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Enhanced steering ability of the distal end of a magnetic catheter by utilizing magnets with optimized magnetization direction

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ABSTRACT

We developed a magnetic catheter with enhanced steering ability of the distal end by utilizing magnets with optimized magnetization directions. The proposed magnetic catheter is composed of a flexible tube and three-ring magnets that enable the magnetic catheter to be steered by controlling external magnetic fields. We analyzed the curvature of the magnetic catheter's distal end and the vertical displacement of the magnetic catheter's proximal end with a mathematical model using the Euler-Bernoulli beam theory, and then determined the optimal magnetization direction of each magnet. Finally, we prototyped the magnetic catheter with optimized magnetization directions and conducted several experiments to verify its effectiveness.

I. INTRODUCTION

Occlusive vascular disease is one of the major causes of human death in modern society.[1] To treat these diseases, there are two conventional treatments, bypass surgery and intravascular intervention. Since bypass surgery requires a complex operation and long recovery time, intravascular intervention is preferred. Intravascular intervention uses a catheter to navigate through blood vessels to target lesions and treat the patient. In intravascular intervention, it is very important to reach the target lesion through complex blood vessels. However, a conventional catheter can only be controlled from the proximal end by medical doctors outside of the patient's body, which makes it almost impossible to control the magnitude and direction of force and torque at the distal end of the catheter. Therefore, it is hard to reach and treat a target lesion when the blood vessel has a complex shape. Also, medical doctors are continuously exposed to radiation from an X-ray imaging device during intravascular intervention, which increases cancer risk.[2]

To overcome these limitations, a magnetic navigation system (MNS) and a magnetic catheter (MC) have been investigated.[3–5] Magnets in the MC make it possible to control the position and

orientation of the distal end by applying magnetic torque to the magnets using an external magnetic field (EMF) generated by the MNS.[6] The main limitation of these MCs is that the distal end cannot form a large curvature, because conventional MCs utilize magnets with the same magnetization direction, and all of them tend to align along the direction of an EMF. Also, the MNS cannot apply different magnetic fields to each magnet position in the workspace.[7] Therefore, the conventional MC does not provide the precise navigating ability required and it may damage blood vessels when navigating through a steeply bifurcated branch of complex blood vessels. As shown in Fig. 1(a), blood vessels such as coronary arteries have a small diameter and complex shapes. To navigate through these blood vessels, it is important to form a large curvature at the distal end of a MC to minimize blood vessel damage.

In this paper, we propose a MC that can form large curvature at its distal end, which allows navigation through a complex blood vessel by utilizing magnets with optimized magnetization directions. The MC is composed of three magnets with optimized magnetization directions and a flexible tube. We developed the design method to optimize the magnetization direction of each magnet
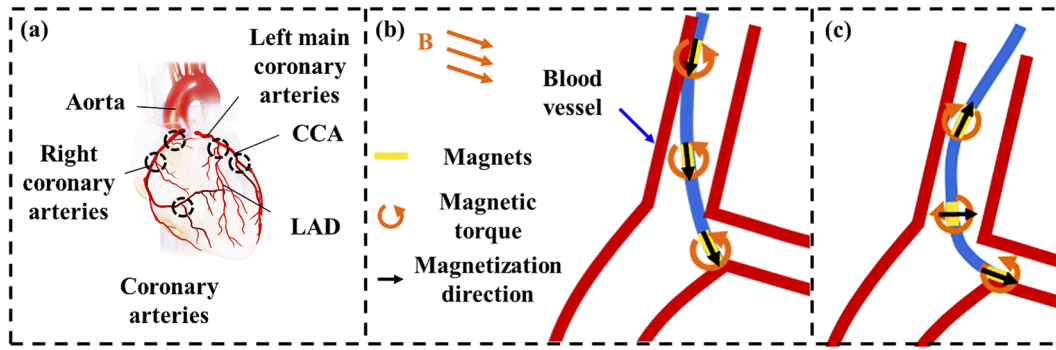
FIG. 1. (a) Coronary arteries are blood vessels with small diameter and complex shapes. (CCA: Circumflex coronary artery, LAD: Left anterior descending coronary artery) (b) Conventional MC, which is unable to form large curvature at its distal end. (c) Proposed MC with magnets having optimized magnetization directions, which is able to form a large curvature at its distal end.

embedded in the MC and analyzed the resulting curvature of the MC's distal end according to various magnetization directions using Euler-Bernoulli beam theory. We prototyped the MC with optimized magnetization directions, and then we verified its enhanced steering ability by measuring the curvature and navigating through a complex path with large curvature.

II. PRINCIPLES OF MANIPULATION

The magnetic torque exerted on the magnets embedded in the MC can be expressed using the following equation when an EMF is applied:[6]

$$T = m \times B \tag{1}$$

where m and B are the magnetic moment of the magnets and the magnetic flux density of the EMF, respectively. Since each magnet has different magnetization direction in this research, the magnetic torque generated at each magnet has a different direction and magnitude, which allows the magnetic catheter to deform only at the distal end. As shown in Fig. 1(b), the conventional MC with all magnets having the same magnetization direction cannot form a large curvature at the catheter's distal end. However, the MC with magnets having different magnetization directions can form large curvature at the distal end by generating different direction and magnitude of magnetic torque in each magnet, as shown in Fig. 1(c).

Since the MC has a small diameter and long thin shaft, the deformation of the MC can be modeled by using the Euler-Bernoulli beam theory as follows:

$$EI\frac{d\varphi}{ds} = M(s) \tag{2}$$

where E, I, φ, M and s are the Young's modulus and area moment of inertia of the flexible tube, the deflected angle at an arbitrary point, the torque applied to the flexible tube, and the arc length of the flexible tube, respectively.[8]

III. ANALYSIS AND OPTIMIZATION OF MAGNETIZATION DIRECTION OF EACH MAGNET EMBEDDED IN MAGNETIC CATHETER

The proposed MC is composed of a flexible tube and three magnets as shown in Fig. 2(a). The magnetization direction of magnet 3

is intuitively assumed to be the same as the x-direction so the distal tip of the MC can align in the same direction as an EMF. Two more magnets were inserted to generate various magnetic torque values to form a large curvature at the distal end. The distance between each magnet is 10 mm and the magnetization direction of magnets 1 and 2 are defined as ϕ_1 and ϕ_2, respectively. Then we defined two parameters for optimization of the magnetization direction of magnets embedded in the catheter, k (curvature of the MC's distal end) and D (maximum vertical displacement of the MC's proximal end) as shown in Fig. 2(b).

To optimize the magnetization direction of each magnet in the MC, we analyzed two parameters defined as k and D. If the distal end of the MC is assumed as a circle, k is proportional to the slope difference of magnet 2 and magnet 3 as follows:

$$k = \frac{1}{R} \propto \theta_3 - \theta_2 = \Delta\theta \tag{3}$$

where θ_2 and θ_3 are the slopes of magnet 2 and magnet 3, respectively. Then we defined $\eta=(k/k_{mean})/(D/D_{mean})$ where k_{mean} and D_{mean} are the mean values when the direction of the EMF is applied from $0°$ to $180°$ in increments of $10°$. The optimization problem was formulated as follows:

$$\text{Find} \quad \phi_1, \phi_2$$

$$\text{Maximize} \quad \eta_{opt} = \frac{1}{19}\sum_{i=1}^{19}\frac{k_i/k_{mean}}{D_i/D_{mean}}$$

$$= \frac{1}{19}\sum_{i=1}^{19}\eta_i(i = 0°, 10°, 20°, 30°, ..., 180°) \tag{4}$$

$$\text{Subject to} \quad \phi_1 \geq \phi_2$$

where ϕ_1 and ϕ_2 are assumed as $0°$, $90°$, or $180°$. The curvature of the MC's distal end should be large and the maximum vertical displacement of the MC's proximal end should be small to minimize blood vessel damage. Since the set of magnetization directions of each magnet cannot be changed after it is manufactured and the blood vessel have various angles, we found the optimum value by calculating maximum η_{opt}. In the simulation, we assumed that the sheath, which holds the MC's proximal end, was to be placed 47 mm
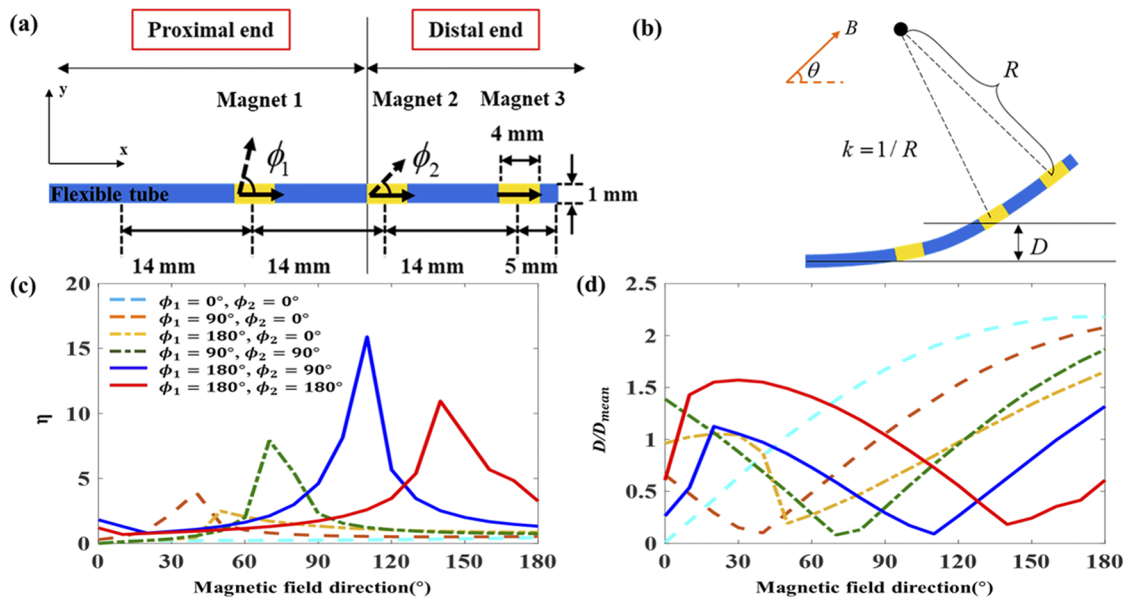
FIG. 2. (a) Structure of MC and design variables for magnetization direction of magnets 1 and 2. (b) Diagram of two parameters (k and D) utilized to optimize design variables ϕ_1 and ϕ_2. (c) η with respect to magnetic field direction. (d) D/D_{mean} of magnetic catheter's proximal end with respect to magnetic field direction. (Case 1: ϕ_1=0° and ϕ_2=0°, Case 2: ϕ_1=90° and ϕ_2=0°, Case 3: ϕ_1=180° and ϕ_2=0°, Case 4: ϕ_1=90° and ϕ_2=90°, Case 5: ϕ_1=180° and ϕ_2=90°, Case 6: ϕ_1=180° and ϕ_2=180°).

away from the tip of the MC's distal end and an EMF of 100 mT was assumed to be applied.

The simulation result for each case is shown in Fig. 2(c). According to the result, case 5 (ϕ_1=180° and ϕ_2=90°) and case 6 (ϕ_1=180° and ϕ_2=180°) have the highest η_{opt} values which are 3.19 and 3.03, respectively. Also, case 5 and case 6 have higher η value compared to the conventional magnetic catheter of case 1 (ϕ_1=0° and ϕ_2=0°) in all magnetic field direction. However, as shown in Fig. 2(d), the vertical displacement of case 6 is higher than case 5 for most of the magnetic field directions which could give damage to blood vessels. As a result, the magnetization directions of magnet 1 and magnet 2 were optimized as 180° and 90°, respectively.

IV. RESULTS AND DISCUSSION

To verify the performance of the MC with magnets having optimized magnetization direction compared to the conventional MC, we prototyped both MCs. MCs were prototyped with a polyimide tube and NdFeB ring magnets. A polyimide tube with an outer diameter of 1 mm, Young's modulus (E) of 7×10^7 Pa and area moment of inertia (I) of 3.549×10^{-14} m^4 was used. The outer diameter, inner diameter, and length of NdFeB ring magnets were 0.95 mm, 0.55 mm, and 4 mm, respectively.

To verify the performance of the MC, we applied an EMF of 100 mT at 170°, which yielded a significant difference between the two MCs. The fixed point in the MC's proximal end was placed 47 mm away from the distal tip, which is the same as the simulation. To compare curvature values, we drew a circle in a red dotted line that fits the MC's distal end and measured the radius of the circle. In the experiment shown in Fig. 3(a) and (b), the MC

with magnets having optimized magnetization direction formed a larger curvature than the conventional MC. The radius of the circle of the MC with magnets having optimized magnetization direction was 12.9 mm, which was 61.1% less than the conventional MC at 33.16 mm. According to the simulation results, the radius of the circle of the magnetic catheter with magnets having optimized magnetization direction was 13.6 mm, which was 59.4% less than the conventional magnetic catheter at 33.5 mm. The experiment result for the conventional magnetic catheter had approximately 1% of error compared to the simulation result. The magnetic catheter with magnets having an optimized magnetization direction demonstrated approximately 5% of error compared to the simulation result. Both the experiment and simulation results showed similar outcome, that the magnetic catheter with magnets having an optimized magnetization direction have a smaller radius of circle than the conventional magnetic catheter. Since the radius of the circle is inversely proportional to curvature, the curvature of the MC with magnets having an optimized magnetization direction was 2.57 times larger than that of the conventional MC, according to the experiment result.

Finally, we conducted an *in vitro* experiment in a glass tube with a complex path as shown in Fig. 3(c). The glass tube had an inner diameter of 5 mm and a maximum angle of 140° relative to the x-axis. The EMF of 40 mT at 50° and 0° with respect to the x-axis was applied to the MC when it was located in path 1 and path 2 of a Y-shaped path. The EMF of 100 mT at 170° with respect to the x-axis was applied to the MC when it was in path 3 at an angle of 140° to form large curvature at the MC's distal end to successfully navigate the path. The conventional MC failed to navigate through the path, because it was unable to form a large curvature at the magnetic catheter's distal end. However, the MC with magnets
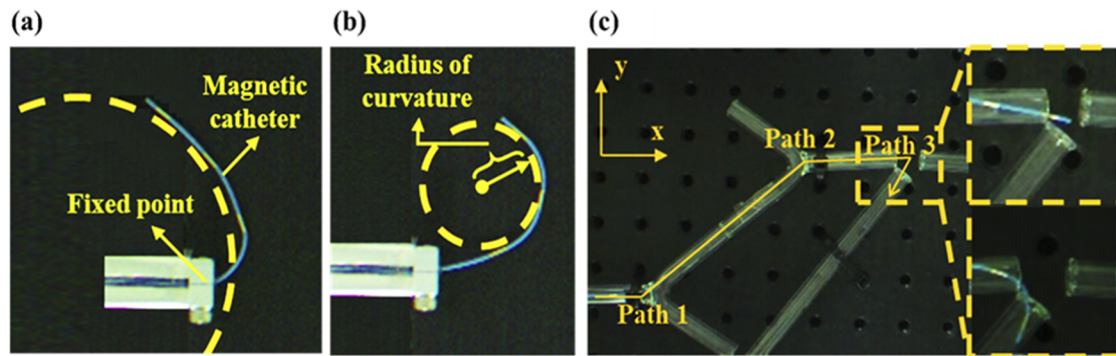
FIG. 3. (a) The conventional MC having 33.16 mm of radius of curvature and (b) the proposed MC with magnets having optimized magnetization direction having 12.9 mm of radius of curvature of MC. (c) *In vitro* experiment to verify the steering ability of the proposed MC (Right-top: the conventional MC, right-bottom: the proposed MC).

having an optimized magnetization direction was able to form large curvature at the MC's distal end and successfully navigate the desired path.

V. CONCLUSION

We proposed a MC with magnets having an optimized magnetization direction that can form larger curvature at the MC's distal end with smaller vertical displacements at its proximal end. The MC with magnets having an optimized magnetization direction will allow navigation through complex blood vessels, because it can form a large curvature at the MC's distal end. We simulated the MC modeled with the Euler-Bernoulli beam theory. Also, we developed an optimization method using the curvature of the MC's distal end and maximum vertical displacement of the MC's proximal end to design an optimal magnetization direction of magnets so as to enhance the steering ability of MC's distal end. We prototyped the conventional MC and the proposed MC with magnets having optimized magnetization directions, which are ϕ_1=180° and ϕ_2=90°. Then, we conducted several experiments to verify the performance of the MC's steering ability. The proposed MC with magnets having optimized magnetization direction formed 2.57 times larger curvature at its distal end than the conventional MC. Also, it successfully navigated through the desired path while the conventional MC failed to do so. This research will contribute to expanding the

application of MCs for the treatment of occlusive vascular diseases in complex blood vessels, which is difficult to reach with conventional catheters.

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