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ORIGINAL ARTICLE

An initial evaluation of the effect of a novel regional block needle with tip-tracking technology on the novice performance of cadaveric ultrasound-guided sciatic nerve block.

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Short title: Evaluation of regional block needle with tip-tracking technology

Summary

Visibility of the needle tip is difficult to maintain during ultrasound guided nerve block. A new needle incorporates a piezo element 2mm to 2.3mm from the tip that is activated by ultrasound. The electrical signal manifests as a coloured circle surrounding the needle tip and allows real-time tracking. We hypothesised that novice regional anaesthetists would perform nerve block better with the tracker turned on rather than off.

Our primary objective was to evaluate the new needle by measuring the performance of novice anaesthetists conducting simulated sciatic block on the soft embalmed Thiel cadaver. Training consisted of a lecture, volunteer scanning and cadaver practice. Testing entailed scanning the sciatic nerve proximally using a 5 to 10MHz curvilinear transducer and conducting 20 in-plane sciatic blocks in the mid-to upper thigh region. Subjects were randomised equally, in groups of five, according to the sequence: tracker on/off/on/off or tracker off/on/off/on. Videos were assessed by six raters for tasks performed correctly and errors committed.

Eight subjects were recruited and 160 videos analysed. Using the tracking needle, 5 steps improved and 1 error reduced. Benefits included better identification of the needle tip before advancing the needle OR 3.4 (95%CI: 1.6 - 7.7), $P < 0.001$; better alignment of the needle to the transducer, OR 3.1 (95%CI: 1.3 – 8.7), $P = 0.009$; and better visibility of the needle tip OR 3.0 (95%CI: 1.4 - 7.3), $P = 0.005$. In conclusion, use of the tracker needle improved the sciatic block performance of novices on the soft embalmed cadaver.

Introduction

Ultrasound guidance has improved the efficacy of nerve block, but the incidence of nerve injury remains similar to that using peripheral nerve stimulation [1]. Failure to reduce nerve damage, secondary to intrafascicular injection [2] and forced needle-nerve contact [3], can be attributed to: insufficient ultrasound resolution [2]; poor interpretation of needle tip position relative to surrounding anatomy [4]; and inadequate training [2]. All restrict the application of ultrasound-guided regional anaesthesia. There is a need for technology that accurately and reliably identifies the position of the needle tip. If needle insertion is made safer, the potential exists to accelerate learning, and encourage the uptake of regional anaesthesia. The clinical benefit of increased use of nerve block would be provision of better pain relief, morphine sparing, and reduction in nausea and vomiting [5].

A new tip-tracking needle has been developed by BBraun (Melsungen, Germany) and Philips (Eindhoven, Netherlands). The device consists of a piezo element embedded 350° around the needle shaft and 2 - 2.3 mm from its tip. Ultrasound generated mechanical waves compress the piezo element and generate an electrical signal, represented on the ultrasound screen as a coloured circle surrounding the needle tip, with the piezo element at its centre.

Four scenarios may occur during needle insertion:

1. A green circle surrounds the needle tip that is clearly seen. The radius of the green circle is 3 mm, thus providing at least 0.7 mm margin of safety during needle advancement.
2. A red circle is seen lying within an expanding blue circle. The needle tip is recognised moving laterally within the ultrasound beam, but does not lie in its centre.
3. A red circle is seen within a contracting blue circle. The needle tip is recognised moving medially within the ultrasound beam, but does not lie in its centre.
4. No circles are seen because the needle tip lies outside the ultrasound beam. The needle tip is not seen.

The accuracy and utility of this tracking technology was recently tested on pig phantoms by 40 anaesthetists. The tip-tracking needle reduced the procedure time and the number of hand movements for ultrasound-guided out-of-plane needle insertion [6]. We have conducted various studies of performance measures that would allow us to evaluate the benefits of the new needle. We have used elastography to provide both colour and black-and-white contrast within the ultrasound image; this allows better recognition of intraneural injection secondary to visual saliency, the subjective perception of items that stand out from surrounding tissue [4, 7]. We have demonstrated construct validity of two 15-item performance checklists for simulated nerve block on the soft embalmed Thiel cadaver, the first consisting of steps indicative of acceptable performance and the second consisting of 15 errors [8]. In addition, we have showed discriminatory validity of eye gaze tracking, a quantitative measure of performance during simulated ultrasound guided regional anaesthesia [9]. Therefore, our primary objective was to evaluate the new needle for the first time on soft embalmed cadavers by measuring the performance of anaesthetists undertaking sciatic block. Our primary outcomes were the number of steps performed correctly, and the number of errors committed, during each cadaveric sciatic block.

Methods

The study was conducted at the Centre for Anatomy and Human Identification, University of Dundee in August 2018. Ethical permission was obtained from the University of Dundee Committee on Non-Medical Ethics. All subjects opted in to the study.

Novices were identified using the criteria set by Dreyfus and Dreyfus [10]. Subjects considered themselves to be novices or advanced beginners. At most, they saw actions as a series of steps, had some working knowledge of key aspects of practice, and were able to achieve some steps using their own judgement, but needed guidance or supervision for the overall task. This included

consultants who did not perform regional anaesthesia regularly, lacked confidence and often sought help and advice from expert colleagues.

The study was characterised by skills training and performance testing. Using the Qualtrics Survey Platform (Qualtrics LLC, Provo, Utah, USA), we collected baseline characteristics including number of supervised and unsupervised nerve blocks performed (0-5, 5-10, 10-15, 16-20, 21-25, 26-30, >30), and details of undergraduate and postgraduate training.

One-to-one training was delivered by an expert regional anaesthetist over one hour. Expertise was defined according to the Dreyfus and Dreyfus criteria [10]: experts were those who performed clinical regional anaesthesia with relative ease, saw the overall picture, had authoritative knowledge, were able to go beyond existing standards, and were able to deal with unique problems. Training consisted of a lecture, followed by scanning and needling practice on low and high fidelity simulators (Fig. 1). The lecture described the mechanism of action of the new tip-tracking needle and its application. Subjects were taught how to scan for nerves using the forearm of a volunteer. Our low fidelity simulator was a pork belly with six embedded tendons that replicated the appearance of nerves (Wetlab-Medmeat, Warwick, UK). Subjects used an Onvision tip-tracking needle attached to an Xperius ultrasound system jointly developed by B.Braun (Melsungen, Germany) and Philips (Eindhoven, Netherlands), with a 4 - 12 MHz linear transducer for scanning. Needles were inserted in-plane tangentially above and below the tendon for 20 min. Our high fidelity simulator was a dedicated soft embalmed Thiel cadaver. Using a 2 – 5 MHz curvilinear transducer (Philips), subjects were taught to identify the tibial and common peroneal nerves in the popliteal fossa, and then scan proximally up the thigh to the subgluteal region. Once the best image of the sciatic nerve was obtained in this region, sciatic nerve block was performed. The block needle was inserted in-plane and approximately 0.25 ml Thiel embalming fluid was injected around the sciatic nerve. Subjects practised needle insertion on both simulators with the tip tracker turned on and off, in order to familiarise themselves with the appearance of the activated and non-activated needle.

We used a second soft embalmed Thiel cadaver to assess performance. Each subject conducted twenty mid-thigh sciatic blocks using an Onvision tip-tracking needle and the Xperius ultrasound system with a 2 - 5 MHz curvilinear transducer. Subjects were fitted with SMI ETG 2W wireless eye-tracking glasses (Sensomotoric instruments, Teltow, Berlin, Germany). Engineers and psychologists sat behind a table at the feet of the cadaver with laptop computers that received live streaming of ultrasound, video and eye tracking data. All data were masked from the view of the subjects and trainer.

Subjects were filmed using two external cameras (Noldus Studio; Tracksys Ltd, city, Netherlands) in order to capture hand, transducer and needle movements but not reveal the subject's identity.

One camera was positioned on the ultrasound machine facing towards the hands of the subject, and the other positioned laterally. An engineer sat behind the ultrasound machine and recorded all ultrasound procedures. Research software (Philips) was used to remove the coloured circle from the ultrasound image in order to allow blinded analysis of both external and ultrasound videos. Prior to each block, a 3-point calibration procedure was performed.

We used a uniform cross-over design that aimed to counter-balance "carry-over effects" secondary to practice and fatigue by randomly allocating subjects using a computer based randomisation programme to two study starting points. Move to para 1 of Results: Four subjects completed blocks 1-5 and 10-15 with the tracker turned on and blocks 6-10 and 15-20 with the tracker turned off (Fig. 1). In contrast, four subjects completed blocks 1-5 and 10-15 with the tracker turned off and blocks 6-10 and 15-20 with the tracker turned on.

Mention primary outcome here....,

Our secondary objectives were to determine which facets of our study had the most impact on performance and capture focused attention using eye tracking technology. Our secondary outcomes were eye tracking metrics such as duration of procedure, fixation count and glance count.

Six raters were previously trained to identify 15 steps and 15 errors on video and ultrasound recordings. The development and validation of steps and errors using the Delphi technique and description of training is described in a previous publication [8]. Raters were blinded to subjects and randomised to video assessment of performance. Each rater analysed 20 videos.

Scores were entered onto a spreadsheet (Excel, Microsoft, WA, USA). Data were treated as dependent because we used one dedicated cadaver for testing. Within-subjects analysis used the Wilcoxon matched-pairs signed rank test. We used the Hodges-Lehmann estimate (Prism 7; Graph Pad, La Jolla, CA, USA) for differences in medians and 95%CI. Paired, correlated binary data from individual task and error questions were analysed using McNemar's test. Repeat measures mixed effects regression analysis was used to calculate the effect of sequence and needle group over time. Our regression analysis outcome was the number of steps and errors measured within each block of five interventions. Reliability was quantified using generalisability theory and estimation of the variance of facets of a measurement, i.e. subjects, items and raters (R Studio version 1.1.146, city, country). Eye tracking data was analysed using Begaze 3.7 software (Sensomotoric Instruments).

Move to discussion: Because this study was the first evaluation of needle tracking technology on cadavers, we did not perform a power analysis. The results from the study will be used to power a much larger study. On the advice of our psychologist, we regarded 8 subjects, measured 10 times with the needle tracker turned on and 10 times with it turned off, to be adequate for an initial evaluation of the new tracker needle. Many psychology and educational studies in which subjects repeatedly conduct tasks tend to have a small number of participants and use a within subjects design.

Results

Eight subjects were recruited, and consisted of five non-expert anaesthetic consultants, two CT1 trainee and one ST3 trainee. Each subject conducted 20 blocks, 10 with the tracker switched off and

10 with the tracker switched on. Thus 160 blocks were performed.

Fig. 2 shows images from block with the tracker turned on **and off**. The blue and red circles (Fig 2A) indicate that the needle tip is moving away from the beam, whereas the green circle (Fig 2B) indicates that the tip is in the centre of the beam. The cadaver proved durable over the course of the study. No needle marks or fluid accumulation were visible during the study between block no. 1 (Fig 2E) and block no. 160 (Fig 2F)

The median [IQR (range)] number of **successful steps** **[what does this mean?]** per volunteer was 8.8 [6.3 – 9.8 (5.5 – 11)] using the activated needle and 6.3 [5.1 – 8.1 (4.5 – 12)] using the non-activated needle, difference between medians 2.5 (95%CI: -2.5 to 4.0), $P = 0.11$. Analysis of paired items showed significant differences that accounted for improved performance (Fig 3A). They were: (i) aligned needle to transducer, OR 3.1 (95%CI: 1.3 – 8.7), $P = 0.009$; (ii) aligned needle at tangent to nerve, OR 2.6 (95%CI: 1.0 - 7.3), $P = 0.04$; (iii) identified needle tip before advancing needle OR 3.4 (95%CI: 1.6 - 7.7 to), $P < 0.001$; (iv) visualised needle tip at all times OR 3.0 (95%CI: 1.4 - 7.3), $P = 0.005$; and (v) identified needle tip before injection OR 2.4 (95%CI: 1.2 – 4.8), $P = 0.009$. Internal reliability of steps (Cronbach's alpha) was 0.75.

The median [IQR (range)] number of errors per volunteer was 3.3 [3.0 – 6.1 (0.5 – 8)] for the activated needle and 4.8 [3.6 – 6.4 (2.5 – 8.5)] for the non-activated needle, difference between medians 1.0 (95%CI: -3.0 – 5.5), $p = 0.42$. One item showed a reduction in errors (Fig 3B) with the activated needle - failure to quickly regain needle tip position when tip visibility was lost, **OR 2.6 (95%CI: 1.1 – 6.8)**, $P = 0.03$. Internal reliability of errors (Cronbach's alpha) was 0.83.

There was no difference in the number of successfully performed steps with regard to block sequence, difference 6.5 (-1.3 – 14.3), $P = 0.12$ or study group, difference 6 (-1.6 – 13.2), $P = 0.10$.

The variance of our primary outcome measures was attributable to items, subjects and their interaction (Table 1). Raters and group accounted for little variance. Residual variance contributed to

more than one third of variance, due to the combination of items, subjects, raters, group and order of administration.

There was no difference in scanning time or glance count (Table 2). Fixation count did not differ during scanning, but increased during the needling phase (Table 2).

Six of eight subjects showed enhanced performance in the learning curve with tracking technology. Figure 4 shows examples from two subjects; subject 8 maintained a superior performance across trials, whilst subject 7 exhibited a great focus of attention over time.

Discussion

Use of needle tip tracking technology improved performance. Five steps improved and one error reduced. The biggest differences occurred in items focusing on visibility of the needle tip.

Our subjects doubled the number of times they achieved continuous visualisation of the needle tip during needle insertion and local anaesthetic injection from 20% to 42% of blocks. These results suggest that this technology is an aid to needle guidance. Identifying expansion or contraction of red/blue circles within the ultrasound beam guides the handling of the transducer towards the needle tip. We feel the primary advantage of the technology is that it identifies the needle tip first, then the shaft of the needle, in contrast to current practice that emphasises identification of the shaft before the needle tip. We feel that this new feature has the potential to improve safety.

We showed differences in steps and errors that focused on needling, in agreement with the observations of Sites et al. [11]. Five subjects were consultants who considered themselves to have either basic or intermediate ultrasound-guided regional anaesthesia skills, but had longstanding experience of ultrasound for central line insertion. Although two had performed > 30 blocks, they lacked confidence in their regional anaesthesia abilities, only sporadically conducted nerve blocks and

often sought assistance from experienced colleagues. We felt that both inexperienced consultants and trainees were likely to show **differences in tracker modalities.**

The strength of our work lies within the study design and use of validated outcome measures. We focused on changes in individual subjects' performance over time, and used a within-subjects design. Indeed, our study may be regarded as a balanced cross-over study with repeated measurements, in which subjects acted as their own controls.

The study showed good internal and external reliability. There has been much debate discussing the merits of inter-rater agreement or intraclass correlation as a measure of study reliability. Inter-rater agreement is defined as the proportion of agreement between raters, whereas intraclass correlation is the proportion of total variance accounted for by within-subject variation. However, both measures failed to acknowledge the contribution of other variables that may have a considerable impact on study outcome, such as subjects, groups and sequence of administration.

In order to evaluate the variance of subjects, raters, groups and sequence of tasks, we used Generalisability theory, or G theory, a statistical framework using in medical education studies to quantify the amount of error caused by each facet and interaction of facets. Items, subjects and their combination showed most identifiable variation, and supported our choice of primary outcome. The sequence of needle use had little overall effect and justified our within-subjects study design.

The association between task and error metrics and eye tracking is complex. For example, there was a positive relationship between performance and attention patterns in two subjects, although it was also evident in other subjects **that increases in attention were due to time on task.** For example, subject 2 showed increased attention but made more errors. The emergence of distinct patterns emerging at this stage is encouraging, and we intend to explore the relationship between attention, effort and performance further in a future study.

Potential weaknesses of the study include the restricted number of cadavers and subjects. We used the same cadaver to test each subject in order to minimise error variability, given the small size of the study, and the contribution to error of items, subjects, sequence, groups and raters. A presumption is commonly made that repeated injection on the Thiel cadaver by several users results in multiple puncture wounds and swelling and distortion of subcutaneous tissue, thus biasing studies by disclosing injection sites to other subjects. In fact, similar to two previous studies, we did not observe any puncture wounds using a 21-G needle, the skin was not indented, and ultrasound images were not distorted. Our images show no difference in tissue integrity between the first and the 160th block.

These remarkable physical properties can be attributed to the retention of elasticity during the embalming process. Young's modulus over nerves and soft tissue is similar to that measured in humans [12]. Fascial planes distend in response to fluid injection and return to pre-injection dimensions, dispersing fluid along tissue planes and permitting repeated injection with little if any change in anatomy. For example, a single Thiel cadaver tolerated injection of > 900 ml embalming fluid over 10 days during simulated interscalene block with only minimal fluid retention in scalenus medius [13]. In contrast, we injected a maximum of 15 ml embalming fluid per day within our present study, one sixth the volume previously used [13]. Moreover, we have successfully run four regional anaesthesia courses since 2016 that use the principles of dedicated practice. Such educational techniques are only possible using a simulator that provides constant conditions for testing subjects' learning curves.

Although we studied only eight subjects, each was exposed to both the activated and non-activated needle, effectively doubling the number of comparisons. In total 160 blocks were performed, which we considered reasonable to allow calculation of numbers for a planned larger study. Using the Wilcoxon test (G3*Power, Dusseldorf, Germany), assuming $\alpha = 0.05$, $\beta = 0.90$, a difference in steps = 2.5, an approximate standard deviation = 3, effect size = 0.8 and taking into account exposure to both needles, we will require 36 anaesthetists performing 40 simulated sciatic blocks. We expect this

to show a difference with much smaller confidence intervals between tracker and non tracker needles.

Unsurprisingly, learning curves were difficult to evaluate using 10 repetitions per needle. Our previous work on learning curves suggests that learning becomes more consistent over 30 repetitions [9]. Nevertheless, we identified two subjects who showed clear benefits with needle tracking: steps were consistently better and errors consistently less. Subject 7 was a CT 1 with 11-15 supervised and 11-15 unsupervised regional blocks, whereas subject 8 was a consultant with experience of over 30 blocks (both at supervised and unsupervised level). The patterns evident in these subjects may suggest that the increased time on task and fixation may be related to horizontal scanning behaviour along the needle trajectory, which translates to performance benefits. This may have conferred an advantage in terms of performance, but we do not have enough data to support this at this time.

?I think move this paragraph up one: Although the sequence of injection only contributed to 2.5% of variance, a theoretical possibility exists that the greater the number of repeated blocks, the greater the potential for study bias. Therefore in order to minimise bias as much as possible we will alternate between needles every two repetitions.

Studies on regional anaesthesia have until now focused on task and error metrics, but neglected to assess the dexterity and visual-motor skills needed to manipulate the transducer and needle. Whilst we are aware that any conclusions from the current sample must be treated with caution given the sample size, these results lay the foundation for further investigation of the relationship between attention and performance with the tracking technology. In conclusion, our within-subjects study showed differences in individual steps and errors relevant to needle tip visibility.

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Table 1 Generalisability results. Most variance attributed to residual error - interaction of items, subjects, raters, group and order. Other major sources of variance were subjects, items and their interaction.

	Steps		Errors	
	Variance	% of total variance	Variance	% of total variance
Item (σ_i^2)	0.041	16.0	0.030	15.5
Subject (σ_s^2)	0.020	7.4	0.003	1.5
Rater (σ_r^2)	0.012	4.7	0.007	3.0
Sequence (σ_o^2)	0.004	1.4	0.005	2.1
Group (σ_g^2)	0.003	1.2	0.001	0.3
Item : Rater (σ_{ir}^2)	0.024	9.4	0.006	2.1
Item : Sequence (σ_{io}^2)	0.003	1.1	0.003	1.5
Item : Group (σ_{ig}^2)	0.004	1.7	0.001	0.3
Subject : Item (σ_{si}^2)	0.049	19.1	0.003	11.0
Subject : Group (σ_{sg}^2)	0.010	3.8	0.012	4.3

Table 2 Eye tracking metrics in **eight subjects / 160 blocks**. Values are median (IQR [range]) or difference in medians (95%CI).

~~Eye gaze fixations increased in activated needle group.~~

	OFF	ON	Difference in medians	P-Value
Scanning phase				
Duration of task; s	18 [12 - 29]	17 [10 - 35]	0.25 (95%CI: -9 - 15)	0.74
Glances; n	2 [1.3 - 2.9]	2 [1.3 - 3.8]	0.25 (95% CI: -1 - 1.5)	0.31
Fixations; n	21 [7.1 - 47]	22 [10 - 45]	2.8 (95% CI: -9.5 - 17)	0.82
Needling phase				
Duration of task; s	21 [18 - 25]	25 [19 - 29]	3.5 (95% CI: -8 - 7.5)	0.64
Glances; n	1.8 [1 - 2.8]	1.3 [1 - 2]	0.5 (95%CI: -2 - 7.5)	0.38
Fixations; n	16 [12 - 25]	23 [13 - 31]	3.0 (95% CI: -2 - 7.5)	0.04

Fig 1. Study plan

Fig 2. Sciatic block with tracker turned on. Sciatic nerve (SN) lying approximately 3cm from the skin. Femur (F) and sciatic nerve (SN) highlighted. Image 2A shows a large blue circle surrounding a red circle. The tip of the needle is not seen within the red circle because it is not in the centre of the ultrasound beam because it is misaligned. Image 2B shows the needle tip within the green circle and the needle shaft has now come into view. Images 2C and 2D are expanded images of 2A and 2B that show more detail. **No deterioration in cadaver quality is detectable between block no. 1 (image 2E) and block no. 160 (image 2F).** The video that images 2A and 2B are taken from is available on-line (Appendix 1). It shows

Fig 3. Metrics. Five out of 15 steps improved (Fig 3A) and 1 out of 15 errors reduced (Fig 3B) using the needle tracker. *** ?is this a significant p value?**

Fig 4. Learning curves from subjects 7 (A -D) and 8 (E – F). **Check wording: With the tracker activated, there is a trend for steps to improve and for errors increase in subject 8.** The reduction in fixations marry the reductions in time taken to perform needling in both subjects.

Movie 1. Video example of tracker system. The video shows episodes in which no circle is seen (tracker not within ultrasound beam); red and blue circles are seen (tracker within beam but needle tip not within centre of ultrasound beam); and green circle (needle tracker in centre of beam and needle tip seen within green circle)