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.[1] The surgeon is literally at the sharp end of the technology.[2] 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.[3-5] 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 fundoplications. 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*[3-5] 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.[3,4] 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.[6] 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).