ORIGINAL ARTICLE

Evaluation of a New Needle Guidance System for Ultrasound

Results of a Prospective, Randomized, Blinded Study

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Background and Objectives: Accurate needle control during ultrasound (US)-guided nerve blocks may be an elusive goal for the anesthesiologist. Despite modifications to increase echogenicity, needle visibility still requires precise alignment within the transducer beam. In this study, we evaluated a magnetically guided ultrasound (MGU) system that produces a real-time, graphic display of the needle position and trajectory that is independent of the US beam.

Methods: The MGU system was compared with echogenic needles and conventional ultrasound (CU) by anesthesiologists with and without prior experience performing US-guided nerve blocks. Participants were asked to perform tasks to quantify accuracy with respect to needle direction (directional accuracy) and needle tip position (positional accuracy). These evaluations were performed in a porcine tissue model.

Results: Regarding directional accuracy, inexperienced subjects were able to contact a target capsule with a single needle pass during both in-plane (IP) and out-of-plane (OOP) approaches using the magnetic guidance system. By contrast, using CU, subjects required redirection 3.8 ± 2.4 (P = 0.02), and 4.5 ± 3.9 (P = 0.04) times, respectively, for IP and OOP approaches. Experienced subjects contacted the target capsule with a single pass for both IP and OOP approaches when using the magnetic guidance system. With CU, experienced subjects were able to contact the target with a single pass using an IP approach but required redirection 3.4 ± 2.8 (P = 0.046) times during OOP approaches. Positional accuracy was also superior for both inexperienced (P = 0.04) and experienced (P = 0.02) users during an OOP approach.

Conclusions: In a tissue model, the MGU system improved control of needle trajectory and needle tip position for both inexperienced and experienced subjects.

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Accurate needle control while performing ultrasound (US)-guided nerve blocks may be an elusive goal for the anesthesiologist. Despite significant advances in US technology, needle guidance is still based primarily on visualization of the needle within the transducer beam.[1–3] The active research to improve needle visualization and control confirms that this issue continues to challenge many clinicians.[3–5]

To date, efforts to improve needle guidance have focused on increasing the echogenicity of block needles. However, structural modifications to increase needle echogenicity have not eliminated the need for precise alignment within the US beam. This alignment is difficult because beam width for high-resolution US transducers may range from approximately 0.5 to 1.5 mm depending on imaging depth.

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The challenge of aligning the block needle precisely within the US beam has restricted many practitioners to using only an in-plane (IP) approach. Moreover, the person performing the block must simultaneously maintain needle alignment and an optimal target image. This can result in the clinician repeatedly shifting their gaze between the US screen and the transducer.

In this study, we evaluate a magnetically guided ultrasound (MGU) system capable of producing a real-time, graphic display of the needle trajectory and needle-tip position that is independent of the US beam. The components of this system are incorporated into a conventional transducer and needle. When the needle is inserted from any position or angle adjacent to the transducer, a virtual needle overlay is displayed on the US image in real time. We hypothesized that while observing a real-time, graphic display of the needle tip and trajectory, anesthesiologists with and without prior experience using US would be able to direct a needle toward a phantom target more accurately than when guided by conventional ultrasound (CU) alone.

METHODS

The institutional review board at the University of Utah appraised this new technology evaluation and determined that it did not constitute human subjects research. The MGU system was compared with CU guidance by 8 faculty anesthesiologists with more than 12 months experience performing (both IP and out-of-plane [OOP]) US-guided nerve blocks as well as 8 anesthesiology residents (postgraduate year 2) without prior experience using US. None of the participants had seen or used the MGU system before taking part in this evaluation.

The prototype US investigational device is designed by General Electric Medical (Milwaukee, Wisconsin). It consists of a transducer with integrated magnetic sensing capability to be used with a magnetically fabricated needle. The transducer and needle used for MGU system are pictured beside a CU transducer and echogenic needle in Figure 1. A virtual needle graphic is used as a guide for the needle trajectory and needle-tip position. The MGU technology is not cleared for human use and is not available commercially.

Participants were asked to perform tasks designed to quantify accuracy with respect to needle direction and needle tip position. These evaluations were performed in porcine tissue obtained through retail vendors. Subjects were randomized to begin the trial using either the MGU or CU system. Similarly, the order for IP or OOP needle approach was randomized.

Tissue Model

A fresh porcine tissue specimen measuring 20 cm in length, 15 cm in width, and 8 cm in thickness was imaged by all participants. In each case, a gelatin capsule measuring 2.5 × 1 cm was positioned 4 cm deep to the superficial surface of the tissue specimen. To avoid tissue disruption between the imaging surface and the target, the capsule was inserted through a stab incision on the dependent surface of the tissue.

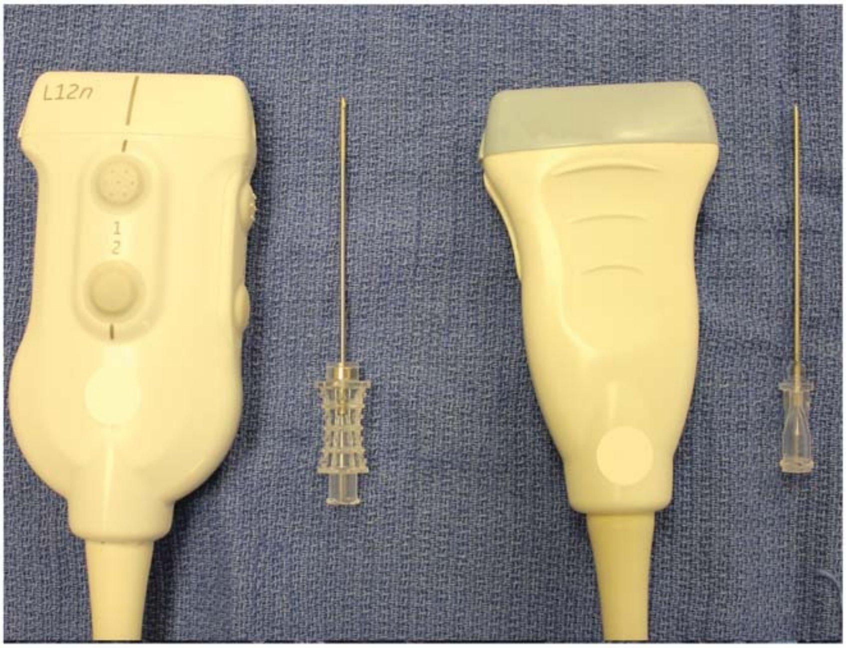

FIGURE 1. The needle and transducer used for the MGU system are pictured on the left. Their appearance is very similar to corresponding equipment used for the CU system pictured on the right. The MGU needle is magnetically fabricated (Bard Industries, Salt Lake City, UT). The variable frequency linear transducer for the MGU system has integrated magnetic sensing capability (GE Medical, Milwaukee, Wisconsin).

Display Characteristics

A number of display features were used to represent the needle position in 3 dimensions on the 2-dimensional US image screen. Figures 2 and 3 are examples of how the needle and its trajectory are displayed when portions are either anterior or posterior to the plane of the US beam. Specifically, those portions positioned either anterior or posterior to the plane of the US beam are displayed by a broken green line. Those segments positioned within the plane of the US beam are displayed as a solid green line.

Directional Accuracy Testing

Subjects were randomized to begin testing with either the MGU or CU system. Likewise, the initial approach (IP or OOP) was randomized. All participants received a brief tutorial on the MGU technology and its display characteristics but were not allowed to trial or handle the device before their actual testing.

To evaluate directional accuracy, each participant was asked to obtain a short axis image of the embedded capsule. Using this image, they advanced the needle to intentionally contact the

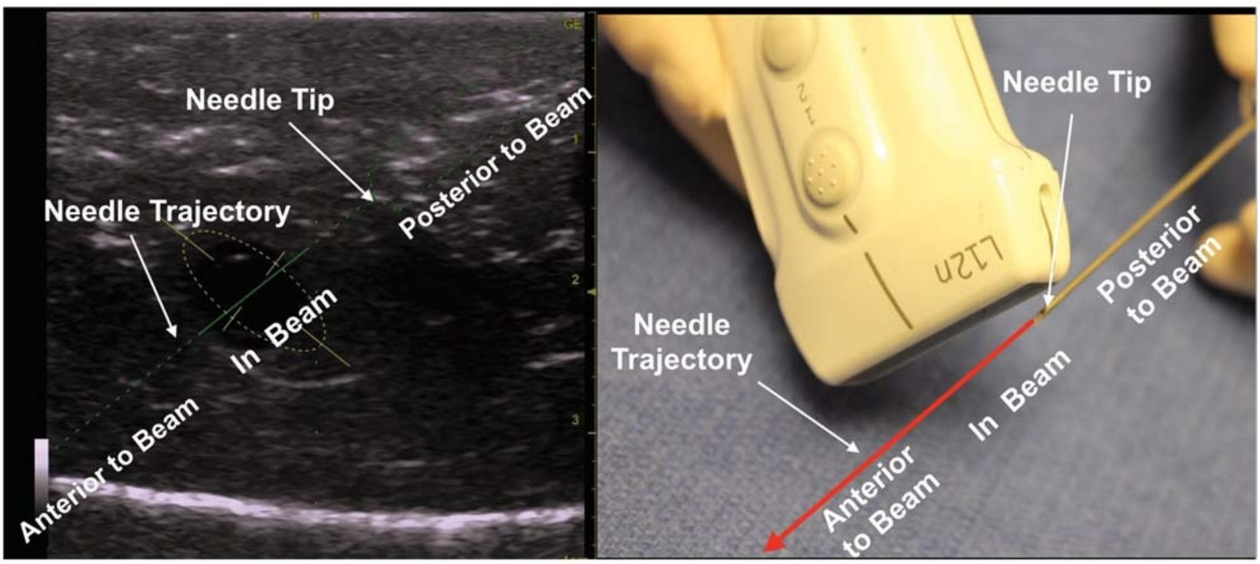

FIGURE 2. This is a virtual display of a needle positioned at an oblique angle relative to the transducer. The broken green line outlining the tip and shaft of the needle indicate that they are posterior to the US beam. The display of the needle trajectory changes from broken to solid and back to broken as it passes posterior, within, and then anterior to the plane of the US beam. The yellow "cross-hairs" move in real time to highlight the position where the needle trajectory passes within the US beam.

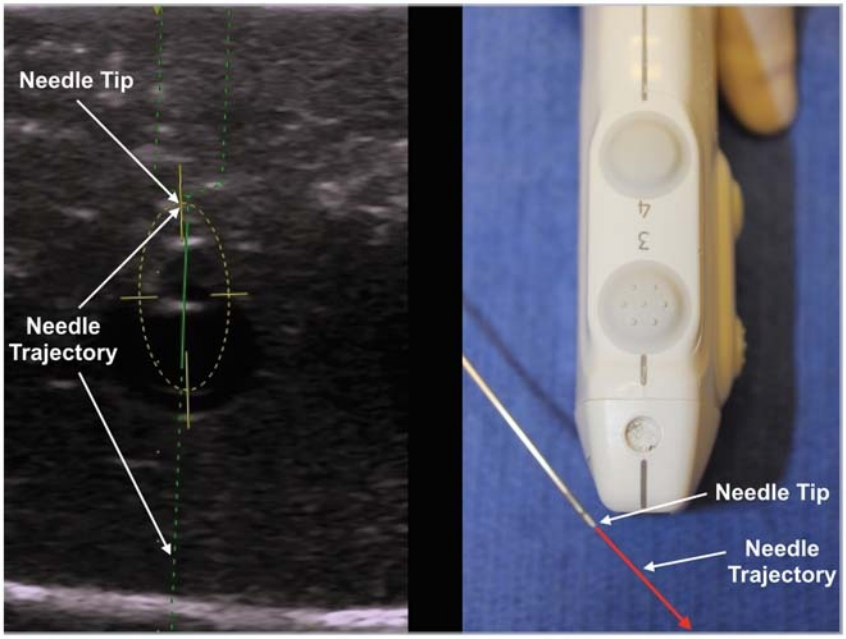

FIGURE 3. This is the virtual display of an OOP needle approach. In this display, the broken green line outlines the portion of the needle tip that is immediately posterior to the US beam. The solid green line and yellow "cross-hairs" show where the needle trajectory crosses the US beam. The broken green line indicates the trajectory as it passes anterior to the US beam.

capsule. Needle contact was verified when the subject felt a tactile end point accompanied by movement of the capsule on the US display as the needle tip impacted the capsule.

When using CU guidance, the subject used an 18-gauge, 2.5-in, echogenic needle (Teleflex Inc, Wayne, Pennsylvania). When using the MGU system, subjects used a magnetically fabricated 18-gauge, 2.5-in needle (Bard Access Systems Inc, Salt Lake City, Utah).

To quantify directional accuracy, the numbers of attempts required to contact the capsule were recorded for each participant. After initiating an advance of the needle toward the target, an "attempt" was defined as any withdrawal of the needle to redirect its trajectory. The performance of each participant was digitally recorded and analyzed offline by a reviewer who was blinded to the system being used.

Positional (Needle Tip) Accuracy

For positional (needle tip) testing, participants were also randomized to begin with either the MGU or CU systems. The initial needle approach was also randomized to IP or OOP. After obtaining the optimal short axis image of the implanted capsule, participants were instructed to advance the needle as closely as possible to the capsule without making contact. Subjects were not limited with respect to time or the number attempts used to optimally position the needle tip.

After the subject positioned the 18-gauge study needle, a 25-gauge, 4.5-in, pencil point needle was advanced through the study needle by the investigator. If the 25-gauge needle could not be advanced beyond the bevel of the study needle without contacting the capsule, the result was recorded as an unintended contact. If the 25-gauge needle could be advanced beyond the tip of the 18-gauge needle to subsequently contact the capsule, both needles were removed in unison and the distance from the tip of the 25-gauge needle to the bevel of the study needle was recorded to the nearest millimeter (Fig. 4). If the entire length of the 25-gauge needle could be advanced without contact with the capsule, the result was recorded as an incorrect trajectory.

For statistical analysis, the outcomes for positional (needle tip) accuracy were considered to be either accurate (correct needle trajectory without capsule contact) or inaccurate (correct trajectory with unintended needle contact with capsule, or incorrect trajectory, missed capsule). In accurate cases (correct needle trajectory without capsule contact), the distance between the needle tip and the capsule was measured and recorded.

Statistical Analysis

The number of subjects to be enrolled in this evaluation was based on a power analysis performed using StatXact software (Cytel Inc, Cambridge, Massachusetts). The number of needle passes required during trials for directional accuracy was compared using a Wilcoxon signed rank test with continuity correction (StatXact software). The results for positional accuracy were compared using a McNemar table with 2-sided exact P value. Additionally, for positional accuracy, an unintended needle contact was assigned the value of zero, whereas an inaccurate trajectory was assigned an infinite value. Accurate positions were given the value of the distance to the target rounded to nearest millimeter. A Wilcoxon signed rank test with continuity correction was used to evaluate the distribution of values.

RESULTS

Sixteen subjects compared the MGU and CU systems. These included 8 faculty anesthesiologists with more than 12 months experience performing US-guided nerve blocks, and 8 anesthesiology residents (postgraduate year 2) without experience performing US-guided regional anesthesia. All of the participants were able to obtain short axis images of the capsule with both the MGU and CU systems. Digital video was recorded and analyzed successfully by a blinded observer for each participant.

FIGURE 4. This figure shows the system used to measure the distance between the tip of the study needle and the target capsule. A 25-gauge, 4.5-cm pencil point needle is advanced through the study needle. The distance between the study needle tip and the target capsule can be measured as shown in the image. If the 25-gauge needle cannot be advanced beyond the tip of the study needle, the result is recorded as an unintentional contact.

Directional Accuracy

The results for directional accuracy are summarized in Table 1. During testing, all subjects were able to advance the needle tip and contact the implanted capsule using both the MGU and CU systems. In addition, all subjects reported a "tactile end point" as the needle contacted the capsule surface. The needle contact was also confirmed by observing corresponding movement of the capsule on the US image.

When performing an OOP approach with the MGU system, all inexperienced subjects were able to contact the capsule with a single pass of the needle. By contrast, when performing an OOP approach with the CU system, a mean of 4.5 ± 3.9 passes was required (P = 0.04). The mean of the differences for OOP approach was 3.5 (95% confidence interval [CI], 0.2–6.8). For IP approaches using the MGU system, inexperienced subjects also contacted the capsule with a single pass of the needle. When using the CU guidance system, however, the mean number of required passes was 3.8 ± 2.4 (P = 0.02). The mean of the differences for IP approach was 2.8 (95% CI, 0.8–4.7).

Experienced subjects also performed OOP approaches with a single pass using the MGU system. For this group, however, the mean number of passes required for the OOP approach using the CU was 3.4 ± 2.8 (P = 0.046). The mean of the differences for OOP approach was 2.4 (95% CI, 0.1–4.7). For IP approaches, experienced subjects were able to contact the capsule with a single pass using both the MGU and CU systems.

TABLE 1. Directional Accuracy (Mean Number of Passes ± SD)

	CU System	MGU System		Mean of the Differences (CI)
Inexperienced subjects (n = 8)				
IP	3.8 ± 2.4	1	P = 0.01	2.8 (0.8–4.7)
OOP	4.5 ± 3.9	1	P = 0.04	3.5 (0.2–6.8)
Experienced subjects (n = 8)				
IP	1	1	N/A	0
OOP	3.4 ± 2.8	1	P = 0.046	2.4 (0.1–4.7)

Positional (Needle Tip) Accuracy

The results for positional (needle tip) accuracy are summarized in Tables 2 to 4. In this phase of the evaluation, there were 3 possible outcomes. First, the needle could be advanced on a correct trajectory but make unintended contact with the capsule. Second, the needle could be advanced on a correct trajectory that was intentionally halted before contacting the capsule. Finally, the needle could be advanced on an incorrect trajectory that missed the capsule completely. Only those cases having a correct needle trajectory without contact between the needle tip and capsule were designated as accurate. The other outcomes (unintended contact, incorrect trajectory) were designated as inaccurate.

When analyzed using a McNemar table (Table 2), results demonstrated that inexperienced users positioned the needle more accurately during an OOP approach if using the MGU system (P = 0.03). For the IP approach, there was not a significant difference between the CU and MGU systems. The measured distances from the needle tip to the target (Table 3) for OOP needle placement were significantly lower when using the MGU system (Wilcoxon signed rank test P = 0.04). There were no significant differences in these measurements when using an IP approach.

For experienced subjects (Table 2), needle position was also more accurate with the MGU system during OOP approaches (P = 0.02). For the IP approach, there was not a significant difference between the CU and MGU systems. The measured distances from the needle tip to the target (Table 4) for OOP needle placement were significantly lower when using the MGU system (Wilcoxon signed rank test P = 0.02). There were no significant differences in these measurements when using an IP approach.

DISCUSSION

The MGU system evaluated in this trial is notable in that it provides a real-time display of the needle that is independent of the US beam. This is a significant departure from existing

TABLE 2. McNemar Table—Positional Accuracy

	CU (Accurate)	CU (Inaccurate)*	Total
Inexperienced (IP)			
MGU (accurate)	4	2	6
MGU (inaccurate)	0	2	2
Total	4	4	8
P = 0.5			
Inexperienced (OOP)			
MGU (accurate)	2	6	8
MGU (inaccurate)	0	0	0
Total	2	6	8
P = 0.03			
Experienced (IP)			
MGU (accurate)	6	2	8
MGU (inaccurate)	0	0	0
Total	6	2	8
P = 0.5			
Experienced (OOP)			
MGU (accurate)	1	7	8
MGU (inaccurate)	0	0	0
Total	1	7	8
P = 0.01			

*Inaccurate position indicates that there was either unintentional needle contact with the target or the trajectory of the needle missed the target.

Two-sided exact *P* value.

TABLE 3. Positional Accuracy for Inexperienced Subjects

	IP Outcome	OOP Outcome
CU	Unintended contact	Inaccurate trajectory
	Unintended contact	Accurate (4 mm)
	Accurate (3 mm)	Inaccurate trajectory
	Accurate (4 mm)	Unintended contact
	Accurate (4 mm)	Inaccurate trajectory
	Unintended contact	Inaccurate trajectory
	Unintended contact	Inaccurate trajectory
	Accurate (3 mm)	Accurate (3 mm)
MGU	Unintended contact	Accurate (1 mm)
	Accurate (2 mm)	Accurate (2 mm)
	Accurate (1 mm)	Accurate (3 mm)
	Accurate (2 mm)	Accurate (2 mm)
	Accurate (2 mm)	Accurate (3 mm)
	Unintended contact	Accurate (1 mm)
	Accurate (1 mm)	Accurate (3 mm)
	Accurate (2 mm)	Accurate (4 mm)

The distance from the needle tip to the capsule is recorded (mm) for cases where the trajectory was accurate and did not result in unintended needle contact.

Inaccurate trajectory was coded as infinite value and unintended contact was coded as zero. A Wilcoxon signed rank test with continuity correction was used to evaluate the distribution of values.

P = 0.38 for IP outcome for CU vs MGU.

P = 0.04 for OOP outcome for CU vs MGU.

TABLE 4. Positional Accuracy for Experienced Subjects

	IP Outcome	OOP Outcome
CU	Unintended contact	Unintended contact
	Accurate (5 mm)	Unintended contact
	Accurate (5 mm)	Unintended contact
	Unintended contact	Unintended contact
	Accurate (2 mm)	Unintended contact
	Accurate (2 mm)	Inaccurate trajectory
	Accurate (1 mm)	Accurate (2 mm)
	Accurate (1 mm)	Unintended contact
MGU	Unintended contact	Accurate (2 mm)
	Accurate (2 mm)	Accurate (2 mm)
	Accurate (1 mm)	Accurate (1 mm)
	Accurate (2 mm)	Accurate (1 mm)
	Accurate (2 mm)	Accurate (1 mm)
	Unintended contact	Accurate (1 mm)
	Accurate (1 mm)	Accurate (1 mm)
	Accurate (2 mm)	Accurate (1 mm)

The distance from the needle tip to the capsule is recorded (mm) for cases where the trajectory was accurate and did not result in unintended needle contact.

Inaccurate trajectory was coded as an infinite value and unintended contact was coded as zero. A Wilcoxon signed rank test with continuity correction was used to evaluate the distribution of values.

P = 0.46 for IP outcome for CU vs MGU.

P = 0.04 for OOP outcome for CU vs MGU.

technology such as beam steering and enhanced needle echogenicity that still require alignment of the needle within the US beam.[1,2,4]

Despite various attempts to improve beam technology and needle echogenicity, none of these has emerged as clearly superior for needle guidance. Ongoing research in this area[1,5–9] suggests that effective needle guidance is still an elusive goal for many clinicians. As seen in Figure 1, the MGU system does not differ in appearance from the transducer or needle used for CU. The proprietary technology of the MGU system incorporates all tracking components into a CU transducer that is used with a normal appearing, magnetized needle. Thus, the equipment used for this system did not create a technical challenge or make procedures more cumbersome. By contrast, other conceptually different magnetic guidance systems require additional equipment such as magnetic field generators and magnetic sensors attached to the block needle.[10–12]

When performing nerve blocks with CU systems, it becomes apparent that target imaging and needle imaging can be competing priorities. For example, after positioning the transducer to obtain an ideal target image, the operator may compromise that image as the transducer is moved to "see the block needle." This is especially problematic if clinicians must shift their gaze between the image screen and the transducer in an attempt to maintain simultaneous images of the needle and target.

With the MGU system, the needle position is accurately displayed on the US image regardless of its position relative to the transducer. An unexpected observation during the trial was that subjects using the MGU system were more likely to maintain their gaze on the US screen when advancing the needle as opposed to averting gaze between the needle and the US screen. By contrast, those using the CU system seemed to shift their gaze repeatedly between the needle and the US screen. However, because our digital recordings of the subjects were focused on the transducer and needle, we were unable to quantify eye or head movements during the procedure. We believe that additional trials focused on eye motion and gaze might demonstrate benefit in this area as well.

An important objective of this study was to compare clinically relevant aspects of the MGU and CU systems. Directional and positional accuracy are relevant to patient care and can be readily quantified. For example, the number of needle passes required to successfully position a block needle reflects both the skill of the clinician as well as the directional accuracy of the guidance system. For patients, multiple needle passes are not only uncomfortable, but may also cause trauma to surrounding anatomic structures.

For this trial, positional (needle tip) accuracy referred to the ability of the subject to place the tip of the needle in close proximity to the capsule without contacting it. Many US-guided procedures require the needle tip to be positioned in immediate proximity to structures such as nerves and blood vessels. As such, needle tip accuracy is important for successful block as well as to avoid painful paresthesias or injury to blood vessels. When using an IP or OOP approach with a CU system, any point at which the needle crosses the US beam can be mistaken for the needle tip. Because the needle image produced by MGU system is not subject to this type of misinterpretation, we postulated that it would more accurately reflect the position of the needle tip.

For inexperienced and experienced subjects using an OOP approach, a significant difference was observed in the measured distances between the needle tip and the target (Tables 3 and 4). This improved needle tip accuracy during OOP approach is notable because increased echogenicity does not reliably differentiate needle tip from shaft as it crosses the US beam.

There are at least 2 important limitations of our study. First, it was performed in a tissue model and does not reflect all of the variables present in a clinical setting. Additional research is necessary to determine if similar results can be produced in a patient-based model. Also, we note that bending of the needle can introduce errors in the display that are not present with a rigid needle. Although the MGU system includes algorithms designed to correct for needle bending, the algorithms were not evaluated in this trial. The 18-gauge needle used in this study is not likely to bend while passing through soft tissue. However, thinner needles such as those used to perform single injection nerve blocks might be affected by changes in trajectory.

In summary, the MGU system is noteworthy in its ability to project an accurate display of the needle that is independent of the US beam. This effectively reduces the competing priorities of visualizing the needle at the expense of the US target. Compared to CU, the MGU system improved directional as well as positional (needle tip) accuracy.

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