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The dual-switch valve

A new hydrostatic valve for the treatment of hydrocephalus

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Abstract The currently available hydrocephalus valves are still far from perfect. Whereas the design principles of differential pressure valves and adjustable devices involve the danger of overdrainage, hydrostatic valves have a tendency to clog. The new dual-switch valve (DSV) avoids overdrainage-related problems such as subdural hygromas/hematomas or slit-like ventricles with the high risk of proximal catheter obstruction by means of two parallel chambers in a titanium casing: one for the the horizontal and the other for the vertical position. The control chamber for the horizontal position is closed by a gravity-activated tantalum ball as soon as the patient moves into an upright position. Now the drainage of CSF is directed into the appropriate controller for the erect position. Thus, the hydrostatic differential pressure between ventricles and peritoneal cavity is counterbalanced and the intraventricular pressure (IVP) remains within physiological values independently of the CSF flow and the position of the patient. To avoid the problem of clogging, the newly designed valve introduces large-area diaphragms to create extensive acting forces. The forces generated in this way are able to overcome sticking forces set up as a result of high protein content or cellular debris. By this mechanism the IVP is maintained in physiological ranges regardless of the CSF composition. The new valve has been investigated with a computer controlled test apparatus especially designed to simulate different positions of the body. The in vitro test results according to ASTM standards document a superior performance in comparison with other valves. When the new device was interposed in external drainage systems precision of its function was confirmed even in the presence of elevated protein content and high CSF flow. Simulation of the upright position of the patient allowed documentation of the valve's reliability in maintaining the IVP within physiological ranges. A clinical trial with implantation of the new dual-switch valve was started at the beginning of 1995; so far follow up has been short. Clinical and computer tomographic monitoring has provided evidence of the valve's capacity to avoid the problems of overdrainage and early clogging.

Key words Hydrocephalus · Ventriculoperitoneal shunts · Valves · Intraventricular pressure · Overdrainage

Introduction

Despite the advantage of ventriculostomy of the III ventricle with the chance of restoring physiological conditions in cases of noncommunicating hydrocephalus, the majority of hydrocephalic patients are still treated with one-way calibrated shuntsystems, and ventriculoperitoneal drainage has proven superior to ventriculo-atrial shunting [5, 14]. Valve-regulated Silastic shunts were introduced more than 40 years ago, but still confront us with severe mechanical difficulties [2, 3, 10, 12, 15, 17, 18].

The main problems result from postural changes of the shunted hydrocephalic patient, causing additional hydrostatic pressure in the upright position (Fig. 1). In the recumbent position, the normal intraventricular pressure (IVP) is between +5 and +18 cm H_2O, whereas in the upright position the IVP drops physiologically to −10 to 0 cm of water [1, 11, 15]. The insertion of a conventional differential pressure valve with an opening pressure of about +10 cm H_2O will not alter the physiological IVP in the recumbent position. If the shunted patient adopts an upright position, however, the additional hydrostatic pressure will result in an increased suction effect, leading to increasing flow [2, 8, 11–13, 15–17]. The sequelae of this so-called siphon effect will be overdrainage and dramatically unphysiological negative IVP (Fig. 1b).

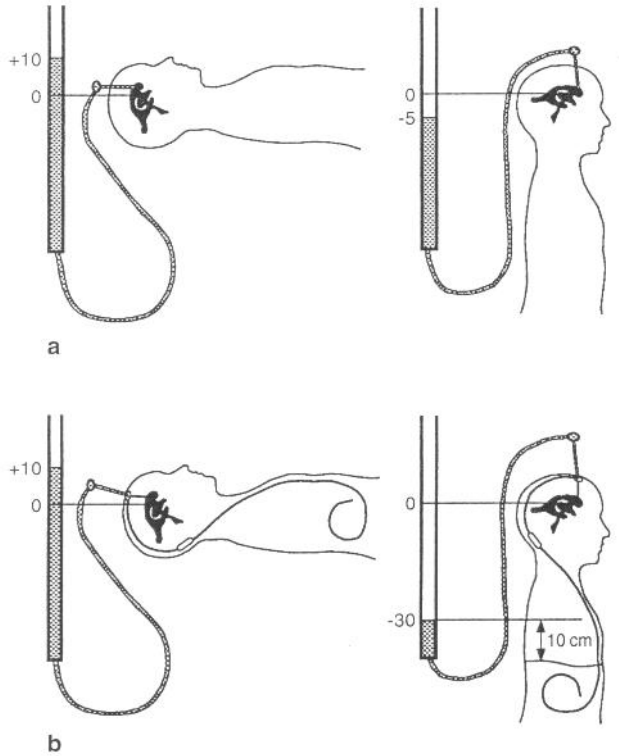

Fig. 1 **a** Physiological intraventricular pressure in supine and upright positions without shunt. **b** Intraventricular pressure in supine and upright positions after shunting with a differential-pressure valve

Table 1 Sequelae of overdrainage as reported in the literature

Low intracranial pressure syndrome
Slit-ventricle syndrome
Subdural hygroma/hematoma
Craniosynostosis, hyperpneumatization and thickening of the calvarium (contracting skull)
Aqueductal block, isolated IV and lateral ventricle
Deterioration of shunt dependency
Precocious obstruction of ventricular catheter
Upper hind brain herniation

The many different types of valves available on the market can be divided into three groups according to the design principles: differential pressure valves with one opening pressure only for the recumbent position (Codman-Spitz-Holter, Cordis-Hakim, PS-Medical standard/contoured, etc.), valves with an adjustable opening pressure for the horizontal position after implantation (Sophysa, Medos-Codman programmable, MDM multipurpose), and so-called hydrostatic devices, which take account of the changing posture of the patient (anti-siphon device (ASD), siphon-control device (SCD), Delta, Orbis-Sigma, Cordis-GCA, Cordis-H-V, Chhabra, Beverly, gravitational shunt, Phoenix Diamond). The first group of valves takes no account of the postural changes of the patient at all [2, 3, 13, 17]. The second group is able to reduce, but not to prevent, the problem of siphoning and overdrainage when patients are in the upright position [2, 3, 13], and most of the devices in the third group have a tendency to clog [2, 3, 13, 16, 18]. Chronic overdrainage can lead to numerous problems (Table 1), ranging from low intracranial pressure syndrome with such clinical symptoms as headaches and nausea to life-threatening complications such as upright herniation of the cerebellum. Saint-Rose and Gruber pointed out the correlation of ventricular collapse and the necessity for premature revision of the ventricular catheter [6, 16, 17].

There is a close relation between overdrainage and shunt dependence. Several authors have pointed out the necessity of reestablishing physiological absorption of CSF to prevent shunt dependence [2, 4, 8, 10, 20] after implantation of a valve-regulated drainage system.

To overcome the danger of overdrainage on the one hand and the complication of early clogging on the other, a new design principle was developed and realized by a study group made up of members of our department working closely with biomedical engineers at the Technical University of Berlin [13] and members of the neurosurgical department at the University of Essen.

Materials and methods

To avoid the well-known problems of overdrainage, the new valve has been designed with two different chambers arranged in parallel,

one for the recumbent and the other one for the upright position of the patient. To overcome the problem of clogging, the new valve introduces large-area diaphragms to create strong acting forces.

Design of the valve

The valve (Fig. 2) has a solid titanium casing to make its function independent of the subcutaneous pressure and to avoid the distortion of the device. In the middle of the valve a spherical body is integrated in the housing. Two mobile titanium plates are associated with this body in membranes made of silicone, which are fixed to the casing of the valve. Each plate together with the spherical body creates a valve seat. Two different springs with defined strength control the position of the plates. There is a stronger spring for the high-pressure chamber, and a weaker one for the low-pressure chamber. A tantalum ball is used to close the low-pressure chamber when the patient is in the erect position. Tantalum was used because of its high specific gravity.

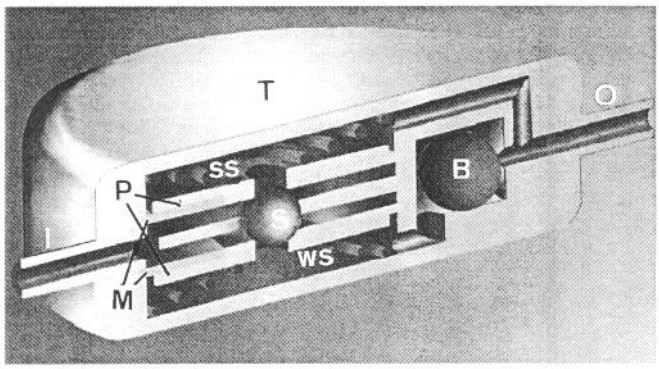

Fig. 2 Schematic cross section of the dual-switch valve (*T* titanium housing, *S* spherical body, *P* titanium plates, *M* membranes, *SS* strong spring, *WS* weak spring, *B* tantalum ball, *I* inlet, *O* outlet)

Function of the valve

Figures 3 and 4 illustrate the four possible adjustments of the valve depending on the posture of the patient and the IVP. If the patient is in the supine position (Fig. 3a) and the IVP stays in normal ranges, the springs are strong enough to press the titanium plates against the integrated spherical body, thus closing both valve chambers. If the IVP is higher than the strength of the weaker spring, the low-pressure chamber is opened and the CSF can pass to the distal tube connection passing the green tantalum ball, which is not closing the outlet cone in the horizontal position on the valve (Fig. 3b).

If the patient stands up (Fig. 4a), gravity moves the ball out of its place and closes the outlet of the low-pressure chamber. If the IVP plus the hydrostatic pressure does not exceed the pressure of the stronger spring, both valve chambers remain closed and the IVP is kept in physiological ranges. Finally, when the IVP reaches the opening pressure of the valve for the upright position overcoming the strength of the stronger spring, the high-pressure chamber opens (Fig. 4b).

Regulation of pressure

To achieve precise regulation of the opening pressures of both chambers and to avoid the problem of clogging, the newly designed valve introduces large-area diaphragms to create extensive acting forces. The area exposed to the fluid pressure is about 20–200 times that in conventional valves. On the other hand, the opening area of the DSV, which is exposed to sticking forces, is almost the same as in conventional valves. Therefore, the forces acting on the valve seat can overcome the sticking forces set up as a result of cell debris or viscous CSF. By this mechanism the IVP is maintained in physiological ranges independently of the CSF composition or rapid changes in CSF production rates.

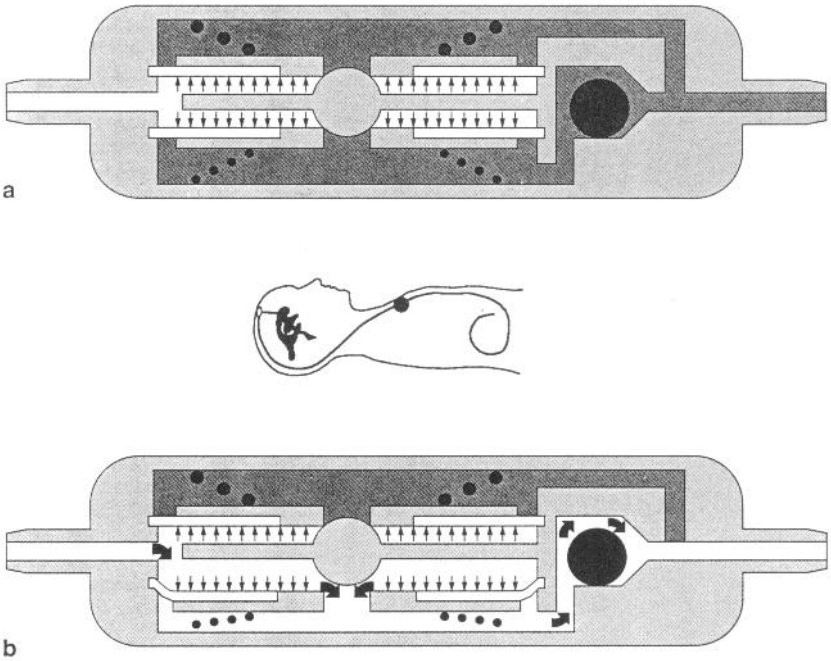

Fig. 3a, b Possible situations of the dual-switch valve with the patient in a horizontal position

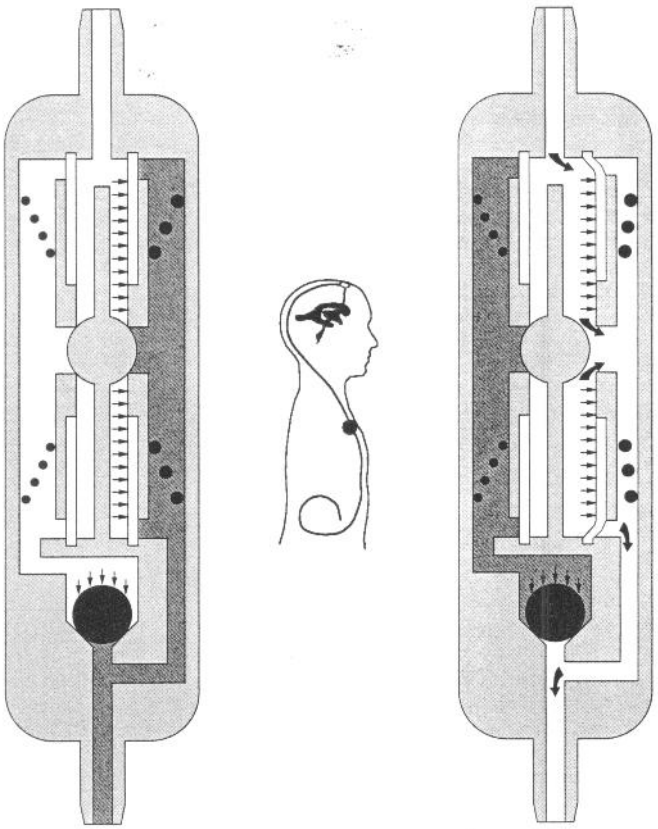

Fig. 4a,b Adjustments of the dual-switch valve with the patient in the sitting or standing position

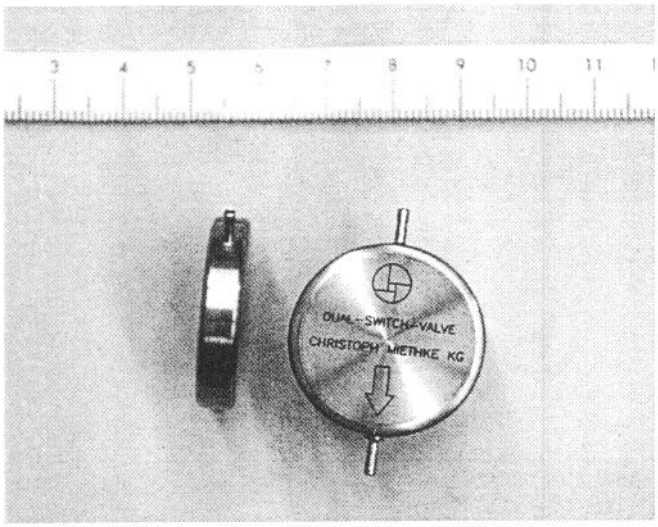

Fig. 5 Different views of the dual-switch valve with ruler to show dimensions

Closing mechanism

The new valve uses an inversion of the well-known principle of the ball-in-cone mechanism, which has proven effective in other devices. Whereas in normal ball-in-cone valves the ball is the mobile element, in our device the spherical body is fixed and the titanium plates are movable. High-precision sealing surfaces guarantee reliable closing properties, avoiding leakage.

Size of the valve and controls

Figure 5 depicts the original new valve. Because of the two chambers and the design principle with large diaphragms, the resulting size is 2.8 cm diameter and 0.53 cm thickness. This seems to be at odds with the worldwide tendency to minimize the size of neurosurgical tools, but in a similar way to cardiac pacemakers it can easily be implanted subcutaneously in the thoracic or abdominal region. In contrast to other hydrostatic devices (ASD, SCD, FRD), the function of the DSV does not depend on the level of implantation. Conventional X-rays (Fig. 6) allow not only a check for correct position and graduation of the valve, but also a test of the movements of the tantalum ball closing and opening the low-pressure chamber.

We also exposed the DSV to a 1.5-T MR to evaluate the size of artifacts and to compare the function of the valve before and after exposure to MR imaging. The artifacts produced by two of our new valves were no more extensive than those of other conventional metallic differential-pressure valves (DP valves) and smaller than those produced by adjustable devices (Fig. 7). Comparison of the function of the valve before and after exposure proved the reliability of the DSV and the resistance of the mechanical principle to exposure to MR (Fig. 8).

In vitro and in vivo tests

To analyze the function of the new valve, a computer-controlled test stand was developed offering the possibility of testing valves at close to physiological conditions [12]. Computer-controlled motors made it possible to simulate stepwise changes in posture. The results of the extensive in vitro testing in our computer-controlled test apparatus have been described elsewhere [12]. The results confirmed the capacity of the valve to maintain the IVP within physiological ranges independently of the induced flow or posture of the figure in our test stand. Compared with other devices, the new double-chamber valve had a superior performance in vitro (Figs. 9, 10). Whereas the DSV kept the IVP within physiological limits regardless of posture, a conventional valve demonstrated a drop of IVP to unphysiological values when the figure in our test bench was in a vertical position simulating the upright position of the patient.

As a first clinical investigation the new valve was tested by interposing the new device in external drainage systems. The upright position of the patient was simulated by changing the valve into the vertical position and lowering the outlet chamber (Fig. 11). Our preclinical test, which took the form of interposing the new valve in external drainage systems of hydrocephalic patients in our intensive care unit, proved the reliability of our valve, even in the presence of a very high protein content and cell count, as in case A (Table 2), when clogging would have been likely in a conventional valve (Fig. 12). This test also confirmed the capacity of the DSV to maintain the intracranial pressure within physiological limits independently of the simulated posture of the patient and the variable flow of CSF with high peaks during the night (Fig. 13).

After completion of our tests in external drainage systems, our valve was tested again in a computer-controlled test apparatus. The performance of all valves was as constant and reliable as before the beginning of the test (Fig. 14).

The excellent results of our in vitro and preclinical tests in external drainage systems encouraged us to start a clinical series. A clin-

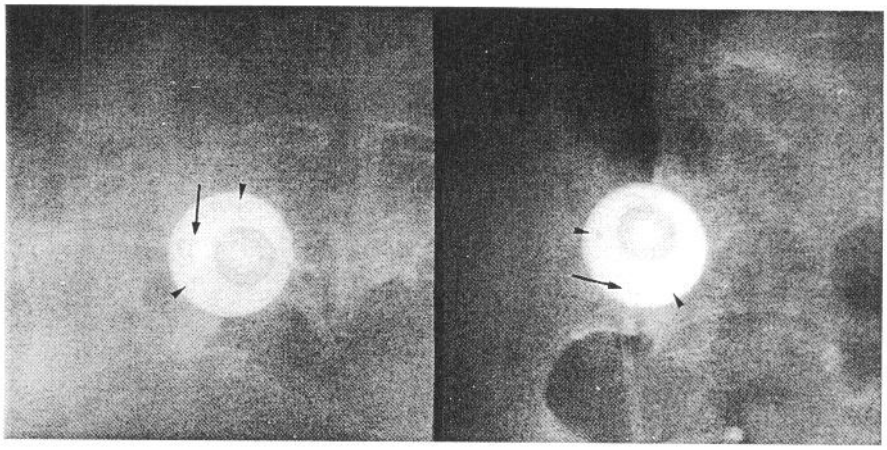

Fig. 6 Conventional X-rays of the same patient in left lateral and standing positions. Note markers for the pressure code of the valve (*arrowheads*) and switching of the tantalum ball in the outlet of the low-pressure chamber (*arrows*)

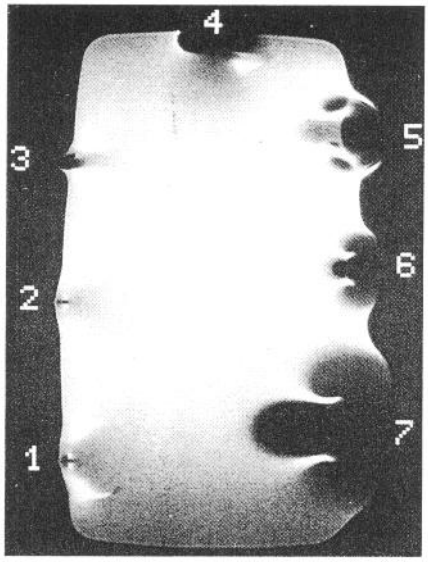

Fig. 7 Size of artifacts after exposure of different valves to a 1.5-T MR (T1-weighted image; *1, 2* dual-switch valves; *3* Holter; *4* Cordis standard; *5* Cordis Hydrostatic horizontal-vertical; *6* Codman-Medos-Hakim programmable; *7* Sophy SU 8-valves)

ical trial was started in early 1995. For ethical and forensic reasons, we implanted the new valve only in adult hydrocephalic patients.

The DSV was designed to be implanted subcutaneously in the abdominal or thoracic region (Fig. 15). These locations for the valve have two advantages: the trunk is an excellent indicator for the posture of the patient, and the subcutaneous tissue in this region allows the insertion of a larger valve with the benefit of large diaphragms creating extensive acting forces for opening and closing. These positive features outweigh the disadvantages of the relatively large size of the DSV and the increased danger of disconnection with physiological growing of the patient because of the resulting threepiece shunt. Implantation of the DSV was easily achieved without any difficulties, the average time needed to implant the DSV being 46 min, and none of the patients suffered an infection.

In Table 3 the trial patients are listed with their different etiologies and types of hydrocephalus. All patients had to undergo a clinical and computer tomographic test 14 days after implantation of the shunt, followed by evaluations 3 and 6 months postoperatively. The clinical test included an extensive neurological examination, neuropsychological tests and evaluation with reference to the Barthel Index. The surgical outcome was more than promising. Up to now, we have seen no surgical complications and none of the phenomena known to result from overdrainage (Table 3). Interestingly enough, the computer tomographic controls revealed only a slight reduction, if any at all, of ventricular size from the preoperative status in all cases but 1, accompanied by an excellent clinical result. An example is shown in Fig. 16, where there is no apparent regression of the ventricular dilatation. This patient (case 5) with a long-standing normal-pressure hydrocephalus was bedridden before the shunting procedure and could manage his household independently 3 months after the implantation of the DSV.

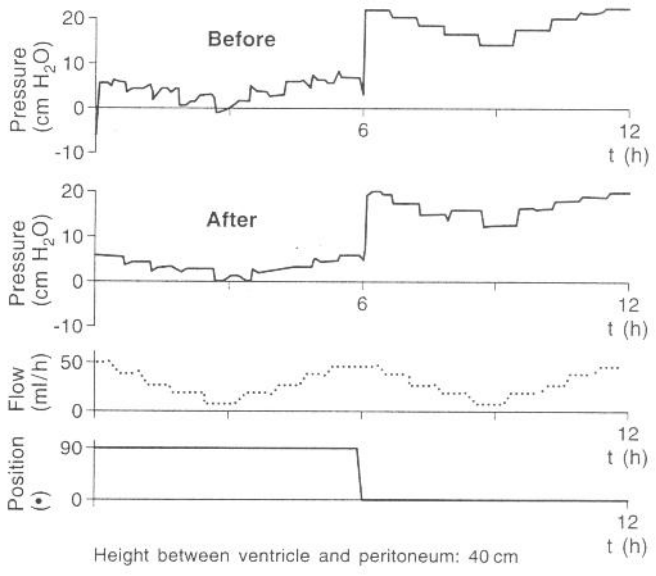

Fig. 8 In vitro test results before and after exposure of the dual-switch valve to a 1.5-T MR

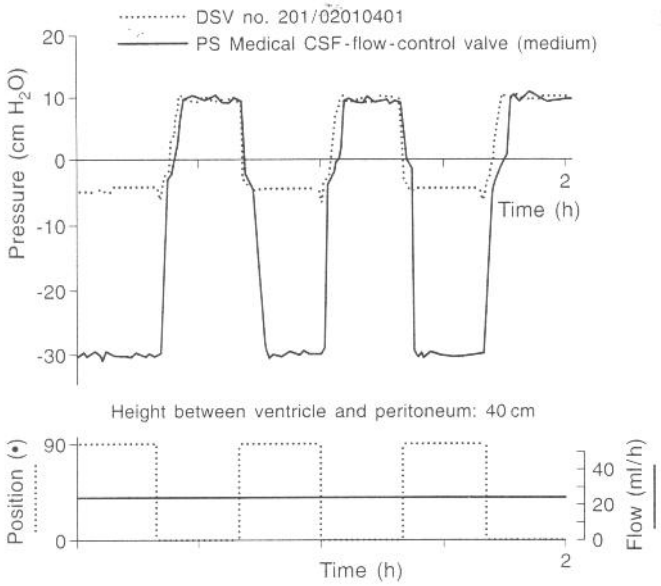

Fig. 9 In vitro test of the dual-switch valve and a conventional differential-pressure valve with changing position and constant flow

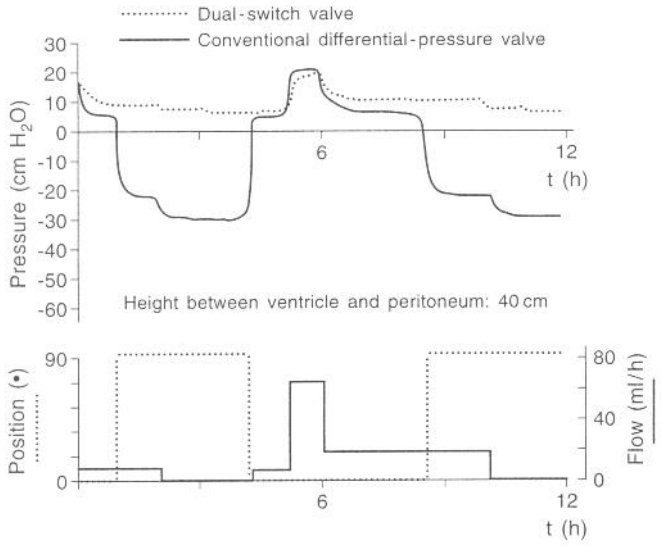

Fig. 10 Comparision of the dual-switch valve and a conventional differential-pressure valve with changing position and different flows

Discussion

To overcome the numerous problems associated with overdrainage, several devices with different design principles have been developed. There is no doubt that the ASD and the SCD can prevent or reduce overdrainage, but these devices depend heavily on atmospheric and subcutaneous

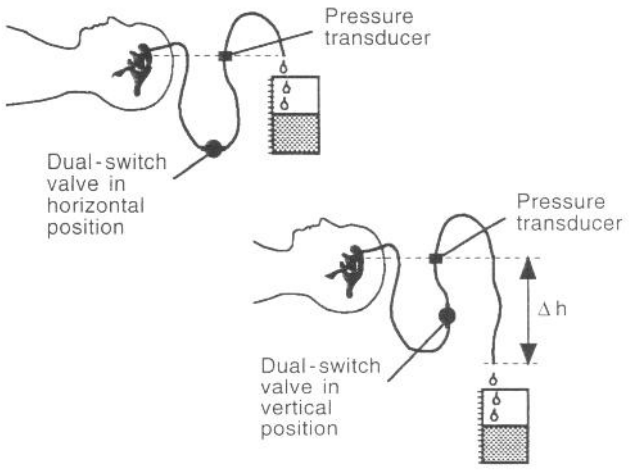

Fig. 11 Preclinical test of the dual-switch valve with simulation of supine and upright positions of the patient

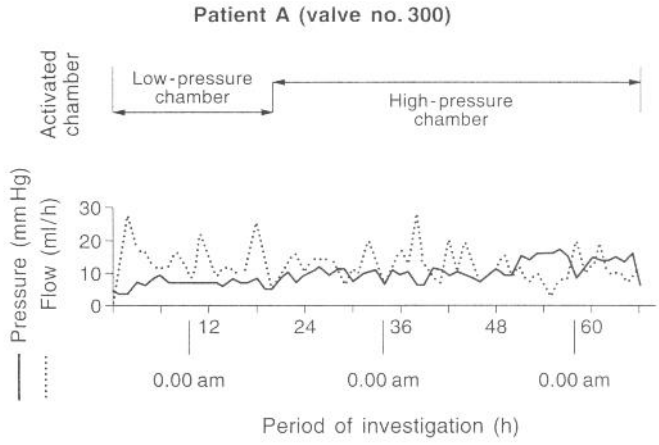

Fig. 12 Patient A: posthemorrhagic hydrocephalic patient with high cell count and protein content of the cerebrospinal fluid

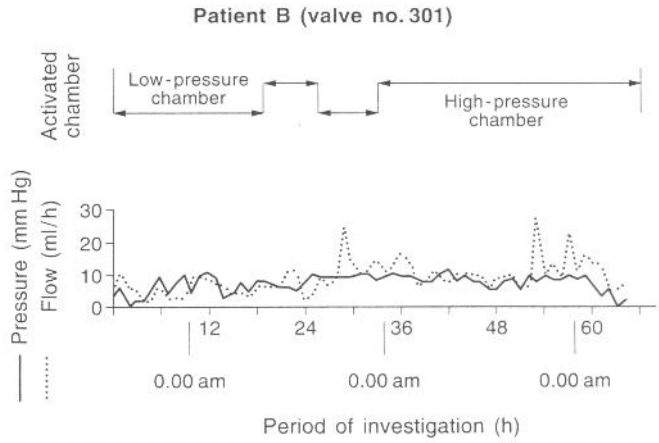

Fig. 13 Patient B: hydrocephalic patient after subarachnoid hemorrhage, with high peaks of cerebrospinal fluid flow around midnight

Table 2 Cerebrospinal fluid composition of three hydrocephalus patients treated with external drainage systems

	Day 1	Day 2	Day 3
Cell number (1/3 cells)			
Patient A (Valve no. 300)	1088	4250	2970
Patient B (Valve no. 301)	697	647	596
Patient C (Valve no. 302)	16	18	47
Protein (mg/dl)			
Patient A (Valve no. 300)	505	567	280
Patient B (Valve no. 301)	278	212	147
Patient C (Valve no. 302)	86	63	54

Table 3 Clinical data and outcome of hydrocephalus patients after implantation of a ventricular-peritoneal-shunt with a dual-switch valve (*NPH* normal-pressure hydrocephalus, *SAH* subarachnoid hemorrhage)

Case no.	Age	Sex	Etiology of hydrocephalus	Follow-up period (months)	Clinical outcome
1	46	F	Post-SAH	9	Good
2	62	F	Post-SAH	9	Good
3	34	F	Benign tumor in III ventricle	7	Excellent
4	26	F	Communicating with spina bifida	6.5	Excellent
5	79	F	Idiopathic NPH	4.5	Excellent
6	61	M	Idiopathic NPH	3	Excellent
7	65	M	Idiopathic NPH	11	Excellent
8	52	M	Post-traumic NPH	9	Excellent
9	30	F	Communicating with slit ventricle	5	Good
10	41	M	Post hemorrhagic	2	Excellent

pressure. Their function can be diminished because they are encapsulated in connective tissue, or they can be blocked if patients lie on them [2, 3, 12].

With its improved ratio between the size of the inlet and outlet chambers of the device and the creation of raised protective rings to hinder the influence of subcutaneous pressure, the Delta valve may be an improvement on the other anti-siphon devices, but the basic problem remains the same [3]. If an ASD or SCD is to be improved, this means improving its function quantitatively. However, the most important deficiency of these devices can only be

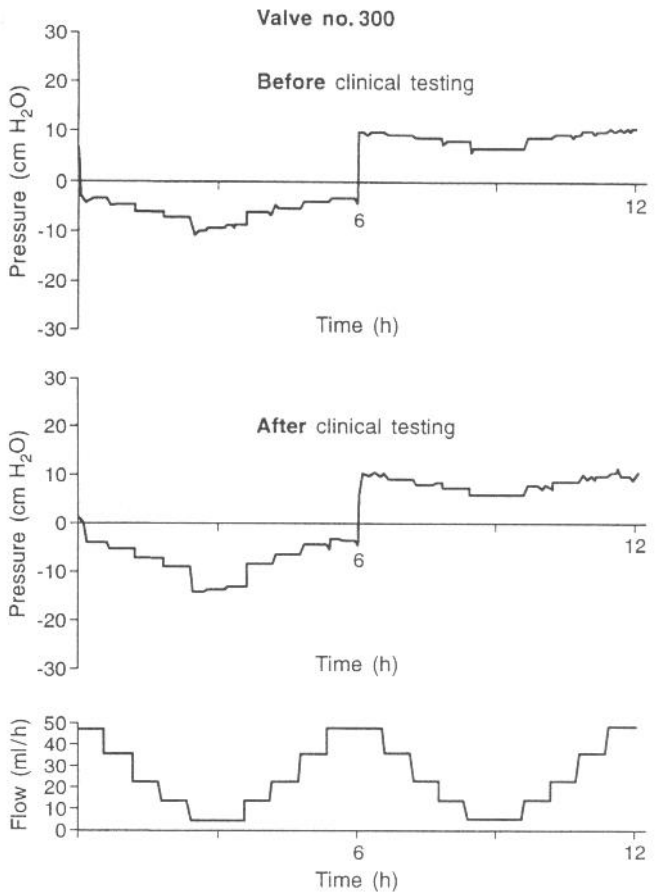

Fig. 14 In vitro test of a dual-switch valve before and after its interposition in an external drainage system for 72 h

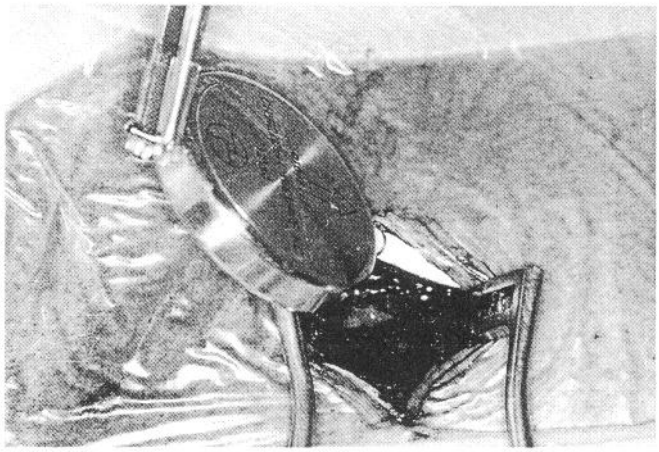

Fig. 15 Implanting the dual-switch valve in subcutaneous tissue of the lower thoracic region

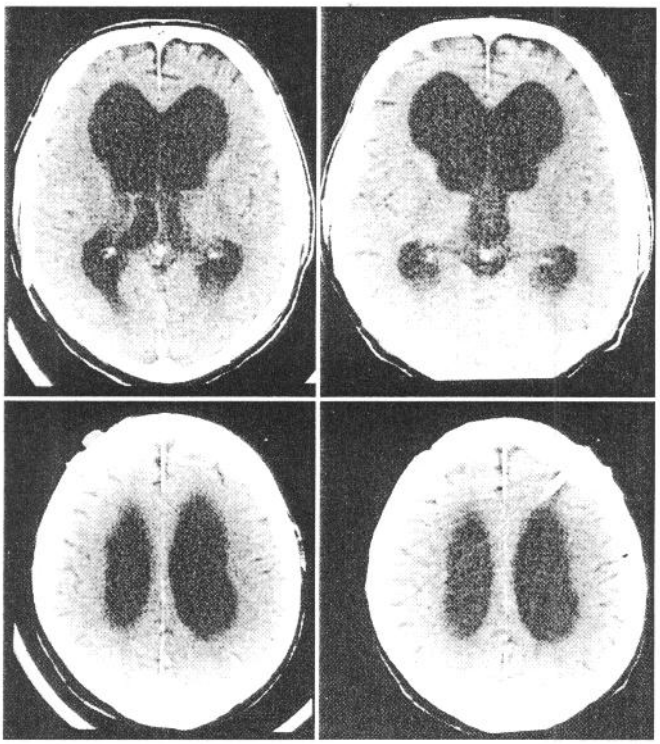

Fig. 16 Pre- and postoperative computed tomography of patient 5. Note the only minimal reduction of the ventricular size 6 months after implantation, paralleled by an excellent clinical result

ameliorated by changing the principle. The function of a long-term implant should not depend on the subcutaneous pressure, which will change unpredictably over wide ranges owing to growth of encapsulating connective tissue around the device, to extracellular fluid pressure or to the posture of the patient [2, 3, 12, 13, 17].

Because of its solid titanium housing, the DSV is independent of the pressure in the area surrounding the valve. In contrast to the ASD, the SCD and the Delta valve, the DSV can be implanted anywhere in the abdominal or thoracic region with no difference in function.

The Cordis-H-V and the Chhabra valves exploit the principle of the gravity-moved balls in a similar manner to the DSV, but with one major difference: whereas in the DSV the flow of the shunted CSF is downward when the patient is in the upright position, thus supporting the closing mechanism of the tantalum ball, in the two other valves the CSF flows against the closing mechanism activated by the gravity acting on the balls. Therefore, the design principle realized in the DSV means that the forces acting on the tantalum ball closing the low-pressure chamber become stronger with rising IVP and/or hydrostatic pressure. Thus, the danger that the closing mechanism will be influenced by normal activities of daily life, such as walking or running, is much lower with the DSV than with the other valves. Simulation of such normal daily activities in our test stand proved the superiority of the closing mechanism of the tantalum ball in the DSV over those in the Cordis-H-V and the Chhabra valves, thus relativizing the criticism of Aschoff et al. [3].

The principle of the Orbis-Sigma valve [17] has two important technical drawbacks:

1. It is claimed that the Orbis-Sigma valve regulates a physiological flow relatively independently of the differential pressure, but the CSF to be shunted depends not only on the differential pressure but also on the posture of the patient.

In the shunted patient there is a flow-balance between input and output. The input is determined by the rate of CSF production. The output depends on the physiological absorption of the patient and the physical properties of the shunt. To maintain the IVP in physiological limits the necessary flow through the shunt varies over a wide range, from 0.6 ml/h to 115.8 ml/h [9]. An ideal flow-regulating device would measure the actual production and absorption, and allow exactly the difference to pass through the shunt. The result would be an appropriate IVP. Because the individual production of CSF and its actual absorption cannot yet be measured, it is impossible to create an adequate flow-regulating device. Thus, the Orbis-Sigma valve is primarily not a flow-regulating device but a differential-pressure valve. The pressure difference acting on the shunt system determines the opening and closing performance of the device. The reasons for changes in differential pressure can be changes in posture, but also changes in the balance between CSF production and CSF absorption. The Orbis-Sigma device, like any other valve, is not able to distinguish between these possibilities. If the pressure difference on the valve is raised because the patient stands up, it is a reasonable response of the Orbis-Sigma valve to reduce the flow by narrowing the opening area of the valve seat. But if the rise in differential pressure is caused by an increasing imbalance between CSF production and absorption followed by a critical increase in IVP, the Orbis-Sigma valve would again reduce the flow by narrowing the opening area. This response is exactly the opposite of what is needed. During time intervals with high production rates the IVP could increase dangerously in patients with the Orbis-Sigma valve, up to values of about 40 cm H_2O when the "safety pressure level for stage III" [17] is reached.

2. The pressure-induced flow regulation is achieved by delicate changes in the small opening area in the valve seat, which leads to a significant rise in the danger of underdrainage, clogging and unintentional changes of valve function [2, 3, 18, 20].

If an Orbis-Sigma valve opens, the free cross section for flow through the valve seat amounts to a very few square micrometers. To double the flow only minimal enlargement of the opened area is needed. The implications of this for a device such as the Orbis-Sigma valve are twofold. On the one hand extremely high claims on tolerances are needed in manufacturing, and on the other – more impor-

tantly – such a device can easily be influenced by any small particle in the fluid, e.g. cell debris, or by changes in the viscosity of the fluid. Any change in the characteristics of the fluid has a potentially significant influence on the function of the valve as well as on the resulting IVP. Saint-Rose himself states a higher occlusion rate for the Orbis-Sigma valve than for other devices [16].

Our preclinical test of the DSV in external drainage systems of hydrocephalic patients with a high protein content of the CSF (Table 2) and the clinical trial up to now (Table 3) seem to prove the reliability of the principle of the large diaphragms combined with relatively large opening areas. In our opinion the advantages of this principle outweigh the drawback of the DSV's relatively large size.

The higher resistance of the DSV to CSF flow in the upright position compared with other valves should support the restoration of physiological absorption in the patient after shunting. Thus, the probability that active hydrocephalus will be changed to arrested hydrocephalus should be reinforced by the design principle of our valve, as has been demanded by several other workers [2, 4, 8, 10, 20].

The fact that excellent and good clinical results were accompanied by computer tomographic controls revealing only slight reduction of ventricular size, if any, compared with the preoperative status in the majority of cases support our experience, and that of several other authors, showing that narrow or slit-like ventricles are not the aim or a "reluctant" goal after shunting [7], but a sequela of overdrainage that should be considered a complication [6, 10, 16, 17, 19].

In conclusion, the two-chamber system, the large-area diaphragms, the improvement to the efficacious ball-in-cone system and the closing mechanism with the tantalum ball are the specific advantages our valve has over conventional devices. Our in vitro test and the preliminary clinical results give strong evidence for the capability of the DSV to maintain the IVP within physiological ranges independently of changes in CSF flow, posture, and composition of the CSF. The small number of patients and the short follow-up period do not allow definitive conclusions. We hope that a joint clinical trial now under way with the neurosurgical department of the University of Essen, with alternate implantation of the new DSV and conventional differential-pressure valves, will make it possible to present unequivocal results in the future.

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