Development of a Distal Tip Extension Mechanism for Endoscopes

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ABSTRACT

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Colonoscopy is the most common procedure to detect and diagnose colon diseases, such as colorectal cancer. However, endoscopists are occasionally unable to reach some areas in the colon to thoroughly examine the colon, especially the cecum. The significance of the distal tip extension mechanism (DTEM) arises when the insertion tube of the colonoscope is no longer able to move further inside the colon and when a longer insertion tube is needed. The main focus of this research is to investigate the development of a novel distal tip extension mechanism (DTEM). To characterize the performance of the DTEM, the ability of the DTEM to extend the distal tip of the colonoscope 16 cm is investigated. To determine the maximum number of turns that the extension knob needs to make in order to move the distal tip 16 cm, the DTEM is used to displace the distal tip in different colon configurations using the silicon tube of colonoscopy training model (CTM). To measure the effective of implanting the DTEM in the colonoscope on the flexibility of the insertion tube, a compliance test is performed. To find the bending radius and bending angle at which the DTEM fails to extend the distal tip 16 cm, bending tests are conducted. The DTEM could enable colonoscopists to reach spots in the colon within a 16 cm limit where regular colonoscopes usually fail. The experimentally collected data was presented and discussed to characterize the performance of the DTEM. The results showed that the DTEM is able to extend the distal tip 16 cm while the colon

is in various configurations. Additionally, the impact of implanting the DTEM on the flexibility of the insertion tube was determined. The bending radius and the bending angle at which the DTEM was not able to move the distal tip 16 cm were pinpointed. The results of this research suggest that the DTEM will be an effective tool to help colonoscopists performing better colonoscopy. Furthermore, it will increase the completeness rate of colonoscopy.

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CHAPTER 1: INTRODUCTION

1.1 Colonoscopy Overview

Colonoscopy is a diagnostic and therapeutic procedure that is utilized to provide visualization of the entire colon and treat the colon of any existing diseases, such as colorectal cancer [1]. Colon diseases are associated with several symptoms such as vomiting, diarrhea, abdominal pain, and rectal bleeding. These symptoms could be indications of the existence of colon diseases [2]. Colorectal cancer, rectal prolapse, and inflammatory bowel diseases are primary examples of colon diseases. In most cases, thorough examination of the colon is required when indications of colon diseases are observed [3]. Colorectal cancer is the second most deadly cancer in the United States: fourth in men and third in women throughout the world [4, 5]. Early detection and prevention through the removal of polyps, which are the precursors to cancer, reduce the mortality rate [6]. Therefore, screening colonoscopy is highly recommended for people age 50 and above, repeated periodically every 10 years in the United States [7], [8]. An incomplete diagnostic colonoscopy could lead to an inaccurate and sometime false negative diagnosis for colorectal diseases, putting the patients at increased risk [9]. The cecal intubation rate, the frequency of successfully reaching the cecum, is an important factor to evaluate the completeness of a colonoscopy. The US Multidisciplinary Task Force on Colorectal Cancer recommended that the cecal intubation rate should be achieved in at least 90% of all performed colonoscopies and 95% of screening colonoscopies [10]. However, about 10% of colonoscopies are unsuccessful in reaching

the cecum [11]-[13]. Loop formations, acute bends, complex configurations of the colon and patient discomfort are the main reasons for an incomplete colonoscopy [13], [14].

The colonoscopy workstation, which is where colonoscopy is performed, must be set up in a way that insures appropriate ventilation and installation of electrical apparatus as well as providing comfortable environment for patients [15]. A colonoscopy workstation typically consists of several parts and devices as shown in Figure 1 [15].

Figure 1. Colonoscopy workstation, (1) examining table, (2) radiography equipment, (3) video tower, (4) power unit and endoscope with video processor, (5) light source, (6) Air supply/pump, (7) suction pump, (8) instrument table for accessories [15].

Typical video colonoscope has three main parts, which are a universal cord and plug, an instrument control head, and an insertion tube as shown in Figure 2 [15]. The

universal cord and plug is used to connect the colonoscope to the supply unit. The insertion tube is the part that goes inside the colon during colonoscopy. It has a bendable section, about 15 cm long, at its distal end, which is referred to as the distal tip [15].

Figure 2. Colonoscope parts, (a) a universal cord and plug, (b) instrument control head, (c) insertion tube [15].

The head of the distal tip contains an air/water spray nozzle, a light guide, an opening to the instrument channel, a lens with lens cover, and a water channel as shown in Figure 3 [15].

Figure 3. The tip of the distal tip of the insertion tube [15].

The air/water nozzle is used to clean the lens of blood and mucus so that the colonoscopist can monitor the inside of the colon clearly. The lens provides video to visualize the entire colon during colonoscopy [15]. The light guide is used to illumine the inside of the colon. The opening to the instrument channel provides an access for forceps to take samples from inside the colon. The instrument control head is the part of the colonoscope that colonoscopists use to hold the colonoscope during colonoscopy as well as to control the movement of the distal tip through angling wheels [15]. The instrument control head also has the buttons and the dials that control all the functionalities of the colonoscope, such as suction, cleansing, air insufflation, video recording, printing, maneuvering the distal tip of the insertion tube, and locking the shape of the distal tip as shown in Figure 4 [15].

Figure 4. The instrument control head, (1) function buttons, e.g., video recorder remote control, (2) freeze button, (3) suction button, (4) air/water button, (5) instrument channel, (6), locking device (7), angling wheel (right/left), (8) angling wheel (up/down) [15].

1.2 Statement of the Problem

Colonoscopy can be associated with many complications such as bleeding, and obstacles, such as loop formations, sharp bends, and a high degree of discomfort to the patients. These obstacles sometimes prevent colonoscopists from reaching the cecum to complete the procedure. However, colonoscopy completeness is a necessity to fully visualize the colon and assure appropriate diagnosis and treatment. The cecum cannot be reached when the insertion tube of the colonoscope is no longer able to move further inside the colon and when a longer insertion tube is needed. Such a case occurs when the insertion tube passes through too many sharp bends, when excessive loop formations form, and/or when the colon is long. Therefore, a new device to enable the distal tip of the insertion tube to reach the cecum when the insertion tube is not able to further move inside the colon is needed.

CHAPTER 2: LITERATURE REVIEW

2.1 Complete and Incomplete Colonoscopy

Colonoscopy is a diagnostic and therapeutic procedure utilized to provide visualization of the entire colon and treat the colon for any existing diseases, such as colorectal cancer [1]. It is necessary to check the colon thoroughly in order for colonoscopists to be certain of the patient's conditions and to avoid missed advanced neoplasia. Otherwise, the diagnosis would not be accurate and that would expose patients to greater risks [9]. The US Multidisciplinary Task Force on Colorectal Cancer recommended that the cecal intubation rate should be achieved in at least 90% of all performed colonoscopies and 95% of screening colonoscopies [10]. Cecal intubation rate is an important marker of the quality of colonoscopy, and it is defined as the process of reaching the cecum, which is the first part of the large intestine [16]. Performing complete colonoscopy is important for colonoscopists to insure accurate diagnosis of the colon. However, colonoscopy is sometimes associated with complications that could stop the operation and prevent colonoscopists from thoroughly screening the entire colon, resulting in an incomplete colonoscopy. Incomplete colonoscopy is caused by many factors, such as age, gender, looping, prior abdominal surgery, severe diverticulosis, and poor preparation [17], [18]. Even though cecal intubation rate has improved with advanced technologies and developed devices that have been used to perform colonoscopy, incomplete colonoscopy still occurs in about 10% of all performed colonoscopies [11]-[13]. Several studies showed even lower cecal intubation rates. A study, conducted in the United Kingdom, including 9,223 colonoscopies reported that

cecal intubation rates were 76.9% [19]. Another study done in the United States on a group of 69 colonoscopists who executed 17,868 colonoscopies reported that 45% of the 69 colonoscopists had cecal intubation rates of less than 90%, 55% colonoscopists had cecal intubation rates higher than 90%, and 9% of the colonoscopists had cecal intubation rates of less than 80% [20]. Another study reported that 14,139 colonoscopies were performed, and incomplete colonoscopy rates were 16.7%, which is higher than the allowed 10% unsuccessful colonoscopy by The US Multidisciplinary Task Force on Colorectal Cancer [21].

2.2 Factors Associated with Incomplete Colonoscopy

As stated above in section 2.1, colonoscopy can be associated with complications that could stop the operation and prevent colonoscopists from thoroughly screening the entire colon resulting in an incomplete colonoscopy. Several factors are associated with incomplete colonoscopy, such as looping, long colon, old age, and female gender [17], [18].

2.2.1 Colonic Loops

Looping is a common problem that colonoscopists encounter while performing colonoscopy. Looping mostly occurs in the sigmoid colon and makes advancing the insertion tube through the colon more difficult [22]. The difficulty to navigate through existing looping depends on the severity of looping. There are different types of looping and the most common types are: N loops, Alpha loops, and reverse Alpha loops, as

shown in Figure 5 [22]. A study done on 100 colonoscopies announced that N loops, Alpha Loops, and reverse Alpha loops occurred in 79%, 12%, and 11% of the cases, respectively [23]. Additionally, Another study conducted on 483 patients in Japan recorded the formation of N loops, Alpha Loops, and reverse Alpha loops in 47.2%, 11.7%, and 6.1% of the cases, respectively [24].

Figure 5. N loops, Alpha loops, and reverse Alpha loops respectively from the Left side [22].

2.2.2 Long Colon

Complete colonoscopy can be hindered by extensive colon length in addition to other factors [17], [18]. The length of the colon was reported to have a significant affect on performing unsuccessful colonoscopy [22], [25]. A study consisting of one hundred patients concluded that the average length of the entire colon of the incomplete colonoscopy group was over 200 cm, the average length of the complete colonoscopy group was less than 200 cm, and the average difference length of the colon between the

two groups was 45 cm [25]. Also, studies reported that the female sex is more associated with incomplete colonoscopy than the male sex [16]-[18], [21], [26]. Studies reported that the total average length of the colon of women is longer than that of men by 10 cm [27], [28]. Furthermore, the age of patients appears to adversely influence cecal intubation rates. Reports showed that older patients are more likely to undergo incomplete colonoscopy [13], [16], [18], [25], [26]. One justification for this is that as patients grow older, their colons grow longer [28]. In summary, long colon, female sex, and old age are associated with longer colorectal length, which increases the possibility of performing incomplete colonoscopy and reduces cecal intubation rates.

2.3 Colonoscopy Devices and Technologies

Colonoscopy is the main procedure to diagnose and detect colorectal cancer and other diseases. This procedure requires advancing the insertion tube, a part of the colonoscope, through the colon. Common obstacles during the procedure, such as looping, can be painful for the patient and can prevent complete visualization of the colon to the cecum. Therefore, many methods and devices have been developed in order to reduce the pain, incomplete intubation rate, and other complications associated with colonoscopy. Variable stiffness colonoscopes, Aer-O-Scope, NeoGuide Endoscopy System (NES), shaft guidance devices and passive bending techniques are created to enable the insertion tube to move readily through the colon without causing any damage to the colon walls and to avoid and prevent loop formation. Furthermore, they are

developed to improve the quality of the colonoscopy procedure and enhance cecal intubation rate.

2.3.1 Variable Stiffness Colonoscope

Flexibility of the insertion tube is required for better navigation and smoother passage through the angulated sigmoid colon; however, this flexibility allows looping to occur more often. On the other hand, the rigidity of the insertion tube can prevent looping, but it is more difficult to navigate and maneuver through colonic flexures, possibly causing damage to the colon wall via mechanical trauma [29]. In order to resolve the conflict between the need for a flexible and stiff insertion tube, the variable stiffness colonoscope was developed [30]. The variable stiffness colonoscope shown in Figure 6 was built to have the flexibility of a pediatric colonoscope, working length (168 cm) of an adult colonoscope, and a stiffening mechanism to stiffen the insertion tube. The flexibility and rigidity of the insertion tube can be controlled through a dial, which is located below the control head of the colonoscope [30]. The mechanism for stiffening the insertion tube uses surrounding metal helical coils and stiffening wires, which have a single cable at the center. To obtain a stiff insertion tube, the central cable is pulled, causing the helical coils to compress and form a rigid configuration. In contrast, loosening the central cable allows the helical coils to become loose, thereby increasing flexibility [30].

Figure 6. The variable stiffness colonoscope [31].

Patient pain is reduced using the variable stiffness colonoscope because it is flexible, which can cause less damage to the colon wall when it passes the colonic flexures. Additionally, the time of the colonoscopy is shorter because the insertion tube moves easier through the colon [30]. The cecum, which is the last part of the colon, should be reached in 90% or more of all colonoscopies. Many reasons, such as looping formations, patient discomfort, and complex configurations of the sigmoid colon, cause a failure to reach the cecum [13], [14]. Using the variable stiffness colonoscope (VSC) increases the rate of cecal intubation due to its ability to be rigid and flexible [32]. In order to determine which outer diameter for the distal tip and insertion tube may make the performance of the variable stiffness colonoscope better, a comparison was conducted among three types of the VSC, which are the pediatric variable stiffness colonoscope (PVSC), nonmagnifying adult variable stiffness colonoscope (AVSC), and

magnifying variable stiffness colonoscope (MVSC) [32]. The diameters of the PVSC, AVSC, and MVSC are 11.3 mm, 12.2mm, and 13.2mm, respectively [32]. The results showed that the PVSC does not decrease the intubation time or patients' pain in comparison to the other two types of VSC [32]. The MVSC may cause more pain due to its larger diameter, and the AVSC has the best performance in terms of reducing discomfort and intubation time [32]. Another study done by Qin Xie showed that Variable-Stiffness Colonoscope reduces the procedure time and enhances the cecal intubation rate [33]. Furthermore, a study was done by César Prieto-de-Frías to compare a Responsive Insertion Technology (RIT) Colonoscope with a Variable-Stiffness Colonoscope in terms of time to reach the cecum and rate of complete colonoscopy [34]. The results showed that the time needed to reach the cecum was reduced using the RIT colonoscope, and the colonoscopy completeness rate was similar with a completion rate of 100% [34]. The Variable-Stiffness Colonoscope shows higher colonoscopy completeness rate and shorter time to reach the cecum [35]. Also, it improves the completeness rate of colonoscopy when used on patients who had an incomplete colonoscopy [36]. However, a study done by D. K. Rex to evaluate the effectiveness of using a Variable-Stiffness Colonoscope presented no effect on cecal intubation time in sedated patients when performed by a single colonoscopist [37].

2.3.2 The Aer-O-Scope

The Aer-O-Scope is a self-propelling, self-navigating colonoscope. Although it has the ability to perform colon screening using a viewing system, it lacks therapeutic

features. The Aer-O-Scope consists of a workstation shown in Figure 7, a disposable propulsion and imaging device. The workstation controls the movement of the imaging device, suction, water supply, and gas pressure [38]-[41].

Figure 7. The workstation of the Aer-O-Scope [41].

The disposable imaging device shown in Figure 8 consists of a rectal introducer, a supply cable and a capsule endoscope rooted inside a balloon named the vehicle balloon. The supply cable is connected to the workstation and to the vehicle balloon. It trails the vehicle balloon during the advancement and withdrawal of the vehicle balloon through the colon. It also provides the embedded capsule endoscope and the vehicle balloon with air, water, and electricity [38]-[41].

Figure 8. The disposable imaging device consists of a rectal introducer, a supply cable and a capsule endoscope embedded inside a balloon named the vehicle balloon [40].

The rectal introducer is a hollow silicon tube that has an external stationary balloon. The stationary balloon is inflated in the rectum to prevent gas leakage during colonoscopy. The vehicle balloon can enter the colon by passing through the rectal introducer. When the vehicle balloon exceeds the rectal introducer, the stationary balloon and the vehicle balloon are inflated, and gas (carbon dioxide) is supplied to generate pressure gradient between the two balloons to move the vehicle balloon forward or backward as needed [38]-[41]. The gas pressure in front, between, and behind the vehicle balloon is controlled by a computer algorithm using automated regulators. The vehicle balloon can take shape of the colonic lumen and the bends. This ability enables the vehicle balloon to travel through the entire colon up to the cecum and backward [38]-[41]. The capsule endoscope consists of two optical lenses mounted on the end of the vehicle balloon, a transparent

dome, white-emission light diodes for illumination, and a digital camera. The lenses are used to provide real-time images that are displayed on the monitor of the workstation for visualization during colonoscopy. The images can also be recorded and saved for later evaluation or examination [38]-[41].

2.3.3 NeoGuide System

The NeoGuide Endoscopy System (NES) shown in Figure 9, introduced in 2009, was designed to be able to diagnose and treat diseases in the colon as well as provide visualization of the colon of each individual patient. The NES uses a fully articulated, computer-controlled insertion tube. The computer controls the shape of the insertion tube by directing the segments of the insertion tube to follow the shape of the colon, which would reduce loop formation and discomfort of the patient [42]-[45].

Figure 9. The console of the NeoGuide Endoscopy System with its insertion tube (NES) [42].

During colonoscopy, the insertion tube is manually moved toward the cecum of the colon, and the other segments of the scope chase the track of the tip. The segments of the scope are individually controlled by motors. Although, the NES and standard colonoscopes have some similar features, the NES has additional features such as a tip position sensor (TPS) and an external position sensor (EPS). The TPS is placed inside the tip segment to evaluate the steering commands, and the EPS is placed at the backside of the patient to measure the length of the inserted portion of the insertion tube. The insertion tube shown in Figure 10 has a total length of 173 cm and the diameter of the scope increases gradually from 14 mm at the tip to 20 at the proximal end. The insertion tube of the NES consists of 16 segments that are controlled by the NES controller. The segments can perform movements in up, down, right, and left directions as well as combinations of movements in these directions [42]-[45].

Figure 10. The insertion tube of the NeoGuide System (NES) consists of multiple controlled segments that work in “Follow-the-Leader” manner [42].

All the segments have the same length, which is 8 cm. Since the insertion tube of the NES is longer and heavier than that of standard colonoscopes, a supporting arm is used to hold the scope to eliminate the need for a colonoscopist to hold the scope during colonoscopy [42]-[45]. As the insertion tube is inserted through the colon, the NES generates a real time visualization of the shape of colon as three-dimensional images. This visualization supplies precise information about the shape of looping of the colon, the insertion tube and the tip segment during colonoscopy. This information helps reduce loop formation and applied forces to move the insertion tube further through the colon [46].

2.3.4 Shaft Guidance

In an attempt to improve the colonoscopic procedure and reduce the pain and discomfort associated with such a procedure, three types of shaft guidance were developed: Shape-locking guide, Rigid-flexible outer sheath, and FORGUIDE. These devices work as a sheath to prevent loop formations, perforations and stretch injury to the colon caused by the direct contact between the inserting tube and the colon walls.

2.3.4.1 Shape-Locking Guide

The Shape-locking guide (SG-1) has the ability to be rigid and flexible as needed [47]. The SG-1 is an overtube that has a metal multilink skeleton, and it also has an inner hydrophilic liner, and an outer coating [47], [48]. Its rigidity and flexibility are controlled by a squeeze handle placed on the shape-locking guide skeleton as shown in Figure 11

[47]. The SG-1 is easily able to cover up the insertion tube of the colonoscope and to pass and maneuver through colonic flexures and sharp bends when the SG-1 is in its flexible form [47]. Once the tip of the SG-1 reaches the wanted point, the shape of the SG-1 is locked using the squeeze handle. The obtained rigid configuration protects the colon wall from the forces applied on the insertion tube of the colonoscope by redirecting the forces toward the tip [29]. In this way, all the forces would be pushing the distal tip of the insertion tube to advance into the colon. To evaluate the performance of the device, it was tried in an artificial colon model and in a pig colon [47]. The obtained data showed that the device is safe to use and able to resist and prevent loop formations in the sigmoid colon, to protect the colon walls from damage, and to improve cecal intubation [47]-[49]. Therefore, this device is less traumatic and painful for the patients, reducing the risk of bleeding and perforation [47], [48].

Figure 11. The SG-1 with rigidity controlling squeeze handle [47].

2.3.4.2 Rigid-Flexible Outer Sheath

A rigid-flexible outer sheath for a flexible endoscopic manipulator was developed to provide a stable and sustained path to support the flexible insertion tube of the colonoscope during colonoscopy. [50]. This device comprises a number of units connected together as a chain by pins. Each unit consists of a link, a slider, a stopper, and an air channel as shown in Figure 12 [50]. The slider is connected to the link and can move inside the slider channel upon the movement of the unit around the pin. The rigidity of the Rigid-flexible outer sheath is obtained by applying air pressure in the air tube, which moves the stopper up to be connected with the slider by the metal teeth. Furthermore, the flexibility can be obtained by stopping the air pressure so that the stopper moves down due to a spring connected to the stopper as shown in Figure 3 [50]. The flexibility of the sheath enables it to readily pass the colonic flexures. On the other hand, the rigidity of the sheath forms a path through the colon to the desired position and provides sufficient support to the flexible instruments [50]. The experimental results showed that this device is able to maintain the shape of the obtained path inside the colon while the flexible insertion tube of the colonoscope advances through the sheath. [50].

Figure 12. Rigid-flexible outer sheath, (a) when it is flexible, (b) When it is rigid [50].

2.3.4.3 FORGUIDE Shaft

A flexible colonoscope is suitable for better and easier advancement of the insertion tube through the sharp bends of the colon. However, this flexibility allows loop formations to occur readily. On the other hand, a rigid colonoscope is required to support the flexible instruments inserted through it and to push the distal tip of the insertion tube towards the cecum [51]. In an attempt to resolve the conflict between the rigidity and flexibility desired for a better, less painful, and less traumatic colonoscopic procedure, an elongated shaft called FORGUIDE was developed [52]. The rigidity of the FORGUIDE is controllable. As shown in Figure 13, the device is made of three layers. The first layer is an inflated tube located in the center of the FORGUIDE; the second layer is a number of cables circled around the central tube and fixed to the distal tip; and the third layer is a stiff ring used to tighten the cables around the central tube [52]. The mechanism of the device depends on keeping the cables in their positions and preventing them from sliding [52].

Figure 13. (a) 3-D view of a FORGUIDE shaft cut open, (b) FORGUIDE shaft in its compliant state, (c) FORGUIDE shaft in its fixed state [52].

To obtain the desired rigidity, the central tube is expanded due to applied pressure with water. This expansion fixes the cables in their position so that they are no longer able to move [52]. Thus, the length of the FORGUIDE is locked and rigidity is obtained. The obtained results showed that having controllable rigidity enables the FORGUIDE to be flexible when it comes to maneuvering and passing sharp bends and to be rigid when the flexible instruments are being used [52]. Loop formations, perforations, and

bleeding are eliminated using FORGUIDE because it protects the colon walls from being damaged by the instruments, and its rigidity prevents loop formations [52].

2.3.5 Passive Bending Technique

Two technological advancements were developed, which are the passive bending and a high force transmission insertion tube, to ease the passing of the insertion tube through sharp flexures of the colon [53]. The passive bending part is a tube with the same structure as the distal tip. It is placed between the insertion tube and the distal tip as shown in Figure 14. The structure of the passive bending part enables the distal tip to bend with a bigger radius along with the insertion tube [53]. This feature eliminates stick phenomenon, which occurs when the insertion tube pushes the colon wall as the distal tip bends in a small radius. The passive bending part bends due to combined external forces applied by the physician and the reciprocal force from the colon wall [53]. Therefore, most of the applied force will be directed to the distal tip to move the insertion tube forward through the colon [53]. The second technological advancement is the high force transmission insertion tube. Using this tube, the applied force by the physician, including push, pull and twist, will be fully transferred to the distal tip. Using an insertion tube with the previously mentioned technological advancements would improve the completeness of difficult colonoscopies [53].

Figure 14. Location of the passive bending portion in the insertion tube [53].

A study was done by G. Hoff and M. Bretthauer to evaluate a new colonoscope, (XCF-Q160AW prototype, Olympus, Tokyo, Japan), as shown Figure 15 in comparison to a standard colonoscope, (Olympus 140 series) [54]. Essentially, the prototype is a standard variable-stiffness colonoscope with a passive bending portion placed between the insertion tube and the distal tip [54]. Cecal intubation rate and the level of patient discomfort were evaluated. 280 patients were included in this study, divided into two groups, and uninformed regarding the type of scope utilized [54]. The collected data showed no significant difference in the cecal intubation rate between the new colonoscope and a standard colonoscope. However, reduction of pain and discomfort was achieved using the new colonoscope due to the use of the passive bending technique [54].

Figure 15. The prototype XPCF-160AWY endoscope [54].

Another study was conducted by G. Hoff and V. Moritz on two prototype colonoscopes (Olympus XCF-Q180YI and XCF-Q180AYI) to evaluate the effectiveness of using a new passively bending hyper-flaccid segment, as shown in Figure 16 [55]. The mentioned two prototypes are similar to each other except that the stiffness of the Olympus XCF-Q180YI is variable as required. The passively bending hyper-flaccid segment is placed between the distal tip and the insertion tube. It is able to bend in all directions, converting the pushing force applied on the insertion tube by the physician gradually to the distal tip to move it toward the cecum. The data obtained from this study, which included 400 patients, concluded that the proposed passive bending reduces pain and helps the insertion tube pass through sharp passages [55].

Figure 16. The passively bending hyper-flaccid segment [55].

2.3.6 Applied Forces and Colonoscopy Force Monitor (CFM)

The CFM, as shown in Figure 17, was utilized in a series of colonoscopies to demonstrate the ability of the CFM to recognize various patterns of applied forces. The study included thirty patients and was performed by seven expert colonoscopists [56]. Forces such as push, pull, and torque were determined and analyzed to show the patterns in which the colonoscopists applied forces on the insertion tube of the colonoscope to maneuver and advance the insertion tube in the colon. The CFM is easy to attach and move on the insertion tube of the colonoscopy without interrupting the procedure, which makes it safe and easy to use. Also, the device has the ability to determine the forces and display them on a computer connected to the CFM via Bluetooth [56]. The obtained results suggested that the device is able to recognize different patterns of applied forces on the insertion tube among different participating colonoscopists [56], [57].

Additionally, the device was found to be a useful tool to determine the best method to perform colonoscopy and to be used to train novices who seek to be professional colonoscopists [56].

Figure 17. Loading the colonoscope shaft into CFM, (a) dual clamshell is open and the insertion tube is placed in a central channel, (b) the device is closed and ready for force monitoring [56].

Through the colonoscopic procedure, different kinds of forces such as push, pull, and torque are applied to the insertion tube of the colonoscope to maneuver and advance it toward the cecum [58]. A force monitor was used to determine these forces as the

insertion tube was being inserted through the colon. The colon was sectioned into three segments: A, B, and C [58]. Segment A starts from the rectum and ends at the descending colon, B starts from where segment A ends and ends at the transverse colon, and C starts from the transverse colon and ends at the cecum [58]. The force monitor was attached to the insertion tube to calculate and display data in real time as the insertion tube was advanced from one part to another part. The data was collected from 49 procedures performed on 49 patients by seven expert and nine novice colonoscopists [58]. The obtained data showed that the applied force increases as the insertion tube moves closer to the cecum [57], [58]. This phenomenon occurs when the insertion tube moves deeper in the colon correlating with more contact surface area and more resistance between the insertion tube and the colon [58].

2.4 Thesis Objectives

The main focus of this research is to develop and preliminary test a novel distal tip extension mechanism (DTEM). The DTEM consists of four components: a compression spring, an extension knob, a distal tip extension link (DTEL), and a telescoping shaft. The investigation demonstrates the ability DTEM to elongate and retract the distal tip of the colonoscope up to 16 cm.

The main objectives of this thesis are as follows:

- 1- Developing a prototype of the distal tip extension mechanism (DTEM) to extend the distal tip 16 cm

2- Characterizing the performance of the DTEM in various configurations of the colon using a colon model

- Effect of implanting the DTEM in the colonoscope on the flexibility of the insertion tube
- Calculating and plotting the number of turns of the extension knob needed to extend the distal tip of the prototype up to 16 cm in various configurations of the colon
- Measuring the success and failure rates of the DTEM to fully extend the distal tip when the colon is in various configurations
- Calculating and plotting the torques applied on the extension knob of the DTEM to extend the distal tip of the prototype up to 16 cm in various configurations of the colon
- Determining the minimum bending radius and bending angle at which the DTEM is able to extend the distal tip 16 cm

CHAPTER 3: DEVELOPMENT OF THE DTEM PROTOTYPE

3.1 First Prototype

The first prototype shown in Figure 18 was fabricated to investigate the feasibility of the proposed extension mechanism and to ensure that it works properly. The distal tip extension mechanism was implanted in the Welch Allyn VS-100 Sigmoidoscope, which does the same functions and has the same structure of a conventional colonoscope, except for the length of the insertion tube. The average length of the insertion tube of the conventional colonoscope without the distal tip is 157cm, and the length of the insertion tube of the short colonoscope without the distal tip is 59 cm. Since the first prototype was fabricated to extend the distal tip up to 9 cm, the lengths of the air channel, water channel, biopsy channel, suction channel, light bundle, objective lens, four coil pipes and four angulation cables, which go through the insertion tube, had to be increased 9 cm. Instead, the insertion tube was shortened by cutting off a 9 cm portion. This action was taken because at this stage of the research, it was easier and cheaper to reduce the length of the insertion tube than buying and replacing the coil pipes and angulation wires. Furthermore, the air channel, water channel, biopsy channel, suction channel, light bundle and objective lens were cut and removed from inside the insertion tube, and only the coil pipes and the angulation wires were left inside the insertion tube. The first prototype of the distal tip extension mechanism (DTEM) consists of four parts shown in Figure 18: a compression spring, an extension knob, a distal tip extension link (DTEL), and a telescoping shaft. These parts are described in the following sections.

Figure 18. The colonoscope with the components of the DTEM: A telescoping shaft, an extension knob, a spring and a DTEL.

3.1.1 Compression Spring

The spring shown in Figure 19 used in the distal tip extension mechanism (DTEM) was affixed with the extension knob from one end using an adhesive, and the other end was fastened with the distal tip link by a nail. The spring was placed and affixed inside the extension knob. After that, it was inserted through the insertion tube and then fastened with the distal tip link. Thus the spring had to have the length of the insertion tube in addition to the length of the part of the spring placed inside the extension knob combined, which is about 61 cm. The spring used is made of high carbon steel and has the following characteristics: overall length 30.48 cm, outside diameter 9.5 mm, wire type round, wire diameter 1.04 mm, end type open, and 12 coils per 5 cm. The

springs used in the first prototype were ordered online from Grainger Company. Since the length of the spring does not match the desired length (61 cm), two springs were affixed together, forming one spring with a length of 61 cm. The spring fits inside the insertion tube, since its outer diameter is 9.5 mm, and the inner diameter of the insertion tube is 10 mm. The number of coils of the spring and the wire diameter determine the size of pitch, which is the space between every two adjacent coils. The pitch has to be big enough to allow the nail on the extension link to fit between the coils of the spring and allow the spring to separately rotate without causing the extension link to rotate.

Figure 19. The spring and the extension knob connected together.

3.1.2 Extension Knob

The extension knob was fabricated and placed between the proximate end of the insertion tube and the telescoping shaft. It consists of an outside metal cylinder, a right bearing and a left bearing as shown above in Figure 18 and Figure 19. The process of assembling the extension knob started by gluing three tubes, 2 cm each, over each other,

forming one tube referred to as the filling tube. The filling tube was used to fill out the space between the spring and the metal cylinder. Then, the spring was glued inside the filling tube. After that, the filling tube was affixed inside the metal cylinder using an adhesive. The right bearing was first slid over the spring until it was inserted inside the metal cylinder. The outside surface of the right bearing was then glued to the inner surface of the metal cylinder. On the other end of the metal cylinder, the left bearing was affixed edge to edge with the metal cylinder using an adhesive. The purpose of adding the two bearings to the extension knob is to allow the extension knob to rotate separately from the telescoping shaft and the insertion tube attached to it.

3.1.3 Distal Tip Extension Link

The distal tip extension link (DTEL), which is made of three plastic tubes, was built to be inserted inside the spring from one end and was affixed to the proximate end of the distal tip at the other end. Thus, the DTEL had to have a distinct diameter for each end. To provide these two distinct diameters, the DTEL was constructed of three tubes, as shown in Figure 20. The first tube, 10 cm long, goes inside the spring; therefore, its outside diameter is slightly smaller than the inside diameter of the spring, in order to allow the DTEL to move through the spring. The third tube, 1.5 cm long, is affixed to the proximate end of the distal tip; therefore, it has the inner and outer diameters of the distal tip (10 and 12 mm), respectively. The second tube, 1.5 cm long, was used to occupy the space between the first tube and third tube, since all the three tubes have to be affixed to

each other. A nail was used to connect the DTEL with the spring. The DTEL is used to provide the 9 cm extension length generated from using the DTEM.

Figure 20. The DTEL is connected to the distal tip from one end and to the spring from the other end.

3.1.4 Telescoping Shaft

The telescoping shaft was constructed with three plastic tubes, as shown in Figure 21. These tubes must not only fit properly, but also be able to smoothly slide inside of each other. Therefore, the diameters of the tubes were adjusted via a lathe machine. The first tube, named the base tube, is the biggest among the three tubes in terms of outside and inside diameters. The base tube, the second tube, and the third tube have a length of 6.5, 5.5 and 6.5 cm, respectively. Using the lathe machine, four protruding lips were made on the three tubes of the telescoping shaft to prevent the tubes from losing connection while they are being expanded. The three tubes were inserted inside of each other so that when the telescoping shaft fully expands, the first and second lips meet together, and the third and fourth lips also meet together, keeping the four lips attached

forming the telescoping shaft. The telescoping shaft primarily has two jobs. The first job is to cover up the extra 9 cm of the wires, pipes, and channels previously mentioned while the distal tip is unexpanded. The second job is to gradually provide additional length needed for the wires, pipes and channels as the distal tip of the colonoscope extends by gradually pushing the base tube over the second and third tubes.

Figure 21. The telescoping shaft is connected to the control head from one end and to the extension knob from the other end.

3.2 Second Prototype

The second prototype shown in Figure 22, which is also the final prototype, was developed in a way that allows the distal tip extension mechanism (DTEM) to extend the distal tip of the colonoscope up to 16 cm. The DTEM is used when the insertion tube of the colonoscope is within the descending colon to help physicians reach the cecum to perform complete colonoscopy. The sixteen centimeters extension was chosen to ensure that the tip of the distal tip reaches the cecum, since the average length of the descending colon is about 16 cm [28]. For this prototype, a CF-100TL Olympus Colonoscope is

used. The colonoscope has a working length of 179 cm including the length of the distal tip, which is 13 cm, and the outer and the inner diameters of the insertion tube are 13 mm and 10 mm, respectively. The CF-100TL Olympus colonoscope has the following parts installed inside the insertion tube: four angulation cables, an instrument channel, an air channel, a water channel, two fiber optic cables, and two wires for the video camera. From now on, I will refer to these parts as the insertion tube instruments. The inner diameter of the insertion tube is 10 mm, which is enough to accommodate the insertion tube instruments. However, its size is insufficient to accommodate parts from the DTEM that should be placed inside the insertion tube. These parts are two compression springs that are placed along the insertion tube. The insertion tube instruments should be placed inside these springs, and then the springs are placed inside the insertion tube. Thus, the insertion tube had to be replaced with an insertion tube that is able to accommodate the springs in order for the DTEM to work. The biggest insertion tube available in current markets has an inner diameter and an outer diameter of 11.55 mm and 13.8 mm, respectively. The new insertion tube was found to be able to accommodate some of the insertion tube instruments and the springs of DTEM. The instrument channel, water channel, air channel were excluded from the prototype. Implanting the distal tip extension mechanism (DTEM) in the colonoscope increases the total length of the colonoscope up to 195 cm when the DTEM is fully extended. Such an operation must be accompanied by replacing the coil pipes, angulation wires, light bundle, and wires of the video camera with longer ones to match the new length of the colonoscope. The angulation wires and the coil pipes are often 200 cm in length and with no stoppers attached to them.

Figure 22. DTEM is implanted in the CF-100TL Colonoscope with the main parts of the DTEM shown.

The stoppers are small metal objects attached to the coil pipes and angulation wires, and they are used to attach the coil pipes and the angulation wires to the instrument control head of the colonoscope. However, providing and placing longer parts would have been both unaffordable and difficult. Thus, I had to cut down the coil pipes and the angulation wires to an appropriate length. Then, the stoppers were attached to both the angulation wires and the coil pipes using solder, which is the method that is usually used to attach the stoppers. The light bundle and the wires of the video camera were not replaced, but instead the universal tube was shortened by 16 cm. The universal tube is the tube that attaches the instrument control head to the supply unit. By shortening the universal tube

by 16 cm, the lengths of the light bundle and the wires of the video camera were also increased by 16 cm.

The distal tip extension mechanism (DTEM) implanted in the second prototype consists of four main parts, as shown in Figure 22: a compression spring, an extension knob, a distal tip extension link (DTEL) and a telescoping shaft. These parts were combined together to elongate the distal tip up to 16 cm. Each part of the DTEM has its own unique structure and role. The compression spring pushes the DTEL. The DTEL moves in and out the insertion tube moving the distal tip along with it. The extension knob rotates the compression spring and separates this rotation from the rest of the colonoscope. The telescoping shaft stores the 16 cm additional length of the insertion tube instruments when the DTEM is not extended and provides length to the insertion tube instruments as the DTEM extends.

3.2.1 Compression Spring

The flexibility of the insertion tube is essential to perform complete colonoscopy. Otherwise, colonoscopists would not be able to manipulate the insertion tube through the curvatures of the colon. Thus, this part of the DTEM was chosen to be a compression spring because of its high flexibility. The compression spring is an open-end spring with no pitch change through the ends of the spring, and it is made of stainless steel. It has inner and outer diameters of 8.4 mm and 11.125 mm, respectively, a length of 170 cm, a pitch of 3.3 mm, and a constant of 0.0639 N/mm. The spring is placed inside the insertion tube. The compression spring is welded to a metal adapter at one end, as shown in Figure

23. The metal adapter is fixed to the extension knob via four screws. The other end of the compression spring is left open to allow the distal tip extension link (DTEL) to slide in and out of the compression spring.

Figure 23. The compression spring of the DTEM attached to the metal adapter.

3.2.2 Extension Knob

The extension knob shown in Figure 24 was created to rotate the compression spring in order to generate the pushing and pulling forces in the compression spring. These forces are used to elongate and retract the distal tip of the colonoscope up to 16 cm. The extension knob also separates the rotation of the compression spring from the rest of the colonoscope.

Figure 24. The extension knob of the DTEM in three different views.

It consists of an aluminum cylinder, two steel ball bearings, two internal retaining rings, an external retaining ring, an aluminum adapter, and two steel adapters, as illustrated in Figure 25. The ball bearings have an outer diameter, an inner diameter, and a width of 31.75 mm, 15.875, and 11.11 mm, respectively. Aluminum 6061 was the chosen material to make the cylinder because of its light weight. The aluminum cylinder also has a diameter of 4.6 cm and a central hole of 12 mm to allow the insertion tube instruments to pass through. The assembly process of the extension knob consists of multiple steps. First, the first steel adapter, which is welded to the compression spring, was affixed to the aluminum cylinder via four screws. Second, one of the ball bearings was placed over the second steel adapter, which holds the insertion tube, using the external retaining ring. Third, the combined ball bearing and steel adapter were placed inside the aluminum cylinder using one of the internal retaining rings. Fourth, the aluminum adapter and the other ball bearing were assembled and placed inside the aluminum cylinder via the second internal retaining ring. The extension knob is connected to the compression spring and the insertion tube at the right end of it and connected to the telescoping shaft at the left end. The extension and retraction of the

distal tip starts by rotating the aluminum cylinder, causing the compression spring to rotate, since they are fixed together via four screws. Additionally, the rotation of the cylinder and the compression spring is separated from the insertion tube and the telescoping shaft because they are connected to the cylinder by the ball bearings.

Figure 25. Components of the extension knob of the DTEM.

3.2.3 Distal Tip Extension Link

As mentioned in the first prototype, a flexible plastic tube was used as a distal tip extension link (DTEL), and it was connected to the compression spring using a steel nail. The same method was first tried in the second prototype; however, it failed for a number of reasons. The first reason is the inner and outer diameters of the plastic tube. The tube must at least have an inner diameter of no less than 8 mm to be able to accommodate the insertion tube instruments. Also, its outer diameter must not be larger than 8.3 mm to be able to slide through the compression spring because the inner diameter of the compression spring is 8.4 mm. Since such a tube does not exist with these diameters, it had to be machined using a lathe machine. Although the tube was machined to the needed

diameters, it did not function as expected for the prototype because of its thin wall thickness. The tube was supposed to hold the steel nail in position when pushing and retracting forces are applied; instead, the nail tore the tube because the wall of the tube was too thin. The second reason is the flexibility of the DTEL. Maintaining the flexibility of the objects of the colonoscope that are inserted through the colon is a major factor to perform complete colonoscopy. However, the flexibility of the DTEM was highly decreased using the machined tube. The tube tightly held the insertion tube instruments because its 8 mm inner diameter barely contained the insertion tube instruments. The part of the insertion tube instruments covered by the tube formed a stiff portion that was unable to bend to the same extent as the rest of the insertion tube.

To overcome the previously mentioned problems associated with using a plastic tube and a steel nail as a DTEL, a spring was used instead. The spring used to make the DTEL shown in Figure 26 is a compression spring with a length of 60 cm.

Figure 26. The DTEL which is a 60 cm compression spring.

Using a compression spring as a DTEL was chosen for various reasons. The first reason is that the DTEL would be flexible and able to bend since it is a flexible spring. The

second reason is that the inner and outer diameters of the DTEL are the same as the diameters of the compression spring, which are 8.4 mm and 11.125 mm, respectively. These diameters are sufficient to hold the insertion tube instruments without forming a stiff portion. The other reason is that using a spring as a DTEL eliminates the need to use any physical object as a connector between the DTEL and the compression spring.

3.2.4 Telescoping Shaft

The telescoping shaft was created as a part of the distal tip extension mechanism (DTEM). It consists of four solid plastic tubes, as shown in Figure 27 (a), rather than three as in the first prototype of the DTEM. The telescoping shaft is fully extended when the DTEM is not in use and fully compressed when the DTEM is fully extended, as shown in Figure 27 (a and b). Since the length of the colonoscope changes as the distal tip extends and retracts, the length of the insertion tube instruments changes. The telescoping shaft is made to provide flexibility in the length of the insertion tube instruments. When the distal tip extends, the telescoping shaft retracts to allow the insertion tube instruments to move along with the extension of the distal tip. When the distal tip retracts, the telescoping shaft extends to store the extra length of the insertion tube instruments inside of it. The length of the telescoping shaft is 8 cm when fully retracted and 24 cm when fully extended. In other words, the length of the base tube is 8 cm, and the extension length of the telescoping shaft is 16 cm. One way to reduce the total length of the prototype is to reduce the total length of the telescoping shaft; however, the 16 cm extension length of the telescoping shaft cannot be reduced since it

needs to match the 16 cm extension length of the distal tip. Thus, the only option to reduce the length of the telescoping shaft is by reducing the length of the base tube. Decreasing the length of the base tube must be accompanied with shortening the other segments of the telescoping shaft and increasing the number of segments. The segments must be shortened so that the base tube can accommodate them when the telescoping shaft is fully compressed. Also, the number of segments must be increased to maintain the 16 cm extension length.

(a)

(b)

Figure 27. The telescoping shaft of the DTEM, (a) illustrates the telescoping shaft when fully extended, (b) illustrates the telescoping shaft when fully compressed.

That is why the telescoping shaft in the second prototype consists of four tubes rather than three tubes as in the telescoping shaft of the first prototype. The four tubes are the base tube (8 cm), the second tube (6 cm), the third tube (6 cm), and the forth tube (5.5 cm). The second tube, third tube, and fourth tube are referred to as movable tubes. The movable tubes generate the 16 cm extension length as follows: 5.5 cm from the second tube, 5.5 cm from the third tube, and 5 cm from fourth tube. The tubes of the telescoping shaft were made of solid plastic bars using a lathe machine to match the DTEM's specifications. The telescoping shaft is placed between the control head and the extension knob. The base tube is attached to the control head, and the distal end of the telescoping shaft is attached to the aluminum adaptor of the extension knob.

3.3 DTEM Functionality

The proposed distal tip extension mechanism (DTEM) was developed to elongate and retract the distal tip of the colonoscope up to 16 cm. The DTEM was implanted in the colonoscope CF-100LT. The distal tip of the colonoscope can be moved forward and backward by rotating the extension knob of DTEM in counterclockwise and clockwise directions, respectively, while the telescoping shaft is being compressed and expanded, respectively. Two ball bearings were used in the extension knob to separate the rotation of the aluminum cylinder of the extension knob and the compression spring from the rest of the colonoscope. When the extension knob is rotated, it rotates the compression spring installed along the insertion tube and overlapped with the DTEL. The rotation of the compression spring pushes the DTEL up and down depending on the direction of

rotation. The DTEL slides along the coils of the compression spring causing the distal tip to extend and retract. The extension of the distal tip is a combination of rotating the extension knob and compressing the telescoping shaft. Partial extension to the distal tip can be obtained without rotating the extension knob. By moving the instrument control head of the colonoscope forward and holding the extension knob in position, the telescoping shaft compresses, and the insertion tube instruments push the distal tip forward. Since the telescoping shaft has three movable tubes in addition to the base tube, the extension of the distal tip is divided into three stages. The first stage is pulling the fourth tube into the third tube and then rotating the extension knob until the distal tip moves forward 5 cm. The second stage is pulling the third tube back into the second tube and rotating the extension knob until the distal tip moves forward 5.5 cm. The third stage is pulling the second tube back into the base tube and rotating the extension knob until the distal tip moves forward another 5.5 cm. Combining the extension of all three stages results in a full extension (16 cm) of the distal tip. For extension, the extension knob must be rotated counterclockwise, and for retraction, the extension knob must be rotated clockwise. During the extension process, the extension knob rotates in the counterclockwise direction along with the compression spring pushing the DTEL gradually out of the compression spring. For retraction, on the other hand, the compression spring rotates in the clockwise direction pulling the DTEL gradually back in the compression spring.

CHAPTER 4: EXPERIMENTS METHODOLOGY

4.1 Introduction

The proposed distal tip extension mechanism (DTEM) was developed to elongate and retract the distal tip of the colonoscope up to 16 cm. The DTEM was implanted in the colonoscope CF-100LT. The distal tip of the colonoscope is supposed to move forward and backward by rotating the extension knob of DTEM counterclockwise and clockwise, respectively, while the telescoping shaft is compressed and expanded, respectively. When the extension knob is rotated, it rotates the compression spring installed along the insertion tube, which causes the compression spring to overlap with the DTEL. The rotation of the compression spring pushes the DTEL forward and backward, depending on the direction of rotation. The DTEL slides along the coils of the compression spring causing the distal tip to extend and retract.

Colonoscopy is associated with complications that in some cases could cause failure to achieve complete colonoscopy. A complete colonoscopy is a term used to indicate that the procedure is done successfully. Also, cecal intubation rate is an important factor in colonoscopy and it should be achieved no less than 90% of the time [10]. Cecal intubation is the process of reaching the cecum, which is the last part of the colon.

Several experiments were conducted to characterize the performance of the DTEM prototype. The experiments study (1) the effect of implanting the DTEM in the colonoscope on the flexibility of the insertion tube, (2) the ability of the DTEM to elongate the distal tip up to 16 cm when loops exist, (3) the success rate of performing a

full extension for the distal tip when the colon is in different configurations, (4) the effect of colon configuration on the amount of the forces exerted on the extension knob during the extension of the distal tip, and (5) the bending radius and bending angle at which the DTEM fails to extend the distal tip of the prototype.

4.2 Flexibility of the Insertion Tube

As mentioned in section 2.3.1, flexibility of the insertion tube is important to enable the insertion tube to advance through the colon and maneuver the bends of the colon. The insertion tube of the colonoscope has to have a balance between flexibility and rigidity [29]. It needs to be flexible to be able to navigate through the bends of the colon and rigid to resist looping in the colon. A more flexible insertion tube helps overcome acute bends along the colon and helps pass through cavities of the colon. However, it is more likely to cause looping. On the other hand, a more rigid insertion tube resists looping, but it is more difficult to pass through the bends of the colon. Although flexibility of the insertion tube has direct effects on the success of colonoscopy, there is not a certain value or limit of the flexibility that the insertion tube needs to have in order to obtain the best behavior of the insertion tube. Unfortunately, there is not a specific value for how flexible the insertion tube should be, since several factors make each colonoscopy procedure a unique case. Some of these factors are age, gender, looping in the sigmoid colon, colon length, existence of diseases, sharp bends, and a narrow colon. Also, some of these factors make the anatomy of the colon vary from patient to patient.

4.2.1 Compliance Test

The distal tip extension mechanism (DTEM) is implanted in the colonoscope with the compression spring along the insertion tube and the distal tip extension link (DTEL) placed at the distal end of the insertion tube. The flexibility of the insertion tube is affected by adding the compression spring and DTEL inside the insertion tube. A compliance test was performed to assess the affect of implanting the DTEM in the colonoscope on the flexibility of the insertion tube. The compliance test was conducted on the insertion tube of the original colonoscope and on the insertion tube of the prototype of the DTEM, which is the same colonoscope but with the DTEM implanted.

The insertion tube was segmented into two regions, which are referred to as first segment and second segment, as shown in Figure 28. The lengths of the segments were chosen to cover two different cases that the insertion tube experiences during colonoscopy.

Figure 28. The two rings where the compliance test is performed. The first ring is at the middle of the first segment and the second ring is at the middle of the second segment.

The first segment, the last 60 cm of the insertion tube, covers the area where the compression spring and the DTEL overlap, and this segment passes through almost all the bends of the colon to enable the distal tip to reach the cecum. The second segment, from the beginning of the insertion tube to the first segment, covers the area where only the compression spring exists. Additionally, at the middle of each segment, a ring of four points A, B, C and D on the surface of the insertion tube, was made, as illustrated in Figure 28. The points are 90° apart forming a complete cycle around the circumference of the insertion tube, as shown in Figure 29. Since the structure of the insertion tube is nonhomogeneous along the circumference, the insertion tube was tested at four positions around the circumference to reduce the nonhomogeneous structural effects and increase the precision of the obtained results.

Figure 29. Cross-section of the insertion tube with the four tested points of each ring. The points are 90° apart forming a complete cycle along the circumference of the insertion tube.

4.2.2 Experiment Setup

The setup of the compliance experiment is shown in Figure 30. It consists of an aluminum frame body, a dual-range force sensor, a Vernier LapPro device, and a portable computer. The aluminum body frame was constructed to hold the force sensor and also to hold the insertion tube in a $\cap$ configuration during the experiment. The frame has three aluminum bars to hold the insertion tube in a $\cap$ shape.

Figure 30. Illustration of the compliance test setup with its main components.

The left side of the $\cap$ shape is the force sensor, the top bar is able to slide up and down, and the right side bar is able to slide to the right and the left, as illustrated in Figure 31.

The top and right side bars are movable to change the size of the $\cap$ shape. The size of the $\cap$ shape can be changed to form a half circle with a range of diameters between 8 cm and 15 cm. Marks were made on the frame to highlight the range of diameters. The aluminum frame is fixed to a stable table to prevent distractions during the experiment.

Figure 31. Detailed illustration of the compliance test setup showing the three bars that form the $\cap$ shape, the insertion tube during being tested.

The Vernier LabPro is a data collection interface that is able to collect data from various environments using digital sensors such as motion detectors and radiation monitors, or analog sensors such as temperature probes and force sensors [59]. The Vernier LabPro should be connected to a computer via a USB cable in order to display the collected data. In order to display the collected data on the computer, software named Logger Pro was installed on the computer. The Logger Pro software was set to collect data for duration of 10 seconds including the zero second. The samples rate of the data

collection was set to 1 sample/second. Thus eleven samples were collected for each trial of the experiment. The Logger Pro software is able to export the collected data to be saved on a computer in text form, GIS format and CSV (Excel). In this experiment, the collected data was saved to Excel using a shortcut, which is select-copy-paste.

The dual-range force sensor used in the experiment has two ranges of forces, which are -10 N to 10 N and -50 N to 50 N. The force sensor was set to the second range of force, which is -50 N to 50 N, since the resistance force of the insertion tube to bend is within the limits of the second range. Before the data was collected, the dual-range force sensor was calibrated to set the initial force value to zero. The force sensor is connected to the Vernier LabPro using one of the four analog channels. The force sensor is attached to the aluminum frame by first mounting the T nut to the aluminum frame and then fixing the force sensor to the T nut using the thumbscrew.

4.2.3 Test Methodology

In order to determine the effect of implanting the compression spring and the distal tip extension link (DTEL) in the colonoscope on the flexibility of the insertion tube, a comparison was made between the insertion tube of the colonoscope and insertion tube of the prototype in terms of the force generated by bending the insertion tube at different diameters. The compliance test was applied on the insertion tube of the colonoscope and the insertion tube of the prototype. The prototype's insertion tube essentially is the insertion tube of the original colonoscope in addition to the compression spring and the DTEL implanted into it. Each insertion tube was tested at the four points at

each of the two segments. The insertion tube was placed between the bars of the aluminum frame in a $\cap$ shape. The insertion tube leans on the right side bar, the top bar, and the dual-range force sensor at the left side of the $\cap$ shape. Each point was tested eight times in each trial by changing the diameter of the $\cap$ shape from 15 cm to 8 cm. The point being tested was located at the middle top part of the $\cap$ shape leaning on the top bar. The compliance test was repeated three times on the insertion tube of the prototype and then three times on the insertion tube of the colonoscope. Points A, B, C, D of the first segment were tested first, and points A, B, C, D of the second segment were then tested. The bending diameter of the insertion tube was reduced gradually for each trial by one-centimeter increments. This was achieved by decreasing the size of the $\cap$ shape each time the experiment was repeated until the bending diameter became 8 cm. Eight centimeters was the minimum diameter chosen for this experiment. The collected data from the compliance test was arranged in two tables, one for the data obtained from the insertion tube of the prototype and the other for the data collected from the insertion tube of the colonoscope. Each table was divided into four areas named point A, B, C, and D representing the points at each segment.

4.3 Looping in the Colon

As stated in section 2.2.1, looping in the colon is one of the complications associated with colonoscopy. It occurs in most of the performed colonoscopies. Sometimes, complications can cause failure by preventing colonoscopists from screening the entire colon. Most of the looping occurs in the sigmoid colon and the transverse

colon. Mostly, loops are formed because of the curvatures of the colon. When the distal tip of the colonoscope hits a bend in the colon and the colonoscopist keeps inserting the insertion tube in the colon, loops start forming. Looping occurs in different shapes. The most common shapes of looping are N shape, Alpha shape, and reverse Alpha shape.

Many techniques are used to overcome looping such as changing the position of the patient and applying abdominal pressure on the area where loops are forming [15]. However, some loops cannot be unformed, unless colonoscopists withdraw the insertion tube out of the patient and reinsert it. Such a practice would prolong the procedure time and make the procedure more uncomfortable for patients. Thus, new methods to enable the distal tip to reach the cecum are needed in order to reduce complications. The DTEM is supposed to be able to elongate the distal tip up to 16 cm even though looping exists, and the insertion tube can no longer be advanced into the colon.

4.3.1 Extension Test

The extension test was performed to investigate the ability of the DTEM to elongate the distal tip up to 16 cm while the colon is in different configurations and loops exist. Also, the extension test was conducted to determine the number of turns that the extension knob needs to make in order to reach full extension for the distal tip. The extension of the distal tip is a combination of rotating the extension knob and compressing the telescoping shaft. Partial extension to the distal tip can be obtained by compressing the telescoping shaft without rotating the extension knob. By moving the instrument control head of the colonoscope forward and holding the extension knob in

position, the telescoping shaft is shortened, and the insertion tube instruments push the distal tip forward.

4.3.2 Experiment Setup

The experiment was set up to simulate the colonoscopy procedure when the colon is in different configurations. A colonoscope training model (CTM) shown in Figure 32 was supposed to be used as a representation of the human colon [60]. The CTM has a flexible soft silicon tube. This tube provides a response similar to that of the human colon. The silicon tube can be set up in multiple configurations to simulate different looping shapes [60].

Figure 32. Demonstration of the colonoscope training model (CTM) with the names of some of its components shown [60].

The CTM has an anal sphincter opening that can be adjusted *via* a hand pump. It also has a skin cover used to cover the flexible colon tube. Lubricant gel provided with the CTM was used to facilitate the manipulation of the insertion tube through the silicon tube. However, the idea of using the CTM was abandoned for two reasons, which are direct visualization and adequate space in the CTM. Direct visualization of the extension of the distal tip through the silicon tube is required to follow the movement of the distal tip and collect data. To overcome this obstacle, the lid at the end of the silicon tube was first removed and the tip of the distal tip was placed at the end of the silicon tube, so that the extension of the distal tip can be observed. Adequate space in the CTM is also needed to provide enough space for the distal tip to move 16 cm outside the silicon tube. However, the CTM lacks the needed space because the silicon tube occupies the entire room inside the CTM. Therefore, the body of the CTM was abandoned and only the silicon tube was used in this experiment.

The silicon tube was removed from the CTM and placed on a table to provide enough space for the distal tip to extend from the end of the silicon tube. The lid at the end of the silicon tube was removed to maintain direct visualization at the distal dip during the extension. Plastic rings and pins were used to fix the silicon tube to the table in different configurations. Also, a colonoscope stand shown in Figure 33, which is developed by one of Ohio University's Engineering Department's mechanical engineering graduate students (Rajesh Ravindra Shanbhag), was used to hold the DTEM prototype during experiments.

Figure 33. The colonoscope holder holds the prototype during performing the extension experiments.

Additionally, training layouts of the most common configurations, which are N loop, Alpha loop, and reverse Alpha loop, come with the CTM. They were used to simulate the shape of the colon and the loops for the extension test, as shown in Figure 34.

Figure 34. Some of the layouts that come with the CTM. The N shape, Alpha shape, and Reverse Alpha shape are shown because they present the most common looping shapes.

4.3.3 Test Methodology

The extension test was conducted to examine the ability of the DTEM to elongate the distal tip 16 cm while the colon is in different configurations and loops. The three most common loops, previously mentioned in section 4.3, were simulated using the silicon tube and the training layouts. Five configurations were set up: Straight-line shape, U shape, N shape, Alpha shape, and reverse Alpha shape, as shown in Figure 35. The straight-line shape does not exist in the human colon; however, it was used as a starting point for the experiment. The insertion tube of the prototype was first inserted through the silicon tube until the tip of the distal tip was at the end of the silicon tube. Then, the desired configuration was formed and fixed to the table. Five trials were conducted for each configuration, and the number of turns was recorded at three points. The points are A, B, and C at 5 cm, 10.5 cm, and 16 cm extension, respectively. The extension process

was divided into three stages. The first stage is that the telescoping shaft was compressed 5 cm, and the extension knob was rotated until the distal tip reached point A. The extension of the distal tip caused by compressing the telescoping shaft and the number of turns were recorded. The second stage and the third stage are similar to the first stage with one exception. The exception is that the telescoping shaft was compressed 5.5 cm in each of the two stages instead of compressing 5 cm. Also, the extension knob was rotated until the distal tip reached point B and point C, in the second stage and the third stage, respectively. The extension caused by compressing the telescoping shaft, and the number of turns was recorded at each point. To compress the telescoping shaft, the extension knob was held in position while the instrument control head of the prototype was pushed toward the extension knob.

Figure 35. Illustration of the five configurations used in the extension test.

4.4 Torque Test

To study the effect of the colon configuration on the torque applied on the extension knob to displace the distal tip 16 cm the torque test was performed. Also, the average torque force and the maximum torque exerted on the extension knob during the extension of the distal tip for each configuration were calculated. During the extension of the distal tip, torque is applied on the extension knob to rotate it, causing the compression

spring to rotate and move the distal tip. The torque is applied by hand on the extension knob. Four colon configurations were formed and studied for the torque test.

4.4.1 Experiment Setup

The setup of the torque test is similar to the setup of the extension test, described in sections 4.3.2 and 4.3.3. The silicon tube was used as well as the table, plastic rings, pins, and training layouts. Four colon configurations were set up, which are: U shape, Alpha shape, reverse Alpha shape, and N shape, as shown in Figure 35. Furthermore, the dual-range force sensor and the Vernier LapPro device described in section 4.2.2 were utilized in this experiment. The force sensor was connected to the extension knob, as shown in Figure 36.

Figure 36. The force sensor attached to the extension knob of the DTEM.

4.4.2 Methodology

The torque test aimed to observe the effect of the colon configuration on the amount of the torque applied on the extension knob to extend the distal tip. The maximum torque applied on the extension knob during the extension process of the distal tip was recorded. Since the extension process of the distal tip was divided into three stages as described in section 4.3.3, average torque for each stage was calculated. For the torque test, U shape, Alpha shape, reverse Alpha shape, and N shape were set up using the silicon tube, plastic rings, pins and flat table, as shown in Figure 35. The force sensor connected to the Vernier LapPro device was attached to the extension knob to record the force applied on it by hand. During the extension of the distal tip, the force sensor was pushed by hand to rotate the extension knob. The data was collected at the end of each stage of the extension process of the distal tip. The obtained results were displayed and saved on the computer, which is connected to the Vernier LapPro device.

4.5 Bending Test

The insertion tube of colonoscope should be able to bend in various degrees to negotiate the bends of the human colon. The bending test is performed to determine the bending limits of the insertion tube of the prototype. Furthermore, the bending radius and bending angle at which the DTEM fails to extend the distal tip and the effect of bending on the number of turns needed to achieve full extension are studied. Two bending experiments are set up. The first experiment is for the bending radius, and the second

experiment is for the bending angle. The first and the second experiments are described in section 4.5.1 and section 4.5.2, respectively.

4.5.1 Bending Radius Test

The bending radius test was performed on the insertion tube of the prototype. The insertion tube has two springs placed inside, which are the compression spring and the spring of the DTEL. The compression spring is placed through the entire length of the insertion tube, and the DTEL spring runs through only 60 cm of the length of the insertion tube from the distal end of the insertion tube. Therefore, two areas on the insertion tube were chosen to perform the test on. The first area, named first segment, is from the beginning of the insertion tube to the beginning of the DTEL, as shown in Figure 37(a). This segment is the portion of the insertion tube where only the compression spring runs through. The second area, named second segment, is from the end of the first segment to the end of the DTEL, which is 60 cm, as shown in Figure 37(b). This segment is the part of the insertion tube where the compression spring and the spring of the DTEL overlap. These segments are tested to compare the effect of having one spring inside the insertion tube to the effect of having two overlapped springs in the insertion tube on the bending radius and the performance of the DTEM.

4.5.1.1 Experiment setup

As mentioned previously in section 4.5.1, the insertion tube of the prototype was divided into two segments. Thus, the setup was repeated twice. A few tools were needed

to set up the experiment, such as the colonoscope stand, metal clamps, pins, and a flat table, as shown in Figure 37. The colonoscope stand was used to hold the prototype during the experiment. The insertion tube was fastened to the table using metal clamps and pins.

Figure 37. Illustration of the bending radius test setups, (a) bending radius test setup for the first segment, (b) bending radius test setup for the second segment.

4.5.1.2 Methodology

The bending radius test was designed to determine the bending limit of the insertion tube at which the DTEM fails to fully extend the distal tip. Also, the effect of bending on the number of turns, which the extension knob needed to make in order to extend the distal tip, was observed. Additionally, the test aimed to compare the bending radius limits of the first and the second segments because the segments have a different number of springs installed along each of them. The insertion tube was fixed to the table with a bending radius of 10 cm. Then, the telescoping shaft was compressed, and the extension knob was rotated until the distal tip reached full extension length (16 cm). Three trials were conducted for each bending radius. The total number of turns needed to achieve full extension was recorded at the end of each trial. The bending radius was decreased at 2 cm increments for each test until the DTEM failed to extend the distal tip 16 cm. The experiment was stopped when the DTEM failed to provide full extension for the distal tip, and that bending radius was marked as failed. The radius where the DTEM failed was excluded, and the radius before was marked as the bending limit of the insertion tube. The same experiment methodology described above was used in both tests since two segments were tested.

4.5.2 Bending Angle Test

The bending angle test was designed to determine the bending angle limits, and to study the effect of bending on the ability of the DTEM to elongate the distal tip in terms of the number of turns of the extension knob,, as well as to determine the bending angle

at which the DTEM fails to extend the distal tip. The experiment covered only the area where the compression spring and the spring of the DTEL overlapped. The bending section of the insertion tube, also referred to as the distal tip, usually bends in different angles in order to maneuver through the bends of the human colon. Furthermore, one of the goals of the DTEM is to enable the distal tip to reach the cecum. Thus, the distal tip should at least be within the ascending colon before the DTEM is used, since the average length of the ascending colon is about 16 cm. A portion of the insertion tube, which is the part right before the beginning of the distal tip, would curve in the hepatic flexure. This curve is simulated in this test by bending the portion of the insertion tube in different angle degrees.

4.5.2.1 Experiment Setup

The setup of the bending angle test shown in Figure 38 required a flat table to lay the insertion tube on, a protractor to measure the bending angles, and a flexible bending tube. Also, metal clamps and pins were used to fix the insertion tube of the prototype to the table. First of all, the protractor was laid down on the table, and then lines were drawn on the table presenting the angles' degrees that were used in the test. The angles started from 0 to 180 degrees. The increment of the bending angle was 30 degrees from 0 to 150, and then the increment was reduced to 10 for the remaining bending angles. Since the DTEM was expected to fail in the interval, 150 and 180 bending angles, the increment of the bending angle was reduced from 30 to 10 in this interval to enhance the accuracy of the results. The flexible bending tube was made of two transparent solid tubes and a

flexible corrugated tube, as shown in Figure 39. The corrugated tube was attached to the transparent tubes. The corrugated tube was used to bend the insertion tube at different angles. The flexible bending tube performs two jobs, which are forcing the insertion tube to bend and holding the insertion tube in position during the experiment.

Figure 38. Setup of the bending angle test with illustration of the main components. The bending angle being tested in this figure is 90° .

Figure 39. The flexible bending tube consists of two transparent tubes and one corrugated tube. The device is used to bend the insertion tube in different angles.

4.5.2.2 Methodology

The bending angle test was performed to investigate the ability of the DTEM to extend the distal tip when the insertion tube is bent into different angles. The angles chosen for this experiment are 0, 30, 60, 90, 120, 150, 160, 170, and 180 degrees. Marks were first made on the flat table to illustrate the bending angle sizes. Then, the flexible tube was inserted over the insertion tube, placing the portion of the insertion tube that was bent in the corrugated tube. The insertion tube along with the flexible tube was fixed to the table using the metal clamps and pins. Once the insertion tube was placed in position for the experiment, the telescoping shaft was compressed and the extension knob was rotated until full extension was reached. Three trials were performed at each bending angle to reduce experimental errors. The total number of turns needed to achieve full extension was recorded at the end of each trial. When the DTEM successfully

extended the distal tip 16 cm, the insertion tube was bent to the next bending angle until the DTEM failed to extend the distal tip. The bending angle at which the DTEM failed was marked as failed, and the experiment was ended.

CHAPTER 5: RESULTS AND DISCUSSIONS

The experiments designed to characterize the performance of DTEM were successfully conducted. The compliance test determined that the flexibility of the prototype was slightly reduced due to use of the DTEM. Additionally, the extension test demonstrated the ability of DTEM to elongate the distal tip 16 cm even though loops existed, achieving a successful rate of 100% for all performed trials. Also, the bending radius test concluded that the prototype has a wide range of bending radius limits. Finally, the bending angle test results showed that the prototype has large successful bending angle limits in which the DTEM is able to extend the distal tip.

5.1 Compliance Test Data

The compliance test aims to determine the effect of using the DTEM on the flexibility of the insertion tube. The obtained results from conducting the compliance test are presented in this section. The collected data from running the compliance test on the prototype was compared to the obtained data from running the same test on the original scope of the colonoscope. Therefore, acquired results from points A, B, C, and D of the first ring and the second ring of the prototype were compared to the data of the same points of the original scope, respectively. The results were plotted, and error bars were added.

Figure 40 illustrates the values of the generated forces from bending the insertion tube of the prototype at point A of the first ring. Also, it shows the values of the forces acquired from bending the original scope at the same position, which is the insertion tube

of the prototype without the DTEM. As shown in Figure 40, the values of the forces increase as the bending diameter decreases. Furthermore, the bending resistance, or generated forces, of the insertion tube of the prototype is larger than the resistance of the original scope.

Figure 40. Bending resistance of the insertion tube of the prototype at point A of the first ring compared to the original scope.

Figure 41 shows the collected data from bending the insertion tube of the prototype at point B of the first ring as well as the obtained data from bending the original scope at point B of the first ring. The resistance of the insertion tube also increases as the bending diameter decreases. Additionally, the resistance of the insertion tube of the prototype is greater than the resistance of the original scope when they are bent at the same bending diameter.

Figure 41. The bending resistances of the insertion tube at point B of the first ring of the original scope and the prototype with different bending diameters.

Figure 42 presents the results of bending the insertion tube of the prototype at point C of the first ring and the results of bending the original scope at point C of the first ring. The resistance of the insertion tube to bending increases as the bending diameter decreases in the insertion tube of the prototype and the original scope. As shown in Figure 42, the generated forces from bending the insertion tube of the prototype are slightly higher than the generated forces from bending the original scope at the same bending diameters.

Figure 42. The generated forces from bending the insertion tube of the prototype at point C of the first ring compared to the generated forces from bending the original scope at the same position.

Figure 43 illustrates the resistance of the insertion tube of the prototype to bending at point D of the first ring compared to the resistance of the original scope at the same point. As seen in the figure, the resistance of the insertion tube of the prototype is larger than the resistance of the original scope when bent at various diameters. Also, the resistances of the insertion tube of the prototype and the original tube increase as the bending diameter decreases.

Figure 43. The resistance to bending of the insertion tube of the prototype at point D of the first ring compared to the resistance of the original scope at point D of the first ring.

Figure 44 presents the obtained results from bending the insertion tube of the prototype at point A of the second ring and the acquired data from bending the original scope at point A of the second ring. The figure shows that the resistance of the insertion tube of the prototype at point A of the second ring is higher than the resistance of the original scope at the same point. Also, the values of the generated forces from bending the insertion tube of the prototype and original scope increase with the decreasing of the bending diameter.

Figure 44. The results of bending the insertion tube of the prototype at point A of the second ring compared to the results obtained from bending the original scope at the same point.

Figure 45 illustrates the obtained forces from bending the insertion tube of the prototype at point B of the second ring and the acquired forces from bending the original scope at the same position. It also shows that the resistance of the insertion tube to bending increases for both the prototype and the original scope as the bending diameter decreases. Furthermore, the resistance of the insertion tube of the prototype to bending is greater than the resistance of the original scope.

Figure 45. The resistance forces to bend the insertion tube of the prototype at point B of the second ring compared to the resistance forces generated from bending the original scope at the same position.

The results obtained from bending the insertion tube of the prototype at point C of the second ring and from bending the original scope at point C of the second ring at different bending diameters are presented in Figure 46. The results show that the resistance of the prototype to bending at point C of the second ring is higher than the resistance of the original scope to bending at the same position and bending diameters. Furthermore, the generated forces from bending the insertion tube of the prototype and the original scope increase as the bending diameter decreases, as shown in Figure 46.

Figure 46. The forces generated from bending both of the insertion tube of the prototype at point C of the second ring and the original scope at point C of the second ring compared.

The resistance forces obtained from bending the insertion tube of the prototype at point D of the second ring and from bending the original scope at point D of the second ring are illustrated in Figure 47. The results show that the bending resistance forces of the insertion tube of the prototype are greater than the resistance of the original scope. Also, the resistance of the tested points increases as the bending diameter decreases.

Figure 47. The resistance forces generated from bending the insertion tube of the prototype at point D of the second ring and from the original scope at the same point.

After calculating the resistance forces at points A, B, C, and D of the first ring for both the insertion tube of the prototype and the original scope, the averages of these forces were calculated. The average resistance forces are displayed in Figure 48. The results demonstrate that the resistance of the prototype to bending is higher than the resistance of the original scope. Also, the average generated forces from bending the insertion tube of the prototype and the original scope at the first ring increase as the bending diameter decreases.

Figure 48. The average resistance forces to bending of the prototype and the original scope of the points (A, B, C, and D) of the first ring.

The obtained results from calculating the average resistance forces of the points (A, B, C, and D) of the second ring for the prototype and the original scope are shown in Figure 49. The displayed results show that the average resistance forces of the insertion tube of the prototype at the second ring are greater than the average resistance forces of the original scope at the same position. Moreover, the bending resistance of the insertion tube at the second ring for both the prototype and the original scope increases as the bending diameter decreases.

Figure 49. The average resistance forces of the four points at the second ring of the prototype and the original scope.

The presented data in Figure 50 was obtained from bending the original scope at the first ring at different bending diameters. The data shows the bending resistance forces generated at points A, B, C, and D of the first ring. The generated resistance forces at points A, B, C, and D vary for the same bending diameter, and this corresponds with the fact that the circumference structure of the insertion tube of the colonoscope is non-homogeneous. The same pattern of variation is also observed as shown in Figure 51, Figure 52, and Figure 53. The non-homogeneity of the insertion tube is proven by the results in Figure 50, and Figure 52, and the reflection of non-homogeneity effect is observed in the results in Figure 51, and Figure 53.

Figure 50. Resistance forces at points A, B, C, and D of the first ring of the original scope.

Figure 51. Resistance forces at points A, B, C, and D of the first ring of the prototype.

Figure 52. Resistance forces at points A, B, C, and D of the second ring of the original scope.

Figure 53. Resistance forces at points A, B, C, and D of the second ring of the prototype.

The average resistance forces at the first ring and the second ring of the prototype and the original scope are calculated and presented in Table 1. The average resistance force represents the average of the generated forces at points A, B, C, and D of each ring. The results in Table 1 also illustrate that the insertion tube of the prototype resists bending more than the original scope does.

Table 1. *Average resistance forces at the first ring and the second ring.*

Position	First Ring		Second Ring	
	Prototype	Original Scope	Prototype	Original Scope
Average Resistance Force (N)	7.73	6.42	9.02	7.7

The main objective of conducting the compliance test is to demonstrate the effect of using the DTEM on the flexibility of the insertion tube. Based on the results in Table 1, percentages of reduction in flexibility due to the usage of the DTEM are calculated and presented in Table 2. The reduction percentages in flexibility represent the effect of using the DTEM on the flexibility of the insertion tube. Furthermore, the effect of using the DTEM on the flexibility of the insertion tube at the first ring is greater than the effect on the second ring, as shown in Table 2.

Table 2. Overall effect of using the DTEM on the flexibility of the insertion tube.

Position	First Ring	Second Ring
Reduction in Flexibility (percentage)	20.4%	17%

Based on the previously mentioned results, the bending resistances of the insertion tube of the prototype at the first ring and the second ring are higher than that of the original scope due to the existence of the compression spring and the spring of the DTEL inside the insertion tube of the prototype. Additionally, reduction in flexibility of the insertion tube of the prototype at the first ring is greater than the reduction in flexibility at the second ring. The first ring is effected more by the use of the DTEM than the second ring because the compression spring and the spring of the DTEL overlap at the first ring, and only the compression spring runs through the second ring. Although, the springs are very flexible, adding them inside the insertion tube of the prototype increases the resistance of the insertion to bending because they occupy the space inside the insertion tube, and they are stuffed with the accessories that originally run through the insertion tube. Loading the springs with the accessories forms a single body with less flexibility. The original insertion tube has accessories installed inside, which are four angulation cables, two electronic wires for the digital camera, and the light bundle. However, they do not occupy the entire room inside the insertion tube. On the other hand, adding the two springs in the insertion tube and loading them with the accessories fills the space inside the insertion tube. In this case, the insertion tube would be stiffer than it was before.

5.2 Extension Test Data

The extension test is conducted to demonstrate the ability of the DTEM to displace the distal tip of the insertion tube 16 cm on a pass/fail basis, and determine the number of turns that the extension knob needs to make in order to extend the distal tip 16 cm. Also, the test aims to study the effect of the colon configuration on the number of turns and on the ability of the DTEM to perform to its full extension. The obtained results from running the extension test are presented in this section. As mentioned in section 4.3.3, the 16 cm extension of the distal tip is a combination of three stages referred to as first segment (5 cm), second segment (5.5 cm), and third segment (5.5 cm).

The first segment is performed by pushing the first tube of the telescoping shaft inside the telescoping shaft and rotating the extension knob. If the distal tip moves less than 5 cm when the first tube is pushed inside the telescoping shaft, the extension knob is then rotated until the distal tip displaces 5 cm. The collected data from compressing the first tube of the telescoping shaft is presented in Figure 54, and the number of turns that is needed to reach the 5 cm extension is shown in Figure 55. The data displayed in Figure 54 illustrates that the distal tip is moved less than 5 cm in the straight-line configuration and the U configuration of the colon; however, it is not moved at all in the N, Alpha, and reverse Alpha configurations. Also, the extension knob is rotated in all of the tested configurations, as shown in Figure 55. Furthermore, the Alpha shape configuration is correlated with the highest number of turns.

Figure 54. The displacement of the distal tip caused by pushing the first tube of the telescoping shaft for the first segment.

Figure 55. The number of turns of the extension knob needed to extend the distal tip in each colon configuration for the first segment.

The second segment consists of pushing the second tube of the telescoping shaft inside the telescoping shaft and rotating the extension knob. If the distal tip moves less than 5.5 cm when the second tube is pushed inside the telescoping shaft, the extension knob is then rotated until the distal tip displaces 5.5 cm. The results in Figure 56 represent the displacement of the distal tip resulting from shortening the length of the telescoping shaft 5.5 cm by pushing the second tube in the telescoping shaft. The distal tip is moved a full distance of 5.5 cm only in the Alpha configuration, it is not moved at all in the N shape, and it is moved just 5 mm in the reverse Alpha configuration, as shown in Figure 56. Furthermore, Figure 57 shows that the extension knob is rotated in all configurations except the Alpha shape. Also, the highest two numbers of turns are observed in the N and reverse Alpha configurations, as presented in Figure 57.

Figure 56. The displacement of the distil tip caused by pushing the second tube of the telescoping shaft for the second segment.

Figure 57. The number of turns of the extension knob needed to extend the distal tip in each colon configuration for the second segment.

The third segment is performed by pushing the third tube of the telescoping shaft inside the telescoping shaft and rotating the extension knob. If the distal tip moves less than 5.5 cm when the third tube is pushed inside the telescoping shaft, the extension knob is then rotated until the distal tip displaces 5.5 cm. Figure 58 shows that the distal tip is moved in all of the studied configurations; however, it does not reach full extension (5.5 cm) in any of the tested configurations. Additionally, the highest displacement for the distal tip occurs in the Alpha configuration. Figure 59 presents the obtained number of turns of the extension knob needed to move the distal tip in the five configurations. Furthermore, the least number of turns is associated with the Alpha configuration, as shown in Figure 59.

Figure 58. The displacement of the distal tip caused by pushing the third tube of the telescoping shaft for the third segment.

Figure 59. The number of turns of the extension knob needed to extend the distal tip in each colon configuration for the third segment.

Figure 60 illustrates the displacements of the distal tip due to shortening the length of the telescoping shaft gradually in three stages. The first stage is pushing the first tube inside the telescoping shaft, the second stage is pushing the second tube in the telescoping shaft, and the third stage is pushing the third tube in the telescoping shaft. The results presented below show that the distal tip moves differently in each stage and in each configuration.

Figure 60. The displacements of the distal tip caused by pushing the three tubes of the telescoping shaft gradually in the telescoping shaft.

Figure 61 demonstrates the numbers of turns of the extension knob for each of the three stages associated with each configuration. Also, it illustrates that the number of turns in each stage varies in each configuration.

Figure 61. The numbers of turns of the three stages in each configuration.

Figure 62 illustrates the total generated displacement from compressing the telescoping shaft 16 cm for each configuration. The presented results also show that when the telescoping shaft is fully compressed, the response of the distal tip to that varies depending on the shape of the configuration. Moreover, the N configuration is correlated with the least displacement among all the tested configurations. The data in Figure 63 demonstrates the total number of turns that is needed to reach full extension for the distal tip in each of the studied configurations. Furthermore, the maximum number of turns that is needed to force the distal tip to extend 16 cm is associated with the N configuration, and it is 91 turns. It is also observed from Figure 63 that each configuration requires a different number of turns. If the straight-line and the U configurations are excluded, the numbers of turns for the other three configurations are found to be associated with reasonably similar values, as shown in Figure 63.

Figure 62. Overall displacement of the distal tip in each configuration generated from compressing the telescoping shaft 16 cm.

Figure 63. Total number of turns associated with each configuration.

Figure 64 shows the displacement percentage caused by compressing the telescoping shaft 16 cm and rotating the extension knob. When the telescoping shaft is compressed 16 cm, the distal tip moves forward less than 16 cm. Therefore; the extension knob is next rotated to force the distal tip to reach the full 16 cm extension. The response of the distal tip to compressing the telescoping shaft varies in accordance with the shape of the configuration, and that influences the number of turns associated with each configuration, as shown in Figure 64.

Figure 64. The displacement percentage caused by both compressing the telescoping shaft and rotating the extension knob.

Table 3 presents the success rate of the DTEM to extend the distal tip 16 cm. The overall number of trials performed in the extension test is 25, five for each colon configuration. Based on the presented results in Table 3, the overall success rate is 100%,

and the DTEM is significantly able to extend the distal tip of the colonoscope to its full extension (16 cm) in all the setup configurations.

Table 3. *The success rates of the DTEM to extend the distal tip 16 cm.*

Shape	Number of trials	Pass	Fail	Success Rate
Straight-line	5	5	0	100%
U	5	5	0	100%
Alpha	5	5	0	100%
N	5	5	0	100%
Reverse Alpha	5	5	0	100%

The shapes of the configurations are found to influence the ability of the DTEM to move the distal tip to its full extension (16 cm) in terms of the displacement caused by pushing the telescoping shaft and the number of turns of the extension knob. The displacement of the distal tip is affected by the friction between the inner surface of the insertion tube and the springs of the DTEM, as well as the number and the degree of the bends along the configurations. The effect of friction is observed from the variation of the displacement among the three stages of extension for each configuration. The displacement from the first stage is less than that from the second stage. Also, the displacement from the second stage is less than the displacement from the third stage. This phenomenon can be explained by the fact that the contact surface area between the inner surface of the insertion tube and the springs of the DTEM reduces as the extension

process moves from the first stage to the second stage and then to the third stage. At the beginning of first stage, the entire length of the DTEL's spring is inside the insertion tube, and a portion, 5 cm, from the length of the spring is out of the insertion tube at the end of first stage. As a result, the amount of contact area lessens during the second stage. Furthermore, at the end of the second stage, 10.5 cm from the DTEL spring's length is out of the insertion tube, which means that the contact area decreases during the third stage of the extension process.

The number and size of the curves along the insertion tube influence the extension process of the distal tip. More complicated configurations require a larger number of turns to overcome the resistance along the curves. Therefore, the N configuration is found to be associated with the maximum number of turns among the studied configurations because it has the highest number of bends. On the other hand, the straight-line configuration is correlated with the minimum number of turns, since it has no bends. Furthermore, the Alpha shape and the reverse Alpha shape have approximately similar numbers of turns because they have the same number, but slightly different sizes, of bends.

Some uncertainties in experimental results can be caused by the springs' coils of the DTEM being wedged in between the coils of the metal flex tube of the insertion tube. The metal flex tube is the internal surface of the insertion tube, as shown in Figure 65. During the extension process of the distal tip, the compression spring is rotated and the DTEL spring is moved through the insertion tube. When the one of the DTEL spring's coils or more is stuck between the coils of the metal flex tube, the extension of the distal

tip is affected. Thus, a larger number of turns will be needed in order to generate a greater pushing force to move the DTEL spring out of the area where the spring is stuck.

Figure 65. The insertion tube of the colonoscope consists of three layers: Polymer resin, mesh tube, and metal flex tube [53].

5.3 Torque Test Data

The obtained results from conducting the torque test are shown in Figure 66. The presented torques are calculated from multiplying the forces recorded by the force sensor by the radius of the Extension knob which is 2.3 cm. The results show that the average torque applied on the extension knob by hand to rotate the compression spring and extend the distal tip decreases as the extension process moves from the first stage to the third stage. Also, it is observed from Figure 66 that more complicated configurations require higher torque to rotate the extension knob. Furthermore, the N shape is associated with the maximum average torque, and the U shape is correlated with the minimum average torque. Additionally, Table 4 demonstrates the maximum torque exerted on the extension knob during the extension of the distal tip for each configuration.

Figure 66. Torque needed to rotate the extension knob and displace the distal tip in each stage of the extension process in all studied configurations.

Table 4. Max torque applied during the extension of the distal tip in each configuration.

Configuration n	U Shape	Alpha Shape	Reverse Alpha Shape	N Shape
Max Torque (N.m)	0.121	0.138	0.143	0.15

The results shown in Figure 67 demonstrate that the shape of the configurations influences the amount of torque needed to rotate the extension knob. More complex shapes need greater torque to rotate the extension knob because they are associated with higher friction. Each configuration has a different number and size of curves along the insertion tube. Therefore, the four configurations require different torques to overcome friction in order to rotate the compression spring and move the distal tip. The N shape is

associated with the maximum torque since it has more curves than the other configurations. Also, the U shape requires the minimum torque to rotate the extension knob because it has the least number of curves. Friction between the inner surface of the insertion tube and the surface of the compression spring and the DTEL spring affect the value of torque needed to rotate the extension knob.

Figure 67. The average torque applied to rotate the extension knob to reach full extension for the distal tip in the configurations.

The results also show that the torque needed to rotate the extension knob decreases as the extension process moves from the first stage to the third stage for all the configurations. This is explained by the fact that when the extension process advances from the first stage to the second stage, friction decreases because the contact surface area between the springs and the inner surface of the insertion tube becomes less. Also,

the friction decreases even more when the extension process moves from the second stage to the third stage because the contact surface area is the least during the third stage.

During the extension of the distal tip in the four configurations, the force sensor recorded some unusually high torque values. The maximum value in each configuration is displayed in Table 4. These high torques were caused by the DTEL spring's coils being stuck between the coils of the metal flex tube shown in Figure 64. When one or more spring's coils are stuck between the coils of the metal flex tube, higher torque is required to move the spring of the DTEL.

The obtained results from the torque test coincide with the results from the extension test. They both prove that as the extension process moves from the first stage to the third stage, the friction becomes less. Also, some uncertainties in the results are caused by the DTEL spring's coils being stuck between the coils of the metal flex tube. Furthermore, more complicated configurations required a higher number of turns and torques to move the distal tip since they have a higher number of curves, which increases friction.

5.4 Bending Test Data

The bending test consists of two tests, which are the bending radius test and the bending angle test. Generally, the bending test aims to determine the bending radius and bending angles' ranges in which the DTEM can generate full extension to the distal tip. Since the test requires the usage of DTEM, the number of turns needed for extension during both tests is recorded as well.

5.4.1 Bending Radius Data

The bending radius test uses different bending radiuses, as shown in Figure 68 and Figure 69. The data presented in Figure 68 is obtained from testing the first segment, which is the part of the insertion tube that has one compression spring stuffed inside. Also, it shows the bending radiuses at which the DTEM successfully extends the distal tip (16 cm). Moreover, it illustrates the number of turns associated with each bending radius. Based on the results shown in Figure 68, the minimum bending radius at which the DTEM is successfully able to elongate the distal tip is 4 cm, which is also associated with the highest number of turns. Therefore, for the DTEM to be able to fully extend the distal tip, the bending radius should be greater than or equal to 4 cm. It is also observed that the number of turns needed to reach full extension increases as the bending radius decreases.

Figure 68. Bending radiuses and numbers of turns obtained from testing the first segment.

Figure 69 presents the results collected from testing the second segment, which is the part of the insertion tube that has the compression spring and the spring of the DTEL filled inside. Additionally, it shows the bending radiuses at which the DTEM is able to displace the distal tip to its full extension (16 cm). It also illustrates the number of turns associated with each bending radius. The minimum bending radius at which the DTEM can perform full extension for the distal tip is 4 cm, which is also correlated with the highest number of turns as shown in Figure 69. Therefore, for the DTEM to function properly, the bending radius should be greater than or equal to 4 cm. Finally, the number of turns increases as the bending radius decreases.

Figure 69. Bending radiuses and number of turns obtained from testing the second segment.

Figure 70 displays a comparison between the results obtained from testing the first segment and the second segment. This figure also shows that the number of turns associated with bending the second segment is higher than the number of turns correlated with the first segment for the same bending radiuses. Furthermore, the minimum-bending radius at which the DTEM is able to extend the distal tip is the same for both segments, which is 4 cm.

Figure 70. Comparison between the obtained results of testing the first segment and the second segment for bending radius.

The ability of the DTEM to move the distal tip is influenced by the size of the bending radius, since a smaller bending radius is associated with higher friction. The friction is produced from bending the insertion tube, which causes the DTEM springs to push back on the inner surface of the insertion tube trying to resist bending and to restore their original shape. The smaller the bending radius is, the stronger the attachment between the internal surface of the insertion tube and the springs of the DTEM is, and also the higher the friction is. Thus, the number of turns needed to move the distal tip increases in order to obtain a higher pushing force on the DTEL spring to surpass the increased friction force as the bending radius decreases. The DTEM fails to displace the distal tip when the bending radius is less than 4 cm because the applied pushing force on

the DTEL spring, produced from pushing the telescoping shaft and rotating the extension knob, does not exceed the friction force between the metal flex tube and the DTEM.

5.4.2 Bending Angle Data

The bending angle test is performed to determine the limits of the bending angles at which the DTEM is able to fully extend the distal tip. The illustrated results in Figure 71 show that the number of turns increases as the value of the bending angle increases. Also, the DTEM is able to successfully move the distal tip (16 cm) while the insertion tube is bent to the bending angles shown in Figure 71. The maximum bending angle at which the DTEM can extend the distal tip is 160°.

Figure 71. Bending Angles and number of turns obtained from testing the insertion.

The extension process of the distal tip is influenced by the size of the bending angle, since a smaller bending angle is correlated with a higher friction force. The friction is produced from bending the insertion tube, which causes the DTEM springs to push back on the internal surface of the insertion tube to resist bending and to restore their original shape. The smaller that the bending angle is, the more coherent the attachment between the inner surface of the insertion tube and the springs of the DTEM is, as well as the higher the friction is. Thus, as the size of the bending angle increases, the needed number of turns to move the distal tip increases in order to generate a higher pushing force on the DTEL spring to exceed the increased friction force. The DTEM fails to extend the distal tip 16 cm when the bending angle is higher than 160° because the pushing force, generated from pushing the telescoping shaft and rotating the extension knob, exerted on the DTEL spring does not overcome the existing friction force.

CHAPTER 6: CONCLUSION

6.1 Development of DTEM prototype

The final DTEM prototype described in section 3.2 consisted of four main parts, which are a compression spring, a distal tip extension link (DTEL), an extension knob, and a telescoping shaft. The compression spring is connected to the extension knob at one end and overlapped with the DTEL spring at the other end. The compression spring rotates with the rotation of the extension knob, generating pushing and pulling forces on the DTEL spring depending of the direction of rotation. The DTEL is connected to the distal tip of the insertion tube and is overlapped with the compression spring. The DTEL moves because of the force applied on it by the compression spring, and this movement displaces the distal tip. The extension knob is used to rotate the compression spring to generate the push and pull forces, and it is also used to separate the rotation of the compression spring from the rest of the colonoscope. The telescoping shaft provides the 16 cm additional length of the accessories during the extension of the distal tip, and it also displaces the distal tip when it is compressed.

6.2 Effect of Implanting the DTEM on the Flexibility of the Colonoscope

The compliance test presented in section 4.2.1 was conducted to determine the effect of implanting the DTEM on the flexibility of the colonoscope. The results showed that the flexibility of the insertion tube of the colonoscope was reduced because of the DTEM. The flexibility was reduced by 20.4% at the area where the compression spring and the DTEL spring overlap, and by 17% at the area where only the compression spring

exists. Therefore, it is concluded that implanting the DTEM affects the flexibility of the insertion tube. This effect cannot be deemed significant or insignificant until the device is used in real procedures, since there is not a specific value of how flexible the insertion tube should be.

6.3 Ability of the DTEM to Extend the Distal Tip

The results presented in section 5.2 demonstrated that the DTEM is able to extend the distal tip 16 cm while the colon is in different configurations. The DTEM was able to successfully displace the distal tip in all of the 25 performed trials. Therefore, the DTEM can help increase the colonoscopy completeness rate by increasing the length of the insertion tube, since incomplete colonoscopy can be caused by a long colon and/or the lack of length of the insertion tube [12]. Additionally, the obtained results from the extension test proved that the circumference structure of the insertion tube is non-homogenous. Furthermore, the maximum number of turns, 91 turns, needed to extend the distal tip was associated with the N configuration. Also, the minimum number of turns, 55 turns, was correlated with the straight-line shape. The variation in the number of turns needed to displace the distal tip 16 cm among the five studied configurations proves that the shape of the configuration influences the number of turns. Complicated configurations necessitate a higher number of turns.

6.4 Effect of Colon Configuration on the Applied Torque

The results presented in section 5.3 proved that the configuration of the colon influences the value of torque applied on the extension knob in order to extend the distal tip. Complicated configurations require higher torque to exceed friction between the internal surface of the insertion tube and the surface of the springs of the DTEM. Also, the torque required to rotate the extension knob decreases as the extension of the distal tip increases since friction decreases with the extension of the distal tip.

6.5 Effect of Bending on the Performance of the DTEM

The obtained results from conducting the bending radius test determined the minimum bending radius at which the DTEM is able to extend the distal tip. The minimum bending radius for the area where the compression spring and the DTEL spring overlap is 4 cm, and it is the same minimum bending radius for the area where only the compression spring exists. Therefore, it can be concluded that the DTEM is able to extend the distal tip as long as the bending radius is greater than or equal to 4 cm.

The bending angle test was conducted to determine the minimum bending angle at which the DTEM is able to displace the distal tip 16 cm. The obtained results showed that the minimum bending angle is 160° . Therefore, it is concluded that the DTEM is able to extend the distal tip as long as the bending angle is less than or equal to 160° .

CHAPTER 7: FUTURE WORK/RECOMMENDATIONS

1. Replace the compression spring and the spring of the DTEL with springs that are made of different material to determine if this would enhance the performance of the DTEM.
2. Reduce the weight of the colonoscope by manufacturing the parts of the extension knob from plastic material.
3. Use an insertion tube with a bigger internal diameter so that it can accommodate the springs of the DTEM and all the accessories of the colonoscope inside. I have used the biggest insertion tube available in current markets. Therefore, you will need to collaborate with a colonoscope company that can custom make the insertion tube for you.
4. Make the telescoping shaft and the extension knob leakage proof to prevent fluids and blood inside the colon from penetrating into the colonoscope.
5. Cover the area between the end of the insertion tube and the beginning of the distal tip, where the extension of the distal tip occurs, with a tube that has high flexibility and high ability to stretch to prevent leakage.
6. Test the ability of the DTEM to extend the distal tip in different colon configurations aside from the common configurations that I studied.
7. Gather a number of medical students who are interested in becoming colonoscopists and some expert colonoscopists to perform colonoscopy on the colon training model (CTM) using the DTEM, and conduct a survey to obtain their feedback about the DTEM.

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