**ORIGINAL ARTICLE**

# Needle tip tracking for ultrasound-guided peripheral nerve block procedures—An observer blinded, randomised, controlled, crossover study on a phantom model

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**Background:** The Onvision needle tip tracking (NTT) is a new technology consisting of a needle with an ultrasound sensor close to the needle tip and a console for computerised signal processing. The aim of the study was to evaluate NTT technology during ultrasound-guided simulated peripheral nerve block procedures in a porcine phantom model.

**Methods:** Forty anaesthesiologists performed in-plane and out-of-plane simulated nerve blocks with and without NTT guidance. The primary outcome measure was procedure time. Secondary outcomes were hand movements and the path length travelled by the hands measured by motion analysis, precision of the needle tip related to the target structure, success rates and violations of the target structure, and the participants confidence whether their procedure would be successful or not.

**Results:** Procedure time was reduced from 66.7 (SD = 47.5) seconds to 43.8 (SD = 29.2) seconds when NTT was used for out-of-plane procedures ($P = 0.002$). The number of hand movements of the probe hand was 13.9 (SD = 30.2) with NTT and 22.8 (SD = 30.0) without NTT ($P = 0.019$). No significant differences were registered during the performance of in-plane procedures. The participants confidence in a presumed block success was increased with both in-plane procedures (8.50 (SD = 1.18) with NTT vs 7.65 (SD = 1.96), $P = 0.004$) and out-of-plane procedures (8.50 (SD = 1.09) vs 7.10 (SD = 1.89), $P = 0.0001$).

**Conclusions:** The new NTT technology significantly reduced the procedure time and the number of hand movements for ultrasound-guided out-of-plane PNB procedures. No significant differences were found for the in-plane procedures.

## 1 | INTRODUCTION

Navigation systems for needle guidance have been developed to facilitate performance, improve success rates and increase safety of ultrasound-guided procedures. Systems with electromagnetic needle tracking (EMT) with active sensors, passive EMT, fibre optic hydrophones, vibrating needles combined with colour Doppler and camera tracking have been used.[1-6] At present, these needle tracking technologies are not commonly used in regional anaesthesia.[7]

The Onvision technology (B. Braun Melsungen AG, Melsungen, Germany and Philips Medical Systems International BV, Eindhoven, The Netherlands) has recently been developed for needle tip tracking (NTT) during ultrasound-guided regional anaesthesia procedures. However, the technology has not been investigated and evaluated in a controlled trial.

The aim of the study was to evaluate the effect of the NTT technology used by anaesthesiologists with varying levels of experience using a phantom model. The effect of the NTT on the conduction and precision of needling procedure, and the anaesthesiologist's confidence whether their procedure would be successful or not in vivo should be investigated in a crossover study setup.

We hypothesised that the NTT technology would reduce procedure time when used in both in-plane and out-of-plane procedures.

## 2 | METHODS

The project was evaluated and assessed by the Committee for Medical Research Ethics, Region South East, Oslo, Norway on 1 July 2016 (2016/1140 A), considering the project was outside the scope of the Health Research Act and should be implemented without further approval. The study protocol was completed before enrolling participants and conducting experiments in the study.

This was an experimental, observer blinded, randomised, controlled, crossover study. Forty anaesthesiologists were asked to perform simulated peripheral nerve blocks in a phantom model. Experiments with an out-of-plane and an in-plane needle approach were considered as independent trials.

### 2.1 | The needle tip tracking technology

The Onvision technology consists of a StimuplexOnvision needle (B. Braun Melsungen AG, Melsungen, Germany) with a piezoelectric sensor close to the needle tip (Figure 1 A) and an electronic console processing computerised signals that is integrated in the Xperius ultrasound system (Philips Medical Systems International BV, Eindhoven, The Netherlands). The ultrasound field, sent out by the transducer for imaging, is collected by the sensor and transferred into the signal processing unit that calculates and projects the position of the sensor on the 2D ultrasound image (Figure 2). The position of the needle tip is indicated by a circle on the ultrasound screen. For in-plane procedures, the centre of the circle is equal to the location of the sensor on the needle. The tip is always located within the circle in the lower half, where the needle tip is close to the edge of the circle. For out-of-plane procedures, the tip is also located within (the lower half) of the circle, but not as close to the edge of the circle. When in proximity to a target structure, the needle tip should be attempted to directly identify the needle tip in the ultrasound image.

A small green circle on the ultrasound screen indicates that the sensor position is within the ultrasound beam (Figure 1B). When the needle is positioned outside but still close to the 2D imaging plane, the sensor can still pick up faint ultrasound signals. Thus, even if the needle tip is positioned slightly outside the imaging

**Editorial comments**

Needle tip guidance for ultrasound-guided peripheral nerve blocks is presently not standard practice. This trial tested a novel navigation system for nerve blocks, using a porcine phantom model, and with a group anaesthesiologists as participants. The results indicated shorter procedure time and fewer hand movements when the needle tip tracking technology was used for out-of-plane technique but not for the in-plane technique. Needle tip guidance shows clear promise, and will continue to be refined.

plane and is invisible for the operator, the position of the needle tip is indicated on the ultrasound screen by a red circle and a blue larger circle (Figure 1C). As the needle tip moves away from the ultrasound imaging plane, the blue circle becomes larger until maximally two times the size of the inner red circle, after which it disappears. Dependent on ultrasound settings and depth, this corresponds to a certain distance between the needle tip and the imaging plane.
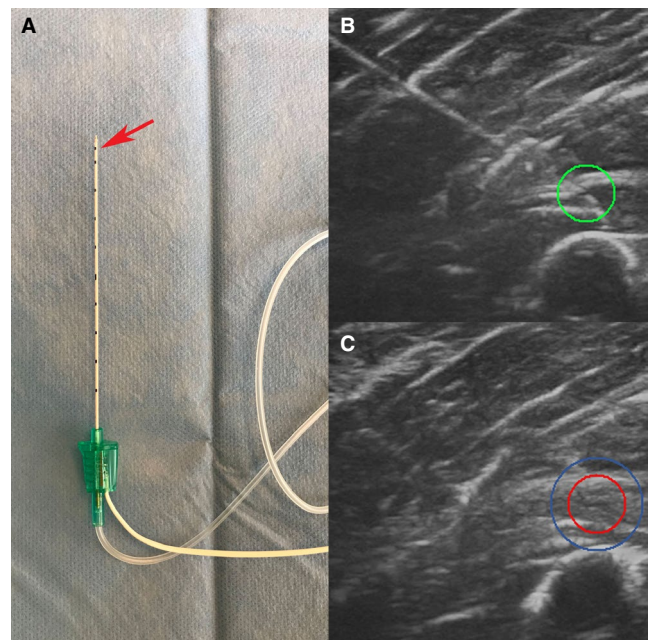


**FIGURE 1** The Onvision needle tip tracking technology. A, A piezoelectric sensor is wrapped around the needle close to the needle tip. The red arrow indicates the position of the sensor. B, A small circle represents the sensor position at the needle tip on the ultrasound screen. A circle with green colour indicates that the needle tip is within the ultrasound image plane. C, When the needle tip is outside of the ultrasound imaging plane, the sensor can still be picking up faint ultrasound signals. Then, the depth of the needle tip is indicated by a red circle and a larger blue circle with increasing or decreasing diameter depending on the distance between the needle tip and the image plane

**FIGURE 2** A piezoelectric sensor close to the needle tip collects the ultrasound waves, sent out by the transducer for imaging. A signal processing unit calculates and projects the position of the sensor on the 2D ultrasound image
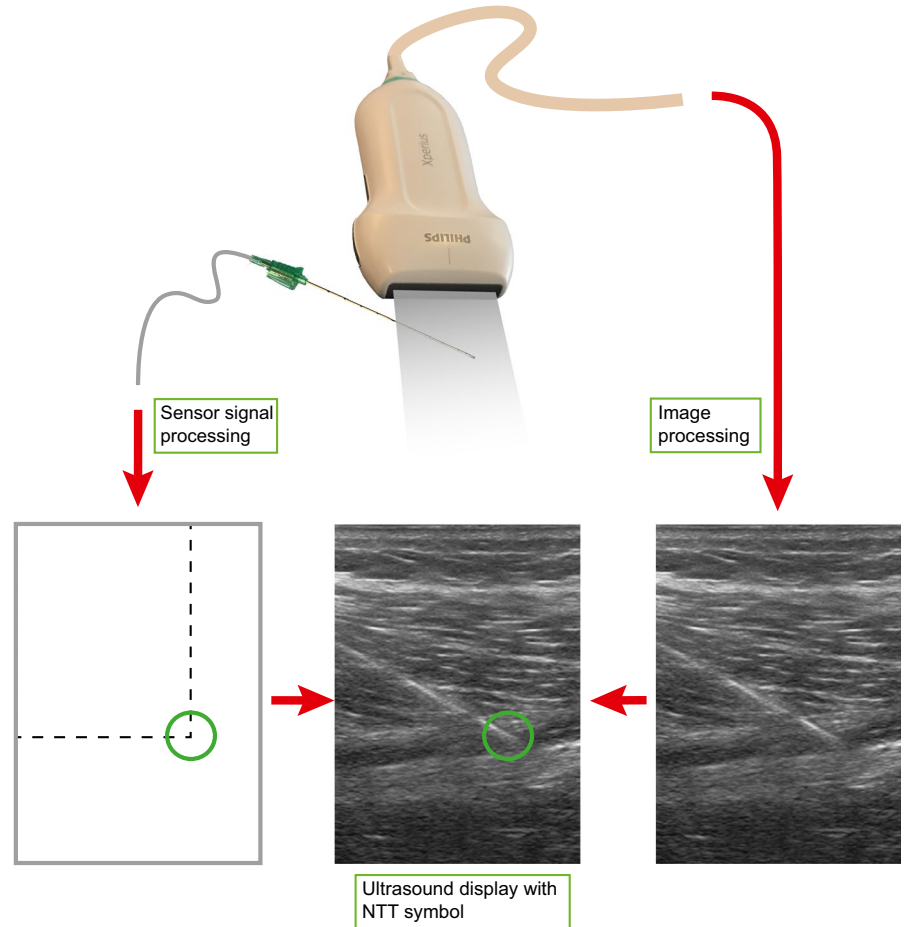
## 2.2 | Phantom model

Boneless pieces of porcine muscle tissue from pork (bottom round) with 2.3 to 2.5 kg weight were placed in acrylic glass boxes measuring 8 × 15 × 26 cm. The artificial nerve was made of a latex rubber tube with an outside diameter of 10 mm and an inner diameter of 7 mm (with a total length of 10 m) that was pulled through the muscle tissue piece using a surgical clam. The depth of the target structure was aimed to be around 4 cm. The tube was filled with 20 mL Omnipaque 300 contrast agent diluted with NaCl 9 mg/mL in a 1:1 ratio and sealed with clamps on both sides of the phantom. (Figure 3A) The tube was pulled out through the muscle tissue after each needling procedure and a 25-cm section was cut for manual inspection of signs of damage after needle contact.

## 2.3 | Ultrasound-guided needling procedures

An Xperius Ultrasound System (Philips Medical Systems International BV, Eindhoven, The Netherlands) with a linear ultrasound transducer and a 100 mm Stimuplex Onvision needle (B. Braun Melsungen AG, Melsungen, Germany) with a 30° bevel was used for ultrasound-guided procedures. The Onvision system (Philips Medical Systems Nederland BV, Best, The Netherlands) was used for procedures carried out with NTT.

In-plane procedures were performed as follows: The participants were asked to place the needle tip in two pre-defined positions close to the tubular nerve-like target structure. The target structure was visualised in short-axis view (Figure 4A). The needle advancement was visualised from left (corresponding to ultrasound orientation marker) to right. The first needle tip position was between 6 and 9 o'clock (in reference to a clock face: 12 o'clock—0 degrees—superficial; 3 o'clock—90 degrees—right image side; 6 o'clock—180 degrees—deep; 9 o'clock—270 degrees—left image side). The second needle tip position was between 3 and 6 o'clock (Figure 4A). Each time the needle tip was placed in one of the pre-defined target positions; the participant tried to optimise transducer position for an appropriate 2D ultrasound image and asked an assistant to save the ultrasound image. NTT was deactivated while saving the image.

Out-of-plane procedures were performed as follows: The artificial nerve was visualised in short-axis view. The participants inserted the needle perpendicular to the plane of the ultrasound beam. They were asked to place the needle tip on the right side and close to the artificial nerve (between 1:30 and 4:30 o'clock in reference to a clock face) (Figure 4B).

After finishing the procedure, the needles were kept in the final position in the phantom for cone beam computed tomography (CT) examination. Having performed one in-plane and one out-of-plane
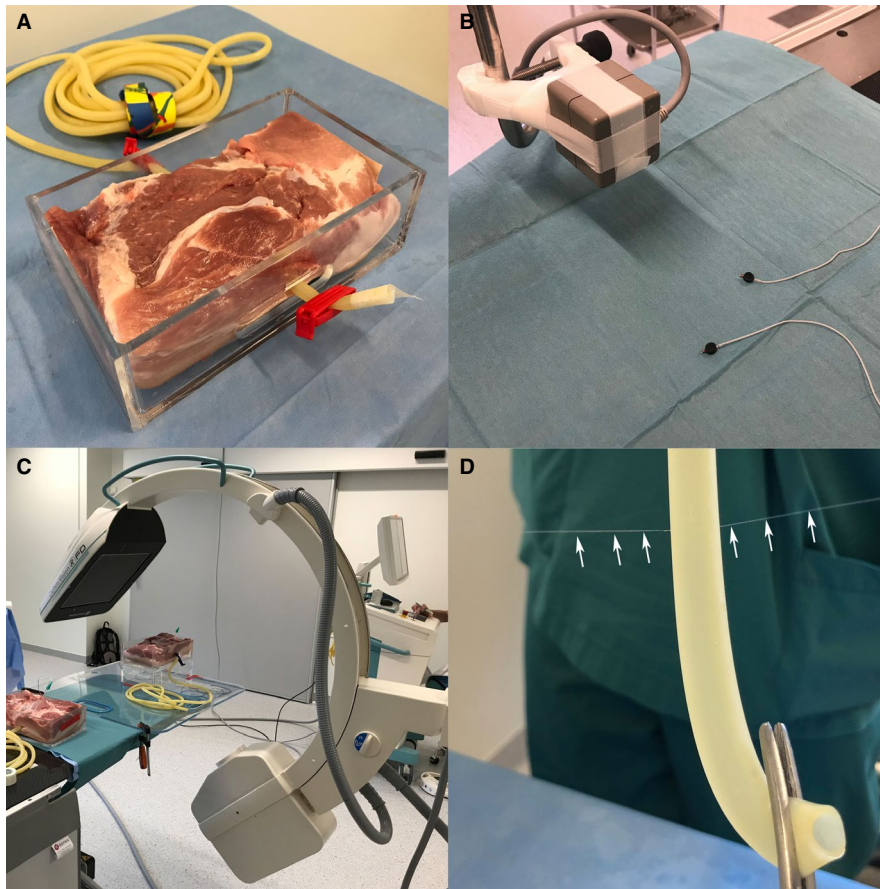
**FIGURE 3** Peripheral nerve block phantom model and measurements. A, Pieces of muscle tissue from pork (bottom round) were placed in acrylic glass boxes and pierced with rubber tubes. The tubes were filled with contrast agent. B, The number of movements and distance travelled by each hand was measured with an electromagnetic motion tracking system. C, A mobile C-arm scanner was used for cone beam computed tomography 3D reconstructions of the phantom models after the needles were placed in the target positions. D, Tube sections were examined macroscopically after the needling procedures to detect violations of the target structure. The white arrows mark leakage of fluid through two perforating holes

procedures with or without NTT in a set of two phantoms (depending on sequence allocation), the participants left the study room while X-ray examination of the phantoms was conducted. After a 10-minutes break, the participants performed a second in-plane and a second out-of-plane procedure.

## 2.4 | Instruction and training

All participants went through a 30-minutes instruction and training period immediately before performing the study tasks. First, the participants watched a video clip demonstrating the NTT technology and received verbal explanations taking a 10-minutes period. Thereafter, they trained for 20 minutes on the use of the NTT technology using the porcine phantom model. The practical training included systematic performance of several in-plane and out-of-plane procedures with feedback and advise from the instructor.

## 2.5 | Outcomes and assessments

### 2.5.1 | Procedure time

The primary outcome measure was procedure time (in seconds) measured from needle insertion until needle placement in the final target position (for in-plane procedures the final target position referred to the second needle position). The timer function of the MotionMonitor
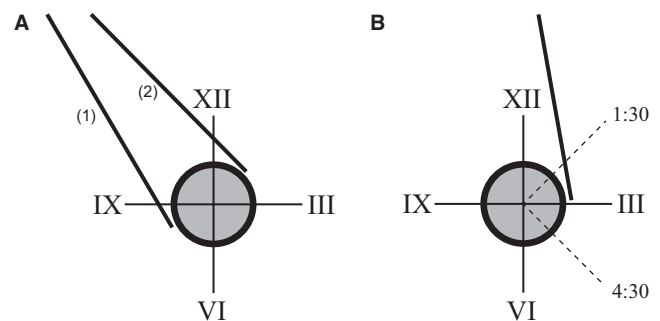


**FIGURE 4** Ultrasound-guided procedures. A, In-plane procedures: The needle tip was placed in two defined positions close to the target structure. The first needle tip position was between 6 and 9 o'clock (in reference to a clock face). The second needle tip position was between 3 and 6 o'clock. B, Out-of-plane procedures: The needle tip was placed in a single position close to the target structure between 1:30 and 4:30 o'clock

xGen software for acquisition, visualisation and analysis (Innovative Sports Training, Inc Chicago, IL, USA) was used for the measurement.

### 2.5.2 | Hand motion analysis

A Polhemus Patriot electromagnetic motion tracking system (Polhemus, Colchester, VT, USA) with The MotionMonitor xGen software for acquisition, visualisation and analysis (Innovative Sports Training, Inc Chicago, IL, USA) was used to measure the number

of movements and distance travelled by each hand (Figure 3B). PolhemusMicro Sensors 1.8 (Polhemus, Colchester, VT, USA) were placed on the distal phalanx of the third finger of each hand. Total path length and the number of hand movements were measured from the time of needle insertion until the needle was placed in the final target position. Based on pilot measurements, a cut-off velocity of 0.03 mm/s and a Butterworth cut-off frequency of 2.0 Hz was chosen to identify hand movements.

### 2.5.3 | X-ray examination

A Ziehm Vision RFD 3D mobile C-arm scanner (Ziehm Imaging GmbH, Nürnberg, Germany) was used for cone beam CT3D reconstructions of the phantom models after the needles were placed in the target positions (Figure 3C). The distance (in millimetres) between the needle tip and the contrast agent inside the target structure was registered as a measure for the precision of needle placement. When the distance between the needle tip and the contrast agent was 3.5 mm or less, a procedure was considered successful. Needle tip positions within the contrast agent were considered as violation of the target structure. Distances between the needle tip and the contrast in the target structure smaller than 0.75 mm were regarded as critically close, while distances between 0.75 and 1.5 mm were defined as very close (considering a 1.5-mm thickness of the rubber tube walls).

### 2.5.4 | Macroscopic examination of rubber tubes

After the needling procedures and cone beam CT measurements, the rubber tubes were removed from the phantom model and filled with saline with a 50-mL syringe. Then the open end was sealed with a clamp, and injection pressure was increased until tube diameters had increased by approximately 50%. Finally, the tubes were then carefully inspected for leakage caused by tube perforations (Figure 3 D).

### 2.5.5 | Confidence in a presumed block success

Immediately after the simulated block procedure, the participants had to state if they expected the procedure to be successful if it was performed on a real patient. A numeric rating scale (NRS) was used to describe the estimated likelihood (0 = procedure success most unlikely, 10 = procedure success most likely).

### 2.6 | Randomisation and blinding

Participants were randomly assigned to the sequence of interventions (ultrasound-guided procedures with or without NTT). Randomised assignment was done independently for in-plane and out-of-plane procedures. A person not involved in the collection or analyses of the data, assigned the participants into two groups of equal size using a list of random numbers, according to the Moses-Oakford algorithm.[8,9] A sealed consecutively numbered and opaque envelope revealing group allocation was opened by one of the investigators

(ARS) immediately before a participant performed the first needling procedure. The assignment weather NTT had to be used or not was shown to the participant. Allocation of both in-plane and out-of-plane procedures trial were placed in the same consecutively numbered envelope.

The independent observers collecting outcome data were blinded for the sequence allocation and were not aware whether the NTT was active or inactive. The observer could see the hands of the participant directing the needle and the transducer while the ultrasound screen displaying NTT symbols was protected from their views. The participants were also asked to verbally indicate that they had finished the needling procedure to ensure correct measurements by the blinded observers.

### 2.7 | Statistical analysis

The primary outcome measure was procedure time (in seconds). Based on previous phantom studies, a standard deviation (SD) of up to 50% can be expected for the procedure time.[10] We considered a reduction of 25% procedure time as clinically significant. In a two-sided crossover analysis, a sample size of 34 participants would have 80% power to detect a difference in means of 25% assuming a SD of 50% and a correlation between paired observations of 0.5, using a paired-sample t-test with alpha 0.05. To allow for missing data or dropouts, we planned to include 40 participants.

In the present study, the in-plane and out-of-plane procedures were two independent experimental trials with identical outcome measures. Therefore, no multiplicity correction was performed for the main outcome procedure time in the in-plane and out-of-plane trial. Considering the exploratory nature of the study, no adjustment for multiple testing/estimation was done for secondary outcomes.

All continuous and discrete data were analysed with paired-sample t tests and corresponding 95% confidence intervals. Binary categorical outcomes were analysed with asymptotic McNemar tests, and categorical variables with more than two outcomes were analysed with score tests for marginal mean scores.[11] Linear regression was used to estimate the effect of experience on procedure time. The statistical analyses were done with Stata/SE 15.1 (StataCorp LLC, College Station, TX). Group allocation was coded during statistical analysis. Codes were broken upon completion of the analysis.

## 3 | RESULTS

Forty anaesthesiologists employed at the Department of Anaesthesiology at the Oslo University Hospital gave written informed consent to participate in the study. Their mean experience in the field of anaesthesiology was 13.0 (SD = 6.7, range 4-34) years. Ten of the participants were residents, and 30 were consultants. Their average number of ultrasound-guided procedures per week was 3.8 (SD = 3.0, range 0-10). The study was conducted between 18 June and 22 June 2018.

**TABLE 1** Comparison of performance time and hand motion analysis with and without needle tip tracking

| | With NTT | Without NTT | Crossover difference | | |
| --- | --- | --- | --- | --- | --- |
| | Mean ± SD | Mean ± SD | Mean (95% CI) | P | n |
| In-plane procedures | | | | | |
| Performance time | 89.1 ± 52.2 | 95.1 ± 67.1 | −6.03 (−27.6 to 15.6) | 0.58 | 40 |
| Needle hand – movements (n) | 24.9 ± 39.1 | 32.1 ± 48.3 | −7.18 (−20.2 to 5.66) | 0.26 | 38 |
| Needle hand – path length (m) | 1.80 ± 3.83 | 1.90 ± 2.62 | −0.10 (−1.27 to 1.08) | 0.87 | 38 |
| Probe hand – movements (n) | 3.00 ± 6.79 | 2.95 ± 5.39 | 0.05 (−2.42 to 2.52) | 0.97 | 40 |
| Probe hand – path length (m) | 0.26 ± 0.40 | 0.33 ± 0.48 | −0.07 (−0.25 to 0.11) | 0.46 | 40 |
| Out-of-plane procedures | | | | | |
| Performance time | 43.8 ± 29.2 | 66.7 ± 47.5 | −22.9 (−37.2 to − 8.66) | 0.002 | 40 |
| Needle hand – movements (n) | 13.9 ± 30.2 | 24.8 ± 30.0 | −10.9 (−20.0 to −1.89) | 0.019 | 39 |
| Needle hand – path length (m) | 0.87 ± 1.88 | 1.37 ± 1.45 | −0.50 (−1.05 to 0.06) | 0.076 | 39 |
| Probe hand – movements (n) | 2.80 ± 7.77 | 2.40 ± 4.21 | 0.40 (−2.06 to 2.86) | 0.74 | 40 |
| Probe hand – path length (m) | 0.29 ± 0.64 | 0.27 ± 0.42 | 0.02 (−0.22 to 0.25) | 0.89 | 40 |

## 3.1 | Skills

The main outcome measure, procedure time, was reduced from 66.7 (SD = 47.5) seconds to 43.8 (SD = 29.2) seconds when NTT was used for out-of-plane procedures ($P$ = 0.002) (Table 1). For in-plane procedures, procedure time was 89.1 (SD = 52.2) with NTT and 95.1 (SD = 67.1) without NTT ($P$ = 0.58). The number of hand movements measured for the needle hand was statistically significant reduced when NTT was used for out-of-plane procedures. Other hand motion measurements did not show significant differences. There were missing data in three of the paired measurements because of defect measurement sensors that had to be replaced.

## 3.2 | Precision of needle placement

For in-plane procedures, the mean distance from the needle tip to the X-ray contrast within the target structure (measured by cone beam CT) was 3.0 (SD = 3.1) mm with NTT and 2.80 (SD = 1.5) mm without NTT (mean crossover difference = 0.22 mm; 95% CI = −0.79 to 1.23 mm, $P$ = 0.66). For out-of-plane procedures, a non-significant shorter distance between the needle tip and target structure (X-ray contrast) was found when NTT was used. The mean distance was 2.41 (SD = 1.04) mm with NNT vs 3.38 (SD = 3.15) mm without NTT (mean crossover difference = −0.97 mm; 95% CI = −2.00 to 0.06 mm, $P$ = 0.063).

## 3.3 | Violation of target structure

When in-plane techniques were performed, one (2.5%) violation was detected by macroscopic inspection after NTT procedures, while two (5%) violations occurred without NTT ($P$ = 0.32). For out-of-plane procedures, no violations were found in NTT procedures. In contrary, three (7.5%) violations were detected in procedures without NTT ($P$ = 0.08).

For in-plane approaches, a very close distance to the X-ray contrast in the target structure (between 0.75 mm and 1.5 mm) was found in four (10%) of the cases with NTT and in four (10%) of the cases without NTT guidance. A critically close distance (less than 0.75 mm) was found in one (2.5%) of the NTT procedures and in two (5%) of the needle approaches without NTT ($P$ = 0.59). For out-of-plane approaches, a very close distance (between 0.75 mm and 1.5 mm) was found in five (12.5%) of the cases with NTT and in four (10%) of the cases without NTT guidance. A critically close distance (less than 0.75 mm) was found in one (2.5%) of the cases with NTT and in one (2.5%) of the cases without NTT ($P$ = 0.71).

## 3.4 | Block success

Block success, defined as a final needle position within 2 mm distance to the outer surface of the target structure (3.5 mm to the X-ray contrast) as estimated by X-ray examination, was 77.5% (n = 31) with NTT and 75.0% (n = 30) without NTT for in-plane procedures ($P$ = 0.74). For out-of-plane approaches, block success was likely in 87.5% (n = 35) with NTT and 75.0% (n = 30) without NTT ($P$ = 0.10).

When ultrasound images of the needle positions (with deactivated NTT markers) were analysed for in-plane procedures, the needle tip could only be identified in 18 (45%) and 20 (50%) images from procedures with NTT and in 18 (45%) and 21 (52.5%) images from procedures without NTT. With the small amount of available data, no further analyses were performed.

## 3.5 | Confidence

The participant's confidence in a presumed block success was higher when NTT was used for both in-plane and out-of-plane procedures. For in-plane procedures, mean confidence in block success on a scale from 0 to 10 was 8.50 (SD = 1.18) with NTT vs 7.65 (SD = 1.96) without NTT (mean crossover difference = 0.85; 95% CI = 0.30 to 1.40,

*P* = 0.004). For out-of-plane procedures, mean confidence in block success was 8.50 (SD = 1.09) with NTT vs 7.10 (SD = 1.89) without NTT (mean crossover difference = 1.40; 95% CI = 0.30 to 2.06, *P* = 0.0001).

## 3.6 | Effect of experience

The number of ultrasound-guided procedures performed by the anaesthesiologists per week, their position in the hospital (residence vs consultant) and number of years of experience in anaesthesiology had no significant effect on the difference in procedure time of the procedures performed with and without NTT.

## 3.7 | Period effect

A significant period effect was detected for the main outcome variable when in-plane procedures were performed: Procedure time was 104.9 seconds during the first needle procedure and 79.3 seconds during the second procedure (mean period difference = 25.6 seconds; 95% CI = 5.6 to 45.7 seconds, *P* = 0.014). For out-of-plane procedures, procedure time was 56.8 seconds for the first procedure and 53.8 seconds for the second procedure (mean period difference = 3.0 seconds; 95% CI = −13.1 to 19.0 seconds, *P* = 0.71).

## 4 | DISCUSSION

A 34% reduction in procedure time was found when NTT was used for out-of-plane ultrasound-guided simulated nerve block in a phantom model. The number of hand movements of the probe hand was also reduced by 44% with needle tip tracking in out-of-plane procedures. No significant differences were detected for the in-plane procedures.

Ultrasound-guided out-of-plane approaches visualisation and correct identification of the needle tip can be more challenging compared with in-plane procedures.[12] Hence, NTT might offer greater benefits when used for ultrasound out-of-plane techniques. In our phantom study, procedure time was significantly shorter when participants performed the second in-plane needling procedure compared with the first in-plane needling. Curiously, such a distinct period effect was not seen with out-of-plane procedures.

Hand motion analysis is an objective and valid measure for procedure performance. The method has been used analyse dexterity, learning curves and expert level during surgical interventions, diagnostic ultrasound examinations, peripheral nerve blocks and centro-axial block procedures.[13-16] Low numbers of hand movements and short path length travelled by each hand indicate better manual, operative and technical skills. Thus, in our study, the reduced number of hand movements was an indicator for improved performance when NTT was used for ultrasound-guided procedures. The reduced procedure time and reduction of the needle hand movements demonstrate better needle control with NTT when performing out-of-plane techniques.

An improved confidence in a presumed block success experienced by the participants in both in-plane and out-of-plane procedures strengthens the impression that NTT facilitates nerve block procedures. However, the importance of confidence as an outcome measure should not be overemphasised.

By the use of a porcine phantom model, we try to simulate clinical reality. The use of muscle models produces a more lifelike simulation compared with gelatine, tofu or Blue Phantom models.[17,18] In PNB phantom models, tubes or cables are often used as target structures. Artificial target structures such as the rubber tubes used in our study, are usually more hyperechoic and less anisotropic compared with human peripheral nerves, making them easier to visualise and to target. Thus, data from studies on phantom models might have higher precision and less variation than studies on living humans. The evaluation of a new clinical method using a phantom demands a model where the procedure is transmissible with similar procedures in clinical practice. In the present study, the ultrasound image of the porcine phantom model with an artificial nerve has similarities with the ultrasound image obtained when performing clinical procedures like sciatic nerve blocks.

The study had some limitations. Our measurements were performed in a phantom model and cannot be transferred directly to the clinical situation. PNBs in patients are more complex compared with needling procedures in a phantom model.

The period effect during in-plane procedures is another limitation. In the study, it was a 10-minute break between procedures tested in the crossover study setup. Participants might have undergone a mental processing and preparation of the tasks performed in the phantom model. A longer washout period between the needling procedures could have reduced such a period effect.

Before carrying out the study tasks, participants received instructions on the NTT and trained with the system during a 30-minute period. In a learning curve study by McVicar et al, 69% of the participants achieved "proficiency" after 30 repetitive needling procedures in a simulator model using an electromagnetic needle guidance system.[4] Participants in our study might not have reached that level on their learning curves.

We considered procedure time and hand motion measurements as suitable proxy markers indicating a better needle control. Improvement of complication rates can also be seen as a relevant outcome. If a technique has high success rates and few complications, it takes a very large sample size to demonstrate significant differences between competing methods. This is often not possible in a single clinical trial.

In our study, active needle tip tracking was compared with ultrasound-guided needle placement without tracking technology. Thus, the present study does not provide any information regarding superiority of the Onvision technology compared with other systems for needle guidance.

To ensure blinding of the observer in our study, all procedures were performed with Stimuplex Onvision needles. According to the group allocation of the participants, the NTT system was either active or inactive. Using needles with echogenic enhancement could have improved needle visualisation in the control procedure. When tested in pilot experiments, the NTT needles were fairly echogenic and provide clinically acceptable reflection of the ultrasound waves.

In a phantom model for vascular access, a successful procedure is defined by fluid aspiration from a tubular target structure.[19] For

PNB models, the definition of a successful procedure is challenging. Frequently, expert evaluations of ultrasound images or video clips have been used to decide whether a simulated PNB procedure is successful or not.[14] Such expert evaluations are highly observer dependent and have a considerable risk of bias. In our phantom study, cone beam CT was primarily used to evaluate the precise needle positions. The needles and the target structures could clearly be identified in all X-ray images. The expert with long and solid ultrasound experience, who tried to evaluate needle positions in ultrasound 2D images, could only identify the needle tip in 50% of the cases. Considering ultrasound as a dynamic method, the use of video loops might have improved successful needle tip identification by the observer.

Conclusively, the new Onvision NTT technology tested in a PNB phantom model significantly reduced procedure time and the number of hand movements for ultrasound-guided out-of-plane procedures. No significant differences were found for the in-plane procedure. Easier block performance and reduced procedure time in out-of-plane procedures support the use of NTT in clinical practice.

## ACKNOWLEDGEMENT

## CONFLICT OF INTEREST

B. Braun Melsungen AG and Philips Medical Systems International BV 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 NTT technology.

## AUTHOR CONTRIBUTIONS

TK, LR, LAR, KU, MWF, PKH, PK and ARS planned and designed the study. TK, LR, KU, PKH and ARS collected and screened the data. MWF performed statistical analysis and calculations. TK, LR, LAR, KU, MWF, PKH, PK and ARS interpreted the data. TK, LR, LAR, KU, MWF, PKH, PK and ARS wrote and edited the manuscript. ARS designed the figures.

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