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Untethered Robotic Motion and Rotating Blade Mechanism for Actively Locomotive Biopsy Capsule Endoscope

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ABSTRACT Capsule endoscopy (CE) is a convenient and promising alternative endoscopic method for the gastrointestinal diagnostics on clinical sites; however, multifunctional utilization with active targeting locomotion is still challenging due to internal power limitations and micro-size manipulation mechanisms. The biopsy is one of the most demanding functions of intestinal CE, and successful developments could significantly improve the intestinal diagnostics for precise decisions and comfortable usage. In this paper, we present a novel active locomotive robotic biopsy capsule endoscope using an externally driven electromagnetic actuation (EMA) system and a battery-free wireless rotating blade mechanism. The external magnetic field from the EMA system controls both locomotion and biopsy operation, and thus, the proposed mechanism does not consume the internal power of the CE. We prototyped the proposed biopsy module and integrated it into an active locomotive capsule endoscope. Simulations were conducted to design the module and analyze the magnetic responses. We performed experiments with the biopsy capsule endoscope both *in vitro* and *ex vivo* to demonstrate its feasibility. In conclusion, the prototyped robotic biopsy capsule endoscope could successfully perform the necessary movements for the capsule in the small intestine and perform a biopsy at the target lesion with sufficient force. The amount of biopsy tissue was sufficient for a histological examination.

INDEX TERMS Biopsy capsule endoscope, wireless capsule endoscope, electromagnetic actuation system, intestinal diagnosis.

I. INTRODUCTION

In 2000, wireless capsule endoscopy (WCE) was introduced as a potential method to visualize and examine the lining of the digestive tract. The WCE assists doctors in observing the small intestine, which can be difficult to reach through either lower or upper endoscopy. Relentless technical progress induces improvements to the duration (recording time) and visualization performance of WCE (frame rate, field of view) [1]. Several types of WCE have been developed such as (M2A, Given Imaging, Israel), PillCam (Given Imaging, Israel), EndoCapsule (Olympus, Japan), MiroCam (IntroMedic, Korea), and OMOM (Chongqing Jinshan Science and Technology, China) [2], [3]. Then, WCE gradually became an effective tool for diagnosing Crohn's disease, coeliac disease, abdominal pain, and tumors. WCE is also more accurate than magnetic resonance imaging systems when used to detect and investigate bowel tumors and small lesions in the gastrointestinal tract [4]. Nevertheless, a common limitation of WCE is its passive locomotion, which relies on the peristaltic motions of the human digestive system. Therefore, WCEs may not detect some abnormal lesions. The use of electromagnetic fields has proved its functional superiority in clinical sites, including medical imaging such as magnetic particle imaging systems [5], [6] and magnetic guidance systems [7]–[9]. Similarly, an active locomotive intestinal capsule endoscope (ALICE) was developed by utilizing interaction between a permanent magnet and magnetic

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TABLE 1. Summary of biopsy mechanisms for capsule endoscope.

Year, [Ref]	Biopsy motion	Cutting tool	Triggered by	Advantage	Limitation
2005, [33]	Rotating	Blade	Electricity	Small-size module	No locomotion, energy consumption.
2008, [25]	Extruding	Micro-spike	Electricity	Small-size module	No locomotion, energy consumption.
2012, [34]	Rotating	Blade	Electricity	Visible biopsy process	No locomotion, energy consumption.
2013, [35]	Rotating	Blade	EPM	No energy consumption	No locomotion, large biopsy module, limited in stomach
2014, [27]	Gripping	Micro-gripper	Thermal	No energy consumption	Low biopsy rate, limited in bowel
2017, [36]	Extruding	Fine needle	EPM	No energy consumption	Limited in bowel
2016, [26]	Rotating	Blade	Electricity	Small-size module	Energy consumption
2017, [37]	Gripping	Gripper	EMF	No energy consumption, small-size module	Biopsy tool is extruded out of capsule body
Our module	Rotating	Blade	EMF	No energy consumption, multi-biopsy	Invisible biopsy process

field [10]; it can be driven actively and flexibly by an external electromagnetic actuation (EMA) system.

In addition to the active locomotion ability, research has been conducted on improving visualization performance by integrating artificial intelligence diagnostics and multi-functional modules to extend the endoscopic capsule's functionalities [11]–[14]. With the advancement of MEMS technology, functional WCEs have been developed for sensing, including gas, pressure, and pH [15]–[20]. Several other electromagnetic-based sensing modules can also potentially be integrated into WCE [21]–[24]. For the tissue level diagnostics, several biopsy mechanisms for WCE have been also introduced [25]–[28] and therapeutic ones have drawn significant attention from researchers developing targeted drug delivery [29]–[32].

Among these applications of the WCE, a biopsy is the most usable functionality in clinical practice. An advanced WCE with active locomotion and a biopsy module for collecting tissue at targeted lesion can be a potential alternative to traditional endoscopy methods, which have several limitations such as short reachability, causing pain, fear, indignity, and even sedative side effects. With the active-locomotion ability, it can reach deeply in small intestine and provide multiple viewing angles to doctors. As it is the size of a pill, ALICE can overcome high curvature sections of the organ or folding structures painlessly and comfortably under the control of EMA system. Additionally, biopsy-functioned WCE is a potential solution for micro-surgical treatment in the future as the biopsy module can respond actively with applied external magnetic field in multi-degree-of-freedom (5-degrees-of-freedom (DOF) in this study), compared to the 2-DOF of flexible endoscopy.

Recently, several biopsy solutions for capsule endoscope have been reported to address the remaining challenges, including the size, energy consumption, and performance [28]. First, in 2005 a rotational biopsy module by Kong et al. was reported. It was used to scratch the tissue of a rabbit intestine [33]. The module utilized a spring and paraffin block to trigger the biopsy blade. In 2008, Park et al. presented a micro-biopsy tool triggered by shape memory alloy (SMA) and a torsion spring combined with slider-crank mechanism [25]. Subsequently, in [34] a biopsy capsule with an anchoring module consisting of three legs and a cylindrical blade was introduced. These modules could sample tissue successfully, but the activation required a large amount of power. Furthermore, they had no locomotive functions and the problem of creating reaction force of the biopsy tool against the intestinal wall could not be solved. Simi et al. used a system of permanent magnets for the torsion spring biopsy module [35]. The biopsy module was activated by an external permanent magnet (EPM). Recently, several studies have introduced active locomotion WCEs integrated with biopsy module. In [27], [36], soft capsules were introduced with a biopsy tool using a micro-gripper and fine needle, respectively. The modules could collect tissue; however, the former mechanism yielded a low rate of retrieval and the latter with soft linkages was limited by locomotion (rolling only) and the working environment (limited in intestine). Previously, Le et al. proposed several biopsy tools triggered by external magnetic fields (EMF) for a commercial WCE platform [26], [37]; however, the problems of energy usage for triggering and stabilizing the camera view during biopsy operation are still challenging. A capsule robot employing electric micro-actuators and being powered wirelessly could be another promising approach [38]. Table 1 summarizes the developed biopsy mechanisms for WCE. Obviously, no study has presented a complete solution for a biopsy capsule endoscope hitherto; each one only solved a particular issue but retained remarkable drawbacks.

In this study, a novel robotic capsule endoscope equipped with a biopsy module for intestinal tissue extraction is presented. The proposed biopsy WCE can address all above-mentioned challenges. The robotic motion is designed based on the commercial WCE platform. It is controlled to move by an EMA system that can generate magnetic torque and force on a permanent magnet. Therefore, biopsy ALICE with a cylindrical permanent magnet can move flexibly in 5−DOF (2 rotational axes and 3 translational axes) to any position in the digestive tract. The developed module has a four-razor blade attached to the permanent magnet that is able to rotate and sample multiple time. Compared to the direct propulsion force of EMA, the resultant force at the

tool tip generated by the magnetic torque is higher; hence, it is utilized to sample the tissue at the surface of the target. The biopsy process is performed by the external magnetic field, implying that energy concerns are eliminated. Moreover, to validate the performance of the design, an ALICE prototype with a pill-shape capsule (12 mm in diameter and 31 mm in length) including a biopsy module was fabricated and tested. We performed both in-vitro and ex-vivo experiments to evaluate the feasibility and confirmed that a biopsy tissue was extracted successfully.

This paper is organized as follows. The overview of active WCE with the EMA system and the design of the proposed biopsy mechanism is introduced in Section II. Section III describes the magnetic manipulation method for capsule locomotion and biopsy operation. In Section III, we present the experiment results for both phantom and fresh porcine intestines. The conclusions and discussions on our work are presented in Section V.

II. SYSTEM OVERVIEW

A. ACTIVE LOCOMOTIVE INTESTINAL CAPSULE ENDOSCOPE

Reliable and stable results were obtained from a new approach of non-invasive gastrointestinal tract investigation based on external magnetic field [10]. The development of active locomotive capsule endoscope was a milestone for intestinal diagnosis and analysis. The conventional method of WCE is based on the peristalsis motion of the human digestive system; however, the movement of WCE is not controlled actively. Therefore, the investigation procedure might leave blind spots. To provide a potential solution for the abovementioned problem, ALICE was developed. Currently, for untethered active locomotion, the usage of a permanent magnet, which can interact with a dynamic magnetic field, is the most effective and reliable solution. In Fig. 1(a), the schematic of how the ALICE system is applied in human treatment is presented. It consists of an EMA system and a capsule endoscope integrated with a permanent magnet. The locomotion and speed of the ALICE capsule can be actively controlled, helping the doctor collect important data for the analysis. Fig. 1(b) presents a schematic of the EMA structure with technical specification that are listed in Table 2. The EMA is composed of two main parts: The first part is uniform magnetic field generator, including one pair of Helmholtz coils and two pairs of uniform saddle coils. These three pairs of coils are fixed perpendicularly to each other in the x, y, and z axes. The second part creates a gradient magnetic field, including one pair of Maxwell coils and one pair of gradient saddle coils fixed along the y and z axes, respectively. The system is connected with five power sources (MX15 (3EA) and 3001LX (2EA) from California Instruments, USA) controlled by LabVIEW software (National Instruments, USA). The region where the magnetic field of the EMA system is uniform called region of interest (ROI) of the system. Owing to the interaction between the magnet inside ALICE and the dynamic magnetic field produced by EMA, ALICE can provide active locomotion and biopsy operation that will be introduced in later part of this paper.

TABLE 2. Technical parameters of EMA system.

Coil	Radius (mm)	Number of turns	Fixed axis
Helmholtz coil	195	556	y-axis
Maxwell coil	195	556	y-axis
Uniform saddle coil 1	105	334	x-axis
Uniform saddle coil 2	141	448	z-axis
Gradient saddle coil	141	448	z-axis

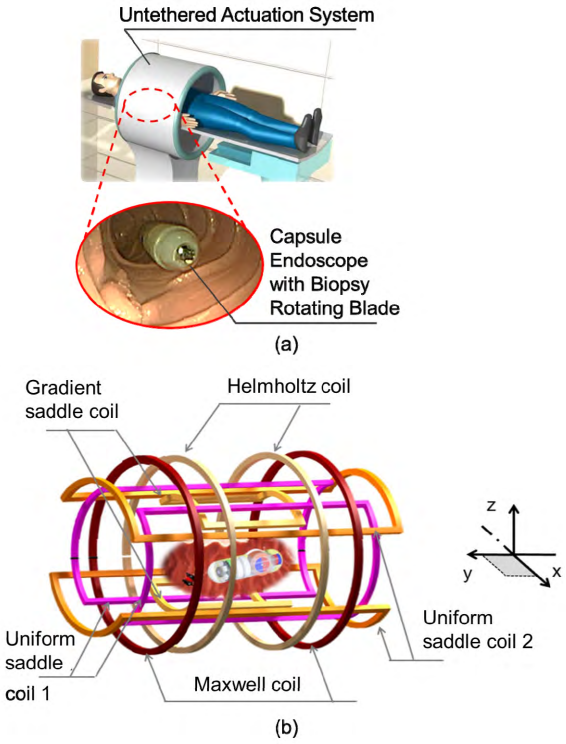

FIGURE 1. (a) Concept of the active locomotive intestine capsule endoscope (ALICE) system using untethered actuation (EMA) system, (b) Schematic structure of EMA system.

B. DESIGN BIOPSY CAPSULE

For the miniaturizing of biopsy tools and capsule endoscope, several factors and requirements should be considered. A WCE should have a video camera, illumination, battery pack, and wireless modules for signal transmission [39]. The shape of the WCE is a medication pill-shape with rounded ends and a tubular body that can move easily in the digestive tract without damaging organs even at the U-shape structures in the small intestinal. The WCE device with a volume of less than 3 cm^3 is suitable for the human digestive system; alternatively, the US Food and Drug Administration has approved a PillCam capsule with dimensions of 32 mm in length and 12 mm in diameter [40]. The WCE should have an active locomotion ability for the thorough investigation at

suspicious lesions. For a biopsy functional module, the biopsy mechanism should be sufficiently small to be integrated into the normal WCE. The energy consumption for biopsy operation should be optimized owing to the limited battery energy of WCE. The destructive stress to sample tissue was reported 1−20 MPa [34], [35]. In this paper, we take 20 MPa as required biopsy stress, which results in high acquisition rate. The volume of collected tissues should be sufficiently large for a histological analysis; as reported in [41], an ideal biopsy tissue should have a volume in the range from 1 mm^3 to 5 mm^3. After the biopsy operation, the capsule could continue the investigation procedure and the collected biopsy tissues should be stored inside the capsule's body.

The structural design of the biopsy module began with a few requirements as follows:

1) A battery-free biopsy module is required. Therefore, the tissue extraction should be performed by a permanent magnet that can interact with EMF from the EMA system. Normally, the magnetic torque created by the EMA is higher than the propulsion force; it can be utilized to cut tissue. Therefore, we first decided that the blade mechanism and its rotation motion can be utilized to collect samples.
2) The active WCE itself contains a locomotion magnet for active movement. If we added one big permanent magnet for the biopsy function, it would be difficult to control owing to the high attraction force between the two magnets. The idea was to utilize the locomotion magnet for the biopsy function. Where the usage of a permanent magnet can solve the problem of interaction between the magnets and the size of capsule endoscope.
3) Single biopsy is not sufficiently reliable because we have no means to confirm the success of acquisition inside the human body. Multiple samples are required to improve the retrieval rate. The biopsy tool, therefore, should have more than one razor and storage room.

Fig. 2(a) introduces the conceptual design of ALICE with the proposed biopsy module. The proposed ALICE consists of a camera module, batteries, and a biopsy module that includes a biopsy blade and rotary magnet. Fig. 2(b) illustrates the structure of the biopsy module with two states of opening and closing. The biopsy blade is designed with four razors and four storage rooms to have the ability to conduct multiple biopsies. The small permanent magnet is fixed to ALICE and the big cylindrical permanent magnet is rotary and attached with the biopsy blade. The rotary big magnet serves for both locomotion and biopsy functions while the small magnet creates a magnetic constrain to big magnet during movement. In the locomotion mode, the attractive force between the two permanent magnets locks the rotation motion of the big magnet; capsule can be aligned and pushed along desired path by a moderate level of magnetic field. In addition, it is to keep the biopsy blade closed during locomotion (normal closed state). In the biopsy mode, a high magnetic field is applied to overcome the attractive force and open razor for extracting the tissue. The biopsy scenario of the

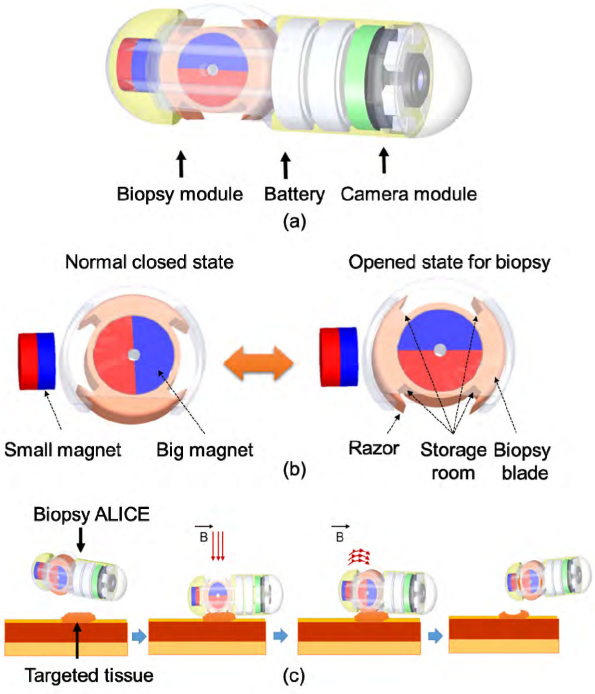

FIGURE 2. (a) Conceptual design of the ALICE with biopsy module, (b) The proposed biopsy module and its states during locomotion and biopsy operation procedure, (c) Biopsy scenario of proposed robotic capsule endoscope.

proposed robotic capsule endoscope is depicted in Fig. 2(c). The capsule can detect the lesion using a visual sensing system and then reach the target. Next, the biopsy blade is opened and pushed toward the organ's wall. The razor cuts the tissue owing to the rotation motion of the biopsy blade. Finally, the capsule with the extracted biopsy tissue is removed.

As summarized in Table 1, a few studies have used the rotation motion to sample the tissues, similar to the method used in this current study; however, the cutting tool and biopsy procedure are completely different, which resulted in a discriminative performance of our design. The developed capsule is superiority than the abovementioned studies. The design is complete, including a biopsy module and visualization components; thus, the dimension is comparable to commercial products. The capsule can move actively and safely in both the stomach and bowel owing to the magnetic attraction between magnets. The tissue can be easily extracted and no onboard energy is consumed during the biopsy process. Moreover, by changing the direction of rotation, we can perform multiple unsorted biopsies at target points because there are four razors and storage rooms of biopsy blade as shown in Fig. 2(b). The module also offers several advantages, including simplicity, ease of fabrication, and low cost.

III. MANIPULATION OF BIOPSY ROBOT

A. LOCOMOTION METHOD

To investigate the insides of the gastrointestinal (GI) tract, basic motions of the capsule are defined as shown in Fig. 3(a).

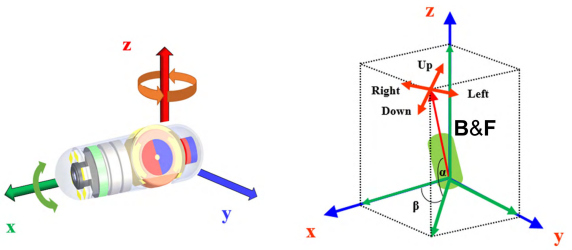

FIGURE 3. (a) Basic motions of ALICE in 3-D space with 5 degree of freedom, (b) Actuation mechanism of proposed capsule endoscope α and β are pitching and yawing angle, respectively.

In the locomotion mode, the rotation motion of the big magnet is locked by the attractive force of small magnet. Two magnets are aligned along the same direction−axial axis of capsule. Following the superposition property of magnetic field, they can be considered as a magnet with volume V (sum of volume of two magnets) and magnetization value M (similar to one of them). Therefore, the proposed capsule will follow the desired magnetic field in the ROI of the control system. ALICE has 5 degrees of freedom (DOF) where 3−DOF are for translation (x, y, and z axes) and 2−DOF for rotation (yawing and pitching motion in Fig. 3(b)), which helps visualize the entire surrounding environment of organ and cutting tissue.

When the electric current goes through uniform magnetic field coils, the resultant magnetic field in the ROI of each coil can be calculated as follows [10]:

$$\mathrm{B_x} = (\mu_0)\,(1909.8)\,(\mathrm{i_{Bx}}) \tag{1}$$
$$\mathrm{B_y} = (\mu_0)\,(2040.1)\,(\mathrm{i_{By}}) \tag{2}$$
$$\mathrm{B_z} = (\mu_0)\,(1907.7)\,(\mathrm{i_{Bz}}) \tag{3}$$

where $\mathrm{B_x}$, $\mathrm{B_y}$, and $\mathrm{B_z}$, and $\mathrm{i_{Bx}}$, $\mathrm{i_{By}}$, and $\mathrm{i_{Bz}}$ are the generated magnetic fields and input currents of the uniform saddle coil 1, Helmholtz coil, and uniform saddle coil 2, respectively. $\mu_0 = 4\pi 10^{-7}$ H/m is the magnetic permeability of free space.

The desired magnetic field **B**, which tends to align the capsule, can be decomposed into basic terms, and then together with (1), (2), and (3) the input current to each electromagnet can be obtained by the following equation:

$$\mathbf{B}_{\mathrm{desired}} = \begin{bmatrix} \mathrm{b}\cos\alpha\cos\beta \\ \mathrm{b}\cos\alpha\sin\beta \\ \mathrm{b}\sin\alpha \end{bmatrix} = \begin{bmatrix} \mathrm{B_x} \\ \mathrm{B_y} \\ \mathrm{B_z} \end{bmatrix} \tag{4}$$

where input values b, α, and β are magnitude, pitching, and yawing angle of desired magnetic field vector, respectively.

The uniform magnetic field is used to control the orientation of ALICE while the gradient magnetic field tends to push the capsule along the aligned path. The gradient magnetic field components at location (x, y, and z) in the ROI created by the Maxwell coils and gradient saddle coils are described as follows [10]:

$$\mathrm{G_M} = (\mu_0)\begin{bmatrix} (-4688.5)\,(\mathrm{x}) \\ (9377.1)\,(\mathrm{y}) \\ (-4688.5)\,(\mathrm{z}) \end{bmatrix}(\mathrm{i_{GM}}) \tag{5}$$

$$\mathrm{G_S} = (\mu_0)\begin{bmatrix} (10661.2)\,(\mathrm{x}) \\ (7404.7)\,(\mathrm{y}) \\ (-18065.9)\,(\mathrm{z}) \end{bmatrix}(\mathrm{i_{GS}}) \tag{6}$$

where $\mathrm{i_{GM}}$ and $\mathrm{i_{GS}}$ are input current to Maxwell and gradient saddle coils, respectively. The resultant force acting on the magnet having a volume of V is described as follows:

$$\begin{aligned}\mathbf{F} &= \mathrm{V}\,(\mathbf{M}\cdot\nabla)\,\mathbf{B} \\ &= \mathrm{V}\begin{bmatrix} \partial\mathrm{Bx}/\partial\mathrm{x} & \partial\mathrm{Bx}/\partial\mathrm{y} & \partial\mathrm{Bx}/\partial\mathrm{z} \\ \partial\mathrm{By}/\partial\mathrm{x} & \partial\mathrm{By}/\partial\mathrm{y} & \partial\mathrm{By}/\partial\mathrm{z} \\ \partial\mathrm{Bz}/\partial\mathrm{x} & \partial\mathrm{Bz}/\partial\mathrm{y} & \partial\mathrm{Bz}/\partial\mathrm{z} \end{bmatrix}\begin{bmatrix} \mathrm{M_x} \\ \mathrm{M_y} \\ \mathrm{M_z} \end{bmatrix}\end{aligned} \tag{7}$$

where $\mathbf{M} = (\mathrm{M_x}, \mathrm{M_y}, \mathrm{M_z})^{\mathrm{T}}$ is the direction of the capsule, ∇ is gradient operation, and the gradient components have values as follows:

$$\partial\mathrm{Bp}/\partial\mathrm{q} = \begin{cases} \mathrm{G_M(q)} + \mathrm{G_S(q)} & \text{if } (\mathrm{p} = \mathrm{q}) \\ 0 & \text{if } (\mathrm{p} \neq \mathrm{q}) \end{cases} \tag{8}$$

where p, q = x, y, z. Similar to (4), by decomposing the desired magnetic force, which has the same direction as that of the alignment vector **B** as depicted in Fig. 3(b), we can obtain the input current for the Maxwell and gradient saddle coils according to the desired value of the magnetic force.

B. MECHANISM OF ROTATING BIOPSY BLADE

After the investigation, the capsule endoscope can approach the targeted lesion and perform the biopsy. As illustrated in Fig. 2(c), the uniform magnetic field aligns along the direction of the capsule endoscope and the gradient magnetic field is created to push ALICE into the intestinal wall. The torque exerted on the permanent magnet by the uniform magnetic field from the external control system can be calculated through the following equation:

$$\mathbf{T} = \mathrm{V}\,(\mathbf{M}\times\mathbf{B}) = \mathrm{V}\begin{bmatrix} \mathrm{M_yB_z} - \mathrm{M_zB_y} \\ \mathrm{M_zB_x} - \mathrm{M_xB_z} \\ \mathrm{M_xB_y} - \mathrm{M_yB_x} \end{bmatrix} \tag{9}$$

To proceed with the biopsy at target point, a rotating magnetic field with a strong magnetic intensity is produced to rotate the biopsy blade in the desired direction. The cutting force at the tip of the biopsy blade can be calculated as follows:

$$\mathrm{F_{Biopsy}} = \frac{\mathrm{T}}{\mathrm{R}} \tag{10}$$

where R is the radius the rotation biopsy blade, which is equal to the distance from the center of the permanent magnet to the tip of the biopsy blade.

To optimize the dimension of the permanent magnet, we calculated the cutting force according to the maximum

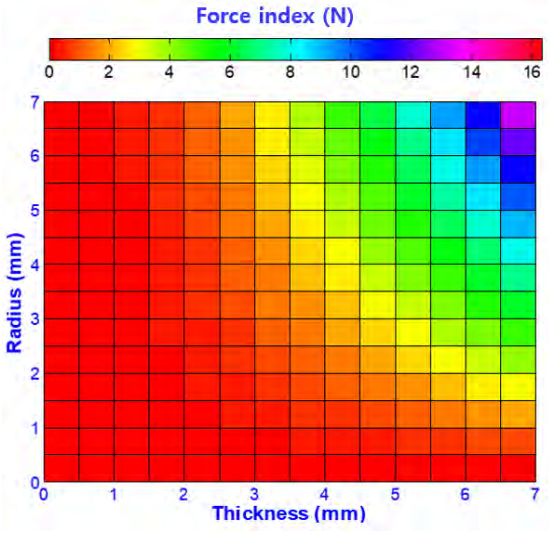

FIGURE 4. Estimation of cutting force at the tip of biopsy blade with various dimension and thickness of permanent magnet.

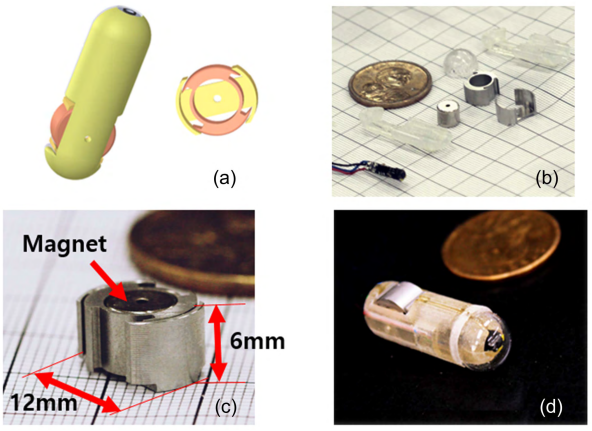

FIGURE 5. Fabrication of ALICE prototype. (a) 3D-printed design of ALICE and biopsy module. (b) Components of ALICE's prototype before assembling. (c) Assembled biopsy module. (d) Completed prototype of ALICE used to conduct biopsy.

uniform magnetic field and various dimensions of the cylindrical Neodymium magnet with a magnetization value of M = 955000 A/m.

To produce sufficient destructive stress at the tool–tissue interface to collect the biopsy tissue of $\tau_{cut} = 20$ MPa, the biopsy razor should be sufficiently sharp. For the current manufacturing technology, a blade with thickness of 0.03 mm can be manufactured by a micro electrical discharge machining (EDM) machine.

The shear stress produced by the rotation of the biopsy blade at the tool–tissue interface can be calculated as follows:

$$\tau_{cut} = \frac{F_{Biopsy}}{Area} = \frac{F_{Biopsy}}{t \times s} \tag{11}$$

where t and s are thickness and length of biopsy razor. The applied shear stress τ_{cut} should be equal or greater than 20 MPa with the given parameters of the biopsy razor t = 0.03 mm, s = 6 mm; therefore, the generated cutting force F_{Biopsy} should be a minimum of 3.6 N.

We conducted a theoretical analysis of the extracting force with various dimensions of the rotary permanent magnet to choose an appropriate permanent magnet for cutting. Fig. 4(a) presents the calculated cutting force at the tip of the biopsy blade. Based on this estimation, we chose a cylindrical magnet with a radius of 3.5 mm and thickness of 6 mm. The estimated cutting force is of 5.3 N, which is sufficient for extracting biopsy tissue.

IV. EXPERIMENTAL RESULTS

A. PROTOTYPING

The prototype of ALICE integrated with proposed biopsy module was designed and fabricated as shown in Fig. 5. The 3D-printed drawing of the capsule and biopsy module are shown in Fig. 5(a). The biopsy blade and outer shell were manufactured by micro-EDM machining, turning, and milling method. The thickness of the biopsy blade tip is 0.03 mm. The permanent magnet N35 with a magnetization of M = 955000 A/m was manufactured with the dimensions of 3.5 mm in radius and thickness of 6 mm. The other components for the biopsy prototype, as shown in Fig. 5(b), were fabricated using high-resolution rapid prototyping 3D printer (Objet30 Pro, Stratasys Direct Manufacturing Ltd, USA). Fig. 5(c) presents the assembled biopsy module with an outer shell and a rotational biopsy blade made of 316 stainless steel. Fig. 5(d) shows the completed prototype of ALICE integrated with the biopsy module with dimension of 32 mm in length and 12 mm in diameter.

B. BIOPSY FORCE EXPERIMENT

After manufacturing the ALICE prototype, the force induced by EMA on ALICE was evaluated. In Fig. 6(a), the experiment setup to measure the locomotion force of ALICE is presented. The capsule was placed within the ROI of the EMA system. One end of ALICE was connected to the load cell (Advanced Digital Force Gauges Series 5, Mark-10) through a polymer string. Using the EMA to drive ALICE forward with various gradient flux density values, we can estimate the propulsion force of ALICE inside the EMA system. The propulsion force, which could be calculated in (7), was also compared with the measured value. The estimated and measured results are shown in Fig. 6(b). The maximum measured pushing force is 0.326 N, which varies slightly from the theoretical results owing to friction force and systematic errors. The propulsion force is higher than the friction force of small intestine (estimated 0.035 N with friction coefficient of 0.5) which is the most difficult environment to move as reported in [42], [43]; therefore, biopsy ALICE can move easily in the GI tract. Similarly, the magnetic torque at razor of the biopsy tool was measured. Instead of connecting the string to the body of ALICE, we connected it to the tip of biopsy blade. By using the rotating uniform magnetic field to rotate the biopsy blade, the torque according to various uniform

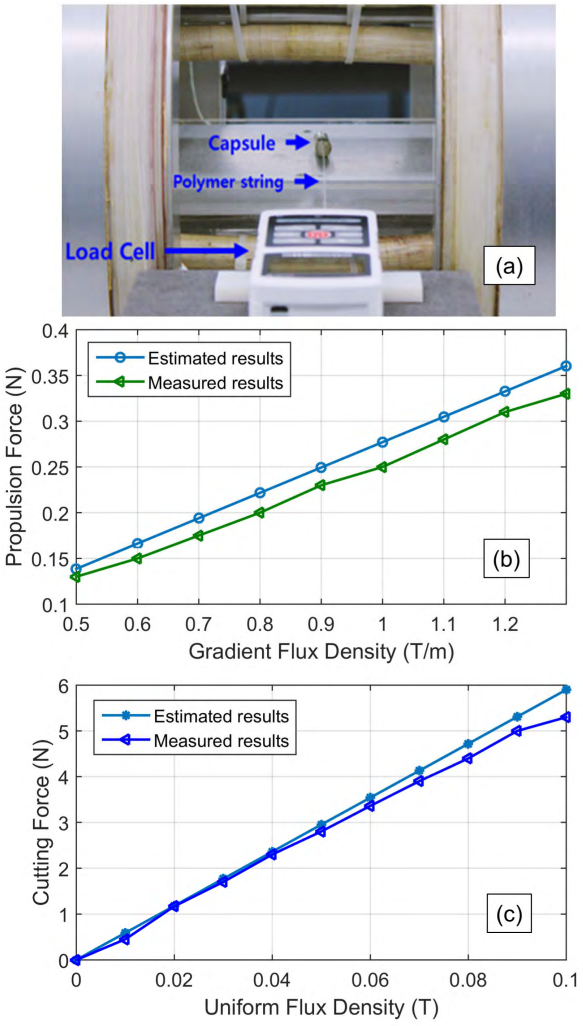

FIGURE 6. (a) Force measurement setup for ALICE inside ROI of EMA system. (b) Propulsion force of ALICE created by EMA system. (c) Cutting force of biopsy modules.

magnetic field intensity values was measured. Fig. 6(c) shows that the maximum torque is 5.19 N at the maximum uniform field density of 0.1 T. This result proves that the biopsy module can create a higher force than the required cutting force of 3.6 N, and it can extract biopsy samples.

The magnetic torque is also used to align the direction of capsule body during locomotion. To prevent the undesired motions of the biopsy blade while moving, the attractive force between the two magnets must be greater than the alignment torque, which is normally fixed at 2 N. To select the appropriate dimension for a small magnet, simulations were conducted to estimate the attraction force using small magnets of various sizes (see Fig. 7(a)). Based on the simulated results, we chose a small magnet with dimensions of 3 mm in diameter and thickness of 2 mm and verified its performance through an experiment. Fig 7(b) illustrates the experiment setup of the measuring force between the two permanent magnets with respect to the differences in the aligned direction. The small permanent magnet was connected with

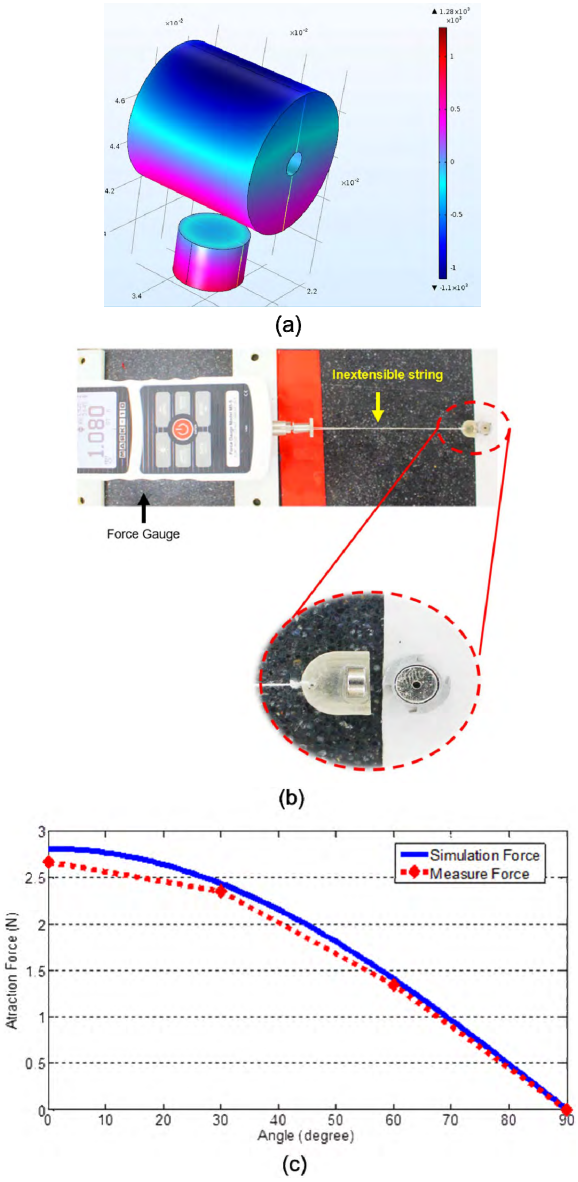

FIGURE 7. Estimate the interaction force between two permanent magnet (a) Simulation model in COMSOL Multiphysics. (b) Real experiment setup. (b) Attraction force between two permanent magnets corresponding to various angles.

the load cell through a polymer string. The big permanent magnet was fixed to the base and could be rotated with several typical angles (0, 30, 60, and 90 degree). Fig. 7(c) presents the simulation and measurement data; the attraction force of the two permanent magnets is a maximum of 2.6 N when the two magnets are aligned along the same direction, and this value is similar to the estimated value. This value shows that the biopsy blade will be disabled during locomotion and could be rotated to extract the tissue using a high magnetic torque from the EMA system.

C. IN-VITRO AND EX-VIVO EXPERIMENT

To demonstrate 5−DOF motion of the proposed capsule in spatial domain, we put capsule inside a transparent

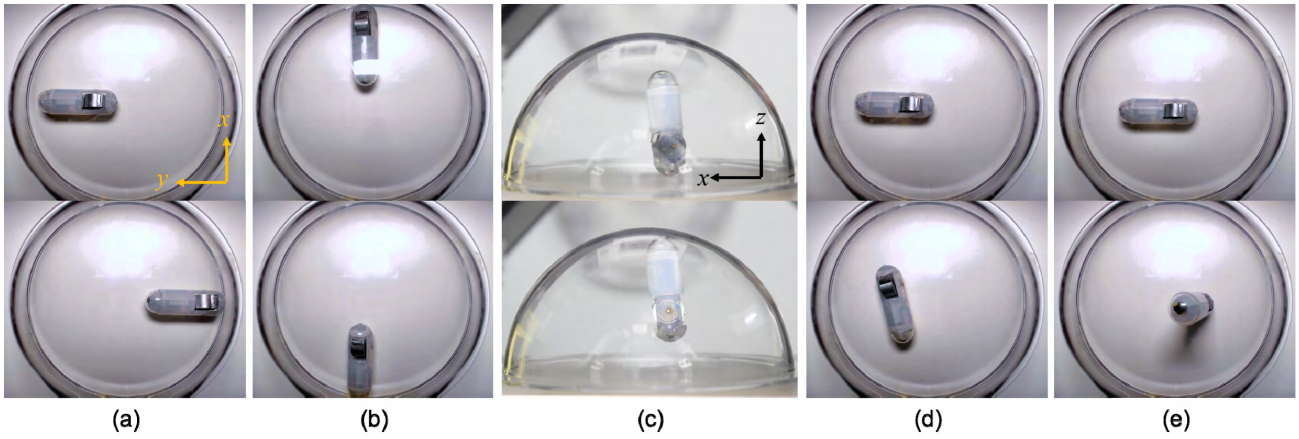

FIGURE 8. Demonstration of 5-DOF motion of prototype in free space. (a) y-axis translation. (b) x-axis translation. (c) z-axis translation. (d) Yawing motion. (e) Pitching motion.

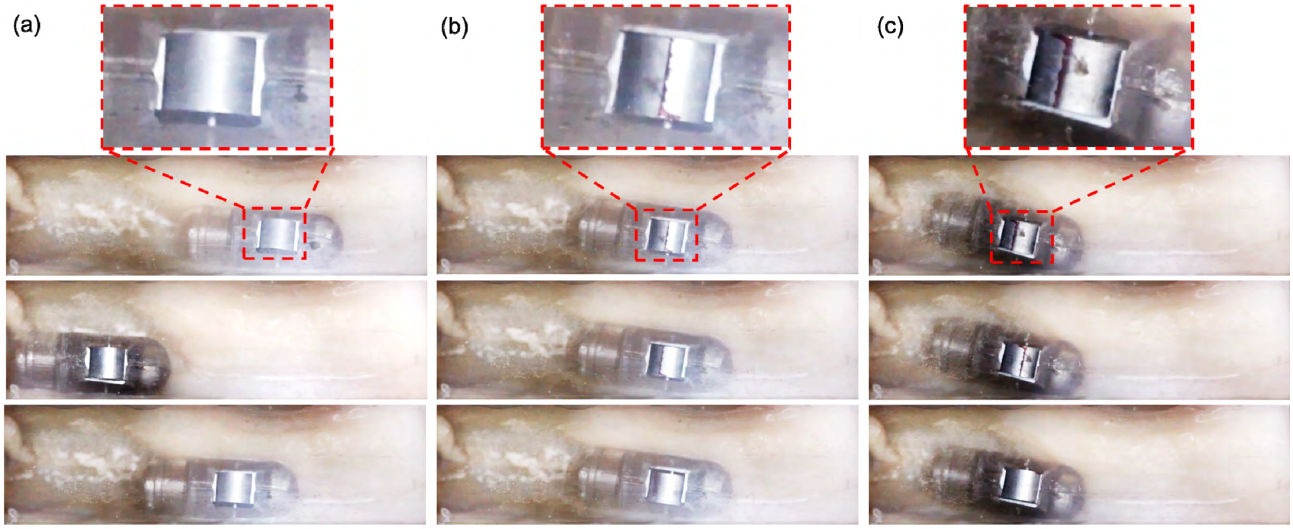

FIGURE 9. *Ex-vivo* biopsy test of ALICE prototype in fresh pig's small intestine. (a) Locomotion. (b) and (c) Biopsy at different positions.

hemisphere inside ROI of EMA system. Two cameras (C930 from Logitech) were used to record the motions of capsule robot in xy-plane and xz-plane. After aligned by uniform magnetic field, capsule was propelled along desired path by gradient magnetic field. Fig. 8(a), (b) and (c) shows the basic translation motions along x, y and z axes. Yawing and pitching motion are presented in Fig. 8(d) and (e). It is confirmed that the biopsy blade was closed during locomotion test. By combining these basic motions, the operator can perform flexible maneuvers to investigate organs thoroughly. We confirm that the proposed biopsy ALICE can perform 5−DOF of spatial motion successfully.

To evaluate the locomotion and biopsy function in real tissue, we conducted an ex-vivo experiment on a segment of the pig's small intestine. Fig. 9(a) shows the active locomotive ability of ALICE, the blade is disable during moving in viscous environment. At the target lesion, once the gradient magnetic field was applied to push the capsule body to the intestinal wall and rotation magnetic field was applied to drive the biopsy blade, sampling was conducted. Fig. 9(b) clearly shows that the biopsy razor (marked with red color) was opened to cut tissue. By changing the direction of rotating magnetic field, another razor could be utilized to extract tissue at the same position. Our proposed biopsy capsule also could translate to another target point to perform multiple sampling. Fig. 10(c) illustrates the biopsy procedure at the second destination by rotating biopsy blade in two directions. During cutting process, there was a small vibration of capsule body due to the attractive force between magnets and the removal of tissue. After that, the biopsy blade returned to its initial position (normal closed state) and ALICE can continue with the investigation locomotion. Through this ex-vivo experiment, it is confirmed that the proposed biopsy WCE could come to two different locations and extract unsorted multiple samples successfully.

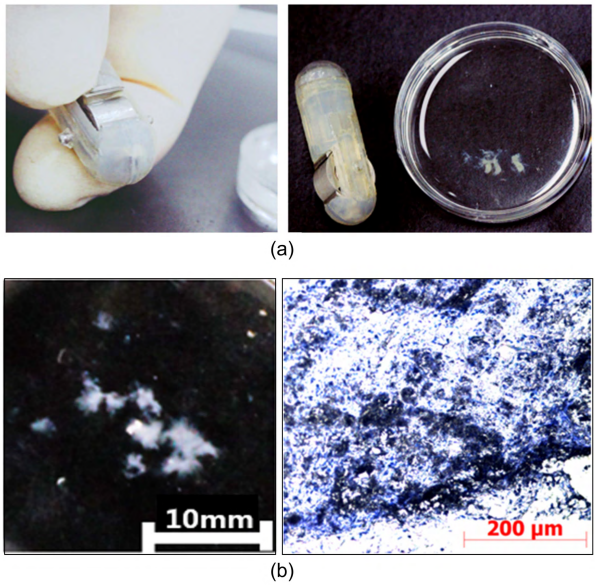

FIGURE 10. Biopsy tissue analysis. (a) Extraction of tissue sample. (b) Biopsy tissue under microscope and tissue's florescent image.

Finally, the capsule was removed for the next step of the tissue analysis. Fig. 10(a) shows the extracted tissue from the biopsy module that was then visualized under the fluorescent microscope. First, the harvested sample was embedded at an optimal cutting temperature compound and stored at −80 °C. After that, the tissue sections (5–10 μm) were mounted on the slide glass and placed in cool methanol for 5 min; they were then rinsed with PBS several times. Finally, they were stained with hematoxylin and eosin following the standard protocol. The fluorescent microscope showed that the nuclei of the cells from the tissue sections appeared to be deep blue, as presented in Fig. 10(b). Therefore, we confirmed that the biopsy capsule prototype could successfully collect several real tissues and the volume of the samples were sufficient for the analysis to determine the potential diseases.

V. CONCLUSION

In this paper, a prototype of the biopsy capsule capable of active maneuvering and targeted tissue extraction inside the digestive tract was presented. A rotating cylindrical permanent magnet with radial magnetization inside the capsule interacted with the non-uniform magnetic field produced by the EMA system to move. A biopsy blade with four sharp razors is attached to the permanent magnet to cut tissue using its magnetic torque. A small permanent magnet worked as a torsion spring to ensure the biopsy blade is closed while moving. We conducted simulations and measurements to verify the feasibility of the proposed biopsy mechanism. The biopsy WCE exhibited flexibility and the ability for active investigation through in-vitro tests in free space. In ex-vivo experiments, several biopsy tissues for the histological analysis were successfully collected and analyzed. The developed WCE can be an effective visual diagnosis device for automatic detection of polyp and bleeding, which can improve the diagnosis accuracy [44], [45], as it maximizes the potential of the camera and its active locomotion. The biopsy module can be developed to be a treatment tool or therapy for digestive organs. Moreover, the externally driven rotating mechanism can be utilized to develop nano-therapy drug delivery and micro-surgical treatment.

For the stable cutting motion, the operator can create a rotating magnetic field and gradient field simultaneously toward the target. However, overlaying the non-uniform magnetic field with the uniform field with an inadequate ratio of these two values may induce an unstable motion. This ratio is important and it depends on the systematic characteristic. If the gradient magnetic field is too strong, it may lead to big distortion of the uniform magnetic field that will result in unstable rotation of the biopsy blade. In contrast, if the ratio is low, a highly uniform magnetic field in generated within the ROI; however, the low magnetic force response (due to the small gradient magnetic field value) might not be enough to push the capsule toward the organ's wall. The operator should conduct the test outside the organ or conduct simulations to analyze the stability of the capsule with respect to the set up ratio and find an optimal value.

There are still a few limitations of this study. Although the locomotion and tissue extraction of the proposed WCE were demonstrated, the experimental environment was different from the practical one. Several disturbances, which might affect the biopsy function such as peristalsis motions, secretion of gastric mucus, effect from nearby organs, and biocompatible property matters in clinical application, were not considered. The biopsy process is invisible. Localization of the WCE using external device is also required to be conquered.

In the future, an adaptive or a robust controller will be developed to compensate for such disturbances in in-vivo experiments. A feedback control system integrated with an X−ray system [43], [46] or magnetic sensor array [47] to track the capsule's position and increase accuracy will be designed. In addition, the proposed mechanism will be extended to a sorted multi-biopsy module to collect abnormal tissues at different locations. Based on the internal battery free advantages of the developed system, the integration of other advanced functions, such as drug delivery and tissue dyeing, with our prototype is also being considered.

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