Dislodgement Resistant Endoscopic Dissecting Cap

Biomedical Engineering Design 200/300

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Abstract

The treatment of gastrointestinal illness through endoscopy is a common practice globally. To enhance the effectiveness of this treatment, it is crucial to accurately view the tissue lining of the digestive tract and have the ability to easily obtain tissue samples. Achieving this requires the use of endoscopic caps, however, these caps frequently dislodge, leading to significantly prolonged operations. Therefore, the primary objective of this project is to design an endoscopic cap that effectively prevents dislodgement from the endoscope during procedures. Additionally, the cap must be designed to securely fit the dimensions of the EVIS EXERA III Olympus gastroscope.

Three preliminary designs were developed, and after evaluating each one, it was concluded that the Flap Cap design would be the most successful. The Flap Cap design utilizes four rounded silicone flaps on the bottom interior surface of the cap that fold upward to apply pressure on the distal end of the endoscope and secure cap from dislodgement. Several materials were considered for the fabrication of the design, however, polycarbonate and silicone were deemed the most suitable choices. The cap was tested using an EVIS EXERA III Olympus gastroscope on a porcine esophagus and stomach to determine the success rate of the dislodgement resistant cap in comparison to the current hospital models. Future work for the project includes creating a reusable design printed with surgical grade materials and dissolvable supports.

I. Introduction

Gastrointestinal diseases have a significant impact on the lives of millions of Americans, affecting approximately 60-70 million individuals [1]. These conditions encompass a range of disorders, such as Celiac disease, Barrett's esophagus, Diverticulosis, Crohn's disease, and Ulcerative Colitis [2]. Importantly, these diseases do not discriminate based on age, race, or gender, making them a concern for a wide demographic. Individuals diagnosed with these gastrointestinal conditions often experience substantial disruptions to their daily lives. For instance, Inflammatory Bowel Disease (IBD), which includes both Crohn's disease and Ulcerative Colitis, affects roughly 1% of the American population [3]. Barrett's esophagus, which fundamentally affects an individual's ability to consume and digest food, is estimated to afflict around 12 million Americans, with only 1.5 million officially diagnosed [4]. The severity of this situation is obvious when reviewing hospitalization statistics. In 2018 alone there were 41 million emergency room visits related to gastrointestinal disease, and in 2019 there were 472 thousand deaths primarily due to gastrointestinal disease. These rates have only increased since 2000 [5], and the most effective method to combat this issue is improving both the diagnosis and treatment process.

The tissues lining the gastrointestinal tract play an important role in common gastrointestinal diseases. These tissues properties, such as thickness or texture, may vary due the body's response to certain diseases or infections. When these tissues don't possess the expected properties digestion becomes exponentially difficult, leading to constant vomiting and diarrhea [6]. In order to have a proper diagnosis and effective treatment, one must be able to closely examine and sample the tissues lining the gastrointestinal tract.

Currently, both diagnosis and treatment of gastrointestinal disease is carried out through an endoscope, a small instrument which assists in viewing internal gastrointestinal tissues. Although endoscopy, the process of utilizing an endoscope to view the gastrointestinal tract, significantly improves diagnosis and treatment by giving a close view to the tissues lining the tract, it can prove difficult to effectively collect tissue samples and safely navigate the gastrointestinal tract. To combat this problem an endoscopic cap was developed, which is placed over the camera on the endoscope. Some endoscopic cap designs currently utilized in endoscopy are the Reveal Distal Attachment Cap [7] and MAJ-2315 Disposable Distal Cap [8], which are comparable in their effectiveness. Both of these options are able to safely navigate the gastrointestinal tract and create an airtight seal to better collect tissue. However these caps, as well as other endoscopic caps, frequently dislodge and fall off the endoscope during the procedure. This significantly affects the ability to diagnose and treat gastrointestinal disease, as the dislodgment of the cap extends the length of procedure, which discourages utilization of the cap. Due to this problem, the goal of this project is to create an endoscopic cap which adequately prevents dislodgement during numerous endoscopy procedures.

II. Background

Client Information and Preliminary Research:

Dr. Amber Shada is an associate professor for UW Health General Surgery specializing in minimally invasive esophageal and gastric surgery. Her work with the esophagus and gastrointestinal tract involves the use of an endoscope to diagnose and treat conditions. An endoscopic procedure uses a camera attached to the end of a thin, flexible tube that enters through the mouth and travels down through the esophagus. Tools are then passed through the endoscope to collect tissue samples and treat problems seen with the camera [9].

In her work with endoscopy, Dr Shada often uses a transparent cap attachment on the distal end of the endoscope. Endoscopic dissecting caps can be a very useful accessory for procedures as they improve the visual field, protect surrounding tissue from endoscopic tools while aligning the target on the correct axis, create suction for taking biopsies and can push aside submucosal tissues [10]. The caps come in several shapes and sizes, the two main models are straight end and beveled ends. Straight end caps are typically sized at 13.9 mm in diameter and 12 mm in length [11]. Beveled or oblique end caps are commonly used for treating larger surface areas and come in an outer diameter of 16.1 mm and length of 14 mm [11]. These caps are generally made from a disposable transparent silicone rubber and polycarbonate resin [12].


Figure 1 (left): *Olympus distal attachment D-201-10704*

Figure 2 (right): *Censitrac Gastroscope Distal Tip*

Design Specifications:

A common issue with the use of distal cap attachments is their tendency to dislodge during procedures. This complication poses a risk to patients, it is a tedious process to retrieve and reattach the cap, which prolongs the length of surgery. Increased surgical procedure length results in an increased risk of complications of about 14% for every 30 minutes [13]. Currently, the only practical way to attach an endoscopic dissecting cap is to tape it directly onto the endoscope using waterproof tape [14]. However, the cap remains susceptible to dislodgement during use, due to the shear stress encountered while navigating through tissue. To mitigate this issue, a new endoscopic dissecting cap must be designed that will prevent this dislodgement.

This cap must stay on the endoscope without the use of tape, it must fit onto the 9.9 mm distal end of an EVIS EXERA III Olympus gastroscope, and should be sterilizable and reusable to reduce cost. Additionally the cap must withstand a pH in the range of 1.5 to 2.0, as well as a temperature of 37 degrees Celsius which matches the conditions of the human gastrointestinal tract. Finally the cost of fabrication of this cap must stay below the project budget of $500.

III. Preliminary Designs

1. Flap Cap

The cap will be similar in material and appearance to caps currently on the market, the main difference will be the interior. There will be five rounded plastic sections that stick out towards the center of the cap. The endoscope will be inserted through the bottom of the cap, folding the flaps upward. They will be flexible so as to not put too much strain on the endoscope, but allow for enough tension to keep the entire cap in place. When the cap is being pulled on while maneuvering through tissue, the flaps will apply pressure on the endoscope and keep the cap from dislodging.

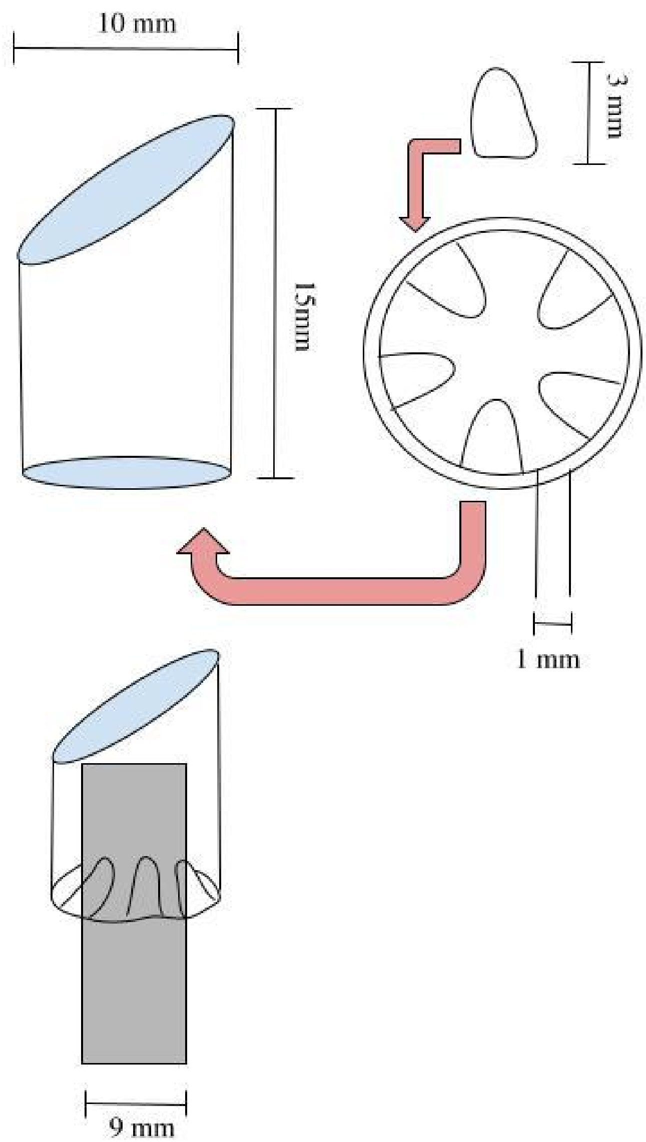


Figure 3: *Flap Cap individually and attached to endoscope*

2. **External Band Compression Channel**

The external band compression channel design would consist of a cap with a channel on the area that goes over the top of the endoscope. The material of the cap will be flexible enough to allow a band in said channel to tighten the cap around the endoscope. The purpose of the channel is to prevent the band from falling off during the operation. The band would resemble a band used for braces.

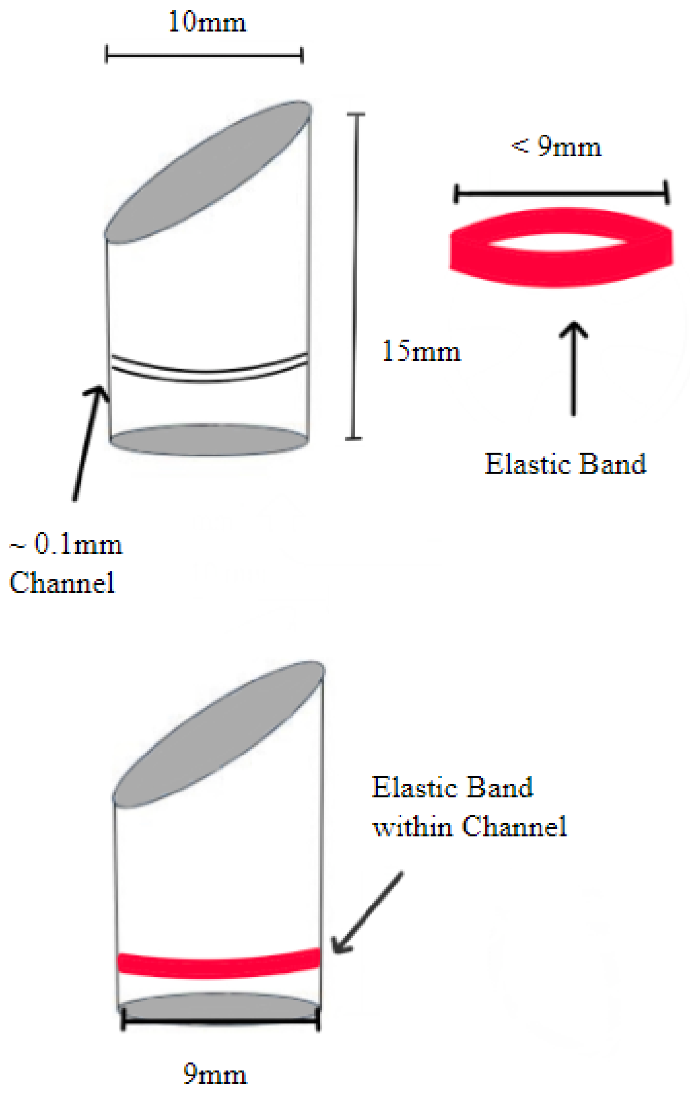


Figure 4: *External Band Compression Channel Cap with and without band attached*

3. **Internal Band Locking Mechanism**

The third design incorporates a high friction rubber band wrapped around the endoscope. Attached is a metal ball that extrudes from the band. The cap will have a cutout on the side as shown in the drawing. When the cap is placed on the endoscope, the ball follows the cutout and fits into place at the end. The high friction of the band and locking mechanism keeps the cap secure. Once used, the band would then be disposable and the cap would be either gas sterilized or autoclaved.

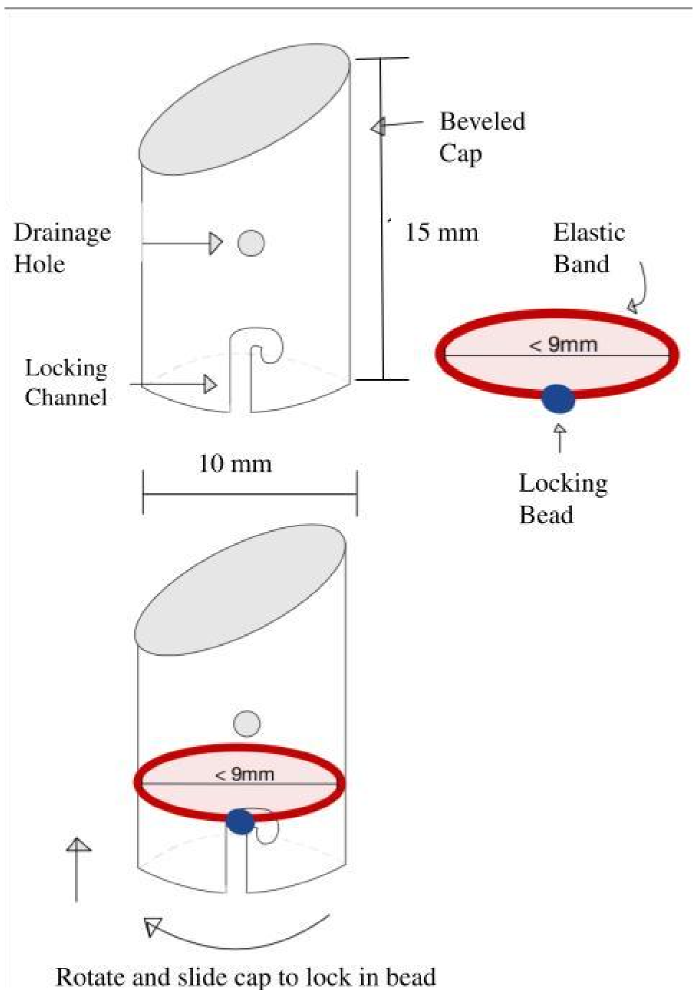


Figure 5: *Internal Band Locking Mechanism cap with and without band attached*

IV. Preliminary Design Evaluation

Table 1. Design matrix for Endoscopic Cap.

Design Criteria	Flap Cap * See Preliminary Design 1		External Band Compression Channel * See Preliminary Design 2		Internal Band Locking Mechanism * See Preliminary Design 3	
Dislodgement Resistance (25)	4/5	20	2/5	10	4/5	20
Patient Safety (25)	5/5	25	3/5	15	4/5	20
Attachment and Detachment (20)	5/5	20	4/5	16	3/5	12
Ease of Fabrication (15)	2/5	6	4/5	12	3/5	9
Reusability (10)	5/5	10	3/5	6	3/5	6
Cost (5)	5/5	5	4/5	4	4/5	4
Total	SUM	**86**	SUM	**63**	SUM	**71**

To evaluate the three designs, a Design Matrix shown in Table 1 was developed. The three designs were scored based on their expected Dislodgement Resistance (25), Patient Safety (25), Attachment and Detachment (20), Ease of Fabrication (15), Reusability (10), and Cost (5).

The dislodgement resistance of the cap was weighted at 25, tied with safety for heaviest weight. This category intended to measure the frequency of dislodgement and the maximum shear force necessary for dislodgement. The Flap Cap and Internal Band Locking Mechanism designs each scored 4/5. These two designs are expected to produce the most frictional resistance to shear forces experienced during a procedure. The External Band Compression Channel received a 2/5 due to potentially low friction between the internal surface of the cap and the endoscope.

The safety of the patient was weighted at 25 due to the direct contact with patients during the procedure. This category judges the potential safety concerns to the patient of increasing procedure length. It is important that the cap does not break or separate from the endoscope to prevent safety risks associated with increased procedure length. The Flap Cap design scored 5/5 because this design is composed of a single piece. The External Band Compression Channel design received at 3/5 because it has a band that could be ruptured during the procedure. The Internal Band Locking Mechanism design received a 4/5 because it has a band that could break.

The ability to easily attach and detach the cap was weighted at 20 because the cap must be easy to use. The Flap Cap design scored the highest, a 5/5, as it is only one part and would allow for the user to put on and take off the cap just as easily as they are with the current cap. The External Band Compression Channel scored a 4/5 because the addition of an elastic band means more effort to attach the cap. Detachment would be similar. The Internal Band Locking Mechanism scored a 3/5 because the attachment would include slightly more precision to engage the locking mechanism.

Ease of Fabrication was weighted at 15 as this category is intended to rank the feasibility of fabrication. The External Band Compression Channel design scored 4/5 as the band can be purchased online while the channel can be fabricated on the lathe with some support for the softer material. The Internal Band Locking Mechanism scored 3/5 as it requires additional machining to get the locking channel in the cap cut. The attachment of the bead increases the complexity of fabrication as well. The Flap Cap design scored 2/5 because the flaps will be difficult to cut out and align to properly hold the cap in place.

Reusability is intended to score the ability for the caps to be sterilized and used in following procedures. This category was ranked at 10 due to design requirements, fabrication and cost. The Flap Cap design scored 5/5, as it is one piece constructed from sterilizable material. The Internal Band Locking Mechanism and External Band Compression Channel designs were both given a score of 3/5, as both designs' bands will need replacement after numerous uses of the cap, decreasing overall reusability of the designs.

Cost was weighted at 5 given the cost of fabrication and maintenance will be low. The Flap Cap design scored 5/5 due to its reusability and lack of additional components. The two remaining designs each scored 4/5 due to their bands requiring replacements.

Material Evaluation

Polycarbonate Biomed Clear Resin was the material chosen for the top portion of the proposed final design. This material was chosen because it is biocompatible and sterilizable which fulfills the design requirements.This material closely mimics the current produced caps in terms of both rigidity and transparency. It can be sterilized by a variety of methods including Ethylene Oxide [15]. For the lower portion of the proposed final design, Elastic Resin silicone was the material chosen. Elastic Resin was chosen because it is flexible and allows for the internal flaps to stretch and bend creating a tight fit over the endoscope. This material is not sterilizable but a similar resin that is not available for prototype fabrication, Biomed Elastic 50 A is produced that is sterilizable and biocompatible [15]. This material could be substituted for Elastic Resin to produce a completely biocompatible and sterilizable design with the proper equipment. Two different types of material were needed for the final design to provide the rigidity necessary to navigate and manipulate tissue, while providing the elasticity necessary to both attach to the endoscope and provide sufficient resistance to dislodgement.

Proposed Final Design

The proposed final design is the Flap Cap design because this design scored the highest in 5 out of 6 categories, earning it a total score of 86/100. This can be attributed to the expected dislodgement resistance, patient safety and reusability scoring. This design will have complex fabrication but overall is expected to give the best results.

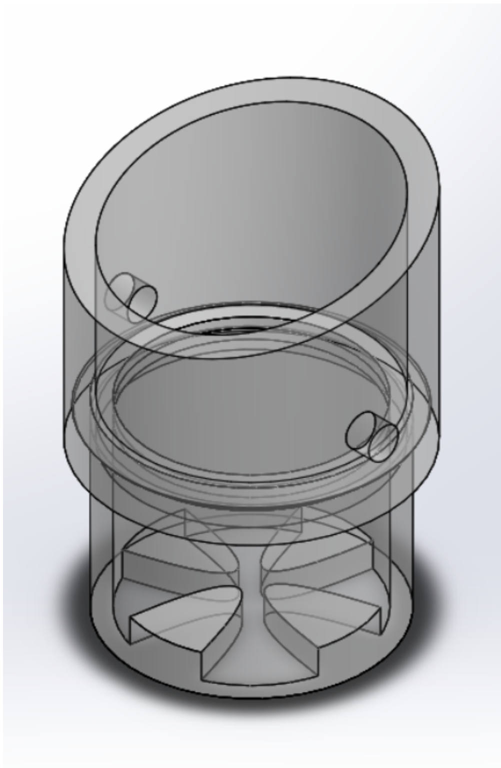
V. Fabrication/Development Process

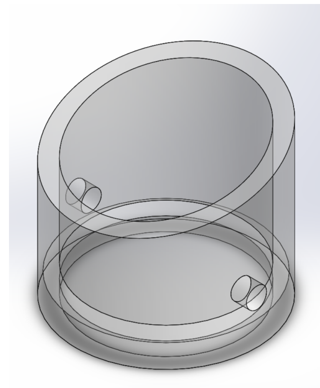
Materials

1. 325.26 cubic millimeters of FormLabs Elastic Resin
2. 419.85 cubic millimeters of FormLabs Biomed Clear Resin

Methods

The design for the dislodgement-resistant endoscopic dissecting cap was modeled in SolidWorks software before fabrication. The two pieces were then printed separately, using FormLabs Elastic Resin for the flexible bottom section and FormLabs Biomed Clear Resin for the top rigid section. To attach the two pieces, the flexible section is inserted into the bottom of the rigid section. The ridge on the top exterior surface of the flexible piece aligns with the channel on the bottom interior surface of the rigid piece, allowing the two to fit together and lock in place.





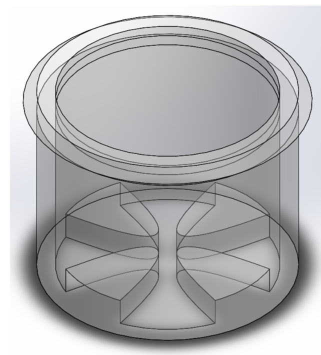


Figure 6 (left): *SolidWorks assembly of entire endoscopic dissecting cap*
Figure 7 (top right): *Solidworks rendering of polycarbonate top piece*
Figure 8 (bottom right): *Solidworks Rendering of silicone bottom piece*

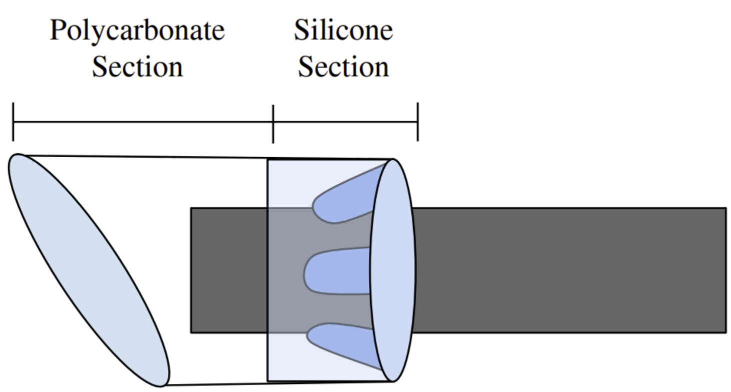
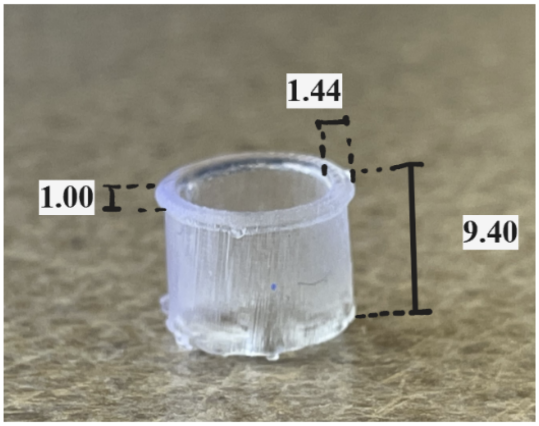


Figure 9: *Model of interaction between internal flaps and endoscope*

Final Prototype

Silicone Piece



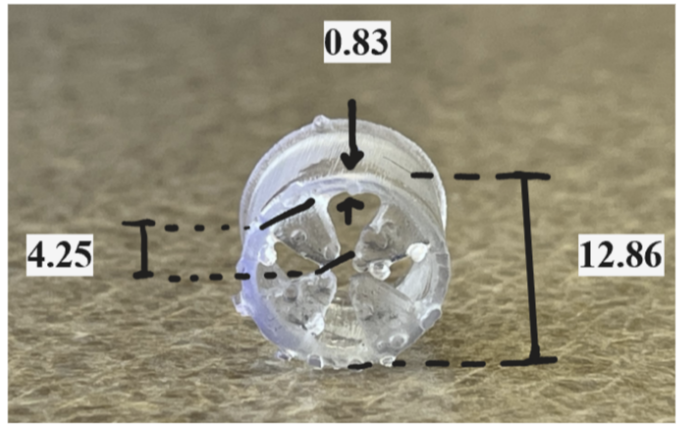


Figure 10 (left): *Silicone section front view (dimensions in millimeters)*
Figure 11 (right): *Silicone section bottom view (dimensions in millimeters)*

Polycarbonate Piece

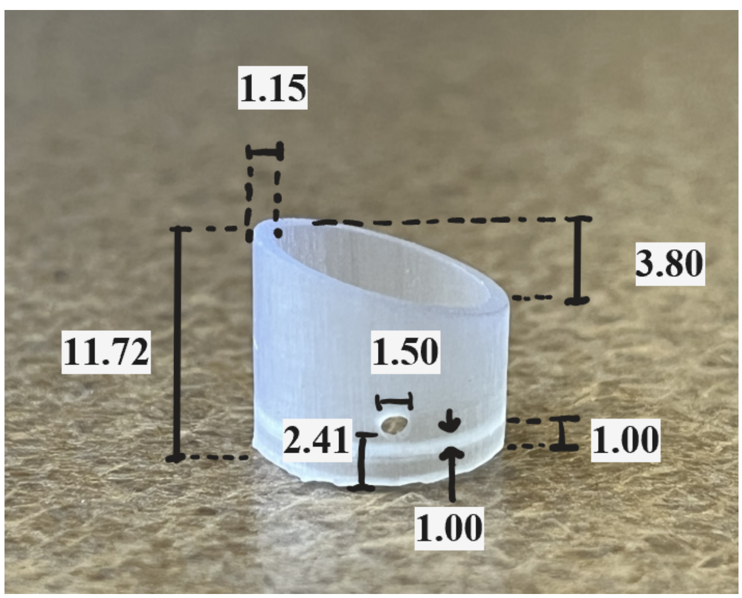


Figure 12: *Polycarbonate section left view (dimensions in millimeters)*

Figure 13 (left): *Full prototype placed on distal end of EVIS EXERA III Olympus gastroscope*
Figure 14 (right): *Full prototype without endoscope*

Testing

The dislodgement-resistant endoscopic dissecting cap underwent testing using an EVIS EXERA III Olympus gastroscope on a porcine esophagus and stomach to simulate a human endoscopy. Porcine organs were chosen as the physiological conditions found in a pig model are comparable to those of a human. The average body temperature of a pig ranges from 101.5°F to 102.5°F [16], and its gastric pH typically falls between 1.15 and 4 [16]. In comparison, the average human body temperature is 98.6°F, and the human gastric pH is approximately 1.5 to 2.0 [17]. Additionally, the diameter of the porcine esophagus is similar to that of humans, with a lumen diameter of 25 mm compared to the human esophagus, which measures 20 mm [18].

The testing comprised two main categories: first, assessing the current cap models, and second, evaluating the dislodgement-resistant design. For the currently used caps, seven trials were conducted, three utilizing a polycarbonate and silicone design, and four employing a completely silicone design. These designs had either been in use or were currently in use in the hospital's surgical department. As for the dislodgement-resistant design, twelve trials were performed, three with the largest dimensions, six with medium dimensions, and three with the smallest dimensions. (See Appendix B for more information).

The variance in the number of testing trials arose due to the quality of the porcine esophagus after repetitive use. Midway through the testing, a newer esophagus had to be used, leading to an additional test on the hospital's current silicone cap and three more tests on the medium-sized dislodgement-resistant cap.

During the trials, the caps were placed on the gastroscope, maneuvered down the esophagus and into the stomach, and then brought back up through the esophagus. The movements employed for testing replicated a typical endoscopic procedure, incorporating a combination of lateral and twisting motions. The goal of the testing was to determine if the dislodgement resistant model would demonstrate greater success in remaining affixed to the endoscope throughout the entire procedure compared to the current hospital models.

Several potential sources of error impacted the testing procedure. Storing the caps at low temperatures caused the silicone section to become slightly brittle, resulting in rips of varying sizes along the bottom of the silicone. This rendered multiple caps unsuitable for testing. Additionally, the conditions of the porcine organs were potential sources of error. Since the tests were not conducted on a live model, the esophagus and stomach used did not maintain the correct physiological temperature and pH levels. With repeated testing, these organs became stretched out, which could have affected the test results. Therefore, further testing would be necessary to determine the success of the dislodgement-resistant model in a human endoscopy.

VI. Results

The first cap that was tested was the silicone polycarbonate cap, which had been previously used in the hospital. In three trials, the cap resisted dislodgement in the first trial and completely dislodged in the following two. Dislodgement occurred when the cap hit the dense tissue connecting the esophagus and stomach when attempting to bring the scope back up the esophagus. The second cap tested was the silicone cap currently being used in the hospital. Similarly, the cap stayed on for the first trial and completely dislodged in three subsequent trials in the same location as the first cap. It was determined that both caps would continue to dislodge and no further trials were conducted. Though the caps were being wiped off between trials, the buildup of fluids on the cap and scope made for more likely dislodgement.

For the new cap design, testing was performed for three sizes of the Flap Cap. Multiple sizes were produced due to limited access to an EVIS EXERA III Olympus gastroscope, causing slight uncertainty about which size would be the best fit. Testing was conducted on the largest size first, but it was clear its diameter was too big for the scope. In all three trials, the cap dislodged. This can be credited to the sizing rather than the design. The medium size of the Flap Cap performed significantly better due to its tighter diameter on the scope, making it far more challenging to dislodge. Six passes through the system were made for this cap, resulting in one dislodgement on the fourth trial. During that particular trial, the polycarbonate end of the cap detached from the silicone, while the silicone remained attached to the end of the scope. The smallest sized Flap Cap fit most securely on the end of the gastroscope. Expectedly, it performed the best, dislodging in zero of three trials. To more accurately test the cap, the porcine organs were switched out for new ones with higher elasticity. No dislodgement occurred and it was determined that further testing would produce the same results.

Following testing, statistical analysis was performed to determine significance of the results. A two sample proportion z test was used with the first sample being pooled data from the two hospital caps and the second sample being pooled data from the small and medium sized Flap Caps. Data from the large Flap Cap was not included, as the design was not contributing to its failure but rather strictly its size. This statistical analysis yielded a p value of 0.0067, meaning at a confidence level of 99%, the results suggest that the Flap Cap dislodged significantly less than the hospital caps [19].

VII. Discussion

As indicated by the results, the Flap Cap demonstrates a 300% greater resistance to dislodgement compared to the currently utilized caps. The success of this design allows for an endoscopic procedure with use of a secure cap that will not dislodge in a patient's gastrointestinal tract, thereby reducing surgery duration and minimizing the risks posed to the patient. According to a meta analysis from Baishideng Publishing Group Inc "the technique of cap-assisted endoscopy demonstrated increased en bloc removal and technical success with decreased time and adverse events as compared to conventional techniques."[20]. Thus it can be inferred that more procedures would benefit from use of a dislodgement resistant cap which proves to be more effective and faster procedures without.

Designing an endoscopic cap demands careful attention to numerous different ethical concerns in order to guarantee patient well-being. One necessary consideration is to confirm that the cap can be safely utilized in esophagus that vary in diameter from 20-30mm [21] without causing pain or damage. It is important to also consider the cost of production in order for endoscopic dissecting caps to be accessible and lower the cost of endoscopic procedure for patients. Another ethical concern is the impact that mass producing the Flap Cap will have on the environment. The current fabrication process involves 3D printing each section of the cap, which produces less waste than other fabrication methods, and future designs are intended to be made reusable eliminating environmental hazards [22].

To improve the quality of the Flap Cap design, several modifications are necessary to ensure patient safety. The primary alteration will be focused on the connection between the two sections of the cap to maintain a secure fit, preventing separation during procedures. To increase the design's sustainability, the cap should be made from reusable materials that can be sterilized using ethylene oxide or an autoclave. Another necessary alteration would be to print the design with surgical grade biomedical materials printed in a Biomed specific printer. The preliminary designs were limited to materials available at the University of Wisconsin Makerspace and quality control measures could not be confirmed. Transitioning to higher quality fabrication methods would also enhance the transparency of the polycarbonate section, as the current clouded appearance has the potential to obstruct the viewing field of the endoscope. To ensure transparency, the Biomed Clear Polycarbonate resin piece must be printed with a 3D printer that exclusively utilizes Biomed filament or is carefully cleaned between filament changes to prevent discoloration due to cross-contamination. Lastly, the caps should be printed using dissolvable supports to increase ease of fabrication and assembly.

Although the design effectively resists dislodgement, some errors were discovered during testing. One such error involved the tendency of the silicone sections to tear when exposed to low temperatures. This issue became evident when transporting the caps for testing in external conditions around 0 degrees Celsius. This factor will need to be addressed for shipping and packaging purposes, but is not expected to affect performance during procedures. Other potential sources of error that may have impacted testing results include the condition of the porcine organs. Since trials were not conducted on living models, the esophagus and stomach used in testing lost elasticity with multiple uses and did not maintain the correct physiological temperature and pH levels. Consequently, it cannot be assumed that the initial success of the dislodgement resistance will be upheld under the correct conditions.

VIII. Conclusions

The aim of this project was to design an endoscopic cap that enhances endoscopic procedures by providing a clear viewing field and enabling easy maneuverability of the endoscope through the gastrointestinal tract without dislodging during use. The cap needed to be constructed from biocompatible materials capable of withstanding the physiological conditions of the human esophagus and stomach, and it had to fit onto the 9.9 mm distal end of an EVIS EXERA III GIF-HQ190 without making any alterations to the device.

The final design comprised a two-part cap, with the two sections made from silicone and polycarbonate. When tested against currently available endoscopic caps on porcine esophagus and stomach, the dislodgement-resistant design was found to be three times more successful in remaining attached throughout the entirety of the procedure. However, although the design showed success in that aspect, the conducted testing did not accurately replicate the correct physiological conditions, as the porcine organs did not replicate the exact temperature or pH that the cap would encounter during a human procedure.

The next steps for this project would involve subjecting the cap to further testing to focus on the aspects not included in the original test. Additionally, further research would be necessary to determine the grade of material required for true biocompatibility. The cap would also need to be manufactured using dissolvable supports to facilitate easier production. Finally, adjustments to the cap's design would be necessary to establish a stronger connection between the two sections, reducing the risk of it falling apart during use.

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X. Appendix

<u>A: Product Design Specification</u>

Function: Dr. Amber Shada's lab performs endoscopies which are procedures where an endoscope is inserted into the esophagus in order to view the human gastrointestinal tract. Currently, the caps are attached to the end of the gastroscope via water resistant tape. The caps however frequently fall off due to the unsecure method of attachment and can become dislodged.

The team plans to improve this by working with the client to create an endoscopic cap that will be secured to the end of the endoscope. The cap will be dislodgement resistant meaning that it will remain at all times attached to the endoscope while in the intestinal tract. This cap will also be detachable for when the endoscope is not being used in the body.

Client requirements:

- Cap must fit onto the 9.9 mm diameter distal end of the endoscope
- Cap must be dislodgement resistant
- Cap must be detachable at the client's discretion
- Cap must be made from material that will not cause harm to the patient
- Cap must be transparent and colorless
- Cap should have a beveled end
- Cap should have some flexibility but overall remain rigid
- Cap should be sterilizable through use of ethylene oxide

Design requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The endoscopic dissecting cap should be able to be easily attached and detached from the endoscope. The cap should also not become dislodged and remain secure during the endoscopy as that could cause damage to the patient undergoing the procedure and increase the length of the surgery. The cap should also be shaped in a way to allow for the endoscope to easily maneuver the walls of the tissue allowing for a better viewing area. Finally, the cap should have some flexibility to allow for easier navigation through the gastrointestinal tract however the cap must overall remain rigid throughout the procedure.

b. Safety: The endoscopic dissecting cap must be made of a safe material that will not harm the patient undergoing an endoscopic discectomy operation. The procedure must be conducted by a professional who has been properly trained [1].

c. Accuracy and Reliability: The cap should be able to navigate various directions throughout the entirety of the procedure without detaching from the endoscope. Accuracy and reliability will be measured by performing a test similar to an endoscopy to mimic the movements of the endoscope along the walls of the gastrointestinal tract. The dislodgement and displacement of the cap during the test will then be measured.

d. Life in Service: Endoscopic cap should be sterilizable through use of ethylene oxide. The device should not dislodge throughout the whole procedure, which can last from 45 minutes to two and a half hours.

e. Shelf Life: The endoscopic cap will be designed to be sterilized through ethylene oxide sterilization and could potentially be indefinitely reused until signs of damage.

f. Operating Environment: The operating environment of the endoscopic cap will be the human gastrointestinal tract. The cap will need to withstand a pH of 1.5 - 2.0, a temperature of 37 degrees Celsius and be fluid resistant to comply with the physiological conditions of the intestines [2].

g. Ergonomics: Endoscopic dissecting cap must be made out of a material that can be used safely inside an organism with no reaction and can be gas sterilized. A potential material could be silicone as it is used for internal medical devices such as catheters and can be sterilized with ethylene oxide. The cap must have the ability to attach and to detach from an EVIS EXERA III GIF-HQ190 gastroscope without making permanent alterations to the device. The cap should have the ability to maneuver through the human gastrointestinal tract without dislodgement. In order to perform endoscopic surgery or tissue samples, the cap must create a tight seal with the endoscope. Otherwise, bodily liquids may interfere with the viewing field.

h. Size: Must have minimum inner diameter of 9.9 mm to attach to distal end of endoscope [3]. Similar products have dimensions of 11.35 mm in outer diameter and 4 mm length from distal end of endoscope [4].

i. Weight: No additional restrictions on weight. Size and material constraints restrict the possible weight of the cap to within the weight range of similar products.

j. Materials: Must be colorless, transparent, non-ferrous, biocompatible, and sterile [5]. Current products are made from Spunbond Polyethylene and are typically soft, smooth, single use [6]. Client prefers a more rigid material.

k. Aesthetics, Appearance, and Finish: Must have smooth, thin and semi-flexible walls, must have ports in walls to release fluid. Must be transparent and colorless [6]. Must be cylindrical and is preferred to have a beveled end in addition to the 4mm length from distal end of endoscope [7].

2. Production Characteristics:

a. Quantity: Only one final model of the endoscopic cap will be produced, but it must be kept in mind that the final product should have the ability to be mass produced in the future.

b. Target Product Cost: The total cost of production, including all prototyped models, has a target cost of $500. Production of solely one final product should ideally be less than $500.

3. Miscellaneous

a. Standards and Specifications: FDA approval of all medical devices in the United States is required. This is therefore applied to endoscopes and endoscopic dissecting caps [8]. Endoscopes are classified as a Class II Medical Device and must comply with all FDA guidelines and regulations under Title 21 [9]. Must adhere to ISO 10993 biocompatibility guidelines [10] as well as ISO 8600-4 endoscopic insertion width requirement [11].

b. Customer: The customer is asking for an endoscopic cap which can fit securely onto the distal end of an endoscope. To prevent additional costs to the customer, the final product is to be reusable and made from a material that can be gas sterilized. The customer prefers a beveled end to the endoscopic cap to allow for easier maneuverability through the gastrointestinal tract.

c. Subject-related concerns: The materials and shape of the cap must ensure that the patient is unharmed during use of the endoscope. Furthermore, the cap must comply with all medical standards and procedures to prevent cross-contamination of bacteria.

d. Competition: Ovesco Endoscopy has a patent filed for a medical gripping device, which is attached onto the front end of the endoscope. The cap has two flexible control mechanisms for the medical gripping device, which allows the operator to use grip onto internal tissues for sampling. [12]

Additionally, Cilag GmbH International has a patent filed for an endoscopic apparatus with an electrode probe placed inside. The apparatus is securely fit onto the endoscope, through locking numerous pieces together. The electrode probe is used to non-thermally ablate tissue within the body. [13]

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B: Testing Data

Cap Design and Esophagus Additional comments from Dr. Shada relevant to each trial.	**Attempt number and description**	**Complete dislodgement (Y/N) and notes**
Current cap Resin/silicone	1D motion #1 Forward and Back with twisting	N
	1D motion #2 Forward and Back with twisting	Y
	1D motion #3 Forward and Back with twisting	Y
Current cap All soft silicone Switched esophagus after this trial	1D motion #1 Forward and Back with twisting	N
Current cap All soft silicone on new esophagus	1D motion #1 Forward and Back with twisting	Y - fell off at coming backwards at the beginning of the esophagus between esophagus and overtube. Potentially an artifact of setup.
	1D motion #2 Forward and Back with twisting	Y - fell off at lower esophagus/stomach muscle.
	1D motion #3 Forward and Back with twisting	Y - fell off at lower esophagus/stomach muscle.
Large Flap Cap. New cap no tape- More resistance going down.	1D motion #1 Forward and Back with twisting	Y - Slide farther down the endoscope. No flaps ripped
Load at the base of the stomach instead of before esophagus	1D motion #2 Forward and Back with twisting	Y - fell off at the muscle. Stayed in one piece. Rip enlarged.

Load again at base - larger rip on cap.	1D motion #3 Forward and Back with twisting	Y - fell off at the same spot.
Medium Flap Cap	1D motion #1 Forward and Back with twisting	No dislodgement on forward movement. No dislodgement on backward movement.
	1D motion #2 Forward and Back with twisting	More pressure - No dislodgement on forward movement. No dislodgement on backward movement
	1D motion #3 Forward and Back with twisting	No tangible dislodgement on forward movement. Potentially pushed further down scope. No dislodgement on backward movement
On new Esophagus- **Small Flap Cap** No rips when removed. Flaps are good.	1D motion #1 Forward and Back with twisting	No dislodgement on forward movement. No dislodgement on backward movement. No movement whatsoever.
	1D motion #2 Forward and Back with twisting	No dislodgement on forward movement. No dislodgement on backward movement. No movement whatsoever
More torque	1D motion #3 Forward and Back with twisting	No dislodgement on forward movement. No dislodgement on backward movement.
Medium Flap Cap #2 trial on new esophagus	1D motion #1 Forward and Back with twisting	No dislodgement on forward movement. Yes dislodgement on backward movement of top half of cap.
	1D motion #2 Forward and Back with	No dislodgement on forward movement. No dislodgement

	twisting	on backward movement.
	1D motion #3 Forward and Back with twisting	No dislodgement on forward movement. No forward push onto scope. No dislodgement on backward movement.

C: Team Expenses

Expenses

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Category 1								
Print 1	First 3D printed prototype	UW Makerspace		11/01	1		$1.22	
Print 2	Second 3D printed prototype	UW Makerspace		11/08	1		$0.53	
Print 3	Third 3D printed prototype	UW Makerspace		11/10	1		$0.36	
Print 4	Fourth 3D printed prototype	UW Makerspace		11/17	1		$1.26	
Print 5	Fifth 3D printed prototype	UW Makerspace		11/20	1		$4.07	
Category 2								
							$0.00	
							$0.00	
						TOTAL:	**$7.44**	