ANTI-SIPHONING DEVICES TO PREVENT THE OVER-DRAINAGE OF CSF IN EXTERNAL SHUNTS

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Abstract. *The watery solution continually produced inside the brain in the choroid plexus tissues is named cerebrospinal fluid (CSF). Humans are estimated to produce about 0.5 ml/kg per hour, or about 500 ml or more of CSF each day. Elevated levels of CSF are associated with traumatic brain injury, meninge infections (meningitis) and a pediatric disease known as hydrocephalus. In all of these cases, an increasing fluid pressure (intracranial pressure), resulting in permanent brain injury and death, can be observed. Following the diagnosis of hydrocephalus, there are few options other than surgery for treatment. Most surgeons use various types of systems called shunts to channel the fluid from the cerebral ventricles to other sites in the body such as the abdominal or peritonial cavities (internal shunts). CSF can also be drained towards an external reservoir (external shunts). External shunts or external ventricular drainage (EVD) systems have several parts or componentes and CSF is channeled out only by pressure gradient. Some conditions can provide a siphoning efect producing a overdrainage. Few seconds of overdrainage can produce irreverssible damage or death. Unfortunately, nowadays EVD systems utilized implicate in elevated overdrainage risk. In the present work a new valve has been proposed in order to prevent the over drainage of CSF in external shunts. Several testes have been carried out showing the operational envelop of the proposed device.*

Keywords*: cerebrospinal fluid, CSF, external shunt, liquor, hydrocephalus*

1. INTRODUCTION

A normal adult produces about 500 ml per day of cerebrospinal fluid (CSF), a watery solution continually produced inside the brain by choroids plexus tissues. The total CSF volume capacity in an adult is limited to 120 – 150 ml. In normal circumstances, CSF is recycled over three times each day. If CSF production exceeds absorption, internal cerebral pressure (ICP) can rise to dangerous levels. An anomalous accumulation of cerebrospinal fluid internal the brain is known as hydrocephalus or, more popularly, water on the brain. Untreated hydrocephalus produces high levels of death and the survivors shows several physical and mental disabilities, in accord to Sood *et al.* (2001).

Hydrocephalus is a pathophisiology of adults and children caused by congenital malformations (like intracranial cysts, aneurisms and others brain anomalies), tumors, inflammations, infections, meningitis and intracranial hemorrhages, traumatisms and other, Pople, (2002).

Hydrocephalus diagnostic can be easily obtained by means of computerized tomography (CT) scan showing enlarged ventricles or by means of magnetic resonance imaging (MRI). Following the diagnosis of hydrocephalus, there are few options other than surgery for treatment. CSF shunting permits to channel the fluid from the cerebral ventricles to other sites resulting in levels of ICP acceptable. Since 1960, when cerebral shunts were first introduced, death rates associated with hydrocephalus have decreased from 54 % to 5 % and the occurrence of intellectual disability has decreased from 62 % to 30 %, - Sood *et al.* (2001).

A semi-permanent internal CSF shunt is a delicate neurosurgical procedure involving a placement of a ventricular catheter into the brain ventricles to bypass the flow and drain the excess of CSF to other site, more commonly to peritoneal cavity. Unfortunately, internal CSF shunt treatment is associated with multiple complications. Shunts are susceptible to failures and malfunctions, just like any mechanical device and the shunt system may need to be periodically revised. When a shunt system shows any problem and need to be replaced, this procedure is referred to as revision. Because the serious problems associated to shunt revision, nowadays a lot of research has been continuously developed for internal shunts.

Under certain circumstances, it is desirable to treat hydrocephalus by draining the excess fluid from the ventricles of the brain to a collection receptacle that is outside the body, such as in the case of surgically induced hydrocephalus which may be only a temporary problem and would not require a totally implanted shunting system. In such a case, an external provisory shunt or drainage system is desirable. In relation to internal semi-definitive totally implanted shunts, external provisory shunts show reveal few studies.

External ventricular drainage in patients with obstructive hydrocephalus is used extensively in many neurosurgical centers as a routine procedure for the temporary relief of ICP. Shalit *et al.* (1979) have found that the use of external continuous ventricular shunt decreased mortality rate most significantly.

Rapaport & Shalit, (1989) relate 59 patients with infratentorial brain tumours associated obstructive hydrocephalus, as evidenced by preoperative CT scan. External shunt drainage was performed in these cases and only 6 cases (10 %) required a subsequent internal shunt. The infection rate was 10 % and the total mortality was 8 %. Provisory external shunts during and following the removal of posterior fossa tumors causing hydrocephalus provides an effective alternative to internal shunt. Use of external shunts permit a post-operative ICP monitoring and drainage of blood and debris laden CSF, increasing the safety and possibly reducing the incidence of meningitis.

If ICP reach levels of 120 to 150 mm of H_2O, there is a risk of rapid internal herniation. Because of the inefficiency of the drugs, the only therapy available is an implant of an external drainage of CSF. In this sense, Pertuiset *et al.* (1976) relate experience with 202 cases of external shunts and its medical complications.

Winkin *et al*., (1999) recommend the use of external provisory drainage of CSF in children in acute hydrocephalus e.g. after intraventricular bleeding or infection. In these cases the drainage has to remain in place until physiological CSF circulation is restored or up to an internal shunt can be inserted.

Several different hydrodynamic studies of external drainage of CSF have been intensively performed out by Maset *et al.* (2005, 2006) and Camilo *et al.* (2005, 2006a) relating several hydro-mechanical aspects of external shunt operation.

2. CSF DRAINAGE

In few words, hydrocephalus is an accumulation of CSF in the brain, resulting from an increased production or, more frequently, a pathway obstruction or decreased absorption. Most surgeons use various types of systems called shunts to channel the fluid from the cerebral ventricles to other sites in the body such as the peritoneal region (ventriculo-peritoneal shunt) or, more frequently, abdominal cavities, where it can be resorbed. Those drainage shunts are denominated of internal shunts and it involves the placement of a ventricular catheter internal the cerebral ventricles in order to drain the excess fluid. An alternative treatment, indicated only for obstructive hydrocephalus, is the endoscopic third ventriculostomy (ETV), a created surgical opening in the third ventricle allows to CSF flow directly to the basal cisterns, thereby shortcutting any obstruction.

Internal shunts have been proposed to be quasi-permanent implants in order to support several years of constant operation. In opposition, external shunts have been proposed to be temporary operating for few days. Several hydrodynamics studies of internal shunts have been carried out since 1960, when the combined invention of artificial valves and silicone led to a worldwide therapeutic breakthrough. After the first generation of simple differential pressure valves, which are unable to drain physiologically in all body positions, a second generation of adjustable, autoregulating, antisiphon, and gravitational valves was developed, but their use is limited due to economical restrictions and still unsolved technical problems. Those problems still the fluid dynamics of internal CSF shunts in until continuous study.

External ventricular drainage (EVD) is a temporary system which allows drainage of CSF from the lateral ventricles of the brain. EVD are commonly utilized within the neurosciences unit for the management of patients requiring drainage of CSF in order to control raised intracranial pressure associated with head injury, subarachnoid haemorrhage, acute hydrocephalus secondary to cerebral aqueduct obstruction, posterior fossa tumors or purulent meningitis. If temporary EVD is unsuccessful, a more permanent intervention such as a ventricular-peritoneal shunt (or other internal shunt) can be placed.

When an internal shunted patient with slit-ventricle syndrome shows a shunt malfunction, in any cases, a drainage utilizing externalized shunt permits a control of an intracranial hypertension. Butler & Khan, (2001) relates the use of controlled intracranial hyper pressure (positioning the external bag in 18.8 cm of height from Monro’s foramen) in four patients with up to 24 shunt revisions for an average of 5.8 days. This procedure reveals a relative increased of the mean transverse third ventricular diameter.

In accord to Sesay *et al.* (2002), the external drainage of CSF has been realized only in emergency situations and frequently external drainage is a provisory condition after the surgery to implant semi permanent internal drainage device. A sketch of an external provisory device for CSF drainage has been shown in Fig. 1. External reservoir is submitted to atmospheric pressure (Patm) and the height H should be carefully determined by surgeon. If the pressure internal the ventricles has values more than the static pressure produced by the liquid column of height H the flow occurs in direction of the external bag. If ICP is less than static pressure of the liquid column produced by height H, the unidirectional valve is activated in order to provoke the blockage of the flow, impeding a reversing flow. The CSF volumetric flow rate is carefully controlled by adjust of the height H.

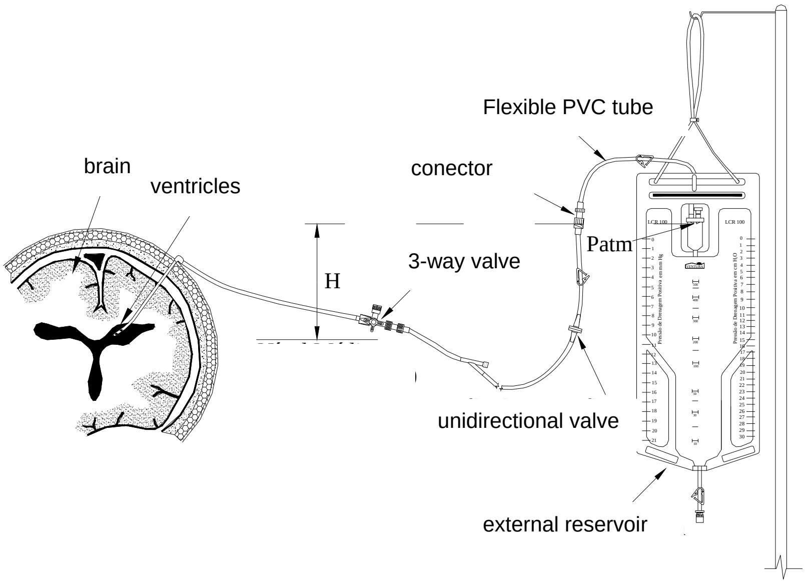

Figure 1. Neurosurgical external gravitational shunt sketch.

Figure 1 shows a typical external system of cerebrospinal fluid drainage. This apparatus consists of a proximal (ventricular) end that is inserted through the skull (via a small hole), through the brain substance, and into the cerebral ventricles. This catheter is connected to a small diameter flexible tube. A typical flexible tube made in PVC is depicted in the Fig. 2. The three-way taps have been utilized in external CSF drainage in order to connect electronic devices for monitoring ICP, to provide a rapid means of drugs infusion (antibiotics for CSF infection or chemotherapy medication for tumors) and to gather samples of CSF to be examined for bacteria, cancer cells, blood or protein, depending on the cause of hydrocephalus. In post-subarachnoid and post-meningitic hydrocephalus, CSF samples are useful for cell counts, protein concentration, and to exclude residual infection. A protein concentration greater than 4 g/l will clog up most ventriculo-peritoneal internal shunt valves. Recently, optimized design of three-way taps for external shunts attracted attention of researchers – Camilo *et al.* (2006 b).

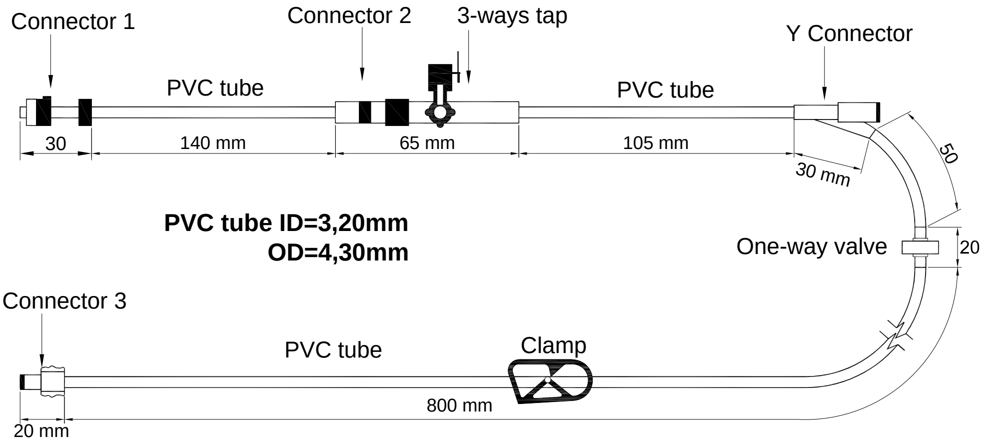

Figure 2. Biomédica mod. LCR - 500 neurosurgical external tube sketch.

In 1999, Aschoff *et al.* (1999) show 127 different types of neurological valves commercially available since 1949 and more than others 70 models in different developing phases. All of these valves have been developed for application exclusively in internal shunts. Internal shunts for drainage CSF utilize a neurological valve to stabilize the ICP controlling the flow rate and, consequently, to avoid the overdrainage. Unfortunately, even at the present day, the drainage characteristics of neurological valves are far from ideal. In this viewpoint, many effort of research are realized to improve neurological valves. In addition the use of internal shunts has created problems of shunt dependence with frequent shunt revisions being the rule for most hydrocephalic children. Because of this inconvenient, internal shunt problems assume a major amount of all neurosurgeon’s efforts and the more target of research. In the other side, few efforts have been realized in research in external shunts. The use of external shunts is an important provisory procedure in a first phase of hydrocephalus treatment, before the implantation of internal shunts.

3. OVERDRAINAGE

Overdrainage (or siphoning effect) refers to several scenarios in which a shunt is functioning (not obstructed) but is removing more fluid than the necessary for that particular patient. Adult humans in normal conditions are estimated to produce continually about 0.5 ml/kg per hour of cerebrospinal fluid (CSF) and this volumetric flow should be absorbed continually by the organism.

Browd *et al.* (2006) utilizing internal shunts have show that overdrainage conditions can present relatively early after shunt insertion with extra-axial fluid or blood collections (subdural hematoma). More commonly, the excessive drainage results in small ("slit") ventricles and in serious complications. Overdrainage may result in collapse of the brain and accumulation of fluid or blood around the brain. Most frequently, benign cerebrospinal fluid collections are observed; however, subdural hematomas are possible.

In accord to Fig. 1, ICP should overpass the height H to produce drain effect. If height H is very small or negative overdrainage (or siphoning effect) occurs after shunting. Over drainage of cerebrospinal fluid can occurs frequently and after few seconds in this adverse condition unavoidable non reversible cerebral damage can be produced. Over-drainage of gravitational external shunts studies have been intensely realized by Camilo *et al.* (2005) and Maset *et al.* (2005). Over drainage of the ventricles can result in collapse of the brain away from the inner surface of the skull with a resultant risk of bleeding with compression of the brain. Long term over drainage can result in headaches of a very debilitating degree.

The more frequent complication associated to an elevated drainage flow rate is a generation of a low ICP. ICP is a physiological constant of fundamental importance and ICP alterations, positive or negative, can determine irreversible damages in neurological system, Gusmão *et al.* (2000).

In this present effort of research work a device for prevention of siphoning effects has been especially developed and proposed in order to prevent overdrainage in external CSF shunts applied to hydrocephalus surgery treatment. Additionally, hydrodynamic test of a first prototype of anti-siphon valve for external shunts has been showed.

4. HYDRODYNAMIC TEST OF SHUNTS

Since the advent of CT several hydrodynamic problems associated to liquor drainage have been observed. Generally, those complications have correlation with mechanical malfunctions of the shunt system. An adult, in normal conditions, generate constantly around of 0.33 ml of CSF per minute, producing a laminar flow regime internal the shunt components. The CSF production rate is constant but, the drainage flow rate by shunt system is strongly influenced for physiological conditions producing. A low flow rate produces a rise of ICP and a high flow rate produces low ICP. Symptoms of hyper ICP are very similar to the symptoms associated to hypo ICP. Hypo ICP can produces irreversible damages in nervous system after few seconds of exposure. In consequence of the flow rate dependence of physiological conditions several apparatus for testing of shunts have been proposed in technical literature – Camilo, (2005).

Neurosurgical implants standards covering flow characteristics are available, for example, ISO 7197 (and ASTM F647. In those publications, several test procedures relative to flow resistance, flow directions and others hydrodynamics characteristics of complete shunts or parts of shunts are detailed.

Because the low flow velocity involved shunt testes must be carried out careful and expensive flowmeters devices should be utilized in order to obtain precise measurement results. Generally, the shunt tests take controlled conditions and automatic data acquisitions are absolutely necessary.

Camilo *et al.*, (2006 a) proposed an especially designed device for testing complete external shunts or parts of shunts in order to measure the behavior of the flow rate as function of loss of pressure. In the reservoir bag the pressure is exactly the value of the local atmospheric pressure. ICP should be sufficient to overpass the hydrostatic barrier of the height H (regarding H positive) depicted in Fig. 1. For different H heights a value of flow rate is observed for each individual shunt. Details of the proposed device for hydrodynamic test of CSF derivative shunts are available in Camilo (2005).

5. ANTISIPHONING DEVICE PROPOSED

The first generation of valves to install in ventricle peritoneal shunts has developed only to operate in function of a pressure difference between ICP and the abdominal pressure. Those valves are very sensitive to physiological conditions and hiperdrainage (or siphoning effect) can be observable. If the implanted shunt has a low pressure loss (for example in neonates), low levels of ICP cause a high CSF flow rate. In opposition, adults with a long tube shunt (consequently, high loss of pressure) in erected position, the gravitational effects provokes a high pressure difference, because the vertical column of liquid, permitting occurs a siphon effects. In order to avoid hiperdrainage, a second generation of valves has designed to maintain ICP in normal physiological range, regardless of patient position. Delta valves, descript in Drake & Saint-Rose, (1994), have been designed to minimize overdrainage of CSF. The normally closed Delta chamber mechanism opens in response to ventricular pressure. Working with the membrane valve, this mechanism minimizes overdrainage by utilizing the principle of hydrodynamic leverage. The normally closed chamber mechanism opens in response to positive ventricular pressure. In normal conditions, two silicone elastomer diaphragms, lying flat against two base outlet ports. CSF flowing from the ventricles pushes the diaphragm surfaces away from the outlet ports, allowing CSF to flow through the ports and out the distal catheter. Internal the chamber, the inlet area of the diaphragms acted on by CSF flowing from the ventricles is 20 times greater than the outlet area of the diaphragms acted on by negative hydrostatic pressure from the distal catheter. This application of hydrodynamic leverage nearly cancels any effect of the negative hydrostatic pressure. Many different design of diaphragm valves have been proposed, for example, Horton & Pollay, (1999) have show an anti-siphon valve operating also with a membrane to utilize in internal systems showing a area ratio (relation between outlet and inlet area) of 26:1. A Delta valve operates by action of two membranes, in opposition, the valve proposed by Horton & Pollay, (1999) utilizes only a unique elastic membrane. Other different designs of anti-siphon valves were extensively proposed, including the regulating valves. Regulating valves permit a fine adjustment of open and close pressure external of the patient without surgical procedure. Unfortunately, regulating valves are very expensive and the operation of a delicate mechanism causes frequent shunt revision.

Nowadays, in opposition to internal shunts, EVD systems or external shunts do not include any device in order to protect for accidental siphoning, and patients can be exposed to a disastrous overdrainage.

In the present effort of work a first prototype of an anti-siphon valve operating by means of an elastic membrane is proposed and tested for utilize in EVD systems. First prototypes, made in resin by rapid prototyping are showed in a 3D view in Fig. 3. An internal view of anti-siphon valve proposed to EVD systems showing a cut image can be viewed in Fig. 4.

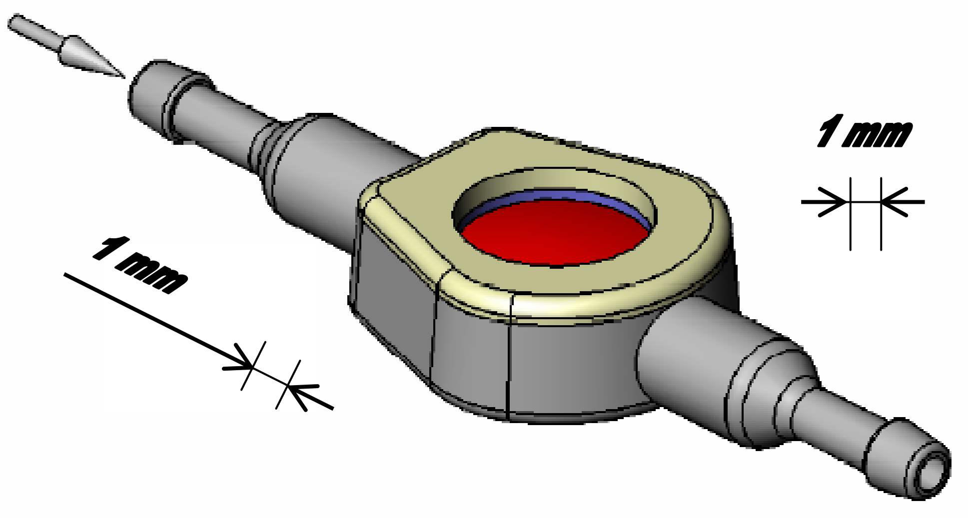

Figure 3. First anti-siphon valve prototype – external characteristics.

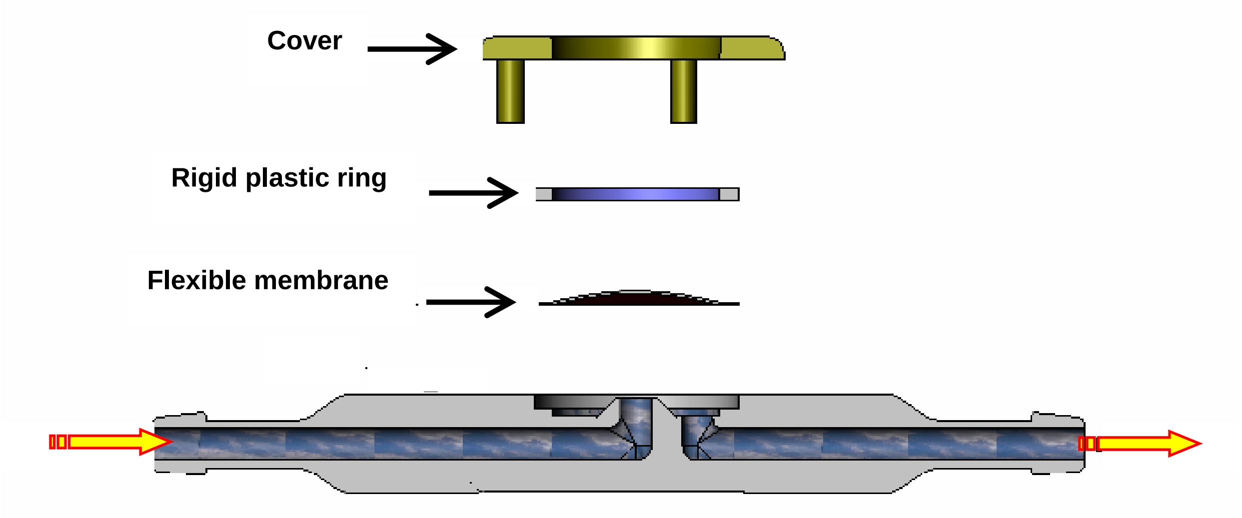

Figure 4. First anti-siphon valve prototype – internal cut view.

The flow direction is from left to right. In normal conditions, the ICP deform the elastic membrane opening the valve and CSF is channeled from ventricles. The outlet area is larger than the inlet area of valve (near the membrane seat) permitting a hydrodynamic leverage action. If negative relative pressure is actuating in distal catheter (outlet of the anti-siphon valve) the elastic membrane is deformed in order to close the valve. The physical mechanical properties of the membrane and the area ratio permits to control of a range of actuating pressure. Because of the simplicity of operation, mechanical failure possibility is minimized and the utilization of plastic materials (non necessary use of radiopaque materials) the proposed anti-hyperdrainage valve is very cheap and reliable.

6. EXPERIMENTAL RESULTS AND DISCUSSIONS.

Several experiments in shunts have been carried out by Kremer *et al.*, (1994) utilizing ICP values of 5.0; 10.0; 15.0 and 20.0 centimeter of water column, the same values adopted in this present work. Those values have been adequately adjusted in the apparatus for shunt testing and the maximum error observed for pressure measurement is less than 1.0 %. In relation to flow rate measurements the error observed is less than 0,12 %. Values of uncertainties have been calculated in accord to Abernethy *et al.* (1985).

The blockage of the flow occurs when the height H (showed in Fig. 1) generate an actuation pressure on elastic membrane for a pre-determined value of ICP. But, the membrane mechanical movement occurs slowly in function of a rise of height H, like depicted in Fig. 5. In this case, a prototype has been submitted to an ICP of 20.00 cm of water column and the flow rate is careful measured near the height H for an actuation pressure in the membrane for blockage the flow. The height H is raised slowly in order to detect the starting point of close operation or the first movement of the membrane restringing the flow rate (in this case, for height H equal to 45.80 cm of water column) and the close operation is finished only when the flow is completely blocked (flow rate null), for the present example, to height H equal to 46.25 cm of column of water. The height difference between the starting to finish point, in this case, is only 0.35 cm of water. In all of measurements carried out the point of closing has been adopted equal to the mean value between the start and finish point of close operation.

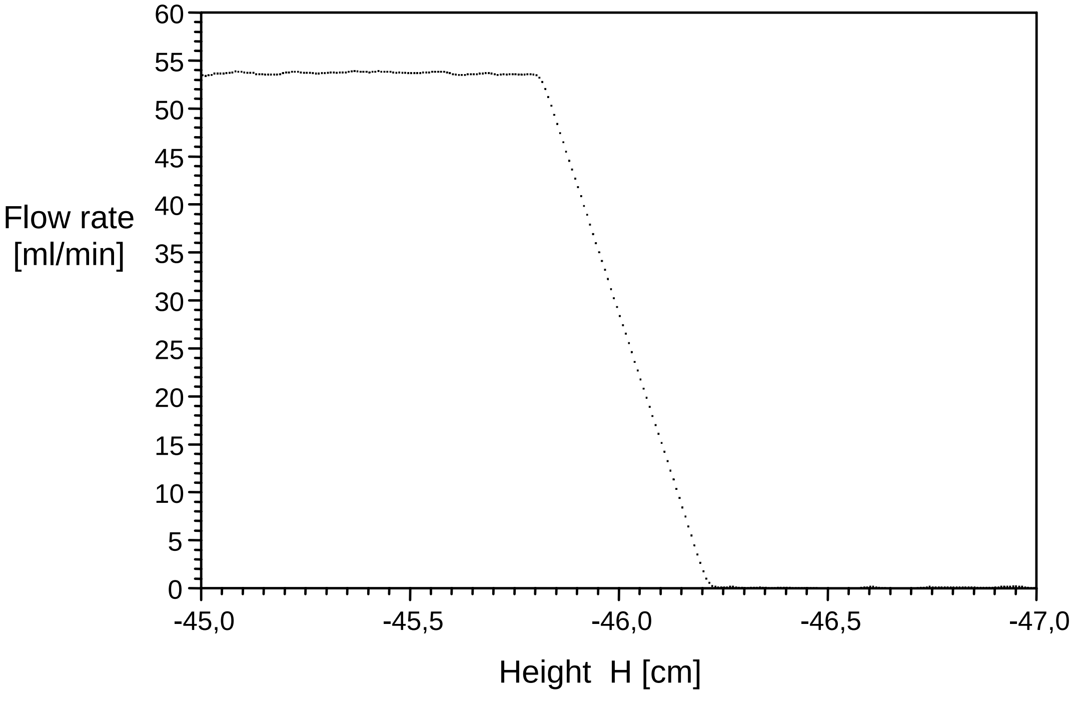

Figure 5. Flow rate of the valve prototype in function of height H – detection of the start and finish point of closing.

The complete behavior of the anti-hyperdrainage valve prototype is showed in Fig. 6. The flow rate is measured in function of the height H for different values of ICP (5.0; 10.0; 15.0 and 20.0 mm of water column). The blockage point can be easily visualized. When the height H generates a negative pressure the flow rate rise significantly generating a drastic overdrainage. In this undesirable situation, the valve membrane actives closing the aperture provoking the flow blockage. After the blockage of the flow the flow rate is null and the drainage is stopped until a neurosurgeon intervention restarting the drainage with an adequate height H sufficient to drainage the CSF in a correct flow rate without overdrainage.

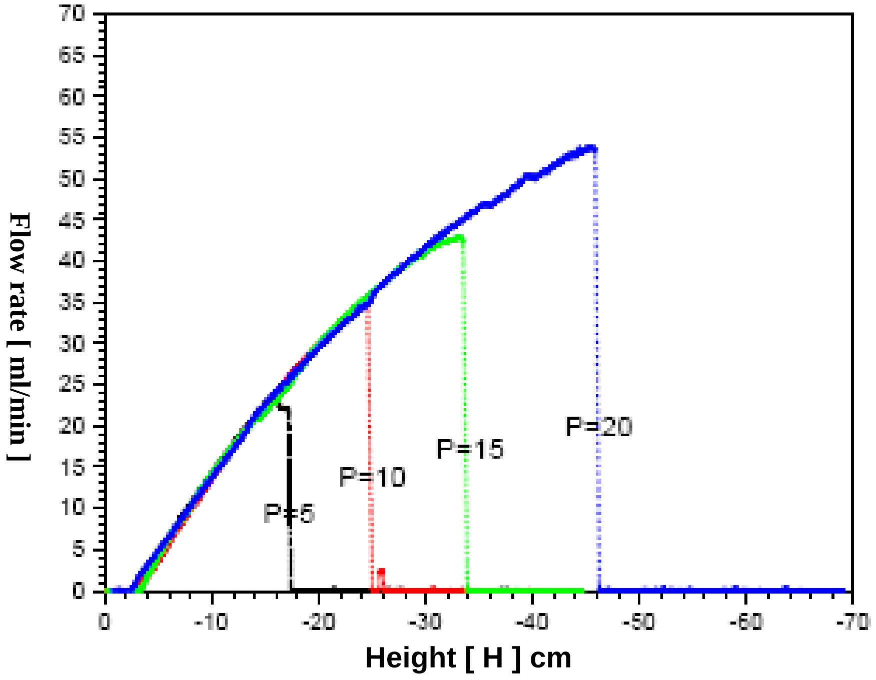

Figure 6. Flow rate behavior of the valve prototype in function of height H for different ICP.

Finally, Fig. 7 shows the closing point (horizontal axis) for the anti-siphon valve prototype in relation of the height H (vertical axis).

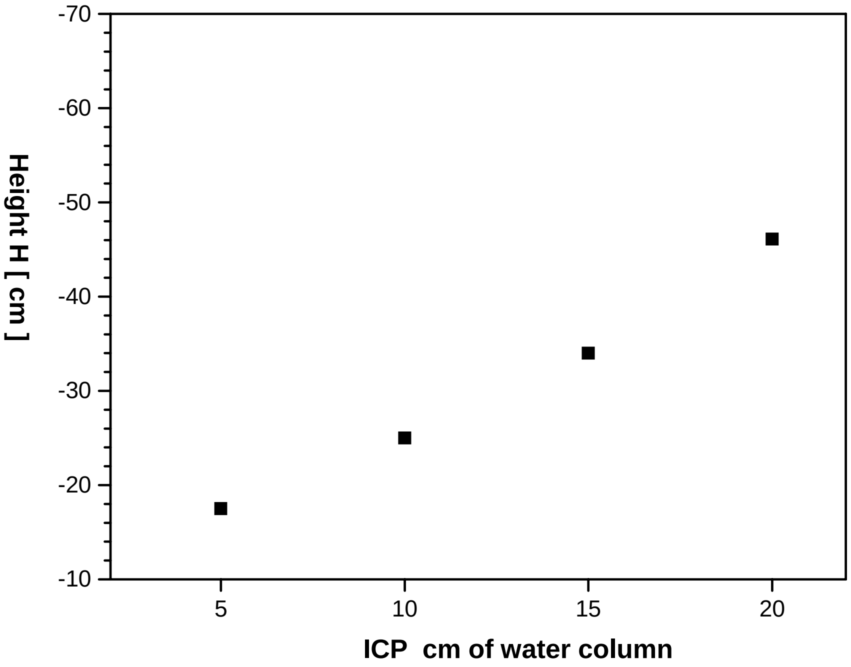

Figure 7. Closing point of the anti-siphon prototype # 6 for different values of ICP.

7. CONCLUSIONS

Shunting has dramatically changed the outlook of children with hydrocephalus, with many of them having normal life expectancies and attaining normal intelligence. During the last 50 years, several new shunt designs have been developed. Nowadays, the cerebrospinal fluid shunting is one of the most common neurosurgical procedures. Unfortunately, shunting for hydrocephalus remains with a high failure rates and most devices are far from satisfactory. In this way, hydrocephalus pathology continues as a challenge to modern biomedicine. These complications can be caused by hydrocephalus itself, surgical technique, infections and mechanical failure. In the engineering viewpoint, mechanical failures should be availed in details. Several engineering criterion of design should be found in order to obtain an optimized shunt operation.

Internal shunts, more precisely, peritoneal shunts have been intensively studied after the sixties and numerous internal shunt valves have been developed to provide an effective flow control, with many of them utilizing complexes and very expensive mechanisms. On the other side, external shunt has been a necessary procedure to several neurosurgical activities and, apparently, few efforts of research have been devoted to establish optimized external shunting.

Implants of temporary external ventricle drainage systems have been realized frequently in several neurosurgical activities and accidental siphoning effects can to provoke overdrainage and irreversible damage in nervous system in a short time period. Presently, the systems of external drainage commercially available are inefficient in order to prevent overdrainage. A first prototype of an anti-siphon valve is proposed in this effort of work in order to avoid overdrainage in EVD systems.

The simplicity of operation, absence of metallic parts, all made in plastic materials, gravity operation independency, cheap and reliable operation turn the anti-hyperdrainage valve proposed possible to be easily connected to EVD systems in order to avoid undesirable siphon effects.

8. ACKNOWLEDGEMENTS

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