The effect of needle tip tracking on procedural time of ultrasound-guided lumbar plexus block: a randomised controlled trial

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Summary
Technology that facilitates performance of deep peripheral nerve blocks is of clinical interest. The Onvision™ is a new device for ultrasonographic needle tip tracking that incorporates an ultrasound sensor on the needle tip that is then represented by a green circle on the ultrasound screen. The primary aim of this study was to investigate the effect of needle tip tracking on procedural time in the first human volunteer study. Secondary outcome measures included: number of hand movements; hand movement path length; block success rate; block onset time; block duration; discomfort experienced by the volunteers; and the anaesthetists’ confidence as to whether their block would be successful. Two anaesthetists performed ultrasound-guided lumbar plexus blocks with an out-of-plane technique, with and without the use of needle tip tracking. In total, data from 25 volunteers were studied. Mean (SD) procedural time was 163 (103) s with needle tip tracking and 216 (117) s without (p = 0.10). Hand motion analysis showed that needle tip tracking was associated with a significant decrease in the mean (SD) number of intended needing hand movements (39 (29) vs. 59 (36); p = 0.03) and path lengths (3.2 (3.1) m vs. 5.5 (4.5) m; p = 0.03). No differences were found for any other secondary outcomes. The use of Onvision needle tip tracking did not reduce procedural time for out-of-plane ultrasound-guided lumbar plexus block but did reduce the number of hand movements and path lengths. This may indicate improved needle control but further studies are needed to confirm this finding.

Introduction
Ultrasound guidance has become the gold standard for the performance of peripheral nerve blocks, allowing real-time visualisation of the injection needles, target nerves and surrounding anatomy. However, visualisation of the needle tip can be challenging, particularly when out-of-plane needle approaches are used [1]. Poor visualisation of the needle tip can lead to prolonged procedural times, reduced precision, more needle manipulations and consequently, increased pain and discomfort for the patient. It may also lead
to complications like accidental intravascular injections, systemic local anaesthesia toxicity and nerve injury. In order to overcome these problems and improve needle visualisation, needle tracking technologies such as electromagnetic tracking systems, fiberoptic hydrophones and camera tracking have been developed [2–7]. Due to limitations such as inaccuracy, a negative impact on clinical workflow and high costs, these technologies are not used commonly in clinical practice [8].

The Onvision™ needle tip tracking (B. Braun Melsungen AG, Melsungen, Germany and Philips Medical Systems International B.V., Eindhoven, the Netherlands) is a new navigation technology customised for the use in regional anaesthesia. In a recent study, 40 anaesthetists with varying ultrasound experience performed simulated nerve block procedures in a porcine tissue phantom with, and without, the use of needle tip tracking technology [9]. Needle tip tracking technology significantly reduced the procedural time for ultrasound-guided out-of-plane procedures. As a measure of needle control, hand motion analysis was implemented in the phantom study. The use of needle tip tracking significantly reduced the number of hand movements during the simulated block procedures.

To the best of our knowledge, no randomised controlled trial has been performed in human subjects to evaluate needle tracking technologies for regional anaesthesia. Thus, in order to verify and confirm the results of our previous phantom study, we conducted the first human volunteer study.

The aim of our study was to investigate the effect of Onvision needle tip tracking on procedural time (primary outcome measure) and hand movements (secondary outcome measure) when performing a peripheral nerve block. We hypothesised that the use of the needle tip tracking system would reduce procedural time, number of hand movements and path length (measured by hand motion analysis) when performing ultrasound-guided lumbar plexus blocks with an out-of-plane approach in healthy volunteers.

Methods
This was a randomised, controlled, observer-blinded, human volunteer crossover study. Ethical approval for this study was gained prospectively. The study was registered at ClinicalTrials.gov and complied with the declaration of Helsinki. A monitor from the clinical trial unit at Oslo University Hospital oversaw the conduct of the trial and the safety of the volunteers. Good clinical practice was followed throughout the study and all participants gave written, informed consent.

Healthy volunteers were recruited by bulletins in the hospital and university area and by announcement on social media. Subjects aged 20–65 years, ASA physical status 1–2, BMI 18–35 kg.m⁻², weight < 95 kg and who were able to understand and speak Norwegian were eligible for participation. Volunteers with neurological diseases, nerve or vascular impairments, known coagulopathy, allergies to amide local anaesthetic agents, skin disease affecting the area of examination or inability to cooperate during the examination were not studied.

The needle tip tracking technology consists of a Stimuplex Onvision needle (B. Braun Melsungen AG) with a piezo-electric sensor close to the needle tip and an electronic console processing computerised signals integrated in the Xperius ultrasound system (Philips Medical Systems International B.V)[9]. The position of the piezo-electric sensor and needle tip is represented by a small circle on the ultrasound screen (Fig. 1). For out-of-plane approaches, the position of the needle tip is in the lower half of the circle, between the centre and edge of the circle. A green circle indicates that the needle tip and sensor are placed within the ultrasound beam, and that the needle tip can be identified within the circle on the ultrasound image. When the position of the needle tip is close (up to 2 cm) but not within the ultrasound plane, the Onvision system can still capture a faint signal. The sensor position will then be indicated by a red circle and a blue circle of increasing diameter (dependent on the distance between the ultrasound plane and sensor) on the ultrasound screen [9].

Standard monitoring during the procedure included pulse oximetry, non-invasive blood pressure measurement and electrocardiography. An intravenous cannula was placed as a safety precaution. No sedation was given before or during the procedure. A nerve stimulator (Stimuplex® HNS 12; B. Braun Melsungen AG) was connected with the cathode to the insulated needle and anode to a solid-gel skin electrode. The volunteers were positioned in the lateral decubitus position with the side to be anaesthetised facing downwards (Fig. 2).

Two consultant anaesthetists (EB and KU) with substantial experience in ultrasound-guided lumbar plexus techniques performed the blocks. Before the study, both anaesthetists had practised the use of the needle tip tracking during a one-week period in Thiel cadavers [10], muscle tissue and gelatine phantom models.

Ultrasound-guided lumbar plexus blocks were performed in a standardised way [11]. An Xperius™ ultrasound system (Philips Ultrasound Inc., Bothell, WA) with a curved ultrasound transducer with frequency range from 2 to 5 MHz and a 100-mm Stimuplex Onvision needle (B. Braun
Melsungen AG) with a 30° bevel were used. The transducer was oriented paramedially on the dependent side of the spine. When the L5 transverse process was identified, the anaesthetist counted the transverse processes upwards and the trident sign (represented by the transverse processes L2, L3 and L4) was visualised in the longitudinal sonogram. A volume of 3 ml lidocaine 2% with adrenaline 5 μg.ml⁻¹ was injected subcutaneously before block needle insertion. The block needle was inserted medially to the transducer using a steep out-of-plane approach. The needle was advanced through the space between the transverse processes of L3 and L4 until the needle tip was close to the lumbar plexus, visualised as a hyperechoic structure approximately 2 cm anterior to the posterior border of the transverse processes within the psoas muscle. A stimulation current of 0.5 mA (with 0.1 s impulse duration and 2 Hz frequency) was applied during the block procedure. Before local anaesthetic injection, the current setting was gradually increased up to 3 mA to determine a current threshold for a neuromuscular response. A total volume of 20 ml lidocaine 2% with 5 μg.ml⁻¹ adrenaline was injected, independent of the weight of the volunteers.

Each volunteer recruited to the study received one block with needle tip tracking technology active and one block without needle tip tracking (control group). This was a randomised controlled A-B/B-A crossover trial. The volunteers were randomly assigned to the sequence of intervention with active or inactive needle tip tracking technology (Fig. 3). Additionally, they were randomly allocated to a block on the left or right side during the first treatment and on the contralateral side during the second treatment. There was a two-week washout period between the two interventions. A person not involved in the collection or analysis of the study data assigned the participants into groups of equal size for each sequence of intervention using a list of random numbers, according to the Moses–Oakford algorithm [12, 13]. A sealed consecutively numbered and opaque envelope revealing group allocation was opened by one of the investigators (AS) immediately before the first needling procedure. The observers measuring the procedure time, hand motion analysis and other data related to the block procedure could not see the ultrasound screen and did not know if the needle tip tracking system was active.
during the block procedure. The observers who assessed the sensory and motor block were not present during block performance and were also blinded to group allocation. All volunteers were also blinded to group allocation and could not see the ultrasound screen during block performance.

The primary outcome measure was procedural time, measured from insertion of the block needle (skin puncture) until completion of local anaesthesia injection. The stopwatch function of the MotionMonitor™ xGen software (Innovative Sports Training, Inc. Chicago, IL, USA) was used for the measurement of time. Hand motion analysis was performed using a Polhemus Patriot™ electromagnetic motion tracking system (Polhemus, Colchester, VT, USA) with the MotionMonitor xGen software used for acquisition, visualisation and analysis, with a cut-off velocity of 0.03 mm.s⁻¹ and Butterworth cut-off frequency of 2.0 Hz. We placed a Polhemus Micro Sensor 1.8™ (Polhemus) on the distal phalanx of the third finger of each hand. Total path length and the number of intended hand movements were measured from the time of skin puncture until the end of the injection of the local anaesthetic (Fig. 2).

Current thresholds to obtain a neuromuscular response were registered. The numbers of injections were counted during each block procedure. Backflow of blood, including just traces of blood, were recorded. During and after the block procedure, the volunteer was asked to report any experience of paraesthesia, defined as an unpleasant sensation with distal radiation not synchronous with the pulse of the nerve stimulator. The volunteers rated discomfort using an 11-point scale, where 0 represented no discomfort at all, and 10 the worst imaginable discomfort. Immediately after the block procedures, the anaesthetist was asked: ‘How much confidence do you have in your block on a scale from 0 to 10, where 0 is totally unlikely that the block will be successful and 10 means that the block undoubtedly will be successful?’

Sensory and motor block were repeatedly assessed every 5 min for first 30 min and then every 30 min for 60 min to 240 min after the block procedure or until resolution of block. Sensory blocks were assessed using ice cubes repeatedly touching the skin on pre-defined sensory areas of the femoral and lateral femoral cutaneous nerves. The following assessment scale was used: 0 – normal sensory sensation (feeling of both touch and coldness); 1 – feeling touch but not coldness (analgesia); or 2 – no feeling at all (anaesthesia). To evaluate motor blockade, we used a CM305 Commander Echo wireless muscle tester (JTECH Medical Industries Inc., Midvale, UT, USA). Muscle strength was assessed in the supine position as active strength against resistance with a handheld dynamometer during knee extension (with 90° flexion of hip and knee joints) for the femoral nerve. Motor assessment of the obturator nerve was assessed during hip adduction with the lower limb extended and 20° abducted. The observer instructed the volunteer to exert pressure with maximal strength against the stationary dynamometer. The maximal value (in kg) of three tests done at 20-s intervals was recorded for each type of movement. A block was defined successful when the femoral and lateral femoral cutaneous nerve had a sensory score of 1 (analgesia) or 2 (anaesthesia) and muscle strength of the femoral nerve and obturator nerve was reduced by at least 50% compared with baseline. Block success rate was determined 30 min after local anaesthetic injection. Onset time was defined as the time from the end of local anaesthetic injection until a successful block was recorded. Block duration was defined as the time from the end of local anaesthetic injection until one nerve had sensory test scores of 0 (feeling both touch and coldness) or if muscle strength of at least 50% compared with baseline in at least one of the blocked muscles was measured. Time to total block regression was defined as the

Figure 2 Setup for lumbar plexus block and measurements. (a) The Onvision needle tip tracking technology consists of an insulated block needle with a piezoelectric sensor close to the needle tip and an electronic console processing computerised signals that is integrated in an ultrasound system. (b) The number of hand movements and distance travelled by each hand was measured with an electromagnetic motion tracking system. (c) An electromagnetic source emits a dipole field for hand motion tracking.
time from the end of local anaesthetic injection until all nerves had sensory test scores of 0 (feeling both touch and coldness) and all muscles affected by the nerve block had at least 50% strength compared with baseline.

Statistical analysis was performed using Stata/SE 15.1 (StataCorp LLC, College Station, TX, USA). The null hypothesis that the difference between procedural times is zero was tested with the matched-paired t-test. We considered a reduction in procedural time of 30% as being clinically significant. Based on previous studies and pilot measurements, assuming a mean (SD) procedural time of 228–340 (170) s, a sample size of 24 volunteers was required ($\alpha = 0.05$, power 80%). In order to compensate for missing data or dropouts, we aimed to recruit 27 volunteers. A matched-paired t-test was used for continuous data and McNemar’s test for paired nominal data. Group allocation blinding was only broken upon completion of the statistical analysis.

**Results**

The study was conducted from 8 October 2018 to 26 October 2018. Twenty-seven healthy volunteers (16 women) participated in the study (Fig. 3). The mean (SD) age, weight, height and BMI of the volunteers were 26 (9) years, 68 (9) kg, 173 (8) cm and 23 (3) kg.m$^{-2}$, respectively. Two participants experienced adverse events and were excluded from the analysis. One volunteer had a high unilateral epidural after a lumbar plexus block without needle tip tracking and one volunteer had symptoms of systemic local anaesthetic toxicity during a lumbar plexus block with needle tip tracking.

Procedural time was similar with, and without, the use of needle tip tracking technology (Table 1). Hand motion analysis showed a significant decrease in the number of hand movements and path length with the use of needle tip tracking (Table 1). The mean (SD) number of injections applied during the lumbar block procedure was lower with

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**Figure 3** Modified CONSORT flow diagram of study participants.
needle tip tracking (1.0 (0.0) vs. 1.2 (0.4), respectively; mean (95%CI) crossover difference –0.2 (–0.3 to 0.0); p = 0.04).

Incidence of paraesthesia during block performance was similar with, and without, the use of needle tip tracking (3/25 vs. 6/26, respectively; p = 0.32). Observation of muscle twitches with a constant stimulation current of 0.5 mA (with 0.1 ms impulse duration) was also identical with, and without, needle tip tracking (2/25 vs. 2/26, respectively; p = 1.00). Mean (SD) current thresholds to obtain a motor response were 1.48 (0.75) mA with needle tip tracking and 1.07 (0.44) mA without needle tip tracking (mean (95%) crossover difference 0.40 (–0.04 to 0.85) mA; p = 0.07).

The assessment of discomfort during the block procedure by volunteers was similar with, and without, needle tip tracking (mean (SD) score 3.9 (1.7) vs. 4.3 (2.1), respectively; mean (95%) crossover difference 0.4 (–1.0 to 0.2); p = 0.18). The mean (SD) anaesthetists’ confidence rating for block success was 8.6 (1.0) with needle tip tracking and 8.4 (1.4) without (mean (95%CI) crossover difference 0.2 (–0.5 to 0.9); p = 0.54).

Block success rates after 30 min were similar with, and without, needle tip tracking (15/25 vs. 17/26, respectively; p = 0.76). No differences were found for mean (SD) block onset time (11.7 (5.8) min vs. 20.4 (23.2) min; mean (95%) crossover difference –8.8 (–24.3 to 6.8) min; p = 0.24), block duration (125.0 (49.3) min vs. 107.5 (39.3) min; mean (95%CI) crossover difference –8.8 (–24.3 to 6.8) min; p = 0.29) and total block regression time (190.0 (47.4) min vs. 205.0 (40.2) min; mean (95%CI) crossover difference –15 (–40.6 to 10.6) min; p = 0.24) with, and without, the use of needle tip tracking, respectively.

### Discussion

We have shown that the use of Onvision needle tip tracking technology for out-of-plane ultrasound-guided lumbar plexus blocks does not reduce procedural time. However, motion analyses of the needling hand showed a 44% reduction in total path length and a 34% decrease in the number of hand movements when needle tip tracking was used. These reductions did reach statistical significance; however, these were secondary outcome measures and the study was not powered for these endpoints. The reduction in the number of injections applied during the lumbar plexus block with the use of needle tip tracking might indicate that the technology helped place the needle tip at the correct position at the first attempt without any redirections.

In our previous study, 40 anaesthetists with different levels of regional anaesthesia experience, performed ultrasound-guided needling procedures using a phantom model. In that study, a statistically significant reduction in procedural time and number of needle hand movements was found when needle tip tracking technology was used for out-of-plane needling procedures [9]. Our present study, however, did not show any statistically significant difference in procedural time.

Different needle tracking technologies have been developed to facilitate needling procedures [2–4, 14]. For regional anaesthesia, the use of needle tracking technology has been tested clinically in case series and cohort studies without control groups. Randomised controlled trials were only done using cadaveric or phantom models. These studies showed improvements in block performance as measured by operator comfort, fewer needle attempts, shorter procedural times and faster learning curves [15, 16]. To the best of our knowledge our study is the first published randomised controlled trial on live humans to investigate needle tracking technologies for regional anaesthesia procedures.

It has been suggested that needle tracking technologies might be beneficial for novice sonographers [7]. In contrast, the anaesthetists participating in our study had substantial experience in ultrasound-guided regional anaesthesia procedures. Further studies should be performed in order to investigate the effect of needle tip tracking technology when used by novice and less experienced doctors.

Procedural time has been used in numerous regional anaesthesia studies as a marker for needling control [17, 18]. Other outcome measures such as the incidence of complications (in particular nerve injury) might be of greater relevance for both clinicians and patients. However, complications associated with peripheral nerve blocks are

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**Table 1** Procedural time and hand motion analysis during lumbar plexus blocks with needle tip tracking compared with control. Values are mean (SD) and mean (95%CI).

|                          | n  | Needle tip tracking | Control | Crossover difference | p value |
|--------------------------|----|---------------------|---------|----------------------|---------|
| Procedure time; s        | 25 | 163 (103)           | 216 (117) | –53 (–115 to 10)    | 0.10    |
| Needle hand movements; n | 25 | 39 (29)             | 59 (36) | –20 (–38 to –2)     | 0.03    |
| Needle hand path length; m | 25 | 3.2 (3.1)           | 5.5 (4.5) | –2.3 (–4.4 to –0.3) | 0.03    |
| Probe hand movements; n  | 24 | 1 (1)               | 6 (19)  | –5 (–13 to 3)       | 0.23    |
| Probe hand path length; m | 24 | 0.3 (0.4)           | 0.8 (1.3) | –0.4 (–1.0 to 0.2) | 0.14    |
relatively rare and very large sample sizes are required to demonstrate any reduction in complication rate. Hence, this is not a suitable as outcome measure for single-centre clinical trials. A reduction in nerve injuries has not been shown in clinical trials comparing different nerve location techniques [19]. It has been suggested that block success rate is the most relevant outcome for regional anaesthesia studies [20]. Depending on the expected success rates, samples sizes for these studies might still be high. These issues could explain why procedural time has been the primary outcome measure in most studies evaluating needle tip identification in ultrasound-guided procedures [7].

In recent years, hand motion analysis has been used to assess dexterity, learning curves and expert status during different manual surgical and medical interventions [21–23]. An important advantage of hand motion analysis is the objective endpoints that can be measured by a computerised tracking system [24]. For regional anaesthesia, hand motion analysis has been validated in two studies involving supraclavicular plexus block and epidural insertion [25, 26]. For validation purposes, the results from hand motion tracking were compared with procedural checklists and global rating scales during the needling procedures. Chin et al. concluded that hand motion analysis could be applied to any task in which manual dexterity is deemed to be an important determinant of skill [25].

The success rate of lumbar plexus blocks in our study was low. This can be explained by the use of a relatively low volume of local anaesthetic (20 ml). This is lower than that recommended by a dose-finding study from our study group where a volume of 36 ml was necessary to provide successful lumbar plexus block in 95% of cases [27]. In our volunteer study, blocks did not have to provide effective anaesthesia or analgesia since none of the participants was scheduled for a surgical procedure. A lower volume, on the other hand, was considered suitable to ensure short and predictable recovery periods and reduce the risk of toxicity.

Our study has some limitations. Performing ultrasound-guided nerve blocks in healthy volunteers differs from the clinical situation where patients often are older with a higher body mass index and comorbidities, and as such, our results cannot be extrapolated to these patient populations. However, the use of needle tip tracking technology might have been more beneficial in patients with more difficult sono-anatomy. The two anaesthetists performing the ultrasound blocks in this study were experienced in performing ultrasound-guided nerve blocks and were performing lumbar plexus blocks for orthopaedic procedures regularly. However, their experience with the Onvision needle tip tracking technology was limited to a test period of one week in which they used the system in Thiel cadavers, muscle tissue phantom and gelatine phantom models. The Onvision technology was only CE approved shortly before the start of the study, thus the anaesthetists could not use the needle tip tracking technology in their clinical practice before participating in the study. More operator experience with needle tip tracking may have influenced the study findings. To ensure blinding of the observers was maintained, needles were not changed: the same type of Onvision needles were used throughout the study with either active or inactive needle tip tracking technology, depending on the group allocation. The use of echogenic needles could have improved the results in the control procedures but based on pilot tests with the Onvision needles and the results of our previous phantom study, we anticipate that any difference would be minimal.

Two of the participants were not analysed due to adverse events. One participant experienced local anaesthetic systemic toxicity symptoms manifested by sudden dizziness, tachycardia and transient tinnitus after injection of 10 ml lidocaine 2% with 5 µg ml⁻¹ adrenaline. The symptoms occurred despite negative aspiration tests and ultrasound visualisation of local anaesthetic spread. After discontinuing the block procedure, the participant recovered from the symptoms within 10 min. Due to the interruption of the local anaesthetic injection, comparable measurements and consecutive data analyses could no longer be performed. The participant was, therefore, not included in the study. The other participant had unilateral epidural spread on the side of the lumbar plexus block with a loss of cold sensation to the level of T3. Heart rate and blood pressure remained stable. Anticipating that the participant could have above average risk for epidural spread from the lumbar plexus block on the second study day, we decided to not include the participant. Although unilateral epidural spread occurred in a block without needle tip tracking, the local anaesthetic toxicity was observed in a needle tip tracking procedure. The incidence of adverse events in our study is likely to be irrespective of the use of needle tip tracking. Lumbar plexus block should, however, be considered as an expert procedure with the risk of potential complications [28].

In summary, the use of the Onvision needle tip tracking technology does not reduce the procedural time when performing out-of-plane ultrasound-guided lumbar plexus block. Hand motion analyses of the needling hand did show a reduction in the total path length and number of hand movements with needle tip tracking which may indicate improved needle control; however, further studies are needed to confirm this finding.
Acknowledgements

We thank T Nyenget and K S Hammeren at the Paediatric Clinical Trial Ward, Department of Paediatric Research, Division of Paediatric and Adolescent Medicine, Oslo University Hospital for their support with the volunteers in the study. This project has received funding from the European Union’s Horizon 2020 research and innovation programmes (grant agreement 691262). B. Braun Melsungen AG and Philips Medical Systems International B V have been partners in the European Union’s Horizon 2020 program. The main task for Oslo University Hospital was to conduct pre-clinical and clinical studies to evaluate the Onvision needle tip tracking technology. Ultrasound system and disposables used in the study were provided by B. Braun Melsungen AG and Philips Medical Systems International B V.

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