Implantable Devices for Hydrocephalus Management

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Abstract

For the past 60 years, hydrocephalus has been managed using passive drainage cerebral shunts. However, 40% of passive shunts fail within two years after implantation due to complications such as obstruction and incorrect drainage. A smart shunt is a powered device intended to solve these problems using cellular obstruction preventive techniques and patient specific drainage algorithms. This study has focused on obstruction resistive designs and obstruction clearing means for prolonging shunt patency. The integrated fluidic topology presented is capable of providing passive, energy efficient means for intracranial pressure regulation and comprises of a built-in flushing mechanism.

The concept was realized using a rotary pump-valve peristaltic system, consisting of a novel peristaltic three-way variable-resistance valve. The shunt topology is capable of continuous drainage, zero opening pressure and is able to reverse flow direction for the purpose of unclogging the shunt. Feasibility calculations suggest it is capable of 150 valve adjustments or 5 flushing cycles before requiring a recharge when using a 2 gram coin-cell battery. A 40 gram smart phone battery could provide 2 weeks of closed-loop operation when regulating intracranial pressure at 10 minute intervals. The mechanical wear the device is subjected to is negligible and intended to support operation for a lifetime. The DC motor, gearhead and encoder required to drive the hypothetical peristaltic system is the size of two AA batteries and weighs 50 gram.

The dimensions of the peristaltic system were obtained via MATLAB simulations and a bench-top shunt system was evaluated using pressure-flow and back-pressure test rigs with LabVIEW. The shunt demonstrated an overall conductance of 0 - 4.90 µL/min/mmH₂O and a back-pressure of 3 mH₂O.

The peristaltic system demonstrated its efficacy as part of an obstruction-free smart shunt. Future development will include miniaturization of the shunting device. A bioreactor connected to the shunt system will start the evaluation of the effectiveness of flushing on cellular obstruction. Simulink computer simulations will allow energy efficient drainage hydraulic designs and algorithms to be tested using a hydrocephalus hydrodynamic model of the brain.
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Chapter 1: Hydrocephalus and Cerebral Shunts

1.1 Hydrocephalus

Hydrocephalus is an excessive accumulation of cerebral spinal fluid (CSF) within the ventricles of the brain, due to an imbalance in CSF production, absorption or flow. This neurological disorder occurs both in children and adults and roughly affects 1 in 500 people [1, 2]. The etiology of the disease can be classified as communicating or non-communicating hydrocephalus. Communicating hydrocephalus occurs when CSF is able to flow between the ventricular system and into the subarachnoid space but is not reabsorbed sufficiently into the tissues surrounding the brain. Non-communicating hydrocephalus is when CSF flow is blocked along one or more of the passages between the ventricles limiting absorption [3].

There are different types of hydrocephalus; congenital cases are due to a medical condition that existed at birth and may have resulted from genetic abnormalities or developmental disorders. Acquired cases can develop at the time of birth or later and may be due to infection, disease or traumatic head injuries. Normal-pressure hydrocephalus (NPH) causes swelling of the brain but does not result in an increase in the pressure inside the skull. This type of the disease predominately occurs in people over 60 years old and may be due to injury, infection or bleeding [4].

In infants the key signs which indicate the presence of hydrocephalus include the increase in head circumference, bulging eyes and failure to gaze upwards. The symptoms experienced by adults are different, which may include headache followed by vomiting, blurred vision, gait disturbance and memory loss [1]. Hydrocephalus is diagnosed using cranial imaging techniques such as ultrasonography, computerized tomography, magnetic resonance imaging or by pressure monitoring [5].
Chapter 1: Hydrocephalus and Cerebral Shunts

1.2 Current treatments

1.2.1 Closed CSF drainage

The most common treatment of congenital, acquired and normal pressure hydrocephalus is via the surgical insertion of a shunt system. Current cerebral shunts drain excess CSF from the ventricles of the brain to another area of the body to be reabsorbed. This displacement of fluid is carried out passively by exploiting the effects of gravity without any power input. These shunts exploit the spatial difference which exists between the proximal and distal ends of the device. The vertical column of fluid inside the tubing of roughly 90 cm in length creates a hydrostatic pressure of 70 mmHg within the shunt [6].

Passive hydrocephalus shunts maintain an ICP set-point by regulating a constant differential pressure that exists across a valve. Valves are fluid control mechanisms which limit flow from a region of high pressure to low pressure, in the case of Hydrocephalus shunts; the flow of CSF down the shunt line is regulated [6].

Prior to implantation of the shunt, the physician chooses a valve pressure category based on the volume of excess CSF required to be drained for the patient. These differential pressure valves can either be adjustable or non-adjustable after implantation. Fixed differential pressure valves, as the name suggests have a resistance of flow fixed throughout the working lifetime of the shunt. Programmable valve mechanisms are more complex in design and can allow the physician to change the conductance of the shunt via a non-invasive programmer [7].

1.2.2 Endoscopic Third Ventriculostomy

An alternative to shunt placement is Endoscopic Third Ventriculostomy (ETV), in which a hole is opened in the floor of the third ventricle with the use of a neuroendoscope introduced through a frontal burr hole, creating a new communication pathway with the basal subarachnoid space [8]. Literature shows that ETV is less effective for certain types of hydrocephalus; causes of the disorder due to meningitis, subarachnoid or intraventricular hemorrhage have been used to exclude patients from the surgical technique. The success rate of the operation is around 50 – 75%, an attractive figure for the chance to do
without placement of unreliable hardware into the brain [9]. If ETV is unsuccessful then shunt placement remains the option for treatment. Due to the discrepancy in the success rate and dependency on the patient’s condition, at this stage ETV is not a reliable replacement for shunt insertion in the treatment of hydrocephalus.

1.3 Shunt malfunction

Even though the industry has over 60 years of experience in using CSF shunts for the treatment of hydrocephalus, it is still a neurosurgical procedure known for notorious failure rates. It is generally accepted that 40% of CSF shunts fail within the first year, 50% in the second year and 85% after 10 years [10-13]. Invasive shunt revision surgeries are required when a shunt fails, which can occur along the proximal catheter, the valve or at the distal tubing [14]. In the United States alone, the cost of hydrocephalus treatment is over a billion dollars a year [15]. Although CSF shunts do improve the patient’s quality of life, there is a vast amount of literature detailing their complications; a review of their progress and failures will be purpose of this section.

Shunting of the ventricles of the brain is plagued with problems; the three most documented causes of hydrocephalus shunt failures are overdrainage, infection and obstruction. The rate of incidence of each has remained more or less the same since the inception of standard differential pressure shunts. Infection occurs a few months after surgery (11 months reported by Boch et al. [16]) with an incidence of 5 – 10% [11, 17-19] and 7.2% per procedure [20]. Overdrainage mostly appears in the first year [10] and takes place when an excessive amount of CSF is drained out of the cranial cavity, figures ranges from 3% to 70% [21-23] with 20% as a commonly mentioned figure [24, 25]. Shunt obstruction is the major cause of failures and revisions, with statistics showing over 50% of shunts fail due to this problem [10, 26, 27]. Obstruction is most frequently observed in the first two years but remains a continual cause of failure [10].

The etiology of cerebral shunt failure can be divided into two categories; pathological & histological responses interacting with the shunt system and mechanical related issues. A positive feedback cycle of raised cellular signaling and cell accumulation due to infection, immune action and hydrocephalic insult
can eventually cause chronic shunt obstruction. Overdrainage of CSF from the ventricles also upsets the physiological equilibrium, changes in the spatial alignment of the shunted ventricles is reported to promote cellular ingrowth and occlusion [28].

Obstruction is the side product of many complicated mechanical and nested bio-chemical processes, henceforth the influence of histological responses and overdrainage on occlusion will be investigated. However, keep in mind that standalone infection or mechanical failures themselves are sufficient for a shunt revision to take place.

1.3.1 Obstruction via physical processes

In the following subsections we will investigate the mechanisms behind blockages and the advances made to reduce them. Obstruction can occur anywhere along the shunt; about 60% takes place at the proximal catheter, 30% at the valve and the rest in the distal section [29]. This cause of shunt failure is multifaceted and can be contributed by normal brain tissue, pathological tissue or inflammatory tissues.

The hydrodynamic effects at the proximal catheter play a part in the type of occlusion produced, some of which can cause chronic obstruction. The blockage of multiple holes on the ventricular catheter has little effect on shunting performance. A study performed by Ginsberg et al. has shown that if all but one catheter holes are blocked, the increase in flow resistance is only 3% [30]. It has been observed that the primary site of ventricular obstruction and ingrowth occurs at the holes most proximal of the catheter (furthest from the catheter tip) [23, 31], proximal infiltration and blockages unlike distal ones, can result in permanent blockage. There are experimental [32, 33] and computational models which indicate the same results with CFD simulations showing 58% of fluid mass flows into the catheter’s most proximal holes [33]. These findings could be used to develop obstruction clearing mechanisms with hydrodynamic focus on clearing holes most proximal of the catheter.

The tissue of the choroid plexus is not particularly reactive, however it has been reported to be the main culprit behind ventricular obstruction [11]. It has been observed to enter the catheter or envelop its holes [34], possibly by following a suctioning momentum [32]. Ingrowth could also be due to the ventricular
wall being in prolonged firm contact with the catheter [35-38], and as such is common in slit ventricle syndrome (SVS) patients [39]. A study has found that hemodialysis catheters with closed bore ends are more likely to pull the vein walls into its holes which become damaged and reduce catheter patency [40]. Perhaps proximal catheter designs with open bore ends could be investigated, as ventricular catheters used in cerebral shunts are all close ended.

Cellular settlement and adhesion due to gravity has been suggested to play a part in the process of catheter obstruction. The effects of gravity have been shown to be responsible for the enhancement of cellular adhesion of macrophages and astrocytes on shunt tubing. In-vitro studies from Harris et al. observed greater cellular attachment to the bottom internal half or top external half of the tubing parallel to the ground [41, 42]. Occasional flushing of the shunt system may be able to disturb cellular buildup within the shunt; this method will be further investigated later in this section.

There exist concerns regarding the usefulness of continuous flow schemes as opposed to on-off flow schemes as displayed in most differential pressure cerebral shunts. Observations and tests have revealed that increased flow through the catheter can result in greater cellular adhesion [32, 33, 43], this can be related to the case of continuous flow schemes. On the other hand, there is some speculation that fluid stasis for extended periods can cause accumulation and adhesion of cell debris, which can lead to bacterial colonization and shunt occlusion [29, 44], this is analogous to on-off flow schemes. Statistics indicate infections are more likely to result in shunt revisions in the first few months [16]. Due to this fact, it may be of interest to provide greater CSF flow through the shunt in these months, possibly by an increased rate of shunt flushing. The corresponding increase in pressure and cellular adhesion may lead to a greater chance of occlusion; however this problem is one which a flushable shunt should be able to overcome.

Since the inception of shunt technology there has been relatively few architectural changes made to the ventricular catheter for the function of limiting occlusions. Early attempts included the use of flanges at the catheter to provide a buffer distance to the choroid plexus, however this turned out to be unsuccessful and difficult to remove during revision surgery [11, 45]. The peel-away sheath was invented
for protecting the ventricular catheter form being occluded during puncture of the brain tissue, but the data obtained from subsequent studies was inconclusive in proving its effectiveness [46]. More recent works include investigation of the catheter’s hole size, location and numbers. This gave rise to the Rivulet catheter aimed at evening out the CSF uptake across perforations [33]. The efficacy of this catheter is unknown, however there is contradicting data which suggest cellular adhesion rises due to the increased shear stress existent in smaller diameter catheter holes [42]. The reason behind the general number of catheter holes present in most marketed catheters is unknown. Most likely, the large array of holes were intended to act as a failsafe mechanism in case some holes become occluded by cells, blocked by the tissue wall or to compensate for insertion misalignment. There is an extensive amount of development on the proximal catheter as the majority of occlusions take place at the ventricles.

1.3.2 Hydrocephalic insult & histological responses

Pathological inflammatory reactions are reported to occur in and around many obstructed shunts [35, 47], (43% as reported by Drake et al. [23]) but not in functioning shunts removed for elective reasons [38]. There is evidence that suggest multiple shunt surgeries can cause increased immune reaction to future shunts [48], this highlights the importance of minimizing the number of shunt revision surgeries.

In addressing the problem of shunt infections, a whole host of surface coatings and drug impregnation methods have been deployed [49-52]. Recent advancements employ the use of antibiotic-impregnated catheters (AICs) to reduce the risk of bacterial adhesion by killing attached bacteria which limits further colonization and proliferation [53-55]. However, systematic literature reviews emphasize that multi-center randomized control trials are required to confirm the difference in infection incidence [56, 57].

Obstruction formation at the ventricular catheter due to hydrocephalic insult and inflammatory response can be caused by remnants of clotted blood, inflammatory cells, healthy and necrotic brain tissue [35]. Cell debris, platelets and RBCs are commonly found in the holes and first few millimeters of the catheter lumina [47, 58] and can even form a sheath around the catheter [59, 60]. The accumulation of cell debris, RBCs, fibroblasts and infectious organisms could be the cause of valve obstructions [11], as it is too distant for ingrowth to take place. Although the use of a flushable shunt is anticipated to be able to
remove such causes of obstructions, an infection in the shunt may require more urgent medical attention.

### 1.3.3 Mechanical related issues

Current passive cerebral shunts are open loop devices which are prone to underdraining or overdraining the ventricular cavity. A common issue is the case of excessive drainage, its symptoms include intermittent or frequent headaches, nausea and vomiting in the vertical position which quickly improves by lying down [61]. If excessive drainage occurs over a period of years a complication called Slit Ventricle Syndrome (SVS) develops [28] which is characterized by chronic, intermittent headaches accompanied by a slow refilling shunt reservoir and “slit” ventricles on radiographic evaluation [62]. This complication is improved either by valve adjustments, medicine or surgical means.

Shunting of infants with hydrocephalus will lead to significant changes in the skull, particularly in its thickness [63]. SVS occur in about 20% of babies who are shunted in infancy, adults patients do not develop complications of the same level of severity [64]. This condition manifests in the form of incompliant ventricles which do not change in size regardless of ICP [65]. Similar to the effects of SVS, overdrainage can cause the ventricular walls to collapse and prolonged firm contact can allow cellular ingrowth [35, 36, 66]. As a result the proximal catheter may intermittently become obstructed due to the reduced ventricular compliance [28].

This complication in differential pressure valves is attributed to the water column which exists within the shunt. In normal subjects ICP is 7 – 20 cmH₂O [67], this is the physiological range which shunts are designed to provide. However when the patient is standing a siphoning effect assisted by gravity can cause a flow rate of up to 170 times normal CSF production rate, which in turn can cause ICP to fall to -44 cmH₂O [68].

A host of improvements to the shunting system have been made in the past in an attempt to augment normal CSF physiology. High pressure valves were used in the past to reduce siphoning [21, 31], however such methods proved ineffective as the fixed pressure valve provided insufficient drainage in the supine
position [21]. Anti-siphon devices (ASDs) were developed to counteract such overdrainage phenomenon. The aim of the ASD is to maintain the outlet of the differential pressure valve close to atmosphere pressure, suppressing the hydrostatic effects within the shunt. [69]. It was found that scar formation and subcutaneous pressure causes the device to be ineffective as it increases flow resistance overtime [70]. The introduction of adjustable differential pressure valves allowed for reduced surgical revisions and improved patient comfort, but again, the problem of siphoning remained unsolved [71, 72].

This overdrainage dilemma has only recently been resolved to a satisfactory degree using fixed differential pressure valves combined with gravitational units [61, 73-75], which are mobile tantalum balls used to reduce flow based on postural changes [76]. Recent developments include the combination of a gravitation valve together with an adjustable differential pressure valve. This further reduces the chance of surgery required due to a valve with inadequate flow resistance. In a 1-year follow up study by Tschan et al. with a patient pool of 55, all of whom previously suffered from clinical and/or radiological overdrainage, reported a 91% reduction in overdrainage symptoms with the adjustable gravitational valve proSA [61]. However, longer term follow up studies are required to investigate their effectiveness against shunt obstruction. Other mechanical failures can occur in the form of fracture, disconnection, migration, misplacement and calcification, but their prevalence is much lower than the three main types of malfunction.

Flushing chambers added to shunt systems allow for manual pumping to drain CSF and provide access for CSF sampling. The speed of refilling the shunt reservoir is used an indicator of whether the shunt is functioning properly. However, the flushing mechanism in passive shunts is incapable of clearing obstructions. This could be due to factors such as the small amount of fluid available in the shunt for flushing, size of pores and the extent to which the pores have been clogged [77]. A frequent flushing schedule could be useful for limiting the amount of occlusion formed in the shunt as well as preventing chronic obstruction from taking place. An infinite reservoir of flushing medium could be achieved by circulating CSF in the proximal region of the shunt.
The problems of inappropriate drainage in passive shunts are expected to be solved using active shunts with closed loop control of actuators based on sensor feedback. The requirements, functioning and advantages of active shunting is the focus of the next section.

1.4 Active shunting

It may be that the aforementioned problems cannot be solved through passive shunt design as 60 years of evolution in passive shunt design have yet to provide reliable solutions. A 2013 review paper from Lutz et al. [78] provides a summary of recent activity in the area of smart shunt development. The author also provides a thorough discussion regarding the use of “smart shunts” for the management of hydrocephalus, which are envisioned to solve the problems associated with current passive shunts.

There are several advantages of using a powered cerebral shunt for the management of hydrocephalus. Sensors implanted into the ventricular cavity can monitor the condition of the patient which could allow weaning the patient off shunt treatment. A closed loop system of sensors and actuators can provide better regulation of ICP and solve the problems of underdrainage and overdrainage. Shunt patency can be extended via the use of implanted sensors which detect signs of occlusion, and actuation mechanisms can interfere before obstructions can take place.

There are three dominant factors which dictate the technical feasibility of powered cerebral shunts; these are power, size and reliability. This trinity of concepts is closely interlinked and the active shunt under design must strive to satisfy all these requirements.

Electrical energy from an implanted battery is required to power the shunt’s microcontroller, sensors and actuators. The bulk of the device is directly related to its energy consumption, which must be kept minimal. This could be achieved for example by the use of cleverly designed hydraulic elements, fluid diversion layouts or control algorithms. The technology of inductive power transfer could be used as a means of recharging an implanted battery; this eliminates the risk of infection via leads that run out of the patient’s body as in the case for LVADs [79].
A major concern for implantable medical devices is operational lifetime. For the device to gain acceptance by patients it must require seldom intervention, for example the battery may need to last a month before a recharge is needed in order to reduce the burden on the patient. In terms of mechanical reliability, the active shunt must show superior outcomes for patients through either providing better regulation of ICP, or extending shunt patency or, preferably both.

1.5 Recent work and challenges

Current advances in hydrocephalus come in the form of novel CSF pumps or valves with drainage control algorithms, implantable MEMS devices or retrofitting shunt systems with existing implantable fluidic control devices [80]. New research into active shunts is fueled by the problems left unresolved and frustrations caused by passive CSF drainage devices as shunting malfunctions can be difficult to diagnose. Active CSF shunts or “smart shunt concepts” typically consist of an implanted mechatronics device and a power source for actuation and sensing purposes.

Groups from university institutions have focused on the development of feedback control algorithms, tested with computer simulations and less frequently with bench-top models of hydrocephalus. Two decades ago, Cote et al. developed an algorithm which was capable of maintaining a constant flow which incorporated a tolerance zone and time delay to reduce power use [81]. More recent shunting algorithms integrate the idea of shunt weaning, which is the reduction or complete elimination shunt dependency [82]. It has been suggested that some brain tissues are able to recover when the pathological stimuli causing hydrocephalus ceases [1]. Current cerebral shunts do not reveal the degree of dependency; rather they lock the patient into one. Allowing natural drainage to work at its maximum capability will reveal the patient’s actual shunt dependency [83]. These ideas are realized by the Al-Nuaimy group, whose developments include decision making frameworks and feedback control algorithms applicable to on-off valves. The focus of this group includes the personalized management [84]; a drainage program which slowly increases drainage via the brain’s natural passageway is believed to assist with recovery of the brain’s CSF drainage function. Self-diagnosis algorithms have also been developed to detect signs of shunt malfunction, which can be used as part of a malfunction prevention system [85].
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The simplest realization of an electronic control element would be an on-off valve which only provides two different resistances to fluid flow. From a mechanical standpoint however, wear on the valve can be quite high as the accuracy of regulation relies on actuation frequency. Also as there are only two fixed states available, it is not possible for the valve to settle at one state for a prolonged period of time to conserve power.

Leonhardt and colleagues have described a linear “tube squeezer” concept which can operate as an on-off valve or as a variable resistance valve capable of holding position without power [86]. The advantage of this design lies in the fact that CSF only comes into contact with biomedical grade silicone tubing and this valveless design is aimed at eliminating valve obstructions. From a power conservation perspective, variable resistance valves have an advantage over on-off valves both electrically and mechanically. Less power is consumed as the valve only needs to actuate for fine tuning the CSF flow rate when maintaining an ICP set point. Mechanical wear is reduced as fewer actuations are required to keep the device running; overall this feature prolongs shunt patency. The group has also developed and tested a device in pigs which contributes to the development of algorithms for control of CSF drainage based on ICP wave analysis [87].

Miniaturization has always been the goal for implantable devices, micropumps and microvalves have been fabricated by groups operating in the area of MEMS. Micro-fabricated polydimethylsiloxane (PDMS) and Parylene one-way valves intended to drain CSF from the subarachnoid space have been developed by Oh et al. [88]. Chung et al. fabricated a Parylene based diaphragm microvalve which replaces existing CSF valves [89]. The previous two implementations are both passive devices capable of operating without the use of a power source. However the drawback of such systems is that once the valves are implanted there is no way of altering their rate of drainage. In terms of active devices, a telemetry powered micropump and pressure sensing shunt system small enough to fit at the top of the patient’s head under their scalp has been developed by Yoon et al [90]. Modern shunt valve designs consist of fine channels and irregularities. It is an often raised concern that the intricate nature of these designs may prove to be more prone to obstruction. Microdevices are much smaller in dimension than current passive shunt
valves, even for microdevices capable of pumping or flushing, it remains uncertain whether these implementations will be able to function without being obstructed often.

Designs to reduce the rate of obstruction or obstruction clearing methods remain a problem rarely tackled for developers of passive shunts or active shunt concepts. An obstruction resistive shunt design should have passive obstruction mitigation means, such as a minimal number of corners, narrow opening and components in the fluid flow path on which obstructions are likely to occur. In terms of fluidic design, the Leonhardt group describes a highly obstruction resistant peristaltic type smart shunt design which eliminates complexities built into the fluidic pathway [86]. A design patented by the New Jersey Institute of Technology uses a catheter with relatively large holes to reduce the chance of clogging at the proximal catheter and places an extracranial replaceable filter to stop occlusions further down the shunt [77].

An example of active obstruction mitigation would consist of a fully implanted obstruction clearing system able to perform a powered back-flush procedure to blow out debris which has entered the shunt. The procedure could be triggered by an abnormal pressure build up in a section of the shunt. One of the earliest descriptions of a flushable smart shunt is from Ko et al. in 1988 which mentioned the use of a pump back-flush mechanism for clearing obstructions [91]. There are several patents filed by medical companies which describe a pump based system for the removal of CSF. The same pump could possibly be used for obstruction clearing purposes, although it is not specifically stated. Patents filed by Medtronic have shown pump-based concepts which can possibly operate using their existing drug pumps [92]. An Integra Lifesciences patent described a pump system which continually operates to either drain or return CSF to or from the ventricles [93]. A patent filed by California Institute of Technology describes a shunt system that uses a hydroimpedance pump for treating hydrocephalus [94]. With less emphasis on flushing as a means of obstruction removal, the Judy group from the University of California has developed an array of deflectable torsional magnetic microactuators capable of displacing biological materials in proximal catheters [95]. There is little information regarding the progress of these obstruction mitigation devices - but none of them have yet made it to market.
1.6 Research objectives

The purpose of this study was to investigate shunt designs which reduce the risk of obstruction and design built-in means of eliminating occlusions.

The specific objectives of the research were to:

1. investigate optimal fluidic topologies and select hydraulic component for use in a flushable shunt
2. determine the feasibility of the proposed shunt concept
3. fabricate and produce a proof-of-concept shunt and evaluate its performance

1.7 Thesis outline

This thesis introduces a novel type of hydraulic element used in an obstruction resistant cerebral shunt system.

Chapter 2 provides a thorough investigation of compact topologies and minimalistic hydraulic component layouts for use in flushable cerebral shunts

Chapter 3 provides the feasibility calculation of the proposed shunt concept with respect to power requirements, device size and operating lifetime when functioning under different operating schemes

Chapter 4 investigates the geometry and dimensions required for a functioning prototype using mathematical modeling and computer simulation techniques

Chapter 5 describes the bench-top shunt prototype and evaluation setups to demonstrate the operating principle, flow control and flushing capability of the concept

Chapter 6 discusses the direction of future work.
Chapter 2: Topologies to Move CSF from A to B

This chapter describes the mechanisms and pathways required to achieve CSF diversion from the ventricles on the brain to the abdominal cavity. An active shunt consists of a connection of valves and or pumps placed at specific locations along a tubing network. Pumping layouts with the ability to deliver a pressure differential to unblock occlusions at any end of the shunt are of particular interest.

In particular the chapter will investigate fluidic designs based on compact topologies and minimalistic hydraulic component layouts capable of:

- A low power consumption mode for ICP regulation with the capability of continuous CSF drainage
- An active pumping high power consumption mode with the capacity of unblocking obstructions anywhere along the shunt system

All of the shunt topologies to be described took inspiration from the topology displayed as Figure 2.1 from the pending patent “Catheter and Shunt System Including the Catheter”, US20130303971 [96].
Figure 2.1: Shunt topology with 4 actuators and 3 sensors and hermetic seal [96]

2.1 Shunt-line topology

The literature review presented in chapter 1 discussed that the majority of obstructions occur at the proximal end of the catheter.

Figure 2.1 above illustrates a general and adaptable, shunt topology describing the placement of hermetically enclosed hydraulic and sensing elements along a network of tubing. The topology depicts a shunt with the Left Proximal Catheter (LPC) on the left, Right Proximal Catheter (RPC) on the right and the distal tubing at the bottom. The hydraulic elements are represented by the four ovals, the pressure sensors are symbolized by the black dots and the hermetic casing is the rectangular enclosure.
A simplified shunt-line topology, a shunt skeleton is shown in Figure 2.2 (a). The resultant topology shows the simplest tubing network which allow for continuous flushing of the shunt without drawing fluid from the abdominal cavity.

![Figure 2.2: Simplified shunt-line topology with potential blockages shown in red; Left Proximal Catheter (LPC), Right Proximal Catheter (RPC)](image)

From here onwards the working of the shunt-line when filled with fluid will be analyzed. For all the cases to be studied, the shunt-line skeleton is orientated with its distal end closest to the ground and its proximal ends furthest from the ground. Under the influence of gravity, fluid passively flows downwards to achieve a lower state of gravitational potential energy. For all scenarios it is assumed that there is an infinite supply of fluid into the proximal catheters.

The principle scenario takes place when no part of the shunt is occluded. In this case, equal amounts of fluid flow from each proximal catheter, converge at the proximal-distal node, flow through the distal tubing and out of the shunt.

The skeleton in Figure 2.2 (b) depicts the scenario in which an occlusion has occurred somewhere along the length of one proximal tubing. This is probably the most common form of obstruction for the shunt-line being discussed. The ideal method of unblocking this obstruction is to close off the distal catheter
and draw fluid from the non-obstructed proximal catheter; which in turn pushes material out of the shunt.

The less common case of obstruction in the distal tubing is depicted in the Figure 2.2 (c). Fluid can be pumped from one or both proximal catheters and be used to clear obstruction in the distal section.

The shunt-line skeleton in Figure 2.2 (d) depicts the exceptional case where both of the proximal catheters are blocked. To clear this obstruction the distal tubing is first closed off, the pump then draws fluid from one proximal catheter which creates a pressure within the fluid to push material out the other proximal catheter’s end.

An alternative and less ideal workaround does exist in the case when the above process is unable to clear the shunt by allowing the fluid already within the shunt tubes to be pump upwards. However, this is likely to need a reservoir as drawing abdominal fluid is unlikely to be an acceptable (or viable) mechanism.

2.2 Hydraulic schematics

This section investigates the placement of hydraulic elements on the topology skeleton. The objective is to minimize the number of actuation elements on the shunt-line while achieving flushing capability at all ends of the shunt.

2.2.1 Hydraulic components

If we examine the operating cycle of the active shunt under development, regulation of flow down the shunt is almost continuous throughout the device’s lifetime, whereas flushing of the shunt seldom occurs. It is favorable therefore, to place one of each control element into the shunt. A variable resistance valve could be used to exploit hydrostatic pressure present in the shunt to regulate flow without any power consumption; an energy intensive pump is used solely for flushing purposes. Using this layout, the mechanical wear on each component is kept minimal.
There are only a select few types of conventional valves capable of satisfying the passive obstruction mitigation requirements mentioned in the previous chapter, namely these components are pinch or diaphragm valves. These hydraulic elements expose no components to the fluid it is manipulating; fluid only ever comes into contact with a piece of elastic tubing. Typically a linear motion is used to reduce the hydraulic diameter of a section of tubing, doing so controls the flow rate through the valve. Peristaltic pumps are a type of positive displacement pump in which a piece of elastic tubing is progressively compressed by a set of wheels attached to a central rotor. Again, fluid never comes into contact with mechanical components, thus complying with passive standards. Both of these elements give rise to a valveless implementation, since they are essentially pieces of open tubing when not operating.

Although diaphragm valves and peristaltic pumps satisfy our passive obstruction mitigation requirements, unfavorable properties of using these control elements concerning electrical reliability and mechanical lifetime do inevitably exist. The amount of wear the device can handle and the power required to operate them will be thoroughly investigated in Chapter 3.

Prior to delving into arrangements for active shunt topologies, the hydraulic components used within them must first be introduced. To optimize for passive mitigation requirements, all of these hydraulic elements are fundamentally peristaltic in nature. Figure 2.3 below introduces peristaltic type actuation elements to be arranged on the shunt-line skeleton topology.
Chapter 2: Topologies to Move CSF from A to B

Figure 2.3: Peristaltic and diaphragm actuation elements

The top two components are rotary peristaltic pumps. The pump shown in Figure 2.3 (a) is bidirectional in nature, capable of flushing fluid in both directions. As with normal peristaltic pumps, a section of tubing is always compressed at any given time. This means fluid is not able to flow through the pump unless the motor which drives the pump head is active. The rate of fluid displacement of the peristaltic pump is dependent on the operational RPM.

The pump shown in Figure 2.3 (b) will from here on be called a bidirectional variable pressure peristaltic pump. This component is of variable pressure because it can generate a pressure difference when a cam is rolled across a section of tubing; thus it is capable of pumping fluid. Yet, at certain angular positions the cam leaves the tubing uncompressed, allowing fluid to flow freely across the section of tubing without any pressure drop.
The bottom two components are hydraulic valves, either diaphragm or peristaltic in nature. The valve shown in Figure 2.3 (c) is a variable resistance two-way diaphragm valve. Using linear means of actuation a section of tubing is compressed, the valve’s resistance to fluid flow depends on the amount of compression. The valve shown in Figure 2.3 (d) will from here-on be called a variable resistance rotary three-way peristaltic valve. As the name suggests, this valve consists of three channels, operates by rotary peristaltic means and has the capacity to vary its resistance to fluid flow. Both of these valves should be able to hold a desired position and hence provide a set resistance to flow even when no power is supplied. The capability of allowing fluid to flow through the shunt passively is a valuable asset, as power consumption can be kept minimal.

2.2.2 Variable resistance valve topologies

![Diagram of valve topologies](image)

Figure 2.4: 3 diaphragm valve topology (a), 2 diaphragm valve & bidirectional peristaltic pump topology (b)

The implementation in Figure 2.4 (a) utilizes three variable resistance linear diaphragm valves. A valve is placed along the LPC, RPC and the distal tubing. It is possible to control the overall flow rate through the shunt by varying the flow resistance of one or more of these valves. Smits has suggested it requires a minimum of two linear peristaltic actuators working in synchrony to displace fluid [97], which is the case here. The design discussed may seem like a viable one, however, the arrangement described does not allow for a high back pressure to be generated due to the limited number of linear actuators.
The implementation shown in Figure 2.4 (b) consists of diaphragm valves placed along the LPC and the distal tubing, a bidirectional peristaltic pump along the RPC. During normal operation only the two diaphragm valves are active when the shunt is used to regulate ICP. The pump is only used for flushing purposes as it is a high power consumption component. Therefore, for the majority of the shunt’s operation fluid only flows from the LPC and down towards the distal tubing. There are three drawbacks to this topology; firstly, there is a stagnant column of fluid within the RPC when the pump is not operating, which may cause obstruction due to cellular settlement and adhesion. Secondly, the pump must be in constant operation in the case when irreversible obstruction of the LPC does occur. This greatly increases wear on the pump’s tubing causing premature failure and would also require a large amount of power to be supplied to the shunt. Lastly, stress is induced in the tubing whenever it is compressed. Constant compression of a section of tubing may make the section more prone to failure and reduce the overall lifetime of the shunt.

The design to follow will attempt to rid the flaws of the above topologies while still maintaining full flushing capability and low power requirements.
2.2.3 Stagnant fluid free topology

![Diagram of diaphragm valves and variable pressure peristaltic pump topology]

Figure 2.5: 2 variable resistance diaphragm valve & variable pressure peristaltic pump topology

The topology shown in Figure 2.5 details the arrangement of diaphragm valves placed along the LPC and the distal tubing. A variable pressure peristaltic pump is placed along the RPC. When the shunt is used to regulate ICP, the diaphragm valves provide a set resistance to fluid flow while the pump is turned to its uncompressed state. This makes the RPC a length of open tubing and allowing free fluid flow, thus no volume of fluid is stagnant during the operation of the shunt. Flushing of the shunt can be achieved by sequentially functioning the pump and valves. As the tubing of the pump becomes uncompressed during a certain period of its cycle, the diaphragm valves must both close permitting no fluid flow while allowing the pump to return to its compressed state. The buildup of pressure within any ends of the shunt could be done by repeating the above process several times.
2.2.4 3-channel diaphragm valve topology

Figure 2.6: variable resistance 3-way diaphragm valve & bidirectional variable pressure peristaltic pump topology

The stagnant fluid free topology in the Figure 2.5 can be further simplified by replacing the two-way valves with a three-way valve, thus providing a more minimalistic design as shown in Figure 2.6. Fluid regulation along the whole shunt can be achieved by placing a variable resistance three-way peristaltic valve at the proximal-distal node. A variable resistance peristaltic pump is placed along the RPC to provide flushing ability. The pump becomes an open length of tubing when the shunt is operating to maintain an ICP set point using the variable resistance capability of the valve. The buildup of pressure within any of the tubing is done using a similar method described in the stagnant fluid free topology.

Figure 2.7: Unblocking mechanisms of the 3-channel diaphragm valve topology
Now that the optimal active topology has been determined, the flushing possibilities will be discussed on a schematic scale with reference to Figure 2.7. The left most schematic shows the active shunt while operating in ICP regulation mode, the peristaltic pump is turned such that the tubing within it is not compressed. For most of the time the variable resistance valve is using passive means to regulate ICP, therefore keeping energy consumption at a minimum.

The middle three schematics of Figure 2.7 show the active shunt operating in proximal flushing mode. The left most of the three schematics depicts a blockage at the LPC’s tip or somewhere along the LPC. The flushing procedure is initiated by fully compressing the distal tubing using the three-way valve and ceasing any flow to the distal end. Next, the pump turns in one direction, drawing fluid from the RPC and pushing it clockwise inside the proximal loop. A sequential motion between the pump and the valve takes place to generate an increasing pressure at the site of blockage until the obstruction is cleared. A similar procedure is used to unblock occlusions at the RPC.

All passive CSF shunts can only operate when the user is in a supine or standing position, if the patient’s head is below the level of their abdomen, CSF doesn’t drain unless their ICP becomes excessively high. An advantage of this active shunt topology is that when the distal end is above both the proximal ends, it is still capable of removing CSF from the brain’s ventricles by operating in the distal tubing flushing mode as shown in the last schematic of Figure 2.7. This is of merit, for example when the shunt user is sleeping and lying with their head at a similar level to their abdomen.

### 2.3 Peristaltic schematics

From here-on the shunt topology of the hydraulic schematic shown in Figure 2.6 will be converted to a peristaltic representation. The outline of the loops in the topology represents the shape of the peristaltic pump or valve. It is of interest to utilize this representation to analyze the operation of the pump-valve system in terms of cam angular positions.
2.3.1 Schematic convention

Prior to studying the sequential operating scheme of the pump-valve system, a convention of recognizing the angular positions of the cams is required. Figure 2.8 below illustrates the topology of the tubing within the peristaltic pump and valve in black. The red arrows represent the location along the tubing within the component where the cam is compressing the tubing most. The number in red alongside the red line corresponds to the bearing which the cam is rotated to, with 0° when the line is pointing to the top.

Figure 2.8 (a) shows the pump’s cam rotated to 135°, here the piece of tubing is left uncompressed; therefore fluid is able to flow through the pump freely. The pump fully compresses the tubing when the cam is positioned at 80° or 190°. Rotating the pump’s cam anticlockwise from 80° to 190° displaces fluid in the anticlockwise direction. Pumping in the clockwise direction is achieved by rotating the pump’s cam in reverse direction.

In Figure 2.8 (b) the valve’s cam rotated to 180°, this is the location where the variable resistance valve offers the lowest resistance to flow. The black lines drawn on the valve tubing’s topology at 60° and 300° are the locations which the tubing can be fully compressed, allowing no flow along a particular section of
tubing. Flushing of the proximal catheters is initiated by turning the cam to $60^\circ$ which closes off the distal tubing. Similarly, flushing of the distal catheter or RPC is initiated by rotating the cam to $300^\circ$. By turning the cam to $0^\circ$ closes off the proximal-distal node which ceases flow across the whole valve. This is required when the pump has rotated to its end position during a flushing procedure and pressure is required to be built up.

Figure 2.9 below captures the orientation of the shunt at a specific time during ICP regulation. The pump is rotated such that it acts as an open channel and the valve is regulating with the lowest resistance to fluid flow.

![Figure 2.9: Peristaltic pump-valve system in peristaltic schematic operating in passive drainage mode](image)

**2.3.2 Flushing sequence**

Using the peristaltic schematic convention outlined previously, a full sequence of the shunt flushing process will be illustrated graphically. All of the sequences below only allow for one cam to rotate at a
time. Figure 2.10 shows the algorithm to decide whether ICP regulation needs to be interrupted for flushing purposes.

![Flow diagram of shunt operating in passive drainage and flushing mode](image1)

Figure 2.10: Flow diagram of shunt operating in passive drainage and flushing mode

![Rotation sequence of one flushing cycle in cam topology](image2)

Figure 2.11: Rotation sequence of one flushing cycle in cam topology

The above sequence of cam movements in Figure 2.11 is used to show the angular positions of the pump-valve system’s cams during one flushing procedure of the RPC by drawing fluid from the LPC.
A) The pump-valve system’s cams in ICP regulation mode
B) Pump’s cam rotates CW to the start flushing position
C) Valve’s cam rotates CCW to block flow to the distal tubing
D) Pump’s cam rotates CW to the finish flushing position
E) Pump’s cam rotates CW to leave tubing an open channel
F) Valve’s cam rotates CW, returning to state before the flushing procedure

A decision is made when the system is at state D for whether an addition flush cycle is required. By using the following sequence in Figure 2.12, it is possible to build up pressure within the tubing. In the case when additional cycles of flushing is needed, state G follows state D, otherwise the sequence continuous to F allowing the system to return to its original state prior to flushing.

![Figure 2.12: Rotation sequence of additional flushing cycles in cam topology](image)

G) Valve cam rotates CCW to block the proximal-distal node
H) Pump cam rotates CW to the start flushing position
I) Valve cam rotates CW to block flow through the distal tubing
J) Pump cam rotates CW to the finish flushing position
If additional pressure is required, the pump can be returned from state J to G and the sequence between G through to J repeated. Otherwise, state E is to follow J and the system is returned to its original state prior to flushing.

The flushing sequence for flushing of the LPC and the distal catheter is included in Appendix A.
Chapter 3: Feasibility Analysis of an Active Shunt

In this chapter, the feasibility of an active CSF shunt will be explored based on the parameters of size, power and reliability by applying design calculations to hypothetical models. The hypothetical shunt architecture outlined in subsection 2.2.4 will be analyzed quantitatively in detail. A spreadsheet consisting of all the device parameters and power consumption for a given operating mode is included in Appendix B.

3.1 Solving the mechanical criteria

In order to calculate the power requirements and mechanical lifetime of the device, we must first understand the operating principle of peristaltic pumps. This type of positive displacement pump operates by progressively compressing a surface against a piece of silicone tubing, which allows fluid to be displaced in a particular direction.

For the purpose of obtaining a set of ball-park figures for the mechanical reliability and power consumption requirements of the sensors and actuators, it is necessary to obtain the torque required to drive the pump. This figure relies on the tubing material, tubing dimension and the diameter of the cam which compresses the tubing.

3.1.1 Torque investigation

The various methods of obtaining torque data include measurement, modeling and published literature. A method of obtaining the torque for calculation purposes includes setting up a computer simulation using a program such as ANSYS (ANSYS Inc., Canonsburg, Pennsylvania). Another is to measure the torque required to turn a prototype pump head using specialized testing rigs. The torque of interest is low requiring very sensitive equipment, not to mention the lengthy process of producing a physical model.
Fortunately pump manufacturers have published data on torque requirements for their pump heads for a range of tubing types and dimensions. These manufacturers have performed extensive testing to find torque requirements during the process of testing pump heads. Their operating manuals are aimed to inform the end user of the motor torque required when using a certain tubing diameter and material.

We assumed this ball park figure to be close enough for the purpose of investigating the feasibility of the pump under design. The figures used in the following calculations were obtained from Masterflex® performance data and general technical data [98]. The set of data used is the result of years of testing under actual application conditions by Holland Applied Technologies. The tubing was tested under various motor speeds, pumping water of 21°C and at a pressure of 0mmHg.

The tubing used for the calculation is the BioPharm Plus silicone material, which offers an average life of 2000 hours when operating at 50 RPM as shown on page TD-20. The P/S® 14 precision pump tubing of 1.6 mm inner diameter was chosen as it is closest to the typical CSF tubing’s inner diameter of 1.3 mm. On page TD-29 of the document, the respective torque required to drive the pump from rest is 128 mNm (1.3 kgcm). It should be noted that the starting torque is roughly three times the maximum running torque.

The company’s pump head used in producing the figures consist of 3 wheels consecutively compressing the silicone tubing one after the other. The peristaltic system under design uses only one wheel to push fluid across the tubing. This should give similar torque requirements but increases the tubing’s lifetime as the forces applied by the wheels is spread across a larger area.

### 3.1.2 Sizing the actuators and sensors

After obtaining the value of the torque required to drive the pump, it is possible to choose a motor with the appropriate output requirements. Some of the parameters used to determine the choice of motor include the desired output torque and the desired output speed, which is 128 mNm and 10 RPM respectively. Such a low speed was chosen to emulate high control accuracy. From these values the
desired output power was calculated using Equation 1 to be 0.134 W, the motor should be rated around 1.5x to 2x this value in the range of 0.2 W – 0.27 W.

\[ P_o = M \omega \]  \hspace{1cm} (1)

Where \( P_o \) is the output power required, \( M \) is the output torque required and \( \omega \) is the output speed required.

The motor specifications used for the following calculations were sourced from Micro Motion Solutions. It should be noted that their DC motor was chosen purely for the purpose of obtaining a ballpark figure of the power requirements. Other motor types may provide greater control resolution, repeatability or other desirable properties. For example piezoelectric rotary motors and motors with worm gear drives are able to fix shaft position when input power is not supplied.

A DC micromotor of series MD1622 was chosen for the calculations which follow, its output power is rated at 0.79 W, with a no load speed of 10400 RPM and an efficiency of 53%. The MD1622 series is the smallest micromotor available to allow a gearhead and encoder to be attached; this explains the high rated output power.

A planetary gearhead of series MD15P with a nominal reduction ratio of 1: 896 was chosen as it was the closest to the theoretical reduction ratio of 1: 1040 to give a desired output speed of 10 RPM; this component has an efficiency of 55%. Since the torque required to drive and compress the elastic tubing is known to be 128 mNm, using Equation 2 below, the input torque required to drive the gearhead (equal to the output torque of motor) is calculated to be 0.26 mNm.

\[ M_i = \frac{M_o}{i \times \eta} \]  \hspace{1cm} (2)

Where \( M_i \) is the input torque required, \( M_o \) is the required output torque specified, \( i \) is the reduction ratio and \( \eta \) is the efficiency of the gearhead.
Now that the output torque of the motor is known, it is possible to calculate the current through the motor at the desired torque. The current through the motor is the sum of the load current and the no-load current. The load current through the motor is related to the torque which the motor produces divided by its torque constant. The no-load current is 0.06 A and the torque constant 3.82 mNm/A. Using Equation 3, this current through the motor is calculated to be 0.128 A.

\[
I = \frac{M_t}{k_m} + I_o
\]  

Where \( M_t \) is the motor torque, \( k_m \) is the torque constant and \( I_o \) is the no-load current.

Lastly, the motor speed at the desired load torque is calculated using Equation 4.

\[
n = n_o \frac{I_m + R}{k_m}
\]

Where \( n \) is the no-load speed at a defined operating voltage, \( n_o \) is the no-load speed, \( I_m \) is current through the motor at the desired torque, \( R \) is the motor’s winding resistance and \( k_m \) is the torque constant.

The no-load speed at 4.2 V is 9707 RPM, the winding resistance is 5.5 Ω and the current through the motor was calculated from Equation 3 to be 0.128 mA. Thus, the motor’s speed at the desired load torque comes to be 7864 RPM. When combined with the gearhead of 1: 896 reduction ratio, the output speed which drives the cam is 8.8 RPM. Thus, the motor and gearhead chosen matches the desired output speed within an accuracy of 88%.

For the motor to operate under optimal conditions, it must be within 70 – 90% of its no load-speed, and 10 - 30% of its stall torque. When operating at 4.2 V these values are calculated to be 76% and 8% respectively.

A DC magnetic encoder of series ME2-16 with 2 channels and 16 cycles per revolution was chosen to provide the system with closed loop control, this has a current draw of 6.3 mA. Overall the
electromechanical system for control of one pump head measures Ø15 x 57 mm, weighs 50.5 g, with a current draw of 6.4 mA and an efficiency of 29%. The physical dimension of the motor, gearhead and encoder chosen is slightly larger than the size of an AA battery. This is a reasonable size for implantation into the human body. The choice of motor is appropriate to allow the exploratory data to be obtained, however, the choice of motor has not been optimized and this is a valuable area to add to future work.

The pressure sensor chosen for the feasibility analysis is the InterMEMS P381A absolute pressure sensor. This particular sensor was chosen because it is sufficiently small enough to be incorporated into the implant. The sensor die is 225 µm x 650 µm x 120 µm (0.67 French), and fits easily into a 1 French Catheter Lumen [99]. The sensor picked is also capable of resolving the magnitude and range of pressures experienced within the hydrocephalic environment. The sensor’s sensitivity is 17.5 µV/V/mmHg, with a pressure non-linearity of ±0.1% FSS. When the sensor is part of a wheatstone bridge and driven with a supply voltage of 3.3 V, the current draw is calculated to be 2.5 mA. The sensor’s drift characteristic is omitted from the electrical specifications; although this is an important design factor for an implanted shunt system, it is not a major concern for the analysis of the proof of concept.

Shunt valves are usually placed under the skin behind the ears, however if the final electromechanical implementation is too large it may be implanted into the abdominal cavity.

### 3.2 Device reliability

An active shunt uses power to regulate the flow of CSF from the ventricular cavity to the abdominal cavity. In principle, this device could dynamically measure the ICP and an electromechanical pump could move the fluid in response to the pressure value. This requires power at all times to drive the pump at the rate appropriate for maintaining set ICP. An alternative option is to set a resistance to flow, and only change this resistance in response to a change in ICP. This only requires continuous powering of the ICP measurement and intermittent powering of the pump mechanism to adjust the resistance. A third option is to only operate the active shunt for the purpose of maintaining the patency of the shunt. These alternatives use progressively less power, and this section deals with understanding the power implications to enable a viable solution to be pursued.
When describing the device’s reliability, a dichotomy exists between its mechanical and electrical forms. Here, the effect of different operation modes on power consumption, recharge frequency and mechanical wear will be examined. The following ballpark calculations will be based off a 120 mAh coin cell battery of dimensions around 5 x Ø 25 mm, as well as actuation and sensory elements chosen in subchapter 3.1.2.

Two fundamentally different modes of operation will be investigated; open-loop (OL) regulation and closed-loop (CL) regulation. The OL method of operation is similar to the way in which passive CSF shunts operate; the resistance of the flow regulating element does not change when exposed to different pressures. The coin cell battery in the OL control scheme is devoted to back-flushing purposes, powering of the pressure sensors and for orientation compensation.

Under the CL control scheme, power is also consumed at regular intervals for fine adjustment of the variable resistance valve to maintain a constant pressure set point. It should be obvious that OL regulation is more energy efficient, allowing for longer periods of use before recharging. Drawing insight from the operation of passive CSF shunts, the sole use of the OL control scheme may be sufficient in managing a patient’s hydrocephalic condition when the valve is adjusted to an optimal position.

### 3.2.1 Open loop operation

When the active cerebral shunt is operating under OL conditions, there are two engagements which contribute to power consumption; adjustment of the valve’s resistance and the back-flush procedure. The valve designed is theoretically capable of offering a continuous variable resistance. For the purpose of simplifying the valve system for calculation’s sake, the valve is only assumed to have 5 discrete settings. Following the convention set in subchapter 2.3.1, the first setting at 60° provides no flow and the sixth setting at 180° provides the maximum flow rate. Each increment is separated by 24°, with the motor operating at 4.2 V, 0.13 mA at 8.8 RPM. Together with the encoder which draws 6.3 mA, 12 Ws is consumed when changing to a new setting. Based on this principle, around 150 consecutive valve adjustments are possible with a 120 mAh coin cell battery. In the OL operation scheme the back-flush
procedure can be initiated when cellular block up of the shunt is suspected. The number of back flushes available before recharging of the coin cell is calculated to be around 5 times.

The current implementation of the shunt lacks an anti-siphon device (ASD), making it prone to the effects of hydrostatic pressure. In the supine position, hydrostatic pressure is not present, however in the standing position a large hydrostatic pressure is created within the shunt. According to Poiseuille’s law, in order to maintain a constant flow rate due to a rise in pressure, the resistance of the valve must increase. The valve could adjust its resistance to flow according to orientation data obtained from accelerometers. Assuming the valve is required to change between four resistance states per day to compensate for orientation, it is able to operate for 30 days before a recharge.

### 3.2.2 Closed loop pressure regulation

One of the advantages of active shunts over conventional passive cerebral shunts is its ability to monitor the patient’s ICP without any external equipment. This could provide valuable ICP data of the patient performing everyday tasks. ICP is obtained by taking pressure readings using the sensors placed in the ventricles of the brain.

In order to obtain a meaningful window of ICP data, pressure sensors should sample at 100 Hz for a 10 second period. In the case of ICP monitoring using a pressure sensor with 2.5 mA current draw (typical of piezoresistive sensors), operating at 3.3 V, 83 mWs is consumed per sample. If the active shunt’s valve resistance is fixed, up to 60 hours of continuous ICP data could be obtained, assuming power is only consumed in powering the pressure sensors. If ICP is only required to be sampled every 1 minute, the battery lifetime can be extended to 15 days.

Essentially in CL operation, actuation elements will draw power in conjunction with the sensing elements. If we assume the ICP is checked every 10 minutes using 83 mWs per sample and the valve setting changes by one increment each time using 12 Ws, the device is able to operate for one day.
The calculations carried out above were centred on CL adjustments based on time scheduling. This is not the best approach to maintaining an ICP set point as the patient’s ICP may elevate above the set point between samples. It is also unlikely that the valve resistance is required to change by one discrete increment per sample. An improved approach in CL regulation involves continuous sampling, adjusting the valve resistance whenever the sampled ICP elevates above the ICP set point. To investigate this, a Simulink model of the ventricular system connected to the active shunt model is required in understand the valve’s actuation frequency required; this is a valuable topic to investigate in future works.

3.2.3 Mechanical lifetime

The mechanical device consists of parts that all have a finite lifetime, the tubing can break down and the motor or gearheads can wear over time. The peristaltic tubing is the component most prone to wear, in 3.1.1 its lifetime was found to be 2000 hours for a single wheeled pump head operating at 50 Hz. If the shunt is to solely operate for unblocking purposes, the number of back flushes available works out to be $6 \times 10^5$ counts. The preliminary calculations of mechanical wear based on the hypothetical shunt design together with its operation schemes shows the peristaltic system is extremely durable. When the device is regulating and adjusting flow resistance at every 10 minutes, it is only active for one minute per day. Considering the tubing has the lowest lifetime, it is still capable of operating for 300 years before failing due to mechanical wear.

3.2.4 Abnormal operation

Although cerebral shunt valves consist of a one-way valve, it is potentially dangerous for hydrocephalus patients to orientate their head below their abdominal level for extended periods of time. This is because passive CSF drainage is assisted by gravity and is unable to drain against hydrostatic pressure. The shunt under design at this stage does not offer passive mechanisms to stop this reverse flow of CSF, as it is essentially an open length of tubing. However, the peristaltic system is not only able to block the reverse flow of CSF but even actively pump CSF from the ventricles of the brain to the abdominal cavity using a series of sequential cam movements. Nevertheless, this is a very energy intensive process and cannot be sustained.
3.2.5 Feasible operation

In terms of reliability, the mechanical wear on the device’s gears or tubing is not of concern. The feasibility of the system is constrained by energy consumption. The encoder chosen in this motor setup seems to be excessively power hungry, requiring 12 Ws per increment compared to 0.24 Ws used by the motor per increment. Assuming a new encoder is found which uses 0.5 Ws —ceteris paribus— the device would be capable of operating for over a week, given it is in CL regulation mode every 10 minutes.

Another way to increase the electrical operating lifetime involves upping the capacity of the battery. Let’s assume a typical phone battery with a capacity of 2000 mAh and dimensions of 60 x 50 x 4 mm is used. Using the 12 Ws encoder with CL regulation every 10 minutes allows the active shunt to operate for just over 2 weeks or 50 flushes. If a 0.5 Ws encoder is used, CL regulation could be sustained for over 5 months or 840 flushes.
Chapter 4: Valve Resistance Simulations

The variable resistance valve under design provides a resistance to flow based on the angular position of its cam. In this chapter, mathematical modeling and analytical simulations will be used to investigate the feasibility of using tube compression to limit fluid flow. The size of the cam used to compress the valve tubing was chosen empirically.

A combined valve and shunt conductance of 0 to \([\frac{3 \text{ ml/min}}{500 \text{ mmH}_2\text{O}}]\) was the design objective for the following simulations. This flow rate and pressure covers the higher sector of commercially available passive hydrocephalus shunts.

The following simulation results were obtained over many iterations of trial and error to determine the dimensions required to achieve the overall shunt conductance specified.

Occlusion is one of the main factors which determine the performance of peristaltic pumps in terms of its tubing life and pumping performance. Occlusion is the minimum distance between the roller and the housing. This amount of ‘squeeze’ is expressed as a percentage of twice the wall thickness and measured using Equation 5.

\[
y = \frac{(2t - g)}{2t} \times 100
\]  

(5)

Where \(y\) is the occlusion expressed as a percentage of twice the wall thickness, \(g\) is the minimum gap between the roller and the housing and \(t\) is the wall thickness of the tubing.

A greater amount of squeezing decreases the tubing life, while less squeezing can cause the pumped medium to slip back and decrease the efficiency of the pump. Note the equation only depends on the tubing’s wall thickness; which is 0.597 mm for the tubing chosen. Typically the occlusion ranges from 10 to 20%, as the silicone tubing to be used for the prototype is relatively soft, 20% was used for the design of the pump and valve housings.
The simulation code for determining the fluidic resistance of the two valve designs are included in Appendix C.

### 4.1 Variable radius housing

The lengths of the proximal catheters and distal tubing are 750 mm and 300 mm respectively, both with an inner diameter of 0.762 mm. The inner diameter used for the valve was 1.98 mm.

#### 4.1.1 Operational principle

The peristaltic valve is able to provide flow resistance by rolling an eccentric cam over a length of elastic silicone tubing. The greater the amount of compression there is on a piece of tubing, the lower the amount of fluid is able to flow through. This is illustrated in Figure 4.1 below:

![Figure 4.1: Tubing in 2 states of compression by an eccentric cam](image)

#### 4.1.2 Mathematical modeling

The tubing under compression in this valve is made of an elastic silicone material; during compression the tubing is assumed to solely undergo elastic deformation. The geometry of the tubing is also assumed to be fully recoverable.

Figure 4.2 examines the cross sectional geometrical deformation when a section of silicone tubing is compressed vertically between two plates. The tubing decreasing in height and increasing in width as it degenerates to the shape of an ellipse.
If the inner diameter of the tubing is much greater in dimension than its wall thickness, it is possible to assume that a much higher portion of the compressive force is used to reduce the volume of the lumen, rather than in stretching the elastic material. Using this deduction, the perimeter of the lumen is assumed to remain the same for the range of compressions the tubing undergoes. This condition is assumed to hold as long as the inner wall of the tubing doesn’t squash against each other.

The mathematical basis on which the simulations are built relies on the Hagen-Poiseuille equation (6) below; it relates the radius of a section of tubing to its fluidic resistance.

\[ R = \frac{8\mu l}{\pi r^4} \]  \hspace{1cm} (6)

Where \( R \) is the resistance of the tubing, \( \mu \) is the dynamic viscosity, \( l \) is the length of the tubing and \( r \) is the radius of the tubing.

However, this equation is only able to compute for the tube resistance when a circular radius is provided. In order to find the circular equivalent called the equivalent diameter of the ellipse geometry, Equation 7 from Heyt & Diaz is used [100]. The equivalent diameter is the diameter of a circular pipe that gives the same pressure drop as an equivalent oval pipe.
\[ d_e = \frac{1.55A^{0.625}}{S^{0.25}} \] (7)

Where \( d_e \) is the equivalent diameter, \( A \) is the cross-sectional area and \( S \) is the tubing’s perimeter.

The perimeter of the ellipse is known from the isoperimetric constraint, however, the cross-sectional area for the tubing is left to be found. The area of an ellipse is simply calculated using Equation 8. As we decrease the known gap between the cam and the circular surface of the housing, it is possible to calculate the width of the elastic tubing (the semi-major length).

\[ A = \pi ab \] (8)

Where \( A \) is the area of the ellipse, \( a \) is the semi-minor length and \( b \) is the semi-major length.

The degree to which an ellipse is compressed can be described in terms of its eccentricity. The eccentricity of an ellipse can range from a scale of 0 to 1, with a value of 0 representing a circle. Normally, Kepler’s equation gives a decent approximation for the perimeter of an ellipse. However as the eccentricity draws near to a value of 1, this approximation can give an error as much as 100%. In this simulation the Sykora-Rivera approximation, shown in Equation 9 was used to define the perimeter of an ellipse, which gives a much lower maximum error of around 0.631%.

\[ S = \frac{4[\pi ab + (a - b)^2]}{a + b} \] (9)

Where \( S \) is the perimeter of the tubing, \( a \) is the semi-minor length and \( b \) is the semi-major length.
Once the equivalent diameters for all of the valve elements are found, it becomes possible to find the fluidic resistances for these elements. The following diagram unveils the method that was used to calculate the resistance of the tubing elements within the valve.

Figure 4.3: Compression of a section of silicone tubing, resistance of the small segment $dR$ in blue

$$dR = \frac{8\mu dx}{\pi(d_{e1} + d_{e2})^4}, \quad R_{Value} = \int dR$$ (10)

Where $dR$ is the resistance of the enclosed segment, $\mu$ is the dynamic viscosity, $dx$ is the length of the enclosed segment, $d_{e1}$ the equivalent diameter of the less compressed section and $d_{e2}$ is the equivalent diameter of the more compressed section.

Figure 4.3 shows a section of the tubing being pressed into the page. The whole length of tubing being modeled was broken down into fine segments, with length increments of $dx$. The resistance of each small segment $dR$ shaded in blue, were calculated using Equation 10 and summed together to obtain the overall resistance of the valve, $R_{Value}$. 
4.1.3 Simulation results

Henceforth, the results of the simulations will be displayed using a polar coordinate system. Figure 4.4 shows the static polar coordinate system which the housing curvature and eccentric cam is based about. The origin represents the rotational center of the cam and is also the point from which the housing curvature is measured from. In other words, the housing curvature is the distance from the rotational center to the housing’s wall. Abiding to this convention, Figure 4.4 shows a cam with an eccentricity (e) rotated clockwise 60° from the vertical axis within the housing.

![Figure 4.4: Eccentric cam rotating within the housing](image)

The following simulations were performed with the cam of the variable resistance peristaltic valve set to 180° unless otherwise stated. The radial shape of the housing curvature from the rotational center of the cam was transformed and graphed onto the 2D polar plot of Figure 4.5 in blue. The profile was of design objective, thus it is not constant in radius. With reference to Figure 4.5, the radius of the housing curvature at 170° is 12.7 mm; this is the distance from the rotational center to the housing wall as shown in Figure 4.4. The value of the housing curvature is independent of the cam’s angular setting. The radius of the housing curvature is roughly 12.6 mm at 0° and 13.3 mm at 280°. Figure 4.4 displays the housing curvature...
curvature at 170°. Less clearly displayed is the sloped profile of the housing radius from 60° to 180° which is used for variable resistance.

The sinusoidal red line of Figure 4.5 represents the distance between the perimeter of the cam and its rotational center when turned to 180°. This distance ranges from roughly 9.6 mm to 11.5 mm. The red line represents the distance from the rotational center of the cam to the cam’s perimeter. The blue line represents the distance from the rotational center of the cam to the housing curvature. The housing curvature was designed to provide the fluidic resistances required.

Figure 4.5: Distance of components from the rotational center of the cam, variable radius valve set at 180°
Figure 4.6 uses the radius information of the housing and cam obtained from Figure 4.5. The red line in the above plot represents the distance between the cam and the housing curvature with the valve set at 180°. This distance ranges from around 1.3 mm to 3 mm; the lower value is where the valve tubing is compressed the most. A point of interest is that in order to change the valve from no resistance to full resistance, a compression distance of only 0.7 mm is required; this is the distance between the valley of the red line and the leveled blue line.

Subtraction of the wall thickness from the above distance gives the height of the inner diameter of the compressed elements across the tubing inside the valve. The width of the elements and equivalent diameter were then found using mathematical techniques described in 4.1.2. An additional constraint was enforced which limits the diameter of the tubing to be less or equal to 1.98 mm.

The blue line of Figure 4.6 shows the equivalent diameter of the deformed tubing within the valve. As expected the equivalent diameter of the tubing is lowest at 180°, a diameter of roughly 0.25 mm. The model follows the inner diameter constraint, resulting in the equivalent diameter kept below 2 mm. Both curves show a sharp change at around 210°, this is the result of the approximation that the tubing in
contact with the cam fully conforms to its housing. However this approximation has little effect on the simulated element resistances; which is revealed in the following plot.

![Peristaltic valve fluidic resistance](image)

**Figure 4.7: Fluidic resistances of valve elements and the peristaltic valve, variable radius valve set at 180°**

After computing for all the equivalent diameters of the tubing within the valve for 0° to 280°, it becomes possible to assign resistance values for each valve element. Figure 4.7 shows the fluidic resistance of each increment of valve element called $dR$ in blue. The characteristic spike at 180° of 1GPa/m$^3$/s is contributed by the fourth power of the tubing diameter in the Hagen-Poiseuille equation. The red line on the same plot accumulates the fluidic resistances of all the individual elements along the valve. The overall shunt resistance which incorporates both the tubing and valve’s resistances is found to be around 13 GPa/m$^3$/s at 180°.
Chapter 4: Valve Resistance Simulations

Figure 4.8: The combined shunt & peristaltic valve’s simulated pressure-flow curve, variable radius valve set at 180°

A simulation of the shunt and valve’s pressure – flow relationship is given in Figure 4.8. At a hydrostatic pressure of 500 mmH₂O the flow rate was computed to be roughly 3.1 ml/min and drops linearly towards a flow rate of 0 ml/min as the hydrostatic pressure depletes.

Figure 4.9: Whole shunt & valve simulated pressure-flow curve at different valve settings (variable radius valve)
The pressure–flow relationship between the different valve resistance settings is shown in Figure 4.9. In these simulations the valve was divided into discrete settings, this was simply for ease of analysis of the system. It is possible to set the valve at any angular position to obtain a finer control of the shunt conductance.

### 4.1.4 Limitations

As the simulation results reveals, the height of the tubing when compressed must be controlled within the sub millimeter scale in order to obtain a variable resistance of around 0 – 3 (ml/min/500 mmH2O). This is extremely difficult to achieve, requiring very strict tolerances between parts. Moreover, it is difficult to guarantee the physical dimension of the tubing returns to the same initial shape and micrometer offsets is bound to occur after each cycle of compression. This finding again expresses the lack of feasibility in using diaphragm valves for variable resistance purposes.

In reality the silicone tubing does not conform to an elliptical shape as the eccentricity increases near 1. Instead, the center of the tubing contacts vertically while the side bulges to form two channels at the ellipse’s opposite ends. This makes control of the gap’s distance more difficult as it results in a buffering effect of the lumen. It would be of interest to further investigate the variable radius housing method focusing on the channels formed due to bulging at the sides during the compression process for the purpose of flow control. However, a constant stress concentration at the sides of the tubing may reduce tubing lifetime.

### 4.2 Constant radius housing

#### 4.2.1 Operational principle

Another method to control the resistance to fluid flow would be the placement of specially designed geometry inside the lumen of the tubing. The strategy of deploying grooves in the interior of the tubing, or ridges on its exterior surface to prevent complete occlusion of the tubing has previously been described in a patent [101]. However, this was to prevent excessive pressure from building up, and preventing the
tubing from rupturing. In this design an altered geometry within the tubing is used to control flow resistance. This allows the eccentric cam to compress the tubing by the same amount for all angular positions.

![Figure 4.10: Tubing with modified inner geometry for constant radius housing](image)

The special tubing’s cross sectional area is shown in Figure 4.10. The top section of the tubing is an empty lumen, while the bottom section is semi-filled with a slit running down the middle of the two solid sections. The housing is designed such that only the top section of the tubing is closed off when compressed vertically. The rectangular slit between the two solid sections opens up to from a triangular lumen when the tubing is pressed.

The gap along the fluid regulating section of the valve is shown in Figure 4.10; this varies in depth along the length of tubing. The position where the gap has the greatest depth deforms to become the largest triangular lumen when compressed, providing the lowest flow resistance. Positions where the gaps are shallower deforms into smaller triangular sections, in turn giving a lower equivalent diameter and a greater flow resistance.

There are two main advantages in using a built-in physical lumen design to control the fluidic resistance. The desired flow is achieved by occluding the large semi-circular lumen which is roughly 1 mm in height. The previous design requires the control resolution to within a tenth of a millimeter. Secondly, the semi-
filled cross section gives an extra volume of silicone material which acts as a mechanical buffer, allowing the physical dimensions of the housing to have less strict tolerances.

### 4.2.2 Mathematical modeling

The modeling component of this design is much simpler compared to the calculations required previously. When the section of tubing is compressed with less than an occlusion factor of 30%, the equivalent diameter of the tubing is 1 mm, which is half the normal tubing’s inner diameter of 1.98 mm. When the tubing is compressed with an occlusion factor greater than 30%, the lumen conforms to the geometry of a triangle; the equivalent diameter of the valve element is approximated to that of half a square duct as shown in Equation 11.

\[
d_e = 0.65a^{0.75}
\]

Where \(d_e\) is the equivalent diameter of the triangle and \(a\) is the depth of the slit.

The objective of this simulation is to solve for the depth of the slit required in the tubing geometry to provide for the conductance specified.
4.2.3 Simulation results

![Distance from cam rotational center to surfaces](image)

In contrary to the varying housing curvature of the previous simulation, the ‘constant radius housing’ hence its name, consist of a fixed radius at 12.2 mm from the rotational center of the cam, as shown in the polar plot of Figure 4.11. It should be obvious the gap between the cam and the housing remains the same for all angular positions of the cam.

The sinusoidal red line of Figure 4.11 represents the distance between the perimeter of the cam and its rotational center when turned to 180° while conforming to the polar coordinate system specified. This distance ranges from roughly 9.6 mm to 11.5 mm.
Figure 4.12: Equivalent diameter of tubing w.r.t. compressed distance, fixed radius valve set at 180°

The red line in the above plot represents the distance between the cam and the housing curvature with the valve set at 180°. This distance ranges from around 0.8 mm to 2.6 mm. A constraint was added to ensure the triangular channel is only used when the tubing occlusion is greater than 30%. The equivalent diameter of the uncompressed parts along the tubing shown in blue has a width of roughly 1 mm. This is because only half of the interior within the tubing can be filled. As shown on the graph, a sloped profile of equivalent diameter of around 0.3 mm at 130° to 0.5 mm at 230° is observed. This linear slope of the equivalent diameter is the direct consequence of the sloped slit profile within the tubing.
Figure 4.13 shows the fluidic resistance of each increment of valve element called $dR$ in blue. There is a spike in fluidic resistance of around 1 GPa/m$^3$/s at 140° which gradually decays to 0.1 GPa/m$^3$/s at 220°. The sudden disturbances at 140° and 220° of the otherwise extremely low resistance profile is due to the simulation’s constraint which only recognizes fluidic resistance in the triangular conduit when the geometry is occluded by over 30%.

The red line on the same plot accumulates the fluidic resistances of all the individual elements along the valve. The overall shunt resistance which incorporates both the tubing and valve’s resistances is found to be around 32 GPa/m$^3$/s at 180°. This resistance is much higher than the previous simulation’s because from the same length of valve tubing, a greater portion is used to provide resistance to fluid flow.
Figure 4.14: The combined shunt & peristaltic valve’s simulated pressure-flow curve, variable radius valve set at 180°

A simulation of the shunt and valve’s pressure – flow relationship is given in Figure 4.14. At a hydrostatic pressure of 500 mmH$_2$O the flow rate was computed to be roughly 2.8 ml/min and drops linearly towards a flow rate of 0 ml/min as the hydrostatic pressure depletes.

Figure 4.15: Whole shunt & valve simulated pressure-flow curve at different valve settings (fixed radius valve)
The pressure – flow relationship between the different valve resistance settings is shown in Figure 4.15. In these simulations the valve was divided into discrete settings, this was simply for ease of analysis of the system. It is possible to set the valve at any angular position to obtain a finer control of the shunt conductance.

4.2.4 Limitations

When the cam compresses onto the variable resistance section, the slit formed may conform a circular lumen deterring from the geometry of a triangular conduit depending on the degree of compression or occlusion. Thus, the occlusion of the tubing may play a big role in the fluidic resistance of this design.
Chapter 5: Bench-top Implementation and Testing of an Active Shunt

5.1 Shunt’s mechanical interface

5.1.1 Standard peristaltic pumps

Conventional rotary peristaltic pumps are based on two designs as shown in Figure 5.1 below. Both of these designs involve the use of rollers to compress a piece of silicone tubing against the pump’s housing. The multiple roller design shown on the left has rollers which revolve in a circular orbit about a central axis, increasing the number of rollers reduces pulsations within the moving fluid. The single cam design on the right has a roller with an eccentricity to the rotational center. Generally by decreasing the number of components allows the system to be less prone to failure.

![Figure 5.1: 3-wheeled peristaltic pump (left), single wheeled peristaltic pump (right)](image)

Here is an analysis of the mechanical dimensioning required to make such devices function in reality. The following sketches made on SolidWorks are used to illustrate the cam and tubing’s position relative to the peristaltic pump and valve profiles in which they are placed.
The dimension of the pump head was designed such that it can be fitted on top of a 40 x 40 mm stepper motor. The silicone tubing chosen for use in the system has an inner diameter of 1.98 mm, this dimension is around the upper end of the inner diameters used in CSF shunt tubing.

5.1.2 Custom housing design

The peristaltic pump design which follows is capable of fully occluding the silicone tubing for pumping purposes, or it is possible to leave the tubing uncompressed to allow free fluid flow.

![Variable pressure peristaltic pump, turned at 180° (left), turned at 135° (right)](image)

The square enclosing the whole system is the housing profile within which the tubing and cam sits. The large circle at the center is a cam which rotates with an offset relative to its rotational center. The dotted line represents the elastic tubing together with its walls. The tubing is physically bound inside the housing to achieve the topology shown in the above figure.

Figure 5.2 shows the pump’s eccentric cam orientated at two positions. On the left hand side, the cam is positioned such that the silicone tubing at the bottom of the pump is fully occluded. When held at this position no fluid will flow through the pump, by rotating the cam clockwise by 270° pumping of fluid in
the pump is achieved. The orientation shown on the right shows the cam positioned such that no section of the tubing within the pump is closed off; this permits fluid to flow freely across the tubing.

The following peristaltic type design is capable of operating as a 3-way valve and as a variable resistance valve.

![Diagram of a peristaltic valve](image)

**Figure 5.3: Variable resistance 3-way diaphragm valve, turned to 180°**

Figure 5.3 is provided to aid with the visualization process required in analyzing the workings of the peristaltic valve. At the orientation shown in Figure 5.3, the eccentric cam is oriented such that the distance between the cam and housing is at a minimum near the bottom of the valve. Thus, the tubing at the bottom of the valve is compressed the most. Compression of other parts of the tubing within the valve is achieved by rotating the eccentric cam to other angular positions.
In the above Figure 5.4 shows the orientation of the eccentric cam within the valve’s housing at 3 angular displacements, note that the silicone tubing is not included in the drawing. This valve compresses around the node at which the proximal catheters and distal tubing converges. The valve’s housing profile was designed to allow for selective occlusion of any of these channels. Using this design it is possible to occlude all three channels at the same time as shown in the middle orientation. It is also possible to selectively occlude one channel while allowing for flow in the other two channels. The left-most orientation shows the cam occluding only the LPC, while allowing for fluid flow from the RPC to the distal tubing. The right-most orientation occludes the distal tubing, while allowing for fluid flow between the two proximal catheters.
Variable flow resistance of the valve is achieved by rotating the eccentric cam between the two angular displacements shown in the above figure. It should be kept in mind that the housing’s profile is of constant radius relative to the cam’s rotational center conforming to the design described in subchapter 4.2. When the eccentric cam is rotated to the position shown on the left in Figure 5.4, the first resistance setting to flow is provided. The position on the right provides the lowest resistance to flow.

5.1.3 Cam system

The cams within the peristaltic system are both eccentric in nature. That is, the cam is circular in shape, but a slight offset exists between its geometric and rotational center. Another cam surrounds the inner cam discussed above, as the inner cam rotates this outer cam translates side to side relative to the rotational center. This translational movement is used to compress the silicone tubing against the pump or valve’s housing. Even though the silicone tubing may stick onto the outer cam, the tubing is merely squashed instead of being dragged to a new position.
5.1.4 Custom tubing

There are two parts of this shunt system which required changes to be made to the silicone tubing, both of which are used within the peristaltic valve. The three channel node required two pieces of tubing to be adhered together, the slit geometry in the interior of the tubing required a section of tubing be semi-filled. Both of the above alterations were made using Momentive RTV 118 one part silicone sealant.

The three channel node, shown in Figure 5.3, is the point at which the proximal catheters and distal tubing are seamlessly integrated. The peristaltic valve relies on the principle that the whole length of tubing fitted inside the housing is compressible. Thus, the joining component at this junction must be flexible; this means a rigid polypropylene barbed connector is not suitable. Notches were cut into the end of the first tubing and the middle of the second. Next they were held in place, RTV adhesive was applied and left to dry overnight.

Production of the semi-filled cross section was more challenging. A piece of plastic cross web found in CAT 6 Ethernet cables was used as the cross member to provide rigidity and separation in the molding process. One side of the cross’ wall had to be trimmed to achieve a sloped profile as shown in Figure 5.6. The cross member was then inserted into the tubing’s narrow interior. This divided the tube into four quadrants; silicone adhesive was then injected into two adjacent quadrants and allowed to solidify overnight. Lastly, the plastic cross member was pulled out leaving the desired solidified slit geometry within the tubing.
5.1.5 Realizing a bench-top setup

The parts which made up the pump and the valve’s housing were created using rapid prototyping. The Trotec Speedy 300 laser cutter was used to produce the cams, housing profile and fixing plates out of 3 mm and 6 mm thick acrylic plates. The placement of the valve’s cams and housing attached to the stepper motors is shown in Figure 5.7.

The tubing used in this peristaltic setup was the T2011 50A Durometer class VI peroxide cured silicone tubing, it has an inner diameter of 1.98 mm and outer diameter 3.18 mm. The large sections of the shunt tubing which is not compressed used T2004 50A Durometer class VI peroxide cured silicone tubing which has an inner diameter of 0.762 mm. Luer connectors were used to connect the pieces of silicone tubing together, both the connectors and tubing were purchased from Qosina. A circular gasket made from RTV silicone adhesive was placed between top plate and the housing plate. M3 x 16 mm hex screws were used to bolt the housing onto the stepper motor. The motor used was a Minebea unipolar 12 V DC stepping motor, capable of providing a holding torque of 210 mNm. The black dials show the position at which the eccentric cam is turned to, hence the location where the tubing is compressed the most.
Chapter 5: Bench-top Implementation and Testing of an Active Shunt

Figure 5.7: The prototype peristaltic system with the housing attached to stepper motors

5.2 Shunt’s electronic interface

5.2.1 Electronic components

The motor controllers used in the bench-top setup are called SD02B stepper motor drivers, they are capable of driving unipolar stepper motors using Universal Asynchronous Receiver/Transmitter (UART) communication. An UC00A UART to USB converter with an integrated level shifter was used as the bridge between the motor drivers and the computer. The SD02B is capable of sending or receiving one to two bytes of ASCII data using the UART protocol to rotate or monitor the shaft’s position.
5.2.2 Interfacing Software

A National Instrument’s LabVIEW program written on a desktop computer was set up to communicate with the motor drivers using an USB port via the Virtual Instrument Software Architecture (VISA) protocol. The program communicates with the motor drivers to track and rotate the angular position of each of the motors.

Micro-stepping was turned on to further reduce the speed and increase accuracy, 1/10 micro-stepping was used meaning every physical increment of the stepper motor is further divided into 10-micro-steps. The motor driver used an open loop method to track the position of the motor shaft by counting the number of pulses sent to the stepper motor. This may seem non ideal for most applications, however for our operation the motors are operating at very low speeds and torque which doesn’t cause shaft slippage.

During normal operation, the eccentric cam is turned to the sector of variable flow resistance. Before each flushing procedure the program queries and records the valve’s motor driver for the motor’s shaft position. Next, the program drives each of the motors sequentially following the flushing procedure outlined in subchapter 2.3.2. Once this process is finished, the program returns the pump and valve back to passive draining mode. That is, the pump’s cam is rotated such that the tubing within is uncompressed and the valve’s cam returns to its recorded position prior to the flushing process. Figure 5.8 below illustrates the interfacing hardware and software protocols involved in controlling the stepper motors.
Figure 5.8: The physical and software connection between the motor, driver and PC

5.3 Pressure-flow evaluation setup

5.3.1 Experimental principles

A range of ICP within the ventricular cavity was simulated using a falling column of water exhibiting a range of hydrostatic pressures. This water column is vented to the atmosphere with a stop valve at the bottom to allow for drainage of water through the peristaltic valve when opened. As water passively drains through the peristaltic valve via gravity, the hydrostatic pressure exerted at the proximal entrances of the shunt decreases accordingly. A gauge pressure sensor placed at the level of the valve is used to measure the column’s hydrostatic pressure continuously.

At the start of each experiment, the valve’s cam is turned to a specific angular position, providing a specific flow resistance. The 90 cm length of the shunt’s tubing and valve are both placed at the same height level; the water column falls and strives to achieve equilibrium with this level. Water being drained through the shunt drips down from the distal catheter’s end and onto a balance. The flow rate through the shunt is measured as the length of time required for a measured change in mass.
The flow rate data is plotted against hydrostatic pressure, creating a scatter graph which displays the pressure-flow relationship for a certain valve setting. Flow data is collected for other valve resistance settings by adjusting the valve’s cam, refilling the water column and repeating the experiment.

The experiment outlined is an open loop analysis of the shunt system; it borrows techniques used to quantify the performance of passive cerebral shunts and valves. A closed loop analysis, which adjusts the peristaltic valve’s resistance according to varying ICP data is outside the scope of this thesis.

### 5.3.2 Physical system

The arrangement and relative position of the hydraulic connections such as valves and tubing used in this experimental setup is shown in Figure 5.9. The structure used to hold the water column is a 700 mm long length of clear polyurethane tubing of 5 mm ID, bound using cable ties onto a piece of perforated hardboard. The inner diameter of the water column’s tubing was chosen to keep the runtime within acceptable bounds. One experimental run takes from 30 minutes to 12 hours depending on the valve resistance. The volume of water which runs through the shunt during an experiment cycle is roughly 10 g. A Honeywell 5 VDC input, analog output, 0 – 700 mmH₂O gauge pressure sensor (HSCDANT001PGAA5) with ± 0.25% FSS and ± 1% total error band was placed at the bottom of the water column.

The sensor was powered using a Keithley 2220-30-1 Dual channel DC power supply, its specifications outline a 0.03% voltage accuracy, 0.1% current accuracy and <3 mV peak-peak ripple and noise. The
analog output voltage signal from the pressure sensor was read using a NI USB-6009 OEM DAQ board. The DAQ card’s analog input has 13 bits single-ended resolution and a maximum sampling rate of 48 kS/s.

The AND GX-800 digital scale used boasts a weighing capacity of 810 g, a resolution and repeatability of 0.001 g and linearity of ± 0.003 g. The sensitivity of the response is set to fast which uses the balance’s lowest averaging time of 2 s. The stabilization range was set to ± 6% of the weight value, giving the best possible accuracy when weighing the water droplets. The digital balance uses a RS232C serial interface and a RS232C to USB converter was used in connecting with the PC’s USB port.

An acrylic stand made using a laser cutter holds the peristaltic valve together with its stepper motor at a height above the digital balance, allowing for a 100 ml Pyrex beaker to fit. The water equilibrium level of the water column and the valve is shown as a dotted red line in Figure 5.9, the pressure sensor is calibrated to read 0 mmH₂O when water in the column falls to this level. The section of water below the red line is intentionally left undrained in the system; this prevents air from moving into the shunt and adding artificial flow resistance. The structure fixing the peristaltic valve and covering the balance’s weighing pan was enclosed in clear plastic wrap to prevent fluctuations in readings due to drafts.

The water column is refilled by first turning the manual 3-way HDPE stopcock to block flow to the valve and only allowing flow between the other two ports. A syringe is used to inject water from the bottom of the column and tubing, flushing air out of the system. The inner diameters of the water column’s tubing, the tubing connecting the column to the proximal catheters and the orifice of the 3-way valves, all have dimensions much greater than the shunt’s components. This reduces undesirable flow resistance added to the CSF shunt system being tested.

A protractor stuck onto the valve stand is used to show the angular displacement of the eccentric cam. The peristaltic valve alone was used in this testing setup and not the peristaltic pump. This is because during ICP regulation mode the peristaltic pump becomes an open channel, which is essentially a length of uncompressed tubing.
5.3.3 Software

The digital scale is linked to the Windows PC using the Virtual Instrument Software Architecture (VISA) which provides the programming interface between the hardware and the LabVIEW development environment. The LabVIEW program is written to poll for the sensor’s data which is done at 110 ms for both the pressure sensor’s data and the digital scale’s weight reading. A drop of water is roughly 0.025 g, the program registers a drop when the mass change is greater than 0.015 g. The time taken for a given mass change is then calculated, and then the flow rate at a certain pressure is calculated. Real-time stabilization algorithms were implemented on LabVIEW to eliminate spikes in the weight measurements due to perturbations foreign to the system.

The pressure sensor’s voltage read via the DAQ card is fed into the LabVIEW program and passed through a moving average filter of the previous 20 readings to remove noise in the sensor readings.
5.3.4 Experimental procedure

1. Set the valve at a fixed angle, in this case at 180°
2. Turn the manual 3-way valve so that only the path between the water column and injection tubing is open.
3. Using a syringe inject water 500 mm above the level of the valve
4. Turn the manual 3-way valve so that only the path between the water column and shunt is open
5. Use a syringe to suck out any bubbles in the shunt and valve system.
6. Inject water into the column until a height of 550 mm is reached
7. Pinch off the distal tubing to cease flow.
8. Turn on the power supply.
9. Zero the scale, run the LabVIEW program to log pressure and flow data.
10. Leave system to run from 30 minutes to 12 hours depending on the valve’s resistance setting.
11. Repeat the same test 5 times without changing the valve resistance.

5.4 Shunt flushing evaluation setup

5.4.1 Experimental principles

This experiment was designed to investigate the pressure generated at the endings of the shunt’s proximal catheters during a flushing procedure. The two proximal catheters were connected to a common reservoir of water representing CSF located inside the ventricular cavity. Blockage of one catheter ending was simulated by closing off a one-way valve which stops water flow to and from the reservoir. During a flushing process, sensors take pressure measurements at hydraulic lines below the site of occlusion. It was of interest to determine the maximum pressure generated at either proximal ends during clockwise and anti-clockwise flushing.
5.4.2 Physical system

The description of the physical setup and its components henceforth will refer to the schematic diagram of Figure 5.11. For this experiment the proximal catheters were connected to the bottom openings of an intravenous (IV) bag filled with water, this provided an equalized hydrostatic pressure at both endings of the catheters. Polypropylene one-way manual stop valves were connected just below the tubing out of the IV bag. The proximal catheters extend down the structure into the peristaltic system. A 3-way connector was placed in the proximal catheter between the stop valve and pump head, here a hydraulic line taps out. The other end of this hydraulic line is connected to a Honeywell HSC series 5 VDC, 10 bar, ± 0.25% accuracy gauge pressure sensor (model number HSCDANN010BGAA5), which measures the pressure within the proximal catheter. The distal tubing was connected to the top of the same reservoir so that no fluid escapes from the system. The pressure at the proximal catheter’s ending is the pressure measured by the sensor subtracted by the hydrostatic pressure due to a height between catheter end and the sensor.

The peristaltic system’s hardware is controlled using the electronic interface outlined in subchapter 5.2. The pressure sensors used in this experiment boast a higher pressure rating, however, its physical packaging and accuracy is the same as the one used in 5.3.2. The pressure sensors of the system are interfaced in a similar fashion to the pressure-flow evaluation’s setup.
Chapter 5: Bench-top Implementation and Testing of an Active Shunt

Figure 5.11: The back-pressure evaluation hardware with hydraulic connections (blue) and signal lines (red)

Figure 5.12: Physical experimental setup for shunt flushing evaluation
5.4.3 Software

The NI LabVIEW program specified in subchapter 5.2 was used to control the cams of the peristaltic pump and valve. The shunt flushing algorithm operated while the pressure generated at the LPC and RPC of the shunt were monitored simultaneously. The pressure data obtained was filtered and logged using the same method outlined in the previous experiment.

5.4.4 Experimental procedure

The following procedure describes the steps required to test for flushing of the proximal catheters:

1. Set all the manual valves to open positions
2. Ensure no bubbles are present along the whole shunt line and along the tubing connected to the pressure sensors
3. Turn the valve to 60°
4. Turn the pump to 135°
5. Turn on the power supply
6. Start the LabVIEW program to control the pump/valve system and log the pressure data

5.5 Results and discussion

5.5.1 Pressure-flow response

The fluid conductance of a shunt is the measure of resistance to fluid flow across its tubing. The conductance is the gradient of the pressure-flow curve when hydrostatic pressure is plotted as the independent variable and the flow rate as the dependent variable.

The valve design consisted of 6 fluidic resistance settings, at 60°, 90°, 120°, 150° and 180°. The lower angular positions provide a greater fluidic resistance compared to higher angular positions. The valve is closed off at 60° and gives maximum flow at 180°.
The pressure-flow data generally have a better $R^2$ value for valve settings of higher resistances. In this evaluation procedure, the flow rate through the shunt at a given hydrostatic pressure was measured as the time between each drop of water dispensed. A droplet is fairly constant in weight, however during high flow rates the time between each drop is short. This produces more error and a worse $R^2$ value than the other extreme when the droplet is accounted for over a longer period of time.

This effect is distinctly shown when examining the pressure-flow response during a single test run. Figure 5.13 shows the results obtained when the valve was set at $180^\circ$, its conductance was computed to be 4.92 $\mu$L/mmH$_2$O with a $R^2$ value of 0.9. Here the data comprises of a divergence of points around the origin fixed linear trend line as hydrostatic pressure increases.

![Experimental pressure-flow relationship](image)

*Figure 5.13: Pressure-flow experimental results and fitted approximation, valve set at $180^\circ$*

A graphical comparison between data obtained from 5 experimental runs of setting the valve at $180^\circ$ is plotted in blue in Figure 5.14. The red line is the fixed origin linear approximation of each set of data points. As shown, the linear approximation between each run is fairly consistent.
Figure 5.14: Pressure-flow experimental results and fitted approximation for 5 test runs, valve set at 180°

A most detailed comparison between the datasets is given in Table 1 below for valve settings 120°, 150° and 180°. The mean and variance of the conductance and $R^2$ was taken over 5 experimental runs. As the valve angle decreased the conductance lowered from 4.90 $\mu$L/mmH$_2$O at 180° to 0.519 $\mu$L/mmH$_2$O at 120°. The $R^2$ value decreased in the same way because a lower flow rate allowed for a more accurate sample. The variance of the conductance within each of the 5 experimental runs are very low, meaning the pressure-flow relationship at a particular valve resistance has a high repeatability.

<table>
<thead>
<tr>
<th>Angle (°)</th>
<th>Simulated value</th>
<th>Experimental mean</th>
<th>Experimental Variance</th>
<th>$R^2$ Mean</th>
<th>$R^2$ Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>120</td>
<td>$1.2 \times 10^{-3}$</td>
<td>$5.19 \times 10^{-4}$</td>
<td>$5.54 \times 10^{-9}$</td>
<td>$9.40 \times 10^{-1}$</td>
<td>$4.21 \times 10^{-5}$</td>
</tr>
<tr>
<td>150</td>
<td>$3.4 \times 10^{-3}$</td>
<td>$2.25 \times 10^{-3}$</td>
<td>$1.17 \times 10^{-7}$</td>
<td>$9.17 \times 10^{-1}$</td>
<td>$4.87 \times 10^{-5}$</td>
</tr>
<tr>
<td>180</td>
<td>$5.5 \times 10^{-3}$</td>
<td>$4.90 \times 10^{-3}$</td>
<td>$6.42 \times 10^{-9}$</td>
<td>$9.05 \times 10^{-1}$</td>
<td>$3.86 \times 10^{-4}$</td>
</tr>
</tbody>
</table>
Referring to Figure 5.15, the results for the valve set at 60° was omitted as the valve performed as expected, producing no flow over a period of 24 hours. The pressure-flow results for the valve set at 90° was also left out intentionally because a conductance value of 0.819 µL/mmHg was obtained, which is not representative of the conductance’s overall trend. This conductance value at 90° is greater than the value of 0.519 µL/mmHg obtained at 120°. The cause of the conductance at 90° to fall outside of the expected range was due to defects produced in the manufacturing process. Subsequent examination of the valve tubing revealed there was insufficient silicone adhesive at the 90° end of the tubing for producing the slits in the tubing. This meant the inner wall of the tubing was unable to fully close off the large semi-circular lumen, which prevented the slit geometry from being utilized.

The peristaltic valve was designed to provide a conductance of 0 to \( \frac{(3 \text{ ml/min})}{(500 \text{ mmHg})} \). Figure 5.15 shows three distinctly different shunt conductance values for the valve being set at 120°, 150° and 180°. Referring back to Table 5.1, there exists marked deviations between the simulated conductances obtained from subchapter 4.2.3 with the experimental data. As a rough estimate, the difference between the simulated and experimental data at 120° is 50%, 150° is 30% and 180° is 10%. These discrepancies, however, do not jeopardize the proof of the peristaltic valve’s ability to achieve different conductances at different cam angles. The experimental results illustrate conductance repeatability of a set cam angle at 180°, as shown in Figure 5.14 and the ability of the valve to change conductance by altering the cam angle is illustrated in Figure 5.15, with further evidence attached in Appendix D.

These errors support more extensive work to be carried out on several fronts; namely improvements in computation simulation, manufacturing of the valve and in the experimental setup. The valve simulations provided only a rough guide to the conductances achievable, a fair degree of cautious approximations were employed for the purpose of simplifying the model. For example, the triangular lumen of the valve was taken to be fixed in morphology in the simulation, whereas in reality it is capable of deforming continuously.

A much higher degree of precision is required to engineer the device. The laser cut housing and cams had dimensional error of ±0.5 mm, machined metal parts are capable of reaching micron level accuracy. The
custom tubing made by hand involved crafting in the sub-millimeter range using a scalpel. Specialty companies that manufacture custom silicone tubing is more suited in making such parts using techniques such as injection molding.

There are several methods capable of reducing the spread of data across the whole range of hydrostatic pressures tested. One possibility is the use of a larger diameter water column, allowing more drops of water to be dispensed per unit of hydrostatic pressure. The moving average of ten data samples can be used to provide a better representation of the flow rate.

A more precise method of obtaining the pressure-flow relationship across the shunt involves the adoption of a fully automated test system similar to one used by the Umeå hydrocephalus group [102]. The proximal pressure of the shunt is controlled by air pressurizing a water filled container. The continuous flow rate through the shunt is calculated using the pressure drop across a glass constriction.

The pressure-flow curves for settings at 90°, 120° and 150° are included in Appendix D.
5.5.2 Shunt flushing

The results to follow were obtained from the shunt flushing evaluation setup described in subchapter 5.4. The pressure generated within the LPC and RPC during the proximal flushing process were recorded. Here, only the results acquired during a single cycle flushing of the RPC will be examined.

![Graph](image)

Figure 5.16: Shunt flushing of the blocked left proximal catheter, letters represent the flushing state

Figure 5.16 displays the pressure within the LPC and RPC during an active flushing procedure attempted to unblock the RPC. The pressure within the LPC over the entire flushing procedure is relatively stable as the LPC is open and fluid is simply drawn through this section.

The arrows located on the red line of Figure 5.16 are used to show the flushing state the shunt is at based on the convention outlined in subchapter 2.3.2. There is a distinct change in the pressure within the RPC, reaching a peak of 3000 mmH$_2$O at the end of one flushing cycle. The pressure built up is released when the pump returns to its open position at the end of the cycle. A constant pressure reading of around 1700 mmH$_2$O exists between state C and D due to a short delay between operation of the pump and valve.
cam. The sequential cam movements required in flushing of the LPC is slightly different and the maximum pressure generated was recorded as 1000 mmH$_2$O.

During evaluation it was found the geometry of the pump was not manufactured to a satisfactory standard. Certain angular positions were found to compress the tubing less than others, resulting in fluid slipping backwards when the pressure within the shunt became high. The plateauing of the pressure within the RPC at around 3000 mmH$_2$O and the maximum pressure reached at 1000 mmH$_2$O during LPC flushing is most likely contributed by such. The shunt was also made to build up pressure over multiple cycles; however the data obtained was less than ideal in showing its potential due to manufacturing defects.

The maximum back pressure achievable is limited by the amount of occlusion, stall torque of the motor, elasticity of silicone tubing used and the degree of sealing between the tubing and connectors. The back pressure generated is proposed to relieve cellular block up, however an excessive amount of pressure may lead to more harm than good. A high back pressure is accompanied by a high flow rate may lead to a dangerous injection of CSF into the ventricles of the brain. High pressure cyclic loading of the shunt may cause early failure; this is especially the case for a section of adhesive connected tubing.

The back-pressure results obtained for flushing while the proximal catheters are unobstructed and flushing of the right proximal catheter is included in Appendix D.
Chapter 6: Progressing to an Implantable Smart Shunt

The analysis of shunt failures provides a reason for prioritizing the approach for extending their functionality. The overall aim of this study was to develop a mechanism that leads to a hydrocephalus shunt lasting longer – without failure from occlusion – compared to current passive shunt devices. Many of the fundamental feasibility issues have been addressed, but much work is required before a device could be put into clinical practice. In this chapter the next steps will be discussed.

The future work can focus on a series of technical objectives and an important validation objective. Technical objectives relate to pumping mechanisms, size, reliability, power and communication. The validation objective is demonstrating a delayed blockage.

There is considerable scope for adding objectives in the area of patient specific feedback and flow regulation.

6.1 Bioreactor experiments

In this thesis we have focused on the design of an integrated shunt system capable of flow regulation and providing a means of flushing. The generation of a high back pressure may be a method for unblocking a fully occluded catheter. However, it seems logical that early intervention may be easier than dealing with a full occlusion. The back pressure required in successfully unblocking chronically obstructed catheters is unknown and may be extremely high, making the power required in actuating the motor infeasible. A preventive method instead of a palliative one may be key to patency. We speculate an alternative method could be used to prevent chronic obstruction; that is by providing a scheduled low back pressure flushing procedure to pacify the rate of cellular attachment, or to push out material before it becomes entrapped.

As discussed earlier in the literature review, the majority of occlusions in the form of cellular ingrowth take place within and around the proximal catheter’s perforations. In this experiment, a bioreactor is
conceptualized to promote increasing levels of growth within a cellular suspension and the fluid is drained through catheters in an attempt to form cellular obstruction. The approach to be used in verifying the hypothesis of the preventive method’s effectiveness involves an occasional flushing procedure to perturb cellular settlement on the catheter, in which a reversible flow of CSF is generated using a pumping mechanism. The delayed onset of catheter occlusion when implementing scheduled back flushing procedures will be an indicator of improved outcome.

A more representative model of hydrocephalus would be using an animal model. Kaolin can be injected into the brain ventricles to induce hydrocephalus [103, 104]. However, the onset of occlusion can be highly variable, so the number of animals and duration of the experimental protocol will need to be evaluated and resourced.

Our premise is that if obstructing tissue is sucked into the proximal end, then by reversing the flow, the tissue material can be pushed back out to clear the obstruction. We speculate that the pressure required in doing this immediately following the obstruction occurring could be small, but if the reversal is delayed, the occlusion might be more difficult to clear (and require a higher back pressure). If a synthetic material representative of the choroid plexus could be found, then a bench top study could look at the relationship between the back pressure required to clear an obstruction against the response time post-occlusion.

The occlusion process of sucking up choroid plexus is quite different from the growth of cells inside the catheter. Reversing the flow may have little impact on the growth of cells. If the pressure difference across the occlusion could be monitored, then the rate of the pressure difference might provide information on the nature of the occlusion. A rapid onset suggesting a sucking up of choroid plexus compared to a gradual increase indicating a narrowing of the catheter opening.
6.2 Computational models

For the purpose of optimizing the shunting device’s size, power and reliability; it is of interest to determine the consequence of altering one design factor has on another. Some of these parameters which could influence design would include the size and geometry of the peristaltic housing; the ICP changes due to daily activities and cardiac fluctuations; and the frequency of closed loop operation and flushing procedures.

For the development of the smart shunt, two closely interlinked simulations are valuable. An ANSYS model could be created to analyze the stresses imposed on the motor shaft and tubing and the motor torque required for the shunt concept. Using a similar model, the geometry of the peristaltic housing and custom tubing could be designed with the aim of reducing its footprint, while at the same time still provide consistent flow resistance. A comprehensive Simulink model which mimics the hydrodynamic behavior of the hydrocephalic brain could be used to formulate different drainage algorithms of the smart shunt concept. This would involve considerations of CSF production, resorption, shunt flow and compliances. In particular, a variable resistance valve would provide the key means of CSF flow in the simulation.

Both of the simulations would be invaluable in evaluating the power consumption and aid in the miniaturization process of the said device.

6.3 Fabrication

The shunt prototype prepared for this thesis has been used to show proof of concept for moving and controlling bi-directional flow but it is only suitable for bench-top evaluations. To prepare an implantable device suitable for submersion and ultimately animal experiments, the equipment must be encapsulated. Due to the specificity of the device, special production techniques may need to be formulated for the manufacturing of the custom peristaltic housing and tubing. A physical torque testing platform should be built to verify the torque required to drive the peristaltic system.
The peristaltic system would need to be fitted with electromechanical actuators, pressure sensors, position sensing hardware, power electronics, telemetry circuitry and logic components. The valve section of the device would need to be encapsulated with a hermetic housing to ensure it is protected from failure due to fluid ingress. Together with its software and built-in drainage and unclogging algorithms a ‘smart’ system is produced.

### 6.4 Shunt evaluation

The reliability of the device will require testing. A series of accelerated cyclic tests should be set up to determine the types of mechanical wear the device is susceptible to and the reliability of the encapsulating casing.

The functioning of the bench-top smart shunt prototype will need to be evaluated using an incubated pressure-flow testing platform simulating the device operating in a bodily environment. The fluid drainage capacity at different tilt angles, power requirements (simulation versus actual) and automated obstruction clearing function of the device will all need testing. The peripherals of the device such as data transfer via telemetry and inductive power transfer will also need development and resourcing.

The use of the bioreactor is anticipated to be instrumental for investigating the processes by which cellular build-up originate and metastasize into chronic obstruction. However, the experimental setup is greatly simplified providing flow of an increasingly cellular dense fluid through the catheter, compared to the complex processes experienced inside the brain with cellular composition and hydrodynamic conditions. The closest way of replicating the conditions of catheter obstruction within a human’s hydrocephalic brain would be to implant catheters long term within animal models.
6.5 Envisioned implantable smart device

Current cerebral shunt valves are implanted behind the ears just underneath the skin, an active implementation may prove too bulky to be placed at the same place. An alternative location for the implant may be in the abdominal cavity as shown in Figure 6.1 (a).

Depicted in Figure 6.1 (b) is an implantable device proposed to actively manage hydrocephalus as described in detailed in this thesis. In summary, the device would consist of a pair of motors used to actuate the cams which are bounded by the custom peristaltic housing; a printed circuit board that holds all of the device’s electronic and logic components; a lithium polymer battery is used to power the electronics, actuators and sensors; a copper coil attached for recharging the battery using inductive power transfer technology. All of the said components are hermetically sealed inside a titanium housing. Plugs at the side of the housing allow the two proximal catheters and one distal tubing to be attached.

It should be noted that the contents of Figure 6.1 (b) are purely used for illustration purposes. The components within the said device, the make and dimensions of the components will be subjected to further miniaturization.
Chapter 6: Progressing to an Implantable Smart Shunt

Figure 6.1: Proposed implantable smart device

6.6 Conclusion

Hydrocephalus patients are suffering due to shunt failure problems. Technological advances such as miniature sensors, electronics and micropumps offer the prospect of improving shunt performance and reliability. With the enabling technologies presented in this thesis, the prospects for creating a smart, active implantable shunt which offers improved patient outcomes looks promising.
References


References


References

Appendix A: Flushing Sequence

Cam sequence for clearing obstruction at the left proximal catheter (Clockwise flushing)

Cam sequence for clearing obstruction at the distal catheter
Appendix B: Feasibility Calculation
### DEVICE ELEMENT SPECIFICATIONS

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<thead>
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<th>Device</th>
<th>Specification</th>
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<td>Tubing - Biopharm Plus Silicone, USP Class VI, Holland APT</td>
<td>Inner diameter (mm)</td>
</tr>
<tr>
<td></td>
<td>Starting torque required (mNm)</td>
</tr>
<tr>
<td></td>
<td>Backpressure (mmHg)</td>
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<tr>
<td></td>
<td>No. wheels in pumphead</td>
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<td></td>
<td>Op. lifetime @ 50 RPM (hours)</td>
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<tr>
<td>Telemetry (2kHz default)</td>
<td>ICP pres. sensor curr. draw (mA)</td>
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<tr>
<td></td>
<td>No. of sensors</td>
</tr>
<tr>
<td></td>
<td>Sampling frequency (Hz)</td>
</tr>
<tr>
<td></td>
<td>Total telemetry current draw (mA)</td>
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<td>Max power output (W)</td>
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<td>Motor current draw (mA)</td>
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<td></td>
<td>Output speed (RPM)</td>
</tr>
<tr>
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<td>Time taken per revolution (s)</td>
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<td>Coin cell battery - assume all elements running at 3 VDC</td>
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<td>Coin cell capacity (mAs)</td>
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<td>FLUID MANIPULATION</td>
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<td>Regulation - design valve for 0 - 3.0 ml/min/mmH20</td>
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<td>Degrees per increment [Inc]</td>
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<td>Flushing procedure</td>
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<td>Sampling period (s)</td>
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<td>Operation time (days)</td>
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</tbody>
</table>
Appendix C: Simulation Code

%%
% Author: Dixon Leung
% Email: dleu006@aucklanduni.ac.nz
% Auckland Bioengineering Institute, Implantable Device Group

% Simulation code for calculating the valve resistance and total shunt
% conductance of the fixed radius peristaltic valve design

% fixedRadiusValve.m

clear;clc;

%% Parameter initializations

u = 0.001002; % at 20C
ID = 1.9812/1000;
OD = 3.175/1000;
t = (OD-ID)/2;
innerTubePeri = ID*pi;
radDist = 0.762/2/1000;
radProx = 0.762/2/1000;
% length of distal & proximal portion (m)
distL = 250/1000;
proxL = 750/1000;
% distal tubing resistance (1 path)
rDist = (8*u*distL)/(pi*radDist^4);
% proximal catheter resistance (2 parallel paths)
rProx = 0.5*((8*u*proxL)/(pi*radProx^4));
% total resistance of shunt with non constricted tubing
rTubing = rDist + rProx; % Pa/m^3/s

tankDia = 5/1000;
%density of water at 37C (kg/m^3)
rho = 991.27;
% Tank area (m^2)
tankArea = (pi*tankDia^2)/4;

%% Cam geometry calculations

theta = linspace(1, 360, 360);
% cam eccentricity from the center of rotation
e = 0.99/1000;
outerCamRad = 10.55/1000; % without tubing

% length from the rotation center to the surface of the cam for 360 deg
for i = 1:length(theta)
    syms d
    [K] = solve(d^2-2*d*e*cosd(theta(i))+e^2-outerCamRad^2 == 0, d);
distInCam(i) = double(K(1));
print = sprintf('%.0f',i/360*100);
print = strcat(print,'%');
disp(print)
end

phi = 180;

%Perform a coordinate transform
xCombCos = [distInCam((360-phi):360), distInCam(1:(280-phi))]; %extend range

% Housing profile mapping
occlusionDepth = 0.4*ID/2;

depthStart = 0;
depthChange = 0.7/1000;

for i = 1:280
    % A fixed housing radius profile
    housingR = 10.55/1000 + 0.99/1000 + ID/2 - occlusionDepth;

    %if the tubing is not half compressed
    if i <= 30
        gapDepth(i) = 0;
    else
        gapDepth(i) = depthStart + depthChange*(i-30)/150;
    end

    %The distance between the outer cam and inner surface of the housing
    minGap(i) = housingR - xCombCos(theta(i));
    if minGap(i) < ID/2*0.9;
        %half the equivalent diameter of a square duct
        equivDia(i) = 0.5*1.3*((gapDepth(i)^2)^0.625)/ (2*gapDepth(i))^0.25);
    else
        equivDia(i) = ID/2;
    end

    % Calculating for the change in tube resistance due to compression
    if equivDia(i) > ID
        equivDia(i) = ID;
    end

touchingDistHigh(i) = ID/2*0.9;
touchingDistLow(i) = ID/2*0.7;
unCompressed(i) = 1.9812/1000;
bottomLine(i) = 0;

%Resistance calculation using Poisellue's Equation
dRes(i) = (8*u*0.04/280)/(pi*(equivDia(i)/2)^4);
if i == 1
    dResCumu(i) = dRes(i);
else
    dResCumu(i) = dRes(i)+dResCumu(i-1);
end

print = sprintf('%.0f',i/280*100/2+50);
print = strcat(print,'%');
disp(print)
end
%% Tank drainage calculations
%Increments of height
n = 10000;
hInit = 500/1000;
hFinal = 10/1000;
h = linspace(hInit, hFinal, n);
qShuntTime(1) = 0;

rValve = sum(dRes);
rTotal = rValve + rTubing;
for z = 1:n-1
    shuntQ(z) = 1000*9.81*h(z)/rTotal*1000000/60; %Pa/(Pa.s/m^3)
%Time taken for each increment of height decrease (mins)
    qShuntT(z) = (tankArea*(h(z)-h(z+1)))*1000000/shuntQ(z)/60;
%Cumulative time progressed (mins)
    qShuntTime(z+1) = qShuntTime(z)+qShuntT(z);
end

%% Graphing
subplot(3,2,1);
plot(0:280,xCombCos, 'r-')
xlabel('Angular position (Deg)');
ylabel('Length from e to perimeter (m)');
hold on
plot(1:280,housingR, 'b-')
legend('Cam profile', 'Housing radius')
hold on
plot(1:280,bottomLine, 'k-')
hold on
subplot(3,2,2);
plot(1:280, equivDia, 'b-')
hold on
plot(1:280, touchingDistLow, 'y-')
hold on
plot(1:280, minGap, 'r-')
hold on
plot(1:280, touchingDistHigh, 'g-')
hold on
plot(1:280, bottomLine, 'k-')
hold on
plot(1:280, unCompressed, 'c-')
legend('equivalent Diameter', 'touchingDistLow', 'minGap', 'touchingDistHigh')
xlabel('Angular position (Deg)');
ylabel('Length (m)');

subplot(3,2,3);
plotyy(1:280,dRes,1:280,dResCumu,'plot')
legend('dR', 'cumulative dR')
xlabel('Angular position (Deg)');
ylabel('Resistance (Pa/m^3/s)');

%P-V curve of whole shunt
subplot(3,2,4);
plot(h(1:n-1),shuntQ);
title('Simulated pressure-flow curve (Whole shunt)');
xlabel('Pressure (mH2O)');
ylabel('Flow rate (ml/min)');

subplot(3,2,5:6);
plot(qShuntTime,h);
title('Tank drained under hydrostatic pressure');
xlabel('Time progressed (Hours)');
ylabel('Water height (m)');

rValve
shuntQ(1)
%%
% Author: Dixon Leung
% Email: dleu006@aucklanduni.ac.nz
% Auckland Bioengineering Institute, Implantable Device Group

% Simulation code for calculating the valve resistance and total shunt
% conductance of the variable radius peristaltic valve design

% variableRadiusValve.m

clear; clc;

%% Parameter initializations

u = 0.001002; % at 20C
ID = 1.9812/1000;
OD = 3.175/1000;
t = (OD-ID)/2;
innerTubePeri = ID*pi;
radDist = 0.762/2/1000;
radProx = 0.762/2/1000;
% length of distal & proximal portion (m)
distL = 290/1000;
proxL = 750/1000;
% distal tubing resistance (1 path)
rDist = (8*u*distL)/(pi*radDist^4);
% proximal catheter resistance (2 parallel paths)
rProx = 0.5*((8*u*proxL)/(pi*radProx^4));
% total resistance of shunt with non constricted tubing
rTubing = rDist + rProx; % Pa/m^3/s

%% Cam geometry calculations

theta = linspace(1, 360, 360);
e = 0.99/1000;
outerCamRad = 10.55/1000; % without tubing

for i = 1:length(theta)
syms d
[K] = solve(d^2-2*d*e*cosd(theta(i))+e^2-outerCamRad^2 == 0, d);
distInCam(i) = double(K(1));
print = sprintf('%.0f',i/360*100/2);
print = strcat(print,'%');
disp(print)
end

phi = 180;
% Perform a coordinate transform
xCombCos = [distInCam((360-phi):360), distInCam(1:(280-phi))];

subplot(2,2,1);
plot(0:280,xCombCos*1000, 'r-')
xlabel('Angular displacement (Degrees)');
ylabel('Length (mm)');
%% Calculating for the change in tube resistance due to compression

occlusion = 0.1; % 10%
gMin = 2*t-occlusion*2*t; %Note: material compression

diff = 0.0015/1000;
endGap = 0.015/1000+diff; %variable to set
noOcclusionAdd = 2*t-gMin-diff-0.0015/1000;

for i = 1:280 %extend range
    if i <= 50
        housingR(i) = 10.55/1000 + 0.99/1000 + gMin;
    elseif i <= 60
        housingR(i) = 10.55/1000 + 0.99/1000 + gMin + noOcclusionAdd*(i-50)/10;
    elseif i <= 180
        housingR(i) = 10.55/1000 + 0.99/1000 + gMin + endGap*((i-60)/120) + noOcclusionAdd;
    elseif i <= 210
        housingR(i) = 10.55/1000 + 0.99/1000 + gMin + endGap + noOcclusionAdd;
    else
        housingR(i) = 10.55/1000 + 0.99/1000 + gMin + endGap + 0.0005 + noOcclusionAdd;
    end

%The distance between the outer cam and inner surface of the housing
minGap(i) = housingR(i) - xCombCos(theta(i));
if minGap(i) < 2*t
    minGap(i) = 2*t+t*0.000000001;
end
%Assume tubing is isoperimetric during compression
%only left with the inner lumin diameter
ovalSideA(i) = minGap(i)-(OD-ID);

syms oSB positive
[K] = solve((ovalSideA(i)/2)^2+(ovalSideA(i)/2)*(4*pi*(oSB/2)-2*(oSB/2)-innerTubePeri)+((oSB/2)^2-innerTubePeri*(oSB/2)== 0, oSB);
storeK(i) = double(K);
ovalSideB(i) = storeK(i);

ovalArea(i) = pi*ovalSideA(i)*ovalSideB(i)/4;
%Find the equivalent circular diameter which gives the same pressure
%drop as the oval shaped compressed tubing
equivDia(i) = (1.55*ovalArea(i)^0.625)/innerTubePeri^0.25;
if equivDia(i) > ID
    equivDia(i) = ID;
end
touchingDist(i) = 2*t;

dRes(i) = (8*u*0.04/280)/(pi*(equivDia(i)/2)^4);
if i == 1
    dResCumu(i) = dRes(i);
else
    dResCumu(i) = dRes(i)+dResCumu(i-1);
end

print = sprintf('%.0f', i/280*100/2+50);
print = strcat(print, '%');
disp(print)
end

subplot(2,2,1);
plot(0:280, xCombCos*1000, 'r-')
xlabel('Angular displacement (Degrees)');
ylabel('Length (mm)');
hold on
plot(1:280, housingR*1000, 'b-')
legend('Distance to perimeter of cam from rotational center', 'Distance to housing from rotational center')

subplot(2,2,3);
plotyy(1:280, dRes, 1:280, dResCumu, 'plot')
legend('dR', 'cumulative dR')
xlabel('Angular position (Deg)');
ylabel('Fluidic resistance (Pa/m^3/s)');

%Increments of height
n = 10000;
hInit = 500/1000;
hFinal = 10/1000;
h = linspace(hInit, hFinal, n);

rValve = sum(dRes);
rTotal = rValve + rTubing;
for z = 1:n
    shuntQ(z) = 1000*9.81*h(z)/rTotal*1000000*60;
end

%P-V curve of whole shunt
subplot(2,2,4);
plot(h, shuntQ);
title('Simulated pressure-flow curve (Whole shunt)');
xlabel('Pressure (mH2O)');
ylabel('Flow rate (ml/min)');

subplot(2,2,2);
plot(1:280, equivDia, 'b-')
hold on
plot(1:280, minGap, 'r-')
hold on
plot(1:280, touchingDist, 'g-')
legend('equivalent Diameter', 'minGap')
xlabel('Angular position (Deg)');
ylabel('Length (m)');

rValve
shuntQ(1)
Appendix D: Flow & Pressure Results

Shunt flushing without blockages (CCW)

Shunt flushing without blockages (CW)
Appendix D: Flow & Pressure Results

Pressure generated within blocked right proximal catheter

Experimental pressure-flow relationship at 150° (n=5)

Valve setting = 150°
P-Q raw data
Fixed origin linear approximation

Flow rate (ml/min)
Hydrostatic pressure (mmH2O)
Appendix D: Flow & Pressure Results

Experimental pressure-flow relationship at 120° (n=5)

Experimental pressure-flow relationship at 90° (n=5)