SELECTIVELY BONDED POLYMERIC CHECK VALVE FOR THE RELIABLE REGULATION OF INTRAOCULAR PRESSURE

Seongmin Im, Byungphil Mun, Jaeyong An, Jongchan Choi
School of Mechatronics, Gwangju Institute of Science and Technology, Gwangju, Korea

Sung Yang[1,2,3], Jonghyun Lee[1,2,3]
[1]School of Mechatronics, [2]Graduate Program of Medical System Engineering
[3]Department of Nanobio Materials and Electronics, Gwangju Institute of Science and Technology, Gwangju, Korea

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Abstract: A glaucoma drainage device for the regulation of intraocular pressure is presented. The device consists of three biocompatible polymer layers: the cover (top layer), the diaphragm (intermediate layer), and the baseplate with a cannular (bottom layer). Finite element analyses (FEA) were performed to find optimal design parameters for the targeted cracking pressure: the diameter of orifice, the thickness of intermediate layer, the width of the channel, and the overlapped length of the orifice over valve seat. Top and bottom layers were made by polydimethylsiloxane (PDMS) replica molding process, and an intermediate thin layer with through-holes was fabricated by PDMS fill-in molding method and hydrophobic treatment. The overlapped area of the bottom layer was coated with Cr and Au by using PDMS as a shadow mask. Metal layers are not to be bonded between the bottom and the intermediate layers so that the device showed the enhanced reliability in operation and the higher yield in production. Oxygen plasma treatment was performed for irreversible bonds between separate three PDMS layers. The experimental cracking pressure of the fabricated valve was 2.50 kPa, which is very close to the target value (2.67 kPa). The experiments showed that the proposed polymer check valve can regulate the pressure of the aqueous humour, fluid in an anterior chamber, within the normal intraocular pressure range (15~20mmHg) with a high repeatability.

1 INTRODUCTION

In microfluidic systems, valves are one of the most important components to control the flow of the systems. One of the most important characteristics of microvalves is reliability, and high reliability makes microfluidic systems successful. Check valves are passive microvalves which allow unidirectional flow. In micro check valve, reliability can be defined as the consistency of cracking pressure, flow rate, and diode-like characteristic. Check valves can be used for flow regulation, on/off switch, and sealing of liquid/gas/vacuum (Kwang W Oh et al., 2006). Glaucoma drainage devices and drug delivery are representative applications of micro check valve for bionics. Currently, the reliable fabrication and operation are the key issues in the micro check valve (Ronalee Lo et al., 2009).

Though prior micro check valves have several advantages: simple fabrication, polymer and cheap, there is a stiction problem in the bonding process of polymer layers (Nooli Jeon et al.,2002). To detach the overlapped area between valve seat and valve orifice, air or water should be introduced quickly during bonding process before polymer layers are irreversibly bonded. If the overlapped area is not completely detached, cracking pressure and flow rate of the fabricated device will vary seriously during operation as shown in Fig. 1.

Glaucoma is the second leading cause of blindness in the world, and it is estimated that 66.8 million people are suffering from glaucoma (Quigley HA., 1996). Glaucoma is theoretically defined as a progressive optic neuropathy as a result of elevation of intraocular pressure (IOP) above the physiological level of individuals (Shiose Y.,1990). Glaucoma drainage devices (GDDs) have the potential to regulate flow reliably and to maintain IOP below 20mmHg.

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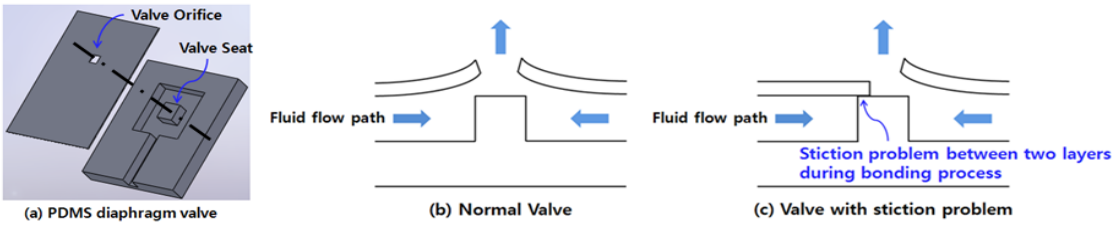

Figure 1: A PDMS diaphragm valve and stiction problem; (a) Schematic drawing of a PDMS check valve, (b) Illustration of a normal valve under forward pressure, and (c) Illustration of a valve with stiction problem.

This paper describes the advancements of the existing micro check valve through the selective bonding of PDMS layers: the high consistency of cracking pressure, flow rate, and diode-like characteristic (Seongmin Im et al., 2010). Also, it will be confirmed that the proposed micro check valve has a great potential as a component of a glaucoma drainage device.

2 DESIGN AND OPERATION

2.1 Design

Fig. 2 shows the micro check valve with two layers, and each layer is made of PDMS. There are four design parameters for the targeted cracking pressure: the diameter of hole, the thickness of membrane, the width of the channel, and the overlapped length of the hole over valve seat. The thickness of membrane is the most critical factor for the cracking pressure. The top layer is thin membrane which has a hole (valve orifice) in it. The thickness of the membrane is 122um, and the diameter of the hole is 350um. The bottom layer is micro channel, and defines the fluidic channel and valve seat. The dimensions of the channel are 100um width and 100um height, and the diameter of the cylindrical post is 450um. Cr and Au are deposited on the valve seat with 20nm respectively. These thin Cr/Au layers are introduced to prevent the stiction problem between the valve orifice and the valve seat during bonding process.

A glaucoma drainage device integrates the cover (top layer), the diaphragm (intermediate layer), and baseplate with a cannular (bottom layer) as shown in Fig. 3. The base plate is a square, 5mm each side.

The cannula dimensions are 15mm length, 1mm width, and 900um height, and internal microchannel is 100um width and 100um height. The square-shaped valve cover is equipped with the cylindrical post array (450um in diameter and the 80um in height). The valve cover is bonded on the

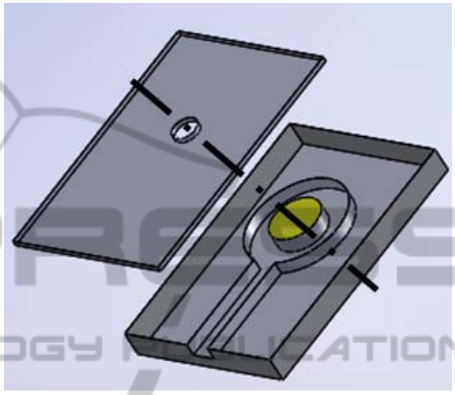

Figure 2: Illustration of a PDMS diaphragm valve with Cr/Au layer on the valve seat for selective bonding of PDMS layers.

intermediate layer after flipping down to prevent conjunctiva from directly contacting with valve orifice so that the stable valve operation of the micro check valve will be secured in terms of cracking pressure and flow rate after the implantation.

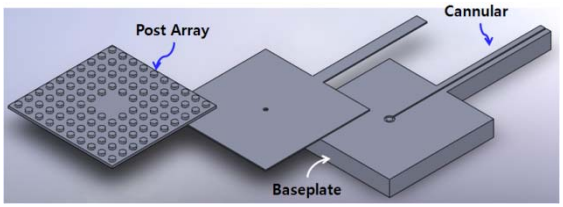

Figure 3: Illustration of a glaucoma drainage device. The device consists of the cover (top layer), the diaphragm (intermediate layer), and the baseplate with a cannular (bottom layer). The cover is bonded on the diaphragm after flipping down.

2.2 Operation Principle

The proposed micro check valve is normally-closed allowing one directional flow. When the internal pressure is higher than external pressure, the valve opens, and the valve remains closed when the external pressure is higher than internal pressure.

After the implantation of a GDD, the end of the

cannula is located in the anterior chamber of the eye ball. When the IOP is higher than the cracking pressure of a GDD, the valve drains the surplus aqueous humour to regulate the pressure of the anterior chamber.

3 FABRICATION

The fabrication of the bottom layer started with spin coating of SU-8 on the silicon wafer. The SU-8 in 100um height on the silicon wafer was patterned, and it served as a mold. PDMS was poured on the mold, and was cured at 90℃ for 1h. The PDMS replica was separated from the SU-8 mold, and the shadow mask was aligned on the PDMS replica. Cr and Au are deposited on the valve seat for the selective bonding between the cover and the diaphragm.

The fabrication of the diaphragm (intermediate layer) with a through-hole started with making a PDMS replica. The PDMS replica has a post 350um in diameter and 122um in height. The hydrophobic treatment using CH4 and He was performed on the surface of the PDMS replica. The PDMS replica was put on a silicon wafer, and uncured PDMS was filled in the space between the PDMS replica and silicon wafer. The uncured PDMS layer was cured at 90℃ for 1h, and the diaphragm was separated from the molds (Jongchan Choi et al., 2010). The cover of the device was simply made using soft-lithography.

Oxygen plasma treatment enables the surface modification of PDMS layers and irreversible bonds each layer. An aligner was used to assemble three layers, and the valve orifice and the valve seat were selectively bonded.

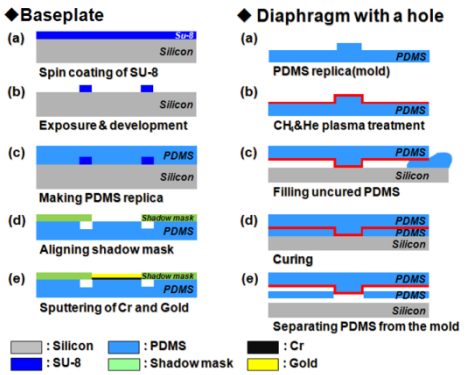

Figure 4: Fabrication sequence; A CH_4/He plasma surface treatment of a PDMS mold was performed to make a diaphragm with a through-hole. Soft-lithography process was used to fabricate the bottom layer.

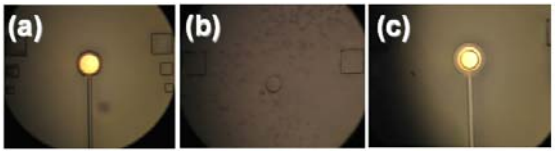

Figure 5: Micrographs of the check valve (Top view); (a) the bottom layer after sputtering of Cr and Au, (b) a diaphragm with a through-hole, and (c) a micro check valve after bonding the diaphragm and the bottom layer.

4 EXPERIMENT AND RESULTS

The performance of the fabricated check valve was tested by using a hydrostatic pressure and analytical balance. After connecting the micro check valve with a pressurized water source, the valve was placed on the analytical balance. In order to experimentally find the cracking pressure of the valve, the flow rates of three devices were recorded with respect to the input pressure. The data were attained for 3 min at high pressure (≥ 3000 Pa) and for 10 min at low pressure (< 3000 Pa). From the Fig 6, the mean value and standard deviation of the cracking pressure was found to be 2444 ± 87.76 Pa and, which is very close to the target value (2666 Pa) for the glaucoma drainage device. When reverse pressures over 10 kPa was applied, the leakage was not occurred.

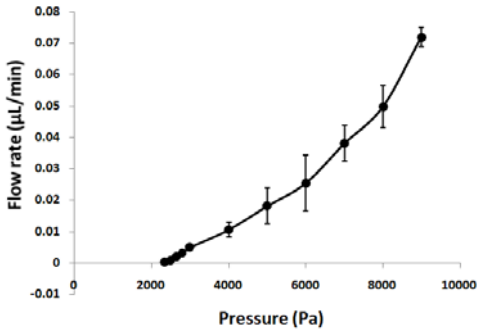

Figure 6: Outlet flow rate versus input pressure. The cracking pressure is 2444 ± 87.76 Pa (n=3). The steady state outlet flow rates were 0.025 ± 0.009 μL/min (n=3, at 6000 Pa). When the reverse pressure over 10 kPa was applied, the leakage was not observed.

Fig. 7 shows the experimental result of the repeatability test. The flow rates in the steady state were nearly 0 μL/min at 2350 Pa (slightly lower than cracking pressure) and 0.0081 μL/min ± 2% at 4000 Pa (sufficiently higher than desirable intraocular pressure). The negligible variance in the repeatability test indicates that the reliability of the valve is considerably enhanced, and the selectively

bonded diaphragm valve has great potential as a component of a glaucoma drainage device.

For the future work, the fabricated glaucoma drainage device will be implanted in a rabbit's eye to find the in-vivo cracking pressure and to monitor the postoperative fibrosis. Furthermore, the biocompatibility of the device will be examined through in-vivo experiments. Even though the body of the device is made of an approved biocompatible material, Cr/Au layers of the device should be checked of biocompatibility.

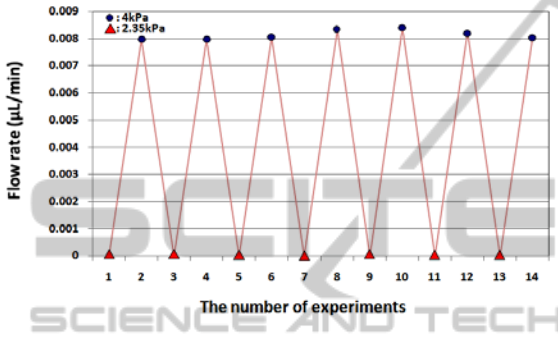

Figure 7: Repeatability of the outlet flow rate. The steady state flow rates were 0 μL/min (n=7, at 2350 Pa) and 0.0081 μL/min±2% (n=7, at 4000 Pa).

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