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Technical note

A novel device for the clearance and prevention of blockages within biomedical catheters

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ABSTRACT

Biomedical catheters are commonly used to move fluids from one part of the body to another, or remove them from the body completely. In some instances, these catheters become occluded due to blood or other debris. Such occlusions may prove fatal or require re-operation with enormous costs and effects on the health-care system and the individual. We developed a model of occlusion in both a ventriculo-peritoneal shut system and en external ventricular drain. Having demonstrated that occlusions can be reliably generated in a manner that resembles the clinical situation we show that vibration can clear the blockages. Vibration in the 50–60 Hz range was able to maintain patency in the catheters or to clear the blockage when the catheter was completely occluded. In high concentrations of blood, 150 s of vibration applied every 30 min was able to maintain the patency of the catheter. Clinically, as the level of blood in the fluid decreases, the time intervals between vibration applications could be increased. We believe that vibration offers a safe, non-invasive method to maintain the patency of biomedical catheters.

1. Introduction

Biomedical catheters are all designed to transport fluid, be it cerebrospinal fluid, blood, urine or other fluids, within, or out of the body. Many of these devices have within them either junctions in tubing or valves that are potentially sites at which blockages may occur. The effects of such blockages can be serious, or even fatal. The revision rate for cerebrospinal fluid shunts may be over 78% in children and close to a third in adults [1,2]. There was a shunt failure rate of close to 50%, with the majority occurring in the first 6 months after placement. The reason behind a shunt failure is not always clear, but the high occurrence in the initial placement period might indicate that blockage might arise in some cases from blood debris within the tubing, and more likely the valve [3].

External ventricular (EVD), or sub-dural drains (SDD) which remove blood and CSF blood from their respective intracranial spaces are also subject to blockage. This is in part due to the nature of the fluid (blood or blood-contaminated CSF) and also due to their relatively small size when compared to similar tubing systems in other parts of the body (i.e. a chest tube). Such catheters can be flushed or "milked", which is time-consuming, and a reactive rather than proactive treatment. Individual practices vary considerably, but failure rates of EVDs may be as high as one-quarter [4]. Patients may require repeated drain insertion due to catheter occlusion. Patients with EVDs are medically unstable and as a consequence any change in ability to drain fluids can be catastrophic.

The authors report a reliable model for occluding both ventriculo-peritoneal shunts and external ventricular drains using a blood and saline solution. We further describe a method of clearing the blockages and of maintaining catheter patency using low-frequency vibration. The device and its function are described and an initial clinical implementation is shown.

2. Methods

Whole human citrated blood combined with a 0.9% saline solution in ratios that varied from 0 to 250 ml in 1 l of saline were run through either an external ventricular drain catheter system or ventriculoperitoneal shunt system (Delta valve performance level 1 TM) (both Medtronic, Minneapolis, MN). Blood was obtained from discarded units from a hematology clinic. The exact hematocrits were not documented, but were all above 50% based upon the clinic's policies. Blood was used within 2 h of collection, although experiments persisted for up to 10 h.

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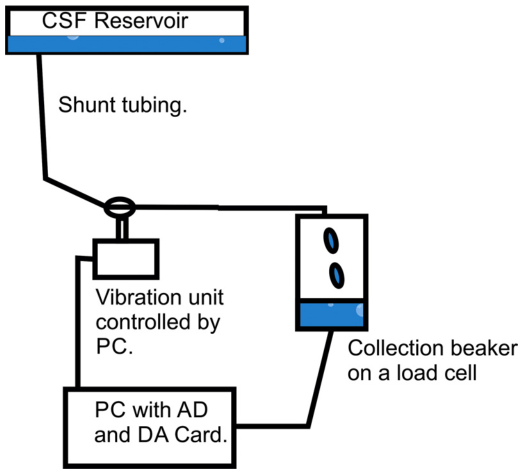

Fig. 1. The experimental setup. Fluid flows from the reservoir, through the shunt valve to a beaker that is placed on a load cell that measures the mass of the beaker, and hence the flow rate. The shunt valve is placed over a mechanical actuator whose vibration is controlled from a PC.

An open beaker at an elevation of 75 cm was used as a reservoir for the CSF/blood mixture. The EVD flow rate from the reservoir was controlled with a simple external compression valve used for intravenous lines. A magnetic stirrer was used to ensure that blood and saline remained adequately for the duration of each experiments. Fluids were kept at room temperature.

Flow rate through the catheter was assessed by measuring the mass of a collection beaker placed at the end of the catheter. The beaker was covered to ensure no loss of fluids through evaporation. The beaker was placed on a mass transducer subsequently connected to an A/D system (Micro 1401, Cambridge Electronic Design, Cambridge, UK) and to a PC running Spike 2 (also Cambridge Electronic Design). Samples were collected at 10 Hz and stored for offline analysis using Matlab (The Mathworks Inc., Natick, MA, USA). A summary figure is shown in Fig. 1.

2.1. Modelling occlusions

For both class of devices, we varied the concentration of the blood placed into the saline solution. Flow rates were adjusted to a flow rate of approximately 10–15 ml/h. The CSF/blood combination was allowed to flow until the flow ceased. All experiments were repeated five times, with the order of blood concentrations randomized. The flow rate is above that seen in clinical situations, but was chosen to allow occlusions to be reliably modelled in a reasonable time frame.

Having determined that a concentration of 400×10^9 red blood cells/ml of saline reliably produced occlusions within a period of a few hours, subsequently used this concentration for the remainder of the study.

2.2. Clearing occlusions

Vibration was applied using a shaker (LDS V201) and controlled through a controller (LDSPA25E, both Brüel & Kjær, Pointe-Claire, QC, Canada). A 6-mm-thick felt pad placed over the vibration shaft to simulate the scalp overlying the shunt valve. For the CSF shunt, the shunt valve was placed on a firm surface and its reservoir brought into contact with the felt pad. For the EVD, the catheter tubing was taped to the felt pad. An occlusion was allowed to develop in the EVD or the shunt. Vibration was applied at frequencies ranging from 10 to 120 Hz. The vibration was not applied until the flow rate was less than 5% of the baseline rate.

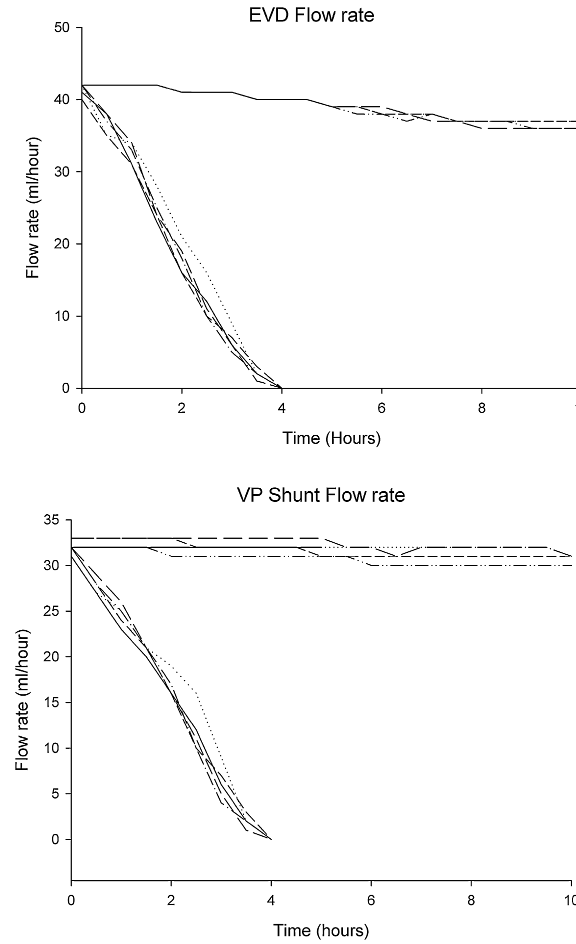

Fig. 2. The effect of the frequency of vibration on the flow rate through the external ventricular drain seeded with bloody saline solution. Both high and low frequencies are less effective at maintaining the flow than frequencies in the mid-teen range.

2.3. Preventing occlusions

A fixed frequency of stimulation (60 Hz) was used for all of these subsequent experiments. Rather than clearing occlusions, we set out to prevent occlusions occurring by applying vibration prophylactically. Vibration was applied for 150 s and the interval between the onset of each stimulation period was varied.

2.4. Clinical application

The shaker provides very precise vibration, but is not feasible for clinical applications because of both its bulk and cost. A variety of simple devices use battery-powered motors spinning an eccentric wheel with to create vibration intentionally such as pagers and cellular telephones. Other devices such as an electric toothbrush create vibration inherent to their function. We adapted these properties into two simple clinically applicable systems. For the CSF shunt, we placed a felt base at the end of the toothbrush handle (Oral B, Procter and Gamble, Cincinnati, OH). For the EVD device, we placed the toothbrush shank into the open barrel of a syringe. The syringe barrel was then taped to the catheter tubing. The toothbrush was turned on and off using the switch on the brush.

3. Results

In the absence of blood, there was no change in flow rate of saline over a period of many hours. However, with a high concentration of