

**Comparing the use of a needle guidance device with free-hand technique in performing out-of-plane ultrasound-guided intervention procedure on a phantom model**

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## **Introduction**

The use of ultrasound for vascular access and regional anaesthetic techniques has become an essential tool for day-to-day anaesthesia & critical care [1]. Ultrasound guidance helps avoid complications such as damage to surrounding important structures [2, 3]. It may also increase the success rate of vascular access especially in patient populations with difficult peripheral vascular access (eg. obesity, IV drug use) [4, 5]. Although the 'out-of-plane' or short axis approach has been demonstrated to be the easier technique for novice users to learn initially [6] and require less insertion time with potentially higher success rates when compared to the "in-plane" approach [7], both techniques require a reasonable degree of hand-eye coordination and technical training in this skill is not straightforward.

The development of an 'in-plane' needle guide mounted to the ultrasound probe has allowed users to ensure the needle is kept within the narrow ultrasound beam to allow better visualization of the needle. These devices have been demonstrated to significantly reduce attempt number and time for procedure when compared with free hand technique for use in ultrasound-guided central venous access [8-10]. They have also been shown to reduce procedural time and improve needle visibility in an in-vitro porcine phantom study on novice users [11]. A recent study conducted at our centre demonstrated that use of the needle guide improved needle visualization, time to successful procedure and better user satisfaction scores [12].

CIVCO has developed a similar purpose 'out-of-plane' Accusite needle guidance system that consists of a reusable bracket and customizable depth needle guides (0.5-3.5cm in 0.5cm increments). We propose that this system will have a great application for peripheral and central vascular access (including PICC lines), and also catheter insertion for regional anaesthesia infusion, because these procedures commonly require out-of-plane approach when performed with ultrasound guidance.

Other forms of ultrasound needle guidance systems such as passive electromagnetic [13] and GPS tracking [14] have been investigated showing variable significance in improving 'out-of-plane' ultrasound-guided procedure success.

To our knowledge, there are no clinical trials comparing a simple, physical, mountable 'out-of-plane' needle guide device with free hand technique. Before we perform a clinical trial, we would like to carry out a pilot study to determine the usefulness of this "out-of-plane" needle guide when used in our department by anaesthetic residents, registrars and consultants with different levels of clinical experience on ultrasound-guided out-of-plane procedure.

The aim of this study is to determine whether the use of the CIVCO Accusite Needle Guidance System will improve the time to successful attempt during ultrasound-guided simulated intervention procedure on a psyllium hydrophilic

mucilloid fiber and gelatin phantom compared with the “free hand” technique when used by anaesthetic residents, registrars and consultants in our department.

## **Study Design**

**Hypothesis:** The use of an “out-of-plane” needle guide decreases time to successful attempt compared with a “free-hand” technique on a phantom psyllium hydrophilic mucilloid fiber and gelatin model.

**Study Type:** Prospective cross-over observer-blinded control trial

## **Methods**

After giving informed consent and an educational session, 30 voluntary anaesthetic residents, registrars or consultants will be prospectively enrolled in this study. Baseline data including the level of clinical experience and the number of prior ultrasound-guided out-of-plane procedure performed will be collected.

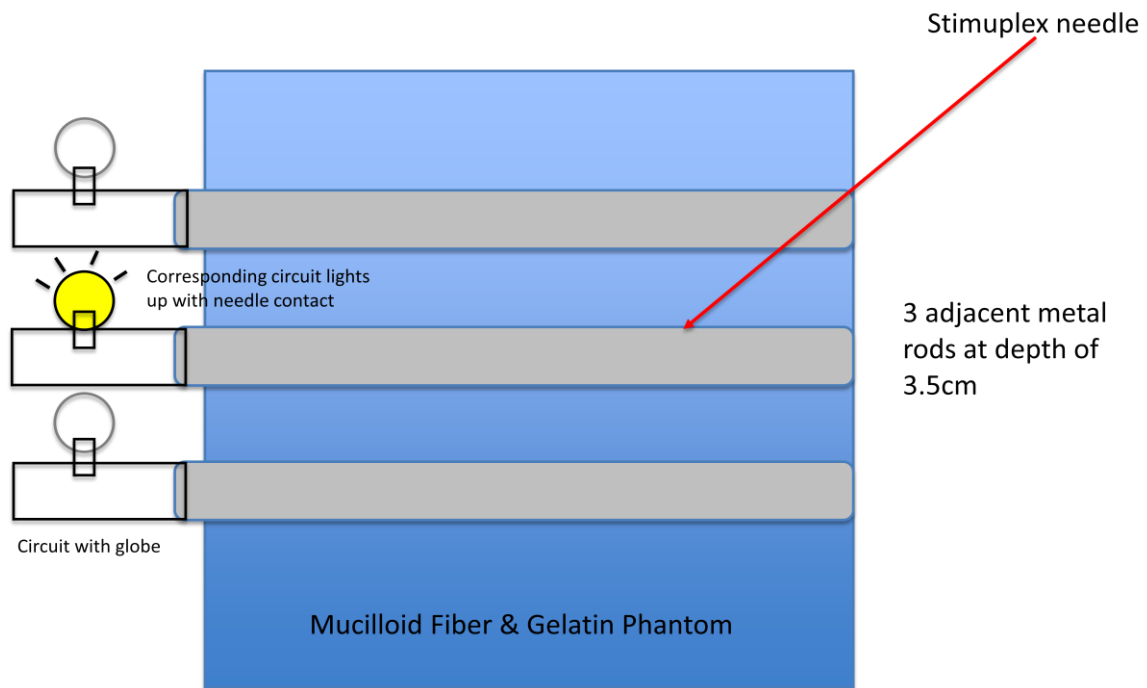
### ***Preparation for the intervention***

All participants will receive a presentation giving an explanation of the use of the needle guide and the anatomy of the specimen. A demonstration of how to attach the needle guide, hold the probe, and perform the procedure on the psyllium hydrophilic mucilloid fiber and gelatin phantom with images obtained in an out-of-plane view will be shown. The participants are permitted to practice needling technique on a Gel Phantom model with and without the

needle guide for 5 minutes. However, they are restricted from practicing on the psyllium hydrophilic mucilloid fiber and gelatin model. Instructors will be available for assistance with altering ultrasound visibility and machine settings in order to achieve the best view. Following this introduction and practice, they will then be randomly allocated to either of the two groups: free-hand group or needle guidance group.

***The phantom:***

The psyllium hydrophilic mucilloid fiber and gelatin phantom will be prepared as described by Bude et al [15]. Approximately 20 x 12 x 8 cm (length x width x height) specimen will be constructed using a mixture of water, psyllium hydrophilic mucilloid fiber (Brand name: Metamucil) and gelatin. Three 14-gauge metal rods, each connected to an individual electric circuit powered by a standard battery, will be placed 2 cm from the surface parallel to each other. A light bulb is placed within each electric circuit and will light up each time a needle makes contact with the corresponding metal rod. The middle rod is assigned to be the correct target. The other two rods represent the incorrect targets. This arrangement mimics a typical neurovascular bundle found in the human body, where vein, artery and nerve typically lie adjacent to each other.



***Interventional Tasks:***

An ultrasound machine (Sonosite MicroMaxx) with a linear higher frequency (13-6MHz) transducer probe and a 21-gauge 100mm stimplex needle will be prepared. The free-hand group (F group) will start the task without the needle guide and the needle guidance group (G group) will start the task with the needle guidance first. A cross-sectional view of the metal rod will be obtained with the ultrasound. The needle will be inserted in an out-of-plane approach until the target is reached, which will be shown as the correct light bulb turns on. The same task is then repeated with the alternate technique.

**Outcomes**

***Primary outcome:***

Total procedural time - the time taken from needle insertion to contact with the correct metal rod (ie. when the correct light bulb switches on)

***Secondary outcomes:***

- Number of needle insertion attempts through the phantom surface.
- Number of times an incorrect light bulb switches on, which indicates the number of times the needle is in contact with the incorrect metal rods.
- Proceduralist's satisfaction score - proceduralists will be asked to rank their satisfaction with both techniques on a scale from 1 (lowest score) to 10 (best score).

**Data Analysis*****Sample size estimation:***

Similar to a previous phantom study [12], we will recruit 30 volunteers with various level of clinical ultrasound experience for this pilot study. A total of 30 paired observations will be assessed.

***Statistical analysis planned:***

Values will be expressed as mean and standard deviation. Median and interquartile ranges will be used for data which are not normally distributed. Comparisons between the groups will be performed by t-test for parametric data and Wilcoxon's signed rank test for non-parametric or not normally distributed data. A P value < 0.05 will be considered statistically significant.

## **Data Management**

Data will be recorded on a standardised case report form and transferred to a Microsoft Excel spreadsheet. All the data and video clips collected will remain anonymous and confidential. A unique subject number, not used for any other purpose, will be used. All the research-related documents and video clips will be stored securely in a locked office in the Department of Anaesthesia and Pain Management at the Royal Melbourne Hospital. Only the principal investigator and the co-investigators are allowed to have access to the documents.

## **Ethical Considerations**

Potential candidates for this study will be approached by one of the investigators (P.T.) at the Royal Melbourne Hospital Anaesthesia Department. P.T. is a registrar of the department, therefore no coercion will be involved. Interested individuals will be explained the research study in detail. Written informed consent will be obtained.

## **Feasibility**

Preparation	4 weeks
Data acquisition & analysis	4 weeks
Manuscript preparation	4 weeks
<i>Total study time</i>	<i>~3 months</i>



## **Significance of Current Study**

This study comparing the use of needle guidance and “free-hand” technique on a phantom model by a group of anaesthetic registrars and consultants from our department would tell us whether by adding needle guidance to perform an ultrasound-guided out-of-plane procedure would improve time to success. This may provide information on planning future clinical study.

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