An Intelligent Hydrocephalus shunt: a New Concept

Abstract - **Hydrocephalus is currently managed using traditional mechanical shunts. These mechanical shunts have both operational and fundamental issues and shortcomings. A smart patient monitoring and shunting system is desirable for both patient follow-up and drainage of the cerebrospinal fluid in order to combat these shortcomings. This paper presents a conceptual work of a smart shunting system focusing on the hardware development required for such systems. In this work the valve mechanism is put under attention and a design layout is proposed. A Novel drainage valve is presented. The valve utilizes both the passive nature of the classical shunts and the controllable feature of the fully automated one as dynamic simulation shows that both a fully automated valve and a fully mechanical valve have their respective disadvantages.**

Keywords: Actuation, Hydrocephalus, Mechatronic valve, Piezoelectric, Shunt, Ultra-sonic motor

I. Introduction

Hydrocephalus (HC) is defined as the disorder caused by "the dynamic imbalance between the production and absorption of cerebrospinal fluid (CSF) leading to enlarged vortices" [1], or simply as the result from the increased CSF amount in the ventricles caused by disruption in flow, absorption, or formation [2], [3]. Hydrocephalus is managed mainly using CSF shunts. There are two types of valves. The fixed differential pressure valves (DPV) which are the first-generation valves, and the Programmable (adjustable) valves. Both valves operation is based on the pressure difference between the intracranial pressure (ICP) and the drainage site pressure [4], [5]. However, with the adjustable valves there is the option of adjusting opening pressure externally using magnetic devices. It must be noted that once the adjustable valves opening pressure is set, they behave exactly like DPV shunts. These valves have been developed in 1980s and are in use since [6], [7].

There are several drawbacks of the currently used shunting system. (i) It does not take into consideration the changes in the dynamic behaviour of ICP which vary, not only from one patient to another but also for the same patient depending on age, health and other elements [3]–[6]. (ii) Current shunting system tends to encourage the patient shunt dependency to increase with time due to the lack of personalization [3], [7]. (iii) The system lacks proactivity and does not recognize the rise in ICP due to normal events such as coughing and sneezing which leads to unnecessary drainage (i.e. over-drainage). The drained CSF could take hours to be re-produced again [8]. (iv) Furthermore, any shunt malfunctions cannot be detected until they manifest clinically as symptoms. This can be life threating based on the type of malfunction and patient's condition. As a result, the monitoring and follow-up of shunted patients is an essential part of ongoing patient safety. Current statistics indicates that 30%-40% of shunts fail within the first year of use, 50% fail within the first two years, and 90% of them fail after five years [9]–[12]. According to the 2017 UK shunt registry report [13], there was 3000 shunt operations in the UK in that year, 1660 for paediatric patients and 1400 for adults. 66.5% of paediatric operations were for shunt revision as appose to primary first-time installation, while 47% of the adult's operations were for shunt revisions.

Most studies on developing new shunts is focused on the use of membrane as appose to traditional valve techniques such as the ball-in-cone valve [8]–[12]. It is understandable as this shunt type results in a more pressure sensitive valve and a much smaller system. However, these designs still have the characteristics of currently used valves and thus prone to the same issues. There are multiple patented designs of CSF management systems that are targeted to use on smart shunts such as Miethke [14], Bertrand et al. [15], and Ludin and Mauge [16]. This work proposes a layout for a smart shunting system for the management of CSF related to hydrocephalus syndrome in order to combat or minimize the mentioned issues.

II. Method

A. System Overview

The shunting system proposed is a promising method able to address most or all the fundamental issues mentioned earlier. In order to address drainage issue real time ICP data is needed. This is due to the fact that the system is a closed loop system as ICP input is used to make a decision on drainage status. Patient head position and posture is also required to recognize both the effect of the hydrostatic pressure in the proximal catheter and ICP changes. This can be achieved by using ICP pressure sensor and an acceleration sensor (tilt measurement). The two sensors will also be responsible for identifying events that cause ICP spikes (sneezing and coughing). Based on these inputs a decision is made in regard of the opening/closing status of the valve. The data collected from the sensors are stored locally (e.g. body area network) in a mobile phone device, and then is sent to a remote data-base made available to physicians or health practitioners.

The pressure sensor and valve are meant to be implanted. They are connected directly to a microcontroller on a miniature circuit board (PCB). The

PCB communicates with the mobile device through a Bluetooth connection for data storage and patient feedback. The smart device relays data through the internet to the physician and stores it into a secure hospital health data-base. Moreover, physicians are allowed to remotely access the system and to set the opening pressure required for the valve. Fig. 1 presents the entire data flow chart of the proposed system

B. Mechatronic Valve

Currently, the valve design is the component lacking major development. It is the core of the shunting system and its design will affect the specifications of the other components. Following section cover valve dynamics affected by ICP modelled signal and results of simulated system.

i. Valve Dynamics

To provide an appropriate design concept of the valve a better understanding of how standard valves and fully automated closed loop valves manage ICP and their operation is presented here.

Anthony Marmarou theory was the first to address all components (CSF production, absorption, circulation, and storage) with in its structure [17], [18]. He used an electrical circuit model to showcase CSF circulation. The current widely used assumption is that the space in the skull can be addressed as a closed cavity. The volume inside is divided into three components. The blood, tissue, and CSF volume. From this assumption a set of mathematical models [18]–[25] are used to model ICP. Mathematical representation of different valves types is also used. Equations for both standard and automated valve are as follow:

$$\dot{V}_{drain}(t) = \begin{cases} 0 & , P_{valve} < OP \\ C_s * (P_{valve}(t) - OP), & P_{valve} \geq OP \end{cases} \quad \text{eq 1}$$

$$\dot{V}_{drain}(t) = \begin{cases} 0 & , ICP < LL \\ C_a * (ICP(t) - UL) & , ICP > UL \\ \dot{V}_{drain}(t-1) & , otherwise \end{cases} \quad \text{eq 2}$$

Where $\dot{V}_{drain}$ is the drained CSF flow rate. P_{valve} is the pressure acting on the gate of the valve. ICP is the intracranial pressure. UL & LL are the upper and lower limits of ICP. C_s & C_a are constants representing the standard and automated valve flow resistance.

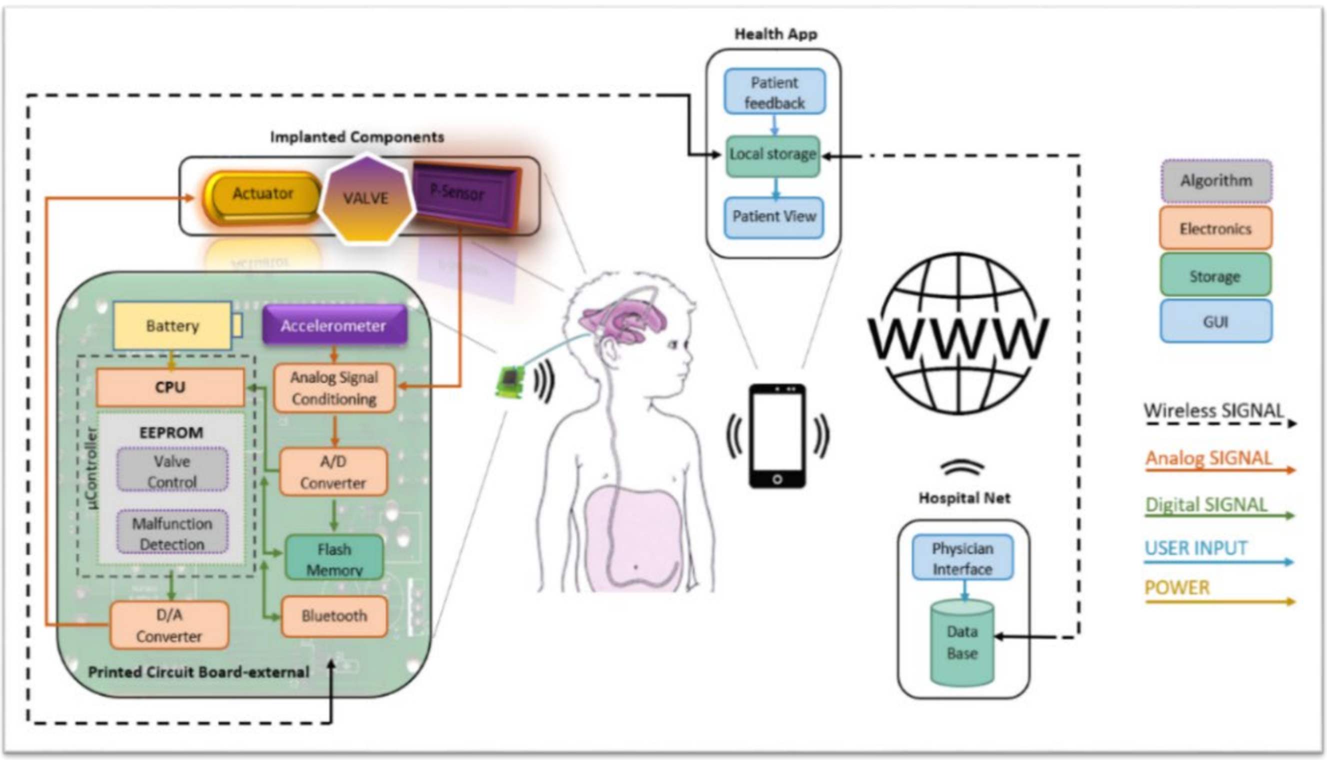

Fig. 1. Flow chart and component of the smart shunt. It comprises of 4 major components. The printed circuit board, the implanted valve, smart device, and the data base on the physician end.

III. Results & Discussion

The numerical simulation was performed by Simulink™ to create the ICP model and implement the model for both the standard and automated valve. The simulation ran for 15 seconds. This low time period is a result of simulating arterial blood pressure (ABP) at a fine time step of 0.001 s. ABP is one of the main components of the ICP signal. This time step yielded a more accurate ABP sinusoidal wave as shown in Fig. 2b and hence, a more accurate ICP signal.

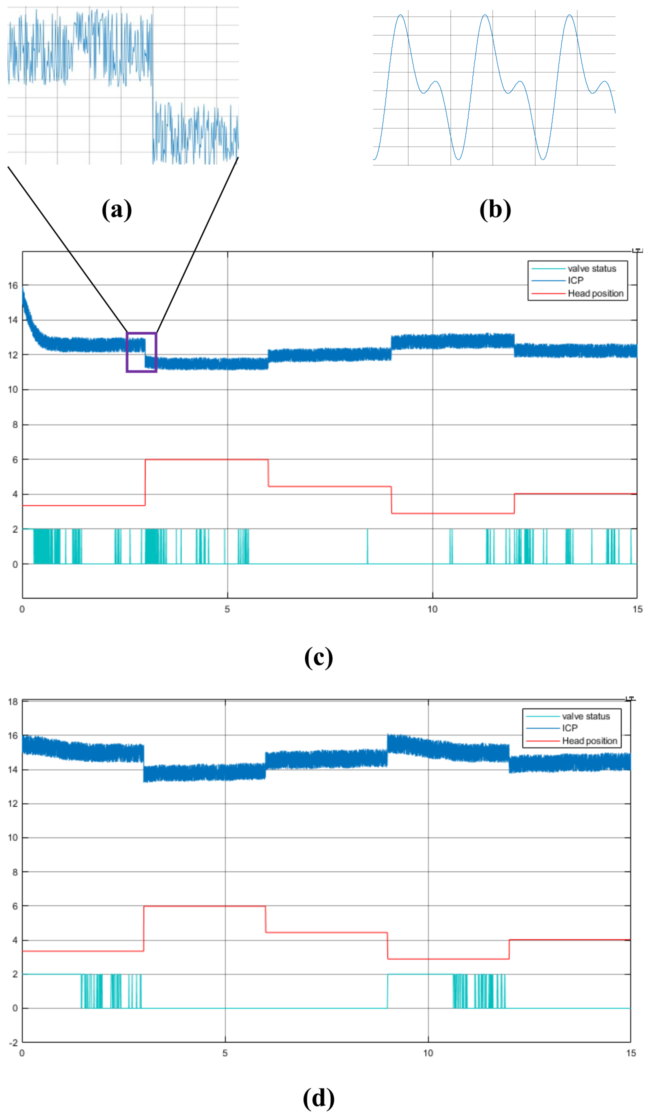

Fig. 2. ICP shunting simulations. (a) Zoomed in version of the overall generated ICP signal. (b) The generated ABP signal at a time step of 0.001s. (c) Classical mechanicl shunt ICP management. (d) Fully automated shunt ICP manaagment.

The models took into consideration the effect of the proximal catheter hydrostatic pressure and the changes in ICP level due to changes in head inclinations. Fig. 2c shows how a normal mechanical shunt handle ICP. The shunt was set to keep ICP below 15 mmHg. It can be seen that the shunt is keeping the ICP much below the wanted level. This is due to the hydrostatic pressure and sudden changes in ICP due to head inclinations. On the other hand, the automated shunt in Fig. 2d was set up to keep ICP between a LL of 14.5 and UL of 15.5 mmHg. The shunt is managing to keep pressure within those limits. However, it is not keeping ICP as smooth as the standard valve. This can be sorted by using a smaller LL and UL limits. Although, this leads to an increased valve operation levels that can be problematic in a system that run on a limited power source. To summarize, the standard valve has a more active operation pattern than the automated valve. However, the automated valve is not affected by the hydrostatic pressure and other events that affect ICP level. From the simulation results it is clear that a merge between the active response of the standard valve and the controllability of the automated valve is the most valuable option.

Three key factors are put in place for the selection of the valve layout and components. The first one is size and compactness. This is simply a space issue as the valve needs to be as tiny as possible as it is implanted under the skin in the area above the ear. The valve also needs to be designed in a way that all components can be in a single housing for compactness. The second factor is component suitability. Above all this relates to materials bio-compatibility. Most materials can cause magnetic interference with MRI machines. Other issues regarding patient inconvenience such as noise (i.e. from friction) as the device is in the patient head. Third factor is power consumption as the valve is meant to be a long-term management system. Therefore, it is important to keep power draw at a minimum.

The vale has two main components addressed here. The fluid diversion mechanism and the actuator. Options viable for the actuation method include magnetic actuation or the piezo actuation. Magnetic actuation is not considered due to the fact that it can cause magnetic interference with MRI machines. For the piezoelectric actuation, a feasible and sophisticated choice is to integrate ultrasonic elements as it can operate with 3-5 V levels. Usually, other forms of piezoelectric actuators have a high voltage demand due to the fact they harness stress directly which require voltages up to 60V. The ultrasonic elements harness vibration from deformation thus requiring much less power. Other advantages include MRI-compatibility, reliability, self-locking features, and high stepping definition and accuracy [26]–[30].

Regarding the fluid diversion mechanism, options include silicon membrane valves – also known as Pneumatic - or elastomers to obstruct and control the flow. They are ideal for controlling flow for small channels [31]. The issue is that these valves are usually actuated through either a magnetic manner or through stress harnessing of piezo material.

The conceptual layout defined in this study is found to possess the utmost advantages based on the available options and is shown in Fig. 3 below.

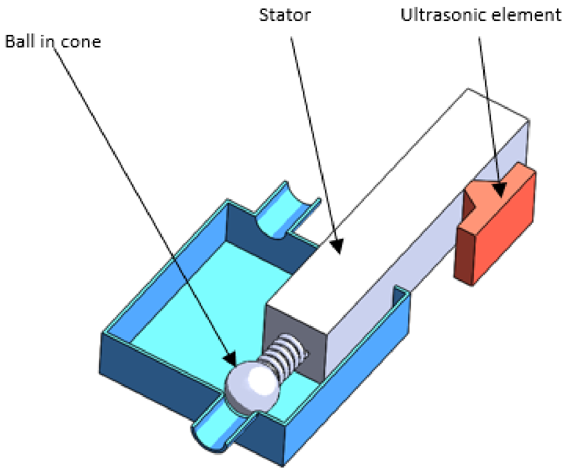

Fig. 3. Proposed mechatronic valve design layout. Consists of an ultrasonic element supplying movment to preloaded stator which control the ball in cone mechanism.

This design utilizes the ultrasonic element to move a stator which is linked to a spring. The ball and spring system act as a conventional mechanical valve requiring no external power and actively managing ICP. The opening pressure of the valve is controlled through controlling the stator which acts upon the spring length and therefore its tension/stiffness. This combination embraces the advantages of both a mechanical valve and a fully automated valve. Most important feature of this system design and layout is that it can continue to function safely and smoothly in case of valve electronic side failures. Thus, in case of electronic failures, the system will just start behaving as a mechanical fixed valve with an opening pressure set by the last working point of the ultrasonic element.

IV. Conclusion

Although the notion of smart shunting is not a new concept, attention to research and innovation around the topic has been mostly lacking. Researchers focused mainly on the conceptual level and algorithms, so far. This is mainly as a result of the small market of HC shunts compared with other neurosurgical devices. This can be clearly seen in the case of ICP sensors as great attention has been given to them. This is because ICP monitoring is necessary for head trauma, intracranial haemorrhage, sub-arachnoid haemorrhage from ruptured brain aneurysm, intracranial tumours and not just of importance for hydrocephalus patients.

The base layout for the proposed valve consists of a ball in a cone system controlled by an ultrasonic motor. The concept is considered feasible with minimum moving parts. Future work will focus on further detailed design, development, and prototyping of the mechatronic valve. It is an essential component that dictates the requirements of most of the other components on the smart shunt.

References:

[1] V. Leinonen, R. Vanninen, and T. Rauramaa, “Cerebrospinal Fluid Circulation and Hydrocephalus,” in *Handbook of Clinical Neurology*, 3rd ed., vol. 145, Elsevier B.V., 2018, pp. 39–50.

[2] A. K. Filis, K. Aghayev, and F. D. Vrionis, “Cerebrospinal Fluid and Hydrocephalus: Physiology, Diagnosis, and Treatment,” *Cancer Control*, vol. 24, no. 1, pp. 6–8, 2017.

[3] I. K. Pople, “Hydrocephalus and Shunts: What The Neurologist Should know,” *J. Neurol. Neurosurg. Psychiatry*, vol. 2, no. 3, pp. 17–22, 2002.

[4] A. Chabrerie and P. M. Black, “Ventricular Shunts,” *J. Intensive Care Med.*, vol. 17, no. 5, pp. 218–229, 2002.

[5] M. Ziebell, J. Wetterslev, M. Tisell, C. Gluud, and M. Juhler, “Flow-regulated Versus Differential Pressure-regulated Shunt Valves for Adult Patients with Normal Pressure Hydrocephalus,” *Cochrane Database Syst. Rev.*, no. 5, 2013.

[6] U. W. Thomale, A. F. Gebert, H. Haberl, and M. Schulz, “Shunt Survival Rates by Using The Adjustable Differential Pressure Valve Combined with a Gravitational Unit (proGAV) in Pediatric Neurosurgery,” *Child’s Nerv. Syst.*, vol. 29, no. 3, pp. 425–431, 2013.

[7] H. Xu, Z. X. Wang, F. Liu, G. W. Tan, H. W. Zhu, and D. H. Chen, “Programmable Shunt Valves for The Treatment of Hydrocephalus: A Systematic Review,” *Eur. J. Eur. Paediatr. Neurol.*, vol. 17, no. 5, pp. 454–461, 2013.

[8] J. Oh, G. Kim, F. Kralick, and H. Noh, “Design and Fabrication of a PDMS/Parylene Microvalve for The Treatment of Hydrocephalus,” *J. Microelectromechanical Syst.*, vol. 20, no. 4, pp. 811–818, 2011.

[9] S. Chung, J. K. Kim, K. C. Wang, D. C. Han, and J. K. Chang, “Development of MEMS-based Cerebrospinal Fluid Shunt System,” *Biomed. Microdevices*, vol. 5, no. 4, pp. 311–321, 2003.

[10] S. B. Johansson, A. Eklund, J. Malm, G. Stemme, and N. Roxhed, “A MEMS-based Passive Hydrocephalus Shunt for Body Position Controlled Intracranial Pressure Regulation,” *Biomed. Microdevices*, vol. 16, no. 4, pp. 529–536, 2014.

[11] E. Chappel, “Design and Characterization of a Passive Flow Control Valve Dedicated to The Hydrocephalus Treatment,” *Cogent Eng.*, vol. 3, no. 1, pp. 1–13, 2016.

[12] H. N. Schwerdt, R. E. Bristol, and J. Chae, “Miniaturized Passive Hydrogel Check Valve for Hydrocephalus Treatment,” *IEEE Trans. Biomed. Eng.*, vol. 61, no. 3, pp. 814–820, 2014.

[13] J. Pickard, H. Richards, H. Seeley, R. F. Mendez, and A. Joannides, “UK Shunt Registry Report,” 2017.

[14] C. Miethke, “Hydrocephalus Valve,” U.S. Patent US6926691, 2005.

[15] W. J. Bertrand, D. J. Harper, L. C. Speckman, A. R. Kiehl, and R. D. Scheer, “Implantable Cerebral Spinal Fluid Drainage System,” U.S. Patent US8292856B2, 2012.

[16] L. Ludin and C. Mauge, “Programmable Shunt with Electromechanical Valve Actuator,” U.S. Patent US8123714B2, 2012.

[17] M. Czosnyka, Z. Czosnyka, K. . Agarwal-Harding, and J. . Pickard, “Modeling of CSF Dynamics: Legacy of Professor Anthony Marmarou,” *Acta Neurochir. Suppl.*, vol. 113, pp. 9–14, 2012.

[18] M. Czosnyka, Z. Czosnyka, S. Momjian, and J. D. Pickard, “Cerebrospinal Fluid Dynamics,” *Physiol. Meas.*, vol. 25, no. 5, pp. 51–76, 2004.

[19] S. Jetzki, M. Kiefer, M. Walter, and S. Leonhardt, “Concepts for a Mechatronic Device to Control Intracranial Pressure,” *IFAC Proc. Vol.*, vol. 39, no. 16, pp. 25–29, 2006.

[20] M. Walter, S. Jetzki, and S. Leonhardt, “A Model for Intracranial Hydrodynamics,” in *Engineering in Medicine and Biology 27th Annual Conference*, 2006, pp. 5603–5606.

[21] D. Schley, J. Billingham, and R. . Marchbanks, “A Model of in-vivo Hydrocephalus Shunt Dynamics for Blockage and Performance Diagnostics,” *Math. Med. Biol. A J. IMA*, vol. 21, no. 4, pp. 347–368, 2004.

[22] W. Wakeland and B. Goldstein, “A Computer Model of Intracranial Pressure Dynamics During Traumatic Brain Injury That Explicitly Models Fluid Flows and Volumes,” *Acta neurochirurgica. Supplement*, pp. 321–326, 2005.

[23] N. Al-Zubi, “Personalised Shunt Optimisation for The Management and Treatment of Hydrocephalus,” University of Liverpool, 2011.

[24] S. Anderson, “Modeling Changes in Brain Pressures , Volumes , and Cerebral Capillary Fluid Exchange : Hydrocephalus,” 2004.

[25] M. Ursino, “A Mathematical Study of Human Intracranial Hydrodynamics Part 1-The Cerebrospinal Fluid Pulse Pressure,” *Ann. Biomed. Eng.*, vol. 16, no. 4, pp. 379–401, 1988.

[26] S. Szczesny, S. Jetzki, and S. Leonhardt, “Review of current actuator suitability for use in medical implants,” in *2006 International Conference of the IEEE Engineering in Medicine and Biology - Proceedings*, 2006, pp. 5956–5959.

[27] K. Spanner and B. Koc, “Piezoelectric Motors, an Overview,” *Actuators*, vol. 5, no. 1, p. 18, 2016.

[28] H. Marth and B. Lula, “Advancements in linear piezoelectric actuator mechanisms,” in *Proc. SPIE 7424, Advances in Optomechanics*, 2009, p. 12.

[29] K. Uchino, “The Development of Piezoelectric Materials and the New Perspective,” in *Advanced Piezoelectric Materials*, 2nd ed., Elsevier, 2010, pp. 1–85.

[30] K. Uchino, “Piezoelectric Ceramics,” in *Handbook of Advanced Ceramics*, Elsevier, 2003, pp. 107–159.

[31] W. . Kwang and H. . Chong, “A review of microvalves,” *J. Micromechanics Microengineering*, vol. 16, no. 5, pp. 13–39, 2006.