

Prospective randomized evaluation of the sustained impact of assistive artificial intelligence on anaesthetists' ultrasound scanning for regional anaesthesia

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ABSTRACT

Objectives Ultrasound-guided regional anaesthesia (UGRA) relies on acquiring and interpreting an appropriate view of sonoanatomy. Artificial intelligence (AI) has the potential to aid this by applying a color overlay to key sonoanatomical structures.

The primary aim was to determine whether an AI-generated color overlay was associated with a difference in participants' ability to identify an appropriate block view over a 2-month period after a standardized teaching session (as judged by a blinded assessor). Secondary outcomes included the ability to identify an appropriate block view (unblinded assessor), global rating score and participant confidence scores.

Design Randomized, partially blinded, prospective cross-over study.

Setting Simulation scans on healthy volunteers. Initial assessments on 29 November 2022 and 30 November 2022, with follow-up on 25 January 2023 – 27 January 2023.

Participants 57 junior anaesthetists undertook initial assessments and 51 (89.47%) returned at 2 months.

Intervention Participants performed ultrasound scans for six peripheral nerve blocks, with AI assistance randomized to half of the blocks. Cross-over assignment was employed for 2 months.

Main outcome measures Blinded experts assessed whether the block view acquired was acceptable (yes/no). Unblinded experts also assessed this parameter and provided a global performance rating (0–100). Participants reported scan confidence (0–100).

Results AI assistance was associated with a higher rate of appropriate block view acquisition in both blinded and unblinded assessments ($p=0.02$ and <0.01 , respectively). Participant confidence and expert rating scores were superior throughout (all $p<0.01$).

Conclusions Assistive AI was associated with superior ultrasound scanning performance 2 months after formal teaching. It may aid application of sonoanatomical knowledge and skills gained in teaching, to support delivery of UGRA beyond the immediate post-teaching period.

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Performance of ultrasound-guided regional anaesthesia (UGRA) relies on the correct identification of sonoanatomical structures.
- ⇒ Commercial artificial intelligence (AI) systems for regional anaesthesia are available that produce a color overlay on real-time ultrasound scans.

WHAT THIS STUDY ADDS

- ⇒ 57 junior UK anaesthetic trainees performed ultrasound scanning for six plan A peripheral nerve blocks at two time points: immediately after teaching and at a 2-month follow-up. Half the scans by each participant were randomly allocated to AI assistance, and the other half without, at each time point.
- ⇒ Acquisition of an appropriate block view, participant confidence and expert global rating of participants showed improvement when scanning with AI assistance.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Such devices may aid the delivery of UGRA beyond the immediate post-teaching period and support clinical practice in competent non-expert practitioners.

Trial registration number [NCT05583032](https://www.clinicaltrials.gov/ct2/show/study/NCT05583032).

INTRODUCTION

Acquisition of an appropriate ultrasound view and the identification of key sonoanatomical structures on that view are essential skills in ultrasound-guided regional anaesthesia (UGRA).^{1–3} This can be challenging,⁴ particularly to non-experts, and anatomy varies within and between patients.^{5–7}

Several recent studies have investigated the potential of using artificial intelligence (AI) to support ultrasound image interpretation in UGRA.^{8–17} Systems have recently become commercially available for this purpose, which applies an AI-generated color overlay on a real-time ultrasound feed, with the intention of highlighting anatomical structures of interest to aid identification.

We have previously demonstrated that the use of an AI-generated color overlay was associated with improved ultrasound scanning performance for six plan A blocks when assessed immediately after formal teaching.¹² However, further assessment of such assistive AI is needed—both to validate initial findings and to determine whether these benefits are maintained beyond the initial period. The latter is important, as opportunities for clinical UGRA performance can be sporadic and retention of knowledge following teaching (eg, via course attendance) fails with time. The present investigation is a randomized, partially blinded prospective study, which evaluates peripheral nerve block (PNB) ultrasound scanning performance by a cohort of anesthetists in their first 3 years of training over a period of 2 months, with and without the use of assistive AI. The primary aim was to determine whether use of the AI-generated color overlay was associated with a difference in participants' ability to identify an appropriate block view in the context of a 2 month follow-up period, as determined by a blinded assessor. Secondary outcomes similarly included the ability to identify an appropriate block view, as determined by a separate unblinded assessor (in real time). The real-time unblinded assessor also provided a global rating score of participant scanning performance, and participants provided confidence scores (all at time 0 and at 2 months).

METHODS

Non-expert participants

57 anesthetists provided written informed consent to participate in the study and were compensated for their time (attendance at a Regional Anaesthesia UK meeting and an incentive to return for the second assessment). All were in their first 3 years of UK anaesthesia training (Core Anaesthesia and Acute Care Common Stem Training) and with limited UGRA experience. Further information on participant background and prior UGRA experience is contained in online supplemental file 1.

Expert participants

Nine experts in UGRA participated in the study; three (AJRM, DB-SL and NH) provided teaching and acted as blinded assessors, six (AP, SW, TA, MPS, AT and JW) undertook unblinded real-time assessments of the participants. To be consistent with our prior study,¹² all expert assessors had completed advanced training in UGRA and/or hold a dedicated qualification in UGRA, regularly delivered direct clinical care using UGRA (including

for 'awake' surgery) and regularly delivered teaching on UGRA (including advanced techniques).

Subjects

11 healthy volunteers were recruited for ultrasound scanning and compensated for their time. The only exclusion criterion was known pathology of the areas to be scanned.

Equipment

Ultrasound scanning was performed using an L15–4 linear probe on the PX SonoSite ultrasound machine (Fujifilm SonoSite, Bothell, Washington, USA).

The AI color overlays were generated by ScanNav Anatomy Peripheral Nerve Block (ScanNav; Intelligent Ultrasound, Cardiff, UK); these correspond closely with recommendations on structure visualization for the plan A and plan BCD blocks in UGRA.^{18–20} ScanNav (CE V.2.0) was connected to the high-definition multimedia interface output of each ultrasound machine, to display the same ultrasound image with the superimposed associated AI-generated color overlay. Further detail on ScanNav has been reported elsewhere.^{4,9–12,21}

Teaching

To minimize the effect of differing scanning techniques on the outcome measures, participants attended a standardized 2-hour teaching session (by AJRM, DB-SL and NH) which defined a consistent scanning approach for each PNB. Six plan A blocks²⁰ were considered: interscalene-level and axillary-level brachial plexus, erector spinae plane, femoral nerve, adductor canal and popliteal-level sciatic nerve blocks. As with the previous study,¹² participants were taught to identify a recommended series of structures for the 'block view' of each block (summarized in online supplemental file 1). These views are based on previously published criteria, endorsed by the UK, European and American specialty societies in regional anaesthesia and illustrated in educational material endorsed by the European Society of Regional Anaesthesia.^{19,22} Of note, the axillary vein(s), a strong recommendation for identification on the block view in the axillary-level brachial plexus block, was not included in this study as ScanNav does not identify it. The teaching included familiarization with ScanNav, so participants were familiar with the device prior to the first assessment.

Sequence of assessment

Assessments were conducted at two time points: immediately after teaching (time zero) and at a 2-month follow-up. The initial assessments (at time zero) were conducted over 2 days (29 November 2022 - 30 November 2022). Participants sequentially performed a scan for each of the six PNBs listed above while being assessed by an unblinded expert (AP, SW, TA, MPS, AT and JW). Each participant, therefore, completed six scans and had one opportunity to scan each anatomical area corresponding to the relevant PNB. To ensure that half of the six scans completed by every participant were performed with the aid of AI assistance and half without, participants were

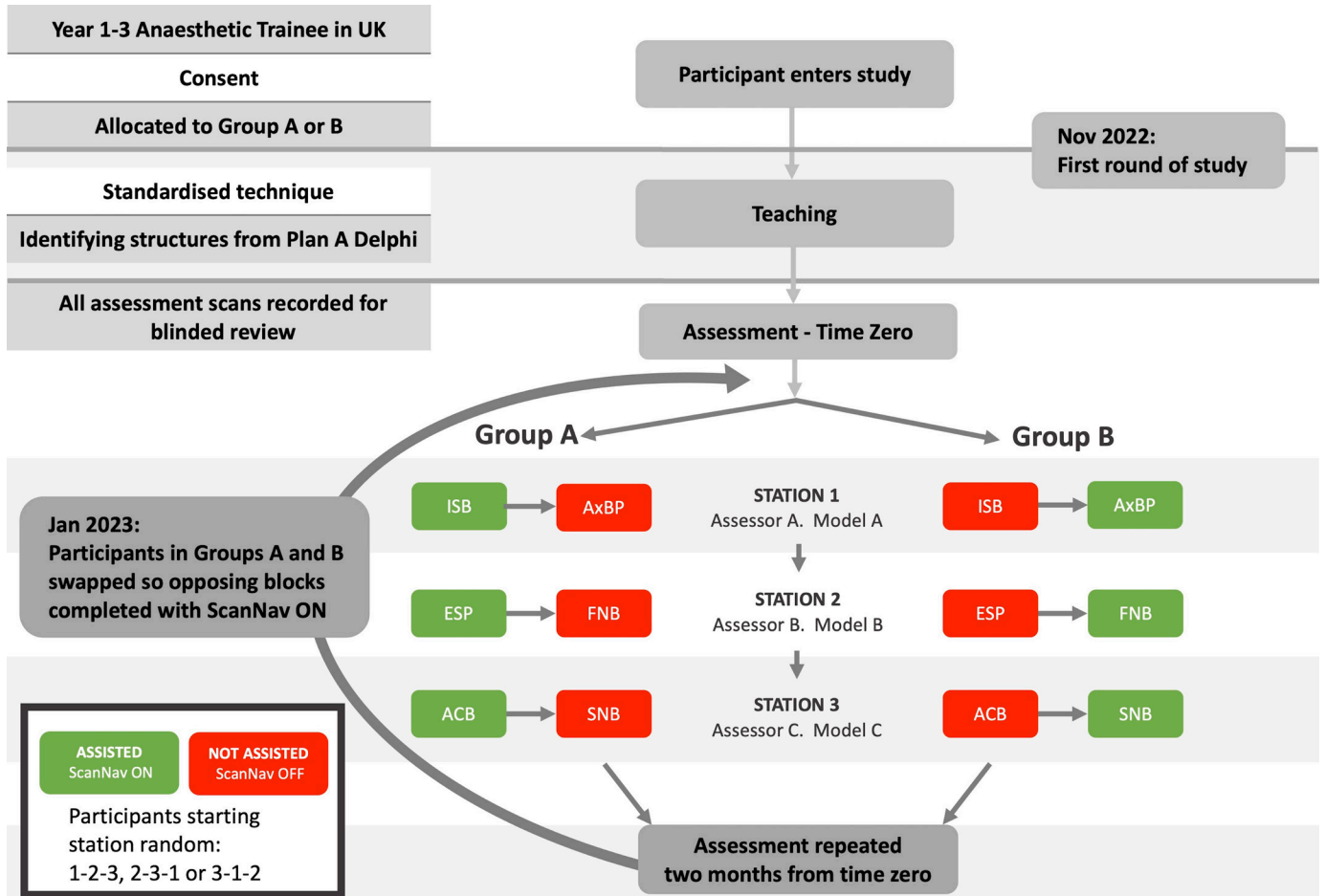


Figure 1 Flow diagram of participants' progress through the study. ISB, interscalene-level brachial plexus block; AxBP, axillary-level brachial plexus block; ESP, erector spinae plane block; FNB, femoral nerve block; ACB, adductor canal block; SNB, popliteal-level sciatic nerve block.

randomized (in alternating order based on study enrolment) to performing their first scan either with (AI-assisted) or without (AI-unassisted) ScanNav. Subsequently, they alternated between with and without ScanNav for the remaining scans.

An unblinded assessor evaluated participants for two of the six scans, which were performed on one subject. This process was repeated with two other assessor/subject pairs, giving a total of six scans, with three assessors and three subjects (figure 1). The same assessment process was conducted for the 2-month assessment (without further teaching), conducted over a period of 3 days (25 January 2023 – 27 January 2023).

For each participant, scans performed with ScanNav at time 0 were performed without at 2 months and vice versa. Participants therefore never used AI assistance when scanning for the same blocks at the initial and follow-up assessments, nor did they scan the same body region corresponding to each PNB on the same subject more than once.

Assessment: primary outcome endpoint

The primary outcome of this study was the acquisition of an appropriate block view (with vs without AI assistance),

as determined by the blinded assessment. To enable this, the participant declared when they had obtained the block view when scanning for each PNB, at which point an assistant froze the ultrasound image. Recordings of these scans (from both time 0 and 2 months) were later shown to three blinded assessors (AJRM, DB-SL and NH). All three experts viewed every scan; they were shown the unmodified ultrasound scans (without AI highlighting) and informed of which PNB was being scanned for. They were blinded to whether AI assistance was used in acquiring the scan, as well as to the results of the unblinded expert assessment at the time and the results of the other blinded assessments. Each blinded expert, therefore, made an independent decision on whether the final frozen image represented an appropriate block view (yes/no). The block view was deemed appropriate if all strong recommendation structures¹⁹ demonstrated in the prior teaching were in view. In each case, a majority opinion was taken (agreement of at least two blinded assessors).

Assessment: secondary outcome endpoints

The secondary outcomes included acquisition of an appropriate block view, as assessed by the unblinded

assessor in real time. After determining whether the acquired view was appropriate for that PNB, the unblinded assessor asked the participant to indicate their confidence on a continuous scale from 0 to 100 (0=low confidence, 100=totally confident). They then gave the participant a global rating score for the overall scan performance for that scan on a continuous 0–100 scale (0=poor, 100=excellent). To avoid influencing subsequent performance, participants were not made aware of their results at any point. These assessments were not blinded to use of ScanNav as it was adjacent to the ultrasound machine during scanning. None of these assessors participated in the earlier teaching or contributed to the development of ScanNav.

Participants were also asked to identify each strong recommendation structure for that PNB.¹⁹ Participants were allowed to refer to the separate AI colour overlay screen if randomized to using ScanNav during the scan and assessment but were required to identify individual structures on the original unmodified frozen image displayed by the ultrasound machine. The unblinded assessor recorded whether each structure identified was correct (yes/no). These data are described in online supplemental file 1.

Sample size, data handling and analysis

Based on our previous study¹² and pilot data from a limited follow-up of these participants, the investigators estimated that at least 33 participants (200 scans) would be required for the primary outcome to reach statistical significance (see online supplemental file 1). As it was difficult to estimate the attrition rate for follow-up assessment, the team aimed to maximize recruitment at the initial stage, to allow for drop-out of participants.

Data were recorded digitally on Microsoft Power Apps and stored in Microsoft Lists, before being transferred to Excel. A small number of data points were lost/not acquired during the study (134/4772; 2.81%)—these are described in online supplemental file 1. Data are reported descriptively and, where appropriate, statistical evaluation (using R software V.4.2.0) was used to assess the relationship between variables. Generalized Estimating Equation analyses were undertaken using Generalized Linear Models to account for potential within-subject correlation, given that repeated measures were taken from each trainee and subject being scanned. Statistical significance was deemed as $p < 0.05$.

Patient and public involvement

As this was an early-stage, exploratory investigation in a simulation setting, patients and the public were not involved in this study.

Reporting

This study is reported in accordance with the Consolidated Standards of Reporting Trials-AI and DECIDE-AI guidelines.^{23 24}

Table 1 Blinded reviewer assessments (648 scans performed; loss of recording/file corruption (26) and removal of scans without real-time unblinded expert assessment (10) resulting in 612 blinded assessments)

Time of assessment	With ScanNav	Without ScanNav
Appropriate block view		
Initial assessment	125/154 (81.17%)	126/167 (75.45%)
Follow-up assessment	94/147 (65.31%)	77/144 (53.47%)
Details of statistical analysis are found in online supplemental file 1.		

RESULTS

57 participants were recruited for the study, all core trainee 1–3s from hospitals in London, UK. Five subjects were scanned during the initial assessments (time 0), two male and three female, with a mean age of 43.17 years (min-max 23–70; SD 21.04) and body mass index (BMI) of 24.46 kg/m² (19.31–30.06; 3.94 kg/m²). Seven subjects were scanned during the follow-up assessments (at 2 months), three males and four females, with a mean age of 44.29 years (23–70; 19.29) and BMI of 24.53 kg/m² (19.31–30.06; 3.66 kg/m²). A full breakdown of participants' prior UGRA experience, experience acquired between the initial and 2-month study assessments, and subject demographics are provided in online supplemental file 1.

Assessments

Data were collected on 342 assessment ultrasound scans performed by 57 participants across 6 PNBs, half with ScanNav and half without, for the initial assessments. At 2 months, 306 assessment ultrasound scans were performed by 51 participants across the same six PNBs, again half with ScanNav and half without (with cross-over assignment of AI assistance).

Primary outcome

AI assistance was associated with a statistically significant improvement in acquisition of an appropriate block view, as determined by the blinded assessors ($p=0.02$) (table 1).

Secondary outcomes

Scans performed with ScanNav were associated with a statistically significant improved performance in all other secondary outcome measures; unblinded expert assessment of block view identification, assessor global rating score and participant confidence score (all $p < 0.01$) (table 2).

Blinded reviewers

Of note, the blinded reviewer majority opinion agreed with the in-person unblinded assessment in 493/612 (80.29%) of scans. Further data are available in online supplemental file 1.

Table 2 Unblinded reviewer assessments (648 scans performed; loss of data affecting 19 scans, resulting in 629 unblinded assessments)

Outcome measure	With ScanNav	Without ScanNav
Initial assessment (342 scans performed; partial data loss affecting 10 scans)		
Appropriate block view	150/162 (92.59%)	143/170 (84.12%)
Mean confidence (min-max; SD)	65.62 (0–100; 20.40)	54.74 (0–100; 24.92)
Mean Global Score (min-man; SD)	63.83 (0–100; 23.69)	53.56 (0–98; 23.93)
Follow-up assessment (306 scans performed; partial data loss affecting 9 scans)		
Appropriate block view	125/153 (81.70%)	114/153 (74.51%)
Mean confidence (min-max; SD)	56.63 (0–100; 25.16)	44.03 (0–100; 29.44)
Mean Global Score (min-man; SD)	59.44 (0–100; 27.54)	46.75 (0–100; 27.55)
Details of statistical analysis are found in online supplemental file 1.		

Trend over time

Overall performance declined for all endpoints, both with and without ScanNav. When potential within-subject correlation was accounted for, statistical analysis confirmed the 2-month follow-up period had a significant negative impact on scanning performance ($p < 0.01$, $\text{coef} = -0.925$).

Supplementary data

Data on individual blocks and a subjective utility questionnaire taken by participants are presented in online supplemental file 1.

DISCUSSION

This investigation is intended to validate findings from our previous study¹² and extends the assessment to evaluate utility over a longer follow-up period. ScanNav was associated with a statistically significant superior rate of acquisition of an appropriate block view by both blinded and unblinded expert assessors during the 2-month study follow-up period. Scanner confidence and expert global assessment were all improved with ScanNav.

The data show variable differences in acquisition of an appropriate block view and identification of structures on that view. Some participants acquired an appropriate block view, as per the primary outcome, many had difficulty identifying the correct sonoanatomical structures without the AI color overlay. Furthermore, the investigators at the follow-up assessment reported that some participants had retained very little knowledge of the scanning required and appeared to benefit little from the color overlay. For example, some participants forgot basic elements such as whether the probe should be placed in the axial/transverse or sagittal orientation, and highlighting was not beneficial when the probe was inappropriately orientated. We propose that the highlighting may be most beneficial if some baseline knowledge is retained, or minor prompts are provided (eg, schematic/video clip) to guide initial probe placement. The scanner can then use the highlighting to confirm acquisition of the block view and sonoanatomical structure identification. It

may be an inadvertent advantage of the AI color overlay that highlighting will appear unclear if the user does not have an appropriate view, as this may deter inexperienced practitioners from undertaking a procedure at an inappropriate site for the intended target.

Scanner confidence and expert global rating were improved throughout, which the authors postulate may support the transfer of scanning and sonoanatomy recognition skills learnt in formal teaching into subsequent clinical practice. Anecdotal evidence suggests that non-experts may attend teaching and feel increased confidence and competence immediately afterwards. However, these features diminish with time—such that, without the support of a more senior/expert clinician, UGRA techniques may not be employed the next time the individual is presented with a suitable case. These data demonstrate this drop-off in performance, but levels of initial unassisted performance are similar to later scans when assistive AI is employed. In addition, subjective feedback from study participants strongly implied that participants would find the AI highlighting helpful in their training and clinical practice. This study, therefore, demonstrates that assistive AI may be one method to support ultrasound scanning performance over time (with respect to acquisition of an appropriate block view and recognition of sonoanatomy). The increased confidence associated with such technology may also potentially support non-experts to increase their UGRA delivery, which is an aim of the Regional Anaesthesia UK Plan A Blocks concept and the Royal College of Anaesthetists 2021 training curriculum.^{20 25}

Several AI systems, which aim to support ultrasound scanning in UGRA, are commercially available. These include ScanNav, cNerve (GE Healthcare, Chicago, USA), Smart Nerve (Mindray, Shenzhen, China), Nerveblox (Ankara, Turkey) and NerveTrack (Samsung, Suwon, South Korea). However, few studies have robustly evaluated these systems for ultrasound scanning in UGRA, and there is no consistent format through which they should be evaluated. These systems may soon become established in mainstream clinical practice and hence must be



robustly and consistently assessed. To the authors' knowledge, highlighting by ScanNav is most closely aligned to recommendations for anatomical structures to identify on ultrasound in UGRA (endorsed by Regional Anaesthesia UK, the American Society of Regional Anesthesia and Pain Medicine and the European Society of Regional Anaesthesia & Pain Therapy).^{18 19} Individual manufacturers can elect which structures to identify, though current variations in highlighting may impede standardized evaluation and clinical adoption. Consistent structure highlighting, guided by the recommendations of learnt bodies,^{18 19} alongside a standardized evaluation of highlighting accuracy^{9 10} and methods through which the potential benefit is assessed,^{11 12} could serve as a framework for this process.

The investigators note limitations to this study. First, along with the randomization in the availability of ScanNav for scans performed over the 2-month follow-up, the subjects being scanned were different. However, our use of regression analysis aims to account for these changes, along with potential correlation due to repeated measures taken from the same participant. A second limitation of this study is the lack of evidence to support what constitutes a validated and reliable assessment of an appropriate block view in the context of academic research (eg, blinding of assessors, optimum number of assessors and acceptable agreement levels) and emerging evidence indicates that interobserver variation exists even among experienced personnel.¹⁷ More evidence is required to validate this. Third, while the data demonstrate statistically significant differences in ultrasound scanning performance, rigorous clinical studies are required to investigate the impact on patient outcomes. Additionally, scanning ability and recognition of sonoanatomy are two requirements of successful UGRA performance, with other parameters such as needling ability, manual dexterity and non-technical skills also being of significance. The choice of a 2-month follow-up period may be another limitation of this study, as it may not represent an ideal 'washout' period from the initial standardized teaching and additional participant experience of UGRA was not controlled during this period. However, there is a paucity of data on what constitutes an appropriate time interval for follow-up assessment to evaluate the impact of AI on scanning ability beyond an immediate teaching session. Therefore, 2 months was a pragmatic choice based on consensus among the UGRA expert authors. In addition, it is reasonable to anticipate and accept that junior anesthetists will encounter UGRA within 2 months of attending formal teaching while not gaining extensive experience or seniority. The lack of control over exposure to UGRA in the interval period is pragmatic and reflects real-life practice. Furthermore, the use of the same participant cohort, with crossover methodology, was chosen rather than a second group of similar learners as this reflects real-world clinical practice—whereby trainees are exposed to training and equipment, but do not necessarily employ them regularly in their work (and so the

impact of such learning drops off). In our study, most participants still had little UGRA experience. Future investigations could better characterize UGRA experience gained during the study (eg, data on individual participants for each block, stricter inclusion/exclusion criteria to help control for ability level at the 2-month period). Our methods and randomization strategy also aimed to reduce the impact of participant heterogeneity and account for potential correlation involving multiple assessments of the same participants, although we note that alternative analyses and a robust assessment of participants' performance change over time (such as cumulative sum learning curves and paired repeat measures analysis) may be avenues for future study. Finally, several study authors (JSB, MM, DB-SL and SM) are affiliated with the manufacturer of ScanNav. The investigators have intentionally involved several experienced and prominent UGRA experts to provide an impartial viewpoint and support a fundamentally sound assessment of the technology in question. No unblinded assessors have direct affiliation with the manufacturer.

CONCLUSION

The use of ScanNav was associated with a statistically significant superior acquisition of an appropriate block view, scanner confidence and expert rating of scanner performance during a 2-month follow-up. This suggests that assistive AI may support the application of knowledge and skills gained in teaching to the subsequent clinical setting, though all systems and approaches should be thoroughly evaluated through the same framework to allow a consistent assessment and best inform clinicians of the potential advantages.

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Contributors Chief investigator and guarantor: JSB. Study concept and design: JSB, MM, AJRM, DB-SL, AP, SW and SM. Participant recruitment and data collection: C-YK, MM, AP, SW, TA, MPS, AT and JSB. Data analysis and manuscript preparation: C-YK, MM and JSB. Manuscript review/editing and approval: all authors.

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Competing interests JSB is a Senior Clinical Advisor for GE Healthcare (and previously Intelligent Ultrasound, receiving research funding and honoraria). MM was employed by Intelligent Ultrasound as a medical writer during this study. DBSL is a clinical advisor for Intelligent Ultrasound, receiving honoraria. NH is the President of Regional Anaesthesia UK. AJRM is the immediate Past-President of Regional Anaesthesia UK and has received honoraria from Intelligent Ultrasound and GE Healthcare. AP is a Past-President of Regional Anaesthesia UK, has received honoraria from GE Healthcare and has consulted for Pacira Biosciences. TA, MPS, AT and JW are board members of Regional Anaesthesia UK. JAN is a senior scientific advisor for Intelligent Ultrasound.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and ethical approval for this study (R70327/RE003) was granted by the Oxford University Medical Sciences Inter-Divisional Research Ethics Committee on August 26, 2022. Participants gave informed consent to participate in the study before taking part.

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