Design and characterization of a passive flow control valve dedicated to the hydrocephalus treatment

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Abstract: A passive valve able to deliver a constant flow rate independently of inlet pressure changes is proposed. The valve, which comprises a hollow cylinder, a piston engraved with a helical groove, a spring and two fluidic connectors, is adapted by design to high pressures and high flow rates. However, it has been shown that this technology is also suitable for the drainage of cerebrospinal fluid at 20 mL/h from the brain ventricles to the peritoneal cavity. To that end, a valve in titanium has been machined and tested at very low pressure using water. Despite small mismatches between theoretical and measured spring stiffness, the experiments confirm the valve’s ability to deliver a substantially constant flow rate in the range from +10 to +35 mbar. To balance the effect of gravity, a hollow piston in PEEK that exhibits an overall density equal to that of the fluid has been tested with success. The effect of friction between the piston and the cylinder is also discussed.

Keywords: hydraulic valve; flow control valve; valve design; pressure compensation; passive device; hysteresis

ABOUT THE AUTHOR

Eric Chappel received a master degree in Physics in 1996 (UJF, Grenoble), and accomplished his PhD thesis at LNCMI. He joined Memscap in 2001 and developed packaging for MOEMS. In 2003 he joined Debiotech SA and developed insulin micropumps, valves, piezo actuators and sensors. More recent work deals with the development of passive flow regulators for immunotherapy and hydrocephalus treatment.

PUBLIC INTEREST STATEMENT

Many medical applications like the diabetes care, the chemotherapy or the hydrocephalus treatment require the delivery or the drainage of a fluid at a constant flow rate. The standard treatment of hydrocephalus, which is caused by a pathological accumulation of cerebrospinal fluid in the brain ventricles, is the placement of a valve that diverts this fluid from the brain to another location of the body, usually the peritoneal cavity, wherein the fluid is absorbed. A new passive valve able to drain at a constant flow rate independently of pressure changes is proposed in this article. The valve comprises a hollow cylinder, a piston engraved with a helical groove, a spring and two fluidic connectors. A valve in titanium has been machined and tested at very low pressure using water. Experimental results confirm the valve’s ability to deliver a substantially constant flow rate in the range from +10 to +35 mbar.
1. Introduction

Passive flow control valves have several medical applications including diabetes care, pain management, immunotherapy, chemotherapy, anaesthesia and hydrocephalus treatment. Moreover, many different engineering applications are also conceivable, such as water saving system, gas combustion, gas analyzer, humidity analyzer or Chemical Vapor Deposition. A comprehensive introduction to the different components of hydraulic systems, including notably valves, is provided in Totten and De Negri (2012). The flow control is usually achieved using active valves that can be coupled with sensors like flowmeters. An original design of a flow control valve for water hydraulics comprising a metering valve located downstream of an active pressure compensator valve is for instance provided in Suzuki and Urata (2008). Specific reviews dedicated to both active and passive microvalves are given in Au, Lai, Utela, and Folch (2011), Oh and Ahn (2006), with a focus on the actuation mechanisms and their applications that include notably flow regulation. From a functional point of view, passive valves can be considered as pressure-control valves except from a specific microfluidic device (Chappel, Dumont-Fillon, & Mefti, 2014) able to regulate a flow from few ml/day to few ml/min depending on its structure. To illustrate the working principle of passive flow regulation, we consider a passive valve having a variable fluidic resistance \( R_f(\Delta P) \), where \( \Delta P \) is the gradient of pressure through the valve. The flow rate \( Q(\Delta P) \) in the valve is:

\[
Q(\Delta P) = \frac{\Delta P}{R_f(\Delta P)}
\]  

In order to get a constant flow rate, the fluidic resistance of the device shall vary linearly with pressure evolution. A variable resistance can be achieved by using a flexible membrane having through holes as in Chappel et al. (2014). The latter device is made of a stack of two plates: the first plate comprises a flexible silicon membrane having through holes while the second plate is a rigid substrate with a cavity, an outlet hole and pillars aligned with the through holes of the membrane. The liquid in the pressurized reservoir flows through the holes etched in the membrane and the gap between the membrane and the pillars. As the pressure gradient increases, the gap becomes progressively smaller, hindering the fluid flow and leading to a non-linear fluidic behavior. A schematic cross-section of the device is provided in Figure 1. Numerical simulations of the fluid dynamics inside the valve are used to design a microfluidic device that exhibits a constant flow rate in a specified range of pressure.

An alternative design compatible with standard machining techniques is proposed here. After a brief introduction to the concept, the dimensions of a device dedicated to hydrocephalus treatment are provided. This valve is intended to drain cerebrospinal fluid from the brain ventricles toward the peritoneal cavity at its physiologic rate of production (typically 20 mL/h), thus minimizing the potential risks associated with both postural and vasogenic overdrainages (Sainte-Rose, Hooven, & Hirsch, 1987). The chemical and physical properties of the CSF are provided in many textbooks of medical physiology (see e.g. Guyton & Hall, 2006). The operating pressure range varies from 10 to 35 mbar, depending on postural changes and intracranial pressure. A valve made of titanium has been...

Figure 1. Schematic cross-section of a flow control valve in silicon.

Source: From Chappel et al. (2014).
machined and tested using water (which constitutes 99% of CSF). Since pressure forces on the piston are very small, the orientation of the piston has a non-negligible effect on the fluidic characteristic. A hollow piston that exhibits the same density as water has therefore been tested with success. The effect of friction between the piston and the cylinder is finally reviewed.

2. Valve design
The flow control valve comprises a hollow cylinder having a precision grinded inner surface guiding a piston, two plugs used as inlet and outlet connectors and a compression spring. O-ring can be placed in the inlet connector to block reverse flow (check-valve). A helical groove is engraved around the piston, creating a channel when the piston is engaged into the guiding part of the cylinder. Cross-sections of the device submitted to low and high pressures are provided in Figures 2 and 3 respectively. The spring can be pre-stressed to block the flow until the pressure gradient reaches the opening threshold $\Delta P_{\text{opening}}$. The cylinder has openings on the inlet side in order to manage a volume of fluid around the upper part of the piston that is submitted to a pressure substantially equal to the inlet pressure. The pressure in the lower part of the cylinder (outlet side) is substantially equal to the outlet pressure. The main pressure drop inside the valve occurs when the fluid is forced to flow inside the channel. The pressure force acting on the piston is balanced by the restoring force of the spring. The pressure gradient necessary to get a contact between the piston and the outer connector is referred to as $\Delta P_{\text{ref}}$. The length of the piston engaged into the cylinder after the openings is $L$ (see Figures 2 and 3). The movement of the piston depends directly on the pressure gradient $P$:

- For $\Delta P < \Delta P_{\text{opening}}$, the length $L$ is constant and equal to $L_{\text{min}}$.
- For $\Delta P_{\text{opening}} < \Delta P < \Delta P_{\text{ref}}$, the length $L$ varies linearly with $P$ when considering a linear spring.
- For $\Delta P > \Delta P_{\text{ref}}$, the length $L$ remains constant and equal to $L_{\text{max}}$.

The fluidic resistance of the channel shall be proportional to the length of the piston engaged into the guiding part of the cylinder and therefore to the pressure in the range $\Delta P_{\text{opening}} < \Delta P < \Delta P_{\text{ref}}$. The channel shall exhibit a regular shape in order to get a constant flow rate in the same pressure range. The pitch of the helix as well as the cross-section of the piston groove is therefore constant.

Several solutions for non-circular channel shapes to the Newtonian viscous-flow equations are provided in Bird, Stewart, and Lightfoot (2007), Guyon, Hulin, and Petit (2001), White (1991). The cross-section of the channel, which is defined by the shape of the lathe tool, is usually not an idealized shape and FEM simulations have been required to determine the fluidic resistance of the channel per unit of length $R/L_{\text{channel}}$. To limit flow rate errors related to machining, the value of $R/L_{\text{channel}}$ shall be maximized and the pitch of the helical channel minimized.

Figure 2. Isometric view of the flow control valve cross-section at low pressure.
This device exhibits a permanent flow or “leakage” between the piston and the guiding part of the cylinder forming an annulus. This “leakage” is not a flow from the valve toward the environment but from one loop of the channel to another one without following the normal route. The formulae for flows through concentric and eccentric annuli (described in White (1991)) are used to estimate the leak rate. It is important to note that the leakage, as well as the flow inside the channel, is regulated since the height of the fluidic annulus, and therefore its fluidic resistance, varies linearly with the pressure gradient in the range $\Delta P_{\text{opening}} < \Delta P < \Delta P_{\text{ref}}$

### 3. Machining and metrology

A valve dedicated to cerebrospinal fluid drainage has been designed. Despite the small pressure force acting on the piston, the dimensions of this titanium implantable device have been kept small, with an outer cylinder diameter of 6.35 mm and a total length of 24.3 mm. The cross-section of the channel shown in Figure 4 corresponds to a lathe tool having the following characteristics:

- Tip curvature radius $R = 0.1$ mm
- Channel angle: 55°

The penetration depth of the lathe tool in the piston is 0.2 mm. The corresponding fluidic resistance per unit of channel length $R_f$ has been estimated numerically at 37°C:

$$R_f(\text{simulation}) = 1.24 \times 10^{13} \text{ Pa s m}^{-3}$$

(2)

The fluidic resistance of this channel can be estimated with the approximation of the hydraulic diameter $D_{\text{hy}}$:

$$D_{\text{hy}} = \frac{4 \text{ Area}}{\text{Wetted perimeter}}$$

(3)

Using basic trigonometric considerations, the calculation of the channel hydraulic diameter yields exactly to the simple formulation:

$$D_{\text{hy}} = 4 \frac{R}{\left(4 \tan \frac{\alpha}{2} + \frac{4}{\cos \frac{\alpha}{2}} + \pi - \alpha\right)^2} = 2R$$

(4)

The Reynolds number associated with the flow in the channel is smaller than 100. The fluidic resistance of the channel, based on classical Darcy–Weisbach equation, takes the form:
where \( \eta \) is the dynamic viscosity and \( L \) is the channel length. The numerical application, for a 1 m long channel and a dynamic viscosity of 0.69 m Pa s (water at 37°C), yields:

\[
R_f^{(\text{theoretical})} = 1.26 \times 10^{13} \text{ Pa s m}^{-3}
\]  

(6)

The good match with simulations indicates that the approximation of the hydraulic diameter is valid for the channel geometry considered here.

The values of \( L_{\text{min}} \) and \( L_{\text{max}} \) indicated in Figures 2 and 3 are equal to 1.5 and 5.3 mm respectively. The arc length of a helix’s loop \( L_{\text{loop}} \) is written as a function of the pitch \( 2\pi b \) (defined as the vertical distance between helix’s loops), the channel depth \( h \) and the piston radius \( R \):

\[
L_{\text{loop}} = 2\pi \sqrt{\left( R - \frac{h}{2} \right)^2 + b^2}
\]

(7)

For a pitch of 1.25 mm and a channel depth of 0.2 mm, the length of each helix’s loop is \( L_{\text{loop}} \approx 12 \text{ mm} \). The total length of the channel at 10 and 35 mbar are 14.4 and 50.88 mm respectively.

The relationship between the channel length \( L_{\text{channel}} \) and \( \Delta L \), the length of the piston engaged into the guiding part of the cylinder, is therefore linear:

\[
L_{\text{channel}} = 9.6 \Delta L
\]

(8)

A dedicated compression spring with flat end coil and very low stiffness has been made to balance these pressure forces. The inner and outer diameters of the spring are 2 and 2.2 mm respectively. The spring has a free length is 10 mm and is pre-stressed by an initial compression of 1.5 mm while the minimum spring length at high pressure is 4.7 mm.

The weight of the titanium piston has not been considered here; therefore the device shall exhibit its nominal characteristics in horizontal position. The critical-to-quality parameters have been characterized and compared to the specifications as shown in Table 1. The cylinder inner diameter is slightly out of specifications as well as the spring which exhibits stiffness 20% higher than expected. The target curve flow rate vs. pressure will be adjusted accordingly during the comparison between experimental and theoretical data.

All parts of the device are made in titanium except the spring made in stainless steel 302. The device has been designed to deliver 20 mL/h at 37°C. The flow in the channel is laminar in the operation range of pressure of the device (Re < 100).
4. Test method

A schematic test setup is described in Figure 5. The device has been assembled and tested in clean room class ISO 7.

The fluidic tests have been performed using pure water at 20 ± 2°C. The fluidic behavior of the device at 37°C has been extrapolated using the typical correction factor of 1.45 which corresponds to the ratio water viscosity (20°C)/water viscosity (37°C) (White, 1991). A pressure controller Druck DPI520 (resolution ± 0.01 mbar in the range −1 to +4 bar is placed upstream a pressurization bottle connected to the device inlet. The outlet of the device is connected to a flow meter Sensirion ASL1600 (resolution ±0.1 μL/min) and the fluid flows up to a large reservoir. The pressurization bottle is placed onto an adjustable plate in order to adjust the flow rate to zero when the pressure controller is vented. The water column between the pressurization bottle and the reservoir is maintained in the range ±1 cm during the test. Large tubing section (ID of 1 mm, total length <1 m) has been used to limit the parasitic pressure drops in the fluidic line. Pressure sweeps and data recording are performed automatically using RS232 interface.

![Figure 5. Fluidic test setup.](image-url)
The two connectors are glued on the cylinder using Loctite 406 to ensure a good tightness. The stabilization period of the pressure controller is 2 s. The measurement of the flow rate is performed 10 s after each change of pressure. The integration time of the flow meter is set at 3 s. The range of pressure investigated is −10 to +50 mbar, using pressure steps of either 1 or 5 mbar. Three device orientations have been studied: +90°, 0° and −90° with respect to the horizontal axis, which correspond to, respectively, the vertical position with outlet above inlet, the horizontal position, and the reverse vertical position with inlet above outlet.

5. Fluidic characterization
The experimental data obtained for a device lying horizontally are provided in Figure 6, using steps of pressure of 1 mbar.

Friction between the piston and the cylinder is responsible for the sawtooth shaped curve. Despite a small slope discussed hereafter, flow regulation occurs in the expected range. Using the metrology data provided in Table 1, a new theoretical curve has been simulated. The main parameter out of specification is the spring stiffness (+20%). This larger stiffness induces a smaller displacement of the piston as the pressure increases; therefore the flow rate is larger than expected, leading to a positive slope as observed in Figure 6. The linear fit of the experimental data at low and high pressures yields to the fluidic resistances $R_{\text{f LP}}$ and $R_{\text{f HP}}$ respectively. The values are compared to the initial target values in Table 2.

The good match between experimental data and the target value at high pressures confirms metrology of the channel cross-section. The larger fluidic resistance at low pressure is partly due to the uncertainty associated with the initial portion of the piston engaged into the cylinder. The pressure shift (+20%), for a device tested horizontally, is due to the spring stiffness out of specification. Using the experimental values $R_{\text{f LP}}$ and $R_{\text{f HP}}$, the fluidic characteristic of the device can be simulated using Equation (9):

$$Q(\Delta P) = \frac{\Delta P}{\left( R_{\text{f LP}} + R_{\text{f HP}} \right) \left( \frac{\Delta P - \Delta P_{\text{opening}}}{k} \right)}$$

where $\Delta P$ is the measured gradient of pressure through the valve, $D$ the measured piston diameter, $\Delta P_{\text{opening}}$ the measured opening pressure of the device, $k$ the measured spring stiffness. The simulated

![Figure 6. Simulated and measured flow rate vs. pressure profiles for a device in horizontal position, using pressure step of +1 mbar; simulated data are derived from Equation (9).]
flow rate based on Equation (9), as shown in Figure 6, exhibits the same positive slope in the range \( \Delta P_{\text{opening}} < \Delta P < \Delta P_{\text{ref}} \) than the experimental data. Except the sawtooth pattern induced by friction, the simulated curve fits well with experimental data when the measured spring stiffness is considered for the estimation of the piston position. Fluidic characteristics of a device tested horizontally, using pressure steps of +5 and −5 mbar, are provided in Figure 7 as well as the initial fluidic characteristic target.

Larger pressure steps do not induce sawtooth pattern. The friction may prevent the movement of the piston for pressure change of 1 mbar. As long as the piston is blocked, the fluidic resistance of the device is constant and the flow rate increases linearly with the applied pressure. This feature probably explains the behavior observed in Figure 6. Larger pressure steps of 5 mbar induce a systematic movement of the piston, preventing therefore any flow rate instabilities as shown in Figure 7. Small hysteresis is observed, corresponding to a difference of about 2 mbar between the curves obtained by increasing and decreasing the applied pressure respectively. The same test performed using pressure steps of ±1 mbar induces also hysteresis but the difference between the two curves oscillates between 0 and +2 mbar as shown in Figure 8. The mean flow rate errors for fluidic characteristics recorded by increasing and decreasing pressure are respectively +5 and −5% with respect to the initial target of 20 mL/h.

The effect of the device orientation on the fluidic characteristics is shown in Figure 9. To write the balance of the different forces acting on the piston along the spring axis, it is necessary to include the weight of the piston if the device is not in horizontal position. The piston weight is equivalent to a positive (respectively negative) pressure offset if the angle defined in Figure 9 is −90° (respectively +90°). The compression of the spring and the length of the channel, for a given pressure gradient in the range \( \Delta P_{\text{opening}} < \Delta P < \Delta P_{\text{ref}} \) are larger for an angle of −90° than for angles of 0° and +90°. The flow rate is indeed smaller at −90° than at +90° as shown in Figure 9.

### Table 2. Experimental fluidic resistances at low and high pressures compared to target values

<table>
<thead>
<tr>
<th>Experiment (Pa s m⁻³)</th>
<th>Initial target (Pa s m⁻³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>( R_{\text{f LP}} ) for ( \Delta P &lt; 10 \text{ mbar} )</td>
<td>2.38E+11</td>
</tr>
<tr>
<td>( R_{\text{f HP}} ) for ( \Delta P &gt; 35 \text{ mbar} )</td>
<td>5.93E+11</td>
</tr>
</tbody>
</table>

![Figure 7. Flow rate vs. pressure profiles for a device tested in horizontal position, using pressure steps of +5 mbar [up] and −5 mbar [down].](image)
6. Test of a hollow piston and discussion
To limit the effect of the device orientation on the flow rate, a dedicated hollow piston made of PEEK has been designed and tested with water. Except the cavity, the characteristics of the piston remain unchanged. A cap in PEEK is glued on the piston in order to close the cavity. The overall density of this piston is equal to the density of water, and thanks to Archimedes' force, the effect of gravity on the device operation shall become negligible. The dimensions of the hollow piston including the helical groove are within the specifications given in Table 1. The device has been tested with water using the cylinder and the spring described in the previous paragraph. The fluidic characteristics of the device tested using positive pressure steps of +1 mbar are shown in Figure 10 for both vertical orientations, respectively +90° and −90°. The sawtooth pattern is still present but there is no significant
difference between each curve, indicating that the device with the hollow piston is not sensitive to gravity effect on the flow rate.

The very low nominal flow rate of the device leads to narrow tolerances for both piston and cylinder diameters, in order to limit flow rate variability. By design, friction shall then be smaller at higher flow rate. Surface coating and a better control of the surface roughness could be implemented to limit friction (Bhushan, 2013). Finally, the use of a second spring antagonist to the first one (inlet side) may help the guiding of the piston inside the cylinder and therefore reduce the small hysteresis observed experimentally.

7. Conclusion
A flow control valve dedicated to the drainage of cerebrospinal fluid from the brain ventricles towards the peritoneal cavity has been designed and tested at low pressure. It has been demonstrated that such device is able to deliver, at a given temperature, a substantially constant flow rate in a predefined range of pressure. Flow rate accuracy is here mainly driven by the relative tolerance of the channel cross-section. The device is therefore well adapted to high flow rate (from mL/min to L/min). Based on Archimedes’ principle, it has been shown that the impact of the device orientation on the flow rate can simply be compensated by the use of a hollow piston made in PEEK. Flow rate variability of ±5% due to friction may be improved by several means, such as an increase of the nominal flow rate, the deposition of a low-friction coating or the use of a second spring at the inlet side which shall improve the piston guiding.
Nomenclature

\(Q\)  Flow rate
\(\Delta P\)  Pressure gradient through the valve
\(Re\)  Reynolds number
\(R_f\)  Fluidic resistance
\(2\pi b\)  Vertical distance between helix’s loop (pitch)
\(D_{hy}\)  Hydraulic diameter
\(R\)  Curvature radius of the channel
\(\alpha\)  Channel angle
\(A\)  Area of the channel cross-section
\(D\)  Piston diameter
\(L_{loop}\)  Arc length of a helix’s loop
\(k\)  Spring stiffness
\(R_{f,LP}\)  Fluidic resistance of the channel at low pressure
\(R_{f,HP}\)  Fluidic resistance of the channel at high pressure
\(\Delta P_{opening}\)  Minimum pressure gradient to move the piston inside the cylinder
\(\Delta P_{ref}\)  Minimum pressure gradient to get a full piston displacement
\(L_{min}\)  Minimum piston length engaged into the guiding part of the cylinder
\(L_{max}\)  Maximum piston length engaged into the guiding part of the cylinder

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