Published in final edited form as:

IEEE Trans Biomed Eng. 2015 March ; 62(3): 890–899. doi:10.1109/TBME.2014.2369956.

Characterization of Force and Torque Interactions during a Simulated Transgastric Appendectomy Procedure

Saurabh Dargar [Graduate Student Member, IEEE], Cecilia Brino [Student Member, IEEE], Kai Matthes, Ganesh Sankaranarayanan [Member, IEEE], and Suvranu De [Senior Member, IEEE]

Abstract

We have developed an instrumented endoscope grip handle equipped with a 6-axis load cell and measured forces and torques during a simulated transgastric NOTES appendectomy procedure performed in an EASIE-R[®] *ex vivo* simulator. The data were collected from 10 participating surgeons of varying degrees of expertise which was analyzed to compute a set of 6 force and torque parameters for each coordinate axis for each of the nine tasks of the appendectomy procedure. The mean push/pull force was found to be 3.64 N ($\sigma=3.54$ N) in the push direction and the mean torque was 3.3 N-mm ($\sigma=38.6$ N-mm) in the counter-clockwise direction about the push/pull axis. Most interestingly, the force and torque data about the non-dominant x and z axes showed a statistically significant difference ($p<0.05$) between the expert and novice groups for five of the nine tasks. This data may be useful in developing surgical platforms especially new haptic devices and simulation systems for emerging natural orifice procedures.

Index Terms

Haptic interface; human factors; surgery; virtual reality

Introduction

Much advancement made in the field of surgery has focused on minimizing the invasiveness of surgical access techniques. The introduction of Minimally Invasive Surgery (MIS) has revolutionized the mainstream surgical community. A further development in the direction of reducing invasiveness is the natural orifice transluminal endoscopic surgery (NOTES). The primary goal behind NOTES is to be an incision-less procedure, with no external scarring and minimized patient trauma [1]. In a NOTES procedure, access to the target organ is obtained by either breaching the lumen of the stomach, colon or cervix through the natural orifices such as the mouth, vagina or anus [2], [3].

While there is significant enthusiasm around the development of NOTES procedures [4]–[7], a cautioned approach is necessary to mitigate patient safety concerns that plagued the introduction of laparoscopic cholecystectomy in the early 1990's. This is particularly important due to the relatively low human experience, lack of long term follow-up data and the high complexity of the procedure that requires multiple skill sets including flexible endoscopy and surgery. Maneuvering a flexible endoscope in a pure NOTES procedure

requires critical scope handling skills to safely approach the target organ while breaching the respective lumen [8] and proper luminal closure [9].

Despite the momentum the NOTES technique has gathered, the unavailability of specialized equipments and dedicated platforms have hampered the widespread clinical adoption of NOTES[10]. However, the NOTES procedure is continually evolving with initially-envisioned procedures such as cholecystectomy and appendectomy now giving way to a variety of newer techniques such as peroral endoscopic myotomy (POEM) [11], endoscopic submucosal dissection (ESD) [12], [13], transanal rectal resection [14] and endoscopic full thickness resection [15]. Thus, continuing NOTES based research work is a critical endeavor, even today.

To address the emerging concerns of NOTES procedures, a working group called Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) was formed and a 2005 whitepaper published by the consortium lays out eight major issues that the community must address to enable safe introduction of NOTES to the clinic [16]. Two of these include development of effective training paradigms and a surgical platform. Understanding the force and torque interactions with the endoscope is critical for both. This force and torque data can be used to develop performance metrics as well as aid in establishing the design requirements for the development of a surgical training and simulation platform.

Previous work by Trejos et al studied the force and torque interactions between the endoscopic tool and target tissue during NOTES [17], however there is no prior work studying the interactions between the user's hand and endoscopic tool in a NOTES procedure. Trejos et al conducted experiments to measure the forces needed to manipulate tissues during a NOTES procedure. They performed a transgastric and transperineal appendectomy on two porcine models with specially instrumented tools, which had strain gauges at the tooltip to measure the applied forces on the tissue. Their study showed that a force of 8 N and 16 N are required for transgastric and transperineal approaches, respectively. Characterizing the tool-tissue interactions provides an understanding of tissue effects and not the forces felt by the user as the endoscope is flexible, not rigid. The forces and torques on the user's hand are important from the perspective of designing a reliable surgical platform or interface for surgical simulation. Hence, the hand-tool interactions must be measured independently.

Studies have been conducted to measure the forces applied by a surgeon's hand on the endoscope during colonoscopy procedures [18]. The device used an inner tube attached to the colonoscope and an outer tube for holding with the user's hand. Appropriately mounted strain gauges housed between the tubes measured the forces. They measured a peak pushing force of 43 N and a pulling force of 17 N and a clockwise torque of 0.8 Nm and anti clockwise torque of 1 Nm. Though this device was developed to measure forces at the hand while operating an endoscope, it was large and needed to be completely opened to move along the scope. In comparison, the forces applied at the tool handle in traditional laparoscopic surgery are found to be in the range of 0–10 N and 0–100 N-mm of torque [19].

Interestingly, prior works have shown haptic interactions to be reliable differentiators of skill, most prominently in laparoscopic procedures. Rosen et al. used Markov models to develop a performance scale based on force and torque signatures from the tool-tissue interactions [20]. Trejos et al. developed several force based metrics to classify skill and showed strong correlation between experience and the force based metrics for laparoscopic tools [21]. Hwang et al. used a combination of laparoscopic tool tip position and force/torque information to develop measures of motor performance (MMPs) [22].

The same force and torque data can be used as reference data to develop surgical simulation platforms, particularly haptic devices. There are a variety of parameters used to define performance specifications of haptic devices, such as force output range and resolution [23]. Studying the specific force/torque interactions for a given procedure can serve as application specific reference data sets for haptic device design. Haptic devices for simulation of endoscopic procedures have been developed before [24]. The two degrees of freedom haptic device developed by Samur et al. was designed specifically for colonoscopy simulations. Yi et al. developed a 2 DOF colonoscopy simulator with a specialized haptic interface to transfer force feedback through a long and flexible tube for colonoscopy procedures [25]. Ikuta et al. designed the Portable Virtual Endoscope System (Portable VES) for colonoscopy simulations using friction rollers and a rubber ball as actuators to render force feedback [26]. Commercial devices for colonoscopic/endoscopic procedures are also available. The EndoVR system available from CAE Healthcare provides modules for gastrointestinal and bronchial assessment [27]. The haptic system provides active force feedback during insertion and removal of the scope from the mannequin. The GI mentor from Simbionix USA Corp. provides a comprehensive endoscopic medical simulator and has been evaluated as a virtual endoscopy simulator for gastrointestinal procedures [28], [29]. Since realistic force feedback is critical for efficient training using surgical simulators, studying the actual force/torque interactions becomes important for determining the required performance specifications of haptic devices for surgical simulations.

In this work our objective is to develop a novel device to measure the task-wise forces and torques felt and applied at the user's hand during a simulated transgastric appendectomy procedure. The data helps us understand the range of forces and torques encountered during this procedure in an *ex vivo* simulator to serve as a reliable indicator for skill level differentiation for some of the tasks and reference data for development of haptic devices for flexible endoscopy based procedural simulators.

Methods & Materials

A. Apparatus

A validated *ex vivo* simulator EASIE-R™ (Endosim LLC, Hudson, MA) with ex-planted pig tissues has been used in this study. The EASIE-R model has been tested extensively at various national and international NOTES courses and at the SAGES learning center since 2008 as a simulation model for NOTES procedures [30], [31]. The simulator consists of intact ex-planted pig organs arranged in a manner to resemble a human's internal anatomy and has ports that mimic the natural orifices such as esophageal and anal access, in order to allow for access into the peritoneal cavity. Specimens are attached to an adapter, which

threads into the esophageal portal or colon portal. This also provides a secure link to fix a portion of the specimen in place, which can be seen in Fig. 1. The remainder of the specimen is secured in place with stainless steel alligator clips that are fixed to the tray. In this study the gastric port was used to perform the transgastric NOTES appendectomy.

The EASIE-R tray is made from washable plastic and is 26"L×15.5"W×6"H in size with a 1.24" threaded esophageal and 1.5" threaded colon portal to mimic natural orifices. The tray has a 6.5" molded esophageal section that keeps the esophagus tissue elongated and straight in place. In Fig. 1(a) the tray is covered with a clear plastic sheet for demonstration purposes only, during the procedure the tray is covered with a 16.5"L×13.5"W×6"H "molded belly" as seen in Fig. 1(b).

B. Instrumentation Hardware

During NOTES the user performs the procedure by holding a flexible endoscope with one hand and the end effector control dials with the other, as shown in Fig. 2. The hand used to hold the flexible endoscope's insertion tube is the sole source of human applied force to the endoscope for maneuvering. It is at this point of hand contact that we are interested in measuring the forces and torques applied by the user. There are no commercially available devices that can readily allow for the measurement of forces and torques exerted on a flexible endoscope. Thus, in order to facilitate the measurement of forces while creating minimal obstruction to the user, a customized instrumented load cell handle was designed.

The handle was prototyped using additive manufacturing techniques. Fig. 3(a) shows the CAD model of the load cell handle with all the assembled components labeled. It consists primarily of an outer contact surface for the surgeon labeled as the 'handle tube', and an inner contact for the endoscope, labeled as the 'scope attachment'. The interface between the inner and outer layers is solely through the load cell. This allows unhindered transmission of forces/torque from the user's hand to the endoscope, in turn allowing the load cell to measure the force/torque applied by the user's hand. Hence, the force/torque being recorded is only due to the user's interaction with the handle. The load cell is secured in place with an aluminum cover on the 'handle tube' to prevent any undesired moments. The endoscope is secured onto the 'scope attachment' using a simple 1/4-inch set screw, which is firmly tightened to prevent any slip. A 4mm clearance between the 'hand screw' and the hole in the outer 'handle tube' was provided to prevent any interference. Fig. 3(b) shows the final manufactured load cell handle, which was used to conduct the studies.

This device has been designed to be user friendly and minimally obstructive during the course of the procedure. The handle tube is designed ergonomically to allow a strong and firm grip on the scope handle. The user has the ability to slide the endoscope handle up and down the endoscope on the fly by a simple adjustment of the 'hand screw' as labeled in Fig. 3(a). This is an important feature if the user desires to reposition the device for better control over the flexible endoscope during the procedure. A simple adjustment to the 'hand screw' by the thumb loosened or tightened the location of the handle, making repositioning straightforward. Alignment markings on the handle and flexible endoscope were used to ensure the same orientation throughout all trials.

For accurate and high precision force and torque data measurement, the device has been instrumented with a small 6-axis load cell (Nano 17 from ATI Industrial Automation, Apex, NC), which senses the force and torque about the 3 axes. The force sensor can accurately measure forces up to 50 N in the x- and y- directions and up to 70 N in the z-direction, with a maximum of 500 N-mm of torque about all three axes. In Fig. 4 we can see the orientation of the 3 axes with respect to the load cell handle, with the push and pull direction being along the Y axis and the torque (Clockwise (CW) and Counter Clock Wise (CCW)) being about the Y axis. The Nano 17 load cell is interfaced with an ATI analog to digital converter unit (ADC unit). The ATI ADC unit is then read using a National Instruments USB Data Acquisition (NI USB 6210). The National Instruments USB Data Acquisition unit communicates with ATI's proprietary software at 62.5 Hz to resolve the analog voltages into forces/torques using a device-specific calibration file from ATI. A generic digital video recorder was also used to record the endoscopic video for each procedure to be used later during the data analysis.

C. Study design and data collection

At the 2013 annual Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) conference in Baltimore, MD, we performed an Institutional Review Board (IRB) approved study using the EASIE-R simulator and the instrumented load cell handle. After agreeing to the verbal consent, the subjects were instructed to perform a transgastric NOTES appendectomy procedure.

Before each procedure the subject was informed of the design and nature of the load cell handle being instrumented on the double channel flexible endoscope. This was done to make the subject aware of the visibly attached device such that it would minimally impact how they usually interact with a flexible endoscope. Once the handle was attached to the endoscope they were given a timeout to get comfortable with holding the handle and were instructed on how to loosen the setscrew in order to move the handle up and down the scope as necessary.

The subjects were then informed of the key tasks (Table 1) to be accomplished during the procedure. This transgastric appendectomy procedure involves inserting the endoscope through the esophagus until it reaches the stomach where an incision is made to reach the peritoneal cavity (gastrotomy) after which the endoscope is driven to the appendix. Once the appendix is removed, the specimen is then retrieved through the stomach and the gastric cavity. The endoscope is then inserted again to close the hole in the stomach (gastrotomy closure). It is to be noted that while performing appendectomy, the tools are inserted through a special channel while the scope is used to control the endoscope tip position and also provide proper traction to manipulate tissues.

D. Data segmentation

Our primary approach to characterizing the appendectomy procedure has been using a task analysis method that is clinically relevant. In order to provide a consistent basis for segmentation of each subject's procedure, we used the tasks given in Table 1 as a guide to create task segments. The start and end of each task segment was clearly defined as shown

in Table 2. Each video was studied to determine the respective start and stop time points for each task, the time markers were then used to segment the collected force data. Prior to conducting the studies, we performed calibration experiments between the video recorder and the force sensor. The force data was collected at a fixed sampling rate throughout the study. The system clocks of the force recording computer and the endoscopic unit were synchronized to the same timeserver to assure reliability on the time stamps. Using the task start/stop times the data was segmented in Matlab, which was then further used to compute various parameters.

E. Calculated parameters

With all the data segmented, each task segment was then processed to compute a set of parameters as shown in Table 3. Before computing the metrics, a 10 Hz low pass Butterworth filter was applied to mitigate any noise components due to interference while preserving the frequency components of human motion, as voluntary limb movements have a bandwidth of less than 10 Hz [32], [33]. From Fig. 4 we can see the orientation of the three axes with respect to the load cell while in use, thus clearly indicating the push/pull ($-y/+y$), up/down ($-z/+z$) and left/right ($-x/+x$) directions of each axis.

F. Statistical Analysis

After segmentation of the subject's data, the experts and novices were placed into their respective separate groups. In order to assess the differences, a 2-tailed Mann-Whitney U test was performed on each parameter of each task using SPSS (SPSS IBM, New York, U.S.A) software. Given the non-normality of the data, the Mann-Whitney U test was an appropriate tool to identify whether the computed parameters within each task showed a statistically relevant difference or not.

Results

The study was conducted with ten subjects with two distinct skill groups, experts ($n=6$) and novices ($n=4$). Subjects were classified as expert if they were an endoscopist or had previously performed a NOTES procedure, while a novice was someone with only laparoscopic experience. The parameters listed in Table 3 were computed for each task, as outlined in Table 1. The results have been displayed in the following format; first we present the characterization of the complete procedure's haptic interaction and then the results of the parameters (Table 3) for each of the nine tasks while comparing experts and novices.

A. Complete procedure force & torque characterization

The primary approach to characterizing the interactions for the appendectomy procedure has been to analyze the distribution of forces and torques along all three axes. Before using a task decomposition approach to analyzing the data, we studied the distribution of forces and torques for all subjects over the course of the procedure. In Fig. 5 and 6 we can see the distribution of applied forces and torques along the x-, y- and z-axes for the full course of the procedure.

Along the x-axis we see a skewed distribution of leftward and rightward forces (median -0.46 N, mode -1.56 N). A small number of occurrences (0.8% of all occurrences) of high rightward forces of greater than 20 N can be seen, while the leftward forces only go up to 14 N. Along the y-axis, the force distribution is fairly skewed with the majority of applied forces in the push direction (median -2.55 N, mode -13 N), with the high force values of up to 25 N only present in the push direction. The forces along the z-axis show a slightly skewed distribution towards the down direction (median -0.48 N, mode -1.66 N). The up and down forces do not exceed 10 N and 11.5 N in magnitude, respectively.

The same approach was taken in analyzing the distribution of torques about their respective axes and is shown in Fig. 6. The torque about the x-axis shows a plateau like distribution, with the majority of torques being in the clockwise direction up to 200 N-mm (median 39.99 N-mm, mode 36.1 N-mm). The counter clockwise torque begins to drop off significantly with only a fraction of the number of occurrences above 100 N-mm of torque. The torque about the y-axis (push/pull axis) shows a normal distribution with a uniform application of clockwise and counter clockwise torques ranging up to 200 N-mm (median -3.26 N-mm, mode -10.11 N-mm). Applied torques about the z-axis shows an interesting bi-modal distribution (median -11.13 N-mm, mode 17 N-mm & -152.49 N-mm). The majority of CW occurrences peak at 75 N-mm with a fraction of occurrences above 75 N-mm. The majority of the torque appears to be in the CCW direction with a fairly consistent occurrence of torques between 25 N-mm and 100 N-mm, eventually peaking at 210 N-mm.

Fig. 7 shows the time series plot of measured force for expert subject 1 and novice subject 2 during the insertion and inflation of the saline based radial expansion balloon (task #4). As a reference, negative values indicate force along the negative direction of the axis and positive values indicate forces along the positive direction of the axis.

The expert and novice show minimal activity of force in the x and z-axis, while the forces along the push/pull (y-axis) are the dominant forces throughout the task. The comparison of push/pull forces between experts and novice shows an interesting difference, primarily in the instances of high forces along the y-axis. In the experts plot, we can see push/pull forces of up to ~ 10 N until we get to the 65 second mark, where the push force jumps to ~ 22 N indicating the expert has pushed the inflated balloon into the previously made incision (task #3) and is poised for the final push to pass through the gastric wall in task #5. In the push/pull plot of the novice, we can see multiple occurrences of push forces between 5 N and 20 N. The multiple occurrences indicate the user tried multiple times to appropriately align the balloon in the previously made incision, and finally managed to at the 225-second mark. It is also to be noted that the expert user spent 100 seconds on the task while the novice spent ~ 500 seconds on the same task.

In Fig. 8 we have compared the applied torques for the same expert and novice subjects. The expert is seen to apply ~ 200 N-mm of torque consistently throughout the task. However at the 65-second mark when the user was able to place the balloon correctly, we can see some unique torqueing behavior. There is no applied torque about the push/pull axis but the scope is torqued CW about the x-axis and CCW about the z-axis. A similar trend cannot be seen with the novice subject, where majority of the torqueing is seen about the push/pull (y-axis)

with ~150 N-mm CW and ~200 CCW torque. The force and torque time series plots of Subject 1 (expert) and subject 2 (novice) were representative of the variation of force and torque as a function of time, primarily the task duration and thus were chosen to illustrate the difference in experts and novices.

B. Task-wise parameter comparison for skill differentiation

The parameters listed in Table 3 were calculated for each subject's tasks, after which the subjects were grouped into their respective skill levels. In Fig. 9 (a) through (r) we show a comparison of each of those parameters for each of the listed tasks required to complete the procedure. For the box plots indicating force parameters (peak & RMS) the positive(+)/negative(-) signs indicate force directionality, while in the torque parameter plots the positive (+) sign indicates clockwise torque and the negative (-) sign indicates counter clockwise torque. A Mann Whitney U test was performed on each parameter of each task to identify statistically significant differences. The null hypothesis stated that the two data sets from the expert and novice were from the same population. A $p < 0.05$ would allow us to reject the null hypothesis with 95% confidence and accept the alternate hypothesis that the two data sets from experts and novices were statistically different. However, not at all parameters showed statistically different results. The parameters within each task that were significant have been marked with a red asterisk (*) in Fig. 9(a)–(r).

Scope insertion into the gastric port through the esophagus primarily requires the user to push the endoscope linearly while providing some torque if necessary. In Fig. 9(a) we see a plot showing the differences in forces being applied by the user during the scope insertion task. The dominant force is seen along the push (-y) direction with experts exerting forces up to ~14 N (median 11.3N) and novices exerting forces up to ~17N (median 8.59 N). The experts apply a median force of 5.4 N on the left (-x) direction while the novices apply a much lower median force of 1N ($p=0.03$). The experts apply a median force of ~1.3 N in the up (+z) direction, much smaller than the novice's median force of 6.1N ($p=0.02$).

Fig. 9(c) compares the force parameters for the experts and novices during the insufflation of the stomach as the user navigates to the gastrotomy site. The force along the +x direction for the novices shows a larger range of 1.3 N to 27.8 N, while the experts forces range between 0.3 N and 2 N ($p=0.03$).

During task #3 when the electrosurgical tool is being used to make the first incision in the gastric wall, there is not much activity ongoing with regards to manipulating the scope. The only time for manipulation is if the user desired to reposition the scope. Fig. 9(e) shows that the median push force (-y) for the experts is (8.8 N) as compared to the novice (6.4 N), however the difference was not statistically significant ($p=0.17$). The torque parameters shown in Fig 9(f) are extremely scattered with no noticeable trend in the torque interactions. Inconsistencies arise since majority of haptic interactions occur using the electrosurgical tool through the endoscopic working channel and not through the load cell handle (i.e., no manipulation to the whole endoscope). Thus no parameters were able to statistically differentiate between the skill groups during task #3.

The task of inflating the radial expansion balloon with saline (task #4) requires pre-positioning of the deflated balloon in the previously made incision during task #3. It is placed such that the center of the balloon coincides with the gastric wall leaving half of the balloon inside and the other half outside. The force interactions during re-positioning are shown in Fig. 9(g). A critical interaction is pushing of the scope into position while having to torque it to obtain the correct orientation. Once again, task #4 was not able to show any statistically significant skill dependent differences.

As soon as the radial expansion balloon has been aligned in the correct location it is inflated and pushed through the incision in the gastric wall (task #5). Fig. 9(i) shows the experts and novices applied ~13 N of force in the push (-y) direction to get the endoscope through the incision. The plot also shows that only the novices pivoted the handle towards the right (+x) while pushing through, shown by a median of 15 N force in the right (+x) direction. Fig. 9(j) shows that experts applied a 34 N-mm torque about the x-axis while novices applied a 132.1 N-mm torque about the same axis. A statistically significant difference between the two skill groups was not detected.

Once the endoscope is within the peritoneal cavity the users located the appendix and began the process of removing it by ligating using an endoloop inserted through the working channel. Thus the only primary interaction with the load cell handle is during advancement of the scope. For task #6, Fig. 9(k) shows that both experts and novices performed substantial push (-y) interactions (9.2 N and 12.3 N median forces respectively) during the procedure. The novices applied a median up (+z) force of 4.8N while experts applied a much smaller 0.6N median up force ($p=0.01$). A significant difference is also seen in the RMS force along the z direction ($p=0.01$). Fig. 9(l) overall illustrates the torque applied during this task. Novices applied a much higher clockwise torque (~70 N-mm) about the z-axis than the experts (~20 N-mm) ($p=0.01$). A significant difference in counter clockwise torque about the x-axis during assessment of the appendix was also observed ($p=0.01$).

In Fig. 9(m) during task #7, we can see that the push (-y) axis is the dominant axis of force interaction with the scope (expert: 11.7 N; novice: 7 N). The force along the up (+x) direction illustrates a difference, with experts applying a median of 2.5N and novices applying a median of ~5N ($p=0.01$). Fig. 9(n) shows high clockwise torques about the x-axis (ranging up to ~200 N-mm) and counter clockwise torques about the z-axis (ranging up to ~200 N-mm) ($p=0.06$).

Once the appendix was divided from the base, it was removed and retrieved (task #8). Fig. 9(o) shows the push/pull (-y/+y) axis as the dominant axis of force interactions. With both experts and novices applying 6.7 N and 7.2 N of median push force and 6.6 N and 4.4 N of median pull force respectively. However no parameter statistically differentiated the two skill groups.

Fig. 9 (q) and (r) show the force and torque interactions during the application of the clips (task #9). Tools using the endoscopes internal channels were used to perform the application of the clips on the open incision of the gastric wall. Both experts and novices apply ~9.4 N of push force (-y) during the task, and 4 N and 2.9 N of pull force (+y) respectively. The

significant differentiating factor during the clip application was the RMS forces about the x- and y-axis. Experts were observed to be applying higher RMS forces along the x (p=0.03) and y (p=0.01) axes. Table 4 provides a summary of the statistically significant results of the 2-tailed Mann Whitney U test performed on each parameter for all nine of the tasks that make up the NOTES appendectomy procedure.

Discussion

The nature of the NOTES procedure requires surgeons to have a high degree of skill in maneuvering the endoscope, not only to gain visualization but also to reach the target organ and achieve proper luminal closure. The series of manipulations required in order to achieve the desired endoscopic behavior is fairly complex. The goal of our study was to collect force and torque data in a simulated transgastric appendectomy procedure, as a whole and also during specific tasks and sub-tasks. The data was also able to reliably serve as a tool for skill differentiation between the expert and novice groups for five out of the nine tasks that constitute the transgastric appendectomy procedure.

Using the instrumented handle we were able to measure the force and torque along/about all three (x,y,z) axes. From Fig. 4 we can see that the y axis is the primary push/pull axis along which the scope is inserted and retracted, while the x and z axis represent the directions of the scope looping and bending. The results from section IIIA provided us critical information in assessing the range and distribution of force and torque for the various types of manipulations. The result for each axis illustrates the general tendency of manipulation along/about that particular axis.

The comparison of the measured parameters given in Table 3 across all tasks for novices and experts shows an interesting picture of skill differentiation. Despite the y-axis (push/pull) being the primary axis for scope manipulation, none of the y-axis parameters were able to show statistically significant differences. Only the gastric closure step (task #9) was able to distinguish the two skill groups using a y-axis parameter. Proper luminal closure after the target organ has been operated upon is currently a challenge in NOTES procedures. Expert surgeons were able to skillfully place the endoscope at the correct target view location, while they used the smaller channels to perform the clip application and repeat for all three clips. Novices were unable to gauge the desired positioning and as a result applied a wide range of translational forces in trying to achieve that goal. This statistically relevant differentiation observed in the RMS force along the y-axis demonstrates the feasibility of using translational forces in identifying skill for luminal closure in this experimental setup. A post hoc power analysis determined that the tasks that did not show a differentiation in skill were deficient in their power (minimum requirement 80%) and thus were unable to statistically differentiate the two skill groups.

The remaining skill differentiating parameters were from axes perpendicular to the primary x-axis and z-axis. The forces and torques about the x and z axes represent the twisting and looping behavior of the user while manipulating the scope. This observation can be explained by the presence of non-specific movement the experts perform to manipulate the endoscope. Non-specific interactions refer to the application of torque and force about/

along x and z axis onto the endoscope. These interactions are not to necessarily rotate or translate the endoscope, but to leverage the current shape/orientation of the endoscope to better position them for a translation/rotation motion in the very next step. From the results in Table 4 we can see that the steps #1, #2, #6, #7 and #9 show a variety of statistically significant parameters ($p < 0.05$) related to the x and z-axes. It is expected that such non-specific endoscopic interactions be seen only in experts, as they already possess the endoscope handling skills, which novices do not yet possess.

From the results we have observed that experts employ a combination of endoscopic manipulations about the dominant (y-axis) and non-dominant axes (x and z). The parameters, which are capable of differentiating skill, depend heavily on the nature of task at hand. This indicates that depending on the nature of the task, the variation of the measured parameters can possibly be used to understand the presence or absence of skill.

The computed parameters for each task of the procedure also forms a comprehensive data set, which can be employed in the development of flexible endoscopy based procedural simulators, for one task or the whole procedure. With the evolution of NOTES procedures leading to new flexible endoscopy based techniques such as peroral endoscopic myotomy (POEM), endoscopic submucosal dissection (ESD), transanal rectal resection and endoscopic full thickness resection, this comprehensive data set serves as a valuable reference for the community intending to develop effective training paradigms and surgical platforms. While this extensive data set provides an idea of what forces and torques may be expected during an actual NOTES procedure on a human patient, pig tissue properties, particularly for this *ex vivo* model, might be different from *in vivo* human tissue and the actual numerical values may be different. However, given the wide variability of tissue properties among patients, as well as within the same patient with age, disease state and other variables, we expect our data and the insights obtained from them to be useful. As a result, for the foreseeable future this comprehensive data set holds the potential to facilitate better training in a variety of flexible endoscopy procedures by furthering the research and development of surgical simulation systems.

Conclusion

In this study we designed and developed an ergonomic grip handle equipped with a 6-axis load cell to measure the force and torque interactions during a simulated transgastric NOTES appendectomy procedure. The procedure was performed by 10 participating surgeons of varying skill levels on the EASIE-R[®] *ex vivo* simulator. The data provided a detailed picture of the distribution of force and torques applied by all 10 participating surgeons spanning the whole simulated NOTES appendectomy procedure. The mean push/pull force was found to be 3.64 N ($\sigma = 3.54$ N) in the push direction and the mean torque was 3.3 N-mm ($\sigma = 38.6$ N-mm) in the counter-clockwise direction about the push/pull axis. The force and torque interaction data was then further processed to compute a set of 6 unique parameters for each of the coordinate axes. The parameters were then analyzed for each of the nine tasks of the appendectomy procedure. Within the experimental constraints of our setup we were also able to distinguish skill level based on characterizing and comparing the haptic interaction data of experts and novices. Most interestingly, the force and torque data

about the non-dominant x and z axes showed a statistically significant difference ($p < 0.05$) between the expert and novice groups for five of the nine tasks. The comprehensive data set also aims to serve as a detailed reference for the design and development of flexible endoscopy based surgical simulation and training systems. In the future we intend on continuing this study on the two skill groups to increase our sample size and eventually attain more power to differentiate the skill groups based on force and torque interactions.

Acknowledgments

The authors would like to acknowledge the funding from the following sources for this work: NIH/NIBIB 5R01EB010037-01, 1R01EB009362-01A2, 2R01EB005807-05A1, 1R01EB014305-01A1. The authors would also like to thank Endosim LLC (Hudson, MA) and Mr. Wayne Thibaudeau (Endosim LLC, Hudson, MA) for helping us in collecting the data. Dr. Kai Matthes has ownership in Endosim LLC (Hudson, MA).

References

1. Rattner D, Kalloo A. ASGE/SAGES Working Group on Natural Orifice Transluminal Endoscopic Surgery: October 2005. *Surg. Endosc.* 2006 Jan; 20(2):329–333. [PubMed: 16402290]
2. Pai RD, Fong DG, Bundga ME, Odze RD, Rattner DW, Thompson CC. Transcolonic endoscopic cholecystectomy: a NOTES survival study in a porcine model (with video). *Gastrointest. Endosc.* 2006 Sep; 64(3):428–434. [PubMed: 16923495]
3. Rolanda C, Lima E, Pêgo JM, Henriques-Coelho T, Silva D, Moreira I, Macedo G, Carvalho JL, Correia-Pinto J. Third-generation cholecystectomy by natural orifices: transgastric and transvesical combined approach (with video). *Gastrointest. Endosc.* 2007 Jan; 65(1):111–117. [PubMed: 17185089]
4. Wagh MS, Thompson CC. Surgery Insight: natural orifice transluminal endoscopic surgery—[an analysis of work to date]. *Nat Clin Pr. Gastroenterol Hepatol.* 2007 Jul; 4(7):386–392.
5. Zorron R, Palanivelu C, Galvão Neto MP, Ramos A, Salinas G, Burghardt J, DeCarli L, Henrique Sousa L, Forgione A, Pugliese R, Branco AJ, Balashanmugan TS, Boza C, Corcione F, D'Ávila Avila F, Arturo Gómez N, Galvão Ribeiro PA, Martins S, Filgueiras M, Gellert K, Wood Branco A, Kondo W, Inacio Sanseverino J, de Sousa JAG, Saavedra L, Ramírez E, Campos J, Sivakumar K, Rajan Pidigu Seshiyer, Jategaonkar Priyadarshan Anand, Ranagrajan M, Parthasarathi R, Senthilnathan P, Prasad M, Cuccurullo D, Müller V. International Multicenter Trial on Clinical Natural Orifice Surgery—NOTES IMTN Study: Preliminary Results of 362 Patients. *Surg. Innov.* 2010 Jun; 17(2):142–158. [PubMed: 20504792]
6. Sotelo R, de Andrade R, Fernández G, Ramirez D, Di Grazia E, Carmona O, Moreira O, Berger A, Aron M, Desai MM, Gill IS. NOTES Hybrid Transvaginal Radical Nephrectomy for Tumor: Stepwise Progression Toward a First Successful Clinical Case. *Eur. Urol.* 2010 Jan; 57(1):138–144. [PubMed: 19406563]
7. Palanivelu C, Rajan PS, Rangarajan M, Parthasarathi R, Senthilnathan P, Prasad M. Transvaginal endoscopic appendectomy in humans: a unique approach to NOTES—world's first report. *Surg. Endosc.* 2008 Mar; 22(5):1343–1347. [PubMed: 18347865]
8. Roberts K, Solomon D, Bell R, Duffy A. 'Triangle of safety': anatomic considerations in transvaginal natural orifice surgery. *Surg. Endosc.* 2013 May; 27(8):2963–2965. [PubMed: 23644833]
9. Santos BF, Hungness ES. Natural orifice transluminal endoscopic surgery: progress in humans since white paper. *World J. Gastroenterol. WJG.* 2011; 17(13):1655.
10. Arezzo A, Zornig C, Mofid H, Fuchs K-H, Breithaupt W, Noguera J, Kaehler G, Magdeburg R, Perretta S, Dallemagne B. The EURO-NOTES clinical registry for natural orifice transluminal endoscopic surgery: a 2-year activity report. *Surg. Endosc.* 2013; 27(9):3073–3084. [PubMed: 23519494]

11. Inoue H, Minami H, Kobayashi Y, Sato Y, Kaga M, Suzuki M, Satodate H, Odaka N, Itoh H, Kudo S. Peroral endoscopic myotomy (POEM) for esophageal achalasia. *Endoscopy*. 2010; 42(4): 265–271. [PubMed: 20354937]
12. Oyama T, Tomori A, Hotta K, Morita S, Kominato K, Tanaka M, Miyata Y. Endoscopic submucosal dissection of early esophageal cancer. *Clin. Gastroenterol. Hepatol*. 2005; 3(7):S67–S70. [PubMed: 16013002]
13. Gotoda T, Yamamoto H, Soetikno RM. Endoscopic submucosal dissection of early gastric cancer. *J. Gastroenterol*. 2006; 41(10):929–942. [PubMed: 17096062]
14. Sylla P, Rattner DW, Delgado S, Lacy AM. NOTES transanal rectal cancer resection using transanal endoscopic microsurgery and laparoscopic assistance. *Surg. Endosc*. 2010; 24(5):1205–1210. [PubMed: 20186432]
15. Ikeda K, Mosse CA, Park P-O, Fritscher-Ravens A, Bergström M, Mills T, Tajiri H, Swain CP. Endoscopic full-thickness resection: circumferential cutting method. *Gastrointest. Endosc*. 2006; 64(1):82–89. [PubMed: 16813808]
16. Bowman DE. ASGE/SAGES working group on natural orifice transluminal endoscopic surgery: white paper October 2005. *Gastrointest. Endosc*. 2006; 63(2):199–203. [PubMed: 16427920]
17. Trejos AL, Jayaraman S, Patel RV, Naish MD, Schlachta CM. Force sensing in natural orifice transluminal endoscopic surgery. *Surg. Endosc*. 2011; 25(1):186–192. [PubMed: 20559663]
18. Mosse MC, Mills T, Bell G, Swain C. Device for measuring the forces exerted on the shaft of an endoscope during colonoscopy. *Med. Biol. Eng. Comput*. 1998; 36(2):186–190. [PubMed: 9684458]
19. Picod G, Jambon AC, Vinatier D, Dubois P. What can the operator actually feel when performing a laparoscopy? *Surg. Endosc*. 2004 Oct; 19(1):95–100. [PubMed: 15772876]
20. Rosen J, Hannaford B, Richards CG, Sinanan MN. Markov modeling of minimally invasive surgery based on tool/tissue interaction and force/torque signatures for evaluating surgical skills. *Biomed. Eng. IEEE Trans. On*. 2001; 48(5):579–591.
21. Trejos AL, Patel RV, Malthaner RA, Schlachta CM. Development of force-based metrics for skills assessment in minimally invasive surgery. *Surg. Endosc*. 2014:1–14.
22. Hwang H, Lim J, Kinnaird C, Nagy A, Panton O, Hodgson A, Qayumi K. Correlating motor performance with surgical error in laparoscopic cholecystectomy. *Surg. Endosc. Interv. Tech*. 2006; 20(4):651–655.
23. Tan HZ, Srinivasan MA, Eberman B, Cheng B. Human factors for the design of force-reflecting haptic interfaces. *Dyn. Syst. Control*. 1994; 55(1):353–359.
24. Samur E, Flaction L, Bleuler H. Design and Evaluation of a Novel Haptic Interface for Endoscopic Simulation. *IEEE Trans. Haptics*. 2012; 5(4):301–311.
25. Yi S, Woo H, Ahn W, Kwon J, Lee D. New colonoscopy simulator with improved haptic fidelity. *Adv. Robot*. 2006; 20(3):349–365.
26. Ikuta K, Iritani K, Fukuyama J, Takeichi M. Portable virtual endoscope system with force and visual display. *Intell. Robots Syst. 2000 IROS 2000 Proc. 2000 IEEE/RSJ Int. Conf. On*, vol. 1. 2000; 1:720–726.
27. [Accessed: 27-Jun-2014] CAE Healthcare. [Online]. Available: <http://www.caehealthcare.com/>.
28. [Accessed: 27-Jun-2014] Simbionix | To Advance Clinical Performance. [Online]. Available: <http://simbionix.com/>.
29. Ferlitsch A, Glauninger P, Guppper A, Schillinger M, Haefner M, Gangl A, Schoefl R. Evaluation of a virtual endoscopy simulator for training in gastrointestinal endoscopy. *Endoscopy*. 2002; 34(9):698–702. [PubMed: 12195326]
30. Gromski M, Alkhoury F, Lee S, Matthes K. Evaluation of NOTES hands-on courses by surgeons at the SAGES Annual Meeting Learning Center. presented at the 12th World Congress of Endoscopic Surgery (WCES), National Harbor, MD. *Surg Endosc*. 2010; 24:229.
31. Tsuda S, Matthes K, Derevianko A. Validation of a high-fidelity NOTES simulator for team training. *Surg Endosc*. 2010; 24:227.
32. Wall SA, Harwin W. A high bandwidth interface for haptic human computer interaction. *Mechatronics*. 2001 Jun; 11(4):371–387.

33. Kunesch E, Binkofski F, Freund H-J. Invariant temporal characteristics of manipulative hand movements. *Exp. Brain Res.* 1989; 78(3):539–546. [PubMed: 2612597]

Fig. 1.

- (a) The EASIE-R™ simulator with ex-planted pig organs and access ports
- (b) The EASIE-R™ simulator with the molded belly

Fig. 2.

A demonstrator holding the flexible endoscope. One hand holds the endoscope handle while the other holds the shaft of the endoscope.

Fig. 3.
(a) CAD model of device attached to endoscope
(b) Front view of force/torque recording device.

Fig. 4.

A schematic identifying the coordinate system of the 6-axis load cell with respect to the location of the user's hand while manipulating the endoscope

Fig. 5.
Histograms of the forces applied by all users (experts and novices) during all of the nine tasks which comprise of the NOTES appendectomy procedure.

Fig. 6.

Histograms of the torques applied by all users (experts and novices) during all of the nine tasks which comprise of the transgastric appendectomy procedure.

Fig. 7.

A time series plot comparing the force signatures of an expert and novice for task #4 which includes the placement of the deflated radial expansion balloon and eventual inflation to increase the size of incision in the gastric wall.

Fig. 8.

A time series plot comparing the torque signatures of an expert and novice for task #4 which includes the placement of the deflated radial expansion balloon and eventual inflation to increase the size of incision in the gastric wall.

Fig. 9.

Plots (a) through (r) compare the peak and RMS force/torque parameters between experts and novices for each of the nine tasks of the NOTES appendectomy procedure. (a,b) Task #1: insertion of endoscope through the esophagus (c,d) Task #2: entry into stomach and insufflation (e,f) Task #3: create gastric wall incision using electrosurgical tip (g,h) Task #4: placement and inflation of controlled radial expansion balloon (i,j) Task #5: push inflated controlled radial expansion balloon through the gastric incision (k,l) Task #6: exposure and assessment of the appendix (m,n) Task #7: dissection and division of appendix (o,p) Task #8: dissection and division of appendix (q,r) Task #9: dissection and division of appendix

#8: Removal of appendix from location of dissection to outside gastric port (q,r) Task #9:
Gastric closure of incision using closure clips.

Table 1

The tasks for a transgastric notes appendectomy procedure

1. Insertion
2. Enter stomach & insufflate Gastrotomy
3. Advance and articulate electrosurgery tip
4. Advance and inflate radial expansion balloon
5. Pass through gastric wall
6. Exposure and assessment of appendix
7. Dissection and division of appendix
8. Removal of appendix
9. Closure

Table 2

The task analysis approach to the data segmentation

Task/Sub-task	Start time	End time
1. Insertion	Scope is inserted into esophagus	Scope reaches end of esophagus
2. Enter stomach & insufflate	Scope enters stomach	Scope reaches location of gastrotomy
Gastrotomy		
3. Advance and articulate electrosurgery tip	Electrosurgery tool appears on screen	Electrosurgery tool is take out of the screen
4. Advance and inflate radial expansion balloon	Expansion balloon appears on screen	Expansion balloon inflation is completed
5. Pass through gastric wall	Balloon is pushed through incision	Scope enters peritoneal cavity
6. Exposure and assessment of appendix	Grasper appears in the screen	Endoloop is threaded on appendix
7. Dissection and division of appendix	Electrosurgery loop appears in the view	Cut is complete
8. Removal of appendix	Cut is complete	Appendix is outside the esophagus
9. Closure	First grapser appears in the view	Last clip has been applied

Table 3

Parameters calculated for each task segment

1.	Maximum CW torque about the (x,y,z) axes
2.	Maximum CCW torque about the (x,y,z) axes
3.	RMS torque about the (x,y,z) axes
4.	Maximum force along the (x,y,z) direction
5.	Maximum force along the (-x, -y, -z) direction
6.	RMS force along the 3 directions

Table 4

Results of Mann Whitney U test

Task name	Parameter	p-value
Scope insertion (#1)	Max Force +Z	0.02
	Max Force -X	0.03
Enter stomach & insufflate (#2)	Max Force +X	0.03
Exposure of appendix (#6)	Max Force +Z	0.01
	RMS Force Z	0.01
	CW Torque Z	0.01
	CCW Torque X	0.01
Dissection & division of appendix (#7)	Max Force +X	0.01
Gastric closure (#9)	RMS Force X	0.03
	RMS Force Y	0.01