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Development of micro check valve with polymer MEMS process for medical cerebrospinal fluid (CSF) shunt system

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Polymer MEMS 공정을 이용한 의료용 미세 부품 성형 기술 개발

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ABSTRACT

We developed the micro CSF (celebrospinal fluid) shunt valve with surface and bulk micromachining technology in polymer MEMS. This micro CSF shunt valve was formed with four micro check valves to have a membrane connected to the anchor with the four bridges. The up-down movement of the membrane made the CSF on & off, and the valve characteristic such as open pressure was controlled by the thickness and shape of the bridge and the membrane. The membrane, anchor and bridge layer were made of the O_2 RIE (reactive ion etching) patterned Parylene thin film to be about 5~10 microns in thickness on the silicon wafer. The dimension of the rectangular nozzle is 0.2*0.2 mm^2 and the membrane 0.45 mm in diameter. The bridge width is designed variously from 0.04 mm to 0.12 mm to control the valve characteristics.

To protect the membrane and bridge in the CSF flow, we developed the packaging system for the CSF micro shunt valve with the deep RIE of the silicon wafer. Using this package, we can control the gap size between the membrane and the nozzle, and protect the bridge not to be broken in the flow. The total dimension of the assembled system is 2.5*2.5 mm^2 in square, 0.8 mm in height. We could precisely control the burst pressure and flow rate of the valve varing the design parameters, and develop the whole CSF shunt system using this polymer MEMS fabricated CSF shunt valve.

Key Words : polymer MEMS (폴리머 MEMS), celebrospinal (뇌척수액), micro valve (마이크로 밸브), parylene (파릴린), medical micro part (의료용 미세 부품)

1. Introduction

Cerebrospinal Fluid (CSF) is in four ventricles, subarachnoid space and spinal cord. The CSF has a role for reducing the effect of the mechanical and heat impact to the skull, and for cleaning waste products that diffuse into the brain from the blood. The CSF is formed in a brain 500 cc/day and circulates through the way to keep the brain pressure in a normal condition. However the increased resistance to the circulation of CSF makes the intracranial pressure be high, and makes the people agitated, confused and sometimes be in coma. This symptom is called Hydrocephalus. Fig 1 shows the patient in Hydrocephalus [1].

The conventional CSF shunt system to be used to treat the Hydrocephalus consists of the ventricular catheter, the valve and the cardiac/peritoneal catheter. The conventional CSF shunt system is usually made of silicone. In fig 2, the picture of the conventional CSF shunt system (Medtronic PS Medical Co.) is shown [2].

We developed the micro CSF shunt valve to be applied in the CSF shunt system. The silicone valves in conventional CSF shunt system are not acceptable for the mass production, because the structure of the silicone membrane is too complex and difficult to be assembled automatically.

Therefore the MEMS fabricated micro CSF shunt valve is suit for the mass production. Also the MEMS processes have the advantages in quality control and the price. Fig 3 shows the schematic drawing of the installation of the MEMS fabricated micro CSF shunt valve in the conventional CSF shunt system. The role of the CSF shunt valve is to block up the backstream and to control the flow rate in abnormal conditions.

2. Materials and Methods

This micro CSF shunt valve unit was formed with four check valves to have a membrane connected with four bridges to the anchor. Fig 4 shows you the schematic drawing of the CSF flow in the assembled CSF shunt valve. This shunt valve consists of the two main bodies, one is 1^{st} wafer as the nozzle and membrane supporter, and another is 2^{nd} wafer as the membrane stop. The up-down movement of the membrane makes the CSF on/off, and the valve characteristics are controled by the thickness and shape of the bridge and membrane. Besides the up-down movement of the membrane is limited by the membrane stop in some height. Some design parameters are determined by the experiment, but the height of the membrane stop and the membrane thickness are determined by the FEM analysis. We can acquire the relations between the pressure difference and membrane displacement acording to the design parameters of the membrane and bridge. We use the HyperMesh software in modeling and ABAQUS in analysis.

Fig 5 shows the stress distribution under Mises stress criterion in the membrane under the pressure difference 20mm Hg, that is the intracranial pressure in abnormal circulation of the CSF. The adhesion force between the membrane and silicon is neglected. The young's moduls is 400,000 psi and Poisson's ratio is 0.4. Fig 6 shows the distribution of the displacement in the membrane and fig 7 shows the opening postures of CSF shunt valve from different angle of views.

The fabrication processes are as follows. At first the nozzles of the 1^{st} wafer were etched by TMAH from backside, remaining 20~50 μm-thick silicon wall for the next step. The remained wall was removed after the 2^{nd} Parylene layer patterning (Nozzle finishing process). After the etching, 1^{st} Parylene thin film was deposited and etched by O_2 RIE (reactive ion etching) to form the anchor layer. For the sacrificial layer, we used the Cromium thin film instead of photoresist [3]. The photoresist is easily attacked with the O_2 plasma during the membrane and bridge patterning, so it is difficult to remove the attacked photoresist to free the membrane. On the Cromium sacrificial layer, the 2^{nd} Parylene film was deposited and etched to form the membrane and bridge. The thickness of the Parylene membrane is about 5~10 μm.

Between the Parylene anchor layer and 1^{st} wafer, the adhesion promotor (A-174) was treated to enhance the adhesion. A-174 has the molecule of which one side is organic, and other side is inorganic. The organic side tightly bonds to the 1^{st} Parylene layer and the in-organic side to the 1^{st} silicon wafer. The dimension of fabricated nozzle is $0.2*0.2\ mm^2$ and of the membrane 0.45 mm in diameter. The bridge width is designed variously from 0.04 mm to 0.12 mm.

To protect the membrane and bridge in the CSF flow, we developed the membrane stop with the deep RIE of the 2^{nd} silicon wafer. Using this membrane stop, we can limit the gap size between the membrane and the nozzle, and protect the bridge not to be broken in the flow.

The 1^{st} wafer and 2^{nd} wafer are bonded by epoxy. The total dimension of the assembled CSF shunt valve is $2.5 * 2.5\ mm^2$ in square, 0.8 mm in height.

3. Results

We developed the CSF shunt valve system with surface and bulk micromachining processes. Fig 9 shows the fabrication result of CSF shunt valve (1^{st}

wafer). The developed valve can turn on & off the flow. Also we could precisely control the burst pressure and flow rate of the valve varing the design parameters.

4. Discussion

In the FEM analysis, the displacement of the membrane under the pressure 20mm Hg was about 70 μm. So we made the depth of the membrane stop be 50 μm and the stress in the bridge was reduced. In this case, the gap between the membrane and the nozzle is too narrow for applying in the CSF, because the CSF contains some bio-molecules and particles. So we will upgrade the shape of the bridge to enable the membrane to move high without the stress concentration.

We design the CSF shunt valve system with four valve units. One valve unit is composed of one nozzle, one membrane and four bridges. The valve units work as the supports to each other in case of the bridge fracture or the nozzle clogging.

The membrane stop has some important roles. One is the protection of the membrane. This stop keeps the membrane not to be lossed away in the CSF, if all four bridges of one membrane would be broken. Another role is to maintain the flow rate in a critical situation. If the intracranial pressure would become too high in a moment, the gap between the nozzle and membrane is maintained fixed by the membrane stop. This critical situation ocassionally occurrs in the patients who wake up in the morning or change the pose of the head in haste.

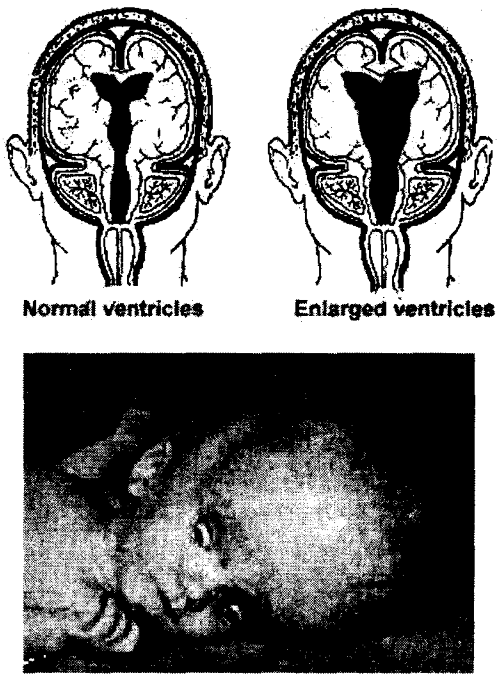

Fig. 1. Picture of the patient in Hydrocephalus

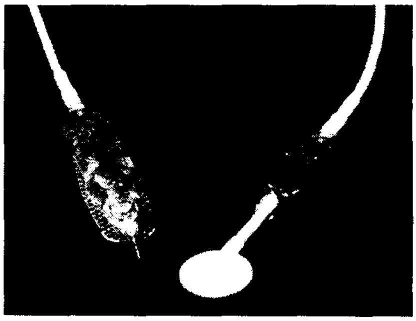

Fig. 2. Picture of the conventional CSF shunt system (Medtronic PS Medical Co.)

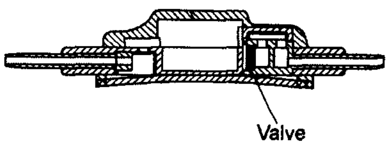

Fig. 3. Schematic drawing of the valve installation in the CSF shunt system

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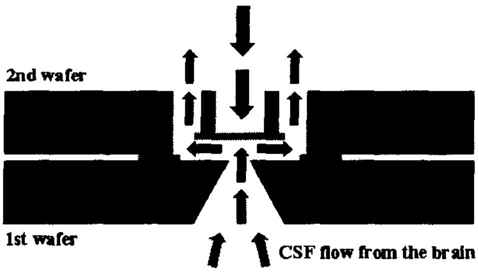

Fig. 4. Schematic drawing of the developed CSF shunt valve

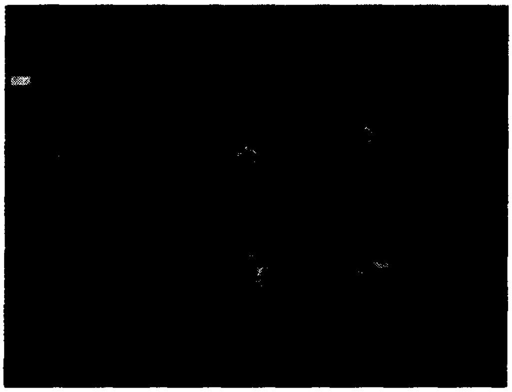

Fig. 5. Stress distribution on the membrane and bridge under Mises stress criterion

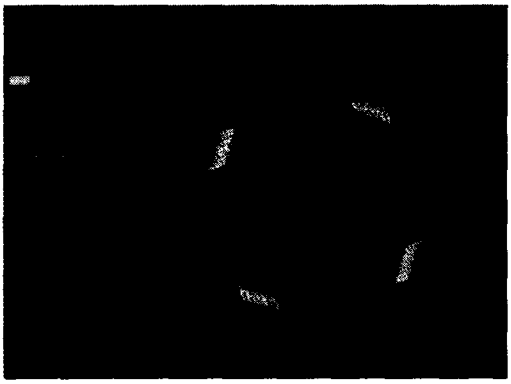

Fig. 6. Displacement distribution on the membrane and bridge

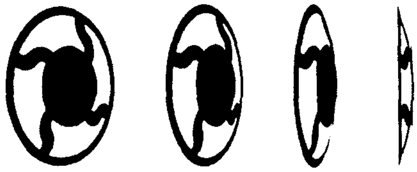

Fig. 7. Opening postures of CSF shunt valve from different angle of views

Fig. 8. Fabricated polmer CSF shunt valve