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A Magnetically Controlled Capsule Robot for Obesity Treatment with Intra-gastric Balloon

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***Abstract* –The intra-gastric balloon (IGB) was designed as a physiological treatment for obesity. The effect has been tested and proved in many ways. But the endoscope can cause severe discomfort to patients. In this paper, a magnetic-controlled Intra-gastric Balloon capsule robot was design to replace the traditional IGB. It is the size of a capsule and can be inflated and deflated using an external rotating magnetic field. Which is mainly divided into magnetic switch, solid chamber, liquid chamber three parts. The rotating magnetic field drives the permanent magnet inside IGB capsule robot to rotate by controlling the current. Switched on by a magnetic switch driven by a permanent magnet, the acid-base reaction produces carbon dioxide that fills the balloon. Deflating is accomplished by changing the rotation direction of the magnetic field. The structure realizes the separate control of charging and deflating by magnetic switch and a screw with different direction threads, which improves the space utilization and security. Finally, the feasibility of the structure is verified by fluid simulation. Both water and gases can flow in the desired direction. IGB capsule robot can perform the functions needed for treatment.**

Index Terms – Intra-gastric balloon, Capsule robot, Helmholtz coil, Magnetic switch

I. INTRODUCTION

With the development of economy, the problem of obesity is becoming more and more serious. According to data from 2017 to 2018, the obesity rate of American adults reached 42%, and the severe obesity rate was 9% [1]. In China, studies have shown that obesity showed explosive growth from 1993 to 2005. The incidence of obesity (according to the STANDARD of BMI≥27.5kg/m^2 of WHO) increased from 4.2% in 1993 to 15.7% in 2015. The overall incidence of abdominal obesity (waist circumference ≥90cm in men and ≥80cm in women) increased from 20.2% to 46.9% [2]. As the problem of obesity becomes more and more serious all over the world, safe and effective ways to lose weight are urgently needed.

The Intra-gastric Balloon (IGB) is designed to address obesity by placing one or more balloons in the stomach during treatment and then removing them at the end of the treatment [3]-[4]. As a weight management method used in clinical, its treatment principles are mainly three aspects. First, the balloon inside the stomach mechanically reduces the stomach's ability to hold more food, reducing the amount of food consumed at each meal. In this way, it reduces calorie intake. Second, IGB stretching the stomach wall may potentially alter the release of gastrointestinal peptides associated with satiety and energy balance, thereby increasing satiety. During the period of IGB treatment, ghrelin briefly increased, then decreased, leptin level decreased, and showed a significant long-term downward trend. There is study which has shown that IGB alone does not cause a decrease in ghrelin, but the mechanical stimulation it causes combined with caloric intake reduces ghrelin levels and ultimately leads to weight loss [5]-[6]. Third, IGB increases gastric emptying time. The process by which food is moved from the stomach into the duodenum is called GE (gastric emptying). IGB causes delayed GE. There is clinical data showing a significant increase in gastric empty time in patients treated with IGB, and GE recovery after IGB removal [7]-[8]. The longer time it takes for the stomach to empty causes the stomach to continue to dilate. The gastric mechanoreceptors continue to be stimulated, sending neural signals to the brain stem to trigger a feeling of fullness, which in turn reduces calorie intake and weight loss.

In 1985, The Gallen Edwards intra-gastric balloon was approved by the FOOD and Drug Administration (FDA) as the first intra-gastric balloon. The balloon is cylindrical structure, there is a hollow channel in the middle, through the endoscope into and out. It can be placed in the stomach for 4 months. Thus, its weight loss results are not ideal and related complications caused by withdrawal from the market [9]. In 1991, BioEnterics developed a balloon containing a mixture of salt and methylene blue that stayed in the stomach for six months. The balloon received FDA approval in 2015 to be marketed as Obalon. Obalon deglutible balloon system, in which the compressed capsules enter the stomach orally and can be self-inflated and filled up. Obese patients can take up to 3 compressed capsules orally according to their own tolerance, and then the inflatable balloon will be removed through endoscopy 6 months later [9]. Yan Liang from Beihang University published a kind of gastric balloon capsule robot with wireless power supply and communication function in 2014. The robot overcomes the defect that the balloon in the stomach needs to be taken in and out by endoscope, and uses signal transmission module, expansion module and deflating module to control the inflating and deflating of the balloon in the stomach. The inflating adopts the reaction of acetic acid and sodium bicarbonate in the module to generate carbon dioxide [10]. In 2016, Thanh Nho Do from the University of California designed a magnetically controlled soft capsule type intra-gastric balloon. The structure is double layer, the inner layer is a soft capsule, and the outer layer is a balloon made of a biocompatible material, which can avoid damage to gastric mucosa and rupture in the stomach. An external magnetic field controls an internal magnet to drive the shaft, binding the reactants together, and inflating carbon dioxide with 60 percent citric acid and sodium bicarbonate. Experiments were carried out in the stomach of fresh pig to prove the feasibility [11].

Traditional IGBs are placed, inflated, and removed using an endoscope, a procedure that can cause severe discomfort to patients. In this paper, a magnetic-controlled IGB capsule robot is taken orally to the stomach. An external magnetic field was used to control the magnetic switch composed of permanent magnets in the capsule robot [12]-[13]. Then the acid-base reactants could mix and generate gas. Filled the balloon to inflate the balloon. After the treatment, IGB was deflated by the external magnetic field to restore the size of the capsule and finally discharged with gastrointestinal peristalsis. It realizes the separate control of charging and deflating by magnetic switch and a screw with different direction threads This avoids the discomfort of the endoscope and makes it easier to control.

II. Design of IGB Capsule Robot

In terms of structural design, the reasonable IGB balloon volume is 600-650ml [14]. After comprehensive comparison of existing experiments, common sodium bicarbonate and citric acid monohydrate were used as the acid and base reactants [15]. There was no obvious reaction between sodium bicarbonate powder and citric acid powder at room temperature. As a result, the reaction chamber is designed into two parts, one for solid chamber, one for liquid chamber. Put sodium bicarbonate and citric acid monohydrate mixed powder in solid chamber. Put water in liquid chamber. The mixed powder is compressed as much as possible to fit more reactants per unit volume, thereby indirectly reducing the size of the capsule. The size of IGB capsule robot can be reduced by using magnetic control instead of electric signal control. So magnetic control is used in this paper.

A. Design of Overall Structure

The IGB capsule robot is shown in Fig. 1. The robot is divided into three parts, solid chamber, liquid chamber, and magnetic switch. Fig. 2 shows the cross section of the robot, with the screw in the middle and the external balloon ignored. After the treatment began, the patient swallowed the robot. When the magnetic switch in liquid chamber is turned on, the water in liquid chamber enters solid chamber through a gap in it. Water comes into contacting with a mixture of sodium bicarbonate and citric acid monohydrate powder in solid chamber and reacts. Carbon dioxide fills the balloon through the gas vent. After finishing the treatment, turn on the second switch in solid chamber. The gas is discharged from holes in the tail of the robot, completing the deflating process. At the same time, due to the volume reduction, it can be discharged from the patient's body along with the digestive tract. The gas vents should insert porous cotton fiber. Reduce the speed of gas discharge and prevent the leakage of contents [10]. Each module of the robot is connected by a threaded rod which is standard M4 thread. It means 0.7mm forward for every turn on the threaded rod. The orientation of screw threads on both sides of the threaded rod is different. The structural design parameters of IGB capsule robot are shown in Table I. Because it is a prototype, its size is relatively large, and on the premise of ensuring the realization of functions, it will be further reduced in the future.

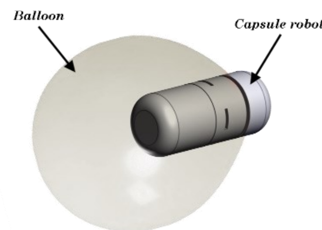


Fig. 1 IGB capsule robot

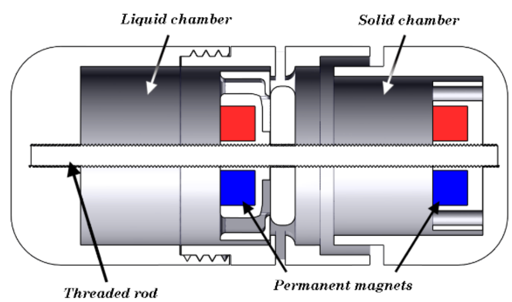


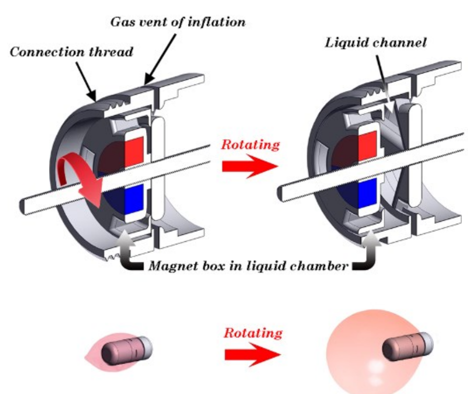
Fig. 2 Cross section of IGB capsule robot

TABLE I
The Structural Design Parameters of IGB Capsule Robot

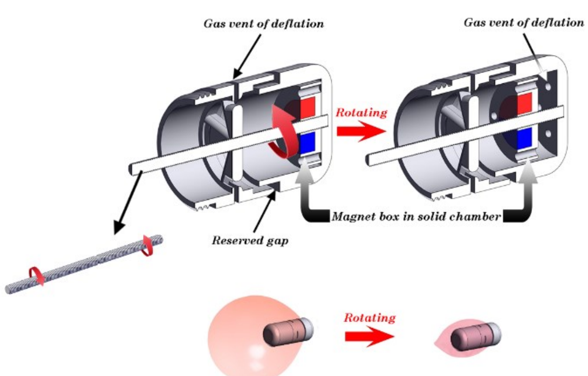
Property	IGB capsule robot
Length of the body	97mm
Diameter of the body	44mm
Diameter of threaded rod	4mm
Diameter of the permanent magnet	20mm
Volume of liquid chamber	30.15ml
Volume of solid chamber	15.83ml
Volume of balloon expansion	600ml
Material of IGB capsule robot	resin material

B. *Working Principle of IGB Capsule Robot*

IGB capsule robot is driven by a magnetic field. Through the control of magnetic field clockwise, counterclockwise rotation, to complete the two switches respectively control. Fig. 3 shows the magnetic switch working process. The middle section of IGB capsule robot contains liquid channel and gas vent. Rounded corners ensure smooth flow. The middle section is connected to the liquid chamber by connecting threads. The reserved gap is used to put the balloon and seal the rubber ring. When the switch is off, these channels are blocked by magnet box in liquid chamber. When the switch is turned on, the liquid passes through this section into solid chamber and reacts with the solid powder. The gas from the reaction enters the balloon through the gas vents in four directions. When the magnetic field rotates clockwise, the permanent magnet rotates clockwise. The permanent magnet in liquid chamber rotates in the direction of the thread. At the same time, the magnet box in solid chamber does not rotate because the threads are opposite. The structure of the magnet box in liquid chamber and middle section allows water to enter solid chamber as soon as the rotation begins. When the magnetic field rotates counterclockwise, solid chamber magnet can rise in the direction of the thread. The gas in the balloon can be expelled through gas vents. In this way, the control of charging and deflating is realized, and the possibility of misoperation is reduced. It also increases the utilization of internal space.



(a) Opening process of inflation switch



(b) Opening process of deflation switch

Fig. 3 Working process of the magnetic switch

C. *External Rotational Magnetic Field*

IGB capsule robot works by means of an external magnetic field. The external magnetic field is generated by a three-axis Helmholtz coil. The three-axis Helmholtz coil consisting of three pairs of coils. There is same current in the pair of coils. The uniform magnetic field can be generated in a certain range whether AC or DC is used. On this basis, a uniform rotational magnetic field on each plane can be generated by superposition of magnetic vectors. By controlling the current amplitude and phase of the AC power supply, the rotational magnetic field is realized in all directions [16]-[17].

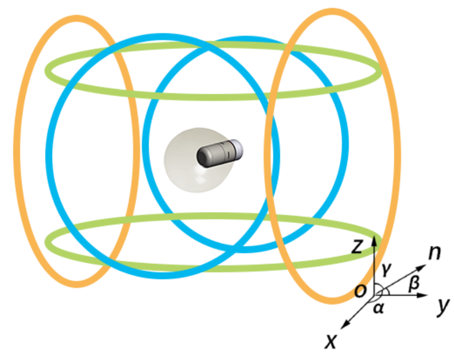


Fig. 4 IGB capsule robot in the model of three-axis Helmholtz coils

To ensure that the magnetic switch can be triggered, we need to evaluate the magnetic force generated by it. The magnetic flux density of any point in the electromagnetic field can be expressed as:

$$B = 2N \times \frac{\mu_0 i R^2}{2\left(R^2 + l^2\right)^{\frac{3}{2}}} = \frac{\mu_0 N i R^2}{\left(R^2 + l^2\right)^{\frac{3}{2}}} \tag{1}$$

where N is the number of turns in the pair of coils, μ_0 is the permeability of the vacuum, i is the electrical current of the coil, R is the radius of pairs of coils, l is the distance from point a to the coil. The spacing of a pair of Helmholtz coils is the radius of the coils. The magnetic induction intensity at the center of Helmholtz coils can be expressed as:

$$B_0 = \frac{8\mu_0 N i}{\sqrt{125}R} \tag{2}$$

The magnetic force produced by the magnetic field on the permanent magnet can be expressed as:

$$F = \iint_v \int \delta_v \cdot B dv + \oint_s \delta_s \cdot B ds \tag{3}$$

After the magnetizing material is magnetized in the magnetic field, there is magnetizing current inside and surface magnetizing current on the surface of the material. Where δ_v is volumetric magnetization current density, δ_s is surface magnetization current density.

$$\delta_v = \nabla \cdot M \tag{4}$$

$$\delta_s = -n \cdot M \tag{5}$$

where M is magnetization of the medium and n is surface normal vector. The force of the magnetic field on the magnet can be expressed as:

$$F = \iint_v \int (\nabla \cdot M) \cdot B dv + \oint_s (-n \cdot M) \cdot B ds \tag{6}$$

$$F = \iint_v \int (\nabla \cdot M) \cdot B dv \tag{7}$$

For isotropic media it can be written as equation (7).

$$M = \frac{\mu_r - 1}{\mu_0 \mu_r} B \tag{8}$$

where μ_r is relative permeability of magnetic media. The equations (9-11) can be obtained by vector operation.

$$F = \frac{\mu_r - 1}{2\mu_0 \mu_r} \iint_v \int \nabla B^2 dv \tag{9}$$

$$\iint_v \int \nabla \varphi dv = \iint_s \varphi ds \tag{10}$$

$$F = \frac{\mu_r - 1}{2\mu_0 \mu_r} \iint_s B^2 ds \tag{11}$$

There are two permanent magnets in IGB capsule robot design and the interaction between the magnets needs to be considered. When calculating the suction force of the non-contact magnet. The equation for calculating the force between two permanent magnets is shown as equation (12). The influence of the magnetoresistance in the permanent magnet and the external space leakage factors is not considered.

$$F_m = \frac{1.5}{1 + aL} \times \left(\frac{B_p}{4856}\right)^2 \times A \tag{12}$$

where a is the correction factor (a = 3~5), which the value varies with the distance between two magnets, L is the distance between two magnets, B_p is the permanent magnetization, A is the magnetic pole area of the permanent magnet [18]. In order to achieve the magnetic switching function, F is much larger than F_m.

III. Simulation Analysis

In order to verify the feasibility of the structure to realize the working process, the flow of gas and liquid is simulated with ANSYS software [19]-[20]. Moreover, it is helpful to optimize the structure design of capsule robot.

First, the liquid flow into the solid chamber is simulated when the liquid chamber switch is opened. Due to mainly observe the liquid through the middle section of the situation, selected part of the structure. The selected model sets the fluid domain and boundaries and the fluid field is set to water. As shown in Fig. 5 and Fig. 6, give an initial velocity to the water in liquid chamber and observe the flow of the liquid. Fig. 5 is the velocity streamline diagram of this part, which shows the approximate flow direction and speed of the liquid. Fig. 6 is the velocity contour diagram of this part in two different cross section directions. Two sections are selected to observe the effect of liquid on gas vents and liquid channels respectively. As is shown in it, the velocity is relatively stable and uniform except in the magnet box where the liquid passes through. The gas vent which inflates the balloon in the middle section has little flow velocity. Through this structure, water from liquid chamber can flow smoothly into solid chamber with as little access to the gas vents as possible. The rounded corners are good for channeling water into the solid chamber.

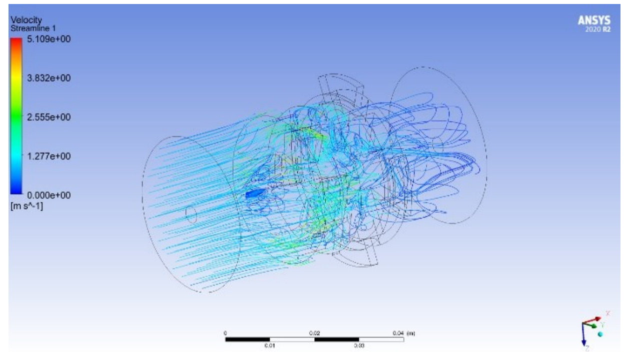
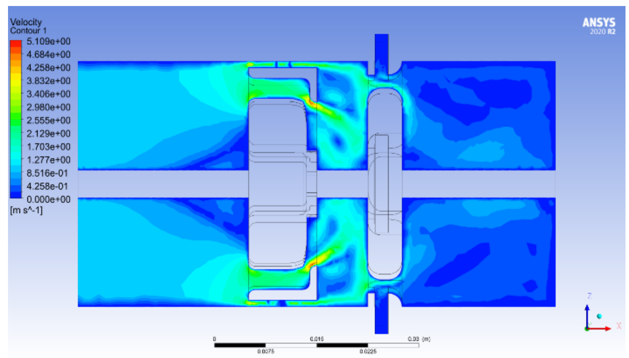
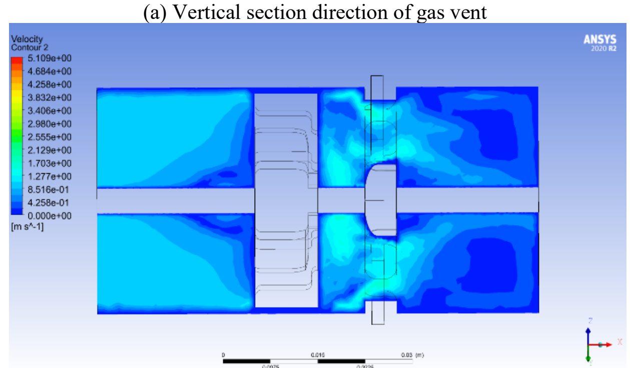


Fig. 5 Streamline diagram of water entering velocity



(a) Vertical section direction of gas vent



(b) Vertical section direction of liquid channel

Fig. 6 Contour diagram of velocity water entering

As the reaction begins, a large amount of carbon dioxide gas is produced, which rapidly fills the robot and flows toward the balloon by the gas vents. The chemical equation of citric acid monohydrate and sodium bicarbonate is

$$C_6H_8O_7 \cdot H_2O + 3NaHCO_3 = Na_3C_6H_5O_7 + 4H_2O + 3CO_2 \tag{13}$$

According to the calculation of the equation, every 210g of citric acid hydrate completely reacts with 252g of sodium bicarbonate in sufficient water to produce 132g of carbon dioxide. Therefore, the ratio of citric acid monohydrate to sodium bicarbonate solid powder should be set to 5:6. The gaseous density of carbon dioxide is 1.997g/L(0°C,101.325kPa). It takes 1.1982g of carbon dioxide to fill a 600ml balloon, which needs 4.193g of mixed solid powder. In other words, a fully reacted 4.193g mixed solid powder is sufficient to fill the required balloon size. The relationship between reactant weight and gas volume is shown in Table II and Fig. 7. In the case of a complete reaction, each reactant has a linear relationship with the gas volume. Since the robot still occupies some volume in the balloon, the volume occupied by the robot should be removed from the calculation. The simulation of gas filling balloon is shown in Fig. 8, the fluid field is set to carbon dioxide, and the entrance surface of gas vent is set as the velocity entrance surface. The gas expands the balloon rapidly in four directions after the reaction beginning. The flow rate of gas from the gas vents gradually slows down.

TABLE II
THE RELATIONSHIP BETWEEN REACTANT WEIGHT AND GAS VOLUME

Gas volume (ml)	Powder quality(g)		
	Citric acid monohydrate powder	Bicarbonate powder	Mix powder
100	0.3177	0.3812	0.6990
200	0.6354	0.7625	1.3979
300	0.9531	1.1437	2.0969
400	1.2708	1.5250	2.7958
500	1.5885	1.9062	3.4948
600	1.9062	2.2875	4.1937

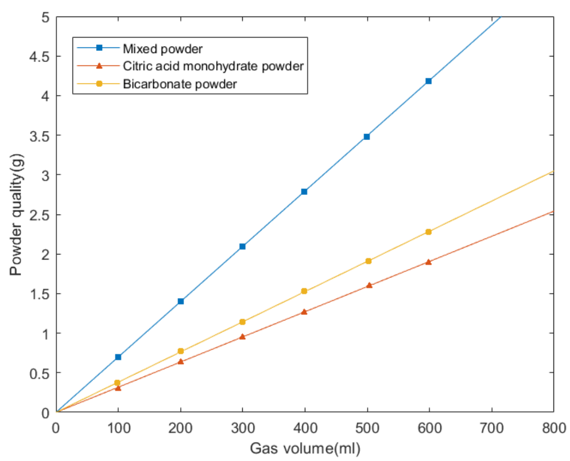


Fig. 7 Linear plot of reactant weight versus gas volume

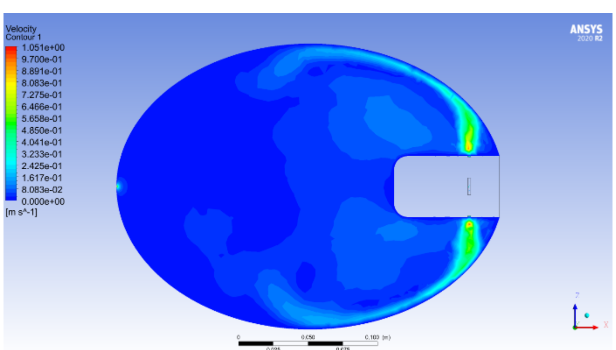


Fig. 8 Contour diagram of inflating gas velocity

When the treatment is complete, solid chamber switch is switched on. The gas is discharged from the robot tail vents, as shown in Fig. 9 and Fig. 10. As the main observation of gas discharge process, the latter part of the robot is selected and the fluid field is set to carbon dioxide. The entrance surface of gas vent is set as the velocity entrance surface, and the surface of the robot tail vents is set as the outlet surface. It can be seen from the simulation that the gas flow rate increases as the channel narrows, so it is necessary to put cotton in the vent at the tail to ensure safety.

The simulation shows that the flow direction can meet the requirements of IGB capsule robot. Water can preferentially enter solid chamber for reaction. The gas can go into the balloon and out of IGB capsule robot.

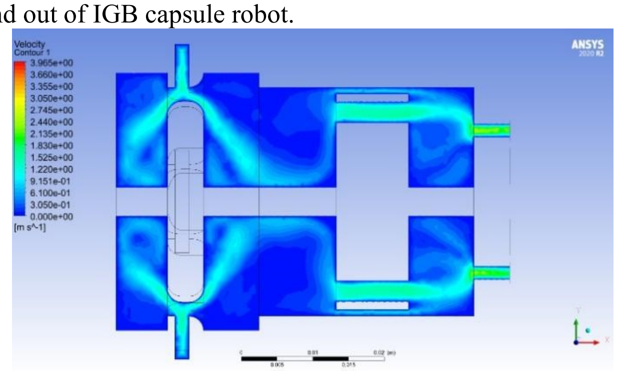


Fig. 9 Contour diagram of gas outing velocity

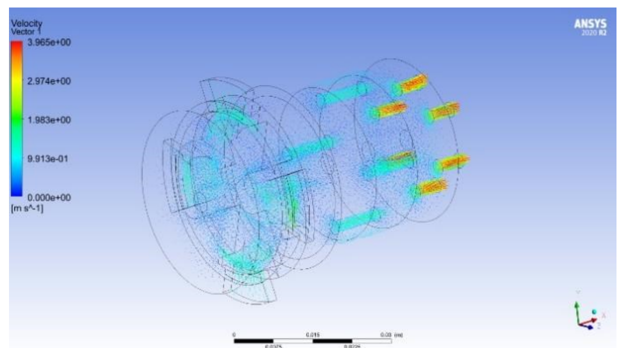


Fig. 10 Vector diagram of gas outing velocity

IV. CONCLUSIONS AND FUTURE WORK

In this paper, a capsule robot was designed for weight loss. It works by placing balloons in the stomach. The IGB capsule robot stores reactants, which consist of citric acid monohydrate and sodium bicarbonate. The carbon dioxide from the reaction filled the balloon. Reactants and products are safe to the stomach environment. The balloon is inflated and deflated by a set of magnetic switches driven by an external magnetic field. By changing the current, the magnetic field intensity and rotation direction in the three-axis Helmholtz coil are controlled. There is a threaded rod with two thread directions in this structure. Two switches can be opened by rotating the magnetic field clockwise and counterclockwise respectively. To realize the external magnetic control of the gas work. The required reactant mass was obtained by calculation. Through simulation, both water and gases can flow in the desired direction. The IGB capsule robot increased controllability and utilization of interior space by optimizing the structure design and control method.

In the future, the prototype will be completed and further consideration will be given to positioning the rotating magnetic field.

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