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A transferable situation recognition system to enable context-aware systems for the scenario-independent support of the surgical team

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1 Introduction, aims, and objectives of the thesis

1.1 Motivation and problem

The perioperative support of surgeons and the surgical team, i.e., before, during, and after surgical interventions, is one of the emerging research topics in computer-assisted medicine. Surgical assistance systems enable the support and optimization of pre-, intra-, and postoperative processes, such as for preoperative planning, intraoperative decisions, or postoperative documentation, through the integration of advanced technologies. The operating room (OR), in particular, is a complex and unpredictable environment [Lee et al. 2019], which means that effective workflows are especially relevant for optimized outcomes. The aim is therefore to provide the best possible support suitable to the intraoperative situation [Neumuth 2012]. In the long term, this will lead to improved surgical and patient outcomes as well as will positively impact aspects such as the surgical workload [Rockstroh et al. 2017], resources, and costs [Lee et al. 2019]. The vision is toward an intelligent OR [Franke et al. 2018; Pirlich et al. 2019] in which systems dynamically adapt their functionality based on the environment and situation, thus behaving context-aware [Pernek and Ferscha 2017; Neumuth et al. 2018]. Thereby, surgical processes can be supported in a targeted manner to relieve the surgical team and increase the quality of care.

Context-aware systems (CAS) provide information and/or services that are relevant to the current situation [Dey 2001] by intelligently responding to changing surgical circumstances and conditions. The variance of possible assistance functions for intraoperative support is comprehensive, ranging from the provision of situation-relevant information to process automation. While [Abowd et al. 1999] and [Dey 2001] categorize context-aware behavior into the presentation of information or services, the automatic execution of services, and the assignment of information to situations, [Barkhuus and Dey 2003] distinguish between more abstract categories, covering personalized, passive, and active behavior. The literature investigates the provision of pending tasks [Christov et al. 2016; Avrunin et al. 2018; Ryniak and Burgert 2020], preoperative images [Frommer et al. 2021], automatically filtered information [Katić et al. 2013; Stauder et al. 2012], or the estimated intervention time [Franke et al. 2013; Twinanda et al. 2019; Bodenstedt et al. 2019]. Furthermore, decision support [Jalote-Parmar and Badke-Schaub 2010], semi-automated surgical reports [Berlet et al. 2022], control of surgical robots [Beyl 2015; Wagner et al. 2021], or automated device configurations [Kasparick et al. 2019b; Rockstroh et al. 2017] are under discussion.

In order to achieve such context-aware behavior, the current situation in the intelligent OR needs to be recognized in a reliable and robust manner. Situation recognition is essential to the understanding and interpretation of relevant information [Katić et al. 2013] to derive knowledge about the current and future intraoperative processes, i.e., achieve situation awareness. [Endsley 1995] defines three levels of situation awareness, i.e., perception, comprehension, and projection, based on which decisions can be made and actions be performed, whereby various factors can impact the situation awareness. Situation awareness is achieved through a comprehensive understanding of the environment. Therefore, contextual information about the intraoperative circumstances, describing any information to characterize the situation of a person, place, or object [Dey 2001], needs to be retrieved from the surgical environment. This includes any data that can be acquired from available intraoperative sensors [Dergachyova et al. 2016]. These are then interpreted knowledge-based to derive the surgical situation [Speidel et al. 2018]. The resulting situation awareness focuses on specific events and information within the context, e.g., the current surgical phase.

To retrieve and incorporate different contextual information, both data sources already present in the OR, e.g., endoscope [Jin et al. 2020] or medical devices [Malpani et al. 2016], as well as additional sensor systems, e.g., RFID tracker [Meißner et al. 2014], can be used. The latter requires the installation of additional equipment [Jin et al. 2018] and must meet the requirements of the sterile environment. State-of-the-art situation recognition approaches prefer to use video data or instrument information but also employ person trajectories, system events, activities, or combinations of different sensor data [Junger et al.

2022b]. Furthermore, other kind of data sources, such as audio [Li et al. 2016; Seibold et al. 2022], may be used as sensor data. Each of the data types has advantages and disadvantages [Malpani et al. 2016]. Theoretically, the sum of data sources already present in the OR covers the necessary information for situation recognition [Speidel et al. 2018]. It is, however, desirable to integrate as many diverse sensors as possible [Kowalewski et al. 2019].

By processing this knowledge, the current situation in the OR can be derived. The acquired information is mapped to the surgical situation [Franke et al. 2018]. The majority of state-of-the-art approaches applies different machine learning (ML) techniques, e.g., CNN, HMM, or SVM, realizing online-capable and offline-restricted approaches [Junger et al. 2022b]. Nevertheless, rule-based approaches also exist (e.g., [Katić et al. 2014; Katić et al. 2015]). While the surgical workflow can be recognized at different granularities [Lalys et al. 2012], existing approaches focus on the recognition of phases in laparoscopic cholecystectomies or cataract procedures [Junger et al. 2022b]. However, some approaches also interpret steps and activities as well as other surgical interventions [Junger et al. 2022b]. These granularities can be assigned to the functional context, whereas resource-, patient-, or procedure-related context can also be defined [Franke and Neumuth 2015b].

In addition to intraoperative tracking and processing of sensor data, the structured formalization of surgical processes and knowledge is another key aspect of context-aware surgical support [Franke et al. 2018; Neumann et al. 2022; Katić et al. 2015]. For machine interpretation, the relevant information must be known and formalized beforehand [Alegre et al. 2016]. Medical knowledge can be incorporated by modeling the course of the surgical intervention or additional process-related information to integrate the knowledge of both sensors as well as processes for situation recognition. Being aware of the possible course of the intervention, the following situation can be recognized more reliably. Complex surgical process models (SPM) [Neumuth 2012; Lalys and Jannin 2014; Neumuth 2017] can depict the surgical context and underlying clinical process steps on different formalization levels, whereas ontologies may be used to represent technical and medical knowledge such as anatomy, surgical strategy, devices, and their usage [Kenngott et al. 2017]. Thus, the surgical workflow can be depicted in fine granularity, for example, by assigning activities to triplets of action, surgical tool, and anatomical structure [Lalys et al. 2013], or a 5-tuple of actor, body part, surgical instrument, surgical action, and anatomical structure [Meißner et al. 2014]. In the literature, a selection of approaches state to use SPMs or ontologies to incorporate process information or realize rule-based interpretation [Junger et al. 2022b].

Overall, several research groups already deal with CAS and situation recognition in general. The promising approaches for intraoperative situation recognition differ in many aspects, from sensor data sources and interpretation methods to recognized granularities and surgical interventions [Junger et al. 2022b]. Most of the existing approaches focus on and support dedicated cases, i.e., they are tailored for a particular surgical intervention and defined sensor input [Junger et al. 2022b]. Some address aspects such as adaptability, but rarely demonstrate these, and if so, then only for selected factors [Junger et al. 2022b]. Presumably, they can only be used to a limited extent in similar or other surgical settings and the effort required to adapt these approaches for other cases is substantial [Junger et al. 2022b]. Other work also mention this lack of generalizability, limiting the application across, for example, interventions (e.g., [Maier-Hein et al. 2021; Glaser et al. 2015; Das et al. 2022; Meißner 2015]).

However, the surgical environment and intraoperative processes are complex [Demir et al. 2023], highly variable, and may be unpredictable. Available data sources and surgical interventions can differ between hospitals, ORs, and patients, as well as be affected by a number of other factors. For instance, the devices used can be different between surgeries and patients [Kasparick et al. 2018], or surgical processes be performed differently between hospitals [Avrunin et al. 2018]. Furthermore, surgical processes and equipment can evolve, for example, leading to new process variants or deviating sensor input. Whole new application areas can emerge that demand situation recognition and context-aware support. Thus, the variability within the surgical field is high.

Despite changing surgical settings, whether caused by case-specific variances or environmental changes, differences across facilities, or even new application areas, an intraoperative situation recognition must function in a reliable and robust manner. It must not fail because a specific sensor is not available or an intervention is performed differently. The variety of influential factors in the dynamic surgical environment, such as surgical processes, involved instruments and devices, or surgeon- and patient-related aspects [Lee et al. 2019; Rockstroh et al. 2017], raises challenges for the broad application of situation recognition approaches. All these challenges must be addressed and overcome to adapt appropriately to deviating surgical processes and equipment [Junger et al. 2024b]. The importance of transferable approaches within the OR is undeniable. However, while many research groups deal with specific issues, e.g., standards for better interoperability of medical systems (see IEEE 11073 Service-oriented Device Connectivity (SDC) standard series [Kasparick et al. 2018]) or common formalization of surgical workflows (see ontology OntoSPM [Gibaud et al. 2018]), significant for achieving better applicability, the overarching question of how a system can use these elements to be transferable on several levels in different contexts is not addressed. As the results of [Junger et al. 2022b] indicate, no approach focuses on a comprehensive, versatile system for situation recognition in the intraoperative area and addresses overarching applicability and transferability in changing surgical settings, i.e., different scenarios.

1.2 Relevance and goal

Situation awareness is the key technology for targeted, context-aware support of the surgical team and is hence a prerequisite of the intelligent OR and situationally adaptive systems. Due to the depicted variability and changeability of surgical settings caused by the dynamic environment between scenarios, the transferability of situation recognition is essential for the versatility and efficiency of an intraoperative system to bring broadly applicable CAS into the clinical routine. In order to cope with the versatile, changing requirements, it is crucial to address all facets as a whole. Otherwise, systems can only be used for dedicated cases and are not reliable in the event of changing or new scenarios. Intelligent systems must be able to adapt to environmental changes, while at the same time must be expandable to ensure broad usage and durability in the long term. Realizing a system that is adaptable and easily transferable to different scenarios, while addressing the entirety of variances and factors, would have a major impact on the future intelligent OR.

Current scenario-specific approaches were not designed to deal with other requirements, need to be specifically tailored in case of varying circumstances, and therefore may require to be developed from scratch. In contrast, a system that generalizes functionalities, shares knowledge, and functions with different sensors would be seamlessly applicable and scalable more efficiently across changing scenarios. Tailored to be compatible and interoperable with different external systems and surgical knowledge, such a system would allow versatility. Due to the amount of functionality and information that such a versatile system would have access to, variations, uncertainties, and perhaps even unforeseen situations can be handled more robustly. Implementing a modular architecture, adjustments can be made in a more targeted manner. Functionalities and knowledge may be reused or components be added, modified, or replaced without affecting the whole system. This ensures better portability. Fewer implementation efforts can be expected to adapt to changing or new scenarios, in contrast to developing another system for each new scenario or altering existing approaches not designed for adaptability. Although a comprehensive system would be more complex as it combines all functionalities and knowledge required for the various scenarios, maintainability resources such as costs and time would be reduced. Maintaining a variety of a large number of specific, differing systems that fail in changing conditions would be more extensive. Thus, highly specialized approaches are not economically viable. Despite promising results from research projects, they are not transferred into the clinical routine.

Overall, an applicable and transferable system that serves all scenarios, instead of only dedicated settings, would surpass scenario-specific approaches due to its versatility and adaptability in the context of the intelligent OR. It may excel in comprehensive knowledge, generalized and adaptive functionalities, and resource efficiency to be applicable and transferable across diverse contexts, thus enabling broadly deployable CAS to improve surgical outcomes in the long term. This requires a system architecture that specifically focuses on adaptability on multiple levels. An intraoperative situation recognition system (SRS), characterized by a generalized, modular system architecture, could enable the desired applicability as well as transferability beyond specific scenarios by specifically implementing transferability-relevant aspects and addressing the full variance of surgical interventions, sensors in surgical environments, and surgical situation recognition methods. Consequently, a scenario-independent recognition of the intraoperative situation could be achieved, regardless of the available sensor technology and the surgical procedure, to realize the targeted support of the surgical team independent of a single use case setting. With the assumption that an appropriate approach for such a flexible, transferable SRS is not yet available for the specific area of intraoperative situation recognition, the main objectives of this work are:

(1) the development of a high-level concept and basic framework prototype for a transferable situation recognition system that can recognize the current situation in the OR independent of the surgical setting and
(2) the proof of concept evaluation of the situation recognition system with a focus on the applicability and transferability to multiple scenarios for broad surgical assistance.

Based on the results of a state-of-the-art review, already used to illustrate the lack of applicability and transferability of existing approaches, the need for a transferable, intraoperative SRS is elaborated as the basis for the following objectives. These focus on the development, prototypical implementation, and evaluation of a high-level concept for scenario-independent situation recognition in the OR, fundamentally enabling applicability and transferability to different surgical settings for broadly applicable context-aware assistance. As no system can solve the many challenges of transferability at once, the concept will need to be iteratively concretized and further developed. Given a framework that allows general adaptability and is easily expandable, the remaining challenges can be addressed step by step to iteratively improve the system. Thereby, a foundation for further incremental development will be given.

Besides these objectives focusing on the overall system, dedicated solutions for sub-challenges need to be addressed in order to achieve transferability. Research questions, such as standardized device communication or ontological knowledge representation, are extensive. Especially dealing with the variability of surgical interventions and standardized provision of the surgical situation for context-aware behavior are elementary prerequisites for realizing a transferable situation recognition and broadly applicable CAS for the support of various interventions. One promising approach is the formalization and modeling of intraoperative processes to incorporate process knowledge. However, flexible modeling techniques are necessary to represent the reality of intraoperative processes in all its facets, including, for example, different process variants and techniques, to justify the highly dynamic domain. Furthermore, the transfer of SPMs to other hospitals and case-specific interventions is essential to enable efficient situation recognition in the OR for a variety of surgical settings, particularly supporting intervention-independency. New approaches that address the high variability of surgical processes would further improve the intervention-independent applicability as well as transferability of the SRS. Moreover, the vision of a comprehensive SRS, following a modular approach, raises the challenge of providing the information to different CAS. As both, situation recognition and context-aware behavior, are complex and individual concepts, the de-coupling of their complexity is reasonable. Standardized communication would enable the consistent provision of contextual information by the SRS, making the recognized information accessible to various external systems to be used on their demand. This information can then be processed and used by different CAS. The added value of such an interface needs to be demonstrated using an exemplary CAS for intraoperative support, which can also be used to derive requirements for design decisions during development. Reasonably, a special focus on sub-components of the SRS on the process level, specifically the process modeling and control of SPMs and the standardized provision of contextual information to CAS, brought up the following secondary objectives:

(1) the investigation of process formalization approaches to specifically address the variability of surgical interventions and
(2) the standardized provision of recognized information to various context-aware systems including the exemplary demo system of the *OR-Pad* project.

Overall, this work intends to significantly contribute to the intelligent OR and the deployment of situationally adaptive systems. The state-of-the-art review, as an important step toward the depicted objectives, will provide a taxonomy for the assessment of situation recognition approaches, depict a comprehensive overview of existing approaches, discussed within categories, and highlight the importance and lack of applicability and transferability. The derived and proposed high-level SRS concept and framework prototype will be an essential contribution and basis for numerous innovations in the intraoperative area, particularly the realization of transferable intelligent systems in the OR and broadly applicable CAS. It will provide design strategies for transferable SRS and a foundation for addressing specific transferability issues to be applicable to different surgical settings. The SRS could be used as the basis for further research and development of a transferable system, applying to the variety of available sensors and surgical interventions. Furthermore, it could provide a platform for tests and assembling approaches. It will imply the potential to reduce the number of individual, specific systems and establish a common information base, characterized by sharing knowledge, reusing functionalities, and even learning from other scenarios. Thus, coping with different challenges could be addressed and new challenges be researched and integrated over time. If transferable situation recognition is possible, CAS could be designed to provide targeted support for intraoperative processes and optimize the work of the surgical team in many aspects.

The specialization of the concept in the area of process modeling and information provision for CAS will demonstrate the expandability and applicability of the SRS as well as show a further step toward transferability between surgical scenarios. New process modeling techniques could lead to improved formalization of intraoperative processes with all variations and enable transferability between ORs and hospitals. As process models are also relevant for supporting other clinical and non-clinical processes, other application areas could benefit from the new concepts. An interface between SRS and CAS could allow standardized provision of contextual information. Thereby, one SRS could serve a variety of different CAS independent of their aim, enabling broadly applicable CAS for the targeted support of the surgical team. The SRS concept and the clinical relevance will be demonstrated via the exemplary CAS of the *OR-Pad* project (in the following referred to as *OR-Pad*), which provides clinically relevant information for the actual surgical situation. Furthermore, the single methods, such as the state-of-the-art results, process modeling techniques, standardized information provision, and context-aware behavior, could also be reused in other work to improve transferability in highly specialized systems.

1.3 Hypothesis and methods

Based on the objectives defined, this thesis pursues the following hypothesis:

> *It is possible to develop a flexible, transferable situation recognition system for different surgical settings to enable broadly applicable context-aware systems.*

This thesis is settled in the interdisciplinary field between medicine and informatics, focusing on software engineering and related computer science topics in the medical context. An iterative development process with incremental refinement and enhancement mixed with a prototyping approach was chosen to achieve the defined main objectives, address the secondary objectives, and finally prove the hypothesis. This should demonstrate the feasibility of a transferable SRS for the realization of broadly applicable CAS for different surgical settings. The established software engineering approaches applied comprise aspects of requirements analysis, design, implementation, and evaluation of systems and their components within the development cycles, leading to the fulfillment of the overarching goal.

Specifically, a systematic analysis of state-of-the-art approaches for situation recognition in the intraoperative area elaborates on the need for a transferable approach. Based on a holistic concept, an initial framework prototype is developed that can evolve to increase its complexity and can be adapted to changing requirements in perspective, employing a combination of a top-down and bottom-up approach. This methodology is characterized by creating an abstract, general concept of the system comprising layers and modules based on requirements, following established software engineering best practices to realize the system architecture with a focus on adaptability and expandability. The result is a high-level view of the system's architecture as well as its structure and major components. Next, a concrete system is derived by realizing the architecture via prototyping and incrementally refining and building the components. Individual components can be specified or extended via the step-by-step design and gradual refinement, addressing further transferability issues. Regular tests within the cycles ensure the quality of the designed and implemented components and communication with external components. Overall, both a high-level design and a gradual refinement and enhancement of functionalities enable continuous improvement and adaption, realizing a balanced and effective development process. Thus, the developed system can evolve while still aligning with changing needs and insights throughout its research and development lifecycle by iterative refinement and enhancement. Thereby, the adaptability and expandability of the approach can also be demonstrated.

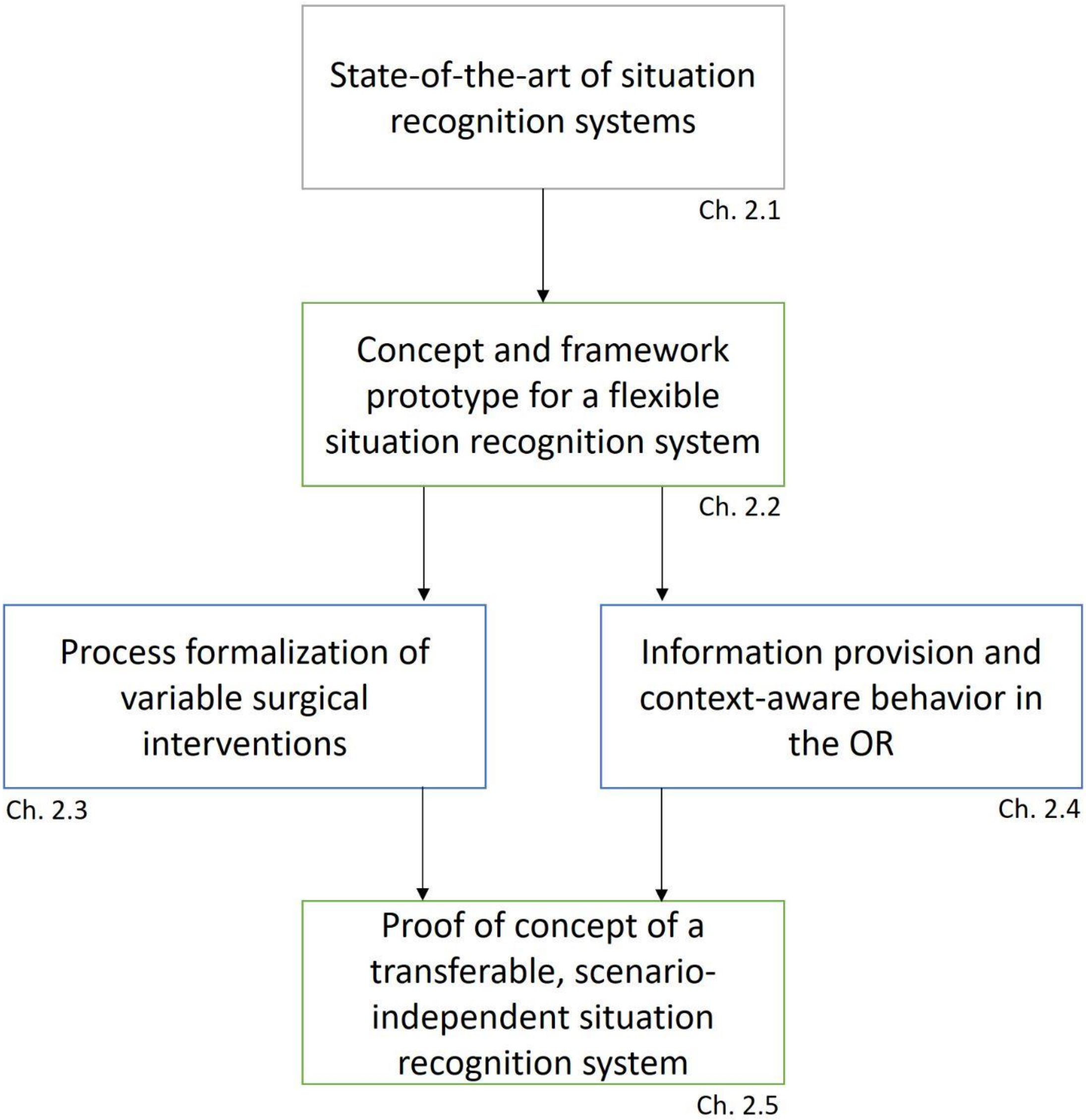

Figure 1: Graphical overview of the main chapters, comprising six publications in the area of situationally adaptive operating rooms (OR), and how they build on each other. The grey chapter (ch.) elaborates on the overall aim, the chapters highlighted in green address the main objectives, and the blue chapters depict secondary objectives. The publications do not follow a time-based sequence but logical order, bringing together the individual contributions at the end.

Following the described procedure, chapter 2 depicts all individual contributions to the overarching goal, comprising a total of six publications (see Figure 1). First, a systematic state-of-the-art analysis of situation recognition approaches for intraoperative procedures in the context of broad applicability and transferability gives a review of the research topic and elaborates on the aim of this thesis (see chapter 2.1) [Junger et al. 2022b]. It further introduces a taxonomy for the assessment of situation recognition approaches to extensively analyze and discuss the state-of-the-art as an important first step. Based on the results, a concept for a flexible and transferable SRS in the OR is outlined, implementing defined requirements for the functionality and transferability of the system, and realized as a basic framework prototype of four layers to demonstrate the overall functionality of the modular architecture (see chapter 2.2) [Junger et al. 2022c]. The system is assessed via a functional evaluation. Furthermore, the potential for applicability and transferability of the system to other sensor data and surgical interventions is shown.

Specific transferability issues are then incrementally addressed to further specify, extend, and thus improve the concept and prototype, comprising work on process formalization of variable surgical interventions (see chapter 2.3). The standards Business Process Model and Notation (BPMN), reaching its limits with complex interventions, and Case Management Model and Notation (CMMN), promising to be more flexible, are investigated for modeling intraoperative processes (see chapter 2.3.1) [Junger et al. 2024a]. The more variable modeling language depicts new process models and a practical comparison highlights the suitability of the modeling languages for situation recognition purposes. Furthermore, work on data provision concepts and context-aware support is carried out to share and use the recognized contextual information (see chapter 2.4). On the one hand, a publish-subscribe interface is designed based on ideas of the initial concept of the SRS (see chapter 2.4.1) [Junger et al. 2022a]. The interface realizes standardized communication via SDC between an SRS and multiple CAS. The result is integrated into the SRS and an exemplary CAS to demonstrate and evaluate the interface. On the other hand, this exemplary CAS, the *OR-Pad* system, realizes a use case for the SRS to demonstrate its usage (see chapter 2.4.2) [Ryniak et al. 2023]. The system is designed and developed to perioperatively support the surgical team by displaying clinically relevant information and intraoperatively providing situation-related information based on the actual surgical phase retrieved from the SRS via the SDC interface.

All research contributes to the development of the desired system. Based on the individual contributions, the initial prototype is further specified and the final prototype is evaluated via a functional and argumentative evaluation to specifically prove the system's applicability and transferability (see chapter 2.5) [Junger et al. 2024b]. It demonstrates all findings combined in the SRS to assess the system in terms of transferability on its different layers and the prototype during various scenarios, applying requirements, scenarios, and system analysis. Overall, each of the publications contributes to proving the hypothesis – the development of a transferable, scenario-independent SRS for context-aware support – while the final evaluation on realistic scenarios provides the proof of concept for such an adaptive system to be fundamentally transferable to different sensor equipment, interventions, CAS, and other surgical settings.

Chapter 3 discusses the results of the six contributions in their entirety in the context of current research and relates them to the objectives, points out limitations and open challenges, as well as possible implications for the research area. Overall, this work demonstrates the development of a transferable SRS for different surgical settings to enable broadly applicable CAS, summarized in chapters 4 and 5.

2 Results and discussion

2.1 State-of-the-art of situation recognition systems for intraoperative procedures [publication 1]

Existing situation recognition approaches are assumed to not sufficiently address adaptability to fulfill the requirements of the dynamic surgical field. A current overview of the state-of-the-art, contrasting the approaches and assessing them in the context of applicability and transferability, is not available. The publication

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describes a systematic review and analysis of existing situation recognition approaches in the OR, highlighting characteristics and trends, and particularly addressing applicability and transferability. Electronic supplementary material is available online for this publication (Online Resources 1 to 6[1]). The material shows the identified situation recognition approaches grouped by different categories and best approaches.

[1] https://doi.org/10.1007/s11517-022-02520-4
[2] https://creativecommons.org/licenses/by/4.0/

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REVIEW ARTICLE

State-of-the-art of situation recognition systems for intraoperative procedures

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Abstract
One of the key challenges for automatic assistance is the support of actors in the operating room depending on the status of the procedure. Therefore, context information collected in the operating room is used to gain knowledge about the current situation. In literature, solutions already exist for specific use cases, but it is doubtful to what extent these approaches can be transferred to other conditions. We conducted a comprehensive literature research on existing situation recognition systems for the intraoperative area, covering 274 articles and 95 cross-references published between 2010 and 2019. We contrasted and compared 58 identified approaches based on defined aspects such as used sensor data or application area. In addition, we discussed applicability and transferability. Most of the papers focus on video data for recognizing situations within laparoscopic and cataract surgeries. Not all of the approaches can be used online for real-time recognition. Using different methods, good results with recognition accuracies above 90% could be achieved. Overall, transferability is less addressed. The applicability of approaches to other circumstances seems to be possible to a limited extent. Future research should place a stronger focus on adaptability. The literature review shows differences within existing approaches for situation recognition and outlines research trends. Applicability and transferability to other conditions are less addressed in current work.

Keywords Situation recognition · Situation awareness · Operating room · Applicability · Transferability

1 Introduction

The vision of intraoperative context-aware systems is the automatic support of processes in the operating room (OR) based on the course of the operation and the current process step. Context-aware systems use context information of the environment to provide services relevant to the current task [51]. This would allow surgeons and their team to be supported in a highly targeted manner. The application area of such systems is comprehensive and ranges from the situation-dependent provision of context-relevant information, like preoperative images (e.g., filter information automatically [26]), to the automatic execution of defined subtasks, such as informing about delays (e.g., estimating the intervention time [17]), or semi-automatic generation of OR reports. To realize these kinds of systems, it is crucial to detect the actual situation reliably to provide information suitable to the situation. For this recognition task, a system that is capable of deriving a "situation" information from sensor input is needed. We define this system as a "situation recognition system" to provide situation and context awareness.

Three of the main aspects of context awareness for surgical support are formal modeling of processes, intraoperative tracking and processing, and implementation of context-aware equipment [18]. The basis for context-aware systems in the OR is knowledge of the intraoperative procedures and the current situation of the operation (situation awareness). For this, the current situation must be recognized at specific granularities [37]. Lalys and Jannin [33] differentiate between procedures, phases, steps, activities, and motions in ascending granularity. Similarly, the ontology of Nakawala et al. [47] includes the granularities: phases, steps, and actions (in our case defined as activities). Activities can be represented by different information [38, 45]. Lalys et al. [38] describe an activity as a triplet of action, surgical tool, and anatomical structure, whereas Meißner et al. [45] define a 5-tuple: actor, used body part, used surgical instrument, surgical action, and

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treated structure. To identify the surgical workflow, data from available sensors in the OR are used [13] to detect different information about the context (instruments, persons, anatomical structures, etc.). Sensors can be of any kind like location sensors, endoscopy images, and medical device communication messages. The acquired data is then used in interpretation systems, in our case defined as situation recognition systems, to automatically recognize the situation in the OR. A situation can be represented internally in various forms (e.g., ontologies, state machines). For situation interpretation, approaches like machine learning techniques or formal methods can be applied [26]. The information about the current situation can then be used for various use cases, such as situation-related displays or workflow automation. The recognition of situations is the foundation for supportive context-aware systems and therefore of significant relevance in research to enable context-aware systems.

For different interventions, solutions already exist in the research literature which enable the recognition of the current situation. But it is doubtful to what extent these approaches can react to process and technology changes to be transferred to other circumstances, like more complex interventions or sensor systems. This would be advantageous considering the additional effort for commissioning, maintenance, etc. for different systems. To examine which approaches already exist to what extent, an overview and analysis of the current state of research could highlight similarities and differences between existing systems and examine aspects of applicability and transferability.

In the area of situation recognition, reviews of literature that deal with data acquisition techniques or situation interpretation already exist. The work of Kranzfelder et al. [32] presents a literature review of 2010 with currently promising technologies for real-time data acquisition in the OR. The feasibility results indicate that methods for continuous sensor-based data acquisition and online analysis based on device information are suitable. Instrument recognition via barcodes, tracking of persons via RFID, and emotion recognition via speech seem promising. Similar work by Pernek et al. [51] deals with a literature review of 2015 with currently existing approaches for automatic context recognition during surgical interventions. The comparison results indicate that there is a large discrepancy in methods, depending on the type of surgical context that is recognized. For future approaches, more elaborate evaluations should be carried out under real conditions. The work of Padoy [49] includes a literature review of 2019 with current machine and deep learning techniques for contextual analysis during interventions, using video data from endoscopes or ceiling-mounted cameras. The results show to what extent videos can be used to recognize phases, instruments, and persons. One of the challenges for current developments is to scale methods to more intervention types and more granular activities.

Other work in the field of situation awareness focuses on specific recognition strategies in defined application areas or summarizes their results. The work of Bouget et al. [7] presents a comprehensive overview of recognition possibilities of vision-based and markerless instruments. The focus is the analysis of available data sets, the comparison of recognition methods, and the analysis of validation techniques. The overview aims to identify key challenges and fields for further development. The work of Ahmidi et al. [1] includes a comparison of different strategies for gesture recognition to evaluate surgical skills. Also, a data set and a consistent methodology for performance assessment are described. Based on the data set, an evaluation of surgical techniques for gesture recognition is performed to provide an overview and recommendations for research. The work of Stauder et al. [56] presents their methods for workflow recognition intending to use this knowledge for context-aware systems. Subsequently, possible future applications, such as context-aware visualizations, as well as a context-aware OR of the future are discussed.

The research works mentioned above provide an overview of techniques, methods, etc. in the context of situation awareness, focusing on different aspects and discussion goals. The review papers do not show any current evaluation of full, closed systems and their applicability. The goal of this research is an up-to-date overview of approaches for automatic information acquisition and analysis in the OR. Therefore, current situation recognition techniques to recognize the current situation of an intervention (cutting-suture) will be presented in a clear and categorized manner. For this purpose, research work is used which presents closed systems for the recognition of the surgical situation on different granularities. The systems will be compared and discussed with regard to relevant aspects such as used sensor technology, area of application, or real-time capability. Focus is also the applicability and transferability of the solutions to different surgical and sensory contexts to examine if the solutions are adaptable to other circumstances. The result provides an assessment of the current state of research in the field of situation awareness in the OR. To the best of our knowledge, no other research group has presented a review of closed situation recognition systems for intraoperative procedures of the last ten years clearly and concisely and in relation to each other, with a focus on applicability and transferability.

2 Methods

A literature search of scientific publications on situation recognition technologies in the operative field was carried out, essentially following the PRISMA 2009 guidelines.

We adapted the procedure from the method described by Pernek et al. [51]. The PubMed research database was queried extensively for search terms such as “situation recognition”, “context recognition”, “workflow recognition”, “phase recognition”, “step recognition”, and “activity recognition” in combination with “operating room”, “operating theatre”, and “surgery” in title/abstract (query: “{situation, context} aware(-ness)”, “{situation, context, workflow, process, phase, step, activity, action, instrument, anatomy} {recognition, detection, identification}” AND “operating {room, theatre}”, “surgery”, “surgical”). The focus was on the identification of papers that address recognition strategies and technologies in the context of situations, and the papers are filtered according to their application in the intraoperative area. Only recent papers published within the last 10 years (2010–2019), written in English, and available in full text have been taken into account. Papers with electronic preprint and print publication in 2020 were included, as far as they could be covered by the search. The last search was conducted on 20.01.2020, where we found 274 papers.

As the next step, we analyzed the titles and abstracts of the identified papers with regard to the topic of situation awareness in the OR to identify those that appear relevant. The focus was set on recognition strategies and technologies for achieving situation awareness in the intraoperative area, regardless of whether instruments, phases, or other aspects are recognized, to get a first overview of any recognition approaches. The 54 identified papers were divided into categories: relevant, adjacent (may be relevant), and review. To include publications not covered by the search terms, we analyzed the references of the papers categorized as relevant and included corresponding papers (95 references) with appropriate title and abstract in the overall list of papers. Papers of the cross-referencing were not re-examined for further references.

After filtering and cross-referencing, we examined the paper’s contents to create a final selection of identified papers. The selection was made based on appropriate topics and sufficient information. Because the focus of this work was set on full, closed situation recognition systems (i.e., recognition of phases, steps, and activities), regardless of the support for which they are ultimately used, we excluded all papers that fall below the granularity of activities (i.e., gestures) or recognize instruments or persons and do not have a recognized phase or similar as result. Papers with a different focus (e.g., not automatic) and missing information (e.g., accuracy) were not considered. A total of 58 papers were finally identified for the literature review. To the best of our knowledge, these are complete according to our research procedure.

To present the state-of-the-art clearly and concisely, a table was created. Therefore, we grouped the papers by the granularity of the used recognition, as this shows which possibilities currently exist for situation awareness in different levels of detail. For the tabular representation, we defined aspects based on [32] and [51], as shown in Table 1. Due to the different levels of detail and the partly ambiguous or incomplete information, we summarized the contents of the papers according to the following procedure.

The category *granularity* was divided into phases, steps, and activities. Because of deviated or inconsistent definitions in and between the papers (e.g., using “task “ or simultaneously “phase” and “step”), our definition based on the definitions of [33, 47] and [38, 45] (see Table 2) was used to classify the papers. The required sensory and overarching methods were extracted for each approach. For the category *sensor data (source)*, the sensor data and data source were identified, but more detailed information (e.g., object to be recognized in the videos, such as instruments via visual features) was left out. For the category *method*, the main techniques (like machine learning and formal methods) were identified while delimiting the highest methods and ignoring details of the recognition. Methods on the feature extraction layer, fine-tuning methods, or similar (e.g., normalization) were largely disregarded, except for unclear boundaries or seemingly important aspects. Abbreviations were used for methods, algorithms, and models (see Table 3). The area of application was determined for the category *application area* according to the data set used for evaluation. For the category *usage*, approaches described as online-capable or respectively intraoperatively applicable (i.e., performance in real-time while only using information obtained up to this point for “live” analysis) were specified as “online.” If defined as real-time-capable, it was assumed that this refers to “online,” unless otherwise stated. If stated as offline, not real-time-capable (i.e., too slow), or data from the entire process was used (i.e., postoperative analysis), it was reported as “offline.” If the online capability was not specified or unclear, the corresponding approaches were defined as “-”. The recognition time (and time for training/model generation) itself was not listed since many papers did not provide detailed information and the numbers are

Table 1 Identified aspects for the categorization of situation recognition systems, defined based on [32] and [51]

• Granularity (phases, steps, activities)
• Year
• Sensor data (source) (video (laparoscope), instrument usage (RFID), measurements (OR devices), etc.)
• Method (support vector machines, hidden Markov models, etc.)
• Application area (cataract, laparoscopic cholecystectomy, etc.)
• Usage (online, offline)
• Evaluation (data set) (training, test) (RealOp, SimOp, SimDat (number of cases for training and test))
• Accuracy (possibly precision etc.) (% value)

Table 2 Definition of granularities for procedures in this work, defined based on [33, 47] and [38, 45]

Granularity	Definition
Phases	Phases describe the execution of the main objectives of a procedure (e.g., "renorraphy")
Steps	Steps are taken within the phases to achieve sub-goals (e.g., "cortical suturing")
Activities	Activities describe the actions performed within steps (e.g., "suture") and may also contain further information about the specific action, such as anatomical structure and used instrument

usually not comparable due to different hardware specifications and programming languages used. For the category *evaluation (data set)*, a distinction was made between data sets recorded during real operations ("RealOp"), data sets recorded during simulated operations mimicking real operations ("SimOp"), and artificially generated data sets using manually annotated data, i.e., simulated data provided by the user, also mimicking real operations ("SimDat"). The number of test data and training data (including validation data) was stated in brackets, if identifiable, regardless of whether this data is used several times in changing combinations. If this information is not available, only the total amount of used interventions was stated. The average results of the approaches were expressed in the category *accuracy* as accuracy value in percent. The accuracy was chosen because it is often stated in the machine learning literature as a primary measure of algorithm performance [67]. The definition of accuracy was taken from the respective papers, even though they might have used different definitions on how the accuracy is measured. If no accuracy value was available, the value for, e.g., precision was used and noted as such in brackets. Since many studies compare different approaches (interpretation methods, sensor combinations, and evaluations), the approach with the best result, i.e., the highest accuracy, was chosen. Other results were ignored to avoid the cluttering of the table. Accordingly, only the sensor technology, method, etc. for this result were stated. Approaches for online use and without manual annotation are favored, even if they have lower accuracy.

Based on the created table, the presentation and comparison of the strategies were carried out using the defined criteria to show their similarities and differences and to identify trends in research, like favored methods, data sources, and use cases. Therefore, we created partial tables, each focusing on one category of Table 1 (see Online Resource 1, 2, 3, 4, 5). The comparison does not include all properties of the very different approaches (e.g., number of defined phases, modified data set), even if these could be decisive for the results. We neither considered aspects such as the system's architecture or the detailed functionality. In the discussion, the approaches were discussed within the categories beyond the given aspects of the table. For discussing the best approaches, another partial table was created (see Online Resource 6). In the following section, we focused on the applicability and transferability of the approaches and evaluated their feasibility for achieving situation awareness in the OR during different surgical procedures and used sensor systems. It should be noted that the results of the approaches are based on different evaluation methods and that the comparative results must, therefore, be considered with caution. In contrast to the chapter 3 *Results*, all values for accuracy, performance, etc. were treated as equal for the chapter 4 *Discussion*, while uniformly referring to accuracy.

3 Results

A total of 58 papers were identified, covering a wide range of different approaches. Six papers differ in granularity or area and were listed separately (see chapter 3.7 *Approaches with differing aspects*). The remaining 52 papers, summarized in Table 4, are fulfilling all inclusion criteria. Thirty-eight papers have been identified that recognize situations at the granularity of phases, ten papers deal with the level of steps, and four focus on activities in a fine-grained way. The papers are grouped according to their granularity and sorted in ascending order by year. As described in chapter 2 *Methods*, only the best results according to the given definition were shown.

3.1 Sensor data (source)

Various approaches for intraoperative data acquisition exist, through which situations can be identified, either with data sources already available in the OR, such as the endoscopic camera [24], or additional sensor technology, such as RFID [45] or infrared trackers [58]. In the identified papers, different video data [12, 24, 59], information about instruments [50] or persons [48], system events [43], activities [27], or combinations of different sensor data [63] are used. The table shows that the majority of the identified works, 34 papers, uses only video data to detect the current situation in the OR through different features recognized in the videos. Eighteen papers deal with laparoscopic or endoscopic videos. Only real data sets with mostly ~ 40–120 interventions are used. Very different methods are used for interpretation. Thirteen of the approaches are based on CNN or LSTM, which are also combined with each other or with

Table 3 Overview of methods, algorithms, and models used in the papers with abbreviations

Abbreviation	Method/algorithm/model (singular)
AdaBoost	AdaBoost
ATM	Adaptive trace model
BA	Bayesian approach
biLSTM	Bidirectional long short-term memory
BN	Bayesian network
BoW	Bag of words
CCA	Canonical correlation analysis
CNN	Convolutional neural network
CO	Cultural optimization
CRF	Conditional random field
CoRF	Composition of random forests
DT	Decision tree
DTW	Dynamic time warping
GMMAR	Gaussian mixture multivariate autoregressive model
GRU	Gated recurrent unit
HC	Hierarchical clustering
HHMM	Hierarchical hidden Markov model
HMM	Hidden Markov model
HsMM	Hidden semi-Markov model
k-d-tree	k-d-tree
k-Means	k-means
k-Means + +	k-means + +
k-NN	k-nearest neighbor
LSTM	Long short-term memory
MDL	Minimum description length
MIL	Multiple instance learning
MLN	Markov logic network
MM	Markov model
mSVM	Multiclass support vector machine
NB	Naïve Bayes
NN	Neural network
NNS	Nearest neighbor search
OWL	Web ontology language
PCA	Principal component analysis
PKI	Prior knowledge inference
ResNet	Residual network
R(D)F	Random (decision) forest
RNN	Recurrent neural network
SPM	Surgical process model
SQWRL	Semantic query-enhanced web rule language
SWRL	Semantic web rule language
ST-CNN	Spatiotemporal convolutional neural network
SVM	Support vector machine
tCNN	Temporal convolutional neural network

other methods. For phase recognition, 15 cases exist, of which 12 of them use laparoscopic cholecystectomies for application. In the remaining three cases, other laparoscopic interventions are used. Eleven approaches that detect phases can be used online and achieved up to 93.3% accuracy. In the case of step recognition, laparoscopic or endoscopic videos are used in three cases for different applications. There are no online-capable approaches, and a maximum of 85% could be achieved.

Microscopic videos are used in 14 papers. Only real data sets with mostly ~ 20–180 interventions are used. Very different methods are used for detection, which does not indicate preferred methods. Ten papers recognize phases, of which seven concern cataract procedures. The remaining three cases use other scenarios like pituitary or epiretinal membrane surgery. Since 2014, there could always be identified methods for phase recognition that are online-capable, including six papers. These achieved accuracies of up to 87.0%, whereas offline-capable approaches reached up to 94.8%. For step recognition, three approaches exist, which all use cataract surgeries. The only online-capable approach reached 91.4%, whereas the unspecified approaches achieved an accuracy of up to 95.6%. One approach detects activities for cataract interventions. It is not specified as online-capable and only achieved an accuracy of 64.5%.

Two papers use external surgical videos. Only real data sets are used. Both approaches are not specified as online-capable and have different use cases. For the recognition of phases, the video of an external surgical camera is used in combination with the endoscopic video. An accuracy of 90% could be achieved. For activity recognition, the multi-view RGBD video of an external surgical camera is used, where an accuracy of 85.53% could be reached.

Instrument information as the only resource, such as usage or position, is used for situation recognition in six papers. All these approaches use simulated data or data collected during a simulation. Favored methods could not be identified. For phase recognition, only two approaches exist for different scenarios. One of them uses the kinematics captured by electromagnetic trackers, the other approach manually annotated data on instrument usage. Both are not online-capable and achieved up to 86.25% accuracy. Three papers focus on recognizing steps. In two cases, manually annotated instrument usage is used in the area of laparoscopic interventions. The remaining paper uses the instrument position via electromagnetic trackers for the lumbar puncture use case. Two of the approaches are online-capable with an accuracy of up to 91.6%. The approach for activity recognition uses RFID and accelerometers to record instrument usage and instrument movement, respectively. The approach is not specified as online-capable but achieved an accuracy of 92%.

Manually annotated activities are used less frequently for phase detection, just in three cases. The focus here is on laparoscopic interventions, whereby different methods are used. Two of the approaches can also be used online and achieved

Table 4 Overview of identified situation recognition systems

Paper	Year	Sensor data (source)	Method	Application area	Usage	Evaluation (data set)	Accuracy
Granularity: phases							
Lalys et al. [34]	2010	Video (microscope)	mSVM, PCA	Pituitary surgery	Offline	RealOp (16)	82.2%
Bouarfa et al. [5]	2011	Video (endoscope, OR camera)	BN, HMM	Laparoscopic cholecystectomy	-	RealOp (9, 1)	90%
Lalys et al. [35]	2011	Video (microscope)	DTW	Cataract	Offline	RealOp (18, 2)	94.8%
Lalys et al. [36]	2011	Video (microscope)	SVM, HMM	Pituitary surgery	Offline	RealOp (16)	93%
Nara et al. [48]	2011	Person trajectories (ultrasound tracker)	MDL, k-means, DT	Neurosurgical tumor resection	-	RealOp (9, 1)	77.18%
Bouget et al. [6]	2012	Video (microscope)	HMM/DTW	Cataract	-	RealOp (20)	94.4%
Weede et al. [63]	2012	Instrument position (tracker), video (endoscope), audio (OR microphone)	NB	Single-port sigma resection	-	SimOp (3, 6)	93.2%
Loukas and Georgiou [42]	2013	Kinematic (electromagnetic tracker)	GMMAR, PCA, k-NN	Laparoscopic cholecystectomy	Offline	SimOp (20, 1)	81.67% (precision)
Charrière et al. [11]	2014	Video (microscope)	NNS	Cataract	Online	RealOp (15, 15)	85.59% (performance)
Katić et al. [27]	2014	Activities (manually annotated)	OWL, SWRL	Laparoscopic cholecystectomy	Online	SimDat (19)	96%
Quellec et al. [52]	2014	Video (microscope)	NNS	Epiretinal membrane surgery	Online	RealOp (23)	87.0%
Quellec et al. [53]	2014	Video (microscope)	CRF	Cataract	Online	RealOp (93, 93)	83.2% (performance)
Stauder et al. [55]	2014	Measurements (OR devices), binary signals object status (OR devices), instrument usage (RFID)	RDF	Laparoscopic cholecystectomy	Online	RealOp (3, 1)	68.78%
DiPietro et al. [15]	2015	Measurements (OR devices), binary signals object status (OR devices), instrument usage (RFID)	SVM	Laparoscopic cholecystectomy	-	RealOp (16, 10)	75.9%
Forestier et al. [16]	2015	Low-level activities (manually annotated), binary signal microscope usage (manually annotated)	DT, HC	Lumbar disk herniation	-	SimDat (22)	87.1% (precision)
Katić et al. [28]	2015	Activities (manually annotated)	SPM, SQWRL	Laparoscopic pancreas resection	Offline	SimDat (11)	90.16%
Quellec et al. [54]	2015	Video (microscope)	MIL, k-NN	Cataract	Online	RealOp (93, 93)	85.6% (performance)
Cadène et al. [8]	2016	Video (endoscope)	ResNet, HMM	Laparoscopic cholecystectomy	Online	RealOp (27, 15)	88.90%
Charrière et al. [10]	2016	Video (microscope)	BN, CRF, k-NN	Cataract	Online	RealOp (25, 5)	82.8% (performance)
Dergachyova et al. [13]	2016	Video (endoscope)	SPM, AdaBoost, HsMM	Laparoscopic cholecystectomy	Online	RealOp (6, 1)	68.10%
Dergachyova et al. [14]	2016	Video (laparoscope)	SPM, AdaBoost, HsMM	Laparoscopic cholecystectomy	Online	RealOp (27, 15)	70.7%
Katić et al. [29]	2016	Activities (manually annotated)	CoRF, CO	Laparoscopic pancreas resection	Online	SimDat (10, 1)	~70%

Table 4 (continued)

Paper	Year	Sensor data (source)	Method	Application area	Usage	Evaluation (data set)	Accuracy
Lea et al. [39]	2016	Video (laparoscope)	ST-CNN, DTW	Laparoscopic cholecystectomy	Offline	RealOp (6, 1)	84.6%
Malpani et al. [43]	2016	System events (daVinci)	tCNN, CRF	Robot-assisted hysterectomy	-	RealOp (23, 1)	76.0%
Twinanda et al. [60]	2016	Video (laparoscope)	CNN, LSTM	Laparoscopic cholecystectomy	-	RealOp (80)	80.7%
Bodenstedt et al. [4]	2017	Video (laparoscope)	CNN, GRU	Laparoscopic cholecystectomy	Online	RealOp (6, 1)	74.5%
Charrière et al. [12]	2017	Video (microscope)	BN, HMM, k-NN	Cataract	Online	RealOp (25, 5)	83.2% (performance)
Stauder et al. [57]	2017	Binary signals instrument usage (OR instruments), binary signals device status (OR devices), measurements (OR devices)	RF, HMM	Laparoscopic cholecystectomy	-	RealOp (17, 1)	82.4%
Twinanda et al. [61]	2017	Video (laparoscope)	CNN, SVM, HHMM	Laparoscopic cholecystectomy	Online	RealOp (40, 40)	81.7%
Volkov et al. [62]	2017	Video (laparoscope)	SVM, HMM	Laparoscopic sleeve gastrectomy	Online	RealOp (9, 1)	92.8%
Jin et al. [23]	2018	Video (laparoscope)	ResNet, LSTM, PKI	Laparoscopic cholecystectomy	Online	RealOp (40, 40)	92.4%
Nakawala et al. [46]	2018	Instrument usage (manually annotated)	SPM, SWRL, OWL	Thoracentesis	-	SimDat (3)	86.25%
Yengera et al. [64]	2018	Video (laparoscope)	CNN, LSTM	Laparoscopic cholecystectomy	-	RealOp (120)	89.6%
Yu et al. [66]	2018	Video (laparoscope)	CNN-biLSTM-CRF, CNN-LSTM	Laparoscopic cholecystectomy	Online	RealOp (80, 40)	83.4%
Hashimoto et al. [21]	2019	Video (laparoscope)	ResNet, LSTM	Laparoscopic sleeve gastrectomy	-	RealOp (88)	82%
Kitaguchi et al. [30]	2019	Video (laparoscope)	CNN	Laparoscopic sigmoidectomy	Online	RealOp (63, 8)	91.9%
Yi and Jiang [65]	2019	Video (laparoscope)	LSTM, ResNet, PKI	Laparoscopic cholecystectomy	Online	RealOp (40, 40)	92.4%
Jin et al. [24]	2020	Video (endoscope)	LSTM, CNN, PKI	Laparoscopic cholecystectomy	Online	RealOp (40, 40)	93.3%
Granularity: steps							
Blum et al. [3]	2010	Video (laparoscope)	DTW, CCA	Laparoscopic cholecystectomy	Offline	RealOp (9, 1)	76.81%
Lalys et al. [37]	2012	Video (microscope)	HMM	Cataract	Online	RealOp (18, 2)	91.4%
Padoy et al. [50]	2012	Binary signals instrument usage (manually annotated)	HMM	Laparoscopic cholecystectomy	Online	SimDat (15, 1)	91.6%
Holden et al. [22]	2014	Instrument position (electromagnetic tracker)	PCA, k-means, MM	Lumbar puncture	Online	SimOp (11, 1)	82%

Table 4 (continued)

Paper	Year	Sensor data (source)	Method	Application area	Usage	Evaluation (data set)	Accuracy
Franke et al. [18]	2018	Device parameter (OR devices SDC), instrument usage (scale), video (endoscope)	ATM, DTW, HsMM	Functional endoscopic sinus surgery	Online	SimOp (23, 1)	94.3%
Zisimopoulos et al. [69]	2018	Video (microscope)	ResNet, LSTM	Cataract	-	RealOp (20, 30)	78.28%
Meeuwsen et al. [44]	2019	Instrument usage (manually annotated)	RF	Laparoscopic hysterectomy	Offline	SimDat (36, 4)	76.8%
Nakawala et al. [47]	2019	Video (endoscope)	CNN, LSTM	Robot-assisted partial nephrectomy	Offline	RealOp (9)	74.29%
Yu et al. [67]	2019	Video (microscope)	CNN	Cataract	-	RealOp (60, 40)	95.6%
Zia et al. [68]	2019	Video (endoscope)	CNN, LSTM	Robotic-assisted radical prostatectomy	-	RealOp (70, 30)	85% (Jaccard)
Granularity: activities							
Thiemjarus et al. [58]	2012	Eye gaze (infrared tracker), video (laparoscope), instrument position (infrared tracker)	BN/NN	Laparoscopic cholecystectomy	-	SimOp (15)	93.3%
Lalys et al. [38]	2013	Video (microscope)	mSVM, DTW	Cataract	Offline	RealOp (19, 1)	64.5%
Meißner et al. [45]	2014	Instrument usage (RFID), instrument movement (accelerometer)	HMM, k-means++	Functional endoscopic sinus surgery	-	SimOp (23, 1)	92%
Twinanda et al. [59]	2015	Multi-view RGBD video (OR camera)	BoW, k-means, SVM	Vertebroplasty	-	RealOp	85.53%

an accuracy of up to 96%. Only one paper deals with personal data as the data source in form of person trajectories collected by ultrasound trackers. Another paper uses device data, system events of the daVinci surgical system.

Combinations of different data sources, such as device and instrument data, are also used more often, in seven papers. Both real data sets and simulated data are used. For detection, different methods are used. In the case of phase recognition, a combination of different data types is used in five cases, of which three use the application area laparoscopic cholecystectomy. Two of them use measurements and binary signals of the object status of devices as well as the usage of instruments via RFID. The other paper uses binary signals of instrument usage as well as binary signals of the device status and measurements of devices. The remaining two papers use the instrument position of trackers, the endoscopic video, and the audio from a surgical microphone or manually annotated low-level activities and the binary signal of microscope usage, respectively. Just one of the five approaches is online-capable, achieving an accuracy of 68.78%, while the remaining unspecified approaches reached up to 93.2%. The only paper to recognize steps uses device parameters via SDC, the instrument usage via a scale, and the endoscopic video as input. With this online-capable approach, an accuracy of 94.3% could be achieved. For recognizing activities, just one paper exists that uses a combination of the eye gaze and the instrument position of infrared trackers as well as the laparoscopic video. The approach is not specified as online-capable but reached an accuracy of 93.3%.

3.2 Application area

Twenty-seven approaches deal with laparoscopic cholecystectomies (21 cases) or other laparoscopic procedures (six cases). For these, video data is mostly used, in 17 cases, but also other sensor data, such as instrument data, solely or in combination with device data, is applied in seven cases. Real data sets of interventions are predominantly used, despite of seven cases, often comprising ~20–120 interventions.

Very different methods are used for recognition. Eighteen of the approaches are based on CNN, LSTM, or HMM, which are also used in combination with each other or with other methods. Fifteen of the approaches can be used online and achieved accuracies of up to 96% by detecting phases, whereas an accuracy of 91.6% could be reached in the case of recognizing steps. The only approach for activity recognition is not defined as online-capable and achieved an accuracy of 93.3%.

Many approaches, 11 cases, focus on cataract procedures that use microscopic videos exclusively. Only data sets of real interventions with ~ 20–180 interventions are used. A preferred method used by these approaches cannot be determined. The identified methods for phase recognition since 2014 are all online-capable. These methods achieved an accuracy of up to 85.6%, whereas 94.8% could be reached offline. Similar for step recognition, online an accuracy of 91.4% could be achieved but 95.6% by an approach not specified as online. Activity recognition reached only 64.5% with an offline-capable approach.

Other interventions are also used for evaluation, twice pituitary surgeries, twice functional endoscopic sinus surgeries, and ten other surgeries. The input data varies widely, from video data to instrument information to combinations. For pituitary surgeries, e.g., just the microscopic video is used. Real data sets are used in eight cases but also simulated data or surgeries. Besides, different methods are used that do not indicate favorites. Only three of the approaches can be used online. For phase detection, online accuracies of up to 87.0% can be achieved but for an unspecified approach 93.2%. For the recognition of steps, online 94.3% can be reached, for the recognition of activities up to 92% for non-online-capable approaches.

3.3 Evaluation (data set)

Thirty-nine out of 52 papers use data sets of real interventions. The remaining works simulate interventions (six cases) or use simulated, manually annotated data (seven cases). The data sets used in the papers contain different naming and amount of situations (i.e., papers recognize their selected phases) as well as different use cases. The amount of data varies a lot. Sixteen of the approaches with real data sets use a total of more than 40 interventions, 12 less than 20 interventions. Since 2018, the approaches for recognizing phases always use more than 70 interventions. Overall, different methods are used, whereby approaches based on CNN, LSTM, HMM, or SVM are listed in 30 cases, which are also used in combination with each other or with other methods. Mostly, all of these papers, 34 approaches, are based on video data; 31 have the use case laparoscopic surgery, especially laparoscopic cholecystectomy, or cataract surgery. About half of the approaches are online-capable. With these, accuracies of up to 93.3% and 91.4% could be achieved in the detection of phases and steps, respectively. For unspecified approaches, an accuracy of 94.8% for phases and 95.6% for steps could be achieved.

The approaches that use simulations of real interventions for evaluation all contain less than 25 interventions. Favored methods could not be identified. The papers use different data sources, but always instrument data is included as input. The use cases are different. Online, only those approaches that recognize steps can be used which achieved an accuracy of up to 94.3%. Unspecified approaches in case of online capability reached an accuracy of up to 93.2% or 93.3% for phases or activities, respectively. Approaches that use manually annotated data as data source evaluate with less than 20 interventions, despite of two exceptions. Different approaches without recognizable focus are used. The approaches focus on manually annotated activities or instrumental usage to interpret the current situation. Laparoscopic interventions were chosen in five cases. Online, the approaches achieved up to 96% accuracy in phase recognition and 91.6% in step recognition.

3.4 Usage

Many of the approaches are not designed for intraoperative use but for postoperative purposes. Twenty-four approaches can be applied online, whereas ten of the approaches can only be used for offline detection. Eighteen papers do not specify this aspect at all. To detect the current situation in the OR online, real data sets are used in 19 cases, mostly with ~ 20–120 interventions. Although various combinations of methods are used, approaches based on HMM or CNN are listed most frequently (13 cases). For recognition, the majority of papers, 18 approaches, uses video data, which is why the focused use cases are laparoscopic and cataract interventions, despite of three exceptions. Phase recognition achieved an accuracy of over 90% in six cases, especially since 2018, with the best result reaching 96%. For the recognition of steps, almost all approaches, despite of one, achieved accuracies above 90%, with the best result being 94.3%.

For offline recognition, seven papers chose real data sets, three simulated data. The methods used are very different. Video data is also preferred (seven cases), and laparoscopic procedures are used in half of the approaches for evaluation. The approaches achieved an accuracy of up to 94.8% for detecting phases, whereas steps can be detected with a maximum of 76.81% and activities with 64.5%. The approaches that are not defined as online or offline predominantly use data sets from real interventions, 13 cases, often comprising ~ 20–120 interventions. Specific methods are not favored. The approaches include more variance in terms of data sources. Video data, as well as combinations, are used for 15 approaches. The approaches are evaluated in different interventions, seven times laparoscopic, but also in many other areas. For phase recognition, accuracies of up to 94.4% can be achieved, for steps 95.6% and activities 93.3%.

3.5 Accuracy

The accuracy of the approaches ranges from 64.5 to 96%. Newer approaches are not necessarily better than older ones. The majority of the papers, 39 approaches, achieved a higher accuracy or comparable unit of over 80%. The best 18 approaches with 90% or more use different methods, whereby approaches based on HMM are used in eight of the cases, also in combination with other methods. For the detection of phases, real data sets are used, despite of three cases, which contain different numbers of interventions. In eight cases, the use case laparoscopic intervention is focused. Nine of the papers recognize only via video data. Six of the approaches are online-capable for which accuracies of up to 96% were achieved. Since 2017, online-capable approaches could always be identified. For the recognition of steps and activities, no favored data source or use case could be identified. More simulated than real data is used (four vs. two cases). Steps were predominantly identified online, with one exception, with up to 94.3%, whereas the only unspecified approach even reached 95.6%. Activities were detected with up to 93.3%, whereas it is not defined whether the approaches are online-capable. The approach with the highest accuracy considering all granularities is online-capable and based on manually annotated activities of laparoscopic cholecystectomies, where phases are recognized via OWL and SWRL.

Twenty-one approaches achieve accuracies of 80 to 90%, 17 of them are evaluated on real data sets. Approaches based on CNN or LSTM could be identified in seven cases, which are also frequently used in combination with each other or with other methods. As a data source, video data is used conspicuously often, in 16 cases. The use cases laparoscopic procedures and also cataract procedures are used in 14 cases. Ten of the approaches are online-capable.

3.6 Method

There are two main approaches for situation interpretation: machine learning techniques and formal methods (e.g., ontologies) for machine-readable modeling of medical knowledge [26]. Machine learning includes algorithms that analyze the data to build a statistical model that is then used to identify unknown aspects. The learning techniques are trained in advance using data sets. The trained models can then be used with sensor data as input (e.g., instrument position) to provide an output that reflects the situation in different granularities. Formal methods, including ontologies or surgical process models (SPM), can be used to represent knowledge about the process or other relevant aspects and use logical links and rules for the interpretation of the situation.

In literature, for used methods, no clear trend could be identified. But it is noticeable that some approaches rely on only one method, while other approaches use a combination of different methods. Particularly in the detection within videos, additional methods are often used to detect features in the image data which have been left out for the overview as far as possible. Overall, machine learning techniques and formal models both are used for approaches, partly both in one approach. It could be identified in the individual categories that methods based on CNN, LSTM, HMM, or SVM (solely or in combination with various methods) are used more frequently, in 33 cases.

3.7 Approaches with differing aspects

Six papers were listed separately due to deviating granularity and application (see Table 5). Three of them recognize only very few intraoperative phases, but more pre- and postoperative phases; one uses states (e.g., “risky situations”). The remaining two papers, and two of the papers mentioned before, deal with trauma resuscitations that do not represent an intervention.

Good results could also be achieved by these approaches. For evaluation, real and simulated data are used. The methods used are different. Four of the papers deal with the recognition of phases. For recognition, different data sources are used. In one case, RFID technologies for person location, instrument/object location, and usage are used. Another paper uses optical trackers to obtain the instrument position. The remaining two papers use the audio of a surgical microphone, solely or in combination with the depth video of an external surgical camera, respectively. Of three online-capable approaches, the best accuracy was 97%. On the granularity of steps, an external surgical video or the object usage via RFID is used as input for recognition. Up to 91.14% was achieved with not as online-capable defined approaches.

4 Discussion

The review shows that there are many approaches with good recognition rates. In the following, these are discussed beyond the table and afterward evaluated for their applicability and transferability to other scenarios and data sources.

4.1 Sensor data (source)

The table shows that up to 96% accuracy can be achieved for the seven cases which are using manually annotated

Table 5 Overview of identified, but differing, approaches concerning situation recognition systems

Paper	Granularity	Year	Sensor data (source)	Method	Application area	Usage	Evaluation (data set)	Accuracy
Bardram et al. [2]	Phases (few intra-operative)	2011	Person location (RFID), instrument/object location (RFID), instrument/object usage (RFID)	DT	Laparoscopic appendectomy	Online	SimOp (3, 1)	77.29%
Katić et al. [26]	Phases (states)	2013	Instrument position (optical tracker)	OWL, BA	Laparoscopic cholecystectomy	Online	SimOp	97%
Li et al. [41]	Phases (few intra-operative)	2016	Depth video (OR camera), audio (OR microphone)	CNN	Trauma resuscitation	Online	RealOp (20, 5)	80%
Gu et al. [20]	Phases (few intra-operative)	2017	Audio (OR microphone)	LSTM	Trauma resuscitation	Offline	RealOp (24, 3)	41.13%
Chakraborty et al. [9]	Steps	2013	Video (OR camera)	MLN	Trauma resuscitation	-	SimOp (10)	91.14% (precision)
Li et al. [40]	Steps	2016	Object usage (RFID)	CNN	Trauma resuscitation	-	RealOp (16)	80.40%

data from activities, microscope usage, or instrument usage. Overall, the results are usually over 85%. Certain work beyond the table can show that the use of manually annotated data, sometimes with a different method, can provide an improvement in accuracy. Dergachyova et al. [13], for example, can increase accuracy from 68.10 (video only) to 88.93% by combining visual and instrument information, using manually annotated data on instrument usage in addition to video data. Similarly, Lea et al. [39] show that if manually annotated data on tool usage is used in addition to video, the accuracy can be increased from 84.6 to 92.8%. The multi-level approach of Charrière et al. [10] shows that compared to the use of video data with 82.8% for phase detection, better results of 98.6% can be achieved with manually annotated instrument data. Similarly, Charrière et al. [12] show that 83.2% can be reached for phase recognition using video, whereas 98.6% could be achieved with manually annotated instrument data. Yu et al. [67] reached an accuracy of 95.6% with videos, while manually annotated instrument usage data can increase the accuracy to 95.9%. Gu et al. [20] (approach with differing aspects) describe a method that achieved 41.13% with audio recordings and 79.12% with manual transcriptions. All these results are due to the fact that errors can already occur during the recognition of instruments etc., which in turn affects the recognition of the current situation. With manually annotated data, these errors do not occur, so approaches can work with perfect data. If the data were collected via intraoperative sensors, worse results can be expected.

Video data is chosen for more than half of the approaches. Instrument data is the second most used data source, partially in combination with device or other data. The accuracies for these are varying. A tendency for single data sources or a combination of data to yield better results could not be observed. Very good results can be reached with only one data source or with a combination of data sources, without focusing on a specific source. In any case, it seems reasonable to include all available inputs for situation recognition. The most promising approach would probably be to integrate as many sensors as possible to take into account inaccuracies of a single sensor and to make the analysis more robust [31].

4.2 Application area

The approaches seem to be designed for a specific intervention and are specially trained for it. Laparoscopic and cataract procedures are focused in research. For these, types of data sources are focused. For example, cataract procedures only used the microscopic video, and laparoscopic interventions focus on the laparoscopic/endoscopic video. Overall, the application area is conspicuously set on standardized interventions or seems to provide the best results for them.

4.3 Evaluation (data set)

Although the individual approaches often show a high degree of accuracy, the evaluations were not carried out during an intervention; either data sets from real interventions or simulated data/interventions were used. The live application was not tested extensively. The data that was recorded during interventions was also used for testing the approaches. No live evaluation in the OR was carried out, which questions the functionality. Some of the studies also describe that the approaches provide good results but are not yet good enough for clinical use. For example, the approach of Franke et al. [18] is suitable for laboratory conditions but must be extended for clinical use. Above all, some approaches cannot be integrated into the OR at all, as they are based on manually annotated data, i.e., they do not use real sensor data for interpretation. To use them, the input data first have to be determined automatically, for example, by intraoperative sensors (e.g., [27, 28]). Also, the number of data in the data sets used should be increased so that more variance can be represented within the data set and the approaches can be extensively trained and tested.

4.4 Usage

Offline approaches can often reach better accuracies, because, for example, the entire video can be used for analysis instead of only using the video available up to the time of the operation (which is the case for online usage). This tendency is not visible in the tabular presentation. Very good results can also be achieved online. However, in Twinanda et al. [61], it is shown that an accuracy of 81.7% can be reached online, whereas offline even 92.0% can be achieved. Similarly, Lalys et al. [37] show that an HMM-based approach reached an accuracy of 91.4% online, while a DTW-based approach achieved 94.4% offline. It can be concluded that it does make a difference whether the approach is used online or offline. But only online-capable systems can be used for situation recognition during procedures. Approaches that are not defined as online-capable can probably not be used live. Offline approaches could be used for postoperative analysis and still be extended for online capability in future work.

4.5 Accuracy

According to the table, the approaches cover a wide range of accuracies. Specific conditions for achieving the best results could not be identified, because of the very different approaches regarding the combination of sensor data, method, area, etc.

4.6 Method

The table shows that models defined as SPM are used by four of the identified papers, which achieved an accuracy of up to 90.15% but do not stand out overall. Two of the approaches have a lower accuracy of 70%. Ontologies are also used in six cases, although not stated in the table, some of which reached an accuracy of more than 90% but do not particularly stick out as well. The use of SPMs in combination with ontologies was also observed in two of the six ontology cases. Nakawala et al. [46] use an ontology to represent knowledge about thoracentesis interventions. For the interpretation, rules based on SWRL and OWL are created to realize an SPM. The approach achieved an accuracy of 86.25%. Katić et al. [27] use a rule-based situation interpretation using OWL and SWRL. The workflow of the interventions is formalized by an ontology. For laparoscopic cholecystectomies, an accuracy of 96% was achieved. Katić et al. [28] present a rule-based situation interpretation using SQWRL. The workflow of the interventions is formalized by an ontology to represent an SPM. In the use case laparoscopic pancreas resection, an accuracy of 90.16% was achieved. Katić et al. [29] combine formal knowledge via an ontology with experience-based knowledge. The approach is based on CoRF and CO and achieved an accuracy of ~ 70% for laparoscopic pancreas resections. Lalys et al. [38] use an ontology, mSVM, and DTW to detect activities based on previously detected phases to automatically generate SPMs of cataract interventions. An accuracy of 64.5% was achieved. Katić et al. [26] (approach with differing aspects) present a combination of machine learning and formal methods, which uses OWL and BA in addition to an ontology-based situation interpretation. An accuracy of 97% could be achieved in the scenario laparoscopic cholecystectomy. Although the papers that use SPMs and/or ontologies are not among the best overall, as there are both good and worse results, it seems to be useful to use SPMs and ontologies to represent knowledge about aspects of the process and to use this knowledge for situation awareness. A combination of machine learning techniques and formal methods seems reasonable.

4.7 Best approaches

To identify clearer trends in the presented papers, the best approaches were defined. These include an accuracy above 90%, the possibility of online usage, and the use of non-manually annotated input data. Seven approaches could be identified with this criteria. It is noticeable that only endoscopic or laparoscopic videos are used for phase recognition (five approaches in total). With laparoscopic interventions as the application area, the best results were achieved from 91.9 to 93.3%. Real data sets with ~ 70–80 procedures were used, except one with only ten procedures. Mostly combinations of methods were used, two of the studies use an approach based on ResNet, LSTM, and PKI. The best approach uses LSTM, CNN, and PKI. For step recognition, no laparoscopic procedures are used but cataract and functional endoscopic sinus surgery (two approaches in total). For the cataract use case, the microscopic video is used, for the other case, in addition to the endoscopic video, device parameters via SDC and information on instrument usage via scale. The accuracies were 91.4% and 94.3%, respectively. For the first approach, a real data set with 20 interventions was used, for the second 24 simulated interventions. No comparisons could be made between the methods. The better approach uses ATM, DTW, and HsMM. The detection of activities could not keep up with the results of the other two granularities.

Video data is always used for both phase and step recognition to achieve the best accuracies. This seems to be a suitable source of data but can only be used for certain interventions that capture such videos. Only one approach uses other data sources in addition, which ultimately resulted in the highest accuracy. This approach is the only one that uses simulated interventions, which is therefore not necessarily meaningful. Overall, the approaches are very current (since 2017), with one exception of 2012. The best approach for phase and step detection is always the most recent one. Favored methods could not be identified unambiguously, but combinations of different methods seem to make sense, as the lowest of the best accuracies are also achieved by those approaches with only one method for interpretation.

4.8 Differing approaches

The best result by approaches with deviating aspects with an accuracy of 97% is reached when detecting states. For this purpose, the instrument position is recorded via optical trackers and interpreted via OWL and BA. The approach is online-capable, but the results were obtained by simulated laparoscopic cholecystectomies. The second best approach achieved 91.14% in the detection of steps in trauma resuscitation. Simulated procedures are also used, with surgical videos as input for recognition and MLN for interpretation. The approach is not defined as online-capable. The approaches show that good solutions also exist in non-focused areas, which can provide good results in deviating use cases. It may be useful to extend these to desired conditions (intraoperative use).

4.9 Concluding remarks

Overall, the table results and discussion only reflect trends, as not all characteristics of the very different approaches can be included. Depending on the case, the data sets may contain different defined phases etc., which may also vary in number. There is no clear definition of the phases, but the research groups define them themselves or they were determined based on existing data sets (number and allocation of activities to a phase varies). In addition, due to the focus on approaches with online usage and without manually annotated data, an increasing number of such approaches are listed. Due to the different evaluation methods, the results are not directly comparable. The comparison results must, therefore, be considered with caution. Nevertheless, it is recognizable that the approaches cover a broad spectrum of methods and sensors. There is a clear tendency towards video data and the corresponding use cases. However, it does not show that certain methods or sensor data only provide good results but rather that very different approaches are among the best, which do not all use the favored data sources or application cases.

4.10 Applicability and transferability

Within the different studies, the approach with the best results is not always favored. Charrière et al. [12] are an example of this. In this paper, a different approach than the one with the best accuracy is recommended, because it can be transferred to other video-monitored interventions and levels. From this, it can be concluded that accuracy is not always the means to measure the best solution. We assume that applicability and transferability to other processes, granularities, and sensor data are also important. The importance of the transferability of strategies within the OR is addressed, for instance, in [19]. This paper discusses that many instrument recognition systems focus on specific interventions and are not generally applicable. Instead, a system that can be used for a large number of operations is defined as necessary [19]. Deducing from this, it is necessary for the broad application of a situation recognition system that it can be easily adapted to different conditions, so that it can be used for a majority of interventions, independent of available data and planned support.

4.10.1 Papers that hypothesize transferability

Applicability and transferability of the approaches are not addressed in all papers. Regarding the flexibility of the sensor technology used, the comparison of the identified systems showed that the approaches are designed for specific sensors. Concerning the usability of sensor sources, the choice often falls on endoscopic, laparoscopic, or microscopic videos, as these are already available in the OR. Using video data avoids the need to install additional equipment in the OR and provides a source of information that must not be controlled by humans, thereby automating the support of surgeons without the need to change the surgical routine [37]. In contrast, other data sources, such as RFID tags or different trackers, require that they were attached to instruments, devices, and people, which can be considerably more complex (e.g., if each instrument has to be equipped with an RFID tag). For using extra cameras or other elements (e.g., scales), they must be installed or integrated in the OR as well. The cost-effectiveness and feasibility of such strategies, which, for example, require modification of instruments, are questionable [19]. Approaches that use video data already available in the OR allow for simpler applicability and transferability, because no change of equipment or processes is necessary. These approaches can theoretically be transferred but only to other video-based interventions, without the need to integrate additional sensors, provided that the method has been trained for them and knowledge about processes and situations exist. Very similar, solutions that use device information such as system events or measurements can be transferred as well if the data is available in the respective OR. However, there is a lack of available and suitable medical device data due to the lack of open communication standards [25]. Not in every OR certain technologies are integrated that can be used to collect data. For interventions for which no video data or sufficient device data are available, additional sensors must be attached for transmission. Moreover, many studies show that additional integrated sensors can achieve good results (e.g., RFID and accelerometers [45]). For as little effort as possible, sensors that are easy to integrate could be used (e.g., [15]).

In addition to the focus on video data, it is also very noticeable that the identified approaches deal with highly standardized interventions. The approaches for these are often designed for a specific intervention and are specially trained for defined phases etc. For individual use cases, there also exist extensive data sets for this purpose, with which the methods can be trained (e.g., using video data). The transferability of the approaches to other interventions is difficult to assess. A 1-to-1 transfer seems very unlikely since interventions can vary greatly (e.g., steps to be performed, instruments used), and therefore, it cannot be guaranteed that a trained approach can be used for other processes in the same way with similar results. In principle, this is possible with adjustments by training the methods for the new interventions and, if necessary, additionally mapping the required knowledge about the new processes (incl. data). Thus, the approach can be trained for other defined phases etc. For more complex, variable interventions, the recognition does not seem to be successful so far due to the non-standardized and flexible processes. These are often unpredictable and make it difficult to define knowledge about the process that can be used to identify the situation. The processes cannot be modeled in a structured way, several data combinations may be possible, and therefore, this knowledge cannot be incorporated into the detection (e.g., dependencies between steps). Thus, many approaches are specialized in highly standardized interventions, which can be better analyzed based on the clear procedures and the often unambiguous assignment of data to situations. The definition of the workflow is only feasible for interventions if their procedure is standardized [32]. A transfer to more variable processes is therefore hardly possible.

The usability of the approaches for other processes is only addressed to a limited extent in the identified papers. For approaches that work with laparoscopic, endoscopic, or microscopic videos, it is more often described that these are, for example, generalizable or scalable and can therefore also be used for other types of interventions (e.g., [13]), more complex procedures (e.g., [4]), or other data sets (e.g., [61]). Rarely, the transferability to other granularities or sensor sources is mentioned. Nevertheless, some papers state that the approach can be adapted to other levels (e.g., [10]), be used in a more fine-grained way (e.g., [62]), or be extended to other sensor data (e.g., [47]). Also when using other data sources, approaches are described as generalizable or scalable and are therefore applicable to other procedures (e.g., [50]) or different settings (e.g., [9]). The detection of different granularities or expandability of sensors is also rarely shown. Few papers describe that the approach is transferable to other levels of granularity (e.g., [16]) or can be extended by sensors (e.g., [41]). Other studies indicate that their approach is not well transferable to other interventions or data sets, for example, in the case of more variable data (e.g., [39]). Additionally, few papers define their approaches as generalizable or extendable but not necessarily applicable to other areas in their actual form, because cues are application-dependent (e.g., [52]) or the approach needs to be trained for each department (e.g., [35]).

4.10.2 Papers that demonstrated transferability

Rather rarely, the transferability of the approaches to other data sets or use cases is demonstrated in tests or experiments. Some papers apply their approach to different data sets, which may also include other use cases or different methods. For example, Jin et al. [23] compare the results for two data sets of laparoscopic cholecystectomies, with slightly different accuracies of 90.7% and 92.4%. Twinanda et al. [60] use the same two data sets and achieved 79.5% with one data set and 80.7% with the other. Lea et al. [39] use two other data sets with laparoscopic cholecystectomy procedures, but the results are very different, 63.7% with one and 84.6% with the other. Quellec et al. [52] show results of two data sets, including different use cases, epiretinal membrane surgeries, and cataract surgeries, which reached 87.0% and 72.9%, respectively. Bodenstedt et al. [4] also use two data sets with different cases, laparoscopic cholecystectomies, and colorectal laparoscopies, which achieved 74.5% and 67.2%, respectively. Katić et al. [27] even use three different data sets for the scenarios laparoscopic cholecystectomy, pancreatic resection, and adrenalectomy which achieved 96%, 90%, and 83%, respectively.

These examples show that when approaches are applied to different data sets, the accuracies can vary greatly, especially when data sets from different interventions are used.

If data sets of the same procedures are used, very similar results could be observed in some cases, although a larger difference can occur here as well. The examples seem to show that one approach cannot be used equally well for other data sets. This is probably due to the differences in the data (e.g., detecting other phases) and to the different process flows (e.g., more complex interventions or ambiguous assignment of data to situations). The data set and thus the use case seem to have a strong influence on the recognition accuracy. The amount of training data will also influence the results. For future approaches, more complex evaluations should be carried out under real conditions [51]. Furthermore, more experiments with more complex and variable interventions should be done.

The transferability of the approaches to other granularities or the recognition beyond one granularity is also rarely shown practically. Nakawala et al. [47] show that, beyond the already recognized step, an ontology-based SPM and rules can identify complementary context (activities, phases, and instruments) based on the step. However, further context could be identified with less accuracy, since the recognition is based on the recognized step. Lalys et al. [38] identify activities based on previously recognized phases, whereas Franke et al. [18] identify steps based on previously recognized activities. Charrière et al. [10] use phases and steps and their influence on each other for multi-level recognition, whereby phases could be recognized with higher accuracy. Similarly, Charrière et al. [12] use knowledge of the relationship between phases and steps to identify situations. Again, the results for phase recognition were better. The examples show that the granularities are interdependent. Beyond one granularity, further knowledge about other contexts can be identified. Furthermore, the granularities seem to be able to influence each other, through which multi-level recognition can benefit. The transferability to other granularities thus seems to be possible in principle via knowledge of the interventions.

Even less frequently, the transferability of the approaches to other sensor data is demonstrated in the papers. A flexible connection of available sensors would result in independence so that transferability to new ORs with other sensor technology is possible. In different works, the results using different sensor data are compared. Malpani et al. [43] show, for example, that a subset of features, in contrast to the system events of a daVinci surgical system, can be used for many interventions (laparoscopic, endoscopic, and open) and can also deliver comparatively good results, only slightly worse with 72.5% instead of 76.0%. DiPietro et al. [15] show that with fewer, rapidly deployable sensors, very good results can be achieved (73.9%), whereas more sensors could reach 75.9%. The examples make it clear that for transferability, it makes sense to choose data sources that can be used for a variety of interventions or that are easy to integrate. So approaches can be used not only for one intervention, for example, by using a specific device. With current techniques, this seems to be possible only to a limited extent.

4.10.3 Concluding remarks

Most papers do not address the transferability of their approaches nor demonstrated it based on different data sets. In these cases, it was assumed that they are not transferable. Some papers state that the approaches are generalizable, but they do not describe in detail or demonstrate only slightly how the individual approaches can be transferred exactly to other interventions, phase definitions, granularities, or sensor data. The approaches always seem to be limited in terms of training data set (type of intervention), process modeling, sensor technology, and other aspects. The methods are trained based on a data set and must, therefore, be trained for the new application. In addition to training based on a new data set, new process models or similar may be necessary. Furthermore, different situations (e.g., additional phases, data sources) must be considered. For easy transferability, all this must be given. Therefore, the approaches, although described as generalizable, do not seem to be used easily without additional effort, because these aspects are not addressed in this way. The papers that show applicability and transferability usually use only two different data sets for evaluation. For this purpose, more different data for sufficient tests or respectively the application directly in the OR would be advantageous. The differences in detection accuracy also make it clear that transferability is possible, but the results can vary greatly. For very similar interventions, simple transferability might be possible without having to adapt the entire approach, but for different interventions, the approaches have to be adapted and, if necessary, extended (training, knowledge, data, etc.).

5 Conclusions

The identified approaches differ in many aspects, such as method, area, or accuracy. The focus is clearly on the use of video data for standardized use cases such as laparoscopic and cataract surgery, although not all of them necessarily achieve good results. Videos are probably preferred as they are already available in the OR. In addition to video, instrument data is also quite often used solely or in combination with other sources. The works are often based on data sets from real interventions but sometimes use only a small amount of data. More data should be used for training and testing. We assume that broader availability of annotated intervention recordings with a broad range of sensor input would be a significant contribution to this research field. Furthermore, the approaches should also be tested live. Often the approaches can be used online, but this is not always stated. During surgery, only approaches that are online-capable can be used, which limits the number of possible systems for intraoperative use. Nevertheless, many online approaches already show very good recognition results. The accuracy of the strategies varies as much as used methods. Many of the studies show very good results with accuracies above 80% or even 90%. However, no clear trend could be identified for methods, although combinations of different methods and the usage of machine learning combined with formal methods seem to be useful.

The discussion of the papers concerning applicability and transferability showed that the approaches can be used in principle to achieve situation awareness about intraoperative processes. Transferability is less addressed in the papers and is hardly ever demonstrated by experiments. Nevertheless, especially the approaches based on video data seem to be transferable to other video-based interventions due to the availability of the data source. Therefore, flexibility in adapting to the changed processes must be guaranteed. The transferability to other processes, granularities, and data sources is only outlined in a few papers and seems to be possible only to a limited extent. Although some studies mention that their approaches can be generalized to other types of interventions etc., they do not show this enough in experiments. Through a few examples, it could be shown that different data sets can strongly vary in recognition. A few studies demonstrate that their approaches can be used beyond a granularity or a specific sensor source combination. The recognition of more context and also the adaptability with regard to sensor data is an important step for the broad usability of such a system. Therefore, future work should focus more on aspects of applicability and transferability to make recognition systems more adaptive. The goal for future developments should be much more on the broad applicability of solutions to reduce highly specific systems for a minimum of interventions. For this purpose, it is recommended to make the system easily adaptable to different circumstances by, e.g., supporting different sensor data sources and application areas. We assume that a unified solution that can be adapted to different processes and granularities of the intraoperative area and that robustly detects the current situation in the OR without requiring specific sensor technologies would allow for greater flexibility, applicability, and thus, transferability to different applications.

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2.2 Concept and basic framework prototype for a flexible and intervention-independent situation recognition system in the OR [publication 2]

The development of a generalized SRS that adapts to different surgical settings could provide the foundation for a transferable solution. A suitable architecture could depict the variance in intraoperative sensor data, surgical interventions, and contextual information to enable basic transferability. The publication

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describes the design and development of a transferable SRS, characterized by a generalized architecture, consisting of layers, modules, and interfaces, to realize flexible use for different scenarios. Electronic supplementary material is available online for this publication (Appendix A[3]). The material shows the requirement analysis and functional evaluation of the SRS.

[3] https://doi.org/10.1080/21681163.2021.2004446

Concept and basic framework prototype for a flexible and intervention-independent situation recognition system in the OR

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Concept and basic framework prototype for a flexible and intervention-independent situation recognition system in the OR

Context-aware systems to support actors in the operating room depending on the status of the intervention require knowledge about the current situation in the intra-operative area. In literature, solutions to achieve situation awareness already exist for specific use cases, but applicability and transferability to other conditions are less addressed. It is assumed that a unified solution that can be adapted to different processes and sensors would allow for greater flexibility, applicability, and thus transferability to different applications. To enable a flexible and intervention-independent system, this work proposes a concept for an adaptable situation recognition system. The system consists of four layers with several modular components for different functionalities. The feasibility is demonstrated via prototypical implementation and functional evaluation of a first basic framework prototype. Further development goal is the stepwise extension of the prototype.

Keywords: situation awareness; intra-operative situation recognition system; adaptability

Word count: 4050

Introduction

Supporting actors in the operating room (OR) is one of the main goals of intra-operative context-aware systems. Context-aware systems adapt their behaviour according to the actual situation for targeted assistance. To realize context-aware behaviour, the context information is retrieved by environmental sensors (Pernek and Ferscha 2017) to detect the actual situation reliably. Knowing the current situation, a system can provide information suitable to the situation, e.g. filter information automatically (Katić et al. 2013) or display pre-assigned pre-operative information (Frommer et al. 2021).

In the literature, various approaches already exist for systems that use different data sources to recognize different aspects regarding the current situation in the OR. A comprehensive literature review on the state-of-the-art situation recognition systems (Junger et al. 2021) identified systems for the recognition of phases (e.g. (Jin et al. 2020)), steps (e.g. (Lalys et al. 2012)), and activities in the intra-operative area. The result showed, that the systems focus on specific interventions and sensors. Most systems do not seem to be easily transferable to other interventions or surgical sites. It was assumed that a generalized system architecture, that can be adapted to different processes, and that does not require specific sensor technologies would allow for greater flexibility, applicability, and thus transferability to different applications.

To enable such a flexible and intervention-independent system, this work proposes a system architecture for an adaptable situation recognition system. The feasibility is demonstrated via prototypical implementation. A functional evaluation is conducted on this prototype to point out achieved and missing requirements.

Materials and Methods

Requirements analysis

Based on the state-of-the-art findings of (Junger et al. 2021), a requirements analysis was conducted in which the vision, goals, and functional and non-functional requirements for an adaptive situation recognition system were defined. All requirements are provided as supplementary material (see Appendix A as supplementary material). A summary is given in the following:

The main goal of the situation recognition system is a flexible and intervention-independent estimation of the current situation of an intervention in the OR. For this purpose, data from different intra-operatively available sensors shall be collected and processed. In addition, the situation recognition system shall know different interventions (e.g. intervention procedure or previous interventions) and transfer this knowledge. The intra-operatively acquired data, as well as knowledge about the interventions, shall then be used to interpret the current situation to provide external systems with contextual information about the current situation of an intervention in the OR. Overall, 25 functional and 41 non-functional requirements were defined based on the goals of the system.

The functional requirements specify functions, data, stimuli, reactions, and behaviour of the system. The system must be able to recognize different context information about the current situation based on knowledge of sensor data retrieved from the OR, surgical planning from external data storage, and the course of the intervention and past interventions from internal data storage. All acquired sensor data and generated data is to be stored. Changed information in sensor data, surgical planning, course of the intervention, or past interventions need to trigger the interpretation. Changed estimated information about the context must be provided to context-aware systems. New sensors and context-aware systems are to be included for interpretation or provision, respectively.

The non-functional requirements define functionality, reliability, usability, efficiency, modifiability, and transferability. The system should consist of modules for expandability (e.g. sensors, context information). Interchangeability, like sensors with the same purpose, should be possible. Context information and its probabilities should be estimated via available knowledge from as many different, relevant sources as possible to minimize bad estimations. The interpretation and provision should be done in a reasonable time. The recognized information is supposed to be used by different context-aware systems at their own risk. Interfaces for these systems should be easily integrable. The system should be operative with local dummy data and exemplary interpretation logics for functional demonstration and serve several ORs simultaneously. Standardized protocols should be used for communication and data be kept confidential. The system should be installable and configurable by experts. User interaction and interfaces for configuration purposes are supposed to be minimal. The system should not exceed the server capacity or overload the hospital network. Functionality tests are supposed to be described for evaluation.

Concept and system architecture

Based on the requirements analysis, the system architecture was designed in a modular way. The concept was inspired by the NASA/NBS Standard Reference Model for Telerobot Control System (NASREM) architecture (Albus et al. 1989) and its successor, the Real-time Control System Version 4 (RCS-4) architecture (Albus 1994), as well as the SitOPT architecture (Hirmer et al. 2017). NASREM implements several layers with different modules for sensory processing, world modeling, and task composition (Albus et al. 1989). RCS-4 consists of several layers as well, depicting different abstraction levels (Albus 1994). SitOPT is based on three layers for sensing, situation recognition, and situation-aware workflow (Hirmer et al. 2017).

The concepts presented above structure functionalities via layers and modules. Especially the architecture and components of SitOPT seemed to be suitable due to its broad applicability by focusing on situational applications that can autonomously adapt to environmental changes. The proposed situation recognition system will therefore also be built up in layers consisting of several modular components for different functionalities. Thereby, ideas of the presented concepts, especially SitOPT, will be used as a reference, e.g. the distribution of sensing and situation recognition or the usage of a sensor registry and kind of situation templates.

Figure 1 shows an overview of the architecture focusing on the components and data exchange. The proposed situation recognition system consists of four layers: The first layer is the **Data Acquisition** layer. In this, available sensors of different devices and systems in the OR provide different data by streaming them to respective networks, sending them continuously (pseudo-streaming, e.g. aggregated data), or transmitting them discretely. Different sensors already available in the OR (e.g. endoscope), as well as additional sensors (e.g. RFID systems) and existing interpretation systems (e.g. for recognizing instruments), should be usable. The relevant networks are then listened to via the *Resource Management* component within the **Sensor Abstraction** layer. The listeners are configured for each OR via the *Sensor Registry* unit. Sensor data acquired by the listeners is persisted. The raw sensor data representing current values, like video or audio signal, instrument and device data, person information, and more, are then processed in the *Sensor Interpretation* component immediately within different interpretation modules by interpreting the data concerning their meaning (e.g. instrument position from related raw values). The configuration also contains (learned) activity rules which are knowledge about how to interpret the data of a specific sensor. For example, the position information of an instrument can be used to generate higher-level sensor information that the instrument is "in use". The interpreted data forms the Sensor knowledge (e.g. used instrument/device, treated structure, performing person) to be persisted and passed to the *Situation Interpretation* component of the **Situation Recognition** layer.

The *Situation Interpretation* contains interpretation modules that map sensor knowledge data to situations (e.g. phases), i.e. recognize the current situation in the OR immediately. For this, situation rules from the internal data storage are used, which contain (learned) interpretation rules for different sensor data. The *Knowledge Management* component provides Process knowledge via its knowledge handler. The process knowledge is retrieved from the *Workflow Engine* as well as from data storages (e.g. the actual step, possible next steps). The interpreted situation data (Situation knowledge of phase, step, activity, remaining surgery duration (RSD), and delay, as well as the pre-interpreted knowledge from sensors and process) is persisted and forwarded to the *Knowledge Management*. Within the *Knowledge Management* unit, different knowledge is requested for the *Situation Interpretation*. This includes Process knowledge from the fourth layer, individual surgical process models (SPMs) from the internal data storage, and OR planning data from an external data storage, an *OR planning system*. In addition, Situation knowledge from the *Situation Interpretation* component is transferred to the **Workflow Management** layer. This contains a *Workflow Engine* (in our case *Camunda BPMN Workflow Engine* (Camunda 2021)) that manages and controls the workflows of the ORs based on SPMs that represent the intra-operative processes taking place and the transferred Situation knowledge. The SPMs can be created via a *Workflow Modeler*. In addition, the engine informs *Context-aware systems* about the current situation in the OR via the *Situation Subscription Management* component.

Results

Implementation

The first implementation of the architecture shown above has the goal to demonstrate that the interaction of the single components is working and that all components and interfaces can be realized. The initial use case was the situation recognition within the project *OR-Pad* (Junger et al. 2019) for the intra-operative presentation of clinical information, like pre-operative images or notes, close to the surgeon. Context-relevant information should be automatically provided based on the actual surgical phase of the intervention (Frommer et al. 2021). The entire pipeline from data acquisition to workflow management was implemented, using python. The main components and flow of communication can be seen in Figure 2. The workflow of the prototype is as follows:

The sensor data is generated within the **Data Acquisition**. For this, a GUI offers the possibility to simulate sensor data manually or automatically for supported sensors assigned to an OR (registry database simulation). Currently, the following sensor types are prototypically implemented: Thermoflator, endoscope, navigation system, instrument/material recognition system, RFID of actors (e.g. surgeon), ultrasound, X-Ray, scissors, and trial implant. The data is sent in JSON format via URL (RESTful).

The **Sensor Abstraction** contains the *Resource Management*, which initializes listener threads, which "listen" to one network. The listeners use Flask to receive the simulated sensor data and store them in a text file. The newest data from the file is passed within the *Sensor Interpretation* to the suitable modules if the sensor is associated with the respective OR. Exemplary interpretation logics for device, instrument, material, and person information were realized to get the position, usage, measurements, and/or performer. For the interpretation of the position of devices etc., the x-, y-, and z-coordinates are compared with activity rules (regions in which the device etc. is defined as “in use”). For measurements of devices, rules defining thresholds are used. The interpreted data is stored in the sensor database simulation. This data is then used to form Sensor knowledge (used instrument, used material, used device, and performing actor), which is stored as well.

The resulting knowledge is further processed in the **Situation Recognition**. The data is passed within the *Situation Interpretation* to each module. Exemplary interpretation logics are implemented for phases, steps, activities, and RSD incl. delay. For the estimation of the phase, step, and activity, parameter combinations and their situation rules from the situation database simulation are evaluated using the Sensor knowledge to get Situation knowledge. Afterwards, the recognized knowledge is adapted by Process knowledge (i.e. the next situation defined by the process model of the intervention is identified), requested by the process knowledge handler (*Knowledge Management*) from Camunda. For the estimation of RSD and delay, just Process knowledge is used. On basis of the norm time of the intervention and the duration so far, the RSD is interpreted exemplarily. The delay results from the difference between the planned end and the calculated end. The *Knowledge Management* component is responsible for the data exchange of process and situation knowledge between the two upper layers via knowledge handler. In addition, the external systems management simulates the exchange with an OR planning system. After interpretation, the Situation knowledge (also including the pre-interpreted sensor and process knowledge) is passed to the highest layer.

The Situation knowledge created from sensor and process knowledge is passed to the *Workflow Engine* in the **Workflow Management** to control the process (workflow model in the *Camunda BPMN Workflow Engine* (Wiemuth and Burgert 2019)) based on the most likely detected phase. For the communication with Camunda, a middleware adapted from (Wiemuth and Burgert 2019) (workflow engine access) is implemented and runs on the server. The workflow management handler can use the functions of the middleware (e.g. get interventions, complete a task) via the middleware URL (RESTful). Variables are transferred in JSON format. The middleware itself implements functions by using Flask and uses the Camunda REST API (Camunda Services GmbH 2021) to access its information by URLs. The process models of the interventions need to be manually deployed in Camunda. The models contain user tasks to control the workflow within the Camunda engine. The recognition of the first task in a procedure automatically triggers the start of the process in the OR. If a process instance is already running, the system checks if it is reasonable to complete the actual running task to automatically start the recognized one. Since the *Camunda BPMN Workflow Engine* does not provide the required management of running activity instances (e.g. after AND gateways all tasks are automatically considered as "running"), these are managed via the workflow database simulation. Additionally, the individual SPM is stored by saving the start and end times of the running and completed tasks (i.e. individual situation). Via SDC connector implemented with sdclib (GitHub, Inc. 2021) the most probable phase and RSD are published, using named pipes. The *Situation Subscription Management* component simulates a context-aware system that subscribes to the phase and RSD metric to be informed in case of changes.

The **Workflow Management** also implements the method to get Process knowledge. Currently implemented are methods for getting the process model, the actual, next, and last situation, as well as the duration. The XML (serialized BPMN) of the intervention is requested from the Camunda engine. The actual situation is identified by the running activity instances. For each actual situation, the next possible situations are figured out by parsing the XML tree. The last situation is identified by the last stored individual situation. The duration is calculated by using the actual start time of the first task and the actual timestamp. The data is stored in the workflow database simulation and returned to the lower layer.

The probabilities of estimated correctness of interpretation are calculated depending on the reliability of the sensor, defined weights, and matching rules. To demonstrate the whole pipeline of the system, two simple use cases were defined with example data for a hip replacement and total hip replacement surgery, gathered from observations in the orthopaedics clinic of the University Hospital Tübingen and the DICOM WG24 “Surgery” white paper (DICOM WG24 „Surgery“ 2007).

Functional evaluation

In a functional evaluation, the defined goals and requirements were contrasted with the actual functionalities of the prototype of the situation recognition system by the developer. The overall system was executed as a demo prototype with an automatic sensor data simulation. A context-aware system was simulated to retrieve and log the most probable phase, RSD, and delay provided by the situation recognition system. Logging was used to comprehend the system's interpretation steps and communication flow. For more implementation details to evaluate all requirements, the code was analysed. All evaluation results are provided as supplementary material (see Appendix A as supplementary material). A summary is given in the following:

All 4 established goals were fully met. Data from different intra-operatively available sensors and knowledge of different interventions are used for the flexible and intervention-independent estimation of the current situation. The interface to context-aware systems provides them with contextual information. The functional requirements were all completely (19 of 25) or partially (6 of 25) fulfilled. Knowledge about past interventions is generated and stored at runtime, but not yet used for interpretation. In addition, rudimentary simulations for OR planning were used and the estimation is just triggered by changed sensor data, not by OR planning etc.

For the non-functional requirements, 26 of 41 requirements were fully met, 5 of 41 just partially. Several aspects could not be verified (6 of 41) or met (4 of 41). Because it is not a product for clinical use, no security concept and installation file is provided. Furthermore, the system was not tested in the hospital network and there is a lack of well-founded data, so many requirements, like minimizing bad estimations or interpreting in a reasonable time, cannot be adequately verified and not be defined as fully met. Because of missing configuration interfaces, no integrated communication interface in the *OR-Pad*, and omitted functional test descriptions, more requirements could not be fully met. In addition, the changeability of components could not be fully evidenced. Sensors are changeable, but other components, like the workflow engine, provide specific functionalities which could differ from others. Furthermore, no real sensor or no real OR planning system was connected as an example.

Discussion

The challenge of situation awareness in the OR is the variability of sensors and the intervention process. Access to sensors as well as handling the unpredictable course of the intervention need to be ensured. We assumed that the proposed modular system architecture allows an adaptive system that can be easily adapted and extended to different circumstances, e.g. other sensors or intervention types.

In the prototypical implementation, the pipeline was completely realized, so that a flow from sensor data to process control is possible as follows: Simulated sensor data is interpreted in different modules. The pre-interpreted data is then further processed to interpret phases and other situation data of the current intervention by using situation rules and process information. With the phase recognized as most probable, the workflow model in Camunda is controlled. Additionally, recognized information is provided for context-aware systems.

To process data from different intra-operatively available sensors, the sensor registry manages these for each OR. The sensors are assigned to a sensor type (e.g. instrument recognition system) as well as sensor data type (e.g. instrument usage). With this information, the sensor data can be forwarded to the appropriate interpretation module and method. New sensors can be registered for an OR and are then automatically included for the sensor data interpretation. In addition, sensor fields are managed in the sensor registry for sensors using JSON format. For new sensors or data types, the components can be extended.

For covering different interventions, process models are deployed on the Camunda engine. All possible phases, steps, and activities of these interventions are created manually within the database simulation. Via situation relations, steps can be assigned to phases etc. Situation rules need to be added for each situation (e.g. phase), because of the rule-based approach. Therefore, situation rules comprise an information (e.g. scalpel) and a knowledge type (e.g. used instrument) and are assigned to a parameter combination which again is assigned to a phase etc. To include new interventions, all the data need to be manually added and is then automatically processed during interpretation. In addition, the process model of the intervention must be deployed.

To support different context-aware systems, the modules estimate a set of different situation knowledge to be provided to external systems. Via the SDC interface, context-aware systems can subscribe to desired knowledge (e.g. phase and RSD) and will be automatically informed about changes of the actual situation. For new situation knowledge, new recognition modules and SDC metrics can be integrated.

Since the main goal of the current project was to demonstrate the overall functionality of the architecture, some of the components were deliberately simulated or implemented as examples. Simulated data based on recordings of real interventions were used and extended to implement rule-based interpretation logics (e.g. interpretation of device position or current phase). The knowledge representation and process models in BPMN are kept simple so far. Because of that, the evaluation results must be considered with caution while interpreting the fulfilled requirements.

Overall, the prototypical implementation and functional evaluation demonstrated the feasibility of the proposed system concept and architecture. The evaluation of the prototypic implementation was encouraging. The prototype will be extended in further iterations to cover more requirements. Real data will be integrated. Furthermore, interpretation logics shall be supplemented exemplarily by machine learning approaches. Also, the initial use of ontologies and application to more complex operations will be realized to optimize the basic framework system to be more adaptable. The extended system will undergo another functional as well as clinical evaluation to further verify the system's concept.

Acknowledgements

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Disclosure statement

The authors declare no conflict of interest.

Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

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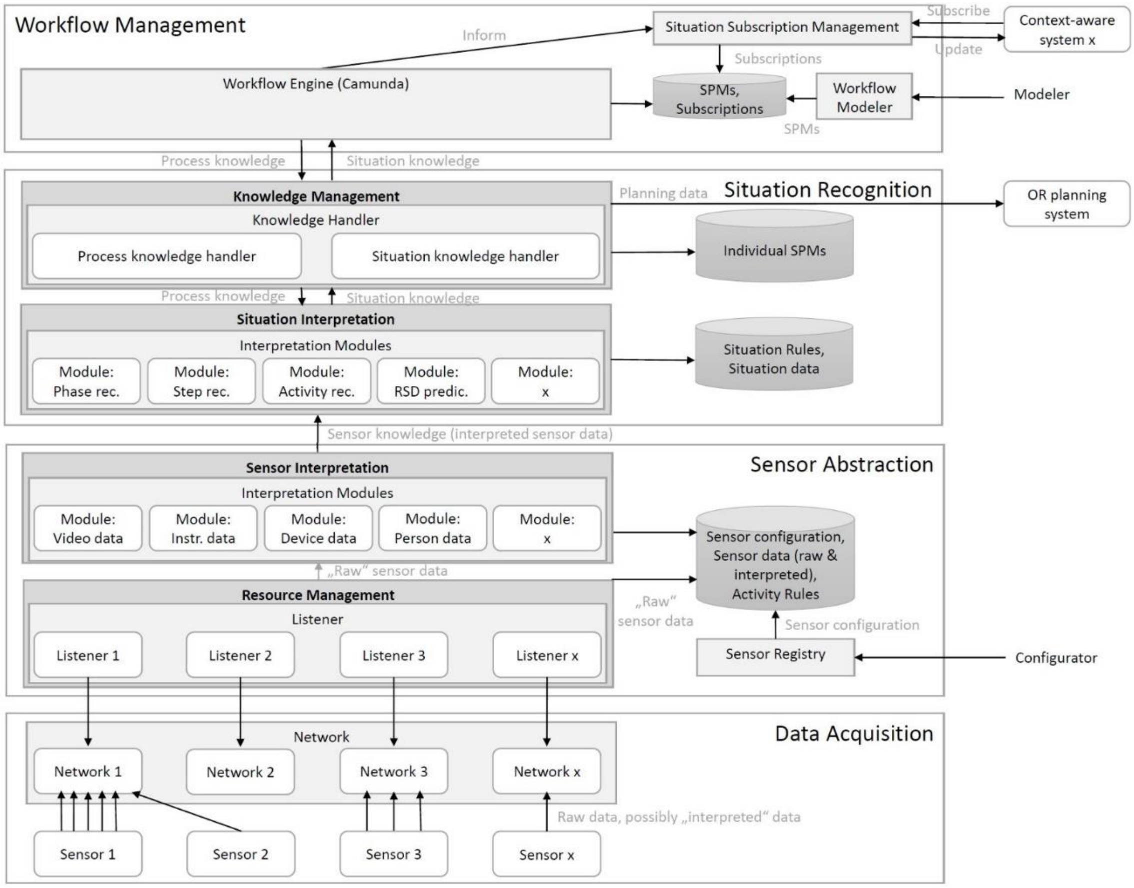

Figure 1. Conceptual architecture of the situation recognition system depicting the main components and communication flow.

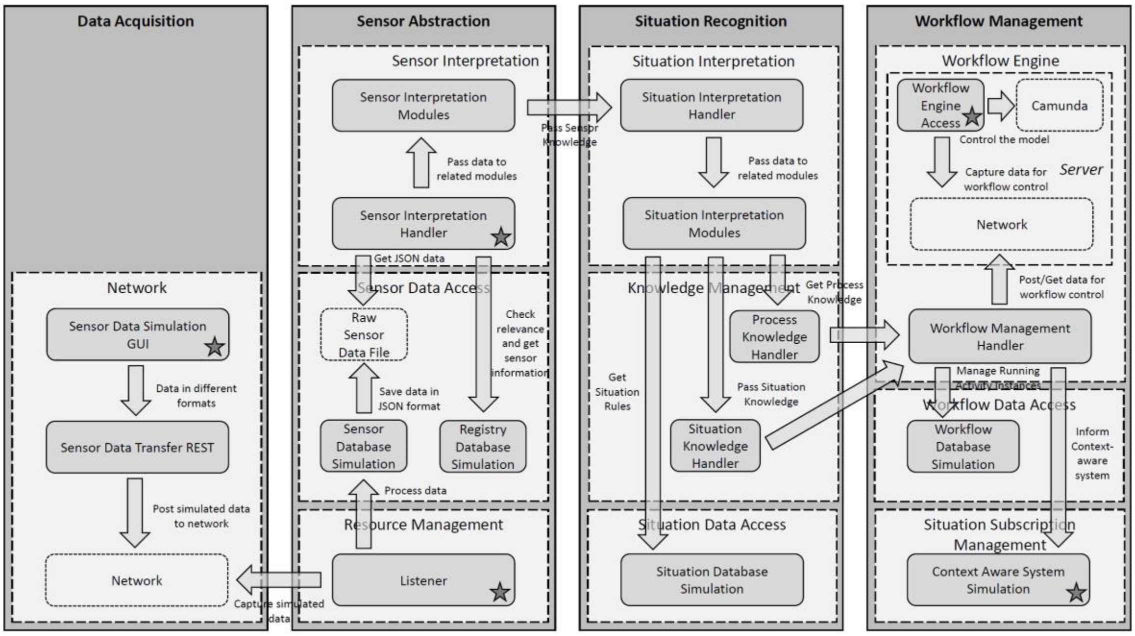

Figure 2. The implemented architecture of the prototype of the situation recognition system depicting the main components and communication flow. Components marked with a star are running as separate processes and initialize the following components.

2.3 Process formalization of variable surgical interventions

2.3.1 Toward an interoperable, intraoperative situation recognition system via process modeling, execution, and control using the standards BPMN and CMMN [publication 3]

The SRS uses SPMs of different surgical intervention types to enrich situation interpretation with process knowledge and reflect the actual course of the intervention. A combination of BPMN and CMMN might be sufficient to formalize variable surgical processes and enable better transferability. The publication

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describes the practical approach of using BPMN and CMMN for the modeling, execution, and control of SPMs within a transferable SRS in the OR, highlighting their suitability and added value for applicability and transferability.

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ORIGINAL ARTICLE

Toward an interoperable, intraoperative situation recognition system via process modeling, execution, and control using the standards BPMN and CMMN

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Abstract

Purpose For the modeling, execution, and control of complex, non-standardized intraoperative processes, a modeling language is needed that reflects the variability of interventions. As the established Business Process Model and Notation (BPMN) reaches its limits in terms of flexibility, the Case Management Model and Notation (CMMN) was considered as it addresses weakly structured processes.

Methods To analyze the suitability of the modeling languages, BPMN and CMMN models of a Robot-Assisted Minimally Invasive Esophagectomy and Cochlea Implantation were derived and integrated into a situation recognition workflow. Test cases were used to contrast the differences and compare the advantages and disadvantages of the models concerning modeling, execution, and control. Furthermore, the impact on transferability was investigated.

Results Compared to BPMN, CMMN allows flexibility for modeling intraoperative processes while remaining understandable. Although more effort and process knowledge are needed for execution and control within a situation recognition system, CMMN enables better transferability of the models and therefore the system. Concluding, CMMN should be chosen as a supplement to BPMN for flexible process parts that can only be covered insufficiently by BPMN, or otherwise as a replacement for the entire process.

Conclusion CMMN offers the flexibility for variable, weakly structured process parts, and is thus suitable for surgical interventions. A combination of both notations could allow optimal use of their advantages and support the transferability of the situation recognition system.

Keywords Situation recognition · Surgical process modeling · BPMN · CMMN · Intraoperative area

Introduction

Formal modeling of surgical processes is one of the main aspects to achieve situation awareness in the operating room (OR) [1]. Surgical Process Models (SPM) are used to better understand and analyze surgical workflows [2] and can be applied for situation recognition purposes [3] to incorporate process knowledge into the recognition logic [4]. Formalization for automated handling and processing is therefore necessary, using, e.g., ontologies, XML schemas, or graphs [2]. To represent knowledge, several approaches state to use SPMs in general [5–8] or an ontology [5, 8–12], as analyzed in [3]. Several research groups rely on using the Business Process Model and Notation (BPMN) for modeling the course of an intervention [4, 13, 14]. BPMN models enable a graph-based visualization based on an underlying XML structure

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to provide machine readability and can be managed via a workflow engine. However, for modeling more complex and variable surgical workflows, BPMN reaches its limits, as activities within the OR can occur in variable order or be performed discretionarily. BPMN provides less flexibility [15] and becomes complex depicting process variants [16]. A modeling language that can reflect the variability of complex and highly flexible surgical workflows is crucial.

Case Management Model and Notation (CMMN) is a modeling language, promising to be more flexible than BPMN [17], and could therefore be well suited for modeling variable surgical interventions [18]. While Zensen and Küster [17] elaborated general advantages and disadvantages of BPMN and CMMN, the work of Wiemuth et al. [18] showed for the medical field how complex sub processes of a Cataract Operation are when modeled with BPMN and how the same process can be modeled easier in CMMN and Decision Model and Notation (DMN). The results showed that using CMMN and DMN to model flexible and weakly structured processes can lead to a more compact model while also being better readable. Furthermore, a combination of BPMN, CMMN, and DMN was addressed to depict a mixture of structured and unstructured process parts including decision support. Nevertheless, CMMN may be more difficult to understand than BPMN. The idea of [18] was further specified in [19] which showed a concept of situation recognition using a combination of BPMN, CMMN, and DMN for process modeling. A combination of BPMN and CMMN is also used in other domains, where it is described as a hybrid modeling approach that defines a process more efficiently while simplifying it [20] or a connection for integrating structured and loosely specified processes [15].

Another work using CMMN for modeling perioperative processes dealt with the transferability of SPMs [21]. Herzberg et al. [21] remodeled a BPMN model of an organ transplantation. To transfer the model to other hospitals, it should represent variable processes. This was achieved using CMMN, which enabled the modeling of the surgical intervention for multiple hospitals, including different treatments. Tasks that occur in all hospitals were modeled as required whereas non-obligatory tasks were depicted as discretionary. Moreover, it was discussed that realizing the same concept in BPMN would be harder, as the different variants need to be modeled via gateways, increasing the complexity of the model.

Concluding from [18] and [21], CMMN is promising to be more suitable for variable surgical interventions than BPMN. It allows tasks to be executed in variable order [22] and is fitting for the representation of optional steps [17]. As the work of [18] focused on theoretical analysis, it lacked a practical evaluation for the use case of situation recognition, also including the execution and control of the models. Furthermore, no CMMN without BPMN and DMN was demonstrated. The concept of [21] using CMMN for better transferability to other hospitals is another important aspect that should be discussed concerning situation recognition.

The Situation Recognition System (SRS) of Junger et al. [4] aims for a flexible and intervention-independent situation recognition in the OR. Knowledge from BPMN models is used in combination with sensor data to recognize the actual situation. Furthermore, the model is executed for workflow control. The gathered information about the situation in the OR is provided to extern context-aware systems independent of their usage (e.g., for automatic information filtering [11] or provision [8, 23, 24], device control [25, 26]). To demonstrate that the SRS can be adapted to support non-standardized interventions, more complex interventions should be integrated. Since BPMN can become quite complex [16, 20], CMMN should be considered as it is promising to keep the models compact for readability, while still depicting variability and optimizing the transferability of the SRS.

In this work, practical approaches of process modeling, execution, and control of more complex, non-standardized surgical interventions for situation recognition are analyzed. BPMN, CMMN, and combination models are developed for two interventions, the Robot-Assisted Minimally Invasive Esophagectomy (RAMIE) and Cochlea Implantation (CI). The established models are used within the extended SRS of [4] for accessing process knowledge and reflecting the course of the intervention. The evaluation comprises the differences in modeling, execution, and control of the SPMs, analyzing the modeling approaches and effects on the SRS workflow. The discussion elaborates on the advantages and disadvantages of the approaches and highlights the effect on the transferability of the SRS employing the models.

Methods

Surgical process modeling of the use cases robot-assisted minimally invasive esophagectomy and cochlea implantation

As the main use case, the RAMIE was chosen, being a complex and demanding intervention in visceral surgery [27] and a current case for phase recognition [28]. It comprises an abdominal part with gastric and distal esophageal mobilization, construction of a gastric tube, and lymphadenectomy along major abdominal vessels, as well as a thoracic part with dissection of the esophagus with lymphadenectomy, stomach pull-up, and an anastomosis of the remaining esophagus and gastric tube [29]. At multiple parts, steps can occur in variable order or be optional. Furthermore, several foreseen events are known. The SPM of [27] depicts the surgical workflow of the RAMIE comprising nine phases and various steps modeled in BPMN and was created as part of preliminary work with the clinical partners of Heidelberg University Hospital providing information like steps, variances, or used instruments. Because the model was intended to be used for an intraoperative checklist [30] that allows the flexible tick-off of the displayed steps, these were modeled as *Tasks* after each other using *Sequence Flows*. For the idea of a transferable SRS, a higher degree of variability is needed to cover the different possible courses of the intervention. Therefore, the SPM was extended to depict the variable order of steps and optional tasks.

To allow process control, the modeled *Tasks* were switched to *User Tasks*. For the first version, *Exclusive (XOR) Gateways* were used for workflow parts where the execution order can vary. Due to the model becoming too complex (e.g., a process part with five tasks in variable order including optional tasks led to ~ 150 possible paths), it was rejected. After considering *Ad-hoc Sub Processes*, but these did not allow the desired distinction between mandatory and optional tasks, they were not used either. The new approach modeled variable steps using *Parallel (AND) Gateways* and optional steps using *XOR Gateways*. For a two-granularity (2G) version, the *User Tasks* (steps) were grouped into *Sub Processes* (phases). Events were exemplarily included using *Signal Boundary Events*. An excerpt of the BPMN model is depicted in Fig. 1 (left).

The very same intervention was realized using CMMN, based on the same clinical information. Steps were modeled as *Human Tasks*. *Sentries* and *Stages* were used to depict dependencies. Optional tasks were integrated without a *Required Rule* but a *Manual Activation Rule* inspired by [17], as *Discretionary Tasks* used in [21] were not supported by the Camunda Engine [31]. Events were exemplarily included using *Event Listener*. For the 2G version, *Stages* equivalent to the *Sub Processes* of BPMN were integrated. An excerpt of the CMMN model is depicted in Fig. 1 (right).

In addition, combination models comprising both notations were modeled. The "mixed" combination relies on a BPMN including *Call Activities* to CMMNs just for variable processes, based on [18]. The "structured" combination contains high-level *Stages* in BPMN and *Call Activities* referring to CMMNs including structured and variable steps. This approach was partly inspired by [19]. An overview of the used notation elements is depicted in Table 1.

As a second use case, the CI based on the BPMN model of [30], comprising steps structured in the five phases preparation, access, operation under and after the microscope, as well as follow-up, was used. This use case is more straightforward, less containing steps in variable order but includes different procedures, e.g., deviated steps according to the cochlea implant that is implanted, and foreseen events. For the BPMN, the model of [30] was used which was created as part of preliminary work with the clinical partners of University Hospital Düsseldorf. Different paths were realized by *XOR Gateways*, *Sub Processes* were used to structure steps in phases. From the BPMN model, a CMMN model was derived the same as for RAMIE, using *Sentries* and *Stages* to depict dependencies as well as phases and *Manual Activation Rules* to model different paths. Furthermore, a mixed and structured combination model was derived.

Workflow within the situation recognition system using surgical process models

The RAMIE use case was integrated into the framework prototype of [4], including parameter combinations and situation rules. To simulate the intervention, acquired knowledge from Heidelberg University Hospital, provided by the clinical partners (see previous subsection), was used, concretely which instrument combination may be used and where the surgeon and assistant will probably be in the room in the respective steps. Therefore, reasonable sensor data combinations were simulated including the name of the used instruments and/or position data of the actors. In addition, the CI use case was integrated. As no sensor data were available for data simulation, we simulated the step name as input for situation recognition. Furthermore, the logic to support more complex BPMN models was extended. Control logic for the established CMMN and combination models were pre-tested in a separate test environment, simulating the step names via the checklist of [30]. The ticked-off checklist point, indicating the end of the respective situation, was used to control the process. Overall, 18 different models of RAMIE and 14 of CI, including CMMN cases of combination models, were tested. After pre-testing, parts of the logic were included, adapted, and extended to fit into the SRS architecture and functionality.

In the following, the SRS functionality is depicted, concentrating on the adapted parts of the system. Further information on the overall concept can be retrieved from [4]. SPMs are used within the architecture for both, obtaining process knowledge and reflecting the actual course of the intervention (process control). The administration and control of the running processes are supported by a Camunda Engine [31] (see Fig. 2, left), whereby most of the control logic, unless otherwise specified, is implemented by the SRS itself. The SRS communicates with the engine via a middleware that provides REST API [32] functions, e.g., to complete a task.

Situation recognition

For situation recognition, *Sensor Knowledge* (e.g., used instrument) retrieved from sensor data and *Process Knowledge* (e.g., next possible steps) retrieved from SPMs are used. Within modules for phase, step, and activity recognition, first *Situation Knowledge* (e.g., surgical step) is interpreted based

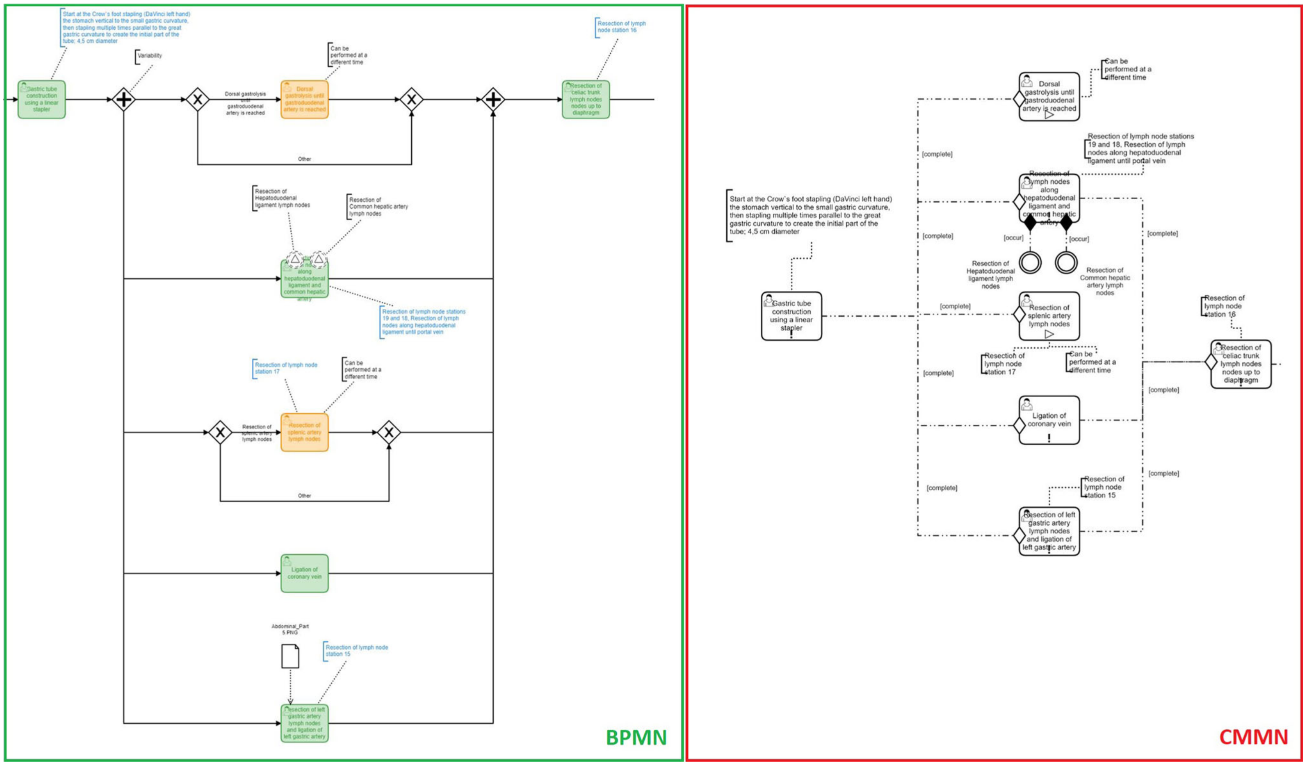


Fig. 1 Excerpt of the RAMIE use case contrasting variable process parts modeled in BPMN (left) and CMMN (right), including steps in variable order and optional tasks

on solely the *Sensor Knowledge* by using situation rules. Secondly, the resulting *Situation Knowledge* is enriched by *Process Knowledge* including the next possible situations. Hereby, a configured value defines the influence of the *Process Knowledge* (see Fig. 3). The module for calculating the remaining surgery duration (RSD) and delay only uses *Process Knowledge* of the duration.

Workflow management (get process knowledge)

To provide *Process Knowledge*, the XML of the intervention's model is used. As the long-term concept is to strengthen the *Process Knowledge* by using similar, already executed case-relevant processes, this is temporarily simulated by always using the BPMN model of the intervention, since it reflects the expected input of similar cases in a structured manner. Via recursive function calls, valuable next steps are retrieved from the XML. Starting from the current step, the next steps are determined based on the modeled sequence by going through all possible paths.

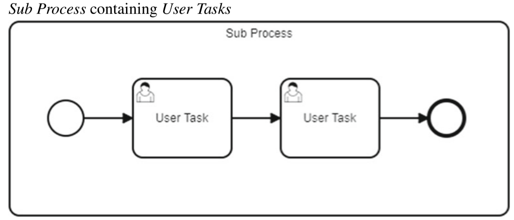
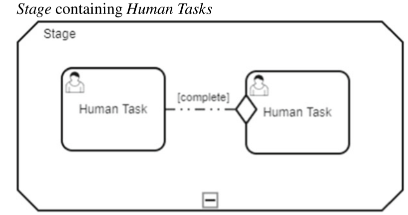
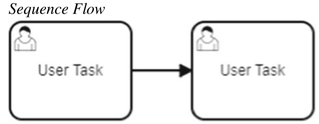
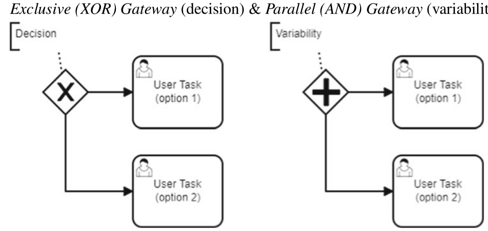
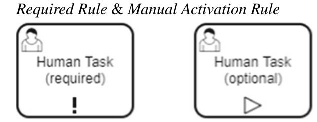
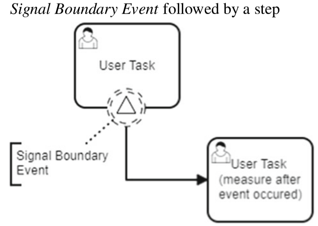
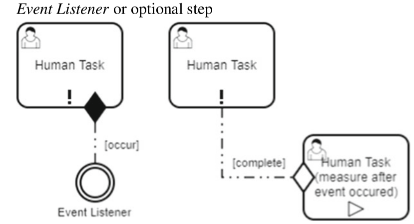
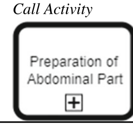
Workflow management (process situation knowledge)

The process is controlled by the recognized situation with the highest probability. Recursive function calls are used to identify whether it is logical to start the next task by parsing the XML of the belonging intervention model. A list of instances that can be completed is constructed while comparing the previous tasks with actual running activity instances. Moreover, the information on whether the new situation is reasonable is returned. Afterward, the matching running task is completed in Camunda, so that the next possible *User/Human Tasks* are activated automatically.

Evaluation

Comprehensibility of the process models is important for clinically correct models. Therefore, clinicians need to comprehend the models to give feedback or even create models themselves. To gain an impression and rough trend of the comprehensibility of the established RAMIE and CI models, a total of 12 user tests were conducted with clinicians associated with the University Hospitals of Heidelberg and Düsseldorf. For the evaluation, a simple form was used. First, it was noted if the modeling notations and intervention are familiar. After a small introduction to BPMN and CMMN, the established 2G BPMN, CMMN, and combination models were presented. The user was asked to explain the modeled process and to identify specific elements, like required or optional steps. The subjective impressions were recorded within the form. Via post-test questions, the user rated the comprehensibility of each model on a scale from 1 to 5 (very

Table 1 Overview of our transfer concept of process information to BPMN and CMMN elements

Process information	BPMN elements	CMMN elements
Phases and steps	*Sub Process* containing *User Tasks* 	*Stage* containing *Human Tasks* 
Order/Dependency	*Sequence Flow* 	*Sentry* 
Variable step sequence	*Exclusive (XOR) Gateway* (decision) & *Parallel (AND) Gateway* (variability) 	If no order is defined 
Required vs. optional steps	Required: No other path is possible Optional: Another path is possible	*Required Rule* & *Manual Activation Rule* 
Foreseen events and the following measure	*Signal Boundary Event* followed by a step 	*Event Listener* or optional step 
Link from BPMN to CMMN	*Call Activity* 	No reference used

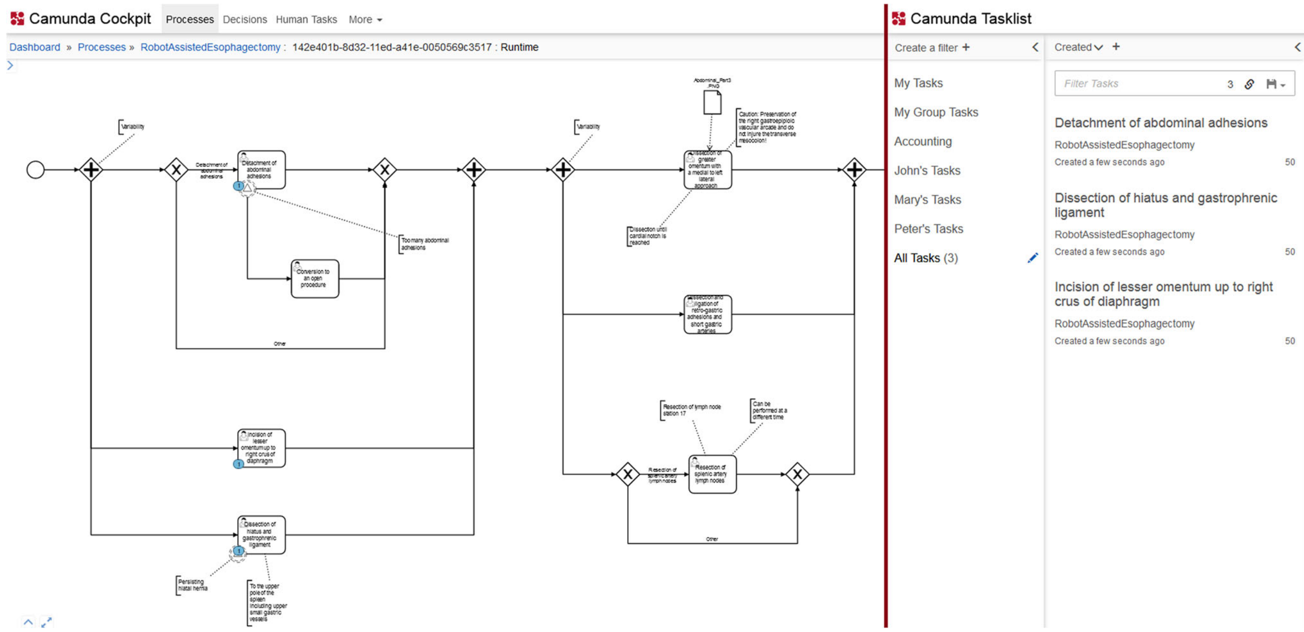


Fig. 2 Camunda cockpit (left), visualizing the process token within the running process, and Camunda Tasklist (right), listing running activity instances of the process

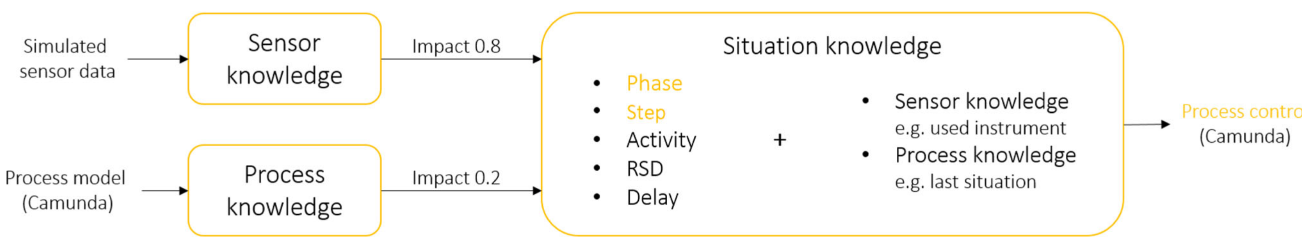


Fig. 3 Combination of knowledge from simulated sensor data and the process model to form *Situation Knowledge* for process control via recognized phase and/or step, while *Impact* represents a configurable value that defines the factor of the *Sensor Knowledge* (here: 80%) and *Process Knowledge* (here: 20%) to form *Situation Knowledge*

easy to very hard). Furthermore, the subjective opinion of the most comprehensible model was accessed. During the whole evaluation, remarks from the user and impressions of the evaluator were gathered.

On basis of the user tests, a selection of the established models was integrated into the SRS. For this purpose, minor changes, mostly referring to the removal of sub stages, were made to allow for comparable cases and uniform modeling. In the end, the 2G BPMN models, the adjusted 2G CMMN models, and the adjusted 2G structured models with a total of nine cases for RAMIE and five for CI were deployed. Although only a selection of models was integrated, the pre-test has already proven that all models can be executed and controlled accordingly.

To evaluate the SRS workflow with more complex interventions, sensor data were simulated via an automatic data simulation, defining a valid path through the process. Furthermore, the flexibility and error-proneness of the models and control logic were tested by simulating the steps of the intervention in unreasonable order via distorting the input data. The performed test cases cover the variable execution of tasks and different paths, the skipping of required and optional tasks, as well as the regression and repetition of tasks. The console output was used to comprehend the recognition steps, interpreted sensor, process, and situation knowledge, as well as subsequent control of the respective process model. In addition, the Camunda Cockpit and Tasklist (see Fig. 2) were viewed to follow the process via token and to retrace active tasks. Via the Camunda REST API, the correct execution of the models was retrieved. Modeled event information (e.g., bleeding) was not included in the tests for now. The system tests focus on the analysis of the execution and control of the process models like peculiarities in the execution and limitations due to the models. Therefore, the results are meant to highlight the recognition behavior in supporting different modeling approaches.

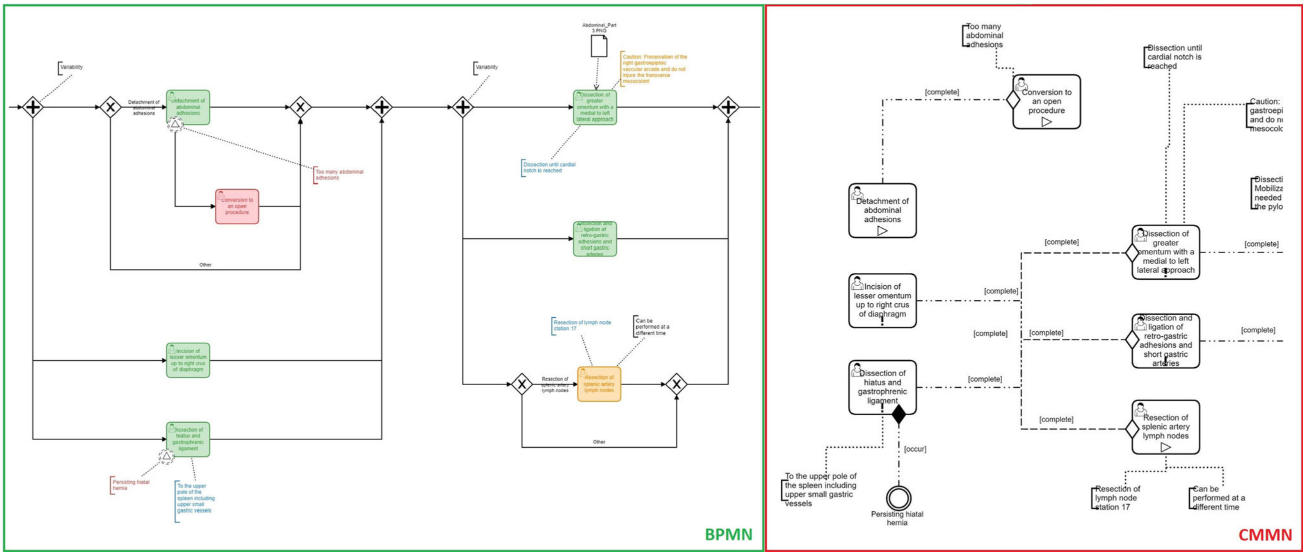


Fig. 4 Excerpt of the RAMIE use case contrasting variable process parts modeled in BPMN (left) and CMMN (right), including steps in variable order and optional tasks

Results

Comparison of the surgical process models and user tests (modeling)

The RAMIE use case shows that via *Sequence Flows,* gateways, and start/end events a clear path is recognizable in BPMN (see Fig. 4, left). Optional tasks can be identified via *XOR Gateways*. Nevertheless, tasks in variable order need to be modeled via workaround (*AND Gateways*), intended to be executed after each other, thus indirectly semi-parallel and not correctly depicted. In contrast, tasks in CMMN can be modeled with fewer dependencies without gateways or start/end events but also *Sentries* and *Stages*, making it possible to represent variable sequences while maintaining some structure (see Fig. 4, right). Via *Sentries* as *Entry Criteria*, sequences to following tasks can be depicted without clarifying their order. The tasks with the *Entry Criteria* are dependent on the completion of the previous elements ("completed" event). Required and optional tasks can simply be recognized via the symbols within the modeled tasks (*Required Rule* and *Manual Activation Rule*).

By modeling different procedures in the CI use case, the *XOR Gateway* in BPMN clarifies that only one path is possible (see Fig. 5, left). In CMMN, the same representation as for variable order is used but the paths are modeled as optional. Thereby, it cannot be differentiated if all paths or just one can be done (see Fig. 5, right). More dependency elements like *Stages* can counteract such uncertainties.

BPMN and CMMN can be combined in different ways. Within the mixed combination model, variable parts of the process are integrated in BPMN via *Call Activities*, referring to the sub process modeled in CMMN (see Fig. 6, left). As the back and forth between BPMN and CMMN is not consistent, no clear separation is apparent. The approach of a structured combination model uses an overlying BPMN comprised of the interventional phases and contains *Call Activities* to the cases (see Fig. 6, right), making it more clear as no mixture of *User Tasks* in BPMN and *Human Tasks* of CMMN are present. The modeled steps in BPMN and CMMN reflect the pure models.

Within the user tests, a total of 12 assessments could be made, seven for RAMIE and five for CI. Despite that a few comprehensibility problems occurred during observation, each test person was able to comprehend the models after getting into the peculiarities of the notations. Every test person stated that knowledge about the intervention is helpful to better understand the process models. In three observations, the test participant already had a few experiences with BPMN (beginner). The results are summarized in Tables 2 and 3.

System tests (execution and control)

2G BPMN

The RAMIE and CI test cases with simulated sensor data in reasonable order ran without errors. Steps in incorrect order were recognized by the system logic as not reasonable due to the inclusion of process knowledge. All required tasks need to be done in a valid order, variable tasks can be executed in any order and different paths be followed as modeled. Skipping or regressing tasks was not possible, except optional tasks can be skipped.

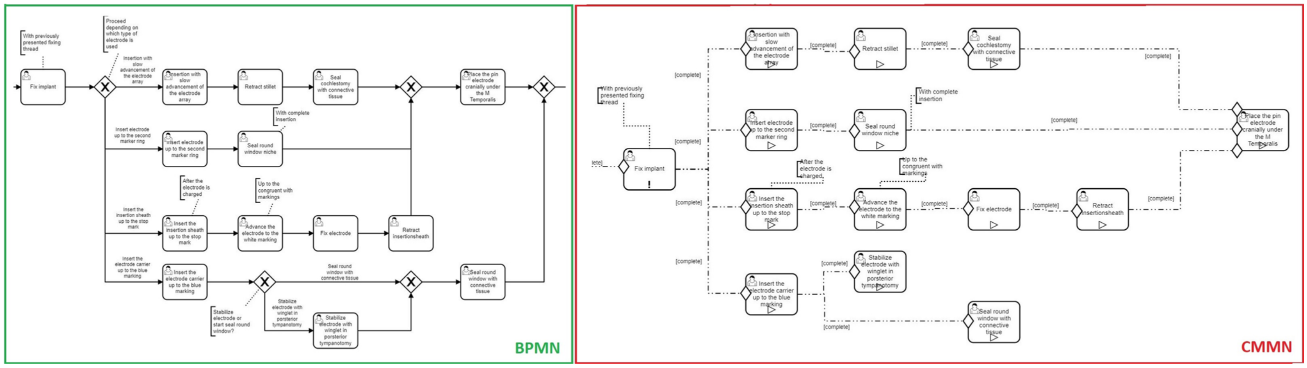


Fig. 5 Excerpt of the CI use case contrasting variable process parts modeled in BPMN (left) and CMMN (right), including different procedures and optional steps

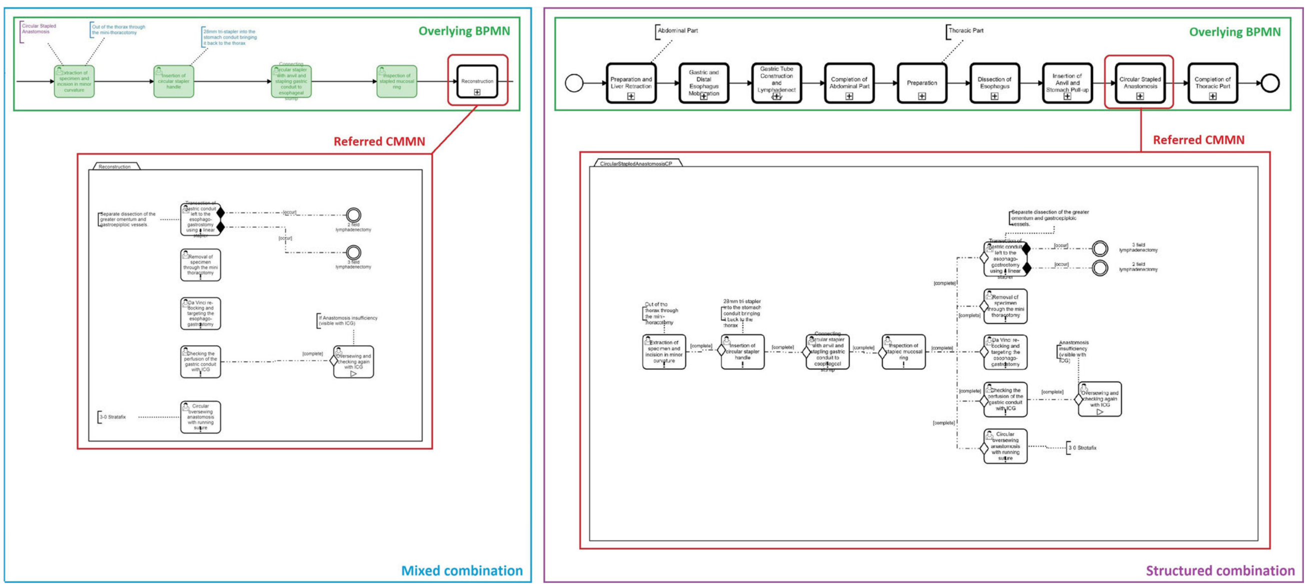


Fig. 6 Excerpt of the RAMIE use case contrasting variable process parts modeled with an overlying BPMN and referred CMMN in a mixed (left) and structured (right) way

Semi-parallel tasks (see Fig. 4, left) are activated and present in the Camunda Tasklist after completing the task before (see Fig. 2). The token automatically jumps to all the tasks, making them possible to complete. Optional tasks after an *AND Gateway* are automatically skipped by the Camunda Engine if another semi-parallel task is recognized first. The optional task can be done afterward but this will not be reflected by Camunda. This peculiarity does not influence the recognition results but only the representation in Camunda. A *Sub Process* is automatically completed by Camunda after achieving the respective end event and started as the process token jumps to its first task.

2G CMMN

The RAMIE and CI test cases with simulated sensor data in reasonable order also ran without errors. Not plausible tasks were recognized the same as for the BPMN, except first stage tasks. All required tasks need to be executed in a valid order, as skipping or regressing tasks was not possible. Variable tasks can be done as liked and optional tasks do not need to be done. Different paths could be executed as modeled. Limits were evident for delayed optional tasks and multiple paths (see subsection Discussion).

For tasks in variable order (see Fig. 4, right), all are activated and present in the Camunda Tasklist after completing the task or stage before, except for optional tasks. In contrast to the BPMN model, optional tasks can be still activated after another variable task was recognized. A *Stage* is not automatically completed by the engine if optional tasks are present within it and therefore needs to be completed "manually" by the system's logic via the Camunda REST API. In contrast, the next *Stage* is activated automatically by Camunda after the completion of the one before. The case itself also needs

Table 2 Overview of the results of the user tests for RAMIE process models, separated if the test person is familiar (fam.) or unfamiliar (unfam.) with the intervention, positive and negative remarks are depicted as ±

	RAMIE (Total of seven test persons)							
	BPMN		CMMN		Mixed combination		Structured combination	
	Fam	Unfam	Fam	Unfam	Fam	Unfam	Fam	Unfam
Amount of test persons	4 (two with beginner experience)	3	4	3	4	3	4	3
Average value of understanding (1 = very easy, 5 = very hard)	2 (2.5 without bias)	2.33	2.25	2.83	2.88	2.5	2.38	2.16
Number of ratings as the favorite model	1 (0 without bias)	2	1	0	0	1	1	1
Comprehension problems	Optional steps in variable order Join gateways Missing conditions for decisions		Optional steps and order Arrangement of the steps Paths		–		–	
Remarks	+ Good representation + No misunderstandings + Self-explanatory and sleek + Clear arrows to follow − More complex parts exhausting to read − Nested for parts with variability and optionality − More difficult to understand than CMMN		+ Advantages visible + More accurate depiction + All contents are directly visible and structure is given via stages + Obligatory and optional tasks more clear and easier than in BPMN + Variability in combination with obligatory and optional more clear than in BPMN − The main path is lost from sight − Need longer to get into the notation − More background knowledge needed − Events are inconsistent		+ Get the best of both notations − References are unattractive as they can be overlooked and logic changes		+ Good overview of the basic sequence + Referenced CMMNs remain small and clear + Complexity is depicted in detail − Subordinate structure less useful − Annoying to jump into the sub processes	

Table 3 Overview of the results of the user tests for CI process models, separated if the test person is familiar (fam.) or unfamiliar (unfam.) with the intervention, positive and negative remarks are depicted as ±

	CI (total of five test persons)							
	BPMN		CMMN		Mixed combination		Structured combination	
	Fam	Unfam	Fam	Unfam	Fam	Unfam	Fam	Unfam
Amount of test persons	3	2 (one with beginner experience)	3	2	3	2	3	2
Average value of understanding (1 = very easy, 5 = very hard)	1.66	2 (3 without bias)	3.16	2.25	2.5	3	2.16	3
Number of ratings as the favorite model	3	1 (0 without bias)	0	1	1	0	1	1
Comprehension problems	Distinguish between gateways		Optional steps and paths, e.g., when one path is mandatory Variable order Next task after optional tasks (missing sequence)		–		–	
Remarks	+ Intuitive + Self-explanatory and logical + Elements and symbols easy to understand + Decisions depicted elegantly + Optional tasks are more clear than in CMMN − Variable order not depicted well − Gateways not intuitive − Good for linear processes but the reality is not linear		+ Not much harder to understand than BPMN + Variable tasks are much clearer than in BPMN + Events are better than in BPMN + "Complete" is nice as feedback + Complex parts better comprehensible due to symbols than BPMN − More complex notation (partly only at first glance) than BPMN − Less intuitive than BPMN, e.g., optional steps − Too much going on you need to pay attention to − Events less clear due to missing elements compared to BPMN		+ Steps are depicted very well in BPMN but variable parts can be modeled via CMMN − Structure less clear than for the structured combination − Level of detail not clear for references − Need to learn both notations		+ Good overview and structuring + Less nested than the mixed combination − Need to learn both notations	

to be completed and closed manually by the system after the last task.

2G Structured combination

The results for the RAMIE and CI test cases were the same as for the CMMN models, except that in addition to stage changes case changes are made. The token of the process automatically jumps to the respective *Call Activities* in the BPMN model, after the process was started or the referenced case was closed. Furthermore, the cases need to be completed and closed manually via the Camunda REST API by the system's logic.

Discussion

Modeling, execution, and control of surgical process models

Modeling

Modeling variable surgical processes via BPMN can lead to extensive models or workaround solutions, i.e., not modeled properly. In CMMN, the order of tasks does not have to be specified explicitly, while the models stay readable and comprehensible, as also stated in [18]. Furthermore, mandatory and optional steps can be easily differentiated using attributes instead of gateways. Tasks that occur only once or multiple times [18] and different procedures [21] can be depicted, whereas a BPMN model would become too complex and incomprehensible. However, clear paths can be depicted in BPMN, whereas CMMN does not provide this information to the same extent, as also stated in [17]. More background knowledge of the process is needed [17] to comprehend if the tasks have a variable order or if only one path is possible, as in CMMN it is more difficult to represent dependencies. By combining BPMN with CMMN, the strengths of both notations can be combined, either by mixing structured parts with unstructured parts or referring from a structured overlying BPMN to unstructured CMMNs.

The user tests showed for RAMIE and CI process models that impressions and opinions differ extremely. BPMN was mostly described as intuitive, clear, and self-explanatory but more complex parts led to comprehensibility problems. CMMN was rather stated as less intuitive and more complex, especially the depiction of order and optional tasks. On the other hand, variable, required, and optional tasks were more clear. For the combination models, some highlighted that using both notations and dividing complexity in sub processes is advantageous, while others disliked this mixture and the references. Despite these remarks, all models scored a similar average between 2 and 3 (easy to neutral), expect two outliers in the CI models. Being familiar with the intervention was stated helpful but differences are not visible in the results. Also, the rating of the favorite model is distributed. For RAMIE, the BPMN and structured combination are slightly favored, a more clear tendency to BPMN was spotted for CI. According to the users, BPMN seems to be the favorite and best to comprehend, nevertheless, also the notation of CMMN scored in some aspects. Although in [18] and in our tests CMMN was mentioned to be more difficult to comprehend, the average scores we obtained indicate comparable comprehensibility. Furthermore, we assume that each approach can be made likewise comprehensible through explanation and practice, as a learning curve was visible during observation.

Execution and control

In the context of situation recognition, the validity of the SPMs was demonstrated. The execution and control of the selected models were challenging. For BPMN, only a path needs to be set for optional tasks and tasks to be completed. For CMMN, apart from completing tasks, optional tasks are to be started manually and *Stages* are to be completed via the system using the Camunda REST API. To control the structured combination model, a similar effort is needed for CMMN only models. In the case of a mixed combination model, more hopping between BPMN and CMMN control would be needed, making execution and control more complex.

The XML structure of the models is also different. In BPMN, the path can be clearly followed via the *Sequence Flows* to determine tasks. In CMMN, elements are structured within *Plan Items* which contain the relevant information about the assigned *Stage* or *Human Task* as well as *Entry Criteria* and rules. As CMMN is less structured, it lacks sequences, branches, and start and end of *Stages*, so the order can be chosen more freely [17], enabling the variable execution of a task. However, this led to a higher error-proneness in validating stage/case changes and when differentiating between variable order, different paths, and optional tasks, so that falsely recognized delayed optional tasks and the execution of multiple exclusive paths were possible. This is due to the chosen modeling approach with CMMN. For example, different paths are depicted as optional although one path needs to be done. Such peculiarities might be solved via other CMMN approaches or an extension of the control logic that is aware of such exceptions. Up to now, the CMMN process control does not have the same deepness as for BPMN to filter out false positives. As CMMN relies on the user or the system knowing what is reasonable and provides all options, integrating more data like similar, executed processes to gain better knowledge about next possible steps is crucial. Overall, it was more difficult to read out the needed information of CMMN and there still is a lack of including all conditions and special cases. Although DMN was excluded in this work, it might be a possible supplement for better workflow control (see [18]) and may counteract the limitations mentioned above.

Applicability and transferability

Integrating CMMN into the system architecture was a crucial step for the applicability and transferability of the SRS. The results show that the SRS not only can support BPMN models of standardized interventions but also complex interventions in both notations, making it applicable for various kinds of interventions and circumstances. Furthermore, combining BPMN and CMMN by referring to CMMN cases based on an overall BPMN structure allows for adaptivity, as addressed in [19], enabling interchangeable cases. For the same intervention conducted in different hospitals, hospital-specific CMMN cases can be used within the BPMN process. On the other side, all variants of the intervention can be modeled within one case [21]. Moreover, process parts outsourced as CMMN cases can be used for multiple interventions. Another aspect to consider is the changeability and extendability of the process models. This could lead to a major change for a more structured model, whereas a more straightforward integration is expected for a less structured model. By supporting CMMN and combination models, the SRS became more transferable as interventions can be supported in a new and more variable way.

Using models for several procedures, interventions, and hospitals can lead to even more complex models, not always just containing the possible steps for the specific use case that it is used for. To enable that the model is still applicable to the different circumstances, the SRS needs to have enough knowledge about the most probable next steps. Recordings of past processes are then more than necessary to be included in the situation recognition workflow to enable error tolerance against unplausible situations. With this concept, the applicability and transferability of the SPMs, and therefore of the SRS, can be further optimized.

Final remarks

Concluding, BPMN is more convenient for very strict courses but CMMN convinces in its flexibility and comprehensibility to be a good alternative for modeling variable surgical processes, especially when BPMN models would become too complex or workarounds should be avoided. We derive, also referring to the results of [17, 18, 21], that CMMN enables a clear representation of highly variable processes in surgery although non-optimal representations need to be reconsidered which led to false positives. A combination of BPMN and CMMN could also be reasonable, as equally stated by [17, 18], and was rated similarly in the user tests. The control of CMMN and combination models in the Camunda Engine offers added value to the SRS, although more effort and knowledge are needed for execution and control to be integrated into the system's logic. As the control logic is crucial to filter out false positive recognitions, it needs to be extended to reduce limitations occurring due to the variable models and to exploit the full potential of CMMN.

Overall, BPMN and CMMN both have their advantages and disadvantages. The proper modeling notation needs to be chosen depending on the use case. For a more standardized process, BPMN is more suitable, for more variable process parts, CMMN can be a good alternative to depict more adequately in less complexity. Nevertheless, the modeling approach for some CMMN parts should be reconsidered in means of either modeling more restrictive or depicting more loosely to better reflect reality. CMMN and combination models can especially be suitable for transferability among procedures, interventions, and hospitals, and should be considered for such goals.

Conclusion

As BPMN may become quite complex for surgical interventions, CMMN is an alternative addressing the variability of weakly structured processes like complex, non-standardized surgical interventions. This work showed that, compared to BPMN, CMMN allows the flexibility needed to correctly depict variable, intra-operative processes to be used within a situation recognition for execution and control. Therefore, CMMN is suitable to be used in addition to BPMN for flexible process parts (a combination of BPMN and CMMN) or as a replacement for the entire process (CMMN only). Especially a combination of both notations promises to optimize the interchangeability and transferability of the models. Nevertheless, the used modeling notation depends on the use case, knowledge about the techniques, and own preferences. A clear recommendation can therefore not be given.

Overall, the support of BPMN, CMMN, and combination models including the integration of process knowledge optimizes the applicability and transferability of the SRS. As demonstrated in the RAMIE and CI use case, complex processes can be depicted. To further evaluate the potential of CMMN models to execute and control surgical interventions in the context of situation recognition, more interventions should be modeled using CMMN or a combination of BPMN and CMMN using different approaches to depict variants and dependencies.

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Author contributions All authors contributed to the research and project. The idea for this article was developed between DJ and OB. The situation recognition system was designed and implemented by DJ, OB supervised the work. JMB, MW, KS and TK supported the work with clinical information. Based on the overall concept and system, EJ derived CMMN models and pre-tested the execution and control possibilities under the supervision of DJ. The final modeling and integration of BPMN and CMMN into the system were done by DJ. The evaluation and discussion were mainly conducted by DJ, pre-test results of EJ were partially integrated. The first draft of the manuscript was written by DJ. All authors commented on previous versions of the manuscript and read and approved the final manuscript.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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2.4 Standardized information provision and context-aware behavior in the OR

2.4.1 Service-oriented Device Connectivity interface for a situation recognition system in the OR [publication 4]

The SRS aims for broad applicability and therefore standardized information provision. A communication interface to loosely couple the SRS with multiple CAS, based on the emerging SDC standard series, might be suitable for this purpose. The publication

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describes an SDC-based publish-subscribe pattern interface between the SRS and different CAS to provide the recognized situation information for context-aware behavior and thus enable applicability and targeted support.

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ORIGINAL ARTICLE

Check for updates

Service-oriented Device Connectivity interface for a situation recognition system in the OR

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Abstract

Purpose Context awareness in the operating room (OR) is important to realize targeted assistance to support actors during surgery. A situation recognition system (SRS) is used to interpret intraoperative events and derive an intraoperative situation from these. To achieve a modular system architecture, it is desirable to de-couple the SRS from other system components. This leads to the need of an interface between such an SRS and context-aware systems (CAS). This work aims to provide an open standardized interface to enable loose coupling of the SRS with varying CAS to allow vendor-independent device orchestrations.

Methods A requirements analysis investigated limiting factors that currently prevent the integration of CAS in today's ORs. These elicited requirements enabled the selection of a suitable base architecture. We examined how to specify this architecture with the constraints of an interoperability standard. The resulting middleware was integrated into a prototypic SRS and our system for intraoperative support, the *OR-Pad*, as exemplary CAS for evaluating whether our solution can enable context-aware assistance during simulated orthopedical interventions.

Results The emerging *Service-oriented Device Connectivity* (SDC) standard series was selected to specify and implement a middleware for providing the interpreted contextual information while the SRS and CAS are loosely coupled. The results were verified within a proof of concept study using the *OR-Pad* demonstration scenario. The fulfillment of the CAS' requirements to act context-aware, conformity to the SDC standard series, and the effort for integrating the middleware in individual systems were evaluated. The semantically unambiguous encoding of contextual information depends on the further standardization process of the SDC nomenclature. The discussion of the validity of these results proved the applicability and transferability of the middleware.

Conclusion The specified and implemented SDC-based middleware shows the feasibility of loose coupling an SRS with unknown CAS to realize context-aware assistance in the OR.

Keywords Context awareness · Situation recognition system · Context-aware system · SDC · OR-Pad · Intraoperative area

Introduction

Context-aware systems (CAS) within the interconnected operating room (OR) are an emerging research topic [1]. CAS provide surgeons with intervention-specific functionality depending on the current intraoperative situation. To achieve this, contextual information, e.g., device parameters, used instruments, etc., needs to be captured and analyzed. One of our applications for CAS is the *OR-Pad* system that addresses the improvement in the information flow for the surgeon within the perioperative area [2]: The system consists of a pre- and postoperative as well as intraoperative mode. Clinical information can be preselected preoperatively for display in specific surgical phases. Intraoperatively, this information shall be displayed automatically at the right time. In addition, the remaining surgery duration (RSD) is provided and new information (e.g., notes) can be added. After surgery, all information is available for postoperative usage.

Denise Junger and Patrick Beyersdorffer contributed equally to this paper.

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To enable context-aware provision, an extern situation recognition system (SRS) should be connected which provides the actual surgical phase and the RSD during surgery.

Junger et al. [3] present a concept and basic framework prototype for an SRS in the OR. The aim of the system is the flexible and intervention-independent recognition of the actual situation in the OR. The estimated contextual information, like the surgical phase or RSD, shall then be provided to CAS. The SRS acts as a self-contained system that collects contextual information from the OR and serves different CAS. It should be unimportant for the SRS what the CAS are designed for. Possible use cases are filtering information automatically [4], providing pre-assigned information [2, 5, 6], selecting and controlling devices [7, 8], or minimizing adverse events [9, 10]. With a uniform SRS, CAS can act context-aware without bothering about implementing own recognition approaches, preventing them to get too complex, and all having the same data basis. This may open up new research projects focusing on context-aware support. To achieve such a flexible system architecture, an interface is needed for providing the collected contextual information of the SRS to CAS appropriately.

A standardized medical protocol is necessary for this interface to support unknown CAS in a non-proprietary vendor-independent way. In a preliminary study, we investigated existing interface standards for their applicability in the context of CAS. The *Health Level Seven Version 2* [11], *Fast Healthcare Interoperability Resources* [12], and *IEEE 11073 Service-oriented Device Connectivity* (SDC) standard series [13] were compared, as these were considered in the *Integrating the Healthcare Enterprise* (IHE) profile for *Service-oriented Device Point-of-care Interoperability* (SDPi) [14] to be possibly suitable for the interoperable networking of medical devices. In addition to this SDPi recommendation, *Digital Imaging and Communications in Medicine* (DICOM) [15] was included in the study since it is also used in research projects [16–18] as well as in clinical routine for computer-assisted planning and assistance. The DICOM *Unified Procedure Step Service-Object-Pair* [15] allows the modeling and provision of temporal and content differentiated contextual information. The *Service-oriented Medical Device Architecture* (SOMDA) of the SDC standards has also proven to be potentially suitable for providing contextual information. However, SDC *Device Specializations* [19] for an SRS and corresponding CAS do not currently exist and are not planned. The growing participation of research and industry in SDC-based medical device networking [20] and the possibility to achieve vendor-independent interoperability [13] justifies investigating how the SDC standards can be used to specify an interface for contextual information.

System architectures for a context-aware OR already exist [21–23], but do not support loose coupling of unknown CAS and an SRS which is essential to allow vendor- and device-independent orchestrations. In this work, we specify and implement an SDC interface for the standardized communication between an intervention-independent SRS and unknown CAS to enable context-aware assistance in the OR (Fig. 1). Intraoperative device connectivity can also be achieved using the *Open Integrated Clinical Environment* [24] or the *Robot Operating System* [25]. The middleware in these architectures provides comprehensive functionality to heterogeneous network nodes. In contrast, our architecture uses a remote procedure call (RPC)-based middleware encapsulating the SDC complexity for exchanging contextual information with simple function calls. For evaluation, our implementation is integrated into the SRS of [3] and the context-aware *OR-Pad* of [2] providing and receiving contextual information by interacting with the middleware during seven simulated orthopedical interventions.

Methods

Requirements analysis

The system idea is concretized by system goals (SG) depicted in Table 1. The requirements for specifying these system goals were extracted from six published articles on prototypic CAS for surgery [1, 7, 13, 21, 23, 26]. Integration of CAS in clinical routine is still pending [1]. Limiting factors that prevent the integration were derived from the publications and formulated as requirements (Table 1). SG1 requires interoperability of the interface to realize the system idea of providing unknown CAS with contextual information. SG2 and SG3 address adaptation to varying medical device orchestrations or different context-aware use cases in an OR, e.g., devices with varying computing capabilities or different types and granularities of contextual information available. SG4 requires reliable risk management.

Selection of a base architecture

Currently, no proven design patterns exist for context-aware ORs [1]. Instead, empirical base architectures were compared.

Context awareness in the system architecture according to [21] is based on rules that follow a strict event–condition–action pattern and are evaluated by the CAS themselves. If a defined event occurs and the stored conditions are fulfilled, an action is automatically triggered. For risk management, the rules are tested in a separate research environment using recorded intraoperative data. For rule creation, it must be known which devices are involved and which intervention is performed. A central component for analyzing and providing contextual information is missing. Estimations about

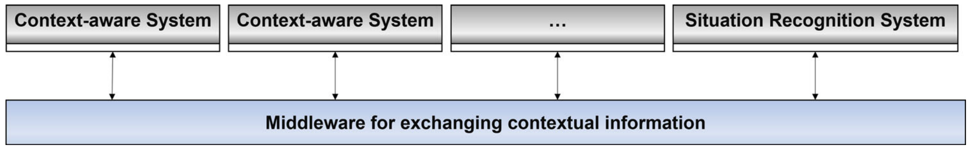

Fig. 1 Desired system architecture for loose coupling an SRS with unknown CAS

Table 1 System architecture goals and requirements

ID	System goals	Requirements			
SG1	Vendor-independent exchange of contextual information	R01	The interface shall be based on a standardized syntax	Interoperability	[13]
		R02	The interface shall be based on a standardized semantic	Interoperability	[13]
SG2	Device-independent exchange of contextual information	R03	Contextual information must be continuously accessible by the CAS	Interaction	[23]
		R04	Resource-constrained devices must be able to act context-sensitively	Interaction	[23]
SG3	Configurable exchange of contextual information	R05	CAS must be able to specifically query contextual information entities	Interaction	[21]
		R06	CAS must be able to subscribe to specifically contextual information entities	Interaction	[23]
		R07	Contextual information can have a varying level of granularity	Interaction	[26]
SG4	Controllable exchange of contextual information	R08	Contextual information must be provided simultaneously to multiple CAS	Risk management	[7]
		R09	The interface is not responsible for triggered context-aware functionality	Risk management	[21]
		R10	Changing contextual information shall be provided atomically	Risk management	[21]
		R11	The interface shall be fault-tolerant regarding missing contextual information	Risk management	[1]

the intraoperative situation purely depend on atomic rules. Multisensory interpretations to provide complex contextual information, e.g., superordinate surgical phases, are not possible. This leads to the decision against using this architecture.

Neumann et al. implemented surgical workflow management using the *BPMN*^{SIX} extension [27] for context-aware remote control and orchestration of medical devices [22]. The orchestration of the CAS and the context-aware functions to be triggered are formalized in the surgical process model (SPM) using the *Business Process Model and Notation* (BPMN) [28], where the *Surgical Intervention Extension* (SIX) allows modeling of intraoperative entities. The required devices in the OR network are discovered using SDC mechanisms based on their offered functions. These functions are automatically started by the workflow management system (WfMS) during the execution of the SPM at the appropriate point of time using the respective SDC *Service and Control Object* (SCO) [29]. This system architecture enables context awareness in the OR exclusively by the WfMS and depends on the SPM for a specific intervention with stored CAS functions to be triggered. The desired loose coupling is not possible using this approach.

Franke and Neumuth developed three message exchange patterns to provide different devices with contextual information [23]. Multi-perspective information [30] is collected by a central *Workflow Information System* (WIS) [31] using intraoperative sensors. Medical devices receive contextual information from this WIS for the adaptation to the current intraoperative situation. Resource-constrained devices cannot process this information themselves, so the WIS provides a service to register rules that specify when and which kind of contextual information shall be sent. Device orchestrations are configured as profiles in a *Configuration Component*. Surgeons can select the appropriate profile for an intervention. The associated rules are then stored in the WIS, thus enabling context-aware behavior for multiple devices. The authors emphasize that the medical devices are responsible for the functions triggered based on the contextual information received, and potential hazards must therefore be considered in the respective risk management.

The components of the latter approach harmonize with our desired system architecture from Fig. 1. The message exchange patterns can fulfill the requirements and enable providing contextual information. Thus, we selected this approach as base architecture. However, rules for notifying the CAS shall not be stored in the SRS to obtain the loose coupling between SRS and CAS. The *Configuration Component* could be used to communicate with the SRS on behalf of resource-constrained devices and control them in a context-sensitive way. The message exchange patterns have been implemented by the authors with the *Open Surgical Platform*, a precursor of the SDC standards. How the contextual information is encoded and via which services it is exchanged is not further specified in [23]. We specified this base architecture with the current version of the SDC standards and embed the message exchange patterns in a middleware.

Specification and implementation of the middleware

The components and their interactions derived from the selected base architecture [23] were specified by the constraints of the SDC standard series, namely by the IEEE 11073 standard parts [29] (*Domain Information and Service Model*), [32] (*Nomenclature*), [33] (*Communication Profile for Web Services*), and [34] (*Protocol Binding*). The *sdcLib* programming library [35] was used for implementation since this library has been successfully applied in other research projects [21, 36–38]. The standardized SDC data transfer of contextual information with associated discovery and security aspects shall be encapsulated by our RPC-based middleware. For evaluation, a prototype was implemented and integrated into the SRS of [3] and context-aware *OR-Pad* of [2] in the research OR of Reutlingen University.

Evaluation strategy

Our system idea is based on three assertions. Firstly, we assert that situation awareness can be outsourced from CAS and contextual information can be provided through an interface by an independent SRS. Therefore, we evaluate the fulfillment of the requirements of CAS from Table 1 to be able to act context-aware, using the middleware. Secondly, we assert that the interface can be specified using the SDC standard series. We evaluate this by verifying whether the constraints of the standard parts, introduced in "Specification and implementation of the middleware" section, have been respected. And thirdly, we assert that by implementing a middleware, contextual information can be easily provided by an SRS and obtained by CAS. For this, we analyze the required amount of development steps and lines of code.

The three evaluation steps are examined during a proof of concept study by integrating the middleware within the SRS [3] and *OR-Pad* [2] project and demonstrating its functionality in this specific use case. The middleware was tested using seven orthopedical interventions of the *OR-Pad*: hip replacement, hip replacement revision, femoral osteosynthesis, lateral partial knee prosthesis, lag screw osteosynthesis reposition, and radial head arthroplasty reposition. For preparation, available information, like preoperative images or reports, were assigned to the surgical phases of the interventions within the *OR-Pad*. In the intraoperative mode, the *OR-Pad* system was waiting for new contextual information of the SRS to provide the assigned information according to the surgical phase as well as the progress in time. During the study, we checked the provided and obtained information for correctness during each of the seven use cases.

Results

Specification of the interface

The SRS is defined as an SDC *Service Provider* [29], which is connected to CAS as SDC *Service Consumers* [29], as illustrated in Fig. 2. The connection must be established from the CAS using explicit discovery [33]. The CAS use the services of the SRS to obtain contextual information.

Data model

Contextual information needs to be stored in the *Medical Device Information Base* (MDIB) of the SRS. For MDIB modeling, only a subset of the [29] capabilities is relevant. The SRS as a *Medical Device* (with *MdDescription* and *MdState*) consists of a lean MDIB with one *Medical Device System* (MDS) and one *Virtual Medical Device* (VMD) with descriptive and stateful parts as presented in Fig. 2. Contextual information is modeled using *String Metrics*, grouped in content-related *Channels*. A metric for timing values would be advantageous but currently does not exist in the [29] data model.

The *String Metric Descriptor* specifies which kind of contextual information is provided, e.g., a surgical phase or the RSD. The current values are stored in the corresponding *String Metric State*, e.g., "Closing" as the current phase. Additional attributes are suitable for better integrating the contextual information in the individual use cases of the CAS. Dependencies between contextual information are modeled using *Relations* between the *String Metrics*, e.g., a contains-relation if a surgical phase contains subordinate surgical steps. The specified MDIB elements are listed in Table 2.

IEEE Standards Association [29, 34] requires that the SDC nomenclature [32] shall be used for machine-interpretable encoding of MDIB elements. The nomenclature currently

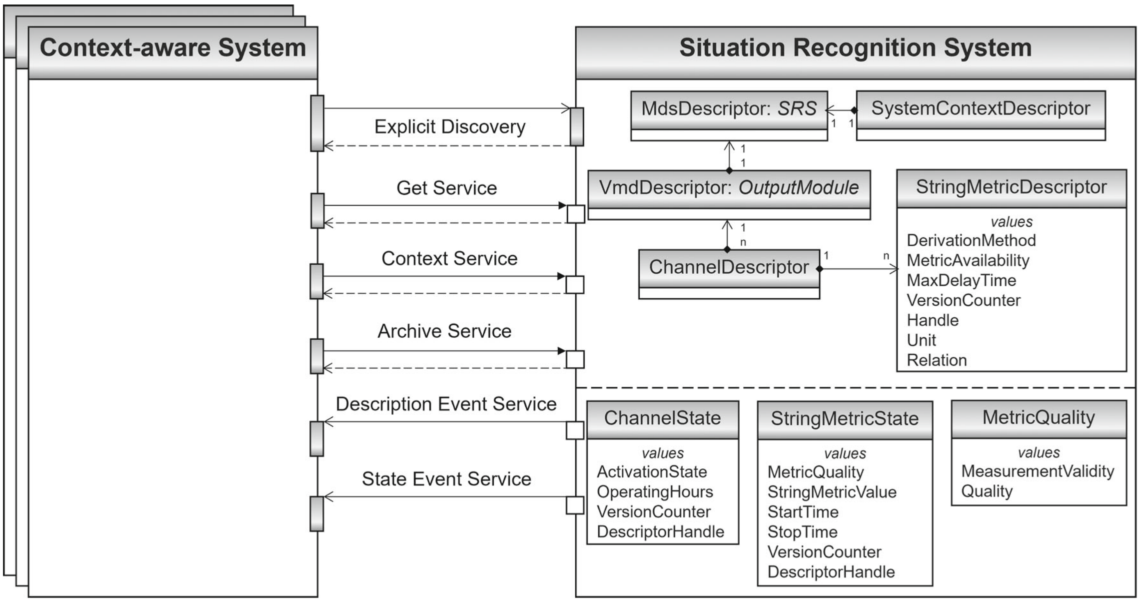

Fig. 2 Interface architecture specified by relevant SDC objects and services. Only an excerpt of the SRS MDIB is illustrated

Table 2 Specification of the SRS' MDIB

Element	Intended use	Example
Channel descriptor		
> Code	Specifies the meaning of the channel semantically unambiguously using the SDC nomenclature [32]	Functional context [30] (local extension)
> Handle	Uniquely identifies the MIDB element	CHAN_FC
String metric descriptor		
> Code	Specifies the meaning of the contextual information entity semantically unambiguously using the SDC nomenclature [32]	Surgical phase (local extension)
> Derivation method	Specifies whether the contextual information entity is acquired automatically or via manual input	Automatically
> Handle	Uniquely identifies the MIDB element	FC_SP
> Max delay time	Specifies the average duration from the determination of the contextual information entity to its provision in the MDIB	500 ms
> Metric availability	Specifies whether the contextual information entity is continuously or intermittently available	Continuously
> **Relation**	Specifies a dependency to another String Metric Descriptor	
>> Code	Specifies the meaning of the relation semantically unambiguously using the SDC nomenclature [32]	Contains (local extension)
>> Entries	Referencing the associated String Metric Descriptor Handles	FC_SS (surgical step)
>> Kind	Specifies the relationship to the associated metrics	Effect on containment tree entries
> Unit	Assigns a measurement unit from the SDC nomenclature [32] to the metric	Dimensionless
Channel state		
> Activation state	Expresses whether the channel provides valid metrics, or if all metrics are currently invalid	On

Table 2 (continued)

Element	Intended use	Example
> Operating hours	Represents how long the channel provides valid metrics	2
String metric state		
> **Metric quality**	Express the representativeness of the current value of the contextual information entity	
>> Measurement validity	Indicates whether the value of the metric is valid or should currently not be used (e.g., if the SRS could not estimate a value)	Valid
>> Quality	Percentage of how confident the estimation of the contextual information value is	0.97
> Start time	Timestamp since when the current value of the contextual information entity has been provided	1640863190706 (December 30, 2021, 11:19:50)
> Stop time	Timestamp until when the value of the contextual information entity was valid or had been replaced by a new value	
> String metric value	Represents the current value of the specific contextual information entity	Implantation of prosthetic stem

Only an excerpt of the MDIB is listed, with elements that are relevant to provide contextual information

Table 3 Local extension of the SDC nomenclature to encode contextual information

Systematic name	Description	Partition::Code
Situation Recognition System|Functional Context	Channel of an SRS containing metrics that offer information about the functional context according to [30]	1::61443
Situation recognition system|Procedure-related context	Channel of an SRS containing metrics that offer information about the function context according to [30]	1::61444
Functional context|Surgical phase	Current surgical phase of the intervention	2::61440
Functional context|Surgical step	Current surgical step specifying a Surgical Phase	2::61441
Functional context|Surgical activity	Current surgical activity specifying a Surgical Step	2::61442
Functional context|Relation|Contains	A granular lower-level entity of the functional context contains a granular higher entity	2::61443
Procedure-related context|Remaining surgery duration	Estimated remaining duration of the intervention	2::61444
Procedure-related context|Delay	Calculated delay of the intervention depending on the RSD	2::61445

The private areas of the nomenclature partition 1 (*Device Nomenclature*) and partition 2 (*Metrics*) were used as exemplary listed for the *OR-Pad* use case

does not contain codes for intraoperative contextual information. Thus, the nomenclature is extended as required in [32] and listed in Table 3.

Service model

The SRS recognizes contextual information and provides it in the MDIB as described above. The behavior of the SRS can be assigned to the *Medical Class A Safety Classification* [29], whereby the information provided may be used in clinical functions of the CAS, but not solely determines diagnostic or therapeutic decisions. The contextual information in the MDIB needs to be accessible for CAS. SDC designed the *Medical Devices Communication Profile for Web Services* (MDPWS) for this purpose [33]. The associated service model [29] defines the `Get` service as mandatory, whose operations can be used to request specific contextual

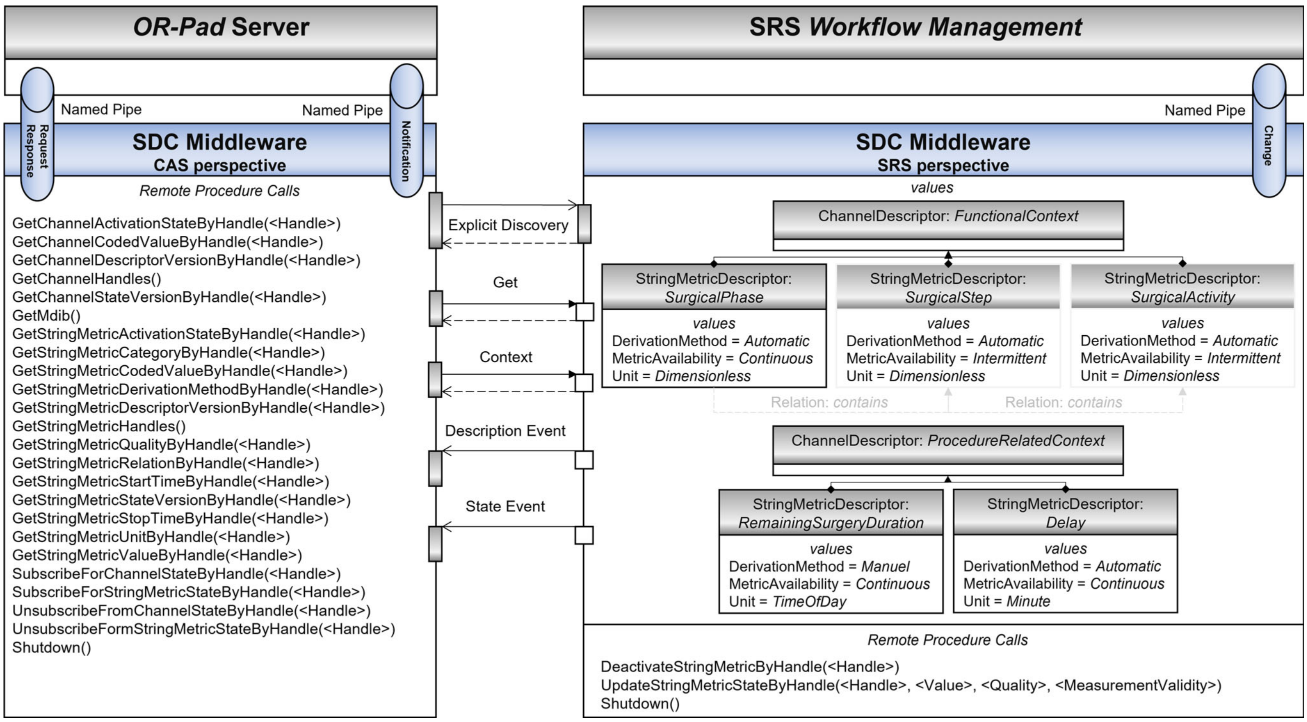

Fig. 3 Applied interface specification for the *OR-Pad* use case resulting in a middleware architecture. Only an excerpt of the SRS MDIB is illustrated. The RPCs are accessible via the named pipes and transformed in MDPWS operations within the implemented middleware

information entities from the SRS. The `Context` service enables the orchestration of the SRS and CAS based on the *System Context* in the respective MDIBs. The `Archive` service shall be provided by an SRS to access previous MDIB states. This allows reconstructing the course of an intervention, e.g., for automatic documentation. For notifying CAS about context changes, the SRS offers the `Description Event` and the `State Event` service. During an intervention, the descriptive part of the MDIB shall not be modified. The temporary unavailability of contextual information entities can be represented via the *Measurement Validity* of the *Metric Quality* without changing the MDIB structure of the SRS. If all metrics in a *Channel* are invalid at some time, the *Activation State* of the *Channel* should be on standby. If CAS subscribed for changes of these MDIB entities, they will be notified automatically about this availability change. The specified services of the SRS are illustrated in Fig. 2.

Implementation of the middleware

Generic implementation

The descriptive part of the SRS' MDIB is imported as an XML file representing the contextual information that can be recognized by the SRS and shall be provided in a standard-conform way using the *sdcLib* functionality.

To avoid adaptation of the SRS and CAS to the *sdcLib* syntax, RPCs were implemented to use the SDC interface within individual programs encapsulating the SDC complexity. Our implementation hides tasks such as connection establishment and MDIB maintenance. The RPCs are initiated via named pipes and transformed by the implemented middleware into MDPWS operations, based on the *sdcLib*. The middleware is executed on the SRS or CAS machines and follows the specified SDC interface as modeled in Fig. 3. The results of the RPCs, e.g., the requested contextual information, are returned via the named pipes to the individual programs. Subscriptions to the SRS can be established with the implemented RPCs. Received notifications are passed from the *sdcLib* functions to a CAS via a separate notification pipe. Changes of contextual information performed by the SRS are also triggered with RPCs through a named pipe. By using this inter-process communication between individual programs and the middleware, any SRS and CAS can exchange and receive contextual information from individual systems in a standard-conform way.

Integration in the OR-Pad use case

The SRS [3] implements the top-down approach according to [26], and thereby, surgical phases are continuously available while providing contextual information on a low granularity level. The *Functional Context* [30] could be specialized with surgical steps and more detailed surgical activities if the *Situation Recognition* [3] provides this differentiated view on the intraoperative situation. This conditional availability is modeled in Fig. 3, using our SDC-conformant specification. The defined contains-*Relation* is used to explicitly express these hierarchical dependencies in the MDIB of the SRS. Temporal values of the *Procedure-related Context* [30] channel, like the RSD, are provided as strings referring to the time protocol specified in the *Clock Descriptor* of the MDIB.

If the SRS has detected a new value of a contextual information entity, the Python-based *Workflow Management* [3] initiates the update of the corresponding metric. The RPCs of the SRS middleware component are used to primarily update the value of the corresponding metric and secondary set the associated attributes of the metrics, representing the current *Metric Quality*. The JavaScript-based *OR-Pad* [2] can request or subscribe contextual information in the SRS' MDIB using the RPCs of the CAS middleware component, as modeled in Fig. 3. In our case, the *OR-Pad* simply uses the *SubscribeForStringMetricStateByHandle* RPC to subscribe to the `IORC_FC_SP` and `IORC_PRC_D` metric. If new information is retrieved via the notification pipe, the *OR-Pad* displays these in the user interface. Depending on the surgical phase, the *OR-Pad* searches for the assigned information and displays this beneath the displayed phase to make the information accessible with one click.

Evaluation

The exchange of contextual information between the SRS and the *OR-Pad* is enabled via the implemented SDC middleware. The SRS provided the most probable recognized surgical phase, RSD, and calculated delay via updating the SDC metrics on phase change. At runtime, the *OR-Pad* subscribes to the surgical phase and delay metric and receives all changes. The retrieved surgical phase and delay are visualized depending on the estimations of the SRS. Context-relevant information that was pre-assigned to the surgical phase within the *OR-Pad* is provided to the user. A simulation of a CAS subscribed in parallel to the SRS to demonstrate that multiple CAS can be served at the same time.

The middleware provides continuous access to contextual information, collected by a central SRS and represented in the specified MDIB (R03). All other requirements (R04-R07) of the interaction category could be met as well. In the risk management category, R08–R10 are fulfilled by persisting the loose coupling between the SRS and CAS. Fault tolerance (R11) is also met since no misbehavior through missing contextual information is assumed, because CAS are informed about the availability and quality of the information entities in the MDIB via the specified attributes. Semantic interoperability (R02) cannot be achieved because the current version of the SDC nomenclature [32] does not encode intraoperative contextual information. Syntactic interoperability (R01) is lost by using the RPCs but is achieved if the plain SDC protocol is used.

Considering the standard-compliant specification of the interface, the data and service model is directly derived from the SDC standard parts [29, 32–34] and fulfills all mandatory constraints. The implementation is based on the *sdcLib*, without inconsistent customizations. The planned `Archive` service is currently not provided by the *sdcLib*.

The integration and usage of the middleware in the SRS and *OR-Pad* programs require only two major steps: During development, provided code snippets in Python, NodeJS, and C++ are to be copy-pasted into the system's project. Afterward, the RPCs (listed in Fig. 3) can be used directly within the own code. Moreover, the MDIB may be adapted according to the SRS' contextual information. The lines of code hardly depend on how many RPCs the software wants to use and if there is any pre- or post-processing of the information. For runtime usage, the middleware needs to be started first and be running during the whole usage.

Discussion

System goals

The presented specification and implementation of the SDC middleware is an important step toward context awareness in the OR. This allows an SRS to provide contextual information via the SDC standardized communication protocol. CAS can access this contextual information using SDC services to provide context-aware assistance.

One advantage of this separation of concerns is that the middleware and also the SRS do not depend on any context-aware use cases. In contrast to the approach of [22], a central WfMS does not decide which assistance functions are triggered and when. Due to the loose coupling to the SRS, these assistance functions are unknown to the SRS and are purely controlled by the CAS. However, unlike [21] and following the approach of [23], a central component exists in which the recognition complexity is aggregated. The SRS itself acts as an independent system, only providing contextual information to other systems. The CAS themselves are responsible for subscribing to desired information and adapting their behavior according to it. It should be noted that the SRS is the single point of failure in this system architecture and CAS and must have appropriate fallback strategies if contextual information cannot be provided or is not sufficient enough concerning the recognized quality. By specifying and implementing the middleware, the standardized security and patient safety constraints are applied [34]. All requirements concerning risk management are fulfilled, and the system goal of controllable exchange of contextual information (SG4) is achieved.

Our middleware encapsulates the complexity of establishing and maintaining an *sdcLib*-based interface. RPCs can be used in the individual programs of CAS or an SRS to access contextual information or update these in the MDIB. This encapsulation allows the developers to easily integrate the SDC interface in their systems as proven for the *OR-Pad* use case. This middleware-based architecture achieves the system goal of device-independent exchange of contextual information (SG2). The RPCs are transformed in an SDC-conform representation within the implemented middleware. The comprehensive data and service model of the SDC standard series enables specification of the configurable exchange of contextual information (SG3) to support individual CAS and the varying recognition capabilities of an SRS. The specification of the MDIB elements and services to access contextual information by an SRS can be seen as prototypic SDC *Device Specializations*.

By locally extending the nomenclature with codes for intraoperative contextual information, it is not possible to achieve cross-institutional and cross-device interoperability. Our extension is derived from the multi-perspective model of surgical situations for the context-aware OR in [30]. We aim at integrating the extension in the SDC standardization process. SPM ontologies [39] may improve the semantic and clear annotation of the contextual metrics and provision of a common structuring of the SRS' MDIB. With these known semantics, medical device manufacturers can implement assistance functions that depend on these defined contextual information entities. If this contextual information is provided in an OR using the standardized interface with known semantics, the devices can access the SRS and automatically interpret the needed contextual information to react context-aware. However, Burgert et al. [40] emphasizes that due to the high inter-process and inter-clinical variability of surgical procedures, surgical information cannot be fully encoded in a standardized manner. In future work, we will address the challenge of local variability of contextual information to achieve the system goal of semantic interoperability (SG1).

Applicability and transferability

In our evaluation, we have shown principal applicability along with the *OR-Pad* use case, only representing some of the capabilities of our middleware. We verified the related assertions in three evaluation steps during this proof of concept study. In the following, we discuss the validity of our results according to [41].

Internal validity [41] considers the influence of study conditions on the results. The evaluation was conducted by the developers, well knowing all system components, and, therefore, the integration of the middleware was quite easy. Other researchers may need to first get into the different RPCs that can be used and identify, how to use them in their systems. Furthermore, the MDIB of the SRS needs to be configured. This is mitigated by providing code snippets and comprehensive documentation.

The transferability of the results is argued based on external validity [41]. The concept was affected by our used SRS and *OR-Pad* as use case scenario. The evaluation was conducted in the research OR of Reutlingen University. Transfer to other research or clinical environments was not tested, but the middleware was kept generalizable to be used within other systems. Due to the standardization and encapsulation, the results are transferable to other use cases, while using the middleware in the intended manner. No matter what kind of SRS or CAS uses the middleware, the RPCs are independent of the software which uses them. Furthermore, our configuration of the generic middleware implemented for the *OR-Pad* use case can still be extended to cover more contextual information, such as the used instrument and the position of the surgeon, as it can be provided by SRS and be useful for other CAS.

Finally, the conclusion validity [41] indicates whether correct conclusions can be derived from the conducted study. We initially defined three assertions with individual evaluation steps for quantitative assessment. These assertions contain the fundamental aspects of our system idea. The assessment was performed once after the specification and implementation of the middleware. The evaluation steps provide successful quantitative results that allow the assertions to be accepted, as presented in "Evaluation" section. During the evaluation, we critically revised the information that the SRS sent as well as the information that was received by the *OR-Pad*. No contextual information has been lost or wrong data have been transferred. The reliability of the middleware and, therefore, of the evaluation results is given. The reliability of the contextual information of the SRS is not controllable by the middleware itself.

Conclusion

We presented an approach that uses the current version of the SDC standard series to provide contextual information to unknown CAS. Our idea focuses on a middleware for loose coupling with an intervention-independent SRS. We showed that our middleware solves limiting factors that currently prevent context awareness in the OR. The applicability is verified using the *OR-Pad* as an exemplary CAS. The standardized modeling and exchange of contextual information enable vendor-independent context awareness. We specified the SDC data and service model for this purpose.

Encapsulating the SDC complexity in an RPC-based middleware allows the exchange of contextual information with low effort. Furthermore, we identified the missing encoding of intraoperative contextual information in the current version of the SDC nomenclature. The semantically clear encoding is essential for automatically interpreting the contextual information by the CAS and enabling the proposed loose coupling with an independent SRS. The integration of a suitable SPM ontology and dealing with the variability of contextual information will be addressed in further work to achieve semantic interoperability with the presented middleware.

Author contributions All authors contributed to the research and project. The idea for this article was developed between Denise Junger and Patrick Beyersdorffer. The situation recognition system was designed and implemented by Denise Junger, Oliver Burgert supervised the work. From the concept, the idea for an SDC interface was specified, designed, and implemented by Patrick Beyersdorffer, and Denise Junger supervised the work with Oliver Burgert. The system modeling process was supported by Christian Kücherer. The integration of the interface and evaluation was done by Denise Junger and Patrick Beyersdorffer. The first draft of the manuscript was written by Denise Junger and Patrick Beyersdorffer. All authors commented on previous versions of the manuscript and read and approved the final manuscript.

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Declarations

Conflict of interest The authors have no competing interests to declare.

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2.4.2 A high-fidelity prototype of a sterile information system for the perioperative area: OR-Pad [publication 5]

Based on the provided information of the SRS, retrieved via the SDC-based interface, targeted assistance of the surgical team can be realized. The applicability of the SRS and the enabled context-aware behavior could be demonstrated via an exemplary CAS. The publication

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describes the *OR-Pad* system that displays clinically relevant information via a timeline and semi-automatically provides situation-related information based on the actual surgical phase and delay retrieved from an SRS. Electronic supplementary material is available online for this publication (Online Resources 1 to 2[6]). The material shows the requirement analysis and functional evaluation of the *OR-Pad* in a summarized and detailed version.

[6] https://doi.org/10.1007/s11548-022-02787-w
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ORIGINAL ARTICLE

A high-fidelity prototype of a sterile information system for the perioperative area: OR-Pad

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Abstract

Purpose Supporting the surgeon during surgery is one of the main goals of intelligent ORs. The *OR-Pad* project aims to optimize the information flow within the perioperative area. A shared information space should enable appropriate preparation and provision of relevant information at any time before, during, and after surgery.

Methods Based on previous work on an interaction concept and system architecture for the sterile *OR-Pad* system, we designed a user interface for mobile and intraoperative (stationary) use, focusing on the most important functionalities like clear information provision to reduce information overload. The concepts were transferred into a high-fidelity prototype for demonstration purposes. The prototype was evaluated from different perspectives, including a usability study.

Results The prototype's central element is a timeline displaying all available case information chronologically, like radiological images, labor findings, or notes. This information space can be adapted for individual purposes (e.g., highlighting a tumor, filtering for own material). With the mobile and intraoperative mode of the system, relevant information can be added, preselected, viewed, and extended during the perioperative process. Overall, the evaluation showed good results and confirmed the vision of the information system.

Conclusion The high-fidelity prototype of the information system *OR-Pad* focuses on supporting the surgeon via a timeline making all available case information accessible before, during, and after surgery. The information space can be personalized to enable targeted support. Further development is reasonable to optimize the approach and address missing or insufficient aspects, like the holding arm and sterility concept or new desired features.

Keywords OR-Pad · Sterile information system · User interface · High-fidelity prototype · Usability test · Perioperative area

Introduction

Access to relevant information in the perioperative area may support surgeons and their team during surgery in the operating room (OR). The visualization equipment within present ORs varies from highly integrated, networked ORs (e.g., KARL STORZ OR1™, Stryker iSuite, Brainlab Digital O.R.) with multiple monitors to less modern ORs with maybe just one smaller monitor. Depending on the intervention and available equipment, monitors may visualize the endoscopic video, radiological images, navigation information, or electronic patient records. In many cases, no display options are available near the operating table [1] or monitors are placed at positions requiring larger head movements resulting in unergonomic setups. Supportive materials, like notes, can hardly be used in the OR [2]. Moreover, the surgeon often cannot interact with the visualization and needs assistance [3]. The application-oriented research project *OR-Pad* [2] aims on improving the information flow in the perioperative area. Via a sterile-packed tablet PC, clinical information is displayed close to the surgeon and can be controlled by the surgeon via touch. To enable context-aware assistance, the information

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can be prepared preoperatively, displayed and supplemented intraoperatively, and also used postoperatively for documentation (see interaction concept and system architecture [2]). A situation recognition is used to minimize the number of necessary interactions by automatically displaying preselected information according to the actual situation in the OR.

The relevance of such context-aware assistance is demonstrated by a large number of works in this field. For example, Franke et al. [4] address a surgical working environment for ENT surgery to enable context-aware assistance like information presentation. Depending on tracking and processing of the surgical situation, automated selection of appropriate video sources (e.g., endoscopic image or PACS viewer) is done for two displays. Katić et al. [5] propose a system for automatically filtering available information based on the recognized phase of laparoscopic liver and gallbladder surgery. Based on the surgical phase, an appropriate visualization in augmented reality, showing the tumor direction, resection line, or vital structure, is chosen. Similarly, Schreiber et al. [6] show a concept for consistent and prioritized presentation of surgical information for FESS surgery. One display was used for essential information; less important information was shown on a second display, both arranging several information entities (e.g., endoscope, navigation, or PACS). Stauder et al. [7] present a workflow-driven system for breast cancer surgery that combines live imaging sources and DICOM files. The sterile draped display is in reach of the surgeon so that the sources can dynamically be switched via gestures.

The displaying approaches differ by provided information, e.g., Franke et al. [4] select an appropriate video source, whereas Katić et al. [5] adapt the augmented reality visualization. The *OR-Pad* [2] has the goal to enable a shared information space for preparation, intervention, and follow-up, covering all available information from HIS and PACS as well as personal information. To avoid information overload and distraction, the information needs to be displayed in a structured and clear form, being easily accessible and usable without additional cognitive load for the surgeon. Our user interface approach is based on a timeline, inspired by other systems visualizing electronic health records [8]. This paper describes the user interface concept consisting of a timeline as the main element combined with other features, like annotating elements in an image, for targeted assistance. Via prototypical implementation and functional as well as preclinical evaluation of the prototype, the feasibility of the *OR-Pad* vision, as well as the usability of the visualization approach, is shown.

Methods

The *OR-Pad* system was developed within four development cycles using a user-centered design process (see [2]). The first user interface focused on separated functionalities in form of independent, supporting features (e.g., section for patient information, notes, or camera source). Expert interviews revealed that the structure and linking of functionalities should be reconsidered. The second approach addressed a process-based view by providing different functionalities depending on the pre-, intra-, or postoperative phase within the OR. Information was provided via a media library, and features were connected to the information (e.g., draw in an image). A usability test showed very good results but made an overload of information apparent. The third iteration focused on supporting the surgeon via access to information and improvement of the information flow. Based on that, the requirements of the final prototype were specified (see Online Resource 1) and the *OR-Pad* system was redesigned.

Interaction concept and system architecture

Our previous work [2] depicts the interaction concept and system architecture of the *OR-Pad* system. The interaction concept consists of the idea of a mobile and an intraoperative mode to support the surgeon before, during, and after surgery. The mobile app can be used on a smartphone or laptop for preparation and follow-up, the intraoperative app on a tablet during the intervention. Before surgery, the surgeon can view upcoming interventions and their available case information. Important information can be highlighted, new information be added, and context-aware support be managed. During surgery, the surgeon can access all case information and the prepared content. Context-relevant content is displayed depending on the surgical phase. Information can be filtered, edited, and added. After surgery, the surgeon can review and edit the gathered information.

The client–server system architecture described in [2] was implemented as a progressive web app. The clients are using responsive user interfaces and hardware access to view and add information. The server is responsible for data management and connecting external systems like HIS and PACS to retrieve patient data. A situation recognition system is connected to enable context-sensitive information display. For the communication with these systems, we used the established standards FHIR and DICOM.

User interface concept

The user interface concept combines the positive features of previous approaches [2] (see Fig. 1). Fast access to interaction functionalities, like recording voice memos or taking pictures, was taken from iteration one. The data-centric approach for viewing and editing clinical information via connected features was taken from iteration two. This led to

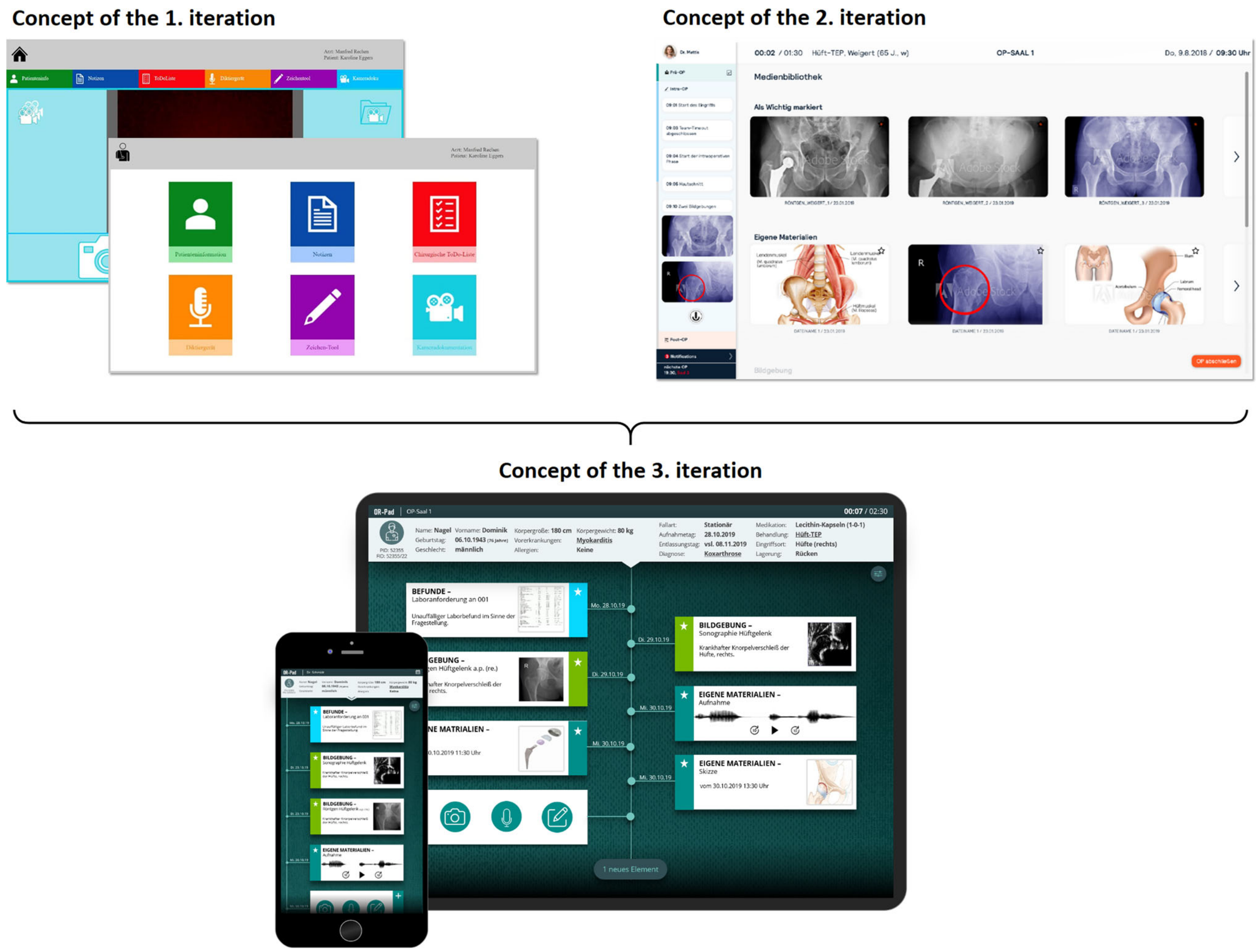

Fig. 1 Evolution of the user interface concepts of the *OR-Pad*. The concept of the third iteration combines the positive features of the previous concepts

a new concept for pre-, intra-, and postoperative use, consisting of a mobile and intraoperative mode that share the same design concept.

The central element is the timeline which displays the available case information of the intervention chronologically, according to the recording times, and categorizes this information by color coding according to its type, e.g., imaging. In addition, at the very bottom of the timeline, a function field is visible which can be used to create new materials, such as a photograph/video, a note, or a voice recording. By clicking on a timeline entry, the corresponding information can be viewed full-screen and, depending on the medium, their view can be modified, e.g., scrolling through the layers of CT images. A filter option in the upper right corner allows individualization of the view and also facilitates quick retrieval. In the upper area of the user interface, the patient and procedure information of the current intervention is displayed. In the intraoperative mode, the status bar also shows the current OR, the scheduled duration, and the time since the start of the surgery. The two modes also differ in the login and first view before getting to the timeline view.

The vector-based graphics software Adobe XD was used to transfer the graphical concept into a clickable prototype which was shown to our clinical partners of the University Hospital Tübingen (see [2]). After the good feedback from our clinical partners, the implementation of the whole system started.

Implementation and evaluation

Prototypical implementation

In the fourth iteration, the developed concepts and approaches described before were realized within a high-fidelity prototype. We simulated a clinical software infrastructure by realizing the HIS, PACS, and their communication interfaces. The open-source FHIR server Aidbox.Dev was used as the HIS and the DICOM server Orthanc as the PACS. Seven de-identified test data sets from orthopedics were used. For retrieval of the stored data, we used the libraries fhir-kitclient and orthanc-client. All clinical information is therefore organized within FHIR and DICOM resources for standardized handling. For testing the situation-related displays, the situation recognition was simulated to enable an independent system that works without dependencies to ensure that all test participants are using the same environment and setting. The infrastructure of the *OR-Pad* system consists of a virtual machine (VM) that serves as the *OR-Pad* server and contains the *OR-Pad* database (MongoDB) and PACS software, an additional physical computer that represents the *OR-Pad* HIS server on which the HIS software Aidbox.Dev is running, and the clients. The communication between clients and server is realized by web sockets.

The *OR-Pad* application was implemented using JavaScript, HTML, and CSS. For the *OR-Pad* demo prototype, an iPad Pro, a Samsung Note, and a Windows 10 PC were used as end devices.

Test setup

The developed prototype was integrated into the research OR at Reutlingen University. The evaluation was split into a functional and preclinical evaluation. In the functional evaluation, the requirements were compared to the actual functionalities by executing the *OR-Pad* demo prototype for the various use case scenarios. Furthermore, feedback from clinical partners was included via expert interviews with our project partners Prof. Stenzl from urology and Prof. Hirt from anatomy of the University Hospital Tübingen.

In the preclinical evaluation, which served as our final evaluation, the usability was tested with clinicians, the functionalities were examined, and a quantitative assessment was done via questionnaires. The prototype was running on a Samsung Galaxy Note 10 Lite with 6.7" and an Apple iPad Pro 3 with 12.9". Both clients communicated with the *OR-Pad* server. The study was conducted with twelve surgeons and assistant doctors from four different clinics in Germany and different disciplines. A neutral meeting room was provided as a test environment. The study was conducted separately with each test person. In the beginning, each participant received a short introduction in which the aim of the system and the planned application were explained. After the introduction, the test person had about ten minutes to familiarize with the system. Subsequently, the participant got typical tasks for the system for the scenarios of preparation and follow-up as well as the performance of an intervention, to solve independently with the help of the mobile and intraoperative app. The clickstream (record the number of clicks) was logged and the person was asked to speak their thoughts out loud (think-aloud method). Audio and screen recording was done.

To be able to evaluate the usability of the system quantitatively, the participant filled out a questionnaire after completing the tasks, which is based on the System Usability Scale (SUS). This is a technology-independent questionnaire comprising ten scale questions to evaluate the subjectively perceived usability in points. The SUS score is calculated from the results of the SUS questionnaire by coding the categories with values from 0 for rejection of the system to 4 for acceptance of the system. These are added and multiplied by 2.5 to allow for a SUS score between 0 and 100, with 100 being the top rating. To evaluate the range of functions, additional open interview questions were asked. These were intended to identify superfluous or missing functionalities as well as further ideas for areas of application.

Results

The *OR-Pad* application was realized as a client–server application and implemented as a progressive web app with various functionalities and operating options. For technical details on the interaction concept and system architecture, please refer to our pre-work [2], as this article focuses on the graphical user interface. The frontend was developed in German; relevant aspects are described in the text.

High-fidelity prototype

Login and intervention overview

After starting the application, the user is asked to log in. After login, the mobile application shows a calendar view of past and future interventions which are assigned to the registered user (see Fig. 2 left). The user can look at detailed information about the intervention by clicking on it, so that more information of the particular intervention is dynamically loaded from the clinical systems. In the intraoperative application, an overview of the upcoming surgery is generated (see Fig. 2 right). Information such as the time of the intervention, the patient, or the type of surgery is displayed. The user can check whether the correct intervention is indicated and start it via a button. Further information is loaded to be displayed.

Main view

After selecting or starting an intervention, the user is taken to the main view (see Fig. 3). This consists of three components: a general status bar at the top, the patient information, and the timeline. The status bar is visible (once logged in) in every view except in the full-screen view of a material.

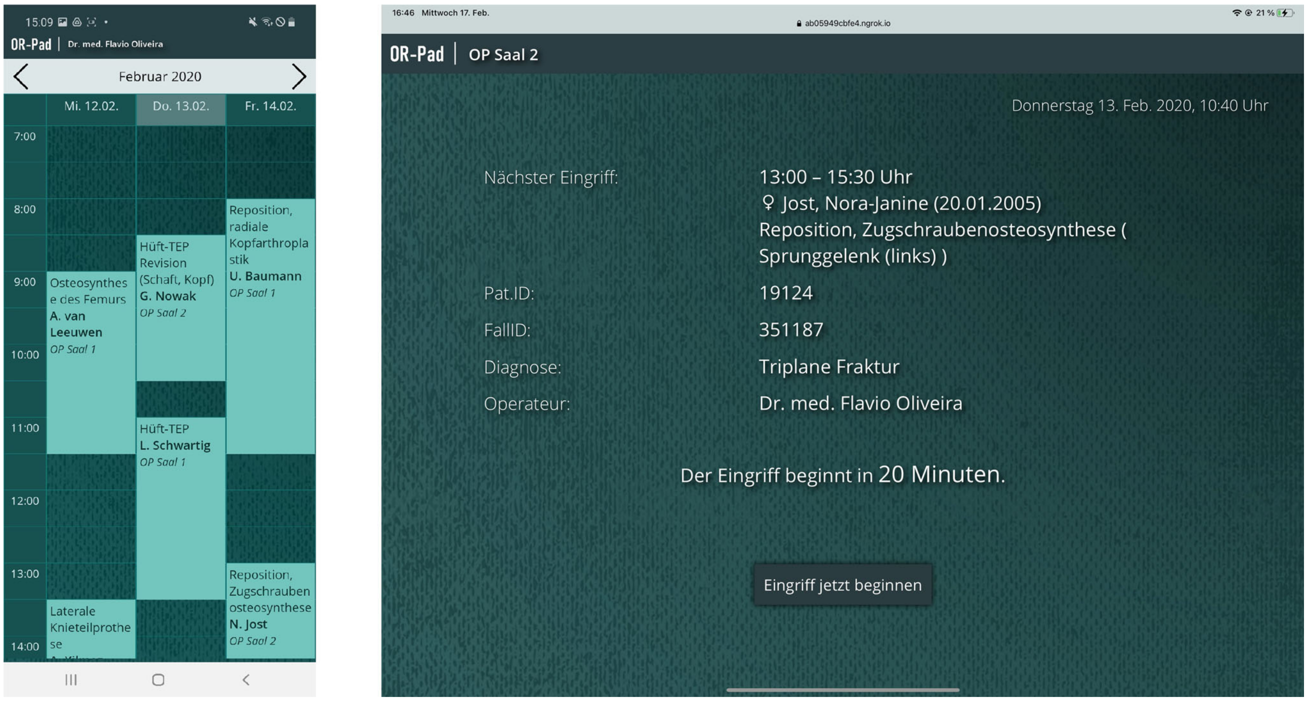

Fig. 2 Calendar of the mobile mode (left) and overview of the upcoming intervention of the intraoperative mode (right)

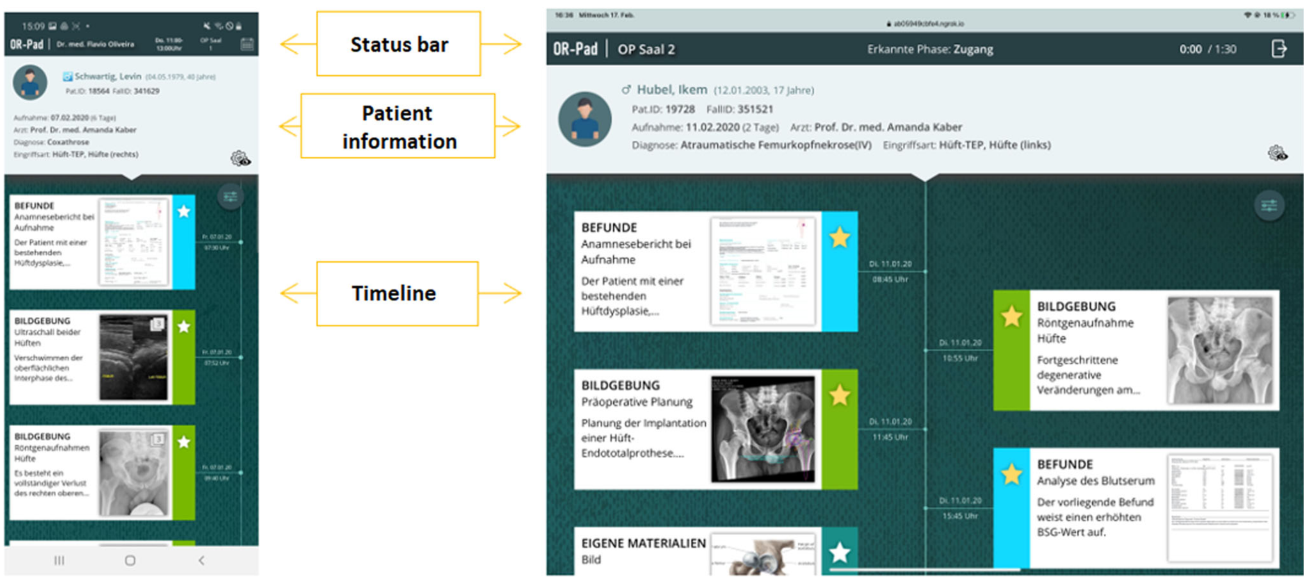

Fig. 3 Main view of the *OR-Pad* application (left mobile and right intraoperative mode)

In the mobile application, the status bar consists of the *OR-Pad* logo, the logged-in surgeon, the time slot of the selected procedure, the location, and a calendar button. In the intraoperative application, the status bar consists of the *OR-Pad* logo, the logged-in OR, the actual phase provided by the situation recognition, the progress of the surgery including the scheduled time, and an exit button. If material is available for the recognized phase, this is indicated by the eye symbol in the status bar and it can be opened via click. The patient information component consists of the name, birthday, and age as well as the patient and case ID of the patient. In addition, the day on which the patient was admitted (including the days since then), attending surgeon, diagnosis, and type of intervention are displayed. The cogwheel symbol at the bottom right provides an overview of the material phase assignment.

The central component of the application is the timeline. It displays all information chronologically, arranged along a vertical timeline. The arrangement is according to the date of creation from old (top) to new (bottom). It also has functions for creating own material at the end of the timeline and the possibility to filter the information. Timeline entries are visualized in containers. A container consists of the name of the category to which the material is assigned (findings, imaging, or own materials), the name of the material, and a text. Next to it is a thumbnail. At the edge of the container, a colored bar (category of the material) with a star symbol (mark as 'Important') is visible. Clicking on the container takes the user to the view of the clicked material. By doing this, all information regarding this material is dynamically loaded from HIS and PACS.

At the top of the timeline in the right corner is the filter button to filter materials according to their category. In the drop-down menu, the user can select 'All', the three categories 'Findings', 'Imaging', and 'Own materials' as well as materials marked as 'Important'. At the very bottom of the timeline, new materials can be created via uploading a file, taking a photograph/video, recording a voice recording, or creating a text note, which are added to the timeline.

Material view

By selecting an entry in the timeline or clicking on the eye symbol, the detailed view of the material is shown (see Fig. 4). Next to the material itself, an overlay with the most important meta-data and the color marking of the category is shown. By clicking on the material, it is displayed in full screen and zooming is possible. The bar above the material contains different elements. The arrow symbol on the far left takes the user back to the timeline view. In the middle is the name of the material, on the far right a bin, cogwheel, and star icon are shown. With the bin symbol, the user can delete materials that belong to the category 'Own materials.' By clicking on the cogwheel icon, a drop-down menu opens in which the user gets a list of surgical phases (see Fig. 5). The user can now select during which phase the selected material should be provided. The star symbol allows the user to mark material as 'Important.' Within the material view, the material can be edited by clicking the pencil icon. In edit mode, the user can draw onto the material (see Fig. 6).

Interaction

The *OR-Pad* application focuses on touch interaction, although operation on a PC/laptop via mouse is also possible. Familiar interactions used include 'tap' (ordinary touch movement, comparable to a 'click'), 'flick' (swipe movement), 'pinch' (pull two fingers together), and 'spread' (pull two fingers apart). In addition, 'scroll' to move content or representations is possible.

Evaluation

Functional evaluation

Online Resource 1 summarizes the evaluation results of the vision, goals, and requirements of the *OR-Pad* system (more details on the evaluation method are found in Online Resource 2). Four of the 5 visions were fulfilled completely. The *OR-Pad* enables the creation and transfer of materials within the perioperative area. Furthermore, the materials and case information can be viewed (quick and uncomplicated access) and relevant information be highlighted. The *OR-Pad* supports the surgeon with context-relevant information during surgery. Nine of the 10 goals were met. In terms of functional requirements, 57 out of 58 were fulfilled. Seventeen of 26 non-functional requirements were met.

For demonstration purposes, the prototype only accesses demo data, a demo situation recognition, a demo HIS, and a demo user administration, so concrete requirements for clinical use with real systems should be collected and implemented. Partially or unfulfilled requirements are mainly due to the prototypic integration in a hospital information system infrastructure and open issues regarding the holding arm and related sterility. Under the assessment of the application exclusively as a demo prototype, the result of the functional evaluation turned out good overall. The expert interviews were very positive encouraging the prototypic implementation.

Preclinical evaluation (usability study and functional scope)

Within the usability study, the most striking task in the evaluation of the clickstreams was the assignment of a material to a surgical phase so that the material can be accessed quickly in this situation. On average, the number of clicks required by the test participant for this task was 4.78 clicks higher than the number of required clicks. Only three subjects needed a minimum of three clicks to complete the task. The think-aloud protocol revealed that the phases are too hidden and the process of assigning was unclear to the participants. The icon for the button was described as not intuitive. When the test persons worked on the tasks, it also became visible in the clickstreams that there were minor problems when working on a material. There was an average deviation of 1.55 clicks between the actual and target values for the number of clicks needed to solve the task. One outlier was particularly noticeable here, which required twelve instead of two clicks to solve the task. The interaction in the material view to start and end the full-screen mode was often described as unclear or unnecessary and also led to the outlier in the clickstream data.

During the usability study, all participants could access case information for interventions fast and without any

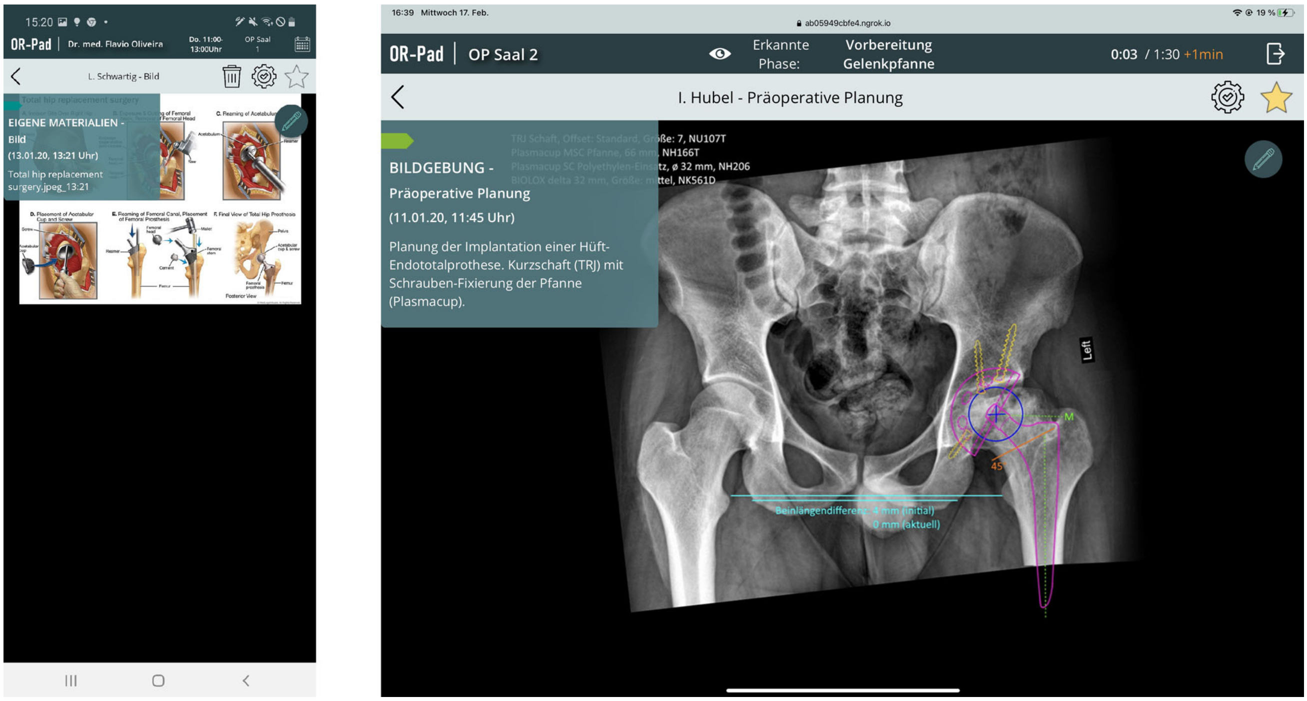

Fig. 4 Material view (left mobile and right intraoperative mode)

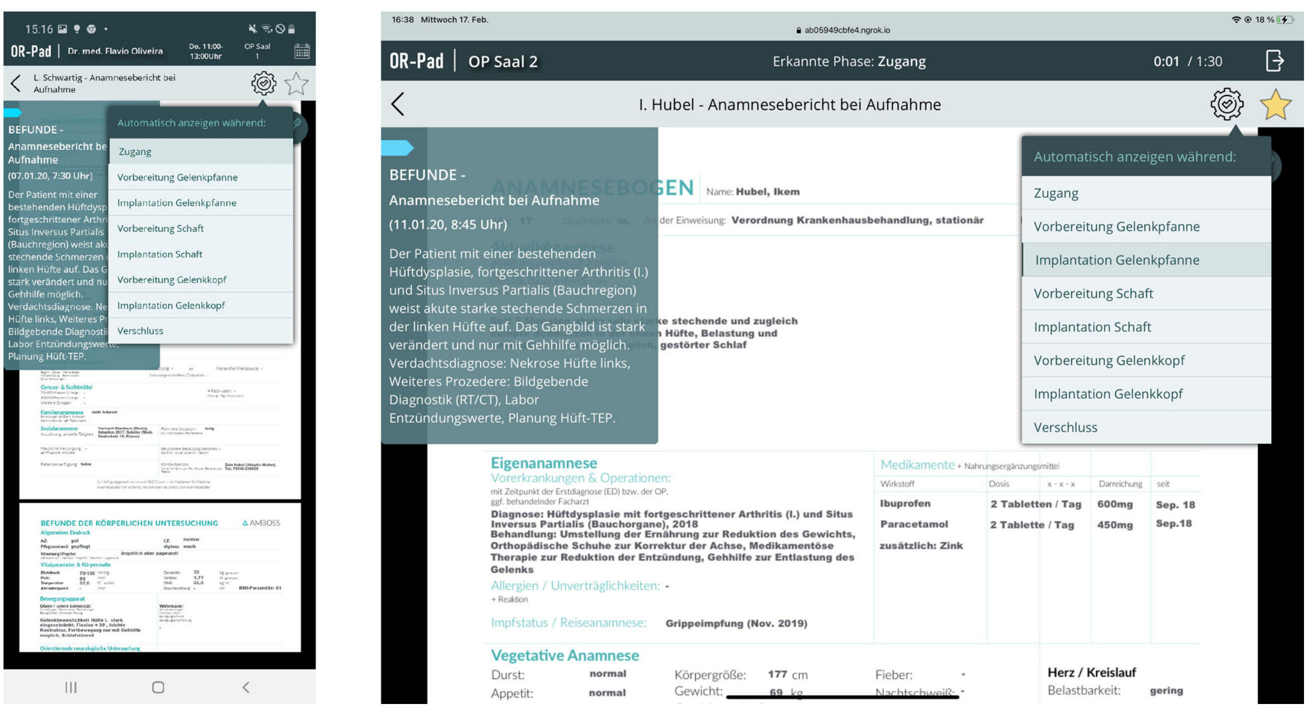

Fig. 5 Drop-down menu showing the surgical phases to assign the material (left mobile and right intraoperative mode)

complications. They quickly found the materials they were looking for in the timeline. The participants were reaching every function or information within a short time and minimum amount of clicks. Furthermore, all of the test persons were noting that they think the design of the graphical user interface is good. Despite this positive feedback, also suggestions referred to the timeline arose: One clinician mentioned that the chronological order of the information within the timeline is less interesting than sorting the information according to the course of the intervention, i.e., surgical

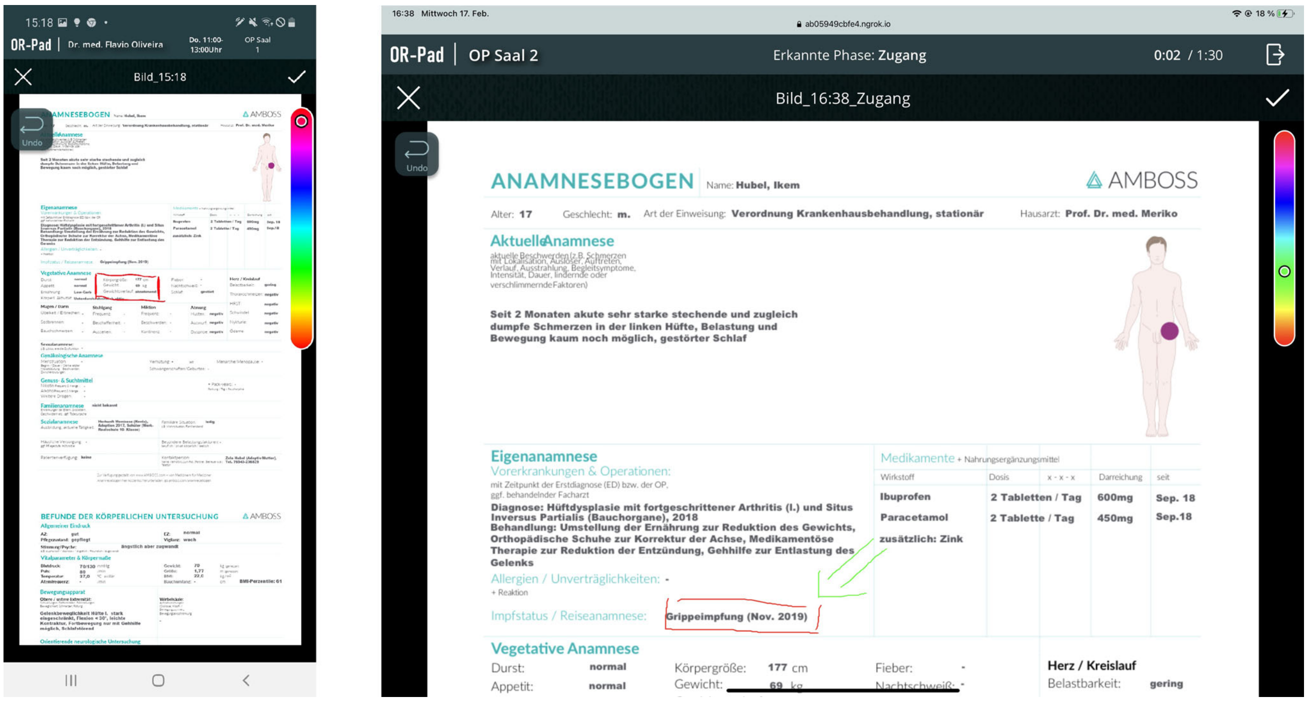

Fig. 6 Editing mode to draw into the material (left mobile and right intraoperative mode)

phases in which the information is needed. Another participant proposed to optically distribute the timeline into sections to differentiate between information that was added before, during, and after the intervention.

The average SUS score achieved is 74.79. This places usability close to the upper quarter of the scale and can be rated as good. An overview of the average score per question is listed in Fig. 7. However, the usability of the prototype shows further potential for improvement. Many test persons described the scope of the system as too large for everyday surgery and better suited for more complex interventions. Nevertheless, many suggestions for extensions were made, some of which are only needed in specific disciplines.

For further development of the system, this results in several points that need to be addressed. The user-friendliness of the system should be adapted, especially concerning the two particularly conspicuous tasks (i.e., material phase assignment and material view/edit). Furthermore, the suggestions referring to the timeline visualization should be investigated. Likewise, the development of new functions is possible to support surgeons even better and to expand the system's areas of application. The most common wish was a dictation function. In addition, it is possible to expand the intraoperative mode, for example, by implementing a stopwatch or timer that can be started when time-critical events such as the clamping of an artery take place. Another suggestion was to connect to other devices such as an endoscope or navigation system to display the information on the screen near the patient. There were also suggestions for expansion in terms of follow-up, such as the semi-automatic creation of OR reports based on a checklist or similar.

Discussion

With the *OR-Pad*, the surgeon can select information preoperatively and has it available intraoperatively on a tablet close to the patient (see Fig. 8). In contrast to Franke et al. [4], in which information presentation is not personalized yet, the surgeons can form their information space by themselves which allows a user-adapted visualization in the *OR-Pad*. Similar to Stauder et al. [7], which use gestures for direct interaction, sterile interaction with the system via touch is possible for the surgeon. The surgeon can access relevant images and other information via an intuitively designed interface, including a timeline. In comparison with the concept of the second iteration, the timeline element puts all the information on a case in a chronological context and thus enables an overview and faster retrieval by the surgeon, instead of only providing a simple cluttered media library. Integrated features, like marking a tumor within a radiological image, are linked directly to the medium as before. The included filter function enables information to be found quickly and reduces information overload. Materials for a surgical phase (provided via the situation recognition simulation) can be accessed with one click. The *OR-Pad* reduces

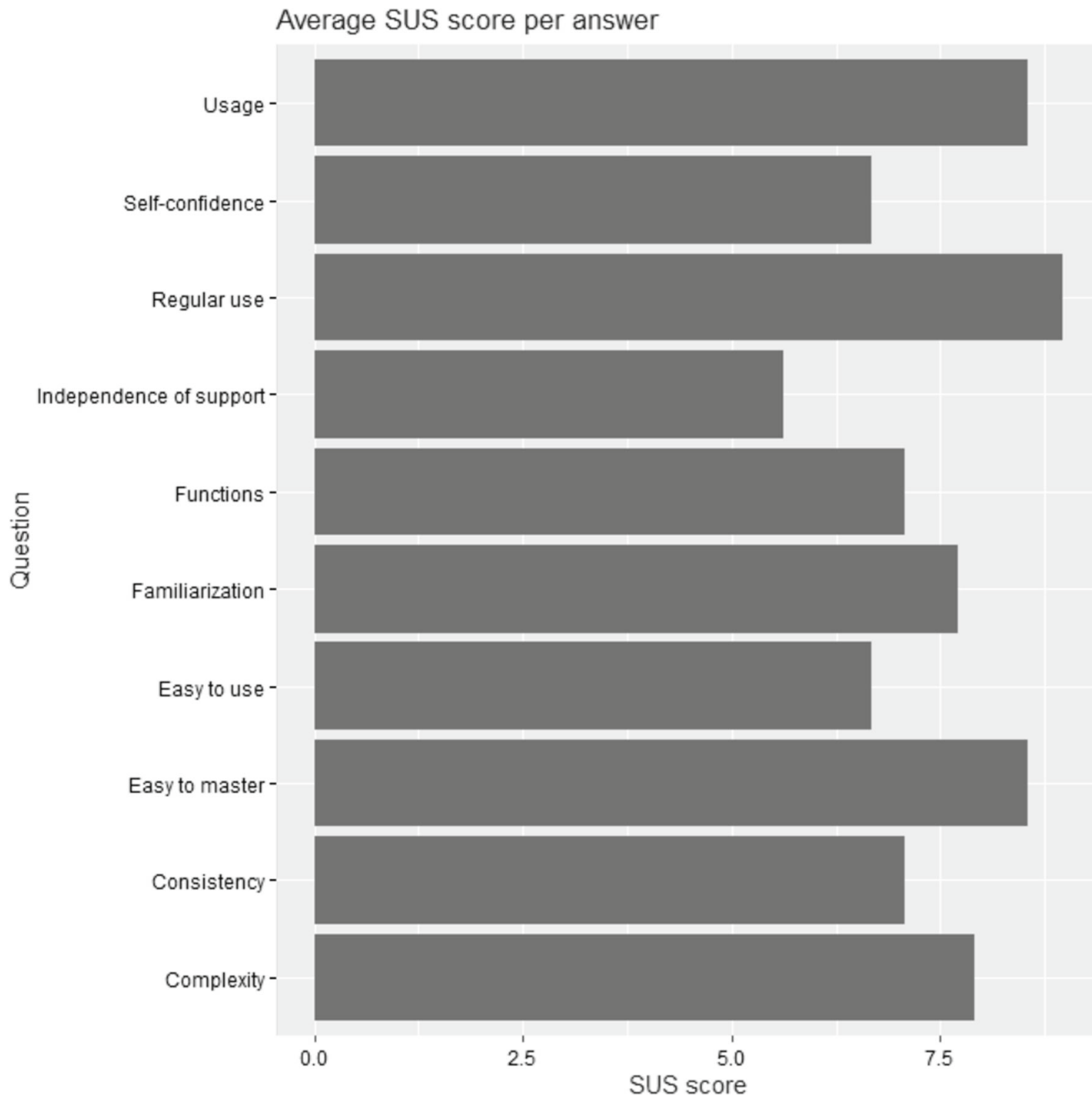

Fig. 7 Average SUS score per answer. A rating from 0 to 10 points is possible for each question, with 10 being the best rating

the interaction in the intraoperative mode by features like filtering, highlighting, and automatic provision. The shared information space allows the user to have all information available regardless of whether the mobile or intraoperative mode is used.

The evaluations showed good results and confirmed the vision and concepts. Usability issues occurred during annotation (drawing) in medical images and during assigning materials to a surgical phase. Two participants also suggested optimizations of the timeline for a better overview and faster retrieval of information. Changing the order of the timeline from chronologically to phase-dependent may be an option, especially for the intraoperative mode. This would allow that information needed in the actual surgical phase can be found quickly. On the other hand, it would lead to a more time-consuming material phase assignment before the intervention and un-assigned information may be overseen. Another option is the distribution of the timeline into the sections 'pre', 'intra', and 'post' for better differentiation of, e.g., preoperative and intraoperative recorded images. Because of different expectations, an optimal solution needs to be identified in further research. Configurability may be an approach to adapt the timeline visualization to different needs and preferences.

Future topics are the integration of new use cases, the provision of video data streams (e.g., endoscope), and the implementation of secure authentication. Desired functionalities, such as communication with other departments from the OR, e.g., in the form of a secure chat, a dictation function, or feedback to the situation recognition, can also be suitably

Fig. 8 Intended intraoperative use case for the *OR-Pad* (information near to the patient, sterile interaction), demonstrated in the research OR in Reutlingen University

integrated. Other possible ideas for expanding the system include supporting patient education with various materials and streaming the video image outside of the OR. Regarding the large range of functions, customizability of the interface and the functions would be one way to prevent the system from appearing too cluttered and still be applicable to all disciplines and preferences while also avoiding information overload. Topics that were not considered sufficiently or at all are IT security (data protection), the adaption of communication interfaces to the hospital's systems, tests in a clinical environment via a clinical evaluation, and consideration and evaluation of the system as a medical device. A concept for holding arm and sterility already exists (see Fig. 8) but needs to be further optimized by addressing open issues, e.g., a sterile cover tailored to the holding arm and tablet.

Conclusion

We are currently incorporating the evaluation results in the next version of the *OR-Pad* application. Afterward, the application will be tested in a clinical setting to better assess the applicability in the OR and the relevance of the information and functionalities. For this, it could also be considered to exchange the simulation of the situation recognition with the basic framework prototype of the situation recognition system from [9]. Therefore, an SDC interface was conceived and realized to provide the context data of the situation recognition to the *OR-Pad* [10].

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11548-022-02787-w.

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Author's contribution All authors contributed to the research and project. The idea for this article was developed between D. J. and O. B. The vision of the information system was done by S. F., C. R., and D. J., involving B. H. and A. S. as clinical partners. The presented concepts and prototype were mainly developed by S. F., C. R., and partially D. J., O. B. supervised the work. The functional evaluation was done by C. R. The usability test was planned and conducted by S. L., M. S., and P. S., D. J. supervised the work with O. B. The first draft of the manuscript and supplemental material was written by D. J. All authors commented on previous versions of the manuscript and read and approved the final manuscript and supplemental material.

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Declarations

Conflict of interest The authors have no competing interests to declare.

Informed consent This article does not contain patient data.

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2.5 Transferable situation recognition system for scenario-independent context-aware surgical assistance systems: a proof of concept [publication 6]

The iterative development toward a transferable and scenario-independent SRS that enables broadly applicable CAS could realize the required adaptions to changing surgical settings, present in the dynamic surgical environment. Transferability needs to be addressed on multiple levels to provide a foundation for a reliable and durable SRS in the intraoperative area. The publication

> *Junger, D., Kücherer, C., Hirt, B. & Burgert, O. Transferable situation recognition system for scenario-independent context-aware surgical assistance systems: a proof of concept. Int J CARS (2024). https://doi.org/10.1007/s11548-024-03283-z*

describes the development and evaluation of a scenario-independent SRS that adapts to different surgical settings due to its modular system architecture, thus demonstrating fundamental applicability and transferability. Electronic supplementary material is available online for this publication (Online Resource 1[8]). The material shows the requirement analysis and functional evaluation of the situation recognition system.

[8] https://doi.org/10.1007/s11548-024-03283-z
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ORIGINAL ARTICLE

Transferable situation recognition system for scenario-independent context-aware surgical assistance systems: a proof of concept

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Abstract

Purpose Surgical interventions and the intraoperative environment can vary greatly. A system that reliably recognizes the situation in the operating room should therefore be flexibly applicable to different surgical settings. To achieve this, transferability should be focused during system design and development. In this paper, we demonstrated the feasibility of a transferable, scenario-independent situation recognition system (SRS) by the definition and evaluation based on non-functional requirements.

Methods Based on a high-level concept for a transferable SRS, a proof of concept implementation was demonstrated using scenarios. The architecture was evaluated with a focus on non-functional requirements of compatibility, maintainability, and portability. Moreover, transferability aspects beyond the requirements, such as the effort to cover new scenarios, were discussed in a subsequent argumentative evaluation.

Results The evaluation demonstrated the development of an SRS that can be applied to various scenarios. Furthermore, the investigation of the transferability to other settings highlighted the system's characteristics regarding configurability, interchangeability, and expandability. The components can be optimized step by step to realize a versatile and efficient situation recognition that can be easily adapted to different scenarios.

Conclusion The prototype provides a framework for scenario-independent situation recognition, suggesting greater applicability and transferability to different surgical settings. For the transfer into clinical routine, the system's modules need to be evolved, further transferability challenges be addressed, and comprehensive scenarios be integrated.

Keywords Intraoperative situation recognition · Scenario-independent · Applicability · Transferability

Introduction

Surgical assistance systems support surgeons and the surgical team before, during, and after surgery. If these systems can adapt their functionality based on the environment and situation, e.g., provide filtered clinical information [1] or pending tasks [2], they are defined as being context-aware. The required context awareness can be achieved using data sources already present in the operating room (OR), e.g., endoscope [3] or medical devices [4], or additional sensor systems, e.g., RFID tracker [5]. Existing approaches mostly focus on supporting a specific surgical intervention with defined data sources [6]. As the intraoperative environment changes depending on different factors, e.g., the available data sources or sequence of the surgical intervention between the clinic or actors, solutions need to be adapted to different surgical settings. To reliably recognize contextual information and be aware of the intraoperative situation in different scenarios, transferability should be focused during system design.

Transferability to other scenarios is challenging and many different aspects need to be considered. In the context of intraoperative situation recognition, the main aspects to allow for an applicable and transferable system are: (1) surgical interventions and their variance, (2) surgical environments and their sensors, and (3) surgical situation recognition methods and their implementation. A widely applicable system therefore needs to be flexible on the sensor, recognition,

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and process layer, thus being able to react appropriately to deviating surgical processes and OR equipment within a scenario. Furthermore, the system needs to be transferable to similar scenarios with known processes or sensors, multiple process and sensor variants, as well as completely new scenarios, e.g., new interventions, sensors, or interpretation methods. Aspects such as configurability, interchangeability, and expandability are particularly relevant to enable applicability for multiple scenarios. The situation recognition system (SRS) of [7] addresses this need and will be the main subject of this work. The system is characterized by a generalized architecture that can be adapted incrementally. By emphasizing transferability beyond specific scenarios, we aim to create a modular framework that not only meets current requirements but also provides a foundation for seamless integration and adaption of scenarios.

Methods

Iterative development process

We follow an iterative development process, characterized by an incrementally refinement and enhancement throughout the research. Deriving from a state-of-the-art analysis [6], we concluded the need for a flexible SRS in the OR, defined requirements for subsequent development stages, and conducted a high-level concept for a modular system architecture [7]: The SRS shall gather and process data from various intraoperatively available sensors and be aware of knowledge about different interventions. Based on these, contextual information shall be formed and then provided to external context-aware systems (CAS). The concept follows software engineering best practices to realize adaptability and expandability, outlining the structure, components, and interfaces of the envisioned system. It consists of 4 layers: (1) Data Acquisition represents the sensors in the OR, (2) Sensor Abstraction realizes the coupling of sensors and sensor data interpretation, (3) Situation Recognition performs situation interpretation based on sensor and process knowledge, and (4) Workflow Management manages process information using a workflow engine and provides contextual information to CAS (see Fig. 1). Via listener interfaces, the SRS is acquiring *sensor data*. The core of the system is constructed of modules for interpreting the *sensor data* using distributed methods, rules, and machine learning (ML) components. Thereby, *situation knowledge* is retrieved based on the *sensor knowledge,* and *process knowledge* is incorporated via surgical process models depicting the course of surgical interventions. The *situation knowledge* is then provided to CAS. Building upon this concept, a basic framework prototype was developed as a tangible and functional representation of the envisioned system. The initial evaluation demonstrated the overall functionality successfully. In further development cycles, existing features can be refined and new functionalities be integrated via adaptions and extensions (e.g., SDC-based data provision [8] or transferable process models [9]). For more details on the conceptual architecture, please refer to [7].

To verify that the SRS is applicable to different surgical settings and transferable to a new context, the evaluation method was specified. We did not find an applicable transferability score in the literature, but the assessment of the quality via non-functional requirements is an established method in software engineering that can be applied to assess transferability. Therefore, we performed a requirements analysis to identify non-functional aspects of the future system according to the ISO/IEC 25010 [10]. This standard defines eight characteristics to categorize product quality properties. The three categories compatibility, maintainability, and portability were stated to have a significant influence on maintenance tasks, therefore being relevant for transferability between scenarios and thus used to refine our requirements. Compatibility defines the degree to which the system and its components can exchange information with other systems or components, maintainability expresses the degree of effectiveness and efficiency with which the system can be modified, and portability describes the degree of effectiveness and efficiency with which the system and its components can be transferred to other environments. Furthermore, we applied the ISO/IEC/IEEE 29148 [11], defining guidelines and characteristics to ensure the quality of requirements. A total of 2 goals and 30 non-functional requirements were derived (see Table 2) for the use case depicted in Fig. 2.

Furthermore, scenarios were integrated to demonstrate the variance of sensors, surgical interventions, and therefore interpretation logic the SRS can support (see Sect. "Scenarios"). Based on the requirements and three main scenarios, the system was evaluated by the developer (see Sect. "Functional evaluation"). The overall system was run as a demo prototype for the different sub-scenarios with an automatic sensor data simulation based on realistic data. Aspects that the defined scenarios cannot fully cover were evaluated using additional system tests. For the assessment, the requirements were contrasted to the successful sub-scenario execution as the primary evaluation method. Furthermore, logging details of the interpretation steps and the communication flow as well as code review to obtain further implementation details were used to assess the fulfillment of the requirements. Due to the lack of sufficient data to evaluate aspects like transferability to other clinics, the assessment beyond the requirements is covered by an argumentative evaluation (see Sect. "Argumentative evaluation"). Thus, a multistage evaluation was realized using requirements, scenarios, and system analysis to assess the ability of the SRS to perform in different and new settings.

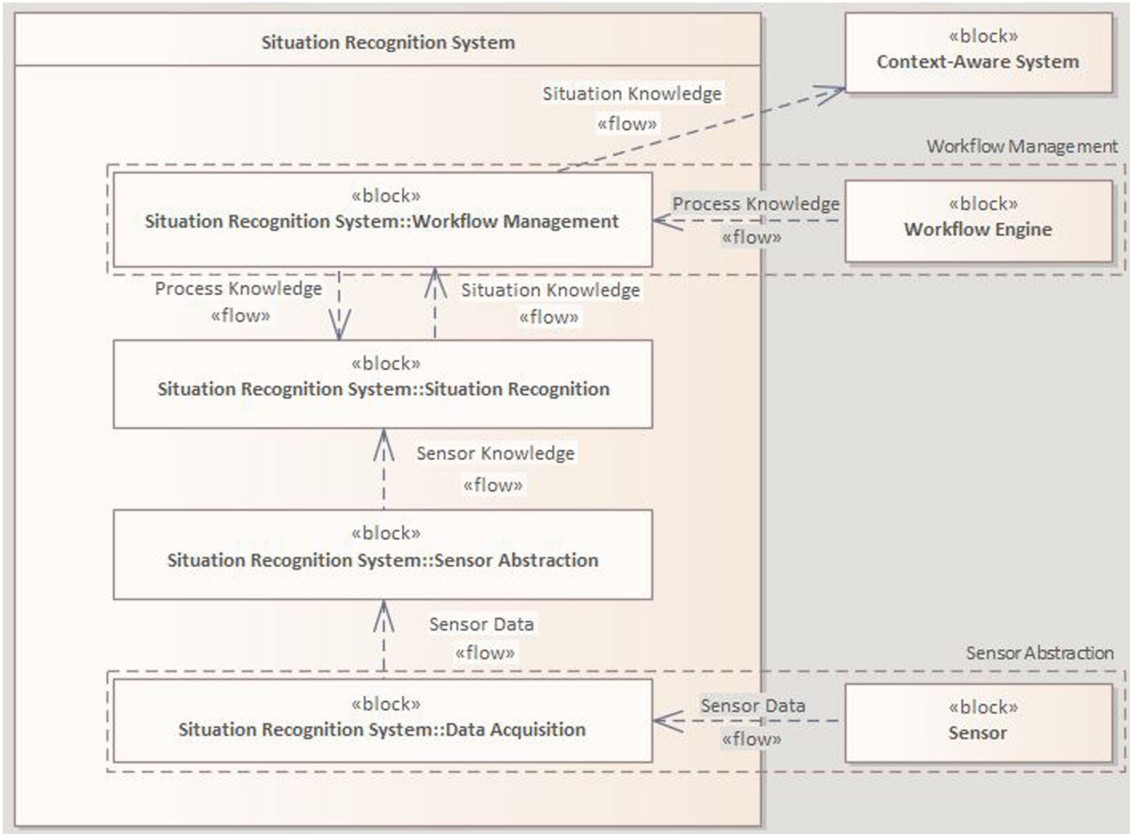

Fig. 1 SysML block definition diagram of the components and interfaces of the SRS, condensed representation of the conceptual architecture [7]

Scenarios

The scenarios listed in Table 1 cover a variety of interventions, sensors, and interpretation logic and serve as the main demonstrators. Each of these covers several sub-scenarios, e.g., by switching between data sources or process models. Further aspects not covered by the three scenarios (e.g., real sensor data via SDC) were evaluated by additional sub-scenarios.

Scenario 1 was created based on the cooperation with the University Hospital Heidelberg [12] which provided comprehensive information on process steps, their sequence, and variance, as well as the used instruments and position of the surgeon and assistant in the respective steps. Thereby, data sources of instrument, position, and step recognition could be simulated realistically. Furthermore, rules for situation recognition and process models [9] could be derived. As exemplary CAS, the *OR-Pad* [13] was included. *Scenario 2* was established based on a project of the University Hospital Munich [14] and the publicly available dataset CholecT50 [15]. Different process variants and sensor data, i.e., phase flickering outputs of [14], endoscope image of CholecT50, and exemplarily parameter of a thermoflator of [16], were integrated. In addition, rules were derived, and ML models were trained on different datasets, e.g., CholecT50 and Cholec80 [17]. *Scenario 3* was created in cooperation with the University Hospital Düsseldorf based on the project for an intraoperative checklist [18], which was also used as a data source for step recognition due to the lack of intraoperative sensor data recordings. For the use case, comprehensive information on process steps, their sequence, and variance were provided to adapt process models [9].

Results

Functional evaluation

The evaluation resulted in 2 out of 2 completely fulfilled goals and 28 out of 30 fully met non-functional requirements. The results are depicted in Table 2 and are summarized in the following. Details of the assessment are found in the Online Resource 1. Different surgical interventions were simulated based on data from intraoperative sensors and process knowledge (/G01/). The SRS recognizes a variety of contextual information and serves CAS (/G02/).

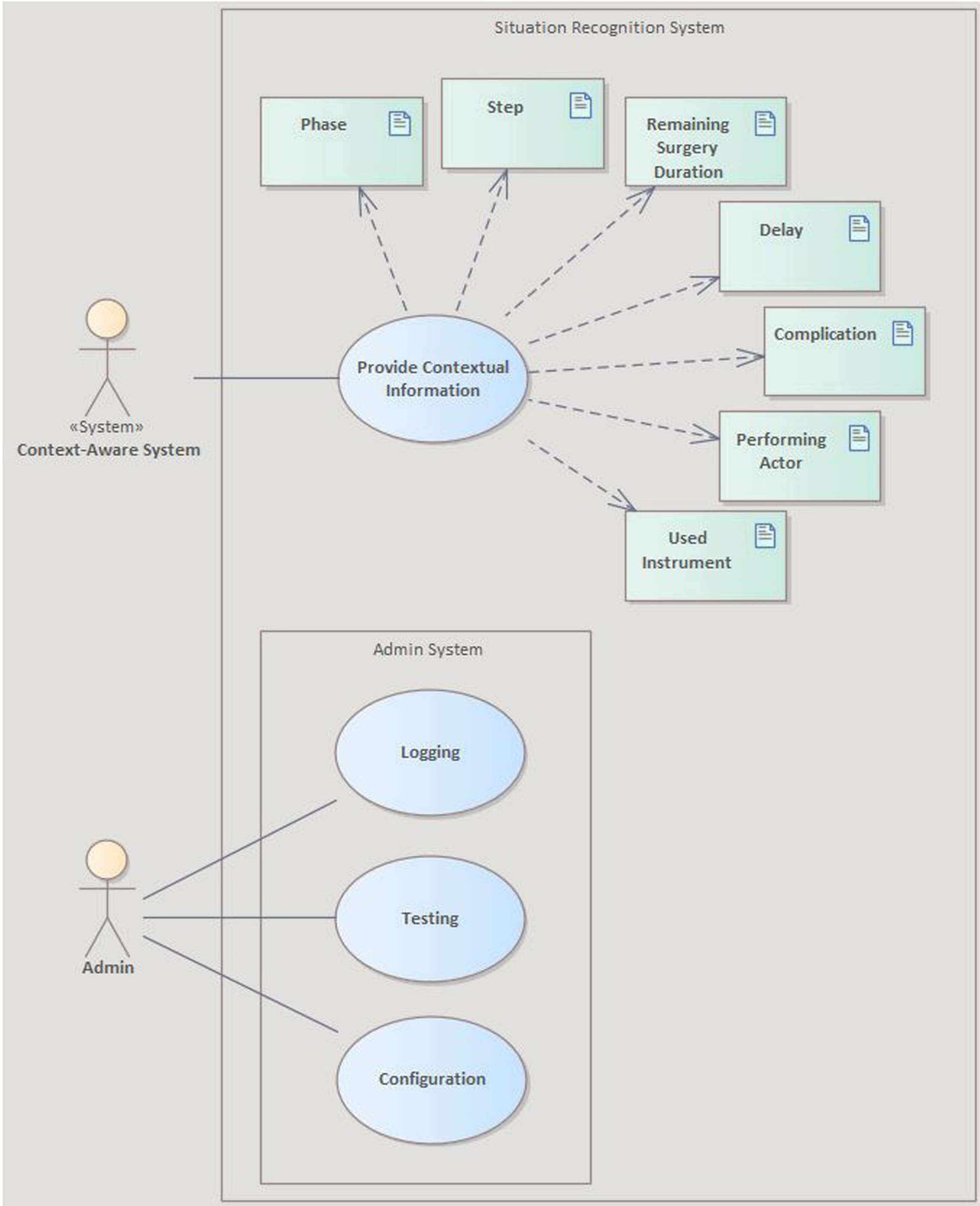

Fig. 2 SysML use case diagram of the interactions between users and the SRS

Compatibility

Different interfaces to sensors are integrated into the SRS, including a RESTful listener, an SDC-based device discovery, and a publish-subscribe SDC interface (/N05/). Sensor data can be simulated via a user interface (/N06/). At least 5 data sources can be used simultaneously, providing single- or multi-sensor data (/N07/). Using SDC interface metrics, several CAS can subscribe to desired information simultaneously (/N08/, /N09/). Sensors and CAS can be coupled and decoupled via listeners and SDC interface, respectively (/N01/). The SRS runs in the research OR with other systems without recognizable restrictions (/N02/). The system communicates with the *Camunda Workflow Engine* [19] via a

Table 1 Overview of the main scenarios of the SRS

	Scenario 1	Scenario 2	Scenario 3
Surgical intervention	Robot-assisted minimally invasive Esophagectomy (RAMIE)	Laparoscopic Cholecystectomy (LC)	Cochlea Implantation (CI)
Processes	Different procedures (step variance)	Different procedures (process variants)	Different procedures (step variance)
Granularities	Phases and steps	Phases	Phases and steps
Process modeling standards	BPMN, CMMN, and combination model	BPMN	BPMN, CMMN, and combination model
Data sources	Instrument and position recognition (simulation), step recognition (checklist)	Phase recognition (simulation of phase flickering), endoscope (dataset), device data (simulation of thermoflator)	Step recognition (checklist and simulation)
Sensor data types	Instrument used and position of surgeon/assistant, name of the step	Name of the phase, endoscope image (instrument used), device parameters of thermoflator	Name of the step
Data formats	SDC and JSON	PNG and JSON	SDC and JSON
Data provision	SDC interface and RESTful listener	RESTful listener	SDC interface and RESTful listener
CAS	*OR-Pad* and CAS simulation (SDC)	CAS simulation (SDC)	CAS simulation (SDC)
Situation data	Phase, step, remaining surgery duration, delay, instrument, and actor	Phase, instrument, and complication	Phase, step, remaining surgery duration, and delay
Interpretation logic basis	Rules	Rules and ML combination	Rules

REST API interface [20] (/N03/). Process models in BPMN, CMMN, and combination models are supported (/N04/).

Maintainability

Sensors are assigned to a sensor data type to distribute data to suitable modules of the SRS and can therefore be exchanged (/N12/). Data of every available, configured sensor is automatically incorporated using the system's implemented listener interfaces (/N21/). Interpretation modules and methods can be exchanged and adapted (/N13/, /N22/). New or modified process models can be integrated via the workflow engine and adaptions to relations, rules, etc. made within data management components (/N11/, /N20/). Due to the REST API interface, the workflow engine can be exchanged, too (/N10/). The SRS continuously interprets knowledge about sensors, processes, and situations (/N14/). The rule- and ML-based interpretation logic is uniformly used for all scenarios but also scenario-specific rules can be defined (/N15/). To reuse established work, trained and tested ML models can be integrated (/N17/, /N25/). Also, process models can be reused but require minimal adjustments for integration (/N16/). To track the system behavior, information is logged in a standardized format at different logging levels, including debug mode (/N18/, /N19/). Furthermore, a GUI for sensor data simulation, defined test cases, and a CAS simulation subscribing to all metrics are available (/N23/, /N24/).

Portability

Scenarios can be added and adapted within the SRS (/N26/). Therefore, components and knowledge can be integrated, customized, and exchanged (/N27/). Available, compatible sensors can be registered (/N28/). Outsourced constants (e.g., weightings) allow the configuration of scenarios but no scenario-specific configuration or user interface is provided (/N29/). A new instance can be used with modified settings for the scenarios (/N30/).

Table 2 Requirements analysis and functional evaluation of the SRS. G = Goal, N = Non-functional requirement

	No.	Goal or Non-functional requirement	Evaluation Result
	/G01/	The SRS recognizes the current situation of different surgical processes in the OR based on data from various intraoperatively available sensors and process knowledge	*Fulfilled*
	/G02/	The SRS provides external systems with contextual information about the current situation of an intervention in the OR	*Fulfilled*
Compatibility	/N01/	The SRS shall connect all external systems (sensors, CAS) through loose coupling	*Fulfilled*
	/N02/	The SRS shall exist in parallel to the OR infrastructure	*Fulfilled*
	/N03/	The SRS shall communicate with the workflow engine via a REST interface	*Fulfilled*
	/N04/	The SRS shall support process models in the modeling standards BPMN and CMMN	*Fulfilled*
	/N05/	The SRS shall communicate with sensors via specified interfaces (e.g., SDC)	*Fulfilled*
	/N06/	The SRS shall be demonstrable with simulated sensors	*Fulfilled*
	/N07/	The SRS shall enable processing data from at least 4 data sources for a scenario	*Fulfilled*
	/N08/	The SRS shall communicate with CAS via an SDC interface	*Fulfilled*
	/N09/	The SRS shall enable to provide data to at least 2 CAS in a scenario	*Fulfilled*
Maintainability	/N10/	The SRS shall enable the exchange of the workflow engine	*Fulfilled*
	/N11/	The SRS shall enable the exchange of process models via the workflow engine for the same intervention	*Fulfilled*
	/N12/	The SRS shall enable the exchange of sensors within a sensor type	*Fulfilled*
	/N13/	The SRS shall enable the exchange of interpretation logic	*Fulfilled*
	/N14/	The SRS shall enable to interpret and provide situation data independently of the CAS currently in use	*Fulfilled*

Table 2 (continued)

	No.	Goal or Non-functional requirement	Evaluation Result
	/N15/	The SRS shall apply interpretation logic across scenarios if reasonable	*Fulfilled*
	/N16/	The SRS shall enable to import existing process models	*Partly fulfilled*
	/N17/	The SRS shall enable to import existing, trained ML models	*Fulfilled*
	/N18/	The SRS shall provide clear and traceable log entries for information, warnings, and errors	*Fulfilled*
	/N19/	The SRS shall log additional information according to the configured logging level (debug) during administrative use	*Fulfilled*
	/N20/	The SRS shall allow the integration of process models via a workflow engine and knowledge for the intervention via a data management component	*Fulfilled*
	/N21/	The SRS shall allow the connection of sensors via an interface and the adaptation of sensor configurations via a data management component	*Fulfilled*
	/N22/	The SRS shall allow the integration and extension of interpretation logic via modules	*Fulfilled*
	/N23/	The SRS shall offer a GUI for simulating sensor data for testing purposes during administrative use	*Fulfilled*
	/N24/	The SRS shall include a CAS simulation for testing purposes for administrative use	*Fulfilled*
	/N25/	The SRS shall use a test dataset for ML-based approaches for testing purposes during administrative use	*Fulfilled*
Portability	/N26/	The SRS shall enable to add a new scenario, particularly concerning intervention types and sensor types	*Fulfilled*
	/N27/	The SRS shall enable changes to existing process models, connected sensors, and integrated interpretation logic (e.g., ML model) within a scenario	*Fulfilled*

Table 2 (continued)

No.	Goal or Non-functional requirement	Evaluation Result
/N28/	The SRS shall enable the registration and use of available, compatible sensors	*Fulfilled*
/N29/	The SRS shall allow the configuration of its functionality (connection to the server, intervals, …) via outsourced constants	*Partly fulfilled*
/N30/	The SRS shall be replaceable by a new instance with a different configuration	*Fulfilled*

Argumentative evaluation

Because it is impossible to cover all aspects of transferability with test scenarios, we are giving further arguments in this section.

Supported scenarios

The scenarios RAMIE, LC, and CI represent realistic demonstrators for the functionality and usability of the prototype, but also other scenarios are supported. Thus, a wide range of variations is covered, offering a versatile platform for demonstrating integrated scenarios. Due to the modular architecture, multiple sensors can be connected, the data are processed in corresponding modules, and different process models and variants can be executed. Switching between supported scenarios requires minimal administrative steps, e.g., to configure the ML model or ensure the connection to sensors and CAS.

Effort for new scenarios

The effort for integrating new scenarios or functionalities can vary depending on the complexity and wealth of previously integrated aspects. In the best case, the new scenario is close to an existing scenario, so that the SRS' functionality can be reused. Otherwise, parts of the functionality have to be modified by adapting or exchanging components. Table 3 shows the main components to identify whether a new scenario can already be supported or adaptions are required. In summary, suitable sensors, interpretation logic, and process information must be available. By integrating further scenarios, the system's complexity will increase, and required adaptations be reduced.

Table 3 Components to check required scenario adaptions and extensions

Layer	Aspect	Required, otherwise, be changed
Sensor Abstraction	Sensor and listener	Sensor interfaces
	Data management	Management of sensors (sensor registry)
	Interpretation logic (incl. *Sensor Knowledge*)	Support of sensor (data) type and data format, functionality of modules/methods, coverage of rules and ML models
Situation Recognition	Interpretation logic (incl. *Situation Knowledge*)	Functionality of modules/methods, support of CAS goals
	Data management	Management of intervention information and rules
Workflow Management	Workflow engine and interpretation logic (incl. *Process Knowledge*)	Process models, functionality of methods
	CAS	Functionality of the SDC interface (metrics)

Configurability, interchangeability, and expandability

The modular architecture plays a decisive role in coping with changing scenarios. In many cases, configurative adjustments, e.g., change sensors or adapt intervals, can be done by an administrator. In contrast, the integration of new functionalities, e.g., support new sensors, requires to involve system experts to add, modify, or exchange components. Following software engineering best practices, the SRS provides key aspects to achieve adaptability: (1) Encapsulation of functionalities in components, (2) data exchange independent of the internal structure, (3) communication via interfaces with uniform data classes, and (4) central management of constants and general functions. Thus, components can be interchanged and expanded without affecting the whole system.

Flexibility of the layers

The scenarios demonstrate that surgical interventions in different variants, a variety of sensor configurations, and different interpretation logic are supported (see Table 1). Thus, the SRS is not limited to a specific scenario but is scenario-independent. Particularly, the usage of generalized and scenario-specific CMMN models [9] gives an outlook on better transferability of process information, whereas the sensor registry and type-specific processing enhance sensor usage on availability. Overall, it nevertheless must be assured for deviating scenarios that depending information and components are covered (see Table 3).

Discussion

Applicability and transferability

The scenarios demonstrate the versatility of the architecture, dealing with different data inputs and surgical interventions to react flexibly to other settings. The SRS uses all resources available to generate multi-faceted sensor knowledge. Thereby, generalized and case-specific interpretation logic can principally be used, switched, and combined to deal with the diversity and variety of data. The combination of sensor and process knowledge enables comprehensive situation recognition for different surgical processes. By addressing compatibility, maintainability, and portability, the system is applicable to different integrated scenarios, but also the transfer to deviating situations can be derived. The fulfilled requirements and argumentation highlighted the characteristics to support convenient adaption. For scenarios with similar surgical settings, many of the existing components may be reused to reduce the integration effort. For completely different scenarios, the architecture provides integration support via layers and modules, so that the system can be adapted target-oriented to deviating processes and OR equipment. Concluding, applicability is given as different sensors, logic, and process variants are supported for the integrated scenarios. Moreover, transferability between scenarios is possible due to the easy adaptability for new scenarios and deviating surgical settings. This enables a flexible, transferable situation recognition for different interventions and sensors that adapts to changing requirements and supports widely applicable CAS.

Based on [6], existing approaches are strongly tailored and therefore limited to specific scenarios. Although a few of the existing approaches deal with multiple sensors (e.g., [21, 22]) or show their performance with other datasets (e.g., [23, 24]), the transferability is not shown sufficiently at different levels. In contrast, our SRS was particularly designed to support a variety of data sources and surgical interventions and be easily adaptable, emphasizing features that transcend the scope of specific implementations. This flexibility is possible due to the layers and modules that work independently of the data source and are not limited to a specific surgical domain. While the architecture stays the same, only scenario-relevant components are used in the specific surgical setting. Thus, the SRS offers a platform for different scenarios and addresses increased flexibility and adaptability to further surgical settings. Compared to specified approaches, lower implementation efforts are expected for new scenarios as the architecture already exists, components can be reused, and functionalities are outsourced to enable efficient adaptions and extensions. In summary, the SRS offers a clear advantage over specific approaches due to its architecture, which is geared toward transferability.

Validity of the results

The validity of the results is assessed according to [25]. *Internal validity* refers to the extent to which valid conclusions can be derived from the evaluation. The prototype was implemented based on the general concept and evaluated by the developer using specific scenarios. Thereby, the input was known and sufficient knowledge of the SRS was available. Expert knowledge may have influenced the assessments of the architecture but is also a prerequisite for adaptions. *External validity* refers to the extent to which the evaluation results can be generalized. The SRS can operate in different scenarios but is not restricted to these. The evaluation highlights the necessary compatibility, maintainability, and portability to realize transferability to other contexts. The realistic scenarios are representative examples, so the results can be transferred to real conditions. *Conclusion validity* refers to the extent to which correct conclusions can be derived from the evaluation. The prototype was evaluated based on requirements, scenarios, and system analysis. Despite the lack of data, the evaluation covers all relevant aspects to assess the SRS' ability. The transfer to real scenarios and evaluation in a surgical environment is not affected by the actual implementation. *Construct validity* refers to the extent to which the evaluation method can measure theoretical concepts. The chosen evaluation method was multistaged. A functional evaluation based on transferability-relevant requirements and scenarios covering different surgical settings was used to prove the transferability. A complemented argumentative evaluation assessed the transferability beyond the requirements. The chosen approach represents a comprehensive and appropriate procedure for evaluating the SRS.

Limitations

One of the biggest pitfalls in developing the prototype was the lack of diverse clinical data to cover the information needed at all layers. Although there are selected, freely accessible datasets, these are mainly based on video data (not multimodal data) and, e.g., do not provide detailed information about the surgical intervention process. This lack of available, sufficient data are also stated in other work (e.g., [26–28]) although research is already addressing the representation of greater diversity (e.g., [29, 30]). Hence, the scenarios were realized based on real data from clinical cooperation combined with available datasets to simulate sensor data, implement exemplary interpretation logic, and model clinic-specific process models. Insufficient aspects were enriched exemplary based on observations or logic. As a result, the structure and process chain were realized and a wide range of scenarios were covered. The depicted limitations can be resolved by adapting and expanding the scenarios and functionality in further development cycles. Based on multimodal data, extensive tests would become possible to further investigate the transferability ability, dealing with the diversity and variety of the surgical sensor and process data.

While the prototypical implementation contains specific technical details and limitations, the architectural concept provides the foundation and vision for a flexible and adaptable system that addresses various transferability challenges. Nevertheless, customization or preparatory work will be required before the SRS can be used in a new environment, as the system cannot be capable of everything. It is essential to create specific process models for each new intervention, add interfaces for unknown sensors or, if necessary, train new ML models and define rules to ensure the functionality of the SRS. The depicted SRS can be used in a variety of scenarios and can be adapted to changing requirements with reasonable effort. Compared to systems not designed for transferability, our SRS uses an established modular system design and specifically addresses transferability-relevant requirements engineering characteristics. Nevertheless, as the variability of the necessary adaptations and the lack of comparability do not allow quantifying transferability, the effort can only be predicted as reasonable based on the assessment in this paper.

Conclusion

Transferability is crucial for versatility and efficiency. The proposed system architecture depicts the approach of a scenario-independent SRS and is characterized by its modularity and adaptability. The framework prototype demonstrates the implementation of the concept, covering a selection of possible sensor variations or interventions. It provides a fundamental platform that, in contrast to scenario-specialized systems, was designed for different settings and can be adapted to new scenarios with expected lower effort. The evaluation method, including a functional and argumentative evaluation, assesses the applicability and transferability of the SRS to different surgical settings. The results show that the architecture is feasible and specifically supports a flexible and transferable SRS that can adapt to environmental changes, can easily be expanded to different surgical settings, and thus enable widely applicable CAS. This proof of concept provides a promising outlook on the possibilities of an SRS that supports many types of intervention and sensor systems and has the required compatibility, maintainability, and portability for new scenarios. In further research, components can be gradually optimized or supplemented to improve interpretation logic and support further scenarios for clinical usage. We assume, that a modular SRS that can be transferred to new scenarios is a key factor in bringing intelligent context-aware surgical assistance systems into clinical routine.

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Declarations

Conflict of interest The authors have no competing interests to declare.

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3 Discussion

3.1 Achievement of objectives and hypothesis

Situation awareness forms the elementary basis for achieving context-aware surgical assistance in the intelligent OR. To estimate the surgical situation, knowledge must be obtained intraoperatively via data sources and be enriched with information about the surgical process. The large number of possible sensors, variance in surgical processes, and other influencing factors due to the clinical infrastructure and equipment, clinical personnel, or the patients themselves make it challenging to achieve reliable and robust situation recognition. Changing surgical settings make it imperative that intraoperative systems can cope with these changes. Thus, a transferable SRS is essential to not only cover individual use cases but also a large number of scenarios, addressing the variability in the dynamic OR.

The lack of applicability and transferability of existing situation recognition approaches was elaborated (see chapter 2.1) via the systematic state-of-the-art review and analysis [Junger et al. 2022b] which compares and discusses different situation recognition approaches and identifies important questions in the context of applicability and transferability. It shows the variance of existing approaches but also highlights the trend in laparoscopic and cataract surgeries, using the surgical video as the data source. Applicability and transferability to other scenarios are less addressed and expected to be only possible to a limited extent. To tackle this elaborated lack, a strategy for the realization of basic transferability is highly necessary for the realization of intelligent systems in the dynamic OR. The hypothesis pursued in this work thus addresses the development of a flexible and transferable SRS for different surgical settings to enable broadly applicable CAS (see chapter 1.3). To prove this hypothesis, the methodology comprises an iterative development process that pursues individual objectives to contribute together to a proof of concept. Based on a high-level concept, a modular system was developed that initially implements the basic characteristics of transferable systems and can be adapted and expanded for the gradual enhancement of transferability issues. The modular approach allows system components to be designed, developed, and evaluated in manageable iterations to realize a framework prototype for sensor- and intervention-independent situation recognition. It further guarantees the stepwise refinement of system components to easily incorporate changes or new features without affecting the holistic system. The system can evolve and be adapted to changing requirements, vivid within the variable intraoperative area. By addressing the variability of surgical interventions and CAS needs in further iterations, the transferability can be optimized, while simultaneously demonstrating its adaptability and expandability. Prototyping characteristics within the research and development cycles encourage early access to feasibility via regular testing and adaption in advance. Quality can be achieved via this balanced and effective development process.

The main objectives of this thesis, the development of an intraoperative SRS that enables applicability and transferability to different scenarios (see chapters 2.2 and 2.5), thus contribute directly to the overarching goal. The high-level concept of the SRS [Junger et al. 2022c] addresses the variance of surgical settings to realize transferability. It outlines a modular system architecture, including main components, data flow, and standardized interfaces, that transfers established software engineering practices into the surgical domain and serves as the basis for an evolving platform for broadly applicable situation recognition in the OR. It proposes four layers – (1) *Data Acquisition*, (2) *Sensor Abstraction*, (3) *Situation Recognition*, and (4) *Workflow Management* – and the encapsulation of functionalities in modules. The aim is a flexible SRS that is adaptable to different intraoperatively available sensors, surgical procedures, and CAS needs. To demonstrate its overall feasibility and synergy, an initial framework prototype was developed and evaluated via requirements, highlighting the basic functionality of the system architecture and derived prototype. Via iterative development, the envisioned SRS can be implemented stepwise and adapted as required to improve its applicability and transferability. The proof of concept of the SRS [Junger et al. 2024b] further depicts the evolving framework prototype and demonstrates its fundamental scenario-independent behavior. Elementary quality criteria for a transferable system to guarantee compatibility, maintainability, and portability were applied within the development cycles. It offers the possibility of configuration, interchangeability of components, and expandability to be adaptable to the changing, dynamic surgical environment and actual needs. Furthermore, it specifically addresses the variability of surgical interventions and standardized information provision. Thus, the SRS enables broad applicability for various surgical settings as well as adaptability to enable incremental refinement to improve its versatility and efficiency. The multi-stage evaluation assessed these abilities via requirements, scenarios, and system analysis, verifying the overall applicability and transferability on the different layers. The resulted scenario-independent SRS can fundamentally be transferred to different surgical settings, enable situation awareness, and will be a key factor to achieve intelligent, surgical CAS.

Via the secondary objectives, individual concepts to address specific transferability challenges and demonstrate applicability were developed. They contribute to the overarching goal of realizing a scenario-independent SRS and were incorporated into the framework prototype pipeline. Process formalization activities, addressing the variability of highly flexible, surgical processes and thereby making process knowledge transferable, depict modeling approaches and highlight their advantages and disadvantages (see chapter 2.3). The flexible process formalization approach [Junger et al. 2024a] demonstrates the suitability of BPMN and CMMN, and proves the practical feasibility within the SRS for modeling, execution, and control, emphasizing the flexibility and comprehensibility of the approaches. Although CMMN is more challenging, it enables better applicability and transferability of the SPMs and therefore the SRS. CMMN or a combination of BPMN and CMMN are advantageous for variable, weakly structured processes. By either using one generalized or multiple case-specific models, the applicability of the SRS to various surgical interventions across disciplines and hospitals can be improved. The flexible use of BPMN and CMMN depending on the use case shows a high potential in optimizing the SRS transferability to different surgical interventions.

Furthermore, a standardized interface for the loose coupling between intraoperative systems for information provision and the realization of context-aware behavior of an example CAS demonstrated the applicability of situation recognition (see chapter 2.4). The SDC-based interface [Junger et al. 2022a] implements a middleware for the provision of interpreted contextual information to different CAS using RPCs. The outsourcing of situation recognition logic from CAS, the usage of the SDC standard, and the low integration effort were evaluated. The publish-subscribe pattern interface realizes loose coupling for context-aware behavior and can be applied for any SRS and CAS, thus contributing to the applicability of the SRS. This allows the SRS to provide any information that could be recognized based on the available intraoperative sensors as well as process information of the surgical interventions, independent of the CAS functionality. In contrast, CAS can only subscribe to information that is of relevance to their context-aware behavior. The proof of concept uses the *OR-Pad* system [Ryniak et al. 2023] as a demo CAS that supports the surgeon perioperatively with clinically relevant information. It illustrates the user interface concept, including context-aware behavior. By pre-selecting and assigning information to surgical phases, this information is automatically displayed based on the provided phase from an SRS to reduce the interaction effort. Furthermore, possible delays are provided. The SDC interface and loosely coupled CAS thus demonstrate the broad applicability of the SRS to trigger context-aware behavior.

Via the six publications, the relevance of the overarching goal was elaborated and all depicted objectives (see chapter 1.2) were achieved. The need for a transferable SRS led to a high-level concept and framework prototype for multiple surgical settings. New process formalization approaches contribute to the transferability of the SRS, at the same time demonstrating its adaptability and expandability. Standardized information provision in combination with an exemplary CAS implementation demonstrates the applicability of the SRS and overall concept. The final proof of concept of the SRS brings together all contributions to realize the desired SRS. It confirms the scenario-independent applicability and shows the implemented transferability-relevant aspects. The SRS enables basic transferability via the modular architecture, especially on the process layer. Data from various intraoperative sensors can be processed.

Within modules, the sensor knowledge, such as the surgical instrument used or the performing actor, is recognized using a set of rules and ML techniques. Situation interpretation is then done to further recognize situation knowledge to output the actual phase or step, remaining surgery duration (RSD), or other CAS-relevant information. Furthermore, process knowledge retrieved from SPMs of multiple surgical interventions is incorporated. The SPMs can depict different process variants, granularities, and process modeling standards, namely BPMN and CMMN. Via an SDC interface, contextual information can be provided to CAS.

In conclusion, the chosen methods of iterative development and prototyping were successfully used to realize a modular system as a fundamental basis for transferability in the intraoperative area, which can evolve in its complexity. The fundamental applicability and transferability of the SRS to different surgical settings to enable CAS were demonstrated and proved via suitable functional and argumentative evaluation. Consequently, by fulfilling all objectives but mostly the final proof of concept, the feasibility and thus the overall hypothesis is regarded as proven:

> *It is possible to develop a flexible, transferable situation recognition system for different surgical settings to enable broadly applicable context-aware systems.*

3.2 Contributions in the context of current research

3.2.1 System architecture for applicability and transferability

This thesis provides a high-level concept for a transferable SRS, characterized by a generalized, modular architecture to fundamentally enable the scenario-independent application to various surgical settings. While the framework prototype demonstrated the general functionality of the architecture, the proof of concept further highlights its characteristics to improve the transferability, giving a rough foundation for the overall concept. The ability to apply and transfer knowledge and features to various scenarios, adapt and extend the system in case of new findings and requirements, and enable a flexible SRS that addresses the entirety of variances and factors would have a major added value to the future intelligent OR. It thereby provides the fundamental basis for developing intelligent systems with situationally adaptive behavior.

The need for a transferable system was elaborated via the systematic state-of-the-art analysis, including a taxonomy for the assessment of situation recognition approaches. The trend in video data and standardized interventions was also identified in other differing reviews. [Garrow et al. 2021] focus on ML-based approaches for surgical phase recognition. The results highlighted the trend in LC interventions, using the surgical video or manual annotated instruments, and the missing standardization of phase definitions. [Demir et al. 2023] focus on deep learning approaches for phase and step recognition. The results depicted the trend in video data and standardized interventions (e.g., LC). Moreover, the problem of generalization and differences in annotations were highlighted. The findings of both reviews further emphasize the relevance of more variance and a transferable SRS. Nevertheless, recent approaches still only hypothesize or rarely demonstrate specific variability- and transferability-related aspects (e.g., [Kawamura et al. 2023; Das et al. 2022; Zhang et al. 2022; Kiyasseh et al. 2023; Sanchez-Matilla et al. 2022]) or state to address such aspects in the future (e.g., [Guédon et al. 2021; Zhai et al. 2024; Takeuchi et al. 2022; Zhang et al. 2021]). Still, several levels, such as differing sensor technology and interventions, are not being investigated for broad applicability and transferability. More holistic approaches that tackle this lack in its entirety were not published in the meantime.

The system architecture for the SRS was designed to address this lack and enable the present variance. In addition to established software engineering best practices and quality characteristics (such as interoperability, modularity, modifiability, adaptability, and replaceability [ISO/IEC 2011]) for transferable systems, design strategies of existing system architectures of other domains based on layers for sensor data processing, predictions and calculations, as well as task planning and execution [Albus et al. 1989; Albus 1994] were incorporated. Furthermore, the SitOPT architecture [Hirmer et al. 2017; Wieland et al. 2015], focusing on an approach that automatically adapts its behavior to the environmental situation, proposes three layers for sensing, situation recognition, and situation-aware workflow. Based on these ideas and concepts, a modular SRS architecture that is not limited to a specific surgical setting was realized. As a result, the SRS can process data from different sensors, following a sensor adapter-based approach such as SitOPT. By integrating various sensors, inaccuracies of a single sensor [Kowalewski et al. 2019] and sensor failures [Pfeiffer et al. 2015] can be compensated. Moreover, even less obvious data may contribute to the overall context [Stauder et al. 2014]. Hereby, the sensor registry plays a crucial role, assigning sensors to types for sensor type-based data interpretation. In addition, process modeling and a workflow management system are used. SPMs depict the possible surgical processes to form process knowledge, while situation relations map granularities. Thereby, multiple surgical interventions can be supported. By outsourcing context-aware behavior, CAS can subscribe to desired information via an SDC interface.

Defined activity and situation rules, similar to the SitOPT situation templates, as well as parameter combinations implement rule-based interpretation methods. Furthermore, ML approaches were integrated. The different logic is encapsulated within respective recognition modules for different sensor and situation knowledge, incorporating weights and calculating probabilities for each knowledge part. In contrast to the similar approach of [Meißner 2015], where surgical activities are recognized based on different perspectives (e.g., used instrument) to achieve applicability for multiple intervention types, the SRS goes beyond this, incorporating the results of all available sensor data as well as the surgical process to gain multi-faceted situation knowledge. Components such as rules can be reused and applied case-independent to promote transferability but also case-specific interpretation logic can be integrated to realize functionality as required. Although generalized approaches are pursued [Das et al. 2022; Kiyasseh et al. 2023; Meißner 2015], unique and application-dependent methods might be necessary [Demir et al. 2023; Quellec et al. 2014]. For this reason, the balance between generalized and case-specific interpretation logic was chosen to enable valid recognition results by switching and combining the approaches to address variety and diversity in the best possible way.

Overall, the proposed SRS does not represent a standard architecture but a new and unique approach in the surgical context, and thus a significant contribution to transferable systems on which other work can build. As most existing approaches focus on highly standardized interventions and follow the extensive trend of video input, they are highly specialized and therefore limited to dedicated use cases. Hence, it is expected that these are significantly less complex and unable to connect different intraoperatively available sensors, support various surgical interventions, and implement multiple situation recognition logic with little effort. Consequently, they are not economically viable. In contrast, the SRS focuses on transferability in multiple areas and was designed from the very start to function for different surgical settings. It is not exclusively designed for camera-based sensor input, restricting its usage. Furthermore, the SRS fundamentally demonstrates the application to more complex and varying cases, although [Kranzfelder et al. 2014] state that situation recognition is only possible for highly standardized surgical interventions. In principle, the SRS can also be applied for open surgeries, function with more or less sensors, or deal with other varying surgical scenarios such as sensor failure. It not only addresses high-level aspects such as different sensor and intervention types but also deals with more fine granular variability, such as different process modeling notations and output contextual information for CAS. It covers various levels as a holistic approach to achieve situation awareness and enable basic transferability. Therefore, the SRS does not have to be redesigned, can be integrated into existing infrastructures, and may reduce the effort for adaption and extension by specifically addressing transferability-relevant compatibility, maintainability, and portability aspects. In conclusion, it is expected that via the modular system architecture, efficient situation recognition in the OR for multiple surgical scenarios could be enabled by establishing a common information base, sharing knowledge, and reusing functionalities. As a consequence, the SRS offers the versatility and adaptability required to be, in contrast to the limited state-of-the-art approaches, better transferred into the clinical routine.

3.2.2 Variability on process layer

The SPMs at the process layer are a key reason for the improved transferability in the context of intervention-independency. The application of SPMs to situation recognition approaches was already demonstrated (e.g., [Katić et al. 2015; Dergachyova et al. 2016; Nakawala et al. 2018]). The SRS uses generic SPMs (gSPM) [Lalys and Jannin 2014; Neumuth 2017] to incorporate all known surgical process variances to improve sensor-based predictions. Furthermore, the gSPMs are applied to verify the plausibility of the recognized situation in order to reduce misinterpretations. Similar to [Bencteux et al. 2020], this forces the SRS to align with the process model.

The BPMN standard is an established notation for depicting business processes and was already transferred to the medical field (e.g., [Neumann et al. 2019; Combi et al. 2021; Pufahl et al. 2022; Rolón et al. 2015]). Situation recognition approaches that focus on highly standardized interventions and depict a low number of surgical phases, can be modeled via BPMN. For approaches that refer to underlying surgical steps, more fine-granular activities, or process deviations, depicting different process variants or events, the SPMs can become quite complex. To address this variability, CMMN for weakly structured processes gained attention. While CMMN was analyzed, contrasted to BPMN, or a combination proposed in other domains (e.g., [Lantow 2018; Routis et al. 2021; Routis et al. 2020; Zensen and Kuster 2018; Passos and Pereira 2018; Delgado and Calegari 2019; Hinkelmann and Pierfranceschi 2014]), the application in the medical field is less researched. Nevertheless, [Wiemuth et al. 2017] describe the strengths and weaknesses of the modeling languages BPMN, CMMN, and Decision Model and Notation (DMN) and how a combination can be advantageous to represent non-deterministic processes. [Herzberg et al. 2015] particularly highlight CMMN models for clinical processes if multiple hospitals and differing tasks need to be depicted and propose general CMMN cases covering all process variants.

To address the required variability of the SPMs, similar modeling approaches based on BPMN and CMMN were determined and contrasted. The combination of both notations has emerged to be appropriate for process modeling, execution, and control in the context of the SRS to depict standardized and flexible surgical processes. Using CMMN for variable process parts enables flexible and transferable SPMs that can cover multiple process variants and consequently indicate cross-clinical applicability. Overall, being flexible in supporting different process notations, the SRS can be applied to more standardized as well as highly variable surgical interventions. The SRS was optimized to be better intervention-independent than only supporting BPMN models with a restricted set of notation possibilities for fine-granular or case-specific SPMs. Thereby, the natural variance in step sequence and overall process can be covered in valid SPMs.

The broad applicability to enable targeted support of perioperative actors is achieved by completely encapsulating situation recognition logic from context-aware behavior. While a situation recognition component for only one CAS can focus on specific outputs, such as the surgical phase, and be integrated within the same system, a comprehensive SRS needs to cover and provide knowledge for different CAS and their purposes. The aim was therefore a publish-subscribe pattern approach for the standardized communication of contextual information. In order to be independent of proprietary solutions, SDC was chosen due to its emerging relevance in research for standardized medical device communication and expected device interoperability [Kasparick et al. 2018]. The SDC-based interface follows the concept of [Franke and Neumuth 2015a] as base architecture. The SRS functions as a workflow information system from which CAS can subscribe to relevant information and trigger context-aware behavior based on the retrieved notifications. Hence, each CAS can follow its concept for context-aware displaying or other supportive functionalities. Furthermore, multiple CAS can easily use the interface to get updates on the intraoperative state and actuate context-aware behavior.

The *OR-Pad*, the initial use case for the SRS that emerged from clinical routine to support the surgeon [Junger et al. 2019; Frommer et al. 2021], subscribes to the surgical phase and delay metric. Pre-selection and assignment of clinically relevant information to surgical phases enable the targeted support of the surgeon. Thus, the approach is consistent with a mixture of personalized and passive context-aware behavior, as defined by [Barkhuus and Dey 2003]. Due to the limited opportunities available to the surgeon to interact with the system intraoperatively and to reduce difficult and unnecessary interaction potentially disruptive to the workflow [Matern and Koneczny 2007], the intraoperative interaction effort for the surgeon is reduced. Context-relevant information (e.g., preoperative images) is provided automatically, based on the course of the surgical intervention, while the retrieved surgical phase and delay from an SRS are continuously displayed. In contrast to automatically filtering information such as in [Katić et al. 2013; Stauder et al. 2012], the *OR-Pad* relies so far on manual assignment to ensure the correctness of the provided information and to keep its complexity low for unrestricted use.

In conclusion, the SDC interface provides a publish-subscribe-based approach for loosely coupling an SRS and multiple CAS and thereby enables the broad application of the SRS for different scenarios and surgical assistance systems in the intraoperative area. The SRS functions independently of the intended use of the recognized situation knowledge, providing information without bringing it into the context of individual CAS, i.e., not distorting the contextual information. The *OR-Pad*, in particular, demonstrates the clinical relevance of context-aware support and due to its intended use for multiple surgical interventions the need for a transferable SRS.

3.3 Limitations of the approaches and open challenges

3.3.1 Variety and complexity

Due to the variety of requirements and influential factors in the dynamic surgical environment, the system concept does not address the entirety of scenarios and specific transferability issues. Immaculate transferability within the OR is difficult to achieve as there are many challenges to overcome to realize transferability to efficiently use intelligent systems in a reliable and robust manner. Nevertheless, the high-level concept is quite complex as it envisions covering different sensors, interpretation methods, and surgical interventions. The concept was demonstrated via prototypical implementation, focusing on the fundamental transferability of the SRS. System components were exemplarily depicted and simulations were used to realize and evaluate the overall architecture and framework. Certain non-focused components were assumed in the future, such as the provision of sensor data via a generalized interface to obtain information from different intraoperative sensors. Consequently, for example, the sensor interfaces were limited to a set of values, simple ML models were integrated that are not as robust or accurate as existing approaches, and the RSD recognition logic was realized as a simplified calculation. Nevertheless, the system demonstrated the feasibility of the approach regarding transferability to achieve situation awareness. As there will be no guarantee that the SRS supports all sensors and process variants, the adaption and development effort was reduced by design choices. The system architecture supports the required iterative refinement to optimize components and address specific challenges target-oriented to improve the complexity and cover the variety of different and any as yet unknown scenarios, for example, to enhance its intervention-independent applicability.

As many factors can impact the sequence of surgical process steps, the SRS requires the investigation of much more complex and variable SPMs to represent reality and address their transferability to other hospitals and personalized processes. Although the SRS follows a generalized approach using gSPMs as [Herzberg et al. 2015], hospital- or case-specific subprocesses referred to from an overlying BPMN could improve applicability to specific use cases. Furthermore, incorporating more information into the SPMs, such as probabilities or rules, could be expedient. A combination with the domain-specific extension BPMN^{SIX} [Neumann et al. 2016; Neumann et al. 2019], which incorporates, for example, concepts to depict anatomical structures or medical devices, BPMN4CP [Braun et al. 2014], which introduces, for example, new task types and gateways for clinical processes, or DMN to incorporate decision support [Wiemuth et al. 2017], could be an advantage for process modeling and execution. The more complex the SPMs will become, the more vague the retrieved process knowledge will be. Comparison with personalized processes, individual SPMs (iSPM) [Lalys and Jannin 2014; Neumuth 2017] of past surgeries, might be addressed by the concept of similarity measurements [Neumuth et al. 2012; Kuss et al. 2018], identifying the most similar iSPM to strengthen the predictions.

Furthermore, the lack of semantic interoperability of the SDC interface for information provision, but also the entire SRS and future CAS, must be addressed. The SRS provides contextual information to different systems and processes a variety of information that originates from various contexts, leading to a large discrepancy. The variability of phase definitions, for example, [Garrow et al. 2021; Demir et al. 2023] is a challenge when it comes to using a system effectively in different clinical contexts. Syntactic and semantic interoperability [Neumuth et al. 2018] could bring surgical differences into relation with each other, for example, via standardized workflow modeling [Neumann and Neumuth 2015; Neumuth et al. 2011]. Ontologies, such as OntoSPM [Gibaud et al. 2018; Katić et al. 2015], Deep-Onto [Nakawala et al. 2019], or SIO [Neumann et al. 2022], may be incorporated in order to address the complexity of surgical information [Nakawala et al. 2017] and ensure a common understanding, for example, to clarify the present ambiguity in phase definitions, and therefore support generalization and semantic interoperability for scenario-independent approaches. They can establish a uniform, semantic knowledge basis for the SRS and CAS to enable the meaning of all contextual information or knowledge about sensors, situations, and processes in the clinical context and thus master the variety and complexity of surgical scenarios.

The synergy and fundamental transferability were proven via evaluation restricted to functional and argumentative assessments. While the basic functionality was assessed by requirements, the final system's transferability was verified by following a multi-level evaluation approach, incorporating the software architecture and design strategies, similar as proposed by [Tarvainen

2008]. A quantitative and qualitative analysis was performed to some extent, applying requirements, scenarios, and system analysis. The evaluation was limited to three simulated but realistic scenarios. The expandability of the prototype allows for a future clinical evaluation with prior intensive data collection and analysis. Nevertheless, the chosen evaluation methods realized the assessment of the system's transferability via success metrics and outcome parameters.

3.3.2 Multi-modal data

A limiting factor for the development and integration of different scenarios was the lack of available and sufficient information to cover the variety and complexity present. A large amount of representative, diverse data for valid SPMs, well-founded rules, training of ML models, and sensor interfaces is required. Due to the holistic, transferable approach, comprehensive multi-modal data from different disciplines and hospitals is crucial. While some annotated data sets exist, mostly for video-based approaches, other data types, enough fine-granular information, and cross-clinical data are less or not at all represented to cover different data sources and surgical process variants. The prototype consequently uses simulations for sensor data as well as the definition of rules and process models based on realistic data.

The lack of large, available data sets is also stated in [Demir et al. 2023; Maier-Hein et al. 2022; Nyangoh Timoh et al. 2023]. Limits are seen in the annotations, described as time-consuming and expensive [Demir et al. 2023; Paysan et al. 2021], the size, present variations, as well as the diversity of data and intervention types [Demir et al. 2023]. Moreover, clinical information is lacking [Nyangoh Timoh et al. 2023]. Hence, large, representative data sets should be the focus of future research to depict the reality of the surgical settings. It is expected that such diverse data will also reveal new transferability-related challenges [Demir et al. 2023] and enable the foundation for addressing these issues. Multi-modal data sets were already addressed in the context of surgical data science [Maier-Hein et al. 2022; Maier-Hein et al. 2017], and work has been done in this direction to realize more diversity (e.g., [Wagner et al. 2022; Hutchinson et al. 2023]). The SRS would strongly benefit from such multi-modal data sets, depicting the variety of intraoperative sensor data and surgical processes across hospitals, to integrate and test further scenarios covering all SRS layers and thus iteratively improving its complexity.

Continuous cross-clinical data acquisition, analysis, and annotation in the intraoperative area could eliminate the lack of multi-modal data. The collection of sufficient data is possible, in principle, using integrated ORs [Garrow et al. 2021] and various sensors [Stauder et al. 2014]. [Schnelldorfer et al. 2024] provide a set of requirements and statements to acquire data, available in the OR but not yet routinely recorded, also containing situation recognition relevant data, such as device data, surgical videos, or kinematics of the surgeon. For persistence, accessibility, and further usage, the recorded data could be saved centrally [Andersen et al. 2018; Rockstroh et al. 2014].

To realize multi-modal data acquisition in the OR, to realize large data sets but also for the integration of the SRS, the lack of standards and interfaces needs to be overcome [Kasparick et al. 2019a]. Situation awareness and process support require a highly interconnected environment [Neumuth et al. 2018; Rockstroh 2021]. While the retrieval of data from intraoperative devices is technically feasible [Kranzfelder et al. 2011], interoperability is usually achieved using proprietary protocols [Gregorczyk et al. 2014], lacking vendor-independent device interoperability [Kasparick 2020; Kasparick et al. 2015; Kasparick et al. 2021]. Standardized medical device communication would affect the overall networking and integration and thus the availability of multi-modal data in the long term. Unfortunately, the emerging SDC standard which aims for medical device interoperability [IEEE 2020] is not yet established in the clinical field but would allow the necessary interoperability for data acquisition, situation recognition, and context-aware support. The standardized provision and acquisition of data via SDC and availability of multi-modal data, post-processed and enriched with cross-clinical information, would be relevant prerequisites to realize transferable systems that cover the variety and complexity within the OR.

3.4 Prospect and outlook

Transferability is an important concept, especially for the dynamic surgical environment, and must be addressed in order to realize efficient, economically viable intelligent systems that can be transferred into the clinical routine and are durable in the long term. The transferable situation recognition approach has the potential to enable situation awareness, an essential prerequisite for context-aware support. Hence, broadly applicable assistance systems can be realized that work more automatically. As a result, the surgical team and other actors within the perioperative area can be supported in a targeted manner depending on the surgical situation. This thesis deals with the overarching challenge of realizing transferable intelligent systems for the OR. Thereby, it does not solve all challenges in order to realize a complex, adaptable SRS for different surgical settings. Instead, it provides different concepts as a foundation toward a scenario-independent situation recognition approach that can process all available information within the OR environment, use configurable recognition logic for suitable reasoning, and incorporate the course of the multiple intervention variants to support a variety of CAS via standardized information provision.

The presented concepts address key challenges within the intelligent OR to achieve a transferable SRS instead of highly specialized approaches. Based on the SRS, surgical CAS (i.e., SCAS) [Neumann et al. 2022], for the scenario-independent and situationally adaptive support of the surgical team can be enabled. The state-of-the-art findings, the system architecture and framework prototype of the transferable SRS, as well as the contributions on process formalization, information provision, and context-aware support can impact the research area of intelligent ORs, directing the attention toward transferable approaches. They moreover build the basis for further work in this area, potentially leading to new emerging application areas. The contributions may be referred to by researchers and also be relevant for other stakeholders, such as biomedical engineering companies, as they demonstrate the relevance to address prerequisites such as standardized device communication. In the long term, effects on broadly applicable intelligent systems for the targeted support of the surgical team and perioperative actors are expected. Hospitals, the clinical staff, and thus the patients themselves can benefit from applicable and transferable intelligent systems, such as an intraoperative SRS and SCAS integrated into the clinical routine. The surgical and patient outcomes can be improved by better working conditions, a reduced surgical workload, and cost reductions. Consequently, the transferable SRS has an impact on the optimization potentials of key challenges within the intelligent OR.

However, the surgical field is highly complex, so that an equally complex SRS is required to realize intelligent systems for the OR. Referring to the depicted limitations of the approaches and further challenges, an improvement in the transferability of the SRS and broadly applicable SCAS is implicated. Further optimization steps are crucial to achieve a valuable solution and to improve the framework system. The system architecture supports this refinement in a targeted manner. Addressing further transferability challenges and merging the results by incorporating them in the modular system architecture of the SRS could resolve single approaches that do not correlate with other relevant issues and realize improved transferability of the SRS and other intelligent systems. By optimizing functionalities, addressing further transferability issues, or supporting new sensors, interpretation methods, or surgical interventions the SRS will evolve and be better adaptable to changing surgical scenarios.

In this context, the SRS does not strive to replace existing solutions. The strength of the SRS lies in the basic framework, realizing the overall functionality of the SRS, not in the individual components or the best possible recognition accuracy. Rather, state-of-the-art approaches can be incorporated into the SRS, either by using the recognition approach as sensor input or by integrating the interpretation logic into the modules of the SRS. The architecture offers the flexibility to combine all ideas and concepts within a generalized architecture to enable context-aware support. It can furthermore be used as a test platform for different sensors, interpretation approaches, and interventions, thus providing a fundamental basis for tests and assembling approaches. Design strategies of the high-level concept as well as specific components can also be derived and applied to other research projects. Moreover, the system architecture can be used for data acquisition to realize clinical studies, train ML models, or assess the surgical workflow, which can be incorporated again to improve the SRS.

While specifically contributing to the holistic approach of a transferable SRS and SCAS, process formalization is also relevant for other use cases. Other systems (e.g., intraoperative checklists [Just et al. 2021]) also use SPMs. Overall, application areas are the visualization and analysis of surgical interventions [Neumuth 2017], training and education [Scheuerlein et al. 2012; Neumuth et al. 2012], process automation and decision support [Neumann et al. 2019], as well as evaluation of approaches [Lalys and Jannin 2014]. Consequently, variable, transferable SPMs may also be beneficial for other research areas. Process formalization of variable surgical interventions forms a relevant foundation for the transferability of process information and process-based approaches and the results can be used as the basis for further process formalization steps.

The principle concept of standardized information provision via SDC can also be used for other use cases to realize standardized information provision via a middleware-based approach. For example, the intraoperative checklist [Just et al. 2021; Brandenburg et al. 2022] was subsequently extended by the SDC interface and can serve as a sensor for the SRS. Increasing work in this area will ideally lead to the SDC standard being further disseminated and broadly integrated into clinical routine in the future. Furthermore, the *OR-Pad* concept of a shared but configurable information space and information-to-phase-assignment enables targeted support of the surgeon. It contributes to the research of intelligent ORs via an approach for timeline-based information provision of HIS and PACS data as well as context-aware behavior which might be reusable concepts for other SCAS.

Bringing all contributions together, a transferable, scenario-independent SRS for context-aware support was developed. The final prototype represents the modular system architecture, specified on the process layer to address the variability and transferability via process formalization and standardized information provision. The evaluation proved that the SRS can fundamentally support different surgical settings varying on the sensor, recognition, and process layers. Due to the unique SRS architecture, focusing on compatibility, maintainability, and portability, it stands out from state-of-the-art approaches in terms of transferability. The characteristics of the SRS are expected to have a high impact on applicability and transferability in a holistic approach. The results hence are a suitable foundation to realize a transferable surgical SRS (SSRS) and thus SCAS for the scenario-independent support of the surgical team in the future intelligent OR.

4 Summary

Reliable situation recognition in the OR is the key aspect of the targeted support of the surgical team. Using intraoperative sensors and information about surgical processes, an SRS can recognize the current situation in the OR and provide this knowledge to CAS. Current approaches for situation recognition focus on specific use cases and are not designed for transferability. However, due to the highly dynamic surgical environment, intelligent systems must be able to adapt to changing conditions. An SRS must therefore not only be applicable to specific surgical settings but also transferable to other scenarios.

A transferable SRS could enable broadly applicable CAS to flexibly support the surgical team in different surgical settings and thus be used scenario-independent. Based on an iterative development process, a comprehensive concept of a modular system architecture with four layers was developed and a framework prototype was derived to achieve fundamental transferability. The SRS can incorporate data from different sensors and uses type-based modules to process the information to support sensor-independent situation recognition. Via SPMs, process knowledge is integrated and used as a crucial component for realizing intervention-independency. New approaches for process formalization based on BPMN and CMMN enable the mapping of standardized and non-deterministic process parts and thus the flexibility required to represent the highly variable intraoperative processes. By combining sensor and process knowledge, the SRS can recognize different situation knowledge, such as surgical phases. To realize broadly applicable CAS, the recognized situation knowledge is provided via an SDC interface. Using a standardized publish-subscribe pattern, various CAS, such as the *OR-Pad* for visualizing clinically relevant information, can subscribe to the context information and trigger context-aware behavior for the targeted support of the surgical team.

The results of the functional and argumentative evaluation proved the feasibility of the scenario-independent applicability and fundamental transferability of the SRS. By focusing on compatibility, maintainability, and portability during system design, several scenarios can be supported by the SRS. Moreover, the effort required to incrementally expand the functional complexity and variety of scenarios can be reduced to meet further challenges of transferability iteratively. Flexibility and easy adaptability characterize the overall system and enable it to cover deviating and new surgical settings. The SRS stands out from state-of-the-art approaches as it was realized with a focus on transferability required in the intraoperative area and promises broad applicability for supporting CAS. The results can be used as a basis for the development of a transferable SRS and also contribute to generally improving the transferability of intelligent systems.

Despite the demonstrated feasibility and added value, the SRS also offers potential for optimization. The lack of sufficient multi-modal and cross-clinical data was a limiting factor during development. Likewise, the required complexity must be further addressed by integrating more scenarios. The framework prototype only realizes the basis for the implementation of the concept and system components must be designed and implemented iteratively. There are also further transferability-related challenges that need to be addressed in the future. For example, the BPMN CMMN combination requires further specification and the SDC interface and the entire system need semantic interoperability for cross-clinical transferability.

In conclusion, this work demonstrates the development of a fundamentally transferable SRS for the broad applicability of CAS. The modular system architecture, the adaptable framework prototype, the BPMN- and CMMN-based process formalization, as well as standardized information provision for CAS, such as the *OR-Pad*, address the transferability necessary for the dynamic surgical environment and can contribute to the realization of intelligent ORs in the long term, in which surgical assistance systems support the intraoperative processes and the surgical team in a targeted and scenario-independent manner.

5 German summary

Zuverlässige Situationserkennung im OP-Saal ist der Schlüsselaspekt für die gezielte Unterstützung des OP-Teams. Mittels intraoperativer Sensorik sowie Informationen über die chirurgischen Abläufe, kann ein Situationserkennungssystem (engl. situation recognition system, SRS) die aktuelle Situation im OP-Saal erkennen und dieses Wissen kontextsensitiven Systemen (engl. context-aware systems, CAS) bereitstellen. Bisherige Ansätze zur Situationserkennung fokussieren sich auf spezifische Anwendungsfälle und sind nicht auf Übertragbarkeit ausgelegt. Durch die hoch dynamische chirurgische Umgebung, müssen intelligente Systeme jedoch in der Lage sein, sich adaptiv an verändernde Bedingungen anzupassen. Ein SRS muss daher nicht nur für spezifische chirurgische Gegebenheiten anwendbar sein, sondern ebenfalls die Übertragbarkeit auf andere Szenarien ermöglichen.

Ein übertragbares SRS könnte breit einsetzbare CAS ermöglichen, um das OP-Team flexibel in verschiedenen chirurgischen Situationen zu unterstützten, und somit Szenarien-unabhängig genutzt werden. Auf der Grundlage eines iterativen Entwicklungsprozesses wurde ein umfassendes Konzept einer modularen Systemarchitektur mit vier Schichten entwickelt und ein initialer Framework-Prototyp realisiert, um grundsätzliche Übertragbarkeit zu erreichen. Das SRS kann Daten von verschiedenen Sensoren einbeziehen und verwendet typ-basierte Module zur Verarbeitung der Informationen, um sensorunabhängige Situationserkennung zu realisieren. Über chirurgische Prozessmodelle wird Prozesswissen eingebunden und als ausschlaggebende Komponente zur Realisierung der Eingriffsunabhängigkeit genutzt. Neue Ansätze zur Prozessformalisierung basierend auf BPMN und CMMN ermöglichen die Abbildung standardisierter und nicht-deterministischer Teilprozesse und somit die benötigte Flexibilität zur Darstellung der hoch variablen intraoperativen Prozesse. Durch die Kombination von Sensor- und Prozesswissen kann das SRS verschiedene Situationen erkennen, z.B. chirurgische Phasen. Um breit anwendbare CAS zu realisieren, wird das erkannte Situationswissen über eine SDC-Schnittstelle bereitgestellt. Über ein standardisiertes publish-subscribe Pattern können diverse CAS, wie das *OR-*

Pad zur Visualisierung von klinisch relevanten Informationen, Kontextinformationen abonnieren und basierend auf diesen kontextbezogenes Verhalten zur gezielten Unterstützung des OP-Teams auslösen.

Die Ergebnisse der funktionalen und argumentativen Evaluation belegten die Machbarkeit der Szenarien-unabhängigen Anwendbarkeit und die grundsätzliche Übertragbarkeit des SRS. Durch den Fokus auf Kompatibilität, Wartbarkeit und Übertragbarkeit beim Systementwurf, können mehrere Szenarien durch das SRS unterstützt werden. Darüber hinaus kann der Aufwand für die schrittweise Erweiterung der funktionalen Komplexität und der Vielfalt der Szenarien reduziert werden, um weitere Herausforderungen der Übertragbarkeit iterativ zu adressieren. Flexibilität und leichte Anpassbarkeit zeichnen das Gesamtsystem aus und ermöglichen es, abweichende und neue chirurgische Situationen abzudecken. Das SRS hebt sich hierbei von bestehenden Ansätzen ab, indem es im Vergleich mit Fokus auf die im intraoperativen Bereich benötigte Übertragbarkeit realisiert wurde und die breite Anwendbarkeit für unterstützende CAS verspricht. Die Ergebnisse können sowohl als Basis für die Entwicklung eines übertragbaren SRS genutzt werden als auch allgemein zur Verbesserung der Übertragbarkeit intelligenter Systeme beitragen.

Trotz demonstrierter Machbarkeit und gezeigtem Mehrwert, bietet das SRS jedoch auch Optimierungspotentiale. So ist der Mangel an ausreichend multi-modalen und Klinik-übergreifenden Daten ein limitierender Faktor bei der Entwicklung gewesen. Ebenso bedarf die benötigte Komplexität der Integration weiterer Szenarien. Der Framework-Prototyp realisiert nur die Grundlage für die Umsetzung des Konzepts und Systemkomponenten müssen iterativ entworfen und implementiert werden. Zudem gibt es weitere die Übertragbarkeit betreffende Herausforderungen, die es in Zukunft zu adressieren gilt. Beispielsweise bedürfen die BPMN-CMMN-Kombination weiterer Spezifizierung sowie die SDC-Schnittstelle und das gesamte System der Realisierung semantischer Interoperabilität zur Klinik-übergreifenden Übertragbarkeit.

Zusammenfassend konnte diese Arbeit die Entwicklung eines grundlegend übertragbaren SRS für die breite Anwendbarkeit von CAS demonstrieren. Die modulare Systemarchitektur, der adaptierbare Framework-Prototyp, die BPMN- und CMMN-basierte Prozessformalisierung, sowie standardisierte Informationsbereitstellung für CAS, wie das *OR-Pad*, adressieren die für die dynamische chirurgische Umgebung notwendige Übertragbarkeit und können daher langfristig zur Realisierung intelligenter OP-Säle beitragen, in denen chirurgische Assistenzsysteme die intraoperativen Prozesse und das OP-Team gezielt und Szenarien-unabhängig unterstützen.

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7 Declaration of contribution of others

This thesis was carried out at Eberhard Karls University Tübingen in cooperation with Reutlingen University in the interdisciplinary field of medicine and informatics. While my doctoral supervisor Prof. Bernhard Hirt supported this thesis mainly from a medical point of view, my professional supervisor Prof. Oliver Burgert supervised it from a computer science perspective.

The introduction and final discussion of the thesis were conducted by me. The systematic review of state-of-the-art situation recognition approaches, development of a high-level concept and basic framework prototype, and proof of concept evaluation of the resulting situation recognition system were mainly done by me:

(1) **Publication 1**: I performed the literature search and data analysis for the systematic review. Sina Frommer helped with the creation of the review table. Prof. Oliver Burgert supervised the overall work.
(2) **Publication 2:** I carried out the requirements analysis, concept, system architecture, framework prototype, and evaluation for the situation recognition system. Prof. Bernhard Hirt supported the work with clinical input, Prof. Oliver Burgert supervised the overall work.
(3) **Publication 6:** I designed, implemented, evaluated, and discussed the evolved situation recognition system. I furthermore elaborated the included scenarios based on cooperation with the referred clinical partners. The evaluation method was discussed with Prof. Christian Kücherer. Prof. Bernhard Hirt supported the work with clinical input, Prof. Oliver Burgert supervised the overall work.

The investigation of process formalization approaches, standardized provision of recognized information, and development of the demo context-aware system were partly performed in collaboration:

(1) **Publication 3:** The process formalization approach was supported by Elisaveta Just. Based on my overall situation recognition concept, Elisaveta Just derived and tested new models under my supervision. I then derived, integrated, evaluated, and discussed further process

models in the context of transferable situation recognition. The use cases included were based on clinical cooperation with Johanna Brandenburg, Prof. Martin Wagner, Dr. Katharina Schaumann, and Prof. Thomas Klenzner. Prof. Oliver Burgert supervised the work.

(2) **Publication 4:** The interface for standardized information provision was realized in collaboration with Patrick Beyersdorffer. Based on the overall situation recognition concept, Patrick Beyersdorffer specified, designed, and implemented the interface approach under my supervision. Patrick Beyersdorffer and I performed the integration, evaluation, and discussion of the middleware in the context of transferable situation recognition. The system modeling process was supported by Prof. Christian Kücherer. Prof. Oliver Burgert supervised the work.

(3) **Publication 5:** The context-aware system was developed in collaboration with Claudia Ryniak and Sina Frommer. Claudia Ryniak, Sina Frommer, and I developed the vision, methods, and concepts. Claudia Ryniak and Sina Frommer implemented the prototype, while I was responsible for the situation recognition part, supervised the usability test performed by Saskia Lohmann, Michael Stadelmaier, and Patrick Schmutz, and extended the results and discussion. Prof. Bernhard Hirt and Prof. Arnulf Stenzl were involved as clinical partners. Prof. Oliver Burgert supervised the work.

Herewith I, Denise Junger, declare, that I have written this thesis independently under the supervision of Prof. Bernhard Hirt and Prof. Oliver Burgert and have not used any sources other than those specified. Furthermore, I declare that I have contributed to the major part of the included publications.

Place, date | Signature

8 Acknowledgments

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