Micro devices for a cerebrospinal fluid (CSF) shunt system

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Abstract

This paper reports a novel cerebrospinal fluid (CSF) shunt system for the hydrocephalus patients. The CSF shunt system consists of a micro telemetry pressure sensor, an electromagnetic micropump and a controller. The pressure sensor has a flexible p+ diaphragm and a planar copper coil that construct an LC resonant circuit. The cerebrospinal pressure is measured from the phase shift at the resonance frequency. The micropump consists of an actuator diaphragm and a pair of passive valves. Each device is fabricated by micromachining technology and tested to obtain the characteristic. The feasibility of the proposed shunt system is evaluated with the in vitro performance test.

Keywords: CSF shunt system; Micro pressure sensor; Telemetry sensor; Micropump; Hydrocephalus

1. Introduction

Cerebrospinal fluid (CSF) is a clear fluid surrounding the brain and spinal cord. CSF protects the brain tissue and transfers nutrients. It drains into cisterns at the base of the brain and is absorbed into the bloodstream. Hydrocephalus is a neurological disease of an abnormal increment in intracranial pressure that occurs when there is an abnormal accumulation of CSF in the ventricles or subarachnoid space of the brain [1].

The CSF shunt system to be used to treat patients with hydrocephalus drains cerebrospinal fluid from the brain to the abdominal cavity. The conventional CSF shunt system consists of a ventricular catheter for access to the CSF, a valve system and a distal catheter, which drains CSF toward a abdominal cavity. The current commercialized shunt valves were mostly designed in 1980s and have successfully contributed to medical treatment. However, the valve opening pressure of the conventional CSF shunt system is not adjustable and not able to manage the problem of over or under drainage. To prevent the siphon effect, anti-siphon devices were developed and have been used. The effect of the anti-siphon device, however, is reported not to meet the target yet [2]. Even though the programmable ventriculoperitoneal (VP) shunt system has been commercialized, the intracranial pressure cannot be monitored after the implantation. Also, it is nearly impossible to adjust it immediately according to the intracranial pressure. Thus, the drawbacks of the conventional open-loop passive shunts cannot be overcome by simple supplements. CSF VP shunt system needs a closed-loop structure for solving above problems.

The shunt system proposed in this paper is a closed-loop control system that regulates the intracranial pressure by adjusting the flow rate of the cerebrospinal fluid drainage, as shown in Fig. 1. The CSF shunt system consists of a micro telemetry pressure sensor, a micropump and a controller. The controller controls the micropump according to the intracranial pressure measured with a telemetry pressure sensor. The telemetry of this system enables monitoring of the intracranial pressure after implantation without causing infection problem. In this paper, micro devices, such as a telemetry pressure sensor and a micropump were fabricated by MEMS technology and tested to obtain the characteristic and the feasibility of the proposed shunt system.

2. Structure and fabrication

2.1. Micro telemetry pressure sensor

The pressure sensors have been developed for the biomedical applications, such as the measurements of the intraocular pressure, the intravascular pressure, the cardiovascular pressure, and the intracranial pressure, etc. [3]. The implantable pressure sensors must be small, biocompatible, and wireless. In this paper, the telemetry pressure sensor is designed and fabricated for the detection of the intracranial pressure. The telemetry intracranial pressure monitoring is useful for the hydrocephalus patients. The telemetry pressure monitoring...
system via data communication includes integrated circuits for the transmission of the power and the signal. Also, the system is fabricated by complicated processes and assembly of many parts, such as a pressure sensor, a rechargeable battery, a transmission system, coils, and a signal processor, etc. But on the other hand, in the case of inductor-capacitor (LC) resonance type telemetry sensor, the sensor is simple and small [4, 5]. Another advantages of this type are the high resolution and the simplicity in the design for the wide range of pressure and temperature [6]. An LC resonator that is composed of a capacitive pressure sensor and an inductor can be implanted in the patient’s cranium and transmits pressure information to an external detector by magnetic coupling.

Fig. 2 shows the structure of the telemetry LC resonance-type pressure sensor [7]. It consists of a Pyrex glass substrate with a micro copper coil, and a silicon substrate with a p+ diaphragm. The Cr/Au electrode below the p+ diaphragm and the Cr/Au electrode on the Pyrex glass constitute a variable capacitor. The variable capacitance depends on the gap between the fixed electrode and the flexible diaphragm subject to the applied pressure. The LC resonant circuit consists of the sensor and an external antenna coil that are coupled magnetically. As the applied pressure increases the capacitance of the sensor, the phase is shifted near the resonance frequency. The total size of the sensor is 8.05 mm × 7.8 mm. The coil is 10 μm thick, and 50 μm wide and the total length is 4900 μm. The number of turns of the coil is 13. The gap between the Cr/Au electrode and the p+ diaphragm is 10 μm. The thickness of the
Fig. 3. The fabrication process of the upper substrate of the pressure sensor. 

The diaphragm has corrugations to release the residual stress and to increase the sensitivity. For the self-alignment there are 20 μm-deep grooves on the silicon substrate and 10 μm.

First, a 0.8 μm-thick thermal oxide layer for an etch mask is grown. To fabricate the air cavity, the front side of the wafer is etched 30 μm with TMAH solution. The silicon oxide is patterned and the silicon is etched by 10 μm with TMAH to form a concentric circular corrugation. Boron is diffused into the surface to make a p+ etch stop layer. Cr/Au (500 Å/3000 Å) is deposited on the p+ layer. The backside of the wafer is etched with EPW solution to fabricate a diaphragm.

Fig. 4 shows the fabrication process of the lower substrate. Cr/Au (500 Å/3000 Å) is deposited on Pyrex glass with a thermal evaporator and the Cr/Au layer is patterned. The silicon nitride (5000 Å) is deposited as an insulation layer by PECVD and etched by a reactive ion etcher. Cr/Au (500 Å/3000 Å), a seed layer of copper electroplating is deposited. After molding with the thick photoresist, electroplating is performed with the solution (CuSO₄·5H₂O:H₂SO₄:DI water = 150 g:200 ml:1 l) at room temperature. When the current density is 10 mA/cm², the thickness of the copper for 30 min is about 10 μm. We measure the thickness with a laser focus displacement meter (Keyence LT-8010).

Fig. 5 shows the photographs of the fabricated parts of the pressure sensor and the assembled pressure sensor.

2.2. Micropump

Recently, it has been illustrated that an electromagnetic micropump is feasible for CSF shunt system [8]. Even though the micropump has a flow characteristic corresponding to the conventional shunt valve, it has some disadvantages such as the complex structure, the difficult fabrication process and the small deflection of parylene diaphragm. Moreover, since the micropump of [8] is equipped with a nozzle/diffuser, it has drawbacks such as a large backward
leakage flow to a backward pressure and a low pump performance. We propose a different electromagnetic micropump that has a silicone rubber diaphragm and a micro flap valve. This micropump has several advantages, such as simplicity of the structure, negligible heat generation, small power consumption and large flow rate.

Fig. 6 shows the structure of the electromagnetic micropump. This micropump consists of a pair of passive valves, a spacer and a silicone rubber diaphragm with a boss and an electromagnetic actuator. As the diaphragm is repeatedly oscillated, a pair of valves are alternately opened and closed according to the chamber pressure variation and the fluid is pumped forward.

Fig. 7 shows the fabrication process of the upper substrate of the actuator. First, a 0.8 μm-thick thermal oxide layer for etch mask is grown. To fabricate the boss, the front side of the substrate is oxidized by thermal oxidation. Then, the diaphragm and a pair of passive valves are fabricated by boron diffusion and etching. After that, the micro flap valve is fabricated by photolithography and etching. Finally, the diaphragm, the passive valves, the micro flap valve and the actuator are bonded together with epoxy bonding.

Fig. 8 shows the fabrication process of the micro flap valve. The micro flap valve is fabricated by photolithography and etching. First, the front side of the substrate is oxidized by thermal oxidation. Then, the etch mask is patterned by photolithography and the etch mask is removed by TMAH etch. After that, the micro flap valve is fabricated by photolithography and etching. Finally, the diaphragm, the passive valves, the micro flap valve and the actuator are bonded together with epoxy bonding.

Fig. 9 shows the photographs of the micropump parts: (a) actuator; (b) micro flap valve.

Fig. 10 shows the measurement setup of the pressure sensor. The network analyzer is used to measure the pressure sensor.
the wafer is etched 300 μm with TMAH solution. Silicone rubber (ShinEtsu KE44G) is spin-coated at 1500–2000 rpm. And the backside is etched again with TMAH to remove the remaining silicon.

Fig. 8 shows the fabrication process of the flap valve. The starting material is a 330 μm-thick n-type (100) silicon wafer. After oxidation, boron is diffused into the surface to make a p+ etch stop layer. To fabricate the through hole, the backside of the wafer is etched with EPW solution. A photoresist sacrificial layer is coated on the p+ layer and is patterned. After aluminum is deposited and patterned, the p+ layer and photoresist is removed. Two same silicon substrates with one flap valve each are bonded together with epoxy resin.

Fig. 9 shows the photographs of the fabricated micropump parts. The size of the micro actuator is 14.0 mm × 9.0 mm × 6.0 mm and the size of the micro flap valve is 7.0 mm × 5.0 mm × 0.6 mm.
3. Experimental results

In order to measure the characteristic of the fabricated pressure sensor, we measure the resonance frequency with a network analyzer (HP 8510C), as shown Fig. 10. The length and width of the feed wire are 13, 1.5 mm, respectively. The diameter of the antenna coil is 20 mm. The pressure sensor is on the bottom of the beaker filled with water. The antenna coil is located under the beaker. Figs. 11 and 12 show the frequency responses of the magnitude and the phase of the impedance of the circuit including the antenna and the sensor when the pressure is 0 mm H$_2$O, respectively. The measured resonance frequency is about 160 MHz. Fig. 13 shows the impedance phase for various pressures. The input excitation frequency is 159 MHz. As the pressure varies from 0 mm H$_2$O to 110 mm H$_2$O, the impedance phase varies linearly. The sensitivity of the pressure sensor is about 0.08°/mm H$_2$O. Fig. 14 shows the effect of the pig skin

![Graph showing impedance vs. pressure for various pressures with a linear trend line.](image)

![Graph showing the effect of pig skin on the phase with two lines representing 'pig skin' and 'no skin'.](image)

Fig. 13. Pressure vs. impedance magnitude.

Fig. 14. The effect of the pig skin on the phase.
on the impedance phase when the skin is inserted between the pressure sensor and the antenna coil. The sensitivity in case with pig skin inserted is similar to that with no skin. This result illustrates the feasibility of the implantation of the sensor in head skin.

Fig. 15 shows the flow characteristic of the micro flap valve. The forward flow rate of the flap valve is proportional to the pressure difference and the backward leakage of the flap valve is negligible in the measurement pressure range.

Fig. 16 shows the flow rate of the micropump for various input frequencies when the pressure difference of the inlet and the outlet are zero and the input voltage is 5 V. The maximum flow rate of the micropump is 230 μl/min at 2.5 Hz. Fig. 17 shows the flow rate characteristic of the fabricated...
micropump for various forward pressure differences in comparison with three commercialized shunt valves. The flow rate of the fabricated micropump corresponds to that of the PS-Medical high-pressure valve. This result illustrates that the proposed micropump can be used for a closed-loop control shunt system. Fig. 18 illustrates the measurement system for the in vitro test of the closed-loop shunt system. The system has driving circuits and a switching circuit to regulate the pressure. If the applied pressure is larger than 110 mm H2O, the fabricated micropump operates and drains the water. When the pressure is lower than 90 mm H2O by the water drainage, and the micropump stops operating.

4. Conclusions
In this paper, we suggested CSF shunt system and developed the parts of the system, such as a telemetry pressure sensor and a micropump by MEMS technology. The proposed telemetry pressure sensor can measure the intracranial pressure ranging from 0 to 120 mm H2O. It is suitable for the implantation in the brain according to the feasibility test with the animal skin. The micropump has a proper flow characteristic. In the near future, the in vivo test in an animal will be performed.

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References


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