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Force Application During Colonoscopy as a Marker of Competence: Development of a Novel Training Device

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Abstract

Colonoscopy is a technically challenging procedure to learn. The colonoscope is prone to forming loops in the colon, which can lead patient discomfort and even perforation. We hypothesized that expert endoscopists use techniques to avoid loop formation, and identify and straighten loops earlier, and thus exert less force.

Using a physical colon simulator model, electromagnetic tracking markers were used to follow the motion of the colon as the scope was advanced. Attending physicians exerted significantly lower mean colonic displacement than trainees.

To allow portability to any simulator, and even the clinical setting, we designed and tested the construct validity of a force-sensing sleeve for the colonoscope. It utilizes piezoresistive sensors applied in a helical orientation along the length of the colonoscope.

Force application is a marker of endoscopic competence. Our colonoscope sleeve has potential for educational and clinical use, alerting endoscopists to dangerous force application, improving patient comfort and safety.

Keywords

Colonoscopy, Endoscopy Training, Resident Education, Gastroenterology, General Surgery, Patient Satisfaction/Safety, Perforation, Electromagnetic Spatial Tracking, Force Application, Force Sensorized Sleeve, Loop Formation

Summary for Lay Audience

Colonoscopy is a procedure that involves the insertion of a long flexible tube with a camera and light via the anal canal. This allows the examination of the colon for diagnosis and treatment. Not surprisingly, the procedure is prone to not only discomfort, but also potential injury to the colon wall, as the scope is negotiated through the turns. Frequently, these anatomic turns in the colon result in loops being formed by the flexible scope. Our research set out to examine the force transmitted from loops in the scope to the wall of the bowel. These loops are responsible for the majority of the discomfort during the procedure, and can increase the risk of perforation.

We hypothesized that expert endoscopists would use techniques to avoid loop formation, and identify and reduce loops earlier, and would thus exert less force.

We first explored the difference between novice and expert endoscopists. We developed a training model that was able to measure how much the colon was displaced from its resting position as the colonoscope was advanced to the end of the colon. Expert endoscopists were able to advance the scope through the colon with a reduction in colonic displacement compared to their novice counterparts. This is a potential marker of competence that could be incorporated into colonoscopy training programs.

Although our simulation model worked well for training and assessment purposes, we wanted to develop a device for clinical use. Our simulation model relied on sensors placed on our model colon. For clinical use we needed our force sensors to be applied to the scope itself. We developed a layered flexible sleeve wrapped around the outside of the scope. Compression between the layers in the sleeve can be used to measure force. The helical shape of the sleeve allows for the flexibility of the scope to be maintained.

Our work has identified force application as a marker of endoscopic competence and should be incorporated into training programs. Our novel sleeve design has the potential for both educational and clinical use, alerting endoscopists to potentially dangerous force application, improving patient comfort and safety.

Co-Authorship Statement

The following thesis contains two manuscripts that are in preparation for submission to a scientific journal (Chapters 2 and 3). As the first author of these manuscripts (co-first author for Chapter 3), I was a significant contributor to all aspects of the studies as well as the manuscript preparations. Specific involvement included: contributions to study design, collection of all data, clinical interpretation of data, drafting of the manuscripts. Dr. Rajni Patel, Dr. Christopher Schlachta and Dr. Terry Peters were my supervisors. They were responsible for the study conceptions, providing guidance and support throughout the entire process.

Chapter 2 is an original research study entitled "Colonic Displacement as a Surrogate Marker for Force: Differentiating Novice and Expert Endoscopists" and is in preparation for submission to Surgical Endoscopy. This manuscript was co-authored by Dr. Jeffrey Hawel, Dr. Kerollos Wanis, Dr. Ahmed Elnahas, Dr. Nawar Alkhamesi, Dr. Rajni Patel, and Dr. Christopher Schlachta. As first author I contributed to study design, collection and interpretation of data, and manuscript preparation. Dr. Kerollos Wanis provided statistical analyses and manuscript review. Dr. Rajni Patel provided software and user interface design for the colonic displacement trackers. Dr. Ahmed Elnahas, Dr. Nawar Alkhamesi, Dr. Terry Peters, Dr. Rajni Patel, and Dr. Christopher Schlachta contributed to study design, data interpretation and manuscript preparation.

Chapter 3 is an original research study entitled "Development of a Force-Sensing Sleeve for the Colonoscope: A Novel Device for Training" and is in preparation for submission to Surgical Endoscopy. This manuscript was co-authored by Dr. Jeffrey Hawel, Nicholas Lavdas, Dr. Ahmed Elnahas, Dr. Nawar Alkhamesi, Dr. Terry Peters, Dr. Rajni Patel, and Dr. Christopher Schlachta. As co-first author I contributed to study design, collection and interpretation of data, and manuscript preparation.

Nicholas Lavdas, co-first author, designed and built the force-sensing sleeve, and contributed to data collection, interpretation and manuscript preparation. Dr. Rajni Patel contributed to the design and construction of the force-sensing sleeve. Dr. Ahmed Elnahas, Dr. Nawar Alkhamesi, Dr. Terry Peters, Dr. Rajni Patel, and Dr. Christopher Schlachta contributed to study design, data interpretation and manuscript preparation.

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This is for you.

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List of Abbreviations

RMS	root mean squared
EM	electromagnetic
PGY	post-graduate year
SAGES	Society of the American Gastrointestinal and Endoscopic Surgeons
CREATE	Course for Residents in Advanced Therapeutic Endoscopy
GI	gastrointestinal
ASGE	American Society of Gastrointestinal Endoscopy
GAGES	global assessment of gastrointestinal endoscopic skill
SEE	Skills Enhancement for Endoscopy
fPCB	flexible printed circuit boards
MEI	magnetic endoscopic imaging
CO_2	carbon dioxide
CBME	competency based medical education
3D	three-dimensional
CIR	cecal intubation rate

CHAPTER 1

1. Introduction

1.1 Colonoscopy

1.1.1 The Colonoscope

Direct visualization of the lumen of the lower gastrointestinal tract provides diagnostic and therapeutic value that today's clinician could not do without. And yet only a few decades ago, such visualization was limited to the very distal-most colon. Endoscopy at the time relied on the introduction of a rigid tube into the colon to view luminal pathology. The flexible colonoscope, developed in 1969 by Dr. William Wolff and Dr. Hiromi Shinya, revolutionized endoscopy [1]. The technology that allowed such an instrument was the fiberoptic bundle. At only 4mm in diameter, this allowed the delivery of light to the colonic lumen, and transmission of the image from the tip of the scope back to the eyepiece. Only three months after they performed the first flexible colonoscopy, the instrument was used to remove a colonic polyp using a flexible snare instrument designed by Dr. Shinya [2]. In 1983, the first video endoscope was introduced, allowing the luminal view to be displayed on a screen, obviating the need for an eyepiece for visualization.

Today multiple companies manufacture colonoscopes, including Olympus, Pentax, Fujinon and Karl Storz to name a few. Although each has unique properties, they all share a similar basic design. Most colonoscope designs are approximately 160cm in length, including a long flexible shaft and a steerable tip. The cables allowing control of this tip travel down the shaft of the endoscope, along with channels to allow for suction and air (or CO_2) insufflation, and a working channel to allow the introduction of instrumentation (e.g., biopsy forceps, polypectomy snares, injection needles, etc.) - all of this fits within an instrument only 12.8 mm in diameter [3]. Many scopes now have technology to vary stiffness along the flexible shaft of the colonoscope. This allows the endoscopist flexibility when required, and rigidity once acute angles in the colon anatomy are overcome. In spite of this, the challenges of negotiating a long flexible tube, through another long hollow flexible tube with variable twists and turns, received skepticism early on as to its feasibility [4].

1.1.2 Colon Anatomy and Colonoscopic Techniques

In a review article during the early experience with colonoscopy, Dr. Bergein Overholt described colonic anatomy: "Although certain segments of the colon are fixed in position, the majority of the 6 feet is attached to a highly mobile pedicle resulting in all manner of configurations – the cause of much frustration to both patient and colonoscopist" [3]. Indeed the ascending and descending segments of the colon are fixed to the retroperitoneum. However, the transverse colon and sigmoid colon can, in most patients, move freely within the peritoneal cavity, limited only by the length of the blood supply and lymphatic drainage traveling within its mesentery. It is these segments of mobility, interspersed between segments of fixation, which result in many of the challenges encountered during colonoscopy, as shown in **Figure 1.1**.

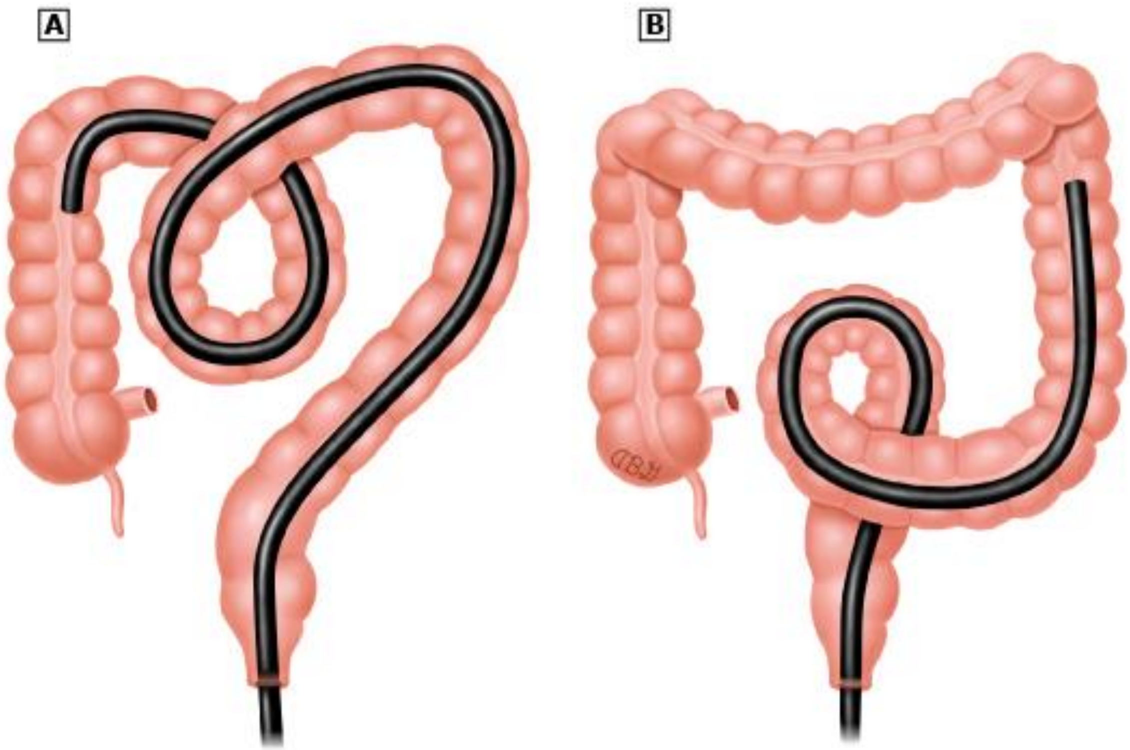

Figure 1.1 - Diagrammatic representation of loop formation during colonoscopy

A shows a 'gamma' loop in a mobile transverse colon. B shows an 'alpha' loop in a mobile sigmoid colon. Reproduced with permission from: Lee L, Saltzman JR. Overview of colonoscopy in adults. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 25th 2020.) Copyright © 2020 UpToDate, Inc. For more information visit www.uptodate.com.

In up to 10% to 20% of colonoscopies, intubation of the cecum may be considered difficult [5], describing a procedure in which it is challenging (or impossible) for the endoscopist to reach the cecum. The primary factor precluding safe advancement of the colonoscope tip to the cecum is looping resulting in acute angulation. Several contributing patient related factors have been described.

Prior surgery, resulting in adhesions or altered anatomy, is commonly encountered. Within this group, abdominal hysterectomy, which often results in scarring and fixation of loops of bowel to the remaining vaginal cuff, has been demonstrated to increase the technical difficult of colonoscopy [6]. Even in the absence of prior surgery, several studies have explored sex as a predictor of anatomic differences in the colon [7]. The female transverse colon is longer than the male colon, resulting in increased mobility and more frequent descent into the pelvis. Also, not unexpectedly, the necessity of the colon to travel around the uterus as it exits the pelvis leads to a greater potential for angulation. The effect of these anatomical variations has been studied using magnetic resonance imaging, which showed more frequent looping during colonoscopy in females [8]. Diverticular disease is another well-described factor in the challenging colonoscopy [9]. Extensive diverticula can make lumen identification challenging, and inflammatory changes from repeated attacks of diverticulitis can result in luminal narrowing and scarring, leaving acute angles in the colon that are difficult to navigate. Body habitus is an interesting variable that affects the degree of difficulty at both ends of the spectrum. The obese patient presents challenges in reducing loops from decreased colonic mobility. Overlying adipose tissue also makes adjunctive maneuvers, such as the application of abdominal wall counter-pressure, difficult, if not impossible. However, body mass that is too low has also been shown to be a risk factor for an incomplete examination. This may be due to a paucity of visceral fat holding the colon in place, or perhaps a smaller abdominal domain in which to reduce loops in the colonoscope [10].

Colonoscopy is usually performed with the patient lying with their left side down, or left lateral decubitus position, facing away from the endoscopist. Changing the positioning of the patient - including supine, right lateral decubitus, and even prone - during colonoscopy has been well studied [11,12]. This allows gravity to be used to the advantage of the endoscopist. Position change can unfold sharp angles in the colon, and allow fluid to pool and weigh down certain segments of the colon to help with straightening of loops.

Torque steering is a commonly discussed concept that can help the endoscopist both prevent looping, and straighten the colonoscope when looping occurs. Torque can be applied to the colonoscope by the right had of the endoscopist, or by rotating the patient in the opposite direction. External pressure on the abdominal wall by an assistant, to counter the propagation of a loop formation, is also commonly utilized. One technique for loop reduction is shown in **Figure 1.2**.

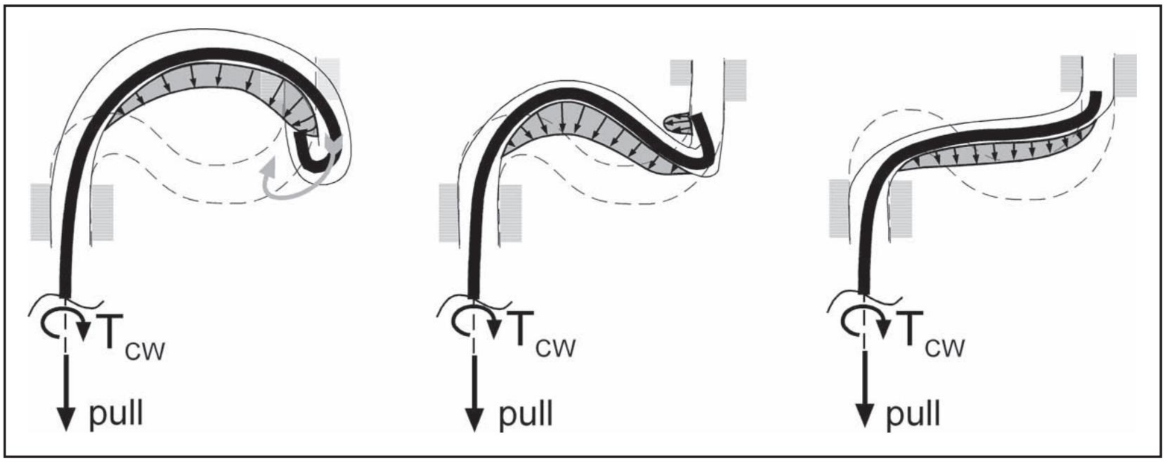

Figure 1.2 - Loop reduction using torque and withdrawal.

We see the formation of a loop as the scope is advanced through the sigmoid colon. The loop is reduced by applying clockwise torque (T_{CW}) and withdrawing the scope, leaving a straightened sigmoid colon. Reproduced with permission from: Loeve AJ, Fockens P, Breedveld P. Mechanical analysis of insertion problems and pain during colonoscopy: why highly skill-dependent colonoscopy routines are necessary in the first place... and how they may be avoided. Can J Gastroenterol 2013;27(5):293-302.

Using water instead of air insufflation is helpful on insertion of the colonoscope. It helps to prevent over insufflation of the colon, which contributes to patient discomfort. This over insufflation also contributes to looping, as filling the colon with air "lengthens" the colon as it distends, predisposing to looping. A randomized trial showed less patient discomfort with water insufflation when compared to air insufflation [13].

Magnetic endoscopic imaging (MEI) allows the endoscopist to visualize the real-time three-dimensional configuration of the colonoscope. This allows the endoscopist to see when loops are being formed, and use the appropriate technique to avoid loop formation. A recent meta-analysis showed the value of this technology as an adjunct during colonoscopy. MEI resulted in higher rates of complete colonoscopy and decreased procedural times, as well as pain scores, when compared with standard colonoscopy [14].

The expert endoscopist utilizes many, if not all of these strategies as part of their endoscopic practice. Many of these techniques require subtle manipulation of the scope and careful decision-making as to the appropriate strategy. This generally requires years of training and practice to acquire. This makes it undoubtedly one of the most challenging, and at times frustrating, procedures to learn, for gastroenterology and surgical trainees alike. There is currently a lack of technology available to endoscopists that provide quantitative feedback about the amount of force being applied. Such a device could be used in physical training models, but could also be adapted for use in patients.

1.1.3 Colonic Disease Burden

In spite of the challenges in performing quality colonoscopy, the need for well-trained endoscopists is clear from the ever-aging population and the growing list of indications for endoscopic evaluation. The number of colonoscopies performed in Ontario has shown steady growth over the past 15 years [15,16]. Using data from billing codes in the Ontario Health Insurance Plan, and distributed by the Ontario Medical Association, the number of colonoscopies performed in 2016 tallied over 460,000.

Although there are many indications for colonoscopy, one of the most common is screening for colorectal cancer. The fundamental concept driving screening programs is the adenoma to carcinoma sequence. This term describes the sequential progression of colonic mucosa from normal to dysplastic epithelium to carcinoma [17]. Intervening on this sequence, through the endoscopic removal of adenomatous polyps, reduces the long-term risk of colorectal cancer [18-22]. Following endoscopic identification and removal of polyps, 30-35% of patients will have additional adenomas detected 3 to 4 years later [23-25]. It is for this reason that regular endoscopic surveillance is required for those prone to adenoma formation [26].

The National Polyp Study Workgroup published the landmark paper in 1993 that showed a decreased incidence of colorectal cancer following regular colonoscopy and polypectomy [18]. Compared to a population based cohort at average risk of colon cancer, the study group, who had adenomatous polyps removed at initial colonoscopy, the incidence of colorectal cancer during follow up was reduced by 76%. Despite this, colorectal cancer remains the second most common type of cancer in Canada, with over 25,000 cases in 2017, and accounting for 13% of all cancers [27]. Population-based studies have compared the stage of colorectal cancer at diagnosis for those cancers detected through screening compared to those presenting with symptoms. These studies demonstrated earlier stage at diagnosis for those found through screening, and furthermore, that survival is higher for screening-detected cancers than symptom-detected cancers, even within the same stage [28,29]. Thus colorectal cancer screening remains our primary weapon against colorectal cancer, effective at detecting cancers earlier, and decreasing mortality [15,30].

1.1.4 Risks of Colonoscopy

Colonoscopy is not without drawbacks - neither the bowel preparation, nor pre-procedure clear fluid diet is appealing. Further, it is an invasive procedure that carries with it much stigma. Many colonoscopic screening regimens require regular examinations throughout a patients' life, and thus maximizing patient compliance is crucial to the success of the program. There is evidence that a poorly tolerated procedure makes patients less willing to undergo future procedures [31,32]. There is also fear regarding the procedure, as many patients are aware of the more common procedural risks of colonoscopy.

Despite multiple advances in endoscopic technique, complication rates from colonoscopy have shown minimal change. Bleeding is a rare complication from scope advancement [33], but is seen more frequently following therapeutic maneuvers such as polypectomy. Splenic injury is a rare but serious complication from colonoscopy that can result in significant intraperitoneal bleeding, making diagnosis challenging. It is thought to occur from tension on the splenocolic ligament and either tears in the splenic capsule or vascular avulsion, and is usually a result of blunt injury and looping [34].

Colon perforation is likely the most well known, and most feared, adverse event resulting from colonoscopy. Although rare [35], its significance stems from the associated high morbidity and considerable mortality [36,37]. Mechanisms for colonoscopic perforation vary, but can include barotrauma, thermal energy and polypectomy. However, with respect to scope advancement, mechanical trauma from loop formation results in the most significant damage to the colon wall [38]. Surgical intervention after perforation is common, and required interventions can range from suture repair to colon resection and anastomosis, or even ostomy, which are occasionally permanent. Patients with blunt injury to the colon (ie. from scope looping) are more likely to receive a stoma, and mortality rate when surgical intervention is required has been described as high as 7% [37].

Given the volume of colonoscopy performed, and the severity of the resulting complications, even rare complications remain a significant concern. The learning curve for endoscopy, and similarly the decline in complication rates, extends beyond the training period for many endoscopists, and into practice. Thus ongoing efforts must be focused on maximizing training opportunities for endoscopic trainees in order to minimize morbidity to patients.

1.2 Endoscopic Training

1.2.1 Current Challenges in Endoscopic Training

A decade ago, American Society of Gastrointestinal Endoscopy (ASGE) advocated minimum procedural numbers during training for gastroenterology trainees. They recommended 140 colonoscopies for fellows [39], while in the United Kingdom, the Joint Advisory Group on gastrointestinal (GI) endoscopy stipulates 200 [40]. In contrast, the residency review committee for surgery requires surgical trainees to complete 50 colonoscopies [41,42]. Despite these relatively low procedural requirements, a subsequent survey of Canadian surgical trainees explored the number of endoscopies performed during training, revealing that none of the surgical residents achieved the minimum number of cases recommended by the ASGE [43]. Since this time, many programs have made important changes to their endoscopic training curriculum to provide adequate exposure for their trainees. However, further studies have emerged, suggesting that an even larger endoscopic experience may be required to achieve competence.

As a technical marker of proficiency, a cecal intubation rate (CIR) (the ability to safely navigate the tip of the colonoscope into the cecum of the colon) of 90% has long been an agreed upon standard [40,44]. A multitude of studies have been published regarding training numbers to reach this target. A recent study, and one of the largest to date, looked at colonoscopy learning curves across all gastroenterology training centers in the United Kingdom [45]. In that study 233 procedures were required on average to achieve cecal intubation rates of 90%. After 100 procedures, only a minority of trainees reached the cecum consistently. This increased to 41% of trainees after 200 procedures, and 76% after 250 procedures [45].

Although few would argue that minimum procedural volumes should be enforced to ensure adequate exposure during training, this does not ensure competence. Indeed prior studies have shown that endoscopist skill can show wide variation despite similar levels of experience [45,46]. Additional variables in skill acquisition during endoscopic training have also been evaluated. For example, gaps in endoscopic training, which is a particular challenge in surgical residency where the majority of endoscopy rotations are early in training, have been shown to affect skill acquisition

[47]. However, learning distributed across training is superior to massed training methods, having been evaluated in technical performance of basic endoscopic surgery [48]. However, training intensity also affects skill acquisition, and thus simply spreading out endoscopy exposure over the duration of training might reveal further challenges [45]. Finally, many initiatives now exist across the United Kingdom (Joint Advisory Group on Gastrointestinal Endoscopy)[49] and North America (Skills Enhancement for Endoscopy)[50], which put increased emphasis on patient positioning and the use of scope imaging technology to help facilitate scope advancement. The use of such training aids has been previously investigated (e.g., Scope Guide and Scope Pilot) and has also been shown to affect skill acquisition [51]. Furthermore, the reliance on procedural number has been challenged given the unknown accuracy of logbooks kept by learners [52]. These records frequently lack specific learning achievements and documentation of goals. Finally, further variables that are more challenging to quantify and study include the quality of instruction received, and of course a trainees' innate ability.

SAGES established a Fundamentals of Endoscopic Surgery taskforce charged with development of a comprehensive program with validated outcome metrics to evaluate basic flexible endoscopic skills. The result was the global assessment of gastrointestinal endoscopic skills (GAGES) for upper endoscopy (GAGES-UE) and colonoscopy (GAGES-C). These instruments are validated for both gastroenterologists and surgeons [53]. This has subsequently been employed to challenge the concept of case numbers as a surrogate for endoscopic competency [54]. The Mayo Colonoscopy Skills Assessment Tool has been validated for the evaluation of the colonoscopy learning curve [55]. Although similar to the GAGES-C, it incorporates some important additional parameters. These include sedation and pathology recognition, for example, as well as quantifying the degree of trainee involvement in the overall procedure. The Rotterdam Assessment Form for Colonoscopy is another tool that facilitates both the assessment of the colonoscopy learning curve, and allows comparison with a group reference [56].

Although each of these methods evaluates progress on the endoscopic skills learning curve, we are still met with the challenges of high endoscopic procedure requirements, amidst ever diminishing opportunities to achieve such high numbers during residency training.

1.2.2 Endoscopic Simulation

Simulation allows an opportunity to improve endoscopic skill in a safe training environment before encountering patients. Available endoscopic simulators can be divided into three main groups: (1) Animal models, (2) Mechanical models, and (3) Computer models.

Animal models use either stomach or intestine, and can be either in vivo or ex vivo. Ex vivo, they are cleaned and affixed to a mount to allow stability for endoscope advancement. We will not, however, discuss animal models at length. Despite offering high fidelity models for the trainee via the use of real tissue, they are generally too costly and labor intensive to be used regularly in training programs.

Mechanical models have been available for endoscopic training dating back nearly to the advent of endoscopy. The first model, developed in 1974, was made entirely of plastic [57]. Mechanical models are most valuable early in a trainees' endoscopic experience. They afford the opportunity to experiment and understand scope mechanics, tip steering, and loop reduction, and allow insight into how the anatomy of the colon affects scope advancement. This is demonstrated in **Figure 1.3**. The materials with which they are constructed affect the fidelity of the model. Although never perfect, they allow for haptic feedback to the trainee, and a "birds eye view" into what happens to the colon during scope advancement [58]. Further, they are comparably low cost and portable.

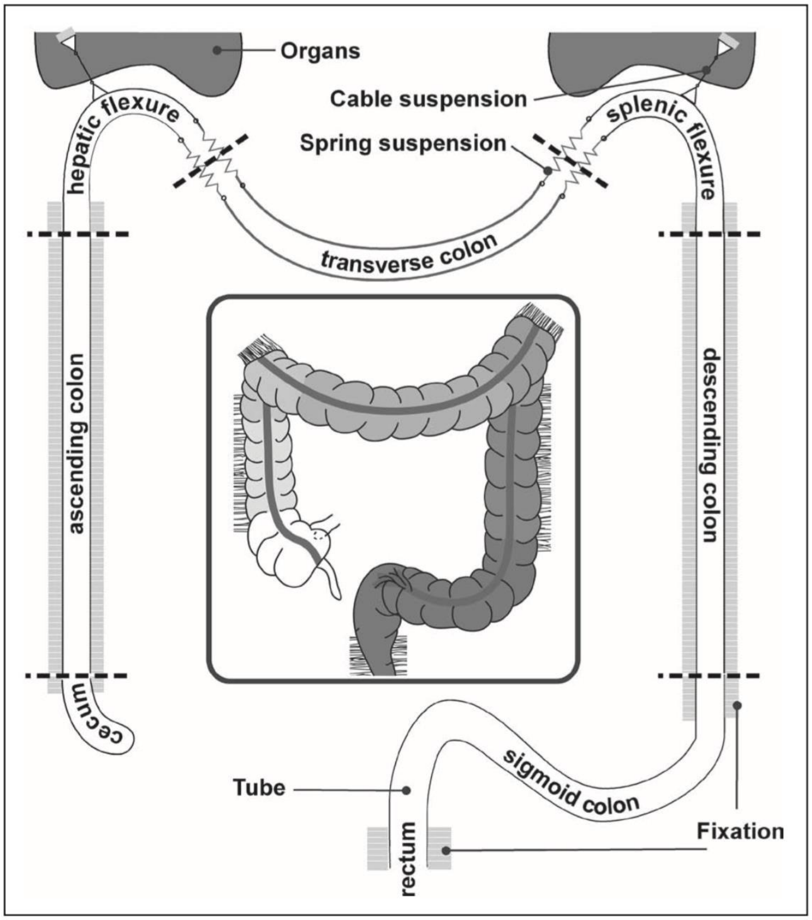

Figure 1.3 - Colonic anatomic points of fixation

Inner image shows the anatomical points of fixation of the colon. Outer image shows how this is approximated using physical simulators. Reproduced with permission from: Loeve AJ, Fockens P, Breedveld P. Mechanical analysis of insertion problems and pain during colonoscopy: why highly skill-dependent colonoscopy routines are necessary in the first place... and how they may be avoided. Can J Gastroenterol 2013;27(5):293-302.

Computer or virtual reality models have a number of advantages. They allow for immediate analysis and feedback regarding task completion efficiency, "patient" discomfort, and procedure time. They allow trainees the opportunity for personalized curricula, and can track the trainees' development in real-time [59]. In a trial comparing two groups of trainees, one using a computer based model and another partaking in normal training, they found that 6 hours of computer simulation training was equivalent to between 15 and 30 colonoscopies to match their performance [60]. Again, among the drawbacks of these models is the cost. Furthermore, it is a frequent criticism that computer models oversimplify complex tasks and the variability seen in human anatomy. Because of this, it has been suggested that their main value is targeted at junior trainees, early in their endoscopic experience [61].

What remains lacking in endoscopic simulators is a high fidelity, physical model that allows the trainee the ability to integrate the haptic feedback from the scope with real-time information about simulated-patient discomfort due to loop formation.

1.2.3 Competency Based Medical Education

Competency, as defined by the ASGE, is the “minimal level of skills, knowledge, and/or expertise derived through training and experience that is necessary to safely and proficiently perform a procedure” [62]. The ASGE statement regarding the granting of hospital privileges for endoscopy states "performance of an arbitrary number of procedures does not guarantee competency." It further emphasizes "the need to use objective criteria of skill, rather than an arbitrary number of procedures performed, when granting privileges to physicians for endoscopic procedures" [63]. However, a comprehensive and agreed upon set of objective criteria of skill has yet to be defined.

An international competency-based medical education (CBME) collaborative summarized the required steps for CBME curriculum planning: “(1) Identify the abilities needed of graduates. (2) Explicitly define the required competencies and their components. (3) Define milestones along a development path for the competencies. (4) Select educational activities, experiences, and instructional methods. (5) Select assessment tools to measure progress along the milestones. (6) Design an outcomes evaluation of the program” [64]. As CBME applies to colonoscopy training, the challenge will lie in the definitions of required competencies, and their components.

For endoscopic training, there are a plethora of assessment tools [65-67] yet there remains a lack of agreement in the optimal approach to colonoscopy training and the evaluation of the outcome of training [68]. A recent nationwide study asked all Accreditation Council for Graduate Medical Education accredited GI program directors and GI trainees to complete an online survey. From the program directors and trainees, it was identified that only 23% of programs have a formal endoscopy curriculum [69]. They concluded that, although many "believe that measuring specific metrics is important in determining endoscopy competence, most programs still rely on procedure volume and subjective attending evaluations to determine overall competence."

Of the quantitative metrics available to the colonoscopy teacher, adenoma detection rate and cecal intubation rate are the most commonly studied. Unfortunately these are end targets for colonoscopy trainees, and although they can be used to confirm competence when defined thresholds are met, they do little to inform the colonoscopy teacher about where the trainee is struggling, and what components of performing colonoscopy should be targeting in their training.

Further benchmarks are required to help evaluate trainees and guide their educational progress. The addition of specific, quantifiable metrics are required as we move into the era of competency based medical education.

1.3 Thesis Objectives and Hypothesis

One of the most important aspects of scope advancement is the ability to minimize loop formation. Loop formation manifests in force between the shaft of the colonoscope and the wall of the colon. Avoiding loops - or reducing them when they occur - decreases discomfort for the patient, decreases risk of perforation, and allows higher cecal intubation rates. An understanding of how force application varies with endoscopic expertise is lacking, and requires further study as a potential marker of competence and expertise for both endoscopy trainees as well as for continuing medical education for practicing endoscopists. Also lacking is a tool to provide measurements of force along the shaft of the colonoscope. Such a device could allow endoscopists insight into how force application is affected by loop formation and reduction. This would provide valuable, immediate feedback for both trainees and practicing endoscopists.

1. We hypothesize that expert endoscopists utilize safe techniques, which minimize the amount of force transmitted to the bowel wall compared to novices. We will apply electromagnetic tracking markers to a commercially available training model of the colon at specific segments at risk of perforation (sigmoid, splenic flexure, transverse, hepatic flexure). We will assess the translational motion in these segments, as a surrogate marker for force application, as a colonoscope is navigated to the cecum. We will define the relationship between endoscopic skill and force application by having both expert and novice endoscopists complete procedures using the model.

2. We will develop and test a novel "sleeve" to be placed over the length of the colonoscope. The sleeve will be constructed using force sensors at defined intervals along its length, while minimizing changes in scope diameter and flexibility. We will assess the ability of this sleeve to accurately measure force application. It will allow real-time measurement and feedback to the endoscopist regarding force transmission during simulated procedures on a physical model. This "sleeve" technology may be ultimately applicable to both training and therapy.

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CHAPTER 2

2. Colonic Displacement as a Surrogate Marker for Force: Differentiating Endoscopic Skill

2.1 Introduction

Colonoscopy is one of the most common procedures performed by gastroenterologists and surgeons in the diagnosis and management of colonic pathology. Since the advent of colonoscopy, deaths from colorectal cancer have decreased by up to 70% [1]. However, colonoscopy is not without risk.

The most feared complication is that of perforation; incidence ranges from 0.03 to 0.65% [2,3]. Furthermore, colonoscopy is uncomfortable. A poorly tolerated procedure makes patients less willing to undergo future procedures [4,5]. In colonoscopic screening regimens, which require regular interval examinations, maximizing patient compliance is crucial to the success of the program.

There is a well-described decline in complication rates, and in particular perforations, with experience [6]. The number of procedures performed during training is thus often cited as a surrogate marker of competency. In the era of trainee work hour restrictions, it is difficult, if not impossible, to achieve the high procedural numbers recommended from direct clinical experience [7]. Focus has now shifted to improved quality of training, rather than quantity. Simulation has become widely embraced by the medical community to provide a safe environment for trainees to develop and practice technical skills without risk to patients [8-12].

Existing colonoscopy simulators, both virtual reality and physical models, are primarily focused on manipulating the colonoscope through to procedure completion with adequate visualization of the lumen. However, perforations and patient discomfort, related to the pressure transmitted from the colonoscope tip and loops to the colon wall, are rarely assessed in simulators with haptic feedback.

It is expected that increased force applied to the colon as the scope is advanced will result in greater translation of the colon from its resting position. This is known to contribute to patient discomfort and perforation risk. We assess the translational motion in segments of the bowel known to be prone to perforation and mesenteric stretch, as a colonoscope is navigated to the colon to the cecum. Translational movement is used as a surrogate for force application.

The objective of this chapter is to define the relationship between endoscopic skill and force application to the colon wall. To our knowledge, this relationship has not yet been described in the literature. We hypothesize that expert endoscopists, as compared to novices, utilize advanced colonoscopic techniques, which produces measurably lower translational movement of the colon.

2.2 Materials and Methods

2.2.1 Colonoscopy Simulator Design

Electromagnetic (EM) spatial tracking markers (NDI Medical, Aurora Systems, Waterloo, Canada) were applied to a commercially available training model of the colon (Kyoto Kagaku, Kyoto, Japan), allowing the position of the colon to be tracked in three-dimensional (3D) space. Specific segments at risk of loop formation and perforation (sigmoid, transverse) were chosen as locations for our tracking markers. The colon was set up on the adjustable mount to simulate both an alpha loop in the sigmoid colon, as well as a mobile transverse colon. Four markers were spaced evenly along the length of the sigmoid colon, and four were evenly spaced along the transverse colon, as shown in **Figures 2.1** and **2.2**. Subsequently this design was altered to have only two EM spatial tracking markers placed along each colonic segment.

Figure 2.1 - Experimental setup for the colonoscopy simulation model

Simulation model and electromagnetic tracking marker data acquisition set up. Although shown with the model supine, for data acquisition the model was placed in the more traditional left lateral decubitus positioning.

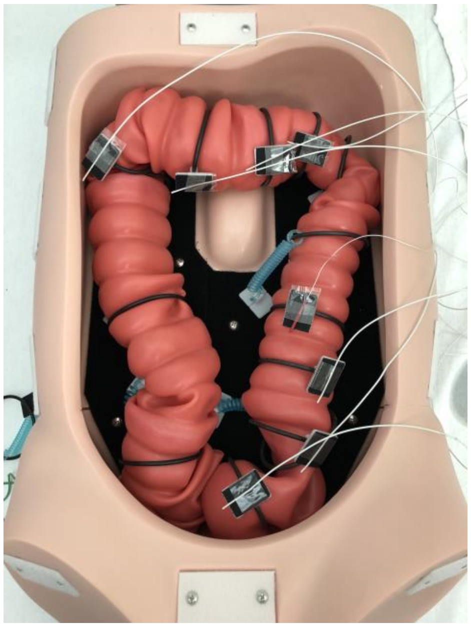


Figure 2.2 - Tracking markers

At right, the colon is shown straightened (without looping in the sigmoid) to illustrate spacing of the EM tracking markers along the sigmoid and transverse colon.

Data collection began when the colonoscope was introduced into the anus and was terminated when the tip of the scope reached the cecum. We calculated time to completion, maximum and average displacement of the colon, as well as maximum acceleration and velocity, for each participant. Data from multiple sensors was calculated using root mean square (RMS). Data was analyzed comparing expert and novice endoscopists, and separately comparing attending physicians with trainees. The primary outcome assessed was maximum and mean displacement. Secondary outcomes included variation by endoscopic technique, handedness, sex and specialty.

2.2.2 Participant Enrollment

Approvals from Western Research Ethics Board (IRB # 112426) and Lawson Health Research Institute (IRB # R-19-244) were obtained (see Appendix).

London Health Sciences Centre gastroenterology and general surgery trainees, and attending physicians who perform endoscopy as part of their clinical practice, were approached to participate in the study. Study enrollment also targeted participants and instructors from local educational courses with national and international attendance - Society of the American Gastrointestinal and Endoscopic Surgeons (SAGES) advanced minimally invasive surgery resident workshops, and Course for Residents in Advanced Therapeutic Endoscopy (CREATE). Participation was voluntary.

Participants were asked to complete a questionnaire detailing their level of training, demographic information and consent (See Appendix). They were then asked to complete a colonoscopy on our colon simulator. Prior to data collection for each participant, the model was reset according to the Kyoto Kagaku Training Guide ‘Case 5 – redundant sigmoid colon and “alpha” loop formation’. Data was recorded directly from the EM spatial tracking markers on our simulator model.

2.2.3 Data Analysis

Data analysis was completed in Microsoft Excel (Microsoft, Redmond WA) and Matlab (MathWorks, Natick MA). Statistical analysis was done using R version 3.6.3. Welch's t-test was used to assess differences in means. For non-normal distributions, bootstrapping was used to calculate confidence intervals.

2.3 Results

2.3.1 Demographics

Seventy-five participants were enrolled in the study. **Table 2.1** outlines the demographic information collected for the participants.

Table 2.1 - Patient demographic information

Sex	No. (%)
Male	37 (49.3)
Female	38 (50.7)
Handedness	
Right	71 (94.7)
Left	4 (5.3)
Level/Type of Training	
Medical Student	2 (2.7)
Surgical Trainee	44 (58.7)
Gastroenterology Trainee	12 (16.0)
Surgical Attending	12 (16.0)
Gastroenterology Attending	5 (6.7)
Primary Technique	
Knob Steering	14 (18.7)
Torque Steering	58 (77.3)
Frequent Patient Repositioning	3 (4.0)

Participants were considered experts if they had performed 200 or more colonoscopies as part of their training, or if they were attending gastroenterologists or general surgeons who performed colonoscopy as part of their practice. According to these parameters, there were 27 (36.0%) novices, and 48 (64.0%) experts enrolled. We further analyzed data comparing all trainees to all attending physicians. There were 17 (22.7%) attending physicians, and 58 (77.3%) trainees.

For trainees enrolled, the endoscopic experience according to their post-graduate year (PGY) of training is outlined in **Figure 2.3**.

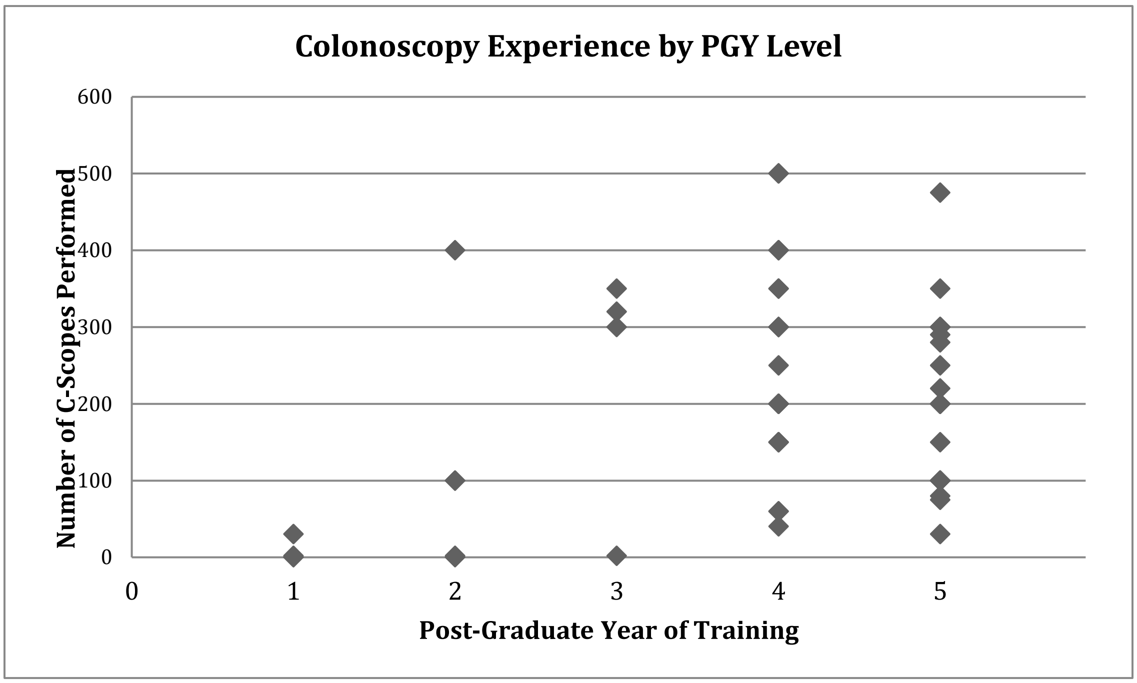


Figure 2.3 - Variations in colonoscopy experience by postgraduate year

2.3.2 Novices versus Experts

The time required for procedure completion was 472.8 seconds(s) and 232.9s for the novice and expert groups respectively (range 57.0 – 1488.2, $p < 0.05$; 95% CI, 100.1 – 385.3). The maximum colonic displacement was 181.3mm (range 48.8 – 383.4) for the novice group and 166.1 mm (range 46.3 – 334.7) for the expert group. There was no statistical difference ($p = 0.51$; 95% CI, -28.0 – 61.1). The mean colonic displacement was 77.8 mm (range 16.4 – 208.8) for the novice group and 73.1 mm (range 14.4 – 161.5) for the expert group. There was no statistical difference (p = 0.69; 95% CI, -18.4 – 27.8). This is displayed in **Figure 2.4**.

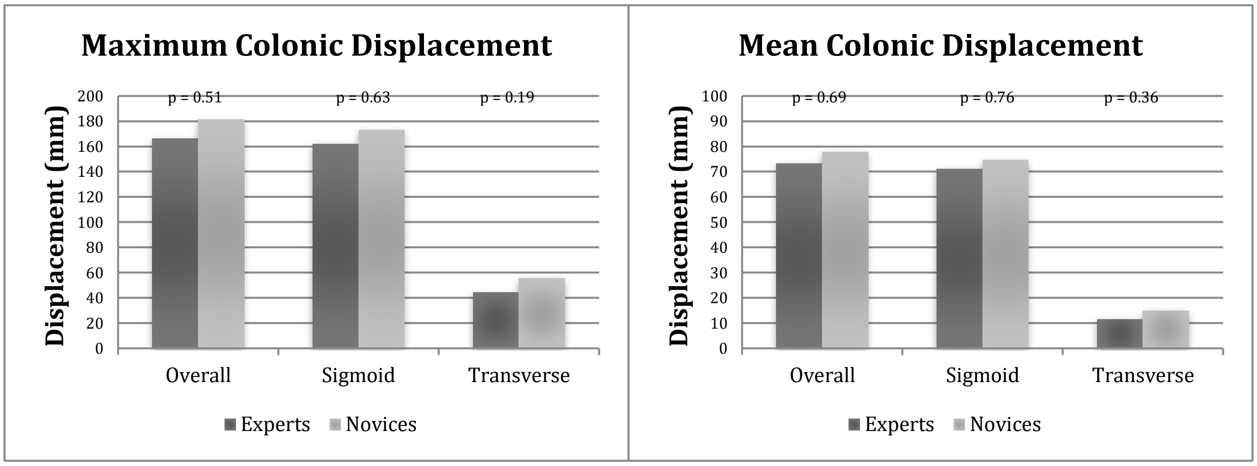


Figure 2.4 - Maximum and mean colonic displacement for experts and novices

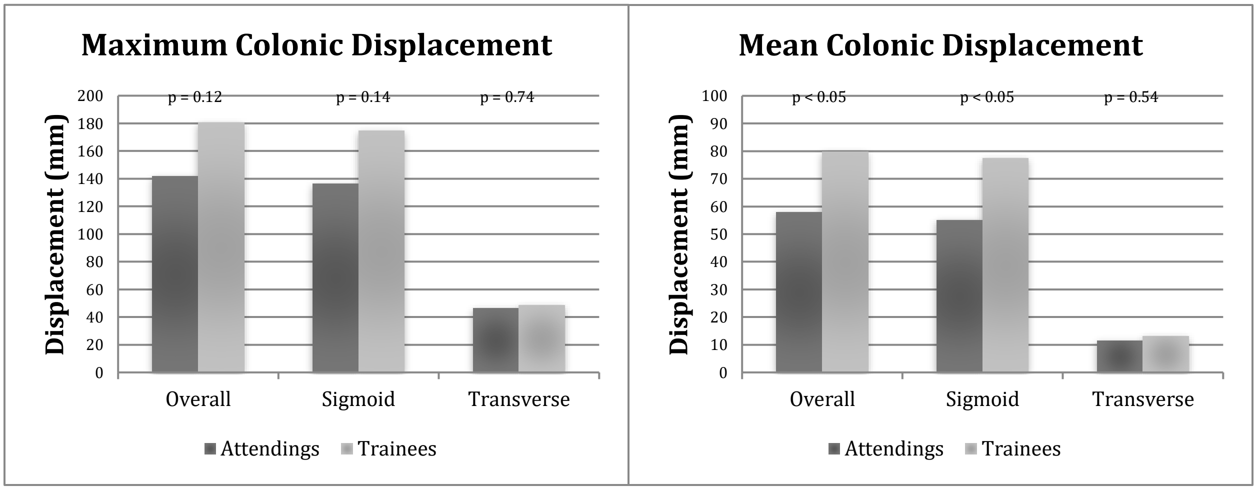
The data is shown for the whole colon, and also separately for the sigmoid and transverse colons. P-values are provided above each.

The maximum velocity displacement was 22.3 mm/s (range 11.1 – 52.5) for the novice group and 27.6 mm/s (range 8.5 – 56.0) for the expert group. There was no statistical difference ($p = 0.05$; 95% CI, -10.2 – 0.07). The maximum acceleration was 22.0 mm/s^2 (range 7.9 – 45.5) for the novice group and 26.7 mm/s^2 (range 8.0 – 52.1) for the expert group. Again there was no statistical difference between the groups ($p = 0.07$; 95% CI, -9.6 – 0.4).

2.3.3 Trainees versus Attendings

Data analysis was subsequently carried out comparing trainees to attendings. The time required for procedure completion was 360.5s compared to 178.4s for the trainee and attending groups respectively (range 57.0 – 1488.2, $p < 0.05$; 95% CI, 93.0 – 269.7). The maximum colonic displacement was 180.3 mm (range 48.8 – 383.4) for the trainee group and 141.6 mm (range 46.3 – 308.3) for the attending group ($p = 0.12$; 95% CI, -7.7 – 83.7). The mean colonic displacement was 79.8 mm (range 16.4 – 208.8) for the trainee group and 57.9 mm (range 14.4 – 116.0) for the attending group ($p < 0.05$; 95% CI, 2.6 – 41.2). This data is displayed in **Figure 2.5**.

Figure 2.5 – Maximum and mean colonic displacement for attendings and trainees



The maximum velocity displacement was 25.9 mm/s (range 8.5 – 56.0) for the trainee group and 25.0 mm/s (range 9.3 – 54.1) for the attending group. There was no statistical difference between the groups ($p = 0.81$; 95% CI, -6.0 – 7.5). The maximum acceleration was 25.1 mm/s^2 (range 7.9 – 45.5) for the trainee group and 24.8 mm/s^2 (range 11.1 – 52.1) for the attending group. Likewise there was no statistical difference between these groups either ($p = 0.93$; 95% CI, -6.5 – 6.8).

2.3.4 Secondary Outcomes

We assessed additional variables as possible contributors to variations in force used during colonoscopy. Technique, self-described by participants, revealed that knob steering showed significant increase in maximum displacement, and a trend was seen in the data for mean displacement. Specialty performing the procedure showed gastroenterologists applying less maximal and mean forces than their general surgery counterparts. All assessed outcomes are listed in **Table 2.2**.

Table 2.2 - Maximum and mean displacement for secondary outcomes					
		Max (mm)		Mean (mm)	
Technique	Knob	224.0	p < 0.05	100.6	p = 0.07
	Torque	162.4		69.9	
Handedness	Left	239.8	p < 0.05	120.6	p = 0.23
	Right	167.7		72.2	
Sex	Female	184.1	p = 0.23	81.8	p = 0.16
	Male	158.7		67.6	
Specialty	GS	179.4	P < 0.05	78.2	p < 0.05
	GI	128.9		57.8	

2.3.5 Colonic Shape Reconstruction

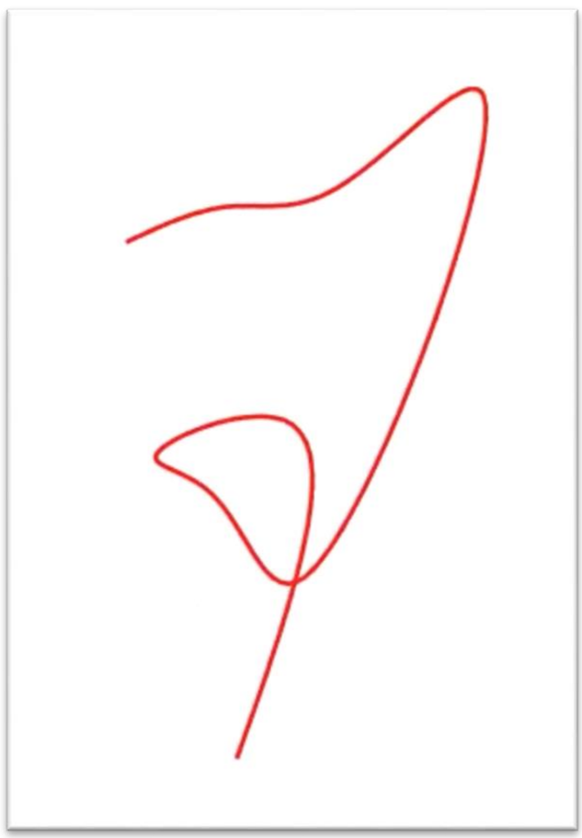


Figure 2.6 – 3D reconstruction

At right is shown a 2D representation of the 3D reconstructions using EM spatial tracking markers. The shape of the colon between the markers was inferred. The ascending colon is not seen in this representation because there were no tracking markers proximal to the transverse colon.

The initial configuration using four EM tracking markers on both the sigmoid and transverse colon allowed for continuous monitoring of the colon's position within the generated field during data collection first 31 patients enrolled (prior to altering the design to only have 2 EM tracking markers per segment). With post-processing analysis, 3D reconstruction of the shape and displacement of the colon could be reviewed. This allowed insight into loop formation for each participant, and tracking of loop reduction.

The colon was configured to be in a loop at the outset of each procedure. Of the participants assessed using 3D reconstructions, none successfully reduced the loop in the sigmoid colon

2.4 Discussion

There is in colonoscopy, as in many procedural skills, an element of "feel" that the teacher finds challenging to articulate to the trainee. One element of this "feel" is the safe amount of force between the scope and the colon wall. Characterization, and more importantly, quantification, are important steps towards making endoscopy education more efficient for trainees, and safer for patients. We have long known that the skilled endoscopist could reduce, or even better - avoid – loop formation in the colonoscope. Indeed the variety of deformations to which the colon is subject during colonoscopy has been described, as well as potential mechanical solutions that can be applied to minimize these [13]. It is an important next step to allow these to be quantified, and allow real-time feedback to the endoscopist.

Prior discussions regarding force application used devices that measured the amount of force that the endoscopist applies to the scope. The Colonoscopy Force Monitoring Device [14] and its predecessor, developed nearly a decade earlier, [15,16] were able to measure the 'push' and 'pull' forces, as well as torque applied to the colonoscope by the endoscopist. Using this device, studies looking at a comparison of force applied by expert and novice endoscopists interestingly suggested that experts apply more force and torque than their novice counterparts [17-19]. This is counterintuitive, as experts would presumably rely more on technique and finesse to advance the scope, rather than pushing through loops to arrive in the cecum. However, this may simply be related to the location of the force measurement. For example, an increase in force applied to the scope may not increase risk or discomfort if the scope is maintained free of loops and is centered in the lumen of the bowel.

Plooy et al. [20] measured the force using a different approach. Again using a physical simulator, the same as that used in our study, they measured force using a force plate interposed between the table and the colon model. The rationale for measuring the force in this particular location was not made clear. They used multiple colonic configurations of the colon model, and for some of these configurations, they showed experienced endoscopists exerting less force than novices. The novices, however, were medical students with no prior endoscopic experience thus not clearly defining its ability to distinguish across the spectrum of endoscopic skill.

Choi et al. [21] developed the "Active Colonoscopy Training Model". A conventional physical colon model was used, with low profile load cells attached along the length of the colon to rubber rings holding the simulated colon in its anatomic configuration. Force measurements could thus be measured during the procedure, as well as a multitude of additional factors. This model is limited by only measuring force at the specific locations where the rings were present, thus not necessarily at the apex of the loop. Subsequent evaluations using the model compared experienced colonoscopists to medical students with no prior endoscopic experience. They did, however, again show experts using less force than novice endoscopists [22].

To our knowledge, ours is the first description of the effects of force application from colonoscope shaft to the colon wall to differentiate endoscopic skill level between resident trainees and experienced endoscopists. We aimed to look at the forces between the shaft of the colonoscope and the colon wall, those forces seen in loops and at the flexures, as it is these forces that increase patient discomfort during the procedure, and increase the risk of perforation [23,24].

Our study has a number of strengths. We enrolled a large number of participants, from a variety of training and practice backgrounds. The SAGES minimally invasive surgery resident workshops occurred over three separate dates. Participants included surgical faculty and trainees from across Canada and the United States. The CREATE Course was comprised of gastroenterology faculty and trainees from fellowship programs across Ontario. This broad range of training and endoscopic experience contributes to the external validity of our findings. Interestingly, this may also have led to inconsistent findings in endoscopic skill.

There was a very broad variation in endoscopic experience depending on the home residency program of the trainee. It is possible that some programs supplement with simulation training, or it may simply represent variations in how procedural experience is documented. Regardless, this remains speculation, as we do not have any data to confirm these theories. We did not find the number of colonoscopies performed to be a consistent indicator of endoscopic skill in our study. Indeed the number of colonoscopies performed by trainees has previously been questioned as an adequate tool to assess competence [25,26]. Further studies might look at improvement in performance as it corresponds to increasing endoscopic experience across a trainee cohort with a more homogenous training experience.

Instead we opted to use "completion of training" - thus expert endoscopists were classified as those who had completed training and achieved fellowship status in their national surgical or medical specialty. This allowed for a more comprehensive assessment of endoscopic skill. Most training programs require both an assessment of adequate procedural numbers, but also assessment of procedural skills using any of the multitude of available, validated outcome metrics [27-29], and ultimately, final confirmation of competence from their program director.

There are of course limitations to the current study. First, any physical simulator is limited in its approximation of the real procedure. The Kyoto Kagaku Colonoscope

Training model, used in this study, is among the few that has been validated and shown to correlate well with the level of expertise of endoscopists [20]. Despite this, it was a challenge to avoid friction between the scope and the latex colon wall, as the lubrication would settle in the dependent portions of the colon model during multiple data acquisition sessions. Furthermore, we only recorded data for each participant during one colonoscopy, using one particular colon configuration. Even amongst expert endoscopists, there is variation in performance from one procedure to the next.

Although the simulator set-up was designed to be a difficult sigmoid colon loop, it was surprising how challenging it proved to be, even amongst our expert endoscopists, to straighten the loop and arrive in the cecum with a straight scope. Again, we suspect that this is due to the increased forces required to torque and straighten due to the limited pliability of the colon material, and increased friction.

Korman et al. [30] showed that the use of Propofol sedation increases the amount of radial and axial force applied to the shaft of the endoscope during colonoscopy. The deeper sedation afforded by Propofol, compared to conscious sedation, results in a loss of feedback from patients regarding discomfort. A similar effect is likely also seen in simulated procedures, where an absence of pain response allows ongoing force application that might otherwise be stymied by patient feedback.

Finally, we did not directly measure force application with our study. Instead, we used the translational movement of the colon as a surrogate marker for the amount of force being applied. An ideal colonoscopy, from the perspective of patient safety and comfort, would have the colon not move at all from its resting position. However, given the mobility of certain segments of the colon due to the mesenteric attachments, a degree of translational movement of the colon likely poses no risk whatsoever. It is only when movement exceeds that afforded by the mesenteric mobility that a dangerous degree of force is transmitted to the colon wall.

Our study did show the ability to create an endoscopic training model for colonoscopy using software and technology available in many simulation centres, and one that is comparatively cheaper than virtual simulators. The use of a physical model allows the development of haptic feedback to the trainee and how that relates to their performance of safe and efficient scope advancement. It is able to differentiate endoscopic skill between attending physicians and resident trainees.

2.5 Conclusions

We have shown that attending physicians advance the scope during colonoscopy in a manner that results in significantly less colonic displacement than resident trainees. This contributes to a safer and more comfortable procedure for patients. Future studies will aim to define safe degrees of colonic displacement for each anatomic variant on the colon model, using attending endoscopists as a reference. Ultimately, the ability to utilize this type of feedback in patient encounters would be invaluable for both practicing and training endoscopists. A colonoscope sleeve that affords the endoscopist immediate quantifiable feedback through force measurement between the scope and colon wall may be the answer.

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CHAPTER 3

3. Development of a Force-Sensing Sleeve for the Colonoscope: A Novel Device for Training

3.1 Introduction

Colonoscopy is among the most common procedures performed by gastroenterologists and general surgeons. Since its advent in the late 1960s [1], the colonoscope has become an invaluable tool in the diagnosis and management of diseases of the colon and rectum. The number of colonoscopies performed in Ontario [2,3] and elsewhere across Canada [4] has shown rapid growth in recent decades.

Training endoscopists is paramount to keep pace with this growth. Yet the future of endoscopic training faces many significant challenges. Colonoscopy is understood to be among the more technically challenging procedures for trainees. The mobile mesenteric attachments of the colon allow for considerable deformation and looping as a long flexible colonoscope is inserted. Indeed, mastery of the performance of colonoscopy is elusive, even amongst practicing physicians with years of experience [5-8]. Not unexpectedly, much of the training literature for colonoscopy suggests high procedural numbers for trainees to achieve competence [9]. To add to this, we have entered an era of medical training with considerable work hour restrictions, absent in the medical training of years gone by. While such restrictions certainly improve trainee quality of life, they result in decreased opportunities for hands-on procedural training [10,11]. We are thus left with the challenges of reconciling high endoscopic procedural requirements amidst ever diminishing opportunities during residency training.

Rethinking how endoscopic training is delivered is mandatory if we wish to continue to produce safe, competent endoscopists. One of the main challenges in colonoscopy for trainees is to develop “feel” for the instrument, and for the tissues within each patient. What forces can be applied safely as the scope is advanced? What resistance to force advancement might represent a loop in the scope and how can this be overcome? Our current training paradigm relies upon countless repetitions of the procedure until such feel becomes second nature to the trainee. Although simulators are a part of many training programs, few provide the haptic feedback of a real scope. Immediate feedback about the forces being applied between the shaft of the scope and the colon wall could help expedite the acquisition of "feel" for the endoscopic trainee.

A number of devices and models have previously been described to measure force application during colonoscopy. Unfortunately, many of these devices have significant shortcomings. In particular, most measure force at a location other than the interface between the scope and the colon wall. Examples include measuring force between the endoscopist's hand and the scope [12-14], between the physical simulator and the table [15], and in the attachments fixing the simulated colon in place in a physical model [16].

Watanabe et al. [17] proposed a design for a thin sleeve to be placed over fiberoptic flexible scopes using thin fabric design. While brilliant, this unfortunately cannot measure the range of forces to which the colon is occasionally subject during colonoscopy, and the fabric changes the friction and grip of the endoscopist. Dogramadzi et al. [18] proposed a design more suitable to gastrointestinal endoscopes, and capable of measuring the range of forces expected during colonoscopy. In their design, sensors were spaced 6cm apart from each other, leading to significant "dead zones" between sensors. While they were able to measure to within ±20 g, for the large static forces often seen during colonoscopy, accuracy was ±50 g. Furthermore, the sleeve increased the diameter of an adult colonoscope by 15%.

What is needed is an instrument that is subtle and integrated so as to not impede the endoscopist's ability to manipulate the scope, but is able to provide specific point measurements of force along the entire usable scope length. Such a device could be used in physical models for training endoscopists, but could also be adapted for use in patients, allowing valuable force feedback for practicing endoscopists as well.

For educational use, such a device would supplement current simulators to alert trainees of unsafe force application as they develop skill handling the instrument. In clinical use, immediate feedback would help minimize discomfort for patients, and most importantly, maximize safety.

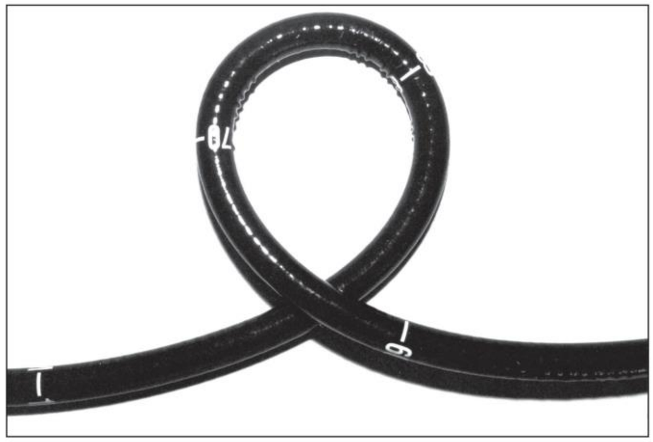
3.2 Materials and Methods

3.2.1 - Design Specifications

The insertion tube of most adult colonoscopes is approximately 160cm long and has a diameter of 12mm. The distal most 10cm of the tube, the active bending section, is controlled by the up/down and left/right control knobs. If inserted to its maximum limits, the proximal most 50cm of a colonoscope is rarely involved in looping. We thus elected to ensure that our sensors covered the intervening region of the scope, over a length of 100cm. This region of the scope is most likely to be involved in loop formation and thus will also likely be responsible for significant forces between the colonoscope shaft and colon wall. The sensors need to detect forces around 360° of the shaft as looping of the colonoscope can occur in all axes. The flexibility of a colonoscope can allow for loops as small as 10cm in diameter [19], as seen in **Figure 3.1**, with maximum force located at the apex of such loops. Thus, distance must be minimized between force sensors to avoid this maximum force falling in a "dead spot" between sensors. Finally, the sensors must not inhibit flexibility of the colonoscope, and add as little to the diameter of the insertion tube as possible.

Figure 3.1 - Colonoscope flexibility

At right, an adult colonoscope is flexed to its smallest loop with a diameter of approximately 10cm. Reproduced with permission from: Loeve AJ, Fockens P, Breedveld P. Mechanical analysis of insertion problems and pain during colonoscopy: why highly skill-dependent colonoscopy routines are necessary in the first place... and how they may be avoided. Can J Gastroenterol 2013;27(5):293-302.



The range of force necessary to injure the colon can vary based on the patient and their anatomy. Cadaveric studies suggest that the muscle and serosa tear first at as little as 27.5 kPa, and full thickness perforation occurs at 28.1 kPa [20].

3.2.2 – Sensorized Sleeve Construction

The sensor sleeve is designed to detect forces applied normal to the tangent of the colonoscope wall. The sensor runs 1.1m axially along the colonoscope with 66.6% of the colonoscope surface being sensorized. There are 36 piezoresistive sensing elements, each of which covers 3cm of the colonoscope in the axial direction. The thickness of the sensor is 0.7mm.

The sensing array is made of three layers, shaped as 3.4m x 1cm strips, which are wrapped in a 21° helix around the colonoscope. A helical shape was selected for sensor application to allow for flexibility overlying the colonoscope. This is shown in **Figure 3.2**.

Figure 3.2 - Helical sensorized sleeve design

Helical sensors (gold) wrapped around the insertion tube of the colonoscope. The 21^{o} angle allows most of the surface of the insertion tube to be sensorized, while retaining its flexibility.

The middle of these three layers of the sensor utilizes the piezoresistive effect of a material called Linqstat™ (Caplinq, Ottawa ON) which has a variable resistance based upon the pressure applied. The outer layers are a pair of flexible printed circuit boards (fPCBs). These printed circuit boards create electrodes that match with electrodes of the other fPCB on the side opposite the piezoresistive material allowing current to be carried through the force-sensitive Linqstat™. Due to the fabrication limitations of fPCBs, the sensor is made in thirds of 1.13m x 1cm strips and soldered together to make up the full 3.4m length.

A microcontroller (Arduino Uno) is then used to read the resistance of the sensing elements with a voltage divider set up. This is shown in **Figure 3.3**.

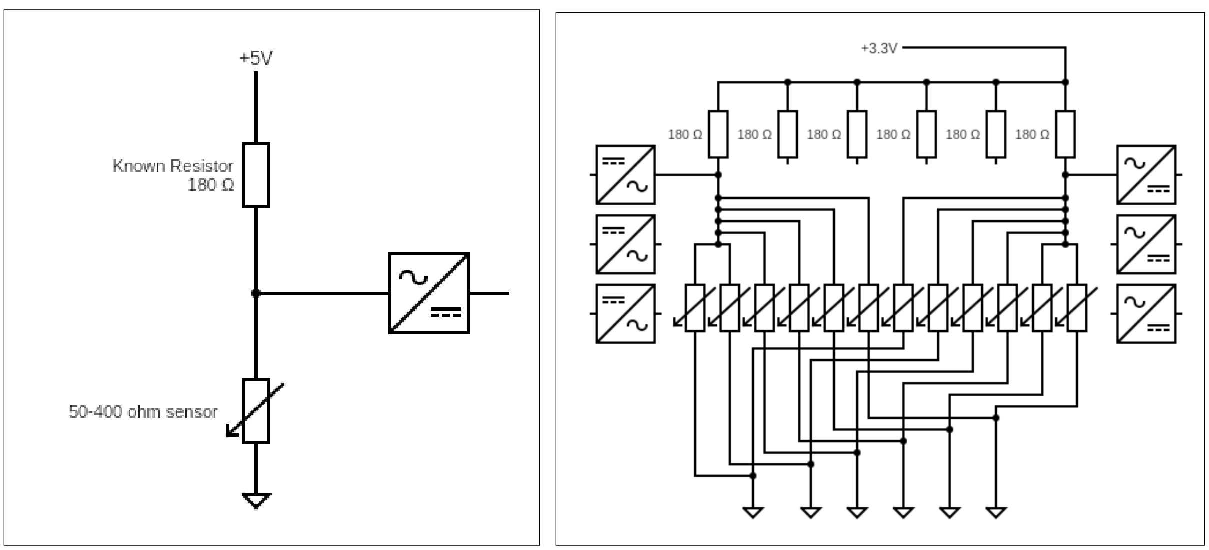


Figure 3.3 - Wiring diagram for the sensorized sleeve

On the left is shown a single sensor. On the right we see how 12 sensors are wired to allow sensorization of the entire colonoscope. Six digital pins control which pair of sensors have current flowing through them. Only one digital pin is set to ground at one time to activate one pair of sensors. Two analog pins going to an analog to digital converter can read the voltage before the active sensors to determine the sensor resistance. When 3 sensor strips are electrically connected, each ground pin activates 6 sensors and 6 analog pins are needed to read the resistance.

The sensor is fixed to the scope at each end, and allowed to freely slide over the scope in between. The attached Arduino is plugged into a computer for processing.

3.2.3 - Force Sensing Sleeve Testing

The colonoscope is not a static instrument, and is contorted into a multitude of shapes as it is advanced through the colon during a colonoscopy. Testing of our device design was conducted to ensure that force measurements are consistent regardless of where along the sensor measurements were recorded. Further, we wanted to ensure that flexion of the scope, and rotation, did not alter our ability to accurately measure the force.

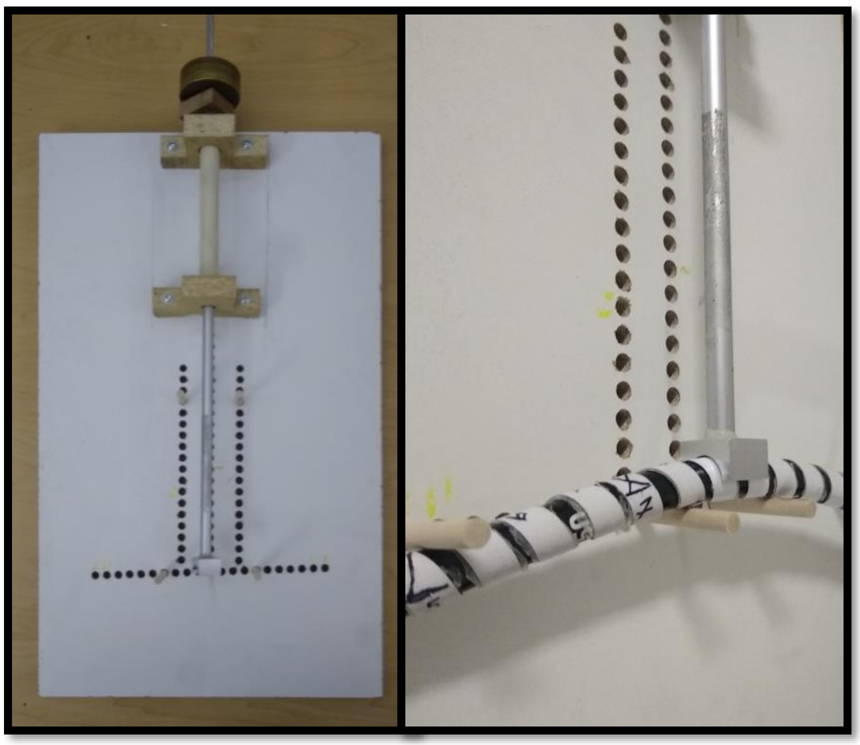
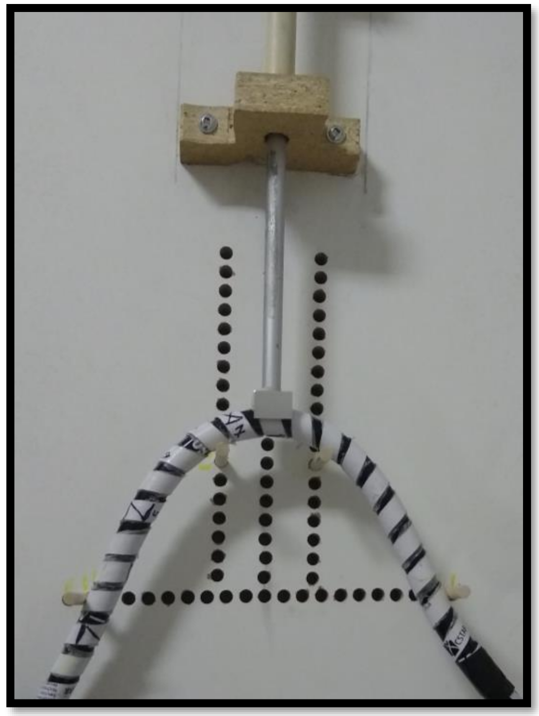


Figure 3.4 - Sensorized sleeve testing apparatus

On the left, photo showing sensor sleeve apparatus. Weights are added at the top applying force down the metal shaft onto the scope. On the right, we see the interface between the metal shaft applying delivering the force, the helical sleeve, and the colonoscope.

To simulate force application, we used the device shown in **Figure 3.4**. This apparatus allowed incremental increases in force applied over a known surface area ($2.34 \times 10^{-4} m^2$). We used the apparatus to alter the shape of the scope and hold it fixed in place during testing. Weights of 100g were sequentially added, to a maximum of 1000g, to ensure that the entire spectrum of required force measurement was tested. Thus for every 100g added, the pressure increased by 4.19 kPa. The full range of the test therefore spanned up to 41.9 kPa, well beyond the force required to cause full thickness injury to the colon.

Figure 3.5 - Adjustability of testing apparatus



At right we show how the adjustable pegs on our testing apparatus can be used to hold the colonoscope in varying degrees of flexion and in loops of variable diameter during data acquisition.

Testing of our scope was focused on ensuring consistency and reliability of our measurements as the shape of the scope was altered, as would be expected during a colonoscopy. We tested for consistency across the following parameters:

i. around the circumference of the scope
ii. across varying degrees of scope flexion

Figure 3.5 shows how the testing apparatus allowed flexion and loops in the colonoscope to be altered and fixed during testing.

3.3 Results

Our device increases the diameter of the colonoscope by 1.4mm (10.9% increase). However, due to its helical formation, this increased diameter does not affect the flexibility of the instrument. Each sensor was calibrated by using the average of three measurements of output in ohms for each increment in 100g weight applied. This was then correlated with the known force applied given the weight, gravitational constant and surface area of the metal shaft applying the force.

3.3.2 Force Measurement with Scope Rotation

As twists and turns in the colon can vary in their direction and orientation, we need to be able to measure force evenly around the circumference of the scope. Using the same sensor for consistency, and our calibrated sensor outputs as a baseline value, we then measured force at 90^{o} intervals around the scope. These results are displayed in **Figure 3.6**.

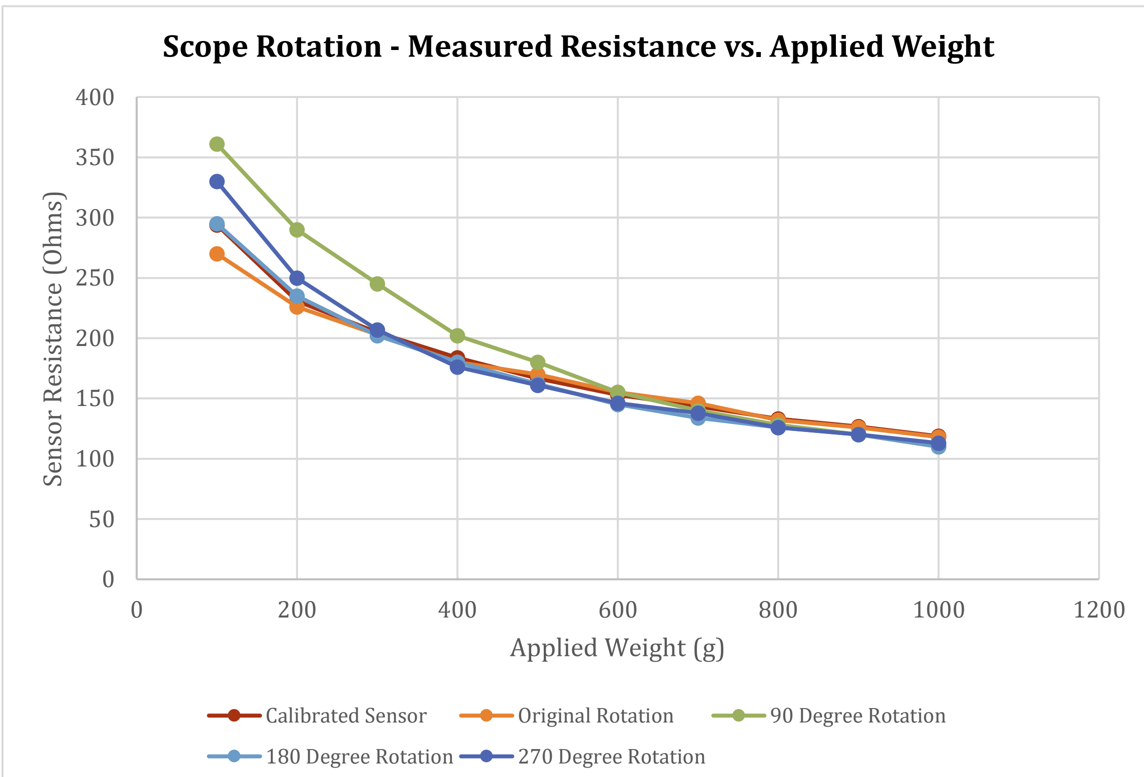


Figure 3.6 – Plot of measured resistance vs. applied weight as it varies with rotation

We then calculated the measured weight from our resistance data. We plotted this for each degree of rotation across increasing increments of applied weight. This plot is shown in **Figure 3.7**.

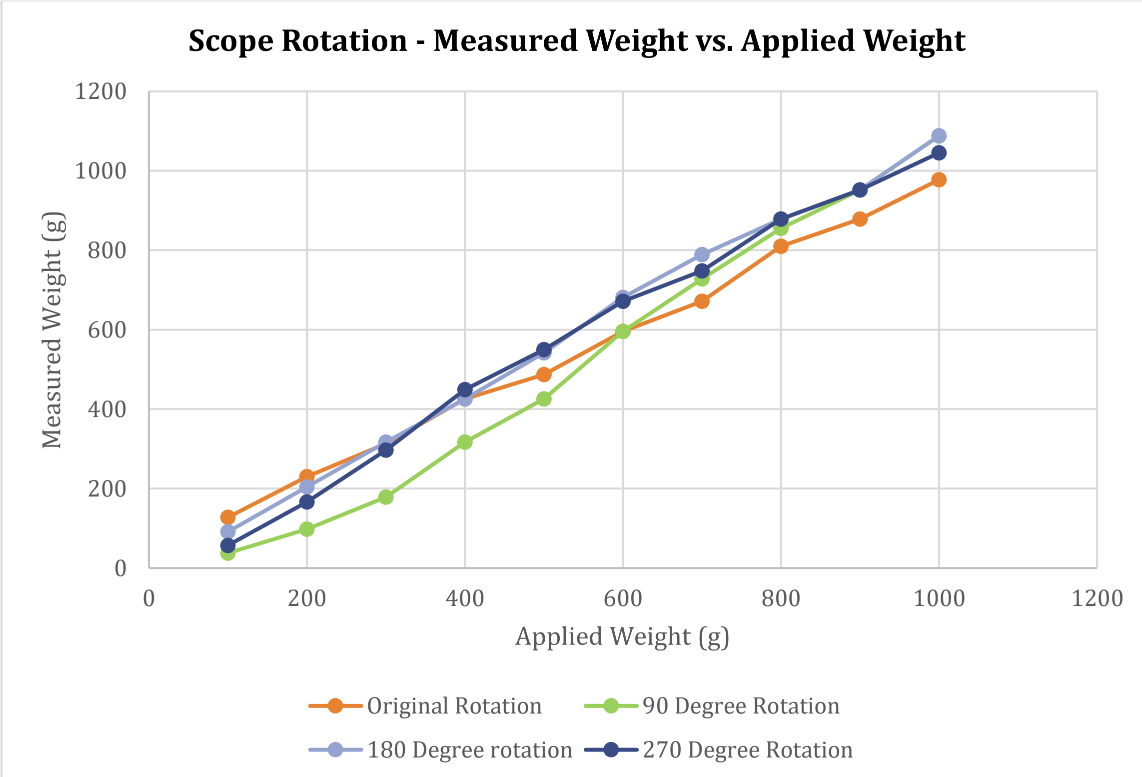


Figure 3.7 – Plot of measured weight vs. applied weight as it varies with rotation

We subsequently calculated the accuracy of these measurements. The mean and maximum error measured in weight was 45.6 g and 121.6 g respectively. This translates to a mean and maximum error of 1.91 kPa and 5.11 kPa. **Figure 3.8** shows a plot of error as it varies as the scope is rotated.

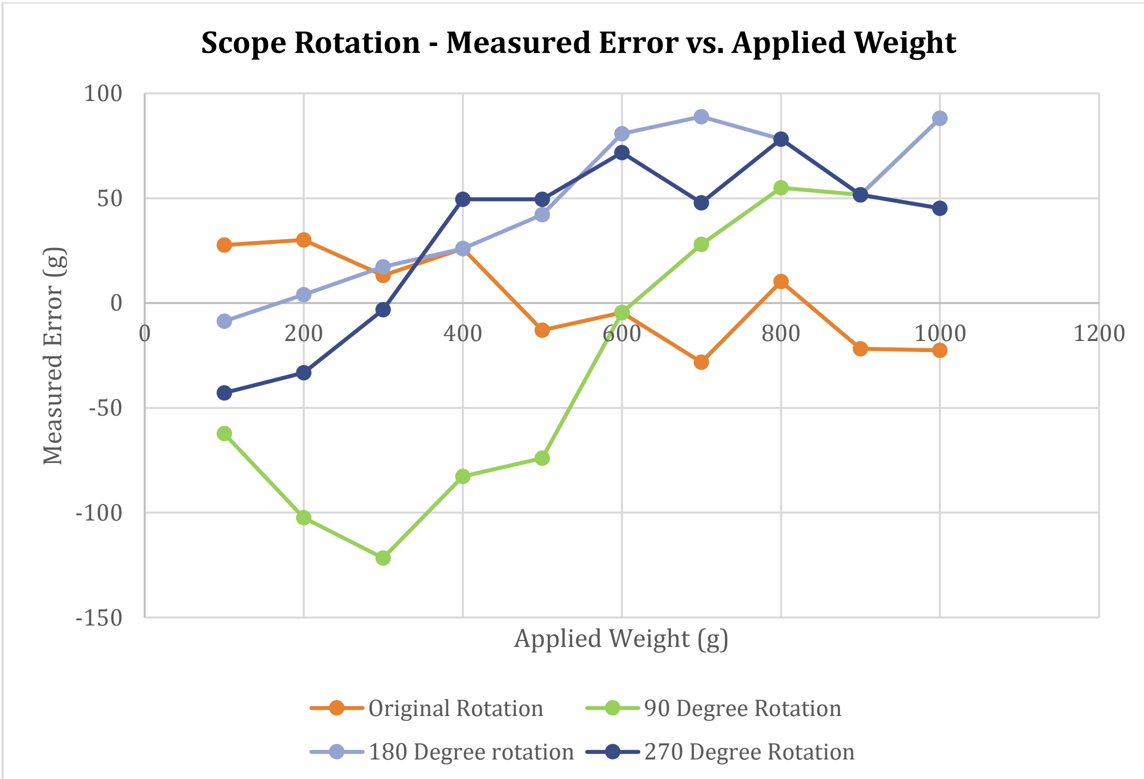


Figure 3.8 – Plot of measured error vs. applied weight as it varies with rotation

3.3.3 Force Measurement with Scope Flexion

As the colonoscope is advanced during a colonoscopy, there is frequently the need for considerable flexion and curvature of the scope around the multiple anatomic turns in the colon. As these areas are at particular risk of perforation, we assessed what effect flexion or looping of the scope has on our instrument's ability to measure force. Using the same sensor for consistency, and our calibrated sensor outputs as a baseline value, we then varied the degree of flexion (minimal, medium and maximum). For maximal flexion the loop radius was approximately 5cm. For minimal flexion, the scope was nearly straight. These results are displayed in **Figure 3.9**.

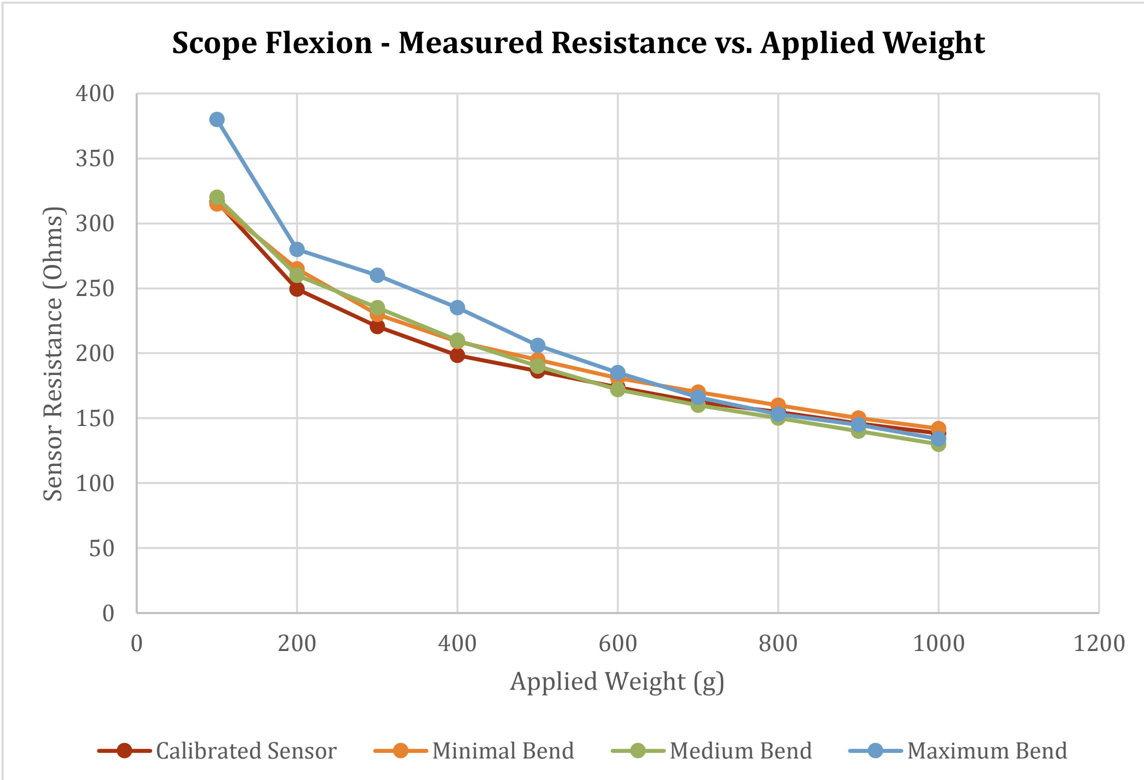


Figure 3.9 – Plot of measured resistance vs. applied weight as it varies with flexion

Again, we used this data to calculate measured weight from our resistance data. We plotted these results for each degree of flexion across increasing increments of applied weight (**Figure 3.10)**.

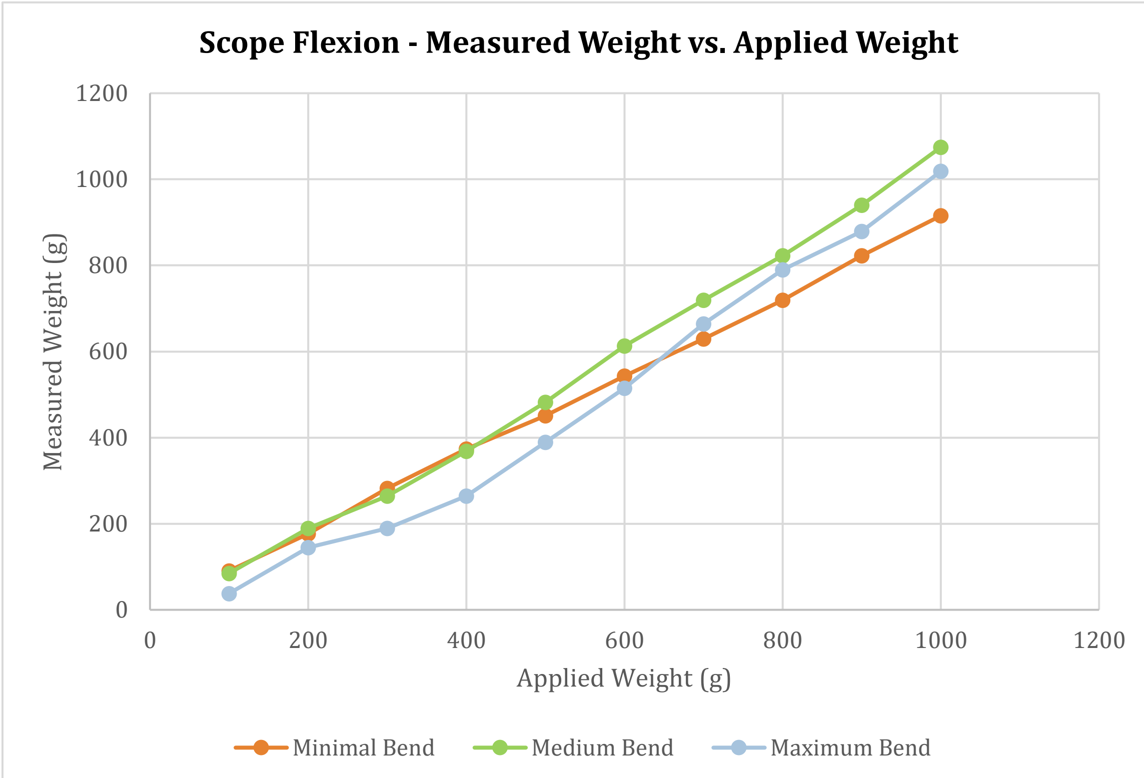


Figure 3.10 – Plot of measured weight vs. applied weight as it varies with flexion

Finally, we calculated the accuracy of these measurements. The mean and maximum error measured in weight was 47.4 g and 135.9 g respectively. This translates to a mean and maximum error of 1.99 kPa and 5.71 kPa. **Figure 3.11** illustrates how this error varies with scope flexion.

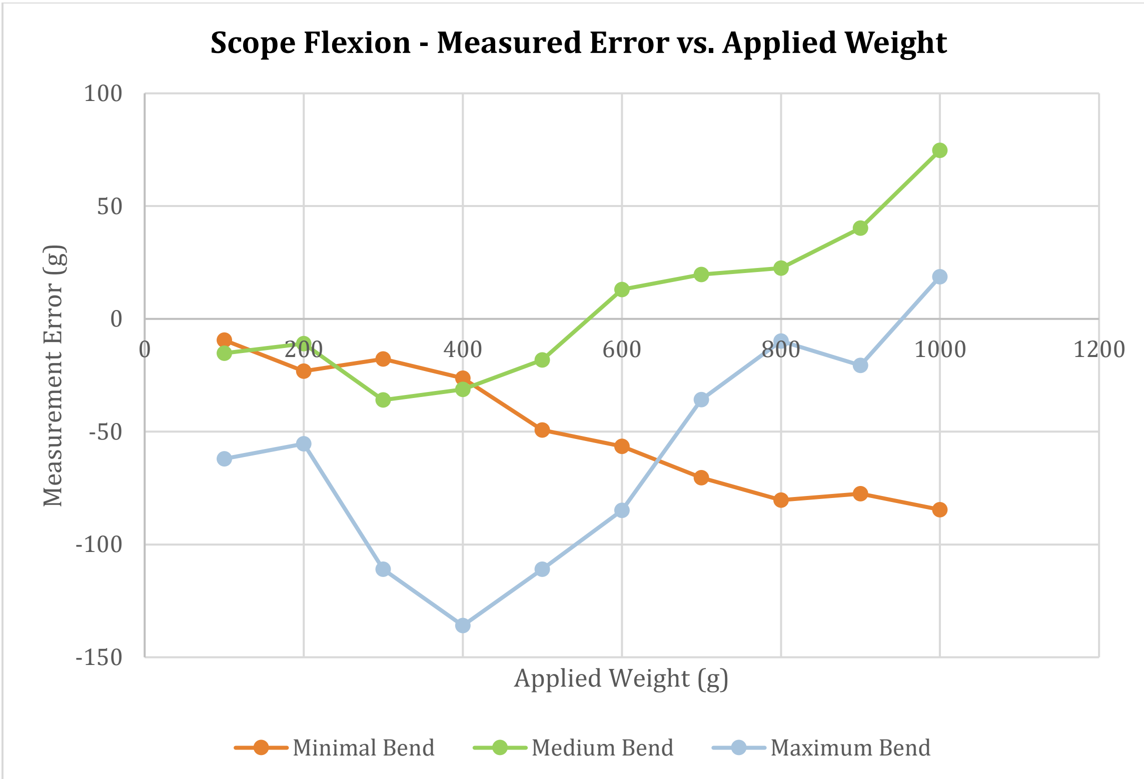


Figure 3.11 – Plot of measured error vs. applied weight as it varies with flexion

3.4 Discussion

Our goal was to design and build a thin, flexible sleeve capable of accurately measuring the force between the colonoscope and colon wall, an objective that was successfully achieved using our design. We are able to measure force application accurately to within 50g (or <2 kPa) which is comparable to prior devices. Our sleeve only adds 10.9% to the diameter of an adult colonoscope, which is an improvement over previously published designs adding 15% [18] to the diameter.

It's helical design, and ability to "float" over the scope between its proximal and distal fixation, means that it has no effect on the flexibility of the colonoscope. It also allows force measurement along the entire length of the shaft of the colonoscope. Further, this design allowed flexion of the scope to occur without impacting force measurement. For example, whenever curvature would happen in the scope, a sleeve fixed to the scope along its length would see a resultant stretch on the outside of the curve and compression on the inside. Designing a sensor that would be unaffected by this, or that could accommodate for such measurements, was thought to be too challenging. The helical design avoided any such issues.

For the sensor, a piezoresistive style was chosen, due to its low profile and flexible qualities. This left us with the option to use piezoresistive/quantum tunneling composite based sensors or capacitive sensors. Capacitive sensors were avoided as the parasitic capacitance of a 36 sensor, 3.4m long array would cause a large uncertainty. Flexible printable circuit boards (fPCBs) were used because they can be made to a very high tolerance and they have the flexibility required to wrap around a bending radius of 6.5mm. fPCBs are very thin at 0.2mm which helped keep the sleeve low profile. Linqstat is a fairly inexpensive piezoresistive material and it is thin. Further, it is unaffected by bending strains. There are, however, more sensitive and precise piezoresistive materials that could be considered for future design iteration.

The Arduino Uno was chosen as a microcontroller due to a number of favourable features. It is relatively inexpensive, comes prebuilt, and the 10-bit analog to digital converter provides reasonable resolution in determining resistance.

Since the sensor cannot provide any information about the shape of the colonoscope, this design has some limitations. Although this would be valuable information for the endoscopist, most major endoscope manufacturers already have technology that allow this. The sensors also do not detect shear forces applied to the colon wall by the friction as the colonoscope slides along it. Again, although this would provide valuable information, we feel that the direct force from non-reduced loops in the endoscope is a larger contributor to patient discomfort and perforation risk. Finally, with regards to reusability of our device, if the sensor is sealed, it can be washed but not sterilized. The heat of an autoclave would melt the adhesives used in the fPCB. Thankfully sterilization for colonoscopes is rarely required.

There is the opportunity for error with our sleeve if pressure is not applied evenly over the sensor. For example, if 1 kPa was applied to a focal area on the large sensor pad, the sensor would have a different reading than if the entire sensor experienced 1 kPa. Fortunately, focal areas of force are rarely encountered during colonoscopy. Of primary interest to the endoscopist is when the colonoscope applies force to the colon wall during looping of the scope. The sensors thus must be calibrated for the specific surface area where force will be measured. Due to the shape of the helical sensor, we calculated the surface area of a half-coil. For any given bend, this is the area of a single sensor that would push on the colon wall. The other half of the coil would be on the inside of the loop and would not be subject to any force.

There is further uncertainty in our final measurement that is derived from the voltage divider used to read the resistance from the sensor. The source voltage was 3.3V +/- 5% and the readings were read to the nearest 0.0049 V due to the 10-bit analog to digital converter. The known resistors were measured to the nearest 0.01 ohms.

It is worth noting that the accuracy of our device seems to improve with increased force. The greatest range of discrepancy seen in our testing is at the lowest end of the forces applied. Indeed, many of these minor forces are likely clinically insignificant. Thankfully, as we enter the range of forces of interest for causation of pain and risk of perforation, the accuracy improves markedly. This trend is seen regardless of the shape of the scope or the orientation around its axis where the force is measured.

There is a need for an educational tool that allows appropriate haptic feedback to the trainee, while quantifying that feedback with information about the relative safety of the resistance they are feeling as the scope is advanced. We believe that a sleeve such as that developed here will help fill that void. Indeed, although many computer simulators available on the market give “force feedback”, the haptics of such systems lack in comparison to their much cheaper counterparts, the physical simulator [21].

3.5 Conclusion

We have developed a colonoscope sleeve capable of measuring force applied between the shaft of the endoscope and the colon wall. We demonstrate our design process and confirmed construct validity of the sleeve. The sensors measure force accurately within the range of values commonly seen in colonoscopy. Our future work with this device will be to first test its role in colonoscopy training in physical simulators. We will use it to test the range of forces expected during colonoscopy across a spectrum of technique and ability. We will test its ability to distinguish expert and novice endoscopists, and define its appropriate role within colonoscopy training curricula. Ultimately, we hope to use this device to increase comfort and safety for patients, using this tool to provide real-time force feedback to the endoscopist.

3.6 References

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CHAPTER 4

4. Conclusions and Future Work

4.1 Review of Objectives

Colonoscopy is a diagnostic and therapeutic procedure of paramount importance to the treatment of colorectal disease. It remains amongst the most challenging procedures to master for general surgery and GI trainees. Indeed even practicing physicians continue to find its mastery a challenge [1-5]. Historically, endoscopic training has relied upon repetition, and thus large procedural volumes to achieve competence. Today's trainee faces diminishing opportunities to achieve these volumes. Greater focus is now targeted at identifying key competencies within colonoscopy in keeping with the adoption of Competency Based Medical Education in training programs. One such competency of interest is force application during colonoscopy.

We hypothesized that experts would utilize advanced techniques to advance the scope, rather than simply pushing harder to arrive in the cecum. Prior studies comparing the amount of force applied by expert and novice endoscopists in some instances have suggested that experts apply more force and torque than novices [6-8], which is counterintuitive. These studies looked at force applied by the endoscopist's hand to the endoscope during insertion. We felt that the more appropriate interface for force measurement, as it relates to patient comfort and safety, is between the colonoscope and the colon wall. This had rarely been explored in prior studies.

In this thesis we set out to define the relationship between force application and endoscopic skill, to validate this as a marker for competency to be used for endoscopic training. Further, we set out to design, build, and test the construct validity of a colonoscope sleeve to measure and give real-time feedback about the force being applied to the colon wall from the shaft of the colonoscope.

4.2 Summary of Results

In Chapter 2 of this thesis we tested the hypothesis that expert endoscopists exert less force than novices, using techniques to avoid or control loops in the colonoscope. Using colonic displacement as a surrogate marker for force, we used EM tracking markers placed on the mobile segments of a physical colon simulator to track the position of the colon in 3D space. The colon was configured according to one of the preset configurations from the manufacturer to predispose to loop formation in the sigmoid colon. Attending physicians were found to cause significantly lower mean displacement and to complete the procedure faster than trainees. Lower displacement of the colon would be expected to translate to lower forces between the colonoscope and the bowel wall. Prior studies have looked at the relationship between force application and endoscopic skill. However, the force application was at alternative locations, rather than between the scope and the colon wall, which is the most important for pain and perforation risk. Further, they compared colonoscopy experts with medical students with no prior endoscopic experience. Ours is the first study, to our knowledge, to show force application as a marker to help define endoscopic skill level. However, our design setup using a physical simulator lacks portability, and does not enable force feedback in vivo.

In Chapter 3 we set out to design a sleeve to fit over a standard adult colonoscope, capable of measuring force at its interface with the bowel wall. Our goal was to design a sleeve that added minimal additional thickness to the instrument and did not affect its flexibility. Prior sleeve designs had 'dead zones' between sensors spaced out along the shaft of the colonoscope. We aimed to minimize such dead zones, so that accurate force measurements could be achieved anywhere along the length of the scope. We built a 3-layer sensor using a piezoresistive layer positioned between two fPCBs. These were arranged in a helical orientation at a 21° in order to sensorize 2/3 of the surface of the colonoscope. The sleeve adds 1.4mm (10.9%) to the diameter of the shaft, resulting in a 27% reduction from prior designs. It measures force accurately to within 50g (<2 kPa). We outlined our design and tested the construct validity of our colonoscope sleeve. This early design will inform future endoscopists of forces applied as they develop comfort with the instrument, and has the potential to provide practicing endoscopists with immediate force feedback during procedures.

4.3 Future Directions

4.3.1 Differentiating Endoscopic Skill with Force Sensing Sleeve

We first showed that experienced endoscopists caused less colonic displacement during colonoscopy on a physical model. We surmised that this would translate into lower force transmission to the colon wall. With our subsequently developed force-sensing sleeve, we can now repeat our experiment in a physical model to confirm that force application can differentiate between novice and expert colonoscopists on the basis of force transmission to the colon wall. Further, we hope to use the sleeve to build a database of procedures with force information, and to use this to define "safe" or "ideal" range of force application for different colon configurations on our model.

4.3.2 Integration of Force Application into CBME Curricula

CBME curricula for colonoscopy require definitions of competencies, and their components, however the role of simulation in endoscopy training is still not defined. While several studies have shown the greatest benefit of simulators early in residency, the relative advantage from simulator training seems transient. In a study comparing simulator to non-simulator trained residents, the simulator-trained group initially showed higher objective and subjective levels of competence.

However, this advantage was no longer observed after 120 cases in patients, and ultimately did not provide any advantage in achieving CIRs of 90% [9]. We suspect trainees will more rapidly acquire "feel" for safe and unsafe force application through the immediate feedback provided by our sleeve. Previously, developing "feel" has relied on repetition and high case numbers. Confirming this suspicion will require randomized trials of colonoscopy trainees to assess its impact on achieving 90% CIR in patients.

4.3.3 Applications for Commercialization and In Vivo Use

Currently, our force-sensing sleeve fits over the colonoscope. Ideally our technology could be incorporated into colonoscopes, rather than functioning as an outer sleeve. The polymer covering of the colonoscope could have our helical force sensors embedded just beneath it. Indeed this would allow our force feedback technology to be utilized by anyone using such a colonoscope.

Many of the major endoscopy manufacturing companies have magnetic endoscopic imaging technology to allow real-time information for the endoscopist about the shape of the colonoscope, including ScopePilot (Pentax, Tokyo, Japan) and Scope Guide® (Olympus, Tokyo, Japan). These provide a small image in the bottom corner of the endoscopy monitor revealing the shape of the colonoscope to the endoscopist. We would hope to integrate force data into such a graphic. The endoscopist could, perhaps, see the scope change color, at the corresponding segment of the scope, from yellow to orange to red as the measured force increases. This would provide invaluable feedback to the endoscopist during the procedure to help achieve our goal of patient comfort and safety during colonoscopy.

4.4 Conclusion

With this thesis we aimed to define the relationship between endoscopic skill and force application between the colonoscope and the colon wall. After showing that attending physicians outperform trainees using this metric, we developed a force sensing sleeve to allow portability of this technology to any physical simulator, and most importantly, to patients. Although still in its infancy, this technology holds great promise to significantly improve the way colonoscopy is taught, and to bring important force feedback information to practicing endoscopists.

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APPENDIX

Appendix A - Lawson Final Approval Notice

LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER: R-19-244

PROJECT TITLE: Measuring Force Transmission During Colonoscopy - Development and Assessment of a Novel Training Device

PRINCIPAL INVESTIGATOR: Dr. Christopher Schlachta

LAWSON APPROVAL DATE: 16/05/2019

ReDA ID: 5259

Overall Study Status: Active

Please be advised that the above project was reviewed by Lawson Administration and the project:

Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

Appendix B - Health Sciences Research Ethics Board Approval

Western Research

Date: 15 October 2019

To: Dr. Christopher Schlachta

Project ID: 112426

Study Title: Measuring Force Transmission During Colonoscopy - Development and Assessment of a Novel Training Device

Application Type: Continuing Ethics Review (CER) Form

Review Type: Delegated

REB Meeting Date: 05/Nov/2019

Date Approval Issued: 15/Oct/2019

REB Approval Expiry Date: 16/Oct/2020

Dear Dr. Christopher Schlachta,

The Western University Research Ethics Board has reviewed the application. This study, including all currently approved documents, has been re-approved until the expiry date noted above.

REB members involved in the research project do not participate in the review, discussion or decision.

Western University REB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The REB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Daniel Wyzynski, Research Ethics Coordinator, on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).

Appendix C - Participant Data Collection Form

Participant Enrollment #: ______________________________

Measuring Force Transmission During Colonoscopy ***- Development and Assessment of a Novel Training Device -***

Participant Information Form

Sex (Circle One):

Male	Female

Handedness (Circle One):

Right	Left

Level of Training (Circle One):

General Surgery Staff	General Surgery Trainee	Gastroenterology Staff	Gastroenterology Trainee

Which best describes your endoscopic technique? (Circle):

Torque Steering	Knob Steering	Frequent Patient Repositioning

Demographic Information – for Staff Physicians	
In what setting do you practice?	Comm/Acad
How many years have you been in practice?	
What % of your practice is upper endoscopy?	
What % of your practice is colonoscopy?	
What % of your endoscopy practice is therapeutic?	

Demographic Information – for Trainees (Residents and Fellows)	
What is your current level of training?	PGY
How many upper endoscopies have you performed?	
Will upper endoscopy be part of your future practice?	YES / NO
How many colonoscopies have you performed?	
Will colonoscopy be part of your future practice?	YES / NO

Jeff Hawel Page 1 5/28/20

Appendix D - Participant Information and Consent Form

CSTAR Western UNIVERSITY · CANADA LAWSON HEALTH RESEARCH INSTITUTE

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Measuring Force Transmission During Colonoscopy - Development and Assessment of a Novel Training Device.

Principal Investigator:
Dr. Christopher Schlachta, MD FRCSC
Professor - Department of Surgery
Professor - Department of Oncology
CSTAR (Canadian Surgical Technologies & Advanced Robotics)
London Health Sciences Centre, University Hospital

Contact Information:
Dr. Jeffrey Hawel, MD FRCSC
Adjunct Professor, Western University
Division of General Surgery, Department of Surgery

Name of Sponsor: Division of General Surgery, Department of Surgery, Western University and London Health Sciences Centre

Conflict of Interest: None

Introduction
You are being asked to participate in a study regarding the amount of force transmitted to the gastrointestinal tract during endoscopy. You were selected as you are in a training program that involves endoscopy, or endoscopy is part of your current practice. We ask that you read this letter carefully before agreeing to participate in the study.

Background/Purpose
The number of procedures performed during training is thus often cited as a surrogate marker of competency. In the era of trainee work hour restrictions, it is difficult, if not impossible, to achieve the high procedural numbers recommended. Focus has now shifted to improved quality of training, rather than quantity. Simulation has become widely embraced by the medical community to provide a safe environment for trainees to develop and practice technical skills without any risk to patients.

Existing colonoscopy simulators, both virtual reality and physical models, are primarily focused on manipulating the colonoscope through to procedure completion with adequate visualization of the lumen. However, perforations and patient discomfort are related to the pressure transmitted from the colonoscope tip and loops to the colon wall. Our research aims to develop a device to monitor this force, and provide immediate feedback to the endoscopist.

Study Design

Prior to undergoing endoscopic assessment, you will be asked to complete a questionnaire detailing your level of training and other demographic information. Approximately 50 participants will be enrolled in the study, based on the number of available trainees and consultants in the divisions of General Surgery and Gastroenterology. Data regarding your assessment will be recorded in a de-identified manner. You will then be asked to complete a colonoscopy on our colon simulator. Data will be recorded directly from our simulator model.

All data will be recorded in a de-identified form and stored in a secure file on the REDCap server. The data collected in this study will only be presented in aggregate at scientific meetings, journals and potentially in the press. Your individual data will not be shared outside of the investigator group.

Voluntary Participation

This is a voluntary study, and your decision to enter will have no effect on your experience today or your relationship with your institution or training program.

Withdrawal from Study

You can withdraw from this study at any point today, or have your information retroactively removed from the database at any point by contacting the team. De-identification will occur when the data is transferred to the REDcap server and is assigned a unique study number. A master list linking the de-identified data will be retained by the data study custodian, Jeffrey Hawel. Your decision to withdraw will have no effect on your experience today or your relationship with your institution or training program.

Risks

There are no identified risks for participants in this study. However, identifying information is collected on the data collection forms, and thus there is a risk of breach of privacy. There may be other unknown risks to this study.

Benefits

Participants may not experience any benefit. By participating in the study, you will help better understand what can be done to improve the performance and teaching of endoscopy, with potential benefit to future patients through improved comfort and decreased procedural risk.

Confidentiality

All information collected during this study will be kept within the investigator group and will not be shared with your institution or training program. Data will be stored in the office of the study data custodian. Study data will be retained for 15 years. Access to study data will be limited to the study team, Western Health Sciences Research Ethics Board, and Lawson Quality Assurance and Education Program.

Costs

There is no cost associated with participating in this study.

Compensation

No compensation is provided for this study.

Rights as a Participant

As a participant in this study, you can withdraw at any time before, during or after your study participation today. The study participant does not waive his/her legal rights by signing the consent. If you do not wish for your information to be used in the study, you can contact the individual listed above and your data will not be included in analysis.

Questions about the Study

You have the right to ask questions about this research study and to have those questions answered before, during or after the research. If you have any further questions about the study, at any time feel free to contact Jeff Hawel by e-mail (xxxxxxxxxxxxxx) or by telephone at xxx-xxx-xxxx. If you request, a summary of the results of the study will be sent to you. If you have any other concerns about your rights as a research participant that have not been answered by the investigators, you may contact the Patient Experience Office (xxx-xxx-xxxx).

Consent

Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep.

Participant's Name (print): ______________________________

Participant's Signature: ______________________________ Date: __________________

Investigator's Name (print): ______________________________

Investigator's Signature: Date:

Appendix E - Curriculum Vitae

JEFFREY HAWEL, MD, FRCSC

Contact Information:

Division of General Surgery, London Health Sciences Centre
University Hospital, 339 Windermere Road, London, Ontario

Academic Background and Training:

1. ***Masters Candidate:*** *Medical Biophysics, Schulich School of Medicine and Dentistry*
    - *Western University (2017 – Present)*
2. ***Fellowship:*** *Minimally Invasive Surgery / Surgical Endoscopy, Dalhousie University (2016 - 2017)*
    - *QEII Health Sciences Centre, Halifax, Nova Scotia, Canada*
    - *Date of Graduation – July 17th 2017*
3. ***Residency:*** *General Surgery, Western University (2011 – 2016)*
    - *London Health Sciences Centre / St. Joseph's Health Care, London Ontario, Canada*
    - *Date of Graduation – June 30th 2016*
4. ***Doctor of Medicine:*** *Schulich School of Medicine and Dentistry, Western University (2007 - 2011)*
    - *Date of Graduation – May 20th 2011*
5. ***Honours Bachelor of Medical Sciences:*** *Medical Biophysics, Western University (2003 - 2007)*

Medical Licensure:

1. ***College of Physicians and Surgeons of Ontario (96448):*** *(2011 – 2016; 2017 – present)*
2. ***College of Physicians and Surgeons of Nova Scotia (17283):*** *Independent Practice (2016 – 2017)*

Research Projects:

<u>Published:</u>

1. *Vourtzoumis P, Elnahas AI, Alkhamesi NA,* **Hawel JD**, *Schlachta CM. Operating during COVID-19: Is there a risk of viral transmission from surgical smoke during surgery? (manuscript accepted for publication by Canadian Journal of Surgery).*
2. ***Hawel, J****, McFadgen, H, Stewart, R, El-Ghazaly, T, Alawashez, A, Ellsmere, J. Interventional radiology-assisted transgastric endoscopic drainage of peripancreatic fluid collections (manuscript accepted for publication by Canadian Journal of Surgery).*
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12. *Lazo-Langner A, **Hawel J**, Ageno W, Kovacs MJ. Low molecular weight heparin for the treatment of retinal vein occlusion: a systematic review and meta-analysis of randomized trials. Haematologica. 2010 Sep;95(9):1587-93*

<u>In Progress:</u>

13. *Predictors of Receiving Bariatric Surgery among Older Patients Referred to a Publicly Funded Bariatric Surgery Program*
14. *Establishing Performance Benchmarks for Intracorporeal Suturing Using a Novel Laparoscopic Bench Model: A Pilot Study*
15. *Duodenal strictures: malignancy rates and delayed diagnoses (manuscript submitted to Canadian Journal of Surgery).*
16. *Patient Expectations and Experiences with Conventional and Propofol-based sedation for endoscopy.*
17. *Modelling Endoscopy Learning Curves in Surgical Residents and Gastroenterology Fellows in Canadian Training Programs Using Competency Based Assessment.*
18. *Outcomes of liver resection for metastases from non-colorectal non-neuroendocrine abdominal malignancies – Does portal drainage matter?*

Presentations:

1. ***PODIUM:*** *American College of Surgeons Clinical Congress (Boston 2018) Carlos Garcia-Ochoa C, McArthur E, Tun-Abraham M,* ***Hawel J****, Skaro A, Leslie K. Overall Complications with Preoperative Biliary Stenting vs. Pancreaticoduodenectomy in Patients with Pancreatic Adenocarcinoma and Obstructive Jaundice. Analysis of the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Registry.*
2. ***PODIUM****: SAGES Annual Meeting (Seattle 2018) Stewart RD,* ***Hawel J****, French D, Ellsmere J. Pneumatic Balloon Dilation for Palliation of Recurrent Symptoms of Achalasia after Esophagomyotomy.*
3. ***POSTER:*** *SAGES Annual Meeting (Seattle 2018) Hamidi M,* ***Hawel J****, Ott M. Learning Curves to Measure Proficiency in Colonoscopy Training Amongst Surgery Trainees: a Novel Competency-Based Approach.*
4. ***POSTER:*** *SAGES Annual Meeting (Houston 2017)* ***Hawel J****, Ellsmere J. Cholangiogram filling defects in biliary pancreatitis: Not always secondary to stone disease.*
5. ***POSTER:*** *SAGES Annual Meeting (Houston 2017)* ***Hawel J****, Eng J, Ellsmere J. Video-Based Coaching for Endoscopy: Use of a Secure Mobile Phone Application for Procedural Video Analysis.*
6. ***POSTER:*** *Canadian Association of General Surgery Annual Meeting, Toronto (2016) M. Meschino, H. Marshall,* ***J. Hawel****, E. Lau, H. Emmerton-Coughlin, C. Yoshy, D. Wiseman, A. Mujoomdar, R. Hernandez-Alejandro, K. Leslie. Synoptic versus free-form CT reporting for determination of resectability in periampullary malignancy. Can J Surg, Vol. 59, (4 Supple 1).*
7. ***POSTER:*** *Canadian Association of General Surgery Annual Meeting, Toronto (2016) Tsang ME, Mahar AL, Martel G,* ***Hawel J****, Rekman J, Boulanger-Gobeil C, Hurlbut D, Meschino M, Morin C, Cleary SP, Gallinger S, Nanji S, Balaa FK, Karanicolas PJ, Jalink D, Ouellet JF, Hernandez-Alejandro R, Wei AC, Hallet J. Assessing Tools for Management of Non-Colorectal Non-Neuroendocrine Liver Metastases: External Validation of a Prognostic Model. Annals of Surgical Oncology. 20(Supp 1):S107.*
8. ***PODIUM:*** *Canadian Association of General Surgery Annual Meeting, Quebec City (2015) E. Lau, K. Bertens,* ***J. Hawel****, M. Meschino, K. Leslie, R. Hernandez-Alejandro. Effect of Surgical Wait Time on Oncological Outcomes in Periampullary Cancer.*
9. ***PODIUM:*** *Canadian Association of General Surgeons Annual Meeting, Quebec City (2015) M. Meschino,* ***J. Hawel****, E. Lau, S. Knowles, K. Leslie, R. Hernandez-Alejandro. Does Surgical Assist Expertise Affect Resectability in Periampullary Malignancies?*
10. ***POSTER:*** *Canadian Association of General Surgery Annual Meeting, Vancouver (2014)* ***J. Hawel,*** *K. Pineda, G. J. Romsa, R. Hernandez Alejandro. Hepatobiliary Scintigraphy (HBS) for the Assessment of the Future Liver Remnant (FRL) in Associating Liver Partition and Portal Vein Ligation for Staged Hepatectomy (ALPPS): Does Volume Equal Function?*
11. ***POSTER:*** *Americas Hepato-Pancreato-Biliary Association Annual Meeting, Miami (2013)* ***J. Hawel****, G. Martel, K. P. Croome, J. Rekman, D. Quan, F.K. Balaa, R. Hernandez-Alejandro. Liver Resection for Non-Colorectal, Non-Neuroendocrine, Non-Sarcoma Metastases: A Multicenter Study. (AHPBA Meeting Abstracts) Volume 15, Issue Supplement S1, Pages 1–92.*
12. ***POSTER:*** *Canadian Association of General Surgery Annual Meeting, Calgary (2012)* ***J. Hawel****, K. Croome, D. Quan, R. Hernandez Acceptable long-term survival in patients undergoing liver resection for metastases from noncolorectal, nonneuroendocrine, nonsarcoma malignancies. (CAGS Meeting Abstracts) Can J Surg,Vol. 55, Suppl., August 2012.*

13. ***POSTER:*** *American Society of Hematology Annual Meeting, Orlando (2009) Alejandro Lazo-Langner,* ***Jeff Hawel****, Michael J. Kovacs, Philip S Wells, Dimitrios Scarvelis, Melissa Anne Forgie, and Marc Rodger. A Systematic Review and Meta-Analysis of Proportions of Thrombosis and Bleeding in Patients Receiving Venous Thromboembolism (VTE) Prophylaxis After Orthopedic Surgery (OS). An Update. Blood (ASH Annual Meeting Abstracts), Nov 2009; 114: 3125.*
14. ***POSTER:*** *American Society of Hematology Annual Meeting, San Francisco (2008) Michael J. Kovacs,* ***Jeffrey D.E. Hawel****, Janelle F. Rekman, and Alejandro Lazo-Langner. Safe Treatment of Pulmonary Embolism on An Outpatient Basis. Blood (ASH Annual Meeting Abstracts), Nov 2008; 112: 1979.*

Book Chapter:

Hawel J*, Ellsmere J. Endoscopic Reflux Treatments. The Sages Manual of Foregut Surgery, First Edition, 2017 (Springer Science and Business Media).*

Educational Activities:

1. ***Advanced Endoscopy Course – Course Coordinator –*** *Canadian Surgical Forum didactic and hands-on endoscopy course for practicing surgeon endoscopists (Victoria BC 2017, St Johns NFLD 2018, Montreal 2018)*
2. ***CREATE Course – Faculty -*** *Annual Course for Gastroenterology Residents in Advanced Therapeutic Endoscopy (London Ontario, September 2018)*
3. ***SAGES Upper GI Course – Faculty*** *- Advanced Laparoscopic Upper GI and Bariatric Surgery Workshop for Senior Surgical Residents (London Ontario, 2016, 2017, 2018, 2019)*
4. ***Medical Student Lecture Series*** *– Peri-Operative Care and Introduction to Pancreatic and Biliary Diseases*
5. ***Curriculum Development and Review*** *– Schulich School of Medicine and Dentistry, Doctor of Medicine Program, (November 2018 – Present)*
6. ***ERCP Surgical Training Program – Director*** *- Training program for ERCP subspecialty training for surgical fellows. (2018 – Present)*
7. ***Advanced GI MIS Fellowship – Faculty*** *– Laparoscopic and Endoscopic fellowship training program (September 2017 – Present)*

Administrative Roles:

1. ***Canadian Association of General Surgeons – Board of Directors*** *(July 2019 – Present)*
2. ***Endoscopy Taskforce Committee – Committee Chair -*** *Canadian Association of General Surgeons (July 2019 – Present)*
3. ***Polyp Adjudication Committee – Chair -*** *Multidisciplinary taskforce to guide care for complicated colonic polyp management (November 2017 – Present)*
4. ***Residency Program Committee*** *– Member (September 2017 – Present)*

Awards and Distinctions:

1. ***Ontario Graduate Scholarship*** *– Western University - $15,000 (2018-2019)*
2. ***Resident Mentor Award*** *– Awarded annually by the graduating resident class to the faculty member who is a role model and is instrumental in providing guidance to graduating trainees. (2018)*
3. ***Dr. GE Meads Award*** *– Given annually to the resident who in the opinion of the faculty best exemplified the combination of superb technical ability in the operating room in combination with a keen interest and ability to teach that knowledge to the residents and students. (2016)*
4. ***General Surgery Resident Research Day – Best Senior Presentation:*** *Synoptic versus Free Form CT Reporting for Periampullary Malignancies: Can we better select operative candidates? (2016)*
5. ***Dr. Ronald Holiday Resident Award in Surgical Professionalism:*** *Awarded annually to a post-graduate trainee in General Surgery who shows outstanding skill as a surgeon, but also as a teacher and mentor of junior residents and medical students. (2015)*
6. ***Canadian Association of General Surgeons (CAGS) Resident Award for Teaching Excellence:*** *Annual award for resident teaching at Canadian General Surgery Training Programs. (2015)*
7. ***American College of Surgeons - Jameson L. Chassin, MD, FACS, Award for Professionalism in General Surgery:*** *(2015) - Finalist*
8. ***Valedictorian:*** *Meds Class of 2011, Schulich School of Medicine and Dentistry at the University of Western Ontario, May 20th, 2011.*
9. ***Honour Society Award:*** *Awarded to students who have distinguished themselves in rendering valuable extracurricular services to the Medical School or the University as a whole. (2011)*
10. ***A.K. Knill Staff Award of Excellence:*** *Presented to the member of residence staff who has earned the respect of the team through leadership and dedication. (2006, 2007)*
11. ***Top Fourth Board at the Pan-American Chess Championships:*** *Earned as a member of the Western Chess team in Miami, Florida. (2003)*
12. ***Valedictorian:*** *OAC Graduating Class, Glendale High School, Tillsonburg ON (2003)*

Professional Memberships & Development:

1. ***Skills Enhancement for Endoscopy (SEE) –*** *Colonoscopy Skills Improvement (Kingston 2018)*
2. ***Skills Enhancement for Endoscopy (SEE) –*** *Train the Endoscopy Trainer (St Johns 2018)*
3. ***Fundamentals of Laparoscopic Surgery (FLS):*** *Certified (2015)*
4. ***Advanced Surgical Skills for Exposure in Trauma (ASSET):*** *(2016)*
5. ***Medical Council of Canada:*** *MCCQE Part I (2011) and MCCQE Part II (2013)*
6. ***College of Physicians and Surgeons of Ontario:*** *Member (2011 – 2016, 2017 - present)*
7. ***College of Physicians and Surgeons of Nova Scotia:*** *Member (2016 – 2017)*

8. ***ATLS Provider Certified:*** *In accordance with the American College of Surgeons (2011 - present)*
9. ***ACLS Provider Re-Certified:*** *Heart and Stroke Foundation of Canada (2013)*
10. ***Ontario and Canadian Medical Associations:*** *Member (2007 - present)*
11. ***Principles and Practice of Clinical Research Course:*** *(October 2011)*
12. ***Surgical Foundations:*** *Royal College Surgical Foundations Examination (2013)*
13. ***Americas Hepato-Pancreato-Biliary Association:*** *Resident Member (2013)*
14. ***American College of Surgery:*** *Member (2011 – present)*
15. ***Simulated Trauma and Resuscitation Team Training Course:*** *September 2012*
16. ***Therapeutic Endoscopy Conference:*** *St. Michael's Hospital, Toronto, ON (2013)*
17. ***Endoscopic Ultrasonography Live Course:*** *University of Chicago, Chicago IL (2014)*
18. ***Advanced Endoscopy and ERCP Course:*** *BIDMC, Harvard University, Boston MA (2016)*
19. ***Society of American Gastrointestinal and Endoscopic Surgeons*** *(2016 - Present)*