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TECHNICAL NOTE

Newton Paes

A new self-adjusting flow-regulating device for shunting of CSF

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N. Paes
Clinica de Coluna,
University of Mogi das Cruzes,
Rua Armindo Guarana, 101,
Tatuape, Sao Paulo, Brazil
Tel./Fax: (55) 11-7283-20-61

Abstract Traditional shunts were primarily designed to manage hydrocephalus by regulating intracranial pressure. However, in some circumstances, their performance characteristics can cause them to underdrain or overdrain CSF. Overdrainage has been linked with clinical complications such as valve-dependent shunt syndrome, cranial stenosis, slit-ventricle syndrome, and subdural hematomas, and it may contribute to ventricular catheter occlusion. In addition to complications associated with hypertension and ventriculomegaly, underdrainage has been linked with residual brain edema, and subcutaneous CSF effusion has been observed at the site of cranial perforation, mainly in pediatric patients. Newer designs attempt to reduce these complications, but fall short for various reasons. The author presents a new shunt design, which utilizes variable aperture technology (patent pending) that results in the physiologic regulation of CSF flow under both positive and negative pressure conditions. This new design offers encouragement for the management of hydrocephalus and the prevention of complications due to overdrainage.

Key words Hydrocephalus · Ventriculo-peritoneal shunts · Shunts · Differential pressure valves · Variable pressure valves · Anti-siphon device

Introduction

The first successful use of one-way regulated shunts 40 years ago was an important step in the management of hydrocephalus. However, since its inception, this procedure has been associated with high complication rates, with infection and clinically significant problems caused by excessive CSF drainage (siphon effect).

The infection rate of shunted patients is associated with many factors. According to medical references, infection rates vary between zero and 38% for this procedure, depending upon the center and the reporting methodology [11]. It is believed that while postsurgical infection is not a direct result of the design of the valve mechanisms, a reduction in the time taken to perform the procedure may be of benefit in reducing infection rates [1], and this can be achieved with good shunt design.

The other main complication of shunting results from overdrainage, with complications described in many medical references. The most important complications cited [5] are the following:

1. Changes in cranial size and volume
2. Negative-pressure syndrome
3. Slit-ventricle syndrome
4. Intolerance of CSF pressure elevations
5. Subdural hematomas

Overdrainage has also been cited as contributing to ventricular catheter occlusion, which accounts for about 30% of all shunt-related complications [13]. It follows that if the incidence of overdrainage from shunts could be reduced, that of complications would also be reduced. The problem, then, is finding a shunt that effectively reduces complications without overdraining or underdraining or

causing other problems that would increase the frequency of other sorts of complications.

Overdrainage, which appears in conventional shunts, is best understood by considering the flow as explained in Poiseuille's law, which is expressed as follows:

$$F = \Delta P\,(\pi/8)\,(1/N)\,(R^4/L)$$

where F = volume of CSF passing through the shunt per unit of time; ΔP = differential pressure between the inlet and the outlet; N = viscosity of CSF; R = radius of the tube; and L = length of the tube.

In this formula, N, R, and L can be considered constant (K), so that the flow through calibrated shunts can be expressed as:

$$F = \Delta P\,(K)$$

When a shunted patient rises from the recumbent to the standing position, the gravitational influence represented by the vertical distance of the column of CSF, as measured between the tip of the ventricular catheter and the outlet end of the distal catheter, produces a dramatically high negative pressure differential from which the siphon effect results [9]. There are wide variations in the differential pressure, related to position, size, and activity of shunted patients when the negative pressure allows the creation of a siphon effect. It is this rapid and dramatic decompression of ICP (intracranial pressure) that is responsible for complications such as subdural hematomas.

The objective of this article is to present an up-to-date review of the different shunts available and to introduce a new kind of shunt, which works in concert with the physiological CSF production rate and patient position to regulate the flow of CSF.

Review of alternative shunts

The anti-siphon device (ASD) reported by Portnoy et al. in 1973 [9] was an important advance in the attempt to counteract overdrainage. However, ventriculomegaly and continuation of clinical symptoms of hydrocephalus may result if the device is not positioned properly at the time of implant [15]. Another problem results from the deformation of the anti-siphon mechanism by tissue encapsulation [2]. Complications can result when excessively high ICP is required to overcome the pressure created by the collagen tissue encapsulation and open the valve [4]. Owing to similarities in design, comparable problems can occur with the Siphon Control Device (SCD) also used in the Delta valve. In addition, in vitro studies have shown that a 25-cm negative fluid column is required for the anti-siphon device to function, precluding its effective use in babies [8].

And finally, these diaphragm anti-siphon mechanisms do not permit the normal physiologic interventricular pressure change that should take place when a patient rises to a standing position. Studies have shown that normal ICP drops from 100±50 mmH_2O to −100±50 mmH_2O when unshunted patients rise from a recumbent position [10]. This pressure change has been shown to be an important factor in the growth of the cortical mantle [6]. In contrast, for an anti-siphon mechanism to function, positive intraventricular pressure must be maintained when the patient stands.

Other research led to development of the Sophy externally adjustable pressure valve. This device allows the transcutaneous change of the opening pressure by the movement of a rotor that changes the position of a semicircular spring plate. Changing the pressure is accomplished by means of a magnetic device held over the patient's skin. The physician can choose low, medium, or high opening pressure. Theoretically, the Sophy valve could avoid a second surgical procedure if the patient were not originally fitted with an appropriate pressure valve (pressure/patient mismatch). But only 3.2% of patients have been cited as having complications resulting from this phenomenon [3]. In addition, the valve has no design provision to prevent overdrainage or underdrainage when the patient changes position or engages in activities that increase ICP (REM sleep, coughing, exercise, etc.) [12]. Another problem of the Sophy valve is related to the metallic parts, which produce interference during CT and MRI procedures. To avoid these artifacts, Itoh et al. suggested the use of Sophy valves in the subclavian region on the anterior chest wall [7]. Additionally, in one study the magnet position controlling the pressure was reported to have changed spontaneously 24 times in a series of 198 patients [17], indicating that the mechanism is susceptible to the influence of EMI (electromagnetic interference).

In an elegant effort to improve on the adjustability of the Sophy valve, Hakim's Medos valve was designed with more options for regulation of the opening pressure of the shunt. However, this device is subject to similar problems related to the siphon effect and interference with CT and MRI. As an externally adjustable fixed-pressure valve, the Medos has no provision for prevention of overdrainage problems related to changes in position or other activities (mentioned above) that increase ICP.

The Orbis-Sigma valve (OSV), introduced in 1987 by its inventor Christian Sainte-Rose, is designed to maintain CSF flow through the valve at between 18 and 30 ml/h when differential pressure across the valve is between 120 and 400 mmH_2O. However, many neurosurgeons do not use the OSV in babies because the pressure required to create physiologic flow is considered excessively high for infants whose skull sutures have not yet closed [3]. In addition, the valve has been linked with a higher incidence of subdural hematomas than ordinary differential pressure valves [16]. It is clear that present valve designs fall short of providing optimal performance characteristics for the management of hydrocephalus.

Theory

It is widely accepted that the mathematical formula that can be used to describe flow through a shunt is best expressed by Poiseuille's law, as follows:

$$F = \Delta P\,(\pi/8)\,(1/N)\,(R^4/L)$$

Substituting the formula for the area of a circle ($A = \pi R^2$ or $R^2 = A/\pi$) makes it possible to modify the formula to reflect any cross-sectional area, rather than only the lumen of a (round) tube. Assuming that the length and viscosity are constant, the following mathematical relationship is derived:

$$F = \Delta P\,(A)^2 * K$$

where: F = volume of CSF passing through the shunt; ΔP = differential pressure between the inlet and outlet; A = area of aperture; and K = mathematical constant.

If, for any reason, the area of the aperture is reduced, the resulting flow through the aperture will be reduced. It has been hypothesized that changes in differential pressure could be used to modulate the area of the aperture, thereby regulating the flow of CSF through the valve.

Flow may also be expressed in terms of resistance as $F = \Delta P/R$. When pressure is represented by the difference between the inlet and outlet pressure, the resistance to flow is represented by the cross-sectional area of the aperture. Elasticity of the flow control mechanism can, therefore, be used to achieve an optimal relationship between pressure, flow, and patient position.

Materials and methods

Based upon the theory expressed above, a new shunt has been designed. The device described below, the Diamond valve, works on the principle that the production rate of CSF is approximately constant and that negative pressure is created by the gravitational influence on the column of CSF created in the shunt tube between the tip of the ventricular catheter and the tip of the distal catheter when a patient rises from the supine to the erect position.

The Diamond valve was developed to reproduce physiologic intraventricular pressure and CSF flow, regardless of patient position, and to minimize the risk of overdrainage and underdrainage. The valve design incorporates the Newton SAFR (Self-Adjusting, Flow-Regulating) mechanism, an elastomeric tube with a longitudinal aperture in the side wall. The tube is fixed over a ring, with the ring's outer diameter being larger than the inner diameter of the tube. This physical situation holds the aperture edges open and creates a specific area. The elastomeric tube is contained within a housing that is unaffected by external pressures such as those exerted by atmosphere and tissue encapsulation, but permits pumping and injection for sampling of CSF or injection of medications. Intracranial pressure acts directly on the outside surface of the tube, while distal pressures act on the inside surface of the tube. Changes in the differential pressure result in changes in the circumference and shape of the elastomeric tube, resulting in a variation in the cross-sectional dimension of the aperture. Either increased proximal pressure or decreased distal pressure reduces the circumference of the tube, reducing the aperture size and thereby increasing dynamic flow resistance and restricting CSF flow. A decrease in proximal pressure, or an increase in distal pressure, returns the circumference of the tube to its normal shape, enlarging the aperture and thereby reducing the dynamic resistance and permitting an increase in CSF flow. Thus, higher differential pressures cause increased resistance to flow, and lower differential pressures cause less resistance to flow. Flow is regulated because higher pressures, which would normally cause higher flow, simultaneously cause increased resistance, which reduces and controls the flow.

Figure 1 shows the valve in a low-pressure condition. CSF flow enters from the ventricular catheter through the inlet (1) into the pumping chamber (2), flows around the tube (3) and through the diamond-shaped aperture (4), then through the very low pressure check valve (5) and out of the outlet (6) to the distal tubing. As pressure begins to increase, the tube (3) contracts and the aperture (4) begins to close, as shown in Fig. 2. This occurs in response to positive ventricular pressure or negative distal pressure. Figure 3 illustrates the function of the mechanism at high pressure differentials, such as those that occur while the patient is standing or sitting. As pressure increases the aperture closes further, restricting flow, until the high pressure relief valve (7) opens at a predetermined pressure, allowing flow of CSF through the tube (3) and out of the check valve (5). This relief mechanism is designed to prevent the occurrence of underdrainage. The aperture (4) and the high-pressure relief valve (5) work in concert to maintain physiologic flow and pressure conditions regardless of patient position. The silicone housing (2) is unaffected by normal external pressures created by tissue encapsulation.

A computer simulation was performed to determine the correct physical relationship between the outer diameter of the ring and the inner diameter of the tube, and the appropriate elastic characteristics of the tube. The simulation shows the effects of changing pressures acting on the outside of the tube to reduce the aperture size (Fig.4). Intracranial pressures of 0, 50, 125, 176, and 250 mmH_2O were simulated. With pressure and flow at zero, the aperture is completely open. As pressure is increased from 0 to 250 mmH_2O, the tubing is compressed and the opening of the aperture is shown to decrease in size, restricting flow through the aperture. The results of these computer simulations were used in the development of a special silicone elastomer formulation to provide the optimal elastic characteristics of the tube.

Prototype and in vitro testing

A prototype was built (Phoenix Biomedical, Valley Forge, Pa.) to verify the performance predicted by the computer simulation. Incorporated at the top of the device is a high-pressure valve, which opens when the differential pressure exceeds a predetermined level. This valve acts in tandem with the Newton SAFR mechanism to manage extreme high pressures. A very low pressure valve was incorporated in the outlet to ensure one-way CSF flow.

In vitro test

A bench test of the prototype valve was performed to simulate a patient assuming an upright position (Fig. 5). A variable flow rate injector was used to simulate the production of CSF, and a pulse was added to simulate the choroidal pulse. A manometer was used to measure pressures on the proximal side of the valve. The distal catheter was lowered by 400 mm to simulate the negative pressure caused by the column of fluid in the shunt system of a standing patient.

With input flow set at 10 ml/h, the distal catheter was lowered to 400 mm, to simulate a patient rising from the supine to the standing position. The proximal pressure dropped very gradually from +100 mmH_2O to –80 mmH_2O over a period of 5 min and leveled off at –110 after 10 min. The observed pressure was within the pressure range of –100 (±50) mmH_2O recorded by Pudenz and Foltz in un-

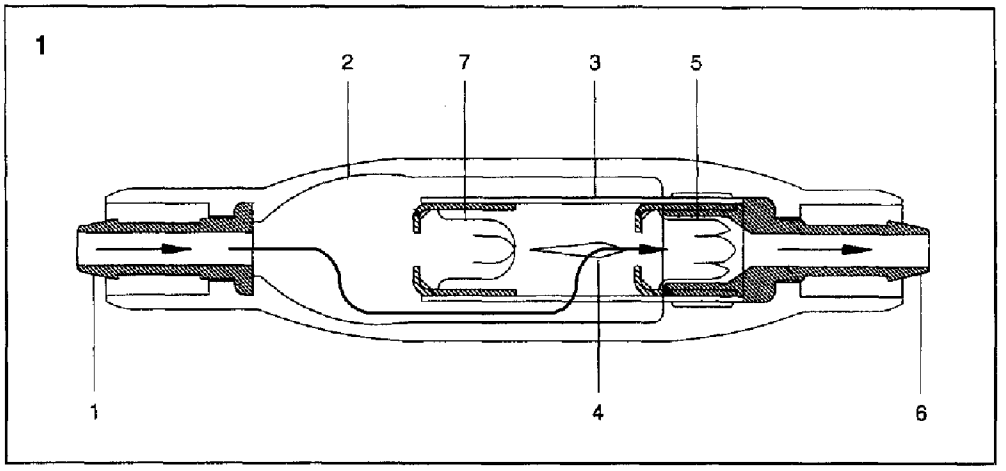

Fig. 1 Normal flow is from the ventricular catheter through the inlet (*1*) into the pumping chamber (*2*), around the tube (*3*) and through the diamond-shaped aperture (*4*) in the tube, then through the very low pressure check valve (*5*) and out of the outlet (*6*) to the peritoneal tube. *Note*: the aperture (*4*) is normally open at low flow or low pressure

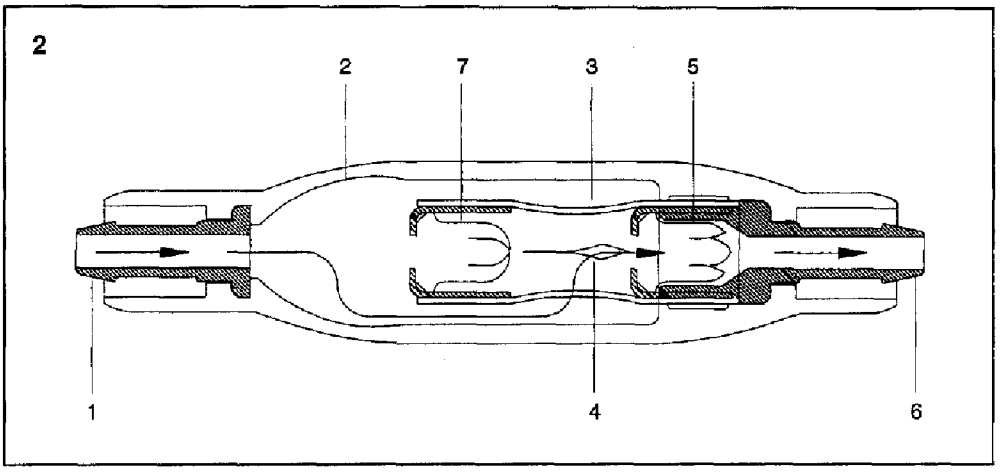

Fig. 2 As pressure or flow increases, the tube (*3*) contracts and the aperture (*4*) begins to close in response to increased positive pressure or flow from the proximal or ventricular side, or increased negative pressure from the distal or peritoneal side. Closing of the the aperture restricts the flow and increases the resistive pressure of the valve

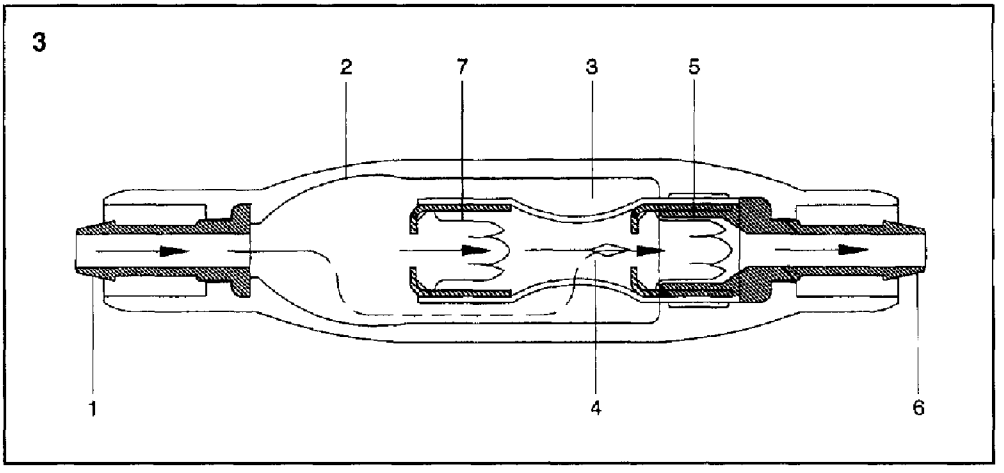

Fig. 3 As the pressure increases, the aperture closes further until, at a predetermined pressure, the high-pressure relief valve (*7*) opens, permitting flow through the tube (*3*), through the check valve (*5*) and out of the distal outlet (*6*). The aperture (*4*) and the high-pressure valve (*7*) work automatically in concert to regulate pressure and flow conditions within physiologic parameters regardless of the patient's position or condition

shunted individuals in both standing and sitting positions [10]. This result was compared with a pressure drop in a diaphragm valve, which fell from 60 mmH_2O to –220 mmH_2O in 30 s, leveling off at –250 mmH_2O after 60 s (Fig. 6). In comparison, pressures observed in the Delta valve remained positive. The pressure in the Orbis-Sigma valve was observed to decline gradually to –20 mmH_2O (Fig. 6a).

The test was repeated with a flow rate of 20 ml/h. There was no noticeable difference from the previous performance of either the diaphragm valve or the Delta valve. The pressure in the Orbis-Sigma valve declined at a slow rate but remained positive. That in the Diamond valve declined at a slow rate and stabilized at approximately –50 mmH_2O after 10 min, within the range of pressures previously reported in standing patients without shunts [10] (Fig. 6b).

To evaluate the ability of the Diamond valve to control flow, an input flow rate of 0.33 ml/min was established and the tubing was

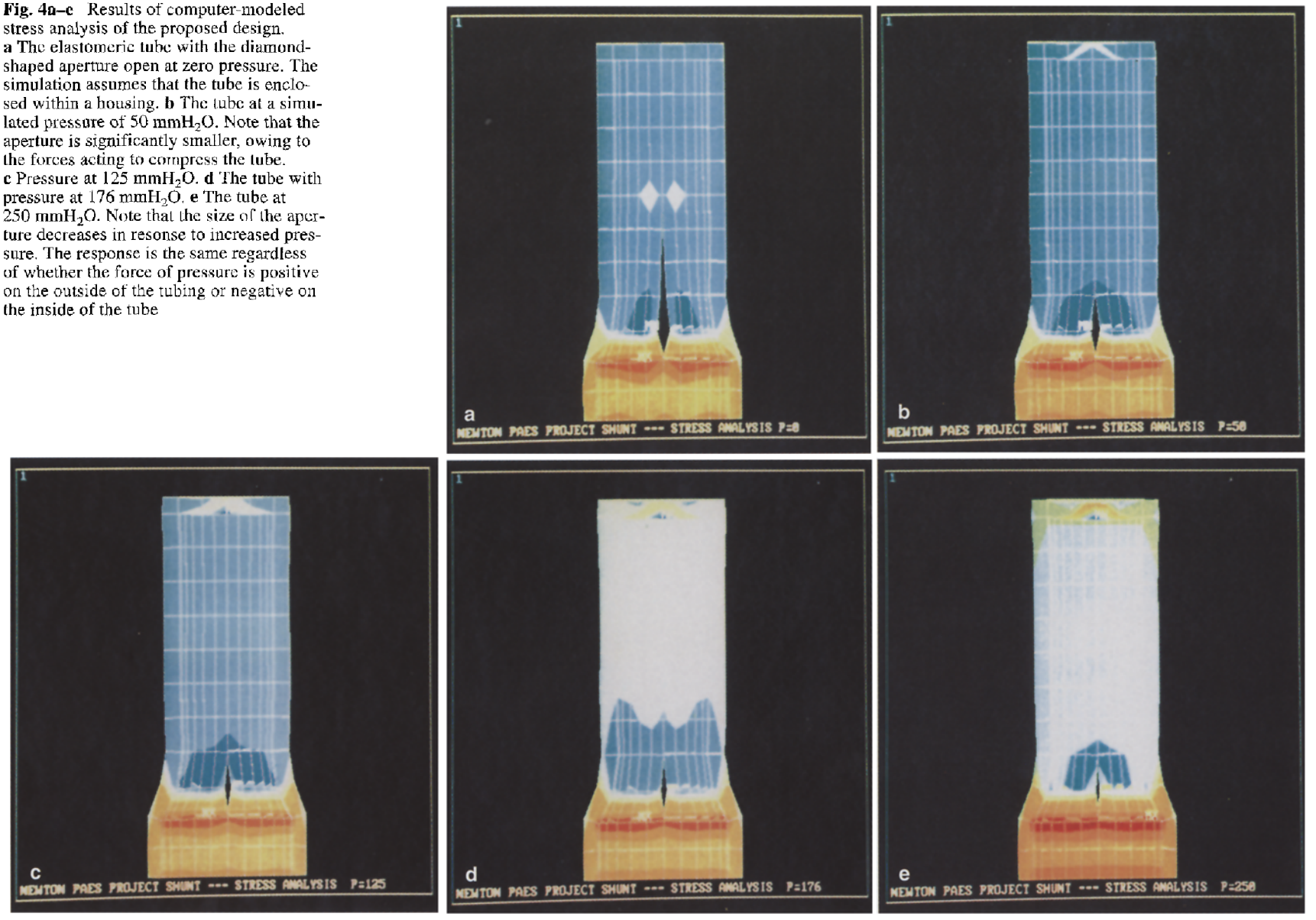

Fig. 4a–e Results of computer-modeled stress analysis of the proposed design. **a** The elastomeric tube with the diamond-shaped aperture open at zero pressure. The simulation assumes that the tube is enclosed within a housing. **b** The tube at a simulated pressure of 50 mmH_2O. Note that the aperture is significantly smaller, owing to the forces acting to compress the tube. **c** Pressure at 125 mmH_2O. **d** The tube with pressure at 176 mmH_2O. **e** The tube at 250 mmH_2O. Note that the size of the aperture decreases in resonse to increased pressure. The response is the same regardless of whether the force of pressure is positive on the outside of the tubing or negative on the inside of the tube

lowered by 400 mm to simulate standing. Fluid volume through both the diaphragm valve and the Diamond valve were measured, and flow rates were calculated every 10 s for 1 min (Fig. 7). Flow through the diaphragm valve increased rapidly from the input flow rate of 0.33 ml/min to 4.1 ml/min, dropping gradually to input flow rate owing to depletion of the fluid reservoir. These results parallel those of Stein, who reported a significant increase in shunt flow measured in 28 patients in the supine position, immediately upon standing, and at 60 and 120 s after. Flow rates in some patients increased by as much as five times the base rate, returning to baseline within 1 min of standing [14]. In comparison, flow through the Diamond valve increased only slightly, to 0.55 ml/min, falling rapidly to 0.45 ml/min, demonstrating the ability of the variable aperture mechanism to control flow under simulated conditions. It should be noted that this test did not account for the effects of brain compliance or the effects of abdominal pressure. Both of these factors should work in favor of the Diamond valve to further reduce flow to the physiologic production rate.

The pressures and flow characteristics of the Diamond valve were judged to make it preferable to the standard diaphragm valve for clinical use, as the pressure change was very gradual and the difference between standing and supine flow rates was not clinically significant. In addition, the final stabilized proximal pressure of the Diamond valve was judged to be essentially equivalent to the physiologic ICP previously reported in unshunted individuals the erect position [10].

The Diamond valve does not require any special handling prior to implant and can be primed for implant in the same way as any standard valve. The device was designed to be small and cylindrical in shape to permit the application of a standard surgical implant technique. To avoid interference during CT or MRI procedures, the device will be manufactured with no metallic parts.

In vivo results

Following 18 months of bench testing, the valve was judged to be safe for human clinical trials. A protocol for the implantation of the device was proposed. Short-term follow-up results in the first patients are promising. Long-term results will be published when available.

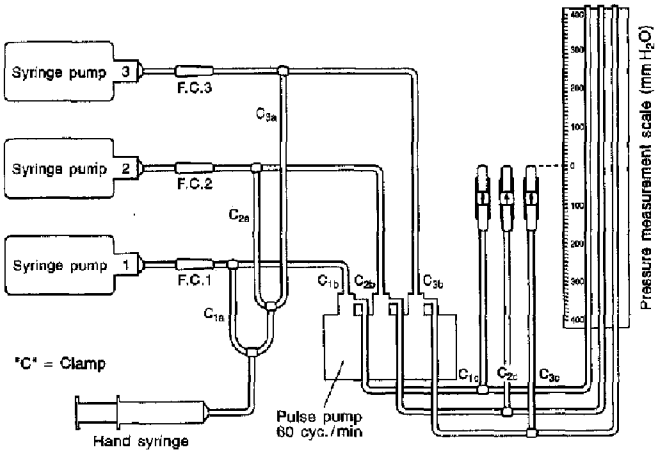

Fig. 5 In vitro pressure test apparatus

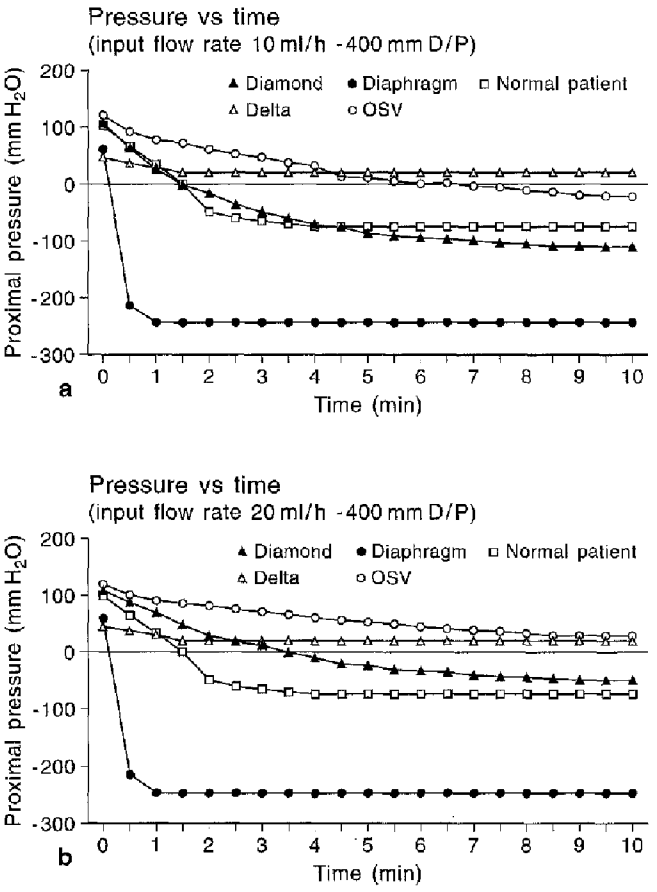

Fig. 6 **a** Relative change in pressure per unit of time that occurs when a patient rises from the recumbent position. At time 0, with simulated CSF production rate of 10 ml/h, all valves register between 50 mmH_2O and 120 mmH_2O. The distal tubing of each shunt is lowered by 400 mm to simulate the patient standing up. Within 30 s the diaphragm valve pressure drops to −220 mmH_2O, demonstrating no resistance to overdrainage. Each of the other valves also shows a drop in pressure. The pressure change of the diamond valve most closely simulates the pressure change previously recorded in standing patients without shunts. **b** Relative pressure change per unit of time that occurs when a patient rises from a recumbent position. With a simulated CSF production rate of 20 ml/h, all valves register pressures between 50 mmH_2O and 120 mmH_2O. Upon simulation of standing, the diaphragm valve pressure is shown to drop precipitously. All other valves also register a pressure change. However, in both the Orbis-Sigma and the Delta valves, pressure remains positive. Only the diamond valve registers a subatmospheric pressure and closely parallels the previously recorded pressure in standing patients without shunts

Conclusions

The use of shunts in the treatment of hydrocephalus remains an important and complex problem. This new device has improved characteristics compared with the currently available shunts, coping with ICP and CSF flow within physiologic limits. It also provided a quick solution

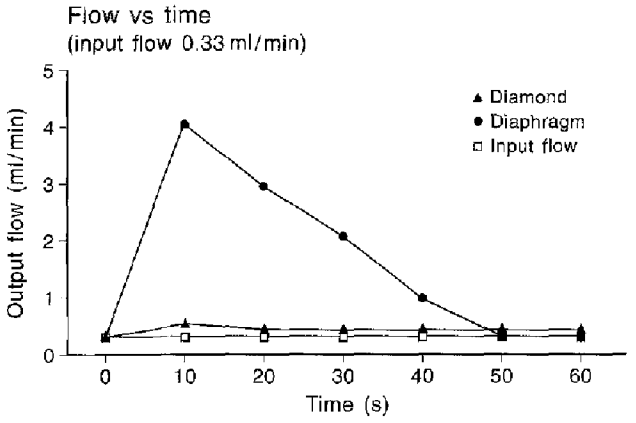

Fig. 7 Recorded change in flow rate upon simulation of standing. Within 10 s of standing, flow through the diaphragm valve increases from the input flow rate of 0.33 ml/min to a rate of 4 ml/min. This rate is shown to drop rapidly as the reservoir is depleted of fluid reserve. In contrast, the change in measured flow through the diamond valve was clinically insignificant

to simulated acute intracranial hypertension. Flow was adequately controlled, and the siphon effect was not observed during in vitro simulations. The preliminary results of clinical use confirm the benefits of the valve's characteristics. Additional studies are necessary to determine the long-term effectiveness of this new device in the treatment of hydrocephalus.

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