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EVALUATION OF SURGICAL INSTRUMENTS FOR USE IN MINIMALLY INVASIVE SURGERY

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ABSTRACT

With the advancement of technology and society's understanding of scientific principles, come new ways to improve the quality of patient's lives, including the prevention of unnecessary morbidity and mortality. Medical advancements provide new medical treatments and technologies that are increasingly safer, less invasive and more successful. One, relatively recent, medical advancement is the creation of Minimally Invasive Surgery (MIS). This field of medicine allows for new as well as traditional procedures to be performed with less risk and greatly improved outcomes. One of the very recent sub-specialties of MIS, having only been established approximately five years ago, is Natural Orifice Translumenal Endoscopic Surgery (NOTES). These procedures are conducted through a flexible endoscope that is inserted into the body through the mouth, anus, vagina or urethra and leave no external scars, reduce length of hospital stays, and greatly reduce the patient's chances of getting an infection.

For these reasons, and others, NOTES is a quickly growing field, but is still in its early developmental stages. In fact, many obstacles exist that have widely prevented NOTES from moving from animal testing to human testing. Perhaps the greatest of these obstacles is the current lack of sufficient instrumentation. This shortage of instruments greatly reduces the number of possible surgical procedures and the number of conditions NOTES could one day cure. Another major hurdle faced by NOTES surgeons is the lack of a standardized testing procedures and task lists similar to those that already exist for laparoscopic surgery (Called "Rosser Station Tasks"). This task list is not only necessary to sufficiently evaluate new instrument designs, but also to train and certify new NOTES surgeons.

The first goal of the research presented in this thesis was to use the "Rosser Station Tasks" list for laparoscopic instruments as a starting point to design a list of tasks for use in endoscopic training and evaluation. This achievement was accomplished by compiling tasks that were designed in three ways. The first three tasks were adopted from previous literature and

modified for use with endoscopic instruments instead of laparoscopic procedures. The first adopted task is the Fuzzy Ball task and tests an instruments ability to complete fine grasping objectives. The second adopted task is the Cup Drop Drill originally presented in the "Rosser Station Tasks" list. This is the only of the Rosser station tasks that was adopted for endoscopic use and it tests the maneuverability and control of a forceps instrument. The last adopted task is the Ring Around task. This task, which is a modified version of the Sea Spike task presented in previous literature, evaluates the instrument's ability to grasp and maneuver fine objects. In addition to the adopted and modified tasks, three new tasks were designed. The first new task is the Material Pull task, which evaluates a forceps' ability to grasp and pull on a soft material that simulates tissue. The second new task is the Simulated Biopsy task and tests a forceps' ability to grasp and remove material from a target as is done in a surgical biopsy. The last task on the list was newly designed for this research and is called the Force Gauge task. The Force Gauge task evaluates the maximum pull-off force that a forceps instrument can deliver. Combined, these six tasks form a new Standardized NOTES Instrument Task List. This task list can now be used to objectively evaluate any NOTES forceps design. However, by modifying or emitting tasks as well as designing additional tasks to test certain functions, this task list can serve as a basis to test any endoscopic instrument, not just forceps. As the field of NOTES continues to grow and is widely implemented for surgical procedures, these training and certification processes will become increasingly more important.

The second goal of the research presented here was to use the new Standardized NOTES Instrument Tasks List to evaluate a new endoscopic forceps instrument currently under development at the Pennsylvania State University. This evaluation was completed by having twelve surgical residents perform the tasks on the list in an endoscopic box trainer with both a commercially available "standard" instrument and the new prototype instrument for comparison. At the completion of the testing, each participant was asked to fill out a survey which evaluated

the various aspects of each instrument. The resulting data and feedback illuminated several important things about the new forceps design. Most importantly the new instrument performed favorably compared to the standard instrument. It was felt that the new design fills a void and provides an instrument that excels at fine grasping, where few instruments of its kind are currently available. It was also identified that the new instrument allows for superior control of intermediate positions between fully opened and fully closed. These advantages as well as other comments from the participants clearly demonstrate that the new instrument is superior to the standard instrument in several respects. However, as with any prototype, several weaknesses were pointed out as well. The most important of these weaknesses is that the prototype design does not perform well as a biopsy forceps. This is primarily due to a lack of teeth on the forceps due to manufacturing limitations, and the tendency of the prototype instrument to remove material by scraping instead of grasping. This is not ideal for biopsies, so the instrument should not be used as such. Several necessary improvements were also identified. Most prominently, it was identified that the prototype design jaw length and distal jaw opening need to be increased. In addition, an increase in the instrument's ability to rotate easily is also desirable. These improvements would further improve the prototype design's ability to grasp fine objects, particularly from awkward angles.

In summary, two goals were set and accomplished by the research. A new Standardized NOTES Instrument Tasks List was created and then used to evaluate an endoscopic forceps instrument being developed at the Pennsylvania State University. This testing has also proved sufficiently challenging to capture and maintain participants' concentration, which is desirable for any testing procedure. The data and feedback provided show that the new design is good and fills a void in instrumentation needs, but needs to be further refined for commercial production. These advancements will prove increasingly more important as NOTES continues to expand and becomes a practical and widely implemented solution to surgical needs.

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Chapter 1

Introduction

Endlessly attempting to enhance their patients' quality of life, medical researchers constantly develop new procedures and devices that treat or cure various diseases and conditions. One very important advancement has been the development and increased use of Minimally Invasive Surgery (MIS). Advantages of minimally invasive surgery over traditional open procedures include: smaller required incisions which greatly reduces the incidence of infection and uncontrolled bleedings, decreased damage to surrounding tissue layers, minimized healing times by often as much as 50 percent, and cosmetic advantages such as smaller resulting scars [1].

Due to the advantages of minimally invasive procedures over traditional open surgeries, MIS has grown continuously more prevalent in surgical medicine. Still a fairly new and rapidly developing field, having been introduced approximately twenty years ago, MIS has branched into multiple surgical sub-specialties as it continues to encompass more procedures and make new operations possible. As such, research presented in this thesis deals with the surgical sub-specialty of Natural Orifice Translumenal Endoscopic Surgery (NOTES). This area of medicine deals with procedures that are conducted using an endoscope inserted into the body through one of several naturally occurring orifices, which include the mouth, anus, urethra and vagina. In this chapter background information as well as previous developments on NOTES will be presented.

Background Information and Objectives

Having only existed officially since 2005, Natural Orifice Translumenal Endoscopic Surgery is a very recent technological advancement and is in its early development stages. While

Minimally Invasive Surgery is defined as surgery done with only a small incision or no incision at all, the NOTES field of medicine is much more specific. As previously mentioned, NOTES deals only with procedures conducted with an endoscope through a natural body orifice. However, due to several limitations and barriers, few surgical procedures have been conducted with NOTES on actual humans.

Largely due to a lack of necessary instrumentation for surgeons in this emerging field, equipment limitations are some of the largest obstacles to the continued advancement of NOTES [2]. Only in the last few years have advances in technology allowed for the development of sufficient endoscopes and basic instruments required for surgical trials. However, a lack of sufficient instrumentation is not the only barrier to overcome as a shortage in available training and testing methods for new NOTES surgeons is also a tangible hurdle. Traditionally requiring physicians to attend training seminars and demonstrate their proficiency by way of simulators and proctored surgical procedures, most commonly utilized methods of surgery, including general and laparoscopic, requires individuals to be trained and credentialed before performing tests and procedures on human subjects [3]. Therefore, it is not only necessary to train NOTES surgeons, but also to test and certify their abilities before clinical trials on human subjects are completed. As a new field of medicine with a great deal of potential, surgical competence must be attained by performing surgeons in order for this field of study to advance.

The goal of the research presented in this thesis is twofold. The first objective was to define standard competencies by way of a standardized set of tasks for the evaluation of surgeons to perform NOTES procedures and to evaluate new surgical instruments. This task list fills an important void, as it could be used as a standard testing procedure for training future NOTES surgeons and for evaluating new instruments. The second research objective was to apply the newly created task list to evaluate a new forceps prototype, via a side-by-side comparison with an

existing endoscopic forceps instrument, and if necessary improve the design. These objectives were accomplished and the results are presented throughout this thesis.

Literature Review

In this section, a chronological summary of the advancements and developments in the areas of training, testing, and instrument design as related to NOTES is presented. This summary begins in 2005, with the official recognition of NOTES, and continues to the present status of this area of medical advancement.

Since the official creation of NOTES medicine, many developments have taken place. The common starting point for most discussions of the history and advancements in NOTES is the January 2005 joint meeting of members of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) and a group of expert endoscopists representing the American Society for Gastrointestinal Endoscopy (ASGE) that took place in Chicago. Convened to discuss the rapidly growing revolution in endolumenal therapies for gastrointestinal diseases, several important topics were covered at this meeting and later published in a paper by Richards and Rattner [2]. First discussed was the current status of technological developments necessary for NOTES to progress. It was determined that suitable endoscopes existed, though modifications were suggested, but the additional equipment needed to perform such procedures was limited or non-existent, greatly reducing the number of possible procedures that could be performed. The same paper addressed a second topic of discussion pertaining to possible NOTES procedures, which included abatement of Barrett's Esophagus and the resection of portions of the GI tract. These discussions lead the group to conclude that NOTES was truly a surgical field and should be lead by trained and competent surgeons [2].

At the proceedings of the joint SAGES/ASGE gathering and presented in the same paper by Richards and Rattner, discussions regarding the future of the NOTES field, uncovered two very important developments. The first was the need for a NOTES program, similar to the Fundamentals of Laparoscopic Surgery program, which would provide students exposure and training in the area of flexible endoscopic surgery. It was further proposed that such a program be named the Fundamentals of Flexible Endoscopy Program and provide students with necessary skill assessments. The second major outcome of this meeting, as also presented by Richards and Rattner, was the recognition of a critical need for additional instrumentation in order for NOTES to be a successful procedure. The group consensus was that the instrumentation must not be developed in isolation, but in collaboration with competent gastroenterologists in order to ensure their quality and practicality [2].

The same group met again in New York City in July 2005 to create a document that would serve as a guide in advancing NOTES. Upon its completion, this document, presented in a paper by Rattnew and Kalloo, restated the advantages of NOTES, including reducing pain and recovery time as well as cosmetic benefits [4]. Polled to determine the most pressing barriers to the advancement of NOTES as a viable surgical field, the group reached a consensus on several of them, including the need to secure gastric closures, the importance of understanding physiological changes caused by NOTES procedures, and the requirement for additional training before NOTES procedures can be conducted on humans [4]. The most pressing issue in this thesis, and one addressed specifically by the group, is the need for additional training. Additional testing and training is necessary not only to educate new surgeons, but to eliminate possible mistakes and complications that could be associated with NOTES procedures [4]. While there are many pressing issues to address in this field, the research presented in the thesis will be focused on addressing this lack of testing and training as well as utilizing a newly designed task list to improve an instrument design.

Using the papers developed and published by the SAGES/ASGE working group, many different doctors and groups of doctors have attempted to progress NOTES as a clinically used procedure group. In just the few years since the working group papers were published, numerous surgical procedures have been proposed, and some have been conducted safely on animals and even humans [5] [6]. Near the end of 2005, one paper proposed several new procedures that could one day be conducted with the use of NOTES techniques. This paper proposes that several new and many traditional procedures could be conducted with NOTES, including therapy for gastrointestinal reflux, endoscopic suturing of the esophagogastric junction, injection of biopolymers, and the possible application of radiofrequency energy into the esophageal wall. However, even though this paper acknowledges the feasibility of these and other NOTES procedures, it also recognizes the need for additional advancements in the areas of training and instrument development [5].

Published in December of 2007, another paper written by Pearl and Ponsky, presented newly recognized additional advantages of NOTES procedures [1]. The first notable advantage of these procedures is the lack of anesthesia necessary to conduct them. While not all NOTES procedures could be conducted without the use of anesthesia, most can be done using conscious sedation which has far less risk of complications. Able to be conducted using conscious sedation, rather than anesthesia, NOTES greatly reduces the amount of necessary equipment, risks of complications due to anesthesia, and recovery time and makes these procedures capable of being performed without a full operating room. Pearl and Ponsky also identified another advantage in that NOTES procedures can be performed in many settings since a single endoscope tower can hold all the necessary instrumentation, and they require a less clean working environment as no open incision is made on the outside of the body. This means that NOTES procedures could ultimately be performed without complications in developing countries, away from sterile operation rooms [1]. Each outlined advantage illustrates the need for the continued enhancement

of NOTES instruments and procedures, so that these benefits can be experienced by those who truly need them.

This need for additional training and testing procedures is the issue addressed by the first objective of the research presented in thesis. In order to address this need, we must begin with testing used in other areas of medicine. The history of training and testing students in laparoscopic procedures is of particular importance as it forms a basis for the tests developed in this thesis. Medical students who wish to become laparoscopic surgeons must undergo training that includes three separate testing mediums. The first type of testing is written standardized tests which test a surgeon's knowledge. The second type is subjective faculty evaluations, which can be confusing and even conflicting as they are based on person perceptions. The third area is of the greatest importance to this research and is technical testing via standardized tasks that measure a student's ability to perform different surgical tasks in a box trainer [7] [3] [8]. This third type of test is the one that this research aims to modify and adapt to NOTES training.

Technical skills training and testing for laparoscopic surgeons is based on a set of tests developed and published in 1997. These tests were developed by Dr. James C. Rosser, and are commonly referred to as "Rosser station tests" [7]. The tests presented in this paper include the Rope Pass Drill, the Cup Drop Drill, the Triangle Transfer Drill, and the Intracorporeal Suturing Drill. These tasks are performed by the students and each drill is timed for comparison amongst students. These tasks form the basis for research presented here and were adapted and modified by the researcher as explained in Chapter 2 of this thesis. This paper by Dr. Rosser, also presents an important concept that the box-trainer training and testing is particularly useful for minimally invasive surgeons because the skills needed are fundamentally different than those used in open surgery. That is, minimally invasive procedures are performed using a 2-Dimensional image on a screen instead of being able to see the object unaided. This is an issue because students must learn to judge depth using triangulation instead of visual depth perception and must get used to

performing surgeries at a distance with minimum force feedback [7]. These are skills that hand-eye coordination alone does not improve. Instead it is necessary to practice repetitively to develop and improve these skills [7]. In addition to the standard Rosser station tasks, other tasks have been developed to test other skills necessary to perform certain types of laparoscopic and NOTES surgeries. One such additional task developed to aid in training NOTES surgeons is called the Sea-spike task [9] [10]. Another task found in literature was the Fuzzy Ball task [11]. These tasks will be further described in Chapter 2 of this thesis.

In addition to understanding what the tasks are, it is critical to understand why the tests need to be developed and utilized. As mentioned in the previously introduced paper by Dr. Rosser, it is necessary for laparoscopic surgeons to practice and develop their surgical skills before performing operations on human subjects. This necessity is further described in other papers by various physicians. In a paper written by Chung et al and published shortly after Dr. Rosser's paper, a study was described involving multiple surgical students [3]. These students were asked to complete a list of six tasks, including the Rosser station tests and several others and then required to attend a training seminar. At this seminar, they practiced these skills and received lessons and feedback from certified surgeons. After the seminar, they were asked to repeat the task list. In both cases, the individual tasks were timed and the students exhibited considerable improvement after the seminar, approximately 8%, in the time it took to successfully accomplish each task. This study shows the effect of training and practicing these skills as well as its benefit in the form of decreased completion time and increased competency in completing basic laparoscopic tasks [3]. A paper written in 1999 by Dr. Dimitri J. Anastakis, presents several additional arguments for using box trainers including the fact that operating room time is expensive and most institutions are being forced by economic conditions to reduce operating room time for each surgeon as well as increase operating time efficiency [12]. Another concern presented by Anastakis is that there could be ethical issues about teaching basic surgical skills on

patients as well as allowing less competent surgeons to perform more complex surgeries due to training time constraints [12]. These risks can be significantly reduced by the use of box trainers, which allow surgical students to practice and develop basic surgical skills at their own rate in a setting which risks no patient lives. However, an alternative to both patient surgery and box trainers does exist in the form of live animal surgical training. This route is largely avoided though, due to cost and ethical repercussions as well as additional risk of contracting communicable diseases for students [12].

In addition to technical skill training, another reason to have and utilize box trainers as well as a standardized task list is the purpose of student skill tracking. A standardized testing procedure allows for students to compare themselves quantitatively to other students as well as to receive vital feedback from professors and other surgeons. These tasks can then also serve as a basis for certification as well as a means of inter-institutional comparisons [8]. These means of comparison will not only aid in training and certifying surgeons, but will also aid in selecting surgeons for certain specialties based on their technical strengths [8]. More recently and in addition to standard box trainers, virtual reality simulators have been developed and are being utilized for laparoscopic training. These devices feature a video screen in the same way a standard box trainer does, but utilized a computer to reproduce the environment and the reactions of the instruments on the screen. However, these devices are still in the developmental stage and have yet to be adapted widely due to their refinement needs and high costs [13]. While virtual reality systems will improve and become more widely used, they will not likely replace conventional box trainers because traditional trainers are inexpensive and require very little maintenance.

The issue addressed by the second objective of this research is the lack of instrumentation for use in NOTES procedures. As progress has continued in the field of NOTES, many additional procedures have been proposed, and some have been successfully performed on animals.

However, many proposed procedures have yet to become a reality as technological advancements have yet to produce necessary instruments [14]. This is not to say that no new instruments have been designed, when, in fact, many instruments have been designed and many more are currently under development. New endoscopes, for example, feature several smaller working channels, as opposed to the single larger channel present in most traditional endoscopes [6]. Several more sophisticated endoscopes have also been developed for use in certain highly technical procedures. For example, an endoscope has been developed for use in transvaginal surgery. This endoscope, called the Transdouglas Endoscopic Device (TED) features deployable arms that spread the surrounding tissue as well as contain built in scissors and a pincer. This device was specifically designed to utilize the anatomy of the vagina to perform complex tasks with minimal damage done to the tissues [6]. This scope is a good example of the complex design and specific nature of more modern endoscopes and endoscopes which will be available in the future.

The general lack of adequate instrumentation has been acknowledged by the field, and in particular the widespread lack of endoscopic scissors and graspers has significantly slowed the advancement of NOTES [1][14]. This lack of scissors and graspers is the main focus of the second objective of the research presented here. The specific device that this research deals with is a 1.0 mm forceps/scissors being developed currently at Penn State. While this instrument will one day, be capable of serving as a forceps and a scissors, current models feature only the forceps ability [15] [16]. This compliant design utilizes a new manufacturing method that allows for exceptional dimensional accuracy at small sizes. This new method, called Lost Mold Rapid Infiltration Forming method, is necessary because traditional manufacturing methods such as CNC machining and wire EDM are difficult if not impossible to use for meso-scale parts [17] [18] [19]. This is due the very small scale of the meso-scale particles used in the manufacturing process, where meso-scale refers to particles that range from a nanometer (10^{-9}m) to 0.1 micrometer (10^{-7} m) in size. The new manufacturing process uses a mold made of polished

polycrystalline alumina substrates which are sintered into a solid mold using a modified UV lithography process. This mold is then coated with several anti-reflective coatings and an additional photoresist which form the smooth bottom of the mold. This mold is then filled with zirconia particles suspended in slurry along with several hardening agents. This slurry is then placed in the mold using a modified squeegee method that ensures sufficient mold infiltration as well as removes as much excess slurry as possible. The slurry is then allowed to dry and harden and any remaining excess is removed using polishing paper. The entire mold and the slurry within it are then sintered, or heated, in an oven, which heats the parts and combines the particles into one solid piece of zirconia ceramic. This sintering cycle also melts and removes the mold material so the only remaining objects are the finished forceps [17] [18] [19]. The forceps used in the testing presented later in this thesis are manufactured using this process; except they are comprised of 316L stainless steel instead of zirconia.

In addition to understanding why it was decided to work on a new 1.0 mm forceps, it is important to understand why the design was tested in the manner it was. This side-by-side comparison of surgical instruments is common with new designs and has numerous precedents [9] [20] [10] [21][11]. However, the testing procedure was used to test students before it was used to test instruments [7]. After publishing his paper on the standard Rosser tasks, Dr. Rosser published another paper about a much larger study involving two hundred ninety-one participants that each completed the Rosser tasks multiple times, and each completion time was measured and recorded. This study was designed and conducted in order to determine the effectiveness of a standardized task list and involved each participant completing the tasks the same number of times. These results were then used to compare the performance and completion times of surgical students versus those of experienced surgeons in a box trainer, and showed that the performance improved and the completion times reduced with additional practice [22]. This same idea is used and modified to compare the performance of individual instruments in the research presented

here. As previously mentioned, many precedents exist that show how to effectively determine the relative strengths and weaknesses of surgical instruments. The first paper that performed such a comparison of surgical instruments was written in 2001. In this paper three different intracorporeal suturing devices were tested. The study was conducted by having 6 experienced laparoscopic surgeons perform certain tasks using the three instruments. These attempts were timed and their average times were then compared to determine the best performer [21]. Another paper used a similar procedure to compare three different scissor-grasper instrument designs. In this study, the standard rosser station tasks were conducted by a laparoscopic surgeon in a standard box trainer. The surgeon then rated the three instruments on a scale of one to five, with five representing optimum performance. These values were then compared to determine the relative strengths and weaknesses of the different instruments [11]. Another paper used a process very similar to that of the one testing grasper-cutters. In this paper four laparoscopic needle drivers are tested and compared. The test was conducted by having three experienced laparoscopic surgeons and three junior residents complete a set list of suturing tasks with the various suturing devices. Upon completion of the tasks, the participants were asked to fill out a questionnaire on which they ranked various aspects of the different devices on a scale from one to five, five representing outstanding performance. The averages of these ratings were then compared.

The testing described in Chapter 2 of this thesis is based off the information presented in this section. Using precedents and standard practices from papers already discussed, a testing methodology was designed and conducted. The methodology will be presented in Chapter 2 and the results will be presented in Chapter 3.

Conclusions

Natural Orifice Translumenal Endoscopic Surgery is a relatively new area of medicine and is still in the developing stages. As it has continued to develop, new possibilities and advantages have become apparent. However, if NOTES is to continue advancing and improve the quality of life of patients, than several important barriers must be overcome. Most importantly a lack of adequate training and testing as well as sufficient instrumentation must be overcome. The research presented here has two objectives. The first objective was to develop a standardized task list for use in training and testing NOTES surgeons. The second objective was to use the new standardized task list to compare a new forceps prototype to an existing forceps instrument. These objectives have been successfully met and their results can be found in the following chapters of this thesis.

Chapter 2

Methods and Materials

The research conducted for this thesis was completed in various phases. To describe the methods and materials used, the content has been divided into three sections: creation of a task list, preparation and manufacturing of the prototypes, and the testing that utilized the task list to evaluate the prototypes evaluated.

Development of Standardized NOTES Task List

The basis for the new standardized list of tasks that was created for NOTES instruments and surgeons was based on common tasks completed during the program currently used to certify laparoscopic surgeons and instrumentation. The new standardized NOTES task list includes tasks developed previously for laparoscopic testing, tasks that are based on laparoscopic tasks but that have been modified for endoscopic instruments, and new tasks that have been created to test additional abilities of forceps instruments. For the purposes of this research, the previously noted tasks have been combined to establish a final list of six standardized tasks. In addition to other measured quantities described with each task, the successful completion times for all tasks were recorded for comparison between the instruments.

Of the final six tasks, three tasks were either adopted from previous publications and utilized directly or were modified for use with endoscopic instruments. The first of these adopted tasks is the Fuzzy Ball task (Figure 2-1(A)). This task features a 1.5 cm diameter plush “fuzzy” ball that is repeatedly picked up, with the tip of the instrument only, and moved with each instrument for comparison. This task evaluates an instrument’s dexterity and ability to grasp fine

objects [17]. This task was adopted as presented in the literature, but with one modification, in that only one instrument can be used at a time due to working channel restraints. Most endoscopes have just one working channel. That means that only one instrument can be inserted through the endoscope at a time. The task presented in the literature required that the ball be passed between two forceps instruments, which is impossible with endoscopic instruments. The second adopted task is presented in the original paper by Dr. Rosser that presents the so called "Rosser Station Tasks" [7]. For the Notes task list, only the Cup Drop Drill was utilized. The other tasks described were the Rope Pass Drill, the Triangle Transfer Drill, and the Intracorporeal Suturing Drill [7]. None of these tests could be incorporated into the research for NOTES due to the inability to use multiple instruments simultaneously through an endoscope. The Cup Drop Drill was adopted, as it is used in laparoscopic testing, but with one modification. Instead of dried beans, which are too large for endoscopic instruments, 0.5 cm diameter fuzzy balls are used. These balls are similar to those used in the Fuzzy Ball task except are significantly smaller (Figure 2-1(B)). The last task which was modified from one found in previous literature is the sea-spike task. In laparoscopic testing, this task involves multiple asymmetric spikes that rings are put on and taken off with each instrument [12] [14]. However, these rings are too thick for use in endoscopic testing. Therefore, a new apparatus was constructed that features a medium gauge sewing needle inserted into a block of wood at approximately a ten degree angle to the horizontal. While completing this task, 0.75 cm diameter brass rings are picked up with each instrument and placed around the needle (Figure 2-1(C)). This modified version of the sea spike drill is called the Ring Around Drill. Both the Cup Drop Drill and the Ring Around Drill are designed to test an instrument's ability to grasp and maneuver an object to a desired location.

In addition to adopting and modifying existing tasks, three new tasks were created to test additional features of endoscopic forceps instruments. The first designed task is Material Pull, which is designed to simulate a forcep's ability to grasp and manipulate tissue. The task involves

the removal of two pins from a piece of foam, one with each instrument. Each pin features a piece of 0.1 cm thick suede leather that is tied around the head and sticks up above the head in a tube like shape (Figure 2-1(D)). The piece of suede simulates tissue, while the motion involved in removing the pins simulates manipulating or tearing tissue. The second designed task is the Simulated Biopsy task, which is designed to simulate the removal of material necessary during a tissue biopsy. This task involves a block of soft, crumble foam with multiple dots, approximately 0.2 cm in diameter, drawn on it. The aim of the task is to completely remove only the material containing the dot (Figure 2-1(E)). The number of attempts required to completely remove the dot were recorded. The average number of attempts necessary to completely remove the dot was then used as a quantitative comparison between the instruments. The last task on the list is the Force Gauge task. This task is designed to measure the maximum pull-off force of the forceps through an endoscope. During this task, each participant used the forceps to grasp a piece of surgical tubing, connected to a force gauge and pulled on the device until it slipped off the tubing (Figure 2-1(F)). The tubing had an outer diameter of 0.25 in and a wall thickness of 0.0625 in. The maximum force measured is therefore the maximum pull-off force. This task was completed with both instruments by every participant and the resulting maximum forces for each instrument were averaged to provide a comparison.

However, before conducting the testing in a controlled laboratory environment it was necessary to ensure the tests would work when presented and tested by an endoscopist or surgeon. This was accomplished by having an experienced endoscopic surgeon perform the tasks in an endoscopic box trainer exactly as test subjects would perform them during later testing. The tests were performed without incident and the consulted surgeons acknowledged that the tests were practical and would be useful for evaluating the important features and abilities of an endoscopic forceps. During this "dry run," all consent, video and data recording procedures were rehearsed to guarantee they would work and record the desired information. The consent procedure

consisted of having each participant view the instructional video, read the research description sheet, and give consent to be recorded on video. The video recording procedure was refined to provide for the maximum amount of information capture. It was decided that video would be recorded from three sources. The imagery from the scope and the stationary camera in the box trainer were recorded by separate computers. The third source was a video camera set up several feet from the participant, positioned such that the participant and the view screen are captured. It was also decided that the data pertaining to the number of attempts to remove the dot in the Simulated Biopsy task and the maximum pull off force as determined in the Force Gauge task would be recorded manually. At this point, the task list was set and determined to be ready for further testing.

The six previously described tasks comprise the list of standardized NOTES tasks. This list of tasks as well as the corresponding images of each task are noted in table 2-1 below.

Table 2-1 The Table of Standardized NOTES Tasks and Their Corresponding Figure Numbers in the Appendix

Standardized NOTES Tasks List

Task Name	**Figure Number**
Fuzzy Ball	2-1 (A)
Cup Drop	2-1 (B)
Ring Around	2-1 (C)
Material Pull	2-1 (D)
Simulated Biopsy	2-1 (E)
Force Gauge	2-1 (F)

This task list was used to test the prototype forceps instrument as described in the third section of this chapter labeled Testing and Comparison of a Prototype Forceps Instrument.

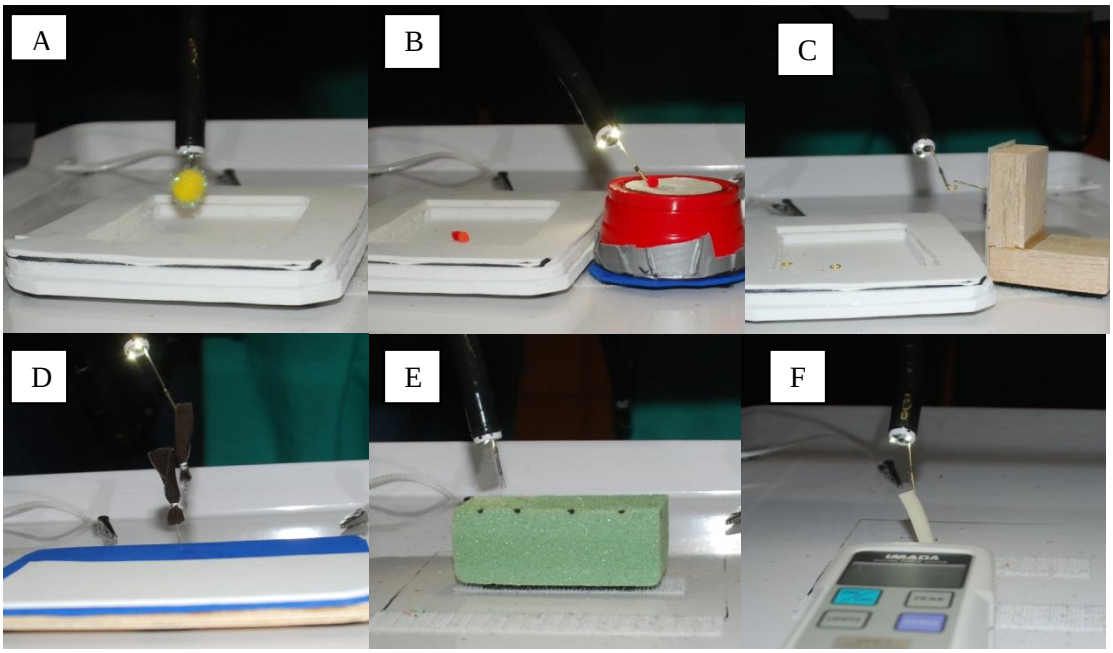

Figure 2-1 Standardized NOTES Tasks: (A) Fuzzy Ball Task; (B) Cup Drop Task; (C) Ring Around Task; (D) Material Pull Task; (E) Simulated Biopsy; (F) Force Gauge

Preparation of Prototype Forceps Instruments

After the creation of the list of standardized tasks for NOTES instruments, it was time to use the tasks to evaluate a new endoscopic forceps design. This design utilizes the lost mold rapid infiltration forming manufacturing process as described in Chapter 1, which was used to produce low cost, compliant forceps for use in prototype construction and testing. While the design and manufacturing of the forceps tips where done by graduate students at Penn State, Milton Aguirre and Greg Hayes respectively, there were several additional steps that had to be completed prior to testing. The first step in this process was to polish the forceps, which was accomplished by first using fine, 2500 grit, sandpaper to remove small burs and then utilizing sonic cleaning and a modified chemical etching process to remove any debris remaining in the gap of the tool tips. The sonic cleaning process consisted of submersing the forceps in a solution

inside of a sonic cleaner. This cleaner than uses high frequency sound waves, transmitted by the solution, to vibrate the forceps and remove any burs or residual material left in the gap between the arms of the forceps. A chemical etching procedure was then used that utilizes an acid bath to further remove any residual material or oxidation by means of a chemical reaction. Upon completion of these processes, the forceps were ready to be welded to their ECHO-1-22 (22 Gauge) single-use biopsy needle system manufactured by Wilson-Cook, which serve as the actuation platform.

The welding process included removing the slanted tip of both the biopsy needle tube and the inner wire used to push material out of the needle. Both the tube and the inner wire were cut back to provide flat ends and the outer tube was cut back to allow approximately 0.6 cm of the inner wire to stick out of the tube when the inner wire was fully inserted. This involved cutting the outer sheath back by approximately 3.0 cm and the inner wire by approximately 2.4 cm. The forceps were then welded to the end of the inner wire using a filament spot welder. This device places the objects in contact, then passes a current through them which raises their temperatures, and binds them together. After the forceps are welded in place, a stainless steel tube with an inner diameter of 1.0 mm and length of approximately 1.25 cm is glued to the needle (Figure 2-2 (A)). Once glued in place, this outer tube forms the actuator as sliding it forward over the forceps forces them to close (Figure 2-2 (B)). When the outer tubes were fixed in place, the forceps instruments were ready for testing. In addition, due to the nature of the actuator for the biopsy needle instrument, a holder had to be designed to make actuating the prototype forceps easier. This instrument was designed and produced using a rapid prototyping machine (Figure 2-4).

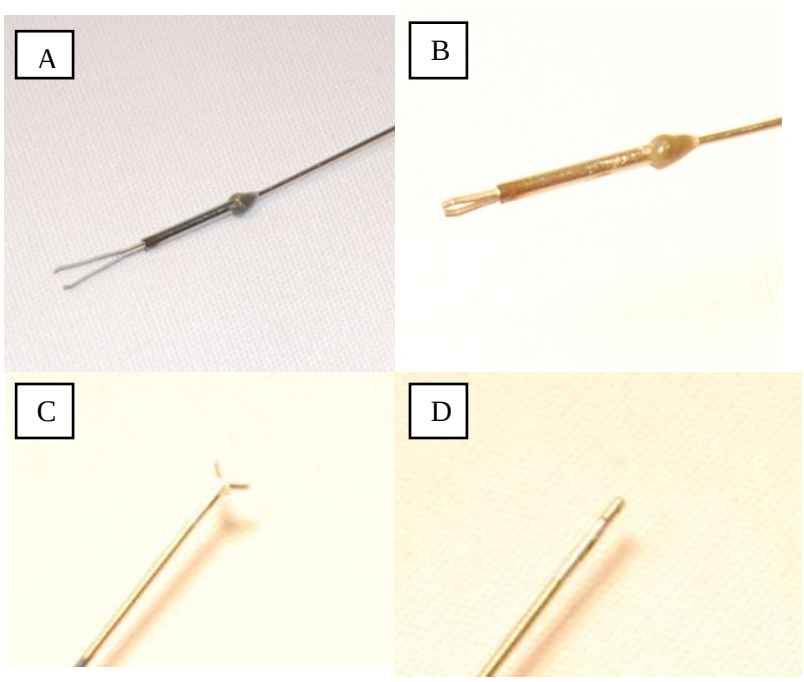

Figure 2-2 Forceps Instruments in both Fully Open and Fully Closed Positions: (A) 1.0 mm prototype forceps in the fully open position; (B) 1.0 mm prototype forceps in the fully closed position; (C) Commonly availble SpyBite 1.0 mm single use forceps instrument in the fully open position; (D) Commonly available SpyBite 1.0 mm single use forceps instrument in the fully closed position

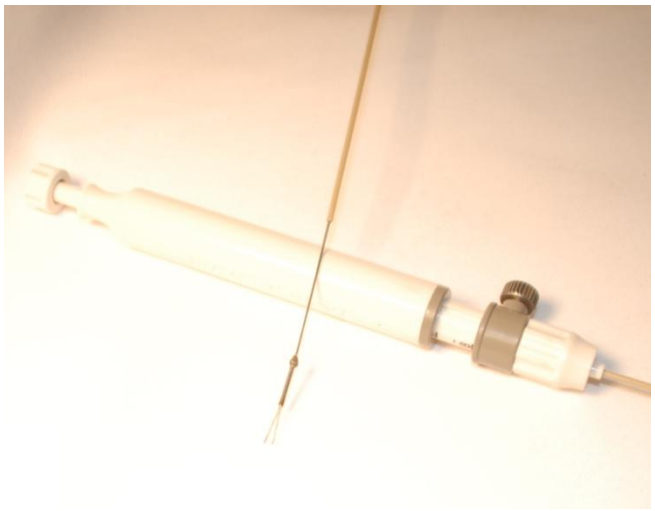

Figure 2-3 Prototype Instrument and Actuator

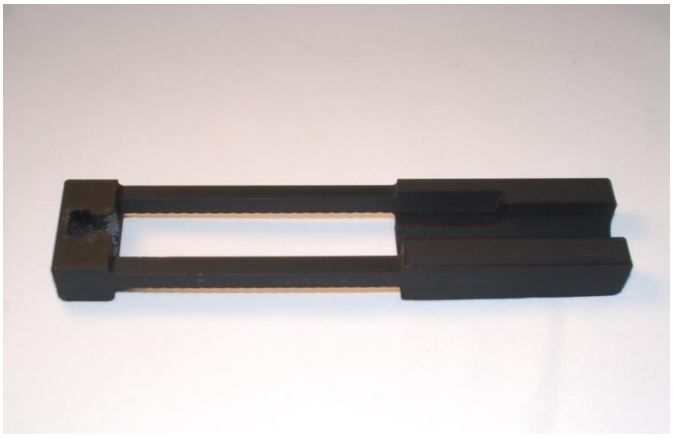

Figure 2-4 Rapid Prototype Instrument Actuator Holder

However, one additional test had to be performed. This test was to determine the minimum working channel diameter and the angle of approach necessary to allow for the safe passing of the forceps instrument through an endoscope handle. This test was necessary because the accessory channel outlet on the endoscope handle exits the handle at an angle called the angle of approach. This angle can be seen in Figure 2-5 below, in this figure an instrument is inserted into the accessory channel.

Figure 2-5 Endoscope Handle and Accessory Channel

This diameter and angle of approach varies amongst endoscopes, so it was necessary to determine which endoscope to use in the testing. In order to perform this test, a device had to be built to simulate the handle of an endoscope. This was accomplished by imitating the intersection of the working channel inlet and the working channel in endoscope handles. These simulated intersections were constructed by gluing pieces of steel tubing two inches in length to a piece of plywood at various angles of approach, ranging from forty to fifty degrees, in two and a half degree increments, with the horizontal. As stated these junctions were made at two and a half degree intervals, allowing for the creation of five intersections at each diameter. Five intersections were then made using steel tubing with three different diameters representing common working channel diameters, namely 2.9 mm, 3.2 mm, and 3.8 mm (Figure 2-6).

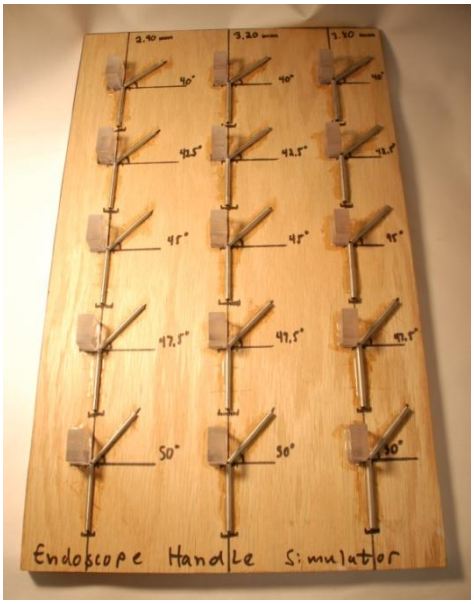

Figure 2-6 Endoscope Handle and Working Channel Simulator

The finished prototype instruments were then tested in these various diameter and angle junctions. The desired information was found by starting with the smallest diameter and sharpest angle, namely 2.9 mm tubing at a forty degree angle with the horizontal. It proved difficult to move the device through this intersection and resulted in considerable deformation to the device.

The same difficulty and deformation resulted from all of the other 2.9 mm diameter tubing intersections as well as all of the 3.2 mm diameter intersections. However, the instrument was able to be passed through all of the 3.8 mm diameter intersections with significantly less difficulty and minimal deformation. From these results, it was obvious that an endoscope with an accessory channel diameter of at least 3.8 mm was necessary for the testing. This test, therefore, successfully identified which endoscope should be used during the testing to avoid bending or breaking the prototype instruments. At this point, the prototype instruments were manufactured and the endoscope selected, therefore, it was time to conduct the testing.

Testing and Comparison of a Prototype Forceps Instrument

The work to this point in the research was to create a new list of standardized tasks for NOTES training and to prepare for the side-by-side comparison of a new forceps design with an existing design that is widely used for developing NOTES procedures. In order to ensure the reliability and accuracy of the results of the testing, a sufficiently large number of participants needed to be recruited. After some discussion and research, it was determined that twelve participants would be sufficient. These participants, all practicing surgeons or surgical residents training to be endoscopic surgeons, were then recruited with the help of the administrative staffs at the Penn State Milton S. Hershey Medical Center.

Once recruited, the participants completed the testing one at a time. The participants were first informed of their rights as they pertain to the testing, video-taping and surveying and gave consent based on these rights. Once consent was given, each participant was asked to perform the tasks on the Standardized NOTES Task List using an OLYMPUS Evis Exera GIF/CE/RCF Type 160 Series Endoscope (Figure 2-7 (A)) in an endoscopic box trainer on an endoscopic tower (Figure 2-7 (B)).

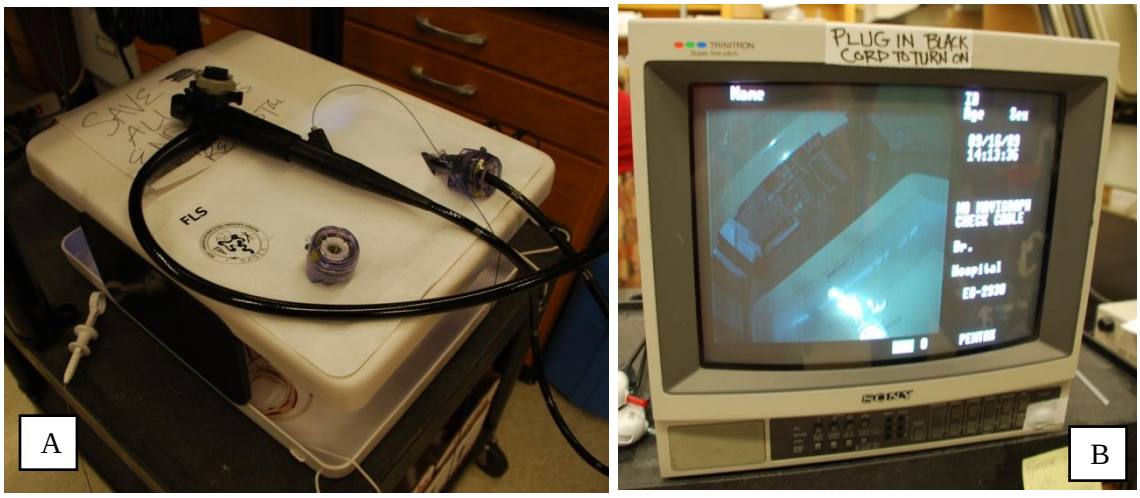

Figure 2-7 Endoscope, Enscopic Box Trainer and Endoscopic Tower: (A) Endoscope and Box Trainer; (B) Endoscopic Tower and Video Monitor

The first task was the Material Pull task, then the Ring Around task, Fuzzy Ball task, Cup Drop task, Simulated Biopsy task and lastly the Force Gauge task. These tasks were performed once with each instrument by every participant. In addition, during the testing, information was collected by the researcher pertaining to the number of attempts necessary and the amount of material collected in the Simulated Biopsy task and the maximum pull-off force determine in the Force Gauge task. This information was also recorded by the video cameras that recorded the testing. In addition to recording data, the researcher served another purpose during the testing and acted as the assistant to the participant. An assistant is needed because the participant operates and manipulates the endoscope, which requires the use of both hands. The assistant then serves to advance and operate the instrument on commands from the participant. The practice of having a surgeon and an assistant to manipulate the instrument is used in conducting NOTES procedures, so it was used in conducting the testing.

Once the tasks were performed with both the prototype and the existing forceps instruments, participants were asked to complete out a survey based on the testing (Figures A-1through A-6). This survey collected quantitative data regarding the relative strengths and

weaknesses of the instruments by asking participants to rate various aspects of each on a scale from one to three, with three being superior and one being poor performance. The survey also solicited open-ended feedback and suggestions about both the device design and the task list from the participants. In addition, the time to complete each task was measured from the video and averaged to provide additional information about the performance of each device. This quantitative and qualitative data was then analyzed to determine what, if any changes were necessary for the prototype design.

During the testing, information was gathered by multiple video recording devices. The first device was a standard high definition digital video recorder which was placed in the lab such that the participant and the assistant were visible on the video. This camera recorded the motion and activity outside of the box trainer necessary to accomplish each task as well as any comments made by the participants. The second video recorder was placed inside the endoscopic box trainer and recorded the actual use of the device from a fixed location and the ways in which it was maneuvered. The third video device was the endoscope itself. The same image shown on the endoscope tower and used by the participants to complete the tasks was recorded by a computer. The Images below will demonstrate the view point of two of the cameras. The first figure (Figure 2-8) shows an example image of the video recorded through the scope. The second figure (Figure 2-9) shows an example image recorded by the stationary camera in the box. Both images were taken at the same time from the two different video sources. This means that they show the exact same action, by the same participant at the same instant.

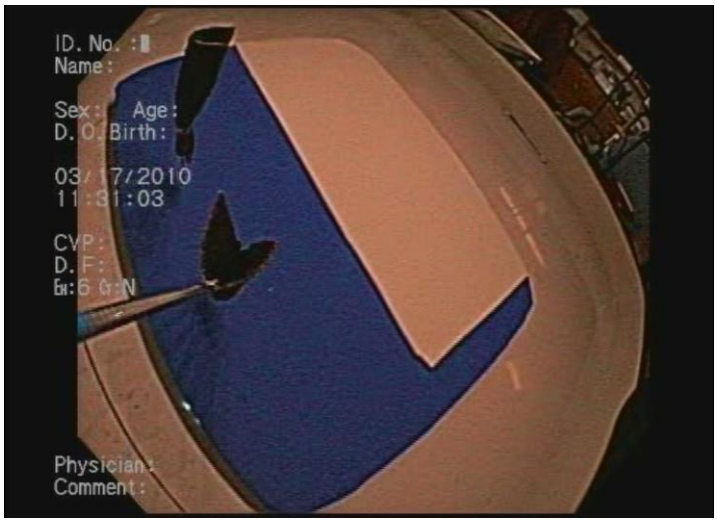

Figure 2-8 Example Image Taken From Video Recorded Through the Endoscope

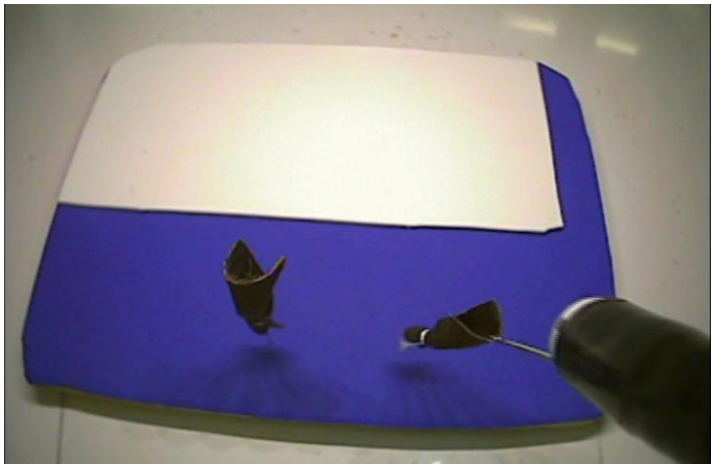

Figure 2-9 Example Image Taken From Video Recorded by the Stationary Camera in the Box Trainer

Imagery taken from the stationary camera located in the lab could not be shown because it contains imagery of the testing participants. As the testing was anonymous, these identities cannot be displayed. This video demonstrates the difficulty of navigating and operating each instrument from the perspective of the operating surgeon and assistant. The video images were then analyzed to gather additional information not made apparent by the surveys themselves. In

particular, the video shows the approaches used by participants that found the tasks easier or got superior results. This information can then be used to determine if resulting issues or comments stemmed from the instruments themselves or the approach used by the participants. After analysis, the video imagery was destroyed in accordance with good testing and survey practice.

Upon completion of the testing, the information gathered by the various sources stated previously was analyzed to provide meaningful design and testing data for the prototype. This information pointed out several strengths and weaknesses of the new design and provided valuable feedback to the group, as further described in Chapters 3 and 4 of this thesis.

Chapter 3

Results

The testing described in the last chapter was completed as described, and the results of that testing are presented in this chapter. To make communicating the results easier, they have been broken into four sections. The first section, entitled Quantitative Survey Results, presents the quantitative data collected by the survey each participant was asked to complete. The data shown in this section is a summary of the various ratings and scorings that each participant filled out. The second section, Recorded Testing Data, describes the data collected by the researcher during the testing. This data pertains to two tasks in particular, Simulated Biopsy Task and the Force Gauge Task, as explained in the last chapter. The third section, entitled Qualitative Survey and Video Results, presents additional feedback gathered by the surveys and various video and audio recording devices that were present during the testing. The final section, entitled Testing Approach Feedback, presents comments made about the testing procedure and the task list.

Quantitative Survey Results

The most important reason for completing the testing described in Chapter 2 was to get feedback on both the testing procedure and the prototype instrument. Quantitative data was collected using a survey tool evaluating responses by use of a numeric scale. The survey can be found in Figures A-1 through A-6 in the Appendix. This section summarizes the results gathered using the first method, that is the numerical ranking and scoring questions. The data presented here are summarized tables of averages created from the individual values. To make the results easier to understand, the results from each question are summarized in a separate table.

The first question of the survey asked participants to rank the standard instrument and the prototype instrument in terms of ease of use of each instrument for each task. The individual rankings as well as the overall averaged ease of use for each instrument on a scale of one to three and the standard deviation of the data are presented in Table 3-1 below. The values shown in bold indicate the instrument that scored higher, and therefore was ranked superior to the other instrument for each task and as a whole.

Table 3-1 Relative Ease of Use of Each Instrument: This table summarizes the ranking of each instrument in terms of ease of use. For this question, 1 is difficult to use and 3 is easy to use.

Relative Ease of Use of Each Instrument

1 is difficult, 3 is easy to use, (DNA = Did Not Answer)

		Material Pull		Ring Around		Fuzzy Ball		Cup Drop		Simulated Biopsy		Force Gauge	
	Participant ID #	Standard	Prototype	Standard	Prototype	Standard	Prototype	Standard	Prototype	Standard	Prototype	Standard	Prototype
1	2	3	1	2	1	3	2	2	1	1	1	3	2
2	3	2	3	2	2	2	2	DNA	DNA	2	1	2	3
3	5	2	3	2	3	2	3	2	3	2	3	2	3
4	8	1	2	3	3	3	3	3	3	1	3	1	3
5	12	3	2	1	2	2	3	2	3	3	3	3	2
6	13	1	2	1	3	3	2	1	2	2	2	3	1
7	14 (1)	3	3	2	2	3	3	3	1	3	3	3	2
8	14 (2)	3	3	2	2	2	3	3	3	3	1	2	3
9	17	3	2	1	3	3	3	2	3	3	1	2	2
10	22	3	3	3	3	3	3	3	2	3	3	3	2
11	23	2	3	1	3	2	3	2	3	1	3	2	2
12	15	3	2	1	2	3	3	2	3	2	3	3	2
	Averages	2.42	2.42	1.75	**2.42**	2.58	**2.75**	2.27	**2.45**	2.17	**2.25**	**2.42**	2.25
	Standard Deviation	0.759	0.640	0.722	0.640	0.493	0.433	0.617	0.782	0.799	0.924	0.640	0.595

Relative Ease of Use of Each Instrument

Overall Averages		Standard Deviation
Standard Instrument	2.27	0.731
Prototype Instrument	**2.42**	0.705

The next two questions in the survey asked participants to identify which features of the instruments made them easy and which made them difficult to use, respectively. The total number of times each instrument feature was identified as well as individual selections are summarized in Table 3-2 and Table 3-3 below. The maximum achievable rating for ease of use, Figure 3-2, would be for a feature to score 72 ratings as making tasks easy. Conversely, for Figure 3-3, 72 ratings is the worst possible score and the lower the number the better the feature performed. The bold in Figure 3-2 indicates the higher number of mentions as making the task

easy and therefore the instrument whose feature performed better. Likewise in Figure 3-3, the bold indicates the instrument whose feature received the most mentions as making tasks difficult, and therefore denotes the instrument whose feature performed more poorly.

Table 3-2 Total Number of Times Each Feature Was Identified as Making Tasks Easy

Parameters That Made Tasks Easy

		Standard Instrument																		Prototype Instrument																	
		Material			Ring			Fuzzy Ball			Cup Drop			Simulated			Force			Material			Ring			Fuzzy Ball			Cup Drop			Simulated			Force		
	Participant ID #	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly
1	2			1		1			1			1			1			1				1			1			1			1			1			1
2	3	1				1			1			1		1				1				1			1			1			1			1			1
3	5						1			1										1			1			1		1	1	1	1	1		1			1
4	8							1				1		1				1							1	1					1			1			1
5	12	1	1		1			1				1			1			1				1			1		1	1			1						1
6	13						1			1				1		1			1		1	1	1	1				1	1	1	1		1			1	
7	14 (1)	1		1	1		1			1	1	1	1		1	1		1	1	1		1	1		1			1			1	1		1			1
8	14 (2)			1			1		1			1			1	1			1	1		1	1			1	1		1	1				1	1	1	1
9	17	1				1				1			1	1					1		1				1	1			1					1			1
10	22		1				1			1			1		1				1			1			1			1			1			1			1
11	23																		1	1	1			1	1		1				1		1	1			
12	15		1	1						1		1			1	1		1	1			1	1			1			1			1		1			1
	Sum	4	3	4	2	3	5	2	3	6	1	7	3	4	6	4	0	6	7	4	3	8	5	2	8	5	3	7	5	3	9	3	2	10	1	2	10

Total Number of Times Each Feature was Cited As Making Tasks Easy		
Standard Instrument	Jaw Length	13
	Distal Jaw Opening	**28**
	Ability to Grasp Firmly	29
Prototype Instrument	Jaw Length	**23**
	Distal Jaw Opening	15
	Ability to Grasp Firmly	**52**

Table 3-3 Total Number of Times Each Feature Was Identified as Making Tasks Difficult

Parameters That Made Tasks Difficult

		Standard Instrument																		Prototype Instrument																	
		Material			Ring			Fuzzy Ball			Cup Drop			Simulated			Force			Material			Ring			Fuzzy Ball			Cup Drop			Simulated			Force		
	Participant ID #	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly
1	2	1			1			1			1			1			1				1			1			1			1			1			1	
2	3			1			1			1			1			1			1	1			1			1			1			1			1		
3	5	1				1			1		1			1	1		1		1																		
4	8																				1												1			1	
5	12	1			1					1											1												1			1	
6	13		1		1	1																					1				1	1		1			1
7	14 (1)																													1			1			1	
8	14 (2)		1												1				1		1			1									1				
9	17		1				1		1			1			1			1		1				1			1			1		1			1		
10	22	1			1			1			1										1			1			1			1		1	1			1	
11	23						1					1		1	1																						1
12	15				1				1		1										1									1						1	
	Sum	4	3	1	5	2	3	2	3	2	4	2	1	3	4	1	2	1	3	2	6	0	1	4	0	1	4	0	1	5	1	4	6	1	2	6	2

Total Number of Times Each Feature was Cited As Making Tasks Difficult		
Standard Instrument	Jaw Length	**20**
	Distal Jaw Opening	15
	Ability to Grasp Firmly	**11**
Prototype Instrument	Jaw Length	11
	Distal Jaw Opening	**31**
	Ability to Grasp Firmly	4

The fourth question in the survey asked participants to rank the importance of the individual features in an endoscopic forceps design. Table 3-4 below presents the individual rankings as well as the overall average importance of each feature on a scale of one to three and the standard deviation of the values.

Table 3-4 Average Relative Importance of Different Features: In this question, 1 is the least important and 3 is the most important.

Relative Importance of Features

1 is the least Important, 3 is the most important

Standard Instrument

	Participant ID #	Material Pull			Ring Around			Fuzzy Ball			Cup Drop			Simulated Biopsy			Force Gauge		
		Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly
1	2	3	2	1	3	1	2	1	2	3	1	2	3	1	2	3	2	1	3
2	3	2	1	3	3	2	1	2	3	1	2	3	1	3	2	1	1	2	3
3	5	3			3	3				3	3		3	1					3
4	8	3			3					3		3		3				3	
5	12	1	3	2	2	2	3	2	2	3	2	2	3	2	3	1	2	2	3
6	13	2	1	3	2	3	2	1	3	3	2	3	3	3	3	3	3	3	3
7	14 (1)	2	1	3	2	1	3	1	2	3	1	3	2	1	3	2	1	2	3
8	14 (2)	2	2	3	2	3	3	2	3	1	2	3	1	2	3	3	2	2	3
9	17	3	1	2	2	1	3	2	1	3	2	1	3	3	1	2	2	1	3
10	22	2	2	1	1	2	1	1	1	1	3	2	1	2	1	2	3	2	1
11	23	1	2	3	1	2	3	1	3	2	1	3	2	1	3	2	1	2	3
12	15	2	3	1	3	1	1	2	2	2	2	2	2	2	2	2	3	2	2
	Averages	2.2	1.8	2.2	2.3	1.9	2.2	1.5	2.2	2.3	1.9	2.5	2.2	2.0	2.3	2.1	2.0	2.0	2.7

Prototype Instrument

	Participant ID #	Material Pull			Ring Around			Fuzzy Ball			Cup Drop			Simulated Biopsy			Force Gauge		
		Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly	Jaw Length	Distal Jaw Opening	Ability To Grasp Firmly
1	2	3	2	1	3	1	2	1	2	3	1	2	3	1	2	3	2	1	3
2	3	1	2	3	1	2	3	2	1	3	2	1	3	1	2	3	1	2	3
3	5			3		3	3			3	3			3		3			3
4	8	3	3		3				3			3		3			3		
5	12	1	3	2	2	2	3	2	2	3	2	2	3	2	3	1	2	2	3
6	13	2	3	3	1	3	3	3	3	1	2	3	3	2	3	3	1	3	2
7	14 (1)	2	1	3	2	1	3	1	2	3	1	3	2	3	2	1	2	1	3
8	14 (2)	3	2	3	2	3	3	2	3	1	3	3	1	2	2	3	3	2	3
9	17	3	1	2	2	1	3	2	1	3	2	1	3	3	1	2	2	1	3
10	22	3	1	1	2	1	2	3	1	2	2	1	1	3	1	2	2	1	1
11	23	1	2	3	1	2	3	1	3	2	1	3	2	1	3	2	1	2	3
12	15	1	2	3	3	2	3	3	2	2	3	2	2	3	2	3	2	3	2
	Averages	2.1	2.0	2.5	2.0	1.9	2.8	2.0	2.1	2.4	2.0	2.2	2.3	2.3	2.1	2.4	1.9	1.8	2.6

Average Relative Importance of Different Features			Standard Deviation
Standard Instrument	Jaw Length	2.0	0.743
	Distal Jaw Opening	2.1	0.758
	Ability to Grasp Firmly	2.3	0.823
Prototype Instrument	Jaw Length	2.0	0.787
	Distal Jaw Opening	2.0	0.780
	Ability to Grasp Firmly	2.5	0.726

Overall Average Relative Importance of Different		Standard Deviation
Jaw Length	**2.0**	0.766
Distal Jaw Opening	**2.1**	0.771
Ability to Grasp Firmly	**2.4**	0.782

The fifth and final ranking/scoring question in the survey asked participants to rank the adequacy of individual features of the two instruments. The ranking was done using a scale of one to three. Table 3-5 below shows the individual rankings as well as the overall average adequacy of each feature of each instrument as well as the standard deviation of the data.

Table 3-5 Average Overall Adequacy of Individual Features of Each Instrument: This question utilized a scale from 1 to 3, 1 being completely inadequate and 3 being completely adequate.

Adequacy of Features

1 is completely inadequate, 3 is completely adequate

		Standard Instrument			Prototype Instrument		
		Maximum Pull-Off Force	Amount Of Material Removed	Ability to Control and Operate Device at Intermediate Jaw Openings Between Fully Open and Fully Closed	Maximum Pull-Off Force	Amount Of Material Removed	Ability to Control and Operate Device at Intermediate Jaw Openings Between Fully Open and Fully Closed
1	2	2	2	3	3	1	2
2	3	2	3	3	3	2	2
3	5				3	2	3
4	8	1	3	2	3	2	3
5	12	2	3	2	3	2	2
6	13	2	2	2	1	3	3
7	14 (1)	3	3	3	3	2	2
8	14 (2)	2	2	3	3	2	2
9	17	3	3	1	2	1	3
10	22	3	3		3	3	
11	23	3	3	3	3	3	3
12	15	3	2	2	2	3	3
Averages		2.36	2.64	2.40	2.67	2.17	2.55
Standard Deviation		0.643	0.481	0.663	0.624	0.687	0.498

Average Adequacy of Features of Both Instruments			Standard Deviation
Standard Instrument	Maximum Pull-Off Force	2.36	0.643
	Amount Of Material Removed	**2.64**	0.481
	Ability to Control and Operate Device at Intermediate Jaw Openings Between Fully Open and Fully Closed	2.40	0.663
Prototype Instrument	Maximum Pull-Off Force	**2.67**	0.624
	Amount Of Material Removed	2.17	0.687
	Ability to Control and Operate Device at Intermediate Jaw Openings Between Fully Open and Fully Closed	**2.55**	0.498

The data presented in this chapter will be further analyzed and discussed in Chapter 4 of this thesis.

Recorded Testing Data

The main reason for conducting the testing described in the previous chapter was to get feedback on the testing and on a prototype instrument, which will be used to improve both the testing procedure and the design of the prototype 1.0 mm forceps. However, as also previously

mentioned, feedback was not the only information collected during the testing. Quantitative data was also collected pertaining to two of the tasks completed by all testing participants. These values were the number of attempts necessary to completely remove a black dot during the simulated biopsy task and the maximum pull-off force measured during the force gauge task. These values were measured for each instrument and individual results as well as average values are shown in Table 3-6 below. This table shows the number of attempts necessary to remove the black dot with each instrument as well as the maximum force measured with each instrument and the averages of these values. In addition, the standard deviation is given for each average value.

Table 3-6 Data Recorded During Testing: the data in this table are the averages of the data taken recorded by the researcher during testing.

Testing Quantitative Data

Number	Participant ID #	# Attempts to Remove Dot		Pull-Off Force (N)	
		Standard	Prototype	Standard	Prototype
1	2	5	7	0.646	0.728
2	22	5	5	1.080	1.461
3	14	5	5	0.801	1.278
4	17	4	6	0.857	0.715
5	13	5	5	1.045	0.400
6	23	5	3	1.461	1.129
7	5	4	3	0.890	0.690
8	3	UTC	UTC	0.712	0.316
9	8	5	3	1.037	0.316
10	15	5	4	1.422	1.009
11	14	4	3	0.691	0.701
12	12	5	4	0.473	0.386
AVERAGES		4.73	4.36	0.926	0.761
Standard Deviation		0.45	1.30	0.287	0.369

UTC = Unable to Complete

Furthermore, despite the difference in the average maximum pull-off forces of the two instruments, the maximum values attained for both instruments were identical, as the highest force recorded for each instrument was 1.461 N. This data will be further analyzed and discussed in Chapter 4 of this thesis.

Qualitative Survey and Video Results

In addition to gathering data through ranking and scoring exercises, the surveys elicited open feedback, both prompted and unprompted. This feedback is invaluable as it provides additional information on the design and the performance of the new prototype instrument. In addition, the comments can and did illuminate issues that the design group did not previously consider to be important.

The comments provided by the participants are summarized in Table 3-7 below. Individual Responses as well as all those made by each person can be viewed in the Appendix (Table A-1). This table not only lists the comments made, but also lists the number of times that participants made the comment, or a similar comment. The list is also organized such that comments are listed in order of descending prevalence.

Table 3-7 Comments Regarding Prototype Instrument Made On Surveys by Testing Participants

Comments Regarding Prototype Instrument Made on Surveys by Testing Participants

Paraphrased Comments	Number of Times Each Comment or a Similar Comment Was Made
Distal jaw opening is too small	5
Prototype jaw length is too short	4
Control of intermediate distances is essential, and this ability is better in the prototype instrument than the standard instrument	3
Prototype should be rotatable to allow for better grasping control	3
Prototype is not well suited for use in biopsies	2
The actuation tube is bulky and impairs vision	1
Prototype's ability to rotate is helpful	1
Prototype is better at grasping objects	1
Prototype instrument allows for more fine control	1
Smaller distal jaw opening allows for more precision when grabbing	1
The standard instrument features a visual cue as to whether the instrument is opened or closed and this feature should be incorporated into the prototype	1

The audio and video recordings were also analyzed for information. However, as no verbal cues were given, few comments were made. The verbal comments that were made are included in the table above. These verbal comments reflected the ones made on the surveys and show the same major concerns that the written comments illuminated.

Testing Approach Feedback

In addition to gathering data about the performance of the newly designed prototype forceps, the surveys and video also helped to gathered information about the testing procedure and the tasks list. Though space was given on the surveys for feedback about the testing procedure, no written comments on the subject were given by the participants. However, comments and observations were recorded by the video and audio recordings. While participant feedback was limited, the comments made about the testing approach did substantiate two important concepts. The most significant was that the testing procedure and the task list succeeded in evaluating the important features and abilities of any endoscopic forceps instrument. The second comment confirmed by the verbal comments was that the testing was challenging and forced the participants to concentrate on the tasks at hand.

Chapter 4

Discussion, Conclusions and Further Research

The results presented in Chapter 3 are analyzed throughout this chapter. The significance of the results as well as what they communicate is discussed in the first section, Discussion. The second section entitled Summary presents a concise summary of the research activities as well as the progress of the goals presented in Chapter 1. The third section, entitled Research Contributions, discusses the deliverables accomplished by the research. The fourth section, Conclusions, presents final thoughts and ideas based on the research as a whole. This section serves as a summary of what was learned and what advancements were made for the field as a whole by the research presented in this thesis. The last section, Further Research, discusses ideas for future research based of the results and conclusions presented here.

Discussion

In order to make reading and understanding the discussion presented here easier, the discussion will proceed through the results presented in Chapter 3 in the same order they were presented. In this section, the qualitative and quantitative results are analyzed and the importance of each is discussed.

The results presented in Chapter 3 are the numerical results ascertained by means of the survey. The results allow for a relative evaluation of the instruments on a numeric scale, instead of a subjective scale like in the open ended questions. However, the sample size is limited to only twelve participants, so the statistical significance of the data is unknown. The first results presented are the average ratings of Ease of Use for each instrument. In Table 3-1 it is seen that

the prototype instrument scored an average higher rating than that of the standard instrument. This indicates that as a whole, the test participants felt the prototype instrument was easier to use than the standard instrument. However, the standard deviations for the ratings are fairly high, so the difference between the prototype and the standard instrument might not be significant. As a result, while the prototype instrument outscored the standard instrument, it cannot be conclusively determined that the new instrumentation is definitively better. In addition, the resulting averages and their standard deviation windows overlap. This means that the prototype instrument scored better than the standard instrument, but that some participants may have disagreed and scored the standard instrument higher than the prototype. While this data is encouraging as it shows that the participants as a whole like the prototype better, it does not definitively show how much better the prototype instrument is.

The second set of data collected is the individual feature evaluation. The information in both Tables 3-2 and 3-3 shows the same overall trend. That is, the jaw length and ability to grasp firmly of the prototype are better than those of the standard instrument. Similarly, the data also shows that participants preferred the distal jaw opening of the standard instrument over that of the prototype. In conclusion, based on the survey administered, the tested participants felt the prototype instrument was superior in terms of its ability to grasp and its jaw length, but that its distal jaw opening is inferior to that of the standard instrument.

Data was then collected pertaining to the individual importance of each feature of the instrumentation. The data (presented in Table 3-4) shows that overall the participants felt the there were three important features of endoscopic forceps. The most important feature was the ability to grasp firmly, followed by distal jaw opening and jaw length, respectively. These findings are helpful when developing future prototypes as it demonstrates that the participants agreed that a forceps that can grasp firmly is more important than one that cannot grasp as firmly but has a long jaw length and a larger distal jaw opening. However, like the data presented for

the ease of use section, this data also has significant scatter as seen by the large standard deviations. Therefore the results show that while the participants agreed that the ability to grasp firmly is the most important feature, the ratings for jaw length and distal jaw lengths show no definitive difference in importance. This fact will be important when designing new forceps instruments in the future.

The last section of quantitative data from the surveys is the average adequacy of each instrument. This data (presented in Table 3-5) communicates several things about the performance of each instrument. First, this data shows that the participants felt that the prototype outperformed the standard instrument in achieving a maximum pull-off force (The actual forces will be discussed later). The data also identified that the participants felt the ability to control intermediate positions of the prototype between open and closed was better than that of the standard instrument. Participants also felt the standard instrument's ability to remove material as in a biopsy was superior to that of the prototype instrument. However, again the standard deviations for these values are fairly large and the averages are very similar. Therefore, while the prototype outscored the standard instrument in two of the activities and underscored it in the other, any attempt to determine, quantitatively, how much more adequate either instrument is at any of the tasks would require further testing and evaluation.

After the quantitative survey data was presented, the data pertaining to values measured during the testing was presented. This data (presented in Table 3-6) pertains to two tasks in particular. The data pertaining to the number of attempts to remove the black dot during the simulated biopsy task shows that the standard instrument outperforms the prototype in this respect. That is to say that the prototype instrument underperformed as a biopsy forceps compared to the standard (biopsy) forceps. However, these values may be skewed as during the testing a significant amount of the dot was often removed by scraping rather than grasping material, particularly with the prototype instrument. The other part of the data shows the average

maximum pull-off force attained by each instrument. Contrary to the ratings discussed above, this data shows that the standard forceps achieved a higher average pull-off force than the prototype instrument. However, the maximum force measured for each instrument was the same. This is an interesting fact since the perception by the participants was the opposite. Most participants ranked the prototype as being better at grasping and pulling, yet the averaged data shows the standard instrument fared better on average. This difference further highlights the scatter in the data and the difference between perception and fact. Most of the participants believed the prototype achieved a greater pull-off force, when the data shows that both instruments achieved the exact same maximum, and in fact, the average pull-off force for the standard instrument was higher. It is believed that this difference is due to several things. The primary reason is that many of the participants took different approaches in grabbing the tubing with each instrument. While this may be due to a lack of familiarity with the prototype instrument, it resulted in varied pulling directions after the tubing was grasped. However, the maximum pull-off forces were attained when a participant pulled the endoscope directly back toward the port hole in the box trainer while the endoscope was straightened out. This means that the maximum pull-off forces are fairly accurate. On the other hand, the average pull-off forces have significant scatter due to these variations in pulling direction. After analysis of the video and comments made by participants it can be concluded that both instruments are capable of exerting approximately the same maximum amount of pulling force, but that the prototype is able to grasp objects more firmly, and maneuver them with less variance, than the standard instrumentation.

The next group of results presented in Chapter 3 is the comments made by participants in response to the open-ended questions on the survey. These comments confirm several of the observations made using the quantitative results as well as presented several new evaluations. More importantly, the comments made the greatest number of times confirm the conclusions

made using the ratings. First, the comments confirm that the distal jaw opening of the prototype is too small. Secondly, the comments confirm the prototype has a better ability to control and use intermediate positions between open and closed and that this improves its ability for fine control and is an important ability of an endoscopic forceps. The comments also confirm that the prototype instrument's ability to grasp firmly is superior to that of the standard instrument and that the prototype is not well suited for biopsies and should not be used as such. In addition, several previously unnoted observations were identified by participants. The first is that the prototype's jaw length is too short and should be increased. This would further improve fine control and the ability to utilize intermediate positions. Another comment made suggested that the prototype be made easier to rotate around its axis, which would make accurately positioning the jaw opening easier. This would usually make determining if the instrument is opened or closed easier as well as make grasping from an awkward angle easier. The feedback also provided two comments about the visibility of the prototype. One of the comments states that the participant found it difficult to see if the prototype instrument was open or closed. This is important as it requires an additional verbal queue, which adds time and complexity to any operation. The second comment shows that the participant found it difficult to see around the actuation tube. That is the participant found the outer metal tube that slides forward and actuates the forceps bulky and obstructive to the view from the camera in the endoscope. This was largely due to epoxy present on the end of the tube nearest the camera. This observation is of limited importance as the epoxy is only present on prototype instruments and would not be present on any commercial versions of the prototype instrument.

The final results presented in Chapter 3 pertain to feedback given on the testing procedure. To this extent, very little feedback was given, and no written feedback was provided by the participants. However, the verbal feedback that was recorded seems to show that the testing procedure and the standardized task list accomplished the goals they were intended to

accomplish. Therefore, the standardized task list seems to be effective at testing the important abilities of an endoscopic forceps and presented sufficient challenge to participants to keep them focused on the testing. However, these evaluations are based on very limited feedback so additional testing and evaluation may be necessary to ascertain the effectiveness of the new task list. Accordingly, all goals set for the standardized task list as well as the evaluation of a prototype forceps, as described in Chapter 1, were accomplished successfully.

Summary

Minimally Invasive Surgery (MIS) is a recent development in the field of Medicine and offers extraordinary benefits and possibilities to patients. Advantages of MIS include greatly reduced tissue trauma, reduced risk of infection and recover time, procedural options to patients that are impossible with open surgery, and results in little or no cosmetic scarring. Due to these advantages, MIS is destined to become more common place in the medical field and may one day all but replace traditional open surgery.

As MIS procedures have developed and replaced some open procedures entirely, they have been divided into sub-specialties. One of these sub-specialties that is a very recent development, established approximately five years ago, is Natural Orifice Translumenal Endoscopic Surgery (NOTES). NOTES procedures are conducted through a flexible endoscope that is inserted into the body through the mouth, anus, vagina or urethra. Through a process known as tunneling, surgeons are then able to gain access to the gastric cavity through a patient's esophagus, stomach, urinary tract or intestines. As such, these procedures leave no external scars and greatly reduce the patient's chances of getting an infection making this is an area of medicine that has great potential. These advantages are important because they may one day allow for

NOTES procedures to be carried out in very poor and therefore un-sanitized locations where open surgical operations are currently very dangerous and not an option

For these reasons, and others, NOTES is a quickly growing field, but is still in its early developmental stages. In fact, many obstacles exist that have prevented NOTES from moving from animal testing to human testing. Perhaps the greatest of these obstacles is the lack of sufficient instrumentation. This shortage of instruments greatly reduces the number of possible surgical procedures and the number of conditions NOTES could one day cure. However, the shortage is not limited to material equipment. The lack of a standardized testing procedure and task list similar to one that already exists in laparoscopic surgery must be established and agreed upon by the medical community. This task list is not only necessary to sufficiently evaluate new instrument designs, but also to train and certify new NOTES surgeons. The research presented in this thesis has shown the methods and procedure used by the researcher to standardize this testing for the future. As presented, a new standardized task list has been made that can be used to test new endoscopic forceps designs and certify NOTES surgeons in their use. In addition to designing and testing the new Standardized NOTES Task List, the researcher tested a new endoscopic forceps instrument currently being developed at the Pennsylvania State University. This was accomplished by having a number of surgical residents perform the standardized tasks in an endoscopic box trainer with both a commercially available standard instrument and the new prototype instrument. Participants were then asked to rate the instruments on various abilities and features. This information was then given to the forceps design team and will be used to improve future versions of the instrument.

Research Contributions

The research presented in this thesis makes several important contributions to the NOTES field. The first major contribution is the Standardized NOTES Task List. Previously, no standard method for evaluating NOTES instruments or surgeons existed. Now, a standard testing protocol and standardized task list exists that not only objectively evaluates endoscopic forceps designs, but that can also serve as a starting point for a standard training regime for aspiring NOTES surgeons as well as a means of certification. In addition, this task list can be used to evaluate any endoscopic instrument. By removing or adapting tasks and adding new tasks to test other features, this list can be used as a basis for an objective evaluation of many endoscopic instruments. The research presented here also involved the creation of a NOTES endoscopic forceps survey. This survey can be used and modified in future research as well to evaluate many new NOTES instruments. These developments could prove increasingly more important as additional instruments become available and more medical students choose NOTES as their area of experience.

The other major contribution to the NOTES field is the improvement of the endoscopic forceps design currently under development at the Pennsylvania State University. The results and comments from the testing presented in this thesis have yielded a significant amount of useful feedback. This feedback will aid the design team in improving and adjusting the design to fit the requirements established by the NOTES surgeons. Ultimately, this will benefit not only NOTES instrument designers and the surgeons that use the instruments, but the outcomes and experiences of the patients they are used on and the procedures they make possible.

Conclusions

The research, testing and results presented in this thesis have taught the research and design teams several important things. The first important development of this research is the creation of the new Standardized NOTES Task List, testing procedure and NOTES instrument survey. This protocol will allow for objective testing and improvement of NOTES instruments in the future where subjective testing has been used previously. This fills a major void that has existed for several years in the NOTES field. While extensive research has been conducted in theorizing and performing new possible NOTES surgeries on animals, little has been done to fill the void created by a lack of adequate testing and evaluation methods. The research presented in this thesis fills this void and effectively establishes a new standard method for evaluating not only NOTES forceps, but all NOTES instruments. In so doing, the goals of designing a standardized task list and establishing a NOTES instrument evaluation protocol and procedure have been successfully accomplished. In addition, the new task list forms a basis that can be used to develop standard training methods for medical students. These tasks can be performed and timed for comparison and allow for inter-institutional comparison like the "Rosser Station Tasks" do for laparoscopic surgery.

However, several changes should be made to the testing procedure to improve the results and to get better, more reliable data. While most of the tasks on the task list worked well and effectively evaluated the features they were designed to evaluate, one task, the Force Gauge task, should be altered. This task resulted in data that exhibited significant scatter and little reliability or repeatability. This scatter was mostly due to the wide variability of the method and approached used by difference participants to grasp the rubber tubing. This procedure should be standardized. The first change should be to the orientation of the force gauge. That is the force gauge should be mounted such that it is aligned with the entrance to the box trainer, not parallel

to the bottom of the box trainer as it was during the testing presented in this thesis. This would result in more useful data that would better show the maximum pull-off force of difference forceps instruments and would reduce the variability that results from pulling in a direction not parallel to the force gauge. The second change should be to the location of the force gauge. The gauge should be placed directly below the box trainer port such that the amount of the endoscope in the box trainer is minimized. This would further reduce the variability in the pull-off force measurements. No additional tasks need to be designed as the tasks already on the list effectively evaluate the important features of an endoscopic forceps, but the force gauge task should be modified as described above to provide more accurate, more precise information.

The second area in which important information has been discovered is that of the prototype instrument design. The prototype instrument was successfully tested by twelve surgical residents and their feedback on its relative strengths and weaknesses compared to those of a commercially available endoscopic forceps have been recorded. This feedback has made several things apparent, and will continue to be of tremendous value to the forceps design team. The most important realization was that the forceps performed favorably when compared to the existing instrument. The new design fills a void and provides a forceps instrument that works well at intermediate positions and though it does not perform well at biopsy tasks, it excels at fine grasping tasks. However, if the design is to be advanced and eventually be made commercially available, several changes need to be made. First and foremost, the distal jaw opening and jaw length must be increased. This is necessary to further improve the instrument's ability to operate at intermediate positions as well as to make it easier to grasp large or misshapen objects. In addition, the instrument needs to be made easier to rotate around its cylindrical axis. This is very important when trying to grasp an object from an awkward position. This change would make determining if the instrument is opened or closed much easier. If these changes are made, the prototype instrument design will be very useful in NOTES surgeries. Based on feedback, both

verbal and written, this instrument will fill a need for a fine grasping forceps, such as those necessary for tissue resections, and will probably be widely implemented in NOTES surgeries throughout the world.

Further Research

In addition to accomplishing the goals as described in Chapter 1, the research presented in this thesis also exposed several opportunities for additional research. Currently, standard endoscopes are used to perform most NOTES procedures on animals. However, as new procedures have been proposed and are now being tested, specialty endoscopes, such as the Transdouglas Endoscopic Device (TED), have been and continue to be designed. One possible opportunity for future research would be to modify the new standardized task list presented in this thesis for evaluating and training surgeons on these specialty endoscopes.

Another avenue for future research would be to create new task lists for other types of endoscopic instruments. The task list presented in this thesis is designed to test endoscopic forceps instruments. Using the tasks on this list, new task lists could be created for testing other types of endoscopic instruments such as cutting and suturing devices as well as biopsy needle devices. These lists would use, modify, and if necessary remove some of the tasks in the new standardized NOTES task list as well as design additional tests to evaluate the desired features of a particular device. As the field of NOTES progresses and enters additional human trials, other types of instruments will also need to be designed and improved if the field is to become a viable solution to surgical problems. As NOTES has vast potential and offers numerous advantages over traditional open surgery, this is only a matter of time. Therefore, this research will eventually have to be completed for NOTES to reach its full potential as a life saving tool.

Appendix A

Survey and Results Tables

16C. Questionnaire

Multifunctional Instrument Evaluation

1. For each of the following tasks, indicate the ease of use of the prototype instrument and the standard instrument, where 1 is difficult to use and 3 is easy to use.

Task	Standard instrument	Prototype instrument
Material Pull	1 2 3	1 2 3
Ring Around	1 2 3	1 2 3
Fuzzy Ball	1 2 3	1 2 3
Cup Drop	1 2 3	1 2 3
Simulated Biopsy	1 2 3	1 2 3
Force Gauge	1 2 3	1 2 3

Figure A-1 Instrument Evaluation Survey Page 1

2. For each of the following tasks, circle the instrument parameters that made the task **easy**.

Task	Standard instrument	Prototype instrument
Material Pull	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Ring Around	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Fuzzy Ball	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Cup Drop	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Simulated Biopsy	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Force Gauge	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly

The figure below shows the basic design parameters of the prototype instrument.

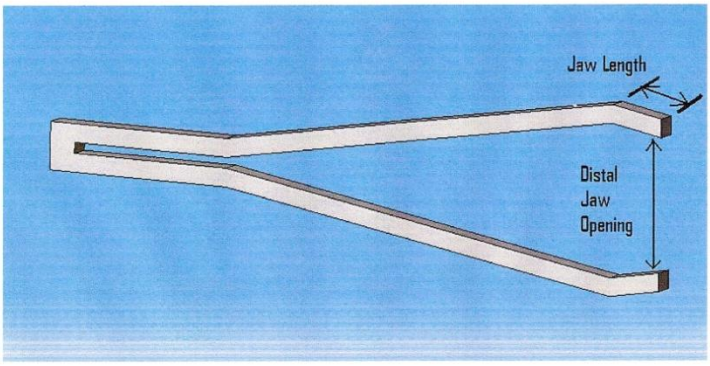

Figure A-2 Instrument Evaluation Survey Page 2

3. For each of the following tasks, circle the instrument parameters that made the task **difficult**.

Task	Standard instrument	Prototype instrument
Material Pull	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Ring Around	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Fuzzy Ball	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Cup Drop	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Simulated Biopsy	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly
Force Gauge	jaw length distal jaw opening ability to grasp firmly	jaw length distal jaw opening ability to grasp firmly

The figure below shows the basic design parameters of the prototype instrument.

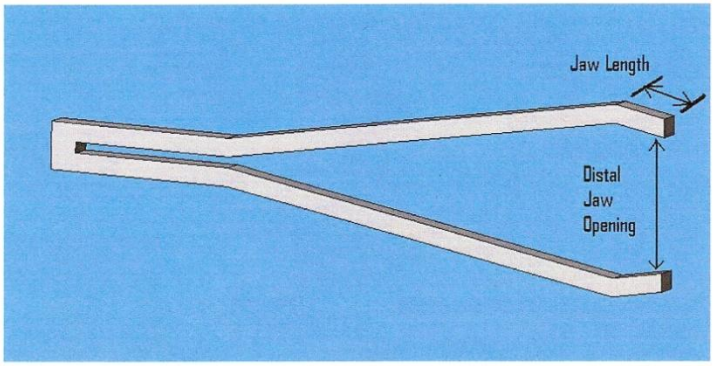

Figure A-3 Instrument Evaluation Survey Page 3

4. In light of the ease or difficulty with which tasks were completed, indicate the relative importance of each attribute, where 1 is least important and 3 is most important.

Task	Standard instrument		Prototype instrument	
Material Pull	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3
Ring Around	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3
Fuzzy Ball	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3
Cup Drop	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3
Simulated Biopsy	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3
Force Gauge	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3	jaw length distal jaw opening ability to grasp firmly	1 2 3 1 2 3 1 2 3

The figure below shows the basic design parameters of the prototype instrument.

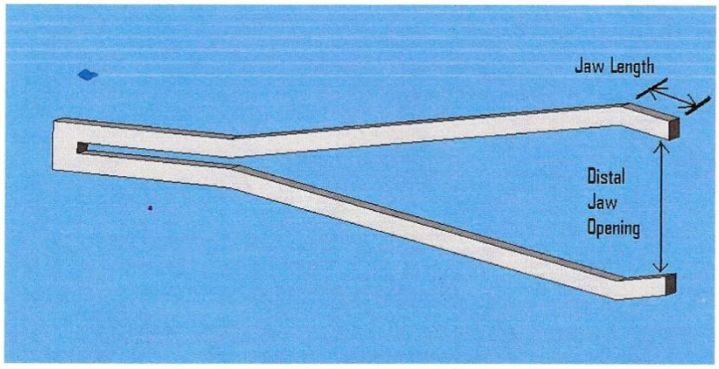

Figure A-4 Instrument Evaluation Survey Page 4

5. In light of the ease or difficulty with which tasks were completed, indicate the relative quality of each metric, where 1 is completely inadequate and 3 is completely adequate.

Metric	Standard instrument	Prototype instrument
Maximum Pulling Force (Force Gauge Task)	1 2 3	1 2 3
Amount of Material Removed (Simulated Biopsy Task)	1 2 3	1 2 3
Ability to Control and Operate the Device at Intermediate Jaw Openings Between Fully Open and Fully Closed	1 2 3	1 2 3

Please Comment on the importance of being able to operate and utilize the instruments at intermediate jaw openings between fully opened and fully closed:

Figure A-5 Instrument Evaluation Survey Page 5

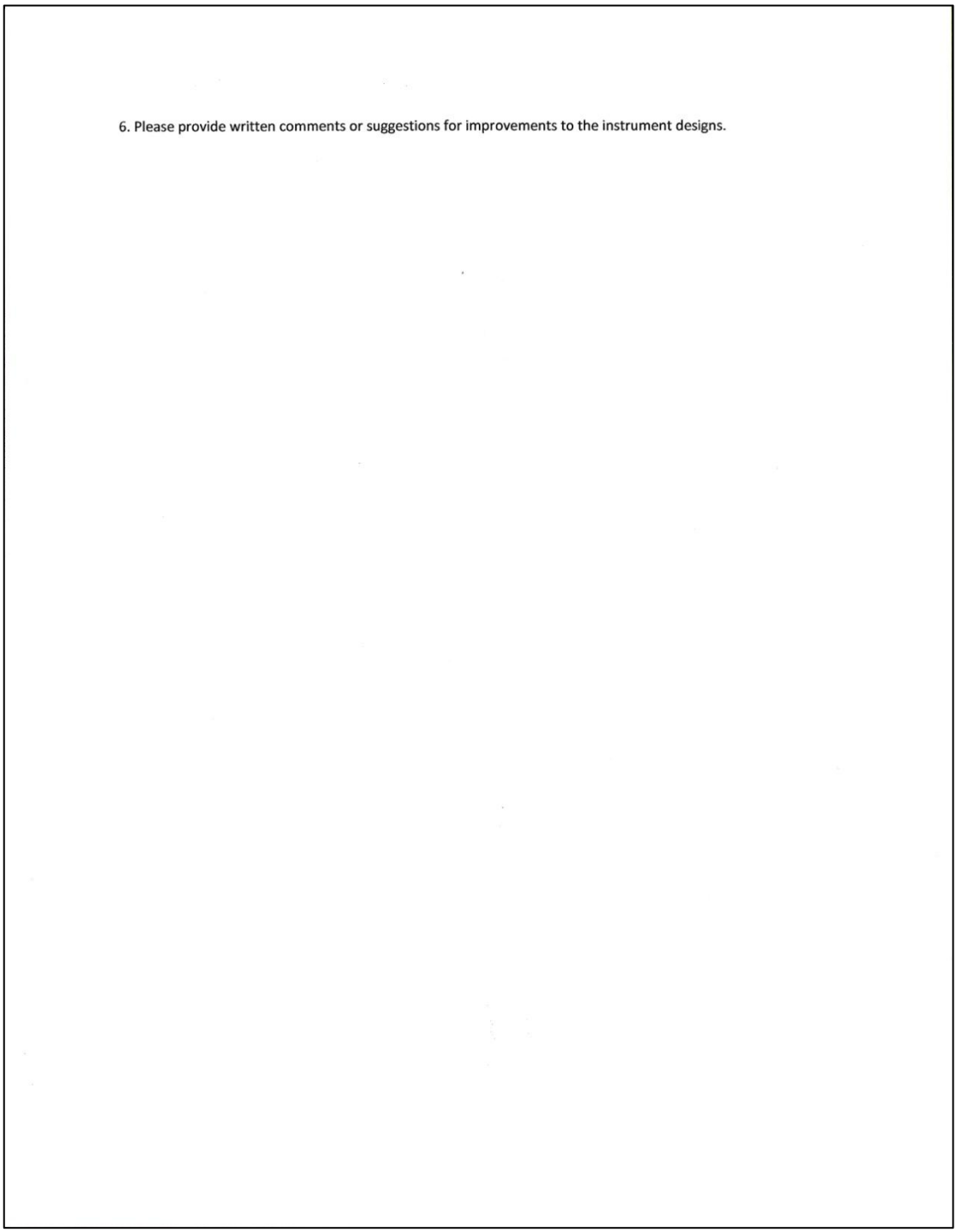

Figure A-6 Instrument Evaluation Survey Page 6

Table A-1 Comments Made On Surveys by Testing Participants: Individual Responses

Comments Made On the Survey by Participants

Participant ID #	Comments
2	Prototype jaw length should be increased; prototype is not well suited for biopsy
3	Distal jaw opening and jaw length should be increased; prototype not well suited for biopsy; the body proximal to the jaw was bulky and at times blocked view of jaw; prototype's ability to rotate is helpful; prototype was better at grasping objects
5	*None*
8	Prototype forceps needs to be longer and open wider
12	Prototype allows for more fine control; smaller jaw opening allows for more precision when grabbing an object
13	*None*
14 (1)	Control of intermediate distances is important for some tasks like grasping a larger polyp; The prototype's biggest limitation is its narrow jaw opening
14 (2)	I did not appreciate that the prototype had a jaw-opening limitation; the jaw-opening width on the prototype could have been better; the gear train on the standard instrument featured a visual cue as to whither the instrument is open or closed; there is no such cue on the prototype and it was a bit hard to know if it was open or not as if required an extra verbal confirmation about open/closed state
17	Controling Intermedia jaw opening positions was not as important in grasping large objects such as the material pull task, but allowed for better precision in the ring around and fuzzy ball tasks; the grasping forceps woud be easier to use if they could easily be rotated 360 degrees allowing for more precision with each grasp; I felt it would be easier to spin the forceps in order to achieve a 90 degree purchase as opposed to larger, less precise movements of the endoscope
22	it appeared that the jaw opening was small to begin with, so no role for an intermediate opening; the opening should be made 1 to 2 mm wider, which would make tasks easier; A wider jaw might give added benefits; The device needs to be rotatable to make it easy to see the jaws open as they tend to take a parallel orientationat times and the operator cannot distinguish the two states. This makes grabbing small things rather difficult, especially given lack of depth perception
23	Ability to control intermediate positions between open and closed is essential
15	the existing instrument was more flexible and when closer to the scope obscured vision making it more difficult to use

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