Development of a mechatronics weight loss pill

Andy Prima Kencana

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WEIGHT LOSS PILL

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**DEVELOPMENT OF A MECHATRONICS
WEIGHT LOSS PILL**

SUBMITTED

BY

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SCHOOL OF MECHANICAL AND AEROSPACE ENGINEERING

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“For it was you who formed my inward parts;

You knit me together in my mother's womb.

I praise You, for I am fearfully and wonderfully made.

Wonderful are Your works; that I know very well.”

Psalm 139:13-14

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ABSTRACT

This thesis introduces a mechatronics based weight loss system for *Intragastric Balloon (IGB)* treatment. *IGB* is a weight loss treatment in which a gas (or liquid)-filled balloon is inserted into the stomach cavity in order to occupy stomach volume and trigger the feeling of satiety. Therefore, it facilitates the patient to reduce the food intake, and hence the patient can lose weight more effectively and naturally.

This treatment has demonstrated its effectiveness in promoting weight loss. However, the current treatment has two major drawbacks. First, it requires a set of insertion tools and an endoscopic system for placement of the balloon, control of its inflation and deflation and its removal. These procedures would cause discomfort to the patient. Second, it inflicts some complications due to patient intolerance to the weight and volume of the *IGB*.

The proposed system aims to demonstrate a remote-controlled *IGB* inflation and deflation mechanism so that the treatment could be performed without the necessity of any insertion tool/tube. The mechanism also provides volume adjustment capability that could improve patient tolerance. It is hoped that the proposed system could reduce the discomfort experienced by the patient and increase the effectiveness of the *IGB* treatment.

In order to achieve this objective, the system is designed to comprise of the inflation/deflation mechanism, wireless communication unit, micro-controller, and battery. The inflation mechanism utilizes gas generating reaction of acetic acid and sodium bicarbonate that generate CO₂ gas. Three prototypes were designed and fabricated. The prototypes have demonstrated the feasibility of the mechanism to inflate a latex balloon (130-200 ml) in *ex-vivo*, *in-vitro* and *in-vivo* experiments. However in due to the dimension of the wireless communication unit, the system was unable to be inserted through the mouth. Therefore, a miniaturized ingestible prototype measuring 16.50 mm outer diameter and 50 mm length has been built and tested in *ex-vivo* experiments. Experiments on pigs will be conducted to test the efficacy of weight loss of the *IGB* device. Currently there is insufficient research to determine the *IGB* volume that will provide the optimized feeling of satiety; the proposed system has the potential to conduct this research further.

Chapter 1

INTRODUCTION

1.1. Background

Obesity is a major contributor to life threatening chronic diseases, disability and death. It is a growing global phenomenon and it is becoming a great concern for the *World Health Organization (WHO)*. Obesity is one of the root causes for some medical disorders and diseases, which include hypertension, high cholesterol level, stroke, *Coronary Heart Disease (CHD)*, diabetes mellitus, gallbladder disease, dyslipidaemia, osteoarthritis, pulmonary diseases, sleep apnoea, breast and colon cancer [1-3]. Obesity also affects one's mental health condition, such as low self-esteem, job discrimination, and clinical depression. Most people believe that being slim and thin is more socially acceptable. This belief motivates many people to lose weight, and the weight loss process might inflict self denial, lower self esteem and also depression [4].

According to the data projection from the *WHO* in 2005, approximately 1.6 billion adults were overweight and more than 400 million adults were obese. Furthermore, *WHO* also predicted that in 2015 there would be approximately 2.3 billion overweight adults and more than 700 million would be obese. The criteria for overweight and obesity is determined by the *Body Mass Index (BMI)*, which is defined as the weight in kilograms divided by the square of the height in meters. The *WHO* defines whose *BMI* $\geq 25 \text{ kg/m}^2$ as overweight and *BMI* $\geq 30 \text{ kg/m}^2$ as obesity.

Intragastric Balloon (IGB) is a weight loss treatment. In this method a gas (or liquid)-filled balloon is inserted into the stomach cavity in order to occupy stomach volume. The balloon triggers the patient to experience satiety so that they may lose their appetite. This treatment would help the patient to reduce their food intake. The idea of inserting an object to occupy the stomach space was initially developed in 1982 [5]. A few studies [6, 7] summarized that the feeling of satiety is due to the volumetric feedback produced by the food in the stomach. Therefore by reducing the food intake of the patient combined with an exercise program would, help the patient to lose weight more effectively and naturally.

1.2. Motivation

Other than *IGB* there are other obesity treatment, namely dietary / lifestyle, pharmacologic, and surgical treatment [8]. The dietary / lifestyle focus on limiting the calorie intake and balancing the nutrition. This method is usually combined with counseling and exercise program. The pharmacologic uses drug therapy to inhibit some physiological functions of the digestive system such as fat absorption and feeling of satiety. The surgical method provides physical alteration to the digestive system, such as gastric banding. The purpose of gastric banding is to reduce the stomach size thus restricting the food intake.

IGB has been commercialized since year 2000 and the efficacy of *IGB* has been studied by many groups worldwide [9-14]. The studies concluded that the *IGB* treatment shows positive results as an effective method for the treatment of obesity. This treatment offers a less invasive method for weight loss treatment as compared with the surgical method. This treatment promotes weight loss mechanically by occupying the volume of the stomach. Thus as compared to the most famous chemical based slimming pill, this treatment will not inflict any drug related side effect.

In the last three decades, there have been various developments on *IGB* which mostly were focused on the balloon characteristics; such as material, shape, dimension, filling, smoothness, and radio-opacity. Because of this developmental direction, most *IGBs* implement similar methods for its insertion and removal.

Currently there are two commercialized *IGBs*, namely *Bioentrics Intragastric Balloon (BIB)* [15], and *Heliosphere Bag* [16]. Both are inserted and removed by the assistance of a set of tools and an endoscope system. The tools consist of an inflation tube, deflation tool and a grasper for balloon removal. An endoscope is a slender, long and flexible device to examine the gastrointestinal tract and to perform some simple surgical procedures, such as polypectomy and biopsy [17].

In order for the tools and endoscope to reach the patient's gastrointestinal tract, it is necessary to put the patient under conscious sedation. For some cases, the patient may be put under general anesthesia. Once the patient is sedated or anesthetized, the tools and endoscope are introduced via the oral passage.

In most cases the patient usually experience the side effects during the recovering period from the influence of sedation or anesthesia. The common side effects are giddiness and nausea. Obviously, the endoscope routine is an unpleasant and might even be a traumatic experience for the patient.

Both commercialized *IGBs* serve as a passive object that only occupies the stomach space. However, as a digestion organ, the stomach is an active and dynamic space. There will be volumetric changes due to the contraction of the stomach muscles.

It was reported from a study of 3,429 patients treated using *BIB* [12] that there were some complications such as nausea and vomiting (8.6%), abdominal pain and other mild digestive disorders (5.0%), balloon deflation and displacement (2.5%). These complications are reported due to the excessive volume of the inflated *IGB*. Since the patients are under sedation or anesthesia during inflation, they could not provide feedback regarding their tolerance to the volume of the inflated balloon that caused the complications. Therefore, an *IGB* that could perform volume adjustment without sedating the patient would reduce the complications due to volume intolerance.

These unpleasant experiences and complications caused by the current *IGB* treatment might reduce the effectiveness of the treatment. Thus, this project attempts to provide a possible solution by developing a mechatronics based *IGB* system that allows tele-operation volume adjustment.

1.3. Objective

The main objective of this study is to design and develop an inflation/deflation mechanism for the development of a mechatronics weight loss system. The system aims to demonstrate a remote-controlled *IGB* inflation and deflation mechanism so that the necessity of inserting any external tool, as compared to the existing system, could be removed from the treatment. The system consists of an inflation/deflation mechanism, wireless communication unit, micro-controller, and battery. It is hoped that the proposed system could increase the effectiveness of *IGB* treatment and reduce the discomfort experienced by the patient.

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

- To perform a critical literature review on the inventions related to the development of *IGB* weight loss treatment.

- To study and model the inflation and deflation process of a balloon.
- To test the feasibility of the inflation and deflation mechanism with a series of experiments including *ex-vivo*, *in-vitro* and *in-vivo* experiment

1.4. Scope

The scope of this project is to design the actuation and mechanical parts of the system. Therefore, the construction of the other individual parts such as the power supply, wireless communication module, and system control are out of the scope of this project. The system is developed to the point of proving the concept and feasibility of an ingestible weight loss pill. As such, medical requirements of biocompatibility and sterility are not considered in this project.

1.5. Organization of the Report

This report consists of 5 chapters, and they are organized in the following manner.

Chapter 1 introduces the background of the *IGB*. It describes the procedure of the available *IGB* system. It also presents the potential problem of the current *IGB* system which is summarized in the motivation section. Lastly this chapter stated the objective and the scope of this project.

Chapter 2 provides the reader with a summary of the literature review of various *IGB* development. It presents the comparison of each work in order to study critically on each developmental work. It also describes related technologies such as capsule endoscopy, drug delivery capsule, sensing capsule which technologies provide valuable insight for the development of the proposed *IGB* system.

Chapter 3 presents the system overview of the proposed *IGB* capsule. It will present the method and the working principle of the system and the conceptual design of the inflation/deflation mechanism. Lastly, this chapter also describes the underlying theory of balloon inflation and deflation.

Chapter 4 elaborates the experiments conducted in order to verify the working principle of the *IGB* system described previously in chapter 3. This chapter contains the necessary experiments conducted for the construction and verification of the prototype.

Chapter 5 concludes this report, and recommends some future works of the project.

Chapter 2

LITERATURE REVIEW

2.1. Introduction

There are many methods proposed and implemented for treating obesity. These vary from the most invasive (surgery); to the less invasive (disciplined diet and exercise). Compared to bariatric surgery, *IGB* has become one of the least invasive method of obesity treatment. *IGB* facilitates weight loss by giving the sense of satiety so that the patient will be motivated to reduce their food intake.

2.2. Intra gastric Balloon

The idea of implanting a balloon for occupying the space in the stomach in order to give the sense of satiety to the patient was initiated in 1982 [5]. For about 27 years *IGB* has been studied and developed as an alternative and less invasive method for treating obesity. The first *IGB* that was commercialized is the *Garren-Edwards Gastric Bubble (GEGB)* [18], which was approved by U.S *Food Drug Administration (FDA)* in 1985. Although the efficacy of *IGB* for obesity treatment was not studied and verified, the *GEGB* was sold about 20,000 bubbles only within 1 year.

From the experience of the patients who were treated by the *GEGB*, it was reported that there were some incidents and safety issues such as balloon obstruction in the intestine, early deflation of the balloon, gastric ulcer, esophageal abrasion or trauma during the balloon insertion and removal [19]. Due to these issues, the *GEGB* was pulled out from the market. In 1987 a comprehensive workshop was conducted by 75 experts at Tarpon Spring, Florida [19]. In order to minimize and avoid the complications based of the *GEGB* experience, the workshop defined the standard protocol of the clinical practice of *IGB* treatment. According to the protocol, endoscopy is the appropriate equipment used for the *IGB* insertion and removal procedure. Prior to the balloon insertion, the stomach cavity will be examined by endoscope routine. The insertion of *IGB* will also be guided closely by the endoscope. Since the balloon has no capability of providing any feedback, the endoscope, which provides visual feedback, becomes very crucial for the *IGB* insertion procedure.

The workshop also defined the characteristics of the ideal *IGB* which include balloon shape, material, and filling substance. Since the size of the balloon will vary depending

on the patient's stomach size, there was no conclusion of the ideal size of the *IGB*. The balloon must be made of a material with smooth surface which is to avoid stomach complications such as gastric ulcer, stomach perforation. The balloon material must be able to last for considerably longer period of time over the *GEGB*'s life span, in order to avoid an early balloon deflation. Radio-opaque marker on the balloon is strongly recommended, so that the balloon location could be traced by X-ray scanning. The more comprehensive regulations decided on the workshop is attached in Appendix A. The *GEGB* was not equipped with the marker and there were some cases that the balloon could not be traced especially on the event of early balloon deflation. Lastly, based on the work in dog and rat model reported by some participants, the liquid filled balloon show higher effectiveness as compared to the air-filled balloon.

After the workshop, other groups developed the *IGB* and tried to meet the new requirements. Since 1987 to 2007 there were about six developmental works of *IGB*, they are *Ballobes* balloon (1989), *Taylor balloon* (1990), *Willson Cook* (1990), *BIB* (1999), *Heliosphere Bag* (2006), and *Ullorex* (2007). Based on the filling substance of the balloon, these *IGB* could be categorized into two, gas-filled balloon and liquid-filled balloon. Each category of *IGB* is discussed in section 2.2.1 and 2.2.2 respectively.

2.2.1. Liquid Filled Balloon

The *IGB* developed as the liquid-filled are Taylor balloon, and *BIB*. The Taylor balloon is made of seamless silicone material and could be inflated to 550 ml of an oblate shape with normal saline solution. The balloon is inserted by using an endoscope and stays in the stomach cavity for about 16 weeks. The result reported that the patients experienced an average decrease of *BMI* of 11.4% [20].

BIB is made of a smooth, transparent silicone and a self sealing valve. It is introduced by Bioentric Corporation, Carpinteria, California. The inflated balloon and the inflation tube picture are depicted in Figure 2.1. *BIB* is filled with sterile saline solution to a perfect spherical shape within the range of 400 to 800 ml [15]. Following the Tarpon Spring requirement, the balloon is equipped with the radio-opaque marker at the circumference of the valve. The inflation tube is made of silicone with outer diameter (OD) of 6.5 mm.

Figure 2.1 : Two inflated *BIB* (400 ml and 700 ml) and its filling catheter [15]

There are two steps for the balloon insertion [15]; the first step is inspection of esophagus and stomach by using endoscope and the second step is the insertion and filling of *BIB*. The patient is required to be anesthetized during the placement of the balloon. The filling catheter, connected to the deflated balloon is used to insert the deflated *BIB* to the stomach. The length marker at the filling tube gives a rough idea the location of *BIB* in the stomach. Before the balloon is inflated, the endoscope is reintroduced to the stomach to make sure the correct placement of the balloon. Then the balloon is inflated by injecting sterile saline solution using a 50 or 60 ml syringe connected at the proximal end of the catheter. The balloon is usually filled up to the volume of 700 ml depending on the size of the patient's stomach. The time span of the balloon in the stomach is about 3 – 6 months.

Similarly, the removal of the balloon also requires the assistance of endoscope and the removal tools [15]. The tools consist of a long endoscopic tool with a needle attached at its end and a grasper. The needle is inserted through the tool's channel to puncture the balloon. The balloon deflates slowly and let the saline flow to the stomach. Once the balloon is deflated, it is removed by pulling it out through the endoscope channel with a grasper tool or polypectomy snare.

The efficacy of *BIB* has been studied by many groups worldwide. In a preliminary study conducted in Italy [9], *BIB* was used in 10 obese patients whose *BMI* mean was 47.6 kg/m². After 3-5 months the *BMI* mean dropped to 43.5 kg/m². They concluded that *BIB* is an effective solution for the treatment of morbid obesity. Another study

[10] that review 30 clinical studies involving 4,877 patients, concluded that *BIB* is effective for promoting short term weight loss. The *BIB* is considered safe although there were still some complications observed such as gastric perforation, bowel obstruction, early deflation, and gastro duodenal ulcers [10].

However, a study conducted in Singapore [21] shows that *BIB* is poorly tolerated by Asian patients. The patient intolerance is possible caused by the weight of an inflated *BIB* which is approximately about 400 to 700 grams. They also studied the patient's tolerance of having *IGB* in their stomach by inserting a lower volume balloon in order to compensate the smaller stomach volume of Asian patients. The patient's intolerance may cause nausea, retching and gastric pain.

2.2.2. Gas Filled Balloon

As the first commercial *IGB* in 1985, *GEGB* was developed to be filled with gas rather than liquid [18]. It has cylindrical shape as depicted in Figure 2.2. It is made of polyurethane of 3 cm OD and 4 cm length.

The balloon is inserted into the stomach with a tube which is also used to inflate the balloon with 200 ml of air. The tube is connected to a syringe at the proximal end, and to the balloon at the distal end. For the inflation purpose, a check valve is installed at the proximal end. After the inflation, an endoscope is reintroduced in order to confirm the placement and the inflation of the balloon in the stomach.

Despite the large initial enthusiasm of this bubble, some studies observed that the bubble alone without any therapy did not appear to provide significant benefit to most obese patient [22]. There were also some complications reported which were mainly due to the material of the balloon and placement issues such as early deflation of the balloon, gastric ulcer, esophageal abrasion.

Figure 2.2: The Garren-Edwards Gastric Bubble [23]

The second gas filled balloon is the *Ballobes* balloon [24]. It was introduced by Danish Obesity Treatment APs, Rødovre, Denmark. *Ballobes* material is made of Polyurethane which is air tight and acid resistant thermoplastic. The balloon is inflated with 400 ml room air using a modified bicycle air pump. For balloon deflation, a needle is passed through the endoscope to puncture the balloon. Lastly, the deflated balloon is grabbed using a rat tooth forceps and then removed from the patient body.

The third air filled balloon, *Heliosphere Bag* [16] was introduced in 2006. The balloon is made of radio-opaque double layer polymer. The inflated balloon and an introduction kit are depicted in Figure 2.3.

The introduction kit consists of a catheter and a deflated balloon which is pre-connected to the catheter. The deflated balloon is protected by a silicone envelope [16]. The introduction kit is lubricated, and then inserted to the patient stomach. The balloon insertion needs to be guided by endoscope for an accurate positioning of the balloon. Once the balloon is well positioned, the silicone envelope is removed from the balloon by pulling a string at the proximal end of the injection catheter. A 60 ml syringe is connected to the valve of the catheter. Once the envelope is removed, the balloon is injected by 960 ml of air, which inflates the balloon to 700 ml. A smaller volume of the balloon is observed due to higher pressure inside the stomach.

Figure 2.3: *Heliosphere Bag* and the introduction kit [25]

The balloon is intended to stay in the patient's stomach for 6 months. During the removal of the balloon [16], the stomach firstly is inspected by using an endoscope. After careful inspection, an endoscopic needle tool is inserted from the proximal end of the endoscope to the distal end in order to puncture the balloon. After the balloon is fully deflated, it is removed from the patient body by using an endoscopic grasper tool. The efficacy and the safety of using *Heliosphere Bag* was studied [11], and they concluded that *Heliosphere Bag* is safe to be used as an alternative solution for treating obesity.

Another development of air filled balloon is called the *Adjustable Totally Implantable Intra Gastric Prosthesis (ATIIP)* or *Endogast* [26]. As compared with the previous balloons described, Endogast implements a different approach for the balloon placement, which implements a mini surgical technique for balloon placement. Endogast consists of a balloon and a catheter, which is depicted, in Figure 2.4. The balloon is made of polyurethane. It has a prolate spheroid shape, and weighs 7 grams in mass. It has the capacity to be inflated to 300 ml. A catheter is attached to the balloon at one end and to an implantable port at the other end.

Figure 2.4: The Endogast balloon [27]

Endogast is inserted into the patient stomach surgically and the port is implanted under the skin [27]. The balloon is inflated and deflated by injecting or releasing air through the port. Although *Endogast* requires a surgical procedure, it has an advantage due to its flexible volume adjustment. The volume adjustment is done by using an inflation catheter connected to the implantable port as shown in Figure 2.5. The volume adjustment is not possible with the other *IGBs* described. This volume adjustment helps the patient to improve their tolerance to balloon volume. Therefore, the intolerance usually reported of using *IGB* such as nausea, abdominal pain, and vomiting could be reduced.

Figure 2.5:Endogast volume adjustment [27]

Another *IGB* called *Ullorex* [28] is the latest development of *IGB* which was published in 2007. *Ullorex* is a small size compressed *IGB* which allows oral administration method for balloon insertion. The *IGB* is swallowed with water as if the patient is taking medicine in the form of a capsule or tablet. The *IGB* is designed with a self-inflation mechanism to inflate the balloon inside stomach cavity. *Ullorex* implements the method of inflating a balloon using chemical reaction. It uses a membrane to separate the two reagents. The membrane is dissolvable by citric acid, which is injected into the capsule before the capsule is taken by the patient. Thus, the balloon will be inflated when the citric acid dissolves the membrane.

The *IGB* is also designed with a self deflating mechanism that enables the balloon to be naturally exerted [28]. After the plug is dissolved by gastric acid, the gas inside the balloon could be released. The idea of having natural administration of *IGB* has a major advantage over the conventional method. By avoiding the endoscope routine, the *IGB* insertion and removal will reduce the risk of health complications and the feeling of discomfort due to the sedation or anesthesia and endoscope insertion.

Once *Ullorex* reaches the stomach, the casing will be degraded by the stomach acid and hence the balloon is released from the casing and inflated. The balloon will be inflated slowly to 300 ml volume [28]. The balloon is also equipped with a bio-degradable plug, which is dissolved by the stomach acid within 25-30 days. Once it is dissolved, the gas will be released to the patient's stomach. After the balloon is deflated, it will be exerted naturally.

The time control method does not provide precise control of inflation, which might cause the balloon to inflate before entering the stomach. The smooth flow of *Ullorex* from mouth to stomach is not fully predictable, and the precise calculation for the duration of *Ullorex* to reach the stomach is quite difficult to be achieved. Similarly for the deflation, there might be a need to deflate the balloon before the treatment period is over. Once it happens, the *Ullorex* will be deflated and removed using endoscope intervention. These disadvantages raise a need to develop an actuation method, which allows remote activation of *IGB* inflation and deflation.

2.2.3. Summary of *IGB* development

Table 1 summarizes the liquid and gas filled balloon respectively.

<i>IGB</i> \ Characteristic	Shape	Material	Volume (ml)	Filling	Insertion and removal
<i>Taylor</i>	Oval/ Pear	Silicone	500	Saline	Endoscope routine
<i>BIB</i>	Spherical	Silicone	400- 700	Saline	Endoscope routine
<i>GEGB</i>	Cylinder	Polyurethane	200	Air	Endoscope routine
<i>Ballobes</i>	Oval	Polyurethane	400	Air	Endoscope routine
<i>Heliosphere Bag</i>	Spherical	Multi layers of polymer	700	Air	Endoscope routine
<i>Endogast</i>	Oval	Polyurethane	250- 350	Air	Surgical implant
<i>Ullorex</i>	Spherical	Thermoplastic polymer	300	CO ₂	Natural digestion

Table 2.1: Summary of various *IGBs*

The workshop at Tarpon Spring [19] tried to determine some characteristics for the ideal *IGB*. The main characteristics are the smoothness of the balloon, radio-opacity, biocompatibility, longer lifetime, and volume adjustability. There were still some unsolved characteristics such as the shape, filling medium and volume. They also suggested that the liquid filling might be more effective compared to air filling. These criterions were suggested due to the experience with the *GEGB*, which was poorly studied and tested prior being offered to the patients.

This suggestion led to the development of the second generation of intragastric balloon in the 1990s, which were liquid, filled, namely *Taylor balloon* and *BIB*. *BIB* was commercialized used worldwide, and it was reported by various studies that *BIB* is effective to help the patient lose weight. However, the good results (mean weight loss 17.8kg [10]) also come with some issues which is due to patient's intolerance. It was reported that the patients experienced nausea, vomiting and gastric pain during the first week of balloon insertion [14, 21], which is suspected due to patient's intolerance of the balloon weight.

The *Heliosphere Bag* is the third commercialized *IGB* after *GEGB* and *BIB*. In order to solve the intolerance problem, the third generation of *IGB* was filled gas. The mass of the gas filled balloon is much lighter compare to the liquid filled balloon. A 700 ml *Heliosphere Bag* only weigh 30 grams whereas 700 ml *BIB* weighs 700 grams.

The insertion and removal procedure also became an important discussion topic during the workshop at Tarpon Spring. At that time, the endoscopic procedure was considered as the most appropriate method although it will cause complications and discomfort experienced by the patient. However, the less invasive method of insertion and removal as proposed by *Ullorex* offers a more advantageous procedure compare to the prior. This natural insertion and removal method will reduce significantly the discomfort experienced by the patient due to the endoscope routine and sedation or anesthesia.

The volume of an ideal *IGB* was an unsolved issue at Tarpon Spring, since it depends on the patient's stomach size. Therefore, it is very important to provide a suitable *IGB* volume for the patient. Excessive volume of *IGB* might cause some complications such as vomiting and abdominal pain, where insufficient volume will not provide feeling of satiety. To most patients, these complications are unavoidable so that they must endure the discomfort, and pain. It becomes one of the reasons that *IGB* treatment is not very popular despite its effectiveness. Suitable volume of *IGB* could be acquired by measuring stomach's volume or by getting the patient's feedback on their stomach feeling. Both methods are not feasible for the current *IGB* because measuring one stomach volume is very difficult and during the inflation process the patient is still under either conscious sedation or anesthesia, thus patient feedback is not available due to the patient is unable to sense his/her stomach.

One possible solution of achieving suitable *IGB* volume is to equip *IGB* with capability for volume adjustment without sedating or anesthetized the patient. The implantable balloon prosthesis, Endogast [26] shows the importance of this capability of an adjustable balloon. The study on 57 patients using *Endogast* reported that there was no complaint of vomiting or abdominal pain. However, *Endogast* has a great disadvantage due to the surgical incision for its placement.

2.3. Medical Capsule Devices

The present work aims to design and develop an inflation/deflation mechanism for the development of a mechatronics weight loss system. This system consists of an inflation/deflation mechanism, wireless communication unit, micro-controller and battery. This section aims to review similar platforms of wireless ingestible system. The related works are categorized based on their functionalities, namely endoscopy, sensing, and drug delivery. Endoscopy capsules briefly describe integration of wireless communication unit, micro-controller, battery and camera into a platform that is able to transmit images. Sensing and drug delivery capsules describe mechatronics aspects, i.e. transducer and actuator. These devices also provide some insights for the design of the inflation/deflation mechanism.

The earliest ingestible medical device development was started in 1957 by the Rockefeller Institute of New York [29]. The device, called as Radio Pill was a small radio-transmitting capsule for internal organs pressure measurement. Over the last four decades, there have been many developmental works on ingestible devices which serve for various purposes such as endoscopy, sensing, and drug delivery [30]. The development of each device based on its functionality is presented at section 2.3.1 to 2.3.3.

2.3.1. Capsule Endoscopy

Capsule endoscopy was developed to examine sections of the gastrointestinal tract that are not reachable by the conventional endoscope. The length of conventional endoscope is about 1 to 1.5 m, and it only could be used for gastric, colon and partial small intestine examination. Capsule endoscopy will also reduce discomfort caused by the conventional endoscope routine. Currently, there are two commercialized capsules,

which are *Pillcam* and *Endocapsule* which are developed by Given Imaging and Olympus respectively.

2.3.1.1. M2A and Pillcam

Figure 2.6: The structure of Given Imaging capsule [31]

Given imaging is an Israel based company which developed two versions of capsule endoscopy, namely *M2A* and *Pillcam*. The structure of the Given Imaging capsule is depicted in Figure 2.6.

The M2A capsule is the first generation capsule and then followed by *Pillcam* which made some improvement from the M2A in the wide angle of view, dynamic lighting system, and higher resolution image. *Pillcam* is the improved version of M2A since the technology and design of both capsules are quite similar.

The size of *Pillcam* is slightly longer compared to *M2A*, which is 11 mm in outer diameter (OD), 31 mm in length and 11 mm OD and 26 mm in length respectively. *Pillcam* has three different versions which are dedicated for a different place of examination, the small bowel, esophagus and colon [32]. The actual picture of the capsule is depicted in Figure 2.7.

Figure 2.7 : The three different type of *Pillcam*, the *Pillcam* System: 1.*Pillcam*, 2.Skin antenna, 3. Data recorder, 4. Carrying belt [32]

The capsule comprises of three major parts, the camera, communications module, and power supply. The picture captured by the camera is transmitted to the data recorder located outside the body. The data recorder is a hard drive to store up to 8 hours of examination data captured and transmitted by the capsule. The patient is required to attach a set of skin antenna on his or her body for transmission purpose.

Figure 2.8: *RAPID* software screenshot [32]

The capsule is removed naturally when the patient passes motion after 24 to 48 hours from the capsule ingestion [33]. The data will be extracted from the data recorder to be analyzed by the physician. The software used for the data analysis is called RAPID which screen shot is depicted in Figure 2.8.

2.3.1.2. *Endocapsule*

Olympus is a Japan based company which developed the second capsule endoscopy called *Endocapsule*. It was launched in October 2005 in Europe. It has a similar working principle with *Pillcam*, which only differs in the camera type, and real time

examination, which *Pillcam* does not provide. *Endocapsule* uses *Charged-Coupled Device (CCD)* camera instead of *Complementary Metal-Oxide-semiconductor (CMOS)* camera. The *CCD* camera has a higher resolution compared to a *CMOS* camera, but it consumes more power. *Endocapsule* is also equipped with 6 *Light Emitting Diodes (LED)* to provide automatic illumination control, in order to provide better image quality.

The real time viewer handheld, depicted in Figure 2.9 allows real time examination. It has a good advantage compared to *Pillcam* which image will only be available after the end of the 8 hours operation.

Figure 2.9: The *Endocapsule*, Data receiver set and Real Time Viewer device respectively [34]

Wireless communication through the human body is one of the challenges of the ingestible medical device technology. There is great difficulty and complexity of transmitting signal through the human body. Both capsules have significant contributions by successfully transmitting images via its wireless communication technology. Both capsules use the *Radio Frequency (RF)* wave transmission for the communication between the capsule and data receiver.

2.3.2. Sensing Capsules

There are other physical examinations, which facilitate the physician to diagnose the patient such as pH, pressure, temperature. There are several ingestible devices developed for this purpose.

2.3.2.1. Smart Pill

Smart Pill, which is depicted in Figure 2.10 [35, 36] is an ingestible sensing capsule for monitoring pH, pressure, and temperature in the gastrointestinal tract. The capsule's dimension is 26 mm length x 13 mm OD. It transmits the data wirelessly to

the data receiver located at outside of the patient body. The data receiver will store the complete record of measurement data while the capsule is in the gastrointestinal tract. A computer installed with the monitoring software called *MotiliGI* is used to analyze and calculate the data collected by the data receiver.

Figure 2.10: Smart pill and data receiver system [37]

2.3.2.2. *Bravo* pH Monitoring System

Bravo pH [38] monitoring system developed by Medtronic is developed for monitoring patient with chronic heartburn or *Gastroesophaegal reflux disease* (GERD). The placement of *Bravo capsule* is at the esophageal rather than to be at the gastrointestinal tract. The capsule prototype picture and the data receiver are depicted in Figure 2.11.

Figure 2.11: The *Bravo* pH capsule and the data receiver respectively [39]

The attachment of *Bravo capsule* on the esophagus is conducted by inserting the delivery catheter to the esophagus as depicted in Figure 2.12. Upon reaching the desired location of *Bravo capsule* placement the vacuum suction is applied. The suction will cause the vacuum chamber at the capsule is filled with the esophagus tissue. Then the locking pin is released in order to secure the attachment of the capsule to the esophagus.

Figure 2.12: The placement of bravo capsule at the esophagus [40]

2.3.3. Drug Delivery Capsules

Drug delivery device is one of the major advancement in the non invasive medical treatment technology. With the latest drugs discovery, the demand of drug delivery device is getting more attention. There are three different ingestible drug delivery devices called *Enterion*, *Intelisite* and Computer Controlled Capsule.

2.3.3.1. Enterion Capsule

Enterion capsule [41] is developed by Phaeton Research from UK. The purpose of this capsule is to provide non-invasive and engineering-based drug delivery at the selected site of the human gastrointestinal tract. The size of the capsule is 11mm OD and 32 mm length. The capsule uses a spring mechanism for drug releasing. Figure 2.13 depicts the assembly picture of *Enterion* capsule.

Figure 2.13: The *Enterion* capsule assembly [41]

Enterion is assembled with a compressed spring held by a latch filament. The filament is attached to a heater and a piston. Between the heater and the piston, a compressed spring is sandwiched. The capsule is activated when it received a low frequency oscillating magnetic field, which is transmitted by an external field generator. The magnetic field induces heating power to the coil embedded in the heater. The heat generated will break the filament and release the spring. Thus, spring force pushes the piston and the drug in the container. Due to the spring release, the pressure in the container will increase and remove off the sealing cap. Therefore *Enterion* capsule is able to release drug at the desired location by using this spring releasing mechanism.

2.3.3.2. *Intelisite* Capsule

The schematic diagram of *Intelisite* capsule [42] is depicted in Figure 2.14. The capsule body consists of two main parts, the inner sleeve and the outer sleeve. The inner sleeve could rotate and slide inside the outer sleeve. The drug is injected from the end of the screw cap to the capsule and flow to the slots located at both sleeve. At initial configuration, the slots at both sleeves are misaligned so that the drug is kept inside the inner sleeve of the capsule.

Figure 2.14: Schematic drawing of *Intelisite* capsule [42]

By using the similar concept of power transmission with the *Enterion* capsule, the *Intelisite* capsule is also activated by magnetic field. The power transmitted by the magnetic field is converted by the resistor to thermal power. The heat generated will be conducted to the NITINol actuator, which will deform at about 40°C. This deformation provides the torque to rotate the inner sleeve. The inner sleeve will rotate to the position where the slots of both inner and outer sleeve are aligned and the drug will be released.

2.3.3.3. Computer Controlled Drug Releasing Capsule

In this work [43], the drug releasing mechanism has a similar drug releasing mechanism as the *Enterion* capsule. The computer controlled capsule introduced a cell generating gas as a new actuating mechanism to push the piston. The cell which has the size of a button battery produces either oxygen or hydrogen gas. The gas producing cell is manufactured by Simatec, Herzogenbuchsee, Switzerland [44]. The gas is produced by using the electro-chemical principle. The gas is produced when the two poles of the cell are connected by an electrical conductor. The schematic diagram of the capsule is shown in Figure 2.15.

Figure 2.15: The schematic drawing of the computer control capsule [45], (1) Release orifice, (2) drug reservoir, (3) thread, (4) piston, (5) gas producing cell, (6) compressed cellulose, (7) mini switch and (8) pH-sensitive membrane

Chapter 3

DESIGN OF THE WEIGHT MANAGEMENT SYSTEM

3.1. System Overview

This project aims to develop an inflation and deflation mechanism of a weight management system. The system attempts to overcome the drawbacks of the current *IGB* treatment by equipping the system with tele-operation volume adjustment. The major drawbacks of the current *IGB* system are the discomfort, and complications experienced by the patient during the treatment. The discomfort is inflicted by the insertion and removal method while the complication is due to patient intolerance of the *IGB* volume. The tele-operation would reduce the discomfort by inflating and deflating the *IGB* without insertion / removal tools, i.e. filling tube, grasper tool, endoscope, and deflation tool. The volume adjustment aims to achieve a suitable *IGB* volume thus reducing the volume intolerance. Figure 3.1 depicts the overview of the proposed *IGB* treatment.

Figure 3.1: The working principle of the weight management capsule

The procedure of the treatment is started by swallowing the weight management capsule with a glass of water. Once the device reaches the stomach cavity the balloon is inflated and its volume is adjusted using the bidirectional wireless communication. At the end of the treatment, the balloon is deflated, and hence the entire device passes through the lower gastrointestinal tract and leave the patient's body.

The inflated balloon in the stomach helps to reduce food intake by inducing feeling of satiety. By reducing the food intake, the patient is facilitated to experience weight loss. Once the treatment is over, the balloon is deflated, the gas is discharged inside the stomach and the capsule leaves the body naturally.

The system must provide a robust control system in order to ensure safety and comfort of the patient while the device is in the patient's digestion tract. In order to meet these requirements, the device are equipped with mechatronics components, and bidirectional wireless communication. Hence it is a closed loop system between the tablet and the external control system. Figure 3.2 depicts the overview of the weight management system.

Figure 3.2: Overview of the system assembly

It consists of the inflation and deflation mechanism, main control unit, communication unit and power supply. The components are covered with the capsule enclosure. The

inflation and deflation mechanism comprises of mechatronics components such as sensor and actuator, which are used to control the inflation and deflation process. The main control unit consists of *micro-controller (MCU)* and actuator driver. The *MCU* also serves as voltage regulator for the various sub-systems and the wireless *RF* transceiver. The communication unit comprises of *RF* transceiver that is operating in the medical implantable service band (402-405 MHz). The safety regulation regarding the wireless transmission through human body is regulated by *Federal Communications Commission (FCC)*, *International of Electrical and Electronics Engineers (IEEE)*, *International Telecommunication Union (ITU)* and *International Commission on Non-Ionizing Radiation Protection (ICNIRP)*. The power supply is the button battery, used for medical implant or device.

The design of the inflation and deflation mechanism was conducted in several steps. The first step is to conduct a study on the theory of balloon inflation. This study provides the parameters required for the detailed design, such as pressure, surface tension, stretch, etc. The second step is to perform conceptual mechanical design. This step will be elaborated in section 3.3. The third step is to fabricate prototypes in order to test its performance. These steps are presented in Chapter 4.

3.2. Theory of balloon inflation

3.2.1. Constitutive Equation of Balloon inflation

The main objective of the inflation/deflation mechanism is to inflate the balloon to a desired volume. The mechanism must be able to provide sufficient amount of gas. Thus studying the process of balloon inflation is important in order to obtain a model, which describes the relationship between the amount of gas in the balloon cavity and the volume of the balloon.

Figure 3.3 depicts an inflated balloon that is modeled with radius r and thickness d , and a small square cut from the balloon membrane. In the non-inflated state the radius and thickness are r_0 and d_0 respectively. The small square cut from the balloon membrane is considered as the focus of analysis.

Figure 3.3: Half spherical balloon [46]

Inflating a balloon is a process of volumetric stretch of balloon membrane. The particles that enter the balloon exert pressure on the balloon which increases the volume of the balloon.

Elastic or rubber like balloon could be modeled as Mooney-Rivlin material that is an incompressible, isotropic, hyper-elastic material. The constitutive equation for Mooney-Rivlin material is:

$$\mathbf{t} = s_- \mathbf{B}^{-1} - P \boldsymbol{\delta} + s_+ \mathbf{B} \quad (1)$$

Where:

$\mathbf{t}$ = Stress tensor of balloon membrane

s_-, s_+ = Mooney-Rivlin elastic constant

$\mathbf{B}$ = Stretch tensor

P = Pressure of the internal balloon

$\boldsymbol{\delta}$ = Kronecker's delta

In the matrix form:

$$\begin{bmatrix} t_{\lambda\lambda} & 0 & 0 \\ 0 & t_{\mu\mu} & 0 \\ 0 & 0 & 0 \end{bmatrix} = s_- \begin{bmatrix} \frac{1}{\lambda^2} & 0 & 0 \\ 0 & \frac{1}{\mu^2} & 0 \\ 0 & 0 & \lambda^2 \mu^2 \end{bmatrix} - P \begin{bmatrix} 1 & 0 & 0 \\ 0 & 1 & 0 \\ 0 & 0 & 1 \end{bmatrix} + s_+ \begin{bmatrix} \lambda^2 & 0 & 0 \\ 0 & \mu^2 & 0 \\ 0 & 0 & \frac{1}{\lambda^2 \mu^2} \end{bmatrix} \quad (2)$$

The derivation of the constitutive equation could be referred to [47]. $\mathbf{B}$ is the stretch tensor that is defined as $\mathbf{B} = \mathbf{F}\mathbf{F}^T$. $\mathbf{F}$ is the deformation gradient, which is defined as

$$\mathbf{F} = \begin{bmatrix} \lambda & 0 & 0 \\ 0 & \mu & 0 \\ 0 & 0 & \lambda\mu \end{bmatrix} \text{ where } \lambda \text{ and } \mu \text{ is the deformation in biaxial loading.}$$

Figure 3.4: Rectangular balloon membrane under quasi-static biaxial loading[46]

The deformation is defined as $\begin{bmatrix} L_\lambda \\ L_\mu \\ L_v \end{bmatrix} = \begin{bmatrix} \lambda & 0 & 0 \\ 0 & \mu & 0 \\ 0 & 0 & \nu \end{bmatrix} \begin{bmatrix} L_\lambda^0 \\ L_\mu^0 \\ L_v^0 \end{bmatrix}$ where L and L^0 is the deformed length and the un-deformed length of the balloon membrane respectively. The direction of the deformed length (i.e. L_λ, L_μ, L_v) is depicted in Figure 3.4. Due to the material incompressibility $\lambda\mu\nu = 1$ such that $\nu = \frac{1}{\lambda\mu}$.

$$\text{Thus } B = \begin{bmatrix} \lambda^2 & 0 & 0 \\ 0 & \mu^2 & 0 \\ 0 & 0 & \frac{1}{\lambda^2\mu^2} \end{bmatrix} \text{ and } B^{-1} = \begin{bmatrix} \frac{1}{\lambda^2} & 0 & 0 \\ 0 & \frac{1}{\mu^2} & 0 \\ 0 & 0 & \lambda^2\mu^2 \end{bmatrix}$$

From equation 2, P could be eliminated between the three equations, and obtain

$$t_{\lambda\lambda} = \left(\lambda^2 - \frac{1}{\lambda^2\mu^2} \right) (s_+ - s_- \mu^2) \text{ and } t_{\mu\mu} = \left(\mu^2 - \frac{1}{\mu^2\lambda^2} \right) (s_+ - s_- \lambda^2) \quad (3)$$

P_λ , P_μ , and $t_{\lambda\lambda}$, $t_{\mu\mu}$ are the load and normal stresses on the surface perpendicular to the λ and μ directions respectively. Since the balloon is isotropic, thus $\lambda = \mu = r/r_0$.

The loads P_λ and P_μ are the result of the pressure difference across the balloon membrane. Since the balloon is isotropic, $t_{\lambda\lambda} = t_{\mu\mu}$ and $\lambda = \mu = r/r_0$. Thus from equation 3, it is obtained,

$$\begin{aligned}
t_{\lambda\lambda} = t_{\mu\mu} &= \left(\left(\frac{r}{r_0} \right)^2 - \left(\frac{r_0}{r} \right)^4 \right) \left(s_+ - s_- \left(\frac{r}{r_0} \right)^2 \right) \\
&= s_+ \left(\left(\frac{r}{r_0} \right)^2 - \left(\frac{r_0}{r} \right)^4 \right) + s_- \left(\left(\frac{r_0}{r} \right)^2 - \left(\frac{r}{r_0} \right)^4 \right)
\end{aligned} \tag{4}$$

Referring to Figure 3.3, by the force equilibrium in the vertical direction, the force due to pressure jumps on the cross section is equal to the total tangential force on the equatorial circular ring.

$$[p]\pi r^2 = t_{\lambda\lambda} 2\pi r d$$

Thus due to material incompressibility, $d\mathbf{r} = d\mathbf{r}_0$:

$$\begin{aligned}
[p] &= 2 \frac{d}{r} t_{\lambda\lambda} \\
&= 2 \frac{d_0}{r_0} \left(\frac{r_0}{r} \right)^3 t_{\lambda\lambda} \\
&= 2 \frac{d_0}{r_0} \left(s_+ \left(\left(\frac{r_0}{r} \right) - \left(\frac{r_0}{r} \right)^7 \right) + s_- \left(\left(\frac{r_0}{r} \right)^5 - \left(\frac{r}{r_0} \right) \right) \right) \\
&= 2 s_+ \frac{d_0}{r_0} \left(\left(\frac{r_0}{r} \right) - \left(\frac{r_0}{r} \right)^7 \right) \left(1 - \frac{s_-}{s_+} \left(\frac{r}{r_0} \right)^2 \right)
\end{aligned} \tag{5}$$

Where:

$[p] = p - p_0$ = pressure difference across the membrane (bar)

s_+, s_- = Mooney-Rivlin constant

r_0 = radius of the un-distorted balloon, when $p=p_0$ (mm)

r = balloon radius at pressure P (mm)

d_0 = thickness of the un-distorted balloon, when $p=p_0$ (mm)

Finally, by using the equation of ideal gas $PV = N(r)RT$ the pressure-radius equation could be derived to the filling-radius equation:

$$\frac{N(r)}{N(r_0)} = \left[1 + \frac{2s_+d_0}{p_0r_0} \left(\left(\frac{r_0}{r} \right) - \left(\frac{r_0}{r} \right)^7 \right) \left(1 - \frac{s_-}{s_+} \left(\frac{r}{r_0} \right)^2 \right) \right] \left(\frac{r}{r_0} \right)^3 \tag{6}$$

Where:

$N(r)$ = The amount of gas (in mol) required to inflate the balloon to radius r

$N(r_0)$ = The amount of gas (in mol) when $r = r_0$

The pressure-radius characteristic describes the relationship between the pressure inside the balloon and the volume of the balloon while the filling-radius describes the amount of gas required to inflate the balloon to a desired volume. Although the derivation is conducted by modeling a spherical balloon, the filling-radius characteristic would be used to describe a non-spherical balloon. The validation of this approach will be elaborated in further details in section 4.1.

3.2.2. *IGB* Materials

Referring to Table 2.1, there are three materials used for *IGB*, namely silicone, polyurethane, and thermoplastic polymer which is not disclosed specifically. Material with high elasticity is preferred because it could save more space as compared to inelastic material. The elasticity will also assist the balloon to return to original size after deflation.

Silicone has good characteristics such as thermal stability, chemical inertness and dielectric strength [48]. Due to these characteristics, Silicone is commonly used for medical devices and implants. However, since it is gas permeable, silicone is not suitable for gas filling *IGB*. Due to this reason, Heliosphere is designed as multilayer of polymer, where silicone is used as the outer layer.

Polyurethane is a biocompatible material, which is used for coating of cardiac pacemaker, breast implants, and intra aortic balloons [49]. In the case of disposable gloves and condoms, this material provides an alternative to latex; since latex allergy has become an increasing problem [50]. Polyurethane made *IGB* comprises of Garren-Edward, *Ballobes*, and Endogast. Since there is no issue reported of using the Polyurethane made *IGB*, thus it is feasible to be used as the *IGB* material for the weight management capsule.

The Mooney-Rivlin constant is a material dependent coefficient. Silicone, Polyurethane, Latex, and Natural Rubber are considered as Mooney-Rivlin material. The constants of each material could be obtained using the finite element

approach[51]. At the current stage of development, rubber and latex balloon would be used for the design of the mechanism.

3.3. Inflation and deflation mechanism

One of the objectives of the weight management capsule is to inflate and deflate an *IGB* in the stomach cavity without the use of insertion / removal tools, i.e. filling tube, grasper tool, endoscope, and deflation tool. Inflating a balloon requires a filling substance which is either gas and liquid. As described in section 2.2, the liquid filled *IGB* is heavier compared to gas filled, thus it causes more complications [11]. In order to reduce the discomfort experienced by the patient, the inflation mechanism will utilize gas as its filling substance.

The current *IGB* systems have the luxury of inflating the balloon using a catheter or tube. However, these tools would inflict discomfort to the patient. In order to reduce the discomfort, the weight management capsule must have the ability to inflate the balloon without inserting any filling tube.

This section aims to describe three proposed methods for the inflation mechanism of the weight management capsule, namely compressed gas in a mini cylinder, electro-chemical gas generator, and gas producing reaction. These proposed methods are dependent on the material characteristic of the balloon such as thickness, surface area, and elastic modulus. In order to make a comparison on the proposed methods, the balloon described on each section, i.e. section 3.3.1 to 3.3.3, is the rubber balloon with thickness of 0.2 mm and initial volume of 40 ml

3.3.1. Compressed gas in a mini cylinder

One of the common practices to inflate a balloon is to use a cylinder containing compressed gas. The compressed gas flow from the cylinder to a balloon until the pressure in the cylinder and the balloon is in equilibrium. The size of the inflated balloon depends on the amount of gas filled or compressed in the mini gas cylinder and the material characteristics of the balloon.

Currently the mini gas cylinder supplied by Leland Ltd, part no 40106 is one of the smallest gas cylinders which has the possibility to be used in the inflation mechanism. The dimension of the cylinder is 9.525 mm OD and 25.4 mm long. It is filled with

0.75 g of CO₂ at 58 bar, 21° C. The internal volume of the cylinder is 1 ml. The amount of gas in mole contained inside the gas cylinder is :

$$N_{CO_2} = \frac{m_{CO_2}}{M_{CO_2}} \quad (7)$$

Where: m_{CO_2} = mass of CO₂ (g)

M_{CO_2} = molar mass of CO₂ (44.0095 g / mol). Thus N_{CO_2} = 0.017041 mol.

Based on ideal gas law equation [52] ,

$$PV = NRT \quad (8)$$

Where: P = Pressure of the gas (bar)

V = Volume of the gas (ml)

N = Number of moles of gas (mol)

R = Universal gas constant: 8.314472 x 10 (ml.bar/ K.mol)

T = Temperature of the gas (K)

The CO₂ gas contained in the cylinder could expand to 411.112 ml in atmospheric pressure (1.01325 bar). The conceptual design that of the compressed cylinder is depicted in Figure 3.5.

Figure 3.5: Conceptual design of using compressed gas method

In this design, a gas valve is required to control the inflation and deflation of the balloon. The valve controls the release of gas from the cylinder to the balloon and from balloon to the external environment.

3.3.2. Electro-chemical gas generator

This method is implemented in the gas-generating cell manufactured by Simatec which is depicted in Figure 3.6.

Figure 3.6: Gas generating cells by Simatec [53]

The gas is generated when the two external poles of the cell are electrically connected with a conductor. The speed of gas generation could be controlled by varying the electrical resistance value (R) of the wire; the larger the resistance the slower is the gas production. There are currently four different sizes commercially available, which are tabulated in Table 3.1.

Size No	Diameter	Height	Capacity
1	25.0 mm	7.8 mm	950 ml
2	11.6 mm	5.4 mm	160 ml
3	7.8 mm	5.4 mm	50 ml
4	7.8 mm	3.5 mm	25 ml

Table 3.1: Various sizes of commercially available gas generating cell

Referring to the various commercial capsules described in section 2.3, the outer diameter of the capsules is about 11- 13 mm. Among the four sizes available cell number 3 and 4 which diameter is 7.8 mm have more potential to be used in the weight management capsule because they are smaller in diameter as compared with cell number 1 and 2. A conceptual design using the cascading cells is depicted in Figure 3.7

Figure 3.7: Conceptual design of the gas generator

Since each cell of no. 3 and 4 could only generate 25 and 50 ml of gas respectively, multiple cells design is required to inflate the balloon to 100-200 ml. The mechanism would require two valves that would function for balloon inflation and deflation.

3.3.3. Gas producing chemical reaction

For the selection of the gas generating reaction, there are two requirements. Firstly, the reaction should happen without external energy, i.e. heat, stirring, etc. Secondly, the reagents and the products of the reaction are safe for the human body.

One of the reactions that meet the two requirements is the reaction of acetic acid (CH_3COOH) with sodium bicarbonate (NaHCO_3) or the baking soda, which are used as a leavening agent in baking. The gas generated from the reaction is carbon dioxide (CO_2) gas, which is commonly found inside the human stomach. The chemical reactions are:

The chemical reaction occurs in two steps. The product of the first reaction, $\text{H}_2\text{CO}_3_{(\text{aq})}$ is an unstable substance and it will separate itself to $\text{CO}_2_{(\text{g})}$ and $\text{H}_2\text{O}_{(\text{l})}$. From the chemical reaction, it could be observed that the coefficient of reaction for each reagent and product is equal to one. Therefore, one mole of $\text{CH}_3\text{COOH}_{(\text{aq})}$ will react with one mole of $\text{NaHCO}_3_{(\text{s})}$ and produce one mole of $\text{CO}_2_{(\text{g})}$.

3.3.4. Selection of Inflation Method

The three inflation methods described are assessed in order to select the most suitable method for the weight management capsule.

The advantage of the compressed gas is its simplicity in terms of generating gas as compared to the electro chemical and chemical reaction method. The disadvantage of this method is its high pressure. The cylinder has 1 ml internal volume and contains 58 bar CO_2 gas, that is about 56.5 times larger than the atmospheric pressure. Currently there is no gas valve available for this pressure level to be attached with the gas cylinder.

The advantage of the electro chemical cell is its low power consumption. The cell will generate gas when the two poles are connected, and the switching could be performed by using transistors. However, the cells do not allow much room for design flexibility, because there are only four sizes available. Another disadvantage of this gas cell is the gas being produced is hydrogen or oxygen. CO_2 is more stable as compared to oxygen and hydrogen that are considered as flammable gas.

The advantage of the gas producing chemical reaction is its safety tolerant. This reaction is considered safe because the compounds are commonly used for food additive. Sodium bicarbonate is used as raising agent in baking process [54]. Vinegar is a diluted Acetic acid which provides sour taste. Acetic acid and Sodium Acetate are categorized as permitted food additive under the code E260, E262 respectively [54]. The disadvantage of this method would be the actuator's power consumption which is larger as compared with the other two methods.

Safety is the most important factor in the selection of the inflation mechanism. The compressed gas cylinder and gas-producing cell have lower safety factor as compared to the gas generating reaction, especially due to the high pressure and flammable gas, respectively. Therefore, among the three methods described, namely the compressed gas, electro-chemical and gas producing reaction, the gas generating chemical reaction

is the most suitable to be implemented in the mechanism due to the safety consideration.

3.3.5. Inflation Mechanism

The main function of the inflation mechanism is to mix the two chemical reagents when it is actuated. *Ullorex* proposes one possible solution, which implements a time delay activation method. The drawback of this method is the risk of balloon inflation before it reaches the stomach. In order to overcome this drawback another mechanism is proposed. The schematic diagram of this mechanism is depicted in Figure 3.8.

Figure 3.8: Schematic diagram of the inflation mechanism

The mechanism has a similar concept with the medical syringe that consists of a cylindrical container and a plunger. The plunger slides along the cylinder to push the acid out of the container. The sodium bicarbonate is stored between the balloon membrane and the capsule enclosure. The plunger is driven by linear actuator in order to control the inflation process.

There are two types of actuators, which are considered to drive the plunger, passive and active actuator. Spring is categorized as a passive actuator. The spring-based actuation is implemented by *Enterion* capsule. The main advantage of spring is the broad range of miniature springs available in the market. However, it only works in unidirectional manner and it does not provide position control. Linear motor, and rotary motor coupled with linear mechanism is categorized as an active actuator. In contrary to the passive actuator, it works in multi-directional manner and provides

position control. Due to these advantages, the active actuator is preferred, even though passive actuator offers size that is more compact.

Driven by the active actuator the plunger is able to slide along the container. The plunger, with radial force acting on the inner wall of the container would prevent any gas leakage, and hence it could serve as a gas valve. However, this radial force also exerts friction force along the axial direction. The actuator is required to exert sufficient force to overcome the friction force. The free body diagram of the piston of the proposed mechanism is depicted in Figure 3.9

Figure 3.9: Free body diagram of the plunger for the inflation mechanism

Using Newton second law [55]:

$$\Sigma F = m . a \quad (9)$$

$$F - f_s - F_p = m . a \quad (10)$$

Where F : Force generated by the mechanism.

f_s : Static friction force between the rubber and syringe inner wall.

F_p : Force generated by the pressure of the fluid inside the syringe.

$$F_p = P . A_p = P . \pi r^2 \quad (11)$$

Where P : Pressure inside the syringe

A_p : Cross sectional area of the plunger, that is assumed as a circle

r : Inner radius of the syringe internal wall.

The static friction force [56] is defined as:

$$f_s = \mu . N \quad (12)$$

Where μ : Coefficient of friction between rubber and material of the syringe.

N : Normal force that is perpendicular to the contact surface between the rubber and the syringes' inner diameter.

The normal force N can be calculated from the Young Modulus of the rubber E , as follow [57]:

$$E = \frac{\sigma}{\varepsilon} = \frac{\text{Stress}}{\text{Strain}} \quad (13)$$

$$\text{Stress} = \sigma = \frac{N}{A} \quad (14)$$

$$\text{Strain} = \varepsilon = \frac{(R-r)}{r} \quad (15)$$

$$A = 2\pi r t \quad (16)$$

Where E : Young Modulus of the rubber material

σ : Stress experienced by the rubber after being inserted into the syringe.

ε : Strain experienced by the rubber due to the deformation of the rubber radius.

R : Radius of the non-deformed rubber.

r : Inner radius of the syringe internal wall.

A : Contact area between the rubber and the internal wall.

t : Thickness of the rubber.

Thus by substituting equation 14,15, and 16 to equation 13 it is obtained :

$$N = E \cdot \frac{(R-r)}{r} \cdot 2\pi r t \quad (17)$$

Lastly substituting equation 17 to equation 12 it is obtained that the static friction force is:

$$f_s = 2\pi\mu E \cdot \frac{(R-r)}{r} \cdot r t \quad (18)$$

Therefore the force generated by the mechanism need to be larger than the total opposing force in order to push the plunger and eject the acid to inflate the balloon.

$$F > f_s + F_p \quad (19)$$

$$F > 2\pi\mu E \cdot \frac{(R-r)}{r} \cdot r t + P \cdot \pi r^2 \quad (20)$$

There are three gas channels designed at the plastic enclosure. The first is the inflation channel at the anterior of the enclosure, which connects the container and the inner part of the balloon. The second is the deflation channel at the posterior of the enclosure, which connects the capsule and the external environment. The third is the interior deflation channel at the container wall, which connects the container and internal part of the plastic enclosure.

The inflation is started when the communication unit receive the inflation command signal, then the control unit will operate the actuator to push the plunger. Due to the resultant force exerted by the actuator, the acid in the syringe will be pushed into the inflation channel. Once the acid gushes out of the mechanism it will react with the sodium bicarbonate instantaneously. This reaction will generate CO_2 gas which inflate the balloon. The schematic diagram of the inflation process is depicted in Figure 3.10.

Figure 3.10: Schematic diagram of balloon inflation

3.3.6. Deflation Mechanism

After the treatment period is over, the system will be removed from the patient's body by deflating the balloon such that the size of the system is small enough to pass through the lower GI tract. The deflation process is started when the physician sends the command signal to the communication unit and then the control unit operates the

actuator to pull the plunger. The schematic diagram of balloon deflation is depicted in Figure 3.11. The syringe mechanism also functions as a valve, which controls the flow of the gas from the inflated balloon. The deflation occurs when the plunger is pulled to the position that the interior deflation channel is opened. The gas would flow out from the balloon to the stomach cavity due to the pressure difference between the internal balloon and the external environment.

Figure 3.11: Schematic diagram of balloon deflation

Chapter 4

PROTOTYPE CONSTRUCTION AND EXPERIMENT RESULT

4.1. Validation for Non-Spherical Balloon

The purpose of this experiment is to validate the implementation of filling-radius characteristic described in section 3.2.1. as the mathematical model for non-spherical balloon. Most of the rubber balloons are non-spherical due to the manufacturing process. The non-spherical shape of rubber balloon is subjected to the mould shape used during the manufacturing process that usually has a non-spherical shape rather than a spherical shape. Due to these reasons, it is very difficult to get a spherical balloon. Thus, a validation of the filling-radius would be required. The experiment is conducted by measuring the volume of the non-spherical balloon and the result is compared with the volume calculated using the filling-radius characteristic.

The balloon used in this experiment is a normal rubber balloon with 40 ml initial volume and 0.2 mm thickness that is depicted in Figure 4.1. The balloon is inflated by releasing a quantified amount of gas. The gas source used in the experiment is the CO₂ mini cylinder as mentioned in section 3.3.1. The number of mole of the inflated balloon ($N(r)$) is the number of mole of CO₂ gas in the mini cylinder is 0.017041 mol.

In order to be coherent with the formula of the filling-radius characteristic, the initial amount of gas particle inside an un-inflated balloon $N(r_0)$ needs to be measured. The $N(r_0)$ is calculated using the ideal gas equation. The volume of an undistorted balloon V_0 is obtained by using a simple method of measuring the volume of water that can be contained into the balloon. Since the water is just poured into the balloon, it is assumed that the water just occupy the initial balloon volume without exerting significant pressure to the balloon membrane. The measurement result indicates that the initial volume V_0 of the non-spherical rubber balloon is about 40 ml.

The subsequent step of the experiment is to insert the mini cylinder and a nail into the balloon. The picture of a mini cylinder, nail and deflated rubber balloon are depicted in Figure 4.1. Then the balloon is filled with 40 ml of room air using a 60 ml syringe. Lastly, the mini cylinder is punctured by knocking the nail to the cylinder's top surface. The knocking action is performed by using a rubber mallet such that the

balloon membrane would still be intact. This knocking releases the CO_2 gas and inflates the balloon to volume V . The picture of the initial volume balloon and the inflated balloon are depicted in Figure 4.2.

Figure 4.1 : The mini cylinder, nail and rubber balloon for the experiment

Figure 4.2 : Initial balloon volume V_0 , inflated balloon volume V

The volume of the inflated balloon is measured by immersing the balloon into a measurement beaker filled with 400 ml of water. The balloon volume is obtained by measuring the increment of the water level at the beaker. Although by immersing the balloon to water, the gas inside the balloon is slightly compressed by the hydrostatic pressure, this volume difference does not cause significant error to the measurement;

in fact, this measurement is a good exercise to simulate the stomach condition, where pressure in the stomach cavity is relatively higher than the atmospheric pressure.

The measurement of the balloon is depicted in Figure 4.3. The resolution of the measurement beaker is 50 ml, and the measurement reading is estimated to 10 ml resolution. The measurement cup of 50 ml resolution is considered sufficient because the aim the inflation mechanism is to inflate the balloon to the range of 200 to 500 ml volume. Due to the limitation on the instrument resolution, the estimation reading of 10 ml resolution during the volume measurement is made. This estimation would contribute to the measurement error. The measurement accuracy could be improved by using a measurement beaker with a higher resolution i.e. 10 ml resolution.

Figure 4.3: Measurement of the inflated balloon volume

Four inflated balloons are measured and each balloon is measured three times for repeatability purpose. The results of the measurement are tabulated in Table 4.1.

	1 st measurement	2 nd measurement	3 rd measurement	Average
1st	410 ml	400 ml	410 ml	406.67 ml
2nd	400 ml	410 ml	410 ml	406.67 ml
3rd	400 ml	410 ml	400 ml	403.33 ml
4th	400 ml	400 ml	410 ml	403.33 ml
Total average				405.00 ml

Table 4.1: The measurement result of volume of inflated balloon

There are some variations on the volume measurement observed from Table 4.1. There are three possibilities that could cause the variations. The first possibility could be due to the volume of finger immersed while holding the balloon. Another possibility could be because of the balloon deformation due to the buoyancy force acted on the balloon. The third possibility is due to the limitation in the resolution of the measurement beaker.

The measurement result is compared with the calculation of using equation 6. The radius of non-inflated balloon (r_0) was calculated as $V_0 = \frac{4}{3} \cdot \pi \cdot r_o^3$, where V_0 assumed to be 40 ml, thus r_0 is 21.22 mm. The $N(r_0)$ was calculated using the ideal gas equation

$$[52] \quad N(r_0) = \frac{p_0 V_0}{RT}$$

where: p_0 = The external pressure, taken to be atmospheric pressure = 1.01325 bar

V_0 = The un-distorted balloon volume = $40 \times 10^3 \text{ mm}^3$

R = Universal gas constant = $8.3144 \times 10^4 \text{ mm}^3 \text{ bar} / \text{K.mol}$

T = Room temperature = 297 K

Calculating using these parameters, the value of $N(r_0)$ is 0.001639 mol. Most rubber balloons are made by dipping a mould into a liquid latex bath so that a thin layer of latex bath sticks to the mould. Therefore, the rubber layer may flow when the mould is lifted from the latex bath. This manufacturing process causes the non-uniformity of balloon thickness.

The balloon initial thickness d_0 is measured using vernier caliper at five different places of the balloon. It is verified during the d_0 measurement that the measured value varied from 0.2 to 0.24 mm. The average d_0 based on the five measurements is 0.22 mm.

The solution of the radius of the inflated balloon r from equation 6 is 45.68 mm or volume of 399.14 ml. The experiment result of 405.00 ml has an error of 1.47 % with respect to the theoretical calculation using equation 6. The result of the volume of the inflated balloon using the filling-radius characteristic and the experiment are quite consistent.

Since the experiment is conducted by using only one input value of 0.017041 mol of CO_2 , the result is not sufficient to characterize the rubber balloon inflation. The limitation on the input variation was inevitable due to the equipment unavailability. Although there was only one result generated from the experiment, it shows a consistency of the calculated balloon volume and the measured balloon volume. Therefore, the filling radius relationship is feasible to be used to describe the inflation and deflation process of the non-spherical rubber balloon.

4.2. Characterization of the Gas Generating Reaction

The purpose of the experiment is to determine the amount of chemical reagents required in order to inflate the balloon to a desired volume. The experiment was conducted by mixing acetic acid and sodium bicarbonate inside a rubber balloon. The chemical reaction equation of acetic acid and sodium bicarbonate comprises of two steps reactions. The first reaction produces unstable carbonic acid (H_2CO_3) solution that would self decomposes to CO_2 gas and water. The two steps chemical reactions are expressed as:

Based on the reaction stoichiometry each substance in both reactions has the same molar coefficient proportion. It means that one mole of acetic acid would react completely with one mole of sodium bicarbonate and generate one mole of carbon dioxide. The molar mass of acetic acid $M_{\text{CH}_3\text{COOH}_3}$, Sodium bicarbonate M_{NaHCO_3} and carbon dioxide M_{CO_2} are 60.05 , 84.007, 44.0095 g/mole respectively.

Referring to the mechanism described in section 3.3.5, the acetic acid solution would be stored inside the container while the sodium bicarbonate would be stored in the balloon inner membrane. The reaction requires sufficient amount of water since it is the ionic reaction of acid and alkaline. Thus in the inner balloon membrane, the sodium bicarbonate powder should be diluted with water required by the ionic reaction.

The volume of the container is limited by the space constraint of the capsule plastic enclosure which volume is about 1-2 ml. In order to simulate the working concept of the mini syringe mechanism, the materials used in the experiment were a 2 ml

measurement tube, acetic acid (Merck, Germany), sodium bicarbonate powder, and rubber balloon. The number of moles N of 2 ml of acetic acid (density = 1.049g/ml) is equal to 0.0349 mol. The acetic acid reacted completely with 0.0349 mol of sodium bicarbonate. Figure 4.4 depicts the materials used for the experiment.

The experiment was started by preparing 10 ml of sodium bicarbonate solution. The solution was obtained by diluting 5 g of sodium bicarbonate with 10 ml of water. Subsequently a tube filled with 2 ml of acetic acid solution (80% mole concentration) was also inserted to the balloon. In order to be consistent with equation 6, the balloon initial volume V_0 was adjusted to 40 ml. The V_0 was obtained by injecting 30 ml of air in addition to the 10 ml of sodium bicarbonate solution in order to get the initial volume V_0 as 40ml. Lastly the balloon was tied and then the acetic acid was released and the reaction was observed for 2 minutes.

Figure 4.4: 2ml tube, acetic acid, sodium bicarbonate, and rubber balloon

The balloon was inflated by the CO_2 gas generated and the volume of the balloon was measured. The measurement was conducted by the similar measurement method as described in section 4.1. The measurements were repeated for different volume of 80 % acetic acid and the results are tabulated in Table 4.2.

Acetic acid			Sodium Bicarbonate			Balloon volume (ml)
Volume (ml)	Concentration	Mole	Mass (g)	Mole	Solution's volume (ml)	
0.5	80%	0.00699	5	0.0595	10	170
1	80%	0.01398	5	0.0595	10	350
1.5	80%	0.02096	5	0.0595	10	490
2	80%	0.02795	5	0.0595	10	630

Table 4.2: Result of balloon's volume measurement

These results were compared with the volume of the inflated balloon calculated by using equation 6. The value of V_0 , r_0 , $N(r_0)$ and T are 40 ml, 19.27 mm, 0.0123 mol and 297 K respectively. The solutions for equation 6 were obtained by using Maple 11 software. The results of the calculations and the experiment error are tabulated in Table 4.3.

$N(r)$ (mol)	Calculated radius (mm)	Calculated Volume (ml)	Measured volume (ml)	Error %
0.00699	33.86	162.60	170	4.35
0.01398	42.71	326.28	350	6.78
0.02096	48.91	489.88	480	2.06
0.02795	53.85	653.64	630	3.75

Table 4.3: Comparison of balloon's volume calculation and measurement

By observing Table 4.3, it shows that the results of volume measurement and calculation are quite consistent with errors shown to be less than 10 %. These experiment results show the feasibility of using 1-2 ml of acetic acid to inflate the balloon. The experiment results also confirmed the assumption of using the filling-

radius characteristic as the mathematical model of the non-spherical balloon inflation made in section 4.1.

4.3. Friction Force Measurement

The purpose of this experiment is to measure the friction force of various syringes. The measurement results are used to choose the suitable linear actuator to drive the mechanism. In order to simulate the design of the mechanism the experiment setup as depicted in Figure 4.5 is used. The equipments consist of the EZlimo linear motion slider, Gallil motion controller, Mecmesin force gauge, and disposable syringe.

The EZlimo linear motion slider simulated the linear actuator of the mechanism. The force gauge attached on the EZlimo linear motion slider was set to measure the maximum force required to push or pull the syringe plunger. The static friction of the rubber plunger and the syringe inner wall is the greatest force to be overcome in order to move the plunger.

Figure 4.5: Experiment set up of the force measurement

Therefore by measuring the maximum force required to push or pull the syringe it could provide the information for the selection of the actuator. The Galil motion controller connected to the linear motor was used to control the EZlimo speed and travel distance.

The speed and travel distance of the EZlimo was arbitrary set to be 0.15 mm/s and 4.5 mm respectively. The proposed inflation and deflation mechanism only operate in a low speed range.

Figure 4.6: 10ml, 5ml, and 3 ml syringe

The syringes used were 3 ml, 5ml, and 10 ml of Becton and Dickinson (BD) syringes as depicted in Figure 4.6 has the OD size of 10 mm, 14 mm, and 16.10 mm respectively. The maximum force measurements were conducted for both pushing and pulling of the syringe and the results are tabulated in Table 4.4.

Syringe	Max Pushing Force	Max Pulling Force
3 ml	0.94 N	1.23 N
5 ml	2.37 N	2.07 N
10 ml	3.35 N	3.47 N

Table 4.4: The result of the maximum force measurement

One possible actuator to drive the mechanism is the linear actuator supplied by Faulhaber Smoovy motor. It is a combination of micro brushless dc motor and a gear head of 125:1 reduction ratio. The maximum linear travel distance is 7 mm. The continuous operation force is 2.8 N and the intermittent operation force is 4.2 N. The nominal voltage is 3 V, and no load current is 0.047 A and it is up to 0.085 A. The more detailed information of the linear actuator, can be referred to the data sheet attached on Appendix B.

From the measurement results it could be observed that the maximum force required to push or pull the plunger of the 3 ml and 5 ml syringe's sizes are still lower than the maximum continuous pushing and pulling force (2.8N). The force required for the

pushing or pulling can be lowered by reducing the operating speed. Therefore, the linear actuator is selected to be used for the mechanism.

4.4. Prototype of the Inflation and Deflation Mechanism

The objective of the first prototype is to build and test the inflation and deflation mechanism described in section 3.3.5 and 3.3.6. The prototype was designed using SolidWorks and the assembled mechanism is depicted in Figure 4.7. The prototype comprises of a fixture base, actuator housing, connectors housing and syringe housing. The mechanical design of the prototype sub-section are described respectively in the following paragraphs

Figure 4.7: Conceptual design of the first prototype (dimension is in mm)

Figure 4.8: Fixture base sub-section

The fixture base serves as the reference structure for the entire mechanism. The dowel pins are provided in order to assist the positioning and alignment of the actuator housing, connectors housing and syringe housing respectively. The fixture base is made of 70 mm x 20 mm x 4 mm of aluminum plate that is depicted in Figure 4.8. The two 2.50 mm slot located in the middle of the fixture base and two M2 x 6 mm length screws are used to attach the actuator housing, connectors housing and syringe housing to the fixture base. Six dowel pins are located on the fixture base in order to improve the alignment of each part during the assembly process. Misalignment of the parts configuration will exert a radial force on the actuator. The purpose of this configuration is to keep the displacement of the leadscrew to be less than its allowable axial and radial displacement, which is 0.03 mm and 0.15 mm respectively.

Figure 4.9: Connectors housing sub-section

The connectors housing connects the actuator and the plunger. The connectors allow the linear actuator to push or pull the syringes' plunger. The connectors housing consists of an actuator connector, plunger connector, ball bearing holder and two sliding pins that are depicted in Figure 4.9. The actuator connector is a 7.50 mm x 3.00 mm x 1.50 mm aluminum plate. It has a M1.6 x 0.2 mm pitch tapped hole, and two 0.65 mm holes. The tapped hole is coupled with the linear actuator. The sliding pins are attached to the 0.65 mm holes by using LOCTITE 648 retaining compound.

The plunger connector is a 7.50 mm x 5 mm x 2.5 mm aluminum plate. It has a 3.50 mm hole and two 0.65 mm holes. The plunger (3.50 mm OD) is attached to the

connector by being inserted to the hole, and using M1 screw to fix the plungers' position with respect to the connector.

The sliding base is a 13.00 mm x 9.00 mm x 4.00 mm aluminum plate. It has two 0.65 mm holes and 3 mm hole. The two 0.65 mm hole allow the sliding pins to move freely in horizontal direction. A ball bearing (3mm OD, 1 mm ID and 1 mm thickness) is attached into the 3 mm hole by using press-fitting method. The function of the ball bearing is to provide the axial and radial support for the actuator.

The sliding pin is a 0.65 mm OD 13.00 mm length SUS304 stainless steel rod. It is supplied by MISUMI (Item code: SFSS R-D0.65-L13.00). The function of the pins is to attach the two connectors and provide one translation degree of freedom to the mechanism.

Figure 4.10: Motor housing sub-section

The function of the motor housing is to provide the motor a fix reference position with respect to the fixture base. The housing that is depicted in Figure 4.10 consists of motor holder1 and motor holder2. The motor holder1 is a 11 mm x 9 mm x 6 mm aluminum plate, and the motor holder2 is a 11 mm x 9 mm x 10 mm aluminum plate. The motor holder1 and motor holder2 parts are fastened using four M1 x 10 mm in length screws. On both part, it has two semi circle holes which dimensions are 3.4 mm in diameter, 6 mm in depth and 3 mm in diameter, 5 mm in depth. The function of

these holes are On both The linear actuator is the *Smoovy* linear actuator 03A S3 which dimension is 3.4 mm OD and 22.85 mm in length.

Figure 4.11: Syringe housing sub-section

The function of the syringe housing which is depicted in Figure 4.11 is to provide a fix reference position of the syringe with respect to the fixture base. It is a 12 mm x 9 mm x10 mm aluminum plate. It has a semi circle hole of 6.58 mm diameter. The syringe (6.60 mm OD) is press lightly into the semi circle hole. In order to ensure the clamping of the syringe, an insulating tape is attached around the syringe to the syringe holder. The engineering drawings of the first prototype are attached in Appendix F.

Figure 4.12: Experiment set up of first prototype

Figure 4.12 depicts the experiment set up for the prototype of the inflation and deflation mechanism. The motor attached on the motor housing is connected to the actuator driver. The driver is Faulhaber SC1810F controller. The actuator driver has a three-phase output port for actuator connection and five inputs namely Up, Umot, GND, Unsoll, and DIR. The block diagram and the description of the inputs of the speed controller are shown in Appendix C and, Table 4.5 respectively.

Input port	Function
Up	Voltage supply for the controller electronic
Umot	Voltage supply for the motor
GND	Ground
Unsoll	Speed control where motor stops at < 0.15 V and runs at > 0.5 V, the voltage range is 0-12 V
Dir	Clockwise direction for High signal ($>3V$) and counter-clockwise direction for Low signal ($<0.5V$)

Table 4.5: Description of SC1801F connections

The actuator is a sensor less *Brushless Direct Current Motor (BLDC)*, which utilizes the back EMF for position and speed control. The pushing and the pulling actions are performed when the motor rotates at counter clockwise and clockwise respectively. A mechanical switch is connected to the Dir input port in order to control the direction of rotation. The rest of the input, Up, Umot, Unsoll, are connected to the power supply.

In this experiment, 1 ml Terumo syringe is used. Since the maximum travel distance of the actuator is 7 mm, thus the maximum volume of acetic acid stored in the 1 ml syringe is about 0.1ml. The plunger is modified in order to be fitted in to the 3.00 mm hole at the plunger connector. The fitting of the plunger into its connector is fastened using M1 screws. Since the syringe is softer as compared to the housing the fitting of the syringe to the syringe housing is done by the press fit method.

The balloon used in this experiment is a rubber balloon with 8 ml initial volume and 0.1 mm thickness. 1 gram of sodium bicarbonate is diluted into 5 ml of water and the solution is inserted to the balloon. The balloon is attached to the syringe using a small

rubber band. For inflating the balloon, the DIR input is connected to High voltage so that the actuator rotates in counter clockwise.

The power supply is configured at 3.7 V. Once the power supply is switched on, the actuator pushes the plunger and thus the two chemical will react to generate CO₂ gas. With this experiment set up the balloon is inflated to about 30 ml which is depicted in Figure 4.13. The volume of the inflated balloon could be both calculated using equation 6 and measured using the balloon dipping method.

Figure 4.13: Balloon inflation using the first prototype

For deflation, the DIR input of the actuator driver is set to Low signal so that the actuator rotates in clockwise direction. Thus, the plunger is pulled back so that the gas could flow out to the external environment through the deflation channel. The experiment set up of the balloon deflation is depicted in Figure 4.14.

Figure 4.14: Balloon deflation using the first prototype

4.5. Prototype of the Weight Management System

The first prototype described in section 4.4 has shown the feasibility of the mechanism to inflate and deflate a rubber balloon. The proposed weight management system

comprises of the inflation/deflation mechanism, wireless transceiver, micro-controller and battery. In order to test the feasibility of the system, the second prototype which integrate the components into a working system is required. At this prototype, the main focus it to overcome the challenges of integrating the different components and show its feasibility to function as the proposed weight management system. Thus, the size of the second prototype is less prioritized.

The objective of the second prototype is to integrate and assemble all the components of the weight management system. The schematic overview of the prototype is depicted in Figure 4.15. It depicts the power and signal distribution of the mechatronics components, namely the actuator, microcontroller and wireless communication units.

Figure 4.15: Schematic overview of the second prototype

4.5.1. Main Control Board

The main control board serves as the main interface and processing unit for the system. It provides the power and signal interface to the other components and the control of its operation. It consists of a micro controller (Texas instrument MSP430) and transceiver (Zarlink ZL70101).

MSP430 is a 16-bit ultra-low power microcontroller. The micro controller enables the system to interpret the received commands, adjust the operation of the capsule modules, and perform the desired task through proper activation of the actuation mechanism. The data sheet of MSP430 is attached on appendix D.

ZL70101 is an ultra low power, high bandwidth RF link for medical implantable applications. The data sheet of ZL70101 is attached on appendix E. The

communication unit consists of a base station and a device station. The base station is located outside of the human body where the device station is inside the human body. The transceiver has two configurations set up for both stations. When it is configured as the device station, it is usually asleep and in a very low current state so that power consumption will be minimized.

Figure 4.16: Flow chart of the wireless communication algorithm

To enable low power consumption, it is not feasible for the wireless RF transceiver to be placed always in an active state (either in receive or transmit mode). Thus, the micro controller only activates the RF transceiver when it is required. In order to ensure smooth and effective data transmission a communication algorithm which flowchart is depicted in Figure 4.16 is implemented for the two-ways wireless communication between the device station and the base station.

The algorithm of the wireless communication consists of six phases. The first phase is when the device station is at the sleep mode in order to minimize the power consumption. To start the communication with the device station, the base station sends a wake up signal to the base station at the second phase. At the third phase, the active device station initializes radio components by performing self-calibration. Once

the device station is ready to establish the two ways communication with the device station, it sends a wake up response back to the base station at the fourth phase. At the fifth phase, the two ways communication link is established once the base station receives the wake up response from the device station. At this phase the two ways communication between the base and device station is established, such that the device station is able to receive command from the base station, i.e. command to inflate or deflate the balloon.

4.5.2. Wireless Transmission Experiment

An *in-vitro* experiment was conducted to test the performance of the wireless communication unit. The system used in this experiment consists of the main control board, antenna, battery and camera. The miniature camera consists of CCD sensor and LED that was used as a substitute of the weight management mechanism in performing wireless transmission. The experiment was conducted in *in-vitro* setting where two pieces of pork meat with thickness of 3- 5 cm were used for simulation purpose is depicted in Figure 4.17.

The command signal was programmed using Zarlink firmware. There were several command signals transmitted which were wake up, LED on/off, image capturing and transmission signals. The experiment was initiated by sending a wake up signal to the device. Upon receiving the signal, the LED of the camera was turned on, and the device station sent a return signal to the base station. Next, the base station sent a command for the camera to capture some images and sent the image back to the base station.

Figure 4.17: The setup of the *in-vitro* experiment

The experiment showed that the communication unit was able to perform two ways communication with the base station. In Figure 4.17, the computer screen depicts an image of the pigs' tissue, which was captured by the camera and transmitted to the base station.

4.5.3. Design of the Enclosure and the Weight Management Mechanism

The objective of this section is to describe the mechanical design of the system enclosures and the inflation/deflation mechanism. The exploded view of the assembly design of the system enclosure is depicted in Figure 4.18. The enclosure consists of five parts namely plug, front cover, middle cover, weight management mechanism, and rear cover. The detailed design of each part of the second prototype is described in the following paragraphs. The engineering drawings of each part is attached in Appendix G.

The function of the plug which is depicted in Figure 4.19, is to fix the balloon to the prototype. The balloon is attached to the prototype by fastening the plug to the front cover using a M5 plastic screw. The screw provides compression force that is used to clamp the balloon. The plug is made of Polysulfone (PSU) material, a medical grade engineering plastic supplied by Röchling.

Figure 4.18 : Exploded view of the second prototype

Figure 4.19. Mechanical drawing of the Plug

The front cover is attached to the main body by using the screw thread method. The pitch of the thread is 1.25 mm. The front cover has the outer diameter of 58.00 and inner diameter of 54.00 mm. A 1 mm inner diameter hole with 1.70 counter bore and depth 5 mm is used to eject the acid out of the enclosure. The hole is labeled as inflation channel as depicted in Figure 4.20. The front cover is made of transparent Poly methyl methacrylate (PMMA) material. This material is used due to its transparency that is required to observe the flow of the acid along the front cover visually.

The middle cover connects the front cover and the rear cover by providing 1.25 mm pitch thread at both ends. In order to enhance the sealing of these connections two O-rings which inner diameter is 52.00 mm and outer diameter of 53.50 mm. The weight management mechanism is attached to the middle cover using the six M1.6 screw thread as depicted in Figure 4.21. The middle cover is made of Polyether ether ketone (PEEK) material.

The rear cover, similarly with the front cover is attached to the main body by using the screw thread method. The pitch of the thread is 1.25 mm. The main function of the rear cover is mainly to provide housing to electrical components. It has the outer

diameter of 58.84 mm and inner diameter of 54.48 mm as depicted in Figure 4.22. The rear cover is made of Polysulfone (PSU) material.

Figure 4.20: Mechanical drawing of the Front Cover

Figure 4.21: Mechanical drawing of the Middle Cover

Figure 4.22: Mechanical drawing of the Rear Cover

Figure 4.23: Assembly drawings of the weight management mechanism

The weight management mechanism of the second prototype as depicted in Figure 4.23 consists of 9 parts namely the main body, actuator, actuator cover, connector 1, connector 2, pin, plunger, syringe, and ball bearing. The main body serves as the

fixture of the mechanism. The actuator, the Smoovy linear actuator, is clamped to the main body by the actuator cover at one end and a ball bearing (3 mm x 1 mm x 1 mm) at the other end. Connector 1, connector 2 and the two 1.50 mm stainless steel pins are attached to form a sliding mechanism. Connector 1 is threaded with M 1.6 x 0.2 mm pitch tapped hole that is used to mesh with the lead screw of the linear actuator, and connector 2 is drilled with 5 mm hole for the attachment. The syringe is a modified 5 ml Terumo syringe that is inserted into the syringe housing using the press fit method. A PVC tube is attached to the tip of the syringe and to the inflation channel of the front cover. The picture of actual second prototype is depicted in Figure 4.24.

Figure 4.24: Picture of the assembled second prototype

4.5.4. Integration of the Second Prototype

The objective of this section is to describe the integrated system and its components. The integrated weight management system consists of several components, namely WM mechanism, actuator driver, main control board, and battery are connected as depicted in Figure 4.25.

Figure 4.25: Picture of the integrated weight management (WM) system

(a) Top side

(b) Bottom side

Figure 4.26: Control Board and Antenna

The main control board mainly consists of a micro controller and transceiver which are MSP430 and ZL70101 respectively. The micro controller and the transceiver is soldered on to a Printed Circuit Board (PCB) which dimension is 45mm x 20 mm x 6 mm. The actual picture of the main control board and the antenna is depicted in Figure 4.26. Similarly, the size of the antenna is 33mm x 27 mm x 3 mm.

Figure 4.27: The Actuator Driver

The actuator driver used, which is depicted in Figure 4.27, is Faulhaber SC1810F controller. The dimension of the driver is 34 mm x 24 mm x 13 mm. The detailed of the actuator driver is described in section 4.4.

Figure 4.28: The Lithium-ion battery

Lastly, the system is powered by four Lithium-ion batteries with the capacity and nominal voltage of each battery is 100mAh and 3.7 V respectively. The size of the battery is 30 mm x 13 mm x 4 mm as depicted in Figure 4.28. The lithium-ion rechargeable cell (Li-ion) is one of the latest rechargeable battery technologies. Lithium-ion battery is one of the lightest rechargeable batteries available today and provides high energy density [58]. Li-ion batteries do not suffer from the memory effect and have a low self-discharge rate. Li-ion batteries are the batteries of choice in notebook computers, wireless telephones and many camcorder models. Lithium-ion batteries can be formed into a wide variety of shapes and sizes to efficiently fill available space in the devices they power.

4.5.5. *In-vivo* Experiment

The second prototype was tested in an *in-vivo* experiment, which was conducted on a one year old, 35 kg male pig at Khoo Teck Puat Advanced Surgery Training Centre (ASTC), NUH. The main objective of the experiment was to validate that the proposed mechanism could inflate the balloon inside the pig stomach using wireless transmission. The system was inserted into the pigs' stomach by gastronomy. The experiment was performed by a surgeon and two assistants. Figure 4.29 depicts the process of inserting the prototype into the stomach cavity.

Figure 4.29: Introduction of the system in to the pig stomach

The balloon used in this experiment is made of Latex with initial volume and thickness of 50 ml and 0.08 mm respectively. The syringe stores 0.9 ml acetic acid (Merck, Germany) of 80% volume concentration. The balloon stores 3 grams sodium bicarbonate (Sigma-Aldrich, Singapore) diluted to 10 ml of distilled water.

After the capsule insertion, the base station was placed near to the stomach in order to test the signal transmission. The experiment set up when the capsule was inserted into the stomach is depicted in Figure 4.30 then the stomach and the body were closed using Prolene suture.

Figure 4.30: Experiment set up outside of the pig

The base station is positioned within 15-50 cm range from the pig stomach. In order to establish the communication channel, a wake up signal is sent from the base station to the device station. The base station was connected via USB to a laptop installed with the graphical user interface (GUI) of the Zarlink communication firmware. To observe the system operation and performance, an endoscope was introduced to the stomach

cavity. From the endoscopic view, the vision of the capsule could be observed. Figure 4.31 depicts the endoscope images of the balloon before and after the inflation. The inflation was initiated when a user activate the signal transmission through the GUI. Once the transceiver received the signal, the actuator is powered to push the plunger and the gas generating reaction take place.

Figure 4.31 : Endoscopic view of the balloon before and after inflation

In this experiment, it showed that the integrated system could perform balloon inflation via the radio transmission. The inflation process took place for about 1 minute and inflated the balloon to about 200 ml. The *in-vivo* experiment demonstrated a working weight management system, which perform remote-controlled balloon inflation. Size of the system is the main limitation of the second prototype.

4.6. Miniaturization of Weight Management Mechanism

The second prototype showed the functionality of the proposed weight management system to inflate the balloon inside the pig stomach as described in section 4.5. However, the dimension of the second prototype is 58.84 mm OD and 157 mm length that is due to the size the other components namely, main control board, actuator driver and battery. The section aims to describe a miniaturized design of the weight management mechanism such that, the system is small enough to be inserted to the stomach through the mouth.

In the current endoscopy practice, an overtube (Guardus Overtube-gastric US Endoscopy) is used to protect the patient against mucosal damage during the insertion and removal of the endoscope and to prevent gas and fluid leakage. The dimension of

the overtube is 50 cm in length, 19.5 mm in outer diameter, and 16.7 mm in inner diameter. Figure 4.32 depicts an actual picture of an overtube.

Figure 4.32: Picture of the Guardus Overtube

The dimension of the overtube is taken as the requirement for the outer diameter of the prototype. The overtube is also going to be used to assist the introduction of the system to the stomach. Thus, the outer diameter of the enclosure is designed at 16.50 mm so that it could be inserted into the overtube.

One possible approach in order to design a more compact mechanism is to remove the syringe and replace it with a cylinder tube in the inner body of the mechanism. The main functions of the syringe are to trigger balloon inflation by pushing the acid and to serve as a gas valve that controls the flow of gas for deflating the balloon. The inner diameter of the cylinder determines the friction force and air tightness of the mechanism. The inner diameter is inversely proportional to the friction force exerted on the plunger. In order to design the diameter of the cylindrical tube, measurement of the outer diameter of the gasket plunger was conducted. The instrument used for the measurement is the profile projector. The instrument was configured for circular measurement with five input points. The measurements were conducted on the rubber gasket of a 5 ml Terumo syringe. Five random samples of the syringe were measured and the result of the measurement is tabulated in Table 4.6.

Sample	OD of 5 ml syringe's plunger (mm)
1	13.332
2	13.300
3	13.315
4	13.294
5	13.306
Average Diameter	13.3094

Table 4.6: Result of profile projector measurement

In order to ensure the air tightness of the mechanism the diameter of the cylindrical tube need to be smaller than the OD of the rubber gasket. The material of the cylinder affects friction force. Three possible engineering plastics were investigated, namely Polyoxymethylene (Delrin), Polyether ether ketone (PEEK), and Polypropylene (PP). The mechanical properties of the plastics are tabulated in Table 4.7.

Material	Density (g/cm ³)	Tensile strength (Mpa)	Tensile modulus (Mpa)
Delrin	1.39	65	2400
PEEK	1.28	90	3600
PP	0.905	27.5	1344

Table 4.7: Mechanical properties of Delrin, PEEK, and PP

A set of measurement block depicted in Figure 4.33, made of the three different materials with inner diameter of 13.20, 13.25 and 13.30 mm respectively, were prepared. Air leaking test and friction force was performed in order to select the diameter and material respectively. The leak test was conducted by attaching an inflated balloon to the block with a plunger of 5 ml Terumo syringe slotted in it. Then the block was dipped into a beaker filled with water and to observe the appearance of air bubble. The block was airtight when there was no bubble observed. The test was conducted on ten different samples of plunger and there was no air bubble observed on the entire set of measurement block. In order to provide the lowest friction force, the subsequent friction force measurement was conducted on the 13.30 mm blocks.

Figure 4.33 : Block samples for friction force measurement

Figure 4.34: Experiment set up of the friction force measurement

The set up of the friction force measurement is depicted in Figure 4.34. The force sensor and data acquisition card used are 6 axis ATI nano17 and NI DAQ PCI 6220 respectively. The resolution of the force sensor and the sampling frequency of the DAQ card are 3.125 mN and 1 kHz respectively.

Figure 4.35 : Friction force measurement result

The force sensor was mounted on a 30x30 mm aluminum profile that was attached on the EZlimo linear stepper motor. The force measurement was conducted by pushing and pulling a plunger along the block that was clamped on the bench vice. The linear stepper motor was configured to move at a speed of 0.4 mm/s, and a distance of 7 mm. The measurement was conducted on the 13.30 mm ID block made of Delrin, PEEK and PP. The force measured is plotted and depicted in Figure 4.35.

The measurement results show that PEEK exerts the lowest friction force. The static force causes the high increment in the earlier part of the measurement. The static force of PEEK in both measurements is 1.67 N (pushing) and 1.78 N for (pulling). Thus, the inner diameter of the cylindrical tube is designed to be 13.30 mm.

The maximum friction force measured on the PEEK is lower compared to the maximum continuous force of the actuator (2.8 N). Based on the mechanical properties, leak test, and friction force measurement, thus PEEK is selected as the material for the third prototype. The conceptual design of the third prototype is depicted in Figure 4.36 and the detailed drawings of the parts are attached in Appendix H.

Figure 4.36: Mechanical design of the third prototype

Figure 4.37: Picture of the third prototype

The prototype, which picture of the prototype is depicted in Figure 4.37, consists of three parts, the anterior enclosure, inner body, and posterior enclosure. The dimension of the inner body is 16.50 mm OD and 49 mm length. The inflation channel is located at the anterior enclosure that is a 1.20 mm diameter hole with length of 2 mm. The wall thickness of the enclosure is 1.00 mm and inner diameter of 15 mm. Thus, the dimension of the prototype is 16.50 mm OD and 50 mm length. The prototype is assembled in the manner as depicted in Figure 4.38.

Figure 4.38 : Assembly of the third prototype

The Teflon white tape is used for the assembly between the anterior enclosure and the inner body in order to prevent water leaking. An experiment was conducted in order to test the performance of the prototype to inflate and deflate a balloon. A latex balloon of thickness 0.12 mm and initial volume of 8 ml is used. 0.7 ml of acetic acid of 80% volume concentration (0.00978 mol) is injected into the cylindrical tube of the inner body. 1 gram of sodium bicarbonate (0.0119 mol) diluted into 3 ml of water is poured into the latex balloon. Then the prototype is inserted into the balloon and tightened at the posterior part. The actuator is connected to the driver located outside of the prototype and powered with 3.7 V. The picture of the described experiment set up is depicted in Figure 4.39.

Figure 4.39: *Ex-vivo* experiment set up of third prototype

The inflation is conducted by rotating the actuator in the counter clockwise direction. Once the acid is pushed out the 1.00 mm hole at the anterior enclosure balloon inflation is observed. Using the current experiment set up the balloon was inflated to about 130 ml. The picture of the inflated balloon is depicted in Figure 4.40.

Figure 4.40: Balloon after inflation

The deflation of the balloon is conducted by rotating the actuator in the clockwise direction. The sliding mechanism retracted back such that the deflation channel at the inner body which connects the cylindrical tube and the external environment, is opened. The deflation channel is opened when the actuator connector of the sliding mechanism is located 7 mm away from the ball bearing. The CO₂ gas flows out of the balloon through the posterior part of the enclosure. The picture of the deflated balloon is depicted in Figure 4.41.

Figure 4.41: Balloon after deflation

4.7. Discussion

There are 3 aspects of the system that are related to the effectiveness of the proposed system in facilitating weight loss, namely, balloon inflation, wireless transmission and safety.

As described in section 1.1, the feeling of satiety is generated by the volumetric feedback due to the food or object that occupies the volume of the stomach. Thus, the *IGB* treatment was developed in order to introduce a balloon, which occupies the stomach of the patient. The objective of this treatment is to promote weight loss by reducing the food intake of the patient.

The weight management system proposed in this thesis is using a similar methodology of reducing the food intake by occupying the volume of the stomach. In order to occupy the volume of the stomach the system needs to inflate a balloon in the stomach without insertion / removal tools that is used in the conventional *IGB* treatment. Currently there is no guideline available regarding the ideal volume of *IGB* [19] as it is subjected to the stomach volume of the patient. The proposed system uses the *GEGB* volume as the requirement for the volume of the inflated balloon, which is 200 ml. The volume of the inflated balloon in the proposed mechanism is proportional to the amount of chemicals, i.e. Acetic Acid and Sodium Bicarbonate. Thus, larger volume of the balloon can be achieved by increasing the amount of the chemical. Alternatively, deployment of multiple weight management system can be conducted when the patient requires larger volume of *IGB*.

In order to realize the proposed system some stages of development and prototyping were conducted. This chapter aims to describe the construction of the prototypes and the feasibility testing conducted. Prior to the design of the prototypes, two measurements were conducted in order to determine the amount of chemical reagents required in order to inflate the balloon to a desired volume. The first measurement was conducted by inflating a non spherical balloon using a quantified amount of gas. The second measurement was conducted by inflating the balloon using the proposed chemical reaction. The results of both measurements showed a good agreement with the calculated volume of the balloon using equation 6.

The first prototype was built in order to show the feasibility the proposed inflation and deflation mechanism which was described in Chapter 3. The mechanism was designed based on the friction force measurement of various sizes of syringe which was described in section 4.3. The experiment result showed that the prototype was able to inflate the balloon to 30 ml volume and as well as to deflate the balloon. The second prototype was then designed in order to perform system integrations of the different component of the weight management system. At the *in-vivo* experiment, the prototype showed the feasibility of inflating the balloon using the wireless two-ways communication to 200 ml. However, the size of the second prototype, which was mainly due to the size of the wireless component at that time, required the insertion of the system to the stomach to be performed invasively. Thus, the third prototype was developed in order enable the insertion of the prototype through the mouth.

In order to test on the performance of the proposed weight management system, the miniaturized main control board, antenna and battery need to be integrated with the third prototype. Unfortunately, at the time this thesis was being written, the miniaturized control board and antenna was still under development. The development of the main control board and the antenna is out of the scope of this thesis. Once the miniaturized board and the antenna are ready, it will be integrated with the third prototype. The integrated system will be then tested in *in-vivo* experiments. At these experiments, the integrated system will be inserted to the stomach through the mouth of the pig with the assistance of the overtube. Once it reaches the stomach the balloon is inflated and the system is left floating inside the pig stomach for one week. The weight of the pig will be measured daily for a week in order to observe any weight loss experienced by the pig.

Other than achieving weight loss, the proposed system must ensure the safety of the patient. In order for the system to perform the treatment without any harm experienced by the patient, the proposed method of gas generating chemical reaction, i.e. reaction between acetic acid and sodium bicarbonate, or citric acid and sodium bicarbonate, must be safety tolerant. Sodium bicarbonate is used as raising agent in baking process [54]. Vinegar is a diluted Acetic acid which provides sour taste. Acetic acid and Sodium Acetate are categorized as permitted food additive under the code E260, E262 respectively [54].

Chapter 5

CONCLUSION AND FUTURE WORK

5.1. Conclusion

In this study, a less invasive *IGB* weight loss treatment was investigated. Based on the literature review, *IGB* treatments have shown the effectiveness to promote weight loss. However, there are still several major drawbacks of the current *IGB* treatments, namely the unpleasant insertion and removal method and the complication caused by balloon intolerance. In order to overcome these drawbacks a mechatronics based weight management system that provides remote-controlled volume adjustment is proposed. The system, which consists of inflation/deflation mechanism, wireless communication unit, micro-controller and battery, is proposed.

In order to define the amount of gas required to inflate an *IGB* to a desired volume a study on the theory of balloon inflation and deflation was conducted. A validation experiment was conducted in order to extend the implementation on the inflation of a non spherical balloon. This provides the fundamental study for the author in order to further develop and design the weight management mechanism.

The inflation/deflation mechanism consists of two parts, the gas generator and the mechanical structure. Section 3.3 described the three possible ways of gas generators, and after careful selection, the chemical reaction was selected as the most suitable method. A mechanical structure that enables the remote activation of the chemical reaction has been designed.

Three prototypes were developed and tested during the course of this project. Each prototype has the objective of testing the feasibility of the weight management mechanism, performing system integration and miniaturization of the mechanism. The first prototype has demonstrated the feasibility of the mechanism to perform balloon inflation and deflation.

The second prototype focuses on integrating a system that performs wireless operation for the less invasive *IGB* treatment. The system which comprises of the mechanism, RF transceiver, micro-controller, and power supply is encapsulated with a plastic enclosure. The integrated system demonstrated remote-controlled balloon inflation in an animal trial.

The third prototype proposed a miniaturized design of the mechanism. The prototype is designed with low friction force for the sliding mechanism. The size of the prototype is 17 mm OD and 50 mm length. The prototype has performed inflation and deflation of a latex balloon.

In conclusion, an inflation/deflation mechanism for the development of a mechatronics weight loss pill has been designed and developed. An integrated weight loss system has been developed and it has demonstrated the feasibility of the mechanism to perform remote-controlled *IGB* inflation and deflation in *in-vitro* and *in-vivo* experiment.

5.2. Future Works

Although the main objective is achieved, further optimization and investigation is required in order to bring the system to the next stage of animal trial. Some of the possible directions for the future development are:

- 1) To conduct further investigation on the bio-compatibility of the balloon material. There are several possible materials such as Polyethylene Terephthalate (PET), Nylon, Polyester, etc. This study will also extend the modeling of the balloon inflation and deflation to more materials.
- 2) Currently there is insufficient study on the physiological effect of different *IGB* volume. Many cases of patient intolerance are due to unsuitable volume of *IGB*. Thus, it might be beneficial to investigate further patient tolerance of various volume of *IGB*, which will lead to obtaining the most suitable volume of *IGB*. More *in-vivo* experiments will be conducted in order to perform this study.
- 3) Exploring other chemical reactions such as citric acid and sodium bicarbonate, will help to improve and optimize the maximum size of the inflated balloon.
- 4) The current proposed mechanism is only one possible design for the inflation/deflation mechanism. Exploring other design possibilities such as using another type of actuator would be beneficial to the design optimization of the system.

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APPENDIX A: Summary of the regulations from "Obesity and the Gastric Balloon: A Comprehensive Workshop" (Tarpon Springs, Florida, March 19-21, 1987)[19]

1. STANDARDS OF CLINICAL PRACTICE

1.1. Preinsertion recommendations

Gastric balloons should be properly leak-tested. This is especially critical when free-floating devices are used because deflation and passage into the distal bowel may result. The upper gastrointestinal tract should be visualized immediately prior to insertion of a gastric balloon. Endoscopy is the appropriate method for this evaluation, the indications for which are to define anatomy and to exclude concomitant disease which would preclude the safe and effective use of the device. Documentation of a pre-insertion gastric ulcer is felt to be a contraindication to balloon insertion.

1.2. Who should insert the balloon?

The procedure should be performed only by qualified endoscopists and only in conjunction with appropriate behavior modification and dietary support. These individuals should be skilled in therapeutic endoscopy and must have available equipment for balloon removal and cardiopulmonary resuscitation. When the procedure is performed outside the hospital environment, the same standards of care apply. Training for the performance of the procedure should include attendance at a course with hands-on experience and with elements related to the global treatment of obese individuals. Specific training in preparation, insertion, and removal of bubbles needs to be provided. The hands-on experience includes practice with models and/or training with an individual qualified in the use of the device.

1.3. Insertion

Direct visualization during insertion, although desirable, is not generally necessary. Should difficulties be encountered introducing a balloon, then visualization is mandatory to ensure proper placement and to prevent complications related to balloon

inflation. Following insertion, it is desirable to confirm appropriate position and inflation of the device. This can be achieved either radiographically or endoscopically.

1.4. Removal

There are a variety of techniques allowing complete deflation and removal of free-floating intragastric balloons. New devices and modifications of existing accessories that will facilitate this activity are becoming available. Should a physician be unable to remove a deflated balloon, timely referral to another endoscopist skilled in the removal of this device is strongly recommended. Surgery for removal of a deflated balloon remaining in the stomach is not warranted in the absence of unusual clinical circumstances.

2. THE CHARACTERISTICS OF AN IDEAL INTRAGASTRIC BALLOON

The balloon should not only be efficacious but should also have low ulcerogenic and obstructive potential. A radiopaque marker is strongly recommended to allow appropriate follow-up of these devices, particularly if deflation and spontaneous small bowel migration should occur. An idealized balloon would have the ability to be adjusted to a variety of sizes. It should be constructed and composed of materials that will last for considerably longer periods of time. A balloon without edges or sharp ridges is considered preferable. Work in dog and rat models reported by some of the workshop participants suggested that larger volumes and the use of fluid rather than air as a filling medium might more effectively limit food intake and maximize weight loss. The ability to individualize volume and measure intake relative to balloon volume would be desirable. One size might not fit all; therefore, a temporary access, such as an oral or nasal cannula, could be available for several days to a week. Such access would allow stepwise, measured inflation or deflation of a gastric balloon after assessing symptomatic responses, which could include abdominal cramping, nausea, and food intake. Unresolved design variables, therefore, include balloon shape, filling medium, and inflation volume.

APPENDIX B: Linear Actuator Data Sheet

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)
			continuous operation	intermittent operation	
	mm/min	g	F _{max} N	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 ... B.

Scale enlarged M2:1

03A S3

For notes on technical data and lifetime performance
refer to "Technical Information".
Edition 2008 Jun. 9

Specifications subject to change without notice.

APPENDIX C: Actuator Diver Block Diagram

APPENDIX D: MSP430 Data Sheet

MSP430x11x MIXED SIGNAL MICROCONTROLLERS

SLAS196D – DECEMBER 1998 – REVISED SEPTEMBER 2004

- Low Supply Voltage Range 2.5 V to 5.5 V
- Ultralow-Power Consumption:
 - Active Mode: 330 μ A at 1 MHz, 3 V
 - Standby Mode: 1.5 μ A
 - Off Mode (RAM Retention): 0.1 μ A
- Wake-up From Standby Mode in less than 6 μ s
- 16-Bit RISC Architecture, 200 ns Instruction Cycle Time
- Basic Clock Module Configurations:
 - Various Internal Resistors
 - Single External Resistor
 - 32 kHz Crystal
 - High Frequency Crystal
 - Resonator
 - External Clock Source
- 16-Bit Timer_A With Three Capture/Compare Registers
- Serial Onboard Programming
- Program Code Protection by Security Fuse
- Family Members Include:
 - MSP430C111: 2k Byte ROM, 128 Byte RAM
 - MSP430C112: 4k Byte ROM, 256 Byte RAM
 - MSP430P112: 4k Byte OTP, 256 Byte RAM
- EPROM Version Available for Prototyping:
 - PMS430E112: 4k Byte EPROM, 256 Byte RAM
- Available in a 20-Pin Plastic Small-Outline Wide Body (SOWB) Package, 20-Pin Ceramic Dual-In-Line (CDIP) Package (EPROM Only)
- For Complete Module Descriptions, Refer to the *MSP430x1xx Family User's Guide*, Literature Number SLAU049

description

The Texas Instruments MSP430 family of ultralow power microcontrollers consist of several devices featuring different sets of peripherals targeted for various applications. The architecture, combined with five low power modes is optimized to achieve extended battery life in portable measurement applications. The device features a powerful 16-bit RISC CPU, 16-bit registers, and constant generators that attribute to maximum code efficiency. The digitally controlled oscillator (DCO) allows wake-up from low-power modes to active mode in less than 6 μ s.

The MSP430x11x series is an ultra low-power mixed signal microcontroller with a built in 16-bit timer and fourteen I/O pins.

Typical applications include sensor systems that capture analog signals, convert them to digital values, and then process the data and display them or transmit them to a host system. Stand alone RF sensor front-end is another area of application.

DW PACKAGE
(TOP VIEW)

TEST/VPP	10	20	P1.7/TA2/TDO/TDI
V _{CC}	2	19	P1.6/TA1/TDI
P2.5/R _{OSC}	3	18	P1.5/TA0/TMS
V _{SS}	4	17	P1.4/SMCLK/TCK
XOUT/TCLK	5	16	P1.3/TA2
XIN	6	15	P1.2/TA1
RST/NMI	7	14	P1.1/TA0
P2.0/ACLK	8	13	P1.0/TACLK
P2.1/INCLK	9	12	P2.4/TA2
P2.2/TA0	10	11	P2.3/TA1

Please be aware that an important notice concerning availability, standard warranty, and use in critical applications of Texas Instruments semiconductor products and disclaimers thereto appears at the end of this data sheet.

PRODUCTION DATA information is current as of publication date. Products conform to specifications per the terms of Texas Instruments standard warranty. Production processing does not necessarily include testing of all parameters.

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1

APPENDIX E: ZL70101 Data Sheet

Zarlink Proprietary and Confidential

ZL70101 Medical Implantable RF Transceiver Data Sheet

Features

- 402-405 MHz (10 MICS channels) and 433-434 MHz (2 ISM channels)
- High data rate (800/400/200 kbps raw data rate)
- High performance MAC with automatic error handling and flow control, typ < 1.5x10⁻¹⁰ BER.
- Very few external components (3 pcs + antenna matching)
- Extremely low power consumption (5 mA, continuous TX / RX, 1 mA low power mode)
- Ultra low power wakeup circuit (250 nA)
- Standards compatible (MICS, FCC, IEC)

Applications

- Implantable Devices e.g., Pacemakers, ICD's, Neurostimulators, Implantable Insulin Pumps, Bladder Control Devices, implantable physiological monitors
- Body area network, short range device applications using the 433 MHz ISM band.

Ordering Information

ZL70101LDG1- 48 pin QFN*, for base stations** (trays, bake and drypack)
ZL70101UBJ - die, implantable grade (trays and drypack)

* Pb Free Matte Tin ** Not for implantable use

Description

The ZL70101 is a high performance half duplex RF communications link for medical implantable applications.

The system is very flexible and supports several low power wakeup options. Extremely low power is achievable using the 2.45 GHz ISM Band Wakeup-receiver option. The high level of integration includes a Media Access Controller, providing complete control of the device along with coding and decoding of RF messages. A standard SPI interface provides for easy access by the application.

Figure 1 - ZL70101 Block Diagram

APPENDIX F: Engineering drawings of the First Prototype

APPENDIX G: Engineering Drawings of the Second Prototype

[illegible]

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS				FINISH:		DEBUR AND BREAK SHARP EDGES		DO NOT SCALE DRAWING		REVISION	
SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:											
				NAME		SIGNATURE		DATE			
DRAWN:											
CHKD:											
APPVD:											
MFG:											
Q.A.											
						MATERIAL:		DWG NO.		A4	
						PEEK					
						WEIGHT:		SCALE: 1:1		Not To Scale	
										SHEET 1 OF 2	