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## Improving Health Care Quality and Safety: The Development and Assessment of Laparoscopic Surgery Instrumentation, Practices and Procedures

Bernadette McCrory

University of Nebraska-Lincoln, bernadette.mccrory@gmail.com

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IMPROVING HEALTH CARE QUALITY AND SAFETY: THE DEVELOPMENT  
AND ASSESSMENT OF LAPAROSCOPIC SURGERY INSTRUMENTATION,  
PRACTICES AND PROCEDURES

by

Bernadette Janae McCrory

A DISSERTATION

Presented to the Faculty of

The Graduate College at the University of Nebraska

In Partial Fulfillment of Requirements

For the Degree of Doctor of Philosophy

Major: Engineering

(Biomedical Engineering)

Under the Supervision of Professor M. Susan Hallbeck

Lincoln, Nebraska

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IMPROVING HEALTH CARE QUALITY AND SAFETY: THE DEVELOPMENT  
AND ASSESSMENT OF LAPAROSCOPIC SURGERY INSTRUMENTATION,  
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Bernadette Janae McCrory, Ph.D.

University of Nebraska, 2012

Advisor: M. Susan Hallbeck

Adverse events due to medical errors are a leading cause of death in the United States exceeding the mortality rates of motor vehicle accidents, breast cancer and AIDS. Improvements can and should be made to reduce the rates of preventable surgical errors since they account for nearly half of all adverse events within hospitals. Although minimally invasive surgery has proven patient benefits such as reduced postoperative pain and hospital stay, its operative environment imposes substantial physical and cognitive strain on the surgeon increasing the risk of error. In order to mitigate errors and protect patients, a multidisciplinary approach was taken to improve minimally invasive surgery. Clinical, human factors, and biomedical engineering principles and methodologies were used to develop and assess laparoscopic surgery instrumentation, practices and procedures. First, the foundational understanding and the imperative to transform health care into a high quality and safe system is discussed. Next, a generalized perspective is presented on the impact of the design and redesign of surgical technologies and processes on human performance. The remainder of this dissertation presents the experimental results of four studies used to develop and assess laparoscopic surgery

instrumentation, practices and procedures. In the first experiment, a novel hand-controlled electrosurgical laparoscopic grasper was developed and evaluated to eliminate the use of foot pedals, reduce surgery-related discomfort, and minimize the risk of actuation errors. The final three studies compared the emerging technique of single-incision surgery to conventional laparoscopic surgery to determine whether there were any technical, physical or subjective performance differences across the two surgical techniques. In all, these studies contribute towards the improvement of the quality and safety of minimally invasive surgery.

Keywords: biomedical engineering, human factors, ergonomics, minimally invasive surgery, patient safety, health care quality, instrument design, simulation

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# CHAPTER 1

## Introduction

The health care sector in the United States (U.S.) accounts for nearly 1.6 trillion dollars, and yet insignificant resources have been devoted to improving its processes and productivity (National Academy of Engineering (NAE) & Institute of Medicine (IOM), 2005). Although work is now being completed, the lack of attention and resources focused on optimizing health care has resulted in a significant amount of medical injuries and monetary costs. Specifically, it was estimated that the total national costs from lost income, lost household production, disability and health care costs due to preventable medical injuries were between \$17 and \$29 billion (Johnson et al., 1992; Thomas et al., 1999). Many of these preventable medical injuries lead to significant morbidity and mortality, with an estimated 44,000 to 98,000 Americans dying in hospitals each year (IOM, 2000). Additionally, the fragmented and disjointed health care system in the U.S. breeds medical mismanagement. For instance, in 2000 for “every dollar spent on health care, thirty to forty cents was spent on costs associated with overuse, underuse, misuse, duplication, system failures, poor communication and inefficiency” (NAE & IOM, 2005). With health care costs rising at double-digit rates and 47 million Americans lacking health insurance (DeNavas-Walt et al., 2007), the U.S. health care system must undergo a drastic transformation to minimize economic hardship, increase access to care, and increase the quality and safety of care. In order to mitigate and prevent future medical errors, a holistic approach to health care delivery reform must be taken to improve its safety, quality, efficiency and overall performance.

While manufacturing, aviation and nuclear industries have implemented the use of various systems engineering tools, health care has predominately focused on diagnostic and therapeutic technological development. This has created the so-called “quality gap,” which is the divergence between the progress in medical science and the quality of care patients receive (IOM, 2001). In 2000 and 2001, the IOM recognized the deepening quality crises and issued the two reports “To Err is Human” and “Crossing the Quality Chasm,” respectively. These landmark reports documented not only the system failures that resulted in as many as 100,000 deaths, but also a call to action for all stakeholders to transform the health care industry. As a result, the National Academy of Engineering and the Institute of Medicine united and initiated a project in 2002 to “1) identify engineering applications that could contribute significantly to improvements in health care delivery; 2) assess factors that would facilitate or impede the deployment of these applications; and 3) identify areas of research in engineering and other fields that could contribute to rapid improvements in performance” (NAE & IOM, 2005). These objectives call for the engineering community to develop a cooperative relationship with health care professionals and to implement engineering tools in order to eliminate the fundamental shortcomings in the way care is organized (IOM, 2001). Although the uptake and progress in both the health care and engineering communities has been slow, improvements have been made towards creating a “twenty-first century system capable of delivering safe, effective, timely, patient-centered, efficient, [and] equitable health care” (NAE and IOM, 2005). Pursuant to the IOM’s (2001) recommendations, these six dimensions of quality form the foundational framework for the analysis, design, and improvement of the U.S. health care system.

## **1.1 Review of Literature**

The application of engineering principles and tools has begun to take hold in health care in areas such as electronic medical records, medication management and patient handoffs (Holden, 2011; Bates & Gawande, 2003; Wayne et al., 2008). Surgery has also received considerable attention due to its complexity, high-risk and financial impact. For over a decade, the operating room has been one of the main targets of health care quality and patient safety research, since surgical errors account for nearly half of all adverse events within hospitals (D'Addessi, 2009; Cuschieri, 2006). As an area already prone to medical error, the implementation of new surgical techniques, technologies and processes poses particular concern especially when they have not been fully investigated and formalized.

### ***1.1.1 Conventional Laparoscopic Surgery (CLS)***

Conventional laparoscopic surgery (CLS) is a form of minimally invasive surgery (MIS) where a surgeon makes several small incisions (0.5-1.2 cm) to insert long, slender instruments and a camera into the patient's abdomen (Figure 1.1). Patient benefits from CLS include reduced trauma, postoperative pain and recovery time (Laurence et al., 2012; Li et al., 2010; Ohtani et al., 2012). However, the disadvantages of CLS include a two-dimensional surgical field, awkward instruments with fulcrum effects, an unstable camera platform and increased static postural stress compared to open surgery (Berguer et al., 1997; Berguer et al., 1999a). Maneuvering laparoscopic instruments also increases muscle activity and requires the adoption of non-ergonomic positions of the upper limbs resulting in arm, shoulder and spine discomfort compared to open procedures (Berguer et al., 1997; Person et al., 2001). Lastly, the physical workload of manual laparoscopic surgery compared to an open surgery has been shown to be significantly greater for an

equivalent procedure (Berguer et al., 1999b; Emam et al., 2000). Despite the greater strain on surgeons, CLS is still considered the gold-standard for many routine surgical procedures.



Figure 1.1: Conventional Laparoscopic Surgery (Protocol Snow, 2012)

In the 1980's there was a surge to perform the new technique of CLS in lieu of open surgeries (Peters et al., 1991; Scott et al., 1992). This quick adoption resulted in significant morbidity and mortality due to a lack of training, proper instrumentation, systematic evaluation, prospective comparative data, standardization and oversight (Deziel et al., 1993; Green et al., 1992; Wherry et al., 1994). Although prospective clinical trials did reveal improved patient outcomes for CLS compared to open surgery (Kane et al., 1995; Majeed et al., 1996; Trondsen et al., 1993), the acceptance and implementation of CLS should have occurred in a more coordinated and responsible manner based to protect patients from undue harm.

As expected, much can and should be learned about surgical error prevention and management from the early failures of CLS. The most poignant lessons learned were that

novel techniques must be critically evaluated prior to widespread adoption (Gilchrist et al., 1991; Hodgson et al., 1994); regardless of surgical specialty and expertise, there is a significant skill acquisition time for new techniques and instrumentation (Lekawa et al., 1995; Sariago et al., 1993); and, there is a need for training and certification of basic knowledge and technical skills outside of the operating room (Dent, 1996; Grundfest, 1993; Parsa et al., 2000). It was also shown that the CLS environment causes fatigue, physical discomfort and cognitive overloading for surgeons (Park et al., 2010; Sari et al., 2010; Szeto et al., 2009; Zhang et al., 2004). In all, these risk factors further predisposed the pioneering CLS surgeons to preventable medical errors. In order to improve health care quality and patient safety, it is critical to learn from past mistakes and to develop a robust system that prevents, identifies and mitigates medical errors. It is also vital to critically assess new techniques, processes and technologies that may impact all or part of the health care system.

### ***1.1.2 Laparoendoscopic Single-site Surgery (LESS)***

As the next evolution of MIS, laparoendoscopic single-site surgery (LESS) is currently being performed without formal guidance or standardization. This seemingly “scarless” surgical technique is performed using a single, small incision (~2.0 cm) typically through the navel. The surgeon inserts several instruments and a laparoscopic camera into the single incision leaving virtually no scar. Although LESS represents the next logical step towards less invasive surgery, its patient benefits and best practices are currently unproven (Gettman et al., 2011; Gill et al., 2010). At present the only recognized benefit of LESS compared to conventional laparoscopy is improved cosmesis (Figure 1.2; Lee et al., 2010; Raman et al., 2009; Tsimoyiannis et al., 2010; Vidal et al., 2010). Single-



institution comparative case reports indicate that potential patient benefits include an increase in patient satisfaction and a decrease in postoperative pain and recovery time compared to CLS (Canes et al., 2010; Chow et al., 2010; Philipp et al., 2009; Raman et al., 2009; Tsimoyiannis et al., 2010). These initial reports demonstrate that LESS is safe, effective and feasible for noncomplex cases (Rivas et al., 2010; Saber et al., 2010; Teixeira et al., 2010); however a large-scale multicenter randomized control trial is needed to verify the reproducibility of these results.

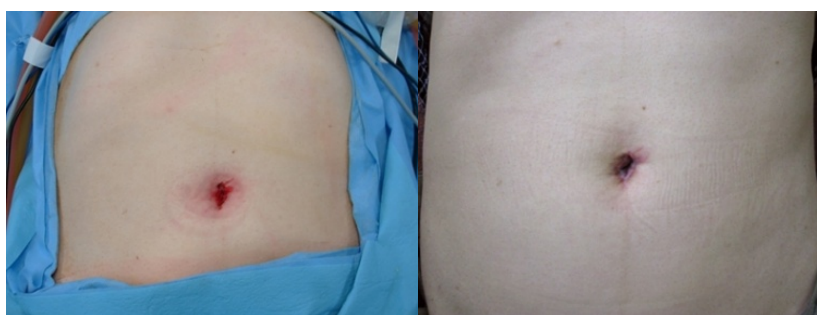


Figure 1.2: Post-surgical Scar for LESS (Wong and Chiu, 2010)

As previously stated, the early adoption of CLS resulted in significant patient harm (Green et al., 1992; Deziel et al., 1993; Wherry et al., 1994). Early complication and conversion to open surgery rates for conventional laparoscopic cholecystectomy were 4% - 8% and 4%, respectively (Peters et al., 1991; Scott et al., 1992). However, today the technique has been thoroughly studied, validated and standardized with complication and mortality rates less than 1.5% and 0.1% for laparoscopic cholecystectomy, respectively (Osborne et al., 2006). For LESS, the preliminary complication and conversion rates appear to much higher than the rates for conventional laparoscopy, which is still considered the gold standard in MIS. From single-institution case reports, the complication and conversion rates for LESS cholecystectomy are as high as 24% and 52% (Table 1.1), respectively. Preliminary comparative studies of LESS and CLS

cholecystectomies show more favorable results (Table 1.2), however many of these studies were performed by expert laparoscopic surgeons on young, healthy patients. Although not a comprehensive review of the current literature, these data are staggering and are cause for concern. The threshold for complications and conversion should be low and reflect the rates of the current standard of practice. As evidenced by these preliminary data, a critical evaluation of LESS is needed. In particular, a coordinated and systematic evaluation of LESS should occur to ensure that the widespread implementation of LESS occurs in a responsible manner that protects patient safety.

Table 1.1: Intraoperative Outcomes of LESS Cholecystectomies

First Author	Year	Patients	Conversion To		Complications
			Conv. Lap.	Open	
Chow, A.	2009	14	NR	NR	7.14%
Edwards, C.	2010	80	11.25%	None	8.75%
Elsey, J.K.	2010	238	2.50%	0.42%	2.10%
Erbella, J.,Jr	2010	100	2.00%	None	None
Ersin, S.	2010	20	5.00%	None	None
Langwieler, T.E.	2009	14	None	None	None
Petrotos, A.C.	2009	10	None	None	None
Philipp, S.R.	2009	29	52.0%	None	24.1%
Podolsky, E.R.	2009	5	None	None	None
Rivas, H.	2010	100	None	None	NR
Roberts, K.E.	2010	56	1.79%	1.79%	5.36%
Romanelli, J.R.	2010	22	4.55%	None	4.55%
Solomon, D.	2010	56	1.79%	1.79%	5.5%
Tacchino, R.	2009	12	None	None	16.7%
Tsimoyiannis, E.C.	2010	20	None	None	5.26%

Note: Conv. Lap. = Conventional Laparoscopy; NR = Not Reported



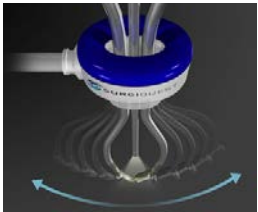
Table 1.2: Cholecystectomy Comparative Studies



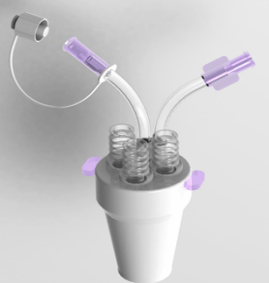
First Author	Philipp, S.R.		Tsimoyiannis, E.C.	
Year	2009		2010	
Intervention	CLS	LESS	CLS	LESS
Patients	22	29	20	20
Operative Time (min)	67 <sup>a</sup>	85 <sup>a</sup>	37.2 ± 9.16	49.65 ± 9.02
Length of Stay (days)	0 <sup>a</sup>	0 <sup>a</sup>	1.10 ± 0.44	1.25 ± 0.44
Complications	13.6%	24.1%	11.1%	5.26%
Estimated Blood Loss (mL)	15 <sup>a</sup>	15 <sup>a</sup>	8.50 ± 6.30	9.90 ± 14.38
Postoperative Pain VAS	2 <sup>a</sup>	4 <sup>a</sup>	0.85 ± 0.67	0.05* ± 0.22

Note: a = median; mean ± standard deviation

LESS has become more prevalent primarily due to the recent development of advanced access port technology (Table 1.3), but also because of the technical performance difficulty of natural orifice transluminal endoscopic surgery (NOTES). On a continuum from more to less invasive, LESS lies somewhere between conventional laparoscopy and NOTES. While NOTES was conceived first, its widespread uptake has been severely hindered due to a lack of patient acceptance, enabling surgical technology, training opportunities and safety concerns (Auyang et al., 2011; Bucher et al., 2011; Slim and Launay-Savary, 2008; Sodergren et al., 2009; Vettoretto and Arezzo, 2010).

Table 1.3: LESS Access Devices

Product	Description	Figure
Triport+ (Olympus America Inc, Center Valley, PA, USA)	A multi-instrument disposable access port that allows up to three instruments to be used simultaneously through a single incision.	 A white, cylindrical, multi-instrument disposable access port with three blue ports on top and a side port.
GelPoint (Applied Medical Corp, Rancho Santa Margarita, CA, USA)	A multi-instrument disposable port that facilitates triangulation of standard instruments through the gel cap. Maximizes internal working diameter and offers greater freedom of movement.	 A purple, cylindrical, multi-instrument disposable port with a clear gel cap and three ports on top.
SILS Port (Covidien, Mansfield, MA, USA)	A flexible laparoscopic port that can accommodate up to three instruments through a single incision. This product is designed to use multiple instruments with maximal maneuverability.	 A blue, cylindrical, multi-instrument disposable port with three ports on top and a flexible side port.
SSL Access System (Ethicon Endo-Surgery, Inc, Cincinnati, Ohio USA)	Enables the insertion of multiple surgical instruments through the seal cap. Seal cap rotates 360° for quick reorientation. Eliminates need for trocars.	 A white, cylindrical, multi-instrument disposable port with a seal cap and a side port.
OCTO Port (dalimSurgNet Corp, Seoul, South Korea)	Detachable port cap with soft silicon cover and different port heights. Includes four ports for introducing instruments via one incision.	 A blue, cylindrical, multi-instrument disposable port with four ports on top and a side port.
AirSeal for Single Port Surgery (SurgiQuest, Inc, Orange, CT, USA)	Insert multiple instruments using a single cannula. Possible to use unique size and shape instruments for triangulation.	 A blue, cylindrical, multi-instrument disposable port with a single cannula and a side port.

Product	Description	Figure
<p>X-Cone (KARL STORZ GmbH &amp; Co. KG, Tuttlingen, Germany)</p>	<p>Reusable access for transumbilical laparoscopy. The design offers high instrument mobility, stable instrument guidance and comfortable introduction technique.</p>	
<p>Cuschieri Endocone (KARL STORZ GmbH &amp; Co KG, Tuttlingen, Germany)</p>	<p>Reusable system was developed as a holistic solution (port-instruments-retraction system) to facilitate the execution of LESS.</p>	
<p>InnoPort (Innovia LLC, Miami, FL, USA)</p>	<p>Simple, cone-shape design grants physicians unrestricted access to the abdominal cavity with up to three rigid, curved, and/or articulating 5mm instruments.</p>	

Although LESS has been well accepted by both patients and surgeons, LESS has similar technical challenges to NOTES (Bucher et al, 2011; Gettman et al., 2011; Gill et al., 2010). Specifically, all of the instrumentation is inserted through a single incision, which results in intracorporeal and extracorporeal instrument collisions, an in-line view of the instruments, transposed instrument viewing (i.e., right instrument operates on the left side in monitor), altered instrument pivot point above the skin incision, and the surgeon's close proximity to assistants (Figure 1.3; Rivas et al., 2010; Saber et al., 2010; Teixeira et al., 2010). As in conventional laparoscopy and NOTES, the surgeon must also still contend with a non-neutral posture due to the instruments, monitor position, foot

pedals, table height and static body position (Mallett et al., 2001; Stassen et al., 2001; van Veelen et al., 2003).

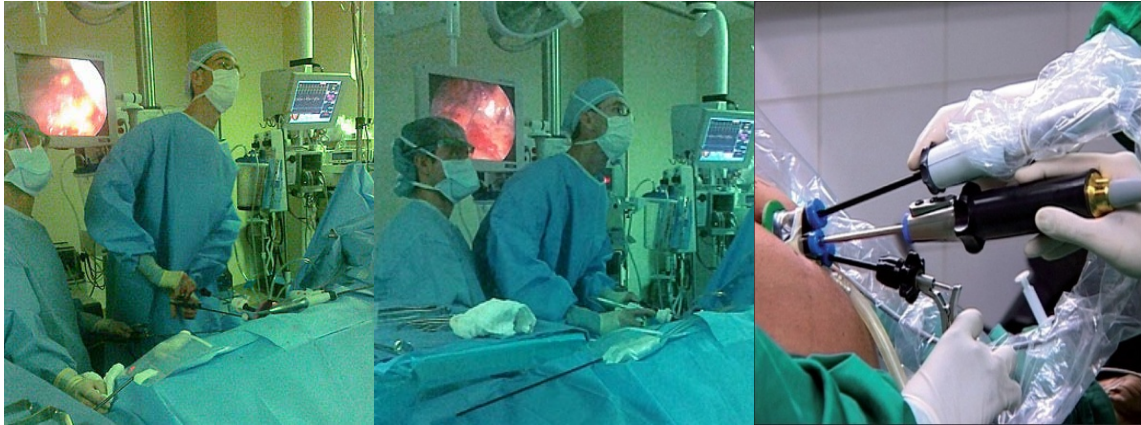


Figure 1.3: The Imperfect Operative Environment of LESS

Due to the multitude challenges facing LESS, a rigorous assessment of the technique and its technologies is needed to optimize surgical performance and mitigate preventable errors. In order for LESS to become the gold-standard in MIS, it is also imperative that the lessons learned from the uptake of conventional laparoscopy two decades ago be integrated into the assessment, refinement and standardization of LESS. Overall, improvements can and should be made to decrease the rates of preventable surgical errors, since they are a significant cause of medical injury and health care cost.

### ***1.1.3 Human Factors and Ergonomics in Surgery***

For over thirty years researchers have been studying the cause and effect of human error (Cuschieri, 2005). Human errors can be defined as unintentional random events that are inherent in all human activities and professions. These events can be characterized as any type of error, mistake, incident, accident, or deviation, regardless of whether or not it results in patient harm. In an effort to increase accountability and consumer access to

health care performance, the National Quality Forum (NQF) created a listing of critical errors, called serious reportable events (SREs). According to the NQF, the now 29 SREs are “largely preventable, grave errors and events that are of concern to the public and health care providers, and that warrant careful investigation, and should be targeted for mandatory public reporting” (NQF, 2002). The list of SREs includes both injuries caused by care management (rather than the underlying disease) and errors that occur from the failure to follow standard care or institutional practices and policies (NQF, 2011). The 29 SREs are categorized into surgical or invasive procedure, product or device, patient protection, care management, environmental, radiological and potential criminal events. Of these medical errors, 18 SREs account for nearly 2.4 million extra hospital days and \$9.3 billion in excess charges every year (Weingart & Iezzoni, 2003). Due to the large variation among hospitals there has been some debate about the magnitude of the impact of medical errors. However, the general consensus is that these serious yet preventable errors lead to a significant increase in mortality, length of stay and cost (Reilly and Reilly, 2004).

“Surgery requires a high level of intellectual preparation, an efficient and controlled workspace, fine motor skills, physical endurance, problem-solving skills, and emergency response skills” (Berguer, 1999). Due to the fact that surgical errors account for nearly 50% of all adverse events and up to 13% of all hospital deaths (D’Addessi, 2009; Tang et al., 2004), it is not surprising that the NQF has specifically targeted the operating room for quality and safety improvement. The NQF surgical or invasive procedure SREs include: 1) surgery or other invasive procedure performed on the wrong site, 2) surgery or other invasive procedure performed on the wrong patient, 3) wrong

surgical or other invasive procedure performed on a patient, 4) unintended retention of a foreign object in a patient after surgery or other invasive procedure, and 5) intraoperative or immediately postoperative/post-procedure death in an American Society of Anesthesiologists (ASA) Class 1 patient (NQF, 2011).

Although the NQF has made strides since 2002 to create visibility and accountability of the most critical and costly medical errors, there have not been substantial gains in patient safety nor health care quality. This is in part because all of the SREs have a high severity or patient effect, high detectability, and yet a relatively low likelihood of occurrence. For example, the likelihood of amputating the wrong leg of a patient is decreased through several checks before and during a surgical procedure. However, this type of unfortunate event is highly detectable and typically well-publicized in the media. It also has a substantial impact fiscally and emotionally on all of the parties involved (e.g., patient, surgeon, family, hospital, etc). Consequently, the overall impact of mitigating these types of errors within the health care system is minimal within the current reporting paradigm. Extensive change can only occur through systematic improvements across all elements of a system including the personnel, microenvironment such as the operating room, and macro-environment such as the hospital, network and region.

In surgery, there has been progress towards analyzing errors rather than complications, which allow personnel to more accurately anticipate, avoid and identify adverse events (Cox et al., 2008). In an effort to prevent, mitigate and identify errors, classifications of human error have been created to determine the underlying source(s) or root cause(s) that lead to errors. For instance, one categorization classifies errors as skill-



based (i.e., faulty execution of the task), rule-based (i.e., misclassification or misdiagnosis leading to the action) or knowledge-based (i.e. from incomplete or incorrect knowledge) (Rasmussen, 1987). An alternative categorization is that errors are either active (i.e. enacted by front-line operators and have an immediate effect) or latent (i.e., hidden within the system and may lie dormant and unnoticed without causing any adverse effect until they summate to create the necessary trajectory for a major catastrophe) (Reason, 1990). Active errors tend to be apparent such as cutting the wrong vessel, whereas latent errors tend to occur in complex and high-technology activities at a later time. Classifying and investigating errors allows policies, procedures and processes to be put in place that aim for optimal performance by reducing errors such that the residual risk within the system is as low as reasonably possible. As portrayed by the two very different error classifications schema, human errors can occur at different levels within a system, occur immediately or with some delay, and can have multiple root causes. The inherent complexity of human error makes it critical to have prospective and prescriptive policies, procedures and processes that reduce the risk of error in the system as a whole. These types of policies, procedures and processes aim to identify what may go wrong, the probability of occurrence, the consequence of occurrence, and the necessary defensive measures to minimize or eliminate risk. One way to create these transparent and accountable structures is to utilize human factors and ergonomics (HFE) analyses, tools and techniques. In general, HFE seeks to improve the surgeon's user experience and thereby improve patient safety and outcomes by implementing changes in the system to minimize risk and make the system more resilient to error. Many of the errors in complex systems can be attributed to the mismatch between the work system

and the capabilities and/or limitations of the human operator (Parker, 2010). These poor surgeon-patient and surgeon-technology interfaces produce a significant level of physical and cognitive stress on the surgeon contributing to surgical errors (van Det et al., 2009). HFE utilizes scientific data-driven analyses such as observations, questionnaires, interviews, checklists, expert appraisals, workload analyses, accident/injury analyses, task analyses, safety analyses, root cause analyses and/or critical incident techniques to understand and implement changes within complex systems (Carayon et al., 2011; Chapanis 1995; Karwowski, 2006; Stanton & Young, 1998).

HFE analyses and techniques are unique since they focus on different stakeholders within the system and create an understanding of the systemic aspects that lead to both excellence and failure in complex systems (Carthey et al., 2000). Until recently efforts to implement HFE practices in the operating room (OR) have been largely unsuccessful (Matern & Koneczny, 2007; Wong et al., 2010). Although there has been progress, there are still no true HFE standards of practice in the OR, and limited standards for the design and testing of medical equipment. For example, medical device manufacturers quickly embraced LESS and have rapidly produced novel, repurposed and redesigned surgical equipment. Although the influx of these highly complex technologies appears to be aiding LESS surgeons in the short-term, there have been no published studies on the HFE of these devices and their potential effects on the surgeon, surgical performance or patient safety. As surgical technologies become more complicated there is an even greater risk of active and latent operative errors due to technology misunderstanding and misuse. As such, it is vital that HFE professionals partner with

medical professionals, hospital administrators and medical device manufacturers to improve these interfaces and processes to protect both patients and surgeons from harm.

Overall, “surgical care is expensive and the costs of errors or delays in surgical treatment are substantial in both economic and human terms” (Berguer, 1999). The prevention, early recognition and mitigation of surgical errors are of paramount importance in improving patient safety and reducing health care costs. It is critical to create transparent and accountable structures throughout the health care system to effectively reduce medical errors and preventable harm. Finally, HFE systems-based approaches have the potential to assist in the transformation of the health care into a more productive, efficient and safer system.

## **1.2 Dissertation Objective and Contributions**

Due to the quality and safety concerns associated with health care, the objective of this dissertation is to conduct a multidisciplinary assessment to improve minimally invasive surgery. Clinical, human factors, and biomedical engineering principles and methodologies are used to critically evaluate and improve minimally invasive surgery. The experimental findings demonstrate that uniting engineering and clinical research principles and methods can improve the quality and safety of surgery. In particular, this work shows that a multidisciplinary approach leads to a more rigorous and comprehensive assessment of surgical instrumentation, practices and procedures. In turn, there can be a more rapid dissemination of evidence-based data to a diverse set of stakeholders, who can impact different aspects of minimally invasive surgery leading towards systematic improvements in performance, safety and outcomes.

The work of the author described in this dissertation has three major contributions to the area of research concerning the quality and safety of minimally invasive surgery:

- 1) provides a link between the theoretical aspects of human performance and the design and redesign of safe and effective medical technologies and processes;
- 2) demonstrates the use of simulation as a safe, reliable, adaptable and reproducible environment to develop and assess surgical technologies, practices and procedures prior to implementation; and,
- 3) provides evidence that multidisciplinary assessment of novel surgical instrumentation and procedures yields high-quality data that can be used to improve medical devices, operative performance and patient safety.

These contributions represent a new integration of surgical technique and instrumentation evaluation, as well as translating evidence-based data into clinical practice. This research is innovative, because no previous studies have completed a comprehensive appraisal of a surgical technique and its technologies using this unique multidisciplinary approach. In all, this dissertation demonstrates the imperative of joint research between engineering and health care professionals to develop and implement effective and sustainable change within the complex health care system.

### **1.3 Dissertation Outline**

This dissertation consists of the following chapters. Chapter 1 provides the foundational understanding of the topics covered in this dissertation, and elucidates the imperative to transform health care into a high quality and safe system. Chapter 2 takes a broader perspective of the human elements that interact in the complex system of health care. In this chapter, the impact of the design and redesign of surgical technologies and processes

on human performance is discussed. In Chapter 3, a minimally invasive surgery device was developed that allows laparoscopic surgeons to hand-operate standard electrosurgical equipment. This novel device eliminates the use of electrosurgical foot pedals, which are prone to activation errors and cause uncomfortable body positions for the surgeon. Three different prototype designs were quantitatively and qualitatively evaluated to determine which optimized functionality, performance and user satisfaction. Chapters 4, 5 and 6 compared the emerging technique of single-incision surgery to conventional laparoscopy to determine whether there were any technical, physical or subjective performance differences across the two surgical techniques. A systematic and multidisciplinary approach was used to conduct this comparative evaluation. These chapters best demonstrate the use of engineering principles and methodologies to produce evidence-based data to define acceptable clinical performance, develop best practices, standardize procedures, and evaluate patient safety. Finally, Chapter 7 discusses the overall contribution of this work to minimally invasive surgery and the health care system. This chapter also includes suggestions for improvements on minimally invasive surgery technologies and processes for the future. Finally, the future work necessary to continue to drive the improvement of surgery and health care delivery is also discussed.

## **CHAPTER 2**

# **Human Performance and the Design and Redesign of Surgical Technologies and Processes**

### **2.1 Executive Summary**

Surgeons require a significant amount of intellectual and physical preparation to perform their highly specialized work tasks. Similar to occupations in the nuclear and aviation industries, surgeons must also be adept at performing these tasks in highly stressful and risky situations (D'Addessi, 2009). The inherent demands of surgery therefore warrant attention on maximizing the surgeon's performance to optimize outcomes. Using human factors and ergonomics (HFE) principles, an overarching goal is to enable optimal performance even under adverse conditions through the design of improved surgical technologies and processes. As detailed in the following sections, HFE, following a systems-based perspective, was used to craft the scientific approach used throughout this dissertation to analyze surgical technologies, performance, and workload towards the improvement of the quality and safety of minimally invasive surgery. Overall, this chapter presents a generalized perspective on the impact of the design and redesign of surgical technologies and processes on human performance.

### **2.2 Human Factors and Ergonomics in Health Care**

In the early 1900s, Frank and Lillian Gilbreth were among the first pioneers to systematically study processes in the operating room. Both were advocates of scientific management and the study of motion (Baumgart & Neuhauser, 2009; Towill, 2009).

They revolutionized surgery by introducing the concept of a “surgical caddy,” now referred to as the scrub nurse, so that surgeons did not waste time searching for instruments (Baumgart & Neuhauser, 2009; Towill, 2009). Poignant even now, they also observed that “surgical practices and instrumentation varied greatly throughout the country, leading to inefficiency and the lack of a best approach to each treatment modality” (Berguer, 1999). Many of the Gilbreths’ ideas are still used in hospital quality assurance and health care delivery improvement programs. The Gilbreths’ efforts provided the initial groundwork for engineers and HFE professionals to examine and improve the quality and safety of surgical procedures.

HFE is defined as “the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimize human well-being and overall system performance” (International Ergonomics Association, 2000). HFE is uniquely constructed to assist surgeons in that it (Dul et al., 2012):

- 1) focuses on the two closely related outcomes of performance and well-being;
- 2) is design driven; and,
- 3) takes a systems approach.

These three fundamental characteristics of HFE enable it to contribute to the design and evaluation of a wide array of work and service systems. HFE also has great potential to impact inherently complex and risky systems, including health care, to shape the system around the capacities and aspirations of humans to optimize performance and the well-being of clinicians and patients. Specifically, the focus is to improve both performance (quality) and well-being (safety) by “designing the integrative whole better, and by

integrating the human into the system better” (Dul et al., 2012). In all, HFE utilizes multidisciplinary tools and techniques to plan, design, evaluate, redesign, and continuously improve tasks, jobs, products, technologies, processes, organizations, environments and systems in order to make them compatible with the needs, abilities and limitations of people (International Ergonomics Association, 2000).

### **2.3 Human Performance**

Surgeons have long been interested in the design of surgical technologies and processes to maximize their efficiency, effectiveness and outcomes (Riskin et al., 2006). Even today, many surgeons develop unconventional instruments and workarounds in order to overcome the inherent challenges in surgery and improve their performance (Riskin et al., 2006). It appears that many surgeons’ design processes are subjective and personal; whereas, HFE strives to generalize and operationalize any design/redesign to increase efficiency, effectiveness and outcomes. In order to show improvement, it is critical to quantify these increases as related to human performance, which can be thought of as any type of user behavior that can be measured (Tullis and Albert, 2008).

Although human performance can be measured in many different ways, typical performance metrics include success (outcome), efficiency (time) and safety (errors) (Tullis and Albert, 2008). Following the landmark publication of “To Err is Human” there was a surge to improve patient safety and mitigate medical errors by improving human performance in the complex health care system (IOM, 2000). The IOM report stated all humans are fallible and make mistakes daily even during the most routine activities (2000). Yet we have come to expect perfection from surgeons in a decentralized



and fragmented health care system or “nonsystem” (IOM, 2000). As a result of the IOM’s efforts there was a renewed interest and awareness of HFE and systems-based analysis.

Over the last decade there has been considerable effort to improve health care through the development and widespread implementation of robust systems that maximize the safety and quality of health care delivery. As expected the human’s performance is critical to the overall functioning of these systems. Within the system, the human(s) and the complex processes/technologies are interdependent for optimal performance. Accordingly, it is pivotal to understand the roots of human performance including its fallibility and variability to develop these robust systems that enable humans to deliver safe and high-quality health care.

### ***2.3.1 Fallibility***

Currently there is no ubiquitous “error check” function in the operating room, however current research between clinicians and engineers is demonstrating the value of such error mitigation functions/practices (Cuschieri, 2005; Rosenfield & Chang, 2009). The outcomes of this joint research can change the status quo of poorly designed surgical technologies and processes that lead to a countless number of preventable errors (D’Addessi, 2009; Cuschieri, 2006). As we build the 21<sup>st</sup> century health care system, the antiquated view that safety and quality lie only with the individual surgeon’s abilities must be eliminated (Dankelman & Grimbergen, 2005). This individualized and “blame and shame” culture does not recognize that surgeons are operating in complex socio-technical environments with a diverse amount of people, various technologies and patient-specific variations (Carayon et al., 2011). Viewing surgical error as a personal

failure at only the individual level, or the person approach, will not enable the root cause of the error to be determined and guarded against (Dankelman and Grimbergen, 2005).

In contrast to the individual or person approach to reduce human error, the HFE systems-based approach recognizes that inherently humans are prone to error regardless of skill level, and that the system must guard against adverse events by mitigating human error to be as low as reasonably possible. For this approach, a system is strengthened by implementing defenses at various levels (e.g., individual, organizational, etc.). Reason's Swiss Cheese Model (1990) provides an excellent depiction of how "holes" in system defenses usually lead to small incidents or failures at each defense level, which can aggregate to form a catastrophic loss within the system (Figure 2.1). This catastrophic loss occurs because each of the holes or failures aligned at every level magnifying the severity of the loss downstream. To decrease the probability of a loss, the systems approach seeks to minimize these "holes" by strengthening the system's defenses.

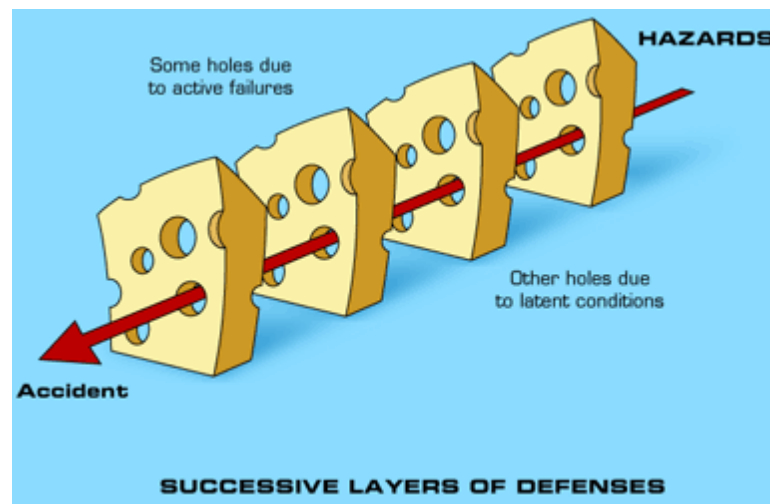


Figure 2.1: Accident Path in the Swiss Cheese Model (Reason, 1990)

For minimally invasive surgery, Dankelman and Grimbergen (2005) identified the following five strategies to reduce errors using the systems approach: 1) reduce

complexity, 2) standardize procedures, 3) implement checklists, 4) improve the quality and standardization of instruments and equipment and 5) training. Each of the five strategies could be targeted at one or more levels portrayed in the hierarchical model of the interacting elements in a surgical system (Figure 2.2). Within this “onion model” of a surgical system, surgeon-instrument interaction could be improved by reducing complexity, standardizing procedures, and improving the quality and standardization of instruments and equipment. Implementing these five strategies would enable the surgeon at the “sharp end” and the overall system to perform at a higher level by eliminating unnecessary and inefficient interactions and processes (Flin, 2008).



Figure 2.2: Surgical System Onion Model (Dankelman & Grimbergen, 2005)

In order to create a more resilient surgical system, errors or near-misses must be identified, studied and mitigated. From the analysis of errors and near misses, such as root cause analysis (RCA) for current systems or healthcare failure mode and effects analysis (HFMEA) for proposed systems, it is critical to identify the weak points or potential hazards in the system and intervene at one or more levels to reduce their risk.

One systems-based method to accomplish this is to create forcing functions, which are purposely designed system elements that make it difficult or impossible for humans to do the incorrect action and actually facilitate performance of the correct action. Although automation is one method to accomplish this, there are inherent problems with automation, and in health care the goal is to maintain as much flexibility and adaptability as possible while minimizing technological complexity. As a result, surgical care requires a unique mix of human and technology-based operations that systematically design safety and error prevention into every system level.

This more robust and error-resistant system will strengthen each defensive level, so that if a failure occurs at one level, the next defensive level will “catch” or mitigate the failure from becoming a more severe error, accident or sentinel event downstream (Figure 2.3). Overall, the systems-based approach can significantly reduce the number of preventable human errors in surgery, if errors and their causes are thoroughly studied and the overall system is strengthened through error-prevention strategies at multiple levels, including good systems design/redesign using HFE principles and practices.

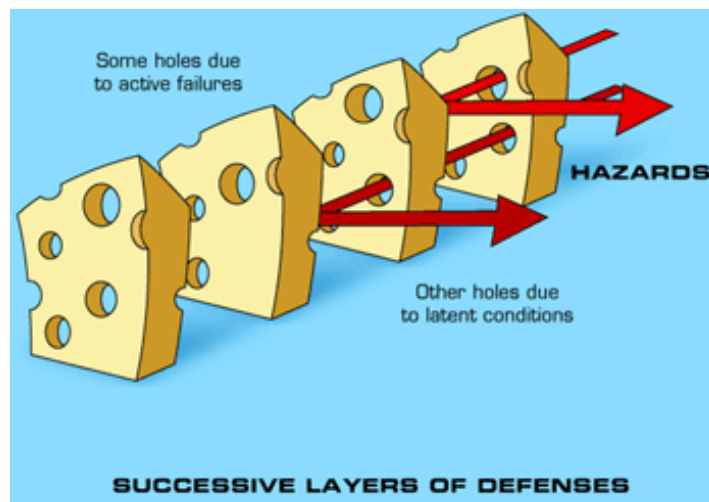


Figure 2.3: Accident Mitigation in the Swiss Cheese Model (Reason, 1990)

### **2.3.2 Variability**

One of the main precepts from the Gilbreths' work was standardization and best practices. The opposite of this is the study of variability among practitioners.

“Traditionally, surgery has been taught by an apprentice model, where the learner imitates the actions of a skilled mentor” (Walter, 2006). Although this model has been effective, it leads to great variation within surgical practice because training and assessment are based heavily upon the mentors' individual abilities of the task, teaching/mentoring and their subjective assessment of the trainee; the antithesis of the Gilbreth's model. The traditional apprentice model is also time inefficient for both the trainee and mentor, because it requires residents to be “exposed to a large number of surgeries performed by a limited number of dedicated teaching faculty” (Walter, 2006).

Surgeons have long understood the need to hone and refine their skills for optimal performance. The rigor of surgical training fundamentally pursues micro-level (individual) optimization and perfection by minimizing errors and variability. However, the proficiency-gain curve, sometimes referred to as the learning curve, is individualized and varies for each surgical procedure (Figure 2.4; Cuschieri & Tang, 2010). It therefore requires a significant amount of time, effort, money and individualized training to reach proficiency using the apprentice model. During residency, each surgical trainee is assessed on his/her proficiency to demonstrate that he/she has the necessary skills and competencies to execute high quality and safe operative procedures. This internal quality assurance program ensures that residents can cope with the demands of surgery and execute at an acceptable level of care. Although surgical proficiency underpins quality and safe surgical practice (Cuschieri, 2005), the inherent variability in surgical skill

acquisition time, new resident duty-hour restrictions, and patient safety concerns call for a change in the fundamental way in which we train and assess surgeons (Buschemeyer et al., 2005; Herring & Hallbeck, 2009; Schneider et al., 2007; Trejo et al., 2007).

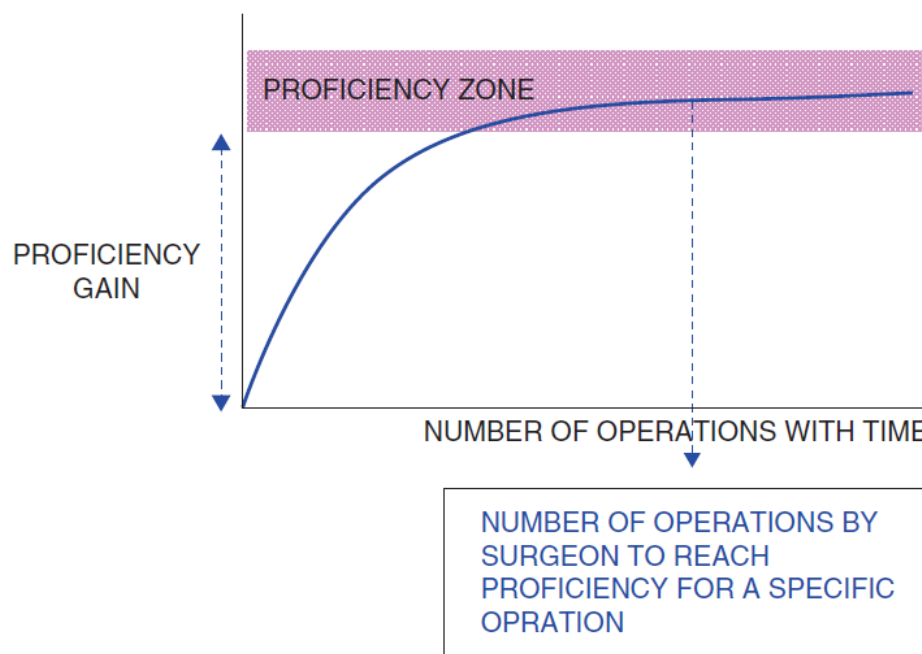


Figure 2.4: A Surgeon's Idealized Proficiency-gain Curve (Cuschieri & Tang, 2010)

Returning to the Gilbreth's precepts for standardization and best practice, it is evident that it contrasts the apprentice model, which inherently generates variability. However, the process of standardizing surgical training and assessment is complex and reducing variability is not as straightforward as minimizing product variation on a manufacturing line. Humans (clinicians and patients) are complex systems unto themselves. The physical, physiological, psychological (affective and cognitive), and social aspects of humans and the variability of human performance make standardization and optimization within the system difficult. Additionally, different levels within the system may or may not benefit from the same strategies. At the micro-level (e.g., humans using tools or performing single tasks), surgeons may benefit from standardized surgical

instrumentation, but this strategy may not enhance human performance at the meso-level (e.g., humans as part of technical processes or organizations) or macro-level (e.g., humans as part of networks of organizations, regions, countries, or the world) (Dul et al., 2012). Accordingly, it is imperative take a holistic, integrative and tailored approach to improve performance and decrease variability among the interacting and interdependent elements throughout a system, to the extent possible. Lastly, determining the appropriate processes to study and how to reduce their variability are important aspects to consider.

### ***2.3.3 HFE and Variability***

All types of work can be considered a process, and processes are the main source of defects or errors due to performance variability (Aft, 1998). Accordingly, understanding and minimizing variability in key processes are critical to improving the quality of the health care system. As defined in Chapter 1, health care quality is safe, effective, timely, patient-centered, efficient and equitable care (NAE and IOM, 2005). For engineers, quality is a broad term that encompasses quality assurance, quality control and quality management. Dr. Joseph M. Juran, the “Father of Quality,” helped define the modern quality movement, and was the first to incorporate human aspects into quality management (Aft, 1998). Juran’s definition of quality was “fitness for intended use,” which can be translated into meeting or exceeding customer expectations (Aft, 1998). Per the International Organization for Standardization (ISO) the currently accepted definition of quality is “the degree to which a set of inherent characteristics fulfills requirements” (ISO 9000:2000). Other agencies within health care have begun to recognize the similarities between the quality efforts within industrial sectors and health care. For instance, the Institute for Healthcare Improvement (IHI) has defined quality as

“turning into outcomes management, and involves minimizing unnecessary variation so that outcomes become more predictable and certain” (2012). Regardless of definition of, it is widely accepted that “variation is the enemy of quality” (Petersen, 1999). Reducing or eliminating variability within systems is the ultimate goal of all quality efforts, because it increases performance and well-being. The strikingly similar approaches to reduce variability and improve outcomes elegantly bridge the gap between the quality efforts in industrial and health care settings.

In all, HFE system-based approaches can assist in the improvement of health care quality through the reduction of variability since HFE principles and techniques are goal-oriented and purposefully design systems around humans and their environment (Dul et al., 2012). This hierarchical approach of fitting humans within the system by focusing on the interactions within their physical, organizational and social environments enables humans better able to contribute to performance (Dul et al., 2012).

## **2.4 Research Metrics**

These HFE design and redesign principles were used to craft the systems-based approach for the evaluation of performance and well-being towards the improvement of the quality and safety of minimally invasive surgery (Figure 2.5). As key elements within performance and well-being, quality and safety were chosen as the primary outcome measures for this research. In addition, the national focus on these two measures makes this work applicable to other health care settings. In order to quantify these outcome measures, multidisciplinary development and evaluation methods were used to analyze laparoscopic surgery at the micro- and meso-levels. These levels correspond to the three inner layers of the surgical system model (Figure 2.3), and include the surgeon, surgeon-



instrument interaction, and interaction between operating room staff and between the staff and technology (Dankelman and Grimbergen, 2005).

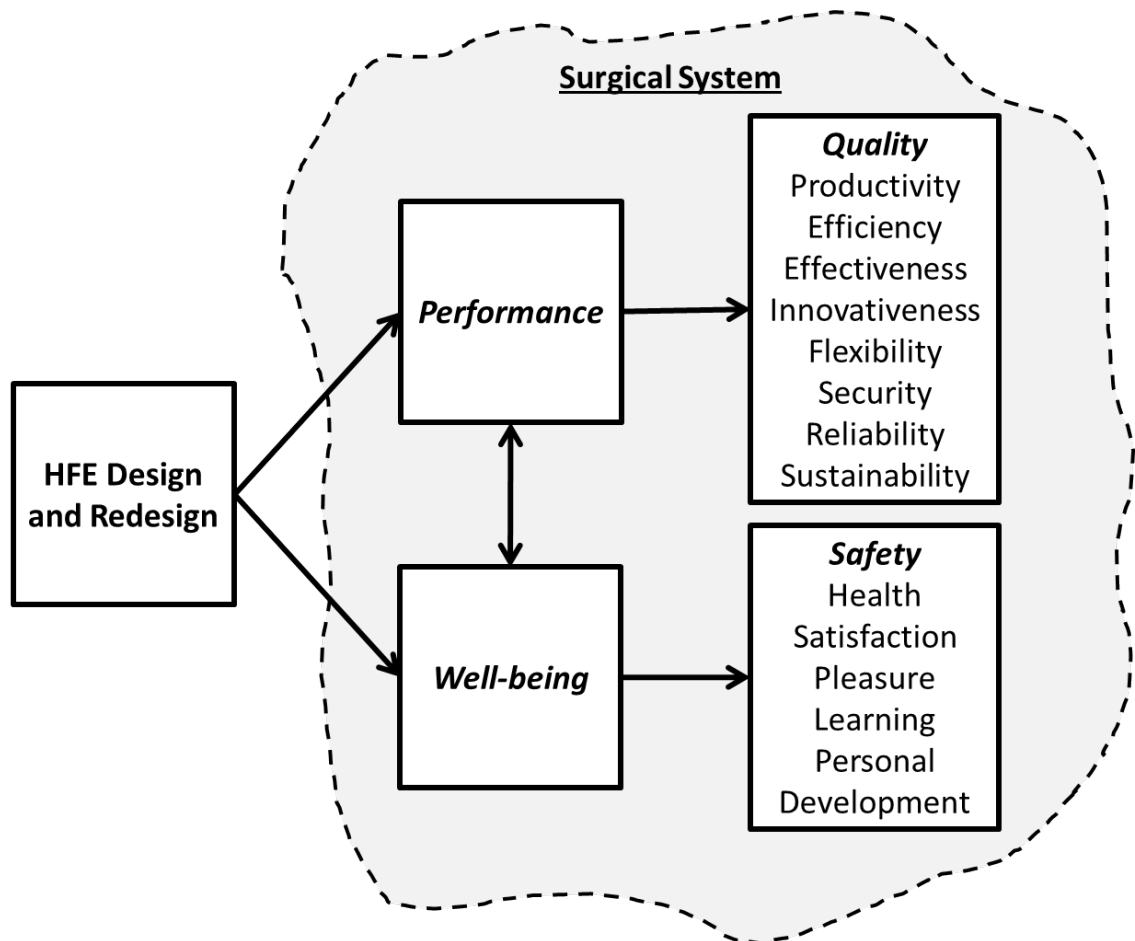


Figure 2.5: Effect of HFE Design and Redesign on Performance and Well-being in a Surgical System (adapted from Dul et al., 2012)

First, ethnographic research was conducted to understand the environment, requirements, usage and limitations in order to develop and assess laparoscopic surgery technologies and processes. In the first experiment, human-centered design principles were used to develop a novel laparoscopic grasper tool with integrated electro-surgical hand controls. Redesigning the electro-surgical controls to be hand operated in lieu of foot pedals created a more efficient, intuitive and safe surgical interface for the surgeon and

surgical staff. The novel laparoscopic instrument was evaluated using standardized laparoscopic surgical tasks in a simulator. Quality and safety were assessed using proficiency metrics (i.e., task completion time), workload (i.e., actuation force and forearm muscle activation) and subjective ratings (i.e., overall preference).

A similar approach was used in the final three experiments to formally compare LESS and conventional laparoscopic surgery using a standardized laparoscopic surgical task. For these experiments, a novel simulation test-bed was created to assess the quality and safety of LESS technologies and the performance of surgical trainees. Test-beds within the surgical domain include inanimate pelvi-trainers, virtual reality simulators and animal models. Although many of these test-beds aim to improve the technical skills and abilities of surgical trainees, the overall purpose is evaluation of the operator, device or system. A test-bed is an ideal stage to critically evaluate processes and technologies under simulated and standardized conditions, because it enables safe, transparent and replicable experimental testing conditions. Since test-beds use standardized surgical tasks and testing conditions they also enable trainees to quantify their proficiency-gain curve and reduce skill acquisition time in the operating room while protecting patients from undue harm (Keyser et al., 2000; Lekawa et al., 1995; Fransen et al., 2011).

For these experiments, the simulation test-bed was redesigned to include engineering-based elements, which allow for a more robust and quantitative evaluation. Quality and safety were assessed using proficiency metrics (i.e., task completion time, errors and task success), workload (i.e. upper limb discomfort and kinematics) and subjective ratings (i.e., ease of use, instrument maneuverability, task difficulty and overall preference).

Since similar quality efforts can be used to improve health care delivery, both quality and one of its primary dimensions, safety, formed the foundational basis for the design, analysis and improvement of minimally invasive surgery processes. In general, this chapter presented a generalized perspective on the impact of the design and redesign of surgical technologies and processes on human performance and well-being. The experimental work in the following chapters was built upon these design principles to craft a novel, multidisciplinary, systems-based approach, which was used to develop and evaluate laparoscopic surgery instrumentation, practices and procedures towards the quality and safety improvement of minimally invasive surgery.

## CHAPTER 3

### Assessment of Electrosurgical Hand Controls

#### Integrated into a Laparoscopic Grasper

**Citation:** Brown-Clerk, B., Rousek, J. B., Lowndes, B. R., Eikhout, S. M., Balogh, B. J. and Hallbeck, M. S. (2011). Assessment of electrosurgical hand controls integrated into a laparoscopic grasper. *Minimally Invasive Therapy and Allied Technologies*, 20(6), 321-8.

#### 3.1 Executive Summary

The aim of this study was to quantitatively and qualitatively determine the optimal ergonomic placement of novel electrosurgical hand controls integrated into a standard laparoscopic grasper to optimize functionality. This device will allow laparoscopic surgeons to hand-operate standard electrosurgical equipment, eliminating the use of electrosurgical foot pedals, which are prone to activation errors and cause uncomfortable body positions for the physician. Three hand control designs were evaluated by 26 participants during the performance of four basic inanimate laparoscopic electrosurgical tasks. Task completion time, actuation force, forearm electromyography (EMG) and user preference were evaluated for each hand control design. Task speed was controlled using a metronome to minimize subject variability, and resulted in no significant completion time differences between task types ( $P > 0.05$ ). Hand control design 1 (CD 1) resulted in the ability to generate significantly greater actuation force for three of the four tasks ( $P < 0.05$ ) with minimal forearm muscle activation. Additionally, CD 1 was rated significantly better for comfort and ease-of-use compared to the other two hand control

designs ( $P < 0.05$ ). As a result, CD 1 was determined to be an advantageous ergonomic design for the novel electrosurgical hand controls.

**Keywords:** laparoscopy, ergonomics, foot pedals, electrosurgery, instrument design

## **3.2 Introduction**

During laparoscopic surgery, surgeons must adopt awkward postures in order to operate handheld instruments, view the monitor, and concurrently depress foot pedals (Mallet, 2001; Stassen et al., 2001). Due to this poor ergonomic environment, various syndromes such as overuse syndrome and surgical fatigue syndrome have become increasingly common among laparoscopic surgeons (Park, 2010; Reyes et al., 2006). Consequently, it is imperative to ergonomically assess and redesign current laparoscopic instrumentation to mitigate surgery-related discomfort and injuries.

Inherently foot pedals create several disadvantages, such as added concentration to operate three limbs, postural instability and discomfort, and operation errors from the lack of direct visual contact with the pedal (Allaf et al., 2008; Kranenburg and Gossot, 2004; Patkin, 2003; van Veelen et al., 2003a; Wauben et al., 2006). Typically laparoscopic surgeons utilize one or more foot pedals on the floor to operate electrosurgical and ultrasonic equipment. Each foot pedal consists of two identical switches that are used to operate the cauterization (cutting) and coagulation functions. The foot pedal is positioned near the foot of the operating table covered by sterile sheets. The surgeon must locate the obstructed pedal and concurrently depress the desired pedal until the electrosurgical function is no longer needed. This can result in an extended period of time of foot flexion and weight bearing on one side of the body. In an effort to

maintain physical contact with the pedal, many surgeons even alter their posture by continually flexing their foot above the pedal, and loading their entire bodyweight on the opposite foot. This physically demanding posture is exacerbated during precise movements, such as electrosurgical tasks, due to the need to continually watch the surgical monitor and operate the foot pedals concurrently. In a recent study, 91% of surgeons occasionally lost contact with the foot pedal, 75% hit the wrong switch, and 53% experienced physical discomfort in their legs and/or feet (van Veelen et al., 2003b). Lastly, 93% of the surgeons would like to control electrosurgery in a different way, with 75% preferring hand controls (van Veelen et al., 2003b). As a result, the unstable and extreme posture required to operate surgical foot pedals can lead to physical discomfort, fatigue and surgical errors.

Only a few studies have quantitatively evaluated surgical foot pedals used in laparoscopy (Allaf et al., 2008; van Veelen et al., 2003b), and only one study (van Veelen et al., 2004) has ergonomically redesigned the foot pedal. Several studies have commented on not only the need for the redesign of surgical foot pedals but also the surgeon's preference for alternative controls (Mallett, 2001; Kranenburg and Gossot, 2004; Wauben et al., 2006). No studies were found that focused on different control methodologies such as hand controls.

Since laparoscopic surgeons face adverse health consequences due to the lack of ergonomic assessment and end-user design of surgical instrumentation (Allaf et al., 1998; Park et al., 2010; Patkin, 2003; Reyes et al., 2006), this study sought to improve the physical aspects of laparoscopy by developing a novel device that will reduce the physical discomfort and potential for errors associated with the operation of

electrosurgical foot pedals. In close collaboration with laparoscopic surgeons, three distinct hand control designs were created and integrated into a standard laparoscopic grasper in order to eliminate the use of electrosurgical foot pedals, optimize functionality, reduce surgery-related musculoskeletal discomfort and minimize the risk of actuation errors.

### 3.3 Materials and Methods

#### 3.3.1 Participants

Due to the novel nature of the design and the time constraints of resident and attending laparoscopic surgeons, twenty-six (14 females and 12 males) novice participants (i.e., undergraduate and graduate students) without formal medical or surgical training were recruited from the local community to participate in this study. All participants were right-hand dominant and free of any musculoskeletal problems within the last year. The participants' mean (standard deviation) characteristic information is shown in Table 3.1 below.

Table 3.1: Participant Characteristic Information -- Mean (Standard Deviation)

	Age (years)	Height (cm)	Weight (kg)
Male	25.3 (3.5)	179 (9.1)	76.7 (11.4)
Female	25.6 (5.9)	167 (5.4)	62.3 (9.0)
Overall	25.4 (4.9)	173 (9.4)	68.9 (12.3)

#### 3.3.2 Apparatus

A standard 5 mm laparoscopic grasper (EndoDissect, AutoSuture, Mansfield, MA, USA) was utilized in this study. Three sets of hand control designs were integrated into the

grasper (Figure 3.1). Each hand control design included a simulated cutting (CUT - yellow) and coagulation (COAG - blue) hand operated membrane switch. Both the palm grip (i.e., thumb outside the ring with the palm resting on the thumb ring) and standard pistol grip (i.e., thumb-in-ring) were utilized in this study, because many laparoscopic surgeons use the palm grip for sustained grasping tasks (Berguer, 1998; Berguer et al., 1999b; Hemal et al., 2001). As shown in Figure 3.1(a), control design (CD) 1 was mounted so that the participant utilized the palm grip and depressed one of the pair of push buttons (i.e. CUT or COAG) with digit 1 (thumb). CD 2 and CD 3 were mounted on the right side of the grasper handle so that the participant utilized the pistol grip and depressed one of the pair of push buttons with digit 2 (index finger, Figures 3.1(b) and 3.1(c). Due to limited surface area on the grasper, CD 2 and CD 3 utilized the same CUT push button.



Figure 3.1: Novel electro-surgical controls designs integrated into a standard laparoscopic grasper (a) CD 1 (b) CD 2 (c) CD 3

### 3.3.3 Simulated Laparoscopic Electrosurgical Tasks

In order to simulate laparoscopic surgical conditions, a clear, plastic, human torso laparoscopic trainer was used to perform the basic, inanimate laparoscopic electro-surgical tasks. The laparoscopic trainer was similar to an insufflated abdomen



(33.0 cm in length, and 25.4 cm wide across the midsection). The trainer included three trocar ports, of which, only the center port was used (Figure 3.2(a)). The inanimate laparoscopic electro-surgical tasks were adapted from the Fundamentals of Laparoscopic Surgery (FLS) program, which was initially developed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in the early 1990s (Peters et al., 2004). The FLS program focuses on basic laparoscopic skill development through hands-on manual skills practice and training. In this case, the laparoscopic electro-surgical tasks were created based on the standardized FLS task 1, peg transfer, using the LapTrainer Skills Set #1 pegboard task (Simulab Corp., Seattle, WA, USA). The peg transfer task was modified to incorporate electro-surgery, which requires the continuous application of current for cauterization or coagulation of tissue at particular points and along specific paths. Based on this concept, two distinct laparoscopic electro-surgical tasks were created that incorporated start, stop and way points for push button actuation. These basic laparoscopic electro-surgical tasks are well-suited for novice users and ergonomic task assessment.

A metronome (Franz, model XB-700) was used to minimize inter- and intra-subject variability for task completion time. Each participant was required to maneuver the laparoscopic grasper's end-effector in time with the metronome (26 beats per minute), so that at each auditory signal the end-effector was at the predetermined position. Tasks 1 and 2 were meant to familiarize the novice participant with the laparoscopic trainer, grasper, and hand control designs. Task 1 required the participant to continuously actuate the CUT push button and trace the square path (25.4 cm perimeter) in time with the auditory beeps of the metronome (Figure 3.2(b)). The participant then

repeated task 1 while continuously actuating the COAG button and tracing the square path. Task 2 required the participant to trace the same square path and actuate the CUT button only at the start point, way points and stop point in time with the metronome. Task 2 was also repeated using the COAG button. Each participant completed the simpler tasks (i.e. tasks 1 and 2) prior to completing tasks 3 and 4.

Tasks 3 and 4 were meant to simulate a more complex and realistic situation, in which, a particular section of tissue or entire organ is removed (Figure 3.2(c)). Task 3 required the participant to continuously actuate each button separately tracing the outer edge of the simulated stomach (54.6 cm perimeter). Task 4 required the participant to trace the outer edge of the stomach and actuate each button separately only at the start point, way point and stop point. To add a degree of difficulty to tasks 3 and 4, each participant was instructed to perform these tasks at the same relative speed as task 1 and 2 without the use of the metronome.

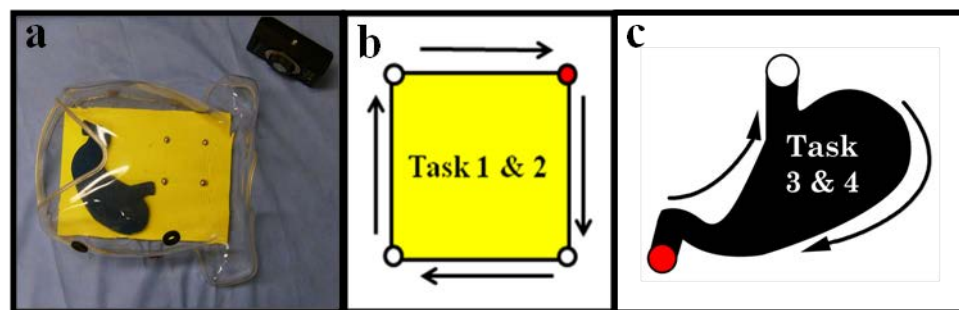


Figure 3.2: (a) Experimental set-up with laparoscopic trainer and metronome (b) Laparoscopic electrosurgical tasks 1 and 2 (c) Laparoscopic electrosurgical tasks 3 and 4 -- red indicates the start/stop point and white indicates way point(s)

### 3.3.4 Procedure

The experimental procedures were explained to each participant prior to the conduct of the study, and all participants provided signed informed consent. Each participant was

instructed to stand in front of the laparoscopic trainer during which time the trocar height was adjusted to the participant's standing elbow height. Prior to testing, each task was demonstrated to the participant, and was followed by a brief hands-on familiarization period of five minutes. Each participant donned hypo-allergenic (Kimberly-Clark SAFESKIN purple nitrile powder-free) surgical/exam gloves in a self-selected size prior to the experiment. The participants were instructed to actuate the push buttons with digit 1 (thumb) using the palm grip for CD 1, and digit 2 (index finger) using the pistol grip for CD 2 and CD 3. The investigators explained which task, control design and grip was to be used prior to each trial. The participants were also instructed to complete each trial as accurately as possible. One trial set consisted of the completion of tasks 1 through 4 using only one control design, which was a total of three completed trial sets per participant. Control designs were randomized for the participants; however, each participant performed tasks 1 through 4 sequentially due to the increasing level of difficulty. After completion of the four tasks using the specified control design, the participants received a three minute rest period, in which they were seated and completed a questionnaire. At the conclusion of the experiment, each participant reported their overall preferred control design to the investigator.

Two force sensing resistors (FSR, Flexiforce, Tekscan, Boston, MA, USA) were mounted under the repositionable membrane switches to sense the force each participant used to actuate the control design. FSR measurements were recorded using the DataLINK (Model DLK900, Biometrics Ltd, Gwent, UK) system with software version 7.0, a channel sensitivity of 1 mV, and a sampling rate of 10/sec.

In order to compare the muscular activity of each task and control design, forearm muscle activity was monitored using surface electromyography (EMG). The activity of flexor digitorum superficialis (FDS) and extensor digitorum superficialis (EDS) were monitored using the DataLINK system with software version 7.0, a channel sensitivity of 1 V, and a sampling rate of 1,000/sec. Using double-sided adhesive tape, each surface electrode was applied along the midline of the muscle on the participants' right forearm in accordance with the recommendations of Zipp (1998). A ground reference cable was positioned on the left forearm and adjusted to fit securely using the elasticized band. Three maximal voluntary contractions (MVCs) were recorded for each participant prior to testing. A Root-Mean-Square (RMS) filter was applied to each EMG waveform using the Biometrics software. Using the average of the three MVC peak RMS values, each participant's mean RMS value was normalized into relative muscular activity (i.e. % of MVC). Lastly, task completion time was extracted for each trial using the DataLINK system.

One questionnaire with two parts was used to assess the comfort and usability of each control design. One copy of the questionnaire was administered to each participant after the completion of each trial set. A verbally anchored 6-point Likert scale (1- Strongly Disagree, 2- Disagree, 3-Slightly Disagree, 4- Slightly Agree, 5- Agree and 6- Strongly Agree) was used to assess the impression of each control design based on six given statements. Part two of the questionnaire required the participant to subjectively rate their hand comfort/discomfort of digits 1 through 5 and their palm. A similar verbally anchored 6-point Likert scale (1-Very Uncomfortable, 2-Uncomfortable, 3-Slightly Uncomfortable, 4-Slightly Comfortable, 5- Comfortable and 6-Very

Comfortable) was used to assess the comfort/discomfort of each hand region. The questionnaire was adapted from the ISO 9241-0:2000(E) standard for assessment of comfort, in order to subjectively compare the physical ergonomics of each control design. Lastly, after all three of the control designs were evaluated each participant stated which CD was preferred overall.

### ***3.3.5 Experimental Design***

A full-factorial analysis of variance (ANOVA) with blocking on subjects was performed for the dependent variables of task completion time, mean actuation force and relative muscular activity using SAS (V 9.2, SAS Institute Inc., Cary, North Carolina, USA) at the 0.05 level of significance. The independent variables were task (4 levels) and control design (3 levels). Based on the significant effects from the hypotheses tests using Type III error, a post-hoc Tukey test was performed for significant main effects, and simple-effect F-tests were performed on significant interactions. Friedman's F-tests were performed for the dependent variable statement rating for each questionnaire statement using SAS (V. 9.2) at the 0.05 level of significance. The independent variable was CD (3 levels).

## **3.4 Results**

### ***3.4.1 Task Completion Time***

Task speed was controlled using a metronome to minimize inter- and intra-subject variability, it was expected that there would be no significant task completion time differences between task 1 and 2 and between task 3 and 4. Accordingly, the only significant main effect for task completion time was task performed (Figure 3.3,  $p <$

0.0001). CD and the interaction effect of CD and task were not significant ( $p > 0.05$ ).

Based on the post-hoc tests, there were no significant differences between tasks 1 and 2 and between task 3 and 4 nor were there differences between CD within tasks 1 and 2 or within tasks 3 and 4. As expected, the more complex tasks, 3 and 4, required significantly greater completion time compared to the simpler tasks, 1 and 2.

Interestingly, the metronome was able to limit task completion time variability for both sets of tasks; tasks 1 and 2 for which the metronome was used, and also for tasks 3 and 4 for which the metronome was not used. Overall, task completion time variability was minimized in order to standardize the task so as to more accurately assess the user's CD actuation forces and muscular activation.

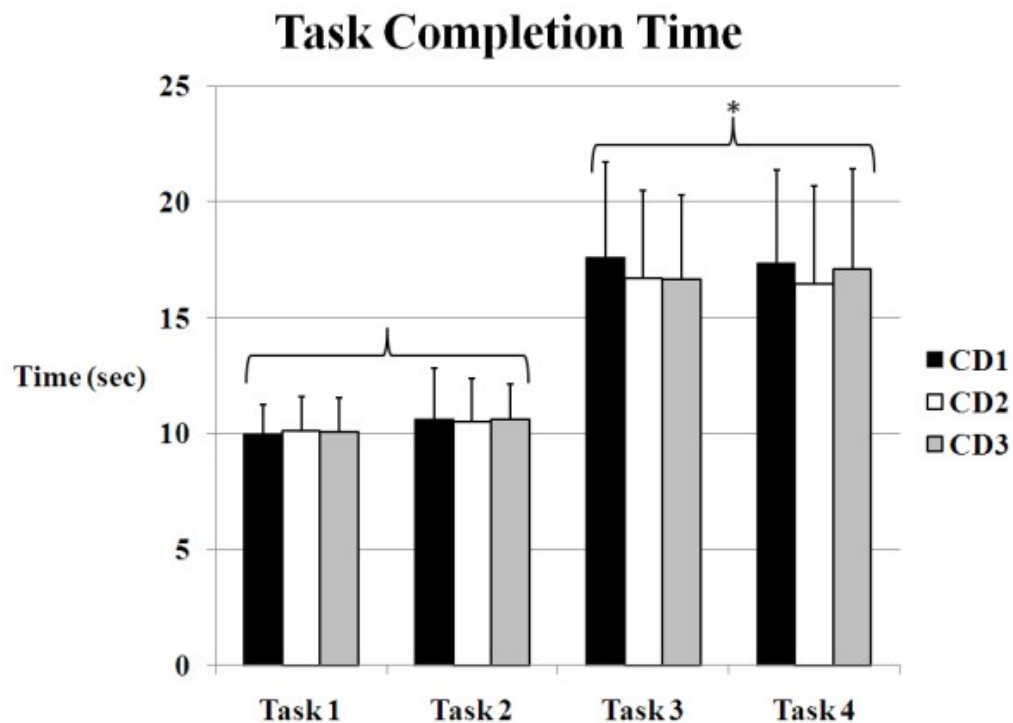


Figure 3.3: Interaction of control design and task completion time

### 3.4.2 Actuation Force

The significant main effects for mean actuation force were task performed ( $p < 0.0001$ ) and CD ( $p < 0.0001$ ). The interaction of effect of task and CD was not significant ( $P > 0.05$ ). Based on the post-hoc tests, task 2 and 4 had significantly greater actuation force compared to task 1 and 3 (Figure 3.4,  $p < 0.0001$ ). These results indicate that tasks 2 and 4, intermittent actuation, had significantly more actuation force compared to tasks 1 and 3. It was observed that the participants had a tendency to depress with greater force during the intermittent actuation tasks compared to the continuous actuation tasks. However, the effects of fatigue were not evaluated in this study and cannot be ruled out as a possibility. Based on the simple-effect F-tests, CD 1 had significantly greater actuation force than CD 2 and CD 3 for tasks 1, 3, and 4 ( $p = 0.004, 0.001, 0.001$ , respectively). In general, these results indicate that each participant was able to generate a greater amount of force utilizing CD 1.

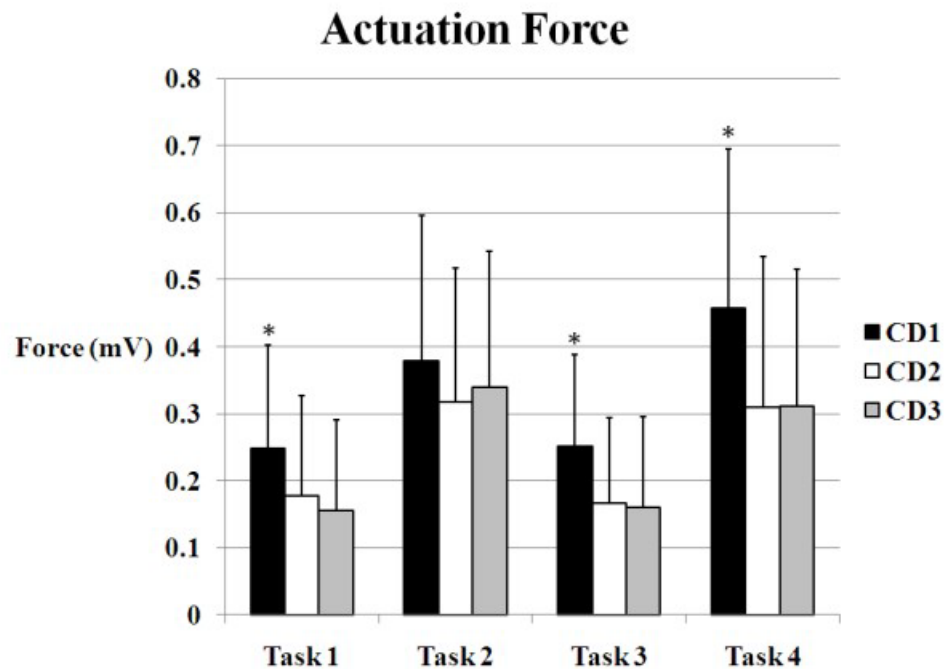


Figure 3.4: Interaction of control design and actuation force

### 3.4.3 Electromyography

The significant main effect for mean EDS activation was task performed ( $p < 0.0001$ ), but CD and the interaction effect of task performed and CD were not significant ( $p > 0.05$ ). Based on the post-hoc tests, task 4 had significantly less EDS activation compared to the other tasks (Figure 3.5,  $p < 0.01$ ). Additionally there were no significant differences between control designs for each task ( $p > 0.05$ ). These results indicate that there may have been a learning effect since the tasks were completed sequentially, or a fatigue effect with lower mean activation. Additionally, FDS showed activation levels at and below 5% of MVC for all tasks and control designs. Based on the effects of noise and subject variability, FDS was excluded from further analysis. Overall, the tasks did not require significant forearm muscle activation most likely due to the simplified electrosurgical tasks. Future studies will need to incorporate more realistic tasks and other muscle groups in order to further validate the device.

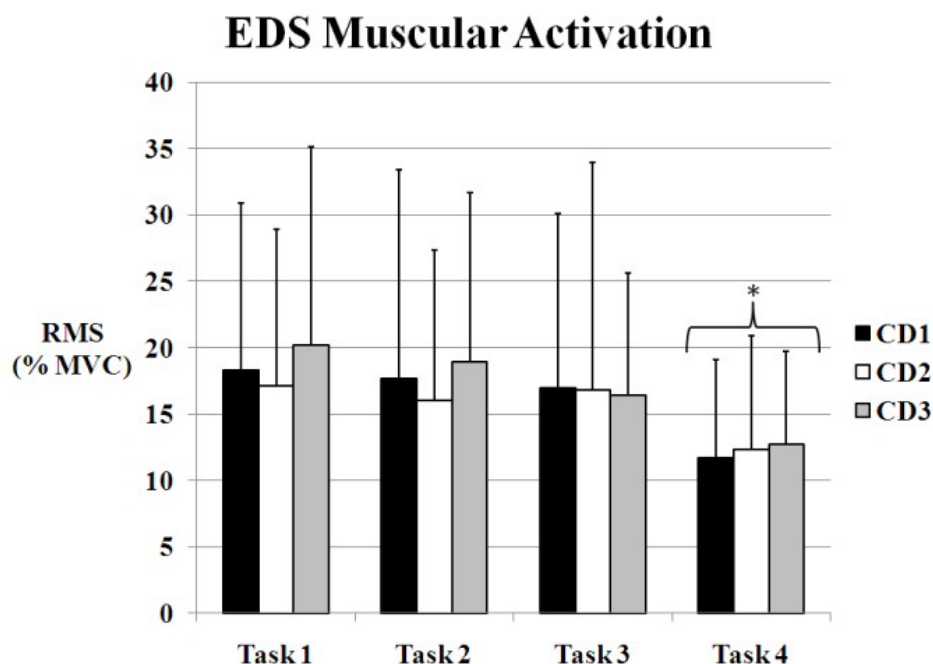


Figure 3.5: Interaction of control design and forearm extensor muscle activation



### 3.4.4 Subjective Assessments

The median statement rating was significantly different between control designs for all statements (Table 3.2,  $p < 0.05$ ) for part 1 of the questionnaire. Participants were more likely to agree that CD 1 was easy to reach, had a comfortable hand position, fit their hand well, and that overall it was easy to use. Participants were also more likely to disagree that CD 1 caused discomfort to their hand. These results indicate that CD 1 was favored compared to CD 2 and CD 3 based on the six given statements.

Table 3.2: Questionnaire Part 1 Statement Ratings -- Median (Interquartile Range)

Statement	CD 1	CD 2	CD 3	P-value
Tasks were easy to complete	5.0 (1.00)	3.0 (1.50)	3.0 (3.00)	< 0.001
CD was easy to reach	5.0 (2.00)	3.5 (3.00)	3.0 (3.00)	<0.001
Hand position was comfortable	4.0 (3.25)	3.0 (2.00)	3.0 (2.00)	0.003
CD caused discomfort to my hand	3.0 (2.25)	4.0 (1.00)	4.0 (1.00)	0.001
CD fit my hand well	4.0 (2.00)	3.0 (2.00)	3.0 (2.00)	0.003
Overall the CD was easy to use	5.0 (1.25)	3.0 (2.00)	3.0 (2.25)	<0.001

Note: 1-Strongly Disagree, 2-Disagree, 3-Slightly Disagree, 4-Slightly Agree, 5-Agree, 6-Strongly Agree

The median statement rating was significantly different between control designs for digit 1 (thumb), digit 2 (index finger) and the palm (Table 3.3,  $p < 0.05$ ) for part 2 of the questionnaire. Accordingly, participants were more likely to rate CD 1 as comfortable (median = 5.0) in comparison to CD 2 and CD 3. Lastly, each participant was verbally surveyed at the end of the experiment for the control design they preferred overall. Of the 26 participants, 23 preferred CD 1, two preferred CD 2, and one preferred CD 3.

Table 3.3: Questionnaire Part 2 Hand Comfort Ratings -- Median (Interquartile Range)

Region	CD 1	CD 2	CD 3	P-value
Digit 1	5.0 (2.00)	2.5 (3.00)	2.0 (1.00)	< 0.001
Digit 2	5.0 (2.25)	3.0 (3.00)	3.0 (3.00)	0.002
Digit 3	5.0 (3.00)	4.5 (2.00)	4.5 (2.25)	0.1790
Digit 4	5.0 (2.25)	5.0 (1.50)	5.0 (2.00)	0.8135
Digit 5	5.0 (3.00)	5.0 (1.00)	5.0 (2.25)	0.293
Palm	5.0 (2.00)	3.5 (3.00)	4.0 (2.25)	0.0076

Note: 1-Very Uncomfortable, 2-Uncomfortable, 3-Slightly Uncomfortable, 4-Slightly Comfortable, 5-Comfortable, 6- Very Comfortable

### 3.5 Discussion

The purpose of this study was to create an ergonomic device that was user-friendly, efficient and comfortable that allows laparoscopic surgeons to hand-operate standard electro-surgical equipment in lieu of foot pedals. The objective analyses indicate that CD 1 provided the ability to generate the greatest amount of force with minimal forearm exertion. The subjective analyses also indicate that CD 1 was preferred over the other control designs, because of its ease-of-use and comfortable hand position. Therefore, based on this initial product development study and ergonomic evaluation, CD 1 was found to be a better laparoscopic electro-surgical hand control design for a standard laparoscopic grasper compared to the other designs.

Current study limitations include the inclusion of only right-handed novices, the potential effects of fatigue and learning, and a lack of a direct comparison to surgical foot pedals. Additionally, CD 1 requires the surgeon to use the palm-grip instead of the standard pistol grip during hand-actuation. Further prototype refinement will need to be

completed in order to ensure a secure grip during actuation as well as the incorporation of a locking mechanism to mitigate accidental actuation. Future studies will include the development of a fully functional prototype and device evaluation with left- and right-handed users with varying surgical experience. Additionally, the device will need to be evaluated using actual laparoscopic electrosurgical tasks in a more realistic in vitro model and in vivo environment. This will ensure that the actuation forces and muscular activity exerted will mirror actual operating conditions. Lastly, throughout the device development and refinement process the prototype will undergo a thorough product evaluation focusing on user-centered design principles.

There is a current trend within the laparoscopic medical device community towards hand-actuated devices, including electrosurgical instrumentation. For example, the ENSEAL® (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio, USA) is a bipolar, temperature-controlled tissue sealing device. The device's power trigger is single-hand actuated and is positioned on the front handle grip directly under the rotation knob. The device can be used by both right- and left-handed surgeons, and includes a color-coded safety lock for the vessel cutting mechanism. However, at this time neither the ENSEAL® nor the next generation the ENSEAL® TRIO include a safety lock for the power trigger. This is a major safety concern, especially as electrosurgical devices move from single function to multifunctional in nature. As Cuschieri (2005) elucidated, the misuse of energized dissection has a long history within the operating room leading to countless procedural and execution errors. As electrosurgical devices become more complicated there is an even greater risk for technical and operative errors due to misunderstanding and misuse. In order to mitigate adverse outcomes with electrosurgical

equipment, medical device designers and human factors specialists must collaborate to ensure the safe operation of these novel devices for patient safety and the long term occupational health of surgeons (Park, 2010). In particular, this will require a thorough ergonomic evaluation prior to publication of industry wide standards and recommendations. As a result, the authors are taking the first step towards not only novel electrosurgical device development, but also towards ergonomic evaluation of hand-actuated laparoscopic electrosurgical devices.

## **CHAPTER 4**

# **Laparoendoscopic Single-site (LESS) Surgery Versus Conventional Laparoscopic Surgery: Comparison of Surgical Port Performance in a Surgical Simulator with Novices**

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### **4.1 Executive Summary**

While LESS surgery is feasible it poses many technical challenges not seen in conventional laparoscopy. Recent interest and widespread implementation of LESS stems from advancements in commercially available access port technology. Consequently, we objectively compared the technical performance between conventional laparoscopic and LESS surgical ports in a modified Fundamentals of Laparoscopic Surgery (FLS) simulator.

Twenty-four novice participants performed the FLS peg transfer task using two conventional laparoscopic 12-mm working ports, the SILS™ Port, the TriPort™ Access System and the GelPOINT™ System with two standard length 5-mm graspers. Each participant completed the task using conventional laparoscopy first for familiarization,

followed by each of the three LESS surgical ports in random order. Task completion time, errors and subjective questionnaire ratings were used to compare conventional laparoscopy and the single-port devices. Congruent with FLS scoring procedures, task completion time and errors were used to compute a standardized task score for each port.

There were no significant differences for task score between conventional laparoscopy and the single-port devices. Additionally, there were no task score differences between trials for either the SILS port or the GelPOINT system. There was a significant performance decrement starting with the TriPort as compared to starting with either the SILS port or the GelPOINT resulting in the lowest overall trial task score ( $p < 0.05$ ). Task completion difficulty and instrument maneuverability resulted in no significant differences between ports. Ease-of-use and overall rank were significant with conventional laparoscopy rated as the easiest to use and the highest overall followed by the GelPOINT System.

Overall, the TriPort may be more challenging for novices to learn LESS compared to both the SILS port and GelPOINT system; and, the GelPOINT system may offer the most consistent platform for LESS performance and novice skill acquisition.

**Keywords:** Single-port, Single-incision, SILS, Laparoscopy, Surgery, Simulation

## **4.2 Introduction**

### ***4.2.1 Laparoendoscopic Single-site Surgery (LESS)***

LESS is a feasible surgical technique performed using a single, small incision typically within the patient's umbilicus (Chouillard et al., 2010; Rivas et al., 2010; Romanelli et al., 2010; Saber et al., 2010; Saber and El-Ghazaly, 2009; Teixeira et al., 2010). Although

other surgical disciplines, such as gynecology, have been performing a variation of single-incision procedures since the early 1970's (Wheless and Thompson, 1973), the reemergence of LESS did not occur until the 1990's (Inoue et al., 1994; Navarra et al., 1997; Pelosi and Pelosi, 1992; Piskun and Rajpal, 1999). Interest in LESS and its widespread implementation in the past five years primarily stems from advancements in commercially available access port technology (e.g., single-port devices, multichannel single-access ports, multiple instrument access devices), yet its patient benefits are currently unproven. At present, the only recognized benefit of LESS compared to conventional laparoscopy is improved cosmesis (Lee et al., 2010; Raman et al., 2009; Tsimoyiannis et al., 2010; Vidal et al., 2010). Potential patient benefits include an increase in patient satisfaction and a decrease in postoperative pain and recovery time.

Moreover, LESS imposes several technical challenges for the surgeon not seen in conventional laparoscopy. Since all of the instrumentation is inserted through a single incision, the surgeon must contend with intracorporeal and extracorporeal instrument collisions, transposed instrument viewing (i.e., the surgeon's right instrument operates on the left side), loss of triangulation, and an in-line view of the instruments. Furthermore, current laparoscopic instrumentation was not designed specifically for LESS. As a result, many surgeons have adapted to this challenging operating environment through compensatory techniques to improve retraction (e.g., ancillary skin punctures with no formal skin incision) and the usage of specialized instrumentation to improve triangulation (e.g., bent, flexible and articulating instruments). LESS' universal acceptance and success hinges upon whether the safety, efficacy, efficiency and cost justify its use over conventional methods. Thus, the aim of this study was to objectively

compare conventional laparoscopic and LESS surgical ports, hypothesizing that LESS is more challenging and less efficient compared to conventional laparoscopy.

### 4.3 Materials and Methods

#### 4.3.1 Participants

Twenty-four healthy novice participants (12 males and 12 females) were recruited to participate in this study. The participants were medical students, undergraduate and graduate students from the local medical center who had no prior experience with laparoscopic surgery. Twenty-two participants were right-hand dominant and one male and one female were left hand-dominant. The participants' mean (standard deviation) demographic information is shown in Table 4.1.

Table 4.1: Participant Demographic Information -- Mean (Standard Deviation)

	Age (years)	Weight (kg)	Height (cm)
Male	24.3 (2.57)	81.9 (12.6)	178 (12.1)
Female	25.3 (5.79)	67.9 (18.1)	167 (8.71)
Overall	24.8 (4.41)	74.9 (16.9)	173 (11.7)

#### 4.3.2 Single-port Devices

The SILS™ port (Covidien, Mansfield, MA, USA) is a blue flexible soft-foam port, which conforms to the patient's abdominal wall to maintain pneumoperitoneum. The bottom half of the port is lubricated and inserted using an atraumatic clamp through a 20-mm incision. It includes three cannula access channels or lumens, which can accommodate three 5-mm cannulae or two 5-mm and one 12-mm cannulae. Cannulae heights can be staggered into multiple arrangements to meet specific procedural needs






and to facilitate instrument maneuverability. The SILS port is removed by pinching and pulling it upwards.

The TriPort™ Access System (Olympus America Inc., Center Valley, PA, USA) can accommodate up to three instruments (two 5-mm and one 12-mm low-profile lumens) through a single incision of 12 to 25-mm. Its distal ring is inserted via a specialized blunt introducer to minimize the risk of visceral trauma. Both the inner distal ring and outer proximal ring are flush with the patient's abdominal wall to maintain pneumoperitoneum. The retracting sleeve is used to adjust the distance between the two rings up to a maximum abdominal wall thickness of 100-mm. Each cannula lumen is sealed with a gel cap to maintain pneumoperitoneum. Instrument shafts must be lubricated to ease insertion through the lumen's gel valves, and larger instruments must also be twisted during insertion. Specimen removal is accomplished by removal of the cap on top of the proximal ring. Both the proximal and distal rings remain secure on the abdominal wall during this process. Firmly pulling the removal ring pulls the distal ring back through the incision and completes removal of the device.

The GelPOINT™ System (Applied Medical, Rancho Santa Margarita, CA, USA) consists of the Alexis wound retractor, GelSeal cap and 5-mm self-retaining trocars. Similar to the TriPort system, the Alexis wound retractor includes a distal and proximal ring that can accommodate a 1.5 to 7-cm incision and a wide-range of abdominal wall thicknesses. Both the TriPort and GelPOINT retraction systems offer wound protection and 360 degrees of atraumatic retraction. The GelSeal cap is a flexible self-healing gel that acts as a pseudo-abdominal platform for the trocars. Each 5-mm trocar may be positioned anywhere within the GelSeal cap, providing additional procedural and

instrumentation flexibility. Larger trocars, although not included in the package, can also be placed through the GelSeal cap as necessary. Specimen removal occurs by unlocking and removing the GelSeal cap from the proximal ring. Once the specimen is removed the device can then be removed by pulling upward on the distal ring's tether cord. These three commercially available single-port devices were chosen for this study because of their prevalent clinical usage. A brief summary of each device is presented in Table 4.2.

Table 4.2: Single-port Devices used in LESS Surgery<sup>a</sup>

	SILS™ Port	TriPort™ Access System	GelPOINT™ System
			
Incision Length	20-mm	12 to 25-mm	15 to 70-mm
Access Points	3	3	3 <sup>b</sup>
Access Point Size	5 to 12-mm	Two 5-mm & One 12-mm	5-mm
Abdominal Retraction	Passively conforms	Adjustable o-ring retraction system	Adjustable o-ring retraction system
Max Abdominal Wall Thickness	50-mm <sup>c</sup>	100-mm	180-mm <sup>d</sup>
Insertion Device	Péan clamp	Blunt Introducer	N/A
Lubrication	Aids device insertion	Instrument insertion	Aids device insertion

<sup>a</sup> Fader et al., 2010; GelPOINT Applied Medical, 2010; Irwin et al., 2010; LESS from Olympus, 2010; MacDonald et al., 2009; SILS Port, 2010

<sup>b</sup> limited by incision size only

<sup>c</sup> maximum height of port

<sup>d</sup> maximum length of retraction sleeve as measured between inner edges of o-rings

### **4.3.3 Fundamentals of Laparoscopic Surgery (FLS)**

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) developed the Fundamentals of Laparoscopic Surgery program (SAGES/ACS, FLS Program, Los Angeles, CA, USA) to encourage a standard set of basic skills in laparoscopy (Keyser et al., 2000; Peters et al., 2004; Ritter and Scott, 2007). The manual skills curriculum consists of five basic laparoscopic surgical tasks, which develop skills such as ambidexterity, depth perception, hand-eye coordination and controlled movement of instruments (Derossis et al., 1998; Fried et al., 1999). FLS task 1, peg transfer, was chosen to objectively assess the performance differences between LESS and conventional laparoscopy. This task is suitable for novice learners and requires the usage of both hands in a coordinated manner. Additionally, Santos et al. (2011) state that the peg transfer task effectively and efficiently allows the comparison of conventional laparoscopy and LESS.

The peg transfer task requires the trainee to grasp and transfer six small triangle shaped objects on a pegboard starting with the non-dominant hand and transferring midair to the dominant hand (Figure 4.1). Once the trainee has repositioned all six objects to the opposite side of the pegboard, the procedure is reversed where the object is grasped with the dominant hand and transferred to the non-dominant hand. The task was set-up in accordance with the FLS instructions with the pegs starting on the participant's non-dominant side for conventional laparoscopy. However due to LESS' transposed instrument viewing, the pegs were positioned on the opposite side of the pegboard for all of the single-port devices. Each participant still grasped each peg first with the non-

dominant hand transferring to the dominant hand, and then reversed the procedure to complete the task.

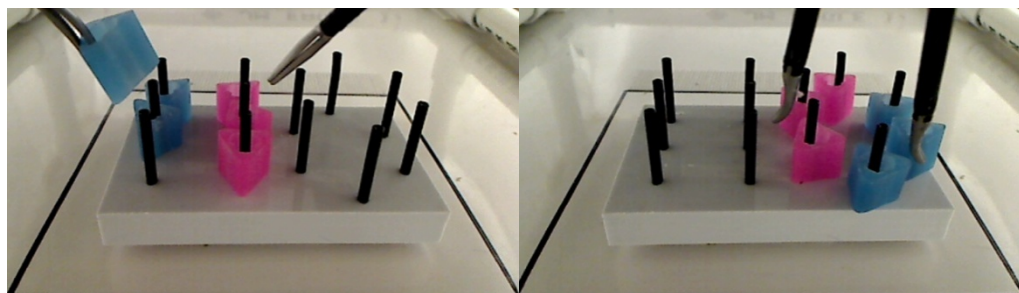


Figure 4.1: Peg Transfer Task -- Conventional Laparoscopy (left) and LESS (right)

Both speed and accuracy are considered important and are the basis for performance evaluation within FLS' manual skills curriculum (Fraser et al., 2003).

Accordingly, performance of the peg transfer task was objectively scored using both task completion time and errors. An error was defined as any peg that was unable to be transferred (i.e., dropped out of field of view). Due to the inclusion of novice participants and the increased complexity of LESS, the maximum cutoff time was set at 600 seconds.

An overall task score was computed using the following formulae:

$$\text{Time Score} = 600 \text{ seconds} - \text{actual task completion time} \quad (1)$$

$$\text{Error Score} = 25 \times \text{number of pegs not transferred} \quad (2)$$

$$\text{Task Score} = \text{Time Score} - \text{Error Score} \quad (3)$$

These formulae were adapted from the standard FLS scoring methodology, where higher scores reflect better overall performance. Overall, the FLS program's manual skills curriculum was utilized in this study to objectively compare conventional laparoscopy and LESS because of its validity and reliability.

#### **4.3.4 Apparatus**

The experimental set-up (Figure 4.2) consisted of a FLS manual skills trainer, FLS peg transfer task, standard monitor tower (OfficeKart 9802 T-20, Karl Storz, Tuttlingen, Germany) with widescreen LCD HD monitor (56-cm, ViewSonic, Walnut, CA, USA), and a stationary high-speed HD camera (Logitech Quickcam Pro 9000 web camera, Fremont, CA, USA). Two standard length non-locking 5-mm graspers (Auto Suture Endo Dissect, Covidien, Mansfield, MA, USA) were used throughout the study. The trainer was securely positioned on an adjustable height table in front of the monitor tower. The stationary HD camera displayed the task field through the monitor at an approximately 30 degree viewing angle. Both the trainer and monitor were placed in-line with the participant.

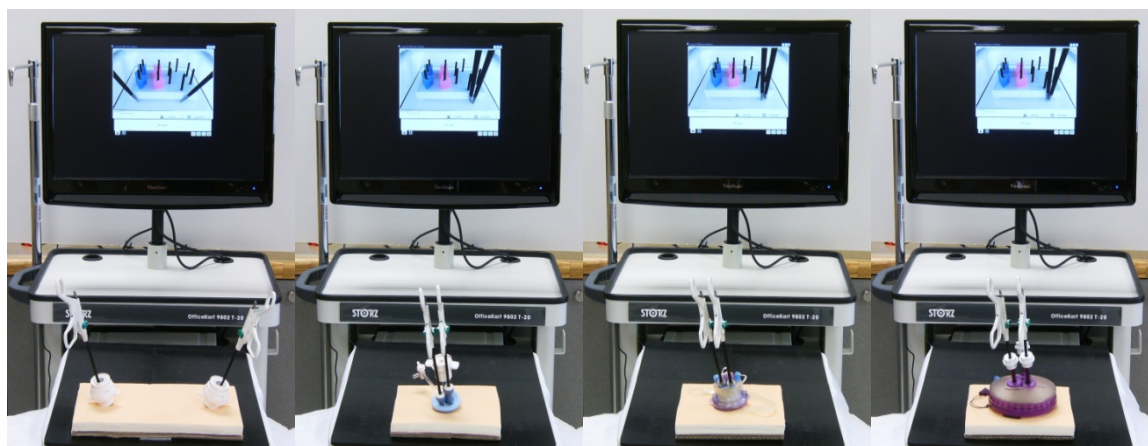


Figure 4.2: Surgical Simulator (from left to right) Conventional Laparoscopy, SILS™ Port, TriPort™ Access System, and GelPOINT™ System

Based on clinical observation, the single-port devices performed quite differently in vivo compared to either a rigid or semi-flexible in vitro interface. As a result, the FLS trainer's PVC skin was replaced with a 15-mm synthetic skin interface (Lapro-Abdominal Pad, Limbs and Things™, Bristol, UK). This interface was chosen because of its common usage in laparoscopic trainers; similar thickness, stiffness and elasticity to

human skin; and, to maximize the study's clinical relevance. Each single-port device was inserted into a 2.0-cm initial incision through the synthetic skin per the manufacturer's recommendations. For conventional laparoscopy, two standard 12-mm working ports were inserted through a 1.5-cm initial incision approximately 18-cm apart in the synthetic skin.

#### ***4.3.5 Procedure***

This study was conducted in accordance with local IRB standards and protocols. The experimental procedures were explained to each participant prior to the conduct of the study. Table height was adjusted to each participant's standing elbow height to minimize discomfort (Berquer et al., 2002; De, 2005). Additionally, the monitor was positioned below eye level for an approximately 15 degree downward viewing angle (Omar et al., 2005; van Det et al., 2009; van Veelen et al., 2004). Each participant donned latex free surgical gloves in a self-selected size. Similar to the FLS program's pretest, each participant watched the FLS peg transfer task video once prior to the conduct of the experiment. Additionally, the FLS proctor script, manual skills written instructions and task performance guidelines were also followed for consistency. Next, each participant completed a brief hands-on familiarization period of five minutes in the conventional laparoscopy setup. Then, each participant performed the peg transfer task using conventional laparoscopic ports, the SILS port, the TriPort access system, and the GelPOINT system with two standard length 5-mm graspers. Each participant completed the task using conventional laparoscopy first, followed by each of the three single-port devices in random order. Since the participants were novices, conventional laparoscopy served as part of the task and instrument familiarization. It was also determined during

pilot testing that the transposed instrument view of LESS created confusion when all four ports were completely randomized. As a result, each participant was randomly assigned one of six experimental trial sequences A through F, which dictated the performance order of the single-port devices. For trial sequence A, the participant completed their first trial (trial 1) using conventional laparoscopy, their second trial (trial 2) using the SILS port, their third trial (trial 3) using the TriPort and the fourth trial (trial 4) using the GelPOINT system. Likewise, trial sequence F has trial 1 conventional laparoscopy, trial 2 the GelPOINT system, trial 3 the TriPort and trial 4 the SILS port. The only difference between each of the six trial sequences were the randomized trials 2, 3, 4 for each of the three single-port devices. Each trial sequence was completed by four participants (two males and two females). A maximum task completion was set at 600 seconds and a five minute rest period was given between each trial. Additionally, each participant completed only one trial per port to minimize fatigue and the effects of learning.

Task score and subjective questionnaire ratings were used to compare conventional laparoscopy and the single-port devices. In order to compute task score, task completion time and errors were extracted using a DataLINK system (Model DLK900, Biometrics Ltd, Gwent, UK) with software version 7.0 at a sampling rate of 200-Hz. Biometric's IS2 Ident Switch or digital event marker was used to record when the participant began and completed the task and if any errors occurred.

A questionnaire with two parts was given to each participant. Part one of the questionnaire was administered after each trial and was used to rate each port's ease-of-use, task completion difficulty and instrument maneuverability on a verbally-anchored Likert scale from 1-very difficult to 6-very easy. The second portion of the questionnaire

was administered at the conclusion of the experiment, where each participant ranked each of the four ports from 1-best to 4-worst. All of the other subjective ratings followed a forced choice method without a neutral or undecided option.

#### ***4.3.6 Experimental Design***

A full-factorial analysis of variance (ANOVA) with blocking on subjects was performed for the dependent variable task score using SAS (V 9.2). The independent variables were port (4 levels) and trial sequence (4 levels). Based on the significant effects from the hypotheses tests using Type III error, a post-hoc Tukey test was performed for the significant main effects, and simple-effect F-tests were performed on significant interactions. Specifically, post-hoc tests were performed for each port for pairwise comparisons of trials 2, 3 and 4; and for each trial for pairwise comparisons of the ports. Friedman's tests with blocking on subjects were performed for the dependent variable statement rating for each questionnaire statement using MINITAB (V. 14.2). The independent variable was port (4 levels). The level of significance for all statistical tests was set at 0.05.

### **4.4 Results**

#### ***4.4.1 Task Score***

There were no significant differences in overall task mean score (i.e., grand mean) between conventional laparoscopy and the single-port devices ( $p = 0.493$ , Table 4.3). Specifically, the main effect of port and the interaction effect of port and trial sequence were not significant ( $p > 0.05$ ). However, there was a significant main effect for trial sequence ( $p < 0.05$ ). The TriPort differed significantly across each of its three trials 2, 3



and 4 ( $p < 0.001$ ). If the participant used the TriPort second (i.e., trial 2), then they had a significantly lower task score than those participants who used the TriPort in either trial 3 or 4. Likewise, participants who performed the task with the TriPort third (i.e., trial 3) also had a significantly lower task score than those who used it fourth (i.e., trial 4). There were no task score differences between trials for either the SILS port or the GelPOINT system. Moreover, the TriPort's second trial (trial 2) mean task score also differed significantly across the three LESS port's second trial ( $p = 0.004$ ). The TriPort had a significantly lower mean task score of 177 compared to both the SILS port and the GelPOINT system with mean scores of 276 and 316, respectively. Both fatigue and learning cannot be discounted as factors for these results.

Table 4.3: Task Score Summary -- Mean (Standard Deviation)

	Conv. Lap.	SILS Port	TriPort	GelPOINT	p-value
Grand Mean	319 (79.8)	297 (92.2)	291 (115)	327 (71.5)	0.4928
Trial 1 Mean	319 (79.8)	-	-	-	-
Trial 2 Mean	-	276 (68.9)	177 (48.3)	316 (85.1)	<b>0.0040</b>
Trial 3 Mean	-	334 (91.7)	284 (95.4)	325 (65.5)	0.4771
Trial 4 Mean	-	287 (113)	397 (68.8)	338 (72.9)	0.0624
p-value	-	0.4671	<b>&lt; 0.0001</b>	0.8527	-

#### 4.4.2 Subjective Assessments

Task completion difficulty ranged from 3-somewhat difficult to 4-somewhat easy with no significant differences between ports (Table 4.4). Instrument maneuverability was rated highest for conventional laparoscopy and the GelPOINT system, but showed no significant differences. Ease-of-use differed significantly between ports with conventional laparoscopy rated as somewhat easier compared to the SILS port, which

was rated as somewhat difficult ( $p = 0.028$ ). At the conclusion of testing, participants also ranked each of the four ports overall from 1-best to 4-worst. Conventional laparoscopy was rated the highest overall, though only the SILS port was rated significantly lower compared to both conventional laparoscopy and the GelPOINT system ( $p = 0.006$ ).

Table 4.4: Subjective Assessments Summary -- Median (Interquartile Range)

	Conv. Lap.	SILS Port	TriPort	GelPOINT	p-value
Task Completion Difficulty <sup>a</sup>	4 (1.00)	3.5 (1.00)	3 (2.00)	4 (2.00)	0.562
Instrument Maneuverability <sup>a</sup>	4 (2.00)	3 (2.00)	3 (1.00)	4 (1.75)	0.225
Ease-of-use <sup>a</sup>	4 (0.75)	3 (1.00)	3 (2.00)	3.5 (1.00)	<b>0.028</b>
Overall Rank <sup>b</sup>	1 (2.00)	3 (1.00)	3 (2.00)	2 (1.00)	<b>0.006</b>

<sup>a</sup> Rated 1-Very Difficult, 2-Difficult, 3-Somewhat Difficult, 4-Somewhat Easy, 5-Easy, 6-Very Easy

<sup>b</sup> Ranked from 1-Best to 4-Worst

## 4.5 Discussion

Currently there is no comprehensive comparison of the single-port devices used in this study, and as such the authors have compiled the initial impressions of each device with regard to their advantages and disadvantages (Table 4.5). This unbiased pro-con listing is meant to inform the potential user and not dissuade the usage of any one device.

Additionally, each port has advantages for application in specific disciplines. For example, the GelPOINT system's larger incision range and GelSeal cap allows for easy removal of larger specimens required when performing nephrectomies. Lastly, each device has at least one critical disadvantage that must be addressed in the near future to improve its universal uptake and utilization. Specifically, the SILS port's difficult insertion and lack of abdominal wall adjustability must be improved to minimize

insertion trauma and to accommodate more of the population. Next, the TriPort's gel seal caps and retraction sleeve must be improved to minimize instrument friction and

Table 4.5: Pros and Cons of Single-port Devices<sup>a</sup>

	Pros	Cons
SILS Port	<ul style="list-style-type: none"> <li>▪ Flexible, soft foam minimizes abdominal bruising</li> <li>▪ Low-profile instrument ports</li> <li>▪ Robust and flexible to accept larger instruments such as staplers</li> <li>▪ Provides stability/support to hand instruments</li> <li>▪ Insufflation tubing away from port's main body</li> <li>▪ Cost</li> </ul>	<ul style="list-style-type: none"> <li>▪ Passively conforms to abdominal wall</li> <li>▪ Lacks adjustability for varying incision lengths and abdominal wall thicknesses</li> <li>▪ Difficult to insert 12-mm cannula</li> <li>▪ Device insertion and removal can be difficult depending on patient characteristics such as BMI</li> <li>▪ Not a wound protector</li> </ul>
TriPort	<ul style="list-style-type: none"> <li>▪ Blunt introducer available</li> <li>▪ Two insufflation-desufflation lines</li> <li>▪ Low-profile instrument ports</li> <li>▪ Retraction system reduces trocar clutter and protrusion into the operative field</li> <li>▪ Varying incision lengths and abdominal wall thicknesses</li> <li>▪ Specimen removal without entire device removal</li> <li>▪ Includes device removal ring</li> <li>▪ Wound protector</li> <li>▪ Cost</li> </ul>	<ul style="list-style-type: none"> <li>▪ Gel caps must be lubricated and treated gently, loss of lubrication results in palpable friction on instrument shafts</li> <li>▪ Lubrication can smudge optics</li> <li>▪ Retraction system complicated with multiple steps including cinching of the sleeve, attachment of two retainer clips and removal of excess sleeve</li> <li>▪ Retraction system loosens during procedure</li> </ul>
GelPOINT	<ul style="list-style-type: none"> <li>▪ Multiple instrument configurations</li> <li>▪ Accepts instruments directly or through trocars</li> <li>▪ Trocars float above the incision</li> <li>▪ Retraction system reduces trocar clutter and protrusion into the operative field</li> <li>▪ Varying incision lengths and abdominal wall thicknesses</li> <li>▪ Large outer working profile</li> <li>▪ Flexible fulcrum for movement</li> <li>▪ Allows extracorporeal anastomosis</li> <li>▪ Specimen removal without entire device removal</li> <li>▪ Includes device removal ring</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only 5-mm self-retaining trocars</li> <li>▪ Adjustment of retraction sleeve requires two personnel</li> <li>▪ GelSeal Cap bows outward during insufflation creating an altered instrument fulcrum</li> <li>▪ Cost</li> </ul>

	▪ Wound protector	
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<sup>a</sup> (Fader et al., 2010; GelPOINT Applied Medical, 2010; Irwin et al., 2010; LESS from Olympus, 2010; MacDonald et al., 2009; SILS Port, 2010)

loosening from the abdominal wall, respectively. Lastly, the GelPOINT system only includes 5-mm self-retaining trocars limiting the usage of larger instruments, such as staplers, that are integral in many procedures. Overall, laparoendoscopic single-site surgery is feasible, however its universal acceptance and success hinges upon instrumentation improvements, and in the near term, pairing of ports with procedures.

Overall, performance of basic laparoscopic skills does not appear more challenging using a single-port device compared to conventional laparoscopy. The novice participants did have a significant performance decrement starting with the TriPort as compared to starting with either the SILS port or the GelPOINT system (Figure 4.3). Alternatively, usage of the TriPort last resulted in the highest trial mean score compared to conventional laparoscopy, the SILS port and the GelPOINT system. Based on this order effect, the TriPort exhibited the most dramatic transfer of training, which may indicate that the TriPort has a steeper learning curve compared to the other single-port devices. In general, the TriPort may be more challenging for novices to learn LESS compared to both the SILS port and GelPOINT system, however future studies will be needed to quantify LESS' learning curve. Surprisingly, the GelPOINT system resulted in the highest grand mean task score compared to the single-port devices and conventional laparoscopy, although this difference failed to reach statistical significance. Additionally, task performance with the GelPOINT system exhibited a narrow spread and consistent symmetry between trial sequences compared to the SILS port and TriPort (Figure 4.3). Accordingly, the GelPOINT system appears to be the easiest system for novices to use

and performed very similar to conventional laparoscopy. Subjectively, both conventional laparoscopy and the GelPOINT system offered the most intuitive and straight-forward platforms for task performance. Although the TriPort showed the greatest performance improvement, the GelPOINT system may be the most consistent platform for LESS performance and novice skill acquisition. Study limitations include the inclusion of only novices and the potential effects of fatigue and learning. Future studies are needed to confirm these preliminary findings, in particular using more difficult training tasks, alternative instrumentation (e.g., bent, flexible and articulating) and varying surgical expertise levels.

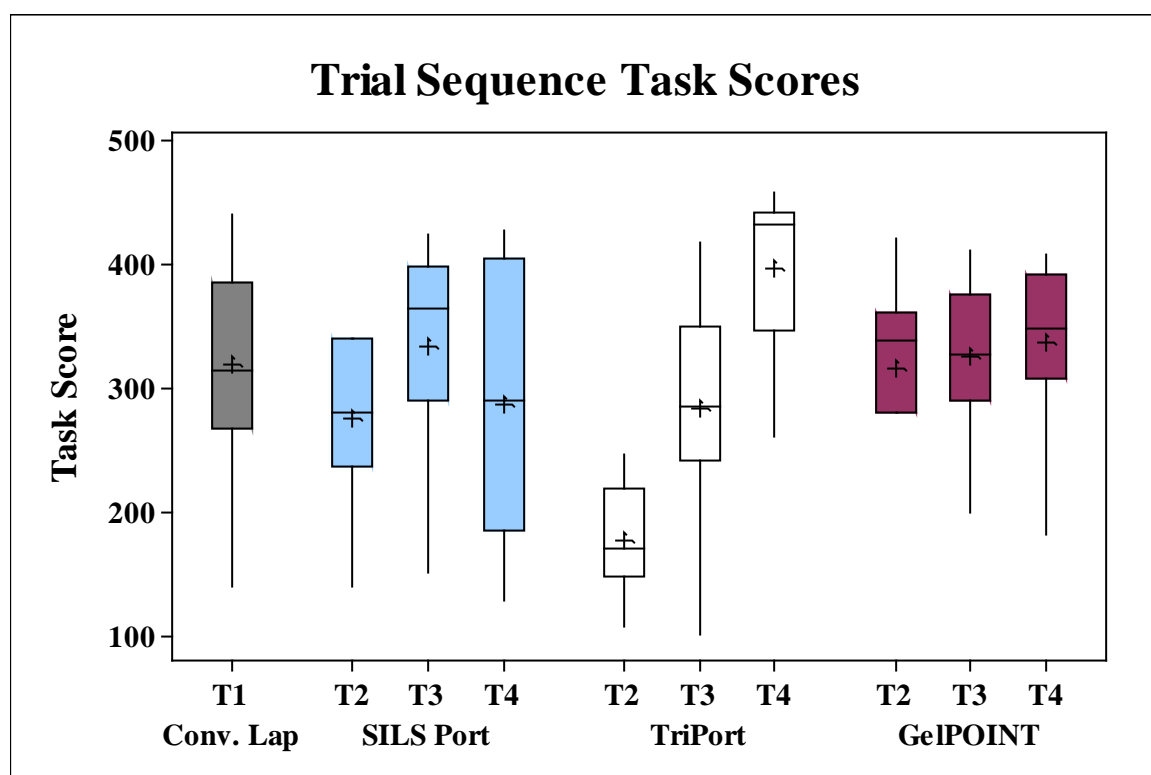


Figure 4.3: Task Score Boxplot with Trial Sequence

Note: Median horizontal line and mean plus sign, Trial 1 (T1) conventional laparoscopy only Trial 2 (T2), Trial 3 (T3) and Trial 4 (T4) were randomized for the single-port devices

## CHAPTER 5

# Ergonomic Evaluation of Laparoendoscopic Single-site Surgery Ports in a Validated Laparoscopic Training Model

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### 5.1 Executive Summary

Although laparoendoscopic single-site surgery (LESS) is feasible among expert laparoscopic surgeons, it poses many technical challenges not seen in conventional laparoscopy (CL). Recent technological advancements in single-incision instrumentation have created more interest and widespread usage of LESS. However, neither LESS nor its novel instrumentation have been thoroughly studied or evaluated using human factors and ergonomics techniques. Consequently, the aim of this study was to compare the physical performance of LESS to CL using a standardized task. Wrist and elbow angular movements, range of motion and physical discomfort were assessed for 24 novice participants. There were no significant differences for physical comfort/discomfort ratings or elbow and wrist flexion/extension range of motion between CL and LESS. However, wrist radial/ulnar range of motion was significantly greater in LESS compared

to CL ( $p < 0.05$ ). Additionally, wrist radial/ulnar range of motion was significantly greater using the SILS Port compared to the GelPOINT ( $p < 0.05$ ). Although further investigation is needed, LESS resulted in greater wrist deviation and range of motion due to the close proximity of the instruments, restrictive nature of the single-port devices, and the need to achieve adequate instrument triangulation and visualization.

**Keywords:** Single-incision, Laparoscopy, Goniometry, Human Factors, Simulation

## 5.2 Introduction

Laparoendoscopic single-site surgery (LESS), the next advance in minimally invasive surgery (MIS), is a feasible surgical technique performed using a single, small incision typically within the patient's navel (Rivas et al., 2010; Saber et al., 2010; Teixeira et al., 2010). The surgeon inserts several instruments and a laparoscopic camera into the single incision leaving virtually no surgical scar. LESS is the newest alternative to conventional multi-incision laparoscopic surgery and natural orifice transluminal endoscopic surgery (NOTES) (Gettmann et al., 2011; Gill et al., 2010). The evolution of LESS primarily occurred due to the recent development of advanced access port technology (i.e., single-port devices) and the technical performance difficulty of NOTES (Auyang et al., 2010; Gettmann et al., 2011; Gill et al., 2010; Slim and Launay-Savary, 2008). However, LESS poses physical, mental and technical performance challenges unique to this surgical technique (Gill et al., 2010). Since all of the instrumentation is inserted through a single incision, the surgeon must contend with instrument collisions, transposed instrument viewing (i.e., the surgeon's right instrument operates on the left side), and an in-line view of the instruments. Similar to conventional laparoscopy, the surgeon must also still contend with a static and non-neutral body posture due to the elongated instruments,

elevated monitor positions, multiple foot pedals and operating table height (Matern and Koneczny, 2007; Park et al., 2010; van Det et al., 2009; van Veelen et al., 2004). Since LESS emerged quite rapidly, surgeons have primarily relied upon conventional laparoscopic instrumentation, which have not been designed or optimized for LESS. Very recently, there has also been an influx of highly complex instrumentation for LESS. Although these novel hand instruments and access ports seem to be aiding LESS surgeons, there have been no published reports on the ergonomics of these devices and their potential effects on surgical performance. As a result, the aim of this study was to compare the physical performance of LESS to conventional laparoscopy.

### **5.3 Materials and Methods**

The same participant population, apparatus and procedure were used as previously described in Brown-Clerk et al. (2011).

#### **5.3.1 Participants**

Twenty-four healthy adults (12 males and 12 females) were recruited to participate in this study. The participants were medical students, undergraduate and graduate students from the local medical center. Participant exclusion criteria included prior surgical experience and experience with the manual skills portion of the Fundamentals of Laparoscopic Surgery (FLS) program. Twenty-two participants were right-hand dominant and one male and one female were left hand-dominant. A descriptive summary of the participants is shown in Table 5.1.



Table 5.1: Participant Descriptive Summary -- Mean (Standard Deviation)

	Age (years)	Weight (kg)	Height (cm)
Male	24.3 (2.57)	81.9 (12.6)	178 (12.1)
Female	25.3 (5.79)	67.9 (18.1)	167 (8.71)
Overall	24.8 (4.41)	74.9 (16.9)	173 (11.7)

### 5.3.2 Apparatus

The experimental set-up consisted of a FLS manual skills trainer, FLS peg transfer task, standard monitor tower (OfficeKart 9802 T-20, Karl Storz, Tuttlingen, Germany) with widescreen LCD HD monitor (56-cm, ViewSonic, Walnut, CA, USA), and a stationary high-speed HD camera (Logitech Quickcam Pro 9000 web camera, Fremont, CA, USA). Two standard length non-locking 5-mm graspers (Auto Suture Endo Dissect, Covidien, Mansfield, MA, USA) were used throughout the study. The trainer was securely positioned on an adjustable height table in front of the monitor tower. The stationary HD camera displayed the task field through the monitor at an approximately 30 degree viewing angle. Both the trainer and monitor were placed in-line with the participant.

The novel surgical simulator (Figure 5.1) was adapted from the FLS manual skills trainer for LESS to include a 15-mm synthetic skin interface (Lapro-Abdominal Pad, Limbs and Things<sup>TM</sup>, Bristol, UK). The SILS<sup>TM</sup> port (Covidien, Mansfield, MA, USA), TriPort<sup>TM</sup> Access System (Olympus America Inc., Center Valley, PA, USA), and GelPOINT<sup>TM</sup> System (Applied Medical, Rancho Santa Margarita, CA, USA) were inserted into an 2.0-cm incision through the synthetic skin. For CL, two standard 12-mm trocars were inserted through a 1.5-cm incision 18-cm apart in the synthetic skin.



Figure 5.1: Surgical Simulator with CL Ports, SILS Port, TriPort and GelPOINT

Note: From left to right

### 5.3.3 Task

The FLS manual skills curriculum consists of five basic laparoscopic surgical tasks, which develop skills such as ambidexterity, depth perception, hand-eye coordination and controlled movement of instruments (Derossis et al., 1998; Fried et al., 1999). The first FLS task, peg transfer, requires the surgical trainee to grasp, lift, transfer and place six small triangle shaped objects on a pegboard starting with the non-dominant hand and transferring to the dominant hand. Once the trainee has repositioned all six objects to the opposite side of the pegboard, the procedure is reversed where the object is grasped with the dominant hand and transferred to the non-dominant hand resulting in a total of 12 peg transfers.

Completion of the peg transfer task in the CL and LESS simulators are shown in Figures 5.2 and 5.3, respectively. The same right-hand dominant participant performed the peg transfer task in Figures 5.2 and 5.3 beginning with the left (i.e. non-dominant) hand. The starting positions of the pegs are reversed during LESS due to the transposed instrument orientation. As seen in Figure 5.2, CL task completion is aided through

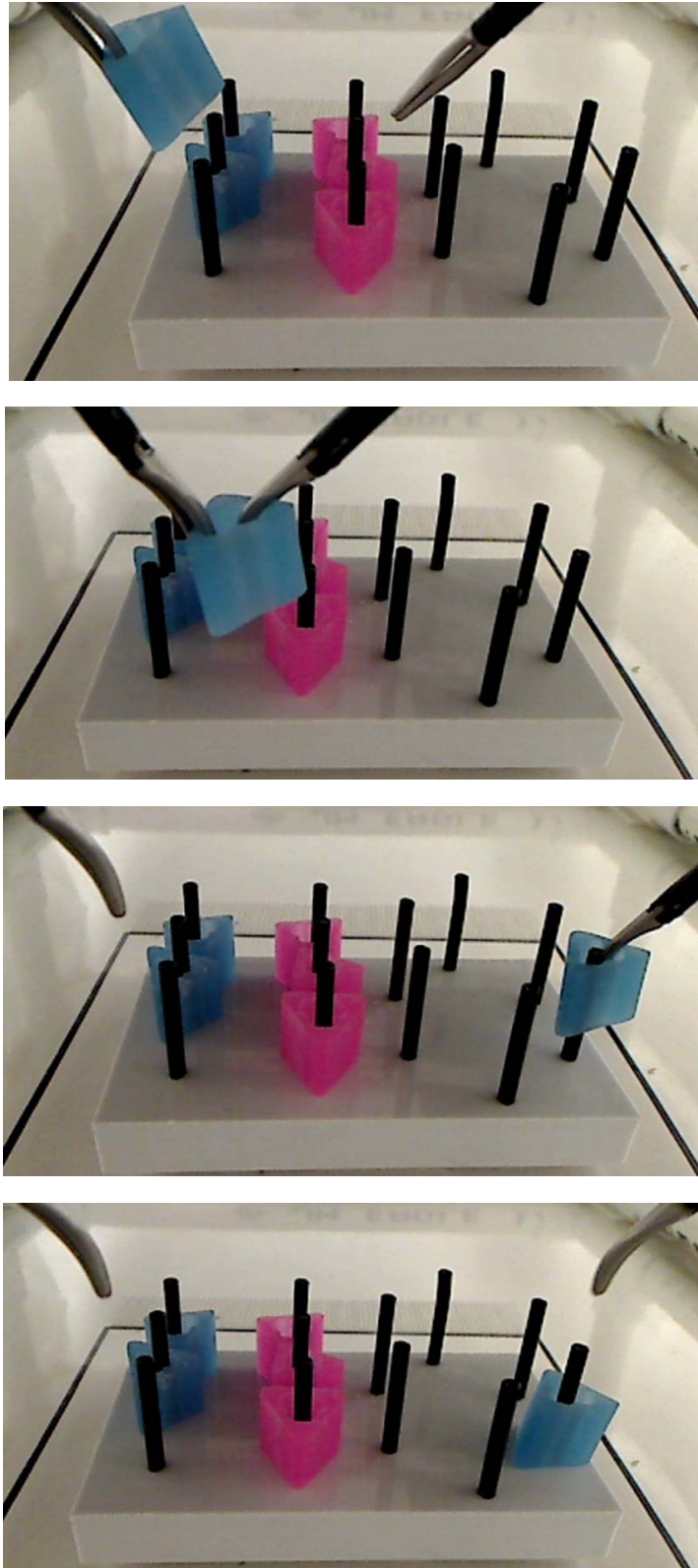


Figure 5.2: CL Peg Transfer Task

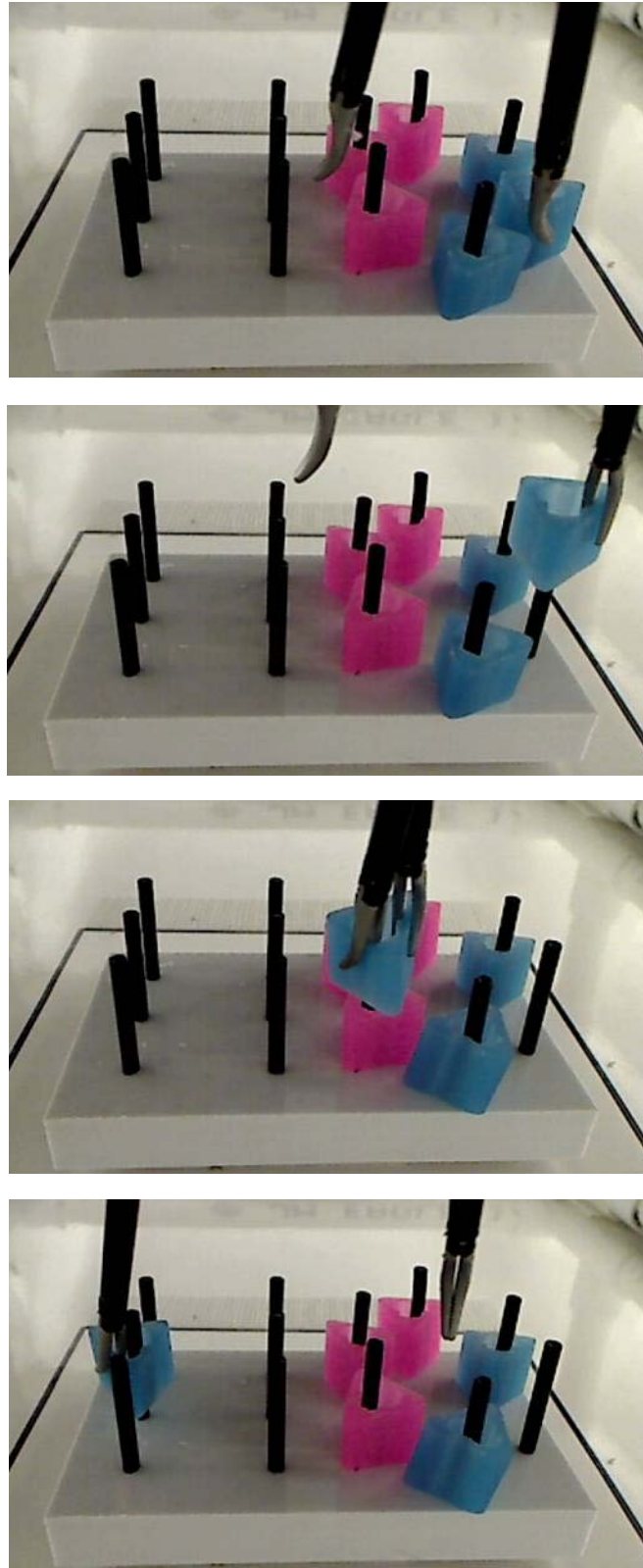


Figure 5.3: LESS Peg Transfer Task

optimal instrument placement that facilitates instrument articulation, triangulation and visualization. In contrast, the location and orientation of the instrumentation in the LESS simulator results in collisions, transposition and an in-line view of the instruments as shown in Figure 5.3.

#### ***5.3.4 Procedure***

This study was conducted in accordance with local IRB standards and protocols. The experimental procedures were explained to each participant prior to the conduct of the study. Demographic data and study inclusion/exclusion criteria were annotated at the start of the study. Table height was adjusted to each participant's standing elbow height (De, 2005), and each participant donned hypo-allergenic surgical gloves in a self-selected size. The FLS proctor script was followed whereby the manual skills written instructions, performance guidelines and video demonstration were explained and shown prior to the conduct of the study. The participants were instructed to complete the peg transfer task in accordance with the FLS criteria.

Next, limb angular movements were used to compare conventional laparoscopy and the single-port devices. Limb angular movement was measured using twin-axis electrogoniometers. Each subject's dominant wrist and elbow angular movements were monitored using electrogoniometers (Biometrics Ltd, Gwent, UK) SG65 and SG110, respectively. Each electrogoniometer was applied using medical-grade double-sided adhesive tape. The wrist was monitored in both the flexion-extension and radial-ulnar deviation planes. The elbow was monitored in the flexion-extension plane. In accordance with the Goniometer and Torsiometer Operating Manual (Biometrics Ltd, Copyright 2002) the datum position for each measurement plane was set for each participant in the

prescribed neutral joint position. Wrist and elbow angular movements were recorded at a sampling rate of 200/sec using the DataLINK system (Model DLK900, Biometrics Ltd, Gwent, UK) with software version 7.0. The maximum and minimum angular positions for each movement plane were calculated using the DataLINK system software. The included elbow angle was calculated using  $0^\circ$  as fully flexed and  $180^\circ$  as fully extended. Range of motion (ROM) was also calculated for each plane by taking the difference between the maximum and minimum angular positions.

Following goniometer placement and calibration, each participant completed a brief hands-on familiarization period of five minutes in the CL setup. Afterwards he or she performed the peg transfer task using CL ports, SILS Port, TriPort, and the GelPOINT with two standard length 5-mm graspers. Each participant completed the task first using CL followed by randomized completion using each of three single-port devices. Due to task length only one task trial was completed for each port resulting in a total of four trials per participant.

A rest period of five minutes was given between each port to minimize fatigue and to administer a short questionnaire. The questionnaire was administered directly following task completion in each of the four ports, and rated the comfort/discomfort of six anatomical regions on a verbally-anchored 6-point Likert scale with a forced choice method.

### ***5.3.5 Experimental Design***

A full-factorial analysis of variance with blocking on subjects was performed for the dependent variable angular position and range of motion for each movement plane using SAS (V. 9.2). Post-hoc Tukey tests were performed for significant main effects.

Nonparametric Kruskal-Wallis' tests were performed for the dependent variable statement rating for each anatomic region and instrument maneuverability using MINITAB (V. 14.2). For all statistical tests the independent variable was port (4 levels) and the level of significance was set at 0.05.

## 5.4 Results

### 5.4.1 Elbow Flexion/Extension

There were no significant differences for the average minimum elbow extension, maximum elbow extension or elbow ROM across ports. As expected elbow angular positioning (i.e. included angle) was relatively static for all ports. Average elbow ROM was the greatest in the TriPort at 38° and the least in CL at 28° as depicted by the dashed line in Figure 5.4.

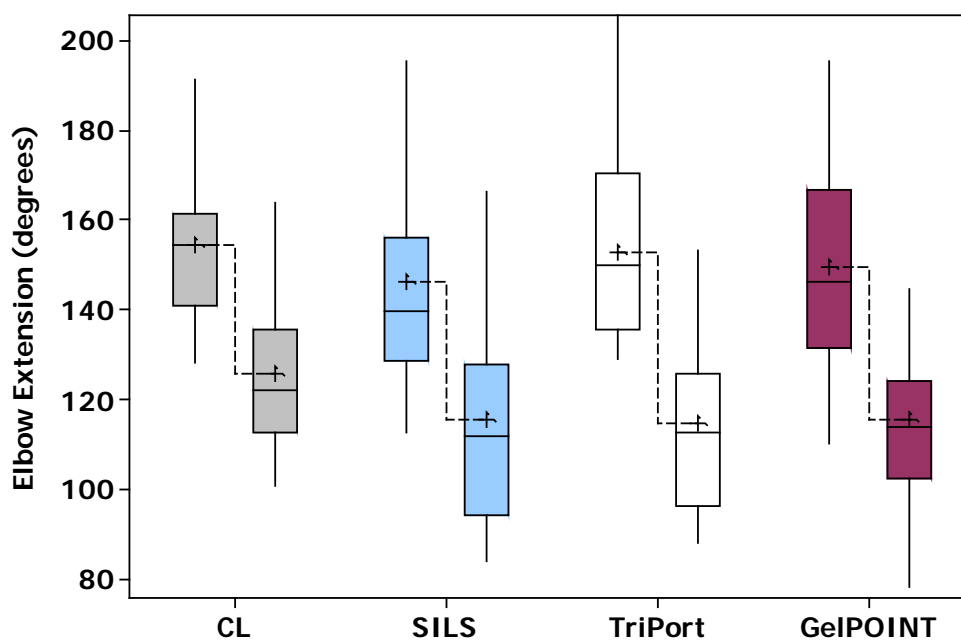


Figure 5.4: Elbow Flexion/Extension

Note: median horizontal line, mean plus sign, mean ROM dashed line

### 5.4.2 Wrist Flexion/Extension

There was no significant difference for the average wrist ROM, which was approximately 70°, across all ports. However, the average maximum flexion and minimum extension were significantly different between CL and both the TriPort and GelPOINT ( $p < 0.05$ ). Specifically, wrist flexion for CL was significantly greater compared to the TriPort and GelPOINT, and wrist extension for CL was significantly less compared to the TriPort and GelPOINT (Figure 5.5). Although the SILS Port failed to reach statistical significance, it exhibits a similar trend to the other single-port devices.

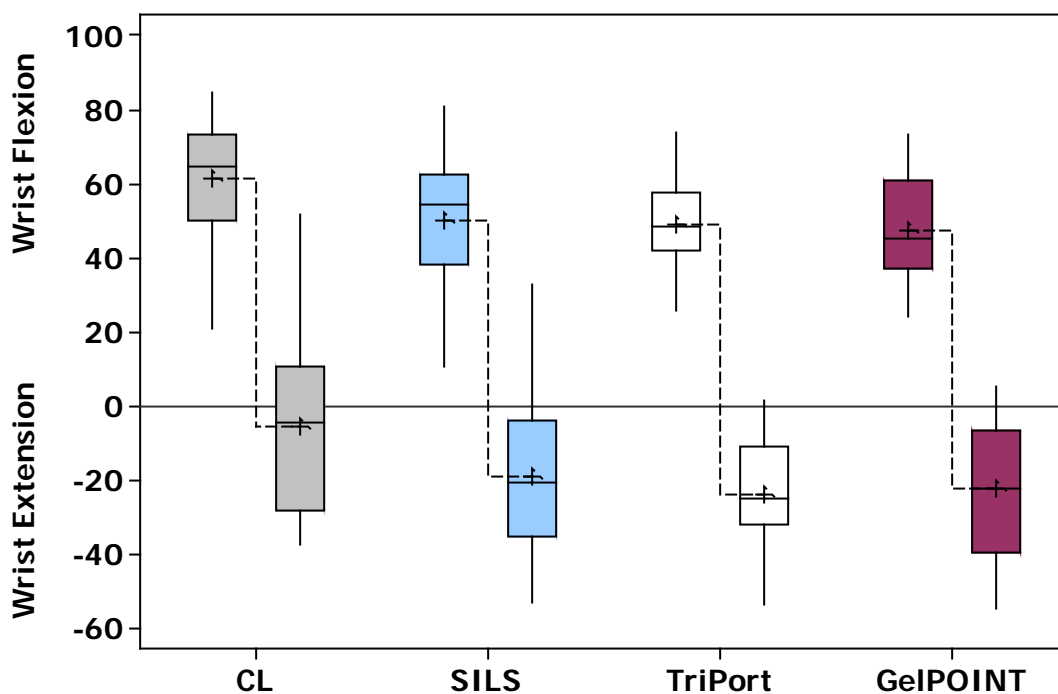


Figure 5.5: Wrist Flexion/Extension

Note: median horizontal line, mean plus sign, mean ROM dashed line



### 5.4.3 Wrist Radial/Ulnar Deviation

Average wrist ROM, radial deviation and ulnar deviation were significantly different across all ports ( $p < 0.05$ ). CL had significantly less ROM at  $31^\circ$  compared to the SILS Port at  $52^\circ$ , TriPort at  $47^\circ$  and GelPOINT at  $44^\circ$  (Figure 5.6). ROM was also significantly less for the GelPOINT compared to the SILS Port. Second, ulnar deviation was significantly less for CL compared to the single-port devices. Lastly, radial deviation was significantly less for the TriPort and GelPOINT at  $10^\circ$  compared to both CL and SILS Port at  $20^\circ$ .

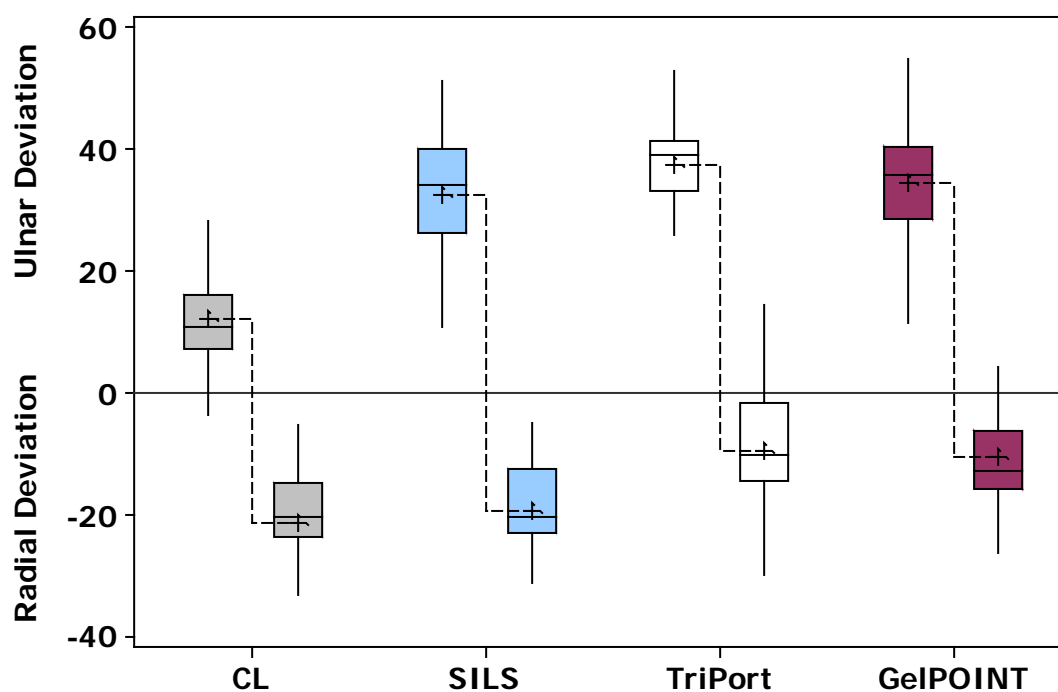


Figure 5.6: Wrist Radial/Ulnar Deviation

Note: median horizontal line, mean plus sign, mean ROM dashed line

#### 5.4.4 Comfort/Discomfort

Laparoscopic instruments have been associated with nerve injury and neuropraxia of the digits, most often the thumb, due to handle design and gripping techniques (De, 2005). Accordingly, it was hypothesized that the thumb, index and middle fingers may experience greater discomfort due to the novel LESS instrumentation. In general there was very little variation between median comfort/discomfort ratings, resulting in no significant differences across ports for all six anatomical regions (Table 5.2). In general, participants were more likely to agree that CL was comfortable and that the single-port devices were comfortable or slightly comfortable for all regions. Overall, there was no significant difference between CL and LESS based on subjective comfort/discomfort ratings of the thumb, index and middle fingers, palm, forearm and upper arm.

Table 5.2: Subjective Comfort Assessments -- Median (Interquartile Range)

	CL Ports	SILS Port	TriPort	GelPOINT
Thumb	5.0 (1.0)	4.5 (1.0)	4.0 (2.0)	4.0 (2.0)
Index Finger	5.0 (1.0)	5.0 (0.75)	5.0 (0.0)	5.0 (0.75)
Middle Finger	5.0 (1.0)	5.0 (1.0)	5.0 (1.75)	5.0 (1.0)
Palm	5.0 (0.75)	5.0 (0.75)	5.0 (1.75)	5.0 (1.0)
Forearm	5.0 (2.0)	5.0 (1.5)	5.0 (1.75)	5.0 (1.0)
Upper Arm	5.0 (1.0)	5.0 (1.75)	5.0 (2.0)	5.0 (1.0)

Note: 1-Very Uncomfortable, 2-Uncomfortable, 3-Slightly Uncomfortable, 4-Slightly Comfortable, 5-Comfortable, and 6-Very Comfortable

## 5.5 Discussion

Based solely on the physical comfort/discomfort ratings, there appears to be no difference between conventional laparoscopy and LESS. However, the simplified task and novice participants may have affected these results. Similarly, range of motion for both elbow and wrist flexion/extension were similar for conventional laparoscopy and the single-port devices. However, upon closer inspection wrist flexion/extension for the single port devices was occurring with less flexion and more extension compared to conventional laparoscopy. Additionally, wrist radial/ulnar deviation and range of motion were dramatically different between conventional laparoscopy and the single-port devices. Presumably the close proximity of the instruments, restrictive nature of the single-port device, and the need to achieve adequate instrument triangulation and visualization for LESS resulted in greater wrist deviation and range of motion. Since the wrist is one of the most common joints to be affected by cumulative trauma disorders (CTDs) (Tanaka et al., 1988), the added strain on the wrist during LESS may result in a new occupational hazard for laparoscopic surgeons. However, these preliminary findings will need to be confirmed in order to determine the likelihood and severity of injury. Overall, further investigation of the ergonomics of LESS is needed in order to better train and equip laparoendoscopic single-site surgeons for optimal performance.

Study limitations include the inclusion of only novice trainees. Future studies will include participants with different levels of surgical experience as well as more difficult training tasks. In addition, bent and articulating instruments are currently being used during many LESS procedures and will also be included in future studies. Finally, since the participants were novices, there may have been effects due to fatigue and learning.

## CHAPTER 6

# Human Factors-based Analysis of Conventional and Single-incision Laparoscopic Surgery

### 6.1 Executive Summary

**Précis:** Medical instrumentation is often selected based on cost, without input from end-users, and without comparative evaluation data. This study utilized competitive usability testing to perform an unbiased comparative assessment of LESS multichannel access ports in order to highlight the need for head-to-head comparison data for objective product selection.

**Objective:** Perform competitive usability testing to assess the user experience of conventional laparoscopic and laparoendoscopic single-site surgery (LESS) ports.

**Background:** Recent advancements in single-incision instrumentation have created more interest in and usage of LESS. However, neither LESS nor its novel multichannel access ports have been thoroughly studied.

**Method:** Using a simulation test-bed and standardized laparoscopic surgery task, the user experience of three commercially-available LESS ports was compared to conventional laparoscopic ports based on time-on-task, errors, task success and perceived ease of use.

**Results:** There were no significant differences across ports for time-on-task or task success ( $p > 0.05$ ). There were significantly more recoverable than unrecoverable errors,

and errors occurred more frequently during the second phase of the task when the dominant hand was more active ( $p < 0.0001$ ). Conventional laparoscopic ports and the GelPOINT were rated more easy to use compared to the SILS port and TriPort ( $p < 0.05$ ).

**Conclusion:** The GelPOINT's design and user interface facilitated more accurate and efficient movements resulting in the lowest task duration, error frequency and the highest overall task success rate. The GelPOINT's user experience was comparable to that of conventional laparoscopy, which may enable a quicker transition to LESS by shortening the learning curve. Further investigation of the human factors and ergonomics of LESS is needed to better equip laparoscopic surgeons and protect patients.

**Application:** These findings demonstrate that competitive usability testing yields objective performance and usability data that can be used to determine the equivalence of commercially-available medical devices.

**Keywords:** LESS, Ergonomics, Competitive Usability Testing, Performance, Errors, Simulation

## 6.2 Introduction

Laparoendoscopic single-site surgery (LESS) is the next advance in minimally invasive surgery (MIS). A single, small incision is made typically within the patient's navel allowing the surgeon to insert several instruments and a laparoscope. LESS is the newest alternative to conventional multi-incision laparoscopic surgery and natural orifice transluminal endoscopic surgery (NOTES). The emergence of LESS occurred because of the recent development of novel multichannel access ports and the technical performance difficulty of NOTES. As with any new and emerging technique or technology, there

will be unanticipated difficulties that must be mitigated to prevent medical errors and protect patients. At present, the only recognized benefit of LESS compared to conventional laparoscopy is improved cosmesis since the surgical scar is concealed within the patient's navel (Podolsky et al., 2010; Chow et al., 2009). Based on preliminary evidence from clinical studies, LESS may also increase patient satisfaction and decrease both postoperative pain and recovery time compared to conventional laparoscopy (Tsimoyiannis et al., 2010; Canes et al., 2010; Kim et al., 2010). Although the feasibility of LESS has been established (Rivas et al., 2010; Saber et al., 2010; Teixeira et al., 2010), it is currently being performed without formal guidance and with imperfect instrumentation. In contrast to conventional laparoscopy, the technical challenges of LESS stem from the fact that all of the instrumentation is inserted through a single incision, resulting in intracorporeal and extracorporeal instrument collisions, an in-line view of the instruments, transposed instrument viewing (i.e., right instrument operates on the left side in monitor), and the surgeon's close proximity to assistants (Rivas et al., 2010; Saber et al., 2010; Teixeira et al., 2010). This imperfect operative environment may increase the complexity and duration of surgeries as well as the cognitive and physical stress on the surgeon, which may lead to preventable errors that impact patient outcomes.

Moreover, current laparoscopic hand instruments were not specifically designed for LESS or its novel access ports. Many surgeons have adapted to this challenging operating environment through teamwork (e.g., surgeon-assistant communication), compensatory techniques to improve retraction (e.g., ancillary skin punctures with no formal skin incision), and the usage of alternative instrumentation to improve

triangulation (e.g., bent, flexible and articulating instruments). An even more extreme example of a compensatory practice is the cross hand technique (Figure 6.1 left). In this technique both instruments are inserted so that they appear correctly on the monitor (i.e., right instrument on right side), then both hands are crossed at the wrist to manipulate the corresponding instrument (Ishikawa et al., 2009). The cross hand technique is meant to reduce the cognitive load of the right-left reversal of the instruments. However, this technique imposes unique physical loads such as an awkward posture and extreme wrist angles potentially resulting in discomfort and injury (Figure 6.1 right). Since various syndromes, such as overuse syndrome and surgical fatigue, have become increasingly common among laparoscopic surgeons (Park et al., 2010; Reyes et al., 2006; Sari et al., 2010), these “workarounds” could lead to an increase in surgeon morbidity and ultimately increase the risk of adverse outcomes. Accordingly, it is imperative to develop, assess and validate LESS-specific instrumentation and practices to improve operative performance and mitigate potential errors and injuries.

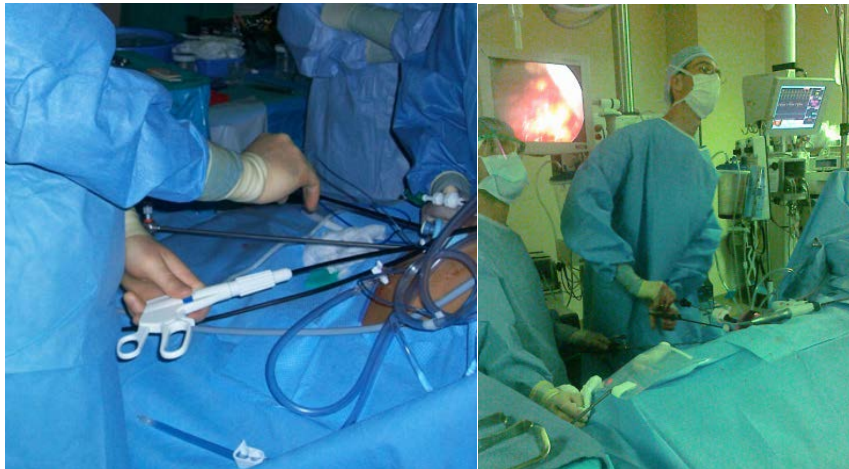


Figure 6.1: LESS Using the Cross Hand Technique

Although LESS has the potential to improve patient outcomes, its procedure- and technology-based shortcomings currently limit the standardization and adoption of this pioneering technique (Gettman et al., 2011, Gill et al., 2010). Based on preliminary clinical use, observations and a review of the literature, it was hypothesized that the user experience of LESS ports differed substantially between product brands. Consequently, the aim of this study was to objectively compare the user experience of conventional laparoscopic and three commercially-available LESS ports using performance and satisfaction metrics.

## **6.3 Materials and Methods**

### ***6.3.1 Study Population***

Competitive or comparison testing is a form of usability testing, which evaluates competitors' products in order to understand the best and worst features of existing products (ANSI/AAMI HE 75:2009; ANSI/AAMI/IEC 62366:2007). For this study, competitive usability testing was conducted as a formal evaluation comparing the user experience of the four ports. Typically five to eight representative users evaluate each product (Wiklund et al., 2011). For this reason, twenty-four (12 females) healthy medical students from the local medical center were recruited to evaluate the four ports. Twenty-two participants were right-hand dominant and one male and one female were left hand-dominant. The average (standard deviation) age, height and weight were 24.8 (4.41) years old, 173 (11.7) centimeters and 74.9 (16.9) kilograms, respectively.



### **6.3.2 Apparatus**

An evaluation test-bed is the ideal setting to critically evaluate emerging techniques and technologies under simulated conditions. These simulation test-beds enable safe, rigorous, transparent, and replicable experimental testing conditions, and have been used throughout the surgical domain (e.g., inanimate pelvi- and box trainers, virtual reality simulators, animal models). Although many of these surgical test-beds aim to improve the technical skills and abilities of trainees, their fundamental purpose is to evaluate the operator, device or system. For this study, an evaluation test-bed was constructed by adapting the existing Fundamentals of Laparoscopic Surgery (FLS) box trainer. This LESS-specific test-bed was created to accommodate LESS technologies and additional laparoscopic evaluation tasks. As previously described by Brown-Clerk et al. (2011), the LESS-specific simulation test-bed included a more robust and realistic 15-mm synthetic skin interface (Laparo-Abdominal Pad, Limbs and Things, Bristol, UK). The SILS Port (Covidien, Mansfield, MA, USA), TriPort Access System (Olympus America Inc., Center Valley, PA, USA), and GelPOINT System (Applied Medical, Rancho Santa Margarita, CA, USA) were each inserted per the manufacturer's recommendations into a 2.0-cm initial incision through the synthetic skin. For conventional laparoscopy, two standard 12-mm trocars were inserted through two 1.5-cm initial incisions 18-cm apart in the synthetic skin. The test-bed was securely positioned on an adjustable height table in front of the monitor tower, while the stationary high-definition camera displayed the task field through the monitor at a 30 degree viewing angle. Both the trainer and monitor were placed in-line with the participant.

### ***6.3.3 Standardized Task***

The FLS program (SAGES/ACS, FLS Program, Los Angeles, CA, USA) consists of five basic laparoscopic tasks that are non-procedure specific (Fried et al., 1999). These tasks emphasize ambidexterity, depth perception, hand-eye coordination and controlled instrument movement (Derossis et al., 1998; Fried et al., 1999). The FLS training curriculum is proficiency-based where each trainee practices the five tasks in order until a pre-defined performance level has been reached (Ritter and Scott, 2007). Once the trainee achieves proficiency on the first task, he or she may proceed to the next more difficult task. Since the study population consisted of novices, FLS task 1, peg transfer, was chosen as the standardized task scenario to be performed in each of the four ports. Two standard length 5-mm graspers (Autosuture Endo Dissect, Covidien, Mansfield, MA, USA) were used for task completion.

For consistency, the FLS proctor script, manual skills written instructions and video demonstration were used as the task performance guidelines (Peters et al., 2004; Ritter and Scott, 2007). According to these guidelines, the peg transfer task required the participant to grasp each of the six triangle-shaped objects with the non-dominant hand, transfer it to the dominant hand, and place it on the opposite side of the pegboard. Once each of the six objects were repositioned to the opposite side of the pegboard, the participant must then grasp each object with their dominant hand, transfer it midair to the non-dominant hand, and replace it on the original side of the pegboard. Restating, during phase 1 of the task the participant began with the non-dominant hand and transferred a total of 6 objects to the dominant hand (Figure 6.2 top). During phase 2, the procedure was reversed and each of the already repositioned objects were grasped with the

dominant hand, transferred to the non-dominant hand, and placed on the starting side of the pegboard (Figure 6.2 bottom). Combining the two task phases there were a total of 12 object transfers by each participant.

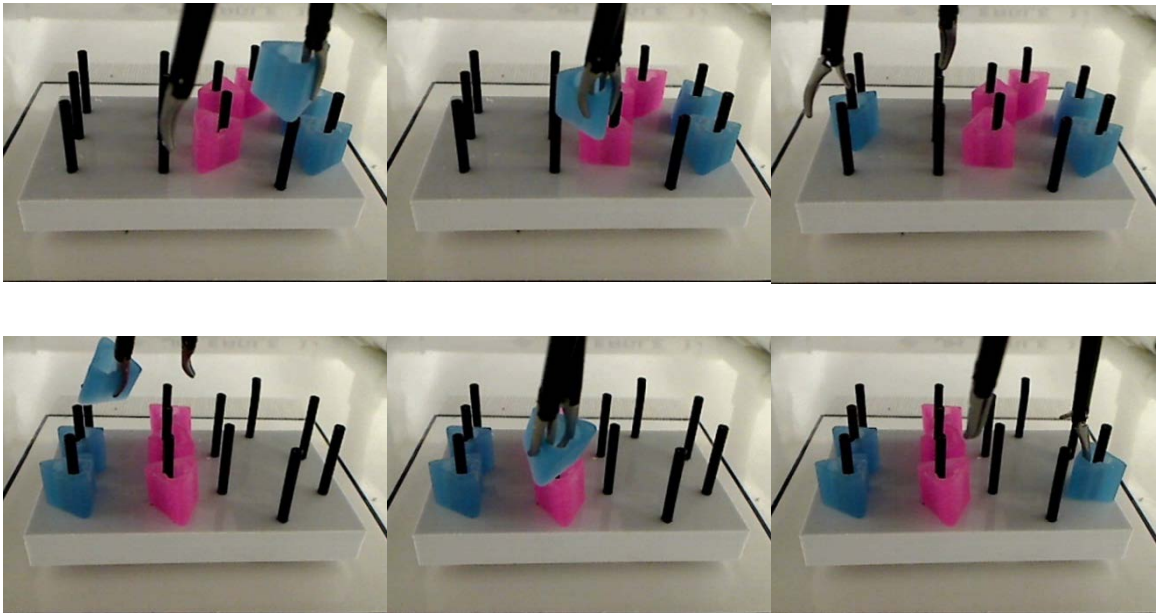


Figure 6.2: Phase 1 (top) and Phase 2 (bottom) of the Peg Transfer Task as Performed by a Right-hand Dominant Individual in a LESS Test-bed

Both speed and accuracy are critical components of task performance. Speed was assessed by calculating the time-on-task, which was the elapsed time between when the participant touched the first peg and when the twelfth peg is placed on its pole. Accuracy was judged by annotating the number, type and time that errors occurred. A recoverable error was defined as a dropped peg within the field of view. In this case, the participant could “recover” from the error by picking up the dropped peg with the same hand that dropped it, and continue the task at the point of the drop. A more serious error, an unrecoverable error, occurred when the participant dropped a peg outside the field of view. In this case the peg could not be replaced and was omitted for the rest of the task trial. The task was reset at the completion of each trial with all six pegs starting on the

non-dominant instrument side of the pegboard. Although the pegs always began on the participant's non-dominant instrument side, due to the instrument transposition in LESS the pegs were initially positioned on the opposite side of the board. For instance, if the participant was right-hand dominant the pegs would begin on the left side for conventional laparoscopy and on the right side for LESS. Regardless of the initial positioning of the pegs, phase 1 began with an initial grasp with the non-dominant instrument.

#### ***6.3.4 Procedure***

University Institutional Review Board requirements were followed throughout the conduct of this study. The experimental procedures were explained to each participant prior to the start of the study. Participants wore non-latex gloves in a self-selected size, and the simulator height was adjusted to each participant's standing elbow height. The participants were shown the FLS peg transfer video demonstration followed by verbal instruction using the FLS proctor script (SAGES/ACS, FLS Program, Los Angeles, CA, USA). Then, each participant completed a 5-minute hands-on familiarization period using the conventional laparoscopic ports. A within-subjects study design was used whereby each participant first completed the task using conventional laparoscopy, followed by randomized completion using each of the three LESS ports. Randomization of the three LESS ports was counterbalanced to minimize order effects. It was assumed that the unfamiliar nature of the task, simulation test-bed and laparoscopic instruments would be overcome through the five minute familiarization period and initial task performance using conventional laparoscopy. Accordingly, the comparative evaluation focused primarily on the user's experience with the randomized LESS ports. In order to minimize

the effects of learning and fatigue, only one task trial was completed for each port and a rest period of five minutes was given between each trial. Lastly, a questionnaire with two parts was given to each participant. Part one of the questionnaire was administered directly following task completion (i.e., post-trial questionnaire) for each port, and part two was administered at the conclusion of the study (i.e., final questionnaire).

Both time-on-task and errors were recorded using a digital event marker (IS2 Ident Switch, DataLINK System, Model DLK900, Biometrics Ltd, Gwent, UK) at a sampling rate of 200/sec. The event marker was used to record when the participant began, completed phase 1, completed phase 2, and when errors occurred. Time and error data were extracted using the DataLINK software (Version 7.0).

### ***6.3.5 Experimental Design and Analytical Methods***

This randomized, controlled, crossover study utilized analysis of variance, logistic regression, Wilcoxon rank sum tests and chi-square tests. All statistical tests were performed using SAS (Version 9.2, SAS Institute Inc., Cary, NC, USA) at the 0.05 level of significance. The dependent variables were time-on-task, errors, success and ease of use. The independent variables were port (4 levels), task phase (2 levels), error type (2 levels), and gender (2 levels). Time-on-task was analyzed using a full-factorial analysis of variance with blocking on subjects. Based on the significant effects from the hypotheses tests using the Type III sums of squares, a post-hoc Tukey test was performed for significant main effects, and simple-effect F-tests were performed for any significant interactions. Contingency tables and chi-square tests were used to examine the associations among categorical variables. Logistic regression was used to model the

binary success variables. A generalized loglinear model using the Poisson distribution was used to model error counts.





## **6.4 Results**

### ***6.4.1 Time-on-task***

Time-on-task, which is a commonly used in both the clinical and engineering domains, was computed for the total duration of the peg transfer task and its phases. This quantitative performance measure provides insight into task speed, efficiency and the learnability of a product. In health care, it has been widely used to develop proficiency criteria and test clinical competency. Overall, the performance speed of the basic laparoscopic task required a similar amount of time using conventional laparoscopic and LESS ports (Table 6.1). There were no significant differences across ports for phase 1, phase 2 or the total task duration ( $p > 0.05$ ). Overall, the TriPort had the highest total mean time of 318 seconds, whereas the GelPOINT had the lowest at 277 seconds. Additionally, there was no significant time difference between phase 1 and phase 2 ( $p = 0.581$ ). During phase 1 of the task, the participant utilized their non-dominant hand to grasp and transfer the peg, while the dominant hand placed the peg into position. During phase 2, this procedure was reversed. It was expected that phase 2 of the task would be quicker than phase 1, because the participants were grasping and transferring with their dominant hand and may have become more familiar with the port during phase 1. Contrarily, trials with conventional laparoscopy, the SILS port and the TriPort each required more time during phase 2. In fact, the TriPort required 15 more seconds during phase 2, which was a much greater mean difference compared to the other three ports between phases. The GelPOINT required the least amount of time for both phases 1 and

2, and required less time during phase 2 than phase 1 of the task. However, the time-on-task differences did not reach statistical significance.

Table 6.1: Time-on-task

	Phase 1	Phase 2	Total
<p>LAP Ports</p> 	143.5 ± 68.4	150.2 ± 59.8	293.2 ± 124
<p>SILS Port</p> 	152.9 ± 64.3	153.9 ± 58.9	309.1 ± 112
<p>TriPort</p> 	154.6 ± 73.7	169.7 ± 76.2	318.3 ± 131
<p>GelPOINT</p> 	139.7 ± 46.0	136.8 ± 43.2	276.5 ± 81.2

Note: LAP = Conventional Laparoscopic, Mean ± Standard Deviation

### 6.4.2 Errors

Task accuracy was measured by annotating the type (recoverable or unrecoverable) and time (phase 1 or phase 2) each error occurred. Error evaluation provides insights into user and product performance, efficiency and underlying usability issues. Of the 96 total task trials performed across all participants and ports, there were 36 (37.5%) trials performed without any errors. Error-free trials were completed by 19 different subjects and were split equally among the four ports (i.e. 9 trials per port). Total error counts were computed by summing the number of errors committed by all participants for each port, task phase and error type. One participant (4.17%) committed no errors, 15 (62.5%) committed 1-4 errors, 6 (25%) committed 5-10 errors, and 2 (8.33%) committed greater than 10 total errors across all four ports. Overall, there were 100 recoverable and 28 unrecoverable errors (Table 6.2). There were significant interaction effects between error

Table 6.2: Errors frequencies by type and task phase

	Recoverable		Unrecoverable		Total
	Phase 1	Phase 2	Phase 1	Phase 2	
LAP Ports	13	14	0	7	34
SILS Port	14	13	4	4	35
TriPort	15	15	2	4	36
GelPOINT	7	9	3	4	23
Total	49	51	9	19	128

type and port as well as error type and task phase ( $p < 0.0001$ ). Total error counts for conventional laparoscopy, the SILS port and the TriPort were almost all identical at approximately 35, while the GelPOINT had considerably fewer total errors at 23. There were also more recoverable than unrecoverable errors with 55% (70/128) of all errors



occurring during phase 2. There was also a substantial increase of unrecoverable errors from 9 in phase 1 to 19 in phase 2. Overall, conventional laparoscopy, the SILS port and TriPort had similar distributions of recoverable errors and unrecoverable errors, whereas the GelPOINT had the fewest total and recoverable errors.

### ***6.4.3 Task Success***

Task success, a common usability metric, was determined to quantify the proportion of participants who were able to complete the peg transfer task according to predetermined performance criteria. According to the FLS program's manual skills curriculum, both speed and accuracy are critical components of task performance. Adapted from the FLS program's manual skills curriculum (Ritter and Scott, 2007), task success was defined as a time-on-task less than or equal to 300 seconds with no unrecoverable errors.

Accordingly, task failure was defined as task performance exceeding 300 seconds or at least one unrecoverable error. Task success based on time was 59.4%, whereas error success (i.e. no unrecoverable errors) was 77.1% across all ports (Table 6.3). Combining both success criteria, the overall task success rate was 45.8%, with conventional laparoscopy the least successful at 41.7%. This was expected since each novice participant's initial experience with laparoscopy and the peg transfer task occurred using the conventional laparoscopic ports. However, there were no significant differences across ports for time success, error success or task success ( $p > 0.05$ ). Time success showed a strong gender effect ( $p = 0.007$ ) where the estimated odds of time success was 3.3 times higher for males than for females after controlling for port type. Based on time success, the GelPOINT was the most successful of the four ports, yet its high frequency of unrecoverable errors resulted in a lower error success rate compared to the SILS port

and TriPort. However, the GelPOINT had the highest overall task success rate, which may indicate that its user interface best facilitates efficient and accurate aiming and grasping movements.

Table 6.3: Task success

	Time Success		Error Success		Task Success	
	Count	Percent	Count	Percent	Count	Percent
LAP Ports	15	62.5%	17	70.8 %	10	41.7%
SILS Port	13	54.2%	19	79.2 %	11	45.8%
TriPort	12	50.0%	20	83.3 %	11	45.8%
GelPOINT	17	70.8%	18	75.0 %	12	50.0%
Total	57	59.4%	74	77.1 %	44	45.8%

#### 6.4.4 Ease of Use

A questionnaire with two parts was administered directly following task completion (i.e., post-trial questionnaire) for each port, and at the conclusion of the study (i.e., final questionnaire). Ease-of-use was assessed in both questionnaires on a verbally-anchored Likert scale from 1-very difficult to 6-very easy. This scale followed a forced choice method without a neutral or undecided option. Due to low expected counts, the categories very difficult, difficult and somewhat difficult were combined into the category “difficult.” Similarly, the categories somewhat easy, easy and very easy were combined into the category “easy.” Post-trial ease of use differed significantly across ports with conventional laparoscopy more often rated as easy compared to each of the LESS ports (Table 6.4,  $p < 0.05$ ). Similarly, conventional laparoscopy was more often rated as easy compared to both the SILS port and TriPort on the final questionnaire ( $p < 0.05$ ).

However, there was no significant difference in ratings between conventional

laparoscopy and the GelPOINT, which were both rated more frequently as easy.

Interestingly, ease of use ratings increased after exposure to all four testing conditions for all LESS ports but not for conventional laparoscopy.

Table 6.4: Self-reported ease of use

	Rated as Easy	
	Post-trial	Final
LAP Ports	79.2%	79.2%
SILS Port	33.3%	41.7%
TriPort	37.5%	50.0%
GelPOINT	50.0%	62.5%

## 6.5 Discussion

As many human factors and ergonomics (HFE) professionals are aware, health care has been a focal point for quality and safety improvement efforts since the issuance of the Institute of Medicine's landmark reports in 2000 and 2001. These reports documented not only the system failures that resulted in nearly 100,000 deaths, but also a call to action for all stakeholders to transform the health care industry. As a result of this call to action, the National Academy of Engineering and the Institute of Medicine united to initiate a cooperative relationship between the engineering community and health care professionals towards improving the health care system (Reid et al., 2005). Although listed as a key engineering tool to improve the quality and safety of care (Reid et al., 2005), the diffusion and implementation of HFE tools and methods has been lacking (Carayon, 2010).

Recently, the United States Food and Drug Administration (FDA) mandated the use of human factors to “ensure that new medical devices have been designed to be reasonably safe and effective when used by the intended user populations” (CDRH Human Factors Team, 2011). The FDA’s revised guidelines promote “effective and focused human factors evaluation and good design practices for medical devices” (CDRH Human Factors Team, 2011). Although an excellent step forward, this current paradigm still does not address the dissemination of objective comparison data of medical products. As reported by the Emergency Care Research Institute (ECRI), there are few technology evaluation or head-to-head comparative assessment studies among product types and manufacturers (ECRI, 2004). As one of the only published studies of this kind, Burns et al. (2007b) determined that suture and endo-mechanical products made by different manufacturers do not have equivalent performance profiles, and that brand seemed to be the most important factor for physicians when evaluating different products. The authors determined that this suggests the value of conducting head-to-head comparisons of the same product from multiple manufacturers. Almost all other industries rely upon independent product reviews and testing, and yet medical products are still often selected based on brand, a hospital-supplier relationship or cost. Without unbiased evaluations of currently available medical products, health care providers and hospital staff cannot make informed decisions regarding the performance, equivalency or acceptability of products prior to purchasing and implementation (Szarmach et al., 2004; Burns et al., 2007a).

Consequently, the purpose of this study was to critically assess the three most prevalent LESS access ports to provide objective information regarding their relative performance and ease of use. Using a standardized task, four usability metrics were

quantified to assess the effectiveness and efficiency of each product. In order to best assess the products, a homogeneous group of novice, but medically competent, users were selected to minimize performance differences. In general, the GelPOINT facilitated efficient and accurate aiming and grasping movements as demonstrated by the quick task times, minimal errors, high task success rate, and ease of use ratings. For task duration, phase 2 of the task was faster than phase 1 for the GelPOINT, which was contrary to the other ports. It may be that task completion difficulty and fatigue were more dominant effects for conventional laparoscopy, the SILS port and the TriPort, since phase 2 of the task should have resulted in faster completion times due to an increased familiarity with the port and the primary use of the dominant hand. Alternatively, it may also be that the GelPOINT's design and user interface actually minimized fatigue, maximized efficiency and aided learnability. However, the effects of fatigue and learning were not investigated and further research is needed to confirm these hypotheses and preliminary findings. Moreover, the GelPOINT had substantially fewer total errors, but still had a similar amount of unrecoverable errors as compared to the other ports. Unrecoverable errors are more serious and may be indicative of patient and product safety. Since untrained medical students participated in this study further work is needed to confirm that these errors can be reduced or eliminated through an appropriate means (e.g., product refinement, user training, patient safety practices). Overall, the GelPOINT's user experience exceeded that of the SILS port and TriPort, and was comparable to that of conventional laparoscopy. The GelPOINT's effective and user-friendly design may enable conventional laparoscopic surgeons to more quickly transition to LESS by shortening the learning curve of this pioneering technique.

Although LESS represents the next logical step towards less invasive surgery, its patient benefits and best practices are currently unproven (Gill et al., 2010; Gettman et al., 2011). In order for LESS to become the gold-standard in minimally invasive surgery, it is imperative that this technique be critically evaluated, refined and standardized prior to universal adoption. This will ensure that the acceptance and implementation of LESS will occur in a coordinated and responsible manner based on scientific evaluation and objective data. To date there have only been a few studies that have evaluated LESS outside of the operating room (Brown-Clerk et al., 2011; Fransen et al., 2011; Miernik et al., 2012; Santos et al., 2011; Schill et al., 2012), and even fewer studies that have examined the human factors and ergonomics of LESS (McCroory et al., 2012; Montero et al., 2011; Tang et al., 2012). This research took one step towards the scientific assessment and standardization of single-incision surgery by conducting a formal comparative evaluation of LESS access ports using HFE techniques.

### ***6.5.1 Key Points***

- Competitive usability testing provides objective performance data to product users and unbiased feedback to product developers.
- Human factors and ergonomics principles and methodologies provide an efficient and effective means to determine equivalence of commercially-available medical products.
- In order to transform health care into a safe and high-quality industry, HFE tools and results need to be implemented and disseminated in a more systematic and widespread manner.

## CHAPTER 7

### Summary and Conclusions

#### 7.1 Summary and Conclusions

The development and testing of new techniques and technologies can be harmful to patients and health care providers. Accordingly, the overall objective of this dissertation was to conduct a robust and impactful analysis of minimally invasive surgery towards improving its quality and safety. To attain this objective, a theoretical perspective was presented and several experimental studies were conducted. As a basis for the experiments that followed, the research provided a link between the variability of human performance and the design and redesign of surgical technologies and processes. Next, multifunctional assessments were conducted in high-fidelity simulators to assess the performance, functionality, risk of error, workload, and joint kinematics of laparoscopic surgery instrumentation, practices and procedures. Key experimental findings include:

- 1) ergonomically designed electrosurgical hand controls integrated into a standard laparoscopic grasper optimized electrocautery functionality, improved safety and reduced surgeon workload by eliminating the use of foot pedals;
- 2) performance of basic laparoscopic skills was not more challenging, error prone, or perceived as more uncomfortable using LESS access ports compared to conventional laparoscopic ports;

- 3) LESS access ports required greater wrist radial/ulnar range of motion due to the close proximity of the instruments, restrictive nature of the devices, and the need to achieve adequate instrument triangulation and visualization; and,
- 4) the GelPOINT Advanced Access Platform's:
  - a) flexible design facilitated more accurate and efficient movements,
  - b) total user experience was comparable to that of conventional laparoscopy,
  - c) intuitive user interface was the most consistent platform for LESS performance and skill acquisition, which may enable a quicker transition to LESS by shortening the learning curve.

These results demonstrate that the unique multidisciplinary assessment approach taken in this research leads to a rigorous and comprehensive assessment of laparoscopic surgery producing high-quality evidence-based data to improve medical devices, operative performance and patient safety. These results also demonstrate that medical simulation provides an optimal environment to safely, reliably and economically develop and assess surgical technologies, practices and procedures prior to implementation. Additionally, this work is the first research to examine the human factors and ergonomics of the pioneering technique LESS. Lastly, these findings warrant attention from health care professionals, medical device manufacturers, engineers, researchers and policy makers to further develop, evaluate and standardize minimally invasive surgery techniques and technologies.

The theoretical and experimental findings presented in this dissertation directly align with the Institute of Medicine's mandate for engineers and health care professionals to cooperatively transform health care into a safe, effective, timely, patient-centered,



efficient and equitable system (IOM, 2001). Specifically, this research provided tangible contributions towards the improvement of the minimally invasive surgery operative environment, surgeon performance and patient outcomes. In all, this innovative work represents a significant step towards improving the quality and safety of minimally invasive surgery.

## **7.2 Future Work**

As the next frontier of minimally invasive surgery, the technical challenges and safety concerns of LESS must be overcome. Although medical device manufacturers have quickly embraced LESS and rapidly produced novel, repurposed and redesigned surgical equipment, there have been limited published studies on the human factors and ergonomics of these devices and their potential effects on the surgeon, surgical performance and patient safety. Additionally, the influx of these highly complex technologies may be increasing the risk of operative error due to misunderstanding and misuse. In the near future, it will be critical to develop, assess and validate LESS-specific practices and technologies that improve operative performance, mitigate potential errors, and enable all laparoscopic surgeons to safely perform this pioneering technique.

The work presented in this dissertation provides the foundation from which to systematically assess LESS techniques and technologies, and to develop tailored instrumentation and training programs that enable a safe and quick transition to LESS. From this work the following two major research areas should be attended to next:

- 1) the development of LESS-specific technologies (e.g., access devices, hand instruments, etc.) that optimize performance and enable current laparoscopic surgeons to transition to LESS in a safe and responsible manner; and,
- 2) the development and validation of a LESS-specific training program tailored to varying levels of surgical experience and multiple surgical disciplines.

Integral in both of these two research areas is the omnipresent need to standardize LESS by validating its best practices based on scientific evaluation and objective data.

For the first research area, work is currently underway to develop novel LESS-specific instrumentation using user-centered design principles. Based on the previous evaluations of the LESS access ports, the aim of this work is to create a more effective, efficient, flexible and user-friendly device that better facilitates instrument triangulation, retraction and visualization. Inherently, the development of medical devices requires a thorough understanding of the environment, user requirements, usage and limitations, which can be a daunting and time-consuming process. However, the development of these enabling-technologies will allow current and future LESS surgeons to deliver a safe, high-quality and less invasive surgical intervention, while protecting themselves from occupational discomfort, fatigue and possible injury.

The second research focus utilizes this research's existing LESS simulator to create and validate a LESS-specific training program geared towards multiple surgical disciplines and experience levels. This program will include training tasks specific to LESS, tasks of varying difficulty to aid novice skill acquisition and expert transition, and procedure-specific tasks to mimic operative performance. Currently the Fundamentals of Laparoscopic Surgery (FLS) program focuses primarily on general surgery; however the

scope of the LESS training program will include urological, gynecological and general surgery tasks. Additionally, the training program will include real-time feedback and teamwork components. Once the LESS training regimen and curriculum have been established it will be necessary to assess and demonstrate the reliability, validity and effectiveness of this program. Program assessment areas will include, but are not limited to proficiency, retention and the impact on operative performance and patient outcomes. Overall, this focus area's long-term research goals include the development and validation of a LESS-specific training program for surgical residents, a transitional training program for practicing laparoscopic surgeons, a competency assessment and certification program, and a continuing education program for certified surgeons. The expected outcomes of this future research are the development of enabling LESS technologies and simulation-based LESS training model. Gains towards both of these goals will disseminate evidence-based information for training and procedural standardization, which will minimize threats to patients and surgeons.

## CHAPTER 8

### Bibliography

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