A new approach in the treatment of hydrocephalus

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To date, most patients suffering from hydrocephalus have been treated by insertion of differential-pressure valves that have fairly constant resistance. Since intracranial pressure (ICP) is a variable parameter (depending on such factors as patient’s position and rapid eye movement sleep) and since cerebrospinal fluid (CSF) secretion is almost constant, it may be assumed that some shunt complications are related to too much or too little CSF drainage. The authors suggest a new approach to treating hydrocephalus, the aim of which is to provide CSF drainage at or below the CSF secretion rate within a physiological ICP range. This concept has led the authors to develop a three-stage valve system. The first stage consists of a medium-pressure low-resistance valve that operates as a conventional differential-pressure valve until the flow through the shunt reaches a mean value of 20 ml/hr. A second stage consists of a variable-resistance flow regulator that maintains flow between 20 and 30 ml/hr at differential pressures of 80 to 350 mm H2O. The third stage is a safety device that operates at differential pressures above 350 mm H2O (inducing a rapid increase in CSF flow rate) and therefore prevents hyper-elevated ICP. An in vitro study is described that demonstrates the capability of this system to maintain flow rates close to CSF production under a range of pressures similar to those observed under various human physiological and postural conditions. Promising clinical results in 19 patients shunted with this valve are summarized.

KEY WORDS • hydrocephalus • ventriculoperitoneal shunt • cerebrospinal fluid flow • differential-pressure valve • variable-resistance valve

ALTHOUGH the introduction of one-way calibrated shunt systems in 195238,70 has proven to be a definite advance in the treatment of hydrocephalus, and shunt technology has evolved over the past three decades,22,9,35,50,52,53,77,81,83,93,99 some problems still remain unsolved. The variety of valves available on the market today is partly related to these uncertainties.40,92 Shunt obstruction14,10,42,73 and infection49,85 are recognized complications associated with prosthesis insertion and have been the subject of many investigations.3,29,37,58,67,72,73,95 Complications due to under- and overdrainage are directly related to the hydrodynamic characteristics of valves, and have been extensively studied over the past 15 years.22,25,31,32,38 These phenomena, which had previously been more or less overlooked, are now well documented; they include shunt dependency,23,24,31 slit-ventriclesyndrome,30,44,47,59,89 subdural hematoma,45,51,90 post-shunt craniosynostosis,48 spinal canal stenosis,49 and orthostatic intracranial hypotension. Moreover, it is not known at the present time whether chronic overdrainage is responsible for some of these poor long-term results.46,52,97

Most commercially available shunts include differential-pressure (DP) valves: once the valves are open, flow is determined by the difference between the cerebrospinal fluid (CSF) input and output pressures.35,79,84 Therefore, when the patient is in the upright position, a DP increase (“siphon effect”) occurs due to the height of the hydrostatic column between the inlet and the outlet of the shunt.7,26,28,105 Overdrainage can be considered constant in standing patients, since in that position the draining capacity of the shunt exceeds the ventricular CSF secretion rate. Several attempts have been made to remedy this situation,27,21,27,34,78,94,104 but for various reasons none of the resulting shunts are completely satisfactory.

The purpose of this article is to describe a shunt system based on a new approach in the treatment of hydrocephalus. The hydrodynamic characteristics of the system and results of the first clinical trials are
presented. The principle of this valve is to operate as a flow regulator within certain DP values.

Materials and Methods

Valve Specifications

In 1982, Portnoy\(^7\) raised the issue of shunt hydrodynamic characteristics and stated: "Several neurosurgeons have commented that the ideal valve should be flow-controlled. Such a valve would have to continuously determine the CSF formation rate and the rate of outflow through natural channels, and regulate the flow through the valve so as to remove only the excess fluid. There is no mechanism now available that can accomplish this without difficulty, much less be capsuled into a volume of 3 ml or less."

The new valve described in this article is designed on the principle that the flow through the shunt should not exceed the CSF production rate throughout the range of physiological intracranial pressures (ICPs). It is well known that flow through a shunt can be expressed as F = DP/R, where F is flow, DP is the difference between input and output pressure, and R is resistance (Fig. 1). On the other hand, since the CSF secretion rate is approximately constant,\(^{13-15,60,87,98}\) it can be postulated that the excess fluid that is not drained through the natural channels and that has to be evacuated through the shunt is roughly constant at physiological ICPs. Since the DP varies under circumstances such as when the patient is standing erect, or during rapid eye movement (REM) sleep or exertion,\(^{11,18,41,54,56,75,86,103}\) the resistance of the shunt should vary in order to maintain a constant flow. These considerations led us to design a variable-resistance shunt to comply with the following requirements.

The hydrodynamic specifications included the need for: suitable drainage at different pressures close to the valve-opening pressure (as, for instance, when the patient is in the supine position); reduction or prevention of overdrainage at large DP's (such as when the patient is standing erect, or during straining, exertion, or REM sleep); and inclusion of a safety device to prevent any accidental intracranial hypertension. The construction specifications included the requirements that, if possible, the shunt should contain no metallic material,\(^{6,66}\) and that the surfaces in the shunt components should be sterile and be unlikely to cause a reaction.\(^{30,96}\) The design specifications demanded a small size to fit pediatric as well as adult patients, and minimal use of connectors.

The hydrodynamic specifications called for a three-stage valve (Fig. 2 left). Stage I should act as a low-resistance valve. When the DP is low, for instance when the patient is in the supine position, there is no risk of overdrainage as long as the resistance of the shunt is correctly adjusted. Therefore, at the first stage the valve should operate as a conventional DP valve with a preset opening pressure. The valve should remain in this

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**FIG. 1.** Relationship between flow and pressure in shunts in the supine position (A) and in the upright position (B). DP = differential pressure; F = flow through the shunt; R = resistance of the whole system; IP = input pressure; and OP = output pressure. Arrows indicate amplitudes and directions of pressures.
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FIG. 2. Diagram showing the mechanism in Stages I, II, and III (see text), and a theoretical flow (F)-pressure (DP) curve of the three-stage system. DP = differential pressure; DPV = DP valve; F = flow through the shunt.

FIG. 3. Left: Photograph of the Orbis-Sigma valve assembled and with and without the antichamber. Right: Diagram showing the operative parts of the system. Arrows indicate the direction of the cerebrospinal fluid flow. For an explanation of Stages I, II, and II and Points A, B, and C see text.

configuration as long as the CSF flow through the shunt does not exceed 20 ml/hr, which is considered to be the average CSF secretion rate. It should achieve this flow rate with a small increase in DP as would a low-resistance valve. Stage II should act as a flow regulator when the DP increases, for instance when the patient is in the upright position. This means that the shunt drainage capacities should remain between 20 and 25 ml/hr. This flow regulation is obtained by an increase of the valve resistance, which means that a large change in DP will result in only a small variation of the flow rate. Stage III, the last stage of the system, is a safety device. If for some reason the DP exceeds 30 mm Hg, as in shunt obstruction, CSF oversecretion, or excessive CSF volume under an elevated ICP at the outset of drainage, the shunt should then operate as a low-resistance DP valve as in Stage I. With such a device, ICP cannot exceed the pre-set safety pressure level.

We have designed a compact device, the Orbis-Sigma valve (OSV),* that fulfills all the above-mentioned specifications (Fig. 3 left). The operative parts of the valve are shown in Fig. 3 right. A plug with an orifice can travel from Point A to Points B and C along a non-cylindrical pin. The plug remains at A as long as the DP is below the opening pressure. When the DP exceeds the opening pressure, the plug moves downward to B, allowing the valve to operate as a low-resistance pressure shunt. The plug remains at B at CSF flow rates of up to 20 ml/hr, and above this value it moves downward to C. The cross-sectional area between the orifice of the plug and its guiding pin decreases abruptly, thereby causing a marked increase of resistance; in this way, the valve operates as a flow regulator. Beyond Point C, the drainage area increases so that the shunt again operates as a low-resistance valve.

In Vitro Test Procedures

To test this new valve in vitro and to compare it to other valves, we used a test bench similar to that designed by Watts and Keith (Fig. 4). This bench allows a testing procedure that takes into consideration the following parameters: the temperature at which the test is performed; the pulsatility of the flow; the compliance

* Orbis-Sigma valve manufactured by Cordis Corp., Miami, Florida.
FIG. 4. Configuration of the test equipment. Not all items are shown.

FIG. 5. Graph showing the pressure-volume curves of the simulated proximal chamber with (2) or without (1) added compliance (application of a rubber membrane).

The testing procedure included flow rates varying from 0 to 60 ml/hr, with or without pulses at frequencies between 60 and 120/min, and with or without added compliance in the proximal chamber (Fig. 5). Test fluids with protein concentrations ranging from 0 to 25 gm/liter were used.

Several prototypes of the valve were tested. Their pre-set specifications included a 4- to 5-mm Hg "opening pressure" for Stage I, flow regulation between 20 and 30 ml/hr for a DP between 10 and 30 mm Hg for Stage II, and a 30- to 35-mm Hg safety pressure level for Stage III. Seven commercially available valves were tested for comparison. These included two Codman Holter mini-valve systems (one medium-pressure Holter mini-valve, No. A 301; and one low-pressure Holter mini-valve, No. P 104); three Cordis Hakim pediatric valve systems (medium closing pressure of 56 to 90 mm H2O, Nos. 144 234, 121 313, and 138 962); and two American Heyer-Schulte low-profile valves (medium closing pressure of 51 to 110 mm H2O, lot No. 489 3660). Two Heyer-Schulte antisiphon devices (lot No. 308 3151) were also tested in connection with different types of valve.

Clinical Studies

Clinical trials were performed in 19 hydrocephalic patients aged from 2 months to 15 years with the authorization of the ethics committee of Les Enfants-Malades Hospital and with the written or verbal consent of the patients' parents. Half of the patients were older than 2 years. Indications for shunt insertion are listed in Table 1.

We deliberately selected patients in whom overdrainage would create a high risk of clinical complications, such as those who had post-shunt pericerebral collections or slit ventricles. Whenever possible, long-du-
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In Vitro Test Results

Pressure-Flow Characteristics. The pressure-flow characteristics of the tested OSV prototypes, measured with a steady flow rate at 37°C, were almost exactly as theoretically expected (Fig. 6). The opening and closing pressures varied from 4 to 6 mm Hg; the shunt acted as a flow regulator at flows between 25 and 35 ml/hr, and as a low-resistance DP valve at a DP slightly above 30 mm Hg. Figure 7 allows a comparison of results with different DP valves. It shows that, although the opening pressure determines the point where the shunt begins to act, the draining capacity itself does not depend significantly on this opening pressure. These draining capacities are far beyond the normal CSF secretion rates, the discrepancy being larger with low-resistance than with high-resistance valves.7,29 Being a variable-resistance shunt, the OSV drains barely more than the normal CSF secretion rate as long as the DP remains under 30 mm Hg.

OSV Pressure-Flow Characteristics Under Different Conditions. Four different types of valve were tested successively with a steady flow and with a pulsed flow. Pulse amplitude was 7 mm Hg and pulse frequency 100/min. Tests were performed with a rigid proximal chamber. When the mean pressures were compared, there were no significant differences in results obtained with steady and pulsed flow, whatever the type of shunt tested (Fig. 8). Two test fluids were used in four different shunts (Fig. 9): distilled de-aerated water and a saline solution containing protein, 10 gm/liter. With the Hakim valve, the differences due to the

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**TABLE 1**

<table>
<thead>
<tr>
<th>Pathological Condition</th>
<th>No. of Cases</th>
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<tr>
<td>aqueduct stenosis/posterior fossa tumor</td>
<td>10</td>
</tr>
<tr>
<td>communicating hydrocephalus</td>
<td>6</td>
</tr>
<tr>
<td>shunt malfunction</td>
<td>2</td>
</tr>
<tr>
<td>slit ventricle</td>
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**FIG. 7.** Comparison of pressure-flow curve characteristics of five different valves showing the effect of valve resistance on shunt performance. Sigma is the system presented here; M.P. = medium pressure; L.P. = low pressure; P = pediatric; AHS low P.M.P. = American Heyer-Schulte low-profile medium-pressure valve; DP = differential pressure.

**FIG. 8.** Pressure-flow curves of four different valves under steady and pulsed flow. OSV = Orbis-Sigma valve; A.H.S. = American Heyer-Schulte valve.
protein content of the fluid were slight; with the Holter and Heyer-Schulte valves, the pressure for the same flow was moderately increased in the proximal chamber when the protein concentration of the fluid was increased. Under the same conditions, the slope of the second part of the curve was steeper with the OSV.

One OSV system was tested continuously for 7 days and the various parameters (steady and pulsed flow, temperature of 20° to 40°C, and protein fluid concentration of 5 to 25 gm/liter) were successively modified. The pressure-flow data obtained throughout the testing procedure varied little, and generally retained the S shape of the curve. From these results, it can be concluded that the hydrodynamic characteristics of the OSV remain within very acceptable limits under the conditions tested (Fig. 10).

Influence of "Siphon Effect" on Flow Rate. To simulate the "siphon effect" observed on shunted patients in the upright position (Fig. 11), a negative pressure was produced in the distal chamber. Tests were performed with a compliant proximal chamber (60-ml volumetric reserve)28 (Fig. 5). For all the tested shunts, the flow delivered by the pump was maintained at 20 ml/hr throughout the procedure (at the beginning it was zero). Under these conditions, the pressure in the proximal chamber (simulating ICP) reached a plateau at a level that depended on the opening pressure and the resistance of the shunt. This was usually obtained within less than 15 minutes, and the distal-chamber pressure was then reduced to -25 mm Hg.

Under these test conditions, the flow through the low-resistance DP valve (Fig. 11 upper left) increased to 240 ml/hr; however, as long as this flow was maintained, the pressure drop in the proximal chamber was limited to -4 or -5 mm Hg due to the buffering reserve of this compliant proximal chamber. Later, when this 60-ml reserve was drained off, the compliance of the proximal chamber decreased abruptly. The flow then returned to the 20-ml/hr rate delivered by the pump because practically no extra fluid could be withdrawn from the proximal chamber. Simultaneously, the proximal-chamber pressure dropped to about -17 mm Hg, the level of this negative pressure being determined by the induced negative output pressure and by the shunt resistance.

When an antisiphon device was inserted in connection with a low-resistance DP valve (Fig. 11 upper right), the proximal-chamber pressure variations were very different. When the distal-chamber pressure was lowered to -25 mm Hg, the antisiphon device closed, so that for more than 15 minutes the rate of flow through the shunting system dropped below 5 ml/hr while the proximal-chamber pressure increased to +15 mm Hg. At that point the shunting system reopened, the flow rate returned to 20 ml/hr, and the proximal chamber remained at 15 mm Hg.

With an OSV, when the distal-chamber pressure was reduced to -25 mm Hg the flow rate increased to only 30 ml/hr while pressure in the proximal chamber decreased to -3 mm Hg, at which point flow and pressure were stabilized for a long period of time. In fact, overdrainage was 10 ml/hr (that is, the difference between 30 ml/hr and the 20-ml/hr flow delivered by the pump). Because, with the test equipment, overdrainage has to exceed 60 ml before the compliance of the proximal chamber decreases, the proximal-chamber pressure was stable for 6 hours at about -3 mm Hg.

Influence of Flow Variations. Short-term 20- to 100-ml/hr flow variations were induced to study their effect on the proximal-chamber pressure with low-resistance valves and OSV's (Fig. 12). With low-resistance valves, the pressure variations were small so that the
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Fig. 11. Simulated "siphon effect" with three different valves. The effects on the proximal-chamber pressure and flow rate through the shunts (dotted line) are shown. With the Orbis-Sigma valve (OSV), the overdrainage is minimal and the pressure in the proximal chamber remains close to zero. D.P. valve = differential-pressure valve; L.R.V. = low-resistance valve; P. = pressure.

Clinical Findings

There were no mechanical or infectious complications in this series. In five patients with shunts, variations in ICP were studied successively in the recumbent then in the upright position. Figure 13 shows a comparison between conventional DP valves and the OSV.
FIG. 13. Influence of the upright position on intracranial pressure in a patient with a low-resistance (LR) medium-pressure (MP) shunt valve and in a patient shunted with an Orbis-Sigma valve (Sigma). Arrows indicate pressure with the patient in the upright position. P = pressure. Compare these results with those of the in vitro tests (Fig. 11).

FIG. 14. Preoperative (upper) and postoperative (lower) intracranial pressure (ICP) recordings in two patients with acute hydrocephalus shunted with an Orbis-Sigma valve. D = day of shunt placement.
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Several attempts have been made to remedy the problem of overdrainage. The selection of "more physiological" sites for CSF drainage has been suggested, such as the sagittal sinus or placing the distal catheter in the internal jugular vein against the direction of blood flow. This is a good remedy in theory, but creates surgical problems. Another proposed solution is to increase the resistance of the shunt. Buchheit, et al., suggested that the resistance of the shunt should be determined by the patient's height. Yamada uses a throttle connected to the shunt to increase its resistance. However, these solutions carry the risk of underdrainage when the DP is close to the opening pressure level.

An externally adjustable opening pressure has also been suggested; however, to solve the problem of overdrainage the valve would have to be manipulated every time the DP changed. Reversible-occlusion valves merit the same criticism. Valves with automatically

Fig. 15. Upper: Preoperative computerized tomography scans in three patients with acute hydrocephalus shunted with an Orbis-Sigma valve. Lower: Scans obtained 7 days after shunt placement in the same three patients.

Fig. 16. Preoperative (upper) and postoperative (lower) intracranial pressure (ICP) recordings in two patients with chronic hydrocephalus shunted with an Orbis-Sigma valve. D = day of shunt placement.
adjustable opening pressure represent an improvement as far as orthostatic overdrainage is concerned, but theoretically they should be revised during growth to adapt their back-pressure to the patient's height. The antisiphon device designed by Fox, et al.,27,78 is efficient in reducing overdrainage;33 however, our results (Fig. 11) and those of McCullough and Wells62 have demonstrated that this device carries a risk of underdrainage and increased ICP in certain circumstances when the patient is in the upright position. The Servo-valve shunt of Hakim34 might be a good solution but, due to unsolved technical problems, is not yet available.

The solution offered by the OSV relies on control of the CSF flow not on primary regulation of the ICP, which is a highly variable parameter.11,41,56,86,88 The principle of operation of the OSV is to drain off the CSF that cannot be reabsorbed through natural channels under physiological ICP's. Thus, the OSV avoids the criticisms to which the other shunts are subject; however, the determination of its parameters (level of opening pressure, flow regulation, and safety pressure) presents difficulties. Since the CSF flow is stabilized by the OSV when the DP is large (such as when the patient is erect), the opening pressure plays a role only when the DP is small (such as when the patient is supine). Taking into account, on the one hand, the ICP values reported in infants, children, and adults,5,19,64,65,74,82,101 and on the other hand, the abdominal pressure values,7 we assumed that an opening pressure between 3 and 5 mm Hg would result in normal ICP's when the DP is small. The determination of the level at which CSF flow should be controlled was based on the CSF secretion rates and flow rates through shunts generally accepted in the literature.

In most recent studies, it is concluded that the CSF secretion rate is constant (at least on the average over each nycterohemeral period), its values varying from 0.3 to 0.5 ml/min.13-15,57,60,87,98 Within certain limits, CSF secretion is independent of ICP and, except for some very rare cases (such as papillomas of the choroid plexus,20,102 and the cases of Cutler, et al.,12 and Rayport and Reiss14), hydrocephalus is not the consequence of CSF oversecretion.

Other information that would help to determine the best flow regulation level includes CSF flow through
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Flow of CSF through shunts has rarely been studied in vivo; de Rougemont, et al.,16,17 reported that CSF flow rates through shunts were slightly lower than the CSF secretion rates measured in children by Cutler, et al.13 Sato, et al.,91 concluded that "the shunt function would be quite adequate when the flow rates are between 0.1 and 0.3 ml/min." Hara, et al.,36,72 found daily flow rates through shunts to be below 350 ml; however, they observed nycterohemeral fluctuations of between 0.05 and 0.78 ml/min. Since the shunts studied were conventional DP shunts, it is very likely that the large CSF flows were measured during overdrainage periods such as related to REM sleep or an orthostatic position. If this is true, these values should not be taken into account.

Since it is difficult to determine for each patient the precise ratio of CSF that should be drained through the shunt, and since underdrainage is not desirable, it was decided to set the flow regulation level at 20 to 25 ml/hr; that is, at about the mean rate of CSF secretion. It is obvious that in many children this flow rate will be greater than the patient's drainage requirements. This overdrainage, 50 times smaller than with conventional DP valves, appears to be acceptable, at least for a beginning. In the worst possible situation (that of a patient with very low excess CSF flow rate), the OSV should avoid the abrupt ICP variations that are probably responsible for postoperative cerebral fluid collections. The point on the flow-pressure curve at which flow control ends (also designated as the "blow-off point") has been set at a DP of 30 mm Hg. This safety pressure level has been chosen because it is comparable to the negative ICP recorded in shunted adults in the upright position61 and because it is approximately the maximal value reached in physiological ICP variations.88

The number of patients treated with the OSV does not allow definitive conclusions. Other clinical trials will be necessary to determine whether one type or several types of OSV, each with different flow regulation levels, will be necessary to treat all patients. It is already certain that the OSV restores an ICP curve with normal physiological variations and that the postoperative evolution of ventricular dilatation is similar to that observed after ventriculocisternostomy60,62 (that is, after restoration of normal CSF absorption). Whether or not this will have any effect on the postoperative mechanical or functional complications remains to be demonstrated by more clinical trials.

Acknowledgment

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