

ORIGINAL ARTICLE

Laparoscopic training instruments designed to provide real-time feedback for surgical trainees

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Abstract

Background: We describe the development and preliminary prototype testing of ‘smart’ real-time feedback systems for four laparoscopic instruments. These provided trainees learning percutaneous needle insertion, trocar insertion, use of laparoscopic forceps, and laparoscopic suturing with increased force, haptic, and visual feedback. Each prototype was assessed to determine whether it had met the design goals of providing real-time feedback, maintaining true-to-life handling of the instruments, and offering educational benefit. **Methods:** The Smart-Needle utilized a laser-diode and 3D-printed housing to transilluminate tissue, allowing for intraperitoneal visualization of an insertion site. The Smart-Trocar utilized a microcontroller to process and report applied forces, angle of advancement, and tissue impedance measured by load-cells. The Smart-Forceps utilized a microcontroller to process and report the grip force, tensile force, and transverse load applied to a laparoscopic grasper. The Suture-Assist device utilized a retractable silicone tip to provide greater haptic and visual feedback during intracorporeal suturing. Pilot studies were conducted to assess each device’s functionality, technical benefit, and training enhancement. **Results:** All prototype feedback systems met the design goals of providing objective and accurate real-time feedback and maintenance of true-to-life handling of the base instrument. Preliminary evaluations of each prototype by expert educators and surgical trainees found that the feedback systems offered increased educational benefit during simulation practice. **Conclusion:** We designed and developed novel surgical training tools to provide enhanced real-time feedback for surgical trainees. All four prototypes met our development goals of fidelity maintenance and continuous feedback.

Keywords: *surgical simulation; surgical education; skills training; laparoscopic surgery; feedback*

Introduction

Surgical educators are tasked with teaching laparoscopic surgical skills, a challenging responsibility in the setting of rapidly advancing medical knowledge and technology.^{1–4} In the era of the prolonged COVID-19 pandemic, maximizing the benefit of simulation training is of increased importance to bridge the gap between didactics and clinical practice. Clinical rotations provide limited opportunities for hands-on training in fundamental laparoscopic procedures; yet, those interested in pursuing surgical careers need to establish foundational experience and basic skills in laparoscopy.^{1,2,5} Educators aim to impart the fundamental principles of laparoscopic surgery so that students can appreciate the fulcrum effect, adjust to altered haptic

feedback, and maintain depth perception while using a two-dimensional monitor.

Laparoscopic simulation training has been demonstrated to improve procedural outcomes, decrease operative times, reduce the incidence of intraoperative complications, decrease the length of hospital stays, and improve trainees’ performance.^{1–3,6–9} Our goal is to develop and conduct prototype testing of a set of ‘smart’ laparoscopic training tools that provide real-time feedback to learners, expanding on the work proposed by Schrope et al.¹⁰ These four instruments, the Smart-Needle, Smart-Trocar, Smart-Forceps, and Suture-Assist device, have the potential to enhance the learning and muscle memory of trainees. The secondary aim was to design these instruments to achieve this goal

while also minimizing any detrimental impact on the fidelity of the simulation itself.

Percutaneous needle insertion is a challenge for some early learners who may tend to insert needles perpendicular or parallel to the surfaces of the room, rather than maintaining an angle appropriate for the spherical surface of the patient.^{1,2,11-14} This presents a space to teach the importance of precision for trainees. Our laser-guided Smart-Needle aims to enhance percutaneous puncture training via transillumination of the insertion site, visible from within the peritoneal cavity. Trocar insertion is also often a difficult learning hurdle for many early surgical learners who struggle to maintain a safe angle of insertion and provide a constant force along the axis of the trocar.^{5,15,16} In addition, changes in the forces applied during trocar insertion by students are difficult to detect and correct for surgical educators. The Smart-Trocar aims to measure the force applied to a trocar, deviation from the safest insertion angle, and continuous depth of the trocar within the tissue. Intraperitoneally, forces applied during laparoscopic tissue handling by surgical trainees are difficult to perceive and correct by both educators and trainees themselves. The Smart-Forceps was designed to report the tensile and grip force applied by the instrument to the tissue during tissue handling. Finally, laparoscopic suturing remains a particularly complex training task for early learners who often struggle to properly load the needle on a needle driver.¹⁻⁴ The Suture-Assist device aims to increase haptic feedback while palpating surgical anatomy to achieve optimal needle orientation within the laparoscopic needle driver.

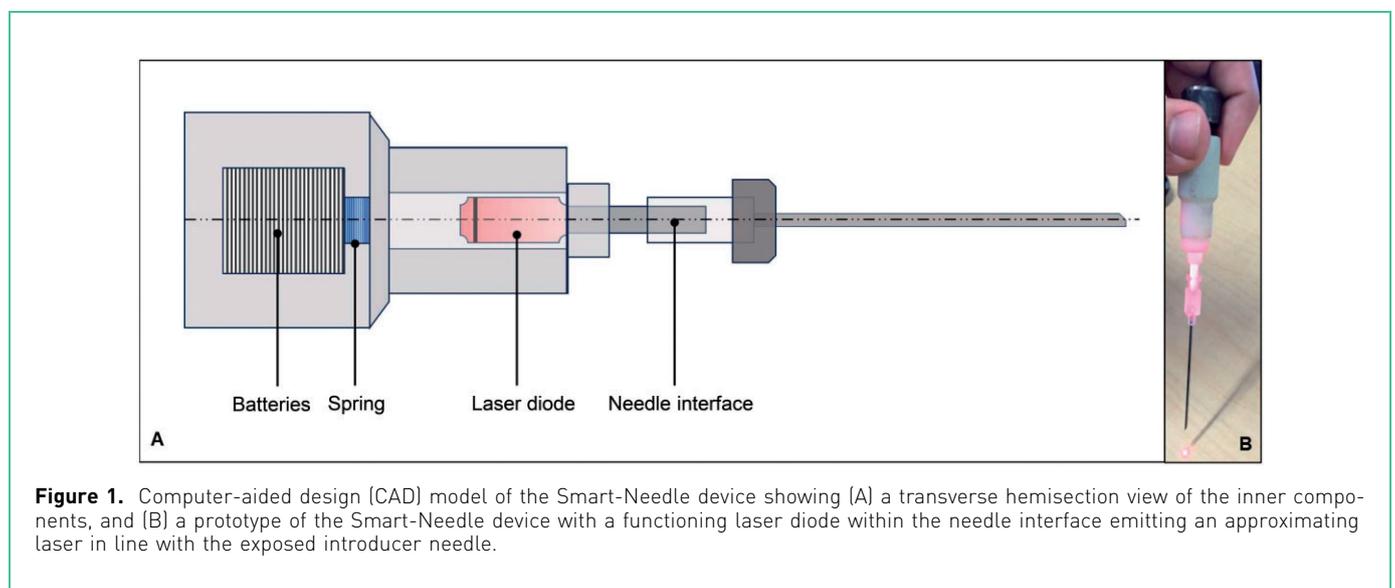
Methods

We describe the design and development of feedback systems for four laparoscopic training instruments. These were developed by students in a biomedical engineering course within the University of Minnesota under the guidance of clinical and engineering faculty experts.

Smart-Needle

We developed a 3D-printed laser attachment for percutaneous needle devices that provides transillumination of the needle insertion site, allowing for visualization of the potential puncture site from within the peritoneal cavity. Transillumination was achieved using a red-light laser diode. Red light of 635 nm wavelength was found to demonstrate the deepest tissue penetration in device development; it was visible through up to 15 mm of tissue. To ensure that the projected light from the diode remained in-line with the introducer needle, a 3D-printed housing was developed, using high-resolution photopolymer resin (VeraWhite 3D Stratasys). This polymer prevented any contraction and warping of the housing. Additionally, to prevent any damage to the surrounding plastic unit and the surrounding tissue, a diode with a maximum of 5 mW of power was used. The diode was powered by three button batteries, with the positive lead of the diode connected to the batteries by a conductive metal spring. The negative lead was secured to the 3D-printed housing by an additional 3D-printed threaded cap component which would close the circuit when tightened, activating the laser (Fig. 1).

An assessment of the prototype of the Smart-Needle was developed using cadaveric porcine models. For the



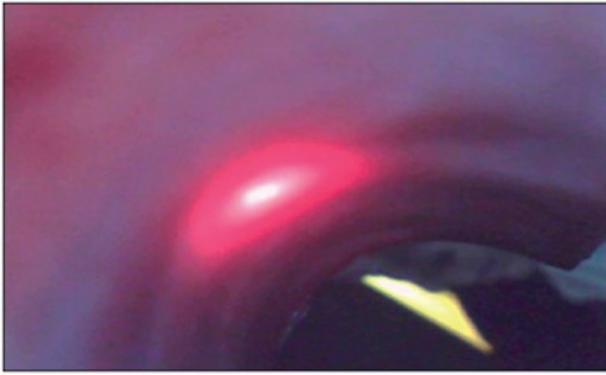


Figure 2. Endoscopic monitor view of tissue transillumination by the Smart-Needle device during needle advancement in a porcine model.

assessment, an endoscopic view of the spherical lumen of the porcine model was projected on a monitor (Fig. 2). Participants would direct the Smart-Needle to the target site using the available display of the laser's transillumination of the target site. The endoscopic view displayed on the monitor allowed for the measurement of the diameter of projected light through the tissue layers on the luminal surface. It also allowed for an approximate calculation of the real-time angle of needle insertion. Expert performance of needle-insertion using the Smart-Needle served as a baseline performance; a successful insertion of the needle into the target site was thus defined as an insertion angle that was perpendicular ($\pm 30^\circ$) to the lumen of the porcine model. To serve as a comparison group for this preliminary prototype assessment, participants were also tasked to perform a needle insertion using a percutaneous needle with a similarly attached commercial laser-pointer. This laser-pointer was incorporated into the same housing design as the Smart-Needle and thus also projected through the channel of the introducer needle. This prototype assessment served as an evaluation of proof-of-concept for the Smart-Needle and would be considered as the basis of future pilot assessments if successful.

Smart-Trocar

We developed a real-time feedback system that provided users with objective data on the forces they applied during trocar placement. These data included the force applied along the axis of the trocar, the angle of insertion, and the impedance of the tissue layers encountered during advancing the instrument. The structural design of this Smart-Trocar was developed to interface with a 10–12 mm industry-standard cannula and consisted of three main components: a 3D-printed handle, a hollow

polycarbonate shaft, and an electrode tip. The 3D-printed obturator handle served as a housing unit for a 3-axis ADXL345 accelerometer (to detect the angle of insertion) and a load-cell (to detect the force of insertion). The electrode tip consisted of two electrodes insulated by concentric rings of polyoxymethylene. Data from the accelerometer, load-cell, and electrode tip were directed to an Arduino Zero Microcontroller for processing and then projected to a Graphical User Interface (GUI) with a 7 inch touch-screen display. This GUI also had the capability to store previously recorded data by the recording tools, allowing for the collation of separate insertion attempts.

To ensure that the system could provide true feedback, an optimal angle of insertion was determined by expert performance and used to calibrate and tare the accelerometer. Positional processing consisted of the following measurements: movement of the obturator tip along the median plane (roll) and the frontal plane (pitch) and the difference between the optimal and real-time roll and pitch vector magnitudes. This permitted the GUI to display how a particular insertion attempt deviated from an optimal performance. The insertion force recorded by the load-cell was converted into electrical output which was also processed by the microcontroller. Thus, it was similarly tared to an optimal performance. Tissue impedance is an inverse measure of current flow through tissue and is unique to specific tissues. Current flows most easily through muscle, followed by fat and air, respectively. The two electrodes in the Smart-Trocar's obturator measured this flow as the tip advanced through tissue. One electrode excited the surrounding tissue with a 30 kHz AC current, and the difference in voltage between the two electrodes was measured. The data were received by an impedance converter and network analyzer (Analog Devices Inc. Wilmington, MA) and processed by the Arduino microcontroller (Fig. 3).

An assessment of the Smart-Trocar prototype was developed using a cadaveric porcine model. The porcine model was reinforced with a malleable plastic housing affixed to the internal lumen of the abdominal wall to maintain the wall's integrity throughout testing. Following preliminary functionality testing on the porcine model, a pilot study was designed to investigate the efficacy and potential viability of the Smart-Trocar as a training tool. For the pilot study, a synthetic abdominal wall simulator was developed. This simulator recreated a three-layer abdominal wall using low-cost materials including readily available latex, cardboard, and fabric. These simulated layers were adhered above the ports of a commercial laparoscopy trainer. The underlying port sites were marked on the overlying simulated skin. Within the covered laparoscopic trainer was a

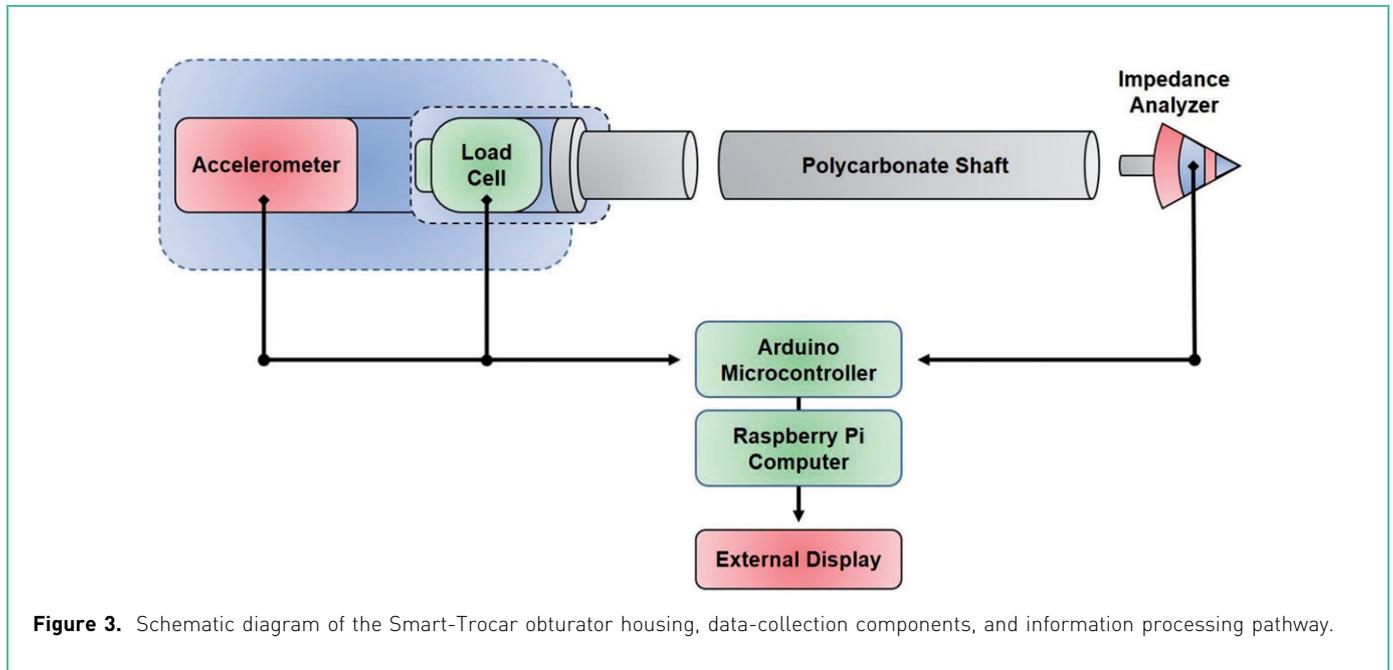


Figure 3. Schematic diagram of the Smart-Trocar obturator housing, data-collection components, and information processing pathway.

positioned bulls-eye target sheet, such that upon trocar insertion through the abdomen, the tip would mark the target sheet (Fig. 4). The diameter of the target was determined through expert performance of the task and yielded a diameter of 12 cm.

The assessment itself was based on a real-world training question; it remains unclear whether early surgical learners perform better with control of both the trocar and the laparoscope as opposed to controlling only the trocar and having the laparoscope controlled by an assistant. The Smart-Trocar provided a potential opportunity to collect refined objective measurements of technical performance during both techniques. Assessment participants would complete a trocar insertion task using two separate insertion techniques. In Technique 1, an assistant controlled the laparoscope and maintained visualization of the target on a monitor while the study participant would control the trocar during the insertion. In Technique 2, the study participant controlled both the laparoscope and the trocar concurrently. Following the assessment tasks, a survey was administered to participants to inquire about various aspects of the Smart-Trocar design, the assessment task, and the device's potential benefit as a training tool. As appropriate, survey item responses were reported on a Likert scale.

Smart-Forceps

We designed a real-time feedback system that provided users with real-time feedback on the forces applied when using laparoscopic forceps. The Smart-Forceps' feedback system provides users with objective real-time data on the

grip force applied by the instrument, the tensile force applied along the instrument's axis, and the transverse load applied perpendicularly to the shaft of the forceps. The feedback system was structurally designed to integrate with an industry-standard laparoscopic forceps while preserving the instrument's functionality. The design included housing components for two load-cells, one attached to the proximal aspect of the instrument's shaft and one in-line with the exterior aspect of the index-finger handle. The load-cells were contained in 3D-printed components and configured in parallel to detect forces up to 100 newtons (N). The measurements obtained by the load-cells were directed to and processed by an Arduino microcontroller. As with the Smart-Trocar, the load-cell measurements were converted to electrical output and then converted to newtons by the microcontroller. The microcontroller then directed the information to an LED display.

The LED display would illuminate a green, yellow, or red diode indicating an increasing intensity of applied force. The stratification of low, moderate, and high ranges of force was tared and calibrated based on small-intestine submucosa, known to tear at approximately 12 N of tensile force.² The low (green), moderate (orange), and high (red) diodes reflect 0–8 N, 8–11 N, and greater than 11 N, respectively. The grip force applied to the tissue by the forceps tip was related to the force applied by the user on the instrument handle. An analog pressure sensor was used to determine that each newton of force applied to the handle corresponded to 0.77 N applied to the tissue with a variance of 1.4%. A compression load-cell was connected to the

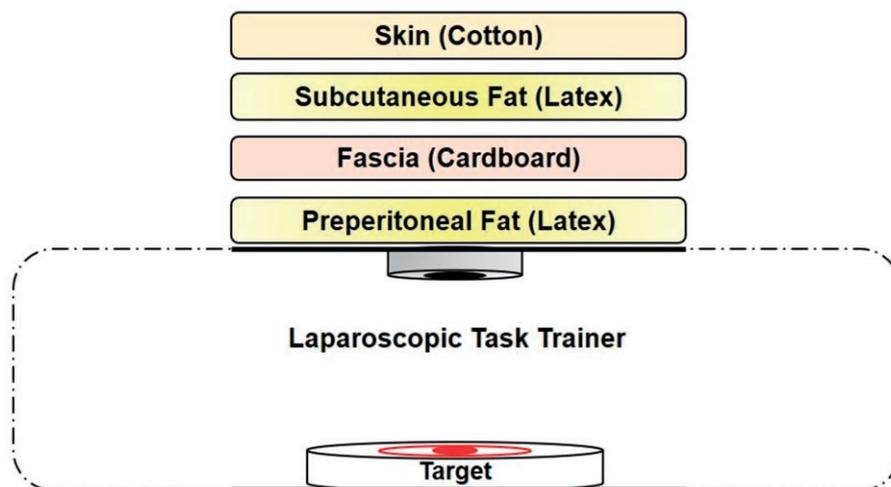


Figure 4. Schematic diagram of abdominal wall simulator with detailed component materials and set-up for Smart-Trocar assessment task using a laparoscopic task trainer.

spring mechanism of the forceps grip and similarly processed by the microcontroller. The stratification of low, moderate, and high ranges of force was based on small intestine submucosal trauma, known to occur at approximately 25 N of grip force.² The low (green), moderate (orange), and high (red) diodes reflect 0–18 N, 18–25 N, and greater than 25 N, respectively. All transverse forces applied to the tissue were detected using a strain gauge attached to the shaft, distally from the tensile force load-cell. The voltage output was processed by a data acquisition instrument. This output was similarly processed by the microcontroller and stratified on the LED display (Fig. 5).

A functionality assessment of the Smart-Forceps prototype was developed using a cadaveric porcine model. Participants in the study were tasked with conducting a series of tissue manipulation along segments of intestine and associated mesentery. These manipulations would apply various tensile and transverse load forces on the Smart-Forceps. Additionally, participants were asked to apply varying levels of grip force during the manipulations. Given the nature of this functionality assessment, evaluation was limited to proof-of-concept testing by participants familiar with abdominal surgery. Recorded metrics during participant completion of the task were recorded and compared to the theoretical values reported in the literature for porcine models.³

Suture-Assist

Surgical trainees frequently struggle with intracorporeal suturing due to the disorientation and impeded depth perception resulting from the lack of a third dimension when

using a 2D surgical monitor. This can lead to improper needle loading, needle drops, and suboptimal needle insertion into the tissue. We designed a retractable silicone tip attachment for laparoscopic needle graspers that aims to substitute for this missing dimension by providing enhanced visual and haptic feedback during laparoscopic suturing. This Suture-Assist attachment was constructed from transparent silicone rubber to allow for safe palpation of the surgical field. The silicone tip was attached to the long-hollow sheath of the laparoscopic grasper (Fig. 6). When in contact with tissue, the tip relays haptic feedback to the user regarding the topography of the tissue surface. To ensure that the opacity of the tip does not impede visualization during surgical maneuvering, a parallel green line is embedded in the silicone, in-line with the instrument axis. The silicone tip itself narrows distally, and the proximal aspect forms a complete cylinder that surrounds the grasper sheath. This cylindrical component is attached to 3D-printed polylactic-acid-based components of a sliding mechanism. The mechanism itself consists of a track, manual slider piece, and I-piece (Fig. 6). The track is fixed to the plane of the grasper proximally, preventing the sheath and tip from rotating. The sliding mechanism is connected to both the sheath and the I-piece element.

A functionality assessment of the Suture-Assist device was developed around an established simulation-based task using a Fundamentals of Laparoscopic Surgery (FLS) trainer. This functionality assessment served as proof-of-concept testing. For this assessment, participants were tasked with completing a series of exercises that evaluated the mechanical integrity of the attachment's design during

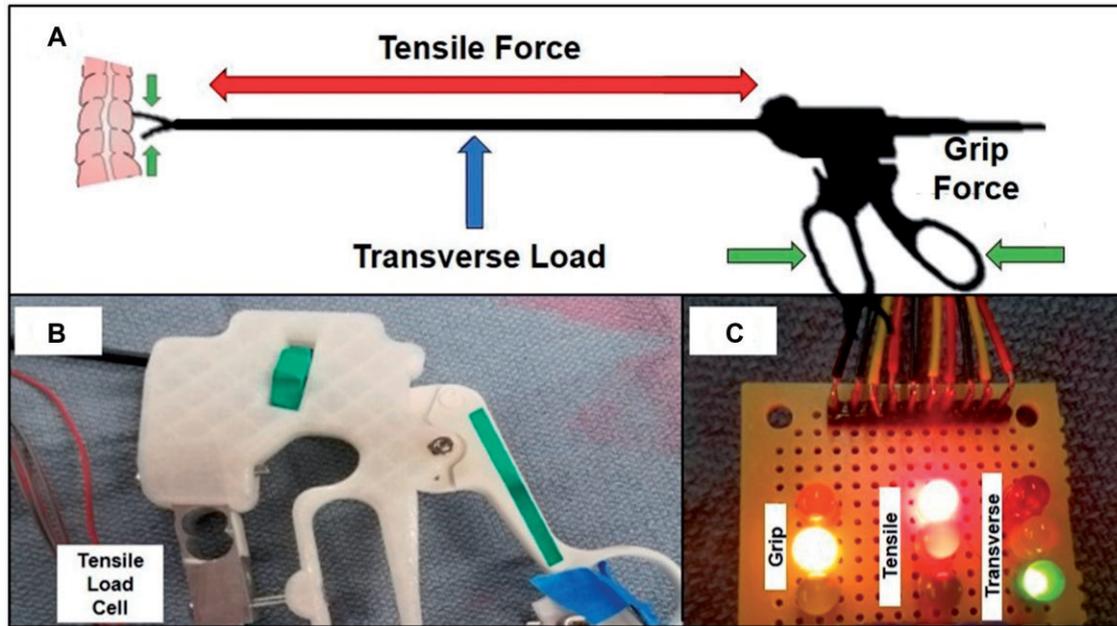


Figure 5. (A) Diagram of the forces measured by the Smart-Forceps, including tensile force applied to tissue along the instrument axis, grip force applied to the handle and the tissue, and transverse load force perpendicular to the instrument axis. (B) Image of the Smart-Forceps 3D-printed body housing with visible tensile load cell component and preserved first-digit holding. (C) Image of the LED display providing real-time visual feedback of applied forces: moderate grip force (orange diode), high tensile force (red), and low transverse load force (green).

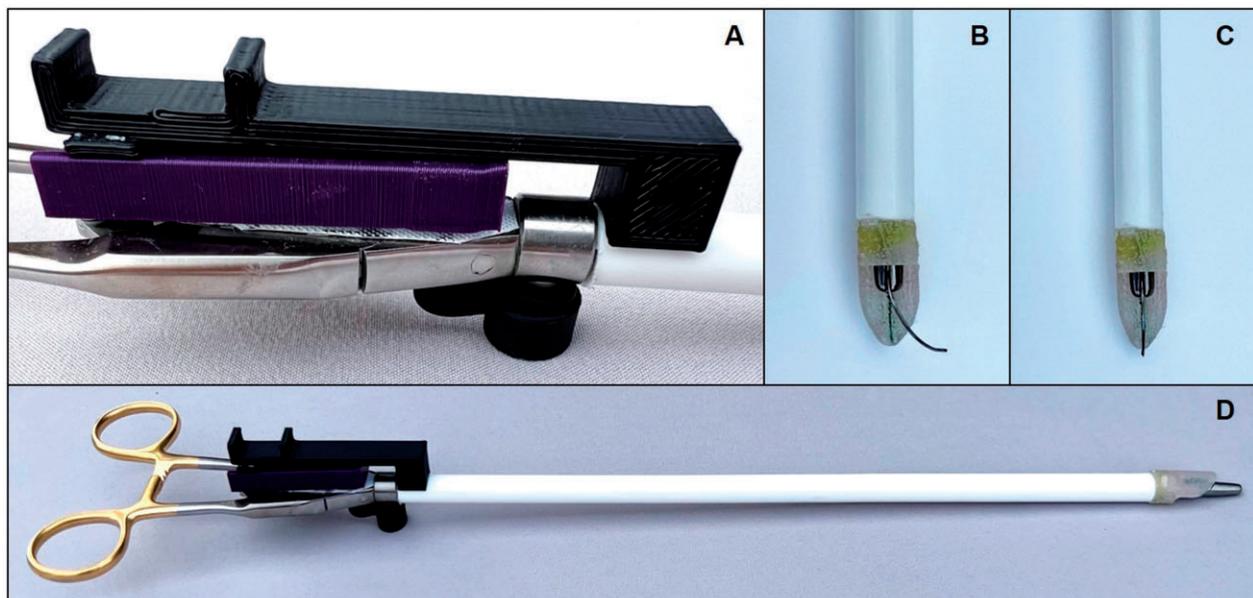


Figure 6. (A) Detailed view of the sliding mechanism of the Suture-Assist device with the connection of the slider to the I-piece and track visible. Close-up view of suture-needle loaded improperly (B) and properly (C)—with the assistance of the green guideline. (D) The Suture-Assist prototype with full-view of the sliding mechanism, sheath, and silicone tip distally.

routine laparoscopic maneuvering. These exercises included evaluating the force required to puncture the silicone tip, test the tensile strength limit of the silicone tip under stretch strain, and conduct a qualitative viability of the device during a routine suturing task.

For the first functionality exercise, participants attempted to laparoscopically puncture the silicone tip of the Suture-Assist attachment with a standard 17 mm RB-1 needle. The Suture-Assist device would be stabilized and participants would control a laparoscopic needle driver attached to a spring load and attempt to puncture the silicone with a held needle. The force required by participants to puncture or tear the silicone would be recorded. These measured forces were then compared to reported data on common needle interaction forces seen in minimally invasive suturing. These common needle interaction forces generally ranged from 1 to 10 N.³ For the second functionality exercise, participants laparoscopically applied progressively greater load strains on the silicone tip resulting in stretching of the attachment until the silicone tip broke or was torn. The maximum load force applied and the resulting elongation of the silicone tip were recorded. These two functionality assessments required fine motor control and were only to be completed by surgeon educators and surgical residents.

For the viability assessment of the Suture-Assist attachment, participants were asked to complete a free-form suturing task using a standard FLS trainer. All participants who completed this viability assessment were administered a qualitative survey on the user-experience with the Suture-Assist attachment.

Results

Smart-Needle

A total of five volunteer participants completed the prototype assessment of the Smart-Needle. Participants included three surgical resident trainees and two surgeon educators. Given the nature of this proof-of-concept investigation, a control group was not obtained. Insertion attempts with use of only the laser-pointer served as a comparison group for the study. Each participant completed the assessment task with the simple laser-pointer and with the Smart-Needle three times each. As such, data were collected from 15 attempts with both the laser-pointer and the Smart-Needle. While all attempts, across both insertion approaches, fell within the target range, a simple *t*-test analysis of the angles of insertion obtained for each attempt found that there was a statistically significant ($P < 0.05$) difference in the angle of insertion between those attempts done with the laser-pointer and the Smart-Needle. This

revealed a statistically significant greater level of precision (angle of insertion closer to 90°) when using the Smart-Needle device to perform a percutaneous needle insertion. Additionally, on averaging the 15 attempts of each approach, it was noted that the diameter of the light illuminating the lumen through the diode of the Smart-Needle was 2.9 mm as opposed to the 4.9 mm transillumination achieved by the laser-pointer. This preliminary proof-of-concept evaluation suggests that the diode-based design of the Smart-Needle may provide a greater degree of precision during needle insertion.

Smart-Trocar

Nineteen medical student volunteer participants completed the prototype assessment of the Smart-Trocar. Participants included pre-clinical medical students in a surgery interest group. Given the nature of this proof-of-concept investigation, a control group was not obtained; inclusion of the Technique 1 approach in the study served as a comparison group for the study. Each participant completed each approach of the trocar insertion twice. The mean distance from the center marker was 6.0 ± 0.7 cm when the laparoscopic camera was held by an assistant (Technique 1) and 4.3 ± 0.5 cm when the volunteer trainee held the laparoscopic camera themselves (Technique 2). The average improvement in accuracy when trainees controlled the laparoscope was 1.7 ± 0.9 cm. Although the difference between the two techniques did not reach statistical significance ($P = 0.095$), the research team noted that participants actively used the real-time data output from the Smart-Trocar to guide their insertion performance (Fig. 7). Though not explicitly measured, it was noted that students would slow down the rate of trocar insertion on subsequent attempts, using the data-display to guide their performance. All 19 study participants completed the post-assessment survey. All respondents reported having had some prior hands-on exposure to trocar insertion. Eighteen participants (95%) reported the Smart-Trocar device to be a more effective training tool than practice using a traditional trocar insertion simulator. All respondents also reported that they felt the Smart-Trocar device was able to accurately demonstrate the metrics of ‘applied force’ and ‘angle of insertion.’ All respondents reported that the ability to receive real-time performance metrics that they would not have otherwise been able to objectively assess, ‘improved’ ($n = 3$, 15.8%) or ‘greatly improved’ ($n = 16$, 84.2%) their ability to perform the task.

Smart-Forceps

Participants included volunteer surgical residents in the first three years of training ($n = 5$). Given the nature of this proof-of-concept investigation, a control group was not

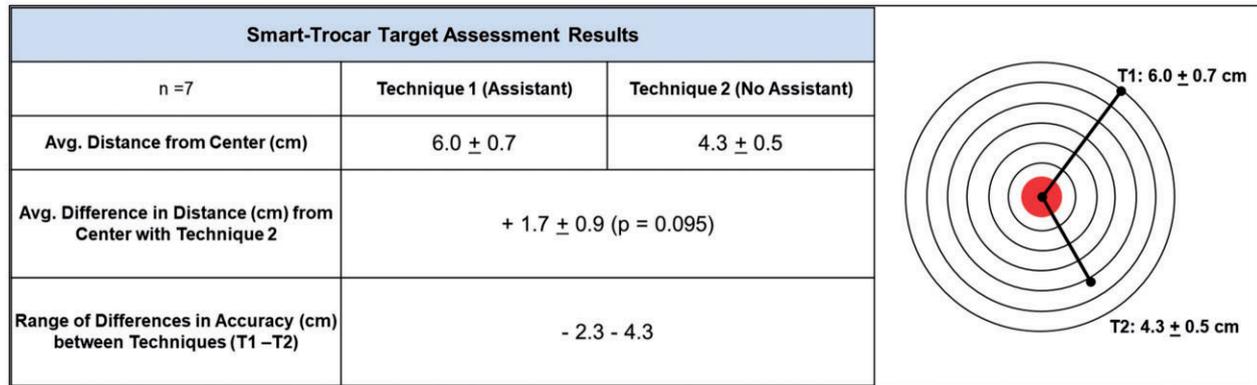


Figure 7. Table of average results of Smart-Trocar target assessment, demonstrating a non-significant difference in accuracy between the two techniques with a visual representation of the circle target.

obtained; comparison of recorded metrics to those found in the literature served as a comparison group for the pilot study. Each participant completed the series of tissue manipulations twice. The Smart-Forceps device was noted to be able to successfully detect variations in applied grip force, tensile force, and transverse load applied to the instrument. In a comparative analysis with the reported literature, the device was determined to have an accuracy of $\pm 3\%$ and a precision error of ≤ 0.5 N throughout the critical 4–15 N range (Fig. 8).

Suture-Assist

Five participants completed the puncturing task. Of the participants, four were first- or second-year surgery residents and one was a third-year medical student on their surgery rotation. The range of forces the silicone needle was able to resist prior to puncture extended from 1.18 to 2.81 N. The average force of puncture the silicone tip was able to resist was 1.94 N.

Three participants (two surgical residents and one surgeon educator) completed the tensile strength assessment of the silicone tip. The maximum loads withstood prior to tearing of the silicone tips were 13.0, 17.5, and 26.0N with a maximum elongation prior to tearing being 15.1, 20.0, and 28.9 mm, respectively.

Six participants completed the viability pilot study of the Suture-Assist device. Participants included two surgical residents, one medical student, and three surgeon educators. All participants completed the survey. Given the nature of this proof-of-concept assessment, a control group was not obtained; the two task attempts completed only with standard laparoscopic instruments served as a control benchmark for participants. Only the medical student reported

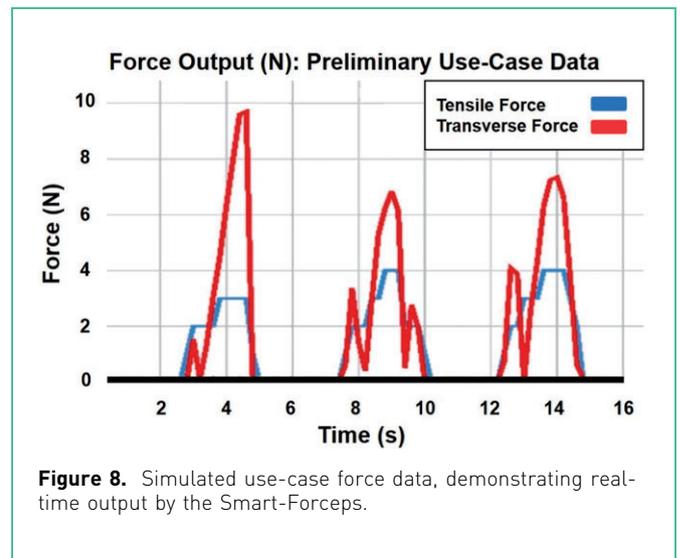


Figure 8. Simulated use-case force data, demonstrating real-time output by the Smart-Forceps.

having no experience with laparoscopic suturing. All participants reported that they were able to ‘feel increased haptic feedback from the silicone tip when pressuring against.’ Five participants felt that the increased haptic feedback would be ‘useful when performing laparoscopic suturing.’ One respondent recused themselves from this question as they had limited experience with laparoscopic suturing. When asked to compare the ease of suturing between standard laparoscopic instruments and the silicone tip attachment, all participants reported that the ‘silicone tip would be advantageous in pressing against tissue.’ All respondents did share that the sliding mechanism for the silicone tip was ‘difficult to extend/retract using the current sliding mechanism.’ When asked to provide open feedback, two respondents reported that the current design was not

'comfortable' or ergonomic and that the mechanism was the greatest barrier for ease of use. Three respondents (one surgeon educator, one surgical resident, and a medical student) reported that the silicone tip may be beneficial in clinical practice. All respondents did report that the silicone tip attachment would be 'beneficial in the training of laparoscopic suturing skills.'

Discussion

Each of our novel training tools provides specific new features to improve real-time learner feedback. The Smart-Needle is the only known use of a laser to provide direct visualization of intraperitoneal needle insertion. The intuitive design emphasizes low-cost construction principles, reusability, and simplicity for the learner. The Smart-Trocar is the only known trocar capable of simultaneously reporting force, axis deviation, and tissue impedance.^{15,16} Our design takes advantage of impedance measurements for a trainee to identify distinct tissue layers during trocar insertion. While force-sensing methodologies have previously been reported, the Smart-Forceps is the only training tool, to our knowledge, that provides linear, lateral, and rotational force feedback to the trainee.^{17–20} The design takes advantage of the inclusion of tensile force as a measurement of instrument manipulation and skill performance. The Suture-Assist device is the only known training tool to facilitate proper needle orientation and real-time feedback of tissue topography in laparoscopic suturing.^{21–23} The design principles are unique in that they take advantage of haptic and visual feedback via 3D-printed elements.

The mastery of surgical skills requires extensive training and experience that many surgical trainees only obtain in the operating room.⁴ To enhance surgical skill acquisition, simulation training modalities and simulators have been extensively developed and validated in order to provide trainees with greater opportunities for deliberate practice.^{5–7} A substantial body of literature demonstrates that deliberate practice is critical for the development of technical skills.^{7–9,11–16,24} Notably, the simulated practice of a surgical skill without guidance or feedback can result in a learner developing and cementing muscle memory of an incorrect technique.^{8,9} Simulation training of surgical skills can be made more efficient by incorporating real-time feedback, effectively reducing the learning curve.⁶ Laparoscopic training tools which offer real-time feedback have the potential to enhance the efficacy of laparoscopic surgical skills acquisition.

As defined by Champagne²⁴ and Ericsson,²⁵ deliberate practice consists of two steps: first, identifying the area of

performance requiring improvement, and second, receiving immediate detailed feedback during performance. The four feedback devices developed in this project assist with both steps of deliberate practice. By quantifying performance in terms of measurable forces and positions, the devices immediately alert trainees when their performance needs to be adjusted, increasing the efficacy of training and reducing the time necessary to master critical skills. An additional benefit of such data-driven training is that it allows for self-guided practice and may reduce the need for supervision while training.

Conclusion

We developed four surgical training tool prototypes that provide enhanced real-time feedback for surgical trainees. Testing provided proof of concept that these novel training tools provided an advantage to learners while maintaining an affordable design, reusability, and delivery of continuous feedback. These prototype assessments present a platform for further pilot studies to be conducted on future iterations of the instruments' designs. Future directions include additional design iterations, large-scale performance studies, and validation assessments. Our ultimate goal is the integration of these training instruments into our surgical simulation curriculum.

Conflict of interest

The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript. The content of this publication is under the sole responsibility of the author/publisher and does not represent the views or opinions of Boston Scientific Corporation.

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