From Theory to Practice: Surgical Process Modeling and Technological Integration

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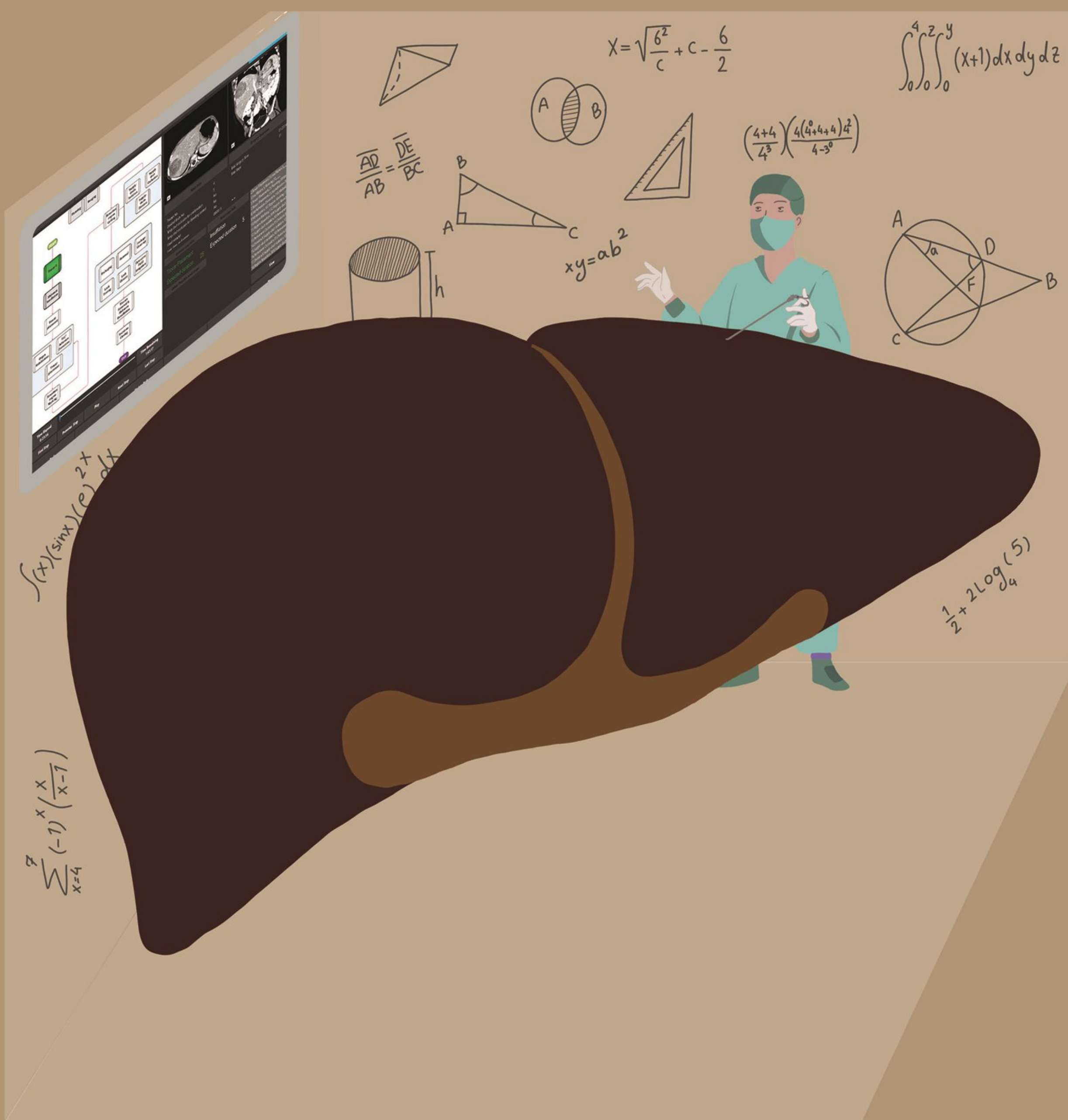

Maryam Gholinejad

From Theory to Practice: Surgical Process Modeling and Technological Integration

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Dissertation

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Dedicated to my beloved husband, who holds the key to my heart, Hadi.
This thesis is dedicated to you, my constant wellspring of inspiration and the love of my life.

Dedicated to my dearest mother, Foroogh.
Your love, sacrifices, and dedication to my well-being have shaped me into the person I am today.

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Chapter 1: Introduction

1.1. Computer-based technologies and surgical process models in the operating rooms

Safe surgery depends on several key parameters, such as the surgeon's experience [1], proper surgical planning and execution [2], and possessing the right information for decision-making. Nowadays, as a result of the introduction of advanced technologies and tools, treatment procedures have become more and more complex, involving complex logistics, much technology, and large teams. Furthermore, procedures are also highly dependent on various factors, such as the surgeon's skills and preferences and patient-specific properties, including patient health condition and clinical history, as well as type, location, number, and size of the treatment areas. These variations make each surgical procedure unique, which adds to the inherent complexity of surgeries and consequently to the complexity of their improvement. To improve upon these challenges at different stages of surgery, various disciplines need to work together [3]. Surgical improvements could be achieved at an early stage by proper training and education of surgeons or at a later stage by efficient surgical planning and, finally, by guiding surgeons during the actual act of performing surgical tasks in the operating room (OR).

Computer-based technology and artificial intelligence (AI) solutions have revolutionized surgeries in the last decades. These technologies are expanding their footprint in clinical systems ranging from clinical databases to intra-operative video analysis for assisting clinical teams [24-26]. Information obtained from the analysis of surgical procedures can help new technologies to be developed for effective use in surgical practice. Therefore, the concern of finding the procedural coherence of complex surgical procedures and obtaining a profound qualitative and quantitative understanding of the relations between different surgical procedures has led to starting methodical analyses of surgical procedures in 2001 [4]. Since then, surgical process models (SPMs) have increasingly been studied to grasp an understanding of various procedures and to attempt to improve their efficiency, efficacy, or quality. Surgical process modelling is a key discipline that could fulfil challenges at different stages toward performing a safe surgery: SPMs have been used in studies for various purposes, such as surgeon skills evaluation and training [5-8], analysing clinical team workload [9, 10] optimization of operating room (OR) management [11-13], the introduction of new technologies [14-16], predicting next surgical task [17-20], and predicting surgery duration [21-23].

The introduction of new technological solutions using surgical process modelling techniques may open up a new avenue for overcoming a broad range of challenges in pre-operative, intra-operative and post-operative phases:

- **Pre-operative preparation and learning phase:** Improving surgeons' training, education and evaluation, by proper user-interaction and visualization of useful information and surgical data from SPMs.
- **Intra-operative and treatment phase:** Improving surgeons' intra-operative performance by aiding surgeons in pre/intra-operative surgical planning and guiding surgeons by suggesting suitable surgical actions and presenting procedural advice.
- **Post-operative control phase:** Improving post-operative surgical tasks by aiding surgeons in post-operative surgery control through enabling playback and review of the entire procedure.

1.2. Research questions and approach

To improve the surgical procedures and overcome the aforementioned challenges, in this thesis, we particularly seek solutions to achieve the abovementioned challenges and to realize such applications of surgical process modelling techniques combined with computer-based technologies. Several questions are addressed of which the main ones are:

- What are the key parameters in surgical process models establishment?
- How can these key parameters be used to model a complex surgical procedures?

- How can the intra-operative surgical steps be predicted by using SPMs?
- How can SPMs benefit the assessment of training sessions in the OR?
- How can a computer-based surgical platform affect the pre-operative learning and intra-operative guiding of surgeons by employing SPMs?

1.3. Guide through this thesis

The goal of this thesis was to structure the strategies in surgical process modelling and use SPMs with computer-based technologies to address several challenges in different surgery phases. These challenges include surgeons' training, education, introduction of new technology and tools, surgery planning, prediction of surgical activities and surgery outcome, and intra-operative guidance of surgeons. Each chapter is based on a published or submitted/ready-to-submit article and is self-contained. Thus, some overlap between chapters might be found. This thesis is composed of three parts:

Part A: Establishment of Surgical Process Modelling

We start with the description of surgical process modelling techniques in Chapter 2. A systematic literature review method is used to survey the available literature. Different strategies and parameters are discussed to provide a guideline for the researchers to opt for suitable modelling strategies tailored for each specific study.

In Chapter 3, the strategies depicted in Chapter 2 are used to establish the generic process model of minimally invasive liver treatment (MILT), compatible with computer simulation studies. The proposed process model was verified through qualitative and quantitative methods, confirming that it covers the variations in performing MILT.

Part B: Applications of Computer-based technologies and Surgical Process Modelling

Chapter 4 revolves around the application of SPMs on finding the *possible sequence of events* in laparoscopic liver resection. The possible sequence of events was discovered, depending on the location of the tumor. Furthermore, with the help of a discreet event simulation model, the *impact of the* *introduction of new technologies*, i.e. here a new navigation platform, on LLR was predicted.

In Chapter 5, the application of SPMs in *surgeons' training* assessment with a newly introduced visualization technology is studied. Microsurgical training sessions on a brain phantom were designed and carried out with surgeons with different levels of experience.

In Chapter 6, a novel platform, named Generic Surgery Analysis Platform (GSAP) is presented to address the challenges in improving the surgeries. The platform enables the improvement of surgeries by taking advantage of surgical process models (SPMs) and the information in surgical videos. GSAP provides an organized storage/retrieval system for training and surgery videos and their corresponding analysis. GSAP introduces new approaches for improving the training of surgeons, evaluating surgeries and surgeons' performance, pre/intra-operative planning of surgeries, and guidance of surgeons during operation.

Part C: Discussions & Conclusions

Chapter 7 provides an overall discussion over the other chapters, summarizes the main findings and provides an outlook to further studies.

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PART A:
Establishment of Surgical Process Models

Chapter 2: Surgical process modelling strategies: Which method to choose for determining workflow?[1]

Abstract

The vital role of surgeries in healthcare requires a constant attention to improvement. Surgical process modelling is an innovative and rather recently introduced approach for tackling the issues in today's complex surgeries. This modelling field is very challenging and still under development, therefore, it is not always clear which modelling strategy would best fit the needs in which situations. The aim of this study was to provide a guide for matching the choice of modelling strategies for determining surgical workflows. In this work, the concepts associated with surgical process modelling are described, aiming to clarify them and to promote their use in future studies. The relationship of these concepts and the possible combinations of the suitable approaches for modelling strategies are elaborated and the criteria for opting for the proper modelling strategy are discussed.

2.1. Introduction

Improvement of the surgical and interventional procedures for treatment of different diseases is a worldwide constant goal of various researchers with different expertise. As a result of introduction of advanced technologies and tools, treatment procedures have become more and more complex, involving complex logistics, much technology, and large teams. Furthermore, procedures are also highly dependent on various factors, such as: the surgeon skills and preferences and patient specific properties, including patient health

[1] The contents of this chapter have been adopted from M. Gholinejad, A.J. Loeve, J. Dankelman, "Surgical process modeling strategies: which method to choose for determining workflow?", *Minimally Invasive Therapy & Allied Technologies* 28.2 (2019): 91-104.

condition and clinical history, and type, location, number and size of the treatment areas. These variations make each surgical procedure unique, which adds to the inherent complexity of surgeries and consequently to their improvement.

Due to surgical uniqueness and complexities, attempts for improvement of surgical procedures by development of e.g. artificial intelligence (AI), new devices, etc., and enhancement of surgical team skills might be inefficient or remain unused in clinical practice as it is difficult to find the true bottlenecks and parameters for improvement. As a part of these developments, in recent years employment of the Artificial Intelligence (AI) in the operating rooms has attracted attentions. AI is a challenging field that has the potential to improve surgical procedures, either via surgeon feedback or by automating technical tasks in the operating room. In both cases, machine learning (ML) can aid to make highly reliable decisions in real-time, and to perform tasks by surgeon properly. Data is the foundation for ML, however, the complexity of surgical treatments make interpretation and management of the huge amount of data difficult. Dividing a surgical procedure into a sequence of identifiable and meaningful tasks aids improvement of different aspects of ML, including data acquisition, data storage, data analysis, etc.

The concern of finding the structural coherence of complex surgical procedures and obtaining profound qualitative and quantitative understanding of the relations between different surgical procedures has resulted in the start of methodical analyses of surgical procedures in 2001 [1]. Since then, surgical process models have increasingly been studied to grasp an understanding of various procedures and to attempt improving their efficiency, efficacy or quality. Different methods of AI can greatly benefit modelling of surgical procedures. These methods, including ML, artificial neural networks, computer vision and natural language processing, are used to establish surgical workflows and build surgical process models, as was shown in [2, 3]. Such methods can automate and increase accuracy of different steps of data acquisition, analysis and modelling for a reliable process modelling. They also provides input for human designers to clearly visualize workflows, making easy-to-interpret models and visualizing relations and patterns between extensive sets of actions and decisions. So far, different studies have aimed at the investigation of employing surgical procedure models for various purposes, such as surgeon skills evaluation and training [4-8], analysing clinical team workload [9, 10] optimization of operating room (OR) management [11-13], introduction of new technologies [14-16], predicting next surgical task [17, 18], and predicting surgery duration [19, 20].

Two previous review papers [21, 22], cover the relevant concepts of surgical process modelling. However, due to the complexity of the field, the dependencies between these concepts and the criteria for selection of the most suitable modelling strategy are not clear. The aim of this chapter is to provide a guide on how to select the best strategy for modelling surgical procedures. Therefore, we will provide essential details of different modelling concepts that should be considered, when attempting to conduct surgical process analyses. Moreover, a new classification of the possible combinations of the involved concepts in surgical process modelling is provided to show how the selection depend on each other. Finally, an application of the modelling strategies in a clinical study demonstrates how the presented concepts can be used in real studies.

2.2. Methods

A literature search was carried out in Scopus [www.scopus.com]. Keywords and their synonyms and alternative spellings were included in the search by using Boolean operators and wildcard characters. The search query used to search titles and abstracts was: ((*surg** OR *therap** OR *"operating room"*) AND (*"workflow analysis"* OR *"process model*"* OR *"workflow model*"* OR *"hierarchical decomposition*"*)) OR "*surgical ontology*". As some terminology are common between different fields or have different meanings, the terms "animal" and "surge" were excluded from the search query. The search included in English written articles and conference proceedings between January 2000 and 1st August 2018.

Inclusion criteria were defined to limit to studies that focused on any attempt aiding to extract the sequential pattern of surgical tasks in the operating room. The inclusion criteria were used to select the publications first based on their title and then on their abstracts. Extra sources were added from the references of the selected publications (backward snowballing). Moreover, relevant publications from the same authors were also considered as extra sources. As a result, a total of 168 publications were selected. Because of the limited number of references allowed by the journal, only the most relevant references were selected per presented concept as examples of groups of references with similar focus/approach. Figure 2.1 shows the result of literature selection procedure.

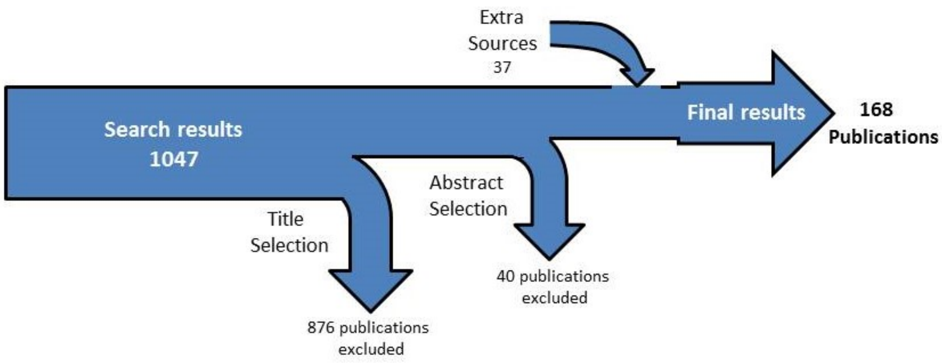

Figure 2.1: Literature selection procedure and results.

2.3. Modelling strategies

A surgical procedure can be defined as a set of sequential and parallel activities, executed by clinical and technical team members with different expertise, through preparing and using equipment and tools with the ultimate goal of high-quality treatment of a patient without complications. In 2001, MacKenzie, et. al. [1] for the first time described a surgical procedure as a sequence of steps: a workflow. Later, various researchers worked on modelling surgical procedures, resulting in the introduction of new modelling strategies, each with its own specifications, advantages and limitations. These modelling strategies are characterized each by their own granularity levels, data acquisition methods, modelling approaches, model representation, modularity design and generalization. An ontology, proper terminology, and definitions for surgical process models, ease the comprehension of models that assist the analysis.

Ontologies, which are explicit and formal descriptions of all the entities of the procedure, largely benefit managing information involved in the surgery. These unique ontologies can be used to assign semantics to data, establish easy-to-interpret models, share information between possible developed software and different studies. Bridging the gap between the field of ontology and surgical process models led to the introduction of different surgical ontologies e.g. [23, 24]. Ontologies reduce the complexity of modelling and increase the model usability and efficiency. The urgency and usefulness of sharable, easy-to-interpret and easy-to-update surgical process models attracts recently particular attention from the expertise in the field to reach a standard and comprehensive ontology in surgical process models [25].

Due to the diversity of modelling strategies, numerous combinations can be used for the procedure analysis. Which combination should be used depends directly on the purpose of the study to be conducted. In the rest of the chapter, we refer to different modelling strategies (granularity levels, data acquisition, model representation, etc.) as different *concepts*. Each concept has different characteristics (manual and computer-based in data acquisition or top-down and bottom-up in modelling approach) and we refer to these as *aspects* of a concept. Aspects can contain different *methods*, such as observation in manual data acquisition or workflow diagrams in numeric model representation.

There are five concepts that need be considered when choosing a workflow modelling approach. These concepts are interconnected and selection of one might affect the choices left for the others. In Table 2.1, the involved concepts are defined, their different aspects are listed, and contributing factors for selection of the proper aspects are proposed. These concepts are further discussed in the following sub-sections.

Table 2.1: Modelling strategies concepts, definitions and dependencies.

Concept	Definition / Aspects	Criteria and dependencies
A) Granularity level	• Description of the procedure at different levels of detail/abstraction. • Low to high	• Purpose of study • Data acquisition
B) Data acquisition	• Acquiring data of surgical procedure for modelling and analysis. • Manual/Computer-based	• Purpose of study • Granularity level • Modelling approach • Benefits and drawbacks • Available equipment and recourses
C) Model representation	• Representation method of modelling surgical procedure • Descriptive/Numeric	• Purpose of study • Data acquisition • Benefits and drawbacks
D) Modelling approach	• Direction of modelling (from low to high granularity levels or vice-versa) • Top-down/Bottom-Up	• Data acquisition • Granularity levels • Benefits and drawbacks
E) Generalization	• Surgical procedure analysis and generalizing the model.	• Purpose of study • Similarity metrics • Statistical analysis • Data mining and data warehousing

2.3.1. Granularity level

The description of a procedure can be done at different levels of detail and abstraction: granularity levels. The concept of granularity levels for description of a surgical procedure was first used by MacKenzie et. al. [1]. They referred to it as a hierarchal decomposition of a surgical procedure and defined the different levels of granularity (from low to high) as “procedure”, “step”, “substep”, “task”, “subtask” and “motion”. Note that more details result in higher granularity level or lower level of abstraction and vice versa. Lalys & Jannin defined different granularity levels as “procedure”, “phase”, “step”, “activity”, “motion” and “low-level information” [22]. Other terminologies are also used for different levels of granularity such as surgical episode [26], surgical deed [27], gesture [28], high level task [2], low level task [19], etc.. Regardless of the specific terminology used for the different granularity levels, there are two factors that determine which granularity levels should best be chosen.

Purpose of the study*:* The level of granularity depends on the aim of study. For example, if evaluation of the performance of an improved surgical instrument for manipulating specific tissue in a surgical procedure is the aim, a high level of granularity is needed. In case the aim of the study is to analyse the effect of the same instrument on the outcome of the entire procedure, less granularity is needed. Lalys & Jannin, in their review paper, defined a phase as ‘a major type of event occurring in the surgery’. However, a major event in a surgery depends on the aim of the study and may be rather subject to preference. If the study aim is to acquire the data at two levels of granularity (e.g. pre-, and post-surgical phases and activities within these phases), one can define the granularity levels as phase and sub-phase, respectively. Therefore, the number of granularity levels is rather arbitrary and depends on how detailed the granularity levels are defined.

Data acquisition: Not all data acquisition methods provide the possibility to achieve all granularity levels. For example if the data acquisition method is based on interviews with a clinical team, only very low granularity levels can be achieved.

The determination of the required granularity levels is a primary step in modelling strategies. If the granularity level is defined properly at the start of modelling, the effort for the remaining steps of modelling decreases tremendously, making the data acquisition and modelling process more efficient.

2.3.2. Data acquisition

Data acquisition of the surgical procedure model can be done manually or computer-based. With manual data acquisition, the data is acquired through observation, available documentation, interviews with experts and literature study. Workflow observations of surgical processes can be done either online e.g. [1, 7, 15] or offline e.g. [1, 15, 29]. In online observation, the observer is present in the OR to record the data and any related information. Online observation has several advantages, including better insight in ergonomics in the OR and the interaction between clinical team members. However, due to large amounts of data and parallel activities in the OR, comprehensive manual online data recording is sometimes impossible and the likelihood of human error in recording the data is high. Offline observation through video recordings of the OR aids to overcome the online observation limitations, but at the cost of losing interaction of the observer with the clinical team. Observation supporting systems have been developed in order to improve the accuracy and completeness of both offline and online observations e.g. [30, 31]. Observations in the OR cannot always provide the required low-level data. Furthermore, these usually lack complete data of the treatment procedure on the patient's organ. In the case of, for example, laparoscopic surgery, there is usually access to the laparoscopic video data, which is a rich source of data with high granularity.

Patient and procedure data documented by the clinical staff as part of their routine can be very valuable in surgical procedure modelling studies, in particular for the collection of preoperative and postoperative data. Interviews with clinical experts e.g. [15, 32] and literature studies particularly provide information for qualitative analysis of the surgical procedure. Figure 2.2 shows the different methods of manual data acquisition and the corresponding benefits and downsides.

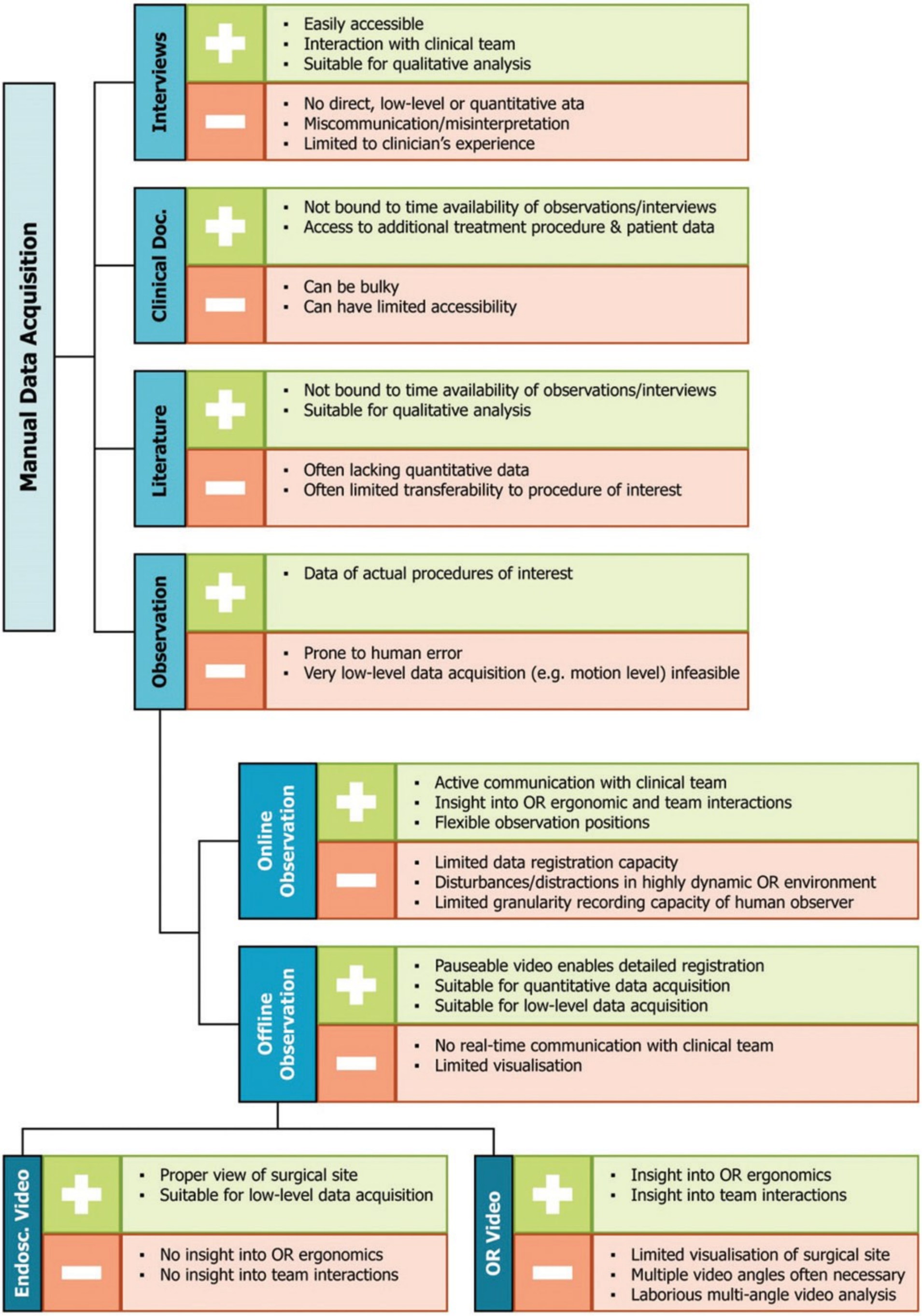

Figure 2.2: Different methods of manual data acquisition and the corresponding benefits (indicated with '+') and drawbacks (indicated with '-').

Computer-based technologies were introduced to automate data acquisition and eliminate human error. Different types of sensors and image processing techniques have been used for data acquisition and tracking of different entities in the OR e.g. [30-38]. The main purpose of using tracking systems is to detect the presence, absence or movements of clinical staff or/and instruments during the operation. The tracking can be done in the OR e.g. [33, 34] or by processing of the videos e.g. [35-37]. Recently, other approaches have emerged, such as an approach based on the combination of video processing and instruments weight [38, 39]. However, the computer-based approaches are not free of pitfalls and limitations either, due to the complexities of the field of surgical process modelling. The first challenge here is that flawless identification of specific task in the surgical procedure based on a signal can be a limiting factor, i.e. the purpose of using an instrument might not be clear based on the acquired signal. For example, a sensor can detect the usage of an electrical surgical knife, however, it does not identify whether it is used to cut the lesion or dissect the fat. Several researchers are focusing on this challenge and try to recognize the related tasks from microscopic, endoscopic and laparoscopic videos e.g. [40-43].

The second corresponding challenge is the development of reliable sensors and tracking systems. The two major tracking systems, optical [44] and electromagnetic [45], each have their own drawbacks and weaknesses. In optical tracking systems, tracking markers must be attached to rigid targets and should always be visible to the tracking system. Therefore, it is difficult to track soft tissues and flexible instruments. Furthermore, these tracking systems do not function if the view is obstructed when the marker is inside the body or when surgeon's hand or clinical team blocks the view [44, 45]. Electromagnetic tracking systems do not suffer from these problems, but their performance deteriorates in the vicinity of metal objects [45]. Apart from tracking systems, useful information may be obtained from several other types of sensors that can be used to monitor patients e.g. [46] or record OR audio and video e.g. [47]. The advantages and disadvantages of the discussed manual and computer-based technologies are summarized in Table 2.2.

Table 2.2 : Benefits and drawbacks of manual and computer-based data acquisition technologies.

	Benefits	Drawbacks
Manual	• Less initial effort for data acquisition (No need to set-up computer-based acquisition systems). • Easier data interpretation. • Acquisition from different sources other than OR (interview, literature study, etc.). • Interactions with clinical team in the OR.	• Time consuming data acquisition. • Not possible to acquire very low-level data (e.g. at the motion level). • Possibility of human error.
Computer-based	• Possibility of acquiring very low-level data. • Precise data acquisition. • Automate data acquisition.	• Time consuming and complex data interpretation. • Possible error in data recording. • Possible error in data interpretation. • Time consuming setting up computer-based acquisition systems. • Usually physical object attached to the tools, clinical team or patient.

Acquiring a comprehensive and solid data set is a crucial step in surgical procedure modelling. An error in the data affects the whole modelled procedure and the underlying analysis. Thus, the selection of proper data acquisition methods is a challenging and crucial step when setting up a clinical workflow study. The choice of data acquisition method highly depends on four aspects:

Purpose of the study: Depending on the purpose of study the questions of '**Who What Which Where When**' are answered to aid proper data acquisition. An example is given to clarify the concept. If evaluation of the performance of an enhanced sealing device for resection of parenchyma is the aim, the performance might be gauged by measuring 1) the total time spent on performing the required resection, and 2) the amount of bleeding to be suctioned by surgeon. For the time registration, the required data is determined as following: **Who**: Not important, **What**: Resection time (cut, suction and coagulation), **Which**: Sealing device, **Where**: Parenchyma, **When**: From when resection start until end. For the bleeding amount the questions are answered as follows: **Who**: Surgeon, **What**: Suction, **Which**:

Sealing device, **Where**: Parenchyma, **When**: During the total duration of suction.

Granularity level: Data acquisition and granularity levels are interconnected. Data acquisition is done based on how detailed the granularity is defined and to which level the data is required. For example if a level of granularity as high as recording the spatial motion of a surgical instrument is required, manual data acquisition is not an option.

Modelling approach: The choice of modelling approach can affect the choice of data acquisition methods, e.g. if a top-down approach is used, only manual data acquisitions are likely to be suitable.

Benefits and drawback of the available methods: See Figure 2.1 and Table 2.2.

2.3.3. Model representation

The way a description of a surgical process model is represented largely determines how and how easy the results can be interpreted and used for further work. Model representations can be categorized as descriptive or as numerical. In **descriptive representations**, the behaviour of a system is described using plain text as a list of encountered activities e.g. [2, 48, 49], surgical milestones e.g. [50], etc.. In **numeric representation** the behaviour of a system is modelled using numbers, mathematical relations or programming languages. Any type of formal (e.g. Petri net, CSP) e.g. [51] and semiformal (e.g. XML, UML) e.g. [14, 27, 52] languages, business process languages (e.g. BPMN, BPEL) e.g. [53], workflow diagrams e.g. [15, 54] and workflow modelling language (e.g. YAWL) e.g. [55] is categorized as a numeric representation. The choice of model representation depends on:

Purpose of the study: Purpose of study determines how and to what extent qualitative or quantitative analysis of the surgical procedure is required. As each model representation provide different possibilities for analysis, the proper model representation should be selected in line with the purpose of study.

***Data acquisition method*:** Numeric representations can be based on both manual and computer-based data acquisition, whereas descriptive representations are usually based on manual data acquisition.

Benefits and drawbacks of different model representations: Descriptive representations are usually easier to comprehend and easier accessible, but they often need to be accompanied by numeric representations for further analysis. The relation between the entities in a workflow are not fully provided in the descriptive representations. On the other hand, numeric representations provide the detailed relations between entities and provide the means for simulations and qualitative analyses, but at the cost of reduced flexibility and great initial efforts.

2.3.4. Modelling approach

There are two main approaches for modelling surgical procedures: top-down and bottom-up [21]. Top-down modelling (applied by, e.g. [15, 54]) starts from the highest abstraction level (with lowest granularity) and works down to the lowest abstraction level (with highest granularity). An overview of the entire procedure will first be formulated and the details of the procedure are modelled in increasingly higher levels of granularity, following the desired granularity levels. Bottom-up modelling (applied by, e.g. [2, 19, 40, 43, 56, 57]) starts from the lowest abstraction level (highest granularity) and then up. Low-level data (e.g., from computer-based technologies) is used to extract meaningful data at the desired granularity level. Much like the selection criteria for the aspects discussed above, the selection of a modelling approach depends on:

Data acquisition method: Data acquisition methods differ for top-down and bottom-up approaches. The top-down approach relies on manual data acquisition, whereas the bottom-up approach can receive data both from manual and computer-based technologies. A top-down approach is usually based primarily on manual data acquisition, because computer-based technologies often acquire data primarily at the highest granularity level. In the bottom-up approach, transferring low abstraction level data to high abstraction level information requires conceptual information about the procedure.

Granularity level: Selection of the modelling strategy might be preferred to bottom-up approaches, when modelling requires data at very high granularity level (e.g. biomechanical properties of the tissue). Such low level information is usually obtained from computer-based data acquisition [22].

Benefits and drawbacks: The top-down approach brings understanding of the entire procedure at a high level of abstraction, which reduces the likelihood of inaccurate identification of the lower abstraction activities. However, as the low level data is initially not modelled, the high level tasks might be identified or described inaccurately due to a lack of profound insight in the procedure. The bottom-up approach has the advantage of having a higher resolution in the data gathered at the lowest abstraction and can therefore be more precise. Yet, because in a bottom-up approach a global overview of the procedure is not established at first hand, identifying the high level tasks from very low level information is usually complex and the results might not accurately resemble reality. In top-down approaches, the designer skills and possession of a good overview of the procedure are of great importance to properly break the procedure into meaningful components [21]. However, in bottom-up approach conceptual information about the procedure is sufficient to start the modelling based on the acquired data and selected model representation principles.

2.3.5. Generalization

Each treatment is a unique procedure. In order to develop a generic model that describes a surgical procedure with all its variations, acquiring data from sufficient individual procedures with one or more similar characteristics is necessary. The observation results from individual procedures are combined into a generic model. Depending on the aim of the study, the level of generalization of the model may vary. The heterogeneity of the data collected directly affects generalizability of the resulting model. If the purpose of the study is the analysis of the procedure model of a general treatment method composed of broad ranges of techniques, the data set should contain sufficiently many registrations of sufficiently many differently executed techniques within the procedure to reliably capture all its variations. Furthermore, the patient condition heterogeneity influences the generality of the procedure model; if all patient conditions are similar, the model establishment is most probably biased. Apart from heterogeneity of data, the way the model is analysed also defines the level of generality. Analysis of the model can be aimed at covering either all the events or only the most probable events in the same population of the treatment procedures.

After determining the sequence of activities and modelling each individual procedure, either descriptive or quantitative, through a top-down or a bottom-up approach, the generalization of the procedures can be done by merging the sets of individual models. For merging sets of procedures, similarity metrics need to be taken into account. Neumuth et. al. suggested granularity similarity, content similarity, temporal similarity, transitional similarity, and transition frequency similarity as possible similarity metrics [58]. Statistical analysis can be employed for merging of the individual models when the modelling language supports the quantitative analysis. In statistical analysis the intermittent events can be filtered out or be considered as an event with low probability and the most frequent events forms the backbone of the general process model [21, 57]. Depending on how big the dataset is, data mining and data warehousing techniques may aid the establishment of the generic surgical procedure model [59, 60].

Figure 2.3 is a compact guide for designers of or researchers on surgical process models and demonstrates what aspects of the modelling strategies concepts are compatible with each other and shows how categories of these concepts are related to each other. Depending on the purpose of study and the available resources, the designer can select one of the possible chains of modelling strategies proposed in Figure 2.3.

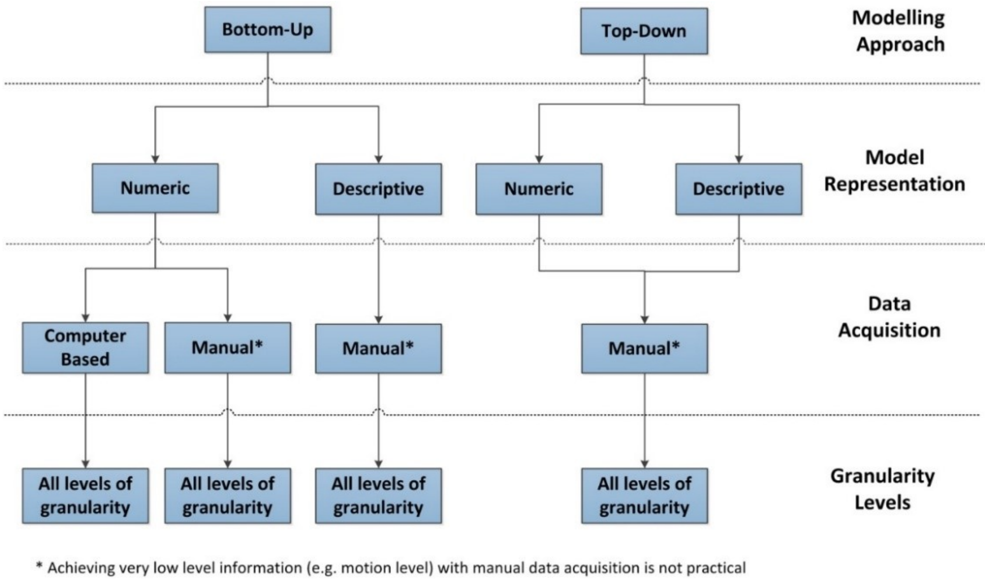

Figure 2.3: Chains of modelling strategies and their compatible aspects.

2.4. Modular design

In order to propose a structured model of a surgical procedure and increase the usability and efficiency of such a model, designing it in a modular way can offer great benefits. In a modular design, a system is composed of components (modules) with specific functionalities. Each module can work independently and interacts with the other modules in the system. Although application of modular design in the development and analysis of a surgical procedure requires great initial design effort, it brings several advantages, such as:

(1) Data acquisition of the desired part of the model is facilitated as each module can be treated separately. In case of observation several observers can work in parallel, while each observer is responsible for one or a few modules for data acquisition. This decreases the workload per person, which results in higher quality data acquisition.
(2) Analysis of the desired part of the model becomes more efficient as each part of the surgical workflow can be modelled with minimal dependency on the other parts. Thus, analysis can easier be focused on individual modules without missing relevant information.
(3) Modules can be used in the description of several types of surgeries when they share the same goal in parts of their procedures.
(4) When using the surgical process model as a basis to improve the surgical procedure, several designers can work in parallel, each responsible for the improved design of one or a few modules.
(5) Updates and changes in the model (because of future technology advancements, etc.) can be easily implemented as the designer only needs to adapt the specific modules or add new modules to the surgical process model.
(6) Testing and error detection are easier because the modules can be treated as black boxes or isolated sub-systems.

2.5. Validation and verification

Any developed surgical workflow model should be verified and validated. Although verification and validation are sometimes interchanged, these are in fact two different concepts. Verification confirms that the model is developed *right*, i.e. it confirms that the developed model reflects the real procedure in clinical practice. On the other hand, validation confirms that the *right* model is developed i.e. it confirms that the developed model suits the purpose of the study and analysis.

The datasets for verification and validation may be obtained from different sources, such as computer simulations, phantoms, simulated OR procedures and real OR data. The data from computer simulations, phantoms and simulated OR procedures provide flexibility at the cost of only delivering artificial data. Data from real OR procedures is more difficult to obtain and less flexible, but it is the data closest to reality.

Qualitative and quantitative approaches can be used for verification and validation. How and to what extent qualitative and quantitative verification and validation are to be carried out may depend on the properties of the developed model. For example, assume that a surgical workflow model is developed which covers an entire treatment procedure and offers the order of the steps in a surgery. Then, a qualitative approach can be used to confirm that all datasets fit the path options offered by the established workflow. Next, a quantitative approach would be applied to confirm that the sum of the individual durations of all workflow elements encountered during a procedure equals the total procedure time [15].

2.6. Example of modelling strategies applied in practice

To show how to use the presented concepts in a real situation, we discuss an envisioned clinical study on evaluation of AI in operating room. The laparoscopic procedure is to be performed in a novel hybrid OR containing a robotic system that supports the task of insertion of trocars. The OR is equipped with a navigation platform consisting of a planning software that assists the surgeon by suggesting suitable locations for trocar insertion. This platform uses machine learning to compare the data of patient conditions with data-sets from previous surgeries to be able to suggest more accurate locations. We would like to analyse the performance of this novel system, evaluate its benefit over conventional manual trocar placement and determine how we can efficiently improve the system for clinical use. The locations of the incisions for the trocars should be planned depending on the target organ, where the tumour is located in the organ and other limitations, such as patient physical condition and clinical history. It is important that clinicians can be easily involved for validation of the workflow and in the decision-making for further improvement of the technology in the system or the workflow for using the system. In order to analyse the effect of this system on the procedure, several research questions should be answered, and some of them quantitatively:

Q1 - How does the system affect the outcome of laparoscopic surgery?
Q2 - Does the system benefit insertion of trocars? If so, to what extent?
Q3 - Which activities in performing trocar insertion are affected by this system? How large is the effect?
Q4 - Are there any effects of this system on other actions in the procedure? If so, in which actions and to what extent?
Q5- Can usage of system be improved to achieve better outcome of the procedure? Which actions are useful to be improved? How those actions are optimised? And how much is the effect of the improvement on the procedure?

These questions may individually require different modelling strategies, as described next.

A) Granularity level: For each of the research questions stated above, the optimal granularity may vary:

A1 - As the effect of the system on the entire procedure is needed, the granularity level is defined very low, at the level of the entire procedure.

A2 - Purpose of the study is evaluation of the outcome of insertion of trocars when the system is in use. Therefore, insertion of trocars can be treated as a black box step composed of several activities sharing the same goal, but with only its end result being of importance. Therefore, an "inserting trocars" step is defined, and the granularity level is chosen at the step level.

A3 - The robotic system and navigation platform affect the physical activities and planning involved with insertion of trocars. In order to determine the influenced activities and the extent of influence, a more detailed granularity level than in 1 and 2 is required. If the effect of using robotic arms in performing the tasks on the biomechanical properties of the tissue is required, a very high granularity level is selected. If the impact of using the system on the duration of planning is needed, a lower granularity level is sufficient.

A4 - Depending on how abstract all actions are defined in the procedure, different granularity levels (very high until entire procedure) could be suitable. However, in its broadest formulation, a very high granularity level is required, with maximum detail and knowledge of all detailed actions and decisions in this procedure.

A5 - The system can be improved either through technical developments or by improving the flow of the system usage during the procedure in clinical practice. Different granularity levels can be determined in analysing which actions can be improved, how and how much. Furthermore, the analysis of the effects of the improvement on the system can be done on all activities in the procedure (as discussed in A4), or only focuses on the set of activities for inserting trocars (like in A2 and A3).

Based on the arguments above, the granularity levels which we would choose in this study are shown in Figure 2.4.

Figure 2.4: Granularity levels used in the study, from lowest level to highest level, from left to right, respectively.

B) Data acquisition: Data acquisition is dictated by the aim of the study, available resources and the benefits and drawbacks of each method. In this study, data acquisition can be selected as computer based or manual. However, as the manual data acquisition is more readily available and the required granularity level is reachable by manual data acquisition as well, we opt for manual data collection.

C) Model representation: For the quantitative analysis of the workflow, numeric modelling is required. Workflow diagrams can be used for a numeric representation. Workflow diagrams are flexible, the relations between the actions are provided and the model is more understandable for involved experts with different backgrounds (e.g. medical doctors and engineers). Modelling the relationships between different entities of the procedure, which is provided in the workflow diagrams, is a point of great use in such a study. These relationships aid analysis of the system improvement by performing simulations to enhance the flow of usage of the system and its development. When the relationships are modelled, supervised machine learning can also be efficiently done by the navigation system for data collection and data analysis.

D) Modelling approach: As the required granularity level is not very high and we are looking at a specific task (inserting the trocars), it is more natural to first set the boundaries for the inserting trocars step and from there work down in the levels of abstraction: top-down approach.

E) Generalization: Based on the defined granularity levels, selected model representation principles and modeling approach (A, C and D), and the data acquired by the selected data acuqisition methods (B), each of the entitled procedures are analysed. In generalization, the individual procedures can be analysed and then combined into a generic model. However, in top-down approach as the procedure is mostly formulated based on overview of the designer, that is not mandatory to model individual procedures to establish the generic model. Based on the similarity metrics, the model representations principles and the defined granularity levels, the generalization process is specified. In this study as the aim is to anaylse the effect of the system on the procedure, infrequent tasks are usefull to be considered in generalization process.

So far, the proper modeling strategies is selected. The data acquired from the selected data acqusition method and proper analysis are used to establishe surgical process models. In this show-case, we acquired data from Oslo Unversity Hospital, Norway (OUH) and Erasmus Medical Center (Erasmus MC), The Netherlands, to establish the workflow of laparascopic liver surgery, see Figure 2.5.

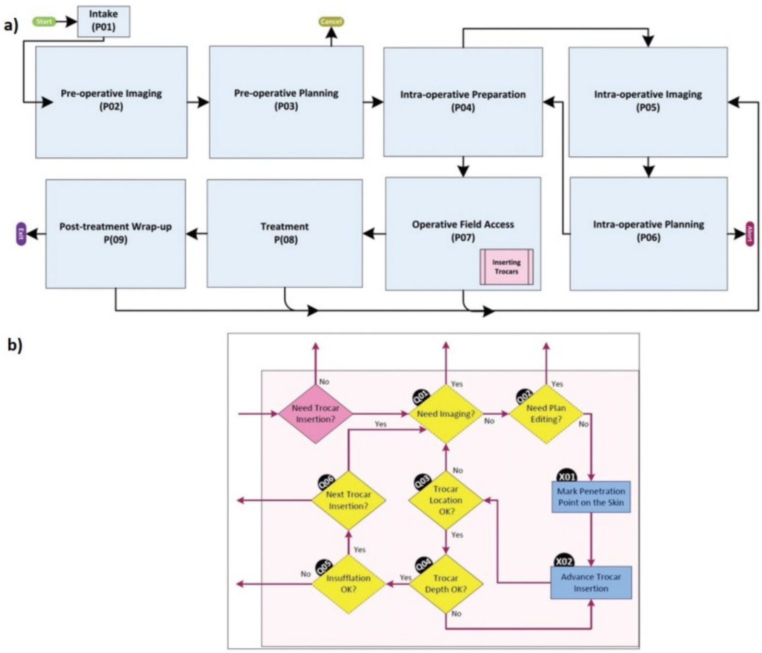

Figure 2.5: Workflow diagram of the laparoscopic surgery (a) at phase level and (b) at activity level for the "inserting trocars". The data was obtained from online and offline observations in OUH and Erasmus MC.

In this study, verification and validation both can be done based data and/or by interviewing experts. However, verification and validation should be taken care of differently:

Verification: The clinical team experience and the data from different sources (e.g. real procedures, phantom or simulations) will aid verifying that the model resembles the clinical performance. Depending on the granularity levels and the entities definitions, the data should be acquired and registered for each and every entity of the procedure to be used for quantitative and qualitative verification.

Validation: Validation confirms that the developed model suits the purpose of the study and analysis. Answering the questions 1 to 5 above requires being able of quantitatively analysis of the modelled procedure and the possible corresponding simulations. The entire logic of the modelling can be tested and validated by data from different resources or generated artificial data for different entities of the procedure. In contrast to verification, in validation the data may not be necessary for all entities when the same logics are used for the model. Validation can be done by experienced researcher in the field of surgical process modelling.

2.7. Discussion

The aim of this review-based guide was to aid selecting the proper modelling strategies depending on the purpose of analysis and the surgical procedures to be studied. Different relevant concepts in surgical modelling strategies and the criteria for selecting the most suitable modelling strategies for a study were described. For each of the involved concepts, the benefits and drawbacks, and dependencies of the aspects in different concepts to each other were explained in a step-wise manner (Table 2.2).

The current study was limited to process modelling in the surgical field, whereas workflow modelling approaches in other fields may very well offer valuable additions. Furthermore, employing AI in surgical process modelling was discussed, however how to employ AI in the field of analysis of surgical procedures should be investigated in more detail. However, within the bounds and limitations of this study it was shown that the selections of the proposed aspects in modelling approach are independent of choices in model representation (Figure 2.4). Top-down and bottom-up approaches can both use descriptive and numeric representations and vice-versa. On the other hand, selection of a modelling approach and model representation can depend on the data acquisition (and vice-versa); e.g. computer based data acquisition normally works with bottom-up modelling [22] and numeric representation, and top-down approaches and descriptive representation can normally work with the data from manual acquisition methods. Different granularity levels can be acquired from different combinations of concepts. However, there are limitations: for example, using a manual approach is mostly not very practical in combination with high granularity levels.

The presented benefits and drawbacks of different methods for data acquisition shown in Figure 2.2 and Table 2.2, can be used during workflow study design for proper selection of combinations of modelling approaches and model representations. Overall, selection of the proper modelling strategy is primarily dictated by the aim of the study and the available resources. However, the concepts are interconnected and the selection of one aspect affects the selection of the others. Being aware of the benefits and drawbacks of each aspect can aid selection of the most suitable modelling strategy for satisfying the aim of the modelling study.

2.8. Conclusion

Surgical process modelling is an innovative approach to establish a firm base for analysis of various aspects of surgical procedures and paves the way for further optimization and improvement of the procedures. Surgical process modelling allows for evaluating the introduction of new technologies and tools prior to the actual development and is beneficial in optimization of the treatment planning and treatment performance in operating room. This potentially saves considerable cost and effort compared to trial and error development. Therefore, surgical process modelling can potentially aid development of technologies and tools to satisfy the requirements of actual usage experience in the clinical practice.

Concepts underlying surgical procedure modelling were discussed and different modelling strategies clarified. The advantages and disadvantages of these strategies and their corresponding methods were discussed. The criteria of selecting and using the most suitable modelling strategy were explained and clarified through examples. The purpose of a study largely determines the selection of the most suitable modelling strategy.

AI benefits surgical process modelling and also can benefit from surgical process models. In this study we provided an example of how the required analysis for surgical process modelling could be done and discussed how evaluation of AI in the operating room can be performed by employing surgical process modelling concepts.

We discussed how the selection of modelling strategies can be aided by applying the provided criteria. Applying modularity may facilitate and improve the efficiency of surgical process modelling studies and subsequent updates and analyses. Combinations of top-down and bottom-up approaches for establishing a surgical process model allows taking advantage of the strengths of both modelling approaches. Similarly, different data acquisition methods could be combined to overcome their individual limitations, achieving a solid, accurate and efficient data base. Overall, the current review illuminates the importance of surgical process modelling for improving different aspects of treatment procedures and provides an overview of various modelling strategies that can be used to establish surgical process models.

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Chapter 3: Generic surgical process model for minimally invasive liver treatment methods[2]

Abstract

Surgical process modelling is an innovative approach that aims to simplify the challenges involved in improving surgeries through quantitative analysis of a well-established model of surgical activities. In this chapter, surgical process model strategies are applied for the analysis of different Minimally Invasive Liver Treatments (MILTs), including ablation and surgical resection of the liver lesions. Moreover, a generic surgical process model for these differences in MILTs is introduced. The generic surgical process model was established at three different granularity levels. The generic process model, encompassing thirteen phases, was verified against videos of MILT procedures and interviews with surgeons. The established model covers all the surgical and interventional activities and the connections between them and provides a foundation for extensive quantitative analysis and simulations of MILT procedures for improving computer-assisted surgery systems, surgeon training and evaluation, surgeon guidance and planning systems and evaluation of new technologies.

3.1. Introduction

For many years, surgery has been considered an art, treating surgery as an artist-driven process. This agrees with the fact that many of the processes during surgery are processed mentally inside the artist's/surgeon's brain. To

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[2] The contents of this chapter have been adopted from M. Gholinejad, E. Pelanis, D. Aghayan, Å. A. Fretland, B. Edwin, T. Terkivatan, O. J. Elle, A. J. Loeve & J. Dankelman "Generic surgical process model for minimally invasive liver treatment methods" *Scientific Reports* 12,1 (2022):1-14

better expose this process, expert consensus meetings, national and international guidelines provide generalized recommendations on a high abstraction level based on the pillars of evidence-based medicine. In recent years, with the introduction of new technologies, tools and hybrid operating rooms (ORs), surgeries became increasingly convoluted [1]. Improving these highly complex surgical procedures is a shared concern of experts with different backgrounds.. However, without a solid knowledge of these treatment processes, they can hardly be improved [2].

In surgical process modelling, surgeries are treated not as an artist-driven process but as a sequence of tasks and steps that are followed by the clinical team [3], which can support analysis and predicting surgical actions. Analysis of surgical process models can reveal the bottlenecks and potential improvements to the surgeries, aiding further advances [4-9]. Such process models are a great means for finding the structural coherence of complex surgical procedures and for obtaining a profound qualitative and quantitative understanding of the relations within the surgical procedure, its variation parameters and its output parameters [10-13]. Hence, these are great tools for training surgical teams and educating young surgeons.

Minimally Invasive Liver Treatment (MILT) is an example of a procedure were different clinicians use different methods and techniques to treat liver lesions through surgical/interventional liver manipulations when non-surgical methods (non-invasive and chemotherapy treatments) are not adequate. After the introduction in the previous century, minimally invasive approach for liver surgery has only in recent years changed the way how benign and malignant lesions are treated [14, 15]. Although the less invasive nature of MILT compared to open surgeries benefits the patient [16, 17], various challenges that can increase the risk of surgical errors remain, including inadequate visualization of the patient's internal structure, lack of tactile feedback and complex navigation towards target treatment lesions [18, 19]. Moreover, the continuous change of the liver shape and location due to, e.g., pneumoperitoneum, patient respiration and manipulation of the liver during an intervention, add to these challenges [1]. Over the last three decades, a broad range of MILT techniques has been introduced. These techniques can be categorized into three methods: laparoscopic liver resection (LLR) [20-24], laparoscopic liver ablation (LLA) [25-29] and percutaneous ablation (PA) [30-34] and robot-assisted resection [35]. This chapter focuses on the first three categories. As a result, different surgeons and interventionists use different methods and techniques, which can all be executed with large process variations. Furthermore, procedures are further dependent on factors such as:

- medical team skills, experience and preferences
- patient-specific properties, such as patient's body topography, patient health condition and clinical history
- type, size, and location of the treatment areas.

These all add to the inherent complexity of MILT procedures. A detailed generic process model of MILT is crucial for assessing these complexities, educating new surgeons and improving MILT procedures. Yet, to the best of our knowledge, such model has not yet been established. The sole study available on modeling the MILT process is a qualitative study describing radiofrequency percutaneous ablation [36]. Therefore, the aim of this study is to establish a generic surgical process model (or surgical workflow) of MILT that covers the entire procedure for a variety of MILT methods and their corresponding techniques. The proposed generic process model provides the relation between entities and allows quantitative and qualitative studies of surgical procedure. The process model was developed in a modular way to increase its usability and efficiency and to facilitate aspects of data acquisition, analysis and procedure improvement [10, 37-39].

3.2. Methods

This study focuses on three commonly distinguished MILT *methods*. Within each method several variations, referred to as *types*, can be distinguished:

- **Laparoscopic Liver Resection (LLR):** Resecting the necessary region of the liver parenchyma using the minimally invasive approach. Depending on the size and location of the resection region, three *types* of operations can be applied: formal resection [40, 41], anatomical resection [42-44] and atypical resection, also known as parenchyma sparing [45-47].
- **Laparoscopic Liver Ablation (LLA**): Laparoscopic ablation of the tumor by placing one or several needles inside or around the target lesion, aiming to destroy target cells by means of burning, electrifying, freezing, or chemicals. The clinician manipulates the internal structures through small incisions to make the treatment region accessible and to ensure that the treatment is performed on the right location. LLA has

four different *types*: Radiofrequency Ablation (RFA) [32-34, 48], Microwave Ablation (MWA) [48-51], Irreversible Electroporation (IRE) [52], Cryoablation (CA) [53-55] and Ethanol Injection (EI) [56-58].

- **Percutaneous Ablation (PA):** Similar to LLA, but without laparoscopic manipulations and ablation needles are inserted directly through the skin into the treatment area. PA has the same treatment *types* as LLA.

3.2.1. Modeling strategies

To establish a generic process model of MILT, the modeling strategies proposed in our previous work [10] were applied as described below.

Granularity level: The generic process model of MILT was established at three levels of abstraction and granularity, see Figure 3.1:

- ***Procedure***: Considering the entire procedure as a single process, starting from patient intake until the end of the intervention. Highest abstraction level, lowest granularity.
- ***Phase (P)*****:** Contains groups of modules and decisions that all share a goal or purpose. Intermediate abstraction level, intermediate granularity.
- ***Module (M)*****:** A chain of actions and decisions aiming to fulfil a specific goal within a phase. Low abstraction level, high granularity.

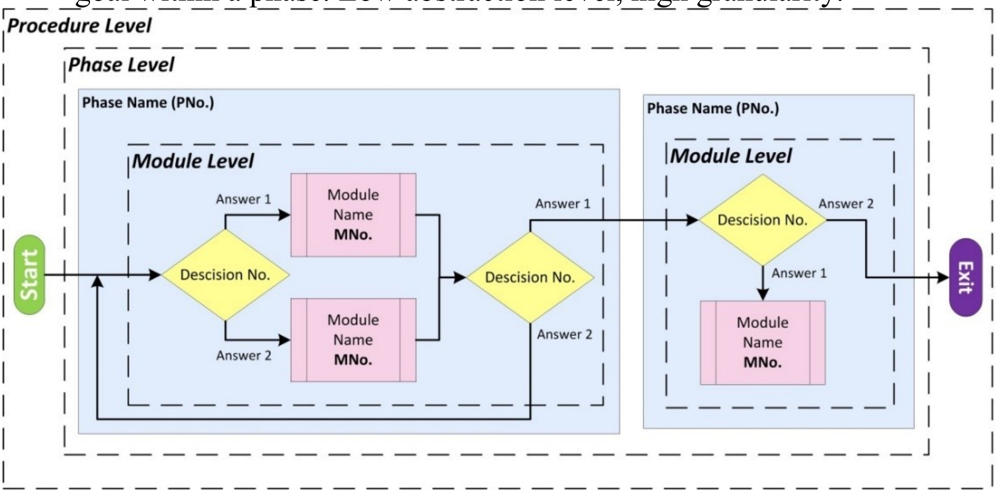

Figure 3.1: Different levels of granularity embodied in the developed surgical process model.

Data acquisition method:

Model design data: Data of the MILT procedures were collected through live observations and offline video observations, literature study and interviews.

The data were acquired from:

- Sixteen live observations at Oslo University Hospital (OUH), Oslo, Norway and Erasmus Medical Center, Rotterdam, Netherlands (Erasmus MC), performed by experienced teams. The live observations were composed of twelve laparoscopic and four ablation treatments.
- Eight interviews with clinical experts at Erasmus MC and OUH.
- Nine offline observations using endoscopic video recordings of laparoscopic liver surgeries and OR recordings of ablation procedures.

The process model was primarily designed based on the live observations in the OR. Interviews with the surgical team members were conducted to verify that the observed procedures were representative for MILT methods in general. To obtain a thorough understanding of surgical methods and to let the teams get used to the observer, the observer also attended several laparoscopic resection procedures of other organs in the aforementioned hospitals. Furthermore, the procedure description of MILT procedures in Refs. [19, 34, 40, 56, 58-66] has been investigated.

Model verification data: After establishing the MILT process model, endoscopic video recordings of laparoscopic liver surgeries of fifteen extra procedures were used for verification. In addition, the author (MG) has attended six intervention sessions in Erasmus MC and Bern University Hospital (BUH).

For final verification, the proposed process model the process model was presented to clinicians and the validity and correctness of the generic process model for different techniques of performing MILT were discussed with the participating clinicians in OUH and Erasmus MC. Example surgical videos were used to discuss how the process model mimics every activities in performing different technics of MILT in clinical practice. Video Marker Software was used to discuss the registered surgical data for the entire duration of sample surgeries over the endoscopic videos.

Ethical approval was obtained from each of the clinical centers in which the data were collected and observations were done for design and verification of the process model (OUH: Regional Ethical Committee of South Eastern Norway- REK Sør-Øst B 2011/1285 and the Data Protection Officer of OUH) and Erasmus MC and BUH with following the hospitals ethical rules). Based on these hospitals rules, informed consents were obtained from patients for further investigation on their surgical procedure. All methods for data acquisition and verification were performed in accordance with the relevant guidelines and regulations of the hospitals.

Modelling approach: A combination of top-down and bottom-up approaches was used to benefit from the advantages of both approaches (see [10]). Based on the data from OR observations, interviews and literature studies, a top-down approach was first used to establish a global overview of the surgical workflow. Next, the endoscopic videos were used as low-level data to model the details of the process model and to improve the initially established general overview bottom-up. This modelling process was iterated until no process model changes resulted from new iterations anymore.

Generalization: Generalization of the MILT process model to LLR, LLA, PA and their different types and techniques should ensure agreement with divergences and differences of the MILT procedures in clinical practice. Therefore, the data for analysis and modelling was acquired in procedures using various MILT types and techniques, with a variety of patient conditions (age, gender, build, clinical history, tumour specification and number, etc.). The individual procedures were merged in the generalization process, covering all events of the treatments and not only the most probable events.

Model representation: The generic MILT process model was concretized by using workflow and process model diagrams. The process model was made to have a modular structure to increase model usability and efficiency [10].

3.2.2. Verification

Qualitative and quantitative verifications were done to confirm that the proposed generic process model of MILT reflects the procedure in clinical practice:

- **Qualitative verification** was performed to confirm that the path options in the established process model fit any observed order of possible actions and decisions occurring during MILT in clinical practice. This was done by registering the sequence of the encountered process model elements (phases and modules) throughout the entire treatment procedure of fifteen offline observation of MILT procedures from OUH. In addition, the author (MG) has attended four intervention sessions at Bern University Hospital and two at Erasmus MC. Furthermore, interviews with clinical teams were done and the process model was discussed with highly experienced surgeons with at least 10 years of surgical experience in OUH and Erasmus MC.

- **Quantitative verification** was performed to confirm that the sum of the encountered workflow elements (phases, modules) duration was equivalent to the total procedure times of fifteen offline MILT procedures from OUH.

As each treatment procedure can be composed of thousands of steps, in-house process model data registration software was developed to facilitate registration of data on the videos of the endoscopic camera (Figure 3.2).

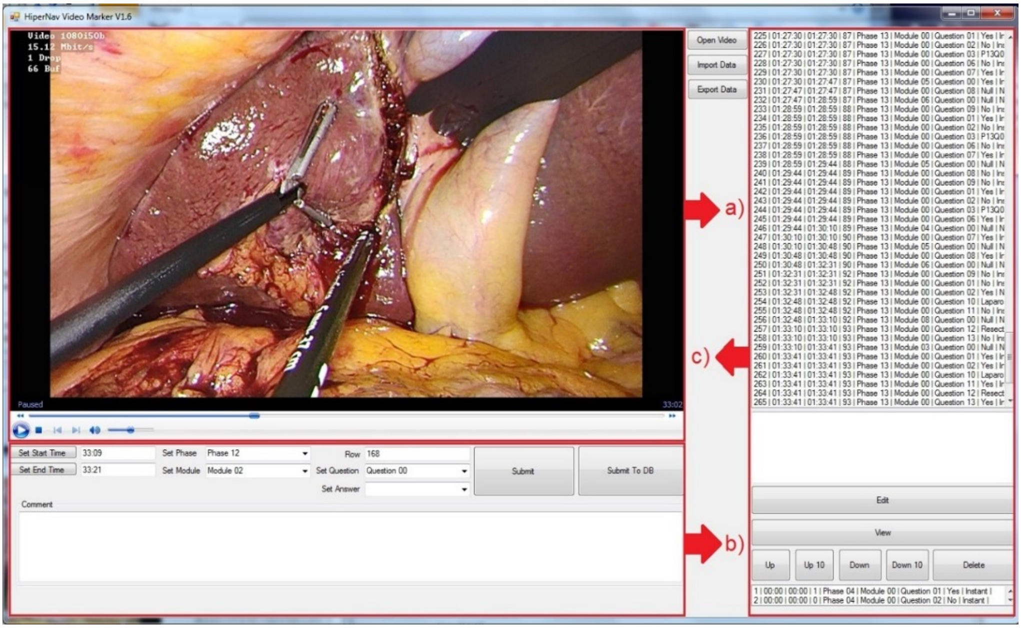

Figure 3.2: A snapshot of the developed process model data registration software (DOI: 10.4121/20163926). The software comprises three main sections: a) endoscopic video player, b) data registration panel to register data at the desired granularity level, locally or in the data-base and c) registered data management.

3.3. Results

4.2.1. Workflow phases

Within the MILT treatment procedure, including its preparations, three hierarchical sub-phases are distinguished clinically:

- **Operation:** the entire process **in the OR**, from when OR and patient are being prepared, until when the patient is moved out of the OR to the recovery room.
- **Intervention:** starts with the first ablation needle manipulation or first incision in the abdomen by the interventionist/surgeon and ends when the last incision is closed.
- **Surgery:** starts with the first incision in the abdomen by the surgeon and ends when the last incision has been closed.
- **Treatment:** the actual physical treatment (resection or ablation) of the target region.

The generic process model of MILT procedures at the lowest granularity level (highest abstraction) is displayed in Figure 3.3, showing all phases The individual phases are explained below:

Phase 01: **Intake** - The patient is admitted to the hospital and complete anamnesis is collected.

Phase 02: **Pre-operative Imaging** - Medical images of the abdominal region are made for planning the MILT procedure prior to a possible operation. Phase 02 can take place right before operation up to a few months prior.

Phase 03: **Pre-operative Planning** - Planning includes all decisions about things like treatment approach, incision locations and resection paths or possible needle placements, size of the target region, etc. prior to the possible operation. The planning is based on the patient anamnesis (from Phase 01), medical images (from Phase 02), available equipment and technical resources and experiences.

Phase 04: **Intra-operative Preparation** - On the day of operation, prior to the intervention, the patient, OR equipment and surgical instruments are prepared for the operation.

Phase 05: **Intra-operative Imaging** - Medical images can be acquired in the OR, before and during the intervention.

Phase 06: **Intra-operative Planning** - The treatment plan can be generated or updated in the OR just before and during the intervention. Any pre-operative data and new images were taken in the OR (from Phase 05) aid in making decisions in this phase. The MILT *method* and *type* might also be changed during the operation. The MILT procedure is considered aborted if it is converted to a non-MILT procedure, such as open surgery.

Phase 07: **Operative field Access** - If LLR or LLA is the preferred method, the surgeon first makes the operative field accessible.

Phase 08a/b: Isolation of the treatment area consists of activities to separate the target region from surrounding structures and prepares the target region for the treatment. Based on the nature of these activities and how they affect the patient's anatomy, isolation can be performed in two ways:

- **Phase 08a:** **Treatment Area Isolation – Destructive** - Isolation by destructive (permanent) dissection or closure of surrounding structures. Only applies to LLR and LLA.

- **Phase 08b:** **Treatment Area Isolation – Non-destructive** - Isolation with temporary effects, using actions such as temporarily closure of vessels or hydro dissection.

Phase 09: **Needle Manipulation** - Maneuvering ablation needle(s) to the desired position.

Phase 10: **Treatment** - The actual treatment of the target region by either resection or ablation.

Phase 11: **Intra-operative Complications** - Handling any complications that might occur during the operation. Such actions may include, for example, blood transfusion and hemostasis (e.g. bleeding vessel ligation) or surgical drainage.

Phase 12: **Miscellaneous** - Other clinical activities that do not directly serve the MILT procedure might take place, such as biopsy and catheter placement.

Phase 13: **Intra-operative Wrap-up** - All activities aimed at wrapping up, such as removal of un-absorbable materials, closing the incisions, etc.

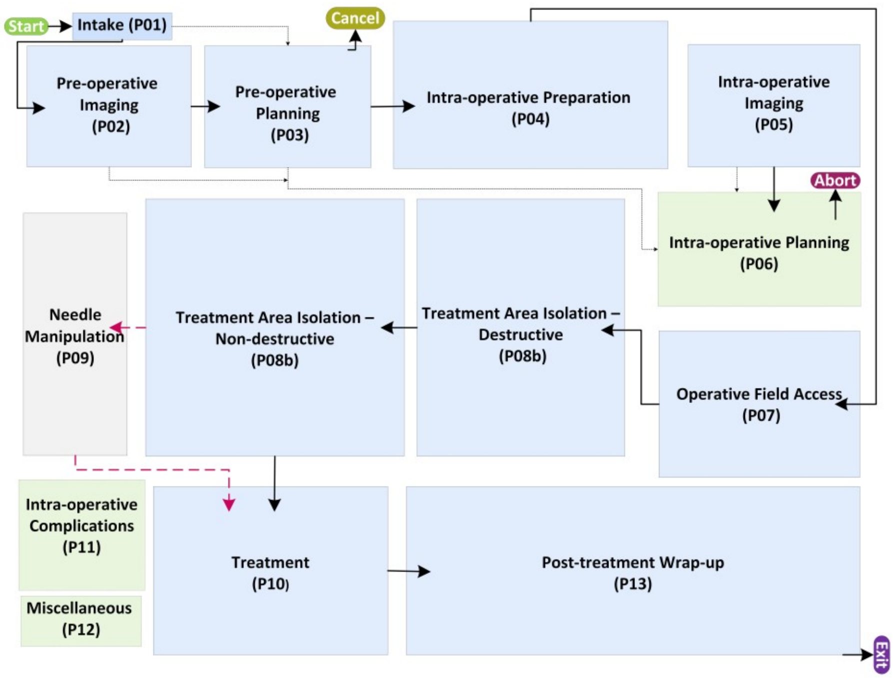

Figure 3.3: Generic process model of MILT at the phase level. Most of the phases are colored blue with solid-line rectangles; these phases are common between ablation and resection procedures. The gray phase, "needle manipulation", is designated only for the ablation procedures. The blue and gray phases are connected by black solid and red dashed arrows showing the flow of activities. The black solid arrows are common between ablation and resection procedures, whereas the red dashed arrows are only used for ablation procedures. The green dashed rectangles show the phases that can happen anytime during the operation. These phases are connected to all other phases, but for the sake of readability, these arrows were left out of the figure. The black dotted-dashed arrows show the transfer of data such as medical images and patient medical history.

The generic process model of MILT procedures at the module level, including the phases, modules and decisions linking the modules, is provided in Figure 3.4. A legend explaining the different symbols used in Figures 3.3 and 3.4 is provided in Figure 3.5. All activities in the entire procedure of MILT including sequential and parallel activities are covered in the presented generic process model. Parallel activities are represented using symbols. Apart from the continuous support of nurses and anaesthesiologist in the entire intra-operative phases and the act of blood suctioning in parallel to other treatment activities during surgery, based on the current data, the parallel activities are associated with two phases: intra-operative preparation phase (Phase 4) and intra-operative imaging (Phase 2) activities. In intra-operative phases, we plotted the connections associated with the imaging phase, where there was a high chance of performing imaging routines. In other places where this is less likely to happen, we used a symbol to show the possibility for imaging. A brief walkthrough of the module-level MILT process model including the contents of the modules in the process model is provided in Appendix A. A brief description of the Modules is provided in Table 3.1.

Table 3.1: Different phases of generic process model of MILT and the corresponding modules according to Figure 3.4.

Phase	Modules	Description
Intake (01)	**-**	All relevant patient information is gathered
Pre-operative Imaging (02)	***CT Imaging (1)***	Different type of imaging modalities that provide different level of information of patient internal structures prior to the operation.
	US Imaging (2	
	MR Imaging (3)	
	FS Imaging (4)	
Pre-operative Planning (03)	***MD Meeting (1)***	Different planning meetings with different purposes can be carried out before the operation MD meeting (M01), so-called multidisciplinary team meeting to decide on the treatment approach. Surgical/interventional team meeting (M02) to discuss the equipment/instrument/patient preparation. The lead surgeon/interventionist (M03) session to pre-visualizes the whole procedure and all its key steps.
	Surg./Interv. Team Meeting (2)	
	Lead Surg./Interv. Meeting (3)	
Intra-operative Preparation (04)	***Equipment Preparation (1)***	Preparations need to be carried out before the starts of the operation. The equipment (M01), patient (M02) and instruments (M04) are prepared and the patient is positioned (M03) based on the pre-operative plan. These four modules are usually executed in parallel.
	Patient Preparation (2)	
	Patient Positioning (3)	
	Instrument Preparation (4)	
Intra-operative Imaging (06)	***CT Imaging (1)***	
	US Imaging (2)	

3. Generic surgical process model for MILT

	MR Imaging (3) ***FS Imaging (4)***	Different types of imaging modalities that provide different levels of information during the operation.
Intra-operative Planning (06)	***Planning (1)*** ***Register Earlier Data (2)***	In the Planning (M01) the clinician can use the intra-operative images and endoscopic video, as well as the data from M02, to generate/update plan according to patient's current condition and anatomy in the OR. In Register Earlier Data (M02) the data of the pre-operative planning and imaging are registered to be used for the intra-operative planning.
Operative field access *(07)*	***Trocar placement (1)*** ***Abdomen Insufflation (2)*** ***Retractor Placement (3)***	In laparoscopic methods (LLR, LLA) the surgeon makes the operative field accessible. Trocar placement (M01) and the patient's abdomen insufflation (M01) with carbon dioxide are performed to obtain access to the operative field. The surgeon can also place a fixed retractor (M03) to hold the liver or its surrounding organs.
Destructive Isolation *(8a)*	***Fat/adhesion Dissection (1)*** ***Organ Mobilization (2)*** ***Supply Ducts Isolation (3)*** ***Temporary Occlusion for Division (4)*** ***Permanent Occlusion for Division (5)*** ***Supply Ducts Division (6)***	This phase includes three main actions: fat/adhesion dissection (M01), mobilization of the liver or its surrounding organs (M02) or dividing the supply ducts (M03, M04, M05 and M06). In order to safely divide the supply ducts, the surgeon might need to first isolate the ducts (M03) from their surrounding tissues and structures. Prior to the division of the supply ducts, they are occluded (M05) with care. Temporary occlusion of supply ducts (M04) might be required in order to confirm the location and closure of the target vessels (usually in formal/major resection). After the supply ducts are confirmed and occluded, they can be divided (M06).
Treatment Area Isolation – Non-destructive (8b)	***Vessels Isolation (1)*** ***Temporary Occlusion Application (2)*** ***Artificial Fluid Injection (3)***	This phase includes two categories of actions. In case of laparoscopic procedures (LLR and LLA), the surgeon can first isolate any relevant vessels (M01) and then occlude them temporarily (M02) in order to reduce bleeding during treatment of the target region (e.g. Pringle maneuver). In case of ablation methods (LLA and PA), the surgeon/interventionists can inject buffer media (M03) between a lesion and the non-target nearby anatomical structures to protect them by absorbing extra energy.
Needle Manipulation	***Needle Manipulation (1)***	In the case of ablation, one or several needles are inserted through the skin to be placed at the desired position (M01) under the guidance of continuous or sequential medical imaging in the OR either. New images are

		also normally taken to confirm the needles are placed at the desired position.
Treatment (10)	***Region Marking (1)*** ***Resection Region Treatment (2)*** ***Target Region Ablation (3)***	In the case of LLR, the surgeon needs to determine the resection margins and might need to mark (M01) physically on the organ (common in case of parenchyma sparing resection). The surgeon can proceed with cutting the resection region (M02). In the case of LLA and PA new images are normally needed before and/or during ablation (M03).
Intra-operative complications *(11)*	***Surgical Drainage (1)*** ***Leakage Clean-up (2)*** ***Blood Transfusion (3)*** ***Repair Damaged Structures (4)***	Complications might arise during the operation. In order to cope with these complications, different actions may have to be initiated, e.g. placing surgical drainage (M01), blood transfusion (M02), repairing damaged structures (M04) and cleaning up leakage (M03) from damaged structures.
Miscellaneous (12)	***Chemo Catheter Insertion (1)*** ***Liver Biopsy (2)***	During the operation, various activities might be carried out that do not directly serve MILT e.g. inserting a catheter into a vessel (M01) to deliver chemotherapy medications or performing a liver biopsy (M02) for further examinations.
Wrap-up *(13)*	***Needle Removal (1)*** ***Packaging (2)*** ***Removal (3)*** ***Leakage Clean-up (4)*** ***Leak Testing (5)*** ***Leak Closure (6)*** ***Operative Field Irrigation (7)*** ***Trocars Removal & Abdomen Desufflation (8)*** ***Incisions Closing (9)***	After the treatment, the surgeon/interventionist tidies up and closes the operative field: ablation needle removal (M01), waste removal (M02 and M03), leakage clean-up and leak control (M04, M05, M06 and M07), and abdomen desufflation and incision closing (M08 and M09).

4.2.2. Model verification

The result of the quantitative and qualitative verifications of the process model confirmed that the process model provides a pathway for all encountered sequences of actions and decisions that were observed to occur during MILT procedures in clinical practice. Appendix B lists all the registered sequence of actions and decisions in the entire duration of endoscopic videos from different surgical procedures for parenchyma sparing of a tumor located in Segments 5&6, 7&8 and 5, performed in OUH. Durations of all entities in the procedure are presented in the Appendix B Table 4.2 shows the duration and occurrence frequencies of every action extracted from the endoscopic video on which the Appendix B data is based, at the module as well as the phase granularity level. Figure 3.6 provides a process model view at the phase level for duration and occurrence frequency of different phases for the typical example of a surgical procedure. Note that during the entire course of a surgery, some timings are out of the view of endoscopic camera or associated with activities other than surgical actions, e.g. the surgeon might need to take out the camera and clean it. The timing of such activities are also extracted and labeled as Idle. Phases 1 to 3 are pre-operative phases and are not captured

3. Generic surgical process model for MILT

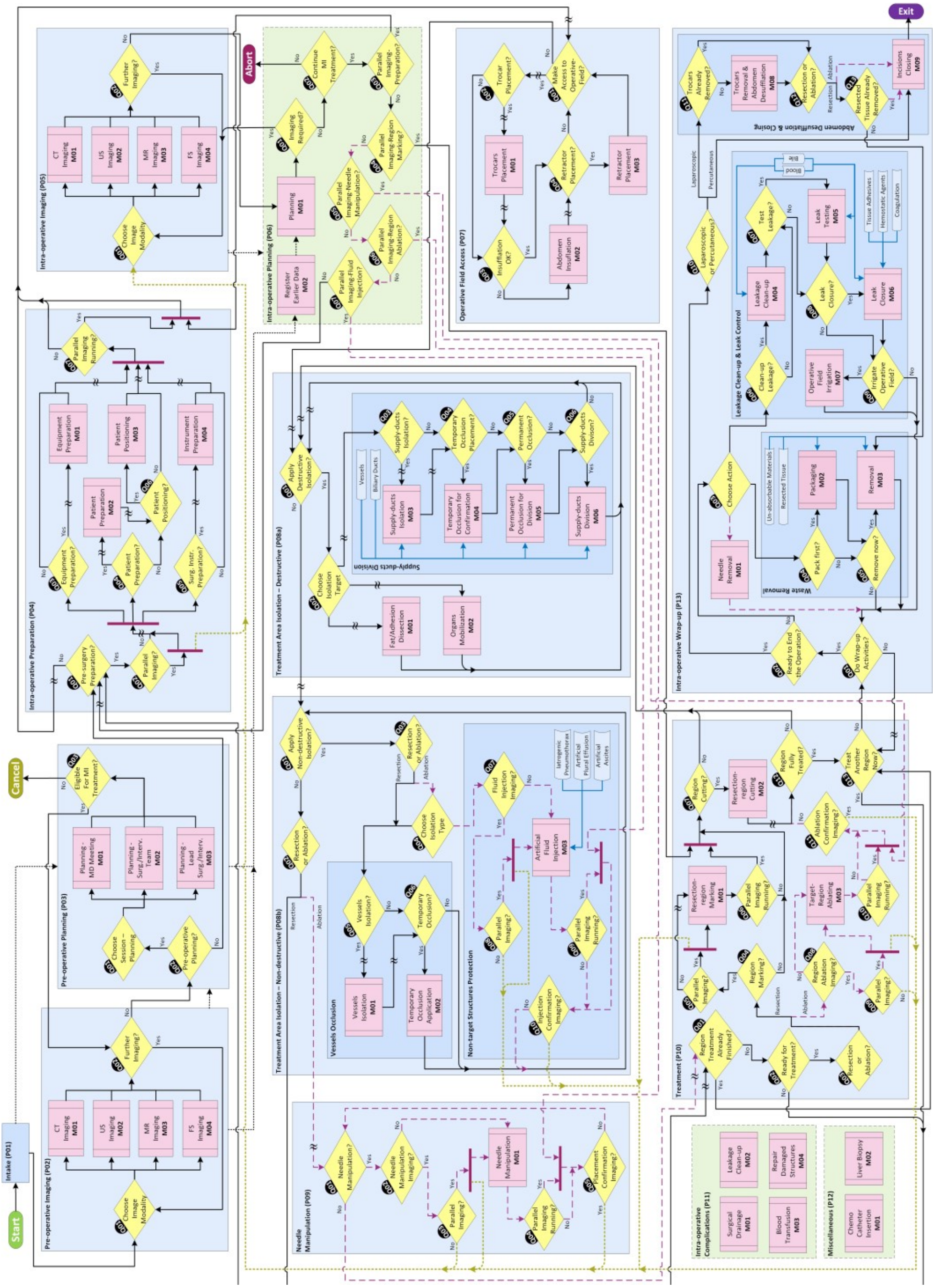

Figure 3.4: Generic process model for MILT procedures at the module granularity level. See Figure 3.4 for explanation of the used symbols and line styles. A high resolution plot can be found at DOI: [10.4121/20163968](https://doi.org/10.4121/20163968)

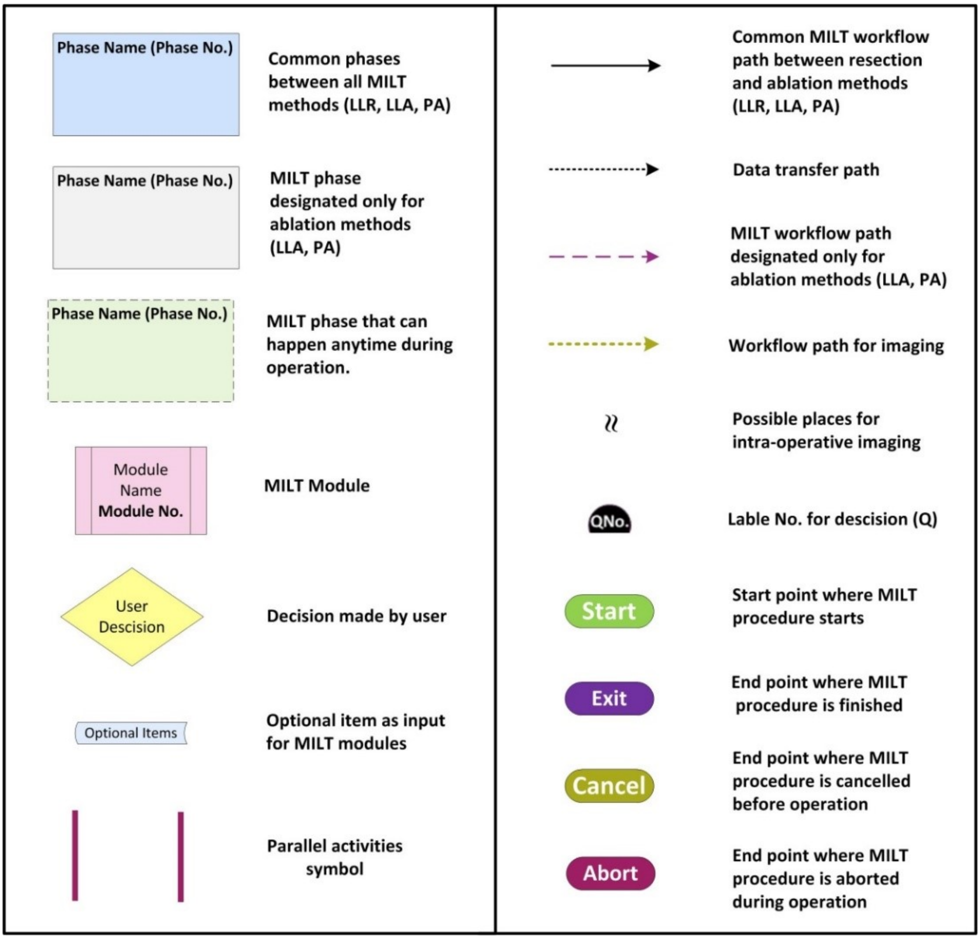

Figure 3.5: Explanation of the symbols and arrow styles used in Figures 3.3 and 3.4.

by the endoscopic videos. These pre-operative phases were verified through attendance to pre-operative imaging and planning sessions and discussions with clinical teams. The result of the verification process shows that there were no activities in any of the observed MILT procedures that were not covered by the proposed process model.

In sessions with two highly experienced surgeons and two assistant surgeons in OUH and Erasmus MC, discussing the validity and correctness of the generic process model for different techniques of performing MILT, it was confirmed that the proposed process model mimics the activities in the clinical practice.

Table 4.2: The results of analysis on the data extracted from the endoscopic video in the both granularity levels of module and phase for a sample surgery (type: parenchyma sparing of a tumor in Segments 5 and 6 presented in Appendix B.

Phase name (number)	**Phase**		**Module Name (Number)**	**Module**	
Phase	**Duration (s)**	**Occurrence**	**Module**	**Duration (s)**	**Occurrence**
Imaging *(05)*	82	1	***Imaging (2)***	82	1
Planning *(06)*	26	4	***Planning (1)***	26	4
Operative field access *(07)*	89	4	***Trocar placement (1)***	89	4
			Abdomen Insufflation (2)	0	0
Destructive Isolation *(8a)*	2534	2	***Fat/adhesion dissection (1)***	90	1
			Organ mobilization (2)	518	1
			Supply ducts isolation (3)	842	21
			***Temporary occlusion for division* (4)**	0	0
			***Permanent occlusion for division* (5)**	267	5
			***Supply ducts division for* (6)**	817	20
Treatment *(10)*	647	3	***Region marking (1)***	171	1
			Resection region treatment (2)	476	2
Intra-operative complications *(11)*	140	11	***Leakage clean-up (2)***	140	11
Wrap-up *(13)*	528	1	***Packaging (2)***	76	1
			Removal (3)	121	1
			Leakage clean-up (4)	112	3
			Leak testing (5)	0	0
			Leak closure (6)	219	4
			Operative field irrigation (7)	0	0
Idle				157	
			Sum	4203	

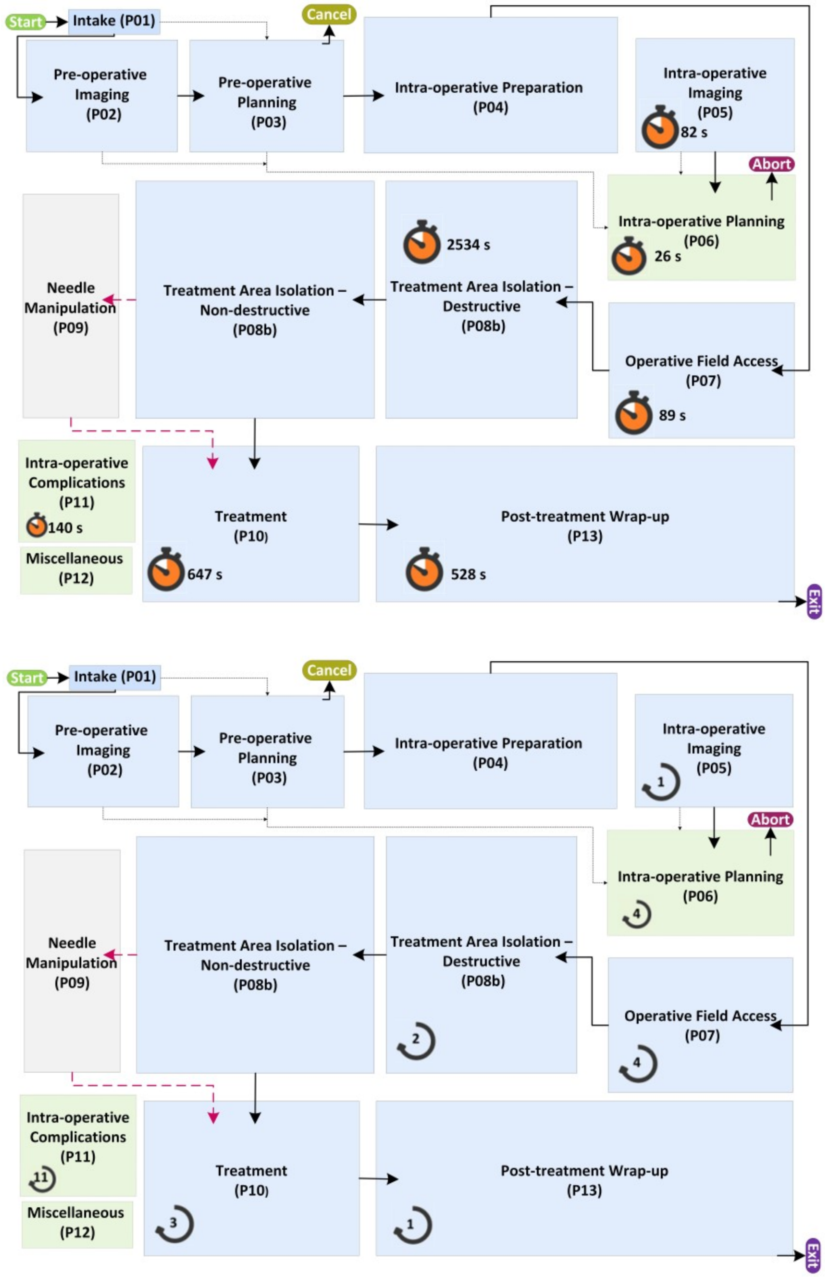

Figure 3.6: Generic surgical process model view at the phase level for duration and occurrence frequency of different phases for a sample surgery presented in Appendix B (type: parenchyma sparing of a tumor in Segments 5 and 6).

3.4. Discussion

Surgical process models bring several advantages and pave the way for further improvement of operations. The presented generic process model covers a broad range of MILT procedures and associated techniques. No deviations from the proposed process model were found in the treatment procedures that were analysed in the verification process. The proposed process model provides relationships between different entities of MILT procedures at the proposed levels of details. Thus, the process model provides the possibility for extensive quantitative as well as qualitative analysis of the procedures at the desired level of detail.

In intra-operative phases, distinguishing between planning and other treatment activities is a complicated task. Planning during operation is an ongoing mental activity and can be considered as an element inside all intra-operative phases. Modelling planning activities in a separate phase in the generic process model provides the foundation for further analysis and improvement of planning. Recognizing the points where planning occurs in the surgical process model and deriving the sequential relationships between planning and other intra-operative activities, show how and to what extent planning is associated with different activities and reveals the possible bottlenecks of planning.

Imaging activities can occur at any moment in the intraoperative phases. Although imaging activities could be defined as a green phase in the proposed generic surgical process model, it was decided to model sequential and parallel dependencies between entities as it highly benefits further analysis of process model and performing possible simulations. Live observations and interviews with experts in two institutions (OUH and Erasmus MC) were performed to determine the low granularity level structure of the process model. The process model was initially established based on the data from endoscopic video analysis and live observations in aforementioned institutions. The data was complimented with literature studies and analysis of videos of procedures available on the web from different institutes (Institute of Medical Education of Novgorod State University in Russia and Unité Hepatobiliopancreatique in Strasbourg, France- Videos can be found at Dr Sergey Baydo and Dr Riccardo Memeo YouTube Channels.) to make the process model as generally applicable as possible. Moreover, in verification process, the endoscopic videos of fifteen additional surgeries performed in OUH were analysed and six live observations of MILT procedures were performed in Erasmus MC and BUH. For these reasons, process model should conform to the procedures in other institutions as well. In this study, we did not take videos from the OR. These recording would make further quantitative validation of the model possible, but also requires special ethical approval, since sensitive information is recorded. In an earlier study, we investigated the consequence of recording in the OR [67]. In this study the pre-operative and not the post-operative phase was included in the generic process model, because the former has a direct influence on performing the treatment, which is the focus of this work. All concepts associated with different techniques of MILT are defined and categorized as different phases and modules. Thus, we expect that variations of performing actions in different institutions by using different techniques/instrument, will hardly cause any deviations from the proposed process model. However, lack of instruments, equipment or knowledge might change the course of actions or introduce innovative ways to tackle problems (that might happen especially in underdeveloped countries), which may not be considered in the presented process model. Recognizing and registration of surgical activities are crucial for performing analysis on surgical procedures, generating and verifying surgical process models and training machine learning methods to develop AI systems for the future hybrid ORs [68]. The in-house developed Video Marker Software in this work aided efficient registration and verification of data over the endoscopic video. The extracted data using the Video Marker Software from surgical videos that are acquired from OUH has been presented in Appendix B. The statistical analysis of the extracted data reveals the bottlenecks in different surgeries. Based on the analysis, the surgeons spent most of their time on the treatment phase (P10); approximately 25 minutes (40% of total surgery time), and almost 85% of the treatment phase duration was allocated to the resection. This result emphasises the importance of treatment phase on the total surgery duration. Development of automated workflow recognition systems that can (semi)automatically analyse the endoscopic videos with appropriate image processing and/or machine learning methods are currently under attention of researchers, especially for analysis of minimally invasive treatments [69, 70]. Such systems can be of great use to aid gathering surgical data for different purposes of process model analysis and verifications [68, 71, 72].

The presented process model aids different aims of analysis for improvement of surgeries/interventions in follow-up studies. Analysis of process models and providing connections between every entities of the surgical procedures, identify the points where AI and software/platform systems can be beneficial, predicts how big the benefits are and determines how these systems can be designed and developed to be employed in clinical practice, see e.g. Ref. [4, 73]. Development phase of the desired technologies and tools for hybrid ORs can also benefit from analysis of such surgical process models. Nowadays, Agile methods (SCRUM, XP, etc.) [74, 75] are being widely used in the process of the development of technologies. These methods aid smooth adaptation to changing requirements throughout the development process by using iterative planning and feedbacks from developers and the end users [74, 76]. With the process model and computer simulations, analysis of the effect of possible changes and their eligibility aids making right decisions and adaptations during the agile sessions.

The process model can widely contribute in the training and skill evaluation of surgeons [77-79]. The optimal treatment option for each surgery with specific conditions can be derived and novice surgeons can be trained based on the probable sequence of events and the possible deviations for each operation. The experienced surgeons can review the steps and possible deviations before or during an operation as a roadmap. For this purpose, real-time recognition of surgical steps over the endoscopic videos is required, a topic which has attracted wide attentions in recent years [80, 81]. The process model benefits analysis of surgeons' learning curves [82, 83]. Durations and occurrence frequencies of surgical steps and deviations from nominal surgery paths can be used as criteria for learning curve analysis, as well as surgeons' skills evaluations. In recent years navigation platforms for guiding surgeons in performing MILT attracted broad attention [84-89]. Analysis of the proposed surgical process model can reveal the optimal treatment options to guide surgical teams using navigation systems by suggesting/predicting next surgical steps and the time required for performing each surgical action [5, 13, 90, 91]. Currently, prior to operation the lead surgeon/interventionist goes into the details of the patient's organ-specific anatomy and mentally pre-visualizes the whole procedure and all its key steps. The complexities of such pre-operative planning activity, can be reduced by the process model which brings the possibility to propose the treatment options for individual procedures. Analysis of surgical process model can prevent extra costs of trial and error in the development phase of technologies and introduction of new technologies into clinical practice. With the process model, it is possible to provide scientific evidence for the possible enhancement of surgeries by the proposed technology for specific methods/types/techniques of performing surgeries. The effects and eligibility of any adjustment in the new technologies can be analysed on the surgical procedure, prior to actual implementation of technologies, resulting in a more efficient business model.

3.5. Conclusion

A generic surgical process model for MILT was established by applying the modelling strategies developed in prior work. The presented model covers MILT methods for laparoscopic liver resection, laparoscopic liver ablation and percutaneous ablation, with their types, techniques and variations as observed in data obtained from various sources. As the presented model was established using a numerical model representation, it can be used for extensive quantitative and qualitative analysis and improvement of MILT procedures through various ways, such as the introduction of new technologies in the OR, training of clinical teams, analysis of learning curves and skills evaluations, optimization of OR management and medical team activities in the OR.

3.6. Bibliography

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3.7. Appendix A - Workflow modules

In this appendix, the MILT generic process model at a module level, shown in Figure 3.3, is explained by a brief walkthrough model and its modules. Modules inside the phases are annotated by an 'M' proceeded by the module number.

Phase 01: **Intake** - All relevant patient information is gathered.

Phase 02: **Pre-operative Imaging** - Images are taken prior to the operation, using any preferred image modalities. Different imaging modalities (M01, M02, M03 and M04) provide different levels of information related to internal organs, bones, soft tissues, or blood vessels.

Phase 03: **Pre-operative Planning** - Planning sessions are held prior to the operation and involve a wide variety of clinical personnel. Typically, there is a planning session (M01), so-called multidisciplinary team (MDT) meeting, during which the clinical experts (surgeons, interventionists, radiologists, and gastrointestinal experts, etc.) discuss the patient's condition and decide on the treatment approach. If MILT is chosen as the treatment approach, before the operation there can be a different preparation/planning sessions between the surgical/interventional team members (M02) (typically lead surgeon/interventionist, surgeon/interventionist assistant and head nurse) to discuss the patient preparation, required instruments and equipment, and any required deviations from standard protocols. Finally, the lead surgeon/interventionist (M03) goes into the details of the patient's organ-specific anatomy and mentally pre-visualizes the whole procedure and all its key steps. In the planning sessions, the clinicians may require new or additional images for different reasons, such as higher quality or extra or updated information. Note that not all meetings are always held and that any can be repeated if necessary. The planning contains any decisions about the desired treatment method, type and techniques, preparation methods and required instruments and equipment, adequate margin for the target region, optimal path to reach the target region, etc.

Phase 04: **Intra-operative Preparation** - Before the surgeon/interventionist starts the treatment procedure, all required equipment is placed in the OR (M01). The sterile nurse together with another nurse(s) prepare the surgical instruments (M04), the patient (M02) and position the patient according to the plan (M03). These four modules are usually executed in parallel. Acquiring new images of the patient's organ is also possible in parallel to performing preparations in this phase.

Phase 05: **Intra-operative Imaging** – Intra-operative imaging can be initiated from numerous places in the workflow during the operation. Therefore, to avoid cluttering the process model scheme, the ≀ symbol is used to indicate jump-outs to possible imaging. If it is highly probable or standard procedure to call imaging modalities at any point, the corresponding decisions and arrows are plotted with thick green dotted-dashed lines. After new images are acquired (M01, M02, M03 and M04), the surgeon/interventionist always checks if an update of the treatment plan is needed.

Phase 06: **Intra-operative Planning** – Any aspects of the treatment plan can be generated or updated in the OR. The process model is flexible to apply these changes. Therefore, the next step after the pre-operative planning is always Phase 04, where **operation** starts. The clinician can use intra-operative images and endoscopic video to generate/update plan according to patient's current condition and anatomy in the OR.

Phase 07: **Operative Field Access** - In laparoscopic methods (LLR, LLA) the surgeon makes the operative field accessible. Firstly, the first trocar is inserted into the patient's abdomen (M01). Typically, when the insertion of the first trocar is successful, the abdomen is insufflated with carbon dioxide (M02). The surgeon continues inserting more trocars according to the plan and need for sufficient insight and tool access. In case of improper abdominal insufflation, the surgeon decides whether to manipulate the trocar in its current insertion point or to change the location of the first trocar. In hand-assisted laparoscopic surgery [79] the surgeons can use their hand instead of a trocar through a hand port. The surgeon can also place a fixed retractor (M03) to hold the liver or its surrounding organs throughout the surgery, whenever needed after successful insufflation.

Phase 08a: **Treatment Area Isolation – Destructive** - In this phase, the surgeon can choose between three main actions: fat/adhesion dissection (M01), mobilization of the liver or its surrounding organs (M02) or dividing the supply ducts (M03, M04, M05 and M06). Typically, the surgeon dissects fat/adhesion (M01) for different reasons: to reach the treatment area, to have a better view of the treatment region, etc. Mobilization of the liver (M02) involves dissection of ligamentous/peritoneal attachments and if present any adhesions. Small branches of supply ducts can be easily occluded and divided using coagulation devices, while the division of larger branches of supply ducts require special care. The surgeon might need to close and divide supply ducts for different reasons such as blocking the fluid exchange between the treatment area and healthy parenchyma (e.g. in case of formal resection), and while performing the treatment (e.g. in case of PR). In order to safely divide the supply ducts, the surgeon might need to first isolate the ducts (M03) from their surrounding tissues and structures. Prior to the division of the supply ducts, they are occluded (M05) with care. As in MILT procedures, the field and quality of view are limited, confirmation (M04) of the location and closure of the target vessels with other techniques is sometimes required before performing permanent occlusions. To this purpose, the surgeon can temporarily occlude any supply ducts and observe the effect of blocking the blood supply to the target tissue (usually in formal/major resection). After the supply ducts are confirmed to be occluded, they can be divided (M06). Several devices are available that allow to occlude and divide the ducts in a single action (e.g. Stapler). Note that in the case of parenchyma sparing and anatomical resection, the activities in supply duct division, can be considered in the treatment phase. However, for the sake of clarity and generality in the generic surgical process model, the activities in supply duct divisions are modelled in destructive isolation phase.

Phase 08b: **Treatment Area Isolation – Non-destructive** - The techniques in non-destructive isolation contribute to reduction of operative bleeding and promote better hemostasis while performing treatment of the target region, or protection of nearby structures. Two different categories of actions are available. In case of laparoscopic procedures (LLR and LLA), non-destructive isolation involves techniques for temporary vessels occlusion (M01 and M02), in which the surgeon first isolates any relevant vessels (M01) and then occludes them temporarily (M02) in order to reduce bleeding during treatment of the target region (e.g. Pringle maneuver). In case of ablation methods (LLA and PA), the surgeon/interventionists can inject buffer media (different types of liquids or gas [80]) (M03) between a lesion and the non-target nearby anatomical structures to protect them by absorbing extra energy. In such cases, the surgeon/interventionist uses medical imaging in the OR to guide the injection of buffer media. Similar approach could also be applied as direct cooling of the sensitive structures (e.g. bile duct cooling) (PMID: 15110804)

Phase 09: **Needle Manipulation** – In the case of ablation, one or several needles are inserted through the skin to be placed at the desired position. The interventionist places the needle(s) at the right position under the guidance of continuous or sequential medical imaging in the OR either. New images are also normally taken after needle manipulation to confirm the needles are placed at the desired position.

Phase 10: **Treatment** – Treatment of the target region can be done either by resection or ablation. In the case of LLR, the surgeon needs to determine the margins to apply when removing the targeted tissue volume. To do so, one might mark (M01) the resection region physically on the organ by using a coagulation device (common in case of parenchyma sparing resection). New images might be needed before and/or during marking. Once resection marking (partially) is completed, the surgeon can decide to proceed with cutting the resection region (M02). In the case of LLA and PA new images are normally needed before and/or during ablation. Continuous or sequential imaging during ablation are used to monitor and control the treatment progress. After a completed ablation, new imaging is preferably taken to check for any complication and to assess the ablative margin to better decide whether to proceed with the treatment or not. In all methods (LLR, LLA, PA) (non-)destructive isolation techniques can be applied while treating the target region, leading the workflow to the corresponding phases during resection or ablation.

Phase 11: **Intra-operative Complications** - Complications might arise during the operation. In order to cope with these complications, different actions may have to be initiated, e.g. placing surgical drainage (M01), blood transfusion (M02), repairing damaged structures (M04) and cleaning up leakage (M03) from damaged structures.

Phase 12: **Miscellaneous** - During the operation, various activities might be carried out that do not directly serve MILT. Inserting a catheter into a vessel (M01) to deliver chemotherapy medications after the operation or performing a liver biopsy (M02) for further examinations are two examples of these activities.

Phase 13: **Intra-operative Wrap-up**- After the treatment is finished, the surgeon/interventionist tidies up and closes the operative field by applying: ablation needle removal (M01), waste removal (M02 and M03), leakage clean-up and leak control (M04, M05, M06 and M07), and abdomen desufflation and incision closing (M08 and M09). The surgeon/interventionist often intermediately applies some of the wrap-up activities (M01 to M06) during surgery after having finished treating one or a part of one target region before proceeding to the next.

3.8. Appendix B - Data

In the verification process of the generic surgical process model of MILT in this work, the endoscopic videos were analyzed to acquire the order and duration of steps in the entire surgical procedures. The presented figures in this Appendix are the data extracted from the endoscopic videos of parenchyma sparing of tumor at segments 5&6, 7&8 and 5. In the following figures, the horizontal axis shows the different surgeries and vertical axis is the number of steps and. For each surgery the videos were analysed The numbers on the graphs are **P**hase number, **M**odule numbers and **D**uration of the step in seconds. Each phase has its own symbol and colour so these are easily distinguished. The Duration of the first few steps (trocar placement and its planning at the bottom of plot) are indicated as NaN at the start of each surgery as there is no record of these steps in the endoscopic videos. The steps in the surgeries are placed chronologically from bottom to top of the plots. The datasets generated during the current study are available in the DOI: 10.4121/20163968

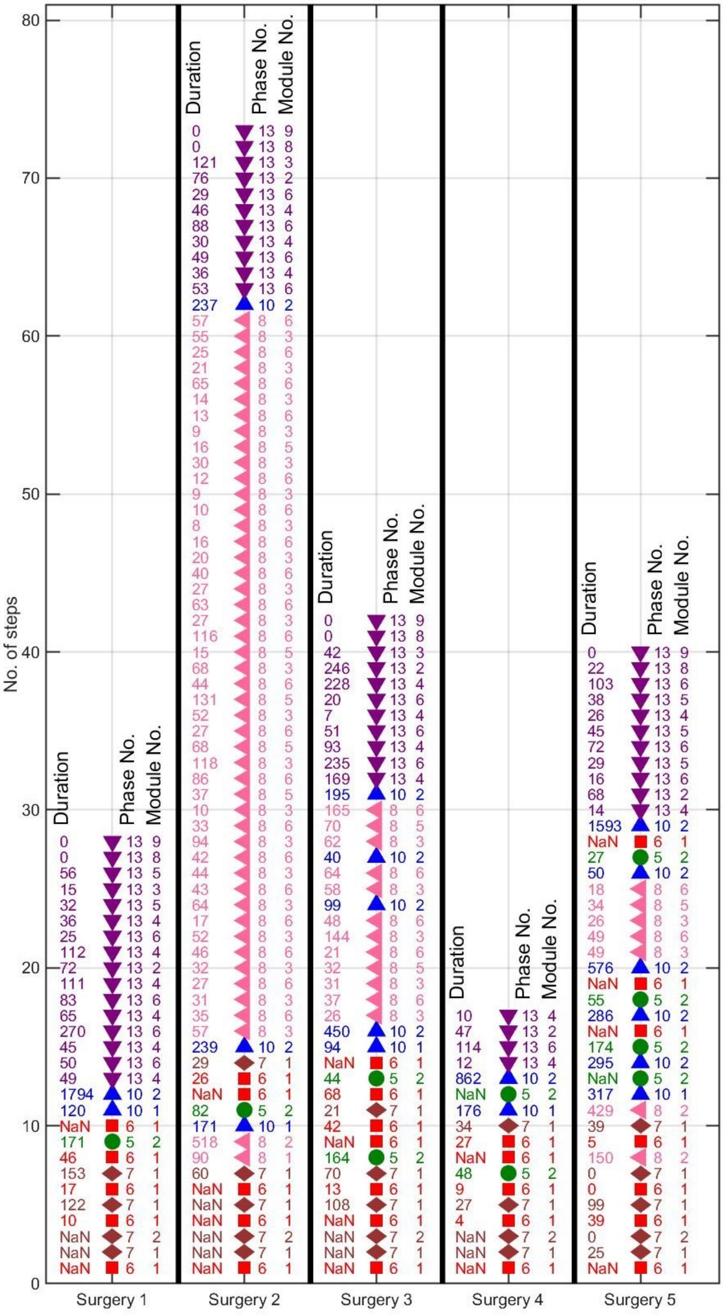

Figure 3.B.1: The data for five endoscopic videos of laparoscopic liver resection of segments 5&6. Please see the main text above this figure for explanation of the figures and symbols.

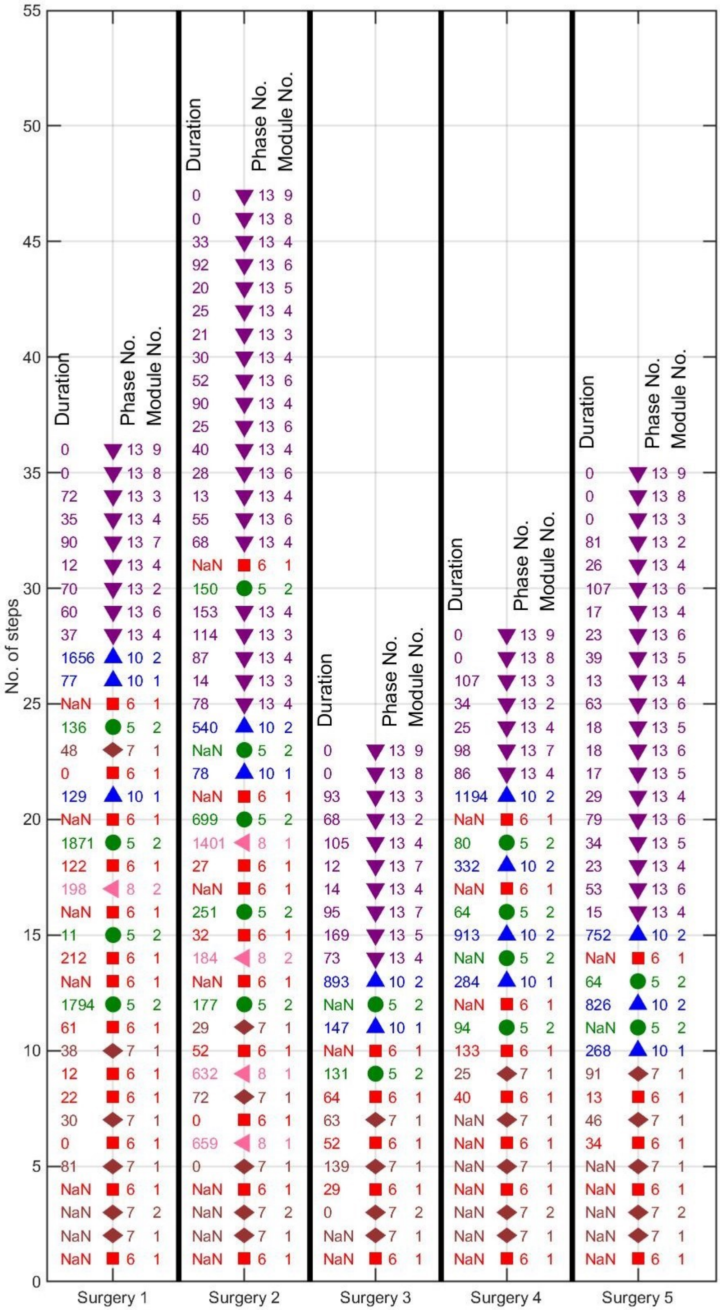

Figure 3.B.2: The data for five endoscopic videos of laparoscopic liver resection of segments 7&8. Please see the main text above this figure for explanation of the figures and symbols.

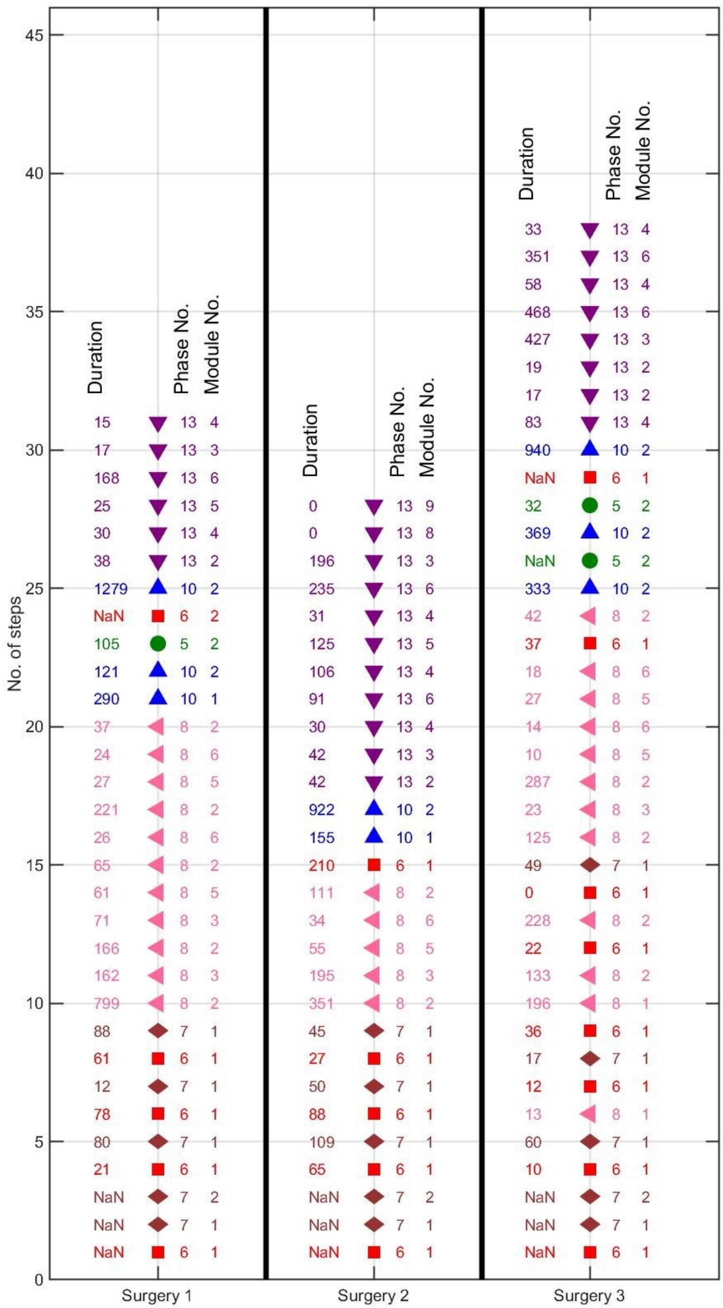

Figure 3.B.3: The data for three endoscopic videos of laparoscopic liver resection of segments 5 with gallbladder removal. Please see the main text above this figure for explanation of the figures and symbols.

PART B: Applications of Computer-based technologies and Surgical Process Modelling

Chapter 4: Process model analysis of parenchyma sparing laparoscopic liver surgery to recognize surgical steps and predict impact of new technologies. [3]

Abstract

Surgical process model (SPM) analysis is a great means to predict the surgical steps in a procedure as well as to predict the potential impact of new technologies. Especially in complicated and high-volume treatments, such as parenchyma sparing laparoscopic liver resection (LLR), profound process knowledge is essential for enabling improving surgical quality and efficiency. Videos of thirteen parenchyma sparing LLR were analysed to extract the duration and sequence of surgical steps according to the process model. The videos were categorized into three groups, based on the tumour locations. Next, a detailed discrete events simulation model (DESM) of LLR was built, based on the process model and the process data obtained from the endoscopic videos. Furthermore, the impact of using a navigation platform on the total duration of the LLR was studied with the simulation model by assessing three different scenarios: (i) no navigation platform (ii) conservative positive effect and (iii) optimistic positive effect. The possible variations of sequences of surgical steps in performing parenchyma sparing depending on the tumour locations were established. The statistically most probable chain of surgical steps was predicted, which could be used to improve parenchyma sparing surgeries. In all three categories (i-iii) the treatment phase covered the major part (~40%) of the total procedure duration (bottleneck). The simulation

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[3] The contents of this chapter have been adopted from M. Gholinejad, B. Edwin, O. J. Elle, J. Dankelman & A. J. Loeve "Process model analysis of parenchyma sparing laparoscopic liver surgery to recognize surgical steps and predict impact of new technologies" *Surgical endoscopy* 37.9 (2023): 7083-7099.

results predict that a navigation platform could decrease the total surgery duration by up to 30%. This study showed a DESM based on the analysis of steps during surgical procedures can be used to predict the impact of new technology. SPMs can be used to detect e.g. the most probable workflow paths which enables predicting next surgical steps, improving surgical training systems, analysing surgical performance, etc.. Moreover, it provides insight into the points for improvement and bottlenecks in the surgical process.

4.1. Introduction

Improvement of surgeries is an ongoing challenge for researchers that can be achieved by providing new technological advancements, guiding surgeons during operation by prediction of next surgical steps, finding and dealing with surgical bottlenecks, improving surgeon's training, etc. To obtain these goals, various disciplines need to work together to provide the right inputs for working on different aspects involved in improving surgical procedures. Surgical Process Models (SPMs) can be used to find the structural coherence of complex surgical procedures and for obtaining profound qualitative and quantitative understanding of the relations within the surgical procedure, its variation parameters and its output parameters [1].

Predicting surgical steps, their sequence and durations, can aid the improvement of operations by supporting surgeons in their needs at the right moment, and by monitoring the time management of surgery. Surgeons can use the predictions and the suggested probable sequence of surgical steps to perform efficient pre-operative planning as well as intra-operative treatment. Monitoring could be specifically helpful for the centralized management of personnel for efficient operation scheduling and resource management [2]. In addition, such predictions can be used to train the young generation of surgeons according to the most probable sequence of surgical steps. Aiming to address the aforementioned challenges, several attempts have been made in previous studies to first establish the surgical steps (either by manual annotation of an observer [3, 4] or by using digital data in the OR [5, 6]) and then try to predict the sequence of the steps [7-9]. Several methods have been proposed for establishing the surgical steps from digital data (e.g. sensor and camera) in the OR such as using hidden Markov model [10, 11], support vector machine classifiers [12], forest trees [13] and random forests [14]. Various data sources, such as anaesthesia and vital sign data [15, 16], OR and endoscopic videos [13, 17, 18], signals from surgical robots [19], tool/device usage [20] and workflow recognition sensors [10, 21] have been used for intra-operative task discovery and predictions. Although several studies on revealing the surgical steps in a procedure are available in the literature, there are only few studies on the intra-operative prediction of successive steps [7-9]. Up to now, most of the prediction studies are focused on risk prediction models [22, 23], prediction of total operation duration [2, 24] and post-operative complications prediction [25-27]. Surgical operations are characterized by their highly variable process and duration. In this type of analysis, it is important to have the information at high level of detail (fine granularity level). Prediction of fine granularity surgical steps is challenging due to difficulties of recognizing surgical tasks, modelling of the highly variable surgical procedures and merging these highly varying procedures in order to determine the possible sequence of surgical steps [28]. Surgemes and dexems are the structure of SPMs in fine granularity levels. Surgemes are surgical steps and are defined as the entire act of performing a certain surgical task, while dexemes are the way of performing a surgical step at a lower level of abstraction, or finer level of granularity [29].

Aim of this chapter is to discover possible sequences and durations of surgical steps with a high level of details (fine granularity) for resection of different segments in parenchyma sparing, minimally invasive liver treatment (MILT), that will be used in predicting surgical steps, surgery durations and predicting impacts of new technologies. By merging sets of individual Surgical Process Models (iSPMs) and an extensive statistical analysis of clinical data, we discover the (most) possible sequences of surgical steps and surgery duration. These sequences/steps are used to build a discrete event simulation model which is then used to predict the effects a novel navigation platform, prior to actual implementation into clinical practice [28]. In this study, we simulated a technologically feasible navigation platform, however, the methodology can be used for assessment of different new technologies.

4.2. Method

4.2.1. Data acquisition

Process data was acquired from endoscopic videos of thirteen parenchyma sparing of laparoscopic liver resection (LLR) for colorectal liver metastasis performed at Oslo University Hospital, Norway (OUH). All lesions were located in the right lobe of liver. To limit the variance in process data, only surgeries treating a single lesion located in one or two neighbouring liver segments were included. Based on the segments that were being treated, the videos were categorized into three groups: (i) five videos of Segments 5&6 (no gallbladder removal), (ii) five videos of Segments 7&8 and (iii) three videos of Segment 5 (with gallbladder removal- cholecystectomy). All the surgeries were performed at The Intervention Center of OUH by four different highly experienced lead surgeons with more than 10 years of surgical experience. After making observations in the operating room and conducting interviews with surgeons at Rikshospitalet, it was found that the surgeons generally employed similar surgical instruments and techniques. Ethical approval for this study was obtained from OUH in which the data were collected (Regional Ethical Committee of South Eastern Norway- REK Sør-Øst B 2011/1285 and the Data Protection Officer of OUH).

4.2.2. Data analysis

The endoscopic videos of the surgeries were analysed in order to divide the surgical procedures into surgical steps and to extract the sequence and durations of these steps. The surgical procedures were analysed based on the generic surgical process model (GSPM) of MILT established in our previous work [30]. The duration, number of occurrence and sequence of each surgical step were obtained by analysis of the endoscopic videos. An integrated in-house built software system was developed for registration, storage, verification, analysis and simulation of surgical process data. Figure 4.1 shows a schematic of the modules in the developed system. The "Video Marker" module (developed in C# language) enables registration of the sequence, start time and end time of surgical steps on endoscopic videos. Next, the registered surgical data was verified using the "Verification Software" (developed in Unity engine, C# and Java). The registered data and relevant registered information for each surgical step was visualised as a layer put over the generic MILT process model to confirm the flow of the registered surgery process. After confirmation, the surgical data was stored and analysed in "Data Analyser" (programmed in Matlab). The results of the data analysis were fed into the Simulation Model of LLR to enable investigation of and judge the impact of introducing potential new technologies on the process and duration of LLR.

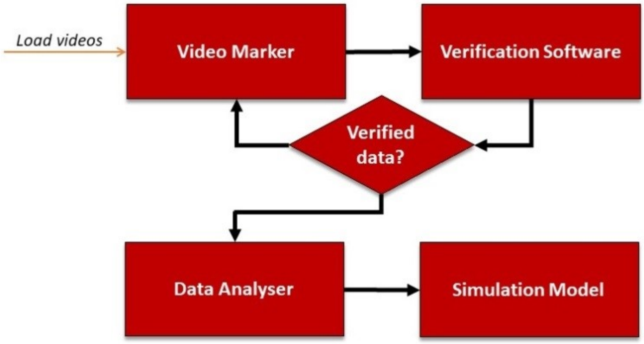

Figure 4.1: Integrated system for data analysis consisting of the software modules Video Marker, Verification Software, Data Analyser and Simulation Model.

The surgical steps were numbered by phase and module numbers according to the process model in [30], see also Chapter 3. For example, "P07M01" refers to Phase 07, Module 01; Trocars Placement. For registration of the occurrence frequency of modules, as long as successive actions or decisions were in the same module, this was counted as a single occurrence. Five of the process model phases and modules were treated in particular ways during data registration and analysis for specific reasons:

- **Intra-operative planning (P06):** The surgeons generate/update the surgical plan while taking ultrasound (US) images. Consequently, in case of taking intra-operative images, imaging (P05M02) and planning (P06M01) run in parallel. During surgery, surgeons often have moments where they need to decide on their next course of action. These moments are typically very brief, usually lasting just a few seconds. As a result, these moments were not included as a separate planning step (planning module) in the surgical process, but instead were incorporated into the duration of the subsequent step. Planning module, on the other hand, refers to moments when the surgeon is examining and investigating the treatment region and surroundings through the endoscopic camera view. These planning moments can occur at any time during the surgery. Certain surgical tasks, like placing a trocar, always require planning, but the planning process is typically very rapid and may occur outside of the endoscopic camera view. In such cases, a zero duration was assigned to the planning step.

- **Supply ducts division (P08aM06):** In the GSPM definition, supply ducts (we also refer to them as supply vessels) include hepatic artery, portal vein, bile duct, and hepatic veins. Small vessels can be divided along with the action of resecting a section of the liver. However, larger branches of supply ducts, which require more attention, have to be isolated, (possibly) occluded and then divided by the surgeon (Modules 03, 05 and 06 in Phase 08a). An action is considered to be "Supply ducts division" when the vessel is distinguishable in the video, the surgeon isolates the vessels and divides them, regardless of whether permanent occlusion of the vessels is performed or not. Permanent occlusion is considered when the surgeon uses a clip or stapling device to occlude supply ducts. It should be noted that in parenchyma sparing, the modules involving supply duct division (Modules 03, 05, and 06 in Phase 08a) can be considered as part of the treatment phase (P10M02). However, we chose not to combine supply duct division with the treatment phase in our study to allow for a separate analysis of supply duct division. If necessary, these modules can be easily combined back into the treatment phase.
- **Leakage clean-up (P11M02 and P13M04):** The activities in this phase were separated in two intraoperative phases: during treatment of lesion as intra-operative complications (phase 12) and in wrap-up activities (phase 13). This is because leakage clean-up prior to completing treating a lesion can happen anytime during surgery, whereas leakage clean-up in wrap-up activities is part of a normal procedure and not a complication.
- **Intra-operative preparation (P04):** Intra-operative preparation (P03) typically takes about an hour and does not depend on tumour size, location, etc.. Therefore, this duration was taken as a fixed time for this phase.
- **Wrap-up activities (P13):** During wrap-up activities (P13) some modules occur after the endoscopic camera has been taken out of the abdomen, therefore, no timings are recorded for these modules (e.g. exsufflation and incision closing-P13M08 and P13M09).

Note that there are moments in laparoscopic surgeries that are considered as Idle time, such as when the surgeon takes out the camera to clean the lens or when the surgeon is not performing any activities visible in the endoscopic video.

4.2.3. Discrete event simulation

Following the approach of Loeve et.al. [28], to study the impacts of new technologies on LLR, a detailed discrete events simulation model of LLR was built in Matlab, based on the process model and the process data obtained from the endoscopic videos. Process model consists of modules and questions.

> **Modules:** Due to the limited number of data points for each module (between 2 and 30), finding the true distribution of modules duration is elusive. The simulations were ran for two diverse distributions: Gaussian distribution and Uniform distribution. In the case of Gaussian distribution, for each module the probability distribution of its duration was calculated by fitting a Gaussian distribution function to the data obtained from the endoscopic videos. The negative tail of the Gaussian distribution was ignored in the simulation model, i.e. the duration probability distributions had a finite lower bound of zero. This means that the final result is a skewed non-symmetrical distribution rather than an actual Gaussian distribution. In the case of Uniform distribution, a random duration between shortest and longest duration of each module was generated.
>
> **Questions:** It was assumed that the question outputs were instant, thus question durations were set to zero. The questions were defined as dynamic points in the simulated model. This means that the probabilities of the question outcomes depended on the number of times that question had already been executed.

Phase 11 of the process model can happen any time during a procedure. Implementation of these phases in the simulation is a tedious task. In order to prevent unnecessary complications in the simulations, the average duration of leakage clean-up (P11M02) were added to the simulations. Note that leakage clean-up is not affected by the introduction of navigation platform in the defined scenarios in the following section, thus it is safe to add the average duration of P11M02 to the simulations. Similar to P11M02, the average duration of Idle time was added to the simulations.

4.2.4. Prediction of impact of new navigation platform

To analyse the effects of new technologies in LLR, we simulated a technologically feasible, new platform that improves visualization of the treatment area for the surgeons by showing a 3D model of the patient's liver and internal structures, including vessels and supply ducts, such as the navigation platform being developed in the HiPerNav project [31, 32] (see also the video in https://www.youtube.com/watch?v=ix2bDXfQ0tc&t=9s). The platform visualizes the position of surgical instruments with respect to internal structures in the 3D model during operation or a visualization of internal structures as an overlay on the laparoscopic video (Augmented Reality). Based on the planned data, the platform guides the surgeons in performing surgical steps during the treatment. In these platforms, the medical images are obtained using different image modalities and a 3D model of the liver is generated based on these images. The described technology is the new technology that we assess its impact on the LLR in this work. Typically, image to image registration, image segmentation and image to patient registration are required in these technologies [33-37]. On the other hand, navigation platforms facilitate several different steps in performing LLR. In order to predict the effects of such a navigation platform on liver surgery, the following three scenarios were defined.

Scenario 1: No use of the navigation platform.

Scenario 2: Navigation platform in use – conservative positive effect. The navigation platform has an impact on various modules including Resection (P10M02), Marking (P10M01), Supply Duct Isolation (P08aM03), Planning (P06M01) and Imaging (P05). Enhanced visualization of patient's organ and improving surgeon's insight on positions of supply ducts , results in performing resection (P10M02) faster than normal. Therefore, the resection (P10M02) time was assumed to decrease by 10%. Additionally, the platform eliminates the need for physical marking of the resection area (P10M01), as it displays tumor borders and suggests the treatment margin in a 3D view. Supply duct isolation (P08aM03) is also simplified due to the known positions of the supply ducts, reducing the duration of this module by 25%. However, the platform adds some computational burden. The time for segmentation was set to 60s due to computational times. Image to 3D model registration will be done to update the 3D model, for which a computational time of 120s was implemented. For taking new images as the input for updating the model 120s was implemented. These technical durations were estimated based on the authors hands-on experience with available navigation systems [38, 39]. It was assumed that the image to patient registration is done prior to start of the surgery. During a surgical procedure, patient positioning might change. In the case of minor adjustments, no additional action is required. However, if significant changes occur, new images must be obtained, and the image-to-patient and 3D model registration processes, as well as image segmentation, must be repeated. For such cases, the additional time should be added to the total surgery time. We assumed no significant changes in patient positioning, however, recent studies have demonstrated that the process of updating the 3D model to account for the deformation of liver shape during surgery, can be accomplished more efficiently using surface reconstruction from intraoperative stereo-video. These methods eliminate the need for the time-consuming and resource-intensive approaches that are considered in the scenarios 2 and 3 [40-42].

Scenario 3: Navigation platform in use – optimistic positive effect. For this scenario more optimistic performance was assumed. The resection (P10M02) time was decreased by 20% instead of 10%. Isolation of supply ducts (P08aM03) is taken to be faster, decreasing the duration of "Supply ducts isolation" by 50% instead of 25%. The time for updating the segmentation was put to 30s instead of 60s and image to 3D registration duration was halved to 60s.

The simulation is designed based on probability distribution functions for all modules occurrences and durations, therefore, criteria for excluding non-logical occurrences are defined. The exclusion criteria are (1) no less than 3 trocars are ever used and (2) the minimum time for resection is half of the minimum resection time observed in video data of that surgery category. The minimum times of resection in the real data-set available for Segment 5&6 was 476s (approx. 8 mins), for Segments 7&8 this was 540s (9 mins) and for Segment 5 with gallbladder removal this was 922s (approx. 15 min). Based on our previous observations in LLR, the resection in the surgeries with the minimum values could have been perform faster than the current total duration, thus, we have taken the half of these minimum values as the lower bound. It was necessary to define a lower bound for the duration of resection, as otherwise unreasonably small values (down to zero) could be allocated to the resection time in the simulations. The operational behaviour of the simulation model was checked by observing the animated output of the simulation, which confirmed that it is comparable to the real data acquired from endoscopic videos.

4.3. Results

Median lesion length in the laparoscopic surgeries that were analysed was 75 mm (range 40-115 mm). All tumours were malignant, except for one. Median patient age was 66 (range 47-80) and 58% were male. Nine patients had prior abdominal surgery; 3 patients on the liver, out of which 2 patients previously underwent open liver resections. Three patients received neoadjuvant chemotherapy (NEO) prior to hepatic resection.

Figure 4.2 shows the approximate resected lesion margins of the laparoscopic surgeries that were analysed in this chapter. It is worth mentioning that some procedures like cholecystectomy (Segment 5 with gallbladder removal) are more consistent and standardized. In the following paragraphs, while we discuss the different procedures for different segments, one can also see how the results altered for the steps of cholecystectomy (Segment 5 with gallbladder removal) with compared to Segments 5&6 (without gallbladder removal).

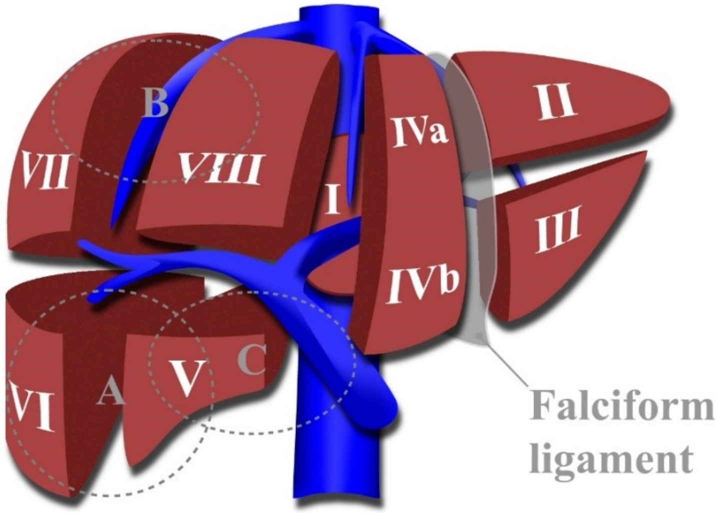

Figure 4.2: Eight functionally independent segments of liver. A, B and C show the resection lesion margins of segments 5&6, 7&8 and 5 with gallbladder, respectively.

The sequence of surgical steps and the registered time per steps for all surgeries are given in Appendix B of Chapter 3, DOI: 10.4121/20163968, and Ref. [30]. Table 4.1 shows the mean durations and occurrence frequencies of phases and modules for the three categories of parenchyma sparing surgeries extracted from the analysed videos. Not all the phases and modules in the generic surgical process model of MILT occur in LLR, as this model also covers MILT variants. To interpret the data in Table 4.1, one needs to note that some modules do not occur in all surgeries (e.g. P08aM01), therefore, the average occurrence frequency can be less than 1. The standard deviation of occurrence frequency is zero for several modules indicating that the occurrence frequency values are the same for that module (e.g. P07M01). The mean duration of each module is calculated as the mean duration of that module in all surgeries, excluding those surgeries in which this module did not occur.

In the Imaging and Planning phases (P05 and P06) and Region Marking module (P0M01) in Table 4.1, while the surgeon is taking images using US (P05M02), planning is normally generated/updated. Hence, the total planning time is the sum of the imaging duration (P05) and the planning duration without imaging (P06), as shown in Table 4.1. Imaging activities (P05) can be done separately or in parallel with Region Marking in Phase 10. In case of parallel Region Marking-Imaging the timing and the occurrence frequencies are considered for both Imaging and Region Marking.

For an easy comparison of modules between different surgery categories, the duration and occurrence frequencies provided in Table 4.1, are also shown in Figures 4.3 and 4.4, respectively.

Table 4.1: The duration (in seconds) and occurrence frequency (number of occurrence) of the modules extracted from the endoscopic videos, presented as "mean (standard deviation)".

		Segments 5&6		Segments 7&8		Segment 5 (with gallbladder removal)	
Phase	**Module**	**Duration (s)**	**Occurrence (-)**	**Duration (s)**	**Occurrence (-)**	**Duration (s)**	**Occurrence (-)**
Imaging *(05)*	*2*	252 (188)	2 (1.2)	1259 (1491)	3.4 (1.3)	235 (184)	1 (1)
Planning *(06)*	*1*	85 (47)	5 (1.2)	181 (146)	7.8 (2.9)	222 (146)	6 (1.7)
Operative field access *(07)*	*1*	157 (87)	3.6 (0.5)	132 (73)	4 (0.7)	170 (40)	4 (0)
	2	N.R.	1	N.R.	1	N.R.	1
Destructive Isolation *(8a)*	*1*	90 (0)	0.2 (0.4)	2692 (0)	0.6 (1.3)	209 (0)	0.7 (1.1)
	2	548 (43)	0.6 (0.9)	191 (10)	0.4 (0.5)	855 (414)	4 (1.7)
	3	400 (370)	5.6 (8.8)	0 (0)	0 (0)	150 (111)	1.33 (0.6)
	5	134 (120)	1.6 (2)	0 (0)	0 (0)	60 (26)	1.67 (0.6)
	6	410 (387)	5.4 (8.4)	0 (0)	0 (0)	38 (10)	1.67 (0.6)
Treatment *(10)*	*1*	176 (86)	1 (0)	197 (85)	1.2 (0.4)	259 (93)	1 (0)
	2	1343 (951)	2.6 (1.8)	1421 (736)	1.6 (0.9)	1210 (253)	1.7 (0.6)
Intra-Operative Complications *(11)*	**2**	222(172)	6.4 (3.3)	291(190)	7 (4.4)	347(291)	8 (7)
Wrap-up *(13)*	*2*	101 (81)	1 (0)	63 (20)	1	38 (3)	1.3 (0.6)
	3	52 (47)	1 (0.5)	105 (32)	1.4 (0.9)	227 (205)	1.3 (0.6)
	4	223 (220)	3.4 (1.7)	225 (222)	4.8 (3.3)	128 (72)	2.7 (0.6)
	5	100 (17)	1 (1.4)	99 (75)	1.2 (1.6)	75 (70)	0.7 (0.6)
	6	252 (120)	3 (1.2)	218 (144)	2.4 (2.9)	438 (340)	1.7 (0.6)
	7	0 (0)	0 (0)	98 (9)	0.8 (0.8)	0 (0)	0 (0)
Idle		193 (67)	-	931(1154)	-	322 (51)	-

N.R.: The duration was Not Recognizable in the videos.

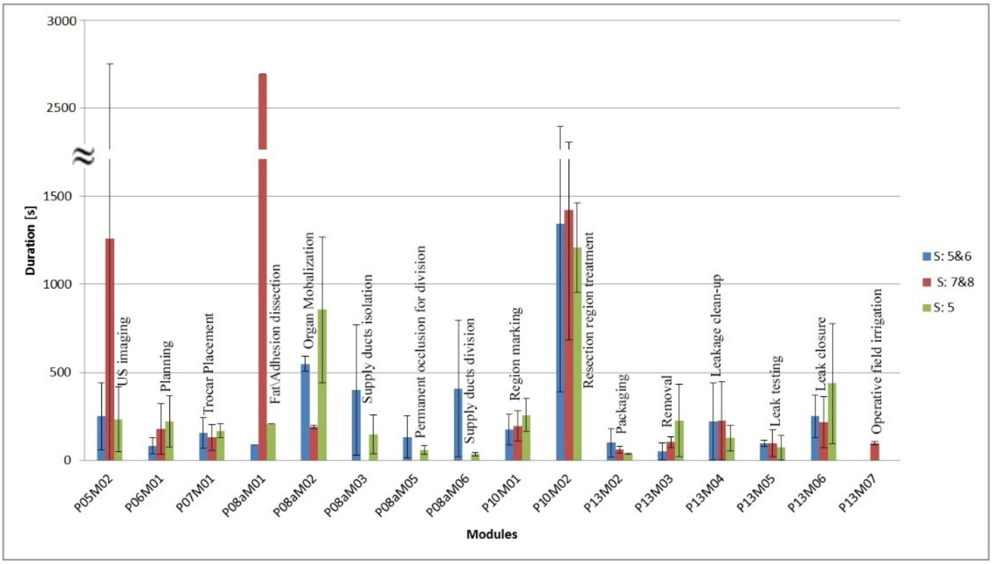

Figure 4.3: Mean duration (standard deviation indicated by whiskers) of the modules for each surgery category.

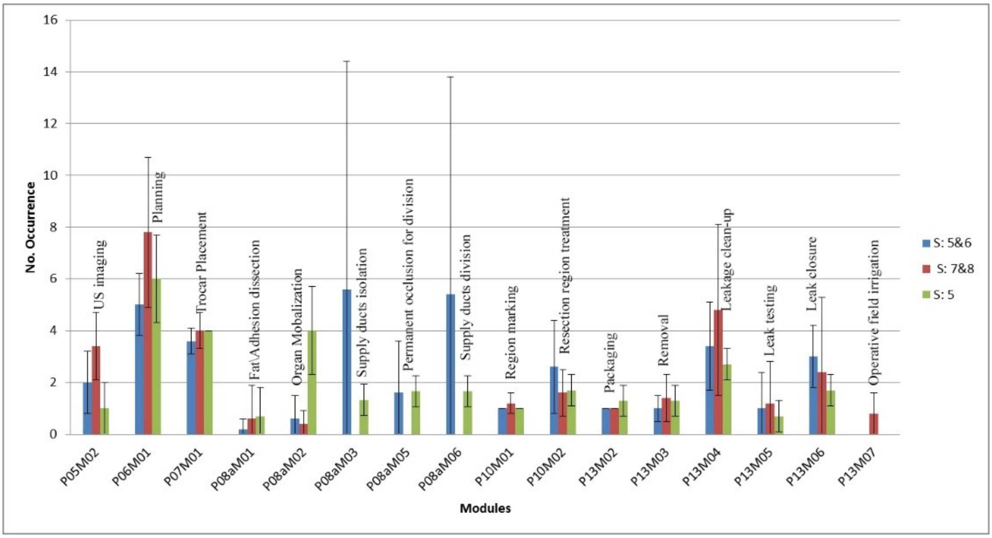

Figure 4.4: Mean occurrence frequency (standard deviation indicated by whiskers) of the modules for each surgery category.

For Segments 5&6 surgeries, 3.6 trocars were used on average compared to an average of 4 trocars for the two other categories. In Segment 5 with gallbladder removal, the surgeon always used 4 trocars, but in Segments 7&8,

the surgeon used between 3 and 5 trocars. In the dataset analyzed for Segments 7&8, no instances of supply duct isolation (P08aM03), occlusion (P08aM05), or division (P08aM06) were observed. This is because although the right hepatic vein passes on the border of Segments 7 and 8 (and its branches penetrate into Segment 7) and a branch of the middle hepatic vein passes Segment 8, the tumours in our dataset were located in the upper parts of Segments 7&8. The occurrence frequency of supply duct isolation (P08aM03) was not equal to that of supply ducts division (P08aM06) for two reasons: 1) the surgeon isolated or divided more than one supply duct in a row in one occurrence of that module, or 2) the surgeon performed other treatment activities after starting to perform isolation of a supply duct while the isolation is not yet completely done. The occurrence frequency of permanent occlusion (P08aM05) was less than isolation and division because not all the vessels require permanent closure before division. In case of Segments 5&6, an average of 1.6 vessels were occluded (with clips or Endo Gia stapler) out of 5.4 divided vessels. Surgeries in Segment 5, which involved gallbladder removal, always required occlusion of two supply ducts, leading to a longer duration for performing supply duct isolation (P08aM03), occlusion (P08aM05), or division (P08aM06) compared to other categories in the dataset. Surgeons typically used surgical clips to occlude the cystic ducts of the gallbladder. Although the permanent occlusion module had an occurrence frequency of less than 2 in Table 4.1, this was because the surgeon only occluded two supply ducts in a single instance of the module. As a result of the analysis, large differences in duration of the imaging module between resections of 7&8 segments and resections of 5 and 6 segments were observed. The result agrees with the fact that wedge resection of tumors in posterosuperior segments is difficult in laparoscopy due to the difficulties for access and poor visualization of these segments, thus assessing parenchyma structure and planning require more time of imaging.

The durations of the “fat/adhesion dissection” module (P08aM01) in Segments 5&6 and Segment 5 with gallbladder removal were considerably smaller than for Segments 7&8. However, the large duration differences of this module between different surgery categories are possibly due to patient condition rather than tumours location. Presence of fat or adhesions is known to be related to parameters such as patient BMI, previous abdominal surgeries and special diseases [43]. Treatment region marking (P10M01) was performed in all surgeries and with similar durations in all surgery categories (~200 s). Treatment (P10M2) durations were similar in different categories, but with different occurrence frequencies. The occurrence frequency of the treatment module in segment 5&6 surgeries was larger than for the other segments, as the surgeons had to take care of large branches of vessels while performing resection, resulting in more transitions in the flow between the treatment phase and the destructive isolation phase for performing supply ducts division during resection. Placement of new trocars and taking new images were other reasons for increasing occurrence of treatment module in different surgery categories. The duration and occurrence of wrap-up activates such as packaging (P13M02) and removal (P13M03) for removing resected tissue and un-absorbable materials, leakage clean-up (P13M04) and leak testing (P13M05) appeared to be not directly linked to the tumour location. Blood leakage volume and the size of the resected region are examples of influencing factors for durations and occurrences of the activities in this phase.

Figure 4.5 shows the average duration of each phase for different surgery categories. In this figure, the fat/adhesion dissection module (P8aM01) was excluded, as its duration was highly influenced by other factors such as BMI and previous abdominal surgeries, more so than all other modules. In all three surgery categories, the surgeons spent most of their time on the treatment phase (P10); approximately 25 minutes (40% of total surgery time), and almost 85% of the treatment phase duration was allocated to the resection. In parenchyma sparing, supply ducts isolation and division may be considered as parts of resection, further increasing the dominance of the treatment phase. Destructive isolation (P08a) and wrap-up activities (P13) each took on average about 13 min (20%) of the surgery time. Imaging (P05) took on average less than 10 min (15%), while planning (P06) itself (without imaging) and making the operative field accessible (P07) each consumed less than 5 min (5%) of the total surgery time.

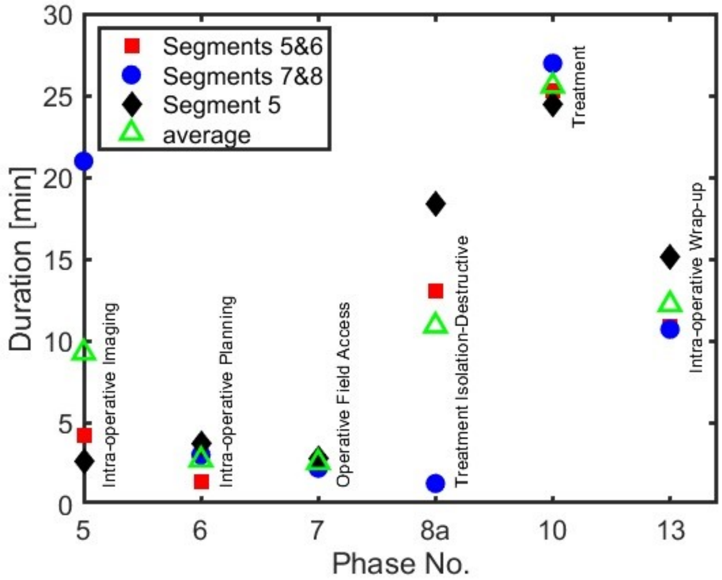

Figure 4.5: Average duration of each phase for different surgery categories. The open green symbols are the average of all three surgery categories. The phase names are given next to the symbols.

Figure 4.6 shows the possible paths of surgical activities in the three different surgery categories, see Figure 4.7 for the explanation of the symbols. The most probable path for each surgery category is indicated by red arrows. The sequence of steps for each category was determined based on the data recorded for each surgery presented in [30] and DOI: 10.4121/20163968. All the possibilities for taking images and generating or updating plans are indicated in the figure. The rectangles show the modules and the occurrence probabilities of the modules are indicated as percentages in the rectangles. The boxes group modules that can occur in any preferred sequence. If the flow goes into one of the boxes, any and several modules can occur successively. In surgeries in Segments 5&6, the surgeon may isolate and divide several ducts during treatment. In this case, *n* indicates the number of occurrences; as the number of occurrence increases the probability of dividing yet another duct decreases.

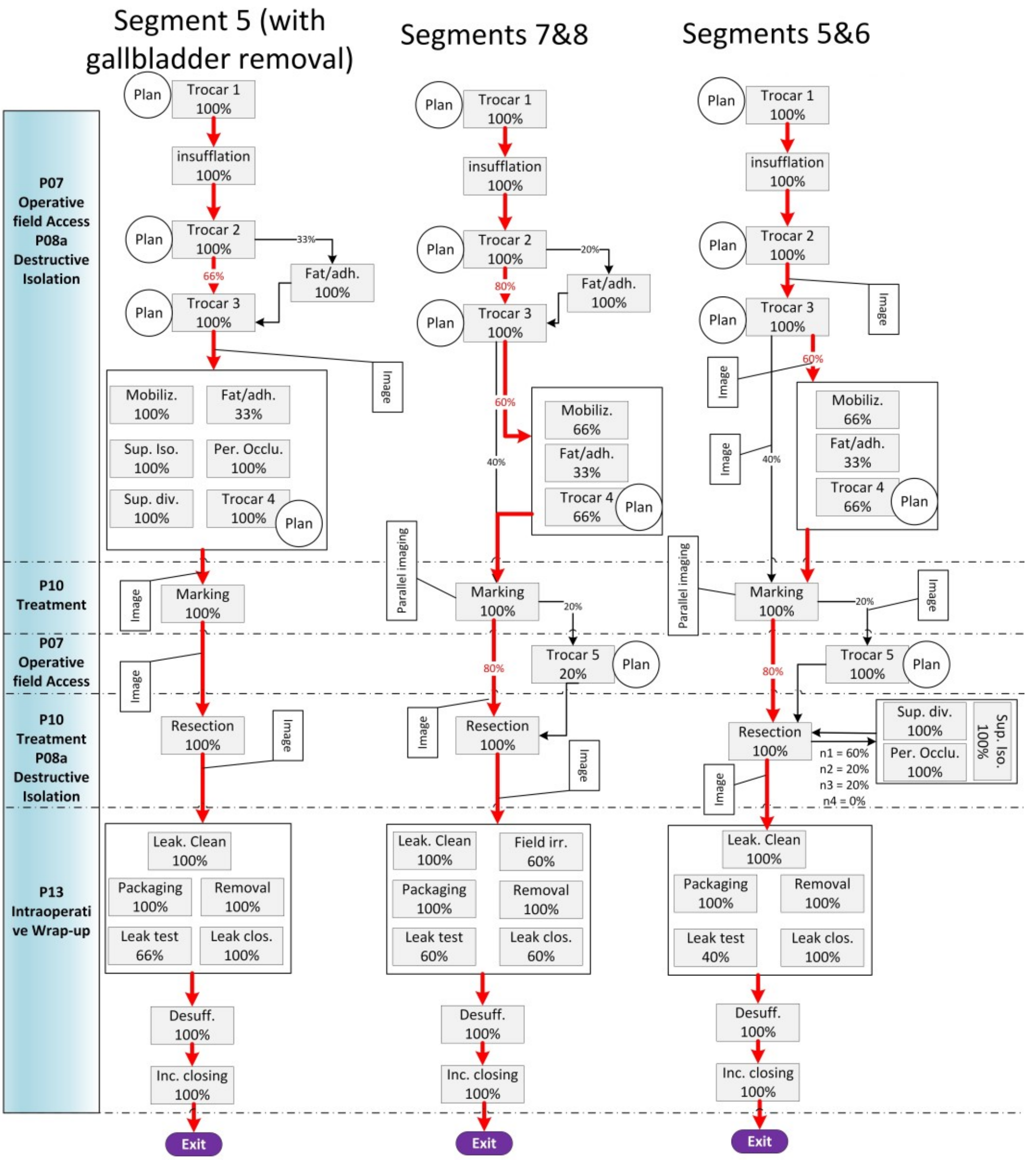

Figure 4.6: Three examples of possible paths of surgical activities in different surgery categories.

Trocar	Trocar Placement **(P07M01)**	Marking	Resection-region marking **(P10M01)**	Field irr.	Operative Field Irrigation **(P13M07)**
insufflation	Abdomen Insufflation **(P07M02)**	Resection	Resection-Region Cutting **(P10M02)**	Desuff.	Trocars Removal & Abdomen Desufflation **(P13M08)**
Fat/adh.	Fat/Adhesion dissection **(P08aM01)**	Packaging	Packaging **(P13M02)**	Inc. closing	Incisions Closing **(P13M09)**
Mobiliz.	Mobilization **(P08aM02)**	Removal	Removal **(P13M03)**	Plan	Planning **(P06M01)**
Sup. Iso.	Supply duct Isolation **(P08aM03)**	Leak. Clean	Leakage Clean-up **(P13M04)**	Image	Imaging **(P05M02)**
Per. Occlu.	Permanent Occlusion for Division **(P08aM05)**	Leak test	Leak Testing **(P13M05)**		
Sup. div.	Supply Ducts Division **(P08aM06)**	Leak clos.	Leak Closure **(P13M06)**		

Figure 4.7: Explanation of the symbols used in Figure 4.6.

To illustrate the differences between different surgery categories, the possible surgical actions for each surgery category are shown in Table 4.2. The table is based on analysis of data recorded for each surgery presented in [30] and DOI: 10.4121/20163968. The percentage in parenthesis show the probability of that module occurring once or more in a surgery. Imaging and planning are done for every surgery category and can happen anytime during the course of a surgery. Therefore, imaging and planning activities are not presented in Table 4.2.

The simulations showed that introduction of the navigation platform will affect the surgical process of LLR in several ways. Based on the exclusion criteria, almost 10% of the simulation data was excluded from the simulation analysis. The convergence of the simulated data was confirmed by comparing the first batch of about 45,000 runs with a second batch of 45,000; the mean values and standard deviations differed less than 0.5% between the first and second batch.

Table 4.2: The workflow of different surgery categories. The percentages show the probability for each module that it will occur (once or more) at some time in the procedure.

Phase name	Segments 5&6	Segments 7&8	Segment 5 (with gallbladder removal)
Operative field access (07)	Trocar 1 (100%)	Trocar 1 (100%)	Trocar 1 (100%)
	Insufflation (100%)	Insufflation (100%)	Insufflation (100%)
	Trocar 2 (100%)	Trocar 2 (100%)	Trocar 2 (100%)
	Trocar 3 (100%)	Trocar 3 (100%)	Trocar 3 (100%)
	Trocar 4 (60%)	Trocar 4 (80%)	Trocar 4 (100%)
	--	Trocar 5 (20%)	--
Destructive Isolation (08a)	Fat/Adhesion* (20%)	Fat/Adhesion* (20%)	Fat/Adhesion* (33%)
	--	--	Mobilization gallbladder (100%)
	--	--	Isolation (100%)
	--	--	Perm. Occlusion (100%)
	--	--	Division (100%)
	--	--	Mobilization gallbladder
	Mobilization Liver (40%)	Mobilization Liver (40%)	Mobilization Liver
Treatment (10)	Marking (100%)	Marking (100%)	Marking (100%)
	Resection (100%)	Resection (100%)	Resection (100%)
Destructive Isolation (08a)	Isolation (60%)	--	--
	Perm. Occlusion (60%)	--	--
	Division (60%)	--	--
Treatment (10)	Resection	--	--
Wrap-up (13)	Leakage clean-up (100%)	Leakage clean-up (100%)	Leakage clean-up (100%)
	Leak Testing (40%)	Leak Testing (60%)	Leak Testing (66 %)
	Leak Closure (100%)	Leak Closure (60%)	Leak Closure (100%)
	--	Irrigation (60%)	--
	Package (100%)	Package (100%)	Package (100%)
	Removal (100%)	Removal (100%)	Removal (100%)
	Desufflation (100%)	Desufflation (100%)	Desufflation (100%)
	Incision closing (100%)	Incision closing (100%)	Incision closing (100%)

*) Might also be influenced by other factors such as BMI and previous abdominal surgeries.

Figure 4.8(a) shows the mean values of total surgery duration for all three scenarios of performing LLR. As can be seen, the choice of distribution function has a large effect on the duration of the surgeries. However, in both cases the navigation platform has a considerable effect on the total surgery duration. The simulation results show the impact of the navigation platform in different scenarios. In Scenario 3, the mean duration of surgeries decreased by 25 minutes compared to Scenario 1. The results in Figure 4.8(a,b) imply that the positive impact of the navigation platform is largest for surgery on Segments 7&8. The improvement percentages (i.e. average of total duration of $Sc._x$ ($Scenario_x$) divided by the average of total duration of $Sc._1$) are plotted in Figure 4.8(b). In Segments 7&8 the total duration of surgeries decreases by 20 and 30% for scenarios 2 and 3, respectively. In Segments 5&6 the total duration of surgeries decreases by 15% for scenario3, however, it shows a minute increase (0.6%) for scenario 2. In Segment 5, total durations decrease 2% for scenario 2 and 10% for scenario 3. A one by one analysis of modules suggests that the larger decrease in Segments 7&8 is due to longer imaging duration than other surgery categories.

The choice of probability distribution has a large effect (up to 30%) on the average of the total duration of surgeries, see the difference between solid line and the corresponding dashed line in Figure 4.8(a). Thus, predicting the true duration of surgeries depends on a reliable choice of distribution function. However, Figure 4.8(b) suggests that the change with respect to Sc.1 of the surgeries for different scenarios only slightly depends on the choice of probability distribution function.

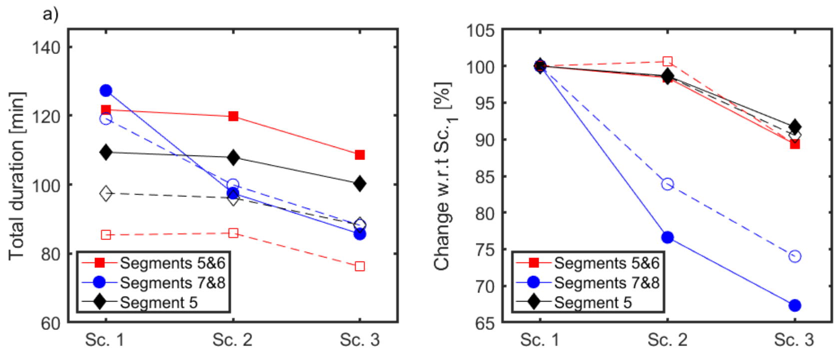

Figure 4.8: (a) The simulation results of the average of total duration of surgeries with Uniform (solid lines) and Gaussian (dashed lines) distributions. The scenarios are: Sc.1 no use of the navigation platform, Sc.2 navigation platform in use – conservative positive effect and Sc. 3 navigation platform in use – optimistic positive effect. (b) The improvements in average of total duration of surgeries in percentage with respect to scenario 1, i.e. average of total duration of $Sc._x$ divided by the average of total duration of $Sc._1$.

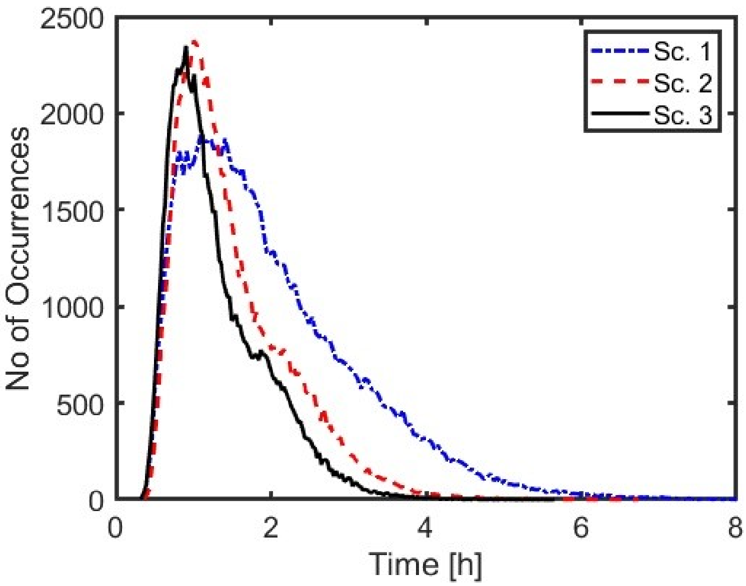

Figure 4.9: Probability distribution functions of total surgery duration of different scenarios for Segments 7&8 with a Uniform distribution for all modules' durations.

The probability distribution functions of total surgery duration for segments 7&8 are shown in Figure 4.9. Based on Figure 4.9, it is clear that in scenarios 2 and 3 the distribution functions are shifted towards lower values. The most probable total durations of surgeries (the peaks of the curves in Figure 4.9) were decreased by 10% and 20% for scenarios 2 and 3 compared to scenario 1, respectively. The simulation data shows that the potential benefit (in terms of procedure duration) of introducing new technologies depends on location of the tumour.

4.4. Discussion

The surgical process model of LLR was analysed for three categories of parenchyma sparing. The most probable workflow paths and the durations and occurrence frequencies of all relevant steps were presented and compared for the three surgery categories. Deriving the possible paths of treatment and the probability distribution of durations and occurrences of the surgical workflow elements out of raw surgical data enables predicting next surgical steps, improving surgical training systems, analysing surgical performance, etc..

Moreover, it provides insight into the points for improvement and bottlenecks in the surgical process.

The analysed surgical procedures were highly variable and determining a sequence between some steps of surgical steps resulted in numerous possible surgical paths. Yet, these are covered by the flowchart in Figure 4.6.

This study focused on parenchyma sparing of three tumour locations in the right lobe of the liver. In this study, we focused on the wedge resection of different segments in the right liver lobe, which is generally considered more complex than the left lobe. Specifically, we chose three categories: 7&8 (posterosuperior segments), 5&6 (anterolateral segments), and 5 (with gallbladder removal-cholecystectomy). We selected data from posterosuperior segments as these are known to be extremely challenging for laparoscopy due to limited visualization, the risk of bleeding, and longer operative time. Thus, we expected the navigation platform to have a more pronounced effect on these segments (7&8). Moreover, we included Segments 5&6 and 5 to compare the results of wedge resection with and without cholecystectomy. Cholecystectomy is a relatively standard procedure, and this comparison could provide valuable insights into how the interpretation of results varies for the steps involving cholecystectomy. Overall, by examining these three categories, we aimed to gain a better understanding of the effectiveness of the navigation platform for different liver segments and procedures.

The data provided in Table 4.1 is based on a limited dataset of 13 interventions. However, first author MG of this paper has attended an additional 15 LLR in OUH (Oslo, Norway), Erasmus Medical Center (the Netherlands) and Bern University Hospital (Switzerland), and performed interviews with surgical teams between 2017 and 2019. These observations and interviews support that the available dataset properly represents everyday clinical practice at least in these three institutes. We made an effort to maintain consistency by selecting certain hyperparameters that could have a large impact on the procedure, such as tumor location, while keeping other factors constant (e.g., same hospital, highly skilled surgeons, malignant tumors, single lesion, right lobe). We acknowledge that a larger dataset would offer a more comprehensive analysis and account for extreme cases, but the challenges of data acquisition and availability across different medical centers, coupled with the time-consuming task of video analysis at the presented granularity level, compelled us to balance the number of analyzed videos and variation of hyperparameters. To avoid evaluating individual surgeon performance and to achieve a more generalizable interpretation of the process, we did not select only one head surgeon. Instead, we chose to analyze surgeries performed by different surgeons with similar levels of expertise. To maintain consistency, we kept the surgical teams as similar as possible by varying the head surgeons and assistants. It is worth mentioning that manual analysis and verification of endoscopic videos is a time consuming task, consuming up to 5 days per processed surgery. Therefore, to gather more data, automated workflow steps recognition and analysis systems using artificial intelligence (AI) would be of great use. Such systems have been explored for minimally invasive surgeries such as cholecystectomy [21], but a working automated workflow step recognition system for the level of process detail presented in this work is challenging and has, to the best of our knowledge, not yet been developed.

Automatic phase/step detection is a critical aspect of analyzing large datasets to accurately predict surgical steps during an operation. In this work, we changed one parameter (location of the tumor), while the other parameters (e.g. number of tumors, patient conditions) were kept similar. However, with automatic video analysis, it is possible to create a large dataset, to cover different variable parameters and consequently plan and predict surgical steps, as well as the remaining time of surgery more accurately. In hybrid ORs, the data gathered from various sources is crucial for making informed surgical decisions, automating certain surgical tasks using robotic arms, and providing valuable support for surgeons to tackle the challenges posed by certain surgical cases. For instance, in LLR, changing the patient's position can cause deformation of the liver, highlighting the need for a more precise 3D model during the operation. Analysis of surgical steps using SPM can help develop context-aware systems that can automate where intraoperative CT/ultrasound is needed to be taken for performing certain surgical steps.

Besides, SPM-based analysis of procedures and deriving possible sequences of identifiable and meaningful tasks out of highly variable surgeries, aid the improvement of different aspects of the development of AI systems for automating surgical tasks. Data are the foundation for AI; however, the complexity of surgical treatments makes interpretation and management of the huge amount of data difficult. Extraction and analysis of surgical steps and the ways of performing them, enable effective data acquisition, data storage, data analysis, surgical steps planning, etc. in AI systems. These capabilities contribute to the extension of existing technologies towards more autonomous surgical actions in the future [44, 45].

Introduction of new technologies will affect the surgical process of LLR in several ways. A discrete event simulation model of LLR was built to investigate different scenarios that were defined for performing LLR. The changes in duration of different process model steps, as results of employing new technologies, introduced in different scenarios were estimated based on the authors' hands-on experience with available systems. Therefore, actual performance benefits may very well deviate from the presented outcomes. It was observed that the choice of the distribution function affects the average total duration of surgeries, thus, finding a reliable distribution function is required for accurate prediction of total surgery durations. However, the compensated total duration of surgeries showed to be robust for the choice of distribution function. Nonetheless, the simulations provided much insight into what could be gained with such technology in different situations. Furthermore, the flexibility of the simulation model allows adaptation of these estimates and any other parameters in future design and optimization of new technologies for LLR. The proposed methodology has the potential to evaluate the impact of various other technologies, such robotic arms performance and surgical instrument design.

4.5. Conclusions

The endoscopic videos from laparoscopic liver surgeries performing parenchyma sparing technique for the tumours located in Segments 5&6, 7&8 and 5 (with gallbladder removal) were analysed to acquire detailed surgical process data. The surgeries were put into three categories based on tumour location and the most probable workflows of the surgeries in different categories were derived. In all three surgery categories, we showed that the actual treatment (P10M02) covers the major part of the total procedure duration. A discrete event simulation model was developed to predict the impact of introducing new technology. It has been shown that the impact of the proposed new navigation platform depends on the location of tumours, and has the potential to decrease the surgery duration by up to 10% in Segment 5, up to 15% in Segments 5&6 and up to 30% in Segments 7&8, which is known to be difficult segments [46]. This shows the relevance of such navigation platform for difficult segments (i.e. 7&8), where visualization is limited. This study showed that a discrete event simulation model based on the analysis of steps during surgical procedures can be used to predict the impact of new technology.

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Chapter 5: Assessment of a new visualization technique on phantom training with the help of surgical process modelling

Abstract

This chapter explores the application of process modelling techniques to enhance surgical training and improve surgical outcomes, through analyzing the surgeon's learning curve, surgical pitfalls, and difficulty levels for surgeons with varying levels of experience. This chapter demonstrates the process modelling as a valuable technique for analyzing the surgical training and gaining insights into surgical challenges and skill development. Specifically, the focus was on microsurgical treatments where the visualization of surgical details plays a critical role in surgical success. To address this, robot-controlled digital microscopes like Modus V™ have emerged to enhance visualization and ergonomics during microsurgery. Hands-on lymphatic suture training sessions using the Modus V™ robotic digital microscope were conducted on a brain phantom. Five distinct scenarios were designed to examine the impact of lymphatic vessel location, size, and angle on the perceived difficulty of the surgery. Process modelling techniques were employed to break down the training session procedures into discrete steps for analysis of the different scenarios. The results were categorized based on participants' experience with conventional optic microscopes. The analysis revealed that the angle and size of the vessels significantly influenced the difficulty of the training scenarios, with larger angles and smaller vessel sizes increasing the level of difficulty. The data showed that the surgeons who had previous experience with a traditional microscope, have a large lead compared to the novice surgeons with limited experience with a traditional microscope.

5.1. Introduction

With the introduction of the new technological advances in the OR in the last decade, the already difficult task of surgeons' training became more challenging. However, the introduction of new devices and technologies in the OR also brings their inherent technological advantages: moving towards more efficient and safer surgeries. Training sessions should be carried out to master the new technologies before their actual use in real surgeries. Analysis of these training sessions can answer questions such as how many training sessions are required before usage of new technology in the OR, what the surgeon's pitfalls are, what the difficult situations are, in which surgery situations the new technology can improve the surgical procedure and outcome, etc.

Modus V^{TM} is a robotically controlled digital microscope and is an example of new technology that recently emerged to improve the visualization and ergonomics during various types of microsurgeries/neurosurgeries. The Modus V^{TM} microscopic camera has not been deployed to many hospitals around the world yet. Hence, the impact of using this technology in performing microsurgery on different surgery scenarios is not yet clear. In micro/neuro-surgical treatments, the surgical outcome is inherently related to the ability to visualize the operational field [1]. Traditionally, the surgeons wear magnifying glasses or use conventional optic microscopes to discern between malignant and healthy tissues or determine different vessel types to properly restore [2]. However, the performance of conventional optical microscopes is hampered by limiting the ability of magnification and focus, difficulty to move the bulky microscope, and limited ergonomics [3, 4]. Modus V^{TM}, as an example of a newly introduced technological advance [5], facilitates performing challenging supra-microsurgical interventions containing tiny lymphatic vessels (depending on where they are located, e.g. average of 0.2 mm in the neck [6] and 1-2 mm in the lower human extremities [7]) or removing tumors in strictly predetermined affected brain areas in neurosurgery. Furthermore, Modus V^{TM} magnification ability facilitates working on smaller vessels during supramicrosurgery [8].

The digital microscope is attached to a robotically controlled arm and moves intuitively by tracking surgical instruments while displaying high-quality images of the surgical field on a monitor, see Figure 5.1. Although the Modus V technology, offers an improved quality-image of the surgical field, the recently introduced Modus V technology provides 2D visualization of the microscopic field on a computer monitor, which limits surgeons' depth perception compared to a traditional microscope. Moreover, the surgeons have to look at a screen in front of them while performing the operation which might be uncomfortable for surgeons.

Figure 5.1. Surgeons performing robotically assisted microsurgery with Modus V technology (courtesy of Synaptive Medical).

The introduced digital microscopy is new for many surgeons. Training is required to get acquainted with the new 2D visualization method before its use in clinical practice and to spot the difficult surgery situations and surgeons' pitfalls [5]. The impact of using the introduced digital microscopy is expected to become most clear under difficult conditions. Therefore, different training scenarios need to be designed and investigated. In this chapter, five different training scenarios are introduced that were carried out in training sessions with the robotic arm digital microscope. The recordings of the training sessions were analyzed by dividing the surgical procedure into surgical steps using surgical process modelling techniques [9-12]. The results were used to study the effect of location, angle, and size of vessels on the difficulty level of training and surgeons' pitfalls. The surgeon's learning curves in using the Modus V™ was analyzed by comparing different trials.

5.2. Method

5.2.1. Training procedure design

Training sessions can be designed for various approaches, such as virtual/augmented realities [13, 14], computer simulations [15, 16] phantoms [17-19], and animal trials [20, 21]. In collaboration with the microsurgeons in the surgery department of the Erasmus Medical Center (Rotterdam, The

Netherlands), phantom training was chosen and the training procedure with the new visualization methods of Modus V^{TM}. The main objective of these training sessions was chosen to be to suture two lymphatic vessels, which is one of the main and most difficult activities in lymphatic surgeries.

The training steps are defined as follows:

Step 1. The surgeon grabs the thread and one vessel with the instrument. The surgeon is free to choose with which part of a vessel to start with (Figure 5.2a). The surgeon passes the thread through the vessel (Figure 5.2a). The surgeon grabs the other part of the vessel and passes the thread through that (Figure 5.2b).

Step 2. The surgeon makes knots (three times) (Figure 5.2c).

Step 3. The assistant cuts the thread (Figure 5.2d).

Step 4. The surgeon prepares the thread for repeating Steps S1 to S4.

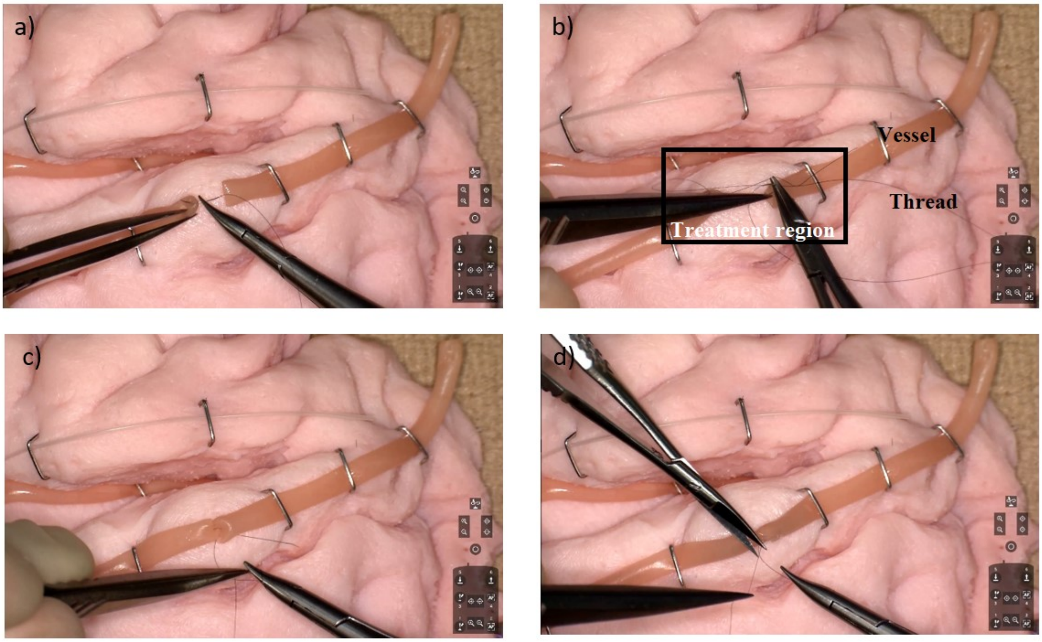

Figure 5.2: Snapshots of training recordings illustrating a & b) Steps 1, c) Step 2, d) Step 3.

5.2.2. Experimental setup and data acquisition

A brain phantom (Brightmatter simulate, Synaptive Medical, Toronto Canada), blood vessel phantom (3mm diameter, Synaptive Medical, Toronto Canada), and supermicrosurgery lymphatic vessel phantom (silicone tube 1mm outer diameter) were used in the training sessions. Five standardized training scenarios were created by working on an angled operating field and in a deep layer of tissue:

- Scenario 1: Sutures on a blood vessel, 0 degrees, superficially on the brain phantom.
- Scenario 2: Sutures on a blood vessel, 30 degrees, superficially on the brain phantom.
- Scenario 3: Sutures on a blood vessel, 60 degrees, superficially on the brain phantom.
- Scenario 4: Sutures on a blood vessel, 0 degrees, deep in the brain phantom.
- Scenario 5: Sutures on a lymphatic vessel, 0 degrees, superficially on the brain phantom.

The location of these scenarios and the different types of vessels are depicted in Figure 5.3. Extra images of the scenarios are provided in Appendix A. Five scenarios were tailored in a way to be able to compare the effect of vessel location, angle, and size. Scenarios 1, 2, and 3 show the influence of vessel angle. Scenarios 1 and 4 show the effect of location and Scenarios 1 and 5 show the effect of size.

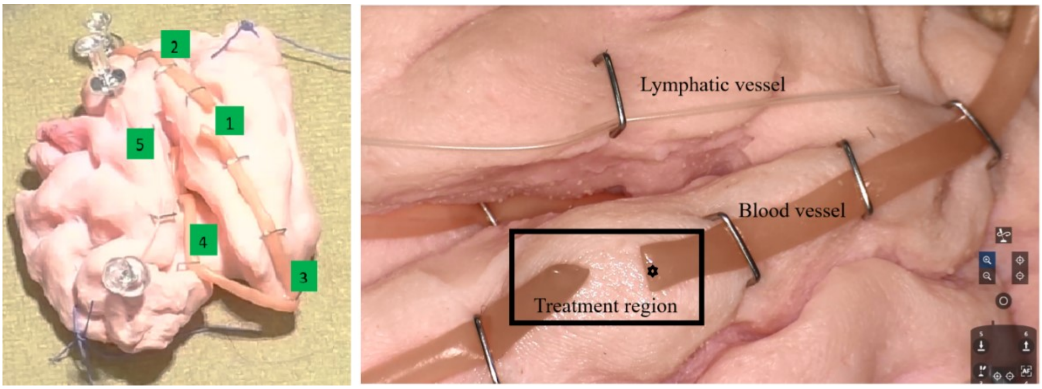

Figure 5.3:The brain phantom, (left) locations of the scenarios on the brain phantom and (right) the blood and lymphatic vessels. The treatment region can be on the blood vessel or lymphatic vessel, depending on the scenario.

Performing five full anastomoses would take around 2 hours (more than 20 mins per scenario). This is longer than the usual duration that surgeons use the microscope. To limit the total duration of training sessions, the working duration per scenario was set to six minutes, amounting to 30 minutes for five scenarios. Suture locations were placed at approximately 0, 90, 180 and 270 degrees, with 0 at the top of the vessel, see the star in Figure 5.3, Additional sutures were placed per surgeon's preference when time allowed. To eliminate the role of the assistant surgeon on the anastomosis outcome, the same assistant was chosen with strictly defined support: to only cut the threads at the end of the third knot on her own initiative or at instruction of the surgeon if needed.

The surgeons started with Scenario 1 and finished with Scenario 5. Performing these five scenarios once was considered the first trial. After that, the surgeons repeated those in a second and a third trial. The scenarios were not randomized because the maximum number of trials was three. Thus, randomization might make the interpretation of the data very difficult. The second and third trials were scheduled on the same day or a few days later, depending on the surgeon and OR availability. The training of the participants was recorded by the build-in Modus V^{TM} camera.

5.2.3. Process model establishment and data analysis

To analyse the training data, the process model of the training was established by dividing the training procedure into well-defined steps [9-12] . Each training step contains a set of activities for accomplishing that step. The process model was made after observation of five training sessions in the OR and ten video recordings of other training sessions. Based on the data from the OR observation and video recordings, a top-down approach was used to establish the process model of training session. The process model was established allowing quantitative analysis of training procedures by providing the relations between training steps. The process model diagrams were used as the model representation method. For more details, we refer to Chapters 2 and 3. The process model was verified by observing the training steps conforming to process model as an *a posteriori* check. Moreover, for each step the possible pitfalls were defined.

The videos of each training session, captured by the Modus V^{TM}, were analyzed to extract the duration of each step. A workflow registration software was developed in-house to facilitate the registration of data on the videos of the training (Figure 5.4). With the software, the duration and the corresponding pitfalls of each step were registered.

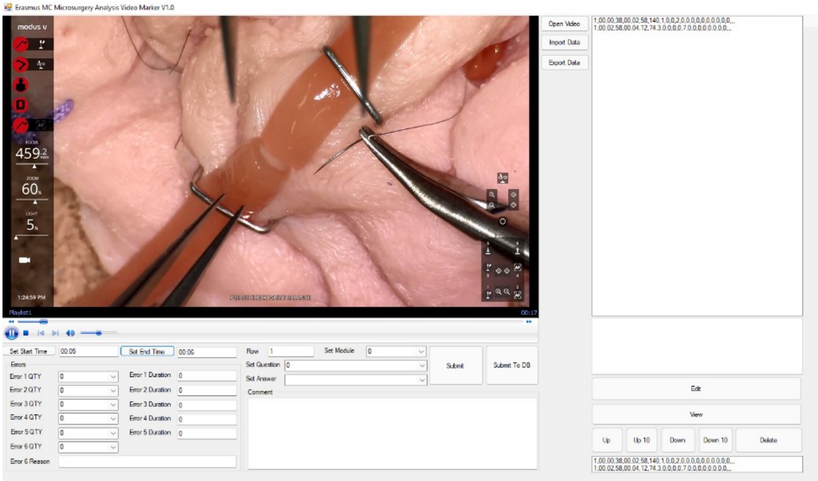

Figure 5.4:A snapshot of the in-house built workflow analyzer software, analysing the step duration and pitfalls.

5.3. Results

The surgical process model for the lymph vessel suturing task during training is provided in Figure 5.5(a). Each purple box shows a training step that contains a set of activities for accomplishing a certain step. Figure 5.5(b) shows as an example, the activities of the step “Tying the knot”. In Figure 5.5(a), the surgeon starts by grabbing the thread and one part of the vessel and passes the thread through the vessel. Next, the surgeon does the same with the other part of the vessel (Step S1). The surgeon then makes the knot three times (Step S2) and the assistant cut the rest of the thread if needed (Step S3). The surgeon prepares the next thread (Step S4) and starts the procedure again. Performing Steps S3 and S4 were required to go to the next cycle. The number of Steps of S1 and S2 together were considered as the number of complete cycles.

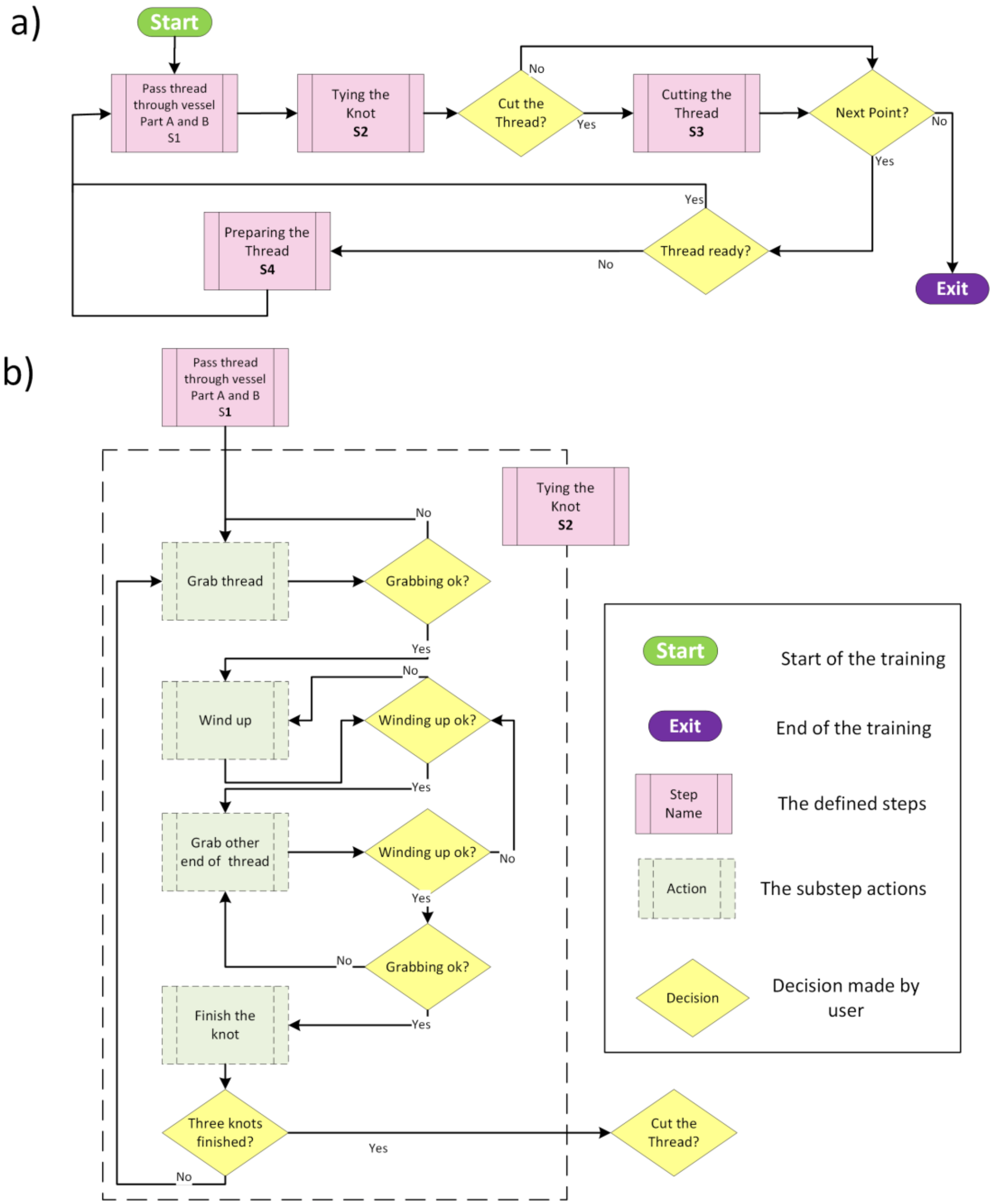

Figure 5.5: Surgical process model of a) the lymphatic surgery training and b) the activities in the Tying the knot step.

The following Pitfalls were defined for Step S1:

1. misgrabbing vessel (referred to as P1S1).
2. misgrabbing threads (referred to as P2S1).
3. mislocating the thread in a vessel (referred to as P3S1).
4. thread passes both walls (referred to as P4S1).

Pitfalls defined for Step S2 were:

1. misgrabbing threads (referred to as P1S2).
2. failing to knot (referred to as P2S2).

Twelve participants from an academic training hospital (Erasmus MC, the Netherlands) participated in this study. The participants were categorized according to their level of experience of lymphatic surgeries with the conventional optical microscope.

- Five experienced surgeons (microsurgeons with more than 5 years of experience).
- Four semi-experienced surgeons (residents with 2 to 4 years of experience).
- Three novice surgeons (medical students without any surgical experience).

All participants completed the first trial for all scenarios. Four experienced and two novice surgeons also carried out the second trial. Three experienced and one novice surgeon finished all three trials.

5.3.1. Scenarios comparison

Figure 5.6a shows the average number of cycles for the first trial of the participants. The effect of angle, location and size of the vessels on the difficulty of training are presented.

Angle: Figure 5.6a shows the number of completed cycles for different scenarios for surgeons with different experience levels. As is expected, experienced and semi-experienced surgeons performed more cycles (per 6 mins) than novice surgeons. Comparing the scenarios showed that the experienced surgeons performed Scenarios 1 and 2 better (i.e. more cycles per time limit) than Scenario 3. Similar trends were observed for semi-experienced and novice surgeons.

Location (superficial or deep): Scenario 4 was done slightly better than Scenario 1.

Size: Comparing Scenarios 1 and 5 showed that as the size of the vessel was smaller, it became also harder for the participants to complete cycles. None of the novice surgeons could complete the Scenario 5 cycle with lymphatic vessels. The experienced and semi-experienced surgeons performed Scenarios 1, 2, and 4 better than Scenario 5. Thus, it was harder to perform the training on smaller vessels than on larger vessels.

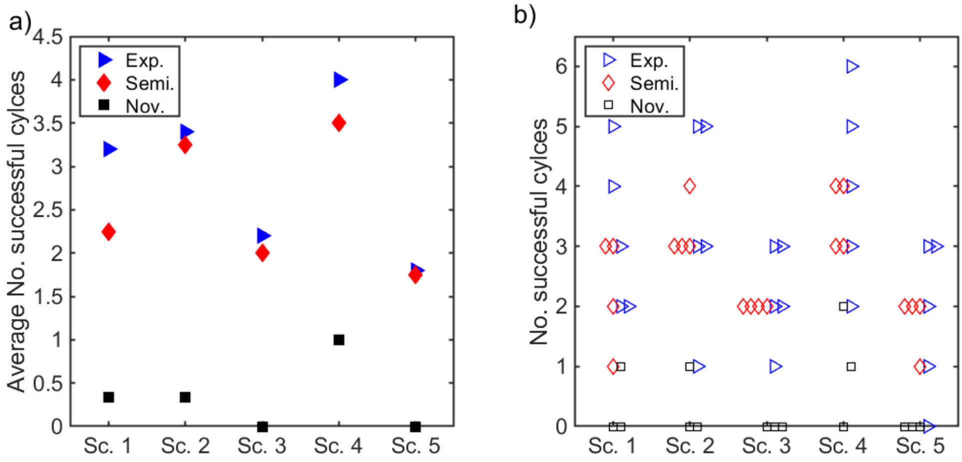

Figure 5.6: Number of successful cycles in the first trial for 5 experienced ("Exp."), 4 semi-experienced ("Semi."), and 3 novice ("Nov.") surgeons. a) Average number of completed cycles for each surgeon category and b) shows the individual WHAT of the same data as in Figure a. Sc.= Scenario.

Figures 5.7(a-c) show the time that surgeons spent for Step S1 for the first occurrence, and for Step S1 and Step S2 in any second (or more) occurrences, respectively. We analyzed the first occurrence of Step S1 separately from the second and more occurrences of those steps because in the first occurrence the vessels are completely apart and consequently Step S1 is more difficult in the first occurrence. Steps S3 and S4 took on average less than 10 seconds and were not the focus of the training sessions.

Figure 5.7 shows that the experienced surgeons consistently spent approximately one minute for each of Steps S1 and S2, amounting to around 2 minutes per cycle. The results of novice surgeons were more scattered (between 2 to 6 minutes for each step), indicating less consistent performance.

Note that if there is no data presented for a step/scenario, it indicates that none of the surgeons in that category reached/finished that step.

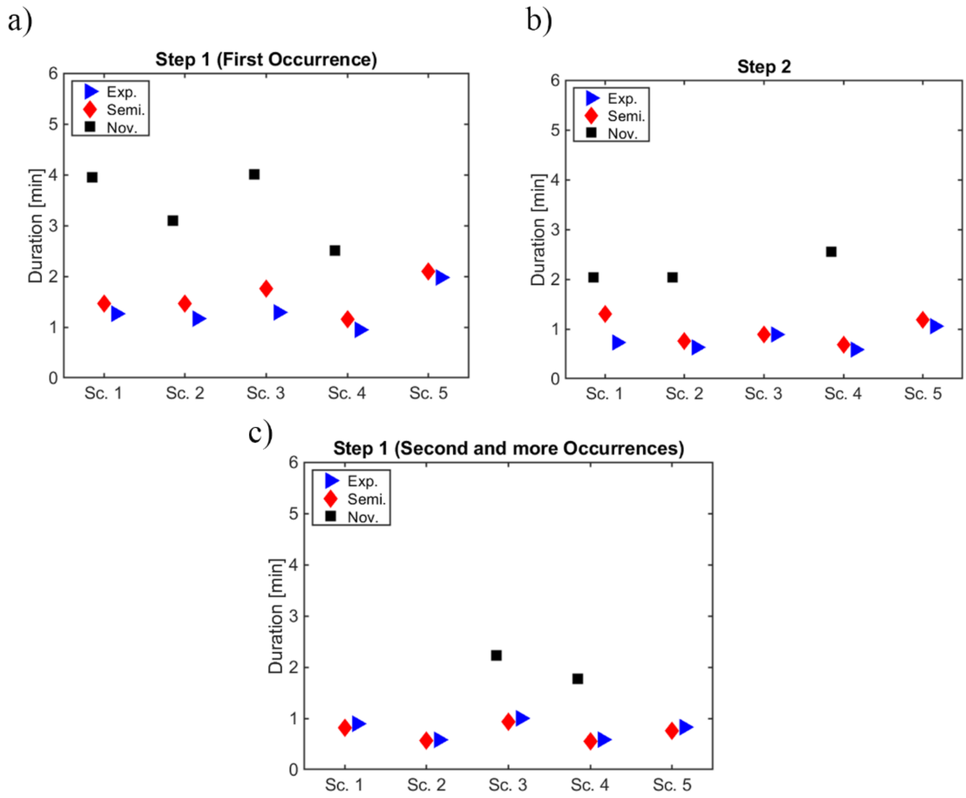

Figure 5.7 (a) Duration of the first occurrence of Step S1 and (b) Step S2, and (c) for any second and more occurrences of Step S1. The data is from the first trial of all surgeons and averaged over 5 experienced surgeons, 4 semi-experienced, and 3 novice surgeons.

5.3.2. Learning curve

Three experienced and one novice surgeon finalized three trials. Figure 5.8 shows the number of completed cycles as a function of trial number. Note that the number of cycles was calculated as an average over Scenarios 1 to 5 in each trial. While both experienced and novice surgeons showed improvement with increasing trials, the novice surgeon showed a more shallow learning curve.

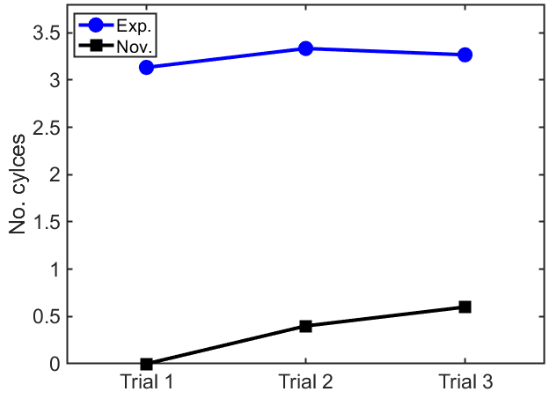

Figure 5.8: Number of completed cycles for different trials. The blue line is the average over Scenarios 1 to 4 and over three experienced surgeons and the black line is averaged over Scenarios 1 to 4 for one novice surgeon.

Figure 5.9 shows the duration of Step S1 when occurring for the first time. This step took 4 mins in the first trial, while it took less than 2 mins in the third trial for the novice surgeon. However, for the experienced surgeon, this step (S1) took approximately 1.5 mins for all trials. Just as for the other variables, experienced surgeons did not show large improvements in the time spent on S1 over successive trials.

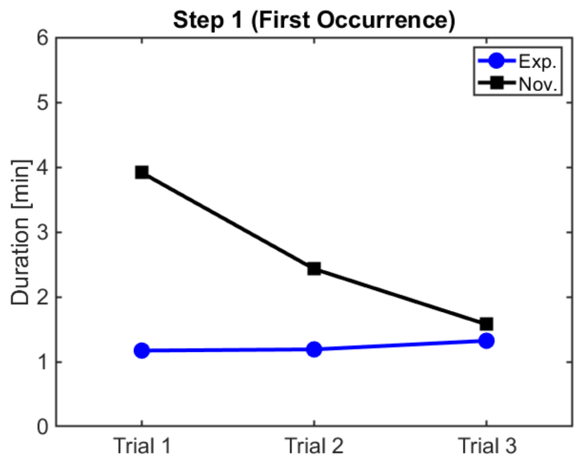

Figure 5.9: Duration of the first occurrence of Step S1. The blue line with dots is for the experienced and the black line with squared is for novice surgeons.

5.3.3. Pitfalls analysis

Figure 5.10 shows the number of pitfalls per step, averaged over different scenarios. A zoom-in window is also provided in the figure. Most of the pitfalls happened on average only less than once per step, however, three pitfalls occurred more frequently for novice surgeons, P2S1, P1S2, and P2S2. The novice surgeons had clear difficulty in making a knot (P2S2), they tried several times until they succeeded in making a knot. They had also difficulty in grabbing the thread (P2S1 and P1S2).

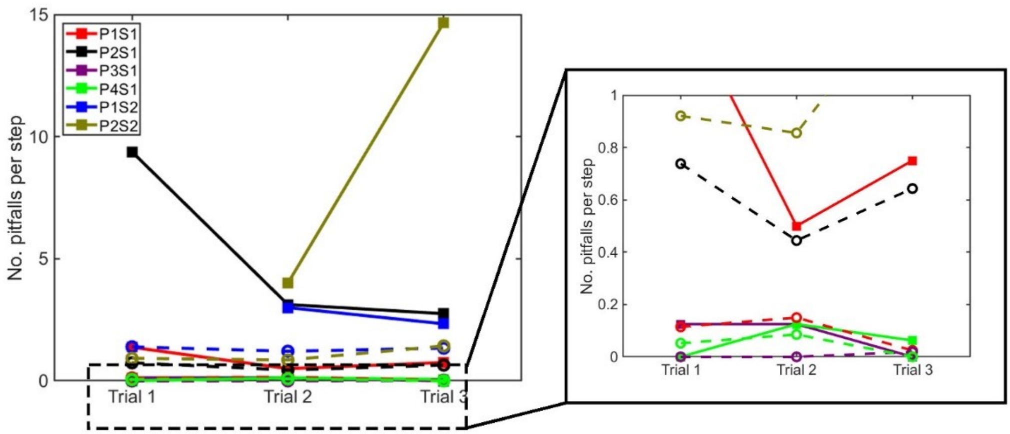

Figure 5.10: The number of pitfalls per step (average over different scenarios) as a function of trials. The solid lines are the data from novice surgeons and the dashed lines are the corresponding data from the experienced surgeons. A zoomed-in window of the bottom of left figure is shown on the right hand-side of the figure.

Figure 5.11 shows the number of pitfalls that occur in the first trial. A closer look at the scenarios, one by one, shows that for novice surgeons, the number of occurrences of P1S1 for Scenario 5 is considerably (approximately 5 times) larger than that of other scenarios. This may be an indication that novice surgeons have difficulty in grabbing the smaller vessel of Scenario 5. The novice surgeons also seem to pass the thread through both vessel walls (P4S1) more frequently specially in Scenarios 3. The data show that the increased angle (Scenario 3) also increases the possibility of passing the thread through both walls; probably due to the extra difficulty of handling the thread and vessel. The pitfall graphs for P2S1-4, P1S3, and P2S3 are given in Appendix B.

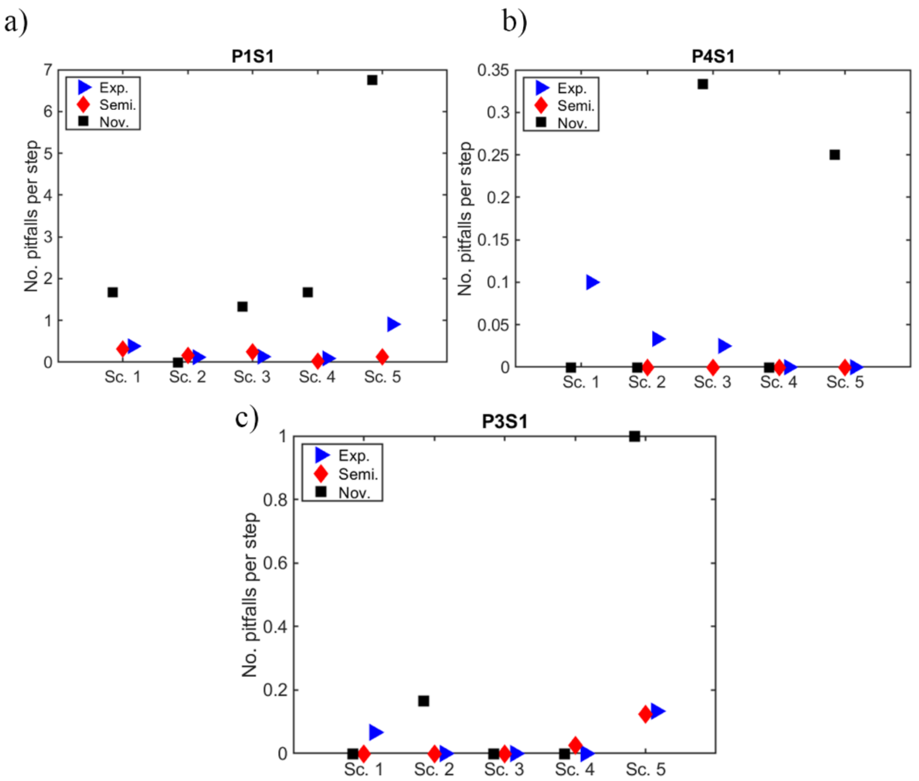

Figure 5.11: Number of pitfalls per step, for (a) P1S1 misgrabbing vessel, (b) P4S1 thread passes both walls, and (c) P3S1 mislocating the thread in a vessel . The data is from the first trial of the surgeons and averaged over 5 experienced surgeons, 4 semi-experienced, and 3 novice surgeons.

5.4. Discussion

In this study, five different surgery scenarios were designed to investigate surgeons' performances while using the new visualization technology provided by Modus V. The training sessions were recorded to evaluate the difficulty levels of training depending on the location, angle, and size of vessels, and to study the learning curve of the surgeons. The training sessions were divided into sequences of steps, taking advantage of surgical process modelling principles, see Chapters 2 and 3. Here, the process model of the training sessions was relatively simple. However, the same methodology can be used for complicated procedures. The procedure's pitfalls were defined and the surgeons' learning curves analyzed. The surgeons' performances in different scenarios and different training steps were compared. As a result, surgery situations that are difficult when using the new visualization technology could be identified.

The results suggest that the vessel angle with respect to the phantom and size are the main contributing factors in determining the difficulty level of a training scenario. Increasing the angle from 30 to 60 increased the level of difficulty of training. It is worth mentioning that the surgeons tried the scenarios subsequently, so when surgeons are performing Scenario 5, they slightly got acquainted with the procedure through Scenarios 1 to 4. This especially holds for novice surgeons.

Overall, the experienced and semi-experienced surgeons performed better (more cycles and fewer pitfalls, see Figures 5.6 and 5.7) than novice surgeons. The experienced and semi-experienced surgeons spent consistently around 2 minutes per cycle. On the other hand, novice surgeons spent between 2 and 6 mins on each step. This suggests that luck or larger variations in skills between surgeons play a large role in the case of novice surgeons, while for the experienced and semi-experienced surgeons the level of experience is the dominant factor.

The result of this study shows a shallower learning curve on Modus V for novices compared to the experienced surgeons. This is understandable, as the experienced surgeons had significant experience with traditional microscopes, thus they performed the first trial at a good level and the room for improvement might not have been large to begin with. The experienced surgeons completed one cycle in less than 2 minutes, hence there was not much room for improvement left. Novice surgeons had no experience with a traditional microscope. They had a larger room for improvement compared to the experienced surgeons.

Misgrabbing a vessel (P1S1) is more often a pitfall for novice surgeons in Scenario 5 than in other scenarios. This is an indication that novice surgeons had difficulty in grabbing the smaller vessel of Scenario 5. The novice surgeons also passed the thread through both walls (P4S1) more frequently for Scenarios 3 and 5. In Scenario 5, because the vessel was smaller, the thread passed sometimes accidentally through both walls. For a larger vessel (Scenarios 1-4), that was not an issue as they had more area for penetration. The data showed that the increased angle also increases the possibility of passing the thread through both walls; probably due to the extra difficulty of handling the thread and vessel. All the surgeons also had extra difficulty in locating the penetration point (i.e. the point that needle is inserted into the vessel) at the correct place as the vessel size decreases. For a correct suture, the needle must go through the wall and should exit the vessel end via its lumen. If the penetration point is far from the end of the vessel, the needle catches the opposing vessel wall. This action becomes more difficult with the smaller vessels as the margin for the error and lumen size are smaller. On the other hand, the penetration point should not be very close to the end of the vessel either as it can tear out the vessel wall.

In this study, based on the available resources, we had twelve participants attending the sessions. While all twelve participants carried out the first trial, six participants performed the second trial and four participants carried out the third trial. The number of participants and trials should be larger to achieve more statistically converged data, however, the limitations that were imposed by the hospitals and the availability of the resources (e.g. surgeons and OR) limited the achievable number of participants and trials, which was worsened by the COVID-19 pandemic. A 3D Modus V is also being introduced, which is expected to further improve the performance of surgeons in scenarios where the depth perception plays an important role. Furthermore, as a recommendation for future work, the effect of the Modus V on surgeons performance should be assessed best when the training of novices with the new Modus V visualization technique can be compared to the training of novices with traditional microscopes.

5.5. Conclusion

In this chapter, we designed and carried out training sessions with the newly introduced advanced robotic microscope of Modus V™. The sessions were recorded for analysis and evaluation of surgeons' performance and learning curves, by dividing surgeries into steps using process modelling techniques. The vessels angle with respect to phantom and size showed to be the main contributing factors in defining the difficulty of a training scenario: larger vessel angle and smaller vessel size increase the difficulty level. The data show that the surgeons who had previous experience with a traditional microscope, have a large lead compared to the novice surgeons with no experience with a traditional microscope. Novice surgeons showed a shallower learning curve with the trials. This could be because the experienced surgeons have less room left for improvement. Pitfalls analysis revealed that novice surgeons have difficulty in making a knot and properly grabbing the thread. It can be concluded that more training sessions than three are specially required in the case of large vessels with an angle and small vessels with or without an angle.

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5.7. Appendix A

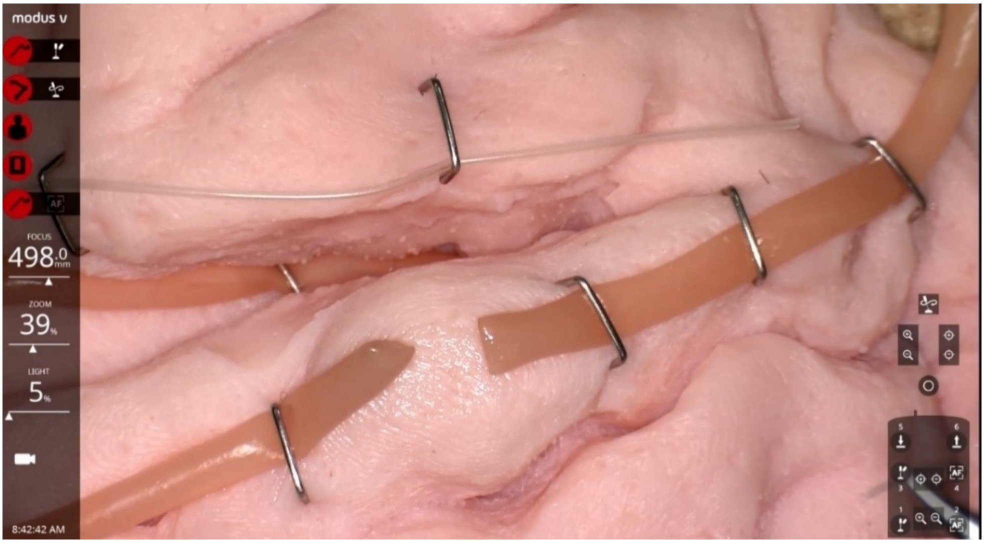

Figure 5.A.1: Snapshot of Scenario 1

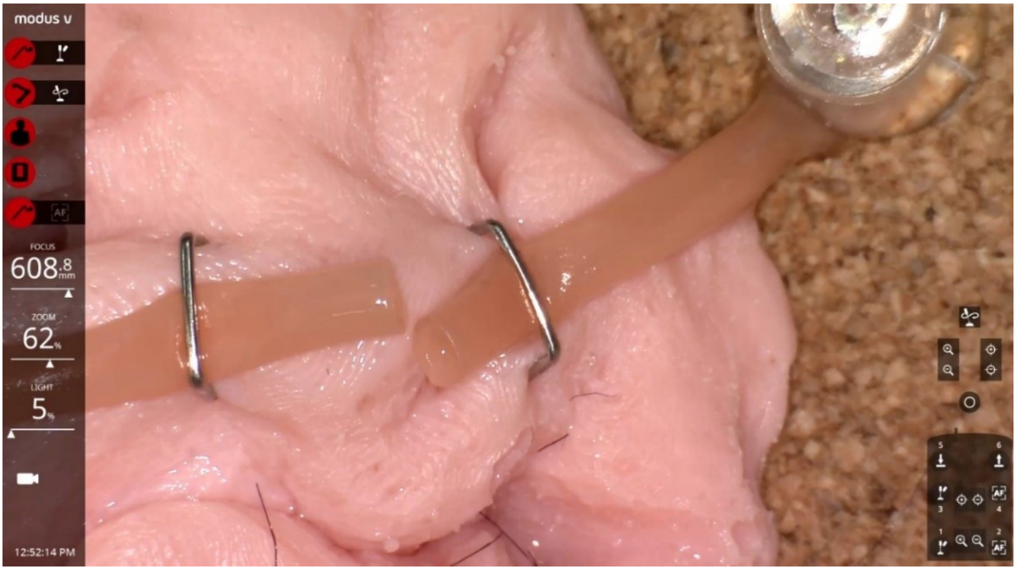

Figure 5.A.2: Snapshot of Scenario 2.

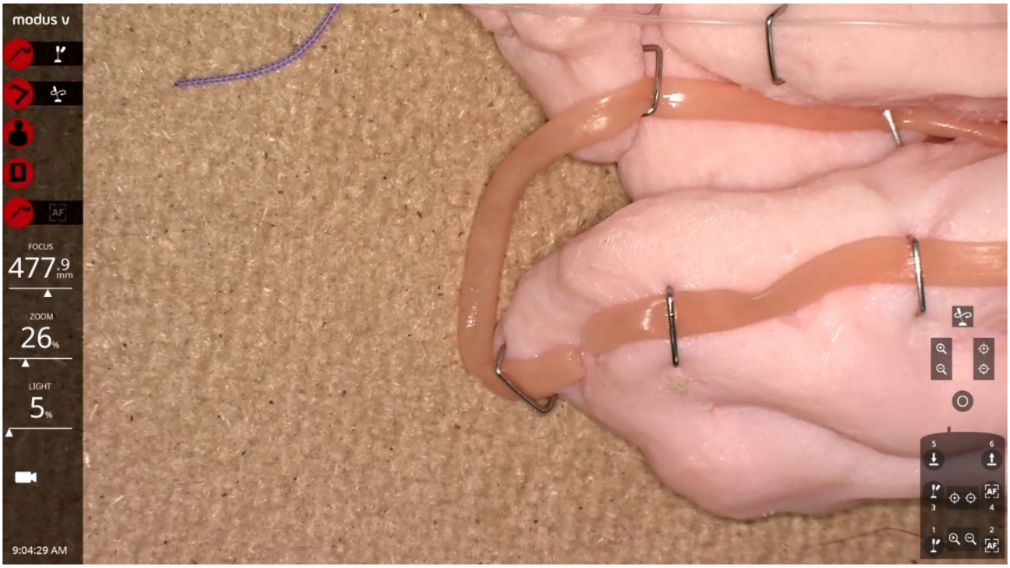

Figure 5.A.3: Snapshot of Scenario 3.

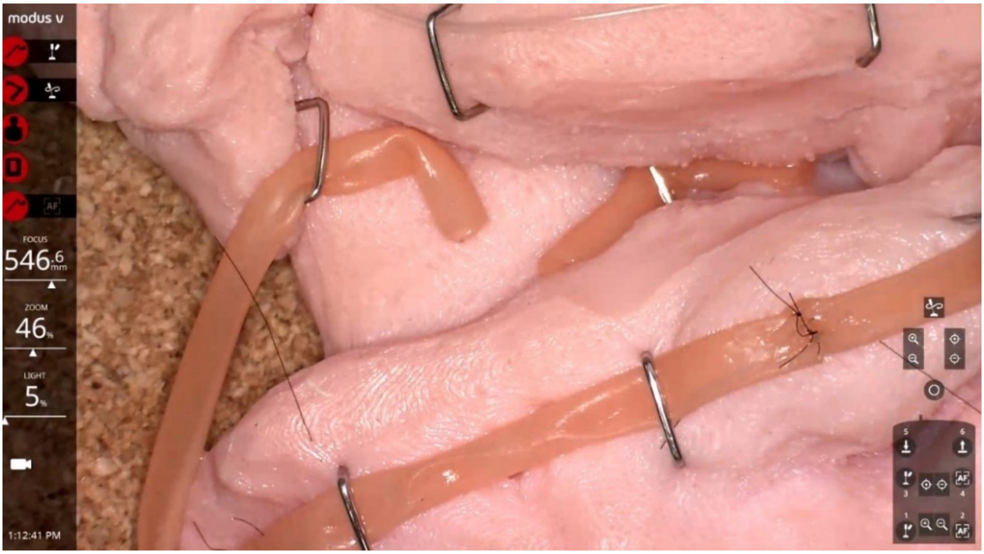

Figure 5.A.4: Snapshot of Scenario 4.

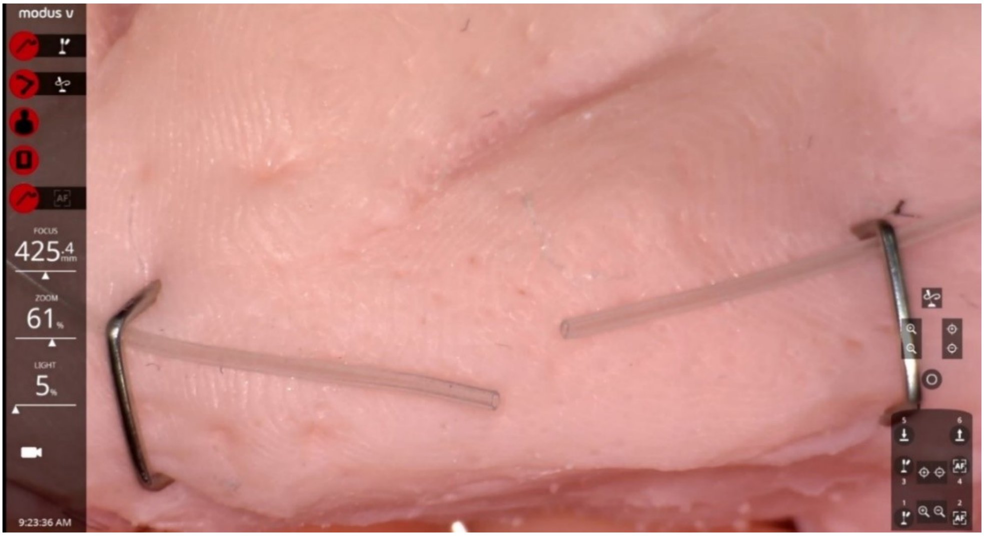

Figure 5.A.5: Snapshot of Scenario 5.

5.8. Appendix B

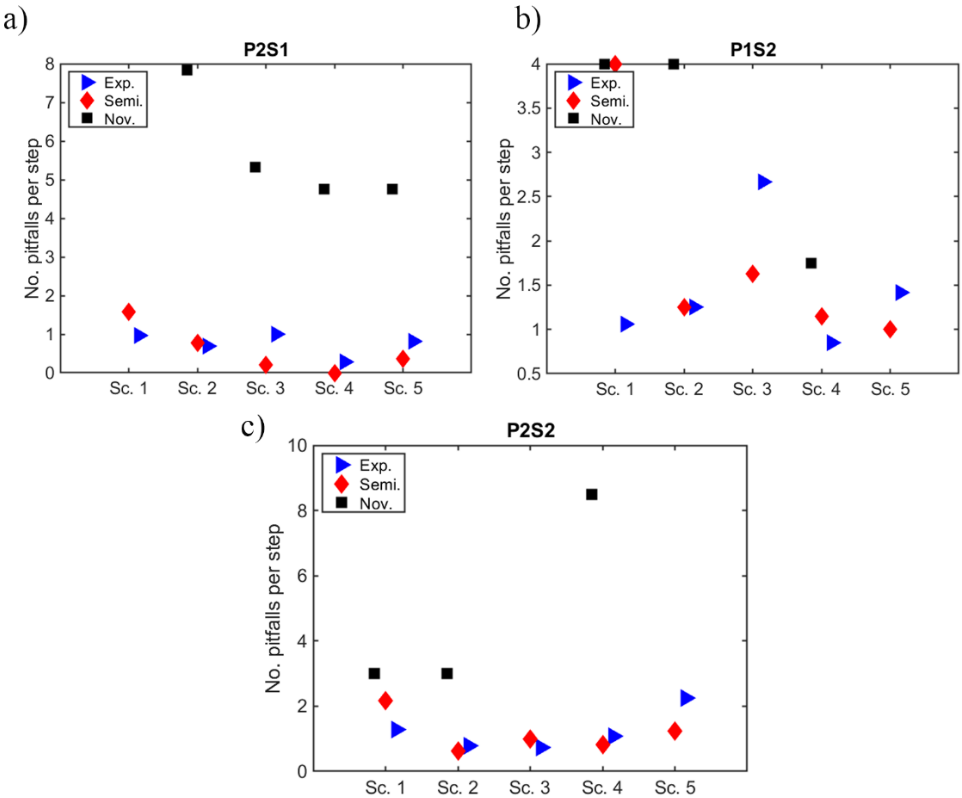

Figure 5.B.1: (a) Number of P2S1 (misgrabbing threads) occurrence per step (b) P1S2 (misgrabbing threads), and (c) P2S2 (failing to knot) per step. The data is from the first trial of the surgeons and averaged over 5 experienced surgeons, 4 semi-experienced and 3 novice surgeon

Chapter 6: A novel platform for improving surgeries using surgical process modelling[4]

Abstract

While Surgical Process Modeling (SPM) is a powerful tool for improving surgeries, its practical implementation into the surgical practice is not yet realized. This work aims to employ SPM techniques and leverage advanced computer science solutions to develop a novel Generic Surgery Analysis Platform (GSAP) for improving surgeries at different surgical stages. These stages include early stages from surgeon training and education, to later stages involving efficient surgical planning and precise surgical action execution during the operation. The platform provides new tools for the analysis of surgical videos and efficient storage and retrieval of the extracted surgical data. With GSAP we have introduced innovative approaches for evaluating surgeries and surgeons' performance, for pre/intra-operative planning of surgeries, and for guidance of surgeons during operation. This platform was designed as generic as possible, enabling its usability in different types of surgeries. By providing surgeons with a patient-specific surgery guidance and planning system, GSAP enables informed decision-making and surgical actions executions. Moreover, the platform facilitates the analysis of surgical actions, allowing for investigation into optimal ways of performing surgical tasks. It also enables a comparison with established professional techniques, fostering continuous improvement and refinement in surgical practices. The work presented confirmed that the GSAP satisfies the needs of the clinicians. Introduction of GSAP into the practice will represent a significant advancement in surgical practices, benefiting patients, surgeons, clinical

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[4] The content of this chapter is in preparation for submission as a journal article. M. Gholinejad, O. J. Elle, B. Edwin, A.J. Loeve, J. Dankelman, "A novel platform for improving surgeries using surgical process modeling"

teams, and engineering professionals throughout various stages of surgical training, education, patient-specific surgical planning, surgical task execution, and navigation in the OR.

6.1. Introduction

Safe surgery is based on several key parameters, such as the surgeon's experience [1], proper surgical planning and execution [2], and possessing the right information for decision-making. Surgical improvements could be achieved at an early stage by proper training and education of surgeons or at a later stage by efficient surgical planning and, finally, during the actual act of performing surgical tasks in the operating room (OR). To improve upon different stages of surgery, various disciplines need to work together. Surgical process modeling (SPM) is a key discipline that could fulfill these challenging tasks [3]. In surgical process modeling, surgeries are treated as sequences of surgical steps that are followed by a clinical team [4]. The surgical process model of a specific procedure represents a population of surgical procedures by merging a set of individual SPMs (iSPM). Each iSPM represents a model of a specific intervention. Training, education, and improved planning and prediction of surgical steps and outcomes could all be achieved by creating SPMs, simulations, and predictions based on big-data analyses of surgical videos [5-11]. There are however several challenges, such as:

- **Surgical data storage and retrieval, and surgery analysis:** Surgical videos contain valuable information for discovering the hidden parameters for improvement of surgeries and for determining best practices based on previous surgical experiences in different situations [12]. However, useful information in surgical videos and images is normally buried under a vast amount of irrelevant information. The urgency of having well-analyzed surgical videos and images is being discussed by researchers since several years ago [13-15].
- **Surgeon training & education and surgery & surgeon evaluation:** Surgeons' training can be achieved through various means, such as virtual/augmented realities [16], computer simulations [17] phantoms [18], and animal trials [19]. While these hands-on sessions are necessary, the recordings of these sessions are also used for education. The experienced surgeons educate the young surgeons by showing and discussing the videos of the treatment. This traditional approach involves various challenges such as the presence/heavy involvement of

the experienced surgeons, limited discussion and analysis due to time limit, the difficulty of covering surgery details, general learning materials that might not be based on learner weaknesses and strengths, etc.

- **Pre/intra-operative planning and navigation:** Assisting surgeons with pre/intra-operative planning and navigation requires information of previously-performed similar surgeries and the possibility to predict the sequence of required surgical steps. The making of SPMs and surgical tasks recognition for predicting remaining surgical steps and durations during surgery has emerged in recent years [9, 20, 21]. Most studies in this field focused on surgical phase recognition using low-level sensor data [22-24]. However, because of the difficulty of recognizing fine granularity surgical steps, analysis of fine granularity surgical steps has not been performed previously in such studies. Moreover, none of the abovementioned approaches considered the intra-operative surgical activities for estimation of, for example, the remaining operation time.

In this study, a novel platform, named Generic Surgery Analysis Platform (GSAP) was designed and proposed as a possible solution to the above-mentioned challenges. The platform functions were tested with two different sets of surgery types (laparoscopic liver resections and lymphatic training data) to assess if its functions worked as expected. Moreover, the platform was presented to surgeons (as the main users) with different experience levels to evaluate different aspects of the platform such as usefulness, user interface, and ease of use.

6.2. Methods

6.2.1. Software Requirement Specification (SRS)

Over the course of 4 years, the authors attended approximately 30 minimally invasive liver treatments at different institutes (Oslo University Hospital (OUH), Erasmus Medical Center (Erasmus MC), and Bern University Hospital), and discussed the needs and challenges with various surgeons (Laparoscopic liver resection (LLR) surgeons: 3 from OUH and 1 from Erasmus MC, Lymphatic surgery training (LST) surgeons: 2 from Erasmus MC) and navigation system engineers (from different companies: Siemens Healthineers, Cascination, and Synaptive Medical Inc.). The authors designed training experiments for surgeons on phantoms (see Chapter 5), recorded training sessions (see Chapter 5), and analyzed more than 30 hours of videos of surgery/training carried out in Erasmus MC and OUH (see Chapters 3,4 and 5). These all resulted in an understanding of the surgeons' needs and the challenges to fulfill these needs. Based on the needs of surgeons, the front-end requirements were established. The front-end pre-design requirements verification was not done, because during the meetings it appeared that this was too abstract for proper co-creation with the users. A post-design verification was performed by receiving feedback on the design and implement the changes accordingly. Next, based on the front-end requirements, the backend requirements were deducted through discussions with other highly skilled software engineers. The front-end and the back-end requirements are as follows:

Front-end Software Requirement Specifications (SRS):

1- Easy storage of surgery/training data.
2- Easy retrieval of surgery/training data.
3- Providing a tool for
   3.1 the analysis of surgical videos and extraction of the relevant data.
   3.2 educating surgeons by enabling them to review surgeries/trainings.
   3.3 educating surgeons by enabling them to evaluate surgeries/trainings.
   3.4 proposing a patient-specific plan for each surgery/training.
   3.5 assisting/guiding surgeons during performing surgery/training.
4- Intuitive use UI for clinicians.
5- Generic platform. Developed such that its software elements/modules and functions can be used for different types of surgeries/trainings.

Back-end Software Requirement Specifications:

B1 - Computationally efficient data warehousing and data management
B2 - Feasibility of platform functions and database going from MVP (minimum viable product) towards a final product.
B3 - Cross-platform design for operating systems Windows, Android and iOS.
B4 - Real-time synchronization of data between platforms running in different operating systems at the same time.
B5 - Platform compatibility with gyroscope sensors.
B6 - Integration of 2D and 3D visualization of SPM data, surgery videos, and medical images.

6.2.2. Data acquisition and surgical process models

Two sets of surgeries/trainings were chosen to show the wide range of applicability of GSAP; two extreme cases of spatial scales (micro vs macro-scales) in different settings (real surgery vs training) and surgery specifications (complex SPM with complicated step prediction vs simple SPM with simple step prediction). Data from the following two types of procedures were used in this study:

- 110 lymphatic surgery trainings (LST) sessions acquired from Erasmus MC, data in Chapter 5
- 18 laparoscopic liver resections (LLR) surgeries acquired from OUH, data in Chapters 3 and 4.

For details of LLR and LST procedures, we refer to Chapters 3 and 5. The detailed generic SPM of LLR was established in Chapter 3.

6.2.3. Software design approach

In order to ensure the detection of flaws in the early stages of the software design and development life-cycle, verification was performed during all ongoing phases of software design. Different design aspects, including data design (defines relationships between data entities), procedural design (defines a well-structured programming approach), and interface design (defines input and outputs for interfaces) were covered. Compliance of the software with the front-end and back-end SRS, coding integrity, and the right combination of panels were verified and validated in testing phases as unit testing, module testing, and system integration testing, using the LLR and LST procedure datasets. For verification, the design approach and software system architecture was also discussed with three more software engineers with over 7 years of professional experience in software architecture and designing and developing software system platforms (apart from the authors), see Figure 6.1.

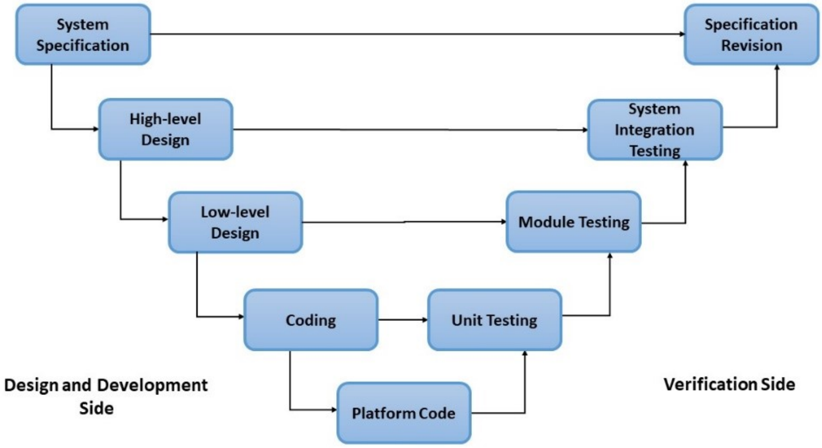


Figure 6.1. The procedure for the verification of the design and development phases.

Apart from the development point of view, the UI and functions of the platform in the platform design phase were discussed with the surgeons (2 laparoscopic liver resection surgeons from OUH and 1 lymphatic surgeon from Erasmus MC), focusing on the suitability of functions, ease-of-use of the UI, the usefulness and completeness of the presented data for each screen in the software interface, finding the suitable data visualization methods for the platform, etc.

6.2.4. Functional requirement

Based on the SRS, the software was built to contain window panels that allowed the user to not only easily select different functions in the software but also see in what part they are and what other parts there are.

New Surgery panel
Fulfilling SRSs: F1 and B1.
Intended users: Technicians supporting clinical teams in surgery and training.
Intended use: Data-input and –maintenance of the database with surgery recordings and trainings.
Functions:

1. A database for the surgery/training with the suitable categorization of data for further analysis. The categorization of data is based on

surgery/training specifications. These specifications determine surgery properties such as tumor location, size and number, patient age, and surgeons' experience level.
2. With the help of the database, the data can be saved in, read, and sorted/edited. Furthermore, the data is centrally stored.
3. Providing surgery/training data including **surgery/training specifications**, videos, images, textual information, extracted data from videos, analysis results on the data, and any relevant docs.

Design approach: Proper categorization of data is the key for the data storage design. The chosen categorization is achieved by discussion with surgeons.

Case Select panel
Fulfilling SRSs: F2 and B1.
Intended users: Surgeons/engineers selecting the desired case for surgery analysis, review, evaluation, planning, and navigation.
Intended use: Surgical data retrieval from the database.
Functions:
1. Easy to filter and retrieve the data based on different **surgery/training specifications**.
2. Easy to find and retrieve similar surgeries/trainings and their corresponding data and iSPMs.

Design approach: The proposed data categorization in the New Surgery panel is used here as well.

Analysis panel
Fulfilling SRSs: F3.1 and B6.
Intended users: Surgeons/engineers using the platform for surgery/training analysis and technicians supporting the team for sensor connections.
Intended use: Video analyzer tool to extract the SPM information from the videos.
Functions:
1. Surgical videos annotation and extraction of iSPM information (surgical step identification, step sequence, start time, and end time of each surgical step) using manual or artificial intelligence techniques at the desired granularity levels.
2. Recording the extra data over the iSPM, such as the possible pitfalls and used instruments associated with each step.
3. Synchronization of possible external sensors/tracking data with GSAP and recording these data for the corresponding entity of the iSPM.

4. Internal analysis of the registered data to calculate the information such as the number of occurrences and duration of each entity of the iSPM.

Design approach: To achieve the abovementioned points, the corresponding SPM is used as the roadmap for video annotation and extraction of iSPM. With the annotation of the video analysis, the visual information of the videos is correlated with textual information that can be further analyzed.

Review panel

Fulfilling SRS: F3.2.
Intended user: Surgeons reviewing the surgeries/trainings.
Intended use: A review tool that enables surgeons to easily navigate through all the surgical steps.
Functions:

1. Illustrates the correlation (extracted in the Video Analysis section) between the iSPM and the video.
2. Easy navigation between steps at the desired granularity levels over the surgical video.
3. Provides an overview of iSPM containing information such as the total number of surgical steps, total pitfalls, total durations, etc.
4. Provides the possibility for communication between surgeons to ask or answer questions on each surgery/training step.
5. Provides the possibility to give advice on each surgery/training step or submit an overall performance score (only applicable for experienced surgeons).

Design approach: Similar to the Analysis panel, the corresponding SPM is used as the roadmap for the design approach of this panel.

Evaluation panel

Fulfilling SRSs: F3.3.
Intended users: Surgeons evaluating their own or other surgeons' performance.
Intended use: An evaluation tool that provides the possibility to compare similar surgeries/training at different granularity levels.
Functions:

1. Find the best-performed similar surgery/training for different conditions (e.g. patient-condition).
2. Compare a surgery/training with its best-performed with a similar condition.

3. Quantitative and qualitative illustrations of the comparisons to clearly spot the weaknesses and strengths of the selected surgery/training compared to the professional ones.
4. Provides textual information to detail the comparisons.
5. Generates a score for each surgery based on predefined criteria depending on the type of operation (e.g. number of errors and step durations).

Design approach: For each selected surgery/training, the platform searches the database and finds the similar surgery/training that obtained the highest performance score. The best-performed surgery/training are chosen based on an average of the score generated by the system and the given score by the surgeons in the Review panel. Furthermore, the platform also finds and shows the best-performed similar step. The selection criteria here are the shorter durations of the step and fewer pitfalls.

The generated score by the system is defined based on the duration and number of pitfalls. In the case of LST, we used the following formula

$$S = a + N_{step} * \bar{t}_{step} * w_{step} - \sum N_{Pitfall} * \bar{t}_{Pitfall} * w_{Pitfall}, \quad (1)$$

with S the generated score, a constant, N_{Step} total number of steps, $\bar{t}_{step}$the average duration of step, w_{step}weighting of durations, $N_{Pitfall}$ total number of pitfalls $\bar{t}_{Pitfall}$ the average duration of pitfalls and $w_{Pitfall}$ weighting of each pitfalls. The values of a, w_{step} and $w_{Pitfall}$ highly depend on the dataset. Nonetheless, the choice of these values is not of importance.

Apart from the scoring system, pitfall analysis provides an insight into the probability of the pitfall occurrence and can be used as a measure for evaluation of the training/surgeries. The pitfall analysis was carried out according to the ISO standard of 14971 and TR 24971 (Figure 6.2). For the risk/pitfall analysis, we used LST which has clearer pitfalls compared to LLR. Four steps were considered in the calculation [25]:

Identifying error situations: All possible pitfalls for performing each step in the surgical process model of the surgical/training procedure were identified.

Pitfall management techniques: Various risk management techniques are described in ISO standard 14971. In the LST example, we used FTA (Fault Tree Analysis) technique. FTA is primarily a means of analyzing pitfalls and starts from a postulated undesired consequence, also called a "top event". We defined the top event as "Cycle with pitfalls" in a pre-defined time limit, see Chapter 5 for the description of a cycle. In FTA, at each level in the tree, combinations of fault modes are described with logical operators (AND and OR). See Figure 3 for the proposed FTA in LST.

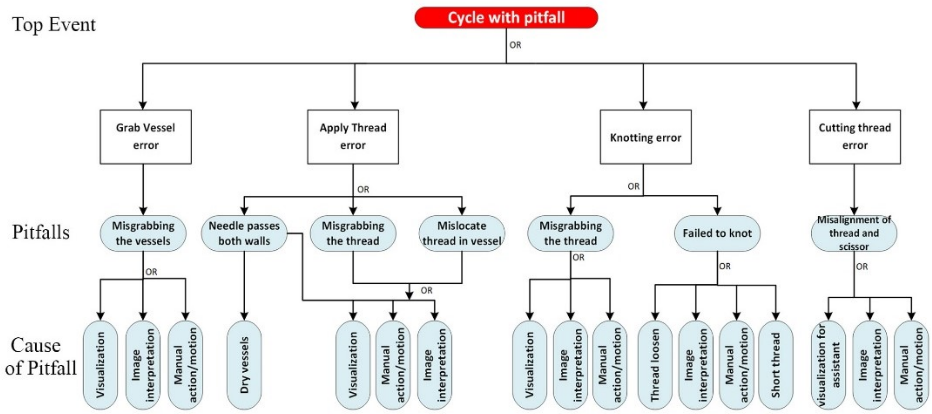


Figure 6.2: Fault Tree Analysis graph for pitfall management technique in LST.

Risk estimation of error situations: Two parameters are contributing to the estimation of risks: probability and severity of pitfall.

Probability: The probability of each pitfall was calculated based on the number of occurrences of unsuccessful attempts (i.e. pitfall) divided by the total number of attempts (unsuccessful or successful) in performing each surgical task. For example, the probability of failing to knot can be estimated by an experiment or retrospective analysis in which one determines:

$$\text{Probablity of failing to knot} = \frac{\text{No. failed attempt to make the knot}}{\text{Total (failed plus successful) attempts to make the knot}}.$$

When the OR operator is used (see Figure 6.2), which means one of several independent errors occurred, the probability of the top event is calculated as one minus the product of the probabilities that no pitfall occurs. For example, the probability of Knotting error is one minus the product of the probabilities of a successful grabbing the thread and making knot i.e.

$$P(\text{Knotting error}) = 1 - (1 - P(\text{Misgrabbing the thread})) \times \big(1 - P(\text{Failed to knot})\big) (2).$$

Severity: In LST, the objective is to complete four cycles in a time limit (6 min). Thus, the severity of pitfall was defined as proportional to the duration of that pitfall. If a pitfall results in re-starting the cycle, such a situation was defined as having a high level of severity because the duration of that pitfall starts from the beginning of the cycle until the point when the error occurred.

Impact assessment of pitfalls: The errors with high probability and severity lead to the worst adverse events. Thus, the multiplication of the probability and severity is an indication of the impact of each pitfall. This number is calculated in GSAP as an indication of the impact of each pitfall for each training.

Planning & Navigation panels

Depending on the surgery type, planning sessions might be different. In case of LLR, there are different planning sessions including multidisciplinary team meeting (decision on treatment approach), surgical/interventional team meeting (discussion about patient preparation and any required deviations from standard protocols), and lead surgeon/interventionist planning (going into the details of the patient's organ-specific anatomy). The presented Planning panel provides the following functions to be used in the lead surgeon/interventionist planning session:

Fulfilling SRSs: F3.4, F3.5, B4, and B6.

Intended users: Surgeons using the panel as a guide and technicians supporting the surgeons in their tasks.

Intended use: Generating an initial plan and guiding surgeons intra-operatively.

Functions:

1. Generates process model planning of surgery based on the patient-specific data.
2. Showing the videos and analysis of similar surgeries, that enables surgeons to explore similar experiences, for aiding the decision-making of surgeons during planning.

3. Illustrate an easy-to-follow walkthrough of planning.

The presented Navigation panel provides the following functions to be used intra-operatively by the clinicians:

1. Notifying surgeons of the useful parameters such as current step, possible next step, the required instruments, and possible duration of the current and next step.
2. Providing textual and illustrative information on the process model plan.
3. Extraction of the surgical data such as iSPM while the surgery is being performed with a limited technician help.

Design approach: The generic SPM was used in the platform as a roadmap for surgery/training planning and navigation. In the Review and Evaluation panels, the individual surgery/training steps (iSPM) were shown. However, in the Planning panel, iSPMs needed to be merged to reach an SPM that fits each specific surgery. The iSPMs were merged according to their state on a timeline, see Figure 6.3. Different iSPMs were aligned and between each set of the always occurring states, the probability of any mid-states to occur was calculated. The mid-states were combined in the boxes. On the left-hand side of Figure 6.3, four iSPMs are shown and on the right-hand side, the merging result of all four is shown.

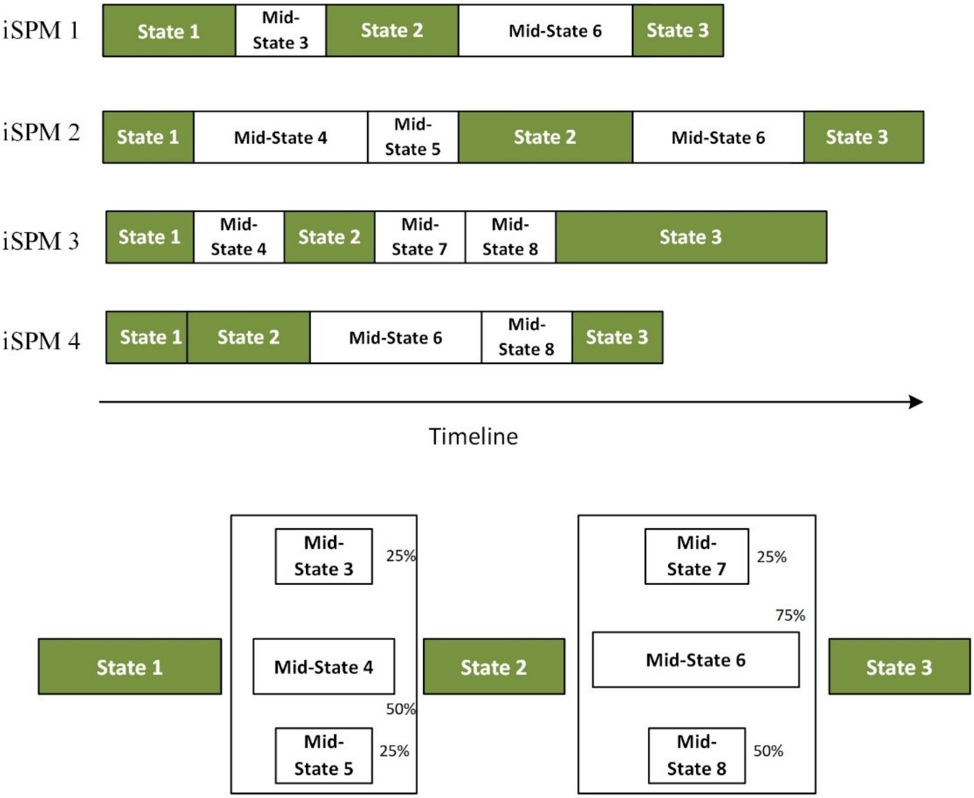


Figure 6.3: The approach for merging iSPMs. Top) four imaginary iSPMs, and Bottom) the result of merging them. Boxes show all the possible mid-states with their probability of occurring in percentage.

Prediction of the sequence of surgical steps is an important parameter during planning and navigation. To predict the next surgical step and guide the surgeon in different situations, merging a considerable number of iSPMs is required. However, acquiring each iSPM is a time-consuming process, and even a large dataset may not cover all possible events and sequences that may occur during surgery. In these situations, a detailed discrete events simulation model (DEMS) can be used to cover different situations and increase the convergence of the data, see Chapter 4. Based on the process model and the process data obtained from the endoscopic videos, a detailed DEMS of the generic process model of MILT was developed in Matlab, see Chapter 4. The simulation outcome will be used in the planning and navigation functions of the platform to make the prediction of process model planning more accurate.

6.2.5. Verification and tests

Process model of LLR/LST: The data from real procedures and trainings were used to verify that the process models resemble the clinical performance. For a detailed discussion about the verification and validation of the LLR process model, see Chapter 3.

DEMS: The operational behavior of the simulation model was verified by observing the animated output of the simulation. The simulation was run 100,000 times to reach convergence. The convergence of the simulated data was confirmed by comparing the first half batch of runs with a second half batch of runs and the differences in mean values and standard deviations between these batches were less than 0.5%, for more discussion, we refer to Chapter 4.

Platform functions tests: While the LLR and LST datasets were used to design different panels, we developed the functions of the following panels and checked whether different components of these panels perform as defined in the SRS.

- *Data storage/retrieval:* were tested for both LST and LLR.
- *Video Analysis:* were tested for both LST and LLR.
- *Surgery Evaluation:* was tested with the LST data.
- *Surgery Review:* was tested with LLR data.
- *Surgery planning and navigation:* Only the LLR dataset was chosen for the *design* purposes. The *development* of surgery planning and navigation panel was out of the scope of the current study.

Platform validation: To ensure whether the proposed platform fits the requirements of surgeons, the platform was presented to one surgeon in lymphatic surgery and neurosurgery and three surgeons in minimally invasive liver treatment in Erasmus MC and Oslo University hospital. The LST and MILT datasets were used to demonstrate the working principle of different panels of the platform to the surgeons, starting from the New Surgery panel to the Navigation panel. The platform was discussed with the surgeons focusing on validation of the platform in different aspects of usefulness, ease of use and the user-interface design.

6.3. Results & Discussion

6.3.1. Platform workflow

An overview of the designed platform can be found in Figure 6.4. The platform can be used either for planning and navigation during surgery or educational/training purposes. For this, two main platform modes, each with its own workflow are made available.

Navigation Mode: This mode was designated for the surgery/training that is going to be performed and the user intends to use the platform for pre/intra-operative planning and navigation. In this mode, after the creation of a new case (Window 1 in Figure 6.1) and inputting the relevant surgery/training data, the created case needs to be selected from the database (Window 3). Based on the selected case, the platforms suggest the planning (Window 4) accordingly. The surgeon can review and modify the suggested planning per their preferences and continue to the Navigation panel (Window 5) for intra-operative navigation.

Education Mode: This mode is designated to the surgery/training that was already performed and the user intends to use the platform for surgery review/evaluation/analysis. Normally the cases would already have been created for pre-operative planning prior to the surgery/training in Navigation Mode. However, if the case was not created, the user creates a new case (Window 1). Otherwise, the user only selects the case (Window 3) from the database. The user can analyze (Window 4) the case or use a previously analyzed case to review (Window 5) or evaluate (Window 6) the surgery/training and surgeon's performance.

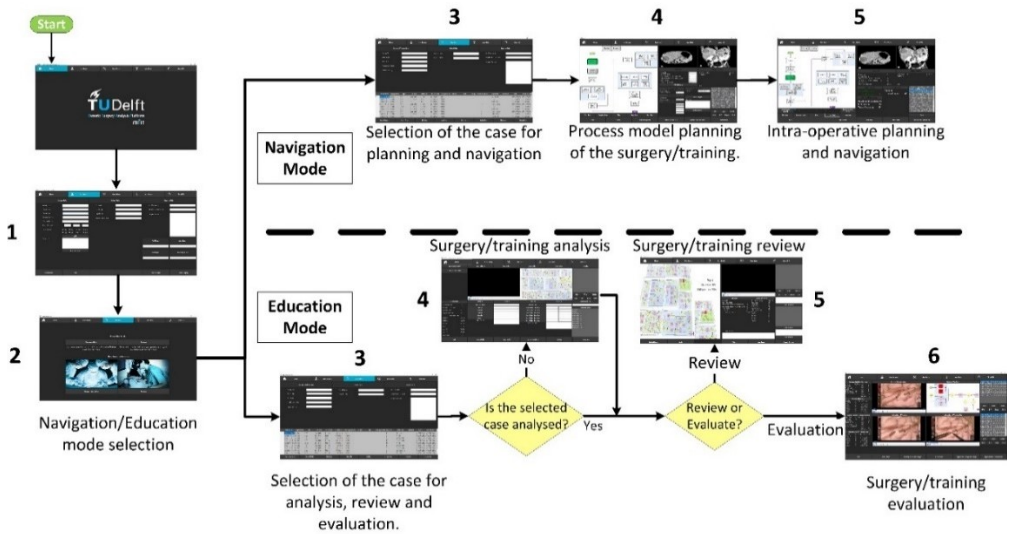


Figure 6.4: Different modes of the GSAP and the workflow of each mode.

6.3.2. GSAP interface design (Front-end design)

In the following, we present the resulted UI for each panel and briefly explain the global overview of the UI. The tests have shown that different panels are working as defined.

“New Surgery”

The “New Surgery” panel is dedicated to the categorization of the data and adding data to the database. For this, the data need to be divided into different categories based on parameters that are involved in making the surgeries unique, such as the segments where the tumor is located in the case of LLR or the angle of the lymphatic vessel in the case of LST, see Figure 6.5 for LLR. This information is categorized into three sections: surgery data, patient/phantom data, and surgeon data.

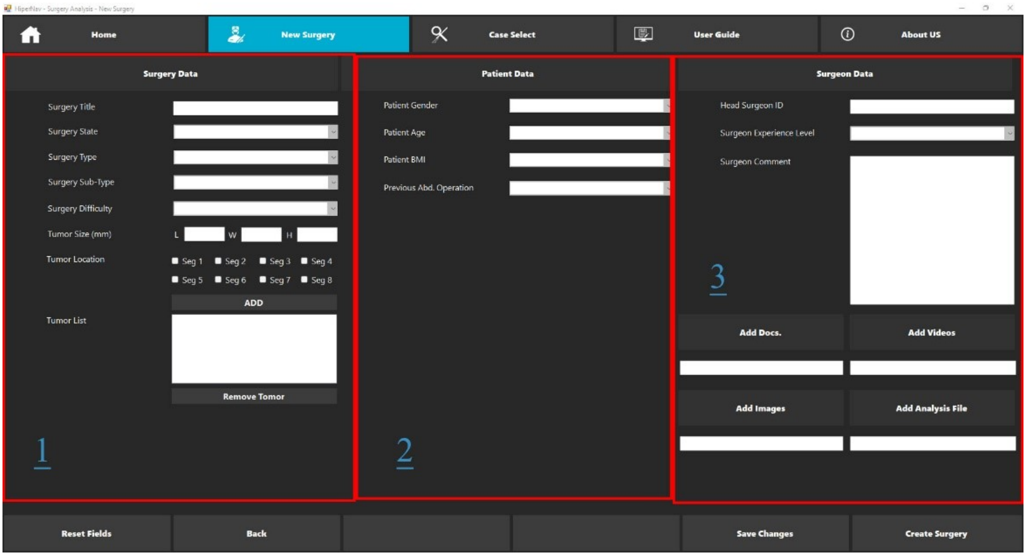


Figure 6.5. Screenshot of New Surgery panel for LLR. 1) Surgery data, 2) Pateint data and 3) Surgeon data

"Case Select"

In GSAP, the videos are categorized based on the information that was acquired in the "New Case" panel. The user can filter the videos based on surgery data (e.g. surgery type, tumor location and size in LLR and vessel angle and size in LST), patient/phantom data (e.g. patient age and gender in LLR and phantom material in LST), and surgeon data (e.g. experience level). In this section, the user initially selects the desired mode: Navigation or Education Modes, see Figure 6.7. Then the desired database, either real surgery/intervention or training, can be selected.

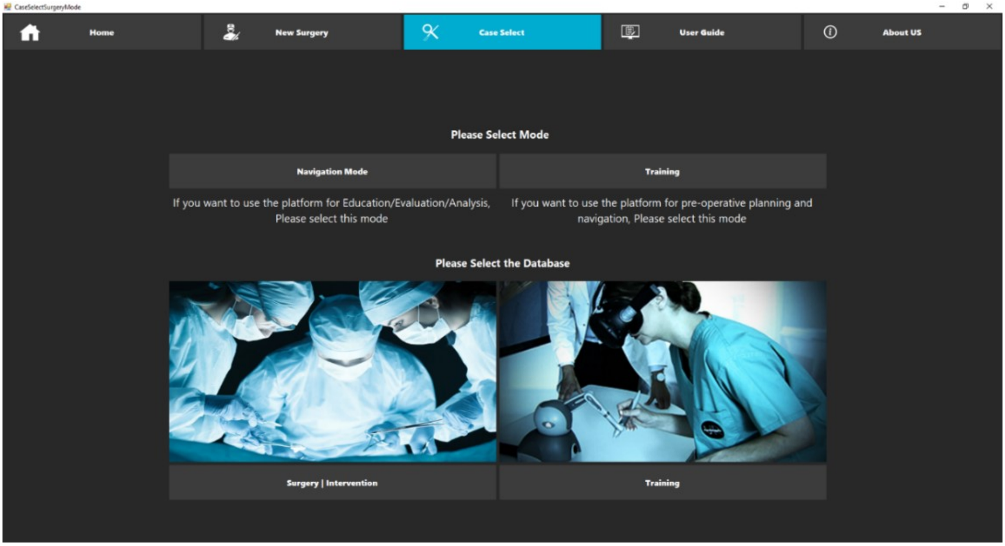


Figure 6.7. The screenshot of the Case Select panel for selecting modes and databases.

Next, the user can narrow down the search by filling in the filtering information, see Figure 6.8. The search result are shown at the bottom of the page.

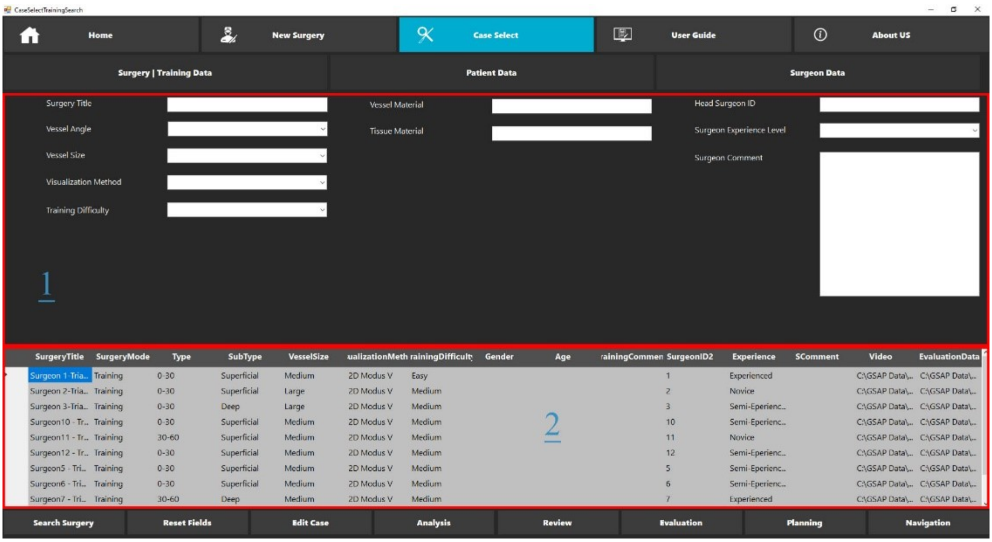


Figure 6.8. The screenshot of the Case Select panel to select the case. 1) Filters and 2) Search results.

“Analysis”

In this panel, the functions for extraction of surgical steps at different granularity levels and the corresponding data for each step, according to an SPM (as the surgery/training analysis map) are described. In the “Analysis” panel, as can be seen in Figure 6.9, the surgery/training videos are loaded. Extraction of the data from surgical videos can be performed at different granularity levels (from high to low levels of granularity: from phases to modules and eventually actions) based on an SPM. The low abstraction level data, such as instrument position, can directly be recorded for each surgical step through sensors/tracking systems. In the future, machine learning techniques can be leveraged in this platform to enable automated analysis of surgical videos and tracking objects. The “Analysis” panel of the GSAP has been successfully used in Chapters 3, 4 and 5 for analysis of LLR surgeries and LST.

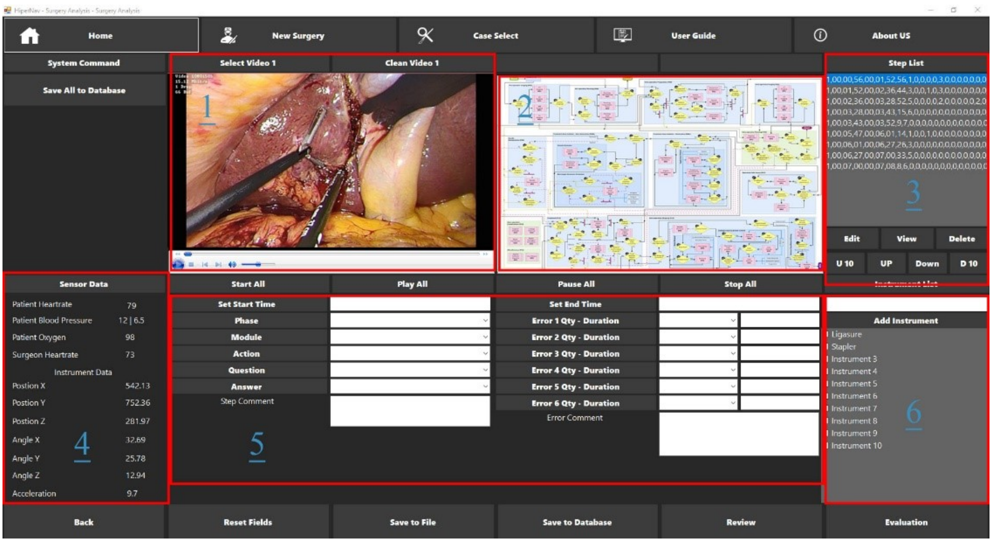


Figure 6.9. The screenshot of the “Analysis” panel, shows different sections of the panel. 1) Surgical video, 2) SPM, 3) List of steps, 4) Sensor data, 5) Extraction tools and 6) Adding instruments.

“Review”

The Review panel provides the functions for sharing expertise between surgeons as well as educating young surgeons. In the “Review” panel, the user can review the analyzed surgeries. The surgery video, extracted surgical steps, surgery overview, main info, and corresponding information of each step are the main parameters that are presented to the user. The corresponding iSPM is shown on the left-hand side of the window, see Figure 6.10. The video of the surgery is loaded by the platform and the data is shown on the iSPM. As the video is being played, the corresponding step of the video is shown on the process model. For each surgical step, the surgeons can *Add comments/advice* or ask questions and give answers. The surgeons can *Add a score* to the surgery to be used in the "Evaluation" and "Planning" panels (only applicable for experienced surgeons).

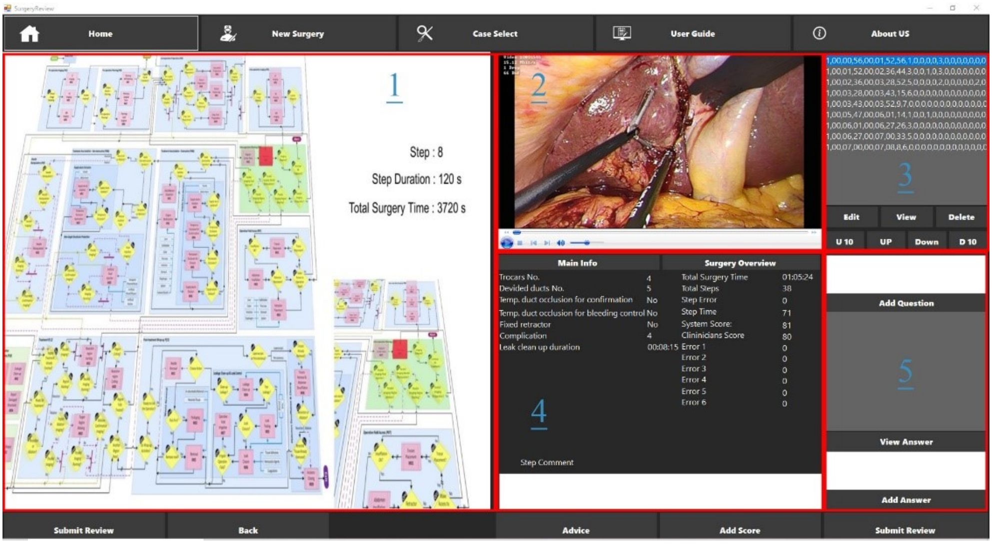


Figure 6.10. The screenshot of the "Review" panel, showing different sections of the panel. 1) iSPM, 2) Surgical video 3) Step lists, 4) Calculated data, 5) Add questions and answers.

"Evaluation"

Learning of surgeons can be achieved by comparing their own surgery/training sessions with the professional ones. The user can select a surgery/surgeon ID (in "Case Select" panel) and the system loads the data and related information in the "Evaluation" panel (see Figure 6.11). When selecting a training, the evaluation points of the selected training are provided in the **Selected Training Overview** and **Selected Overview Table**. The system also searches for training, that has the highest score, and shows the relevant data of that training at the bottom of the page. The three videos are: (i) selected video is the young surgeon's trial (ii) highest scored video is the professional trial with the overall highest score and (iii) highest score step is the video of the current specific step with minimum errors and short duration.

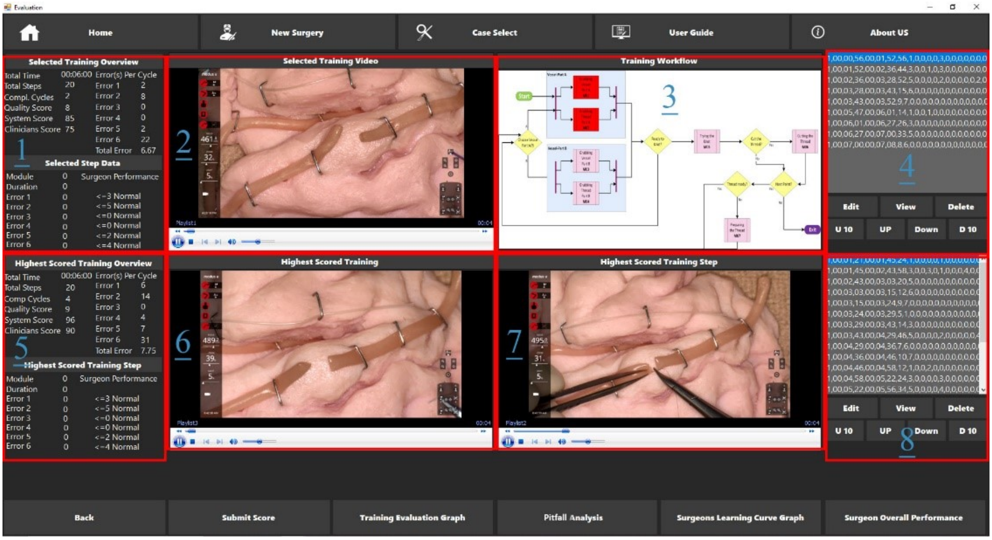
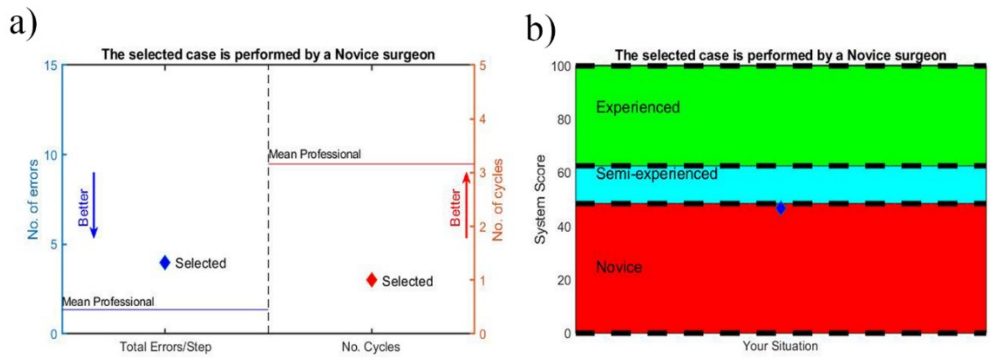


Figure 6.11. Screenshot of "Evaluation" panel, showing different sections of the panel. 1) Data of the selected video, 2) Selected video 3) Graphs, 4) Step list of the selected video 5) Data of the highest scored video, 6) Highest scored video, 7) Highest scored step, and 8) Step list of the highest scored video.

The platform provides different graphs for a better understanding of the situation. In case of LST *Evaluation Graph* shows where you (selected video) stands in terms of number of completed cycles and number of pitfalls with respect to an average professional performance. Figure 6.12(a) shows the *Evaluation Graph* for LST data for a sample case. *Surgeon Overall Performance* shows the calculated score for the selected video, see Figure 6.12 (b). *Surgeon learning curve graph* is available only when a training has been carried out by a surgeon several times and the learning curve is the point of interest. In the case of LST, this button shows number of completed cycles with respect to the trial number. The *Pitfall Analysis* button calculates the risk in a table. The surgeons can see where they stand in terms of pitfall analysis compared to the average surgeons pitfall analysis results, see Figure 6.12(c). In this table, the user can see the average impact and average probability of happening of the errors. The corresponding data for the selected video is also shown, enabling comparing the performance of the selected video with that of the average.



c)

The selected case is performed by a Novice surgeon

Module Number	Error descriptions	Average Impact	Impact-Selected video	Average of Probability of happening: Professional	Semi-Professional	Novice	Probability of happening-Selected Video
Grabbing vessels and thread (S1-2)	*Misgrabbing the Vessel*	0.58	0	39%	45%	81%	70%
	Misgrabbing the thread	2.11	5				
	Needle passes both walls	0.37	0				
	Mislocating the needle	0.65	0				
Tying the know (S3)	*Misgrabbing the thread*	1.62	3.3	29%	59%	28%	70%
	Failed to knot	2.83	6.2				

BLACK: The data for selected Video
BLUE: The average data
RED: Worse than average

Figure 6.12: Example of (a) The Evaluation Graph, (b) Surgeon Overall Performance graph and (c) pitfall analysis table for a professional trial in LST dataset.

“Planning”

Planning sessions are held prior to an operation and involve a wide variety of clinical personnel. In “Planning” panel, see Figure 6.13, the platform provides a **surgery overview** and information, such as nominal surgery duration, number of trocars, etc. All the steps of the treatment are presented in the step list on the right-hand side of the interface. Simplified SPM is presented on the left-hand side of the interface. The information of the current step, most probable next step, and other possible next steps are visually shown on the process model with different colours as well as in text format in Section 3. The *Similar Surgeries* button can be used by the surgeon to easily review similar surgeries that are shown by the system, and to use the desired planning parts of those surgeries. Once the plan is finalized, the user can use the planning in the OR and enter the navigation mode.

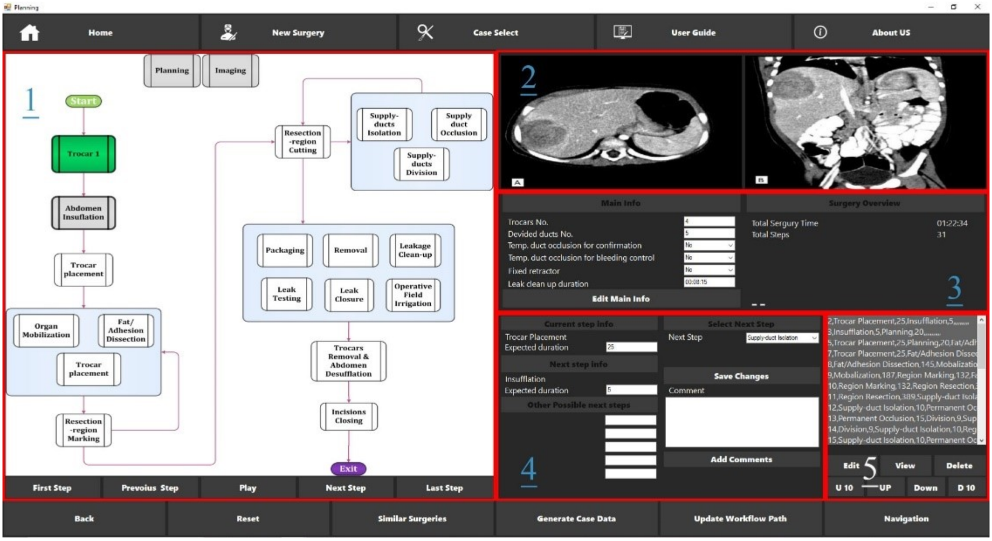


Figure 6.13. Screenshot of "Planning" panel to select the case. 1) Simplified SPM, 2) Medical images, 3) Main data, 4) Step planning and 5) Step list.

As described in the method section, a DESM can benefit the Planning panel. We have shown how a DESM can be used to show the impact of new technologies and navigation platforms in Chapter 4. The DESM presented in Chapter 4 can be incorporated in GSAP. The importance of DESM is shown in Figure 6.14: the probability distribution function of the total surgery time for simulation and real clinical data. Note that the simulations are built based on real clinical data. In the clinical data, we have analyzed five surgeries and the total surgery times are shown by the five dashed lines. The blue distribution function is for approximately 90,000 runs of simulations and it covers rare surgeries with a total duration of 4 hours as well. The platform benefits from the simulation data to better predict the sequence of events, their durations and the remaining time of the surgery.

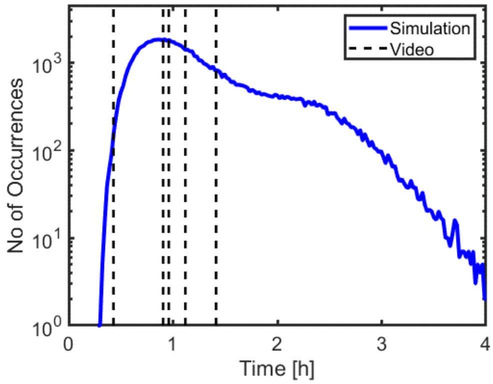


Figure 6.14: The distribution function of total surgery time for 90,000 runs of simulation. The blue curve is the simulation data and the dashed lines are the video data of five surgeries (LLR surgeries in 5&6 segments).

"Navigation"

The Navigation panel serves two main purposes:

- **Assisting surgeons**: "Navigation" panel notifies the surgeons with parameters such as current step, possible next step, the required instruments and possible duration of the current and next step. GSAP provides both textual and illustrative information on the process model plan, hence the surgeons easily visualize the plan during operation. Using the "Navigation" panel, not only do all the persons in the OR become aware of which surgical step they are in, but also everyone can prepare their task for efficient support of surgeons with the upcoming step. With the provided information in this panel, the possibility of surgeons forgetting/missing a step also decreases. Note that in the case of high precision surgeries (e.g. lymphatic surgery), the navigation panel serves as the foundation for analysis of high granularity surgical data such as instrument/hand movement and surgeon's pose, in order to guide surgeons in properly performing surgical actions during the operation.
- **Surgical data extraction:** The required tools are considered in the "Navigation" panel to easily extract the surgical data while the surgery is being performed without concrete implementation of real-time AI techniques. For this purpose, the platform provides suitable tools for both cases of minor and major changes in the plan. For minor changes, during the operation, the "Navigation" panel provides the tools to easily skip or change a surgical task or stop/extend the duration of each

surgical task. For major changes, the platform can update the entire surgical plan based on the analysis of previously-performed similar surgeries. At the end of the surgery, the updated planning data, can be used as a draft for analysis of the videos or used directly as the final analysis file. This method of data extraction with the little contribution of a technician greatly aids in completing the GSAP database and prevention of time-consuming offline analysis of surgical videos. Note that the abovementioned functionalities in the Planning and Navigation were designed and incorporated in the UI, but not implemented functionally yet.

The essential information from pre-operative planning are presented in “Navigation” panel (see Figure 6.15) together with the medical images of patient organ.

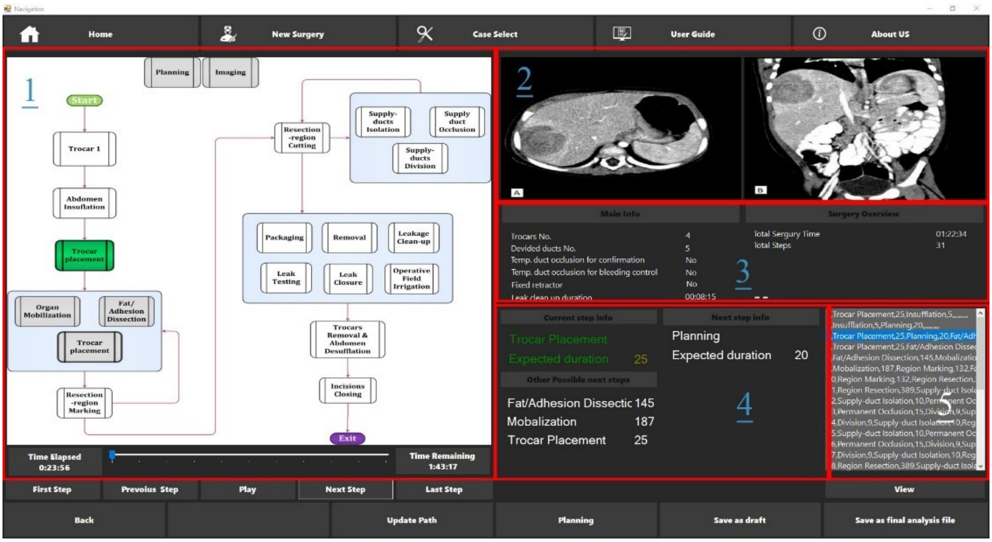


Figure 6.15. The screenshot of “Navigation” panel.1) Simplified SPM, 2) Medical images, 3) Main data, 4) Step data, and 5) Step list.

6.3.3. GSAP architecture design (Back-end design)

The overall system architecture of the platform, composed of all (sub-)system functions, their connections, and their input/outputs, were designed. Compatibility with different operating systems (Android, iOS, and PC) was taken into account in the architecture design of the GSAP. For interested readers, more details are given in Appendix A.

6.3.4. Platform validation

The functions of the Analysis panel were used to analyze LLR and LST videos. The results of the analysis of LLR procedures with the video analysis tools are presented in Chapters 3, 4, and 5. The related functions of different panels were demonstrated and discussed with the surgeons (one lymphatic surgeon and three MILT surgeons) in order to validate if the platform meets surgeons' requirements/expectations and the front-end requirements in SRS. Based on the discussions, we found an interest on the platform and its functionalities. While all four surgeons participating the discussions were happy with the different parts of the platform, they were keen to use and validate the platform at its full extend in practice. Thus a more complete validation can be only done when the platform is fully/further developed and tested in situ.

6.3.5. Limitations and outlook

Currently, GSAP relies mainly on video analysis by a user. Although a novel approach is proposed in the Navigation panel to be less dependent on the video analysis by a user after a surgery/training, an automatic step detection is extremely helpful. Machine learning and artificial intelligence techniques can provide a tool for the detection of the steps. However, intraoperative step detection is still a challenge [8, 9, 26]. Furthermore, object detection and tracking techniques can aid extraction of movement data to further educate and guide surgeons. While the design of GSAP was done in co-creation with surgeons and software developers, extensive in-action experiments are required to evaluate the true benefits and drawbacks of GSAP. Discussions with more surgeons from other institutions are encouraged. As a follow-up study, we will develop the current GSAP specifically for micro/neurosurgery.

6.4. Conclusion

In this chapter, the front and back end design of the Generic Surgery Analysis Platform (GSAP) and its capabilities were presented and discussed. Using surgical process modelling and novel technologies in computer science, GSAP provides solutions for challenges involved at different stages toward performing an efficient and safe surgery. GSAP can be used by engineers and clinicians for improving surgeries at an early stage by proper training and education of the surgeons or at a later stage during efficient surgical planning and the actual act of performing surgical tasks in the operating room (OR). The platform is designed considering the desired specifications such as the provision of a user-friendly UI for clinicians and software extendibility. GSAP provides solutions for the analysis of surgical videos and efficient storage/retrieval of the extracted surgical data. Based on extensive analysis of surgical data, the platform enables prediction of the process model planning of surgeries. GSAP uses a method that is independent of the implementation of real-time surgical step detection systems for (automatic) extraction of surgical tasks and predictions of remaining surgical tasks and durations in the OR. GSAP introduces a new approach for improving the training of surgeons, evaluating surgeries and surgeons' performance, pre/intra-operative planning of surgeries, and guidance of surgeons during operation.

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6.6. Appendix A

Figure 6.A.1 The system architect layer design of the GSAP consisting of five layers: **User-Interface**, **API Gateway**, **Core-Business Logic**, **Data Access** and **Database**. The core language chosen was C# .NET MVC 5 (as the framework). The database language chosen was Microsoft SQL Server. The user interface was designed for *PC/Web Applications*. The user interface is connected to the software core through *REST API Gateway*. *Business Core Logic* dictates the main logic of the software, e.g. the user cannot make a new surgery in the platform before they choose the segments that tumor is located in. *Business task logic* defines tasks that needed to be done, e.g. when the analysis is finished, save the data on the servers. *Data Access Micro ORM Dapper* is responsible for the connection between the software core and the

database. All the calculations in the database are done in the *Database Function*, e.g. calculations for finding the main info of the surgeries. *Database Stored Procedures* contain the actions in filtering the database, e.g. return back the surgeries with the tumor resections in Segments 5.

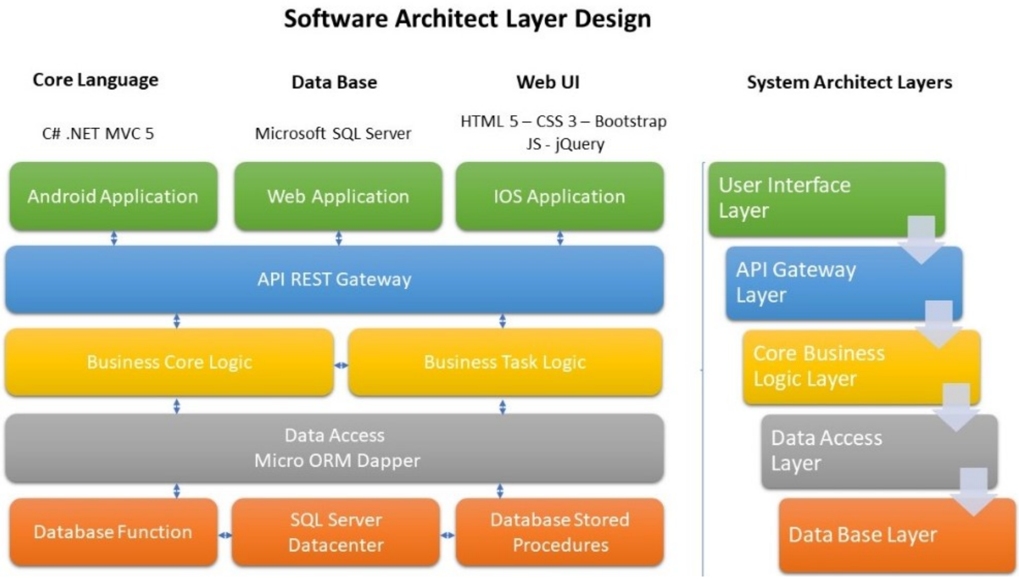

Figure 6.A.1: GSAP architecture layer design.

PART C: Discussions & Conclusion

Chapter 7: Discussion, outlook and conclusions

7.1. Accomplishments & clinical relevance

In this thesis, surgical process modeling and its applications were described. In the first part of this thesis, a literature study on the surgical process modeling was performed and a complete guide for researchers, enabling them to choose the proper process modeling strategies tailored to their purpose of the study was proposed in Chapter 2.

Next, in Chapter 3, the proposed guideline and modeling strategies were used to establish the generic surgical process model of minimally invasive liver treatments. Generic process models of surgeries are scarce due to the high level of complexity of making a process model that covers every unique surgery. However, we showed how the proposed modeling strategies can be used to successfully establish and verify the generic surgical process model of one of the most challenging and complicated surgeries: minimally invasive liver treatment. The presented process model was built in a way that enables us to employ the model for further statistical analysis and computer-based simulations. For the clinical relevance of this chapter, we quote from a highly experienced surgeon "*I always wanted to have such a model. This is very helpful, I can educate surgeons with it, let the residents read it and learn a lot from it*" and "*This process model prevents surgeons from a misunderstanding in the OR*". Such process models are a valuable source for students and residents who want to learn about minimally invasive liver treatments.

To this end, it was shown how complex surgical process models can be established and verified. In the second part of this thesis, we moved one step forward towards the applications of surgical process modeling in clinical practice. In Chapter 4, first, laparoscopic liver resection data (tumors located on different segments) was used to extract the most probable sequence of steps in LLR, depending on the tumor location. Our data from three different segment areas (segments 5, 5&6, and 7&8) showed what the most probable sequence of steps were in these three segment areas. This also benefited the prediction of surgical steps pre/intra-operatively to assist surgeons in surgical planning. Then the impact of the introduction of new technology, navigation platform, into the clinical theatre was studied. To study the impact, a discrete event simulation model was built. Three different scenarios were defined and the simulations were run for tumors located in all three segments. This study successfully showed how to predict the potential impact of introducing navigation platforms before their actual implementation, thereby avoiding unnecessary production and testing costs. Chapter 4 is clinically relevant as the experienced and novice surgeons can use the presented data and the following analysis in this chapter to see the differences in sequence of events of LLR procedures on different segments. Based on personal discussions with the experienced surgeons, they learned over time what steps to follow in different segments, but such a statistically-proven model of possible surgical paths is a valuable source for novice surgeons to advance their learning path and to train surgeons for different surgery situations based on the findings from well-analyzed similar surgical situations.

In Chapter 5, another application of surgical process modeling is discussed: surgical process modeling in training assessments. This chapter revolves around the assessment of the recording of training sessions (with the new visualization technology) for micro/neurosurgeons. A brain phantom was used to define different scenarios; enabling evaluation of the effect of different parameters (e.g. angle, size, and location) on the difficulty level of training for surgeons in different experience levels. Different steps/tasks in the training were discussed and the frequent pitfalls per step were extracted. Analysis of different parameters based on surgeons' experiences can benefit answering questions such as whether there are pitfalls that happen because of being accustomed to using traditional microscopes in the case of (semi)experienced surgeons. The learning curve of surgeons with different levels of experience were studied as well. This chapter is clinically relevant as it provides materials for the evaluation of the new visualization technology in different surgery situations, as well as learning material for the students/residents to become aware of the frequent pitfalls and have a benchmark that they can compare with.

In the last chapter on the applications of surgical process modeling, Chapter 6, we worked on the introduction of the Generic Surgery Analysis Platform (GSAP). The knowledge from previous chapters and solutions from computer science were used to come up with a generic platform that can be used for educating the young surgeons and also guiding/helping experienced surgeons pre/intra-operatively. The approach of Chapter 4 was used as the backbone of plan generation and guidance of surgeons pre/intraoperatively. Moreover, analysis of the surgical data can open up a new avenue of training by providing customized-personalized advice and training through evaluating the surgical videos in a structured way as well. The proposed platform enables the young surgeons to self-study, by showing them how a proper action can be done and comparing their actions with the professional ones. GSAP has the potential to suggest and predict surgical actions and corresponding information during operation. Moreover, it provides requirements for analyzing high granularity surgical data from sensors and possible AI methods on surgical videos. This analysis is important for assessing detailed surgical data, such as instrument movement and surgeons posture, to guide surgeons during operations for proper execution of surgical actions. After completion and trials, GSAP can be used in the hospitals to educate young surgeons and guide surgeons in performing surgeries intraoperatively.

Regarding clinical relevance, GSAP, even in its infancy, has attracted the attention of clinical institutions and has won a grant competition from the Top Consortium for Knowledge and Innovation (TKI), also known as Health-Holland, in Erasmus MC, in 2021 to continue more specifically on microsurgery section.

Proper training of surgeons is a crucial step in achieving safe and effective surgery. The current typical educational approach involves several challenges, such as: the presence of the experienced surgeons is required, the discussions between experienced surgeons and students on the learning material are limited to a few surgeries due to time limits, covering the decision makings over the entire surgical videos is a tedious task, the learning material and input are different from one experienced surgeon to another, the learning is not usually tuned to cover learners' own weaknesses or strengths. With the emergence of the COVID pandemic in 2020, the lack of and need for proper remote surgical training and education became clearer. The introduced methodologies in the platform provide a foundation for education of surgeons, while addressing the challenges in the current educational approaches.

GSAP was introduced by applying it to two different types of surgeries: on macro- and micro-scales. GSAP showed that it is possible to provide a generic platform to be used for different surgeries. However, each surgery has its own bottlenecks and challenges. In liver treatment, a challenging step is the surgery planning. On the other hand, in microsurgery, as the surgeon works on micro-scales, preventing pitfalls and achieving the right level of precision in performing surgical actions are the challenges. Thus, the platform functionalities may need small adaptations for each individual targeted surgery type to maximize the applicability.

7.2. General limitations and recommendations for future work

The presented work in this thesis is the first, but a major, step towards the actual/commercial application of the surgical process models in clinical practice. Our MILT dataset was obtained mainly from two institutions. While it is expected that there are no critical deviations from the generic process model in other institutions, more data from other institutions is needed to statistically confirm that.

As discussed, the planning and navigation panels of GSAP were only designed and not implemented yet. Surgical data is the backbone of the planning and navigation panels, and that was one major hindrance to the development of those panels. A rich source of clinical data is needed to be able to successfully generate planning, depending on where the tumor is located. For the further validation of the GSAP, the different panels need to be developed, undergo trials, receive further comprehensive in-action feedback from clinicians, and possibly be adjusted accordingly. However, the unfortunate emergence of COVID and the subsequent strict lock-downs suppressed our access to the clinical data and training sessions even further.

As future work, a more extensive study on the effect of the introduction of Modus V can be performed. Training sessions with the traditional microscope need to be carried out as well to truly assess the impact of the new visualization method on different scenarios. A 3D Modus V is also being introduced, which is expected to improve the performance in scenarios where the depth of field plays an important role. Surely, more trials than three are needed to be able to properly assess the learning curve and draw strong conclusions about the benefits/drawbacks of 2D and 3D Modus V compared with traditional microscopes.

For the discrete event simulation model and finding for the most probable sequence of events, the data was categorized based on the location of the tumor. If a larger data set is available, a more restricted categorization can be applied by selecting two or more categorization parameters e.g. based on tumor location, previous abdominal surgery, gender, and BMI. Furthermore, the most probable sequence of events for other segments can be also obtained to provide a complete LLR guideline for the young surgeons.

GSAP has a lot to offer as future work. Apart from further development and trials of the currently designed GSAP, it can be combined with AI and machine learning techniques for automatic surgical process model's phase detection using deep learning techniques such as convolutional neural network. It is a challenging task, but when it is properly done, GSAP can automatically analyze the surgical videos and enhance its database: the larger the database, the more accurate GSAP becomes. The next, even more challenging, step is to perform live automatic phase detection intra-operatively so GSAP can continuously update the planning and guide the surgeons accordingly.

7.3. Conclusions

In this thesis, the strategies for establishing surgical process models were proposed, according to the purpose of each study. As an example of the methods, The generic process model of a complex surgery, minimally invasive liver treatment, using the proposed strategies was established. This model can be used to improve various methods of performing minimally invasive liver surgeries. Next, several applications of surgical process modeling, combined with computer-based technologies, were applied to show the feasibility and value of this novel approach. This effort resulted in introduction of a novel platform for improving surgeries, so called GSAP. The continued development of the novel GSAP and its usage in both pre-operative and intra-operative procedures will make significant contributions to the global endeavor of enhancing surgical practices. This advancement holds great promise for enhancing surgeries for multiple stakeholders, including patients, surgeons, clinical teams, and engineering professionals. By providing surgeons with a patient specific surgery guidance system, GSAP empowers them to make precise and informed decisions before and during operation and perform procedures with enhanced accuracy. GSAP will enhance surgeons' skills, as well as their education and training, and reshape the path to becoming a surgical expert, fostering the development of highly skilled professionals. The profound impacts of GSAP encompass various aspects of surgical care. It promises to improve surgery safety by reducing risks and minimizing errors, ultimately leading to better patient outcomes. The utilization of GSAP can also accelerate surgical speed, enabling more efficient procedures and reducing operating room time, optimizing surgical techniques, and minimize patient recovery time. Ultimately, the introduced novel solutions will significantly enhance the lives of patients.

Summary

The vital role of surgery in healthcare requires constant attention for improvement. Surgical process modelling is an innovative and rather recently introduced approach for tackling the issues in complex surgeries. The goal of this thesis is to structure the strategies in surgical process modelling and to seek the applications of surgical process models (SPMs) with computer-based technologies to address various challenges in different surgeries. These challenges include surgical training, introduction of new technology and tools, surgery planning, prediction of surgical activities and surgery outcome, and intra-operative guidance of surgeons.

This thesis is composed of two main parts. The first concerns the strategies for establishment of the process models. The second focuses on the application of the surgical process modelling techniques on surgery improvement.

The surgical process modelling field is very challenging and still under development. Therefore, it is not always clear which modelling strategy would best fit the needs in which situations. We have provided a guide for choosing fitting modelling strategies for determining surgical workflows. The concepts associated with surgical process modelling are described and clarified, aiming to promote their use in future studies.

Next, SPM strategies were applied for the analysis of different Minimally Invasive Liver Treatments (MILTs), including ablation and surgical resection of the liver lesions. After that, a generic surgical process model for these differences in MILTs is introduced. The generic surgical process model was established at three different granularity levels. The generic process model, containing thirteen phases, was verified against videos of MILT procedures and interviews with surgeons. The established model provides a foundation for extensive quantitative analysis and simulations of MILT procedures for improving computer-assisted surgery systems, surgeon training and evaluation, surgeon guidance and planning systems and evaluation of new technologies.

Using surgical process modelling and analysis of clinical data, we established the possible variations of sequences of surgical steps in performing parenchyma sparing surgeries depending on the tumour locations. Then, the most probable chain of surgical steps was predicted, after which, a discrete event simulation model of surgeries was built to predict the impact of

introducing potential new technologies. The results suggest that navigation platform technology could decrease the total duration of surgery by up to 30%.

Next, process modelling techniques were applied for improving surgery through surgeons training analysis. In microsurgical treatments, the proper visualization of surgical details is an important factor for the outcome of a surgery. Robot-controlled digital microscopes, such as Modus V™, recently emerged to improve the visualization and ergonomics during microsurgery. Hands-on lymphatic suture training sessions on a brain phantom, using the Modus V™ robotic digital microscope, were designed and carried out. The aim was to try assessing different suturing scenarios with Modus V™ using process modelling techniques. Five scenarios were tailored in a way to reveal the impact of location, size, and angle of lymphatic vessels on the perceived difficulty of surgery. The training session procedures were divided into distinguishable steps using process modelling techniques to analyse the different scenarios. The results of the analysis were categorized based on the participant's level of experience with the conventional optic microscope. The angle and size of the vessels proved to be the main contributing factors in the difficulty of a training scenario: larger angle and smaller vessel size increase the training difficulty level. Previous experiences of experienced surgeons with a traditional microscope surely help when using Modus V. This research showed that process modelling is a useful technique for analysing the surgical training process.

In the last part of this thesis, we employed SPM techniques to develop a novel Generic Surgery Analysis Platform (GSAP) for improving surgeries. The platform provides new tools for the analysis of surgical videos and efficient storage and retrieval of the extracted surgical data. This platform was designed as generic as possible, enabling its usability in different types of surgeries. To illustrate the wide applicability of GSAP, its use was demonstrated for two different sets of applications as examples of usability of the platform. The platform was tested with laparoscopic liver resections and lymphatic training data. Furthermore, the platform was presented to surgeons with different experience levels in meetings in order to validate its functions and to discuss its benefits, user interface, and ease of use for clinicians.

The work presented in this thesis confirmed that the GSAP satisfies the needs of the clinicians. With GSAP we have introduced a new approach for evaluating surgeries and surgeons' performance, for pre/intra-operative planning of surgeries, and for guidance of surgeons during operation. By harnessing the potential of GSAP, we aspire to achieve significant improvements in surgical outcomes, benefiting surgeons and patients alike on a global scale.

Samenvatting

De vitale rol van chirurgie in de gezondheidszorg vereist voortdurende aandacht voor verbetering. Modellering van het chirurgische proces is een innovatieve en vrij recent geïntroduceerde benadering om de problemen bij complexe operaties aan te pakken. Het doel van deze scriptie is om de strategieën in de modellering van het chirurgische proces te structureren en de toepassingen van chirurgische procesmodellen (SPM's) met op computertechnologie gebaseerde systemen te onderzoeken om verschillende uitdagingen bij verschillende operaties aan te pakken. Deze uitdagingen omvatten chirurgische training, introductie van nieuwe technologieën en instrumenten, operatieplanning, voorspelling van chirurgische activiteiten en operatieresultaat, en intra-operatieve begeleiding van chirurgen.

Deze scriptie bestaat uit twee hoofddelen. Het eerste deel behandelt de strategieën voor het opstellen van de procesmodellen. Het tweede deel richt zich op de toepassing van de technieken voor het modelleren van het chirurgische proces ter verbetering van de chirurgie.

Het veld van modellering van het chirurgische proces is zeer uitdagend en nog steeds in ontwikkeling. Daarom is het niet altijd duidelijk welke modelleringsstrategie het beste aansluit bij de behoeften in verschillende situaties. We hebben een gids gegeven voor het kiezen van passende modelleringsstrategieën voor het bepalen van chirurgische werkstromen. De concepten die verband houden met het modelleren van het chirurgische proces worden beschreven en verduidelijkt, met als doel het bevorderen van hun gebruik in toekomstig onderzoek.

Vervolgens werden SPM-strategieën toegepast voor de analyse van verschillende minimaal invasieve leverbehandelingen (MILTs), waaronder ablatie en chirurgische resectie van de leverlaesies. Daarna wordt een generiek model van het chirurgische proces voor deze verschillen in MILTs geïntroduceerd. Het generieke model van het chirurgische proces is opgesteld op drie verschillende granulariteitsniveaus. Het generieke procesmodel, bestaande uit dertien fasen, is geverifieerd aan de hand van video's van MILT-procedures en interviews met chirurgen. Het opgestelde model biedt een basis voor uitgebreide kwantitatieve analyses en simulaties van MILT-procedures ter verbetering van computersystemen voor ondersteunde chirurgie,

chirurgische training en evaluatie, begeleiding en planningsystemen voor chirurgen, en evaluatie van nieuwe technologieën.

Door middel van modellering van het chirurgische proces en analyse van klinische gegevens hebben we de mogelijke variaties in de volgorde van chirurgische stappen bij het uitvoeren van ingrepen om het weefsel te sparen, afhankelijk van de locatie van de tumor, vastgesteld. Vervolgens werd de meest waarschijnlijke reeks chirurgische stappen voorspeld, waarna een simulatiemodel van de operaties werd gebouwd om het effect van de introductie van potentiële nieuwe technologieën te voorspellen. De resultaten suggereren dat navigatieplatformtechnologie de totale operatieduur met wel 30% zou kunnen verminderen.

Daarna werden modelleringstechnieken toegepast om de chirurgie te verbeteren door middel van de analyse van chirurgische training. Bij microchirurgische behandelingen is een juiste visualisatie van chirurgische details een belangrijke factor voor het resultaat van een operatie. Robotgestuurde digitale microscopen, zoals de Modus VTM, zijn onlangs ontwikkeld om de visualisatie en ergonomie tijdens microchirurgie te verbeteren. Hands-on trainingssessies voor het hechten van lymfevaten op een hersenmodel, met behulp van de Modus VTM robotgestuurde digitale microscoop, werden ontworpen en uitgevoerd. Het doel was om verschillende hechtingsscenario's met de Modus VTM te beoordelen met behulp van modelleringstechnieken voor het chirurgische proces. Vijf scenario's werden op maat gemaakt om het effect van de locatie, grootte en hoek van de lymfevaten op de ervaren moeilijkheid van de operatie te laten zien. De procedures van de trainingssessies werden opgesplitst in onderscheidbare stappen met behulp van modelleringstechnieken om de verschillende scenario's te analyseren. De resultaten van de analyse werden gecategoriseerd op basis van het ervaringsniveau van de deelnemers met de conventionele optische microscoop. De hoek en grootte van de vaten bleken de belangrijkste bijdragende factoren te zijn voor de moeilijkheid van een trainingscenario: een grotere hoek en kleinere vatgrootte verhogen het moeilijkheidsniveau van de training. Eerdere ervaringen van ervaren chirurgen met een traditionele microscoop helpen zeker bij het gebruik van de Modus V. Dit onderzoek toonde aan dat modellering van het proces een nuttige techniek is voor de analyse van het chirurgische trainingsproces.

In het laatste deel van deze scriptie hebben we SPM-technieken toegepast om een nieuw generiek platform voor chirurgie-analyse (GSAP) te ontwikkelen ter verbetering van operaties. Het platform biedt nieuwe tools voor de analyse van chirurgische video's en efficiënte opslag en ophaling van de geëxtraheerde chirurgische gegevens. Dit platform is zo generiek mogelijk ontworpen, zodat het bruikbaar is in verschillende soorten operaties. Om de brede toepasbaarheid van GSAP te illustreren, werd het gebruik ervan gedemonstreerd voor twee verschillende sets toepassingen als voorbeelden van de bruikbaarheid van het platform. Het platform werd getest met laparoscopische leverresecties en lymfatische trainingsgegevens. Bovendien werd het platform gepresenteerd aan chirurgen met verschillende ervaringsniveaus tijdens bijeenkomsten om de functionaliteit, voordelen, gebruikersinterface en gebruiksvriendelijkheid voor clinici te valideren en te bespreken.

Het werk dat in deze scriptie wordt gepresenteerd, bevestigt dat GSAP voldoet aan de behoeften van clinici. Met GSAP hebben we een nieuwe benadering geïntroduceerd voor de evaluatie van operaties en pre/intra-operatieve planning, evenals de begeleiding van chirurgen tijdens de operatie. Door gebruik te maken van het potentieel van GSAP streven we naar significante verbeteringen in de resultaten van chirurgische ingrepen, ten goede van zowel chirurgen als patiënten wereldwijd.

Scientific output

Journal publications:

M. Gholinejad, A.J. Loeve, J. Dankelman, "Surgical process modeling strategies: which method to choose for determining workflow?", *Minimally Invasive Therapy & Allied Technologies* 28.2 (2019): 91-104.

M. Gholinejad, E. Pelanis, D. Aghayan, Å. A. Fretland, B. Edwin, T. Terkivatan, O. J. Elle, A. J. Loeve & J. Dankelman "Generic surgical process model for minimally invasive liver treatment methods" *Scientific Reports* 12,1 (2022):1-14

M. Gholinejad, B. Edwin, O.J. Elle Elle, A.J. Loeve and J. Dankelman. Process model analysis of parenchyma sparing laparoscopic liver surgery to recognize surgical steps and predict impact of new technologies. Surg Endosc 37, 7083–7099 (2023).

M. Gholinejad, O. J. Elle, B. Edwin, A.J. Loeve, J. Dankelman, "A novel platform for improving surgeries using surgical process modeling" (To be submitted as a journal article).

Conferences & workshops:

Image guided surgery, soft tissue navigation and modelling strategies, Oslo University Hospital, Rijkshospitalet, Oslo, Norway, September 2017 (Workshop and Oral presentation).

Image guided surgery, soft tissue navigation and modelling strategies, Norwegian University of Science and Technology (NTNU) and Olav Hospital, Trondheim, Norway, September 2017 (Workshop and Oral presentation).

Navigated percutaneous ablations and laparoscopic liver resections, University Hospital of Bern, Artorg center and Cascination company, Bern, Switzerlands, March 2018 (Workshop and Oral presentation).

High performance computing for image and video processing, deep learning and beyond using heterogonous memory system, University of Cordoba, Cordoba, Spain, September 2018 (Workshop, Oral presentation and Poster presentation).

Image quality assessment and deep learning in medical computer-aided diagnosis, University Paris 13, Paris, France, December 2018, (Workshop and Oral presentation).

Real-time simulation, linear elasticity and applications of numerical simulation in medicine, National Institute for Research in Digital Science and Technology (INRIA), Strasbourg, France, December 2018 (Workshop and Oral presentation).

BME Conference, Egmond aan Zee, The Netherlands, January 2019 (Poster presentation).

NVEC Conference, Amsterdam, Netherlands, April 2019 (Poster presentation).

EAES Conference- Sevilla, Spain, June 2019, Nominated as 5 best research for Karl Storz award (Oral presentation).

Image-guided surgery and advanced navigation in surgeries, Siemens Healthineers Company, Forchheim, Germany, June and July 2019 (Workshop and Oral presentation).

SMIT Conference, Heilbronn, Germany, October 2019, Presenting as an Invited Speaker (Oral presentation).

Validation methods of new algorithms and methods in navigation platforms and participation at the European computer assisted liver surgery society meeting in Bern, University Hospital of Bern, Inselspital, Artorg center and Cascination company, Bern, Switzerlands, October 2019 (Workshop and Oral presentation)

ECALSS Conference (European Computer Assisted Liver Surgery Society)
October 2019, Bern, Switzerland (Oral presentation and poster presentation)

Human-machine interaction, risk and risk management, workflow design, analysis and optimization, Delft University of Technology (TUDelft), The Netherlands, February 2020 (Workshop and Oral presentation).

SMIT Conference , Chicago, USA, December, 2020 (Oral presentation).

SMIT Conference, Oslo, Norway, May 2022 (Oral presentation).

IGSMP international e-Conference, December, 2022, Brighton East Melbourne, Australia , Presenting as an Invited Speaker (Keynote speaker).

NVEC Conference, Amsterdam, Netherlands, April 2023, Presenting as an Invited Speaker (Oral presentation).

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