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Development of Pressure-Driven Micro Active Catheter using Membrane Micro Emboss Following Excimer Laser Ablation (MeME-X) Process

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Abstract— **The world's smallest micro active catheter of ϕ~300μm was successfully fabricated using membrane micro emboss following excimer laser ablation (MeME-X) process. The catheter has a one-sided hollow bellows at the tip made of thin polymer membrane. The bellows is composed of a series of folded micro-chambers and microchannels connecting the micro-chambers. The folded-chambers expand on one side by increasing inner water pressure using a syringe, thus the whole bellows bends toward one direction within 0 to 180 degree. This micro active catheter should be useful for safe intravascular surgery in narrow and complicated blood vessels. Moreover, the nonelectrical actuation mechanism of this catheter can be widely applied to micro-actuators and micro-robots which need high safety.**

I. Introduction

Recently, catheterization has been widely applied to intravascular surgery, instead of conventional highly invasive surgery. In catheterization, a doctor inserts a thin flexible tube called catheter into a blood vessel from the leg or arm. The catheter can be advanced into the heart or brain, where treatments or inspections take place. The operation leaves just a tiny puncture on the arm or leg where the catheter has been inserted, and therefore, causes less damage to the patient compared to conventional open surgery.

One big problem of catheterization, however, is the difficulty of manipulation in narrow and branched blood vessels. Since conventional catheters have no active bending capability at the tip, a doctor has to control the direction of the tip just by pushing and rotating the catheter at the inlet far apart from the tip. Thus, the catheterization in narrow and complicated blood vessels is of extreme difficulty.

To solve this problem, several types of active catheter have been proposed [1-4]. They are classified into two types depending on its bending mechanism. The first type is electrically driven active catheters [1-3]. These catheters have actuators using e.g. shape memory alloy or polymer gel at the tip, and can be bent from outside of the body by applying current to the actuators. Even though electrical actuators are suitable for miniaturization, the use of electricity inside the heart or brain has a risk of fatal damage due to microshock or heat in case of an accident [5, 6].

The second type is a pressure-driven active catheter proposed by Ikuta et al. [4]. It has a hollow bellows made of soft silicone rubber at the tip, and the tip can be bent by supplying saline water into the bellows through a tube connected to the bellows. Since no electricity is necessary for actuation, it is superior in safety compared to electrically driven active catheters. Additionally, it can be used under monitoring with MRI, which is a fundamental tool in catheterization, because no metal parts are used in this catheter. In spite of its superiority, the minimum size of this type of catheter attainable with conventional injection molding processes using a pair of a male and a female mold is ϕ~1mm, whereas the catheter must be smaller than ϕ~300μm for complex intravascular surgery. This limitation derives from the difficulty of 3-dimesnional fabrication of a pair of a male and a female mold with micrometer accuracy.

Although a pressure-driven balloon-type micro-actuator made by poly-dimethylsiloxane (PDMS) molding technique was reported in MEMS field [7], it cannot be applied to catheterization due to the risk of damage to blood vessels caused by large expansion of the actuator during bending.

In short, there is no process available to fabricate micro-size pressure-driven active catheters.

II. Membrane Micro Emboss Following Excimer Laser Ablation (MeME-X) Process

To break-through the miniaturization limit of the pressure-driven micro active catheter, we developed MeME-X process (Fig.1), which is an advanced process of our original MeME process [8-10].

The MeME process was originally developed for fabrication of "membrane microchannel", which was a novel concept in micro-fluidics field [8]. Based on the "membrane microchannel" concept, we have already developed size-selective sampling device [9] and artificial capillary network device [10] using MeME process.

However, MeME process is not simply for the fabrication of micro-fluidic devices. It can also be extended to fabrication of novel micro actuators and sensors based on membrane structure. As a new application of the MeME,

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here, the process is combined with excimer laser ablation technique to create the MeME-X process, which realizes a pressure-driven micro active catheter composed of thin membrane.

The MeME-X process needs a master mold of the bellows, thermoplastic membrane and a deformable plastic support substrate. Different from conventional injection molding using a pair of a male and a female mold, MeME-X process needs only the male mold. At first, the mold is pressed against the membrane at the glass transition temperature of the membrane. During the pressurization, the membrane is deformed to fit the surface of the mold by backpressure from the support substrate. After cooling to the initial temperature, the mold is removed. And then, embossed membrane is sealed with another membrane by heat-sealing or other sealing methods. Using excimer laser ablation, the bellows is cut out, and an opening is made at one end for microtube connection. After the bellows and a microtube are connected with silicone adhesive, the support substrate is removed by melting or dissolving with a selective solvent.

Since the resolution of this process is ~1μm [8], the minimization limit of the catheter diameter attainable with this process assumed to be ϕ50μm, which is far smaller than the conventional injection molding process. Furthermore, this process is applicable for versatile thermoplastic materials, and suitable for future mass production and automation.

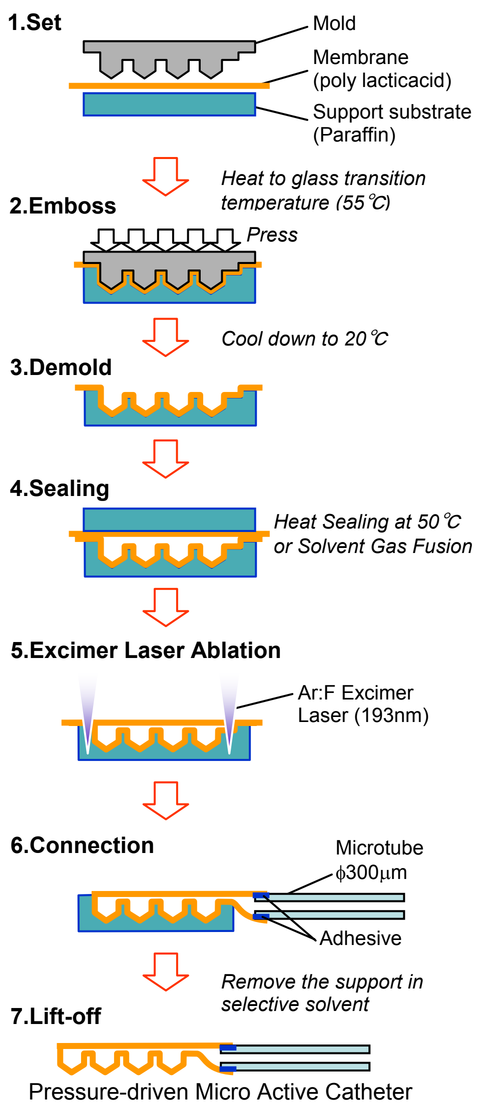

Fig. 1. Fabrication of the pressure-driven micro active catheter using MeME-X process: Firstly, the mold is pressed against the membrane at the glass transition temperature of the membrane. After cooling to the initial temperature, the mold is removed. Then, the embossed membrane is sealed with another membrane. The outline of the bellows is cut out and an opening is made at one end for microtube connection using an excimer laser. After the bellows and a microtube are connected, the support substrate is removed.

III. Design of The Pressure-Driven Micro Active Catheter

We designed a catheter ϕ~300μm composed of a hollow bellows made of biocompatible polymer membrane (thickness = 5μm), a motorized syringe and a Teflon microtube (Fig.2a). A pressure gauge was attached to the microtube at the base to monitor and feedback the pressure to the motorized syringe. The diameter of the catheter was set to ϕ300μm because of the availability of the microtube.

The bellows is composed of a series of folded

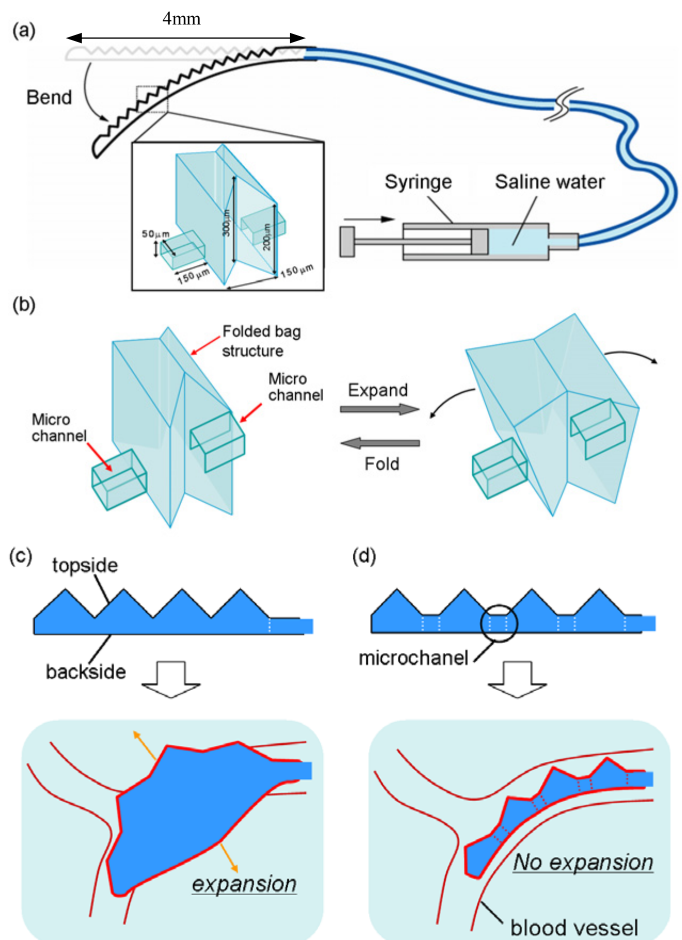

Fig. 2. (a) Design of the pressure-driven micro active catheter with a bendable bellows made of thin membrane at the tip (b) Bending principle of the bellows through expansion of each folded micro-chamber (c) Schematic of the bellows actuation of the previous version (d) Schematic of the bellows actuation of the new version

micro-chambers and microchannels connecting them. Since the bottom of each folded chamber is fixed to another membrane, only the upper part of the chamber can expand when increasing inner pressure of the chamber. Thus, the whole bellows can be bent to one direction by supplying saline water from the syringe through the microtube, because only one side of the bellows extends (Fig.2b).

The previous version of the bellows was composed of only folded micro-chambers [11]. Since there was no structure connecting the topside and backside membrane, the diameter of the bellows slightly expanded during bending (Fig.2c). In catheterization, that leads to a serious damage to blood vessels. To solve this problem, the microchannels were set between micro-chambers in the new version. Each microchannel works as a rigid frame to connect the topside and backside membrane, preventing the expansion of the bellows during bending (Fig.2d).

IV. Fabrication of The Pressure-Driven Micro Active Catheter

The master mold of the bellows was made of photocurable epoxy resin (SCR751, D-MEC, Japan), and fabricated using micro stereolithography (Fig. 3a). The surface of the mold was coated with a fluoropolymer for reduction of friction against membrane during deformation, and for smooth detachment of the mold from the embossed membrane. The deformable plastic support substrate (15mmx15mmx1mm) was made from paraffin (mp.70deg.C). The membrane for the bellows was made of biocompatible poly-lacticacid by spin-coating the polymer solution, and the thickness was adjusted to 5µm. The outer diameter of the polymer microtube was 300µm.

The MeME-X process was done in an improvised tabletop apparatus. The master mold was pressed onto the membrane at 0.5µm/sec for 500sec. at 55deg.C. After cooling to 25deg.C, the mold was removed. The embossed membrane was heat-sealed with another membrane of the same material. Using an excimer laser (ArF, 193nm), the outline of the bellows was cut out, and an opening was made at one end. After the bellows was connected to a microtube by adhesive under an optical microscope, the support substrate was selectively dissolved by immersing in hexane. At last, the catheter was successfully fabricated (Fig.3b). All the process was done in 10-15min. The bellows composed of a series of folded micro-chambers and microchannels was precisely fabricated both on the outside and inside (Fig.3c, d). Since the excimer laser ablation cause little mechanical load on the target, the thin membrane structure of the bellows was almost unchanged after excimer laser ablation process (Fig.3d).

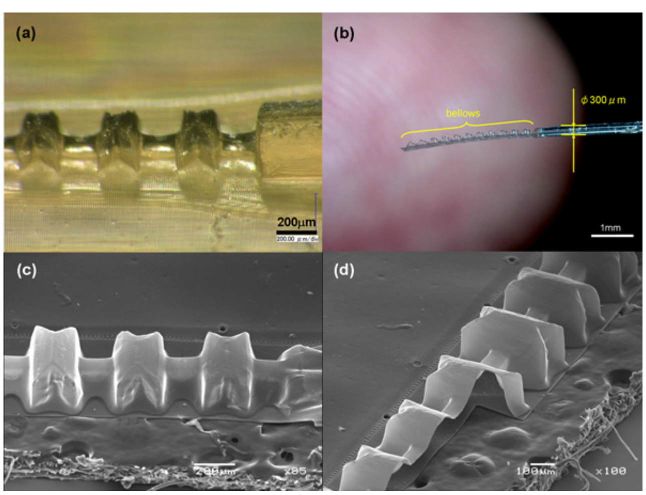

Fig. 3. (a)Optical microscopy of the master mold of the bellows (b)Optical microscopy of the world's smallest pressure-driven active catheter of ~ϕ300µm (c)SEM image of the bellows (d) SEM image of the bellows cut at middle by excimer laser to show the inside structure

V. Mechanical Strength of The Heat-Sealed Interface of The Membranes

For bending of the bellows, pressure difference must be applied between inside and outside of the bellows. The differential pressure P causes load $\sigma = PD/2$ (D: diameter or width of the bellows) at the heat-sealed interfaces of the two membranes composing the bellows (Fig. 4a). For safe manipulation of the catheter inside blood vessels, the sealed interface must have enough strength to bear the load. Therefore, the breaking strength of the interface was measured for varying sealing conditions including heating duration and heating temperature. The breaking strength was measured by pulling the unfixed end of the sealed membrane in a direction perpendicular to the interface (Fig. 4b).

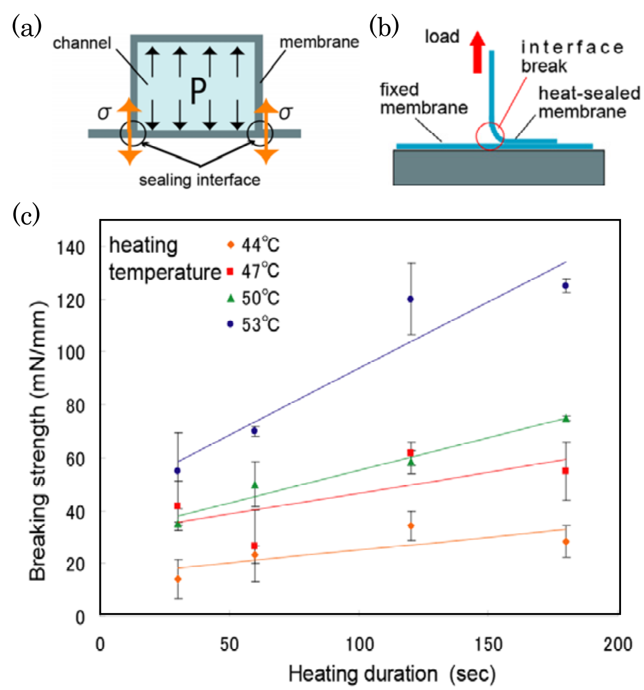

Fig. 4. (a) Schematic of the cross-section of the bellows. P denotes the differential pressure inside the bellows. The load σ on the interface should be P/2. (b) Breaking strength test of the heat-sealed interface; membrane material: poly lacticacid, thickness: 5µm, load speed: 10µm/sec, temperature: 25deg.C (c) Resulting relation between the breaking strength and the heat-seal duration

Although the higher temperature increases the breaking strength in heat-sealing, the temperature should be lower than 50deg.C here, since the embossed membrane structure starts to deform near the glass transition temperature of the material 55deg.C. The test results showed that enough strength could be achieved even at lower heating temperature by increasing the heating duration (Fig. 4c).

VI. Validation of The Pressure-Driven Micro Active Catheter

The bellows was bent at an arbitrary angle within 0 to 180deg by water pressure applied by a motorized syringe (Fig.5a and attached video file). The range of bending angle can be extended by increasing the folding angle of each micro-chamber of the bellows, and also by increasing the number of micro-chambers. More importantly, little increase of the diameter of the bellows was observed during bending due to the microchannels inserted between microchambers. This leads to a safer and smoother insertion of the catheter at bifurcations.

For *in vitro* demonstration of the active catheter, a small blood vessel model made of PDMS was fabricated using lost-wax method. The model consists of narrow blood vessels ϕ1~3mm wherein conventional active catheters could not be inserted. The pressure-driven micro active catheter was actuated and inserted into the small vessel (Fig.5b). The catheter was bent to left (Fig.5c) at the bifurcation by supplying pressure from the syringe, then turned to the desired direction, and successfully introduced into the target aneurysm at last (Fig.5d).

The catheter has high safety because it uses no electricity for operation. Also, the thin membrane hollow structure of the bellows dramatically reduces damage to blood vessels, by giving softness at the tip far over the conventional catheters.

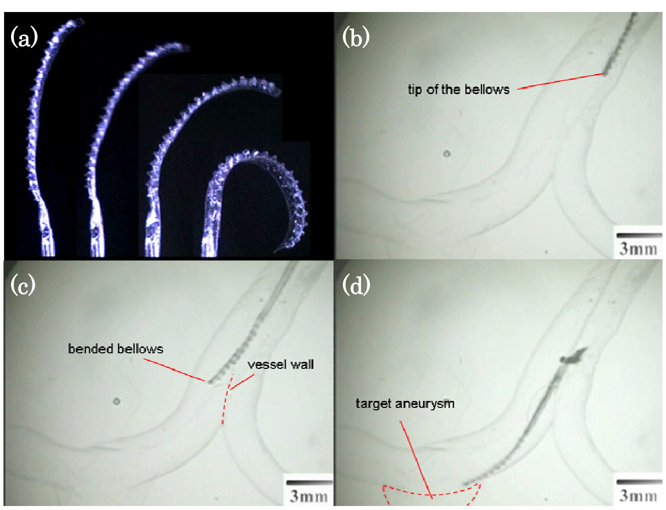

Fig. 5. (a) Bending demonstration of the pressure-driven micro active catheter from 0 to 180 deg. For detail, see the attached video file. (b-d) Insertion of the catheter into 3D vascular model: The catheter was inserted into narrow blood vessels ϕ1-3mm, where conventional catheters could not be inserted. The operator can chose left or right (c) blood vessel at the bifurcation by bending the bellows. At last, the catheter reached the target aneurysm (d).

In addition, the catheter is fully MRI compatible since it is made of only polymers. As further improvements, microchannels for medicine injection and/or blood sampling should be attached aside the bellows. This can be done by just adding microchannel templates on the master mold.

VII. Conclusion

The world's smallest pressure driven micro active catheter was proposed and developed by MeME-X process – combination of our original MeME process and conventional excimer laser ablation technique. The novel pressure-driven micro active catheter, with extreme smallness and high safety should promote the application of catheterization in complex intravascular surgery which is impossible with conventional surgical tools.

Furthermore, the nonelectrical actuation mechanism of this catheter using folded micro-chamber structure can be widely applied to novel safe medical tools and pressure-driven micro actuators in MEMS and micro-robotics field.

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