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Experimental validation of a test setup for hydrodynamic characterization of hydrocephalus shunts

https://doi.org/10.1515/cdbme-2025-0214

Abstract: Hydrocephalus is typically treated through the implantation of shunt systems, which aim to manage the imbalance in cerebrospinal fluid (CSF) production and absorption. Programmable shunt valves (PSVs), such as the Polaris® SPV200, are commonly used in these treatments as they allow for non-invasive adjustments to regulate CSF drainage. This study provides information on the improvement of a validated test setup using the different opening pressures of a programmable shunt valve to open up the hydrodynamic characterization of shunts as a field of application. The testing was conducted under controlled conditions, measuring both flow rates and pressures at different opening pressures. The experimental results were then compared to the target values. The findings revealed slight deviations between the measured performance and the target results. These deviations highlight the potential influence of environmental factors and testing conditions on valve performance. The results suggest that further investigation, including testing under varying temperature conditions, is necessary to optimize the used test setup.

Keywords: hydrocephalus shunt, *in vitro* test setup, hydrodynamic characterization

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1 Introduction

The implantation of a shunt system is the most commonly performed neurosurgical procedure for treating hydrocephalus [1]. Hydrocephalus is a clinical condition characterized by an imbalance between the production and absorption of cerebrospinal fluid (CSF), primarily due to impaired CSF absorption. CSF is produced by the choroid plexus in the lateral ventricles of the brain. Intracranial hypertension (IH), which is associated with abnormally elevated CSF pressure, imposes mechanical stress on brain tissue, potentially leading to neurological damage. To counteract this, a shunt system diverts excess CSF from the brain to other body cavities, most commonly the abdominal cavity. A shunt system consists of a valve and a catheter, both of which have specific hydrodynamic properties. Additionally, the valve can be adjusted to regulate opening and closing.

The use of programmable shunt valves (PSVs) for the intervention of hydrocephalus has increased significantly [2]. Unlike fixed shunt valves, programmable devices enable the operator to adjust the amount of CSF drainage without requiring shunt revision or valve replacement. This allows the operator to adjust the hydrodynamic properties of the PSV to the respective conditions non-invasively.

The operating pressures that can be set with the PSV to regulate the CSF are specified by the manufacturer (target values). The flow rate is regulated based on the given pressure thresholds.

Within the current work, we used a conventional PSV for hydrodynamic characterization as a new field of application for a validated *in vitro* test setup. The characterization included the investigation of the various opening pressures. Afterwards a comparison between the target values und measurement data was carried out.

2 Materials and methods

2.1 The Polaris® shunt valve

In this paper, we used the Polaris® SPV200 (Sophysa Ltd. Orsay, France) as a shunt valve for hydrodynamic analysis. The Polaris® adjustable pressure valve, see figure 1 has been designed for the treatment of hydrocephalus by means of shunting CSF to the abdominal cavity or the right atrium of the heart. The cerebrospinal fluid CSF enters the valve through the inlet connector (1), flows through the valve body (5), and exits via the outlet connector (6). The connectors are manufactured from stainless steel, while the valve body is constructed from silicone coated polysulfone [2].

The suture holes (2), located on either side of the inlet connector, serve the purpose of securely attaching the valve to subcutaneous tissues, thereby preventing migration. An arrow (8) on the upper surface of the valve indicates the direction of CSF flow, thus aiding the correct positioning of the valve during implantation. The lower surface of the valve is marked with a unique serial number for identification purposes. The valve body incorporates a ball-in-cone mechanism that regulates the operating pressure. In normal conditions, this mechanism provides anti-reflux functionality. The valve body is rigid to protect the internal mechanism from mechanical shocks, prevents attempts to pump or puncture the valve, and ensures resistance to variations in percutaneous pressure.

The Polaris® valve enables non-invasive adjustment of resistance to accommodate the patient's clinical progression, thus obviating the necessity for re-operation. The adjustment mechanism is based on the application of varying pressure to a ruby ball (7) by a flat, semi-circular spring (4) at different points along its curvature. The spring is attached to a rotor (11), which rotates within the valve body around its central axis (9). The latter is composed of ruby and titanium.

The operating pressure of the Polaris® valve is dependent upon the angular position of the rotor, with five distinct pressure levels (30, 70, 110, 150 and 200 mmH_2O) available for each model. Position 1 corresponds to the lowest pressure, while Position 5 represents the highest pressure. Radio-opaque studs made of titanium (10), located on the right side of the valve body, serve to indicate the position of the rotor on imaging. Furthermore, radio-opaque markers (3) positioned to the left of the inlet connector serve to indicate the valve's pressure range. A micro-computed tomography scan of the valve can be seen in Figure 1.

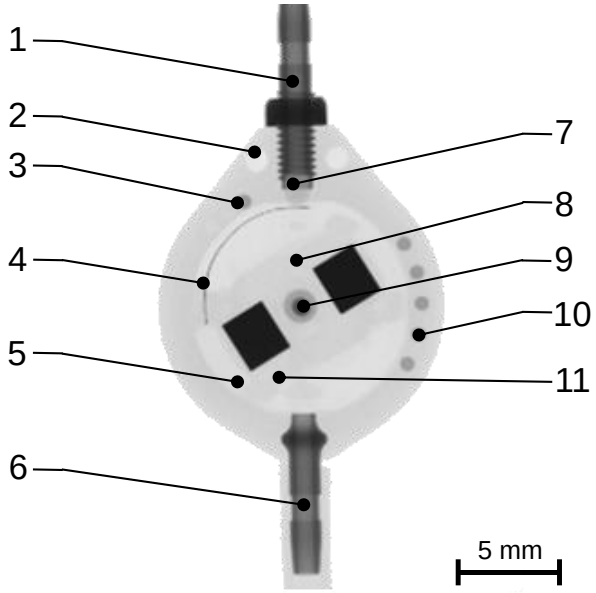
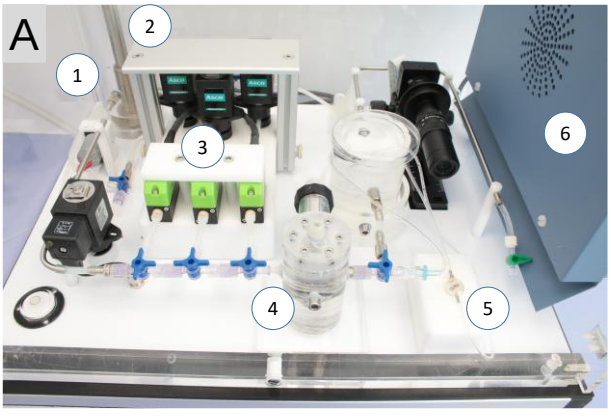


Figure 1: Micro-CT scan of the Polaris® SPV200: (1) inlet connector, (2) suture holes, (3) radio opaque points, (4) semi-circular spring, (5) valve body, (6) outlet connector, (7) ruby ball, (8) arrow, (9) central axis (11) rotor, (10) titanium made radio-opaque points,

To adjust the opening pressure of the valve, which leads into a different amount of CSF drainage, non-invasively the clinician uses an adjustment kit according to the instruction for use [3].

2.2 Measurement setup

The proposed shunt system test setup (see figure 2) was developed based on a hydraulic testing system previously utilized for evaluating the flow characteristics of glaucoma drainage implants (GDI) [4].



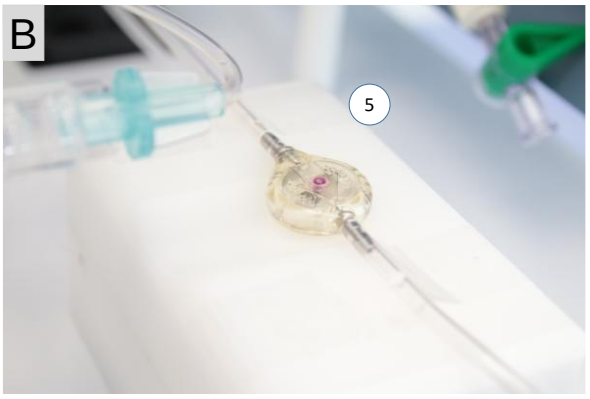


Figure 2: Test setup for hydrodynamic characterization of shunt systems (A) and detailed view of the tested shunt (B); 1: water column, 2: heating unit, 3: flow meter, 4: test chamber with pressure transducer, 5: Polaris® SPV200, 6: heating of climate chamber

This setup enables pressure measurements of up to 400 mmH_2O using a pressure transducer (DMP 331, BD SENSORS GmbH, Germany) and volume flow measurements of up to 5 ml/min with a liquid flow meter (SLI-2000, Sensirion AG, Staefa, Switzerland). The measurement accuracies of the sensors were 0.35% and 5% of the recorded value, respectively. Pressure was applied to the test specimens via a 400 mmH_2O water column, a method commonly employed in similar experimental setups [5].

The outflow from the test chamber is directed into an overflow reservoir exposed to atmospheric pressure. Fluid temperature is regulated through a heating unit equipped with a temperature sensor. Given the low volume flow rates, additional environmental temperature control is required, necessitating the enclosure of the entire experimental setup within a climatic chamber (SI60D, Bibby Scientific Limited, UK). Data acquisition and control electronics were custom-developed in-house.

Stiehm et al. demonstrated the suitability of the previously described test setup for the evaluation of hydrocephalus shunts by utilizing a simplified hydraulic model of a shunt system [6]. For the hydrodynamic characterization, the flow rate-pressure curves provided by the manufacturer were utilized, see figure 3.

According to those values and the DIN EN ISO 7197 the following test plan was developed: controlled pressurization of the shunt within a range of 0 mmH_2O to 270 mmH_2O, with increments of 27 mmH_2O [7]. A total of $n = 4$ measurements for each opening pressure were performed. As a test medium ultrapure water with a temperature of $\theta = 37°C$ was used ($\rho = 993$ kg/m^3 and $\mu = 0.691$ mPa s).

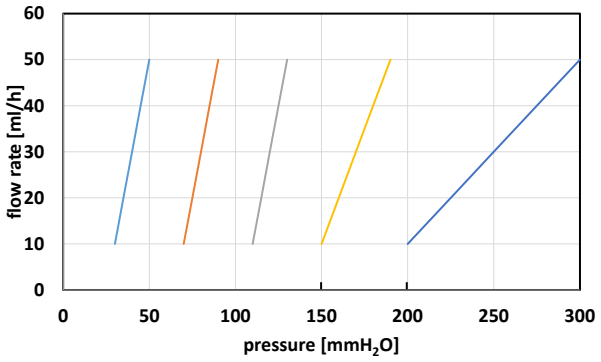


Figure 3: Target values of different opening pressures of the Polaris® SPV200: flowrate as a function of inlet pressure

3 Results

To compare the target values given by the manufacturer and the *in vitro* values, the measurements are depicted with a corresponding function and a resulting trend line, see figure 4.

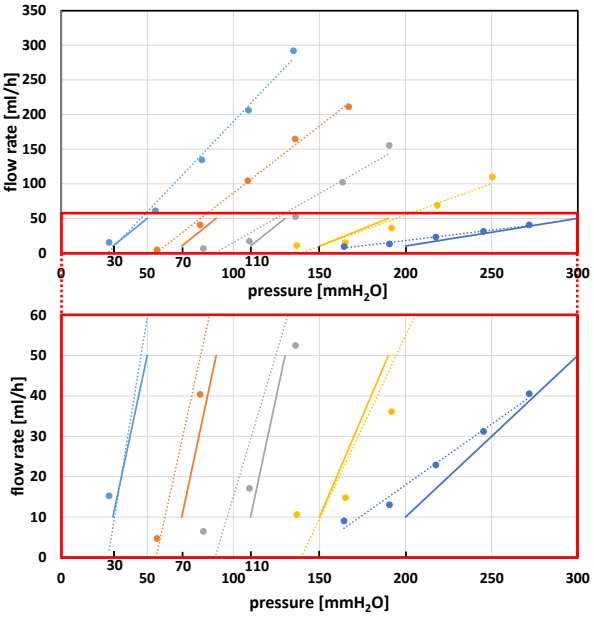


Figure 4: Graphical representation of the relationship between flow rate and pressure at the given opening pressures: comparison between the target values and the averaged measurement values ($n = 4$ measurements at five pressure stages)

In order to show the differences and similarities between the corresponding functions of the target values and measurements, the gradient of the functions are compared below, see table 1. The gradient shows the linear relationship between the flow rate and the prevailing pressure

Table 1: Comparison of the gradients between the target values and the *in vitro* measurements

opening pressure [mmH_2O]	gradient (target values) [$^{ml/h}/_{mmH_2O}$]	gradient (measurements) [$^{ml/h}/_{mmH_2O}$]
30	2	2.6
70	2	1.9
110	2	1.7
150	1	1.1
200	0.4	0.3

The gradients for an opening pressure of 30 and 150 mmH_2O for the measurements are higher than the gradients for the target values, which causes the valve to open before the target value is reached.

For 70, 110 and 200 mmH_2O the gradients for the target values are higher, which causes the valve to open within a higher opening pressure than indicated.

4 Conclusion

The hydrodynamic characterization of programmable shunt valves (PSV) for hydrocephalus treatment provides insights about the behavior at different openings pressures, which has a direct impact on CSF drainage [1].

To investigate the hydrodynamic properties of hydrocephalus shunts, a validated test setup was used [4, 6]. The test matrix was designed based on the opening pressures specified by the manufacturer and replicated using the test setup. The recorded measurements were subsequently compared with the target values. Based on the data, trend lines were fitted, and the corresponding gradients were determined. Examining the gradients provided in the manufacturer's specifications reveals an interval ranging from 2 to 0.4 $^{ml/h}/_{mmH_2O}$, whereas the measured values span from 2.6 to 0.3 $^{ml/h}/_{mmH_2O}$. Due to the fact that the gradient reflects the linear relationship between the flow rate and the pressure, it also indicates the working range for the shunt valve.

The different gradients result in a different opening behaviour for the hydrocephalus shunt. As said in the results for 30 and 150 mmH_2O the gradients of the functions for the measured values are higher than the gradients for the target values. Therefore the expected flow rates according to the target values need a lower pressure in *in vitro* environment. The expected flow rates of the target values need a higher pressure in *in vitro*.

The test was performed according to the DIN EN ISO 7197, since the IFU did not provide information of the test fluid. Despite its contributions, this study is subject to certain limitations. Deviations from the target values cannot be ruled out due to capillary effects that may occur during testing. This represents a major challenge, particularly due to the low flow rates and the unavoidable capillary effect at the outlet valve. To further substantiate the behavior of the shunt valve at different opening pressures, additional testing under varying ambient temperatures and fluids with altered viscosity must be conducted.

Author Statement

Research funding: Financial support from the European Regional Development Fund (ERDF) and the European Social Fund (ESF) within the collaborative research program between economy and science of the state of Mecklenburg-Vorpommern is gratefully acknowledged. Additionally, funding from the FORUN and ROCINI program of the University Medicine Rostock is also acknowledged.

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