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**DEVELOPMENT OF A TAGGING MECHANISM
FOR AN INGESTIBLE CAPSULE**

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SUBMITTED

BY

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SCHOOL OF MECHANICAL AND AEROSPACE ENGINEERING

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ABSTRACT

In the field of non-invasive surgery (NIS), non-interventional methods for internal examination of the gastrointestinal (GI) tract, wireless ingestible capsule has advantages over conventional endoscope and push enteroscope by allowing doctors to monitor inside the entire GI tract of a patient in a comfortable, effective and safe manner. However, current commercial capsules lack locomotion ability and therapeutic options which have been deployed widely in other methods using endoscope. To date, the capsule has yet been developed to effectively perform surgical and therapeutic options.

Endoscopic marking is a therapeutic procedure performed with the assistance of endoscope to localize a tumor, lesion, polyp and cancer preoperatively. It is currently not possible to be performed inside the small bowel. To improve endoscopic diagnosis with the advancement of miniaturization technology, an innovative solution is to develop a tagging mechanism onboard the current capsule for marking purposes. As soon as a tumor or bleeding symptoms are discovered based on real time transmission of GI images from the capsule, the doctor could make an immediate decision to activate the tagging mechanism to leave a tag on the intestine wall via remote control. If the capsule is able to perform this procedure, accuracy and time taken to detect tumor or cancer for resection would be improved.

The design and the design guidelines for the development of the tagging mechanism have been studied and included in the report. An ingestible wireless capsule, diameter 17 mm and length 50 mm including the tagging mechanism has been developed. The tagging mechanism, a spring-loaded mechanism for releasing a surgical stainless steel tag, is controlled wirelessly by an operator. Repeated *ex-vivo* experiments were conducted on explanted tissue to test the functionality of the developing therapeutic capsule in terms of efficiency in sending out the tag and reliability of the remote control.

In conclusion, this study reports the successful conceptual design of the surgical tagging mechanism deployed on the wireless endoscopic capsule, paving the way for a new generation of capsule devices which are able to perform both diagnostic and therapeutic tasks.

CHAPTER 1 - INTRODUCTION

1.1 Background

Human gastrointestinal (GI) tract is a tubular organ that extends from the mouth to the anus in which the movement of muscles and release of hormones and enzymes help to digest food [1]. Many diseases associated with the GI tract can be significantly problematic or even fatal. The diagnosis of those diseases can sometimes be challenging given current medical technology. Diseases in the small bowel are particularly difficult to diagnose.

The most common method to perform interior diagnosis of human GI tract is using a flexible endoscope. The first endoscope, introduced by Bruening in 1907, was a rigid instrument that allowed inspection of the upper GI tract. Later, a flexible fiber optic endoscope was introduced for assessing further into stomach, upper bowel, and lower GI tract with light sedation [2-3]. However, conventional endoscopy has limitations of assessing the small bowel because the small bowel is not only long (3 to 5 meters) but also convoluted [4]. Currently, the small bowel can only be diagnosed partially by a push enteroscope whose length (2 meters) is longer than the standard endoscope.

The endoscope, on the other hand, has additional channels to allow entry of different therapeutic devices, and hence can perform several Non-Invasive Surgery (NIS) treatments, for example, polyp or lesion resection through natural hole like mouth or anus, in the GI tract. It has also been used for preoperative localization of complicated diseases that require open surgery for resection [5]. Some well-known methods for localizing and investigating disease inside the GI tract vary from endoscopic tattooing, endoscopic clipping, to barium enema with an aid from X-Ray fluoroscopy [6-8]. That is to say, the endoscope has become well established as a diagnosis and therapeutic device for the GI tract.

However, effectiveness of NIS treatments using endoscopy depends strongly on the compliance of the patient to undergo the procedure. One of the most important reasons for lack of acceptance to endoscopic screening is the discomfort from its procedure. It is caused by forces exerted on the mesentery during enteroscope

pushing and luminal air insufflating used for better vision. With the aim to reduce discomfort for patients in endoscopy screening, an alternative to conventional endoscopy and enteroscopy for GI tract is a wireless ingestible capsule, first presented by Given Imaging [9]. The capsule, carrying a complementary metal oxide semiconductor (CMOS) chip camera along into the tract, is able to examine the entire GI tract completely with ease.

Movement of the capsule depends on peristalsis motion (the natural muscle activity that causes food to move along the GI tract) of the GI tract starting from stomach. The time taken to travel passively along the entire tract is about 8 hours. The capsule captures images and transmits wirelessly to external sensors. The acquired images are displayed on a monitor to be inspected by the doctor (Figure 1.1). A patient, after taking the wireless capsule, can still perform his usual activities while the capsule records all image data of his GI tract. Figure 1.1 shows the GI tract images captured during capsule endoscopy process. Based on these images, the doctor will define the condition of the tract and provide necessary treatment if required.

Figure 1.1: Illustration of capsule operation from Given Imaging [10]

As compared to conventional endoscope and push enteroscope, a wireless ingestible capsule has more advantages by allowing doctor to monitor inside the entire GI tract of a patient in a comfortable, effective and safe manner. However, there is a limitation of the current wireless capsules used for diagnosis of the GI tract. Although being capable of capturing images of the entire tract, the capsule lacks locomotion ability and therapeutic options. In order to enhance its capabilities, many mechanisms have been studied and developed in the field of locomotion [11-14] and therapy [15-16], aiming to integrate into the current

capsule. The emphasized challenge is to miniaturize the sizes of those developed mechanisms so that they could fit into an ingestible capsule.

1.2 Motivation

As mentioned in the previous section, though being able to reach the small bowel of the GI tract, the current wireless capsule has limitations of lacking locomotion ability and therapeutic options. The rapid convergence of several technological advances, such as miniaturized actuators and mechanisms, reliable two-way communication, battery with high energy density as applied in the revolutionary field of wireless capsule technology, has enabled the development of ingestible devices that can perform practical surgical procedures. On the other hand, endoscopic marking, a therapeutic procedure to localize a tumor, lesion, polyp and cancer in preoperative and resection [17-18] is unable to be performed inside the small bowel due to the limitations of current endoscope.

In order to utilize the capsule's ability to overcome the limitations of conventional endoscopes, an innovative solution is to develop an integrated tagging mechanism for the capsule. When the capsule is able to perform a marking procedure, accuracy and time taken to detect tumor or cancer in resection performance will be improved. Discovering a tumor or bleeding symptom based on real-time images, the doctor can make an immediate decision to activate the tagging mechanism to leave a tag on the intestine wall wirelessly.

The idea of this mechanism integrated into capsule technology is illustrated in Figure 1.2. And this tagging mechanism not only has the potential to work within the small bowel, which can hardly be reached by an endoscope, it could also be used for diagnosis of other parts in the entire GI tract, for example colon. This therapeutic capsule developed with the new on-board localizing mechanism would be a valuable forerunner for other surgical procedures such as Natural Orifice Transluminal Endoscopic Surgery (NOTES).

Figure 1.2: Tagging performance of the developing capsule

1.3 Objective

The objective of this project is to develop a novel mechanical tagging mechanism for wireless endoscopic capsule to improve GI tract's diagnosis performance. In order to assist the doctor in localizing a tumor or disease, the project aims to provide a detectable marking tag at the targeted GI spot in an accurate and effective manner. When the capsule is able to perform a marking procedure, accuracy and time taken to detect tumor or cancer in resection performance will be improved.

In order to achieve the objective there are several sub-objectives defined as follows:

- To perform literature review on the conventional markings and other inventions related to the development of the tagging capsule
- To perform mathematical analysis for the proposed mechanism
- To design and test the feasibility of the mechanism with *ex-vivo* experiments

1.4 Scope

For the accomplishment of this master of engineering degree, the scope is limited to the design and math modeling of a shooting mechanism to deploy a detectable

tag in the GI tract. In order to access the feasibility of the conceptual design, a series of *ex-vivo* experiments with explanted intestine tissue will be carried out.

The system will be developed to the point of proving the concept and feasibility of the tagging capsule. As such, medical requirements of biocompatibility and sterility would not be considered in this project.

A complete wireless endoscopic capsule requires other basic components like camera, battery, antenna and microcontroller. Except for the tagging mechanism, development of other components are being studied by other researchers working on the project and therefore not within the scope of this thesis.

1.5 Organization

The report contains six chapters in total. They are organized in the following manner.

Chapter 1 introduces the background and motivation of this project. The objectives and scope are also outlined along with the organization of the report.

Chapter 2 gives a literature review for the project. It consists of five main sections: medical introduction of human gastrointestinal tract, conventional systems used for diagnosis of the tract, conventional-endoscopic marking methods, endoscopic capsule robots and potential- miniature actuators.

Chapter 3 discusses about all the requirements for the design to decide the suitable mechanism for the project's objective.

Chapter 4 discusses about the design guideline along with mathematical analysis of the selected mechanism. Morphological chart and discussion are presented in order to evaluate the conceptual designs and to make a decision on the final design.

Chapter 5 presents an experiment setup for measuring penetration force and a mathematical calculation to choose essential components for the tagging mechanism. Two *ex-vivo* experiments will be conducted to prove the feasibility of the mechanism.

Chapter 6 gives a conclusion and future work for the project.

CHAPTER 2 - LITERATURE REVIEW

This chapter provides the literature review for the project. This review is organized into four main sections. Conventional endoscopic systems such as gastro endoscope, push enteroscope and wireless capsule used for examining the interior of the GI tract are described in section 2.1. A brief description of the GI tract with focus on the small intestine is described in Appendix A.

By changing the tool via tool channel, the endoscope is able to perform treatments such as biopsy, resection and marking. Endoscopic marking, which is very useful for open surgery or laparoscopic surgery in resection, will be introduced in section 2.2. The section also describes three common endoscopic marking methods using ink, dye and clip. Section 2.3 presents some research capsules related to the project. Also, section 2.4 provides information of three types of miniature actuators which could be selected to actuate the developed mechanism.

2.1 Conventional Systems for Gastrointestinal Tract

In order to examine the interior of the GI tract, conventional systems that have been used so far can be listed from gastro endoscope to push enteroscope and the wireless endoscopic capsule. This section would provide an introduction to the three mentioned endoscopic systems.

2.1.1 Gastro Endoscope

Endoscopy is a minimally invasive diagnostic medical procedure used to assess the interior surfaces of digestive system by inserting a tube into body through a natural orifice. The instrument may have a rigid or flexible tube body with a light delivery system to illuminate the organ or object under inspection. The light source is normally outside the body and the light is directed via an optical fiber system. The endoscope not only provides real time images for visual inspection, it is also able to perform therapeutic treatments such as biopsy, cutting polyps, stopping blood and retrieval of foreign objects, to name a few. As shown in Figure 2.1, two additional channels allow entry of medical instruments for operation in a fast and effective way. However, conventional endoscopy has limitations of assessing the

small bowel because the small bowel is not only long (3 to 5 meters) but also convoluted [4].

Figure 2.1: Two channel endoscope with its feature

2.1.2 Double Balloon Enteroscopy

One of the conventional endoscopic systems which enables assess into the small intestine is the double-balloon enteroscopy. This system, also known as push-and-pull enteroscopy, is a long endoscope used for assessing and treating the upper or lower part of the small bowel [19]. An illustration of the push enteroscope is shown in Figure 2.2. The technique involves the use of a balloon at the distal end of a special enteroscope and an overtube. Overtube is a tube used to fit over the endoscope and lets the endoscope move along inside smoothly. After being inserted together through the mouth, the enteroscope and the overtube pass through the esophagus and stomach to reach the small bowel.

Figure 2.2: Push Enteroscopy [23, 24]

The principle of double balloon is illustrated in Figure 2.3. To push the enteroscope forward, a balloon attached to the overtube is inflated. Using the friction between the balloon of the overtube and the intestine wall, the

enteroscope is pushed forward (Figure 2.3, Push Process). After that, the balloon of the overtube is deflated while the balloon of the enteroscope is inflated. Again, using friction between the balloon of enteroscope and intestine wall, the overtube is pushed forward. Then the balloon of the endoscope is deflated and the balloon of the overtube becomes the base for the endoscope to move forward. This pushing process continues until the enteroscope reaches the terminal ileum. When moving backward, the balloons are inflated, and the overtube and the enteroscope are pulled back (Figure 2.3, Pull Process). The help of the overtube and the inflated balloon is necessary in this system for the reason that the bends of intestine are unpredictable. Furthermore, the intestine wall is much thinner compared to esophagus or stomach wall, and at the bend, the intestine wall may be torn if strong pushing force is applied on the scope, consequently abdominal complications may occur.

Figure 2.3: Principle of the double-balloon technique [20]

2.1.3 Commercial Capsule

One of the first endoscopic capsule commercial products is the M2A (Mouth to Anus) introduced by Given Imaging Ltd. The size of the capsule measures 11 mm x 26 mm and weighs 3.7 grams. It contains a complementary metal oxide semiconductor (CMOS) chip video camera of 256 x 256 pixels, six white light emitting diode illumination sources, two silver oxide batteries, and a radio telemetry transmitter (Figure 2.4). The image field of view is 140° and the magnification is 1:8 from a depth of 1 mm to 30 mm. Once swallowed, the capsule is propelled by intestinal peristalsis. Images, captured at two frames per second

rate, are transmitted by radio frequency to a sensor array in a belt placed around the patient's abdomen. The patient wears this digital data recorder for the duration of the battery life (eight hours) which allows taking up to 55,000 jpg image. Subsequently, the recorded images are downloaded to a workstation and used to produce a video of segmented bowel that can be reviewed at any time thereafter.

Figure 2.4: Structure of the capsule [10]

Up to now, more than 300,000 PillCam (M2A) capsules have been used worldwide since the development of this technique, and the vast majority of published evidence in peer reviewed journals is based on this type of video capsule [9]. The internal of an actual M2A Capsule is shown in Figure 2.5. It is essential to study the current capsules to identify room for improvement on the existing features of the pill, particularly in terms of size and capability. As mentioned in the motivation section, in order to implement other treatment devices into an ingestible form, sizes of the entire existing components need to be scaled down.

Figure 2.5: Dissembled M2A Capsule

A rival of M2A capsule is Olympus capsule, a new type of capsule launched in December 2004, using a charge-coupled device (CCD) with electronic enhancement of image quality and several additional features[9]. Figure 2.6 illustrates the EndoCapsule system from Olympus. Two main differences between M2A capsule and Olympus capsule are real-time observation and quality of image colors. Olympus capsule has a high-resolution CCD camera which supports real time imaging transmission. With the 'Real Time' Viewer device in hand, a physician can confirm a real time imaging recorded by the capsule endoscope and then estimate the capsule position in the GI tract during the procedure. The Olympus capsule also includes software which is able to detect red colour that may facilitate indentifying bleeding.

Figure 2.6: EndoCapsule system of Olympus [21]

2.2 Conventional Endoscopic Marking

Endoscopic marking is a therapeutic procedure to mark a boundary of a tumor or a polyp before resection performance. It is especially useful for resection performance at serosal side, which is the outer side of the intestine, because there are many difficulties in locating a tumor or polyp during early stage at small intestine. Some well-known conventional endoscopic markings to facilitate tumor localization can be listed as dye staining, ink injection and metal clipping, all of which are described in the next segments. Therefore, it is rational to take these methods into considerations for the design of tagging mechanism for the capsule. The most important challenge is to overcome the constraint in size of the capsule to deliver an adequate amount of ink or to generate sufficient force to grab tissue. Hence, it is important to discuss all relevant information and considerations together with some preliminary tests.

2.2.1 Methylene Blue Staining

Methylene blue is used in endoscopic polypectomy as an adjunct to saline for injection into the submucosa around the polyp to be removed. This allows the submucosal tissue plane to be identified after the polyp is removed, which is useful in determining if more tissue needs to be removed, or if there has been a high risk for perforation.

Methylene blue is also used as a dye in chromoendoscopy, and is sprayed onto the mucosa of the gastrointestinal tract in order to identify dysplasia or pre-cancerous condition. This method is currently applied for the Barrett's esophagus and intestine to identify dysplasia esophagus at the distal end of esophagus and intestinal metaplasia [22-23]. To apply Methylene Blue dye, with the assistance from Olympus catheter, doctor firstly cleans the perificial mucus of the esophagus with 20 mL to 40 mL of a 10% solution of N-acetylcysteine. After that, 10 mL to 20 mL of a 0.5% of Methylene Blue solution is sprayed along the length of esophagus. Then, 120 mL to 300mL of pure water is sprayed along the stained length of esophagus to clean off the exceed dye. In order to define the symptom, doctor would compare the intensity and color of the dye from images of dying area (Figure 2.7). However, due to its large volume of dye required which cannot be contained by the capsule size (2.5 mL), endoscopic staining is not involved in this project.

Figure 2.7: Contrast Color of Esophagus wall in Methylene Blue Staining[24]

2.2.2 Ink Injection

There are three types of commonly used ink analyzed in this section: Indocyanine green ink, India ink and SPOT ink. The description as well as the effect of these three types would be described in portions below. This section also defines the most suitable ink type if the ink-injection method is considered as a conceptual design in chapter 3.

a. India Ink

Historically, tattooing has been used from ancient time until now for various purposes such as cosmetic or make-up. In 1975, India ink tattooing was firstly used by Ponsky and King [25] to produce a serosal tattoo in preoperative surgery. This technique since then has become one of the best marking methods for rapid and accurate localization of polyps. Moreover, the use of this technique in concert with laparoscopic surgery is particularly important because the ability to palpate the bowel is lost.

Figure 2.8: Endoscopic view of India ink Injection [18]

In order to perform India ink marking, saline solution is firstly injected into submucosa layer to create an artificial pseudopolyp [18] (as shown in Figure 2.8a). After that, a small volume of India ink is injected into the elevated submucosa. The two-step injection prevents the India ink needle from penetrating other tissue layers that would lead to complication in peritoneal cavity inside patient's abdomen. Carbon in India ink provides permanent marking that will remain inside the patient for life unless dissection is done on the marked area. Without the use of marking, laparoscopic identification of intraluminal lesions can be impossible because there might be no visible serosal signs from the lesion.

b. Indocyanine Green Injection

Indocyanine green, evaluated surgical usefulness for endoscopic marking [26], is an alternative to India ink. Though complication when using India ink is rare, there are reports of side effects on patients including inflammatory pseudo-tumor, abscess and postoperative adhesion ileus. In addition, after injection, India ink will stay in the patients' abdomen for the rest of their lives. As compared to the lifelong duration time of India ink, Indocyanine green ink is found to last in a short interval from a few days to a week. Figure 2.9 shows the appearance of Indocyanine green being seen from laparoscopic view. When resection is performed in a short time from the date of diagnostic, Indocyanine green ink can be an alternative to India ink. Nevertheless, for cases require long interval, for example the growth of lesion or cancer cell, use of Indocyanine ink is not appropriate.

Figure 2.9: Laparoscopic view on Indocyanine green ink injection[26]

c. SPOT Ink

SPOT ink is the first and only non-India-ink based FDA approved product for endoscopically marking lesions or so-called “temporarily tattooing” inside the GI tract [27]. While India ink remains permanent, SPOT ink just stays for a short interval of about 30 days due to its compositions that will be discussed later. Therefore, SPOT is commonly used for those lesions required surgical removal within 30 days. Compared with India ink, SPOT ink has some advantages in clinical use since some clinical studies show SPOT to be a safe, effective, and convenient method for marking GI lesion.

Figure 2.10: SPOT ink from GI Supply

Each syringe of SPOT ink shown in Figure 2.10 contains 5cc of sterile, biocompatible, non-pyrogenic suspension and highly purified carbon particles [28]. Meanwhile, India ink composition contains shellac, phenol, and ammonia which even in dilute solutions would preferably be avoided. When SPOT ink is injected, high-carbon particles remaining in the submucosal site create a black mark that remains visible on the mucosal and serosal surface of the intestine. With volume from 0.5 to 0.75 mL of the marker in each injection [28], a black blush of the marker is produced on the colon measuring 1-2 cm in diameter.

According to the product guide, to use SPOT ink in effective manner, doctor needs to inject four times to create a quadrant mark on intestine wall around the lesion. The quadrant mark is useful to define boundary of the marked lesion in removal surgery. Since the ink can be seen as a black blush from serosal site, the mark also helps the doctor easily find the inspected location from peritoneal cavity in laparoscopy surgery or open surgery.

For the use of SPOT ink, it is shown that if the volume of ink is less than 1 mL per injection, 58% is recognized at the inspected location. If the volume of ink is increased more than 1 mL per injection, 100% is recognized successfully [33]. In addition, the injecting needle should be inserted into the intestine wall at an acute angle so that the beveled tip of the needle is entirely beneath the mucosa. If the needle is inserted perpendicular to the mucosa, there is a risk of penetrating the serosa and injecting the marker directly into the peritoneal cavity.

d. Evaluation of Ink Volume

In summary, there are three types of commonly used ink analyzed in this section: Indocyanine green ink, India ink and SPOT ink. The description as well as the effect of these three types could be referred above. Table 2.1 summarized three injection methods for the three respective inks regarding to and lasting time of the injected mark [18, 26, 28]. This section will define the suitable ink type for the proposed ink-injection mechanism introduced in chapter 3. Furthermore, based on the measured volume size as a constraint, the concept of the mechanism could be designed and evaluated.

Table 2.1 Comparison between conventional marking methods

	Volume per injection	Procedure	Duration Time
Indocyanine Green	2 mL saline	Submucosa elevation	8 days
	1 mL ICG	Ink Injection	
	2 mL saline added	Pushing out the ICG remaining in the needle	
India Ink	1 mL saline	Submucosa elevation	20-30 years
	1-1.5 mL India Ink	Ink Injection	
	1 mL saline added	Pushing out the ICG remaining in the needle	
SPOT	0.5-0.75 mL SPOT Ink	Ink Injection	30 days

Judging on the volume per injection and the lasting time of the created mark, SPOT ink is considered the best option because of its small volume and acceptable duration time. In terms of volume, both India ink and Indocyanine green ink need more than 3mL to produce a detectable mark. The volume recommended from SPOT manufacturer, varies from 0.5 to 0.75 mL, which is significantly lesser as compared with the other two. That volume of SPOT ink typically produces a mark measuring 1-2 cm in diameter. In addition, performance of India ink and Indocyanine ink injection is more complicated due to having more steps in procedure, while SPOT ink injection is performed in one shot. SPOT ink, a mixture of water used carbon particle, is good to use directly without adding additional components.

As the volume of 0.75 mL would occupy nearly one third of the space of the current capsule (2.4 mL), an experiment with SPOT ink was carried out to verify the required volume for a detectable mark. Experiment set up and results are shown in Appendix B. Results showed that a volume of 0.4 mL of SPOT ink was sufficient to create a detectable mark.

2.2.3 Endoscopic Clipping

Haemoclips is a popular mean to stop GI bleeding. It consists of a clip that is detachable and strongly compresses the openings of the wound tissue together so that the bleeding can be stopped. The haemostasis procedure is illustrated in Figure 2.11. With the assistance from endoscope, the doctor can release the clip at a desired location. Figure 2.11 also describes how the doctor is able to hold and remove the clip by push and pull method via tool channel of endoscope.

Figure 2.11: The haemostasis procedure of using clips [29]

Besides the ability of stopping GI bleeding, haemoclip is also known as a marking device. The position of the attached clip is located by using X-Ray fluoroscopy on patient before operation. Picture 9 in Figure 2.12 reveals these attached metal clips as white thin objects on the X-Ray film. Applying the clip mechanism into a capsule requires consideration on the size of the clip as well as the tissue gripping force. Firstly, the clip, together with other components, must fit in an ingestible form. Secondly, the force generated from a small actuator powered from limited battery source inside capsule may be insufficient to attach the clip and cause it slipped. This issue will be discussed in section 3.2.2 and 3.5 in order to evaluate the suitable mechanism for the project.

Figure 2.12: Clipping with X-Ray Fluoroscopy [30]

2.3 Recent Research on Capsule

There are various researches focusing on different applications for wireless capsule, beside the ability to diagnose the GI tract, such as drug delivery, locomotion, navigation, pH measurer, biopsy device, etc. However, this report only covers the drug-delivery ideas due to the similarity of their functionality to the tagging mechanism. The idea is to deploy a capsule form as a mean to directly transport a drug to the desired location of small bowel. To reach the targeted area, the drug-delivery capsule needs a guiding system to localize its position after being taken into the patient's body. The limitation of drug-delivery capsule is the lack of vision ability because most of space in the capsule is utilized as a drug container. Three drug-delivery capsules: High Frequency capsule, Enterion Capsule and iPill, would be discussed in more details later on.

2.3.1 High Frequency Capsule

High frequency (HF) capsule concept, the first generation of drug-delivery capsule was developed in the early 1980 [31]. The idea is to send an amount of drug to the targeted intestine under remote control. The design of the HF capsule is depicted in Figure 2.13. A high frequency generator placed outside the body generates the heat to melt a nylon thread which is used to hold a compression spring in highest state of stored potential energy. Power is received via an oscillating circuit to charge the capacitor. In order to deliver drug at the desired location, the heating element is heated up to make the nylon thread burn. Consequently, the compression spring will fire a needle to pierce through a latex balloon which was designed as a drug

reservoir. Drug after being released will be absorbed by intestine at the targeted location.

Figure 2.13: High Frequency Capsule [31]

2.3.2 Enterion Capsule

Enterion Capsule, a drug delivery capsule robot, was developed by Pharmaceutical Profile, a well-known firm for its research on drug absorption [31-32]. Enterion Capsule is also known as Phanteon Capsule with an ingestible size of 32 mm x 11 mm. The body of this capsule contains 1 milliliter (1 mL) liquid or powder of drug to be expelled to a targeted area inside the small bowel.

Figure 2.14 shows the design of the Enterion Capsule. A nylon thread is used to hold a compressed spring firmly in the highest state of stored-potential energy. On reaching the desired area, tracked by radio gamma camera, the heat generated by a heater, which is activated by a doctor, will instantly burn the nylon thread. Consequently, the compressed spring is released to push liquid or powder contained in its reservoir out of the capsule. The effect from drug absorption will be studied by the doctors after that. However, in order to reach the targeted area, the patient needs to swallow a radioactive marker to allow the doctor to trace the approximated position of the capsule.

Figure 2.14: Structure of Enterion capsule [31]

2.3.3 Philip's iPill Capsule for Drug Delivery

For some kinds of digestive tract disorders such as Crohn's disease, Colitis and colon cancer, delivering drug to a specific location in the intestinal tract becomes more crucial to reduce side effects. Philip Research, with the iPill, has proven the research ability of electronically controlled drug delivery [33]. The iPill has a microprocessor, a battery, a pH sensor, a temperature sensor, a RF wireless transceiver, a fluid pump and a drug reservoir in an ingestible form of 11 mm diameter and 26 mm long. The prototype is said to be capable of reaching the interested location with the pH measurement sensor mounted inside the iPill [33]. After that, under the control of the microprocessor, the internal pump is operated to spray out a small amount of drug contained inside its reservoir.

Figure 2.15: iPill for controlled drug delivery [33]

The idea of using an internal pump from i Pill can be applied in staining GI tract by spraying an amount of ink. However, staining ink amount to be sufficient for long-lasting marking needs further research. If the amount of ink is large, the required size for ink reservoir may take over the space allocated for the camera in the proposed capsule (Figure 2.15). If the amount of ink is too little, the doctor may not be able to detect from serosal side in laparoscopic, or the ink may be leaked or absorbed before any subsequent treatments.

2.4 Actuators

Since the actuator used to actuate the mechanism must fit in an ingestible capsule, the first consideration to select an actuator is its size. Furthermore, the torque or force generated from the actuator must be able to meet the required input of the mechanism. There are four types of actuators that have been applied widely in current capsule research due to their small sizes, namely Shape Memory Alloy (SMA), Piezomotor, Micro DC Motor, and compression spring. The second consideration, the limited power of the capsule, would decide the appropriate actuators for the mechanism.

2.4.1 Shape Memory Alloy (SMA)

A shape memory alloy (SMA), known as a smart alloy, is able to return to the original shape after being deformed by applying required heat at a certain temperature [34]. Memory ability of SMA works on the arrangement of crystal structure at different temperatures. Nowadays, in medical or robotic applications, based on its small size, SMA is considered as an alternative solution for some conventional actuators such as hydraulic and pneumatic. Particularly in robotic capsule field, there are some studies on using SMA to operate capsule's locomotion and biopsy tools [16, 35].

However, changing shape to the initial shape can only be done at a certain high temperature and that requires a high heat generated from a high power. Currently, the power source of wireless capsule is from built-in button batteries, which is unable to generate that high power. Capsules that applied SMA technology use power transferred from an external power source via wire. Hence, although

promising, SMA is not suitable for capsule's application of this project due to its high-power consumption.

2.4.2 Compression Spring

Compression spring is considered the simplest actuator, which is able to generate force from its potential energy stored inside the compressed form. Force generated depends on the spring constant and the distance from compressed length to free length. The highest potential energy stored by a compression spring is achieved when the compressed length is compressed to the solid length. The advantage of compression spring is stated that though its size is small, the potential energy inside a compression spring could produce a high force and a high speed. In order to be released from the compressed state, the compression spring needs a switch or a motor to trigger. A compression spring only works once after releasing from its compressed state. Therefore, to be applied in recurrent activities, it requires a particular mechanism to compress it to the compressed state.

2.4.3 Micro Motor

There are two types of commercial-miniature motors which can meet the size requirement: Piezomotor and Micro DC motor.

Figure 2.16: Linear Piezomotor [36] and Smoovy DC linear Motor [37]

Piezoelectric motor is a type of solid-state actuator based upon the change in shape of a piezoelectric material when an electric field is applied [38-39]. In the piezomotor, a voltage is applied to the piezoelectric element to generate alternating expansions and contractions, either in the ceramic body itself or in an attached metal piece [38]. The motor uses these ultrasonic vibrations to obtain a driving force which then drives the motor using friction. Due to their sterile, non-magnetic

and ceramic nature, piezomotors work well in medical design applications. Figure 2.16 shows the linear piezomotor with its printed circuit board (PCB) from Physic Instrument (PI) [36]. The linear shaft of the motor can travel with a velocity of up to 200 mm/s in 2 mm distance. Force of up to 0.15 N can be achieved and operating voltage of this motor is given at 5 V.

Micro DC Motor is another promising actuator for the project. The Micro DC motors introduced by Faulhaber Group [37] and Namiki Precision Jewel Company [40] are considered the smallest DC motors available in the world. The diameter of this motor is 3 mm which may be able to fit inside the limited space of the capsule. Furthermore, this rotary motor can convert rotation motion to linear motion by changing its gear head attached with a lead-screw mechanism. The specification and dimensions of this linear motor can be referred to Appendix C. The Faulhaber 0308 rotary DC motor with a special gear head is able to convert the rotation to linear motion. The pushing force of the linear motor can reach up to 2.8 N [37], making Micro DC Motor a better choice for the project as compared to the force of 0.15 N generated by Piezoelectric. Besides, an advantage of motor as compared to compression spring is the controllable ability to vary its force, torque, position, direction, and speed.

CHAPTER 3 - MECHANISM CONSIDERATIONS

In this chapter, the requirements as well as the evaluation on different marking methods are provided. Section 3.1 introduces an overview of the whole capsule system. Section 3.2 describes an overall concept of three methods: ink-injection method, clipping method, and tag-shooting method, and details for each method are provided in section 3.2.1, 3.2.2 and 3.2.3 accordingly. Section 3.3 would evaluate the three methods to choose the most suitable method for the project's objective.

3.1 Overview of the System

Figure 3.1: Conceptual schematic of the system

Figure 3.1 illustrates an overview of the operational mechanism of a capsule system. The system comprises two main modules: an ingestible capsule and an external control unit/base station. The ingestible capsule can pass through the digestive track of a patient, collecting images and/or physiological parameters of the body, or performing a task such as tagging a desired location. The external control unit collects data from the capsule and controls the operation of the capsule. It is usually a wearable device that can be carried by the patient. This unit may be connected to a PC to transfer its data to the PC for enhanced image display and analysis.

Figure 3.2: Conceptual schematic of the wireless capsule

For better understanding of the wireless capsule, a conceptual diagram of the capsule is depicted in Figure 3.2. As shown, the system consists of five main modules: control unit, wireless communication unit, power source, image sensor, and actuator. The wireless communication unit is an essential part of the system that makes it possible for the in-body capsule and the external controller to communicate. It is employed to send the operational commands to the capsule and/or to extract the data and status of the capsule. The system is powered using Lithium Ion electrochemical batteries.

In the developed prototype, a Zarlink ZL70101 transceiver [41] in conjunction with a fabricated antenna is utilized as the wireless communication unit. Using this transceiver, a bidirectional communication between the capsule and the external communication unit at 433 MHz industrial, scientific and medical (ISM) band can be established.

The MSP430 ultra-low power microcontroller from Texas Instruments (TI) [42] was used to implement the control unit of the system to control the operation of the capsule. Aside from low cost, this microcontroller benefits from low energy consumption and has been widely used in many low-power industrial, medical, and automotive applications. The developed platform provides a bidirectional wireless communication between an in-body capsule and an external control unit and is able to drive brushless direct current (DC) motors to manage different sensor signals simultaneously. The implemented control unit should be able to interpret the received commands, adjust the operation of the capsule modules, and perform the desired task through proper activation of the actuation mechanism.

There are several actuation mechanisms, namely maneuverability module of the camera, weight management module and tagging module, being under

development for the whole capsule project. However, only the tagging module is under the scope of this report and the development of the design for the tagging module will be further discussed in the sub-segment sections. Designs for other modules of the whole system are studied and developed by other researchers in the group, and hence, not included in this thesis.

3.2 Conceptual Ideas of Marking Mechanisms

As introduced in the literature review, the three common methods used for clinical marking inside the GI tract with the assistance from endoscope are ink injection, dye staining, and clipping. Therefore, these methods are considered for the design of the tagging mechanism for the capsule. The most important challenge is to overcome the constraint in size and force. When ink injection or dye staining is used, the size of the reservoir will acquire a considerable space inside the capsule. Bearing that in mind, dye staining is not appropriate for this project due to its large volume of dye required. Similarly, when the clipping is used to grab a tissue, generating a sufficient force by a small actuator poses the difficulty.

Based on the above-mentioned methods, three tagging mechanisms are introduced for this project: ink-injection, clipping, and tag-shooting. The first two mechanisms are inspired by endoscopic injection and endoscopic clipping. The objective of the first mechanism is to inject an amount of ink to create a detectable mark. The second mechanism is designed to release a clip in order to grab a fold of tissue. The clip must remain at the desired location for a short period in the GI tract until operation is performed. The third mechanism is developed to shoot a metal tag into intestine tissue, and the tag will be consequently detected by an X-ray device to locate its position on radiology films.

A tagging mechanism requires an actuator to activate upon execution, and each mechanism has its own characteristics that require the corresponding qualities from the actuator. Table 3.1 introduces three types of linear actuators: compression spring, linear motor and piezomotor, but their operation is different in terms of force producing and movement speed. The piezomotor, however, is not selected to be the actuator for the tagging mechanism because its operation requires high voltage which cannot be supplied by button batteries, the common energy source being used for the capsule.

Table 3.1 also provides some possibilities for the selection of actuator for each type of tag in each mechanism. The next three sections will elaborate and discuss reasons for each selection.

Table 3.1 Actuator and tag selection

Option	Main Actuator	Tag	Mechanism
1	Compression Spring	Ink	Ink injection
2	Linear motor	Clip	Clipping
3	Piezomotor	Tag	Tag shooting

3.2.1 Ink-Injection Mechanism

As mentioned in the literature review, the ink-injection method has been used widely for endoscopic marking in clinic. Using a long tube and a controllable needle, this method can be performed easily via free tool channel of the endoscope. Either performed outside the body or inside via endoscope, the appropriate procedure of ink injection always has three steps: insertion, injection, and retraction. The three-step procedure of normal injection is illustrated in Figure 3.3. First step is to push the sharp needle into tissue layers. Second step is to press on the piston of the syringe containing saline or ink to inject ink solution. After injecting the required amount of the solution, the third step is to pull back the syringe and the needle out of the tissue layers. Since ink injection requires continuous activities, it might pose a tough task for a miniature mechanism of capsule. The following sections will introduce a conceptual mechanism design to perform a simplified procedure for ink injection which includes only two steps as there is only one actuator to provide the actuation. These sections also provide an analysis of the feasibility of applying such mechanism into the capsule.

Before the ink injection mechanism is sketched, it is essential to define the most appropriate type of ink as well as the required volume of the selected ink. As presented in section 2.3 of the literature review, SPOT ink was chosen due to its small volume required and the lasting time.

Figure 3.3: Three-step procedure of injection

Idea of Ink-Injection Mechanism

This idea consists of one large reservoir containing ink called syringe, one sharp needle, and one actuator to power up the mechanism (Figure 3.4). The needle will be pushed forward at the targeted spot and then retracted so that the capsule can continue moving. The actuator that can be used for this mechanism therefore must be able to provide a two-way motion of pushing and retracting. While a linear actuator can cater for such motion, a compression spring is only capable of one-way motion. As a result, a controlled linear motor is chosen for this mechanism.

The reservoir and the linear motor are both mounted in the capsule body. The piston, the component used to push liquid, is attached with a needle. There is a small hole which allows liquid to flow through at the junction between the needle body and the piston plate. At the same time, the needle is attached to a lead screw of the linear motor. Consequently, when the linear motor is controlled to actuate forward or backward, the needle will be moved accordingly along a straight direction. When the needle is pushed forward to pierce into the intestine layer, the piston plate will move forward accordingly, compressing the liquid inside the reservoir and then pushing the ink liquid to flow through the small hole via needle's body to the tip. The ink will be pushed into the intestine tissue slowly.

Figure 3.4: Illustration of the ink-injection idea

3.2.2 Clipping mechanism

Similar to ink-injection method, endoscopic clipping has been performed via the tool channel of an endoscope. A clip, which is closed in its natural state, would be threaded through the channel and be forced open to grab a tissue fold. The force to open the clip is transferred via a flexible stainless steel wire by the doctor. In the same way, the idea presented in this section also uses a spring-effect clip, and the force is generated by an actuator inside the capsule. A haemostatic clip from Olympus [30] is shown in Figure 3.5. With the size given, a clip may occupy considerable space inside the capsule. This idea of clipping mechanism consists of an actuator, a metal clip with spring effect, and a cam tube which forces the clip to open when being pushed forward by the actuator. Similarly to what was mentioned in section 3.2.1, the selected actuator for pushing the clip forward is considered between a linear actuator and a compression spring. For this mechanism, the compression spring is more appropriate due to its higher force and fast-releasing speed.

Figure 3.5: HX-3L Clip from Olympus [30]

Illustration of the clipping idea is shown in Figure 3.6. At the initial state, the clip stays inside the cam tunnel at its natural closing position while the compression spring is compressed to its highest level of potential energy. When the spring is activated, it would push the clip forward; at the same time, the narrow designed wall of the cam tube pressurizes on the clip to force its grippers open. The objective of the clip is to grab a tissue's fold with its grapping state. The procedure completes when the clip is continuously pushed forward until out of the cam tube. Due to its spring effect, the clip returns to its natural closing state when there is no pressurized force on its body.

Figure 3.6: Illustration of the clipping idea

3.2.3 Tag-Shooting Mechanism

The tag-shooting mechanism is similar to the clipping mechanism in terms of tag detection as both mechanisms require X-ray to detect the tag. However, the tag designs of the two methods are different. Tag-shooting mechanism is described as a shooting mechanism that comprises a metal tag and a hollow cylinder containing a compression spring inside. The size of the tag in this design is as small as a needle tip's size, and that would not occupy much space of the tag container. A piston used to push the needle is triggered by a compression spring. The compression spring is selected because its high releasing speed is very important for this design. High potential energy as well as the releasing speed from the spring could help the tag to penetrate soft tissue easily.

When triggered by the doctor, the compression spring is released and pushes the piston forward to hit the needle. The needle will penetrate and stay in the soft tissue due to its high speed and sharpness. The shooting method is illustrated in Figure 3.7. As the size of the needle is small, finding its location would occasionally require several X-ray screenings at different angles.

Figure 3.7: Illustration of the shooting idea

3.3 Design Criteria

As mentioned, the tagging mechanism is designed to be integrated together with other basic components into a capsule so as to provide an additional function to the capsule robot. Thus, it is subject to certain criteria which are listed as follows.

3.3.1 Size of the Capsule

The size of the tagging mechanism together with other parts affects the comfort and safety of the developing capsule, and eventually, the usage feasibility. If the capsule is too big to go through the GI tract, the system is considered failed.

It is ideal that the size of the developing capsule is as small as that of the commercial capsule. As compared to the actual commercial capsule, the developing capsule must have a larger size to allocate to additional parts such as the tagging mechanism, the actuator, and two-way communication part besides its vision part and controller board.

To ascertain the requirements of the size for the developing capsule, a possible reference is the commercially available Guardus overtube [43] shown in Figure 3.8 for use during endoscopic procedure. It is a tubular medical device that is inserted from the mouth and can reach the stomach of a human patient. It is designed to protect the patient esophagus from mucosal shearing and tearing. The Guardus overtube has an outer diameter 19.5 mm and an inner diameter of 16.7 mm with a length of up to 50 cm for use on human patient. If the capsule size is smaller than 19.5 mm, it is able to be endoscopically inserted through the esophagus to reach to the patient stomach.

Figure 3.8: Guardus Overtube [43]

3.3.2 Marking Speed

The releasing speed of the tag has to be taken into consideration as well since the capsule lacks locomotion control. In order to successfully put a tag at the desired spot before next peristalsis movement, the releasing speed of the mechanism must be fast.

There is no specific figure of how long the intestine stops and squeezes again. However, one can roughly estimate the capsule's travelling distance interval for each period. Studies have been made for the movement of the GI tract in the literature review. As the length of the intestine is approximately about 7 meters and time taken for the capsule to travel along the entire tract is 8 hours, and peristalsis movement is about 15 to 20 seconds, hence the distance capsule could move in every squeeze is calculated as 4.8 mm. So in that period time, after receiving the command signal from the doctor, the capsule must be able to deliver the tag to the target location. Thus the marking speed of the developing mechanism is recommended to be fast to reduce the chance of missing the shot.

3.3.3 Diagnosis Device

The first two methods, ink-injection and clipping, are clinically accepted. Both the ink mark and the clip can be detected by using endoscope or X-ray. However, the proposed tag-shooting mechanism has no supporting evidence to prove that the tag can be detected by X-ray. Hence, it should be taken into consideration whether the shape of the metal tag could be visualized on the display film under X-ray.

Figure 3.9: X-ray image of the tag

An experiment was then conducted with the help from Institute of Microelectronics of Singapore. Figure 3.9 shows an image of a titanium tag, which is considered as biocompatible material with filled Barium BaSO₄ powder to enhance the image quality. The titanium tag has the height of 0.8 mm and the diameter of 0.7 mm. The bore diameter and the height of the bore for filling the Barium powder are 0.5 mm and 0.4 mm respectively. The tag was put into a silicon model whose properties are similar to body tissue. The X-ray image of the model was taken and exposed noticeably on the film. The image could also be zoomed in with 700 times magnification for better visualization as shown in Figure 3.9. It is therefore concluded that a tag with that size could be detected by using X-ray.

3.3.4 Design Complexity

To be integrated into an ingestible capsule, the size of the tagging mechanism must be as small as possible. To achieve this, the mechanism needs to be designed simple, although one or two actuators may be required to actuate the mechanisms. The simpler the design is, the smaller the overall size of the design is expected to be. Moreover, the simpler the design is, the easier miniaturization could be performed in the future.

3.4 Mechanism Evaluations

Given the criteria for a tagging mechanism for the capsule, the three proposed mechanisms were analyzed in order to decide the most feasible method to fulfill the project's requirements. Table 3.2 describes an overall comparison between the three methods.

Table 3.2: Mechanism comparison

Mechanisms	Advantages	Disadvantages
Ink injection	Clinically accepted Detected by eyes	Large Volume Complicated design Slow injecting
Clipping	Clinically accepted Detected by X-ray Fast releasing	High force required Complicated design
Tag shooting	Small size Detected by X-ray Fast releasing	Require multiple X-ray screening

In addition, a matrix table, Table 3.3 is built to provide a quantitative analysis of the three mechanisms based on the four criteria. The scale is based on the 5-point Likert scale. Scale from 1 to 5 represents very dissatisfied, dissatisfied, somewhat satisfied, satisfied, and very satisfied respectively. The last column is the total marks for each method. The four criteria are as follows:

- 1) Size of the design including the main mechanism and the actuator. The overall size of the tagging mechanism proposed must be small in order to be feasibly implemented into an ingestible-size form.
- 2) Speed of releasing the tag. Because the capsule lacks locomotion control, in order to successfully put a tag at the desired location before next peristalsis movement, the releasing speed must be fast enough.
- 3) Diagnosis device availability. For instance, in the case of clipping method, the clip will be detected by using X-ray.

4) Design complexity. The simpler the design is, the smaller the overall size of the design is.

Table 3.3: Evaluation table for three mechanisms

Method	Size	Speed	Device	Design	Total
Ink injection	1	1	5	1	8
Clipping	3	3	5	2	13
Tag shooting	5	4	3	4	16

At a glance, ink injection and clipping mechanisms have an advantage in the third criteria since they have been used clinically. However, small size is a very important factor to select the most suitable mechanism for the project's objective. This decides the size evaluation of the three mechanisms and results in low rating for ink injection and clipping mechanisms. Moreover, ink-injection and clipping designs are much more complicated as compared to the tag-shooting mechanism's design. A detailed analysis to zoom in on reasons for some main scores of each method is followed below.

Ink injection mechanism uses linear motor as the actuator and SPOT ink as the marking material. As mentioned in the actuator review, the linear motor recommended by Faulhaber Group has the size of 3.4 mm diameter and 7 mm length of stroke. The reason for choosing this motor is its small-size and the force generated can reach up to 2.8 N. The maximum distance the leadscrew can move is 7 mm, the length of the stroke of the linear motor. Meanwhile, since the volume of required ink is about 0.4 mL (Appendix B), the minimum amount to create a reliable mark size for detection inside a volatile environment like the GI tract. Given the ink volume, the diameter of the reservoir is calculated about 8.5 mm. The calculation was derived from the equation below of calculating a cylindrical volume based on its diameter and height:

$$V = \frac{\pi \times d^2 \times l}{4}$$

Eq. 3.1

In the formula, V, d and l is the reservoir volume, the reservoir diameter and the length of the motor stroke. Since the diameter of the reservoir has the minimum

length of 8.5 mm, the minimum diameter of the mechanism, summed of motor diameter and reservoir diameter, is about 11.9 mm. Besides, the capsule needs to carry other components such as controller board, antenna and battery, etc. As such, the capsule size might be too big for ingestion. Hence, this injection method is not suitable for being implemented into the capsule due to the size constraint.

Compared to ink-injection mechanism, size of the clip is much smaller than the reservoir. However, it has a long body which causes design complexity of how to position the clip inside the capsule together with other components. With only one possibility of placing the clip along the 26mm-length of the capsule body, providing sufficient force to push it completely out of the capsule is another challenge. The size of the actuator of clipping mechanism to generate that force might have to increase as well. For these reasons, the clipping method is not selected.

The third mechanism has more potential as compared to the first two mechanisms. Overall, the third mechanism has a simple design which results in the smallest size and fastest releasing speed compared to the other two. Moreover it also gets the highest rating based on the four criteria though this method might require additional screenings to detect the tag and its clinical acceptability is still under study. The mechanism and its drawbacks are discussed in subsequent chapters.

Figure 3.10: Two states of the tag-shooting mechanism

Taking into consideration of the size and the shooting speed, this design is the most feasible mechanism which could be implemented into the proposed capsule. Figure 3.10 shows a better visualization of the two states of the tag-shooting mechanism, namely the idle state and the firing state. The analysis and development of the conceptual design of the tag-shooting mechanism are presented in chapter 4.

CHAPTER 4 - CONCEPTUAL DESIGN

This chapter discusses the development of the tagging mechanism. Section 4.1 provides possible designs for different components as well as their pros and cons. In section 4.2, the various designs in section 4.1 are evaluated and components of the final prototype are chosen. Section 4.3 describes the final tagging mechanism as well as its technical specifications.

4.1 List of Designs with Morphological Chart

After determining that tag-shooting mechanism is the most feasible method for the tagging mechanism, various components are conceptualized for the various possible designs. The great difficulty of the tagging mechanism design is the size, which needs to be optimized in the way of miniaturization yet maintaining their functionality. In order to be fabricated by conventional machining, all the components are aimed to be designed as simple as possible. The morphological chart for the various designs of tagging mechanism's components is shown in Figure 4.1.

The most important component of the tag-shooting mechanism is its main linear actuator, which produces the penetration force for the tag. As discussed and analyzed in section 3.4, compression spring was selected to be the actuator for the tag-shooting mechanism due to its high potential energy and fast-releasing speed. Other components of the mechanism would be selected in tandem with compression spring.

The first component, used to trigger the compression spring, is the holding mechanism. In idle state, the holding mechanism must hold the compressed spring firmly against the spring force. At the same time, the holding mechanism must be able to free the spring instantly when activated so that the spring can push the piston forward.

The next component required for the mechanism is called the sub-actuator which is used to actuate the holding mechanism. It is controlled by the doctor wirelessly. Given the limited space of the capsule, the position between the sub-actuator and the holding mechanism will be considered as well.

The third component of the tag-shooting mechanism is the tag itself. Pressure at the tip of different types of the needle determines the penetration capability of the tag. Last but not least, the casing which is used to encapsulate all of the components in a closed shell is introduced as well.

Components	Options			
Holding mechanism	<p>Pulling mechanism with a thread</p>	<p>Turning mechanism with one holding shaft</p>	<p>Turning mechanism with two holding shafts</p>	<p>Latch mechanism</p>
Sub-actuator	<p>Rotary motor</p>	<p>Linear motor</p>	<p>Heater pad</p>	
Needle tag	<p>Bevel tip 22⁰</p>	<p>Franseen tip</p>	<p>Bevel tip 45⁰</p>	
Casing	<p>Screw tightening</p>		<p>Press fitting</p>	

Figure 4.1: Morphological chart for the components designs of the mechanism

The detailed study on the various items inside the morphological chart as well as each item's advantages and disadvantages are presented in the following sections.

4.1.1 Sub-Actuator

Three potential sub-actuators introduced to trigger the compression spring are rotary motor, linear motor to microheater pad. Among these, properties of linear and rotary motors can be referred to section 2.4.3 of the literature review. Meanwhile, microheater, mentioned under section 2.3, was applied as actuator for drug-delivery capsule such as High Frequency capsule and Enterion capsule. The study on these types of capsule shows that they transfer their electrical power completely to the heater for the heating up process. In spite of high-power consumption, the size of the microheater is much smaller compared to the size of the other motors, making it one of the best choices for the actuator. Figure 4.2 shows several types of microheater pad from Minco Silicon Rubber Heaters [44]. The smallest size in the category of standard polyimide and rubber heaters could be as small as 6.4 mm x 6.4 mm x 0.5 mm. To heat up, the pad requires an operating current about 1.2 Ampere and the voltage is up to 12 V.

Nevertheless, the objective of the developing capsule is to be able to perform both actions of capturing images and tagging. Thus the power in the developing capsule needs to distribute to other components such as the camera, the antenna and the microcontroller as well. That is to say the current of the battery should be sufficient to heat up the heater at any time during the 8-hour journey inside the GI tract of the capsule. Hence, to maintain the current, the capsule may need to carry the battery with higher capacity but larger in size.

Figure 4.2: Few types of microheater from Minco Silicon Rubber Heaters [44]

4.1.2 Holding Mechanism

The next component used to trigger the compression spring is the holding mechanism. At its idle state, the holding mechanism must hold the compressed spring firmly against the spring force. At the same time, the holding mechanism

must be able to free the spring instantly when activated so that the spring can push the piston forward.

The positioning between the main actuator, the compression spring and the sub-actuator to fit into the limited space of the capsule are both taken into consideration (Figure 4.3). There are three possible positions: the concentric position, the non-concentric position and the perpendicular position. In the concentric position, the center of the sub-actuator is planned to be parallel and coincident to the center of the compression spring. The second option for positioning those actuators is the non-concentric position where the sub-actuator is placed at the side of the piston but parallel. Thirdly, the sub-actuator can also be placed at the right angle to the axis of the compression spring.

(a) Concentric; (b) Non-concentric; and (c) Perpendicular positions

Figure 4.3: Three positions between the sub-actuator and the holding mechanism

Referring to the three possible positions, four feasible designs of the holding mechanism were conceptualized. They are the pulling mechanism with a thread, two holding mechanisms with different designs of the holding key, and the latch mechanism.

a. Thread-Releasing Mechanism

The first holding mechanism, illustrated in Figure 4.4 uses a high tensile strength thread to pull the piston back in order to compress the spring. The thread is made of Nylon 6, 6 [45] having 45MPa tensile strength which is sufficient to be against the strong force applied by the compressed spring. With reference to the literature review, the most common actuator used to trigger this mechanism is a micro heater. The filament thread is designed in close contact with a microheater fastened to the firm base. Due to the rapid heat released from the micro heater, the nylon

thread softens and breaks once the heater is triggered. This action releases the compressed spring and pushes the piston forward.

Figure 4.4: Pulling mechanism with a Nylon thread

However, the melting point of this Nylon thread varying from 216 to 265 degree Celsius is considered very high [45]. To obtain the required temperature, those heaters mentioned from the above section, require very high voltage varying from 24 V for heating up. Heat proof for other electronic components may need to be taken into considerations as well if this mechanism is chosen.

b. Key with Single Holding Shaft

Figure 4.5: Turning mechanism with one holding shaft

The second holding mechanism illustrated in Figure 4.5, consists of one piston and one small turning key. This mechanism is intentionally actuated by a rotary motor. To actuate the mechanism, the motor torque needs to overcome the friction force between surfaces of the key and the piston. The motor shaft is tightened to the key and the shaft of the key is used to hold the piston against the pushing force from the compression spring at idle state. When the compression spring is triggered to release, a firing shaft of the piston will be pushed to hit the tag at the spot. The piston is designed with a slot which lets the key slips through when the motor is

triggered. Because the key stays at the center of the piston, the firing pin of the piston is placed at a certain distance from the center axis. With this design, the piston needs a guiding cylinder with three guiding shafts as shown in Figure 4.6, otherwise the firing pin of the piston may not hit precisely at the tag spot.

This single holding shaft mechanism was fabricated and tested. The key can turn into the slot when triggered but the piston was stuck at the starting point due to the unbalancing momentum caused the compression spring and one-side support of the key. Hence, an enhancement was made on another design improved with double holding shaft which will be introduced in the next portion.

Figure 4.6: Guiding system for the turning mechanism with one holding shaft

c. Key with Double Holding Shafts

The third holding mechanism as shown in Figure 4.7 also consists of one piston and one small turning key but with two supporting shafts. It is designed in such a way that the firing pin of the piston is placed at the center of the piston; and hence, this mechanism works without a complicated guiding mechanism. This mechanism is also actuated by using a rotary motor to overcome the friction force between surfaces of the key and the piston. The axis of the motor is coincident with the axis of the key and the piston. The motor shaft is also tightened to the key, and the shaft of the key is used to hold the piston against the pushing force from the compression spring at idle state. With a slightly different design, the piston has two slots to let the key slip through when the motor is triggered. As compared to the

second mechanism, the advantage of this design with two holding shafts is that the piston is able to auto balance under the pushing force from the spring. If the piston is tilted to one side by the momentum caused by the pushing force, it may get stuck inside the piston holder when released.

Figure 4.7: Turning mechanism with two holding shafts

d. Latch Mechanism

Finally, the latch mechanism as shown in Figure 4.8 comprises of one piston and one small turning key. Similarly to the two above mechanisms, when the motor is turning, the key will turn and release the below piston shaft to discharge the compress spring from its initial compressed state. This L-shape design can reduce the total length of the motor and the piston holder as compared to the second and third mechanisms. Bearing in mind that the piston holder is at least as long as the free length of the compression spring and the motor has a long body with its length varying from 15 mm to 20 mm (for micromotors from Namiki [40] and Faulhaber [37]), this mechanism has advantage to be fitted inside the ingestible-size capsule over the other two mechanisms. .

As previously mentioned, the capsule's orientation and motion cannot be controlled, and the body of capsule is also wrapped and in contact with the intestine. Thus, it is rationale for the tagging mechanism to shoot the tag to the intestine tissue from the side of the capsule. As such, if the motor is used as the sub-actuator to trigger the spring and knowing that the potential motors introduced in the literature review have long bodies, the only option to arrange them inside the ingestible-size capsule is the perpendicular position. Therefore, where the perpendicular arrangement is required, this latch mechanism will be chosen accordingly.

Figure 4.8: Latch mechanism

4.1.3 Tag Study

In order to design the shape of the tag, section (a) provides a study on the importance of the tag shape in a penetration process tested on organs such as liver. It is also essential to know the characteristic of the interaction force between the needle tag and an organ tissue in needle insertion process. Section (b) will give a clear understanding on this interaction force.

a. Shape of the Tag

To understand the how the shape of the tag affects the penetration when pushing into tissue, a study was made and presented in this section. There are many types of needle tip, which are listed in Figure 4.9. Shergold et al. verified that the insertion of a sharp punch into skin and rubber causes the formation and wedging open of a crack [46].

Figure 4.9: Different types of needle tip [47]

Toufic Azar [48] tested the size of open crack regarding to three different shapes of needle tip. Dimensions of the three different needle tips in the test are listed as follows: (A) Franseen tip suture needle with diameter of 0.84 mm; (B) sharp standard bevel tip syringe needles with diameter of 0.71 mm, 1.27 mm, and 2.1 mm (22° bevel); (C) true short bevel tip liver biopsy needle (45° bevel tip) with diameter of 1.47 mm. The cracks, examined using a microscope under $\times 10$ magnification, are shown in Figure 4.10. The diameter of a needle and the geometry of its tip are good predictors for both geometry and size of mode-I cracks. The paper also shows the depth has little effect on the crack size. The branch crack was estimated to be roughly 1.5 times larger than the needle diameter that inserted into the tissue. However, for the sharp bevel tip (22°), the crack length is about the size of the diameter of the needle. It was proven that the crack size is larger than needle diameter which accounts for a larger insertion force.

Figure 4.10: Microscopic observations of fresh porcine liver [48]

From the study above, it can be seen that the shape of the needle is an important factor which affects much to the insertion force. The bevel tip shape 22° as reported needs less insertion force as compared to others. However, the study did not include the conical needle tip since it is not commonly used in medical insertion. The reason is that in medical application, the needle usually needs to be hollow for medicine injection. However, in other applications, for example in the military, the bullet has a conic shape due to its superior aerodynamic shape and the air moving around the conical bullet is much more uniformly distributed as compared to a bevel shape. In conclusion, two shapes of the needle, bevel 22° and conic could be considered for the design.

b. Characteristic of Interaction Force

The characteristic of interaction force in needle insertion is complex because the insertion process is made up of four different but continuous phases [48]. There are four phases involved when the needle is pushed into soft tissue and retracted after that. The illustration of four phases is shown in Figure 4.11.

Phase 1: Deformation happens when the needle tip is pushed to tissue and firstly deforms tissue but not pierces through yet. The force depends on the elasticity of the interacted tissue. This phase terminates when the needle starts puncturing.

Phase 2: Steady-state penetration is described as the needle breaks tissue's deformation and goes inside the tissue layer. The force increases in depth. This phase terminates when the needle stops.

Phase 3: Relaxation is described as when the motion of needle stops. Consequently, the force relaxes.

Phase 4: Extraction phase is the last phase when the needle is withdrawn. The force comes from friction and the release of stored elastic strain energy.

Figure 4.11: Phases of needle insertion [48]

For the first two phases, it can be seen that the force depends on the elastic deformation of the tissue and the depth of insertion. The deeper the insertion of the needle tip is, the higher the pushing force [48]. This study gives us a consideration of relationship between force and displacement. Unlike liver or other organs,

intestine tissue is remarkably elastic. The thickness and the elasticity of intestine tissue depend much on the size of the food squeezed from the stomach. The more the food is digested, the thinner the intestine layers are due to their highly elastic deformation.

An experiment to sense the insertion force acted on the needle will be described in section 5.1. The experiment would provide a clearer understanding of the characteristics of thin tissue like the intestine. Since the tag is not supposed to be taken out in a tagging process, only the first three phases, deformation, insertion and relaxation of needle insertion are expected to happen.

4.1.4 Casing

Casing is used for water proofing and protection of the internal components against the squeeze force from the stomach and the intestine. The material of the casing needs to be biocompatible as well as it needs to be neutral with lots of substance in the environment of the GI tract, especially acid for food digestion. For the development, the cover is chosen from several types of polymer such as transparent polycarbonate, transparent polyethylene, polyether ether ketone (PEEK) and Delrin. For each part of the casing, different material may be used, for example, front covers used to protect the camera need transparent polycarbonate so that it will not affect the vision. However, this report used partially transparent polycarbonate to make the three parts of the casing due to low cost. At the moment, camera is not integrated into this capsule, hence it is not necessary to use transparent material which requires high-quality polishing.

Figure 4.12: Two types of casing

To assemble the electronic components and the tagging mechanism, the casing is designed and divided into three portions: namely, front part, body and rear part. To join them together, fitting is required. There are two types of tightening considered for the casing: screw tightening and press fitting as shown in Figure 4.12. For screw tightening, external and internal threads are made on the meshing part between the cover and the capsule body. This design allows the interchange of different components or modules of the capsule. Nonetheless, the screw-thread design increases the wall thickness of the casing when compared to the press fitting type. Although press fitting cannot offer the assembling flexibility for components, it is considered size-advantageous over screw tightening. To prevent water leakage in pressing fitting type, some methods such as glue or ultrasound plastic welding method [49] would be applied. The ultrasonic plastic welding method is currently used for encapsulating the commercial capsule casing.

4.2 **Conceptual Design**

In order to decide on the most feasible method to fulfill the project's requirements, a matrix table was developed to provide a quantitative analysis of the listed components based on the five criteria. The scale is based on the 5-point Likert scale. Scale from 1 to 5 represents very dissatisfied, dissatisfied, somewhat satisfied, satisfied, and very satisfied respectively. The last column is the sum of marks of all criteria for each component. If the criterion is not suitable for evaluation of the component, no mark would be given. The five criteria are as follows:

- 1) **Power consumption.** It is to evaluate how much the power needs to run the sub-actuator in order to trigger the holding mechanism. The battery provided by another research staff, is a lithium polymer battery. The battery has the size of 28 mm x 15 mm x 4 mm. It has the voltage of 3.7 V, the current of 100 mA and capacity of 100 mAh. The outside look of the battery is shown in Table 4.1. So the power of the battery will be used as a benchmark for the sub-actuator. If the consumption power of the sub-actuator is lower than the power provided by the battery, it will be given 4 or 5 points.

- 2) Speed. It is to evaluate how fast the releasing speed of the holding mechanism is to fire the piston. It is also to evaluate the operation speed of the sub-actuator used to trigger the mechanism.
- 3) Size of the design. The design must aim to be small in order be feasibly implemented into an ingestible-size form. The casing size is employed to be the benchmark for the size evaluation. The outer diameter of the casing must not exceed 19.5 mm (the diameter of the Guardus overtube [43]).
- 4) Complexity of the design. The simpler the design is, the smaller the overall size of the design is.
- 5) Force. This is to compare the force that the mechanism must produce to push the needle tag into the intestine tissue. The smaller the force is required, the higher the rating point is given. The rating will be based on the study of the tag which was presented in section 4.1.3.

Table 4.1: Evaluation table for components designs of the mechanism

Component	Option	Power	Speed	Size	Design	Force	Total
Sub-actuator	Motor	5	3	3	3	N.A.	13
	Heater	1	2	4	4	N.A.	11
Holding mechanism	Thread	N.A.	2	4	4	N.A.	10
	Single Shaft	N.A.	3	3	1	N.A.	7
	Double Shaft	N.A.	3	3	3	N.A.	9
	Latch	N.A.	3	3	4	N.A.	10
Shape of the tag	Bevel 22⁰	N.A.	N.A.	3	4	5	12
	Bevel 45 ⁰	N.A.	N.A.	3	4	3	10
	Conic	N.A.	N.A.	3	5	4	12
Casing	Screw tightening	N.A.	N.A.	3	3	N.A.	6
	Press fitting	N.A.	N.A.	5	4	N.A.	9

The evaluation starts from the sub-actuator and based on what type of the sub-actuator is chosen, the holding mechanism will be decided.

Rating of the size of the micro heater is given 4 points because its size is about 6.4 mm x 6.4 mm x 0.5 mm. To heat up, the heater pad requires an operating current

about 1.2 Ampere and the voltage is up to 12 V. It is much higher than the power of the chosen battery. So rating of the heater pad is given 1 in the power criteria. In the list of micromotors shown in Appendix C, the SBL04-08 has the highest current about 100 mA and an operating voltage of 3 V. Other motors from the Appendix C have lower power consumption than the SBL04-08. Because the power consumption of the micromotor is lower than what the battery can provide, the micromotor is given 5 points. Sizes of the micromotors are also shown in Appendix C. To sum up, the micromotor is chosen over the microheater because the current to heat up the heater cannot be provided by the battery, not to mention that the battery needs to provide current for other operations such as image capturing and transmitting.

Since the sub-actuator selected is the micromotor, it is reasonable to choose the latch mechanism over the others based on the analysis presented in section 4.1.2. This is because the motor has a long body, and only the latch mechanism, which was designed to position the sub-actuator and the spring perpendicularly, can be fitted into the desired diameter (17 mm) of the developing capsule.

For the design of the tag, based on the review described in section 4.1.3, the bevel 22^0 shape and the conic shape have the highest rating in force criteria. However, the conic shape is considered to be used in the project due to easy machining in fabrication process. Hence, it is given 5 points in the design criteria. If the conic tag is unable to penetrate and adhere to the tissue in the experiment, the bevel 22^0 shape will be used.

The final component, the casing for the capsule is the press-fitting type due to its smaller size and simpler design. This fitting type requires ultrasound welding to join two parts together for water proof.

In summary, the final conceptual design of the tagging mechanism is described as a shooting device used for firing a stainless steel tag with a conic shape into intestine tissue, and the tag stays at the target location as a mark to help with localization of tumor. Figure 4.13 shows the cross section of the tagging mechanism without the casing. In this design, a coupling shaft is used to connect the motor with a key and a bearing is to support the radial load to prevent damage on the motor shaft. The coupling shaft is also welded with the key while the key of

the latch mechanism is designed in such a way that it is able to hold the piston against the compressed force at idle state. Both of the piston and the spring are housed inside the needle holder. When the coupling shaft is actuated by the motor, the piston will be released by the key turning and travel inside the hollow holder before hitting the tag away.

Figure 4.13: Concept using motor to trigger the compression spring

The 3D design of a completed capsule is shown in Figure 4.14 with all of its essential parts such as the casing, the tagging mechanism, the micro rotary motor, the controller board and the antenna. Due to the cost of fabrication, the front and rear of the casing is not designed in a hemisphere shape. The overall dimension has the diameter of 17 mm and length of 50 mm. The casing also gives additional space in front of the tagging module for the camera when required. The capsule casing is designed at this size in order to accommodate the developing controller board which has a dimension of 16 mm x 35 mm. The controller board used to control the camera, the motor, receiver and transceiver at this point of time, is still in the testing phase. However, sizes of these parts are able to be scaled-down in future with application-specific integrated circuit (ASIC) technology [50], which is described as an integrated circuit (IC) customized for a particular used rather than intended for general-purpose use. Because the non-recurring engineering cost of an

ASIC can run into the millions of dollars, many testing phases of the controller board need to be conducted before manufactured.

Figure 4.14: 3D illustration of a completed capsule

In summary, the conceptual design of the tagging capsule was introduced based on the analysis of all essential components. Continuing with the conceptual design, a mathematical analysis would be performed and presented in the next section in order to understand the relationship between the input from the motor and the compression spring with the final output like the penetration depth.

4.3 Mathematical Analysis

This section will present a mathematical formula to compute how far the tag travels inside the intestine tissue given the spring's potential energy and other parameters. The operation of the tag-shooting mechanism proposed in section 3.4 is shown in Figure 4.15.

Due to the conservation law, the potential energy from the compression spring would be transferred to the piston in kinetic-energy form. After that, when the collision between the piston and the tag happened, partial-kinetic energy from the piston is transferred over to the tag. Travelling at high speed causes a high pressure at the sharp point of the tag and that makes the tag pierce through the tissue with ease. A study on the calculation of the relationship between the input from the compression spring and the output stated as the penetration depth of the tag inside the targeted tissue will be presented step by step as follows.

Figure 4.15: Illustration of the tagging mechanism for analysis

Using Hooke's law, the force from compression spring is:

$$F = k (X - X_0) \quad \text{Eq. 4.1}$$

Where

- $(X - X_0)$ is the displacement vector - the distance and direction in which the spring is deformed
- F is the resulting force
- k is the spring constant or force constant of the spring

The force with which the spring pushes back is linearly proportional to the distance from its equilibrium length. The maximum force is stored when the spring is compressed to its solid length. When the compression spring is released, the potential energy of the compression spring is converted to kinetic energy of piston after triggered following the work-energy principle.

$$\frac{1}{2} k (X - X_0)^2 = \frac{1}{2} m_p V^2 \quad \text{Eq. 4.2}$$

All of the symbols of the equations used in this report are listed:

m_p : Mass of the piston

m_t : Mass of the tag

V : Velocity of the piston after being triggered by the spring

V_p : Velocity of the piston before hitting the tag

$V_{p'}$: Velocity of the piston after hitting the tag

$V_{t'}$: Velocity of the tag after being hit by the piston

μ_1 : Coefficient of friction between the piston and the piston holder

μ_2 : Coefficient of friction between the tag and the tag holder

g : Gravitational constant

L : Travelling distance of the piston inside the piston holder

l : Travelling distance of the tag inside the tag holder

When the piston travels inside the hollow cylinder, there is friction causing heat loss between the piston and the cylinder. Considering the heat loss from the friction, the kinetic energy of the piston just before striking to the tag is derived as:

$$\frac{1}{2}m_p V_p^2 = \frac{1}{2}m_p V^2 - \mu_1 m_p g L \quad \text{Eq. 4.3}$$

At the moment of the collision between the piston and the small tag, the kinetic energy of the piston is transferred partially to the tag. The piston still goes forward with a slow-down speed $V_{p'}$ since the mass of the piston is bigger than the mass of the tag. It is essential to know that there is heat loss in the collision but if the collision is assumed elastic, heat loss is neglected.

$$\frac{1}{2}m_p V_{p'}^2 = \frac{1}{2}m_p V_p^2 - \frac{1}{2}m_t V_{t'}^2 \quad \text{Eq. 4.4}$$

In a head-on collision, the force or the momentum of the piston and the tag are constrained to be the same by Newton's third law. From that, the equation of collision momentum of the system is as follows:

$$F_{piston/tag} = -F_{tag/piston}$$

$$m_p V_p = m_p V_{p'} + m_t V_{t'} \quad \text{Eq. 4.5}$$

From (Eq. 4.4) and (Eq. 4.5), after collision, the speeds of the tag and the piston are derived as:

$$V_t' = \frac{2 \times V_p}{\frac{m_t}{m_p} + 1} \quad \text{Eq. 4.6}$$

$$V_p' = V_p \frac{m_p - m_t}{m_t + m_p} \quad \text{Eq. 4.7}$$

The velocity of the tag when being fired into the intestine is assumed as V_t' speed because the intestine wall is mostly in contact with the tip of the tag. The impact force, or the penetration force, between the tag and the intestine tissue could be calculated from the conservation energy and the application of the relationships for work and energy. For a straight-line collision, the net work done is equal to the average force of impact times the distance traveled during the impact. If a moving object is stopped by a collision, extending the stopping distance will reduce the average impact force. Equation 4.8 displays the relationship between conversion of the change in kinetic energy and heat into the impact force and travelling distance of the tag inside the intestine wall.

$$\begin{aligned} \text{Impact force} \times \text{distance traveled} \\ = \text{change in kinetic energy} + \text{heat loss from friction} \end{aligned} \quad \text{Eq. 4.8}$$

The kinetic energy will be converted to the work energy to penetrate and travel inside the tissue wall. The travelling distance of the tag inside the tissue is symbolized as **d**.

$$F_{\text{penetrate}} d = \frac{1}{2} m_t V_t'^2 - \mu_2 m_t g l \quad \text{Eq. 4.9}$$

From (Eq. 4.6) and (Eq. 4.9) the relationship between the penetration depth and the compressed force from the spring is derived as follows:

$$F_{\text{penetrate}} d = \frac{1}{2} m_t \left(\frac{2 \times V_p}{\frac{m_t}{m_p} + 1} \right)^2 - \mu_2 m_t g l \quad \text{Eq. 4.10}$$

Submitting V_p which is calculated from Equation 4.2,

$$F_{penetrate} d = \frac{1}{2} m_t \frac{8 \left(\frac{1}{2} k (X - X_0)^2 - \mu_1 m_p g (X - X_0) \right)}{m_p \left(\frac{m_t}{m_p} + 1 \right)^2} - \mu_2 m_t g l \quad \text{Eq. 4.11}$$

The final formula is presented as:

$$F_{penetrate} d = m_t m_p \frac{4 \left(\frac{1}{2} k (X - X_0)^2 - \mu_1 m_p g (X - X_0) \right)}{(m_t + m_p)^2} - \mu_2 m_t g l \quad \text{Eq. 4.12}$$

4.4 Procedure for components selections and experiments

This section introduces a procedure for selecting motor and spring and conducting experiments, which are presented in chapter 5. The procedure is described in a flowchart as shown in Figure 4.16.

Firstly, equation 4.12 is used to calculate the potential energy required from the spring. To do that, the formula requires the penetration force and depth, the masses of the piston and the tag and other factors such as coefficient of friction, travelling distance of the tag and piston inside the holder to be known. The value of the penetration depth and force would be measure in section 5.1. The value of masses and other factors are obtained from the design and the Engineering handbook [57].

Based on the previous calculation for the spring factors, the compression spring is chosen from the catalogue of Shincoil Pte, Ltd [51]. The spring load is used to calculate the minimum requirement for the motor torque. Both chosen motor and spring are tested with a test jig. The selected motor must be able to actuate the holding mechanism to release the compressed spring from its initial idle state to firing state. Also, the compression spring must provide sufficient force to let the tag penetrate the intestine tissue. If either component is not found satisfied, the selection process will be repeated accordingly. The jig test also allows investigating the capability of the controller board which is used to control motor's operation.

After the jig test has proven the feasibility of the mechanism, the tagging mechanism is integrated into the capsule with other components, such as the

wireless control and the battery, which are developed by other researchers. This *ex-vivo* experiment will show that the capsule is able to deploy the tag wirelessly to attach successfully to intestine tissue. Several tests will be performed to verify the adhesion capability of the tag within the tissue.

Figure 4.16: Procedure of selection of motor and spring

CHAPTER 5 - EXPERIMENTAL RESULTS AND DISCUSSIONS

An experiment for measuring the penetration force is presented in section 5.1. Section 5.2 shows how to select components such as the compression spring and motor based on the mathematical formula. Section 5.3 provides an intermediate prototype (a test jig) for verifying the feasibility of all the necessary components in order to build a completed capsule. Consequently, the last section 5.4 presents a completed capsule and result of an *ex-vivo* experiment conducted on explanted tissue.

5.1 Penetration Force Measurement in Phantom Model

This experiment was designed to measure the required force to penetrate intestinal tissue, with acquisition of the measurement of the compressive force related to needle tip displacement. This section lists all the equipment for the experiment which is followed by the calibration of the system. Data was collected to characterize the penetration force.

5.1.1 Setup of the System

Figure 5.1: Setup of the experiment of needle force

The system for the experiment consisted of a motion control part, a force measuring part, a medical needle, and a tissue model. The configuration of the experimental system is shown in Figure 5.1. The linear motion of the needle was acquired by using an EZlimo linear motion slider (model No. EZS3-15) [52]. A Windows XP Pentium IV 3GHz computer with Galil DMC1820 Motion control

card inside was used to control the linear slider and collect the data. ICM-2900 Interconnect Module was used to provide easy connections between Galil controller and other system elements. For the convenience of connection, the interconnect module for the Galil motion control card and wires were kept in the electronic box.

To measure the interaction force, an ATI Nano 17 loadcell [53], the smallest commercially transducer which is able to measure force and torque in 6 axes (X, Y Z forces and torques) was used. Z axis stays along the needle length. Its resolution is stated as 0.319 gram [53]. The interaction including torque and force between the needle and the tissue would be recorded in a set of data in an Excel file for analyzing later.

To hold the ATI 6-axis loadcell, the needle holder and the needle, a loadcell base holder was designed and fixed onto the slider's carrier. For the experiment, the pig intestine was tested at room temperature on the same day it was bought. In addition, three types of common needles listed in Table 5.1 were used in the experiment. The penetration force was predicted to vary with different sizes of the tag and at different speeds respectively. Table 5.1 lists three common types of needles used in medical injection. The thickness, the inside and outside diameter are listed corresponding to the name of the needle.

Table 5.1: Three common needles with dimension [54]

Needle gauge	Outside dia. (mm)	Inside dia. (mm)	Length (mm)	Display Image
23	0.635	0.318	35
25	0.508	0.241	25	
27	0.406	0.191	13	

The tissue holder was designed as shown in Figure 5.2. A long intestinal tissue was cut to small pieces by a rough dimension of 4 cm x 4 cm and was mounted on a Styrofoam platform which had a square hole cut at the center. This setup would let the needle pass through the Styrofoam after the needle penetrates through the tissue. The Styrofoam can be adjusted in vertical direction along two aluminum

profiles to ensure that the needle tip would point into the hole. Moreover, there were four locating pins used to fix the intestinal tissue at the desired position. The deformation of the tissue may be affected by the set up but the experiment results would give an estimation of the interaction force between the tissue and the needle.

Figure 5.2: Close view of the experiment

5.1.2 Calibration of the System

Before the experiment, the loadcell was calibrated. A set of weight with different load from 100 gram to 500 gram was put on the loadcell and force in direction Z was used to compare to the load of the weight. Gravity acceleration constant, $g_n = 9.80665 \text{ N/kg}$ is used to convert weight in gram to Newton force unit. Ten readings were recorded for calculating the average value of different weight. The average and standard deviation of the calibration taken is shown in Table 5.2.

Table 5.2: Calibration for ATI loadcell

Theoretical Load (g)	100	200	300	400	500
Theoretical Load (N)	0.98067	1.96133	2.942	3.92266	4.90333
Average Measured load (N)	0.97749	1.95533	2.93117	3.91268	4.88652
Standard Deviation (N)	0.00091	0.001239	0.00169	0.00152	0.00211
Error (N)	0.0032	0.006	0.011	0.00998	0.0168
Error (%)	0.32	0.31	0.37	0.25	0.34

The resolution of the ATI loadcell according to its catalog is 0.319 gram. Table 5.2 gives a result of slight difference between the theoretical load of the weight stated on the weight and the average readings from the loadcell. The error is calculated in average of 0.32 % which may come either from human errors or from the mass itself. The error may also come from the digital ATI loadcell as its resolution converted is approximately 0.00313 N.

5.1.3 Results from the Force Measurement Experiment

After calibration, the experiment was conducted to measure the penetration force from different needles into intestine tissue. Following the experiment setup and capability of ATI loadcell, six values of data for each corresponding speed would be recorded in real time when the needle tip was controlled to move and penetrate through the pig intestine.

At the initial state, the position of needle was set by 2 mm from the tissue plane. When being pushed by the motor, the needle would travel for 8 mm. That distance was sufficient to ensure the needle penetrates through the intestine tissue from its initial position. Based on the design of the tag, the mass of the tag is calculated to be 2.72×10^{-6} kg. The approximate velocity of the tag based on the list of micro-springs [51] is about 40 m/s. The maximum speed the linear actuator can achieve is 0.3m/s or 300 mm/s. This speed is significantly smaller than the speed of the tag. However, when the linear motor is controlled to achieve its maximum speed, the fast acceleration and deceleration of the sliding table will affect the loadcell's reading. It will be difficult for the analysis since there are several peaks of force values in the recording data. Preliminary speed tests were carried out and it was found that at the speed of 3 mm/s, the force plot was less noisy. That is the reason why 3 mm/s was chosen as the maximum speed in the experiment.

In order to find the trend of the penetration force, five speeds 0.15 mm/s, 0.75 mm/s, 1.5 mm/s, 2.25 mm/s and 3 mm/s were selected to carry out the experiments. The trend will define whether the force is proportional to the speed of the needle. It also helps to understand on the relationship between the penetration force and needle size. Three types of medical needle were used to conduct in five different speeds, and the results of the penetration force in Z axis recorded are plotted on the graph in Appendix D.

Referring to Table 5.1, the 23 Gauge needle has the biggest size, while the size of the 27 Gauge needle is the smallest. The experiment results do not show that the force increased in tandem with the size of the needle. The reason is probably because the needles used in the experiments had different lengths, and also they were pointed to different spots on the intestine specimen. Length and diameter decide the stiffness of each needle. The stiffness of the commercial needle would somewhat affect the force measurement. A better result can be achieved if the needles were of the same length. As in the experimental process, after the first penetration, a tiny hole appears on the tissue. Hence, the styro foam is to be adjusted so that in the following penetration, the needle would go to a different spot. After several penetrations, the tissue needed to be replaced. Hence, the stretch resulting from tissue change may have had an effect on the deformation characteristic of the tissue. However, by using the 27 Gauge needle (the smallest size), the puncture force was decreased dramatically to less than 0.1 N as compared to 0.35 N for the 23 Gauge needle and 0.7 N for the 25 Gauge needle.

The characteristic of force phases in the experiment plotted in Figure 5.3 is slightly different from the graph in Figure 4.11. From [48], at first the force is to overcome the deformation of the tissue and break or puncture into the tissue layers (Figure 4.11) and it happened in the same way to intestine tissue. Due to the thinness of the intestine tissue, after deformation phase and insertion phase, the needle continued going and therefore pierced through the serosal layer from inside the tissue. That explained another increment of force right after the peak value in the graph, noted as Deformation II and Puncture II. After Puncture II is the relaxation phase. The retraction phase was not displayed on the graph since the data recorder stopped when the needle stopped moving. The reason is that the tag would not be retrieved back after being shot into the tissue, therefore the retraction phase was not recorded.

Figure 5.3: Phases of insertion process of 23 Gauge Needle at 1.5 mm/s

Figure 5.4 shows at higher speed, trend of the peak value of the penetration force slightly declined. The penetration force varied followings many parameters such as size and length of needle, sharpness and shape of needle tip, the pushing speed, property of soft tissue and the insertion distance. Not all of the listed parameters were fully analyzed in the experiment because the objective of the experiment is to find out the force required for penetration. Nevertheless, this measured force is only used for assumptions of preliminary calculations to select the design's components such as motor and compression spring. In order to simplify the calculation of the design, the value of penetration force is taken at 0.7 N, which is the highest value in the experiment. Furthermore, the diameter of the tag must be smaller than the outside diameter of the 23 Gauge needle (0.635 mm).

Figure 5.4: Peak value of penetration force of different needle sizes

5.1.4 Experiment Result of Intestine Thickness

From the literature review, the intestine thickness varies according to the volume of food digested from the stomach. However, an average value of the intestine thickness was measured with explanted intestinal tissue to provide an approximate estimation for calculation model. The intestine thickness is divided in two types of different thickness as shown in Figure 5.5.

Figure 5.5: Photo of intestine tissue

For each type of intestine, the thickness was measured with a digital veneer calliper for 10 times, subsequently their average thickness and standard deviation were calculated and tabulated in Table 5.3. With reference to the results obtained, the penetration depth of the needle should be about 0.6 mm. Nevertheless, it could be adjusted from time to time to respond to the slippery intestine environment.

Table 5.3: Measured value of intestine thickness

Tissue	Average thickness (mm)	Standard Deviation (mm)
Thin portion	0.43875	0.0366
Thick portion	0.596667	0.069258

5.2 Computation for Selection of Components

Referring to the equation 5.1 (Eq.4.12), to calculate the spring parameters with two respective factors namely the spring stiffness k and the compressed length $(X - X_0)$, all of the parameters in the equation need to be known. These parameters include mass of the piston and the tag, the coefficient of friction, the travelling distance of the piston and the tag inside the holder as well as the penetration force and depth. From section 5.1, the penetration force and depth were measured respectively 0.7 N and 0.6 mm.

To obtain the coefficient of friction μ between two surfaces, materials of the tag, the piston, the key and the holder need to be defined. With the test jig, the tag and the piston is intentionally made of stainless steel due to strength while the holder was made of aluminum due to cost. Referring to Engineer Handbook [57], the value of coefficient of sliding friction between stainless steel and aluminum is 0.47 in dry condition.

$$F_{penetrate} d = m_t m_p \frac{4 \left(\frac{1}{2} k (X - X_0)^2 - \mu m_p g (X - X_0) \right)}{(m_t + m_p)^2} - \mu m_t g l \quad \text{Eq. 5.1}$$

The mass of piston and the tag is estimated based on their volume estimated from a mechanics design software called SolidWorks 3D CAD. This software was used to design most of the parts of the mechanism and the capsule. The densities of stainless steel and aluminum, which were taken from the Engineer Handbook [57], are 7850 kg/m³ and 2700 kg/m³ respectively. The masses of the piston and the tag were calculated accordingly based on their designs. Table 5.4 shows the mass of the piston and the tag designed for the test jig.

Table 5.4: Calculation table of mass of piston and tag

	Volume (mm ³)	Volume (m ³)	Density (kg/m ³)	Mass (kg)	Mass (g)
Piston	14.166	14.166x10 ⁻⁰⁹	2700	3.826x10 ⁻⁰⁵	0.03826
Tag	0.3488	3.488x10 ⁻¹⁰	7850	2.738x10 ⁻⁰⁶	0.2738

The compression spring was chosen from the catalogue of Shincoil Pte, Ltd [51]. Some preliminary studies were performed to calculate the value of the potential energy of the spring and the heat caused by the friction between the piston, the tag and the holder. Since the mass of the piston and the tag is too small, the heat could be neglected from the theoretical computation. The equation 4.12 can be reduced to its simpler form as follows:

$$F_{penetrate} d = m_t m_p \frac{4 \left(\frac{1}{2} k (X - X_0)^2 \right)}{(m_t + m_p)^2} \quad \text{Eq. 5.2}$$

With given value for all the mass, the penetration force and depth, the minimum potential energy is calculated as follows:

$$E = \frac{1}{2}k(X - X_0)^2 \geq \frac{1}{4}F_{penetrate} d \frac{(m_t + m_p)^2}{m_t m_p} \quad \text{Eq. 5.3}$$

$$E = \frac{1}{2}k(X - X_0)^2 \geq \frac{1}{4}0.7 \times 0.0006 \frac{(2.738 \times 10^{-6} + 3.826 \times 10^{-5})^2}{2.738 \times 10^{-6} \times 3.826 \times 10^{-5}} \\ \geq 1.685 \times 10^{-3}(W)$$

Eight compression springs were selected from the catalogue and all of them satisfied the condition of required energy. The spring's free length could not be too long or in other words it cannot exceed 10 mm, which was the maximum length that the holder of the test jig can adjust to achieve. Nevertheless, the intention was not to choose a long spring because of the size constraint of the capsule. Several compression springs were chosen and listed in Table 5.5. Consequently, the motor torque T_m was calculated with the length of the key as 1.3 mm, which was known from the design. This value motor torque would be used to choose the essential motor accordingly.

Table 5.5 also shows the compressed length of the spring derived from its free length and its height at compressed state of 2.6 mm in the design. Based on spring factors, the load of the spring F_s was calculated (Eq. 5.4). Knowing the coefficient of friction μ as 0.47, the load of the motor to overcome the friction force F_r to actuate the mechanism was calculated as well. Consequently, the motor torque T_m was calculated with the length of the key 1.3 mm which was known from the design. This value motor torque would be used to choose the essential motor accordingly. The table also provides the potential energy of the spring calculated from its stiffness and compressed length. Finally, the last column displays the ratio between the actual potential energy of the spring and the minimum requirement (1.685 milliWatt). The spring **SSC-035032-1** was selected for design because of its smallest ratio. If the tag is unable to penetrate with the selected spring, stronger springs with higher stiffness will be chosen step by step.

$$F_s = k \times x \quad \text{Eq. 5.4}$$

$$F_r = F_s \times \mu \quad \text{Eq. 5.5}$$

$$T_m = F_r \times r \quad \text{Eq. 5.6}$$

Table 5.5: Calculation of the output of the mechanism

Spring	k (N/m)	x (m)	Load F_s (N)	Friction Force F_r (N)	Motor Torque T_m (mNm)	Spring Energy E_s (W)	Ratio
SSC-035032-1	970	0.0037	3.589	1.687	2.193	0.00664	3.940
SSC-035032-2	618	0.0068	4.202	1.975	2.568	0.01429	8.478
SSC-036040-1	2276	0.0030	6.828	3.209	4.172	0.01024	6.077
SSC-036040-2	1452	0.0057	8.276	3.890	5.056	0.02359	13.994
SSC-014AB-1	1216	0.0038	4.622	2.173	2.824	0.00878	5.211
SSC-014AB-2	941.8	0.0054	5.086	2.390	3.107	0.01373	8.147
SSC-016AB-1	2129	0.0038	8.089	3.802	4.943	0.01537	9.119
SSC-016AB-2	1658	0.0054	8.953	4.208	5.470	0.02417	14.342

Motor Selection

The load of the motor must be high enough to actuate the key which holds a pushing force from the compressed spring at idle state. Furthermore, the motor load must be higher than the friction force between the key and the piston. The coefficient of friction is the same with the above calculation as 0.47. In addition, the motor load is calculated with two parameters such as the stall torque of the motor and the radius of the key. There are several available micro rotary motors such as SBL02-06H1 PG 337, SBL04-0829 PG04-337 from Namiki Precision Jewel company [40] and Smoovy 0308 from Faulhaber [37]. Following the list, their stall torque is 0.69 mNm, 5.59 mNm and 1.32 mNm respectively. Regarding to Table 5.5, the second motor SBL04-0829 with its gearbox PG04-337 from Namiki was chosen because its stall torque is higher than the calculated torque required.

5.3 Experiment with the Test Jig

After selecting the compression spring and the motor, the test jig was designed in order to preliminarily test the feasibility of the mechanism. The test jig was considered an intermediate prototype before the tagging mechanism is integrated into the capsule. Because most of the parts such as controller board, battery, transceiver and receiver have been developed independently by other researchers, it is important to build and test their functionalities on the prototype, especially for

controlling the motor wirelessly. Many considerations should be taken, for example, the power source of the Lithium battery may not last in a certain time required and insufficient to power up the motor, or the high attenuation from body might absorb the radio energy sent by antenna at the base station. Thus, the aim of the test jig is to test the functionalities of the essential parts before integrating and miniaturizing all the components so that they could be fitted into the ingestible form.

The following sections report the design of the test jig based on the selected components and its experiment result.

5.3.1 Design of the Test Jig

Figure 5.6 illustrates a 3D design of the test jig. The mechanism is actuated by the Namiki SBL04-0829 with its gearbox PG04-337 to trigger the piston by turning the holding key. The motor shaft is tightened with a coupling shaft by an M1 screw and the coupling shaft is supported by a bearing housed inside a bearing holder as shown. Since the axial load onto the motor shaft is small as 0.1 N, it is important to have bearing supporting in the design. The coupling shaft also becomes the base for the spring. The bearing and the coupling shaft are designed to tolerate both axial and radial load. They will protect the motor shaft which is easily to get damaged.

Figure 5.6: 3D design of the test jig

Furthermore, the coupling shaft was welded together with the key, which is designed to hold the piston against the compressed force from the spring. When the

coupling shaft is turned by the motor, the piston will be released by the key at the opening position accordingly. The design of the key and the piston can be referred to Figure 4.13. After being released, the compression spring would push the piston along the tag holder and hit the tag, which is staying at the tag hole. Both of the piston and the spring are housed inside the tag holder. The cylindrical hollow of the tag holder is also used to guide the center of the piston to hit the tag. Moreover, the piston is designed with proper thickness so that it would not flip in the cylindrical during the shooting process. The actual design of the test jig is shown in Figure 5.7. The actuation of the mechanism from the motor driver will be presented in the next section following by its experiment result.

Figure 5.7: Actual Design of the test jig

5.3.2 Actuation

As mentioned above, Brushless Direct Current Namiki SBL04-0829 motor was used to actuate the mechanism. This motor should be commuted electrically. The motor was driven by a three-phase inverter using a six-step commutation. Figure 5.8 illustrates the schematic of the motor control unit.

Figure 5.8: Motor control unit

A six-step commutation with conduction phase of 120° was applied to allow the current to flow in only two phases at each time. The applied voltage waveform to operate the motor is plotted in Figure 5.9. The command signals to control the gates of the transistors are issued by MSP430 microcontroller. Motor's Back-EMF can be utilized to estimate the position and speed of the motor. Using this method, angular position and speed of the motor can be controlled in a closed-loop manner.

Figure 5.9: Schematic of motor driver (3-phase inverter) and voltages of motor phases

5.3.3 Result of the Experiment with the Test Jig

To prove the feasibility of the mechanism, the test jig was tested with explanted intestine tissue. The tissue was cut and mounted on two pieces of styro foam as shown in Figure 5.11. The jig was positioned in contact with the tissue after the spring had been loaded inside the mechanism with full of compressed length. Then the experiment started when the controller board provided a trigger command to let the motor turn at low speed. Consequently, the key set the piston free, and with the high potential energy from the spring, the piston pushed the tag into the tissue.

Figure 5.10: Illustration of how the tag adheres to the tissue

Figure 5.11: Testing with explanted tissue

The experiment was conducted 20 times. After being fired into the intestine, the tag underwent four tests, namely visual test, air test, water test and force test. In the visual test, the tag must be able to be observed by naked eye from both sides of the tissue. From the observation, after shooting, the tag penetrates through the intestine and adheres at the shooting location. The illustration of the adhesion is plotted in Figure 5.10. In the air test, the tissue was placed at an air outlet, which was controlled at 4 bars by a pressure regulator. If the tag was still attached at the target location, it would be put under a water flow at a normal water tap. The last test was the force test where a pin was used to flick the tag. Figure 5.12 shows captured images of four tests.

Figure 5.12: Captured images of the jig test

The results of the experiment are divided into two types, pass and fail. Pass result was recorded as 1, meaning the tag satisfied the criterion of each test. If it could not penetrate the tissue or dropped off, it was considered as a failure and recorded as 0. Experiment result was recorded and tabulated in Appendix E.

Figure 5.13 shows a chart depicting the pass rate of the four tests. The pass results were all 90% for the visual test and the air test. It dropped to 85% and 70% for the water test and the force test.

Figure 5.13: Result of the jig test

From the observations, in the air test, the air pressure did not affect much the tag because of the highly elastic characteristic of the tissue. The tissue elasticity also helped the tag stay still under the water and force tests and the pass percentages were considered high at 85% and 70% respectively. The force test saw a fail record only when the author tried to apply more force to pluck or poke the tag out of the tissue. However, the purpose of these tests was just to examine the adhesion ability of the tag into the tissue under high pressure and force.

With the 90% success rate in sending a small tag to attach to the intestine tissue, it was concluded that the mechanism had achieved its goals. The motor was able to trigger the holding mechanism and the selected compression spring could provide sufficient force to let the tag penetrate the tissue. As such, both of the selected motor and spring could be used in the tagging capsule.

5.3.4 Two-Way Communication Link

In order to control the motor wirelessly, the receiver of the capsule, which has been developed by another research group, must be able to receive the command signals from the user. Attenuation of wireless communication is an important consideration in the project due to high absorption when the signal transfers through the human body. Hence, an in-vivo experiment was carried out to test the bidirectional communication link and performance of the system in live animal.

The experiment was conducted on a male pig. The prototype was inserted into the pig stomach by gastronomy. After putting the capsule in the stomach, the stomach and the body were enclosed and the system was activated and controlled wirelessly by an external controller. To observe the system operation and performance, an endoscope was introduced to the stomach cavity. The prototype, depicted in Figure 5.14, consisted of the camera, control unit, wireless transceiver, antenna, and the battery. These components were introduced into a capsule enclosure.

Figure 5.14: In vivo Experiment for testing communication link

The external controller could successfully configure and extract the images from the camera. Figure 5.14 also presents an image extracted from the capsule in the experiment. To further verify the communication from the external unit to the capsule, commands to turn on/off the LEDs and operate the motor were sent to the capsule and the capsule could perform the desired tasks. In conclusion, the capsule system is able to extract the images and also receive the commands signals from external controller, hence the requirements to build a wireless capsule, which can actuate the desired mechanism, is fulfilled. Consequently, the prototype of the wireless capsule system included the tagging mechanism will be presented in the next section.

5.4 Development of the Capsule System

Regarding to the promising results from the experiments in section 5.3, the prototype of the capsule including the tagging mechanism was designed and fabricated. Figure 5.15 shows the assembly drawings of the developed capsule and the actual capsule with all fabricated and developed components are shown in Table 5.6.

Table 5.6: List of components for the wireless tagging capsule

Front side of Controller board	Back side of Controller board

Lithium Battery	Rotary Namiki motor

Antenna	Tagging mechanism

Tag	Casing

Figure 5.15: Assembly of the developed capsule

The completed capsule has the size of 17 mm in diameter and 50 mm in length. The overall diameter of the capsule is smaller than the external diameter of the overtube which is shown in picture C of Figure 5.16. With that size, the capsule is able to be inserted endoscopically into the GI tract with an assist of an endoscope.

Figure 5.16: Prototype of the developed capsule

Figure 5.16 also shows a comparison between the developed capsule and the commercial capsule PillCam from Given Imaging (Image A). Compared to the components from the disassembly of the PillCam capsule presented in section 2.2.3, the controller board and the battery being developed, is obviously not at the optimized size. That explains the reason why the developed capsule has a larger size. Though the controller board could be miniaturized by using ASIC technology [50], which allows the board to be scaled down to the commercial size, more tests need to be conducted with the developed board. ASIC technology, however, is only suitable for mass production due to setup cost for the fabrication process. In addition, the tagging mechanism with its actuator and the battery in larger size also

accounted for the larger size of the developed capsule when compared to the PillCam. However, on the development of the technology, miniaturizations of the actuator as well as power transmission wirelessly have been reported recently with promising results.

Figure 5.17: Two states of the tagging mechanism

Figure 5.17 shows how the the actual tagging mechanism works in two diferent states. State A, so called idle state, is where the compression spring is compressed by the holding mechanism. In state B, so called activated state, the motor is actuated to turn the key and then release the piston. Consequently, the compressed spring would push the piston up to hit the needle tag. The mechanism was tested to ensure it was working properly before an *ex-vivo* experiment was conducted, where the mechanism was controlled wirelessly.

5.5 Ex-vivo Experiment and Result

An *ex-vivo* experiment was carried out to test the performance of the developed capsule and verify the feasibility of the proposed tagging mechanism. The experiments and a summary of results are presented in the following sections.

The experiment was conducted on explanted intestine tissue. The capsule prototype was inserted into the intestine manually. Figure 5.18 illustrates the *ex-vivo* experimental setup. The base station with a transceiver was successfully set up to send the command signals wirelessly. After enclosing the capsule within the intestine, the tagging mechanism was activated wirelessly by receiving commands from the base station as shown. When the receiver of the capsule received the command signal from the base station, the motor was controlled to actuate the tagging mechanism and the tag was delivered to the tissue.

Figure 5.18: *Ex-vivo* experiment with wirelessly control

Similar to the experiment of the test jig (section 5.3.3), after being fired into the intestine, the tag underwent four tests, namely visual test, air test, water test and force test. Figure 5.19 shows captured images of the four tests. In the jig test, the intestine tissue was cut to be mounted on styro foam. However, in this capsule experiment, the intestine tissue was not cut so that the capsule could be inserted in. Thus, the intestine could be inflated in the air and water tests shown in Figure 5.19.

Figure 5.19: Captured images of the capsule test

The experiment was conducted 20 times. The results of the experiment were also divided into two types, pass and fail. Pass result was recorded as 1, meaning the tag satisfied the criterion of each test. If it could not penetrate the tissue or dropped off, it was considered as a failure and recorded as 0. Experiment results were recorded and tabulated in Appendix F.

Result and Discussion

Figure 5.20 shows a chart depicting the pass rate of the four tests. The pass results were all 85% for the visual test and the air test. It decreased to 75% and 70% for the water test and the force test.

In the visual test, the tag was observed from both sides of the intestine, the serosal side and the mucosal side. Results showed that the capsule was able to deliver the tag successfully to adhere to the intestine tissue, with the pass rate 85%. Similar to the jig test, in this capsule experiment, the air pressure did not affect much the tag because of the highly elastic characteristic of the tissue. However, inflation of the tissue under water test reduced the elasticity of the tissue. That resulted in a decrease of 10% to 75% pass rate in the water test.

The result declined to 70% in the force test. It was explained with the same reason for the jig test. If tag could stand the water pressure, it was certainly able to stand the flicking force unless the author tried to apply more force to pluck or poke the tag out of the tissue.

Figure 5.20: Test result of the tagging capsule

With the success rate of 85% in sending a small tag to attach to the intestine tissue, it was concluded that the tagging capsule had achieved its goals. First, the capsule with all necessary components were encapsulated into a closed shell and tested. Second, the motor was able to be controlled wirelessly to trigger the holding mechanism. The tag was fired by the pushing force from the released spring. Finally, the tag was tested under pressure and force tests to prove the adhesion tolerance of the tag. In summary, the wireless tagging mechanism has proven its feasibility in *ex-vivo* experiment with explanted tissue.

CHAPTER 6 - CONCLUSION AND FUTURE WORK

6.1 Conclusion

Due to the limitations of commercial capsules such as lacking of locomotion and therapeutic options, there is a need to help the doctor in diagnosis as well as treatment more effectively. This report discussed the motivation and the conceptual design of the tagging mechanism developed for a wireless capsule. In the literature review, conventional and currently developed systems for diagnosis and treatment on the GI tract are reviewed.

Based on the review, a study was made on the requirements for the design of the prototype. Three mechanisms, namely the ink-injection mechanism, the clipping mechanism, and the tag-shooting mechanism inspired from the two conventional endoscopic markings to mark inside human GI tract were proposed. From that, an analysis was performed, determining that the suitable mechanism to be used was the tag-shooting method. The size, the marking speed, the available diagnosis device, and the complexity of the design made the tag-shooting method more suitable than others.

The tag-shooting method is described as a shooting mechanism that comprises a metal tag and a hollow cylinder containing a compression spring inside. The size of the tag in this design is as small as a needle tip's size, and that would not occupy much space of the tag container. A piston used to push the needle is triggered by a compression spring. The compression spring is selected because high speed is very important for this design, and it has high potential energy as well as the releasing speed that could help the tag penetrate soft tissue easily. High speed, moreover, decreases chances of missing the shot. When being triggered by the doctor, the compression spring is released from its stored potential energy and pushes the piston forward to hit the tag. The needle will penetrate and stay in the soft tissue due to its high speed and sharpness. As the size of the needle is small, finding its location would occasionally require several X-ray screenings from different angles.

On the development of the tagging mechanism, this thesis provided the mathematical analysis of the input and output of the mechanism. Various designs options with different associated components were evaluated to select the suitable

components for the conceptual design. A force measuring experiment was set up to measure the output requirements, i.e., the penetration force required for a common needle to pierce through intestinal tissue. As an intermediate step, before proceeding to the final prototype, a test jig was designed to validate the spring strength selected by preliminary calculations. The result from the test conducted with explanted tissue showed the feasibility of the design in capability of sending a needle tag to stick into the tissue.

Finally, the capsule prototype integrated with the tagging mechanism was fabricated and tested on explanted intestine tissue. For water proofing, the tagging mechanism together with others electronic components were located inside an encapsulated casing. It has the size of 17 mm diameter and 50 mm length. The experiment was repeated 20 times and tested in four tests, namely visual test, air test, water test and force test. The result showed a high successful rate of 85% in sending the tag to adhere the tissue. Moreover, after being released to mark, the tag was able to be observed by naked eyes and prove its adhesion tolerance under pressure and force tests. As such, it can reach to the conclusion that the developed capsule is able to achieve its objectives and goals. The results reported in this report look promising for a wireless therapeutic device in the GI tract. However, further research and development are required to further miniaturize the wireless tagging capsule to the commercial size (11 mm diameter and 26 mm length).

6.2 Future Work

In this report, the tagging mechanism embedded into an ingestible capsule was presented, allowing the doctor to perform endoscopic marking when diagnosing human GI tract. The developed capsule paints the future on the development of therapeutic devices for the capsule. This report, however, only tested the capability of the tagging mechanism on explanted intestine tissue. With its current size, the capsule can be inserted endoscopically into the GI tract with the help from an endoscopist.

Although the main objective of the project has been achieved, further optimization and investigation are required in order to bring the system to the next stage of animal trials. On the development of the wireless tagging capsule, several possible future directions are proposed.

Currently, the size of the controller board is the size-constraint of the developed capsule. It can be reduced in future along with the actuator, the antenna and the battery. As mentioned above, if ASIC technology were used to fabricate the board, the size of the board could be reduced significantly. Moreover, reduction of power consuming from the board can reduce the size of the battery as well. To optimize the tagging mechanism, a smaller compression spring and a smaller motor may be selected. The motor has been under development by other researchers to achieve the size required yet it still provides sufficient power to actuate the mechanism. If the motor is customized to be shorter in length, the holding mechanism with double supporting shaft can be considered for the design.

To prevent the tag from piercing through and going into the abdominal area, the tail of the tag needs to be broadened. It is suggested to have a spine along the body of the tag too. In addition, material of making needle should be taken into consideration since the tag may cause a side effect or complication. The needle could be made of some kinds of titanium such as biomaterial, which was mentioned in section 3.3. Several approaches are suggested to enhance the rate of localizing of the tag. Barium could be filled inside the titanium tag to enhance screening images. Moreover, fluorescence may be applied on the surface of the tag so that the glow lights from that fluorescence can be searched under UV light.

With regards to the development of the capsule robot, several possible future directions with add-in features are proposed that may turn the capsule into a promising diagnosis-device in the GI tract. It is important to note that modification or slightly different design of the mechanism would allow deployment for different tasks, such as biopsy or controlled drug delivery, depending on the intended application. The tagging mechanism will be more comprehensive if it can perform more than one marking at different locations inside the GI tract. The mechanism can be designed as the actuator can trigger several compressed springs one by one that allows shooting several tags in several times at different locations.

Another suggestion is to fill the tag with a small amount of drug powder or liquid so that the capsule would able to deliver drug or medicine to the tumor location inside the GI tract in a fast and effectively controlled way. The drug reservoir can be allocated at the hollow space inside the tag. The drug reservoir is made of

gelatin which is commonly used to encapsulate drug powder. Thus after the gelatin is dissolved, the drug can be absorbed by the GI tract to have a direct effect at the specific location.

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APPENDIX A - GASTROINTESTINAL TRACT

The Gastrointestinal (GI) tract is a continuous tubular organ that extends from the mouth to the anus [4, 55]. In other words, it is the passage in the human body having a direct contact with the food from just being consumed to being excreted. It consists of organs such as the mouth, most of the pharynx, esophagus, stomach, small intestine, large intestine and anus as well as accessory organs such as liver, gallbladder and pancreas. The accessory organs never come into contact with the food themselves but produce secretions that aid digestion. In this project, the study of the GI tract focuses on small intestine because this is the organ where the gastrointestinal scope cannot currently reach. Esophagus, stomach and colon are not included in the study because they can be easily examined with the GI endoscope.

The journey of the capsule starts from pharynx, passing through esophagus to stomach, then traveling along small intestine and large intestine, and coming out at anus. The pharynx, known as the throat, is a coned shaped tube about 12.5 cm long. The esophagus is a straight 23-25 cm long muscular tube and about 2.5 cm in diameter that connects between the stomach and the pharynx. Its main role is simply to carry the food from the pharynx to the stomach using contraction and relaxation of its smooth muscle. Food travels through the GI tract by peristalsis, a process where the muscle at the top part contracts itself, pushing downward while the muscle below relaxes allowing food to move through. Peristalsis wave is performed every 15 to 20 seconds to mix the food with the fluid secreted by the body.

The stomach is the expanded section of the digestive tube between the esophagus and the small intestine. Continuing from the pylorus of stomach, small intestine comprises three sections, the duodenum, jejunum and ileum, followed by the large intestine. Although the small intestine is longer than the large intestine by 4 to 5 times, its diameter is much smaller. On average, the diameter of the small intestine of an adult human measures approximately 2.5-3 cm, while the large intestine measures about 6-7 cm in diameter. In human over 5 years old, the small intestine is approximately 7 m long and can vary from 4-7 m with many bends, making the small intestine extremely convoluted.

Figure A.0.1: Illustration of human GI tract [56]

The small intestine has five layers, comprising serosa, muscularis externa that has longitudinal and circular layers, submucosa, and mucosa. These layers of the ileum are illustrated in Figure A.0.2. Under microscope, the three sections of the small intestine look similar to each other, but there are some important differences. The duodenum's submucosa has Brunner's glands and Meissner's plexus while the jejunum and the ileum do not have Brunner's glands. The last inner layer is mucosa containing mucosa muscularis, lamina propria, and Goblet. Nutrient food will diffuse through the walls of the small intestine into blood vessels. This process is called as absorption.

Figure A.0.2: Illustration of Ileum Layer [4]

APPENDIX B - EXPERIMENT WITH SPOT INK

The visibility of the mark on explanted intestine tissue was tested according to different volumes of ink. The experiment setup shown in Figure B.0.3 involved a 5 mL syringe containing SPOT ink, pig's intestine and one digital Vernier caliper for measurement. Pig's intestine was cut along the length of the tract and stretch on a horizontal surface. Before injected, syringe was shaken to distribute high carbon particles uniformly in the solution. The needle used in experiment was Terumo 23 Gauge which reduces leaking after retraction. When injected, the needle tip was moved slowly into intestine layers to prevent penetration.

Figure B.0.3: Test SPOT ink on pig intestine

In the experiment, three different amounts of SPOT ink (0.2 mL, 0.4 mL and 0.6 mL) were tested. Volume of injected amount was recognized from available marks of a ruler along the syringe body. Since the quantity of SPOT ink was limited, two measurements were conducted for each amount. After injection was performed, a photo of an ink blush was taken. Size of the ink marks in each test measured by Vernier caliper was recorded.

Size corresponding to each injected volume was displayed in Table B.0.1 together with visualization of ink blush. It can be seen that the size of the black blush increased when larger amount of ink was distributed though the blush's shape was different. Size of mark created from 0.2 mL was slightly smaller than the one created from 0.4mL, and the latter was considered easy to be recognized. As for 0.6 mL used, ink was leaked and started running out of the injected hole after withdrawing the needle. As a result, 0.4 mL volume is selected for the design of the ink reservoir.

Table B.0.1: Size and visualization of the test with SPOT ink

Volume	Size	Visualization
0.2 mL	11 mm x 19 mm
	18 mm x 17 mm	
0.4 mL	21 mm x 21 mm
	22 mm x 17 mm	
0.6 mL	24 mm x 60 mm
	20 mm x 45 mm	

APPENDIX C - MICRO DC MOTORS

Micro Brushless DC-Motors

0,014 mNm

Electronic Commutation

For combination with
Gearheads:
03A
Drive Electronics:
BLD 05002 S, SC 1801 F

Series 0308 ... B

	0308 H	003 B	
Nominal voltage ¹⁾	U _N	3	Volt
Terminal resistance, phase-phase	R	33,8	Ω
Output power ¹⁾	P _{2 max}	6,3	mW
Efficiency	η _{max}	16,5	%
No-load speed	n ₀	15 000	rpm
No-load current (with shaft ø 0,6 mm)	I ₀	0,047	A
Stall torque	M _H	0,017	mNm
Friction torque, static	C ₀	0,017	mNm
Speed constant	k _n	25 758	rpm/V
Back-EMF constant	k _E	0,039	mV/rpm
Torque constant	k _M	0,371	mNm/A
Current constant	k _i	2,697	A/mNm
Slope of n-M curve	Δn/ΔM	2,3 · 10 ⁶	rpm/mNm
Terminal inductance, phase-phase	L	65	μH
Mechanical time constant	τ _m	14	ms
Rotor inertia	J	2 · 10 ⁻⁴	gcm ²
Angular acceleration	α _{max}	609	· 10 ³ rad/s ²
Thermal resistance	R _{th1} / R _{th2}	29 / 186	K/W
Thermal time constant	τ _{w1} / τ _{w2}	2 / 20	s
Operating temperature range		-20 ... +60	°C
Shaft bearings		jewel bearings	
Shaft load max.:			
– radial at 3 000 (1 mm from mounting flange)		0,2	N
– axial at 3 000 rpm (push-on only)		0,2	N
– axial at standstill (push-on only)		2	N
Shaft play:			
– radial	≤	0,03	mm
– axial	≤	0,15	mm
Housing material		Nickel alloy	
Weight		0,33	g
Direction of rotation		electronically reversible	

Recommended values - mathematically independent of each other

Speed up to	n _{0 max}	15 000	rpm
Torque up to ²⁾	M _{0 max}	0,014	mNm
Current up to (thermal limits) ²⁾	I _{0 max}	0,085	A

¹⁾ effective value of pure sinus voltage

²⁾ thermal resistance R_{th2} by 55% reduced

For notes on technical data and lifetime performance refer to "Technical Information", Edition 13.02.2008

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Specifications subject to change without notice.

www.faulhaber-group.com

Micro Planetary Gearheads

smoovy® Technology

0,88 mNm

For combination with
Micro Brushless DC-Motors:
0308

Series 03A

	03A
Housing material	plastic
Geartrain material	steel
Recommended max. input speed for:	
– continuous operation	15 000 rpm
Backlash, at no-load	4"
Bearings on output shaft	bronze
Shaft load max.:	
– radial (1,5 mm from mounting face)	0,1 N
– axial	0,2 N
Shaft press fit force, max.	1 N
Shaft play (on bearing output):	
– radial	≤ 0,03 mm
– axial	≤ 0,15 mm
Operating temperature range	– 20 ... + 60°C

Specifications

reduction ratio (absolute)	weight without motor	output torque		direction of rotation (reversible)
		continuous operation	intermittent operation	
	g	M _{max} mNm	M _{max} mNm	=
25 : 1	0,20	0,28	0,42	=
125 : 1	0,18	0,88	1,32	=

Note: The Planetary Gearheads are only available in combination with the micro brushless DC-motor series 0308 ... B.

For notes on technical data and lifetime performance
refer to "Technical Information".
Edition 2009 Aug. 11

Specifications subject to change without notice
www.faulhaber.com

Linear Actuators

2,8 N

For combination with
Micro Brushless DC-Motors:
0308

Series 03A S3

	03A S3
Housing material	plastic
Geartrain and spindle material	steel
Nut material	bronze
Recommended max. input speed for:	
– continuous operation	15 000 rpm
Max. linear travel	7 mm
Bearings on output shaft	bronze
Shaft play (on bearing output):	
– radial	≤ 0,03 mm
– axial	≤ 0,15 mm
Operating temperature range	– 20°C ... + 60°C

Specifications

reduction ratio (absolute)	Max. speed	weight without motor	Nominal push force ¹⁾		direction of rotation (reversible)
	mm/min	g	continuous operation F _{max} N	intermittent operation F _{max} N	
25 : 1	120	0,36	0,47	0,7	=
125 : 1	24	0,34	2,80	4,2	=

¹⁾ Capability of pushing/pulling the nut with a bearing at the end of the shaft.

Note: The Linear Actuators are only available in combination with the micro brushless DC-motor series 0308 ... 8.

Scale enlarged M2:1

Electronically commutated sensorless motor, slotless stator design

General data		
19 Operating temperature range	-10 ... +50	°C
20 Max. temperature raise at stall	20	°C
21 Bearing type	Sintered sleeves	
22 Max. permissible press fit force, gearhead output	2.9	N
23 Max. radial play, gearhead output	0.06	mm
24 Max. axial play, gearhead output	0.1	mm

SBL02-06H1PG18 corresponds to:
Motor SBL02-06H1 +
Planetary gearhead SPG02-18

SBL04-08

Electronically commutated sensorless motor, slotless stator design

Sensorless brushless motor drive circuit SSD04

Ordering number	SBL04-0829 PG04-4.3	SBL04-0829 PG04-18	SBL04-0829 PG04-79	SBL04-0829 PG04-337
1 Nominal voltage	3	3	3	3 V
2 Terminal resistance	29	29	29	29 Ω
3 Gearhead reduction ratio	4.3	18	79	337 :1
4 Gearhead number of stage	1	2	3	4
5 Max. output power, gearhead output	0.02	0.02	0.01	0.01 W
6 Max. efficiency	12	11	11	9 %
7 No-load speed, gearhead output	7000	1500	350	85 rpm
8 No-load current	44	45	46	50 mA
9 Stall torque (2-points measurement), gearhead output	0.13	0.43	1.5	5.7 mNm
10 Friction torque	0.10	0.35	1.25	5.59 mNm
11 Back-EMF constant	0.2	1.1	4.7	17.8 mV/rpm
12 Torque constant	2.3	7.7	27.3	111.8 mNm/A
13 Coil inductance	74	74	74	74 μ H
14 Mechanical time constant, motor only	5	5	5	5 ms
15 Gearhead length, L1	5.8	7	8.2	9.4 mm
16 Total length, L2	13.8	15	16.2	17.4 mm
17 Rotor inertia, motor only	9×10^{-4}	9×10^{-4}	9×10^{-4}	9×10^{-4} gcm ²
18 Total weight	810	990	1010	1030 mg

General data

19 Operating temperature range	-20 ... +70	°C
20 Max. temperature raise at stall	55	°C
21 Bearing type	Sintered sleeves	
22 Max. permissible press fit force, gearhead output	5	N
23 Max. radial play, gearhead output	0.044	mm
24 Max. axial play, gearhead output	0.15	mm

Ordering example

SBL04-0829PG18 corresponds to:
 Motor SBL04-0829 +
 Planetary gearhead SPG04-18

DRIVE ELECTRONICS SERIES

SSD04

Sensorless brushless motor drive circuit

For Micro DC brushless motors SBL02-06 and SBL04-08

Description

SSD04 is a 3-phase sensorless drive circuit designed to operate brushless motor SBL02-06 and SBL04-08 exclusively. The operating voltage can be adjusted by VR trimmer and motor shaft direction can be reversed by connecting CW/CCW input to Vcc, if not connected the SBL02-06 runs CW while SBL04-08 CCW. FG (Frequency Generator) output provides a pulse per motor revolution. Internal thermal protection circuit included.

Specifications

	SSD04			
	Min.	Typ.	Max.	
Voltage supply	2.7		6.0	V
Output voltage			4.9	V
Output current			0.8	A
Operating temperature range	-20 ... +75			°C
Weight	1.9			g

APPENDIX D - PENETRATION FORCE

Penetration force regarding to different needle sizes

APPENDIX E - RESULT OF THE JIG TEST

Tests	Observations																				Total	Prob.
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20		
Visual	1	1	1	0	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	18	0.90
Air	1	1	1	-	1	1	1	1	1	1	1	1	1	1	-	1	1	1	1	1	18	0.90
Water	1	1	1	-	1	0	1	1	1	1	1	1	1	1	-	1	1	1	1	1	17	0.85
Force	1	1	1	-	1	-	0	1	1	0	1	1	1	1	-	1	1	1	0	1	14	0.70

APPENDIX F - RESULT OF THE CAPSULE TEST

Tests	Observations																				Total	Prob.
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20		
Visual	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	17	0.85
Air	1	-	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	-	1	1	17	0.85
Water	1	-	1	1	1	1	1	-	1	0	1	1	1	1	1	1	1	-	1	1	16	0.75
Force	1	-	1	1	1	1	1	-	1	-	1	0	1	1	0	1	1	-	1	1	14	0.70