UNIVERSITY OF CALIFORNIA, SAN DIEGO

Design and manufacturing of a disposable endoscope and an overtube using 3-D printing technology

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by

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2017

The thesis of Anay Mahesh Pandit is approved, and it is acceptable in quality and form for publication on micro film and electronically:

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Chair

University of California, San Diego

2017

DEDICATION

To my parents, Mahesh Pandit and Sucheta Pandit

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ABSTRACT OF THE THESIS

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by

Anay Mahesh Pandit

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Professor Frank E. Talke, Chair

Even after cleaning and disinfecting an endoscope, the possibility of contamination is high and can have negative effects on the health of patients. U.S. Centers for Disease Control (CDC) reports that there are about two million infected victims yearly and about 20,000 succumb to this infection. In recent news, several deaths at the UCLA Ronald Reagan Medical Center have been linked endoscope bacteria contamination. Thus, there is

a need for designing an endoscope which will reduce or eliminate the chances of these deadly bacteria entering the body.

3-D Printing has been rapidly advancing and can be used as a potential solution for this problem. 3-D printing is being used in printing human tissues and also has a history of printing biocompatible materials, including medical devices. This provides a chance of manufacturing a biocompatible, programmable and disposable endoscope that functions in the same way as present endoscopes, without the risk of contamination.

The aim of this project is to design and manufacture a prototype of a 3-D printable, disposable endoscope to eliminate infection rates using different actuation techniques. The preliminary design of endoscope is an active device which can be actuated using various actuation techniques and can be guided through an obstacle course resembling a human colon.

1 Introduction

Chapter 1 describes the fundamental concepts of endoscopy. The chapter also discusses the main components of an endoscope and an overtube. In addition, Chapter 1 describes various 3-D printing techniques.

1.1 Endoscopy

Endoscopy is a nonsurgical procedure used to examine digestive organs in a human body. An endoscope is a medical device, which is specially designed for this procedure. Endoscopy is typically categorized in three types Fig. 1 [1].

1. Upper endoscopy: It is the procedure to examine the organs staring from the esophagus to small intestine and biliary ducts. While performing an upper endoscopy, an endoscope is pushed through the mouth into the esophagus. This allows doctors to view the esophageal tract and the gastrointestinal tract [2]. Fig. 1.a describes an upper endoscopy. It also helps inspecting parts of small intestines. Endoscopic Retrograde Cholangio-Pancreaticography (ERCP) is a special form of upper endoscopy, which allows inspection of pancreas, gallbladder, and bile ducts.

2. Colonoscopy: Similarly, an endoscope can also be used to pass through the rectum into the sigmoid and the colon to see parts of the large intestine and to examine the lower digestive tract. This procedure is commonly referred to as lower endoscopy. Fig 1.c. shows colonoscopy.

3. Bronchoscopy: This procedure is performed to observe lungs and other organs in the respiratory tract such as trachea or wind pipe [2]. Fig. 1.b.

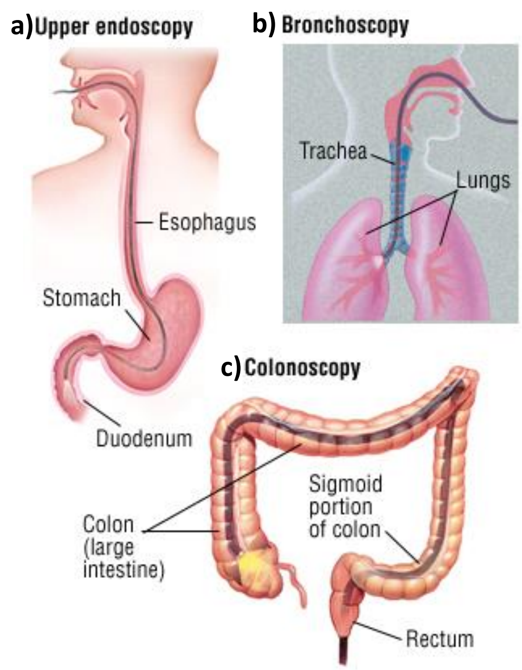

Figure 1: Types of endoscopy [1]: a) upper endoscopy b) bronchoscopy c) colonoscopy

Figure 2 shows a typical digestive tract of a person. The digestive tract consists of the esophagus, the stomach, the small intestine and a larger intestine, also known as colon.

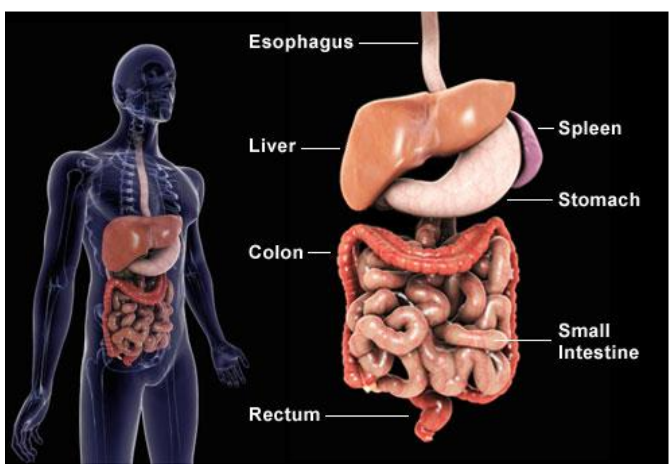

Figure 2: The digestive tract of an average person [2]

1.2 History of endoscopy

Phillip Bozzini in Mainz, Germany, invented the first endoscope in 1806, which was called “Lichtleiter” then. This device was used to see the digestive tract of a human. Fig. 3(a) shows a Lichtleiter. However, this invention was disregarded and not implemented in actual medical procedures due to reasons unknown.

Figure 3: History of endoscope [3]: a) Lichtleiter b) First light sourced endoscopy

The first successfully implemented endoscope was developed by Sir Francis Cruise in 1865 and is shown in Fig. 3(b). The use of electric lighting system in endoscopy was a remarkable step in the endoscope development. Sir Francis Cruise invented the first light sourced endoscope in 1865. It was implemented in endoscopy procedures at Mater Misericordiae Hospital in Dublin, Ireland [3].

Basil Hirschowitz and Larry Curtiss [3] invented the first fiber optic cable endoscope in 1957. This was called a fiberscope. It transmitted an image of the internal structure of an organ. This proved useful in both medical and manufacturing industry. Subsequent research led to further improvements in image quality. [3]

Parallel to improvements in the image quality, there were also advancements in the ability to move and steer an endoscope. This led to the invention of a tip-controlled endoscope, which one sees in the market today. A new study for re-using endoscopes after sterilization was brought up later in 1970s, and S.E. Miederer invented the first sterile and reusable endoscope in 1976 in University of Bonn, Germany [3].

1.3 Endoscope and its components

An endoscope is a medical device used to look into the human digestive tract. Endoscopes are used in various procedures such as colonoscopy, laparoscopy, uretroscopy, ERCP procedures and many others. There are different kinds of endoscopes for their respective procedures.

Endoscopes are usually used for three purposes:

1. Investigation: This process is for observing a patient's regular organ activities. Abnormalities such as abdominal pain or respiratory disorders can be examined using an endoscope. An endoscope is used to search the cause of some injuries in the stomach such as ulcers or internal bleeding.
2. Confirmation: This process uses an endoscope to perform biopsy and other procedures to confirm a diagnosis of disease in the kidneys, urinary tract, and others.
3. Treatment: An endoscope can also be used for direct treatment if an immediate action is required. For instance, cauterization of blood vessel or laser ureteroscopy to remove kidney stones utilizes an endoscope. An endoscope is also used as an assisting tool, for example, deflecting the esophagus during a heart fibrillation surgery or pushing a chunk of food that can block the esophagus [4].

Common types of an endoscope include:

1. Gastrointestinal tract: An endoscope is used to examine the gastrointestinal tract that includes esophagus, stomach, duodenum, small intestine, large intestine/colon,

bile duct and rectum. Duodenoscope and colonoscope are two different types for examining the GI tract [5].

2. Respiratory tract: Examining the respiratory tract, especially nose (rhinoscope) and lower respiratory tract including lungs (bronchoscope) are used.

There are other respective medical procedures that utilize an endoscope. They include the following:

- Ear (otoscope)
- Urinary tract (ureteroscope)
- Female reproductive tract (gynoscope)
- Through a small incision: abdominal or pelvic cavity (Laparoscope), interior of a joint (arthroscope), organs of the chest (thoracoscope and mediastinoscope) [5].

The components of a typical endoscope include the following.

- Tube: The tube is the main load-bearing member of an endoscope. It is made of stainless steel and coated with biocompatible sheath, carrying all the components inside. The tube is made of small linkages, which are either rigid or flexible depending on the scope of the device. The tube can be divided into two parts:
  1. Bending section: This section can bend in all the directions and has a capacity of 180° rotation in the transverse and the cylindrical axis. This allows doctors to steer the endoscope in any required direction during endoscopy
  2. Follower (flexible) section: The follower section is the passive part that follows the bending section. This section does not have any active parts or any sensors.

- Control section: This section has two knobs to control the rotational movement of the endoscope. Also, the control section is the first interface from which doctors get feedback during endoscopy.
- Light source: The light source is the illuminating part in the endoscope assembly. This component is usually at the end of the bending section and it illuminates the pathway. The light source is connected through a fiber optic cable and is flexible enough to bend according to the pathway.
- Lens system: The lens system uses fiber optics to transfer images from the inside of the patient's body during endoscopy. The lens system is the most expensive part of the scope. High resolution lenses help surgery.
- Display Screen: This is the direct output source of the endoscope, one of the feedback systems in the endoscope design. Doctors use the display output to evaluate the procedure.
- Additional channel: The additional channel allows for other medical instruments or manipulators to be inserted into the patient's body. One of the examples for this is the irrigation channel, which releases water for lubrication and irrigation in the body. Figure 5 shows the components of a typical endoscope [6].

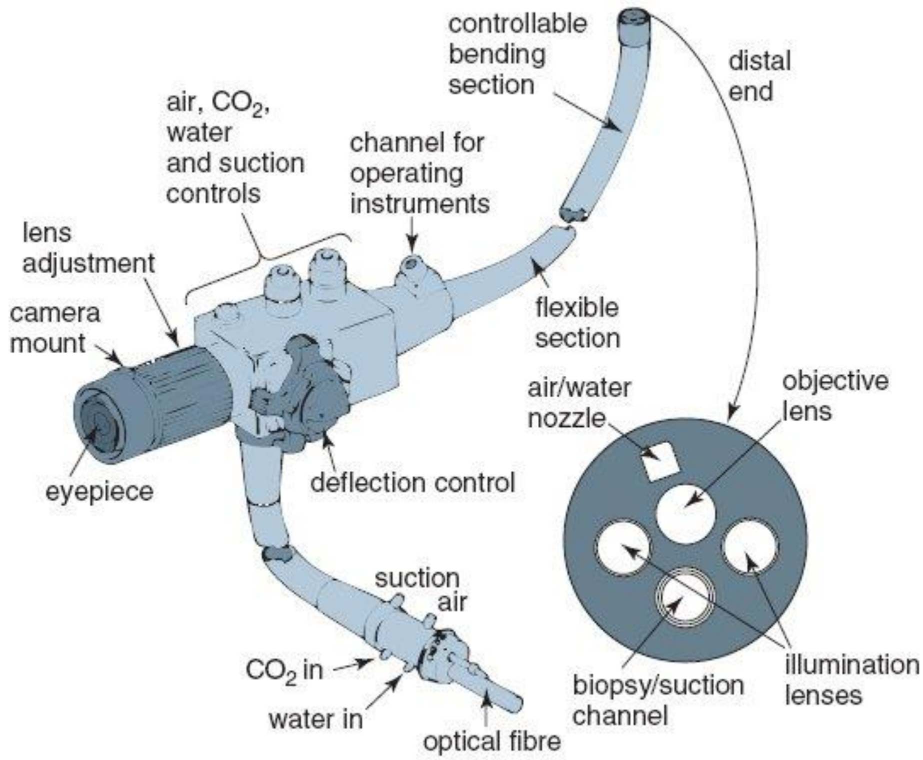

Figure 4: Components of a typical endoscope [6]

1.4 3-D printing

3-D printing is an additive manufacturing process in which we can make a 3-D object from a virtual model. Additive manufacturing is a process of first building a base layer, then adding thin layers of material over the base to “print” the model.

The process of 3-D printing starts with creating a three-dimensional CAD (computer aided design) model. Fig. 7 shows a graphical representation of a typical 3-D printing process. [7]

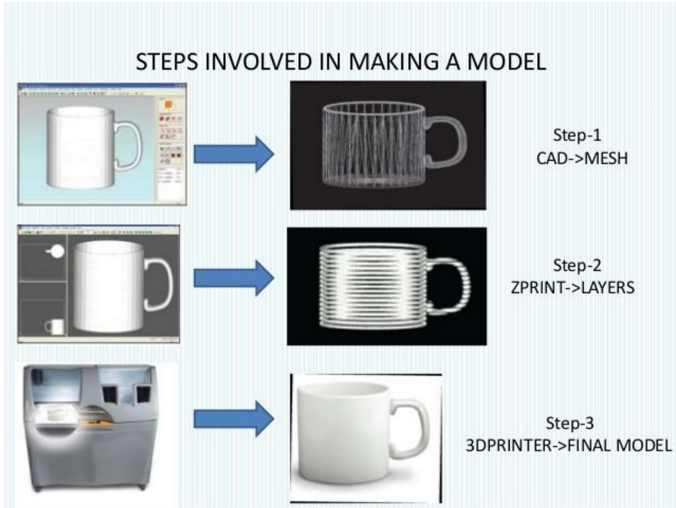

Figure 5: Graphical representation of a 3-D printing process [8]

The process for 3-D printing is divided in 3 steps. They are as follows:

1. CAD (Computer Aided Design) Modeling:

   CAD modelling is a process where a geometric model is made using 3-D modeling software, such as SolidWorks. 3-D modeling of an object can be used to examine design flaws, such as misalignment. The model is converted into an STL file and processed for 3-D printing.

2. Converting to STL file and G-code:

   Before 3-D printing an STL file, one must check for possible errors. Many errors can occur, such as badly converted holes, facets, shells, and intersections due to direct scanning of a 3-D object using a 3-D scanner into an STL file. A step called “repair function” helps to resolve these problems.

3. 3-D printing:

Once the STL file is finished, then the software has a section called 'slicer' which converts this STL file into a 'G-code' which has instructions tailored to the specification of the 3-D printer. Printer resolution describes layer thickness and X-Y resolution in micrometers or millimeters. Typical layer thickness is around 100 micrometer, although some machines can print layers as thin as 16 micrometers. 3-D printing helps in reducing the manufacturing time as compared to contemporary methods of manufacturing. 3-D printing is an extremely useful tool for fast prototyping where conventional machining falls short. Fig. 8 shows a graphical representation of a typical 3-D printing procedure [9].

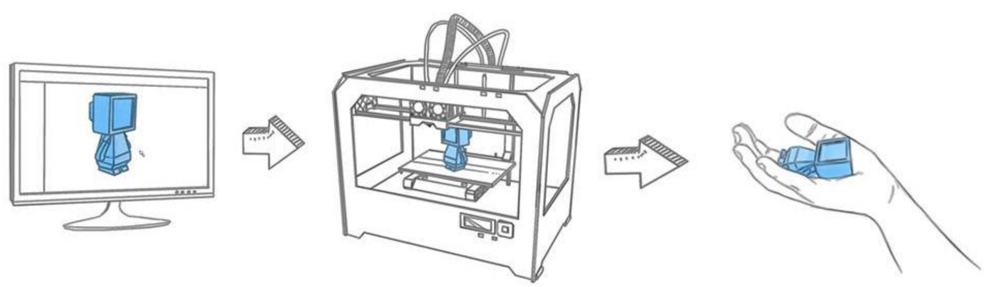

Figure 6: Stepwise graphical description of 3-D printing [10]: a) CAD modeling b) Layer deposition in 3-D printer c) 3-D printed model

We are able to smoothen the surface of the design by using Acrylonitrile Butadiene Styrene (ABS) with a use of acetone. In 3-D printing, we can also use printing materials varying mechanical properties . Some 3-D printers also use support materials and rafts for stability of the structure during the printing process. They can be removed mechanically or chemically [11].

There are various types of 3-D printing technique.

1. Fused Deposition Modeling (FDM): This is the most widely used 3-D printing technique. This method is the most affordable form of 3-D printing and is commonly seen with enthusiast and small businesses. The extruder acts like a nozzle, where it heats up the material above its melting point and pressurizes it through a nozzle. The filament is placed layer by layer, over each other, until the final object is completely printed. The most commonly used filaments are ABS and PLA. Fig. 9 shows a schematic of the FDM process [12].

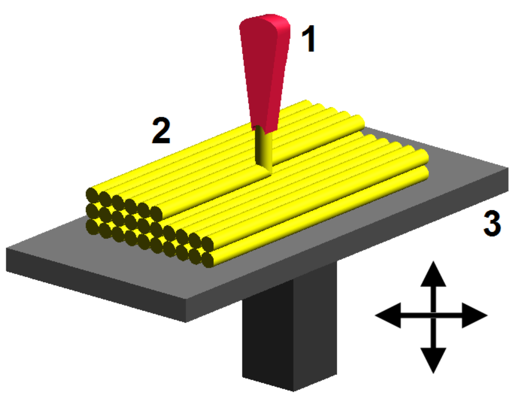

Figure 7: Schematic of a typical FDM printing technique

2. Light Polymerized 3-D printing: This process uses a light sensitive polymer, or, more specifically, a photopolymer. A photopolymer is a material which changes

its material properties, whether mechanical or chemical, when subjected to a certain light frequency, usually ultraviolet. For instance, the polymer is in a liquid state and when it is exposed to UV light, it changes its material properties and transforms into a solid layer. The UV light helps to establish chemical bond and Van der Waals forces to solidify the print. This method is one of the fastest methods of manufacturing and can produce some strong materials. This can also be used to make materials of variable mechanical properties such as flexibility. This is more expensive than the FDM, but efforts are being made to make the process more cost effective. This process is also called stereolithography (SLA) [13]. A light polymerized 3-D printer is shown in Fig. 10 below.

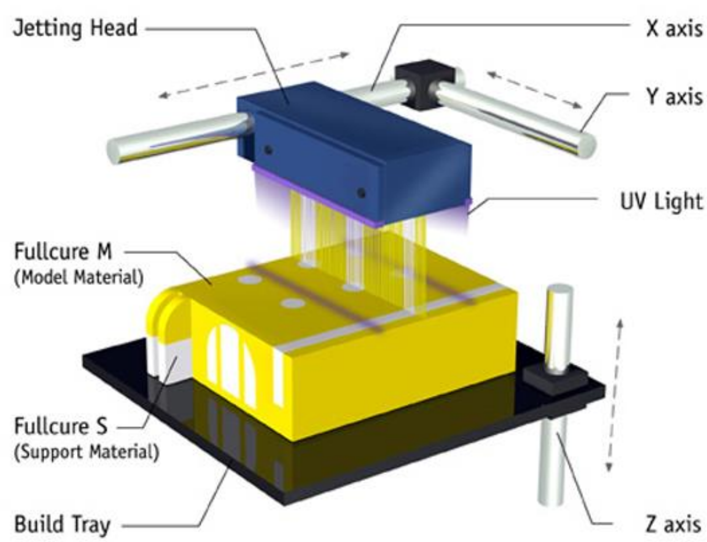

Figure 8: A typical light polymerized 3-D printing graphic[9]

3-D Printing via digital light processing (DLP), is very similar to SLA (stereolithography). The main difference is that SLA normally uses UV light or other forms of laser while DLP uses the light emitted from devices such as projector. It should be noted that DLP can also use a laser as a light source which would increase the expense of the 3-D Printer. Figure 11 shows a typical DLP 3-D printing graphic. [14]

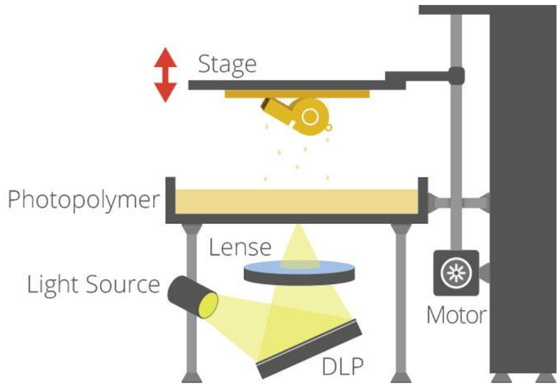

Figure 9: Schematic of DLP 3-D printing technique

3. Selective Heat Sintering (SHS): In this process, the print head is at one place and the print bed moves relative to the head. This uses thermoplastic powder as a filament and the heat in the system is used to melt the powder. The powder is placed on the bed, and the print head is heated. As the heated head meets the powder, the powder melts giving the proper shape to the filament. This is cheaper than other printers as this method does not use a laser as a heat source. The precision is not as high as the other printers and thus, this is only used to show proof of concept rather than to produce a final product. [15]
4. The Electron Beam Fabrication (EBF): This process, invented by NASA, was the first of its kind. It 3-D printed a metallic object with a help of a highly powered electron beam. This method uses a powerful electron beam to bond two metals, forming an alloy, which is then passed through an extruder to form layers. The layers add up to form a final design. This method is used to manufacture a complex

design made up of alloys. Post processing of this method is finishing the design for aesthetic appearance and to get rid of unwanted extra material. Electron beam melting is similar to EBF, but it only uses titanium alloy and is performed under vacuum condition. This method uses titanium powder as the filament and is very accurate. This is more expensive than EBF because of the cost of the material and the difficulty in the process [16]. The EBF manufacturing is shown in Figure 12.

Figure 10: EBF 3-D printing of steel [16]

5. Direct Metal Laser Sintering (DMLS) is also a method to print metal alloys similar to EBF. This method uses metal alloy as its filament. This method uses sintering process as in welding the metal parts using laser source. In this method, the metals are used in a powder form. Then they are sintered using a high power laser. In this method, the print bed moves as well along with the laser source and it picks up the amount of powder necessary for the print.

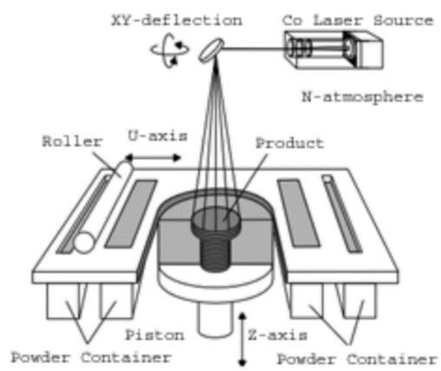

Figure 11: Typical DMLS 3-D printing technique

The DMLS method has a very high accuracy and high precision as it uses a laser source. Its application is mainly in the dental and the medical industry and manufacturing some surgical tools. Stainless steel and Titanium are the two major metals used in this method.

Selective laser melting (SLM) and selective laser sintering (SLS) use laser as the heating source in the process of 3-D printing. SLM uses a nozzle to push out a metal alloy while SLS uses a powdered filament, which is treated by a laser. They both have weaker final products than the methods such as EBF and DMLS. SLM can be only used with metal and alloys while SLS can be used with thermoplastics as well [16].

6. Plaster based 3-D printing: This method uses a mixture of dry powder and water to print a 3-D object. When the powder is mixed with water, it becomes paste-like. When heated, past a certain temperature (100 °C), water evaporates, hardening the plaster. This principle is used in 3-D printing and is also called binder jetting. Plaster based 3-D Printing uses inkjet heads similar to those in regular home (2-D) Printers and can 3-D Print Plaster in full color. PP is excellent for artistic projects,

especially those in structures, like a wall in a house. The picture below shows how plaster based printing is done. Figure 14 shows a schematic of plaster 3-D printing.

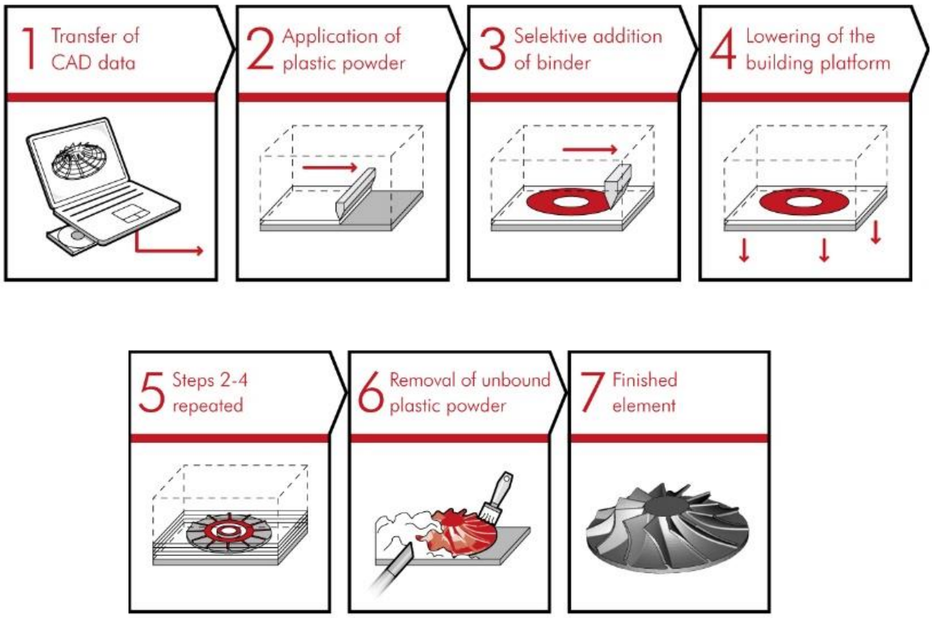

Figure 12: Schematic of 3-D printing of plaster

The print bed holds the powdered plaster and the print head deposits a binding material in the desired shape into the sections. Plaster powder is then placed over that layer. The process is repeated many times until the object is completely printed. Unused powder is then removed [17].

1.5 Thesis Organization

This dissertation focuses on a) design and analysis of endoscopes using finite element analysis, b) manufacturing of a disposable endoscope, and c) an overtube using 3-D printing technology to eliminate the superbug infections.

Chapter 1 introduces several types of endoscopies and a short description of the so called superbug infections, followed by a brief history of endoscopes. It also describes current endoscopes and its components. It briefly describes various 3-D printing techniques.

Chapter 2 explains the current designs of endoscopes and overtubes in detail.

Chapter 3 presents the finite element models and finite element analysis of the design and explains the various boundary conditions for the designs.

Chapter 4 shows the testing results of 3-D printed designs.

Chapter 5 presents the conclusion of this dissertation.

2 Current endoscopes, Elevator endoscope and Overtube

In chapter 2, detailed designs of current endoscopes and overtubes are discussed. The chapter also introduces the super bug infection, ERCP endoscopes and their ineffectiveness to avoid superbug infection. Chapter 2 briefly describes the need for manufacturing a disposable endoscope and overtube.

2.1 Current endoscope design and actuation techniques

The internal assembly of an endoscope is very tight and sophisticated. The so called insertion tube carries this assembly. The insertion tube is manufactured in such a way that it is “rigid enough” to hold this assembly and “flexible enough” to follow the bending tube. The handling of the insertion tube is the main characteristic of different types of endoscopes. The ERCP endoscope specifically, the insertion tube has to be flexible enough to go through bends and loops in the GI tract. The insertion tube has to give a 1:1 torque ratio, as the torque applied by the physicist should be equal to the torque at the bending end. The insertion tube is manufactured with metal strips at a predetermined distance. It is the covered with a stainless steel mesh wire. This wire allows the tube to transfer the torque to the distal end. The stainless steel mesh is covered with a polymer base layer, which is made up by mixing two polymers. This makes the insertion tube light and flexible. This whole assembly is then covered with a final layer of low friction polymer coat. This helps to reduce organ injuries by excessive rubbing and friction during the procedure. The insertion tube is light and can easily slide in the system without injuring the organs [18]. A typical insertion tube is shown in figure 15.

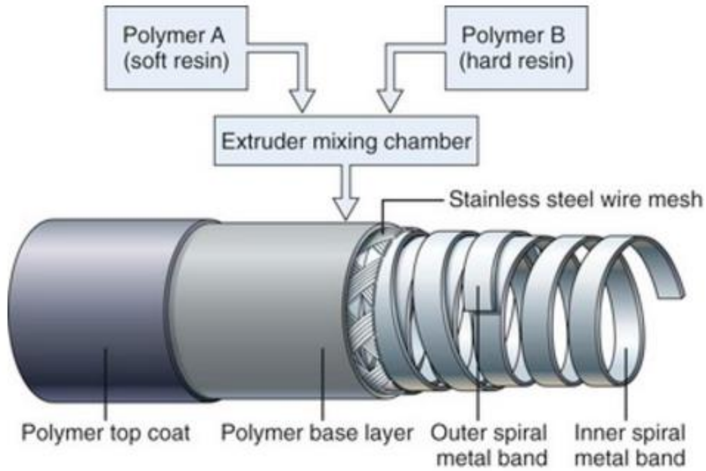

Figure 13: Internal structure of an insertion tube [18]

The insertion tube has to carry many wires in the assembly. The assembly is extremely sophisticated and changes according to each scope. The main components in an insertion tube assembly are tubes for suction, air and water feeding, biopsy cables, fiber optic cable for camera and wiring for the lens, the wiring for automation and as well the wiring for actuation of the scope. The endoscope for ERCP procedures has an extra wire assembly for the up and down movement of the elevator. A typical insertion tube assembly is shown in figure 16.

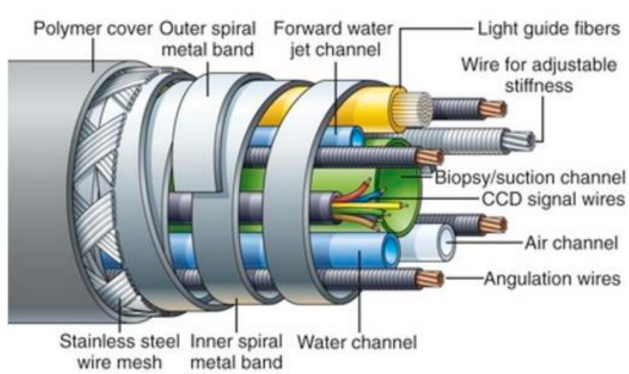

Figure 14: Internal assembly of an endoscope tube [18]

The distal end of the endoscope differs mainly according to the size or the type of the scope. The scope used for colonoscopy has a straight circular shaped face end. The bending tip is cylindrical in shape. The end tip assembly is similar to the insertion tube, but contains all main components. Most of the cylindrical area is allocated to the lens, the camera and the light source with CCD image sensor [18]. There is also an outlet for the biopsy cable and an outlet for the irrigation cable. The cross section of a particular colonoscope is illustrated in figure 17.

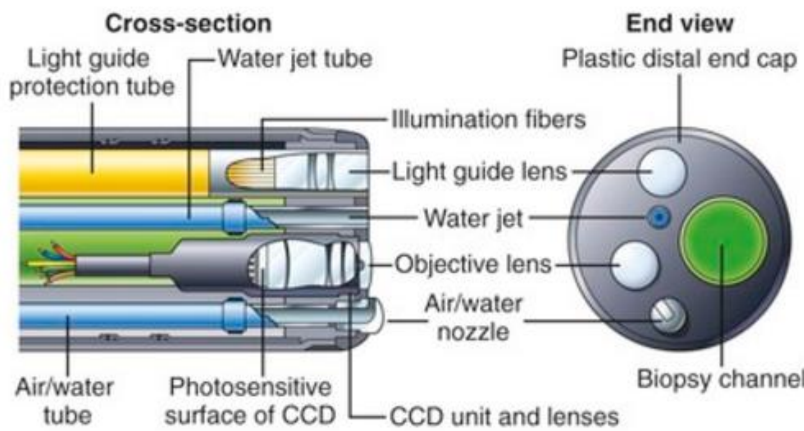

Figure 15: Internal assembly of distal end of an endoscope [18]

2.1.1 Endoscope actuation

Currently, endoscopes are manufactured using either casting or molding. The follower section is manufactured of flexible polymer. The bending tip is manufactured using small linkages made up of steel castings. This steel link has a ball and socket arrangement, which allows the scope to rotate in all degrees of motion. The steel links are attached to each other by the tension of wires, which helps in the actuation of the tip [18]. This can be elaborated using the following figure 18.

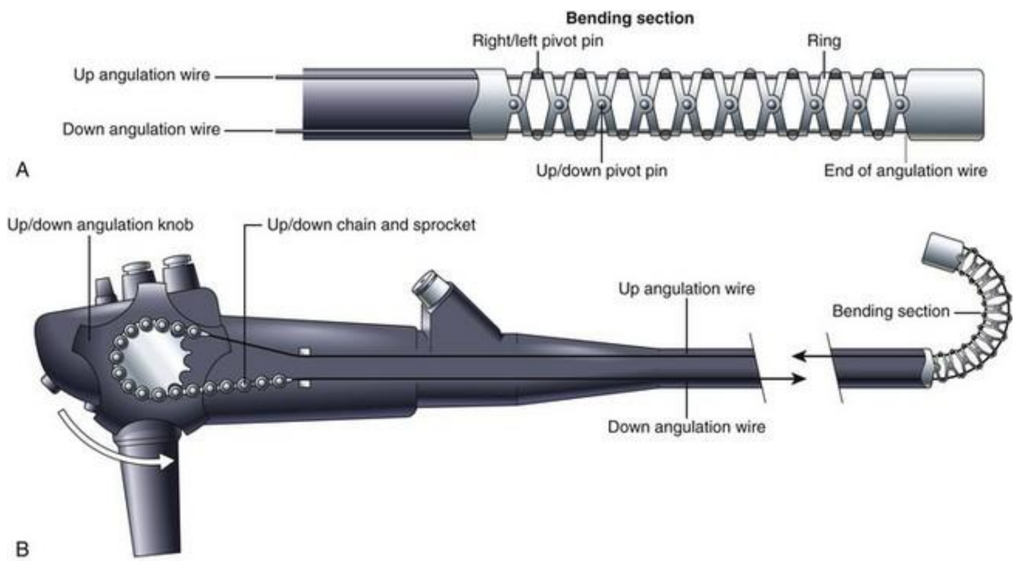

Figure 16: CAD drawing of an endoscope [18]

The length of the current endoscope varies according to the procedure for which the endoscope is going to be used. The endoscopes are steered in the following ways:

1. Chain and sprocket arrangement

This arrangement is usually used with 1-DOF freedom endoscopes. The chain is attached to the pre-tensed wire, which pulls the bending tip of the endoscope while the sprocket is attached to the knob of the endoscope handle. The knob is controlled by the physician and indirectly controls the bending of the tip through the sprocket and chain arrangement. Figure 19 shows a cross section of chain and socket assembly [19]

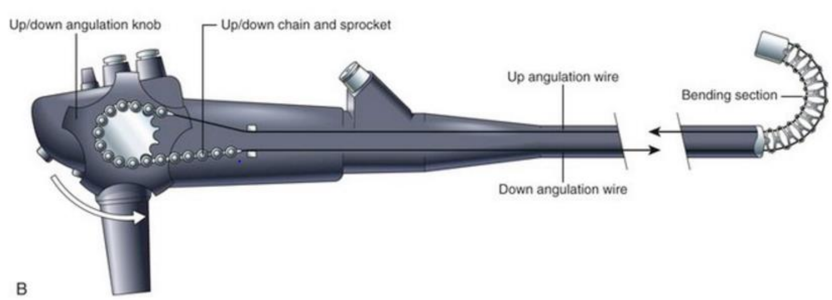

Figure 17: Cross section of chain and sprocket assembly [18]

This design has accuracy since it does not slip any place. Precise control of tip movement is possible with knob rotation. Figure 20 shows an illustration how a 2-way chain and sprocket works

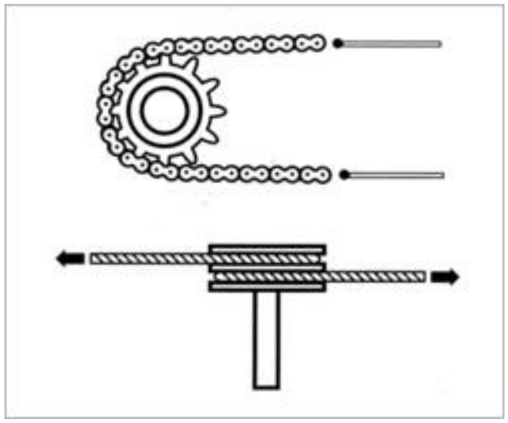

Figure 18: Illustration of a 2-way working of a chain and sprocket [19]

2. Using Shape memory alloy wires/ springs:

Shape memory alloys, also known as smart metals, remember their original shape and configuration. When heated up, an SMA transforms to its original shape. There are two main types of SMA, Nickel Titanium Alloys (Ni-Ti) and Copper Zinc Titanium alloys. Ni-Ti alloys are the most commonly used SMAs. Martensite changes to austenite on heating, thus causing a change in the shape of the material. This property is used in many applications including the aircraft industry, the automobile industry and medical devices. The shape changing property of an SMA wire or spring is used to actuate or bend the endoscope tip in the desired position [20]. This is illustrated in figure 20.

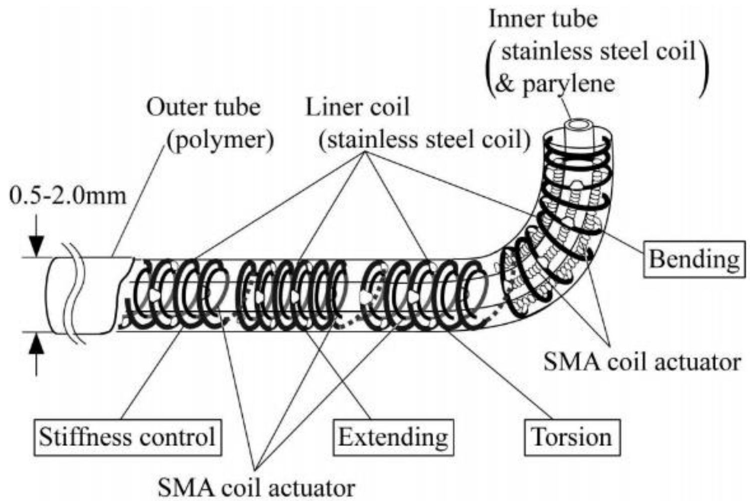

Figure 19: Endoscope distal tip actuated by SMA coil [20]

The figure 20 shows that the bending section is an assembly of linkages. A single linkage assembly has 6-8 small steel links, which allows the linkage to rotate in all degrees of rotation. The linkage assembly of the tip, precisely called the bending section, is controlled using SMA coils. The coils are designed in such a way that the pre-tension in them keeps the bending tip in a straight position. When a current passes through the spring, it contracts proportionally to the current passed. This contraction of the spring is used to apply a load in the transverse direction, which results in bending the tip. The current passed through the spring is proportional to the load and thus the bending can be controlled precisely in each direction. Figure 22 shows an endoscope tip controlled by SMA coils [21].

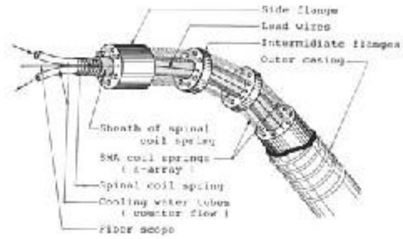

Figure 20: SMA coil actuated endoscope tip [21]

3. Wire and motor arrangement:

A simple wire and motor arrangement has a pre-tensed wire in an assembly attached to the motor driving it. The motor is a servo motor and thus requires a power source for actuation. The pre-tension in the wire keeps the endoscope links in a straight alignment. As the motor rotates, the particular wire tightens and applies a pulling force in that direction. This pulling force can be used as a bending force for the tip of the endoscope. The actuation by this method is the simplest and fastest method [22]. A 2-way motor system is illustrated in figure 23.

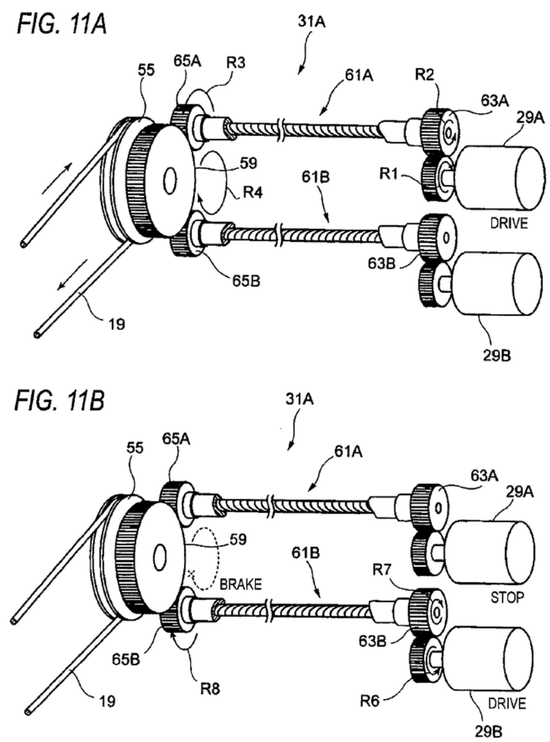

Figure 21: 2-way rotating motor to control endoscope tip [22]

2.2 ERCP Procedure

The Endoscopic retrograde cholangiopancreatography (ERCP) procedure is performed on the upper GI tract of the human body. This procedure is done to inspect parts of the duodenum and small intestine [23]. This procedure uses an ERCP specialized endoscope, which has an elevator portion in it. The elevator design helps the scope to work perpendicular with respect to the GI tract allowing the doctor to examine the parts of pancreas and the bladder [24]. ERCP endoscope, referred in medical terms as duodenoscope, is used on a large-scale. Approx. 250 million procedures per year are performed in the United States of America [25]. ERCP is an important and frequent medical procedure that allows doctors to evaluate blockages from the channels (bile and pancreatic ducts) that drain a patient's liver. Figure 24 shows an ERCP procedure in computer graphics. In the figure, the catheter is pushed in a pancreatic duct using an elevator and side-viewing camera

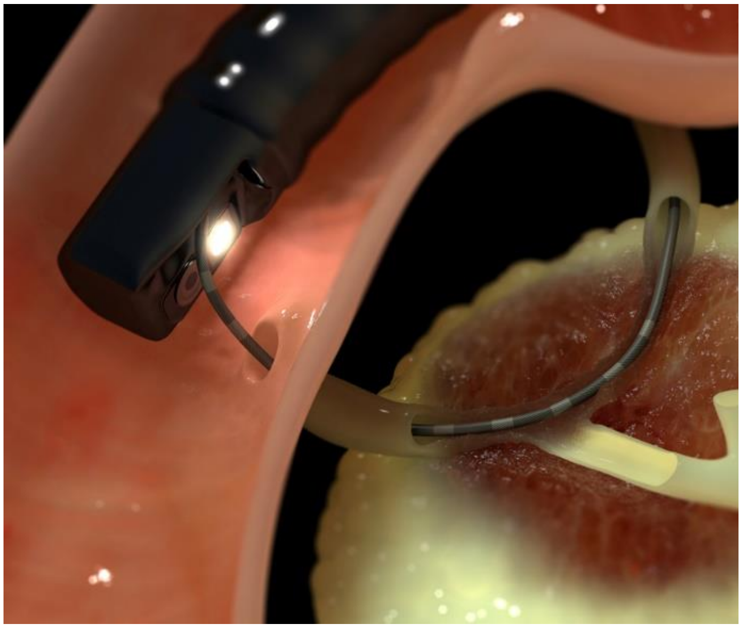

Figure 22: ERCP procedure performed [25]

2.3 ERCP endoscope

The pancreatic duct opening is very small (of the size 3mm-6mm) and a duodenoscope cannot enter the pancreatic cavity. This cavity is also in the perpendicular direction to the travel path of the scope, i.e. it is difficult for the scope to turn 90 degree in such a small space [26]. For this reason, the end part of the duodenoscope containing a so-called elevator portion.

The elevator is a small part in the assembly and acts as a simple linkage. The elevator is assembled at the rear end of a duodenoscope. The elevator is attached to a lever by a spring coil and a thin wire to actuate the mechanism. This wire connects the rear end of the elevator to an elevator control knob [27]. The elevator wire is passed through a channel, which controls the elevator movement. This is explained in the figure 25 below.

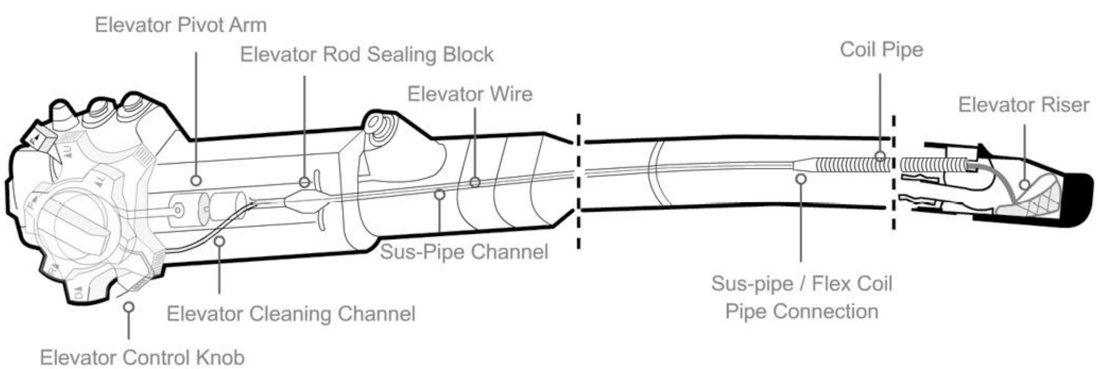

Figure 23: . 2-D drawing of an elevator [27]

The elevator riser is a small linkage, which is allowed to rotate with tension applied to the elevator wire. The elevator riser allows the biopsy cable or a catheter to turn in range from 0 degrees to 90 degrees with a precision of 5 degree. The elevator riser is controlled by the doctor using elevator knob which is at the front end of the endoscope. The coil pipe in the assembly is used to stabilize the system, giving an accuracy of 5 degree and retreating the elevator to its original position. Figure 26 shows a cross view of the light system in a duodenoscope.

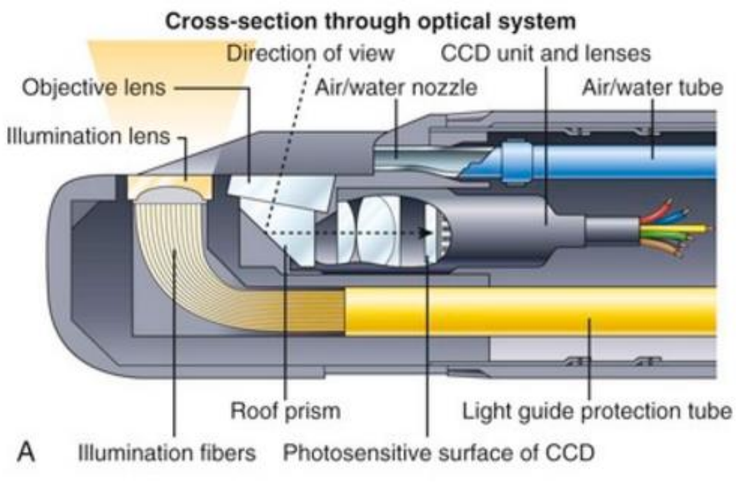

Figure 24: Cross section of a duodenoscope tip [29]

The distal end of an ERCP endoscope has a different assembly than a normal scope. The camera and the lens are attached to a face perpendicular to the motion of the scope. Also, the biopsy outlet is at an angle, which can be changed to the travel direction of the endoscope. This is mainly due to the entry in the pancreatic cavities at the start of the small intestine. These cavities are smaller in diameter and are perpendicular to the direction of smaller intestines [29]. This angular movement is achieved through the elevator portion discussed in the previous section. This is shown in the figure 26 below. The elevator also locks the catheter in position, resulting in a more stable procedure.

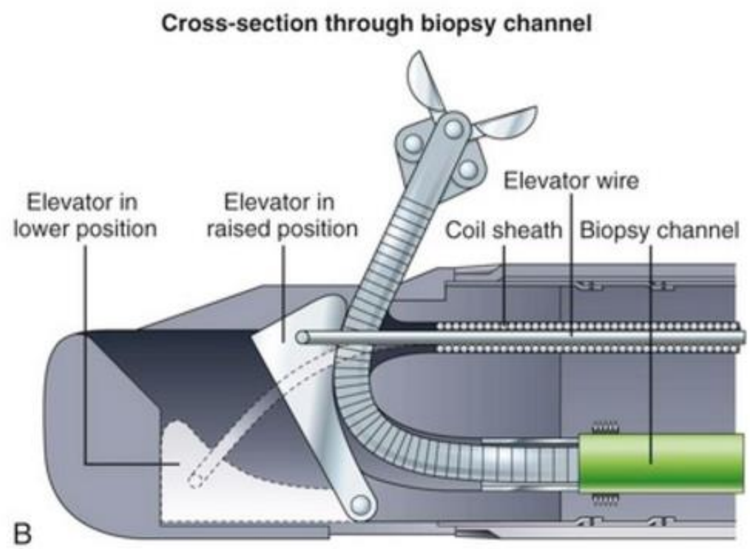

Figure 25: Cross section view of an elevator in duodenoscope [29]

Small cavities are present at the back end of the elevator. These cavities are very difficult to clean. Due to this difficulty, there is a possibility of bacteria accumulating at the end of the scope, which makes the disinfection of the scope difficult. This is the main reason for the superbug infection to spread and researchers are still working to find a solution for the same.

2.4 Cleaning process of ERCP endoscope

The ERCP endoscope goes through a very stringent cleaning procedure. The process starts with a machine cleaning, where all channels are supplied with pressurized solution of water and disinfectant. This pressurized solution helps clean out any debris after the surgery in those channels. The exterior surface is also cleaned with brushes and solution of the water and the disinfectant, and is then cleaned manually. Figure 29 shows a typical way of cleaning an endoscope [30].

Figure 26: Machine cleaning of an endoscope [30]

The manual cleaning starts with a brush cleaning of the exterior pipe as shown in figure 30 and is then followed by a cleaning of all channels. The channel cavities are cleaned using spoke brushes, for better access to the cavities.

Figure 27: Manual cleaning of an endoscope

The spoke brushes also clean the rear end of the elevator, but it is very difficult to access that region of a duodenoscope. This makes it tedious to clean that end and thus, results in a chance of infection. Figure 31 graphically shows the difficulties in cleaning the posterior end on an elevator

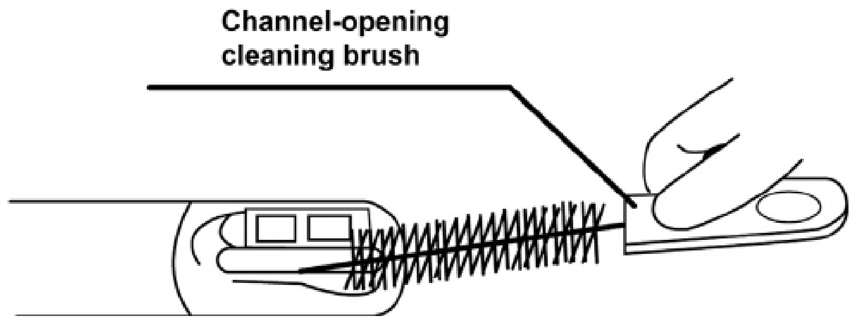

Figure 28: Graphical description of cleaning an elevator

The cleaning is repeated with another round of machine and manual cleaning followed by suction of all the liquid, which is the last round of cleaning before the endoscope can be reused. In this cleaning process the endoscope is hung around a stand and then the suction pipes suck all the water, resulting in a clean and re-usable endoscope [31]. This can be seen in Figure 32 below.

Figure 29: Cleaning machine with suction pipes [31]

2.5 Super-bug infection

Antimicrobial resistance (AMR) is the ability of a bacteria to resist the effects of medication previously used to destroy them. Carbapenem-resistant enterobacteriaceae (CRE) or carbapenemase-producing enterobacteriaceae (CPE) are bacteria that are resistant to the carbapenem class of antibiotics, the latter considered the drugs of last resort for such infections. They are resistant because they produce an enzyme called carbapenemase that disables the drug. As of 2013, hard-to-treat or untreatable infections of Carbapenem-Resistant Enterobacteriaceae (CRE) were increasing among patients in medical facilities. Enterobacteriaceae are a family of bacteria that include Klebsiella species and Escherichia coli (E. coli) [34], which are found in a human's intestines (gut). Sometimes these bacteria can spread outside the gut and cause serious infections, such as pneumonia, bloodstream infections, urinary tract infections, wound infections, and meningitis. [31] Enterobacteriaceae are one of the most common causes of bacterial infections in both healthcare and community settings [34]. CRE are an emerging threat to public health as they are resistant to nearly all available antibiotics. To get a CRE infection, a person must be exposed to CRE bacteria. CRE bacteria are most often spread person-to-person in healthcare settings through contact with infected people, particularly contact with wounds or stool. CRE can cause infections when they enter the body, often through medical devices like intravenous catheters, urinary catheters, or through wounds caused by injury or surgery [32]. Almost half of hospital patients who get bloodstream CRE infections die from the infection [32]. Hospitals are primary transmission sites for CRE-based infections. Up to 75% of hospital admissions attributed to CRE were from long-term care facilities or transferred from another hospital [33]. Suboptimal maintenance practices of medical devices are the largest cause of CRE transmission.

2.6 Need for disposable endoscope

Currently, the U.S. Center for Disease Control (CDC) is providing consultation to the Los Angeles County Health Department as it investigates, in collaboration with the University of California, Los Angeles (UCLA) Medical Center, a cluster of carbapenem-resistant enterobacteriaceae cases. In this investigation, exposure to duodenoscopes used in a lifesaving procedure called endoscopic retrograde cholangiopancreatography was associated with transmission of CRE [34]. Presently the situation is such that there are approximately 2500 cases in USA reporting serious gastrointestinal problems per day and most of them require a screening to be done using a duodenoscope. The chances of an individual succumbing to death after getting a CRE infection is 40 to 50% [35]. Mostly the CRE infection is due to endoscopes thus designing a disposable scope is a pressing task for a medical community. According to the U.S. Center for Disease Control (CDC), each year about 2 million people are infected with the antibiotic resistant bacteria, and approximately 23,000 of them die from the infection [34]. CRE overwhelms the body. Bacteria spread throughout the body over a period of a couple of days to a few weeks. Since the individuals are already ill, it worsens their health [35]. Even with cleaning and disinfecting an endoscope there is a sizeable chance of CRE being present on the device. Thus, there is a need for designing an endoscope, which will reduce or eliminate the chances of these deadly bacteria entering the body. Thus, implementing a disposable endoscope would be a major landmark advance for endoscopy management.

2.7 Disposable medical device using 3-D printing

The cleaning of the elevator is a difficult process and there is no surety of it being completely disinfected. The only way we are 100 % sure that a disinfected device is used for the following procedure is by making the device disposable. The issue as to making just the distal tip or the entire scope disposable is a debatable topic. In this light, designing a disposable component instead of reusing the elevator portion can be a promising solution for the CRE superbug problem.

The parts of the current endoscopes are manufactured using a casting process and all the inner parts in the assembly are made using methods like milling and grinding. The plastic and non-metallic parts are manufactured using injection molding process. Making a cast for the scope and the mold is an expensive process and an ERCP endoscope costs about $60000-$75000 per unit [36]. It is highly important to make cheaper products, in case of disposable endoscopes. Thus, to manufacture a disposable endoscope, cheaper manufacturing processes could be used. 3-D printing is an additive manufacturing process, which is currently used on a large scale in every industry. There have been instances where a tissue in the body is 3-D printed. 3-D printed materials as discussed in the previous chapter are inexpensive, flexible as well as rigid and most importantly, biocompatible. Thus, 3-D printed disposable endoscopes could be a solution for the CRE superbug problem in ERCP endoscopes.

3 Endoscope and Overtube design

In Chapter 3, various designs for the endoscope are discussed. A finite element analysis model is setup for various tests and boundary conditions are discussed accordingly. Results for the finite element analysis are explored in this chapter.

3.1 Endoscope design

In the previous chapter, the current state of the art designs were discussed. The designs for an endoscope were inspired by those designs and the following sections will discuss the designs for disposable endoscopes. The discussed design is drafted with respect to 3-D printing as the manufacturing technique. In this section, we will also discuss the significance of each design feature. Kim et. al [37] proposed a ball and socket joint for the linkage assembly of the endoscope and our preliminary designs were based on that design. The designs were then optimized taking into account the flexible material printing properties of 3-D printing. The designs are as follows:

3.1.1 Preliminary design

This design is based on the proposed approach of ball and socket movement. The design shown in Figure 33 has the dimensions of 16 mm, 5mm and 2mm for outer diameter, overall height and outer wall thickness respectively. The linkages are assembled using wires. The tension in the wires holds the assembly in proper configuration. Additional tension in the wire guides the tip to bend in a particular direction [38].

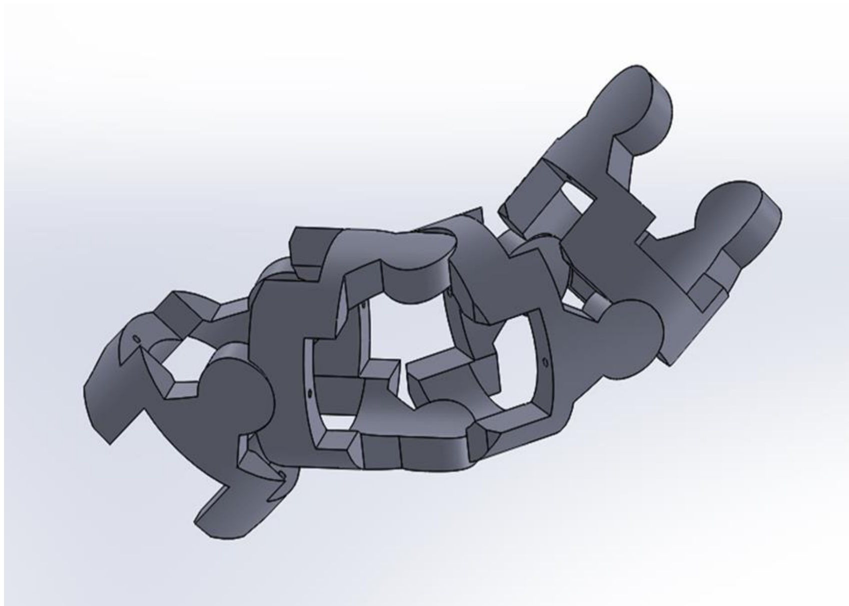

Figure 30: CAD model of a preliminary design

The ball and socket are arranged in crisscross as shown in Figure 33 and the movement of the linkage is per the ball and socket movement. Figure 34 shows a 3-D printed preliminary design. This design is 3-D printed on a stratasys connex 3-D printer.

Figure 31: 3-D printed assembly of preliminary design

3.1.2 V cut groove design

The design was inspired by Guang et. al. [39]. In this design, the V-shaped grooves are cut in the body material. The paper mentioned that ideal v-cut grooves range from 30^{o} to 45^{o}. The v-cut groove design is as shown in figure 35.

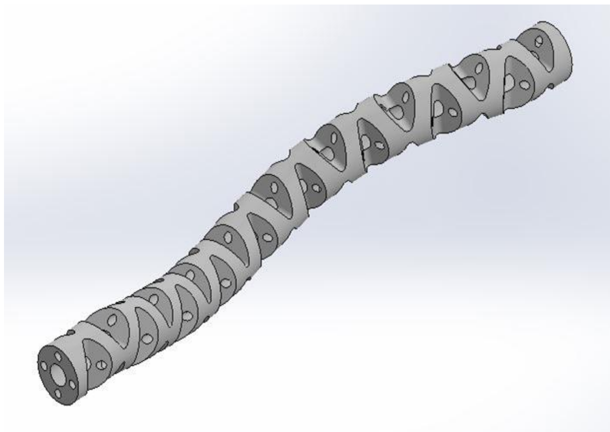

Figure 32: Follower of endoscope with v-cut groove

The dimensions of the endoscope are similar to a typical ERCP endoscope. The outer diameter is 16mm and the length varies from 30 cm to 60 cm. Figure 36 shows the assembly of a V- cut groove design.

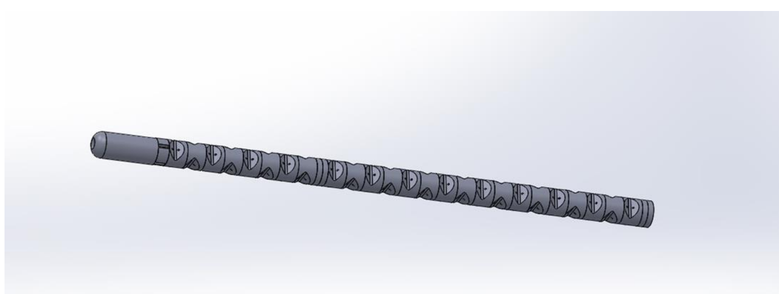

Figure 33: CAD model of an assembly for v- cut grove

The design was manufactured with a Stratasys Connex 3-D printer and the product can be seen in Figure 37. The design was optimized with a trial and error method using v-cut angles ranging from 15^o to 60^o. Table 1 shows the percent tear and maximum angle bend within the range of 15^o to 60^o angle of the v-cut. Percentage tear was calculated by comparing the tear on the design with maximum tear on a design with 60^o v-cut angle.

Figure 34: 3-D printed follower for v-cut groove design

Table 1. Comparison of different v-cuts

Angle of v-cut groove	Percentage tear	Maximum bend without kink
15^o	0%	30^o
30^o	0%	75^o
40^o	0%	120^o
45^o	10%	140^o
50^o	52%	150^o
55^o	78%	180^o
60^o	100%	180^o

Larger angles gave us more tear as compared to lower angles. The table shows the percent tear and maximum angle bend within the range of 15^o to 60^o. The optimized tip design with camera carrying unit can be seen in Figure 38.

Figure 35: 3-D printed design for v-cut groove endoscope

Figure 39 shows a model covered with a heat shrink to reduce the friction while travelling in a body cavity.

Figure 36: The v-grove endoscope assembled with a biocompatible shrink

3.1.3 Cylindrical Spacer design

This design is based on current endoscope design. This design has cylindrical linkages separated by spacers. The dimensions are on the same scale as the previous endoscope design. The outer diameter of the design is 16 mm and has an outer wall thickness of 2 mm. The cylindrical linkage height is 5 mm and the spacer height is 1 mm. A similar design was proposed by Kim ET. Al [37] to achieve the required bending. This design is slightly better than the previous one, as it has less wear compared to the v-cut groove design.

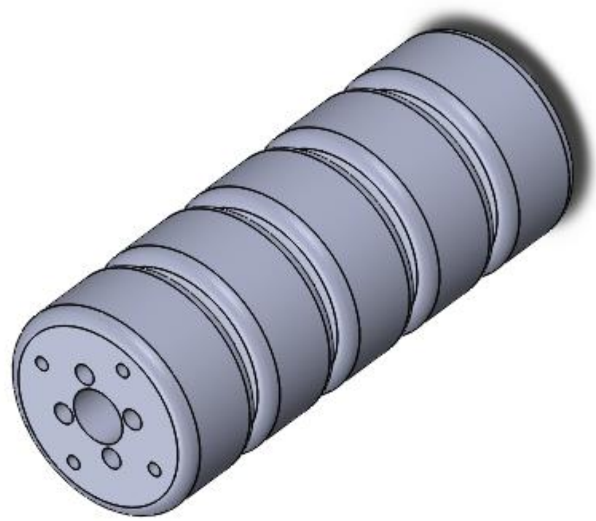

Figure 37: A single linkage of cylindrical body

In addition, this design is better with respect to manufacturing on a 3-D printer. The manufacturing time is reduced by 10% and the cleaning time is reduced by 30%. Figure 41 shows the cylindrical design and Figure 42 illustrates a 3-D printed model of the same.

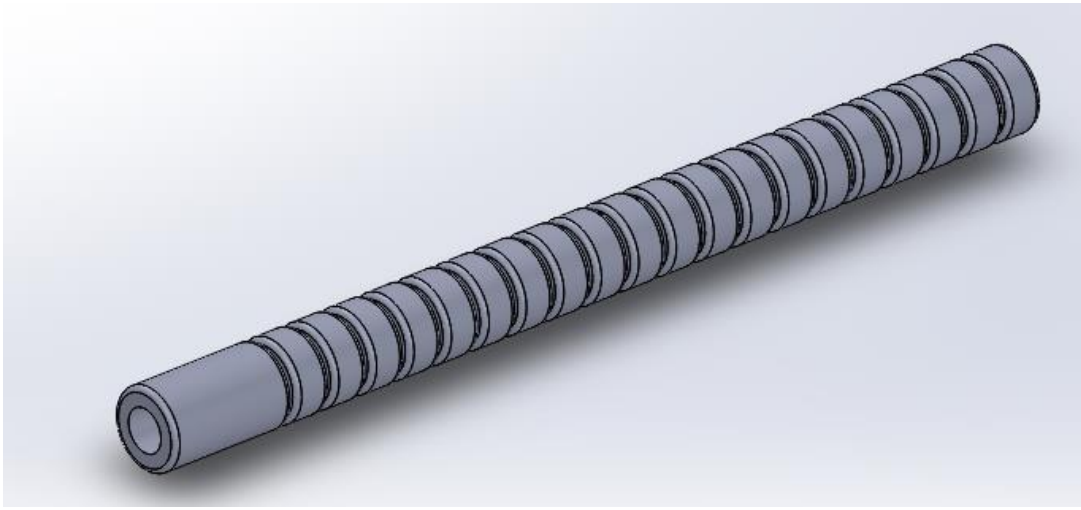

Figure 38: Assembly of endoscope tip with the body

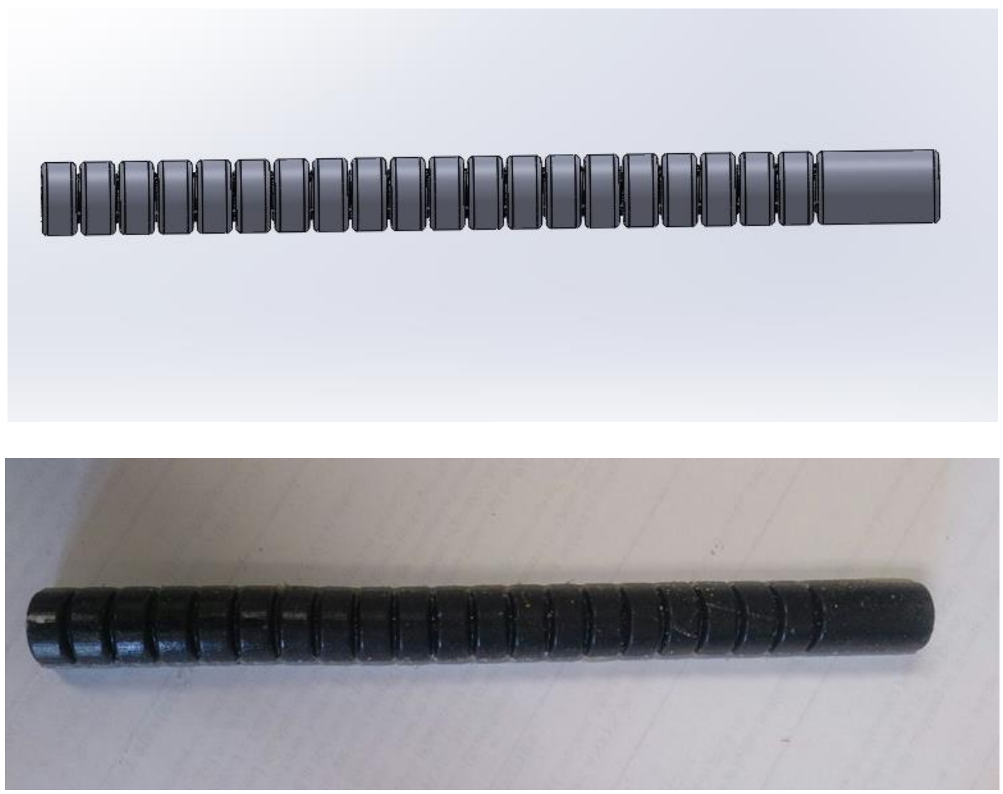

Figure 39: 3-D printed assembly of cylindrical design

3.2 Overtube design

An overtube is a medical device that guides an endoscope through a body cavity. The state of the art overtube design is made up of plastic and is opaque. The overtube has two layers of plastic coating over a steel spring, which avoids kinking. A typical overtube is shown in Figure 43.

Figure 40: A typical overtube used in upper endoscopy

The overtube diameter is slightly greater than the insertion tube which prevents pinching of an organ tissue. The inner diameter is 16.06 mm and the length is greater than the endoscope used. Figure 44 shows the assembly of an overtube with an ERCP endoscope [40].

Figure 41: Overtube assembled with an ERCP endoscope [40]

3.2.1 Disposable smart overtube

The overtube design in this section is an alternative design for the ERCP endoscope. This overtube design can turn 90° and helps the doctor guide the endoscope to the prescribed location. It can also be used to jam at a single position using jamming devices like a balloon. The overtube design is like the cylindrical endoscope design. It has cylindrical linkages connected through spacers. The dimension of the overtube is of the same scale of an actual overtube. The Inner diameter is 17mm, which is, slightly higher than the endoscope outer diameter. Figure 45 illustrates the CAD design of overtube.

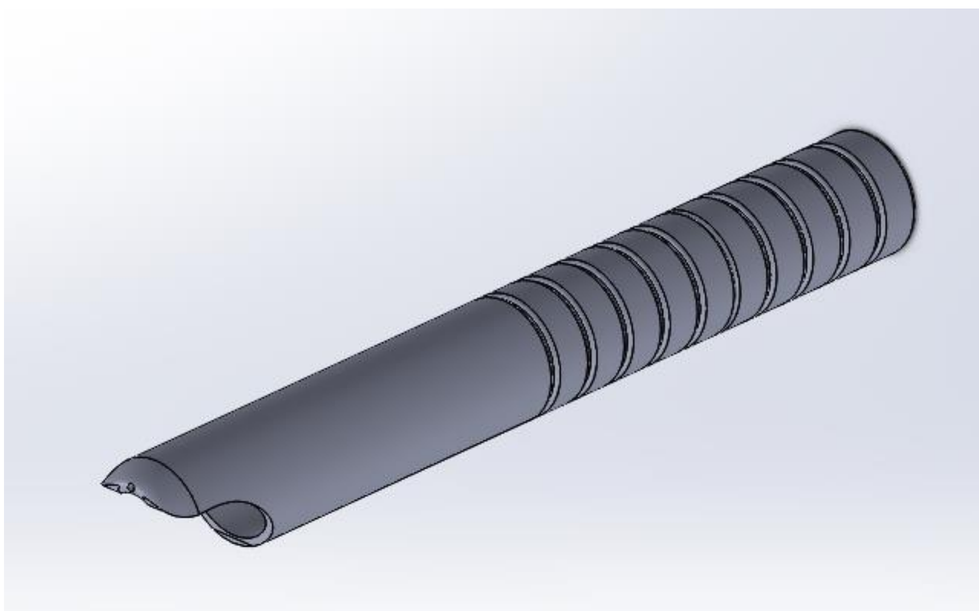

Figure 42: Overtube design

This design can bend the tip and a bent tip design can be seen in Figure 46. The designed tip is controlled by a string. When the string is pulled, the tip is bend in 90 degrees as shown in the figure below.

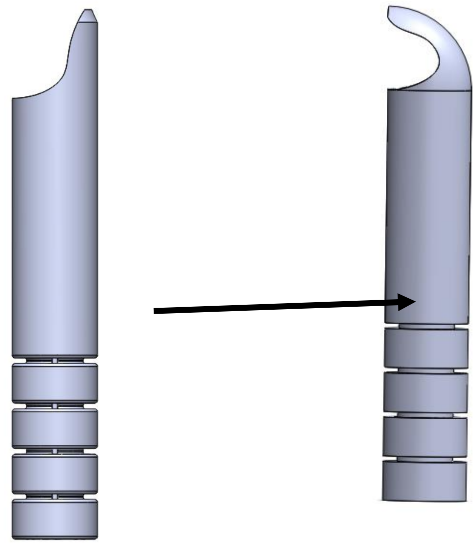

Figure 43: Bent tip design

The overtube and endoscope pass through the GI tract. A typical overtube and endoscope assembly can be seen in Figure 47.

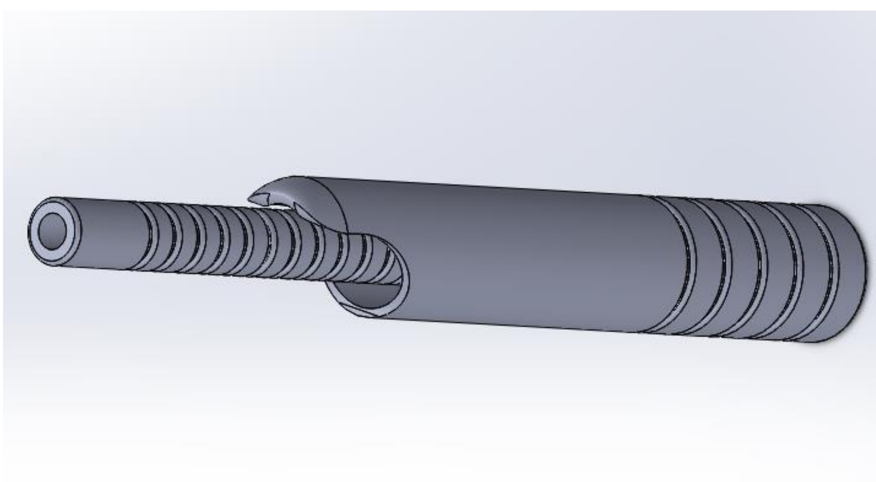

Figure 44: Overtube assembled with an endoscope

The balloon jamming technique is used to jam the overtube in a position. A balloon after inflation exerts pressure on the organ and locks the overtube in that position. Figure 48 shows an overtube with balloon inflated around it.

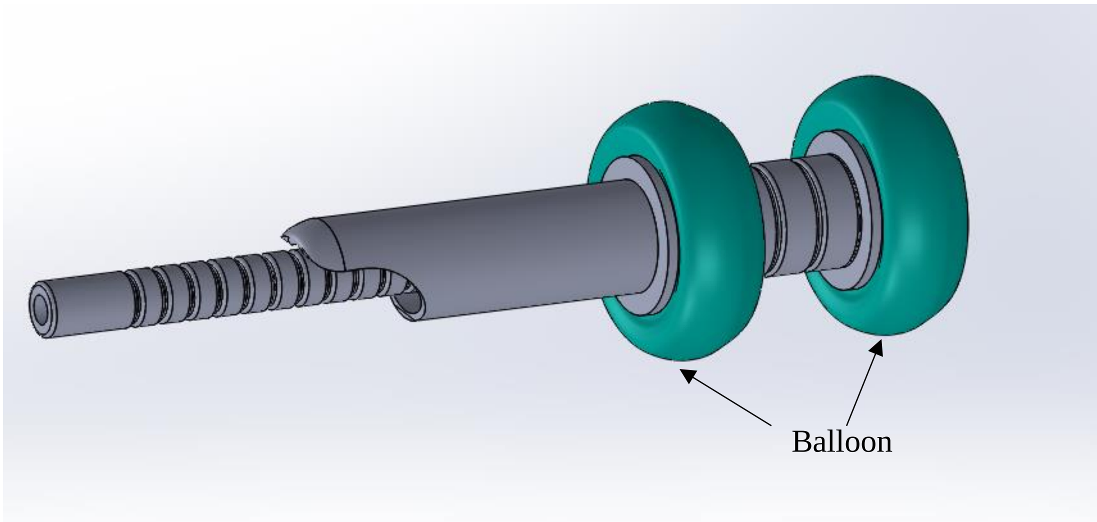

Figure 45: Overtube with an inflated balloon

Making a smart overtube, which can function as an elevator in ERCP procedure, can be a promising approach to avoid the superbug infection problem.

The overtube design can be a potential solution to the superbug problem. With the overtube, we can use a front viewing scope instead of an ERCP scope. The overtube is disposable and the front viewing scope can be cleaned with a standard process. The overtube design is a potential alternative to elevator portion in duodenoscope or the entire duodenoscope.

3.3 Finite Element Method and Analysis

Finite element method (FEM) approximately solves boundary value problems based on the boundary conditions. Finite element analysis is a process in which a a design is discretized into small elements. The process of forming these small elements is called meshing.

Finite element analysis is a tool used to simulate practical situations without manufacturing the design and manually testing it. After 3-D modelling in SolidWorks, the model is meshed in the same software. The model is discretized in small elements such as tetrahedral elements or hexagonal elements. Figure 49 shows a discretized model. This procedure is also called pre-processing of the design.

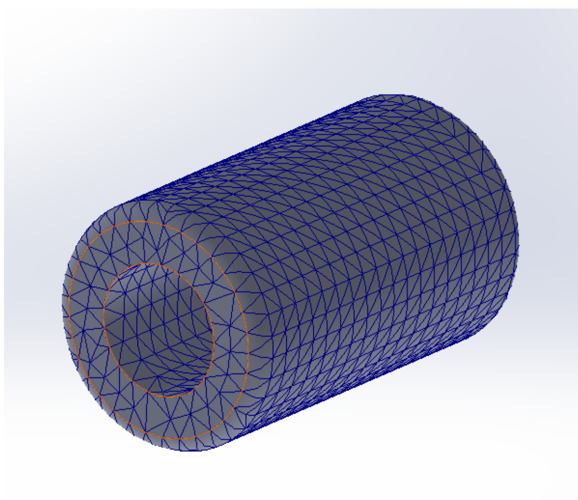

Figure 46: Meshed tip of an endoscope.

After meshing in SolidWorks, the design is analyzed for various conditions. We use a post processor such as SolidWorks Simulate to run the analysis. This solver is a Finite element analysis solver. All software packages are commercially available.

3.3.1 Material properties and Meshing

The material properties of the 3-D printed material are assumed to be similar to natural rubber. The material properties of 3-D printed materials were calculated using uni-axial testing and are similar to the properties of natural rubber. The natural rubber material in SolidWorks software has the following properties.

Table 2: Material properties of natural rubber

Property	Value (Unit)
Elastic Modulus	$12000\ Pa$
Poisson's ratio	0.4
Mass density	$960\ Kg/m$^3
Tensile Strength	20000 KN/m^2
Thermal Conductivity	$0.2256\ W/(m.k)$
Specific heat	$1386\ J/(Kg.k)$

Figure 50 shows a meshed endoscope model. The tip and the cylindrical linkage is meshed using 4-node tetrahedral elements. The tip has a 4-node element with the dimensions of 0.3mm. The critical areas such as the spacer and the holes have a finer mesh with mesh size of 0.01 mm. The total number of nodes in this meshed endoscope are 104151. The total elements in the endoscope are 56738.

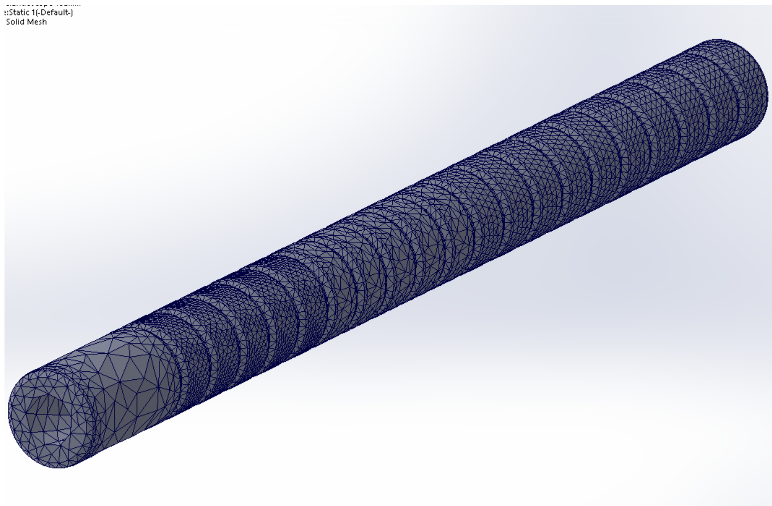

Figure 47: Endoscope design after meshing

3.3.2 Boundary condition

Boundary conditions are set to apply constraints and the loading condition to our design. The results provided by the FEA are highly dependent on the accuracy of the boundary conditions. A small change in the boundary conditions can cause the final result to change by orders of magnitudes. Thus the preciseness of the boundary conditions plays a very important role in accuracy of the final FEA solution. The endoscope design is the 150 mm design portion from the tip of the endoscope. The last linkage of the endoscope is assumed to be a fixed support. The nodes at this linkage are fixed with no movement in all 6 Degree of Freedom (DOF). When the endoscope is pushed in the direction of travel, it slides on one wall. Thus, this wall was fixed. There is a force of 1 N applied at the tip of the endoscope to check buckling and stresses in the model. Between different components, the surface-to-surface contact was created on the linkage and tip interface and inter linkage interface. The design shown in Figure 51 is a simplified version of the endoscope. It does not show any wiring and other components in the assembly.

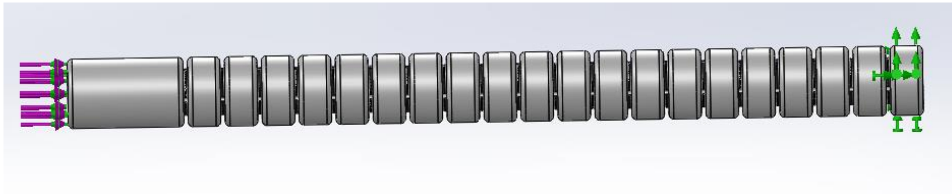

Figure 48: The Boundary condition for stress and buckling test

3.3.3 Finite element method

The model design parameters are shown in Figure 49. All design parameters were compared to a base model from Olympus with dimensions shown in Table 3.

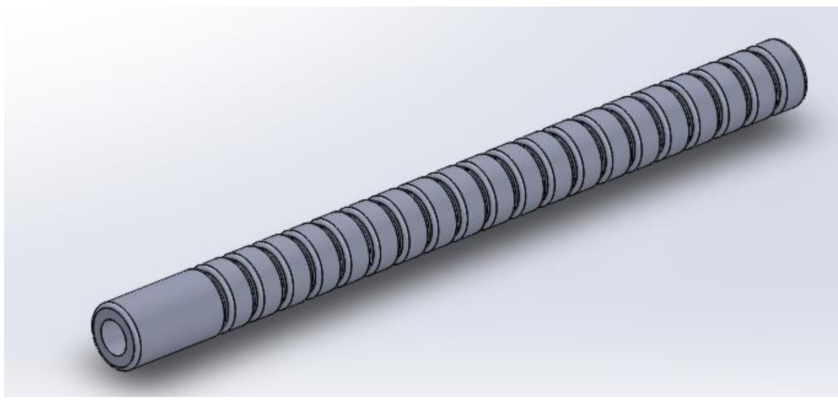

Figure 49: Design parameters in model

Table 3: Design parameters of base model and 3-D model

	Length (mm)	Thickness (mm)	Diameter (mm)
Lens	20	2	16
Bending tip	150	3.5	15
Follower	350	3.5	16
Camera unit	20	N/A	4
Guiding wire	500	N/A	0.5

3.3.4. Stress and Buckling analysis

The stress calculation for the model was done using SolidWorks software. Structural analysis was performed to investigate the stresses in the design. This study allows checking for high stress concentration regions in the design. Figure 53 shows the resultant displacement contours for the boundary condition on the base model. There is a displacement of 1.522 mm observed at the distal tip of the endoscope.

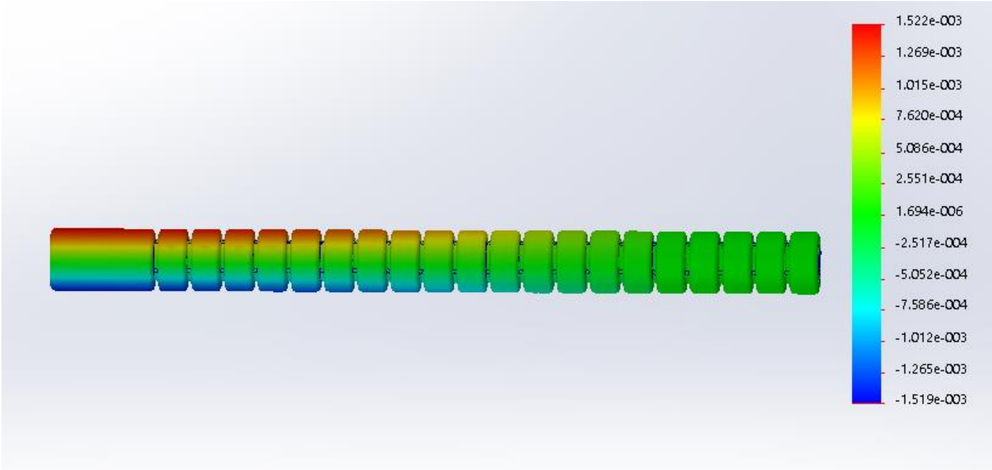

Figure 50: Displacements of the endoscope

Figure 54 shows the stress distribution of the endoscope model. A maximum Von-Mises stress of 2.958 MPa is observed in the spacer region of the assembly. The endoscope is assumed to be manufactured of natural rubber and the yield stress is 12 MPa. High stress results are observed at the spacer regions. This is due to a sudden change in the area and holes for the wires. However, the stresses are below the yield limit by a factor of five.

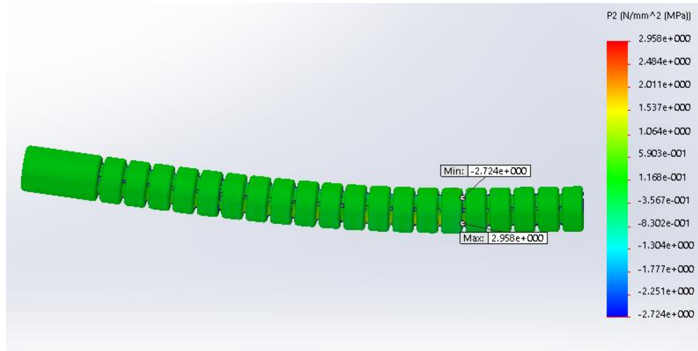

Figure 51: Stress contours in MPa

The Buckling analysis show the buckling frequencies. The boundary conditions for buckling are similar to stress calculation. Figure 55 shows 4 modes of buckling.

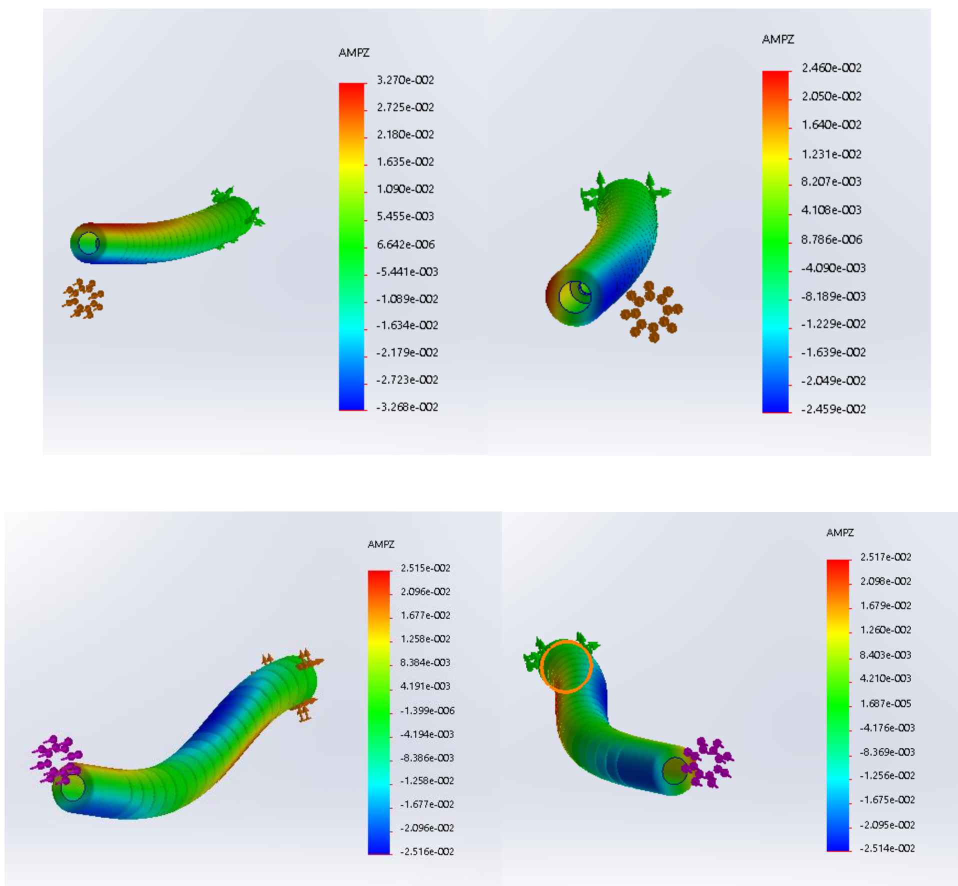

Figure 52: Buckling modes in Hz

3.3.5 Frequency (Modal) analysis

A resonant frequency is a natural frequency of vibration determined by the physical parameters of the vibrating object[27]. The majority of structures can be made to resonate, i.e. to vibrate with large oscillatory motion. Resonance is one of the reasons causing vibration and noise related problems that occur in structures and operating machinery. Modal analysis is a common way to determine the modes of vibration of a structure. The modal modes are determined by the material properties (mass, damping, and stiffness), and by the boundary conditions of the structure. A multiple degree of freedom system can be described by following equation [41]:

$$\mathbf{M}\ddot{\mathbf{x}}(t) + \mathbf{C}\dot{\mathbf{x}}(t) + \mathbf{K}\mathbf{x}(t) = \mathbf{f}(t),$$

where $\mathbf{M}$ is the mass matrix, $\mathbf{C}$ is the damping coefficient matrix, $\mathbf{K}$ is the stiffness matrix, $\mathbf{x}$ is the displacement, and $\mathbf{f}$ is the external force matrix. Figure 55 shows a meshed model of the endoscope.

The modal analysis calculates the natural frequencies of the endoscope design. It shows the different modes of vibration and their corresponding frequencies. The natural frequency of the design is very low. It is 7.683 Hz.

Table 4: Frequency response of the model

Mode type	Cylindrical Design (Hz)
1st bending	15.59
2nd bending	30.26
1st torsion	11.14
2nd torsion	13.48
Natural Frequency	7.69

Table 4 shows a collocated result of the different vibration modes. This is illustrated in figure 56. Figure 57 shows the CAD modal analysis with its 4 modes of vibration

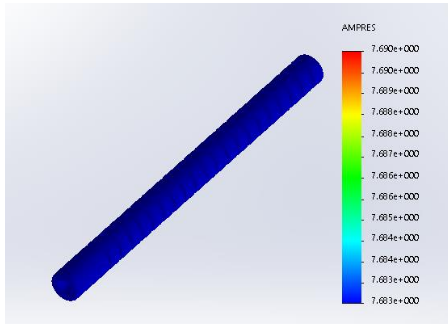

Figure 53: Natural frequency of the 3-D model

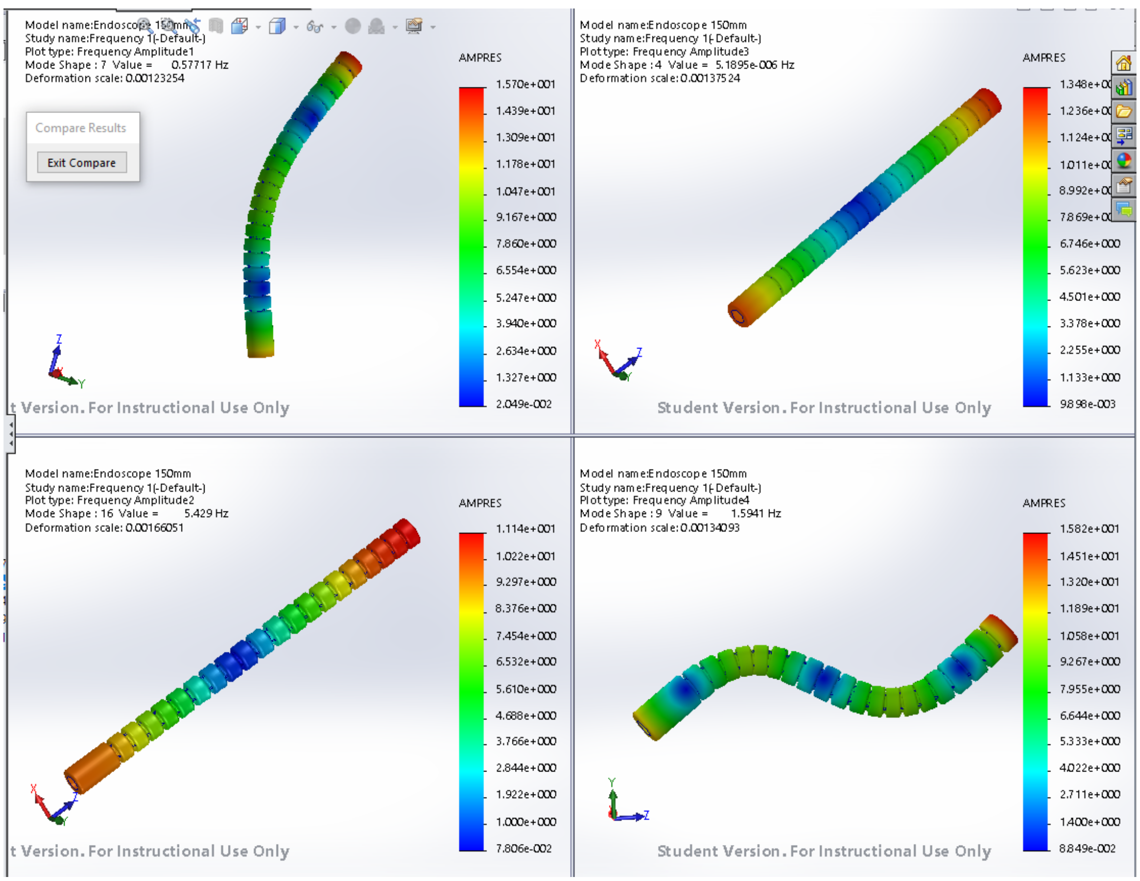

Figure 54: Frequency response of 3-D model in Hz

3.4 Discussion

This chapter investigated optimization for the individual design parameters, such as diameter, thickness etc., one at a time. In this chapter, the displacement of the distal end of the endoscope was observed to be 1.5 mm for 1N compressive load. The maximum stresses observed were 2.5 MPa, well below the yield stress of rubber. The frequency response for the design shows a natural frequency as low as 7.8 Hertz and is considered safe. Among the design parameters, the material properties plays an essential role in determining the final displacement and the working of the endoscope.

The tip of the endoscope can be optimized to achieve the requirement of improving surgical performance. A true optimal design can be obtained by defining a cost function and changing all design parameters simultaneously while minimizing the cost function keeping maximum stress and the frequency response in a permissible range. In this case, the most important control variables are material, ways of actuation techniques. This can be explained in chapter 4

4 Testing and results

Chapter 4 discusses functionality tests of the design. In this chapter, results of these tests will be illustrated and explained in detail. The chapter also focusses on the faults in the design and the future prospective studies for the project.

4.1 Test bed

A testbed was developed to evaluate if the designed endoscope can turn 90° at a given point as required by a medical doctor endoscope user. The paths which an endoscope must follow can be unpredictable, so the test bed was also built with an s-like path, to test if the endoscope could follow varying paths throughout the procedure. The test bed consisted of a foam guide path, to emulate the gastrointestinal tract, mounted on a simple wooden platform. The two paths are shown in Figure 59 in a top view of our test bed.

Figure 55: Test bed for the endoscope design

It can be clearly seen that this test bed is a simple arrangement of foam. The foam pipes are similar to the esophagus in terms of stiffness and rigidity. The angled foam tests the 90 ° turn capability of the overtube and the endoscope. The tests were performed using both designs. The following sections show these tests in detail.

4.2 Actuation test

This design used both Shape Memory Alloy (SMA) springs and a motor and wire method to actuate the tip. The bending of the SMA actuated endoscope tip is shown in Figure 60.

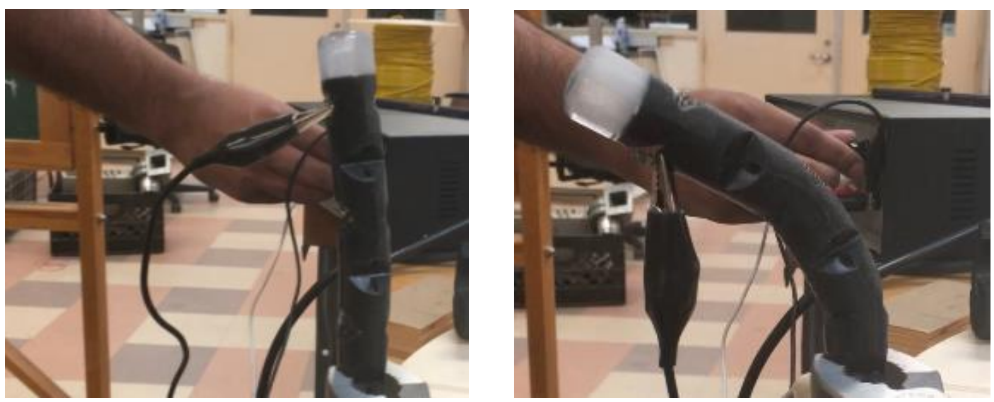

Figure 56: Shape memory alloy actuation

The figure illustrates that the maximum angle of the tip is approx. 60°. It was observed that the SMA springs were not strong enough to bend the design through 90°. The SMA springs also heat up during the process resulting in the melting of 3-D printed material melting. Also, the heat in the spring melts the spring attachment design and tears the 3-D printed material. This can be seen in Figure 61.

Figure 57: Melt points in the endoscope design (point arrow to tear point)

An alternative way to actuate the endoscope is to actuate a simple motor and wire assembly which is commonly used for traditional endoscopes. This method gave us a 1 ° precision change with an Arduino microcontroller. The setup of the motors can be seen in Figure 62.

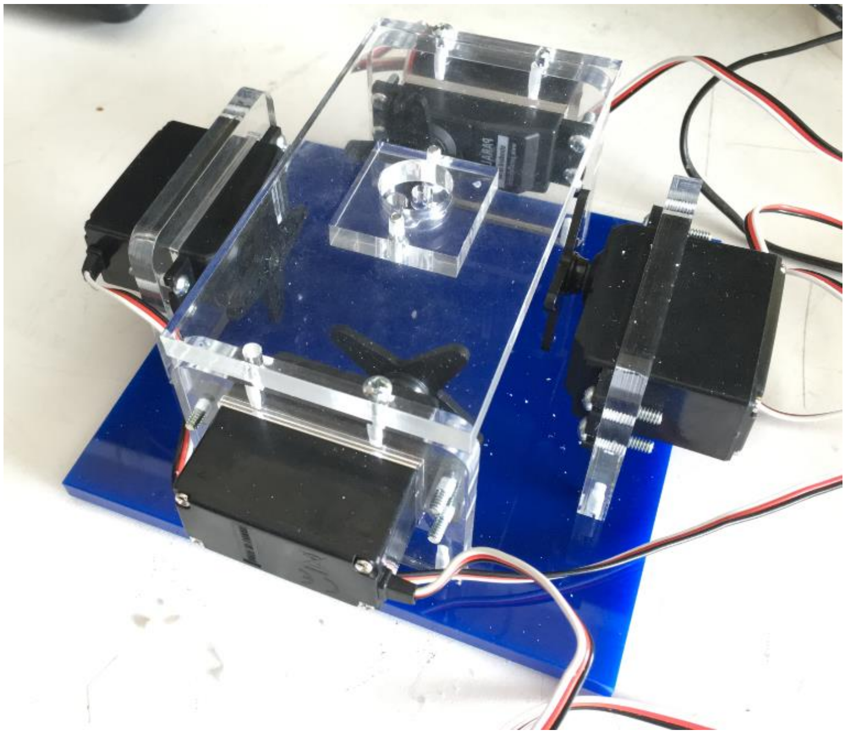

Figure 58: Motor and wire setup

The highest bend angle achieved with this test was 160 °. The method is faster than the SMA approach and has precision control. The wire and motor actuation can be seen in figure 63.

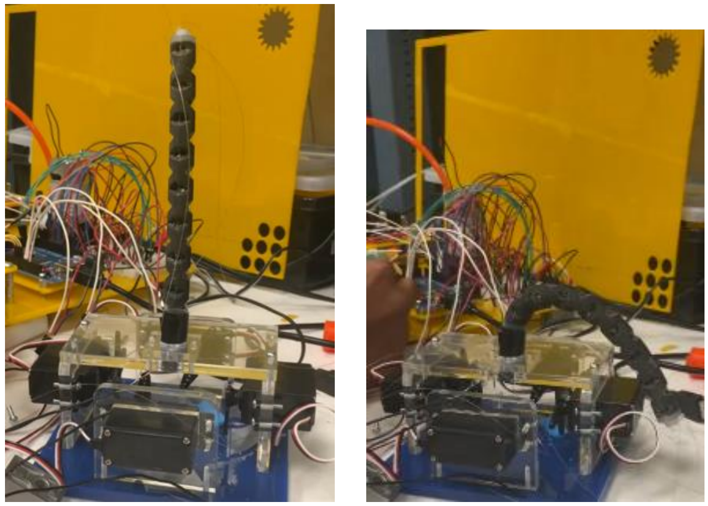

Figure 59: Wire and motor actuation

The motor and wire actuation was used to guide the endoscope through the defined foam pipe. The table compares the time for both actuation techniques to turn 90° of both the designs of endoscope and the maximum bend angle for both actuation techniques.

Table 5: Comparing actuation techniques through parameters

	V-cut grove design	Cylindrical design	Max. bend angle (Degrees)
Shape memory alloy actuation	512 Seconds	495 Seconds	60°
Motor and Wire actuation	12 Seconds	9 Seconds	180°

4.3 Bending Test

The bending tests were performed using the test bed to verify if the endoscope and the overtube can bend instantaneously to 90°. The bend test verifies the main purpose of our designs. This test is to verify if the overtube and the endoscope assembly could potentially replace an elevator.

The test was first performed using only the endoscopes, to verify their 90° bend criteria. This test was also a proof for a front viewing scope to perform ERCP procedures. Figure 64 shows a v-cut grove scope performing bend test.

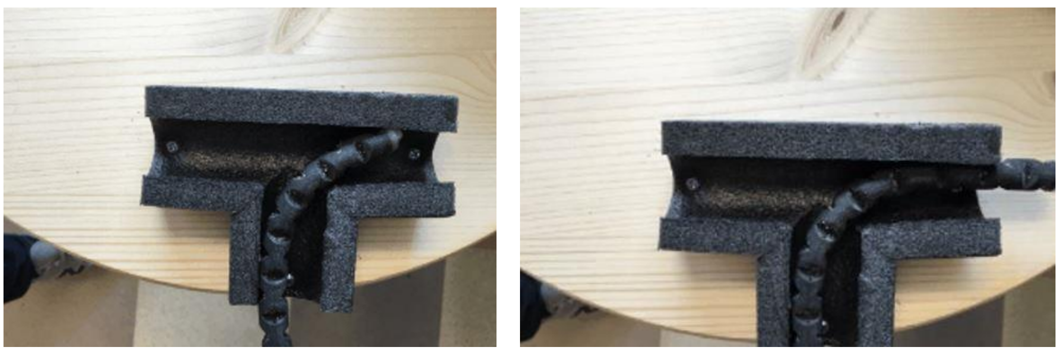

Figure 60: Actuation of a v-cut design

The next step was to test whether or not the overtube could achieve a 90° bend. The travelling of the endoscope with an overtube was observed to be faster and more stable than only the endoscope. Figure 65 shows the bend test of endoscope with an overtube.

Figure 61: Actuation of an overtube tip with an endoscope

Table 5 compares the timing of the procedure when an endoscope uses an overtube and when it does not use an overtube. It can be seen that using an overtube helps in increasing the speed of the procedure.

Table 6: Comparison of procedure with and without an overtube

Timing	V-cut design (W/O overtube)	V-cut design (W/ overtube)	Cylindrical design (W/O overtube)	Cylindrical design (W/ overtube)
90° Bend	12 Seconds	12 Seconds	9 Seconds	8 Seconds
Whole path	1412 Seconds	921 Seconds	1352 Seconds	855 seconds

4.4 Result and discussion

It is seen from the testing that the Shape Memory Alloy (SMA) springs are not recommended to actuate this 3-D printed endoscope. The SMA springs heat up the material above the melting point.

The cylindrical design results show that it can be manufactured faster than v-cut groove design. Also, the cleaning of the cylindrical design is easier and faster than the v-cut groove. The test results show that the cylindrical design passes through the pathway faster than the v-cut groove design.

The tests show that all the designs are able to perform the bend test. Also it shows that the overtube helps in stabilizing the endoscope travel. The time required for the travelling of an endoscope with an overtube is less than the one without overtube. This concludes that using an overtube can help improve the ERCP process.

These designs are promising alternative to the elevator in an endoscope. All results are summarized in the next chapters of this thesis.

5 Conclusion and Future scope

Chapter 5 summarizes the dissertation, concludes the disposable endoscope and overtube designs, and discusses the future perspective of the project.

5.1 Conclusion

Presently, there are about 2 million cases per year where an ERCP procedure is performed. According to the U.S. Center for Disease Control (CDC), approximately 2,500 cases of superbug are reported every year. In 2014, the CRE superbug caused death of 22 people throughout the U.S, and 2 cases were from the UCLA's Ronald Reagan Medical Center. With an increase in the CRE's resistance to anti-bacterial sterilization method, it is necessary to seek for a new and alternative method to sterilization.

This dissertation investigates a new approach for developing a disposable endoscope and overtube, which can be a potential solution to the super-bug problem. It also elaborates on the design, FEA and testing of the new 3-D printed models of the endoscope.

The current endoscope characteristics and the specifications are studied and are used as a comparison to the new 3-D printed design. By analyzing the results in the previous chapter, the following conclusion can be drawn:

- The current design is 3-D printed using a Stratasys connex 3-D printer. The manufacturing time for both endoscope and overtube is less than 8 hours. The final product is biocompatible and can be used after one round of cleaning, and sterilizing.

- The current design can perform the motions and movements of current endoscopes. The speed using a wire and a motor assembly is on the same scale when compared to the state of art endoscopes.
- The current design can carry all acquired surgical instruments that an endoscope can carry, like a tweezer, biopsy cable, etc. The design is also capable of carrying a lens and a camera unit.
- The current design was tested for buckling and modal analysis. The results indicate that it has a factor of safety of 3, i.e. the maximum stress in the design is 1/3 of the yield stress of the material. This design can be used like a modern endoscope for any GI tract procedure. The stress test show that the stresses range from 0.2 MPa to 0.8 Mpa which proves that the design is robust enough for performing the procedure.
- The test bed was designed to check the capability of the design to turn 90^o. The endoscope design can turn 90^o in the space. The overtube design is also capable of doing the same. The test results in previous chapter that the test with overtube is faster and more stable.
- The disposable endoscope with a current lens system costs approximately $8000. This cost is about 10% of the cost of current ERCP endoscopes. The method of 3-D printing is safe and the design is proved to be rigid enough to go through these procedures.
- The disposable endoscope and overtube is a promising approach to solve the superbug problem.

5.2 Future scope

One of the problems that the 3-D printed design has encountered is the actuation of the tip using SMA actuation. Shape memory alloy springs are used to bend the endoscope link in the desired direction. However, the springs heat up once a current passes through them. The heat dissipated from the springs melted the 3-D printed material, as the 3-D printed material has a melting point of approximately 55^{o} C. When we pass the current through the springs, it increases the temperature above 65^{o} C [42]. This increase in temperature causes the material to melt, resulting in the tearing of the material.

A promising approach to overcome the problem is 3-D printed material a having higher melting point than 80^{o} C. The stiff material has a higher melting point, and it can be stable as the spring temperature reaches 70 ^{o}C. The stiff material (Vero clear) can form a layer over the soft material, thus making a heat insulation between the spring and the soft material. This can be illustrated in Fig. 66.

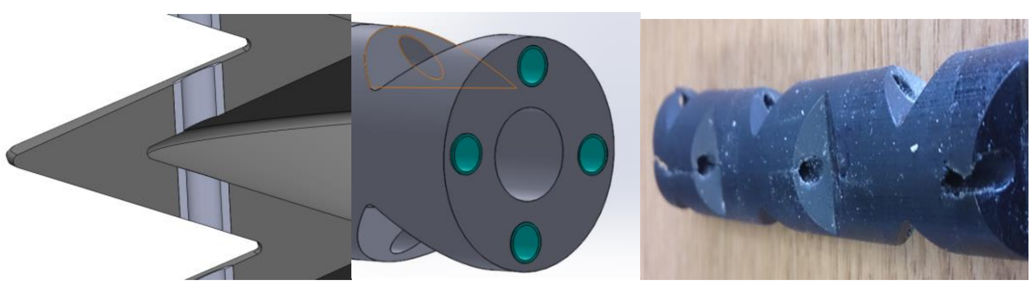

Figure 62: veroclear material coating across the spring holes

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