Design and Evaluation of an Educational Device for Ultrasound-Guided Interventional Procedures

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ABSTRACT

This paper presents the development and evaluation of an educational system for training and skills assessment of students performing ultrasound-guided interventional procedures. The system consists of: a needle guidance software which overlays virtual needle trajectories on the ultrasound screen, a custom course creation module, an automated procedure logging and evaluation module, and custom anatomical phantoms tailored to specific anesthesiology procedures.

The system serves two distinct functions. As a learning tool, it provides guidance overlays that show the trajectory of the needle in real-time, aiding the development of skills required to handle the ultrasound probe and needle to achieve the correct trajectory. As an evaluation tool, it quantifies learning and provides feedback to the student and instructor.

A set of 13 quantitative metrics were identified for student skill assessment, notably "distance of the needle tip to target", "total procedure time" and "total number of attempts". The system was evaluated in a semester-long study involving 35 nursing students covering four regional anesthesia procedures. Each student performed the procedures twice: once with instrument guidance, once without instrument guidance. Statistically significant differences were found between the with-guidance and without-guidance groups. The study was able to show that students consistently performed better under EDU's guidance for all four procedures.

Keywords: Ultrasound-Guided Procedures, Deep Learning for Instrument Detection, Educational Device for Ultrasound-Guided Procedures, Optical Tracking, Needle Guidance, Regional Anesthesia, Student Skills Assessment for Ultrasound-Guided Procedures, Navigation System

1. INTRODUCTION

Ultrasound-guided interventional procedures have become an essential tool in clinical specialties such as anesthesia, emergency medicine, and sports medicine. Research over the past decade has particularly highlighted ultrasound's key role in improving patient outcomes for procedures such as central vein catheterizations and peripheral nerve blocks.[1,2] As a result, professional certification organizations have begun recommending ultrasound guidance as the gold standard of care for such procedures.[3,4]

Increasingly, the responsibility for performing these procedures now falls to Certified Registered Nurse Anesthetists (CRNAs). This is especially true in underserved rural locations, where CRNAs can represent more than 80% of the anesthesia providers. Many rural hospitals are critical access hospitals which rely on independently practicing CRNAs for anesthesia care. The ability of CRNAs to safely deliver pain management for cancer patients and others is therefore vital. As of August 2022, there were 130 accredited nurse anesthesia programs in the United States and Puerto Rico utilizing 2,366 active clinical sites.[5] In 2019, the Council on Accreditation of Nurse Anesthesia Educational Programs revised the curriculum to require the educational program to have a written systematic plan for continuous self-assessment that includes: "an established assessment procedure to

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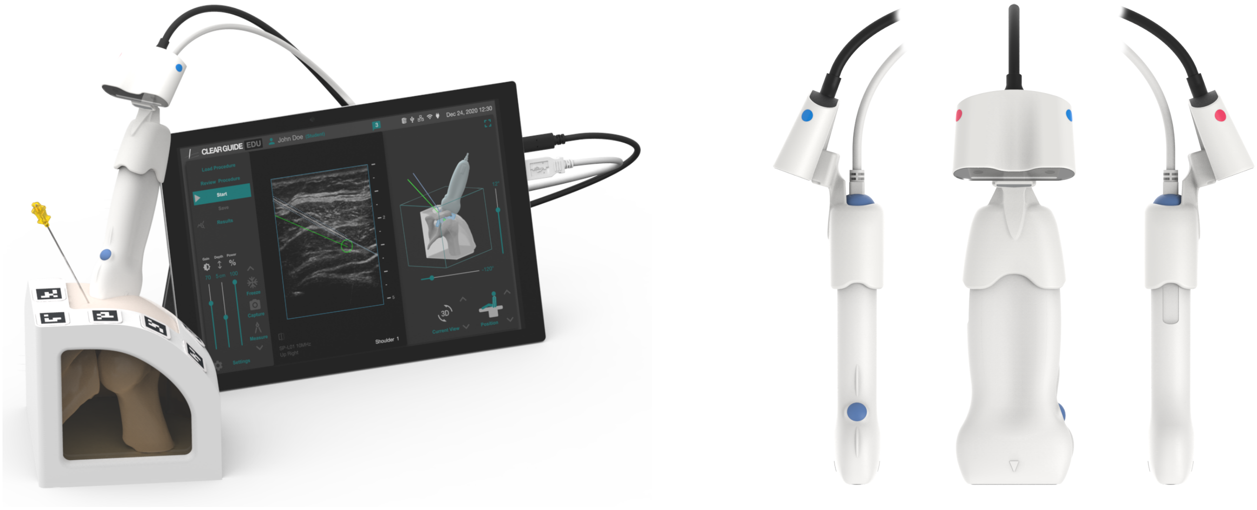

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Figure 1. Left: The EDU system. Right: EDU SuperProbe: linear ultrasound probe with optical head.

verify competence in scholarship skills relevant to the area of academic focus" and "faculty advising provides students with ongoing feedback, both formal and informal".[6]

While the status of ultrasound guidance as an essential tool is well supported by the evidence, and a structured approach to assessment has been mandated,[6] there is at present a lack of detailed empirical research addressing the optimum strategy for training novice providers in its application. Currently, the main method of evaluating a student's skill is a professor's observation of the student performing the intervention. While simulation training has been highlighted as a proven method of enabling deliberate practice in a safe environment,[7] procedural specifics are lacking, as is a deeper understanding of how best to ensure an accurate mapping between training and real-world clinical environments.

Fundamental to a successful procedure is the assessment of potential needle entry positions for safe clearance of anatomical structures, such as the lung and major vessels. This is crucial for minimizing possible complications resulting from inadvertent needle placement. The development of advanced psychomotor skills is therefore essential, but constructing a reliable and repeatable environment within which these can be acquired is difficult. Real-time, in-plane, and out-of-plane direct visualization of needle entry is needed, coupled with a system capable of generating benchmarked constructive feedback throughout the training process.

The educational system, EDU, outlined in this paper is designed to address the challenges of handling an increased training load while maintaining consistent and transparent benchmarking. The EDU system overlays the trajectory of a hypodermic needle in real-time, with visual cues to help place the probe correctly on the target. This aids in developing the skills required to handle the ultrasound probe and needle simultaneously while maintaining the correct alignments throughout. The combination of needle guidance and probe handling guidance allows students to develop their muscle memory, acquiring an intuitive understanding of how to move the probe even when the target is temporarily obscured.

2. METHODS

2.1 System Overview

The EDU system (Figure 1a) is comprised of an Interson ultrasound probe, a tablet computer with software which mirrors and augments the ultrasound screen with guidance overlays, a Clear Guide Medical (CGM) optical head with stereo cameras (Figure 1b), and CGM custom phantoms (Figure 4). The optical head is connected to the tablet via a single USB 3.0 connection which provides both power and data transmission. The ultrasound probe is connected to the tablet via a USB 2.0 connection. The tablet receives high resolution stereo images from the cameras and ultrasound images from the probe.

The EDU system optically tracks the needle in real-time by processing the images form the cameras, and overlays the trajectory of the needle on the ultrasound image, with visual cues to help place the probe correctly on the target. The system quantifies student performance based on a comprehensive set of metrics (section 2.4), providing feedback to the student and instructor while also enabling self-directed learning.

2.2 Training System Software Design

A computer-assisted training system for ultrasound-guided interventions, called Clear Guide EDU, was developed based on the Clear Guide SCENERGY navigation system,[8] which is commercially available and is being used for CT/US and MR/US fusion in procedures such as liver biopsy and ablation. The EDU system provides ultrasound-only guidance and facilitates fast and effective learning of ultrasound-guided procedures.

The general workflow is as follows:

- **Procedure creation.** An expert (instructor) prepares a phantom by attaching fiducial markers around the area of intervention. The geometry of those markers is scanned using the optical head, which establishes a common coordinate system which is needed later for evaluation. The instructor then selects the anatomical target area in ultrasound. The system saves this constellation of markers and the target, so that they can be loaded as a single "procedure entity" at a later time. The expert will perform the procedure one time, and the software will record ultrasound probe orientations and needle tip path for later evaluation.
- **Student training.** A student performs the same procedure, either with or without instrument guidance (Figure 2). In both cases, the needle path and probe pose are recorded similarly. The anatomical target selected by the instructor will be visible as a green circle (see Figure 2) in both with-guidance and without-guidance mode of operation.
- **Performance evaluation.** Procedures recorded by the students can be evaluated. For this purpose, metrics were developed which measure student performance by comparing the performance to the procedure plan, or by calculating the differential between student and expert. See table 1 for a list of these metrics.

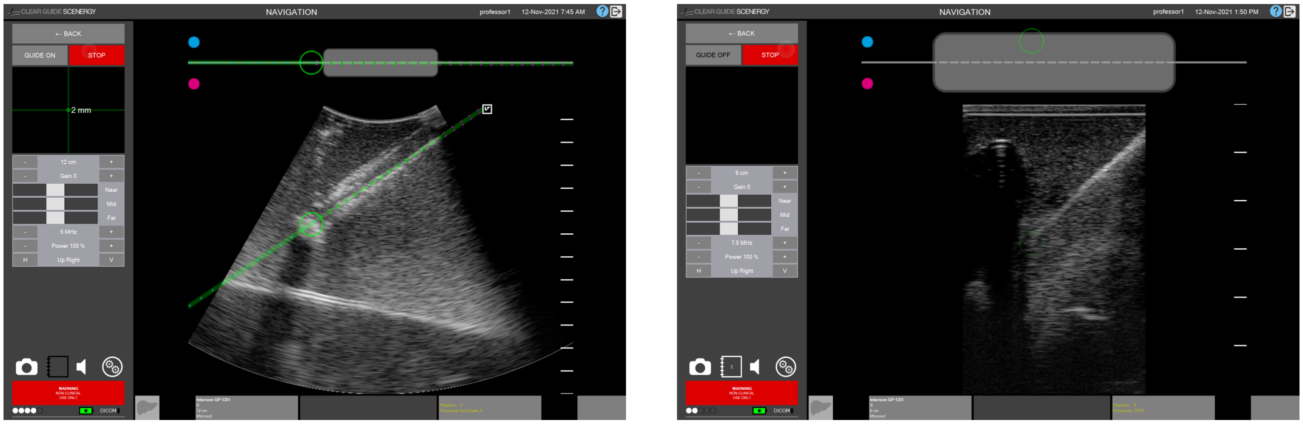

Figure 2. Left: The EDU system displays the ultrasound image with a pre-selected target and guidance information overlaid. Left: Guidance information displayed. Right: Guidance information hidden; the target remains visible.

Since the fiducials and the coordinate system defined by them does not change between procedures, it is sufficient to record the following data to be able to calculate the metrics:

– Phantom geometry and locations of the fiducials

– Ultrasound probe geometry (STL file)

- All calibration data
- Ultrasound device settings
- Timestamped location and orientation of the ultrasound probe and image in the common coordinate system
- Timestamped location and orientation of the needle (including tip position) in that same coordinate system

2.3 Needle Detection and Tracking using Neural Networks

The EDU system performs real-time tracking of the needle hub using two neural networks: 1) A a residual neural network (Resnet)[9] that operates on the full image and 2) a convolutional neural network (CNN) that is tuned to work on a cropped sub-region. Both networks provide three output values: a binary value that indicates whether a needle is present in the image, the 2D image location where the hub meets the shaft of the needle, and the approximate orientation vector of the needle (Figure 3).

During the procedure, the Resnet first runs on the full image (1280×720) to localize the needle hub. After the needle hub location is initialized, the lighter CNN is activated on a small sub-window (200×200) around the needle location in the previous frame. If the needle is moved out of this sub-window, the Resnet is utilized to re-initialize the hub location. The interplay between these two networks ensures fast real-time hub tracking. Line detection algorithms[10] are applied in the vicinity of the localized hub to estimate the orientation of the needle in real time. The needle geometry is reconstructed in 3D using the camera calibration information.[10] Standard pivot calibration is used to calibrate the location of the needle tip with respect to the hub. The pre-calibrated needle shaft length is added to the hub point along the orientation vector, thereby locating the needle tip in real-time — including when the needle is partially inserted in the tissue.

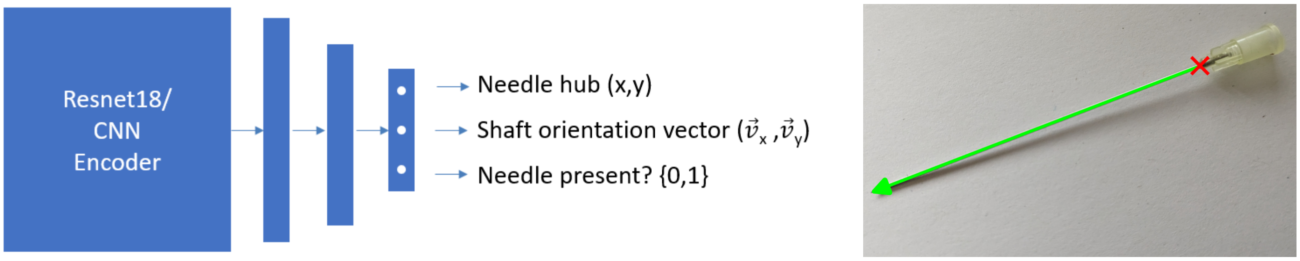

Figure 3. Left: Hub Localization Network architecture. Right: Resnet and CNN supply the location of the needle hub (red cross) and approximate orientation of the needle shaft; Line detection supplies the needle orientation at higher resolution (green arrow). Pre-defined needle length allows tracking of needle tip.

2.4 Evaluation Metrics

The metrics described in table 1 are calculated off-line, after procedures have been recorded, typically by the instructor. Since recorded data is timestamped and shares a common coordinate system, most calculations are simple. In this section, we give a description of the implementation of the non-trivial ones.

Distance to target: Calculate the distance between the final needle tip location and the pre-defined target. Note timestamp as t_{target}.

Total procedure time (needle in tissue): Using phantom geometry, find first time the needle tip is inside the phantom. Calculate time until t_{target}.

Total procedure time (probe): Using phantom and ultrasound probe geometry, find the first time a vertex of the probe is inside or on the surface of the phantom. Calculate time until t_{target}.

Needle visualization time in ultrasound: For each recorded needle location and orientation, find the ultrasound image location and orientation with the same timestamp. Needle is considered visible if the (infinite) line defined by the needle is never further than 5mm from the ultrasound image plane within image boundaries.

Metric	**Description**
Distance to target (mm)	The distance in millimeters between the final needle-tip position and the target region selected by the instructor.
Total procedure time (minutes)	The total logged time between procedure START and STOP.
Total procedure time (needle in tissue)	The time between the instrument penetrating the phantom surface and the needle-tip reaching the target.
Total procedure time (probe)	The time between the probe being placed on the phantom surface and the needle-tip reaching the target.
Target visualization time (% of total time)	The amount of time the nerve target remained at the center of the screen, expressed as a percentage of total procedure duration.
Needle visualization time in ultrasound (minutes)	The amount of time the needle remained in view in ultrasound. This is measured only for in-plane procedures.
Needle acquisition time in ultrasound (seconds)	The time between the needle entering the phantom and the needle shaft being clearly and consistently visible on the display. This is measured only for in-plane procedures.
Instrument jitter (mm/s^2)	A measure of smoothness of the needle-tip trajectory curve.
Probe stability (degrees/s)	A measure of the steadiness of the ultrasound probe during the procedure.
Potential tissue damage (cm^2)	The total area of phantom tissue the needle would cut through
Needle path length in tissue (cm)	The length of the tip trajectory from phantom insertion point to target.
Number of attempts	The number of times the needle was redirected or withdrawn during the procedure.
Trajectory similarity (with the expert)	A measure of the degree of correspondence between the student and expert needle tip trajectories.

Table 1. Performance Assessment Metrics

Instrument jitter: Calculate the integral of the squared second order derivative of the recorded needle tip locations.

Probe stability: Calculate the average of probe orientation changes (degrees per second).

Potential tissue damage: Iterate over the recorded tip locations and accumulate the area of triangles defined by current needle position, previous needle position and point where the needle entered the phantom.

Instructor trajectory similarity: The recorded needle tip positions of both student and instructor are ordered by timestamp. The distance d is calculated using Dynamic Time Warping (DTW)[11] and normalized for M points as $\left|\frac{M-\text{distance}}{M}\right|$.

2.5 Phantom Design

The EDU system includes anatomically correct, custom phantoms for four regional anesthesia procedures: 1) infraclavicular peripheral nerve block, 2) anterior approach to the sciatic nerve, 3) paravertebral peripheral nerve block, and 4) emergency cricothyrotomy. These procedures were chosen to represent a stepwise increase in complexity of anesthesia procedures.

Realistic 3D models for phantom bones structures were obtained from an anonymized public database of CT volumes.[12] The models were 3D-printed using an additive manufacturing technique called stereolithography.

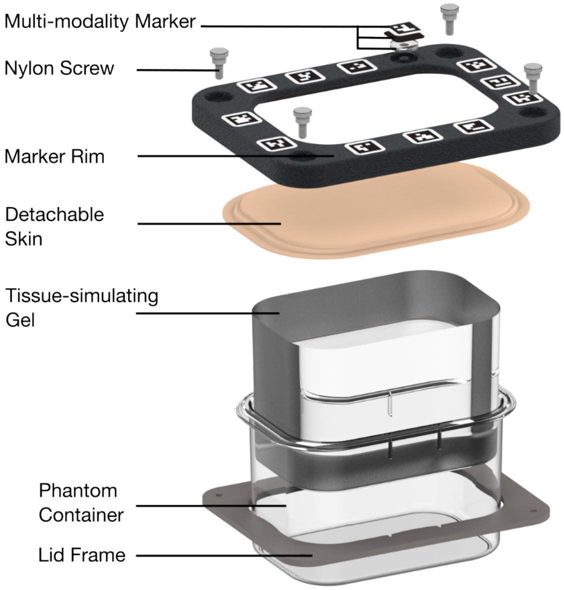

Figure 4. Phantom Assembly

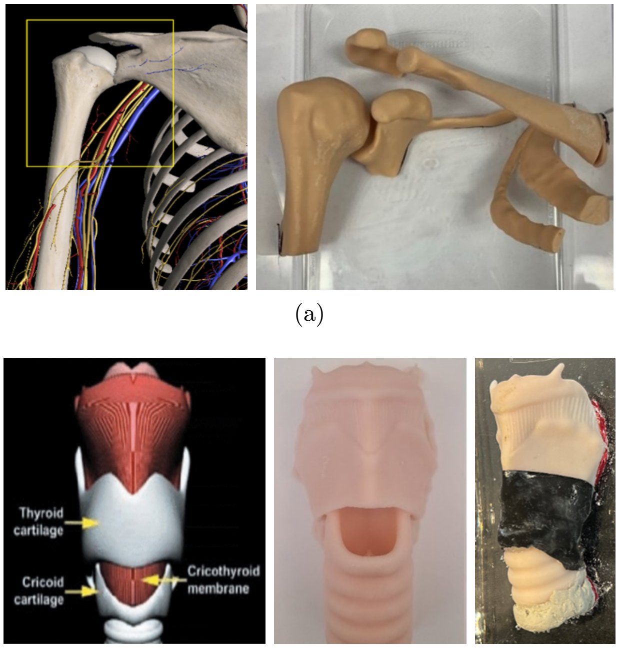

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Figure 5. (a) Infraclavicular brachial plexus phantom. Left: The anatomy; the yellow box covers the key regions covered by the phantom. Right: 3D printed bones. (b) Cricothyroid phantom. Left: The anatomy. Center: 3D printed bones. Right: The airway sealed using instant concrete and tape. The cricothyroid membrane is simulated using a self-adhering black tape providing tactile feedback to the user.

The bones were then placed in their precise anatomical positions and affixed using epoxy. A mixture of gelatin and fiber supplement was used to mimic the tissue. Silicone tubing and threads were employed to simulate the vessels and nerves respectively. Figure 4 illustrates the assembly of the detachable skin and a rim with fiducial markers that is attached to the container. Details of a infraclavicular brachial plexus phantom and a cricothyroid phantom are given in Figure 5.

3. STUDY AND RESULTS

A total of 38 second-year Student Registered Nurse Anesthetists (SRNAs) from the University of Miami participated in the study, which covered four anesthesia procedures. Each student performed the procedure twice: once with instrument guidance and once without instrument guidance.

Figure 7 shows scatter plots for the metric “distances to target” under both guidance modes for all four procedures; results for all metrics across all procedures are given in table 2. It is evident that both accuracy of needle insertion and total procedure times were enhanced by the use of instrument guidance for all four procedures. The EDU system also allows the visual comparison of the student’s and expert’s needle trajectories, in addition to a metric that evaluates their trajectory similarity score (Figure 8).

4. DISCUSSION AND CONCLUSION

The study was able to show that students consistently performed better under EDU’s guidance for all four procedures, across all evaluation metrics (see Table 2). When comparing with-guidance and without-guidance scenarios, statistically significant differences were seen for the number of attempts and distance to target. The

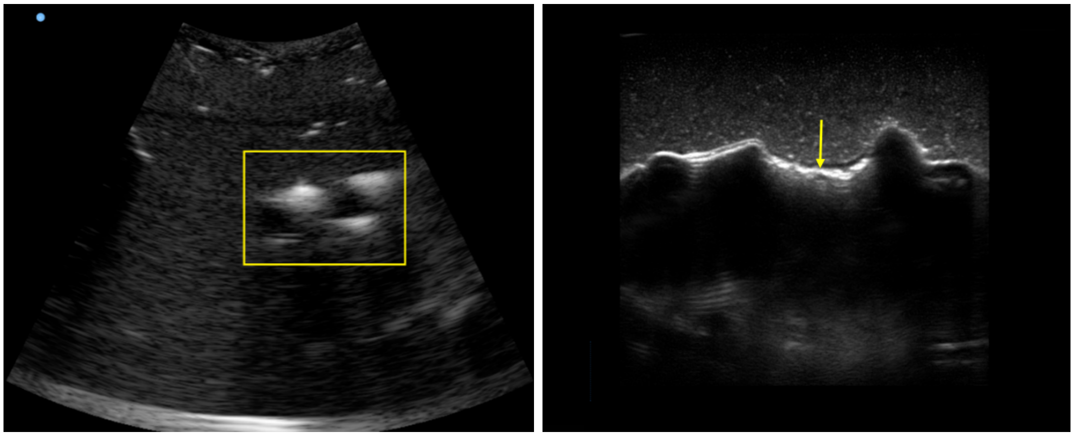

Figure 6. The custom phantoms observed under ultrasound. Left: Infraclavicular brachial plexus: The three nerve cords (lateral, medial and distal) and the auxiliary blood vessels. Right: Cricothyrotomy: The arrow points to the cricothyroid membrane, which is the point of insertion.

Metric (Mean ± SD)	**Guidance ON**	**Guidance OFF**
Distance to target (mm)	2.73 ± 1.61	7.26 ± 10.09
Total procedure time (minutes)	2.35 ± 1.1	3.21 ± 2.93
Target visualization time (% of total time)	91.53%	82.37%
Needle visualization time in ultrasound (minutes)	1.34 ± 0.63	1.18 ± 0.26
Needle acquisition time in ultrasound (seconds)	15.4 ± 16.91	11.35 ± 12.01
Instrument jitter (mm/s^2)	1.34 ± 0.64	1.92 ± 0.72
Probe stability (degrees/s)	1.92 ± 0.54	2.09 ± 0.57
Potential tissue damage (cm^2)	62.71 ± 79.14	85.95 ± 107.18
Needle path length in tissue (cm)	24.4 ± 15.45	50.8 ± 46.61
Number of attempts	1.18 ± 3.88	4.74 ± 2.39
Trajectory similarity (with the expert)	0.7 ± 1.09	0.87 ± 1.39

Table 2. Evaluation metrics for the infraclavicular brachial plexus nerve block;[13] summary of data from 38 students.

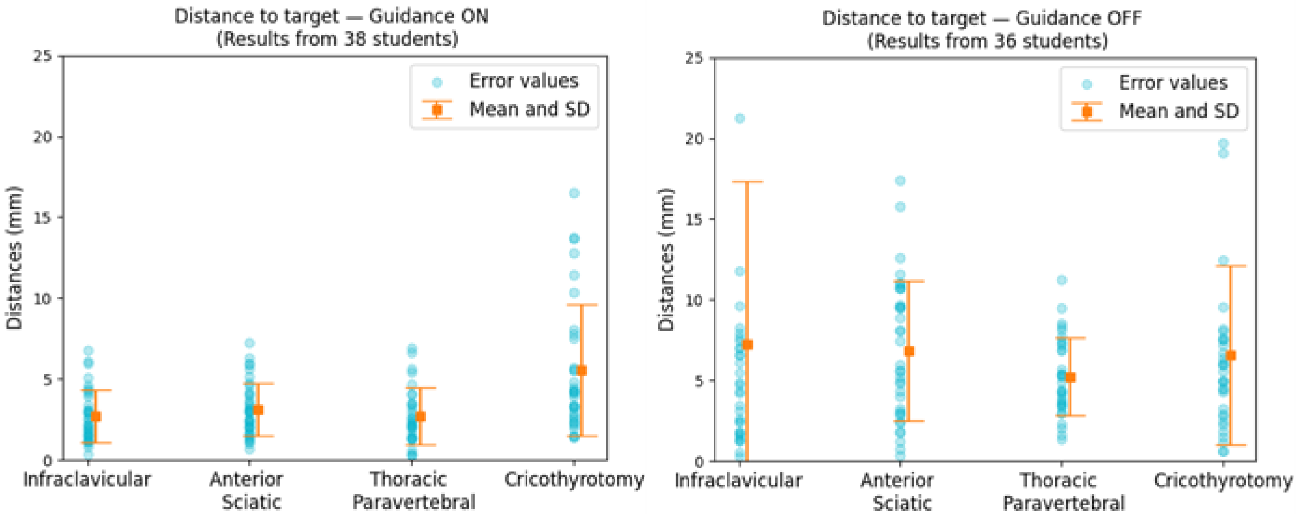

Figure 7. Scatter plots for distance of needle tip to target. Left: Guidance ON Right: Guidance OFF.

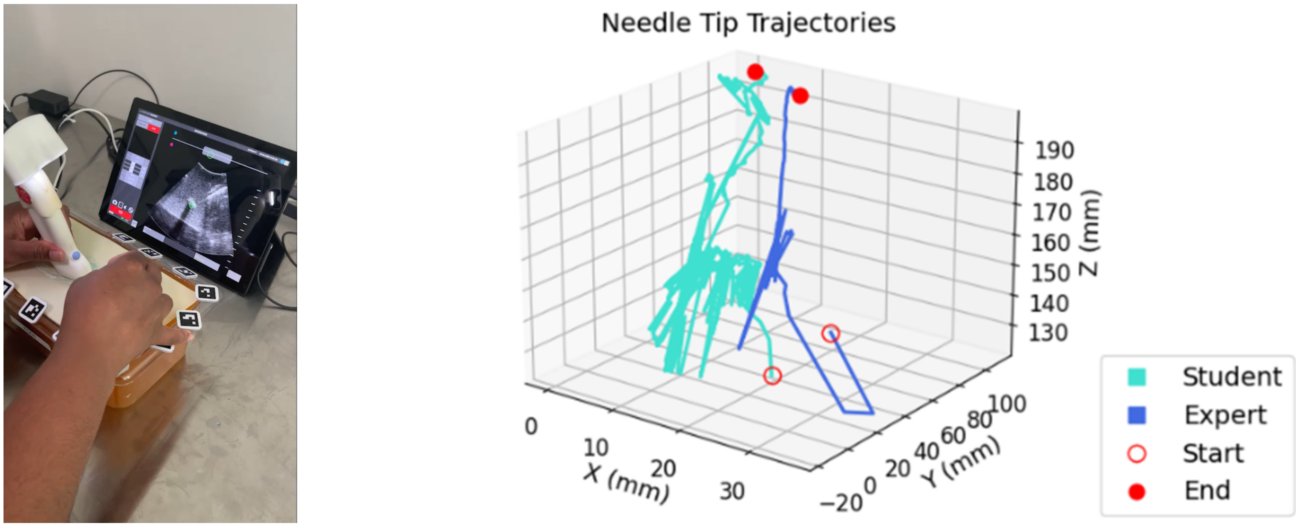

Figure 8. left: Student using the EDU system in the classroom. Right: Needle path of student and instructor.

number of attempts ranged from 2 to 10 (M = 4.74, SD = 2.39) without guidance and from 1 to 5 (M = 1.18, SD = 3.88) with guidance, a statistically significant ($p < 0.001$) difference. While none of the students were able to complete the puncture in their first attempt without guidance, 92% of the students with guidance were able to complete the puncture in their first attempt.

In future, the system will include additional probe guidance functionalities and artificial intelligence based anatomical landmark detection to facilitate self-directed learning. Future student trials will include a multi-center study involving two universities. This will ascertain the robustness of the results outlined in this work, confirming whether the results remain similar for a different cohort, faculty and curriculum. Additionally, a cadaver and clinical trial is planned to establish whether training with the EDU system results in improved clinical performance at a later stage.

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