

## Clinical Experience with a New Pressure-Adjustable Shunt Valve

A. Reinprecht, T. Czech, and W. Dietrich

Department of Neurosurgery, University of Vienna, Vienna, Austria

### Summary

The pressure-adjustable valve system Codman Medos allows valve pressure adjustment in 18 steps between 30 and 200 mm H<sub>2</sub>O. A series of 90 patients, 15 children and 75 adults, who were shunted with this new programmable valve, is reported. Indication for shunt insertion were various types of hydrocephalus in 79 cases, malfunction of a medium pressure membrane valve shunt system in 9 cases and an arachnoid cyst and pseudotumour each in one case. The valve pressure was programmed prior to insertion to 200 mm H<sub>2</sub>O in the adults and according to age in children and was modified postoperatively according to the clinical course.

Underdrainage with subdural fluid collections appearing in 5 patients could be managed by valve pressure adjustment alone in 2 cases. One malfunctioning of the valve mechanism was due to mechanical obstruction. At the time of follow-up, 7 to 29 months after operation, outcome was excellent in 64 patients, good with marked improvement but residual symptoms in 19 patients and unchanged in 7 patients.

The possibility of adjusting the valve pressure to the patient's demands was frequently used in children and adult normal pressure hydrocephalus patients with satisfying clinical results.

*Keywords:* Cerebrospinal fluid shunt; pressure-adjustable valve; hydrocephalus.

### Introduction

Since the introduction of valve-regulated shunt systems in the treatment of hydrocephalus many efforts have been made in shunt technology to approach physiological conditions. The problem of overdrainage of differential pressure valves created new concepts such as the anti-siphon device or the flow-regulated shunt system [5, 22–24]. But not all experiences have been as encouraging as the underlying theoretical considerations and some problems still remain unsolved [1, 2, 15, 19, 30].

Differential pressure valves have been designed to suite the individual patients cerebrospinal fluid (CSF)

hydrodynamics but the preoperative selection of the most suitable valve pressure type is still controversial [20, 29]. The introduction of pressure-adjustable valves offered the possibility to adjust noninvasively the opening pressure of the implanted valve to the patients' demands. The first pressure-adjustable valve, the Sophy SU8, offers three possibilities of pressure selection in clinical use: low (50 mmH<sub>2</sub>O), medium (110 mmH<sub>2</sub>O) and high (170 mmH<sub>2</sub>O). Especially in the treatment of normal pressure hydrocephalus and arachnoid cysts a certain clinical advantage was reported [17, 18, 26, 27].

A new programmable valve shunt system (Codman Medos, Medos S. A., Tournelles 17, 2400 Le Locle, Switzerland) is considered to facilitate a more precise pressure adjustment for the individual patient by 18 possible pressure selections between 30 mmH<sub>2</sub>O and 200 mmH<sub>2</sub>O (Fig. 1). Step by step adaption to hydrodynamic changes and a close approach to the patients' pressure demands are the specific facilities of the

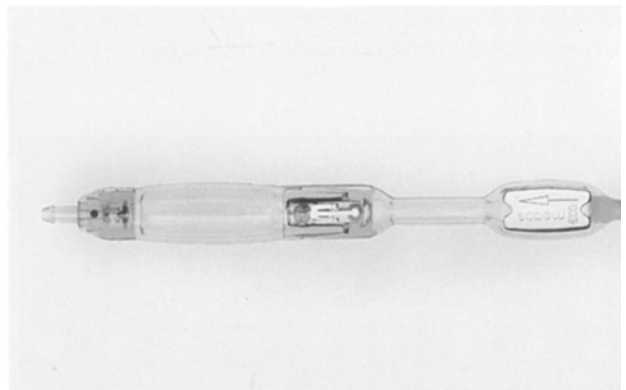


Fig. 1. The Codman Medos pressure-adjustable shunt valve

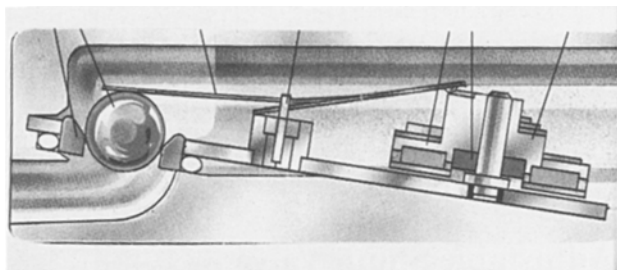


Fig. 2. Side view of the programmable mechanism of the inlet valve unit

valve that are considered to exceed the possibilities of a constant pressure valve type in spite of the proceedings made to select the proper valve pressure type. We report the results of the first two years of clinical use of this new programmable valve shunt system in the Department of Neurosurgery at the University of Vienna Medical School.

**Material and Methods**

*Valve Mechanism*

The programmable mechanism of the CodmanMedos programmable valve shunt system is based on a noninvasively adjustable pressure setting of a flat spring in the inlet valve unit (Fig. 2). The spring lies upon a synthetic ruby ball in a cone at the CSF inlet of the valve. A stepper motor within the valve housing changes the pressure setting of the spring if activated by an external programmer. The external programmer transmits a codified magnetic signal to the motor allowing eighteen valve operating pressure settings ranging from 30 mm to 200 mmH<sub>2</sub>O in 10 mm steps that have been determined with a flow rate of 15–25 mlH<sub>2</sub>O. The outlet valve consisting of a helical spring set at zero tension holding a ruby ball functions as a check valve. Prior to use the valve must be programmed to the desired pressure. After implantation of the valve the pressure can be adjusted by positioning the external programmer above the inlet valve which can be palpated transcutaneously. The desired pressure is chosen by depressing the pressure selector button. To check the selected pressure the pressure indicator on the white ring of the inlet valve is visible by x-ray (Fig. 3).

The valve unit is connected to a straight ventricular catheter by a straight stainless steel connector. A right angle adapter allows right angle bending of the ventricular catheter at the burr hole. The

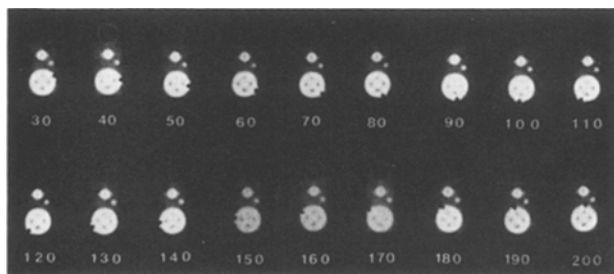
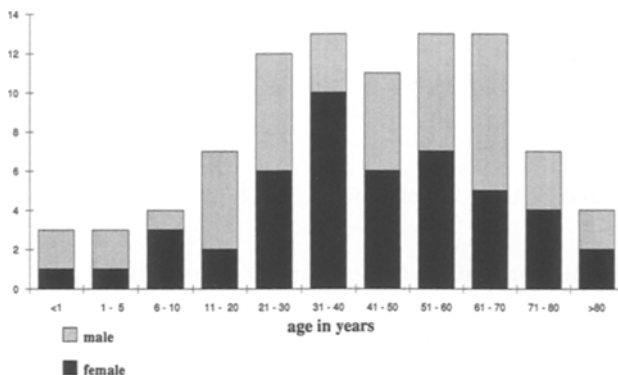


Fig. 3. Valve pressure settings as visible by x-ray

Table 1. Age Distribution of 90 Patients with CodmanMedos Valve Shunts



drainage catheter of the shunt system can be used for atrial or peritoneal placement showing four rows of three slits on one end.

*Selection of Patients*

Between February 1992 and December 1993 47 female and 43 male patients were chosen for shunt surgery with the Medos programmable valve system. The age range was 7 weeks to 85 years, median 43.5 years (Table 1). Fifteen patients were children younger than 16 years. In this patient group hydrocephalus was caused by neoplasms in 5 cases, perinatal intraventricular haemorrhage in 2 cases and spina bifida and aqueductal stenosis each in one case. Treatment was performed by ventriculo-atrial shunting in 5 patients and by ventriculoperitoneal shunting in 4 patients. Congenital unilateral hydrocephalus was treated by ventriculo-atrial shunting in two patients. Two children had congenital midline cysts, treated with cysto-atrial and ventriculo-atrial shunting in one of them and by ventriculoperitoneal shunting alone in the other. In two children with overdrainage phenomena a medium pressure membrane valve was replaced by a programmable valve (Table 2).

In the adults the aetiology of communicating hydrocephalus was idiopathic normal pressure hydrocephalus (INPH) in 32 cases, posthaemorrhagic in 12 cases, neoplastic in 5 cases and posttraumatic in 3 cases. Occlusive hydrocephalus was caused by neoplasms in 9 patients and by cerebellar infarction or haemorrhage in 3 patients. Atrial placement of the drainage catheter was preferred. One cysto-atrial shunt was implanted in a patient with a temporal arachnoid cyst and one lumboperitoneal shunt was inserted in a patient with pseudotumor. Additional indications for insertion of a Codman Medos programmable valve shunt were overdrainage of medium pressure membrane valve shunt systems in two patients

Table 2. Diagnosis in 15 Children

Diagnosis	Number of patients
Neoplastic hydrocephalus	5
Posthaemorrhagic hydrocephalus	2
Congenital unilateral hydrocephalus	2
Spina bifida	1
Aqueductal stenosis	1
Congenital cysts	2
Shunt overdrainage	2

Table 3. *Diagnosis in 75 Adults*

Diagnosis	Number of patients
INPH	32
Neoplastic hydrocephalus	14
Posthaemorrhagic hydrocephalus	12
Posttraumatic hydrocephalus	3
Cerebellar infarction or haemorrhage	3
Shunt overdrainage	2
underdrainage	7
Pseudotumour	1
Arachnoidal cyst	1

and chronic underdrainage in 7 patients with congenital hydrocephalus (Table 3).

In all adult patients the valve pressure was programmed to 200 mmH<sub>2</sub>O prior to insertion. In children the valve pressure was programmed to different levels according to age and ventricular size. After insertion the pressure setting was adjusted according to the clinical course. The follow-up period was 7 to 29 months (median 13 months).

## Results

### Complications

Complications occurring in 11 patients are listed in Table 4. The infection rate is 4.4%. All patients with infections were treated by explantation of the infected shunt system, external ventricular drainage and systemic and intrathecal application of antibiotics. After successful therapy a new programmable shunt system was inserted in all four patients.

Overdrainage phenomena with subdural fluid collections appeared in 5 patients, 3 children, and 2 adults. In two children small subdural hygromas presenting with mild symptoms disappeared by adjustment of the valve pressure setting to higher levels. In one child burr hole drainage of the subdural hygroma and implantation of a new valve became necessary because the implanted valve could not be adjusted by the external programmer and remained at the level of 100 mmH<sub>2</sub>O. This was the only malfunctioning of the

Table 4. *Postoperative Complications*

Complication	Number
Infection	4
Subdural effusion	5
Catheter obstruction	
ventricular	1
peritoneal	1
Total	11

the valve mechanism in our series. Two adult patients needed operation because of symptomatic space-occupying subdural haematomas.

Peritoneal catheter obstruction and ventricular catheter obstruction were the reason for shunt underdrainage needing re-operation in two cases.

### Outcome

In sixty-four patients the result was excellent with complete reversal of clinical signs and symptoms. Improvement with residual symptoms was seen in 19 patients. Eleven patients with INPH showed good improvement with residual mild memory impairment or gait disturbance. Three patients with neoplastic hydrocephalus showed remaining psychomotor deficit and four patients with posthaemorrhagic hydrocephalus suffered of residual headache. One 16 year old girl with severe low intracranial pressure syndrome showed slow but marked improvement after insertion of the programmable valve system and various pressure adjustments but still complains about some headache.

Seven adult patients did not show any clinical improvement after the shunting procedure. Two of them are apallic being in a long-term rehabilitation programme. Five patients with normal pressure hydrocephalus (NPH) showed no improvement of the neurologic deficits inspite of various pressure adjustments.

### Valve Operating Pressure

In all children the valve pressure was adjusted at least once. In 7 children it was adjusted two or three times and in 5 children more than three times. The pressure setting at the time of follow-up is listed in Table 5.

The valve pressure was never adjusted after insertion in 20 adult patients and thus remained at the level of 200 mmH<sub>2</sub>O (Table 6). All patients with obstructive hydrocephalus due to cerebellar infarction or haemorrhage and half of the patients with neoplastic hydrocephalus (n = 7) are in this group as well as one third of the patients with posthaemorrhagic hydrocephalus (n = 4). Only 12.5% of the patients with INPH (n = 4) had no pressure adjustment during the follow-up period.

Pressure was adjusted only once within two weeks after operation in 23 patients, among them being half of the patients with posthaemorrhagic hydrocephalus (n = 6) and 28.5% of the patients with neoplastic

Table 5. Valve Pressure Selection at the Time of Follow-up

Valve pressure (mmH <sub>2</sub> O)	30–50	60–80	90–110	120–140	150–170	180–200
Children (n)	3	4	1	2	5	0
Adults (n)	1	3	4	11	30	26

Table 6. Number of Valve Pressure Adjustments During the Follow-up Period

Valve pressure adjustment (n)	0	1	2 or 3	>3
Children (n)	0	3	7	5
Adults (n)	20	23	24	8

hydrocephalus (n = 4) as well as 21.8% of INPH patients (n = 7). In half of the INPH patients (n = 16) and 21.5% of the patients with neoplastic hydrocephalus (n = 4) valve pressure was adjusted two or three times. In 5 INPH patients valve pressure was adjusted more than three times. Although the valve operating pressure was adjusted more than once in 21 of the INPH patients (65.6%) the finally selected operating pressure at the time of follow-up was above 150 mmH<sub>2</sub>O in 27 patients (84.4%). Only in 6 adult patients the valve was adjusted to an operating pressure below 120 mmH<sub>2</sub>O, four of them treated for INPH, one for shunt dysfunction after congenital hydrocephalus and one for an arachnoid cyst.

## Discussion

Clinical experience and experimental findings provide a rather detailed knowledge and understanding of the hydrodynamics and biomechanics of the cranial cavity [3, 4, 8, 10, 13, 21, 28]. Advanced understanding was accompanied by new concepts in the management of hydrocephalus [4, 9, 12, 14] and by improvement in shunt technology [5, 11, 22, 23, 25]. Based on his interpretations of the pathophysiology of hydrocephalus S. Hakim searched for a valve adaptable to changing hydrodynamic conditions [11]. To keep the forces between CSF and venous system balanced in the shunted patient changing the valve opening pressure should be possible when the ventricular size reduces. In a growing child a valve pressure adaptable to the physiologically expected increase in intracranial pressure in accordance to age is considered to diminish problems of shunt dependency and symptoms of chronic overdrainage.

The first commercially available shunt system that

realized this therapeutical concept was the Sophy SU8. Since 1985 it offers the possibility of adjusting the valve opening pressure by an external programmer to low, medium and high pressure levels corresponding to 50, 110, and 170 mmH<sub>2</sub>O [1, 2, 6, 17, 18, 26, 27]. As the convincing advantage in postoperative management certain complications due to overdrainage could be solved noninvasively by valve pressure adjustment [6, 26, 27]. In our series a failure of the programming mechanism prevented the possibility of managing one case of subdural fluid collections in a 8 year old girl by pressure adjustment. The failure was due to mechanical blockage of the cam axis by a tiny tissue particle. Subdural effusions related to low valve opening pressure is reported by Kuurne *et al.* [16]. Most authors stress the problem of siphoning in differential pressure valves [22–25]. But the anti-siphon device, the temporary occlusive valve or the flow-controlled Orbis-Sigma valve could not totally avoid the development of subdural haematomas [7, 22, 30]. Only the avoidance of opening the subdural space and of loss of CSF during operation could solve this problem, which is difficult to achieve [22]. Space-occupying haematomas presenting with severe symptoms as in two cases of our series need operative drainage.

A pressure-adjustable valve appears to be beneficial especially for patients treated for NPH and for arachnoid cysts [26]. This is confirmed by our experience in the treatment of NPH. The Codman Medos valve, one of the most accurately constructed valve systems as in vitro tests confirm [2] is of special benefit in clinical use by its accurate adjustment to the patient's pressure demands. Compared to the patients with other types of hydrocephalus valve pressure adjustment was performed more frequently in INPH

patients and finally led to good results. Twenty-seven patients (84.4% of all INPH patients) showed complete disappearance of at least two major symptoms (dementia, gait disturbance or urinary incontinence). McQuarrie reported a good outcome in 70% of patients with a non-advanced NPH (without urinary incontinence) shunted with a low pressure valve while patients shunted with a medium pressure valve showed improvement only in 39% [20]. In contrast 75% of the NPH patients with complete disappearance of symptoms and 81.8% of NPH patients with improved but residual symptoms in our series did best with pressure levels above 150 mmH<sub>2</sub>O. Similar observations were made by Larsson [17] who implanted a Sophy SU8 valve with good results at a high pressure level and without further improvement at lower levels. To us it was surprising that no deterioration with lower pressure levels was reported as we observed some NPH patients reacting very sensitive to reduced valve pressure which might be due to different flow characteristics of both valves.

MRI may change the selected valve pressure as in the other adjustable valve [18, 26, 27] and x-ray is necessary after each MRI scanning to control the valve pressure setting. The need of x-ray to make the selected pressure adjustment visible is a certain disadvantage in practical use. No change of the selected pressure setting by common magnetic fields to which the patient is exposed in daily life was observed.

In our series we could show encouraging results in the treatment of children. The design of the valve allows insertion even in small infants without technical problems and without cutaneous complications. The risk of such complications due to the size and rigidity of the Sophy SU8 valve limited its use in pediatric patients [26]. Due to the length of the Medos valve a frontal placement is to prefer. If the possibility of adapting the valve pressure to the physiological increase of intracranial pressure in children with advancing age will decrease the sequelae of chronic overdrainage needs further investigation in a long-term follow-up study.

## References

1. Aschoff A, Benesch C, Kremer P, von Haken MS, Klank A, Osterloh M, Fruh K (1993) The solved and unsolved problems of hydrocephalus valves: a critical comment. *Advances in Neurosurgery*, Vol 21. Springer, Berlin Heidelberg New York Tokyo, pp 103–114
2. Aschoff A, Kramer P, Benesch C, Klank A (1991) Shunt-technology and overdrainage—a critical review of hydrostatic, programmable and variable-resistance valves and flow-reducing devices. *Eur J Pediatr Surg* 1 [Suppl 1]: 49–50
3. Barnett GH, Hahn JF, Palmer J (1987) Normal pressure hydrocephalus in children and young adults. *Neurosurgery* 20: 904–907
4. Brogesen SE, Gjerris F (1987) Relationships between intracranial pressure, ventricular size, and resistance to CSF outflow. *J Neurosurg* 67: 535–539
5. Chabra DK, Agrawal GD, Mittal P (1993) “Z” flow hydrocephalus shunt, a new approach to the problem of hydrocephalus, the rationale behind its design and the initial results of pressure monitoring after “Z” flow shunt implantation. *Acta Neurochir (Wien)* 121: 43–47
6. Dietrich U, Lumenta C, Sprick C, Majewski B (1987) Subdural hematoma in a case of hydrocephalus and macrocrania. Experience with a pressure-adjustable valve. *Childs Nerv Syst* 3: 242–244
7. Faulhauer K, Schmitz P (1978) Overdrainage phenomena in shunt treated hydrocephalus. *Acta Neurochir (Wien)* 45: 89–101
8. Gaab MR (1981) Die Registrierung des intrakraniellen Druckes, Grundlagen, Ergebnisse und Möglichkeiten. *Habil. Schrift, Medizinische Fakultät, Würzburg*
9. Gaab MR, Koos WT (1984) Hydrocephalus in infancy and childhood: diagnosis and indication for operation. *Neuropediatrics* 15: 173–179
10. Hakim C (1985) The physics and pathophysiology of the hydraulic complex of the central nervous system. The mechanics of hydrocephalus and normal pressure hydrocephalus. Ph D Thesis, Massachusetts Institute of Technology
11. Hakim S (1969) Observation on the physiopathology of the CSF pulse and prevention of ventricular catheter obstruction in valve shunts. *Develop Med Child Neurol* 11 [Suppl 20]: 42–48
12. Hakim S, Duran de la Roche F, Burton JD (1973) A critical analysis of valve shunts used in the treatment of hydrocephalus. *Develop Med Child Neurol* 15: 230–255
13. Hakim S, Venegas JG, Burton JD (1976) The physics of the cranial cavity, hydrocephalus and normal pressure hydrocephalus: mechanical interpretation and mathematical model. *Surg Neurol* 5: 187–210
14. Kosteljanetz M (1985) Resistance to outflow of cerebrospinal fluid determined by bolus injection technique and constant rate steady infusion in humans. *Neurosurgery* 16: 336–340
15. Kremer P, Aschoff A, Kunze S (1991) Therapeutic risks of anti-siphon devices. *Eur J Pediatr Surg* 1 [Suppl 1]: 47–48
16. Kuurne T, Servo A, Porras M (1983) Subdural effusions reappearing after shunts in patients with non-tumoral stenosis of the aqueduct. *Acta Neurochir (Wien)* 67: 127–134
17. Larsson A, Jensen C, Bilting M, Ekholm S, Stephensen H, Wikkelsö C (1992) Does the shunt opening pressure influence the effect of shunt surgery in normal pressure hydrocephalus? *Acta Neurochir (Wien)* 117: 15–22
18. Lumenta CB, Roosen N, Dietrich U (1990) Clinical experience with a pressure-adjustable valve Sophy in the management of hydrocephalus. *Childs Nerv Syst* 6: 270–274
19. McCullough DC (1986) Symptomatic progressive ventriculomegaly in hydrocephalics with patent shunts and antisiphon devices. *Neurosurgery* 19: 617–621
20. McQuarrie IG, Sainte-Luise L, Scherer P (1984) Treatment of

normal pressure hydrocephalus with low versus medium pressure cerebrospinal fluid shunts. *Neurosurgery* 15: 484–488

21. Penn RD, Bacus JW (1984) The brain as a sponge: a computed tomographic look at Hakim's hypothesis. *Neurosurgery* 14: 670–675
22. Portnoy HD, Schulte RR, Fox JL, Croissant PD, Tripp L (1973) Anti-siphon and reversible occlusion valves for shunting in hydrocephalus and preventing post-shunt subdural hematomas. *J Neurosurg* 38: 729–738
23. Portnoy HD, Tripp L, Croissant PD (1976) Hydrodynamics of shunt valves. *Childs Brain* 2: 242–256
24. Pudenz RH, Foltz EL (1991) Hydrocephalus: overdrainage by ventricular shunts. A review and recommendations. *Surg Neurol* 35: 200–212
25. Sainte-Rose C, Hooven MD, Hirsch JF (1987) A new approach in the treatment of hydrocephalus. *J Neurosurg* 66: 213–226
26. Sindou M, Guyotat-Pelissou I, Chidiac A, Goutelle A (1993) Transcutaneous pressure adjustable valve for the treatment of

hydrocephalus and arachnoid cysts in adults. *Acta Neurochir (Wien)* 121: 135–139

27. Sutcliffe JC, Battersby RDE (1992) Do we need variable pressure shunts? *Br J Neurosurg* 6: 67–70
28. Tans JTJ, Poortvliet DCJ (1989) Relationship between compliance and resistance to outflow of CSF in adult hydrocephalus. *J Neurosurg* 71: 59–62
29. Walsh JW, James HE (1982) Subtemporal craniectomy and elevation of shunt valve opening pressure in the management of small ventricle-induced cerebrospinal fluid shunt dysfunction. *Neurosurgery* 10: 698–703
30. Wiedemayer H, Sackers S (1993) Clinical experience with a new flow-regulating hydrocephalus shunt system. *Advances in Neurosurgery*, Vol 21. Springer, Berlin Heidelberg New York Tokyo, pp 151–155

Correspondence: Andrea Reinprecht, M.D., Department of Neurosurgery, University of Vienna Medical School, Währinger Gürtel 18–20, A-1090 Wien, Austria.