United States Patent [19]

Hakim

[11] **3,924,635**

[45] **Dec. 9, 1975**

[54] **VENTRICULAR SHUNT HAVING A VARIABLE PRESSURE VALVE**

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[21] Appl. No.: **478,434**

Related U.S. Application Data

[62] Division of Ser. No. 280,451, Aug. 14, 1972, abandoned.

[52] **U.S. Cl.** ..... **128/350 V;** 128/274

[51] **Int. Cl.²** **A61M 27/00**

[58] **Field of Search** ..... 128/350 V, 350 R, 349 BV, 128/274; 251/342

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Assistant Examiner—Henry J. Recla
Attorney, Agent, or Firm—Kenway & Jenney

[57] **ABSTRACT**

Proper cerebral hydraulic conditions may be maintained in the treatment of hydrocephalus by means of a ventricular shunt having a variable operating pressure valve, such that the CSF pressure may be controlled according to the size of the ventricle to correct the imbalance of forces developed by the CSF pressure against the ventricular area. These forces can be sensed in the dural region and utilized to control the operating pressure setting of the valve.

1 Claim, 8 Drawing Figures

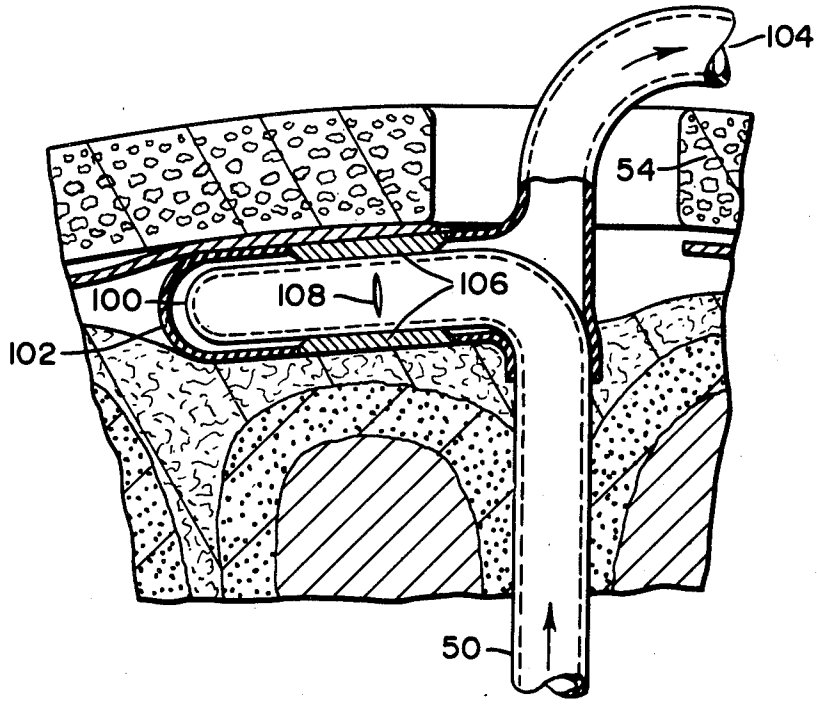
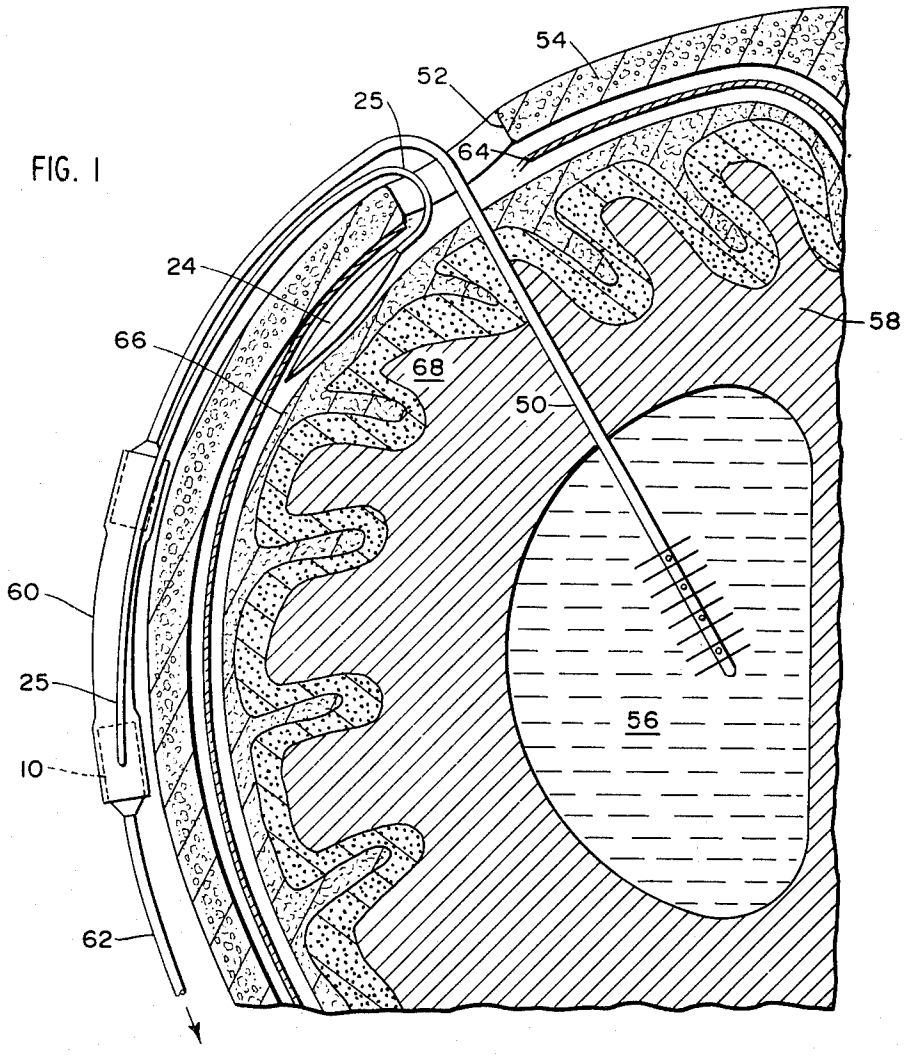


FIG. 1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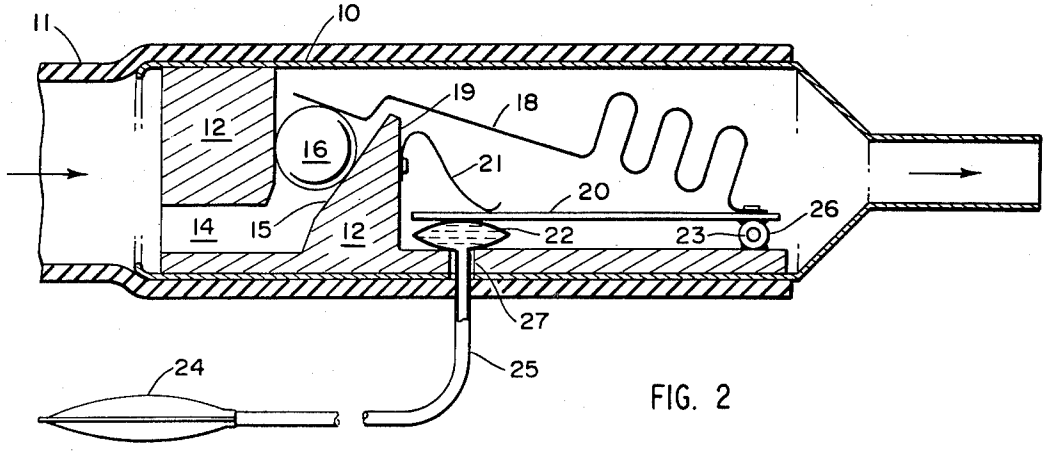
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FIG. 2

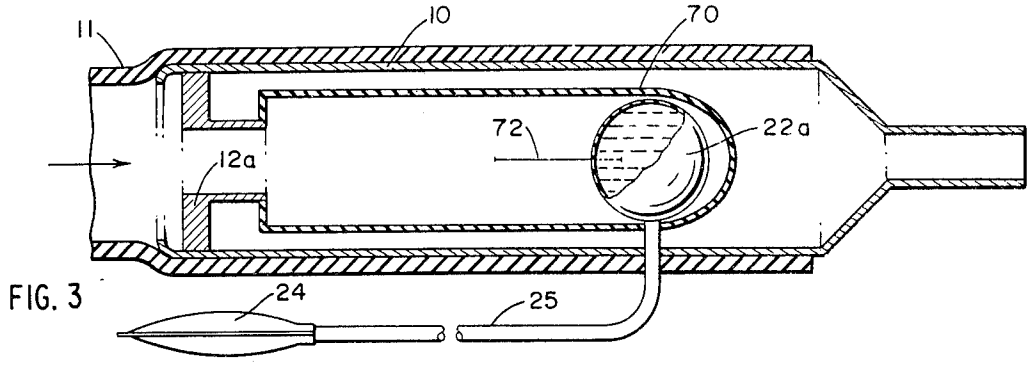

FIG. 3

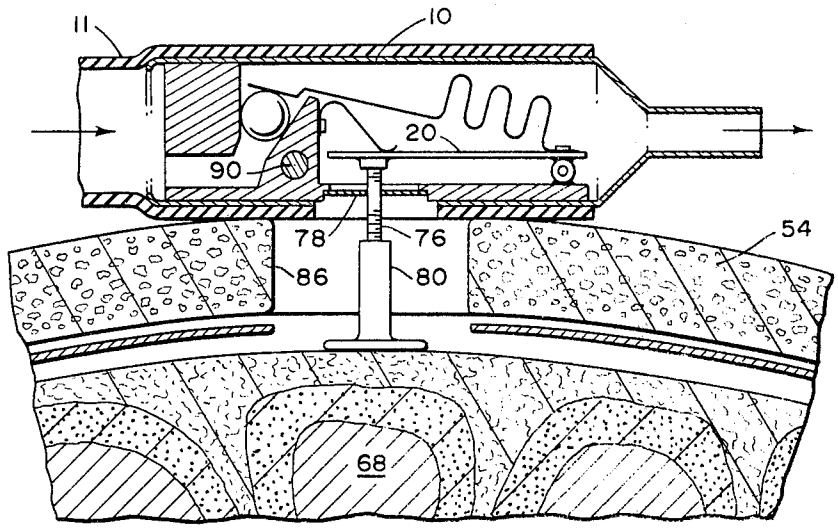

FIG. 4

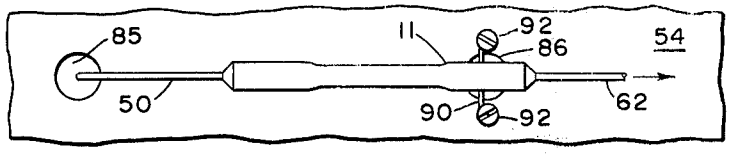

FIG. 5

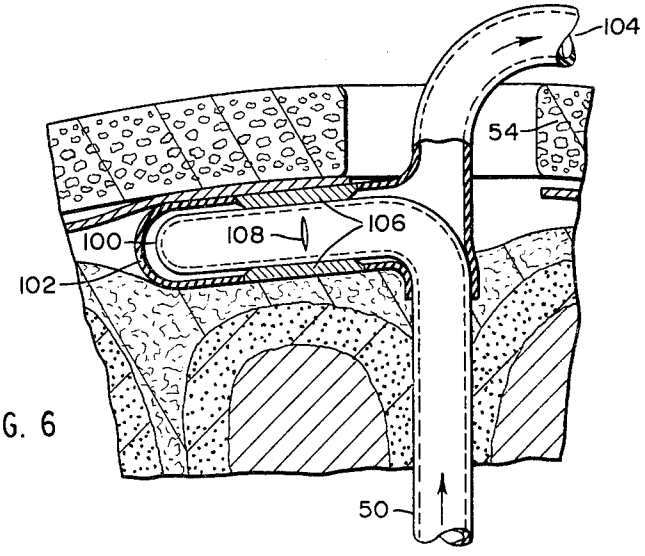

FIG. 6

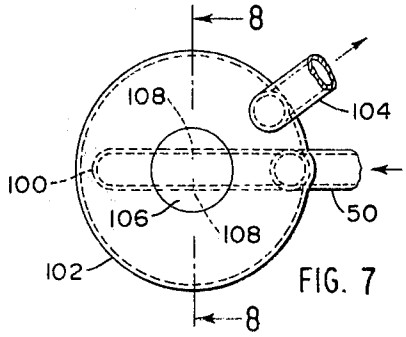

FIG. 7

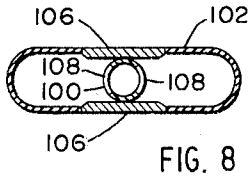

FIG. 8

VENTRICULAR SHUNT HAVING A VARIABLE PRESSURE VALVE

This is a division, of application Ser. No. 280,451 filed Aug. 14, 1972 and now abandoned.

BACKGROUND OF THE INVENTION

The treatment of hydrocephalus frequently involves the provision of a ventricular shunt for draining excess cerebral spinal fluid (CSF) from the ventricle in the brain. The shunt generally consists of a cerebral catheter inserted through the brain tissue into the ventricle and connected through a one-way valve system to drain into the jugular vein or another resevoir in the body. The shunt provides for removal of excess CSF from the ventricle and consequent reduction in its size. Control over the drainage is provided by the one-way valve, which normally operates at a fixed closing pressure.

Although hydrocephalus is frequently associated with an abnormally high CSF pressure, there are numerous cases where hydrocephalus is associated with the CSF at normal pressure, see Ojemann, Robert G., Normal Pressure Hydrocephalus, Clinical Neurosurgery, Vol. **18** pp. 337–370, 1971.

An analysis of the hydromechanics involved in normal pressure hydrocephalus syndrome leads to the conclusion that the effective force expansion from the ventricles is not dependant on the CSF pressure alone, but is the product of the CSF pressure and ventricular area. In other words, in the presence of ventricular enlargement a "normal" pressure is acting. Thus, in normal pressure hydrocephalus the ventricle remains enlarged, because the area subjected to the pressure of the CSF is larger than normal and hence the total force on the brain tissue, the product of the pressure times the area, is excessive. (See S. Hakim and R. D. Adams., The special clinical problem of symptomatic hydrocephalus with normal cerebrospinal fluid pressure: Observations on cerebrospinal fluid hydrodynamics. J. Neural. Sci., Vol. 2 pp. 307–327. 1965).

In addition to the forces developed by the CSF pressure, the brain tissue is subjected to a counterforce developed by the venous pressure within the intraparenchymatous system, within the brain tissue itself. Wheras CSF pressure tends to enlarge the ventricles, the venous pressure tends to reduce their size. These two forces are normally in balance so that the ventricular size does not increase nor decrease, but remains constant through life.

Accordingly, the aim in treating hydrocephalus by shunting procedures is not merely to arrest the condition, but to restore, as much as possible, normal ventricular size. Once hydrocephalus has developed, this restoration is accomplished by reversing the imbalance of the two forces acting on the brain parenchyma. The CSF pressure must be reduced by an amount proportional to the size of the ventricles to offset the increase force developed by virtue of their enlarged area. Then the forces developed within the venous system can cause the compressed brain tissue to "spring back" against the lower CSF force, and the venous bed will regain its lost volume and free flow. This way brain metabolism becomes normal and the tissue recuperates.

In treating hydrocephalus, a reduced CSF pressure is established by a shunt which includes a oneway valve having an operating pressure equal to the desired CSF pressure. With the shunt in place the CSF pressure remains at a maximum level determined by the implanted

valve and drainage of CSF fluid from the ventricles continues as long as CSF pressure is not less than the operating pressure of the valve. Since the correction of normal pressure hydrocephalus requires the implantation of a valve having a lower than normal operating pressure, e.g. 30–40 mm. H_2O, the CSF pressure remains lower than normal as the ventricle decreases in size. On the other hand the venous pressure remains normal; as a consequence the force imbalance is reversed. The venous system force becomes greater than the CSF system force because of the progressively smaller ventricular area and lowered CSF pressure. Accordingly, once the ventricle is again normal size the intraventricular CSF pressure must be brought back to normal levels. Otherwise there is not enough force within the ventricle to keep the brain normally expanded.

If on the other hand lower than normal CSF pressure is maintained, overcorrection of hydrocephalus may cause undesirable pathological consequences, such as "swelling" or engorgement of the veins, cerebral edema, "slit ventricles" and microcephaly. In other cases complications such as subdural hygromas, hematomas and overlapping of the skull bones are known to occur.

The ability to control the CSF pressure with respect to the ventricular area is important to the proper treatment of hydrocephalus, because proper balance within the brain must eventually be established.

In brief the problem in correcting and maintaining correct normal hydrodynamic balance in the cranial cavity is to maintain the interventricular CSF at a pressure corresponding to the ventricular area. When the ventricle attains normal size, the valve provided for the initial drainage should be replaced with one having a closing pressure equivalent to a normal CSF pressure (125–150) mm. H_2O.

To date there has been little recognition of the problem of maintaining the correct balance of CSF pressure, ventricular area and venous pressure within the brain.

In an ideal shunt system the valve should provide for initial drainage at a lower than normal pressure and thereafter operate at an operating pressure that maintains the correct intercranial balance.

Accordingly, in one aspect this invention provides a ventricular shunt valve having means to adjust and vary the valve operating pressure with respect to ventricular area such that the proper balance of forces within the cranium may be maintained.

In another aspect the invention makes use of the fact that the brain tissue is itself a viscoelastic solid which transmits the force developed at the ventricles outwardly to the dura region. This force may be sensed and utilized to control the operating pressure of the ventriculoatrial shunt valve appropriately to maintain proper drainage condition and balance of forces.

BRIEF DESCRIPTION OF THE INVENTION

The present invention provides a valve for a ventricular shunt characterized by an operating pressure that is variable with respect to the ventricular area so as to permit proper balancing of the force exerted on the brain by the CSF pressure in the ventricle with the constraining force developed by the venous pressure. This valve may accordingly be implanted to regulate the drainage of CSF from the ventricle at a properly low valve operating pressure (e.g. 45 mm. H_2O) when the

force of the CSF is excessive, and to provide for an elevated operating pressure as the brain tissue relaxes and the ventricular area decreases.

Applicant has discovered that the force on the brain resulting from the CSF pressure exerted over the area of the ventricle is transmitted through the brain tissue as a viscoelastic solid and may be sensed in the subdural space where the brain lies adjacent to the skull. This invention features a sensor adapted to be inserted into the dural region between the brain and the skull, in association with a ventricular valve having a working pressure that varies inversely with the force applied to the sensor.

In the preferred embodiments of the invention, inverse variation of the operating pressure of the valve is provided by a feedback arrangement, preferable hydraulic, wherein the force applied to the sensor is transmitted to counteract the spring bias which controls the operating pressure, thus to lower the operating pressure as the force increases. The spring which is biased to hold the valve closed, is unloaded in response to the force applied by the brain to the sensor.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred embodiment of this invention is described below with reference to the accompanying drawings in which:

FIG. 1 is a schematic illustration showing the valve system in its physiological enviornment;

FIG. 2 is a longitudinal cross-sectional view of the preferred valve mechanism and sensor of this invention;

FIG. 3 is a longitudinal cross-sectional view illustrating an embodiment featuring a resilient slotted tube valve mechanism;

FIG. 4 is a longitudinal cross-sectional view illustrating a valve mechanism featuring a mechanical brain force sensing control element;

FIG. 5 is a plan view showing the implantation of the valve mechanism illustrated in FIG. 4;

FIG. 6 is a longitudinal cross-sectional view, including a partial sagital section, illustrating a resilient slotted tube valve mechanism directly operable by brain forces;

FIG. 7 is a top plan view of the embodiment shown in FIG. 6; and

FIG. 8 is a transverse cross-section taken in 8—8 in FIG. 7.

The implantation of the ventricular shunt in illustrated in FIG. 1. A ventricular catheter 50 inserted through a burr holw 52 in the skull 54 and through the brain tissue 58 into the ventricle 56 connects through a one-way drainage valve 60 to a drainage catheter 62 which will normally lead to the right artium, the peritoneal cavity or some other suitable reservoir. The improved shunt valve of this invention is contained in the valve 60. The force exerted on the brain is sensed by a fluid filled bladder 24 which hydraulically connects by tube 25 to the valve 60 mechanism described below. The sensing bladder is inserted also through the burr hole, and preferably through the dural membrain 64 to lie against the arachnoidal membrain 66 over one or more convolutions e.g. 68. Best response to the forces in the brain require close association of the sensing bladder with the brain tissue (cortex). The subarachnoid space surrounding the convolutions is itself subject to CSF pressure, and would tend to give a pressure, rather than a force, response to a sensor output. The object, it will be noted, is to sense the force exerted by the brain tissue as distinguished from the pressure of the CSF.

As in general with ventricular shunts the entire drainage assembly is ultimately covered and held in place by the scalp (not shown).

The hydraulic servo shunt valve of this invention as embodied in FIG. 2 constructed generally as described in applicant's U.S. Pat. No. 3,288,142, and features a housing 10, a valve body 12 formed with a conical valve seat 15 which forms the outlet from an inlet channel 14. A spherical valve member 16, held down by a spring 18, rests within the conical seat and maintains the valve closed until the fluid pressure at this inlet is sufficient to overcome the bias force of the spring.

The spring 18, is mounted on a base plate 20 which is pivoted to the body 12 at the end of the spring away from the valve sphere. A preloading spring 21 extends from a forward shoulder 19 of the body and positions the base plate 20 for normal or maximum valve spring bias. The base plate 20 lies in spaced relation to a recess portion of the valve body on which is mounted a valve bladder 22 which is hydraulically connected by tube 25 to the sensing bladder 24. The valve bladder 22 is constructed to expand when hydraulically loaded to push the base plate 20 against the force of the preloading spring 21 and thereby unload the valve spring by moving it in the direction away from the valve sphere 16. The valve spring 18 is thus unstrained such that the force applied to the sphere is reduced, correspondingly reducing the working pressure of the valve; which is the fluid pressure at the inlet required to open the valve. When implanted the outward force exerted by the brain is applied to the sensing bladder 24 situated in the subdural region between the brain and the skull, and is transmitted hydraulically to the valve bladder 22. Thus when the force exerted by the CSF pressure applied over the ventricular area is increased, the operating pressure of the valve is reduced, and vice versa. Accordingly as the hydraulic brain contracts from CSF drainage, the resultant reduction in the brain force brings about an increased operative pressure effective to maintain proper drainage and a balance of forces.

Both the sensing bladder 24 and the valve bladder 22 are conveniently constructed of silicone rubber discs cemented together at their edges by means of silicone cement which may be of the RTV type or polymerizable by ionizing radiation. Silicone tubing 25 attached to the discs provides for hydraulic connection between the bladders. The bladders and tubing are conveniently filled with a radiopaque oil such as ethyl iodophenyl undecylate which provides appropriate viscous dampening of the valve mechanism, permits the hydraulic servo connection to be radiologically viewed, and is a safe material frequently used in myelography.

It will be understood that the valve mechanism described in FIG. 2 is the downstream end of the check valve pair described in U.S. Pat. No. 3,288,142, and is mounted in a flexible length of hollowing tubing 11 which surrounds the housing 10.

The actual construction is more or less conventional, with stainless steel being preferred for the housing 10, valve body 12, spring 18, base plate 20 and preloading spring 21. The spherical valve member 16 is preferably synthetic sapphire. The biasing spring 18 is spot-welded to the base plate 20 and the preloading spring 21 is spot-welded to the transverse shoulder 19. The pivotal

mounting of the base plate **20** to the downstream end of the valve body consists of a pin member **23** spot-welded to the lower side of the base plate **20,** received at its ends within sleeves **26,** conveniently formed of pieces of hypodermic needle tubing, spot-welded to the top side of the downstream end of the valve body **12.** The tube **25** passes through an opening **27** in the valve body **12** and also through the tubing **11** to which it may be sealed by silicone cement.

Implantation of the valve of this invention in a ventriculoatrial shunt system follows standard surgical procedures, with the additional procedure of inserting the sensing bladder **24** into the subdural region. Most conveniently this is introduced through the burr hole and then laterally a short distance away to lie between the brain and the skull.

After the system has been implanted, it may be desirable to make hydraulic adjustments to the servo connection to insure that the valve will open and close properly in response to variations in the force at the sensor. This may be accomplished by shimming the sensor with thin pieces of silicone, or by injecting or removing fluid with a hypodermic needle, preferably through a side branch tube (not shown) which may subsequently be sealed.

In the embodiment illustrated in FIG. **3** the valve consists in a resilient hollow closed tube **70** formed with a longitudinal slit **72.** The CSF fluid enters the valve tube **70,** and under sufficient pressure causes the slit **72** to open for drainage. The slit is also under the control of an internal spherical bladder **22***a*, hydraulically connected to the sensing bladder **24** and expansible under hydraulic pressure to urge the slit to open.

In the embodiment illustrated in FIGS. **4** and **5,** the construction is generally as described with reference to FIG. **2** with the exception that the control mechanism consists of a pin **76** mounted to the underside of the base plate **20,** passing through a silicone rubber seal **78.** The pin **76** is adjustably connected, e.g. threaded, to a sensing button **80,** adapted to be placed in contact with the exterior of the brain in the dural region. The threaded engagement between the pin **76** and the sensing button **80** provides for adjustment to the individual patient.

The mounting of this embodiment is illustrated in FIG. **5** and features two burr holes **85** and **86,** the former accommodating the catheter **50** and the latter accommodating the sensing mechanism. The valve mechanism is conveniently attached to the skull by a mounting pin **90** which passes through the valve body **12** and terminates in eyes by which the valve can be fastened to the skull, e.g. by screws **92.**

In the embodiment illustrated in FIGS. **6, 7,** and **8,** the valve mechanism is contained within a resilient chamber **102,** e.g. silicone rubber, formed for direct placement in the dural region in contact with the brain. The catheter **50** leads into the chamber **102** and terminates in a resilient closed tube **100** having a transverse slit **108** on a side wall protion. The top and bottom of the tube **100** contact opposite top and bottom walls of the chamber **102** and may incorporate small metal discs **106.** A drainage catheter **104** leads from the chamber **102.**

In operation, sufficient CSF pressure will cause the slit **108** to open and provide drainage from the catheter **50** into the chamber **102.** Should excessive forces develop, the chamber **102** becomes squeezed and the discs **106** compress the tube **100** causing the slit **108** to tend to open. Drainage at a lower CSF pressure is thus provided. As the brain contracts the force applied by the discs **106** is lessened and an increased CSF pressure becomes necessary for drainage. Thus proper drainage conditions and balance of forces may be maintained.

From the foregoing it will be noted that this invention has been described with specific reference to its preferred embodiment, it is contemplated that numerous modifications and alternatives will readily occur to those skilled in the art and familiar with the principles herein disclosed and that such may principles herein disclosed and that such may be adapted or utilized without departing from the scope of this invention.

Having thus disclosed my invention, I claim and desire to secure by Letters Patent:

1. A cerebrovascular shunt valve comprising a resilient valve body adapted to be inserted into the dural region, said valve body having opposed wall portions adapted to bear against the skull and the brain respectively;

a resilient tube which extends into said valve body between said wall portions and is adapted for connection to a ventricular catheter, the end of the tube being closed within the valve body, there being a slit in the side wall of the tube within said valve body for communicating CSF from said catheter into said valve body, said slit extending in a direction normal to the direction of the longitudinal axis of the tube and positioned between said opposed wall portions thereby being oriented with respect to the wall portions of said valve body to produce opening of said slit when said wall portions are driven against said tube by pressure of the brain against the skull; and

outlet means for venting CSF from said valve body to a location outside of the skull.

* * * * *