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AN INVESTIGATION OF MEDICAL DEVICE DESIGN AND PHYSICAL ERGONOMICS IN HEALTHCARE

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Human factors and process engineering are becoming a prominent area of research and application for industrial engineering principles as healthcare providers seek to improve patient safety, quality the optimization of resources. Human factors engineering and ergonomics play a crucial role in the pursuit of operational excellence and patient safety in healthcare. These disciplines contain the tools required to develop instrumentation, technology and training that can improve the usability of medical technology and the quality of care that patients receive. Designing tasks, tools and processes for optimal human use can enhance performance, reduce errors and improve safety. This thesis encompasses three journal articles. The first paper addresses how physical ergonomics can be used to evaluate and improve skill acquisition in endotracheal intubation. Significant differences in muscle utilization and wrist postures were observed between experience levels and genders of clinicians. Differences in muscle utilization and wrist postures were found to be significantly related to instrument grasp characteristics, identifying potential ergonomic best practices. The second paper investigates the mechanical design of laparoendoscopic single-site (LESS) surgical ports from a human factors perspective. This study characterized the differences in resistance

and range of motion afforded by each LESS port during simulated single-incision use. The resistance of each port varied significantly with respect to instrument positions. The final paper explored each LESS surgical port against standard laparoscopy by using a validated laparoscopic training task to assess the usability and performance of each device. Instrument mobility was restricted by the LESS ports, but it did not affect task performance significantly. While each device exhibited positive and negative human factors attributes for clinicians and patients, it was concluded that procedural factors rather than device familiarity should influence LESS port selection.

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1. INTRODUCTION

Human factors engineering involves the investigation of how humans interact with tools, systems and processes to optimize both system performance and human well-being. This field includes applications of the tools and knowledge from the fields of physiology, psychology, engineering, design, statistics and a variety of other technical and non-technical fields. Through the use of these tools, human factors engineering provides the ability to improve productivity, safety, and quality by understanding how humans interact with the people, technologies, environments and processes in which they are surrounded. Physical ergonomics is the specific study of understanding how environments, processes and products affect human comfort and performance and the examination of the capacity of the individual(s) compared to the demands of the job. Applications of the principles within physical ergonomics study can range from the understanding and derivation of standard work within industrial operations and processes to the design and testing new consumer products.

Through the use of human factors and ergonomic engineering, there is an opportunity to develop products and processes which originate from a clear understanding of the role and requirement of the user. This approach, referred to as user-centered design, evaluates human usability against the criteria of effectiveness, efficiency and satisfaction; examining how well a system or product allows a user to achieve their goals, the resources required to achieve the end result, and the sentiment that the end user has toward the solution. Once a clear understanding of the context of use and expected nature of the user is defined, the ISO 13 407 Usability Model can be applied to

systematically create products and processes that focus upon the usability of the end user throughout the entire development cycle (ISO 13 407, 1999). This iterative process (planning the human centered process) coordinates the design of products or processes around the context of human use, beginning with an understanding of the users, tasks and environments for required use. The next step in the process requires that the organization and user requirements be defined within specific reference to the context of use previously defined. From this point, design solutions are generated and evaluated against user context and user/organization requirements until an optimal design emerges based upon end-user usability testing. By applying user-centered design methodology, companies can ensure that their products meet the expectations and desires of their customers, and that business or manufacturing processes are designed to optimize safety, quality and productivity.

Understanding and applying user-centered design requires a clear understanding of users and objectives, which may not always be immediately intuitive to business or organizational requirements. Within manufacturing or healthcare, the customer for a process may be a warehouse, laboratory, downstream process or the end user itself. However, when applying user-centered design to optimize human performance and productivity, the temptation to optimize toward downstream customers and users will fail to develop exemplar processes for the immediate customer, the user within the developing process. Within the design of medical devices, there may be multiple users or customers affected by the design of a process or a product; the user-centered design process must consider the requirements and context of a variety of users to capture a full

understanding of usability. Within training, user-centered design must similarly be sure to focus upon the context and requirements of the trainee, understanding tasks, environments and constraints from the point of view of the clinician learning the process. While broad in its application, the ability to clearly define the user and their requirements for a process or product is crucial in the successful implementation of user-centered design.

Technological advancements, operational improvements, and a growing body of awareness and knowledge of patient safety create ample opportunity to apply the principles of human factors engineering and user-centered design within healthcare. The interaction between humans and equipment is vital in patient safety and healthcare quality. Technology or processes developed without an understanding of users, contexts and requirements can lead to mistakes, patient injury, clinician anxiety or stress, and the improper use or underutilization of technology. In these instances, workarounds are developed, the consistency of care and human performance are compromised. Medical equipment and processes need to be designed with high usability and proper ergonomics, adapting the device to the human, the task and the environment.

1.1 THESIS OBJECTIVE

The application of human factors engineering principles to processes and product development within healthcare provides an opportunity to optimize clinician development and performance through user-centered analysis. The specific objectives of this thesis were to evaluate the use of existing and new medical devices and procedures from a usability and physical ergonomic standpoint. Within this objective, physical

ergonomics was used to examine how medical device usability and performance differed between clinicians of varying experience levels within a difficult and critical clinical procedure. By focusing upon the specific postures associated with different user groups, this investigation provided insight into how clinicians adapt to instruments and procedures where user-centered ergonomics best practices have not yet been defined. Additionally, the procedure within the endotracheal intubation study relies heavily upon traditional instrumentation which lacks ergonomic innovation in design.

Conversely, the second portion of this research focuses upon the relationship between emerging medical device technologies and human usability. Technological innovations have significantly altered surgical tools procedures, increasing the complexity and user requirements during minimally invasive surgery. While clinical outcomes and patient benefits have been initially explored (White, et al., 2009; Rivas, et al., 2010), a lack of data exists regarding the human factors and usability considerations for these new surgical devices. As such, human factors engineering provided an opportunity to evaluate the impact of the design of a medical device has on the usability and task performance for minimally-invasive surgeons.

2. HUMAN FACTORS IN HEALTHCARE AND MEDICAL DEVICES

2.1 MEDICAL DEVICE DESIGN & TECHNOLOGY

Advancements in device, information and systems technology have rapidly changed the environment and delivery of care within modern medicine. In many instances, the integration of technology into procedures and management has elevated the capabilities

of clinicians and improve the healthcare delivery process. Information technology and intelligent devices have modernized the communication of information and tracking of patients within hospitals and medical clinics. Medical devices provide clinicians with instantaneous information, reminders and warning signals. The use of information technology has provided better visibility into patient condition and increased rapidity in the transmission of information between departments and resources. To optimize the use of such technologies within modern, complex hospital environments an understanding of user requirements and environments for device use is required to verify that technology can be used safely, effective and intuitively.

Similarly, the rapid advancement of medical device technology is changing the way that clinical procedures are developed, taught and performed. Imaging technologies have provided hospitals with the ability to accurately investigate, analyze and diagnose patients without the need for exploratory surgery or invasive procedures. Advancements in medical devices have also transformed the operating room with the adoption and evolution of minimally invasive surgery. The development of laparoscopic cameras and instrumentation have drastically altered surgical best practices as procedures are transitioned and validated through minimally invasive surgery technologies. Minimally-invasive technology provides patients with improved cosmesis, reduced post-operative pain, a reduction in tissue damage and a decreased hospital stay (Ganpule, et al., 2009). Laparoscopic technology and minimally-invasive surgery also benefit hospital operations by reducing post-operative inpatient stay and improving the accuracy and reducing the

complication rates of some surgical procedures (Ganpule, et al., 2009; Hansma, et al., 2004; Langwieler, et al., 2009; White, et al., 2009).

2.2 HUMAN FACTORS ENGINEERING & USER-CENTERED DESIGN

Innovations in medical technology provide clinicians with improved methodologies and information, however proper application of human factors principles is required to leverage clinical technology into improved patient safety and healthcare quality. Without proper human factors analysis, the integration of technology into medical devices, systems and clinical procedures can impose additional requirements upon the user. The use of cognitive and physical ergonomics provides an opportunity to design medical devices and systems that allow for optimal human use.

Increases in information technology can increase the complexity and accessibility of this information, as well as creating opportunities for information error between devices, systems and the user (Murff, et al., 2001). Human factors engineering plays a critical role in understanding human usability within the context of clinical environments, medical procedures and information systems. The correct interpretation of information from a medical device or system has been found to be improved when the communication from the device corresponds appropriately and intuitively with the type information being conveyed (Murff, et al., 2001). For example, visual and auditory alarms need to communicate through sound, shape and color in a manner that is intuitive to the user and the situation. To provide value and improve human performance within a complex system and environment, human-machine/device interfaces and alert systems must be

designed with a well-defined understanding of usability, environments and human requirements (Murff, et al., 2001).

Similarly, the design and usability of physical devices within medicine requires comprehension of user requirements and environments. Advancements in medical device technology resulting in significant changes in medical procedures can improve clinical outcomes and patient satisfaction, however, the usability of the device for the clinician must be balanced against clinical benefits of new devices and procedures. In the case of minimally invasive surgery, advancements in device technology radically changed the tasks and equipment used for common medical procedures. Adopting new surgical techniques such as laparoscopy requires the surgeon to adapt to the use of endoscopes and laparoscopic instrumentation; which are significantly different from the scalpels, hemostats, retractors and cautery tools used in open surgery. In addition to new instrumentation, the surgeon must also adapt to work using instrument triangulation to access the surgical field, through the use of cameras and mounted two-dimensional monitors within the operating room. As such, laparoscopy requires significant training and practice to develop instrument control and the required hand-eye coordination necessary to safely perform surgical procedures. Therefore, the development of user-centered tools is critical to the successful adoption of new skills and procedures for surgeons.

Laparoendoscopic single-site surgery (LESS) procedures elevate the user requirements compared to standard laparoscopy. The development of LESS surgical ports provides surgeons with a single mechanical passageway, typically inserted into the umbilicus,

through which all surgical instrumentation and cameras must be inserted. LESS ports must contain mechanisms for inserting surgical instrumentation while maintaining insufflation of the abdomen, without severely restricting the movement or mobility of each laparoscopic instrument. Additionally, all instrumentation must cross the transverse and sagittal plane within the LESS port, resulting in inverted controls of each instrument as well as the camera. Consequently, significant user-centered design efforts are incorporated into the development of LESS instrumentation, creating articulating devices that seek to overcome the inherent challenge of transposed instrument positions. Alternatively, the markedly varying design of LESS ports suggests that user-centered design understanding and incorporation may vary significantly between medical device companies. Device manufacturers reference the ease of insertion, retraction and accommodation of varying incision diameters and depths; all parameters characteristics of patients and procedures. Little emphasis has been given toward the usability of each device for the surgeon, and the opportunity exists to classify how each LESS port impacts instrument mobility and task performance.

According to the U.S. Food and Drug Administration (FDA), a majority of reported clinical adverse events are the result of medical device quality or usability flaws (U.S. Food and Drug Administration, 2011). Increasing competition, tightening profit margins and cost reduction requirements restrict product quality within medical device design and manufacturing, which constrains the ability to develop and validate user-centered devices. The FDA listed significant opportunities to improve device quality and usability, which included incorporating human factors engineering and reliability and

manufacturability focuses into product development and design. Difficulties were noted in designing and validating devices for a wide variety of applications and environments; recognizing the gap between laboratory and clinical validation. The disconnect between engineering design, laboratory testing and environmental use represents a significant opportunity to apply human factors principles into the design and validation process.

Consequently, the application of human factors engineering is required if manufacturers and providers wish to leverage technological advancements into demonstrated improvements in operations, costs and healthcare quality. The journal articles presented represent the type of analysis and information that can improve the use of existing medical devices as well as the validation of future technologies. A detailed study of users, usability and environments, human factors engineering provides the opportunity to understand how devices and systems impact human performance. Through the identification of best practices and physical ergonomic considerations, this thesis illustrates the improvements that can be made to medical device usage and design.

3. SUMMARY OF THESIS PAPERS

3.1 PAPER I – Physical Ergonomics and the Effect of Practitioner Experience during Simulated Endotracheal Intubation

Endotracheal Intubation (ETI) is an airway procedure commonly used to secure the airway for a variety of medical conditions. The procedure is commonly performed preoperatively within anesthesia and preventatively in emergency and internal medicine

when a patient's condition requires assisted ventilation due to illness or injury. Additionally, ETI procedures are often required emergently both within the hospital and in pre-hospital settings. In situations of cardiac arrest or trauma, successfully performing ETI procedures are a critical skill for anesthesiologists, certified nurse anesthetists, paramedics and emergency medicine physicians. Complications arising during ETI procedures can result in esophageal intubation, soft tissue damage or dental trauma, and asphyxiation due to fluid or other blockages within the airway. Such complications are typically the result of insufficient clinical experience, difficult airways or patient anatomy, and incorrect instrument usage. In controlled (pre-operative) settings, complications during ETI procedures resulting in failed endotracheal tube placement are often non-critical; however, complications during emergent intubation procedures are often linked to significant patient morbidity or mortality (Berkow et al., 2009; Smale et al., 1995, Smith et al., 2011).

Proficiency in ETI procedures requires significant clinical experience and task exposure, with varying successful procedures required to gain competency within respective medical fields. Within anesthesia and emergency medicine, training for ETI procedures has often followed the apprenticeship model (see-one, do-one, teach-one) within a live environment, where medical residents are instructed and supervised by attending physicians. Recent studies (Ti, et al., 2009) have shown that incorporating clinical simulation-based training and alternative instruction methods can improve skill acquisition and retention. The use of standardized training within a simulated setting

may also provide and environment more conducive to instruction and training, while improving patient safety and reducing complications related to ETI errors.

The apprenticeship model of skill acquisition within ETI procedures often overlooks human factors and ergonomic best practices, focusing primarily upon patient position and procedural steps (Levitan, et al., 2000; Vozenilek, et al., 2004). Previous research has evaluated the relationship between experience, gender, intubation ability and the lifting forces generated with the laryngoscope (Waddington, et al., 2009; Bucx et al., 1992; McCoy et al., 1996), however, insufficient data currently exists describing the physical ergonomics of successful direct laryngoscopy. Researchers were interested in quantifying the specific wrist postures and muscle utilization rates of a varied population of clinicians (gender and experience) to determine which variables may specifically characterize successful and unsuccessful intubation attempts.

The research objectives of this study was to examine the specific influence of experience level, participant gender and hospital bed heights against ETI completion time, ETI attempts and error rates. Furthermore, researchers used these dependent variables to investigate trends within wrist flexion/extension, wrist radial/ulnar deviation, and forearm supination/pronation during ETI trials using surface-mounted goniometer and torsiometer devices. Understanding that significant lifting force is required during ETI trials and that wrist postures may correspond to muscle exertion, the utilization of the flexor carpi radialis (FCR), extensor carpi radialis (ECR), bicep brachii and anterior deltoid were observed using surface-mounted electromyography sensors.

The participant population included novice and expert clinicians from the University of Nebraska Medical Center, which were differentiated by their exposure to ETI procedures. 16 Novice participants (9 male, 7 female) were selected from the UNMC College of Medicine, and 5 expert participants (4 male, 1 female), serving as attending physicians, were recruited from the Department of Emergency Medicine. After receiving an overview of the instrument, manikin and the procedure, participants used a standard laryngoscope and a blade to perform ETI trials on an airway manikin trainer at two standardized hospital bed heights (96 and 62 cm). Participants were evaluated based on ETI time, attempts, and error as well as wrist postures and muscle utilization gathered through the use of the goniometer/torsiometer and EMG equipment. Maximum voluntary contractions were recorded for each muscle on all participants to analyze the proportion of maximum effort demonstrated during the trials.

Expert participants completed ETI trials more rapidly than novice participants, while committing significantly fewer errors. Contrary to initial hypotheses, the setting of the hospital bed height had little effect on task completion time, error rates or muscle utilization within participants. Expert participants (male) exhibited less ulnar deviation and forearm supination during task trials than novice participants (male). Female participants (novice) required significantly greater muscle utilization during ETI trials when compared to men of equal experience level. Errors due to incorrect laryngoscope position were significantly related to wrist postures and muscle utilization for both genders, and improper hand and arm positions resulted in suboptimal muscle utilization and increased wrist deviation from neutral.

Additionally, significant differences in wrist postures and muscle utilization were found to be associated with three distinct grasp styles of the laryngoscope. Blade-style grasps were characterized by increased ECR, bicep brachii and anterior deltoid utilization, as well as a reduction in forearm supination. Mid-handle grasps were characterized by a reduction in ulnar deviation compared to distal and blade-style grasps. Distal-style grasps were characterized by an increased utilization of the FCR muscle, increased forearm supination and decreased wrist extension. Expert participants adopted blade and mid-handle grasps, characterized by an in-line orientation of the laryngoscope and the left forearm. Proper laryngoscope grasp and instrument positioning among novices was found to minimize awkward wrist postures and higher and improper muscle utilization.

Using human factors engineering principles, researchers were able to characterize the specific wrist postures and muscle utilization corresponding to clinicians of differing genders and experience levels while completing identical procedures. The data obtained from this study suggests that a set of best practices may be developed to for laryngoscope grasps. By encouraging ergonomic best-practices in hand and arm postures during ETI training, the opportunity exists to both improve patient safety and reduce the learning curve associated with ETI procedures.

3.2 PAPER II – Evaluation of Instrument Dexterity and Static Resistance of Laparoendoscopic Single-Site (LESS) Surgical Ports

Laparoendoscopic single-site (LESS) surgery is an emerging surgical technology that leverages the cosmetic benefits of laparoscopic surgery by introducing multiple instruments through a single surgical port. Unlike standard laparoscopy, single-incision surgery triangulates the surgical target using transposed instrumentation, which cross within the surgical port. The LESS ports are designed to be inserted within an incision in the umbilicus, maintaining insufflation of the abdomen while allowing an access port for surgical instruments and cameras to be introduced into the abdomen. LESS procedures have been assumed to present several benefits over standard laparoscopy, including a reduction in postoperative pain, a decrease in surgical recovery time and the improved cosmetic appearance of a “scar-less” laparoscopic surgery.

From a human factors perspective, LESS surgical procedures have been found to increase the duration of laparoscopic procedures, while limiting the mobility and access points for surgical instrumentation. In addition, surgeons must struggle with completing familiar procedures using transposed instruments, requiring the alteration of the common hand-eye and instrument coordination in standard laparoscopy to LESS. Given the narrow incision criteria (25-60mm) and multiple instruments introduced through the LESS port, it is hypothesized that LESS surgical ports may also present additional challenges to surgeons in the form of LESS port resistance and instrument mobility limitations. Despite the increasing application of LESS port technology, there is a lack of data on instrument dexterity and interface resistance with respect to the available LESS ports a surgeon may

select. Because the design of these surgical ports varies so significantly, a comparative analysis was conducted to characterize the force required to maneuver laparoscopic instruments at various working angles within three commercially available LESS ports. A novel test fixture was created where working angles of the instruments were systematically varied in both the horizontal and sagittal plane within several insert interfaces. To simulate the effect of varying patient body-mass-index, two inserts were created out of synthetic abdominal suturing pad to contain the LESS ports at thicknesses of 15mm and 30mm. To evaluate the resistance of the LESS port in isolation, a rigid interface with a 25mm hole was created. Two standard 5-mm laparoscopic graspers and a 10-mm simulated laparoscope were inserted into the trocars of the SILS™, TriPort™ and GelPOINT™ LESS ports. The positions of the laparoscope and grasper were fixed, while the working instrument's position was systematically varied to create a range-of-motion. The static force required to maintain a specific position for working instrument was measured against the fixed instrument using a digital force gauge for various included angles for all three ports

The resistance created by each LESS port was most noticeable at greater separation angles. The position of the stationary instrument (position from center) had a lesser effect that the absolute separation between the instruments (separation angle), however, moderate separation of the instrument did require greater force when the stationary instrument was introduced at angles greater than or equal to perpendicular to the LESS port. The orientation of the working instruments in relationship to the transverse plane did not have a significant effect on the forces required to maintain instrument positions.

The GelPOINT™ provided the least resistance to instrument movement at all separation angles, and the benefit in mobility afforded by this LESS port was more apparent at greater separation angles. The SILS™ port exhibited minimal resistance to narrow and moderate movements of the instruments and performed well within the 15mm skin insert, despite being the most difficult to insert into the simulated fascia. The TriPort™ LESS port required the greatest amount of force at all angular positions and exhibited significant resistance to maintaining instrument positions at extreme working angles. Lastly, each port exhibited increased resistance with the 30-mm thick skin interface as compared to the 15-mm thick skin interface.

Resistance created by each LESS port increased with greater angular separation, as expected. Increased thickness and rigidity of the abdominal wall resulted in greater static forces and reduced instrument range-of-motion for all surgical ports. LESS port design and geometry heavily influenced overall instrument range-of-motion, as well as the resistance found at extreme separation angles. Due to the variations in design and significant performance differences at wide separation angles or extreme working positions, surgical port selection may be best determined by considering the incision size, target location and instrumentation required during LESS procedures. This research provides data to assist in that selection, specifically, by considering the degree of instrument mobility required and the features and benefits of each LESS port, surgeons have the opportunity to improve patient safety through an understanding of their own needs and requirements and selecting the instrumentation that enables them to perform LESS procedures with the minimum discomfort and ergonomic compensation.

3.3 PAPER III – Laparoendoscopic Single-site (LESS) Surgery Versus Conventional Laparoscopic Surgery: Comparison of Surgical Port Performance in a Surgical Simulator with Novices

As previously introduced, LESS is an emerging surgical technology which requires significantly different instrumentation, processes and human factors considerations. Despite the feasibility of LESS procedures, the methodology presents numerous technical challenges not experienced in conventional laparoscopy. The adoption of LESS procedures and instrumentation has been accelerated by the entrance of several single-port commercial devices. Due to the unique human-factors requirements associated with LESS procedures, a study was design to evaluate technical performance of LESS ports against conventional laparoscopy using a modified Fundamentals of Laparoscopic Surgery (FLS) simulator.

To evaluate task performance in a simulated environment, twenty-four novice participants were recruited to complete the FLS peg transfer task using conventional 5-mm laparoscopic graspers. Standard 12-mm trocars and 15-mm synthetic skin were used to simulate conventional laparoscopy, which was evaluated against single-incision procedures using the SILS™ Port, the TriPort™ Access System and the GelPOINT™ LESS ports. Completion of the peg transfer task was performed initially using conventional laparoscopy for all participants, followed by performing the task using a randomized sequence of LESS ports. Trial performance and LESS port evaluation were determined by examining task completion time and error rates, as well as through the use

of a subjective questionnaire. To determine the overall task performance for trials, a standardized process developed by FLS was used to calculate trial score based upon task completion time and error rates.

Procedure methodology (conventional laparoscopy or LESS) failed to reveal significant differences in task score, illustrating that among novice participant, initial task completion performance did not differ between standard laparoscopy or LESS methodologies. Trials performed using the GelPOINT™ and SILS™ Port revealed similar task performance results. Trials in which participants began by using the TriPort™ were characterized by the largest performance increase as participants moved to other LESS ports. Conversely, the performance when starting with either the SILS™ Port, or the GelPOINT™ resulted in much more consistent trial performance over all three ports. Trials in which participants began with the TriPort™ also resulted in the lowest overall trial task score ($p < 0.05$). The subjective assessment by participants revealed no significant difference in either task difficulty or instrument maneuverability between any ports. Alternatively, conventional laparscopy and the GelPOINT™ LESS port were ranked higher in ease-of-use and overall rank when compared to the SILS™ Port, the TriPort™ LESS ports.

Initial results suggest that novice participants, who are unfamiliar with standard laparoscopy or LESS procedures, did not exhibit significant performance differences between surgical methodologies. The differences in form and function between the LESS ports revealed that the TriPort™ may be more difficult to use than other LESS ports, resulting in a low initial score. The SILS™ port and GelPOINT™ system offered

consistent performance and ease-of- use for novice participants compared to the TriPort™, and the GelPOINT™ system demonstrated the greatest consistency in task performance especially for novice participants. As a result, it may be concluded that LESS port selection could influence skill development and task performance as novice clinicians adapt to single-incisions procedures.

4. CONCLUSION

By understanding the relationship between the user and the task, human factors engineering can help to improve the quality of human performance, the accuracy in skill development, and the usability of new devices. Based on this study, it was determined that medical tools without a user-centered design will result in user adaptations and work-around solutions within clinical procedures that may not be intuitive to novice participants. In such instances, it may be beneficial to incorporate ergonomic best practices to ensure that skill development is characterized by optimal instrument usage. By defining and communicating ergonomic best practices, an opportunity exists to improve task performance and learning among novice participants.

These studies have also shown that variations in product design can create significant differences in device usability and performance testing. Skill acquisition and ergonomic challenges could both be improved during LESS procedures through the use of user-centered design and a clear understanding of how usability of a

device can impact human performance from the onset of product or process development. Through the use of usability testing and human factors engineering, devices and processes can be aligned to optimize human performance by encouraging intuitive use and eliminating design characteristics likely to result in usability issues and physician compensation.

Consequently, the knowledge and application of human factors principles provides the framework for increasing patient safety and healthcare quality by adapting tasks, procedures and instrumentation to fit the context and requirements of the user. Through usability analysis and ergonomic study, the capability exists to optimize user human capital, reduce avoidable errors and improve system performance within healthcare.

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6. FULL-LENGTH PAPERS

6.1 PAPER I – Physical Ergonomics and the Effect of Practitioner Experience during Simulated Endotracheal Intubation

Physical Ergonomics and the Effect of Practitioner Experience during Simulated Endotracheal Intubation

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1. Introduction

1.1 ETI Overview

Proficiency in endotracheal intubation (ETI) requires significant training and real world experience, as errors are frequent and potentially life threatening. Training, teamwork and difficult air-way management are paramount concerns in the field of intubation training and practice (Casey, Smally, Grant & McQuay, 2007). Because of the inherently chaotic environment of emergent situations, personnel proficiency performing intubation procedures can range widely. ETI procedures are typically performed by nurse anesthetists and resident and attending physicians within anesthesiology and emergency medicine departments.

Specific postures and practitioner ergonomics are not universally defined within intubation training, and instruction typically follows the apprenticeship model of "see one, do one, teach one" within a variety of medical fields (Vozenilek, Huff, Reznek, Gordon, 2004). Identifying best practices in intubation postures could shorten the time to proficiency, improve ETI success rates and reduce ventilation time in both emergent and controlled intubation situations while also providing objective metrics for intubation teaching and learning.

1.2 ETI Procedures

To initiate ETI, the clinician uses their right hand to maintain the patient's head, neck and atlanto-occipital joint positions while operating the laryngoscope with their left hand. Accurate placement of the endotracheal tube requires that the clinician be able to expose

and visualize the vocal chords of the patient by placing the laryngoscope at the base of the epiglottis and applying force along the axis of the laryngoscope. Once the vocal chords are exposed, the endotracheal tube is then inserted beyond the trachea under direct vision, until a mid-trachea depth is achieved. Mid-trachea depth varies based upon patient anatomy, however in adult patients this depth is typically 21-23cm beyond the teeth. At this point, the endotracheal tube cuff is inflated, protecting the lungs from aspiration while allowing for ventilation to begin. Figure 1 illustrates the proper insertion of the laryngoscope at the base of the vallecula, the ideal force vector for lifting force and the optimal insertion depth of the endotracheal tube (ETT).

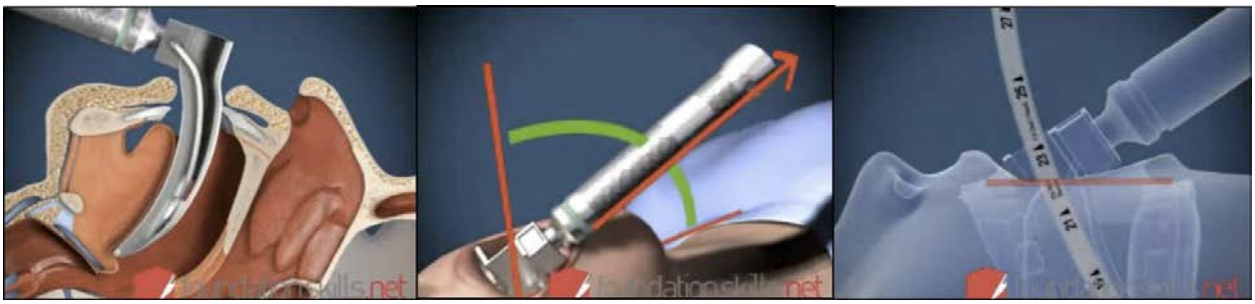

Figure 1 – Laryngoscope and Style Position (Foundationskills.net, 2011)

1.3 ETI Complications & Risks

Intubation success rates, occurrence of errors and instances of complications vary significantly across patient conditions and intubation environments (Smale, et al.,1995). In a 2006 study, blunt trauma was the leading adverse event experienced by patients during ETI procedures (Casey et al., 2007). Intubation failure rates of .13% - .30% and difficulty rates of 1.10% – 3.80% exist even in the controlled environment of the

operating room (Crosby et al., 1998). The consequences of intubation complications are most severe in respiratory failure situations, and the inability to intubate and ventilate in such situations often results in patient morbidity and mortality (Berkow et al., 2009). Other ETI related complications include aspiration, anoxic brain injury, and fluid or blood in the airway (Smale et al., 1995; Smith & Dejoy, 2011).

1.4 ETI Training

Traditional intubation training involves a combination of didactic and experiential learning (Stewart, et al., 1984). Clinicians acquire ETI skills within the scope of their respective medical functions, and it has been observed that the evaluation and definition of intubation proficiency varies among emergency medicine, paramedic, and anesthesiology training (Mulcaster, Mills, Hung, MacQuarrie, Law, Pytka, Field, C., 2003). The Accreditation Council for Graduate Medical Education (ACGME) and Residency Review Committee (RRC) have specified that a minimum of 35 ETI procedures be performed (either directly via patient care or simulation) by a resident physician to comply with program requirements for Emergency Medicine (Vozenilek et al. 2044; Accreditation Council for Graduate Medical Education, 2002). Among In a 2006 study of ETI success rates by emergency medical residents (EMRs), training periods averaged 86 intubations in clinical rotations and laboratory settings, and residents were capable of intubating 91.6% of their patients by their third procedural attempt (Casey et al., 2007).

According to the US National Emergency Airway Registry (NEAR) database, first-attempt success rates with ETI procedures among emergency medicine residents increases from 72% to 93% between postgraduate years 1-4, however, the number of cases a medical resident may see is largely dependent upon the residency program (Reed, 2007). Among anesthesia residents performing in excess of 90 cases per year, it was estimated that the recommended case load to achieve a 90% success rate was 57 attempts (Konrad et al., 1998). Errors during intubation training range from early struggles with procedural mechanics and endotracheal tube placement to view-related issues near proficiency. In a study of the first 100 intubations performed by a single emergency medicine resident over a 5-year residency period, complications with esophageal intubation occurred until the 12th case, at which point the complication rate greatly improved by the 30th case, and an overall complication rate of 8% was observed (Reed, 2007).

1.5 Related Studies

Improvements in skill acquisition and retention have been studied, comparing factors such as experiential versus guided learning with ETI (Ti et al., 2009). Physical ergonomics and the effect of patient position have not been adequately addressed within the literature. Multiple studies have explored the movement, position and force transmitted through the laryngoscope. McCoy et al. (1996) discovered a significantly relationship between the force exerted during ETI procedures and the body-mass index of the patient, confirming that larger patients with create increased physical demands for clinicians performing ETI procedures. Bucx, et al (1992) also found positive correlations

between the force exerted upon the laryngoscope versus an increase in the height and weight of a population of 40 patients. Bishop et al. (1992) examined the lifting force generated during ETI procedures among groups of novice and expert clinicians, finding similar average lifting forces among novice and expert clinicians while also noticing significantly greater force impulses among novices early during ETI procedure trials.

Waddington et al., (2009) found that men and women of equal experience (novice and expert) generated similar lifting forces during ETI procedures and displayed no differences in their ability to intubate or the duration of the procedure. However, it was observed that expert clinicians completed ETI procedures more accurately and rapidly than novice clinicians, and that as experience increased, lifting force applied against the instrument tip decreased, and ability increased (Waddington et al. 2009). Waddington had also observed that different grasp styles on the laryngoscope were significantly related to variations in lifting forces applied to the laryngoscope.

Preliminary studies examining ETI procedural ability and lifting forces indicate that minimal differences exist between novice and expert clinicians, aside from the influence of experience on success rates and task completion time. Even slighter differences were noted between the ability and physical output demonstrated by men and women of equal experience (Waddington, et al 2009; Bishop et al., 1992). Despite similar research initiatives examining force, gender and experience within ETI procedures, previous electromyography and postural research have not been conducted to further characterize the differences that may exist between experts and novices and clinicians of opposing genders. By applying the tools of human factors engineering, the opportunity exists to

define specific biomechanical postures and muscle exertions that may help characterize optimal physical ergonomics during ETI procedures.

1.6 Research Objectives

This study has been designed to explore muscle utilization and hand, arm and wrist positions of novice and expert practitioners at varying hospital bed heights. Researchers hope to explore and characterize how gender, patient position and clinical experience levels effect laryngoscope grasp, ETI procedure performance and strength requirements. Of specific interest to this research objective is the evaluation of trends within laryngoscope usage, muscle utilization and wrist postures against task performance metrics in pursuit of defining optimal physical ergonomics for the laryngoscopist, or best practices.

Conversely, researchers were also interesting in exploring the relationship between wrist postures, muscle utilization and laryngoscope grasp and the occurrence of instrument position error (dental trauma) to determine if trends existed in cases where errors were observed. The literature surrounding ETI training and learning curves cite dental and soft-tissue trauma during ETI procedures to be a significant contributor to failures and complications during both routine and emergent endotracheal intubation (Berkow, et al., 2009; Casey, et al., 2007; Crosby, et al., 1998). ETI training and literature seldom reference the proper hand and arm positions required for best practices in laryngoscope positioning. Successful ETI trials require both precise positioning of the laryngoscope at the base of the vallecula, as well as the proper administration of axial force along the

laryngoscope handle. Figure 2 (below) illustrates the appropriate positioning and application of force on the laryngoscope, along the green axis.

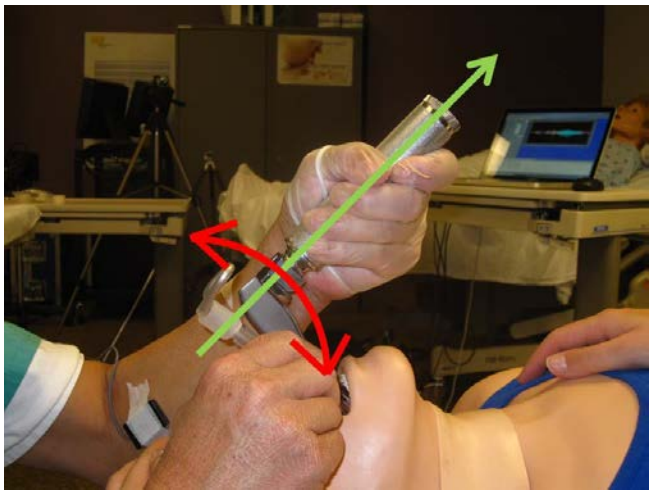

Figure 2 – Optimal Laryngoscope Positioning & Force Vector

A secondary objective of this study was to evaluate if participants adapted wrist postures and muscle utilization across a brief period of evaluation. Researchers hypothesized that novice participants may exhibit trends in these variable as well as ETI completion time and success rates as they progressed through the experimental procedure. Conversely, researchers expected to see consistent task performance, wrist postures and muscle utilization for expert-level participants.

2. Methods

2.1 Participants

Twenty-one novice and expert participants were recruited from the University of Nebraska Medical Center to participate in this study. Sixteen third and fourth-year

medical students were recruited to participate as novice subjects based upon a lack of prior experience with ETI procedures and airway equipment. Five expert participants were selected from the department of Emergency Medicine. All expert participants had more than 5 years of experience in emergency airway management. All participants reported that they had not experienced any musculoskeletal injuries in their left hand, arm or shoulder within the past 12 months. The participants' mean (standard deviation) demographic information is displayed in Table

Table 1- Participant Information

		Novice		**Expert**	
		Male	**Female**	**Male**	**Female**
Number		9	7	4	1
Age	years	25.3 (1.4)	23.9 (2.0)	49.5 (7.0)	36 (0.0)
Weight	cm	177.3 (28.6)	125.6 (12.4)	174.3 (18.2)	300 (0.0)
Hand Dominance	(R/L)	7 / 9	7/7	4 / 4	1 / 1
Stature	cm	179.4 (5.8)	165.2 (3.3)	179.8 (8.5)	186 (0.0)

2.2 Apparatus & Approach

All ETI trials were completed in the Clinical Simulation Laboratory at the University Nebraska Medical Center. Simulated ETI procedures were completed using a Difficult Airway Trainer (Laerdal, Wappingers Falls, NY) situated in a supine position atop an adjustable-height hospital bed (Advanta, Hill-Rom Services, Inc., Batesville, IN). The trials took place at the maximum and minimum heights of the adjustable bed (96 cm and 62 cm). Researchers held the forehead and abdomen of the airway manikin to resist lifting forces during each trial. A standard C-Cell laryngoscope (Rüsch Model No. 8321000, TeleFlex Medical Inc.), McIntosh No. 4 blade and size 7.0 endotracheal tube

and stylet were used to complete the ETI procedures. Experimental equipment, including the electromyography and goniomenter/torsiometer data gathering equipment is pictured in Figure 3. An example of an ETI trial at each bed height is illustrated in Figure 4.

Figure 3 – Experimental Equipment: Laryngoscope (left), manikin (center) join goniometry equipment (left)

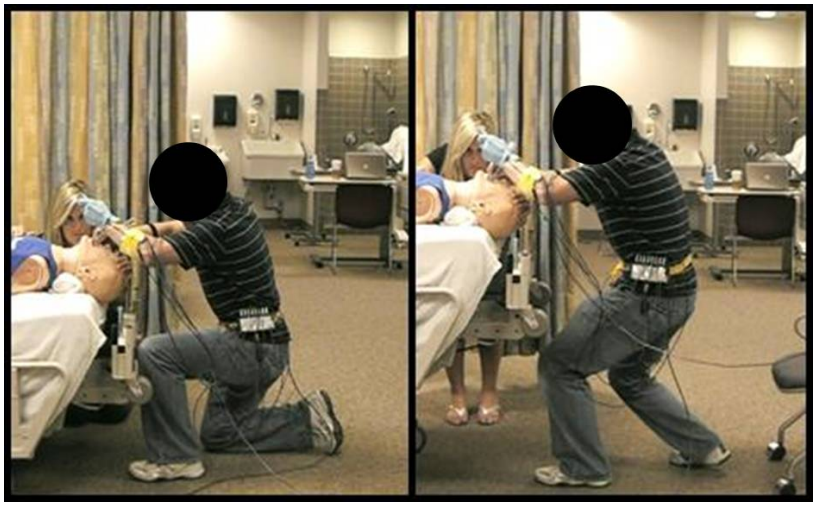

Figure 4 – ETI Trial at 62 cm (left) and 96 cm (right)

Wrist positions and muscle activity of the intubating (left) arm were measured during ETI trials to determine the effect of participant experience and patient position in relation to

muscle utilization and wrist postures. Researchers chose to observe wrist flexion and extension, radial and ulnar deviation, and forearm pronation and supination to define the range of motion during ETI procedures (Figure 5).

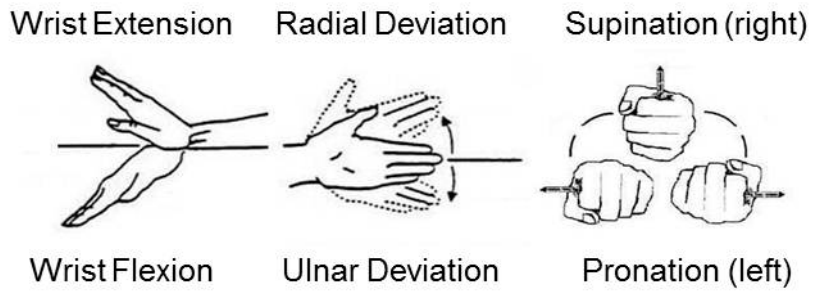

Figure 5 – Wrist Postures Evaluated

Wrist posture data was gathered using a dual-axis goniometer (model No. SG150, Biometrics Ltd.) and torsiometer (model No. Q110, Biometrics Ltd., Gwent, UK). Researchers selected the flexor carpi radialis (FCR), extensor carpi radialis (ECR), bicep brachii and anterior deltoid muscles to evaluate grasping and lifting muscles associated with the task. Muscle utilization was recorded using bipolar surface electromyography (EMG) sensors (SX230, Biometrics Ltd., Gwent, UK), aligned along the center of each muscle and sampled at a rate of 1000 Hz (Perotto, 2005, Zipp, 1982, Stegeman, et al., 1999). A digital event marker was utilized to record trial events. All equipment was connected to an eight-channel Biometrics DataLINK™ DLK900 system and recorded using DataLINK PC Software (V. 7.0, Biometrics Ltd., Gwent, UK).

2.3 Experimental Procedure

All subjects were informed of the purpose of the study, procedures and associated risks prior to participation and voluntarily signed informed consent and waiver agreements. Anthropometric measurements of stature, acromial height, elbow height, xiphoid process height, upper-arm length, forearm length, hand length, hand breadth, hand spread and grip span were recorded for all participants using a GPM™ anthropometer, sliding digital calipers and a conical measuring device, respectively. After gathering anthropometric data, each participant responded to a brief questionnaire regarding areas of medical interest and ETI procedure perceptions and experience.

Participants were then seated and prepped for EMG sensor application using a sterile alcohol-based swab. Surface EMG sensors were individually placed over the ECR, FCR, bicep brachii and anterior deltoid muscles and fixed with a temporary two-way adhesive and athletic tape. Muscle location was determined using anthropometric landmarks (Perotto, 2005) as well as active data from the EMG sensor and DataLINK™ software. Resting and maximum static contraction values were recorded for each observed muscle so that muscle utilization during the task could be normalized against a maximum impulse level specific to each participant, following the SENIAM recommendations (Stegeman, et al., 1999).

To position the goniometer, each participant sat with their left hand and arm resting on a table and their palm resting naturally against the surface. The dual-axis goniometer was positioned along the second metacarpal, on top of the wrist and along the dorsal side of

the left hand. The torsiometer was positioned alongside the goniometer, extending along the forearm. To ensure a neutral starting position, the torsiometer was placed while the participant extended their left arm along the surface of the table, rotating their forearm into a neutral position alongside the vertical face of a box on the tabletop. Once positioned, the goniometer and torsiometer were calibrated for these neutral positions. Figure 6 displays the placement of EMG goniometer and torsiometer sensors on the left hand and arm during a trial.

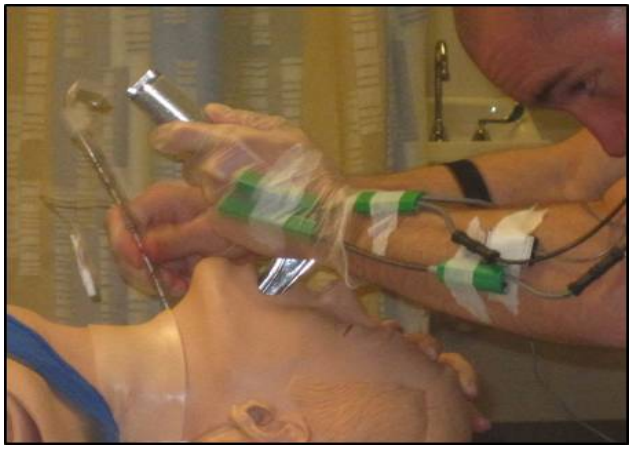

Figure 6 – Location of goniometer and torsiometer sensors on left hand and arm

2.4 Trial Procedure

The novice subgroup was unfamiliar with emergency airway management, ETI procedures and laryngoscopy equipment. Prior to performing task trials, each novice participant received a brief overview of airway anatomy, the airway trainer, standard terms in ETI procedures, step-by-step instructions for completing ETI tasks, and an introduction to laryngoscopy equipment (Levitan, et al., 2000). Participants also observed

one example ETI procedure per-formed by the researchers. Participants were then made aware of what data would be recorded for each trial as well as specific errors to avoid during the task, such as dental trauma. Prior to trial commencement, each novice participant was allowed a single practice trial to familiarize themselves with the trainer and task, and to clarify any areas of uncertainty.

Task time was assessed as the time between the introduction of the laryngoscope and the secure placement of the endotracheal tube. Participants were responsible for determining correct endotracheal tube depth and notifying researchers when they felt confident that the trial was complete. After each trial, researchers would evaluate trial duration, endotracheal tube depth and placement, the number of intubation attempts, and any incidents of dental trauma. Participants were also asked to assess the laryngeal view achieved using the Cormack and Lehane (C & L) scale (Krage et al., 2010).

Novice participants completed six total trials, three at each hospital bed height (62 cm and 96 cm). The starting order for bed height was randomized between participants. Each participant received a 60 second break between trials, and a five-minute break between trials three and four while bed height was adjusted. After trial 6, all participants completed a task-related questionnaire regarding ETI procedures.

Expert participants acknowledged proficiency with ETI procedures and were only acquainted with the airway trainer and study objectives. Due to the limited availability of expert participants, as well as a mild learning effect noticed during novice data collection, the trial procedure for expert participants was modified to improve the reliability of trial

data. Expert participants completed five ETI trials at each hospital bed height starting with 96 cm and ending at 62 cm, for a total of 10 trials. Due to the limited sample size, the starting height was not randomized for the expert subgroup, they started with 96 cm. Expert participants received 60-second rest breaks between trials and a five-minute break between the 96 cm and 62 cm trial sets. Expert participants completed a similar pre and post-procedure questionnaire adapted for their skills and experience with ETI procedures. All trial performance metrics were consistent between expert and novice participants.

2.5 EMG Data Processing

In accordance with the primary research objective of characterizing the muscle utilization and wrist postures during ETI procedures, the data captured from the electromyography sensor, torsiometer and goniometer needed to be altered to reflect only the appropriate hand movements and muscle exertions. A digital event recorded was utilized to signal the beginning and end of each trial, as well as trial interrupts or repositioning of the laryngoscope when outside of the airway manikin. Using these data points, muscle utilization and wrist posture data captured during the ETI trials was trimmed to contain only data from the trial time associated with the lifting of the laryngoscope and insertion of the endotracheal tube.

To process the data into a format suitable for analysis, each EMG data channel was modified using an Add-for-Zero and root mean square (RMS) filters, set at a sampling interval of 500 ms (Stegeman, et al., 1999). Identical filtering and cropping processes were completed for all ETI and maximum contraction trials for each participant. The

mean muscle utilization figure (mV) for each muscle during task trials was then divided by the average maximum contraction value across multiple samples, resulting in a proportion of muscle utilization required to perform ETI procedures for each muscle observed, specific to the participant and trial. The data obtained from goniometer and torsiometer readings required no additional processing and were adjusted for task duration only. All EMG and torsiometer/goniometer data analyzed was processed using DataLINK™ (V. 7.0) PC Software.

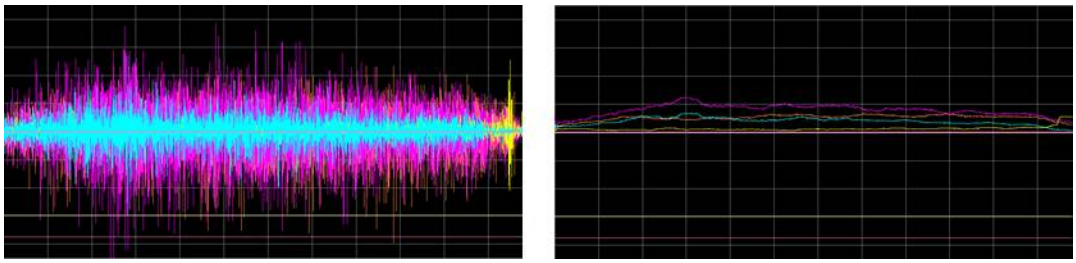

Figure 7 – Raw (left) and Filtered (right) EMG data

2.6 Experimental Design

The dependent variables of wrist postures, muscle utilization and descriptive trial statistics (task completion time, laryngeal view, error occurrences and ETI attempts) were examined in this study. A 95% confidence interval for the mean of each dependent variable was created for all dependent variables within each data set and outlier data points were removed. A combination of ANOVA, linear regression, Fisher's test of independence, independent sample t-tests and paired-sample t-tests were used to analyze the relationship between the dependent variables and the independent variables of

participant experience, participant gender, hospital bed height, trial sequence, error occurrence, elbow abduction and grasping characteristics. Post hoc (Tukey) tests were performed for statistically significant ANOVA test results to determine the mean differences between treatments of independent variables. All analyses were performed using SPSS (V. 19.0) statistical software and a significant level of 0.05 was used for all tests.

2.6.1 Data Reduction and Testing

2.6.1.1 Initial Analysis & Paired-Sample Testing

An initial analysis was performed to investigate the overall differences between novice and expert with respect to ETI task completion time, ETT Depth, and error occurrences at both hospital bed heights. Next, several paired-sample databases were created specific to experience level and gender to examine the influence of hospital bed height against the dependent variables of trial statistics, muscle utilization and wrist postures. Paired-sample t-tests were used to directly compare each participant's results at both hospital bed heights. Fisher's test was used to determine the effect that gender, experience and bed height (IVs) had on the dependent variable of dental trauma error.

2.6.1.2 Trial Sequence Testing

Due to differences in trial sequences and repetitions for novice and expert subgroups, a portion of study data was refined to create a data set of identical task heights and overall sequences. Novice data was limited to cases where participants performed trials in the sequence performed by the experts (96cm followed by 62 cm). The additional trials performed at each height by expert participants (trials 4, 5, 9 and 10) were removed from

expert records so that each expert participants were only evaluated on their first 3 trials at each bed height. This data set was then analyzed using ANOVA and post-hoc testing to determine if the height-specific trial sequence (1, 2, 3) and total trial sequence (1,2,3,4, 5, 6) yielded significant results for ETI trial statistics, muscle utilization and wrist postures. Additionally, linear regression was used to determine the effect of ordinal trial data (IV) against the dependent variables of completion time, wrist extension, ulnar deviation, forearm supination and the utilization of the ECR, FCR, bicep brachii and anterior deltoid.

2.6.1.3 Novice and Expert Comparison

To avoid capturing gender differences while examining the main effects of participant experience, a data set was constructed to specifically evaluate muscle utilization and wrist position differences between novice and expert male participants. Due to low study recruitment of expert female participants (Table 1), only data from male participants was analyzed to in this comparison. Initially, independent sample t-tests were used to evaluate differences between novice and expert participants across wrist postures, muscle utilization and all ETI trial statistics. Next, an interaction variable was created to allow researchers to test the effects of experience level and hospital bed height directly. The interaction variable was used to code data specific to the trial height and experience level, creating four test treatments. Simple one-way ANOVA and Tukey tests were then performed for the dependent variables of EMG and wrist posture and the trial height/experience combination as the independent variable to allow for significance testing between treatment levels.

2.6.1.4 Gender Comparison

In addition to the hypothesized differences between novice and expert participants, researchers also hypothesized that gender would like be a significant variable due to the known physical requirements of ETI procedures and the likely in muscle utilization between genders (Waddington et al. 2009; Bishop et al., 1992). Therefore, analyses were performed by segregating novice data sets by participant gender to analyze the relationship between gender, muscle utilization, wrist postures and task performance. To evaluate these effects, independent sample t-tests were used to evaluate overall differences between male and female results for wrist postures, muscle utilization and all ETI trial statistics. Similar to the expert and novice analysis performed for male participants, an interaction variable was again created to define gender and height classifications within the data. The main effects and effects between treatments of the combination variable were then analyzed using ANOVA and post-hoc testing, where appropriate.

2.6.1.5 Analysis of Incorrect Laryngoscope Positioning and Dental Trauma Errors

To investigate the research hypothesis that certain wrist postures and muscle utilization may result in dental trauma or soft-tissue damage errors, cases within novice and expert data were coded to record incidents of incorrect laryngoscope positioning or force vectoring. Separate data sets were created for novice male and female participants (very few errors were recorded among expert participants) to allow testing between cases with and without error, using independent sample t-tests. These tests were performed against

the dependent variables of ETI completion time, wrist posture and muscle utilization data.

2.6.1.6 Arm and Instrument Positioning (Elbow Abduction) Analysis

During novice ETI trials, it was observed that novices adopted a wide range of instrument grasp styles and arm positions while performing ETI procedures. The most significant characteristic observed in contrast to expert participants was the position of the left elbow. Expert participants and higher-performing novice participants adopted a left arm position locating the laryngoscope axially with respect to their left forearm. The left arm in these cases was considered adducted, or closer to the sagittal plane. By contrast, some novices' participants attempted to perform ETI procedures with left elbow abduction. These cases were noted and coded within the data to determine if the left elbow position had significant effects for trial statistics, wrist postures and muscle utilization. ANOVA and post-hoc testing was used to determine if significant differences existed between abducted and adducted trials (independent variable) against the dependent variables of ETI task completion time, error rates, wrist postures and muscle utilization.

2.6.1.7 Laryngoscope Grasp Analysis

Lastly, based upon the findings of Waddington et al. (2009), researchers investigated the effect of the dependent variable of grasp type against the independent variables of ETI task completion time, laryngeal view, error rates, wrist postures, and muscle utilization. Videos and photographs captured during experiment trials allowed the data to be coded for three distinct instrument grasps defined as blade, mid-handle and distal. ANOVA and Tukey testing were performed to determine if significant differences existed across

experience and gender groupings that would indicate a relationship between grasp style and the key variables within the study.

3. Results

3.1 Initial Analysis & Paired-Sample Testing

Novice participants required greater time to complete ETI procedures than expert participants while also making significantly more errors ($p \leq 0.050$). Laryngeal view (C & L) and Endotracheal tube insertion depth (ETT Depth) did not vary significantly between participant experience groups or hospital bed height. Aggregate task-related statistics across genders are displayed in Table 2.

Table 2 – Descriptive Trial Statistics

Group	Height (cm)	Time (sec)	ETT Depth (cm)	VC View	Avg. Error/Trial	Error Rate
Novice	62	18.49 (8.36)	21.9	2.06	0.44	37.50%
Novice	96	21.32 (8.40)	21.7	2.08	0.65	47.92%
Expert	62	8.37 (2.25)	22.1	2.04	0.08	8.00%
Expert	96	9.56 (2.37)	21.4	2.08	0.16	16.00%

Table 3 illustrates the main effect of patient position, as dictated by the independent variable of hospital bed height. The results from the paired-sample t-test analysis are presented in Table 3. Overall, all participant groups exhibited varying degrees of wrist extension, ulnar deviation, and forearm supination during ETI procedures. Muscle utilization varied between gender and participant types, however all groups exhibited the greatest exertion of the Anterior Deltoid muscle during ETI procedures.

Table 3 – Effect of Patient Position on Task Statistics, Muscle Utilization and Wrist Postures

	Expert Males			Novice Males			Novice Females		
	96 cm	62 cm	*p-value*	96 cm	62 cm	*p-value*	*96 cm*	*62 cm*	*p-value*
Trial Statistics									
Time	**9.96**	**8.73**	***0.020***	17.07	18.77	*0.280*	**26.38**	**17.83**	**0.003**
Dental Trauma Error	0.0%	0.0%	*1.000*	12.8%	15.4%	*1.000*	42.9%	41.7%	1.000
VC View (C & L Score)	2.00	1.90	*0.494*	2.04	2.04	*1.000*	2.14	2.10	0.853
ETI Attempts	1.05	1.00	*0.330*	1.41	1.56	*0.537*	1.38	1.38	1.000
ETT Depth	22.13	21.48	*0.055*	21.65	21.54	*0.550*	22.26	21.91	0.193
Wrist Postures (degrees)									
Extension	23.56	23.05	*0.757*	**21.99**	**16.07**	***0.000***	22.55	18.22	0.092
Ulnar Deviation	5.27	3.47	*0.295*	13.70	13.28	*0.761*	18.18	15.38	0.323
Supination	**1.57**	**6.27**	***0.006***	7.37	9.45	*0.392*	**14.94**	**21.21**	**0.014**
Muscle Utilization (% MVC)									
ECR	36.2%	38.1%	*0.053*	34.5%	33.9%	*0.582*	47.0%	44.1%	0.212
FCR	**16.1%**	**14.2%**	***0.019***	14.3%	14.8%	*0.554*	**21.5%**	**25.2%**	**0.003**
Bicep Brachii	12.7%	12.7%	*0.941*	10.1%	10.6%	*0.528*	13.0%	14.0%	0.127
Anterior Deltoid	43.1%	44.6%	*0.441*	**33.7%**	**36.3%**	***0.039***	46.4%	52.6%	0.086

Expert participants required less time to complete trials at the lower bed height ($p = 0.020$), despite the minimal time differences between heights. This finding is not considered significant to the study due to the experimental design required for experts due to low-study enrollment (starting height was not randomized for expert participants, who all began the study at the 96cm height). Expert participants exhibited significantly greater forearm supination at the lower hospital bed height ($p = 0.006$), as well as a decrease in the utilization of the flexor carpi radialis muscle ($p = 0.019$) in comparison to the 96cm hospital bed height. Conversely, expert participants did not display significant differences in error rates, laryngeal view, required attempts, ETT insertion depth or any other wrist posture and muscle utilization analyzed for either bed height examined ($p \geq 0.050$).

Among male novice participants, patient position (bed height) did not yield any statistically significant differences for the trial statistics analyzed ($p > 0.050$). Male novices also exhibited significantly greater wrist extension at the 96cm bed height than the lower position. Female novice participants completed ETI procedures much quicker at the lower patient position observed ($p = 0.003$), while exhibiting greater forearm supination ($p = 0.014$) and flexor carpi radialis utilization ($p = 0.003$) than at the higher position. Neither novice group exhibited any significant difference in error rate, task attempts, ETT insertion depth or laryngeal view (VC view) between hospital bed heights ($p \geq 0.050$). Additionally, overall task completion time did not vary significantly between male and female participants ($p = 0.104$).

Dental trauma errors were evaluated against the independent variable of hospital bed height for all participant groups using Fisher's and McNemar's test. In all cases, hospital bed height was found to be unrelated to the frequency of dental trauma errors ($p > 0.050$). Significant differences were noted in error frequencies between error novice and expert participants ($p = 0.004$) and between genders among novice participants ($p = 0.014$).

3.2 Effect of Trial Sequence

Figure 8 illustrates the effect of trial sequence against task completion time. ANOVA testing revealed that the main effect of trial sequence (IV) was not a significant predictor for task completion time (DV) for expert participants ($p = 0.679$), however was a significant predictor for novice task completion time ($p = 0.006$). Post-hoc testing for non-homogeneity between treatments of the 'trial' variable among novice participants indicated that while visible differences exist between trials, only trials 1 versus trials 5

and 6 were statistically significant from one another (p = 0.008 and p = 0.016, respectively).

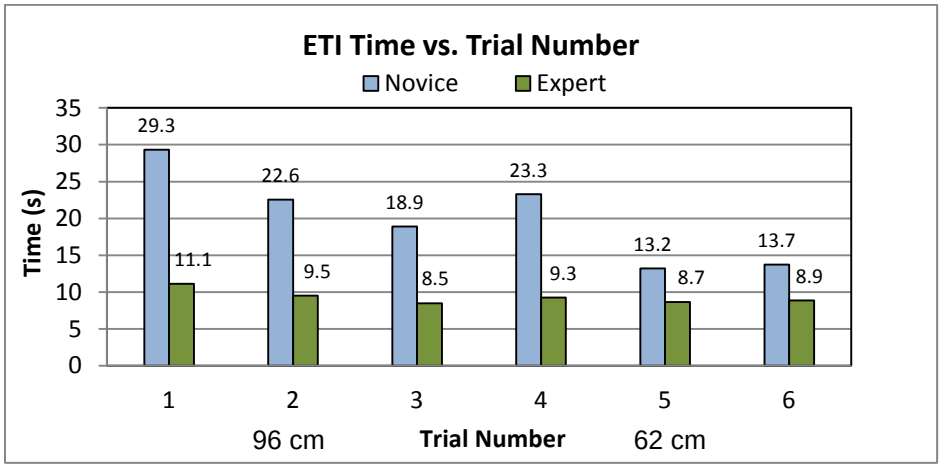

Figure 8 – The Effect of Trial Sequence on ETI Completion Time

The effect of adjusting to the lower bed height is also illustrated in Figure 7 as the task completion time for both novices and experts increases from trial 3 to trial 4. Contrary to research hypotheses, significant differences did not exist across trials for any other independent variables within the study for either novice or expert participant groups. Muscle utilization and wrist posture data yielded poor significance levels (p = 0.80 and above), indicating that trends for muscle utilization and wrist positions did not emerge during the study as novice and expert participants adapted to the task.

The ANOVA results were confirmed using simple linear regression. Trial sequence was found to be a significant factor for task completion time for novice participants only (p = 0.002). For both novice and expert participants, no significant relationship existed between wrist postures and muscle utilization when compared to the depended variable of trial sequence.

Wrist Postures and Muscle Utilization

3.3 Novice and Expert Comparison (Males Only)

Wrist posture and muscle utilization data was analyzed using the independent variables of experience and bed height. While task completion time varied significantly ($p < 0.001$), the main effect of participant experience was only significant for ulnar deviation ($p = 0.019$) during ETI trials. Muscle utilization varied slightly between expert and novice participants and was most evident in the utilization of the anterior deltoid muscle, however all results from ANOVA and independent-sample t-tests returned non-significant test results ($p > 0.050$). Figures 9 and 10 illustrate the wrist posture and muscle utilization results from the ETI trials with respect to participant experience and hospital bed height.

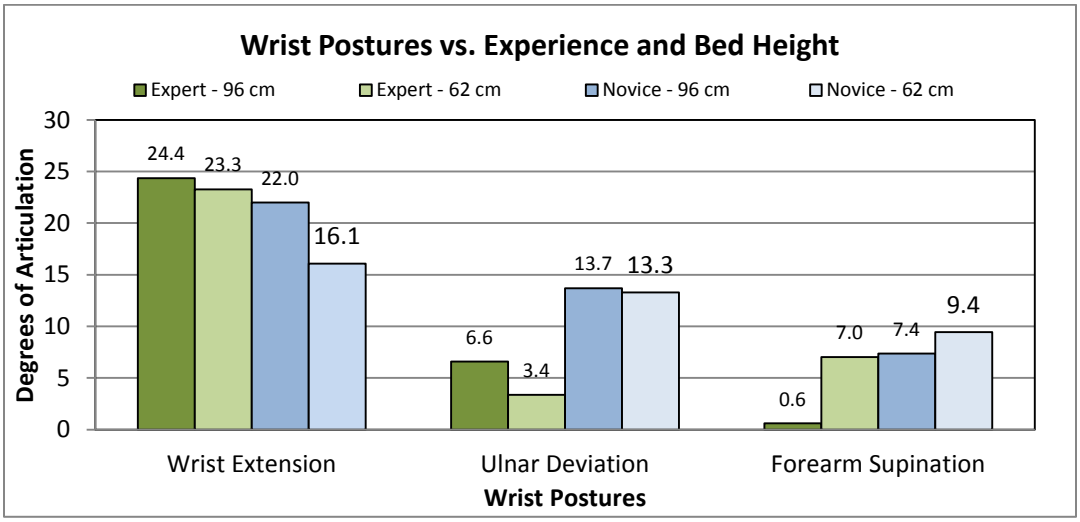

Figure 9 – The Effect of Experience and Bed Height on Wrist Postures

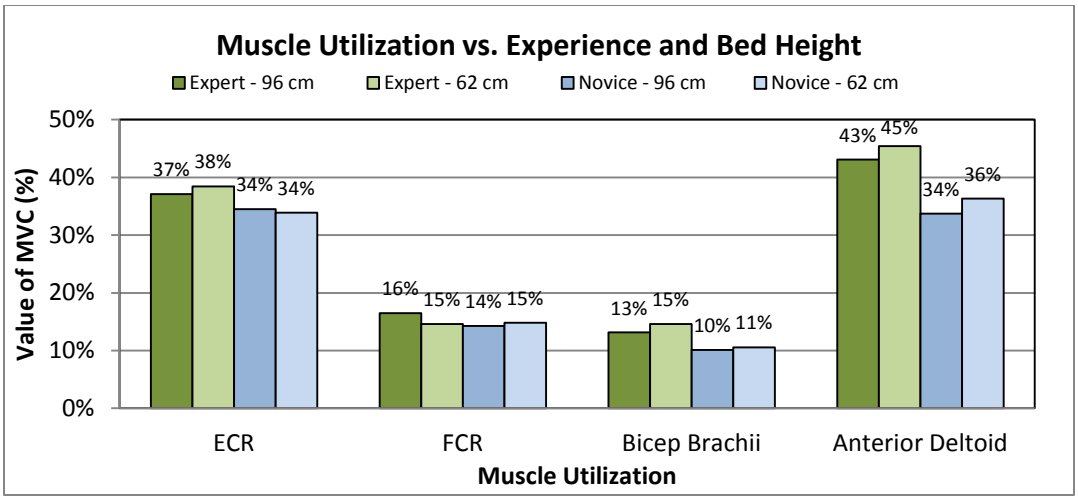

Figure 10 – The Effect of Experience and Bed Height on Muscle Utilization

Although statistically significant results were not observed between novice and expert male participants for several wrist posture and muscle utilization variables, the results do illustrate commonalities in the biomechanics of ETI tasks between male participants. On average, both novice and expert males participants exhibited a lesser degree of wrist extension and ulnar deviation, and a greater amount of forearm supination ($p = 0.096$) at the lower bed height. Similarly, the muscle utilization data suggests that male participants recruit marginally greater amounts of the large lifting muscles (bicep brachii and anterior deltoid) when performing ETI procedures at the lower hospital bed height (Figures 9 and 10).

3.4 Novice Male and Female Comparisons

Table 4 presents the significant main effects of gender on ETI task completion time, muscle utilization and wrist postures. Highly-significant gender effects were observed for all muscle data observed; novice female participants required much greater muscle utilization of all lifting and grasping muscles while performing ETI trials ($p = 0.002$ or

less). Additionally, the laryngoscope grasp adopted by female participants exhibited significantly greater forearm supination compared to male participants ($p = 0.024$).

Table 4 – The Effect of Participant Gender on Experiment Results

		Males		Females		Sig.
		Average	S.D.	Average	S.D	p-value
Time	seconds	18.5918	6.9	21.8378	9.7936	0.086
Muscle Utilization						
ECR	% MVC	34.19%	16.98%	46.30%	13.02%	**0.000**
FCR	% MVC	14.55%	6.20%	23.54%	7.45%	**0.000**
Bicep Brachii	% MVC	11.05%	5.04%	13.57%	6.84%	**0.002**
Anterior Deltoid	% MVC	35.02%	8.06%	51.38%	25.76%	**0.000**
Wrist Postures						
Wrist Extension	degrees	19.03	10.59	18.64	10.90	0.862
Ulnar Deviation	degrees	13.49	8.87	16.31	9.62	0.141
Forearm Supination	degrees	8.41	21.79	19.05	22.97	**0.024**

To further explore these differences, an analysis identical to the comparison performed in Section 3.4.1 was completed to investigate wrist posture and muscle utilization data against independent variables of gender and bed height. The main effects of the interaction variable were not significant against wrist postures, however, the interaction variable was a significant predictor of ECR ($p = 0.005$), FCR ($p < 0.001$), bicep brachii ($p = 0.015$) and anterior deltoid ($p = 0.001$) utilization. Post-hoc Tukey tests revealed significant differences for muscle utilization between genders, however no significant differences exists within genders between 96 cm and 62 cm hospital bed heights. Figures 11 and 12 illustrate the results from this analysis.

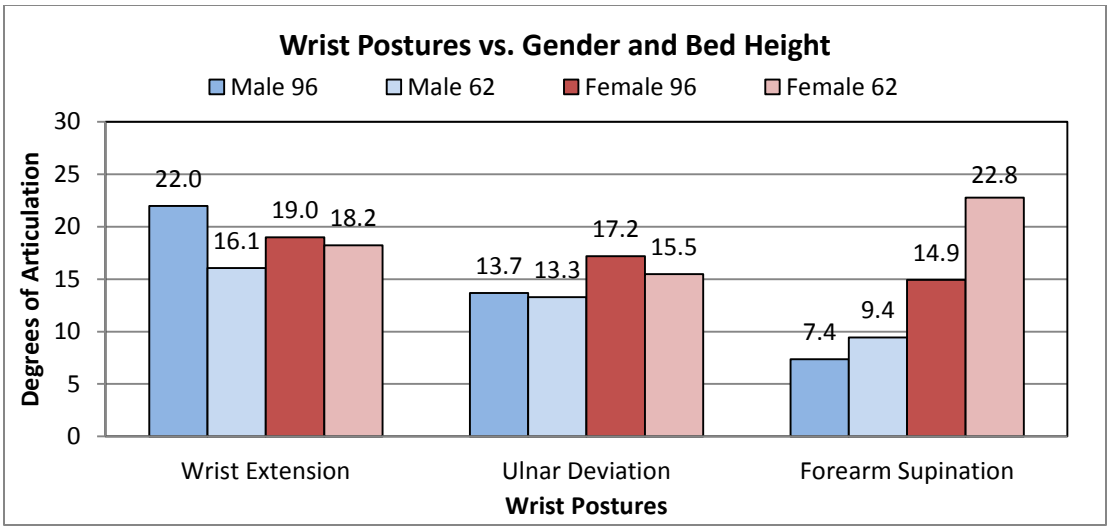

Figure 11 – The Effect of Gender and Bed Height on Muscle Utilization

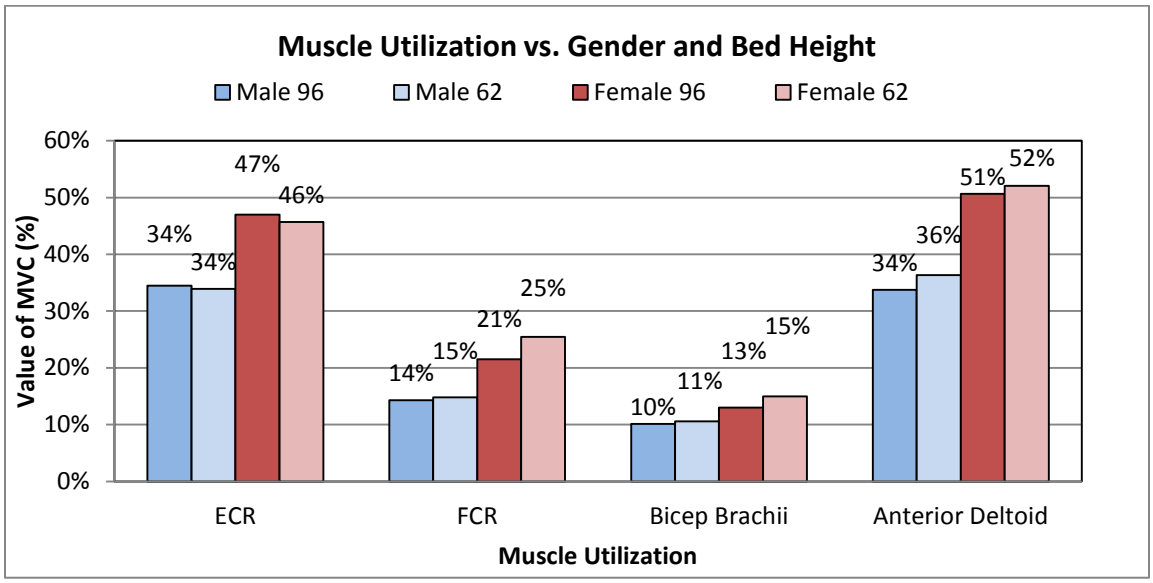

Figure 12 - The Effect of Gender and Bed Height on Muscle Utilization

3.5 Dental Trauma Errors and Corresponding Study Characteristics

Insufficient errors occurred to characterize proper and improper wrist positions and muscle utilization within expert participants, however, significant errors were present within male and female novice ETI trials. Rotations about the proximal end of the

laryngoscope blade (see in red, Figure 2) were observed to result in dental trauma among novice participants.

Male participants demonstrated an overall dental error rate of 14.1 % without any significance difference in error rate found at either bed height ($p > 0.050$). Female participants exhibited a dental error rate of 42.3%, significantly greater than male participants ($p = 0.014$). Hospital bed height did not affect the error rate of female participants ($p > 0.050$). Due to the significant difference in error rates and well as muscle utilization between male and female participants, dental-trauma error data and the implications on practitioner biomechanics were evaluated within genders. This data was analyzed for significant trends related to muscle utilization and wrist postures to determine if optimal positions existed among novice practitioners.

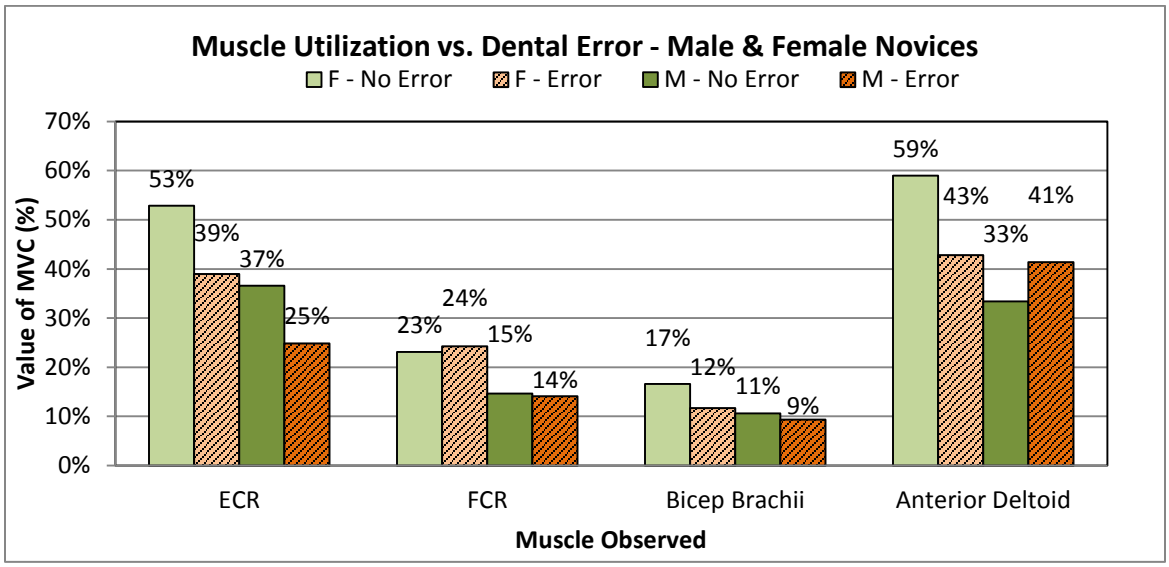

Figure 13 – Analysis of Muscle Utilization by Dental Error & Gender

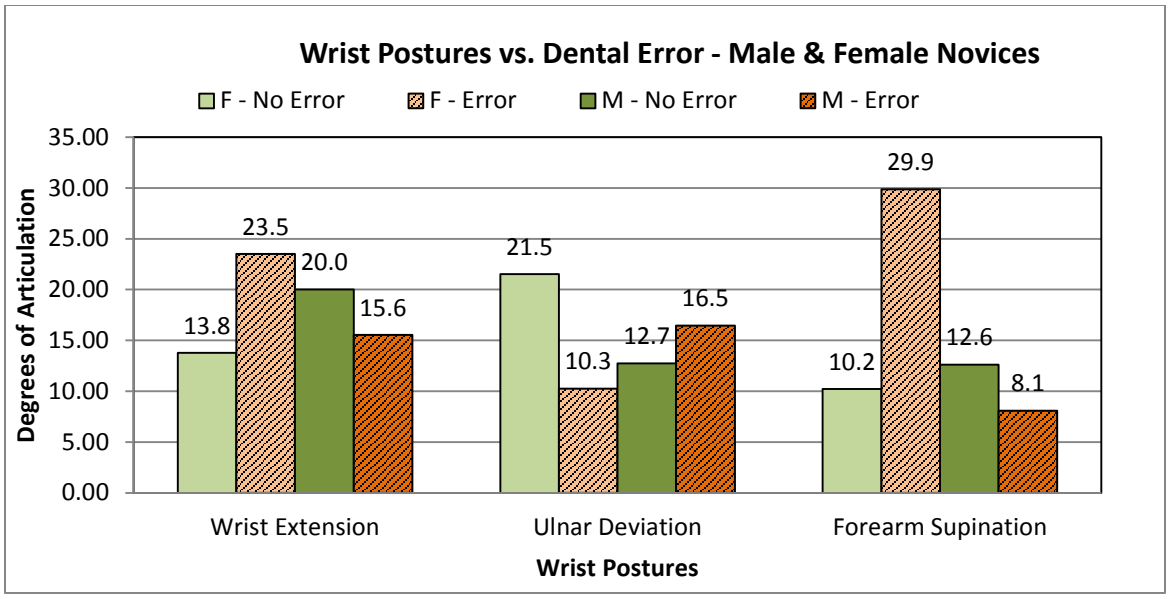

Figure 14 – Analysis of Wrist Postures by Dental Error & Gender

Figures 13 and 14 illustrate the differences in wrist postures and muscle utilization corresponding with trials containing dental error, and those which did not contain dental error, with respect to participant gender. Among female participants, trials without dental error exhibited significantly greater utilization of the FCR muscle ($p < 0.001$), and significantly greater utilization of the Bicep Brachii ($p = 0.023$), as well as less wrist extension ($p = 0.004$), greater ulnar deviation ($p < 0.001$) and decreased forearm supination ($p = 0.006$). Male participants inflicting dental error with the laryngoscope exhibited significantly greater utilization of the ECR muscle ($p = 0.003$) and a decreased utilization of the Anterior Deltoid ($p = 0.003$), as well as increased ulnar deviation ($p = 0.067$) and decreased forearm supination ($p = 0.004$).

3.6 Elbow Abduction Analysis

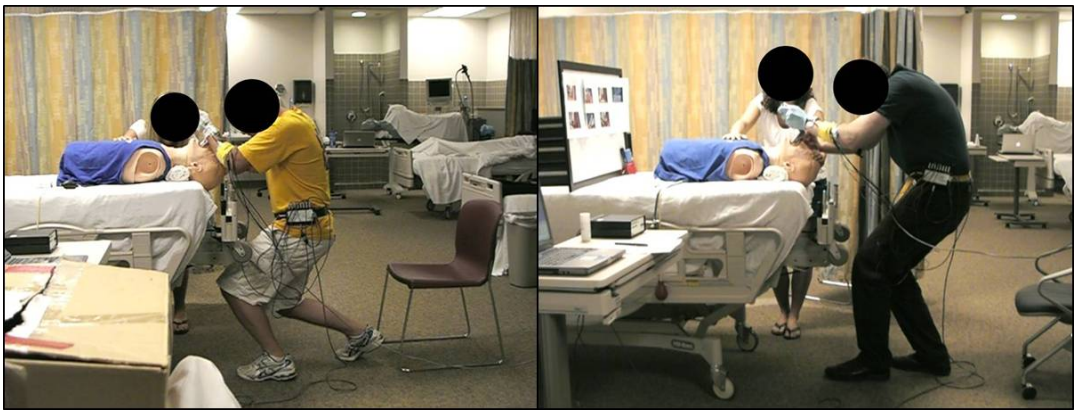

Figure 15 – Novice Participants Demonstrating Alternate Elbow and Arm Positions

Figures 15 (above) illustrate novice participants demonstrating abducted and adducted elbow positions. Participants who completed ETI trials with improper elbow position did not exhibit differences in error rates or task completion time ($p = 0.131$ and $p = 0.057$), however significant differences did exist for all wrist postures and several muscles utilized.

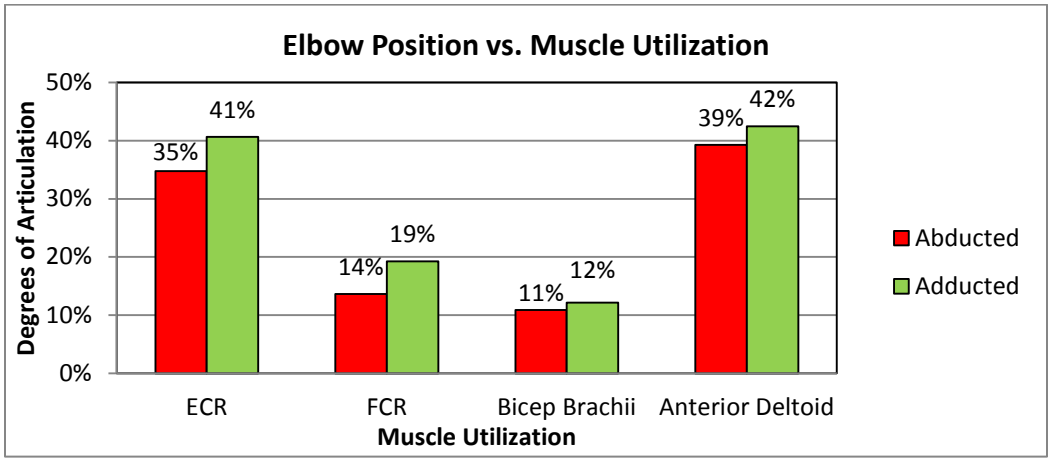

Figure 16 – Elbow Position and Muscle Utilization

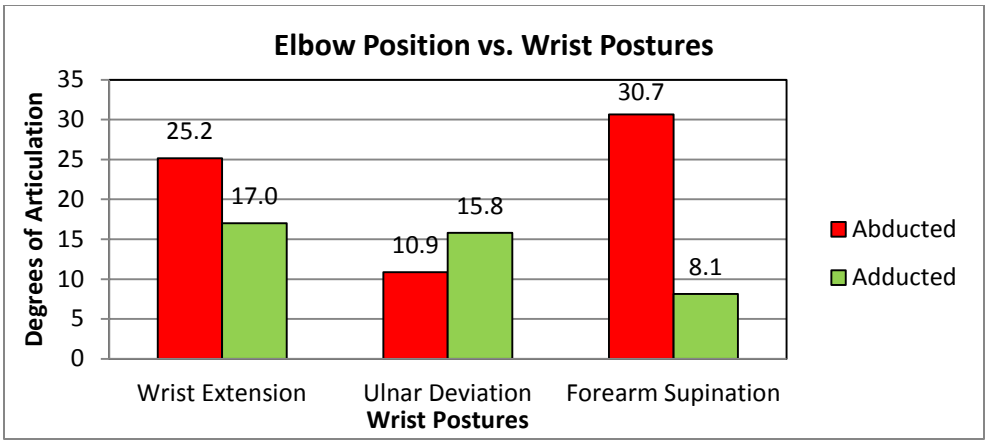

Figure 17 – Elbow Position and Wrist Postures

Participants adopting the correct orientation of the left forearm and elbow exhibited significantly less wrist extension ($p = 0.002$), greater ulnar deviation ($p = 0.031$), and much less forearm supination ($p < 0.001$). Additionally, novice participants adopting an in-line orientation of the left forearm also utilized higher percentages of the FCR ($p = 0.007$) and ECR muscles ($p = 0.039$). The average values for wrist postures and corresponding to each grouping are displayed in Figures 16 and 17.

3.7 Laryngoscope Grasp Analysis

Table 5 – Overview of Laryngoscope Grasp Adoption

		Blade	**Mid-Handle**	**Distal**
Male	Novice	1	2	5
Female	Novice	1	3	2
Male	Expert	0	4	0
Female	Expert	1	0	0
	Total	**3**	**9**	**7**
	Percentage	*16%*	*47%*	*37%*

Table 5 defines the adoption of laryngoscope grasp style for the entire study population. Two novice cases were not evaluable (n=14). All expert participants either adopted a distal or mid-handle grasp. In contrast, 44% of novice participants adopted a distal grasp. Among both groups, the mid-handle grasp was the most common grasp representing 47% of all cases in the study. Additionally, grasp adoption was not significantly related to gender ($p > 0.050$). ANOVA testing revealed that task completion time was significantly related to grasp style ($p = 0.001$). Cases exhibiting a blade grasp yielded an average ETI completion time of 12.34 seconds, while mid-handle cases averaged 14.34 seconds and distal cases averaged 19.44 seconds. Dental trauma error rates were not significantly related to grasp adoption ($p = 0.636$), and laryngeal view ranged from 2.00 (distal) to 2.27 (blade) without a significant relationship to grasp adoption ($p = 0.089$).

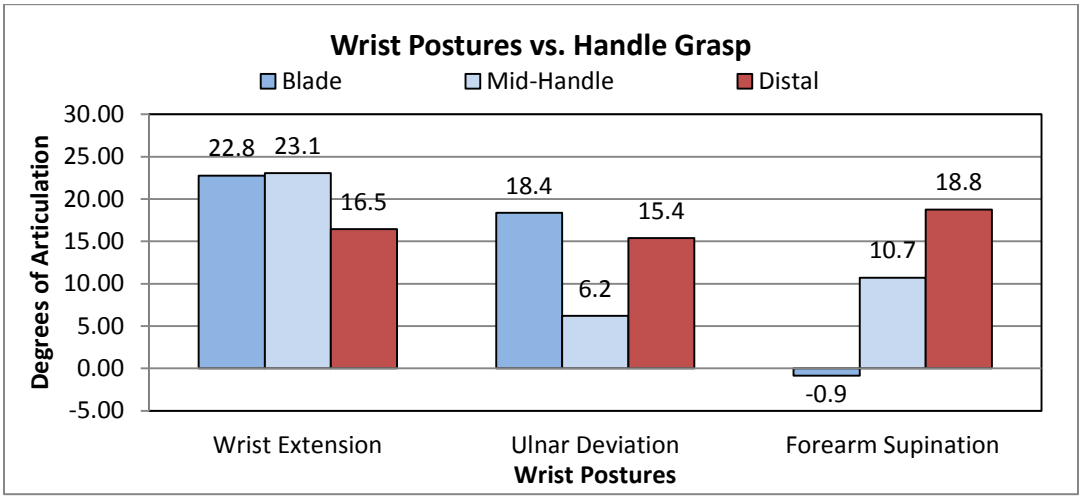

Figure 18 – Grasp Style and Wrist Postures

The impact of grasp style on wrist postures is illustrated in Figure 18. The dependent variable of laryngoscope grasp style was statistically significant for wrist extension ($p = 0.018$), ulnar deviation ($p < 0.001$), and forearm supination ($p < 0.001$). Participants

exhibiting a distal laryngoscope grasp exhibited significantly greater forearm supination and reduced wrist extension, compared to the other grasps. Blade style grasps were found to be associated with minor forearm pronation in contrast to the moderate and high levels of forearm supination exhibited during trials with the mid-handle and distal grasps. Additionally, mid-handle grasps resulted in significantly less ulnar deviation than either the blade or distal grasps, illustrating a key difference in instrument and arm positioning during the respective trials.

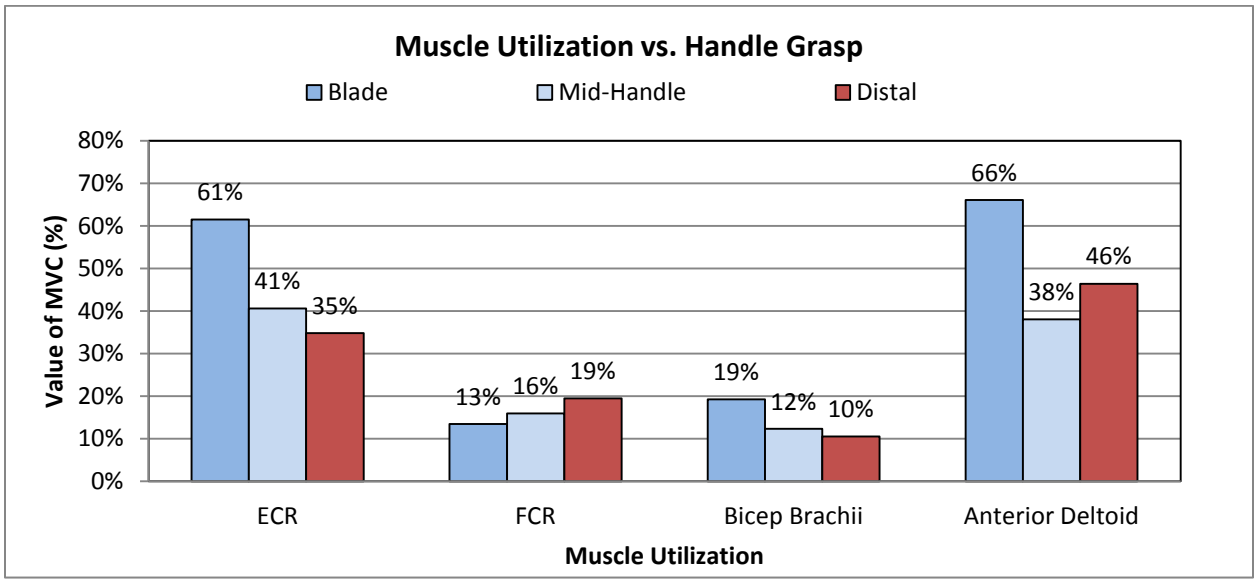

Figure 19 – Grasp Style and Muscle Utilization

The average values for each muscle observed with respect to laryngoscope grasp are displayed in Figure 19. Laryngoscope grasp adoption was found to have a strong impact on utilization of the ECR ($p = 0.002$), FCR ($p = 0.002$), bicep brachii ($p < 0.001$) and anterior deltoid ($p < 0.001$). Participants adopting a blade style instrument grasp exhibited significantly greater utilization of the ECR muscle, requiring an average of 61% of their maximum output during ETI trials. Similarly, blade style grasps were also

associated with much higher utilization of both the bicep brachii and anterior deltoid in comparison to mid-handle and distal grasp style. Differences in muscle utilization between mid-handle and distal grasps were only significant for the FCR muscle, where the distal grasp required the greatest utilization of the FCR during ETI trials.

4. Discussion

The purpose of this study was to examine the relationship among experience level, patient position (hospital bed height), muscle utilization and wrist postures with respect to the completion of ETI procedures. Because of the variety of circumstances requiring endotracheal tube placement, researchers were hoping to provide substantial evidence that proper patient positioning would reduce the amount of time required to perform ETI procedures, while reducing task-related errors. Additionally, researchers expected to see significant differences for wrist postures and muscle utilization between expertise and gender subject groups.

4.1 ETI Task Statistics, Bed Height and Trial Sequence

Significant reductions in error rates and task completion times were not related to hospital bed heights across most participants. Consequently, the hypothesis that clinicians would adopt significantly different hand and arm positions at suboptimal (lower) patient positions was proven untrue. Analysis of the ETI trials revealed that compensation hospital bed height was predominately made in the bend of the hips and knees by either squatting or kneeling to perform ETI trials. Because of this, clinicians were able to assume similar positions of the head, shoulders, arms and instrument when compared to the optimal height closer to the clinician's xiphoid process.

The position of an ETI trial within the sequence of total trials failed to yield significant findings for any study variables aside from ETI completion time for novice participants. The significance of this relationship suggests that novice participants improved their ETI completion time performance as they became acquainted with the procedure and equipment. The lack of significance between trial sequence, wrist postures and muscle utilization data indicate that changes in wrist postures and muscle utilization between trials within participants were non-existent or statistically insignificant. Due to the limited ETI trials under observation, a learning effect for wrist postures and muscle utilization can neither be confirmed nor denied among both novice and expert participants and it should be assumed that these values were relatively static among participants.

4.3 Novice and Expert Comparison (Males)

Minor variations in muscle utilization existed between experience groups among male participants; however significant differences in muscle utilization were not observed between novice and expert participants. Both novice and expert male participants exhibited greater recruitment of the ECR and anterior deltoid muscles in comparison to the utilization of the FCR and bicep brachii muscles. In addition, slight increases in the large lifting muscles were witnessed among male participants at the lower hospital bed height, indicating that more lifting force might have been required when the patient was in a suboptimal position. Expert participants exhibited significantly less ulnar deviation, as well as slightly greater wrist extension when compared to novice participants, while achieving similar orientations of the laryngoscope blade and handle. Expert participants

also exhibited a lesser degree of forearm supination than novice participants at both hospital bed heights.

The differences in the wrist postures adopted by expert and novice participants suggests that hand and arm positions may have been different between the two participant groups. The significant findings form this this data supports the observation that experienced practitioners grasp the laryngoscope in-line with their forearm and across their palm, rather than gripping the handle normal (perpendicular in orientation) to the forearm. Figure 20 illustrates the difference between the orientation of the laryngoscope and the practitioners left forearm. The orientation of the instrument (green) and the left forearm (red) are notably different for many novice and expert cases. This difference in orientation and grasp within the palm can be supported by the increased levels of ulnar deviation required for many novice participants to achieve proper laryngoscope positioning.

Figure 20 – Comparison of Expert (left) and Novice (right) Instrument and Arm Positions

4.4 Novice Male and Female Comparisons

Significant differences existed in muscle utilization between male and female novice participants for all muscles observed, with female participants requiring greater recruitment of forearm and upper arm muscles during ETI procedures ($p < 0.050$). Female participants used a greater proportion of the ECR, FCR, bicep brachii and anterior deltoid muscles, and exhibited a slight increase in muscle utilization for the FCR, bicep brachii and anterior deltoid at the lower hospital bed height. The significant findings related to muscle utilization differences between genders confirm related studies exploring the relationship between genders and lifting force generated during ETI trials (Waddington, et al. 2009; Bishop, et al., 1992). These studies revealed that similar task completion time and lifting forces were generated between males and females of equal experience, however, ETI completion tasks were noted to be more strenuous for female participants. The observed sustained muscle exertion approaches and in some cases exceeds of 50% of maximal static exertion, validating the demanding nature of ETI procedures on practices practitioners with weaker musculature. The effect of gender on the utilization of the anterior deltoid and ECR further demonstrate the importance of these muscles in the lifting and grasping requirements during ETI procedures.

4.5 Dental Trauma Errors and Corresponding Biomechanical Characteristics

Incorrect laryngoscope positions associated with dental trauma error were also found to yield significantly different wrist postures and muscle utilization for male and female novice participants. For both genders, trials without error were characterized by a greater utilization of the ECR muscle. Female participants also performing tasks without errors

also utilized a greater proportion of their anterior deltoid and marginally more bicep utilization, suggesting that proper lifting technique during ETI trials could be exhibited by an increased reliance on the large lifting muscles observed. Wrist postures associated with dental trauma were less conclusive and did not exhibit consistent trends between male and female participants.

Female participants performing ETI procedures without error exhibited greater ulnar deviation then trials where errors occurred, while also exhibiting lesser degrees of forearm supination. Contrarily, male participants exhibited greater ulnar deviation and lesser forearm supination while performing ETI trials containing dental trauma errors. Given these varied results, it is important to consider that the occurrence of dental impact was a momentary impact of the manikin's teeth; however the significant differences in wrists postures and muscle utilization represent values over the entire trial period. In such cases, a brief improper positioning of the laryngoscope may have resulted in the error, however, the sustained exertion of the muscles characterizing correct and incorrect trials indicate that overall technique may be more accurately characterized by muscle recruitment, in which better performing participants utilized the larger a greater amount of the ECR, and anterior deltoid muscles (female participants).

4.6 Elbow Abduction Analysis

All expert participants exhibited similar adducted positions of the left elbow; keeping the elbow close to the body and the forearm approximately in-line with the laryngoscope handle. The position of the practitioner's left elbow varied more significantly among novice participants, with several participants exhibiting moderate degrees of elbow

abduction. Examination of elbow abduction during ETI trials confirmed that compensations in wrist postures and muscle utilization were made for participants who adopted hand and arm positions where the left elbow was abducted away from the body. Cases were the elbow was abducted were characterized by decreased utilization of the ECR and FCR muscles, and a slight decrease of the larger lifting muscles (bicep brachii and anterior deltoid). Additionally, elbow abduction was also significantly related to increase wrist extension, decreased ulnar deviation and a much greater degree of forearm supination. ETI task completion time was not significantly different among abducted cases, however, the additional wrist manipulation and decreased utilization of muscles associated with these trials signify that these postures are suboptimal when compared against the wrist postures and muscle utilization exhibited by experienced practitioners.

4.7 Laryngoscope Grasp Analysis

While examining the effect of gender and experience on intubation ability and the forces generated, Waddington et al. (2009) discovered that laryngoscope grasp positions along the body of the laryngoscope had significant effects on the amount of force generated at the instrument tip (tissue force). Participants grasping the laryngoscope toward the blade generated less force at the instrument tip, while those grasping the laryngoscope near the distal end of the handle generated significantly greater amounts of tissue force on the instrument. In these cases, the additional length of the laryngoscope handle utilized during distal grasps resulted in increased leverage about the tool tip. Consequently, this grasp created a mechanical advantage increasing the force generated upon the instrument tip, while also increasing the rotational forces about the instrument tip. Therefore, it was hypothesized that participants using a distal grip would require less muscle exertion to

generate equal lifting forces, while potentially increasing the amount of lower-arm muscle and wrist posture coordination to counteract the rotational forces created by additional leverage (Waddington, et al. 2009).

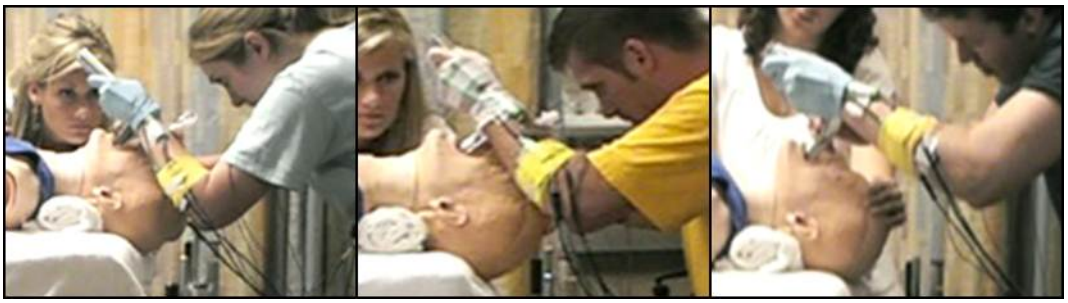

Figure 21 – Blade (left), Mid-Handle (center) and Distal (right) Laryngoscope Grasps

Figure 19 illustrates the three grasp styles exhibited during the experimental procedure. Data obtained within this study revealed that laryngoscope grasp style had significant impact on the wrist postures and muscle utilization of study participants. Distal grasps were only selected by novice participants while higher-performing novices and expert participants adopted either mid-handle or blade grasps. Participants adopting blade and mid-handle grasps performed ETI trials significantly faster than those adopting distal-style grasps.

The independent variable of laryngoscope grasp style was significantly associated with wrist postures and muscle utilization, while adoption did not follow specific trends with respect to gender or experience level. This consideration revealed the strong influence that laryngoscope grasp exerted on the key research variables within this study. Participants adopting a distal grasp of the laryngoscope exhibited significantly less wrist extension. Mid-handle grasps were characterized by reduced ulnar deviation, and blade-style grasps were characterized by mild forearm pronation, rather than forearm supination

exhibited by the two other grasping styles. These key differences illustrate how these grasps differ in terms of hand and arm position. Those adopting a distal grasp position their hand farther from their body, resulting in decreased wrist extension during ETI trials. Individuals using a blade grasp exhibited a very neutral forearm position because compensations did not need to be made for clockwise rotation of the laryngoscope handle body against the axis of the blade, required by other grasps to keep the instrument in-line with lifting forces. Lastly, mid-handle grasps were characterized by a much lesser degree of ulnar deviation in the left wrist. The low levels of ulnar deviation exhibited by participants adopting mid-handle grasps were characterized by a consistent relationship of the instrument and left forearm, which was much more prominent with this grasp than either the blade or distal grasp (Figures 20 & 21). The mid-handle grasps allowed participants to grasp the laryngoscope across their palm and in-line with their forearm, requiring less wrist manipulation than both the distal and blade grasp styles.

The variable of laryngoscope grasp style was also a significant predictor of muscle utilization among all participants observed. Trials characterized by blade-style grasps yielded significantly greater utilization of the ECR, bicep brachii and anterior deltoid muscles. Due to the decreased leverage associated with a grasp near the laryngoscope blade, the increased utilization of the muscles supports the observations made by Waddington (2009) that grasp styles influence the force imparted on the laryngoscope, and therefore, the muscle output required to perform ETI procedures. The dramatic increase in anterior deltoid utilization exhibited during blade-style grasp trials illustrates the increased physical exertion required, compared to other grasp styles.

Conversely, cases in which participants adopted distal-style grasps exhibited significantly greater utilization of the FCR muscle. It should be noted that expert participants performing ETI procedures with optimal wrist postures and instrument positions exhibited significantly less FCR utilization than novice participants. The increased level of FCR utilization for distal-style grasps further supports the theory that distal-style grasps require additional counter-force and manipulation to counteract the effect of the instrument leverage and the generated rotational forces.

5. Conclusion

In summary, expert practitioners exhibited fewer awkward wrist and forearm postures while completing ETI procedures, resulting in greater recruitment of appropriate lifting muscles and a reduction in task completion time. An analysis of incorrect instrument use and improper instrument position among novice participants illustrated that as proper technique among novices yielded wrist postures and muscle utilization more consistent with experienced clinicians. Additionally, it was also observed that distinct characterizations of wrist posture, muscle utilization and task completion time could be generated on the bases if instrument grasp characteristics of the practitioner. Expert practitioners and higher-performing novice practitioners adopted instrument grasps that yielded lesser instrument force at the vallecula (Waddington, et al. 2009), requiring clinicians to apply force along the appropriate instrument vector without additional torque created about the instrument tip. These grasp styles provided clinicians with greater control of the instrument, resulting in improved task completion time while minimizing the occurrence of incorrect wrist postures. Consequently, the findings within

this study suggest that best practices exist among experienced clinicians when performing ETI procedures.

As medical procedure training for many clinical tasks still relies upon the pedagogical methods of teaching by observing, adopting the use of physical ergonomic best practices into emergency medicine and anesthesia training may improve the transition of skills and knowledge from experienced to inexperienced clinicians. In addition to the consideration and communication of clinician-based human factors standards, incorporating increased simulation-based training into early-residency periods provides an opportunity to accelerate the development of clinical skills while providing a mechanism for the illustration of ideal and suboptimal physical ergonomics during clinical procedures (Vozenilek, et al. 2004). Further applications of the physical ergonomic best-practices illustrated within this study could also contribute to an ergonomic redesign of the laryngoscope handle and blade to improve the intuitive hand, arm and tool relationships.

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6.2 PAPER II – Evaluation of Instrument Dexterity and Static Resistance of Laparoendoscopic Single-Site (LESS) Surgical Ports

Evaluation of Instrument Dexterity and Static Resistance of Laparoendoscopic Single-Site (LESS) Surgical Ports

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1. Introduction

Laparoendoscopic Single-Site Surgery (LESS) is an emerging approach in minimally invasive surgery, which represents a significant departure from the standard practice of independent instrument introduction and task triangulation found in conventional laparoscopy (White, et al., 2009). LESS most commonly refers to introducing laparoscopic instruments and a laparoscopic camera through a single incision, typically within the patients' umbilicus. LESS offers cosmetic benefits previously only available from NOTES procedures. Sufficient experimentation has not yet been completed to scientifically conclude that LESS procedures provide absolute measureable clinical benefits over standard laparoscopy (Stolzenberg, et al., 2009; Romanelli, et al., 2010). However, preliminary studies suggest that LESS procedures have the potential to minimize patient discomfort, decrease the risk of incision-related complications and shorten convalescence (White, et al., 2009; Ganpule, et al., 2009; Hansma, et al., 2004; Langwieler, et al., 2009).

Early experimentation with single-incision surgery was relatively unreliable due to a lack of the necessary technology and instrumentation. However advancements in surgical port, camera and instrument technology have vastly improved the viability of single-site laparoscopic surgery (Piskun, et al., 1999). Even with novel technologies, single-incision procedures require greater levels of dexterity for the surgeon due to limited task triangulation (Stolzenburg, et al., 2009). Furthermore, during standard laparoscopy surgeons operating beyond a relatively narrow window of tool articulation require significantly greater muscular output of the shoulder and lower-arm muscles (Berguer, et al., 2001).

Intracorporeal and extracorporeal collisions are common between the instruments and laparoscope during laparoscopic and LESS procedures, limiting the overall instrument range-of-motion and ease of instrument movement (Romanelli, et al., 2010). Transposed instruments and an in-line view of the task area increase procedure complexity for surgeons (Hansma, et al., 2004; Tracy et al., 2008). In a study of LESS donor nephrectomy, these challenges resulted in longer operative and warm ischemia times compared to standard laparoscopy (Canes, et al., 2010). Thus, due to the additional challenges associated with LESS procedures, this study was conducted to determine instrument range-of-motion and the force required to maintain instrument positions within three commercially available LESS surgical ports.

2. Methods

2.1 Materials

There is significant design variation among the current commercially-available LESS ports. The SILS™ port (Covidien, Mansfield, MA, USA), the TriPort™ Access System (Olympus America Inc., Center Valley, PA, USA), and the GelPOINT™ System (Applied Medical, Rancho Santa Margarita, CA, USA) all approach single-site surgery from different design perspectives most notably by port size, material and instrument interaction. The required incision range and insertion depth also varies significantly between LESS ports. Due to these considerations, it was hypothesized that the three LESS ports used in this experiment would have significantly different usability characteristics with regard to static force over the instrument range-of-motion.

The SILS™ Port is constructed from a contoured foam body, which conforms to the abdominal wall of a patient via a 20-mm incision. Instruments are supported by three specially designed 5-mm cannulae that are inserted into the surgical port allowing for the maintenance of pneumoperitoneum. The cannulae can be staggered to varying depths within the surgical port, minimizing collisions of the proximal and distal ends of each trocar. 10-mm and 12-mm instruments can be introduced via the SILS™ port by using the VERSASEAL™ (Covidien, Mansfield, MA, USA) cap, which can also aide in specimen removal. The SILS™ port is introduced using a long curved clamp, which compresses the distal flange of the foam port for placement within the abdominal wall.

The TriPort system consists of two primary pieces, the retractor sleeve and TriPort Boot™, which work together to ensure pneumoperitoneum. The TriPort™ system can accommodate incision lengths from 12 – 25-mm as well as an abdominal wall thickness up to 100-mm in depth. This versatility is accomplished through the retractor sleeve, which is adjusted and secured using the locking outer proximal ring. Instruments are introduced via Gel Valves™ positioned on top of the TriPort Boot™, which can accommodate two 5-mm instruments and a single 10-mm or 12-mm instrument. The Gel Valves™ are located on top of each lumen and are molded out of a firm rubber to form the TriPort Boot™ cap. The TriPort Boot™ is secured against the surface of the patients' abdomen, held in place by the tension within the retractor sleeve. Specimen removal occurs by removing the TriPort Boot™ to expose the surgical site, maintained by the retractor sleeve, locking ring, proximal and distal rings.

The GelPOINT™ Advanced Access Platform™ incorporates the company's GelSeal™ cap, creating a PsuedoAbdomen™ platform that allows a wider range of trocar

placements and theoretically an increased degree of triangulation. Similar to the TriPort™ system, the GelPOINT™ system uses a retraction sleeve and affixing GelSeal™ cap, maintaining pneumoperitoneum and allowing for easy specimen removal. Incision length for the GelPOINT™ port is 15-mm to 70-mm with an incision depth up to and beyond 100mm. Included with the GelPOINT™ system are four 5-mm trocars, designed to pierce and secure against the walls of the GelSeal™ cap. However, larger instruments can also be introduced through larger laparoscopic trocars placed through the gel membrane.

Figure 1 - SILS™ (A), TriPort™ (B) and (C) GelPOINT™ Single-Site Ports [11-13]

A novel test fixture was developed allowing repeatable, measureable force measurements for predetermined instrument positions. Specifically, the novel test fixture was used to assess the force required to manipulate instruments within each surgical port within the transverse and sagittal plane (Figure 2). The test fixture was designed to provide 160 degrees of articulation within the transverse plane, and 60 degrees of articulation within the sagittal plane.

Additionally, the fixture was designed to accommodate three different insert materials to secure the surgical port. Two synthetic skin inserts and a single rigid insert were created

to evaluate the restrictiveness of each surgical port in a variety of conditions. Synthetic skin (Lapro-Abdominal Pad, Limbs and Things™, Bristol, UK) was used to create simulated abdominal walls of 15-mm and 30-mm depth. Each simulated abdominal wall included a 7-in x 7-in synthetic skin insert retained within a rigid-frame perimeter. A 20-mm incision was made in both skin inserts to accommodate each of three surgical ports. The thickness of the synthetic skin inserts were chosen based on prior studies of male and female patients in normal health or mild systemic disease [14]. The rigid insert was created out of 12.7-mm plywood, which contained a 22-mm circular hole to isolate movements of the port from movements of the insert material.

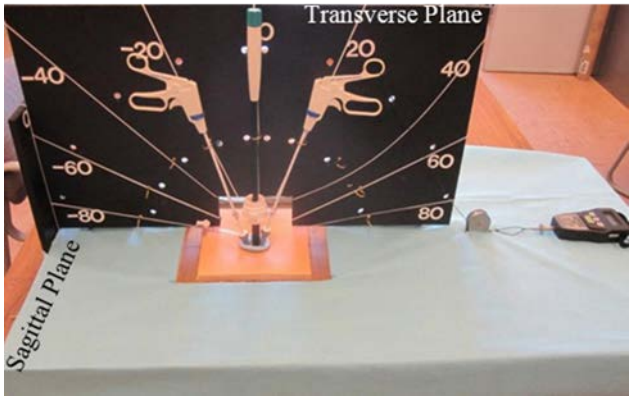

Figure 2 – Experimental Setup

Two standard non-articulating 5-mm EndoGrasp instruments (AutoSuture™, Covidien, Mansfield, MA, USA) and a single 10-mm simulated laparoscope were used to simulate two working instruments and a stationary laparoscope. The 10-mm "scope" was introduced into the SILS™ port and GelPOINT™ port using a VERSASEAL 10/12-mm trocar (Covidien, Mansfield, MA, USA), and was directly introduced into the larger lumen of the TriPort™ surgical Port. Instrument cannulae/lumens on the SILS™ and TriPort™ were spaced approximately 15-mm apart. To ensure consistency in working

angles and instrument/trocar collisions, the trocars included with the GelPOINT™ system were spaced in an identical 15-mm pattern to mirror the fixed positions of the instruments found in both the SILS™ and TriPort™, despite the diameter of the GelPOINT™ allowing a maximum trocar spacing distance of approximately 100-mm.

2.2 Test Methodology

To examine the relationship between port resistance and instrument range-of-motion, the concept of a "separation angle" was created to describe the relationship between the working instruments (Figure 3). Each trial consisted of a fixed instrument and a working instrument, where the force to maintain the working instrument's position was measured using a digital force gauge (Mecmesin, Sterling, VA, USA). Figure 3 illustrates the stationary grasper (G1), the working grasper (G2) and the stationary laparoscope (L), as well as the separation angle created between the positions of each grasper.

The position of the stationary grasper was varied in 20-degree increments from negative 80 to positive 80 degrees in the transverse plane. Positions for the working grasper were evaluated in 20-degree increments from 0 (perpendicular to axis of transverse plane) to positive 80 degrees, which can be seen in Figure 2. Force values at each instrument position combination were recorded three times to determine an average force value at each separation angle. Additionally, each possible instrument position combination was evaluated for each surgical port (3 levels) within each insert (3 levels) at 90, 60, and 30 degrees within the sagittal plane (3 levels), where the entire test fixture with tools are rotated back from the perpendicular orientation shown in Figure 2.

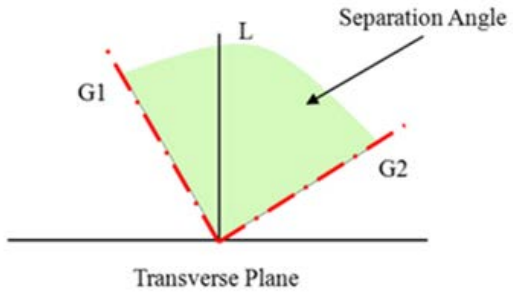

Figure 3 – Instrument Positions & Separation Angle

2.3 Experimental Design

Due to limitations within each surgical port as well as the simulated abdominal walls, the entire set of instrument positions could not be attained for every permutation of the test setup. For example, the 30-mm thick synthetic skin and rigid inserts did not allow for extreme tool positions in both the sagittal and transverse plane for all surgical ports. As a result, several different analytical approaches were used in order to account for these differences.

Analysis 1 included a wide range-of-motion for the instruments. This analysis included all positions within the sagittal plane (90, 60, 30 degrees), all stationary tool positions excluding +80 (-80, -60, -40, -20, 0, 20, 40, 60 degrees) in both synthetic skin inserts and all three surgical ports. Analysis 2 features a reduced data set in order to include the rigid insert, and therefore represents a narrower range-of-motion of the instruments. Analysis 2, included only two positions within the sagittal plane (90 and 60 degrees), fewer positions within the transverse plane (-60, -40, -20, 0, 20, 40 degrees), all inserts (15-mm skin, 30-mm skin, rigid), and all three surgical ports. Thus, only the positions that were

found in the most restrictive condition (rigid) were compared over all three insert conditions.

Due to additional limitations within the data, a third analytical approach was performed for both data sets (Analysis 1 and Analysis 2) to investigate LESS port resistance at incremental separation angle values rather than over the entire range-of-motion. These results expand upon the findings of the initial two analyses, and are presented after the results of Analysis 1 and 2.

All analyses were performed using full-factorial analysis of variance (ANOVA) with blocking on surgical port and insert material for the dependent variable of observed force using SPSS (PASW, V 18.0). A portion of the data was analyzed using SAS (V 9.2). Post-Hoc Tukey tests for non-homogeneity were conducted on the dependent variable of observed force for the independent variables of surgical port, insert material, starting tool position, separation angle and working angle within the sagittal plane for all significant effects. A 0.05 level of significance was set for all statistical tests.

3. Results

3.1 Analysis 1 – Wide Range-of-Movements

The results from Analysis 1 revealed significant main effects for insert type, LESS port type, stationary tool position, moving tool position, separation angle, and sagittal plane angle ($p \leq 0.01$ for all). Additionally, the interaction of LESS port type and insert material was also significant ($p = 0.036$). The findings indicate that for all ports and insert materials, the force required to maintain tool position was related to increasing angular displacement of one or both tools.

Post-hoc tests revealed that there was no significant difference between mean force at varying levels of stationary and moving instrument positions and included angles ($p > 0.05$). However, as hypothesized, more extreme stationary and moving tool positions (greater than 40 degrees from center) resulted in higher average force values than moderate tool positions (less than 40 degrees from center). Similarly, greater values of separation angle resulted in larger average force values observed.

Next, statistically significant differences were noted for the independent variables of LESS port type and insert material for the dependent variable of observed force ($p \leq 0.001$). Post-hoc tests were performed for all LESS port types and both synthetic skin inserts. Tests were performed by blocking on both LESS port and insert material to analyze the significant main effects of each alternate variable.

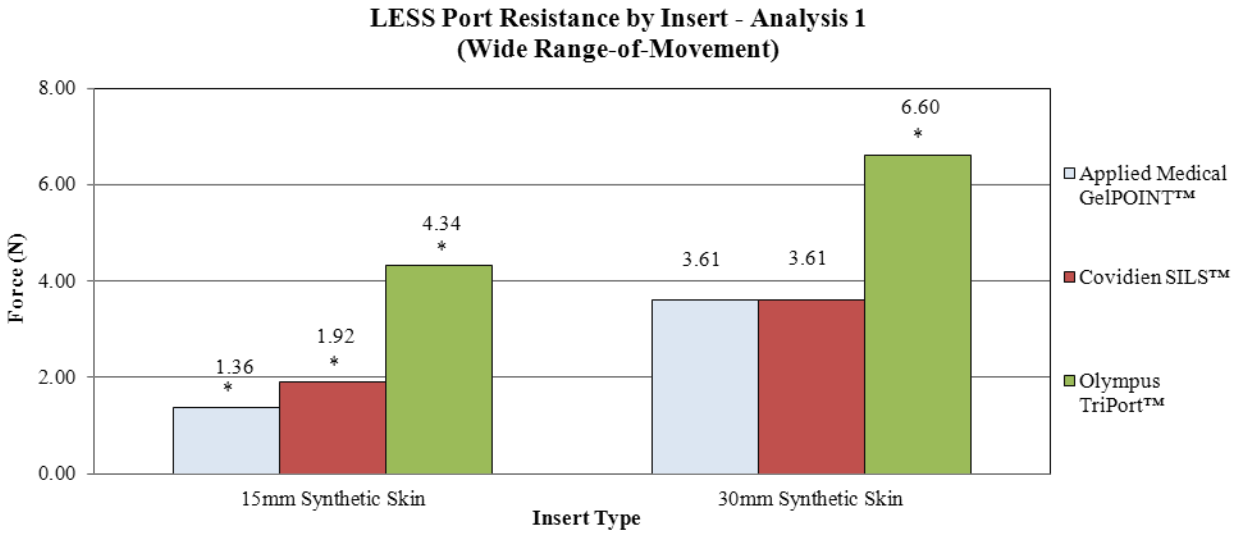

Figure 4 – Post-Hoc Test Results for LESS Port & Insert (Analysis 1)

As shown in Figure 4, statistically significant mean differences ($p \leq 0.05$) are identified with an asterisk. Mean differences exist for all three LESS ports in the 15-mm skin insert. Additionally, each LESS port required greater force in the 30-mm insert ($p \leq 0.001$). The force required to maintain instrument positions in the GelPOINT™ and SILS™ ports within the 30-mm insert were less than the force required to maintain identical instrument positions in the TriPort™ in the less restrictive 15-mm insert. The average values of 1.36 N , 1.92 N and 4.34 N for the GelPOINT™, SILS™, and TriPort™, respectively represent statistically significant mean differences within the 15mm synthetic skin insert ($p \leq 0.001$). The same analysis performed for the 30-mm skin insert revealed mean differences of 3.61 N, 3.61 N, and 6.60 N for the three LESS Ports, with the TriPort having a significantly largest mean resistive force.

3.2 Analysis 2 – Narrow Range-of-Movements

The results from Analysis 2 revealed significant main effects for insert type, LESS port type, stationary tool position, moving tool position, and separation angle ($p \leq 0.001$ for all). Consistent with the findings in Analysis 1, these tests indicated that tool positions and separation angle were statistically significant for observed force regardless of insert or LESS port type. Again for Analysis 2, statistical significance was found for the independent variables of LESS port and insert material for force data ($p \leq 0.001$). Post-hoc tests were performed by blocking on both LESS port and the three insert materials to analyze the significant main effects of both port type and insert material.

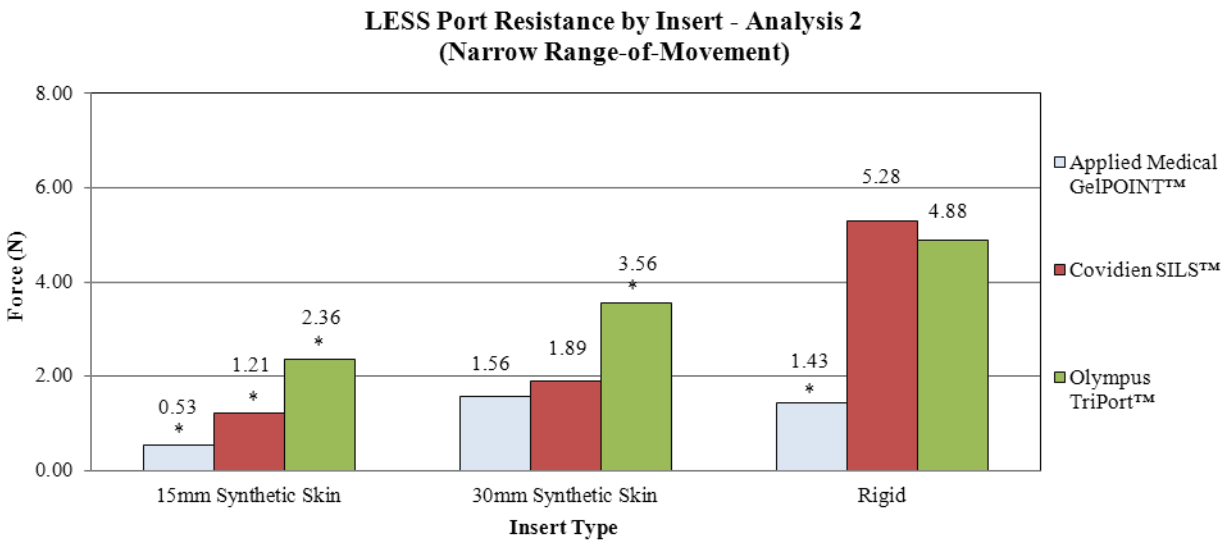

Figure 5 – Post-Hoc Test Results for LESS Port & Insert (Analysis 2)

As shown in Figure 5, mean differences between ports within the 15-mm insert were all statistically significant ($p \leq 0.001$). Significant differences existed within the 30-mm interface only between the TriPort™ and the other LESS ports ($p \leq 0.001$). Analysis within the rigid insert revealed significant differences only with respect to the GelPOINT™ against the other LESS Ports ($p \leq 0.001$). Mean differences that were statistically significant from other values ($p \leq 0.05$) are identified with an asterisk.

Both the 15-mm and 30-mm synthetic skin inserts revealed statistically significant increases in force between each insert material when evaluated by port type ($p \leq 0.001$). Both the TriPort™ and SILS™ ports exhibited significantly greater resistance in the rigid insert compared to the synthetic skin inserts ($p \leq 0.001$), however the GelPOINT™ port required less force in the rigid insert when compared to test results from either skin insert (Figure 5). Additionally, the TriPort™ was unable to complete greater separation angles

at extreme instrument positions within the rigid interface. Due to this limitation, a final third analysis was completed to further investigate LESS port resistance.

3.3 Additional Analysis

The results in Figures 4 and 5 represent aggregate resistance values for each LESS port and insert material across all instrument positions within each data set. Understanding how force and resistance values differ at discrete tool positions is not possible in these analyses, prompting the detailed review presented in this analysis. The data sets for Analysis 1 and Analysis 2 were further stratified into subsets based upon separation angle and ANOVA and post-hoc tests were performed for LESS port and insert material.

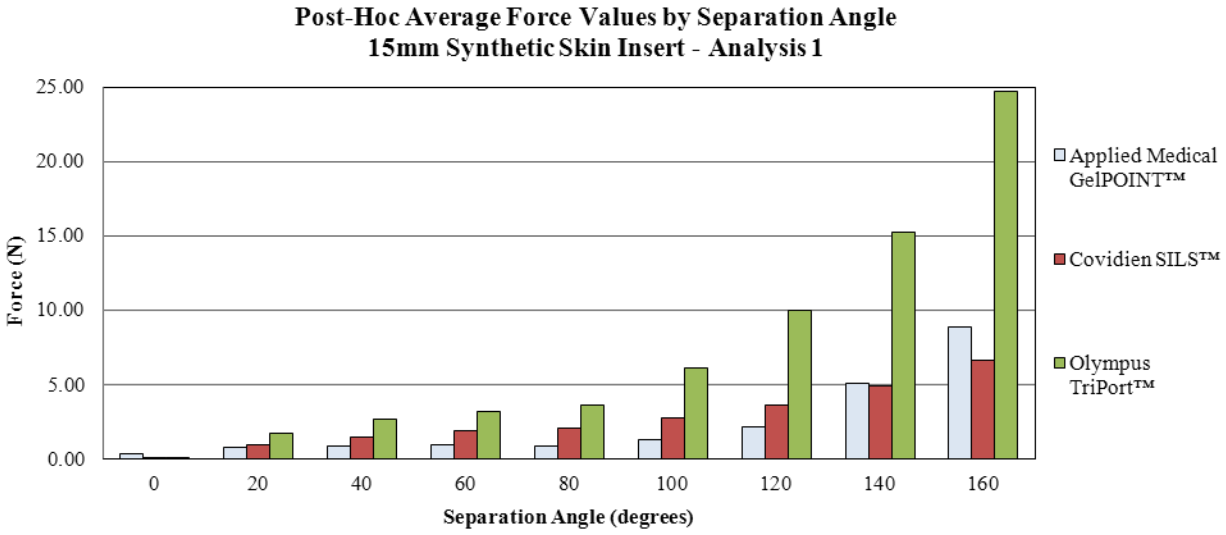

Figure 6 – Average Force Values by Separation Angle – Analysis 1 (15-mm Skin)

The average force values for each LESS port type contained within the 15-mm skin insert are displayed in Figure 6 above. All LESS ports required greater force to achieve wider separation angles and all ports behaved similarly at levels less than 80 degrees of

instrument separation. Statistically significant mean differences between LESS ports did not emerge until greater than 100 degrees of separation, and were only between the TriPort™ and the other LESS ports ($p \leq 0$ .05). Additionally, resistance to instrument range of motion and differences between LESS ports becomes increasingly pronounced at greater separation angles.

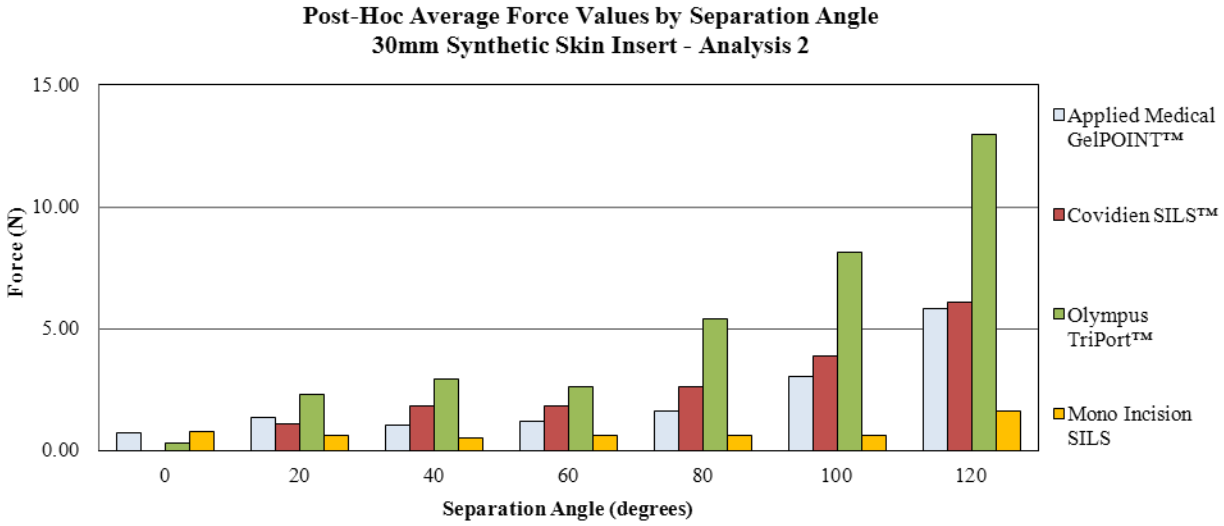

Figure 7 – Average Force Values by Separation Angle – Analysis 2 (30-mm Skin)

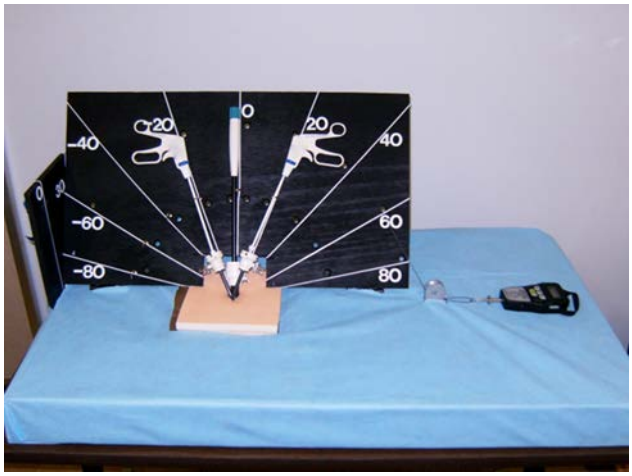

Figure 8 – Mono Incision SILS

The average force values for each LESS port type evaluated within the 30-mm skin insert are presented in Figure 7. Statistically significant mean differences were observed between the GelPOINT™ and TriPort™ ports at separation angles of greater than 80 degrees ($p \leq 0.05$). At separation angles larger 80 degrees, the resistance observed in the GelPOINT™ and SILS™ remained similar while the resistance in the TriPort™ increased well beyond both other ports.

Single-site procedures were performed prior to the availability of LESS ports by introducing multiple trocars into a single incision of the fascia [3, 9, 15, 16]. For supplementary purposes identical experimentation was performed using two 5-mm trocars introduced into smaller incisions within the primary fascia incision in the 30-mm skin insert (Figure 8) to simulate a mono-incision single-incision procedure (3 trocars, single incision and no surgical port). As shown in Figure 8, all LESS ports require greater force to manipulate instruments in comparison to a mono-incision single-incision procedure and the force to maintain tool positions using the mono-incision technique is minimal. However, the mono-incision technique poses additional risks such as tears within the fascia and may not be suitable for all procedure types and/or patients.

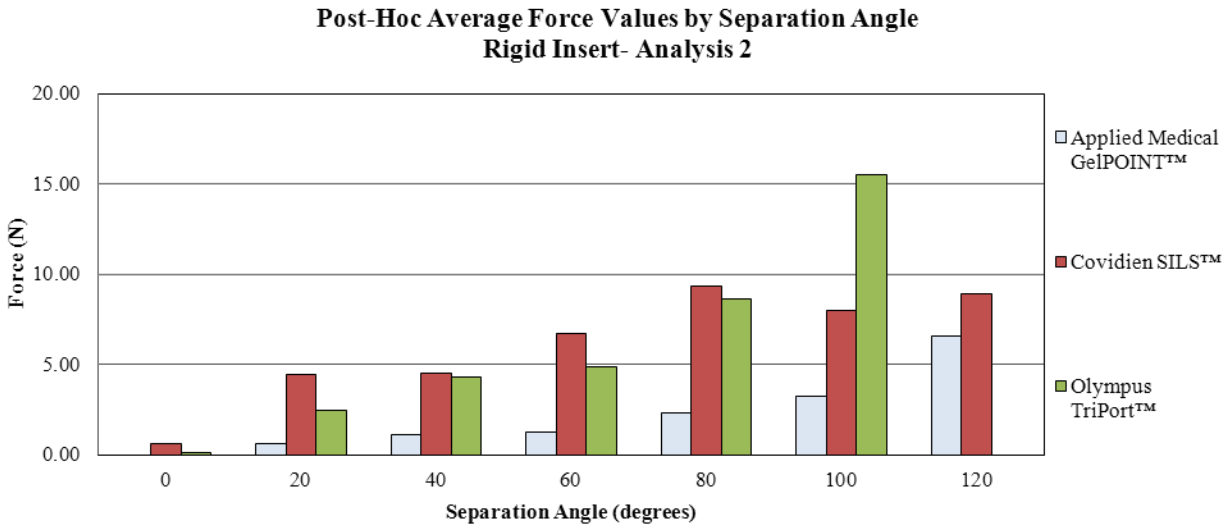

Figure 9 – Average Force Values by Separation Angle – Analysis 2 (Rigid)

The average force values for each port type contained within the rigid insert are displayed in Figure 9. Due to the constrictive nature of this interface, the data set used in Analysis 2 (narrow range of motion) was again used. Figure 5 displayed the pronounced force value increases for each LESS port when evaluated within the rigid insert. In particular, the rigid insert significantly restricted instrument mobility within the TriPort surgical port. The data above illustrates that the TriPort™ could not achieve 120 degrees of separation, leading to an understated average force value for this port when evaluated within a rigid interface (Figure 5). As shown in Figure 9 above, all ports required more force as the separation angle increased. However both the GelPOINT™ and TriPort™ provided the less resistance over the SILS™ port until the separation angle of 100 degrees was encountered.

4. Discussion

The independent variables of stationary tool position, moving tool position, and included angle revealed significant associations with observed force for both Analysis 1 and Analysis 2. Given the nature of this experiment and the physics of the instrument and port interaction, these results were expected and validated our hypothesis about the relationship between instrument range-of-motion and LESS port resistance. Specifically, insert material and LESS port type had significant effects on instrument range-of-motion and the force required to maintain instrument positions. Furthermore, each port required greater force in the 30-mm synthetic skin insert compared to the 15-mm insert. The GelPOINT™ exhibited the least inherent resistance to instrument movement, while the TriPort™ required the greatest force to maintain instrument positions. Lastly, as the range-of-movement of the instruments increased, the differences between the SILS™ and GelPOINT ports became less significant (Figure 6 versus Figure 5).

The rigid insert was selected to evaluate the resistance of each LESS port in isolation from the inherent flexibility of the synthetic skin. Acting as a neutral-type interface, the rigid interface revealed significant differences in the resistance between the GelPOINT™ and SILS™ LESS ports, which were not immediately apparent in previous analyses. In this test, the resistance for the GelPOINT™ port was minimal due to narrow set of instrument positions and the high level of instrument dexterity offered by the GelSeal™ cap. The SILS™ port became noticeably more restrictive, most likely because this port moves within the fascia and abdominal wall rather than being outside of it as with the GelPOINT. The SILS™ port translates much of the tool movement into the surrounding fascia due to its position within the abdomen and the rigid cannulae that the instruments

operate within. As a result, the SILS™ port was able to achieve all positions within the rigid insert; however the wider positions caused a high level of stretching and collision between the foam port and the rigid trocars. This analysis illustrated that previously observed resistance values for the SILS™ port represent movement and deformation of the port as well as that of the synthetic skin interface. The firm construction of the TriPort Boot™ and molded lumens, required higher levels of force to separate and flex the instruments and significantly resisted wider instrument positions (Figure 10). Consequently, the TriPort™ was unable to attain all positions within the rigid insert, and it demonstrated more resistance to tool movement than the GelPOINT™ despite their similar cap and sleeve design.

The TriPort™ and GelPOINT™ surgical ports sit on top of the abdomen, with the retraction sleeve maintaining a passageway for the tools into the abdomen. Force values for these LESS ports represent a different interaction between the port and the fascia. In particular, angular displacement of the instruments in the GelPOINT™ caused no noticeable strain or resistance in the GelSeal™ cap and very little deformation of the skin insert. When evaluating the GelPOINT, a majority of the resistance originated from the instruments acting against the fascia itself through the simulated incision. Resistance within the TriPort™ was attributed to the rigid nature of the TriPort™ boot and the interaction of the instruments against the fascia. The molded TriPort Boot™ provided significant resistance at wider separation angles. This resistance is combined with the force required for the instruments to displace the synthetic skin material. Even at modest separation angles each LESS port behaves differently and seems to inflict different stresses upon the abdominal wall. This finding may also be clinically relevant as the

LESS ports (which compress and move the abdominal skin and fascia) may lead to bruising, skin trauma, and possibly increased pain.

Figure 10 – Port & Insert Behavior under Moderate Instrument Articulation

Examination of the data in Figures 6, 7 and 9 illustrate the different behavior between each LESS port as separation angle changes. Minimal force is required to manipulate tools within the GelPOINT™ port until very wide angles. At extreme tool positions the height of the GelSeal™ cap and distance to the fulcrum (incision) become a source for increased resistance within the port itself. The relationship between resistance and separation angle is relatively linear until such extreme positions at which point the resistance increases dramatically. The geometry and material construction of the TriPort™ prohibits extreme working angles of the instruments and the associated resistance values are considerably larger than those observed in the GelPOINT™ and SILS™ ports. The SILS™ port displays the most linear relationship for resistance and separation angles due to its conforming foam body and ability to conformity within the simulated abdominal wall. Higher force values were observed in the SILS™ port for moderate instrument positions but the SILS port best accommodates extreme tool positions within the analyses. The manner in which the SILS™ port conforms to and moves within the abdominal incision rather than resting atop the umbilicus may actually provide surgeons with a greater range-of-motion. Additional research and clinical

observation is required to analyze how each LESS port affects the damage to the abdomen and fascia during surgery at wider ranges of motion.

Table 1 – LESS Port Performance Overview (++ Good, + Acceptable, - Poor)

Range-of-Motion	Degrees	Applied Medical GelPOINT™	Covidien SILS™	Olympus TriPort™
15-mm Synthetic Insert				
Narrow	*< 60*	++	++	++
Moderate	*60 - 100*	++	++	+
Wide	*>100*	+	++	-
30-mm Synthetic Insert				
Narrow	*< 60*	++	++	+
Moderate	*60 - 100*	++	+	-
Wide	*>100*	+	+	-
Rigid Insert				
Narrow	*< 60*	++	+	++
Moderate	*60 - 100*	++	+	-
Wide	*>100*	+	+	-

The implications of LESS port resistance may be important to consider in a wider application than that which is currently presented. The working instrument positions evaluated within this study were constrained by the test fixture and apparatus, and do not replicate the high-level of variability within instrument and camera relationships that routinely occur during single-incision (LESS) procedures. Specifically, in the current study the simulated laparoscope was fixed within the transverse plane with both working instruments. Conversely, many modern cameras used in minimally invasive surgery utilize an angled lens at the distal end of the camera body, which provides an optimal view of the target area while also reducing instrument and camera collisions (Figure 11).

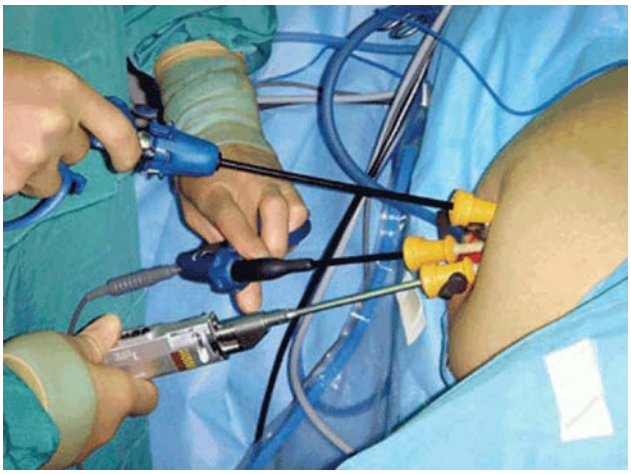

Figure 11 – Instrument and Camera Positions during LESS Procedure [9]

Additionally, the test fixture used for evaluation simulated a patient positioned in supine position, with the LESS port positioned atop a level coronal plane. In this manner, instruments and the simulated laparoscope were inserted into the LESS port normal to the coronal plane, and systematically varied within the transverse and sagittal planes. Instrument positions relative to anatomical planes during LESS procedures are constrained by the umbilicus and the target area for the procedure, resulting in additional variability in instrument and LESS port position relationships when compared to those investigated within this study. For many LESS procedures, it is common to reposition the patient to achieve optimal instrument access to the target area (normal instrument vector to target area). However, ideal access to target areas cannot always be achieved by repositioning patients prior to surgery for all procedures, and therefore situations exist where surgeons may work for prolonged periods of time at high-resistance working angles relative to optimal (normal) instrument positions within LESS ports.

In light of these additional factors not evaluated in the current study, it is possible that the examined LESS ports may exhibit additional resistance to instrument mobility than

currently presented. Specifically, under the optimal circumstances within the control of this study, the narrower range of instrument positions were found to not yield significant differences among the LESS ports. However, variations in the relationship between the surgical instruments, laparoscope and LESS port due to patient position and procedural requirements should warrant consideration for the range of motion required during minimally invasive procedures, and therefore similar consideration for the inherent LESS port resistance among available devices.

5. Conclusion

Variations in the separation angle between working instruments were shown to affect the force required to maintain instrument positions during laparoendoscopic single-site (LESS) procedures. Significantly different average force values were obtained for each LESS port contained within multiple simulated insert materials. The GelPOINT Advanced Access Platform™ afforded the best overall range-of-motion with minimal resistance to instrument movement. The Olympus TriPort Access System™ required the greatest force to maintain instrument positions and allowed the narrowest range-of-motion. Further research is necessary to investigate how LESS port selection can optimize quality, efficacy, and efficiency of single-incision procedures. As with most surgical technology, a single LESS port is likely not adequate for every surgical procedure. Therefore, consideration of the range of motion required during a planned LESS procedure and patient body habitus is important when selecting a LESS port.

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Disclosure Statement

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6.3 PAPER III – Laparoendoscopic Single-site (LESS) Surgery Versus Conventional Laparoscopic Surgery: Comparison of Surgical Port Performance in a Surgical Simulator with Novices

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

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1. Introduction

1.1 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 (Wheeless 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.

2. Materials and Methods

2.1 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)

2.2 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[a]

	SILS™ Port	TriPort™ Access System	GelPOINT™ System
			
Incision Length	20-mm	12 to 25-mm	15 to 70-mm
Access Points	3	3	3[b]
Access Point Size	5 to 12-mm	Two 5-mm & One 12-mm	5-mm
Abdominal	Passively	Adjustable o-ring	Adjustable o-ring

Retraction	conforms	retraction system	retraction system
Max Abdominal Wall Thickness	50-mm[c]	100-mm	180-mm[d]
Insertion Device	Péan clamp	Blunt Introducer	N/A
Lubrication	Aids device insertion	Instrument insertion	Aids device insertion

[a] Fader et al., 2010; GelPOINT Applied Medical, 2010; Irwin et al., 2010; LESS from Olympus, 2010; MacDonald et al., 2009; SILS Port, 2010
[b] limited by incision size only
[c] maximum height of port
[d] 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.

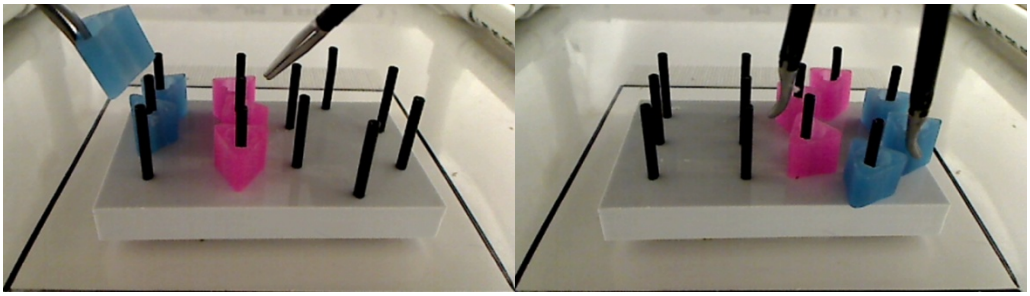

Figure 4.1: Peg Transfer Task -- Conventional Laparoscopy (left) and LESS (right)

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.

2.3 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.

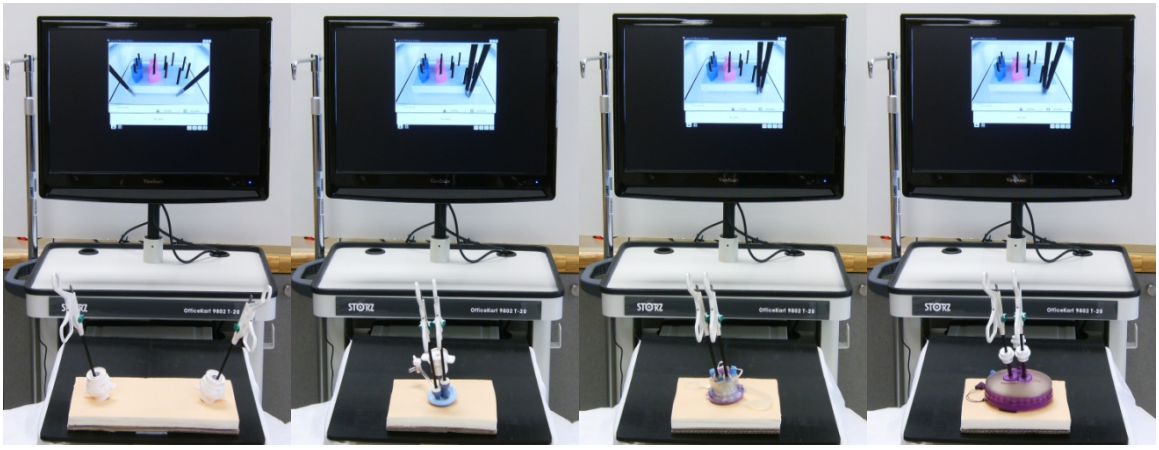

Figure 4.2: Surgical Simulator (from left to right) Conventional Laparoscopy, SILS™ Port, TriPort™ Access System, and GelPOINT™ System

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.

2.4 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. 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.

2.5 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.

3. Results

3.1 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)	**0.0040**
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	< **0.0001**	0.8527	-

3.2 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[a]	4 (1.00)	3.5 (1.00)	3 (2.00)	4 (2.00)	0.562
Instrument Maneuverability[a]	4 (2.00)	3 (2.00)	3 (1.00)	4 (1.75)	0.225
Ease-of-use[a]	4 (0.75)	3 (1.00)	3 (2.00)	3.5 (1.00)	**0.028**
Overall Rank[b]	1 (2.00)	3 (1.00)	3 (2.00)	2 (1.00)	**0.006**

[a] Rated 1-Very Difficult, 2-Difficult, 3-Somewhat Difficult, 4-Somewhat Easy, 5-Easy, 6-Very Easy
[b] Ranked from 1-Best to 4-Worst

4. 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[a]

	Pros	Cons
SILS Port	▪ Flexible, soft foam minimizes abdominal bruising ▪ Low-profile instrument ports ▪ Robust and flexible to accept larger instruments such as staplers ▪ Provides stability/support to hand instruments ▪ Insufflation tubing away from port's main body ▪ Cost	▪ Passively conforms to abdominal wall ▪ Lacks adjustability for varying incision lengths and abdominal wall thicknesses ▪ Difficult to insert 12-mm cannula ▪ Device insertion and removal can be difficult depending on patient characteristics such as BMI ▪ Not a wound protector
TriPort	▪ Blunt introducer available ▪ Two insufflation-desufflation lines ▪ Low-profile instrument ports ▪ Retraction system reduces trocar clutter and protrusion into the operative field ▪ Varying incision lengths and abdominal wall thicknesses ▪ Specimen removal without entire device removal ▪ Includes device removal ring ▪ Wound protector ▪ Cost	▪ Gel caps must be lubricated and treated gently, loss of lubrication results in palpable friction on instrument shafts ▪ Lubrication can smudge optics ▪ Retraction system complicated with multiple steps including cinching of the sleeve, attachment of two retainer clips and removal of excess sleeve ▪ Retraction system loosens during procedure

GelPOINT	▪ Multiple instrument configurations ▪ Accepts instruments directly or through trocars ▪ Trocars float above the incision ▪ Retraction system reduces trocar clutter and protrusion into the operative field ▪ Varying incision lengths and abdominal wall thicknesses ▪ Large outer working profile ▪ Flexible fulcrum for movement ▪ Allows extracorporeal anastomosis ▪ Specimen removal without entire device removal ▪ Includes device removal ring ▪ Wound protector	▪ Only 5-mm self-retaining trocars ▪ Adjustment of retraction sleeve requires two personnel ▪ GelSeal Cap bows outward during insufflation creating an altered instrument fulcrum ▪ Cost

[a] (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.

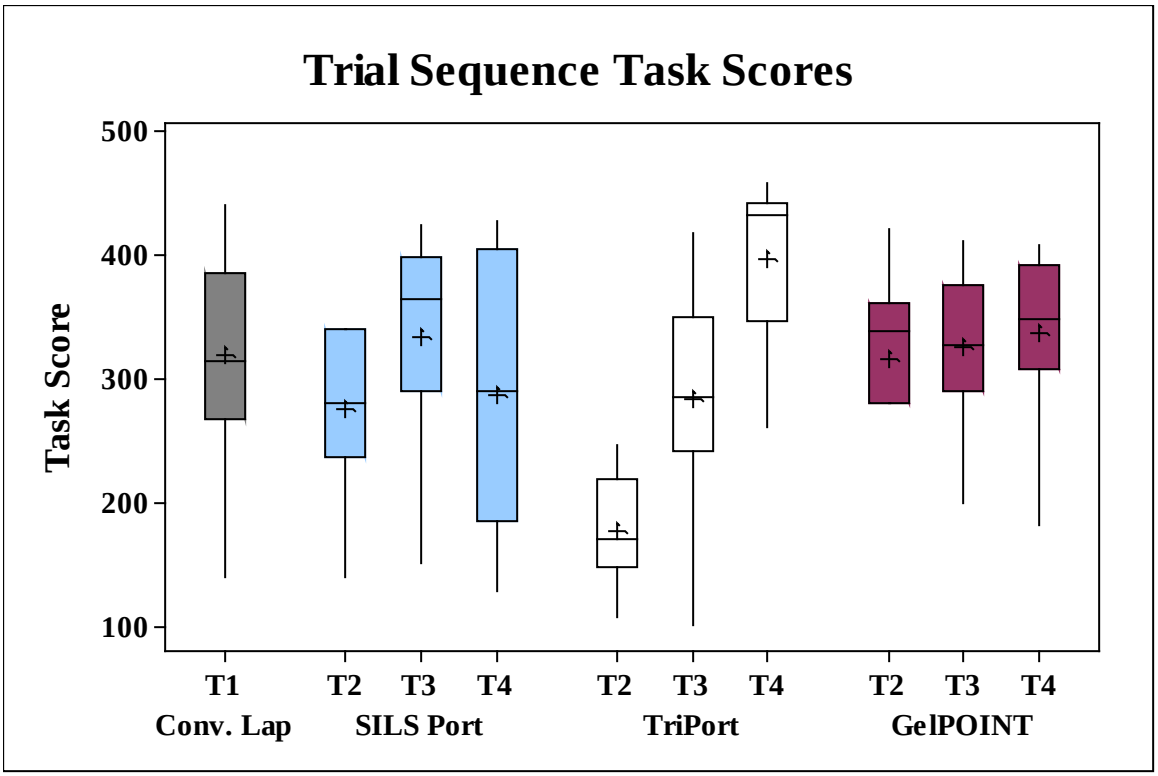

Figure 4.3: Task Score Boxplot with Trial Sequence

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

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