Hydrodynamic properties of hydrocephalus shunts: United Kingdom shunt evaluation laboratory

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Abstract

Background—Although about 80% of properly diagnosed patients with hydrocephalus improve after implantation of any model of shunt, the remaining 20% may develop further complications because of inadequate shunt performance. Therefore, hydrocephalus shunts require careful independent laboratory evaluation.

Method—Computer supported shunt testing, based on the new International Standard Organisation directives, characterises various aspects of pressure-flow performance of shunts such as variability with time, susceptibility to reflux, siphoning, temperature related behaviour, external pressure, the influence of a strong magnetic field (for example, MRI), presence of pulsation in differential pressure, particles in drained fluid, etc.

Results—Seven different models of valves, representing most common constructions, have been tested so far. Most contemporary valves have a hydrodynamic resistance which is too low. This may result in overdrainage both related to posture and during nocturnal cerebral vasogenic waves. A long distal catheter increases the resistance of these valves by 100%–200%. Most shunts are very sensitive to the presence of air bubbles and small particles in drained fluid. Few shunt models offer reasonable resistance to negative outlet pressure, preventing complications related to overdrainage. Valves with an antisiphon device may be blocked by raised subcutaneous pressure. All programmable valves are susceptible to overdrainage in an upright position.

Conclusion—The behaviour of a valve during such testing is of immediate relevance to the surgeon and may not be adequately described in the manufacturer's product information.

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Hydrocephalus shunts drain excess CSF from the fluid spaces of the brain to elsewhere in the body. An ideal shunt should restore the normal circulation of CSF and the normal pattern of extrachoroidal fluid flow within the brain, prevent excessive build up of intracranial pres-

sure, and encourage restitution of the cerebral mantle, comprising both grey and white matter. This is difficult to achieve because CSF reabsorption works as a "physiological" shunt with unique properties. The rate of CSF reabsorption is proportional to the difference between the CSF subarachnoid pressure and sagittal sinus pressure. Reabsorption ceases if this difference becomes negative, acting as a valve in which the opening pressure is equal to the sagittal sinus pressure.^{1,2} Posture related hydrostatic differences between the CSF and sagittal sinus pressures do not exist; hence drainage is not accelerated in an upright position. So far, attempts to produce a shunt which restores physiological mechanisms have failed.^{3,4}

Various shunt products are available on the market but there is little systematic knowledge available by which their comparative cost effectiveness can be judged by the practising surgeon. Some 80% of shunts fail within 12 years, with the patient, surgical technique, and shunt technology each playing a part.^{5,6} The surgical management of hydrocephalus alone represents an annual multimillion pound investment by the National Health Service. Historically, surgical devices, unlike new drugs, have been introduced with only modest, formal independent scrutiny.

Various laboratory techniques have been described for testing the physical performance of shunts.^{8–10} The aim of the United Kingdom Shunt Evaluation Laboratory, founded by the Department of Health Medical Device Agency, is to assess systematically the hydrodynamic properties of all shunts available on the United Kingdom market independent of the manufacturer. Tests have been designed to characterise the shunt's ability to drain CSF, to check whether the shunt performs according to the manufacturer's specification, whether it complies with the international standard, and to provide a ready source of reference to practical information for the surgeon, physician, or interested patient or relative.

The intention of this paper is to describe the methodology of shunt testing and present the most important properties relevant to treatment of hydrocephalus with seven models of contemporary shunts.

Material and methods

Seven types of hydrocephalus shunts, representing different constructions and specific properties in CSF drainage control have been

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Table 1 Characterisation of tested shunts

Name	Manufacturer	Functional type	Construction of valve	Short name
PS Medical Delta valve	Medtronic PS Medical (USA)	Siphon preventing	Silicone diaphragm	Delta
Heyer-Shulte low profile valve with antisiphon device	Saba Medical group (USA)	Siphon preventing	Silicone diaphragm	LPV
Sophy programmable valve	Sophysa (France)	Programmable	Ball on spring	Sophy
Codman-Medos programmable valve	Johnson & Johnson (USA)	Programmable	Ball on spring	Medos
Heyer-Shulte in-line valve	Saba Medical Group (USA)	Classic differential	Silicone mitre	In-line
PS Medical lumboperitoneal shunt	Medtronic PS Medical (USA)	Classic differential	Distal slit plus tube	LP
Orbis-Sigma valve	Cordis (France, USA)	Flow regulating	Moving diaphragm	Sigma

tested to date. The official test reports are published separately and are available from the Department of Health Medical Device Agency (MDA, Room 1207, Hannibal House, London SE1 6TQ), who retain the copyright. Table 1 lists the tested valves, their types, constructions, and abbreviated names (used further in this paper).

THE RIG

Figure 1 shows the test rig. The shunt under test is submerged in a water bath (W28, Grant Instruments, UK) at a constant temperature and a defined depth (*h*). The working fluid (deionised and deaerated water) is supplied by the fluid container or infusion pump (55–2222 Harvard Apparatus, MA, USA). A pulse pressure of controlled amplitude created by the pulse pressure generator (601A, Biotek Instruments, USA) can be added to the static pressure. The viscosity and specific gravity of water reflect the physical properties of CSF under normal conditions. A model of resistance to CSF outflow can be added before the shunt to study the shunt’s performance in conditions mimicking the in vivo environment. Input pressure to the shunt is measured with a Luer lock pressure transducer (Gaeltec Ltd, UK) submerged in the bath. Fluid flowing through the shunt is collected in a container

placed on an electronic balance (LC 2200 P, Sartorius, Germany).

Measurement is controlled by a standard IBM compatible personal computer with the software designed in house (by MC and ZC, also described in Czosnyka *et al*¹⁰). It reads and zeros the balance periodically (every 55 seconds), weighting the outflowing fluid incrementally, and cancels the influence of fluid vaporisation from the outlet container. The computer analyses the pressure waveform using a spectral analysis algorithm to minimise the influence of mechanical disturbances (vibrations, gravitational waves, vortices in the water bath, etc) and to control the rate of the infusion pump. The effect of changes in atmospheric pressure are compensated for by using a reference pressure transducer of the same type, kept within the water bath at the stabilised temperature. The shunt and pressure transducer are placed on the same level. The water column in the container (*H*), the degree of the shunt submersion (*h*), and the level of the outlet tubing (*O*) may be changed according to the test protocol.

THE PROTOCOL

Before the shunts are placed in the rigs the preassembled junctions are tested for resistance to a 1 kg force axial load. Then, three

Figure 1 Shunt testing rig. Components are explained in the text.

Figure 2 Flow and pressure recorded during pressure-flow (A) and flow-pressure test (B). P_{close} = closing pressure of the valve; P_{open} = opening pressure.

shunts of the same type are filled with deionised and deaerated water. Air bubbles are gently flushed out according to the manufacturer's instructions. The shunts are mounted in three identical rigs. When the calculated variables are stable for two consecutive tests, the testing procedure commences. The shunt is tested with two different regimes, referred to as pressure-flow and flow-pressure tests (fig 2). During the pressure-flow tests, flow through the shunt is measured while the differential pressure across the shunt is controlled by the falling level of the water column as fluid flows out of the container. In flow-pressure tests, flow through the shunt is controlled by changing the rate of the infusion pump. Flow is the independent variable and the resulting differential pressure is the dependent variable. These two regimes are able to measure both the shunt's ability to drain CSF according to current differential pressure (pressure-flow) and a pressure response to the forced flow through the shunt (flow-pressure) to describe how the shunt stabilises an intraventricular pressure.

Both outlet level (O) and depth at which the valve is submerged in the water tank (H) may be changed (fig 1). These manoeuvres are able to show whether the shunt is susceptible to alteration in CSF drainage caused by postural changes and external pressure. Both posture-related overdrainage¹⁴ and the possibility of underdrainage when subcutaneous pressure is increased²¹ are reported as having an impact on the shunt's performance in vivo.

Effect of change in ambient temperature and MRI compatibility are also assessed. The influence of a pulsating pattern in the inlet pressure simulating the intracranial pressure (ICP) pulse wave is tested, as it may alter both short term and long term properties of CSF drainage.⁷⁻⁹ Susceptibility to reflux is tested according to the International Organisation for Standardisation/Draft International Standard (ISO/DIS) 7197 standard.

A long distal catheter may alter conditions to

drainage,⁷ particularly in valves constituting low hydrodynamic resistance. Therefore, pressure-flow performance is carefully studied with and without a distal catheter.

The valve's durability is tested by comparing the pressure-flow performance at the beginning and end of the protocol, which takes around 40 days and involves daily testing as recommended by international standard procedures.

Microspheres injected into the valve's chamber simulate the presence of bigger particles in CSF (red cells 10 μm or bigger proteins and tissue debris 25 μm) to assess their possible influence on drainage. Although we cannot be sure how exactly microspheres approximate to real conditions, they are of well defined diameter and they do not aggregate in saline during the test. Therefore, this method can be used safely for comparison of how different shunts react to the graded obstruction.

Finally, the durability to shock waves of up to 200 mm Hg (simulating the maximal increase in CSF pressure provoked during coughing) and a reversed pressure of the same magnitude are tested. These tests are designed to check whether a shunt may be physically damaged by the rapid increases in ICP seen during coughing and other bodily exercises.

THE VARIABLES

The pressure-flow performance curves are plotted continuously throughout each test.

Closing pressure is a differential pressure below which flow through the shunt ceases. It is measured as the intercept of the regression line with the x axis, drawn between pressure (x axis) and flow (y axis) for flows from 0.2 to 0.05 ml/min.

Hydrodynamic resistance is defined as the change in pressure divided by the decrease in flow from about 1.2 to 0.3 ml/min—that is, as the linear regression gradient between pressure and flow.

Differential pressures for high flow (0.83 ml/min), and for low flow (0.083 ml/min) are measured and compared with the values given by the manufacturers (the range defined by the new ISO/DIS 7917 standard).

Additionally, during the flow-pressure tests the opening pressure is measured as the minimum differential pressure above which non-zero flow through the shunt is measured during the ascending ramp of the infusion rates (fig 2B).

Results

Table 2 presents a summary of the most important variables.

PRESSURE-FLOW CURVES

The pressure-flow performance curves have an exponential non-linear shape for the diaphragm (Delta, LPV) and mitral (In-line) valves (fig 3). "Ball on a spring" valves (Medos, Sophy) have a more linear pressure-flow curve. The mechanical performance of the spring and the cone shape in which the ball is travelling have an influence on non-linear distortion of the pressure-flow performance curve within the range

Table 2 Summary of measured properties of tested shunts

	Delta	LPV	Sophy	Medos	In-line	LP	Sigma
Resistance without distal catheter (mm Hg/ml/min)	1.9 (0.2)	2.9 (0.4)	2.8 (0.9)	1.4 (0.3)	7.5 (1.3)	25 (6.2)	Very high
Resistance with distal catheter	3.8 (0.4)	5.6 (0.5)	5.3 (0.8)	5.1 (0.8)	9.3 (1.5)	NA	Very high
Closing pressure was as specified by the manufacturer	No (lower)	No (lower)	Yes	Yes	No	No†	Yes
Closing pressure was as specified after connection of distal catheter	Yes	Yes	Yes	Yes	Yes	NA	Yes
Drainage increased by negative outlet pressure of -23 mm Hg	No	No	Yes	Yes	Yes	NA	No at pressure < 5 mm Hg
Drainage decreased by external pressure of +7 mm Hg	Yes	Yes	No	No	No	NA	No
Pressure pulsations decreased closing pressure	No	Yes	No	Yes	No	No	No
Low temperature increased closing pressure	No	No	No	No	Yes	No	No
Small microspheres altered performance	No	Yes*	Yes*	No	No	No	Yes (blocked)
Large microspheres altered performance	Yes (opened)	Yes (opened)	Yes (opened)	Yes (opened)	No	No	Yes (blocked)
MRI altered performance	No	No	Yes (always)	Yes (1 out of 3)	No	No	No
Sample related variability	No	No	No	No	No	Yes	No
Programming	No	No	Yes	Yes	No	No	No
Variable fluctuate with time (28 days minimum)	No	No	No	No	Yes†	Yes†	No

*Resistance increased permanently > 100%.

†Opening/closing pressure increased.

‡Closing pressure larger than specified.

Figure 3 Pressure-flow curves ("medium pressure" if different ranges are available) of seven valves. For all but the flow regulating valve, the curves without (1) and with (2) distal catheter were plotted (the pressure-flow curve for the flow regulating valve is affected by the distal catheter only above the threshold for relief pressure). Line 3 shows the gradient for the pressure-flow curve resulting from the normal value of the CSF reabsorption resistance. Any curve with the higher gradient indicates that the valve has hydrodynamic resistance less than physiologically normal resistance to CSF outflow.

Figure 4 Fluctuations of pressure-flow curves recorded during 10 days of testing (left graph—Medos). Pulse wave added to a differential pressure (right graph) introduced deformation of the curves for low flow (< 0.2 ml/min) and decreased closing pressure by a half of the peak to peak amplitude of pulsations.

of low flows (< 0.1 ml/min). A flow regulating valve (Sigma) has a pressure-flow curve of unusual shape, resembling that seen during autoregulation of cerebral blood flow (fig 3).

The pressure-flow curves may fluctuate in time (In-line, LP), depending on the presence of a pulse wave in differential pressure (Medos, LPV) (fig 4), or negative outlet pressure (Medos, Sophy, In-line, Sigma).

HYDRODYNAMIC RESISTANCE OF SHUNTS

The static resistance of some of contemporary shunts (Delta, Medos) is much lower (< 2.5 mm Hg/ml/min) than the physiological value of 6–10 mm Hg/ml/min. The connection of a standard catheter (1.2–1.3 mm internal diameter, 90–120 cm long, resistance from 2 mm Hg/ml/min to 2.6 mm Hg/ml/min per 1 m) increases resistance of these valves to 50–80% of the physiological value (fig 3 and table 1). Resistances of the LPV and In-line valves are close to the physiological range. The LP shunt has high resistance resulting from the hydrodynamic resistance of thin and long tubing (0.8 mm diameter). The Sigma valve has theoretically infinite resistance within the range of flow regulation.

OPENING AND CLOSING PRESSURE

Opening and closing pressure was much better defined in “ball on spring” than in silicone diaphragm valves. The later constructions usually have a tendency to “leak” at very low flow rates (< 0.05 ml/min), a phenomenon which can be detected only using very accurate testing equipment. Therefore, the closing pressure measured in such valves (Delta, LPV) was lower than specified. In both valves closing pressure increased to the specified range after connection of a standard peritoneal catheter (fig 3).

In all shunts not equipped with an antisiphon or siphon control mechanism, the opening and closing pressures are strongly affected by the negative outlet pressure. In addition, the opening and closing pressures may be affected (decreased) by the presence of pulse pressures, particularly when stiff springs are used (Medos). The difference between the opening and closing pressures reflects a hysteresis of the pressure-flow performance curve which theoretically may lead to unstable behaviour of the shunt. A particularly wide hysteresis was found in the Sigma valve. Pressure waves of different periods (usually from a few seconds to one minute) and amplitudes theoretically equal to a difference between the opening and closing pressure may be recorded when fluid flow is forced through the shunt at a rate equivalent to the normal CSF production rate of 0.3 ml/min (fig 5).

SHUNTS IN ALTERED CONDITIONS

Siphoning (-23 mm Hg, according to the new ISO standard) increases drainage rate (> 1 ml/min) dramatically in all valves not equipped with a siphon preventing mechanism (In-line, Medos, Sophy). Delta and LPV valves prevent siphoning. The Sigma valve, being a flow regulating device, also prevents siphoning related overdrainage, providing that CSF ventricular pressure in an upright position does not exceed +5 mm Hg.

External pressure (up to 7 mm Hg according to the ISO standard) does not have a noticeable influence on shunts, with the exception of shunts with antisiphon membranes (Delta, LPV). In these shunts the closing pressure is increased by a value equivalent to the external pressure. A strong magnetic field (as in MRI scanners) does not affect most shunts, with the exception of those programmable by external magnets (Sophy and Medos). These shunts may be reprogrammed at random by a static or

Figure 5 When the difference between opening and closing pressure is significant, fluid flow may produce oscillations of the amplitude comparable to $P_{open} - P_{close}$ (A). The phenomenon occurs at physiological flow rates (< 0.4 ml/min on average; production rate for CSF is 0.3 ml/min), and is unable to keep the shunt permanently open. If flow increases much above the normal CSF production rate (B; to the right from the black vertical line), the waves disappear and the differential pressure remains permanently higher than the valve's opening pressure (Sigma valve).

Figure 6 Difference between pressure flow performance in normal conditions (A) and after injection of large microspheres (B) (LPV shunt). Flow increased immediately after injection and closing pressure decreased to 0 mm Hg.

dynamic field.

Changes of temperature within the range 30°C to 40°C have little effect on a shunt's performance, with the exception of the In-line "mitre" valve (an increase in closing pressure, although probably not clinically important, was measured at a temperature of 30°C). The addition of a model of "residual" reabsorption of fluid before the shunt usually decreases the transitional period between a completely opened and closed valve, making the closing pressure more stable, particularly in diaphragm valves.

Small particles (10 μm) in the reagent may increase the shunt's resistance (LPV) or block the shunts permanently (LPV and Sigma). Large particles (25 μm) may either block shunts (Sigma), or open them permanently (suspend balls above surface of cone or membrane above the outlet orifice; fig 6: Delta, Medos, LPV, Sophy). Only In-Line and LP valves have so far seemed to be resistant to large particles.

None of the shunts (except the LP shunt, which increases its resistance with time, probably being gradually blocked by ultrasmall parti-

cles deposited in a long thin tube; this also happens to a small extent with the In-line valve), showed a significant change in variables during one month of testing. None of the shunts was damaged due to shock waves of up to 200 mm Hg (simulated coughing).

PROGRAMMING OF OPERATING PRESSURE

External programming works in both types of programmable shunts (Medos, Sophy) according to the manufacturers' specifications (fig 7). Problems may occur when the shunt's body rotates relative to the surface of the programmer. Confirmation of correct program setting should always be performed to the manufacturer's specification.

Discussion

Historically, there have been examples of valves being withdrawn from the market when their performance was noted to be drastically different from that specified by the manufacturers but of the seven types of shunts tested, only the LP shunt fell drastically outside the manufacturer's specification. Even in this case, the much higher than specified resistance and opening pressure seemed to be beneficial from the point of view of prevention of overdrainage in an upright position. However, it is remarkable that most manufacturers (with the exception of Medtronic-PS Medical) do not follow the ISO standard for minimum testing of a valve's specification. In consequence there is a wide variability of criteria being used, leading to confusing claims that "a shunt performed incorrectly".¹¹ A reasonable (± 2 mm Hg) variability of closing pressure should be accepted as normal. Variability in the flow-pressure curve should always be compared with a specified region of performance, not to one example curve as illustrated by the manufacturer.

The initial question is whether variables tested in the laboratory have an impact on a shunt's performance in vivo. The most direct evidence comes from comparison of CSF infusion studies before and after implantation of a known valve.¹² The characteristics of the particular valve are seen to be imposed on the patient's own pressure-flow performance.

Figure 7 Recorded relation between programmed (x axis) and measured (y axis) operating pressure for two types of programmable valves ((A) Medos; (B) Sophy). Vertical bars show 2 SE in measurement of closing pressure.

About 80% of correctly diagnosed patients will tolerate any type of shunt short term. In 20% of patients shunt related problems such as underdrainage or overdrainage may occur. In these patients the shunts' pressure-flow performance is important. Little is known of how the hydrodynamic performance may influence the rate of common complications such as infection or blockage.¹³⁻¹⁵

A low hydrodynamic resistance might be supposed to increase the risk of complications related to overdrainage in shunts without an antisiphon mechanism. In addition to posture related overdrainage, low resistance valves may provoke overdrainage related to strong vasomotor waves seen during sleep (known as B waves). A fluctuating vascular bed acts like the membrane of a water pump with a low resistance outlet valve. After increased ICP during B wave activity seen in overnight recordings in patients with implanted low resistance valves, a period of decreased pressure is often recorded.²³ Early morning headaches in a patient with a shunt in situ may be partially explained by this type of overdrainage. Siphon control devices such as those in Delta or LPV valves will not protect against this phenomenon. The flow-regulating Sigma shunt¹⁶ should theoretically limit this type of overdrainage. Unfortunately, this in turn may produce excessive increases in CSF pressure during cerebrovascular fluctuations, particularly in patients with limited pressure-volume compensatory reserve.

Siphoning is conventionally thought to be responsible for slit ventricles, haematomas, or subdural collections of CSF¹⁷⁻¹⁹ although Hakim presents cogent counter arguments.²⁰ Constructions with a subcutaneous membrane exposed to atmospheric pressure are efficient, but the drainage may be disturbed by raised subcutaneous pressure.²¹ New designs allowing change in performance when the patient is in an upright position or the "referential" Beverly valve may improve the situation, but these valves need further evaluation.

Externally programmable valves have proved effective in clinical use.²² Unfortunately, none of the present designs (Medos or Sophy) limit posture related overdrainage.

Accidental reprogramming is possible as there is no system which offers a 100% fool-proof guarantee against external programming. The possibility of very fine programming, as in the Codman-Medos programmable valve, seems tempting, but CSF pressure pulsations will variably lower the opening pressure such that the value of very small programming steps requires thoughtful evaluation.

It is not known whether microspheres mimic the presence of particles in CSF, but differences between shunt performance in the presence of microspheres may predict susceptibility to clogging or permanent opening by particles such as erythrocytes or neural or inflammatory tissue debris in the CSF.

Conclusions

Practicalities useful in planning and perform-

ing shunt surgery are recalled here. Some of them are obvious, but we think that all of them may contribute to a reduction of shunt related problems:

- Because air bubbles may permanently alter a shunt's performance, particular attention should be paid to the filling of the shunts during implantation
- A hydrocephalus shunt system should be considered as a whole and not simply in terms of the valve. As the peritoneal catheter may increase a shunt's resistance by as much as 200%, never shorten it without careful consideration
- Many valves have a resistance that is very much lower than physiological and may render patients susceptible to low pressure headaches in the morning. Not all early morning headaches are the effect of raised pressure!
- A flow regulating shunt (Sigma) is "more physiological" than pressure differential shunts and may to some extent prevent posture related overdrainage. However, in some cases underdrainage may occur. These shunts are contraindicated in patients with a low pressure-volume compensatory reserve who have high nocturnal ICP fluctuations.
- Care should be taken with implanting low-resistance shunts into patients with gross ventricular dilatation or greatly increased cerebrospinal compliance and their subsequent mobilisation if no siphon control mechanism is added.
- A shunt's function in vivo may be assessed objectively by pressure-volume testing.²³ Implantation of a separate Ommaya reservoir and intraventricular catheter greatly facilitate assessment in difficult patients. Progressive changes in behaviour of a valve (noted with testing valve using an infusion study²³) will be detected with such testing.
- Setting of externally programmable valves should be checked after MRI or when unpredicted symptoms occur.

This testing laboratory has evolved over the past five years from a very simple rig created by Helen Adams, a fourth year medical student in Southampton.

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MC is on leave from Warsaw University of Technology, Poland.

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