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Technical Report

Problems with Laparoscopic Instruments: Opinions of Experts

K.T. DEN BOER, M.D.,[1,2] T. DE JONG,[2] J. DANKELMAN, M.Sc., Ph.D.,[1] and D.J. GOUMA, M.D., Ph.D.[2]

ABSTRACT

Introduction: **Laparoscopic surgery is particularly known for its complex technique, which calls for operative analysis of laparoscopic instruments. This study investigates 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 complications 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 to cause solid organ injuries. Insufficient functionality of the instruments and insufficient quality of the image were indicated to contribute to the instrument's risks.**

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

INTRODUCTION

OPERATIVE ANALYSIS OF SURGICAL INSTRUMENTS is important to identify the clinical problems of instruments during operative use.[1–4] Laparoscopic instruments in particular are indicated 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 postoperative outcomes, morbidity or mortality rates, and quality of life parameters.[11] Available knowledge in the 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 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.

[1]Delft University of Technology, Design, Engineering, and Production, Mekelweg, Delft, The Netherlands.
[2]Academic Medical Centre, Department of Surgery, University of Amsterdam, Amsterdam, The Netherlands.

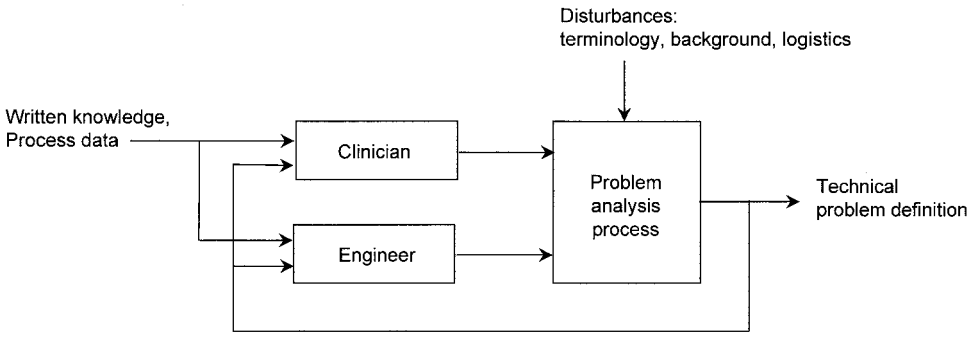

FIG. 1. Clinically driven instrument design requires close communication between clinician and engineer. The joint problem analysis process is shown, leading to a detailed technical problem definition after several cycles.

This study used a questionnaire to identify expert knowledge about operative problems of laparoscopic instruments. The opinions of 20 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 from the board of the Dutch Society of Endoscopic Surgery. After a short introduction about the questionnaire (aim, example), the surgeons were asked to describe the amount 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 six categories; three categories consisting of general laparoscopic complications that were assessed in most types of laparoscopic procedures, and three categories of procedure type related complications (Table 1). Conversion was included as a seventh 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 five 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

TABLE 1. ASPECTS CONSIDERED IN THE QUESTIONNAIRE: THE SELECTED INSTRUMENTS, THEIR POSSIBLE TECHNOLOGICAL DEFICIENCIES, AND THE COMPLICATIONS THEY MIGHT CAUSE

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

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 as 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 sight on the operation field through a camera.[22,23] Eye-hand coordination 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 misorientation).[21–23] Furthermore, hand movements are displayed mirrored, scaled, and amplified on the monitor, which may result in manipulation difficulties during the operative process.

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 contribution, scale 5 = maximum contribution). Figure 2 shows an example of the questionnaire for gastrointestinal organ 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. Afterward, 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.

Data analysis

The magnitude of the instrument's role was calculated by averaging the expressed ratings for the instruments' role (ratings 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 20 surgeons had performed a mean overall number of 977 laparoscopic operations (with a maximum of 2500) during the past 10 years, consisting of a mean number of 485 laparoscopic cholecystectomies, 67 laparoscopic appendectomies, 32 laparoscopic fundoplications, and a 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) 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 gastrointestinal 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 gastrointestinal 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 coordination are particularly indicated to be a problem to inexperienced surgeons.

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 isolation, bad dosing, sparkling, defects on cables and connectors, no ability to seal big 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, and lack tactile and proprioceptive feedback, making it difficult to control the instrument cautiously. An additional problem of the re-

GASTRO INTESTINAL TRACT INJURY, e.g.:

- **Bowel**
- **Esophagus**
- **Stomach**

Instrument	Role	Relative role of technical factor				
		Quality of Image An undisturbed, clear view at the entire field of operation.	**Depth perception** An optimal perception of three dimensional proportions.	***Functionality*** The intended intervention can adequately be performed with the instrument.	***Ergonomics*** The intervention can comfortably be performed with the instrument.	***Eye-hand coordination*** A reliable perception of the direction and speed of movement during the intervention.
	No role Max. role	No Max.	No Max.	No Max.	No Max.	No Max.
	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 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 (hook, scissors, grasper)	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

FIG. 2. Example of one page (one complication group) of the questionnaire, concerning gastrointestinal injuries, to rate instruments' risks and their technological deficiencies on a scale from 1–5. The other complication groups are designed equally.

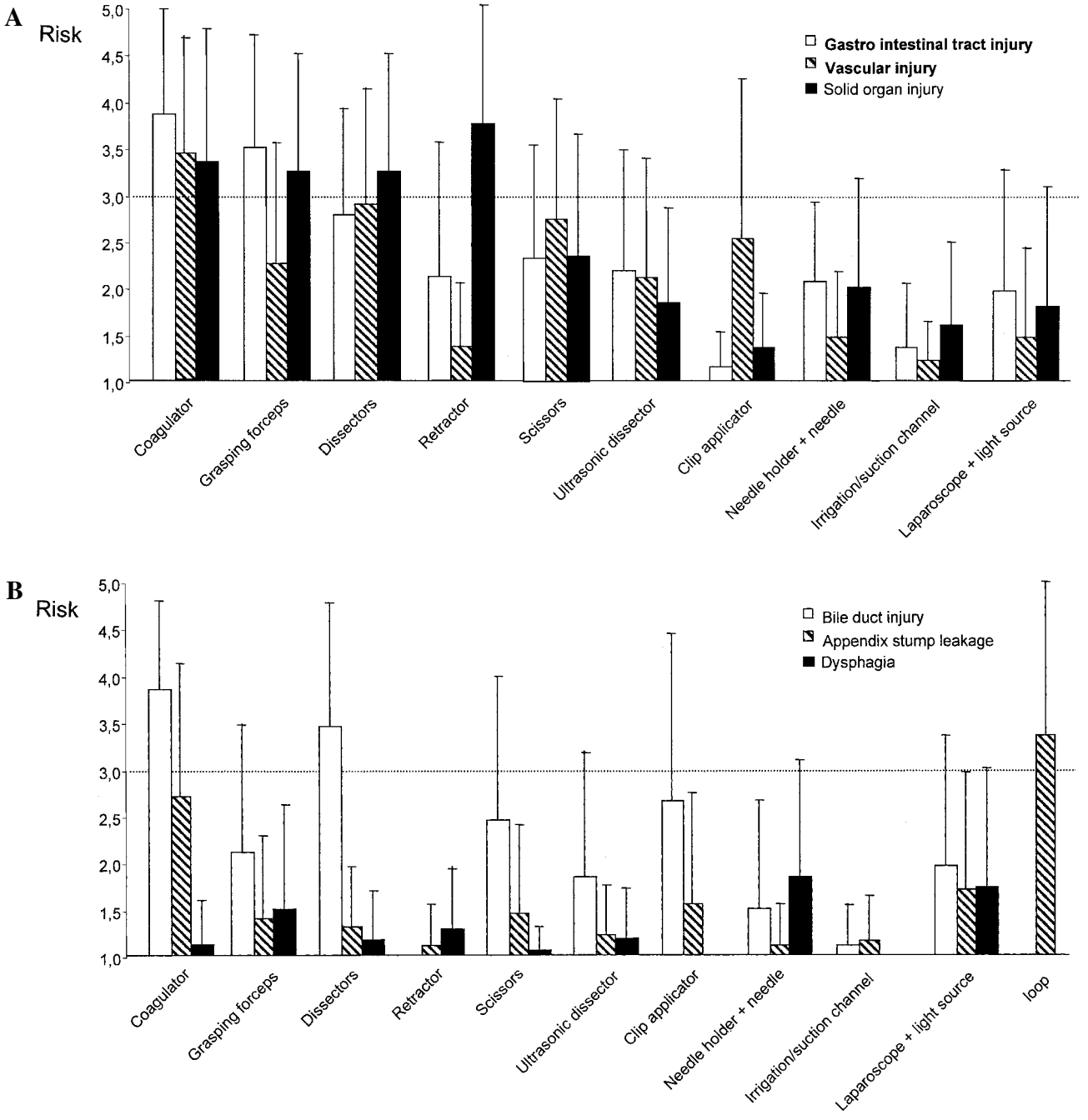

FIG. 3. (**A**) The average risk to cause a general complication for each instrument. White bars represent the average risk to cause gastrointestinal tract injuries, striped bars the average risk to cause vascular injuries, and black bars the average risk to cause solid organ injuries. A score >3 was 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. (**B**) 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.

tractor is that it is out of sight during a significant part of the operation; there is no visual check and injuries can develop without notice. 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

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

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 irrigation/suction channel, or by expanding the degrees of freedom of the laparoscope with an extra hinge. The opinions about three-dimensional imaging technology vary 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, and to improve tactile and proprioceptive feedback, and the quality of image.

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 first 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, bad dosing, sparkling, no ability of sealing big vessels, and smoke production. For the graspers and dissectors, improved alternatives are being worked on by the Minimally Invasive Surgery and Interventional Techniques (MISIT) program of the Delft Interfaculty Research Centre on Medical Engineering. The MISIT program uses 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 adept at adjusting themselves to 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 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.[24] evaluated erroneous task performance of surgeons, analyzing 20 laparoscopic cholecystectomies using observational methods. 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 wrong way technically, 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 are reported in the literature, but objective technological evaluation is rarely notified in a clinical setting. 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 real clinical improvement and safety of the alternatives, for bipolar coagulation in an experimental clinical setting.[25] 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.

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Address reprint requests to:
K.T. den Boer
Academic Medical Centre
University of Amsterdam
Department of Surgery G4-143
P.O. Box 22700
1100 DE Amsterdam, The Netherlands

E-mail: j.dankelman@wbmt.tudelft.nl