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A Novel Multi-biopsy Mechanism Embedded in a Capsule Endoscope for Colonoscopy

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***Abstract* – This paper presents a novel multi-biopsy mechanism embedded in a capsule endoscope. The biopsy device can perform multiple samplings and save the tissue separately for each sampling. It consists of a trigger with a lever, a cutter, a storage module and drivetrain of gear transmission connected with a torsion spring. The cutter is driven via one small gear which can be driven at higher speed by a larger gear connected with the torsional spring. The basic idea to sample the suspected pathological tissue from the lining of the colon is that the cutter with sharp edge rotates at high speed so that the tissue pressed to the surface of capsule can be cut where a part of blade skims out of surface of capsule. Owing to the cutting can be finished within very short time, the tissue can be avoided to be teared as it happen sometimes in traditional biopsy. A trigger can be activated via a lever multiple times. In addition, this method is expected to be used in tumor resection through multiple samplings. In this paper the basic principle of the new multi-biopsy mechanism is analyzed as well as a preliminary prototype made by a 3D printer is built, and finally the feasibility of the proposed biopsy device was preliminarily verified via taking biospies from a piece of pig skin.**

Index Terms* – Capsule Endoscope, Mechanisms Design, Multi-biopsy .

I. INTRODUCTION

At present, capsule endoscopes have been widely used in clinical practice. There are five companies which dominate the capsule endoscopes market such as Medtronic (Pillcam-SB3), Intromedic (Mirocam), Olympus (EndoCapsule), JINSHAN Science and Technology (OMOM) and Capsovision (CapsoCam Plus) [1]. Comparing to conventional endoscope, Capsule endoscopy cause almost no discomfort to patients and even reduce medical specialists workload.[2-5] Although the capsule endoscopes are successfully used for bowel diagnosis using images alone, the current capsule endoscope lack biopsy function. In order to exactly diagnose the disease, Doctors will get samples by the traditional endoscope which cause additional cost and discomfort.

Many researchers are making efforts to proposed a capsule endoscope with an integrated biopsy function. Currently, there are mainly two categories biopsy methods embed into capsule endoscope. The first is taking tissue sample by means of biopsy forceps. Sunkil Park et al. [6] designed a biopsy forceps device that uses a crank slider driven by the Torsion spring to achieve a biopsy. The trigger mechanism consists of a Polymer string and an SMA heating wire, which is triggered by melting the Polymer string. Wen-Wen Chen et al. [7] designed two biopsy devices that driven by a motor, one is sleeve-jaw with screw and sleeve, and the other is slide-jaw using slid1ing. Xiaofei Pan et al. [8] proposed biopsy forceps driven by a rack and pinion. Although the biopsy forceps can better take the tissue sample, there are many problems that they are easy to accidentally injure patients and can only be sampled once. The second is to sample by rotating the blade. The tissue is embed into the capsule and cut out with a razor blade. Kyoung-chul Kong et al. [9] proposed a biopsy device which consists of a trigger with paraffin block and rotational razor blade with a torsion spring. It uses a coil to heat the melted wax block to complete the trigger. In addition, Kyoungchul Kong et al. [10] designed a biopsy device that can observe the polyp and biopsy it with the visual feedback in real-time. It used the electric energy to heat the chip resistor to complete the trigger. Massimiliano Simi et al. [11] designed a mechanism for tissue sampling in the small bowel. Magnetic torsion spring is composed by coaxial cylindrical diametrically magnetized permanent magnets. This structure using the rotational blade is relatively simple and can avoid accidental injury to patients. But there still have problems on multi-biopsy. In addition, there are some novel sampling methods. Sehyuk Yim et al. [12] propose a magnetic capsule endoscope which can release micro-grippers (u-grippers) and retrieve them after they have self-folded to grab tissue samples. Donghoon Son et al. [13] proposes a magnetically actuated soft robotic capsule robot, which takes biopsy samples using a fine-needle biopsy technique.

The biopsy device embedded in capsule endoscope can only be sampled once. To overcome this problem, we present a novel multi-biopsy mechanism embedded in a capsule endoscope for colonoscopy in this paper. The biopsy device can perform multiple samplings and save the tissue separately for each sampling. In this article, the multi-biopsy mechanism was designed and a preliminary prototype is made by a 3D printer was built. Finally, the feasibility of the proposed biopsy device was preliminarily verified.

II. DESIGN OF THE MULTI-BIOPSY MECHANISM

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The biopsy device consists of three plates, a spiral spring, a trigger lever, a storage, a cover, capsule shell, two gear shafts and the cutter and stop baffle is fixed to one of gear shaft, as shown in Fig.1. The biopsy device can perform multiple samplings and save the tissue separately for each sampling. There are many studies on the control of capsule motion by magnetic field [14-16]. The movement of the capsule in the intestine is achieved by means of a magnet to control the capsule[4]. The acceptable diameter of the prototype is 36 mm and the thickness of the capsule aperture is 5 mm. Its working principle is as follows:

(1) The external torque rotates the gear shaft to accumulate the torsional spring. After the accumulator is completed, the gear is at rest and the cutter is stationary due to the action of the stop baffle, as shown in Fig. 2(a). The physician controls the capsule in the intestine through a magnetic medium, and a suspicious location can be found in the image receptor. The materials of biopsy device are diamagnetic stuff. External magnetic field does not affect the action of the biopsy mechanism.

(2) When the capsule moves close to the sampling position, physician pulls the string and the lever releases the limit. The gear shaft starts to rotate under the elastic energy installed in the torsional spring, which leads to quick rotation of the cutter. The lever is reset by the action of the tension spring., as shown in Fig. 2(b).

(3) The cutter can rotate quickly and cut the tissue outside close to the surface of the capsule because the distance of its rotational center to the shell of capsule is shorter than the radius of the cutter. Then, the tissue is restored inside of the cutter. After the stop block has whirled one circle, it is again resisted by the lever. The tissue is thrown into a certain place on the receiver groove owing to its inertia as shown in Fig.2(c).

(4) At the same time, a string rotating around and fixed on the gear shaft pulls the receiving structure to rotate, which can result that the sampled tissue can be stored in different grooves as shown in Fig.2(c).

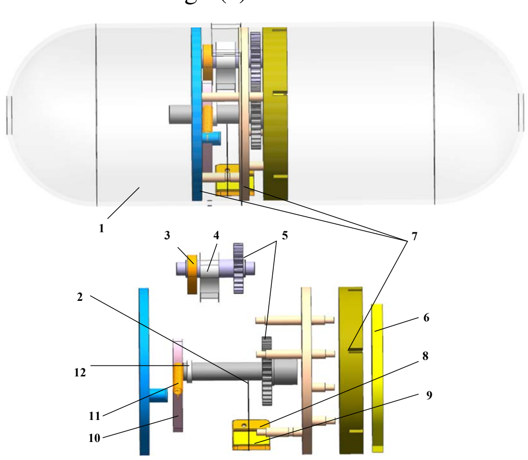
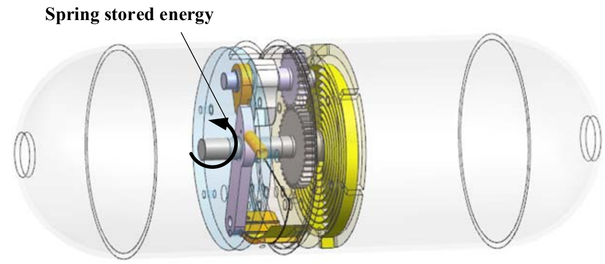
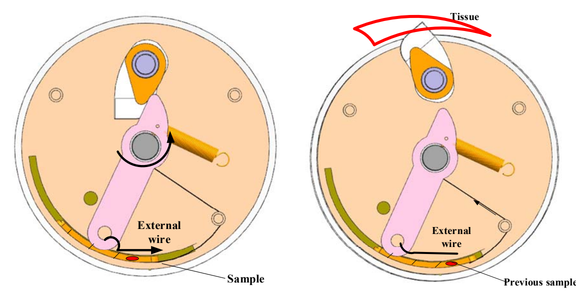


Fig. 1 Schematic diagram

1-Capsule Shell 2-String 3-Stop Baffle 4-Cutter 5-Gear Shaft 6-Spiral Spring 7-Plate 8-Storage 9-Cover 10-Lever 11-Spring 12-ring



(a) Initial state



(b) Triggering (c) Taking a biopsy

Fig. 2 Working multiple (a)-(b)-(c)

III.Design and Fabrication of prototype

A. The Energy Storage Unit

The spiral spring acts as an energy storage component that determines the cutting force and cutting speed of the blade. Therefore, there is a need for a spiral spring that can store higher energy. In order to extract the tissue, the cutter should be able to apply a shear stress larger than the destructive stress ($\tau_{des} = 20MPa$ [17]) of the tissue. The force that the cutter applies to the tissue can be calculated by the following formula

$$F_\tau = ts\tau_{ex} \quad (1)$$

where τ_{des} is the destructive stress; t is the thickness of the sharp edge of a blade and s is the effective width of the cutter. Then, the torque of output shaft can be calculated by

$$T_2 = F_\tau l \quad (2)$$

where F_τ is the force that the cutter applies to the tissue and l is the length from the edge of the blade to the axis of the output shaft. The torque of the input shaft T_1 can be calculated as

$$T_1 = \frac{T_2}{\eta i} \quad (3)$$

where T_2 is the torque of the output shaft, η is the transmission efficiency and i is the transmission ratio. Finally, the output of the spiral spring T_s is equal to T_1.

The spiral spring has a non-contact flat spiral spring and a contact-type flat spiral spring. Non-contact type flat spiral springs are generally used to generate reaction torques, and contact-type flat spiral springs are often used to store energy. Here, the contact-type flat spiral spring is used for the energy storage unit. In order to complete multi-biopsy, T_s should be greater than minimum output torque T_{s1}. The maximum output torque T_{s2} and T_{s1} of the spiral spring are calculated as follows

$$T_{s2} = K\frac{bh^2}{6}\sigma_b \tag{4}$$

$$T_{s1} = 0.6T_{s2} \tag{5}$$

where K is a fixed coefficient that is related to the fixed end, b is the width of the spiral spring, h is its thickness and σ_b is the tensile strength limit of the spring material.

B. Drivetrain

The cutter with sharp edge rotates at high speed, but the spiral spring cannot offer the high speed rotation. Taking into account the limitations of the size of the capsule structure, we took the gear shaft as the drivetrain. The gear shaft is actuated by the spiral spring, and the gear pair plays the role of increasing speed and transmitting force. Here we have initially selected the gear pair that $i = 5/7$. Owing to the cutting can be finished within very short time, the tissue sample can be avoided to be teared and tissue bleeding.

C. Trigger Module

The trigger module consists of the block and lever as shown in the Fig.3. The stop baffle is fixed to the gear shaft and the lever uses the input shaft as a fulcrum. The upper part of the lever is connected to the pin on the left side baffle by a tension spring. The bottom end of the lever is connected to the wire that is controlled by the physician. When the lever push the baffle to complete the trigger, the lever will be reset through the tension spring. In order to make full use of the lever principle, the lever arm of the lever is initially designed as 14 mm.

Here, when the flat spiral spring stores energy, the gear will drive the cutter and the stopper to rotate in the opposite direction as shown in Fig.4. It must be considered that the lever does not hinder the stopper. At the same time, the lever must be designed to block the stopper when the tool moves in the forward direction.

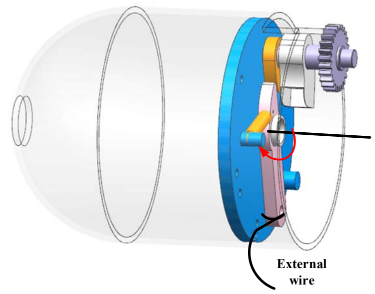


Fig. 3 The triggering module

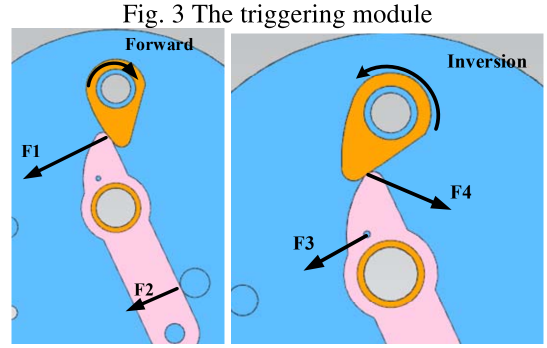


Fig.4 Force analysis in different direction

D. Storage module

The multi-biopsy samples stored in the same location may affect tissue testing. To ensure that the tissue samples taken each time are stored at different locations, the storage unit is designed in the form of a plurality of grooves (shown in Fig.5). During the cutting process, the gear shaft pulls the storage module through the wire to complete the multiple separate storage. In addition, the cover is fixed over the grooves to ensure that the tissue will not be thrown out during the movement of the capsule.

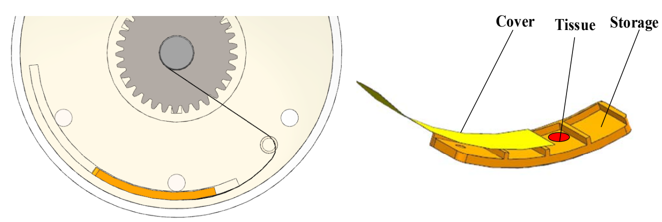


Fig. 5 Storage and Cover

E. Cutting module

The cutting module consists of a blade and a tool holder. To cut the tissue within very short time, a very sharp blade must be used. We initially used three blades around the tool holder. The cutting edge of the blade has a thickness lower than 0.1 mm and the thickness of the blade holder is 4mm. For a clinical biopsy, a biopsy volume of 1 to 5 mm^3 should be sufficient [18, 19]. By changing the position of the blade in the tool holder, we can get the right tissue sample. In addition, we used 3D software for interference detection to verify if the biopsy device can cut tissue samples, as shown in Fig.7.

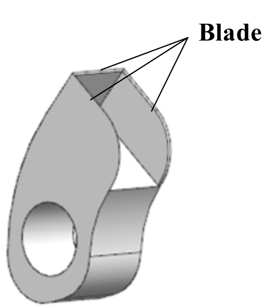


Fig.6 The cutting unit

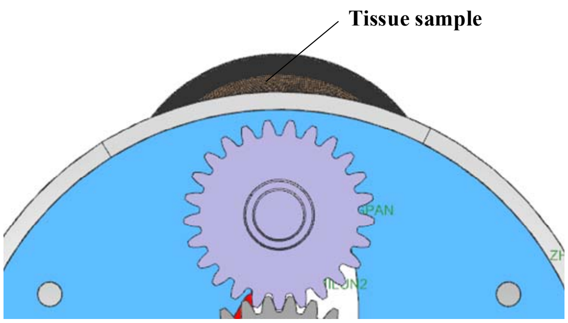
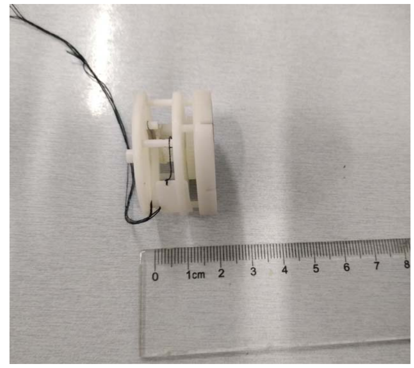


Fig.7 Simulation of cutting

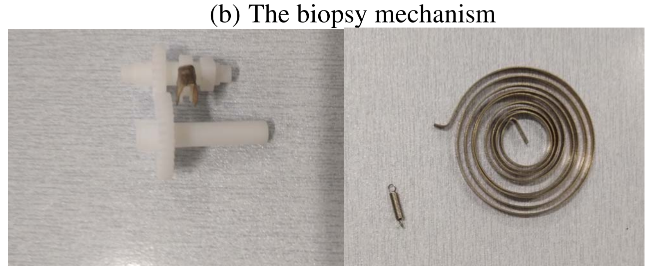
F. Fabrication of the Prototype

The capsule prototype is made by 3D printing (Photosensitive resin). A spring with a thickness of $0.35mm$ and a width of $2.3mm$ is used. A $0.1mm$ piece of iron blade is wrapped around the surface of the tool holder. The number of teeth of the two gears is $z_1 = 35$ and $z_2 = 25$ respectively. The tension spring has a diameter of $2mm$ and a length of $10mm$. The diameter of the biopsy device is $36mm$ and length is $20mm$.

(a) The prototype of capsule



(b) The biopsy mechanism



(c) Drivetrain and the spiral spring

Fig.8 Photos of prototype

IV. PRELIMINARY EXPERIMENT

A preliminary experiment was conducted by using a piece of pig skin to replace human tissue as shown in Fig. 9. During the experiment, the biopsy device was triggered by manual. Fig. 10 represents the collected tissue samples and a piece of pig skin. The results demonstrate that the idea of high speed cutting can be used to the acquisition of biopsy tissue and the proposed mechanism can implement multiple biospies.

Fig.9 Capsule in place

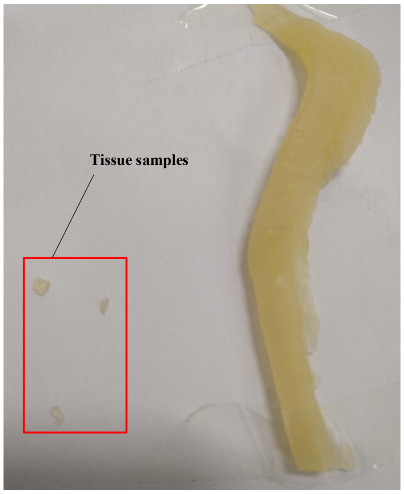


Fig.10 Samples and a piece of pig skin

V. CONCLUSION AND FUTURE WORK

This paper presents a novel multi-biopsy mechanism embedded in a capsule endoscope. The biopsy device can perform multiple samplings and save the tissue separately for each sampling. It consists of a trigger with a lever, a cutter, a storage module and drivetrain of gear transmission connected with a torsion spring. The cutter is driven via one small gear which can be driven at higher speed by a larger gear connected with the torsional spring. In this paper the basic principle of the new multi-biopsy mechanism is analyzed as well as a preliminary prototype made by a 3D printer is built, and finally the feasibility of the proposed biopsy device was preliminarily verified.

In the future, because the current capsule still does not meet clinical needs in size, future work will focus on decreasing the size of the capsule prototype and its performance improvements and structural optimization.

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