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NOVEL INVERTED TUBULAR DESIGN FOR IMPROVED ENDOSCOPE POSITIONING

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ABSTRACT

To detect and treat colorectal cancers endoscopes are commonly used to perform colonoscopies, with an estimated 15 million performed in America every year. Endoscope designs rely on physicians physically pushing the long device into position through the intestine thereupon applying potentially damaging forces to the intestinal wall. To improve endoscopic procedures this paper presents the novel concept of Inverted Tubular Element Locomotion (ITEL) to reduce interaction forces between the endoscope and the intestine wall. Experiments are performed that demonstrate functionality of the tubular design and less than 3.5 kPa to deploy. The tube material thickness has a linear relationship with the force required. This unique design has the potential to enhance patient safety and to improve procedural efficiency.

Keywords: Endoscope, Colonoscopy, Inverted Tube

INTRODUCTION

Colorectal Cancer is the second leading cause of cancer related deaths in America [1]. Approximately 4.6% of men (1 in 22) and 4.2% of women (1 in 24) will be diagnosed with colorectal cancer (CRC) in their lifetime. The risk of CRC also increases with age. CRC incidence increased from the 1970's to the mid 1980's but has been declining since. The decline in CRC before the 2000's can be attributed equally to change in risk factors such as smoking and the use of screening which allows for the removal of premalignant lesions [2]. However, the recent rapid decline can be solely attributed to the increase in colonoscopies. Colonoscopy has nearly doubled in adults over 50 years old, from 34% in the 2000 to 63% in 2015 [2]. Regular screening is recommended by the American cancer society beginning at age 45 for people at average risk of CRC [3] and earlier screening is recommended for people at increased risk based on family history or certain medical conditions [2]. 2-3 negative colonoscopy screenings can imply a lifetime protection against CRC [4].

The high number of colonoscopies performed necessitates the need for the procedure to be both safe and time efficient. Two major challenges of colonoscopies are the risk of intestinal damage, such as by colonoscopic perforation (CP), and the high operator skill and time needed to properly position the probe into place [4]. Colonoscopies are performed using an endoscope which is a long slender tube with a camera at the tip. Endoscopes are not only used for colonoscopies but several other procedures that involve visually inspecting the gastrointestinal tract. Typical endoscopes are steered through the convoluted intestines by manipulating the bending of the tip using cable driven mechanisms and physically pushing the endoscope into place [5]. This physical pushing is a challenging method of positioning because the flexibility of the endoscope can cause it to loop inside the body and the flexibility of the intestines causes them to shift away from the moving endoscope [6]. Looping of the endoscope is extremely common and can occur 91% of the time [7]. This difficulty in insertion causes the procedure to be longer than necessary, requires great skill by the operator to insert, and can create high forces between the endoscope and the body which can cause the serious complication of CP [8]. Minimizing the forces imparted on the intestine during the positioning of the probe through the convoluted intestinal track is the key to reducing the occurrence of CP. Simplifying the endoscope insertion process will allow the procedure to be done quicker and require less operator skill.

Overtube methods exist to allow for deeper positioning inside the small intestine through double balloon enteroscopy (DBE) (Fuji Photo Optical Co, Ltd, Saitama, Japan), single balloon (SBE) (Olympus Ltd, Tokyo, Japan), and spiral enteroscopy (Spirus Medical, Inc, Stoughton, MA, USA) systems. Push pull colonoscopy and spiral enteroscopy positioning methods, rely on tissue to device rubbing to assist in positioning, which can damage the intestinal wall. Double and single balloon endoscopies can avoid much of this active rubbing and are effective methods at reaching deep targets inside the intestines. However, they are extremely time consuming procedures and are considered very difficult interventions to perform [9]. Studies have shown DBE and SBE takes between 45-70 min to perform [10] [11]. Studies have shown this longer procedure time relative to other endoscopy procedures results in greater patient pain and discomfort [12]. In addition both SBE and DBE are generally performed by two people which greatly adds to the cost of the procedure [13].

New robotically controlled and actively driven endoscope devices have been studied by researchers to improve the insertion process. The NeoGuide Endoscopy System (NeoGuide Endoscopy System Inc, Los Gatos, CA) has been shown to reduce insertion forces by utilizing real time 3d mapping to atomically conform electromechanically controlled scope segments to fit the intestinal path [14]. The endoscopic operation robot (EOR) allows for remote operation by the user and provides the user with accurate haptic feedback to assist the insertion of an endoscope for a colonospocy [15-18]. Another automated driven method includes that of the Invendiscope (Invendo Medical GmbH, Germany) which uses 8 wheels and an electric motor to drive an endoscope with an inverted sheath. This is the only mention of an inverted sheath concept that the authors found; similar to the approach proposed in this paper [19, 20]. This earlier work lacks information about the mechanics of inversion and utilizes a complex motor system to forcibly drive the inversion process.

To simplify the endoscope insertion process and reduce the damage to the colorectal wall a new concept of Inverted Tubular Element Locomotion (ITEL) is proposed as shown in FIGURE 1. As shown, this concept works in three unique steps. Step 1, the inflatable tube is compressed and positioned at the opening of the body. Step 2, the tube is partially inflated; safely extending through the convoluted intestines and deep into the body. Step 3, the tube is further inflated and the probe is gently placed into position by unraveling the tube where the inside of the tube is rolled to the outside of the tube. As shown in FIGURE 1, point A on the tube starts on the inside but from the unraveling travels to the outside. The unravelling of the tube adjacent to the colon wall exhibits a pure rolling motion thereby resulting in zero frictional rubbing between the endoscope and the colorectal wall. This greatly reduces the possibility of any tissue damage. With this concept the endoscope can be inserted in less time, with less damage to the intestines, and in a more simplified manner that requires lower skill.

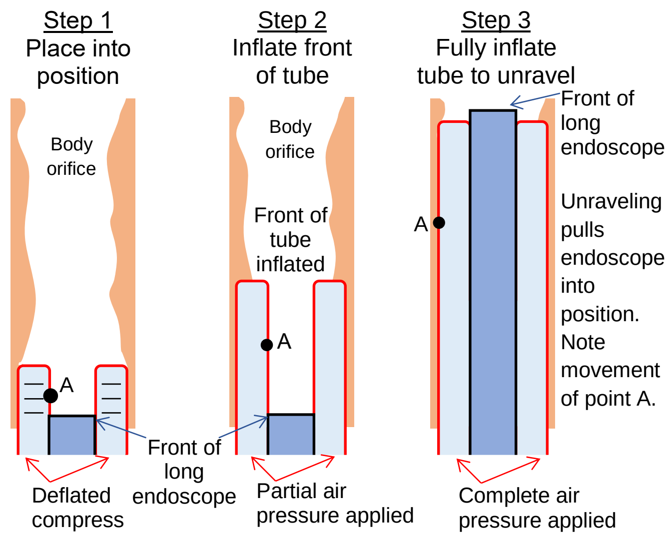

FIGURE 1: CROSS SECTION VIEW SHOWING THREE STEPS OF INVERTED TUBULAR LOCAMOTION CONCEPT

Through experimentation this paper explores the pressure required to physically unravel an inverted tube design. These results are then discussed in detail and conclusions presented.

METHODOLOGY

To test the pressure necessary to unravel an inverted tube, two experiments on inverted tubes of varying thicknesses were performed. Three different plastic tubes made of low-density polyethylene, 48.50 mm in diameter, and material thicknesses of 0.05 mm, 0.10 mm, and 0.15 mm were tested. In the first experiment the tubes were placed outside and freely allowed to inflate FIGURE 2. Pressure was gradually added until the tube began to unravel. This unraveling pressure was then recorded using a digital manometer. Three trials were performed for each of the three tubes. In the second experiment the inverted tubes were inflated inside of an intestine tube model made by Kyoto Kagaku (Kyoto, Japan), as shown in FIGURE 3. The pressure was gradually increased, and the unravelling pressure was recorded, 3 trials for each tube. The results were then analyzed to determine the influence of material thickness and restriction of the colorectal wall.

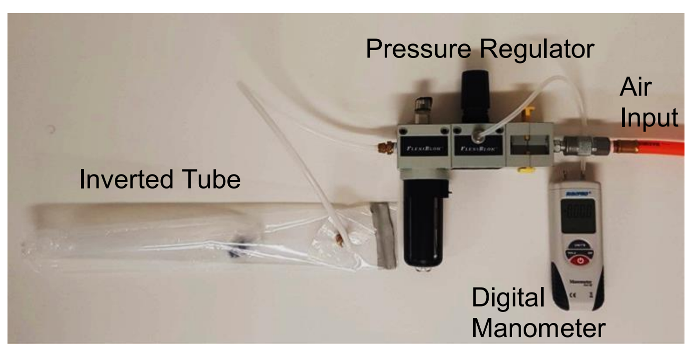

FIGURE 2: EXPERIMENTAL SETUP WITHOUT MANIKIN

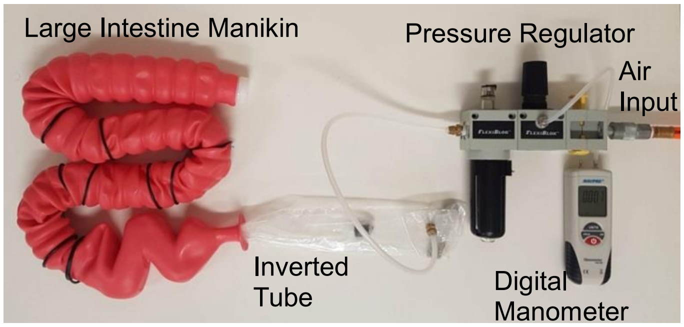

FIGURE 3: EXPERIMENTAL SETUP WITH MANIKIN

RESULTS

The results of the inverted tube experiment are shown in FIGURE 4. As anticipated in both experiments the least amount of pressure is required for the thinnest material tube to unravel, 0.05 mm, and the most pressure is required for the thickest tube to unravel, 0.15 mm. The relationship between the material thickness and the pressure is linear as represented by Equation (1) for the tube in open space (FIGURE 2), where P is the pressure needed to initiate unravelling of the tube in kPa and t is the material thickness in mm. A very similar linear relationship was observed, Equation (2), when the inverted tubes were inflated inside the intestine model (FIGURE 3), despite the increased resistance offered by the intestine walls. It is anticipated that at very thin materials (thickness less than 0.05 mm) the pressure required would approach 0; however, for the range tested the linear relationship is evident with $R^2 > 0.98$ for both equations.

$$P = 30.6\, t - 1.18 \quad (1)$$

$$P = 20.7\, t - 0.63 \quad (2)$$

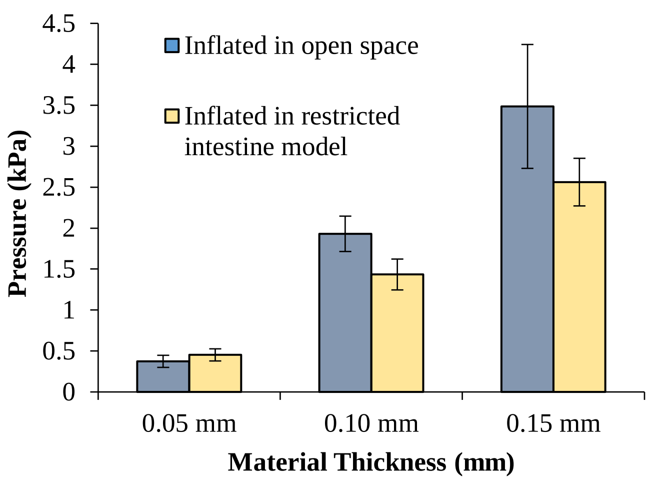

FIGURE 4: PRESSURE NEEDED TO UNRAVEL INVERTED TUBES OF VARYING THICKNESS WHEN PLACED IN OPEN SPACE AND WHEN INSERTED INTO THE INTESTINE MODEL.

Minimizing the pressure required is necessary to minimize the energy of insertion. In order for Step 3 in FIGURE 1 to work through convoluted intestines the forces must be kept to a minimum while still providing material and material thickness that is durable enough not to break in operation. The minimal pressure of less than 3.5 kPa was needed to unravel the tube in both the open space test and inside the intestine model.

CONCLUSION

The concept of ITEL is presented and experiments were successfully performed. It was found that material thickness provides a near linear relationship to pressure needed to unravel. The increase in resistance due to the intestine did not increase the pressure required to unravel. This is significant as this low pressure through the convoluted intestines would be necessary for safe implementation inside the body. Future studies will focus on exploring how much ITEL can decrease the interaction forces between the colorectal wall and the endoscope.

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