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Feasibility Study on Magnetically Steerable Guidewire Device for Percutaneous Coronary Intervention

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Abstract: In this paper, we proposed a magnetically steerable guidewire device composed of two parts: steering part and feeding part. The steering part consists of a magnet attached to the end of a commercial guidewire and 2-pair Helmholtz coils, and the feeding part consists of a motorized stage and a device for holding the guidewire. In detail, the 2-pair Helmholtz coils generate a uniform magnetic field that can align the guidewire magnet in the region of interest (ROI) along a desired direction. In addition, the feeding part remotely controls guidewire insertion and the length of the flexible part of the guidewire extruded from a catheter. For accurate alignment at the end of the guidewire, we controlled the flexible length of the guidewire extruded from a catheter and the intensity and direction of the uniform magnetic field using the feed-forward method. In addition, to reduce alignment error due to unpredicted disturbances and friction effects between the test-bed and the guidewire, proportional-integral-derivative control is introduced as a feedback control algorithm. Using the control algorithms, we demonstrated accurate actuation of the steerable guidewire device with a steering angle error of less than 0.5°. We expect that the proposed steerable guidewire device can be applied to the development of a 3-D locomotive guidewire with position recognition for percutaneous coronary intervention (PCI).

Keywords: Catheter, guidewire, magnetic steering system, percutaneous coronary intervention, uniform magnetic field.

1. INTRODUCTION

Recently, the occurrence of cardiovascular diseases has increased owing to increasing average age, unhealthy eating habits, and stress. For treatment of cardiovascular diseases, percutaneous coronary intervention (PCI) using catheter with stents and balloons is employed widely and is regarded as a general treatment method. In detail, cardiologist used a guidewire for positioning a catheter at the target lesion in the blood vessels [1–3]. Based on angiography in the intervention, cardiologist select the shape and core diameter of the guidewire by considering the diameter of the ascending aorta, location of the coronary artery opening, and direction of the proximal coronary artery. The selected guidewire can be a key factor in the success of PCI treatment [4]. In addition, X-ray fluoroscopy and a contrast medium can be used to recognize the guidewire tip position and the blood vessel shape in real time. For reducing the radiation hazard, cardiologist are required to wear a heavy shielding cloth when operating PCI treatments, resulting in joint pains and radiation exposure due to unstable shielding [5].

To solve these problems, many researchers have focused on externally steerable catheter systems. The control methods of various steerable catheter systems proposed thus far can be classified into tendon-driven mechanisms and external magnetic actuation methods. First, as tendon-driven mechanisms, steerable catheter systems such as Magellan (Hansen Medical) and CorPath (Corindus) were developed, where multiple thin wires are installed into the catheter and the catheter tip can be steered by the tension of the thin wires [6–9]. However, because two or more wires should be inserted into the catheter, it is very difficult to minimize the catheter diameter when using the tendon-driven mechanism. Second, using an external magnetic field, a catheter tip made of magnetic material can be steered along a desired direction. As a steerable catheter system using external mag-

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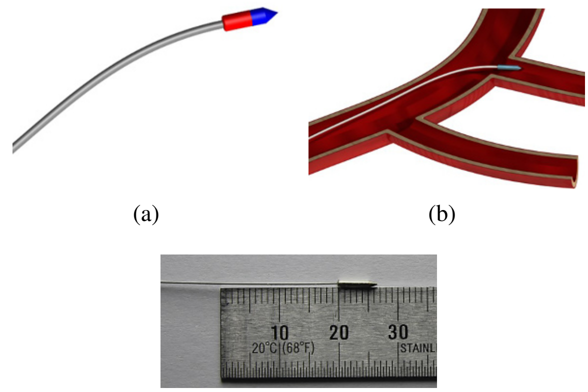
netic actuation, there are two representative examples: Epoch System (Stereotaxis) and CGCI (Catheter Guidance Control and Imaging, Magnetecs) [10–12]. The magnetic catheter of the Epoch System uses two large external permanent magnets to control the direction of the small permanent magnet attached on the catheter tip and to steer the catheter tip. The magnetic catheter of CGCI steers and moves the catheter to the desired point using magnetic fields generated by eight coil-core electromagnets. However, because the Epoch system has a slow response speed, it lacks coping capabilities in emergencies. Moreover, because CGCI has a thick 7Fr (2.2mm) magnetic catheter, its motion is limited in blood vessels with sharp bends and small diameters. Therefore, the CGCI has been applied restrictively to the diagnosis and treatment of cardiac arrhythmias. Recently, a guide catheter steering system using a magnetic resonance imaging (MRI) machine was reported [13–15]. A coil is wound around the catheter tip, and the current applied to the coil is controlled. Because MRI generates a uniform magnetic field through a Helmholtz coil with a bore shape, a catheter tip can be steered using the relationship between the uniform magnetic field and the magnetic field acting on the catheter tip. However, current is applied to the coil at the catheter tip, and Joule heating occurs.

In this paper, we proposed a magnetically steerable guidewire device using simple 2-pair Helmholtz coils, as well as its control algorithm including feed-forward and PID feedback method. We tested the steering accuracy of the proposed guidewire device according to the applied control algorithms. Through insertion tests using a phantom with several branches having various insertion angles, we verified that the proposed magnetically steerable guidewire device can be steered and inserted precisely into the phantom branches.

2. MATERIALS AND METHOD

2.1. Design of magnetically steerable guidewire

Fig. 1 shows our proposed magnetically steerable guidewire, which consists of a commercial guidewire (Conquest Pro 12, ASAHI Intecc, Japan, Tip outer diameter: 0.23mm) with a bullet-shaped magnet (NdFeB, Diameter: 1mm, Length: 7mm) attached to its end. Figs. 1(a) and (b) show the design concept and prototype of the magnetically steerable guidewire, respectively. And Fig. 1(c) shows the fabricated magnetically steerable guidewire. The bullet-shaped magnet attached to the end of the guidewire can be aligned along a desired direction through an external magnetic field. Fig. 2(a) shows a schematic diagram of the magnetically steerable guidewire device, which consists of the steering and feeding parts. First, the steering part, composed of 2-pair Helmholtz coils and the proposed guidewire, should control the magnetic guidewire along a desired direction in complex vessels. Second, the feeding part with a motorized stage should remotely insert the guidewire to a desired position in the blood vessel. Fig. 2(b) shows the experimental setup of magnetically steerable guidewire device.



(c)

Fig. 1. Prototype of magnetically steerable guidewire: (a) design of magnetically steerable guidewire, (b) concept design of magnetically steerable guidewire in blood vessel, and (c) fabricated magnetically steerable guidewire.

2.2. Steering mechanism

Fig. 2(c) shows the steering mechanism of the magnetically steerable guidewire. Generally, a Helmholtz coil can generate a uniform magnetic field, and uniform magnetic fields can generate the torque of a permanent magnet in a region of interest (ROI). Therefore, the magnetically steerable guidewire can be aligned along a desired direction. The torque ($\mathbf{T}_{\text{mag}}$) generated by the Helmholtz coil is expressed as follows:

$$\mathbf{T}_{mag} = V\mathbf{M} \times \mathbf{B}, \tag{1}$$

where V and $\mathbf{M}$ denote the volume and magnetization of the magnet in the proposed guidewire, respectively, and $\mathbf{B}$ denotes the magnetic flux of the external magnetic field, respectively [16–18]. In addition, (1) can be expressed differently as follows:

$$T_{mag} = VMB\sin(\theta_B - \theta_d), \tag{2}$$

where θ_B and θ_d ($\theta_d \neq 0°$) denote the angle of magnetic flux of the external magnetic field and the desired steering angle of the guidewire, respectively. To maximize the generated torque, the generated magnetic field is set to be perpendicular to the desired steering angle ($\theta_B - \theta_d = 90°$). When the same current is applied to the Helmholtz coil, it can generate the maximum torque. In term of power use, we can control the guidewire magnet efficiently. The

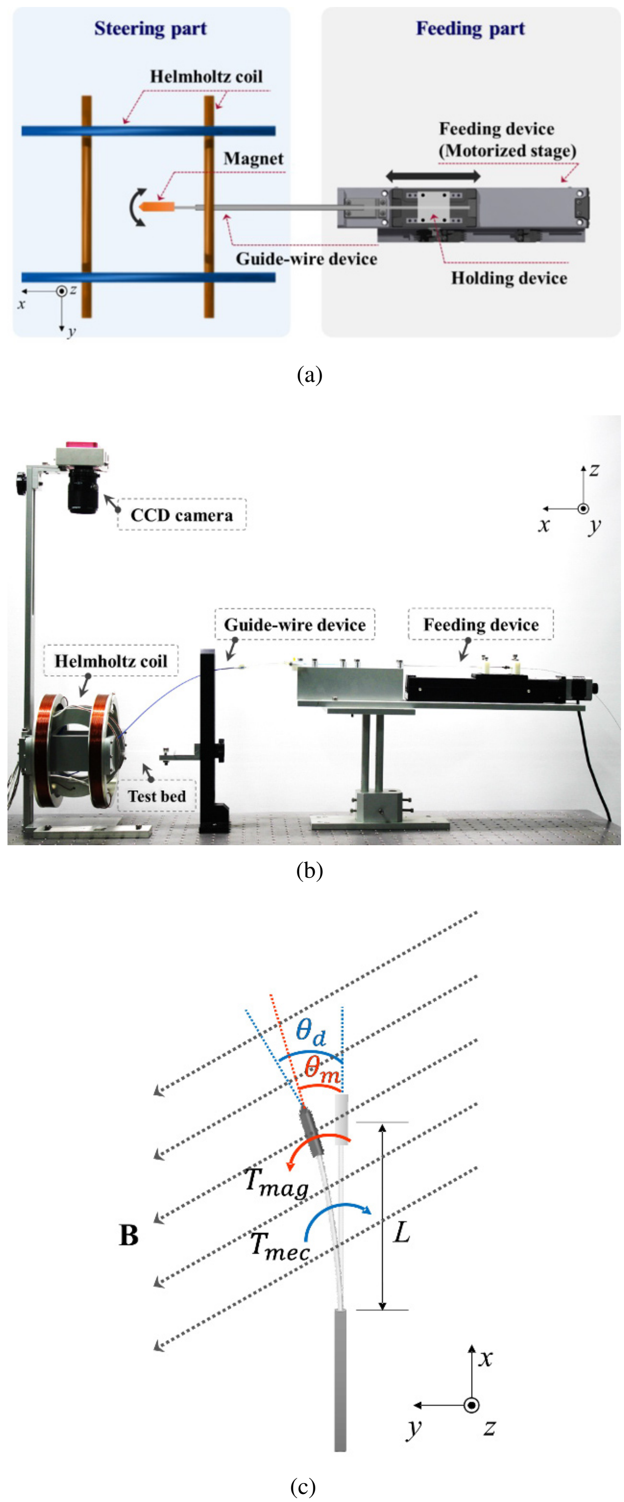


Fig. 2. Magnetically steerable guidewire device with steering and feeding parts, and steering mechanism : (a) schematic diagram, (b) experi-mental setup, and (c) steering mechanism of magnetically steerable guidewire.

relationship between the angle of magnetic flux of the external magnetic field and the desired steering angle of the guidewire is as follows: $\theta_B = \theta_d + 90^\circ$.

Owing to the intrinsic flexibility of the guidewire, a mechanical restoring torque (T_{mec}) can be generated and modeled using a cantilever beam model of the guidewire [13].

$$T_{mec} = (\frac{EI_A}{L})\tan\theta_d, \tag{3}$$

where E, I_A and L denote Young's modulus, moment of inertia, and length of the guidewire, respectively. Therefore, based on the difference between T_{mag} and T_{mec}, the measured guidewire (θ_m) steering angle can be determined. For precisely matching θ_m and θ_d, we control the current applied to the Helmholtz coils.

2.3. Steering control method

When the direction of a blood vessel branch is the same as the alignment direction of the guidewire magnet, the proposed steerable guidewire can minimize damage to the blood vessel. Therefore, for aligning the guidewire magnet along the direction of a blood vessel branch, the following currents are applied to the 2-pair Helmholtz coils:

$$I_{Hx} = m_{ff}\cos(\theta_d + 90^\circ), \tag{4}$$
$$I_{Hy} = 1.195 m_{ff}\sin(\theta_d + 90^\circ), \tag{5}$$

where I_{Hx} and I_{Hy} denote the currents of the x- and y-axis Helmholtz coils, respectively, m_{ff} and θ_d denote the applied current for the feed-forward method and the desired steering angle of the guidewire. In this case, the Helmholtz coils generate a uniform magnetic field when the applied currents share the relationship $I_{Hx} : I_{Hy} = 1 : 1.195$ Specifications of the 2-pair Helmholtz coils are summarized in Table I. According to Section 2.2, the magnetic flux of the external magnetic field acts at an angle of $\theta_B = \theta_d + 90^\circ$. Under this condition, the guidewire tip can be controlled efficiently by the applied current, while power consumption can be reduced.

Based on this principle, we controlled the magnitudes of the currents applied to the x- and y-axis Helmholtz coils such that the measured guidewire steering angle (θ_m) is equal to the desired guidewire steering angle (θ_d). Thereafter, the applied current for the feed-forward method in the x- and y-axis Helmholtz coils was determined. For these tests, the guidewire length was changed from 10 mm to 45 mm in steps of 5 mm, and the desired guidewire tip steering angle was changed from 5° to 50° in steps of 5°, respectively.

Fig. 3(a) shows the applied currents for feed-forward method at a given guidewire length and a desired steering angle. Based on these data, we generated a lookup table for linear interpolation of the feed-forward method to the steerable guidewire device. For the desired length (10 mm $\sim$ 45 mm) and steering angle ($-50^\circ \sim 50^\circ$) of the guidewire tip position, the applied current of the feed-forward method can be calculated using the lookup table and linear interpolation. Because the feed-forward

Table 1. Specification of EMA System.

Coils	x-axis Helmholz coil	y-axis Helmholz coil
Radius (mm)	90	68
Turns	154	139
Resistance (Ω)	2.34	1.97
Magnetic field Intensity (A/m)	1461	1223

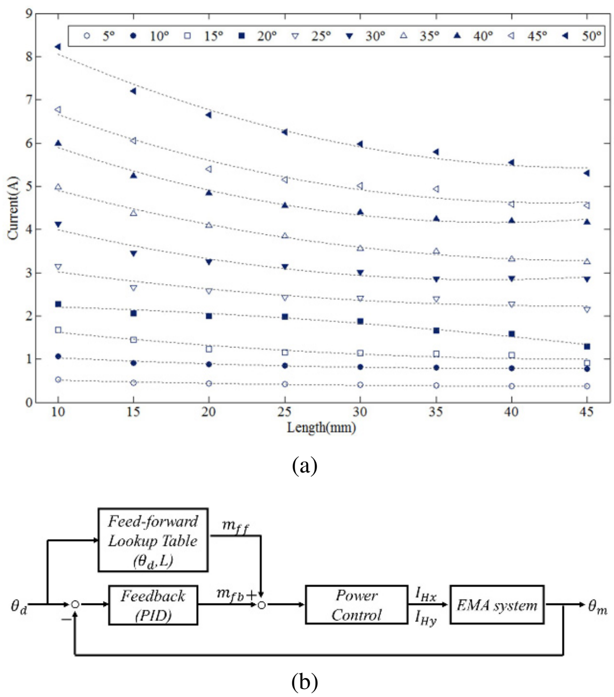


Fig. 3. Control of magnetically steerable guidewire: (a) applied current inputs along guidewire length (feed-forward method) and (b) block diagram of steering control method (feed-forward and PID feedback methods).

method uses the lookup table and linear interpolation, unpredicted disturbances such as the friction between the test-bed and the guidewire and the fabrication errors can generate the steering errors of the steerable guidewire. To avoid the steering errors, we adopted a PID feedback control with the feed-forward method, as follows: First, we measured the steering angle (θ_m) by using a CCD camera along the z-axis at the applied current for the feed-forward method. Second, the steering error between the measured (θ_m) and desired steering angles (θ_d) of the guidewire was calculated in real time. Finally, to compensate for the steering error, the PID feedback control algorithm was simultaneously used and the control algorithm is described as follows:

$$I_{Hx} = (m_{ff} + m_{fb})\cos(\theta_d + 90^\circ), \quad (6)$$

$$I_{Hy} = (1.195 m_{ff} + m_{fb})\sin(\theta_d + 90^\circ), \quad (7)$$

where m_{fb} denotes the compensated magnitude of the applied current in the PID feedback method. In addition, Fig. 3(b) shows the block diagram of the feed-forward and PID feedback method.

3. EXPERIMENTS

3.1. System setup

The fabricated magnetically steerable guidewire device consists of 2-pair Helmholtz coils for steering the magnet attached to the guidewire tip, CCD camera (DS1-D1024-80-CL-10, photon focus) for observing the guidewire tip in real time, and feeding device for remote guidewire insertion (Fig. 2(b)). In addition, a square-shaped acrylic test-bed was fabricated for positioning a phantom in the ROI. To observe the guidewire motion, the CCD camera was installed along the z-axis, and real-time images were acquired using a frame grabber (PCIe-1430, National Instruments). The coil currents were controlled using a power supply unit (MX15, California Instruments), GPIB communication, and PCIe using LabVIEW 2012 (National Instruments) software. In addition, using the geometry pattern matching method, the guidewire steering angle was calculated in real time.

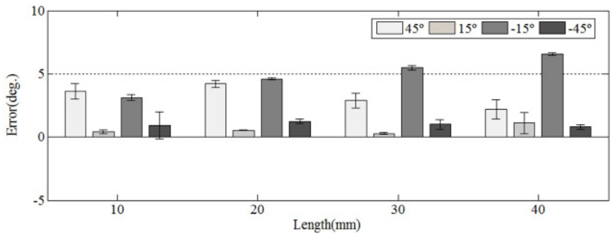
3.2. Basic tests

Fig. 4 shows the experimental results of the steerable guidewire using the feed-forward method, as well as the feed-forward and PID feedback methods, where the steering error refers to the absolute value ($|\theta_d - \theta_m|$) of the difference between the measured (θ_m) and desired steering angles of the guidewire tip ($\theta_d = 45^\circ$, 15°, -15°, and -45°) according to the guidewire length ($L = 10$ mm, 20 mm, 30 mm, and 40 mm). From the experimental results, when we used only the feed-forward method, the steering angle error of the guidewire was approximately 7°. However, when we applied the PID feedback method in conjunction with the feed-forward method, the steering angle errors decreased dramatically to below 0.5°. Compared with the feed-forward method, when PID feedback was added, the steering angle error decreased by up to 92.86%, and more accurate guidewire steering performance was achieved.

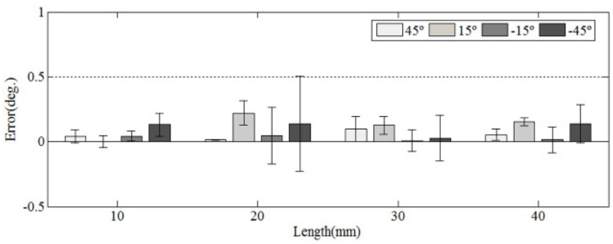
3.3. Phantom test

We fabricated a phantom with five branches (approximately 4 mm in diameter, insertion angles: 35°, 15°, −15°, and −35°; progress angles: 45°, 30°, −30°, and −45°) for performing a steering test of the proposed guidewire. The tests were executed using the feed-forward method and the PID feedback method in the phantom.

First, tests involving insertion of the guidewire into the five phantom branches were performed using the feed-

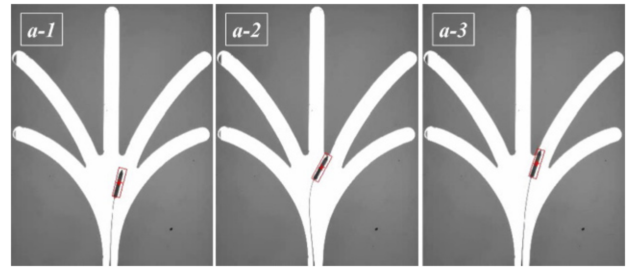


(a)

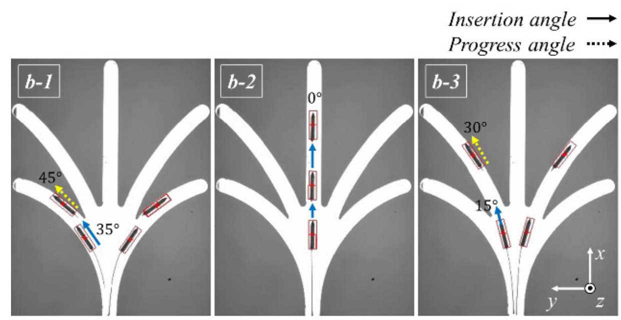


(b)

Fig. 4. Steering angle error of magnetically steerable guidewire ($L = 10$ mm, 20 mm, 30 mm, and 40 mm; and $\theta_d = 45°$, $15°$, $-15°$, and $-45°$). Values are expressed as mean and standard deviation ($n = 3$): (a) feed-forward method and (b) feed-forward and PID feedback method magnetically steerable guidewire.



(a)



(b)

Fig. 5. Results of insertion and progress test of magnetically steerable guidewire in five-branch phantom: (a) guidewire insertion tests (*a-1*: initial guidewire position (L: 15 mm and insertion angle: $-15°$), *a-2*: feed-forward method, and *a-3*: feed-forward and PID feedback method) and (b) insertion and progress tests of magnetically steerable guidewire with feed-forward and PID feedback method (*b-1*: insertion angle: $\pm 35°$ and progress angle: $\pm 45°$, *b-2*: insertion and progress angles: 0° and *b-3*: Insertion angle: $\pm 15°$ and progress angle: $\pm 30°$).

forward method, as well as the feed-forward and PID feedback method. The initial guidewire length was set to 15 mm, and the tests were conducted for three desired insertion angles. The feed-forward and PID feedback method had an insertion success rate of 100%, whereas the feed-forward method had an insertion success rate of about 75%. Fig. 5(a-1) shows the initial guidewire position (L: 15 mm and insertion angle: $-15°$), and Figs. 5(a-2) and (a-3) show the insertion results obtained using the feed-forward method, and the feed-forward and PID feedback method, respectively. From the results, the feed-forward and PID feedback method can reduce the interactive force with blood vessels and surrounding tissue because the guidewire is inserted precisely into the desired blood vessel's path.

Finally, the guidewire insertion motion using the feed-forward and PID feedback method was tested in multiple branches. Fig. 5(b) shows the experimental guidewire steering and insertion results; the guidewire insertion performance in the phantom is shown in a supplementary video.

4. CONCLUSION

In this paper, we proposed a magnetically steerable guidewire device using 2-pair Helmholtz coils. The proposed steerable guidewire device can effectively move a magnetic guidewire tip to locations inside complicated blood vessels. In addition, a control algorithm based on a combination of the feed-forward and PID feedback methods was proposed and adopted for the steerable guidewire device. Through various experiments, we confirmed that the steering angle error of the steerable guidewire device was less than0.5°. In addition, the proposed guidewire device yields accurate steering and insertion performance in the phantom tests. Compared with the existing PCI procedure, the magnetically steerable guidewire can reduce dependence on the surgeon's skill and minimize radiation hazard to cardiologist through remote control. In future, we will develop a dual feeding structure for a guidewire and a catheter, as well as an integrated catheter system with the dual feeding structure. Because the guidewire and catheter will be controlled separately, the integrated catheter system will be used widely for PCI.

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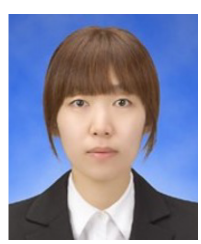

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