EPiC Series in Health Sciences
Volume 1, 2017, Pages 248–253
CAOS 2017. 17th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery

Intraoperative Workflow Optimization by Using a Universal Foot Switch for Open Integrated OR Systems in Orthopaedic Surgery

Armin Janß, Anna Vitting, Benjamin Strathen, Melanie Strake and Klaus Radermacher

Chair of Medical Engineering, Helmholtz Institute for Biomedical Engineering, RWTH Aachen University, 52074 Aachen, Germany, janss@hia.rwth-aachen.de
janss@hia.rwth-aachen.de

Abstract

Nowadays, foot switches are used in almost every operating theatre to support the interaction with medical devices. Foot switches are especially used to release risk-sensitive functions of e.g. the drilling device, the high-frequency device or the X-ray C-arm. In general, the use of foot switches facilitates the work, since they enable the surgeon to use both hands exclusively for the manipulation within the operation procedures. Due to the increasing number of (complex) devices controlled by foot switches, the surgeons face a variety of challenges regarding usability and safety of these human-machine-interfaces.

In the future, the approach of integrated medical devices in the OR on the basis of the open communication standard IEEE 11073 gives the opportunity to provide a central surgical cockpit with a universal foot switch for the surgeon, enabling the interaction with various devices different manufacturers. In the framework of the ongoing OR.NET initiative founded on the basis of the OR.NET research project (2012-2016) a novel concept for a universal foot switch (within the framework of a surgical workstation) has been developed in order to optimize the intraoperative workflow for the OR-personnel.

Here, we developed three wireless functional models of a universal foot switch together with a standardised modular interface for visual feedback via a central surgical cockpit display. Within the development of our latest foot switch, the requirements have been inter alia to provide adequate functionalities to cover the needs for the interventions in the medical disciplines orthopaedic surgery, neurosurgery and ENT.

The evaluation has been conducted within an interaction-centered usability analysis with surgeons from orthopaedics, neurosurgery and ENT. By using the Thinking Aloud technique in a Wizard-of-Oz experiment the usability criteria effectiveness, learnability and user satisfaction have been analysed.

Regarding learnability 83.25% of the subjects stated that the usage of the universal foot switch is easy to learn. An average of 77,2% of users rated the usability of the universal foot switch between good and excellent on the SUS scale. The intuitiveness of the graphical user interface has been approved with 91.75% and the controllability with 83.25%. Finally, 86% of the subjects stated a high user satisfaction.

1 Introduction

Nowadays, foot switches are used in almost every operating theatre to support the interaction with medical devices. Foot switches are especially used to release risk-sensitive functions of e.g. the drilling device, the high-frequency device or the X-ray C-arm. In general, the use of foot switches facilitates the work, since they enable the surgeon to use both hands exclusively for the manipulation within the operation procedures. Due to the increasing number of (complex) devices controlled by foot switches, the surgeons face a variety of challenges regarding usability and safety of these human-machine-interfaces. Field studies and reports of neurosurgeons show, that up to 10 different foot switch units occur e.g. in the case of neurosurgical interventions (Blaar et al., 2015). Sterile drapes often obstruct the view onto the (sometimes colour-coded) foot switches. Therefore, the surgeons have to find and release them blindly, which inevitably leads to use errors, especially when foot switches are displaced or fell off the footboard (Blaar et al., 2015). In addition, the unsterile OR-personnel has to replace the foot switch for the surgeon (after it falls down or in case another foot switch is needed according to the operating procedure), which leads to an interruption of the workflow and a time delay for the entire OR team. Another deficit is that different devices include various concepts of usage so that surgeons not only need to use a multitude of different foot switches but also have to understand the mode of operation of those foot switches (Van Veelen et al., 2003).

2 State of the Art

Only a few proprietary concepts for universal foot switches already exist, which integrate different functions and devices, but none of them takes an overall concept of operations of (open-connected) devices into consideration (Niederlag, 2014). The iSwitch e.g. from Stryker uses a wireless USB connection and provides to operate four devices in a proprietary integrated system and incorporates a three-button and two-pedal foot switch that communicates to a receiver console (Stryker, 2003). For the iSwitch concept, a visual feedback regarding the actually selected functional setting, is missing. Steute Schaltgeräte GmbH & Co. KG developed a foot switch with two pedals and four sensors for the selection and control of different devices and functions (Steute, 2008). The concept uses the sensor-based recognition of different postures of the foot in order to change the controlled device. Until now, no concept for a universal foot switch in the (open) integrated OR providing an open platform of workflow related configurable universal interface to multiple (foot switch controlled) medical devices has been developed yet.

3 Approach

In the framework of the OR.NET initiative we developed two wireless functional models of a universal foot switch (Dell'Anna et al., 2016) (Figure 1; left and right up) together with a standardised modular interface for visual feedback via a central surgical cockpit display (using the IEEE 11073 open communication standard) (Figure 1; down right). Exemplary use scenario for the development of these foot switches has been a cervical decompression and fusion operation in spine surgery.

The foot switch version 2.0 consists of three elements (two pedals and one rocker switch) for the device/function release and two elements/buttons for the functional assignment of the interaction elements. The GUI (Figure 1; down left) consists of: A model of the footswitch with the actual functional assignment in the center of the screen, a selection of single device functions for the yellow pedal and the grey locker switch, a selection of process-specific function pairs ('presets') on the right side and a small model of the two configurable pedals with the actual function set on the lower left edge (Figure 1). Both foot switch concepts have in common that the blue pedal is permanently assigned with the bipolar coagulation function in order to facilitate vascular obliteration in case of spontaneous bleeding. In contrast, the left and center pedals are programmable. First usability evaluations of the foot switch (version 2.0) have been conducted in comparison with the classical foot switch "organ" in the OR (Dell'Anna et al., 2016).

Figure 1: Universal foot switch (left up version 1.0 and right up version 2.0) and the corresponding graphical user interface of foot switch version 2.0 (lower left) and the surgical workstation (lower right)

Within the development of the foot switch 3.0 the requirements have been inter alia to provide adequate functionalities to cover the needs for the interventions in the medical disciplines orthopaedic surgery, neurosurgery and ENT. Regarding orthopaedic interventions field studies on a broad range of operations, including spine surgery as well as e.g. knee arthroscopy, have been conducted in order to analyse the specific context of use, its boundary conditions and requirements. Here, especially medical devices and functions, controlled by a foot switch, have been identified. Additionally, the devices' usage time sequences have been recorded and further analysed regarding workflow-dependent risks and requirements. This information will also be an important input for computer based semiautomatic surgical checklists, workflow management and workflow navigation assistance based on the OR.NET concept of open modular networks and inter-device communication ("internet of things") with a central surgical workstation ("cockpit"). The computer assisted work-sequence, time line and risk analyses have been conducted using the (ontology-based) tablet based CUREMeD process recording tool and human error risk analysis method (CUREMeD – Center for Usability and

Risk Engineering of Medical Devices (Aachen, Germany)). The CUREMeD human risk analysis is based on the mAIXuse method developed at the Chair for Medical Engineering at the RWTH Aachen University and uses formal, normative models to predict user-, interaction- and system-behaviour. With the help of specific task categories and the integration of temporal relations, the use process status can be modelled and a systematic human error analysis on the basis of human error taxonomies can be conducted (Janß et al., 2016). Furthermore, an online survey related to Human-Machine-Interaction issues with foot switches in the OR has been developed. Feedback from 20 surgeons from different surgical disciplines (orthopaedics, neurosurgery and ENT) has been evaluated, addressing frequently used functions, deficits and use-errors with interaction elements on foot switches as well as opinions and wishes of the OR-personnel.

Based on usability studies with different functional mock-ups, including criteria oriented formal analyses, interviews with surgeons, interactive testing and computer-based risk analyses, the final concept has been implemented (Figure 2).

Three pedals, two push-buttons and a foot-joystick have been selected as interaction elements for the final design of the universal foot switch. Inter alia the following devices have been integrated: high frequency cutting device, X-ray C-arm, milling device, ultrasound cutting device, shaver, endoscopic camera, OR microscope, etc. The push-button “mode” allows to switch between a „preset mode“ to assign all interaction elements at the same time with various functions (e.g. because of process-specific needs) and four “single selection modes” in order to individually assign the other push button, the grey and the yellow pedal as well as the joystick with various medical device functions. The blue pedal is always assigned with the bipolar coagulation function (as in the previous foot switch models) in order to guarantee effective and efficient handling of spontaneous bleedings. The joystick provides the shifting between the function assignments on the interaction elements in the “preset mode” as well as in the “single selection mode” by a horizontal movement. Vertical movement of the joystick provides the selection of the functions “confirmation” (joystick up) and “cancel” (joystick down).

The conceptual design of the GUI for visual feedback on the foot switch assignment as a modular panel of the surgical workstation has been implemented with Microsoft Expression Blend for Visual Studio and is presented in Figure 2. Here, the output can be generated in XAML, which enables a transfer to the source code of the workstation, respectively the connection with the binding code (connector).

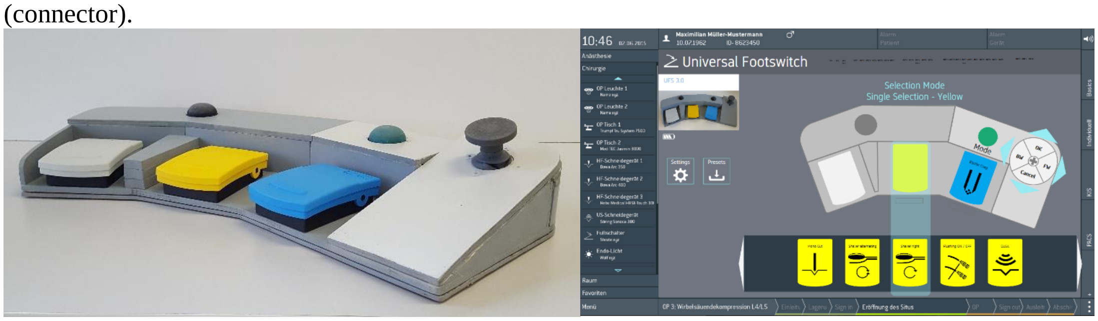

Figure 2: Universal foot switch (left) and corresponding GUI on surgical workstation (right)

4 Evaluation

The final evaluation has been conducted within an interaction-centered usability analysis. 9 surgeons from orthopaedics, neurosurgery and ENT have been participating in the usability test. By using the Thinking Aloud technique in a Wizard-of-Oz experiment the usability criteria effectiveness, learnability and user satisfaction have been analysed. The test setting can be seen in Figure 3. A camera recorded the subjects' feet-specific interactions.

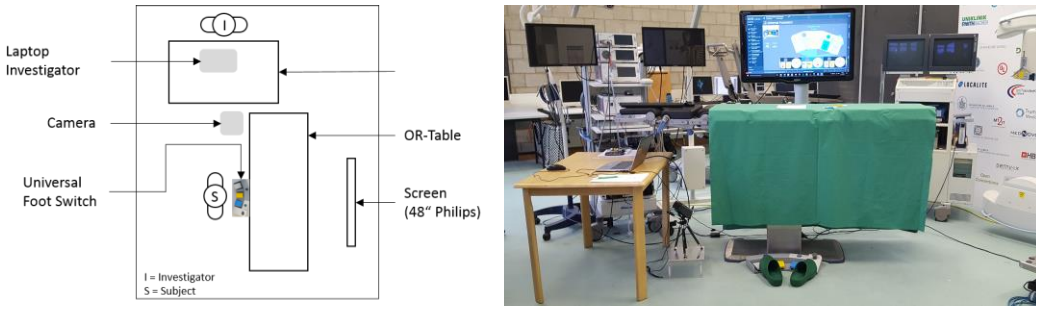

Figure 3: Test setting

Regarding the test design, the subjects had to fulfil 4 working tasks (e.g. adjustment of foot switch in "preset mode", assigning the joystick with various functions in the "single selection mode", release of the interaction elements according to a predefined order). Afterwards subjects had to complete a questionnaire regarding user satisfaction based on the SUS usability analysis questionnaire (Brooke, 1986). The effectiveness of the system has been measured by the ratio of fulfilled tasks to use errors. The learnability has been assessed by comparing the effectiveness of consecutive task cycles.

Regarding the effectiveness errors in the fulfilment of the tasks "release the single selection mode", and "cancel or confirm the actual function assignment" occurred in the first task cycle (of four cycles). During the last (fourth) cycle all the tasks have been fulfilled by 100%, which shows high learnability.

Regarding learnability, 83.25% of the subjects stated that the usage of the universal foot switch is easy to learn. An average of 77,2% of users rated the usability of the universal foot switch between good and excellent on the SUS scale (a value above 68% in the SUS scale constitutes good usability).

The intuitiveness of the graphical user interface has been approved with 91.75% and the controllability of the system has been rated with 83.25%. In addition, on average 83.25% of the subjects confirmed that the work tasks could be carried out to their satisfaction. The user satisfaction is i.a. confirmed by the question, whether the users like to work with the system. Here, 86% of the subjects stated a high user satisfaction.

5 Conclusion and Outlook

The novel concept of a universal surgical foot switch presented in this paper, has been developed for ENT, orthopaedics and neurosurgery. The fulfilment of the requirements of these three medical disciplines has been challenging, as each medical discipline has its specific medical devices (and functionalities), specific user tasks and specific contexts of use.

Although, a universal foot switch for all three medical working areas has been implemented and evaluated positively, the concept of specific universal foot switches for each surgical discipline could be an alternative reducing complexity of the device.

The universal foot switch has been measured regarding effectiveness, learnability and user satisfaction. Here, still some bottlenecks regarding the interaction concept with the GUI and the hardware of the foot switch have been identified.

Exemplarily, the interaction process with the joystick has shown a weakness regarding the height. Furthermore, the release force of the joystick has been insufficient. Thus, most subjects had problems regarding the joystick's haptic feedback, while adjusting the foot switch modes and hence, there has been an uncertainty regarding the joystick's position status, especially when the user had to release "ok" or "cancel" for the functional assignment. In conclusion, a mechanical redesign of the joystick is one objective of our ongoing work.

References

Blaar, M., Janß A, Dell'Anna, J., Höllig, A., Radermacher, K., Clusmann, H., 2015. Bottlenecks and needs in human-human and human-machine interaction - a view from and into the neurosurgical OR. In Dössel, O. (eds.) Journal of Biomedical Engineering / Biomedizinische Technik, Band 61, Heft 2, 135–146.

Brooke, J, 1986. SUS: a "quick and dirty" usability scale. In: Usability Evaluation in Industry. London: Taylor and Francis.

Dell'Anna, J., Janß, A., Clusmann, H., Radermacher, K., 2016. A Configurable Foot switch Unit for the Open Networked Neurosurgical OR – Development, Evaluation and Future Perspectives. i-com, 15(3), 227–247.

Janß, A., Plogmann, S., Radermacher, K., 2016. Human Centered Risk Management for Medical Devices - New Methods and Tools. Journal of Biomedical Engineering / Biomedizinische Technik, 61(2), 165–181.

Kasparick, M., Schlichting, S., Golatowski, F., Timmermann, F., 2015. Medical DPWS: New IEEE 11073 Standard for safe and Interoperable Medical Device Communication. in 2015 IEEE Conference on Standards for Communications and Networking (CSCN) (CSCN'15), Tokyo, Japan, 223–228.

Niederlag, W., 2014. Der digitale Operationssaal. 2., erw. Aufl. Berlin: De Gruyter (Health academy)

Steute Schaltgeräte GmbH & Co. KG, 2008. Multifunktions-Fußschalter. Patent angemeldet durch steute Schaltgeräte GmbH & Co. KG am 15.10.2008. Anmeldenr: DE202008013551U1. Veröffentlichungsnr: DE202008013551U1.

Stryker GmbH & Co. KG, 2003. Foot-operated control console for wirelessly controlling medical devices. Patent angemeldet am 27. Juni 2003. Anmeldenummer: US 10/607,810. Veröffentlichungsnummer: US20080140158 A1.

Van Veelen, M. A., Snijders, C. J., Van Leeuwen, E., Goossens, R. H. M., Kazemier, G., 2003. Improvement of foot pedals used during surgery based on new ergonomic guidelines. Surgical endoscopy, 17(7), 1086–1091

Disclosures

This research work has been funded in parts within the projects "OR.NET - Secure and Dynamic Networking in Operating Room and Hospital" (German Federal Ministry of Education and Research - BMBF; grant no.: 16KT1203) and the project "ZiMT - Certifiable Integrated Medical Technology and IT Systems based on Open Standards in the Operating Room and Hospital" (State of North-Rhine Westphalia and the European Commission - European Regional Development Fund (EFRE); grant no.: EFRE-0800454).height.