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Implementing patient safety in laparoscopic surgery: quality assessment and process analysis

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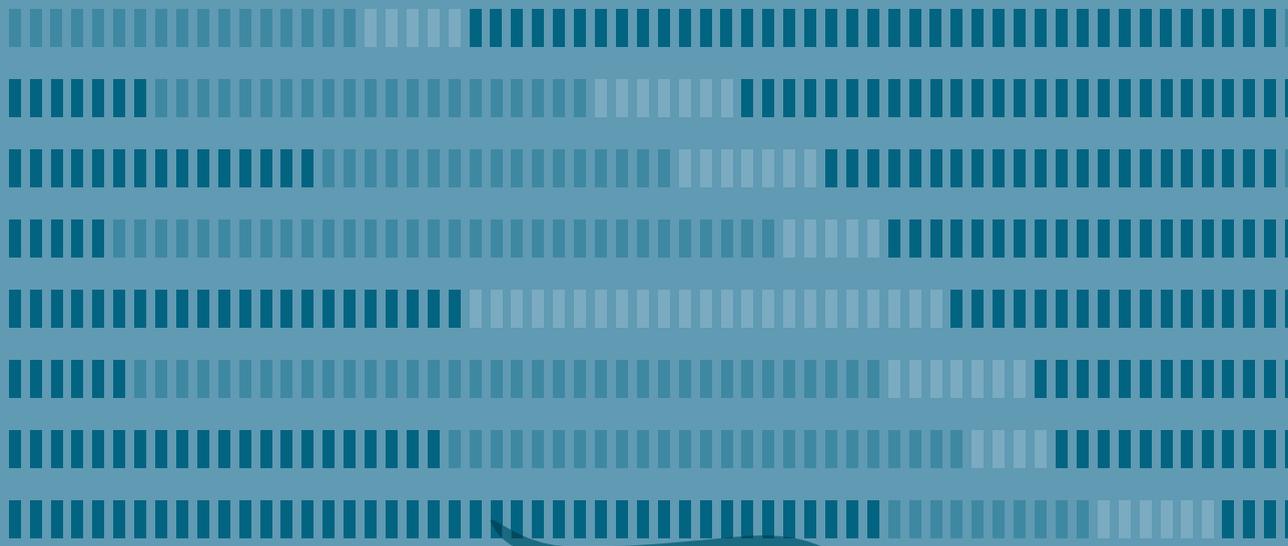


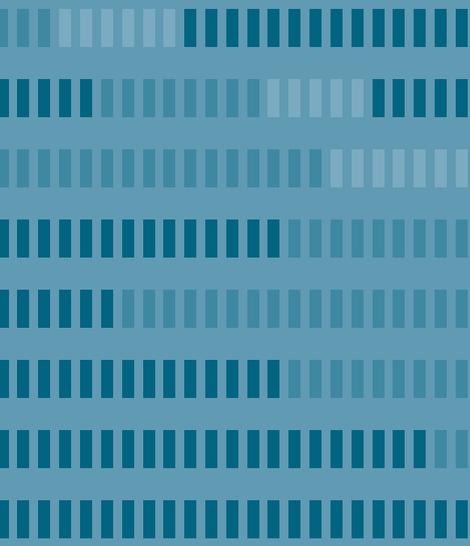
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Chapter 8

Digital Operating Room Assistance: a novel system to predict the remaining procedure duration by automated procedural progress monitoring

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Submitted

Abstract

Background: To test whether transforming the planned procedure duration into a summation of the average historical durations for each surgical phase (i.e. reference data) provides a reliable estimation of the actual procedure duration and to describe the basic technical components of an automated real-time procedural progress monitoring system.

Methods: Historical operating procedure data were obtained from all OR procedures that were performed at the Leiden University Medical Center between May 2011 and December 2012. Reference data for the anesthesia induction and surgical preparation ($T_{\text{preparation}}$) and anesthesia emergence phase ($T_{\text{emergence}}$) specific to each surgeon were computed based on procedures performed in 2011. The transformed procedure duration (T_{DORA}) was computed by adding $T_{\text{preparation}}$ and $T_{\text{emergence}}$ to the planned procedure duration (T_{planned}) and corrected with the historical deviation specific to each surgeon (i.e. the Digital Operating Room Assistance (DORA) model). The reliability of the DORA model was tested by simulating the effect of T_{DORA} on procedures performed in 2012.

Results: Reference data were computed based on 3,515 procedures performed in 2011. T_{DORA} was computed for 6,712 procedures performed in 2012. Compared to T_{planned} , T_{DORA} was significantly more accurate (41 ± 49 versus 8 ± 47 minutes too short, $p < .001$).

Conclusions: Transforming the planned procedure duration into a summation of historical durations specific to each surgical phase results in a more accurate estimation of the actual procedure duration. Combining this approach with a system that is able to perform real-time phase detection of the operative procedure will enable dynamic prediction of the remaining duration of the surgical procedure.

Introduction

The adage “what happens in the operating room, stays in the operating room” was applicable until the end of the 20th century in terms of legal perspectives [1]. Nowadays, it is still applicable in terms of procedural progress monitoring. The operating room (OR) acts as a ‘black box’: patient, surgeon and OR staff enter the room at a certain point in time to perform an intended procedure and all come out when the procedure that they actually performed is finished [2]. Usually, the performed procedure goes as planned and approximately within the scheduled time. However, quite often procedures do not go as initially foreseen and take up either less but usually more time [3]. OR managers are still limited in their ability to monitor the progress of the procedure. For example, they can only call the OR or be physically present in the OR (creating a disturbance and sterility hazard), or peer through the small OR-window and/or look up some specific time notes (e.g. ‘first incision’) that are manually entered into the electronic patient record (EPR) (provided that this has been done immediately and correctly) [4].

Because the OR is one of the most expensive facilities of the hospital, it is important to optimize OR occupancy by accurate preoperative scheduling and thorough monitoring of the procedural progress [5]. Furthermore, in terms of process management, the complete perioperative process consists of multiple parts besides the procedure itself. Therefore, optimized OR efficiency also affects, for example, the patient ward, hospital transport, the holding unit, OR cleaning services, recovery unit and vice versa [5, 6]. Furthermore, optimizing OR occupancy decreases the number of procedures that have to be rescheduled to another day resulting in higher patient satisfaction and lower costs [7].

Currently, operative procedural progress monitoring in the OR resembles traffic control in the mid-20th century [8]. Without speedometers or real-time traffic information, the estimated time of arrival (ETA) was purely based on experience. Nowadays, by using the global positioning system, combined with both real-time and historical traffic data and the behavior of the driver, the ETA is very accurate and, moreover, real-time adjusted if unexpected events occur.

To facilitate a more modern procedural progress monitoring system for the OR, multiple methods have been described to divide the procedure into different phases by identifying unique ‘landmarks’. The passing of these landmarks indicates the procedural progress. Table 8.1 shows a summary of the most useful methods. Guédon et al. used radiofrequency identification (RFID) to track the location of patients within the OR complex [9]. The patients’ vital signs are also easily obtainable predictors of OR occupancy [10]. More detailed information on the procedural progress can be provided by continuous image analysis [4]. Bhatia et al. described several consecutive phases that are generic for every procedure: an

Table 8.1 Methods to determine procedural progress

Method	Sensor	'Landmark' during procedure
Patient identification	RFID	Position of patient on OR-complex / OR-occupancy ⁹
Anesthesia vital signs	Pulse oximetry / Electrocardiography	OR-occupancy ¹⁰
Double bed state	Image analysis	OR-occupancy ⁴
Blue drape on/off	Image analysis	Surgery phase ⁴
Activation pattern of electrosurgical device	Audio analysis	20–30 minutes before end surgery phase ¹¹
Segmentation & recognition of surgical workflow	Low-level sensors & video analysis	Intra-operative surgical phases ¹²
Task recognition during laparoscopy	Video analysis	Intra-operative surgical phases ¹³⁻¹⁵

RFID = radiofrequency identification; OR = Operating room.

empty OR bed, a patient on the OR bed, a patient covered in blue drapes (as start of the surgery phase), removal of the blue drapes (directly after last stitch) and an empty OR bed again. These four general states were detected with 99% accuracy. Additionally, Guédon et al. used the activation pattern of the electrosurgical device to predict 'if it was time to prepare the next patient'; optimally this is done 25 minutes before the last suture [11]. Furthermore, Dergachyova et al. have proven that automatic real-time segmentation and recognition of the surgical workflow is feasible [12]. Their combination of sensors and video analysis detected intraoperative surgical phases with a reliability of 91%. Last but not least, task recognition on laparoscopic video is rapidly advancing, allowing for accurate surgical phase recognition [13-15].

Presumably, the combination of the above-mentioned sensor methods will provide an automated and reliable real-time identification of the current phase within the surgical procedure. By linking this output to historical information on the duration of the procedure beyond this phase, the remaining duration of the procedure can be estimated. This estimation based on real-time data is the crucial parameter necessary to transform OR scheduling from a static to a dynamic process [6].

The aim of this study was to test whether transforming the planned procedure duration into a summation of historical durations for each surgical phase provides a reliable estimation of the actual procedure duration. Additionally, the basic technical components of an automated real-time procedural progress monitoring system are described.

Materials and methods

Historical operating procedure data were collected from all OR procedures that were performed by all surgical specialties at the Leiden University Medical Center, Leiden, the Netherlands between May 2011 and December 2012. All data were anonymously withdrawn from the EPR system and therefore are exempt from patient consent. Relevant perioperative phases were defined as shown in Figure 8.1. All stated timestamps had to be manually entered into the EPR during the operative process (see Figure 8.1).

Average historical duration of the surgical phases between the timestamps “patient on OR”, “start surgery”, “end surgery”, and “patient leaving OR” were obtained to compute reference data. Thereby estimations for the average duration of the preparation phase ($T_{\text{preparation}}$) (i.e. anesthesia induction and surgical preparation combined), surgery phase (T_{surgery}), and anesthesia emergence phase ($T_{\text{emergence}}$) were acquired. Thus, the planned procedure duration is not a fixed time length, but a summation of these three phases marked by the four timestamps that are applicable to every procedure (underlined in Figure 8.1).

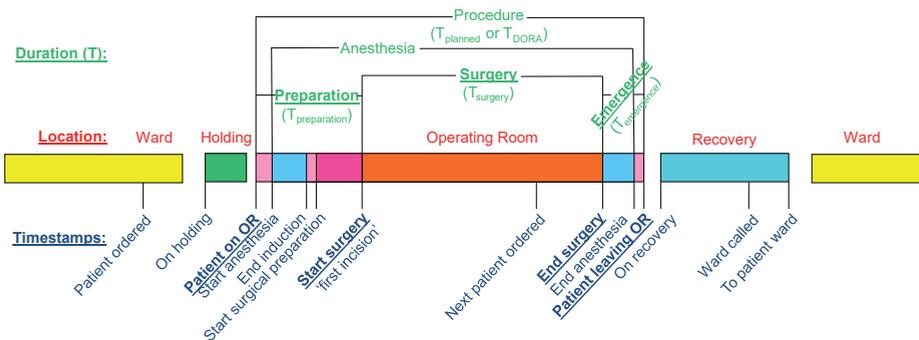


Figure 8.1 Schematic representation of the perioperative process.
DORA = Digital Operating Room Assistance.

Obtaining reference data

Operating procedure data were obtained from procedures performed between May and December 2011. Per surgeon and per specialty, $T_{\text{preparation}}$ and $T_{\text{emergence}}$ were computed. T_{surgery} is obviously preoperatively estimated by the surgeon. However, at present, this estimation is used as the planned procedure duration (T_{planned}). Therefore, in order to correct for any consistent underestimation or overestimation of the surgeon, the average difference between T_{planned} and T_{surgery} (i.e. deviation) was computed. This computation was stratified into categories: $T_{\text{planned}} < 60$ minutes; 60–119 minutes; 120–180 minutes; and >180 minutes. To

allow transforming of T_{planned} in case no reference data for that specific surgeon was available, reference data specific to each specialty were also computed.

Surgeons with ≤ 3 procedures per category were excluded. Similarly, prior to computation of the reference data, outliers were excluded (i.e. duration preparation phase < 5 minutes or > 105 minutes; duration anesthesia emergence phase 0 or > 90 minutes; difference between planned and actual surgical duration < -90 minutes or > 90 minutes, standard deviation (SD) of the average preparation phase > 20 minutes or SD of the mean difference between planned and actual surgical duration > 45 minutes).

T_{DORA} was computed by a model that was called “Digital Operating Room Assistance” (DORA). In this model, $T_{\text{preparation}}$ and $T_{\text{emergence}}$ were added to T_{planned} and corrected for the deviation specific to the surgeon (stratified per ‘planned procedure duration’-category). If no reference data for that specific surgeon were available, reference data for this surgeon’s specific specialty were used.

Validation of the DORA model

The reliability of the DORA model was tested by simulating the effect of transforming T_{planned} . This simulation was based on procedures performed between January and December 2012. T_{planned} and T_{DORA} were compared for individual procedures and for a series of procedures that were planned consecutively in a specific OR on a specific day (i.e. an OR session). Only sessions with ≥ 2 procedures and planned during the daytime (between 8:00am and 3:30pm) were simulated. The applied duration for OR cleaning between two procedures (i.e. turnover time) was 20 minutes.

Statistical analysis

Pivot tables in Microsoft Excel® 2010 were used for analysis and simulation. For statistical analysis, SPSS 23 statistical software was used. A paired samples T-test was used to compare differences between historical data and DORA. A $p < .05$ was considered statistically significant and a 95% confidence interval (CI) of the difference was provided.

Results

Obtaining reference data

Between May and December 2011 13,082 procedures were performed, of which the EPR of 3,515 procedures contained all data necessary to compute the reference data for all three phases. Incomplete operating procedure data were due to missing or invalid time stamps, most likely caused by incorrect manual data entry in the EPR system.

Validation of the DORA model

Between January and December 2012, 20,556 procedures were performed, of which the EPR of 6,712 procedures contained all data necessary to compute T_{DORA} and subsequently test its validity. The following were reason for exclusion: incomplete or invalid time stamps ($n = 7,515$); combined surgical procedures ($n = 5,255$); planned duration >300 minutes and emergency procedures outside office hours ($n = 897$); and missing reference data ($n = 177$).

$T_{planned}$ was 88 ± 55 (average \pm SD) minutes and T_{actual} was 129 ± 84 minutes (average difference 41 ± 49 minutes too short). $T_{surgery}$ was 81 ± 70 minutes. T_{DORA} was 121 ± 62 minutes (average difference with T_{actual} 8 ± 47 minutes too short). Compared to $T_{planned}$, T_{DORA} was significantly more accurate (average difference 32.7 minutes, 95% CI 33.1–32.3, $p < .001$) (Table 8.2).

A total of 421 sessions (in total consisting of $N = 1,312$ procedures) were simulated. Mean actual turnover time was 21 minutes. Of all 421 sessions, 54% ($N = 229$ sessions) actually ended past 3:30pm. Based on the simulated durations of DORA, the overtime of 35% ($n = 148$ sessions) was predicted, which means 65% (148 of 229 sessions) could have been anticipated. The overtime of the remaining 19% ($n = 81$ sessions) would not have been predicted preoperatively by DORA. Furthermore, DORA predicted incorrectly that 43 sessions would end past 3:30pm (10%, average overtime by DORA 49 ± 41 minutes; whereas actual end time of the sessions was on average 2:51pm ± 31 minutes).

Basic technical components of an automated real-time procedural progress monitoring system

Based on the results outlined above, the approach of the DORA model is a feasible basis for an automated real-time procedural progress monitoring system. This approach has to be implemented in a technical system that facilitates generic and reliable phase detection during any surgical procedure. Such systems have been described in the literature [4, 9, 11, 16].

Table 8.2 Average procedure and phase durations (in minutes) of the procedures performed in 2012 (N = 6,712)

	Average	±	SD	Min	-	Max
Procedure duration:						
T_{planned}	88	±	55	5	-	280
T_{actual}	129	±	84	8	-	830
T_{DORA}	121	±	62	12	-	331
Actual phase duration:						
$T_{\text{preparation}}$	36	±	18	2	-	177
T_{surgery}	81	±	70	1	-	733
$T_{\text{emergence}}$	12	±	10	0	-	137
Reference data:						
$T_{\text{preparation}}$	31	±	10	5	-	71
$T_{\text{emergence}}$	11	±	3	3	-	25
Deviation	10	±	10	-24	-	70

SD = standard deviation; T_{planned} = originally planned procedure duration (estimation by surgeon); T_{actual} = actual procedure duration; T_{DORA} = transformed planned procedure duration based on Digital Operating Room Assistance (DORA) model (average $T_{\text{preparation}}$ and $T_{\text{emergence}}$ are added to T_{planned} and corrected for the average historical deviation); $T_{\text{preparation}}$ = duration of anesthesia induction and surgical preparation combined; T_{surgery} = duration of surgery; $T_{\text{emergence}}$ = duration of anesthesia emergence; Reference data = Average historical duration of the surgical phases; Deviation = historical difference between T_{planned} and T_{actual} in order to correct for any consistent underestimation or overestimation of the surgeon.

Figure 8.2 provides a schematic outline of the basic technical components. A ceiling-mounted dome IP-camera, a microphone, and a RFID reader are examples of readily available sensors able to deliver relevant and reliable information from the OR. Algorithm-1 analyzes this raw sensor information and provides a binary output for registry in the ‘current data’ database. This algorithm replaces the manual entry of the timestamps, as shown in Figure 8.1. Since this algorithm directly analyzes the raw sensor information (e.g. it is constantly checking for the presence/absence of blue surgical drapes [4], ‘listening’ to the specific frequency of the coagulation device [11], etc.), no data are stored and privacy concerns are not an issue. See Figure 8.3 for an example of the binary output of these sensors that allow the algorithm to identify the current phase within the surgical procedure.

On a server, Algorithm-2 uses the reference data combined with the current data – consisting of general information from the EPR system (patient name, type of procedure, OR suite etc.) complemented with the timestamps – to compute the remaining time of the procedure. The remaining procedure duration is computed by subtracting the procedural progress from T_{DORA} . For example, a surgeon usually plans 120 minutes for a laparoscopic hysterectomy procedure. Including the $T_{\text{preparation}}$ (e.g. 15 minutes) and $T_{\text{emergence}}$ (e.g. 10 minutes) in total T_{DORA} becomes

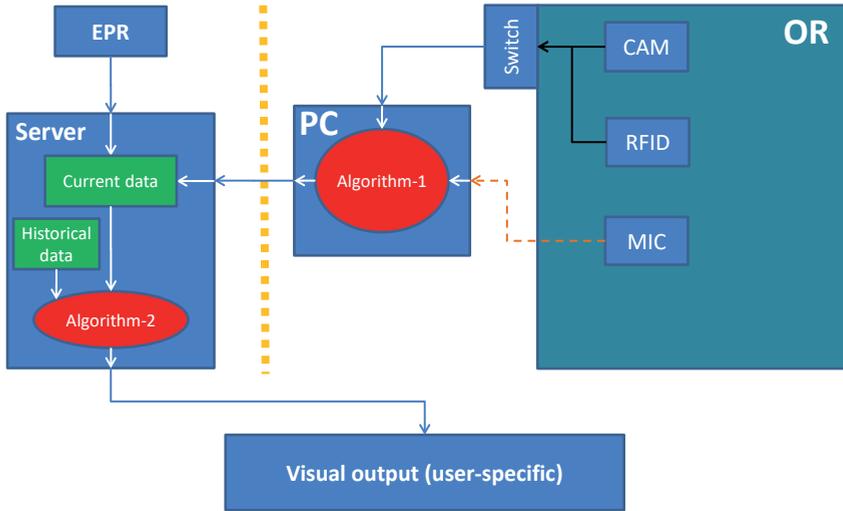


Figure 8.2 Schematic outline of the basic components required for an automated real-time procedural progress monitoring system.

OR = Operating room; CAM = IP-Camera (detecting patient on OR-bed / blue drapes etc.); RFID = Radiofrequency identification (detecting OR-occupancy by patient / personnel / devices); MIC = (Wireless) microphone (detecting electrocoagulation device activity); PC = Personal computer (containing Algorithm-1 that transforms sensor data real-time into timestamps); EPR = Electronic patient record system; Current data = Database containing all necessary information about the current operative procedures in the OR-complex (withdrawn from EPR) supplemented with the timestamps entered by Algorithm-1; Historical data = Phase specific reference data (surgeon & specialty specific); Server = Computer allowing the storage of the databases and containing Algorithm-2 that computes the transformed planned procedure duration and real-time adjusted remaining procedure duration. A visual output (user-specific) of all relevant information is made.

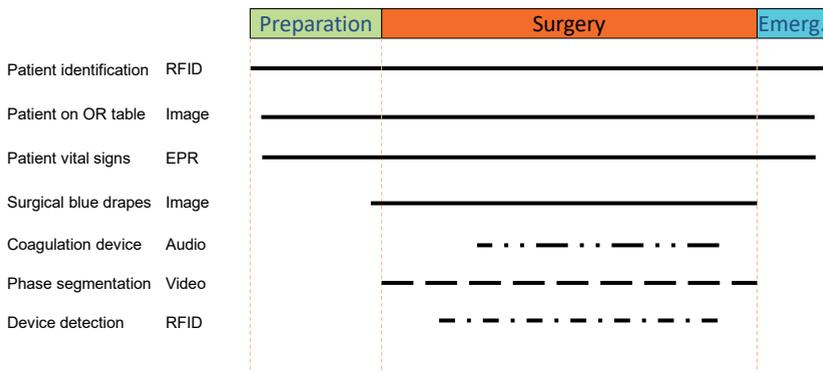


Figure 8.3 Example of the binary output of the different sensors allowing the algorithm to identify the current phase within the surgical procedure.

Emerg. = Anesthesia emergence phase; RFID = Radiofrequency identification (detecting OR-occupancy by patient / personnel / devices); EPR = Electronic patient record system.

145 minutes. However, in this case the uterus needs to be morcellated and therefore the surgeon adds 30 minutes to T_{planned} . At the start of this laparoscopic hysterectomy procedure the remaining procedure duration is 175 minutes. And at the start of the surgical phase the remaining procedure duration generally will be 160 minutes (175–15). However, in case of delay during the anesthesia preparation, from the minute this takes longer than $T_{\text{preparation}}$ the model will start adjusting the time that the procedure will end.

Discussion

The DORA model shows that transforming the planned procedure duration into a summation of historical durations specific to each surgical phase results in a reliable estimation of the actual procedure duration. Furthermore, the basic technical components required to perform real-time phase detection of the operative procedure have been highlighted. Combining these two features into one system will facilitate real-time prediction of the remaining duration of the procedure.

By transforming the planned procedure duration using historical deviation specific to the surgeon or his/her specialty and adding time for preparation and anesthesia emergence, the DORA model was able to show a significant reduction in the mean difference between the planned and actual duration of surgical procedures (8 ± 47 minutes). However, the SD of this difference (meaning 68% of the procedure durations are accurate within a window of 1.5 hours) is still high. No clinically relevant decline in this SD could be obtained by alterations to the DORA model. Additionally, in one in five sessions (19%) the overtime would not have been predicted by the DORA model either, resulting in procedure cancellations and overtime for OR personnel. We hypothesize this is due to the unpredictability that is intrinsic to surgery. Consequently, since the cause of this difference between the planned and the actual procedure duration cannot be prevented, this limitation can only be ‘treated symptomatically’. This highlights the urgency to implement automated real-time procedural progress monitoring.

Procedural progress monitoring in the OR is still in its infancy. By showing the real-time adjusted remaining duration of a procedure, all participants involved in the perioperative process are able to plan their activities and react to ad hoc changes in the OR schedule immediately [6]. This could provide a boost in efficiency regarding workflow in the patient ward, holding department, hospital transport, OR cleaning services, surgeon for the next procedure, etc.

Based on the DORA model, every procedure can be divided into phases. Using a technical system, as described, every phase can be real-time identified and compared to the

historical duration, thereby allowing a dynamic estimation of the remaining procedure duration. Although more detailed surgical phase segmentation and identification is not yet incorporated, implementing the presented system would already be a major first step forward in automated procedural progress monitoring. To obtain more precise information on the procedural progress, large databases should be created containing all kinds of operative information (e.g. anesthesia machine settings, usage pattern of electrocoagulation and other devices, etc.). Additionally, analysis of the video image is a promising option to automatically detect surgical phases [4, 12-14, 17]. Based on this method, Malpani et al. were able to detect surgical phases with an accuracy of 74% in a series of robotic hysterectomies [18]. The integration of more advanced big data analysis and surgical phase detection by video will allow segmentation within the surgical phase of the procedure. This will be an important improvement, since unforeseen factors during the surgery phase are the main cause of the large standard deviation in the estimated procedure duration [6, 19].

Multiple methods of predicting the remaining intervention duration have been described in the literature. Based on a surgical process model, Franke et al. were able to provide an accurate estimation of the remaining procedure duration (mean absolute error between 13 and 29 minutes) [6]. However, they needed a human observer to record surgical tasks. Tran et al. were able to perform phase segmentation based on automatic surgical workflow analysis from video images [17]. They were able to divide the laparoscopic cholecystectomy procedure into phases of 12.8 minutes on average, thereby potentially allowing more precise monitoring of the progress. Although these phases were appropriately determined in 84% of the time, their model was only applicable to a single type of procedure that was simulated in a laboratory setting.

The strength of our approach is that it can be applied to every surgical procedure. Furthermore, reference data (based on procedures performed in 2011) proved to be valid in a simulation of procedures performed in the next year. However, this is still a rigid way of obtaining reference data. In future models, reference data could be based on a number of the most recent procedures instead of the average from the previous year. This will ensure that the reference data are constantly kept up to date. Another advantage of this approach is that it allows the surgeon to take patient and procedure characteristics into account while planning the initial duration of the surgical phase. Afterwards, to correct for historical underestimation or overestimation, the surgeon-specific deviation is applied. This method of preoperative planning of the procedure duration is supported by prior research [20, 21]. Similarly, Travis et al. demonstrated excellent predictions by orthopedic and plastic surgeons and an average underestimation of 35 minutes by anesthetists, thereby highlighting the potential differences between specialties and the importance of taking ‘anesthesia time’ into account [22].

The power of large data registries and big data analysis has been recognized before [23]. Although a major limitation of the present study was the amount of missing data in our historical data, due to the high number of procedures ($N = 3,515$ & $N = 6,712$) and the fact that the reference data could be validated, the results support the assumption that the missing data did not have a significant influence on the accuracy of the estimation. Currently, in our hospital, fourteen time stamps need to be manually entered into the EPR system during the complete perioperative process (Figure 8.1). This obviously causes delayed, incorrect and missing data. Automation of the entry of these (and other) timestamps would ensure more accurate and more precise reference data. Consequently, this will result in an even better estimation of the remaining procedure duration. Entering accurate and meaningful data into the EPR – without repetitive chart review or the need to enter data manually – supports the ultimate goal of having clinical support tools that provide real-time information about the patients, their outcomes, and the quality of care that is being delivered [23].

In conclusion, the implementation of automated procedural progress monitoring to predict the remaining procedure duration will facilitate a transition from static to dynamic OR scheduling. This will make the next generation of ORs truly intelligent and would support all participants involved in the perioperative process to better plan their tasks instead of acting in a reactive manner, thereby enhancing patient safety [12].

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