



Peroperative analysis of the surgical procedure

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Abstract. The increased technological complexity of surgery and the growing importance of quality assessment demand objective analysis of the surgical process. However, until now no standard method existed for analyzing the peroperative process. In this article, a methodology is discussed to describe and to analyze the surgical process. A method is given to measure the correctness and efficiency of task performance, protocols, and instruments used. In addition, reference values are defined so as to compare new instruments, alternative protocols, and the performance of new tasks with a standard. Finally, recommendations are given for improving new surgical tasks, the development of clinically driven instrument design, and new protocols.

Key words: Time-action analysis — Surgical task performance — Instrument evaluation

Surgery is becoming more complex because with the introduction of new surgical techniques and instrumentation, more difficult operations can be achieved [13, 14, 31, 32]. To evaluate the quality of the peroperative surgical process, task performance and functionality of the instruments have to be analyzed objectively [7–9, 12, 24, 42]. However, the current quality analysis is mostly restricted to the analysis of the postoperative outcome of patients in terms of morbidity, mortality, survival, and the analysis of learning curves, which is generally expressed in complication rate and total operation times. For medical instruments, international standards exist for the design phase (medical device directives 93/42/EEC, prEN 1331, and ISO 9000/IEC guide 51), but no standards exist to evaluate the functionality of instruments objectively during peroperative use [7, 26, 28].

In aviation, nuclear power plants, and production processes, detailed process analysis is used to analyze the quality and efficiency of the process. Furthermore, in aviation extensive training and testing are performed in simulators before and after completion of the education. In surgery, similar analysis and training methods could be used to improve surgery.

This article describes a methodology to analyze the peroperative surgical process. The basic principles of process analysis will be described, and the terminology will be defined. The methodology analyzes the correctness and efficiency of task performance and the efficiency and limiting factors of the peroperative procedure in seven steps. As an example of the general method, the peroperative analysis of laparoscopic cholecystectomies will be discussed. Finally, recommendations will be provided, applying the methodology to support the training of surgical tasks and the development and evaluation of new instruments.

Description of the surgical process

In industry, methods for task analysis exist to analyze complex production processes including the modeling of human-machine interaction and the analysis of human errors or technological failures [25, 27, 40, 41]. A similar methodology can be used to describe and to analyze the surgical process [34]. As in industry, the first step in surgical process analysis is to distinguish the different subsystems, the parameters of the process (type of procedure, tasks, and basic actions), their mutual interactions, and the disturbances acting on the subsystems. The second step is to analyze the subsystems by evaluating the process parameters. The following subsystems can be distinguished:

- The person performing the tasks of the protocol (surgeon or resident)
- The person(s) assisting the surgeon (e.g., resident and instrumenting nurse)

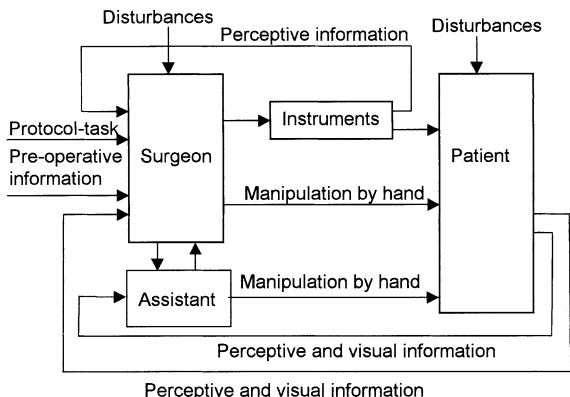


Fig. 1. Block diagram of the open surgical process. The surgeon can manipulate the tissue with the hands and with surgical instruments; both provide the surgeon direct feedback. In addition, the surgeon has direct 3D visual feedback. In the laparoscopic surgical process, the block diagram would be slightly different because the surgeon has no direct eye or hand contact with the tissue and only receives the perceptive and visual feedback information indirectly.

- The interface (operation instruments and instrumentation)
- The subject undergoing the actions (patient)

In open surgery, the subsystems of the surgical process can be represented in a block diagram (Fig. 1). Figure 1 shows that the surgeon operates using the hands and instruments to manipulate the tissue. In addition, the surgeon has to integrate information collected prior to the operation (preoperative diagnostic workup of the patient and prescribed tasks of the operation protocols) with the information collected during the operation (perceptive and visual information) [38]. The environment (e.g., operating room) can influence and may possibly disturb the surgical process. For laparoscopic surgery, the surgical process is different because the surgeon has no direct contact with the tissue (no direct “manipulation by hand”), no direct three-dimensional (3D) view on the operation field, and an unnatural line of sight, and his movements are displayed mirrored, scaled, and amplified on the monitor. Consequently, the perceptive and visual feedback information is only received indirectly by the surgeon, which makes the procedure different from open surgery. Consequently, the laparoscopic surgical process may have other difficulties than those of open surgery; hence, it may need different solutions than those for open surgery.

The surgical process will be analyzed from the surgical point of view, considering the surgeon as the central subsystem. The surgeon can be influenced by internal disturbances (mental and physical workload) or external disturbances (environment, functionality of the instruments, and health status of the patient). Both kinds of disturbances may influence the outcome of the surgical process. This article describes the analysis of the external influences on surgical performance; the physical or mental workload will not be studied.

For the analysis of the surgical process, three conditions have to be fulfilled. The process tasks and basic actions have to be distinguished and have to be defined

strictly. Next, quantitative measures have to be defined to enable a quantitative analysis of the process. Finally, the measured values have to be compared to reference values in order to draw conclusions from the analysis results.

Terminology

Process tasks and basic actions

In this article, a *protocol task* refers to the surgical task that is prescribed in the operation protocol. *Basic actions* are defined as the elementary components of which a protocol task is composed. For example, in order to dissect the cystic artery (protocol task in cholecystectomy), several basic actions have to be performed, such as stretching the gallbladder, dissecting the Calots triangle, and clipping the artery.

Quantification of the surgical process

The following measures are used to analyze the preoperative surgical procedure:

- The correctness of the task performance
- The efficiency of the peroperative parameters
- The limiting factors

The *correctness of the task performance* is determined by counting the number of correct and incorrect tasks performed as judged by experienced surgeons. Incorrect task performance can be defined as a task that is not (completely) performed or performed using the wrong technique. The *efficiency of the peroperative procedure* is determined by comparing an experimental procedure to a reference (standard procedure) with respect to (1) the time needed to complete a task or phase of the procedure and (2) the number of basic actions needed for each task or phase. The efficiency of the procedure can be determined for each protocol task or for each specific operation phase [9]. A useful division of the procedure is the division into *an opening, a dissection, a reconstruction, and a closing phase*, as described previously [7–9, 35].

The *limiting factors* are defined as factors that do not support the goal of the procedure (e.g., bleeding complications, technical problems, waiting for personnel, and superfluous action repetitions). The number and the types of the limiting factors are determined.

Reference values

To be able to determine the efficiency of a resident, a new protocol, or a new instrument, and also to interpret the outcomes, the measured values have to be compared to reference values [8, 12]. No *reference values* exist in surgery; therefore, they have to be defined and subsequently determined by analyzing standard procedures. A *standard procedure* has been defined as a procedure performed under current optimal conditions, e.g., using

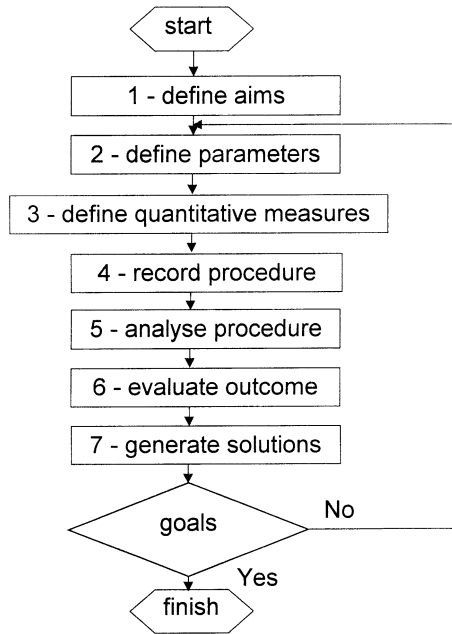


Fig. 2. Flowchart of a structured analysis of the peroperative procedure.

the best currently available instruments, performed by an experienced surgeon, assisted by an experienced team, and in accordance with the current standard protocols for that procedure [9].

Process analysis in seven steps

The flowchart in Fig. 2 shows seven steps to analyze the peroperative surgical process. Laparoscopic cholecystectomy (LC) will be used as an example to illustrate the seven analysis steps.

Step 1

The aim of each study should be defined exactly. The aim could be to improve the peroperative process or to compare different procedures by analyzing task performance (e.g., in LC, learning LC tasks), new instrumentation (e.g., evaluating the dissection of the gallbladder with bipolar instead of monopolar coagulation), or protocols (e.g., comparing LC versus open cholecystectomy).

Step 2

The surgical process has to be described by identifying the subsystems (e.g., surgeon, interface, and patient) and by defining the parameters. For example, possible protocol tasks for each operation phase of LC are defined in Table 1, basic actions in Table 2, and instruments in Table 3. The protocol tasks and basic actions can also be defined in more detail, if necessary [22].

Step 3

The measures to analyze the correctness and efficiency should be defined in accordance with the aim defined in Step 1, and the corresponding reference values have to be determined.

To *analyse task performance*, the correct and incorrect tasks as well as the efficiency of the task performance can be determined. For example, incorrect task performance can be scored for each protocol task of LC (Table 1) by an experienced surgeon. The efficiency of task performance of a resident can be determined by measuring the time and the number of actions needed to complete a task and to compare these with reference values (same set of instruments, comparable environment and patient, and same protocol tasks, but now performed by experienced surgeons).

To *analyze a new instrument*, the time, number, and type of basic actions and limiting factors of the dissection phase have to be defined and determined, as does the basic set of instruments used. The values obtained with the new instrument have to be compared with those of a currently available instrument with a similar function. For example, bipolar dissection in LC can be compared to the currently used monopolar coagulation. Limiting factors could be defined as the number of rebleedings after coagulation (monopolar or bipolar), the number of times that other tissue is coagulated unintentionally, the number of times one has to wait for the instrument, etc. The reference values are measured in a standard LC using monopolar coagulation instead of bipolar dissection [7].

To *evaluate protocols*, a new protocol should be compared to the current standard protocol [36]. For example, LCs were compared to the standard open procedure after the introduction of laparoscopic surgery. Initially, the postoperative outcome between both procedures was compared, followed by analysis of the peroperative process. Although the types of tasks differ between them, the efficiency per phase and the number of limiting factors could be compared objectively.

Step 4

The peroperative process has to be recorded using both video and voice recording. It is recommended to record an overview of all basic actions performed by the operating team simultaneously with a detailed image of the hands of the surgeon. Furthermore, the remarks of the surgeon should be recorded. Procedures are recorded to enable repeated detailed evaluations outside the operating theater without interference with the operative process. The total number of procedures that is necessary to determine accurate results for each study depends on the aim of the study and on the variability of the subsystems (e.g., surgeon and patient) and the disturbances. A resident will show larger fluctuations in the correctness and efficiency of task performance than will an experienced surgeon. In addition, the patients, the instruments, and the environment are never the same; therefore, their influence on the operation process al-

Table 1. Phases and protocol tasks of laparoscopic cholecystectomy

No.	Phase of operation	No.	Tasks		
1	Create CO ₂ pneumoperitoneum	1.1	Insert Veress needle		
		1.2	Insufflate the abdomen with CO ₂		
		1.3	Remove Veress needle		
2	Insert access ports	2.1	Insert 1st (optical) port		
		2.2	Insert laparoscope		
		2.3	Inspect abdomen		
		2.4	Insert 2nd port under direct sight		
		2.5	Insert 3rd port under direct sight		
		2.6	Insert 4th port under direct sight		
		2.7	Inspect possible bleeding site		
3	Dissect and expose cystic artery (CA) and cystic duct (CD)	3.1	Insert 1st forceps		
		3.2	Insert 2nd forceps		
		3.3	Insert 3rd forceps		
		3.4	Dissect adhesions to gallbladder (GB)		
		3.5	Dissect and mobilize Hartmann's pouch		
		3.6	Dissect and isolate the CD		
		3.7	Dissect and mobilize CA		
		4	Clip and transect CA and CD	4.1	Place two clips on proximal end of CA and CD
				4.2	Place clip on distal end of CA and CD
				4.3	Transect CA and CD between clips
5	Detach GB from liver bed	5.1	Dissect medial side of GB up to fundus		
		5.2	Dissect lateral side of GB up to fundus		
		5.3	Separate undersurface of GB from liver		
		5.4	Secure any bleeding from liver bed		
		5.5	Insert retrieval bag		
		5.6	Place GB in bag		
6	Final check and irrigation	5.7	Extract bag containing GB		
		6.1	Check and coagulate any bleeding site		
		6.2	Check CA stump and clips		
		6.3	Check CD stump and clips/ligature		
		6.4	Irrigate and suction operative field		
7	Close up patient	6.5	Control hemostasis		
		7.1	Remove irrigation fluid		
		7.2	Remove instruments		
		7.3	Remove operating ports		
		7.4	Check access wounds		
		7.5	Release CO ₂ from abdomen		
		7.6	Remove laparoscope		
		7.7	Remove optical port		
	7.8	Suture the port wounds			

ways varies. Consequently, strict selection criteria have to be defined for the patients, for the instruments used, and for the environment to reduce this variation. For example, patients undergoing elective LC could be included and acute cholecystitis excluded. The overview images and the image of the laparoscope should be recorded as well as additional images of laparoscopic ultrasonography or peroperative cholangiography using a video mixing device [9].

Step 5

The actual analysis of the peroperative process is performed, in accordance with the aim and objectives formulated in steps 1 through 3, using the video recordings. In addition, the postoperative outcomes of the patient should be controlled. The analysis results should be evaluated to detect problems or shortcomings of the tasks performed and instruments or protocols used. These results should be combined with the postoperative outcomes of the procedures. This combination of pre- and postoperative complication detection can provide

detailed insight into the existing clinical problems. For example, Branum et al. [10] showed the preoperative causes of major biliary complications after LC by evaluating the videotapes of the original operations. To reduce variation caused by the analysis, the observers have to be trained and, if possible, the recordings should be analyzed twice by different observers. In addition, the accuracy of the measured values should be controlled by calculating the standard deviations and by assessing the intra class correlation (ICC) coefficient for the inter- and intraobserver variation [33].

Step 6

When all problems and deficiencies are detected, the impact of each should be discussed in a multidisciplinary team consisting of experienced surgeons and other members of the operation team, engineers, ergonomists, designers, etc. For example, Joice et al. [22] noted that coagulation with the coagulation hook in LC caused most erroneous task performance.

Table 2. Basic actions and limiting factors of laparoscopic cholecystectomy

Action	Definition
Insert Veress needle	Insert the Veress needle through abdominal wall into peritoneal cavity
Prepare medical devices	Instruments, fluid irrigation system, coagulation, gas system, camera and light system
Insert 1st trocar	Insert the first trocar (blind) through abdominal wall into peritoneal cavity
Insert 2nd, 3rd, 4th, etc. trocar	Insert the 2nd, 3rd, 4th, etc. trocar through abdominal wall (under direct sight) into peritoneal cavity
Stretch	Stretch tissue in order to enable dissection (using graspers, retractors, etc.)
Dissect	Separate tissue (sharp and blunt) using forceps, scissors, hook (and/or coagulation, laser or ultrasonic coagulation, etc.)
Place clip	Place clip
Place suture	Placing a ligature
Palpate	Palpate tissue in order to obtain information about tissue characteristics or to clear the operation area using graspers or dissectors with closed tips
Inspect	Inspect the operation field or a specific structure using the laparoscope
Insert/ reposition/ remove instrument	Insert, reposition, or remove an instrument: forceps, scissors, retrieval bag, cannules, trocars, etc.
Extract tissue	Remove tissue (e.g., gallbladder) out of the abdominal cavity
Control bleeding site	Recoagulate, clip, or suture a (re)bleeding site after dissecting actions
Waiting for personnel	Wait for personnel handing over or preparing instrumentation; camera and light system, irrigation system, gas system, coagulating systems, anaesthesia Waiting for personnel carrying out an order; turn on/off light, pt. in (anti-)Trendelenburg
Waiting due to technical limitations	Waiting due to technical causes: correct gas pressure, sufficient lavage fluid inflow/outflow, problems with technological equipment
Cleaning	Clean the tip of an instrument or the camera
Irrigation/suction	Irrigate fluid into the abdominal cavity or to suck blood or fluid out of the abdominal cavity
Release CO ₂ gas	Release gas from abdomen
Close abdominal wounds	Close the abdominal wounds by suturing

Table 3. Instrumentation used during laparoscopic cholecystectomy

Veress needle
Trocars (1st, 2nd, 3rd, etc.)
Preparation forceps
Graspers
Scissors
Coagulation hook
Clip applicator
Laparoscope
Irrigation cannule
Retrieval bag
Optional (e.g., ligatures, ultrasonic instruments)

Step 7

Problems that most severely influence the patient's outcome negatively and problems with the highest impact on the quality of the operation should be reduced first by training tasks, optimizing instruments, or protocols. For example, in LCs the clinical problem with most negative impact is bile duct injury, commonly caused by incorrect task performance by the surgeon. The occurrence of bile duct injuries can be prevented by prescribing the dissection of the triangle of Calot as protocol task, by training these actions, and possibly by using improved instruments [10, 22, 39].

Recommendations for improvements

The training of tasks and the development of new instruments and protocols can reduce possible problems and can enhance the quality of operations. These changed or new instruments and tasks trained should be

evaluated in detail to control the actual improvements, for which the methodology described in this article can also be used. The training of tasks and development of medical devices and protocols can be evaluated at three stages: technical experiments, simulated experiments, and clinical settings (Table 4). Stepwise quality and efficiency analysis

Training surgical tasks

Training has two aspects—a learning aspect for the resident to acquire new tasks and a controlling aspect for the supervisor to evaluate the correctness of task performance and the efficiency of learning [1]. At stage 1, experiments are set up for training new surgical techniques in pelvi-trainers or virtual reality (VR) simulators (e.g., positioning tasks, passing and suturing drills, or tasks needed for specific procedures) [11, 19, 30]. In addition, the coordination between both the hands and the various instruments can be trained, which is especially complicated in laparoscopic surgery. At stage 2, animal experiments or VR simulations are used to train surgical tasks in a simulated clinical setting [16, 18, 21, 23, 29]. The clinical setting allows the trainees to learn to plan the operation tasks (protocol), the correct handling of tissue, and the prevention or correction of peroperative complications, in addition to pure task training. For example, laparoscopic courses for residents frequently use pelvi-trainers followed by laparoscopic cholecystectomies in pigs. At stage 3, the trained tasks are carried out in real operations, enabling the analysis of both the correctness and the efficiency of task performance [8]. The analysis of stages 2 and 3 can be performed as described in Fig. 2.

Table 4. Stepwise quality and efficiency analysis

Stage	Evaluation parameters		
	Device development	Protocol development	Training program
0. Instrument tests	Reliability Instrument characteristics Safety		
1. Technical experiment	Functionality Ergonomics Safety		Basic tasks or drills Coordination Correctness
2. Simulated experiment animal experiment	Functionality Ergonomics Safety	Safety Quality	Simulated surgical actions Simulated protocol tasks Tissue handling Planning operation Risk prevention
3. Clinical setting	Functionality Ergonomics Efficiency Safety	Safety Quality Efficiency	Planning operation Risk prevention Correctness Efficiency

Medical devices

For medical devices, a technical evaluation has to be performed to assess reliability, safety, and specific function tests (e.g., force characteristics, tactile feedback, sealing forces, or coagulation characteristics) of new medical devices before the functionality tests at stage 1 [6, 35]. At stage 1, functionality, safety, and ergonomics should be analyzed in a laboratory setting (e.g. in pelvi-trainers). At stage 2, the experimental setup should simulate the clinical setting, enabling analysis during clinical use, without risk for the patient [7, 17, 37]. If the quality and safety of the prototype have been proved to be sufficient, the instruments might be evaluated in clinical practice. [5]. Evaluation at stages 2 and 3 can be performed similar to the surgical process analysis described previously.

Protocol development

Protocols should be improved by changing logistics and/or protocol tasks (e.g., for cholecystectomies open as well as laparoscopic and minimal access protocols exist). New technology can support the improvement of protocols [36]. New protocols should be tested in simulated clinical settings and compared to the standard protocol (stage 2). If the quality and efficiency are significantly better, the protocol can be applied in a real clinical setting. Tasks of the new protocols should be trained during the three stages.

Discussion

In this article, a methodology is discussed to describe and to analyze the surgical process, providing extensive correctness and efficiency information from a limited number of analyzed procedures [5, 7, 9, 12]. Peroperative surgical analysis should be supplemented to the studies assessing postoperative morbidity, mor-

tality, and quality of life [10]. The problems indicated by the postoperative outcomes can subsequently be studied in more detail using time-action analysis [9, 12].

The methodology is not designed as a rigid manual because every surgical procedure has its own specific objectives, demanding the methodology to be flexible. For example, in a previous study we identified three categories of incorrect task performance: not, partially, or wrongly performed tasks [8]. More extensive error classifications can be defined as, for example, described in Joice et al. [22], resulting in very detailed error detection but at the expense of relatively time-consuming analysis. The level of detail has to be such that the objectives of the study can be achieved with a minimum of superfluous analysis steps. In addition, different measures can be used to analyze the peroperative process; for example, Sjoerdsma et al. [36] used the ratio between the number of goal-oriented actions and the total number of actions. Furthermore, the basic actions can be categorized as high-risk or low-risk actions during the analysis (e.g., clipping a cystic artery is potentially more dangerous than dissecting fat tissue). To facilitate the analysis, software is available to support routine observational examination, especially facilitating statistical data analysis (e.g., The Observer, Noldus, Wageningen, The Netherlands).

The study criteria have to be defined strictly by a team of experts. Experienced surgeons have to analyze the correctness of task performance, whereas a multidisciplinary team of experts have to evaluate the instruments' safety and functionality [8] Thereafter, part of the analysis can be performed by trained observers in order to save experts' time. [5, 7–9] In addition, close collaboration between surgeons, engineers, designers, ergonomists, and managers can support relevant problem solving, ensuring that clinically important problems are solved.

In aviation, process industry, and nuclear power plants, structured quality analysis of task performance is incorporated in the training program, and competence

control is repeated thereafter on a regular basis. In surgery, no recurrent competence control exists to evaluate surgical skills or competence. Most competence evaluations are still based on subjective personal judgments of residents, incidentally combined with the total operation time and post operative complication assessments [2, 3, 43]. The resident mostly trains for new tasks directly in the operating room under supervision of an experienced surgeon, who teaches, corrects, and controls the quality of the resident's task performance. Therefore, the training of residents depends on the clinical operations available and on the subjective judgment of supervisors, and it can be dangerous for the patient. The efficacy of training could be increased by additional training of tasks in laboratory or simulated clinical settings in combination with an objective evaluation of task performance [1, 18, 21, 23]. This could be achieved by a training program combining laboratory and clinical training settings. For example, bowel anastomoses can be reliably trained and recurrently tested using VR simulations. Detailed evaluation of training provides direct feedback information for the resident about his or her skills, indicating the specific individual problems that have to be trained more extensively [11, 16, 24]. The methodology described in this article could be used to introduce competence evaluation in the medical profession as in industry.

This article indicates the importance of standardization of methodology for evaluation of the efficiency and quality of task performance and instruments or protocols used. In the future, ergonomic variables could also be included because good ergonomic characteristics of the instruments and operation room (OR) environment will improve surgery by decreasing physiological and mental fatigue and discomfort of the surgeon [4, 27, 28]. In addition, methods to assess mental and physical workloads on surgeons could be developed and applied in order to detect and to reduce intolerable pressures [15, 20]. The information can optimize the planning of the OR, the operation protocols, and the preoperation diagnostics, adjusting them to the needs of the individual patient and the operation team and thus resulting in improved surgery and patient outcome.

Summary

In this article, a methodology is formulated to model and to describe the surgical process. It describes how to measure the correctness and efficiency of task performance, protocols, and instruments used. In addition, it describes how to compare new instruments, alternative protocols, or task performance with reference values. Finally, recommendations are given for improvements of new surgical tasks, the development of clinically driven instrument design, and new protocols.

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