Safe surgical signatures

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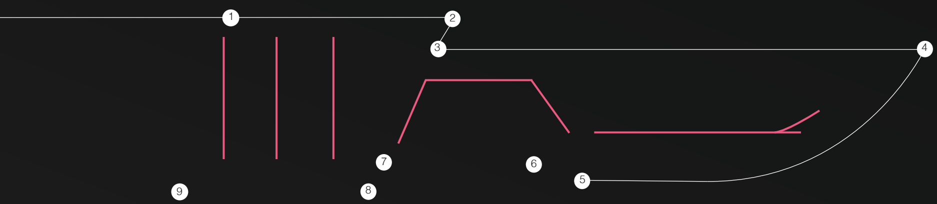
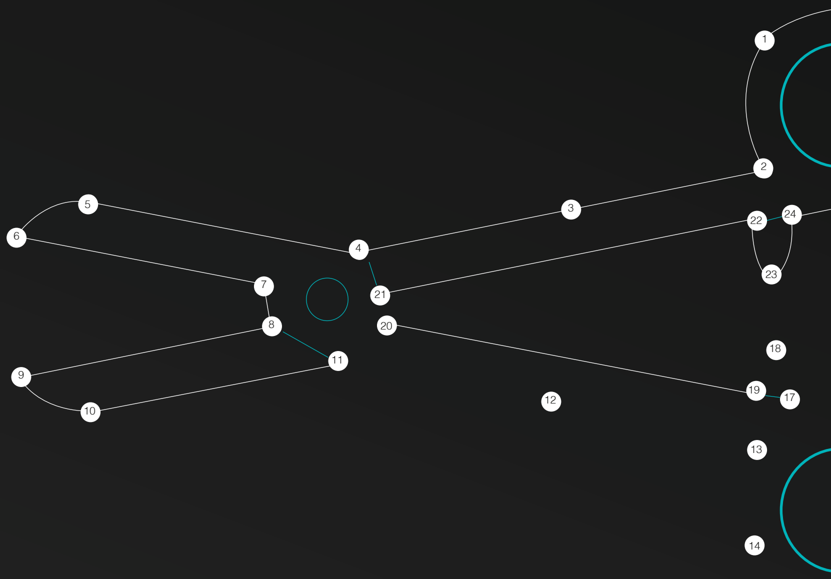
SAFE SURGICAL SIGNATURES

Frédérique C. Meeuwsen





SAFE SURGICAL SIGNATURES

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SAFE SURGICAL SIGNATURES

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Technische Universiteit Delft,
op gezag van de Rector Magnificus prof. dr. ir. T.H.J.J. van der Hagen;
voorzitter van het College voor Promoties,
in het openbaar te verdedigen op
woensdag, 29 mei 2019 om 12:30 uur

door

Frédérique Cornelie MEEUWSEN

Doctorandus in de Geneeskunde, arts
Erasmus Universiteit, Nederland
geboren te Alkmaar, Nederland

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SUMMARY

In this dissertation, we analyse the safe use of medical technology, considering the training of users, technical demands of used devices and instruments, and the surgical workflow. As each of these elements will vary depending on the experience of the user, the equipment used, and variations in the environment; a unique set of parameters for safe use emerges: a *'safe surgical signature'*.

The aim of this thesis is to objectively measure safe application of medical technology in the Operating Room (OR), considering the three main pillars linked to the user, the devices, and environment. All three pillars need to be addressed, present and lined up, to reach its final goal; safe use.

In **Part 1**, we specifically focus on electrosurgery, which is a surgical device using electrical energy to manipulate tissue. Despite its worldwide and frequent use during surgical procedures, its use is also related to serious adverse events. Therefore, training is required to reduce the number and severity of these events. We evaluate the educational training program in electrosurgery for surgical residents. Respondents are not satisfied with the set-up of the program, and the acquired theoretical competences of themselves and their supervisors. More extensive education for both residents and their supervisors is needed to enhance patient safety.

The level of theoretical knowledge also influences the manner in which electrosurgery is applied, which has a serious effect on the outcome of the procedure, the safety, and the well-being of patients. We monitor the variability in activation patterns of the electrosurgical device of experienced surgeons and residents. Results of the current measurement data show differences in the way electrosurgery is applied by surgeons and residents during laparoscopic cholecystectomies.
Furthermore, we monitor electrosurgical use during various other procedures. Differences in approaches are found among surgeons, which may arise from the complex interplay between settings, choice of electrode, experience, and the task at hand. Surgeons seem to have a preferred setting, and adjust the application technique to different tasks.

In **Part 2**, we take a closer look into the surgical environment in which instruments and devices are used. Surgical Process Modelling (SPM) offers the possibility to automatically gain insight in the surgical workflow with the potential to improve OR logistics and surgical safety. We describe an approach that demonstrates the broad applicability of SPM, by recognizing surgical phases during a laparoscopic hysterectomy; a complex laparoscopic procedure with inherent variability in procedure time.

To accurately monitor surgical workflow, reliable real-time intraoperative data is necessary. However, capturing this data is a challenge and many approaches have been explored. We present a pilot study using a track and trace system to monitor intraoperative surgical instrument use. The system uses sterilisable RFID-sensor equipped instruments and is tested in an OR setting, and during a real-life intraoperative procedure. The results contribute to the development of reliable track and trace systems for phase recognition purposes.

Conclusion

Safe use of medical technology means: 'a safe product, in the hands of a trained user, in an environment that can guarantee safe use'. But not the sole presence of these pillars constitutes safe use; all elements need to be properly aligned with each other. *'Safe surgical signatures*' serves as a guide for a succesfull alignment through objective measurements of the three pillars. The true added value of this alignment is the creation of situational awareness, which is a prerequisite for the safe use and implementation of medical technology.

SAMENVATTING

In dit proefschrift analyseren we het veilig gebruik van medische technologie, rekening houdend met de training van gebruikers, technische vereisten van apparaten en instrumenten en de chirurgische workflow. Elk van deze elementen zal variëren, afhankelijk van de ervaring van de gebruiker, het type apparatuur en variaties in de omgeving. Hierdoor zal een unieke reeks parameters voor veilig gebruik naar voren komen, oftewel een veilige chirurgische handtekening - a '*safe surgical signature'.*

Het doel van dit proefschrift is het objectief meten van een veilige toepassing van medische technologie in de operatiekamer (OK), rekening houdend met de drie belangrijkste pijlers gekoppeld aan de gebruiker, de apparaten en de omgeving. Alle drie de pijlers moeten worden aangepakt, aanwezig zijn en uitgelijnd worden om hun uiteindelijke doel te bereiken; veilig gebruik.

In **Deel 1** richten we ons specifiek op elektrochirurgie, een chirurgisch apparaat dat elektrische energie gebruikt om weefsel te manipuleren. Ondanks het wereldwijde en frequente gebruik tijdens chirurgische ingrepen is het gebruik ervan helaas ook gerelateerd aan ernstige bijwerkingen. Daarom is training vereist om het aantal en de ernst van deze gebeurtenissen te verminderen. We evalueren het educatieve trainingsprogramma in elektrochirurgie voor snijdende arts-assistenten (AIOS en ANIOS). De respondenten zijn niet tevreden met de opzet van het programma en de verworven theoretische competenties van henzelf en hun leidinggevenden. Er is meer uitgebreid onderwijs nodig voor zowel arts-assistenten als hun supervisors om de veiligheid van de patiënt te verbeteren.

Het niveau van theoretische kennis beïnvloedt ook de manier waarop elektrochirurgie wordt toegepast, hetgeen een serieus effect heeft op de uitkomst van de procedure, de veiligheid en het welzijn van de patiënt. We monitoren de variabiliteit in activeringspatronen van het elektrochirurgische apparaat van ervaren chirurgen en arts-assistenten. De resultaten van de meetgegevens tonen verschillen in de manier waarop elektrochirurgie wordt toegepast door chirurgen en arts-assistenten, tijdens een laparoscopische cholecystectomie. Verder monitoren we elektrochirurgisch gebruik tijdens verschillende andere procedures. Tussen de chirurgen zijn verschillen in aanpak te vinden, die kunnen voortvloeien uit de complexe wisselwerking tussen instellingen, elektrodekeuze, ervaring en de taak die voorhanden is. Chirurgen lijken een voorkeursinstelling te hebben en passen hun applicatietechniek aan de verschillende taken aan.

In **Deel 2** gaan we dieper in op de chirurgische omgeving waarin instrumenten en apparaten worden gebruikt. Surgical Process Modelling (SPM) biedt de mogelijkheid om automatisch inzicht te krijgen in de chirurgische workflow, met de potentie om OK-logistiek en chirurgische veiligheid te verbeteren. We beschrijven een benadering die de brede toepasbaarheid van SPM demonstreert, door chirurgische fasen te herkennen tijdens een laparoscopische hysterectomie; een complexe laparoscopische procedure met inherente variabiliteit in operatieduur.
Om de chirurgische workflow nauwkeurig te kunnen volgen, zijn betrouwbare real-time intra-operatieve gegevens noodzakelijk. Het vastleggen van deze gegevens is echter een grote uitdaging en veel benaderingen zijn hiervoor al onderzocht. We presenteren een pilotstudie met een track en trace systeem om het gebruik van intra-operatieve chirurgische instrumenten te controleren. Het systeem maakt gebruik van instrumenten die met een steriliseerbare RFID-sensor zijn uitgerust en is getest in een OK-setting én tijdens een intra-operatieve procedure. De resultaten dragen bij aan de ontwikkeling van meer betrouwbare track en trace systemen voor faseherkenning van de operatie.

Conclusie
Veilig gebruik van medische technologie betekent: ‘een veilig product, in de handen van een getrainde gebruiker, in een omgeving die een veilig gebruik kan garanderen’. Maar niet alleen de aanwezigheid van deze pijlers garandeert veilig gebruik, alle elementen moeten goed op elkaar zijn afgestemd. Door objectieve metingen van de drie pijlers, dient ‘*Safe surgical signatures*’ als een gids voor een succesvolle en veilige afstemming. De grootste toegevoegde waarde van deze afstemming is het creëren van situational awareness, wat een vereiste is voor het veilige gebruik en de implementatie van medische technologie.

CHAPTER 1

INTRODUCTION


Dräger
Movita
MAQUET

BACKGROUND

In 2011 the covenant 'Safe application of medical technology in the hospital' was presented to the Minister of Health, Welfare and Sport by the Dutch Association of Hospitals (NVZ), the Dutch Federation of University Medical Centers (NFU) and Rehabilitation Netherlands (RN).[1] The covenant serves as a guidance for risk management and safe application of medical technology within direct patient care. It stresses the need to set up a quality system with procedures for all phases of the life cycle of medical technology (purchase, implementation, application and depreciation).

Since 1 January 2013, hospitals must officially adhere to the covenant. However, follow-up reports in 2014-2015 by the Dutch Healthcare Inspectorate (DHI) showed that implementation is not a sinecure.[2] Randomly chosen hospitals were visited, and the majority had not adequately implemented the requirements of the covenant. The shortcomings mainly include the absence of administrative responsibility, integrated multidisciplinary approach, and guarantee of the users' competencies and qualifications. While the responsibility was often assigned to the department of medical technology in the 'old' situation, a cultural shift will be required to achieve a hospital-wide responsibility. Safe application of medical technology can only be realized when both care departments and supporting departments share responsibility in successfully implementing the covenant.

The covenant is built on three pillars: First, a safe product is achieved by, among others, a well-conducted risk inventory prior to the purchase, by a careful intake and release of the product, and by an effective registration and management system. Second, to ensure that the user is sufficiently trained to handle the product independently, training is required. The last pillar of the covenant is the environment that can guarantee safe use. It is important to realize that these three pillars are closely connected to each other, which is effectively expressed by the adage: 'safe application means a safe product, in the hands of a trained user, in an environment that can guarantee safe use'.

Obviously, the covenant is not the first to address the importance of safe use of medical technology. This international issue has also been recognized by the U.S. Food and Drug Administration.[3] Many studies have been devoted to achieve and even improve safe application. For instance, one recent initiative, Digital Operating Room Assistant (DORA) strives to improve the management of medical technology. The DORA system automatically checks the safety status of OR devices through continuous communication with the technical facility management system. It informs the OR staff real-time and facilitates notification of malfunctions.[4] It hereby reduces the risk that equipment that is at the verge of breaking down is anyhow used in procedures due to incomplete reporting and registration of malfunctions.

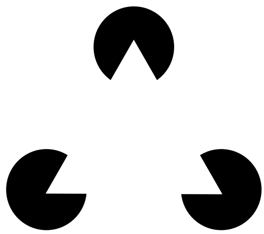

Figure 1. In this illusion, a white triangle completes the space between the black figures.

MAIN OBJECTIVE

Ensuring qualified and competent/trained users has always been a popular theme. Over the years, many training devices have been developed, especially for laparoscopic applications.[5-7] The importance of these skills has also been recognized by diverse (inter)national associations for medical specialists and has prompted them to add obligated courses to their residency programs, covering acquisition of laparoscopic skills, electrosurgery and knowledge about diagnostic imaging techniques.[8-10] However, it is equally important to guarantee that the users indeed stay competent and qualified during their employment.

Due to the increasing complexity of the surgical working environment, more solutions must be found to aid the OR teams' situational awareness before and during surgical procedures. Through analysis of intra-operative data, additional technologies can assist the OR personnel in providing the right patient-specific information at the right time.[11] For example, the Surgical Procedure Manager, which is an intraoperative workflow and documentation system; currently particularly suitable for interventions with low sequence variability. During the procedure, the Surgical Procedure Manager indicates the ongoing and upcoming surgical steps through verbal and pictorial information, and documents important surgical parameters.[12-13] This kind of approaches have the potential to improve safety by reducing the number of distractions and workload for the health care professionals. Moreover, they may reduce health care costs by increasing the efficiency of OR workflow.[11]

When striving for safe use, it is important to take the interaction between all three pillars into account. But not only the sole presence of these pillars constitutes safe use; all elements need to be properly aligned with each other for true safety to emerge. We can recognize these thoughts in the famous phrase of Kurt Koffka: "the whole is something else than the sum of its parts".[14] The central principle of this philosophy is that the mind forms a global whole, independent of the parts. In the illustration of Figure 1, one could see a group of black Pac-men, or one can image a triangle to complete the space. The new created form is not just the sum of the elements, but something totally different: a new 'whole'. The goal of the medical covenant is likewise. All three pillars need to be addressed, present and lined up, to reach its final goal. Safe use of medical technology is the new 'whole' that is created.

In this thesis we will analyze the safe use of medical technology; considering the training of users, technical demands of used devices and instruments, and the surgical workflow. As each of these elements will vary depending on the experience of the user, the specific equipment used, and variations in the environment/patients; for each situation a unique set of parameters for safe use emerges: *a safe surgical signature.*

Our main objective is to objectively measure safe application, taking into account the parameters linked to the user, the devices and environment.

APPROACH AND OUTLINE

In **Part 1** we focus on the application of high-risk surgical instruments in electrosurgery. This device is used in almost 80% of surgical procedures across medical disciplines. With the use of electricity, the surgeon cuts through tissue and coagulates blood vessels. Although widely used, it can cause major complications if not handled with care. These complications occur in 1-2 per 1000 procedures and range from perforated intestines to burn wounds.[15] Surprisingly, studies have also shown that surgeons' theoretical knowledge about this device is poor.

To make sure that safe use of electrosurgery is guaranteed, we aim to align the 3 pillars (user, device, environment). In **chapter 2** we investigated how electrosurgical education is currently organized in the Netherlands. By means of a digital questionnaire; information about training, supervision and adverse events was acquired from residents of six surgical subspecialties.
To learn how electrosurgery is applied during real-life procedures, we measured in-vivo how electrosurgical devices are operated by different users. **Chapter 3** will present the differences in use between surgeons of different expertise during laparoscopic cholecystectomies.
For a more in-depth analysis of the motor skills of the surgeon, we investigated if the use of electrosurgery is adapted to different types of tasks. Various breast surgery procedures were analyzed and the results are discussed in **chapter 4**.

In **Part 2** we learn how to use intra-operative data as a source to monitor workflow. By recording instrument use, surgical phases can be distinguished. Automatic monitoring of surgical progress can help in streamlining procedures. **Chapter 5** explores the possibility to apply surgical phase recognition to laparoscopic hysterectomies. Data is acquired through manually annotated videos. In **chapter 6** we present a different approach to gather intra-operative data. Surgical instruments are equipped with sensors to be able to reliably monitor instrument use during a procedure. This RFID-based system is tested in the OR and resulted in a proof-of-principle to be used for in vivo measurements. Finally, a discussion and conclusion is provided in **chapter 7**.

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CHAPTER 2

THE ART OF ELECTROSURGERY: TRAINEES AND EXPERTS

ABSTRACT

Background
The benefits of electrosurgery have been acknowledged since the early 1920s, and nowadays more than 80% of surgical procedures involve devices that apply energy to tissues. Despite its widespread use, it is currently unknown how the operator's choices with regard to instrument selection and application technique are related to complications. As such, the manner in which electrosurgery is applied can have a serious influence on the outcome of the procedure and the well-being of patients. The aim of this study is to investigate the variety of differences in usage of electrosurgical devices. Our approach is to measure these parameters to provide insight into application techniques.

Methods
A sensor was developed that records the magnitude of electric current delivered to an electrosurgical device at a frequency of 10 Hz. The sensor is able to detect device activation times and a reliable estimate of the power-level settings.

Results
Data were recorded for 91 laparoscopic cholecystectomies performed by different surgeons and residents. Results of the current measurement data show differences in the way electrosurgery is applied by surgeons and residents during a laparoscopic cholecystectomy. Variations are seen in the number of activations, the activation time, and the approach for removal of the gallbladder. Analysis showed that experienced surgeons have a longer activation time than residents (3.01 vs 1.41 seconds, $P < .001$) and a lower number of activations (102 vs 123).

Conclusion
This method offers the opportunity to relate application techniques to clinical outcome and to provide input for the development of a best practice model.

INTRODUCTION

Over the course of many years, there has been a great increase of the use of medical technology in hospitals all over the world.[1] The term medical technology encompasses the range from simple blood pressure pumps to very complex DaVinci robots in the operating room (OR). The main purpose for all devices is to improve patient safety, efficiency and workflow. At this moment patient safety is a very important item on many agendas.[2-6] Safe use of medical technology represents a safe product, in the hands of a trained user, in an environment that can guarantee safe surgery. Many studies specifically focus on patient safety in the OR, since it has been recognized as a place where many incidents can occur. Baines et al. found that more than 50% of all adverse events were related to surgical procedures,[7] and Wubben et al. show that 15.9% of incidents during surgical procedures are equipment-related.[8] In particular, the use of electrosurgical devices is often associated with hazards that may seriously influence the outcome of the procedure.[9]

Over 80% of surgical procedures performed today involve devices that apply energy to tissues. First introduced in the 1920's by Bovie,[10] electrosurgery is used for surgical cutting or to control bleeding by causing coagulation (hemostasis) at the targeted surgical site. Electrical currents and voltages are delivered through an active electrode, causing desiccation, vaporization, or charring of the target tissue.[11] Despite significant advantages for tissue dissection, hemostasis, and ablation, major adverse events can and do occur during the application of electrosurgery. The most common unwanted events include: direct misapplication, capacitive coupling, direct coupling and insulation failure, leading to damage to adjacent structures.[9] Furthermore, alternative site burns (e.g. pads, prostheses, surgeon hand) frequently occur.[11] According to the Association of periOperative Registered Nurses (AORN), in the US there are approximately 40,000 patient burn cases annually due to faulty electrosurgical devices, and in 1999 alone, nearly $600 million was paid in claims for those injuries.[12,13] In addition, the prevalence of bowel injuries related to electrosurgery during laparoscopic surgery is estimated at 1 to 2 per 1,000 patients, with high morbidity related to unrecognized injuries.[14]

Most of the above-mentioned adverse events are considered to be preventable by ensuring a proper understanding of the technologies and their applications and an awareness of potential risks.[15] Many complications are based on the faulty use of the instruments and settings, therefore knowledge and basic skills in operating these devices are of great importance. However, while surgeons and surgical trainees may use energy-based devices on a daily basis, they are not always familiar with their basic principles and functions. Recent studies found many gaps in the knowledge about the safe use of electrosurgical devices.[16,17] At this moment no specific guidelines about the application of electrosurgery exist. The industry suggests that in general the lowest setting possible should be used and single activations of the device should be as short

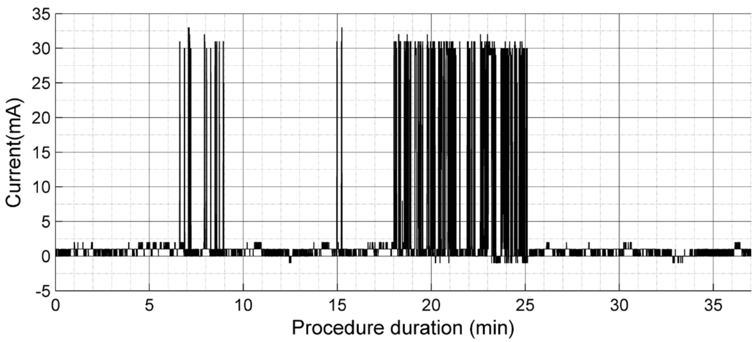

Figure 1. Example of an activation pattern of the electrosurgical device during a laparoscopic cholecystectomy. Peaks in the recorded current correspond to activations of the device.

as possible.[18] With so many complications and risks associated with the use of electrosurgery, it is remarkable that there is no standardized and mandatory curriculum, teaching surgeons to safely and effectively operate such devices. Moreover, there is no procedure to certify basic skills prior to their application. The latter is mostly due to the current lack of a best practice model for electrosurgery. In fact, very little is known about the details of practical use by different surgeons. No complete training for residents can be developed, as long as the actual use of these instruments is unknown and objective assessments based on validated metrics are lacking. For these reasons, it is necessary to obtain information about the current application methods of electrosurgical devices throughout a procedure. We are not aware of other studies that investigated the use of electrosurgical devices in depth.

The aim of the work presented in this article is to get insight in the application of electrosurgical devices during surgical procedures. Our approach is to delineate ways of handling the technique by obtaining detailed registrations of the actual activations of the electrosurgical device during surgical cutting and coagulation. In this study, we evaluate the variability in activation patterns by experienced surgeons and residents. The work provides input for the establishment of a best practice model and contributes to the development of a training program focused on safe use of electrosurgery.

METHODS

Data acquisition

A custom-made measurement device was used to record the magnitude of electric current delivered to an electrosurgical device (Valleylab, Force FX or Valleylab Force triad). While plugged in between the power plug of the device and socket, it recorded the magnitude of current at a frequency of 10 Hz. The device did not interfere the procedure in any way. The recorded data was stored on a SD card for post-operative data analysis. An example of the activation pattern of the electrosurgical device during an entire laparoscopic cholecystectomy procedure is shown in Figure 1.

Recorded clinical procedures

For this study, elective laparoscopic cholecystectomies were chosen because of their frequent performance and relatively standard execution. A standard procedure can be divided in three phases. First the patient gets prepared for minimal invasive surgery, small incisions are made in the abdomen and trocars are placed. In the second phase instruments enter the ports, the gallbladder is identified and removed from the body. In the last phase, the instruments and trocars are removed again and sutures are placed to close the incisions. Electrosurgery is mainly used in the second phase, to remove the gallbladder from the liver, to establish hemostasis of the bleeding gallbladder bed and to coagulate small vessels. A total of 91 laparoscopic cholecystectomies were recorded, performed by five different surgeons (>1000 laparoscopic cholecystectomies performed) and 11 different residents (100-300 laparoscopic cholecystectomies performed). The surgeons executed a total of 45 procedures and the residents covered the remaining 46, under supervision. All procedures were recorded in the OR of a Dutch teaching hospital between March 2014 and July 2015.

Patient characteristics

Relevant patient information and perioperative details about the procedure were obtained from the hospital information system (CS-EZIS, ChipSoft, Amsterdam, The Netherlands). Surgery was performed on 30 men and 61 women, with an average age of 54 years (range 18-86 years). With an average BMI of 29 (range 18-44) our patients were generally overweight. Forty-five patients had abdominal surgery before, which may lead to adhesions and could make surgery more difficult. Four patients were admitted with an acute diagnosis, all others patients were scheduled on an elective basis. Spillage of gallstones and bile during the procedure was even for surgeons and residents, resp. 14 and 10 times. Blood loss was not reported in 28 of procedures, so is excluded in this analysis. No conversions to laparotomy have occurred.

Data analysis

The used sensor, measuring the electric current supplied to the electrosurgical device, enables accurate detection of device activation and a reliable estimate of the power level settings. A threshold of 15 mA was selected in the data sets to detect single activations of the electrosurgical device. An activation started when the signal reaches a value higher than 15 mA and ended when the signal dropped below it. The start and end time of procedures were obtained from the hospital information system and the current sensor data was selected manually according these timestamps.

Combining all available information, we were able to detect the following parameters:

- First moment of activation during the process
- Last moment of activation during the process
- Number/amount of activations
- Duration of separate activations
- Estimated height of activation
- Duration of total device usage

Statistics

To control for possible effects of patient characteristics on the use of the electrosurgical device we first determined whether the sex, age, BMI and previous abdominal surgery was correlated with any of the above-mentioned parameters. Pearson product-moment correlation coefficients were obtained to see whether there was a relation between the number and duration of activations and the duration of use of the device. Student's t-tests were performed to determine whether there were significant differences between the means of the grouped data of experts and of the residents. Analysis was done with use of MATLAB (version R2014b, MathWorks, Natick, Massachusetts, U.S.A).

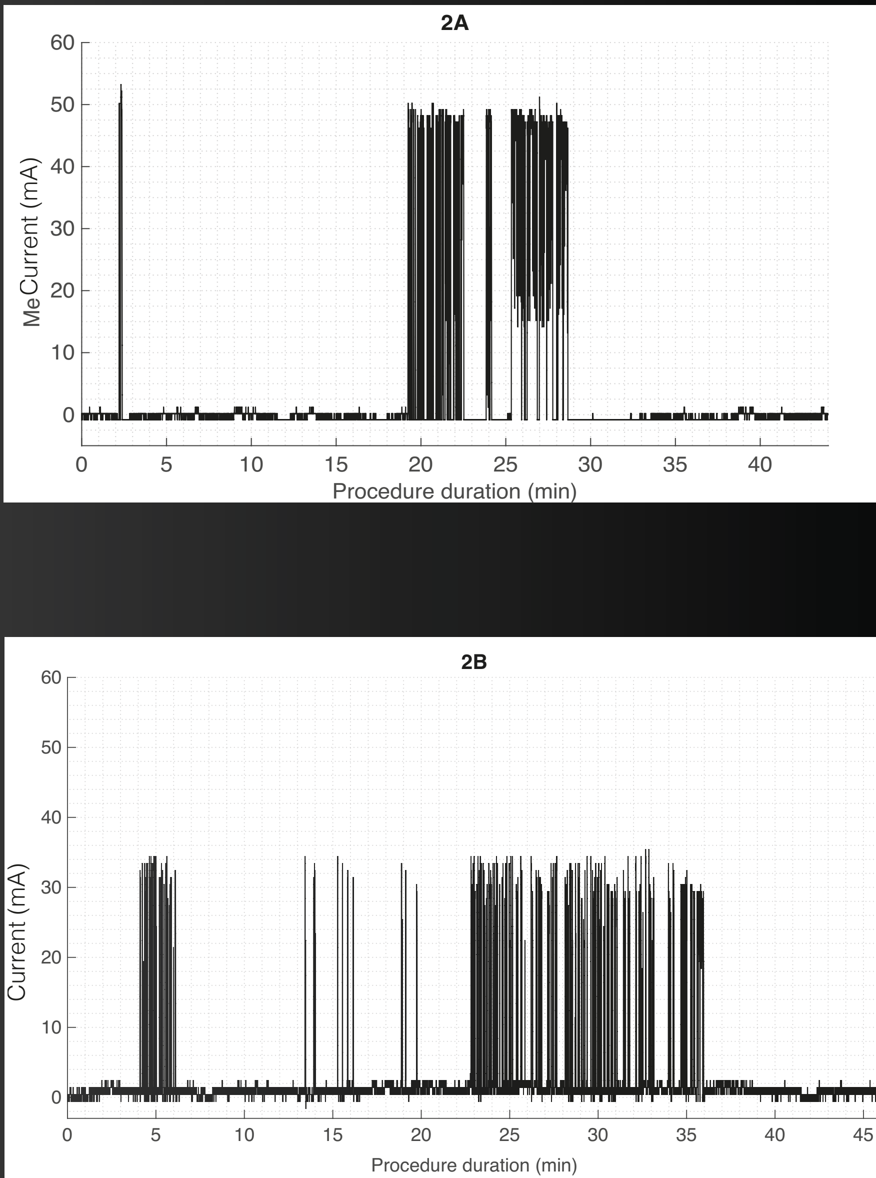

Figure 2. The activation patterns of the electrosurgical device of a surgeon (A) and a resident (B). On the horizontal axis the time in minutes is shown, starting immediately at the time of first incision and ending with the actual end-time of the procedure. On the y-axis the measurement data are provided.

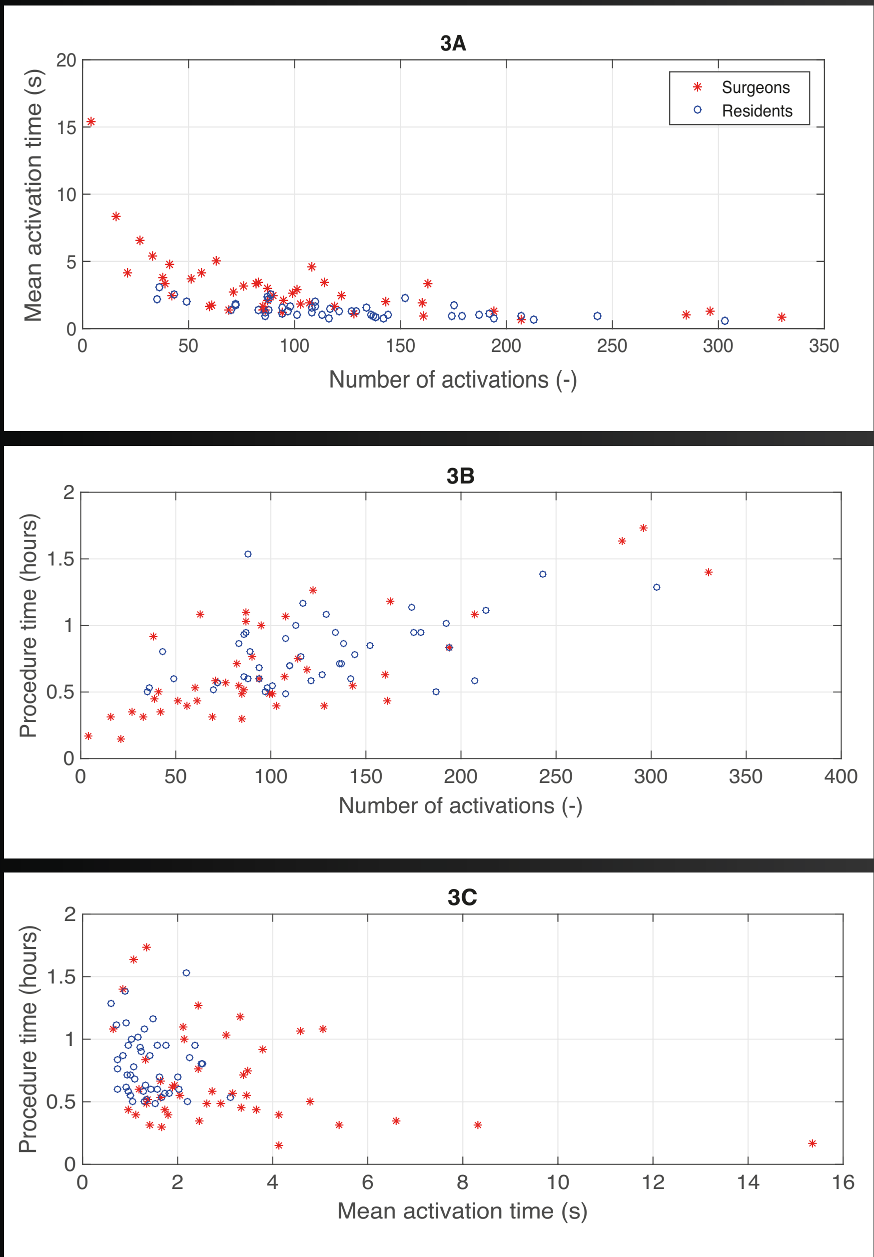

Figure 3. Number of activations (A and B) and mean activation time (C). Data obtained from surgeons (stars) and residents (circles).

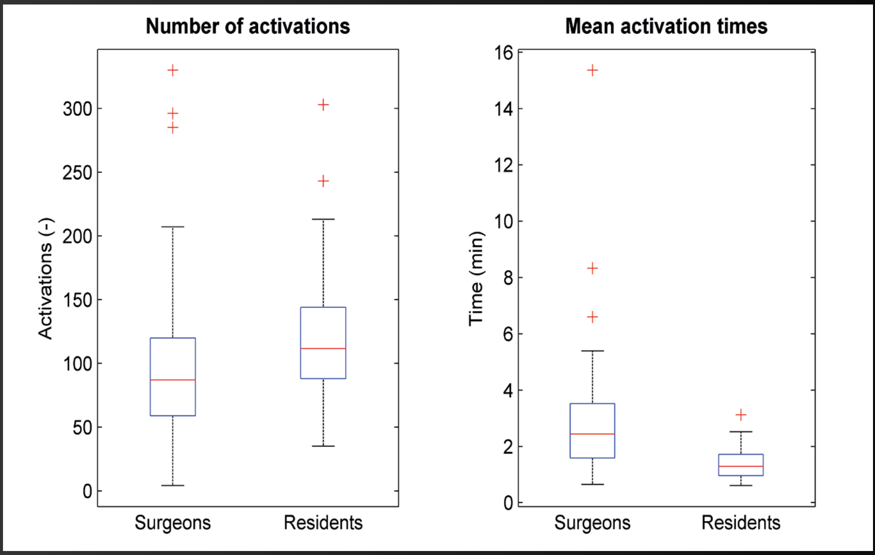

Figure 4. Boxplots of the number of activations and the mean activation time per procedure.

RESULTS

Activation patterns
Laparoscopic cholecystectomies know a relatively standard execution. However, in this study the total procedure time varied extensively (range 9 min - 1h 44 min, average 44 min). As an illustration, figure 2A shows that the use of the electrosurgical device was initiated about 19 minutes after the first incision, indicating that this was the time needed for placing the trocars and reaching the gallbladder. Next, the electrosurgery device was activated between the 19th and the 22nd minute. At around the 25th minute a second burst of activations is seen. In contrast, in Figure 2B a more frequent use of the device is seen. With respect to the activation patterns of the electrosurgery device, several patterns were observed. Figure 2A shows the pattern of an expert surgeon, whereas Figure 2B shows the performance of a surgical resident.

Activation parameters
Analysis showed that there were no correlations between the different patient characteristics, such as BMI, sex, age, previous abdominal surgery, and the activation parameters that were measured in this study. Figure 3A shows the number of activations within a single procedure on the horizontal axis and the mean duration of activations for that procedure on the vertical axis. Combining the surgeons and residents, a correlation coefficient of $r = 0.52$ ($p<.001$) was obtained for these two parameters. Figure 3B shows a rise in the number of activations of both surgeons and residents when the procedure duration increases ($r = 0.66$, $p<.001$). Figure 3C shows that residents tend to use the same activation time regardless of the duration of the procedure ($r = -0.33$, $p = .002$).

Comparing the activation parameters averaged across the groups of surgeons and residents, differences between approaches in handling the device are observed. Surgeons have a mean number of activations of 102 times per procedure (median 87, IQR 60.8), while residents tend to use the device more often with 123 times per procedure (median 111.5, IQR 56). This difference is not statistically significant however. The Student's t-test ($t = -4.2$, $p<.001$, $df = 89$) does however show that the mean activation time of surgeons (median 2.44 s, IQR 1.9) is significantly higher than the residents (median 1.30 s, IQR 0.8), see Figure 4.

DISCUSSION

This article presents a way to gain insight into the application of electrosurgery during a surgical procedure. In this study, we obtained detailed measurements on the use of electrosurgery in laparoscopic cholecystectomies to examine potential differences in handling techniques between operators and whether experience plays a major role in the way electrosurgery is applied. Our main findings show that different approaches in application technique can be distinguished among different operators; typically, a higher amount of activations goes along with a short activation time and vice versa. Furthermore, differences between surgeons and residents in the number of activations and the activation time of the electrosurgical device were found. All residents use a higher number of activations with a shorter activation time, while various surgeons seem to choose for the opposite approach.

Recent guidelines regarding the application of electrosurgery describe that operators should take the following parameters into account to enhance safety: the lowest power setting possible, a low-voltage waveform (cut), and brief intermittent activations.[5,18] When considering the behavior of the residents in terms of these guidelines we see clear commonalities. One could suggest that residents adhere to the guidelines better than surgeons do. However, many other factors are involved in the art of electrosurgery, such as operation speed of the surgeon and the instrument's contact area with the tissue. The final goal of electrosurgery is to develop a specific tissue effect using the appropriate instrument and wattage, furthermore causing minimal damage to the surrounding tissue.[19]

The skilled surgeon is aware of the various factors influencing the desired outcome. Thus, he or she combines basic knowledge of electrical biophysics and surgical skills to a preferred approach of the tissue. Yet it remains to be determined whether differences in the approach result in differences in clinical outcome.

It is not clear how different approaches develop in the first place. Different operators might have created their own application technique while becoming more experienced. Another interpretation of our results is that some operators are simply more careful in using energy-based devices.

Furthermore, local habits of supervising surgeons are often copied by residents without further explanation.[16] This behavior could be the result of hierarchy issues, since the same supervising surgeons are responsible for the assessments. In any case, this study shows that clear differences in use of the electrosurgical device among operators exist.

Possibly the apparent lack of knowledge about the theoretical background is a factor in the development of different application methods among surgeons and residents. An initiative from SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) called the Fundamental Use of Surgical Energy (FUSE) program is introduced to improve knowledge among surgeons and residents about this subject.[6,14] Also other studies about knowledge-based programs show positive results.[20] However, none of the currently offered teaching programs deal with all practical aspects of safe application of electrosurgery.

In the current study, we took the first steps in obtaining data on the application of electrosurgery from a large number of procedures to eventually define the objectives for an outcome-based training program. Outcome-based education is an educational method that centers each part of an educational system on goals (outcomes). An example is the constructive alignment theory by Biggs.[21] According to this theory, the objectives, learning activities, and assessments should be in line for effective teaching and learning. For example, if students need to learn how to present, they should be given the opportunity to practice giving presentations, not only reading a book about it. If this theory is applied to the training in electrosurgery, residents in surgery should not only have theoretical education but also be offered practical skills training and assessments. In this respect, without clear knowledge of the objectives, an effective training program cannot be developed according to Biggs theory. Our approach makes it possible to gain detailed insight into the use of electrosurgery devices by surgeons of different levels of expertise.

With the availability of objective measurement techniques, we can take the next step in developing a more solid training program for surgical residents. We propose including a hands-on component in the training curriculum for electrosurgery. This could include a session in which the application technique of the resident is monitored in real-time and in which the effects of application of different settings are made explicit. This could be embedded in basic laparoscopic courses.

We conclude that differences are seen in the application of electrosurgical devices between experienced surgeons and surgical residents in terms of the number of activations and the activation times during a procedure. Detailed application measurements can offer the opportunity to relate technical approaches to clinical outcome and to provide input for the development of a best practice model.

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CHAPTER 3

ELECTROSURGERY: SHORT-CIRCUIT BETWEEN EDUCATION AND PRACTICE


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ABSTRACT

Introduction: *Electrosurgery is used in 80% of surgical procedures. The technique allows surgeons to skilfully dissect tissues and achieve haemostasis. Since improper use of electrosurgery can lead to serious adverse events, training is required to potentially reduce the number and severity of these events. In this study we evaluate education and training in electrosurgery for surgical residents.*

Material and methods: *Residents from six surgical subspecialties in the Netherlands were invited to anonymously complete a digital questionnaire about training, supervision and adverse events regarding electrosurgery.*

Results: *Of the 197 respondents, 69% had received some form of training; mostly a single theoretical lecture. The feeling of competence in theory and practical skills was positively rated by 39% and 71%, respectively. Moreover, 35% judged the theoretical knowledge of their supervisors as insufficient and 65% changed their electrosurgical application technique to the preference of the supervisor. 30% of the residents had encountered a serious adverse event (e.g., burn wounds) related to the application of electrosurgery.*

Conclusions: *The training of residents in theoretical aspects of electrosurgery is limited. Residents are not satisfied with the acquired theoretical knowledge of themselves and of their supervisors. Since adverse events related to electrosurgery occur frequently, more extensive education for both residents and their supervisors is needed to enhance patient safety.*

INTRODUCTION

Electrosurgery is used in over 80% of procedures across surgical specialities. The technique allows surgeons to skilfully dissect tissue and achieve rapid haemostasis. Especially in minimally invasive procedures, electrosurgery offers precise haemostatic control during complicated surgeries on structures that are highly vascular in nature. However, difficulties in predicting the effects of combinations of the magnitude of electrical current, heat generation, numerous patient factors, and the interactions with other surgical tools can lead to severe complications.

Complications from electrosurgical devices come in reproducible patterns, such as faulty direct application and insulation failure.[1] A direct application injury can result in spreading thermal heat beyond the tissue that the surgeon intended to treat. Hence vulnerable tissue, like the bowel, can be harmed and this could seriously influence a patient's outcome. Insulation failure is a defect in the insulating material that covers the instrument. Such defects occur in 13%-39% of laparoscopic instruments.[1] Generally, the incidence of complications due to unintended surgical energy is 1-2 per 1000 procedures.[2] This is comparable to other high-profile surgical safety issues, such as retained surgical foreign bodies that has an incidence of 0.7-1 per 1000 abdominal surgeries.[3] Since it is easy to misdiagnose surgical burns or thermal injuries, the prevalence of complications is likely to be under-reported by the surgical community.[4] To use electrosurgical devices to its fullest potential, it is necessary for the clinicians to have a thorough understanding of the working principles, the potential risks, and the appropriate settings for each procedure and each type of device. However, studies have shown that among clinicians this knowledge is insufficient. [5-11]

The problem of insufficient training on operating room technologies is also ranked fifth on the list of 2016 Top 10 Health Technology Hazards, published by the Emergency Care Research Institute (ERCI) institute. [12] The Institute estimates that approximately 70% of accidents involving a medical device can be attributed to user error or the technique of use. Many of these incidents could have been avoided if the user had a better understanding of the instructions and operation principle of the device. However, currently there is no official training curriculum about electrosurgery available for surgeons, nurses, and other operating staff.[5] Although some excellent resources are available, such as the recommendations from the Association of periOperative Registered Nurses (AORN) on the safe use of electrosurgery, these do not address the full range of devices and have no assessment component.[13] Brill et al. suggested that medical societies should set standards of practice for laparoscopic monopolar electrosurgery.[4] Feldman et al. made an initial analysis of the demands and wishes for training, as well as of the present status of physician's knowledge regarding surgical energy.[14] Together with the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), Feldman developed the Fundamental Use of Surgical Energy (FUSE) program, [15-17] which is an online educational teaching module complemented with an exam.

Limited training opportunities for physicians are not only recognized in the field of electrosurgery, but are applicable on a large scale. Recently, the Dutch Healthcare Inspectorate (DHI) published its concerns on the rapid increase of medical technology in hospitals and related risk for patient safety.[18] According to this report, training of personnel is generally unstructured and uniformity across the country is lacking. Moreover, no high-quality structured assessment system that guarantees qualified and competent staff is available. In response to these findings, the DHI demanded a discipline-exceeding approach to these problems.[19] This included a demand for structured training programs for high-risk medical technology and its implementation into specialist training programs. However, three years later, a subsequent report revealed that the proposed measures to ensure the safe use of medical technology were not fully executed yet.[20]

The relatively slow implementation of improvements may be due to the lack of insight in how electrosurgical training is currently organised, and what the exact needs are to achieve better outcomes. In this paper, we investigate how theoretical and practical training of electrosurgery is balanced during the residency of surgical residents. We question how residents judge their own competences and of their supervisors. We further study how often they encounter incidents or near misses due to a lack of competences during the use of electrosurgery. We did so by conducting a digital survey among surgical residents.

MATERIALS AND METHODS

Participants

All Dutch residents from six surgical subspecialties (general surgery, gynaecology, urology, thoracic surgery, plastic surgery and orthopaedic surgery) were invited to fill out anonymously a digital questionnaire about electrosurgery during August - December 2015. They were approached by the affiliated resident associations through e-mail or newsletter.

Questionnaire

The survey was developed in Collector (Version 6.7, Zurich, Austria) and contained 31 questions, both open-end and close-end. The first questions were of general content and informed about the respondent's background. Then the current situation of education in electrosurgery was investigated by ten questions about the character, frequency, practical and theoretical aspects of the training. Subsequently, through a five-point Likert scale (1: strongly disagree, 5: strongly agree), the respondents could evaluate on statements about electrosurgical competences of themselves and their use in the OR. [21] In addition, the residents were asked to share any incidents concerning electrosurgery, and the way it was dealt with by the attending personnel. The final part covered the competences of the supervisors and other OR staff, and the general importance of electrosurgery. In Textbox 1 a summary of the survey questions can be found.

For seven questions, a category 'other' was used in addition to the given answers. For example, the question "Which training did you receive?" was accompanied with the answers "CASH 1.1", "basis laparoscopic course (BLC)", "training by industrial representatives", "training by hospital/ department" or "other; please describe below." CASH 1.1 is an annually three-day course for surgical residents, organized by the Dutch Society of Surgery. This course covers a range of subjects, like basic techniques, wound treatment, infections, trauma, and also electrosurgery.

Textbox 1: A summary of the survey questions.

Questions

General

Sex, age, function, specialty, year of residency, experience.

Training

Did you receive any training in electrosurgery?

If yes; please indicate for each training:

- What kind of training?
- What type?
- Frequency
- Obligatory

For practical training: indicate the material you worked with.

For theoretical training: indicate the elements and risks that are covered.

How did you gather the most practical knowledge?

How did you gather the most theoretical knowledge?

If you did not receive any training; please describe if you have missed this.

Competences

Indicate your extent of agreement, from 0 (I strongly disagree) to 5 (I strongly agree) with the following statements:

- I feel competent in the theory about electrosurgery
- I feel competent in the practical skills of electrosurgery
- The theory of electrosurgery is easy to learn
- The use of electrosurgery is easy to learn

With the knowledge you possess now, would you know which setting to use for which procedure?

In what extent are you allowed to work without supervision?

Practical use

Which form of electrosurgery is used in the OR you work at?

In how many per cent of procedures is monopolar or bipolar electrosurgery used?

Indicate your extent of agreement, from 0 (I strongly disagree) to 5 (I strongly agree) with the following statements:

- The use of electrosurgery varies per surgeon
- My personal use of electrosurgery is influenced by the supervisors
- My personal use of electrosurgery is influenced by the supervisor of the day
- My personal use of electrosurgery will change when I'm a specialist

Incidents

Did you ever experience an adverse event regarding electrosurgery?

If yes, please explain:

- In how many per cent of procedures in the Netherlands does this type of incident happen?
- Which measures did the personnel take after the event?

Importance of electrosurgery

Indicate your rating of the following competences, from bad - excellent:

- The theoretical knowledge of surgeons
- The practical skills of surgeons
- The theoretical knowledge of OR assistants
- The practical skills of OR assistants

Indicate the level of importance, from 0 (not at all important) to 5 (very important) for the following aspects:

- Enough theoretical knowledge about electrosurgery
- The right way of using electrosurgery
- General interest of electrosurgery in the OR

RESULTS

General

Approximately 1.540 residents of the six surgical specialties were approached. A total of 217 responses was collected and 197 respondents completely filled out the survey, a response rate of 13%. In Table 1 a summary of the data is shown.

Training program

Of the 197 respondents, 69% had received training. The most frequent attended training program was the BLC course (89%) followed by the CASH 1.1 course (42%), and training given by industrial representatives (35%).

Respondents stated that their theoretical knowledge was mostly gained through educational programs (74%). Practical skills were primarily gained during supervised surgical procedures (76%). The questionnaire provided space for additional remarks about the training they had experienced so far. A total of 49 respondents expressed their concerns about the low frequency and the content of the training. The vast majority (60%) of residents who did not receive training, experience this as a shortcoming in their education.

Competences

In response to the item, "I feel competent about the theory", 39% of residents agreed. The rate of agreement for the item "I feel competent about my practical skills" was higher with 71%. The relationship between the competency and the experience of the residents is depicted in figure 1 and 2. In daily practice, 67% of the residents is allowed to perform surgery, thus using electrosurgical devices without supervision. When evaluating their supervisors, 75% of respondents claim that the use of electrosurgery differs per supervisor, and 72% states that their own handling is influenced by the preference of the supervisor. For 64% of respondents their use of electrosurgery even differs per day. More than one-third of residents (36%) is not satisfied with the theoretical knowledge of their supervisors. At the same time, 68% of respondents is content about the practical skills of supervisors.

Table 1. A summary of the characteristics of the respondents.

Characteristics		
Sex		
Female	123	
Male	74	
Subspecialty	Respondents (approached)	Response rate
General surgery	36 (400)	9%
Gynaecology	90 (350)	26%
Urology	34 (134)	25%
Thoracic surgery	7 (28)	25%
Plastic surgery	22 (111)	20%
Orthopaedic surgery	8 (413	2%
Experience (no. of procedures)	No. (% of total)	
0-50	33 (17%)	
50-100	36 (18%)	
100-200	40 (20%)	
200-400	52 (26%)	
400-600	14 (7%)	
>600	22 (11%)	
Median months of residency (IQR)		
35 (32)		

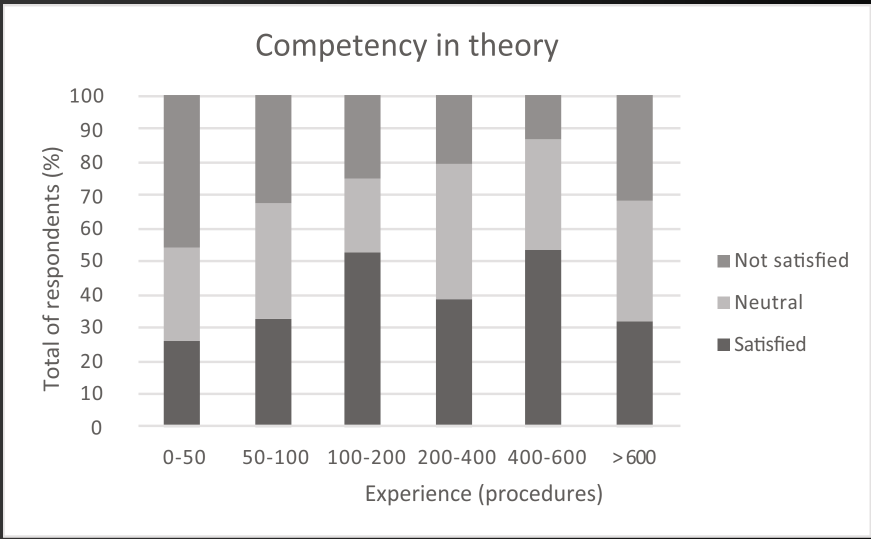

Figure 1. Feeling of competence in theory among residents of different experience.

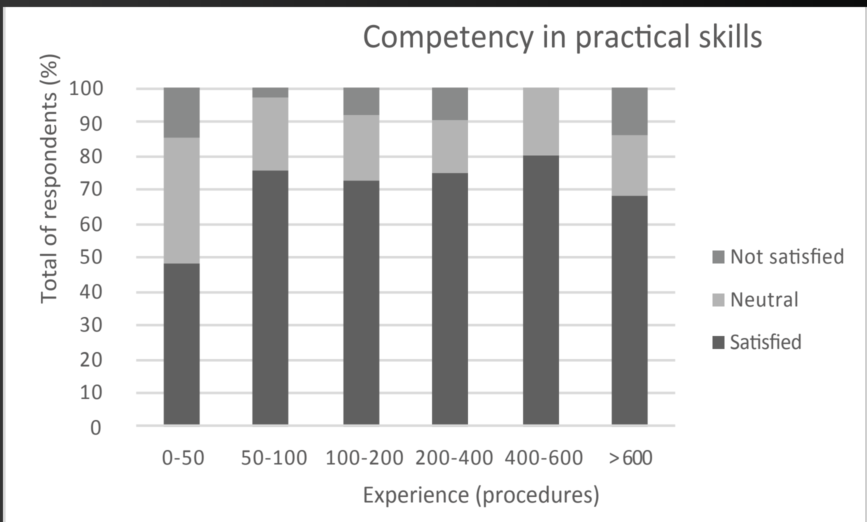

Figure 2. Feeling of competence in practical skills among residents of different experience.

Incidents

Respondents were asked about their experiences with any incidents or complications regarding electrosurgery. A total of 53 respondents (27%) encountered such an incident. From the 59 events reported, 31 were described as superficial burn wounds and 12 as lesions in intestines, vagina, or liver. Due to one of the two technical defects described, the procedure had to be cancelled. In 40 of 59 incidents the patient was harmed. And in 50% of these cases, no post-operative explanation was given to the patient. More detailed information about the incidents is shown in Table 2.

Table 2. Details of the incidents described by the residents.

Type	Frequency	Location	Cause	Harmed one
Burn wound	31x	Skin superficial	Direct contact (19x) Desinfectants (2x) Unknown (4x) Capacitive coupling (3x) Stray voltage (2x) Broken wire (1x)	Patient (26) Surgeon (5)
Lesion	6x 5x 1x	Intestines Vagina Liver	Unknown (3x) Direct (2x) Capacitive coupling (1x) Capacitive coupling Capacitive coupling	Patient
Shock	11x 1x	Hand Leg	Dielectric breakdown Dielectric breakdown	Surgeon
Technical defect	2x	N/A	Wrong settings	Patient
Fistula	1x	Skin	Direct contact	Patient
Needlestick injury	1x	Unknown	Unknown	Surgeon

DISCUSSION

In this study, the current status of training in electrosurgery was investigated through a digital questionnaire among surgical residents. The survey also investigated the level of satisfaction in the acquired theoretical knowledge and practical skills during the residency. Moreover, opinions were asked about the use and knowledge of electrosurgery of their surgical supervisors. In addition, we asked for any encountered incidents or near misses regarding electrosurgical devices.

Since a national training curriculum does not exist, not everybody had received some form of training in surgical energy use. Mostly offered was either a single, obligatory, theoretical lecture during the CASH 1.1 course, or a more practical training during the basic laparoscopic course. Both are offered only once during the residency. Respondents complained about the low frequency of training and requested more repetition of the theory. Also, more detailed explanation of the devices' settings was requested.

Concerning the acquired theoretical knowledge and practical skills; residents do not feel fully competent. However, almost 70% of respondents is allowed to perform surgery and also use surgical energy without supervision. When it comes to the competences of the supervisors, one-third of respondents qualifies the theoretical knowledge of their supervisors as poor or bad. Nevertheless, they are more satisfied with the practical skills of their superiors. Residents agree with the statement that the use of electrosurgery differs per surgeon. This could explain that the way of using electrosurgery is altered per day according to the supervisor they work with.

A wide range of incidents was reported. The majority of incidents was labelled as burn wounds, either inflicted on the patient or the surgeon. But also very severe bowel perforations were described, some resulting in long hospital stays and re-operations. In the cases described as 'light', no action was taken after the incident happened. In the case of serious incidents, an explanation was given to the patient, and OR personnel discussed the case together. However, an extra training or change in application of electrosurgery was rarely seen.

The respondents' opinion about the low theoretical knowledge of their supervisors is remarkable, and of great importance when setting up a training curriculum. Transmission of knowledge and skills is essential in surgical training. In the medical field, this traditionally takes place according to the apprenticeship model (learning on the job). This means that the resident initially performs small steps of an operation under continuous supervision and is gradually allowed to expand this as the intensity of supervision decreases.[22] Over the course of years, surgical training has evolved and more training programmes have been added. However, this has not been the case for electrosurgery. As long as residents question the capabilities of their supervisors, they will not get the education they need. Moreover, because of the hierarchy present in ORs, it is not likely that the safety of surgical approaches are openly discussed.[23] This suggests that active participation of supervisors and experienced surgeons training programmes may be a prerequisite for success.

The results of this survey are in line with the studies from Feldman[14] and Modaffari.[7] They found that only a small percentage of specialists consider themselves experts in the field of electrosurgery. Other studies analysed the level of knowledge in surgical residents or specialists by tests and determined that clinicians are not sufficiently trained in electrosurgery.[6,7,11,15] It is often suggested that more hands-on training is necessary, while this survey shows that respondents would rather have more frequent theoretical sessions. Moreover, this study adds the opinion of residents about their supervisors and the way the hierarchical situation in the OR influences their daily work.

In our opinion, a reorganisation of the current training curriculum is necessary. At this point, residents do not learn enough about electrosurgery and, more important, do not feel competent. This feeling of incompetence could result from an incomplete training program. Furthermore, it is worrisome that those who do not feel competent enough are allowed to operate without supervision. This is a potential dangerous situation for both patient and personnel. The need to monitor the competency of employees has also been recognized by the Dutch Healthcare Inspectorate. [19,20] They encourage hospitals to incorporate a qualified & competent system for employees. This system should include training modules and assessments to secure that personnel retain their skills and knowledge. Through up-to-date in-service training they can also improve these competences. When looking at the results of this survey, we can suggest the following for electrosurgery; a frequent obligated training programme is needed in which the theory is fully covered, and practical use of settings is explained. E-learning modules for residents are currently under consideration by the Dutch Surgical society, but much more is needed to ensure proper education, and to guarantee safe use of electrosurgery.

Another interesting observation is the statement that residents adjust the approach to the preferences of the daily supervisors. Most supervisors often have a personal working style and may request the resident to follow. Although these professionals have years of experience, their training in medical devices might be out dated. In that sense, the residents may even have more up-to-date knowledge about the proper use of the devices. This also argues for recurrent obligated training programs for supervisors. This is emphasized by the noteworthy number of incidents reported by the residents that may be inflicted by themselves, as well as the supervisor.

One limitation of this study is that only residents from the Netherlands were addressed. Also, the response rate of the different specialties was unbalanced. However, we believe that the way the training programs are offered and organised does not differ extensively from one discipline to the other, and that this is representable for most West-European countries.

In conclusion, surgical residents are not satisfied with their acquired competences in theory and practical skills regarding electrosurgery. They are also not satisfied with the theoretical knowledge of their supervisors. Since complications regarding surgical energy frequently occur, more training for both groups is needed to ensure patient safety.

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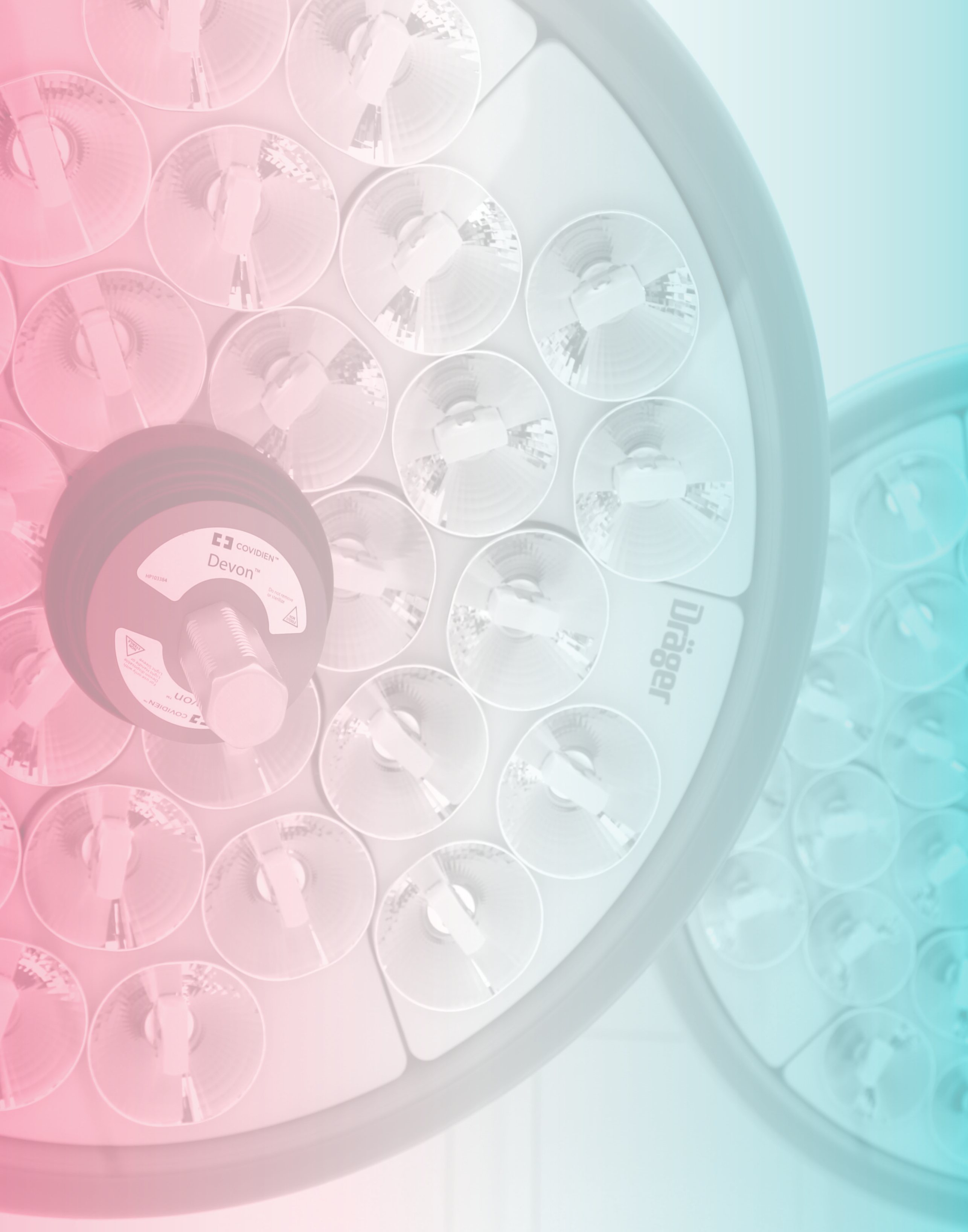
CHAPTER 4

TASK-ADAPTED BEHAVIOUR IN MONOPOLAR ELECTROSURGERY APPLICATION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ABSTRACT

Background
Electrosurgery is a source of hazardous situations. The theoretical knowledge and motor skills are most important in handling this device. Prolonged application of energy on the tissue at a slow pace results in more thermal damage than quick and intermittent application does. In this observational study, we specifically study whether the surgeon's choices in settings, electrodes and application technique are consistent with the actual task demands.

Methods
The electrosurgical device activation was recorded in 64 breast surgery procedures with different precision demands: lumpectomies (n=23), mastectomies (n=16), sentinel node dissections (n=20), the removal of fibroadenomas (n=4) and one nipple-sparing mastectomy. Nine different surgeons performed surgery on 41 women. Electrosurgery settings, activation time and the weight of the removed breast material were also recorded.

Results
A total of 80 measurements was made, of which 57 were covered by expert surgeons. The mean activation times of residents and experts were the same (2.4s±2.1 s and 2.4±2.1 s). Activation times were longer for mastectomies (3.3±2.6 s) than for the lumpectomy (2.0±1.9 s), the sentinel node dissection (2.0±1.8 s), or the removal of fibroadenomas (2.5±2.0 s). Electrosurgery settings were mostly based on the surgeons' personal preference.

Conclusion
This study demonstrates task-adjusted behaviour of electrosurgery use in various breast surgery procedures. Surgeons show a prolonged activation time when performing continuous cutting tasks, such as a mastectomy procedure, as oppose to precise dissection tasks, like the lumpectomy. No uniformity in surgical settings was seen among surgeons. This information is valuable for professional clinical electrosurgical education.

INTRODUCTION

Electrosurgery is commonly used in modern-day surgery. The term refers to the passage of alternating electrical current through tissue in order to achieve a specific surgical effect. With its numerous combinations of settings and types of electrodes, a wide range of tissue effects is possible. The device can also be a source of hazardous situations. Recently, the Emergency Care Research Institute (ECRI) listed the electrosurgical device in their healthcare technology hazards top 10.[1] They suggest to take special precautions for unholstered electrosurgical active-electrode pencils on or near the patient, as this can potentially lead to burns or fires. Also, insulation failure and direct coupling are known hazards in the laparoscopic setting. The latter refers to an accidentally activated electrode, while in close proximity to another metal instrument. Current from the active electrode flows to the adjacent instrument through the path of least resistance, and can potentially damage adjacent structures or organs not directly visible within the visual field of the surgeon.[2]

With the possibility of such complications, it is of utmost importance that clinicians receive adequate training to understand the underlying working mechanisms of electrosurgery.[3] Only with thorough knowledge and appropriate training can safe application be guaranteed. In general, the following basic rules are described: Use the lowest possible power setting, use a low-voltage waveform(cut), and use brief intermittent activation as opposed to prolonged activation.[2,4] However, several international studies have found a lack of basic knowledge in principles of electrosurgery and equipment among clinicians.[4-7] A recent study inquired about the educational system regarding electrosurgery for surgical residents.[8] Results show that respondents currently receive a poorly organized training program and complain about the lack of theoretical information they receive. Moreover, residents confess that they are not satisfied with the theoretical knowledge of their supervisors, however they are still prone to follow the practical behaviour of their supervisors.

So what exactly are the possibilities regarding monopolar electrosurgery? The final tissue effect is determined by many variables, such as the amount of current generated by the device, by the type of electrode, the speed of the electrode, and the active contact time between electrode and tissue.

[9-11] Basically, two modes can be found on every modern electrosurgical device. These include the cutting mode (low-voltage continuous waveform) and the coagulation mode (high-voltage intermittent waveform). Various other settings are offered to alter these outputs and their names (like 'desiccation' and 'spray') can often be found interchanged between manufacturers.[9,12-13] In the cutting mode, application is done by lightly touching the tissue and no sparkling should be visible.[11] In the contact coagulation mode: touch the surface and blanching of the tissue will be seen. In the fulgurating mode, the electrode is held above the confined area to apply the energy. This is useful to treat a larger area. Sparks are visible because the air between the electrode and the tissue is resistant to the passage of the current.[11] Also, different types of electrodes are available, varying in thickness, from fine-tip needles to blades or ball, as different modes demand for different tools. For instance, for clean cutting with little hemostasis, it is advised to use a fine-tip electrode in the continuous cutting mode, using the lowest possible power setting.[14]

Apart from the settings and type of electrodes used, the motor, cognitive, and decision-making skills of the surgeon are also important factors for success. In particular, it is of utmost importance how the surgeon applies the technique. The time the activated electrode is in contact with the tissue is directly related to the amount of energy that is released to the tissue.[11] Prolonged application of energy on the tissue may result in thermal damage to surrounding structures.[14] It is therefore advised to use short intermittent activations to allow the tissue to cool before the next pulse.[10] However, a previous study showed that the application patterns of electrosurgery may differ among surgeons.[15] Considering the various factors involved, these differences may arise from the complex interplay between settings, choice of electrode, experience, and the task at hand. Presumably, tasks having different demands (e.g. cutting vs coagulation) will require adjustments of the settings of the electrosurgical device, the electrodes used, and the applied activation technique. Still, it is by no means clear what the combined effect is of the many possible variations in these parameters, and whether the surgeons' choices are made in a systematic manner.

This study presents an investigation in the electrosurgical approach surgeons use to handle different surgical tasks. In a variety of different breast surgery procedures, the (nipple sparing) mastectomy, the lumpectomy, the sentinel node procedure, and the removal of a fibroadenoma, we monitor the settings and electrodes used, as well as what activation pattern is applied. We specifically study whether the surgeon choices in settings, electrodes and application technique are consistent with the actual task demands.

MATERIALS AND METHODS

A custom-made current sensor was used to record the magnitude of electric current delivered to an electrosurgical device (Valleylab, Force FX or Valleylab Force triad).[16] It was placed between the power plug of the device and socket, while recording at a frequency of 8 Hz. The sensor did not interfere with the performance of the electrosurgical device or the workflow of the procedure. The recorded data was stored on a SD card for post-operative data analysis. All procedures were observed by one of the authors and the following parameters were noted: electrosurgery settings, choice of electrode, start and end time of procedure and the weight of the removed breast material. As the residents often performed only part of the procedure we noted when the surgeons switched their role.

Data analysis

The used sensor, measuring the electric current supplied to the electrosurgical device, enables accurate detection of device activation.

Analysis was done with use of MATLAB (version R2014b, MathWorks, Natick, Massachusetts, U.S.A). For each (part of a) procedure performed by an individual surgeon we determined the mean duration of the intermittent activations of the electrosurgical device. Hence, a procedure completed by a single surgeon resulted in one measurement of the mean activation duration. In case one surgeon started the procedure and another finished the remaining part we obtained one measurement for each of them. Finally, when they switched roles multiple times, we obtained multiple measurements for each of them for the same procedure in the same patient. In this study, we mainly focus on the various parameters that might influence the surgeon's use of electrosurgery.

Table 1. Characteristics of the recorded procedures. Note that NS mastectomy denotes nipple-sparing mastectomy.

	Mastectomy (n=16)	Lumpectomy (n=23)	Sentinel Node (n=20)	Fibroadenoma (n=4)	NS mastectomy (n=1)	Total (n=64)
Total patients	13	23	20	4	1	41
Mean surgical time (min) [range]	59 [30-179]	33 [18-46]	20 [8-35]	28 [16-46]	69	41,8
Mean activation time (s) [range]						
Total	3,3 [0.8 - 6.4]	2,0 [0.6 - 3.8]	2,0 [0.7 - 3.0]	2,5 [1.4 - 3.1]	0,9	2,4
Experts	3,2 [1.2 - 5.5]	2,1 [0.6 - 3.8]	2,0 [0.7 - 3.0]	-	0,9	2,4
Residents	3,4 [0.8 - 6.4]	1,9 [1.0 - 2.9]	1,9 [1.3 - 2.6]	2,5 [1.4 - 3.1]	-	2,4
Mean BMI patient (kg/m^2) [range]	23 [19-30]	26 [20-33]	26 [20-33]	21 [19-25]	21	23,4
Mean age patient (y) [range]	53 [36-67]	63 [40-87]	61 [43-87]	23 [17-27]	54	50,8
Mean weight breast tissue (g) [range]	522 [180-1033]	36 [10-65]	-	-	120	226
Total measurements						
Total	23	32	20	4	1	80
Experts (n=3)	17	25	14	0	1	57
E1	7	5	4	0	0	16
E2	5	17	8	0	1	31
E3	5	3	2	0	0	10
Residents (n=6)	6	7	6	4	0	23
R1	1	1	2	1	0	5
R2	0	5	2	0	0	7
R3	2	0	0	1	0	3
R4	1	0	1	0	0	2
R5	2	0	0	1	0	3
R6	0	1	1	1	0	3

RESULTS

Recorded clinical procedures

In this study 64 breast surgery procedures were analysed: lumpectomies (n=23), mastectomies (n=16), sentinel node dissections (n=20), the removal of fibroadenomas (n=4) and one nipple-sparing mastectomy. Surgery was performed on 41 women, with an average age of 56 years (range 17-87 years) and an average BMI of 25 (range 19-33). Three patients were subjected to a double mastectomy. Of the remaining 10 patients receiving a mastectomy, three were combined with a sentinel node dissection. Of the 23 patients undergoing a lumpectomy, 17 were combined with a sentinel node dissection. The fibroadenomas were removed in four different patients. The procedures were executed by nine different surgeons, of which three experts (>1000 breast surgeries performed) and six residents (100-300 breast surgeries performed). All procedures were recorded in the OR of a Dutch teaching hospital between August and October 2015.

In total 80 measurements were made, of which the experts covered a total of 57. The exact distribution among surgeons and other procedure-related characteristics can be found in Table 1. The average surgical time is the highest for a mastectomy (59 min, range 30-179min) and the lowest for the sentinel node dissection (20 min, range 8-35min). Patients that were subjected to fibroadenoma removal were 23 years on average, while the patients for the other procedures were >50 years on average. The average weight of breast tissue removed was highest after a mastectomy (522g).

Electrosurgery settings

The use and combination of electrosurgical settings was diverse. In Table 2 an overview of all cutting (CUT) and coagulation (COAG) settings and electrodes of the different procedures can be found. Note that the nipple-sparing mastectomy is not included in the table, which was performed with a blade on blend 40/spray 40. All mastectomies and removals of fibroadenomas were performed with the blade electrode. Of the 23 lumpectomies, 7 were performed with a blade, and 16 with a needle. Of the 16 mastectomies, 8 were performed with the settings CUT blend 35/ COAG fulgurate 35. Of the lumpectomies, 16 were performed with COAG

Table 2. An overview of the electrosurgery settings used, during the different procedures. Note that the nipple-sparing mastectomy is not included in this table.

Mastectomy (n=16)			
Electrodes used: all blade			
		COAG	
		Fugurate 35	Spray 40
CUT	Blend 35	8	-
	Blend 40	-	2
	Pure 35	3	-
	Pure 40	-	3

Lumpectomy (n=23)			
Electrodes used: blade (7x) needle (16x)			
		COAG	
		Fugurate 35	Spray 40
CUT	Blend 35	3	-
	Blend 40	-	9
	Pure 35	4	-
	Pure 40	-	7

Sentinel node procedure (n=20)				
Electrodes used: blade (10x) needle (10x)				
		COAG		
		Fugurate 35	Fulgurate 36	Spray 40
CUT	Blend 35	4	-	-
	Blend 40	-	-	7
	Pure 35	4	-	-
	Pure 36	-	1	-
	Pure 40	-	-	4

Fibroadenoma (n=4)			
Electrodes used: all blade			
		COAG	
		Fugurate 30	Fulgurate 35
CUT	Blend 35	-	2
	Pure 30	1	-
	Pure 35	-	1

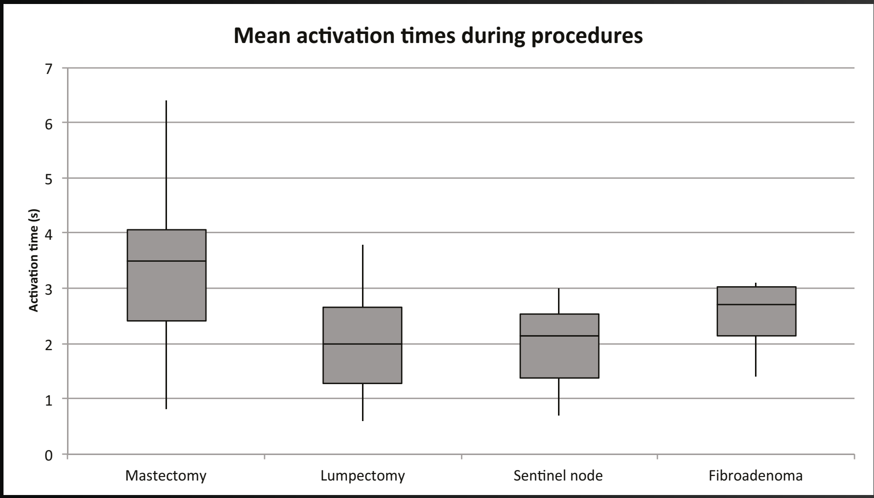

Figure 1. *Boxplot of mean activation times of the electrosurgical device during different breast surgery procedures. The midline in the box denotes the median, the bottom and top of the box are the first and third quartiles and the whiskers indicate the minimum and maximum value.*

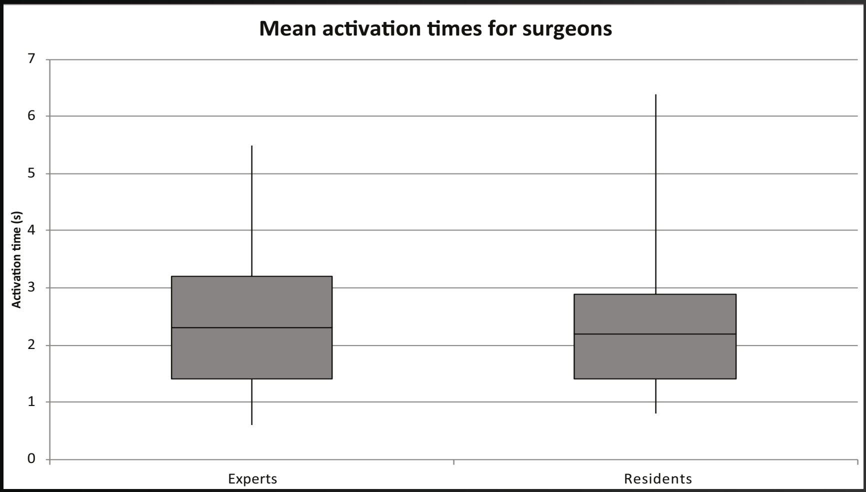

Figure 2. *Boxplot of mean activation times of the electrosurgical device of experts (left) and residents (right). The midline in the box denotes the median, the bottom and top of the box are the first and third quartiles and the whiskers indicate the minimum and maximum value.*

spray 40 (9 of them with CUT blend 40 and 7 with CUT pure 40) and the needle electrode. Of the 20 sentinel node dissections, 7 were performed with CUT blend 40/COAG spray 40. The needle and blade electrode were each used in 10 of these procedures. In 2 of 4 fibroadenomas the chosen setting was CUT blend 35/COAG fulgurate 35. Overall, the height of the CUT and COAG setting was equal in every procedure (e.g. CUT pure 40/ COAG spray 40). The settings of the sentinel node procedures did not differ from the accompanying mastectomy or lumpectomy settings.

Surgeon 1 and 2 used the blade and COAG fulgurate 35 for all procedures, although the CUT setting interchanged between blend 35 and pure 35. Surgeon 3 used COAG spray 40 for all procedures, but changed the electrode according to the procedure, using a blade for the mastectomies and a needle for the lumpectomies.

Activation times

Analysis showed that there were no correlations between the activation parameters measured and the patient characteristics, such as BMI and age. Figure 1 and 2 shows the mean activation times for each type of procedure, and for experts and residents. Activation times were longer for mastectomies (3.3±2.6 s) than for the lumpectomy (2.0±1.9 s), the sentinel node dissection (2.0±1.8 s), or the removal of fibroadenomas (2.5±2.0 s). The nipple-sparing mastectomy noted a mean activation time of 0.9s. In three patients, a mastectomy was combined with a sentinel node dissection performed by the same surgeon. The mean activation time of these mastectomies versus the time for the SN was the following: 3.6s vs. 2.6s, 6.4s vs. 2.5s, and 1.6s vs. 1.7s. The mean activation times of residents and experts were the same (2.4s±2.1 s and 2.4±2.1 s).

DISCUSSION

This study presents an investigation in the application of electrosurgery during four types of breast surgery procedures. Through measurements and observations, we obtained detailed information about the various factors that lead to a surgeon's application technique. We specifically studied the interplay between electrosurgical settings, activation time and, procedure type. Our main findings show differences in activation times between different procedures. The mastectomy is performed with a longer device activation time than the other procedures. Also, differences in electrosurgical settings are observed between different procedures and among surgeons.

Although electrosurgical devices entail many different settings to manipulate the tissue, surgeons do not seem to make full use of these options. In most cases, individual surgeons use the same setting and electrode for both mastectomy and lumpectomy procedures, even though these choices may differ across surgeons. For instance, one surgeon may use the blade electrode and COAG fulgurate 35 for lumpectomies, while one other uses the needle and COAG spray 40 for the same type of procedure. These observations were confirmed by many verbal statements of the participants in which they described their approach in electrosurgery use. This anecdotal information included explanations such as: "I always use blue, because everyone does so in this hospital" or "My preferred electrode is the needle, I have seen it being used during plastic surgery and I like it" or "I always use setting 40 because it feels better". Thus, it seems that the choices made are mostly based on the individual surgeon's preference or training and that these are much less determined by the exact task demands. This finding is in line with a previous study that revealed surgical residents adopt the preferred settings of their supervisor. [8]

Nevertheless, we do see that surgeons adapt their approach to different tasks by changing the activation times of the electrosurgical device. The smaller the surface is, the longer it takes to accurately dissect the tissue. When taking the basic principles into account, this would mean that the surgeon has to use series of short intermittent activations. When a larger surface is treated, a longer activation of the electrode can be used, as long as the electrode moves quickly through the tissue. For example, during a mastectomy, the tissue exposed allows for a more prolonged period of activation because the plane of dissection is more obvious for a more prolonged period of time. For a lumpectomy or sentinel node procedure, more frequent adjustment of the retractors is required because of a smaller working space. In this respect, the nipple-sparing mastectomy is even more demanding. The clinician has to show a very delicate and precise approach to the tissue. Although we have only collected information from one single procedure, the very short activation times of the electrosurgical device (mean 1.0 sec) are indicative for its precise nature. A similar observation is made in those cases where the same surgeon performs a mastectomy with a sentinel node dissection on the same patient. Here, a continuous task and a precision task are performed while all other circumstances (e.g. surgeon, patient parameters) are equal. In two of the three cases the difference in approach is visible (6.4s vs 2.5s and 3.6s vs 2.6s), with one case showing a difference of four seconds between the mastectomy and the sentinel node dissection.

Thus, our results suggest that the task's nature causes surgeons to adapt their activation pattern to the speed of motion of their electrode. Such dependencies can be conceptualized in Fitts's law, that considers the effect of movement speed on accuracy with respect to manual goal-directed tasks.[17] It predicts that the time required to rapidly move in a target area is a function of the ratio between the distance to the target and the width of the target.[17] In short, the smaller and further away the object is, the longer it takes to accurately reach it. Fitts's law applies to many different skilled movements, like grasping and pointing, but also more complex actions, like eating and drawing.[18] Presumably such trade-offs are also present in surgical tasks so that when the precision demands of the task changes, the speed of motion is adjusted in concert with the activation pattern of the electrosurgical device. However, in this study we did not record the actual motions of the instruments, so we cannot ascertain that the movements of the surgeons were truly faster or slower during some tasks.

Our results show that surgeons adapt their application technique to the task at hand to ensure safe treatment of delicate structures and the surrounding tissue. Such necessary adjustments in the approach may be of importance when instructing residents in the early phases of gaining practical experience. In case the task is very demanding, it would be best to use intermittent activation. Once skilled and smooth movements have been developed, it is more effective to use a more prolonged activation to obtain the best results. Also, it is important to make residents acquainted with the variety of different electrosurgery settings and electrodes. Only by experiencing the instrument and its effects themselves, they can decide what their own best practice is. This way they can develop a ‘weapon of choice’, just like their supervisors did.

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CHAPTER 5

SURGICAL PHASE RECOGNITION IN MINIMALLY INVASIVE SURGERY

ABSTRACT

Background
Surgical Process Modelling (SPM) offers the possibility to automatically gain insight in the surgical workflow, with the potential to improve OR logistics and surgical care. Most studies have focussed on phase recognition modelling of the laparoscopic cholecystectomy, because of its standard and frequent execution. To demonstrate the broad applicability of SPM, more diverse and complex procedures need to be studied. The aim of this study is to investigate the accuracy in which we can recognise and extract surgical phases in laparoscopic hysterectomies (LHs) with inherent variability in procedure time. To show the applicability of the approach, the model was used to automatically predict surgical end-times.

Methods
A dataset of 40 video-recorded LHs was manually annotated for instrument use and divided into ten surgical phases. The use of instruments provided the feature input for building a Random Forest surgical phase recognition model that was trained to automatically recognise surgical phases. Tenfold cross-validation was performed to optimise the model for predicting the surgical end-time throughout the procedure.

Results
Average surgery time is 128 ± 27 min. Large variability within specific phases is seen. Overall, the Random Forest model reaches an accuracy of 77% recognising the current phase in the procedure. Six of the phases are predicted accurately over 80% of their duration. When predicting the surgical end-time, on average an error of 16 ± 13 min is reached throughout the procedure.

Conclusions
This study demonstrates an intra-operative approach to recognise surgical phases in 40 laparoscopic hysterectomy cases based on instrument usage data. The model is capable of automatic detection of surgical phases for generation of a solid prediction of the surgical end-time.

INTRODUCTION

The Operating Room (OR) complex is a cost-intensive part of the hospital, as it typically accounts for more than 40% of a hospital's total revenue and a similarly large proportion of its total expenses. Almost 60% of the patients admitted to hospitals receive operative surgical care.[1] Thus, efficient usage of OR capacity is crucial. To ensure sufficient organisational capacity, it is of utmost importance that the OR scheduling is well planned and managed timely.

Optimization of OR scheduling is a complex task, as surgical procedure times are inherently linked to uncertainties. Various factors can alter the surgical time, such as procedure-related problems (unexpected bleeding and other adverse events) and personnel-related issues (e.g. miscommunication). However, also equipment/instrument related issues (malfunctioning or wrong positioned) and environmental related problems (such as disturbances by telephone or radio) are described.[2]

Surgical time duration is determined by a broad range of factors such as patient characteristics, individual surgical skills and occurrence of complication. However, the current methods of OR planning are often based only on either average surgery durations or estimates by the surgical staff.[3] As both average surgery duration and estimates made by the surgical staff provide suboptimal predictive value on the real duration of the surgery, this limited approach on OR planning leads to inconsistencies between planned and actual surgery durations.[4,5] If a procedure takes longer than scheduled, subsequent procedures have to be postponed or cancelled. On the other hand, when operations run short, the operating rooms are unutilized at the end of the day.[2]

One aspect of managing OR logistics is to keep the schedule updated as the day progresses. OR schedulers typically use visual inspection to check the status of a procedure. Still, the progress is not always recognizable and one must be familiar with many procedures. An alternative is making phone calls or actually entering the OR, which is a disturbance of the surgical team. Thus, there are still major improvements to make when it comes to real-time progress monitoring.

Over the years, the interior of ORs have evolved into high-end technological masterpieces. The OR is storing a wealth of useful information through many different sources. This could range from the OR door movements and lights to the details of the anaesthetic device and the use of surgical instruments. Analysis of these data can reveal behavioural patterns, which we call the surgical workflow. With the use of intelligent algorithms, a model can be built to autonomously detect and identify different steps in the surgical procedure.[6] Through recognition of different phases during a procedure, we can also estimate how long the procedure will take and thus optimize our schedule.

Most studies have focussed on phase recognition modelling of the laparoscopic cholecystectomy, because of its standard and frequent execution.[7-10] However, to add more challenge to the phase recognition system and to extend the range of applications, more diverse and complex procedures need to be studied. By this rationale, we choose to analyse the more complex laparoscopic hysterectomy, the minimal invasive removal of the uterus. With over 600,000 hysterectomies performed yearly in the US, it is the second most common gynaecological surgical procedure.[11] Since the 1990s, a shift is seen from the traditional abdominal surgical approach to the laparoscopic or robotic one.[12] We assume this is a very suitable procedure for surgical phase recognition, due to its variability in total duration (between 98-214 minutes).[2] The aim of this study is to find in what extent accurate phase recognition can be beneficial for long and complex procedures. Therefore, we monitor the instrument use and investigate the accuracy reached in a clinically relevant task, like surgical end-time prediction.

MATERIALS AND METHODS

Recording and transformation of surgical data

The dataset used contains 40 cases of laparoscopic hysterectomy (LH), which were recorded between November 2010 and April 2012 in the Bronovo Hospital in The Hague, The Netherlands for the purpose of a study on surgical flow disturbances by Blikkendaal et al. (2017).[2] The procedures were recorded using three cameras and four audio signals using an audio-visual recording system (MPEG Recorder 2.1, Noldus Information Technologies, Wageningen, The Netherlands). More detailed information about the methods used can be found in a previous publication.[13]

The LH surgery was separated into 10 surgical phases and 36 surgical steps based on the method of perioperative analysis of surgeries by Den Boer et al.,[2,13] see Table 1 for a description. The phases do not necessarily occur in a chronological order. The annotated event log was exported to a plain-text file for further analysis and contained start- and endpoints of all observed surgical steps, together with the 12 instruments used in predefined steps. These events represent the features used in building the Surgical Phase Model (SPM). A single entry in the time-based log does not capture all relevant information that could be used to train the model to distinguish phases. Therefore, extra features, such as surgical time, cumulative used time of each instrument, and total number of instruments currently in use, were derived from the indicators of instrument to improve the model performance. These additional data transformation and the model generation was performed using the R programming language (R Foundation for Statistical Computing, Vienna, Austria).[14] and RStudio IDE (RStudio Inc., Boston, U.S.A.).[15]

Surgical phase modelling

For the purpose of this study, a Random Forest (RF) surgical phase recognition model was used.[16]. This is an ensemble model consisting of a collection of decision trees, where each node represents a subset of the data and poses a certain question (e.g., $x < 5$). The answer to this question is used to further split the data set and leads to another question at the following node. Finally, at the so-called leaf node, a categorical or numerical prediction of the outcome variable is obtained. Each decision

Table 1. Intra-operative surgical phases and steps commonly occurring during a laparoscopic hysterectomy procedure. Table copied from Blikkendaal et al. (2017) [2], based on earlier work by Den Boer et al. (2002) [13]

Phase	Step
1. Create CO2 pneumoperitoneum	1.1 First incision and insert Veress or Hasson
	1.2 Insufflate the abdomen
2. Insert access ports	2.1 Insert first (optical) port
	2.2 Insert laparoscope
	2.3 Inspect abdomen (active bleeding, 360 look, operatability)
	2.4 Insert second port under direct sight
	2.5 Inspect and judge operatability/unexpected pathology)
	2.6 Insert third port under direct sight
	2.7 Insert fourth port under direct sight
3. Preparation operative area	3.1 Dissect adhesions to uterus/ovaria/intestine in pelvis
	3.2 Mobilize intestine out of pelvis
4. Expose uterine arteries	4.1 Dissect ligaments and mobilize uterus
	4.2 Skeletonized uterine arteries
	4.3 Push off bladder
	4.4 Identify location of ureters
5. Transect uterine arteries	5.1 Transect left uterine artery
	5.2 Transect right uterine artery
	5.3 Check color of uterus
	5.4 Check if bladder and arteries are skeletonized enough
6. Separate uterus from vagina	6.1 Colpotomy
	6.2 Pneumoperitoneum is lost
7. Specimen retrieval	7.1 Morcellated uterus
	7.2 Extract uterus through vagina
8. Closure of the vaginal cuff	8.1 Insert needle
	8.2 Suture vaginal cuff
	8.3 Extract needle
9. Final check and irrigation	9.1 Check hemostasis
	9.2 Check vaginal cuff stump
10. Close-up patient	10.1 Remove instruments
	10.2 Remove accessory operating ports (under direct sight)
	10.3 Check access wounds/bleeding
	10.4 Release CO2 from abdomen
	10.5 Remove laparoscope and first trocar port
	10.6 Suture port wounds
	10.7 Remove draping

tree is trained on a random subset of the training set and considers a random subset of features at each split. The prediction of each tree counts as a vote for the overall prediction. The modal (in case of classification) or mean (in case of regression) prediction of all trees provides the final prediction of the model.

Model optimization

An important aspect of modelling is out-of-sample validation, which involves the partitioning of the data into test and training sets. The model is generated based on the training data; validation of the model is performed on a set of unseen test data. In the current study, we use k-fold cross-validation, in which the data is split into k folds, which each act as a single out-of-sample test set, while the model is trained on the remaining data.

Another important consideration is the choice of a performance metric for use in the out-of-sample validation. In case of a numerical prediction, a commonly reported metric is the mean absolute error (MAE). Further, at each split in the tree, a random subset of features is evaluated for deciding the best split. The number of features to select at each split is one of the most important parameters in RF. The default value for the number of selected features is $floor(\sqrt{D})$, with D being the number of features of the object.[17] In this paper, model optimization was performed using 10 mutually exclusive folds, each containing 4 surgeries. The number of features considered per split was varied with a grid search of 12-log spaced integers between 1 and 99. During the optimization n = 100 trees were grown for each RF model. The model performance was assessed by the out-of-sample accuracy, defined as the fraction of correct predictions on an unseen set of test data.

Surgical End-Time Prediction

The performance of the RF model is evaluated with respect to a relevant task in clinical practice in the OR: the prediction of surgical end-times. This refers to the number of minutes that the prediction is off compared to the real duration of the surgery. For this, a second model is obtained that uses the phase predictions to estimate the remaining surgical time. The end-time prediction is given by a multiple linear regression model using the elapsed surgical time, the phase, the number of seconds that the surgery has been in that phase and the interaction terms between phase and seconds in phase as independent variables. The mean absolute error

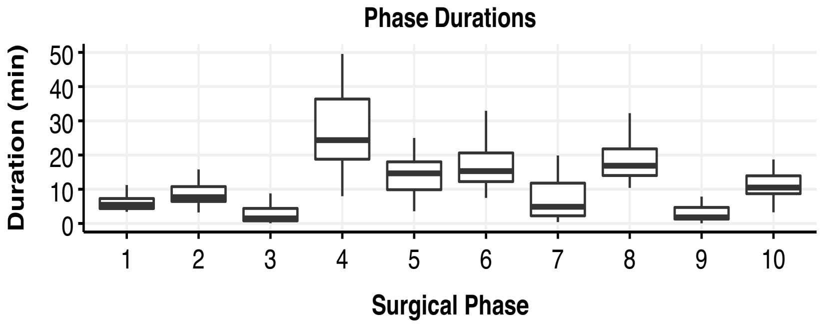

Figure 1. The duration of surgical phases is different per phase, but also varies strongly between procedures. The fourth phase, exposing the uterine arteries, takes the longest time to complete on average (29 min ±13 min SD), whereas the ninth phase - final check and irrigation - has the shortest time span (3 min ±3 min SD).

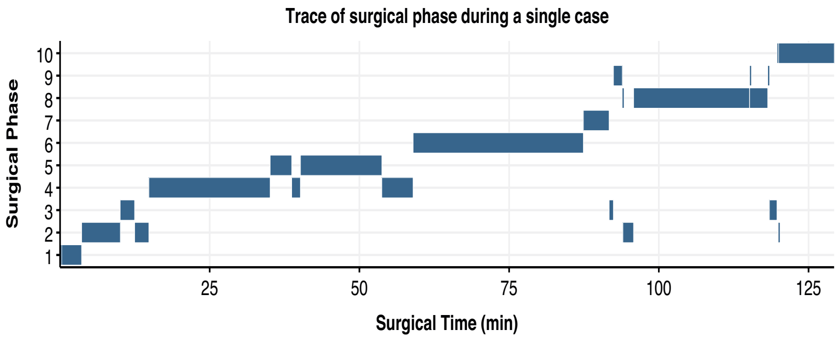

Figure 2. Progression of the surgical phase during a representative laparoscopic hysterectomy case. The shown case has a median case duration (129 minutes) and features 22 phase transitions, which is slightly above the average of 19.

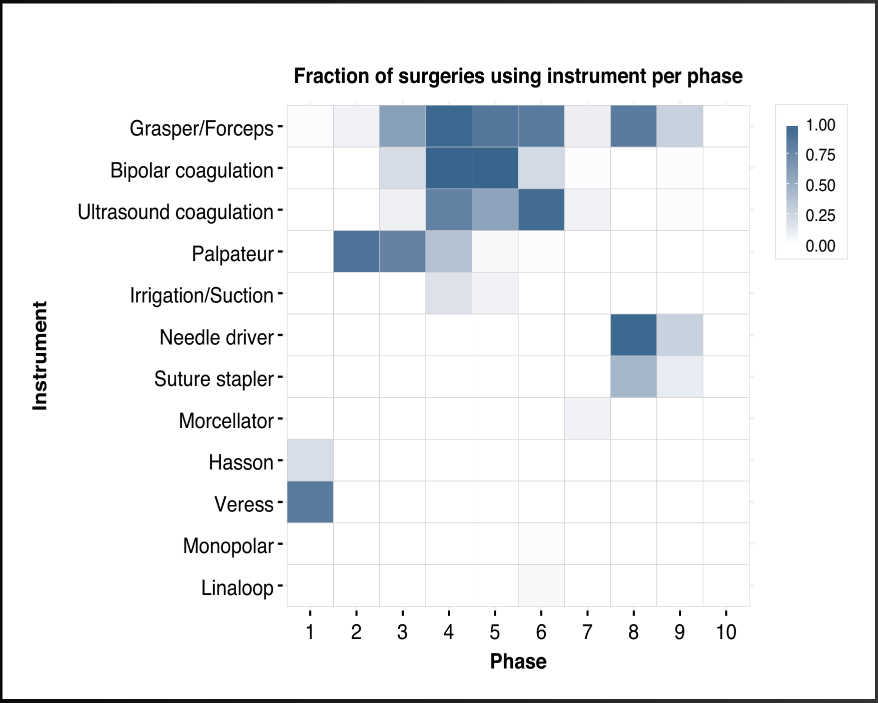

Figure 3. Heat map showing the frequency of instrument use per surgical phase. The fraction indicates the share of procedures during which the instrument or tool was used in the specified phase, with one indicating use in all forty LH cases. Grasper/Forceps are observed in nine out of ten phases, while the morcellator, Hasson cannula, Veress needle, monopolar coagulation and monopolar loop are only used in a single phase.

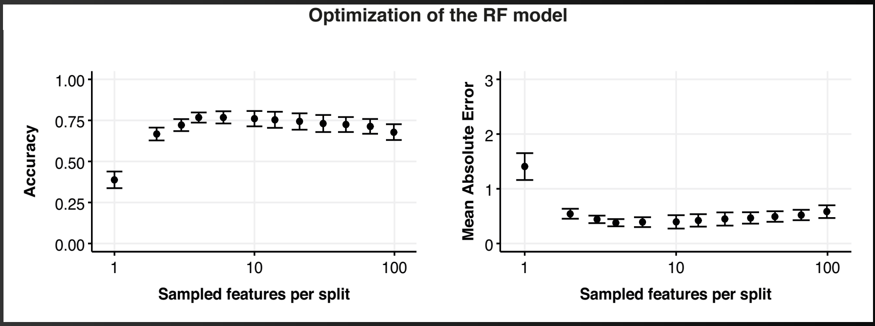

Figure 4. *Optimization of the RF model using 10-fold cross-validation on a grid-search of 12 log-spaced parameters ranging from 1 to 98. Error bars indicate 95% confidence interval of the mean.*

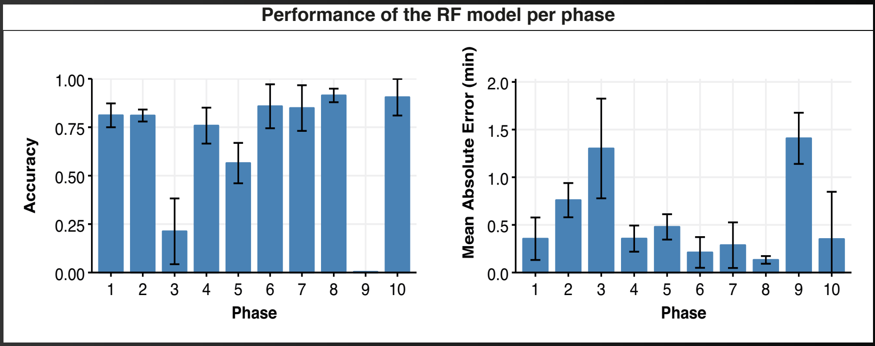

Figure 5. *The performance of the optimized Random Forest model differs visibly per phase, ranging from 91% accuracy in phase 8 to 0.03% in phase 9. The accuracy and mean absolute error measures of model performance are strongly correlated (r=-0.93). Error bars indicate 95% confidence interval of the mean.*

RESULTS

(MAE) in the end-time prediction was also calculated.

Laparoscopic Hysterectomy

The analysed laparoscopic hysterectomies (n=40) had an average surgery time of 128 minutes (±27 minutes SD), with the individual surgical phases also showing a high variance in duration between cases (Figure 1). In 33 of the LH cases, all ten phases occurred. The preparation of the operative area (phase 3) was omitted in seven cases, the closure of the vaginal cuff (phase 8) was not annotated in two cases. Although each surgery started in the first phase and ended in the last phase, phase transitions occurred 19 (±6 SD) times per procedure on average. Most transitions, 70%, were between adjacent states, such as a transition from state one to state two. During all procedures, 68% of the state transitions were towards higher phases. A trace of the surgical phase during a representative case is shown in Figure 2.

Instrument use

The patterns of used instruments and devices differ per surgical phase (Figure 3). With nine different phases, the grasper and forceps are most broadly used throughout the surgery, followed by the bipolar and ultrasound coagulation tools, which were both observed in six distinct surgical phases. Five tools and devices were exclusively used in one phase: the Hasson trocar and Veress needle (phase 1), the monopolar coagulation device and monopolar loop (phase 6) and the morcellator (phase 7). Some tools are observed systematically across different cases: the bipolar coagulation device is used in phase 4 and 5 in all 40 cases, the grasper/forceps in 39 cases during the fourth phase, the needle driver in 37 cases during phase 8 and the ultrasound coagulation device in 38 cases during phase 6.

Model optimization

The RF model was optimized by varying the number of evaluated features per split (Figure 4). The ideal value was found to be 6 randomly sampled features, providing an accuracy of 76.8% (±5.2% S.D.) and a mean absolute error of 0.39 phase (±0.13 phase S.D.).

The overall accuracy of the model was shown to be 76.8%, however the performance differs per phase (Figure 5). Six of the phases are predicted accurately over 80% of their duration; phase 1 (81%), phase 2 (81%), phase 6 (86%), phase 7 (85%), phase 8 (91%), phase 10 (90%). The performance in phase 9 is lowest with an error rate of 99.7%. Again, the MAE is shown to be strongly correlated to the accuracy (r=-0.93), and hence shows a similar performance pattern across the different phases.

Surgical end-time prediction

The model performance was evaluated by application to a clinically relevant task: surgical end-time prediction. The multiple linear regression model predicts the surgical time left as the dependent variable, using surgical time passed, phase, duration within the phase and the cross terms between the phase and duration within the phase. Using ground-truth phases we obtained a mean absolute error of 16.2 minutes (±14.2 minutes S.D.) over all cases. For the regression model based on the RF-predicted phases, a MAE of 15.6 minutes (±12.9 minutes SD) was found. Two hours before the end of the surgery, the end-time is predicted with an MAE= 17.8 minutes (±14.9 minutes SD). This error stays rather constant for 60 minutes (MAE = 16.0 ± 14.0 minutes SD) and 45 minutes (MAE = 17.4 ± 11.7 minutes SD). At 30 minutes before the end of the surgery the error drops to MAE = 12.6±13.2 minutes SD.

DISCUSSION

This study demonstrates an intraoperative approach to recognize surgical phases in 40 laparoscopic hysterectomy cases based on manually annotated instrument usage data, with application to surgical end-time prediction and surgical phase extraction. The accuracy of phase detection is 77%. The performance differs per phase, ranging from 91-0.03%. Large variability in duration is seen between phases. For example, the phase in which the uterine arteries are exposed, takes 29 min ±13 min SD. Evaluation of the end-time prediction task shows an MAE of 15.6 minutes (±12.9 minutes SD), which means that throughout the procedure the end-time can be calculated with an error of roughly 16 minutes.

In this study, we found major differences in the variability of the duration of the various phases. A high variability of a phase has a high influence on the total procedure time. Therefore, when this subset of phases has passed, the procedural time can be calculated most accurately. In this dataset phases 4, 6 and 10 are the most variable and have the most influence on the total surgical time. Detection of these phases is of utmost importance for accurate end time prediction. Phase 9 is short in time and is the least variable. In that sense, the low accuracy of detection is not of clinical relevance.

The current study features ten surgical phases, which is higher than the number of phases observed in previous literature and as such renders the classification task more challenging, which was exactly the goal of this study. Still, the accuracy of 77% is in the range of previous findings on phase recognition using RF models (69-84%).[10,18,19] Further, previous literature predicting end-times, reported an MAE of 10 minutes [20] and 20 minutes,[21] which is in line with our findings. However, a direct comparison is not possible due to the large differences in used data and approaches, as these previous results use either pre-operative data [20] or sensor-based recordings. [21]

A major limitation of this study is the use of manually annotated data of video recordings, which cannot be used for real-time phase recognition. To further implement this technology, real-time sensor data have to be acquired. For example, promising steps have been made with the acquisition of real-time data on instrument use with an RFID-based tracking system.[22-24] Sensor data is often subject to noise, which may affect the accuracy of the model output. However, RF models have shown to be robust against noise. Also, their high computational speed is an advantage when considering use of SPM in real-time.[16]

We conclude that a phase recognition model, based on the Random Forest method, shows promising accuracy to support OR planning and workflow management. Moreover, we show that tracking instruments only is sufficient to generate viable results. This study has paved the way to in-vivo application of intra-operative monitoring of surgical progress.

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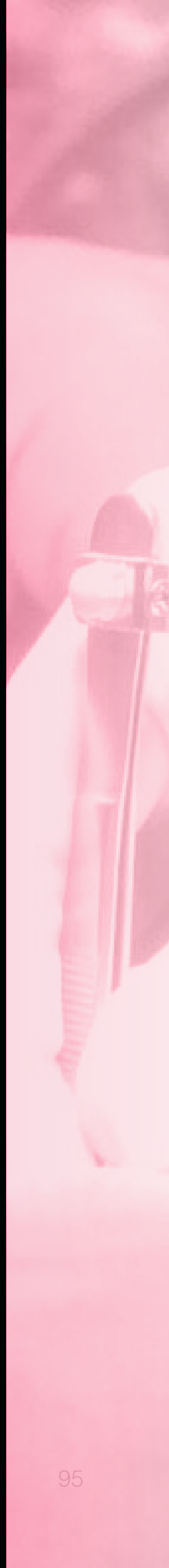
CHAPTER 6

INTRAOPERATIVE MONITORING OF SURGICAL INSTRUMENT USE WITH RADIO FREQUENCY IDENTIFICATION -A PILOT STUDY



ABSTRACT

Background
Tracking medical instruments is key for the improvement of hospital logistics and monitoring the instrument cycle. Real-time detection of instrument use during procedures may further enable surgical phase recognition thereby also supporting logistic improvements and operating room (OR) planning. In this chapter, we present a radio-frequency identification (RFID) sensor-based system to monitor instrument use in real-time.

Methods
Twelve surgical instruments for use in a Total Extraperitoneal Procedure (TEP) were equipped with a RFID tag. The design of the RFID and the attachment was such that it can be incorporated in the entire instrument cycle, including cleaning and sterilisation. Detection of the instruments in the surgical area was evaluated in the OR of a Dutch teaching hospital. We performed ten tests without patients, and one during an TEP procedure intra-operatively. During the procedures, the instrument changes and detection of instruments were recorded. The accuracy in detection was determined by comparison of recorded data with manually annotated instrument use.

Results
All instruments could be detected with the system. In the tests without patients, 86% of instrument changes were correctly identified when within a range of 60 cm of the antenna. However, the average detection rate varies across instruments (Range 100 - 2.5%). In the intraoperative setting, 12.5% of instrument changes were detected and a lower average detection date was recorded (Range 63 – 0%).

Conclusion
We present a system that can detect sterilisable RFID-sensor equipped instruments during procedures. The detection rate during the OR tests was much higher than the measurements during the real-life intraoperative procedure. The positioning of the antenna could play a major role. For real-time detection during procedures, the placement of the antenna has to be optimized to ensure a sufficiently reliable signal for surgical phase recognition.

INTRODUCTION

Almost 60% of the patients admitted to hospitals receive operative surgical care, making the surgical unit the most expensive department of the hospital [1-2]. Operating room (OR) staff have to deal with an overload of information, so new strategies for intelligent automation in hospitals are needed to save time and resources, and increase efficiency and the quality of patient care. [3] Tracking of necessary resources could support surgical staff in various perioperative functions, like patient tracking and clinical documentation, as well as improve logistics, especially for inventory management and control of sterilization and maintenance cycles. [4]

Radio Frequency Identification (RFID), which is a wireless method of automatic identification, is widely used in inventory management and retail. Recently, the technology is also being explored for tracking various resources within the hospital environment, for example for patient identification and logistics. [5-8] A huge advantage of RFID over other techniques is the unique identification number, which makes it an excellent candidate for maintenance purposes. Additionally, for RFID detection, no line of sight is necessary as in barcode.

Besides logistics, RFID-equipped instruments could also be of aid in an intraoperative setting. As a procedure progresses, the surgeon often uses a combination of distinctive instruments. With this information surgical phases can be recognized, as many procedures consist of a series of typical phases. Automated phase recognition could support in increasing the safety and efficiency of the procedures by, for instance, detecting risks when deviating from the surgical protocol, streamlining and scheduling the flow of resources, or aid in performance evaluations. [9-11] Several studies showed that surgical phases in laparoscopic procedures can be identified with high accuracy based on instrument use alone. [12-14] For this purpose, multiple studies proposed the use RFID technology to obtain real-time data on instrument use [5,6,15-17]. However, to obtain real-time data on instrument use during procedures is challenging as the sensing technology used should not hinder the clinical processes and must fulfil all requirements in terms of medical safety.

Implementing RFID in an OR environment is much more demanding than under industrial or retail conditions. First of all, surgical instruments need to be equipped with permanent RFID tags, without losing the CE-mark. Second, for sterilization and cleaning purposes, the tags need to withstand hundreds of cleaning cycles without being damaged or fall off. Third, the detection of instrument use has to be of sufficient accuracy to ensure robust identification of detection of surgical phases. Fourth, the whole system should not bother the OR staff in any way. The tags attached to the instruments must be small and positioned in such a way that they do not disturb the dexterity of the surgeons. Also, the other equipment should not impose an additional workload on the team and must not interfere with the daily surgical workflow. [9] But maybe most important, it must not impede patient safety.

The aim of this study is to evaluate the use of RFID sensor technology for real-time monitoring instrument use during surgical procedures for phase recognition purposes. In this study, we have equipped a set of laparoscopic instruments with small sterilisable semi-permanent RFID tags conform medical safety standards. The goal of the study is to determine the reliability of the detection of the tags, and therefore the instruments, when they were proximate to the surgical site. Our set-up is tested under two conditions: in a test-setting in the OR, and during an intraoperative procedure of a Total Extraperitoneal Procedure (TEP).

Table 1. Details of the instruments and tags used.

No.	*Instrument name*	*Tag*	*Dimensions*
1	Scalpel holder	HID small	5 x 5 x 3 mm
2	Langenbeck retractor	HID large	10 x 2.5 x 2.5 mm
3	Trocar 11 mm	HID large	10 x 2.5 x 2.5 mm
4	Endoscope	Xerafy XS	Ø 6 x 2.5 mm
5	Trocar 5mm #1 green	Xerafy Dot XXS	Ø 4.08 x 2.58 mm
6	Laparoscopic handle #1	HID large	Ø 10 x 2.5 x 2.5 mm
7	Trocar 5 mm #2	Xerafy XS	Ø 6 x 2.5 mm
8	Laparoscopic handle #2	Xerafy Dot XXS	Ø 4.08 x 2.58 mm
9	Electrosurgery cable	Xerafy Dot XXS	Ø 4.08 x 2.58 mm
10	Tweezers	Xerafy Dot XXS	Ø 4.08 x 2.58 mm
11	Needle forceps	HID small	5 x 5 x 3 mm
12	Cup (small)	HID small	5 x 5 x 3 mm

MATERIALS AND METHODS

RFID tag design

Twelve distinctive surgical instruments were equipped with RFID tags of two different suppliers; Xerafy [18] and HID [19], see Table 1. The tags operate on ultra-high frequency (UHF) with a range of 866 to 868 MHz. These types of tags are designed to withstand high temperatures (max 150 degrees) of the medical sterilization process. The attachment of the tag comprises of housing, a stainless steel (316) ring shaped holder, in which the RFID element is embedded. The tags are covered by PEEK epoxy within the housing. The housing is mounted on a support that is clamped to the surgical instrument (Figure 1). The construction and attachment of the tags was approved by the medical device safety officer of the testing hospital. Sterilization of the instruments was done conform guideline ISO 15.883-1.

RFID system

The passive RFID-based instrument tracking set-up consisted of a Harting RF-R500-c-EU RFID-reader with a sample frequency of 10Hz. Furthermore, a Harting Ha-VIS RF-ANT-WR30-EU antenna was used with a power of 2W. [20] The reader and antenna were connected to a Dell Latitude D360 laptop [21] and corresponding software Ha-VIS RFID Config V2.05.02 [20] was used to access the data. A custom-made Graphic User Interface (GUI) [22] was used as an input for the experimenter to support manual annotation of instrument use.

Set-up

For the OR tests, the system was implemented in the OR of a Dutch teaching hospital. The antenna was mounted to an IV pole, and positioned in such a way that the radiation pattern of the antenna covered the surgical site. The distance of the antenna to the surgical site was about 60cm, which is the area within detection of tags will be tested. All instruments outside of this area should not be registered by the system. To ensure that other commonly used OR equipment in the room were not disturbed by the system, the functioning of an electrosurgery device, an anesthetic machine, an IV pump and a patient monitor were tested in a pilot setting before performing the instrument detection experiments

Protocol

Following standard clinical protocol, the instruments were placed on the Mayo stand. Once the instruments are handed to the surgeon, they are detected by the antenna and considered 'in use'. When the instrument was handed back to the assistant and placed back on the Mayo stand, the instrument was considered 'not in use'.

During the test setting in the OR, video recordings of a surgical procedure were shown on an additional laptop, and were re-enacted by a medical doctor and assistant investigator. During the intraoperative measurement, the regular OR staff performed the procedure. Approval from a local accredited MREC was obtained on 12-05-2017, with reference number 17-079. In the intraoperative setting the same set-up of antenna and RFID system was used, see Figure 2. In the test setting in the OR the antenna was placed next to the operating surgeon. However, in the in intraoperative procedure the antenna was placed opposite to the operating surgeon, because of space constraints. To validate the accuracy of the RFID tracking system, the GUI was used to manually annotate the instrument use during both, the test and the intraoperative setting.

Data analysis

Analysis was done with use of MATLAB. [22] We specifically looked at moments of instrument changes, meaning either the introduction or the removal of an instrument in the surgical site. The time of first and last detection of instruments were compared with the annotated time. When the time detected by the system differed more than 10 seconds from the annotated time, the change was considered as NOT detected. We considered 10 seconds to be a representative time between the change of the instrument and the investigator's manual annotation. Also, the total detected time and annotated time of instrument use was compared. We quantified the detection rate as the percentage of time the instrument was detected by the system while the instrument was in use.

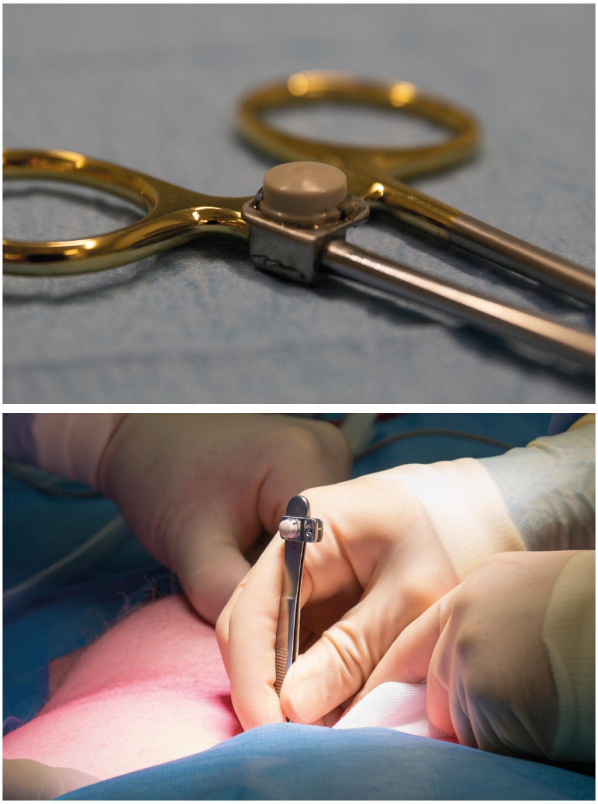


Figure 1. Instruments equipped with an RFID tag.

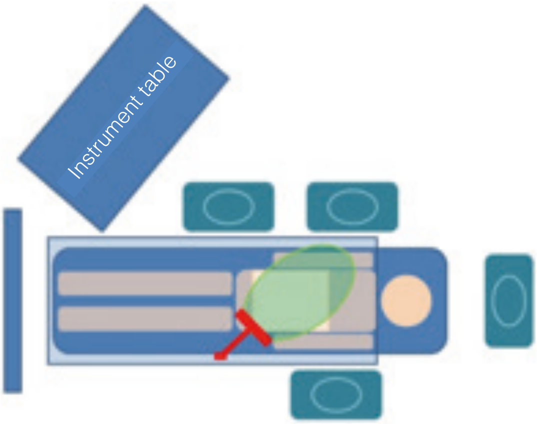


Figure 2. Schematic representation of the positioning of the antenna (red) relative to the operating table and the staff during the intraoperative setting.

RESULTS

RFID-based instrument detection was evaluated during a total of 10 re-enacted test procedures, based on endoscopic videos of TEP surgery. The average procedure time was 14:40 minutes. Each procedure was performed by the same 2 investigators (FM and JK). The same RFID tagged instruments were used in the test setting, as in the intraoperative OR setting. After regular sterilization procedures, the instruments were incorporated in the clinical process following standard protocols. No additional handlings were necessary to work with the instruments.

Test procedures

All instruments were used in all test procedures, except for the cable which was not used in the first test. In total, all instruments used in the test procedures were, at least once, detected by the RFID system. A total of 238 instrument changes were manually recorded. The scalpel was used twice in every test procedure, which means four instruments changes per test procedure. All other instruments were used once and thus count up to 2 changes per instrument. Of all these instrument changes, 86% was detected by the antenna (Table 2).

Table 2. Instrument changes in OR tests

	Scalpel		*Langen-beck*		*Trocar 11 mm*		*Endo-scope*		*Trocar 5 mm #1*		*Trocar 5mm #2*		*Lap. handle 1*		*Lap handle 2*		*Twee-zers*		*Needle forceps*		*Cable*	
Test	in	out	in	out	in	out	in	out	in	out	in	out	in	out	in	out	in	out	in	out	in	out
1	2	2	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	n/a	n/a
2	2	2	0	1	1	1	1	0	1	1	0	0	1	1	1	1	1	1	1	1	1	1
3	2	2	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1
4	2	2	0	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	0	1	1
5	2	2	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1	0	1	1	1
6	2	2	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	1	1
7	0	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1
8	2	2	1	0	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1
9	2	2	1	1	1	1	1	0	1	1	1	0	0	1	1	1	0	1	0	1	0	1
10	2	2	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	0	0	0
Total	18	20	8	7	10	10	9	7	10	10	6	5	9	10	10	10	9	10	5	8	6	8
Detection (%)		95		75		100		80		100		55		95		100		95		65		78

Instrument changes	238	100%
Not detected (colored)	32	13%
Not applicable (N/A)	2	1%
Total detected	**205**	**86%**

Table 3. Detection rates (%) of instruments in the OR tests. The red-green colour scale indicates the success rate (red=low, green=high)

Test	Scalpel	Langenbeck	Trocar 11mm	Endoscope	Trocar 5mm #1	Trocar 5mm #2	Lap. Handle #1	Lap. Handle #2	Tweezer	Needle forceps	Cable
#1	100	100	47	39	96	4	85	96	100	43	N/A
#2	100	100	25	8	51	2	76	53	60	20	100
#3	100	100	24	21	65	6	77	85	100	11	100
#4	100	100	44	27	98	0	73	70	100	0	30
#5	100	100	52	25	72	4	96	54	100	10	27
#6	100	100	41	26	60	2	86	33	100	20	5
#7	100	100	32	13	68	3	95	74	100	25	3
#8	100	100	21	8	100	1	85	48	90	50	19
#9	100	100	40	5	24	3	95	35	100	11	2
#10	100	100	95	26	50	0	91	9	100	60	23
Overall	100	100	42,1	19,8	68,4	2,5	85,9	55,7	95	25	34,3

Table 4. Detection rates during the intraoperative test.

Instrument	*Detection (%)*
Scalpel holder	44
Langenbeck retractor	11
Tweezers	3
Endoscope	63
Trocar 5mm #1	2
Laparoscopic handle #1	0
Trocar 11mm	6
Laparoscopic handle #2	9
Needle forceps	0
Average	15

Differences in detection rates are found during the test procedures. The scalpel and Langenbeck retractor were correctly detected during the annotated time. On average, the scalpel, Langenbeck retractor, laparoscopic handle #1, and tweezers were detected in 85-100% of the time. The trocar 5mm # 1 scored the least, with an average of 2,5%. Between tests, variability in detection rate was noticed. (Table 3) For example, the cable scored 100% in test 2 and 3, but 2% in test 9. A few miscounts happened while instruments were placed on the Mayo stand, thus considered 'not in use'. The Langenbeck retractor showed miscounts in 2 tests. The tweezers and scalpel show a few miscounts in test 9.

Intraoperative procedure

Nine of the 12 tagged instruments were used on the surgical site. Three instruments were not used because of various reasons. Of the 9 used instruments, the system detected only seven. In total, 32 instrument changes were annotated, of which only 4 were detected by the system (12.5%) The detection rates varied between the instruments, as can be seen in Table 4. The overall detection rate is 15%, in which the endoscope showed the best result with a detection rate of 63%. A few miscounts of e.g. the laparoscopic handle #2 were seen.

DISCUSSION

This pilot study presents a system for real-time monitoring of surgical instrument using RFID-based sensor technology. In a test setting, all tagged instruments could be detected within the surgical working field. Detection rates of 86% were obtained, which is of sufficient accuracy for real-time registration of the surgical workflow. [14] However, in the intraoperative test much lower detection rates were obtained. The exact reasons for the differences in detection between the OR tests and the intraoperative measurement are not entirely clear. Although the placement of the antenna can play a major role. In the test procedures it was placed next to the operating surgeon, whereas in the intraoperative measurement the antenna was placed next to the supervising surgeon. As the radiation pattern of the antenna is of great importance for the detection of these specific small RFID tags, perhaps the pattern was not well aligned with the surgical site. In further research, different positions of the antenna should be explored to reach an optimal detection distance.

Several other studies have used RFID technology to track surgical instrument use. In oppose to our approach, in which we point the antenna directly to the surgical site, others realised an indirect set-up in which the antenna was positioned in the Mayo stand. [6, 23] However, this approach involves an indirect way of instrument use monitoring, since the instrument is considered 'in use' when it is not on the stand. One limitation of this approach is that when instruments are temporarily put aside they are not placed back at the mayo stand (e.g. held by the surgical assistant). Moreover, not all instruments are placed on the Mayo stand in the case of complex procedures with more instrument tables. Meissner et al. compared both set-ups during simulated procedures, and positioned antennas at both the Mayo stand and the surgical site. [5] No differences in accuracy were observed between both locations. In our opinion, detection of instruments within the surgical site is a direct way of measurement of instrument use and will presumably result in a more reliable identification of surgical phases.

Although our results show that the system did not detect most of the instruments changes in the intraoperative test, it is probably of sufficient accuracy for the purpose of phase recognition. In our previous study, robust phase recognition was already obtained by capturing the presence of instrument within the time span of a surgical phase. [12] Thus, the most important feature of surgical phase recognition based on instrument use, is whether an instrument has been used within a certain time span. It remains to be determined what temporal resolution is necessary to detect relevant transitions between different surgical phases.

To reliably monitor surgical instrument use, a detection system must adhere to certain requirements. It should not interfere with the OR-staff and show reliable detection rates. The instruments presented in this article serve this purpose and adhere to all medical safety requirements. The tags withstand the sterilization process and require no extra handling by the OR staff after cleaning. Detection was possible for all tagged instruments in a controlled OR test setting.

Conclusion

In this study, we present a track and trace system to monitor surgical instrument use. The system, using sterilisable RFID-sensor equipped instruments, was used during both OR tests and a real-life intraoperative procedure. A reliable detection of instruments is obtained in a controlled test setting, however, the detection rate in the intraoperative procedure was still too low. This could be explained by the positioning of the antenna relative to the operating table. Although, the system meets all requirements in terms of medical safety, more research is needed before the detection rates are reliable enough for clinical use. Still, the results of this study contribute to the development of track and trace systems for phase recognition purposes.

Ethics

Approval from a local accredited MREC was obtained on 12-05-2017, with reference number 17-079.

Acknowledgments

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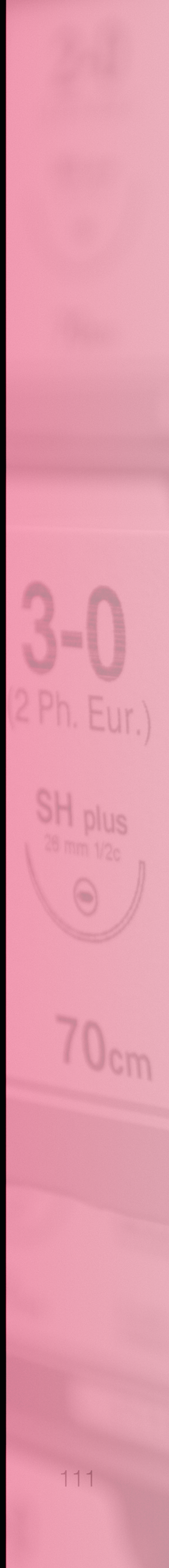
CHAPTER 7

DISCUSSION

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TOWARDS SAFE USE OF MEDICAL TECHNOLOGY

The aim of this thesis is to objectively measure application of medical technology in the Operating Room (OR), while considering factors related to the user, the devices and the environment. All these aspects need to be addressed, present and lined up, to reach its final goal; safe use. In this final chapter we will discuss the main findings in relation to their broader clinical implications and relevance for the clinical field. Also, recommendations for future research are shared.

First, the structure of Dutch national training programs regarding medical technology was investigated. The study in Chapter 2 focused in particular on the electrosurgical device, as it is a high-risk instrument often used in surgical procedures. A digital questionnaire among surgical residents in the Netherlands revealed that electrosurgical training is limited, often not obligatory, and mostly consists of a single theoretical lecture. Respondents are not satisfied with the acquired theoretical knowledge and wish for a more extensive theoretical training of the instrument. Furthermore, the respondents state that their practical competencies are only acquired during in vivo procedures in the OR, where mostly the preferred approach of the daily supervisor is followed.

In Chapter 3 and 4, the approach in use of electrosurgery was investigated in depth. We specifically looked at differences in activation times of the instrument and the preferred electrosurgical settings among surgeons for various procedures. Intraoperative measurements of device activations reveal that, despite guidelines from educational programs and the manufacturers' instructions for use, surgeons seem to have found their own individual preference in handling the instrument. Surgeons do adapt their approach to the task at hand and their own competency, such that all adopt a unique approach to come to the desired clinical outcome.

Next to parameters related to the user and device settings, safe application depends on environmental factors such as the workflow in which medical technology is applied. In chapter 5 and 6, different means to monitor and improve the peroperative workflow in the OR are being explored. Chapter 5 describes means by which automatic identification of ongoing surgical phases could be used to streamline the sequence of events in the OR. In this study, a Random Forest based phase recognition model based on measurements of surgical instrument use is applied to laparoscopic hysterectomies. A high accuracy in phase recognition was obtained, showing the feasibility of the approach for automated monitoring of OR processes. Additionally, in chapter 6, a system based on Radio Frequency Identification was realized to perform real-time intraoperative detection of surgical instrument use, for the purpose of phase recognition.

In the Introduction of this dissertation, the need for a proper alignment of the pillars was emphasized. Safe use of medical technology can only be reached when the user, the device and the environment are addressed, present, and lined up. But what exactly does it mean and what is the true added value of this alignment?

A critical aspect of alignment for improving safety is the ability of the clinician to combine all important aspects that contribute to safe use. This includes theoretical knowledge and practical experience, but also encompasses patient information and other clinical data. To ensure safe application of the technology, clinicians must consider all environmental factors that can influence their activities. Taking all this into account, the clinician acquires a bird's eye view over the surgical situation, crucial for taking the right decisions.

Additionally, medical technology could aid the surgical staff in taking decisions. By monitoring clinical important factors, the safety and efficiency of procedures can be enhanced. For example, by tracking surgical instrument use, various surgical phases are recognized. Subsequently, real-time phase recognition systems can support in various perioperative processes, like OR planning and logistics, because the flow of resources can be streamlined and scheduled. However, the most important goal of intelligent automation in hospitals is to provide a clear overview of ongoing and upcoming clinical processes at each instant.

Considering the above, the true added value of alignment is the creation of situational awareness which is defined as 'the perception of environmental elements and events with respect to time or space, the comprehension of their meaning, and the projection of their future status'.[1,2] Thus, situational awareness is a prerequisite for the safe use and implementation of medical technology, which can only be obtained by the alignment of the user and the technology in its environment.

Conclusion

Currently still many preventable errors occur in the operative trajectory. Adding more technology and new therapies is not always the key to success. To make the patients' journey safer, new medical technology must be developed with the sole purpose to improve situational awareness.

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APPENDIX

LIVING LABS: THE SMOOTH OPERATOR

SUMMARY

More and more medical technology is finding its way to the Operating Room, which is a great benefit for efficiency and patient safety. However, it may also cause disturbances in the workflow. Living labs and test beds such as a Research Operating Room can provide a real-life setting in which safe implementation/research in the field of work processes and protocols can be studied. In this paper we discuss the added value of such a Living Lab, illustrated by two cases.

INTRODUCTION

The perioperative process is a complex, high-risk core activity within a hospital in which the activities of many professionals of different disciplines should be managed and aligned to ensure a safe environment for the patient. The potential of new technology to improve the quality, efficiency and safety of healthcare delivery is undisputed. However, introducing novel medical technology may inflict unexpected changes in the workflow and could introduce unforeseen risks and dangers for the patient; even the smallest disruptions of the normal workflow may induce delays or deviations from protocol, thereby reducing patient safety and efficiency in the entire care pathway (Arora et al., 2010; Wiegmann, ElBardissi, Dearani, Daly, & Sundt, 2007). Moreover, not all medical devices undergo clinical trials prior to introduction. In fact, many novel medical technologies are in conflict with the request for efficient treatment processes, which in the end results in increased costs and unviable products (Kumar, 2011).

A major challenge for safe introduction of novel medical technology is the management of proper work processes and protocols that go along with the application of the technology. This includes the availability of properly trained clinical staff, device compatibility with other necessary medical equipment and materials, all of which have to be joined at a defined point of time and at a specified location. However, the limited saliency of small disruptions of the workflow in daily routine will not stimulate active reorganisations of the working processes and severe disruptions that impose major risks might only happen once in several years. Ideally, there should be continuous surveillance and monitoring based on methods that are sufficiently sensitive to detect problems, however small they may be.

Living Labs and Test Beds

Active seeking and defining the best methods of organizing healthcare delivery is crucial to detect problems with new and existing technologies and to maintain patient safety. An essential feature of this approach is the validation of the service or the product in an (small scale) implementation setting. Validation in a real-life setting can be achieved in so-called Living Labs (LL) or Test Beds (TB). These facilities provide an environment with actual end-users in which both new work processes and validation of new products and services (Living Labs) or just validation (Test Beds) of new products and services can be performed. To illustrate the benefits and potential of such facilities for both the development of novel technologies and the evaluation of the safety or safe use of existing technology we discuss in this paper two cases that were studied in such a real-life setting; the Research Operating Room (OR) that was established in the Reinier de Graaf hospital (RDGG) in Delft, The Netherlands. The RDGG is a Top clinical Training hospital providing an appropriate range and format of accessible healthcare facilities and resources.

The RDGG Research OR is equipped with monitoring technology for automated recording of critical steps during surgical procedures. Thereby, objective data can be gathered on the impact of novel technology on changes in the OR resource management and on safety aspects. While the availability control of medical staff and medical devices could be achieved with for instance clinical information systems, the management and automated monitoring of other resources is in normal OR settings limited or not possible at all. Within the RDGG Research OR, an appropriate assistance system for validation of new technologies and protocols is already in place (i.e. Digital Operating Room Assistant(Guedon et al., 2014)), which allows assessing the impact of events in advance to the actual implementation of the proposed technology.

In the following we will discuss two cases that were studied in the Research OR. Case 1 focuses on the validation of the application of pattern recognition methods for automatic phase detection in surgical procedures. The developed system automatically informs the OR staff about the optimal timing to start preparing the next patient(Guedon et al.,2016). Case 2 targets detailed registration of the application of a common but high-risk technology, electrosurgery(Meeuwsen et al., 2017). Electrosurgery is used in 80% of surgical procedures and allows surgeons to skilfully dissect tissue and achieve rapid hemostasis.

CASE 1. PHASE DETECTION IN SURGICAL PROCEDURES

The usage of devices and instruments can provide essential information about the progress of a procedure (Blum, Padoy, Feussner, & Navab, 2008b). Patterns in the usage of devices and instruments can be detected for various types of procedures. These patterns can then be used to detect the actual phase of a surgical procedure. Several pattern recognition approaches explored in previous studies have presented the potential of automatic recognition of the phase of procedures (Blum, Padoy, Feussner, & Navab, 2008a).

During a laparoscopic cholecystectomy, electrosurgery is activated during the removal of the gallbladder from the liver, which matches a certain stage of the procedure. Therefore, the activation of the electrosurgical device is suited to monitor for pattern recognition purposes. Activations of the electrosurgical device were detected by measurements of the current delivered to the device at a frequency of approximately 10 times per second. Each peak in the amount of current corresponds to an activation of the device.

Predicting endtime

During 57 laparoscopic cholecystectomies, the activation pattern of the electrosurgical device was measured to train an algoritm suitable for automated monitoring of surgical progress. The main goal of the experiment was to study the feasibility to use these activation patterns as input for predicting the end time of the procedure, which in turn can be used to streamline the scheduling of procedures. A real-time prediction system was developed which was used to communicate the predicted end-time of the procedure to the OR staff.

The reliability and usability of the system's predictions were tested during 21 subsequentially performed laparoscopic cholecystectomies. The mean absolute error was smaller for the prediction system (14 min) than for the OR staff predicting the end-time (19 min). The results show that the system's predictions were more reliable for procedures with average or long duration than for the ones with short duration. For procedures longer than 40 min, the mean absolute error was 9 min and therefore within the margins of reliable predictions. For these procedures, the system's predictions outperformed the OR staff's predictions, which presented a mean absolute error of 29 min. The predicted end time was used to estimate the optimal time to prepare the next patient. To receive feedback we asked the OR staff (i.e. anesthesiology assistant) to rate this estimation via a software interface presented on a tablet.

The timing to start preparing the next patient was predicted slightly later than optimal by the system and mostly earlier than optimal by the OR staff. Nevertheless, the main benefit lays in the enhanced access to information on the progress of the procedure from outside the OR. This information can be used by the OR schedulers without having to interrupt the surgical process. Additionally, information on the progress of the procedure is valuable for the nursing staff, who can anticipate the preparation and transport of patients from and to the nursing department (Guedon et al., 2015). It can also reduce the efforts of the nursing staff to update the persons accompanying patients about their progress.

CASE 2. APPLICATION ELECTROSURGERY

In this study, current measurement technology was used to get insight in the actual application of electrosurgery devices. This study was motivated by recently published reports by the Dutch Healthcare Institutions (Dutch association of hospitals (NVZ) and Dutch association of university hospitals (NFU), 2011; Dutch Healthcare Inspectorate (IGZ), 2014). These reports express concerns about the rapid increase of medical technology, its related risks to patient safety and the lack of structured certification systems to assess necessary competences in using medical equipment. Crucial for such an certification program is to have proper and frequent assessments for each type of medical technology. Therefore it is necessary to understand how devices are used in real-life.

For this study we obtained a detailed registration of 91 laparoscopic cholecystectomies performed by five experienced surgeons and 11 residents in training. The main objective was to examine potential differences in handling techniques between operators and to determine whether experience plays a major role in the way electrosurgery is applied.

Our main findings show that different approaches in application technique can be distinguished among the operators; typically, a higher amount of activations goes along with a short activation time and vice versa. Figure 1 left shows the pattern of an expert surgeon, whereas Figure 1 right shows the performance of a surgical resident. Also, differences between individual surgeons and residents were found.

All residents use a higher number of activations with a shorter activation time, while various surgeons seem to choose for the opposite approach. The latter is remarkable as the guidelines suggest using brief intermittent activations. Such insights are valuable information when setting up a certification system according to the earlier mentioned reports.

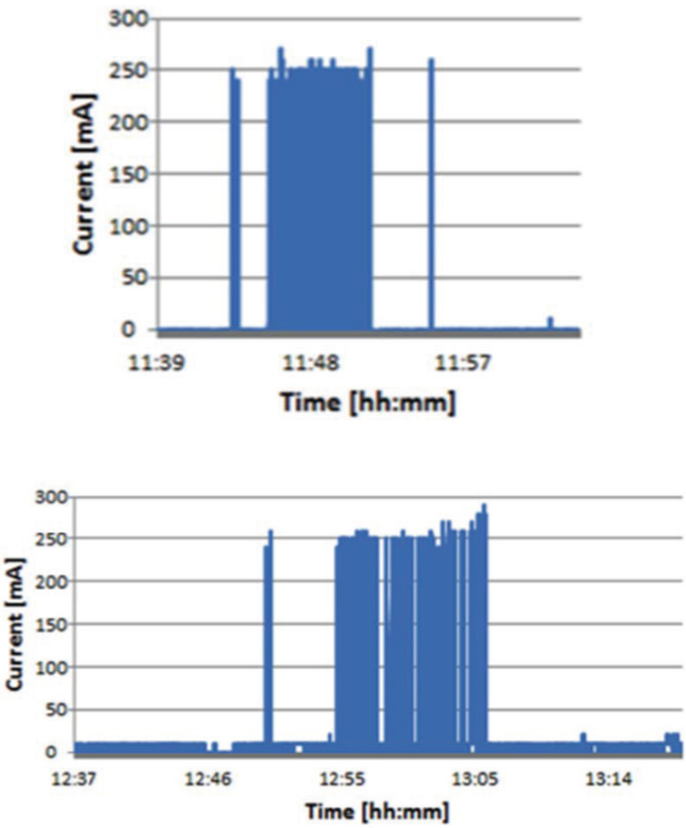

Figure 1. Application of electrosurgery by an experienced surgeon (above) and a resident (below)

DISCUSSION

Evaluating the safety medical technology in Living Labs allows assessing its impact in advance of the actual implementation. The need for such facilities is further strengthened by the guidelines formulated in the 'Dutch Convenant safe use of medical equipment' that prescribes hospital to ensure that a competence assessment and certification system is in place. Living labs and test beds such as the Research OR offer the real-life setting in which necessary protocols and training programs for using the technology can be designed and validated.

The two cases on measurement of activation patterns of electrosurgical devices show the potential of non-obtrusive monitoring of surgical handling. Systematic and continuous recording of detailed use of medical equipment may provide insight in many aspects of the surgical workflow. Table 1 lists the key features that should be part of any working protocol; that is, all resources that are part of the clinical procedure such as devices, instruments and personnel. Therefore, well-designed protocols are not only relevant for dealing with new technology but it also touches upon the performance of the involved staff and the smooth flow of essential resources.
In short, Living Labs allow us to introduce new technology with minimum waste and maximum benefit for health care system.

Table 1. Most important aspects of the Research OR protocol.

	DOMAINS RESEARCH-OR		
	1. devices	**2. instruments**	**3. personnel**
Development goals 3 years	*Devices monitoring:* • Link with planning • Integration in time out procedure • Maintenance and reports of defects	*Just in time delivery:* • Supporting supply management at sterili-sation department • Visualisation of problems in processes by automatic check of delivery (tracking, RFID, barcodes) • Digital communication system, IT support	*Safe use of medica devices:* • Development of measurements for competences • Link to training modules • A complete competent & certified system for electrosurgery
Products	• Device status and safety monitoring sys-tems • Support systems preoperative and dynamic OR planning • Support systems for maintenance devices	• Track & trace system for OR instruments • Support systems for resource planning and supply management • Monitoring systems for safe cleaning instruments	• Automatic registration system for safe and certified use of high-risk medical devices • Training programs for high-risk medical devices

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