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Instantiating a Mechatronic Valve Schedule for a Hydrocephalus Shunt

Lina Momani, Abdel Rahman Alkharabsheh, Nayel Al-Zu'bi and Waleed Al-Nuaimy

Abstract— **Hydrocephalus is caused by blockage or reabsorption difficulty that upsets the natural balance of production and absorption of cerebrospinal fluid in the brain, resulting in a build-up of the fluid in the ventricles of the brain. One of the recent advances in the treatment of hydrocephalus is the invention of a mechatronic valve. The desirability of such valve lies in the potential of having shunt that not only control hydrocephalus but also seeks to treat it. In contrast to current valves, such a valve is regulated based on a time based schedule not on the differential pressure across the valve. Thus the effectiveness of such valve is highly dependant on selecting an appropriate valve schedule that delivers personal dynamic treatment for every individual patient. Providing such a schedule is likely to be one of the obstacles facing the implementation of the mechatronic valve.**

In this paper, an algorithm is proposed to help in developing such a schedule that dynamically change based on the patients' own intracranial pressure data and a novel figure of merit, thus providing the physician with an easy tool that facilitate the use of the mechatronic valve. The algorithm was implemented in $MATLAB^{TM}$ and $Simulink^{TM}$. Real ICP data for three hydrocephalus patients (before shunting) were used to test this algorithm and the resulted schedules along with the resulted intracranial pressure data have illustrated the effectiveness of the algorithm in providing schedule that maintain ICP within the normal limits.

I. Introduction

The brain is surrounded by a fluid called the cerebrospinal fluid (CSF), that protects the brain from physical injury, regulates intracranial pressure, keeps the brain tissue moist and transports the products of metabolism. CSF is continually produced and absorbed by the natural drainage system back into the blood resulting in preserving a constant amount inside the brain.

Hydrocephalus can commonly result when either too much CSF is produced (very rare), or when it is prevented from circulating or being reabsorbed. As in these circumstances CSF is constantly produced but cannot get out, it accumulates and causes raised pressure inside the brain. This can lead to one of the three types of hydrocephalus; communicating, noncommunicating and normal pressure hydrocephalus.

In principle the solution for hydrocephalus inserting a tube into the swollen ventricles and drain off the excess fluid, thereby returning the pressure inside the head to normal again. Nowadays, a mechanical shunt is used to treat hydrocephalus patients. It regulates the CSF flow according to the differential pressure across a mechanical valve. This passive operation causes many problems. Example of their documented drawbacks are overflow, underflow and suitability.

By using a shunt, the hydrocephalus is not "cured", but controlled. Today there are numerous types of shunt but while they all look different they work in a very similar way. None can be said to be significantly better or worse than another, and the shunt is usually chosen by the surgeon on the grounds of experience, cost and personal preference [1].

In 2005, Miethke [2] claimed patent to a hydrocephalus valve with an electric actuating system. This valve would allow improved adaptation to the situation existing in a patient in the case of a hydrocephalus valve [3]. Prudent exploitation of such a mechatronic valve opens the door for different shunting systems to be developed. The use of such a valve in a closed loop shunting system would allow the valve to respond to actual intracranial pressure in the ventricles instead of a pressure at distance from the ventricles (differential pressure across the valve) as the case in current valves. Also the mechatronic valve would add a new option for hydrocephalus shunts that is aiming to treat hydrocephalus not only controlling it. This could be achieved by establishing either a controlled arrest of the shunt dependency or at least reducing the shunt dependency.

This mechatronic valve could be controlled by a time based schedule. Such schedule would incur many disadvantages e.g. overdrainage/underdrainage, if its selection is arbitrary. In order to optimise the usefulness of such a valve, its schedule should be selected in way that delivers a personalised treatment for each patient. Achieving such a goal is not an easy task due to the dynamic behaviour of intracranial pressure that not only varies among patients but also within individual patient with time. There are two extremes for schedule alternatives. One is a dynamic schedule that responds to the instantaneous intracranial pressure which requires an implanted pressure sensor, i.e. closed loop shunting system. The other extreme is a fixed schedule that has a fixed open frequency over 24 hours. This alternative lacks flexibility and ignores the intracranial dynamic behaviour while the first is impractical.

The work in this paper is an intermediate step in developing an intelligent implanted shunting system that would regulate a mechatronic valve by dynamically modifying the valve schedule based on different sensory inputs, and in the long run reduce shunt dependency [4], [5]. In this paper, a schedule structure is proposed that offers a compromise between the two schedule extremes. Thus to facilitate the process of schedule selection and to add some degree of flexibility, a 24-hours schedule, shown in Fig. 1, is divided into 24 one hour subschedules. Each subschedule is identified

L. Momani, A. Alkharabsheh, N. Al-Zu'bi and W. Al-Nuaimy are with the Department of Electrical Engineering and Electronics, University of Liverpool, Brownlow Hill, Liverpool L69 3GJ, UK, {l.momani,a.kharabsheh,nael,wax}@liv.ac.uk

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by three parameters; the targeted hour (hr), open duration (d_{ON}) and closed duration (d_{OFF}) for that specific hour.

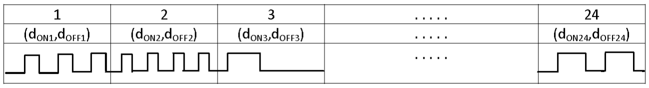


Fig. 1. A 24 hour schedule structure.

II. Initial Schedule Design

The valve schedule can be personalised to the needs of the patient through utilising the patients' intracranial pressure readings whether it was taken by an external or implanted pressure sensor. An algorithm is proposed to derive such a schedule. This scheduling algorithm is intended to facilitate the dynamic modification of a mechatronic valve schedule in order to be responsive to the dynamic intracranial pressure behavior, especially when it is used within an intelligent shunting system [4], [5]. The scheduling algorithm is illustrated in Fig. 2. It derives the open and number of drainage periods for each hour (subschedule) based on the corresponding available pressure data of 24 hours sample. The effect of implementing each subschedule on this specific patient is evaluated through numerical simulations that predict ICP in response to the subschedule. Then a figure of merit (FoM) is used to evaluate the performance of different alternatives. As a result a subschedule is chosen that corresponds to the maximum FoM value. The functions of the components of the algorithm are described in the following sections.

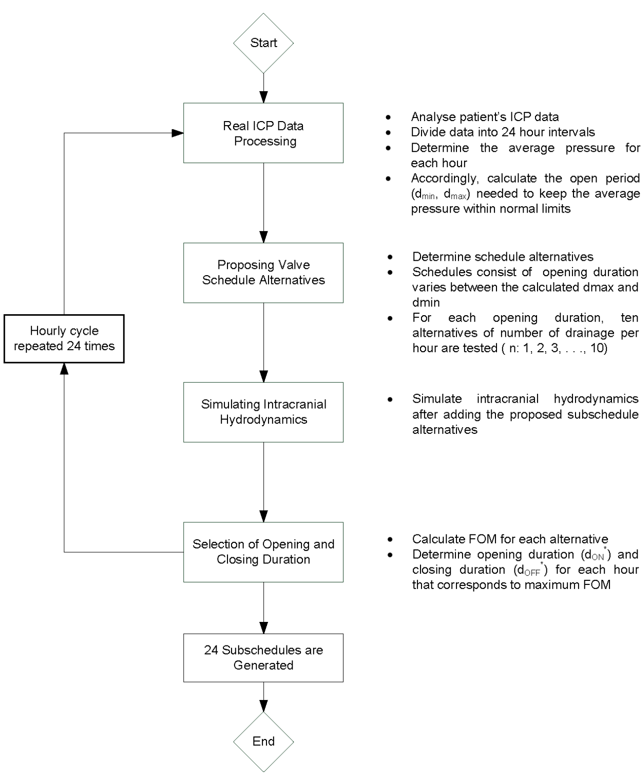


Fig. 2. A general scheduling algorithm.

A. Management of Real ICP Data

A 24-hour ICP trace is collected for the patient as part of the hydrocephalus diagnosis process (i.e. before shunting) and is used to derive a personalised valve schedule for him/her. The objective of this step is to instantiate alternatives for the open durations and number of drainage times based on the available real data. According to the proposed algorithm, this data is filtered to obtain the variation of average ICP with time. Then the data is divided into one hour samples of a total of 24 samples. The average pressure (ICP_{avg}) is then determined for each sample. Based on this pressure, maximum and minimum total opening durations for each hour ($\triangle t_{min}$ and $\triangle t_{max}$) are calculated. These are the intervals the valve needs to be open in order to reduce ICP_{avg} to the upper and lower normal limits, respectively. The rate of ICP changes for the cases of open and closed valve are estimated, whereas the natural increase/decrease is derived form the real ICP data. The rate of ICP drainage ($\frac{\delta ICP}{\delta t}$)(which is pressure dependent) is estimated using numerical simulation for the mechatronic valve. By assuming that the rate of ICP drainage while the valve is open is constant and is not dependent on pressure, the values of $\triangle t_{\mathtt{min}}$ and $\triangle t_{\mathtt{max}}$ can be estimated as follows,

$$\triangle t_{\mathtt{min}} = \frac{ICP_{\mathtt{avg}} - P_{\mathtt{UL}}}{\frac{\delta ICP}{\delta t}} \quad (1)$$

$$\triangle t_{\mathtt{max}} = \frac{ICP_{\mathtt{avg}} - P_{\mathtt{LL}}}{\frac{\delta ICP}{\delta t}} \quad (2)$$

where $\frac{\delta ICP}{\delta t}$ is the drop in ICP with time when the mechatronic valve is opened, and $P_{\mathtt{UL}}$ and $P_{\mathtt{LL}}$ are the upper and lower normal limits for ICP, respectively. Thus the total open duration $d_{\mathtt{tot}}$ for the hour under investigation could take any value between $\triangle t_{\mathtt{min}}$ and $\triangle t_{\mathtt{max}}$ to ensure that the resulting ICP would be maintained between the normal limits, i.e. no over/under-drainage occurs.

For each alternative of the total open duration, ten alternatives of number of drainage periods per hour n are tested, where the open duration (in minutes) for each period is calculated as follows, then it is rounded to the closet integer,

$$d_{ON} = \frac{d_{\mathtt{tot}}}{n}, n = 1, 2, .., 10 \quad (3)$$

n could take the value of zero if there was no need to open the valve i.e. ICP is already within the normal limits.

Each of these subschedules is studied individually within a simulated intracranial environment to investigate, monitor its effect on maintaining ICP within normal limits and evaluate its performance as described in the following sections.

B. Simulation of Intracranial Hydrodynamics

In this paper, mathematical models ([6], [7], [8], and [9]) were utilised to simulate the intracranial hydrodynamics with a mechatronic valve.

To enhance the personalising aspect of the treatment, *Simulink*^{TM} model was used to implement these equations and at the same time to reproduce the available specific patient's real ICP data. Then the model is used to predict the intracranial hydrodynamics in response to each of the subschedules individually for that specific patient.

C. Performance Evaluation

Based on the output of the simulation for each subschedule alternative, a figure of merit (FoM) is calculated to evaluate the performance of the mechatronic valve under the specified subschedule. A multi-dimensional FoM is proposed that varies with the intracranial dynamics between 0 (poor performance) and 1 (best performance). It would incorporate the following proposed dimensions,

$$FoM = \text{Average of} \begin{cases} FoM_1 & \text{normality measure} \\ FoM_2 & \text{maintainability measure} \\ FoM_3 & \text{open duration measure} \end{cases}$$

1) **Normality Measure**
FoM_1 is a simple indicator of the normality of the ICP values. It measures whether the mean ICP is within the physiological limits, i.e. upper and lower limits. This measure will also give an indication whether the patient was suffering from over/under-drainage or not. These are two of the most common shunt problems, in which CSF is either drained more/less than needed thus causing abnormality in the intracranial pressure.
2) **Maintainability Measure**
This dimension measures the fraction of time for which ICP was maintained within normal limits over any given observation window.
3) **Opening Duration Measure**
This measures the level of optimisation in the opening of the valve, based on the premise that the valve should not be open for longer than necessary to regulate ICP.

For each hour, the subschedule with the highest FoM among the subschedule alternatives is selected to be part of the final schedule.

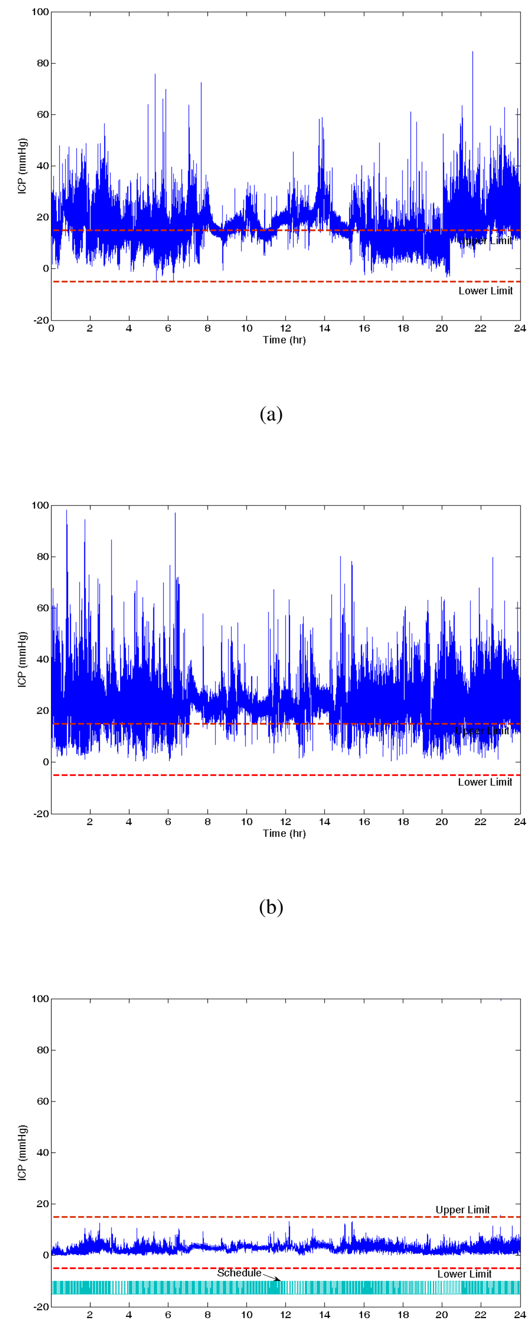
III. Results

All simulations have been performed for a total of 24 hours, where $Matlab^{TM}$ was used to implement the algorithm while $Simulink^{TM}$ was used for implementing the schedule alternatives on an intracranial hydrodynamics model.

The algorithm was tested by applying it on real ICP data for a group of three hydrocephalus patients. Simulation is done for each hour of the 24 hour separately.

Fig. 3(a) shows real ICP data for one of the hydrocephalus patients, while Fig. 3(b) shows the reproduced ICP for this patient before treatment. Fig. 3(c) presents the predicted ICP after adding a mechatronic valve equipped with a personalised schedule that has scored the highest FoM for this specific patient.

Fig. 4 shows a sample report generated as an outcome of the algorithm after being automated by $Matlab^{TM}$ and $Simulink^{TM}$. It contains the resultant 24-hour schedule and average ICP before (ICP_b) and after (ICP_a) applying the



(a)

(b)

(c)

Fig. 3. ICP traces for hydrocephalus patient. (a) Real ICP, (b) reproduced ICP before adding mechatronic valve, and (c) predicted ICP after adding the valve.

subschedule for each hour. It also contains the open duration (d_{ON}), closed duration (d_{OFF}) and the maximum FoM value for each hour on which the selection was based.

Initial Schedule Design Results
Output Summary

Hour	Mean ICP_b*	Mean ICP_a*	d_{ON}	d_{OFF}	FOM
1	35.33	4.75	5	15	0.7345
2	23.51	3.30	4	12	0.7273
3	21.59	4.23	3	12	0.7326
4	21.71	4.73	3	12	0.7301
5	22.34	3.69	9	30	0.7274
6	22.09	4.97	4	15	0.7256
7	21.58	3.77	4	15	0.7273
8	20.80	4.07	4	15	0.7275
9	24.45	5.37	4	15	0.7233
10	21.37	3.93	4	15	0.7291
11	23.88	5.19	4	15	0.7250
12	21.05	4.23	3	12	0.7297
13	21.88	4.56	3	12	0.7289
14	20.77	3.74	8	30	0.7279
15	24.97	5.16	4	15	0.7284
17	22.35	4.90	3	12	0.7255
18	21.65	4.73	3	12	0.7270
19	21.59	4.23	4	15	0.7273
20	23.22	3.84	6	20	0.7249
21	19.51	3.32	8	30	0.7267
22	22.20	3.72	9	30	0.7233
23	21.18	4.52	3	12	0.7276
24	21.90	4.34	4	15	0.7269

*Mean ICP_b is for the un-shunted patient, and Mean ICP_a is for shunted patient.

Fig. 4. A sample report generated for one of the patients.

The relation between ICP and optimum open duration d_{ON} and closed duration d_{OFF} (that has maximum FoM) was investigated. Numerical simulations were performed for each hour at different average ICP values and the FoM was calculated for each trial. As a result, d_{ON} and d_{OFF} corresponding to the maximum FoM was projected against the average ICP values. Fig. 5 illustrates the empirical relation between them.

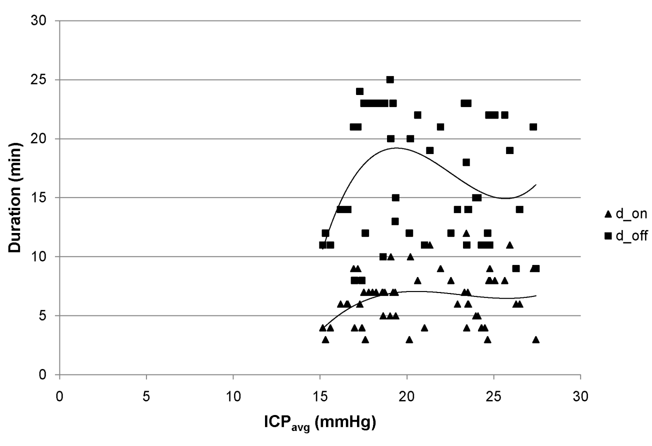


Fig. 5. A graph of the relation between ICP and optimum open duration d_{ON} and closed duration d_{OFF}.

This relation was modelled using the third order polynomial minimum square error fit, as below:

$$d_{ON}^{*} = 0.0082P^3 - 0.5705P^2 + 13.039P - 91.2460 \quad (4)$$

$$d_{OFF}^{*} = 0.0346P^3 - 2.3399P^2 + 51.7150P - 356.1000 \quad (5)$$

IV. Conclusions

The realisation of truly autonomous shunting systems for personalised hydrocephalus treatment is closer than ever. This require the use of implanted mechatronic valve. Selecting a suitable schedule for a mechatronic valve is vital step in the success of such valve in overcoming the drawbacks of current treatments (e.g. under/over-drainage). For a schedule to be effective, it should be personalised and dynamically modified to accommodate intracranial changes. The above algorithm can help in designing a personalised schedule that has optimum performance based on a figure of merit. The optimisation process can be carried out subsequently to update and further personalise the schedule whenever new real ICP data is provided. Whether this algorithm is valid in vivo procedures needs to be examined in further animal or even human studies.

Future enhancements would include incorporating more parameters in developing the initial valve schedule, e.g. regular day in the patient life (patient sleeping and working times, type of work (sitting, standing)) and other parameters derived from ICP traces, would enhance the performance of initial schedules.

V. Acknowledgements

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