BME Design

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Client:

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Advisor:

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Abstract

Gastrointestinal diseases are an increasingly common issue in many humans and the need for effective treatment has never been greater. In order to make treatment more effective, accurate viewing of the tissue lining the tract, as well as the ability to take acceptable tissue samples are essential. To accomplish this, endoscopic caps are utilized; however, the caps dislodge frequently leading to significantly prolonged operations. The goal of this project is to create and validate an endoscopic cap which effectively combats dislodgement from the endoscope. Furthermore, the cap must be designed to securely fit the dimensions of the client's endoscope. The design team generated three preliminary designs and after evaluation of each design, it was determined that the Internal Flaps design would be most successful. The Internal Flaps design utilizes five rounded plastic sections folded upward from the bottom of the cap to increase the friction forces acting on the cap, which increases the cap's secureness on the endoscope. Multiple materials were considered for design fabrication, however polycarbonate was deemed to be most appropriate. In the future, the team will manufacture and test a prototype of the Internal Flaps design based upon the input from the client.

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. 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 [2]. 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 [3]. 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 [4], 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 [5]. 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 [6] and MAJ-2315 Disposable Distal Cap [7], 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:

Our client 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 [8].

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 [9]. 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 [10]. 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 [10]. These caps are generally made from a disposable transparent silicone rubber polycarbonate resin [11].

Design Specifications:

Dr. Shada has come across the issue of distal cap attachments dislodging during procedures. While this complication does not pose a risk to patients, it is a tedious process to retrieve and reattach the cap, it can also prolong the length of surgery. Currently, the only practical way to attach an endoscopic dissecting cap is to tape it directly onto the endoscope using waterproof tape [12]. However, the cap remains susceptible to dislodgement during use due to the shear stress encountered while navigating through tissue. Our client is looking for a new endoscopic dissecting cap design 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, it should be sterilizable and reusable to reduce cost, and the cost of fabrication must stay below the project budget of $500.

III. Preliminary Designs

A. Internal Flaps

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.

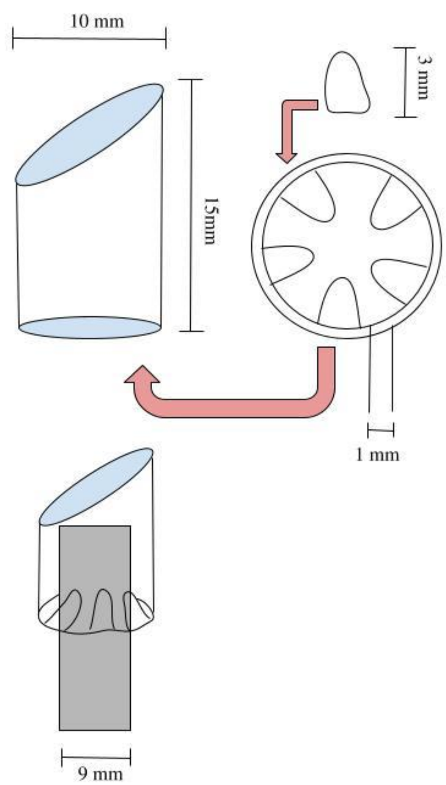


Figure 1: *Internal Flaps Cap individually and attached to endoscope*

B. External Band Compression Channel

This idea is very simple and does not differ much from the existing cap. There would be a channel cut into this cap, on the area that goes over the top of the endoscope. The idea is that 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 be something similar to a band used for braces.

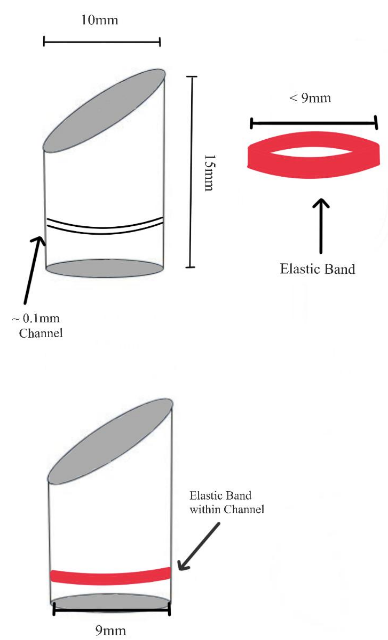


Figure 2: *External Band Compression Channel Cap with and without band attached*

C. Internal Band Locking Mechanism

The main idea of the locking mechanism is the use of 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.

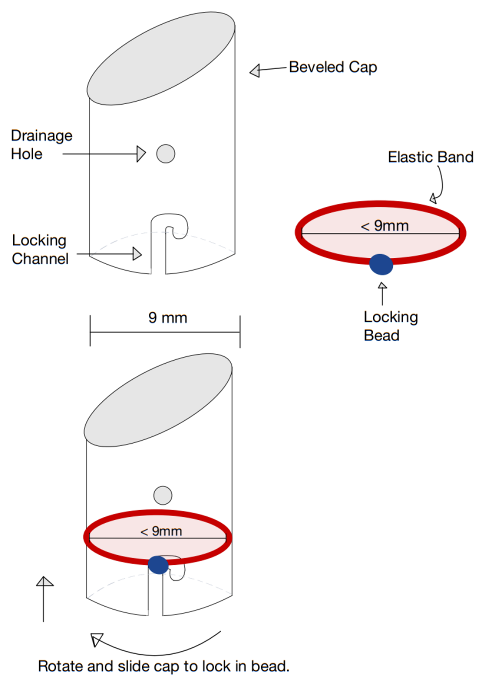
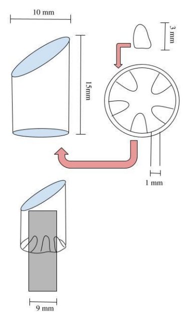
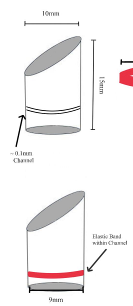
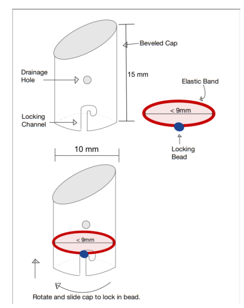


Figure 3: *Internal Band Locking Mechanism cap with and without band attached*

IV Preliminary Design Evaluation

Table 1. Design matrix for Sample Holder.

Design Criteria	**Internal Flaps** 		**External Band Compression Channel** 		**Internal Band Locking Mechanism** 	
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 Internal Flaps 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 Internal Flaps 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 for the client. The Internal Flaps 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 Internal Flaps 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 client preferences, fabrication and cost. The Internal Flaps 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 Internal Flaps 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.

The proposed final design is the Internal Flaps 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

A. Materials

The material used for the design will be Polycarbonate as this is the material currently used for the cap design. This material fits the criteria specified in the PDS. Polycarbonate is colorless and transparent, so it will not obscure the endoscope imaging window. It is both easily sterilizable with ethylene oxide and reusable [13]. Polycarbonate possesses no known safety concerns or risks to the patient during endoscopy procedure. Finally polycarbonate is affordable, very accessible and easy to fabricate with.

B. Methods

The design will likely be fabricated in two steps, fabricating the flaps as well as attaching the flaps to the cap. The flaps will be fabricated using a thin sheet of polycarbonate at 2 mm thickness which will lasercut to a circle of 10.2 mm diameter as outlined in the PDS. The flaps will also be cut out using the laser cut to allow for 5 flaps of 3 mm length each with 1 mm spacing between each flap. The separate flap assembly will then be attached to the main cap through the use of epoxide glue which is commonly used to attach pieces of polycarbonate.

C. Final Prototype

The team has not yet created a final prototype. Plans are currently being made to create this prototype in reference to the design image.

V. Testing/Future Work

A. Dislodgement Resistance Testing

The PDS specifies that the cap must remain secured to the endoscope through the duration of the endoscopy. This is due to the fact a dislodged cap could potentially cause harm to the patient and would be difficult to remove. In order to test the degree to which the prototype is dislodgement resistant, the team will 3D print a model endoscope end of equivalent diameter and texture. The team will then secure the cap to the endoscope and expose the cap to various movements and pressures that are meant to simulate movement of the endoscope through the esophagus and upper stomach. The team will then measure how much the prototype moved during testing and modify the prototype as necessary. For our final prototype the team plans to move on to further testing stages in hope of eventually giving the prototype to Dr. Shada to use during endoscopies.

B. Bodily Conditions Testing

The PDS specifies that the cap must be able to withstand the internal conditions found in the human body, specifically the esophagus and upper stomach for the duration of the endoscopy. The team will first test for pH by procuring an acidic solution with a pH of 2 meant to mimic the acidic conditions in the stomach and submerge our cap for a duration of 2 hours. The team will then assess the condition of the cap. The team will then test for temperature by placing the cap on a heating plate set to 100 degrees fahrenheit meant to mimic internal physiological conditions. The team will then assess the condition of the cap.

C. Image Obscurement Testing

The PDS states that the cap must not obscure the end of the endoscope. If the end of the endoscope was obscured in any way, this could lead to compromised or blurry images. In order to test for this, the team plans to test the cap on the endoscope and procure images with the cap attachment. The team will then assess if the image quality is adequate or if there was any obscurement involved.

VI. Discussion

Following testing, it will be extremely evident to what extent the new endoscopic cap can resist dislodgement. By mimicking the loads it would be exposed to during an endoscopy, the axial dislodgment of the original and modified cap can be compared, showing the effectiveness of the new cap design. Because of the standardization of endoscopic caps in the medical field and lack of testing against other designs, the tests performed on the new design will produce very valuable information. One ethical consideration to consider is the material used in testing that will be simulating physiological conditions. Without the option or necessity to test with human organs, a material must be created to mimic bodily conditions as best as possible without having to use any animal tissue. Another consideration is the environmental impact of the endoscopic cap. This will include the recyclability of the material used as well as any parts of the cap that aren’t serializable and would have to be discarded and replaced with every use. At this stage of the project, it is still entirely possible that prototypes of multiple designs will be fabricated. If this remains true, more extensive testing would be possible, and the dislodgement resistance of three designs could be compared to each other.

VII. Conclusions

Endoscopes are intricate and expensive instruments that provide medical professionals an essential view of the tissues lining the gastrointestinal tract. Our team will design and manufacture an endoscopic cap to help assist the client, Dr. Amber Shada, in her research in upper endoscopy. Specifically, Dr. Shada intends to utilize the caps to better view and extract tissue samples from the gastrointestinal tract. For this task, multiple rounded flaps will be placed onto the end of the endoscope, and folded upward to provide increased stability for the cap. In spite of the small scale of the cap, we believe a polished and effective endoscopic cap can be delivered to Dr. Shada.

Our team will continue with the Internal Flaps design, using polycarbonate. The Internal Flaps will be the simplest and most effective way to prevent dislodgement of the cap from the endoscope. Furthermore, the team will focus our efforts on manufacturing the flaps for the Internal Flaps design. Fabrication of the flaps may be difficult due to the high level of precision needed for an endoscopic cap, however to minimize human error during fabrication, laser cutting will be utilized to ensure accurate dimension on the prototype. Once the prototype is complete, our team will conduct both dislodgement resistance and attachment testing on a 3D printed model endoscope, to ensure that the cap is effective in both aspects for the client's specific endoscope. The cap will also be tested against simulated physiological conditions as well as image quality on the client's endoscope.

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IX. Appendix

A: Product Design Specification

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 client uses caps for the end of the endoscope which are attached via water resistant tape. The caps however frequently fall off due to the unsecure method of attachment and can become dislodged.

Our 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 3.5-6, 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 a 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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