

A design of brain port with a built-in bi-directional check valve improves the ventriculostomy

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Abstract

The increase of intracranial pressure is a life-threatening condition which requires urgent treatment to prevent the further neurologic problem. A design of the brain port is proposed, in which a bi-directional check valve controls the flow of the cerebrospinal fluid depending on the intracranial pressure in accordance with the other devices. Drug administration and cerebrospinal fluid drainage could be performed easily without any additional surgery other than the transplant of a brain port. The intracranial pressure value at which the cerebrospinal fluid should be drained is adjustable by altering the pressure of the drainage bag. The results of the experiment with the simulated brain system are supporting and verifying the substance of this article.

Keywords

Ventriculostomy, chemo port, bi-directional check valve, external ventricular drain, intracranial pressure measurement, cerebrospinal fluid drainage

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Introduction

Ventriculostomy is a treatment to control the intracranial pressure (ICP) by draining the cerebrospinal fluid (CSF) for the hydrocephalus which is caused by meningitis, brain tumors, traumatic brain injury, intraventricular hemorrhage, and subarachnoid hemorrhage.¹ Depending on the symptom, the drainage of the CSF could be temporary or permanent. External ventricular drain (EVD) is the typical device/method for temporal drainage, which includes catheter inserted and ICP-monitoring devices. Because of the invasive nature, EVD is inherently prone to exposure to infection and often causes complications.² This is one of the reasons why EVD cannot be applicable to long-term drainage. On the other hands, ventriculoperitoneal shunt grants permanent drainage, which uses siphon connected between cerebral ventricles and the ventricular atrium or peritoneal cavity. Lots of the complications of ventriculoperitoneal shunt comes from the complexity of the procedure, which include bleeding from subcutaneous vessels, CSF leak from the puncture site, and the collapse of the ventricles and the wrong section of

tubing punctured.³ Especially there is no way to deliver drugs in ventriculoperitoneal shunt procedure.

In any case of treatments mentioned above, there is no way for the patients to avoid the repeated painful surgery and drug injection. The effort exerted on this study is to design a system in which the ICP monitoring, the drainage

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of CSF, and drug administration are carried out easily and repeatedly without any additional surgery for a long time. The operation of the brain port transplant is the only and one-time surgery required.

Lots of methods to monitor the ICP have been developed for decades, and it is crucial in neurosurgery and neurology fields. Despite the inherent risk of complication, the invasive methods like the EVD and micro-transducer devices are still assessed as being superior to the non-invasive methods including transcranial Doppler, tympanic membrane displacement, optic nerve sheath diameter, and computed tomography (CT) scan/magnetic resonance imaging (MRI) and funduscopy, in the sense of accuracy and the anatomical coverage.⁴ In the view of the ICP-monitoring method, this study suggests an invasive method utilizing the characteristics of a valve transplanted in the patient's brain, which defines the pressure difference (ΔP) between the ends of the valve as a function of the flow rate (Q) of the fluid passing through the valve. The estimation of the ICP is carried out differently whether the drug is injected or the CSF is drained. Using this $Q - \Delta P$ relation, the pressure at one end of the valve (ICP) can be estimated by sensing the flow rate of drug and the pressure of the other end of the valve (injection pressure) during drug administration. In case there is no forced flow after the injection of drugs is finished, the valve being designed to respond differently depending on whether the pressure difference exceeds some threshold (cracking pressure) or not acts as a device which monitors an interesting point of pressure at which the drainage of CSF is required.

A bi-directional check valve (BDCV) is designed to control the fluid flow in the brain port. While the conventional check valve grants one-way flow, the BDCV permits both-way flow only if the pressure exceeds the so-called cracking pressure. The BDCV is used in medical devices like the intravascular catheters for chronic vascular access including hyperalimentation, chemotherapy hemodialysis, and plasmapheresis,^{5,6} as well as in the mechanical hydraulic system.⁷ Mechanically, the cracking pressure is fixed and cannot be altered, once being transplanted. The prepressurized drainage bag, however, allows the adjustment of threshold pressure which initiates the drainage of CSF. The brain port (BDCV) and the drainage bag are coordinated with the other devices including infusion pumps, sensors (flow rate, pressure), solenoid valves, data acquisition device (DAQ), and host PC to regulate the ICP safely.

The experimental result shows that the designed valve allows the flow rate less than 0.1 mL/h at the pressure difference around 5 mm Hg along the drainage direction, and the $Q - \Delta P$ relation can be modeled with sixth-order polynomial with errors less than 1 mm Hg over some pressure range of interest along the drug injection direction. A simple experiment performed with a device mimicking the ICP generation in the human brain to verify the system shows the promising results that the ICP is regulated within pre-defined values (19–21 mm Hg) with the ICP estimation errors less than 2 mm Hg.

Method

Functional requirements

The functions of the proposed system can be summarized as follows.

The ICP is monitored in accordance with the purpose of the system.

The CSF is drained when the ICP exceeds the pre-defined value.

Drug administration is done without any surgery. The transplant of the brain port is the only surgery required.

Design of the brain port with the BDCV

The brain port is an essential device in this study (Figure 1(a) and (b)), which delivers drugs and drains the CSF according to the pressure difference between both ends of the BDCV. Once transplanted, only the needle inserted through the septum acts as a channel between the BDCV and the outside of the body, which minimizes the exposure to the infection.

The BDCV is a sort of check valve which grants flow in both-way only when the pressure difference between ports is greater than some value (cracking pressure) as shown in Figure 1(c). One of the ports is connected to the catheter that reaches the lateral ventricle and the other is to the injection pump or drainage bag according to the state of the solenoid valve as shown in Figure 3(a). When there is no need of drug injection or CSF drainage, the pressure difference across the ports of BDCV is small enough to shut the valve by the elastic force of spring exerting on the inner/outer valve and no flow is allowed (Figure 2 (a)). During drug injection, the pressure induced by the pump prevails over the spring force and pushes the outer valve back (Figure 2(b)). If the ICP increases and reaches some pre-defined threshold, then the pressure difference becomes large enough to have the inner valve retreat and the CSF can be drained (Figure 2(c)).

To secure the closeness of sealing in the valve, the outer valve is made of the elastic sealants, which eliminates the necessity of O-ring and contributes the smaller form factor of the valve. The outer valve is fabricated using casting, and the three-dimensional (3D) printer is used for fabricating the mold.

System operation

The system operates differently according to whether the drug is being injected or the CSF is being drained. Drug-injection is done by the infusion pump, which controls the pressure to regulate the flow rate steadily while the solenoid valve is configured to connect the flow meter to an infusion pump (Figure 3(a)).

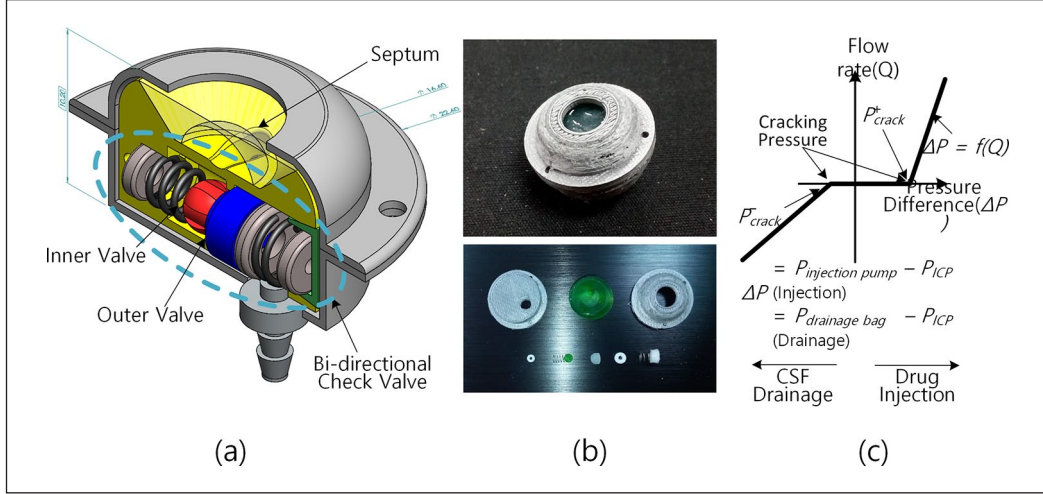


Figure 1. Brain port with bi-directional check valve (a, b) and its characteristics (c).

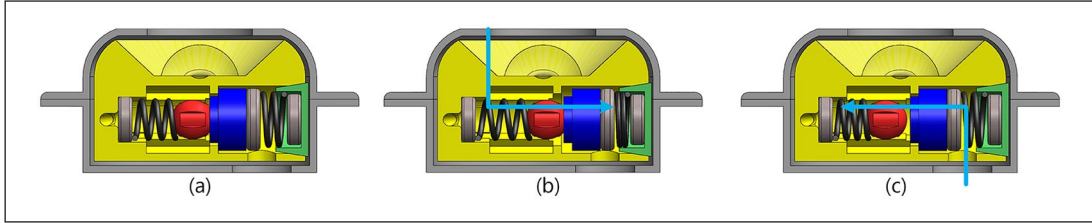


Figure 2. Operations of BDCV, while (a) closed, (b) drug injection, and (c) CSF drainage.

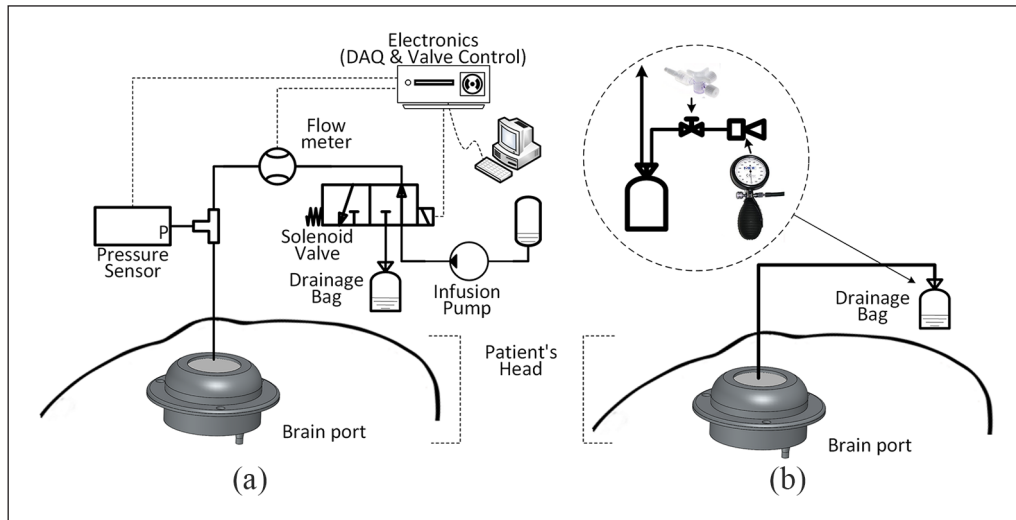


Figure 3. Diagram of the system (a) during and (b) after the drug administration.

With known the relation of “flow rate vs pressure difference” of the BDCV as shown in Figure 1(c), it is possible to calculate the ICP using the following equations during injection

$$\Delta P = P_{\text{Injection Pump}} - P_{ICP} = f(Q) \quad (1)$$

$$P_{ICP} = P_{\text{Injection Pump}} - f(Q) \quad (2)$$

where P_{ICP} , $P_{\text{Injection Pump}}$, and Q are the ICP, the pressure of the injection pump, and the flow rate through the valve (Figure 1(c)), respectively. The electronics calculates the

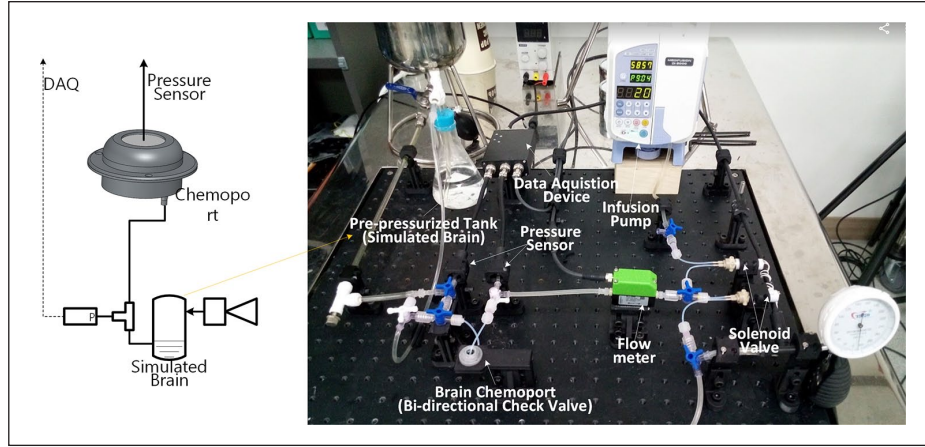


Figure 4. Setup for experiment.

ICP using this equation. As the ICP increases to reach some pre-defined value, the electronics diverts the path of the flow to the drainage bag from the infusion pump so that the CSF can be drained.

When the drug injection is completed, most of the devices in Figure 3(a) could be removed, let alone the infusion pump. The only device necessary is the drainage bag as shown in Figure 3(b). In this case, the BDCV in the brain port oversees the ICP as the followings. As the ICP increases and ΔP reaches P_{crack}^- (Figure 1(c)), the BDCV is open and grants the drainage. Let $P_{ICP_Drainage}$ be the ICP at which the drainage starts, then

$$\Delta P = P_{Drainagebag} - P_{ICP} \quad (3)$$

$$P_{crack}^- = P_{Drainagebag} - P_{ICP_Drainage} \quad (4)$$

$$P_{ICP_Drainage} = P_{Drainagebag} - P_{crack}^- \quad (5)$$

where $P_{Drainagebag}$ is the pressure in the drainage bag (Figure 1(c)). Considering P_{crack}^- is fixed when the BDCV is manufactured, the pressure at which the drainage starts ($P_{ICP_Drainage}$) can be adjusted by altering the pressure of the drainage bag ($P_{Drainagebag}$). An example of the drainage bag and the pressure adjustment devices are shown in Figure 3(b).

One of the reasons $P_{ICP_Drainage}$ should be adjustable is that P_{ICP} is somewhat different from the actual ICP, which is the pressure at the lateral ventricle rather than at the entry port of BDCV. Let ΔH be the height difference between the port of BDCV and the lateral ventricle, then the pressure error δP can be expressed as follows with some simple assumptions

$$\delta P = \rho g \Delta H \quad (6)$$

where ρ and g are the density of the CSF and gravitational acceleration, respectively. As the pose of the patient's head

changes, $P_{ICP_Drainage}$ should be adjusted to compensate for the variation of ΔH . This compensation can be done by adjusting the threshold pressure at which the solenoid valve changes the flow path during drug injection and by varying the pressure in the drainage bag after drug injection, as mentioned before.

Results

An experiment was performed with the setup shown in Figure 4, which includes a pre-pressurized chamber to simulate the ICP generation in human brain.

Valve characteristics and mathematical model

The relation of the flow rate versus pressure difference across the BDCV is measured as shown in Figure 5(a), in which the hysteresis exists and the flow rate is somewhat smaller during the pressurizing phase than releasing. Considering the way system is operating, it is certain that the flow rate varies along the pressurizing curve during drug injection and follows the releasing curves while the CSF is drained. The result shows that the flow rate around 5 mmHg is less than 0.1 mL/h along the CSF drainage direction.

The characteristics of BDCV during injection is interpolated and modeled into the sixth-order polynomial as shown in Figure 5(b). The modeling has been done with the error less than 1 mmHg within the region of interest (200–260 mmHg), which is the span of pressure the infusion pump exerts to inject drugs. This polynomial model, a function of the flow rate Q , is utilized to estimate the ICP using equation (2).

Drug administration and CSF drainage

With the BDCV characterized as in Figure 5, an experiment to regulate the ICP has been conducted in accordance with the proposed method—(1) infusing saline into the

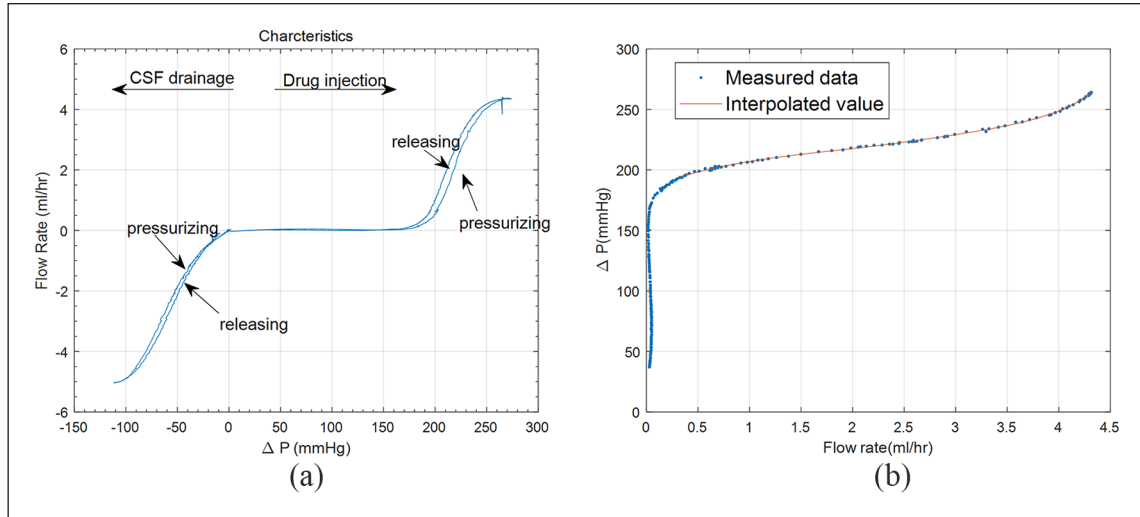


Figure 5. Characteristics of the BDCV in the (a) brain port and (b) modeling result.

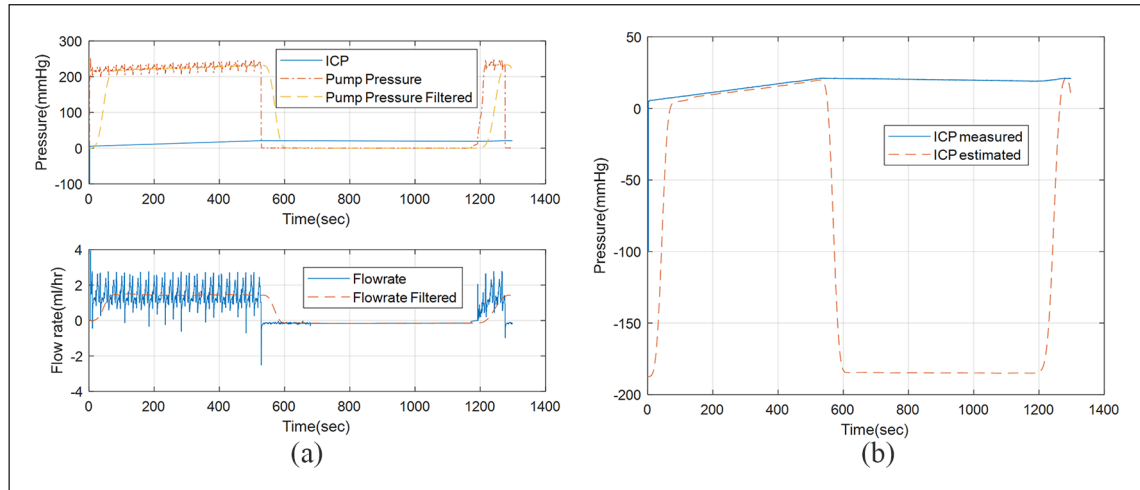


Figure 6. Pressure and flow rate variation during ICP being regulated (a) and ICP change compared with the estimated value (b).

simulated brain until the ICP (the pressure in the simulated brain) reaches 21 mm Hg, (2) draining saline by controlling the solenoid valves and diverting the flow path, and (3) infusing saline again after the pressure in the simulated brain is lowered below 19 mm Hg. Figure 6(a) shows that the ICP is regulated within 19–21 mm Hg.

As shown in Figure 6(a), the infusion pump, a kind of pinch pump, generates lots of pressure fluctuation and causes severe variation of the flow rate. An equi-ripple finite impulse response (FIR) filter with a maximum passband frequency at 1 mHz, minimum stopband frequency at 40 mHz, and -0.1 and -80 dB as minimum passband gain and maximum stopband gain, respectively, is adopted to flatten these fluctuating sensor signal and get the equivalent steady response.

With the filtered sensor data, the ICP can be estimated by equation (2). The result is shown in Figure 6(b), in which the

estimated ICP has the difference smaller than 2 mm Hg from the measured ICP at 150–550 s, which is the interval from when the filtered signals reach the steady state after the drug is injected to the moment that the CSF drainage begins.

Discussion

A ventriculostomy system is proposed, which allows the operations including drug injection, ICP monitoring, and CSF drainage to be performed repeatedly but requires only one-time surgery for the transplant of a brain port in the patient's brain. The BDCV which is located in the brain port controls the CSF to be drained out before the ICP gets higher and puts the patient's health in danger. A mechanical design of the BDCV is proposed so as to be small enough to fit in the brain port, and a method to estimate the ICP is suggested using the “flow rate (Q)–pressure difference (ΔP)” characteristics of

the BDCV. The experiment shows the electronics coordinates all the system devices including sensors, solenoid valves, and the injection pumps so that the estimated ICP is regulated within a pre-adjustable range of pressure, and the ICP estimation error has the reasonable bound.

Combined treatment of an Ommaya reservoir and EVD^{8,9} might be one of the most similar approaches with this study, which also includes the delivery of drugs, monitoring the ICP, and drainage of the CSF. The BDCV in the brain port, however, makes this study distinguishable in a sense that the ICP regulation can be done anytime, regardless of the drug injection, only with simple and limited equipment. No doubt with the EVD, it is cumbersome or even impossible to carry the devices in normal life, let alone the vulnerability to infection. For the infection issue, considering that the BDCV is a closed valve at normal condition and the fluid circuit is a closed system inherently even during the injection/drainage operation, the infection issue might be far less considerable than the other issues like the accuracy of the ICP measurement.

If putting aside the zero-drift error, the error of the ICP estimation, measured in the experiment, is less than 2 mm Hg. The zero-drift is a well-known problem for the invasive sensors due to the fact that it is impossible to recalibrate the sensors, once being implanted.^{10,11} The physical property to observe the pressure in the BDCV is the force of spring, which is expected to cause comparatively less drift than that of the other invasive sensors, most of which are utilizing the resistance change of strain gauge.⁴ With this, in the sense of accuracy, this study can be considered to be comparable with the other invasive methods like micro-transducer of which the zero-drift errors vary from 1.3 to 15 mm Hg according to the sensor types.⁴

The complications and accuracy are the main concerns in ICP measurement, for which lots of studies have been done to evaluate for the various measurement methods;¹⁰ likewise, the more sophisticated and delicate evaluation of these issues are required for this study too. Furthermore, in view of medical fitness, practical realization, usefulness, and convenience, there must be lots of difficulties left to overcome. The drainage bag needs big improvement to be practical. More devices such as the infusion pump are required to be automated, and the design of the brain port should be modified under the consideration of productivity and biocompatibility. Nevertheless, the efforts to improve the treatments to be simpler and more convenient are reflected enough in this study, and the result of the experiment supports this.

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co-authors. Then, Kwang Gi Kim and Yong-Cheol Yoon equally contributed to this effort. Therefore, Kwang Gi Kim and Heon Yoo are Co-corresponding authors

Declaration of conflicting interests

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