PATIENT-MAINTAINED PROPOFOL SEDATION: THE ANAESTHETISTS' POINT OF VIEW

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ABSTRACT

Many operations within the UK do not require general anaesthesia, and are instead carried out under sedation. A doctor normally provides this, and as the patient is not in control, they may be either under or over-sedated due to a misjudgement of patient anxiety. One solution would be to allow the patients to directly control their own sedation level. This paper presents an invention for innovation (i4i) project developing such a Patient Maintained Propofol Sedation Device (PMPSD). Due to the health risks associated with under and over-sedation, the anaesthetists' interface takes on an added importance to ensure they can oversee the process and intervene when needed. Through the project, a unique opportunity has arisen where anaesthetists have been involved throughout the interface design process, contributing to the development and testing of a prototype. We present this prototype, highlight its key features and how it differs from existing sedation pump interface systems. As the project continues, the interface will be used as part of a clinical trial at Nottingham University Hospitals NHS Trust involving 80 orthopaedic patients throughout the rest of 2018 and into 2019.

KEYWORDS

Participatory Design, Usability, Interface Design, Healthcare HCI

1. INTRODUCTION

In the UK, over 800,000 medical operations are performed annually with an anaesthetist present but without using general anaesthesia (Sury et al. 2014). During such procedures, a substantial number of patients report feeling anxious (Mitchell 2009), which in addition to being an intrinsically negative experience has also been consistently linked with deleterious surgical outcomes including post-operative pain (Munafò and Stevenson 2001). In order to reduce patient anxiety, a number of techniques have been found to have an effect, including visual distraction (Man et al. 2003), patient education (Jlala et al. 2010), music therapy (Bradt, Dileo, and Shim 2013), and pharmacological sedation (Mackenzie 1996).

Target Controlled Infusion (TCI) of Propofol, under the direction of an anaesthetist, is an often-preferred choice for intra-operative sedation due to the drug's pharmacokinetic profile; this is how the drug is absorbed, distributed, metabolised and excreted by the body (Schnider et al. 1998). However, judging the level of anxiety of the patient has proven difficult, and anaesthetists can be inaccurate judges of pre-operative patient anxiety (Badner et al. 1990). This can result in either over or under-sedation in comparison with the actual requirements of individual patients. One possible solution for overcoming this issue is to allow patients control over their depth of sedation.

Patient-maintained Propofol sedation has been previously tested in dental (Leitch et al. 2004), endoscopy (Stonell, Leslie, and Absalom 2006) and outpatient surgical (Yun et al. 2008) settings. Although this research has had favourable outcomes in terms of sedation concentration, patient recovery time and anxiety levels, to date there has not been a truly human-centred approach specifically considering the changing role of the anaesthetist in such a system. Previous work has acknowledged the inter-individual variability of patients' Propofol consumption (Irwin, Thompson, and Kenny 1997), but there has been little consideration of how such data is presented to the anaesthetist in order for them to ensure the procedure is safe and intervene when appropriate.

The interface design of an infusion pump can affect error rate, task completion times and the overall mental effort required of the supervising anaesthetist (Schnittker et al. 2016). Therefore, it is important that any such interface used as part of a patient-maintained system is designed so that the anaesthetist can safely and effectively monitor the process, as issues related to under and over-sedation are still a possible risk (Hewson et al. 2018).

This paper introduces an invention 4 innovation (i4i) project testing the suitability of a Patient Maintained Propofol Sedation Device (PMPSD) when used for lower limb orthopaedic surgery. In developing the system, a participatory design approach has been used, where anaesthetists have been fully involved in the process of creating the anaesthetist interface. In doing this, key HCI differences when considering a patient-maintained approach have been identified, and also improvements on some issues related to existing pump interfaces made.

2. PMPSD SYSTEM DESIGN

In order to investigate the suitability of patient maintained Propofol sedation for lower limb orthopaedic surgery, the following prototype system has been developed (see figure 1):

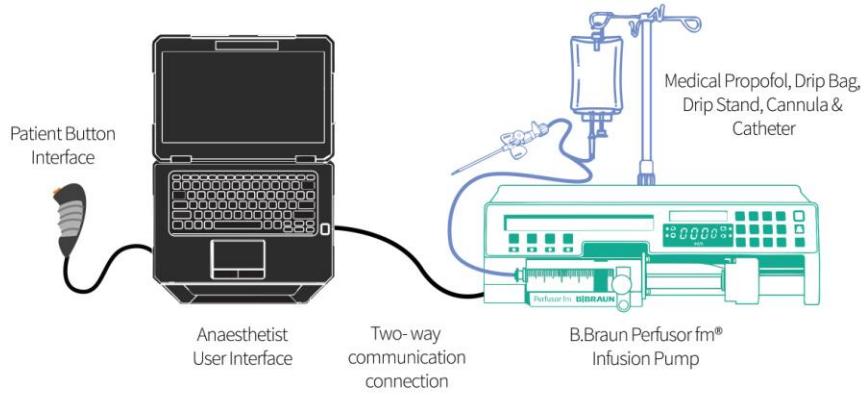

Figure 1. PMPSD Prototype System

The system consists of:

- Infusion pump (B.Braun Perfusor fm) and Drip setup. This is attached to the patient as per normal operating procedure.
- Anaesthetist User Interface. This is presented to the anaesthetist through a laptop that is both connected to the infusion pump (through a serial port connection), and to the patient button (through a USB port).
- Patient Button Interface: A trigger button that through pressing allows the patient an increase in sedation.

The principle component of the system is the anaesthetist interface, as it controls the pump's rate of infusion, monitors and responds to requests from the patient to increase sedation, and presents information regarding both to the supervising anaesthetist. It is also the pathway by which the anaesthetist can take back control of the sedation process, if the need arises for safety reasons.

3. USER AND INTERFACE REQUIREMENTS

Over a six-month design period, running from September 2017 to March 2018, monthly design review meetings were held to define the user and interface requirements, and evaluate the interface design iteratively as it was developed. Project members, software developers and anaesthetists who will be operating the system during the project, were in attendance. Through this process, the following initial requirements were derived, both in terms of functionality and features that ensure safe operation (see table 1):

Table 1. PMPSD User and Interface Requirements

Interface (System) Requirements	User Requirements
Baseline effect-site concentration of 0.5mcg.ml^{-1}: All patients start at a baseline level of sedation and do not drop below unless the system is deactivated	**Clear display of sedation metrics on screen:** Metrics like infusion rate, current sedation levels and total Propofol consumed clearly visible
Ceiling effect-site concentration of 2.0mcg.ml^{-1}: Patients' sedation level cannot go above ceiling unless anaesthetist feels it is appropriate	**Sedation pause:** Anaesthetist can pause sedation at any time (in order to replace syringe etc.)
Lock-out time of 2 minutes: After a request by the patient, further button presses will not cause an increase during lock-out time	**Anaesthetist override:** Anaesthetist can take over the system, disabling the patient button and controlling sedation level
Decrement of 0.1mcg.ml^{-1} every 15 minutes: If button not pressed by patient, sedation level slowly decreases over time	**Button Display:** Anaesthetist can see when/how often patient uses button to request increased sedation

4. ANAESTHETIST INTERFACE PROTOTYPE

Based on the previously mentioned requirements, and adhering to Nielsen's (Nielsen 1995) 10 heuristics for user interface design, the following anaesthetist interface prototype was developed for used with the PMPSD system (figure 2). The interface was developed using the C++ language and the Qt (www.qt.io) development environment:

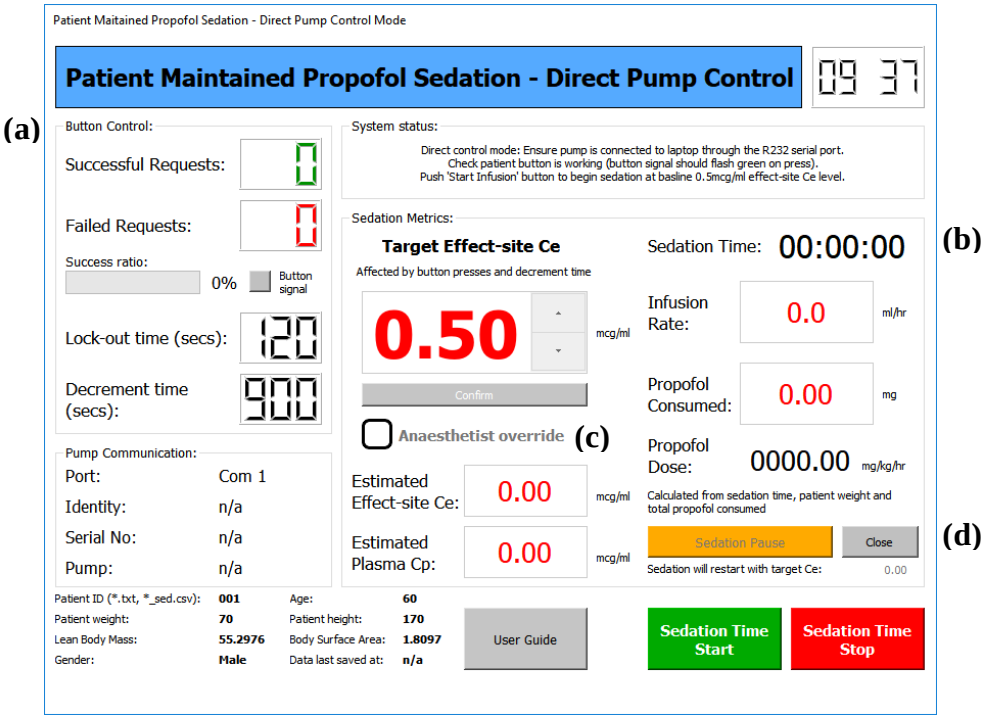

Figure 2. Prototype Anaesthetist Interface with the following displays: (a) – Button control display showing successful and failed patient requests for increased sedation; (b) – Sedation metrics display displaying sedation information; (c) – Anaesthetist override button allowing the anaesthetist to take system control; (d) – Sedation Pause button allowing the anaesthetist to pause sedation

4.1 Interface Prototype Evaluation

In order to evaluate the suitability of the prototype anaesthetist interface for use with patient maintained Propofol sedation, an evaluation workshop took place on a simulation version of the PMPSD system. On 16th February 2017 three anaesthetists from Nottingham University Hospitals NHS Trust took part in the workshop. They were asked to evaluate both the PMPSD interface prototype along with an existing infusion pump interface, considering their usability and to what degree they achieve Nielsen's design heuristics. As part of this process, they were asked to rate their agreement with statements regarding the interface design and its ease of use on a 9-point scale, with 9 meaning 'strongly agree' and 1 meaning 'strongly disagree'. Table 2 shows the scores given by the anaesthetists for each interface:

Table 2. Anaesthetists' Scores regarding Nielsen's Design Heuristics

Design Statement	Existing Pump Score	PMPSD Interface Prototype Score
The pump always keeps the user informed	7	8.5
The interface speaks the users' language	7	8.5
The interface supports 'undo' and 'redo'	5.5	7
The interface language is consistent	8	8.5
The interface is designed making it unlikely that problems occur	8	9
The interface minimises user memory load	7	8
Frequent actions are easy to access at speed	6	9
Dialogues only contain relevant information	7.5	7.5
Error messages are displayed in plain language	8	9
Documentation is easy to search, focused and list steps to carry out	4	8.5

Table 3 summarises some of the comments made during the workshop comparing the existing pump interface with the PMPSD interface prototype, adding context to the heuristic scores shown in table 2:

Table 3. Anaesthetists' Comments during the Evaluation Workshop

Existing Infusion Pump	PMPSD Interface Prototype
"The screen is way to small and crowded, you have to be directly in front of it to read it…"	*"Screen much clearer with button choices easy to read…"*
"Its not clear how to perform a syringe change, do you just pull the lever?"	*"The syringe change mode is easy to operate and clearly displayed on screen…"*
"It doesn't show all the sedation data at once, you have scroll through – not very helpful!"	*"All the sedation data is clear to read and on screen at the same time…"*

5. CONCLUSION

The involvement of the target user group (anaesthetists) throughout the design process of the PMPSD anaesthetist interface has resulted in a number of benefits to the process. These benefits are magnified by the fact that the software developers involved with the project do not have a medical or anaesthesia background, and so perhaps cannot identify so easily some of the more prevalent issues regarding patient maintained sedation.

At the beginning of the design process, the anaesthetists involved were able to clearly outline the initial system and user requirements that would need satisfying. Many of these requirements are unique to a patient maintained sedation system (anaesthetist override, button usage display etc.), and so would not have been easily derived through a review of existing infusion pump interfaces. Having this information early on in the process has made the development process more efficient, reducing the number of major changes required due to requirements being poorly understood or overlooked.

In addition to issues unique to a patient maintained system, more general problems regarding existing infusion pump interfaces were identified throughout the design process. Issues regarding the clearness of sedation data and its size and position on screen were pointed out as possible areas of improvement. Although there might exist a clear advantage due to the platform of the PMPSD being a laptop, allowing

space for a greater amount of data to be displayed more clearly, the identification of such problems should still inform future designs of both patient and anaesthetist controlled infusion pump interfaces.

By taking a participatory design approach that involves anaesthetists throughout the process, it is hoped that the resulting PMPSD anaesthetist interface will be usable and therefore safe to operate in the upcoming clinical trials of the system throughout 2018 and 2019.

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