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Enhancing Standard Operation Procedures to design SDC Workstations for Cervical Decompression and Spinal Fusion

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Abstract

Cervical spine surgery, particularly for dorsal decompression and fusion in cervical myelopathy treatment, requires precise usage of surgical devices and instruments to achieve an optimal outcome. The surgery aims to decompress the spinal cord by removing any structures compressing the nerves. [2]

While open networked central workstations have the potential to increase efficiency and safety, they can face workflow-driven conflicts, such as limited input resources, insufficient screen space for device or patient information, and inadequate control methods. Moreover, current standard operating procedures (SOP) lack detailed information about the inter-device communication requirements.

Preventing workflow-driven errors is already addressed in high-risk applications, such as airspace [4] and nuclear power plant control rooms [1]. This paper proposes a method to mitigate workflow-driven conflicts for open networked ISO IEEE 11073 SDC service-oriented device connectivity workstations. By extending clinical SOPs by specific device and instrument usage specifications (eSOP) especially related to human-machine-interaction (HMI) requirements, we could identify potential conflicts in a proposed central OR workstation solution before bringing devices into service. The eSOP has been discussed with spine surgery specialists from the University Hospital RWTH Aachen.

1 Introduction

During surgeries, controlling medical devices and monitoring values on those are essential. With the advancement of the open communication standard ISO IEEE 11073 SDC, open networks of interoperable medical device systems are introduced in clinical settings. Central SDC workstations could enable remote controls for all interoperable medical devices. By reducing the number of human-machine-interfaces to a few or even a single touchscreen may cause conflicts due to limited screen size and input modalities. This paper presents a method to detect workflow-driven conflicts for workstations in open networked operating rooms by integrating device and instrument usage in standard operating procedures (SOP).

2 eSOP for Cervical Decompression and Spinal fusion

The SOP of dorsal cervical decompression and spinal fusion for myelopathy treatment employing surgical navigation can be split into 8 parts: **Patient preparation, opening, CT acquisition, navigation, screw placement, decompression, rod bending, and verification**. During each step, devices will be used, adjusted, or monitored at the same time or in sequences. Multiple stakeholders (anesthetist, surgeon, assistant physician, and surgical assistant) are involved in this procedure and have different responsibilities and tasks (monitoring and adjusting ventilation and medication, performing the surgery, assisting the surgeon, and performing device control). After intraoperative field analysis of spinal surgeries, we modeled the procedure in **Figure 1** using timeline analysis. Device usage is partly colored: yellow for monopolar cutting, blue for bipolar coagulation, red for drilling, and light green for tracking camera-related usage. By extending the standard operating procedure (**eSOP**) we can perform a workflow-driven conflict analysis.

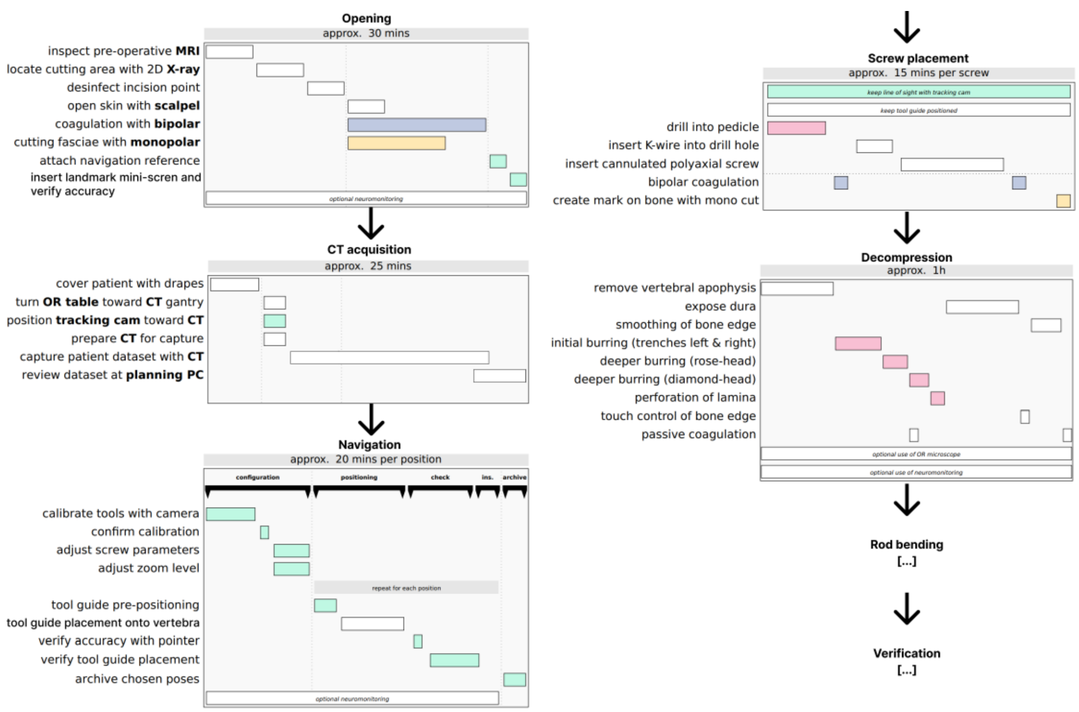

Figure 1: Extended standard operating procedure (eSOP) with device and instrument usage for a dorsal decompression and spinal fusion for myelopathy treatment employing surgical navigation

3 Requirement collection and OR Workstation Proposal

After extending SOPs to include specific device and instrument usage, the requirements from those workflow steps can be collected, and an initial integrated application-specific OR workstation interface solution for open networks of interoperable medical device systems can be proposed. We suggest using touchscreen displays, as commonly used for medical devices, with additional input devices such as foot- and hand switches. The workstation can have different views, which the user can switch. The content of the individual views is determined by the clinical process step on the one hand and by the emergencies that may occur on the other. This work will collect requirements from the first two workflow steps (**opening** and **CT acquisition)** and the devices used and propose an OR SDC Workstation Solution.

3.1 Opening

Several tasks must be performed during the opening of the surgery (see **Figure 1** top left). Those without medical device control (disinfection, opening skin with a scalpel, attaching navigation reference, insertion of mini-screw) and those with device interaction (inspecting MRI and X-ray, monopolar cutting, or bipolar coagulation). Therefore, we need at least the following requirements for an integrated application-specific workstation interface solution

- View and inspect MRI images (min. 2 MP resolution, luminance between 1-350cd/m²) [3]
- View, inspect, and edit X-ray (min. 3 MP resolution, luminance between 1-350cd/m²) [3]
- Enable activation of HF device for monopolar cutting and bipolar coagulation and adjust power values and modes

3.2 CT acquisition

When reviewing the CT acquisition (see **Figure 1** center left), we have the following devices- and SOP-related requirements:

- Perform OR table movement
- Position and check tracked landmarks
- Perform CT movement CT
- Activate CT remotely from outside the OR
- Review the recorded dataset by identifying relevant structures

3.3 Device Requirements

Device-specific requirements could address the displayed GUI or control methods to change properties. Previous work identified a method to describe those as part of a UI Profile [5].

- Min. Resolution and maximum pixel pitch (0.21mm) for MRI and X-ray screens [3]
- Input methods for navigating through MRI and X-ray images
- Tracking system display (MRI and X-ray images can be integrated into such a system)
- Tracking system interaction method over touch or mouse/keyboard
- Safe CT adjustment and multi-step hardware activation method

- Emergency stop using hardware push button for OR table
- Hardware buttons for OR-table and X-ray motion control
- HF power, mode, activation method, connected instrument, and neutral electrode status display
- HF activation using foot pedal or hand-switch

4 SDC Workstation proposal

Based on the workflow and device requirements analysis for the opening and CT acquisition steps, we propose a comprehensive SDC workstation solution, as shown in **Figure 2**. Integrating device usage into the SOPs and using it as a base to build such an application-specific SDC workstation interface solution has the potential to prevent workflow-driven conflicts before bringing devices into service.

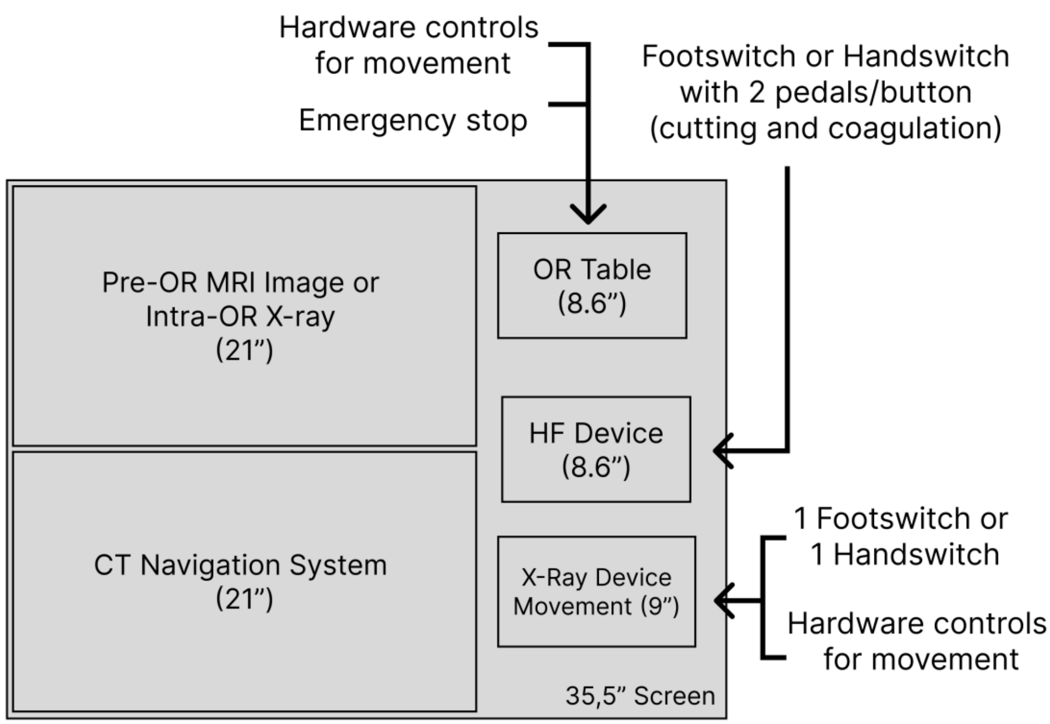

Figure 2: Proposed workstation solution consisting of Screens for the navigation system, MRI Screen, OR table, HF Device, and X-Ray device.

The total number of input methods consists of a foot- and hand-switch combination with three buttons/pedals, hardware controls for the OR Table and X-ray devices, and an emergency stop for the OR Table. The X-ray device GUI does not contain the recorded X-ray image but a display as feedback for moving the X-ray device.

For safety reasons, we recommend installing this workstation solution twice. In case of an error, the second system could be used. Depending on the user, the solution must be covered by a sterile foil. By including all workflow steps in this methodology, the view could be enlarged, split into multiple views, or even integrated into different views on one workstation, and the user could switch between the views.

It is essential that required information is visible at all times and critical functions are available at all times.

4.1 Overview of conflict potentials

Several potential conflicts to be addressed by enhanced SOP specifications can impact efficiency and safety in designing application-specific solutions for integrated workstations, such as for cervical spine surgery:

- **Limited Screen Size**: Limited screen space may cause device interfaces to be displayed in a way that makes the view or control unusable.
- **Information Overlap:** Critical information or controls must not be hidden during certain workflow steps, such as when a CT image hides HF activation options.
- **Limited input resources)**: Insufficient input devices may not support all required functions simultaneously, such as conflicting foot pedal function requests that are available on foot switches during specific steps. This can be prevented by selecting appropriate and sufficient input devices based on the proposed eSOP.
- **Inadequate input modalities:** Human resources might be occupied in parallel critical tasks, preventing device operation (e.g., surgeons needing both hands).
- **Insufficient controls display:** Critical functions, such as emergency stop, OR table, or X-ray motion control, should always be easily identifiable and accessible for the user.
- **Redundancy:** Device failures without redundancy could lead to operational shutdowns, like a monitor failure causing a total system halt.
- **Excessive GUI Switching**: Frequent interface changes could increase cognitive load, complicating navigation in operations. Especially when users cannot get used to where to find which information.

5 Conclusion

In conclusion, this paper presents a workflow- and device-requirement-driven design approach for the design of SDC workstations. By extending standard operating procedures with device and instrument usage specifications and reviewing device-specific requirements, we could identify and address those issues and build an application-specific SDC workstation.

6 References

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