



Proposed Method for Hydrocephalus Shunt Removal Based on Mechatronic Shunting System

Author

Abdelrahman A. Alkharabsheh

Computer Eng. Dept, Faculty of Engineering and Computer, Qassim Private Colleges
Alqassim, Kingdom of Saudi Arabia

Email: abdkr2011@gmail.com

Abstract

Hydrocephalus is a neurological disorder whereby the cerebrospinal fluid (CSF) surrounding the brain builds up, causing severe pain and swelling of the head. This is particularly prevalent in infants, and is becoming more common. Shunts were used for decades to treat hydrocephalus patients, where mechanical valves were the popular type for draining the CSF. The problem is these valves have serious drawbacks e.g. overflow, low long-term accuracy, drift, low durability.

The ever-lasting dream of a fully shunted hydrocephalus patient is to (re)gain shunt independence and to be shunt-free. While this may have been only a dream in the past, recent advances have made this a realistic prospect for some. Clinical trials have illustrated that (re)activation of natural drainage and adapting the patient to abnormal ICP levels is achievable.

In this paper, a new technique is introduced to determine the actual shunt dependence and then singling out shunt independence in an attempt of progressively shunt removing thus minimising the risks. In addition, three novel enhancements are investigated to actively establish shunt independence (controlled arrest of hydrocephalus). The mechatronic shunting system would ease clinician and researchers concerns regarding shunt removal since it would adopt an algorithm that would personalise the weaning plan to the individual patient's needs and response.

Keywords: *Hydrocephalus, Shunt Removal, Mecharonic Shunt, Shunt Weaning, CSF.*

1. Introduction

Shunt designers modified shunt goals to have the option of re-establishing shunt independence step by step. Especially that most patient seems to be only partially shunt dependent which even allows the eventual removal of the shunt. This means that the statement of Hemmer "once a shunt, always a shunt" may no longer be true, as the next generation of shunts should be able to achieve a controlled arrest of hydrocephalus in the long run.

The possibility of shunt removal for hydrocephalus

patients has been controversial. In the 80s and 90s, shunt removal in hydrocephalus patients has been intensively argued and investigated in literature. Nowadays this interest has faded even though the valve technology has developed significantly since then So-called "weaning" has been considered in the literature in two different aspects.

First one was passive, in which all trials were directed towards singling out shunt independence that has been naturally and spontaneously developed by the patient for different reasons (e.g. premature babies' natural

drainage developing with time). Thus the patient no longer needs a shunt. In this case, the researchers' and clinicians' focus was on developing methods to identify such shunt independence to help in making a decision regarding shunt removal. In general, methods used were based simply on detecting the non-functionality of the valve that might have occurred for various reasons such as blockage, disconnection or mechanical faults. As patients in these cases do not tend to suffer from any symptoms, they do not complain, making the identification of such cases difficult. In the other aspect, only few researchers^[1] handled shunt removal and shunt dependence actively, i.e. the controlled arrest of hydrocephalus (shunt weaning). This is defined as shunt removal after subsequent steps of gradual brain adaptation to high intracranial pressure (ICP) that will not only normalise the ventricular size but also activates the regular circulation of cerebrospinal fluid (CSF).

2. Current Methodologies for Shunt Removal

Nowadays, some issues are considered before removal of the shunt such as hydrocephalus type (e.g. communicating and non-communicating) and status e.g. (not present anymore, arrested, compensated, uncompensated), shunt status (e.g. functional, non-functional) and the risks and benefits of shunt removal^[2]. Current methodologies for shunt removal can be grouped into singling out shunt independence and shunt weaning.

2.1 Singling Out Shunt Independence

Special tests have been used to measure CSF flow in an attempt to detect valve functionality through measuring shunt dependent flow. For example, thermometric measurements, i.e. heating/cooling of the flowing CSF^[3] or valvography, i.e. injection of radiopaque dye into shunt^[4]. These methods are considered unreliable and impractical in the clinical settings. Others^[5] have used implantable devices to measure CSF flow, but it is difficult to draw conclusion when the test shows no flow whether flow is so low that it cannot be detected or

there is no flow at all due to non-functionality/idleness of the valve. In addition, some methods i.e. ^[6] for singling out shunt dependence are based on determining outflow resistance of the natural drainage system. These tests were extremely invasive and involved temporal occlusion of the valve, placement of an ICP monitor and infusion of fluid into the subarachnoid or ventricular space under general endotracheal anesthesia.

2.2 Shunt Weaning

Controlled arrest of hydrocephalus is performed by shunt removal after subsequent steps of gradual brain adaptation to high intravenous pressure that is expected not only to normalise the ventricular size but also activate the regular circulation of CSF^[7]. Takahashi^[1] attempted to increase the pressures of adjustable valves stepwise, and managed to remove 59% of shunts out of 114 shunted patients within 2 years. Unfortunately, this study lacks longer observations and sufficient data, although these trials demonstrate that there is an unexhausted potential for controlled arrest of hydrocephalus^[2]. His work illustrated that the success rate of shunt removal becomes significantly higher when programmable valves are used restoring normal CSF circulation by gradually increasing the pressure. He also concluded that it is possible to remove the shunt systems in 50% or more of pediatric hydrocephalus cases in which programmable valves were used^[1]. According to Takahashi's methodology, if the patient did not develop symptoms of intracranial hypertension and there was no significant ventricular enlargement, the valve pressure was quickly increased over months to 14.7 mmHg (200 mm H₂O) and then removed. Patients who developed intermittent symptoms were weaned more slowly, and if "clear" symptoms did not develop, the shunt was removed. Takahashi's interesting investigation, and some basis for his approach may come from earlier studies in cats suggesting that increasing ICP may open or activate existing CSF absorptive pathways^[8]. However, Whitehead^[2] has raised a question whether shunt removal is ever worth the risk. And he concluded that it is difficult to draw firm

conclusions from Takahashi's work because follow-up is short and ill defined, and objective neuropsychiatric evaluations were not performed^[2].

3. Risks and Benefits

Generally clinicians believe that there are limited clinical situations that would warrant a trial of shunt removal because of the significant risks involved. In addition, considerable literature sources agree that regardless of circumstances removing a shunt from a patient who needs it can lead to subtle intellectual and developmental decline, intracranial pressure increase with irreversible injury to neural tissue and even sudden death^[2]. These concerns are mainly due to the lack of non-invasive means to determine shunt dependence and to monitor intracranial hydrodynamics thus making shunt removal a highly risky proposition that could potentially endanger patient's life.

Removal of the shunt can have psychological benefits for the patient and family. In addition, the patient is no longer threatened by the complications of infection or over drainage. The risk in shunt removal that there is no absolute indication to put a patient through a trial of shunt removal^[2].

4. Progressive Shunt Removal

Invention of mechatronic valve^[9] has inspired the introduction of mechatronic shunting system that autonomously monitors both ICP and shunt itself and responds to patient needs. The mechatronic shunt will decide when to start weaning process based on patient's intracranial hydrodynamics after consulting this decision with a physician. The mechatronic valve is easily opened at any required pressure. The wean threshold (i.e. opening pressure) will be increased in smoother steps thus providing safer shunt weaning process with much less risk than programmable valves, since the patient and the shunt are continuously monitored. In addition, the proposed system will be able to identify any possibility of sudden increase in ICP thus eliminating the risks associated with current wean methodologies. The proposed system will be similar to Logatti and Carteri implantable system^[10], except

that it is implementing an implantable pressure sensor and mechatronic valve. At the same time the system will be following the basics of Takahashi's methodology in achieving controlled arrest of hydrocephalus. The proposed system will have two main tasks; capture the actual shunt dependence and gradually reduce it.

4.1 Capturing the Actual Shunt Dependence

Capturing actual shunt dependence is an important issue in determining whether the patient (still) requires a shunt or not. Especially that in most of the cases, the patient is only partially shunt dependent, varying from 1% to 100%.

Unfortunately, current shunts do not distinguish the patients in this aspect, thus most probable, on the long run; patients are turned to be fully shunt dependent. A scheduled closed loop will be implemented to capture the actual shunt dependence. A schedule will determine the periods of time at which the valve is either closed or operating in closed loop mode. This schedule proposed and tested by^[11] and it satisfies this specific-patient for a reasonable period of time. While the valve is in a closed loop mode, it will only open if the ICP readings are above certain threshold, i.e. the upper normal limit, Thn (10 mmHg). For each hour the percentage of time per drainage at which the valve was open is calculated. Then this value is used in addition to the percentage of time ICP is maintained within normal limits per hour and the rate of change of ICP during closed valve periods, to update the schedule of the closed loop for that hour. Open duration will be decreased till it reaches a point at which the increase in ICP cannot be handled. Furthermore,^[12] proposed an intelligent implantable wireless shunting system for hydrocephalus patients with features that help and play a vital role in capturing shunt dependence.

$$a. \text{ Open Duration per Hour (OD)} = \frac{\text{Actual Open Duration}}{\text{Duration of Closed Loop Mode}} * 100\% \quad (4.1)$$

$$b. \text{ Duration of ICP Normal} = \frac{\text{Duration ICP is Normal}}{\text{One Hour}} * 100\% \quad (4.2)$$

$$c. \text{ Rate of ICP Change (at Close Valve)} = \frac{\Delta ICP}{\text{One Hour}} \quad (4.3)$$

The resultant percentage of open duration will

represent the actual shunt dependence. In the long run, if the open duration is around zero and ICP is still maintained normal, this indicates a possibility of shunt removal. The decision is empowered if the rate of change of ICP at close periods is around zero.

4.2 Reducing the Shunt Dependence

After the actual dependence is captured, an algorithm will reduce the dependence to a level that is accommodated by patient in an attempt of achieving shunt independence. Utilising a mechatronic valve with an implanted pressure sensor will enable fine tuning of the opening valve pressure thus performing the weaning process more smoothly. In contrast to the documented trials, when shunt independence is reached, the mechatronic shunt will not be removed but kept in sleeping mode. The shunt would be only activated as a closed loop system in case of any arising emergency thus avoiding any risk on patient's life. At this stage, the system would noninvasively monitor the activity of the shunt thus warranting the success of prospective shunt removal on the long run. Having such system should give a relatively absolute indication whether to put a patient through a trial of shunt removal.

Three methodologies for controlled arrest of shunting system were investigated and compared. These methodologies are closed-loop timed threshold, schedule with shrinking slots and scheduled closed-loop. Each of these methodologies will gradually attempt in its way to personalise the reduction of shunt dependence while considering patient response based on evaluation measures such as rate of ICP increase, the figure of merit, average ICP and mean absolute deviation. Implementing such methodologies would avoid subjecting the patient to any shunt removal disappointments and avoid endangering his/her life.

4.3 Characteristics of Proposed Shunt

The proposed system will reduce the risks associated with current shunt removal, due to its ability to give relatively absolute indication

whether to remove the shunt or not. In addition, it will be able to monitor the ICP and the shunt itself for the patient before, during and after weaning process. Thus most issues (aspects) that usually arise when removing a shunt would either answered or does not apply. As a result of this, long follow-up periods will be provided. Especially that the shunt will not be removed, it will be just monitoring ICP and valve is kept in sleeping mode for a reasonable period of time to be activated in case of emergency. It also could have the option of performing psychiatric test for the patient that is embedded in the patient device. Mechatronic shunt, in contrast to current weaning methodologies will aim to single out the functionality and idleness of the valve instead of just its functionality. Finally, the valve does not need to be changed while increasing the open pressure threshold during weaning process, as it is the case in the programmable valves, since mechatronic valve can be opened at any pressure.

5. Patient Types

Previous shunt removal studies (e.g. [1],[10]) revealed that intracranial hydrodynamics respond to temporarily occluded valves in different ways. These can be grouped into four types, as shown in Figure 1.

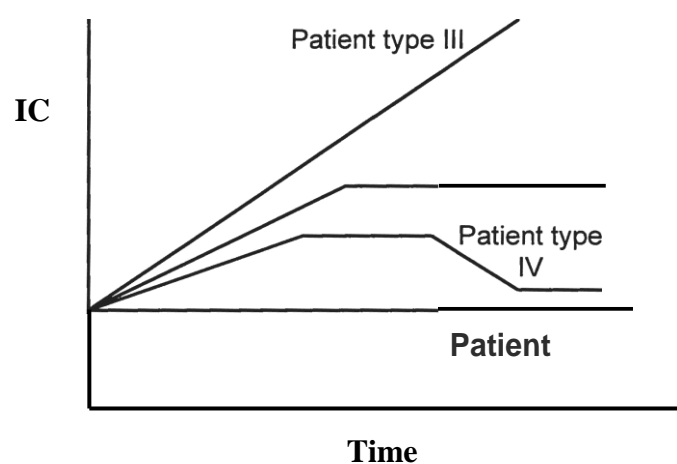


Fig.1 ICP Response upon Valve Occlusion for the Different Patient Types

Patient type I: ICP is within the normal range even though valve is occluded. From this it can be interfered that this type of patient is no

longer needs the shunt. In other words, his/her natural drainage has been activated spontaneously. According to Takahashi's trial^[1], such type can be weaned step by step without being accompanied by any adverse symptoms. Developing such type of patients is the objective of any weaning process.

Patient type II: Intracranial hydrodynamics proportionally increase with time then stabilise at certain ICP level which is above the upper limit of the normal ICP range. Such type is usually accompanied with intermittent symptoms and ventricle size increases to certain level at which it stabilises.

It can be inferred that such patient is partially shunt dependant and according to Takahashi^[1] there is an opportunity to wean such patient but it takes longer time and higher valve opening pressures, i.e. greater risk.

Patient type III: In this type, ICP keeps increasing when valve is occluded and might reach high levels at different rates, thus endangering patient's life.

The ability to identify such patient is the objective of any shunt weaning or removal process, in order to avoid any risk on the patient and try intelligently maneuvering the ICP to convert such patient into type II.

Patient type IV: This represents Takahashi's patient that adapt and respond to the weaning treatment by reactivating the natural drainage system, thus maintaining ICP within acceptable normal limits after being abnormal.

Ability to identify patients of type III, maneuver and adapt their hydrodynamics to be of type II is an objective of weaning process in order to avoid any risk. These types were simulated by^[11] using Simulink Model, and used as a testing environment for the proposed weaning techniques.

6. Modelling the Change in Intracranial Hydrodynamics Parameters

Modelling the effect of weaning process on the intracranial hydrodynamics (i. e. the natural

drainage system) parameters is essential in improving the weaning methodologies. An empirical formula was derived to relate the change in natural absorption resistance with the accumulated CSF volume through the natural drainage system which has a direct relation with intracranial pressure. Assuming that the natural absorption resistance (R) varies exponentially with the weaning duration, as shown in Figure 2(a). At starting time of weaning (i.e. $t=0$), the natural absorption resistance has the value of R_H which is R in hydrocephalus case. On the other hand, t_r is the expected period (in months) for a weaning process to be accomplished, at which R has the value of R_N (i.e. R in normal case). Thus this relation can be presented as follows,

$$R = a \cdot \exp(-bt) \quad (6.1)$$

$$a = R_H \quad (6.1.1)$$

$$b = -\frac{1}{t_r} * \ln \frac{R_N}{R_H} \quad (6.1.2)$$

The values of R_H , R_N , and t_r were estimated based on the outcomes of Takahashi's trial. Then the relation between the natural absorption flow (F) with weaning period was drawn (as shown in Figure 6.2(b)) based on the following equation,

$$F = \frac{ICP}{R} \quad (6.2)$$

The integration of this equation gives the natural absorption volume (V) that is accumulated with the weaning time, as shown in Figure 6.2(c). From Equations 6.4.6.1 and 6.2, the relation between R and V can be projected as shown in Figure 6.2(d). These equations were modelled using Simulink™. As a result of the numerical simulations and by using the minimum square error, a best fit model is roughly estimated as follows,

$$R = 300 \cdot \exp(-5 * 10^{-6} V) \quad (6.3)$$

This model is simulated using Simulink™ thus the effect of different shunting methodologies on such type of patient can investigated and improved.

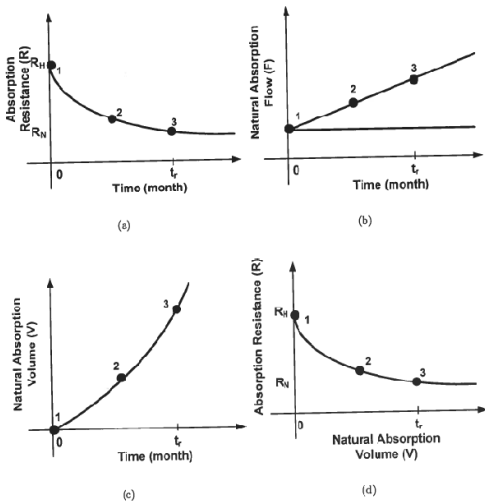


Fig.2 Modelling the Change in the Natural Drainage parameters. (a) Natural absorption resistance versus wean duration, (b) Natural drainage flow versus wean duration, (c) Natural drainage volume versus wean duration, and (d) Natural absorption resistance versus Natural drainage volume.

7. Proposed Methodologies

In this section the terms normal thresholds (Th_n) and weaning thresholds (Th_w) will be used to represent the upper normal ICP limit (10 mmHg) and a variable ICP value at which valve should open (0, 10 . . . 40 mmHg), respectively. The following three methodologies were investigated:

Closed loop timed threshold: This methodology is implemented in real time. A block diagram of this methodology is shown in Figure 6.3. Here a timer is used where it is turned on when ICP crosses the normal threshold. On the other hand it is turned off when ICP falls within normal limits. The wean threshold is increased with time (0, 10, 20, . . . , 40 mmHg). According to this methodology the valve will open either if ICP crosses the wean threshold (Th_w), or the timer duration elapsed. And the valve will close when ICP is below the normal threshold (Th_n).

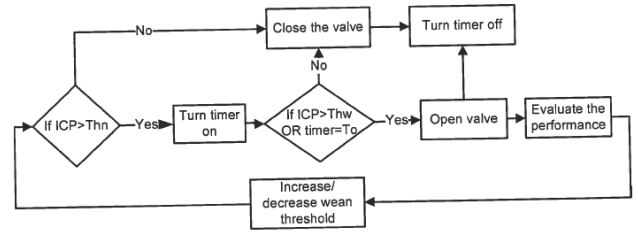


Fig. 3 An illustration of closed loop timed threshold technique.

Scheduled closed loop: In this methodology, a schedule will be used to determine whether to close the valve or open it in closed loop mode. The weaning threshold (Th_w) will be active only when the closed loop mode is turned on. This threshold will vary with time according to the influence of the treatment on the patient. Figure 4 illustrates this methodology.

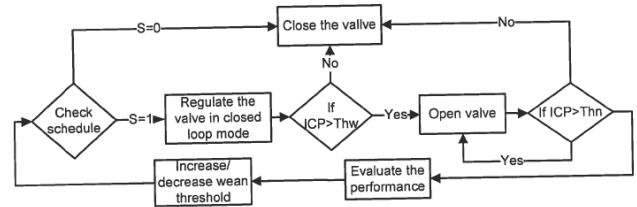


Fig. 4 Illustration of Scheduled Closed Loop Technique.

Schedule with shrinking slots: This methodology will be implemented off- line, i. e. the changes will implement over days not instantaneous. In this methodology the open duration will be reduced for each hour subset individually. The hour subset will be chosen based on the minimum average ICP per hour. This methodology is illustrated in Figure 6.5. This step is repeated, i.e. open duration is reduced, till either reaching a zero open duration or there is a negative dramatic influence on the intracranial hydrodynamics.

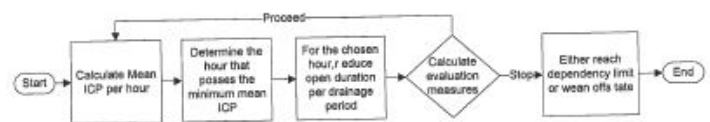


Fig. 5 Illustration of Schedule with Shrinking Slots Technique.


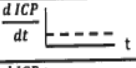
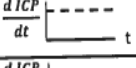
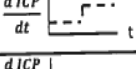
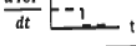
8. Performance Measures

Three performance measures were used to hourly evaluate the effect of each weaning step,

- Rate of ICP change in closed-valve periods

$$\frac{dICP}{dt} = (\text{mean of } ICP_{end} - \text{mean of } ICP_{start}) / (\text{one hour}(\text{min})) \quad (8.1)$$

Table 6.1: Decision Criterion Based on Performance Measures.

$\frac{dICP}{dt}$ per hour		Average ICP per hour			
		$\leq Th_w$		$\geq Th_w$	
Zero		A	MAD	B	MAD
Constant (low)		C	MAD	D	MAD
Constant (high)		E	MAD	F	MAD
Two constants		G	MAD	H	MAD
Constant & zero		I	MAD	J	MAD

Case G and H: Natural drainage is working at its maximum power, but this is not enough to handle the excess of CSF. Thus ICP is increasing at new rate. Wean step should be re-evaluated.

Case I: ICP was increasing, and then kept at constant low level. Wean step has succeeded in reducing shunt dependence by reactivating natural drainage.

Case J: ICP was increasing, and then kept at constant high level. Wean step has succeeded partially in reducing shunt dependence by reactivating natural drainage. But further steps needed to reduce ICP to be within normal range.

9. Results and Discussion

A mathematical model was utilised to simulate the intracranial hydrodynamics in three types of a hydrocephalus patient that are shunted with a mechatronic shunt. Each of the above methodologies was implemented on every patient type and the corresponding intracranial hydrodynamics were analysed. Performance measures would be used to interpret the best methodology that suits each patient case. Figure 6 show a sample report that is generated after

each weaning step. This report contains a summary of the evaluation parameters.

Weaning Performance Measures Results			
Patient Type: II			
Weaning Technique: Closed Loop Timed Threshold			
Timer Duration = 5 min			
Normal Threshold = 10 mmHg			
Closing Threshold = 10 mmHg			
Weaning Threshold = 15 mmHg			
Hourly parameters	Hours		
	1	2	3
ICPavg (mmHg)	8.01	8.02	8.01
ICPavg at start(mmHg)	8.01	8.02	8.02
ICPavg at end(mmHg)	8.01	8.02	8.01
Rate of ICP change (mmHg/min)	0.0001	0.0000	-0.0000
MADavg at start(mmHg)	1.41	1.41	1.42
MADavg at end(mmHg)	1.41	1.41	1.41
MADavg (mmHg)	1.41	1.41	1.41
Rate of MAD change (mmHg/min)	0.0000	-0.0000	-0.0000
No. of drainage periods	60.00	62.00	64.00
Summation of drainage periods (min)	10.00	10.33	10.67
FoM1	1.2122	1.2120	1.2122
FoM2	1.0000	1.0000	1.0000
FoM3	1.0000	1.0000	1.0000
FoM4	0.8333	0.8278	0.8222
FoM5	-0.0000	-0.0000	-0.0000
FoM6	0.8333	0.8278	0.8222
FoMavg	0.8131	0.8113	0.8094
Effective open duration (min)	0.8333	0.8011	0.7708
False open	1.0000	1.0000	1.0000
False close	0.0000	0.0000	0.0000

Fig. 6 Sample Report Consisting Summary of Evaluation Parameters for Closed Loop Technique.

Evaluation parameters were calculated after every weaning step. They were able to give a good indication whether the patient is shunt dependent or not, *i.e.* Patient Type I, thus helping to decide whether patient needs shunt for that specific hour/day. And in case of deciding shunt removal on the long run, it helps in providing answers to the aspects commonly considered at the time of removal. In addition, these parameters were able to identify patient type III thus avoiding any unexpected consequences that might result due to weaning. Figure 6.7 shows a sample of the calculated evaluation measures for different modelled patients and weaning methodologies. Figure 6.8 presents a sample of ICP responses for patient type II before and after implementing closed loop timed threshold, scheduled closed loop and schedule with shrinking slots, respectively.

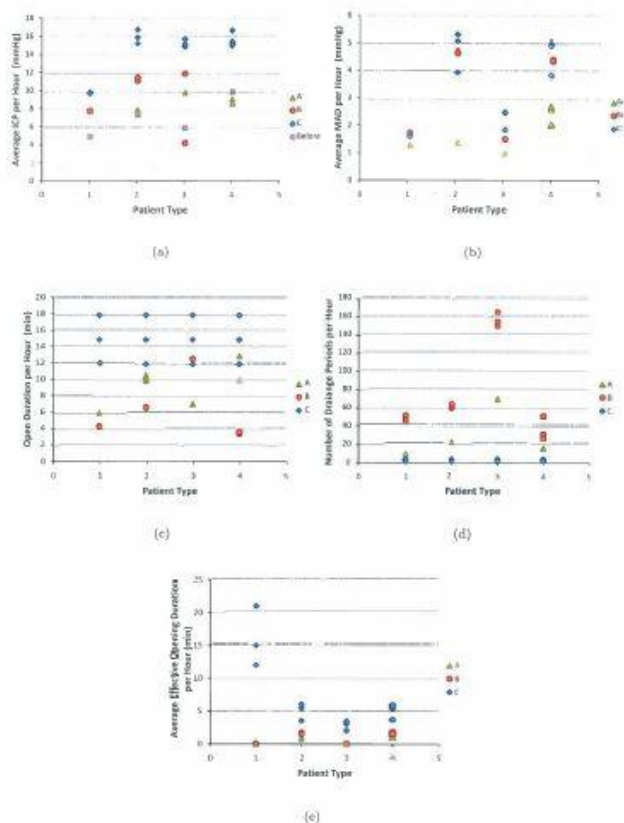


Fig.7 Sample of the Calculated Evaluation Measures per hour for Different Modelled Patients and Weaning Methodologies; (a) Mean ICP, (b) Mean MAD (c) Open duration, (d) Xo. of drainage periods, and (e) Effective open duration.

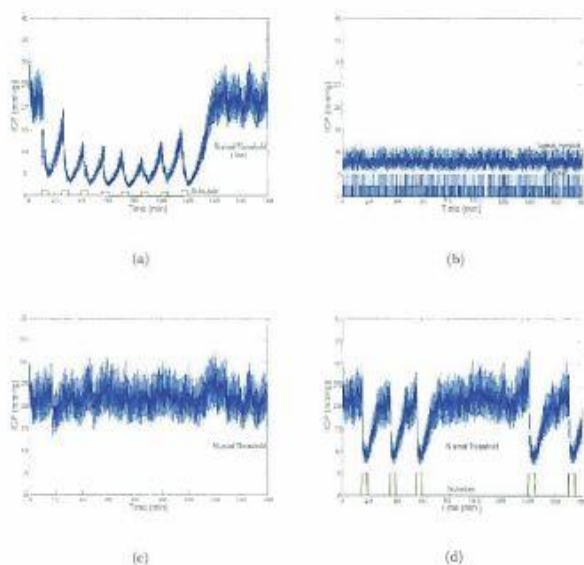


Fig.8 Modelled ICP Traces for Patient type II; (a) Before weaning, (b) After implementing one step of closed loop timed threshold, (c) Scheduled closed loop, and (d) Schedule with shrinking slots techniques.

Simulation results for all patient types showed that closed loop timed threshold was more successful in optimising the opening of the valve than the scheduled closed loop. In other words, it only opened the valve when there was real need for that, not with the fluctuation of ICP as the case in scheduled closed loop. Thus reducing power consumption and wearing rate. On other hand, the open duration was relatively longer since the scheduled closed loop only opens according to the schedule. These two methodologies can be effective in adapting patient’s brain gradually to moderate pressure as intermediate step before reducing opening duration (if it was applicable). To gain the advantages of both techniques, they can be merged to have scheduled closed loop timed threshold. Thus the valve will only operate in closed loop mode based on a schedule. During which the valve opens based a timer and threshold.

As for the third technique, schedule with shrinking slots, has proved to be a good way to reduce the opening duration in very small gradual increments that only have minor local effects. As a result reactivating the natural drainage and adapting the brain in smoother way than the current proposed studies. This technique is little more aggressive than above two techniques which are more patients’ ICP driven. Evaluation parameters were calculated after every weaning step. They were able to give a good indication whether the patient is shunt dependent or not, i.e. patient type I, thus helping to decide whether patient needs shunt for that specific hour/day. And in case of deciding shunt removal on the long run, it helps in providing answers to the aspects commonly considered at the time of removal. In addition, these parameters were able to identify patient type III thus avoiding any unexpected sequences that might result due to weaning.

10. Conclusions

Shunted hydrocephalus patients are susceptible to becoming fully shunt dependent in the long run. As a proactive step to preventing such dependence, the actual shunt dependence is here determined thus providing the natural drainage system with only the required amount of assistance.

A scheduled closed loop timed threshold technique has proved (in simulations) to be an effective way in attaining minimum shunt dependence. After which, schedule with shrinking slots can be used to smoothly and gradually attempt to wean the patient. Based on simulation results, these two techniques seems to be suitable for any type of patients.

Utilising the proposed evaluation parameters could help in identifying patient type. As a result, they give an indication whether it is safe to remove the shunt as is the case for Patient Type I or it is of high risk *as* the case for Patient Type III. The outcome of this study could play important role in reducing patient suffer and at the same time reducing if not eliminating the risk of achieving controlled arrest of the shunt using conventional means. Implementing AI methods to arrive at a decision concerning shunt withdrawal/removal when to proceed to the next weaning step and determine its parameters would enhance and automate the weaning methods.

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Authors Profile



Abdelrahman Alkharabsheh, he is currently working as an Assistant Professor in the Department of Computer Engineering, Faculty of Engineering and Computer Science, Qassim Private University. He completed his PhD in Computer Engineering from University of Liverpool in 2010. His research areas include Expert System, Fuzzy Logic, IoT, Multi-agents Systems and Wireless Technology .