Needle tip visualization, although fundamental to the safety and efficacy of ultrasound-guided regional anesthesia (UGRA), can be extremely challenging with traditional block needles. This problem is most marked at steep insertion angles. Studies in synthetic and cadaveric UGRA phantom media demonstrate that echogenic needle designs have the potential to offer improved visibility and accuracy. However, the results of needle studies in phantom media need to be interpreted with caution because appearances in live human tissue can be very different. We compared the Pajunk Sonoplex Nanoline echogenic needle (Pajunk Medizintechnologie, Geisingen, Germany) against our standard nerve block needle, the Pajunk Uniplex Nanoline, in patients undergoing femoral and/or sciatic nerve block as part of their routine anesthetic management. These nerve blocks were chosen as common regional techniques that would provide a broad spectrum of needle insertion angles and target nerve depths.

Suggested limitations of UGRA research to date are that experts have conducted the blocks and that there has been a lack of randomized clinical trials. Our study design aims to address these issues and hence to maximize the external validity of our results. This work represents the first randomized controlled clinical trial of an echogenic needle in patients undergoing UGRA.

METHODS

Following Human Research and Ethics Committee approval, adult patients scheduled to undergo femoral (n = 30) or sciatic nerve blocks (n = 30) as part of their anesthesia were recruited (60 blocks total). Consecutive patients were approached with no selection criteria applied to minimize bias. Patients were excluded if they refused, were unable to give consent, or required a catheter technique or popliteal sciatic nerve block. In-plane ultrasound imaging was chosen as this provides the most relevant test of needle echogenicity. Catheter techniques were excluded as these require different needle designs, and there was no Sonoplex catheter needle in production at the time of our study. In addition to femoral nerve blocks, only proximal and mid-thigh approaches to the sciatic nerve were included in an attempt to maximize the range of target depths and needle insertion angles obtained. Nerve blocks performed with a low-frequency transducer (5 - 2-MHz) were excluded (see Discussion).

Study Equipment

The Sonoplex Nanoline needle (Pajunk Medizintechnologie) is the production model of a previously studied echogenic prototype. Both designs have performed well in cadaveric research by one of the authors (G.H.). It utilizes texturing of the needle surface with “cornerstone” reflectors. These indentations are specifically oriented to function best at steep needle insertion angles. The principle is the same as that used in bicycle reflectors, where light is reflected back to its source regardless of the angle at which it approaches. Two circumferential pattern-embossed sections, each 10 mm in length, are arranged at the distal end of the needle separated by an untextured segment (Fig. 1).

The Uniplex Nanoline needle (Pajunk Medizintechnologie) is a nonechogenic design that was previously used routinely for peripheral nerve blocks in the study institution. It differs from the Sonoplex needle only in its lack of echogenic texturing and as such was chosen as our control.
Although both are valid, it is important to understand which method is being used to allow comparison with previous work.

**Data Acquisition**

All anesthesiologists (specialists, fellows, and senior registrars) who use UGRA within our department were invited to take part, giving a range of technical skill. After written informed patient consent, individual nerve blocks were randomized to either a Sonoplex or a Uniplex needle using computer-generated block randomization and sealed envelopes. Needle length and gauge were standardized (femoral, 22-gauge 50 mm; sciatic, 21-gauge 120 mm). The patient, proceduralist, and clinician analyzing the data were blinded until the point of needle insertion. Because the 2 needles look identical at working distance, the proceduralist was discouraged from examining them more closely. Blinding was not always possible once imaging had commenced, as the echogenic needle looked obviously different if a good in-plane image was obtained. Once patients had been randomized to a particular needle, no further standardization of block technique was specified. The anesthesiologists were allowed to perform their standard in-plane technique without specific restriction. Nerve stimulation is available with both needles, but no anesthesiologist chose to use it during any of the blocks.

The ultrasound imaging from each nerve block was recorded onto DVD for later analysis. Recording commenced on skin puncture and stopped at the time of final needle removal (total block time). Following each block, the proceduralist was asked to subjectively score the percentage time he/she had visualized the needle tip (5-point scale: 1 = 0%–20%, 2 = 20%–40%, 3 = 40%–60%, 4 = 60%–80%, 5 = 80%–100%). Patient demographics and technical block details were recorded. All patients were followed up for complications via our local audit system as previously described in this journal.

Data on one block (Uniplex group) were rejected before analysis because of a change of proceduralist part-way through the procedure for clinical reasons (fellow substituted by supervising consultant). DVD recordings were checked intermittently by the principal investigator (S.H.) to exclude technical failures. Data on 2 further block procedures (Sonoplex group) were rejected through this process (DVD failed to record). Following completion of the study, 3 further blocks were randomized by an independent person to complete the required numbers.

**Review of Ultrasound Imaging**

On completion of data collection, all DVD footage was reviewed with Media Player Classic Home Cinema (http://mpc-hc.sourceforge.net/) by a single investigator (S.H.). Ultrasound imaging was displayed at half-speed, slowing to quarter speed and pausing as necessary to precisely define the presence or absence of the needle tip on the ultrasound imaging. This allowed measurement of the absolute time the needle tip was in view during each block to the nearest second (time in view). An objective measurement of percentage tip visibility was calculated for each nerve block (time in view / total block time × 100). Needle insertion angle relative to the surface of the transducer was measured to the nearest degree at the point of first perineural injection of local anesthetic. Depth from the surface to the center of the target nerve was recorded to the nearest 0.25 mm (scaled from ultrasound image to give true anatomical distance).

Needle insertion angle is critical to interpreting needle visibility research but can be expressed in 2 opposite ways. Most studies in UGRA, including this one, measure needle insertion angle relative to the skin/transducer surface, meaning zero is perpendicular to the beam. Radiologists usually describe the angle between the ultrasound beam and the surface of the needle (“angle of insonation” or “needle to probe angle”), which is parallel to the beam. Although both are valid, it is important to understand which method is being used to allow comparison with previous work.

**Power Calculation**

The primary outcome measure was percentage tip visibility, estimated subjectively and measured objectively. Study power was based on data from the subjective needle visibility study by Jandzinski et al. using an SD of 0.9 on a 5-point visibility scale and a difference of 1 point as being clinically significant. This was used as no method for the dynamic, objective measurement of needle tip visibility has previously been described. Calculation gave a minimum sample size of 30 block procedures, assuming data to be nonparametric. We applied this number to both femoral and sciatic blocks to allow independent analysis of each block type, giving a total sample size of 60 block procedures.

**Statistical Analysis**

Wilcoxon rank sum test was used to compare tip visibility data for the 2 groups. To determine the relationship between objective and subjective tip visibility, we divided the continuous measurements into the same categories as the grouped measurements and used Cohen weighted k for agreement. Linear regression was used to examine the impact of needle type (Sonoplex or Uniplex) and insertion angle on the objectively measured percentage tip visibility. The interaction between needle and insertion angle was considered to allow for uneven slopes, and other variables considered for potential inclusion.

**TABLE 1. Patient Demographics**

<table>
<thead>
<tr>
<th></th>
<th>Sonoplex</th>
<th>Uniplex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male, 15; female, 15</td>
<td>Male, 12; female, 18</td>
</tr>
<tr>
<td>Age, y</td>
<td>49 (21)–83</td>
<td>57 (21)–87</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>83.8 (20.9)</td>
<td>70.8 (17.1)</td>
</tr>
<tr>
<td>Height, m</td>
<td>1.69 (0.1)</td>
<td>1.68 (0.1)</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>29.0 (5.7)</td>
<td>25.0 (4.8)</td>
</tr>
</tbody>
</table>

Results are expressed as number or mean (SD) (range).

*Statistically significant difference.
in a final model were sex, age, weight, height, depth, ultrasound transducer, and block.

To assist statistical interpretation of the objectively measured data, we chose a range of angles to compare the groups. Subsequent to fitting the regression models, we examined this range of angles and compared the predicted mean visibility from the model at each angle.

**RESULTS**

Sixty nerve blocks were performed in 56 patients. Four patients underwent both femoral and sciatic nerve blocks, but all blocks were randomized independently. When sciatic and femoral data were assessed separately, there were no fundamental clinical differences. Combined data are therefore presented for clarity. Patient demographics are presented in Table 1. Sonoplex group had larger body mass index (mean, 29.0 vs 25.0 kg/m²; \(P = 0.01\)) and steeper needle insertion angle (mean, 31 vs 22 degrees; \(P = 0.03\)). As a teaching institution, most blocks were performed by anesthesia fellows (Sonoplex, 93%; Uniplex, 83%) rather than specialist anesthesiologists.

Subjective needle tip visibility data are shown in Figure 2. The Sonoplex group had better tip visibility, both subjectively and objectively (\(P = 0.002\)). Comparison of subjective and objective visibility measurements showed at best only moderate statistical agreement (Cohen weighted \(\kappa = 0.44\), overall proportion of measurements that agree 37%).

Needle type and insertion angle both had statistically significant effects on objective tip visibility (\(P = 0.0001\)) as shown in Figure 3. Tip visibility decreased with increasing insertion angle when using the control needle (\(P \leq 0.0001\)) (Table 2). No significant change in visibility was seen when using the Sonoplex (\(P = 0.95\)). Angle-specific comparison of tip visibility at 5, 20, 35, and 50 degrees showed significant difference at angles of 20 degrees or more (Table 3). When needle insertion angle was shallow (ie, virtually perpendicular to the ultrasound beam), there was little difference in tip visibility. At steeper angles (20, 35, and 50 degrees), the Uniplex needle showed significantly lower tip visibility than the Sonoplex.

An example of the visibility of the Sonoplex needle during a femoral nerve block is shown in Figure 4. Because the untextured segment of the Sonoplex needle is physically the same as the shaft of the Uniplex needle, this section demonstrates how visible a standard Uniplex needle would appear under the same conditions.

Target nerve depth, time to first needle tip visualization, and total block time were not significantly different between the 2 needles. Depth of target nerve did not significantly affect needle tip visibility over the range seen in our study (maximum, 4.6 cm). No other factor studied in the regression model influenced objective needle visibility. No block complications had

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**TABLE 2. Block Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Sonoplex</th>
<th>Uniplex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion angle, degrees</td>
<td>31 (16) (0–57)</td>
<td>22 (14) (5 to 50)*</td>
</tr>
<tr>
<td>Target nerve depth, cm</td>
<td>2.5 (0.9) (1.2–4.5)</td>
<td>2.2 (0.9) (0.8–3.8)</td>
</tr>
<tr>
<td>Time to 1st needle tip view, secs</td>
<td>15 (12) (4–57)</td>
<td>25 (27) (4–102)</td>
</tr>
<tr>
<td>Total block time, secs</td>
<td>174 (76) (72–426)</td>
<td>207 (118) (72–533)</td>
</tr>
</tbody>
</table>

Results are expressed as mean (SD) (range). *Statistically significant difference.

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**TABLE 3. Relationship Between Insertion Angle and Objectively Measured Percentage Tip Visibility**

<table>
<thead>
<tr>
<th></th>
<th>Sonoplex, %</th>
<th>Uniplex, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 degrees</td>
<td>55.6</td>
<td>57.3</td>
</tr>
<tr>
<td>20 degrees</td>
<td>55.4</td>
<td>39.6*</td>
</tr>
<tr>
<td>35 degrees</td>
<td>55.3</td>
<td>22.0*</td>
</tr>
<tr>
<td>50 degrees</td>
<td>55.1</td>
<td>4.3*</td>
</tr>
</tbody>
</table>

*Statistically significant difference.
DISCUSSION

Our study demonstrates improved tip visibility using an echogenic needle in actual clinical practice despite steeper needle insertion angles and larger body mass index. In contrast to previous studies, tip visibility with the Sonoplex needle was independent of insertion angle. Although nerves can often be approached with a shallow needle insertion angle, this is not always the case, and a needle that remains visible at steep insertion angles may further broaden the application of UGRA. We have noticed increased flexibility in our approach to nerves while using the Sonoplex. This may help explain the steeper mean insertion angle seen in the Sonoplex group (31 vs 22 degrees).

No standardized method for objective assessment of needle visibility exists. Most studies use subjective scoring systems with limited observer rating static images. Several groups have devised objective measures of needle visibility in still images. Our study includes, to the best of our knowledge, the first attempt to objectively quantify needle visibility on dynamic clinical imaging in patients. We focused solely on the needle tip, as this will be responsible for either therapeutic benefit or harm. Although interpretation of real-time ultrasound imaging remains unavoidably subjective, we considered a binary response (present or absent) at each point in time gave us the most pragmatic quantitative assessment of tip visibility.

Subjective tip visibility estimates consistently exceeded the corresponding objective measurements (mean difference when compared on same 5-point scale = +0.83). This is likely to represent the operator’s overall confidence, rather than corresponding accurately to specific tip visibility. Accuracy will also be limited by the fact that, during clinical practice, the proceduralist must focus foremost on the patient and the procedure. Given this, our objective method represents a step toward more accurate assessment of needle visibility and may prove valuable in comparing the evolving UGRA needle technologies. It also raises potential methodological problems for studies relying on subjective measures alone.

Mean objective tip visibility was relatively low (46.1%). This is likely, in part, to reflect the fact that nonexperts performed the majority of blocks (see Results). Scanning is a dynamic process, and there will inevitably be times when the tip is lost from view, particularly while learning. Tip visualization improves with experience, although data show that the problem can persist after more than 100 UGRA procedures. However, our data are likely to be more representative of actual clinical practice than studies showing data obtained during UGRA performed exclusively by international experts. Experienced operators often use surrogate markers of tip position such as local tissue movement, hydrolocation, or fascial pops, or combined nerve stimulation, particularly when imaging is poor. Hence, even experts may not actually achieve 100% needle tip visibility. Another factor that will impact on measured tip visibility are the predictable and often deliberate periods where the needle was not in view, such as from skin puncture to first needle tip visualization (mean, 11% total block time). Understandably, proceduralists are cautious until they gain their initial needle image. Although this time may seem long, it occurs when the needle is usually still within subcutaneous tissue and is therefore unlikely to cause harm. Dynamic scanning along the axis of the target nerve was often noted, which, in the authors’ experience, is performed to further confirm local anatomy or assess local anesthetic spread. This is acceptable provided no needle movement occurs during this time but will reduce the objectively measured tip visibility measurement. We chose not to remove these time periods and rather present the blocks in their entirety as this better reflects actual clinical practice.

The study has several limitations. Blinding was challenging because the 2 needles have different sonographic appearance. If a good in-plane image was obtained, then the needle in use may have been evident to both the proceduralist and the author reviewing the imaging. There was no way of avoiding this. Our results cannot necessarily be extrapolated to predict the performance of Sonoplex needles when using other ultrasound equipment. The dimensions of the cornerstone reflectors that are fundamental to this echogenic technology are determined by the frequency of the ultrasound with which they are designed to work. Lower frequencies require broader dimensions, but these are limited by the wall thickness of the needle. This may explain why similar echogenic technologies have failed to perform in the field of interventional radiology, where target depths are greater and lower frequencies are required. Needle type can never be fully isolated from potential confounding factors with such an open study design, but their effects should be minimized by randomization. Our approach aimed to assess needle performance in actual clinical practice to make the results more relevant to our fellow anesthesiologists. Such methodology may struggle when differences in needle performance are less marked. Although no block complications were identified, the study was not powered to assess either block efficacy or safety. Such clinical end points are important in the assessment of new UGRA technology, but much larger studies are required.

CONCLUSIONS

The Sonoplex echogenic needle is more visible than its nonechogenic counterparts during in-plane ultrasound-guided femoral or sciatic nerve block. Measured needle visibility is essentially independent of needle insertion angle. This may be

FIGURE 4. Ultrasound image of a femoral nerve block using a Sonoplex needle. The untextured segment (small arrow) demonstrates how visible a Uniplex needle may be in the same conditions. FA indicates femoral artery; IL, iliacus muscle; FN, femoral nerve; large arrow, needle tip; small arrow, untextured segment.
useful when performing UGRA at steeper needle insertion angles. Our novel method for the dynamic, objective measurement of needle tip visibility in clinical practice may prove useful in the assessment of future echogenic needle technology.

ACKNOWLEDGMENTS

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REFERENCES


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