

# Two-dimensional mapping to assess direction and magnitude of needle tip error in ultrasound-guided regional anaesthesia

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## SUMMARY

*We assessed whether echogenic needles reduce tip location error, by comparing three echogenic designs (Pajunk Sonoplex, Lifetech, B. Braun Stimuplex D+) with a non-echogenic control (Pajunk Uniplex), using a novel assessment technique in unembalmed human cadavers. Multiple images were taken of each needle at shallow (15 to 25°), moderate (35 to 45°) and steep (55 to 65°) insertion angles. Twenty anaesthetists with varied experience in ultrasound-guided nerve blocks identified needle tip position and stated their confidence level in estimates. Actual tip position was determined at the time of image generation but concealed from the anaesthetists. Two-dimensional mapping of 'tip-error' involved measurement of the distance and orientation of each clinician's estimate of tip position in relation to the actual tip position. There were no significant differences in confidence or overall needle visibility at shallow insertion angles. At steeper angles, the Sonoplex showed significantly higher confidence and visibility scores. The remaining echogenic designs did not show any significant differences from the non-echogenic control. Objective measurements of tip error followed the same pattern as the subjective data, although were not universally significant. Two-dimensional mapping showed that as needle visibility deteriorated, so precise tip location was lost but the needle shaft/insertion path remained well-identified. As visibility deteriorated further, accuracy in this axis was also lost. When inaccurate, clinicians generally assessed the needle tip to be more superficial and inserted less far than it actually was. This has important implications for the safety of ultrasound-guided regional anaesthesia. Effective echogenic needle technology has the potential to address these concerns.*

**Key Words:** regional anaesthesia, peripheral nerve block, needle visualisation, ultrasound, error

Accurate needle tip imaging is fundamental to safe and effective ultrasound-guided regional anaesthesia<sup>1</sup>. This task becomes progressively more challenging at steeper needle insertion angles<sup>3,11</sup>. This problem is not new and has been the motivation behind a significant body of research in interventional radiology over the last two decades<sup>4,5,9-19</sup>. Technologies to increase ultrasound visibility have been investigated, with echogenic needle designs proving to be one of the more successful areas of research<sup>4,10,12,18,19</sup>. While advances have been made, some consider the problem to be largely unresolved<sup>6</sup>. Research from our own institution has demonstrated the potential of echogenic technology when

compared to standard needle designs<sup>3,20</sup>. In this study, we used a progression of previous methodology to provide a two-dimensional ultrasound visibility assessment of three echogenic needles in unembalmed human cadavers. Our aim was to use this information to determine the direction and magnitude of tip location error and whether this was affected by needle design.

## METHODS

The study was conducted following ethical approval from the Fresh Frozen Cadaver Committee of the University of Western Australia. The methodology was developed from our previous needle visibility work<sup>3</sup>, with the aim of making a two-dimensional ultrasound assessment of needle tip localisation error.

### *Study needles*

Samples of currently available echogenic needles were obtained from the manufacturers and tested alongside a non-echogenic control. The manufacturers had no influence on any aspect of study design or data analysis. Three of the needles have specific echogenic designs while the fourth has none.

Parts of the data were presented as a poster at the Australian Society of Anaesthetists National Scientific Congress, Melbourne, 2-5 October 2010.

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The 22-gauge Sonoplex Nanoline® needle (Pajunk Medizintechnologie, Geisingen, Germany) is the production model of a previously-studied echogenic prototype<sup>3</sup>. Both the prototype and production model have previously performed well in cadaveric research<sup>3,20</sup>. The needle uses texturing of the needle surface with ‘cornerstone’ reflectors. These indentations are specifically orientated to function best at steeper needle insertion angles. The physical 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.

The 22-gauge Stimuplex D+® needle (B. Braun, Melsungen, AG, Germany) is an echogenic design that uses an echogenic texturing method with the pattern arranged over a 20 mm length at the distal end of the needle. Indentations are designed to reflect part of the ultrasound beam back to the probe, even at steep angles.

The 21-gauge LifeTech® (LifeTech Inc., Stafford, Texas, USA) is a prototype echogenic needle design with texturing applied by circumferential laser etching of the distal 12.7 mm of the shaft, starting 3 mm from the needle tip. A 22-gauge version was not available.

The 22-gauge Uniplex Nanoline® (Pajunk Medizintechnologie, Geisingen, Germany) is a non-echogenic version of the Sonoplex that is used as standard for single-shot peripheral nerve blockade in the study institution and was thus chosen as the control.

#### *Image acquisition*

All ultrasound images were obtained using a single Sonosite M-Turbo® system (Sonosite, Bothell, Washington, USA), high frequency 13 to 6 MHz linear array transducer and standard ultrasound gel. Image depth and software settings (‘nerve’ and ‘resolution’) were standardised. Needles were inserted to a maximum needle depth of 4 cm in the subgluteal region of first-thaw unembalmed cadavers, avoiding areas of previous needle insertion. Standardised insertion length isolated the angle as the major variable, confirmed with a protractor relative to the skin/transducer surface. Tip placement near a structure was avoided as this may have provided additional information about tip location to observers. The subgluteal region allowed adequate muscle depth for a range of insertion angles within the same muscle area. Most needle trajectories in clinical practice will pass through muscle to the nerve;

hence this was chosen as the best tissue in which to image the needle. The maximum depth would be comparable to infraclavicular or sciatic blocks, both of which often require steep approach angles depending on technique<sup>21</sup>.

Thirty-six images were obtained, consisting of three images of each test needle at three insertion angles: steep (55 to 65°), moderate (35 to 45°) and shallow (15 to 25°). The shallow angles would be comparable to those required for interscalene or supraclavicular blocks. The moderate angle would be similar to that used for a femoral nerve block. One researcher experienced in ultrasound-guided regional anaesthesia generated all images. Needle and transducer were manipulated to obtain the best possible image of the needle and bevel in a long axis view. At this point the image was frozen and one image saved. We marked our best estimate of needle tip position based on the dynamic study and a second image was saved. For simplicity of expression, this will be described as “actual tip position” throughout the study, although this will be discussed in the limitations.

#### *Image review by clinicians*

Twenty clinicians with regular experience in ultrasound-guided regional anaesthesia agreed to participate. Each received a standardised introduction. The characteristics of each needle were described along with example ultrasound images of each. Study images were digitally stored and presented in random order as a PowerPoint presentation (Microsoft Corporation, Redmond, Washington, USA). The presentation was such that two identical images (with and without the tip marked) were exactly superimposed; the unmarked covering the marked. The observer moved a marker on the screen to precisely where they felt the tip was located on the unmarked image and expressed how confident they were in their estimate (‘very’, ‘moderately’ or ‘not’) for each image. They also provided a subjective score of overall needle visibility for each image (‘not seen’, ‘poor’, ‘acceptable’ or ‘very good’). Observers did not know which needle or insertion angle was used for any image. Presentations were viewed on a single 15-inch Inspiron 1520 laptop (Dell Corporation Ltd, Bracknell, UK), under standard lighting conditions. In this way, image quality was felt to reproduce that seen on the ultrasound machine screen, rather than using printed images. No time limit was imposed and all observers viewed all 36 images. At the end of the assessment, the unmarked images in the presentation were deleted leaving the marker overlaying the concealed marked image.

### Data analysis

For each marked image, the distance between estimated and actual needle tip positions (referred to as “overall tip error”) was measured, along with the orientation of this error (angle in degrees) in relation to the needle tip. Given the image magnification on the screen, we considered marker placement and measurements accurate to 0.5 mm and angle measurements accurate to five degrees. From this data we calculated the co-ordinates of each estimated tip position in relation to actual tip position. The x-value represents tip error along the axis of the needle shaft and the y-value represents tip error perpendicular to this, with the origin sited at the actual tip position. This methodology allowed assessment and analysis of the data in two dimensions. Since all needles were imaged ‘in-plane’, error in the third dimension was not considered.

### Confidence and visibility scores

A linear mixed model approach was used to determine the effect of needle type and needle angle on the confidence and visibility scores provided for the 36 images by the 20 assessors. An appropriate covariance structure was used to account for the repeated measures on the same images by the clinicians.

### Analysis of x-error, y-error and overall tip error

A linear mixed model approach was used to determine the impact of needle type and insertion angle on x-error, y-error and overall tip error separately. For analysis purposes, maximum tip errors

were imputed for images where a clinician was unable to locate the needle tip at all. Due to the skewed distribution of the data, all analysis was undertaken on log-transformed values.

## RESULTS

All 20 clinicians completed the study presentation.

### Analysis of confidence and visibility

At 20° there were no significant differences in confidence or overall visibility between the four needles ( $P > 0.1$  for all analyses). At steeper angles, there was significantly higher confidence and visibility with the Sonoplex needle compared to all other needles (confidence, all  $P < 0.05$ ; visibility, all  $P < 0.001$ ). The remaining echogenic designs did not differ significantly in terms of confidence or visibility scores from the non-echogenic control ( $P > 0.05$  for all analyses). Confidence scores at all angles for all needles are shown in Figure 1.

### Tip errors in x and y direction and overall

The two-dimensional tip error for all needles and insertion angles (Figure 2) ranges from  $\pm 30$  mm in both axes. Data points to the left of the y-axis represent an underestimate of the length of needle inserted – the needle tip was inserted further than the clinician realised. Data points above or below the x-axis represent failure to recognise the needle trajectory, because the shaft lies directly along this axis. Data points in the upper left quadrant represent the greatest risk to patient safety because in this position, the needle was inserted further and deeper than the clinician realised.

In 41 of 720 estimates the marker was left in the default position, as the clinician had no idea where to place it (Sonoplex  $n=0$ , B. Braun  $n=19$ , LifeTech  $n=8$ , Uniplex  $n=14$ ). No difference in overall tip error was observed at shallow insertion angles. Sonoplex overall tip error at 40° was significantly less than either the B. Braun ( $P=0.029$ ) or the Uniplex needle ( $P=0.024$ ). At 60°, the Sonoplex overall tip error was significantly less than either the B. Braun ( $P=0.007$ ) or the LifeTech tip error ( $P=0.001$ ).

No significant differences in x-error were observed in any of the four needles at 20°. At 40° x-error for the Sonoplex needle was significantly less than for the B. Braun ( $P=0.001$ ) and Uniplex ( $P=0.015$ ), but not the Lifetech needle ( $P=0.11$ ). At 60° x-error for the Sonoplex needle was significantly less than the B. Braun ( $P=0.004$ ) and the Lifetech ( $P=0.002$ ), but not the Uniplex needle ( $P=0.21$ ). No significant differences in y-error were observed between any needle at 20° or 40°. At 60° y-error for the Sonoplex

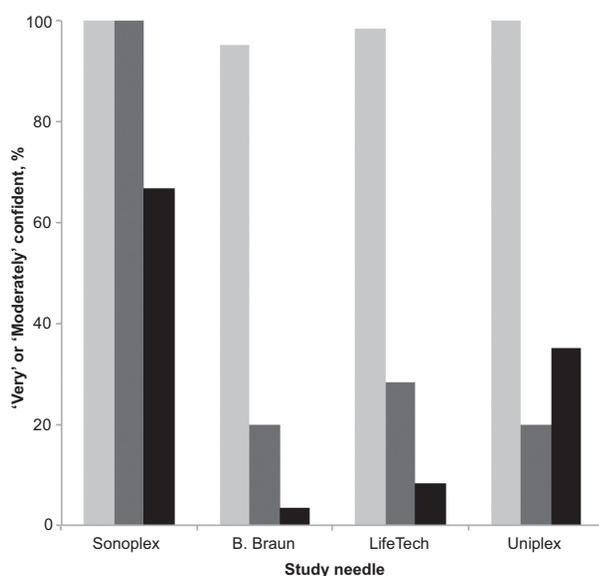


FIGURE 1: Summary of confidence data for each study needle at each insertion angle. Light grey=20°, mid-grey=40°, dark grey=60°.

needle was significantly less than all other needles ( $P < 0.001$  for all analyses).

DISCUSSION

Two-dimensional analysis of tip error revealed interesting patterns. As needle visibility starts to deteriorate, the clinician loses the distinction of the tip from background tissue but can still make out the path of the needle shaft therefore increasing x-error, but not y-error. Once needle imaging has deteriorated to the point of virtual invisibility, the clinician also

loses track of the needle shaft and tip localisation becomes guesswork: a combination of both x and y-error.

Another relatively consistent pattern of inaccuracy was seen in the estimates of needle tip location. Where needle tip location was incorrect, the needle was most frequently located deeper and further than the clinicians estimated. This is not an isolated finding and has important safety implications<sup>22,23</sup>. A needle inserted deeper and further than intended may damage underlying anatomical structures or lead to

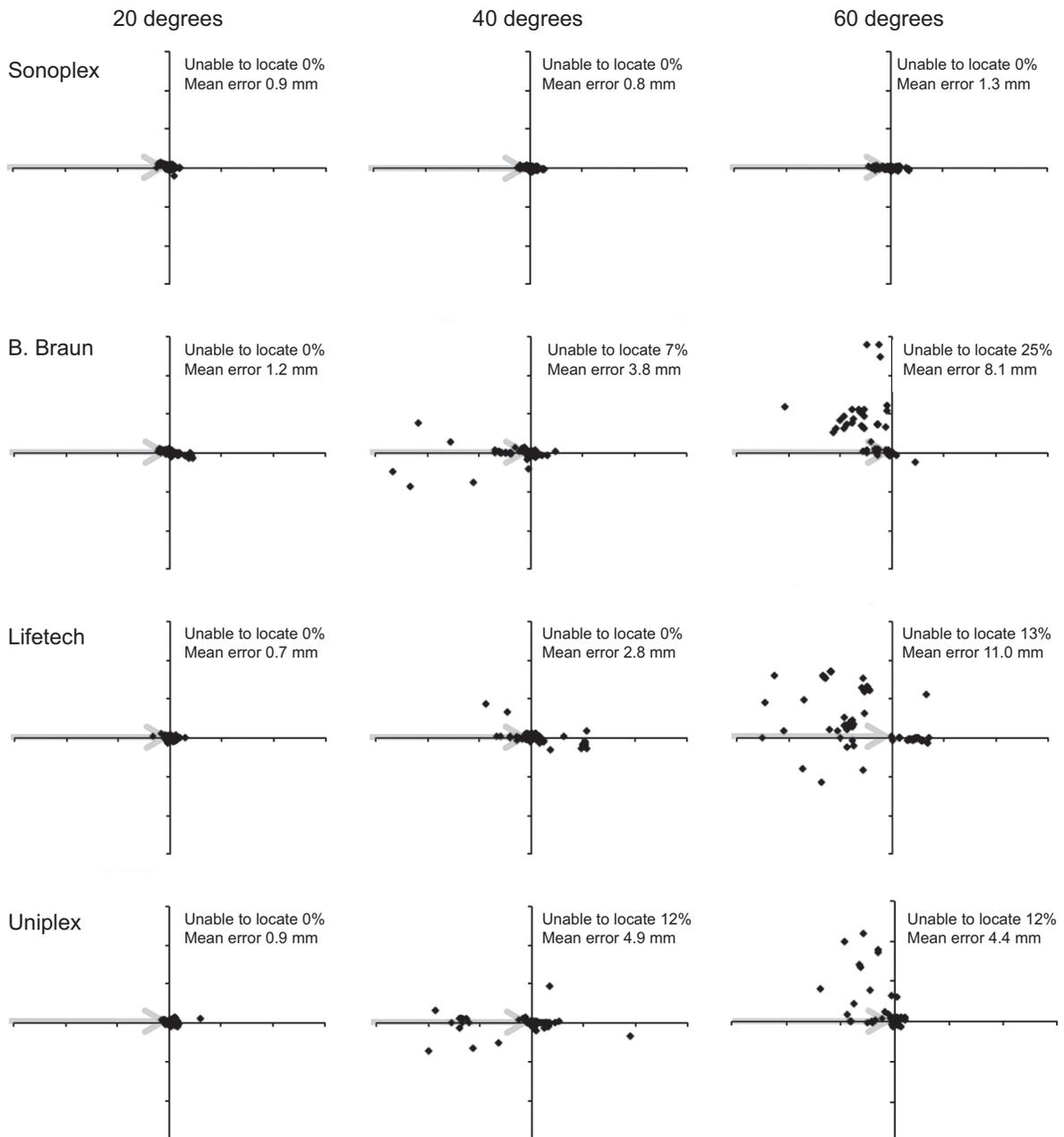


FIGURE 2: Two-dimensional estimates of needle tip location. Graphs show results for each needle at each insertion angle. The needle shaft is represented by the grey arrow; actual tip location centered on the graph origin. The axis scale is -30 to +30 mm.

local anaesthetic injection at an unintended location. Such complications could potentially be minimised by effective echogenic needle technology, as seen in our results.

Studies in ultrasound needle visibility from both the anaesthetic and the radiology literature are limited by the lack of a consistent, objective assessment tool for needle visibility and also a standard phantom medium<sup>4,6-8,10</sup>. Objective estimates of needle brightness (pixel density and optical density units) have been described<sup>7,24,25</sup>. By asking clinicians to locate the needle tip in a series of images, we endeavoured to obtain a clinical assessment of needle performance. Potential refinements to our method could be to show a video clip of the ultrasound imaging and then stop it on a still image before asking the observer to mark the tip location. This represents clinical practice more accurately but may introduce the influence of observer skill levels, rather than testing the needle technology in isolation. Others, as well as ourselves, have previously stated that the substance in which visibility is tested is fundamental to needle performance<sup>6,11,26</sup>. Needle visibility is determined by the difference between the background echogenicity of the test-medium and the echogenicity of the needle. Visibility in a less-echogenic media (e.g. gelatin) can be heightened by the use of image optimisation technology, now available on most ultrasound machines. In the highly echogenic background of human tissue, this effect is far less marked. As previously, we tested these needles in cadaveric tissue rather than live human tissue<sup>3</sup>. While we have previously demonstrated that in vivo comparison of needles is possible<sup>20</sup>, we suggest that multiple needle comparison is generally impractical in patients and unethical in volunteers. Testing new needle technology in a 'next best' phantom medium, such as a first-thaw unembalmed cadaver, seems the logical step prior to progression to randomised clinical trials.

Due to inherent subjectivity in the interpretation of all ultrasound imaging, there will inevitably be some error in the assessment of the "actual tip position" that we defined. Identification of "actual tip position" was reliant on one operator, in agreement with a second clinician. Neither was blinded to which needle was being examined (as this would have been difficult to achieve), so subconscious bias during image generation cannot be excluded. Although this study was conducted using static images, we suggest that the results are relevant to clinical practice because all needles were assessed under the same conditions.

This study suggests that as needle visibility deteriorates, needle tip error increases and clinicians

may be more likely to underestimate how far and how deep the needle tip has been inserted. This has important safety implications and may lead clinicians to consider the use of echogenic needles. However, not all designs offer the same benefit in visibility or the accuracy of needle tip location over non-echogenic needles. Our methodology and the suggested refinements offer possibilities for the assessment of future needle designs.

#### ACKNOWLEDGEMENTS

We wish to thank the anaesthetists at Sir Charles Gairdner Hospital for their co-operation. We had intended to include the Hakko Echostim needle in our study<sup>27</sup>. Unfortunately, the product samples were received too late for inclusion in this study but its visibility has been assessed previously at our institution<sup>3</sup>.

#### DISCLOSURE

The anaesthetist who designed the Pajunk Sonoplex needle works part-time within the same Department of Anaesthesia as the authors. He was given no opportunity to contribute to study design, execution, data analysis or conclusions. The authors have no financial or other interest in the needle, nor do they have any financial or other affiliation with Pajunk.

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