## Articles

# A Novel Device for Training and Evaluating Ultrasound-Guided Procedures in Anesthesia

*25 Minutes*

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*To improve dynamic needle-tip visualization, nurse anesthesiology students were evaluated during simulated ultrasound-guided procedures. This quasiexperimental study utilized two computed tomography 3D printed models. Thirty-two students performed each procedure twice, once without and once with needle guidance. Measures focused on accuracy and procedural performance to determine the impact that guidance versus no guidance had on attempts. Students evaluated their experiences, self-confidence, feasibility, and usability using needle guidance technology. Needle guidance improved the distance to target, total procedure time, phantom penetration time, number of attempts, completion rate, and effectiveness in both procedures. Overall, a decrease in distance to target in millimeters was uncovered when needle guidance was utilized ($Z = -5.723$, $P < .001$). Needle guidance showed a decrease of 3.96 attempts when guidance was utilized for the infraclavicular ($F[1, 22] = 51.79$, $P < .001$) and 0.96 attempts during the thoracic paravertebral procedure ($F[1, 22] = 6.02$, $P = .023$). Students found that needle guidance enhanced ease, speed, and overall performance, while feeling significantly more confident performing the infraclavicular ($P < .001$) and thoracic paravertebral ($P < .001$) procedures. The use of needle guidance technology showed improvement in accuracy comparable with results obtained using external tracking technology.*

***Keywords:*** distance to target; needle guidance technology; procedural performance; realtime needle acquisition; real-time dynamic needle-tip visualization

The use of ultrasound for interventional guidance has expanded significantly over the past decade, becoming an important tool for clinical specialties such as Anesthesia, Critical Care, Emergency Medicine, Sports Medicine, and Radiology. In this context, real-time dynamic needle-tip visualization is essential to safely performing procedures: the assessment of potential needle entry positions for safe clearance of anatomical structures such as the lung and major vessels is crucial to minimize the potential complications of inadvertent needle placement. However, despite growing evidence supporting the use of ultrasound guidance as a transformational tool for improving procedural performance, empirical data on the optimization of novice provider training and the subsequent impact on patient outcomes remain sparse. We present the findings of a pilot study using a novel computer-assisted training device which can provide a consistent scoring mechanism for ultrasound-guided procedures, thus providing a reliable measure of student performances as benchmarked against expert usage.

Precise visualization and guidance of the needle and needle tip during ultrasound-guided regional anesthesia is of paramount importance and can be challenging, even for experts. Ultrasound imaging is commonly used but requires extensive training and clinical experience to perfect. Too often insufficient contrast results in difficulty in identifying anatomical structures such as vessels, nerves, and soft tissue. Added are the challenges in needle visualization in both the out-of-plane and in-plane approaches. The conditions for successful and safe needle-tip positioning require accurate and reliable needle appearance on the ultrasound screen, needle interpretation, nerve visualization, and nerve interpretation by the provider. It has been estimated that novices would require approximately 28 supervised procedures before achieving competency in needle visualization.[1] Despite the approximation of 28 supervised procedures, the proficiency of providers identifying anatomical sonoanatomy improved significantly over 8–10 learning sessions.[2]

Fundamental to the reported benefits of ultrasound-guidance is the belief that real-time visualization of the needle and sonoanatomy prevents needle related complications, while facilitating placement of the local anesthetic to close proximity of the nerve. Research highlights provider inconsistencies in optimizing ultrasound images, differentiating artifact, and maintaining needle tip visualization.[2-6] In fact, failure to visualize the needle tip is a common occurrence, prompting providers to perform nonvalidated maneuvers to manipulate the needle and probe.[7] Although techniques such as walking down from a shallow angle of insolation before moving to deeper angles have been used, needles often have poor echogenicity during large angle insertions, particularly when ultrasound beams are reflected outside the probe's aperture.[8,9] Consequential misinterpreting of the location of the needle tip can result in severe complications, such as peripheral nerve injury.[10-12] Although ultrasound guidance regional anesthesia postoperative neurologic symptoms is reported as only 0.4 per 1,000,[13] the addition of ultrasound guidance has no significant effect on the incidence of postoperative neurologic complications.[14]

To overcome barriers in failing to observe the needle, several methods to improve needle visibility during ultrasound guidance have been used and are broadly grouped into image-based needle segmentation algorithms, needle excitation to maximize needle echoes, and external needle tracking systems.[15] A new method for enhancing the training for needle and needle-tip visualization was manufactured by Clear Guide Medical (CGM). The educational device (EDU) utilizes CGM's one orientation technology and computer-assisted instrument guidance, which provides optical tracking through the addition of a navigation accessory. This provides real-time needle guidance by using artificial intelligence and augmented reality to determine the projected path and overlay the projected needle path onto the live ultrasound image. Optical imaging needle guidance offers a proven means to improving interventional procedural performance that may help further mitigate those risks. Needle path visualization of the ultrasound imaging plane and angle of entry before skin penetration has shown to improve accuracy and speed of procedural performance.[15,16] Improving procedural performance and success rate for the first attempt should result in reduced complications, and shortened procedural duration leading to improved patient comfort. Needle-tracking devices that optimize real-time ultrasound beam-needle tip alignment of the predicted and current needle position have been shown to improve those outcomes.[15,16] Of interest, the use of an ultrasound needle guidance system improved the technical needling skills of novice trainees, with the needle guidance group reaching competence more often.[17]

Novice learners develop mastery through purposeful and systematic deliberate practice. That is achieved through simulation training, which has a safe and proven effectiveness in medical education, procedural, and equipment testing before their use in the clinical setting. Simulation can help improve a novice's ultrasound-guided regional anesthesia accuracy, speed, and overall success in procedural performance.[18,19] The EDU system seeks to aid in the novice learner's proficiency by assisting in needle and needle-tip guidance. The aim of our trial was to assess student performance using the EDU system in administering ultrasound-guided infraclavicular (IC) and thoracic paravertebral (TPV) peripheral nerve blocks. The target to be achieved was preselected by the instructor prior to the study and the target remained the same for all participants. The objectives were to evaluate differences in needle guidance versus no needle guidance on procedural performance, system performance, and student impressions and preferences.

## METHODS

Our study was a single-center, quasiexperimental crossover design utilizing two 3D printed simulated models, IC and TPV. Local institutional review board approval was obtained. The study was conducted in two parts during regularly scheduled simulation sessions.

• ***Participants***. The study participants comprised second-year resident registered nurse anesthetists (RRNAs) from a private southeast Florida university. This time frame was chosen as it coincided with the curriculum and instructional content. Inclusion criteria were RRNAs enrolled in their final semester of their second year in the curriculum. Those who were not enrolled in the corresponding class were excluded from participating.

• ***Interventions***. All participants meeting the inclusion criteria performed each procedure twice (with EDU guidance and without guidance). Two procedures were utilized for the pilot study, an IC brachial plexus block and a TPV block. Each procedure was performed on a 3D printed ballistic gel simulation model. Each model was created from a computed tomography scan to be anatomically appropriate. The target to be achieved was preselected by the instructor prior to the study for consistency and remained the same for all participants in the study. At the beginning of the semester, students were randomized to determine the order of guidance. Group 1 used the EDU for guidance for the first puncture and the EDU without guidance for the second puncture. Group 2 performed the first puncture without EDU guidance and with the EDU guidance for the second procedure. That resulted in each participant performing each procedure twice using each model and served as his or her control.

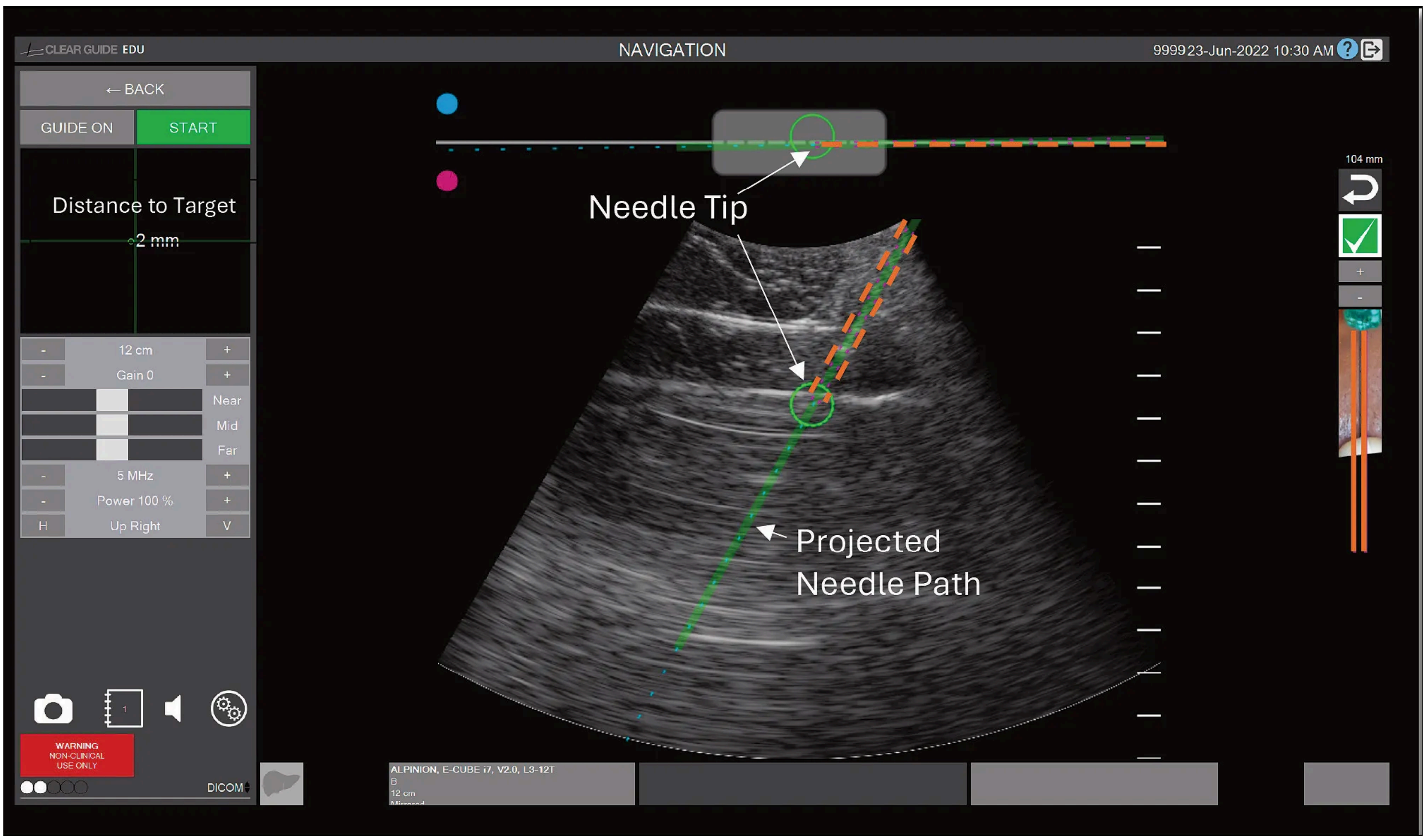


*Figure 1. Clear Guide Medical Educational Device Under a With-Guidance Mode Distance to Target The green lines indicate the projected needle path in both the probe orientation (top) and depth orientation (bottom). The orange dashes indicate the actual needle, with distance to target (green circle) displayed as 2 mm in the left upper corner.* »

The CGM EDU system provides artificial intelligencebased instrument guidance, which allows faculty to select a target and provide student guidance regarding the orientation of the needle in the two planes required to reach the target prior to insertion. It can operate under a with-guidance mode and without-guidance mode, with the ability to evaluate the same performance metrics for both cohorts. The EDU device is comprised of an Interson ultrasound (www.interson.com), a tablet computer which mirrors the ultrasound screen with guidance software to overlay the virtual needle trajectory, a CGM Optical Head with tiny video cameras, and a custom phantom (Figure 1). CGM Visimarkers were placed around the intervention site on each phantom model to ensure 3D imaging volume for target tracking.

Image frames, distance to target, total procedure time, total procedure time (phantom penetration), and image stability were captured and stored on the EDU system and then transferred for archiving and statistical analysis. Needles selected were the Braun Stimuplex 20-gauge × 4-inch Ultra 360 Insulated Echogenic Needle available institutionally to enhance needle echogenicity.

• ***Outcomes***. The researchers developed a preprocedural baseline survey to capture demographic data on gender, age, years of nursing experience, baseline IC and TPV procedural performance, and self-reported confidence. During the performance of the two simulated procedures, all participants were observed and evaluated using a global rating scale (GRS) to assess technical skills.[19] Construct validity for the global rating scale was reported as having interclass correlations between assessors of .795. The GRS provided an overall assessment of the students' performance and consisted of a 5-point Likert scale ranging from 1 = very poor to 5 = clearly superior.

• ***Evaluate Student Accuracy and Performance***. To evaluate the students' accuracy and performance on each simulated procedure, IC and TPV, the following metrics for all procedure attempts were captured: 1) minimal distance to target-minimal needle-tip position to target in millimeters; 2) total procedure time–time between the start of the procedure and the needle-tip reaching the target in minutes; 3) phantom penetration time–time between the instrument penetrating the phantom surface and the needle tip reaching the target in minutes; 4) number of attempts–number of times the needle was redirected/withdrawn; 5) image stability–amount of time the target remained at the center of the screen (percentage of total procedure duration), a summary across all attempts irrespective of guidance. A two-way repeated measures analysis of variance (ANOVA) for mean differences was conducted with guidance (with and without) and procedure type (IC vs TPV) as the two within-subjects variables for the following metrics: 1) respect for tissue–observed measure of how the student handles tissues appropriately with minimal damage; 2) time and motion–economy of movements (a measure of maximum efficiency versus unnecessary movements); 3) instrument handling–holds the probe appropriately and fluidity of movements; 4) knowledge of instrument–knowledge or confirmation of screen orientation; 5) flow of procedure–planned progression of the procedure; 6) use of assistants–strategically used assistants to the best advantage during performance; 7) knowledge of procedure–scanning of anatomy, proper identification of target and the procedure; and 8) overall performance–observed performance of the procedure as a measure of competence (very poor, competent, to clearly superior). After each procedure, the students were surveyed on their ability to perform the procedure and self-reported confidence and use of the CGM EDU guidance.

For each procedure, a completion rate on first time success was calculated by assigning a binary value of "1" if the test participants completed the procedure with one needle pass and "0" if they did not. Effectiveness with guidance versus without guidance was calculated by the following formula: number of successful procedural performance with one needle pass/number of attempts taken × 100%. Endpoint needle distance to desired anatomical target was measured and compared between the EDU with and without guidance.

• *Evaluate Student Experience.* At the completion of all the procedural performances, a postsurvey was conducted to obtain student feedback on the feasibility and provider experience using the CGM EDU technology for procedural guidance and as a learning platform. Two separate surveys evaluated overall satisfaction and feasibility of the CGM EDU system. Satisfaction was assessed using questions about overall satisfaction, comfort, and accuracy of the EDU system using a 7-point Likert scale ranging from 1 = strongly agree to 7 = strongly disagree. Feasibility and usability were assessed using the System Usability Scale (SUS), a widely used standardized questionnaire in industrial usability studies. A 5-point Likert scale was utilized with a scale ranging from 1 = strongly disagree to 5 = strongly agree.

• *Statistical Analysis.* All survey data and rater observations were captured using Qualtrics software and exported to SPSS for analysis. The researchers performed a two-way repeated measures ANOVA test for mean differences. The within-subjects variables are procedure (IC vs TPV) and guidance (with guidance vs without guidance). Using SPSS, a two-way repeated measures ANOVA test for mean differences was conducted. G*Power 3.1 was used to determine effect size. With a total sample size of 35, power at 80%, and alpha at 0.05, the model was estimated to be sensitive enough to detect effects as small as $f = .25$. Distance to target, completion rate, effectiveness, pre-IC and pre-TPV self-reported confidence levels were compared with self-reported post confidence levels using a Wilcoxon signed-rank test to determine the effect of guidance.

## RESULTS

• *Preprocedural Baseline Data.* Thirty-two students participated, 20 females (62.4%) and 12 males (37.5%), with a median age of 31 years. Years of nursing experience ranged from < 2 years to > 10 years with a mean experience of 2.66 years (SD = .971). Most students (93.8%) indicated that they had not performed an IC peripheral nerve block prior to the study, while two (6.3%) indicated that they had performed the block in the past ($M = 1.06$, SD = .246). All the students (100%) indicated no confidence in the procedure. Thirty-one of the students (96.9%) had no prior experience performing a TPV peripheral nerve block, with one student (3.1%) identified as having performed the procedure in the past ($M = 1.03$, SD = .177). Thirty-one students (96.9%) indicated no confidence in performing a TPV block, and one (3.2%) expressed being somewhat confident.

• ***Distance to Target (mm)***. Both the IC and the TPV minimum distance to target was combined into with guidance and without guidance. A Wilcoxon signed-rank test was conducted to determine the effect of guidance on the minimum distance to the target. The results indicated a significant difference in millimeters (mm) between the utilization of guidance ($M$ =1.37; SD = 0.94) and without guidance ($M$ = 5.37; SD = 4.96), with guidance significantly decreasing the distance to target ($Z$ = -5.723, $P$ < .001) when performing the simulated procedures (Table and Figure 2).

• ***Phantom Penetration Time and Time to Puncture (min).*** The phantom penetration time ranged from 0.02 min to 11.92 min ($M$ = 2.94, SD = 2.33) without guidance and from 0.45 min to 3.93 min ($M$ = 1.99, SD = 0.78) with guidance. A two-way ANOVA revealed there was a statistically significant interaction between the effects of no guidance on the type of procedure performed, $F$ (1, 19) = 5.99, $P$ = .024, with no guidance during the IC procedure taking a mean of 1.87 min longer time than during the TPV procedure (Table 1). The use of guidance did not result in any significant differences in time taken when performing both the IC [$F$(1, 19) = 0.51, $P$ = .489] and TPV procedures [$F$(1, 19) = 4.13, $P$ = .056]. Note that this includes preparation time-moving the probe to locate the target, acquiring, and orienting the needle-as well as the needle insertion time until the target is achieved.

• ***Number of Attempts.*** Descriptive statistics revealed that the mean number of attempts was five (SD = 2.63) for the IC procedure without guidance, 1.04 (SD = 0.21) when using guidance, 1.96 for the TPV without guidance, and 1.0 (SD = 0.00) with guidance (Table 1 and Figure 2). A two-way ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures [$F$(1, 22) = 18.38, $P$ < .001] and no significant difference between using guidance when comparing the IC and TPV procedures [$F$(1, 22) = 1.00, $P$ = .328]. When performing the IC procedure, the use of guidance resulted in a significant mean decrease of 3.96 number of attempts [$F$(1, 22) = 51.79, $P$ < .001]. When performing the TPV procedure, the use of guidance resulted in a significant mean decrease of 0.96 number of attempts [$F$(1, 22) = 6.02, $P$ = .023].

| Category | Guidance | | IC Procedure Guidance | | TPV Procedure Guidance | | IC Procedure | TPV Procedure |
|---|---|---|---|---|---|---|---|---|
| | No | Yes | No | Yes | No | Yes | | |
| Minimum distance to target (mm) | 5.37 | 1.37[a] | | | | | | |
| Phantom penetration time (min) | 2.94 | 1.99 | | | | | | |
| Effectiveness (%) | 37.38 | 98.29[a] | | | | | | |
| Number of attempts | | | 5 | 1.04[a] | 1.96 | 1[a] | | |
| Completion rate (%) | | | 0 | 94.3[a] | 54.8 | 100[a] | | |
| Image stability (%) | | | | | | | 96.13 | 86.25 |
| **GRS: The 5-point Likert scale ranged from very poor (1) to clearly superior (5).** | | | | | | | | |
| GRS: Respect for tissue | | | 2.78 | 3.96[a] | 3.57 | 4.43[a] | | |
| GRS: Time and motion | | | 2.42 | 4.09[a] | 3.61 | 4.39[a] | | |
| GRS: Instrument handling | | | 2.83 | 4.04[a] | 3.78 | 4.39[a] | | |
| GRS: Flow of procedure | | | 2.35 | 4.04[a] | 3.61 | 4.39[a] | | |
| GRS: Use of assistance | | | 2.7 | 3.7[a] | 3.52 | 4.17[a] | | |
| GRS: Overall performance | | | 2.48 | 4[a] | 3.57 | 4.35[a] | | |

*Table. Accuracy, Time, and GRS Assessment When Using Guidance vs Without Guidance aSignificant improvement with guidance (< 0.05) Abbreviation: GRS, global rating scale; IC, infraclavicular; TPV, thoracic paravertebral.* »

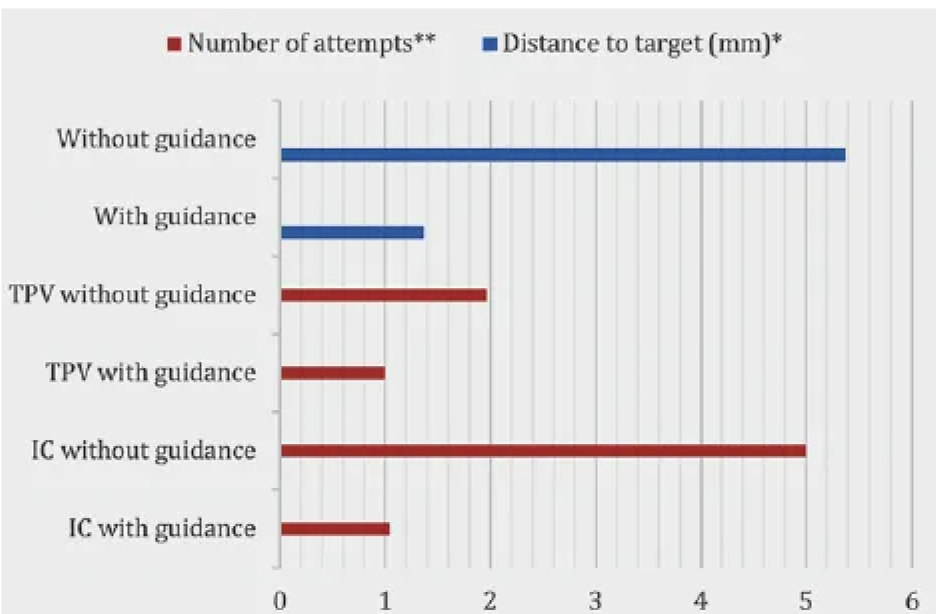


*Figure 2. Distance to Target and Number of Attempts *A Wilcoxon signed-rank t...* »

• ***Completion Rate.*** To examine completion rates on first time success, the following results highlight the differences for each procedure based on students performing the procedure without guidance versus with guidance (Table 1). When the procedures were done without guidance, the IC procedure resulted in a 0% completion rate and the TPV procedure resulted in a 54.8% completion rate. When the procedures were done with guidance, the IC procedure resulted in a 94.3% completion rate and the TPV procedure resulted in a 100% completion rate. A Wilcoxon signed-rank test was conducted to determine the effect of guidance on student completion rates for both the IC and TPV procedures. The results indicate a significant decrease in completion rate when guidance was not utilized in the IC procedure ($Z$ = -5.10, $P$ < .001] versus no guidance. A significant lower completion rate was also found when not utilizing guidance for the TPV procedure ($Z = -3.74$, $P < .001$] when performing the simulated procedures.

• ***Effectiveness***. Both the IC and the TPV effectiveness was combined into with guidance and without guidance. A Wilcoxon signed-rank test was conducted to determine the effect of guidance on student effectiveness levels. The results indicate a significant difference between the utilization of guidance ($M = 98.29$; SD = 7.44) and without guidance ($M = 37.38$; SD = 22.35), with no guidance being significantly less effective ($Z = -4.11$, $P < .001$) when performing the simulated procedures (Table 1).

• ***Image Stability***. Students showed improved image stability for the IC block (75.55% to 100% [ $M = 96.13$, SD = 5.43]) compared with the TPV block (49.47% to 100% [ $M = 86.25$, SD = 15.06]) (Table 1). The percentage of time that the nerve target remained in view varied from 45% to 100% ($M = 92.63$, SD = 8.66). Because both groups received the same visual cues regarding the target, this metric is a summary across all procedure attempts irrespective of the instrument guidance.

• ***Global Rating Scale***.

• ***Respect for Tissue***. Descriptive statistics revealed the mean score for time and motion was 2.78 (SD = 0.736) for the IC procedure without guidance, 3.96 (SD = 0.475) when using guidance, 3.57 (SD = 0.788) for the TPV without guidance, and 4.43 (SD = 0.590) with guidance (Table 1). A two-way ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures on respect for tissue [$F(1, 22) = 11.10$, $P = .003$]. When performing the IC procedure, the use of guidance resulted in a significant mean increase in superiority of 1.17 [ $F(1, 22) = 95.46$, $P < .001$]. When performing the TPV procedure, the use of guidance resulted in a significant mean increase in superiority of 0.870 [$F(1, 22) = 18.57$, $P < .001$].

• ***Time and Motion***. Descriptive statistics revealed the mean score for time and motion was 2.42 (SD = 0.73) for the IC procedure without guidance, 4.09 (SD = 0.67) when using guidance, 3.61 (SD = 0.84) for the TPV without guidance, and 4.39 (SD = 0.78) with guidance (Table 1). A two-way repeated measures ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures on time and motion ($F[1, 22] = 27.56$, $P < .001$).

The use of guidance resulted in a significant mean increase in superiority of 1.652 [ $F(1, 22) = 80.22$, $P < .001$] when performing the IC procedure. The use of guidance resulted in a significant mean increase in superiority of 0.783 ($F[1, 22] = 9.71$, $P = .005$) when performing the TPV procedure.

• ***Instrument Handling***. Descriptive statistics revealed the mean score for instrument handling was 2.83 (SD = 0.89) for the IC procedure without guidance, 4.04 (SD = 0.71) when using guidance, 3.78 (SD = 0.74) for the TPV without guidance, and 4.39 (SD = 0.72) with guidance (Table 1). A two-way ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures on instrument handling ($F$[1, 22] = 14.96, $P$ < .001). The use of guidance resulted in a significant mean increase in superiority of 1.22 [$F$(1, 22) = 47.13, $P$ < .001] when performing the IC procedure. The use of guidance resulted in a significant mean increase in superiority of 0.61 ($F$[1, 22] = 7.36, $P$ = .013) when performing the TPV procedure.

• ***Knowledge of Instrument and Procedure.*** Knowledge of the instrument and knowledge of the procedure could not be evaluated due to lack of variability.

• ***Flow of Procedure.*** Descriptive statistics revealed that the mean score for flow of procedure was 2.35 (SD = 0.83) for the IC procedure without guidance, 4.04 (SD = 0.77) when using guidance, 3.61 (SD = 0.84) for the TPV without guidance, and 4.39 (SD = 0.78) with guidance (Table 1). A two-way repeated measures ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures on flow of procedure ($F$[1, 22] = 23.36, $P$ < .001). The use of guidance resulted in a significant mean increase in superiority of the flow of procedure by 1.67 ($F$[1, 22] = 69.71, $P$ < .001) when performing the IC procedure. The use of guidance resulted in a significant mean increase in superiority of the flow of procedure by 0.78 ($F$[1, 22] = 8.63, $P$ = .008) when performing the TPV procedure.

• ***Use of Assistance.*** Descriptive statistics revealed that the mean score for flow of procedure was 2.70 (SD = 0.559) for the IC procedure without guidance, 3.70 (SD = 0.559) when using guidance, 3.52 (SD = 0.665) for the TPV without guidance, and 4.17 (SD = 0.576) with guidance (Table 1). A two-way ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures on the use of assistance ($F$[1, 22] = 19.96, $P$ < .001). The use of guidance resulted in a significant mean increase in the superiority of the use of assistance by 1.00 ($F$[1, 22] = 63.25, $P$ < .001) when performing the IC procedure. The use of guidance resulted in a significant mean increase in superiority of the use of assistance by 0.65 ($F$[1, 22] = 14.14, $P$ =.001) when performing the TPV procedure.

• ***Overall performance.*** Descriptive statistics revealed the mean score for overall performance of the procedure was 2.48 (SD = 0.730) for the IC procedure without guidance, 4.00 (SD = 0.603) when using guidance, 3.57 (SD = 0.843) for the TPV without guidance, and 4.35 (SD = 0.714) with guidance (Table 1). A two-way ANOVA revealed there was a statistically significant interaction between not using guidance when comparing the IC and TPV procedures on the overall performance of the procedure ($F$[1, 22] = 21.48, $P$ < .001). The use of guidance resulted in a significant mean increase in superiority of the overall performance of the procedure by 1.522 ($F$[1, 22] = 99.82, $P$ < .001) when performing the IC procedure. The use of guidance resulted in a significant mean increase in superiority of the overall performance of the procedure by 0.783 ($F$[1, 22] = 10.36, $P$ =.004) when performing the TPV procedure.

• ***Student Self-Reported Pre-Post Procedure Confidence Levels**. A* Wilcoxon signed-rank test was conducted to determine the effect of training on student self-reported confidence levels for both the IC and TPV peripheral nerve block. The following Likert scale was utilized when reporting self-confidence levels: 1 = no confidence, 2 = little confidence, 3 = somewhat confident, 4 = very confident. The results indicated a significant difference between the pre-IC procedural confidence ($M$ = 1.0; SD = 0.00) and the post-IC procedural confidence ($M$ = 3.03; SD = 0.400), with confidence being significantly increased after the training program ($Z$ = −5.33, $P$ < .001). Similar results for the TPV procedure indicate a significant increase in self-reported confidence from before training ($M$ = 1.04; SD = .272) to after training ($M$ = 3.25; SD = .532; $Z$ = −5.33, $P$ < .001).

• ***Student Satisfaction**.* Twenty-one students responded to the eight satisfaction questions rated on a 7-point Likert scale ranging from, 1 = strongly agree to 7 = strongly disagree: 19 students (90.5%) felt comfortable using the EDU with two (9.5%) somewhat disagreeing ($M$ = 2.24; SD = 1.22); 16 (76.1%) thought that the ultrasound view was clear while using the EDU, two (9.5%) neither agreeing or disagreeing, and three (9.5%) disagreeing ($M$ = 2.57; SD = 1.54); 10 students felt strongly that hand movements were accurately detected by the EDU needle tracking ($M$ = 1.67; SD = .73); four (19%) strongly agreed and three (14.3%) strongly disagreed that their ultrasound views were affected by the EDU ($M$ = 4.14; SD = 2.10); 10 students (47.6%) believed they would need the support of a technical person to be able to use the EDU, four neither agreed or disagreed, and seven (33.3%) believed they would not need any technical support ($M$ = 4.0; SD = 1.70); 20 students (95.2%) believed that with proper training and instruction, they would use the EDU, one (4.8%) student neither agreed or disagreed ($M$ = 1.52; SD = .81).

• ***Feasibility and Usability System Usability Scale**.* Twenty-five students responded to the 12 feasibility and usability questions rated on a 5-point Likert scale with a scale ranging from 1 = strongly disagree to 5 = strongly agree. Results indicate that overall, 25 students (100%) were satisfied with the ease of the EDU technology when performing the procedures ($M$ = 4.36; SD = .86) and the amount of time it took to complete the procedures while utilizing the EDU ($M$ = 4.48; SD = .87). Twenty students (80%) thought they would use the EDU technique frequently, three (12%) neither agreed or disagreed, and two (8%) disagreed ($M$ = 4.12; SD = 1.05); seven students (28%) thought the EDU technology was unnecessarily complex, two (8%) neither agreed or disagreed, and 16 (64%) did not find the technology unnecessarily complex ($M$ = 2.48; SD = 1.30); 19 (76%) students thought the EDU technology was easy to use, two (8%) neither agreed or disagreed, and six (24%) found the EDU not easy to use ($M$ = 3.96; SD = 1.06); 15 (60%) students thought they would need the support of a technical person to be able to use the EDU, three (12%) neither agreed or disagreed, and seven (28%) believed they would not need any technical support ($M$ = 3.4; SD = 1.41); 24 students (96%) thought the various functions in the EDU system well integrated while one student (4%) neither agreed or disagreed ($M$ = 4.48; SD = .59); five students (20%) thought there was too much inconsistency with the EDU technology, five students (20%) neither agreed or disagreed, and 15 (60%) disagreed and thought the technology was consistent (*M* = 2.36; SD = 1.19); 22 students (88%) thought that people would learn the use of the EDU technology very quickly, with three (12%) neither agreeing or disagreeing (*M* = 4.32; SD = .69); seven students (28%) found the EDU technology to be very cumbersome to use, one (4%) neither agreed or disagreed, and 17 (68%) did not find the EDU cumbersome (*M* = 2.32; SD = 1.46); 20 students (80%) felt very confident using the EDU technology for the procedures, with four (16%) neither agreeing or disagreeing, and one (4%) disagreeing (*M* = 3.96; SD = .74); seven students (28%) thought they had to learn a lot of things before they could get going with the EDU technology for procedural performance, six (24%) neither agreed or disagreed, and 12 (48%) disagreed and didn't think they had to learn a lot before using the EDU technology (*M* = 2.64; SD = 1.19).

## DISCUSSION

The use of the CGM EDU optical tacking system was evaluated by comparing procedural performance with the guidance turned off and on during simulated IC and TPV peripheral nerve blocks. Overall, distance to target, total procedure time, phantom penetration time, and number of attempts, completion rate, and effectiveness were all enhanced with the utilization of guidance in both the IC and TPV procedures and confirm the usefulness of our approach in a live educational environment, specifically: 1) the computation of standardized student performance assessment metrics on ultrasound usage, benchmarking against expert usage in both with instrument guidance and without instrument guidance modes, and 2) the provision of instrument targeting cues to the student which assist in targeting faster and more accurately with fewer attempts and needle redirections. Results corroborate other studies in which the use of an optical tracking device for invasive procedures reported a decrease in the time to target, number of needle redirections, and procedural accuracy.[15,16]

The results were particularly striking in exhibiting a decreased number of attempts, resulting in an increase in the first time completion and effectiveness rates when RRNAs utilized the guidance mode of the EDU unit during both the IC and the TPV procedures. When performing the initial IC procedure, the completion rate without guidance was 0% (N = 35). During the second procedure (TPV) the without guidance completion rate jumped to 54.8% (31). An increase in completion rate when using guidance also increased from 94.3% (N = 35) during the IC procedure to 100% (32) during the second TPV. When looking at the global rating score, all perameters with the exception of knowledge showed significant increase in the superiority of using guidance for both the IC and TPV procedures. Each metric, outside of knowledge, showed impovements during the second TPV procedure when performing without as well as with guidance. The results suggest that the initial use of the CGM EDU technology resulted in a learned benefit when performing the second procedure (TPV) both without and with guidance. Improvements may translate into subsequent procedures and a clinical improvement in procedural performance when the guidance is not available; something not investigated in this study but worth future consideration.

Evaluations pertaining to the technology usability, feasability, and student satisfaction were positive, highlighting the ease of use and perceived benefits of the CGM EDU. In a prior study, 50% of residents preferred the use of a similar guidance system, with 67% reporting an increased confidence.[3] Similar findings were found in this study, in which 25 students (100%) students satisfied with the ease of the EDU technology when performing the procedures, 19 students (90.5%) felt comfortable using the ED, with a significant increase in self-reported confidence.

Generally, utilization of ultrasound by experienced providers results in accurate needle placement. However, the novice user has challenges with accurate visualization of anatomy and real-time needle guidance resulting in inaccurate needle placement. That may result in a failed peripheral nerve block or worse, an unattended complication from needle misalignment. Likewise, incorrect needle insertion may result in needle redirection and repeated needle insertion attempts, causing patient discomport and pain. The accuracy results obtained using the CGM EDU are comparable with results obtained with other external tracking studies.[9]

Our study had several limitations, with the evaluation of the EDU system on IC and TPV 3D printed anatomical simulators as the main limitation. However, every attempt was made to create a realistic model replicating anatomic correctness. Results may differ in an actual clinical setting. Time and number of attempts were not limited and therefore do not reflect a true clinical experience where patient experiences would limit the students' time and number of attempts while performing.

## CONCLUSION

Ultrasound imaging plays an important role in procedural performance. Although ultrasound is an accessible needle tracking method, it is often challenging because of the low-quality images, shadows, and/or artefacts. That is compounded when accounting for needle deflection, tissue deformation, and target movements. This pilot study presents a method to improve needle-tip tracking and procedural performance by predicting the needle path tip path and real-time needle acquisition. Although not evaluated, improvements seen during this study in simulated procedural performance may translate to improvements in patient care and procedural safety. Future work will focus on using the system across a wider set of procedures.

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