Incidence and management of subdural hematoma/hygroma with variable- and fixed-pressure differential valves: a randomized, controlled study of programmable compared with conventional valves

Peter W. Carmel, M.D., D.Med.Sc., A. Leland Albright, M.D., P. David Adelson, M.D., Alexa Canady, M.D., Peter Black, M.D., William Boydston, M.D., David Kneirim, M.D., Bruce Kaufman, M.D., Marion Walker, M.D., Mark Luciano, M.D., Ph.D., Ian F. Pollack, M.D., Kim Manwaring, M.D., M. Peter Heilbrun, M.D., I. Richmond Abbott, M.D., and Harold Rekate, M.D.

University of Medicine and Dentistry of New Jersey, Newark, New Jersey; Columbia Presbyterian Hospital, New York, New York; Children's Hospital of Michigan, Detroit, Michigan; Children's Hospital and Brigham & Women's Hospital, Boston, Massachusetts; Scottish Rite Children's Hospital, Atlanta, Georgia; Loma Linda University Children's Hospital, Loma Linda, California; St. Louis Children's Hospital, St. Louis, Missouri; Primary Children's Hospital, Salt Lake City, Utah; Cleveland Clinic Foundation, Cleveland, Ohio; Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania; Phoenix Children's Hospital, Phoenix, Arizona; University of Utah, Salt Lake City, Utah; New York University Medical Center/Beth Israel Hospital North, New York, New York; St. Joseph's Hospital and Medical Center, Phoenix, Arizona

Shunt systems with differential pressure valves are prone to the complications of overdrainage. A programmable valve permits adjustment of the opening pressure of the valve. In this paper the authors report the incidence of subdural fluid collections in a randomized trial of programmable compared with conventional valves, and they describe methodologies used in management of this complication.

A multiinstitutional, prospective, randomized trial of the Codman Hakim programmable valve and conventional fixed-pressure valves was undertaken. Two classes were defined: "new" and "replacement" valves. Randomization of the type of valve in each group was performed at each study site. Clinical and radiological studies were required at fixed intervals over a 104-week period. All complications were reported. The experimental valves were required to be reprogrammed after magnetic resonance imaging studies, but all other decisions regarding pressure setting were left to each investigator.

Three hundred seventy-seven patients were randomized; 194 were treated with a programmable valve and 183 with a fixed-pressure valve. The two groups were statistically similar in demographic composition, as were the "new" and "replacement" categories. The investigators made 540 valve pressure changes (five per patient; range one-41 changes). More than half of the reprogramming adjustments were made in the first 3 months postplacement; 70% were made within 6 months. More than half of all

reprogramming adjustments were required in a group of 30 patients.

Four treatment modalities were observed: 1) 30% of the fluid collections resolved spontaneously (25% in the patients with programmable valves and 36.3% in those with conventional valves) and were largely found to be hygromas in infants and children; 2) four subdural fluid collections were unresolved and under observation; 3) the subdural hematoma was drained and the shunt removed (in 8.3% of patients with the programmable valve and 36.3% of those with the control valve); 4) the pressure of programmable valve was raised in 58% of patients (seven of 12), and this increase in opening pressure was a feature used by investigators to affect treatment.

There was no significant difference in the incidence of subdural fluid collections between the programmable and fixed-pressure valve treatment groups. The programmable feature provided a considerable advantage in treatment when subdural collections occurred.

Key Words * hydrocephalus programmable valve * subdural fluid collection * shunt complication

Cerebrospinal fluid (CFS) shunting is one of the most important procedures in the neurosurgical armamentarium, exceeding any other cranial operation in the number of lives saved and neurological function preserved. However, the operation continues to be associated with a series of well-known complications.[1,2,7,11,12,14,15,22,27] Differential-pressure valves that open when the drop in pressure across the valve exceeds a certain point are particularly prone to complications of overdrainage, including subdural hematoma or hygroma, slit ventricles, and low-pressure headaches. Underdrainage results in persistent ventriculomegaly.[2,3,7,9,12,17,19,22,27,30,31] Both siphon-controlled and flow-regulated valves do not escape these types of complication.[10,14,26,35] A programmable shunt valve allows the surgeon to adjust the opening pressure of the shunt. Two models are readily available: the Sophy valve, which has four pressure settings, and the Codman Hakim programmable valve (Johnson and Johnson, Raynham, MA) which has 17 settings.[4,29] A multiinstitutional, prospective, randomized controlled trial was undertaken to analyze the safety and efficacy of the Codman Hakim programmable valve in comparison with conventional valves.[26] A system for the rigorous reporting at regular intervals of shunt-related complications was required. The follow-up period was 104 weeks. In this paper we will describe the incidence of subdural hematoma/hygroma in two groups of patients: those with the programmable and those with fixed-pressure valves. We will also discuss the strategies used by the surgeons to correct this complication, and six illustrative cases will be used to highlight the treatment strategies.

CLINICAL MATERIAL AND METHODS

In the patients who were enrolled in the study either a ventriculoatrial or ventriculoperitoneal shunt was required to control hydrocephalus. The surgeon chose patients whom he believed required a valve opening pressure between 30 mm H₂O and 200 mm H₂O. Patients undergoing anticoagulant drug therapy, those with known bleeding disorder, an active infection, or those required two valves simultaneously were excluded from the study. Patients or their families were told the follow-up period would be for 24 months and that follow-up evaluation was required. Randomization was stratified at each study site. The patient's status was classified as "replacement" if he or she had previously had undergone placement of a shunt for hydrocephalus. The status of those with no prior history of shunt placement was classified as "new." Patients were randomized to undergo shunt system placement with a Codman Hakim programmable valve or a commercially available nonprogrammable valve within each of these two

subgroups.

The study required that the programmable valve in all patients in whom it had been placed be reprogrammed after any imaging study because of concern that the valve setting would alter in the magnetic field.[13,20,23] Other than this instruction, decisions regarding the programmable valve pressures were left entirely to the respective investigator's judgement.

Clinical evaluation was required at 1, 3, 6, 12, 18, and 24 months postoperatively. Further follow-up visits were left to the investigator's discretion as warranted by the patient's clinical situation. At each visit the patient's clinical signs and symptoms were recorded, and the investigators were asked to evaluate whether the patient was "well" or "symptomatic," and if symptomatic, whether these symptoms were related to the shunt system. Radiological studies were required at the 3-, 12-, and 24-month follow-up visits. In these studies, the ventricular size was qualitatively designated by the investigator. All changes in the setting of a programmable valve had to be reported as part of the study protocol. All complications and shunt revisions in both groups were reported. Complications included hemorrhage, malabsorption of CSF, subdural hematoma/hygroma, neurological deficits, catheter perforation, foreign body reaction, infection, and "other" complications.

The programmable and conventional-valve groups were statistically equivalent in terms of age at enrollment, age at diagnosis, weight, height, and gender. The primary purpose of the study was to evaluate the safety and efficacy of the Codman Hakim programmable valve system in comparison with conventional fixed-pressure valves in shunt systems used to treat hydrocephalus. The study was conducted under a Food and Drug Administration-approved investigational group exemption. The investigators' group also felt it might be possible within the study to identify clinical situations in which the use of a shunt system with a programmable valve would confer a therapeutic advantage over those with conventional valves.

ILLUSTRATIVE CASES

The following six cases illustrate the use of the programmable valve in the treatment of subdural fluid collections. Two of the cases (Cases 1 and 5) come from a small earlier feasibility study. Other cases from this early study have been reported.[5] The patients in Cases 2 and 3 took part in the multiinstitutional randomized study. The patients in Cases 4 and 6 were treated after the release of the valve for commercial use. Only the patients in Cases 2 and 3 are included in the analysis described in the **Results** section; the other cases are offered to illustrate the treatment strategies.

Several methods have been described for accurate measurement of ventricular pressure in a patient undergoing operation.[27,34] In the illustrated cases the patients were supine with the shoulder elevated on the side in which the shunt was placed. This allowed the head to be in the horizontal position, with the sagittal sinus parallel to the floor. Endotracheal inhalation technique was used, as was direct catheter measurement of ventricular pressure. The manometer was adjusted to the height of the foramen of Monro. At the time of measurement, end-tidal PCO₂ was adjusted to be 35 to 37 mm Hg.

To allow "impedance matching" between the intraventricular pressure and the valve setting, the operation was initiated by placing a precoronal burr hole. The ventricular pressure was measured, and the valve was then set using the outer, nonsterile plastic case, thus assuring accurate valve setting. The package was opened and the sterile contents passed to the field.

Case 1

This boy was noted to have progressive head enlargement shortly after birth. Magnetic resonance (MR) and computerized tomography (CT) studies obtained at age 4 months revealed massive dilation of the lateral and third ventricles with an obstructed aqueduct (Fig. 1 upper left). His neurosurgeon placed a shunt system with a conventional high-pressure valve. There was continued growth of the head, and follow-up imaging study performed 5 months after placement of his original shunt demonstrated no decrease in ventricular size. The surgeon then replaced the high-pressure valve with a low-pressure valve. Two months after the shunt revision, a CT scan revealed normal-sized ventricles and bilateral subdural hygromas (the patient was now age 11 months). At age 13 months the child experienced intermittent vomiting and increased irritability. A new scan revealed slit ventricles with larger bilateral subdural hygromas (Fig. 1 upper right). The valve was replaced with a programmable valve when the patient was 14 months of age, and the subdural hygromas were drained. The valve was programmed at a pressure setting of 120 mm H₂O.

Fig. 1. Case 1. Imaging studies. Upper Left: An MR image obtained in the patient at 4 months of age revealing massive dilation of the lateral and third ventricles with an obstructed aqueduct. Upper Right: A CT scan obtained at age 13 months when the child experienced intermittent vomiting and an increase in irritability, revealing slit ventricles with larger bilateral subdural hygromas. Lower Left: CT scan. The low-pressure valve was replaced with a programmable valve when the patient was 14 months of age, and the subdural hygromas were drained. The valve was programmed at a setting of 120 mm of H₂O. Two months later the ventricles had enlarged and the subdural hygromas had resolved. Lower Right: A CT scan obtained at 9 months after placement of the programmable valve,

demonstrating that the ventricles were normal in size and the subdural hygromas had disappeared. The valve pressure was left at 80 mm H₂O.

Two months later the ventricles had enlarged and the subdural hygromas had disappeared (Fig. 1 lower left). Over the next 7 months the valve pressure was reprogrammed four times, decreasing 10 mm of H₂O each time. At 9 months after the placement of the programmable valve, the ventricles were demonstrated to be normal in size, and the subdural hygromas had disappeared (Fig. 1 lower right). The valve pressure was left at 80 mm H₂O.

Elevation of the ventricular pressure to 120 mm H₂O effectively helped to obliterate the subdural collections by enlarging the ventricles. The pressure was slowly lowered until the ventricles were normal sized.

Case 2

This 11-month-old girl is one of a twin birth, born at full term. At birth she was noted to have anomalies of the hands and fingers. At 10 months hip dysplasia was suspected, and she was seen in orthopedic consultation. The orthopedist noted the large head and frontal bossing and suspected hydrocephalus. An MR imaging study was performed that revealed a large cyst in the pineal region, hydrocephalus, and a large left parietal bulge caused by porencephaly. There was slight left to right shift and agenesis of the corpus callosum (Fig. 2 upper left). At surgery the ventricular pressure measured 270 mm H₂O. The valve pressure selected was 120 mm H₂O. A CT study performed 1 day after surgery demonstrated a small left subdural hygroma. Eight days later the child returned because of vomiting and a bulging fontanel. The valve pressure was lowered to 100 mm H₂O, and the child seemed better. One month later MR imaging revealed a large left subdural hygroma and a small right-sided fluid collection (Fig. 2 upper center and right). The anterior fontanel was flat. The child was taken to the operating room where the left subdural hygroma was drained, and a left-sided reduction cranioplasty was performed. The valve resistance pressure was raised to 170 mm H₂O.

Fig. 2. Case 2. Imaging studies. Upper Left: An MR image revealing a large cyst in the pineal region, hydrocephalus, and a large left parietal bulge caused by porencephaly. There was slight left to right shift and agenesis of the corpus callosum. Upper Center: A CT scan was obtained 1 day after surgery, demonstrating a small left subdural hygroma. Eight days later the child returned with vomiting and a bulging fontanel. The shunt valve pressure was lowered to 100 mm H₂O. The child appeared to be better. Upper Right: One month postoperatively an MR image was obtained. A large left subdural hygroma and a small right-sided collection were demonstrated. Lower Left and Right: CT scans obtained 4.6 years postoperatively, revealing that the ventricles were well decompressed, no sign of increased intracranial pressure, absence of subdural collections, and greatly reduced porencephaly.

After operation the left subdural hygroma was greatly reduced, the right fluid collection was gone, and the ventricles were large. Over the next 18 months the valve pressure was slowly lowered in four steps to 70 mm H₂O. Four and one-half years postoperatively her ventricles were well decompressed, and there was no sign of increased intracranial pressure (Fig. 2 lower left). There were no subdural fluid collections, and the porencephaly was greatly reduced (Fig. 2 lower right). Her neurologist has made a diagnosis of orofaciocaudal syndrome. She remains somewhat behind milestones and has an intelligence quotient of approximately 70. (Her functional level, however, is much better than had been expected based on her original MR image). The size of her ventricles has remained virtually unchanged for 4 years.

In this case, the valve pressure chosen was too far below the ventricular pressure and rapid ventricular decompression contributed to subdural hygroma formation. There was also significant cerebral-cranial disproportion.

Case 3

This 15-year-old boy had a 3-year history of decreasing mentation, progressive failure in school, and progressive confusion. His family finally sought help when he could no longer safely find his way home from school, having been found wandering around the neighborhood. On examination he had an extremely large head (62.4 cm) and decreased mentation. Magnetic resonance imaging revealed four ventricular enlargement, with convexity CSF present (Fig. 3 upper left and center).

Fig. 3. Case 3. Imaging studies obtained in a 15-year-old boy who had a 3-year history of decreasing mentation, progressive failure in school, and progressive confusion. On examination he was shown to have an extremely large head (62.4 cm), as well as decreased mentation. Upper Left and Center: An MR image revealing four ventricular enlargement, with convexity CSF present. Upper Right: On 6-week follow up he felt more alert, and his parents noted that he was less confused. The CT scan demonstrated that the ventricles were reduced in size, to somewhat larger than normal. This was undiagnosed at 18 months (upper right). Lower Left: At 24 months postshunting, he complained of intermittent headaches, light headedness, and decreased appetite. A CT scan revealed slitlike ventricles and the development of small bilateral subdural hygromas. The valve was reprogrammed to a pressure setting of 130 mm H₂O. His headaches abated within several days, and he continued to attend school. Lower Center and Right: Computerized tomography studies. At 5.6 years postoperatively the ventricles have remained stable for 3 years. The late appearance of symptomatic subdural hygromas was easily treated by raising the valve pressure only 30 mm H₂O.

At operation the intraventricular pressure was 185 mm H₂O, and a programmable valve was placed at an

opening pressure 130 mm H₂O. At 6-week follow-up the patient felt more alert, and his parents noted that he was less confused. The ventricles were reduced in size and were now somewhat larger than normal. The valve pressure was lowered to 110 mm H₂O. The ventricular size was not shown to change on several CT scans obtained over the next 18 months (Fig. 3 upper right). At 24 months after shunt placement, he complained of intermittent headaches, light headedness, and decreased appetite. A CT scan revealed slitlike ventricles and the development of small bilateral subdural hygromas (Fig. 3 lower left). The valve pressure was reprogrammed to 130 mm H₂O. His headaches abated within several days, and he continued to attend school. At follow up 5.6 years postoperatively the ventricles had remained stable for 3 years (Fig. 3 lower center and right), and he is now in his 3rd year of college.

The late appearance of symptomatic subdural hygromas was easily treated by raising the valve opening pressure by only 30 mm H₂O.

Case 4

This 68-year-old woman had undergone resection of an ovarian carcinoma and chemotherapy 5 years before admission. Three years prior to admission she developed brain metastases, for which she received focal and whole-brain radiation therapy. Six months later she developed hydrocephalus and underwent placement of shunt system with a medium-pressure valve.

When seen 3 years after shunt placement, she complained of a 2-month history of headache, urinary incontinence, and difficulty with gait and balance. A CT scan was obtained that revealed that the ventricular size had slightly increased compared with that seen on an earlier scan (Fig. 4 upper left). The shunt depressed and refilled well. A shunt tap was performed to measure pressure. With the patient well relaxed, the pressure was 152 mm H₂O. It was decided to revise the shunt system and to install a programmable valve, and the opening pressure was set at 100 mm H₂O. Within the 1st day postprocedure her headaches had resolved, and within days she noticed that there was no incontinence. The balance difficulty and gait disturbance improved.

Fig. 4. Case 4. Computerized tomography studies obtained in a 68-year-old woman who had undergone resection of an ovarian carcinoma 5 years before admission. Upper Left: A CT revealing a slight increase in ventricular size as compared with that observed on an earlier scan. Upper Right: Two months postoperatively she was doing well. The CT scan demonstrated smaller ventricles but the presence of bilateral subdural hygromas, greater on the left than right side. Lower Left: A CT obtained at 2 months follow up, demonstrating a midline shift from left to right. The valve was reprogrammed to an opening pressure of 140 mm H₂O. The patient continued to feel well. On examination at 6 months after raising the pressure she had no headache. There was no incontinence and only minor balance problems. Lower Right: A CT scan obtained 6 months postoperatively, demonstrating that the ventricles were slightly larger, there was a decrease in the size of the subdural fluid collection, and the midline shift had resolved. The subdural fluid collections were reduced, and she was asymptomatic when the pressure valve was set at 140 mm H₂O, while she had symptoms of normal pressure hydrocephalus at 152 mm H₂O. The programmable feature of the valve allowed treatment without operative intervention.

She was seen 2 months postoperatively and was doing well. A CT scan demonstrated smaller ventricles but with bilateral subdural hygromas, greater on the left than on the right side (Fig. 4 upper right). There was a midline shift from left to right (Fig. 4 lower left). The valve was reprogrammed to an opening pressure of 140 mm H₂O. She continued to feel well. On examination 6 months after raising the valve pressure she experienced no headache, and there was no incontinence and only minor balance problems. A CT scan demonstrated that the ventricles were slightly larger, there was a decrease in the size of the subdural fluid collection, and the midline shift had resolved (Fig. 4 lower right).

She continued to do well until 8 months later when she developed metastases in her liver. There was no further neurological complaint.

In this case the subdural collections were reduced, and the patient was asymptomatic when her valve pressure was at 140 mm H₂O, whereas symptoms of normal-pressure hydrocephalus were demonstrated at 152 mm H₂O. The programmable feature allowed treatment without operative intervention.

Case 5

A 65-year-old woman had a 2-year history of progressive gait disturbance, frequent falls, urinary incontinence, and mentation difficulty. She had undergone a lobectomy of the lung for squamous cell carcinoma 13 years previously and had a 3-year history of excessive drinking. A CT study revealed the presence of ventriculomegaly (Fig. 5 upper left). At surgery the ventricular pressure was 150 mm H₂O, and the programmable valve was set at 140 mm H₂O. There was no change in the size of of the ventricles over 2 weeks (Fig. 5 upper center), and the valve pressure was reduced to 80 mm H₂O in three steps over 2 weeks. A CT scan obtained at 6 weeks postshunting demonstrated that bilateral subdural hygromas had developed (Fig. 5 upper right). The valve pressure was raised to 120 mm H₂O. Three weeks later she developed headaches following a minor tripping episode. A CT scan then revealed the presence of blood in the subdural space (Fig. 5 lower left). The clot was drained at a local hospital.

Fig. 5. Case 5. Imaging studies obtained in a 65-year-old woman who had a 2-year history of progressive gait disturbance, frequent falls, urinary incontinence, and mentation difficulty. Upper Left: A CT scan demonstrating ventriculomegaly. During surgery the ventricular pressure was set at 150 mm H₂O, and the programmable valve at 140 mm H₂O. Upper Center: A CT scan obtained after 2 weeks, during which time there was no change in

the ventricular size. The valve pressure was reduced to 80 mm H₂O in three steps over 2 weeks. Upper Right: A CT scan obtained 6 weeks postshunting demonstrating development of bilateral subdural hygromas. The valve pressure was raised to 120 mm H₂O. Lower Left: Three weeks later she developed headaches following a minor tripping episode. The CT scan revealed the presence of blood in the subdural space, and the blood clot was drained at an outside hospital. Lower Right: An MR image obtained 10 months postoperatively demonstrating no subdural fluid collection. This scan also revealed demyelination in the pons, which was confirmed on subsequent scans. A diagnosis of central pontine myelinolysis was made. She continued to deteriorate and died 26 months postoperatively.

Three months after the shunt placement procedure she experienced a seizure while traveling outside her home state. An imaging study performed at the university hospital demonstrated a small hygroma on the right side. The shunt was ligated. Approximately 8 hours later, she became unresponsive, experiencing bradycardia and apnea. The ligature was removed, and the patient slowly returned to baseline status over 5 days. She returned home and the valve was raised to 160 mm H₂O. At 10 months postoperatively MR imaging demonstrated the absence of subdural collection. This study also revealed demyelination in the pons, which was confirmed on a subsequent imaging study (Fig. 5 lower right). She was diagnosed as having central pontine myelinolysis. She continued to deteriorate and died 26 months postoperatively.

In this case the rapid decrease from 140 to 80 mm H₂O postoperatively may have facilitated the development of the subdural hygroma. The early appearance of the hygroma postoperatively may indicate a predisposition to subdural hematoma in adults. Finally, a procedure involving ligation of the shunt to resolve hygromas entails considerable risk.

Case 6

This 43-year-old man, in whom a diagnosis of "cortical collapse" was made, was seen 2 months after revision of a failed shunt. He was scheduled to receive an elective shunt system with a programmable valve but was admitted on an emergency basis because of sudden development of headache. A CT scan then demonstrated a blood clot within the subdural hygroma (Fig. 6 upper left and right). At operation the intraventricular pressure measured 350 mm H₂O, and the valve was programmed to 190 mm H₂O. The clot was drained via a single burr hole. The cortical collapse was corrected by postoperative surgery Day 2 (Fig. 6 lower left). The patient remained asymptomatic and the valve was reprogrammed to 170 mm H₂O. Two weeks later the ventricles were shown to have enlarged, although the patient remained well (Fig. 6 lower right). The pressure was reduced slowly in 10-mm H₂O increments.

Fig. 6. Case 6. Computerized tomography studies obtained in a 43-year-old man in whom "cortical collapse" had been diagnosed 2 months after revision of a failed shunt. He was scheduled to receive an elective shunt system with a programmable valve but was admitted on an emergency basis because of sudden development of headache. Upper Left and Right: Computerized tomography scans revealing a blood clot within the subdural hygroma. At operation the intraventricular pressure was 350 mm H₂O, and the valve was programmed to 190 mm H₂O. The clot was drained via a single burr hole. Lower Left: The cortical collapse was corrected by postoperative Day 2. The patient remained asymptomatic, and the valve was reprogrammed to 170 mm H₂O. Lower Right: Two weeks later the ventricles were enlarged, although the patient remained well. The pressure was reduced slowly in 10-mm H₂O increments.

RESULTS

Three hundred seventy-seven patients were randomized into the clinical study in the period between June 1993 and December 1994. Of this group 194 patients underwent placement of a shunt system with the programmable (experimental) valve and 183 patients with the conventional (control) valve (Table 1). Randomization of the two groups was successfully achieved, and there was no statistical difference between the groups for the various descriptive parameters, nor were there significant differences in the "new" and "replacement" categories.

TABLE 1 DATA OBTAINED FROM THE TWO TREATMENT GROUPS	
Feature	No. of Patients (%)
no. of patients	377
reprogrammable valve	194 (51)
control valve	183 (49)
new valves	235
reprogrammable valve	119 (32)
control valve	116 (31)
replacement valves	142
reprogrammable valve	75 (20)
control valve	67 (18)

Programmable Valve Settings

The Codman Hakim programmable valve can be set while the valve is packaged and sterile. In the study 95% of the initial pressure settings were programmed prior to implantation, and only 5% of initial pressure settings were performed after implantation. Several centers used the process of "impedance matching" to program the valves. In this method, the intraventricular pressure is first measured under standard conditions. Seventy percent of all the initial pressure selections fell between the pressures of 70 mm H₂O and 140 mm H₂O.

The investigators were asked to assess shunt function qualitatively by ventricular size at the 3-, 12-, and 24-month follow-up visits. Criteria for inclusion in the "severe overdrainage" group included slitlike ventricles and extraaxial fluid collections. Severe underdrainage was suggested by the failure to obtain reduction in ventricular size after placement of the shunt. The values for both severe overdrainage and severe underdrainage at qualitative assessment are given in Table 2. These figures show no statistical difference between the experimental- and control-valve groups.

TABLE 2 DATA OBTAINED FROM QUALITATIVE ASSESSMENT OF DRAINAGE REGULATION				
Follow-Up Visit	Severe Overdrainage (%)		Severe Underdrainage (%)	
	Experimental Group	Control Group	Experimental Group	Control Group
3 mos	5	6	6	10
12 mos	6	3	8	5
24 mos	5	2	7	3

Incidence of Valve Reprogramming

There were a total of 540 instances in which valve pressure was reprogrammed in the experimental group during the study period. In over two thirds of patients in the experimental group one or more episodes of valve-pressure reprogramming was made after the surgeon's initial estimation of the appropriate setting. The average number of additional reprogramming adjustments was five ($\pm$ five) for each patient (range one-41 adjustments). More than half of the valve-pressure adjustments occurred within the first 3 months after implantation, and 70% occurred within 6 months. Figure 7 shows the percentage of reprogrammings compared with the total number of patients. Analysis reveals that well over half of all the reprogrammings took place in a group of just 30 patients.

Fig. 7. Graph showing the percentage of valve-pressure reprogramming adjustments compared with the overall number of patients. Note that over 50% of all pressure adjustments were performed in a group of 30 patients.

Incidence of Subdural Hematoma/Hygroma

There were 23 subdural hematomas or hygromas reported in the study, for an incidence of 6.10%. Of these, 12 (6.19%) occurred in patients with experimental valves, and 11 (6.01%) were found in the control valve group. There was no statistical difference in the incidence of subdural fluid collections between the two groups. When the patients in the new and replacement shunt groups were compared, a 7.3% incidence of subdural hematoma/hygromas was demonstrated in the group undergoing first-time shunt placement and 5.18% in the group undergoing shunt valve replacement. The age and diagnosis for each of the 23 patients with subdural fluid collections are given in Table 3. Although the average ages of the two groups are skewed by several older patients in the control group, the median age in the experimental valve group was 0.85 years and in the control group the median age was 2.8 years.

TABLE 3 AGE AND DIAGNOSIS IN 23 PATIENTS IN WHOM SUBDURAL FLUID COLLECTION DEVELOPED*			
Programmable Valve Group		Control Valve Group	
Age	Diagnosis	Age	Diagnosis
12.5	tumor	0.1	aqueductal stenosis
0.1	holoprosencephaly	2.8	SP hemispherectomy
0.6	IVH	0.2	myelomeningocele
0.1	colprocephaly	0.2	aqueductal stenosis
1.0	cyst	80.8	NPH
0.8	foramen magnum stenosis	0.1	tumor
1.0	cyst	2.2	unknown
0.1	aqueductal stenosis	0.4	IVH
2.5	infection	51.6	cyst
5.0	porencephaly	17.9	IVH
0.8	IVH	30.8	aqueductal stenosis
41.0	IVH		

* The median ages were 0.85 years and 2.8 years in the experimental and control group patients in whom subdural fluid collection developed. Abbreviations: IVH = intraventricular hematoma; NPH = normal-pressure hydrocephalus; SP = status post.

MANAGEMENT OF SUBDURAL FLUID COLLECTIONS

Four treatment modalities were discerned in the management of those patients in whom subdural fluid collections developed.

Resolved Without Treatment. In three (25%) of the 12 experimental valve patients and in 4 (36.3%) of the 11 control-valve patients the subdural fluid collections resolved without further treatment. Thus a total of seven (30.4%) of 23 postshunt collections disappeared under observation. Most (six of seven) of the patients in whom spontaneous resolution occurred had subdural hygromas rather than hematomas. They tended to be a young group; six of the seven patients were younger than 2.6 years of age, and half were either infants or neonates.

Unresolved and Under Observation. This group includes one patient from the experimental group (8.3%) and three from the control group (27.2%). In these cases the patients experienced either no or quite minor symptoms referable to their subdural fluid collections. The investigators involved chose to observe these patients, and they continued to be observed at the end of the 104-week reporting period.

Resolved by Operative Drainage and Removal of the Shunt. Drainage of the fluid and shunt removal were performed in one patient (8.3%) of the experimental group and in four (36.3%) of the control group. Although these valves were removed by the end of the formal follow-up period, all of these patients were shunt dependent and required another shunt procedure.

Resolved by Increasing Valve Pressure With or Without Drainage of the Fluid. This modality was applicable only in patients in whom shunts were placed with the programmable valve. In seven (58.3%) of the 12 patients in this group who developed subdural collections the investigator used the programmable feature in the treatment of the collection. In six cases this was accomplished solely by raising the pressure and continuing to observe the patient. In one instance the valve pressure was raised and a hematoma was removed.

DISCUSSION

A clear finding of this study is that the use of the programmable valve did not change the incidence of subdural fluid collections when compared with the use of fixed-pressure valves. This finding may be subject to several interpretations.

The first interpretation is that the process by which ventricles suddenly decompress and allow large extraaxial fluid collections to develop may be solely related to siphoning. Some investigators believe that siphoning is inherent in any differential-pressure valve system.[2] Thus siphoning can theoretically occur at almost any pressure differential. The volumes involved would then be dependent on the rate of siphoning and the length of time that the siphoning continued. This interpretation would readily explain why subdural fluid formation occurred nearly equally in both groups in this study.

Another explanation might be that the investigators had not properly used the programmable feature. Data from the Dutch Normal-Pressure Hydrocephalus Study has indicated that subdural effusions occurred in 71% of patients with a low-pressure shunt valve and in only 34% of patients with a medium-pressure shunt valve system.[6] As shown by some of our illustrative cases, the surgeon may use too great an "impedance" mismatch initially or may reduce the valve pressure too rapidly after shunt placement. Over the course of the study, the investigators tended to match the initial program pressure more closely with the intraventricular pressure. They also tended to make changes at longer intervals and with smaller differences in valve setting. The determination of the real ability of a programmable valve to prevent the development of subdural fluid collections may be contingent on the development of a more stringent and rigidly controlled experimental protocol.

Results obtained from this study and from reports in the literature suggest a qualitative difference between late and early complications after implantation of a shunt.[24,25] Moreover, there is a difference in whether the subdural effusions occurred in very young children or adults. In children, the development of subdural hygroma in the early period following a shunting procedure (< 2 months) seems to be of little significance. This condition accounted for the great majority of our cases in which the effusion spontaneously resolved. Nishimura, et al.,[21] found that 85% of these early subdural hygromas in infants resolved spontaneously.

This finding is in marked contrast with the appearance of hypodense subdural collections in adults shortly after placement of a shunt.[28] Raftopoulos, et al.,[28] found that in four of 10 adult patients in whom early subdural hygromas had formed rapid development of symptomatic subdural hematomas occurred. This is consistent with our findings and is illustrated by Cases 5 and 6. In the same prospective analysis of adult patients with hydrocephalus, investigators found that hypodense subdural fluid collections that appeared more than 2 months after surgery did not seem to be a threatening condition.[8,28] None of the three patients in whom subdural fluid collected went on to develop a subdural hematoma. This is illustrated by our Case 3. In infants, however, late development of subdural hygromas posed more ominous significance. A number of authors have described the development of chronic subdural hematomas within these areas of fluid collections, often followed by calcification. This situation has been described as the "armored brain." [7,24,33]

An important finding of the current study is the effectiveness of the programmable feature in the management of the subdural fluid collection.[4,16,18,29,32] In six of 12 cases, raising the valve pressure alone was all the treatment required. This spares the patient further operative intervention. In another case, the ability to increase the intraventricular pressure was an important aspect of the treatment after drainage of the subdural hematoma.

In addition to being able to alter the valve pressure to treat subdural fluid collections, the shunt system with the programmable valve allows for continued treatment of the patient's known hydrocephalic condition. The use of either shunt explantation or shunt ligation to obliterate a subdural fluid collection is always a risky proposition. The near-fatal outcome of the patient in Case 5 in whom shunt ligation was performed underscores the high potential for deterioration in these patients. To raise the pressure of the programmable valve while allowing high-pressure drainage confers a considerable degree of safety. Despite the small number of patients involved, the utility of the programmable-valve feature in patients who develop postshunting subdural fluid collections is apparent.

References

1. Aoki N: Lumboperitoneal shunt: clinical applications, complications, and comparison with ventriculoperitoneal shunt. **Neurosurgery** **26**:998-1004, 1990
2. Aschoff A, Kremer P, Benesch C, Fruh K, et al: Overdrainage and shunt technology. A critical comparison of programmable, hydrostatic and variable-resistance valves and flow-reducing devices. **Childs Nerv Syst** **11**:193-202, 1995
3. Baldini M, Princi L, Vivenza C: Subdural hematoma secondary to CSF ventricular shunt. **Schweiz Arch Neurol Neurochir Psychiatr** **127**:5-14, 1980
4. Belliard H, Roux FX, Turak B, et al: [The Codman Medos programmable shunt valve. Evaluation of 53 implantations in 50 patients.] **Neurochirurgie** **42**:139-145, 1996 (Fr)
5. Black PM, Hakim R, Bailey NO: The use of the Codman-Medos programmable Hakim valve in the management of patients with hydrocephalus: illustrative cases. **Neurosurgery** **34**:1110-1113, 1994
6. Boon AJ, Tans JT, Delwel EJ, et al: Dutch Normal-Pressure Hydrocephalus Study: randomized comparison of low- and medium-pressure shunts. **J Neurosurg** **88**:490-495, 1998
7. Caldarelli M, Di Rocco C, La Marca F: Shunt complications in the first postoperative year in children with myelomeningocele. **Childs Nerv Syst** **12**:748-754, 1996
8. Destian S, Heier LA, Zimmerman RD, et al: Differentiation between meningeal fibrosis and chronic subdural hematoma after ventricular shunting: value of enhanced CT and MR scans. **AJNR** **10**:1021-1026, 1989
9. Dietrich U, Lumenta C, Sprick C, et al: Subdural hematoma in a case of hydrocephalus and macrocrania. Experience with a pressure-adjustable valve. **Childs Nerv Syst** **3**:242-244, 1987
10. Drake JM, Kestle J: Rationale and methodology of the multicenter pediatric cerebrospinal fluid shunt design trial. Pediatric Hydrocephalus Treatment Evaluation Group. **Childs Nerv Syst** **12**:434-447, 1996
11. Driesen W, Elies W: Epidural and subdural haematomas as a complication of internal drainage of cerebrospinal fluid in hydrocephalus. **Acta Neurochir** **30**:85-93, 1974
12. Faulhauer K, Schmitz P: Overdrainage phenomena in shunt treated hydrocephalus. **Acta Neurochir** **45**:89-101, 1978
13. Fransen P: Transcutaneous pressure-adjustable valves and magnetic resonance imaging: an ex vivo

- examination of the Codman-Medos programmable valve and the Sophy adjustable pressure valve. **Neurosurgery** **42**:430, 1998 (Letter)
14. Hassan M, Higashi S, Yamashita J: Risks in using siphon-reducing devices in adult patients with normal-pressure hydrocephalus. Bench test investigations with Delta valves. **J Neurosurg** **84**:634-641, 1996
15. Izumihara A, Orita T, Tsurutani T, et al: [Shunting operation with the Medos programmable valve shunt system.] **No Shinkei Geka** **22**:731-735, 1994 (Jpn)
16. Kamano S, Nakano Y, Imanishi T, et al: Management with a programmable pressure valve of subdural hematomas caused by a ventriculoperitoneal shunt: case report. **Surg Neurol** **35**:381-383, 1991
17. Kasdon DL, Magruder MR, Stevens EA, et al: Bilateral interhemispheric subdural hematomas. **Neurosurgery** **5**:57-59, 1979
18. Kikuchi K, Kowada M, Sasaki J, et al: [Ventriculoperitoneal shunts with the use of pressure-adjustable valve in the management of hydrocephalus.] **No Shinkei Geka** **18**:241-245, 1990 (Jpn)
19. Lam CH, Dubuisson D: Treatment of hemispheric collapse and herniation beneath the falx in a case of shunted hydrocephalus. **Surg Neurol** **33**:202-205, 1990
20. Lumenta CB, Roosen N, Dietrich U: Clinical experience with a pressure-adjustable Sophy valve in the management of hydrocephalus. **Childs Nerv Syst** **3**:270-274, 1990
21. Nishimura K, Mori K, Sakamoto T, et al: Management of subarachnoid fluid collections in infants based on a long-term follow-up study. **Acta Neurochir** **138**:179-184, 1996
22. Oi S, Matsumoto S: Infantile hydrocephalus and the slit ventricle syndrome in early infancy. **Childs Nerv Syst** **3**:145-150, 1987
23. Ortler M, Kostron H, Felber S: Transcutaneous pressure-adjustable valves and magnetic resonance imaging: an ex-vivo examination of the Codman-Medos programmable valve and the Sophy adjustable pressure valve. **Neurosurgery** **40**:1050-1058, 1997
24. Piatt JH Jr: Cerebrospinal fluid shunt failure: late is different from early. **Pediatr Neurosurg** **23**:133-139, 1995
25. Piatt JH Jr, Carlson CV: A search for determinants of cerebrospinal fluid shunt survival: a retrospective analysis of a 14-year institutional experience. **Pediatr Neurosurg** **19**:233-242, 1993
26. Pollack I, Albright AL, Adelson PD, et al: A randomized controlled study of a programmable shunt valve versus a conventional valve for patients with hydrocephalus. **Neurosurgery** (In press, 1999)
27. Pudenz RH, Foltz EL: Hydrocephalus: overdrainage by ventricular shunts. A review and recommendations. **Surg Neurol** **35**:200-212, 1991
28. Raftopoulos C, Massager N, Baleriaux D, et al: Prospective analysis by computed tomography and long-term outcome of 23 adult patients with chronic idiopathic hydrocephalus. **Neurosurgery** **38**:51-59, 1996

29. Reinprecht A, Dietrich W, Bertalanffy A, et al: The Medos Hakim programmable valve in the treatment of pediatric hydrocephalus. **Childs Nerv Syst** **13**:588-594, 1997
 30. Schneider SJ, Wisoff JS, Epstein FJ: Complications of ventriculoperitoneal shunt procedures or hydrocephalus associated with vein of Galen malformations in childhood. **Neurosurgery** **30**:706-708, 1992
 31. Sgouros S, Malluci C, Walsh AR, et al: Long-term complications of hydrocephalus. **Pediatr Neurosurg** **23**:127-132, 1995
 32. Sindou M, Guyotat-Pelissou I, Chidiac A, et al: Transcutaneous pressure adjustable valve for the treatment of hydrocephalus and arachnoid cysts in adults. Experience with 75 cases. **Acta Neurochir** **121**:135-139, 1993
 33. Spadaro A, Rotondo M, Di Celmo D, et al: Bilateral calcified chronic subdural hematoma. Further pathogenetic and clinical considerations on the so-called "armored brain". **J Neurosurg Sci** **31**:49-52, 1987
 34. Steinbok P, Boyd M, Flodmark CO, et al: Radiographic imaging requirements following ventriculoperitoneal shunt procedures. **Pediatr Neurosurg** **22**:141-146, 1995
 35. Watson DA: The Delta Valve: a physiologic shunt system. **Childs Nerv Syst** **10**:224-230, 1994
-

Manuscript received August 18, 1999.

Accepted in final form September 2, 1999.

Address reprint requests to: Peter W. Carmel, M.D., D.Med.Sc., 90 Bergen Street, Suite 7300, University of Medicine and Dentistry of New Jersey, Newark, New Jersey, 07103.