2017 CMBEC40 Conference
Winnipeg MB
May 23–26, 2017

PRELIMINARY DEVELOPMENT OF A MRI-COMPATIBLE SYRINGE PUMP ADAPTER

Charlene Leung[1], Dr. Stephan Malherbe[2], Anthony Chan[1,3]
[1]Biomedical Engineering, University of British Columbia
[2]B.C. Children's Hospital Research Institute, B.C. Children's Hospital
[3]Biomedical Engineering, British Columbia Institute of Technology

ABSTRACT

In pediatric magnetic resonance imaging (MRI), an anesthetic agent is often administered using an infusion pump to ease the child's discomfort and reduce their movement during the scan. Conventional infusion pumps, however, are prohibited from the scanner room due to its ferromagnetic and metallic components. The interaction between these materials and the scanner's strong magnetic fields can lead to patient injury or death. Commercially available MRI-compatible pumps are expensive, have different user interfaces than conventional in-house pumps, and do not offer a standby function which is critical in a clinical pediatric setting. Common but cumbersome, unsustainable and wasteful work-around solutions involve directly infusing the anesthetic using consecutive extension intravenous (IV) lines connected to an infusion pump in an adjacent room. The MRI Syringe Pump Adapter (SPA) acts as an intermediate device that facilitates the transfer of the infusion rate delivered by the pump to the anesthetic-filled patient syringe. The preliminary development process of the MRI SPA consisted of needs finding through clinical interviews and observations, concept generation, risk analysis, rapid prototyping, and testing. The SPA costs $32, can be 3D-printed in less than 2 hours, and is constructed of ABS-M30 plastic. Preliminary verification tests revealed the system transfers the infusion rate from the syringe pump to the patient with an acceptable 10% accuracy. This setup, however, created a significant increase in the line pressure, which requires further investigation and mitigation. Continual development and testing are being performed to verify the accuracy and pressure profile of the SPA system.

INTRODUCTION

Consciously laying still in the confined bore of a MRI machine, whose sounds form a frightening mixtape of whirs, chirps, truck horns, dial up internet tones, and banging metal, is an uncomfortable experience for the patient receiving the MRI scan. Pediatric MRI is particularly difficult as children have the tendency to squirm during the scan, which creates motion artifacts in the image thereby increasing the difficulty of obtaining an accurate diagnosis. To ease their discomfort and reduce their movement during the scan, an anesthetic agent such as propofol can be administered to the child using an infusion pump. The strong magnetic fields created by MRI scanners, however, restrict the presence of conventional infusion pumps in the room. Interference with the MRI's radiofrequency waves can distort and create susceptibility artifacts in the MR image. Interactions with ferromagnetic forces can cause metallic objects such as infusion pumps and medical instruments to succumb to the projectile effect, where they are projected across the room towards the patient in the scanner's bore. The resultant adverse effects can include misdiagnosis and physical harm to the patient [1].

Anesthesiologists and nurses have stated that MRI-compatible infusion pumps are not suitable for pediatric MRI due to its unfamiliar user interface and software, and the absence of a standby function. A common cumbersome "work-around" alternative is to directly infuse the anesthetic using a series of IV lines that connect them to a conventional infusion pump located outside of the MRI scanner room [1]. The issues with this unsustainable method include a large ecological footprint, disconnections in the line, and a time-consuming and effortful setup for each patient.

This paper presents the preliminary development of a cost effective and user friendly MRI SPA as a favourable alternative to expensive MRI-compatible pumps and unsustainable work-around methods. The MRI SPA is an intermediate device used to facilitate the infusion of anesthetic between the conventional syringe pump and patient. Its development process reflects the first two phases of the biodesign process, i.e. identification and invention [2]. The preliminary design of the MRI SPA consists of risk mitigation features, incorporates user input, reduces medical waste, and saves the hospitals approximately $20,000 annually in disposable parts plus the additional cost of the MRI-compatible pump. Further development and testing of the preliminary MRI SPA is currently being conducted to improve and verify its performance.

METHODOLOGY

Development of Specifications and Risk Analysis

An in-depth understanding of the problem and its constraints were gained from informational interviews with anesthesiologists and nurses, and observations of the MRI suite. This combination was critical in uncovering subtle yet significant environmental constraints, user needs, barriers to device use, and safety hazards. This information was refined into a list of quantifiable specifications which acted as the framework for the design. The initial MRI SPA system consisted of a Braun Perfuser Space Infusion Syringe Pump connected to five 124 cm IV lines through which propofol was transferred to the patient using a series of three 20 mL syringes and the SPA. The infusion rate applied by the pump to the Syringe 1, filled with water, is transferred to Syringe 2 then Syringe 3, filled with anesthetic, thereby delivering the anesthetic at the same rate (Fig. 1). Unlike the work-around methods, only the patient syringe and IV line need to be replaced after each use.

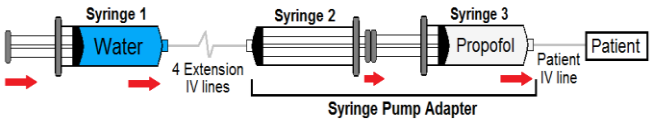

Figure 1: Schematic of the SPA system.

Using a Hazards Analysis Table and Failure Modes Effects and Analysis (FMEA) approach, several iterations of a risk and usability analysis were performed on the initial design of the SPA system. The overall risk of each hazardous event was quantified as a risk index determined by the probability of the harm occurring and the severity of the harm. It was imperative that risk control measures were applied at the design level such that risk mitigation was inherent to the adapter and independent of the user. The post-mitigation risk index was calculated to determine if the residual risk was acceptable or required further mitigation. The three hazardous situations with the highest pre-mitigation risk indexes were: discrepancy between syringe sizes in the infusion pump and SPA, a system disconnection due to syringes falling out of the SPA, and interference with the MRI scanner's radiofrequency waves and magnetic fields. The risk control measures for these hazards were reflected in the design specifications and device features of the SPA.

Design and Prototyping

The function of the MRI SPA is to transmit the infusion rate delivered by a conventional syringe pump to the syringe containing the anesthetic agent. The adapter was designed to meet the specifications as to ensure performance, safety, user-friendliness, and efficient construction. The probability of a syringe size discrepancy was mitigated by designing the SPA to only be compatible with 20 mL syringes. The length of the plunger interface was set at 96.8 mm, i.e. the distance between the flanges of Syringe 2 and 3 at a maximum allowable volume of 20 mL (Fig. 2). A shorter or longer interface would compromise the maximum volume to be infused. To optimize the ergonomics and maneuverability, the width (60 mm), height (28 mm) and mass (121 g) of the SPA were determined using anthropometric data for hand size [3] and grip strength [4]. A horizontal syringe orientation was chosen over a vertical one as it was intuitive and familiar to the intended user's training and experience. The portion of the adapter which holds the syringe barrel was set to a length of 74.8 mm to provide complete visibility of the barrel and plunger head at volumes less than 5 mL (Fig. 2). This allows the

anesthesiologist to glance and verify that the remaining volume in the syringe corresponds with the pump's low volume alarm. A discrepancy would suggest a leak in the system. The probability of syringes becoming displaced from the SPA was mitigated using an interference snap-fit locking mechanism, which provides tactile and audio feedback to the user once the syringe has "snapped" into place. To minimize the probability of interfering with the scanner's radiofrequency waves and magnetic fields, prototypes were printed with ABS-M30 plastic on the Stratasys Fortus 400mc 3D printer. A fused deposition modeling (FDM) sparse support style was used to minimize material. The final design of the SPA is a single part with no moving components or support material, therefore it simplifies construction, minimizes material and printing time, is easy to clean, and can be built on any 3D printer.

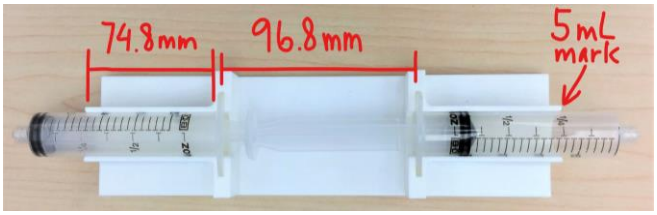

Figure 2: Design features of the SPA.

The material cost of the final prototype was $32. If the adapter is replaced semi-annually, the SPA system has a total estimated annual cost of $6,400 which is 3 times less than the work-around method. Furthermore, the hospital will not need to purchase the expensive MRI compatible pump. Since the SPA can be 3D printed, it is easily replaced without extra costs for procurement or maintenance. The reduced number of components and longer replacement interval decreases the amount of waste produced by the system, ie. less than half of the 300 lbs of annual waste produced by work-around methods. The SPA system can be expected to save the hospital hundreds of thousands of dollars in resources.

RESULTS

Preliminary tests evaluated the SPA's adherence to the design specifications by testing its structural integrity, locking mechanism, infusion rate transfer accuracy, usability, syringe pump compatibility, and pressure profile of the system. The test setup simulated the clinical setup (Fig. 3). Syringe 3 and the patient IV line were fed into a collection container placed on a balance. To replicate a venous back pressure of 5 mm Hg, the end tip of the patient IV line was placed 7 cm above the nozzle of the first syringe [5, 6]. Using the volume-to-mass equivalence of water, the infusion rate transfer from Syringe 1 to the collection container was evaluated by recording the balance reading. Pressure readings were recorded to evaluate the system's pressure profile. To replicate the duration of use, verification tests were conducted as 20 minute infusions every hour for 8 consecutive hours.

Figure 3: Verification test setup.

At a low infusion rate of 12 mL/h (0.2 mL/min), the average flowrate recorded over a 20-minute infusion was 0.18 ± 0.01 mL/min. At a high infusion rate of 60 mL/h (1 mL/min), the average flowrate was 0.97 ± 0.01 mL/min (Fig. 4). The pressure profile increased with each test sequence (Fig. 5), where it doubled from 175 mm Hg to greater than 400 mm Hg between the first and last run. The reading for the eighth run was not recorded due to excessive pressure.

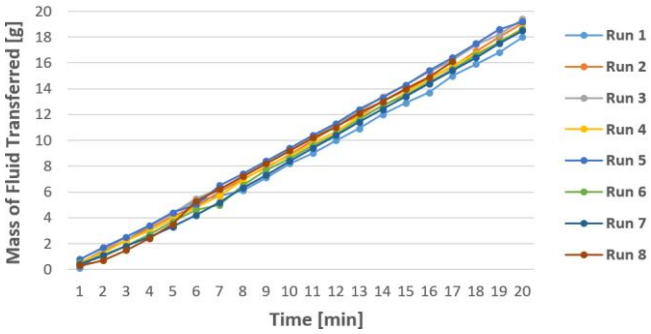

Figure 4: Infusion rate transfer at 60 mL/h.

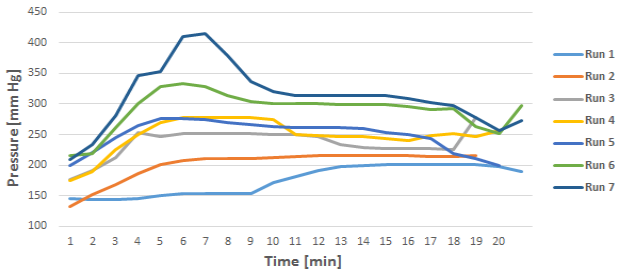

Figure 5: System pressure profile at 60 mL/h.

DISCUSSION

The flowrate transfer accuracy of both infusion rates met the design specification that required 10% accuracy, which had been determined as an acceptable margin of error by the collaborating anesthesiologist [6]. The accuracy of the tests was limited by the balance resolution (±0.1 g), which did not afford readability below 10% accuracy, i.e. accurate readings were not available for low flowrates with volume changes less than 0.1 mL. Several factors that may have contributed to the pressure build-up included: stiction between the plunger head and inner wall of the syringe barrel, expansion of the plunger head due to fluid absorption, and repeated fluid transfer in a closed system.

The accuracy of the results obtained from the preliminary tests were limited by the test equipment available at the time, therefore additional tests are currently being performed to verify the SPA system. The syringes and IV lines used in the preliminary tests had been used numerous times throughout the months prior to the documented tests; as such, the wear of the syringe and liquid absorbed by the plunger head in this time increased the effect of stiction on the system pressure. Current tests use a new set of syringes and IV lines for each test sequence.

The accuracy of the infusion rate transfer readings is improved by using an analytical scale with a resolution of 0.1 mg. With pressure build up at low flowrates as the main concern of the system, different mitigation methods are currently being tested. These include using a single extension IV line to connect the first and second syringe to remove the pressure build up at connection points, and applying a dry lubricant to the plunger head to reduce stiction.

CONCLUSION

The preliminary test results show promising outcomes of the SPA that encourage its continual development and further testing. The SPA system met the design specifications for mechanical strength, syringe securement, alarm compatibility, and an infusion rate transfer accuracy of 10%. Mitigation methods to reduce and minimize pressure build-up are currently being evaluated. Further tests are being conducted using an analytical scale with a resolution of 0.1 mg, as well as new syringes and IV lines, to verify the infusion rate transfer is within 10% accuracy and that the pressure profile does not exceed the default pump occlusion alarm of 487 mm Hg. The successful performance and final development of the MRI SPA system would reduce hospital costs and medical waste significantly, as well as, improve the system user interface.

ACKNOWLEDGEMENTS

The authors would like to thank Nancy Paris and the staff at BCIT MAKE+ for their prototyping expertise and facilities, and the anesthesiologists and nurses at B.C. Women's and Children's Hospital for their time and valuable insight.

REFERENCES

[1] M. Sesay, P. Tauzin-Fin, O. Verdonck, V. Dousset and P. Maurette, "A wireless remote controlled infusion pump for anaesthesia during magnetic resonance imaging", *British Journal of Anaesthesia*, vol. 100, no. 6, pp. 862-863, 2008.

[2] P. Yock et al., *Biodesign: The process of innovating medical technologies*, 2nd ed. Cambridge University Press, 2015, p. 47.

[3] C. Gordon et al., "1988 Anthropometric Survey of U.S. Army Personnel: Summary Statistics Interim Report", 1989.

[4] H. Roberts et al., "A review of the measurement of grip strength in clinical and epidemiological studies: towards a standardized approach", *Age and Ageing,* vol. 40, no. 4, pp. 423-429, 2011.

[5] "Arterial Blood and Central Venous Pressure Monitoring Devices", *University of Iowa Children's Hospital*. [Online].

[6] S. Malherbe, "Venous Pressure & Infusion Rate Accuracy", BC Women's and Children's Hospital, 2016.