# Novel Navigated Ultrasound Compared With Conventional Ultrasound for Vascular Access—a Prospective Study in a Gel Phantom Model

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**Objectives: The authors hypothesized that, compared with conventional ultrasound (CUS), the use of a novel navigated ultrasound (NUS) technology would increase success rates and decrease performance times of vascular access procedures in a gel phantom model.**

**Design: A prospective, randomized, crossover study.**

**Setting: A university Hospital.**

**Participants: Participants were 44 anesthesiologists with varying clinical experience.**

**Interventions: Anesthesiologists performed in-plane and out-of-plane vascular access procedures using both NUS and CUS for needle visualization in a gel phantom model.**

**Measurements and Main Results: Procedure time was measured from needle insertion to verbalization of final needle positioning by the participants, and successful needle placement into the simulated vessel was verified by aspiration of simulated blood. By employing ultrasound navigation capabilities in addition to real-time ultrasound imaging during in-plane/long-axis vascular access procedures, median procedure time showed a nonsignificant decrease (7.5 seconds *v* 13.0 seconds; $p = 0.028$), and the observed increase in procedure success rate (90.9% *v* 100%; $p = 0.125$) did not reach statistical significance. For out-of-plane/short-axis vascular access procedures, a significant reduction in median procedure time (5.0 seconds *v* 11.5 seconds; $p < 0.001$) and a significant increase in procedure success rate (75% *v* 100%; $p < 0.001$) were achieved by using navigation technology combined with real-time ultrasound.**

**Conclusions: NUS technology improved the performance times and success rates of vascular access procedures conducted by anesthesiologists in a gel phantom model.**


*KEY WORDS: ultrasound, real-time ultrasound navigation, Ultrasonix GPS, SonixGPS, gel phantom model, vascular access, central venous, central catheter*

ULTRASOUND TECHNOLOGY for needle guidance is emerging to assist anesthesiologists not only in regional anesthesia but also in performing vascular access techniques. Multiple studies have demonstrated various benefits of ultrasound-guided regional anesthesia, ranging from increased procedure success rates[1] and increased cost-effectiveness[2] to improved postoperative analgesia[3] and recovery.[4,5] In addition to its increasing role in regional anesthesia, ultrasound imaging has been adopted widely to achieve vascular access.

The traditional landmark approach for vascular access is based on anatomic reference structures. However, even with substantial clinical training and experience, the landmark technique may prove unsuccessful because of anatomic variations.[6] If landmarks are poor, multiple needle passes may be required, increasing the incidence of procedure-related complications, such as secondary tissue damage, bleeding, and hematoma. Compared with the landmark technique, ultrasound visualization during vascular access has been shown to increase procedure success, while reducing complication rates.[7,8] Whether using ultrasound beforehand to locate the vascular structure or using real-time imaging during cannulation, ultrasound also has been shown to reduce central venous catheterization time compared with the landmark technique.[9,10] The technical and manual skills required for ultrasound imaging during vascular access procedures can be challenging, especially for inexperienced anesthesiologists.[11] Correct needle visualization and precise needle tip control during vascular access and regional anesthesia procedures require clinical experience and training and are often difficult, especially for the novice user. For the novel guided positioning system (GPS) technology tested in this study, real-time ultrasound imaging is combined with on-screen navigation to assist in visualizing and guiding the needle and controlling the needle tip. Visualizing and projecting the needle path during vascular access, ultrasound procedures potentially can be simplified by real-time navigation, providing benefits for experienced and inexperienced anesthesiologists. In this prospective trial, the authors hypothesized that GPS ultrasound navigation improves success rates and decreases procedure times for vascular access in an ultrasound gel model compared with conventional ultrasound (CUS) without navigation.

## METHODS

This study was approved by the local ethics committee and the staff council of the University Hospital of Cologne, Germany, and conducted according to the tenets of the Declaration of Helsinki. After obtaining written informed consent, 44 anesthesiologists were enrolled for participation. Medical training of participants ranged from first-year residents to board-certified anesthesiologists with many years of specialist experience. Each participant received a standardized 5-minute verbal introduction to the GPS technology and the study design. All participants had no prior experience with navigated ultrasound (NUS), and no testing of the device was allowed before participation.

Using the SonixGPS ultrasound navigation system (Ultrasonix Medical Corporation, Richmond, BC, Canada), participants were

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asked to perform in-plane (IP) and out-of-plane (OP) vascular access procedures on an ultrasound gel model (Blue Phantom, Item# BPNB150, CAE Healthcare, Sarasota, FL) using either CUS or NUS imaging, visualizing the vessel in cross-sectional view for all attempts.

The navigation technology of the ultrasound device is based on an electromagnetic field that communicates with a transducer and an electromagnetic sensor sheathed by a vascular access needle. Needle movements and related magnetic field variations allow the navigation system to compute the locations of the transducer and needle in three-dimensional space.

The electromagnetic field is created by a transmitter attached to a telescopic arm with joints, allowing its movement in all 3 space directions. To achieve the most accurate navigation readings, the electromagnetic field source head is positioned in close spatial relationship to the transducer and needle during procedures. Visual reference for adequate positioning is provided by a signal strength scale consisting of 5 colored bars in the lower right-hand corner of the ultrasound image (Figs 1, 2). Insufficient signal strength is visualized by 3 or fewer yellow or red bars. Correct positioning is achieved when 4 to 5 green bars appear on the signal strength scale.

For each participant, correct navigation system setup and sufficient signal strength of at least 4 out of 5 signal strength bars were ensured by the investigator before navigated vascular access procedures. Using a linear transducer and an 8-cm 19-gauge metal needle without a plastic catheter sheath, the ultrasound scanner was set to 10-MHz frequency, 4.0-cm depth, and 55% gain.

The positioning data are visualized in the ultrasound image by a transducer head pictogram and respective needle positioning in the lower right-hand corner of the ultrasound screen (Figs 1 and 2). In addition, the navigation technology provides real-time visual information about the needle positioning, the projected needle path, and the projected needle-tip entrance point into the current ultrasound image plane. Using NUS, a red outline visualizes the position of the needle, and a green trajectory line marks the projected needle path in IP-NUS (Fig 1) and OP-NUS (Fig 2). In OP-NUS, a white cross represents the projected point of entrance of the needle in the ultrasound image, changing its color to green when the needle tip enters the current ultrasound image plane.

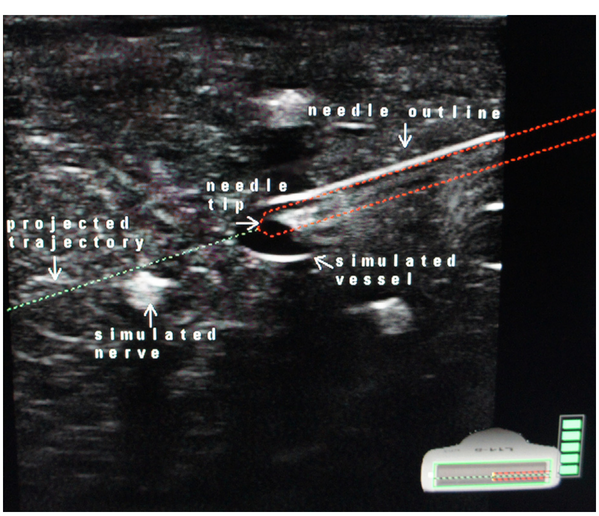


**Fig 1. In-Plane Navigated Ultrasound. In-Plane real-time navigated ultrasound (IP-NUS) showing the needle tip placed in the simulated vessel. Note the red needle outline, its green projected trajectory, the needle-transducer orientation pictogram, the signal strength bars, and the simulated nerve.**

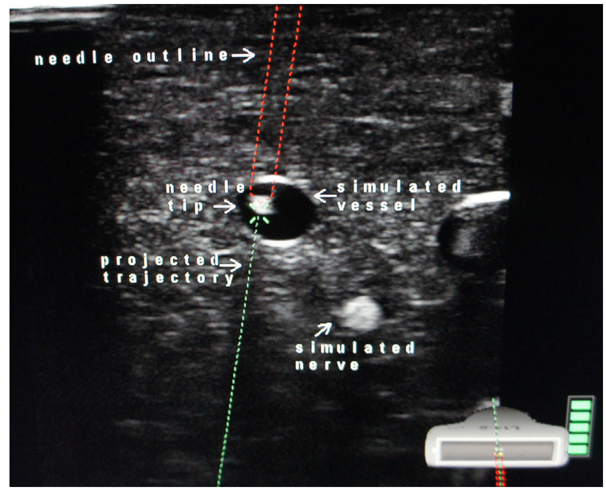


**Fig 2. Out-of-Plane Navigated Ultrasound. Out-of-Plane real-time navigated ultrasound (OP-NUS) showing the needle tip placed in the simulated vessel. Note the red needle outline, the green cross marking the correct positioning of the needle tip, the green projected trajectory, the needle-transducer orientation pictogram, the signal strength bars, and the simulated nerve.**

The gel model, 17 cm × 13 cm × 6 cm in size, contains simulated vessels filled with red fluid as well as nerve structures. As an ultrasound procedure training model, the Blue Phantom provides clearly identifiable vascular and nerve structures in a nonanatomic relationship as seen in Figs 1 and 2. The model was covered with typical surgical drapes to mimic clinical procedure conditions.

Procedure time from needle penetration into the gel model to achieving vascular access was measured in seconds using a stopwatch. The time measurement began with needle insertion in the gel model and was stopped when the participant confirmed correct needle placement verbalizing "stop" to the investigator. Procedure success was verified by aspiration of simulated blood from the gel model, and images of final needle positioning were recorded. The procedure sequence for each participant was assigned randomly and distributed in opaque envelopes. Participants completed IP and OP vascular access procedures using CUS and NUS for 4 procedures (IP-CUS, IP-NUS, OP-CUS, and OP-NUS). For statistical analysis, IBM SPSS Statistics version 22.0 (IBM Corp, Armonk, NY) was employed. Endpoints of the study were the procedure performance time and the procedure success. The Wilcoxon signed rank test for paired observations was used to compare the performance times. Success rates for vascular access were compared using the McNemar test. Significance level was set to 5%. Adjusting for multiplicity with the Bonferroni method, p values $\leq$ 0.0125 (0.05/4) were considered statistically significant.