6 Multi-functional Active Catheter

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Contents

6.1 Introduction

In recent years, catheter-based interventional diagnosis and therapy have become increasingly popular. Doctors have to control the tip of the catheter by moving the catheter from the outside of the body (Figure 6.1). However, conventional catheters are difficult to stear and consequently, operations with catheters require certain human skill. Doctors monitor the position of the catheter tip using X-ray radioscopy and angiography but the information obtained is insufficient because the image observed is two-dimensional and there is no detailed information about the vessel wall near the tip of the catheter.

Active catheters have been developed for controllable steering [1, 2]. The tip of the catheter is controlled from outside the body and moves like a snake utilizing a multi-joint mechanism with distributed shape memory alloy (SMA) actuators (Figure 6.2). Active catheters can perform several motions, not only bending but also torsional, and can extend by changing the configuration of the SMA actuators and bias springs.

First, designs and mechanisms of each function are described, then the fabrication of active catheters and the concept of active guide wires are discussed. Finally, circuit integration and development of ultrasound probes, optical pressure sensors and magnetic sensors to obtain information near the tip of the catheters and that help the steering of the active catheter are considered.

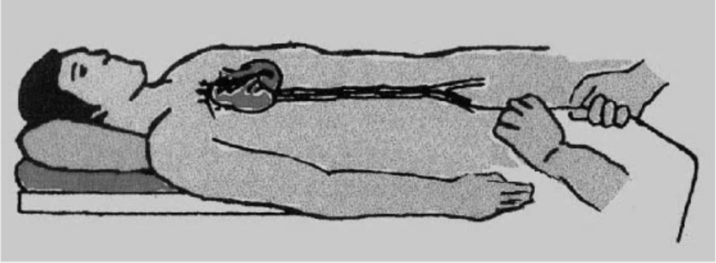


Figure 6.1. Catheter-based intervention.

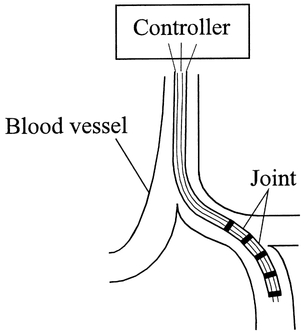


Figure 6.2. Concept of active catheter.

6.2 Designs and Mechanisms of Active Catheters

Catheters have a working channel that is used for the injection or suction of fluids or insertion of micro tools as shown in Figure 6.3. Contrast medium is used to make blood vessels visible with x-ray fluorography (angiography). Anticoagulant is injected in to the working channel to remove thrombus in blood vessels. Laser probes or various micro tools are inserted in to the working channel for reperfusion. A micro coil or liquid polymer is conveyed through the working channel for embolization therapy.

The active catheters also have a working channel as a lumen of an inner tube for such purposes. Active catheters have actuators and an outer tube that covers the inside mechanisms for waterproofing and electrical insulation.

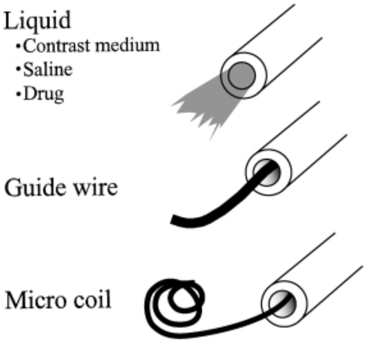


Figure 6.3. Functions of working channel.

6.2.1 Bending Mechanism

6.2.1.1 Silicon–glass Link Active Catheter

First, active catheters with silicon–glass link structures were developed (Figure 6.4). Many joints are serially connected and each joint can bend in six directions. Three SMA coil actuators are attached to each link as joints at equilateral triangular locations to bend in six directions. A restoring force is provided by the elasticity of the stainless-steel bias spring. Silicone rubber tubes were used as the inner and outer tubes. When the SMA coil is heated above a certain transition temperature by an electrical current, the SMA coil contracts. A 250 μm outer diameter SMA coil made of 50 μm diameter SMA wire was used. The transition temperature of the SMA is about 55–65 °C.

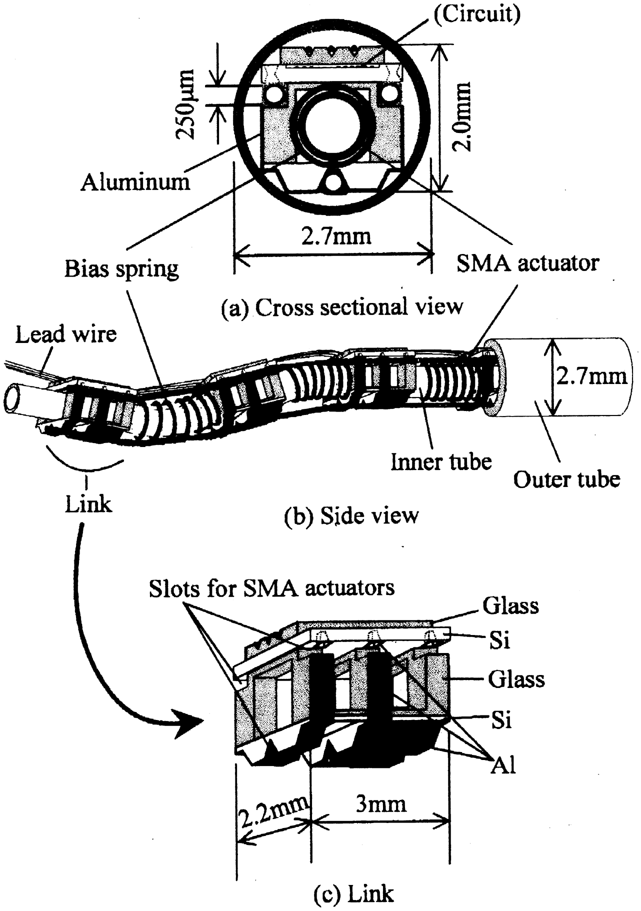


Figure 6.4. Silicon-glass link active catheter (multi-joint bending mechanism).

6.2.1.2 Linkless Active Catheter

When thin-walled silicone rubber tubing is used as an outer tube, it extends locally and obstructs the bending motion of the catheter and therefore the bending is limited. A thin-walled outer tube supported by the liner coil can be applied. This is very effective for large bending. The liner coil has an extra function of preventing mechanical stresses from outside.

By fixing SMA actuators to the liner coil directly, a link can be eliminated and the liner coil is used as a skeleton and a bias spring. Furthermore, every part works as a joint and hence bends more flexibly than that with links [3].

The structure of a multi-joint, multi-directional linkless active catheter is shown in Figure 6.5. Three SMA coil actuators are fixed inside the stainless-steel liner coil and the liner coil is used as a common ground in the electrical circuit, as shown in an equivalent circuit depicted in Figure 6.5b (one of three SMA coils is shown for simplicity). Each joint is individually controlled by supplying driving current from the center of each joint and making the current run into the common ground through the SMA actuator. For this purpose, a lead wire is connected to the center of each joint and both sides of each joint are electrically connected to the liner coil, as shown in Figure 6.5c.

In this fabrication, insulator is coated on the liner coil and removed locally using a YAG laser for making the electrical connections. An electrically conduc-

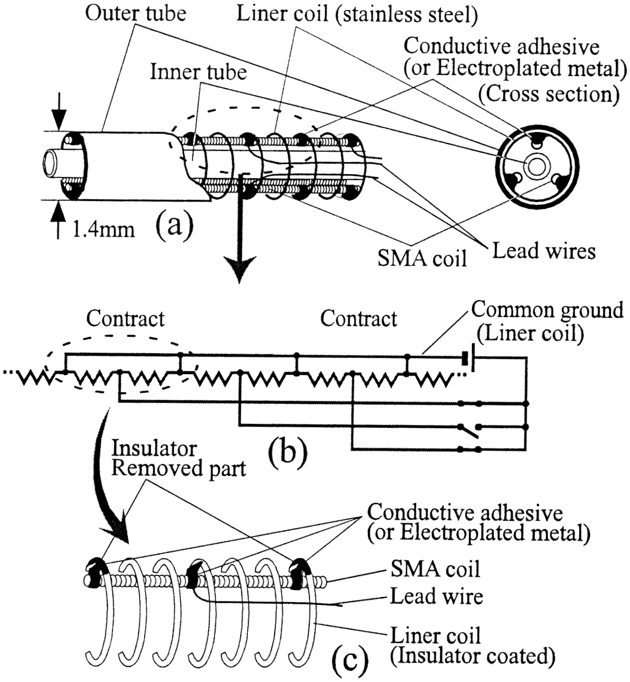


Figure 6.5. Structure of linkless active catheter (multi-joint bending mechanism).

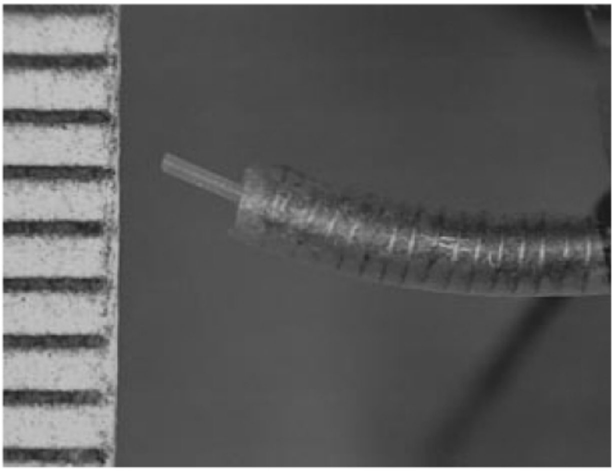


Figure 6.6. Photograph of linkless active catheter (multi-joint bending mechanism).

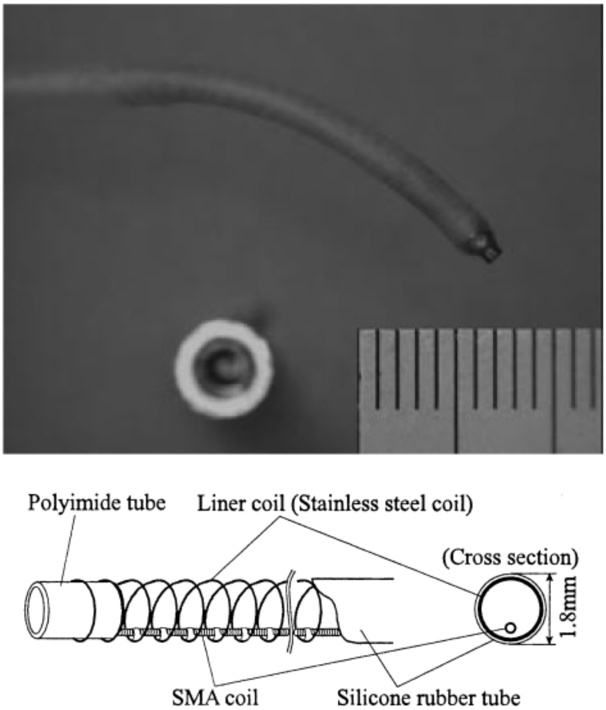


Figure 6.7. Bending mechanism fabricated for test in water (one-joint, one-directional bending mechanism).

tive adhesive is used in this case, but electroplated metal can be used instead of the adhesive, as mentioned later.

A photograph of the fabricated bending mechanism of which outer diameter is 1.4 mm is shown in Figure 6.6.

The multi-joint, multi-directional mechanism is relatively complicated. A one-joint, one-directional bending mechanism can be applied for many practical uses as mentioned later in Section 6.7.1. The structure and a photograph of the one-joint, one-directional 1.8 mm outer diameter bending mechanism are shown in Figure 6.7. This catheter was tested in water. The bending characteristics in air (25 °C) and water (38 °C) are shown in Figure 6.8. This design has a benefit of tolerable surface temperature on the outer tube to be used in the human body. The setup for surface temperature measurement of the active catheter using a small thermocouple is shown in Figure 6.9 and the result is shown in Figure 6.10. The surface temperature was below 41 °C when the bending mechanism was actuated by a current of 80 mA in water at 38 °C.

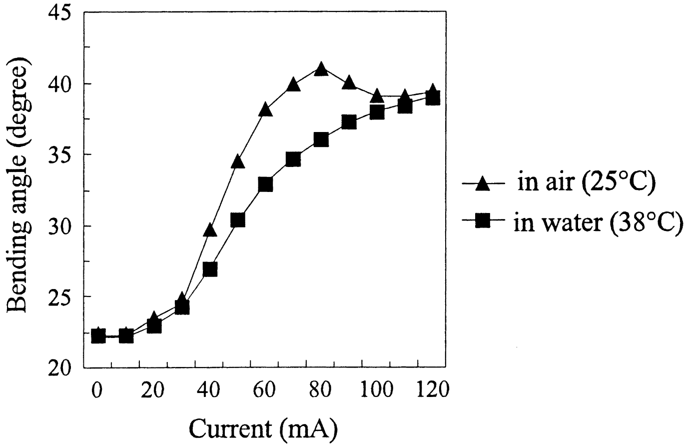


Figure 6.8. Bending characteristics in air (25 °C) and water (38 °C).

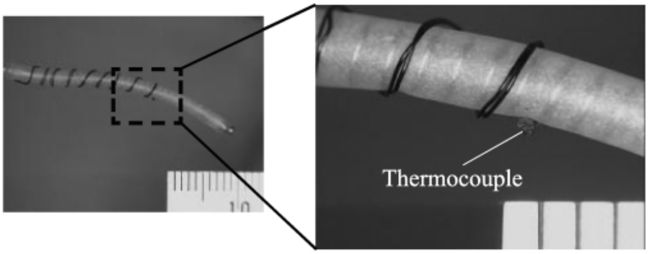


Figure 6.9. Surface temperature measurement of active catheter using a thermocouple.

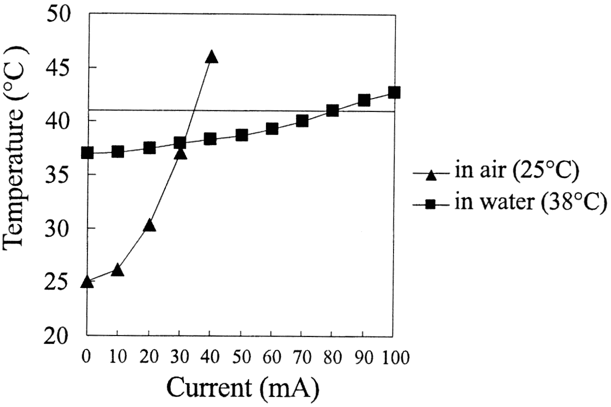


Figure 6.10. Surface temperature of active catheter in air (25 °C) and water (38 °C).

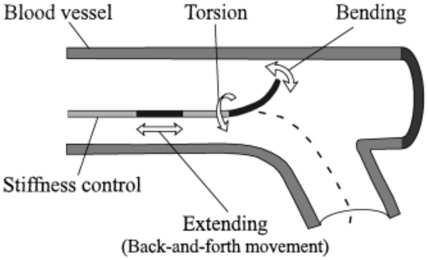


Figure 6.11. Bending, torsional, and extending active catheter.

6.2.2 Torsional Mechanism

For steering the catheter through branches of blood vessels, the J-shaped tip of the catheter or guide wire is torsionally rotated from the outside conventionally. However, the torque cannot be transmitted with good control when a blood vessel has a loop or complex configuration. This problem can be solved by installing an active torsional mechanism in the catheter or the guide wire [4]. This torsional mechanism can function effectively when it is installed behind the bending mechanism as shown in Figures 6.11 and 6.12.

The structure of the torsional mechanism is shown in Figure 6.13 a. This mechanism consists of a liner coil and a twisted SMA coil fixed coaxially inside the liner coil. The liner coil plays the role of a bias spring and a lead wire. When the SMA coil is heated above a certain transition temperature by an electrical current, the SMA coil is untwisted. Conversely, the liner coil twists (turns back) the catheter when electrical current is turned off. The fabrication of the torsional mechanism and its characteristics will be discussed in Section 6.4.

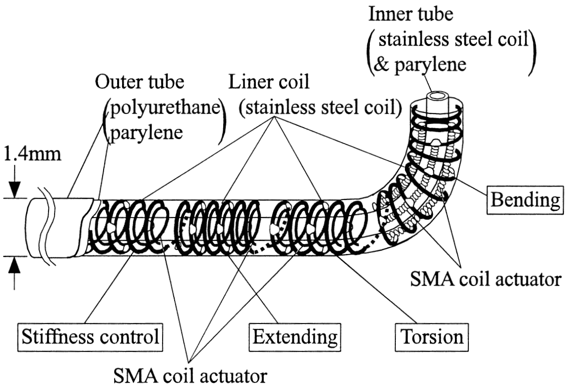
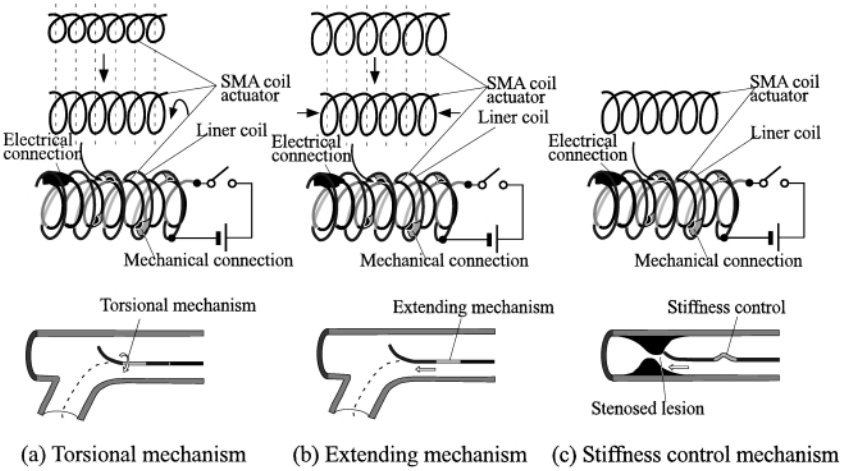


Figure 6.12. Structure of bending, torsional, and extending active catheter.



(a) Torsional mechanism (b) Extending mechanism (c) Stiffness control mechanism

Figure 6.13. Principles and fabrication methods of torsional, extending, and stiffness control mechanisms.

6.2.3 Extending and Stiffness Control Mechanisms

To move the catheter or the guide wire forward, they are pushed from the outside conventionally. When a blood vessel has a loop or complex configuration, the forward movement is inaccurate because of the flexing of the catheter or the guide wire body (poor pushability). In contrast, retracting the catheter or the guide wire is relatively accurate. To position the tip at an aimed-for lesion, the tip has to be moved forward beyond the lesion and then retracted. The risk of perforation increases if the body of the catheter or the guide wire is hard whereas pushability and torque control are poor when they are soft.

Fine positioning of the tip is realized when an extending and retracting mechanism is mounted near the tip of the catheter or the guide wire as shown in Figure 6.11 and Figure 6.12 [4]. The structure of the extending mechanism is shown in Figure 6.13 b. This mechanism consists of a liner coil and a compressed SMA coil fixed coaxially inside the liner coil. The liner coil plays the role of a bias spring and a lead wire. When the SMA coil is heated above a certain transition temperature by an electrical current, the SMA coil extends. Conversely, the liner coil restores the catheter shape when the electrical current is turned off. A 1.4 mm outer diameter extending mechanism was fabricated and its motion was confirmed.

A stiffness control mechanism also makes the steering of a catheter or a guide wire easy. As shown in Figure 6.13 c, the body of the catheter or the guide wire should be hard when the mechanism goes straight, whereas the body should be soft to prevent perforation when the mechanism passes through a stenosed portion. The stiffness control mechanism consists of a liner coil and a natural state (not deformed) SMA coil fixed coaxially inside the liner coil. The SMA coil does not deform but hardens when electrical current is applied.

6.3 SMA Actuators

6.3.1 SMA Coil Actuators

In order to obtain a large bending motion, 50% NiTi SMA micro coil actuators were used. Figure 6.14 shows a photograph of SMA coil actuators which were used for active catheters. For the bending mechanism, extension-type SMA coils (outer diameter 250 µm, wire diameter 50 µm) (Figure 6.14 a) were used. Figure 6.15 shows the characteristics of the SMA coil actuator. The curve at 0 mA cor-

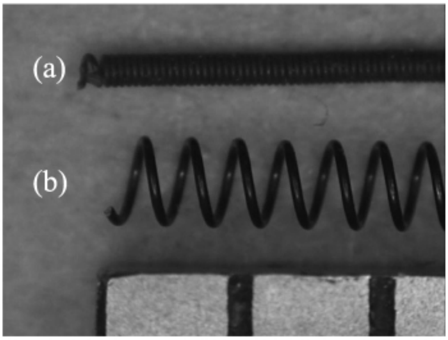


Figure 6.14. Photograph of SMA (NiTi) coil actuators. (a) Extension-type SMA coil (outer diameter 250 µm, wire diameter 50 µm); (b) compression-type SMA coil (outer diameter 650 µm, wire diameter 75 µm).

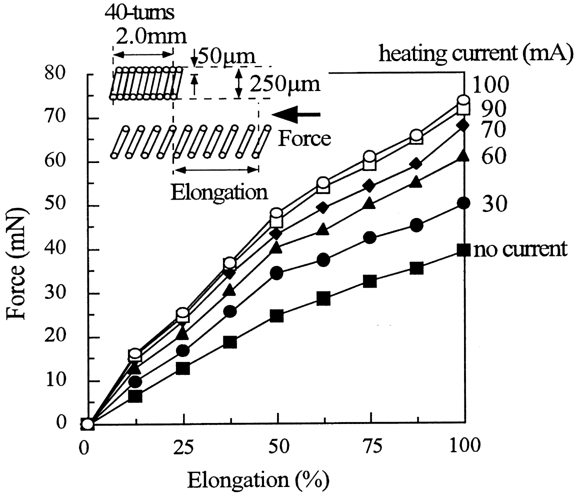


Figure 6.15. Characteristics of SMA coil actuator.

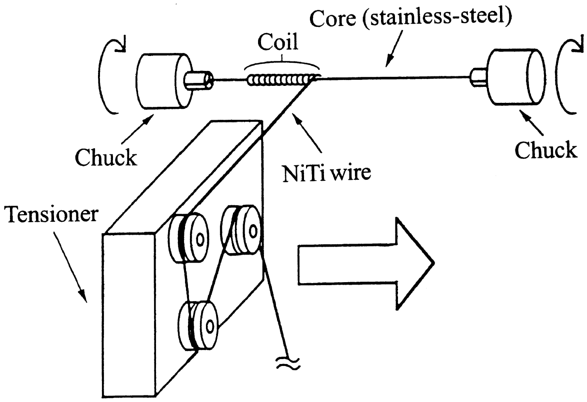


Figure 6.16. Fabrication of SMA coil actuators.

responds to the elastic force of the SMA actuator at room temperature. SMA coils make a multi-directional bending mechanism possible because SMA coils which are not applied current can passively extend when the other side SMA coil shrinks and bends its joint. Compression-type SMA coils (outer diameter 650 μm, wire diameter 75 μm) (Figure 6.14b) were used for torsional, extending and stiffness control mechanisms.

SMA micro coils (eg, outer diameter 75 μm, wire diameter 25 μm) are fabricated by winding an SMA wire as shown in Figure 6.16. The SMA micro coil can be heated with low power, hence a cooling system is not needed. It permits rapid motion because of its small size.

6.3.2 Batch Fabrication of SMA Actuator Using Electrochemical Etching

6.3.2.1 Flat Meandering SMA Actuators

To satisfy the requirements for a small outer diameter and a wide inner working channel, thin actuators such as S-shaped planar springs are effective. In order to obtain a thin actuator with a small width and large actuation stroke, a fine pitch spring is needed. A batch fabrication method for an SMA (NiTi) sheet based on electrochemical pulsed etching with a sacrificial dummy metal layer has been developed and flat, meandering S-shaped SMA actuators have been fabricated as shown in Figure 6.17 [5]. The fabrication process is shown in Figure 6.18. An electrolyte of sulfuric acid in methanol was used as an etchant and pulsed etching was chosen instead of DC etching because it is suitable for the etching of a narrow mask space. An negative photoresist (OMR 83, Tokyo Ohka Kogyo) was used as an etching mask. In order to realize uniform etching, a sacrificial conduc-

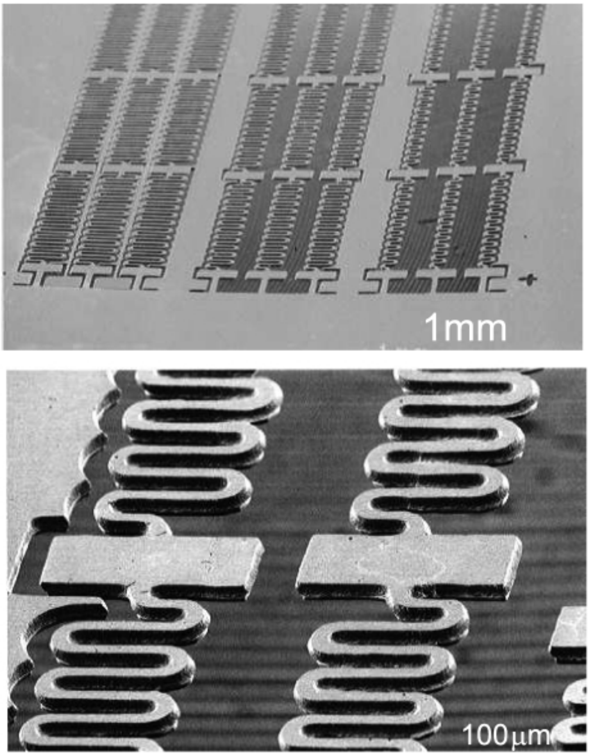


Figure 6.17. Batch-fabricated flat meandering SMA (NiTi) actuators using electrochemical etching.

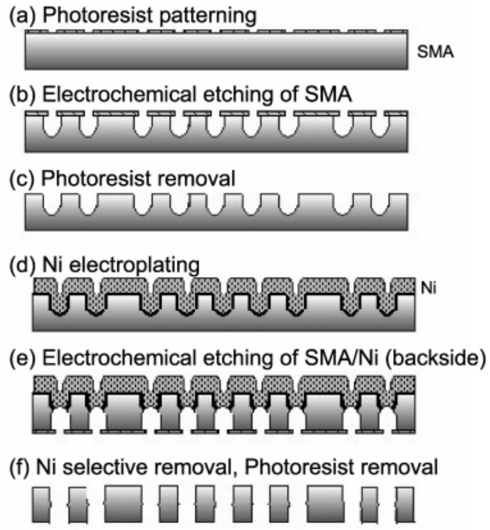


Figure 6.18. Process flow of flat meandering SMA actuators using electrochemical etching.

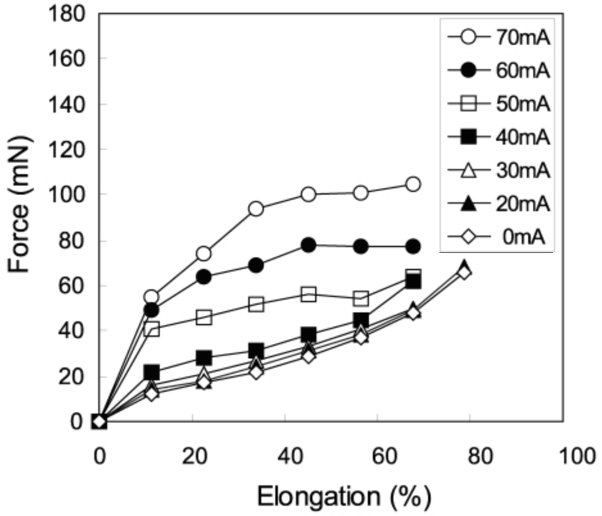


Figure 6.19. Characteristics of flat meandering SMA actuator.

tive dummy layer (Ni) was used on the rear side of the SMA so that current passage can be maintained after the SMA layer has been etched through.

This process is more suitable for mass production than a non-batch process such as laser cutting and electrodischarge machining.

The characteristics of the actuator are shown in Figure 6.19. The curve at 0 mA corresponds to the elastic force of the SMA actuator at room temperature. The thickness, length, and width of the flat meandering SMA actuator are 38 μm,

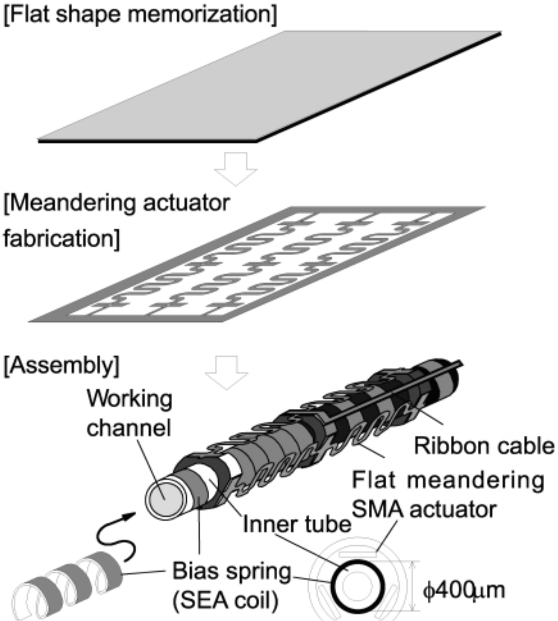


Figure 6.20. Assembly of active catheter using flat meandering SMA actuator.

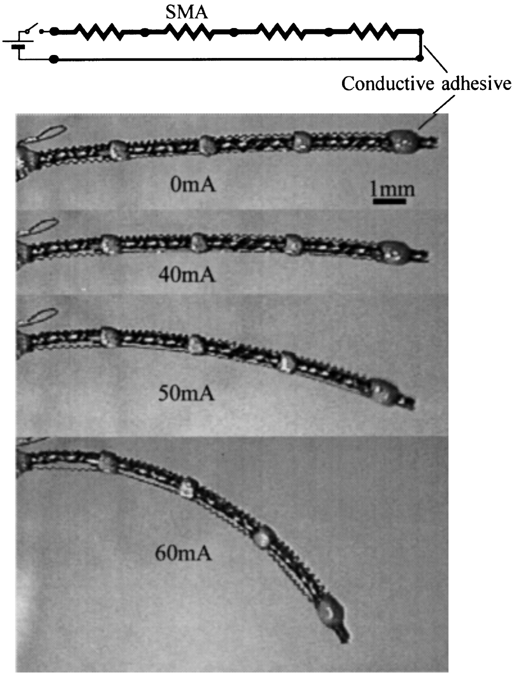


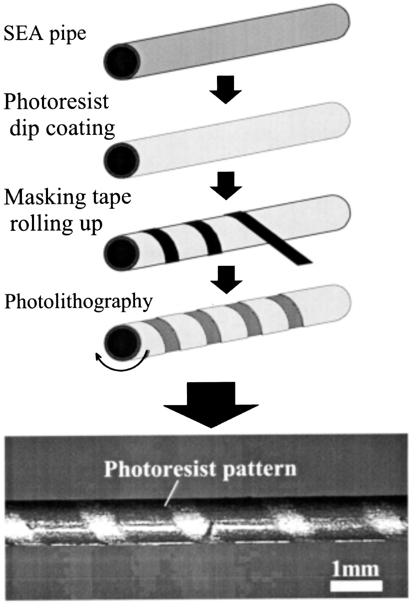
Figure 6.21. Bending motion of active catheter using flat winding SMA actuator.

4.4 mm and 290 µm, respectively. The maximum generated force of the actuator at 70 mA was 75 mN.

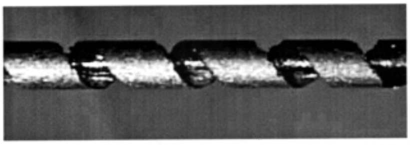
An active catheter which has three meandering SMA actuators was fabricated as shown in Figure 6.20. A bending test on the active catheter is shown in Figure 6.21.

6.3.2.2 *Fabrication of Helical Ribbon SEA and SMA*

The batch fabrication process was also applied to the micromaching of 51% NiTi super elastic alloy (SEA) pipe whose outer and inner diameters are 1.0 and 0.8 mm, respectively, to make a bias spring for active catheters. The fabrication method and fabricated coil are shown in Figure 6.22. Dip-coated photoresist on the surface of the SEA pipe was patterned by photolithography with rolled-up masking tape. This method can be also applied to an SMA pipe to make an actuator which can be used for a torsional, extending, or stiffness control mechanism as shown in Figure 6.13.



Photolithography



Electrochemical etching (100µm thick)

Figure 6.22. Helical etching of SEA (NiTi) pipe using electrochemical etching.

This micromachining technique for the NiTi seems to be applicable not only for the catheter but also for other MEMS in a wide field such as cardiovascular stents and micro actuators of various shapes.

6.4 Assembly of Active Catheters

6.4.1 Required Conditions for Assembly of Active Catheters

The following conditions are required to make all the mechanisms of active catheters mentioned above:

(a) making mechanical connections between the SMA coil and the liner coil;

(b) keeping the process temperature below 40 °C to avoid SMA deformation;

(c) making electrical connections between the SMA coils and lead wires, and between the SMA coil and the liner coil;

(d) rapid and low-cost assembly.

Active catheters have been assembled using electrically conductive and nonconductive adhesives [3]. However, it is not easy to make many small connections between the SMA coil and the liner coil. UV-curable resins or laser-assisted (chemical vapor deposition) (CVD) [6, 7] can be also applied but it takes a long time because many connections have to be formed individually.

To solve these problems, the following batch assembly method using nickel electroplating and acrylic resin electrodeposition was developed [4].

6.4.2 Assembly Using Electroplating

A torsional mechanism mentioned earlier (Section 6.2.2) was assembled using electroplating. The assembly process is described in this section.

6.4.2.1 Making Mechanical Connections Between SMA Coil and Liner Coil

First, insulator was coated on the SMA coil using electrodeposition of acrylic resin (CMEX, Shimizu) as shown in Figure 6.23. This process can be replaced by parylene evaporation. Next, insulator was removed locally using a YAG laser at the required positions as shown in Figure 6.24. Subsequently, nickel was electroplated at the positions where insulator had been removed simultaneously as

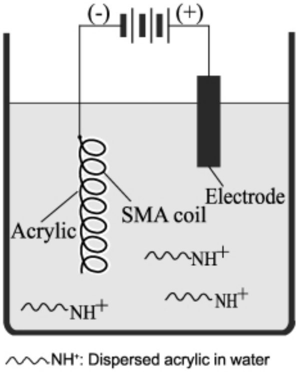


Figure 6.23. Setup for coating of insulator on SMA coil.

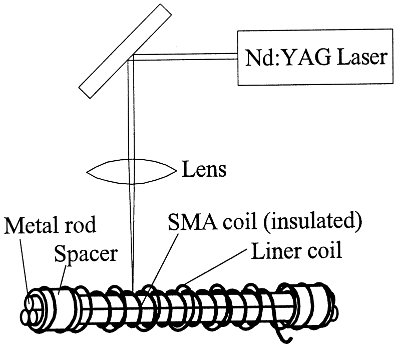


Figure 6.24. Removing of insulator on SMA coil by YAG laser.

shown in Figure 6.25 a. The structure after the nickel electroplating is shown in Figure 6.25 b. The rods inside the SMA coil constituted a jig which was removed later. After slightly moving the liner coil close to the nickel, thick UV-curable acrylic resin (UA-51, Shimizu) was electrodeposited as shown in Figure 6.26. The acrylic resin was dried by exposing it to vacuum and cured by UV irradiation (1200 mJ/cm^2). The deposited acrylic resin was clear and smooth, as shown in Figure 6.27, after dehydration. Mechanical connections between the deposited nickel on the SMA coil and the liner coil were formed simultaneously in this process.

6.4.2.2 Making Electrical Connections Using Ni Electroplating

As described earlier, electrical connections between the liner coil and the SMA coil are necessary to utilize a liner coil as an electrical circuit to apply current to the SMA coil. As shown in Figure 6.28, the electrical connections were formed by a second nickel electroplating after local removal of the insulator on the SMA coil and the liner coil using a YAG laser. Finally, lead wires were electrically con-

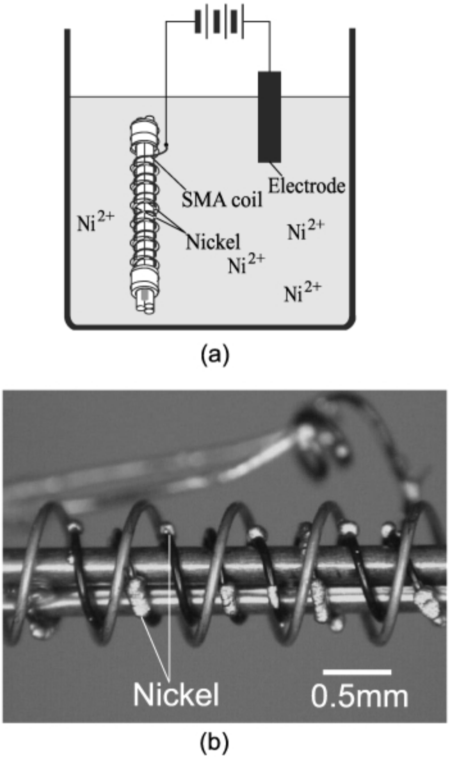


Figure 6.25. Nickel electroplating on SMA coil. (a) Setup for nickel electroplating on SMA coil; (b) deposited nickel on SMA coil.

nected to the SMA coil by placing lead wires on the SMA and subsequent nickel electroplating.

6.4.2.3 Active Catheter Assembled Using Electroplating

A torsional mechanism fabricated using nickel electroplating and acrylic electrodeposition is shown in Figure 6.29. The outer diameter of the mechanism is 1.3 mm without the outer tube and the length is 7 mm. An electrical connection was formed at the tip to use the liner coil as a part of the electrical circuit. A torsional rotation of 70° was obtained with a current of 80 mA, as shown in Figure 6.30.

The bending mechanism was also assembled using the nickel electroplating and acrylic electrodeposition as shown in Figure 6.31.

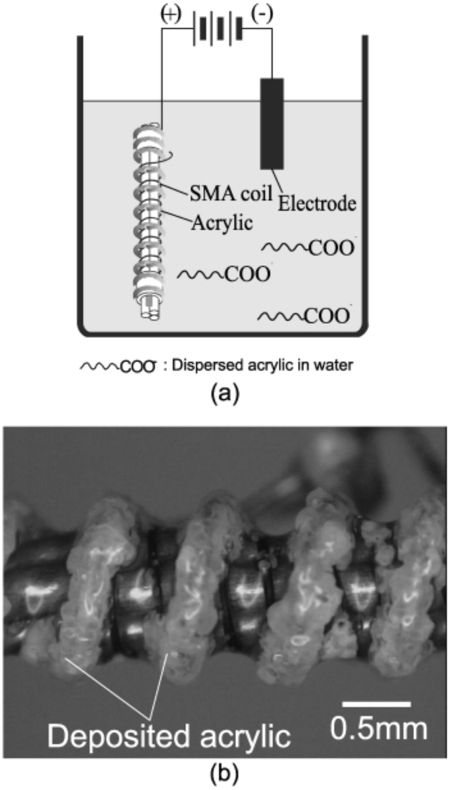


Figure 6.26. Acrylic resin electrodeposition on liner coil. (a) Setup for acrylic resin electrodeposition on liner coil; (b) deposited acrylic resin on liner coil.

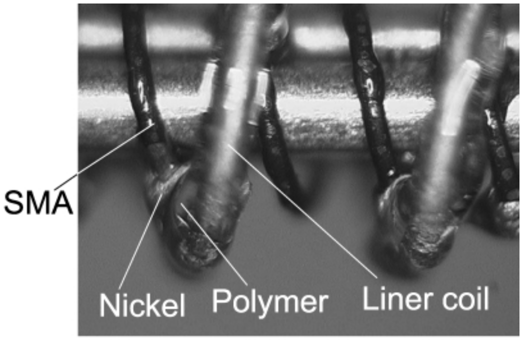


Figure 6.27. Mechanical connections between SMA coil and liner coil of torsional mechanism (after drying and UV cure).

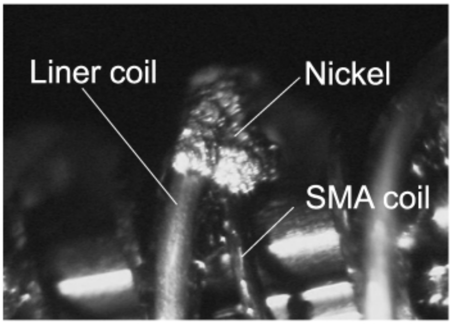


Figure 6.28. Electrical connection between SMA coil and liner coil.

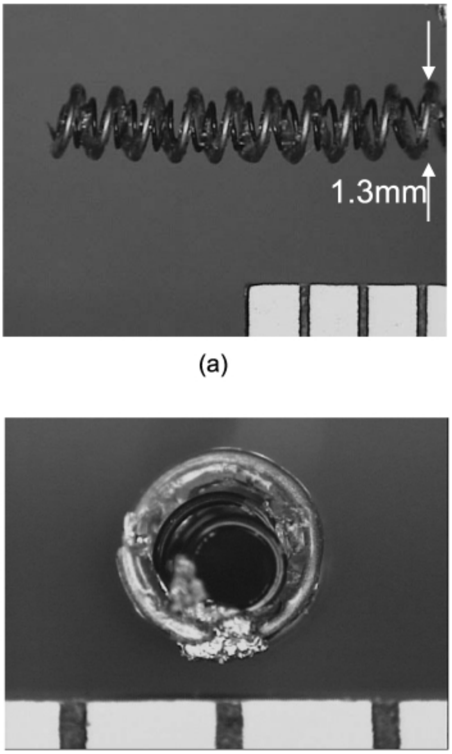


Figure 6.29. Torsional mechanism assembled using electroplating. (a) Side view; (b) front view.

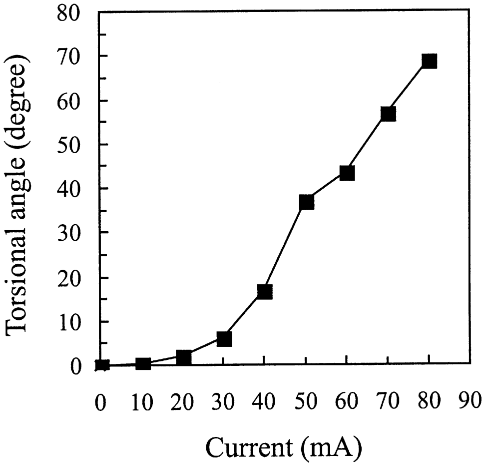


Figure 6.30. Characteristics of torsional mechanism.

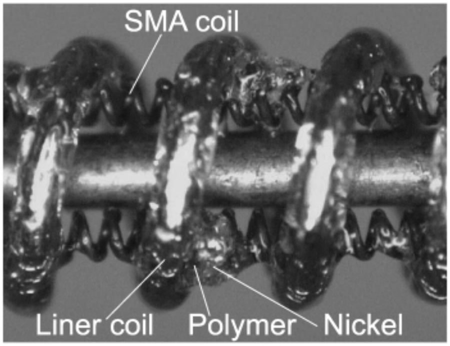


Figure 6.31. Side view of bending mechanism assembled using electroplating.

6.4.3 Inner Tube and Outer Tube

6.4.3.1 Inner Tube

As mentioned earlier, an active catheter has a working channel as a lumen of the inner tube that is used for injection or suction of fluids or insertion of micro tools. Silicone rubber tubing was used as the inner tube of the active catheters. Tubular structures consisting of a metal spring coil and an evaporated parylene membrane shown in Figures 6.32 and 6.33 can be also used as the inner tube. The tube shown in Figure 6.32 was obtained by parylene C (poly(monochloro-*p*-xylylene)) evaporation on the stainless-steel extension coil spring. The tube shown in Figure 6.33 was obtained by parylene evaporation on the stainless-steel extension coil spring both ends of which were sealed with adhesive.

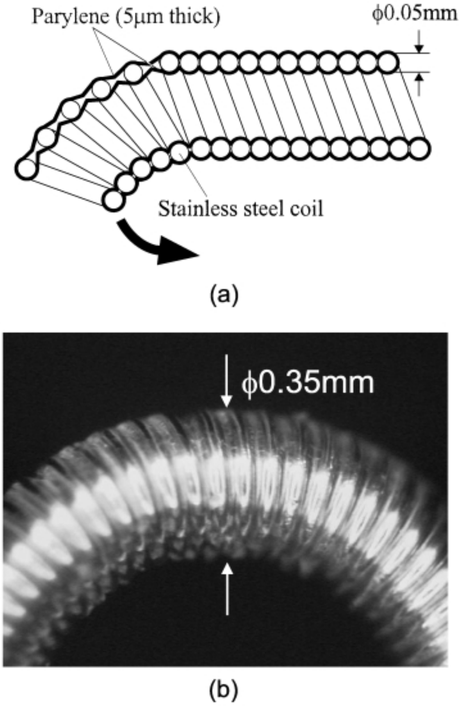


Figure 6.32. Coil spring with coated parylene on inner and outer sides. (a) Structure; (b) photograph.

6.4.3.2 Thin-walled and Anticoagulant Outer Tube

The active catheter has an outer tube for use in blood vessels or other environments as mentioned in Section 6.2. A thick-walled or hard outer tube prevents the motion of the active catheters. A thin-walled (outer diameter 1.4 mm, wall thickness 0.1 mm) tube has been used previously as an outer tube of the active catheters [1], but thin-walled tubes easily collapse and therefore a supporting liner coil was adopted to solve this problem, as mentioned above.

To make such a tubular structure, the liner coil is covered with a thin parylene layer and then coated with thin-walled anticoagulant polyurethane as shown in Figure 6.34. The fabrication process is shown in Figure 6.35. First, a bending mechanism is covered with a silicone rubber tube (Figure 6.35 b) and parylene C is evaporated to make an inner wall between the turns of the liner coil (Figure 6.35 c). After rubbing the outside (Figure 6.35 d), the silicone rubber tube is removed using silicone rubber etchant (KSR-1, Kanto Chemical) (Figure 6.35 e). A photograph of this step is shown in Figure 6.36 a. After sealing both ends, it is dip-coated with polyurethane (Pellethane 2363-80AE, Dow Chemical) diluted in dimethylformamide (4 wt.%) (Figure 6.35 f). A photograph of this step is shown in Figure 6.36 b. Finally, the end sealings are removed and an inner tube is in-

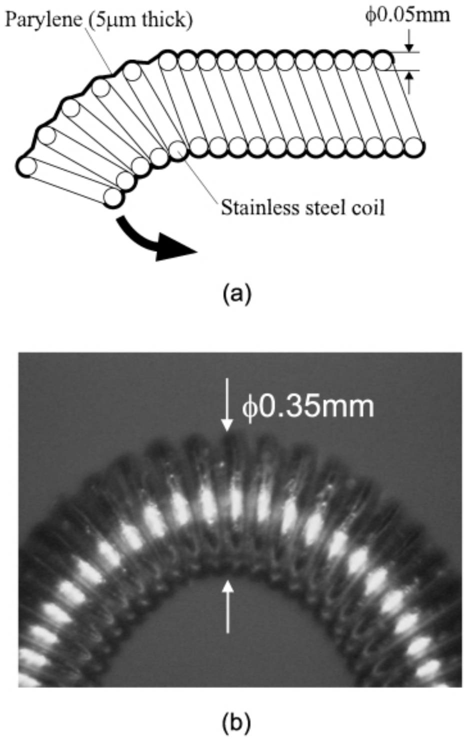


Figure 6.33. Coil spring with coated parylene on outer side. (a) Structure; (b) photograph.

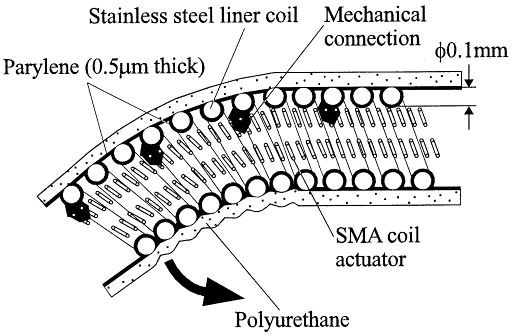


Figure 6.34. Active bending mechanism with polyurethane outer tube supported by coil spring.

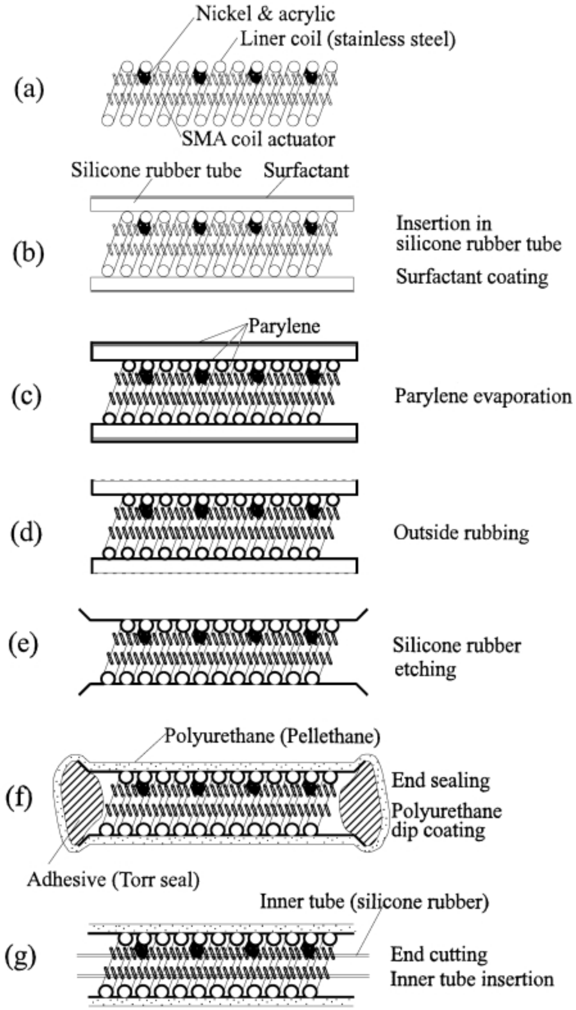


Figure 6.35. Process flow of polyurethane outer tube on active bending mechanism.

serted (Figure 6.35 g). This process can be applied after fabricating active mechanisms and the outer tube acquires anticoagulant by dip coating with polyurethane, which is used for conventional catheters.

The process can be used for a small-diameter active mechanism as an outer tube of an active guide wire, which will be discussed in the next section.

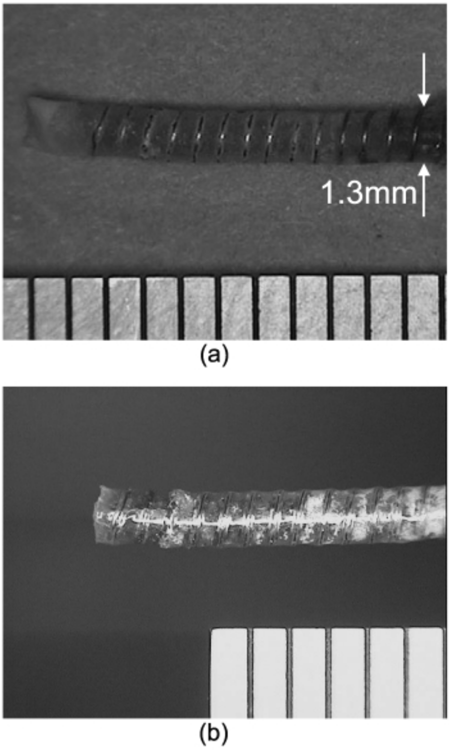


Figure 6.36. Polyurethane outer tube on active bending mechanism. (a) Photograph taken before polyurethane coating (corresponds to Figure 6.35 e); (b) After dip coating of polyurethane (Pellethane) (corresponds to Figure 6.35 g).

6.5 Active Guide Wire

Guide wires are used to guide catheters. In a conventional method, a guide wire which has an appropriate tip shape is selected and moved forward and rotated from the outside of the body. It is used for steering at a branch of a blood vessel, reaching to the lesion and passing through the stenosed lesion (Figure 6.37). The guide wire is usually inserted in the catheter and can be replaced by another tip-shaped guide wire if necessary.

The active catheter has a working channel, whereas the active guide wire does not have any working channel but the outer diameter is much smaller than a catheter.

The concept of a 0.5 mm outer diameter active guide wire which has bending, torsional, extending and stiffness control mechanisms is shown in Figure 6.38. Figure 6.39 shows a photograph of the outer tube of the active guide wire, which consists of a stainless-steel liner coil and evaporated parylene membrane. Active guide wires can be used with most conventional medical catheters.

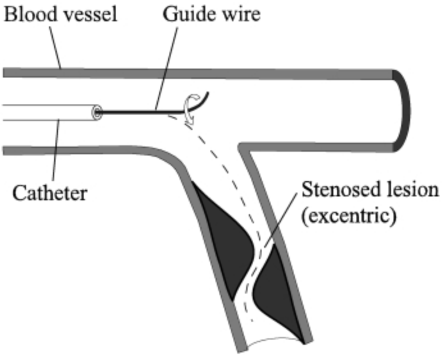


Figure 6.37. Operation of catheter using guide wire.

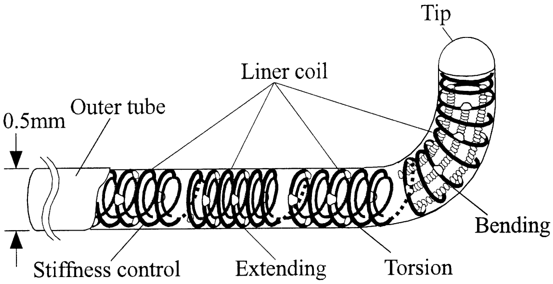


Figure 6.38. Concept of active guide wire.

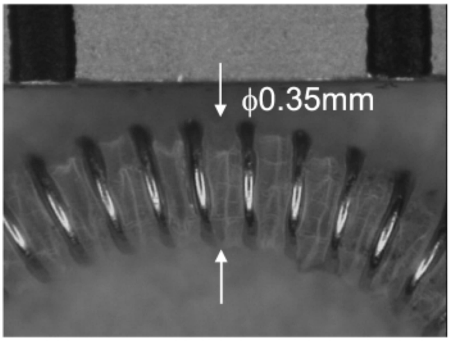


Figure 6.39. 0.35 mm outer diameter thin-walled parylene tube supported by coil spring for active guide wire.

6.6 Active Catheter with Communication and Control Chips

A major problem with an active catheter which has many joints and mechanisms is that too many lead wires are required to control each SMA actuator. To minimize the number of lead wires, flexible polyimide-based integrated complementary metal oxide semiconductor (CMOS) interface circuits for communication and control (C&C IC) have been developed and assembled on the active catheter, which has polymer links (Figure 6.40) [8].

The C&C ICs are incorporated within the links and require only three common lead wires to address all the links and control the selected SMA actuators in the active catheter, as shown in Figure 6.41. A metal oxide semiconductor (MOS) transistor with a large channel width is used for switching the SMA actuator. A block diagram of the integrated C&C IC is shown in Figure 6.42. The clock (CLOCK) and the data (DATA) are discriminated by a data–clock separator. To reduce the system size and simplify the assembly work, the C&C IC and three lead wires are fabricated on the same substrate using a CMOS-compatible

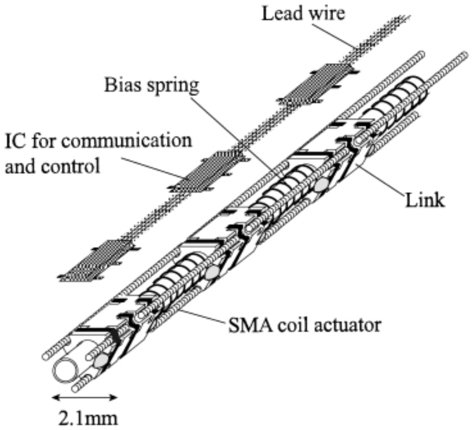


Figure 6.40. Structure of active catheter with communication and control IC chips.

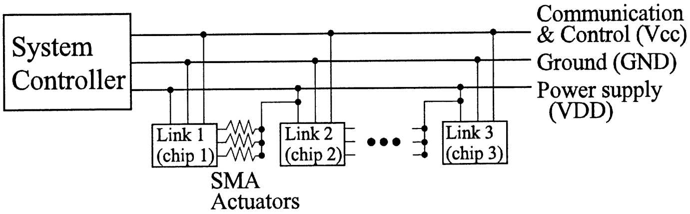


Figure 6.41. Interface system.

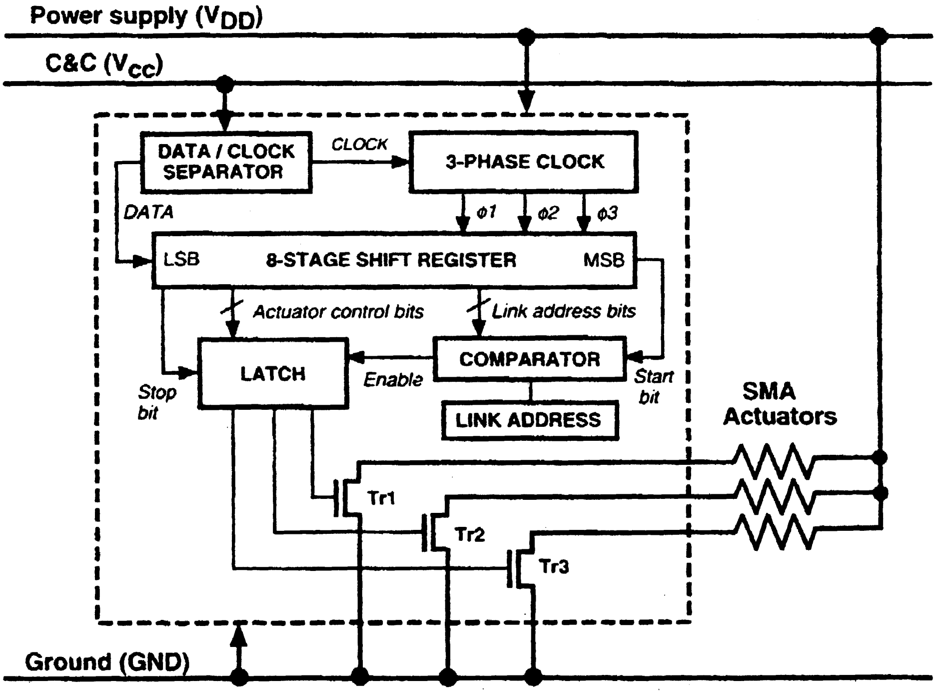


Figure 6.42. Block diagram of the integrated communication and control circuit.

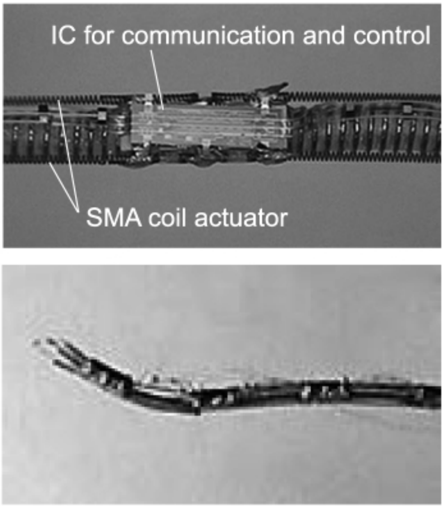


Figure 6.43. Photograph of active catheter with communication and control IC chips.

polyimide-based process. The outer diameter of the fabricated active catheter is approximately 2.0 mm without an outer tube.

The fabricated C&C IC chips with flexible interconnect leads were attached to the links individually. Photographs of the active catheter with the C&C IC chips after the assembly process and its bending are shown in Figure 6.43.

6.7 Ultrasound Imager

A forward-looking color image inside the body can be obtained by using an endoscope with optical fiber bundles or a charge-coupled device (CCD) imager. However, flushing with saline is necessary to remove blood cells, which scatters light. Consequently, real-time observation is impossible.

Although the resolution is relatively low and monochrome, ultrasonography does not need flushing with saline and continuous monitoring is possible. Furthermore, a three-dimensional image and images of the surrounding blood vessel can be obtained. Recently, small-size ultrasonography probes in blood vessels called IVUS (intravascular ultrasound) have been developed.

6.7.1 Side-looking Ultrasound Imager in Kidney

Figure 6.44 shows an application of the active catheter to a conventional ultrasound imaging probe used in a kidney [3]. The active catheter has a mechanical scan ultrasound transducer at the tip. This transducer is rotated inside the active catheter by transmitting the rotational movement from outside using a flexible shaft. This catheter was designed to be introduced into renal pelvis and renal calyces located at the lower part of the kidney where conventional catheters cannot

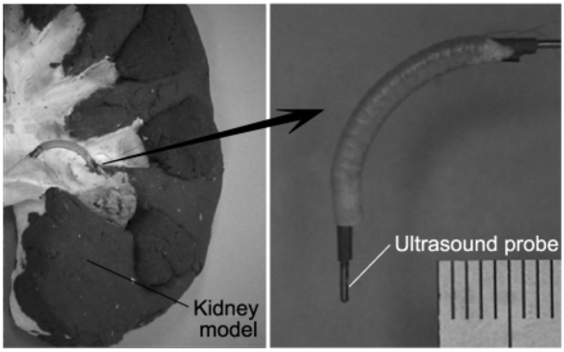


Figure 6.44. Active catheter with ultrasound probe for ultrasonography in kidney model.

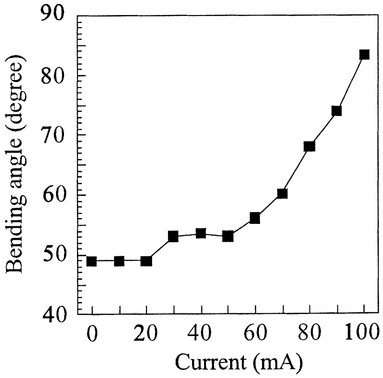


Figure 6.45. Bending characteristics of active catheter with ultrasound probe.

reach. As only one-side bending is needed, one SMA coil is used in this linkless-type active catheter. Bending characteristics are shown in Figure 6.45.

6.7.2 Forward-looking Ring Array Ultrasound Imager

An ultrasound forward-looking imaging system was developed for catheter use. A ring-shaped ultrasound probe (outer diameter 3 mm, inner diameter 2 mm) consisting of eight ultrasound transducers with flexible lead wires was mounted on the catheter tip [9]. The structure, a photograph of the ring array probe and the imag-

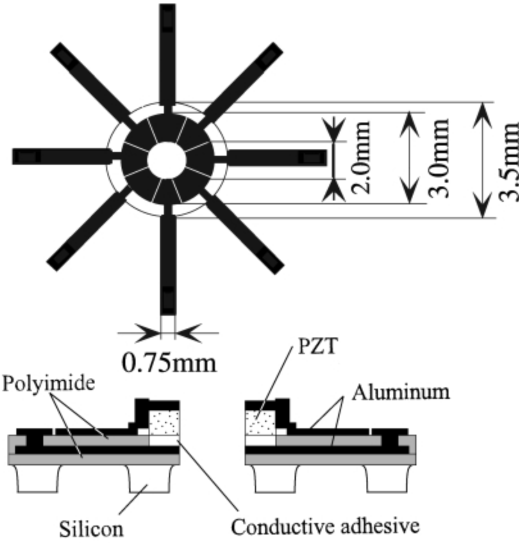


Figure 6.46. Structure of forward-looking ring array ultrasound probe.

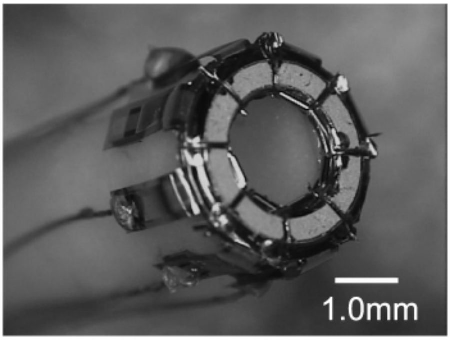


Figure 6.47. Photograph of forward-looking ring array ultrasound probe mounted on the end of the catheter.

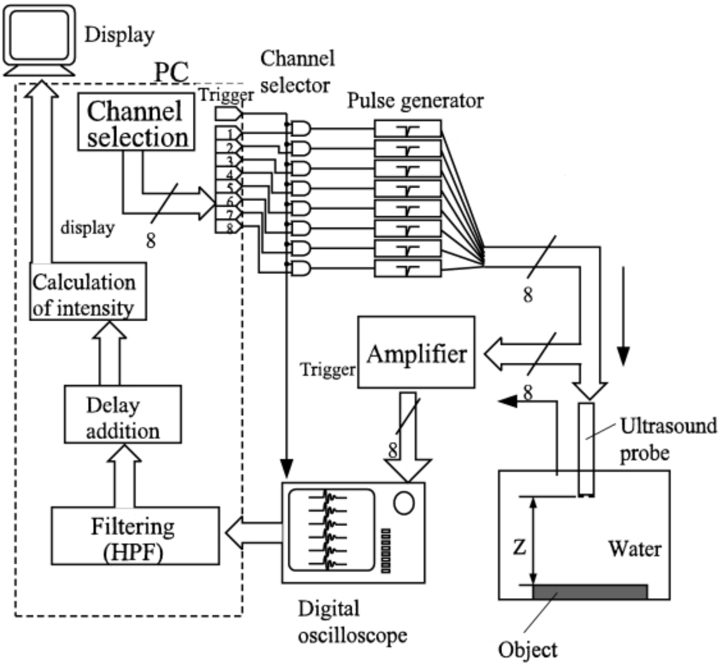


Figure 6.48. Ultrasound imaging system.

ing system are shown in Figure 6.46, 6.47 and 6.48, respectively. A working channel is retained at the center of the ring array. A frequency of 10 MHz was chosen considering the resolution of the image and the measurement range. An ultrasound image of a 3.0 mm diameter steel ball was acquired experimentally, as shown in Figure 6.49. In this figure, many artifacts are observed because the transmitted ultrasound pulse is not very short.

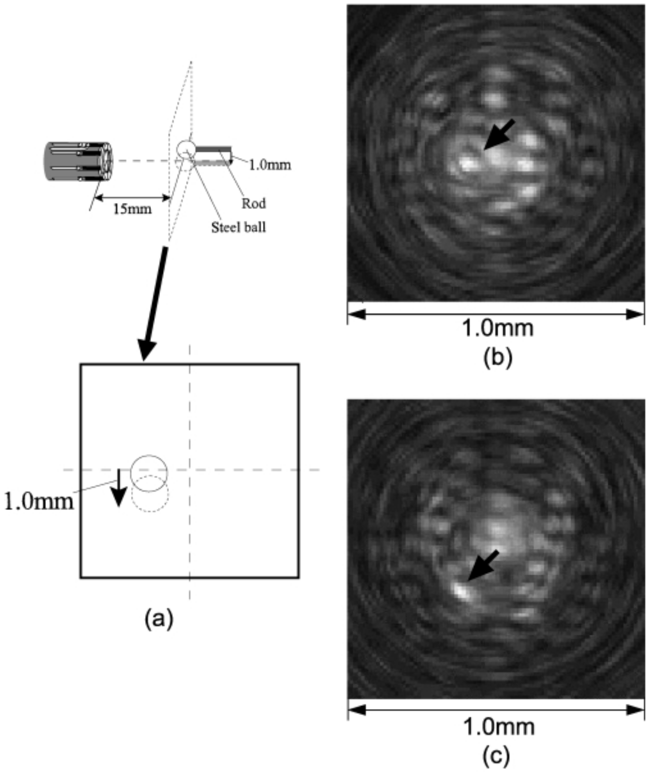


Figure 6.49. Evaluation of forward-looking imager. (a) Setup; (b) image of steel ball.

6.7.2.1 *Fabrication of a 1–3 Composite Ring Array Ultrasound Transducer*

To reduce the artifacts mentioned above, an ultrasound probe with lead zirconate titanate (PZT)–polymer 1–3 composite transducers was developed. PZT–polymer 1–3 composite transducers have the following benefits:

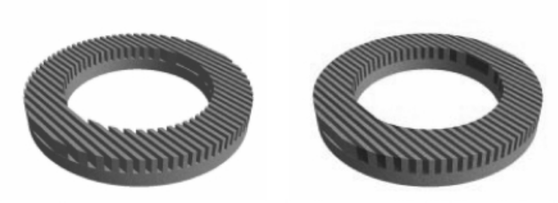
(1) low *Q*, which allows short ultrasound pulses;

(2) low acoustic impedance, which improves acoustic mismatch;

(3) high electromechanical coupling coefficient;

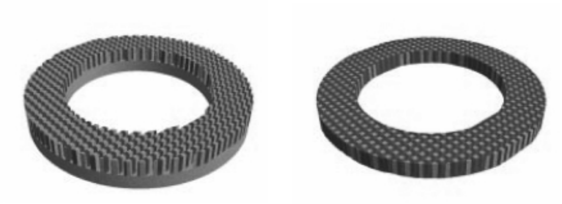
(4) transducer array can be made without grooves because the acoustic coupling between transducers can be small.

The thickness of the piezoelectric transducer is 130 μm, because the desirable frequency for the ultrasound pulse is 10 MHz. A 1–3 composite transducer is fabricated using the ‘dice and fill’ method [10]. Ideally, it is required that the pitch of



(a) dice to make grooves in one direction

(b) polymer is cast into the grooves



(c) dice to make grooves in another direction

(d) polymer is cast into the grooves and the base is removed mechanically

Figure 6.50. Dice and fill method for 1–3 composite.

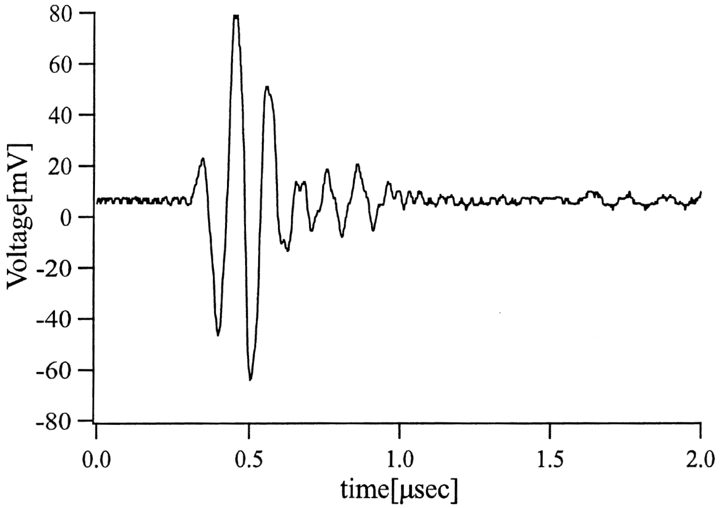


Figure 6.51. Measured characteristics of 1–3 composite transducer.

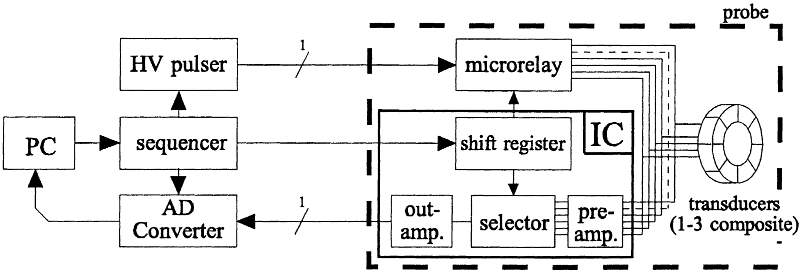
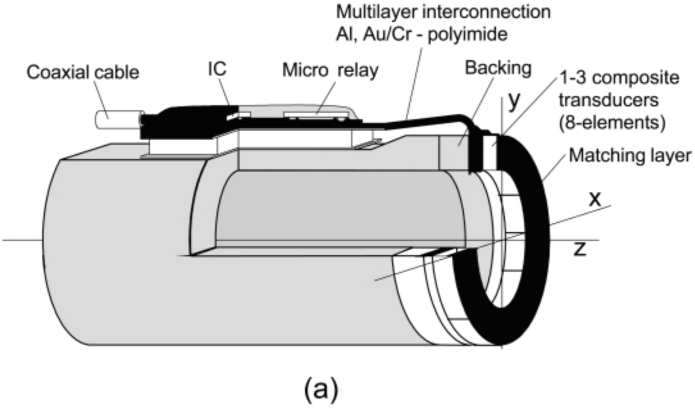
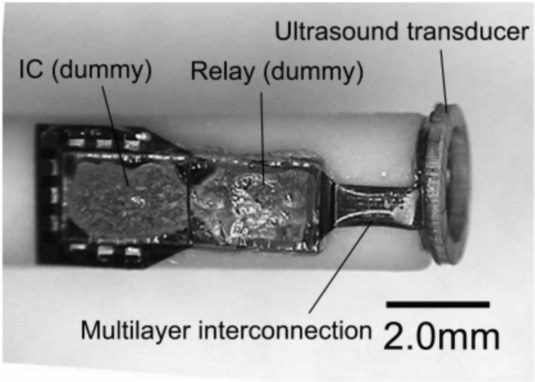


Figure 6.52. Block diagram of integrated ultrasound probe.





(b)

Figure 6.53. Integrated forward-looking ring array ultrasound probe. (a) Concept; (b) fabricated probe with dummy IC and relays.

the grooves is less than 56 µm. Because PZT is brittle material, the pitch is limited by the dicing process, and a 70 µm pitch array is obtained by the dice and fill method (Figure 6.50) [11]: (a) dice to make grooves in one direction; (b) polymer is cast into the grooves; (c) dice to make grooves in another direction; (d) polymer is cast into the grooves and the base is removed mechanically.

The measured characteristics of this transducer are shown in Figure 6.51. This indicates that a short pulse is obtained using the 1–3 composite probe.

6.7.2.2 Integration for Forward-looking Ultrasound Imaging

An integrated forward-looking ultrasound probe is being developed. As shown in Figure 6.52, this probe has an integrated circuit located close to the transducer [11]. The integrated circuit selects the receiving channel and amplifies the signal, and the probe has a micro relay which selects the transmitting channel [12] to reduce the number of lead wires, and consequently permits a ring array probe which has more than eight transducers to improve the quality of the image. Each component is mounted on a flexible film which is made of metal layers and polyimide layers to facilitate easy mounting of the probe at the catheter tip. The concept and fabricated probe which has dummy IC and relays are shown in Figure 6.53.

6.8 Fiber Optic Pressure Sensor

The small diameter (125 µm) fiber optic pressure sensor shown in Figure 6.54 was developed for catheter use [13]. A thin diaphragm is formed at the end of an optical fiber and the deformation by the pressure is detected interferometrically. A silicon rod on which a diaphragm is formed is made by deep reactive ion etching (RIE) of a silicon wafer (Figure 6.55) and it is bonded to the fiber end, and finally silicon is etched out with XeF_2 gas as shown in Figure 6.56. The fabricated sensor and the sensor output versus pressure are shown in Figures 6.57 and 6.58, respectively.

6.9 Magnetic Sensor System for Detecting Position and Orientation of Catheter Tip

Catheter operation requires real-time information on the position and orientation of a catheter tip for navigation. Angiography using contrast medium and real-time x-ray radioscopy is generally used to navigate the catheter in a blood vessel. A

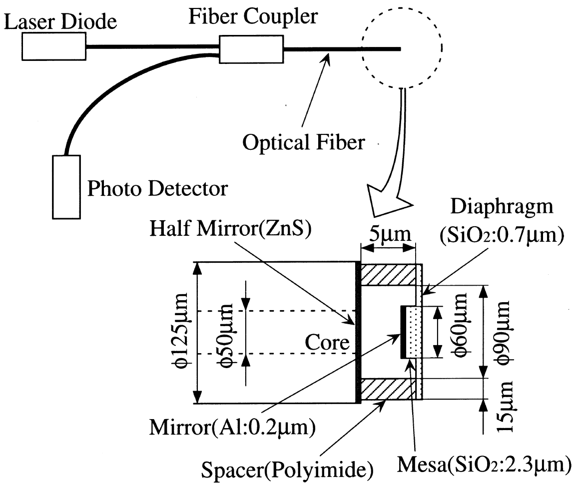


Figure 6.54. System and structure of 125 μm outer diameter fiber-optic pressure sensor.

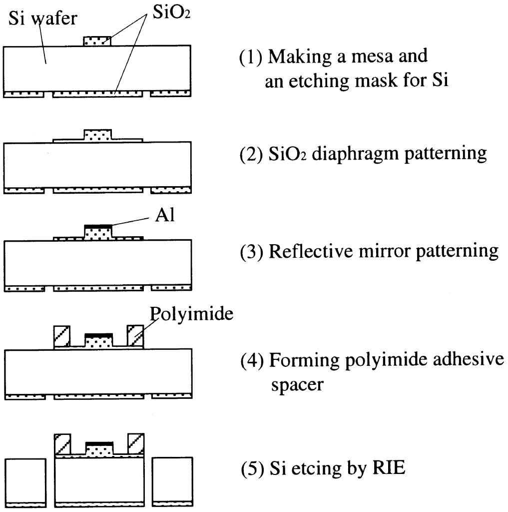


Figure 6.55. Process flow of sensing element.

simple sensor system for detecting the position and orientation using the Earth's magnetic field and an AC (10 kHz) magnetic field generated by two source coils which are located near the human body has been developed [14]. Real-time information about the position and the orientation and map of the blood vessels makes the navigation possible. The map of the blood vessels can be obtained in advance using x-ray helical computed tomography (CT) or magnetic resonance (MR) angiography. Figure 6.59 shows the configuration of the sensor system. Three-axis MI sensors (magneto-impedance effect sensors) for measuring the Earth's mag-

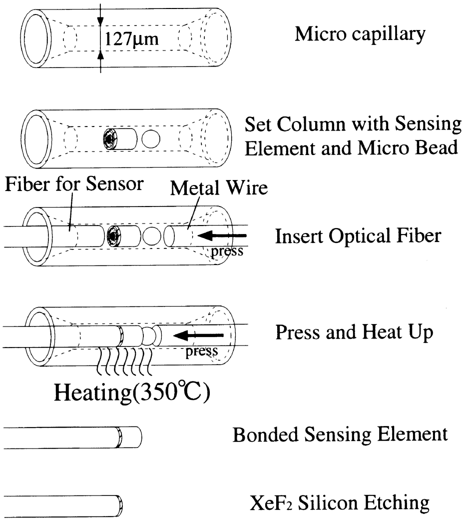


Figure 6.56. Process flow of bonding.

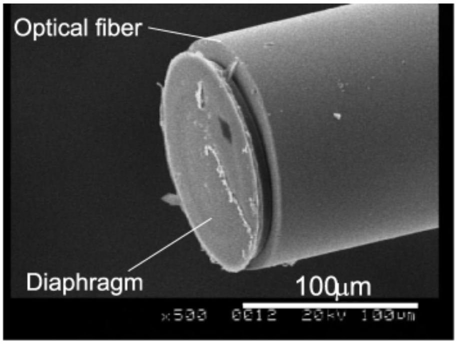


Figure 6.57. Scanning electron micrograph of fiber-optic pressure sensor.

netic field and AC magnetic field are mounted on the catheter tip. The sensor signal is used to estimate the position and orientation of the catheter. On the display, the position and orientation of the catheter tip will be superimposed on the three-dimensional map of the blood vessels.

Figure 6.60 shows the structure of the MI sensor, the size of which is about 1.5 mm square. A 6 MHz and 5 mA current is applied to an amorphous wire and the impedance of the wire is measured using its voltage drop. The impedance depends on an external magnetic field. Bias magnetic fields are generated by the bias coil to determine the polarity of the external magnetic field. MI sensors are connected to an external electrical circuit using coaxial cables of 1 m length and 250 μm diameter. Detection of the position and the orientation were confirmed.

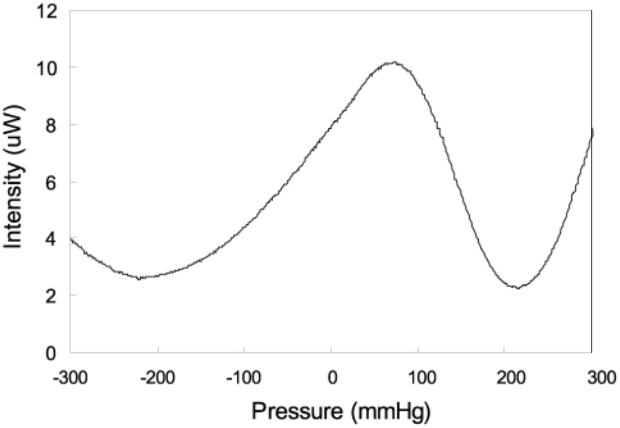


Figure 6.58. Intensity of reflected light from sensor versus applied pressure.

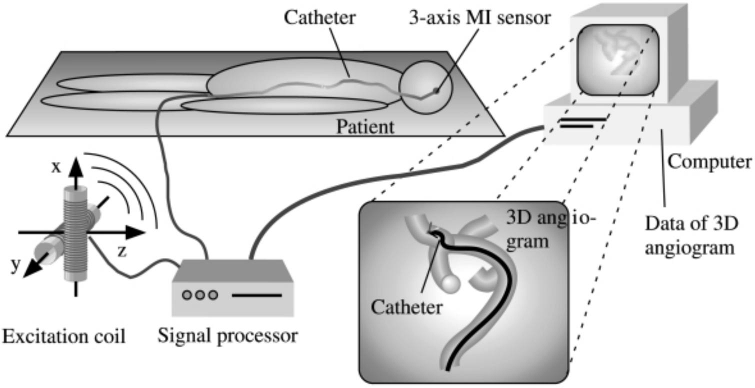


Figure 6.59. Magnetic sensor system for detection of position and orientation of catheter tip.

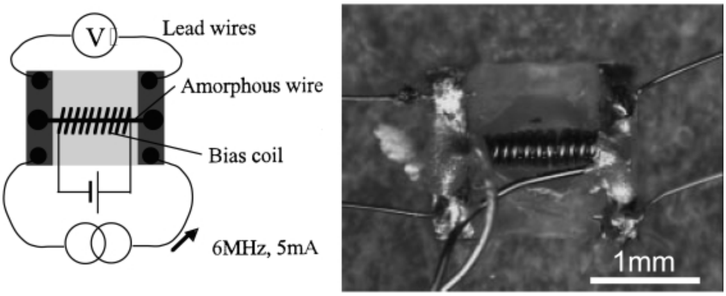


Figure 6.60. Structure of MI sensor.

6.10 Summary

Active catheters which move like a snake utilizing distributed SMA actuators have been developed for catheter-based minimally invasive diagnosis and therapy. Active catheters can have bending, torsional, extending, and stiffness control mechanisms. A novel batch assembly method for active catheters which connects SMA actuators, a liner coil and lead wires using nickel electroplating and acrylic electrodeposition was developed for low-cost assembly. Fabrication methods for the inner and outer tubes of the active catheters using parylene evaporation were developed. These new assembly and fabrication methods for the active catheter permit the fabrication of active guide wires which are used with conventional catheters for catheter-based intervention.

Several IC, and sensors have been attached to the active catheters. Communication and control chips reduce the number of lead wires needed to control the active catheter. A forward-looking ultrasound probe and magnetic sensor mounted at the tip of the active catheter are useful for navigation of the catheter and for reduce x-ray exposure. Future multi-functional active catheters might provide information as virtual reality to the doctor, making doctor feel as if he or she is inside the blood vessel, and enabling delicate steering and operation of the catheter.

6.11 References

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