

## Intelligent Tools for Minimally Invasive Surgery: Safety and Error Issues

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### INTRODUCTION

There is a three- to six-month technology turnover in the area of advanced tools for minimally invasive surgery. This is more rapid than information technologies for human-computer interaction, or virtual and augmented environments. The first human laparoscopic cholecystectomy was performed in France in 1987; only a decade later, almost all abdominal procedures had been attempted through minimally invasive approaches.

The accelerated development of these technologies, often without controlled testing and evaluation prior to their introduction into the operating theater, has led to their rapid inclusion in almost all surgical specialties. Because of patient demands, some procedures like gall bladder removal are performed infrequently now using traditional open methods. This will soon be the case for many minimally invasive surgical procedures. As system complexity increases in the operating room, there is increased opportunity for equipment failure and human error.<sup>1</sup> The surgeon is literally at the sharp end of the technology.<sup>2</sup> Patient safety must be paramount.

### REMOTE MANIPULATION IN ENDOSCOPIC SURGERY PROJECT

The authors have been evaluating endoscopic technologies from the perspective of the tool user.<sup>3-5</sup> With current technologies, endoscopic surgery is an extremely difficult, highly demanding, remote manipulation task. However, skilled surgeons make their surgical tasks appear easy, often using inadequate or relatively primitive tools for the tasks they are performing. The Remote Manipulation in

Endoscopic Surgery project had these objectives:

1. Identify task requirements and constraints in endoscopic surgery;
2. Determine advantages and disadvantages of current endoscopic manipulators and viewing systems;
3. Compare surgeons' performance of surgical tasks using various minimally invasive technologies; and
4. Make recommendations for future technologies (eg, innovative tools, augmented environments for training, etc).

A clear goal was to assess the surgical tasks and tools, not patient outcomes, from a surgeon-centered approach. This included safety constraints. The collaborative team included surgeons, researchers, engineers, head operating room nurses, biomedical technicians, and patients, all of whom provided informed consent for the research activities. As well, medical device providers agreed to cooperate "at arm's length" with the research objectives and results.

The Remote Manipulation in Endoscopic Surgery project used controlled experiments, surveys, and observational/clinical methods. Over a three-year period (1995-1998), 23 laparoscopic procedures were observed and videotaped in operating theaters of local teaching hospitals in the Lower Mainland of British Columbia, Canada. These included 8 cholecystectomies, 5 inguinal hernia repairs and 10 Nissen funduplications. The videotapes provided split-screen images of both the endoscopic camera's view and the video camera's view (and audio) of the surgical team in the operating room (OR), from start to end of each procedure. Detailed, extensive annotation of the videotapes included team interaction in the OR,

conversation (teaching, comments on the technologies and tools), difficulties encountered, and specific tools used, with primary interest in the eye, head, and hand movements of primary and assisting surgeons, and movements of the end effectors of the endoscopic tools. These yielded time-stamped information and operational measures for the hierarchical decomposition of procedures through surgical steps, tasks, and subtasks to the level of motions of the end effector of the tools. This abstract is limited to a brief description of the clinical research in the OR, with a focus on safety and error issues. The interested reader may consult the *Medicine Meets Virtual Reality*<sup>5</sup> for other recent reports.

## RESULTS

Problems and errors were minimal considering the many hours of laparoscopic procedures that were observed. However, there was no shortage of identifiable factors relevant to patient safety and errors. In general, problems were encountered more frequently at the beginnings of surgical procedures, and in the transitions between surgical steps, tasks, and subtasks.<sup>3,4</sup> Safety and error issues were related to: the tools for manipulation and visualization by the surgeon; equipment integration and layout in the operating room; actions of the surgeons; and, communication, coordination and collaboration among OR team members.

*Tools:* With respect to tools, the authors observed loose end-effectors on the endoscopic graspers on more than one occasion. In one instance, early in the surgical procedure it took more than five minutes for the surgeon to realize that this was the problem, which was obvious from visual examination of the tool once removed. Also observed were instances of poor design and initial difficulties with the hand-handle interface (buttons, switches, dials) when new tools were introduced. As an example,

although some rigid tools permit rotation about the longitudinal axis through use of a rotary dial on the proximal end of the tool, this is ergonomically a poor design. Surgeons rarely chose to use this dial since both hands were actively occupied; rather, surgeons adopted awkward postures to achieve rotation about the tool's longitudinal axis through shoulder, wrist, and/or supination/pronation movements. Surgeons became fatigued; some complained of local aches, and there were occasional reports of repetitive strain injuries. Of paramount concern is the issue of electrical hazards—a slight break in the insulation of tools is serious. Surgeons were frequently dissatisfied with their cautery, suction, and irrigation tools. Also, at the procedure's completion, it is important that all end effectors be viewed and target tissues and organs be released prior to removal of specialized tools.

*Viewing systems:* The viewing systems are crucial; without them the surgeon works blindly.<sup>6</sup> In one instance, the video display was lost for approximately five seconds due to a loose cable connection. The scope itself was frequently cleaned due to blood; fogging of the lens also obscured the view. Surgeons were frustrated by problems with image clarity, focus, color, and contrast on video monitors. One of the major limitations of current systems is the limited field of view; surgeons continually zoomed in and out on the target area to provide both the necessary detail and surrounding anatomical context. It is life critical that the surgeon has a clear, direct view of the operative site and trochar insertion sites (using safety trochars), and that active/inserted tools are always in the field of view. There have been cases where (a) the aorta had been punctured by insertion of the first trochar (not in our study), and (b) tools not centered and observed by the surgeon in the field of view had punctured/perforated vessels and organs (eg, bile duct, bowel, liver, esophagus).

*Surgeons' actions:* Frequently the foot pedals activating cautery were confused (for scissors and scalpel), or activated inadvertently. Inadvertent activation of the cautery can cause burning of contacting tissue/objects. On more than one occasion, surgeons were so immersed in the procedure that their roles as primary surgeon (manipulating tools) or assisting surgeon (moving camera) were confused. For example, on one occasion the surgeon moved his hand and was surprised that the view didn't change correspondingly; in fact, the surgeon was moving a grasper, not the camera. This speaks to the complexity of the visumotor transformations required by the surgeon, and the presence experienced by the surgeon's brain.<sup>7</sup> Also, there was a strong sense of presence experienced by the surgeon, making him/her potentially unaware of the consequences of this confusion.

*Equipment integration and layout:* In the operating room, there were many independent, isolated pieces of equipment. Layout is key, and poor initial placement created ongoing frustration during the procedure. Monitors, IV, cautery, suction, were frequently difficult to access or in the way. There was on several occasions electrical "cross-talk" between cabling for cautery and viewing devices which gave rise to interference on the display. Other equipment, carts, or the drape placed by the anesthetist over the patient also obscured the view of the monitor by the primary or assisting surgeons. The large number of cables from these independent pieces of equipment made navigation difficult in the crowded operating theaters. Biomedical engineers/ technicians tested the equipment. Needed, however, is a plan or system for layout, setting up and integration of all the pieces.

*Communication and coordination in the OR:* There was much background noise from equipment, intercom paging systems, and conversation in the operating theaters of teaching hospitals. Communication among the surgical staff (surgeons, residents, anesthetists, and nurses) was not always clear. Several instances of miscommunication or misunderstanding were observed, for example, when a surgeon orally requested specific tools, trochar reducers, or specific drugs. On one occasion, there were frequent intercom interruptions/alerts, and all persons in the operating room were confused repeatedly by the identical beeping sound of the cautery device and a personal pager in the operating theater. Given these observations, the dominant impression, however, was that of a cohesive team approach in the operating theater.

#### SUMMARY AND CONSEQUENCES

This study has identified qualitatively issues and factors related to reducing error through a detailed, extensive annotation of 23 laparoscopic procedures performed by highly skilled, respected general surgeons in the Greater Vancouver area. Some issues have potentially lifesaving/life-threatening consequences, like puncturing key organs. Others may contribute to patient morbidity or iatrogenic illness as a consequence of errors, inadvertent actions, or difficulties in executing the surgical procedures. At the very least, problems with endoscopic technologies and their integration affect the ease and efficiency of the surgeon's work. Time equals money in the operating room. A fatigued or frustrated surgeon is more likely to make an error.<sup>2</sup> The goal is to move beyond the primitive, current tools evolved from traditional open surgery and, from a surgeon-centered perspective, to provide specifications and requirements for the design of intelligent tools for minimally invasive procedures. In this way, opportunities for human error will be reduced, and patients will ultimately be safer.

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