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Electromagnetic field intensity triggered micro-biopsy device for active locomotive capsule endoscope

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ABSTRACT

For an active and precise diagnosis, we developed an active locomotive intestinal capsule endoscope (ALICE), which can be wirelessly driven and controlled using an electromagnetic actuation (EMA) system. Since then, there has been a need to develop a biopsy device integrated into ALICE which can take a biopsy sample inside the gastrointestinal tract for a historical analysis of cancer disease. Toward this goal, this paper proposes a smart-triggered biopsy device for the ALICE using a micro-reed switch, where the integrated micro-reed switch is turned on using a strong magnetic field, and the biopsy device mechanism is activated by a micro-reed switch. To execute the biopsy process, first, the ALICE with the biopsy device is driven by an EMA system, where a moderate intensity magnetic field is used for driving the ALICE to reach a target region on the intestinal wall. After that, by increasing the magnetic field above a critical value, the ALICE is pushed hard against the target lesion, the micro-reed switch is turned on, and the biopsy device is triggered. The biopsy process, therefore, is totally wirelessly controlled by the external magnetic field of the EMA system, without an additional controller module. The prototype of the biopsy device, with dimensions of 12 mm in diameter and 5 mm in length, was integrated into the ALICE and the prototype of the ALICE, with the biopsy device having dimensions of 12 mm in diameter and 32 mm in length. The working principle and mechanism of the proposed biopsy device are introduced and the feasibility of ALICE with the biopsy device is demonstrated through in-vitro experiments.

1. Introduction

Recently, the technology of the capsule endoscope (CE) has emerged as a spotlighted solution for investigating and diagnosing common diseases of the gastro-intestinal (GI) tract or celiac disease. There are several commercialized CEs, including the PillCam (Given-imaging, Israel), OMOM (Jinshan, China) [1], MIRO (Intromedic, Korea) [2], and Endo capsule (Olympus, Japan) [3]. They are untethered CEs the size of a pill, integrated with a high definition camera which can capture images of the gastrointestinal (GI) tract, and transfer them to a portable receiver device through the CE's telemetry module. They can be swallowed and moved passively by the peristaltic motion of the digestive system. Because of their passive locomotion, however, the diagnostic ranges of most CEs are limited to tubular organs, such as the esophagus and small intestine. In addition, valuable functions, such as pH sensing and biopsies for the diagnosis of the GI tract, could not be integrated into most CEs [4].

Therefore, to have an active and precise diagnosis, an ALICE system driven by EMA is developed [5]. The ALICE, containing a small permanent magnet, can be manipulated by the magnetic field of the EMA system, and can perform effective targeting movements in the patient's gut environment. Next, for the definitive diagnosis of digestive diseases, there is a need to develop various functional devices for sensing, drug delivery, and biopsy, which can be integrated into the ALICE.

In this paper, a biopsy function for the ALICE is presented. While recently, several research studies on biopsy modules have been reported. First, Kong et al.,et al., proposed a biopsy module using a spring rotational mechanism with a tissue-cutting razor triggered by a paraffin block [6]. The biopsy module can sequentially operate a quick rotation to extract the tissue, sealing and fixing the biopsy sample. Park et al., reported a micro-biopsy spike to extract the biopsy sample [7], which was triggered by a shape memory alloy (SMA) wire, and moved forward and backward using a slide-crank mechanism. The above two biopsy devices have small dimensions, and can be integrated into CEs; however, they could not generate a sufficient reaction force for an effective extraction process from their biopsy mechanisms acting on the tissue and

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intestinal wall and also it is not clear whether they could collect sufficient volume of tissue for histological analysis. Kong et al., also proposed an anchoring biopsy module, which was introduced with complete visual guidance [8]. The anchoring biopsy module solved the restriction of the reaction force, but the challenge of its huge size of capsule endoscope (40 mm x 15 mm) and high power consumption remains. Furthermore, the above three biopsy modules need an additional controller module for their triggering signal via radio frequency. Because the biopsy modules were not integrated into CEs with locomotion function, it is very difficult for them to extract a biopsy sample from the target lesion.

Second, M. Simi et al., proposed a wireless biopsy capsule triggering system with an external permanent magnet, and solved the problem of the restriction of an additional controller module [9]. The capsule, with one concentric couple of fixed and freely rotating cylindrical permanent magnets inside, created a magnetic torsion spring to extract the biopsy sample. The biopsy module has advantage of using external permanent magnet therefore it does not consume internal power of capsule. However, there is a weak point that the size of the biopsy module (9 mm in diameter and 24 mm in length) is too large. The dimension is too large (more than 2/3 size of normal CE) to be integrated to capsule endoscope which has limited space due to storing others component: wireless module, battery and camera. In addition, the system of the fixed and freely rotating cylindrical magnet of the biopsy module could not maintain internal magnetized direction of the permanent magnet; therefore, the biopsy module could not be able to be integrated into ALICE to perform flexible motion in the external electro-magnetic field.

Finally, an SMA based biopsy device for ALICE was reported [10], in which an effective biopsy performance was demonstrated; however, the size of the permanent magnet inside the ALICE is still quite large, and it requires the modification of a telemetry module to make it possible to receive the radio frequency of the triggering signal. Therefore, in this paper another approach of executing biopsy tissue was studied and applied. The novel proposed biopsy device for ALICE with small dimension is triggered by a micro-reed switch and EMA system, without changing ALICE's initial telemetry module. Through in-vitro experimentation, the feasibility of the ALICE with the proposed biopsy device has been confirmed.

The remainder of this paper is organized as follows. In Section 2.1, the working principle and the main components of ALICE are provided. Section 2.2 describes the design specifications of the biopsy device which could be integrated into the capsule endoscope. Section 2.3 and 2.4 explain the mechanism and design of the biopsy device using the micro-reed switch. The fabrication results and the characteristics of the ALICE with the biopsy device are reported in Sections 3.1 and 3.2. Finally, through in-vitro tests, Section 3.3 verifies the feasibility of the ALICE with the biopsy device.

2. Materials and methods

2.1. Active Locomotive Intestinal Capsule Endoscope (ALICE)

As a powerful diagnostic tool for diseases of the stomach, esophagus, and duodenum, CEs have been widely used by clinical doctors. However, due to their passive locomotion which relies on the peristaltic motion of the digestive organs, CEs can only work effectively in small tubular digestive organs, such as the small intestine and esophagus, but ineffectively in larger organs like the stomach or colon. To solve the current problem, an ALICE with flexible targeting locomotion in the entire whole GI tracts was proposed in [5]. The ALICE is a capsule endoscope with a small permanent magnet, and is actuated by an EMA system. In addition, through various experiments, we demonstrated that the ALICE showed effective locomotion and flexible motion, with 5 degrees of freedom (DOFs), and could be a feasible tool for diagnoses in the GI tract.

The EMA system, as it was introduced in [11], consists of two parts: part 1 is three pairs of Helmholtz coils perpendicular to each other in the *x, y*, and *z*-axes, while part 2 is composed of three Maxwell coils that are also perpendicular to each other in three coincident directions. Each coil pair was controlled by a PCI controller with LabVIEW software (National Instruments) connected to an MX12 power supply (3EA) (California Instruments).

2.2. Design specifications of the biopsy device

Most CEs have a shape of a large pill, and consist of one tiny camera and a lighting system, integrated sensors, programmable electronics, wireless communication, and a power supply [12]. In this paper, a biopsy tool which could be integrated into the ALICE is proposed to help a physician take a biopsy sample in parallel with an endoscopic examination. Due to the unique characteristics of CEs, the following requirements for the biopsy device for the CEs must be satisfied. First, the biopsy device should be sufficiently small enough to be integrated into swallowable CEs. In this paper, the target dimension of the ALICE prototype with the biopsy device was a size similar to the PillCam COLON video capsule, with a diameter of 12 mm and a length of 32 mm, which has already been approved by the US Food and Drug Administration (FDA) [16]. Second, the CE should have a targeting locomotive mechanism to reach the target lesion during internal surgery. Third, the biopsy device should have wireless activation ability, and cutting capability with enough force or a cutting pressure of 20 MPa at the tool-tissue interface [13]. Fourth, the biopsy procedures should be executed with little energy consumption, and the CE with the biopsy device should remain in a stable position during the sampling process. Finally, the sampled tissue should have a sufficient volume ($1 \sim 5\ mm^3$) for the histological analysis [14,15].

2.3. Mechanism of the biopsy device triggered by a micro-reed switch

Fig. 1(a) shows the conceptual design of the ALICE with a biopsy tool. For the flexible targeting locomotion of the ALICE using the EMA system, two permanent magnets with different magnetization directions were included. Fig. 1(b) shows the schematic diagram of the EMA system for the ALICE, where the EMA system consists of three pairs of Helmholtz coils and three pairs of Maxwell coils arranged perpendicular to each other in the *x, y*, and *z*- axes. Fig. 2(a) depicts the schematic design of the proposed biopsy device, which consists of an elliptical hole in the body, a biopsy extracting razor connected to a spring, a smart triggering module with a micro-reed switch, a polymer string, and an SMA wire. Fig. 2(b) describes the operational mechanism of the biopsy device. In advance, the biopsy extracting razor connected to the torsional spring was fixed with a polymer string. After the micro-reed switch was triggered, the SMA wire was heated up and the polymer string was cut. Then, the biopsy extracting razor was rotated using the torsional spring.

Fig. 3 describes the entire biopsy procedure in sequence. First, the EMA system produced a magnetic field inside its region of interest (ROI), at a medium level, to move the ALICE to the target lesion. Second, the ALICE was driven to be attached to the target and intestinal wall. Third, the magnetic field intensity was raised to an excited level, which was greater than the pull-in value of the micro-reed switch. The higher magnetic field turned the micro-reed switch on, and gained the pushing force of the ALICE to the intestinal wall. Finally, based on the tissue sampling mechanism in Fig. 2(b), the cutting razor of the biopsy device in the ALICE could extract a biopsy sample.