Acta Neurochir (2002) 144: 525–538
DOI 10.1007/s00701-002-0922-9

Acta Neurochirurgica
Printed in Austria

Clinical Article

Laboratory Testing of Hydrocephalus Shunts – Conclusion of the U.K. Shunt Evaluation Programme

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Published online June 20, 2002

Summary

16 models of valves, currently in use in the U.K., have been tested long-term in the U.K. Shunt Evaluation Laboratory according to the protocol based on the new ISO 7197 standard. Valves tested were:

Medtronic PS Medical: Delta Valve, Flow Control and Lumbo-Peritoneal Shunt

Heyer-Schulte Nero-Care: In-line, Low Profile and Pudenz Flushing Valve

Codman: Codman-Hakim Programmable, Hakim Precision, Accu-Flo, Holter, Uni-Shunt, and siphon-preventing device – SiphonGuard

NMT: Orbis-Sigma Valve, Omni-Shunt and Hakim Valve

Sophysa: Sophy Programmable Valve

Radionics: Contour-Flex Valve.

The majority of the valves had a non-physiologically low hydrodynamic resistance (with the exception of Orbis-Sigma, PS Lumbo-Peritoneal and Heyer-Schulte In-Line). 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%. Drainage through valves without siphon-preventing mechanism is very sensitive to body posture. This may produce grossly negative intracranial pressure after implantation. A few shunts (Delta, Low Profile and Pudenz-Flushing with Anti-Siphon Devices) offer a reasonable resistance to negative outlet pressure, and hence potentially might prevent complications related to overdrainage. On the other hand, valves with siphon-preventing devices may be blocked by raised subcutaneous pressure (exception: SiphonGuard, but this device may block the drainage because of its faulty design). In most of the silicone-diaphragm valves, closing pressure varied and reached values lower than that specified by the manufacturer (exception: Heyer-Schulte Pudenz Flushing Valve). All programmable valves are susceptible to overdrainage in the upright body position. Programmed settings may be changed by external magnetic fields. Most shunts are very sensitive to the presence of small particles in the drained fluid.

The behavior of a valve revealed during such testing is of immediate relevance to the surgeon and may not be adequately described in the manufacturer's product information. These results are also relevant to the assessment of shunt function in-vivo using an infusion test.

Keywords: Hydrocephalus; shunts; in-vitro testing.

Introduction

A wide variety of shunt products (around 127 generic types, with numerous sub-types and performance levels – not counting some local devices in use in developing countries) are available on the market [2]. There is little systematic knowledge available by which their comparative cost-effectiveness can be judged by the practicing surgeon. Similarly, there is very little known about whether a specific type of shunt can be matched to an individual pattern of disturbed CSF circulation.

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 pressure and encourage restitution of the cerebral mantle, comprising both grey and white matter. As shunting is a purely mechanistic method of treatment, the biomechanics of a patient's pressure-volume compensation should ideally be examined before a shunt is implanted.

After shunting, the hydrodynamic performance of the shunt interacts with the patient's own CSF circulatory pattern. The result of shunting (averaged resting pressure) can be forecasted by a parallel connection of the model of CSF dynamics (measured by bolus, constant rate infusion, perfusion, etc., [12, 15, 18]) and pressure-flow characterization of the shunt [4].

When the patient does not improve after shunting or improves then deteriorates [20], overnight ICP monitoring or a simple infusion study may confirm shunt malfunction [5, 14, 20] if a shape of pressure-flow performance curve of a shunt is known.

Table 1. *Names, Manufacturers, Principles, and Constructions of the Shunts Tested*

Name	Manufacturer	Functional type	Construction of the valve
a. Hakim Valve	NMT	classic differential	ball on spring
b. Hakim Precision Valve	Codman	classic differential	ball on spring
c. Omnishunt	NMT	classic differential	ball on spring
d. Holter Valve	Codman	classic differential	distal slit
e. In-line Valve	Hayer-Schulte	classic-differential	silicone mitre
f. Accu-flo	Codman	classic differential	silicone membrane
g. Radionics Contour Flex	radionics medical products	classic differential	silicone membrane
h. CSF Flow Control	medtronic PS medical	classic differential	silicone membrane
i. Delta Valve	medtronic PS medical	siphon-preventing	silicone membrane
j. Low Profile Valve with Anti-Siphon Device	Heyer-Schulte	siphon-preventing	silicone membrane
k. Pudenz-Flushing	Heyer-Schulte	siphon-preventing	silicone membrane
l. Uni-Shunt	Codman	classic differential	distal slit
m. Lumboperitoneal Shunt	medtronic PS medical	classic-differential	distal slit + tube
n. Hakim Programmable Valve	Codman	programmable	ball on spring
o. Sophy Programmable Valve	Sophysa	programmable	ball on spring
p. Orbis-Sigma Valve	NMT	flow-regulating	moving diaphragm

The U.K. Shunt evaluation program financed by the Department of Health Medical Devices Agency was commenced in 1994 and finished in early 1998. Four years of long-term shunt testing according to the unified protocol in multiple computer-control testing rigs gave us an opportunity to gain an experience in shunt technology. Fragmentary findings were published [6–10] and sixteen reports printed by Department of Health Medical Devices Agency distributed nationally among consultant-neurosurgeons (1995–1998). The aim of this concluding paper is to characterize and compare the performance of shunts of different construction and provide a reference for shunt testing in-vivo.

Material and Method

Shunts

Sixteen types of shunts of different construction were tested. They may be divided into different groups according to the mechanism of CSF drainage control (see Table 1)

1. Silicon membrane – flow is controlled by an elastic membrane that changes the area of the outlet orifice.
2. Ball-on-spring – flow depends on compression of a spring (flat or helical) supporting a ball moving along the cone that constitutes the outlet orifice
2. Mitre valve – flow depends on deflection of the silicon mitre controlling diameter of the outlet orifice
3. Proximal or distal slit valves – flow depends on area of a slit in soft silicone rubber
4. Moving diaphragm – where flow is stabilized within certain fixed range of pressure

Testing

The test rig has been previously described in detail [6, 7], with its schematic diagram presented in Fig. 1. Measurement is controlled by a standard IBM compatible personal computer with software designed in-house (M. Czosnyka and Z. Czosnyka) which precisely measures flow through the shunt and differential pressure over minimum 28 days period.

Three shunts of the same type are filled with deionised and dearated water and mounted in three identical rigs. Pressure-flow performance curves are tested over 16 days. The performance of shunts in altered conditions is subsequently studied. Both the outlet level (−23 cm, according to ISO 7197 standard) and depth at which valve is submerged in the water tank may be changed. These maneuvers are able to demonstrate whether the shunt is susceptible to alteration in CSF drainage caused by postural changes and external pressure. The effect of change in ambient temperature is also assessed.

The influence of a pulsating pattern in inlet pressure simulating the ICP pulse wave is tested. Susceptibility to reflux is tested according to ISO standard.

A long distal catheter may alter conditions to drainage, particularly in valves with a 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 the international standard.

Microspheres injected into the valve's chamber simulate the presence of larger particles in CSF (red cell – 10 μm, or bigger tissue debris – 25 μm) to assess their possible influence on drainage. Previous studies [3] demonstrated that shunts are not sensitive to increased protein content up to very high concentration. Therefore, microspheres are not intended to mimic change of viscosity of the testing reagent, but the physical effect of fine-seeded particles on the opening and closing mechanism of the valve.

Finally, the durability to shock waves of up to 200 mm Hg (simulating the maximal CSF pressure increase provoked during coughing), reversal pressure of the same magnitude and behavior in static magnetic field (like during MRI scanning) are tested.

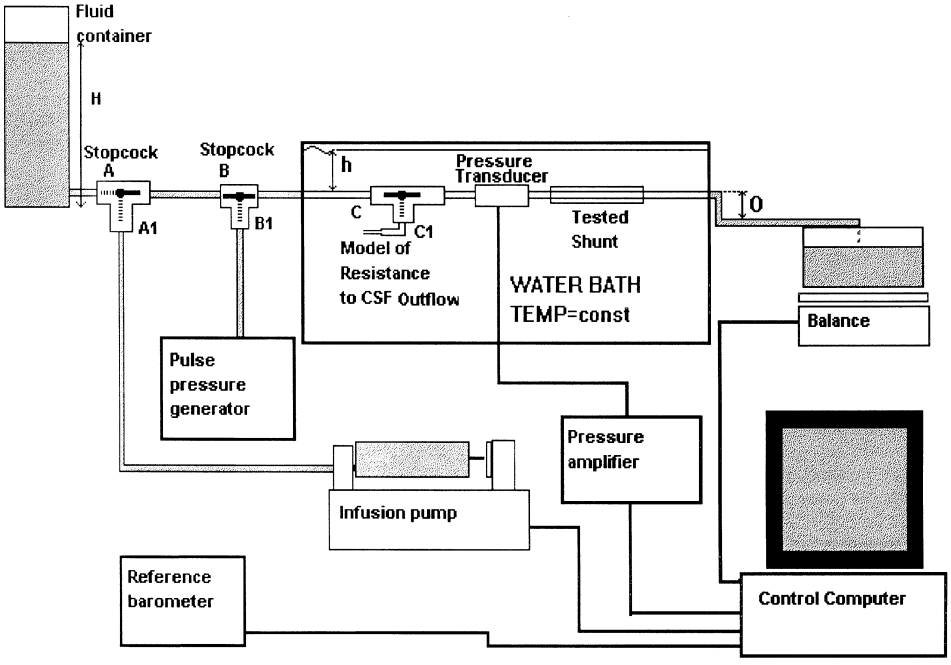

Fig. 1. Schematic diagram representing shunt testing rig. Adopted from [5] with the permission from authors

Results

Tabular representation of the results of testing is presented in Table 2. It contains the hydrodynamic resistance with and without a distal drain and the operating pressures. Table 3 contains descriptive results. Scatters of the pressure flow-performance curves from all tested samples of valves during 16 days of pressure-flow testing are presented against (when specified by the manufacturer) parallelogram demonstrating performance region or typical pressure-flow performance line (Fig. 2). Graphs present pressure-flow curves (in most cases for medium range of performance levels) for shunt working without distal catheter. With a standard catheter of internal diameter 1.2 mm and length 90 cm the hydrodynamic resistance of most of shunts increases by 2–2.5 mm Hg/(ml/min). In some cases connection of a catheter had any other influence on pressure-flow performance of the shunt.

NMT Hakim Valve

This shunt had an almost perfectly linear performance curve reflecting that the spring valve was either completely opened or closed, with virtually no transient zone between these two states (Fig. 1a). All the measurement points were contained within the performance region as specified by the manufacturer. Variations in pressure-flow performance over 16 days were small (less than ± 1 mm Hg along pressure axis). Measured operating pressure was within the narrow limits specified by the manufacturer for all five performance levels. The hydrodynamic resistance of the isolated valve was much lower than the physiological value of the resistance to cerebrospinal fluid (CSF) outflow. The valve's resistance increased by 300% after connection of a standard 90 cm long catheter, although still remained low. The drainage rate was significantly increased (above 3 ml/min) by a negative outlet pressure. Operating pressure decreased in the presence of a pulsatile pattern in the input pressure.

Codman Hakim-Precision Valve

As with the NMT Hakim valve this shunt had an almost perfectly linear performance curve (Fig. 1b). With a distal drain, the gradient of the pressure-flow curve decreased almost threefold. Pressure pulsations tended to reduce the closing pressure. Because the valve has a low hydrodynamic resistance (Table 2), the drainage rate increased (above 3 ml/min) when the negative outlet pressure (-17 mm Hg) was applied. In patients likely to develop clinical complications related

Table 2. *Selected Numerical Values (Averages of 3 Samples Measured at Least in 16 Independent Tests)*

	The Shunt		Resistance [mmHg/ml/min] no distal catheter	Resistance [mmHg/ml/min] with distal catheter	Operating pressure for flow = 0.3 ml/min with distal catheter	Critical pressure for infusion 1.5 ml/min with distal catheter
1.	Delta Valve	level-1	1.9	3.6	3.4	13.8
		level-2	2.2	3.7	8.1	18.65
2.	Low Profile Heyer-Shulte	low	2.2	3.8	5	15.7
		med	2.9	5.6	9.7	23.1
		high	4.8	7.6	13.5	29.9
3.	Pudenz-Flushing Heyer-Shulte with ASD	low	1.8	4.8	3.9	16.1
		med	1.67	5.2	6.06	18.9
		high	1.7	5.6	11.0	24.4
4.	In Line H-S	low	3.4	4.4	8.5	20.0
		med	7.5	9.4	12.5	31.6
		high	10.2	12.5	17.5	45
5.	Contour-Flex Radionix	low	2.3	3.5	3.95	14.2
		med	2.5	3.8	8.2	18.9
		high	2.8	4.23	12.45	23.8
6.	Holter-Valve Codman	low	3.9	7.55	9.2	25.5
		med	4.7	9.1	12.4	31.05
		high	5.2	10.06	16.6	36.7
7.	Hakim-Precision Codman	v. low	1.42	4.8	2.7	14.9
		low	1.65	4.92	4.9	17.28
		med-low	1.83	5.1	7.1	19.75
		med-high	1.96	5.23	9.1	21.95
		high	2.2	5.46	12.8	26.0
8.	Accu-Flow Codman	low	3.1	4.7	5.4	17.1
		med	3.3	4.9	6.5	18.9
		high	4.6	5.2	9.3	21.5
9.	Omni-shunt NMT (Cordis)	low	1.05	3.9	5.4	16.25
		med	1.05	3.9	8.2	19.05
		high	1.05	3.9	10.4	21.25
10.	Codman Uni-shunt regulae	low	NA	2.4	3.6	12.2
		med	NA	3.9	4.5	15.36
		high	NA	8.7	8.6	26.25
	Codman Uni-shunt elliptical	low	NA	3.1	6.5	16.15
		med	NA	4.8	6.0	18.2
		high	NA	11.4	10.1	32.2
11.	CSF-Flow Control standard	low	1.3	2.7	2.2	11.17
		med	1.5	3.1	7.48	17.1
		high	2.2	4.5	10.7	22.5
	CSF-Flow Control contoured	low	1.6	3.3	2.51	12.5
		med	2.1	4.3	8.16	19.6
		high	2.2	4.5	12.4	24.15
	CSF-Flow Control burr-hole	low	1.4	2.9	2.05	11.4
		med	1.3	2.7	6.9	15.95
		high	1.6	3.3	10.9	20.85
	CSF-Flow Control button	low-low	1.0	2.06	0.92	9.01
		low	1.25	2.6	4.5	13.4
		med	1.34	2.7	2.6	11.65
12.	Hakim Valve NMT (Cordis)	v. low	1.05	4.3	3.2	14.65
		low	1.2	4.45	5.15	16.8
		medium	1.1	4.3	7.3	18.75
		high	1.15	4.3	11.7	23.15
		v. high	1.2	4.5	15.8	28.75
13.	Sophy-Programmable	programmable	2.8	5.3	programmed	dependent on settings
14.	Hakim-Programmable CODMAN	programmable	1.4	5.1	programmed	dependent on settings
15.	PS-Medical L-P	one level	25	NA	22	64
16.	Orbis-Sigma NMT	one level	Very high	very high	anything between: 7–27	32

Table 3. *Comparison of Tested Properties of the Shunts*

	Delta Valve		Low profile H-S with ASD	Pudenz-Flushing(H-S)		SOPHY progr.	Hakim-progr. COD-MAN	In-Line H-S	PS-Medical L-P	Contour-Flex Radionix
	Level 1	Level 2		No ASD	ASD					
Closing pressure was as specified by the manufacturer	yes	no	no	yes[5]	yes[5]	yes	yes	no	no[6]	yes
Closing pressure after connection of distal catheter was as specified by the manufacturer	yes	yes	yes	yes	yes	yes	yes	yes	NA	yes
Drainage increased by negative outlet pressure of −23 mmHg	no	no	no	yes	no	yes	yes	yes	NA	yes
Drainage decreased by external pressure of +7 mmhg	yes	yes	yes	no	yes	no	no	no	NA	no
Pressure pulsation decreased closing pressure	no	no	yes	yes	yes	no	yes	no	no	no
Low temperature increased closing pressure	no	no	no	yes[1]	yes[1]	no	no	yes	no	no
Small microspheres altered the performance	yes	yes	yes	no	no	yes[4]	no	no	no	yes[4]
Large microspheres altered performance	yes	yes	yes	yes[3]	yes[3]	yes[3]	yes[3]	no	no	yes[3]
MRI altered performance	no	no	no	no	no	yes	yes 1 out of 3	no	no	no
Sample-related variability	no	no	no	no	no	no	no	no	yes	yes[11]
Programing	no	no	no	no	no	yes	yes	no	no	no
Number of performance levels	1	1	3	3	3	program-mable	program-mable	3	1	3

to overdrainage, implantation of an anti-siphon device should be considered. However, the risk of overdrainage related to vasomotor nocturnal waves may still be high [5].

NMT Omni-Shunt

As with the two previous ball-on-spring valves, variations of pressure-flow performance over 16 days was very low (±1 mm Hg) and all the measurement points were contained within the parallelogram region of performance specified by the manufacturer (Fig. 1c). There was no significant difference observed in hydrodynamic performance between the Omnishunt Burr Hole and Omnishunt One Piece valves. The valve had a very low hydrodynamic resistance (see Table 2). The shunt was sensitive to negative outlet pressure, increasing drainage rate considerably. Although posture-related overdrainage is considered of lower risk in pediatric cases, the shunt should be avoided in adults in whom the risk of complications is increased (i.e. thin cerebral mantle and/or a non-communicating form of hydrocephalus). The possibility of overdrainage related to nocturnal vasocycling should always be considered as a possible complication.

The Codman Holter Valve

This valve had a fairly linear shape of the performance curve that was slightly distorted in the range of low flow (0–0.1 ml/min) as the result of gradual opening of the slit valve. Variations of pressure-flow performance over 16 days was marked (±3 mm Hg) (Fig. 1d). There was no difference in hydrodynamic performance between valves with elliptical or straight reservoirs. The length of the valve (regular or mini valve) had no influence on the measured pressure-flow performance. The operating pressure of medium and high pressure valves was found to be above the ranges specified by the manufacturer. Unlike the majority of contemporary valves, the Holter Valve has a hydrodynamic resistance close to the physiological value of resistance to CSF outflow. Therefore, the risk of overdrainage in an upright body position is limited. The 'sticking' of silicone slits causes a relatively wide hysteresis in the pressure-flow performance curve. The

Table 3. *Continued*

	Hakim Valve (NMT)	Omni-shunt NMT	Holter-Valve Codman	Hakim-Precision Codman	Accu-flow Codman	Uni-Shunt – Codman		CSF-Flow Control		Orbis-Sigma NMT Cordis
						Reservoir regular	Reservoir elliptical	Standard	Burr-hole	
Closing pressure was as specified by the manufacturer	yes[7]	yes[9]	no[5,8]	yes[7]	yes	no	no	yes	yes	yes
Closing pressure ater connection of distal catheter was as specified	yes[7]	yes	no[8]	no[1]	yes	NA	NA	yes	yes	yes
Drainage increased by negative outlet pressure of −23 mmHg	yes	yes	yes	yes	yes	yes	yes	yes	yes	no
Drainage decreased by external pressure of +7 mmHg	no	no	no	no	no	no	no	no	no	no
Pressure pulsation decreased closing pressure	yes	yes	yes	yes	no	no	no	yes	yes	no
Low temperature increased closing pressure	no	no	yes slightly	no	no	no	no	no	no	no
Small microspheres altered the performance	yes	yes	yes	no[1]	yes	yes	yes	yes	yes	yes[2]
Large microspheres altered performance	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes[2]
MRI altered performance	no	no	no[10]	no	no	no	no	no	no	no
Sample-related variability	no	no	no	no	no	no	no	no	no	no
Programing	no	no	no	no	no	no	no	no	no	no
Number of performance levels	5	3	3	5	3	3(6)	3(6)	3	3	

[1] Not significantly; [2] shunt permanently blocked; [3] shunt permanently opened; [4] resistance of the shunt increased permanently >100%; [5] significant difference between opening and closing pressure; [6] opening/closing pressure increased compared to the specification; [7] not specified by the manufacturer, but YES: the operating pressure (correlated with closing and opening) was within the limits; [8] the values are not specified by manufacturer but: the operating pressure extended above the limits resulting from other data provided; [9] just a range, not exact values; [10] the shunt moved slightly, but it is very unlikely that the shunt may be displaced in vivo; [11] this is a value without a catheter.

shunt does not start to operate in a stable fashion immediately after initial filling with water. It reaches a steady state after two days.

Heyer-Schulte In-line Valve

This valve had a non-linear performance curve with a tendency to increase its gradient at the higher flow. This is a specific feature of mitre valves, in which the area of the outlet orifice increases gradually as the differential pressure opens the mitre. Some of the measurement points (30%) fell beyond the upper limit so that shunts may have a higher resistance to flow than that specified by the manufacturer. The In-Line valve, like most silicon shunts (but in contrast to the first three ball-on-spring constructions), does not have a stable closing pressure, but operates within a range in which an average intraventricular pressure will be maintained after implantation. The operating pressure is specified as a range rather than a definite value, which may be as wide as 5.3–8.5 mm Hg (for the Medium Pressure Valve).

Like the Holter Valve, the In-line valve, particularly the Medium and High Pressure versions, have higher hydrodynamic resistance which may limit the rate of drainage in an upright body position.

The Codman Accu-Flo Pressure Valve

This valve had a marked non-linearly distorted performance curve as a result of very gradual displacement of the closing membrane with a decreasing differential pressure (this feature is present in almost all silicone-membrane valves). Variation of pressure-flow

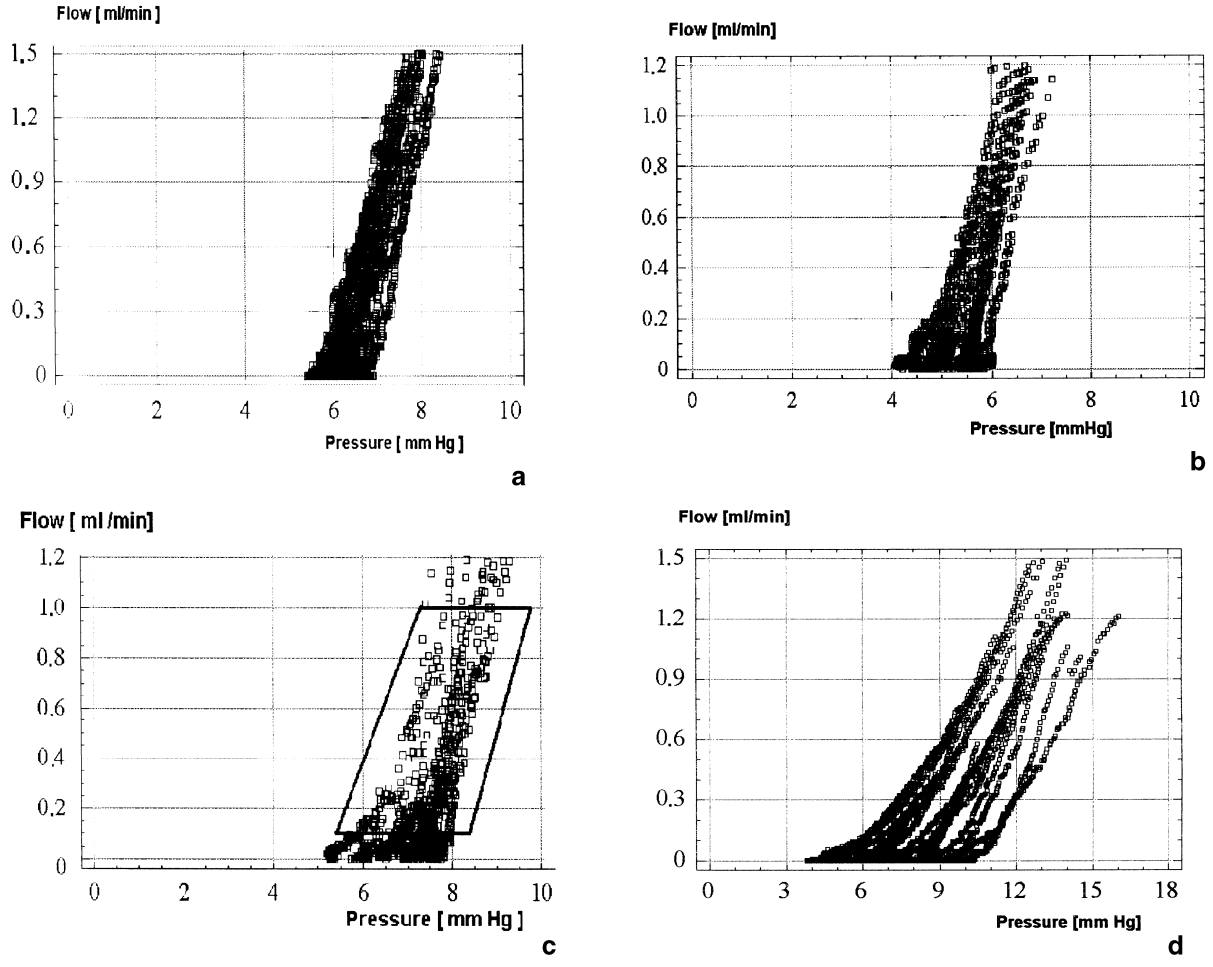

Fig. 2. Composite graphs showing pressure-flow performance curves of 16 different valves (medium performance range) tested over 16 consecutive days with three samples of the same valve. When available, region of performance as specified by the manufacturer was drawn as parallelogram or two parallel lines. (a) Hakim Valve – (b) Hakim Precision Valve – (c) Omnishunt – (d) Holter Valve

performance over 16 days was marked (± 2 mm Hg) but more than 90% points of the measurement points lie within the parallelogram region of performance specified by the manufacturer (Fig. 1f).

The shunt is sensitive to negative outlet pressure and has a very low hydrodynamic resistance (Table 2). This may increase the risk of overdrainage related to body posture and nocturnal intracranial pressure waves.

The Radionics Contour-Flex Valve

This valve had a non-linear performance curve like all silicone-membrane valves – see Fig. 1g. Variations of pressure-flow performance over 16 days are considerable with closing pressures varying within a range of 5 mm Hg. However, despite scattering and sample differences, 99% of the measurement points fell into the region specified by the manufacturer. The shunt increased drainage rate when a negative outlet pressure was applied and presented a low hydrodynamic resistance. Both factors may increase the risk of overdrainage with body posture and nocturnal intracranial pressure waves.

Medtronic PS Medical CSF-Flow Control Valve

The CSF-Flow Control Shunts are classic differential valves intended to stabilize intraventricular pressure after implantation. The four different models of this shunt (Standard, Contoured, Burr-Hole and Button Valve) share the same basic design of a silicone membrane valve. All shunts had non-linear performance curves – similar to Accu-Flo and Contour-Flex

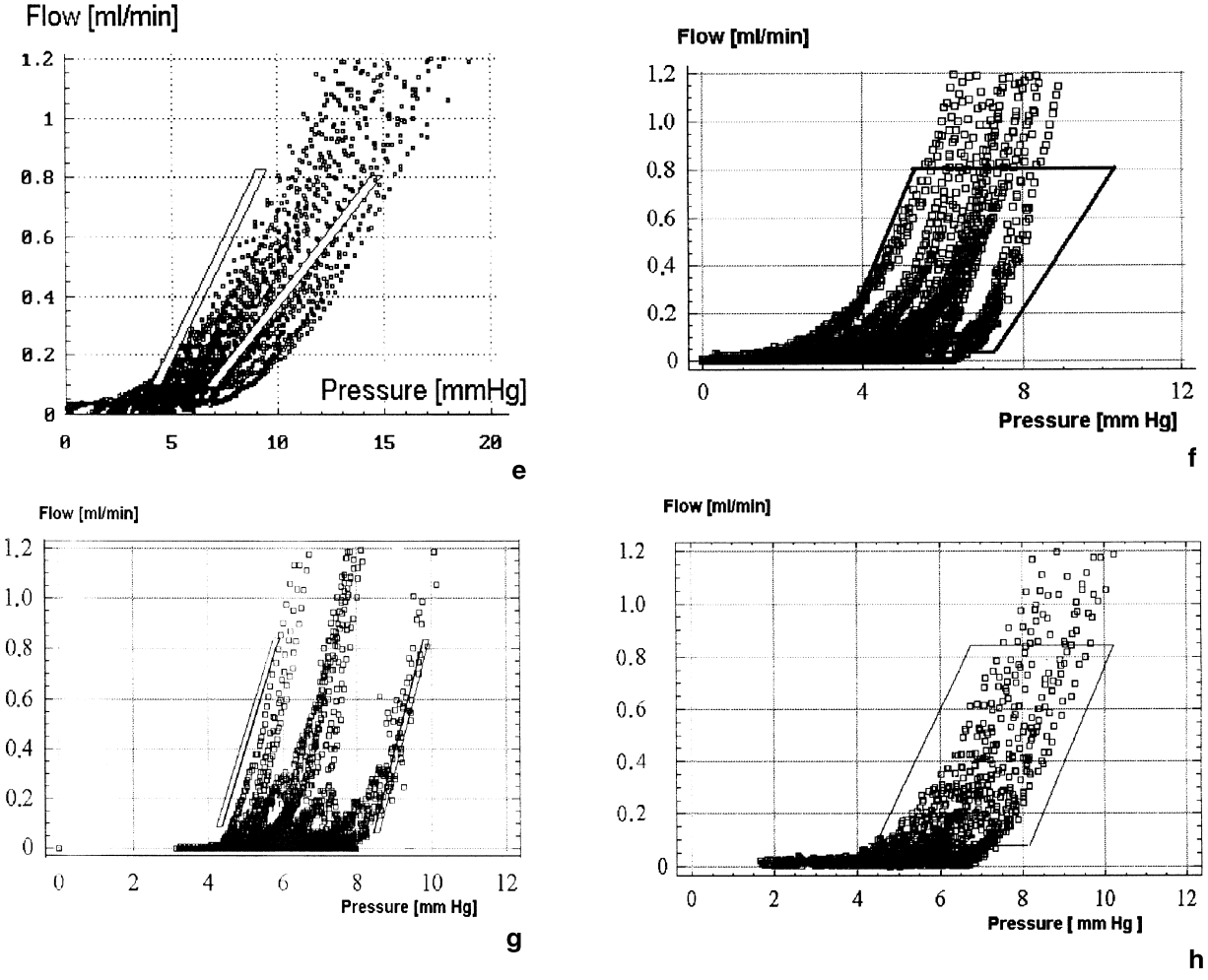

Fig. 2. (e) In-line Valve – (f) Accu-flo – (g) Radionics Contour Flex – (h) CSF Flow Control

Valves (Fig. 1h). The gradients of the curves are very steep, reflecting the shunts' ability to drain CSF at a high rate when the inlet pressure increases above the nominal opening threshold. All the measurement points fit into the performance region specified by the manufacturer. The valve allows the drainage rate to increase above 3–4 ml/min when the body position is upright. In patients likely to develop clinical complications related to overdrainage, implantation of a Delta Valve instead of CSF-Flow Control Valve should be considered.

Medtronic PS Medical Delta Valve

The pressure-flow curve (Level 2) exhibited a decrease in its gradient when the flow decreased below 0.5 ml/min as has been observed with other silicone diaphragm valves. Very low flow could be maintained even for differential pressures well below the limit of closing. The valve was still "dripping" even for differential pressures well below 3.7 mm Hg (see Fig. 1i), which is the specified limit for the closing pressure. However, this effect disappeared when a 90 cm peritoneal catheter was added. The distal catheter shifted the curve to the right, increasing closing pressure.

In a composite plot, more than 36% of the points were below the lower limit of performance specified by the manufacturer.

The shunt incorporates a Siphon Control Device (SCD) [13] to reduce CSF overdrainage in the vertical body position. External pressure may proportionally increase to valve's operating pressure. The shunt probably works predominantly in the horizontal body position, as the physiological value of intracranial

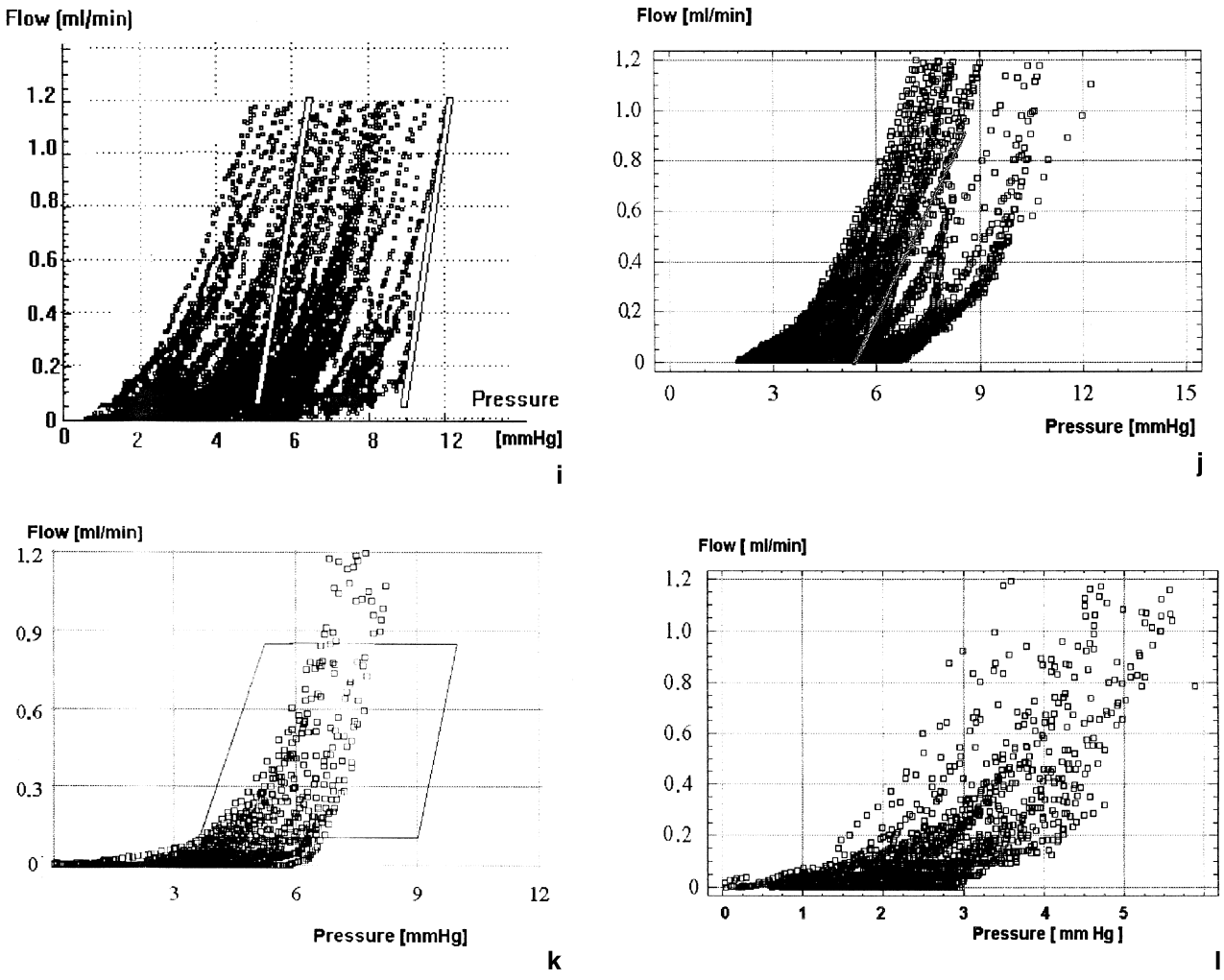

Fig. 2. (i) Delta Valve – (j) Low Profile Valve with Anti-Siphon Device – (k) Pudenz-Flushing – (l) Uni-Shunt

pressure in the vertical body position is sufficiently negative to close the SCD.

The Heyer-Schulte Low Profile Valve with Anti Siphon Device (ASD)

The valve had a non-linear performance (Fig. 1j). The manufacturer did not specify the exact region of performance. All the measurement points are spread around the line specified by the manufacturer. Variations of operating pressure over 16 days are limited, to $\pm$2.25 mm Hg. With a distal catheter the opening pressure increased significantly but was still within the specified limits.

The valve incorporates a mechanism preventing overdrainage related to posture (anti-siphon device, ASD) similar functionally to SCD [16]. Differences between the hydrodynamic properties of ASD and SCD are practically negligible [7]. Like the Delta Valve, this shunt may be blocked by raised subcutaneous pressure and works predominantly in the horizontal body position.

The Heyer-Schulte Pudenz-Flushing Valve

This burr-hole valve shares hydrodynamic properties with the Low-Profile Valve. The valve had a non-linear performance curve see Fig 1k. Variations of pressure-flow performance over 16 days were limited ($\pm$1.5 mm Hg), but all measurement points fell into the specified region. The Heyer-Schulte Pudenz Flush-

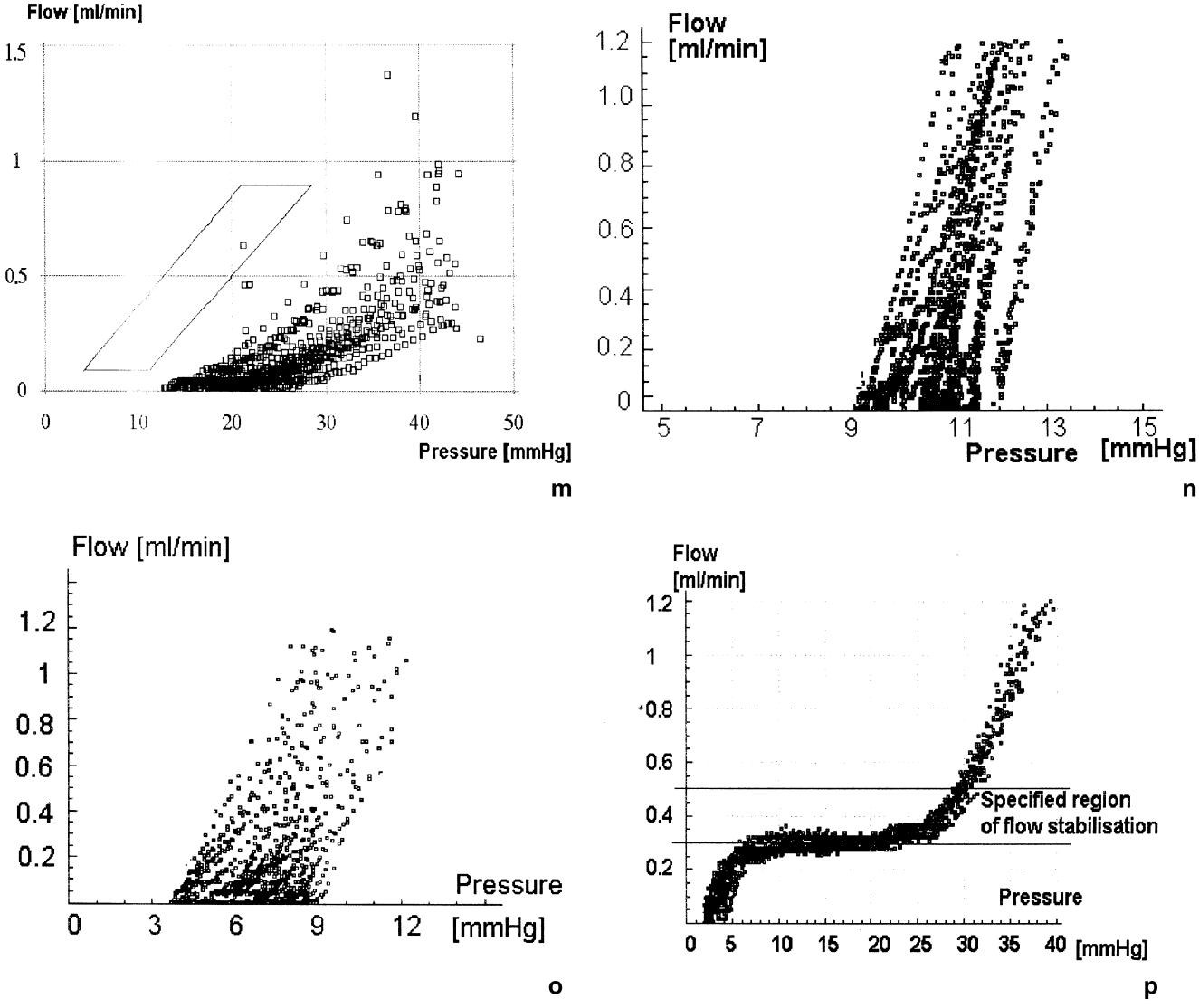

Fig. 2. (m) Lumboperitoneal Shunt – (n) Hakim Programmable Valve – (o) Sophy Programmable Valve – (p) Orbis-Sigma Valve

ing Valve is available with the option of an integrated ASD.

The Codman Uni-Shunt

This one-piece shunt had a non-linear performance curve showing a tendency to decrease its gradient when flow decreased. This distortion reflects the mechanism of closure of the distal slits in soft silicone rubber – see Fig. 1l. Variations of pressure-flow performance over 16 days are ± 1.5 mm Hg with the closing pressure being well below the specified limit. There was no large difference in hydrodynamic performance between valves with elliptical or regular reservoirs. The length of the valve (five different lengths are available) has a limited influence on the measured pressure-flow performance. The valve, particularly the low pressure option, has a low hydrodynamic resistance. Therefore, the possibility of posture-related overdrainage should be always considered as an important risk factor.

The closing pressure of medium and high pressure valves was measured to be below the manufacturer's specified limits when the distal end of the valve was kept wet (suspended 2–3 mm beneath surface of water). When the shunts were tested according to the manufacturer recommendation (with its end hanging freely in the air), the closing pressure was measured within the specified limits. This illustrates the historically es-

tablished belief that the distal slit valve may be partially or completely obstructed, depending upon its environment in the abdominal space. Small particles increase the valve's resistance permanently.

Medtronic PS Medical Lumboperitoneal Shunt

This valve, like the Uni-Shunt, had a non-linear performance curve. The gradient of the pressure-flow curve measured with a CSF Reservoir in line was higher, with the opening pressure and shape of the curve remaining unchanged. All of the measured curves fell above the upper limit specified by the manufacturer (Fig. 1m). The shunt has a high resistance and a high opening pressure. This helps to maintain a physiological level of CSF drainage in the vertical position, but may lead to underdrainage in the horizontal position. Therefore, the shunt will drain insufficient CSF when patients are bed bound for long periods. The shunt increases both its opening pressure and its resistance with time. Resistance to drainage of CSF may increase when the shunt is blocked by particles of diameter greater than 25 microns. Once the shunt is blocked, there is little facility for external flushing to clean the shunt of debris. Therefore, the shunt can be regarded as a temporary measure and able to drain CSF only over a limited period.

Codman-Medos Programmable Valve

The valve without a distal catheter and with no pulsatile pressure wave had almost linear characteristics. Scattering of the pressure-flow curves was narrow ($\pm$1 mm Hg) (Fig. 1n).

Pulsations superimposed on the differential pressure have an impact on the shape of the flow-pressure curve. They decrease its gradient for low flow (below 0.2 ml/min) and reduce the closing pressure by a value comparable to half the peak-to-peak pulse amplitude. The shunt can be reliably programmed in 18 precise steps from 3 to 20 cm H_2O. The shunt without a distal drain exhibits an extremely low resistance to fluid flow. Therefore, its function should be considered, not in isolation, but in combination with the distal catheter, peritoneal or atrial, with careful thought given to any shortening of the catheter. Flow through the valve is extremely sensitive to negative hydrostatic outlet pressure. When necessary, implantation of a siphon-preventing device in-line with the valve should be considered. The shunt may be accidentally re-programmed by external magnetic field (not only in an MRI scanner but also by a solid magnet as used in earphones, for example).

Sophy Programmable Pressure Valve

Valves without a distal catheter had a parabolic characteristic at low flow (0.2 ml/min). For higher flow (>0.3 ml/min) the pressure-flow curve may be approximated by a straight line (see Fig. 1o). Pressure pulsations had no influence on the shape of the pressure-flow curves.

The shunt can be programmed in 3 precise steps. The precision of 5 intermediate steps is lower (available only in model SU8). Air bubbles, as in almost all of the contemporary valves, may disturb fluid drainage. They can be removed by gentle pumping of the proximal reservoir (recommended by the manufacturer). The Sophy valve, unlike valves with an elastic chamber, is a little more difficult to free of air bubbles. The flow through the valve is sensitive to a posture-related negative hydrostatic outlet pressure. This may cause clinical complications related to overdrainage. The shunt may be accidentally re-programmed by an external magnetic field.

Orbis Sigma Valve

This valve had a non-linear characteristic. Three regions may be defined (see Fig. 1p):

- from the opening pressure to the pressure where flow reaches a plateau (i.e. plateau pressure)
- from the plateau pressure to the relief pressure (flow was stabilized)
- above the relief pressure.

The composite graph showed a very little scattering of the pressure flow-curves. The area between the black horizontal lines (Fig. 1p) represents the region of flow stabilization specified by the manufacturer. In around some 50% of pressure-flow tests, the recorded flow was a little below the lower specified limit (0.3 ml/min, but the difference never exceeded 0.05 ml/min). The pressure-flow curve indicates the shunt's ability to stabilize the drainage rate (0.3–0.5 ml/min). The Intracranial Pressure after shunt implantation may be as high as 24 mm Hg or may fluctuate. High ICP does not indicate shunt malfunction, as the shunt stabilizes drainage not pressure.

The valve has a high hydrodynamic resistance. This may contradict its use in patients presenting with

high vasomotor-induced fluctuations of intracranial pressure. The high hydrodynamic resistance reduces the rate of drainage in the upright position. Hence, the shunt is potentially safer from the point of view of complications related to overdrainage than other classic-differential constructions. Small particles may block the shunt permanently.

Discussion

Need for Independent Shunt Testing

Many of the parameters of the tested shunts are never disclosed, or are disclosed insufficiently or even inaccurately by the manufacturers. Contrary to the popular opinion, a shunt constitutes a complex hydrodynamic system of highly non-linear flow characteristic. Its ability to drain CSF continuously in repetitive manner over long-term period is crucial in management of hydrocephalus. Independent laboratories in Europe, known from their publications are placed in Heidelberg [1, 2], Hannover [19] and Cambridge [6–10]. All they use a little bit different protocols, but physical basis of shunt testing are in all centers aimed on careful analysis of the pressure-flow performance curves under different conditions. Results about different shunts are generally convergent. Personal opinion and conclusions vary from time to time. The strengths of these laboratories depend on the fact that their work independently on each other and on the manufacturers. Presented results play an important role in refining quality in treatment of hydrocephalus.

Programs of shunt evaluation created an opportunity to understand and demonstrate some important phenomena related to the hydrodynamics of CSF fluid in shunted patient and create guidelines for 'more physiological' valves: First, in spite of advance in shunt technology, shunts are still unable to restore physiological pathways of CSF circulation. Long ventriculoperitoneal tubing produces a hydrostatic pressure gradient which, in spite of some ingenious technological advances, may still constitute an important source of secondary clinical complications. In normal conditions, ICP is always coupled to and a little higher than the venous pressure in the sagittal sinuses. Ventriculoperitoneal shunting disturbs this coupling, resulting in ICP, which may be intermittently much lower than sagittal sinus pressure. It may be noticeable in an upright body position but also during coughing and other bodily movements associated with an acutely raised central venous pressure. Theoretically, such an unphysiological situation may contribute to excessive pressure gradients between cortical and bridging veins and CSF pressure, thereby increasing the risk of subdural or epidural bleeding.

The operating pressure for flow around 0.3 ml/min marks the range of ICP which can be measured in a patient with a properly functioning shunt in a horizontal body position. In ball on-spring valves this pressure is very stable over time, but is sensitive to dynamic changes in ICP. In contrast, in silicone-membrane valves, the operating pressure may vary within a range of 4–6 mm Hg in low, medium, or high ranges. Are ball-on-spring valves better than silicone membrane? Randomized trials [Drake, Pollack] failed to demonstrate supremacy of any specific construction. Our own experience shows that physiologically ICP is variable within limits 0–15 mm Hg. Any attempt to set it constant with a valve of minutely determined opening pressure and very low hydrodynamic resistance may not be the most relevant objective. Ideally, the resistance of the valve should be close to the normal range of resistance to CSF outflow, i.e. 6–10 mm Hg/ml/min. It would be interesting to see a programmable valve constructed with a fixed opening pressure (2–3 mm Hg) but hydrodynamic resistance programmable in steps, between 3 and 21 mm Hg/ml/min.

Hydrodynamic Parameters Vary

Opening and closing pressure may be programmed externally in some models. Magnetic programming was used for the first time in a French model – the Sophy Programmable Valve. The next generation of programmable valves was designed by S. and C. Hakim and produced in Switzerland by Codman-Medos. Much more precise programming (18 steps) has been achieved. The mode of valve activation using magnetic pulses has proved to be less susceptible to accidental reprogramming by an external magnetic field. But reprogramming is still possible not only in a MR scanner but also with a solid magnet generating comparatively weak magnetic fields. Magnetic toys should be strictly avoided in pediatric cases, where programmable valves are in use. Neither of these programmable valves prevents posture-related overdrainage. Therefore, in patients at a high risk of complication associated with posture-related overdrainage, an external siphon-

controlling device should be inserted in-line with the valve. It should be noted that the performance of the new Siphon-Guard (Codman) device intended to prevent overdrainage with the Hakim-Programmable Valve is far from ideal [10].

As the majority of contemporary valves have a low hydrodynamic resistance, the shunt's net resistance depends to a great extent on the diameter and the length of the distal drain [1, 8, 11]. In patients likely to develop clinical complications related to overdrainage, implantation of an anti-siphon device should be considered. However, the risk of overdrainage related to vasomotor nocturnal waves may still be high [5]. A standard peritoneal open end catheter (usually around 90 cm long, 1.1–1.2 mm diameter) constitutes a resistance of 2.5–3.5 mm Hg/(ml/min). This may amount to 100% to 200% of the overall resistance of the valve itself. It must be recognized that shortening of a drain decreases overall shunt resistance, making it potentially more susceptible to overdrainage. It is worthwhile to notice that hydrodynamic resistance of the drain increases with the fourth power of diameter. PS Medical Lumboperitoneal Shunt (internal diameter 0.9 mm) has the resistance very high (25 mm Hg/ml/min). Moreover low diameter makes it susceptible to blockage with small particles.

Open-end catheter performs very different to slit-opening catheters (or distal slit shunts). Hydrodynamic resistance dramatically depends on whether the end was wet or dry and how was positioned inside the outlet tube. This illustrates the historically established belief that the distal slit valve may be partially or completely obstructed, depending upon its environment in the abdominal space.

In some cases a very high hydrodynamic resistance is an attribute of the valve itself, as in the Orbis-Sigma Valve, and this may prevent posture-related overdrainage [17]. But, contrary to low-resistance valves, this valve stabilizes flow not differential pressure. Therefore, patients suffering from high vasogenic pressure waves, with a normal baseline pressure level, may not improve because the shunt cannot suppress the magnitude of the pressure oscillations.

All shunts – programmable, non-programmable, classic differential, flow regulating or siphon-compensating are subjected in vivo to the constant presence of small particles in the CSF. They can be as large as erythrocytes, or even larger-protein particles, choroidal debris, etc. All shunts can be permanently clogged with larger debris. But also membrane and ball-on-spring valves can be permanently opened by particles of the size of erythrocytes – as illustrated by experiments with graded diameter microspheres or blood [3].

Guidelines for Shunt Testing In-Vivo

There is a growing number of patients who have never improved following shunting or initially improved and then deteriorated [20]. Decisions about shunt revision are made on the basis of clinical assessment of symptoms and repeated imaging. In cases of slow deterioration shunt should ideally be tested in-vivo. Overnight ICP monitoring can be used, or more precisely infusion test via the lumbar space or pre-implanted Ommaya reservoir [5].

A patient with a properly functioning shunt should have his ICP in horizontal body position lower than shunt's operating pressure. However, in some cases this pressure is lower (particularly in NPH patients) not because shunt functions properly, but because all CSF produced is drained into brain parenchyma extracellular fluid. During infusion test pressure increases and end-equilibrium pressure achieved is the most stable parameter characterizing shunt function in vivo. It should not increase above the value given by the equation:

$$\textit{Maximum end equilibrium pressure} < \textit{shunt operating pressure} + \{\textit{resistance of shunt} * \textit{infusion rate}\} + 5\ \textit{mm Hg.}$$

The 5 mm Hg is a safety factor that has been used in a considerable number of in vivo studies.

Critical values of end-equilibrium pressure for all fixed-pressure shunts and infusion rates 1.5 ml/min were given in Table 2. For programmable valves the following formula can be proposed:

Hakim Programmable: 12.85 + set level (cm H_2O)/1.356

Sophy Valve: 13 + set operating pressure (in mm Hg)

Conclusion

Independent shunt testing is important as many of shunt properties are never disclosed by the manufacturers. The hydrodynamic properties of most commonly used valves vary considerably and the knowledge of these differences may be helpful in matching the shunt to a patient presenting with a specific profile

of CSF circulation and ICP dynamics and understanding of common shunt-related complications like underdrainage or overdrainage.

Knowledge of shunts' hydrodynamic parameters give a foundation for shunt testing in-vivo using infusion test technique.

Acknowledgment

The authors wish to express their gratitude to the U.K. Department of Health Medical Devices Agency for funding the U.K. Evaluation Laboratory in Cambridge in years 1994–1998.

The manufacturers: Medtronic PS Medical, Heyer-Schulte NeuroCare, Codman, Elekta Implants, Sophysa, and Radionics for providing us with a test samples free of charge.

Dr. Marek Czosnyka is on unpaid leave from Warsaw University of Technology, Poland.

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Comments

This article describes laboratory testing in 16 models of CSF valves currently available in U.K. at the United Kingdom Shunt Evaluation Laboratory and provides detailed information regarding the performance of valves on the bench. It may be remembered that 211 valve design have emerged since 1949 and there are 137 valves currently available (Aschoff *et al.*). The study is well documented. The authors claim that behavior of a valve revealed during such a testing is of immediate relevance to the surgeon and helpful for the assessment of shunt function in vivo using infusion tests. Unfortunately, no detailed model of hydrocephalic brain is available that can be used to tell in advance how the valve would perform in the patient. The response of the hydrocephalic brain to shunt insertion is very complex. No question that shunt design has a major impact on the management of hydrocephalus. However, the ideal design for a particular patient group has simply not been defined.

Surgeons should remember that in most of the silicone-diaphragm valves, closing pressure varied and reached values lower than that specified by the manufacturer, and all programmable valves are susceptible to overdrainage in the upright position.

Most important message of the study is that in vitro testing highlights potential poblems with specific shunts, which should be monitored in patients long-term.

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