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Evaluation of three new models of hydrocephalus shunts

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Summary

Objective. To assess the hydrodynamic properties of three new types of hydrocephalus valve.

Methods. Three new constructions have been recently tested in the UK shunt Evaluation Laboratory: the magnetically adjustable Strata Valve (Medtronic PS Medical), the gravitational Miethke Dual-Switch Valve (Aesculap) and the ventriculo-sinus SinuShunt (CSF Dynamics). Pressure-flow performance curves were assessed in a minimum of three samples of each valve to study their long-term variability, influence of temperature, negative outlet pressure, external pressure, presence of pressure pulsations, etc.

Results. The operating pressure of the Strata Valve can be adjusted magnetically in five steps. This Shunt prevents 'siphoning' but is sensitive to external pressure. The Dual Switch Miethke Valve is a system of two fixed-pressure ball-on-spring valves with a lower opening pressure operating in a horizontal body position and higher when vertical. This function is designed to cancel the effect of siphoning related to body posture. Both Strata and DSV valves have a low hydrodynamic resistance (less than 3 mm Hg/ml/min), and hence they cannot prevent overdrainage related to nocturnal vasomotor waves. The SinuShunt has a higher resistance (9 mm Hg/(ml/min)) and a lower opening pressure. The valve is intended to drain CSF from ventricles to the transverse sinus.

Conclusion. New shunt technology continues to evolve. Laboratory evaluation independent of the manufacturer forms an important link between R&D laboratories and clinical practice.

Keywords: Hydrocephalus; shunt; laboratory evaluation.

Shunting for the management of communicating hydrocephalus remains the mainstream strategy. To help the neurosurgeon choose from the many types of shunt available, information about each shunt's hydrodynamic properties should be available. The amount of technical information provided by the manufacturers varies. In the mid-1990s, the new ISO standard (ISO 7197) attempted to regulate the minimal requirements for the description of hydrodynamic properties of the shunt, but this has not been fully implemented by all manufacturers.

The UK Shunt Evaluation Laboratory has attempted to provide technical information, independent of the manufacturer and conforming to international standards [2]. The testing protocol has been developed and subsequently applied to at least 20 different models of hydrocephalus shunts currently in use or being introduced to clinical practice in the UK. This study describes the relevant hydrodynamic properties of three relatively novel shunt models.

Material and methods

Medtronic strata valve

The two primary attributes of this valve are opportunity to change the valve's operating pressure after implantation and its clinical ability to prevent siphoning. The Strata Valve is a differential-pressure hydrocephalus ball-on-spring valve (Fig 1a) incorporating a magnetically programmable mechanism to specify the operating pressure. The Strata valve is integrated with a Delta Chamber (also known from the literature as the Siphon Control Device [4]), which prevents overdrainage related to the body posture.

Dual switch miethke valve (DSV)

This valve belongs to the group of gravitational valves, which have been used for many years. It incorporates two different pathways for CSF for the horizontal and for the vertical body position – Fig 1b. The DSV is a fixed pressure valve. The valve is available in 9 combinations of performance levels in horizontal [10, 13, 16] and vertical position [30, 40, 50], coded xx/yy where xx and yy are opening pressure levels in cmH_2O relatively horizontally and vertically. Recently, xx = 5 cmH_2O has been introduced (not tested) to aid the treatment of Normal Pressure Hydrocephalus.

SinuShunt

The SinuShunt is a differential pressure valve designed to drain cerebrospinal fluid from brain ventricles to the cranial transverse venous sinus [1] – Fig 1c.

CSF is drained proportionally to the difference between intracranial pressure and transversal venous sinus pressure. The opening pressure of the SinuShunt is intended to be low (0 mm Hg) and its

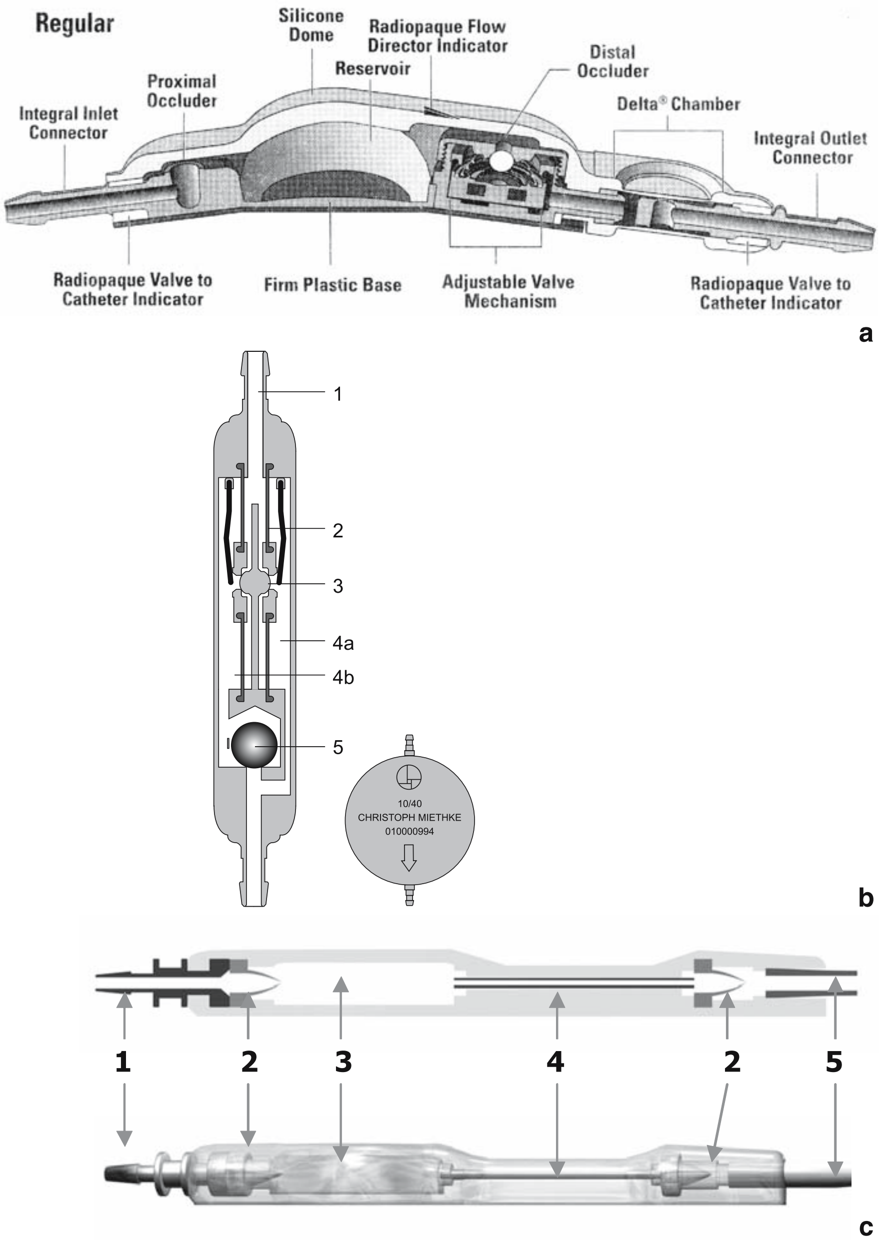

Fig. 1. Constructions of the three valves (provided by the manufacturers): (a) Strata Valve, (b) DualSwitch Valve. *1* Titanium casing; *2* Silicone diaphragm supported by flat spring. Left-low tension; Right-high tension spring; *3* Closing ball; *4* Outlet chambers. Right chamber (outlet from high-pressure valve) is always open. Left chamber (outlet from the low-pressure valve) is open only in horizontal position; *5* Heavy tantalum ball blocking low pressure valve in vertical position. (c) SinuShunt: *1* Connector; *2* One way valves; *3* Pre-chamber; *4* Resistance tube; *5* Distal catheter

hydrodynamic resistance-close to physiological resistance to CSF outflow (8 mm Hg/(ml/min)). With such parameters, the shunt is supposed to restore physiological conditions of CSF outflow, usually disturbed in hydrocephalus [1].

The testing rig has been previously described in detail [2], with its schematic diagram presented in Figure 2. Measurement is controlled by a standard IBM compatible personal computer with software designed in-house (M.C.) which precisely measures flow through the shunt and differential pressure. Three shunts of the same type are filled with deionised and deaerated water and mounted in three identical rigs.

Results

Numerical values of variables: opening pressures and hydrodynamic resistances with and without distal catheters of all valves are given in Table 1.

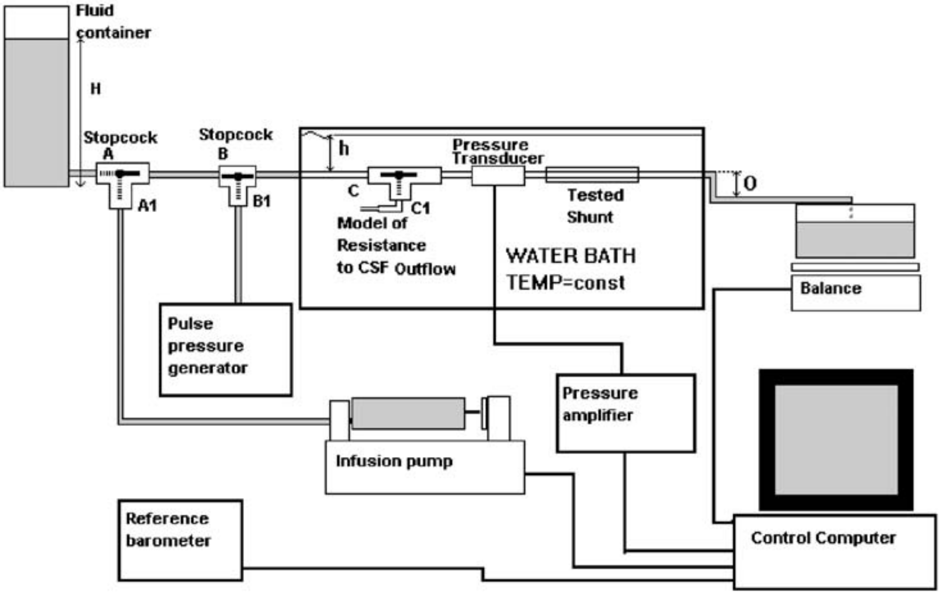

Fig. 2. Schematic diagram of testing rig

Table 1. *Basic hydrodynamic parameters of the tested shunts. Values are given as mean ± standard deviation*

Valve	Performance level	Opening Pressure [mm Hg]	Hydrodynamic resistance (no drain)	Hydrodynamic resistance (with drain)
Strata	0.5	1.5 ± 0.5	1.7 ± 0.6	2.8 ± 0.5
	1	4.2 ± 0.7	"	"
	1.5	6.1 ± 0.9	"	"
	2	8.4 ± 1.5	"	"
	2.5	10.7 ± 0.8	"	"
DSV	10 H	7 ± 0.6	2.2 ± 0.8	2.9 ± 1.1
	13 H	9.5 ± 0.4	"	"
	16 H	12 ± 1.1	"	"
	30 V	22 ± 2.1	"	"
	40 V	28 ± 1.9	"	"
	50 V	38 ± 2.2	"	"
SinuShunt	one level only	2.5 ± 1/2	9.6 ± 0.96	9.8 ± 0.8

DSV Dual Switch Valve. This valve consists of two parallel valves, coded by the values of their opening pressures in cm of water. H indicates that the valve works in horizontal and V – in vertical position. Opening pressure is given in mmHg and hydrodynamic resistance in mm Hg/(ml/min)

Strata

When tested without a distal catheter the valve had an almost a linear pressure-flow characteristic (Fig 3a). Measurement points showed a good convergence within and between tested samples. A negative outlet pressure (−17 cm H_2O, an equivalent to the value recently reported [5]) did not alter the valve's drainage rate. However, the valve's closing pressure changed when an external (environmental) pressure was applied.

Programming of the valve was checked and the pressure-flow curves found to be consistent with the nominal data provided by the manufacturer (see Table 1). The valve may be accidentally re-programmed by external non-homogeneous magnetic fields around 14 mT.

DualSwitch valve

The valve demonstrated an almost linear pressure-flow curve (Fig 3b) with a good convergence of the measurement points within and between tested samples. The DSV demonstrated an alteration in the

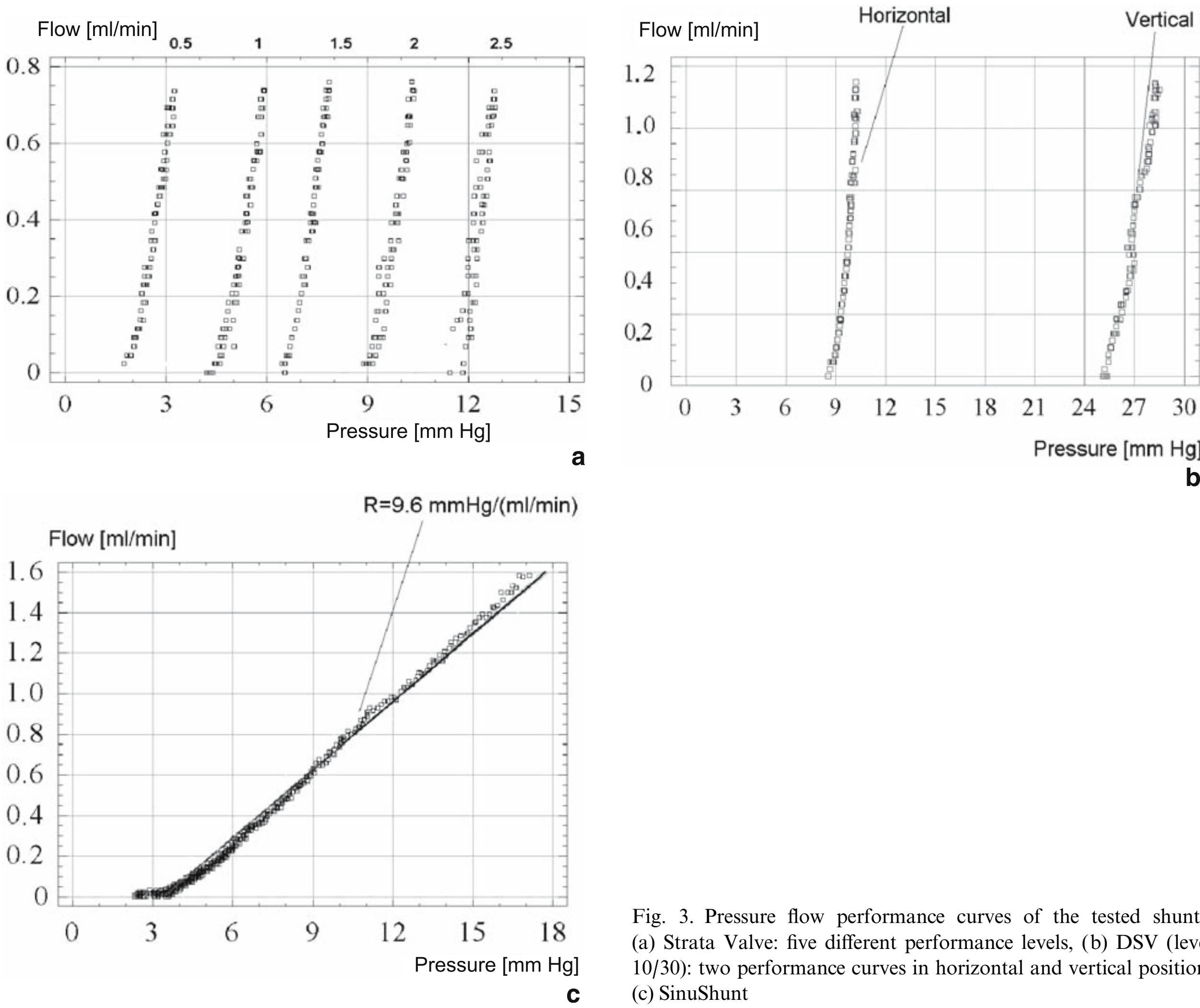

Fig. 3. Pressure flow performance curves of the tested shunts: (a) Strata Valve: five different performance levels, (b) DSV (level 10/30): two performance curves in horizontal and vertical position, (c) SinuShunt

drainage rate when a negative outlet pressure was applied. With the valve in horizontal position, the pressure–flow curve shifted toward low pressures. This is compensated by an increase in operating pressure due to the change in the body position to vertical by 20, 30 or 40 cm H_2O, depending on shunt operating pressure. There was no effect of external pressure. Pressure flow curve shifts to the right when the position of the valve switches from horizontal to vertical. There is no significant change of the slope of this curve (i.e. both low and high pressure valves have the same hydrodynamic resistances). Magnetic field 3T did not have any influence on the shunt's performance.

SinuShunt

The valve had almost linear characteristic. All the measurement points from the first 16 pressure-flow tests from three valves showed a good convergence within and between tested samples (see Fig 3c). The flow through the SinuShunt was affected by negative outlet pressure (siphoning) but this effect is eliminated in-vivo by positioning the inlet (ventricles) and outlet (transverse sinus) at the same hydrostatic level. None of the tested parameters changed when an external pressure was applied. 3 Tesla MRI did not alter the valve performance.

All three shunts shared some hydrodynamic properties

A pulse waveform applied to the input pressure with an amplitude changing from 1 to about 18 mm Hg produced a significant decrease in operating pressure of the range from 0.2 to 7.4 mm Hg. None of the parameters (opening, closing pressure and resistance) were altered by a temperature change from 30 °C to

40 °C. Opening and closing pressures displayed very limited (less than 1.5 mm Hg) variations during all the tests. The changes were not systematically time-related. Good agreement of the operating pressures with the nominal data has been recorded (differences less than 1 mm Hg). No significant differences in measured parameters were found between the three samples of each of the valves tested. The valves did not show any reflux when tested according to the ISO standard. Valves did not exhibit reversal of flow for an outlet-inlet differential pressure of up to 100 mm Hg.

Discussion

All of the assessed valves represent the latest progress in shunt technology. All of them resist the siphoning effect, each one in a different way. The Strata incorporates an anti-siphon device, the Miethke valve takes advantage of gravitational forces and the SinuShunt eliminates the problem by the way it can be implanted. All three valves thus prevent CSF overdrainage related to body position. However, in clinical practice, complications related to posture related overdrainage amount to only few percent of all reported shunt-related complications (unpublished data from UK Shunt Registry). Only the Strata Valve is adjustable. External adjustment may help decrease the number of revisions after shunting, but the programming mechanism is sensitive to external magnetic fields. The valve can be accidentally reprogrammed, which is a common feature of all currently used programmable valves (also Sophy and Codman-Hakim) [7].

The Strata Valve is sensitive to external pressure. The valve may be blocked by excessive subcutaneous scarring of the scalp. The Strata and DSV valves have low hydrodynamic resistance. This may make them prone to overdrainage of CSF in the presence of nocturnal ICP vasogenic waves [2]. No matter how well the opening/closing pressure mechanism is engineered, variations of ICP (via pulse or respiratory waves) may decrease a valve's performance levels. There are clinical reports in the literature about use of the presented shunts. The Miethke DSV valve has been enthusiastically described, particularly by German neurosurgeons [6] where it has been claimed to reduce the problem of overdrainage. The SinuShunt requires more complex surgery than other shunts. There has been a learning curve in the original centre – its implementation in other centres are awaited [1, 3]. The Strata Valve is becoming gradually more popular as an alternative to the Codman-Hakim Valve. It has only 5 programming levels as opposed to 18 in the Codman-Hakim model. However, this may be sufficient in the management of hydrocephalus. The Strata Valve, unlike Codman-Hakim, does not require X-ray to confirm the desired programming level. Patients with any of these three valves may be safely MRI-scanned. The Strata Valve should always be re-programmed after scanning.

Acknowledgment

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