Implementation of a novel thoracostomy tube trainer with real-time feedback

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ABSTRACT

Objectives Simulation-based training leads to improved clinical performance but may be influenced by quality and frequency of training. Within simulation training, chest tube insertion remains a challenge as one of the main pitfalls of insertion is a controlled pleural entry. This study evaluates the efficacy of a novel training model with real-time pressure monitoring, the average force to pleural entry in a model and the utility of audio and visual feedback.

Methods This proprietary training model comprised a modified Kelly clamp device with three force sensors at the index finger (sensor 1) and two finger loops (sensors 2 and 3), and a manikin with a replaceable chest wall pad. Standard force values (Newtons (N)) were obtained by experts; expert data revealed that 3–5 s was an acceptable time range to complete the chest tube insertion. Participant level ranged from Post-graduate Year (PGY)-1 to PGY-6 with 13 total participants. Each individual was provided an introduction to the procedure and chest tube trainer. Force (N) and time (ms) measurements were obtained from entry through dermis to pleural space puncture. A significant pressure drop suggested puncturing through the chest wall (completion of the procedure).

Results Force data were captured during each phase of the procedure—linear, plateau, and drop. Linear phase (~3000 ms) was from start of procedure to point of maximum force (<30 N). Plateau phase was from maximum force to just before a drop in pressure. Drop phase was a drop in pressure by 5+ N in a span of 150 ms signaling completion of procedure. All participants were able to complete the task successfully. Force for pleural entry ranged from 17 N to 30 N; time to pleural entry ranged from 7500 to 15 000 ms. There was variability in use of all three sensors. All participants used the index sensor, however there was variability in the use of the loop sensors depending on the handedness of the participant. Left-handed users relied more on sensors 1 and 3 while right-handed users relied more on sensors 1 and 2. Given this variability, only force measurements from sensor 1 were used for assessment.

Conclusions This novel force-sensing chest tube trainer with continuous pressure monitoring has a wide range of applications in simulation-based training of emergency surgical tasks. Next steps include evaluating its impact on accuracy and efficiency. Applications of real-time feedback measuring force are broad, including vascular access, trocar placement and other common procedures.

Level of evidence Level IV, prospective study.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Chest tube insertion requires repetition and skill to execute controlled pleural entry and avoid complications.
⇒ This study evaluates a novel training model with real-time audio-visual pressure monitoring to enhance trauma simulation in trainees.

WHAT THIS STUDY ADDS

⇒ This novel real-time haptic chest tube trainer can produce consistent, real-time pressure readings, is easy to use, and economical.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Training has become more mobile but variable in quality on real-time feedback.
⇒ Here we present an innovative, portable and economical haptic trainer with baseline technology that could be applied to other procedures such as vascular access, laparoscopy or robotic surgery.

INTRODUCTION

Chest tube insertion or tube thoracostomy may be indicated for traumatic pneumothorax or hemothorax, however mastery of this potentially life-saving procedure requires repetition and real-time supervision. Common pitfalls encountered with a thoracostomy include injury to the intercostal neurovascular bundle, and uncontrolled pleural entry leading to inadvertent injury or malpositioning with an overall complication rate of up to 40%.[1–3] Mastering this invasive procedure can be a challenge because of infrequent hands-on practical training in addition to utilization of minimally invasive techniques such as pigtail insertion. The purpose of this study was to design a functional, feasible, and affordable model for force-sensing and real-time force feedback during thoracostomy.

The measurement of applied forces and application of force feedback to surgical simulation is an expanding interest within surgical education. Several force-based metrics have been used to evaluate surgical performance, such as instantaneous force, maximum force, minimum force, rate of change in force, and total force used over time. Laparoscopic simulation studies have demonstrated correlation between various force parameters and participant experience for tasks such as tissue handling, suturing, and knot-tying,[4] with at least...
one study employing a similar model with the sensor embedded in the instrument. In general, inexperienced providers use higher mean forces, peak forces, and force volumes for complex tasks, which can be particularly problematic in the goal of controlled pleural entry.

Concerns for patient safety under the traditional ‘see one, do one, teach one’ model and the implementation of resident work hour restrictions have ushered in a golden age of surgical simulation. Despite growing opportunities for residents to practice their skills in a consequence-free setting, achieving a gradual transition in autonomy between teacher and learner remains difficult to achieve for ‘high-stakes low-frequency’ procedures requiring a single provider. In performing thoracostomy, there is limited opportunity for real-time feedback since the teacher cannot feel what the learner feels. By comparing user data to preset acceptable ranges, a force-sensing chest tube trainer could deliver instantaneous audio-visual feedback to prevent adverse events before they could occur. In our final testing, we confirmed appropriate audio-visual feedback for low, medium, or excessive forces, hitting bone, and slow time to pleural entry. To the best of our knowledge, no prior study has captured the mechanics of pleural entry by recording forces in real-time. The device therefore has potential to 1) improve technique in the simulation setting, 2) improve patient safety in the clinical setting and given its versatility, 3) be applied to a variety of settings where monitoring pressure forces is important (trocar placement, tissue handling, etc).

MATERIALS AND METHODS

We collaborated with a biomedical engineering program and various design alternatives were considered before formulating the final design. The final design had to fulfill criteria such as portability, ease of use, low cost, and accuracy of data collection and analysis. The following specifications were set by the team:

1. Standard Kelly clamp as part of the chest tube insertion kit with modifications that still permit normal tool use.
2. Chest wall pads and manikin from the manikin kit without modifications.
3. Force feedback as well as auditory and visual feedback once the thoracic cavity has been entered.

Design

We created a three-dimensional (3D) printed case that clipped onto a Kelly clamp, the main instrument used to enter the chest cavity and place a thoracostomy tube. Sensors were placed in strategic areas based on where most healthcare providers exerted pressure.

A prototype was created with a 3D printed case that snapped onto the Kelly clamp with sensors placed at the index finger, thumb, and ring finger locations. During the initial pilot testing, there was significant variability and inconsistencies in the data collected with the thumb and ring finger loop sensors so only the index finger sensor was used in the final prototype (figure 1).

To perform the experiments, the materials needed are the Kelly clamp case, an index finger sensor, the wiring, and the display screen with pressure gauge for visual feedback in addition to a standard manikin and replaceable chest wall pad that included gaps for rigid plastic ‘bones’ to mimic a chest wall. The steps of chest-tube insertion for the purposes of this study were limited to entry with the Kelly clamp. On this particular manikin, the chest wall pad consists of a soft, silicone and dense foam pad with four channels to contain four plastic ‘ribs’. It is then secured within a torso manikin by a set of two screws on the interior portion of the manikin. The skin incision is made with a scalpel (not included in this study), then the user inserts their fingers on the Kelly clamp. Users were instructed to place the index finger on the body of the Kelly clamp, and the first and third fingers within the clamp loops. The Kelly clamp would then be inserted through the incision, above the rib and measurements recorded in real-time (figures 2 and 3). This approach differs from a real-life chest tube insertion in that the experiment is limited to just the pleural entry with the clamp and without the initial skin incision, finger thoracostomy and thoracostomy tube insertion.

The goal of this continuous monitoring system was to evaluate, via an Ohmite force sensing resistor on the index finger location, the force a trainee exerts to pierce through the manikin chest wall pad, simulating entry into the pleural cavity (figure 3). The force data would then be processed by the Arduino Uno microcontroller to then provide real-time audio-visual feedback to the user from the speaker and liquid-crystal display (LCD) screen.

Baseline force data collection

The first set of experiments was conducted by a trained trauma surgeon to determine baseline force thresholds; this experiment was repeated at least 10 times, on the same chest wall pad in different areas. The chest wall pad also contained rigid plastic ‘bones’ to mimic ribs. Simulated pressures including pushing on ‘bone’ (very high pressure), pushing through subcutaneous tissue (linear) through subcutaneous fat and muscle (plateau) prior to entering the pleural space (‘pleural entry’ or ‘drop phase’ where the force would drop to 0). The linear phase threshold for time...
Experiment

There were two phases to this experiment as the prototype was built. The first phase included 13 trainees from PGY-1 through PGY-6 to obtain force data over time. PGY-1 classes had little to no experience with tube thoracostomy placement. PGY-2s and above had varying experience with chest tube placement but this amount was not recorded. Junior trainees were instructed how to hold the Kelly clamp and pleural entry without the auditory and visual feedback options. One attempt was made by each trainee unless the initial Kelly clamp handling or technique required repetition and correction. Force (N) and time (ms) were recorded for each attempt (refer to online supplemental video).

The second phase incorporated visual and auditory feedback. This second phase was tested by the engineering students only given the timeline and development of the project.

The start of procedure was from subcutaneous entry and ended at the time of pleural space puncture. Audio-visual feedback was incorporated into the experiment using a pressure gauge and a sound system. The auditory feedback was a series of beeps if the user was exerting too little force to puncture the chest wall or an alarming set of beeps if the user was exerting too much force. If in the appropriate force range, no auditory cues were provided. Visual feedback was provided on the LCD screen display depicting a pressure gauge in yellow if the user was not exerting enough force, green if the user was using an appropriate amount of force, or red if the user was exerting excessive force. The device was validated to ensure appropriate auditory and visual feedback by testing the final prototype under different conditions such as low, medium, or high force, slow timing, and hitting bone. For example, if the subject was hitting bone, the sound system would release fast alarming beeps and the screen would display a large ‘X’ indicating to the user to abort and relieve pressure. To account for the time-sensitive component of this procedure, if a participant was inserting the clamp too slowly (ie, more than a certain amount of time spent exerting an amount of force below threshold), the system would release a series of fast beeps to signal to the subject to speed up the procedure. Finally, an ending beep signaled to the participants the completion of the procedure, determined by a significant pressure drop simulating clamp entry into the pleural cavity.

RESULTS

The force data force (N) versus time (ms) is represented in figure 4. All participants completed the procedure with successful puncture of the chest pad. All readings had three phases: linear, plateau, and drop. Linear phase occurred from the start of the procedure with subcutaneous puncture to the time at which the maximum force value was reached. The average elapsed time for this phase was 3±0.45 s.

The experiment was conducted with the aforementioned thresholds. All participants successfully completed the procedure. The average applied force during the experiment was 17–30 N with time to completion of procedure ranging from 7.5 to 15 s. While the prototype originally had three force sensors (one index and two finger loop sensors), the force data from loop sensors were variable due to differing hand shapes and sizes. Interestingly, right-handed users reliably used index sensor 1 and finger loop sensor 2 while left-handed users used index sensor 1 and finger loop sensor 3. Only the index range for force in Newtons thereby alerting the user when a force was exerted outside the appropriate range.
finger force sensor provided consistent force data among the participants and was therefore used as the only point for data collection.

Feedback phase
The two finger loop sensors were removed for the final testing phase of the device. This phase was performed to test audio-visual feedback under different conditions, with these being low, medium, or high forces, hitting bone, or slow time. If a user was below 10 N after 3 s, auditory feedback through a series of beeps would alert the user to speed up the procedure. The plateau phase occurred from time point of maximum force to just prior to large drop in force. The average applied force was 20 N±1.34 N. If a user was applying a force 10 N greater in magnitude than the set threshold or maximum average of 20 N (ie, 30 N), then the user was assumed to be hitting bone and alerted with audio-visual feedback to stop the procedure and attempt again. The final phase was the drop phase which occurred when there was a drop in force of >5 N within a timespan of 150 ms. This drop in force was set as the threshold so that if there was >5 N drop in force within 0.6 s, audio-visual feedback on completion of the procedure was provided to the user.

Audio-visual feedback quality was evaluated, on a scale from poor to satisfactory to good. The results of the auditory and visual output for each condition were tested at least 5 times and evaluated by several team members with an overall consensus of good quality.

Despite altering the case with removal of loop sensors, the case still appropriately fit on the Kelly clamp and was reusable for different clamps.

Ease of use
Participants in the first experimental phase (trainees PGY-1–PGY-6) remarked that the device did not hinder procedure or functionality with all participants stating the tool felt ‘natural’ and ‘familiar’ given the flexible case except some participants did note some restriction and limited movement around the finger loops.

Cost
Our total cost of non-reusable device parts (3D printed Kelly clamp case, force sensor, hemostat) was <US$200. Our device was tested on a commercial trainer manikin and could be used with inexpensive high-fidelity simulation models with a cost per use as low as US$15. The overall cost of materials was <US$750.

DISCUSSION
In this pilot study, we successfully created a novel force-sensing chest tube trainer device with continuous force monitoring. The intent of this device is to enhance training of emergency surgical tasks and potentially apply this tool in a real-time setting. Advantages of this device include its portability, accuracy, ease of use, and low cost. This 3D printed case fit snugly onto a surgical instrument without hindering functionality or adding bulk. Moreover, an additional advantage to this product is that it uses a battery and can last up to 3 hours and can be charged using a simple USB cable without the need for disposable batteries.

While force sensing enables discrimination between trainees and experts, force feedback can positively impact the novice learning curve trajectory. Options for real-time force feedback include (1) continuous feedback, in which there is a constant
feedback signal, (2) bandwidth feedback, in which there is a feedback signal only above a certain force threshold and (3) fade-in feedback, in which the feedback signal is proportional to force. In our study, we used a combination of all three modalities to optimize real-time feedback. Forces were continuously displayed visually on the monitor, and numerical values were accompanied by a meter that moved proportionally to force applied. Similar visual feedback signals are described in the literature and in one case, led to a reduction of applied force and improved tissue handling skills. Additionally, we included bandwidth audio feedback for forces exceeding the threshold for being inappropriately low/high/in contact with bone. Although all three feedback modalities have improved technique in laparoscopic simulation studies, bandwidth feedback appears most efficacious, likely by encouraging familiarity with acceptable limits for force. Our bandwidth feedback was translated to real-time audio to ensure the user could receive timely feedback without having to look away from the task.

Simulation-based training has demonstrated the ability to improve trainee performance and reduce complications. Simulation-based training, however, can be expensive with variability in frequency and quality of training. Current modalities in trauma simulation range from using high-fidelity manikins, virtual reality concepts such as serious gaming or hands-on practice with tissue models or cadaveric models. While manikins do provide a means for residents to physically work through and learn the steps involved in a procedure such as chest tube placement, they generally do not provide much real-time technical data on the user’s technique such as if the user is exerting too much force. On the other hand, gameplay allows for users to practice a procedure and receive step-by-step feedback, but this method lacks the physical training aspect found in manikins. Lastly, tissue models and cadavers offer a robust training experience with a physical aspect, but these can be expensive and limited in quantity for procedures that require repetition, and do not provide real-time data on the user’s technique. Future studies should include evaluating differences in handedness and using more sensitive finger loop sensors for assessment of force differences based on handedness. Additionally, this tool has applications in surgical education and could be used in the assessment of skill proficiency by comparative analysis of time and force differences from novice to expert level. For example, defining thresholds for PGY-1–PGY-2 residents to PGY-3–PGY-5 senior residents to fellows/attendings could then serve as formative feedback in surgical training.

A distinct advantage of force sensing was the ability to designate distinct stages to the thoracotomy process. After recording expert activity, we retroactively identified a linear, plateau, and drop stage by correlating objective force data with patient anatomy. In a broader context, this breakdown of one process into three concrete steps aligns with the paradigms in simulation-based education to subdivide procedural skills and permit learners to independently master the key steps essential to the intervention success. In this study, defining limits for force parameters during each stage allowed us to develop feedback signals to specifically prevent the complications associated with each stage. Notably, the device was programmed to alert the user to speed up during the linear stage, avoid contact with bone during the plateau stage, and terminate entry once pleural entry was achieved in the drop stage.

In the simulation setting, force sensors may either be embedded in the instrument or in the environment of the instrument. In this study, we chose to modify the Kelly clamp rather than the chest wall pad to minimize cost and avoid sensor damage and inaccurate force readings across multiple trials. The force-measuring device on the Kelly clamp tool measures force exerted by the index finger during the insertion procedure. Because the index finger was the main driver of force regardless of handedness, the force-measuring device was able to accommodate both left-hand and right-hand dominant users. In addition, the force-measuring device did not seem to interfere with the usability of the Kelly clamp tool with users reporting no or little restriction with the modified tool. This force-measuring device is modular in that it breaks down the data-driven technical aspects of chest tube placement into discrete modules including avoidance of anatomical structures such as bone and exertion of the appropriate amount of force. Finally, the Arduino used in this study refreshes every 93 ms, comparable to the 10 Hz update rate established as ‘real-time’ feedback in the virtual reality surgical simulation setting.

Design alternatives

We considered several options and weighed the benefits of accuracy, ergonomics, and cost. Initially, the sensor at the tip of the Kelly clamp was considered due to its advantage to directly collect data; however, placing a sensor in a small surface area such as the tip of the clamp would be difficult and prone to damage or dislocation during the procedure.

Next, a sheet of sensors within the replaceable chest wall pad was considered because no modification of the clamp would be necessary, however it was rejected due to high cost of replacement of chest wall pads and potential sensor damage during the clamp insertion.

Finally, gloves embedded with force sensors were considered due to their versatility, low cost, and ease of use; however, because of issues with glove size, left-right handedness, and potential hindrance with dexterity, this idea was abandoned.

There are several limitations to this study, including limited sample size. This study used descriptive data rather than a quantitative validated assessment of device feasibility and intuitiveness of audio-visual feedback. For future studies, we could consider using a validated scale such as the NASA Task Load Index which assesses mental demand, physical demand, temporal demand, performance, effort, and frustration. An additional limitation is the use of a single sensor for obtaining force-related feedback which may not provide a comprehensive understanding of the kinetic interactions between tool and user. Although next steps will include establishing evidence-based acceptable ranges for forces that are translatable from the manikin to real patients, we have nonetheless created a force-sensing model with real-time feedback capability that is feasible and affordable. Finally, the focus of this experiment was only pleural entry; however, chest tube insertion comprises many other subtasks such as avoidance of neurovascular bundle, abdominal or retroperitoneal entry, or incomplete finger sweeps, all of which can serve as potential pitfalls that would require further training in order to enhance surgical performance. This tool did not explore the possible changes in resistance or pressure when inserted into the abdomen or retroperitoneum. This study also did not externally validate these forces, which we believe would be the next best step in cadaveric or animal models.

Next steps involve assessing interuser reliability in forces across multiple expert surgeons, establishing evidence-based ranges for acceptable force, and determining whether implementation of force-sensing reduces the incidence of complications in the clinical setting. Additional data points of future interest include determining if the feedback system leads to a reduction
in force usage by a learner and assessing the time from an erroneous movement to an attempt to correct it by the learner. Moreover, our model could be improved by capturing positional data, and there is potential to use force feedback in conjunction with augmented reality to visualize the tip of the hemostat in reference to individual patient anatomy. Future directions could also include application of this tool in other emergency/surgical tasks such as needle decompensation, vascular access, and trocar placement. Real-time force-sensing may also have potential in the military setting, where it can facilitate safe thoracotomy or other bedside procedures by less experienced providers in remote or low-resource settings.

CONCLUSIONS
In this study, we successfully designed a training model for controlled pleural entry during thoracotomy that employed continuous, real-time force-sensing and force feedback. The model is affordable, does not interfere with the training exercise, and can provide immediate audio-visual feedback in response to abnormal force sensing. There is a wide application for this technology to simulation-based training of emergency surgical tasks and patient care. Next steps will involve using this model to establish inter-user reliability and discriminate between expert and novice force patterns.

Contributors CP as senior author accepts full responsibility for the work and/or the conduct of the study, has access to the data, and controlled the decision to publish. All authors have provided critical elements to this study, including design, data analysis, testing, writing and critical revisions.

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Data availability statement Data are available on reasonable request.

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REFERENCES