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Interaction concept and system architecture for the sterile information system *OR-Pad* in the perioperative area

Abstract: Access to clinical information during interventions is an important aspect to support the surgeon and his team in the OR. The *OR-Pad* research project aims at displaying clinically relevant information close to the patient during surgery. With the *OR-Pad* system, the surgeon shall be able to access case-specific information, displayed on a sterile-packaged, portable display device. Therefore, information shall be prepared before surgery and also be available afterwards. The project follows an user-centered design process. Within the third iteration, the interaction concept was finalized, resulting in an application that can be used in two modes, mobile and intraoperative, to support the surgeon before/after and during surgery, respectively. By supporting the surgeon perioperatively, it is expected to improve the information situation in the OR and thereby the quality of surgical results. Based on this concept, the system architecture was designed in detail, using a client-server architecture. Components, communication interfaces, exchanged data, and intended standards for data exchange of the *OR-Pad* system including connecting systems were conceived. Expert interviews by using a clickable prototype were conducted to evaluate the concepts.

Keywords: OR-Pad, sterile information system, interaction concept, system architecture.

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1 Introduction

Providing access to clinical information in the operating room (OR) is an important aspect in terms of supporting the surgeon and his team during surgery. Easy access to electronic patient records is not possible in most ORs [1]. Monitors are often too far away [2] from the surgical area. Therefore, relevant information for the surgeon, like preoperative images, is hard to read. Moreover, the surgeon needs assistance to view desired information [3] or to change information on monitors. Taking supportive materials like handwritten notes or surgical planning into and out of the OR is also difficult.

Several research groups already deal with supporting the surgeon within the OR, e.g. by providing clinical information in form of intraoperative usage of the electronic patient record [4] or displaying context-relevant information [5][6]. The demand of the surgeon to have clinical and helpful personal information, like notes, nearby, directly interact with the system and also be supported by automatically presented information, is not focused.

The idea of the application-oriented research project *OR-Pad* [7] is the improvement of the information flow for the surgeon in the perioperative area. Before surgery, the surgeon should be able to preselect relevant information such as X-ray images or personal notes to be available during the intervention. In the OR, all clinically relevant information should be displayed close to the surgeon. Due to a sterile touch-display, direct interaction with the system is possible. During the intervention, new information such as intraoperative images or spoken notes can be acquired and is accessible after surgery. This paper describes the *OR-Pad* system, focusing on the interaction concept and system architecture, leaving aside details of the other concepts.

2 Methods

The *OR-Pad* system is developed iteratively using an user-centered design process. In each development cycle, clinical observations, qualitative or quantitative surveys with clinicians are conducted. The collected data is analyzed and used to specify and update the requirements for the system. These requirements resulted in interaction concepts which were implemented as a clickable prototype. Usability and functionality are evaluated with our clinical partners from departments of urology and anatomy at the University Hospital Tübingen as well as with other clinicians.

The first concept was very static and the user interface was structured along with functionalities, like show patient data, view preoperative images or make notes. The second approach focused more on process-accompanying support and linked functionalities (e.g. make notes in images). In the third iteration, the process-based approach was discarded as well due to the user test results. In accordance with these results, a new vision was pursued that focused on the original core idea of information sharing: Supporting the surgeon by providing access to information and improve the information flow. The third iteration combined the advantages of both concepts and all knowledge achieved through the cycles before, to provide static but linked functionalities. Furthermore, the system was reduced to core functionalities due to information overload, which was perceived in iteration two.

Via requirements analysis, the vision and goals of the system were specified as follows:

1. Access available case information of an intervention fast and uncomplicated.
2. Create materials and transfer them to/from the OR.
3. Provide materials and case information close by the surgeon during surgery.
4. View and highlight materials and case information.
5. Support the surgeon with context-relevant information during surgery.

A quantitative user survey, comprising the specification of the planned system, was conducted to verify readiness for use and usability in order to subsequently create new concepts. 46 surgeons from twelve disciplines participated. The demand for use was recognizable, but other functions were also requested.

On basis of the requirements analysis and quantitative survey, the *OR-Pad* system was redesigned. Concepts for interaction design, communication interfaces to relevant external systems, standards to be used for data exchange, infrastructure with components, data and their communication, graphical user interface, hardware, and situation recognition were created.

To develop the interaction concept, knowledge from the iterations before, like requirements, were taken into account. For the system architecture, main components, communication interfaces to external systems, data to be exchanged, and the communication standards to be used were identified.

The system architecture was designed in detail based on the concepts before by defining structure, components, interactions, and data model. The goal was to develop an emergent design that is easily maintainable and easy to follow. Components should be separated to ensure independent development and expandability for further requested functions. Seven example use cases from orthopaedics were chosen because of the diversity of information to demonstrate the system's functionalities.

3 Results

3.1 Interaction concept

The *OR-Pad* system was designed to support the surgeon during the three phases before, during, and after surgery. Therefore, the system consists of a mobile and an intraoperative mode.

The mobile application can be used before and after an intervention, consisting of the same functionalities, and is designed to run on the personal device (e.g. smartphone) of the surgeon or any desktop computer in a web browser. After login with his personal login data, the surgeon can see an overview of upcoming interventions in a calendar. For each intervention, all available case information, e.g. patient data or radiological images, is loaded from clinical systems. The surgeon has now the opportunity to mark important information he wants to be highlighted during surgery. He also can enrich information, e.g. highlight a tumor, as well as add new content like notes or schematic diagrams useful for the upcoming intervention. In addition, the surgeon can specify, in which surgical phase he wants to automatically see this information. This information is persisted to be present during the intervention.

In the intraoperative phase, the intraoperative application is used on a tablet PC near the patient and directly at the surgical field. Therefore, a flexible holding arm, e.g. attached to the operating table, is applied to ensure information to be in immediate vicinity to the surgeon and in ergonomic visual axis. Sterile packaging is used to ensure that direct interaction by the surgeon via touch in the sterile environment is feasible. After login with the OR associated login data, an overview of the intervention is displayed. For this intervention, all case information from clinical systems as well as prepared content is made available. Information marked as important can be filtered for faster retrieval. Information is displayed automatically depending on the actual operating phase if this was specified in advance. During the intervention, the surgeon also can create and add new content like notes, photos, or voice recordings as well as edit information. This additional information is persisted to be present after the intervention.

Figure 1: Main view of the mobile and intraoperative application modes of the *OR-Pad*, displaying information in a timeline.

For follow-up, the mobile application can be used again by personal login to get an overview of past interventions. For each intervention, all case information as well as content prepared before and created during intervention is displayed. The surgeon can use this data for follow-up, e.g. the creation of the surgical documentation. He also can edit and add content like in the two phases before.

Both, the mobile and the intraoperative application, share the same design concept (see Figure 1). General patient information and data from the situation recognition are shown at the top. The central element is the timeline in the large central area of the interface. It displays the available case information of the intervention chronologically, and categorizes this information by color coding. In addition, at the very bottom of the timeline a function field is visible to add materials to the timeline.

3.2 System architecture

Figure 2 visualizes the main components of the *OR-Pad* system, its communication interfaces and data that is exchanged. The *OR-Pad* system itself was developed as a progressive web app, because of the advantage of being platform-independent and simultaneously have the appearance of an app. Accordingly, a client-server architecture was chosen.

The client was planned for touch interaction with tablets and smartphones to provide information to the surgeon via responsive user interfaces. To view those information, a viewer for different formats, e.g. PDF, was implemented. To enable the creation of new materials via camera and microphone, a component for hardware access was contemplated to control the needed hardware of the displaying device. For communication between clients and server, websockets were used. The *OR-Pad* server was implemented using the Node.js platform.

To enable context-sensitive information, the server will be connected to a situation recognition system to get the surgical phase the intervention is currently located. For data exchange, a publish-subscribe pattern will be used so that the *OR-Pad* system can register itself to the situation recognition to automatically get updated situation information. For data acquisition and analysis, the situation recognition component needs to receive information from various sensors in the OR providing data, e.g. cameras to obtain an OR video, RFID sensors to obtain position data of instruments, or device data to obtain status information. The connection of these devices will be implemented based on the SDC standard and the underlying OSCP protocol. For testing the current stage of the prototype, the situation recognition was replaced by a mock-up providing pre-defined intervention states.

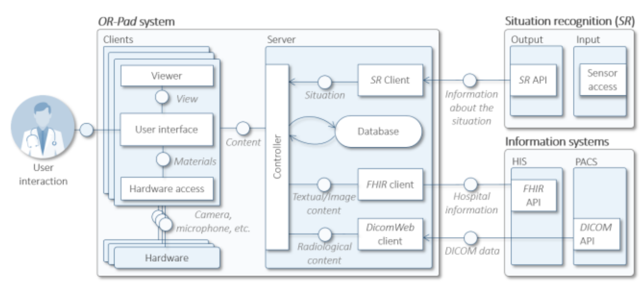

Figure 2: Components, communication interfaces, and exchanged data of the *OR-Pad* system including connecting systems (FMC structure diagram).

The connection to the HIS and the PACS will be used to obtain the information available of the case of the intervention. Via HIS, the *OR-Pad* server will receive the information of the intervention, such as operation planning data or case information. In addition, it will provide references to image data in the PACS, which is then retrieved via the corresponding connection. Created materials (e.g. images taken intraoperatively) are also added to the case file in the HIS. Therefore, this connection is intended to be bidirectional. For clinical information exchange, a FHIR interface which can be accompanied by other standards, e.g. HL7v2, as needed, was implemented. The communication to the PACS is realized using the DICOMweb standard. For the actual prototype, no real productive HIS and PACS were used.

The NoSQL database provided on the *OR-Pad* server will only store data that is not already, or is not intended to be, in HIS or PACS, like phase mappings or favorites for the respective intervention to ensure data consistency. The intervention represents the central element of the data model. By coupling the OR and the associated surgeons, each surgeon involved will be able to shape this information space.

Based on the concepts before, the *OR-Pad* system architecture was detailed. To separate the functionalities, a layered architecture was chosen based on the divide & conquer principle. The client and server part were designed up to component level in individual layers. Overall, the *OR-Pad* system follows the Model View ViewModel architecture (MVVM) and thus reduces the amount of data within the system to the relevant information by means of the intermediate ViewModel.

To define the communication processes, i.e. the exchange of messages between the server, clients, and external systems, repetitive flow charts were used to define all sub-processes. The principle of parallelization was planned to minimize loading times by simultaneous computations on client and server side. For good scalability, the amount of data transfer will be taken to a minimum by using data transfer objects and bidirectional, event-based communication without polling by using a websocket. To keep the query times in the *OR-Pad* system between server and clients low, a data model for the transfer was defined.

3.3 Expert interviews

For evaluating the concepts, expert interviews were conducted with the two project partners from urology and anatomy of the University Hospital Tübingen. In both conversations, the current status was presented, the prototype was shown and the further procedure was discussed.

Both project partners confirmed the concept. The prototype and the operating concept were described as intuitive and well thought out. There were only minor comments, e.g. regarding wording or the specification of certain designations. Other ideas for securing the tablet, such as attaching it to the patient's abdomen or torso with sterile tape, were mentioned. It was also stated that a security concept is needed to protect the tablets from theft in the OR. Furthermore, data security must be ensured and data management must be limited to the hospital system.

With the feedback and confirmation of the project partners, the development of the high-fidelity prototype could start in the last cycle of the fourth iteration. Security aspects were only considered to be relevant for the transfer into a product and thereby were left out for implementation.

4 Discussion

The *OR-Pad* system enables access to all available case information of an intervention by clinical systems, like HIS and PACS, before, during, and after surgery. At any time, the surgeon can directly interact with the system without the need of assistance, providing e.g. preoperative images close by.

Moreover, through the possibility to upload own images, create notes and edit information, e.g. circle a tumor in a radiological image, to be useful during intervention or for follow-up, the information flow can be supported as desired. The surgeon can take case information and prepared content into the OR as well as information created during surgery out of the OR. At any time in the perioperative workflow, relevant information can be accessed and modified, supporting the surgeon. Through the timeline element, all information and self-created materials are available chronologically and thus make it possible for the surgeon to find the information more quickly. The surgeon can further be supported through reducing interaction effort by automatically providing context-relevant information [8] as well as highlighting content. By supporting the surgeon in the complete perioperative process, it was expected to improve the information situation in the OR, and thereby also improve the quality of surgical results.

For demonstration, only orthopedically use cases are integrated. The clinical need depends on the use cases, so further development may be required to adapt the concept to better assist other interventions from different disciplines, like surgeries solely being done via endoscope.

For the system architecture, a layered architecture was chosen to separate responsibilities and achieve a decomposition into a set of self-contained loosely coupled components. Thus, a clear, understandable structure of the system with clear function ranges and the possibility for independent development could be achieved. As stated before, the system was reduced to core functionalities, but can be extended for other clinical needs in further development.

The different information requirements, the real-time demand, and the synchronicity of the clients regarding their data, the size of the data volume, and the bidirectional communication between clients and server were challenging during conception. Furthermore, a challenge with the data model was to handle a large amount of complex data and its distribution over the different external systems.

5 Conclusions

The *OR-Pad* system was designed to support the surgeon in the perioperative area by providing relevant information near the patient and enable direct interaction with the system. The research project went through several iterations of an user-centered design process, emerging in the third iteration in the final vision. Based on that, the interaction concept and system architecture were designed in detail to cover the requirements of accessing case information, creating materials, transferring all information to be provided in the OR, and supporting via context-relevant displaying. Expert interviews confirmed the concepts.

In the fourth iteration, the developed concepts were realized within a high-fidelity prototype. Therefore, dummy data was created, the infrastructure was built, and clinical communication was implemented. In addition, the communication within the application and client functions were realized. The demo application was integrated and tested in the research OR. The result was then checked with the help of a technical and functional evaluation. The developed prototype will now undergo thorough pre-clinical and clinical evaluation to assess the final usability and usefulness of the prototype. On the basis of this evaluation, the system will be expanded to include further wishes and needs for broad applicability.

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