MICRO HYDRAULIC BENDING ACTUATOR FOR MINIMALLY INVASIVE MEDICAL DEVICE

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ABSTRACT

Micro hydraulic actuators have been fabricated to improve the operability of minimally invasive medical instruments, such as guidewires, catheters, and endoscopes. The actuators consist of a metal spring coil, evaporated parylene membrane, and a metal wire. Since parylene is used as the membrane, the actuator can be made with a diameter smaller than 1 mm and several actuators can be batch fabricated. As shown in Fig.1, the actuator elongates except for the side that is restricted by a metal wire when water is injected, allowing the actuator to bend. Since the actuators use water to achieve the bending motion and consist of biocompatible materials, they are safe in the human body.

KEYWORDS

Hydraulic actuator, parylene, micro, guidewire

INTRODUCTION

Recently, the practice of minimally invasive intervention for diagnosis and surgery is increasing. Devices such as guide wires, catheters, and endoscopes, are used for these procedures. A catheter is a thin tube which is inserted in a body cavity or vessels for various purposes, e.g. angioplasty, direct measurement of blood pressure, drainage of fluid collections, and administration of medication. To insert a catheter into blood vessels, a guide wire is usually inserted prior to the catheter to make a pre-defined path to the point where the procedure takes place. The insertion of catheters and guide wires is a difficult procedure, especially in percutaneous coronary intervention (PCI), because blood vessels have limited inner diameter and bend, twist and branch in a complex manner. Inserting conventional catheters and guide wires safely into such blood vessels requires skills. Therefore, several micro actuators for catheters and guide wires has been reported to improve their operability, including actuators using shape memory alloy (SMA) [1] and ionic conducting polymer film (ICPF) [2]. Making actuators with multi-degree of freedom can be easily done with SMA. ICPF actuators have simple structure, allowing them to be made into thin actuators. The drawback of these actuators is that they run by electricity and has the risk of excessive electrical leakage in the event of an accident.

Several fluidic actuators for medical instruments have been reported [3]. We have fabricated hydraulic actuated catheters [4]-[5].These actuators doesn't have the risk of electrical leakage or excessive heating since they move by fluid. They have flexible structures, which makes them less likely to damage the patient's body.

In this paper, micro hydraulic bending actuators have been fabricated for minimally invasive medical instruments. The actuators consist of a metal spring coil, evaporated parylene membrane, and a metal wire. Since parylene is used as the membrane, several actuators can be batch fabricated. When water is injected, the actuator elongates except for the side that is restricted by a metal wire, allowing the actuator to bend as shown in Fig. 1. Since the actuators use water to achieve the bending motion and consist of biocompatible materials, they are safe in the human body.

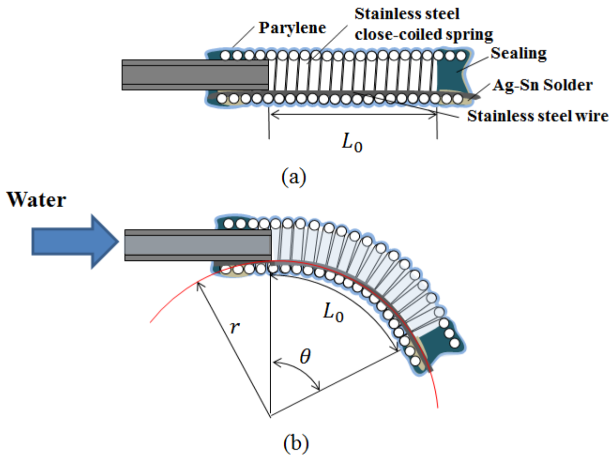

Figure 1: Schematic diagram and principle of the bending actuator. ((a) The initial state of the actuator. (b) The state of the actuator when water is injected. L_0 is the initial length of the actuator. θ, r are the bending angle, radius of the actuator.)

DESIGN

The structure and the principle of the bending actuator is shown from the cross-sectional view in Fig. 1. A close-coiled spring coil is the skeleton of the actuator. The tip of the coil is sealed, and parylene deposited on the coil creates a membrane which covers the surface of the coil, creating a chamber to enclose the injected water. When water is injected and pressures the actuator, the coil elongates. A metal wire is located on the inside wall of the coil and fixed at both ends of the coil using Ag-Sn solder. This wire restricts the elongation of one side of the coil, hence the actuator bends toward the restricted side when pressured (Fig.1 (b)). As shown in Fig. 1, the initial length L_0 of the actuator is defined as the length of the part that is capable of bending, i.e. part where only the restraining wire is present inside the coil, and not the total length of the coil.

Type A

The object of type A actuator is to introduce it into the tip of a PCI guidewire. Its diameter must be smaller than that of a guidewire commonly used for PCI, i.e. 0.014" (= 0.36 mm). Since the lumen diameter of the left circumflex branch is about 2.8 mm [6], the actuator need to bend up to a curvature with a bending radius of 3 mm, and a bending angle over 90°.

Type B

Type B actuator is designed to attain a bending angle over 180° by creating a relatively long parylene membrane between the coil wires.

FABRICATION

Here are two fabrication processes of the actuator. Type A is a process for fabricating a bending actuator with a diameter small enough to be used as an active guide wire. Type B is a process for fabricating a bending actuator with a long parylene membrane, using silicone rubber tube.

Type A

First, a core wire with a cross section shown in Fig. 2(a) was cut out of a Ni-Ti wire with a diameter of 200 µm using a dicing saw. To form a surface oxide layer on the part that lost the oxide layer during the dicing process, the Ni-Ti core wire was heat treated in an electric furnace for 30 minutes at 500 °C. Then a stainless steel wire with a diameter of 60 µm was wound around the strands of wires. The winding pitch of the coil was first set as 60 µm for 20 mm and changes to 90 µm for 0.5 mm. This cycle was repeated three times (b). Rectangular stainless steel wires (10 µm× 100 µm) were cut out of a stainless sheet (100 mm× 50 mm× 10 µm) using a dicing saw. The rectangular stainless steel wire and a core wire were inserted into the wound coil (c). The rectangular stainless steel was soldered onto the coil at the spots that are not close-coiled, i.e. places where the pitch was set as 100 µm (d). Ag-Sn solder balls were used for this process. The Ni-Ti core wire allowed the rectangular wire to stay parallel to the coil's medial axis and lie along the inner wall of the coil. Since the surface oxide layer of Ni-Ti does not join with the solder balls, the Ni-Ti core wire can be pulled out after the soldering process. The coil was cut into units at each spot where the Ni-Ti wire was Ag-Sn soldered (e). One end of each unit coil was sealed with epoxy adhesive (AR-R30, Nichiban Co.). Next, stainless pipe with an outer diameter 0.15 mm and an inner diameter of 0.1 mm was inserted from the open end of the unit coil and attached to the coil using epoxy adhesive. At

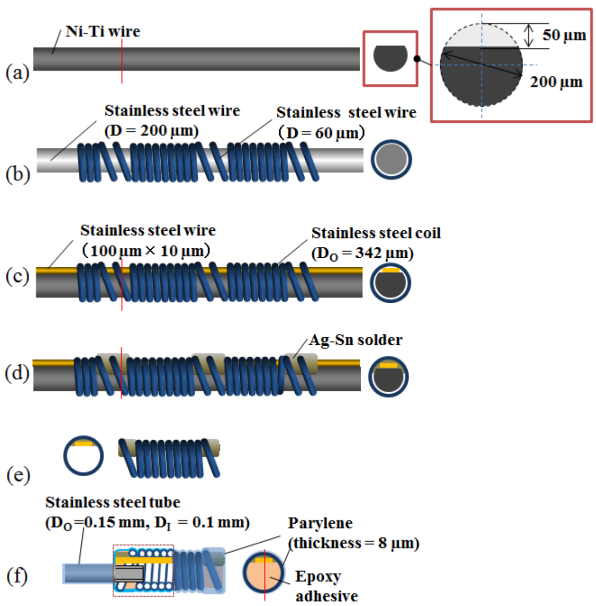

Figure 2: Fabrication process of type A actuator

last, 8µm of parylene membrane was formed on surface of the structure by chemical vapor deposition (CVD) using parylene dimer diX-SR (Kisco Ltd.) (f).

Type B

First, a silicone tube with an outer diameter of 1.5 mm and an inner diameter of 1.0 mm was stretched and inserted into a stainless steel coil with an outer diameter of 1.7 mm, an inner diameter of 1.5 mm, and a length of 15 mm (a). The coil is stretched 2.6 times its original length when the silicone tube is released. The released silicone tube regains its original diameter and press onto the coil, fixing the coil to its stretched state with a pitch of 0.26 mm. Then, 8 µm of Parylene was formed on the surface of the coil and the silicone tube by CVD using diX-SR (b). Then, the silicone tube was wet-etched using a silicone resin solubilizer (KSR-1, Kanto Chemical Co.) (c). Next, a rectangular stainless wire (0.3 mm×0.05 mm) was placed along the inner wall of the coil and Ag-Sn soldered onto each end of the coil (d). Lastly, the tip was sealed with epoxy adhesive, and silicone tube with an outer diameter of 1.5 mm and an inner diameter of 1.0 mm was attached for insertion of water (e).

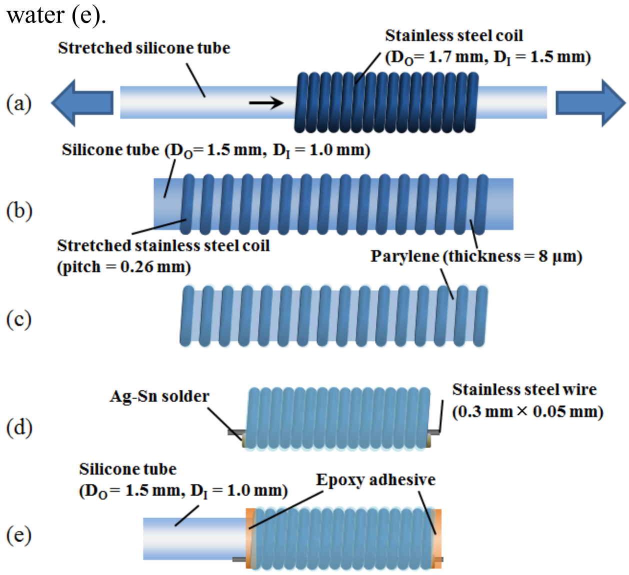

Figure 3: Fabrication process of type B actuator

CHARACTERIZATION

Type A

The fabricated actuator is shown in Fig. 4. The bending angle and radius of the actuator was observed. The maximum pressure was set as 1000 kPa considering the strength of the parylene membrane. Fig. 5 shows the bending behavior of the actuator. The bending angle was proportional to the pressure (Fig.6). The maximum bending angle was 97°. The minimum bending radius was 10.0 mm.

The blocking force of the actuator was measured as well. Blocking force is an external force required to suppress the displacement of the pressured actuator, which also means the maximum force exerted by the actuator. The setup for measuring the blocking force is shown in Fig. 7. The sensor of the force gauge was placed next to the tip of the actuator. The actuator's displacement is suppressed by the brass board placed along the side opposite from the restrained side of the actuator and the sensor part of the force gauge. When 800 kPa of pressure was applied, the blocking force of the actuator was 0.017 mN. The blocking force decreased as the pressure applied increased from 800 kPa to 1000 kPa, because the actuator buckled under the high pressure applied.

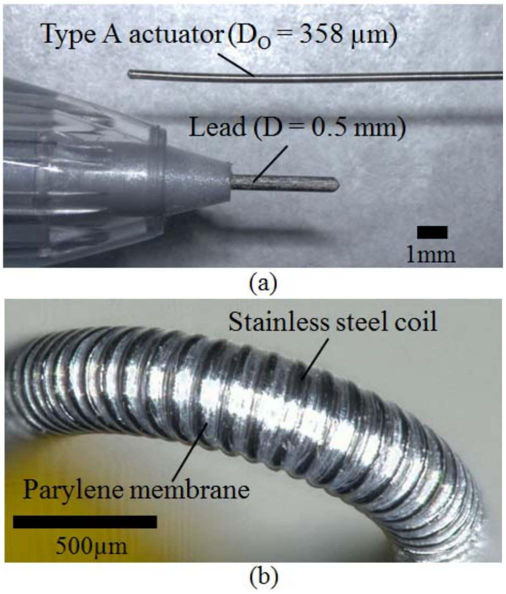

Figure 4: Fabricated type A micro hydraulic bending actuator (outer diameter D_O = 358 μm). ((a) The photograph of the actuator and a mechanical pencil lead (diameter D = 0.5 mm). (b) The parylene membrane formed on a coil by deposition.)

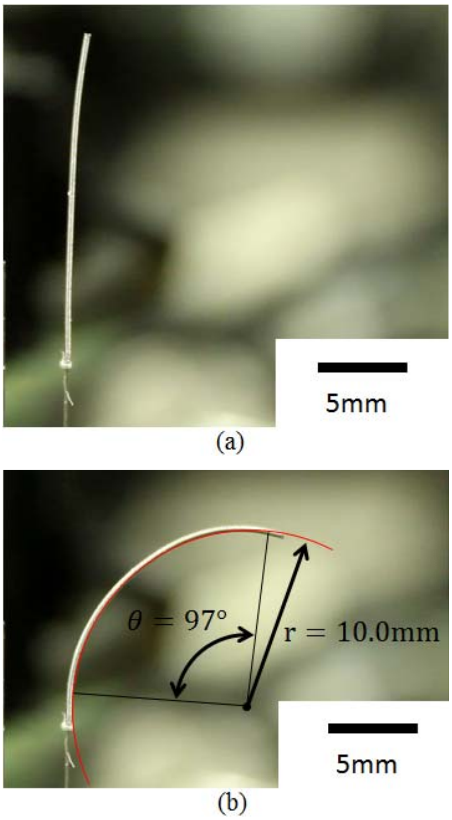

Figure 5: Bending behavior of type A actuator. ((a) The initial state of the actuator. The initial length of the actuator is 16.8 mm. (b) The state of the bending actuator when 1000 kPa of pressure was applied.)

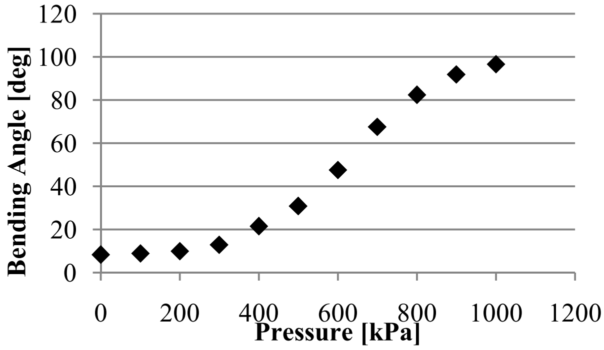

Figure 6: The relationship between the bending angle and the pressure applied on type A actuator

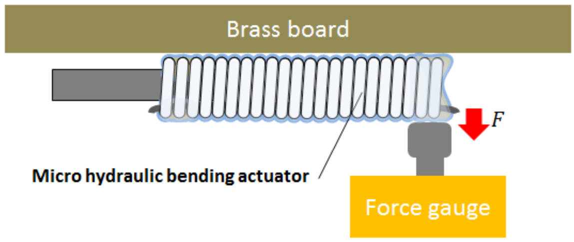

Figure 7: Setup for measuring the blocking force of the actuator

Type B

Type B actuator with an initial length of 16 mm bent 410° when 400 kPa of pressure was applied (Fig. 8).

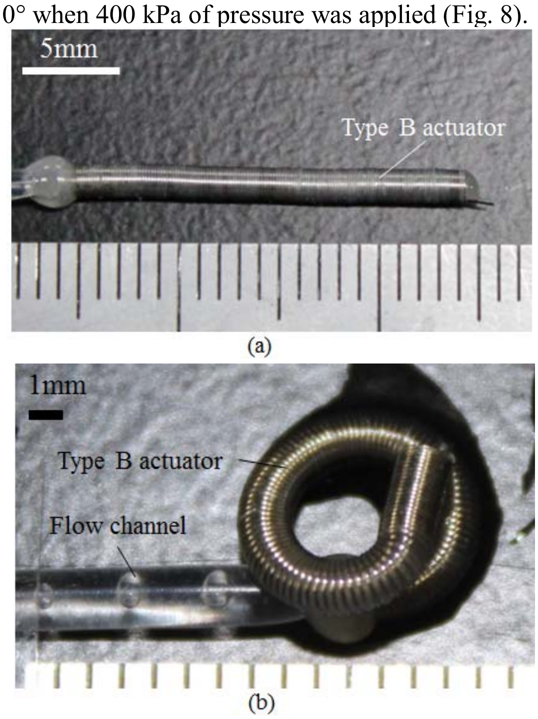

Figure 8: Bending behavior of type B actuator. ((a) The initial state of the actuator. The initial length of the actuator is 16 mm. (b) The bending actuator when 400 kPa of pressure was applied.)

The relationship between the bending angle and the applied pressure was observed. Here, the maximum pressure was set as 200 kPa considering the strength of the parylene membrane. As shown in Fig. 9, the bending angle proportionally increases as the applied pressure increases.

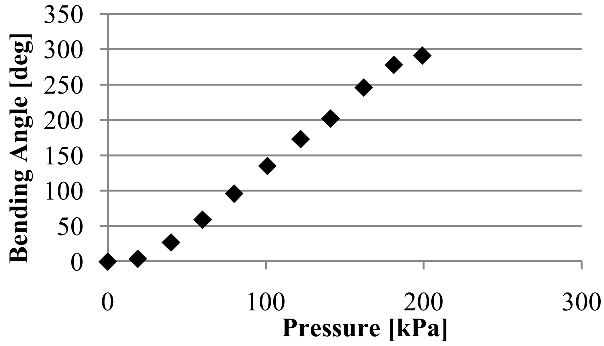

Figure 9: Relationship between the bending angle and the pressure applied on type B actuator

The blocking force of the actuator was measured as well. The setup used was the same as type A's setup (Fig. 6). When 200 kPa of pressure was applied, the blocking force was 0.059 N.

DISCUSSION

A hydraulic bending actuator with a diameter of 358 μm was achieved by type A. It bent up to 97° and generated a blocking force of 0.017 N when 800 kPa of pressure was applied. Its diameter was small enough to use it on an active guide wire, but the bending radius did not reach the target radius. Although, the fabricated actuator only bent up to a radius of 10.0 mm, it may be used on a guidewire in a different way. The tip shape of a guidewire can be very complex at times, e.g. double-bend shape. A guide wire with a double-bend shape tip usually has a sharp curve on the end, and a rather obtuse curve on the proximal side. Type A actuator may be used for changing the angle of this obtuse curve. The next step will be constructing an active guidewire by attaching the actuator on a long stainless pipe with an outer diameter of 360 μm.

By fabricating parylene membrane in between the coil wire, a hydraulic bending actuator which can attain a bending angle over 180° was attained with type B. It bent up to 410° when 400 kPa of pressure was applied. This actuator showed that the hydraulic actuators made with parylene membrane, coil, and a metal wire are capable of bending in large angle. The blocking force was 0.059 N when 200 kPa of pressure was applied. The next step will be to increase the generating force of the actuator, so that it may be used to operate rather larger devices, such as endoscopic forceps. There are several measures to achieve this. First, thicker parylene membrane can be deposited to enhance the pressure-resistance, but the thick membrane may hold back the coil from extending, which will hold back the actuators from bending in large angle. Another method is to change the cross section of the coil. By changing the circular cross section to a semi-lunar shape, the actuator will be less likely to buckle in directions other than the flat side of the actuator.

It can be considered that the pressure applied on the fabricated actuator was within the safe range to be used inside a human body. This can be said by comparing the pressure applied to the actuators with the pressure used to inflate balloon catheters. The nominal pressure of percutaneous transluminal coronary angioplasty (PTCA) balloon range from about 600 kPa to 1200 kPa, and the rated burst pressure range from about 1000 kPa to 2000 kPa. The maximum pressure applied on type A actuator was 1000 kPa, which is within the range of PTCA balloon's nominal pressure. Therefore the pressure applied for actuator's characterization could be applied inside a human body as well.

Water was injected to apply pressure to the actuators, but the air inside the actuators was not completely removed. When the actuator is used inside blood vessels, the air must be removed and pressured with saline as with balloon catheters. When the actuators are used in areas like abdominal cavity and intestine, air may be used to pressure the actuator. The response time of the actuator is shorter when it is pressured with incompressible fluid, i.e. water, compared to compressible fluid, i.e. air. On the other hand, actuator is more durable when compressible fluid is used.

The micro hydraulic bending actuators bend only in one direction, but several of them may be bundled together to make an actuator with multiple fluid pass, which could bend in multiple directions by controlling the pressure applied on each micro hydraulic bending actuator.

CONCLUSION

Two types of micro hydraulic bending actuator were made. They can be easily used as actuators in the human body, since they consist of biocompatible materials and use fluid pressure as its power source. The actuators consist of a metal spring coil, evaporated parylene membrane, and a metal wire. Type A's diameter was 358 μm, and it achieved a bending angle of 97° at 1000 kPa. Type B bent up to 410° at 400 kPa.

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