ABSTRACT: A device for draining cerebrospinal fluid automatically to the venous system in cases of hydrocephalus. The device includes an outer elastic tube which houses in its interior identically flow oriented upstream and downstream check (unidirectional) valves respectively communicating with the cerebrospinal fluid and the venous system. Each check valve includes an inner elastic tubular member within the outer tube and having an upstream open end and a downstream closed end. At the region of its downstream closed end each inner tubular member is formed with at least one axially extending slit which forms the outlet of the valve. Within each inner elastic tubular member is a freely movable ball member located in the region of the closed end of the inner tubular member where the slit is situated. A rigid tube is situated within each inner elastic tubular member and has a downstream end at a short distance from the closed end of the tubular member to provide the freely movable ball member with a restricted extent of axially free movement. Because of the free movability of this ball member within each check valve the interior thereof is kept clean, particularly at the region of the slits, and thus malfunctioning due to clot formations at the slit is reliably avoided. Moreover, since the slit extends to substantially the closed end of the tubular member, dead space in which blood can clot to obstruct flow is substantially eliminated and the danger of infection is substantially reduced.
DEVICE FOR DRAINING CEREBROSPINAL FLUID

BACKGROUND OF THE INVENTION

The present invention relates to devices for draining cerebrospinal fluid to the venous system. The device of the invention is that type of device which is disclosed in U.S. Pat. No. 2,969,066.

Such a device conventionally includes an outer elongated elastic tube within which identically flow oriented spaced upstream and downstream check valves are situated for respective communication with the cerebrospinal fluid and the venous system. Each check valve includes an inner elastic tubular member within the outer tube. Formed in the region of the downstream end of each inner tubular member is an axially extending slit which forms a valve opening. The valves are designed to automatically open when the pressure within each inner tubular member exceeds the pressure at the exterior thereof by a given slight amount, a slit automatically opening due to this pressure differential, while the slit will automatically close when the internal pressure is less than the external pressure of each tubular member, by less than the pressure required to open the slit.

According to the theory of operation of this type of drainage device, it will permit ready flow of fluid from the brain to the venous system; if the fluid clots as by clotting, or if flow reverses, pressing on the outer elastic tube between the check valve will constrict the inner space of the outer elastic tube between the check valves to force fluid out through the downstream check valve to the venous system. When the outer elastic tube is released, so that it expands back to its initial configuration, additional fluid is sucked from the cerebrospinal space into the space between the check valves through a slit of the upstream check valve. Such pumping action, brought about by way of pressing and releasing the outer elastic tube between the check valves, is intended to keep the slits clean and avoid clogging thereof. However, it has been found that there is a serious drawback to this construction, in that clotting of blood at the slits of the valves takes place in some cases to such an extent that pressing and releasing the outer elastic tube between the check valves is not capable of opening the slit of each valve, with the result that the device malfunctions and causes the death of the person who carries the device unless suitable measures are taken soon enough.

SUMMARY OF THE INVENTION

It is accordingly a primary object of the present invention to improve a structure of the above type in such a way that clogging thereof, as by the formation of blood clots, in the slits or outer elastic tube, is reliably avoided.

In particular, it is an object of the present invention to provide for a device of the above type a structure which will operate automatically to maintain the device clean, particularly at the slits thereof, so that the valve slits cannot become clogged.

In addition, it is an object of the present invention to provide for a device of the above type slits which in themselves have a construction which will contribute to the reliability of the operation.

Also, it is an object of the invention to provide a construction of this type which is composed of a relatively small number of elements, in addition to those which are required by the conventional structure, which can be readily and easily assembled with the remainder of the structure and which will reliably prevent malfunctioning.

According to the invention, the outer elastic tube houses in its interior identically flow oriented spaced upstream and downstream check valves for respectively communicating with the cerebrospinal fluid and the venous system. Each check valve includes an inner elastic tubular member having an open upstream end and a closed downstream end, and in the region of its closed downstream end each inner tubular member is formed with at least one axially extending slit. The downstream end of each inner tubular member is of a substantially hemispherical configuration and the slit which is formed therein intersects the hemispherical portion of the inner member so that the opening of the slit takes place not only along an axially extending portion of the inner tubular member but also at a curved transversely extending portion at the hemispherical closed end, to greatly enhance the springy opening and closing of the slit, greater opening, i.e., a wider spacing between the lips of the opened slit and better opening and closing accuracy, as compared to the functioning of a slit which extends only through a purely axial cylindrical wall portion of the inner tubular member, and also to eliminate dead space at the downstream ends of the inner tubular members.

Moreover, the new arrangement will eliminate the formation of stagnant pools of cerebrospinal fluid, thus reducing infection problems experienced with prior art devices.

Each inner tubular member is provided in its interior, in the vicinity of its closed downstream end, with a freely movable ball member. In the interior of each inner tubular member is a rigid tube having a downstream end situated upstream of the ball member and spaced from the closed end of the inner elastic tubular member by a distance which will provide for the ball member, a given extent of free axial movement for at least about the length of the associated slit. Because the ball members in the check valves are capable of moving about freely due to any movements of the person who carries the device, these ball members are constantly moving so as to maintain fluid within the inner tubular elastic members constantly in motion, thus preventing clogging of the valve slits.

Other objects of the invention in part will be obvious and in part will be pointed out hereinafter.

The invention accordingly consists in the features of construction, combinations of elements and arrangements of parts which will be exemplified in the device hereinafter described, and of which the scope of application will be indicated in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is illustrated by way of example in the accompanying drawings which form part of this application and in which:

FIG. 1 is a schematic representation of the manner in which the device of the invention is employed.

FIG. 2 is an enlarged longitudinal sectional elevation of the device of the invention.

FIG. 3 is a transverse section taken along line 3-3 of FIG. 2 in the direction of the arrows and showing the structure on a scale which is enlarged as compared to FIG. 2; and

FIG. 4 is a perspective illustration of one of the check valves, also shown on an enlarged scale as compared to FIG. 2.

DESCRIPTION OF A PREFERRED EMBODIMENT

Referring to FIG. 1, the device 10 of the invention is schematically indicated in the condition it has during use. An elongated inlet tube 12 made of medical grade silicone rubber, for example, extends through a skull opening 14 into the lateral ventricle to communicate with the cerebrospinal fluid. For this purpose the inlet tube 12 may terminate within the skull in a closed end in the region of which the tube 12 is formed with a plurality of openings extending through its wall, so that the cerebrospinal fluid can freely enter into the tube 12. The fluid can then flow through the inlet tube 12 into an outer elongated elastic tube also made of medical grade silicone rubber and housing the series of check valves of the invention, which are described in greater detail below. A discharge tube 18, made, for example, of polyethylene, is connected at its bottom end to the jugular vein, so that in this way the device 10 provides a path of flow for the cerebrospinal fluid to the venous system in the event that entrance in the former exceeds pressure in the latter by an amount sufficient to open the check valves. This discharge tube 18 is secured in the jugular vein 20, schematically shown in FIG. 1, through a suitable incision.
Secured within the upstream end of the outer elastic tube 16 is an upstream check valve 22, while a downstream check valve 24 spaced from the valve 22 is housed within the tubular member 16 in the region of its downstream end FIG. 2. Both valves are identically flow oriented to pass fluid in an upstream-downstream direction upon a slight pressure differential.

The upstream check valve 22 includes an inner elastic tubular member 26 of silicone rubber of medical grade, for example. This inner elastic tubular member 26 extends into the interior of a thin substantially rigid 0316 stainless steel sleeve 28 fixed within the upstream end of the interior of the outer elastic tube 16. At its upstream end which is open, the inner elastic tubular member 26 is provided with an outwardly extending flange 30 engaging an inner shoulder of the rigid sleeve 28, and a substantially rigid inner metallic tube 32 which is made of 0316 stainless steel, extends into the interior of the elastic tubular member 26. This tube 32 has between its ends a flange 34 engaging the upstream end of the flange 30 and holding it against the shoulder of the sleeve 28. Flange 34 may have a press fit within the sleeve 28 so as to remain reliably fixed thereto. Upstream of its flange 34 the rigid tube 32 is connected with the inlet tube 12. The exterior surface of the sleeve 28 and the exterior surface of the part of tube 32 which is received in the tube 12 may be corrugated so that with the use of silk string or the like it is possible to tie the outer elastic member 26 against the exterior surface of sleeve 28, extending into the corrugations thereof, and the inlet tube 12 against the exterior surface of the tube 32, also extending into the corrugations thereof. In this way a secure connection is provided between the elastic tubular members 16 and 12 and the metallic tubular members 28 and 32, respectively.

The inner elastic tubular member 26 of the check valve 22 terminates in a closed downstream end 36 which is of hemispherical configuration. According to one of the features of the invention the tube 26 (see FIG. 4) is formed with a pair of diametrically opposed axially extending slits 38 which have at their downstream ends inner edges 40, respectively, which form extensions of the interior surface of the tube 26. As a result these axially extending slits 38 directly intersect and extend through a portion of the hemispherical end 36 leaving the latter only with a central permanently closed portion whose diameter is equal to the distance between the edges 40 of the slits 38 and thus equal to the inner diameter of the tube 26. Thus, the downstream end of each slit 38 extends through a portion 42 at the hemispherical end 36, this portion 42 being curved inwardly from the exterior surface of the tube 26 so as to extend substantially transversely thereof towards the central region of the end 36.

Therefore, when each slit 38 opens, the manner in which it opens, and also the manner in which it closes are exceedingly efficient because of the possibility of circumferential spreading of the downstream ends of the slit surfaces at the transverse wall portion formed by the outer peripheral region of the hemispherical closed end 36 which is intersected by each of the opposed axially extending slits 38.

The situation of the slits 38 so that they extend all the way through to the downstream surface of the tube 26, where it is convexly curved at its hemispherical end portion, is of great importance. If the slits 38 were to terminate inwardly of the hemispherical end portion, while the exterior surface of the tube 26 did not curve inwardly, then opening of such a slit could be brought about only by an accompanying reduction in the length of the tube, so that a considerable force would be required to open each slit due to the necessity of shortening the length of the tube when the slit opens. In other words, the closed end of such a tube would have to be pulled toward the upstream open end thereof when a slit situated inwardly of the hemispherical end of the tube opened. However, with the construction of the invention, as shown in FIGS. 2 and 4, the wall thickness of the tube gradually diminishes in the region of the downstream end of the tube, and the external diameter of the closed hemispherical end of the tube increases the flexibility of this hemispherical end and permits the downstream ends of the slit to turn away from each other so that this construction greatly reduces the opening resistance which would be present if the slits terminated at their downstream ends upstream of the closed end of the tube.

A further feature of the invention resides in situating in the interior of the tubular member 26 a freely movable ball member 44 made of nylon, for example. The rigid steel tube 32 extends from its flange 34 axially along the interior of the tube 26 in a downstream direction and terminates in an open-ended downstream end 46 situated at a given distance upstream of the closed end 36 so as to provide for the ball member 44 a given degree of free axial movement about equal to the length of the slits before it will engage either the closed end 36 or the end 46 of the tube 32. Thus, the ball member 44 can move freely between the closed end 36 and the end 44 in response to any motion of the individual who has implanted in him the device of the invention. Therefore, the ball member 44 constantly moves about and maintains the fluid within the elastic member 26, constantly in motion. In this way the interior of the inner elastic tube 26 is kept clean, particularly at the region of the slits 38, so as to further prevent the possibility of clogging of these slits, as by debris.

In addition it will be noted that the end 46 of the tube 32 is of a circular configuration and has an outwardly flaring end surface which will, in fact, form the equivalent of a valve seat for the ball member 44. Thus, when this ball member 44 engages the end 46 of the member 32, these elements will act as a check value to prevent back-flow of fluid. There is, in effect, an inner reverse check valve situated within the outer check valve formed by the tube 26.

It is to be noted that the tubular member 26 is provided with an exterior diameter equaling the inner diameter of the sleeve 28 only upstream of the slits 38. This portion of larger diameters is connected by a shoulder 48 to the downstream elongated portion of the tube 26 which is of lesser wall thickness so as to be spaced inwardly from the inner surface of the sleeve 28. This portion of thinner wall thickness is formed with the slits 38 described above. The ball 44 is of slightly lesser diameter than the internal diameter of the tube 26 to prevent sticking.

The downstream check valve 24 is substantially identical with the upstream check valve 22. This check valve 24, in fact, has an inner elastic tubular member 50 identical with the tubular member 26. This member 50 is housed within a rigid metallic sleeve 52 which at the downstream end of the outer tube 16 has a tubular extension 54 about which the outlet tube 18 is constricted in the manner shown in FIG. 2. An elongated rigid inner 0316 stainless steel tube 56 extends into the interior of the inner elastic tubular member 50 and terminates at its downstream end in the circular end face 58 which coaxes with a nylon ball member 60 in the same way that the end 46 of tube 32 coaxes with the ball member 44. The ball member 60 has within the inner tubular elastic member 50 the same degree of movement that the ball member 44 has within the tubular member 26. The diametrically opposed slits 62 of the tubular member 50 are indentical with the diametrically opposed slits 38 described above and operate in the same way. It will be noted that both of the rigid tubes 32 and 56 have downstream end portions of reduced wall thickness extending beyond the upstream ends of the slits and spaced from the inner elastic members adjacent the slits so as to increase the ease with which the slits can be opened. The rigid tube 56 terminates at its upstream end in a flange 64 which functions in the same way as the flange 34 described above.

The operation of the structure described above is believed to be clear. The cerebral spinal fluid flows through the inlet 12 to the left, as viewed in FIG. 2, as indicated by the dot-dash lines and arrowheads in FIG. 2. Assuming that the pressure of the fluid in the interior of the inner elastic tubular member 26 of the upstream check valve 22 is sufficiently in excess of the pressure of the fluid between the pair of check valves, then the slits 38 will cause each slit cut into the closed hemispherical end of the tube to flow through the open check valve into the space within the outer elastic tube 16 between the pair of check valves. In this way the fluid
will reach the downstream check valve 24 where with the same pressure differential the latter valve will also automatically open to pass the fluid into the discharge tube 18.

All of the elastic components may be made of medical grade silicone rubber while all of the metal components may be made of stainless steel, and the ball members 44 and 60 may be made of nylon. The check valves are designed to respond (open) to a pressure differential of between 23 and 27 mm. of water. In the reverse, back-flow direction, the valves will reliably remain closed since they are capable of withstanding a pressure in the reverse (back) direction of up to the region of 200 mm of mercury. In an actual construction, the inner elastic tubular members 26 and 50 each have an inner diameter of 0.070 inches while the diameter of each ball member 44 and 60 is 0.0625 inches. The overall length of the device 10 is about 2-3/16 inches. The entire device, and the tubes 12, 18 are implanted under the wearer's skin to be removed only in the event of the cure of the hydrocephalus or for replacement. Medical grade silicone rubber is made of silicone polymers, silica filler, and catalysts (organic peroxides).

It thus will be seen that there is provided a device which achieves the various objects of the invention and which is well adapted to meet the conditions of practical use.

As various possible embodiments might be made of the above invention, and as various changes might be made in the embodiment above set forth, it is to be understood that all matter herein described or shown in the accompanying drawings is to be interpreted as illustrative and not in a limiting sense.

1. In a device for draining cerebrospinal fluid to the venous system, an elongated outer elastic tube; upstream and downstream identically flow oriented spaced check valves respectively located in said tube and each having an upstream inlet and a downstream outlet, means communicating with the upstream inlet of said upstream check valve for placing the latter in communication with cerebrospinal fluid, means communicating with the downstream outlet of said downstream check valve for placing the latter in communication with the venous system, and each check valve comprising an inner tubular elastic member housed within said outer elastic tube and having an open upstream end forming said inlet and a closed downstream end, said inner tubular member of each check valve being formed in the region of its closed downstream end with an axially extending slit which forms an outlet in response to an excess in the internal pressure of said inner tubular member with respect to the external pressure at the region of said slit for automatically opening the latter to provide for flow of fluid downstream through each inner tubular member out through said slit, each slit automatically closing in response to an increase in the external pressure over the internal pressure of said tubular member to prevent fluid from flowing in an upstream direction, a ball member situated in the interior of each inner tubular member in the region of said closed end thereof and being freely movable therein, and a substantially rigid tube situated in each inner tubular member and having a downstream end situated adjacent said ball member at a distance from the closed end of each inner tubular member sufficiently great to provide a predetermined extent of movement of the ball member, so that the moving ball member will maintain fluid in each inner elastic member in motion for preventing malfunctioning of said slit due to clotting and also eliminates dead space in the inner tubular member.

2. The combination of claim 1 and wherein said closed end of each inner tubular member is of a substantially hemispherical configuration and said slit extending in an axial plane through part only of said closed end of hemispherical configuration.

3. The combination of claim 2 and wherein each inner tubular member is formed with a pair of said slits which are diurnically opposed to each other.

4. The combination of claim 3 and wherein the distance between said slits at said closed end of each inner tubular member is equal to the inner diameter of the latter tubular member so that said slits have at said closed hemispherical end of each inner tubular member inner edges respectively forming continuations of the inner surface of said inner surface of said inner tubular member.

5. The combination of claim 1 and wherein said slit of each inner tubular member extends from the immediate vicinity of said closed end thereof in an upstream direction beyond said downstream end of said rigid tube.

6. The combination of claim 1 and wherein each inner tubular member has at its downstream closed end a pair of said slits diametrically opposed to each other and extending partly only into said closed end, said closed end being of a hemispherical configuration and said slits respectively terminating at said closed end in inner edges respectively forming continuations of the inner surface of said inner tubular member, said pair of diametrically opposed slits of each inner tubular member extending axially from said closed end thereof in an upstream direction at least about equal to the axial length of the slits.

7. The combination of claim 1 and wherein each rigid tube is formed at its downstream end with a circular end face to be engaged by said ball member during movement thereof in an upstream direction in each inner tubular member, so that said ball member and rigid tube also functions as an inner check valve to prevent back-flow of fluid.

8. The combination of claim 1 and wherein each ball member is made of nylon.

9. The combination of claim 8 and wherein said outer tube and inner tubular members are made of silicone rubber, said rigid tubes being made of stainless steel.