Review

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Surgical process modeling

Abstract: Due to the rapidly evolving medical, technological, and technical possibilities, surgical procedures are becoming more and more complex. On the one hand, this offers an increasing number of advantages for patients, such as enhanced patient safety, minimal invasive interventions, and less medical malpractices. On the other hand, it also heightens pressure on surgeons and other clinical staff and has brought about a new policy in hospitals, which must rely on a great number of economic, social, psychological, qualitative, practical, and technological resources. As a result, medical disciplines, such as surgery, are slowly merging with technical disciplines. However, this synergy is not yet fully matured. The current information and communication technology in hospitals cannot manage the clinical and operational sequence adequately. The consequences are breaches in the surgical workflow, extensions in procedure times, and media disruptions. Furthermore, the data accrued in operating rooms (ORs) by surgeons and systems are not sufficiently implemented. A flood of information, "big data", is available from information systems. That might be deployed in the context of Medicine 4.0 to facilitate the surgical treatment. However, it is unused due to infrastructure breaches or communication errors. Surgical process models (SPMs) alleviate these problems. They can be defined as simplified, formal, or semiformal representations of a network of surgery-related activities, reflecting a predefined subset of interest. They can employ different means of generation, languages, and data acquisition strategies. They can represent surgical interventions with high resolution, offering qualifiable and quantifiable information on the course of the intervention on the level of single, minute, surgical work-steps. The basic idea is to gather information concerning the surgical intervention and its activities, such as performance time, surgical instrument used, trajectories, movements, or intervention phases. These data can be gathered by means of workflow recordings.

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These recordings are abstracted to represent an individual surgical process as a model and are an essential requirement to enable Medicine 4.0 in the OR. Further abstraction can be generated by merging individual process models to form generic SPMs to increase the validity for a larger number of patients. Furthermore, these models can be applied in a wide variety of use-cases. In this regard, the term "modeling" can be used to support either one or more of the following tasks: "to describe", "to understand", "to explain", to optimize", "to learn", "to teach", or "to automate". Possible use-cases are requirements analyses, evaluating surgical assist systems, generating surgeon-specific training-recommendation, creating workflow management systems for ORs, and comparing different surgical strategies. The presented chapter will give an introduction into this challenging topic, presenting different methods to generate SPMs from the workflow in the OR, as well as various use-cases, and state-of-the-art research in this field. Although many examples in the article are given according to SPMs that were computed based on observations, the same approaches can be easily applied to SPMs that were measured automatically and mined from big data.

Surgical process models (SPMs) – motivation, definition, and delimitation

Worldwide, technological developments are gaining momentum and infiltrate more and more areas of everyday life. New information technologies, such as the Internet of Things or Industry 4.0, new miniature technologies, new energetic or storage systems, or the fact that intricate technology can be mass produced and thus is easily available around the globe at reasonable prices, transform our world profoundly. For the benefit of the patients and the promotion of human health, surgery and other medical disciplines are slowly merging with emerging technical disciplines, becoming more and more complex hybrids.

Overall, this development must be regarded as mostly positive, as it offers increasingly efficient treatment for patients, including enhanced patient safety and the treating possibilities of conditions that were regarded as untreatable before, minimally invasive interventions, and the prevention of errors. However, it also heightens the pressure under which surgeons and other medical professionals must operate. This situation also has engendered a new policy in hospitals, which must rely on a wide variety of factors, including economic, social, psychological, qualitative, practical, and technological factors.

In congruence with the quickly evolving medical, technological, and technical possibilities, surgical procedures are becoming ever more sophisticated [1]. This offers increasing advantages for patients, such as enhanced patient safety, wound care, and trauma management, as well as a reduction of scarring and of highly invasive therapies. However, the growing surgical sophistication also entails other developments.

Surgical procedures are becoming more and more complex. The reasons for this growing complexity are manifold. First, the growth of surgical knowledge, in general, entails a heightened number of possible surgical procedures, methods, and techniques that the surgeons must learn, remember, and practice. Second, the altered policy of medicine, in general – in accordance with the growing patients' demands – has brought about a change of the overall objective of surgical interventions' need to be minimal invasive, cost-efficient, and as easy on the patients as possible. The new policy therefore relies on more resources, such as economic [2–4], social, psychological, qualitative, practical, and technological aspects, enhancing patient safety and eliminating medical malpractices [5].

The technological factor is the one that has possibly had the greatest impact on modern surgery. Medical disciplines, especially surgery, are slowly merging with technical disciplines. The number of technical and technological appliances in the operating room (OR) is steadily on the rise, requiring the surgeons to adopt – in addition to their medical formation – a more technical background and to gather knowledge and experience regarding the best possible application of modern technology [6, 7] for the sake of the best possible outcome for the patients and to adhere to current best-practice as well as to economic aspects.

Although the OR, in general, is the most expensive hospital unit with regard to patient treatment [8, 9], the current information and communication technology (ICT) in hospitals is not able to support the clinical and operational sequence adequately [10–13], thus creating breaches in the surgical workflow, prolongations in

routines, additional staff or room idle times, and media disruptions. The growing amount of information gathered in the OR by means of technology, the big data, and the knowledge concerning surgical "modi operandi" that might support Medicine 4.0 are not sufficiently inspected, selected or discarded, interpreted, and employed to the advantage of the intervention at hand or to that of the overall management of all ORs and the hospital or the patients in general. Thus, it becomes clear that a more consistent, process-oriented support of the ICT is needed. This support can be founded on a basic and comprehensive describability of surgery and of surgical interventions.

The problem, however, is that surgical interventions entail a vast amount of variability and complexity. Therefore, conventional modeling approaches alone, such as the top-down modeling approach [14, 15], a method based on the experience of the process modelers and/or on interviews with experts of the domain in question [16, 17], abstracting the knowledge from its upper levels down to the smaller details, have been proven unfit for the task at hand. The main drawbacks of these approaches are their time-consuming, expensive, and subjective nature and the insufficient resolution, longevity, and quantifiability of the results. Another problem is that usually surgical processes are reviewed only from a single perspective, for instance, as a business process or as a workflow system. This can result in the exclusion of aspects that are important for the overall process.

Therefore, more adequate methods are needed for the acquisition and generalization of process models for surgical interventions and procedures, and more suitable possibilities for the employment of the models thus attained need to be devised to the advantage of surgeons, other hospital staff, the administration, and – last but not least – the patients. The development of advanced and validated methods for defining, gathering, saving, and documenting surgical processes out of the big data in the OR is necessary to improve the documentation and evaluation of surgical tasks. These innovative methods would make an identification of objective topics that influence the progression of surgical procedures possible and thus an assessment of the significance of emerging or existing technologies, pioneering surgical assist systems (SAS), or surgical techniques in general [18].

To summarize the argumentation so far, it can be said that accurate SPMs are very much needed to enhance modern surgical performance and to support Medicine 4.0 in the OR. Such models could help in the implementation of new surgical techniques, of evaluating and ameliorating existing techniques, and to organize, optimize, and manage the surgical process as well as adherent

processes, such as OR scheduling or cost-planning. The problem, though, is that the required data are difficult to obtain and to structure. New approaches are needed to be able to compose models of surgical procedures that can be generalized and computed by information systems, can preserve patient specificity, and can be employed in a meaningful and customizable way. To achieve this aim, it is important to identify the clinical and technical motivation for such models as well as possible limitations. Furthermore, some definitions and a delimitation of notions such as surgical process, SPMs, and other connected concepts are needed.

Clinical motivation

It is possible to appraise certain facets of a surgical intervention objectively. Examples for such objective aspects are the duration of single work-steps or whole intervention phases or whether or not one approach is more effective than another approach. However, the overall evaluation of surgical practice is very intricate, complex, and highly subjective. There is no method available or described in the appertaining literature that allows for an objective and reliable quantification of surgical practice from a process point of view.

Nevertheless, such an appraisal is more important than ever for various reasons. One of these reasons is the context of the reduction of working hours for medical residents according to the changed working time directives of European law, which might induce an extra pressure on the surgeon to perform faster and to complete more interventions in a single working day. Furthermore, the number of medical – and foremost surgical – students is on the rise. This aggravates the already existing problem with providing enough practical training for each of them.

However, the problem expands to other areas as well. The current situation is such that increasing numbers of novel and innovative technologies become available. The implementation of these technologies into the medical routine with the aim of providing the best possible treatment for patients sometimes competes against ethical or financial concerns, especially when these technologies have not yet been subjected to a multicenter cost-benefit-ratio investigation. With regard to ethical concerns, one example would be a new technology that becomes available that would ameliorate the overall outcome of an intervention but that cannot be financed by reimbursements. In this case, the management of a hospital would have to choose between financial loss and ethical behavior. Effectively, it has to be stated that the overall standard

of surgical training faces some serious issues, such as heightened workloads for surgeons, a need for more efficient training structures, increasing complexity of medical technological systems, increasing economic pressure, and a decreasing amount of time-per-patient.

Today, there is an urgent necessity to record, model, and analyze surgical practice by means of computers. This recording technology has to be objective and unbiased and needs to function robustly and unfalteringly. Furthermore, its implementation into a regular OR has to be well thought-through and practical so as not to take up valuable operating space and not to place a financial burden on the hospital or organization employing it. Furthermore, the use of the technology needs to be effortless so as not to disrupt daily clinical practice and heighten the pressure on surgeons and other OR staff. In addition, these systems need to be adjustable and adaptable to different surgical procedures.

The data thus collected might be used to describe the single surgical work-steps and the whole surgical procedures, with the aim of modeling the overall intervention, including all possible or all necessary information. In this regard, the term "modeling" can be used to support one or more of the following tasks: "to describe", "to understand", "to explain", to optimize", "to learn", "to teach", or "to automate". The issuing models can be used to compare different types of interventions, such as approaches using different surgical tools or instruments, to compare single surgeons or whole OR teams, or to evaluate and compare different surgical procedures.

Technical motivation

From a technical point of view, SPMs can be used for different aims. One of these aims is requirements analyses and product specification. The advantage for engineers is the possible graphical representation of the results instead of a representation as text. Furthermore, such data are quantifiable, thus allowing for a derivation of technical or clinical constraints as, for instance, average durations of performance steps, total number of performance steps, or number of iteration cycles. Additionally, benchmark studies can be performed to compare surgical strategies, substitutive technologies, or approaches or to assess the skill level of resident surgeons in comparison to senior surgeons. Product comparisons are another use-case for SPMs. By means of these comparisons, for instance, the invasiveness of one surgical product can be evaluated in contrast to another product. In addition, the data can be used for risk and quality management. Furthermore,

the SPMs can be used as input for workflow management systems so that the infrastructure and technical systems in the OR can be automatically triggered or controlled according to the actual surgical situation. These and other technical merits will be further described in "Model application examples".

Terms and definitions

To define an SPM, various other notions have to be defined first, such as medicine, surgery, process, and model. However, the next paragraphs will only give a very brief introduction into this topic and not a comprehensive account, as this is not within the scope of this paper.

"Medicine" is the "science or practice of the diagnosis, treatment, or prevention of disease" [19]. As a branch of medicine, the overall goal of "surgery" is the same. To achieve this goal, surgery is using special means. Thus, surgery is a branch of medicine treating diseases and conditions in humans or animals using manual or instrumental procedures to diagnose, cure, or alleviate a pathological condition [19–21]. The term Medicine 4.0 is adapted from the definition of Industry 4.0 [22]. It emphasizes strategies and technologies for patient-specific individualization of treatment, hybridization of medical treatment and accompanied services, and the increasing involvement of stakeholders of the surgical treatment, such as hospital administration.

A "work-step" or activity" can be defined as "a description of a piece of work that forms one logical step within a process" [23]. In consequence, a "process" can be defined as a "network of activities and their relationships, criteria to indicate the start and termination of the process, and the information about the individual activities, such as participants" [23]. In accordance with this definition, a "surgical process" can be defined as "network of surgical or surgery-related activities and their relationships, criteria to indicate the start and termination of the process, and the information about the individual activities", whereas a "surgical work-step" or "activity" can be defined as "description of a piece of work that forms one logical step within a surgical process".

Furthermore, a "model" is a simplified and constrained description of a fraction of reality that is built for a specific purpose. Thus, "modeling" can be understood as a simplified (formal or semiformal) representation of a suitable excerpt of reality using a suitable method for representation [24]. In consequence, an SPM can be defined as "a simplified (formal or semiformal) representation of a network of surgical or surgery-related activities and their

relationships, criteria to indicate the start and termination of the process, and the information about the individual activities". It is important to bear in mind that the simplified representation should reflect a predefined subset of interest [25] and that the method of representation should be suitable to the overall application of the model.

Delimitation

SPMs focus on the description of surgical work-steps. These activities represent the most important value-adding processes within the OR. Therefore, the goal of SPM needs to be to suitably represent these value-adding processes. Within an SPM, every surgical process needs to be represented as a chain or a network of single surgical or surgery-related work-steps (such as device setup in the OR, patient positioning, briefing, or instrument passing), including detailed information.

In most cases, SPMs cover the cut-suture-time of a surgical procedure. Activities before or after this period are usually not considered within SPMs. In general, SPMs focus on intraoperative work-steps. Perioperative events, such as anesthesiologic activities or activities performed by nonmedical staff within the OR, are of little or no importance.

However, there are some exceptions in which some of these external activities are of interest for the surgical workflow. This, for instance, is the case for a quantitative assessment of the impact of an SAS on the overall intervention course. In this case, the setup times of these systems, which occur preoperatively, need to be taken into consideration.

Model generation

This section will give an introduction on the strategies that can be employed for the generation of SPMs. Subsequently, strategies for the acquisition of data will be demonstrated. Third, the concept of model generalization will be explained. This strategy is mainly used for achieving an extended scope of application. Lastly, an overview on existing modeling languages will be given along with examples of use-cases.

Modeling strategies

In general, there are two different strategies for modeling surgical processes: top-down and bottom-up strategies.

Top-down modeling

This method can be employed if a process as a whole is too complex and must be broken down into single parts. The requirements for top-down modeling are simple but important. The modeling relies heavily on the interaction of experienced clinicians and process professionals. Top-down modeling results in a formulated overview of the process that is represented. Subsequently, every subpart of this process is refined and more details are added to the model. This method can be applied down to the desired level.

This approach offers some advantages. For instance, this modeling strategy is highly flexible and very readily available. Also, a breaking down of a procedure might help to better understand the single work-steps, simplifying each part of the process. In addition, parts of the models thus achieved can be reusable.

However, this approach also has some restrictions. For instance, this solution provides only limited coverage at the beginning. Furthermore, the possible resolution achieved by employing this method is rather limited and the degree of quantification is rather low, whereas the sheer number of work-steps represented can be overwhelming. Additionally, the experts using this approach to model a process might have problems with time estimation, rendering the models rather inaccurate. Also, the variability of the process might not be dutifully represented. Furthermore, there is a possibility that even an expert has wrong perceptions of certain aspects of the overall work, thus tainting the resulting model.

Current descriptions of surgical processes have further limitations. Sources, such as clinical guidelines or surgical textbooks, are valuable and easily accessible references to apply to the top-down modeling strategy. However, the applicability of these sources regarding analytical resolves has restrictions because of the deficient attention to detail, the lacking objective quantifiability, and the subjective point of view of the creator(s) of the model. Also, the variability of the process is insufficiently represented. Due to these facts, it is important and sensible to develop and implement new approaches for the acquisition of information about surgical processes, providing a basis to overcome the current limitations.

Bottom-up modeling

Bottom-up modeling works the other way around. In this approach, individual steps of a process are described

and then linked together. These in turn are then interlinked until the overall process system is represented. The requirements for this strategy are an appropriate data acquisition modality and knowledge abstraction algorithms that give semantics to the big data.

The main disadvantage of this strategy is the very high complexity these models can achieve, rendering them very difficult to understand and process. The advantages, however, include a very high precision of the overall model, a possibility to consider process variability, and a possible acquisition of quantitative information, such as performance or usage time. Even if bottom-up modeling has some drawbacks, it is widely used.

Model types

Model information can be expressed by symbolic or numeric values. This section introduces both main types briefly. However, it is also possible to combine both model types. Top-down modeling results in symbolic model types, and bottom-up modeling can result in both types.

Symbolical models

Symbolical models are models that are expressed by means of natural language expression in plain text. The prerequisites of such models are a mutual terminology or the creation or definition of an underlying ontology. Furthermore, a sufficient computerized observation support for projects that need data acquisition during long time periods is highly recommended.

The advantages of these symbolical models are high flexibility and quick availability. Furthermore, there is no need to mine low-level semantics out of the data. Also, unexpected situations can be handled with relative ease while using this strategy. However, on the downside, the resolution of symbolical models is lower than that of sensor-based models. Furthermore, the risk of errors introduced by the observer is increased.

Numerical models

Numerical models are represented by physical measurements that are represented by numerical values, such as trajectories representing movements. The prerequisites for

the application of numerical models are existing sensor systems and suitable knowledge abstraction algorithms to derive symbolic representations from the numerical models to verify it with clinicians.

The main advantage of numerical models is their very detailed level of representation. Additionally, due to the extraction of the data using sensors, acquisition errors due to human failure are relatively low. On the downside, semantic abstraction algorithms are needed and there are very few suitable sensor technologies available at the moment (see "Data acquisition by sensor systems"), although these technologies are rapidly ameliorated and researched. Additionally, these technologies are quite inflexible, can be quite expensive, and might need a high level of maintenance.

Data acquisition strategies for bottom-up modeling

There are different existing strategies for data acquisition. They all have in common that there is no "one and only" universal strategy to encompass the multitude of potentially interesting entities within the OR. In the following section, different data acquisition strategies will be described. As per definition, these strategies are not needed for top-down modeling strategies.

Data acquisition by observation

Data acquisition strategies are methods that are of interest to the process modeler and can be employed for the realization of surgical and technical use-cases. In [25, 26], a quick and flexible strategy for the acquisition of data produced by different entities in the OR by means of observation has been described. This strategy is based on the definition mentioned above, namely, that a surgical process is a succession of surgical work-steps [27–29]. These work-steps are in turn represented by various entities that are represented as perspectives. These perspectives are, for instance,
- The functional perspective describing "what" is done in a surgical work-step,
- The organizational perspective that describes "who" is performing a work-step,
- The operational perspective that describes the "instrument(s)" used to perform a certain work-step,
- The spatial perspective that represents "where" a workplace is performed (e.g. at which anatomical structure), and

- The behavioral perspective that describes the "time" at which a certain work-step is performed.

Actual data acquisition is performed by means of tablet PCs that are equipped with a specialized software operated by especially trained observers (cf. Figure 1) [30]. The observers are present in the OR during the complete course of the intervention and record every surgical work-step they observe.

This data acquisition strategy has been validated and it has been shown that the mean accuracy for the description of surgical work-step contents was approximately 92% and the temporal delay less than 2 s [25]. The benefit of this strategy is that it was unnecessary to include a work-step of knowledge abstraction in the processing pipeline that interprets numerical data into clinically interpretable knowledge, is usually surgery specific, and might be very complex.

Using this data acquisition strategy, more than 1000 single surgical processes have been recorded, thus demonstrating that the method can be used independently for different surgical disciplines. The recorded interventions were from ENT-surgery, cardiovascular surgery, neurosurgical surgery, pediatric surgery, and interventional radiology. The models thus acquired were of varying complexity according to the length and intricacy of the surgical process recorded. For instance, median model sizes for cataract surgeries comprised 20 activities. Other, more complex interventions comprised 100–150 activities (spinal disc surgery or sinus surgery) or 200–250 activities (mitral valve repair). The most complex interventions recorded, namely, interventions for brain tumor removal, comprised more than 400 single work-steps.

Data acquisition by sensor systems

Furthermore, there are many data acquisition strategies that rely on sensors rather than on human observers. In the past, several research groups using sensor systems have focused largely on a single perspective or have attempted to work without the use of an explicit process model. Additionally, many current works are centered on the usage of surgical instruments and device parameter recognition. The recognition of the actual intervention phase or state is a precondition for workflow analysis, optimization, and management.

The general challenge is that, in surgery, there usually are no intrinsic data or signal available to identify single manual tasks. To solve this problem,
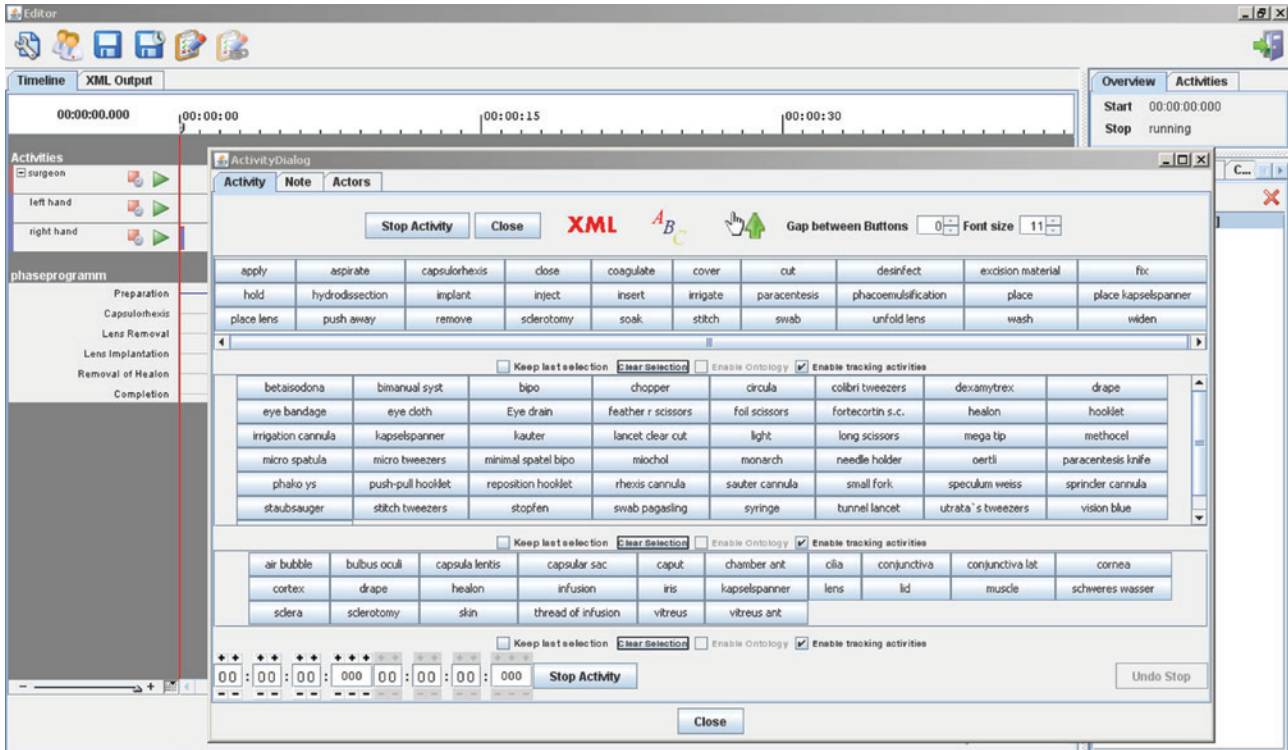
Figure 1: Workflow editor for recording SPMs (cataract surgery example configuration) [26].

an analysis of endoscopic and microscopic video has been proposed [31–33]. Markov models and dynamic time warping (DTW) were used to identify single work-steps based on the presence of surgical instruments [34–37], and radiofrequency identification (RFID), visual approaches, and weight analysis methods [38] have been employed to recognize instrument use [37, 39, 40]. For laparoscopy, another approach using a camera on the trocar and color wheels was proposed by Toti et al. [41]. Other technologies proposed were hand gesture recognition using thermal imaging [42] and accelerometer data analysis [43]. In robotic minimal invasive surgery (RMIS), a mixture of video and kinematic data was employed to identify gestures [44].

All of these approaches address different levels of granularity from ranged gesture recognition (surgemes) [42, 44, 45] to low-level tasks [33], high-level tasks [46, 47], and intervention phases [35, 48]. James et al. [49] tried to recognize the current surgical situation indirectly by estimating the positions and movements of the members of surgical teams within the OR or by deriving information from other indirect features. Most of these approaches achieve accuracies of between 80% and 90%. Additionally, this research, in general, focused on several different clinical use-cases, such as pituitary surgery [33],

laparoscopic sigmoidectomy [50], cataract surgery [51, 52], or laparoscopic cholecystectomy [36].

Model generalization and transformation strategies

The ultimate goal for the developers of SPMs is the creation of models that can, according to the paradigm of individualization in Medicine 4.0, flexibly represent a multitude of surgical cases, disciplines, patients, and instruments. However, this aim is hard to achieve due to some characteristics of surgical processes, the most challenging being the high complexity and the high variability: adverse or unexpected turnouts of events are possible at every stage of the intervention, causing the overall workflow to deviate from the expected "standard". This variability depends on many aspects, such as patient or surgeon properties, employed technical resources, and the hospital. Additionally, these interventions can be unstandardized as well as unplanned and otherwise highly variable.

To be able to encompass this high level of variability of surgical processes, approaches using top-down models, on the one hand, need to detail each possible
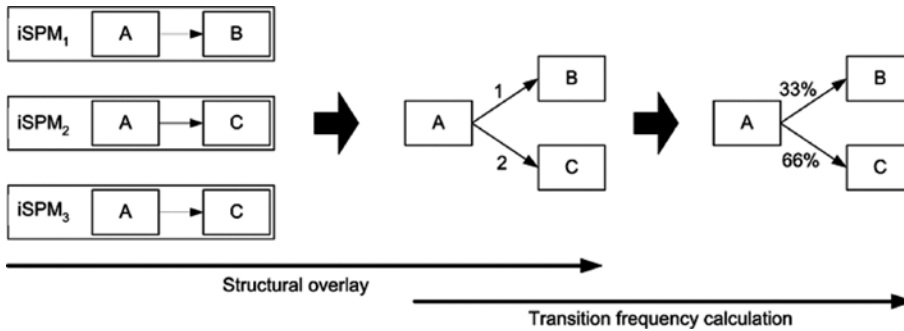
Figure 2: Simplified gSPM generation procedure example with surgical activities A …C and statistical transition probabilities.

outcome in sufficiently high resolution. Button-up model approaches, on the other hand, need to find strategies to transpose valid single recordings to represent other cases as well. This can be achieved by means of model generalization.

The basic idea of the generalization of workflow recordings is to merge activities. For an improved distinction, the terms patient-individual SPM (iSPM) will be used for an SPM before generalization and generic SPMs (gSPMs) will be used for an SPM after generalization subsequently.

The single process steps first need to be identified by defining certain features, such as, for instance, recognizing equal work-steps in different processes (cf. Figure 2). These work-steps can be used for process mining, a strategy transferred from business information systems. Thus, after the selection of the feature in focus, the various elements from the SPMs are merged and transferred to represent a new work-step in the generalized model. If a feature is unique, i.e. if it does not appear in any other recorded workflow, it is not merged and results in a new branch of the generalized SPM [53].

This strategy can be supported by an application of sophisticated data mining methods [54]. The choice of these methods is dependent on the objective and the size of the actual study. It can be assumed that the higher the number of merged individual process models is, the higher and the more stable the resulting generalized process model will be. Figure 3 shows an example of a gSPM for activities of a surgeon while performing different surgical activities during cataract procedures.

In the example shown in Figure 3, 53 iSPMs of inpatient cataract surgeries were recorded and merged into a gSPM. The iSPMs containing surgical work-steps of the left and right hands of the surgeon were measured individually. Subsequently, activities of the same name in the iSPMs were combined into one activity in the gSPM, such as all activities of "paracentesis (with) paracentesis

knife (with) right hand (at) cornea" (see bottom activity in Figure 3). If activities of the same name are followed by different activities, this results into a branching of the model. This approach enables different strategies: on the one hand, the gSPM contains all variability that was measured between the iSPMs; on the other hand, each iSPM is still present in the overall model and can be tracked to the gSPM.

Modeling languages

Basically, there is no designated or recommended language for the modeling of SPMs yet. Which language is chosen therefore entirely depends on the given circumstances, such as the requirements on the system, the scope of use of the models, the choice of system itself, or the expressive powers or the mightiness of the language.

In addition to the minimum requirement to be able to represent nodes and edges, the available elements of the language determine whether or not a language is applicable within a certain approach. Possible characteristics are the degree of mathematical formalization, the representation of spatial or temporal information, and the representation of probabilities but also the coverage of qualitative information such as the detection of conditions or risks associated with single work-steps.

A language with a high level of formalization should be employed whenever the process models to be represented need to be used as procedure algorithm for computer programs. The advantage of a language with a high formalization level furthermore is the possibility of verifying the models as early as during the design phase, for instance, with regard to the accessibility of work-steps or the presence of blind ends.

In general, there is a multitude of languages in existence that could be used to represent SPMs.
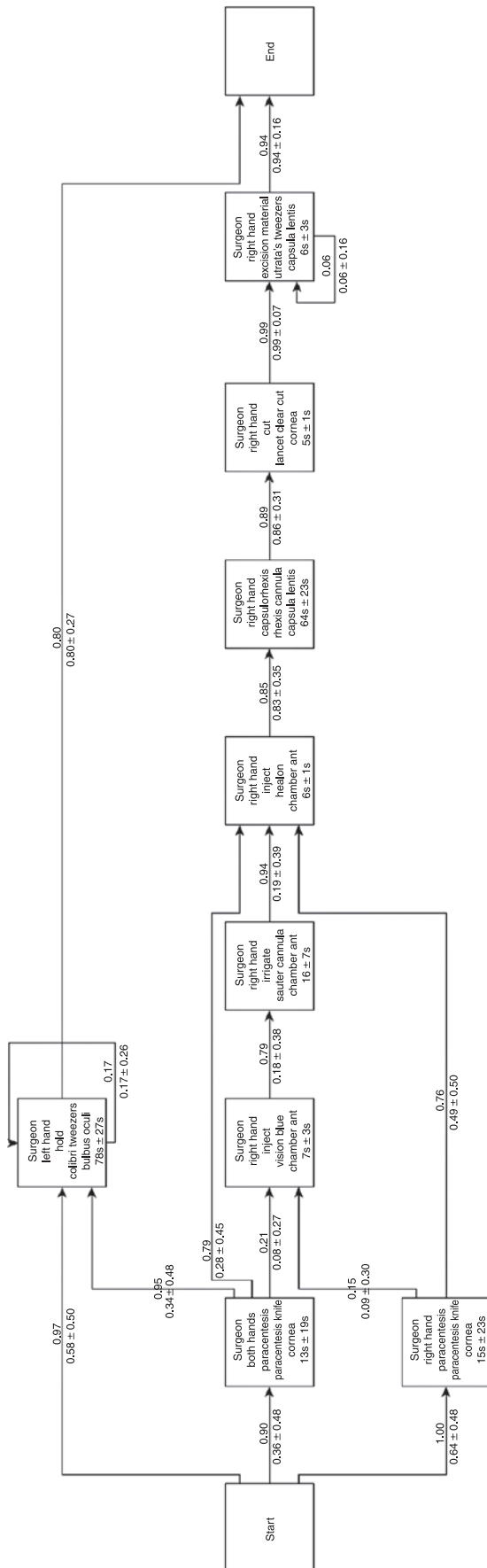
Figure 3: gSPMs for Capsulorhexis phase in cataract interventions (solid line style, "mean" path of right hand; dotted line style, "mean" path of left hand).
Nodes indicate activity descriptions and average performance time of the activity, and edge label indicate local (upper value, the predecessor-successor node probability related to the predecessor) and global transition probabilities (lower value, the predecessor-successor node probability related to the overall iSPM sample). The gSPM was filtered by removing edges with global transition probabilities of less than 5% to remove blur.

Overall, a number of more than 650 process modeling languages are known. Most of these languages have their origin in information systems. The most influential and best-known of these languages for the field of business information systems are the XML Process Definition Language (XPDL) created by the Workflow Management Coalition (WFMC), the Business Process Modeling Notation (BPMN) and the Unified Modeling Language (UML) both developed by the Object Management Group (OMG), and the Business Process Execution Language (BPEL) created by the Organization for the Advancement of Structured Information Standards (OASIS). Other languages include the Event-Driven Process Chains (EPC) or Yet Another Workflow Language (YAWL). Languages with a higher level of formalization include Petri nets, state charts, and activity charts. A review and evaluation of modeling languages for SPM can be found in [55].

Model application examples

The application range of SPMs is diverse and multifaceted. In the following section, some possible applications will be presented, such as visualization, analysis, and workflow management.

SPMs for visualization and analysis

Alongside the performance of analyses, SPM is one of the easiest yet most effective application areas to allow for a useful and utilizable visualization of the course of a surgical intervention. In the past, it has become apparent that these visualized procedure courses are a useful support instrument for interdisciplinary work, such as a cooperation between surgeons and engineers. By means of this visualization, both professions can gain a thorough understanding of the single work-steps and the overall procedure, thus allowing them to combine their

professional points of view to find trigger points for optimizations or to discuss the impact of new SAS.

The use of SPMs to the advantage of clinical users is a necessary criterion for an effective application. Moreover, the applicability across different intervention types and diverse disciplines of surgery is a key requirement. In the following section, the implementation of SPMs will be demonstrated in several use-cases.

Performing requirements analyses using SPMs

In [56], SPMs were used to derive certain working condition parameters for a neurological SAS from a number of iSPMs of the same procedure type. With the help of the parameters thus computed, the requirements for the operation of a milling system employing navigated-control to be used at the spine were projected. To realize this objective, neurosurgical interventions of lumbar discectomies were analyzed to predict time-based requirements for the computerized milling system.

The presented approach described an objective method for assessing the potential advantages of an SAS before its actual deployment or even before its development. The focus of this research was on the minimal requirements a projected system needs to be more advantageous than a conventional or existent method or system. Furthermore, the method to procure these requirements from routine clinical data was researched.

Lumbar discectomies are interventions in which surgeons extract material from the lumbar disc(s) of a patient. First, the surgeon removes a part of the vertebra to gain access to the actual location of the material to be extracted. Second, the surgeon removes as much of the lumbar disk as might be reached. These two steps are iterated until the targeted material has been completely extracted. This strategy is employed to minimize the impact on the vertebra and its supporting function.

The research question in this study was whether an alternative strategy employing an automated milling system was more effective than the conventional method. The difference between the conventional system and the new system was that, in the latter, the mill worked automatically within a predefined volume, namely, the total amount of material to be extracted. The new computer-assisted system was expected to eliminate the need of iterations, thus shortening the procedure to the benefit of patients, hospital, and OR staff.

Human observers recorded the interventions with the help of software tools shown in Figure 1. These recordings were computed into gSPMs. Subsequently, the relevant work-steps (e.g. "removing disk tissue") were analyzed according to their distribution along the procedure (e.g. the work-step iteration of removing tissue and removing bone material was performed ~15 times during the procedure) and their temporal occurrence. The latter revealed that the automated milling system should not perform longer than ~20 min per procedure [56]. The information was than processed to calculate how fast the new system needed to work to gain a quantitative advantage on the conventional method. This was mainly possible thanks to the detailed and exact-to-the-second recording and representation of surgical activities.

The methods presented in this work are transferrable to other procedure types and might be used for a systematic analysis of other requirements as well. For instance, it can be used for a systematic analysis of technical requirements. Based on such analyses, manufacturers can derive parameters for planned systems that are indicative of their success or failure on the market. Additionally, hospital administrations might request that manufacturers demonstrate fulfillment of such requirements to prove the superiority of their system and the worth of the investment.

With regard to the overall goals of improving and planning novel systems based on SPMs, this approach method creates a better and more appropriate support systems for the surgeon by integrating the surgical workflow into development considerations.

Evaluation of SAS using SPMs

The question of whether a new SAS contributes to the surgical performance needs to be answered qualitatively and quantitatively, supported by evidence gathered from structured data analyses. In [57], gSPMs were used to evaluate SAS. Laparoscopic and telemanipulator-based Nissen fundoplications in pediatric surgery were compared, with the aim of calculating the impact of the telemanipulator on the overall process. In the study, the system's impact on the process was investigated and quantified based on process models. By comparing both gSPMs for the laparoscopic and telemanipulator-based strategies, it could be demonstrated that the use of a telemanipulator is not recommended for this clinical use-case. This approach demonstrated to be a valuable method to estimate the impact of an SAS on the surgical workflow. The SPM analysis results demonstrated that the telemanipulator strategy followed to close the laparoscopic strategy. Hence, significant faster intervention times could not be achieved even for subphases or work-steps [57] or even were less efficient due to the spatial and sensual limitations. For the investigated
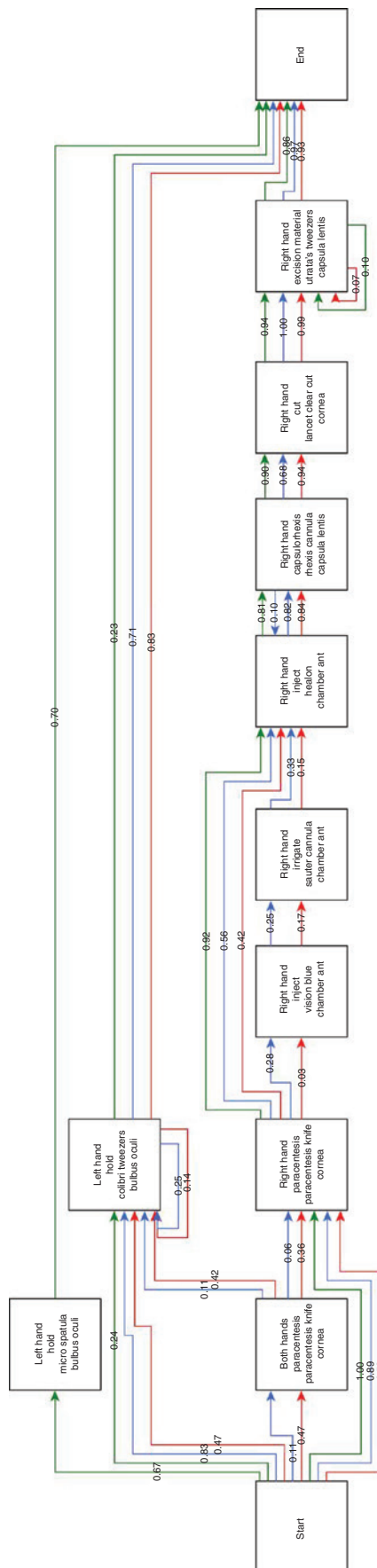
Figure 4: SiTPs as gSPMs of three surgeons for the intervention phase Capsulorhexis.
The graph shows the most commonly recorded work-steps for surgeons "red", "blue", and "green". The activities are labeled in the nodes and the edges are labeled with global predecessor-successor probabilities. The gSPM was filtered to remove transitions with low probabilities to remove blurring.

use-case, changes in the overall course of the intervention may be necessary to fully benefit from the advantages of a telemanipulator in Nissen fundoplications.

Evaluation and comparison of surgical approaches

In [58], SPMs were used to optimize patient treatment strategies. In this study, a potential advanced training for surgeons from an ophthalmological department of a university medical center was planned based on the models generated from their performed interventions, called surgeon-individual treatment profiles (SiTPs). The surgical interventions observed were standard cataract procedures. These were performed by three experienced surgeons during their daily routine. A total of 105 procedures were recorded and computed used to generate iSPMs. For each surgeon, separately, the resulting iSPMs were again computed into gSPMs (cf. Figure 4). Surgeon-individual workflows, activity frequencies, and median performance durations of activities were analyzed and compared. By comparing the three SiTPs, concrete recommendations for further training could be derived. Especially for gSPM segments with extended performance times or an increased number of iterations of surgical work-steps, the respective surgeon might benefit from an individualized and specific training.

Process compliance assessment

Until now, the use for SPMs to perform requirements analyses, evaluations, and comparison has been presented. In [59], these models were used to assess the quality of the outcome of surgical interventions using process benchmarking. This approach examined the compliance of 450 surgical processes assessing the relationship between the course of the intervention and its outcome.

For this aim, skill practices using rapid prototyping models in minimally invasive surgery training were assessed. From these assessments, representations of surgical processes were extracted and compared by applying process-oriented similarity metrics to the outcome of the "best practice" procedure. Thus, it was shown that a

high process compliance that corresponds to low process deviation significantly supports good intervention outcomes, which is relevant for optimal patient care. Also, this method can be used to give the surgeons feedback with regard to human factors and also for inducing further changes in the overall workflow.

SPMs for workflow management in the OR

In modern ORs, the need for intelligent information presentation has been identified to prevent an information overload for surgeons and other OR staff [60–63]. In the pertaining literature, context-dependent support is frequently mentioned as one of the chief objectives in the research field of SPMs [64–68]. However, these systems need to be intelligible and not overtaxing for their user(s) [69] as well as suitably balanced between proactivity and transparency [70].

Proactive support is based on appropriate SPMs. In [67, 71], the design and implementation of a surgical workflow management system based on SPMs that can provide a robust guidance for surgical activities was described. The number of required iSPMs was investigated by a randomized selection of iSPMs to create a gSPM and subsequent testing of a disjunct iSPM against the gSPM. Additionally, the method of investigating the number of SPMs needed to develop such a system was investigated. The models were mapped onto workflow nets, a dialect of Petri nets, as workflow execution templates to outline the behavior of the intraoperative workflow management system. The application of SPMs for the implementation of situation-dependent assistance is expected to reduce the workload of the surgeon during endoscopically performed ENT procedures as described in [72–74].

There are many possible application fields of surgical workflow management systems within the scope of Medicine 4.0 in the digital OR of the future with integrated medical device networks. These include programmed parameterization and governing of SAS, a situation- and context-dependent information visualization for surgeons, resulting, for instance, in a timely presentation of previously acquired patient examination results or the providing of decision support systems for resident surgeons. Additionally, the ensuing surgical workflow management system could be linked to the hospital information system (HIS), thus allowing for an automatic and timely call for the next patient according to the predicted beginning of the next intervention. These use-cases could ameliorate the surgical process qualitatively and therefore be beneficial to the patients' safety.

The developing integration of modern medical devices and IT systems in the ORs of the future is an empowering technology. A wide variety of implementations of SAS – from management and administration to support – may be constructed based on data provided by medical devices, such as online prediction of the remaining procedure time [75] or estimating the probability of medical device applications [68].

Conclusion

The ensuing synergy between surgeons and technology is not yet fully matured, leading to breaches in the surgical workflow, delays of operating times, and media disruptions. Additionally, only fragments of the "big data" accrued in ORs by surgeons and machines are not used to its full extent. This is mainly due to infrastructure breaches and communication errors. The ICT used in hospitals cannot manage the clinical and operational sequences effectively.

To improve this state, SPMs, defined as simplified, formal, or semiformal representations of a network of surgical or surgery-related activities and their relationships, reflecting a predefined subset of interest, can be used. To create such models, various strategies can be used such as top-down or bottom-up modeling, different underlying languages or ontologies might be employed, and different data acquisition strategies can be used such as benchmarking and data mining. As a result, these models can represent surgical interventions down to a very fine granularity level in very high resolution, thus contributing qualifiable and quantifiable information on the intervention course, on interventional phases, or on surgical work-steps.

The focus of this research lies on the gathering of information concerning surgical intervention and its underlying activities. Such information includes the use of surgical tools, task duration, trajectories of instruments or movements of persons in the OR, or intervention phase recognition. The methods to accrue these data are manifold, such as a manual or automatic workflow recording, knowledge abstraction, live or camera recordings. These data are then abstracted to represent the surgical process as a model. Further abstraction can be generated by merging several iSPMs to create more gSPMs that are valid for larger patient samples.

The resulting SPMs can be used in a widespread variety of use-cases in the context of Medicine 4.0. Examples are requirements analyses, evaluating SAS, generating surgeon-specific training-recommendation, creating workflow management systems for ORs, and comparing different

surgical strategies. In the future, the research field of SPMs will become more and more important for the orchestration of technology and for a situation-dependent support of the surgeon. It will be employed to create and manage the advances that are brought about due to arising new medical technologies and growing knowledge. Additionally, there is also a high probability that the research field of SPMs will spawn a technology of its own.

Author Statement

Author Contributions

Thomas Neumuth: Writing of the manuscript; Approval of the manuscript.

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Reviewer Assessment   **Open Access**

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Surgical process modeling

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Reviewers' Comments to Original Submission

Reviewer 1: Markus Kleemann

Feb 09, 2017

Reviewer Recommendation Term:	Accept with Minor Revision
Overall Reviewer Manuscript Rating:	70

Custom Review Questions	Response
Is the subject area appropriate for you?	4
Does the title clearly reflect the paper's content?	5 - High/Yes
Does the abstract clearly reflect the paper's content?	4
Do the keywords clearly reflect the paper's content?	5 - High/Yes
Does the introduction present the problem clearly?	5 - High/Yes
Are the results/conclusions justified?	5 - High/Yes
How comprehensive and up-to-date is the subject matter presented?	5 - High/Yes
How adequate is the data presentation?	5 - High/Yes
Are units and terminology used correctly?	5 - High/Yes
Is the number of cases adequate?	N/A
Are the experimental methods/clinical studies adequate?	N/A
Is the length appropriate in relation to the content?	4
Does the reader get new insights from the article?	4
Please rate the practical significance.	2
Please rate the accuracy of methods.	4
Please rate the statistical evaluation and quality control.	N/A
Please rate the appropriateness of the figures and tables.	3
Please rate the appropriateness of the references.	4
Please evaluate the writing style and use of language.	5 - High/Yes
Please judge the overall scientific quality of the manuscript.	5 - High/Yes
Are you willing to review the revision of this manuscript?	Yes

Comments to Authors:

The authors described an actual and well known problem of data Management in and around Surgical procedures. They offer in a very analytical and abstract way of modern IT-Solutions for improved data Management. For surgeons the publication would be probably more helpful, if terms of „Big Data" or „ Medicine 4.0" would be integrated and explained. Furthermore the publication could gain more effort to non-IT-specified surgeons, if the analytical and theoretical written Solutions would be explained or breaked down to a e.g. specific surgical procedure, that shows the improvement or overcome of actual obstacles. Nevertheless it is a very well written publication to an actual sugical IT-Problem.

Reviewer 2: Oliver Burgert

Feb 09, 2017

Reviewer Recommendation Term:	Accept with Minor Revision
Overall Reviewer Manuscript Rating:	80

Custom Review Questions	**Response**
Is the subject area appropriate for you?	5 - High/Yes
Does the title clearly reflect the paper's content?	5 - High/Yes
Does the abstract clearly reflect the paper's content?	3
Do the keywords clearly reflect the paper's content?	4
Does the introduction present the problem clearly?	5 - High/Yes
Are the results/conclusions justified?	4
How comprehensive and up-to-date is the subject matter presented?	4
How adequate is the data presentation?	3
Are units and terminology used correctly?	4
Is the number of cases adequate?	N/A
Are the experimental methods/clinical studies adequate?	4
Is the length appropriate in relation to the content?	4
Does the reader get new insights from the article?	5 - High/Yes
Please rate the practical significance.	4
Please rate the accuracy of methods.	5 - High/Yes
Please rate the statistical evaluation and quality control.	N/A
Please rate the appropriateness of the figures and tables.	4
Please rate the appropriateness of the references.	5 - High/Yes
Please evaluate the writing style and use of language.	4
Please judge the overall scientific quality of the manuscript.	4
Are you willing to review the revision of this manuscript?	Yes

Comments to Authors:

The paper describes current developments in surgical process modeling. From the title and the introduction, I got the impression this should be a review paper covering work of different groups and incorporating those in a generalized conceptualization, which gives a structure helpful for clinical and technical readers. After reading the paper, I'm not sure whether I got the intention wrong, or if the authors intentionally focused stronger on the approach of observation based bottom up modelling, because other approaches covered by other groups (BPMN modeling, process mining, machine learning approaches, …) are just shortly mentioned and covered in a relatively small part of the paper. It should be made clear in the introduction, what the focus of the paper shall be. In my review, I will assume, that the focus shall be observation based bottom up modelling, if I am wrong with my assumption, the paper would require significant extension and modification. For the rest of the review, I'll follow the document structure and mention issues as they occur.

I would consider the section "clinical and experimental research" for this paper instead of "general surgery".

The keywords should contain "process modeling", I see just little evidence for the keyword "medical device networking".

The Abstract is a nice introduction to the topic of surgical process modeling - but it is not an abstract! An abstract should cover the contents of the whole paper and present all topics, methods, results and conclusion in very condensed form. The authors just give an introduction. It must be completely re-written.

The motivation in chapter 1 is well written.

At the end of the last paragraph, "new approaches are needed to be able…" - are you going to present those? The modeling descriptions in the later chapters are a bit vague. From the following sentence, one gets the impression, that after identification of motivations and limitations and a few definitions, the problem would be solved. When you are talking about "new approaches", what exactly are you referring to?

In 1.1 you are writing: "There is no method available or described in the appertaining literature that allows for an objective and reliable quantification of surgical practice.", but later on you are citing such literature and you are giving examples.

1.1: "by means of technological systems that are supported by specialized computers." Sounds a bit strange for using a tablet PC with dedicated software (as you describe later on). You do not use "specialized computers" but common hardware.

In this chapter, you are motivating automated or semi-automated process recording - a point which is not elaborated in the rest of the paper (just mentioned in a small section 2.2.2).

The sentence "In this regard, the term modeling can be understood as either one or more of
the following terms: "to describe", "to understand", "to explain", to optimize", "to learn", "to teach"
or "to automate"." is wrong. Modeling can be *used* for those tasks, but it cannot be *understood* as one of them. Later on (1,3), you are correctly describing, what a model is. Maybe you should move that section closer to the beginning.

In 1.2. "One of these aims is the performance of requirement…" might be misleading, just delete "the performance of" and the sentence is more clear.

1.3. I do not understand why readers of this journal need a definition of "medicine" and "surgery", since those terms are later on just used in the common meaning.

1.3: Your definition of "model" lacks the specific purpose a model is built for. This is important, since you are later on arguing, that certain models are useful for certain tasks.

1.4: "of surgical work steps in a computer model" - the computer is not really needed - a BPMN drawing on paper can be a SPM, too.

1.4: "Therefore, the goal of surgical process modeling needs to be to suitably represent these procedures." - this sentence is unclear. Which procedures? The surgical work steps?

1.4: "Within a surgical process model, every surgical process needs to be represented…" - what is "every surgical process" in this sentence? A surgical process instance (aka performed intervention) would make sense since you are having several of them, but then the sentence would not be true if you are neglecting unlikely intervention courses. Such a model will always be incomplete, since unexpected events can occur. Please clarify.

1.4: "a chain or a network of…" - this is not a "network" but a "directed graph". (please check the whole paper for it, it occurs again)

1.4.: "As artificially set boundaries for a surgical procedure the cut-suture-time is used" ◊ "in most cases, surgical process models cover the cut-suture-time of a surgical procedure".

2.1: "processes. On the one hand, there are top-down, and, on the other hand, there are bottom-up strategies." ◊ "processes: top-down, and bottom-up strategies." Is much more readable.

2.1.1: "The requirements for top-down modeling are simple but important." - which requirements? "Clinical expertise and interaction with technicians"? This is not a requirement of a method. Maybe the sentence should just be deleted (and please remove the "hands" from the following sentence for better readability).

2.1.1: Even though bottom up modeling has drawbacks, it is widely used. That should be mentioned, and maybe one graphical example should be given (you have some in your own group, but you could as well use clinical guidelines or work of other groups)

2.1.2: "hierarchical layer of components" neither layer nor components are introduced and defined.

2.2.1: "Symbolical models are models that are expressed by means of natural language expression" - that would mean "plain text". You are using a formal structure as well, e.g. your definition of actors, work steps, etc.

2.2.1: "Furthermore, a sufficient technical support for long term projects is highly recommended." What does this sentence mean? What is a "long term project"? What is "technical support"? What kind of support is needed? Is this just true for symbolic models or for other model types, too?

2.2.1: "Furthermore, there is no need to abstract complex algorithms." - I have no idea what you want to tell here.

2.2.1: "Furthermore, the risk of recording errors is increased" can be misunderstood in a way that you record an error, which occurs during the intervention.

2.2.2: You do not mention one of the largest drawbacks of numerical models: The lack of semantics! You just have numbers, but no meaning. Nonetheless, you should make a connection between this chapter and chapter 2.3.2 where you are describing sensor systems.
The combination of symbolic and numeric descriptions is not considered. Is this on purpose?
Is figure 1 created for this paper or was it published before? If it was published before, a reference is needed.
You are giving an extensive state of the art for sensor systems, but you do not do so for observation (mainly your own papers) or for top down modeling (no references). Please do not shorten the references in section 2.3.2.

2.3.2: [James2007] ◊ style

2.4: "developers of such models" ◊ „developers of surgical process models"

In 2.4 you are describing one of the most important parts of your paper (at least according to your introduction). Considering the importance, the methods are not described in sufficient detail. E.g. you are writing about „sophisticated data mining methods" without reference or further indication, which methods shall be used.

The simple method in figure 2 illustrates a very simple case, but it might happen that if you are fusing paths in the graph, theoretical intervention courses can be created, which will not be performed in the real world. How do you solve this problem? If you don't solve it, you should just speak of „statistical transition probabilities" between work steps. I experienced significant confusion when I showed such models to clinicians who just tried to „follow the arrows".

Fig. 3 is unreadable

2.5: instead of „mathematical formalization" I would prefer just „formalization" since mathematics don't play a huge role (it is more informatics, and yes, you can transfer most informatics problems to mathematical problems, …).

2.5: You are listing many modeling languages, but you don't give any advise which language is appropriate for which modeling use case. You even don't tell, which can be used to store iSPM, gSPM, … (or why they can't be used).

3.1.1: „By means of observers using tablet PCs with a specialized software program," - ref to fig. 1, „by means of observers" should be rewritten (e.g. „human observers recorded the interventions with help of the software tools shown in fig 1").

3.1.1: Was the only result the information about how fast the new system should be? That could have been determined using a stop watch without any process model… I assume there are much more detailed results! Please show some!

3.1.2: How did the SPM help to show that the tele manipulator was not appropriate?

3.1.3: Which concrete recommendations could be derived? And how was the analysis done?

3.1.4: Again: numbers, clear evidence!

In general, chapter 3.1 is interesting and motivates the use of SPM, but the results are not shown. For a clinician, it is unclear what the benefit of the modeling step is, how the data can be analyzed and how results can be interpreted. Please be more detailed (and if you your space is limited, shorten the introduction chapters)

3.2: How was the number of process models investigated? What was the result?

3.2.: „workflow nets" and „workflow schemata" are not introduced.

3.2.: please quantify the „reduced workload"

You are ignoring the main problem in intraoperative workflow support: The detection of the surgical work step or the effort needed for recording. You should mention this critically, either in 3.2 or in the conclusion.

4: Heading „Summary": I would prefer a „conclusion" since the „abstract" is already a summary. And what you are writing is closer to a conclusion then to a summary.

The first two paragraphs are repetitions of the introduction and shall be deleted (or moved to introduction)

Ref [21] is incomplete

Ref [23] has encoding problems

The paper should be proofread again, there are several typos (e.g. surgerly, processual,

Authors' Response to Reviewer Comments

Mar 03, 2017

Dear reviewers,

thank you for your suggestions. Please find the changes to the original submission in a separate letter as attachment.

I thank both reviewers for their comments. I carefully revised the reviewers comments and tried to follow them if possible.

Reviewer #1:

The authors described an actual and well known problem of data Management in and around Surgical procedures. They offer in a very analytical and abstract way of modern IT-Solutions for improved data Management. For surgeons the publication would be probably more helpful, if terms of "Big Data" or " Medicine 4.0" would be integrated and explained. Furthermore the publication could gain more effort to non-IT-specified surgeons, if the analytical and theoretical written Solutions would be explained or breaked down to a e.g. specific surgical procedure, that shows the improvement or overcome of actual obstacles. Nevertheless it is a very well written publication to an actual sugical IT-Problem.

The terms big data und medicine 4.0 were added. The requested solution and breakdown was explained in sect . 2.4

Reviewer #2:

The paper describes current developments in surgical process modeling. From the title and the introduction, I got the impression this should be a review paper covering work of different groups and incorporating those in a generalized conceptualization, which gives a structure helpful for clinical and technical readers. After reading the paper, I'm not sure whether I got the intention wrong, or if the authors intentionally focused stronger on the approach of observation based bottom up modelling, because other approached covered by other groups (BPMN modeling, process mining, machine learning approaches, …) are just shortly mentioned and covered in a relatively small part of the paper. It should be made clear in the introduction, what the focus of the paper shall be.

The text was changed to: "Although many examples in the article are given according to surgical process models that were computed based on observations, the same approaches can be easily applied to surgical process models that were measured automatically and mined from big data."

In my review, I will assume, that the focus shall be observation based bottom up modelling, if I am wrong with my assumption, the paper would require significant extension and modification.

For the rest of the review, I'll follow the document structure and mention issues as they occur.

I would consider the section "clinical and experimental research" for this paper instead of "general surgery".

I don't understand the comment. There is no section "general surgery"

The keywords should contain "process modeling", I see just little evidence for the keyword "medical device networking".
Process modeling was included. "medical device networking" was removed.

The Abstract is a nice introduction to the topic of surgical process modeling - but it is not an abstract! An abstract should cover the contents of the whole paper and present all topics, methods, results and conclusion in very condensed form. The authors just give an introduction. It must be completely re-written.
I decided to leave the Abstract as it is. The article was requested to be a book chapter, not a research article. Therefore it gives a short introduction and overview of the paper contents. Of course you are right and it is not a usual abstract of a research article and more likely a summary.

The motivation in chapter 1 is well written.
At the end of the last paragraph, "new approaches are needed to be able…" - are you going to present those? The modeling descriptions in the later chapters are a bit vague. From the following sentence, one gets the impression, that after identification of motivations and limitations and a few definitions, the problem would be solved. When you are talking about "new approaches", what exactly are you referring to?
A sentence was included to emphasize this topic
"New approaches are needed to be able to compose models of surgical procedures that can be generalized and computed by information systems, preserve patient specificity, and can be employed in a meaningful and customizable way."

In 1.1 you are writing: "There is no method available or described in the appertaining literature that allows for an objective and reliable quantification of surgical practice.", but later on you are citing such literature and you are giving examples.
I added "…from a process point of view" to the claim.

1.1: "by means of technological systems that are supported by specialized computers." Sounds a bit strange for using a tablet PC with dedicated software (as you describe later on). You do not use "specialized computers" but common hardware.
"technological systems that are supported by specialized …" was deleted

In this chapter, you are motivating automated or semi-automated process recording - a point which is not elaborated in the rest of the paper (just mentioned in a small section 2.2.2).
The sentence "In this regard, the term modeling can be understood as either one or more of the following terms: "to describe", "to understand", "to explain", to optimize", "to learn", "to teach"
or "to automate"." is wrong. Modeling can be *used* for those tasks, but it cannot be *understood* as one of them. Later on (1,3), you are correctly describing, what a model is. Maybe you should move that section closer to the beginning.
"Understood" was changed to support, "terms" was changed to tasks.

In 1.2. "One of these aims is the performance of requirement…" might be misleading, just delete "the performance of" and the sentence is more clear.
This was done.

1.3. I do not understand why readers of this journal need a definition of "medicine" and "surgery", since those terms are later on just used in the common meaning.
It was included to relate it to medicine 4.0. This was emphasized by including a more explicit definition of medicine 4.0 after the definition of medicine.

1.3: Your definition of "model" lacks the specific purpose a model is built for. This is important, since you are later on arguing, that certain models are useful for certain tasks.
I included "… that is built for a specific purpose"

1.4: "of surgical work steps in a computer model" - the computer is not really needed - a BPMN drawing on paper can be a SPM, too.
You are right. It was deleted

1.4: "Therefore, the goal of surgical process modeling needs to be to suitably represent these procedures." - this sentence is unclear. Which procedures? The surgical work steps?
It relates to the previous sentence. The term procedure was exchanged by the term value-adding processes.

1.4: "Within a surgical process model, every surgical process needs to be represented…" - what is "every surgical process" in this sentence?
A surgical process instance (aka performed intervention) would make sense since you are having several of them, but then the sentence would not be true if you are neglecting unlikely intervention courses. Such a model will always be incomplete, since unexpected events can occur. Please clarify.
This interpretation is out of context. The sentence is "… every surgical process needs to be represented as a chain or network of surgical … work steps…". It was left as it is.

1.4: "a chain or a network of…" - this is not a "network" but a "directed graph". (please check the whole paper for it, it occurs again)
The term network was taken from the WFMC definition for a process (reference 22). Since I just extended that definition I left it as it was.

1.4.: "As artificially set boundaries for a surgical procedure the cut-suture-time is used" ◊ "in most cases, surgical process models cover the cut-suture-time of a surgical procedure".
I followed the suggestion.

2.1: "processes. On the one hand, there are top-down, and, on the other hand, there are bottom-up strategies." ◊ "processes: top-down, and bottom-up strategies." Is much more readable.
I followed the suggestion.

2.1.1: "The requirements for top-down modeling are simple but important." - which requirements?
"Clinical expertise and interaction with technicians"? This is not a requirement of a method. Maybe the sentence should just be deleted (and please remove the "hands" from the following sentence for better readability).
The sentence was changed to "The modeling relies heavily on the interaction of experienced clinicians and process professionals." Both elements are required to get a reasonable result.

2.1.1: Even though bottom up modeling has drawbacks, it is widely used. That should be mentioned, and maybe one graphical example should be given (you have some in your own group, but you could as well use clinical guidelines or work of other groups)
The sentence was included: "Even if bottom-up modeling has some drawbacks, it is widely used."

2.1.2: "hierarchical layer of components" neither layer nor components are introduced and defined.
The sentence part was deleted

2.2.1: "Symbolical models are models that are expressed by means of natural language expression" - that would mean "plain text". You are using a formal structure as well, e.g. your definition of actors, work steps, etc.
I added "are models that are expressed by means of natural language expression in plain text."

2.2.1: "Furthermore, a sufficient technical support for long term projects is highly recommended." What does this sentence mean? What is a "long term project"? What is "technical support"? What kind of support is needed? Is this just true for symbolic models or for other model types, too?
"Long-term project" was changed to "data acquisition during long time periods"
"technical support" was changed to "computerized observation support"

2.2.1: "Furthermore, there is no need to abstract complex algorithms." - I have no idea what you want to tell here.
"no need to abstract complex algorithms" was changed to "no need to mine low-level semantics out of the data".

2.2.1: "Furthermore, the risk of recording errors is increased" can be misunderstood in a way that you record an error, which occurs during the intervention.
Was changed to "… the risk of errors introduced by the observer is increased"

2.2.2: You do not mention one of the largest drawbacks of numerical models: The lack of semantics! You just have numbers, but no meaning. Nonetheless, you should make a connection between this chapter and chapter 2.3.2 where you are describing sensor systems.
Included: "On the downside, semantic abstraction algorithms are needed…"
A link to sect. 2.3.2. was also included

The combination of symbolic and numeric descriptions is not considered. Is this on purpose?
Yes, there are use cases for that. But no one seems to have it done yet. I included a sentence in 2.2.

Is figure 1 created for this paper or was it published before? If it was published before, a reference is needed.
Done

You are giving an extensive state of the art for sensor systems, but you do not do so for observation (mainly your own papers) or for top down modeling (no references). Please do not shorten the references in section 2.3.2.
I included the references

2.3.2: [James2007] ◊ style
It was fixed

2.4: "developers of such models" ◊ "developers of surgical process models"
It was changed

In 2.4 you are describing one of the most important parts of your paper (at least according to your introduction). Considering the importance, the methods are not described in sufficient detail. E.g. you are writing about "sophisticated data mining methods" without reference or further indication, which methods shall be used.
Further references were included

The simple method in figure 2 illustrates a very simple case, but it might happen that if you are fusing paths in the graph, theoretical intervention courses can be created, which will not be performed in the real world. How do you solve this problem? If you don't solve it, you should just speak of "statistical transition probabilities" between work steps. I experienced significant confusion when I showed such models to clinicians who just tried to "follow the arrows".
The term was added.

Fig. 3 is unreadable
I put it into landscape format. I hope it can be printed that way.

2.5: instead of "mathematical formalization" I would prefer just "formalization" since mathematics don't play a huge role (it is more informatics, and yes, you can transfer most informatics problems to mathematical problems, …).
Done

2.5: You are listing many modeling languages, but you don't give any advise which language is appropriate for which modeling use case. You even don't tell, which can be used to store iSPM, gSPM, … (or why they can't be used).
I included a reference to a document that evaluates several languages.

3.1.1: "By means of observers using tablet PCs with a specialized software program," - ref to fig. 1, "by means of observers" should be rewritten (e.g. "human observers recorded the interventions with help of the software tools shown in fig 1".)
Done

3.1.1: Was the only result the information about how fast the new system should be? That could have been determined using a stop watch without any process model… I assume there are much more detailed results! Please show some!

The respective information were added as examples.

3.1.2: How did the SPM help to show that the tele manipulator was not appropriate?

The explanation was added:

"By comparing both gSPMs for the laparoscopic and the telemanipulator-based strategy, the SPM analysis results demonstrated that the telemanipulator strategy followed to close the laparoscopic strategy. Hence, significant faster intervention times could not be achieved or even were less efficient due the spatial and sensoric limitations."

And 3.1.3: Which concrete recommendations could be derived? And how was the analysis done?

It was added

"By comparing the three SiTPs concrete recommendations for further training could be derived. Especially for gSPM segments with extended performance times or an increased number of iterations of surgical work steps, the respective surgeon might benefit from an individualized and specific training."

And 3.1.4: Again: numbers, clear evidence!

Some relevant numbers were added to illustrate the example

In general, chapter 3.1 is interesting and motivates the use of SPM, but the results are not shown. For a clinician, it is unclear what the benefit of the modeling step is, how the data can be analyzed and how results can be interpreted. Please be more detailed (and if you your space is limited, shorten the introduction chapters)

3.2: How was the number of process models investigated? What was the result?

The number of required iSPMs was investigated by randomized selection of iSPMs to create an gSPM and subsequent testing of a disjunct iSPM against the gSPM.

3.2.: "workflow nets" and "workflow schemata" are not introduced.

It was changed to "The models were mapped onto workflow nets, a dialect of petri nets, as workflow execution templates ..."

3.2.: please quantify the "reduced workload"

The sentence was changed to "is expected to reduce the workload". The study is ongoing.

You are ignoring the main problem in intraoperative workflow support: The detection of the surgical work step or the effort needed for recording. You should mention this critically, either in 3.2 or in the conclusion.

I disagree. I do not longer consider this to be a problem. We sniff the communication bus protocol of the integrated OR an infer the current process state from that.

4: Heading "Summary": I would prefer a "conclusion" since the "abstract" is already a summary. And what you are writing is closer to a conclusion then to a summary.

The section was renamed to Conclusion.

The first two paragraphs are repetitions of the introduction and shall be deleted (or moved to introduction)

The two paragraphs were moved to the introduction.

Ref [21] is incomplete Ref [23] has encoding problems The paper should be proofread again, there are several typos (e.g. surgerly, processual,

That was fixed

Again, thank you for your valuable comments.

Reviewers' Comments to Revision

Reviewer 1: Markus Kleemann

Mar 29, 2017

Reviewer Recommendation Term:	Accept
Overall Reviewer Manuscript Rating:	70

Custom Review Questions	**Response**
Is the subject area appropriate for you?	3
Does the title clearly reflect the paper's content?	4
Does the abstract clearly reflect the paper's content?	4
Do the keywords clearly reflect the paper's content?	4
Does the introduction present the problem clearly?	4
Are the results/conclusions justified?	4
How comprehensive and up-to-date is the subject matter presented?	5 - High/Yes
How adequate is the data presentation?	4
Are units and terminology used correctly?	5 - High/Yes
Is the number of cases adequate?	N/A
Are the experimental methods/clinical studies adequate?	N/A
Is the length appropriate in relation to the content?	4
Does the reader get new insights from the article?	4
Please rate the practical significance.	2
Please rate the accuracy of methods.	N/A
Please rate the statistical evaluation and quality control.	N/A
Please rate the appropriateness of the figures and tables.	4
Please rate the appropriateness of the references.	4
Please evaluate the writing style and use of language.	4
Please judge the overall scientific quality of the manuscript.	4
Are you willing to review the revision of this manuscript?	Yes

Comments to Authors:

thank you very much for revising the manuscript. Nevertheless I still miss a concrete surgical process improvement based on a real surgical procedure and the theoretical background may probably not be easy to adopt for surgical Readers, I suggest to accept the manuscript. The intention of Innovative Surgical Sciences is to bring new technologies and methods to clinical surgeons. Following this Intention, your paper brings the theoretical background of surgical process modelling from the point of an engineer to the surgeon.

Reviewer 2: Oliver Burgert

Mar 03, 2017

Reviewer Recommendation Term:	Accept
Overall Reviewer Manuscript Rating:	90

Custom Review Questions	**Response**
Is the subject area appropriate for you?	5 - High/Yes
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Does the abstract clearly reflect the paper's content?	3

Do the keywords clearly reflect the paper's content?	5 - High/Yes
Does the introduction present the problem clearly?	5 - High/Yes
Are the results/conclusions justified?	4
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Is the length appropriate in relation to the content?	5 - High/Yes
Does the reader get new insights from the article?	5 - High/Yes
Please rate the practical significance.	4
Please rate the accuracy of methods.	5 - High/Yes
Please rate the statistical evaluation and quality control.	N/A
Please rate the appropriateness of the figures and tables.	5 - High/Yes
Please rate the appropriateness of the references.	5 - High/Yes
Please evaluate the writing style and use of language.	4
Please judge the overall scientific quality of the manuscript.	5 - High/Yes
Are you willing to review the revision of this manuscript?	Yes

Comments to Authors:
Thanks for including the remarks in the final paper - this is a nice overview paper.
The issue regarding the abstract should be discussed with the editor.