps in this field, however, no complete solution is ready to be implemented in the near future.

2.4 Automated Colonoscopes and Colonoscope Mechanisms

Automated colonoscopes and mechanisms have and are being developed to eliminate the need for physician interactions during parts of the colonoscopy procedure. These devices aim to reduce human error and increase cecal intubation rates.
2.4.1 Self-Intubation Scopes and Mechanisms

Self-intubating scopes provide a method for autonomous and nearly autonomous intubation of a patient with the goal of reducing discomfort, colon trauma, and achieving high cecal intubation rates. This is especially useful for inexperienced physicians, who are less likely to reach the cecum and more likely to cause complications. Multiple mechanisms have been developed to achieve self-intubation, however, complications arise from navigation, propulsion efficiency, and cost.

The Invendoscope, a self-propelling colonoscope, is a newly developed single-use and remotely controlled device. A driving unit structure containing eight driving wheels that grips and propels the scope from outside the body is seen in Figure 11. The wheels rotation direction results in the forward and backward intubation motion of the scope. Intubation and removal of the scope, as well as the distal tip steering, are controlled with a hand-held device (also seen in Figure 5) containing forward and backward buttons for the intubation actions and a joystick for distal tip manipulation [14].
Initial testing for the Invendoscope resulted in a necessity with higher hardware reliability due to 5 out of 39 subjects dropping out of the study due to technical difficulties with the scope. In the remaining 34 patients, 28 had successful colonoscopies performed with the invendoscope [14]. A second study, conducted a year after the first, consisted of similar testing on 61 patients. Using the Invendoscope, this study produced a complete colonoscopy rate of 98% (60/61) with an average intubation time of 15 minutes and only 5% of the patients requiring sedation. This study concluded the Invendoscope is a promising device, but still required improvements on reducing the time needed to complete intubation [18]. Furthermore, due to being a single-use intubation tube, the Invendoscope is a costly compared to conventional colonoscopy [14].

Other self-intubating robots being developed as a possible driving mechanism for the colonoscope are an earthworm-like robot and a spiral robot seen in Figure 12. The earthworm-like robot uses the principles of an earthworm to move: inducing a periodic wave that causes differences in friction along the outer edge of the device to propel itself
while the spiral robot uses its rotating spiral body, which is in contact with the colon wall, to create linear motion [20]. Both mechanisms were tested within a straightened pig colon with successful propulsion, however, neither mechanism has been tested within a curved section. Furthermore, neither robot has yet to be adapted with all the tools and equipment contained on a conventional colonoscope [19] [20].

Figure 9. (a) Earthworm-like robot and (b) spiral robot [20].

Self-intubating mechanisms for colonoscopy are a popular idea due to their potential to reduce physician interaction during intubation and removal. This will help create more successful cecal intubation rates and reduce complications when being performed by less experienced physicians. The Invendoscope is leading the development of self-intubating scopes, already proving high intubation rates, however, improving intubation time and lowering cost are factors still being pursued. Other novel
mechanisms, such as the earthworm-like robot and the spiral robot, are in early development stages, yet show promising results for future devices.

2.4.2 Distal Tip Centering Colonoscope

The distal tip centering colonoscope is another device designed to improve intubation rates while reducing colon trauma caused by the scope. This is accomplished by automating the steering knobs in order to keep the distal tip centered within the colon during intubation. The centering automation is accomplished with two add-on pieces to a conventional colonoscope; a distal tip piece and a control headpiece. The distal tip add-on piece includes three equally spaced infrared sensors that measure distance from the colon wall. This data is sent to a controller within a second add-on piece attached to the control head. The control head attachment also contains two DC motors to control the steering knobs. Both pieces can be seen in Figure 13. Algorithms in the controller interpret the sensor data and adjust the steering knobs so that the distal tip stays centered within the colon. After the scope reaches the cecum, the control head add-on piece can be removed for physician-controlled observation as the scope is removed from the colon [21].

The colon-centered logic of the mechanisms were created for a straight-line pathway, and therefore, require special cases in the code to handle the bends of the colon. Furthermore, areas where the colon has narrow radii as well as various lighting schema caused logic issues that prevent the tip from staying centered. Finally, delay in distal tip movement was caused by tensioning and loosening of the cables. While prominent issues
were present, the centering device did successfully traverse the colon simulator within the Active Training Colonoscopy Model [21].

![Figure 10](image_url) (Left) Distal end infrared attachment and (right) DC motor and controller attachment on control head [21].

The distal tip centering colonoscope provides a self-intubating technology that would be useful for less experienced physicians and residents to achieve high cecal intubation rates with shorter intubation times. The centering scope completed initial testing within the Active Colonoscopy Training Model, however, still needs improvements to efficiently navigate the colon bends and sections with small radii.

### 2.4.3 Automated Colonoscope Tip

In order to reduce perforation and make the colonoscopy procedure easier on the physician, an automated colonoscope tip was designed. This tip is automated to adjust its shape to the colon wall as well as reduce and increase stiffness. It is comprised of three
pressure chambers positioned 120 degrees apart from each other which are pressurized by three actuators to change shape and stiffness. The chambers are bound by plates located at the ends and the midpoint of the structures. Three optical fiber sensors are placed at the tip (also spaced 120 degrees apart) to detect the colon wall and provide the means of determining how to maneuver [22]. The automated tip can be seen in Figure 14.

*Figure 11. Automated tip controlled by three pressure chambers [22].*

Testing for the device included observing an open-loop step response to observe how a signal voltage can trigger a deformation. Figure 15 shows the open-loop response, which appears to settle relatively quickly. These tests led to a closed loop test that consisted of inserting the automated tip into a clear tube that was positioned to have a slight bend [22]. The results from the distance sensors can be seen in Figure 16.
It can be seen that the automated tip mechanism holds great promise in becoming incorporated into colonoscope. Figure 15 shows a fast response time for displacing the tip, while Figure 16 shows a proof of concept trial for the tip traversing a curved tube without contacting the wall. However, future development is needed to reduce the size of
the design in order to match an endoscope or colonoscope’s diameter. Furthermore, a new scope must be developed to incorporate this new tip [22].

2.5 Improved Colonoscope Features

Colonoscope features aim to improve procedure or learning efficiency while making the experience easier for physicians. While they are not automations, they add functionality to the scope in order to overcome specific problems.

2.5.1 Gesture Distal Tip Steering Colonoscope

An interactive grip, seen in Figure 17, was made in an attempt to increase intuitiveness of the colonoscope controls and decrease introduction time (time it takes to reach the cecum). The grip, located at the base of the insertion tube, contains orientation sensors that steer the distal tip by mirroring the grips’ change in orientation. Furthermore, the buttons controlling air, water, and suction are attached to the grip. This eliminates the need for any left-hand interactions during the procedure as the right-hand now steers the tip, drives the scope in and out of the colon, and manipulates the air, water, and suction [15].
Figure 14. Intuitive grip with orientation steering and (1) air, (2) suction, and (3) water buttons [15].

The main objective of the grip is to reduce the introduction time in colonoscopy procedures. A study to observe the difference in introduction time between the developed grip colonoscope and a conventional colonoscope was performed using 12 medical students who had knowledge of the procedure but never before trained or performed a colonoscopy. With 6 students using the conventional colonoscope and 6 students using the grip colonoscope, a colonoscopy was performed twice by each student on a simulator providing force measurements the scope exerted on the colon as well as procedure times. The grip colonoscope produced a faster average introduction time on the first and second colonoscopy trial compared to the conventional scope (315 and 226 seconds respectively compared to 487 and 382 seconds with the conventional scope) with
no significant difference in forces. The rate of improvement between the first and second trial (in seconds) showed no significant difference between the conventional and grip scope. These results indicate that this new grip colonoscope provides an immediate reduction in colonoscope introduction time without increasing colon forces [15].

The grip colonoscope effectively and immediately reduces introduction time without causing increased forces exerted on the colon. This device can be considered more intuitive, and therefore, a potentially useful means for decreasing the number of procedures needed to achieve competency. However, more testing is needed to prove significance in this area. Furthermore, the grip colonoscope increases activity for the right hand and wrist, which will cause higher strain. Therefore, the grip colonoscope, while overall more intuitive than a conventional colonoscope, increases the risks for a colonoscopist.

2.5.2 Variable Stiffness Colonoscope

Variable stiffness colonoscopes (VSC) have been developed in order to reduce looping within the colon. The VSC has a smaller diameter and allows the physician to change stiffness while the scope is inserted [23]. This is valuable in reducing looping by using a more flexible setting to maneuver the sigmoid colon, while changing to a stiffer setting within the descending colon [24].

The variable stiffness colonoscope’s advantages are highly debated and many studies produce varies conclusions on the matter [24] [23]. A large database study, Xie, Qin, et al, [23], combined data from multiple related studies to draw conclusions on cecal
intubation rate and cecal intubation time. It was found that cecal intubation rate was slightly improved with a VSC compared to a standard adult colonoscope, but with no significant difference in intubation time. This study also noted that many of the studies that they included in their data had conflicting results [23].

2.5.3 Control Head Holder

Fatigue arising from the physician controlling the colonoscope has been found to reduce productivity and even create the need for early retirement. To reduce this fatigue, Shanbhag, et al, [25], fabricated a control head stand which supports the weight of the colonoscope while allowing the physician to maneuver the steering knobs. To validate the merit of the control head holder, fatigue was quantified as reduction in strength and observed through the maximum voluntary contraction test (the largest force that can be outputted) of the left biceps and forearm using two dynamometers. Furthermore, electromyography was used as a second method for observing reduction in muscle activity.

Shanbhag’s, et al, [26], study had twelve participants perform a fatigue test on both the colonoscope while using the stand and the colonoscope without the stand. The testing consisted of manipulating and controlling the scope for twenty minutes and taking a maximum voluntary contraction (MVC) reading before and after the test. Furthermore, electromyography voltage data was collected throughout the twenty minutes of the subject controlling the scope. This resulted in a 6.7% and 6.33% reduction in strength for the biceps and forearm respectively when comparing the MVC test while not using the
stand before and after the fatigue test. Fatigue was not, however, observed while using
the stand (with an actual small increase in strength for both the biceps and forearms).
The electromyography results for the last minute of the fatigue test further show
reduction in the biceps and forearms, however, with large variations between subjects in
both cases [26].

For further evaluation of the control head holder, ten students performed a
colonoscopy on a colon simulator for each case: without the stand and with the stand.
Cecal intubation time was recorded for the study, as well as survey question results
evaluating the value of the control head holder. The control head holder resulted in an
average intubation time 32% less than without the holder. Furthermore, eight out of ten
subjects acknowledged that the control head was heavy and burdensome to control, while
all ten subjects agreed on the survey questionnaire that the control head holder was
necessary equipment [26].

2.6 Objectives

With the increasing awareness of the screening benefits to one’s health as well as
demand for colonoscopy procedures, expectations for physicians performing colonoscopy
to adhere to high standards has risen. To meet these standards, a physician needs proper
training and experience. Furthermore, the physician’s health, in terms of colonoscopy
injuries, cannot be compromised in order to maintain high standards in every procedure,
as well as to perform a heavy load of colonoscopies.
While it is obvious that physician health and training is critical for the success of colonoscopies, current studies contradict the ideas that American endoscopists are appropriately trained and have the proper equipment to prevent injury. Medical devices such as the pill cam, self-intubating scopes, and the grip steering colonoscope try to address these problems, however, they lack effectiveness and reliability, and may also incur high costs. Therefore, more research in this area is necessary in order to continue providing high standards of care to patients, to produce competent physicians, and to reduce risks applied to performing such procedures.

This paper outlines the design and testing of a new colonoscope prototype that implements a hand-held remote steering input, motor actuated steering knobs, and a base that allows quick removal of the scope. The goal of this new device is to reduce the risks of fatigue injuries associated with performing colonoscopy with the left wrist, hand, and thumb while creating a more intuitive steering system to decrease the learning curve of colonoscopy. The main objectives are:

I. Fabricate a prototype colonoscope that has includes:
   - Hand-held input device
   - Motor-actuated distal tip steering
   - Stand that supports colonoscope and can quickly setup and remove scope

II. With respect to the ergonomics of the prototype, examine the strain/fatigue the prototype colonoscope exerts on the user compared with a conventional colonoscope.
III. With respect to the intuitiveness of the prototype, examine the prototype’s effect on learning time for colonoscopy compared to a conventional scope.
CHAPTER 3: PROTOTYPE

This chapter outlines the main components included in the prototype to make a mounted, motor actuated colonoscope controlled by a hand-held device. This includes five main subsystems: the motors, the belt system, the stand, the electromechanical circuitry, and the hand-held device.

3.1 Design Overview

The colonoscope prototype aims to reduce physician fatigue and make steering the distal tip more intuitive. Automated steering knobs controlled by a steering input mechanism have been included in the prototype to reduce fatigue of the left thumb and wrist, as well as be more intuitive. The initial build include buttons for activating air, suction, and water; however, the automation of those valves will not be completed for this thesis. These inputs are for expansion of the device for if, and after, it has been verified as having high potential. The main components that will be added to the colonoscope are a hand-held steering device, a microcontroller, motors, and a stand. A high-level overview of the design showing the main components is seen in Figure 18.
Figure 15. Main components of colonoscope design.

The high-level design includes a motor connection between each of the steering gears on a conventional colonoscope where the motor is connected to the steering knob through either a direct inline connection or a belt connection. The motors’ position, speed, and direction are controlled with an Arduino microcontroller (connected through a motor shield to the motors). Both the motors, the motor shield, and the controller are powered by an external power source that provide 12 volts DC to all components within the system. A wireless connections from the Arduino to the hand-held device sends steering input to the system, allowing the motors to manipulate the colonoscope. In order to reduce fatigue, the hand-held steering device is the only item a physician will need to hold in order to steer the distal end of the colonoscope. All other components are mounted on a stand near the patient.
3.2 Motor Overview

The motor was chosen based on the torque needed to rotate the steering gears to their limit. The procedure to find torque was based on a previous thesis, Litten, John D., [27]. In this thesis, torque was acquired by fitting a dial over the control knob and wrapping a string around the dial. The end of the string was connected to a Vernier Dual-Range Force Sensor. The string was tensed at a 90° angle to the dial’s radius where the force from the string was being applied. The force sensor then sent and recorded information to a Vernier DAQ system which connected to LoggerPro software [27]. The data collection and setup can be seen in Figure 19.

Figure 16. Force acquisition setup using dial, string, and a force sensor [27].

For the current test, the force sensor started with approximately no force tensing the string when the knob was at the starting position. Then, the force sensor was pulled in a straight path until the steering knob rotated to its limit. While pulling the force sensor, rotational speed of the knob was attempted to be keep constant. The force data for the small and large steering knob are seen in Figure 20.
Figure 17. Experimental force results for A) small knob and B) large knob.

Figure 20 shows that the force for both knobs linearly increases as the knob is turned. Furthermore, the larger knob requires more force than the smaller knob with a maximum force of 22.49 and 20.09 N respectively. Using Equation 1 and the maximum force measurement from the large knob, maximum torque needed to be supplied by the motor is calculated to be 255 oz-in.

\[ \tau = F \times r \]  

(1)

In Equation 1, \( \tau \) is torque, \( F \) is force, and \( r \) is radius from the center of rotation to where the force is acting upon.

Based on the maximum torque needed, an observable rotation of more than 180° (excluding standard servo motors), and a need for position information as to prevent the motor from turning the knob beyond its limit, a geared Pittman GM8224 DC motor with encoder, as seen in Figure 21, was chosen to provide actuation to the steering knobs. This motor has a continues torque value of 113 oz-in [28], which is still below the
required torque, however, high enough to resolve the torque through the use of a belt drive system described later.

![Pittman motor with encoder.](image)

**Figure 18.** Pittman motor with encoder.

### 3.3 Belt System

The belt system is the physical connection between the motors and the control knobs. Apart from being the medium, the belt systems increase the torque output of the motors through a gear ratio between the pulley (pitch diameter 0.764”) on the motor shaft and the pulley on the shaft that previously held the control knobs (pitch diameter of 2.037” for the pulley). The ratio of pitch diameters creates a 2.66 gear ratio, bringing the output torque from the motor applied to the control knob shaft to over 300 oz-in (255 oz-in was required). The two pulleys can be seen in Figure 22.
Figure 19. (a) 2.037” pulley on colonoscope shaft and (b) 0.764” pulley on motors.

The colonoscope shaft, on which the steering knobs were fit on, contains gear teeth that mate with teeth on the steering knobs. To fit the two pulleys onto the colonoscope shaft, the steering knobs were turned down until only the teeth remained. These were press fit into the pulleys and secured using glue. The result of the pulley that fits where the smaller steering knob was previously located can be seen in Figure 21a. To hold both gears onto the shaft, a lock nut design was implemented to fit over the gears. The complete design can be seen in Figure 23.
Figure 20. Belt system with two pulleys attached to the colonoscope shaft and held in place by a locknut piece.

3.4 Stand Overview

The main purpose of the stand is remove the colonoscope from the physician’s hands in order to reduce fatigue from gripping the scope. To be effective, the stand must stabilize the colonoscope in order to allow motor actuation of the control knobs. Furthermore, the stand must allow for quick and easy setup of the colonoscope and belt system in order to allow quick and easy removal and sanitation of the scope after every procedure. Finally, the stand must mount all electrical components and both motors on it. The complete stand can be seen in Figure 24.
3.4.1 Stand Stabilizers and Scope Supports

Four pieces are responsible for holding and stabilizing the colonoscope on the stand. The first piece (the cord support), seen in Figure 25a, contains a slot running vertically down the side that is large enough to slip the universal cord of the colonoscope in and out of the part. The center of the cord support has a tapered hole running vertically through the part that sits flush with the top of the universal cord, which increases in diameter as it reaches the control head (upper cord). The taper in the cord support has a snug fit onto the upper section of the universal cord, providing stability in any horizontal direction. The second part (intubation tube support), seen in Figure 25b, provides support for the far end of the control head section where the intubation tube begins. This part has a semi-circular opening that fits the cylindrical body of the control head’s far end within it. The intubation support holds the opposite side of the control head than the cord support, creating a simply supported system.
Apart from the pieces holding the colonoscope, two clamps are attached to the bottom of the base in order to clamp the complete structure onto the operating table. The clamps on the prototype can clamp onto a table up to and inch a half thick, and provide stability from movement of the whole stand while the physician performs procedures. The clamps can be seen in Figure 26.
3.4.2 Motor Mount

The motor mount system holds the two dc motors that actuate the control knobs of the colonoscope, as well as allows the motors to slide closer to the knobs in order to quickly release the tension belts and remove the colonoscope. The mount itself is a single piece of PLA plastic that was 3D printed, as seen in Figure 27. To allow the quick release motion, the mount is bolted on top of a linear slide system as seen in Figure 28. The slide can be locked in place by a locking nut located on the side of the slider which can be tightened by a wrench. Locking the slide is necessary to keep the timing belts tensioned.
Figure 24. Motor mount for two Pittman DC motors.

Figure 25. Linear slide with hex nut locking mechanism.

3.5 Circuit System

The logic system of the prototype colonoscope controls the motors based off of user input. To ensure the steering knobs are not rotated past their limit, the system
monitors rotation of each motor shaft and stops the motor as it reaches said limit. Furthermore, the system logic observes the torque being outputted by the motors and stops motor function if the torque becomes too high (meaning the distal tip of the scope is pressing too hard against the colon wall).

The system contains two Arduino microcontrollers, a bluetooth module, a motor shield, a current sensor, and two motors with encoders as seen in Figure 29. The first Arduino is responsible for receiving input through the bluetooth module and executing said commands. Therefore, the logic to control the two motors is contained here, as the motor movement is dictated by the incoming input received by the Bluetooth module.

![Figure 26. Circuit system with arduino, motor shield, bluetooth, current sensor, and motor with encoder.](image)

The second controller deals with monitoring and limiting the amount of rotation that can be achieved by the motors, as well as the amount of torque that is being
outputted by the motors. Rotation is monitored using interrupt functionality on the Arduino to read encoders attached to each Pittman motors. Due to high precision encoders, the controller has a high amount of utilization, therefore, creating the need for the second controller to avoid lagging from when the user instigates a command to when it is performed. The second controller also reads data from the current sensor and relates that value to a torque. If the torque or position reaches its limit, an alert signal is sent to the steering Arduino. The complete architecture of the electro-mechanical interaction can be seen below in Figure 30.

![Electro-mechanical system block diagram.](image)

*Figure 27. Electro-mechanical system block diagram.*

It can be seen in Figure 30 that commands sent from the mobile device are received by the bluetooth and passed to the first Arduino. Inputs that are received initiates control logic that is sent to the motor driver in order to perform the desired motor movement. Motor rotation is tracked by two encoders (one on each motor) connected to the second Arduino. If the steering knob limit is reached for either knob, defined by an
encoder value reached, the second Arduino will send a signal to the first Arduino to prevent more motor rotation in that direction.

3.6 Hand-Held Device Overview

The input steering device is an android phone (galaxy s3) with a custom application creating a client/server connection between the phone and the bluetooth module connected to the Arduino. The mobile device hardware was chosen because of the ability to utilize all components needed to create a wireless steering system (i.e. user interface, input method, bluetooth hardware), as well as pre-built libraries for programming. The user interface can be seen below in Figure 31.

![Android application user interface for colonoscope control.](image)

*Figure 28. Android application user interface for colonoscope control.*

Java code is used for the main application with xml for the view. A touch listener is implemented on each button to sense when the button is pressed down and released.
Integers associated with the touch and release actions of each button are transmitted to
the Arduino, which has programmed functionality for every case. Water and suction
functionality has been added to the interface, however, no functionality exists on the
prototype to execute this functionality (this is for future expansion).

### 3.7 Power Overview

The fabricated colonoscope is powered by 12 volts direct current. The power to
the Arduino controller and the two Pittman motors is tied, meaning both will be powered
with the 12 volt source. For testing, a DC source was provided to complete the proof of
concept, however, a 125 VAC wall plug leading into a transformer and a rectifying
circuit, as seen in Figure 32, would be a more permanent solution to make a production
model.

![Figure 29. 120 VAC to DC circuit (iCircuit).](image)
CHAPTER 4: METHODS

This chapter covers the methods used to validate the prototype design in terms of fatigue and intuitiveness. Both tests evaluated the prototype and a conventional scope, as well as compared the significance in difference between the two scope’s results.

4.1 Fatigue Examination

The objective of the fatigue examination is to provide experimental data comparing the fatigue a physician experiences controlling a conventional colonoscope versus the new prototype colonoscope within the left thumb and forearm. Fatigue was evaluated as a reduction in maximum voluntary contraction (MVC) (the maximum force output the muscle group can exert) within the left thumb and forearm. The MVC was obtained before and periodically throughout the fatigue test using two dynamometers: the strain gauge dynamometer for the thumb and the Jamar dynamometer for the forearms, as seen in Figure 33. The MVC reading before the test will be considered a baseline reading, and all four readings taken during the test will be normalized using the baseline value in order to quantify the degree of fatigue.
4.1.1 MVC Thumb Reading

The thumb MVC reading were taken with a custom built dynamometer using a pair of strain gauges connected on a delrin cylinder piece that was pressed with the left thumb. The other fingers on the left hand gripped an aluminum rod to offer stability throughout the pressing motion. During the MVC test, the subjects were told to keep their left arm parallel to the ground in order eliminate mechanical advantages. The grip and pressing setup of the hand on the dynamometer is seen in Figure 34.
Readings on the strain gauge dynamometer were collected through a half-bridge Wheatstone bridge configuration with two precision grid style gauges with a resistance of 120 ohms ± 0.3% when no strain is being applied. Two other resistors were used to complete the bridge with a resistance of 150 ohms each. The voltage across the bridge was collected by a 6.5 digit resolution Fluke 8846A multi-meter with USB data acquisition capabilities. The setup was powered by a 5 volt port on an Intel Galileo controller. Figure 35 shows the strain gauge mounted on the delrin cylinder, the bridge circuit, and the Fluke multi-meter.
To find an accurate MVC value for each participant, every reading required the user to press down and release with their thumb three times. The average voltage magnitude difference, defined as the maximum voltage when pressing down minus the voltage before the press, of the three readings became the MVC of that instance. The three presses were recorded on a USB device and transferred to a computer. A typical plot with the three presses can be seen in Figure 36. It can also be mentioned that while voltage data is being collected, the force being applied to the strain gage is linearly related to the strain. Furthermore, the strain is linearly related to the force applied to the delrin cylinder based on small strain assumption validating Hooke’s law. Therefore,
converting the voltages to forces and normalizing the force data will yield equal results to normalizing the voltage data.

Figure 33. Typical data with three presses to determine MVC (top), and methodology for determining voltage magnitude of each press (bottom).

It can be seen from the bottom plot in Figure 36 how the change in voltage magnitude for each thumb press was determined. The point before each individual rise was used as the resting voltage. The magnitude output for each press was considered to
be the maximum value at the peak minus said resting voltage before the rise occurred. All three determined magnitude values were averaged to find the ‘real’ MVC value. It can also be seen that the voltage has a slight downward slope. This is due to the bridge and precision gages heating up from the Fluke meter, creating the need to specify a different resting voltage before each peak.

4.1.2 MVC Forearm Reading

The MVC reading for the forearms was taken on a Jamar dynamometer as seen in Figure 33b. For each MVC reading, the subject was asked to hold the dynamometer in their left hand while keeping their forearm parallel to the ground. Furthermore, the participants were told to keep their forearm and upper arm (bicep) at about a 90 degree angle to each other. To get an accurate MVC value, the subjects performed three trials on the dynamometer, which were averaged into the resultant MVC value.

4.1.3 Recruitment and Procedure

For this evaluation, 8 medical students were recruited to perform a fatigue test with both scopes: the prototype and conventional scope. The participants were required to be able to utilize their left arm and hand in a plethora of movements, and any injuries or conditions preventing this excluded the subject. Recruited students received written information about the study including an overview and a description about what role they will play (including what actions they were required to perform). Upon arrival to the first test, participants will received a consent form and had a chance to ask any questions.
After completion of the consent form, subjects received instructions on how to control the distal tip of the colonoscope they will be using on that day. To obtain similar initial baseline MVC values for both scopes, a day’s rest was be required between the test on the different scopes (at least a 24 hour rest period).

After the subject learned to control the scope, the fatigue test began. The test, using either the conventional or prototype scope, followed the procedure below.

1. A baseline MVC reading was taken for the thumb and forearms.
2. Participants moved the distal tip of the scope in a ‘+’ pattern six times using the control knobs or the hand-held steering device depending on which scope they are using (they performed two tests, one with each scope).
3. After the required amount of pattern repetitions, the participants paused controlling the scope in order to take an MVC reading on the forearms and thumb.
4. Steps two and three were repeated a total of four times.

4.1.4 Analysis

Data was collected for the MVC of the forearm and thumb before, after, and periodically during the test. The data was used to test two null hypothesis:

1. The prototype scope does not reduce muscle fatigue of the forearms compared to a conventional scope.
2. The prototype scope does not reduce muscle fatigue of the thumb compared to the conventional scope.

The initial MVC value for every individual on both scopes served as a baseline measurement and was used to normalize the rest of the readings with. The average normalized MVC values for each reading were found for the conventional and prototype scopes for all four MVC readings during the test for both muscle groups: forearm and thumb. A standard deviation and 95% interval range was calculated for every average MVC reading and compared to the baseline value. Two bar plots, one for forearm fatigue and one for thumb fatigue, were created to show the results of the average normalized values of the conventional and prototype scope over the four MVC readings. These include the 95% confidence interval bars in order to visualize the relationships between the baseline value and the other readings. Furthermore, two scatterplots were included for both forearm and thumb cases. For each of these plots, the prototype and conventional scope data was fit with a linear trend line with a set intercept at 1 (that would be considered the normalized value before the fatigue testing starting).

4.2 Learning Curve Evaluation

The objective of the learning curve experimentation is provide data indicating that the prototype scope is more intuitive to control than a conventional scope. Intuitiveness was observed through two values: cecal intubation time and learning rate. These values were measured and compared between the two scopes as medical students performed multiple procedures on the Active Colonoscopy Training Model (a colon simulator) as seen
in Figure 37 [30]. Cecal intubation rate was considered as the duration from insertion of the scope into the simulated colon to reaching the end of the colon (cecum). Learning rate was classified as the amount of cecal intubation rate reduction between the first (baseline) and last cecal intubation time recorded.

Figure 34. Active Colonoscopy Training Model simulator with LabView for force measurements [30].

4.2.1 Recruitment and Procedure

For this evaluation, 16 pre-medical students with no prior colonoscopy training or experience were recruited for this study. Recruitment consisted of voluntary participation from premedical students who receive a recruitment email including an overview about the study as well as the consent form attached. The students were split into two groups that determined which scope, the conventional or prototype scope, they used for learning and performing the experiment. Scope selection for each participant was assigned based on when the subject joined the study. A coin flip determined the scope that the first person
used, and, thereafter, the scopes were alternately assigned to students as they joined the study.

During their scheduled session, students performed four colonoscopy procedures on the colon simulator. When the participants arrived, they were given the consent form and allowed to ask any questions before beginning the test procedure. Before the testing started, participants were required to watch a training video containing information about how to use their specific scope to perform a colonoscopy, general information and guidelines about the procedure, as well as a demonstration with a professional endoscopist performing a colonoscopy on the simulator with their specific scope. After the video, the procedure for the colonoscopy trials proceeded as follows:

1. Participants were given two minutes to familiarize themselves with steering their scope.
2. Students started the colonoscopy procedure and a proctor began a stopwatch when the scope entered the simulator.
3. When the student reached the end of colon, time was recorded and the student was asked to remove the scope while keeping a clear view of the colon.
4. Steps 2 and 3 were repeated a total of four times.

4.2.2 Analysis

Two null hypotheses will be tested with the acquired data:
1. Using the prototype scope does not decrease the intubation time compared to a conventional scope.

2. Using the prototype scope does not increase learning rate of colonoscopy compared to the conventional scope.

A t-test with a 95% confidence was used to find significance between the mean intubation time means between the two scopes. Furthermore, normalized average intubation time between prototype and conventional scope on all four trials will be compared against each other to test the first null hypothesis. The intubation time over the four trials will be fit with a trend line, and a comparison between the slopes will be compared. This comparison will observe the differences in learning rate to test the second null hypothesis.

Two plots will be included in this analysis: the first being a scatterplot showing the intubation over the four trials, and the second being a bar plot showing the last three intubation normalized with the first trial. The scatterplot will be fit with a best fit regression line in order to characterize the rate at which the students are improving their time. The second plot will contain 95% confidence intervals to visualize if the intubation time has significantly reduced from the initial (which will be referred to the baseline) procedure.
CHAPTER 5: RESULTS

This section reveals the results from the fatigue test as well as the learning curve evaluation. Within this section, the data will be presented and significance of said data will be determined.

5.1 Fatigue Evaluation

Eight medical students performed the fatigue tests on both the conventional and prototype scope, however, one subject was excluded due to test performance being affected by weather. In this case, the subject performed the first fatigue test in the early morning after walking to the test site in the cold conditions. MVC output values for the thumb increased throughout the four readings during the testing (1.075, 1.077, 1.23, and 1.35). This may have been caused by a warm-up effect producing significantly higher muscle output as the study progressed (an opposite result compared with the other participants). Exclusion of the subject was determined by assessing that the subject’s MVC force values from testing where outliers in the sample data. A box-and-whisker plot, as seen in Figure 38, shows the distribution of the normalized data for the four thumb MVC readings taken during the test including the disqualified subject’s data.
Considering the thumb MVC values of the subject in question (1.075, 1.077, 1.23, and 1.35 for trials 1 to 4 respectively), it can be seen that the last MVC reading from the subject (reading #4) is an outlier to the rest of the data. Due to this outlier, exclusion of the subject was justified. The average normalized forearm MVC values for the remaining seven subjects can be seen below in Figure 39.
Figure 36. Average normalized forearm MVC results for prototype and conventional scope.

Figure 39 shows a scatterplot (top) and bar graph (bottom) of the normalized MVC data comparing the prototype and conventional scope. Both data sets, the prototype and the conventional, were fit with a linear least squares regression line with the y-intercept set to one as seen in the top plot of Figure 39. This resulted in a slope of -
0.0023 and -0.0462 for the prototype and conventional scope respectively. Furthermore, the bottom plot of Figure 38 shows average normalized forearm MVC data including 95% confidence interval for each reading on both scopes. The prototype scope’s baseline MVC force value for the forearm case was included within the confidence interval for every reading, however, the conventional scope only contained the baseline value within its confidence interval for the first and second reading. Table 1 shows the average normalized means over the four trials for both scopes, as well as the t-test results between the means for each trial.

Table 1. Forearm average normalized force (ANF) results with t-test for each trial

<table>
<thead>
<tr>
<th>Trial</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prototype ANF</td>
<td>0.996</td>
<td>1.013</td>
<td>1.002</td>
<td>0.976</td>
</tr>
<tr>
<td>Conventional ANF</td>
<td>0.928</td>
<td>0.871</td>
<td>0.874</td>
<td>0.831</td>
</tr>
<tr>
<td>P-Value</td>
<td>0.251</td>
<td>0.005</td>
<td>0.010</td>
<td>0.009</td>
</tr>
</tbody>
</table>

It can be seen from Table 1 that the average force corresponding to the four MVC readings is significantly different (p < 0.05) for the second, third, and fourth MVC reading between the conventional and prototype scope. A t-test comparing the rate of average normalized MVC output decrease was also computed (i.e. the slope from the first to fourth normalized MVC reading). An average slope of -0.0393 and -0.00421 for the conventional and prototype scope respectively was calculated, which resulted in a p-value of 0.0068. Finally, parameter uncertainty was calculated for the slope obtained from the trendline. The conventional scope and prototype scope resulted in
uncertainties of 0.024 and 0.0068 respectively. The results for the forearm fatigue can be seen below in Figure 40.

Figure 37. Average normalized thumb MVC results for prototype and conventional scope.
Figure 40 shows the MVC data for the thumb with a scatterplot (top) and a bar graph (bottom) including the 95% confidence intervals. For both scopes, the average MVC force readings for the four trials were fit with a linear least squares regression line with the y-intercept set at one. This resulted in slopes of 0.0038 and -0.0393 for the prototype and conventional scope respectively (as seen in the top plot of Figure 39). The bottom graph of Figure 39 shows the the average normalized data with their 95% confidence intervals. The prototype scope contained the baseline force value for all four MVC readings (as seen from the confidence interval containing 1), while the conventional scope only contained the baseline MVC value in the first two readings. For the third and forth MVC reading, the conventional scope had a reduction in output force and did not contain the baseline within its 95% confidence interval. Table 2 shows the thumb average normalized means over the four trials for both scopes, as well as the t-test results between the means for each trial.

Table 5. Thumb average normalized force results with t-test for each trial

<table>
<thead>
<tr>
<th>Trial</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prototype ANF</td>
<td>0.978</td>
<td>1.010</td>
<td>0.995</td>
<td>1.033</td>
</tr>
<tr>
<td>Conventional ANF</td>
<td>0.898</td>
<td>0.950</td>
<td>0.840</td>
<td>0.876</td>
</tr>
<tr>
<td>P-Value</td>
<td>0.310</td>
<td>0.543</td>
<td>0.131</td>
<td>0.043</td>
</tr>
</tbody>
</table>

Table 2 shows that the first three average normalized MVC readings for thumb fatigue did not show a significant difference between the conventional and prototype scope with p-values of 0.31, 0.54, and 0.13 respectively. Significance was obtained in
the fourth reading with a p-value of 0.044. A t-test was also performed on the rate of reduction of normalized MVC throughout the four readings. A slope of -0.0306 and 0.0083 was calculated for the conventional and prototype scope respectively, which resulted in a p-value of 0.086. Finally, the standard error was calculated for the best fit trend line slope parameter on both scopes. This resulted in an error of 0.0325 and 0.051 for the conventional and prototype case respectively.

5.2 Learning Curve Evaluation

Fourteen subjects performed the learning curve evaluation, however, two student were disqualified (one from each scope) after it was determined that they both produced multiple intubation time outliers over the four trials. The first subject that was disqualified, using the prototype scope, had high intubation times due to looping occurring within the colon model. The subject resulted in an outlier for both the second and third colonoscopy procedure trials. Furthermore, looping also affected the first trial, which did not result in an outlier, however, a noticeable increase in the intubation time for the sample data could be observed. Figure 41 displays a box-and-whisker plot showing the sample results for the four trials including the disqualified subject. The outliers can be seen on the second and third trials, with a large whisker on the first trial as a result from the disqualified subject. The second disqualification occurred on the conventional scope, where the third and fourth trial had a high intubation times that were both outliers. Similar to the prototype data, Figure 42 shows the distribution of the sample data over the four trials for the conventional scope.
Apart from the two outliers for both the prototype and conventional data-set caused by the disqualified subjects, a third outlier is present in both cases. These outliers
are seen on the fourth trial of the prototype data-set (Figure 41), and the first trial of the conventional scope’s data (Figure 42). Unlike the subjects that were disqualified, these subject had normal data for the other trials, and, in order to keep the number of subjects who performed the test on each scope equal to six, they were not disqualified themselves. Figure 43 shows the resulting average intubation times for the remaining six subjects on the conventional and prototype scope.

![Average Cecal Intubation Time](image)

*Figure 40. Average cecal intubation time for conventional and prototype scope.*

Figure 43 shows similar intubation times for the conventional and prototype scope over the four trials. Fitting each curve with a power trend line in the form $Ax^{-b}$, the conventional and prototype data set resulted in a leading coefficient value of 196.03 and 201.87 respectively. Furthermore, the conventional and prototype case yielded a power of -0.569 and -0.497 respectively. The $R^2$ value associated with fit lines had values 0.929
and 0.950 for the conventional and prototype case respectively. Table 3 shows the average intubation times over the four trials for both scopes, as well as the t-test results between the means for each trial.

Table 6. Intubation time t-test results between conventional and prototype scope

<table>
<thead>
<tr>
<th>Trial</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prototype CIT</td>
<td>209.67</td>
<td>136.33</td>
<td>109.5</td>
<td>109.5</td>
</tr>
<tr>
<td>Conventional CIT</td>
<td>197.5</td>
<td>123.33</td>
<td>119.67</td>
<td>83.17</td>
</tr>
<tr>
<td>P-Value</td>
<td>0.764</td>
<td>0.559</td>
<td>0.285</td>
<td>0.058</td>
</tr>
</tbody>
</table>

Table 3 shows the first three trials showed no significant differences between the conventional and prototype scope with p-values of 0.76, 0.56, and 0.28 respectively. The fourth trial resulted in the average intubation time of 83.17 and 109.5 seconds for the prototype and conventional scope respectively. This led to a p-value of 0.058, bordering on significance. The normalized average intubation (normalized with the first trial) can be seen below in Figure 44.
Figure 41. Average normalized cecal intubation time.

Figure 44 shows the average cecal intubation time for the last three trials normalized with the first trial (baseline). It can be seen that both the prototype and conventional scope had large reductions in intubation time compared to the baseline procedure (a 52% intubation time reduction on the conventional scope and a 47% reduction on the prototype scope for the last trial). Furthermore, the 95% confidence intervals on the graph shows that every trial proceeding the first is significantly lower on both scopes. Table 4 shows the average normalized intubation time mean over the four trials for both scopes, as well as the t-test results between the means for each trial.

<table>
<thead>
<tr>
<th>Trial</th>
<th>Prototype CIT</th>
<th>Conventional CIT</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.659</td>
<td>0.668</td>
<td>0.939</td>
</tr>
<tr>
<td>2</td>
<td>0.533</td>
<td>0.693</td>
<td>0.199</td>
</tr>
<tr>
<td>3</td>
<td>0.528</td>
<td>0.481</td>
<td>0.614</td>
</tr>
</tbody>
</table>
It can be seen from Table 4 that none of the normalized intubation means for the trials comparing the two scopes were significantly different. The first and third trial had little difference between the normalized means (0.009 and 0.05 difference respectively). The second trial did have a larger difference, 0.16, compared to the other trials, however, also had the largest standard deviation for the conventional scope (0.245), reducing the significance between the means.
A prototype colonoscope was fabricated and tested with regards to its ability to reduce fatigue and decrease learning rate of the colonoscopy procedure. This chapter discusses the prototype’s performance as well as the results it yielded in regard to the fatigue and intuitiveness.

6.1 Prototype Discussion

The prototype successful allowed a user to steer the distal tip of the modified colonoscope within the Active Colonoscopy Training Model with the touchscreen input device. Both motors provided enough torque to turn the steering knobs through their full rotation. Furthermore, the stand provided enough stability to the scope in order to completely remove the left hand from the control head. This allowed the left hand to freely move to the most convenient and comfortable position for the user.

During the trials on the colon simulator, it was noted that the user would sometimes miss the buttons to steer the scope, resulting in the user looking down. It seems that this happened to a various degree depending on the user. There was an especially noticeable difference between the professional endoscopist and the medical students who performed the trials, where the endoscopist had to look down more. This could be because of a disconnect between ages, where younger generations are more comfortable and experienced using touchscreens. This indicates a design should be done to increase the efficiency of the input device. A new design might include, but not be
limited to, making the buttons bigger on the touch screen, etching a pattern in the
touchscreen to allow the user to feel the position of their fingers on the glass, or change to
another physical device such as a joystick to steer the distal tip.

Another consideration to made with evaluating the prototype scope is the velocity
the tip can move. It can be observed that the conventional scope’s distal end can be
turned faster than the motors can turn the prototypes’. This can be changed on the
prototype scope by increasing the voltage supplied to the motors, however, some rewiring
will have to be done to make this change due to the Arduino’s controller max input
voltage is 12V (which is what is currently being supplied to the Arduino and motors).
Whether or not this should be changed or whether the speed of the tip should be
adjustable to accommodate the preference of the physician using the scope is to be
determined. When considering the students who participated in the second study, the
ability to move the conventional scope’s tip faster resulted in overall faster intubation
times for the final trial procedure. However, a limit on the distal tip speed may be helpful
in keeping students learning colonoscopy from rushing insertion and removal, especially
as they start to become more comfortable with the procedure.

One feature that worked well was the motor mount located on the linear slide in
order to quickly remove the timing belts and remove the scope. This easily allowed the
scope to be removed, which is important for disinfecting purposes after every procedure.
Furthermore, it allows quick switching of scopes in between multiple procedures.
Considering this, the locking mechanism for the slide could be improved (right now
consisting of a nut that needs to be tightened with a wrench) to allow for locking of the
slide with a simple lever, and eliminating the need for a tool.

6.2 Fatigue Discussion

The fatigue testing showed no significant decrease in muscle output force that the
thumb or forearm can produce when using the prototype scope. During the four MVC
readings, the output force had a maximum average reduction of 2.3% and 2.4% for the
thumb and forearm respectively, with corresponding 95% confidence intervals of ±12%
and ±9% respectively (baseline force value is included within these confidence intervals).
Furthermore, every other MVC reading for the prototype scope also included the initial
MVC value within their confidence intervals. This shows that no significant force
reduction occurred in either the left forearm or thumb, and that user did not experience
any fatigue while using the prototype scope during testing.

Reduction in the thumb and forearm output force was observed when subjects
used the conventional scope. Testing resulted in a maximum average force decrease of
16% percent for the thumb and 17% for the forearm. The baseline forearm force was not
included in the second, third, or fourth MVC reading when considering a 95% confidence
interval. Furthermore, while the baseline forearm force was included within the 95%
confidence interval for the first MVC reading, an average forearm force reduction of 7%
was observed. The significant reduction in forearm output force starting at the second
MVC reading clearly indicates fatigue being experienced by the subjects. Furthermore,
the reduction in output force seen on the first trial (although not significant) demonstrates
the quickness at which fatigue is affecting the subjects’ forearms while using the conventional scope. In regards to the thumb, the baseline force was not included within the confidence interval for the third and fourth MVC readings. Similarly to the forearms, the thumb has significant reduction in output force for these two trials, indicating user fatigue.

T-tests with 95% confidence comparing the average forearm force output between the two scopes reveals significant differences on the second, third, and fourth MVC readings with p-values of 0.0047, 0.01, and 0009 respectively. Considering the normalized means of the prototype scope (1.01, 1, and .97) and the conventional scope (0.87, 0.87, and 0.83) for the last three MVC readings, it can be seen that the significant differences between the means is a result of the conventional scope producing large reductions in output force for the forearm. Furthermore, a t-test comparing the average rate in which the output force is reducing over the four trials (with a mean of -3.9% per trial and -0.421% per trial for the conventional and prototype scope respectively) resulted in a p-value of 0.0068. This reveals that the conventional scope has a significantly larger rate of fatigue compared to the prototype scope.

The use of a t-test to compare the average thumb output force between the conventional and prototype scope showed significance on the fourth MVC reading with a p-value of 0.043. Similarly to the forearm case, the significant difference between means can be credited to the reduction in thumb force on the conventional scope (with a mean reduction of 12.4% on the conventional). It can also be seen that the third MVC reading had a p-value (p = 0.13) approaching significance. This indicates fatigue started
becoming a factor by the third MVC reading. A p-value of 0.086 was obtained when comparing the average rate at which output force was reduced over the four trials (-3.06% per reading and 0.8% per reading for the conventional and prototype scope respectively). This value borders on significance and indicates that the fatigue rate is higher for the conventional scope than the prototype scope in regards to the thumb.

The results indicating that users operating the conventional scope will experience fatigue on the thumb and forearm are consistent with the findings in Shergil, et al, [9], who rated the fatigue of the muscle groups by comparing an MVC reading taken after an endoscopy procedure to a baseline MVC reading taken before the procedure. This study showed that the thumb and forearm had an MVC reduction greater than 30% and 50% for the two cases respectively. The results in the current study agree with these results, as the forearm showed a larger force reduction during the testing compared to the thumb when using the conventional scope. This is made apparent by considering the slope of the normalized conventional scope MVC readings for the thumb and forearm with, which resulted in -3.9% and -3.06% respectively. Furthermore, significant reduction in MVC while using the conventional scope was seen by the second MVC reading in the forearm case, while significant decrease in the thumb MVC did not occur until the fourth reading, indicating more fatigue is experienced on the forearm than the thumb.

Another study, Shanbhag, [26], also supports the conclusion that an improved scope can decrease fatigue felt by a physician. In his study, fatigue from controlling a conventional colonoscope was compared with and without the use of a stand that held the control head. Quantifying fatigue as a reduction in MVC for the biceps and forearms, it
was found that the forearm and biceps had a 6.33% and 6.7% reduction respectively while not using the holder [26]. The forearm MVC reduction for the conventional scope in the current study was about 17%. The difference in magnitude between the two studies is likely caused by differences in simulating the fatigue, where Shanbhag’s fatigue testing required less iterations of turning the steering knobs spread out over more time. However, similar to his study, the current study observed no forearm fatigue when using the modified scope. While different procedures make it impossible to draw conclusions about how much fatigue is being reduced by the holder stand and how much fatigue is being reduced by the touchscreen input device in the current study, it can be concluded that mounting the colonoscope in both studies has a significant role in reducing fatigue.

While the results of the testing did show fatigue reduction, some considerations can be taken to improve the data taken, as well as improve the methodology for the future. The study revealed larger variations in force output when users performed an MVC on the thumb dynamometer compared to the forearm data. This indicates that more subjects should be tested in order to reduce the error for the thumb output force. Considering the data taken in this test, two values may have become significant with an increase in sample size: the mean thumb force differences between two scopes on the third trial, and the rate of change of the MVC for the thumb case. These instances resulted in p-values of 0.13 and .086 respectively. With such a small sample size (n=7), these numbers may not be representative of the population, and a slightly larger sample size may have led to these values crossing the threshold for significance.
Another consideration for decreasing force error read by both dynamometers is creating more uniformed test conditions for performing the MVC reading. Consistent form and repeatability for the subjects taking the forearm and thumb MVC test over the four readings was particularly difficult and could be improved. For the forearm dynamometer, subjects had a tendency to start bending their arm at the elbow and turning the wrist when they were straining to pull the lever. This caused a variation in the posture when taking this test, which could give some participants a mechanical advantage over other subjects. Furthermore, the subject may experience a learning effect over the four trials resulting in altering their posture slightly to improve the MVC values. These differences between the posture between subjects as well as between individual subjects over the different MVC readings would add error into the results. To observe a true reduction, the posture and form needs to as uniform as possible for all the subjects over every reading. One consideration to help achieve a more uniform experience, would be to fix the dynamometer to something to eliminate the subject rotating their arm and/or wrist. The platform the dynamometer is fixed to would need to allow for the vertical position to be changed before the testing to accommodate the different heights of the subjects.

The thumb dynamometer also had similar problems with uniformity and repeatability between the postures the subjects used to reach obtain an MVC value. For this evaluation, the strain gauge dynamometer rested on a table. The subject was told to grip the aluminum tube with their left hand and keep the left arm parallel to the ground. A mechanical advantage would occur if the elbow was raised above the wrist, as the
subject would be applying their body weight onto the thumb rather than strictly using muscle to press down. Similar to the forearm MVC test, subjects would drift towards this mechanical advantage in the case of a learning effect, where they can figure out how to press harder. Furthermore, some differences in gripping the cylinder as and variation in hand-size may have had effects on the results. To fix help address these issues, I would recommend mounting the strain-gauge dynamometer on a vertically adjustable base and setting the height of the dynamometer based on the height of the subjects (more specifically the height of the subjects left arm when they have a 90 degree angle between their bicep and forearm and are holding it parallel to the ground. This may put the body in a more natural position and help resist major changes in posture of the arm. This seems to be more important for the strain-gauge dynamometer compared to the forearm dynamometer as more variation was observed on the thumb MVC values. A more uniformed test may have resulted in more significance and overall better results.

Apart from the MVC equipment, some methodology changes in the experiment could have provided more information. In Shergil, et al, [9], fatigue of the endoscopy procedure was classified as recommended to modify the activity to prevent repetitive strain injury if the MVC reduced $\geq$30% of the baseline MVC and highly recommended to modify of the activity due to a high chance fatigue injury if said activity reduced the baseline MVC value by $\geq$50%. To quantify and compare the prototype scope to the conventional scope, as well as these defined limits, subjects could have taken a baseline MVC test, and then performed a practice colonoscopy on the ACTM. This would include insertion as well as observation of the colon during the removal of the scope. After the
scope is removed, another MVC reading would be taken. This procedure would allow the subjects to control the scope in a more realistic fashion (closer to how an endoscopist controls the scope) as well as better reflect the time a procedure takes. Using this methodology would produce more applicable fatigue results (in regards to the fatigue felt in an actual procedure) for the two scopes, and comparison to the threshold values (≥30% and ≥50%) mentioned above could also be presented. The current methodology is shorter than an actual procedure (the test took about 15 minutes for the subject to receive instructions and take the test), making this impossible to compare the results to the thresholds mentioned above.

In general, this study showed that no significant fatigue on the forearm or thumb was experienced on the prototype scope while during testing. In comparison, the conventional scope saw significant reduction in forearm and thumb force during the four readings. Furthermore, a much higher rate of fatigue was observed on the conventional scope for the thumb and forearm (-3.06 and -3.9% per MVC reading respectively) compared to the prototype scope (0.83 and -0.4 respectively). Considering the relatively large number of injuries procured by physicians using conventional scopes (32% of endoscopist suffer from carpel tunnel syndrome and 19% suffer from thumb pain [31]), it can be concluded that this study has promising results indicating that the prototype scope may reduce the number of forearm and thumb fatigue injuries experienced by physicians. While further testing and improvements can strengthen this conclusion, the test accomplished verifying that prototype scope reduced fatigue in comparison to a conventional colonoscope.
6.3 Learning Curve Discussion

The learning curve evaluation observed significant intubation time reductions of 52% and 47% compared to the initial procedure performed by the subjects on the conventional and prototype scope respectively by the fourth trial. Furthermore, all three trials showed significant decrease in intubation compared to the first procedure performed by the subjects. This can be seen by the normalized intubation time for the conventional and prototype scope not containing the value of ‘1’ within the 95% confidence interval for all three trials preceding the initial procedure. The percent reduction from the first to fourth procedure shows no significant difference between the two scope (p = 0.61), indicating a similar net learning effect experienced by the subjects on both scopes.

The trend lines fitting the data further shows no difference between the learning rates of the two scopes. The conventional and prototype scope, fit with a power function trend lines (R^2 = 0.93 and 0.95 respectively), resulted in decreasing powers of -0.57 and -0.5 respectively. Considering these in logarithmic form, the conventional and prototype scope had decreasing slopes of -0.57 and -0.5 respectively with y intercepts of 2.29 and 2.305 respectively. It can be seen that both scopes have a similar y-intercept as well as slopes that are not significantly different (p = 0.93). This indicates no difference in learning rate is experienced by the students on either scope. It should be further mentioned that, if further trials were conducted, an approximated settling time will be reached where the users have maximized their skills resulting in minimizing intubation.
time. If more trials were to be performed, the power function may not be the best fit line for the data.

T-tests comparing the average intubation time resulted in no significant difference between the prototype and conventional scope for all four procedures. The last trial did, however, result in a p-value bordering on significance (p=0.058), indicating the true population data might have significantly different intubation times for this trial. Considering the intubation times for the prototype and conventional scope on the fourth trial (109.5 and 83.17 seconds respectively), it can be concluded that, as the user becomes more comfortable with the scope, the conventional scope is more capable of allowing said user to reduce intubation time. As the scopes had no significance between the means over the first three trials (p-values of .76, .56, and .28), it can observed that the conventional scope does not offer an advantage in intubation time until a certain skill level is reached.

The lower intubation time of the conventional scope compared to the prototype scope observed in the fourth procedure may be due to a limiting feature of the prototype scope. Namely, the prototype scope has a maximum velocity that the distal tip can be moved based on the voltage being supplied to the motors. The conventional scope, on the other hand, allows the user to move the tip as fast as the knobs can be spun. This allows the user more flexibility in increasing the intubation rate on the conventional scope by allowing them to faster steer the scope’s distal tip. The prototype scope limits the user’s ability to improve by not allowing increases to be made in distal tip velocity.
Concluding that a prototype scope does not increase learning rate or reduce intubation time is supported by Kuperij, et al, [15], who also performed a comparison on intubation time between a conventional and ‘more intuitive’ scope with modified grip and gesture steering of the distal tip. In this study, no significance was found between the two scopes’ average intubation time on either of the two trials performed [15]. However, Kuperij, et al, [15], did observe an offset (although not significant) between the means of the two scopes, where the designed scope had lower intubation times than the conventional in both trials, which was not seen in the current test. In fact, three of the four trials in the current test resulted in the conventional scope having smaller average intubation times.

A second study, Xie, et al, [23], found similar results in regard to intubation time when comparing a variable stiffness colonoscope to a standard colonoscope: namely, there is no significance between the means. Cecal intubation rate (how often the cecum was reached), however, was significantly higher when using the variable stiffness scope. This indicates better versatility of the scope to help the physician overcome obstacles the colon may present in a procedure, including tight bends and obstructions. While intubation rate was not tested with prototype scope, it may have an advantage over the conventional scope in this regard due to its ability to navigate turns and obstacles without requiring extra attention to control the scope as seen in the conventional scope. When a conventional scope needs to steer the distal tip, the force required to turn the steering knob will increases linearly corresponding the degree of the tip displacement. Furthermore, a force must be constantly applied to the steering knob in order to
counteract the tension forces within the scope pulling the distal tip back to the neutral position. Considering these factors in controlling the two scopes, the prototype scope may be advantages in cecal intubation rate by reducing the effort and focus that is needed to be applied to moving the distal tip of the scope into a position that allows for advancement of the scope. This advantage would not have been observed in the learning rate assessment because of the relatively simple colon configuration used for testing.

A third study, Shanbhag, [26], had results contradicting the conclusions made from the previous studies. Shanbhag found that, while using a control head stand, intubation time was reduced by 32% compared to using a conventional scope without the stand [26]. The intubation time may have been reduced for this study because an improvement, which did not change anything fundamentally about steering the scope, was added to a design which has existed and proved its value over many years. In all the previous studies, a modification which drastically changes how the physician uses and controls the scope is added. This produces many new factors that play into learning and controlling the scope (all of which cannot be predicted when creating and/or designing the advancement). Shanbhag added no large underlying factors with a stand, which resulted in positive reduction in intubation times.

During testing, some factors may have impacted the intubation times, and therefore the test result, on either the prototype scope, the conventional scope, or both scopes. For instance, hand size and strength seemed to play a large role in how easily subjects could stabilize and control the conventional scope. Larger hand sizes could more easily reach the steering knobs and resulted in a more comfortable hand position.
Subjects with smaller hands seemed to need and use more stabilization, which was achieved by resting the scope against their leg and/or table. Furthermore, subjects with smaller hands were required to stretch more with their thumb in order to reach the steering knobs. The prototype scope resolved the issues experienced on the conventional scope, however, created some factors of its own.

The prototype scope, using the touchscreen to control the movement of the tip, created a need for subjects to look down at the device in order to find and press the buttons. The amount of times a subject looked down at the device varied greatly between subjects, as well as between the students performing the study an endoscopist who performed a few procedures with the prototype. The endoscopist seemed to have more of a need to look down and find the buttons compared to the students in the study. This difference may be caused by the age of the endoscopist compared to the younger students. Differences between the students could be hypothesized to be due to the type of phone the student currently uses (smart phone vs. a standard phone), the amount of experience a student has using a touchscreen, and, perhaps, the experience the subject has with playing video games.

Personality and gender may also been a factor for intubation time on both scopes. For instance, males may have initially had more confidence in advancing the scope than females. Furthermore, personalities seemed to dictate the precision at which the subject centered the scope in the colon before advancing. Some subjects advanced the scope when they had a clear view of the lumen (but not necessarily centered), while others spent extra time completely centering the scope before advancing.
Considering all these factors, a reduction in intubation time may be achieved on the prototype scope compared to the conventional scope if more design was done on the prototype scope in order to eliminate or reduce the factors mentioned above that play a role on the prototype scope. In this case, a design for a hand device for which users would not have to look down to locate the buttons as well as having a larger adjustability of distal velocity would remedy the main problems for the prototype scope. However, these improvement would not guarantee that this will reduce the intubation time, as many factors such as personality and gender cannot be eliminated from the procedure.

In conclusion to this study, both scopes will yield significant improvements on intubation time when subjects train on them. Furthermore, no significance on either the average intubation time or the average normalized intubation time reveals that learning rate is unaffected by which scope the user operates on. The fourth trial did see a negative offset of the conventional scope intubation time compared to the prototype scope, however, this may be a result of the prototype scope having a set speed the distal tip may be turned, and, therefore, limiting the improvement of a subject as they increase in skill.

While it can be concluded that the prototype scope did not reduce learning rate or offset intubation time, it also did not increase the learning rate or, for the most part, increase intubation time compared to a conventional scope. Furthermore, the scope provided a small device that was simple to hold (negligible stability needed) and could be easily and more uniformly manipulated by a variety of subjects compared to the conventional scope (i.e. hand size and strength had negligible impacts when controlling the prototype scope). Considering the first experiment showed that using the prototype
scope did not cause fatigue, and this experiment observed no decrease in learning rate or intubation time, it can be concluded that the prototype scope has value in its ability to reduce fatigue experienced by the physician, while not decreasing efficiency at which students learn the colonoscopy procedure in comparison to a conventional scope.
CHAPTER 7: ADDITIONAL AND FUTURE WORK

The prototype scope successfully allows a user to remotely control the mounted colonoscope, however, many improvements would be required to make a production model. This chapter outlines some of the future work that would be required in order to make this a viable option for replacing the current conventional scope.

7.1 Current Sense Fix

While replacing the knob steering with motor actuated steering may reduce fatigue and be more intuitive, it also eliminates tactile feedback felt by the physician while using a conventional scope. This is important for the physician to judge if the scope is pressing too hard against the colon. To solve this problem, a current sensor was added in attempt to create a control system limiting torque of the system, however, unstable and noisy current readings created impossible conditions for implementing such a system. Below outlines the problem as well as the solution of the problem to be implemented in future work.

During the build and testing of the current sensor on the prototype, it was found that noisy data was being outputted from the current sensor. The current sensor, being a high-side sensor, was placed on the live wire in-between the power source and the motor driver. The motor driver consists of a dual h-bridge with pulse width modulation (PWM) for speed control. This setup was tested in icircuit. Outputs for voltage drop and current over a DC motor can be seen in Figure 45.
It can be seen that the PWM speed control produces an oscillating voltage drop across the motor (top signal in Figure 45) in order to slow and speed up the motor. This results in oscillating current running through the motor (bottom signal in Figure 45), which makes relating current and torque very complicated.

To solve this problem, PWM can be removed from the motor system. This can be done easily, as the colonoscope steering functionality does not require multiple speeds of operation. When the PWM is removed from the circuit, a constant voltage drop, and therefore current, will occur over the motor when a constant torque is applied. Figure 46 shows a possible circuit to achieve this, and Figure 47 shows the resulting voltage drop and current from that circuit.
As seen from Figure 47, current across the motor is constant and can now be directly related to torque based on Equation 2.

\[ \tau = kI \]  

(2)
In Equation 2, \( \tau \) is torque in oz-in, ‘I’ is current in amps, and \( k \) is a constant coefficient. With a linear relation between torque and current, a control system that limits the torque being outputted by the motors can be made using the current sensor. This will solve the problem of losing tactile feedback when the knob steering is replaced by motor actuated steering. The torque required to spin a control knob can now be related to the amount of rotation of the output shaft of the motor.

7.2 Input Device

The input device successfully allowed the user to control the distal end of the scope, however, user interaction with the device could be improved to reduce how much attention the user must commit to the hand-held device. The touchscreen input led to users having to look down in order to find the buttons in some instances. This could be resolved with a number of ways such as creating larger buttons on the touch screen, etching a pattern in the glass to allow the user to feel for the button location, or changing the input device to something different such as a controller with a joystick. The quality of the input device can remove attention away from the scope steering and apply it to focusing on other aspects of the procedure. Due to this, a design for the input device should be done in order to observe how a variety of people would interact with different devices as well as how efficiently they can use the device.

Apart from how the user interacts with the input device, more functionality needs to be added to the input device. This includes adding hardware to allow air water and suction to be controlled from the remote device. Furthermore, when the sensory system
is added that allows monitoring of the force the scope is applying against the colon, a warning sound or vibration should alert the user. These features will increase safety as well as completely remove the physician’s left hand away from the scope under all navigational aspects of the colonoscopy.

7.3 **Base Improvements**

The overall structure and support system for the modified scope should be improved in order to increase long term reliability, functionality, and be easier to sterilize. For a medical device, being able to sterilize the equipment is monumental. Therefore, the base should be made of a plastic rather than a steel in order to allow for it to be cleaned. Furthermore, a plastic or acrylic covering should be incorporated into the design in order to shelter the motor and circuit components which cannot be sanitized. The cover should be easily detachable for cleaning purposes.

Some properties of the base can be changed too in order to improve the design. For instance, the current base is a large rectangular steel piece, which has unused space on it. A new design can decrease the effective space the mounted colonoscope occupies by reducing the size and perhaps the shape of the base plate. This is important to incorporate as reducing the size will allow a physician more space to reach the controls of the video unit for the colonoscope, as well as reduce how much area is being blocked between the physician and the patient.
7.4 Controller, Circuit, and Electromechanical

The circuit system needs a few improvements and components in order to be more efficient and complete. A wall plug needs to be added to power the system. This can either be done with a wall converter or a circuit including a transformer and rectifying circuit depending on the voltage that is needed (perhaps a 15 volt input will be wanted in the future to increase the motor speed, in which a wall converter will be hard to find). Included in the power considerations is that if a voltage above 12 volts is wanted in the future, a voltage regulator or divider must be incorporated to supply voltage to the Arduino controller, which can have a maximum input voltage of 12 volts.

The interaction between the motors and the controller should be improved as well in respect to the H-bridge as well as the effectiveness of the controller reading the encoder on each motor. It was already mentioned in section 7.1 that the use of pulse width modulation control will make current reading impossible, and therefore, a simple H-bridge design should replace the motor driver. If variable speed is wanted feature, set voltages can be applied to the motor through the use of relays controlled by the controller or by a physical switch.

A change of either the controller or the encoder should be considered in order to have more accurate position information. The current encoder has very high accuracy (many holes), which can cause some holes to be missed with by the Arduino’s interrupt functionally with a 16 MHz clock. This can cause a drift in the neutral position (where the distal tip is perfectly straight in relation with the intubation tube), and may require
calibration before every procedure. A less accurate encoder (less holes) or a more powerful controller would fix this problem.

A last improvement that would add value to this prototype would be a self-calibrating system to determine the neutral position of the distal tip. This neutral position will be defined as the distal tip being in-line with the intubation tube directly behind it (no vertical or horizontal offset of the distal tip). This calibration would occur when the system is turned on, and is important because many times the scope is turned off without aligning the distal end to the center. Currently, when the power is turned on, the user must manually maneuver to the neutral position and hit the reset button on the controller tracking the position of the motors. While this is not difficult, an automation would increase the user experience with the system.
REFERENCES


APPENDIX A: EXPERIMENTAL DATA

This appendix contains the data found in the two experiments performed to satisfy objectives two and three: namely, the fatigue and learning curve evaluation. Included is the raw data and calculated values for normalization and statistical analysis.

Table 8. Fatigue data for conventional scope

<table>
<thead>
<tr>
<th>Reading</th>
<th>Subject 01</th>
<th>Subject 02</th>
<th>Subject 03</th>
<th>Subject 04</th>
<th>Subject 05</th>
<th>Subject 06</th>
<th>Subject 07</th>
<th>Subject 08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thumb Max (X1000)</td>
<td>1</td>
<td>0.15913</td>
<td>0.27027</td>
<td>0.156</td>
<td>0.14413</td>
<td>0.1072</td>
<td>0.17767</td>
<td>0.13783</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.1734</td>
<td>0.24677</td>
<td>0.12873</td>
<td>0.094733</td>
<td>0.096533</td>
<td>0.18863</td>
<td>0.11577</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0.15247</td>
<td>0.27443</td>
<td>0.12117</td>
<td>0.110955</td>
<td>0.10947</td>
<td>0.2039</td>
<td>0.13303</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0.14867</td>
<td>0.2565</td>
<td>0.10503</td>
<td>0.083687</td>
<td>0.0906</td>
<td>0.17847</td>
<td>0.12307</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>0.12207</td>
<td>0.27037</td>
<td>0.133</td>
<td>0.096762</td>
<td>0.098567</td>
<td>0.1725</td>
<td>0.1308</td>
</tr>
<tr>
<td>Forearm Max</td>
<td>1</td>
<td>37.67</td>
<td>51.5</td>
<td>17.17</td>
<td>18.5</td>
<td>28.5</td>
<td>31.67</td>
<td>39.33</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>39.67</td>
<td>50</td>
<td>17.67</td>
<td>16</td>
<td>26.17</td>
<td>29.33</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>37.83</td>
<td>45.33</td>
<td>16</td>
<td>14.33</td>
<td>23</td>
<td>29.67</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>33.33</td>
<td>43.83</td>
<td>16</td>
<td>16.67</td>
<td>23.83</td>
<td>31.33</td>
<td>28.5</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>31.33</td>
<td>39.83</td>
<td>14.5</td>
<td>16.17</td>
<td>21.33</td>
<td>31</td>
<td>30</td>
</tr>
</tbody>
</table>

| Thumb Max (X1000) | 1 | 1.089675108 | 0.913049913 | 0.825192308 | 0.657261002 | 0.900494003 | 1.061687998 | 0.839947762 |
| | 2 | 0.958147427 | 1.015392015 | 0.776730769 | 0.766999242 | 1.021175373 | 1.147633253 | 0.965174449 |
| | 3 | 0.93426758 | 0.94905949 | 0.873269231 | 0.581872299 | 0.845149254 | 1.00450273 | 0.892911558 |
| | 4 | 0.767108653 | 1.00037 | 0.852564103 | 0.671372968 | 0.919468184 | 0.970901109 | 0.948995139 |
| | 5 | 0.767108653 | 1.00037 | 0.852564103 | 0.671372968 | 0.919468184 | 0.970901109 | 0.948995139 |

| Forearm Max | 1 | 1.053092647 | 0.970873786 | 1.029120559 | 0.864846865 | 0.918245614 | 0.926113041 | 0.737350623 |
| | 2 | 1.004247412 | 0.880194175 | 0.933358789 | 0.774594595 | 0.807017544 | 0.936864753 | 0.762776506 |
| | 3 | 0.884786957 | 0.851067961 | 0.931857892 | 0.901081081 | 0.836140351 | 0.989264286 | 0.72467681 |
| | 4 | 0.83169631 | 0.773984058 | 0.844496214 | 0.870406474 | 0.748242053 | 0.978844332 | 0.762776506 |
| | 5 | 0.83169631 | 0.773984058 | 0.844496214 | 0.870406474 | 0.748242053 | 0.978844332 | 0.762776506 |

| Population Normalized Average Thumb Max | 1 | 1 | 0.999999999 | 1.020696436 | 0.926130657 | 0.807017544 | 0.936864753 |
| | 2 | 0.950179036 | 0.12608862 | 0.101306329 | 0.080701754 | 0.504166756 |
| | 3 | 0.840146229 | 0.143971571 | 0.115199132 | 0.080701754 | 0.504166756 |
| | 4 | 0.875825751 | 0.110821914 | 0.98867457 | 0.080701754 | 0.504166756 |
| | 5 | 0.875825751 | 0.110821914 | 0.98867457 | 0.080701754 | 0.504166756 |

| Population Normalized Average Forearm Max | 1 | 1 | 0.000000001 | 0.000000002 | 0.000000003 | 0.000000004 | 0.000000005 |
| | 2 | 0.928532019 | 0.086638731 | 0.078945977 | 0.068244159 | 0.059482776 |
| | 3 | 0.871076997 | 0.085338977 | 0.078945977 | 0.068244159 | 0.059482776 |
| | 4 | 0.874117444 | 0.077230094 | 0.069715981 | 0.060190159 | 0.051666666 |
| | 5 | 0.830526647 | 0.074339351 | 0.059482776 | 0.051666666 | 0.043846159 |

STD DEP 95% CI
Table 9. Fatigue data for prototype scope

<table>
<thead>
<tr>
<th>Reading</th>
<th>Subject 01</th>
<th>Subject 02</th>
<th>Subject 03</th>
<th>Subject 04</th>
<th>Subject 05</th>
<th>Subject 06</th>
<th>Subject 07</th>
<th>Subject 08</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.19783</td>
<td>0.26243</td>
<td>0.156</td>
<td>0.1106</td>
<td>0.10847</td>
<td>0.15783</td>
<td>0.09587</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.19393</td>
<td>0.20197</td>
<td>0.14157</td>
<td>0.13157</td>
<td>0.10253</td>
<td>0.17057</td>
<td>0.092967</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0.1922</td>
<td>0.2412</td>
<td>0.1082</td>
<td>0.12117</td>
<td>0.10117</td>
<td>0.16833</td>
<td>0.1333</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0.19333</td>
<td>0.24637</td>
<td>0.13253</td>
<td>0.10667</td>
<td>0.086333</td>
<td>0.16267</td>
<td>0.135</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>0.20733</td>
<td>0.2367</td>
<td>0.15113</td>
<td>0.10117</td>
<td>0.10923</td>
<td>0.1699</td>
<td>0.12597</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Thumb Max (X1000)</th>
<th>Subject 01</th>
<th>Subject 02</th>
<th>Subject 03</th>
<th>Subject 04</th>
<th>Subject 05</th>
<th>Subject 06</th>
<th>Subject 07</th>
<th>Subject 08</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>42.67</td>
<td>41.83</td>
<td>21.17</td>
<td>20.67</td>
<td>29</td>
<td>26</td>
<td>35.17</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>42</td>
<td>46</td>
<td>17</td>
<td>20.17</td>
<td>31</td>
<td>28.33</td>
<td>33.5</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>42.33</td>
<td>46.83</td>
<td>19.83</td>
<td>20.17</td>
<td>30.17</td>
<td>26.33</td>
<td>35.67</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>40.67</td>
<td>45.83</td>
<td>18.83</td>
<td>20.67</td>
<td>30.5</td>
<td>27.67</td>
<td>33.67</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>38.67</td>
<td>48.83</td>
<td>18.83</td>
<td>19.67</td>
<td>29</td>
<td>26</td>
<td>32.32</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Forearm Max</th>
<th>Subject 01</th>
<th>Subject 02</th>
<th>Subject 03</th>
<th>Subject 04</th>
<th>Subject 05</th>
<th>Subject 06</th>
<th>Subject 07</th>
<th>Subject 08</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.980286104</td>
<td>0.769614754</td>
<td>0.9075</td>
<td>1.18960217</td>
<td>0.945238315</td>
<td>1.080719762</td>
<td>0.969749757</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.971541222</td>
<td>0.919101227</td>
<td>0.693589744</td>
<td>1.09556962</td>
<td>0.932700286</td>
<td>1.066527276</td>
<td>1.390468044</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0.977253397</td>
<td>0.938607228</td>
<td>0.849551282</td>
<td>0.964466546</td>
<td>0.795915921</td>
<td>1.030650906</td>
<td>1.498200945</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1.048020286</td>
<td>0.901958487</td>
<td>0.967872051</td>
<td>0.914713794</td>
<td>1.097065646</td>
<td>1.076474686</td>
<td>1.314007994</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>096257324</td>
<td>1.167340401</td>
<td>0.88946226</td>
<td>1</td>
<td>1.02724138</td>
<td>1.046230769</td>
<td>0.957350014</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Thumb Max (X1000)</th>
<th>Subject 01</th>
<th>Subject 02</th>
<th>Subject 03</th>
<th>Subject 04</th>
<th>Subject 05</th>
<th>Subject 06</th>
<th>Subject 07</th>
<th>Subject 08</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normalized with</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Reading 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forearm Max</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Normalized with</td>
<td>0.984298102</td>
<td>1.099689218</td>
<td>0.803023146</td>
<td>0.975810353</td>
<td>1.08965517</td>
<td>1.089651585</td>
<td>0.952516349</td>
<td></td>
</tr>
<tr>
<td>Reading 1</td>
<td>0.992031873</td>
<td>1.119513147</td>
<td>0.936702881</td>
<td>0.975810353</td>
<td>1.040344828</td>
<td>1.012692308</td>
<td>1.014216662</td>
<td></td>
</tr>
<tr>
<td>Population</td>
<td>0.953128662</td>
<td>1.095625119</td>
<td>0.89946226</td>
<td>1</td>
<td>1.02724138</td>
<td>1.046230769</td>
<td>0.957350014</td>
<td></td>
</tr>
<tr>
<td>Average Thumb Max</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Population</td>
<td>0.977350123</td>
<td>0.122396641</td>
<td>0.09793593</td>
<td>0.137492872</td>
<td>0.147293251</td>
<td>0.137492872</td>
<td>0.147293251</td>
<td></td>
</tr>
<tr>
<td>Average Forearm Max</td>
<td>0.994979504</td>
<td>0.1840816</td>
<td>0.147293251</td>
<td>0.137492872</td>
<td>0.147293251</td>
<td>0.137492872</td>
<td>0.147293251</td>
<td></td>
</tr>
<tr>
<td>STD DEV</td>
<td>0.087774968</td>
<td>0.07023331</td>
<td>0.054235085</td>
<td>0.054235085</td>
<td>0.054235085</td>
<td>0.054235085</td>
<td>0.054235085</td>
<td></td>
</tr>
</tbody>
</table>
Table 10. Intubation time data for conventional scope and t-test results (disqualified subject excluded)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Intubation Time</th>
<th>Normalized Intubation Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Subject 1</td>
<td>375</td>
<td>140</td>
</tr>
<tr>
<td>Subject 3</td>
<td>156</td>
<td>99</td>
</tr>
<tr>
<td>Subject 5</td>
<td>160</td>
<td>134</td>
</tr>
<tr>
<td>Subject 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject 9</td>
<td>154</td>
<td>128</td>
</tr>
<tr>
<td>Subject 11</td>
<td>202</td>
<td>175</td>
</tr>
<tr>
<td>Subject 13</td>
<td>138</td>
<td>64</td>
</tr>
<tr>
<td>Average</td>
<td>197.5</td>
<td>123.333</td>
</tr>
<tr>
<td>STD</td>
<td>81.7389</td>
<td>34.6298</td>
</tr>
<tr>
<td>95% CI</td>
<td>71.646</td>
<td>30.3538</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trial</th>
<th>Intubation Time</th>
<th>Normalized Intubation Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>P-Value</td>
<td>0.76381</td>
<td>0.5587</td>
</tr>
</tbody>
</table>

Table 11. Intubation time data for prototype scope (disqualified subject excluded)

<table>
<thead>
<tr>
<th>Trial</th>
<th>Intubation Time</th>
<th>Normalized Intubation Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Subject 2</td>
<td>278</td>
<td>159</td>
</tr>
<tr>
<td>Subject 4</td>
<td>208</td>
<td>125</td>
</tr>
<tr>
<td>Subject 6</td>
<td>201</td>
<td>113</td>
</tr>
<tr>
<td>Subject 8</td>
<td>208</td>
<td>117</td>
</tr>
<tr>
<td>Subject 10</td>
<td>190</td>
<td>200</td>
</tr>
<tr>
<td>Subject 12</td>
<td>173</td>
<td>104</td>
</tr>
<tr>
<td>Subject 14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>209.667</td>
<td>136.333</td>
</tr>
<tr>
<td>STD</td>
<td>32.8667</td>
<td>33.315</td>
</tr>
<tr>
<td>95% CI</td>
<td>28.8084</td>
<td>29.2013</td>
</tr>
</tbody>
</table>
APPENDIX B: ANDROID AND ARDUINO CODE

This section contains the code used on the android device and the two Arduino controllers. The android code provided is the main code including the xml view (GUI) code and the java code for the model. The complete code for both controllers are also located in this section.

Android View

//Project name: Prototype Steer
//Author: Corey Sheerer
//Overview: Android application for controlling colonoscope
//User interface code (PrototypeSteer/res/layout)

<RelativeLayout
    xmlns:android="http://schemas.android.com/apk/res/android"
    xmlns:tools="http://schemas.android.com/tools"
    android:id="@+id/container"
    android:layout_width="match_parent"
    android:layout_height="match_parent"
    tools:context="com.example.prototypesteer.DoStuff"
    tools:ignore="MergeRootFrame"
    android:background="@color/black"
>
    <SeekBar
        android:id="@+id/seekBar1"
        android:layout_width="match_parent"
        android:layout_height="wrap_content"
        android:layout_alignParentLeft="true"
        android:layout_alignParentTop="true"
        android:max="100" />

    <Button
        android:id="@+id/upbtn"
        android:layout_width="40dp"
        android:layout_height="80dp"
        android:layout_alignParentTop="true"
        android:layout_centerHorizontal="true"
        android:layout_marginTop="105dp"
        android:background="@drawable(drawables)"
    />

    <Button
        android:id="@+id/leftbtn"
        android:layout_width="80dp"
    />
android:layout_height="40dp"
android:layout_below="@+id/upbtn"
android:layout_marginTop="20dp"
android:layout_marginLeft="55dp"
android:background="@drawable/drawables"
/>

<Button
android:id="@+id/rightbtn"
android:layout_width="80dp"
android:layout_height="40dp"
android:layout_below="@+id/upbtn"
android:layout_marginTop="20dp"
android:layout_alignParentRight="true"
android:layout_marginRight="55dp"
android:background="@drawable/drawables"
/>

<Button
android:id="@+id/downbtn"
android:layout_width="40dp"
android:layout_height="80dp"
android:layout_centerHorizontal="true"
android:layout_below="@+id/leftbtn"
android:layout_marginTop="20dp"
android:background="@drawable/drawables"
/>

<Button
android:id="@+id/waterbtn"
android:layout_width="150dp"
android:layout_height="100dp"
android:layout_alignParentBottom="true"
android:layout_alignParentLeft="true"
android:layout_marginLeft="20dp"
android:layout_marginBottom="40dp"
android:background="@drawable/drawables"
android:text="@string/waterbtn"
android:textColor="@color/blue" />

<Button
android:id="@+id/suctionbtn"
android:layout_width="150dp"
android:layout_height="100dp"
android:layout_alignParentBottom="true"
android:layout_marginBottom="40dp"
android:layout_alignParentRight="true"
android:layout_marginRight="20dp"
android:background="@drawable/drawables"
android:text="@string/suctionbtn"
android:textColor="@color/blue" />

<Switch
android:id="@+id/mySwitch"
android:layout_width="wrap_content"
android:layout_height="wrap_content"
android:layout_alignParentLeft="true"
android:layout_below="@+id/seekBar1"
android:text="Edit Speed"
android:textColor="@color/blue" />

<TextView
android:id="@+id/textViewProgress"
android:layout_width="wrap_content"
android:layout_height="wrap_content"
android:layout_alignParentRight="true"
android:layout_alignTop="@+id/mySwitch"
android:text="100%"
android:textAppearance="?android:attr/textAppearanceLarge"
android:textColor="@color/blue" />
</RelativeLayout>

Android Model

//Project name: Prototype Steer
//Author: Corey Sheerer
//Overview: Android application for controlling colonoscope
//Model code (PrototypeSteer/src/com.exampleprototypesteer/DoStuff)

package com.example.prototypesteer;

import java.io.IOException;
import java.io.OutputStream;
import java.util.Set;
import java.util.UUID;

import android.support.v7.app.ActionBarActivity;
import android.support.v7.app.ActionBar;
import android.support.v4.app.Fragment;
import android.text.Layout;
import android.util.DisplayMetrics;
import android.annotation.SuppressLint;
import android.bluetooth.BluetoothAdapter;
import android.bluetooth.BluetoothDevice;


import android.bluetooth.BluetoothSocket;
import android.os.Bundle;
import android.view.Display;
import android.view.LayoutInflater;
import android.view.Menu;
import android.view.MenuItem;
import android.view.MotionEvent;
import android.view.View;
import android.view.View.OnClickListener;
import android.view.View.OnTouchListener;
import android.view.ViewGroup;
import android.widget.Button;
import android.widget.CompoundButton;
import android.widget.RelativeLayout;
import android.widget.SeekBar;
import android.widget.Switch;
import android.widget.TextView;
import android.widget.Toast;
import android.widget.CompoundButton.OnCheckedChangeListener;
import android.widget.SeekBar.OnSeekBarChangeListener;
import android.os.Build;

public class DoStuff extends ActionBarActivity {
    private View viewwaterinstance;
    private View viewsuctioninstance;
    float density;
    float pixHeight;
    float pixWidth;
    float btnWidth;
    BluetoothAdapter BTAdapter;
    BluetoothDevice btdevice;
    private OutputStream out;
    private BluetoothSocket btsocket;
    Set<BluetoothDevice> devices;
    Button up, down, left, right, water, suction;
    int updownPosition, leftrightPosition;
    String sendString;
    private SeekBar bar;
    private Switch onOff;
    private TextView value;

    @Override
protected void onCreate(Bundle savedInstanceState) {
    super.onCreate(savedInstanceState);
    setContentView(R.layout.activity_do_stuff);
    viewSetup();
    BTAdapter = BluetoothAdapter.getDefaultAdapter();
    findPairedDevice();
    createSocket();
    //setInitialPosition();
    buttonSetup();
}

private void viewSetup(){
    Display display = getWindowManager().getDefaultDisplay();
    DisplayMetrics outMetrics = new DisplayMetrics();
    display.getMetrics(outMetrics);
    density = getResources().getDisplayMetrics().density;
    pixHeight = outMetrics.heightPixels;
    pixWidth = outMetrics.widthPixels;
    btnWidth = (int)((pixWidth-90)/2);

    viewwaterinstance = (View)findViewById(R.id.waterbtn);
    viewsuctioninstance = (View)findViewById(R.id.suctionbtn);
    RelativeLayout.LayoutParams param1 =
    (android.widget.RelativeLayout.LayoutParams) viewwaterinstance.getLayoutParams();
    RelativeLayout.LayoutParams param2 =
    (android.widget.RelativeLayout.LayoutParams) viewsuctioninstance.getLayoutParams();
    param1.width=(int)btnWidth;
    param2.width=(int)btnWidth;
    viewwaterinstance.setLayoutParams(param1);
    viewsuctioninstance.setLayoutParams(param2);
}

private void findPairedDevice(){
    devices = BTAdapter.getBondedDevices();
    if(devices.size()>0){
        for(BluetoothDevice d:devices){
            if(d.getName().equals("RN42-4530")) //Note, you will
            {btdevice = d;
            break;
            }}}}
else {
    Toast.makeText(getApplicationContext(), "could not find", Toast.LENGTH_LONG).show();
}

private void createSocket() {
    UUID uuid = UUID.fromString("00001101-0000-1000-8000-00805f9b34fb"); // Standard SerialPortService ID
    try {
        btsocket = btdevice.createRfcommSocketToServiceRecord(uuid);
    } catch (IOException e) {
        // TODO Auto-generated catch block
        e.printStackTrace();
    }
    try {
        btsocket.connect();
    } catch (IOException e) {
        // TODO Auto-generated catch block
        e.printStackTrace();
    }
    try {
        out = btsocket.getOutputStream();
    } catch (IOException e) {
        // TODO Auto-generated catch block
        e.printStackTrace();
    }
}

private void setInitialPosition() {
    // updownPosition = 1090;
    // leftrightPosition = 2090;
    // sendData("1090");
    // sendData("2090");
    //
}

private void buttonSetup() {
    bar = (SeekBar)findViewById(R.id.seekBar1);
onOff = (Switch)findViewById(R.id.mySwitch);
up = (Button)findViewById(R.id.upbtn);
down = (Button)findViewById(R.id.downbtn);
left = (Button)findViewById(R.id.leftbtn);
right = (Button)findViewById(R.id.rightbtn);
value = (TextView)findViewById(R.id.textViewProgress);
bar.setProgress(100);
bar.setEnabled(false);
bar.setOnSeekBarChangeListener(seekstuff);
onOff.setChecked(false);
onOff.setOnCheckedChangeListener(switchStuff);
up.setOnTouchListener(steerUp);
down.setOnTouchListener(steerDown);
left.setOnTouchListener(steerLeft);
right.setOnTouchListener(steerRight);
}

private void sendData(int msg){
    try {
        out.write(msg);
    } catch (IOException e) {
        // TODO Auto-generated catch block
        e.printStackTrace();
    }
}

final OnTouchListener steerUp = new OnTouchListener() {
    //public void onClick(View v) {
    //    sendData(0);
    //}
    @Override
    public boolean onTouch(View v, MotionEvent event) {
        if (event.getAction()==MotionEvent.ACTION_DOWN) {
            sendData(0);
            return true;
        }
        else if (event.getAction()==MotionEvent.ACTION_UP) {
            sendData(2);
            return true;
        }
        return false;
    }
};
final OnTouchListener steerDown = new OnTouchListener() {

@Override
public boolean onTouch(View v, MotionEvent event) {
    if(event.getAction() == MotionEvent.ACTION_DOWN){
        sendData(1);
        return true;
    }
    else if(event.getAction() == MotionEvent.ACTION_UP){
        sendData(2);
        return true;
    }
    return false;
}
//public void onClick(View v){
//    sendData(1);
//}
};

final OnTouchListener steerLeft = new OnTouchListener() {

@Override
public boolean onTouch(View v, MotionEvent event) {
    if(event.getAction() == MotionEvent.ACTION_DOWN){
        sendData(3);
        return true;
    }
    else if(event.getAction() == MotionEvent.ACTION_UP){
        sendData(5);
        return true;
    }
    return false;
}
//public void onClick(View v){
//    sendData(1);
//}
};

final OnTouchListener steerRight = new OnTouchListener() {

@Override
public boolean onTouch(View v, MotionEvent event) {
    if(event.getAction() == MotionEvent.ACTION_DOWN){
        sendData(4);
        return true;
    }
}
else if(event.getAction() == MotionEvent.ACTION_UP) {
    sendData(5);
    return true;
}
return false;

final OnSeekBarChangeListener seekstuff = new OnSeekBarChangeListener() {
    int barValue;
    @Override
    public void onProgressChanged(SeekBar seekBar, int progress, 
    boolean fromUser) {
        barValue = progress;
        // TODO Auto-generated method stub
        //value.setText(progress);
    }
    @Override
    public void onStartTrackingTouch(SeekBar seekBar) {
        // TODO Auto-generated method stub
    }
    @Override
    public void onStopTrackingTouch(SeekBar seekBar) {
        // TODO Auto-generated method stub
        sendData(barValue + 10);
        String txt = Integer.toString(barValue) + "%";
        value.setText(txt);
    }
};

final OnSeekBarChangeListener seekstuff = new OnSeekBarChangeListener() {
    int barValue;
    @Override
    public void onProgressChanged(SeekBar seekBar, int progress, 
    boolean fromUser) {
        barValue = progress;
        // TODO Auto-generated method stub
        //value.setText(progress);
    }
    @Override
    public void onStartTrackingTouch(SeekBar seekBar) {
        // TODO Auto-generated method stub
    }
    @Override
    public void onStopTrackingTouch(SeekBar seekBar) {
        // TODO Auto-generated method stub
        sendData(barValue + 10);
        String txt = Integer.toString(barValue) + "%";
        value.setText(txt);
    }
};

final OnCheckedChangeListener switchStuff = new 
OnCheckedChangeListener() {
    @Override
    public void onCheckedChanged(CompoundButton buttonView, 
    boolean isChecked) {

Arduino Input Controller

// Project name: Colonoscope_steering_v3
// Author: Corey Sheerer
// Overview: Arduino code to receive input from bluetooth and signal motor movement

// Serial library
#include <SoftwareSerial.h>

// Bluetooth rx and tx pins (enabled through softwareSerial library
int bluetoothTx = 5;
int bluetoothRx = 4;
SoftwareSerial bluetooth(bluetoothTx, bluetoothRx);

// Motor direction and speed pins
int m1_speed = 6;
int m1_dir1 = 7;
int m1_dir2 = 8;
int m2_speed = 9;
int m2_dir1 = 10;
int m2_dir2 = 11;

// DirectPin on or off to tell 2nd controller which direction motor is turning to allow for + or - encoder values
int directPin = 13;
boolean directBool;

// Input limit pins. When the limit is reached by the encoder,
// second controller turns pin high
int verticalLimitPin = 2;
int horizontalLimitPin = 3;

void setup(){
    //Setup usb serial connection to computer
    Serial.begin(115200);

    //Setup Bluetooth serial connection to android
    bluetooth.begin(115200);

    //initialize motor direction and speed pins
    pinMode(m1_dir1, OUTPUT);
    pinMode(m1_dir2, OUTPUT);
    pinMode(m2_speed, OUTPUT);
    pinMode(m2_dir1, OUTPUT);
    pinMode(m2_dir2, OUTPUT);
    analogWrite(m1_speed, 255);
    analogWrite(m2_speed, 255);
    //initialize limit reached pins
    pinMode(verticalLimitPin, INPUT);
    pinMode(horizontalLimitPin, INPUT);
    pinMode(directPin, OUTPUT);
}

void loop(){
    //Read from bluetooth and write to usb serial
    if(bluetooth.available())
    {
        //read in serial data
        int recieved = bluetooth.read();
        //Serial.println(recieved);
        //up button pressed
        if(recieved == 0){
            m2BackwardMotion();
        }
        //down button pressed
        if(recieved == 1){
            m2ForwardMotion();
        }
        //up or down button released
        if(recieved == 2){
            m2Stop();
        }
    }
}
// left button pressed
if (received == 3) {
    m1ForwardMotion();
}

// right button pressed
if (received == 4) {
    m1BackwardMotion();
}

// left or right button released
if (received == 5) {
    m1Stop();
}
if (received > 9) {
    changespeed(received);
}

if (digitalRead(verticalLimitPin)) {
    verticalLimit();
}
if (digitalRead(horizontalLimitPin)) {
    horizontalLimit();
}

void changespeed(int newSpeed) {
    newSpeed = map(newSpeed, 10, 110, 0, 255);
    analogWrite(m1_speed, newSpeed);
    analogWrite(m2_speed, newSpeed);
}

void m1ForwardMotion() {
    digitalWrite(directPin, HIGH);
    directBool = true;
    digitalWrite(m1_dir1, 1);
    digitalWrite(m1_dir2, 0);
}

void m1BackwardMotion() {
    digitalWrite(directPin, LOW);
    directBool = false;
    digitalWrite(m1_dir1, 0);
    digitalWrite(m1_dir2, 1);
void m1Stop() {
    digitalWrite(m1_dir1, 0);
    digitalWrite(m1_dir2, 0);
}

void m2ForwardMotion() {
    digitalWrite(directPin, HIGH);
    directBool = true;
    digitalWrite(m2_dir1, 1);
    digitalWrite(m2_dir2, 0);
}

void m2BackwardMotion() {
    digitalWrite(directPin, LOW);
    directBool = false;
    digitalWrite(m2_dir1, 0);
    digitalWrite(m2_dir2, 1);
}

void m2Stop() {
    digitalWrite(m2_dir1, 0);
    digitalWrite(m2_dir2, 0);
}

void verticalLimit() {
    m1Stop();
    analogWrite(m1_speed, 120);
    if (directBool == true) {
        m1BackwardMotion();
        while (digitalRead(verticalLimitPin)) {

        }
        delay(120);
        m1Stop();
    }
    else {
        m1ForwardMotion();
        while (digitalRead(verticalLimitPin)) {

        }
        delay(120);
        m1Stop();
    }
}
analogWrite(m1_speed, 200);
}

void horizontalLimit(){
    m2Stop();
analogWrite(m2_speed, 120);
if(directBool == true){
    m2BackwardMotion();
    while(digitalRead(horizontalLimitPin)){
}
delay(120);
m2Stop();
} else{
    m2ForwardMotion();
    while(digitalRead(horizontalLimitPin)){
}
delay(120);
m2Stop();
}
analogWrite(m2_speed, 200);
}

Arduino Encoder Controller

#include <Wire.h>
#include <Adafruit_INA219.h>

Adafruit_INA219 ina219;

float currentAverage = 0;
int currentSum;
long verticalCount = 0;
long horizontalCount = 0;
int directPin = 13;
int horizontalStopPin = 5;
int verticalStopPin = 4;
int current[5];
int currentCount = 0;

void setup(){
    uint32_t currentFrequency;
    ina219.begin();
    Serial.begin(115200);
    pinMode(directPin, INPUT);
    pinMode(horizontalStopPin, OUTPUT);
    pinMode(verticalStopPin, OUTPUT);
    attachInterrupt(0, horizontalChange, RISING);
    attachInterrupt(1, verticalChange, RISING);
}

void loop(){
    //currentRead();
    //change from 35000 to 38000
    if(horizontalCount > 39000 || horizontalCount < -39000){
        digitalWrite(horizontalStopPin, HIGH);
    }
    if(horizontalCount < 39000 & horizontalCount > -39000){
        digitalWrite(horizontalStopPin, LOW);
    }
    //changed form 32000 to 35000
    if(verticalCount > 36000 || verticalCount < -36000){
        digitalWrite(verticalStopPin, HIGH);
    }
    if(verticalCount < 36000 & verticalCount > -36000){
        digitalWrite(verticalStopPin, LOW);
    }
    //currentRead();
    delay(100);
}

void currentRead(){
    //    current[currentCount] = abs(int(100*ina219.getCurrent_mA()));
    //    currentCount++;
    //    if(currentCount == 5){
    //        currentSum = 0;
    //        for(int i = 0; i < 4; i++){
// currentSum += current[i];
// }
// currentAverage = currentSum / 5.0;
// currentCount = 0;
// Serial.print(verticalCount); Serial.print(","); Serial.print(int(currentAverage));
// Serial.print(\"n\");
// }
    currentAverage = ina219.getCurrent_mA();
    Serial.println(currentAverage);
    }

void verticalChange(){
    if(digitalRead(directPin)){
        verticalCount++;
    } else{verticalCount--;}
}

void horizontalChange(){
    if(digitalRead(directPin)){
        horizontalCount++;
    } else{horizontalCount--;}
}
APPENDIX C: TECHNICAL DRAWINGS

This section provides pictures of the 3-D model and the mechanical drawings for major parts. This includes the three printed parts and the locknut used to hold the gears on the knob shaft. The parts will appear as follows:

1. Cord Support
2. Intubation Tube Support
3. Motor mount
4. Lock Nut

Figure 45. Cord support model.
Figure 46. Cord support mechanical drawing
Figure 47. Intubation tube support model.
Figure 48. Intubation tube support mechanical drawing.
Figure 49. Motor mount model.
Figure 50. Motor mount mechanical drawing.
Figure 51. Lock nut model.
Figure 52. Lock nut mechanical drawing.
Fatigue Experiment Consent

Ohio University Consent Form

Title of Research: Fatigue Evaluation of an Android Controlled Colonoscope

Researchers: Corey Sheerer, JungHun Choi

You are being asked to participate in research. For you to be able to decide whether you want to participate in this project, you should understand what the project is about, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked to sign it. This will allow your participation in this study. You should receive a copy of this document to take with you.

Explanation of Study

This study is being done to test a new prototype colonoscope’s ability to reduce the risk of fatigue injuries to physicians performing colonoscopies compared to a conventional scope. A physician’s left thumb and forearm are specifically vulnerable to receiving these injuries due to fatigue arising from controlling the scope and heavy procedures loads. Reducing these risks will aid in maintaining high standards for colonoscopies.

If you agree to participate, you will be asked to perform two fatigue tests: one with a conventional scope and one with the prototype scope. The testing will take place at Stocker Center room 015B (located on West Green). During the test, you will be steering the colonoscope tip in a distinct pattern six times in a row. After completing the pattern with the required number of repetitions, you will pause and take a maximum voluntary contraction (MVC) test on your thumb.
and forearm. Steering the colonoscope in the pattern as well as taking the MVC reading will be repeated four times in a row. The forearm MVC test will consist of gripping a device with maximum force, and the thumb MVC will require you to press down on a cylinder with maximum force using your thumb. To avoid bias, the test for each scope will be taken on separate days.

If you have injuries or conditions of the left arm and hand that will prevent you from holding the scope or turning the control knobs with your thumb, you should not partake in this study. Furthermore, if you have an injury or condition that impairs the ability to grasp a small cylindrical tube with your right hand, you should not participate.

Your participation in the study will last about 20 minutes for each test (a total of two tests).

**Risks and Discomforts**

During the testing, participants of the study may become fatigued in their left arm, wrist, and hand as a result of holding and controlling the colonoscope. While this study investigates fatigue injuries, these are usually a result of long-term repetitive motion. Participants will have minimal chance of experiencing any injury during or after testing.

**Benefits**

There are no benefits to you if you participate. There are potential benefits to society. The benefits of colonoscopy, including cancer prevention and early cancer detection, are well known. As public awareness increases, the demand for the procedure also increases. In order to keep high standards with colonoscopy procedures, it is essential to maintain the health of the physicians performing the procedures. Fatigue injuries in the thumb and forearm can limit the physician’s ability to maneuver the scope and clearly check the colon for cancerous growths.

**Confidentiality and Records**
Your study information will be kept confidential through not publishing any identifiers within the research. During the study, the data will be recorded with identifiers in order to match the tests on each scope with the individual performing them. However, in the data analysis, you will be de-identified by use of a code in order to retain identifiers from the work. The code linking the identifier a discrete name will be kept within a password protected file and destroyed one year after completion of the study.

Additionally, while every effort will be made to keep your study–related information confidential, there may be circumstances where this information must be shared with:

* Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;
* Representatives of Ohio University (OU), including the Institutional Review Board, a committee that oversees the research at OU;

**Contact Information**

If you have any questions regarding this study, please contact Corey Sheerer, Primary Researcher, cs185708@ohio.edu, (614) 307-4707.

If you have any questions regarding your rights as a research participant, please contact Chris Hayhow, Director of Research Compliance, at Ohio University, (740) 593-0664.

By signing below, you are agreeing that:

- you have read this consent form (or it has been read to you) and have been given the opportunity to ask questions and have them answered
- you have been informed of potential risks and they have been explained to your satisfaction.
- you understand Ohio University has no funds set aside for any injuries you might receive as a result of participating in this study
- you are 18 years of age or older
- your participation in this research is completely voluntary
- you may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you and you will
not lose any benefits to which you are otherwise entitled.

Signature________________________________________ Date________

Printed Name________________________________________

Version Date: 08/28/14

Learning Rate Consent Form

Ohio University Consent Form

Title of Research: Fatigue Evaluation of an Android Controlled Colonoscope

Researchers: Corey Sheerer, JungHun Choi

You are being asked to participate in research. For you to be able to decide whether you want to participate in this project, you should understand what the project is about, as well as the possible risks and benefits in order to make an informed decision. This process is known as informed consent. This form describes the purpose, procedures, possible benefits, and risks. It also explains how your personal information will be used and protected. Once you have read this form and your questions about the study are answered, you will be asked to sign it. This will allow your participation in this study. You should receive a copy of this document to take with you.

Explanation of Study

This study is being done to test a new prototype colonoscope’s ability to reduce learning time of the colonoscopy procedure through being more intuitive than a conventional colonoscope. Studies indicate that endoscopist are being
allowed to perform colonoscopies before they are competent at the procedure. An endoscopist who has not reached competency is more likely to cause complications such as perforation of the colon. Furthermore, inexperienced physicians are less likely to reach the end of colon, leaving areas unchecked for cancerous growths. Creating a more intuitive scope can decrease learning time and skill needed to perform the colonoscopy procedure and improve initial skill of physicians who complete the requirements to practice the procedure independently.

If you agree to participate, you will perform four colonoscopy procedures during a single session with either the conventional or prototype scope on a colon simulator. The session will take place at Stocker Center, room 015B. Prior to your testing, you will receive, and be asked to watch, an informational colonoscopy overview video as well as a training video for your assigned scope.

If you have injuries or conditions of the left arm and hand that will prevent you from holding the scope or turning the control knobs with your thumb, you should not partake in this study. Furthermore, if you have an injury or condition that impairs the ability to grasp a small cylindrical tube with your right hand, you should not participate.

Your participation in the study will last about 45 minutes for the session.

Risks and Discomforts

During the testing, participants of the study may become fatigued in their left arm, wrist, and hand as a result of holding and controlling the colonoscope. While fatigue injuries do occur in physicians performing these procedures, these are usually a result of long-term repetitive motion. Participants will have minimal chance of experiencing any injury during or after testing.

Benefits

There are no benefits to you if you participate. There are potential benefits to society. The benefits of colonoscopy, including cancer prevention and early cancer detection, are well known. As public awareness increases, the demand for the procedure also increases. In order to keep high standards for colonoscopy procedures, it is essential for physicians to have the appropriate
amount of training and experience. A device to improve training time will increase the initial skill of the physicians who complete the requirements to perform procedures independently.

**Confidentiality and Records**

Your study information will be kept confidential through discrete data publishing. Identifiers will be used to assign scopes to the all individuals and identify which scope you receive when performing the tests. In the data analysis, you will be de-identified by use of a code in order to retain identifiers from the work. The code linking the identifier a discrete name will be kept within a password protected file and destroyed one year after completion of the study. No identifiers will be published.

Additionally, while every effort will be made to keep your study-related information confidential, there may be circumstances where this information must be shared with:

* Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;
* Representatives of Ohio University (OU), including the Institutional Review Board, a committee that oversees the research at OU;

**Contact Information**

If you have any questions regarding this study, please contact Corey Sheerer, Primary Researcher, cs185708@ohio.edu, (614) 307–4707.

If you have any questions regarding your rights as a research participant, please contact Chris Hayhow, Director of Research Compliance, at Ohio University, (740) 593–0664.

By signing below, you are agreeing that:

- you have read this consent form (or it has been read to you) and have been given the opportunity to ask questions and have them answered
- you have been informed of potential risks and they have been explained to your satisfaction.
• you understand Ohio University has no funds set aside for any injuries you might receive as a result of participating in this study
• you are 18 years of age or older
• your participation in this research is completely voluntary
• you may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you and you will not lose any benefits to which you are otherwise entitled.

Signature___________________________________________ Date__________

Printed Name_________________________________________

Version Date: 09/11/14
APPENDIX E: RECRUITMENT EMAIL

Fatigue Recruitment Email

Hello Students,

The mechanical engineering department is looking for pre-medical students to participate in a study evaluating the fatigue of two different colonoscopes.

**Study Overview**

This study is being done to test a prototype colonoscope’s ability to reduce the risk of fatigue injuries to physicians performing colonoscopies compared to a conventional scope. Physicians left thumb and forearm are specifically vulnerable to receiving these injuries due to fatigue arising from controlling the scope and heavy procedures loads. Reducing these risks will ensure high standards for colonoscopies are kept.

**Participants Role**

To simulate the fatigue experienced while controlling the scope, you will be asked to repeatedly steer the distal tip of the scope in a distinct pattern. Before, after, and systematically during the test, your maximum voluntary contraction (the maximum force you can output) (MVC) of your thumb and forearm will be measured using two dynamometers. MVC measurements will consist of tightly gripping the forearm dynamometer and pressing down on a cylindrical object for the thumb dynamometer. You will be asked to perform a fatigue test on each of the colonoscopes with at least a day in between tests. Each test will take approximately 20 minutes and take place at Stocker Center, Room 015B located on West Green.

Because you will be controlling the scope with your left arm and hand, anyone with an injury or condition preventing them from holding the scope, steering the knobs with your thumb, or performing fatigue tests should not participate in this study. Furthermore, the right hand will be used to hold the intubation tube while the study is being performed. If you have injuries or conditions preventing you from grasping a small cylindrical object, you should not
participate. If you agree to participate, you are acknowledging that you do not have any injuries preventing you from performing the necessary tasks.

Other Information
Attached is the consent form, which will provide you with more information about the study and the role you will play. Furthermore, a paper copy of this consent form will be presented upon arrival to the first test if you participate.

Contact Info
If interested, please contact Corey Sheerer by email at cs185708@ohio.edu.

Learning Rate Recruitment Email

Hello Students,

The mechanical engineering department is looking for medical students to participate in a study evaluating the learning rate of two different colonoscopes.

Study Overview
This study is being done to test a new prototype colonoscope’s ability to reduce learning time of the colonoscopy procedure through being more intuitive than a conventional colonoscope. Studies indicate that endoscopist are being allowed to perform colonoscopies before they are competent at the procedure. An endoscopist who has not reached competency is more likely to cause complications such as perforation of the colon. Furthermore, inexperienced physicians are less likely to reach the end of colon, leaving areas unchecked for cancerous growths. Creating a more intuitive scope can decrease learning time and skill needed to perform the colonoscopy procedure and improve initial skill of physicians who complete the requirements to practice the procedure independently.

Participants Role
If you agree to participate, you will perform four colonoscopy procedures during a single session with either the conventional or prototype scope on a colon simulator. Prior to your testing, you will receive, and be asked to watch,
an informational colonoscopy overview video as well as a training video for your assigned scope. The testing session will last about 45 minutes and take place in Stocker Center, room 015B located on West Green.

Because you will be controlling the scope with your left arm and hand, anyone with an injury or condition preventing them from holding the scope, steering the knobs with your thumb, or performing fatigue tests should not participate in this study. Furthermore, the right hand will be used to hold the intubation tube while the study is being performed. If you have injuries or conditions preventing you from grasping a small cylindrical object, you should not participate. If you agree to participate, you are acknowledging that you do not have any injuries preventing you from performing the necessary tasks.

**Other Information**
Attached is the consent form, which will provide you with more information about the study and the role you will play. Furthermore, a paper copy of this consent form will be presented upon arrival to the first test if you participate.

**Contact Info**
If interested, please contact Corey Sheerer by email at cs185708@ohio.edu.