ssessment using Time-Action Analys

Stellingen

Behorende bij het proefschrift "Surgical Task Performance"

1 Kwaliteit van chirurgisch handelen is meetbaar. (dit proefschrift)

2 De functionaliteit en efficientie van chirurgisch instrumentarium kan ook in een klinische situatie gemeten worden. (dit proefschrift)

3 In laparoscopische cholecystectomieën is een eenvoudige mechanische positioneerder (PASSIST) even efficient als een technologisch geavanceerde positioneerder (AESOP voice controlled robot) of een chirurgische assistent. (dit proefschrift)

4 Zonder eenduidige afspraken over referentiewaarden en -normen kan het begrip kwaliteit niet geoperationaliseerd worden, dit geldt met name als er met verschillende disciplines over eenzelfde kwaliteitsbegrip wordt gesproken.

5 De chirurgische opleiding kan efficienter worden als nieuwe techieken en vaardigheden eerst in een laboratorium getraind en getoetst zullen worden.

6 Tijd- en handelingenanalyse van het chirurgische proces kan als input dienen voor 'clinically driven design'.

7 Naast de eventuele klinische verbetering van een nieuw instrument moet de klinische relevantie van die verbetering getoetst worden.

8 Als de chirurg beter instrumentarium wil hebben, moet hij niet alleen blijven dokteren.

9 Gezien de opzet van hun opleiding zal een chirurg liever de eerste passagier van een piloot zijn dan dat een piloot de eerste patient van een chirurg is.

10 De komende schaarste aan artsen zal paradoxaal genoeg deeltijdwerk versneld mogelijk maken.

11 Kwaliteitsmeting en -toetsing van de medische kennis en vaardigheden nemen af naarmate de opleiding vordert. Deze toetsing stopt formeel als de opleiding beeindigd is.

12 Gedwongen onthaasting leidt tot stress.

Surgical Task Performance

Assessment using Time-Action Analysis

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Assessment using Time-Action Analysis

Proefschrift

ter verkrijging van de graad van doctor
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Rector Magnificus	Voorzitter
Prof. dr. ir. H.G. Stassen	Technische Universiteit Delft, promotor
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Prof. dr. ir. P.A. Wieringa	Technische Universiteit Delft
Dr. L. Th. de Wit	Onze Lieve Vrouwe Gasthuis, Amsterdam

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Ter herinnering aan

mijn Opa

Met dank aan mijn vader

1

Introduction

Background

Surgery lacks a standardized method to analyse the operative process objectively. Detailed operative analysis is considered important because surgeons indicate various operative problems, especially during the ever increasing technological complexity of the surgery.[1-4] In addition, the rapidly growing variation and complexity of instruments demand objective clinical evaluation.[5-7] Objective problem analysis requires a method which can measure the quality and safety of the surgical process. Analysis of the peroperative process is expected to provide detailed insight into the surgical process, eventually enabling a better control and improvement of the process.[8-11] Because surgery lacks such a method, the research described in this thesis aims to develop an objective method for the analysis of the peroperative surgical process. Recently, the first step towards a surgical process analysis resulted in a time-action analysis of surgical procedures. Time-action analysis evaluates the time, the type and the number of basic actions in order to provide insight into the efficiency of the peroperative process.[3;12;13]

The current state of quality analysis in surgery

Several studies in literature stress the importance of quality assessment and expertise in surgery in reducing mortality rates, in-hospital stay, and costs.[2; 14-16] Furthermore, clinical guidelines promote best practices to improve the outcomes of treatment.[17-19]

Current quality analysis of task performance is mostly restricted to learning curve analysis, expressed in total operation times and occurrence of post-operative complications.[20-23] In the literature it is assumed that a surgeon is experienced if the total operation time and complication rates are stabilized at a certain minimum level after a number of procedures, varying from 5 to over 25 procedures. However, learning is not restricted to a reduction in time. Sjoerdsma introduced a methodology to distinguish goal-oriented and non-goal-oriented actions of the surgeon in the peroperative process, thus providing insight into the efficiency of the operation.[12] No standardized method is available to assess the quality of education or the safety of task performance. To enable the analysis of the peroperative quality and safety, the actual correctness and efficiency level of peroperative task performance have to be measured.[3; 13; 24; 25] The growing variation in procedures and techniques increases the need for more detailed task analysis in surgery.

Current quality analysis of surgical instruments is mostly restricted to laboratory testing.[5;6] International standards have been formulated for medical instrument development, prescribing structured risk analysis during the design process, and testing whether the essential quality requirements are met.[7; 26] In general, the development of new instrumentation follows a cyclic process: analysis of the process → new concept → engineering drawing → prototype construction → evaluation (technical, experimental, clinical) → new or altered concept.[7; 27] Initial prototypes are evaluated in laboratory and surgical skill training settings to document their function and to determine any limitations that may require modifications of the original specifications.[5; 28-31] All instruments for clinical use should be manufactured according to international standards (medical device directives 93/42/EEC, prEN1331, ISO 9000/IEC guide 51).[7] Clinical testing usually follows after the laboratory testing of the instruments. Current clinical testing evaluates the post-operative complication reduction, the change in total operation times, or investigates the subjective comfort of the surgeon and easy handling of the instrument.[31; 32] Instruments and techniques are rarely analysed objectively with respect to the clinical functionality or efficiency.[5; 6] The rapidly growing variation in instruments increases the need for objective comparison of instruments, techniques, and extra costs, to support accurate decision-making.

Summarizing, surgery lacks a standardized method to measure the actual efficiency level or correctness of task performance, or to assess the quality of training, and the functionality of medical devices, during the peroperative process. Consequently, a surgical process analysis has to be developed. This can be done using analysis methods developed in industry, because the surgical process can be considered to be a complex process, similar to complex processes found in industry.

Industrial process analysis

In industry, complex systems are analysed to improve the safety, the efficiency, the quality, and the work environment of the process.[8]

Taylor, one of the pioneers of process analysis, introduced time measuring of process variables in 1881.[33] He improved the productivity of the Midvale Steel company by determining time standards for standardized jobs and by separating the planning from the execution of work.[34] In 1885 Gilbreth introduced another method using motion studies.[35] He analysed the basic actions of bricklayers by studying photographs of bricklayers at work.

In order to analyse a process, a successful way is to model the system, in order to describe and to improve the safety and productivity of the process. The system can be modelled by measuring the input u(t) and output y(t) of the process (Fig. 1); often disturbances v(t) act also on the system. The causal relations between the input u(t) and output y(t) will lead to a model of the system.

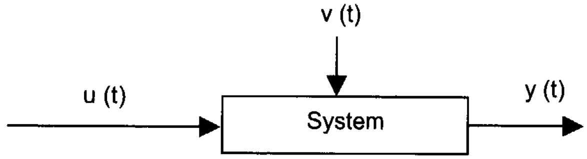

Figure 1. Block diagram, representing the system as a black box, with input u(t), output y(t), and possible disturbances on the system v(t).

More detailed insight into the system is obtained by breaking down the system into its constituent components (subsystems) and by evaluating the causal relations of the subsystems.[8] Figure 2a, shows a description of an industrial process with the Human Operator (HO) as one of the system components. The input u(t) prescribes the goal or set point of the industrial process. The output y(t) of the process is fed back and is compared with the process goal. The HO acts as the controller by performing actions using the controls of the Man Machine Interface (MMI), and by observing the output y(t) via the Displays. Possible disturbances can act on the system, e.g. environmental disturbances v(t) act on the process, and performance shaping factors w(t) can act on the human operator.

The surgical process as a complex system

In Fig. 2b, the surgical process is described as a complex system. The tasks of the operation protocol are the input u (t) for the surgeon. The surgeon uses instruments and hands to perform the surgical actions on the patient. The surgeon receives proprioceptive and visual feedback giving information y (t) whether the protocol tasks are achieved.

In accordance with process analysis in industry, the surgical process analysis should firstly break down the process into its subsystems by identifying them (surgeon, instruments, patient). Secondly, quantitative measures should be developed to analyse the peroperative process. The task u(t) should be well-defined, and if possible the variables v(t) and w(t) should be estimated. Thirdly, the outcomes of the analysis should be judged using reference measures. Finally, problems of the process should be analysed and solutions be generated to reduce the problems and to improve the surgical process.

As Fig. 2a and 2b show, the surgical process and the industrial process can be described similarly. Therefore, surgery can learn from industrial process analysis how to analyse the process in order to get insight into the operative process and its problems. Objective insight into the surgical process is urgently needed because surgery lacks a standardized method as was explained in the previous sections.

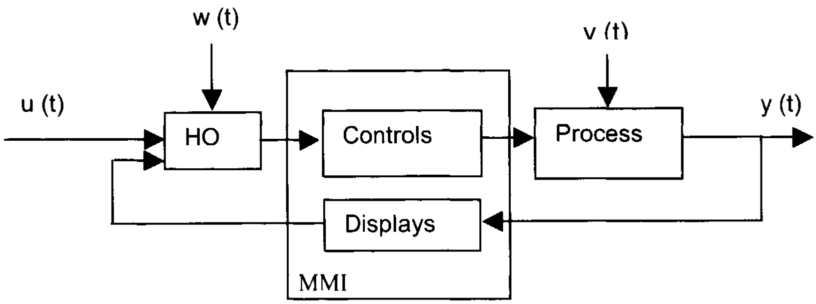

Figure 2a. *Industrial system, with input u(t), output y(t), and possible disturbances v(t) and w(t), HO = Human Operator, MMI = Man Machine Interface (adapted from Stassen et al. [11])*

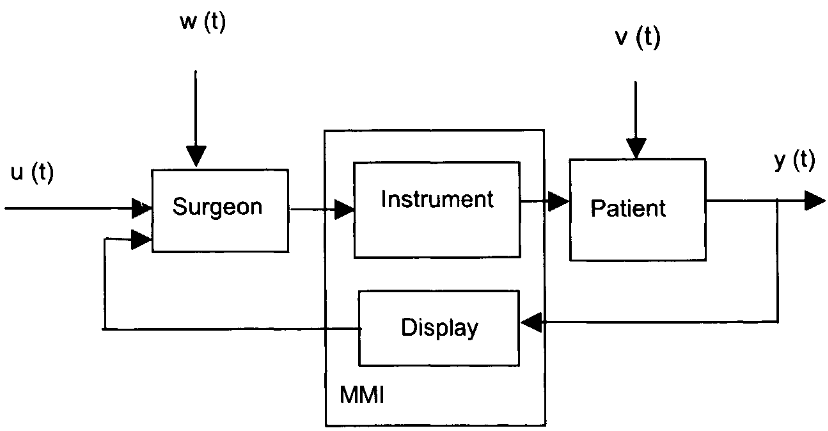

Figure 2b. *Surgical process, with the operation tasks as input u(t), output y(t), possible disturbances v(t) and w(t), and visual and tactile feedback information via display, MMI = Man Machine Interface (adapted from Stassen et al. [11])*

Aim of the thesis

This thesis aims to develop a method to analyse and to improve the peroperative surgical process. The analysis method should:

- Measure the quality, efficiency, and detect difficulties of surgical task performance and instruments in quantitative terms;
- determine current reference values for the quality and efficiency of surgical task performance and instruments.

Impact

Process analysis is considered to be important because the analysis can provide insight into the peroperative process. The analysis results provide a frame to discuss the detected peroperative problems in a multidisciplinary team consisting of surgeons, paramedical staff, and engineers. This multidisciplinary team can generate solutions for the peroperative problems, in order to improve the process. Process analysis can provide among others, insight into the problems of surgical task performance and instruments.

Insight into the surgical task performance can be used to:

- Detect specific task performance problems;
- select the most efficient and safe operation protocol;
- support the surgical education by providing insight into the learning of tasks;
- measure the actual skill level of surgeons performing a certain operation.

Insight into the use and function of the instruments can be used to:

- Detect specific technological problems in a clinical setting, supporting clinically-driven design;
- select the current best set of instruments;
- measure the clinical improvements of new instruments, by comparing objectively the currently available instruments with new prototypes.

For the patient, the improved surgical process can result in less complications, reduced period of anaesthesia, improved quality of surgery, shorter duration of illness. This will possibly reduce the morbidity and mortality rates and increase the quality of life of the patients. The improved surgical process can lead to a more efficient surgical treatment. The quantitative results of this method support objective decision making to select the current best set of alternatives.

Outline of the thesis

This thesis describes the development of a methodology for peroperative analysis of the surgical process in quantitative terms. As a consequence, measures are defined for both the quality and the efficiency of the tasks and basic actions performed by the surgeon, and for the instruments used by the surgeon. Reference measures are defined to interpret the outcomes. This thesis mainly focuses on the analysis of laparoscopic surgery, because laparoscopy involves a more complex operational technique compared to conventional open surgery. Laparoscopy lacks direct vision and touch, has different hand eye coordination and depends strongly on the technology applied. The surgical process will be analysed to detect the shortcomings of the peroperative process, and to help to translate a clinical problem into a technical problem definition.

Chapter 2 describes a questionnaire used to investigate expert knowledge about difficulties of the surgical instruments during operations. Twenty experienced laparoscopic surgeons have been questioned to identify which laparoscopic instruments are prone to cause peroperative complications and which technical factors contribute to that risk. The results identify those instruments which are considered to be clinically dangerous. The questionnaire also provides an opportunity for engineers and surgeons to discuss and to translate the clinical problems into technical problem specifications.

Chapter 3 and 4 evaluate the quality and efficiency of diagnostic laparoscopies using time-action analysis. Chapter 3 analyses the current peroperative problems of instruments used and protocols applied in diagnostic laparoscopy, and identifies reference measures by determining a standard diagnostic laparoscopy. Chapter 4 evaluates the correctness and the efficiency of the task performance of a resident relative to an experienced surgeon in diagnostic laparoscopies. It defines measures to evaluate the quality and the efficiency of learning new laparoscopic tasks in quantitative terms.

Chapters 5 to 7 describe the evaluation of instruments in three phases of the development: in a laboratory setting, in a simulated clinical setting, and during actual operations. Chapter 5 describes specific functionality tests of a prototype in a laboratory setting. It evaluates the sensory feedback quality of a new low friction laparoscopic dissector and of currently used laparoscopic instruments. Chapter 6 describes the second evaluation step for instruments: evaluation in a simulated clinical setting. This chapter compares the functionality, efficiency, and shortcomings of three surgical dissection techniques, in an animal model. Chapter 7 describes the third and final checking step: evaluation in clinical practice. Passive and active instrument positioners are evaluated, comparing the outcomes of conventional laparoscopic cholecystectomies performed with a surgical assistant, with laparoscopic cholecystectomies performed usings instrument positioners instead of an assistant.

Finally, Chapter 8 combines the elements of the Chapters 3 to 7 to describe a general methodology for process analysis of the surgical process, analysing the peroperative procedure in quantitative terms. This chapter formulates seven steps to analyse each surgical process with respect to the correctness and efficiency of task performance, instruments and protocols used. Chapter 9 entails the conclusions of the research and provides recommendations for future research.

References

1. Satava RM. Surgery 2001, a technological framework for the future. Surg Endosc 1993; 7:111-113.
2. Cuschieri A, Ferreira E, Goh P, et al. Guidelines for conducting economic outcomes studies for endoscopic procedures. Surg Endosc 1997; 11:308-314.
3. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA. Quantitative standardised analysis of advanced laparoscopic surgical procedures. Endosc Surg Allied Technol 1995; 3:210-213.
4. Cuschieri A, Melzer A. The impact of technologies on minimally invasive therapy [editorial]. Surg Endosc 1997; 11:91-92.
5. Boer den KT, Straatsburg IH, Schellinger AV, Wit de LT, Dankelman J, Gouma DJ. Quantitative analysis of the functionality and efficiency of three surgical dissection techniques; a time-motion analysis. Laparoendosc & Adv Surg Techn 1999; 9:389-395.
6. Joice P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery-a human reliability analysis. Applied Ergonomics 1998; 29:409-414.
7. Mattsson F. An introduction to risk analysis for medical devices. Complicance Engineering European Edition 1995; 6:29-38.
8. Kirwan B, Ainsworth LK. A guide to task analysis - The task analysis working group. London: Taylor and Francis, 1993;
9. Reason J. Human Error. New York: Cambridge University Press, 1998;
10. Rasmussen R. Skills, rules and knowledge; signals, signs, and symbols, and other distinctions in human performance models. IEEE Transactions on Systems, Man and Cybernetics SMC 1983; 13:257-266.
11. Stassen HG, Dankelman J, Grimbergen CA, and Meijer DW. Man-machine aspects of minimally invasive surgery. 7-18. 1998. Proceedings of the 7th IFAC Symposium on Analysis, Design and Evaluation of Man-Machine Systems; September 16-18, Kyoto, Japan. Conference Proceeding
12. Sjoerdsma W. Surgeons at Work. 1998. Thesis at Delft University of Technology. Thesis/Dissertation
13. Boer den KT, Wit de LT, Gouma DJ, Dankelman J. Per-operative Time-Motion Analysis of Diagnostic Laparoscopy with Laparoscopic Ultrasonography. Br J Surg 1999; 86:951-955.
14. Cuschieri A. Whither minimal access surgery: tribulations and expectations. Am J Surg 1995; 169:9-19.

15. Lieberman MD, Kilburn H, Lindsey MBMF. Relation of Perioperative Deaths to Hospital Volume Among Patients Undergoing Pancreatic Resection for Malignancy. Ann Surg 1995; 222:638-645.
16. Gordon TA, Bowman HM, Tielsch JM, Bass EB, Burleyson GP, Cameron JL. Statewide Regionalization of Pancreaticoduodenectomy and its Effect on In-Hospital Mortality. Ann Surg 1998; 228:71-78.
17. Agachan F, Joo JS, Sher M, Weiss EG, Nogueras JJ, Wexner SD. Laparoscopic colorectal surgery. Do we get faster?. Surg Endosc 1997; 11:331-335.
18. Society of American Endoscopic Surgeons (SAGES). Framework for postresidency surgical education and training-a SAGES guideline. Surg Endosc 1994; 8:1137-1142.
19. Feder G, Eccles M, Grol R, Griffiths C, Grimshaw J. Clinical guidelines - Using clinical guidelines. B M J 1999; 318:728-730.
20. Bennett CL, Stryker SJ, Ferreira MR, Adams J, Beart RW, Jr. The learning curve for laparoscopic colorectal surgery. Preliminary results from a prospective analysis of 1194 laparoscopic-assisted colectomies Arch Surg 1997; 132:41-44.
21. Deschamps C, Allen MS, Trastek VF, Johnson JO, Pairolero PC. Early experience and learning curve associated with laparoscopic Nissen fundoplication. J Thorac Cardiovasc Surg 1998; 115:281-284.
22. Higashihara E, Baba S, Nakagawa K, et al. Learning curve and conversion to open surgery in cases of laparoscopic adrenalectomy and nephrectomy. J of Urology 1998; 159:650-653.
23. Liem MS, van SC, Boelhouwer RU, et al. The learning curve for totally extraperitoneal laparoscopic inguinal hernia repair. Am J.Surg 1996; 171:281-285.
24. Boer den KT, Wit de LT, Davids PHP, Dankelman J, Gouma DJ. Analysis of the quality and efficiency of learning laparoscopic skills. Surg Endosc 2001; 15: 497-503
25. Traverso LW, Koo KP, Hargrave K. Standardizing laparoscopic procedure time and determining the effect of patient age/gender and presence or absence of surgical residents during operation, a prospective multicenter trial. Surg Endosc 1997; 11:226-229.
26. Rau G, Radermacher K, Thull B, von PC. Aspects of ergonomic system design applied to medical work systems computer integrated surgery. In Taylor RH, Lavallee S, Burdea GC, Mösges R., eds. Computer Integrated Surgery - Technology and Clinical Applications. MIT Press, 1996; 203-221.
27. Tendick F, Jennings RW, Tharp G, Stark L . Sensing and manipulation problems in endoscopic surgery: Experiment, analysis, and observation. Presence 1993; 2:66-81.
28. Sjoerdsma W, Herder JL, Horward MJ, Jansen A, Bannenberg JJG, Grimbergen CA. Force transmission of laparoscopic grasping instruments. Min Invas Ther & Allied Technol 1997; 6:274-278.
29. Frank TG, Cuschieri A. Prehensile atraumatic grasper with intuitive ergonomics. Surg Endosc 1997; 11:1036-1039.
30. Melzer A, Kipfmüller K, Halfar B. Deflectable endoscopic instrument system DENIS. Surg Endosc 1997; 11:1045-1051.
31. Edelman DS, Unger SW. Bipolar Versus Monopolar Cautery Scissors for Laparoscopic Cholecystectomy: A Randomized Prospective Study. Surg Laparosc Endosc 1995; 5:459-462.

32. Spivak H, Richardson WS, Hunter JG. The use of bipolar cautery, laparosonic coagulating shears, and vascular clips for hemostasis of small and medium-sized vessels. Surg Endosc 1998; 12:183-185.
33. Taylor FW. The principles of scientific management. New York: Without publisher. Library of the Delft University of Technology, 1915
34. Juran JM, Gryna FM. Quality planning and analysis. New York: McGraw-Hill, 1980;
35. Barnes RM. Motion and time study: Design and measurement of work. New York: John Wiley & Sons, 1980

2

Problems with laparoscopic instruments;
opinions of experts

K.T. den Boer, T. de Jong, J. Dankelman, D.J. Gouma.
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Abstract

Introduction: Laparoscopic surgery is particularly known for its complex technique, which calls for operative analysis of laparoscopic instruments. This study investigated the opinion of experts about clinical problems with instruments occurring during laparoscopic surgery.

Methods: A questionnaire was used to obtain the opinions of expert laparoscopic surgeons about difficulties experienced operatively, using laparoscopic instruments.

Results: The laparoscopic surgeons indicated that coagulators were especially prone to cause lesions of the gastro-intestinal tract, vascular and bile duct injuries. Dissectors were considered to play a role in the occurrence of solid organ and bile duct injuries, and retractors to cause solid organ injuries. Insufficient functionality of the instruments and insufficient quality of the image were indicated to contribute mostly to the instrument's risks.

Conclusion: The questionnaire identified technological deficiencies prone to cause operative complications. The results provided a basis for the interaction between surgeons and engineers and serve as pilot information on which to base an in-depth objective evaluation of instrument problems.

Introduction

Functional analysis of surgical instruments during operations is important to identify the clinical problems of instruments during operative use.[1-4] Laparoscopic instruments in particular are indicated by surgeons to have technological deficiencies and poor ergonomics.[1; 2; 5-10] New laparoscopic instruments are frequently introduced without accurate clinical testing, or even without evident clinical need. Moreover, the quality of surgery currently tends to be evaluated by post-operative outcomes, morbidity or mortality rates, and quality of life parameters.[11] Available knowledge in literature does not provide detailed insight into the actual operative complications or risks, nor into the technological failures causing complications.[12] Therefore, operative analysis is needed to identify the clinical problems of instruments. These clinical problems can provide input for clinically driven instrument design.

For effective and profound analysis of the instrumental problems, close collaboration should be established between clinicians and engineers. Figure 1 shows the process of problem analysis; problem related information has to be acquired, understood, and integrated by the engineer and clinician. The available knowledge in literature has to be analyzed and combined with the knowledge of experts. The engineer and the surgeon should work together to translate the clinical problem description into technological design specifications, because the clinical problem experienced by the surgeon does not

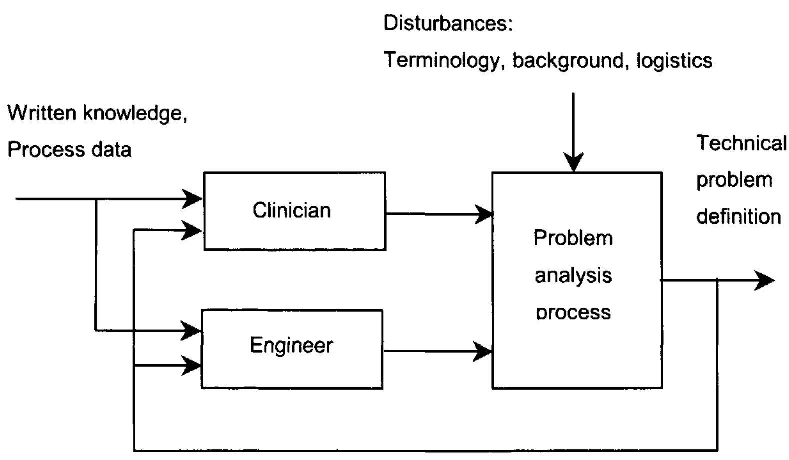

Figure 1. *Clinically driven instrument design requires close communication between clinician and engineer. The joint problem analysis process is shown, leading to a detailed technical problem definition after several cycles.*

necessarily point out the underlying technological deficiencies directly. The problem analysis process can be disturbed due to different languages and different interpretations of terminology, caused by different backgrounds of the disciplines. Questionnaires can be used to identify expert knowledge about operative problems, pointing out very efficiently the most important problems experienced by surgeons.

This study used a questionnaire to identify expert knowledge about operative problems of laparoscopic instruments. The opinions of twenty experienced laparoscopic surgeons were assessed with respect to technological deficiencies of laparoscopic instruments in the peroperative process.[13]

Methods

Questionnaire

Twenty experienced laparoscopic surgeons were selected among the Dutch Society of Endoscopic Surgery. After a short introduction about the questionnaire (aim, example), the surgeons were asked to describe the number and type of procedures they had performed over the last 10 years, indicating their laparoscopic experience. In addition, they were asked to specify the general characteristics (brand, disposable/reusable) of the instruments regularly used. Subsequently, the laparoscopic surgeons completed the questionnaire, using their expert knowledge of peroperative complications and technological deficiencies of instruments based on literature, personal experience, and the experience of colleagues.

The questionnaire was restricted to intra-abdominally used laparoscopic instruments, because failures due to the Veress needle, the trocars, or the creation of the pneumoperitoneum have already been studied extensively.[14] The laparoscopic instruments were selected from the instruments listed in operation manuals used at the Academic Medical Center of Amsterdam (Table 1).

The most frequently described operative complications in literature were included in the questionnaire. These complications were grouped into 6 categories; 3 categories consisting of general laparoscopic complications which were assessed in most types of laparoscopic procedures, and 3 categories of procedure type related complications (Table 1). Conversion was included as a 7th complication group, despite the fact that it is usually not regarded as a complication in literature, but the need to convert is frequently linked to technological limitations due to the laparoscopic approach.

The technological deficiencies of laparoscopy reported in literature were included in the questionnaire. These deficiencies were grouped into 5 categories, which are also listed in Table 1. Insufficient functionality includes instruments hampering correct task performance due to damaged or inappropriate designs.[1; 2; 10; 15-17] Insufficient ergonomics includes deficiencies due to inadequate workplace and instrument design, resulting in back pain, finger numbness, and muscle fatigue.[2; 5; 8; 9; 18-20] The quality of the image was defined insufficient if the camera image was disturbed or did not provide a clear overview of the complete area where manipulations were carried out.[21-23] Disturbed depth perception is caused by the indirect two dimensional view on the operation field through a camera. [22; 23] Eye-hand co-ordination in laparoscopy is disturbed as a result of the unnatural line of sight; surgeons look at a monitor image instead of their hands performing the tasks (display-control discordance, and mis-orientation).[21-23] Furthermore, hand movements are displayed mirrored, scaled, and amplified on the monitor, which may result in manipulation difficulties during the operative process.

Table 1. *Aspects considered in the questionnaire; the selected instruments, the complications they might cause, and their possible technological deficiencies*

Instruments	Complication groups	Technological factors
Grasping forceps	*General complications*	Insufficient functionality
Scissors	Gastro-intestinal injury	Insufficient ergonomics
Dissectors	Vascular injury	Insufficient image quality
Coagulator	Solid organ injury	Depth perception problem
Ultrasonic dissector	*Procedure related*	Eye-hand coordination
Clip applicator	*complications*	problem
Needle holder & needle	Bile duct injury	
Retractor	Appendix stump leakage	
Irrigation / suction instr.	Dysphagia	
Retrieval bag	*Conversion*	
Loop		

The questionnaire used rating scales to depict the role of instruments in causing operative complications and their underlying technological deficiencies. Experienced surgeons were asked to rate the role of the instruments in causing particular operative complications on a scale ranging from 1 (no role) to 5 (maximum role). Likewise, the surgeons were asked to rate the contribution of the instrument's potential technological deficiencies to the complications (scale 1=no role, scale 5=maximum role). Figure 2 shows an example of the questionnaire for gastro-intestinal tract injuries. The other complication groups were designed equally. The surgeons first indicated the instruments at risk by marking the rating score in the first column. The surgeons rated the other columns (technical factors) for instruments with scores higher than one. Afterwards, time was arranged for additional remarks of the experts concerning specific problems of instruments, suggestions for improvement and remedies to prevent complications caused by instruments. The surgeons were interviewed on site to guarantee accurate and integral completion of the questionnaire, which took approximately half an hour each person.

GASTRO-INTESTINAL TRACT INJURY, e.g.: • Bowel • Esophagus • Stomach		Relative role of technical factor				
		Quality of Image	**Depth perception**	**Functionality**	**Ergonomics**	**Eye-hand coordination**
		Undisturbed, clear view at the entire field of operation.	An optimal perception of three dimen-sional proportions.	The intended intervention can adequately be performed with the instrument.	The intervention can comfortably be performed with the instrument.	A reliable perception of the direction and speed of movement during the intervention.
Instrument	**Role**					
	No 1 — Max. 5	No 1 — Max. 5	No 1 — Max. 5	No 1 — Max. 5	No 1 — Max. 5	No 1 — Max. 5
Grasping forceps	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Scissors	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Dissectors	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Coagulator on instrument	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Ultrasonic dissector	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Clip applicator	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Needle holder (+needle)	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Retractor	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Irrigation-suction channel	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Retrieval bag	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o
Laparoscope + light source	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o	o o o o o

Figure 2. *Example of one page (one complication group) of the questionnaire, concerning gastro-intestinal injuries, to rate instrument's risks and their technological deficiencies on a scale from 1-5.*
The other complication groups are designed equally.

Data analysis

The magnitude of the instrument's role was calculated by averaging the expressed ratings for the instruments' role (rating from 1 to 5). Instruments rating higher than 3 were considered to involve a serious risk in causing complications. The mean contribution of each technological factor contributing to that risk was determined, also by averaging the expressed contribution for each technical factor for each instrument.

Results

The twenty surgeons had performed a mean overall number of 977 laparoscopic operations (with a maximum of 2500) during the past 10 years, of which a mean number of 485 laparoscopic cholecystectomies, 67 laparoscopic appendectomies, 32 laparoscopic fundoplications, and a rest group of 393 other laparoscopic operations. Reusable instruments were more frequently used by the surgeons than disposable instruments, because of the lower costs. Storz® (Tuttlingen, Germany) and Ethicon® (Inc., Johnson & Johnson, NJ, USA) provided the greater part of the brands used, 26% and 25%, respectively.

The overall number of times the coagulator was pointed out to play a role in causing complications was highest (71%), followed by dissectors (61%), and grasping forceps (53%). Figure 3a shows the instrument scores rated by the surgeons for gastro-intestinal complications, vascular injuries, and solid organ injuries. Coagulators are shown to be of highest overall risk (>3) in causing all three general complications. Grasping forceps are indicated to be especially prone to cause gastro-intestinal and solid organ injuries; dissectors and retractors are especially prone to cause solid organ injuries. Figure 3b shows the mean instruments scores for the three procedure-related complications, indicating that coagulators and dissectors are regarded to be of serious risk in causing bile duct injuries. The loop is indicated to be prone to cause appendix stump leakage.

Table 2 shows the contribution of the five technological deficiency categories to the risks of the instruments (coagulators, dissectors, graspers). Insufficient functionality is indicated most frequently as the main technological limitation, followed by inadequate ergonomics. Good image quality is mostly indicated to be an initial requirement (the application of any instrument is dangerous without a clear image). Disturbed depth perception and eye-hand co-ordination are particularly indicated to be a problem to inexperienced surgeons.

Table 2. *Mean contribution score of each technological deficiency to the instrument's risk, assigned by the surgeons on a scale from 1 (not important) to 5 (most important).*

	insufficient functionality	insufficient ergonomics	insufficient image quality	disturbed depth perception	disturbed eye-hand coordination
Coagulator	3.3	2.6	2.9	2.7	2.4
Dissectors	3.3	2.9	2.8	2.8	2.4
Graspers	3.5	2.8	2.5	2.4	2.2

Additional remarks

The surgeons could make additional remarks after completion of the questionnaire, without being restricted to rating scales. These remarks are stated as they were expressed by the surgeons. They usually complemented the questions of the interview with personal experiences or solutions for technological problems.

The coagulator was considered to be a highly dangerous instrument, due to disturbed or insufficient functionality: e.g. electricity leakage, insufficient insulation, incorrect setting, sparking, defects of cables and connectors, no ability of sealing large caliber vessels, coagulation outside the camera image, and smoke production obscuring the image. The coagulation hook was considered dangerous due to the sharp edges, which increase the risk of damage if they are applied with a slight force overshoot. The retractor was considered hazardous in causing solid organ injuries, because retractors have a small surface compared to the human hand, have sharp edges, lack tactile and proprioceptive feedback, making it difficult to control the instrument cautiously. An additional problem of the retractor is that it is out of sight during a significant part of the operation; there is no visual guidance and injuries can develop unnoticed. The grasping forceps were considered to have similar shortcomings as the retractor, resulting once more in a thin line between grasping sufficiently firm and causing trauma.

For conversion, deficiencies of the laparoscope or light source were most frequently mentioned as the direct urge to convert to an open procedure, due to a contaminated scope and smoke production. The problems with the image might be reduced by improving the laparoscopic irrigation/suction channel, or by expanding the degrees of freedom of the laparoscope with an extra hinge. The opinions about three-dimensional imaging technology varied between the surgeons, but depth perception was indicated as a technological factor that should be improved in laparoscopy.

Overall design remarks: surgeons demanded firm, reliable, simple instruments. They suggested that in future advanced technologies should be applied to make instruments multifunctional, to expand the degrees of freedom of instruments and to improve tactile and proprioceptive feedback, and improve the quality of image.

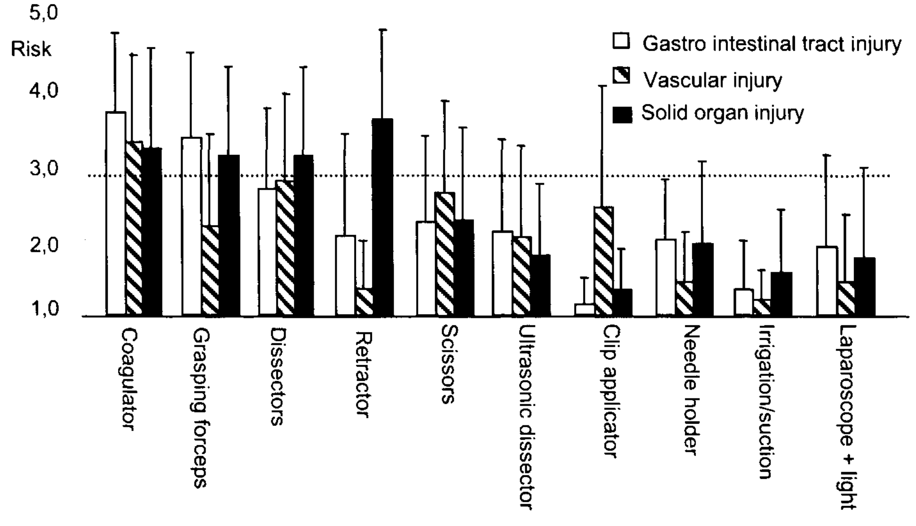

Figure 3a. *The average risk to cause a general complication for each instrument. White bars represent the average risk to cause gastro-intestinal tract injuries, striped bars the average risk to cause vascular injuries, and black bars the average risk to cause solid organ injuries. A score >3 was defined as a serious risk, which margin is indicated by the dashed line. Error bars are shown on top of each bar, representing one standard deviation.*

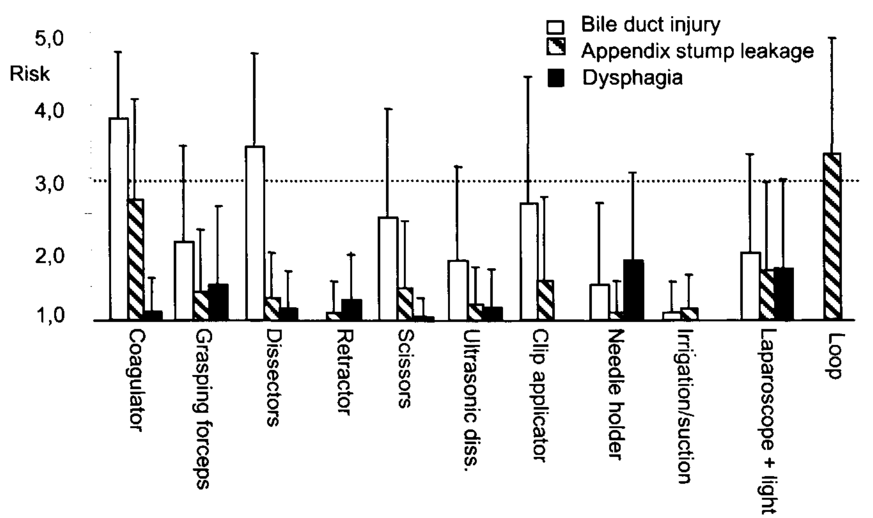

Figure 3b. *The average risk to cause a procedure related complication for each instrument. White bars represent the average risk to cause bile duct injuries, striped bars the average risk to cause appendix stump leakage, and black bars the average risk to cause dysphagia. A score >3 was defined as a serious risk, which margin is indicated by the dashed line. Error bars are shown on top of each bar, representing one standard deviation.*

Discussion

The study showed that coagulators were considered to be especially prone to cause operative complications, followed by graspers and then dissectors. The complications were merely indicated to be caused by disturbed or inappropriate functionality or ergonomics of the instrument. Consequently, better alternatives have to be found firstly for coagulators, graspers and dissectors. For the coagulator, alternatives have already been introduced (e.g. bipolar coagulation and ultrasonic dissection), which could probably solve the problems of electricity leakage, incorrect setting, sparking, no ability of sealing big vessels, and smoke production. For the graspers and dissectors, improved alternatives are worked on by the Minimally Invasive Surgery and Interventional Techniques (MISIT) program of the Delft Interfaculty Research Center on Medical Engineering. The MISIT program uses among others the present study as input for the technological design specifications.

A disadvantage of questionnaires is that they are subject based and the results should be interpreted with care. Anonymity, motivation, and rating scales were used to reduce possible distortions in this study. In addition, surgeons are probably not aware of all shortcomings in the clinical situation, because they are very talented to overcome the limitations of existing techniques. However, the interviewed surgeons considered the analysis of technological deficiencies to be highly important. By way of the interview they could point out many shortcomings of the instrumentation used. The interview has provided a tool to evaluate and to integrate knowledge of surgeons and engineers, which is essential to come to a common understanding of the clinical problem. The results point out the probably most serious clinical problems, which may serve as input for clinically driven instrument design and as a pilot for the in-depth analysis of the underlying technological factors.

The observational study of Joice et al. evaluated erroneous task performance of surgeons, analyzing 20 laparoscopic cholecystectomies using observational methods.[24] Graspers were reported to be the most frequently involved in erroneous task performance of surgeons (n=70 errors in 20 procedures), varying from dropping the gallbladder to tearing the grasped tissue. The graspers were followed by the use of clip applicators (n=41), and the electrosurgical hook knife (n=40). The electrosurgical hook knife was particularly prone to be used in a technically wrong way, and resulted in the highest number of errors needing correction (50%).[24] These results correspond to the conclusions of our study.

In addition to the study of Joice et al.[24], this study revealed technological deficiencies of the instruments that could potentially provoke the risk of complications. Technical literature describes international standards to control the quality of instruments (medical device directives 93/42/EEC), prescribing safety measurements and usability tests in laboratories to assess the effectiveness, efficiency and satisfaction of prototypes (ISO DIS 9241-11).[15] Limiting factors detected by these laboratory tests have been reported in literature, but objective technological evaluation is rarely notified in a clinical setting.[7; 10] Actual clinical evaluation is mostly restricted to subjective investigation of comfort for the surgeon and easy handling of the instrument.[1-3; 8; 10; 25; 26] Further technological research is necessary to study the exact technological deficiencies and improvements needed, based on more detailed prospective observational studies.

Objective clinical studies have been performed to assess the true clinical improvement and safety of the alternatives, for bipolar coagulation in an experimental clinical setting.[27] The present study is used as the base of a prospective time-action analysis of laparoscopic procedures. Furthermore, it is used to design and evaluate improved alternative laparoscopic instruments. These studies are now incorporated in the MISIT program. In-depth evaluation is necessary to reveal the underlying technological deficiencies of the other clinical problems raised by the surgeons. Future research should be directed to analyze and define the technological design specifications to improve technically deficient instruments, for instance using observational task analysis methods.

References

1. Cuschieri A. Whither minimal access surgery: tribulations and expectations. Am J Surg 1995; 169:9-19.
2. Berguer R. Surgical technology and the ergonomics of laparoscopic instruments. Surg Endosc 1998; 12 (5):458-462.
3. Satava RM, Ellis SR. Human interface technology. An essential tool for the modern surgeon. Surg Endosc 1994; 8(7):817-820.
4. Cuschieri A, Melzer A. The impact of technologies on minimally invasive therapy [editorial]. Surg Endosc 1997; 11:91-92.
5. Berguer R. The application of ergonomics in the work environment of general surgeons. Reviews on Environmental Health 1997; 12 (2):99-106.
6. Herder JL, Horward MJ, Sjoerdsma W. A laparoscopic grasper with force perception. Min Invas Ther & Allied Technol 1997; 6:279-286.
7. Herfath C, Schumpelick V, Siewert JR. Pitfalls of minimally invasive surgery. Surg Endosc 1994; 8:847
8. Rau G, Radermacher K, Thull B, von PC. Aspects of ergonomic system design applied to medical work systems computer integrated surgery. In Taylor RH, Lavallee S, Burdea GC, Mösges R., eds. Computer Integrated Surgery - Technology and Clinical Applications. MIT Press, 1996; 203-221.
9. Sjoerdsma W, Herder JL, Horward MJ, Jansen A, Bannenberg JJG, Grimbergen CA. Force transmission of laparoscopic grasping instruments. Min Invas Ther & Allied Technol 1997; 6:274-278.
10. Tendick F, Jennings RW, Tharp G, Stark L . Sensing and manipulation problems in endoscopic surgery: Experiment, analysis, and observation. Presence 1993; 2:66-81.

11. Memon MA, Fitzgibbons RJ. Assessing risks, costs, and benefits of laparoscopic hernia repair. Annual review of Medicine 1998; 49:95-109.
12. Majeed AW, Troy G, Nicholl JP, et al. Randomised, prospective, single-blind comparison of laparoscopic versus small-incision cholecystectomy [see comments]. Lancet 1996; 347:989-994.
13. Kirwan B, Ainsworth LK. A guide to task analysis - The task analysis working group. London: Taylor and Francis, 1993;
14. Mayol J, Garcia-Aguilar J, Ortiz-Oshiro E, De-Diego Carmona JA, Fernandez-Represa JA. Risks of the minimal access approach for laparoscopic surgery: multivariate analysis of morbidity related to umbilical trocar insertion.World J Surg 1997; 21:529-533.
15. Mattsson F. An introduction to risk analysis for medical devices. Complicance Engineering European Edition 1995; 6:29-38.
16. Stassen, H. G., Dankelman, J., Grimbergen, C. A., and Meijer, D. W. Man-machine aspects of minimally invasive surgery. 7-18. 1998. Proceedings of the 7th IFAC Symposium on Analysis, Design and Evaluation of Man-Machine Systems; september 16-18, Kyoto, Japan. Conference Proceeding
17. Satava RM. Surgery 2001, a technological framework for the future. Surg Endosc 1993; 7:111-113.
18. Boer den KT, Herder JL, Sjoerdsma W, Meijer DW, Gouma DJ, Stassen HG. Sensitivity of laparoscopic dissectors; what can you feel? Surg Endosc 1999; 13:869-873.
19. Cartmill JA, Shakeshaft AJ, Walsh WR, Martin CJ. High pressures are generated at the tip of laparoscopic graspers. Aust N Z J Surg 1999; 69:127-130.
20. Matern U, Waller P. Instruments for minimally invasive surgery: principles of ergonomic handles. Surg Endosc1999; 13:174-182.
21. Gallagher AG, McClure N, McGuigan J, Ritchie K, Sheehy NP. An ergonomic analysis of the fulcrum effect in the acquisition of endoscopic skills. Endoscopy 1998; 30:617-620.
22. Hanna GB, Shimi SM, Cuschieri A. Task performance in endoscopic surgery is influenced by location of the image display. Ann Surg 1998; 227:481-484.
23. Breedveld, P. Observation, Manipulation, and Eye-Hand Coordination Problems in Minimally Invasive Surgery. Proceedings 16th European Annual Conference on Human Decision Making and Manual Control, december 9-11, Kassel Germany, 219-231. 1999. Conference Proceeding
24. Joice P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery-a human reliability analysis. Applied Ergonomics 1998; 29:409-414.
25. Frank TG, Cuschieri A. Prehensile atraumatic grasper with intuitive ergonomics. Surg Endosc 1997; 11:1036-1039.
26. Melzer A, Kipfmüller K, Halfar B. Deflectable endoscopic instrument system DENIS. Surg Endosc 1997; 11:1045-1051.
27. Boer den KT, Straatsburg IH, Schellinger AV, Wit de LT, Dankelman J, Gouma DJ. Quantitative analysis of the functionality and efficiency of three surgical dissection techniques; a time-motion analysis. Laparoendosc & Adv Surg Techn 1999; 9:389-395.

3

Peroperative time-action analysis of diagnostic laparoscopy with laparoscopic ultrasonography

K.T. den Boer, L.T. de Wit, J. Dankelman, D.J. Gouma
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Abstract

Background: Advanced technology is introduced rapidly in laparoscopic procedures, frequently without an accurate evaluation of their functioning. In this study, standardised time-action analysis is applied to evaluate the peroperative surgical process and the technical equipment used in 18 Diagnostic Laparoscopies with Laparoscopic Ultrasonography (DLLU).

Method: The image through the laparoscope, the ultrasonograph, and an overview of the operating theatre were recorded simultaneously. The time per phase, efficient actions (e.g. to identify lesions by inspection, making an ultrasonogram, or taking a biopsy) and limiting factors (e.g. technical problems, time spent waiting) were determined, and a current standard was defined.

Results:. Of the actions performed, 52% of the actions were qualified as efficient actions, 17% were classified as time spent waiting for personnel, instruments were positioned in 13%, and unnecessary instrument exchanges were involved in 10%. The evaluation led to a significant reduction of delay-times and resulted in design criteria for improved biopsy instruments. The current standard was calculated from the average time and actions determined per phase.

Conclusions: This time-action study provided detailed insight into the peroperative process of DLLUs, leading to improvements in the surgical process and instruments used. The defined current standard will enable evaluation of the learning curve and new technologies.

Introduction

Laparoscopic surgery is being applied increasingly as an alternative to conventional surgery[1-5]. Laparoscopic surgery has the advantage of reduced trauma for the patient and a shorter hospital stay, but presents a more complicated technique for the surgeon[2,3,5,6]. Direct contact with the tissue and direct three-dimensional vision is lost due to the interposition of instruments[4,6-9]. The more advanced laparoscopic procedures are becoming increasingly difficult with a high impact of advanced technology[10]. New laparoscopic instruments and techniques are introduced very rapidly, frequently without an accurate evaluation of their functioning[1]. It is doubtful whether the technique and instruments used are optimal for these complicated procedures. Therefore, critical evaluation of the surgical process and the technical equipment is of great importance[3-5,7-11]. Surgical procedures and protocols have frequently been analysed with respect to the post-operative complications[8,12-18]. However, these analyses provide limited or no insight into the specific peroperative limiting factors of the instrumentation used, or into the process of surgeons learning these complex procedures.

This paper introduces a standardised quantitative method to evaluate the peroperative surgical process. It analyses Diagnostic Laparoscopies with Laparoscopic Ultrasonography (DLLU) to evaluate the effectiveness of the instrumentation used and determines a current standard DLLU. In addition, this study discusses the accuracy and other fields of application of the time-action method used.

Patients and Methods

Patients

Patients with a peri-ampullary pancreatic tumour were included, after standard non-invasive staging (e.g. CT-scan, ultrasonography combined with colour-Doppler) had shown that the tumour was locally resectable and without distant metastases. Patients who were not fit for an extensive surgical procedure were excluded. Except for the diagnosis, no patient specific data have been recorded. The study protocol was approved by the local Ethics Committee.

Procedure

Diagnostic Laparoscopy with Laparoscopic Ultrasonography (DLLU) has been performed by an experienced surgeon in order to prevent influences inherent to the learning process and it was carried out in accordance with the existing standard protocol described before[13,14]. The DLLU-protocol was divided into five phases. The first phase, the opening phase, started with the first incision after which the CO_2-pneumoperitoneum was installed and all three trocars were inserted. It was followed by the inspection phase in which metastases of the peritoneum, liver, mesenterium and hepatoduodenal ligament were investigated. The third phase, the ultrasonography (US) phase, assessed the tumour ingrowth into the vessels and surrounding tissue, and metastases in the liver and lymph nodes of the coeliac vessels, using a 7,5 MHz linear array US-probe (Aloka). In the biopsy phase, biopsies of suspect lesions were taken with biopsy forceps or a true-cut needle. The last phase was the closing phase, ending with the completion of the last suture. The opening and the closing phase have been regarded as general phases because they are present in every laparoscopic procedure, whereas the inspection, the ultrasonography and the biopsy phases has been regarded as specific for the DLLU procedure. In this study, DLLUs have been excluded if no suspect lesions were found and no biopsies were taken during the peroperative procedure.

Instrumentation and data processing method

An overview of all actions performed by the operating team was recorded simultaneously with sound and the images of the laparoscope and the laparoscopic ultrasonograph. The instrumentation for recording the procedures was mounted in a portable cabinet, thus allowing instant use in any of the operating theatres and the placement outside the range of action of the operating team. Furthermore, the recorded procedures were analysed outside the operating theatre and hence did not interfere with the peroperative process.

Per phase, the time and actions were analysed using a thesaurus of 35 strictly defined basic actions peroperatively performed by the surgeon. The accuracy and reproducibility of the quantitative analysis was statistically validated for different observers using the thesaurus. After the analysis, the actions were divided into efficient actions, assessing an accurate tumour staging as was the goal of every DLLU, and limiting factors, delaying the procedure (Table 1). The most disturbing limiting factors were determined by combining the values for frequency of occurrence and delay-time.

Delay due to anatomic variation was regarded as natural variation and not as a limiting factor. A current standard DLLU was defined and calculated from the average time needed and average number of actions performed by the surgeon, for each phase.

The data were processed using a spreadsheet program and analysed using the statistical program SPSS for Windows. The data are presented as mean (standard deviation). The two sided student t-test was used to compare data, and $P < 0.05$ was considered significant. The quantitative method has been validated by calculating the intraclass correlation coefficient (ICC) for single ratings[19].

Table 1. *The action thesaurus used in the time-action study of diagnostic laparoscopies with laparoscopic ultrasonography. The actions are categorised as efficient actions or limiting factors. In this table groups of actions are shown, instead of every classified individual action.*

Efficient actions	
Inspection with the camera	to depict suspect lesions and assess tumour extension.
Inspection using ultrasonography	to depict suspect lesions and assess tumour extension.
Taking a biopsy	taking a biopsy from a suspect lesion using biopsy forceps or true-cut biopsy needles.
Instruments exchange	necessary (for example: inserting the ultrasonography probe).
Dissecting	to stretch, to cut, to coagulate.
Limiting factors	
Waiting	for personnel, instrumentation, irrigation fluid, or gas, and due to a technical problem.
Positioning	to position an instrument correctly, to present a structure with an instrument or to search a structure.
Instruments exchange	unnecessary (for example: for camera lens clearance, technical problems of instruments).
Other	non classified delaying actions.

Results

DLLU was performed in 21 patients with peri-ampullary tumours, of which 3 patients were excluded because no suspect lesions were found and no biopsies were taken. 18 patients were included; 15 patients with a pancreatic head tumour and 3 patients with a distal bile duct tumour.

The efficient actions and the limiting factors of the specific DLLU phases (the inspection, the ultrasonography, and the biopsy phase), were divided into categories and the average number of actions was calculated per category (Table 2).

Table 2. *The average frequency distribution of the efficient actions and the limiting factors in the specific phases (inspection, ultrasonography and biopsy phase) of the 18 analysed DLLUs for tumour staging of the pancreatic head region or distal bile duct. The average number of actions is shown per category (percentages).*

Category	number of actions (%)	
efficient actions	**60 (52%)**	
* number of times inspecting (with the camera or the ultrasonography probe) or taking a biopsy		46 (40%)
* number of instrument exchanges		14 (12%)
limiting factors	**55 (48%)**	
* number of times spent waiting		19 (17%)
* number of times positioning		15 (13%)
* number of unnecessary instrument exchanges		12 (10%)
* other		9 (8%)
total	**115 (100%)**	

The analysis showed that the total percentage of limiting factors was high, ranging from 36% to 56%, with a mean of 48%. The major limiting factors were time spent waiting for personnel and the functional problems of the biopsy instruments used. The biopsy forceps used to take a superficial liver biopsy, was too blunt to cut a well circumscribed part out of a suspect lesion, resulting in unnecessary damage to and bleeding of the surrounding healthy tissue. The true-cut needle used to puncture an intrahepatic lesion was not designed for laparoscopic procedures and it was difficult to position the needle, under ultrasonographic guidance, in the exact location of the suspect lesion.

After the analyses of the first eleven DLLUs, the causes of the limiting factors were evaluated and discussed with a team consisting of surgeons, engineers and designers. This resulted in a significant reduction of the long (> 1 min.) waiting times from 10% of total operation time (average 5 min; range 1 - 16 min.) in the first eleven DLLUs, to 0% in the 12th to 18th DLLU ($P = 0.02$). In addition, design criteria were developed for improved biopsy instruments.

The 18 DLLU patients have been divided in a group with only superficial liver, peritoneum or omentum biopsies (n = 11) and a second group with at least one deep liver or lymph node biopsy (n = 7) (Table 3). It took significant more time and actions to take a deep liver biopsy with a true-cut needle or a lymph node biopsy than to take a superficial biopsy, resulting in a significantly longer biopsy phase and total operation time in the deep biopsy group (Table 3).

Table 3. *The 18 DLLU patients were divided in two groups: 11 patients with only superficial biopsies (from the liver, peritoneum or omentum) and 7 patients with deep biopsies (with at least one deep liver or lymph node biopsy). Average numbers and mean times are given with their standard deviations (±SD), and differences between the superficial and deep biopsy groups were tested using the double sided student t-test, $P < 0.05$ was considered significant (*).*

	patients (n = 18)		
	superficial biopsies (n = 11)	deep biopsies (n = 7)	t-test
number of biopsies	2.4 (±1.3)	2.0 (±0.8)	P = 0.52
actions per biopsy phase	37 (±12)	57 (±27)	P = 0.04*
time per biopsy (min.)	3.3 (±1.5)	9.9 (±3.2)	P < 0.001*
time of biopsy phase (min.)	6.6 (±2.1)	14.6 (±5.1)	P < 0.001*
total time of operation (min.)	40.6 (±6.3)	50.6 (±8.1)	P = 0.03*

Current standard

The current standard is shown in Figure 1. The average time and the number of actions for all the DLLU phases, with their standard deviations, have been calculated from the 18 analysed DLLUs carried out by an experienced surgeon who had performed over 300 DLLUs. The calculated standard deviations remain small notwithstanding the variety in anatomy and pathology encountered, hence the standard DLLU based on these 18 procedures may be considered accurate (Figure 1).

Validation

The intraclass correlation coefficient (ICC) proved that the time-action analysis was accurately and reproducibly carried out by the responsible observer, resulting in an ICC of 0.98 for the inter-observer agreement[19]. The ICC for the intra-observer agreement was 0.85, showing that observers from different disciplines have analysed the DLLUs accurately, using the strictly defined thesaurus. The observers were the experienced surgeon who performed the DLLUs, an experimental laparoscopic surgeon, an engineer, and a MD Ph-D student.

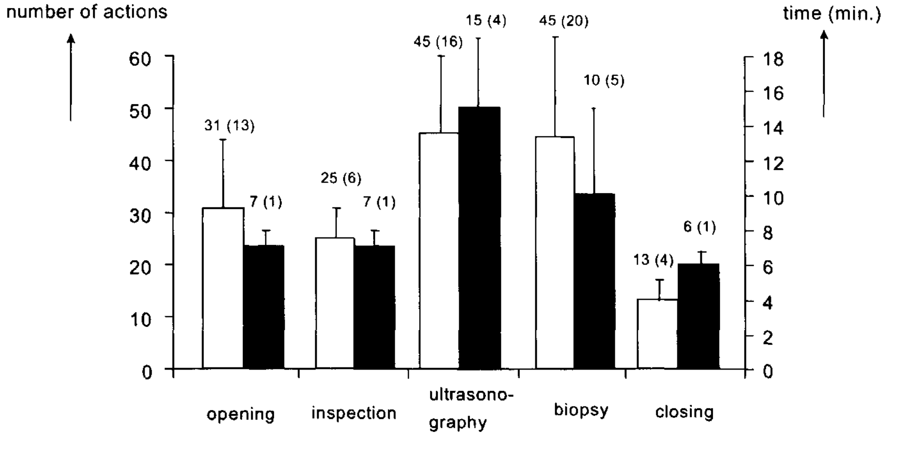

Figure 1. *Bardiagram of the current standard calculated from the 18 diagnostic laparoscopies with laparoscopic ultrasonography for staging of tumours in the pancreatic head region or distal bile duct. The white bars show the average number of actions per phase and the black bars show the mean time needed in minutes, with their standard deviations (SD). The left Y-axis shows the number of actions and the right Y-axis shows the time in minutes.*

Discussion

Peroperative time-action analysis of laparoscopic procedures is a very recent development[1]. Therefore, a relatively simple laparoscopic procedure has been analysed with a strong dependency on advanced technology (e.g. ultrasonography and biopsy instrumentation) to evaluate the efficiency and validity of the time-action method used.

The results of the analysed DLLUs and the statistical validation prove that the analysis method can be applied accurately and reproducibly, to detect and quantify the limiting factors, the efficient actions, and the time spent per phase of a laparoscopic procedure. Evaluation of the time and actions of these DLLUs provided the surgeons a detailed insight into the limiting factors delaying the peroperative process, and resulted in a significant reduction of long waiting times and in detailed insight into the functionality of the instruments used. In the future, this method will enable detailed evaluation of more complex laparoscopic procedures, which will be particularly important in procedures involving visual and depth perception and complex manipulation problems. In addition, it will be possible to perform objective tests of the functionality and reliability of newly developed or existing instruments.

The opening and closing phases are similar in every laparoscopic procedure, the times of these phases could therefore be compared with a multi-centre trial standardising the times per phase of 359 laparoscopic cholecystectomies (LC) [10]. In this LC trial, the average times (standard deviations) per phase were 13 (±7) min. for the opening and 12 (±6) min. for the closing phase, in our study this was 7 (±1) min. and 6 (±1) min., respectively. Part of the difference in time was probably due to the extra trocar that was inserted in LC and consequently the extra skin incision that had to be closed. Furthermore, the LC study was a multi-centre trial which could have caused part of the wider variation in their results. However, these arguments probably explain only part of the differences and consequently, compared to the large LC study, the current standard times determined in our study can be regarded as accurate.

The calculated standard can demonstrate to surgeons, residents and medical students how the DLLU procedure should be carried out. Furthermore, this standard can be compared with the recordings of a resident carrying out the DLLU, which will provide insight into the influences of the learning process on the surgical performance. It will elucidate clearly the critical points in the procedure where the resident could improve his technique, enabling personal training aimed specifically at these points. Consequently, the recording of surgical procedures will not only assist education by demonstrating techniques, but can also be used for specific personal feedback.

The current standard can also be used to evaluate the effectiveness and reliability of instruments or techniques. Procedures carried out with new instruments or techniques can be analysed and subsequently be compared with the standard calculated previously. In this way, the clinical improvements of any new developed instrumentation can be critically tested and the difference with other instruments can be proved statistically. Even experimental prototypes can be tested with this method, by analysing the prototypes in psychophysical models or in animal experiments. Therefore, this method will be able to test the safety, reliability and efficiency of each instrument evaluated.

References

1. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA. Quantitative Standardised Analysis of Advanced Laparoscopic Surgical Procedures. End Surg 1995; 3: 210-213.
2. Cuschieri A. Whither Minimal Access Surgery: Tribulations and Expectations. Am J Surg 1995; 169: 9—19.
3. Satava RM, Ellis SR. Human interface technology. An essential tool for the modern surgeon. Surg Endosc 1994; 8; 7: 817-820.
4. Sjoerdsma W, Herder JL, Horward MJ, Jansen A, Bannenberg JJG, Grimbergen CA. Force transmission of laparoscopic grasping instruments. Min Invas Ther & Allied Technol 1997; 6: 274-278.
5. Rau G, Radermacher K, Thull B, von Pichler C. Aspects of ergonomic system design applied to medical work systems computer integrated surgery. In: Taylor RH, Lavallee S, Burdea GC, Mösges R, eds. Technology and Clinical Applications 1996; 203-221.
6. Herfath C, Schumpelick V, Siewert JR. Pitfalls of minimally invasive surgery. Surg Endosc 1994; 8: 847.
7. Herder JL, Horward MJ, Sjoerdsma W. A laparoscopic grasper with force perception. Min Invas Ther & Allied Technol 1997; 6: 279-286.
8. Soyer Ph, Mosnier H, Choti MA, Rymer R. Intraoperative and laparoscopic sonography of the liver. Eur Radiol 1997; 7: 1296-1302.
9. Tendick F, Jennings RW, Tharp G, Stark L. Sensing and manipulation problems in endoscopic surgery: Experiment, analysis, and observation. Presence 1993; 2: 66-81.
10. Cuschieri A, Melzer A. The impact of technologies on minimally invasive therapy. Surg Endosc 1997; 11: 91-2.
11. Traverso LW, Koo KP, Hargrave K, et al. Standardizing laparoscopic procedure time and determining the effect of patient age/gender and presence or absence of surgical residents during operation, a prospective multicenter trial. Surg Endosc 1997; 11:226-229
12. Bezzi M, Merlino P, Orsi F. Di Nardo R, et al. Laparoscopic Sonography During Abdominal Laparoscopic Surgery: Technique and Imaging Findings. AJR 1995; 165: 1193-1198.
13. Bemelman WA, de Wit LT, van Delden OM, Smits NJ, Obertop H, Rauws EAJ, et al. Diagnostic laparoscopy combined with laparoscopic ultrasonography in staging of cancer of the pancreatic head region. Br J Surg 1995; 82: 820-4.
14. van Delden OM, de Wit LT, Nieveen van Dijkum EJ, Smits NJ, Gouma DJ, Reeders JWAJ. Value of laparoscopic ultrasonography in staging of proximal bile duct tumors. J Ultrasound Med 1997; 17: 7-12.
15. van Dijkum EJ, de Wit LT, van Delden OM, Rauws EA, van Lanschot JJ, Obertop H, Gouma DJ. The efficacy of laparoscopic staging in patients with upper gastrointestinal tumors. Cancer 1997; 79; 7: 1315-1319.
16. Gouma DJ, de Wit LT, Nieveen van Dijkum E, et al. Laparoscopic ultrasonography for staging of gastrointestinal malignancy. Scand J Gastroenterology - Suppl 1996; 218: 43-49.

17. Nieveen van Dijkum EJM, de Wit LT, Obertop H, Gouma DJ. Port-site mestastases following diagnostic laparoscopy. Br J Surg. 1996; 83:1793-4.
18. Schrenk P, Wayand W. Value of diagnostic laparoscopy in abdominal malignancies. Int Sur 1995; 80: 353-355.
19. Shrout PE, Fleiss JL. Intraclass correlations: Uses in assessing rater reliability. Psychological Bulletin 1979; 86:420-428.

4

Analysis of the quality and efficiency of learning laparoscopic skills

K.T. den Boer, L.Th. de Wit, P.H.P. Davids, J. Dankelman, D.J. Gouma
Surgical Endoscopy 2001; 15: 497-503.

Abstract

Objectives: The study demonstrates the application of time-action analysis to evaluate the task performance in diagnostic laparoscopy with laparoscopic ultrasonography.
Methods: The first 25 diagnostic laparoscopies with laparoscopic ultrasonography performed by a surgical resident were analysed and compared to the outcomes of an experienced surgeon. The time, actions and correctness of task performance were evaluated. Furthermore, outcome correctness and post-operative complications were assessed.
Results: No post-operative complications occurred, once the resident made a wrong diagnosis of which the cause was detected by peroperative analysis. Additionally, 1% of the sub-tasks were only partially performed, 3% not at all, and 2% using the wrong technique. The efficiency for most diagnostic tasks remained significantly lower compared to the experienced surgeon ($P<0.001$).
Conclusions: Time-action analysis can be used to provide detailed insight into the quality and efficiency of learning surgical skills. It enables personal feedback and an objective measurement of the correctness of task performance, and the time and action efficiency.

Introduction

Laparoscopic surgery demands detailed analysis and support of learning surgical skills because it has introduced numerous new techniques and skills the surgeon needs to acquire.[1] Several suggestions have been made for standardising skill training programs and assessing guidelines for resident education.[1; 2] However, no standardised method exists to assess the quality of education and to describe the actual efficiency level or correctness of task performance.[2-6] In surgery, the importance of quality assessment studies is increasingly recognised, however, the surgeon–resident relationship of most education programs makes task analysis difficult.[7] Literature assumes that a surgeon is experienced if the total operation times and complication rates are stabilised at a certain minimum level after a number of procedures, varying from 5 to over 25 procedures.[8] Several studies stress the importance of expertise in reducing mortality rates, in-hospital stay, and costs.[9] However, time reduction and hospital mortality rates do not provide insight into the actual peroperative complications or risks, nor into the expertise of each single surgeon. Therefore, the analysis of the learning process should not only address the outcome in terms of morbidity, mortality, and overall time reduction, it should also analyse task performance. Laparoscopic training is carried out using simulated surgery as well as actual surgery and time-action analysis could be used to evaluate either. In this article we analysed actual operative training.

This paper provides an example of the use of time-action analysis to analyse the learning of new tasks (first 25 procedures) of a surgical resident being introduced to Diagnostic Laparoscopy with Laparoscopic Ultrasonography (DLLU). This basic laparoscopic procedure was selected to demonstrate the evaluation of learning diagnostic laparoscopic skills with respect to the time and action efficiency and correctness of task performance, comparing a resident with an experienced surgeon. Actions within each phase are identified using a reference table of 35 basic actions and the corresponding actions and times were recorded. This article is closely related to an existing publication[3] in which an experienced surgeon was analysed and average values obtained over 18 patients. These results were used as a reference for the present study.

Patients and Methods

Patients

Patients with a suspected peri-ampullary pancreatic tumour were selected after standard non-invasive staging (e.g. ultrasonography combined with colour-Doppler, spiral CT-scan) showed that the tumour was locally resectable and did not show signs of distant metastases. Patients were excluded if they were not fit for an extensive surgical procedure. No patient specific data were recorded except for the diagnosis and outcome of operation, and the recordings were labelled by a specific number. The study protocol was approved by the local Ethics Committee of the Academic Medical Center (A.M.C.) of Amsterdam.

Procedure

Diagnostic laparoscopy with laparoscopic ultrasonography (DLLU) was selected for study, firstly, because it is a basic laparoscopic procedure and, secondly, this standardised procedure has been performed on a regular basis in more than 500 patients in the A.M.C. since 1992, in accordance with a strictly defined standard protocol.[10-12] Briefly, the protocol was divided into five phases. The first phase, the opening phase, started with the first incision. It was followed by the inspection phase in which metastases of the peritoneum, liver, mesentery and hepatoduodenal ligament were sought. The third phase, the ultrasonography phase, assessed tumour ingrowth into the vessels and surrounding tissue, and metastases in the liver and lymph nodes of the coeliac vessels, using a 7.5 MHz linear array ultrasonography (US) probe (UST-5522-7.5 Aloka Co, Tokyo Japan). In addition, the abdominal cavity was irrigated with 500 ml isotonic saline, which was sampled for cytological examination. In the fourth phase, the biopsy phase, biopsies of suspect metastatic lesions were taken under direct laparoscopic or ultrasonographic guidance, using biopsy forceps or core-biopsy needles. The last phase is the closing phase. Diagnostic Laparoscopy was always performed in combination with Laparoscopic Ultrasonography for tumour staging, as a separate procedure before surgical exploration and resection. During the procedure, an experienced radiologist interpreted the US-image together with the surgeon or resident performing the US-phase or biopsy phase. DLLUs for peri-ampullary tumour staging were carried out by one surgical resident, starting with his first performed DLLU (under the supervision of an experienced surgeon) until the 25th DLLU. The surgical resident had never performed a DLLU before the start of this study, but had performed 100 other basic laparoscopic procedures.

Recording Instrumentation

During the surgical procedure, an overview image of the operating theatre was recorded simultaneously with the image from the laparoscope and the laparoscopic ultrasonograph, using a four-channel video mixing device. Sound was also recorded. All actions performed by the operating team were recorded with a video camera placed next to the operating lights to guarantee a central overview. The instrumentation for recording the procedures was mounted in a portable cabinet, thus allowing instant use in any of the operating theatres and placement outside the range of action of the operating team. The analysis of the recorded procedures took place outside the operating theatre, so as not to interfere with the operative process.

Data processing method

The correctness of task performance was studied in DLLUs, with respect to the correctness of the technique applied, failure of DLLU, post-operative complications and outcome correctness. The outcome of DLLUs was divided into four groups; tumour was diagnosed as *resectable* after DLLU, as *possibly irresectable* – which could however not be proven by pathology –, as *proven irresectable* by pathology of the biopsy specimen, or the patient had *no tumour*. The DLLU outcome of (ir-)resectability was compared to the outcome at laparotomy, which was considered the golden standard, proving whether the outcome of DLLU was correct or not. The correctness of the performance of the resident was evaluated by an experienced surgeon, after all 25 DLLUs were recorded. For each subsequent task of the standard DLLU protocol, the experienced surgeon verified whether the task was performed correctly (C) or incorrectly, i.e.: partially (P), not at all (N), or using the wrong technique (W). If no suspect lesions were detected, some sub-tasks were considered not applicable (N.A.), e.g. taking a biopsy in case there was no lesion suspected.

A quantitative time-action analysis was carried out to evaluate the speed of task performance and the number of basic actions. The time-action results of the surgical resident were compared to a standard DLLU based on the results of 18 DLLUs of an experienced laparoscopic surgeon (who performed 800 basic and advanced laparoscopic procedures of which 300 were DLLUs).[13] First, for each phase, the time and actions were analysed using a general thesaurus of 35 strictly defined actions, previously defined and validated quantitatively.[13] Secondly, for the learning of specific diagnostic skills, the US-phase tasks were studied in detail because the resident had no former experience in performing US-tasks. Table 1 shows the specific US-phase action thesaurus used to analyse the efficiency of the resident compared with the standard, which was based on the results of US-phases performed by the experienced surgeon. Table 2 shows the specific protocol sub-tasks used to analyse the correctness of task performance.

The data were processed using a spreadsheet program and analysed using the statistical program SPSS for Windows. The differences between the times and actions of the resident compared to the mean time and actions of the experienced surgeon have been analysed by calculating a Difference Score for time and actions (DS) (e.g. $DS_{time} = time_{resident} - time_{standard}$). The time-action results of the resident were log-normally distributed, and thus the data were normalised by a log-transformation. The differences in log-transformed times and actions were tested using an one-sample t-test and the differences in variances with a F-test (24,17 df). $P < 0.05$ was considered significant.

Table 1. Specific US-phase action thesaurus.

Main task	Definition
Searching a structure	Search, find and recognize a structure on the US-image.
Scanning the liver for suspect lesions	Scan the liver superficially and deep for suspect lesions (metastases) using the US-probe.
Locating the place of the suspect lesion	Locate and name the 3D-position of the suspect lesion.
Following a structure	Follow the path of a structure (vessel, bile duct etc.) in the US-image.
Examining a suspect lesion in detail	Examine the lesion's characteristics (e.g. diameter, regularity, ingrowth, consistency) and relation to surrounding tissue (e.g. ingrowth) in detail.
Freezing the US-image	Radiologist freezes the US-image in order to measure the lesion's size.
Waiting	Waiting for personnel to hand over instrumentation or execute an order.

Results

This study analysed 43 DLLUs carried out for peri-ampullary tumour staging. 18 DLLUs were performed by an experienced surgeon and 25 DLLUs by a surgical resident. A supervisor actively participated in the first 7 DLLUs performed by the resident, controlling the correctness of sub-tasks performed. These first 7 DLLUs were therefore only included for the time-action analysis, and excluded from the correctness evaluation. The biopsy phase was only evaluated for correctness of task performance and not for the efficiency analysis due to the small number (4) of biopsies taken in the 25 DLLUs performed by the resident.

Correctness

The Clinical Outcomes are shown in Table 3 for the procedures of the resident without a supervisor (n=25-7=18) and the experienced surgeon (n=18). No failures of DLLU or complications occurred in either group. The outcome of DLLU was correctly diagnosed in 17 out of 18 procedures of the resident. Once, the resident misdiagnosed the tumour as resectable, which was proven incorrect during laparotomy as metastases were detected in the omentum and mesocolon of the patient. The cause of the misdiagnosis made by the resident could not be traced by the post-operative outcomes. The experienced surgeon diagnosed all 18 procedures correctly, even in the five cases in which the irresectability could not be proven by pathology during the DLLUs.

Table 2. *Correctness of DLLU sub-tasks performed according to the standard protocol.*
** C = Correctly, P = Partially, N = Not, W = wrong technique, N.A. = Not Applicable*

No.	Task	No.	Sub-tasks	C *	P	N	W	N.A.
1	Create CO2 pneumoperitoneum	1.1	Insert Veress needle				18	
		1.2	Insufflate the abdomen with CO2	18				
		1.3	Remove Veress needle	18				
2	Insert access ports	2.1	Insert 1st (optical) port	18				
		2.2	Insert laparoscope	18				
		2.3	Inspect abdomen	18				
		2.4	Insert 2nd port under direct sight	18				
		2.5	Insert 3rd port under direct sight	18				
		2.6	Inspect possible bleeding site	18				
3	Inspect using laparoscope	3.1	Insert 1st forceps	17			1	
		3.2	Insert 2nd forceps	18				
		3.3	Inspect Treitz ligament	13	2	3		
		3.4	Inspect mesocolon	15	2	1		
		3.5	Inspect hepatoduodenal ligament	17	1			
		3.6	Inspect omentum	18				
		3.7	Remove 1st forceps	18				
		3.8	Remove 2nd forceps	18				
		3.9	Insert irrigation equipment	18				
		3.10	Insert lavage fluid	18				
		3.11	Suck off 200ml lavage fluid	18				
		3.12	Inspect liver (all segments)	16	2			
		3.13	Inspect lymphnodes	18				
		3.14	Inspect peritoneum	18				
		3.15	Examine each suspect lesion in detail (seize, consistency, aspect, ingrowth)	12				6
		3.16	Remove irrigation equipment	18				
4	Inspect using US-probe	4.1	Insert US-probe	18				
		4.2	Inspect liver (all segments)	18				
		4.3	Inspect pancreatic duct	18				
		4.4	Inspect common bile duct	18				
		4.5	Inspect superior mesenteric vein	16		2		
		4.6	Inspect portal vein	18				
		4.7	Inspect confluens	16		2		
		4.8	Inspect coeliac trunk	17		1		
		4.9	Inspect lymphnodes	18				
		4.10	Inspect common hepatic artery	18				
		4.11	Inspect superoir mesenteric artery	17		1		
		4.12	Examine vessel ingrowth / tumor extension	15	2	1		
		4.13	Examine a suspect lesion in detail (seize, consistency, aspect, ingrowth)	16				2
		4.14	The radiology resident freezes, measures and saves the US-image	18				
5	Take a biopsy	5.1	Insert biopsy forceps or needle	4		1		13
		5.2	Position instrument in the suspect lesion	4		1		13
		5.3	Take a biopsy from the suspect lesion	4		1		13
		5.4	Hand over the specimen	4		1		13
		5.5	Check possible bleeding site	4		1		13
		5.6	Control haemostasis	3		1	1	13
6	Close up patient	6.1	Remove irrigation fluid	18				
		6.2	Remove instruments	18				
		6.3	Remove operating ports	18				
		6.4	Check access wounds	4		14		
		6.5	Release CO2 from abdomen	18				
		6.6	Remove laparoscope	18				
		6.7	Remove optical port	18				
		6.8	Suture the port wounds	18				
	Total			808	9	31	20	86

Table 2 shows that the resident performed the majority of the sub-tasks technically correct (94%; Correct=808 + Not Applicable=86). The resident performed 31 sub-tasks incorrectly. He performed the insertion of the Veress needle incorrectly in 18 cases, blocking the safety mechanism by a slightly incorrect positioning of the hand. Once, the 1st forceps was not inserted under direct sight, and in the closing phase the resident failed in 14 cases to double check the insertion wounds of the trocars for bleeding vessels. Table 2 also shows that the resident performed diagnostic sub-tasks not or only partially; the inspection for tumour ingrowth into the ligaments or the vessels was not performed in 11 cases and partially performed in 9 cases. In one DLLU, the resident wrongly omitted to take a biopsy of a suspect intra-hepatic lesion and thus to perform all sub-tasks of the biopsy phase. He once controlled the hemostasis wrongly, resulting in a slight coagulation damage to the liver. Furthermore, the sub-task analysis revealed that the cause of the misdiagnosis had been that the resident only partially performed a crucial diagnostic sub-task, thereby missing the metastasis. From the recorded comments of the surgeon during the operation it was clear that the resident was convinced that he had performed all diagnostic sub-tasks correctly and completely. In 86 cases the resident correctly considered a sub-task as not applicable due to the absence of suspect lesions.

Table 3. *Failure of laparoscopy, complications, and outcome of DLLU.*

	Resident (n=18)*	Experienced surgeon (n=18)[3]
Failure of laparoscopy [Δ]	0	0
Complications[+]	0	0
Outcome correctness[#]	correct/ incorrect	correct/ incorrect
resectable	14/1	8/0
possibly irresectable	0/0	5/0
proven irresectable	1	5
no malignancy	2	

*Δ Failure of laparoscopy: a laparoscopic procedure which had to be converted to an open procedure because of major complications. + Complications: all complications registered in the patient file (per and post-operative). # Outcome correctness: the number of times a diagnosis made during DLLU was proved to be (in-)correct during laparotomy. * 18 DLLU's performed without a supervisor.*

Time-action analysis

Figure 1 shows that the total operation time and the number of actions of the resident was significantly higher compared to the standard based on the mean times and actions of the experienced surgeon ($P<0.001$). Especially, the inspection and US-phase differed significantly between the resident and the surgeon (Fig. 1,2).

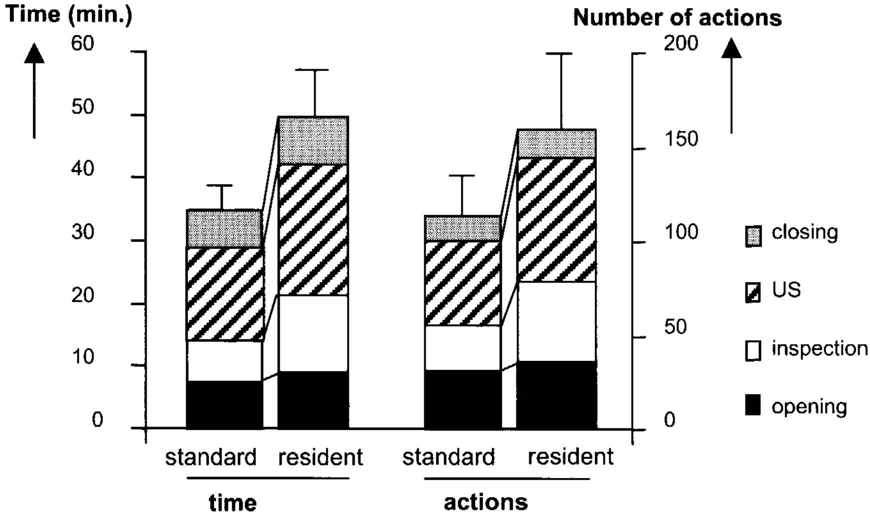

Figure 1. *The mean operation time (in min.) and mean number of actions of the standard compared to the resident. The first two bars show the total operation time for the standard and the resident, with each colour representing the contribution per phase, and the last two bars show the total number of actions, also divided into phases.*

Figure 2 shows the difference scores (DS) of the times and number of actions of each consecutive DLLU performed by the resident relative to the standard for the opening (a), inspection (b), ultrasonography (c) and closing phase (d), including linear trend lines. It shows that the DS_{time} for the opening and closing phase did not differ from the standard. The inspection and US-phase show a significant difference for the DS_{time} and $DS_{actions}$ ($P<0.01$), and a larger variance than the standard ($P<0.05$). Figure 3 shows the three different time and action distributions encountered in the tasks of the US-phase. Fig. 3a shows the distribution of the DS for the task: scanning of the liver, remaining significantly above the reference line and showing no significant decrease in the linear trend lines for the DS_{time} and $DS_{actions}$ (no increase in efficiency). Fig. 3b shows the DS for the searching of a structure in the US-image, with decreasing trend lines (increasing efficiency), and Fig. 3c shows the DS for waiting for personnel, which is randomly distributed around the reference line without any correlation and varying widely among the procedures. Accordingly, the DS_{time} and $DS_{actions}$ of waiting for personnel is not significantly different between the resident and the standard, illustrating that the task depends on the operating team and is independent of the operating surgeon.

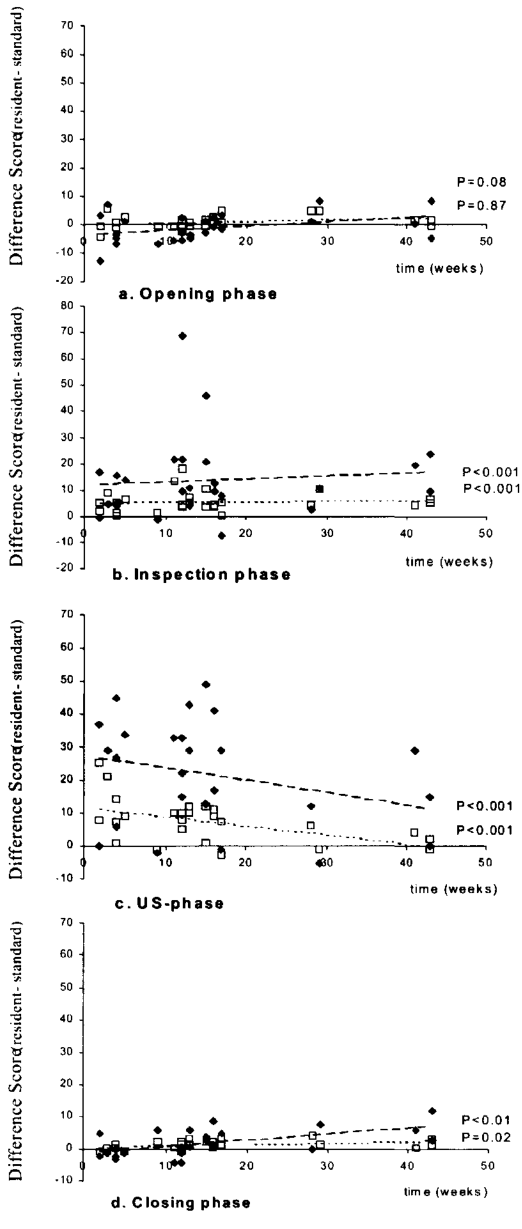

Figure 2. *The Difference Scores (DS) for the time in min. (□) and number of actions (♦) between the resident and the standard are shown for the opening (a), inspection (b), ultrasonography (c) and closing phase (d). Linear trend lines are included for the DS_{time} (dotted line) and DS_{action} (dashed lines). The P-values shown are based on the one sample t-test of the log-normalised values.*

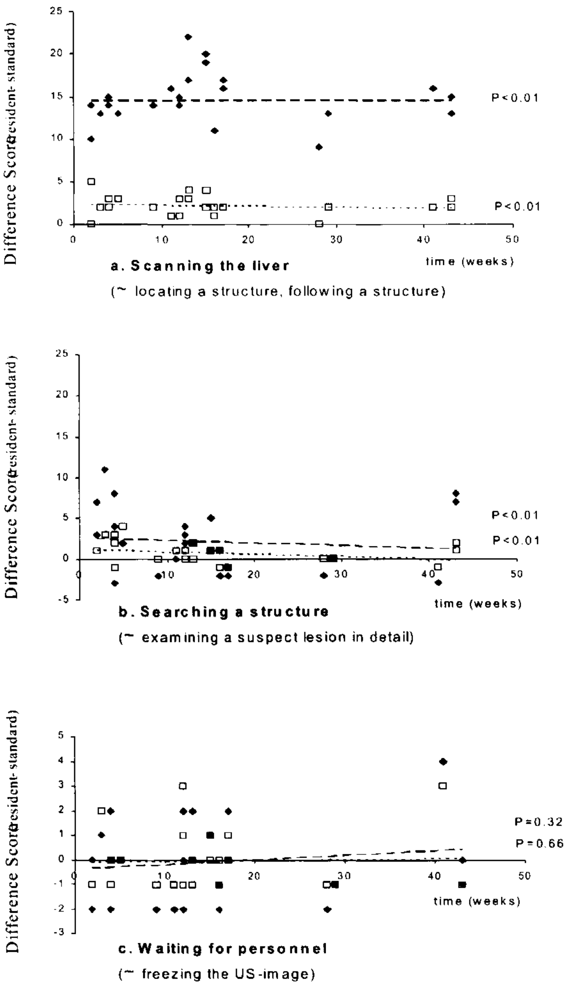

Figure 3. *The Difference Scores (DS) for the time in min. (□) and number of actions (♦) between the resident and the standard are shown for the US-tasks. Figure 3a, scanning of the liver, Figure 3b, searching a structure in the US-image, Figure 3c, waiting for personnel to hand over instrumentation or execute an order. The distribution of the actions; locating and following a structure are similar to Fig. 3a, examining a suspect lesion in detail is similar to Fig. 3b, and freezing the US-image by the radiologist is similar to Fig 3c as is indicated in brackets. Linear trend lines are included for the DS_{time} (dotted line) and DS_{action} (dashed lines). The P-values shown are based on the one sample t-test of the log-normalised values.*

The distribution of the diagnostic US-tasks: following and locating an anatomic structure or lesion are similar to Figure 3a, the examining of a suspect lesion in detail is similar to Figure 3b. showing also decreasing trend lines, and the freezing of the US-image (performed by the radiologist) is similar to Figure 3c. The standard variations of the US-tasks do not differ from the standard, except for the time of examining the lesion in detail (F=3.4, 24,17 df).

Discussion

Time-action analysis was recently developed for the evaluation of the peroperative surgical procedure, and proved to detect and to quantify the efficient actions, limiting factors and time spent on different phases of surgical procedures, accurately and reproducibly.[3; 13] The present study demonstrated that time-action analysis could also evaluate learning of skills with respect to efficiency and correctness of task performance, providing insight into the learning of skills additionally to total operation times, and the post-operative outcomes.[8] It applied the method to a relative simple laparoscopic procedure (DLLU) with a high amount of new laparoscopic tasks to illustrate the application. However, it can be applied to all types of procedures, including open and laparoscopic procedures.

Caution should be taken not to generalise the conclusions of this study to other surgical tasks. This study demonstrated the applicability of a methodology on DLLUs. For other surgical tasks, the methodology should be used to analyse other types of operations, determining a data base of quality and efficiency reference parameters for each specific procedure. These data could be used to control the quality of surgical courses, and assess the expertise of residents in both the laparoscopic and the open surgery. Caution should also be taken not to answer the question of clinical benefit of DLLUs from the post-operative outcomes of the 43 patients studied, because that was not the aim of our study, and a reliable answer is being described in literature.[13]

Literature describes the quality of performance mostly in terms of mortality rates, number of post-operative complications, or local recurrences in cancer surgery.[14] However, these studies do not provide insight into the underlying causes of these complications or incorrect outcomes. The sub-task analysis of this study could detect that the misdiagnosis was due to an incorrectly performed sub-task, and it revealed additional incorrectly performed sub-tasks, which fortunately did not cause more incorrect diagnoses in these cases. Nevertheless, every incorrect task performance increases the risk of complications, and thus should be reduced. The first step in reducing incorrect tasks is to detect them.

To residents, incorrectly performed tasks are usually pointed out by the supervisor. However, experienced surgeons only supervise the first procedures and, as this study shows, even supervision do not reveal all incorrect task performance. The incorrect insertion technique of the Veress needle was only detected by the detailed correctness analysis and not during the first seven supervised DLLUs or other laparoscopic procedures the resident performed under the supervision of an experienced surgeon. This stresses the importance and additional benefit of detailed peroperative correctness and efficiency analysis.

The method described in this study is detailed and therefore relatively time-consuming, the analysis of one procedure takes generally as long as the total operation time of the analysed procedure. However, the level of detail can be reduced, depending on the objectives of each study. Furthermore, software is becoming available to facilitate and quicken the data collection and evaluation (e.g. The observer®, Noldus information technology, Wageningen, the Netherlands).

The US-phase consisted of the highest component of new tasks for the resident. Accordingly, this study showed that US-tasks were most difficult to learn; most incorrect task performance occurred due to the interpretation of the US-image, and the efficiency difference between the resident and the standard was highest for the US-phase ($P<0.001$). Learning to increase the efficiency appeared to be a slow process, most diagnostic tasks performed by the resident did not increase in 25 DLLUs, except for two specific US-tasks. The task efficiency strongly depends on the type of task and is probably also influenced by the personal technique, routines transferred from other procedures, and the supervisors training the resident.

Laparoscopic operations have become a primary component of general surgery and therefore, curriculum guidelines for resident education are important.[1; 2] These guidelines should contain an outline of knowledge and tasks to be mastered in basic and advanced laparoscopy. Time-action analysis proves to be accurate in clarifying the specific learning difficulties providing valuable feedback information and it can support to generate guidelines for efficient training.[15-17] Specific skill training could be started in laboratory settings, without the need of an extra supervisor. For example, in DLLUs the interpretation of the ultrasonographic image could well be trained in skills laboratories involving surgical trainers, computer simulations or animal models.[15] This will enhance the quality of the surgical technique before the procedure is carried out in the operating room, thereby reducing the risk of complications and wrong diagnosis in a patient. In addition, time-action analysis can help the supervisor to focus his/her instructions on the difficult tasks required for a particular procedure, and it can support transfer of training and individual feedback.[18] Time-action analysis could also assess the quality of courses, or simulation programs, or of conventional education by a supervising surgeon, and is therefore very well applicable for evaluating the learning of standard surgical skills in both the laparoscopic and the open surgery.

Conclusion

The study shows that peroperative analysis can evaluate the efficiency and quality of task performance, objectively and accurately. In future, time-action analysis could become implemented routinely to describe the quality of surgical courses and the task performance of surgeons in both the laparoscopic and the open surgery. The learning of diagnostic laparoscopic skills was analysed as an example of the use of time-action analysis. The example shows that the resident's efficiency for each specific diagnostic task remained significantly lower compared to the experienced surgeon ($P<0.001$), except for two US-tasks. The tasks were performed correctly in 94 % of the sub-tasks, partially in 1%, not at all in 3%, and using the wrong technique in 2% of the sub-tasks. The post-operative analyses did not reveal these incorrect sub-tasks performances, nor did the supervisor correct all the technically wrong task performance.

References

1. Society of American Endoscopic Surgeons (SAGES). Integrating advanced laparoscopy into surgical residency training. Surg Endosc 1998; 12:374-376.
2. Cuschieri A, Wilson RG, Sunderland G, et al. Training initiative list scheme (TILS) for minimal access therapy: the MATTUS experience. J R Coll Surg Edinb 1997; 42:295-302.
3. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA. Quantitative standardised analysis of advanced laparoscopic surgical procedures. Endosc Surg Allied Technol 1995; 3:210-213.
4. Bessell JR, Baxter P, Riddell P, Watkin S, Maddern GJ. A randomized controlled trial of laparoscopic extraperitoneal hernia repair as a day surgical procedure. Surg Endosc 1996; 10:495-500.
5. Traverso LW, Koo KP, Hargrave K. Standardizing laparoscopic procedure time and determining the effect of patient age/gender and presence or absence of surgical residents during operation, a prospective multicenter trial. Surg Endosc 1997; 11:226-229.
6. Barnes RM. Motion and time study: Design and measurement of work. New York: John Wiley & Sons, 1980;
7. Leval de MR. Human factors and surgical outcomes: a Cartesian dream. Lancet 1997; 349:723-725.

8. Deschamps C, Allen MS, Trastek VF, Johnson JO, Pairolero PC. Early experience and learning curve associated with laparoscopic Nissen fundoplication. J Thorac Cardiovasc Surg 1998; 115:281-284.
9. Lieberman MD, Kilburn H, Lindsey MBMF. Relation of Perioperative Deaths to Hospital Volume Among Patients Undergoing Pancreatic Resection for Malignancy. Ann Surg 1995; 222:638-645.
10. Delden van OM, Wit de LT, Nieveen van Dijkum EJM, Smits NJ, Gouma DJ, Reeders JWAJ. Value of laparoscopic ultrasonography in staging of proximal bile duct tumors. J Ultrasound Med 1997; 17:7-12.
11. Gouma DJ, de Wit L.T., Nieveen van Dijkum EJM, et al. Laparoscopic ultrasonography for staging of gastrointestinal malignancy. Scand J Gastroenterology 1996; 218:43-49.
12. Nieveen van Dijkum EJM, Wit de LT, Delden van OM, et al. The efficacy of laparoscopic staging in patients with upper gastrointestinal tumors. Cancer 1997; 79:1315-1319.
13. Boer den KT, Wit de LT, Gouma DJ, Dankelman J . Per-operative Time-Motion Analysis of Diagnostic Laparoscopy with Laparoscopic Ultrasonography. Br J Surg 1999; 86:951-955.
14. Gordon TA, Bowman HM, Tielsch JM, Bass EB, Burleyson GP, Cameron JL. Statewide Regionalization of Pancreaticoduodenectomy and its Effect on In-Hospital Mortality. Ann Surg 1998; 228:71-78.
15. Rosser JC, Rosser LE, Savalgi RS. Skill acquisition and assessment for laparoscopic surgery. Arch Surg 1997; 132:200-204.
16. Chew FS, Smirniotopoulos JG. Educational efficacy of computer-assisted instruction with interactive videodisc in radiology. Invest Rad 1993; 28:1052-1058.
17. Shapiro SJ, Paz-Partlow M, Daykhovsky L, Gordon LA. The use of a modular skills center for the maintenance of laparoscopic skills. Surg Endosc 1996; 10:816-819.
18. Wickens CD. Memory, Learning, and Training. In Pearson L, Caterer MC., eds. Engineering Psychology and human performance. HarperCollins Publishers Inc., 1992; 211-257.

5

Sensitivity of laparoscopic dissectors;
What can you feel?

K.T. den Boer, J.L. Herder, W. Sjoerdsma, D.W. Meijer,
D.J. Gouma, H.G. Stassen
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Abstract

Background: Sensory feedback is considerably reduced in minimally invasive procedures due to the interposition of instruments, causing loss of direct manual contact with the tissue. The purpose of this study is to evaluate the feedback quality of commercially available reusable and disposable laparoscopic dissectors.
Methods: Thirty-one participants were asked to feel a simulated arterial pulse, with their bare fingers, through laparoscopic dissectors, tweezers, an orthopaedic forceps, and a laparoscopic low-friction prototype. The absolute sensory threshold was determined by the psychophysical method of limits.
Results: The sensory feedback quality is significantly better for the reusable dissectors tested than for the disposable dissector ($p<0.001$). Nevertheless, the reusable dissectors are at least eight times less sensitive than bare fingers. Furthermore, sensitivity qualities are highly variable, depending on the dissector tested.

Introduction

It is highly important for surgeons to feel the tissue they are operating on.[3,5,8] In open surgery there is direct manual contact between the tissue and the surgeon's fingers, hence there is direct tactile and proprioceptive feedback.[1,5,6,8] This feedback information enables the surgeon to feel the structure and properties of tissues as well as the pulsation of arteries, which is of great importance in assessing the extension of tumours or infiltrates or the localisation of arteries. Moreover, this feedback information provides direct and accurate information about the force applied to grasp, expose or fixate the tissue, in order to prevent damage of the tissue. In laparoscopic surgery this direct contact is lost due to the interposition of instruments between the tissue and the surgeon's fingers.[2,3,5,6,8,13] This will reduce the quality of feedback information and therefore, it will complicate the control of handling the tissue and applying the exact force needed to cut or grasp the tissue. The risk of unnecessary tissue damage will be enlarged, as a result. In addition, dexterity is decreased as a consequence of the long and rigid structure of the instruments, the freedom of movement is constrained by the limited degrees of freedom caused by the positioning of the instruments through the trocars. Therefore, a considerable force is needed to position these relatively heavy instruments.[5,9,10] and the instruments reduce the accuracy of the feedback information experienced by the surgeon.[5,6,12]

Although surgeons have frequently reported that the reduced feedback quality due to the interposition of instruments complicates the laparoscopic surgery,[8,9,10,13] this loss in sensitivity has never been quantitatively assessed. The procedure of laparoscopic surgery can be depicted by a block diagram containing the surgeon, the patient, and the instruments in between (Figure 1).

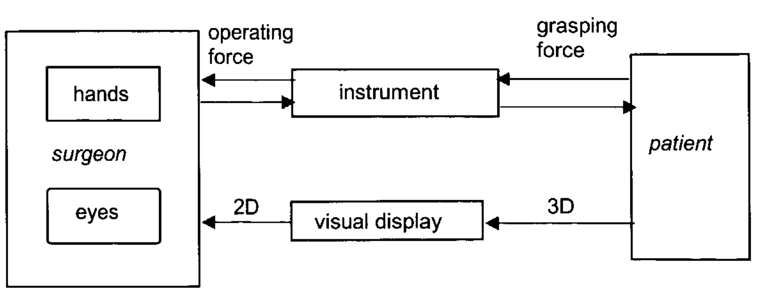

Figure 1. *Model of the procedure of minimally invasive surgery. The tactile-, proprioceptive-, and depth-perceptions are limited because the instruments and the visual display are interposed between the tissue and the surgeon's hands and eyes, respectively.*

Figure 1 shows clearly that the surgeon receives force and position information about the dissecting activities via the instrument and its handle. The skin receptors will translate this information in order to provoke a consciously experienced sensation.[5,4] Figure 1 also shows the main disadvantage of the loss of direct three-dimensional vision on the operation field, which is only partly compensated for by 2D visual display.[1,3,5,8,11] The surgeon has to compensate for the reduced feedback quality and dexterity problems by intensive training. The reduced visual perception has to be combined with the remaining tactile perception and the surgeon's experience in order to get a reliable impression of the structure or the forces applied on the tissue. Consequently, the learning process of laparoscopic surgery will be more intensive and prolonged compared to open surgery.[3,8]

The sensory feedback information perceived by the surgeon does not only depend on the characteristics of the instruments, but also on the properties of the information transferred through the instruments to their handles (modality, intensity and duration) and on the way in which the receptors in the skin translate this information into action potentials, which will be sent to the central nervous system. A useful concept in psychophysics is the absolute sensory threshold, defined as the minimal intensity of a signal necessary for a surgeon to consciously experience the signal.[4] This threshold is fixed by the subject's perception. If a high input intensity is required to reach the subject's threshold level, then low mechanical efficiency leading to poor feedback is implied for that instrument.

This study quantifies the loss of sensitivity due to the interposition of an instrument with particular focus on evaluating the differences in commercially available laparoscopic instruments.

Materials and methods

An experimental set-up has been developed in a collaboration between the Delft University of Technology and the Test Centre for Experimental Surgery at the Department of Surgery at the Academic Medical Centre of Amsterdam. This experimental set-up aims at a simulation of a pulsating artery in order to evaluate the sensory feedback qualities of the instruments. The input signal to achieve sensory threshold was determined for bare fingers as well as commercially available reusable and disposable laparoscopic dissectors (Figure 2). For comparison, tweezers were included as a representative of an instrument used in open surgery. A frequently used arthroscopic preparation forceps was included as a representative of orthopaedic surgery. The Wilmer® dissector, a prototype of a low-friction laparoscopic dissector designed by the Delft University of Technology, was also tested.[6]

Figure 2. *The instruments tested (from left to right); 5 mm disposable dissector, 10 mm reusable dissector, 5 mm reusable dissector, Wilmer® dissector, orthopaedic dissector, tweezers.*

Experimental set-up

The experimental set-up consisted of a silicone tube filled with water (Figure 3). Pulses could be guided through the tube by way of a pressure pulse generator, activated by a computer, so as to simulate an arterial pulse. The generated signal created a variation in fluid pressure with 'systolic' and 'diastolic' pressures. The basic pressure was set on 80 mmHg as the average diastolic pressure in medium-sized arteries. The pulse train was added to this basic pressure. The amplitude of this pulse train could be varied in order to make the signal in the tube stronger or weaker. The fluid pressure was measured by pressure transducers on either side of the silicone tube. The second pressure transducer was used as a double check of the recorded pressure. A simulated pulse frequency of 70 beats per minute turned out to be so good a resemblance of a human arterial pulse at rest, that the participants were not able to distinguish them from the effects of their own pulses. In order to prevent this confusion, the frequency of the pulse train was set to 150 beats per minute.

The participants were asked to grasp the tube first with the fingers of their dominant hand, and then successively with each of the dissectors mentioned above. The dissectors were carried by a rigidly fixed trocar to enable the participants to pay full attention to the signal coming from the pulsating silicone tube and guided through the dissectors. The dissectors were positioned with the silicone tube in the tip of their jaws, enabling them to compress the silicone tube slightly on both the sides, without fully blocking the passage of fluid through it. In this way the opening angle of the jaws was kept nearly constant. During the experiment the proper position of the dissector jaws and the free passage of fluid through the tube were monitored continuously.

Participants

Thirty-one persons (25 males, 6 females) participated in this experiment. Their ages ranged from 21 to 53 years, with a mean age of 39 years. They all worked at the A.M.C. and their professions were various (e.g. medical doctors, engineers, students, secretaries, electricians, instrument makers). The participants were only allowed to use their tactile and proprioceptive senses for the perception of the pulse train, without any visual or hearing feedback.

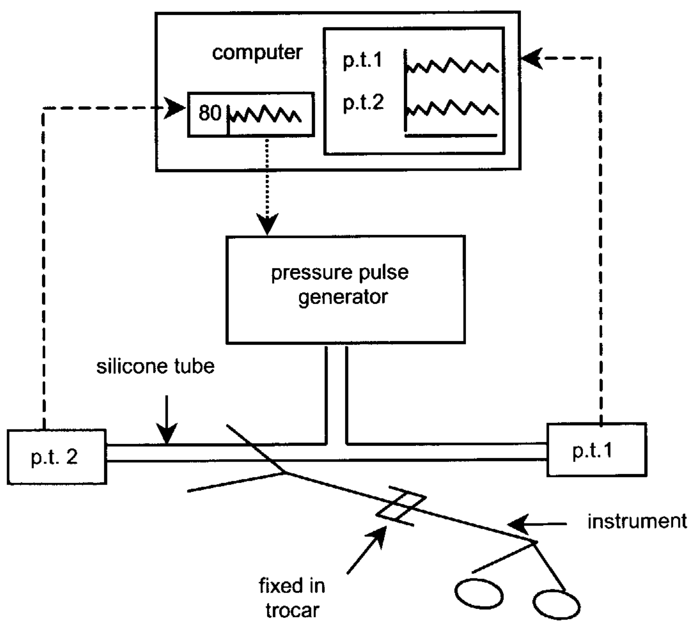

Figure 3. *The experimental set-up, consisting of a pressure pulse generator connected to the thin-walled silicone tube (filled with water), two pressure transducers (p.t.1,2) and one computer. Dotted lines show the route of the generated signal from the computer to the pressure pulse generator. Dashed lines show the routes of the recorded signal from the pressure transducers to the computer.*

Instruments

Commonly available laparoscopic dissectors can be divided into two groups: reusable dissectors and disposable dissectors. The manufacturers of reusable laparoscopic dissectors all use an almost identical mechanical configuration for their instruments, based on a pull rod structure, which is connected to a hinge mechanism with four pivots on one side, and to a shears-like handle on the other side.[12] Therefore, a 5 mm preparation dissector and a 10 mm bowel clamp were considered as good representatives of most reusable instruments. The mechanical configuration of disposable instruments is comparable with that of the reusable ones, except for the hinge mechanism of the jaw, which consists of one pivot and sliding hinges.[12] A 5 mm disposable laparoscopic dissector was included as a representative of the disposable mechanism. The three laparoscopic instruments tested had not been used before and all of them had been made by leading manufacturers.

Every connection and pivot in the construction of a dissector results in a certain amount of friction, causing friction energy losses ranging from 58% - 92%.[12] These mechanical deficiencies result in low mechanical efficiencies (8%-33%).[12] In addition, the force transmission functions of the commercially available laparoscopic instruments are not constant.

The included prototype is based on a rolling-link mechanism instead of the slide bearing structure that is seen in commercially available instruments, leading to a considerable reduction of friction energy losses (4%) in the prototype compared to the commercially available ones (Figure 4).[6]

Measurement procedure

The measurement method starts by presenting a signal below the threshold. This signal is gradually increased up to the point where the person starts to feel the signal and says 'yes'. This point is called a response transition point (Figure 5).[4] After the person has said 'yes', the amplitude of the input signal is increased a little further (by elevating the upper pressure) in order to be well above the sensory threshold. Next, the ascending sequence of the pulse train's upper pressure is reversed into a descending sequence, until the person stops feeling the pulse train and says 'no', marking another response transition point (Figure 5). This procedure is repeated until ten response transition points have been recorded for each instrument. The signal's amplitude in this experiment is defined as the difference between the peak and basic pressure measured in one response transition point. The absolute sensory threshold of an instrument is taken as the average amplitude of the ten transition points of that instrument.

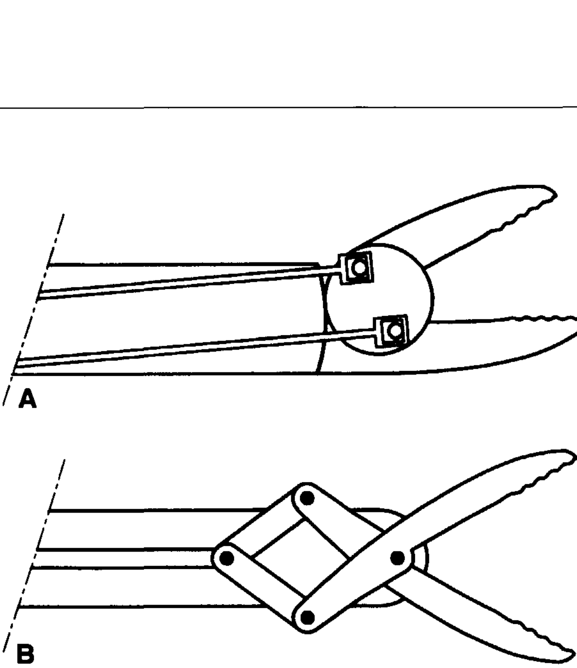

Figure 4. *This figure shows the differences between the rolling-link mechanism (A) and the slide bearing mechanism (B) in laparoscopic dissectors.*

A pilot study shows that averaging a larger number of repetition improves the reliability of the mean threshold. However, more than ten repetitions reduce the concentration, thereby causing less accurate threshold values again. Therefore, a sequence of ten transition points has been chosen.

The sensitivity variation between persons is known to be relatively high, depending on sex, age, training, and environmental influences.[4] To reduce the variation, a standard situation was created by performing the experiment in an identical environmental setting and with equal instrument's sequence for each participant. In this experiment, the average sensitivity varied by a factor of two. The sensitivity of the least sensitive participant was 1,2 to maximally 2,7 times lower than the average sensitivity depending on the instrument tested. The instrument Sensitivity Index (SI) was calculated by dividing the Instrument's Sensory Threshold (IST) by the Subject's Sensory Threshold (SST) (i.e. SI = IST / SST). This was done to compensate for individual differences in sensory threshold.

To minimise the variation within the data of one person, the concentration of the participants should remain high during the whole experiment.[4] The various instruments were tested with several breaks in between. The entire experiment did not take more than half an hour. To prevent an error of habituation or expectation, the computer generated an outgoing signal that changed the ascending or descending velocity of the sequence at random. The time between the response transition points was randomly changed in this way and could not be anticipated.

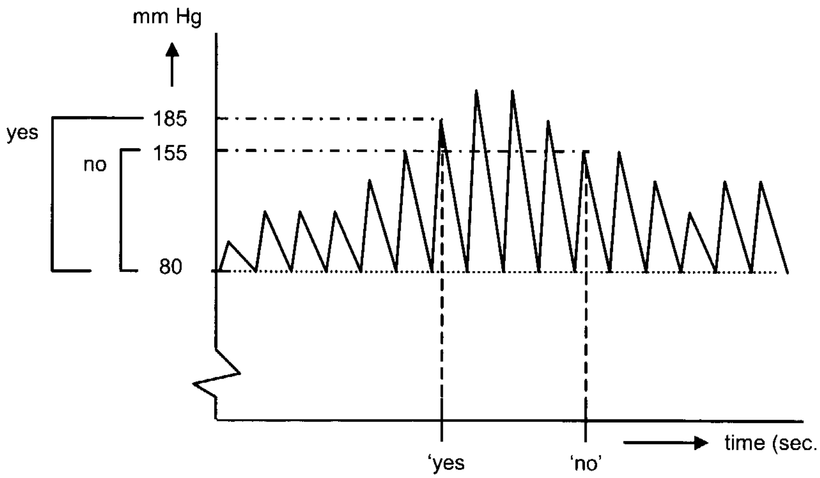

Figure 5. *The generated pulse train in the silicone tube. The Y-axes shows the pressure of the input signal in mm Hg. Basic pressure: 80 mm Hg (dotted line). The dotted - dashed horizontal lines show the amplitude's magnitude of a response transition point where one starts ('yes') and where one stops ('no') feeling the stimulus, indicating the 'yes' and 'no' sensory threshold levels, respectively.*

The computer recorded the amplitudes of the response transition points and sorted these values for each participant by dissector, thus making a calculation of the absolute sensory threshold for each separate instrument. From these thresholds the SIs and their standard deviations were calculated for each instrument. The differences between the SIs of the tested instruments were analysed statistically with a two-sided student t-test with unequal variances.

Results

The average SIs for the reusable dissectors were 8.7 for the 5 mm reusable and 16 for the 10 mm reusable dissector (Figure 6). The exact sensory threshold for the 5 mm disposable dissector was too high to be determined with this experimental set-up because the pulse train was hardly ever felt by the participants, even at the maximum pulse amplitude that could be generated with this set-up. Given the fact that the SI was higher than 20, the disposable dissector is at least twenty times less sensitive than bare fingers. The SIs of the other tested instruments were 4.1 for the tweezers, 8.2 for the orthopaedic dissector and 2.7 for the Wilmer® dissector. The standard deviation was highest for the 5 mm disposable dissector and decreased in the same sequence as the SIs did (Figure 6).

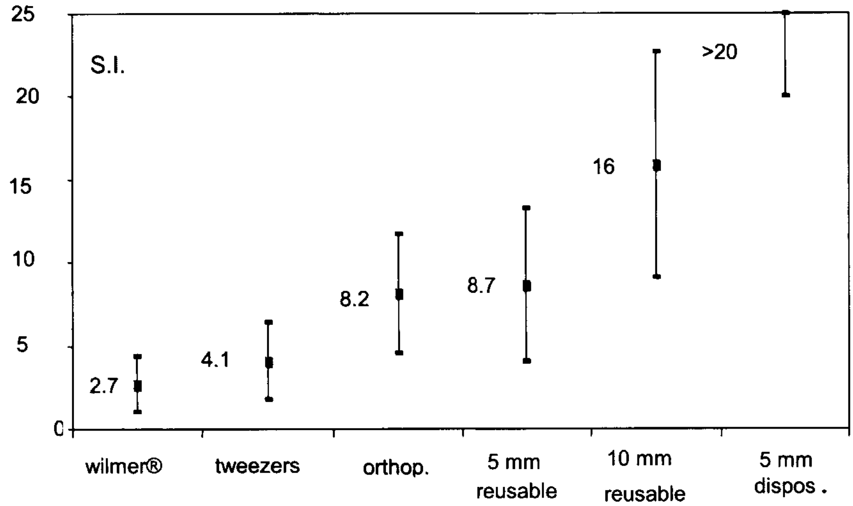

Figure 6. *Average Sensitivity Index (SI) of the instruments (black dots) and their standard deviations (SD's). The instrument's SI was computed by dividing the instrument sensory threshold (IST) by the subject's sensory threshold (SST).*

The SI was significantly higher for the reusable dissectors tested than for the disposable dissector tested ($p<0.001$) (Table 1), hence the reusable instruments were much more sensitive than the disposable one. The sensitivity of the 5 mm reusable dissector was better than the sensitivity of both the 10 mm reusable and the disposable one, but it was not significantly different compared to the orthopaedic dissector (Table 1). The Wilmer® SI was significantly lower compared to all commercially available instruments tested ($p<0.001$), and was therefore far more sensitive than the other instruments tested in this experiment.

Table 1. *P-values of the student t-test for comparison of the differences in sensitivity indices (SI) between the various instruments tested.*

Table 1	Wilmer®	tweezers	orthopaedic	5mm reusable	10mm reusable	5mm disposable
Wilmer®	-	0.01	<0.001	<0.001	<0.001	<0.001
tweezers		-	<0.001	<0.001	<0.001	<0.001
orthopaedic			-	0.63	<0.001	<0.001
5mm reusable				-	<0.001	<0.001
10mm reusable					-	<0.001

Discussion

The sensitivity feedback qualities of the commercially available laparoscopic dissectors were at least eight times lower than the feedback quality of bare fingers. Hence, the sensitivity loss due to the interposition of instruments is prominent, especially when compared to the natural sensitivity variation between persons which is considered to be high.[4] In this experiment, the natural sensitivity variation accounted for a factor two which is relatively low compared to the factors 8 unto 20 for the loss of sensitivity. To determine whether the differences in SI are clinically relevant, a further investigation is required into a psychophysical model in which a complete operation can be simulated.

The sensory feedback properties of the laparoscopic dissectors tested correlate with the mechanical efficiencies of these dissectors with a correlation coefficient of -0.91 (Table 2).[12] Apparently, the feedback quality of an instrument deteriorates as the mechanical efficiency becomes lower, and hence the SI increases. The 5 mm disposable dissector has the lowest efficiency of the laparoscopic dissectors tested and it is the least sensitive (Table 2). On the other hand, the Wilmer® prototype both has the highest sensitivity and the highest mechanical efficiency.[6]

***Table 2.** Average sensitivity index (SI) and mechanical efficiencies (ME) [6,12] of the laparoscopic instruments tested.*

	Wilmer®	5mm reusable	10mm reusable	5mm disposable
SI	2.7	8.7	16	>20
ME	96%	33%	28%	8%

The good feedback properties of the prototype demonstrate that it is possible to feel more accurately with carefully designed dissectors. In addition to the rolling-link mechanism, the Wilmer® dissector is supplied with an ergonomic hand grip instead of the scissors-like hand grip of most commercially available instruments.[7] This hand grip is designed to result in less fatigue and discomfort for the surgeon. Hence, this dissector will probably enlarge the tactile and proprioceptive feedback information, resulting in a more detailed sensing of the tissue's structure. However, the prototype still has to be tested in practice.

We have assumed in the experiment that the instruments tested were manufactured in an identical way. However, given the fact that each reusable instrument was produced by hand these instruments will show tiny variations. These variations will, however, be very small compared to the variation in sensitivity, and consequently it will not have influenced the test results considerably.

It is known that disposable instruments tend to lose some of their stiffness when they are used. This loss of stiffness could not be quantified with this experiment because the sensory feedback quality itself was already too low to be determined. Therefore, it was not possible to detect any slight changes in stiffness.

Conclusion

According to surgeons, the interposition of instruments results in reduced sensory feedback through these laparoscopic dissectors. This study quantifies the overall sensitivity loss through instruments by determining the sensory threshold. This turned out to be an accurate method for determining the sensory feedback qualities of the various instruments tested.

The sensory feedback was significantly higher for the reusable dissectors, than for the disposable dissector ($p<0.001$). Nevertheless, the sensory feedback of all commercially available dissectors tested were at least eight times lower compared to bare fingers. In addition, feedback qualities were highly variable, depending on the instrument tested.

Acknowledgements

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References

1. Classen M, Knyrim K, Seidlitz H, Hagenmuller F (1987) Electronic endoscopy, the latest technology. Endoscopy 19: 118-123.
2. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA (1995) Quantitative standardized analysis of advanced laparoscopic surgical procedures. End Surg 3: 210-213.
3. Cuschieri A (1995) Whither Minimal Access Surgery: Tribulations and Expectations. Am J Surg 169: 9—19.
4. Gescheider GA (1976) Psychophysics, method and theory. J Whiley, NY.
5. Grimbergen CA (1997) Minimally Invasive Surgery: Human-Machine Aspects and Engineering Approaches. Perspectives on the human controller. Lawrence Erlbaum associates, Mahwah, New Yersey 18: 223-231.
6. Herder JL, Horward MJ, Sjoerdsma W (1997) A laparoscopic grasper with force perception. Min Invas Ther & Allied Technol 6: 279-286.
7. Herder JL, Maase S, Voorhorst F, Sjoerdsma W, Smets G, Grimbergen CA, Stassen HG (1997) Ergonomic hand grip for laparoscopic graspers. Min Invas Ther & Allied Technol 6: suppl. 1: 55.
8. Herfath C, Schumpelick V, Siewert JR (1994) Pitfalls of minimally invasive surgery. Surg Endosc 8: 847.
9. Jansen A, Cuesta MA (1993) Basic and advanced instruments needed for developments in minimally invasive surgery. In Cuesta MA, Nagy AG, Minimally Invasive Surgery in Gastrointestinal Cancer, Edinburgh Churchill, Livingstone 15-25.
10. Melzer A (1992) Instruments for endoscopic surgery. In: Cuschieri A, Buess G, Prissat J eds, Operative Manual of Endoscopic Surgery. Berlin, Springer verlag 14-36.
11. Satava RM (1993) Surgery 2001, a technologic framework for the future. Surg Endosc 7: 111-113.
12. Sjoerdsma W, Herder JL, Horward MJ, Jansen A, Bannenberg JJG, Grimbergen CA (1997) Force transmission of laparoscopic grasping instruments. Min Invas Ther & Allied Technol 6: 274-278.
13. Tendick F, Jennings RW, Tharp G, Stark L (1993) Sensing and manipulation problems in endoscopic surgery: Experiment, analysis, and observation. Presence 2: 66-81.

6

Quantitative analysis of the functionality and efficiency of three surgical dissection techniques;

A time-action analysis

K.T. den Boer, I.H. Straatsburg, A.V. Schellinger, L.T. de Wit,
J. Dankelman, D.J. Gouma

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Abstract

Introduction: The increasing technological complexity of surgery demands for objective evaluation of surgical techniques. Alternatives for laparoscopic ligation, such as monopolar coagulation and the relatively new bipolar scissors combining dissection with coagulation, should be analyzed and compared in particular. This study tests the efficacy of quantitative time-action analysis in evaluating and comparing the functionality and efficiency of dissection and ligation techniques in a clinical setting.

Materials and Method: Standard dissection with ligation of vessels, bipolar scissors and monopolar coagulation were consecutively applied to dissect four meters of small bowel mesentery of pigs, in random order. All actions performed were recorded and analyzed, using a standard action list. The efficiency for each technique was expressed in mean dissection time and number of actions, and the safety in occurrence of complications and severity of microscopic damage.

Results: Time-action analysis evaluated the efficiency objectively and reproducible (ICC 0.98). Bipolar scissors were significantly more efficient (time 7±2 min., actions 129±33) compared to the standard technique (28±6, 771±185) and monopolar coagulation (14±5, 368±32) ($P<0.01$). Furthermore, bipolar coagulation needed significantly less re-coagulation of an oozing vessel (0.5% of the total dissected vessels) compared to monopolar coagulation (10.4%), and the damaged zone was significantly smaller ($P<0.05$). Significantly less time was spent waiting or exchanging instruments with bipolar scissors compared to the standard technique ($P<0.05$).

Conclusion: This time-action analysis could objectively compare the efficiency and functionality of three surgical dissection techniques during clinical use. Bipolar scissors were more efficient compared to both the other techniques, and coagulated vessels more safely than monopolar coagulation.

Introduction

Increased technological complexity of laparoscopic surgery and the rapid introduction of sometimes poorly adapted equipment demand objective evaluation and comparison of the instruments developed, whereas the cost-control pressures on surgeons demand efficient surgery[1-4]. In general, the development of new instrumentation follows a cyclic process: concept → engineering drawing → prototype construction → evaluation in laboratory and surgical skills training systems → new or altered concept[5-7]. This development process is controlled by international standards. Clinical testing usually follows the laboratory testing of the instruments. The clinical testing step, focuses on evaluating the post-operative complication reduction, shorter total operation times, or investigating the comfort for the surgeon and easy handling of the instrument, in subjective parameters[1-3; 5-8]. However, no objective analysis of instruments and techniques with respect to the clinical functionality or efficiency is described. Nevertheless, the rapidly growing variation in instruments increases the need for objective comparison of instruments or techniques to support accurate decision-making.

In laparoscopy, the loss of direct contact and direct vision on the operation field, and the disturbed eye-hand coordination, have complicated surgical actions and introduced additional risks. For example, instrument exchanges increase the risk of accidental tissue damage and strongly decrease the surgical efficiency[9; 10]. In addition, dissection of tissue and safe ligation of vessels have become very difficult, complicating in particular colon resections due to the frequent alternation of dissection actions with small vessel ligation. Various alternatives for ligation of vessels have been introduced such as monopolar coagulation, bipolar scissors, or staplers[2; 8; 10]. Bipolar scissors are described in literature as a better alternative for vessel ligation compared to monopolar coagulation or conventional ligation of small to medium sized vessels[11-13]. These studies are based on animal models for induction of microscopic damage or on subjective clinical evaluation, scaling the surgeon's impression from 1 to 5 about coagulation, smoke, and overall satisfaction after the operation[14; 15]. However, no objective analysis is available, evaluating the actual efficiency and functionality improvements of bipolar scissors compared to conventional surgical techniques in a clinical setting[1; 2; 8; 10; 16].

The present study aims to evaluate if time-action analysis could objectively assess the clinical functionality, efficiency, and safety of instruments used during the per-operative process. This study compares the relatively new bipolar scissors with monopolar coagulation and conventional dissection with ligation of vessels. Time-action analysis was applied to evaluate the time, number of actions, and complications for each technique. In addition, the microscopic damage caused to the dissected tissue, was investigated histologically.

Material and Methods

Three surgical dissection techniques were compared with respect to their efficiency and functionality in a clinical setting. These techniques are normally used in operations with frequent dissecting and ligating actions (e.g. colectomies). Therefore, an experimental pig model was selected, simulating these surgical actions. The study protocol was approved by the local research committee and the Animal Research Committee of the Academic Medical Center at the University of Amsterdam. Animal care and all procedures were performed in compliance with National Guidelines for Care of Laboratory Animals in the Netherlands.

Animals

Six healthy female pigs (mean weight 21 kg, ranging from 19,3 – 23,6 kg) were sedated, using a mixture of ketamine (15 mg/kg), dormicum (1 mg/kg), and atropine (0,1 mg/ 5 kg), for pre-medication. Anesthesia was induced with halothane by mask in a mixture of O_2/N_2O 1:1. Animals were intubated and ventilated with O_2/air/halothane 0,4-0,8%. After intubation, the animals received a single dose of sufentanil (5 μg/kg, i.v.) and pavulon (0,1 mg/kg, i.v.). Anesthesia was maintained with an infusion of sufentanil (3 μg/kg/hr i.v.) and ketamine (8 mg/kg/hr, i.v.). The ECG, temperature, blood pressure and end tidal CO_2 were monitored during the experiment. At the end of the experiment, animals were terminated, still under anesthesia, using a bolus injection of potassium chloride i.v. (10 ml, 3 mMol/ml).

Surgery

An experienced surgeon performed a laparotomy via a midline incision, the viscera were placed aside, and the small bowel was exposed and divided into three parts of four meters each. The three surgical techniques were used in random order to dissect four consecutive meters of small bowel mesentery per pig: bipolar scissors (PowerStar* BP540 and bipolar cable BP 900, Ethicon inc., Johnson & Johnson Company, New Yersey, USA), monopolar coagulation (reusable hand switching pencil E 25550, Valleylab inc, Boulder, CO 80301-3299, USA), and the conventional way of dissection combined with ligation of vessels as the golden standard (Fig. 1). The pig model was selected because it enabled a controlled experimental setting to compare the functionality and efficiency of the techniques, under similar environmental and operational conditions, without pathology interfering with surgical actions. Bipolar and monopolar coagulation were applied for small to medium sized vessels (mean diameter of 1-2 mm.), and only if they could be used safely according to the experienced surgeon, otherwise the surgeon would use ligation of these vessels. Tissue biopsies were taken from the monopolar and bipolar dissection sites of the mesentery and processed for histologic examination. The electrosurgical generator

(Valleylab Force 20, Valleylab inc, USA) was set at the lowest for effective coagulation, and the same electrosurgical generator was used in all experiments, equipped with monopolar and bipolar technology.

Data collection and processing

A quantitative time-action analysis was carried out to evaluate the speed of skill performance and the number of actions, as described before[9; 10]. Briefly, all actions performed by the surgeon were recorded with a Charged Coupled Device (CCD) video camera, placed on the head of the operating surgeon to guarantee a central overview of the operation field and sound was recorded at the same time. The instrumentation for recording the procedures was mounted in a portable cabinet, outside the range of action of the operating team. The recorded procedures were analyzed off-line to insure that the analysis did not interfere with the per-operative procedure.

The total time for each technique needed to dissect 4 meter small bowel mesentery, from the first until the last dissecting action was determined. In addition, all actions performed by the surgeon during the operation were analyzed, using a strictly defined thesaurus of actions, enabling quantitative analysis and evaluation. The actions were divided into efficient actions, supporting the goal of the procedure (e.g. dissecting sharp/blunt, stretching tissue, ligating, knotting), and limiting factors, delaying the procedure (e.g. waiting for personnel, correcting a complication such as re-coagulating a bleeding vessel, and changing or cleaning an instrument). Re-bleeding was scored from a slight oozing of blood out of the vessel to a major bleeding complication. Delay due to anatomic variations will be regarded as natural variation rather than a limiting factor. The times and actions of each experiment were analyzed by two observers, whose results were averaged. The mean time and number of actions per technique were determined for all six experiments.

All data were processed using a spreadsheet program and analyzed using the statistical program of SPSS for Windows. The data were presented as mean ± standard deviation. The two sided student t-test was used to compare data, and $p < 0.05$ was considered significant. The time-action method and histologic measurements were validated for the inter-observer agreement, by calculating the intraclass correlation coefficient (ICC) for single ratings [17].

Histology

Mesentery biopsies were snap frozen in liquid N_2 and sectioned (8μm), post-fixed, and stained with Giemsa and Hematoxylin & Eosin. Stained sections were scanned and converted to digital information using a color scanner (Scan Jet 6250C; Hewlett®packard, Palo Alto, CA, USA) and HP Precision Scan Pro software (Hewlett®packard).

Figure 1. *Photographs of techniques used in dissection of the small bowel mesentery in pigs, showing combined dissection and coagulation function of bipolar scissors (A), monopolar coagulation of a blood vessel via tweezers (B), and conventional ligation of a vessel (C).*

Images were stored as TIFF-files and evaluated by two observers in a blinded setting using morphometry software (Leica Qwin, Leica, Germany) and light microscope (magnification 40-100x). Collateral coagulation, damaging the surrounding tissue, was investigated microscopically and the depth of coagulation (in mm.) into the vessels was assessed, because optimal surgical coagulation should combine safe vessel hemostasis (no re-bleeding) with minimal coagulation depth into the vessel and no damage due to collateral coagulation. The depth of coagulation into the vessel was defined as the distance from the coagulation border (i.e. the coagulated edge of the biopsy) to the most distal coagulated blood vessel that was evident within the mesentery section. Total coagulation was defined as a section in which all vessels were coagulated, including the last evident vessel of the section.

Results

Surgery

In neither of the experiments, change to ligation of the vessels (Fig. 1c) was necessary during the use of monopolar or bipolar coagulation, because all blood vessels could be coagulated safely and no major bleeding complications occurred. The surgeon used the monopolar pencil on tweezers placed in the middle of a blood vessel (Fig. 1b), and thermal diffusion damage was observed macroscopically along the monopolar path by whitening and heating of the mesentery away from the dissection plane. With bipolar scissors, the surgeon coagulated the vessels over a 1-2 cm trajectory before cutting them (Fig. 1a), resulting in a whitening locally at the place of coagulation (1-2 cm long). The power of the electrosurgical generator was set at the lowest for effective coagulation, turning out to be 36 Volts on average for bipolar coagulation and 38 Volts for monopolar coagulation, which was not significantly different.

Time-action analysis

An action and a time standard were determined for each method (Fig. 2), revealing that dissection of the mesentery using the bipolar scissors reduced the numbers of actions by 83% and the time by 75% compared to the standard method ($p<0.01$). Compared to monopolar coagulation, bipolar scissors diminished the actions by 63% and the time by 50% ($p<0.01$).

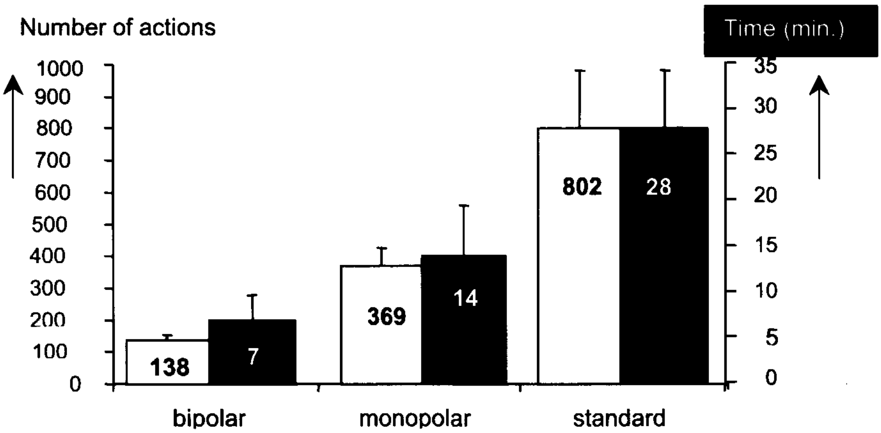

Figure 2. *Time and Action standard. Bars represent the average time in min. (black bars) and the average number of actions (white bars) for each surgical method (error bars represent one standard deviation). The times and actions of bipolar coagulation are compared with those of monopolar coagulation and of the standard, using the student t-test; P<0.05 was considered significant.*

Table 1 shows that additional coagulation for re-bleeding vessels was significantly less frequent after bipolar coagulation compared to monopolar coagulation. However, no severe bleeding occurred, and re-bleeding of vessels was mainly observed as slight to moderate oozing of vessels. Time needed by the surgeon for exchanging instruments was significantly shorter with bipolar scissors and time spent waiting for assistance was significantly reduced compared to the standard method. However, bipolar scissors were moistened and cleaned more frequently compared to the standard method ($p<0.05$).

Table 1. *Limitations related to techniques*

	bipolar scissors	monopolar coagulation	standard
% vessels re-coagulated §	0.5%	10.4% *	0.1%
Changing instrument ¥	0	408 *	724 *
Waiting for assistance ¥	2	8	23 *
Cleaning or moisturizing ¥	27	4 *	0 *

*§ = percentage of re-coagulated vessels relative to the amount of coagulated vessels in all 6 experiments. ¥ = total number of times the surgeon changed, waited for, or cleaned instruments in all 6 experiments. * = P<0.05, bipolar scissors versus monopolar coagulation and bipolar scissors versus standard.*

The time-action method was validated, determining the ICC for the inter-observer agreement. Both the observers analyzed all 6 experiments, using the defined action thesaurus, resulting in an ICC of 0.98.

Microscopic evaluation

Collateral coagulation damage to the mesentery was minimal; no cellular changes were observed in the tissue surrounding the coagulated vessels, no pyknotic nuclei or variation in staining intensity was evident. The coagulation of blood vessels resulted in clotting of blood vessel contents and phase separation, i.e. separation of aggregated blood cells (solid phase) from serum (fluid phase), in both Giemsa and H&E stained sections (Fig. 3) and was measured in mm. The coagulation depth into the vessels was significantly smaller after bipolar coagulation (4.3 mm ± 3.4 mm) compared to monopolar coagulation (7.0 mm ± 1.8) ($p<0.05$). Total coagulation of the section occurred in 25% of monopolar coagulated mesentery sections and in none of the bipolar coagulated mesentery sections.

The measurement of the depth of coagulation and the length of the sections was highly accurate and reproducible, resulting in an ICC of 0.98 and 0.97, respectively.

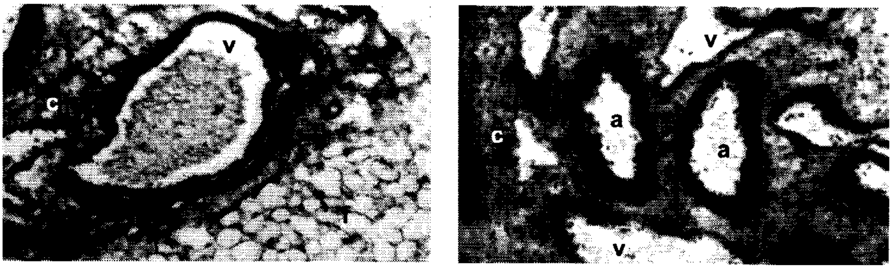

***Figure 3.** Photomicrograph of mesentery biopsy sections after monopolar (A) and bipolar (B) coagulation illustrating a coagulation clot obstructing a mesentery vein (A) and mesentery vessels free of coagulation clots (B). (a, artery; c, connective tissue; f, fat tissue; v, vein; Giemsa stain; magnification 160x)*

Discussion

The present study clearly shows that time-action analysis can objectively evaluate the efficiency and functionality of three dissection techniques in quantitative terms, enabling reliable statistical analysis. In addition, an ICC of 0.98 proves that time-action analysis was an accurate and reproducible method. Using this method, any combination of surgical instruments could be evaluated during the per-operative process in humans or animal experiments. In future, time-action analysis could complete current testing methods of prototypes and instruments in laboratories, by objective evaluation of the instrument's functionality and efficiency in a clinical setting.

This study compares the efficiency of three techniques, bipolar scissors prove to be significantly more efficient than the standard technique with respect to dissection time and number of actions. In addition, the surgeon had to wait for assistance and had to change instruments less frequently than in the standard method, as a result of the simultaneous cutting and coagulation function of the bipolar scissors. This study also evaluates and compares the functionality of bipolar scissors, dissection with monopolar coagulation and dissection with ligation of vessels, which is considered to be the golden standard in conventional surgery. The results show that both the monopolar and the bipolar coagulation are safe alternatives to ligation of small vessels, because the surgeon could coagulate all blood vessels safely with these techniques without major bleeding complications and without the need to switch to ligation of vessels. Compared to monopolar coagulation, bipolar coagulation was more accurate and reliable in coagulating vessels up to 3 mm in diameter, needing less control of hemostasis due to oozing of a vessel. However, caution should be taken before transferring these efficiency and functionality results into clinical practice. It is possible that the experimental parameters of this study (animal model, dissection of mesentery of pigs) may not be equivalent to those found in laparoscopic or open surgery. Dissection actions for dissecting the mesentery can, however, be compared to the actions carried out during the mobilization of the colon, and furthermore, clinical use of bipolar scissors indicate also increased efficiency and accurate hemostasis. In addition, the reduction in instrument exchanges will also be present in humans if bipolar scissors are used and will especially be beneficial in laparoscopic surgery because every instrument exchange in laparoscopy introduces additional risks of tissue damage and is particular cumbersome and time-consuming. Finally, in humans, adipose tissue is frequently obscuring small vessels, increasing the risk of accidentally dissecting not yet identified vessels. This risk is relatively high if cutting is used in combination with ligation or monopolar coagulation of vessels, and could probably be reduced by the simultaneous cutting and coagulation function of bipolar scissors .

The evaluation of the microscopic damage shows that coagulation of vessels in the mesentery hardly causes collateral coagulation, damaging the surrounding tissue, which is probably due to the structure of the pig mesentery, consisting only of some collagen fibers and fat cells. The depth of coagulation into the vessels was shorter with bipolar scissors compared to monopolar coagulation, however, it is not clear what the consequences will be on patient outcome. The differences in damage due to coagulation are confirmed by other studies in literature, which states that re-bleeding is more frequently seen in monopolar coagulation in comparison to bipolar coagulation[11; 13; 15].

A limitation of this study was that the maximal depth of damage could not always be identified with certainty, because in total coagulated sections, the last evident vessel was also coagulated, suggesting that the depth of coagulation could have reached beyond the margins of the section. However, the percentage of total coagulation was higher in monopolar biopsies and the total section length was shorter in monopolar sections (7.4 mm) than in bipolar sections (12.4 mm) ($p<0.05$), resulting in a possible underestimation of the coagulation depth for monopolar coagulation. Furthermore, in bipolar coagulation, the surgeon coagulated the vessels over a 1-2 cm trajectory before cutting them, resulting in a broader coagulation area and possible more damage than would have been necessary.

In conclusion, the difference in damage due to coagulation between bipolar scissors and monopolar coagulation might be underestimated in this study. These differences in damage can be explained by the differences in current distribution characteristics between bipolar and monopolar coagulation. The current in bipolar scissors mainly passes through the tissue between the closely spaced electrodes in the two blades of the scissors. In contrast, in monopolar coagulation, the electric current is flowing to ground (via the ground plate and electrosurgical generator) using the patient as the intermediary conductor. As a consequence, the power applied to the tissue is dissipated and diminishes gradually with distance away from the electrode. The spread of dissipation depends on the geometry and resistivity of the anatomical structure, leading to a less controlled and more diffuse dissipation of power. The power dissipation to the surrounding tissue was observed in our study by whitening and heating of the mesentery away from the dissection plane in monopolar coagulation. In addition, in monopolar coagulation the risk is increased of high-frequency leakage, alternate site burns related to capacitive coupling, direct coupling, insulation failure, or unintended burns along the monopolar path.

The bipolar scissors were cleaned and moistened more frequently than the two other techniques, especially during the first experiments. However, blades moistened with a physiologic salt solution caused a shortcut in the current by forming salt crystals in the pivot, which disabled coagulation. The surgeon consequently diminished these actions. This problem is, however, not relevant in laparoscopic surgery due to the different constructions of the tips of the bipolar instruments. Cleaning actions were also decreased after the first experiment by setting the power as low as possible for effective coagulation, resulting in a reduction of cleaning in later experiments.

In conclusion, the present study showed that time-action analysis can objectively evaluate the functionality and efficiency of surgical instruments or techniques in a clinical setting. It showed that the efficiency of bipolar scissors was higher compared to monopolar coagulation and the standard dissection method, significantly reducing the time, number of actions and instrument exchanges. Most optimal coagulation was obtained with bipolar scissors because the shorter depth of coagulation into the vessel was combined with a smaller percentage in re-bleeding and with the most efficient functioning compared to monopolar coagulation. In future, time-action analysis could be applied for objective evaluation of surgical instruments in a clinical setting with respect to the functionality and efficiency, thereby completing the currently used testing methods of prototypes and instruments in laboratories.

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References

1. Cuschieri A. Whither minimal access surgery: tribulations and expectations. Am J Surg 1995; 169:9-19.
2. Berguer R. Surgical technology and the ergonomics of laparoscopic instruments. Surg Endosc 1998; 12 (5):458-462.
3. Satava RM, Ellis SR. Human interface technology. An essential tool for the modern surgeon. Surg Endosc 1994; 8(7):817-820.
4. Cuschieri A, Melzer A. The impact of technologies on minimally invasive therapy [editorial]. Surg Endosc 1997; 11:91-92.
5. Frank TG, Cuschieri A. Prehensile atraumatic grasper with intuitive ergonomics. Surg Endosc 1997; 11:1036-1039.
6. Tendick F, Jennings RW, Tharp G, Stark L. Sensing and manipulation problems in endoscopic surgery: Experiment, analysis, and observation. Presence 1993; 2:66-81.
7. Melzer A, Kipfmüller K, Halfar B. Deflectable endoscopic instrument system DENIS. Surg Endosc 1997; 11:1045-1051.
8. Rau G, Radermacher K, Thull B, von PC. Aspects of ergonomic system design applied to medical work systems computer integrated surgery. In Taylor RH, Lavallee S, Burdea GC, Mösges R., eds. Technology and Clinical Applications. 1996; 203-221.
9. Boer den KT, de Wit LT, Gouma DJ., Dankelman J. Per-operative Time-Motion Analysis of Diagnostic Laparoscopy with Laparoscopic Ultrasonography. Br J Surg 1999; 86:951-955.
10. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA. Quantitative standardised analysis of advanced laparoscopic surgical procedures. Endosc Surg Allied Technol 1995; 3:210-213.
11. Baggish MS, Tucker RD. Tissue actions of bipolar scissors compared with monopolar devices. Fertility and Sterility 1995; 63:422-426.
12. Liboon J, Funkhouser W, Terris DJ. A comparison of mucosal incisions made by scalpel, CO_2 laser, electrocautery, and constant-voltage electrocautery. Otolaryng-Head and Neck Surg 1997; 116:379-384.
13. Spivak H, Richardson WS, Hunter JG. The use of bipolar cautery, laparosonic coagulating shears, and vascular clips for hemostasis of small and medium-sized vessels. Surg Endosc 1998; 12:183-185.
14. Savides TJ, See JA, Jensen DM, Juthabha R, Machicado GA, Hirabayashi K. Randomized controlled study of injury in the canine right colon from simultaneous biopsy and coagulation with different hot biopsy forceps. Gastrointest Endosc 1995; 42:573-577.

15. Edelman DS, Unger SW. Bipolar Versus Monopolar Cautery Scissors for Laparoscopic Cholecystectomy: A Randomized Prospective Study. Surg Laparosc Endosc. 1995; 5:459-462.
16. Berguer R. The application of ergonomics in the work environment of general surgeons. Reviews on Environmental Health 1997; 12 (2):99-106.
17. Crosthwaite G, Chung T, Dunkley P, Shimi S, Cuschieri A. Comparison of direct vision and electronic two- and three-dimensional display systems on surgical task efficiency in endoscopic surgery. Br J Surg 1995; 82:849-851.

7

Time-action analysis of instrument positioners in laparoscopic cholecystectomy;

A multi-centre prospective randomised trial

K.T. den Boer, M. Bruijn, J.E. Jaspers, L.P.S. Stassen, W.F. M. van Erp, A. Jansen, P.M.N.Y.H. Go, J. Dankelman, D.J. Gouma.
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Abstract

Introduction: Instrument positioners (IP) can position and lock a laparoscopic instrument. This study uses time-action analysis to evaluate objectively if IPs can substitute a surgical assistant efficiently and safely.

Methods: 78 Laparoscopic cholecystectomies (LC) were randomly assisted by a surgical assistant or an IP (AESOP™ and PASSIST), in four hospitals. The efficiency and safety of LCs were analysed with respect to time, number and type of actions, positioning accuracy, and peroperative complications. A questionnaire evaluated the difficulties for each operation, and the comfort of use of the IPs.

Results: The PASSIST and AESOP™ were able to replace the surgical assistant during LCs, both without significantly changing the efficiency and safety of the operation. The questionnaire showed that the surgeons preferred to operate with an IP.

Conclusion: This study assessed objectively that IPs can substitute a surgical assistant efficiently and safely in elective LCs.

Introduction

Various (supporting) instruments have been developed to facilitate laparoscopic surgery. An example of a supporting instrument is the instrument positioner (IP), which can help to lock a laparoscopic instrument, and yet allow for adjustment of position[1]. Usually, during a laparoscopic procedure, a surgical assistant controls the laparoscope and when needed, an additional grasper. Consequently, the surgeon has no direct control over his viewing direction and the laparoscopic image is often unstable, due to tremor and sudden movements of the surgical assistant. Furthermore, the positioning task is a relatively static and tiresome task for the surgical assistant. IPs could take over the task of the surgical assistant, return camera-control to the surgeon, and stabilize the laparoscopic image. IPs are divided into two main groups: passive positioners, which are manually repositioned by the surgeon, and active positioners, which are repositioned by a robotic device. An example of a passive positioner is the PASSIST. An example of an active positioner is the AESOP™[1-3] . Laboratory experiments with IPs show that observation and manipulation tasks can improve when the surgeon has direct control over his viewing direction in laparoscopic procedures[4]. A clinical experiment indicated that the use of an active IP does not increase the total operation time[2].

The aim of this study was to analyse objectively if IPs could substitute a surgical assistant efficiently and safely in a clinical situation, comparing laparoscopic cholecystectomies (LCs) performed with a surgical assistant and LCs performed with an IP instead of an assistant. This study analysed the efficiency of the procedure in terms of time and actions needed per phase, using time-action analysis, and it evaluated the safety in terms of the incidence of peroperative complications, the positioning accuracy of the image, and the judgment of the surgeons.

Methods

Patients and procedure

A multi-centre, randomised, prospective clinical trial was used to compare LCs performed with a surgical assistant (As-group) with LCs without an assistant, using IPs (IP-group) instead. Patients (ASA I-III) undergoing elective LC for symptomatic cholelithiasis were included. Patients were excluded if they met at least one of the exclusion criteria, as listed in Table 1. These inclusion and exclusion criteria were generally used in the participating hospitals to select patients for LC, and were therefore sustained in this study. Acute cholecystitis was excluded because this study was a multi-centre trial and thus we had to be able to plan the procedures in advance. Seventy-eight laparoscopic cholecystectomies were performed in 4 hospitals, by 4 surgeons who were experienced in performing LCs

Table 1. Exclusion Criteria.

Age < 18
Quetelet-index > 40
Pregnancy
Previous upper-abdominal surgery
Recent pancreatitis
Clinical, chemical or radiological suspicion of cholestasis/ stones in the ductus choledochus
Cholecystitis
Other infection in the right upper abdominal quadrant
Suspicion of perforation or empyema of the gallbladder
Porcelain gallbladder
Diagnosed cancer
Bleeding disorders

and by 1 resident. LC was selected for this study, because LCs are performed on a regular basis and in accordance with a standard protocol used in the participating hospitals. All surgeons randomly performed LCs in the As-group or in the IP-group as decided by drawing lots. An equal number of lots were distributed in the As-group as in the IP-group for each surgeon, to compensate for any variations caused by differences in individual surgical techniques and hospital policy. The study protocol was approved by the local Ethical Committees of the participating hospitals.

Instrument Positioners

In the IP-group, one surgeon used the active voice-controlled AESOP™ (Computer Motion, Santa Barbara, California, USA), because he was already experienced in using the AESOP™ to position the laparoscope. The other surgeons used the recently developed passive IP called PASSIST[5]. The PASSIST and AESOP™ allow movements in four degrees of freedom; all three rotations around the incision point in the abdominal wall and one translation through this incision. None of the surgeons were experienced in solo-surgery, because residents used to assist LCs performed with or without IPs as part of their surgical training.

The active voice controlled AESOP™ was selected as a representative of the commercially available active positioners (see Figure 1a). The active IP can position and lock the laparoscopic camera using voice control, without interruption of the operating actions of the surgeon. Active IPs are rather expensive, not sterilisable, and only control the camera.

The PASSIST (see Figure 1b) is a manually controlled mechanical arm, capable of locking the laparoscope and an additional grasper in the desired position allowing for adjustments of position using one hand[5]. The PASSIST is slender, and thus does not interfere with the surgeon's actions, as some bulky active IPs do. In addition, the PASSIST can be mounted at the OR-table rail next or opposite to the surgeon, without

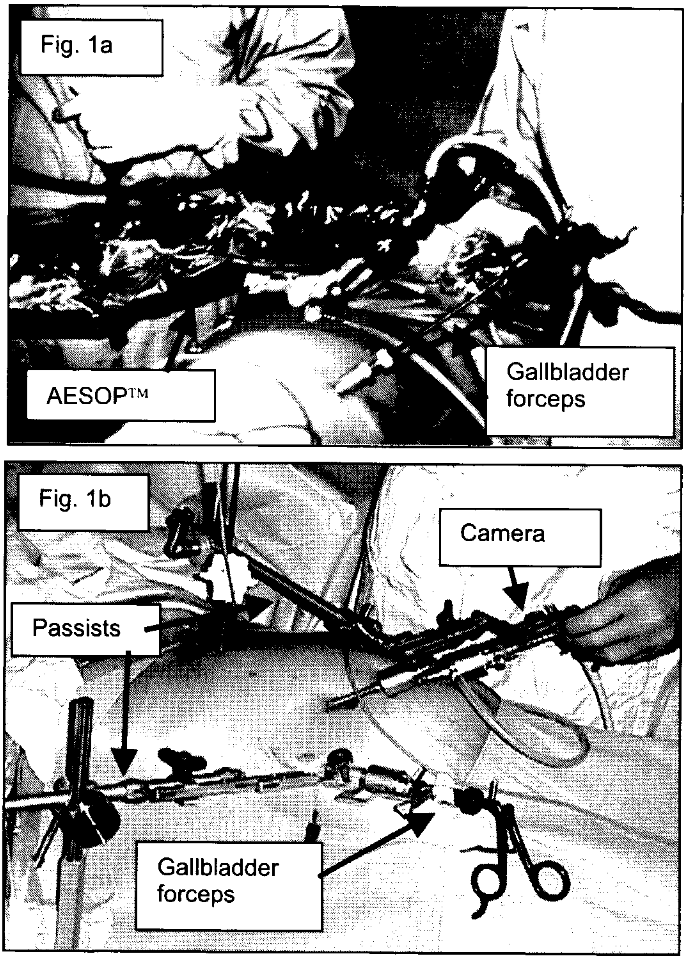

Figure 1. *1a) Active voice-controlled positioner: AESOP™ by computer motion. 1b) Passive positioner: PASSIST, two positioners are shown: one positioning the camera; the other positioning the gallbladder forceps.*

interfering with the surgeon's actions, and is sterilisable. Two PASSISTs can be used at the same time. Thus, if a surgeon uses 4 trocars for LC, he can use 2 PASSISTs to position both the laparoscope and the gallbladder forceps.

Recording procedure

During the surgical procedures, the images from the laparoscope and the images from two additional external CCD-cameras were simultaneously recorded, using a 4-channel mixing device. The small CCD-cameras recorded one central overview of the surgical procedure, and a detailed image of the hands of the surgeon. In addition, an omni-directional microphone recorded the comments of the surgeon during the operation. The equipment was placed outside the range of motion of the operating team and the recorded procedures were analysed outside the operating theatre to prevent interference with the peroperative procedure.

Data analysis

The efficiency and safety were determined for each procedure, using the recently introduced time-action method to analyse the peroperative process objectively[6-8]

The efficiency of the operation was analysed by comparing the time and the number of actions, needed for each operation phase between the As-group and the IP-group. The type of actions were analysed using a modified list of actions (Table 2) as defined by Claus et.al. [6]. The outcomes of the As-group were used as the standardised reference for the IP-group. For the As-group, the total number of actions of the surgeon and the surgical assistant were scored. For the IP-group the total number of actions of the surgeon were scored. Additionally, the actions that the scrub-nurse took over from the surgical assistant were also scored in both procedures. For example, in case the AESOP™ and 4 trocars were used, sometimes the scrub-nurse had to hold the gallbladder forceps because the AESOP™ only held the laparoscope. The efficiency was analysed in 3 phases (set-up, dissection and closure phase) as reported previously[7-9]. In short: the set-up phase was defined to start after the last sterile sheet was placed and to end with the first intra-abdominal dissection. The dissection phase was defined as the interval between the first intra-abdominal dissection and the removal of the gallbladder from the abdomen. The closure phase was defined as the interval between the removal of the gallbladder from the abdomen and the placing of the last suture.

***Table 2**. List of defined actions.*

Surgical	*Instrument*	*Others*
Dissect	Insert instrument	Waiting for personnel
Stretch	Remove instrument	Waiting for instruction
Coagulate bleeding site	Reposition laparoscope	Waiting for tech. reason
Clip	Handle positioner	Command to reposition scope
Percussion / palpation	Reposition gallbladder forceps	Other verbal instruction
Irrigation / Suction	Clean instrument	Apply bandage
Suture	Set-up supporting-systems	
	Use retrieval bag	

The safety of the procedure was evaluated by determining the peroperative complications (e.g. arterial bleeding, gallbladder leakage, bowel injury), the positioning accuracy of the image, and by assessing difficulties during the operation by the surgeons. Signs of mild cholecystitis, that became apparent during the operation, was also scored as a complicating factor, because cholecystitis makes the dissection more complicated.

The positioning accuracy was defined as the accuracy with which the laparoscope showed each dissecting action in the centre of the image. Experienced surgeons were asked to indicate in which field of the monitor image the actions should be performed for safe task performance. Accordingly, the centre of the image was defined as a circle with a diameter of 2/3 of the height of the monitor (Figure 2). The position of the manipulating instruments' tip was determined in the image: completely in the centre of the image, at the border of the image, or partly outside the monitor (Fig. 2). For electro-surgical instruments, the tip was defined as the non-insulated part of the instrument. For other instruments, the tip was defined as the part between hinge and point. The position of the tip of the instrument was scored for each manipulating action of the experienced surgeons in the dissection phase. In addition, the number of times the laparoscope was repositioned (manually/or by verbal command) was analysed.

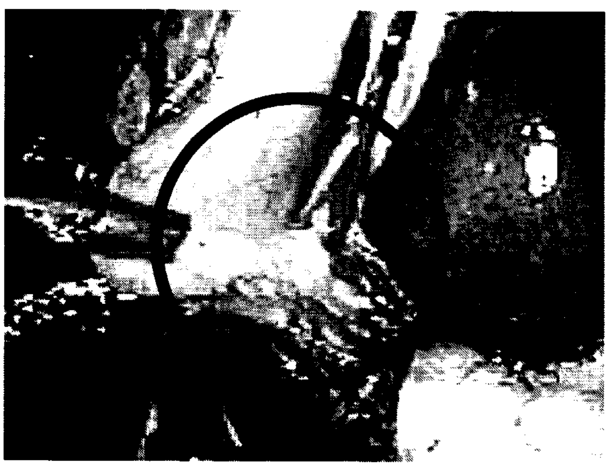

Figure 2. *Positioning accuracy. The diameter of the circle in the centre is 2/3 the height of the monitor image.*

Difficulties during the operation and the comfort of use of IPs were both evaluated using a questionnaire, which was completed after each procedure by the surgeon (Table 4). The surgeons were asked to rate the answers on a scale ranging from 1-5 (1=not at all, 5=yes, absolutely). The average ratings of each answer were calculated to compare the As-group with the IP-group.

The resident's results were analysed separately from the results of the experienced surgeons because the operation times for the resident are significantly longer compared to those of an experienced surgeon. In addition, a sub-analysis was performed, analysing the outcomes of the AESOP™ and the PASSIST separately.

The mean values and standard deviations were calculated for the time (in minutes) and number of actions, and for the positioning accuracy. The two-sided student t-test was used to compare the outcomes, $p < 0.05$ was considered significant.

Results

There was no significant difference in patient characteristics (age, gender) or in number of peroperative complications between the As-group and the IP-group (Table 3), and no conversions to open cholecystectomy occurred in either group. Of the total of 78 LCs, the surgeons performed 30 LCs with a surgical assistant and 30 without, the resident performed 9 with and 9 without a surgical assistant. One surgeon used the AESOP™ instead of the PASSIST (5 LCs in each group).

Table 3*. Patients characteristics and peroperative complications.*

	Assistant-group (n=39)	*IP-group (n=39)*	*t-test* *
Males / Females	11 / 28	6 / 33	n.s.
Mean Age (yrs) (±SD)	51 (15.3)	51 (15.6)	n.s.
Cholecystitis	8	5	n.s.
Arterial bleeding	4	1	n.s.
Gallbladder perforation	18	15	n.s.
Endobag used	8	9	n.s.

* n.s.= not significant

Efficiency

The total operation time did not differ significantly for LCs performed with a surgical assistant (42±21 min.) compared to LCs performed with an IP (49±23 min., p=0,18)(Figure 3). Moreover, the total number of actions did not differ either between the As-group (635±251 actions) and the IP-group (646±265 actions, p=0.86). The results per phase show that only the time for the set-up phase was increased significantly in the IP-group compared to the As-group. The number of actions did not differ between the 2 groups for any operation phase (Figure 3).

Positioning of laparoscope

The number of times the laparoscope was repositioned during an operation decreased significantly when an IP was used (49±27) instead of a surgical assistant (114±54, p<0,001). Nevertheless, the positioning accuracy of the laparoscope did not differ

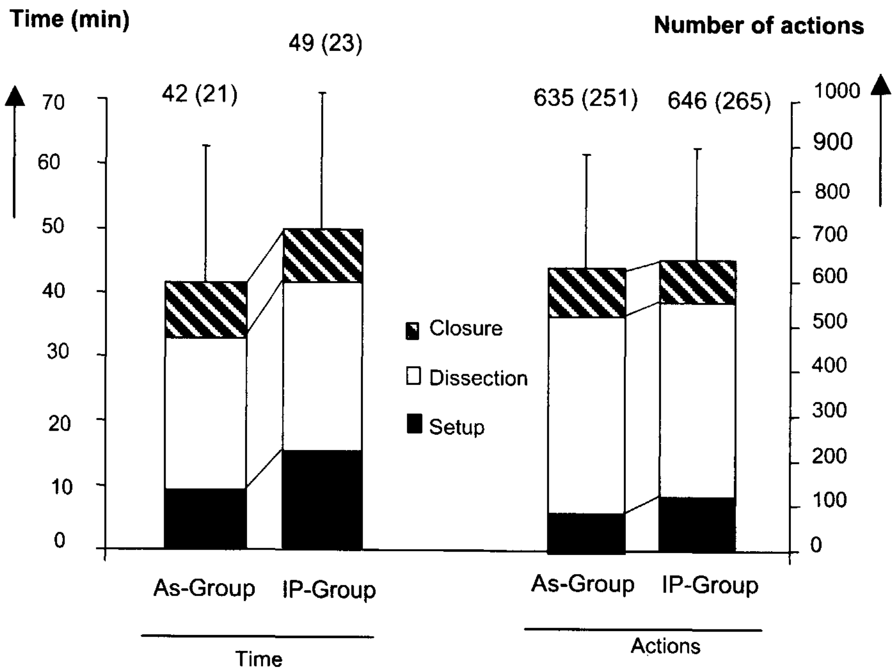

***Figure 3.** Time-action results. Average time and number of actions are shown per phase for the As-group and the IP-group of the experienced surgeons. Total time (± standard deviation) in minutes and number of actions are shown on top.*

significantly between the groups: 43% of all dissections (80 manipulating actions ±45) were performed completely within the defined centre in the As-group; and 42% (86±50) in the IP-group (p=0,91)(Fig. 4). Furthermore, 46% (72±29) of all dissecting actions were performed outside the defined centre in the As-group, and 11% (18±16) took place outside the monitor image. In the IP-group this was 49% (92±45) and 9% (13±13) respectively. The gallbladder forceps, held by the surgical assistant in the As-group and by the PASSIST in the IP-group, was repositioned on average 10 times per LC in the As-group, and 7 times in the IP-group (p=0,10).

Sub-analysis

Both the use of the AESOP™ and the PASSIST did not result in a significant change in total operation time (33±7, 53±23, respectively) and total number of actions needed (489±118, 678±275, respectively), compared to LCs performed with a surgical assistant

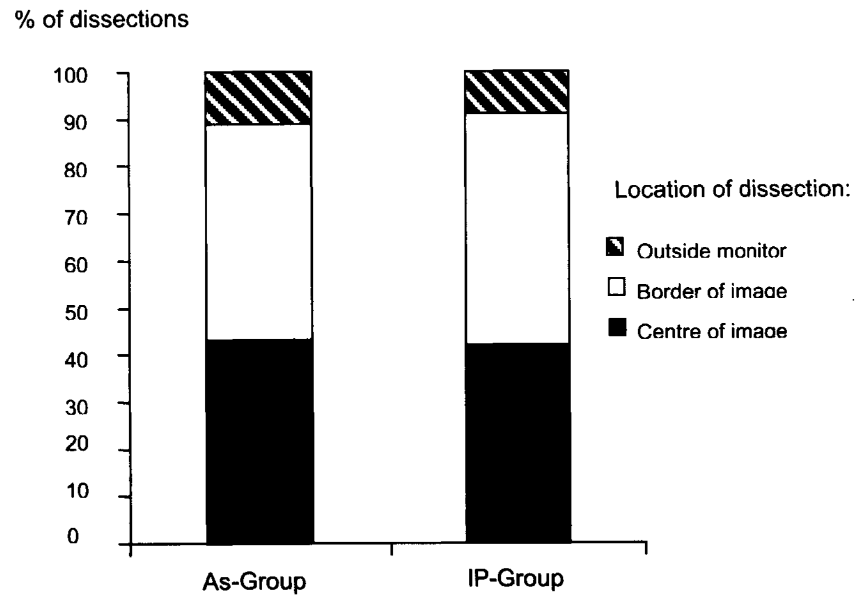

***Figure 4.** Positioning Accuracy. Percentage of actions performed inside the central circle, outside the circle, and totally outside the monitor are shown for the As-group and the IP-group of the experienced surgeons.*

(42±21 min., 635±251 actions). The number of times the laparoscope was repositioned reduced significantly in both groups.

The results of the LCs performed by the resident did not differ significantly between the As-group and the IP-group (p=0,58). Naturally, the average total operation time (As-group 86 minutes, IP-group 90 minutes, p=0,69) and the total number of actions needed (As-group 1081±187, IP-group 1023±211, p=0,58) were higher for the LCs of the resident, compared to the results of the experienced surgeons.

Questionnaire

The results of the questionnaire (Table 4) showed that surgeons judged the operations as equally difficult and efficient for both groups. The surgeons indicated that an IP could replace the surgical assistant. Furthermore, the surgeons indicated that they preferred the use of an IP to a surgical assistant, and finally they were more satisfied with the laparoscopic image if IPs positioned the laparoscope.

***Table 4**. Difficulties and comfort questionnaire:*
Mean rating score, for each question per group, as expressed by the surgeons †.

Question	*Assistant-group (n=39)*	*IP-group (n=39)*
1. The operation was difficult.	2.3	2.0
2. The operation was efficient.	4.5	4.8
3. The installation of the positioners was easy. *		3.8
4. I was content with the laparoscope-positioner. *		4.5
5. I was content with the forceps-positioner. *		3.2
6. I can do this procedure without an assistant. *		4.9
7. I would have preferred to operate with an assistant. *		1.8
8. I was satisfied with the laparoscopic image.	3.9	4.2
9. Overall the image centered correctly.	3.5	4.2
10. The video-recording and persons involved bothered me.	1.0	1.0

†The answer had to be scored on a range from 1 to 5 : 1=No, not at all - 5 = Yes, absolutely.
* These questions were only asked in the IP-group

Discussion

This study showed that the use of instrument positioners enables surgeons to perform elective laparoscopic cholecystectomy without a surgical assistant. Our study proved that there was no change in total operation time and number of actions needed when IPs were used instead of a surgical assistant. In addition, the laparoscope was repositioned 60% less frequently when IPs were used while retaining the positioning accurateness of the image. Furthermore, the occurrence of peroperative complications (Table 3) did not differ between the groups and the complications that occurred did not have any consequences for the operative use of IPs or the outcome of the IP-group.

The total operation time did not change significantly, but the average set-up time did increase significantly with 6 minutes when IPs were used. This increase was caused by the time needed for the installation. The surgeons often waited with installing the IPs until they were finished with their normal set-up procedure. In future, set-up time will be reduced if the surgeons become experienced in using the IPs and installing the IPs during the pneumoperitoneum. Furthermore, the design of the PASSIST could possibly be improved to reduce the time needed for installation.

The surgeons in this study were not experienced in solo-surgery, which possibly might have resulted in a bias. The analysis results in this study revealed that the average set-up time was longer in the beginning and decreased during the 10 procedures performed with the PASSIST. The dissection and closing phases in the IP-group did not decrease during the ten procedures and were not longer than those phases in the assistant-group. Therefore, the inexperience of the surgeons might have caused an underestimation of the efficiency of the set-up phase of the IP-group, particularly for the surgeons using the PASSIST.

This study showed that IPs can substitute a surgical assistant. This is especially relevant in the setting of a non teaching hospital. In the teaching setting, residents frequently assist LCs as part of their surgical training program. IPs would deprive residents of this opportunity of learning laparoscopic skills. In fact, in our study a surgical assistant was often present during LCs with an IP because of the educational aspect for residents. Sometimes, this resulted in the resident participating in a positioning task because he was at hand, although it was against the study protocol. In these cases, the actions of the assistant were added to the total number of actions of the IP-group. The surgeons indicated afterwards that they were fully convinced that those actions could have been done either by themselves or by the scrub-nurse. In other procedures when no resident was present, the surgeons indeed proved that they could operate fully without a surgical assistant. Of the total number of actions performed per LC, the surgeon himself performed on average 74% of the surgical actions in the As-group (471±193), and 88% in the IP-group (565±229, p=0,10). The number of actions performed by the resident did decrease significantly (23% in the As-group and 9% in the IP-group, p<0,001), without increasing the number of actions performed by the scrub-nurse (3% versus 3% p=0,46).

The positioning accuracy was assessed using a central circle. Experienced laparoscopic surgeons indicated that a safe diameter of the circle would be 2/3 of the height of the monitor. However, over 50% of the actions were performed outside the central circle. Apparently, in the clinical situation the surgeons often preferred a de-central view over an extra repositioning action. In our study, the actions performed outside the central circle did not lead to an increase in complications.

This study was set up to compare the efficiency and safety of IPs with those of a surgical assistant, in a clinical setting. The study was not set up to analyse erroneous task performance or post-operative complications in detail. Detailed data concerning the occurrence of complications in LCs can be found in the literature. For example, the study of Joice et. al. analyses peroperative complications in detail [10]. In addition, various clinical studies assess postoperative complications in LCs [11;12].

The questionnaire revealed that surgeons preferred to operate with an IP instead of a surgical assistant. The main reasons mentioned were: the stable image; the absence of misunderstandings of verbal commands between the surgeon and the assistant; and the reduced need to clean the lens of the laparoscope, which is also described in literature[11]. Furthermore, the surgeon was able to concentrate more on his dissection task, because less attention was required to position the laparoscope and the gallbladder forceps or to guide the assistant. In the case of the resident operating with the IP, the supervising surgeon mentioned that he could focus better on the training aspect, e.g. by pointing out structures on the monitor, because he did not have to attend the laparoscope.

Conclusion

This study showed that the use of instrument positioners enables surgeons to perform elective laparoscopic cholecystectomy without a surgical assistant. Furthermore, replacing the surgical assistant with an IP does not result in a significant increase in time and number of actions needed for LC. The use of instrument positioners reduces laparoscope repositioning without significantly changing positioning accuracy. Surgeons subjectively prefer to operate with an instrument positioner instead of a surgical assistant.

References

1. Sackier JM, Wang Y: Robotical assisted laparoscopic surgery. From concept to development. Surg Endosc 1994; 8: 63-66.
2. Omote K, Feussner H, Ungeheuer A, et al: Self guided robotic camera control for laparosopic surgery compared with human camera control. Am J Surg 1999; 177: 321-324.
3. Buess GF, Arezzo A, Schurr MO, et al: A new remote controlled endoscope positioning system for endoscopic solo surgery. The FIPS endoarm. Surg Endosc 2000; 14: 395-399.
4. Voorhorst FA, Meijer D, Overbeeke KJ, Smets C: Depht perception in laparoscopy through perception-action coupling. Min Inv Ther & Allied Technol 1998; 7: 325-334.
5. Jaspers JEN, Boer den KT, Sjoerdsma W, Bruijn M, Grimbergen CA: Design and Feasibility of PASSIST, a Passive Instrument Positioner. Laparoendosc & Adv Surg Techn 2000; 10: 631-636.
6. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA: Quantitative standardised analysis of advanced laparoscopic surgical procedures. Endosc Surg Allied Technol 1995; 3: 210-213.
7. Boer den KT, Straatsburg IH, Schellinger AV, Wit de LT, Dankelman J, Gouma DJ: Quantitative analysis of the functionality and efficiency of three surgical dissection techniques; a time-motion analysis. Laparoendosc & Adv Surg Techn 1999; 9: 389-395.
8. Boer den KT, Wit de LT, Gouma DJ, Dankelman J: Per-operative Time-Motion Analysis of Diagnostic Laparoscopy with Laparoscopic Ultrasonography. Br J Surg 1999; 86: 951-955.
9. Sjoerdsma W, Meijer DW, Jansen A, Boer den KT, Grimbergen CA: Comparison of efficiencies of three techniques for colon surgery. Laparoendosc & Adv Surg Techn 2000; 10: 47-53.
10. Joice P, Hanna GB, Cuschieri A: Errors enacted during endoscopic surgery-a human reliability analysis. Applied Ergonomics 1998; 29: 409-414.
11. Branum G, Schmitt C, Baillie J, et al: Management of major biliary complications after laparoscopic cholecystectomy. Ann Surg 1993; 217: 532-541.
12. Strasberg SM, Hertl M, Soper NJ: An anlysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Col of Surg 1995; 180: 101-125.

8

Peroperative analysis of the surgical procedure;

Method for quantitative analysis of surgical procedures, surgical training, and development of new instruments

K.T. den Boer, J. Dankelman, D.J. Gouma, H.G. Stassen,
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Abstract

The increased technological complexity of surgery, and the growing importance of quality assessment demand for objective analysis of the surgical process. However, until now no standard method exists to analyse the peroperative process. In this position paper, a methodology is discussed to describe and to analyse 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 to be able 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.

Introduction

Surgery is becoming more complex, because with the introduction of new surgical techniques and instrumentation, more difficult operations can be achieved.[1-4] To evaluate the quality of the peroperative surgical process, task performance and functionality of the instruments have to be analysed objectively.[5-10] However, the current quality analysis is mostly restricted to the analysis of the post-operative outcome of patients in terms of morbidity, mortality, survival, and more recently 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, ISO 9000/IEC guide 51), but no standards exist to evaluate the functionality of instruments objectively during peroperative use.[8; 11; 12] In aviation, nuclear power plants and production processes, detailed process analysis is used to analyse the quality and efficiency of the process. Furthermore, in aviation extensive training and testing is performed in simulators, before and after completion of the education. In surgery, similar analysis and training methods could be used to improve surgery.

This paper describes a methodology to analyse the peroperative surgical process. The basic principles of process analysis will be described, and the terminology will be defined. The methodology analyses the correctness and efficiency of task performance and the limiting factors of the peroperative procedure in seven steps. As an example of the general method, the peroperative analysis of laparoscopic cholecystectomies (LCs) will be used. Finally, recommendations will be described, 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 analyse complex production processes including the modelling of human-machine-interaction, and the analysis of human errors or technological failures.[13-16] A similar methodology can be used to describe and to analyse the surgical process.[17] As in industry, the first step in the 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 analyse the subsystems by evaluating the process parameters. The following four subsystems can be distinguished:

- The persons performing the tasks of the protocol (surgeon/resident)
- The persons assisting the surgeon (e.g. resident, scrub/running nurse).
- 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. 1a). Figure 1a shows that the surgeon operates using the hands and instruments. In addition, the surgeon has to integrate information collected prior to the operation (pre-operative diagnostic work up of the patient, prescribed tasks of the operation protocols) with the information collected during the operation (perceptive and visual information).[18] The environment (e.g. operating room) can influence and may possibly disturb the surgical process.

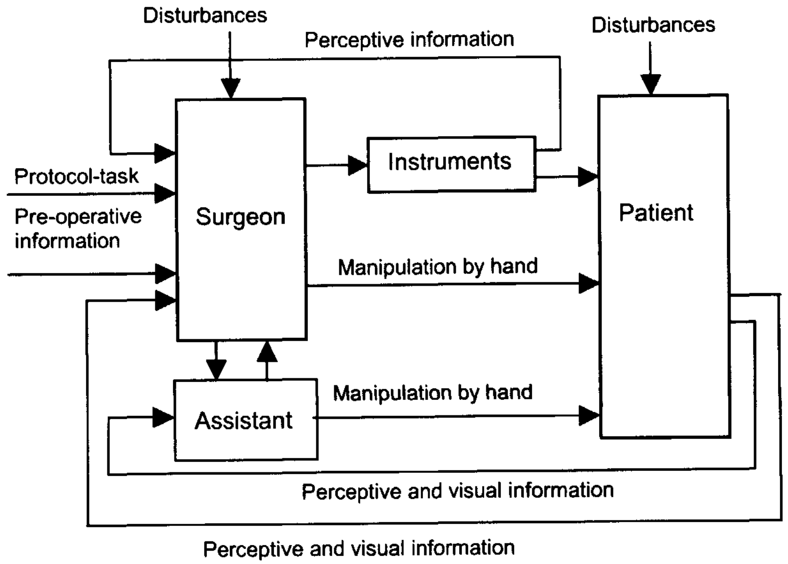

Figure 1. *a) Block diagram of the open surgical process. The surgeon can manipulate the tissue with the hands and with the surgical instruments; both providing the surgeon with direct feedback. In addition the surgeon has direct 3D visual feedback.*[18]

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 view on the operation field, 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 laparoscopic procedure different from open surgery, Figure 1b. Consequently, the laparoscopic surgical process may have other difficulties than open surgery, hence it may need different solutions than open surgery.

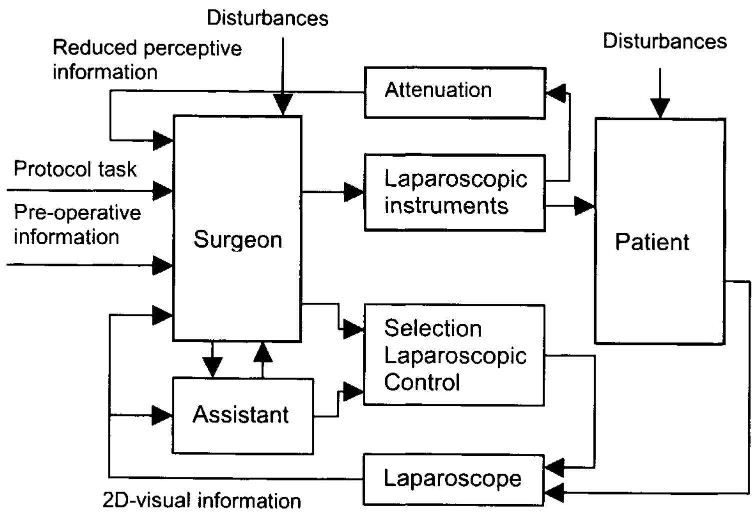

Figure 1. *b) Block diagram of the laparoscopic surgical process. The surgeon manipulates the tissue via laparoscopic instruments. Due to friction and poor ergonomic design of instruments, the perceptive information is reduced. The laparoscope is controlled by an assistant, providing the surgeon with a 2D image.*[18]

The surgical process will be analysed from the surgical point of view, considering the surgeon as the central subsystem. The surgeon can be influenced by internal disturbances (mental and physical work load) or external disturbances (environment, functionality of the instruments, health status of the patient). Both kind of disturbances may influence the outcome of the surgical process. This paper will discuss the analysis of the external influences on surgical performance, the physical or mental workload will not be described.

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 out of the analysis results.

Terminology

Process tasks and basic actions

In this paper, a *protocol task* will refer to the surgical task that is prescribed in the operation protocol. *Basic actions* have been 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 like retracting the gallbladder, dissecting the Calot's triangle and clipping the artery.

Quantification of the surgical process

The following three measures are used to analyse the peroperative 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 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;

- The time needed to complete a task or phase of the procedure
- 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.[5] A useful division of the procedure is the division into *an opening, a dissection, a reconstruction, and a closing phase*, as described previously.[5; 8; 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, 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, of a new protocol, or of a new instrument, and to interpret the outcomes, the measured values have to be compared to reference values. [6; 9] No *reference values* exist in surgery and, therefore, they have to be defined and subsequently determined by analysing standard procedures. A *standard procedure* has been defined as a procedure performed under current optimal conditions, e.g. using 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.[5]

Process analysis in seven steps

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

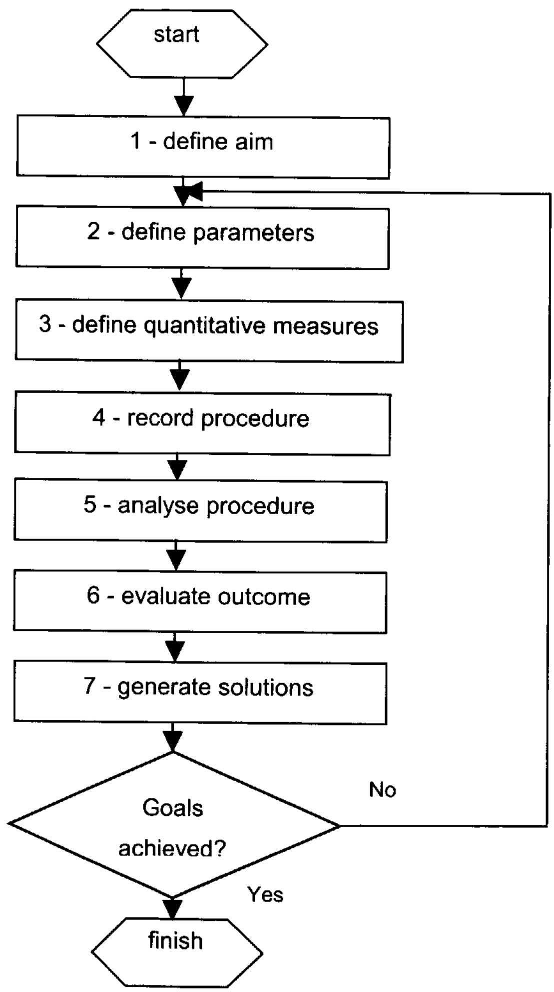

***Figure 2.** Flow chart of a structured analysis of the peroperative procedure.*

Step 1. The aim of each study should be defined exactly. The aim could be to improve the peroperative process or comparing different procedures by analysing:

- Task performance (e.g. in LC: learning LC tasks), or
- 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, patient), and by defining the parameters. As an example, possible protocol tasks for each operation phase of LC are defined in Table 1.

Table 1. *Phases and protocol tasks of laparoscopic cholecystectomy*

No.	Phase of operation	No.	Tasks
1	Create CO2 pneumoperitoneum	1.1	Insert Veress needle
		1.2	Insufflate the abdomen with CO2
		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 mobilise Hartmann's pouch
		3.6	Dissect and isolate the CD
		3.7	Dissect and isolate 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
		5.7	Extract bag containing GB
6	Final check and irrigation	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
		6.5	Control haemostasis
7	Close up patient	7.1	Remove irrigation fluid
		7.2	Remove instruments
		7.3	Remove operating ports
		7.4	Check access wounds
		7.5	Release CO2 from abdomen
		7.6	Remove laparoscope
		7.7	Remove optical port
		7.8	Suture the port wounds

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 1^{st} trocar	Insert the first Trocar (blind) through abdominal wall into peritoneal cavity
Insert 2^{nd},3^{rd},4^{th} etc. trocar	Insert the 2^{nd},3^{rd},4^{th} 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/ re-position/ remove instrument	Insert, re-position, or remove an instrument: forceps, scissors, retrieval bag, cannules, trocars etc.
Extract tissue	Remove tissue (e.g. gallbladder etc.) out of the abdominal cavity
Control bleeding site	Re-coagulate, 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, and ultrasonographic systems, anaesthesia, instruments. Waiting for personnel carrying out an order; turn on/of 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

Basic actions are defined in Table 2, and instruments in Table 3. The protocol tasks and basic actions can also be defined in more detail, if necessary.[19]

<u>*Step 3*</u>. The measures to analyse 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. As an 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, same protocol tasks but now performed by experienced surgeons).

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)

To *analyse 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 well as the basic set of instruments used. The values obtained with the new instrument have to be compared with that 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 re-bleedings after coagulation (monopolar or bipolar), the number of times that other tissue is coagulated unintentionally, the number of times waiting for the instrument, etc. The reference values are measured in a standard LC using monopolar coagulation instead of bipolar dissection.[8]

To *evaluate protocols*, a new protocol should be compared to the current standard protocol.[20] For example, LCs were compared to the standard open procedure after the introduction of laparoscopic surgery. Initially, the post-operative outcome between both the procedures was compared followed by the analysis of the peroperative process. Although the type of tasks differs 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 theatre 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 an experienced surgeon. In addition, the patients, the instruments, and the environment are never the same and, therefore, their influence on the operation process always varies. Consequently, strict selection criteria have to be defined for the patients, for the instruments used, and for the environment, to reduce this variation. In LC, for example, patients undergoing elective LC could be included and patients with acute cholecystitis excluded. The overview images and the image of the laparoscope should be recorded, as well as additional images of e.g. laparoscopic ultrasonography or peroperative cholangiography, using a video mixing device.[5]

Step 5. The actual analysis of the peroperative process is performed, in accordance with the aim and objectives formulated in Step 1-3, using the video recordings. In addition, the post-operative outcomes of the patient should be assessed. 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 post-operative outcomes of the procedures. This combination of per- and post-operative complication detection can provide detailed insight into the existing clinical problems. For example, Branum et al. showed the peroperative causes of major biliary complications after LC by evaluating the video tapes of the original operations.[21] To reduce variations caused by the analysis, the observers have to be trained, and if possible, some recordings should be analysed 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 intra-observer variation.[22]

Step 6. When all problems and deficiencies are detected, the impact of each of them should be discussed in a multidisciplinary team consisting of experienced surgeons and other members of the operation team, engineers, ergonomists, designers etc. For example, the study of Joice et al. pointed out that coagulation with the coagulation hook in LC caused most erroneous task performance. [19]

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, optimising 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 coagulation instruments.[19;21;23]

Possible 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 paper 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).

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

Training surgical tasks.

Training surgical tasks can be set up at these three stages (Table 4). 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.[24] At Stage 1, experiments are set up for training new surgical techniques in pelvi-trainers or virtual reality simulators, e.g. positioning tasks, passing and suturing drills, or tasks needed for specific procedures.[25-27] 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.[28-32] 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 efficiency of task performance.[9] The analysis of Stage 2 and 3 can be performed as described in Figure 2.

Medical devices.

For new medical devices, a technical evaluation has to be performed to assess reliability, safety, and specific function tests (e.g. force characteristics, sensitivity feedback, sealing forces, or coagulation characteristics) before the functionality tests at Stage 1.[33; 34] At Stage 1, the functionality, safety and ergonomics should be analysed in a laboratory setting, e.g. in pelvi trainers. At Stage 2, the experimental set up should simulate the clinical setting, enabling analysis during clinical use, without risk for the patient.[8; 35; 36] If the quality and safety of the prototype have been proved to be sufficient, the instruments might be evaluated in clinical practice.[37] Evaluation at Stage 2 and 3 can be performed similar to the surgical process analysis as 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.[20] 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 at the 3 stages.

Discussion

In this paper, a methodology is discussed to describe and to analyse the surgical process, providing extensive correctness and efficiency information from a limited number of analysed procedures.[5; 6; 8; 37] Peroperative surgical analysis should be supplemented to the studies assessing post-operative morbidity, mortality, and quality of life.[21] The problems indicated by the post-operative outcomes can subsequently be studied in more detail using time-action analysis.[5; 6]

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.[9] More extensive error classifications can be defined as for example described in Joice et al., resulting in very detailed error detection, however, at the expense of relatively time-consuming analysis.[19] 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 analyse the peroperative process, for example Sjoerdsma et al. used the ratio between the number of goal oriented actions and the total number of actions.[20] Furthermore, the basic actions can be categorized in 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 analyse the correctness of task performance, whereas a multidisciplinary team of experts have to evaluate the instruments' safety and functionality.[9] Thereafter, part of the analysis can be performed by trained observers, in order to save expert's time.[5; 8; 9; 37] 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 plant, 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 judgements of residents, incidentally combined with the total operation time and post-operative complication assessments.[38-40] The resident mostly trains 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 judgement of supervisors. In addition, training of residents 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.[24; 29; 31; 32] 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 virtual reality 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.[26; 28; 30] The methodology described in this paper could be used to introduce competence evaluation in the medical profession as in industry.

This paper indicates the importance of standardisation of a methodology for the evaluation of the efficiency and quality of task performance, 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.[12; 15; 41] 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.[42; 43] The information can optimise 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, resulting in improved surgery and patient outcome.

References

1. Satava RM. Surgery 2001, a technological framework for the future. Surg Endosc 1993; 7:111-113.
2. Cuschieri A, Ferreira E, Goh P, et al. Guidelines for conducting economic outcomes studies for endoscopic procedures. Surg Endosc 1997; 11:308-314.
3. Satava RM, Ellis SR. Human interface technlogy. An essential tool for the modern surgeon. Surg Endosc. 1994; 8(7):817-820.
4. Cuschieri A. Whither minimal access surgery: tribulations and expectations. Am J Surg 1995; 169:9-19.
5. Boer den KT, Wit de LT, Gouma DJ, Dankelman J. Per-operative Time-Motion Analysis of Diagnostic Laparoscopy with Laparoscopic Ultrasonography. Br J Surg 1999; 86:951-955.
6. Claus GP, Sjoerdsma W, Jansen A, Grimbergen CA. Quantitative standardised analysis of advanced laparoscopic surgical procedures. Endosc Surg Allied Technol 1995; 3:210-213.
7. Traverso LW, Koo KP, Hargrave K. Standardizing laparoscopic procedure time and determining the effect of patient age/gender and presence or absence of surgical residents during operation, a prospective multicenter trial. Surg Endosc 1997; 11:226-229.
8. Boer den KT, Straatsburg IH, Schellinger AV, Wit de LT, Dankelman J, Gouma DJ. Quantitative analysis of the functionality and efficiency of three surgical dissection techniques; a time-motion analysis. Laparoendosc & Adv Surg Techn 1999; 9:389-395.
9. Boer den KT, Wit de LT, Davids PHP, Dankelman J, Gouma DJ. Analysis of the quality and efficiency of learning laparoscopic skills. Surg Endosc 2001; 15: 497-503.
10. Kenyon TAG, Lenker MP, Bax TW, Swanstrom LL. Cost and benefit of the trained laparoscopic team. Surg Endosc 1997; 11:812-814.
11. Mattsson F. An introduction to risk analysis for medical devices. Complicance Engineering European Edition 1995; 6:29-38.
12. Rau G, Radermacher K, Thull B, von PC. Aspects of ergonomic system design applied to medical work systems computer integrated surgery. In Taylor RH, Lavallee S, Burdea GC, Mösges R., eds. Computer Integrated Surgery - Technology and Clinical Applications. MIT Press, 1996; 203-221.
13. Swain AD, Guttman HE. Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications. US Nuclear Regulatory Commission, 1983;
14. Kirwan B, Ainsworth LK. A guide to task analysis - The task analysis working group. London: Taylor and Francis, 1993;
15. Meister D. Simulation and modelling. In Wilson JR, Corlett EN., eds. Evaluation of Human Work - A practical ergonomics methodology. London: Taylor and Francis, 1992;

16. Swain, A. D. THERP. Sandia Lab. SCR-64-1338. 1964. Albuquerque, NM, USA.
17. Sjoerdsma, W. Surgeons at Work. 1998. Thesis at Technical University Delft.
18. Stassen HG, Dankelman J, Grimbergen CA. Open versus minimally invasive surgery: a man-machine system approach. Trans Inst M C 1999; 21:151-162.
19. Joice P, Hanna GB, Cuschieri A. Errors enacted during endoscopic surgery-a human reliability analysis. Applied Ergonomics 1998; 29:409-414.
20. Sjoerdsma W, Meijer DW, Jansen A, Boer den KT, Grimbergen CA. Comparison of efficiencies of three techniques for colon surgery. Laparoendosc & Adv Surg Techn 2000; 10:47-53.
21. Branum G, Schmitt C, Baillie J, Suhocki P, Baker M, Davidoff A, Branch S, Chari R, Cucchiaro G, Murray E, Pappas T, Cotton P, Meyers WC. Management of major biliary complicaitons after laparoscopic cholecystectomy. Ann Surg 1993; 217: (5) 532-541
22. Shrout PE, Fleiss JL. Intraclass correlations: Uses in assessing rater reliability. Psychological Bulletin 1979; 86:420-428.
23. Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surgeons 1995; 180: (1) 101-125
24. Barnes RW. Surgical Handicraft: Teaching and Learning Surgical Skills. Am J Surg 1987; 153:422-427.
25. Rosser JC, Rosser LE, Savalgi RS. Skill acquisition and assessment for laparoscopic surgery. Arch Surg 1997; 132:200-204.
26. Chung JY, Sackier JM. A method of objectively evaluating improvements in laparoscopic skills. Surg Endosc 1998; 12:1111-1116.
27. Hanna GB, Frank TG, Cuschieri A. Objective assessment of endoscopic knot quality. Am J Surg 1997; 174:410-413.
28. Derossis AM, Bothwell J, Sigman HH, Fried GM. The effect of practice on performance in a laparoscopic simulator. Surg Endosc 1998; 12:1117-1120.
29. Hanna GB, Drew T, Clinch P, Hunter B, Cuschieri A. Computer-controlled endoscopic performance assessment system. Surg Endosc 1998; 12:997-1000.
30. Reznick R, Regehr G, MacRae H, Martin J, McCulloch W. Testing technical skill via an innovative "bench station" examination. Am J Surg 1997; 173:226-230.
31. Higgins GA, Meglan DA, Raju R, Merril JR , Merril GL. Teleos(tm): Development of a Software Toolkit for Authoring Virtual Medical Environments. Presence 1997; 6:241-252.
32. Kenyon RV, Afenya MB. Training in virtual and real environments. Ann Biomed Eng 1995; 23:445-455.
33. Boer den KT, Herder JL, Sjoerdsma W, Meijer DW, Gouma DJ, Stassen HG. Sensitivity of laparoscopic dissectors; what can you feel? Surg Endosc 1999; 13:869-873
34. Sjoerdsma W, Herder JL, Horward MJ, Jansen A, Bannenberg JJG, Grimbergen CA. Force transmission of laparoscopic grasping instruments. Min Invas Ther & Allied Technol 1997; 6:274-278.
35. Spivak H, Richardson WS, Hunter JG. The use of bipolar cautery, laparosonic coagulating shears, and vascular clips for hemostasis of small and medium-sized vessels. Surg Endosc 1998; 12:183-185.

36. Frank TG, Willetts GJ, Carter F, Cuschieri A. Clamping the small intestine during surgery: predicted and measured sealing forces. Proc Inst Mech Eng[H.] 1995; Part H - Journal of Engineering in Medicine. 209:111-115.
37. Boer den KT, Bruijn M, Dankelman J, et al. Time-action analysis of instrument positioners in laparoscopic cholecystectomies Surg Endosc 2001; (in press)
38. Begg CB, Cramer LD, Hoskins WJ, Brennan MF. Impact of Hospital Volume on Operative Mortality for Major Cancer Surgery. JAMA 1998; 280:1747-1751.
39. Bennett CL, Stryker SJ, Ferreira MR, Adams J, Beart RW, Jr. The learning curve for laparoscopic colorectal surgery. Preliminary results from a prospective analysis of 1194 laparoscopic-assisted colectomies [published erratum appears in Arch Surg 1997 Jul;132(7):781] [see comments]. Arch Surg 1997; 132:41-44.
40. Watson DI, Baigrie RJ, Jamieson GG. A learning curve for laparoscopic fundoplication. Definable, avoidable, or a waste of time?. Ann Surg 1996; 224:198-203.
41. Berguer R. The application of ergonomics in the work environment of general surgeons. Reviews on Environmental Health 1997; 12 (2):99-106.
42. Czyzewska E, Kiczka K, Czarnecki A, Pokinko P. The surgeon's mental load during decision making at various stages of operations. Eur J Applied Physiol 1983; 51:441-446.
43. Haslegrave CM. What do we mean by a 'working posture'? Ergonomics 1994; 37:781-799.

9

Conclusions and future research

Conclusions

The studies presented in this thesis aimed to develop a method for the analysis of the peroperative surgical process. The developed method has been formulated in Chapter 8. The method can be used to analyse open as well as laparoscopic procedures with respect to task performance, instruments and protocols used.

Chapter 1 formulated that the analysis method should satisfy two requirements:

1. Measure the quality, the efficiency, and detect difficulties of surgical task performance and instruments in quantitative terms;
2. determine current reference values for the quality and efficiency of surgical task performance and instruments.

The thesis divided each requirement of the method into two parts and each part was applied in specific clinical situations, to illustrate the implementation of the method.

Requirement 1 was divided into:

1a Measure the quality, the efficiency, and detect difficulties *of surgical task performance* in quantitative terms;

1b measure the quality, the efficiency, and detect difficulties *of instruments* in quantitative terms.

1a: The quality, the efficiency, and difficulties of task performance were measured in diagnostic laparoscopies in Chapters 3 and 4. Chapter 3 identified and defined the basic actions performed by an experienced surgeon. The actions were categorised as efficient actions (e.g. identifying lesions by inspection, making an ultrasonogram, or taking a biopsy) or as limiting factors (e.g. technical problems, time spent waiting for personnel). In 18 diagnostic laparoscopies the time, type and number of actions were determined for each phase of the operation. Chapter 4 identified the basic actions and the sequential sub-tasks of the operation protocol for diagnostic laparoscopies. The efficiency and (in)correct task performance were defined and determined for each sub-task of diagnostic laparoscopies performed by a surgical resident.

1b: The quality, the efficiency, and difficulties of instruments were measured in Chapters 2, 3 and 5-7. Chapter 2 used a questionnaire to reveal the laparoscopic instruments prone to cause peroperative complications. Coagulation was indicated to be especially prone to cause complications followed by the dissectors and retractors. Chapter 3 determined the difficulties of the instrumentation used in diagnostic laparoscopies, detecting the difficulties of biopsy instruments. Chapter 5 determined the sensitivity for feedback information of surgical instruments comparing the absolute sensory threshold of 31 participants using laparoscopic dissectors with the participants using their bare fingers. Chapter 6 measured the efficiency and difficulties of three different dissection techniques, in a simulated clinical setting. Chapter 7 measured the efficiency and difficulties of active

and passive instrument positioners in a clinical setting. It showed that laparoscopic cholecystectomies could be performed without a surgical assistant, using instrument positioners instead, without changing the efficiency and safety of the operation.
Concluding, the chapters showed that the quality, efficiency, and difficulties of task performance and instruments can be measured in quantitative terms, meeting Requirement 1 of the aim of the thesis.

Requirement 2 was divided into:

2a Determine current reference values for the quality and efficiency *of surgical task performance*;

2b determine current reference values for the quality and efficiency *of instruments.*

2a: Reference values were determined for the efficiency of task performance of diagnostic laparoscopies in Chapter 3, and these values were used in Chapter 4.
2b: Reference values were determined for instruments in Chapters 5-7. Chapter 5 defined and determined a Sensitivity Index (SI), and used the SI of bare fingers as reference for the SI of laparoscopic dissectors. Chapter 6 assessed the efficiency and difficulties of standard dissection with ligation as reference for the efficiency and difficulties of monopolar and bipolar dissection. Chapter 7 determined the efficiency and difficulties of laparoscopic cholecystectomies assisted by a surgical assistant as reference for laparoscopic cholecystectomies performed with active or passive instrument positioners.
Concluding, the chapters showed that reference values can be determined for the quality, efficiency and difficulties of current task performance and instruments, meeting Requirement 2 of the aim of the thesis.

Concluding, in this thesis a method to analyse the peroperative surgical process has been developed and tested. The thesis showed that the method is capable of measuring the quality, efficiency, and difficulties of the process, and of determining current reference values, enabling an objective operative analysis. The quantitative method of analysing the quality and safety of the surgical process was urgently needed in surgery, and it provides a more complete insight into the actual task performance and instrumental problems that occur during operations.

Future Research

In the thesis a method for the analysis of the peroperative surgical process has been developed. It showed that the quality, efficiency, and difficulties of task performance, instruments and operation techniques can be measured. Future research should firstly focus on solving currently indicated or detected difficulties in the surgical process, by improving the surgical instruments and training. Secondly, future research should extend the type of procedures and measures analysed. Thirdly, a cost analysis could be developed to analyse the financial consequences of the alternatives, with respect to quality, safety, production costs, etc.

Improvement of instruments

The detected difficulties of the surgical process can be used as input for clinically-driven instrument design. The clinical difficulties have to be translated by a multidisciplinary team into technical design specifications on the base of which a new prototype can be designed. Some projects of the MISIT-program (Minimally Invasive Surgery and Interventional Technology) of the Delft University of Technology aim to decrease the difficulties and limitations related to the technical aspects of minimally invasive surgery. Subsequently, the methodology can be used to compare new prototypes objectively with the currently available instruments, supporting the selection of the best set of instrumentation, the OR set-up, and the logistics, with respect to benefit and costs.

Improvement of task performance

The task performance analysis can be used to detect individual problems of surgeons or trainees, and to measure the actual skills level of surgeons. These task analysis results could be used to improve both the efficiency of training for the residents and the safety for the patient. The task analysis outcomes can support the design of new training programs for residents, by training more tasks in laboratory settings, and by measuring the individual training difficulties and progress, objectively. Residents can learn new actions or tasks for example in pelvi-trainers, animal models, or in virtual reality simulations. There, residents can learn new skills without patients, independent of the type and number of operations available, and under close supervision. Time-action analysis can evaluate the training in detail, both in the clinical and the laboratory settings. In addition, it can provide detailed individual feedback, so that the resident can learn from his/her own recordings. Furthermore, it can compare the efficacy of training programs itself, such that the best training program can be selected. Future research should design standardized training programs for each surgical task and procedure, and determine reference values for the desired quality and efficiency of task performance.

Procedures

In this thesis, a limited number of procedures has been analysed due to the limited scope of Ph.D. research. Sjoerdsma used time-action analysis to analyse laparoscopic colon surgery, open colon resections, and laparoscopic hernia repairs. Bemelman used time-action analysis to compare three techniques for the establishment of the pneumoperitoneum (open Hasson approach, Veress needle, and the TrocDoc). The TrocDoc is a modified blunt trocar which is as efficient in establishing the pneumoperitoneum as the Veress needle, and which is in addition as safe as the Hasson technique without the need for stay sutures or sutures to seal the abdominal cavity. In future, more types of procedures should be analysed to detect the quality, efficiency, and difficulties for each type of operation, to provide a complete overview of surgical procedures. In principle all types of procedures can be analysed, and for all procedures, reference values should be assessed. Besides abdominal operations, other medical procedures can be analysed as well. For example, general vascular catheter interventions are analysed in the MISIT programme using time-action analysis to assess the limitations and critical phases in the application of interventional catheters. In addition, orthopaedical surgical procedures are analysed using time-action analysis in the DIPEX programme (Development of Improved endoProstheses for the upper EXtremities) to assess the problems occurring during shoulder operations.

Sub-systems.

Besides the surgeon and instruments, other sub-systems can be analysed, for instance: the resident or assistant surgeon, the scrub nurse, the anaesthesiologist. For the resident or scrub nurse, similar measures can be used to analyse the quality and efficiency of their task performance as were used for the surgeon. For the anaesthesiologist, the task- and action-concept used in this thesis can be adapted. However, the anaesthesiologist has a monitoring and controlling task instead of an operating task and thus new tasks have to be defined for the different tasks of the anaesthesiologist. For the patient, objective measures should be developed to control the health status and stress level of the patient which has to be controlled closely during the operation. The anaesthesiologist measures already several physiological parameters, and these measures could be incorporated in a standard overall analysis of the surgical process. The inclusion of more sub-systems enables a more complete insight into the surgical process and its possible disturbances.

Measures.

In addition to the correctness and efficiency measures defined in this thesis, new measures could be defined to analyse other aspects of the task performance, instruments and operative techniques used. For instance, the ergonomics of the operating room and the instruments used could be analysed. Good ergonomics of the workplace is important for optimal task performance of the operating team, to reduce problems with the instruments and to decrease tiredness. Objective measures have to be defined to measure the current ergonomy of the operating room and of new instruments developed. For example, the position (i.e. in angles) of the arms and wrists of the surgeon could be analysed during the use of instruments as well as the position of the back of the surgeon.

New measures could also be developed to analyse the mental workload or cognitive processes of the operating team members during task performance. The cognitive parameters are especially important in human reliability analysis in which risks have to be calculated and predicted. In nuclear power plant and aviation, reliability analysis is essential because one mistake or error can cause injury or death to a lot of people, and thus the workspace (i.e. control room) has to be designed to minimize error likely situations. In surgery, it is also important to try to reduce error likely situations. However, the "product" is a living patient and a patient cannot be redesigned to reduce error likely situations as it is possible for a control room. Therefore, the insight into and the control of the disturbances of the surgical process has to be intensely pursued to prevent error likely situations in the operating room.

Finally, the current best set of instruments and operation techniques should be selected and prescribed for each operation. Selection criteria have to be defined for the surgical instruments and techniques, in a multi disciplinary team in order to guarantee the judgments from different view points (e.g. patients health, technical aspects, economic aspects, educational aspects). Ideal treatment for patients is not always the same as the best economic alternative. Which instruments and techniques will be selected depends on the selectors and the accurateness and completeness of the process analysis results.

Concluding, a more complete analysis and insight into the surgical process should be pursued to be capable of controlling the quality of operations in the future. This thesis provided only a first and basic step toward objective measurement of the quality and efficiency of operations.

Summary

Summary

Surgery lacks a standardized method to analyse the operative problems objectively. A detailed operative analysis is needed because surgeons experience various operative problems, especially by the ever increasing technological complexity of the surgery. In addition, the rapidly growing variation and complexity of instruments demand objective clinical evaluation.

The aim of the thesis was to develop and to test a method to measure the quality and efficiency of the surgical tasks performed, and the instruments and techniques used. The method developed describes the surgical process as a complex system similar to industrial systems. Chapter 1 formulates that the method should satisfy two requirements:

1. Measure the quality, the efficiency, and detect difficulties of surgical task performance and instruments in quantitative terms;
2. determine current reference values for the quality and efficiency of surgical task performance and instruments.

Each part of the method was applied in clinical situations to test the applicability of the method and to show that the requirements were met.

In short, twenty experienced surgeons indicated in the questionnaire that coagulators were especially prone to cause lesions of the gastro-intestinal-tract, vascular injuries, and bile duct injuries. Dissectors were considered to play a role in the occurrence of solid organ and bile duct injuries, and retractors caused solid organ injuries. These results can support clinically-driven instrument design, and will form the base for more detailed observational studies.

The analysis of the task performance showed that 52% of the actions performed by an experienced surgeon in diagnostic laparoscopies with laparoscopic ultrasonography (DLLU) were classified as efficient, 17% were classified as time spent waiting for personnel, and in 10% unnecessary instrument exchanges were performed. A current efficiency standard, based on the results of the experienced surgeon, was calculated for each phase in order to determine reference values for diagnostic laparoscopies. The analysis results were discussed with the surgical team, such that a significant reduction in delay times could be obtained. Furthermore, it resulted in design criteria for improved biopsy instruments. The time-action analysis method was also used to evaluate the correctness of task performance, the efficiency of learning, and individual task performance problems of a surgical resident performing his first 25 DLLUs. The correctness analysis showed that 1% of the sub-tasks was only partially performed, 3% not at all, and 2% using the wrong technique. The efficiency of the resident for most diagnostic tasks remained significantly lower than the reference standard.

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The technical analysis of instruments showed that the overall sensitivity loss through instruments could be assessed and that sensory feedback was low for commercially available instruments; 8 times less sensitive compared to bare fingers. Reusable instruments performed better than disposable ones. A low friction prototype resulted in a significantly higher feedback quality (2.7 times less sensitive than bare fingers) compared to commercially available instruments, indicating that careful design can decrease the overall sensitivity loss.

For the functional analysis of instruments, the functionality of three different dissection techniques were compared in a simulated clinical setting. The analysis showed that bipolar scissors were significantly more efficient than the standard technique (dissection with ligation) and monopolar coagulation. Furthermore, bipolar coagulation needed significantly less re-coagulation of a re-bleeding vessel, than monopolar coagulation, and the microscopical damage was significantly less pronounced.

For the clinical analysis, instrument positioners (AESOP or PASSIST) were compared with a surgical assistant in laparoscopic cholecystectomies (LC). The analysis showed that LCs could be performed without a surgical assistant, using instrument positioners instead, without changing the efficiency and safety of the operation. The surgeons indicated to prefer to operate with instrument positioners instead of a surgical assistant.

Finally, the general use of the time-action analysis method is described. The method distinguished 4 sub-systems (surgeon, assistant, instruments, patient) and identified protocol tasks, basic actions and limiting factors as measures to be analysed. The time-action method described how the quality, efficiency, and difficulties of the operation can be measured, and current reference values determined.

Concluding, in the thesis a basic method capable of measuring the quality, efficiency, and difficulties of surgical task performance and instruments used, during operations is developed and tested.

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Samenvatting

Samenvatting

In de chirurgie bestaat geen gestandaardiseerde methode om de taakuitvoering van een chirurg objectief te analyseren. Een gedetailleerde operatieve analyse is echter noodzakelijk omdat de chirurgen verschillende operatieve problemen aangeven, met name als gevolg van de toenemende technologische complexiteit van de chirurgie. Bovendien vereist de groeiende diversiteit en complexiteit van instrumenten een objectieve klinische evaluatie. Het ontwikkelen en testen van een methode om de kwaliteit en efficiëntie van de chirurgische handelingen en gebruikte instrumenten te meten was daarom het doel van dit promotieonderzoek.

De ontwikkelde methode beschrijft het chirurgische proces als een complex systeem, vergelijkbaar met de beschrijving van complexe industriële systemen. In hoofdstuk 1 worden twee voorwaarden geformuleerd waaraan de methode moet voldoen:

1. Het meten van de kwaliteit, de efficiëntie en het opsporen van problemen bij de uitvoering van taken en de gebruikte instrumenten, in kwantitatieve eenheden.
2. Het bepalen van huidige referentiewaarden voor de kwaliteit en efficiëntie van de taakuitvoering en de gebruikte instrumenten.

Elk onderdeel van de methode is toegepast in klinische situaties om de toepasbaarheid van de methode te testen en aan te tonen dat de methode aan deze twee voorwaarden voldoet.

Twintig ervaren chirurgen gaven via een vragenlijst aan dat met name coagulatoren aanleiding kunnen geven tot complicaties aan het maagdarm-, vaat- en galwegstelsel. Prepareertangen kunnen beschadigingen aan vaste organen en galwegen veroorzaken en retractoren kunnen aanleiding geven tot beschadigingen van vaste organen. Deze resultaten kunnen klinisch gestuurd ontwerpen van instrumenten ondersteunen en een uitgangspunt vormen voor gedetailleerdere observationele studies.

De tijd- en handelingenanalyse van een ervaren chirurg tijdens diagnostische laparoscopieën toonde aan dat 52% van alle uitgevoerde handelingen als efficient werd geclassificeerd, 17% als wachten op personeel, en 10% als onnodige instrumentverwisselingen. Een huidige standaard voor de efficiëntie van handelen werd berekend aan de hand van de resultaten van de ervaren chirurg, om zo referentiewaarden te bepalen voor diagnostische laparoscopieën. De resultaten van de analyse werden besproken met het chirurgische team waardoor een significante reductie van de wachttijden bereikt kon worden. Bovendien resulteerde de analyse in ontwerpcriteria voor verbeterde biopsie-instrumenten. De tijd- en handelingenanalyse werd ook gebruikt om de operatieve efficiëntie, correctheid en individuele problemen te meten in de eerste 25 diagnostische laparoscopieën van een chirurg in opleiding. De correctheidsanalyse toonde aan dat 1% van de subtaken slechts gedeeltelijk, 3% helemaal niet, en 2% met de

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verkeerde techniek uitgevoerd werden. De efficiëntie van de chirurg in opleiding bleef significant lager voor de meeste diagnostische taken vergeleken met de standaard.

De technische analyse van instrumenten toonde aan dat het totale sensitiviteitsverlies door een instrument gemeten kon worden en dat dit verlies hoog was voor de commerciëel verkrijgbare instrumenten; tenminste 8 keer minder gevoelig vergeleken met de sensitiviteit van een vinger. Instrumenten voor hergebruik zijn in dit opzicht beter dan wegwerpinstrumenten. Een prototype met lage wrijvingseigenschappen is slechts 2,7 keer minder gevoelig dan vingers. Dit toont aan dat zorgvuldig ontwerpen het totale sensitiviteitsverlies kan reduceren.

Voor de functionele analyse werden drie verschillende dissectietechnieken vergeleken in een gesimuleerde klinische setting. De analyse toonde aan dat de bipolaire schaar significant efficiënter was dan de standaardtechniek (dissectie met onderbinden) en monopolair coaguleren. Bovendien was er bij bipolaire coagulatie significant minder re-coagulatie nodig voor hernieuwde bloedingen vergeleken met monopolaire coagulatie, en de microscopische beschadiging was minder uitgebreid.

Voor de klinische analyse werden instrumentpositioneringssystemen (AESOP of PASSIST) vergeleken met een chirurgische assistent in laparoscopische cholecystectomieën. De analyse toonde aan dat laparoscopische cholecystectomieën even efficiënt en veilig uitgevoerd konden worden met instrumentpositioneringssystemen als met een chirurgische assistent. De chirurgen gaven bovendien aan dat zij bij voorkeur met instrumentpositioneringssystemen opereerden.

Tenslotte wordt de algemene toepassing van de tijd- en handelingenanalyse beschreven. In de methode zijn vier subsystemen gespecificeerd (chirurg, assistent, instrumenten, patiënt) en zijn protocoltaken, basishandelingen en beperkende factoren onderscheiden. Tevens is beschreven hoe de kwaliteit, efficiëntie en problemen van de operatie gemeten kunnen worden en .hoe huidige referentiewaarden kunnen worden bepaald.

Concluderend, in dit proefschrift is een basismethode ontwikkeld en getest om de kwaliteit, efficiëntie en problemen van de chirurgische taakuitvoering en van de gebruikte instrumenten te meten tijdens het operatieve proces.

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Zusammenfassung

Zusammenfassung

Bis heute gibt es keine Standardmethode in der Chirurgie für das Analysieren von Operationen und den dabei auftretenden Problemen. Eine genaue Analyse ist jedoch dringend erwünscht, da Chirurgen auf verschiedene Probleme aufmerksam machen insbesondere im Zusammenhang mit der stets komplexer werdenden Technik. Außerdem fordert die rasch wachsende Vielfalt und Komplexität der verwendeten Instrumenten eine objektive klinische Bewertung. Ziel der vorliegenden Promotionsarbeit war es, eine Methode zu entwickeln und zu testen, um die Qualität und die Effizienz von chirurgischen Handlungen, Instrumenten und Techniken zu messen.

Die entwickelte Methode sollte dabei einen chirurgischen Prozess als komplexes System ähnlich einem industriellen System beschreiben. Kapitel 1 enthält die zwei Anforderungen, die an die Methode gestellt werden:

1. das Messen der Qualität, der Effizienz und der Probleme von chirurgischen Handlungen sowie der verwendeten Instrumente.
2. Das Bestimmen von Referenzwerten für Qualität und Effizienz der chirurgischen Handlungen und Instrumente.

Um das Erfüllen der Anforderungen und die Einsatzfähigkeit der Methode unter Beweis zu stellen, wurde die gesamte Methode in einem klinischen Umfeld getestet.

Eine Befragung von 20 erfahrenen Chirurgen machte deutlich, dass insbesondere die Verwendung von HF-Chirurgie-Zangen Komplikationen des Magen- und Darmsystems sowie Verletzungen der Blutgefäße und Gallenwege mit sich bringen kann. Außerdem können Fasszangen und Präparierzangen feste Organe verletzen und letztere darüberhinaus auch Gallenwege beschädigen. Diese Ergebnisse der Enquete können einen Beitrag liefern bei der Entwicklung von Instrumenten und können als Basis dienen für weitergehende Studien.

Die Ergebnisse der Zeit- und Handlungsanalyse von Operationen eines erfahrenen Chirurgen zeigte, dass 52% aller Handlungen eines erfahrenen Chirurgen als effizient klassifiziert wurde, 17% als Warten auf assistierendes Personal und 10% als unnötige Instrumentenwechsel. Anhand der Resultate der erfahrenen Chirurgen wurde ein Standard für die Effizienz der Handlungen ermittelt, und hiermit wurden Referenzwerte bestimmt. Die Ergebnisse der Analyse wurden auch mit dem Operationsteam durchgesprochen, womit eine signifikante Verminderung der Wartezeiten erzielt werden konnte. Außerdem konnten aufgrund der Analyse Entwurfskriterien für verbesserte Biopsieinstrumente aufgestellt werden. Die Zeit- und Handlungsanalyse wurde darüberhinaus benutzt, um die Effizienz, die Korrektheit und die individuellen Probleme der ersten 25 diagnostischen Laparoskopiëen eines Chirurgen in Ausbildung zu bestimmen. Die Korrektheitsanalyse zeigte, dass 1% der Handlungen nur teilweise, 3%

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gar nicht und 2% mit der falschen Technik ausgeführt wurde. Die Effizienz des Chirurgen in Ausbildung lag bei den meisten Handlungen signifikant unterhalb des Standards.

Die technische Analyse der Instrumente zeigte, dass der Sensitivitätsverlust bei der Verwendung von Instrumenten gemessen werden kann und dass dieser Verlust bei den auf dem Markt verfügbaren Instrumenten hoch ist. Diese Instrumente sind mehr als achtmal unempfindlicher als ein bloßer Finger. Wiederverwendbare Instrumente sind dabei besser als Wegwerfinstrumente. Ein Prototyp eines Instrumentes mit niedriger Reibung war lediglich 2,7 mal unempfindlicher als ein Finger. Hiermit wird deutlich, dass ein guter Entwurf eines Instruments den Sensitivitätsverlust deutlich vermindern kann.

Bei der funktionalen Analyse von Instrumenten wurden drei verschiedene Präpariertechniken in einem simulierten klinischen Umfeld miteinander verglichen. Die Ergebnisse zeigten, dass die bipolare Schere effizienter war als monopolare Koagulation und als herkömmliche Technik (Schnittführung und Nähen). Außerdem war bei der bipolaren Schere aufgrund der geringeren Anzahl von Nachblutungen wesentlich weniger Re-koagulation nötig, und die Mikro-Beschädigung war ebenfalls geringer.

Bei der klinischen Analyse wurden Instrumentpositioniersysteme (AESOP und PASSIST) verglichen mit einem chirurgischen Assistenten während laparoskopischen Cholecystektomiëen. Die Analyse machte deutlich, dass die laparoskopischen Cholecystektomiëen mit Instrumentpositioniersystemen und mit chirurgischen Assistenten gleich effizient und sicher ausgeführt werden konnten. Darüberhinaus war von den Chirurgen zu vernehmen, dass sie vorzugsweise mit Instrumentpositioniersystemen operierten.

Im letzten Kapitel wird die entwickelte Methode für die Zeit- und Handlungsanalyse von Operationen beschrieben, wobei vier Subsysteme spezifiziert (Chirurg, Assistent, Instrument, Patient), sowie Protokollieraufgaben, Basishandlungen und komplizierende Faktoren unterschieden werden. Außerdem wird erläutert, wie die Qualität, Effizienz und Probleme einer Operation gemessen und Referenzwerte bestimmt werden können.

In dieser Promotionsarbeit wird eine Basismethode entwickelt und getestet zur Messung von Qualität, Effizienz und Problemen sowohl der Arbeitsweise eines Chirurgen als auch der benutzten Instrumente bei Operationen.

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Glossary

absolute sensory threshold	minimal intensity of a signal necessary for a person to experience the signal consciously (Gescheider, G.A.)
action	a particular way of doing or accomplishing something (Merriam and Webster)
ampulla	a flask like dilation or sac (Merriam and Webster)
appendix of the colon	a supplementary part attached to the colon
basic action	elementary components of which a protocol task is composed (this thesis)
biopsy	removal of tissue from the living body, performed to establish precise diagnosis
bowel	the intestine
Calot's triangle	the triangle formed by the cystic artery superiorly, the cystic duct inferiorly, and the hepatic duct medially
cholecystectomy	gallbladder removal
cholecystitis	inflammation of the gallbladder
cholelithiasis	bile stones
clinically driven instrument design	the approach to design technology on the basis of criteria derived from an analysis of clinical task performance
coecum	a blind pouch or cul-de-sac, the first part of the large intestine, forming a dilated pouch into which open the ileum, colon, and the appendix vermiformis
colectomy	removal of the colon
colon	that part of the large intestine which extends from the coecum to the rectum; sometimes used inaccurately as a synonym for the entire large intestine
complication	a secondary disease or condition developing in the course of a primary disease or condition. (Merriam and Webster)
conversion	the transition from a laparoscopic procedure to an open procedure, usually due to complications during the operation.
correct task performance	the complete and right execution of a task according to the appropriate protocol (this thesis)
diagnostic laparoscopy	determination of the nature or cause of a disease in the abdomen using a laparoscope
distal bile duct	bile duct: any of the ducts that convey bile in and from the liver (distal: farther from any point of reference)
duodenum	the first of proximal portion of the small intestine, extending from the pylorus of the stomach to the jejunum; so called because it is about 12 fingerbreadths in length.
dysphagia	difficulty in swallowing
efficiency	a comparison of actual results with those that could be achieved with the same expenditure of energy (Merriam and Webster). In this thesis, efficiency is determined by comparing an experimental procedure to a reference (standard procedure)

	with respect to; the time, number and type of actions needed to complete a task or phase of the procedure.
gastro-intestinal tract	the stomach and intestines in continuity
hepatoduodenal ligament	a peritoneal fold that passes from the porta hepatis to the superior portion of the duodenum. It contains the hepatic artery, portal vein, bile duct, nerves and lymphatics.
laparoscopy	examination of the interior of the abdomen by means of a laparoscope
laparotomy	abdominal section to gain access to the peritoneal cavity
limiting factor	factor that does not support the goal of the procedure, e.g. bleeding complications, technical problems, waiting for personnel, superfluous action repetitions (this thesis)
mesentery	a membranous fold attaching various organs to the body wall, or the peritoneal fold attaching the small intestine to the dorsal body wall (mesenterium)
metastases	a growth of abnormal cells distant from the site primarily involved by the morbid process
minimally invasive surgery	surgery through small incisions in the skin
pancreatic head	the discoidal mass forming the enlarged right extremity of the pancreas, lying in a flexure of the duodenum
perception	the subjective cognitive representation due to external physical stimuli
periampullary	situated around an ampulla, as around the hepatopancreatic ampulla
peritoneum	the serous membrane lining the abdominopelvic walls and intestine.
peroperative	per-:a prefix meaning throughout in space or time, so throughout and during the operation.
phase	subdivision/part of the procedure e.g. *opening, dissection, reconstruction, and closing phase* (this thesis)
pneumoperitoneum	the presence of gas in the peritoneal cavity
porcelain gallbladder	gallbladder with a porcelain (white, translucent) aspect due to (chronic) inflammation
positioning accuracy	the accuracy with which the laparoscope is positioned. Ideally, the laparoscopic image shows each dissecting action in the center of the monitor image (this thesis)
procedure	a series of tasks followed in a regular orderly definite way (Merriam and Webster)
proprioception	the flow of information from sensors sensitive to stimuli within the body, serving as input to the central nervous system for the awareness and control of the musculoskeletal system.
protocol	a rigid long established code prescribing the plan of a scientific or medical experiment or treatment (Merriam and Webster)
pyknotic nuclei	pertaining a thickening, especially degeneration of a cell in which the nucleus shrinks in size and the chromatin condenses

	to a solid structured cell mass
quality	degree of excellence or degree of conformance to a standard (as of a product or workmanship) (Merriam and Webster)
Quetelet index	weight (kg)/ length^2 (m), quality measure to estimate the amount of fat tissue in a person
rectum	the distal portion of the large intestine, beginning anterior to the third sacral vertebra as a continuation of the sigmoid and ending at the anal canal.
resident	surgical trainee
sensory feedback	the flow of information from sensors sensitive to stimuli from outside the body, serving as input to the central nervous system for the awareness of the environment
standard surgical procedure	a procedure performed under current optimal conditions, e.g. using the best currently available instruments, performed by an experienced surgeon, assisted by an experienced team, and in accordance with the current standard protocol for that procedure (this thesis)
tactile feedback	the flow of information from sensors in the skin, sensitive to external pressure
task	something that has to be done, or need to be done and usually involves some difficulty or problem and that can be allotted to someone as his duty (Merriam and Webster). In this thesis: the surgical action that is prescribed in the operation protocol
time-action analysis	the evaluation of required time, and the type and the number of basic actions in order to give insight into the efficiency of the peroperative process (Sjoerdsma and this thesis)
tumour	a new growth of tissue in which multiplication of cells is uncontrolled and progressive
tumour staging	the classification of the growth of tissue in which the multiplication of cells is uncontrolled and progressive
ultrasonography	the visualisation of deep structures of the body by recording the reflections of pulses of ultrasonic waves directed into the tissues
viscera	large internal organs in any one of the three great cavities of the body, especially in the abdomen

Dankwoord

Dankwoord

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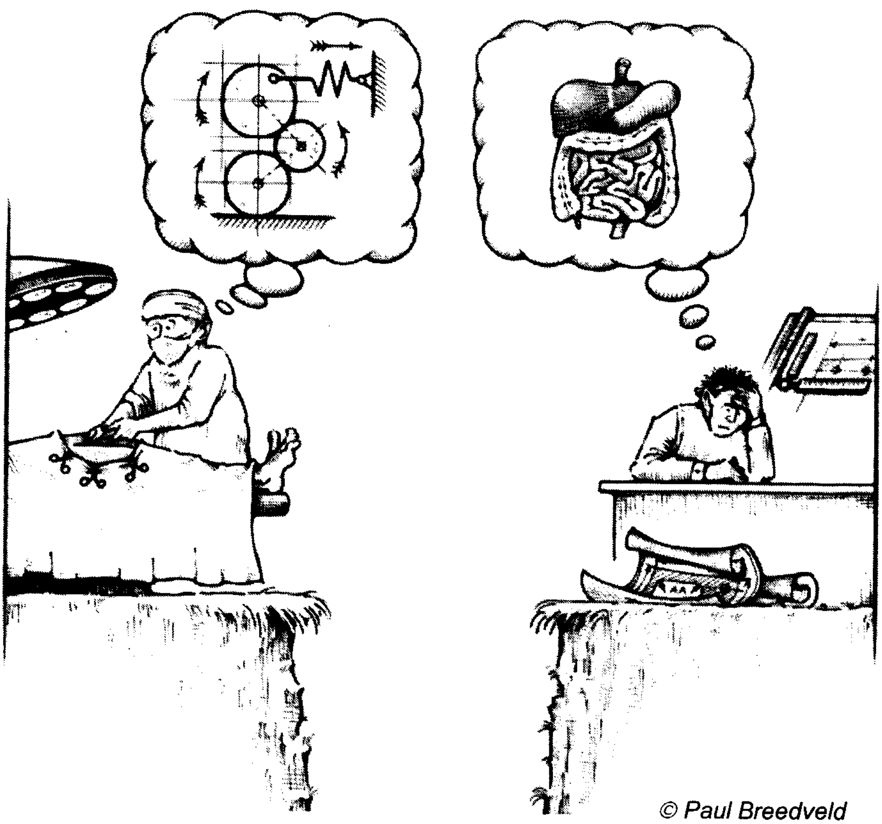

Sectie Mens-Machine Systemen:

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Curriculum Vitae

Karen T. den Boer was born the 27th October, 1970 in Huizen, the Netherlands. She attended secondary school at the Erfgooiers College (in Huizen) and graduated in 1989. She started her medical studies at the University of Utrecht in the same year, getting her degree of medical doctor in 1996. She participated in research projects at the Delft University of Technology and at the Harvard Medical School, Boston (USA), and she did additional internships in Cochabamba (Bolivia) and Karlsruhe (Germany), during her medical study.

After her medical education, she studied mechanical engineering during one year at the Delft University of Technology at the department of Mechanical Engineering and Marine Technology, section Man-Machine Systems. In 1997 she started as researcher of the MISIT-program (Minimally Invasive Surgery and Interventional Technologies) of the Delft Interfaculty Research Center on Medical Engineering, Project 1: Task Analysis of the Surgical Process. She performed the studies described in the thesis at the section of Man-Machine-Systems at the Delft University of Technology (Prof. dr. ir. H.G. Stassen) and at the Department of Surgery at the Academic Medical Center of the University of Amsterdam (Prof. dr. D.J. Gouma).

She attended in 1999-2000 the Management Course for Engineers of the TSM Business School, International Institute for Management of Technology & Business Development at the University of Twente.