Intraoperative process monitoring using generalized surgical process models

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Referat

Der Chirurg in einem modernen Operationssaal kann auf die Funktionen einer Vielzahl technischer, seine Arbeit unterstützender, Geräte zugreifen. Diese Geräte und damit auch die Funktionen, die diese zur Verfügung stellen, sind nur unzureichend miteinander vernetzt.

Die unzureichende Interoperabilität der Geräte bezieht sich dabei nicht nur auf den Austausch von Daten untereinander, sondern auch auf das Fehlen eines zentralen Wissens über den gesamten Ablauf des chirurgischen Prozesses. Es werden daher Systeme benötigt, die Prozessmodelle verarbeiten und damit globales Wissen über den Prozess zur Verfügung stellen können.

Im Gegensatz zu den meisten Prozessen, die in der Wirtschaft durch Workflow-Management-Systeme (WfMS) unterstützt werden, ist der chirurgische Prozess durch eine hohe Variabilität gekennzeichnet. Mittlerweile gibt es viele Ansätze feingranulare, hochformalisierte Modelle des chirurgischen Prozesses zu erstellen. In dieser Arbeit wird zum einen die Qualität eines, auf patienten individuellen Eingriffen basierenden, generalisierten Modells hinsichtlich der Abarbeitung durch ein WfMS untersucht, zum anderen werden die Voraussetzungen die, die vorgelagerten Systeme erfüllen müssen geprüft. Es wird eine Aussage zur Abbruchrate der Pfadverfolgung im generalisierten Modell gemacht, das durch eine unterschiedliche Anzahl von patientenindividuellen Modellen erstellt wurde. Zudem wird die Erfolgsrate zum Wiederfinden des Prozesspfades im Modell ermittelt. Aussedem werden die Anzahl der benötigten Schritte zum Wiederfinden des Prozesspfades im Modell betrachtet.

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Chapter 1

Introduction

1.1 Motivation

The modern health service provider is in the area of conflict of the rising demand for cost-effective but at the same time high-quality health care. To meet this demand in a rapidly changing healthcare environment, healthcare providers must strive to constantly improve efficiency [1]. For years, the demand for high-quality healthcare has been met by an increasing number of computer-assisted and robot-assisted surgical procedures. Robot-assisted surgery is now well established in many surgical disciplines such as knee arthroplasty [2], hip arthroplasty [3], spine surgery [4], and otolaryngology-head and neck surgery [5].

To further improve quality and at the same time turn the cost screw, the field of computer-assisted surgery has been steadily expanded. In contrast to robotic surgery, where the robot performs individual steps or entire process units independently, in computer-assisted surgery the surgeon alone acts. The computer only fulfills a supporting function. The surgeon in a modern operating room (OR) can access the functions of a large number of such technical devices that support his work. Despite the work of various groups and organizations worldwide, these devices and thus the functions they provide are insufficiently interconnected [6], [7]. In addition to the lack of multiple use of data, such non-integrated systems also offer the surgeon only a fraction of the possible support.

Driven by this realization, integrated OR solutions have been offered by various manufacturers for some time. In these systems, the components of the same manufacturer are usually fully interoperable with each other. Interoperability across manufacturer boundaries is a requirement that these solutions do not meet. The insufficient interoperability of the devices refers not only to the exchange of data among themselves, but also to the lack of a central knowledge of the entire surgical process. In [8] the authors assume this knowledge and the resulting possibilities as an essential point on the way to the digital operating room (DOR) of the future. With the knowledge of the process progress, the devices involved can make their data and functions available at the right time in the right form and in the right place. Hence, systems are needed that can work with process models and thus provide global knowledge about the process.

For example, in the automotive and banking industries, systems are in operation in many areas that provide knowledge about the overall process and its progress in processing [9], [10]. These so-called Workflow Management Systems (WfMS) support the execution of a standardized business process by making context-sensitive data and information available to employees and the systems involved. In this way, resources can be used optimally. By transferring such systems into the operating room, the quality of patient care can be increased [11] and the costs of treatment can be reduced. The reduction of costs is an additional reason to push the development in this area, especially under the knowledge that the operating room is the most expensive unit in the hospital [12], [13].

In contrast to most processes supported by WfMS in the economy, the surgical process is characterized by a high variability. This is due to the diversity of patients and their varying anatomies, the different skills of surgeons and the various techniques they have learned [13]. Although there are clinical guidelines for many procedures [14], [15], the granularity and degree of formalization is insufficient to support the surgical process with WfMS.

In surgery, the process is monitored by a WfMS in a two-stage sequence (Figure 1.1). Firstly, a process model of the procedure (surgical process model) must be available before successful monitoring the procedure. In this model, all steps and their inter-dependencies are documented. Secondly, the current status of the procedure must be determined over the entire period (surgical process observation) and compared with the process model. Sensor systems take over the task of determining the current status by picking up and interpreting all data available in the OR. Through interpretation, the large amount of available sensor data is converted into a form that can be compared with the previously loaded process model.

Figure 1.1: Two-stage process monitoring sequence - Surgical process model (left) as basis for surgical process monitoring (right)

In research, several groups are currently working on the development of surgical process models with which the process can be described in more detail and in a more formalized way. These models form the basis of an IT-based control of the process. While most of the work is focused on the development of a suitable model for the representation of the surgical process, this work on the one hand examines the quality of an existing model with regard to the processing by a WfMS, and on the other hand the requirements that the upstream systems must fulfill are examined.

1.2 Problems and objectives

The two-stage approach to process monitoring described above involves two fundamental problem areas. On the one hand, it can happen that the interpretation of the sensor data correctly reflects the current process step, but the process model alone is insufficiently specified. This occurs if states or state transitions of the current process are not contained in the model. In this case the WfMS cannot find the current process step and therefore cannot fulfill its supporting function.

- **Problem 1:** Failure of the support function of the system in the event of a breakdown of the path tracking due to an incomplete process model.

The path tracing through the entire intervention is strongly dependent on how well the process model maps the current intervention. It is therefore of interest to what extent a modeling to create the generalized process model, depending on the number of patient-specific models, works.

- **Objective 1:** A statement is made about the abort rate of path tracing in the generalized model, which was created by a different number of patient-specific models.

In these two publications

Liebmann P, Neumuth T. Model driven design of workflow schemata for the operating room of the future. In: Fähnrich K-P, Franczyk B. (Hrsg.), INFORMATIK 2010. Service Science – Neue Perspektiven für die Informatik. Band 1. Bonn: Gesellschaft für Informatik e.V.. (S. 415-419).

Neumuth T, Liebmann P, Wiedemann P, Meixensberger J. Surgical Workflow Management Schemata for Cataract Procedures. Process Model-based Design and Validation of Workflow Schemata. In: Methods of information in medicine 51.5 (Okt. 2012). PMID: 22614847, S. 371–382. issn: 0026-1270. doi: 10.3414/ME11-01-0093.

first describes how a surgical process model was transferred into a workflow schema. Then it was shown how generalized process models can be created from different amounts of patient-specific models. The patient-individual models originate from cataract operations on the one hand and from discectomy operations on the other hand. Statistical outliers were eliminated by different filter levels. Subsequently, patient-individual models were tested against the generally valid model from a disjoint set. It was evaluated how high the success factor is for the complete tracking of the process by the model. A detailed description of the study is provided in the publications.

A second problem area is the possibility that the sensor system delivers incorrect or no data at all. This can lead to the fact that the downstream systems for the interpretation of the sensor data deliver wrong or no results at all. In this case the behavior of the model is undefined and the process path in the model cannot be correlated with the current events of the intervention.

- **Problem 2:** Unknown model behavior with misinterpreted sensor data.

While the completeness of the model can be influenced by the modeler, the completeness of the sensor information is not in his hands. For a future system it is therefore necessary to be able to estimate whether and how long it will take to find the path again after the tracking has been interrupted.

- **Objective 2.1:** The success rate for finding the process path again in the model is determined.
- **Objective 2.2:** The number of steps required to find the process path again in the model is determined.

In addition, it is interesting to make a statement about the particularly sensitive areas of the model. Thus, special attention can be paid to these areas already during the development and installation of the sensor technology in the operating room.

- **Objective 2.3:** Statements are made about the sensitivity of individual perspectives of the model with regard to their failure.

In the publication

> *Liebmann P, Meixensberger J, Wiedemann P, Neumuth T. The impact of missing sensor information on surgical workflow management. Int J Comput Assist Radiol Surg. 2013;8(5):867–875. doi:10.1007/s11548-013-0824-8*

generally valid models from patient-individual models were again created for this purpose. The model was then tested against the existing patient-specific interventions. Uncertainties were incorporated into the existing test data to simulate the misinterpreted sensor data. A detailed description of the study is given in the publication.

Chapter 2

State of research

2.1 Definitions of terms

For a better understanding of the following chapters and to distinguish them from known terms, the following four sub chapters introduce the essential linguistic definitions on the topic of surgical workflow management.

2.1.1 Surgical process

The term *surgical process* refers to the surgical procedure itself. That is, the term refers to the surgical procedure performed by the surgeon on a patient. It is based on the definition of the term Business Process of the Workflow Management Coalition (WfMC). This term is defined as follows:

> „a business process is ... a set of one or more linked procedures or activities which collectively realize a business objective or policy goal, normally within the context of an organizational structure defining functional roles and relationships[16]".

In terms of the surgical process, this is characterized by the fact that all activities that take place from the start of the procedure to its end and are directly linked to it are called surgical processes. Therefore, not only the actions of the surgeon, but also everything that the instrumentation staff and the systems involved in the intervention contribute to the surgical process, fall under this term. In the following text the surgical process is abbreviated as SP, for Surgical Process. A *activity* or a *task* of a process is the most elementary entity.

2.1.2 Surgical Process Model

A mapping of the SP is referred to as a *surgical process model*. Like the term SP, the term *surgical process model* is derived from the definition of the term Business Process Model of the WfMC [16] and was described in [17] as follows:

> „... a Surgical Process Model is defined as the simplified pattern of a Surgical Process that reflects a predefined subset of interest of the Surgical Process in a formal or semi-formal representation".

In the following, the surgical process model is abbreviated to SPM. SPM stands for Surgical Process Model. As described by Herbert Stachowiak in [18], SPM is also subject to the three main paradigms of modeling: mapping, shortening and pragmatism. In addition, the SPM can be divided into two main groups: patient-specific SPMs (iSPMs) and generalized SPMs (gSPMs). An iSPM represents an intervention on a specific patient and is therefore only to be recognized as a valid model for this patient. In contrast, a gSPM describes an intervention category and is therefore generally valid for an intervention type.

2.1.3 gSPM and surgical workflow

In [19] the term *surgical workflow* is introduced and orientates itself, as already the two terms just mentioned, at the definition of the WfMC [16] on the term workflow:

> „... the automation of a business process in the surgical management of patients, in whole or part, during which documents, information, images, or tasks are passed from one participant to another for action, according to a set of procedural rules".

In this paper, the term surgical workflow is defined somewhat more narrowly and the automation aspect of the definition is not considered. In [20] the author concludes a very similar view, but places additional emphasis on the defined rules which must be observed when executing a workflow. The German Institute for Standardization (DIN) differentiates the terms process model and workflow according to their potential for computer-aided administration, organization and control [21]. Consequently, the terms gSPM and surgical workflow are synonymous in this paper. Both terms denote the definition of a surgical process. In the following, the term surgical workflow is abbreviated by SWF, for Surgical Workflow.

2.1.4 Surgical workflow management system

The last important definition is the term *surgical workflow management system* (S-WfMS). This definition was also derived from the WfMC definition, according to which a workflow management system is introduced as follows:

> „A system that defines, creates and manages the execution of workflows through the use of software, running on one or more workflow engines, which is able to interpret the process definition, interact with workflow participants and, where required, invoke the use of IT tools and applications."[16]

This definition is supported by Greiling et al. in [22]. An S-WfMS is therefore called a software system consisting of several components that support the definition, creation and management of surgical processes. The components (Figure 2.1) are designed to support the requirements introduced in the definition.

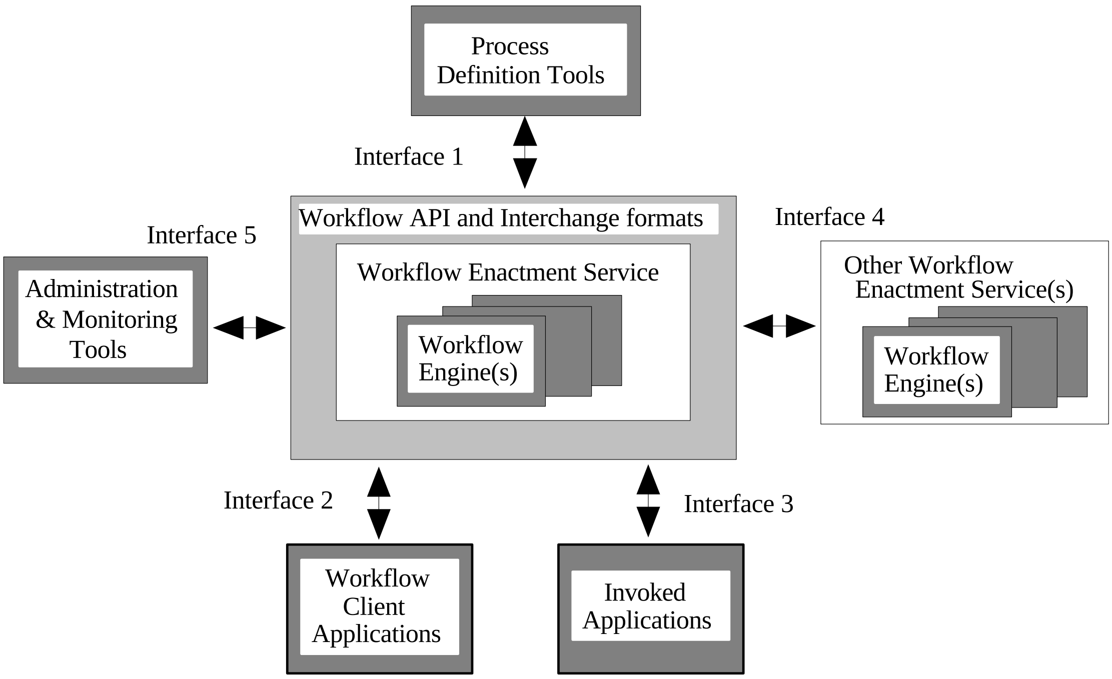


Figure 2.1: Reference model of the surgical workflow management system according to [23]

These components are used to define and execute the surgical process and enable interaction with the process. The following list provides a brief introduction to the tasks and functions of the individual modules:

- **Process Definition Tools:**This module includes all tools with which process definitions can be created manually, automatically or semi-automatically.

The output format of the process definition must be an executable data format for the Workflow Engine.

- **Workflow Client Applications** are applications that communicate directly with the Workflow Engine via an API[1]
- **Invoked Applications**: These applications are systems that can only contact the Workflow Engine indirectly and with a higher configuration effort.
- **Other Workflow Enactment Services**: All other workflow engines the system interacts with. Since it is now largely a matter of standardized communication, these services can also come from third-party manufacturers.
- **Administration & Monitoring Tools:** Form the part of the system required to monitor the functionality. This module also offers the possibility to make administrative interventions in the system.

Unfortunately there are several definitions of WfMS in the literature. But what most of these definitions have in common is the statement that the functionality of a WfMS can be summarized as follows: A WfMS is a software system that supports the process by providing the right task to the right person at the right time [24]. Extended to the requirements of surgical workflow management, the S-WfMS is a system that provides the right information at the right time and in the right place.

2.1.5 Summary

In the figure 2.2, the terms introduced in the chapters 2.1.1 to 2.1.4 and their dependencies relevant for this work are again graphically represented.

Figure 2.2: Sorting of the terms according to the order of their creation

[1]Application Programming Interface - An interface provided by a software system to allow external access to functions of the software system.

2.2 Workflow Management Systems

This section provides an overview of WfMS used in everyday clinical practice. Furthermore, these systems are discussed with regard to their applicability as S-WfMS for monitoring intraoperative processes. As the last system the YAWL-WfMS is described. This system was used in the studies for this thesis.

2.2.1 Agfa HealthCare - ORBIS

With installations in 950 facilities and over 500,000 users daily [25], the *ORBIS* system from AGFA is the one with the highest market share. *Orbis* covers many functions of a classic hospital information system. In addition to modules for functional areas such as outpatient clinic, anesthesia, intensive care and others, it contains an extension for the OR. This module supports the surgical area with OR planning, OR documentation, quality assurance and evaluation. Unfortunately, this system does not offer any functionality for the higher resolution of the process required in the studies, so that it had to be abandoned.

2.2.2 Siemens Clinical Solutions - Soarian

The *Sorian* system [26] of the company Siemens is with 400 installations (as of 2012 [27]) the system which is used second most often in hospitals. To control and monitor clinical processes *Sorian* uses a workflow engine based on a web-based SOA architecture. In addition to the functionalities usually found in such products, *Sorian* also offers a surgery management module. In this module material consumption data, anesthesia data and patient flow planning can be performed. Even with this product the process could only be modeled on a level that was still too abstract for the requirements of this work.

2.2.3 Karl Storz - ORchestrion

ORchestrinon is the only information system available on the German market that is exclusively intended for the operating theater [27]. This system is based on the following three main components [28]:

- **RPM** - Resource Planning Module: Module for planning rooms, equipment and personnel in relation to various surgical procedures.
- **SLM** - Steering and Localization Module: Control of the processes by

task assignment from the system. The position of patients, devices and instruments can be determined and tracked with this module.

- **IMM** - Instrument Management System: With this module it is possible to monitor the instruments. It is possible to record the complete sterile goods inventory and track it RFID[2] based.

The WfMS of *ORchestrion* is based on the workflow management engine inubit from Bosch Software Innovations GmbH. This system offers all possibilities to manage an intraoperative process. The fact that this was a commercial product and therefore not available free of charge excluded the system from use.

2.2.4 YAWL BPM

YAWL - for Yet Another Workflow Language - is a free and open source workflow management system[3]. It is based on the process description language of the same name, the YAWL language for modeling business processes [29]. Petri-nets serve as a basis for YAWL. Since Petri-nets do not support all workflow patterns [30], [31], YAWL has developed an extension for the missing workflow patterns. Since YAWL, similar to XPDL[4] or BPML[5] [32], is only a description language for business processes, a WfMS was developed by [33] that can exploit the full functionality of the language. This WfMS was created according to the reference model of the WfMC [23], [16] and thus contains all components recommended by the WfMC (Figure 2.3).

[2]Radio Frequency Identification - a system based on radio waves for local tracking of items
[3]https://yawlfoundation.github.io/index.html
[4]XML Process Description Language
[5]Business Process Modeling Language

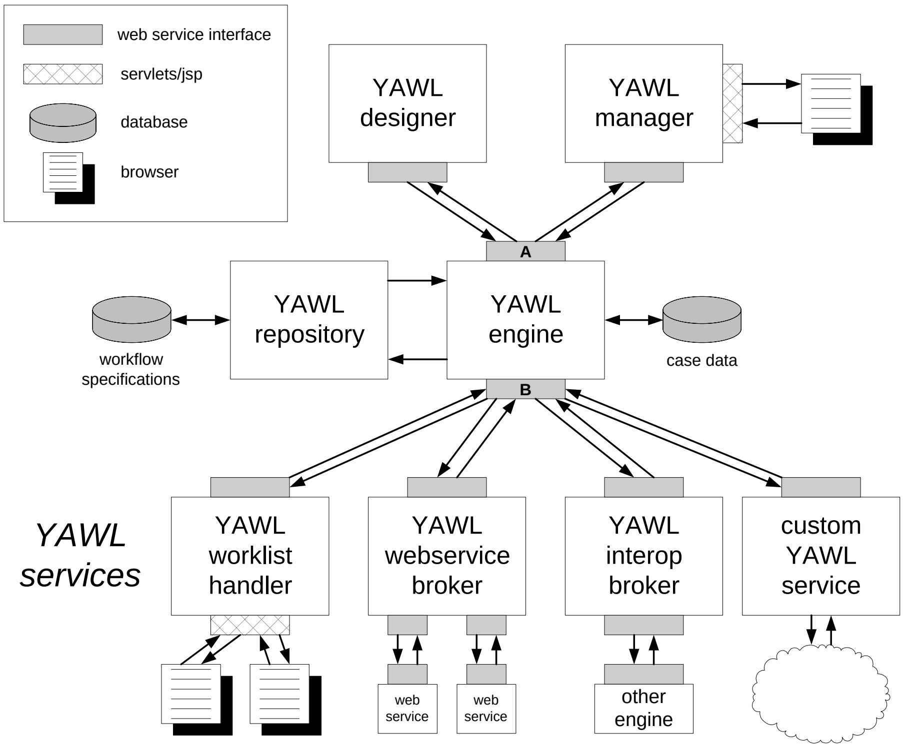


Figure 2.3: YAWL Architecture [33]

As shown in figure 2.3, the system also contains a component for graphical modeling of business processes (YAWL-Designer). This component offers not only the possibility to model processes, but also to load existing processes and test them for their formal correctness. For all studies described in this thesis, the syntactic correctness of the transformation of gSPMs into YAWL workflow schemas where checked in this component.

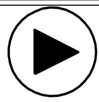
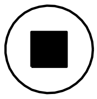
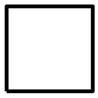
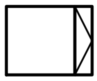
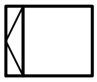
The table 2.1 lists the elements that were necessary to model a gSPM in YAWL. These elements were provided by the YAWL designer.

In addition to the large scope of the system and the formal description of the workflow patterns, YAWL and the associated system is developed under the GNU Lesser General Public License [34] as an Open Source product and could thus be used free of charge and easily adapted for the studies.

2.3 Sensor systems

In order for a WfMS to support the surgical process it must know the actual state of the process. Only then can it draw conclusions about the next step(s). Research and development in the field of process state detection is still relatively new [35].

Table 2.1: Elements for modeling processes in YAWL with associated symbol and the correlating one in gSPM

YAWL Name	Symbol	gSPM Name
Input condition		Start activity
Output condition		End activity
Atomic task		activity
XOR-split-task		Branching
XOR-joint-task		Merger

What they all have in common, however, is the use of different sensors or sensor systems to record what is happening in the operating room.

In DIN1319 the term transducer is introduced as a synonym for sensor. It is defined there as part of a measuring device that responds directly to a measured quantity [36]. This measurand can have both physical and chemical origin and is qualitatively or quantitatively detected by the sensor and converted into an electrical signal for further processing. This definition focuses on the technical and direct component of the sensor. In addition, video-based and software-based analyses, as well as observation and logging by human observers can also be called sensor technology, since these also serve to evaluate the properties measured in this way.

In the following sub items an introduction to the possibilities and the state of the art of research in the field of sensor technology, in relation to the application for the recognition of surgical procedures, will be given.

2.3.1 Sensors according to DIN1319

In their work, the authors in [37] exclusively use RFID sensors to identify the surgical instrument used in a simulated environment. The authors use a multi-level model that fuses the information from the sensors at different locations to provide a higher probability of recognition. In [38] the study is supplemented by the use of acceleration sensors. Thus, not only the instrument but also the surgical activity can be detected.

Table 2.2: Literature on the use of different sensor systems for recording the workflow in the operating room

Authors	Recording method
[37]	RFID
[38]	RFID, Acceleration sensors
[39]	Acceleration sensors
[40]	Force-torque sensor
[41]	Kinematics of the telemanipulator
[42]	Ultrasonic sensors
[43]	Video-based
[44]	Video-based
[45]	Video-based
[46]	Video-based
[13]	Human-based

Accelerometers are also used by this group [39]. The authors use the so-called Motif Discovery technique from the field of data mining to infer the movement of the instrument by the surgeon from the large amount of sensor data.

In [40] the authors use force-torque sensors on a laparoscopic gripper to measure the forces and moments acting on the tool. Synchronized with the video recordings of the procedure, the authors obtain 14 different tool tissue action patterns. In the study, the action patterns of experienced surgeons are compared to those of inexperienced surgeons in order to be able to draw conclusions about the level of training of inexperienced surgeons.

The group around [41] concludes via the kinematics of the telemanipulator on the position of the instrument during the intervention.

Using ultrasound sensors, the trajectories of the OR personnel are recorded in [42] in order to be able to draw conclusions about the current OR phase.

2.3.2 Video-based sensor technology

In [43], [44] and [45] instruments as such or their movement on video images are recognized and evaluated. A model of the intervention in relation to the instruments used can then be created from the chronological sequence of the use of the instruments.

An approach based on Markov models is used in [46] to derive high-level tasks from low-level sensor data. For this purpose, three video sources (overview image, instrument table and endoscopic image) are used whose noise is filtered by a Bayesian network.

2.3.3 Human-based sensor technology

A further possibility to record processes in the operating room is the logging by human observers. In [13] such a system is described. Medically trained persons record the course of the operation step by step with the help of a software especially developed for this purpose. This procedure is described in detail in chapter 2.5.

2.3.4 Summary

All of the above mentioned methods offer the possibility to record the events in the operating room from a predetermined point of view. The most comprehensive of the methods just described is the one from [13]. This allows to capture the action as well as the actor, the instrument and the anatomical structure being worked on. For this reason, this homicide is used to simulate the process observation.

2.4 Process model

In the previous chapter, an introduction was given to the possibilities for determining the actual state in the surgical process. However, a process model is still needed to effectively support the process with a WfMS. This process model represents the target state of the process and serves the WfMS to derive the subsequent steps. In this chapter an overview of different process models is given. The differences in their creation and their meaning are explained. The classification is based on [47] and was extended to the current state.

A basic classification of process models can be made with regard to their creation. The main distinguishing feature is whether the model was created by process observation (bottom-up) or by subsequent analysis of the process (top-down). In the former case, the individual entities involved in the process are documented in a chronological sequence by observing the existing process. The second method attempts to document the process retrospectively by means of analysis by experts.

2.4.1 Top-Down

In order to develop a planning system that integrates a robot to assist the surgeon, fronto-obital advancement interventions were modeled in [48]. A main focus of the authors were the specific robot-related workflows. The structure of the process is represented by an instruction graph. The nodes in the statement graph are called

Table 2.3: Publications with top-down (above) and bottom-up (below) modeled process models [47]

Authors	Recording method
[48]	unavailable
[49]	Observation, protocol/conversation analysis
[50]	Interviews
[51]	Interviews
[52]	unavailable
[49]	Observation, protocol/conversation analysis
[53]	Observation
[54]	Software-supported observation
[55]	Observation
[45]	Analysis of video images
[43]	Analysis of signals

activities. Activities process input predicates such as executing instance, tool used, restrictions in relation to the workspace, etc. and provide output data.

This process model is very much designed for use in robot-assisted surgery and is therefore very difficult to adapt to general surgery procedures.

In [49] both approaches (bottom-up and top-down) are used iteratively to model laparoscopic fundoplications. Videos of training sessions for this procedure serve as a database. The underlying model consists of five hierarchical levels that are oriented according to the granularity of the recorded data (Step > Substep > Task > Subtask > Movement). In the lowest level (movement) the surgeon's elementary movements are documented (reaching and orienting, grasping and holding, pushing, pulling and releasing). Sequences of movements are combined to form a subtask, sequences of subtasks are combined to form a task, etc. until the complete procedure is documented.

Using this approach, interventions can be broken down into their most elementary steps and thus documented. Unfortunately this approach lacks two basic features. First, the names of the steps are not based on any ontology, i.e. the names of the steps are arbitrarily defined. Secondly, there is no description of how to create a generally valid model for this procedure from a patient-specific record.

A model for the management of multimodal information (functional, anatomical or pathological structure) of supratentorial tumor procedures was developed by the group [50]. The data was collected pre- and postoperatively by means of a questionnaire and sorted in the model into three levels of granularity (intervention > step > action). Furthermore, this model offers the possibility to distinguish between planned and performed steps.

An essential disadvantage of this model results from the top-down modeling. In this model, top-down modeling does not allow you to differentiate between parallel steps or to save the time information for a step.

In [56] the two authors present their concept of a Workflow Integration Matrix (WIM). Several categories are defined to describe the course of an intervention. These categories are attached in the form of a matrix. Subsequently, the transitions from one category to the other can be documented and thus the course of an operation can be recorded.

The disadvantages of this model are the lack of formalization and the non-consideration of parallel workflows. In addition, the data is collected through discussion between surgeons and technicians and not through observation. This makes the result highly dependent on the group that collected the data.

The [52] supports interoperability, comparability and exchange of information about surgical procedures. For this purpose, the minimum requirements of a structure for a terminology of terms of this domain are defined. ISO 1828 is applicable to surgical procedure terminologies of all surgical disciplines. However, it does not itself provide rules for modeling a surgical procedure.

2.4.2 Bottom-Up

The work of [49] has already been introduced in chapter 2.4.1 and is only mentioned here again for the sake of completeness, since both approaches are used in this work.

An ontology consisting of activity, instrument and resource is published in [53]. This ontology was developed to investigate the use and position of the endoscope in functional nasal paranasal oil procedures (FESS). The images were taken during the procedure by human observers, without software support. The anatomical structure was documented as part of the action and is difficult to separate afterwards.

In [54] a methodology is presented which records the course of the operation in a relatively fine granular and very structured way with respect to the recorded entities. Since the models of this group serve as data basis for this work, they are explained in detail in the chapter 2.5.

[55] record the eye movement of the surgeon during a laparoscopic cholecystectomy in pigs. The recordings form the model of the procedure. Sequences of eye movement are classified by comparison with the video image of the procedure. This approach is very much based on the application of this procedure and therefore

can only be generalized with a very high effort.

From microscope images of a pituitary tumor intervention [45] extracts data about the intervention by means of recognition of image features and subsequent principal component analysis. This data is used to identify the phase of the procedure. The [45] approach, using a Support Vector Machine (SVM), provides a detection rate of over 80% of correct phase. The disadvantage of this approach is that the recognition is specialized on the phase level and a recognition on a lower level cannot be realized yet according to the authors.

2.4.3 Summary

In this thesis the process model of [54] is used, because it offers two decisive advantages over the other process models just mentioned. First, resolution is very high with respect to the granularity of the recorded steps. I.e. the recording takes place on the activity level of the recorded entities. On the other hand, the scope of the recorded entities is easily scalable. With this method, the activities of any person, but also devices, can be recorded and evaluated. The following chapter gives an introduction to the creation of such a process model.

2.5 Methods for creating the ICCAS process model

In order to counter the high variability of the surgical process in modeling, the generalized process model is created by fusion of several patient-specific processes. The method described in detail in [54] is used for this. In the following, the individual steps are briefly explained for better understanding. Due to the many different process variants, top-down modeling is only possible at a very rough level of detail.

2.5.1 Recording of the iSPMs

At the beginning there are several patient-specific models. For this purpose, human process observers record the individual steps during the operation. The granularity of the observation of the steps can be determined individually. The spectrum ranges from the recording of individual movements, such as cutting or sucking, to the recording of the start and end of a surgical phase. The workflow editor developed at ICCAS is used for recording. The Workflow Editor was developed especially for this task and is operated on a Tablet PC with pen input (Figure 2.4).

Figure 2.4: Workflow editor for recording the process model by a medically trained observer.

At least one person must be present in the operating room during the procedure to record the progress of the operation step by step. On the one hand, the recorder must have a certain level of medical knowledge to be able to follow the course of the operation, as well as having received an introduction to the recording tools. At ICCAS, medical students have been employed for this purpose who have received an introduction to the ICCAS Workflow Editor. The result of the recording is a step sequence of observed events which reflect the course of the operation in a time-discrete manner (Figure 2.5).

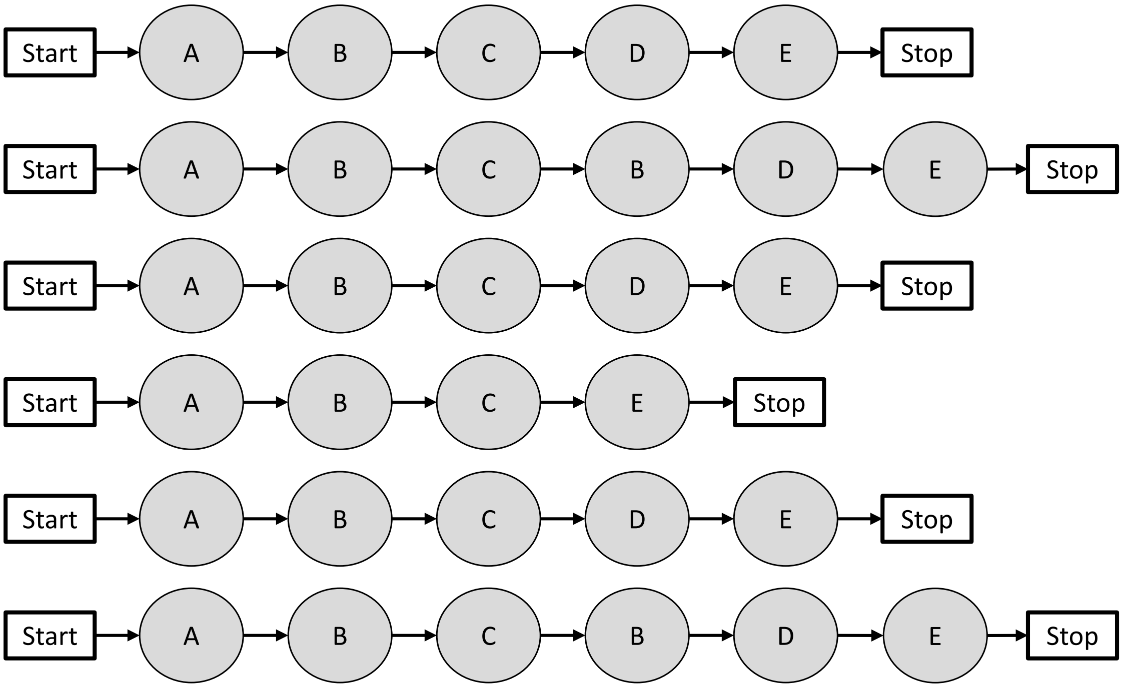


Figure 2.5: Schematic representation of six iSPMS with different numbers of activities

2.5.2 Creation of the gSPMs

Several individual process models are combined to create a general process model (gSPM). For this purpose the iSPMs are divided into their process phases. Corresponding activities are then determined in the individual iSPMs for each phase and then transferred to a common activity in the gSPM. In this way, all predecessor and successor activities are determined for an activity and connected by transitions. These transitions are probable transitions between the individual activities. The probability of a transition from one activity to the next results from the frequency of occurrence of the transition in the iSPMs. Through statistical averaging, based on when several iSPMs are merged, the gSPM represents an averaged model of a surgical procedure. Figure 2.6 schematically shows a gSPM with five activities and nine transitions between activities. This gSPM was created from the iSPMs in Figure 2.5.

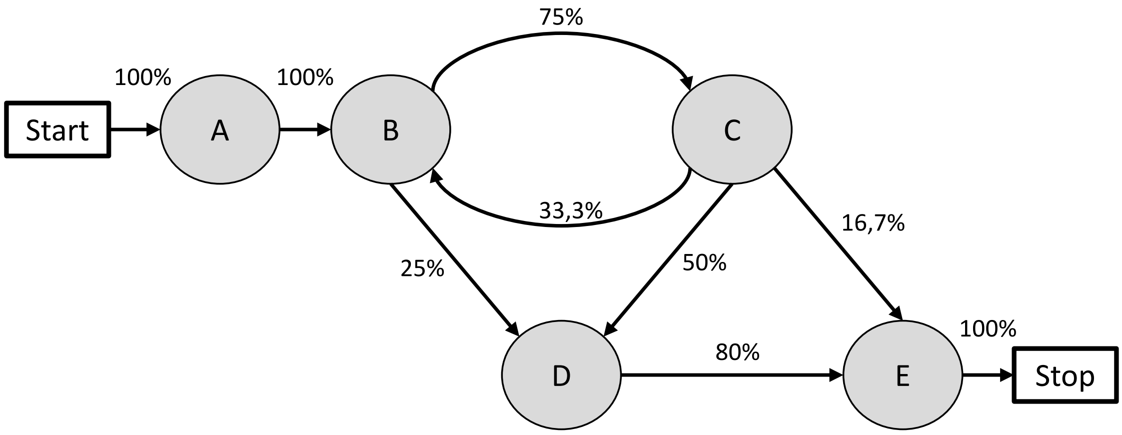


Figure 2.6: Schematic representation of a gSPM with five activities and nine probable transitions.

In the above-mentioned method of creating a gSPM, all iSPMs are included. To eliminate statistical outliers, you can start a filter run after generating the gSPM. During this run, all transitions below a previously selected level are deleted. This process is mainly used to better display the average surgery progress for the human observer. Figure 2.7 shows an example. The gSPM was created based on the data in figure 2.5 and then filtered with a filter level of 20%. One can see that the transition from activity C to E has been removed.

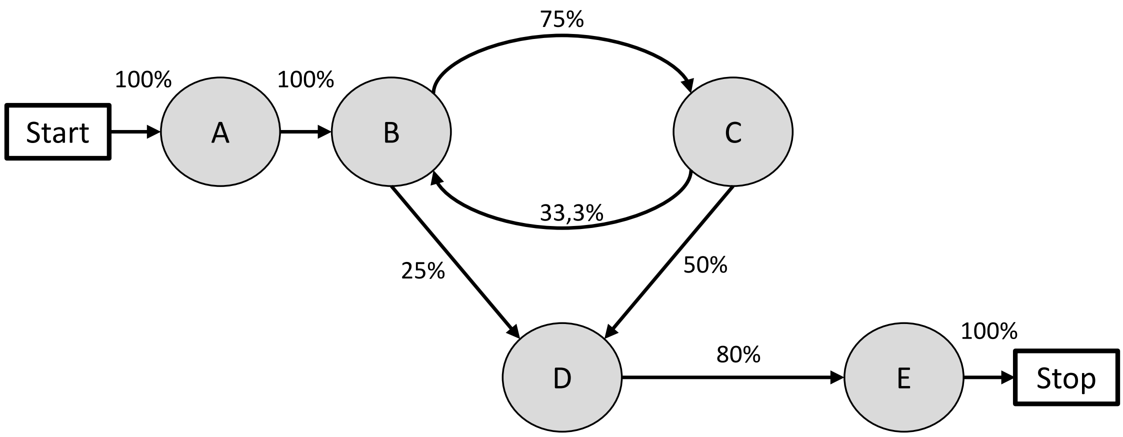


Figure 2.7: Application of a filter level of 20% to the gSPM from Figure 2.6

2.6 Summary

In the previous sub chapters the basic terms were defined, an overview of WfM systems was given and the application of different sensor systems in the surgical environment was explained. Finally, different process models were discussed and a description of how to create the process model used for the work was provided. As described in the introduction, the subject of this thesis is on the one hand the investigation of the problems that arise when path tracking is broken off due to an incomplete process model. On the other hand the unknown model behavior in case of misinterpreted sensor data. These questions are answered in the following three main chapters on the basis of the publications mentioned above.

Chapter 3

Model-based design of workflow schemas

Title

Model driven design of workflow schemata for the operating room of the future

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Citation

Liebmann P, Neumuth T. Model driven design of workflow schemata for the operating room of the future. In: Fähnrich K-P, Franczyk B. (Hrsg.), INFORMATIK 2010. Service Science – Neue Perspektiven für die Informatik. Band 1. Bonn: Gesellschaft für Informatik e.V. (S. 415-419).

Keywords

Workflow; Surgical Process Model; Workflow Schema

3.1 Abstract

Many assistance systems are available in modern operating rooms. These systems are poorly interconnected to each other and therefore cannot provide their information in a context sensitive manner. Those systems need to be considered as distributed systems when targeting the development of an workflow management systems to pilot the control flow between surgical assist systems. To achieve the best possible interaction between the systems the workflow management engine needs a reliable description of the underlying process. Because of the high variability of the surgical process a top-down approach cannot be used. In this article we describe a model driven approach to create a workflow schema out of a Surgical Process Model (SPM).

3.2 Introduction

In modern operating rooms a high variety of technical devices can be found. Each of these devices is made to assist the surgeon during his work by reducing complexity, operating with minimal invasive techniques, or to reduce the overall cost of the intervention. Most of these Systems are stand alone systems developed to provide specific functionality at a specific point in time or during a certain phase of the surgery. Therefore it is hardly possible to combine information from these systems on a single central display and in addition a redundancy of functionality could occur.

Figure 3.1: Computer based assistance systems inside the OR

A common cooperation or the exchange of information between those systems is hardly realizable because of the lack of standardized interfaces or the missing overall coordination of the single devices [7][12]. Surgical workflow management systems may support the surgeon by the means of requesting and displaying relevant information from other systems needed in the current work step.

In contrast to the administrative business world, were workflow management is highly established, the achievement of standardized business processes is not possible. This originates from the high variability of surgical processes due to patient individual characteristics, surgical skills, and the use of different surgical intervention techniques [13]. This high variability eliminates the possibility of a top down modeling of the process such as is common in administrative business or rather leads to a process description on a rough detail level [57].

This article describes a method to inductively model a surgical process by using protocols of many patient individual surgical process models (SPM) of the same intervention.

3.3 Model driven design of surgical workflow schemata

3.3.1 Recording of patient individual surgical process models

Models of surgical procedures courses were obtained by trained medical observers with the use of the Surgical Workflow Editor of the s.w.an-Suite[1], a software tool for the structured modeling of surgical processes. The Surgical Workflow Editor is a software tool for the structured acquisition of SPM data and was operated on a tablet PC by the observer. The workflow editor allows the user the creation of a detailed observation protocol by selecting relevant anatomical structure, surgical actions performed at the structure, involved resources, and the person who is carrying out the action (Figure 3.2). The accuracy of this method was validated in [13]. It was shown that the result of the observation leads to accurate patient individual Surgical Process Models (iSPM).

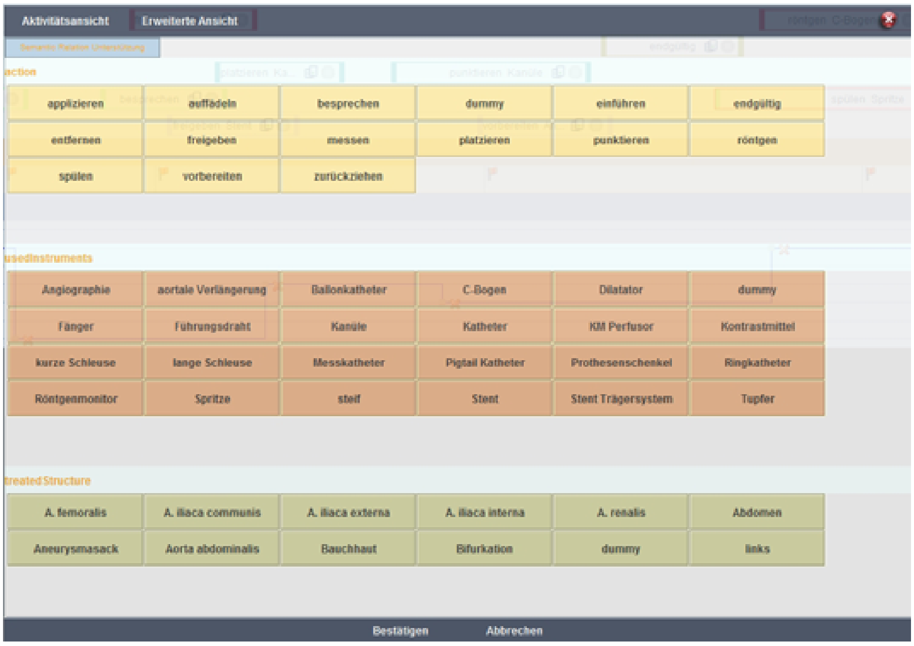

Figure 3.2: Surgical workflow editor interface

3.3.2 Generating generalized SPM from iSPMs

A sample of patient individual Surgical Process Models is used to create a generic Surgical Process Model (gSPM). To create a gSPM, the activities of the iSPMs

[1]SWAN - Scientific Workflow Analysis GmbH; http://www.scientific-analysis.com

are registered to each other. Subsequently, predecessor-successor relationships between activities are calculated as transitions, quantified and probabilities for subsequent activities are computed for each activity. The gSPM therefore is a statistically averaged model of many observations of the surgical intervention (cp. Figure 3.3).

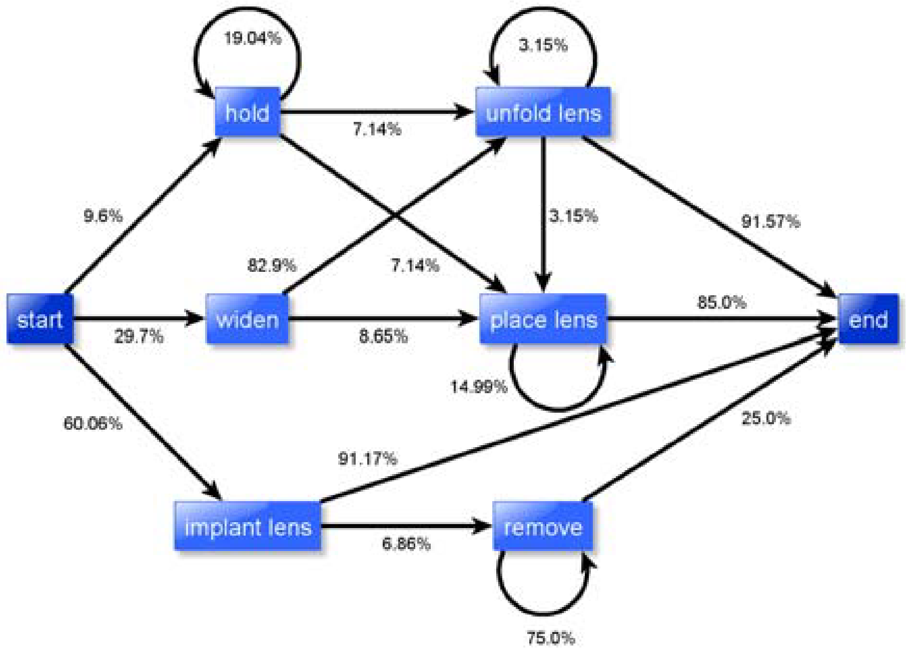

Figure 3.3: Example of a generic surgical process model

Due to the inductive creation of a gSPM it is possible to face the high variability of surgical processes. The gSPM itself is a flowchart of all possible transitions between the process steps. With the use of a filter which cuts out the transition below a defined filter level it is possible to get a simplified, more generally accepted model of the surgical intervention. It has been shown in previous works that this cleanup can be performed and the resulting models still fulfill the requirements of the clinical guidelines of the intervention.

3.3.3 Transforming gSPM into workflow schemata

The availability of a valid gSPM is the main requirement for the successful generation of a workflow schema. A workflow schema is the representation of a process in a form that is process able by the underlying workflow management system [58]. The workflow schema is required to control the workflow.

In our case the YAWL[2] system [33][29] was used as workflow management system. The gSPM resulting from the previous step is transformed in the Petri-net based YAWL workflow language by converting the elements of the gSPM into the elements of the YAWL language. While Petri-nets cover already quite a lot workflow patterns they lack of support for cancellation, XOR, or multiple instance patterns. YAWL was developed with the purpose to covering all available workflow patterns.

Subsequently the schema is loaded into the YAWL engine where a consistency check is performed. Figure 3.4 shows the workflow schema representation of the gSPM from Figure 3.3.

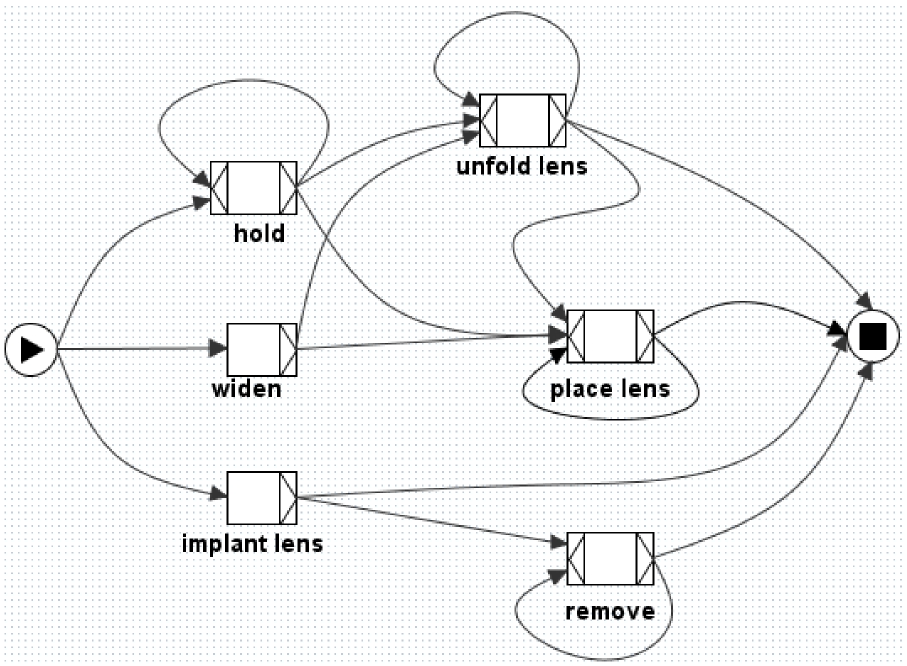

Figure 3.4: Example of a workflow schema for YAWL

[2]Yet Another Workflow Language

3.4 Summary and Outlook

To ensure a better quality in patient treatment and to increase the surgical efficiency in the context of increasing amount and complexity of computer based surgical assistance, workflow control could be the key technology to support the surgeon. The control has to be context sensitive and needs to consider the high variability of surgical interventions. A workflow management system that is located in the logical center of a distributed system design sets up the central theme of the intervention for all the other systems.

In future system design decisions the use of workflow management system, based on the modeling of workflow schemata described in this article, will be considered. The use of gSPM model as described in this article allocates a language neutral description of surgical processes. These descriptions can easily be transformed in almost any runtime language used by a workflow management system which was shown in example for YAWL.

Chapter 4

Model-based validation of workflow schemas

Title

Surgical workflow management schemata for cataract procedures. Process model-based design and validation of workflow schemata

Authors

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Citation

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Keywords

Operative surgical procedures; Workflow; Computer-assisted decision making; Information system; Computer-assisted surgery; Process assessment (Health Care); Surgical process model

4.1 Abstract

Objective: Workflow guidance of surgical activities is a challenging task. Because of variations in patient properties and applied surgical techniques, surgical processes have a high variability. The objective of this study was the design and implementation of a surgical workflow management system (SWfMS) that can provide a robust guidance for surgical activities. We investigated how many surgical process models are needed to develop a SWfMS that can guide cataract surgeries robustly.

Methods: We used 100 cases of cataract surgeries and acquired patient-individual surgical process models (iSPMs) from them. Of these, randomized subsets iSPMs were selected as learning sets to create a generic surgical process model (gSPM). These gSPMs were mapped onto workflow nets as workflow schemata to define the behavior of the SWfMS. Finally, 10 iSPMs from the disjoint set were simulated to validate the workflow schema for the surgical processes. The measurement was the successful guidance of an iSPM.

Results: We demonstrated that a SWfMS with a workflow schema that was generated from a subset of 10 iSPMs is sufficient to guide approximately 65% of all surgical processes in the total set, and that a subset of 50 iSPMs is sufficient to guide approx. 80% of all processes.

Conclusion: We designed a SWfMS that is able to guide surgical activities on a detailed level. The study demonstrated that the high inter-patient variability of surgical processes can be considered by our approach.

4.2 Introduction

Modern operating rooms are equipped with a variety of technical devices. The purpose of these devices is to support the surgeon's work, i.e., to achieve surgical efficiency by decreasing the invasiveness of the surgical strategy, reducing work complexity, and performing cost-effective treatments. Most of the technical equipment is stand-alone technology that fulfills a dedicated task during a dedicated surgical work step. Unfortunately, comprehensive cooperation between these devices is rarely possible due to of a missing "global" guidance system that supports the overall surgical process on the one hand, and amends the lack of interoperability between the single devices [6][12][59][60][61][62] on the other hand.

Currently, no workflow guidance has been developed for a "digital" operating room with extended connectivity and interoperability of devices that, for instance, displays context-sensitive information, depending on the current situation of the surgery, by augmenting microscopic views or surgical displays, that triggers and parameterizes technical devices and surgical assist systems, such as intraoperative measurements, that supports quality management by automatically documenting the surgical procedure, or that enhances the facilities for surgical training.

Management systems with global knowledge concerning the guided business process are well established for administrative business applications [9][63]. These systems support the performance of standardized business processes by providing data and information to support the accomplishment of administrative processes and activities. Thus, resource use is optimized, and business operation costs are reduced. These systems should be transferred to the operating room, which is one of the most cost-intensive units in hospitals [12][64][65].

However, until now, the application of business process modeling methods for surgical processes is hardly possible, due to the high variability of the latter. This high variability is caused by individual patient properties, such as anatomical characteristics, surgical capability and techniques, or the by the use of different technological resources [13]. The standardized generation of process models based on expert knowledge, partly derived from clinical guidelines [66][67], is hardly applicable due to the high level of detail of workflow schemata that is required to support surgical activities with workflow management. The objective of this work is to demonstrate how to overcome these challenges using the example of cataract surgeries, having the largest proportional variability among specialties [68].

In the pertinent literature, different approaches to workflow management in hospitals have been described. General requirements for workflow support in the health care domain were highlighted by Mans et al. [69]. Approaches for workflow management support were presented to assist the performance of clinical guidelines, protocols, or clinical trials [70][71][72][73][74]. More specifically, workflow management systems were used to support patient registration in hospitals [75], to control the provision of supplies and instruments [64], or to manage unscheduled health care processes [76].

Workflow management systems were also used to support the work of clinical departments, such as emergency healthcare [77], radiology [78][79], or gynecology [80]. Disease-related applications were published for stroke management [81] and heart-disease identification [82]. Additionally, the work of surgical wards and nursing [83][84][85][86] and medical image processing [87][88] has been supported.

Inside the operating room workflow management systems are considered as patient-safety critical systems [89]. Workflow support of surgical processes so far has examined two fields: anesthesia [90][91] and computer-assisted surgery [48][92][93]. To provide high-level support for surgical processes, Dickhaus et al. have applied intraoperative workflow modeling to brachytherapy interventions [92], and Münchenberg et al. have used a workflow management system for robot control in cranio-maxillo-facial surgery [48].

However, existing approaches have some limitations. An application of any of the mentioned approaches to our goal does not seem reasonable because they are either focused on related fields, such as radiology or nursing, with altogether different types of processes that require much less detailed process support than surgery, they consider superordinated processes, such as clinical guidelines, or they are specifically suited to one technology such as surgical robots.

However, none of the available approaches has dealt with the generation of workflow schemata from patient-individual surgical processes to encompass the high variability. In contrast to existing approaches, this work emphasizes the implementation and intraoperative application of a surgical workflow management system (SWfMS) that works with workflow schemata generated from individual process models. We provide an approach that, on the one hand, considers the high variability of surgical processes and, on the other hand, provides process models with a high level of detail.

In a broader sense, approaches for the generation of generic models from individual processes have been reported for simulated hospital process logs [94] or for the modeling of peripheral processes in the operating room [95]. Additionally, mining algorithms were used to discover process models in clinical pathways

[96][97][98][99][100][101]. These works did not use their models further to generate workflow schemata.

The SWfMS and the bottom-up generation of the workflow schema are described in the Methods section. The design and the experimental results of the system validation based on 100 example patient data-sets from cataract surgery are presented in the Results section. It will also be shown that high-resolution generation of the workflow schema is desirable to improve the system's ability to follow the surgical process. These schemata consider the high variability of surgical processes and can be used as basis for the development of workflow management systems in the operating rooms of the future.

4.3 Methods

4.3.1 Surgical Process Modeling

Analogously to the definition of a business process [102], we define a surgical process as "... a set of one or more linked procedures or activities that collectively realize a surgical objective within the context of an organizational structure defining functional roles and relationships". Thus, we refer to the execution of an actual surgical procedure as a surgical process.

Furthermore, we define a surgical process model (SPM) as "a simplified pattern of a surgical process that reflects a predefined subset of interest of the surgical process in a formal or semi-formal representation" [13]. These models are made up of activities that reflect the work steps of the surgeon during the surgical procedure. An SPM that represents a surgical process performed on a single patient is denoted as an individual surgical process model (iSPM), respectively a process instance.

To model an iSPM, we used the common method of modeling by observation as described by Neumuth et al. [13][103][104]. In previous works it has been shown that this method results in reliable iSPMs and is applicable to a wide variety of surgical disciplines and intervention types [104][105][106][107]. Other approaches for automatic process model acquisition are available [43][45], but are not generic due to application of specific sensor systems.

To acquire data, a specially trained and experienced observer operated a modeling software, the Surgical Workflow Editor [108], while he observed the surgical procedure in a live setting. The surgical process was described with the help of activities and states [13]. Activities were used to describe surgical work steps and states were used to describe surgical phases. To identify activities and states, and to separate them from one another, we labeled them using a composite key. The elements of this key were called perspectives [13]. The organizational perspective contained values on who performed a work step (e.g. the surgeon, the assistant), the functional perspective described what the acting person was doing (e.g. suctioning, grasping, cutting for activities, or the name of the surgical phase), the operational perspective described which tools were used (e.g. scalpel, hook), the spatial perspective described where the work step was performed (e.g. skin, muscle tissue x, bone y), and the behavioral perspective described when a work step or a surgical phase was performed.

To describe surgical phases, we used the functional and the behavioral perspective. To describe surgical work steps we used the functional, the organizational, the operational, the spatial, and the behavioral perspective (see Figure 4.1, upper part). The lower half of Figure 4.1 shows the activities of the surgeon during the surgical phase Capsulorhexis in cataract procedures.

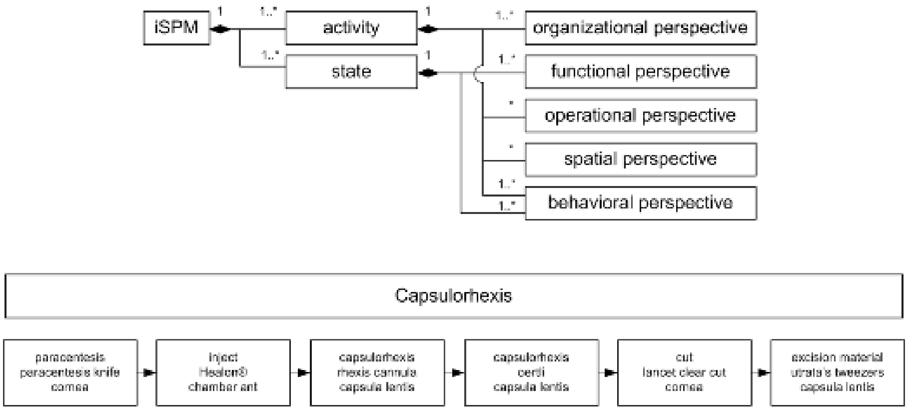


Figure 4.1: UML class diagram of iSPM-components (upper half) and cut-out of an iSPM. The activities of the surgeon during the surgical phase Capsulorhexis in cataract procedures (lower half, time information from behavioral perspective not depicted).

The surgical activities and phases were composed by the observer during the preparation of the study and verified in discussions with a senior surgeon.

This approach of using information perspectives as composite keys was necessary to describe the activities of the surgical process in detail. The application of a simple key was unfavorable because this key would have to contain all possible the observation support software. By assuming mean numbers of 2-3 participants, 20 surgical actions, 20-30 instruments and supplies, and 10 anatomical and pathological structures of an average surgery, this would have result in several hundred simple keys that are not efficiently operable by the observer.

The Surgical Workflow Editor as observation support software was running on a tablet-PC and the observer selected the perspective information to create the appropriate key for the current situation. The software output was a file in the eXtensible markup language (XML) format. The iSPMs were stored in a database after having been acquired.

Cataract procedures from eye surgery were recorded as iSPMs in preparation of the technical study. In Germany, cataract surgery is the surgical procedure performed most often [109]. The main surgical phases of the procedure are Preparation, Capsulorhexis, Lens removal, Lens implantation, and Removal of Healon®. During these phases, the capsule is sliced, the opacified lens is removed, a new lens is implanted and liquid is discharged that was used to support the procedure.

We acquired 100 clinical cases of cataract procedures. The number of cases was restricted prior to the study to limit the study costs by neglecting sensitivity. Only patients with cataract diagnosis were included in the study. The clinical data was recorded between March and September 2006 at the Department of Ophthalmology at the University Hospital of Leipzig. The clinical cases were performed by three experienced surgeons during their daily routine.

All iSPMs were acquired by one observer using the methodology described above. The observer was a medical student who had received a comprehensive training before the data acquisition. The observer received training from experienced surgeons about the characteristics of cataract procedures, including the typical intervention course and the clinical guidelines. He also received training concerning the names and applications of surgical instruments, materials, and supplies. Finally, she had to train the operation of the Surgical Workflow Editor to ensure a comprehensive handling of the observation support software.

4.3.2 Workflow Schema Generation

Subsequently, we merged several iSPMs from the iSPM database based on surgical phases and activity information to create a generic surgical process model (gSPM). gSPMs are statistically averaged models from multiple iSPMs and represent a "mean" statistical surgical procedure [103].

The fusion started by splitting the iSPMs into surgical phases and by adding artificial start and end activities. Afterwards, all activities with corresponding perspective information in the same surgical phase of the different iSPMs were merged into one activity. Likewise, corresponding predecessor-successor relations between activities of the iSPMs were merged into one transition in the gSPM. Finally, transition probabilities were calculated based on the observed frequency in the iSPMs. For each activity, all subsequent transitions were labeled with the respective probability [103]. Please note, that the gSPM did not contain behavioral perspective information. Behavioral perspective information was only used to determine which activities belong to which surgical phase and to identify the order of activities within a surgical phase. In previous works, it has been shown that this strategy results in reliable and clinically correct gSPMs that satisfy and adhere to the clinical guidelines [103].

The resulting gSPM represented all of the activities of the respective surgical phase and their associated probabilities, where high probabilities indicated frequently occurring process model segments and mean process branches. The upper part of Figure 4.2 shows the UML class diagram of gSPM elements and an unfiltered example for the surgical phase Capsulorhexis (lower part).

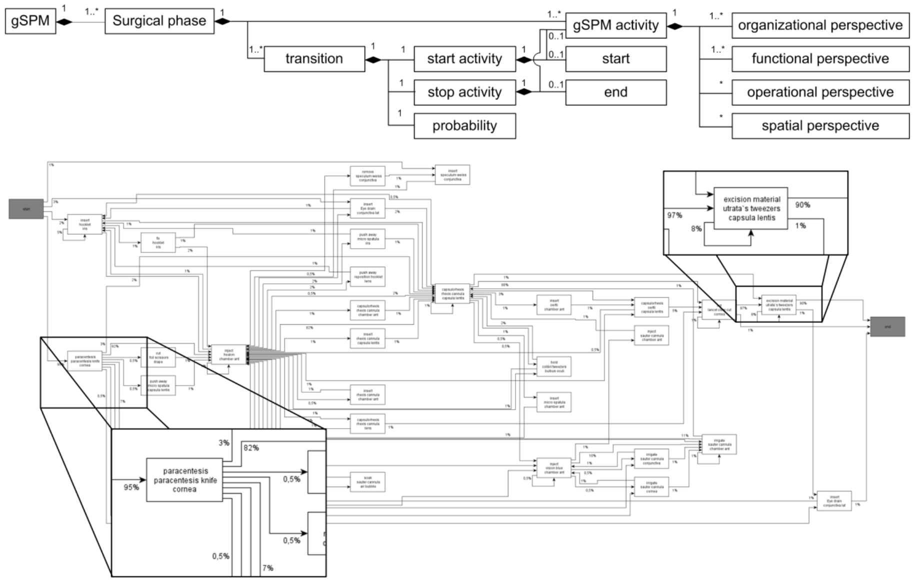


Figure 4.2: UML class diagram of gSPM-components (upper part) and gSPM for the surgical phase Capsulorhexis in cataract procedures aggregated from 90 iSPMs with activities (boxes) and transitions (edges). The value near the edges indicates the transition probability that was calculated based on the observation frequency.

Since the gSPM resulted in a model with many transitions, we also implemented a filter strategy to provide a facility to de-noise the models from very infrequently occurring activities below a given filter threshold. The filter is then applied to eliminate low frequent transitions below the threshold. A filtered gSPM for the surgical phase Capsulorhexis and an applied filter of 1% is shown in Figure 4.3 (left).

Subsequently, the gSPMs of the surgical phases form the basis for the generation of the workflow schemata. The workflow schemata were used to drive the surgical workflow management system (SWfMS). The filtered gSPM structure was mapped onto workflow nets [110], a formal workflow language. Workflow nets are a Petri-net dialect and can be formally verified, which supports the subsequent application of the system in the sensitive OR environment. The workflow nets served as workflow schema for the open source YAWL (Yet Another Workflow Language) workflow management system (cp. Figure 4.3 right, [29]) which was used to perform the validation study by priming the execution of the workflows. To verify the proper functionality of the SWfMS, we checked that all 100 iSPMs could pass the workflow schema that was generated from them.

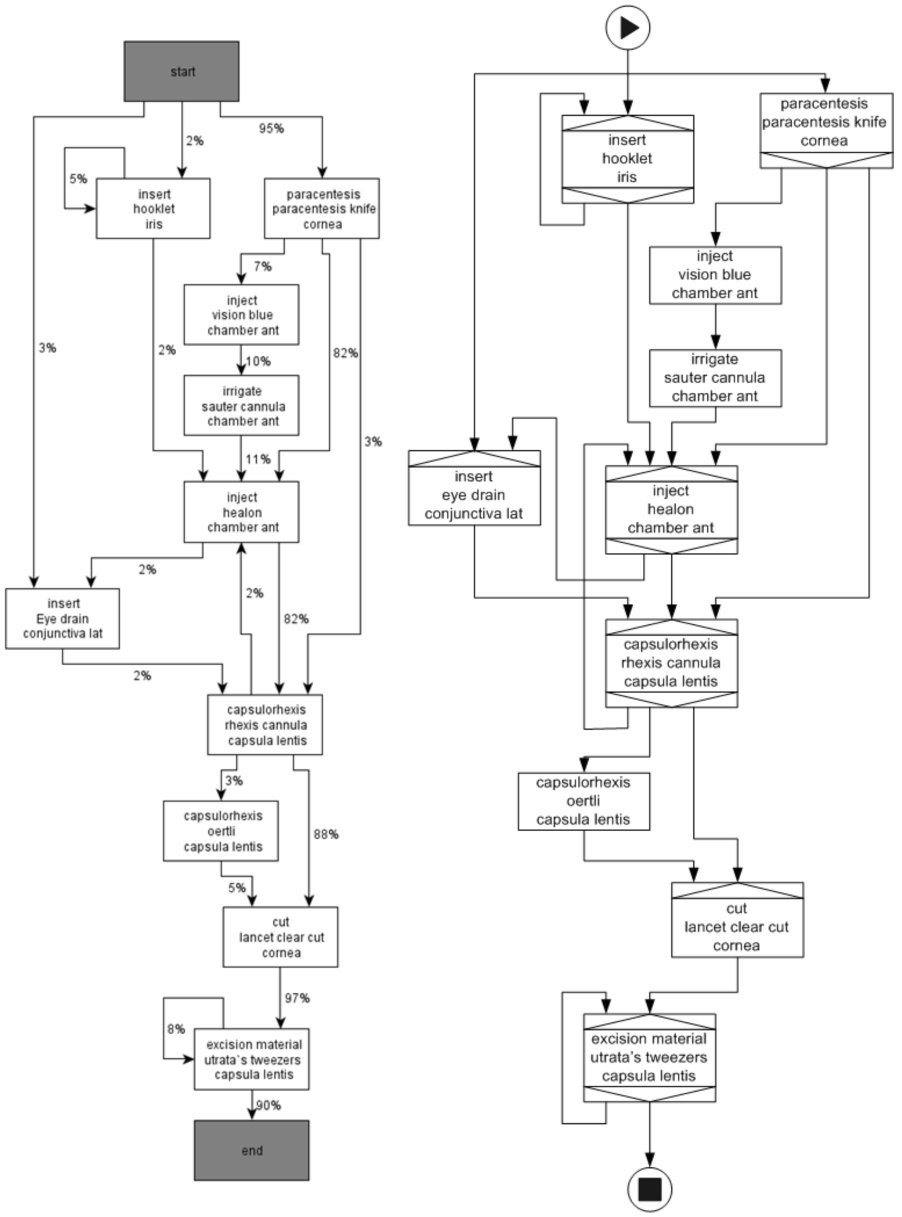


Figure 4.3: Generic Surgical Process Model (gSPM, numbers indicate mean transition probabilities, filtered with 1%) and derived workflow schema for the surgical phase Capsulorhexis (organizational perspective not depicted).

4.3.3 The Surgical Workflow Management and Simulation System

The surgical workflow management and simulation consisted of three parts: process model base, workflow management system, and analysis unit. In Figure 4.4, the structure of the simulation system is presented.

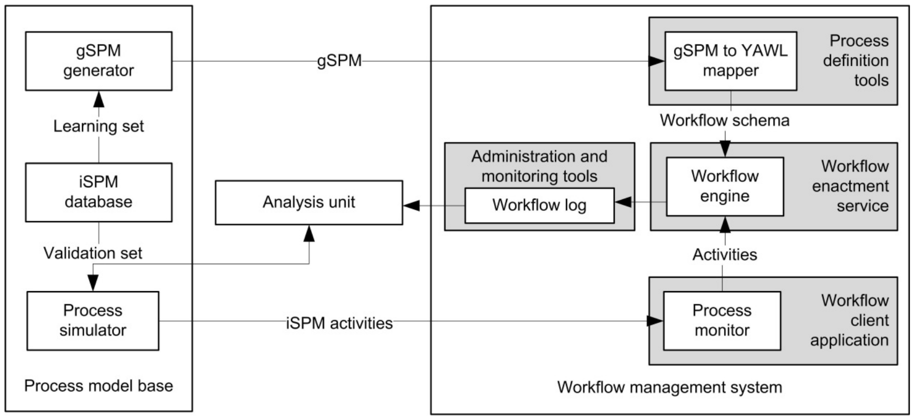


Figure 4.4: Design of the surgical workflow management system consisting of standard components of workflow management systems (shaded grey, [111]) and the simulation unit extension with the gSPM database, the gSPM generator, the process simulator, and the analysis.

The process model base hosted the iSPM database (Postgres 8.2 database, [112]), the gSPM generator, and the iSPM simulator. First, the gSPM generator randomly selected iSPMs from the database, generated a gSPM from them as described in the previous section, and de-noised it according to the given filter threshold.

Next, a proprietary Java application was used to realize the mapping of a gSPM onto its corresponding workflow schema. This mapper transformed the artificial start and end activities into the corresponding elements of the YAWL language. Additionally, all perspective information of an activity in the gSPM was concatenated and mapped onto a YAWL atomic task. Afterwards, the transitions without labels were added in between the atomic tasks. Finally, the tasks were automatically transformed into XOR-joins and XOR-splits. In cases of multiple incoming transitions for one task, an XOR-join was added, and in cases of multiple outgoing transitions, an XOR-split was added to complete the workflow specification. The workflow schema was then sent to the process definition interface of the workflow management system for execution.

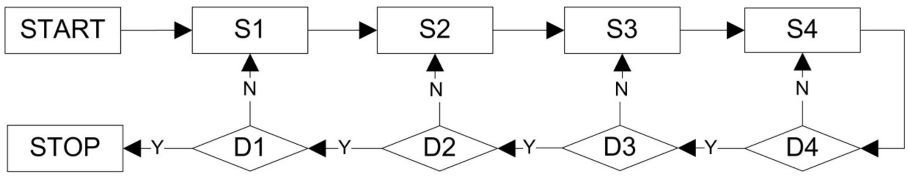
The iSPM process simulator randomly selected an iSPM from the database, concatenated its perspective information for each activity, and sent it, activity by activity, via web service to the process monitor interface of the SWfMS. The process monitor received the activities and forwarded them to the engine. If the perspectives of the activity matched with one of the name of the next scheduled tasks according to the workflow schema, the engine moved on to that task, logged successful execution of the task, and waited for the next task to be received. In the case of a missing transition or unscheduled task, an exception was caused, the execution of the workflow schema was terminated, and unsuccessful execution was logged. After the process simulation, the workflow log was transferred to the analysis unit for statistical analysis.

4.3.4 System Validation Study Design

To determine whether the SWfMS can work with the help of a workflow schema generated from a gSPM for a surgical phase, a sophisticated study was designed.

The success of a workflow schema generated from a set of iSPMs was assessed using the success rate as a dependent variable. The success rate is a binary value that indicates whether or not the simulation of a randomly chosen iSPM was successfully finished without exception by the workflow schemata, i.e., if every surgical activity and every transition in the iSPM could be guided by the workflow schema.

To conduct the study, the design presented as a flow chart in Figure 4.5 was used. Initially, two disjoint subsets were generated from the whole set of all 100 iSPMs: the learning set was used to generate the gSPM and the workflow schema, and the validation set, containing 10 randomly chosen iSPMs for later testing against the workflow schema. The learning-set size increased from 10 to 90 iSPMs in steps of 10. Subsequently, the generated gSPM was filtered according to the filter value set 0%,1%,2%,3%,5%,7%,10%. The filtered gSPM was afterwards transformed into the workflow schema. Finally, all iSPMs of the validation set were simulated against the workflow schema. To incorporate randomization, the full study was repeated 1,000 times. We generated approx. 3,800,000 data sets based on the 6 surgical phases, 9 learning-set sizes, 7 filter levels, 1,000 repetitions during the validation study, and on 10 iSPMs in each validation set.



Step	Decision
(S1) Randomly select iSPMs and activities for the learning set and generate gSPM	(D1) Was the study repeated 1000 times?
(S2) Filter gSPM and generate workflow schema from gSPM	(D2) Were all filter values $\{0\%, 1\%, 2\%, 3\%, 5\%, 7\%, 10\%\}$ applied?
(S3) Select iSPM from the validation set	(D3) Were all iSPMs from the validation set simulated?
(S4) Sequentially test activity of the iSPM from the validation set	(D4) Were all activities of the iSPM simulated?

Figure 4.5: Test performance design for the validation study with respective steps and decisions.

The statistical analysis was performed using the R-project system [113] and SPSS statistics software [114]. Means and standard deviations were calculated for the results. A variability measure was not included, because the high correlation between surgical activities may not provide unbiased point estimates. Thus, results for standard errors or 95% confidence interval calculations might be misleading. Furthermore, a linear regression was performed to assess the influence of the independent variables of learning-set size and filter level on the success rate.

4.4 Results

In our validation study we investigated how many cases of iSPMs were needed to create a robust gSPM as a basis for the workflow schema for complete surgical phases of cataract procedures.

The success rates in Table 4.1 and Table 4.2 indicate the number of iSPMs that were needed to generate a workflow schema that is able to complete the respective surgical phase and which filter level can be applied to limit the number of infrequently occurring transitions and activities.

Table 4.1: Success rates of workflow schemata with a filter level of 0% and different learning-set sizes (1st line: mean, 2nd line: standard deviation).

learning-set size (no. of iSPMs)	**Preparation**	**Capsulorhexis**	**Lens removal**	**Lens implantation**	**Removal of Healon®**	**Completion**	**Mean**
90	88.7	77.4	80.0	90.0	73.6	87.0	**82.8**
	9.9	13.2	12.4	9.4	13.2	10.8	**11.5**
80	87.6	76.2	80.3	90.0	72.9	87.2	**82.4**
	10.5	13.3	12.2	9.0	13.5	10.8	**11.6**
70	85.5	75.0	79.5	89.4	71.8	78.0	**81.4**
	11.1	13.7	12.1	9.9	13.5	11.2	**11.9**
60	84.4	74.6	78.8	88.3	70.7	86.5	**80.6**
	11.6	12.9	12.4	10.2	14.4	11.0	**12.1**
50	82.9	73.2	78.0	87.7	69.1	86.6	**79.6**
	11.7	13.5	12.2	10.4	14.9	10.6	**12.2**
40	81.9	71.8	76.6	86.6	66.2	85.8	**78.2**
	12.5	13.5	12.8	11.2	14.7	11.1	**12.6**
30	79.7	69.4	74.1	84.2	63.0	84.7	**75.9**
	13.0	14.4	13.8	11.7	15.4	11.5	**13.3**
20	75.3	67.2	71.5	81.9	58.1	83.0	**72.8**
	14.0	14.0	14.5	12.6	15.4	13.5	**14.0**
10	66.6	61.1	65.6	77.6	49.4	75.5	**66.0**
	15.8	16.1	16.0	13.3	16.7	17.2	**15.9**

Table 4.2: Success rates of workflow schemata with a learning-set size of 90 iSPMs and different filter levels (1st line: mean, 2nd line: standard deviation).

Filter level (in %)	**Preparation**	**Capsulorhexis**	**Lens removal**	**Lens implantation**	**Removal of Healon®**	**Completion**	**Mean**
0.0	88.7	77.4	80.0	90.0	73.6	87.0	**82.8**
	9.9	13.2	12.4	9.4	13.2	10.8	**11.5**
1.0	88.7	77.4	80.0	90.0	73.6	87.0	**82.8**
	9.9	13.2	12.4	9.4	13.2	10.8	**11.5**
2.0	80.2	69.9	76.4	86.0	63.5	85.1	**76.9**
	12.2	14.6	13.5	10.7	14.2	11.3	**12.8**
3.0	77.9	66.1	72.1	83.8	61.8	85.1	**74.5**
	12.8	14.6	13.7	11.2	14.6	11.3	**13.0**
5.0	72.3	63.1	70.5	77.9	57.3	85.1	**71.0**
	14.2	15.1	13.8	12.4	15.2	11.3	**13.7**
7.0	67.4	61.9	70.1	77.1	49.1	85.1	**68.5**
	13.7	14.9	14.1	12.9	15.3	11.3	**13.7**
10.0	67.4	61.9	63.2	70.0	45.9	84.4	**65.5**
	13.1	14.9	14.7	13.5	15.1	12.5	**14.1**

Figure 4.6 shows the progression of the mean success rate s for all surgical phases. Table 4.1 shows the rate of successful completion of unfiltered workflow schemes

that were generated from a number of iSPMs given in the test set. For instance, a number of 20 iSPMs can be used to generate a workflow schema that guides 72.8% (sd=14.0%) of the cataract procedures and a test-set size of 50 iSPMs can be used to guide 79.6% (sd=12.2%) of the cataract procedures. The minimum success rate of 49.4% (sd=16.7%) for the surgical phase Removal of Healon® shows that even a number as low as 10 iSPMs can be used to guide 50% of the cataract procedures. Please note that the model represents a structural model and that the transitions do not include correlations to each other (see Discussion).

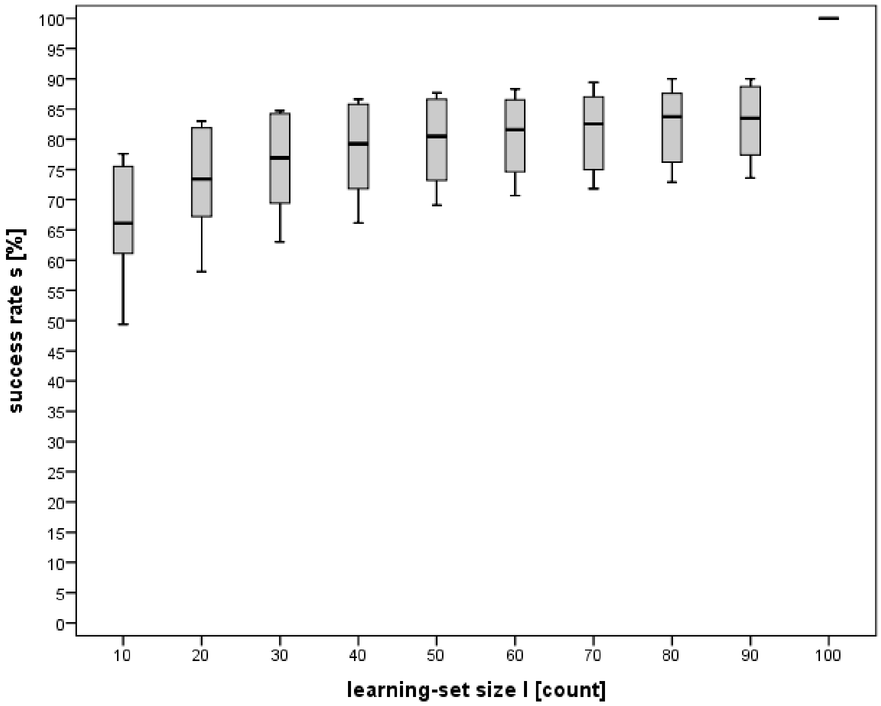


Figure 4.6: Progression of mean success rate for all interventional phases s depending on the number of iSPMs in the learning-set size.

Table 4.2 shows the mean success rates for different filter levels for a learning-set size of 90 iSPMs. As expected, an increasing filter level reduces the chance for a successful completion of the workflow schema. For example, 82.8% (sd=11.5%) of the iSPMs were completely simulated in each surgical phase at a filter level of 1%, while only 74.5%±13.0% were successfully simulated at a filter level of 3%.

Combinations of the results of the two independent variables learning-set size and filter level are shown for two surgical phases as contour maps in Figure 4.7. The figures indicate the "success border" for the phase Capsulorhexis (left) and the for the phase Completion (right). According to the desired success rate, which is represented by the respective contour lines, learning-set size and filter level can be chosen. For instance, a desired successful workflow guidance of 75% of cataract cases for the phase Capsulorhexis can be achieved by using at least 70 iSPMs and applying a maximum filter level of 1%. In contrast, the same result may be achieved for the phase Completion by using only 40 iSPMs and applying a maximum filter level of 6%.

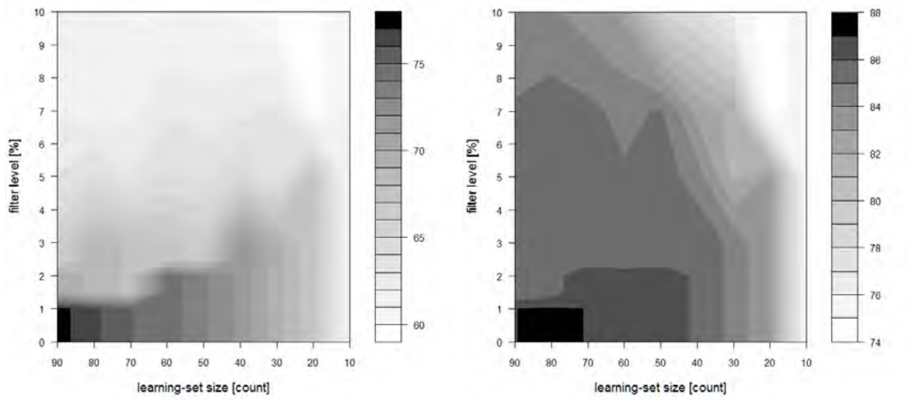


Figure 4.7: Contour plots for the surgical phase Capsulorhexis (left) and Completion (right) show the levels of success rate (percentages) depending on the learning-set size and the filter level.

The prediction of the success rate s by the independent variables using learning-set size l and filter level f was investigated by performing a linear regression analysis. The R-square values in Table 4.3 indicate the coefficient of determination ranges between 0.631 for the phase Completion and 0.760 for the phase Lens implantation. The linear regressions showed intercepts between 60 and 84. All regression coefficients were significant (p<0.001).

Table 4.3: Linear regression equations and R^2 values of the regression equations for the success rate s depending on the learning-set size l and the filter level f.

Phase	linear regression equation	R^2
Preparation	$s = 76.16 + 0.11l - 1.69f$	0.699
Capsulorhexis	$s = 67.83 + 0.07l - 1.23f$	0.658
Lens removal	$s = 70.20 + 0.09l - 1.26f$	0.744
Lens implantation	$s = 83.99 + 0.06l - 1.42f$	0.760
Removal of Healon®	$s = 60.44 + 0.13l - 2.23f$	0.734
Completion	$s = 80.19 + 0.10l - 0.49f$	0.631

4.5 Discussion

Usual methods for creating workflow schemata for the workflow management systems face the challenge of encompassing the high variability of surgical processes. Within our work, we presented a strategy to overcome this challenge. Due to the acquirement of gSPMs from iSPMs, it was possible to consider the high variability of observed surgical processes. Our method allowed for the estimation of the number of iSPMs that were required to compute a workflow schema for cataract surgeries. Based on two independent variables, the number of necessary iSPMs for a desired success rate could be estimated in advance to the systems design. The R-square values for the regression formulas suggested this dimension with a value of 70%. Although the presented approach was designed for cataract surgeries, we expect the methodology to be applicable to different surgery types, since the presented data acquisition strategy and the post-processing methods are not dependent on a specific type or kind of surgery.

It is not yet clear what a "good" percentage for a successful guidance of cataract surgeries is, and which success rates are clinically accepted. This needs to be investigated in future clinical studies with the objective to adhere to the right balance between clinical benefit and economic effort to design and execute SWfMS. However, we provided the necessary requirements for these investigations by introducing the method of workflow schema generation from iSPMs to consider high variability. On the other hand, the deployment of the filter threshold as mechanism to de-noise the models provides a mean for the "fine-tuning" of the required success rate, e.g. with some practical applications for removing blur of visualization for a surgical decision support system that shows the next possible activities on a screen for a learning surgeon.

Our methods can be further improved by developing the computation strategy of the gSPM. The current gSPM generation approach used transitions between activities and concatenated them to build the model. Since transitions were considered locally and only between predecessor and successor activity, the model did not contain a history or trace. The computation of a gSPM that incorporates Bayesian analyses is a valuable future work topic. Although some more advanced approaches are available in current research in business information systems [115][116][117][118][119], we applied the more elementary method to support the understanding and discussions with clinicians to verify the correctness of the models.

Further investigations also comprise the development of an effective exception handling with automatic recovery that needs to be implemented after an abortion of the workflow schema. Additionally, the system's behavior in response to inconsistent data needs to be investigated. Furthermore, it must be determined if and how fast the system can resume tracking. Finally, testing the system by automatically monitoring the process data could support SWfMS development, which could be done by replacing or enhancing the process generator with sensor system input.

The application of surgical workflow management to cataract interventions is of particular interest for many use cases. In combination with an accurate sensor strategy to automatically recognize the current surgical work step, such as proposed in [120] or [35], and customized web services for command performances, several applications might emerge.

The first group of applications is the intraoperative presentation of preoperatively acquired information by augmentation in microscopic views or monitors. Preoperative examination results, such as corneal topography, wavefront aberrotomy, autorefraction, keratometry, pupillometry, automated assessments of cataracts [121][122][123][124], or lens-power calculation [125], can be visualized dependent on the situation by augmented reality to support the surgeon during critical work steps.

Secondly, technical devices and assist systems could be parameterized and intraoperative measurements could be triggered by the workflow management system. Examples for these applications comprise intraoperative dioptric power measurements [126], real-time intraocular pressure measurements during various stages of the cataract surgery [127], measurements of incision quality by medical imaging [128][129], and augmentation of the imaging models with the real microscopic view, or automatic image-capturing and transmission in the context of ophthalmologic telemedicine [130].

Furthermore, surgical workflow management of cataract surgeries is of relevance for quality management, documentation, and patient scheduling. A trigger for the automatic transfer of intraoperative measurements, such as results of the calculation of the position of the implanted lens for later checking with postoperative follow-ups [131][132][133], to the electronic patient record, might support the quality management of the surgery. Generally, the trace of the process instance through the model can be recorded for automatic documentation of the surgical activities during the treatment [134]. Additionally, this trace can be checked in real-time for completeness of all work steps, since studies have shown that especially novice surgeons are liable to forget single work steps [135]. In addition, the surgeon might be supported by a process navigation system that proposes next work steps until completion of the intervention. Based on the current progress of the intervention, the prediction of the completion might be calculated for the preparation of the next patient [136] and the generated workflow schema can also be used to simulate different variants of cataract surgeries and to simulate the effect of missing supplies etc. [137].

Finally, surgical education and training is an application field of interest. Since current virtual reality training systems for cataract procedures are mainly focused on individual parts, such as phacoemulsification or hydrodissection [138][139][140][141][142][143][144][145], or support concepts like model-driven therapy [146] in general, these systems might profit from the workflow schemata to enable the simulation of different variants of the surgery and surgical work steps in context to each other.

However, our approach focuses on the design, implementation, and validation of a robust surgical workflow management system from the technical point of view. Hereafter, the system can be tested in clinical practice to derive more clinical applications based on the approach.

4.6 Conclusion

The application fields of surgical workflow management systems in the digital operating room of the future are manifold. These systems might be used for situation- and context-dependent information visualization for the surgeon, such as timely presentation of previously acquired patient examination results, the automatic parameterization and control of surgical assist systems, or the provision of decision support for learning surgeons. Additionally, a communication with the hospital information system (HIS) can be employed, e.g. for an automatic and timely call for the next patient according to the predicted end time of the current intervention. All of these use cases could qualitatively ameliorate the process sequence of the surgeon and, therefore, be beneficial to the patients' safety.

The high model granularity that is required for the control of technical resources for the assistance of the surgeon causes a major challenge: The higher the granularity of the surgical process to be supported, the higher its variability. The term variability was used in this context as a general term to express the deviation of iSPMs from each other. Since no metrics exist to express the variability of surgical processes, quantification is part of the ongoing research.

The objective of this work was the design, implementation, and validation of a surgical workflow management system. It was shown that even a small learning set of 10 iSPMs can be used to generate a workflow schema for cataract surgeries that is able to guide 66% of the procedures. If higher success rates are desired, an increased number of 50 iSPMs can be used to achieve, for instance, 80% success rates.

The unique property of this system was the facilitation of a workflow schema that was generated from a number of individual surgical process models. We presented the system together with the approach, to generate the workflow schemata in a bottom-up manner from iSPMs with a comprehensive validation study on 100 patient data sets of cataract procedures from eye surgery.

The study demonstrated that the high variability of surgical processes can be considered with the presented approach, since a higher number of iSPMs can be guided by the SWfMS than the number of iSPMs that were necessary to generate the workflow schema.

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Chapter 5

Influence of missing sensor information

Title

The impact of missing sensor information on surgical workflow management

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Workflow L01.906.893; Information system L01.700.508.300; Surgery, computer-assisted L01.700.508.100.710.800; Process assessment (health care) N04.761.559.650; Surgical process model; Redundant sensor system

5.1 Abstract

Objective: Sensor systems in the operating room may encounter intermittent data losses that reduce the performance of surgical workflow management systems (SWfMS). Sensor data loss could impact SWfMS-based decision support, device parameterization, and information presentation. The purpose of this study was to understand the robustness of surgical process models when sensor information is partially missing. SWfMS changes caused by wrong or no data from the sensor system which tracks the progress of a surgical intervention were tested.

Materials and methods: The individual surgical process models (iSPMs) from 100 different cataract procedures of 3 ophthalmologic surgeons were used to select a randomized subset and create a generalized surgical process model (gSPM). A disjoint subset was selected from the iSPMs and used to simulate the surgical process against the gSPM. The loss of sensor data was simulated by removing some information from one task in the iSPM. The effect of missing sensor data was measured using several metrics: (a) successful relocation of the path in the gSPM, (b) the number of steps to find the converging point, and (c) the perspective with the highest occurrence of unsuccessful path findings.

Results: A gSPM built using 30% of the iSPMs successfully found the correct path in 90% of the cases. The most critical sensor data were the information regarding the instrument used by the surgeon.

Conclusion: We found that use of a gSPM to provide input data for a SWfMS is robust and can be accurate despite missing sensor data. A surgical workflow management system can provide the surgeon with workflow guidance in the OR for most cases. Sensor systems for surgical process tracking can be evaluated based on the stability and accuracy of functional and spatial operative results.

5.2 Introduction

In modern operating theaters, the surgeon is surrounded by a large variety of technical devices, all with the purpose of giving him assistance during the operation. Because of the lack of interoperability between those devices, some functionality cannot be used or could only be used with additional preliminary effort [6]. The lack of interoperability not only affects data integration but also causes context integration issues. Context integration describes the possibility of sharing common knowledge of the surgical process. By using surgical process models described in [147], comprehensive knowledge of the surgical process can be provided during the operation by a workflow management engine (WfME).

To provide surgical assistance system with the current step of the operation, the WfMS has to know the actual step of the surgery. To detect this process information, the WfMS must rely on the interpretation of various sensor information gathered in the OR. Based on this sensor information, the current step can be derived and aligned with the process model loaded by the WfMS. From the knowledge of the actual step and the pre-loaded model of the overall intervention, the system is able to derive the next step. Therefore, services can be activated and devices can be parameterized accordingly. The two most important requirements for successful implementation of the aforementioned approach are the availability of a valid process model and accurate sensor information.

However, in practice, the accuracy of the sensor information cannot be guaranteed. The data can be inaccurate due to various disorders or nonexistent due to sensor failure. In addition to this, the interpretation of different sensor data can produce the wrong result. Since the WfMS receives an interpretation of the sensor data as input information, an incorrect interpretation can cause the WfMS to be completely unsynchronized or to arrive at the wrong step completely. Therefore, a high quality of sensor information is needed. This can be achieved by fusing information of many sensor systems [35]. To reduce the overall complexity of the system and the computational operating cost, it is of interest to not make every sensor system redundant, but to evaluate which information and which sensors are error prone. From this, a system can be developed which takes the quality of information into account.

In other words, having high-quality sensor information is just as important as the generation of a sufficiently accurate and valid process model. In business information systems, process models can be created due to their relatively high linearity using a top–down analysis of the process. In surgery, this approach is limited due to the high variability of the process [148]. The high variability is due to the diversity of patients, their diagnosis, and the skill of the surgeons. A top–down modeling approach leads to relatively coarse descriptions of the procedure. In [148], the authors describe an inductive method for the generation of a surgical process model. This method is based on the fusion of process models from many observations.

The aim of this work is to assess an inductively created process model with respect to the problems that can arise from incomplete or erroneous sensor information. Incomplete sensor information can lead to a break in the path observation of the process model and thus lead to an undefined state in the process. In the case of such an event, the system must be set to an exception state until the path in the model has been found again. As a prerequisite, we use the 6-layer approach published in [35]. Here, the sensor information is transformed through 6 abstraction layers from a very basic representation (hardware abstraction layer) to a generic, human readable representation (application layer). The application layer of this approach is, with a few adaptations, readable for every WfMS. In this study, we clarify the question of how many steps are required to re-converge upon the correct track in the process model after the system has lost its way. Furthermore, we investigated how the model responds to the absence of entire categories of sensor information.We also investigated sensitive input parameters in order to derive a prioritization of compensatory strategies.

In the literature, there are different approaches to dealing with surgical workflows. In [149], all processes in and around the operating room were recorded by using a structured time recording sheet in order to investigate potential weaknesses of the process. The analysis revealed a significant inefficiency of unused surgical capacity caused by delays in the perioperative environment. The documentation of the surgical process is also the subject of the question in [150]. The process was recorded from multiple significant points using four video sources in the operating room. By combining the video recordings with text-based recordings of events during the intervention, some evaluation questions could be answered in a subsequent analysis which could not be answered prior to the study. By analyzing the size of the compression of video data, the group in [151] investigates the movement in the OR. Their work aims to detect higher movement of the OR personnel during critical situations in the process. An overview of various sensor systems for monitoring in the operating room is presented in [152]. The authors identify knowledge of the surgical procedure as a prerequisite for the development of error-prevention systems in the OR. None of the above-mentioned works use process models of the intervention to predict the next step and therefore none determine their models with respect to robustness of the process model. In automotive systems, the handling of sensor data is a routinely done task. In [153], the authors present a detail overview of commonly used fault tolerant design techniques in this domain. The authors of [154] introduced a new multistep ahead predictive filter scheme with a predominant performance in compensation of missing data compensation. Nevertheless, in this domain, the underlining process model is very basic compared to the surgical process in itself.

In this work, we show, based on 100 clinical recordings of cataract eye surgery, how a generalized and inductively generated surgical process model reacts to the failure of sensor information. In the methodology section, we will first address the clinical records and the creation of a general surgical process model. In addition, the construction of the test system and the study design for the validation of the model are described.

5.3 Methodology

5.3.1 Surgical process modeling

From a modeling perspective, the term surgical process model (SPM) refers to an actual surgical intervention. This definition is based on the definition of the Workflow Management Coalition [102] where a process model is described as: ". . . a set of one or more linked procedures or activities that collectively realize a surgical objective within the context of an organizational structure defining functional roles and relationships ." A surgical process model is defined as: ". . . a simplified pattern of a Surgical Process that reflects a predefined subset of interest of the Surgical Process in a formal or semi-formal representation" [13]. In this model, every activity corresponds to one specific action of the surgeon during the intervention. A process model based on the procedure of one single patient is referred to in this paper as an individual surgical process model (iSPM).

Each activity consists of a tuple of five elements that give different perspectives on the particular surgical step (Fig. 5.1). These perspectives are defined as follows:

- Organizational: The entity under consideration
- Functional: The action undertaken by the entity under consideration
- Operational: The instrument which is used for this activity
- Spatial: The anatomical structure currently being worked on
- Behavior: The duration of the activity

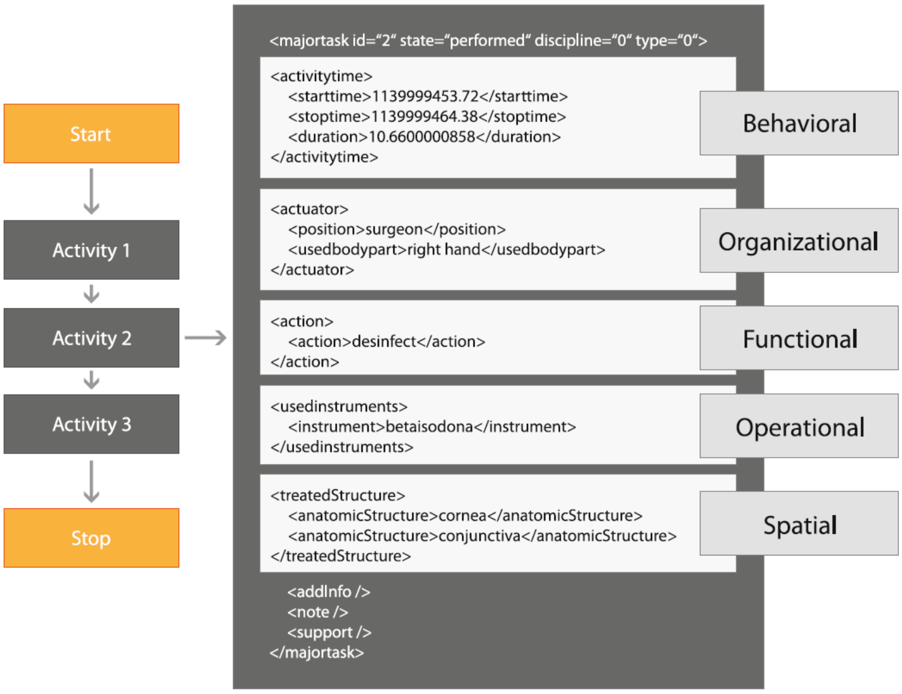

Figure 5.1: A simplified iSPM is shown on the *left*. The XML representation of a single task with the corresponding perspectives is depicted on the *right*

Since these are generic definitions from the field of process management, in this paper, we refer to them as following (Table 5.1).

Table 5.1: Explanation of the terms used in this paper

Generic term	Surgery-specific term	Abbreviation in figures
Organizational	Actuator (e.g., surgeons right hand)	-
Functional	Action (e.g., cut)	a
Operational	Instrument (e.g., scalpel)	i
Spatial	Structure (e.g., anterior capsule)	s
Behavior	Time	-

To produce a generalized surgical process model (gSPM), several iSPMs are combined. The iSPMs are first divided into their surgical phases. Subsequently, for each surgical phase, the corresponding activities of the iSPMs are determined and combined into one activity in the gSPM. Similarly, the predecessor and successor activities are determined and connected by transitions between the activities. The probability of a transition from one activity to the next is determined based on the frequency of occurrence in the iSPMs. By statistical averaging based on the merging of multiple iSPMs, the gSPM represents an averaged model of a type of surgical intervention. A schematic example of a gSPM is given in Fig. 5.2.

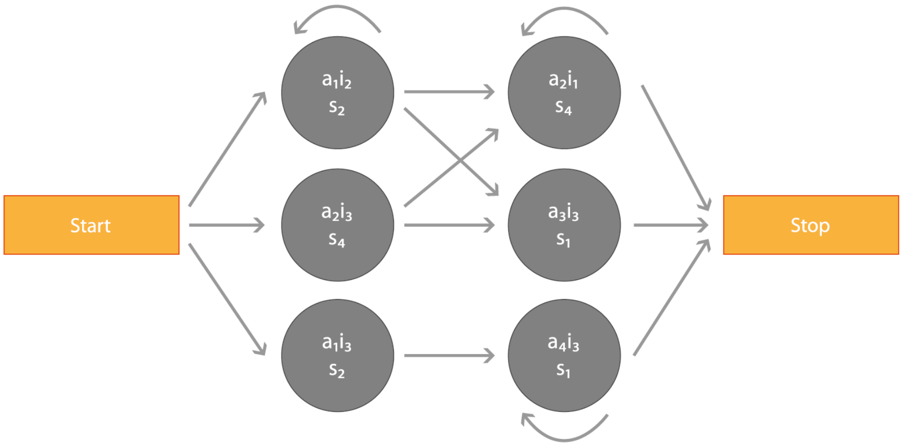

Figure 5.2: Schematic representation of a gSPM with six activities and three perspectives (a, i, s) per activity

The aforementioned problem of the high variability of the surgical procedure and hence the resulting problems of modeling can be taken into account in this model. By mapping the variability through probabilistic transitions, all possible process variations in the model are considered.

The gSPM was implemented as a XML data structure. For further processing, this data structure must be converted into a format which is able to be processed by the workflow management system. For this research, the Yet Another Workflow Language (YAWL) [29] and the matching YAWL workflow management system were used. YAWL implements, based on the formal logic of Petri-nets, all of the workflow patterns proposed by the workflow patterns initiative [33] and extends them to the patterns of concurrency and cancellation.

5.3.2 Test system

To conduct this study, a test system was developed. This system consisted of four interconnected standalone software components (Fig. 5.3).

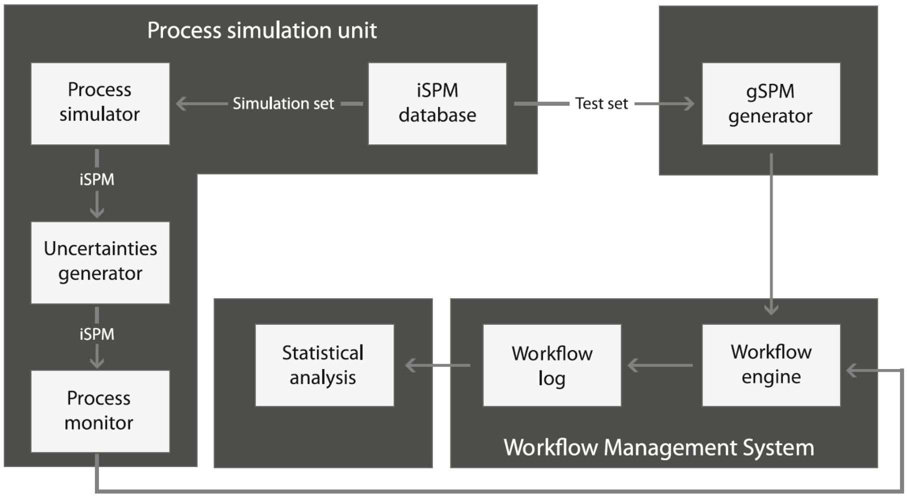

Figure 5.3: Design of the test system consisting of the workflow management systems, the process simulation unit with the iSPM database, the gSPM generator, and the statistical analysis unit

In the process simulation unit, the gSPM was created from the iSPMs in the SPM database. The simulation set, consisting of iSPMs, was then provided to the process simulator. The process simulator passed each activity from each iSPM in the test set to the uncertainty generator. Perspectives were randomly deleted from each activity to simulate uncertainties in the sensor data. The process monitor then sent the activity one by one to the workflow management system. To store the iSPMs, a Postgres 8.2 [112] database was used. All other components were proprietary developments in Java.

To generate a gSPM from the test set, the set was sent to the gSPM generator. The resulting workflow schema was sent to the workflow management system. The workflow management system executed the process model within the workflow engine. In the workflow log, the success of the execution was logged for later analysis. The analysis was done with the statistical tools R [113] and SPSS [114].

Since the goal of the study was to investigate the model regarding the problems that could arise from incomplete or erroneous sensor information, the uncertainties generator simulated sensor defects. For this purpose, perspectives were hidden from subsequent activities. This could lead to the problem that the path of the gSPM was not clearly identifiable, and thus the unambiguous tracking of the path could not be guaranteed. This situation can occur in reality when a sensor system, like the instrument tracking system, cannot produce any output, for example, the system detects the action "cut" and the anatomical structure but not whether the instrument is a scalpel or the scissors. In this situation, multiple paths must be followed until a unique path is found. An example is given in Fig. 5.4. On the left side, a fully defined iSPM and the corresponding gSPM are depicted. During the course of the intervention, simulated by the iSPM, the WfMS was able to find a corresponding activity in the gSPM for each activity of the intervention. On the right side of Fig. 5.4, on task two of the iSPM, the perspective b is corrupted (marked with the underscore). From that, two possible process states in the corresponding gSPM can be found. The WfMS must follow the two possible paths until a unique entry point can be found.

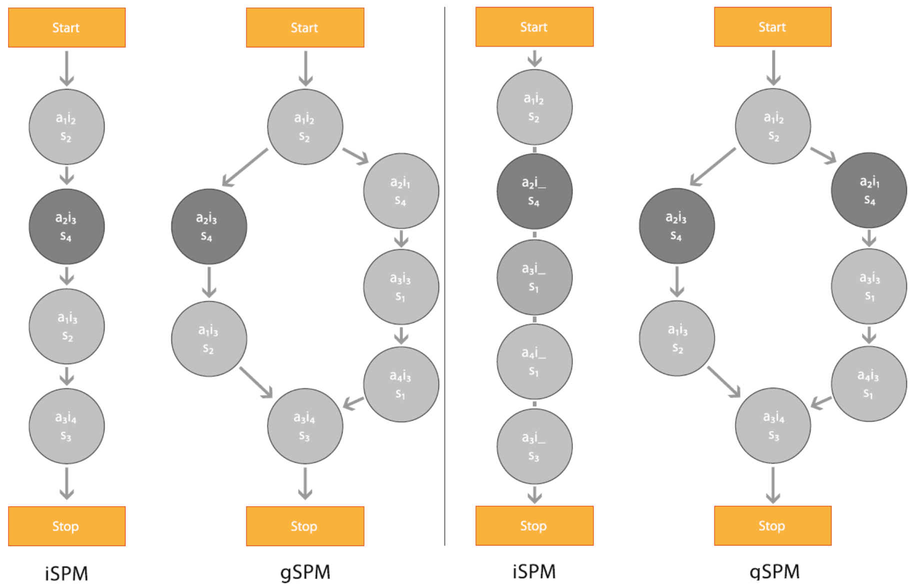

Figure 5.4: *Left* no sensor information is missing, so the path can be uniquely found. *Right* because of the missing sensor data, more than one path must be followed

5.3.3 System evaluation study design

Cataract operations for the surgical treatment for glaucoma [155] were used as the data for the study, as they are one of the most frequently performed eye surgeries in Germany. For the study, 100 cataract operations were recorded as described below. The operations consisted mainly of four different phases. First, the anterior capsule is opened and then the opacified lens is removed, after that the artificial intraocular lens is implanted, and finally, viscoelastic material used to support the operation is removed. All the operations were performed by three different surgeons at the University Hospital Leipzig, Germany.

The recordings of the iSPMs were made by means of a method developed at the ICCAS institute for the generation of surgical process models. This method is based on the recordings of trained medical students. The recordings were used to simulate the interpreted sensor data. In [13], this method is described in detail and explains the assurance of a valid and accurate process model. The students used the ICCAS surgical workflow editor to record the operation step by step. The ICCAS Surgical Workflow Editor is a piece of software developed specifically for this task and operates on a tablet PC with pen input. After recording and analyzing the iSPMs, a total of 120 individual surgical tasks could be defined. Thus, a gSPM consists of a maximum of 120 tasks.

In order to test the reliability of the workflow schema that was generated from iSPMs, two criteria were selected as dependent variables. The first criterion was the identification of a successful entry point. This variable tests the model with respect to the existence of a point at which the system can converge back to the correct path. The second criterion was the number of activities sent by the process monitor that was needed to successfully track the path again. With the combination of these variables, a statement can be made about how long it takes to locate a unique path in the model.

The study was guided by the following procedure: first, iSPMs were randomly chosen from the SPM database to create a gSPM as a test set, first from 10%, then from 20, 30, up to 100% of the available iSPMs. The gSPM was then tested against 10 disjoint iSPMs from the database. To guarantee the highest possible randomization of the study, the aforementioned steps were repeated 250 times (Fig. 5.5). Based on 250 runs, 10 different test-set sizes, six intervention phases, 10 tested iSPMs, and the gradual deletion of three different perspectives, 450,000 records were produced.

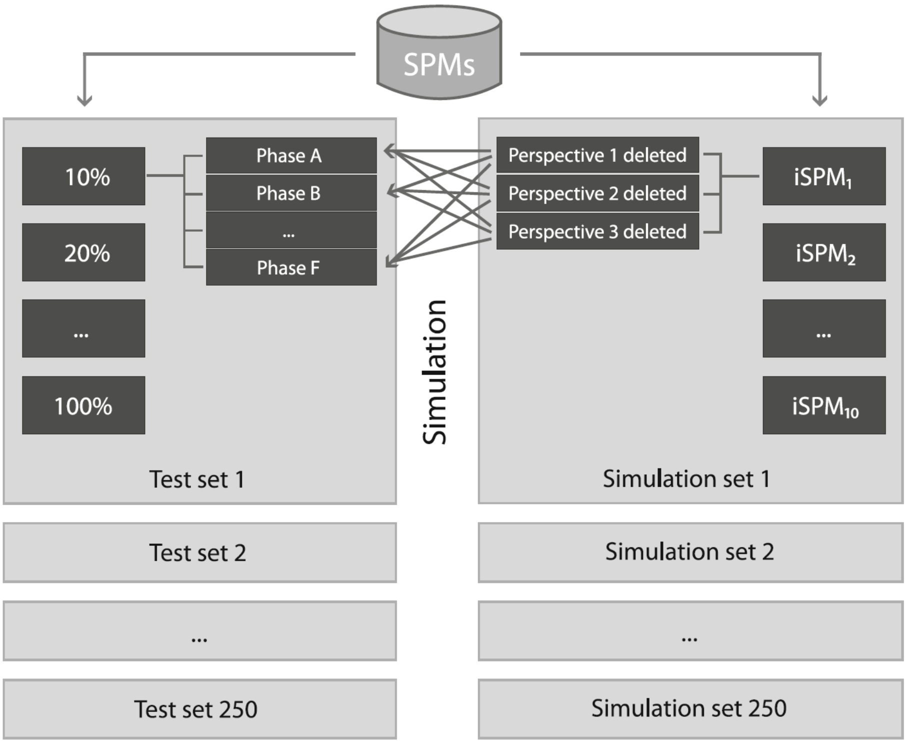

Figure 5.5: Test performance design for the validation study

5.4 Results

In this validation study, we investigated how many iSPMs were needed to build up a generalized model of the process to successfully relocate the path in the model after it was lost. This was to gain knowledge of the variation of the model. In order to do that, the number of iSPMs to build the gSPM was varied. The number of steps required to converge was also recorded. We also investigated the influence of the perspectives on successful path location. Our dependent variables were the rate of locating a path, the steps needed to locate it, and the deleted perspective.

In Table 5.2, the "Test-set size" column indicates the variation of the test set used to generate the gSPM. Columns "Success rate of path location" and "Number of step to find the converging point" are subdivided according to the observed perspective of the process. The columns inside of the "Success rate of path location" section display the mean success rate as a percentage, the standard deviation, and the maximum and minimum. Correlating to this, the column "Number of step to find the converging point" in Table 2 shows the number of steps required to locate the path dependent on the number of iSPMs used to build the gSPM and the deleted perspectives.

Table 5.2: Success rates of locating the right path (in percent) and the number of steps to find the converging point with different learning- set sizes in the surgical phase "Removal of Healon®"

	Success rate of path location			**Number of step to find the converging point**		
Test-set size (no. of iSPMs)	**Action**	**Instrument**	**Structure**	**Action**	**Instrument**	**Structure**
	100,0	**100,0**	**100,0**	**1,90**	**2,10**	**1,96**
100	0,0	0,0	0,0	0,28	0,26	0,31
	-	-	-	[1,84;1,95]	[2,05;2,15]	[1,90;2,02]
	93,04	**94,52**	**93,28**	**1,69**	**1,92**	**1,80**
90	7,63	7,60	7,79	0,28	0,37	0,31
	[92,09;93,99]	[93,58;95,46]	[92,31;94,25]	[1,69;1,77]	[1,88;1,96]	[1,76;1,85]
	92,20	**95,00**	**93,56**	**1,69**	**1,90**	**1,77**
80	9,16	6,78	7,90	0,28	0,37	0,31
	[91,06;93,34]	[94,16;95,84]	[92,58;94,54]	[1,65;1,72]	[1,85;1,94]	[1,73;1,81]
	92,24	**94,84**	**94,72**	**1,69**	**1,81**	**1,76**
70	7,90	7,07	7,56	0,30	0,36	0,34
	[91,26;93,22]	[93,96;95,72]	[93,78;95,66]	[1,63;1,70]	[1,77;1,86]	[1,72;1,80]
	91,72	**94,60**	**92,52**	**1,66**	**1,76**	**1,69**
60	8,77	6,77	8,62	0,28	0,36	0,30
	[90,63;92,81]	[93,76;95,44]	[91,45;93,59]	[1,62;1,69]	[1,71;1,80]	[1,65;1,73]
	91,72	**92,88**	**92,68**	**1,61**	**1,67**	**1,63**
50	9,26	8,15	8,29	0,30	0,36	0,31
	[90,57;92,87]	[91,87;93,89]	[91,65;93,71]	[1,57;1,65]	[1,63;1,72]	[1,59;1,67]
	90,92	**93,84**	**92,08**	**1,54**	**1,61**	**1,59**
40	9,50	7,89	8,62	0,33	0,33	0,32
	[89,74;92,10]	[92,86;94,82]	[91,01;93,15]	[1,50;1,58]	[1,57;1,65]	[1,55;1,63]
	91,36	**91,88**	**92,20**	**1,46**	**1,52**	**1,49**
30	8,58	9,61	8,57	0,30	0,30	0,31
	[90,30;92,42]	[90,69;93,07]	[91,14;93,26]	[1,42;1,50]	[1,48;1,56]	[1,45;1,53]
	90,80	**90,08**	**89,68**	**1,31**	**1,45**	**1,35**
20	9,02	10,26	10,13	0,32	0,31	0,32
	[89,68;91,92]	[88,81;91,35]	[88,42;90,94]	[1,27;1,35]	[1,41;1,49]	[1,31;1,39]
	86,92	**84,52**	**87,20**	**1,07**	**1,30**	**1,16**
10	11,98	14,14	11,24	0,26	0,30	0,29
	[85,44;88,40]	[82,77;86,27]	[85,81;88,59]	[1,04;1,10]	[1,26;1,34]	[1,12;1,19]

In Fig. 5.6, the average success rate is shown dependent to the deleted perspective and size of the learning set. For example, with the deleted perspective "instrument" the success rate drops from 95% ± 6.78% to 92.88% ± 8.15% when the learning-set size is reduced from 80 to 50%.

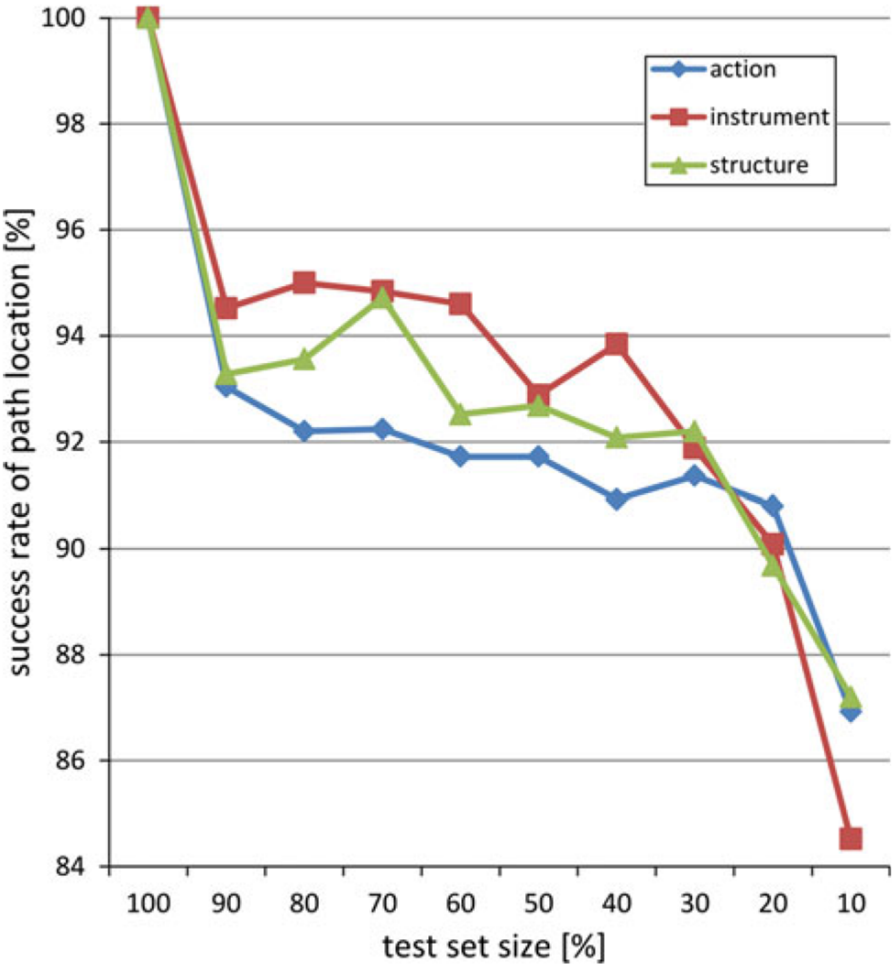

Figure 5.6: Decline of mean success rate of path location for the surgical phases Removal of Healon®, depending on the number of iSPMs in the test-set size

Fig. 5.7 shows the decline in the number of the steps needed to locate the paths with respect to the learning-set size. For instance, when using 70% of the iSPMs to create the gSPM and deleting the perspective instrument, 1.81 ± 0.36 steps are needed to locate the path in the model again. The decline of these values results from the lower success rate of locating a path in the model.

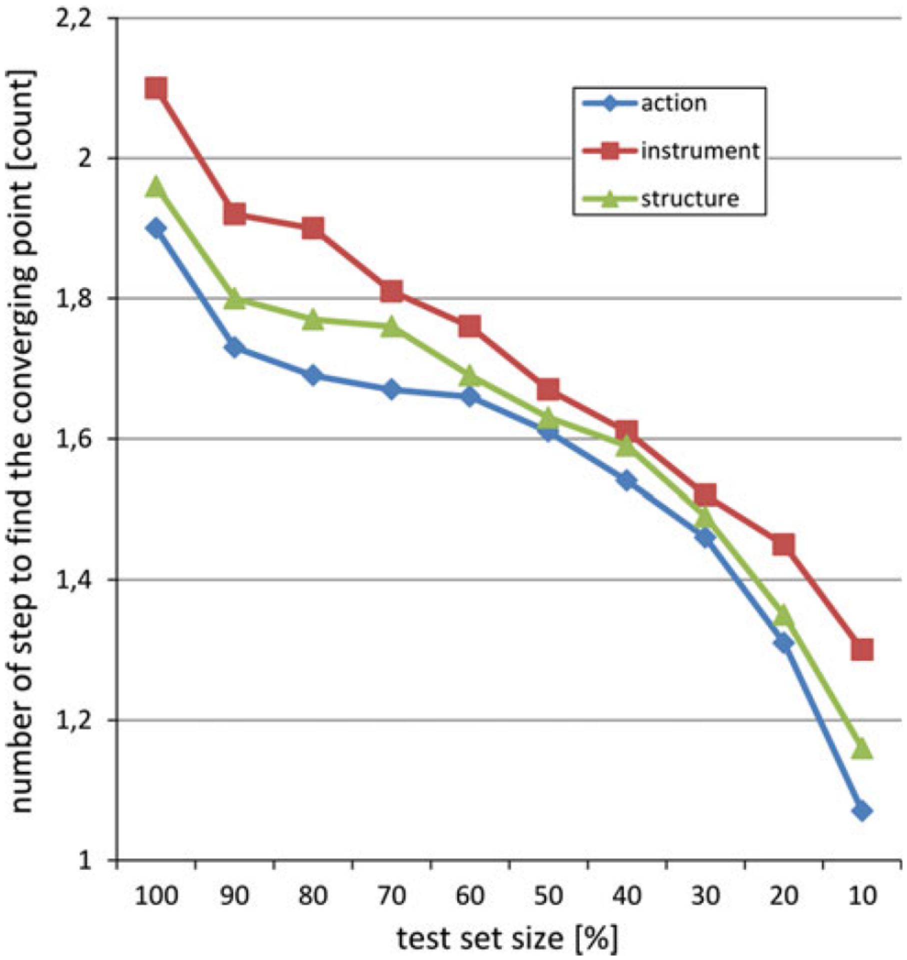

Figure 5.7: Decline of mean number of step to find the converging point for the surgical phases Removal of Healon®, depending on the number of iSPMs in the test-set size

5.5 Discussion

In this work,we tested a process model created from patients individual models with respect to the relevance of the completeness of sensor information to monitor the process. It was possible to determine how many steps were needed to resume the process flow after losing track of the path.

The inductive model, i.e., the fusion of many patient specific process models, already takes into account the fact of the high variability of surgical procedures during its creation. In the resulting model, all possible process variations can be shown.

Exactly 100 models of individual cataract surgery operations were used for the study. These interventions were recorded by trained medical students using the

ICCAS workflow editor. The cataract surgery offered a good basis for the study through its frequency and high degree of linearity. Because of the high degree of formalization and automation in conducting this study, any other operations available as individual process models could be tested equally.

In our validation study, we investigated how many individual iSPMs were needed to create a robust gSPM as a basis for a workflow schema that can relocate the path in the model after it was lost due to a variation in the actual process. Furthermore,we investigated how long it would take to locate the path again. We showed that even with a small set of only 30% of iSPMs, a workflow schema could be generated that finds the path more than 90% of the time. Since the model built from the iSPM should reflect the cataract surgery at the University Hospital in Leipzig, we did not created a surgeon-specific model. In the future, this model could be approved by being more specific in choosing iSPM for its creation, for example, all selected iSPMs are from one surgeon, from patients with similar preconditions, and similar age.

We showed that correct information of all three perspectives is crucial for successful process tracking. The data also show that the functional and spatial perspectives are more sensitive with respect to missing information. Missing information in these perspectives leads to more interruption of process tracking and poorer detection of convergence points. We did not investigate to which extend a specific action or a specific anatomical structure influences this. The operational perspective in comparison is less sensitive to missing information. This could be because a certain action can be performed with more than one instrument but not vice versa (e.g., cutting can be executed with a scalpel or the scissors but you can only cut with the scalpel or the scissors). This leads to more unique actions in the gSPM even if the operation perspective is missing.

There are a variety of potential uses for a surgical workflow management system in the operating room of the future. For example, the correct information could be displayed at the right place at the right time, the relevant devices can be automatically parameterized, and the remaining duration of the operation can be estimated and thus the next patient can be prepared at the right moment. Prerequisites for all of these potential applications however are the presence of high quality models of the operation and correctly interpreted sensor information.

Through this study, it was shown that an inductively created process model can serve as a valid basis for a surgical WfMS. Even after losing track of the path, in most cases, a convergence point could be found.

5.6 Conclusion

The creation of a process model that represents a surgical procedure accurately but is also robust to variance is a challenging task. Inductive creation of a process model has proven itself to be a method which takes in account the different needs.

The aim of this study was to validate generalized process models that were generated by using many patient-specific process models. This validation took place by finding the number of required steps to return to the valid path after diverging. In addition, which perspectives of the process model are particularly important during the process observation were determined. About 100 models of cataract surgery were used to create a generalized process model. In addition, a system was developed that supports the processing of the above questions.We showed that the functional and the spatial perspectives were almost equally important with respect to successfully re-converging on the path in case the process tracking was interrupted.

We showed that such models can be a valid solution to the problems of high variability in tracking surgical procedures.

5.7 Acknowledgments

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5.8 Conflict of interest

The paper is not, nor was it previously, under consideration by any other journal. The funding sources had no involvement in the study design, data collection, analysis or interpretation of the results, or in the writing of the report. All authors have no conflicts of interest. The decision to submit the paper for publication was ours alone.

Chapter 6

Summary and outlook

6.1 Summary

Using surgical workflow management systems is a new and promising approach to support the surgical process. Essential in this approach is the use of surgical process models. The first objective of this work, as described in the introduction, was to make a statement about the termination rate of path tracing in the generalized model.

In the first publication (Model driven design of workflow schemata for the operating room of the future) it could be shown that the use of gSPM as described in this article allocates a language neutral description of surgical processes. These descriptions can easily be transformed in almost any runtime language used by a workflow management system which was shown in example for YAWL.

The second publication (Process model-based design and validation of surgical workflow management schemata for cataract procedures) shows that even a small learning set of iSPMs can be used to generate a workflow schema that is able to guide vast amount of the procedures. If higher success rates are desired, an increased number of iSPMs can be used to achieve higher success rates.

In the third publication (The impact of missing sensor information on surgical workflow management) the answers to the Objective 2, 3, and 4 of this work where made. Objective two of this thesis where that the success rate for finding the process path again in the model could be determined. It could be shown that even with a small set of iSPMs, a workflow schema could be generated that finds the path almost every time.

The third Objective of this thesis where to answer the question for the number of steps needed to find the process path in the model is determined. The data of the study tells us that the path could be found after 2 steps the latest.

A statement about the sensitivity of individual perspectives of the model with respect to failure where the last Objective of this work. It could be shown that correct information of all three perspectives is crucial for successful process tracking. The data also show that the functional and spatial perspectives are more sensitive with respect to missing information.

In this thesis it could be shown that the used process models can provide the information about the process even under less than optimal conditions. It could be shown that navigation through the process is also possible in case of missing or wrong information of the process support systems. Whether the remaining error rate disturbs the surgical process to a higher degree than it supports it has to be investigated in at least one clinical study.

Additionally in this thesis it could be shown that the inductive approach to create generalized process models is a means to create models of sufficient quality. In one study, models generated in this way could be examined for their robustness against missing state transitions. It was shown that the model quality is strongly dependent on the number of patient-specific processes used.

6.2 Outlook

In [1] the authors systematically review publications with the effort to improve intraoperative efficiency. In the 39 publications, that met the inclusion criteria for the study, three major findings to improve intraoperative efficiency crystallized. Besides standardizing tasks and maintaining effective team communication collecting and using actionable data was major discovery. Collecting and using intraoperative data is one of the core topics of a surgical WfMS. The collected data could be used to generate even more robust generalized process models with a higher task resolution.

The intraoperative process support by means of a WfMS is strongly dependent on the generalized process model. The algorithms for the creation of these models have reached a quality level where first clinical tests can be performed. For the creation of these models, however, as many patient-specific models as possible are needed. Since the generation of these data by means of human observation is relatively cost-intensive, methods will be required in the future that perform this as fully automated as possible. This means that sensors will be needed in the operating room to take over this task completely. This sensor technology is not only used to collect new data, but can also be used to observe the process.

For continuous improvement, the newly generated patient-specific models can be incorporated into the generalized model immediately after the intervention. Thus each process variation automatically becomes part of the next model of the intervention. From a certain number of patient-individual models on, patient-individual characteristics such as age, gender and BMI can be taken into account more strongly when creating the generalized model. This method promises to produce a generalized model that is better adapted to the patient.

The points just mentioned all serve to improve the process model. On the side of the WfMS manufacturers there is still a need for research and development. The actual behavior of a WfMS in case of an unforeseen event is a topic that needs to be considered with increased attention, especially in surgery. Since in this area a delay or complete standstill of process support by a WfMS always means damage to an individual, methods for rapid problem communication and the resulting alternative intervention scenarios must be developed. Different approaches in this regard are already being pursued by several groups.

In this thesis two essential problems of a future IT-based process support of surgical intervention were considered. Questions could be clarified in these sub-areas, for many other areas that are affected by these problems new questions were raised.

"The dwarf sees farther than the giant, when he has the giant's shoulder to mount on."
(Samuel Taylor Coleridge)

Zusammenfassung der Arbeit

Dissertation zur Erlangung des akademischen Grades
Dr. rer. med.

Intraoperative process monitoring using generalized surgical process models

eingereicht von:	MSc. Philipp Liebmann
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Betreuer:	Prof. Dr. Thomas Neumuth

Juli 2021

Der Chirurg in einem modernen Operationssaal kann auf die Funktionen einer Vielzahl technischer, seine Arbeit unterstützender, Geräte zugreifen. Diese Geräte und damit auch die Funktionen, die diese zur Verfügung stellen, sind nur unzureichend miteinander vernetzt.

Die unzureichende Interoperabilität der Geräte bezieht sich dabei nicht nur auf den Austausch von Daten untereinander, sondern auch auf das Fehlen eines zentralen Wissens über den gesamten Ablauf des chirurgischen Prozesses. Es werden daher Systeme benötigt, die Prozessmodelle verarbeiten und damit globales Wissen über den Prozess zur Verfügung stellen können.

Im Gegensatz zu den meisten Prozessen, die in der Wirtschaft durch Workflow-Management-Systeme (WfMS) unterstützt werden, ist der chirurgische Prozess

durch eine hohe Variabilität gekennzeichnet. Mittlerweile gibt es viele Ansätze feingranulare, hochformalisierte Modelle des chirurgischen Prozesses zu erstellen. In dieser Arbeit wird zum einen die Qualität eines vorhandenen Modells hinsichtlich der Abarbeitung durch ein WfMS untersucht, zum anderen werden die Voraussetzungen die, die vorgelagerten Systeme erfüllen müssen geprüft. Es wird eine Aussage zur Abbruchrate der Pfadverfolgung im generalisierten Modell gemacht, das durch eine unterschiedliche Anzahl von patientenindividuellen Modellen erstellt wurde. Zudem wird die Erfolgsrate zum Wiederfinden des Prozesspfades im Modell ermittelt. Aussedem werden die Anzahl der benötigten Schritte zum Wiederfinden des Prozesspfades im Modell betrachtet.

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Philipp Liebmann | Jürgen Meixensberger | Peter Wiedemann | Thomas Neumuth

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Erklärung über die eigenständige Abfassung der Arbeit

Hiermit erkläre ich, dass ich die vorliegende Arbeit selbstständig und ohne unzulässige Hilfe oder Benutzung anderer als der angegebenen Hilfsmittel angefertigt habe. Ich versichere, dass Dritte von mir weder unmittelbar noch mittelbar eine Vergütung oder geldwerte Leistungen für Arbeiten erhalten haben, die im Zusammenhang mit dem Inhalt der vorgelegten Dissertation stehen, und dass die vorgelegte Arbeit weder im Inland noch im Ausland in gleicher oder ähnlicher Form einer anderen Prüfungsbehörde zum Zweck einer Promotion oder eines anderen Prüfungsverfahrens vorgelegt wurde. Alles aus anderen Quellen und von anderen Personen übernommene Material, das in der Arbeit verwendet wurde oder auf das direkt Bezug genommen wird, wurde als solches kenntlich gemacht. Insbesondere wurden alle Personen genannt, die direkt an der Entstehung der vorliegenden Arbeit beteiligt waren. Die aktuellen gesetzlichen Vorgaben in Bezug auf die Zulassung der klinischen Studien, die Bestimmungen des Tierschutzgesetzes, die Bestimmungen des Gentechnikgesetzes und die allgemeinen Datenschutzbestimmungen wurden eingehalten. Ich versichere, dass ich die Regelungen der Satzung der Universität Leipzig zur Sicherung guter wissenschaftlicher Praxis kenne und eingehalten habe.

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