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A multicenter prospective cohort study of the Strata valve for the management of hydrocephalus in pediatric patients

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Object. Previous reports suggest that adjustable valves may improve the survival of cerebrospinal fluid shunts or relieve shunt-related symptoms. To evaluate these claims, the authors conducted a prospective multicenter cohort study of children who underwent placement of Strata valves.

Methods. Patients undergoing initial shunt placement (Group 1) or shunt revision (Group 2) were treated using Strata valve shunt systems. Valves were adjustable to five performance level settings by using an externally applied magnet. The performance levels were checked using an externally applied hand tool and radiography. Patients were followed for 1 year or until they underwent shunt revision surgery.

Between March 2000 and February 2002, 315 patients were enrolled in the study. In Group 1 (201 patients) the common causes of hydrocephalus were myelomeningocele (16%), aqueductal stenosis (14%), and hemorrhage (14%). The overall 1-year shunt survival was 67%. Causes of shunt failure were obstruction (17%), overdrainage (1.5%), loculated ventricles (2%), and infection (10.6%). Patients in Group 2 (114 patients) were older and the causes of hydrocephalus were similar. Among patients in Group 2 the 1-year shunt survival was 71%.

There were 256 valve adjustments. Symptoms completely resolved (26%) or improved (37%) after 63% of adjustments. When symptoms improved or resolved, they did so within 24 hours in 89% of adjustments. Hand-tool and radiographic readings of valve settings were the same in 234 (98%) of 238 assessments.

Conclusions. The 1-year shunt survival for the Strata valve shunt system when used in initial shunt insertion procedures or shunt revisions was similar to those demonstrated for other valves. Symptom relief or improvement following adjustment was observed in 63% of patients. Hand-tool assessment of performance level settings reliably predicted radiographic assessments.

KEY WORDS • hydrocephalus • ventriculoperitoneal shunt • valve • outcome • pediatric neurosurgery

IN pediatric patients, hydrocephalus is most commonly managed with VP shunt placement. To reduce the failure rate of these mechanical devices, recent investigators have been focused on valves that are incorporated into the VP shunt system.^{1,2,5,7-9} Researchers have not yet identified a valve that is clearly superior to the other available devices when used in a broad range of children with hydrocephalus.

Valves are currently available with a wide variety of pressure flow characteristics. In the past, a surgical procedure was required to change a valve setting; recently, valves that are externally adjustable with the aid of a magnet have become available. In theory, the use of these devices could decrease the frequency of shunt revision. Clinical experience with the Codman Hakim programmable valve (Raynham, MA) has been reported in an uncontrolled series of 583 patients (children and adults).^{8,9} The authors reported a

5-year shunt survival of 53% and a low (2%) incidence of valve malfunction among patients undergoing initial shunt placement. The findings of a randomized trial comparing the Codman Hakim programmable valve with differential pressure valves demonstrated that the safety and efficacy of the Codman Hakim programmable valve is comparable to that of conventional valves.⁵

Despite the current interest in the adjustability feature of the Codman Hakim programmable valve, the absence of a flow- or siphon-control mechanism was a concern. In the current study we assessed a new adjustable valve. The Strata valve (Medtronic Neurosurgery, Goleta, CA) allows for noninvasive adjustment to different pressure flow profiles, referred to as performance level settings. The Strata valve also includes a siphon-control mechanism and allows for evaluation of the performance level setting without the use of radiography. To assess the performance of the new valve in children with hydrocephalus, a prospective multicenter cohort study was conducted. The objective of the study was to determine the safety and efficacy of the Strata valve and to compare it with the performance of currently accepted nonadjustable valves.

Abbreviations used in this paper: CI = confidence interval; IVH = intraventricular hemorrhage; SDT = Shunt Design Trial; VP = ventriculoperitoneal.

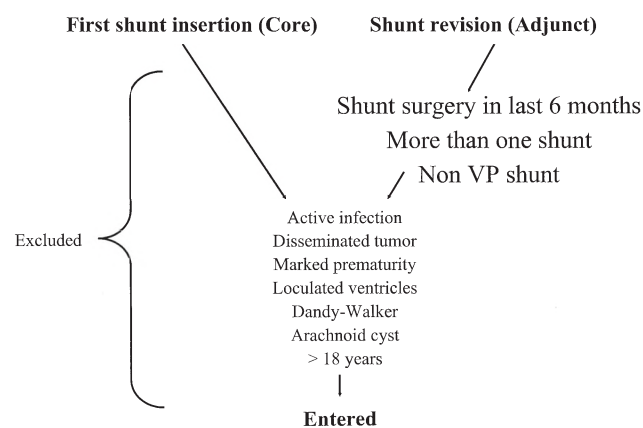


FIG. 1. Chart indicating the enrollment criteria for Groups 1 (Core) and 2 (Adjunct).

Clinical Material and Methods

Patient Population

This study was a nonrandomized prospective cohort study in which all patients underwent placement of a Strata valve. There were two study populations: Group 1, in which patients underwent insertion of their first VP shunt, and Group 2, in which patients underwent shunt revision. The entry criteria for the two groups are outlined in Fig. 1. In Group 1, the entry criteria were intentionally designed to be similar to the entry criteria in the SDT;¹ this was done to make the patient population similar to that of the SDT and to strengthen the comparison of the results.

Surgical Procedures

The primary study end point was shunt revision surgery. This was defined in four categories: obstruction, overdrainage, loculated compartments, or infection. These definitions are the same as those used in previous hydrocephalus trials, including the SDT and the Endoscopic Shunt Insertion Trial.^{1,3} This was done to strengthen the comparison between the current study and the historical literature.

In all of the surgeries (shunt insertion or revision), the Strata valve was placed; other flow-control devices were not allowed. The choice of ventricular and/or peritoneal tubing, the surgical technique of insertion, and the details of perioperative care were determined by the individual surgeon. The protocol suggested that the initial performance level of the Strata valve should be 1.0; however, if the surgeon determined that a different initial performance level was required, this was allowed.

Data Collection

Data (including symptoms and severity) were collected at baseline; discharge; and at 1, 3, 6, and 12 months postoperatively, and at any other time that was clinically indicated. If a patient underwent follow-up examination and the valve was adjusted, symptoms were reassessed within 24 hours. Any valve adjustments were followed by skull radiography. The performance level setting obtained from the skull radiograph was compared with the performance level setting that was obtained at the bedside with the use of the hand-held tool. Patients who presented with either

loculated compartments in the ventricular system or infection did not undergo valve adjustment; they were treated according to the surgeon's usual practice. Patients who presented with shunt obstruction or overdrainage were eligible for adjustment. The protocol allowed up to three adjustments within a 72-hour period, as long as symptoms were improving. If symptoms were persistent or progressive despite these adjustments, revision was recommended in accordance with the surgeon's usual practice.

Sample Size

The study was designed to generate a 1-year shunt survival for the Strata valve with a 95% CI. To make a comparison to the SDT, the shunt survival from that study was used in calculating our sample size. In the SDT, the overall 1-year shunt survival was 61%, and the lower limit of the 95% CI was 51%. Because the valves in the SDT are all commonly used in current clinical practice, we chose the SDT result (a lower limit of the 95% CI equal to 51%) as our minimum acceptable 1-year shunt survival. We calculated a sample size for the Strata valve that would have a CI with a lower limit of 51% or greater. Using these parameters, a power of 80% and alpha of 0.05, we determined that 152 patients needed to be evaluated in Group 1 and followed for a minimum of 1 year.

Patients undergoing shunt revision (Group 2) were enrolled in the study to generate additional outcome data. There was no specific hypothesis proposed or tested with regard to these patients and, therefore, a specific sample size was not calculated.

Individual participating institutions submitted proposals to the appropriate institutional review board and joined the study once approval was obtained. The valve had not yet been approved by the Food and Drug Administration at the beginning of the study but was approved on February 11, 2002, based on an interim data report provided by the manufacturer. Data collection and site monitoring were performed by Medtronic, Inc.; data analysis and interpretation were performed by the authors.

Results

Patient accrual began in March 2000 and closed at the end of February 2002. The follow-up phase closed at the end of February 2003. Three hundred fifteen patients were enrolled—201 in Group 1 and 114 in Group 2.

As expected, in view of the entry criteria, the baseline characteristics of the patients in Group 1 of this study were similar to those in the SDT (Table 1). The patients were infants (median age 0.41 years) at the time of shunt placement. A little more than half were boys, and the median birth weight was 3026 g. As expected for such a young population, the most common causes of hydrocephalus were myelomeningocele, aqueductal stenosis, brain tumor, and IVH. Shunts were inserted via a frontal approach in 87 cases and via a posterior/parietal approach in 103 patients. Some form of assistance during insertion of the ventricular catheter (endoscopy, ultrasonography, or other imaging) was used in 21% of patients. Perioperative antibiotic agents were used in all patients in Group 1. The median time from study registration to hospital discharge, was 2 days, and the median surgical time was 40 minutes. The overall 1-year

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TABLE 1
Summary of the baseline characteristics of patients in Group 1 compared with those from the SDT

Characteristics	Group 1	SDT
no. of patients	201	344
median age (yrs)	0.41	0.22
sex (% M/F)	57/43	56/44
birth weight (g)	3026	2825
cause of hydrocephalus	myelomeningocele, aqueductal stenosis, tumor, IVH	myelomeningocele, IVH, tumor, aqueductal stenosis

shunt survival was 67% (95% CI 60–74%; Fig. 2). The most common cause of shunt failure was obstruction, which occurred in 17% of patients. Overdrainage occurred in 1.5% of patients, loculation in 2%, and infection in 10.6%.

In Group 2 patients the median age was 8.7 years. The 1-year shunt survival was 71% (95% CI 62–80%; Fig. 3). In these patients, obstruction was the most common cause of failure, occurring in 20% of patients. Overdrainage occurred in 3.7%. No patient developed loculated compartments within the ventricular system, and the infection rate was 6%.

After valve implantation, the initial performance level setting in Group 1 was most commonly 1 or 1.5 (30 and 40%, respectively). In Group 2 patients, 1.5 and 2 were the most common initial performance level settings (56 and 23%, respectively; Table 2).

A total of 256 valve adjustments were made in 141 patients. In Group 1, 92 (46%) of 201 patients underwent valve adjustment. Fifty-five of these patients underwent single adjustments and 37 underwent multiple adjustments. In Group 2, 49 (43%) of 114 patients underwent valve adjustment. In 24 patients a single adjustment was performed, and in 25 patients multiple adjustments were required. Of the 256 valve adjustments the reason for the valve adjustment was shunt obstruction in 23 and overdrainage in 59. In the remaining 174 adjustments, the patients' presenta-

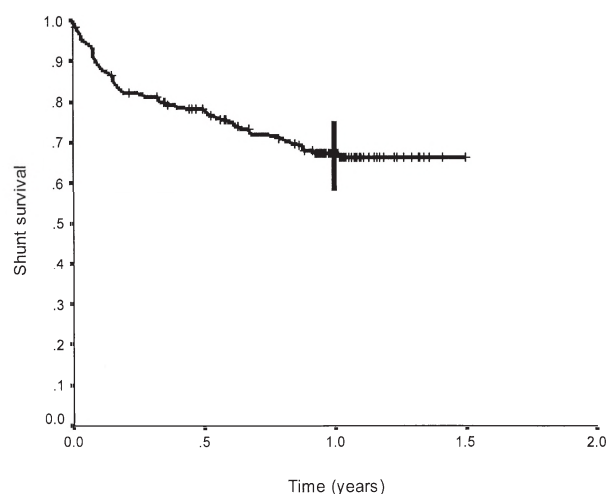


FIG. 2. Graph. The 1-year shunt survival rate (time to first shunt failure) in the 201 patients in Group 1 was 67%.

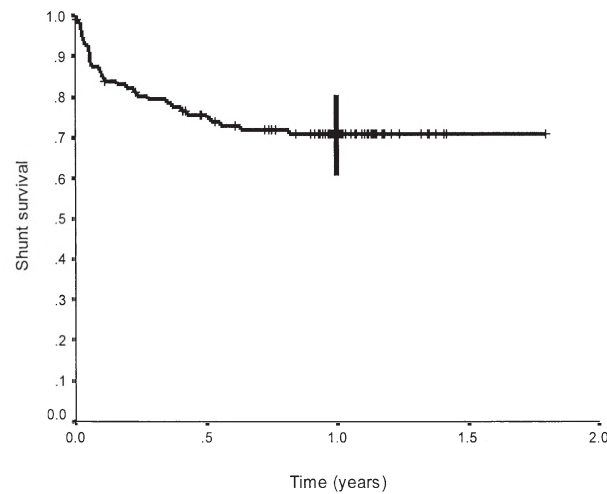


FIG. 3. Graph. The 1-year shunt survival rate (time to first shunt failure) in the 114 patients in Group 2 was 71%.

tion did not meet the definition of obstruction or overdrainage; the most common reason was headache.

After valve adjustments were performed, patients and/or families reported symptoms as completely resolved, improved (but not resolved), the same, or worse. Follow-up information was available after 236 of the 256 adjustments. Overall, symptom improvement or resolution occurred in 149 (63%) of 236 adjustments. In 61 instances (26%), complete symptom resolution occurred, and in 87 (37%) of 236 instances, symptoms were improved but not resolved. The improvement or resolution of symptoms occurred within 24 hours in 132 (89%) of 149 occasions. The 1-year survival rate for adjusted valves was the same as that for valves which were not adjusted (Fig. 4).

During the study, radiographic confirmation of the performance level setting was obtained after 238 valve adjustments. These readings were compared with the hand-held instruments that were used at the bedside to evaluate the performance level setting. The agreement between these two methods was very good; the same reading was obtained in 234 of 238 instances. There were four discrepancies observed between the radiographic and the hand-held tool performance level settings: 0.5 compared with 1; 1 compared with 0.5; 1.5 compared with 0.5; and 2 compared with 2.5, respectively.

Surgeons were asked to report surgery- and device-related complications that occurred during the implant. No such complications were reported in Group 2. In Group 1, there were two surgery-related complications listed as “small cortical bleeding stopped with coagulation” and “cerebrospinal fluid tracking up the peritoneal end.” In Group 1 there were also two device-related complications recorded as “valve too big for neonate” and “tear in dome on imaging, second valve implanted.” One surgeon reported “brief bradycardia without consequences” in the device- and surgery-related categories.

There was one death in the study, which was due to progression of Hurler syndrome and not related to shunt malfunction.

An unexplained change in the performance level occurred 25 times among 22 patients treated in eight investi-

TABLE 2
Summary of initial settings for patients in
Groups 1 and 2*

Initial PL Setting	Group 1 (%)	Group 2 (%)
0.5	10	2
1.0	30	16
1.5	40	56
2.0	15	23
2.5	5	3

*PL = performance level.

gational sites. Seventeen of these patients were asymptomatic and five experienced symptoms (headache, irritability, and lethargy in two; and hemiparesis, seizures, and slit ventricles in one each). Three of the five symptomatic patients had their valves reset, as did seven asymptomatic patients. There were 12 asymptomatic patients in whom valves were not reset.

Discussion

In hopes of reducing the failure rate of VP shunts for hydrocephalus in pediatric patients, considerable research has been focused on valves. Adjustable valves that allow noninvasive changes to be made in the pressure flow characteristics have recently become available. Theoretically, these devices offer potential advantages such as improved shunt survival and the ability to change ventricular size and/or relieve symptoms.

In this study, the Strata valve was evaluated in a prospective cohort of children, some of whom underwent initial shunt placement and some of whom underwent implantation of the new valve at the time of shunt revision. The 1-year shunt survival of the Strata valve when used at the time of initial shunt insertion was 67% (95% CI 60–74%), a rate similar to that for a number of other valves that are currently on the market. The strongest comparison from historical data is to the SDT¹ because the entry and outcome criteria in the two studies were similar. The shunt sur-

vival curve for the Strata valve and the point estimates of the 1-year shunt survival for the valves in the SDT are demonstrated in Fig. 5. The 1-year survival was 67% for the Strata valve, 66% for the Sigma valve, 61% in the standard group (differential pressure valves), and 56% for the Delta valve. The 95% CIs for the Strata valve and the three valves in the SDT overlap, implying that the failure rates are similar. Our study design does not provide convincing evidence that the Strata valve has a survival advantage; a randomized trial would be required to test this hypothesis.

There has only been one previous study in which direct comparison of adjustable and nonadjustable valves is reported.⁵ In a randomized trial the Codman Hakim programmable valve was compared with differential pressure valves in a mixed group of patients which included adults and children undergoing shunt revision and shunt insertion. The shunt survival rate curves in those two groups were virtually identical, and both curves were similar to the results of the current study.

The literature that is provided with the Strata valve and our study protocol suggested that the valve be implanted in the coronal position. If the valve is implanted below the midposition of the ventricle, there is a concern that it may remain open and lead to overdrainage. In this study, the majority of valves (103 of 201 in Group 1) were implanted using a posterior parietal approach; therefore, the valve might have been below the midposition of the ventricle in some or all of those patients. Regardless, overdrainage was rare (1.5%). In the SDT the incidence of overdrainage was 7.8% with the Delta valve, 2.6% with the standard (differential pressure) valve and 0% with the Sigma valve. It is difficult to evaluate the importance of valve position based on the findings of these two studies because overdrainage is a late complication and the follow-up period was much longer in the SDT than in our study.

Repeated studies with different valves, both adjustable and nonadjustable, and with and without siphon control mechanisms, have demonstrated similar 1-year shunt survival in the 60 to 70% range.^{1-6,8,9} It appears that there is no single best valve to treat all forms of hydrocephalus in pedi-

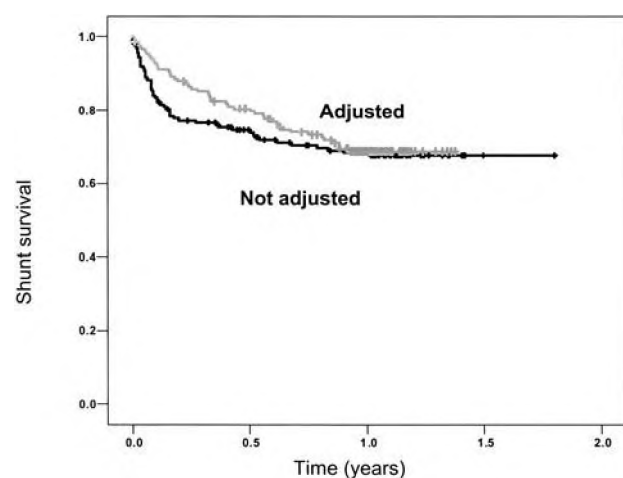


FIG. 4. Graph indicating the time to first shunt failure for shunts that were and were not adjusted.

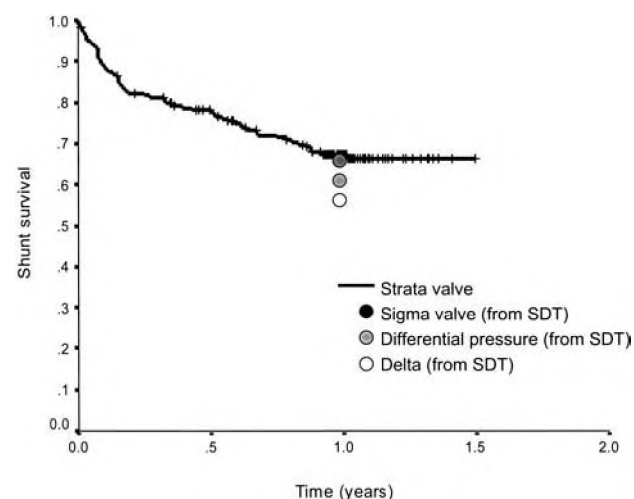


FIG. 5. Graph indicating the survival rates of the Strata valve and other (nonadjustable) valves from the SDT.

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atric patients. Individualized valve choice based on age, ventricle size, and perhaps other factors may be important.

The potential advantages of adjustable valves may not yet be realized. One potential advantage might be the ability to reduce the size of ventricles slowly and/or to maintain a larger ventricle size than that obtained with nonadjustable valves; this was not part of the protocol for the current study. Although such an approach has yet to be assessed formally, it is currently being attempted by some surgeons.

The majority of patients who presented with symptoms resulting in valve adjustment did not meet the criteria for study end point (obstruction or overdrainage). Valve adjustment was associated with improvement in symptoms almost two thirds (63%) of the time. When improvement or resolution of symptoms occurred it did so within 24 hours in the vast majority of patients. In view of such rapid improvement in symptoms, it appears likely that a surgeon will know fairly quickly whether valve adjustment will be beneficial. Because the majority of symptoms were subjective in nature (headaches), and the symptom scoring was self-reported, the possibility of a placebo effect exists. Placebo valve adjustments were not performed in this study.

Conclusions

The 1-year shunt survival for the Strata valve was similar to the survival demonstrated for other valves. Valve adjustments resulted in symptom relief or improvement in more than half of the patients. The correlation between the hand-held device for checking the performance level setting and the radiographs was very good. It is our belief that the hand-held device obviates the need for radiography, except in circumstances that might be indicated clinically, such as lack of symptom improvement.

Appendix

The following participants and institutions participated in the Strata Valve Clinical Study.

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