Using Augmented Reality to 3D Map Needle Pathways in Real Time to Enhance Neuraxial Anesthesia

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Background:

Neuraxial anesthesia (spinal and epidural) has traditionally been a 'blind' technique. The subarachnoid or epidural space is identified via anatomical landmarks, relying on operators' feel and skill, both are subjective, lack complete accuracy and highly influenced by patient body habitus where obese patients or those with anatomical variations, or spinal abnormalities are shown to be quite challenging[1,2]. Neuraxial anesthesia is not a benign procedure as multiple attempts or inaccurate trajectories of the needle can not only be anxiety provoking and cause patient discomfort but can also lead to patient morbidity in the form of spinal/epidural hematomas, infection, dural puncture headaches and nerve injury[3].

The use of ultrasound (US) has become routine for peripheral nerve blocks as it allows for real-time views of needle position for peripheral blocks to achieve higher rates of success, fewer complications, reduced patient discomfort, and quicker procedural times[4]. The needle and/or target structures are kept in constant view with the use of ultrasound during the block procedure to allow for higher accuracy. As such, US guidance has become the *de facto* standard of care for peripheral nerve blocks and in fact, is now mandated by the Royal College of Physicians of the United Kingdom for central line insertion[5].

Though increasing in popularity, US guidance for neuraxial procedures is still relatively uncommon due to technical challenges of real-time guidance in conjunction with the difficulties of US imaging of bony structure[6]. However, different from US-guided peripheral nerve blocks, the common technique for US use in neuraxial anesthesia is to provide *pre-procedure* landmarks so the operator has an accurate prediction for the placement of the needle tip, depth and trajectory before actual needle insertion. Anatomical landmarks are visualized using the US along multiple viewing planes and skin markings are made based on these images. The US probe is then placed at rest and subsequent needle insertion is done in a semi-blind manner based on the skin markings and knowledge of approximate depth and trajectory from memory.

Multiple reviews have been published recently detailing the procedure of US-guided spinal and epidural anesthesia at the lumbar spine, though not in real time[6,7]. They have shown that US reduces procedure time, number of needle passes, needle contact with bone, and other complications compared to traditional placement techniques based on operator feel[7,8]. Despite this, the process of placing the US probe at rest and then moving forward with the procedure based on skin markings has the downfall of trying to imitate accurate needle trajectory beneath the skin based on the operator's memory[9]. This may also lead to multiple attempts at needle placement or failure of the procedure, challenges that are important to consider when attempting thoracic spine neuraxial techniques. Notably, due to the steep angulation of the spinous processes at the thoracic level, achieving needle trajectory to get to the epidural space can prove to be quite challenging[10].

In contrast to lumbar epidurals where a midline approach is used, the common technique for thoracic epidurals is a 'paramedian' approach. This involves purposely contacting lamina with the needle and continuously adjusting in a cephalad/midline direction to ensure that the operator is walking up the bone until the epidural space is entered. The paramedian approach mitigates having to navigate the difficult bony landmarks at the thoracic level. However, hitting bone with the needle can cause patient discomfort. While US landmarks can be done with thoracic epidurals, the needle trajectory is of greater difficulty to predict if the insertion is made solely on memory from the US images. Hence, US is yet to be commonly adopted as an approach for thoracic epidurals unlike lumbar spine neuraxial techniques.

To address the problem, we propose to use augmented reality technology as a tool to provide a superimposed US image as an *objective* alternative to the operator's memory. Microsoft HoloLens is a head mounted augmented reality device, which allows for overlaying computer-generated elements to the real

world. Notably, this technology presents a unique opportunity where we will be able to combine the US image and angulation of the US probe to instantly create, in real time, spatially stable holograms overlaying the patient's anatomy in the user's field of view. Thus, when the operator locates the anatomical landmarks using an US for a neuraxial technique, a holographic needle trajectory can be instantaneously generated and remains on the patient even after the US probe is placed at rest.

The model we propose in this project is truly innovative in medical content and involves a partnership with software and engineering experts. In collaboration with our partners, we have recently designed and developed the first model of a live holographic anatomical marking system using Microsoft HoloLens. We aim to pilot the prototype on a three-dimensional (3D) printed see-through thoracic spine phantom by four experienced staff regional-anesthesiologists to determine the accuracy of the holographic trajectory. We strongly believe, that using augmented reality, it will be possible to provide an accurate *live* road map for the needle path hidden under the patient's skin. Also, this alongside 3D object recognition will bring in a variety of potential uses in anaesthesiology.

Overall Aims and Objectives:

Our goal is to combine academic, medicinal and industrial expertise in a partnership to create a new technique for use in medicine. This partnership will strengthen the important area of human health, neuraxial anesthesia, and ultimately, will better facilitate the translation of research discoveries into applied therapies.

The objectives of this study are to assess whether the use of augmented reality in the form of creating a holographic marking of the site of needle insertion and optimal angulation will 1) reduce procedure time by increasing first past success when used as a guide to the thoracic epidural space, and 2) increase needle accuracy when compared to traditional ultrasound landmark-based techniques.

Hypothesis:

We hypothesize that using augmented reality through HoloLens, the creation of a newly developed holographic tool for neuraxial anesthetic techniques will increase needle accuracy thereby decreasing procedure time.

Methodology, Experimental Design and Evaluation

The 3D Phantom model. A thoracic spine ultrasound phantom (Figure 1) was constructed utilizing open source BodyParts3D library anatomy files. This library was created based on whole body MRI images with 2mm slice thickness of a healthy male volunteer[11]. A container and associated parts were designed and 3D printed using AutoDesk Fusion 360 and a Creality CR-10S from PLA, respectively. When filled with compatible gel and covered with a layer of surgical glove material (to obscure the location of the spine with the opaque gel[12]), the model has interlaminar acoustic windows and depth characteristics compatible with population averages when viewed with a portable ultrasound[13]. The phantom has similar palpation characteristics to a patient, and a standard loss of resistance to saline occurs on entrance of a needle to the spinal canal cavity.

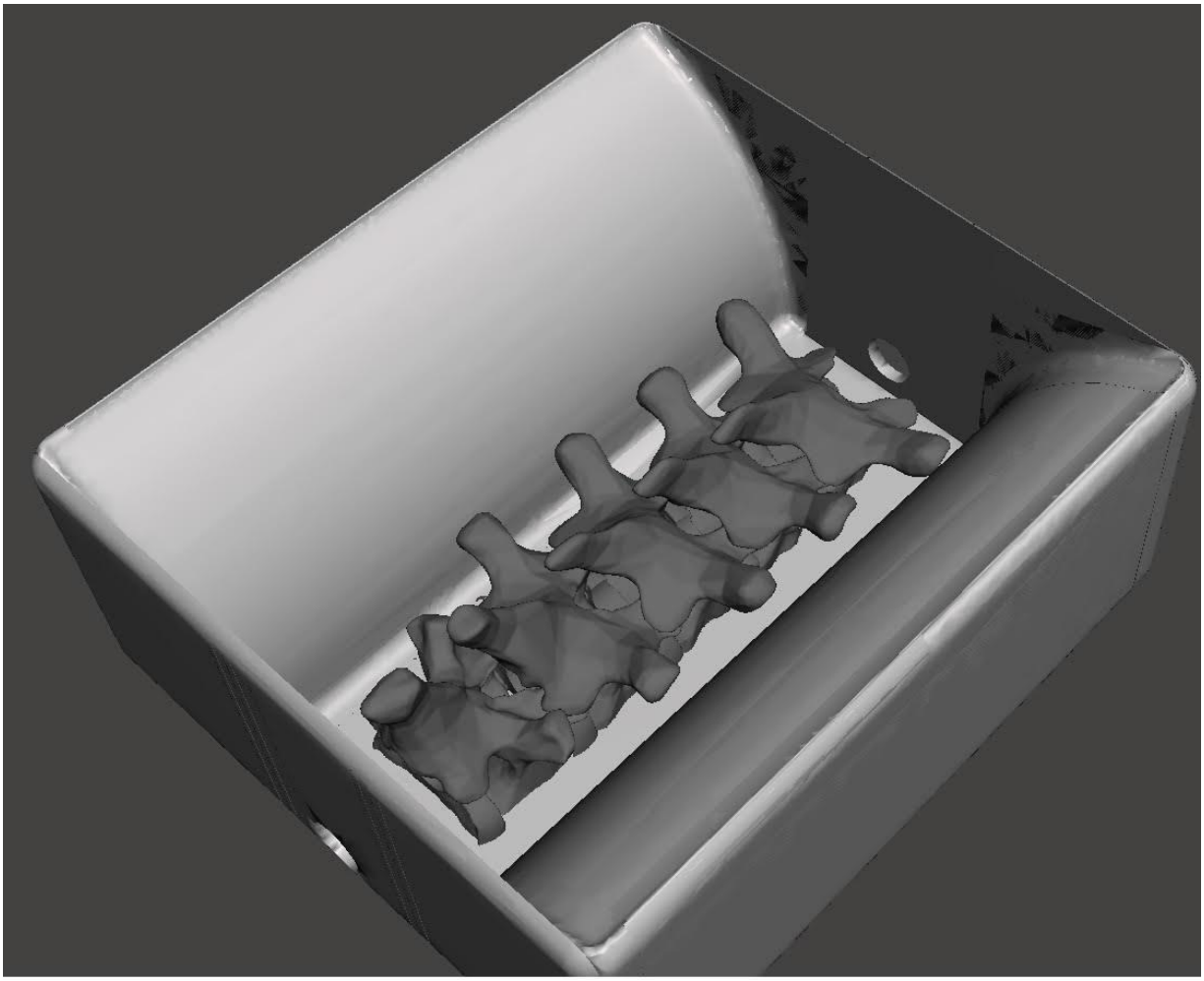

Figure 1: 3D Model of Thoracic Spine Ultrasound Phantom

Study design and workflow.

Local research ethics approval will be sought prior to study participant's recruitment. Only participants who meet inclusion/exclusion criteria (Table 1) will be approached for participation in this study.

We aim to study 84 sequential thoracic epidural events and randomize them to one of two study groups: Group 1, landmark based thoracic epidural technique (control) or, Group 2, HoloLens-assisted thoracic epidural technique (intervention). Sunnybrook Health Sciences has a dedicated regional block room and four experienced regional anesthetists that are trained and experienced in the thoracic epidural technique and will perform thoracic epidurals for this study (see Table 1 for inclusion criteria). Prior to the start of the study, the four expert anesthesiologists will practice needle insertion on the above described phantom model by attempting needle insertion 20 times each, or until they felt comfortable with the system, while wearing the Microsoft HoloLens. The anesthesiologist performing the thoracic epidural insertion procedure will be randomized to either study Group 1, or 2.

In Group 1 (control), the staff anesthesiologist will follow the traditional technique for US-guided thoracic epidural insertion. Briefly, the anesthesiologist will use the US to identify and mark the appropriate spot for placement of the thoracic epidural catheter. The US probe is then placed at rest and the anesthesiologist will proceed with thoracic epidural needle insertion following standard techniques.

In Group 2 (intervention), the staff anesthesiologist will use the HoloLens tool to assist with the traditional technique as described above for Group 1. In combination with the US, a hologram image of the trajectory towards the epidural space will be generated, thereby mitigating the need to walk off the lamina. The holographic system will mark the appropriate spot for placement of the thoracic epidural catheter. Then, the needle will be inserted following the holographic trajectory overlaid on the patient's back. The hand movements and realtime ultrasound images of the small portion of the patient's spine with no visually identifying features will be recorded during procedure. The anesthesiologists' hands and needle movement will be captured and will be used post-procedure as a back-up to real-time assessments by anesthesiologists and research assistants to confirm the procedure time and needle movements. The recordings and ultrasound images will be stored in a de-identified manner.

Inclusion Criteria: ***Anesthetists***	***Exclusion Criteria:*** ***Patients***
• Trained in US-guided epidural technique with fellowship • Performed >100 thoracic US-guided epidural procedures	• Age <18 • Lack of verbal patient assent after study introduction

Table 1. HoloLens study participants inclusion and exclusion criteria.

Sample Size Calculation and Statistical analysis:

A previous published studies have revealed that mean thoracic epidural catheter placement using traditional palpation and landmark guidance requires 10 minutes with a standard deviation of 3 min[14,15]. Therefore, having 2 minutes reduction in procedure time (i.e. 20% relative reduction) will be considered a meaningful in the context of patient comfort and operating room efficiency. Considering a 2-sided type I error rate of 5% and power of 80%, 36 participants will be required per group, and 72 participants will be required to complete the study. Assuming possible participants withdrawal from the study, we will recruit 84 study subjects to compensate for an expected 15% withdrawal rate. Each of the four anesthesiologists will complete an equal number of thoracic epidurals.

Secondary outcomes that are continuous in nature (e.g. number of skin punctures, number of needle movements, procedural pain score) will be analyzed in the same manner. For binary outcomes (parasthesias, dural puncture, PCA in PACU) the Chi square test (or Fisher's exact when expected cell counts are less than 5) will be utilized. To account for multiple comparisons, we will use the Holm-Bonferroni method and an adjusted $p<0.05$ will be considered significant.

Expected Outcomes measures:

To address our specific objectives of whether the HoloLens tool and methodology, that is designed to allow a holographic marking of the needle insertion site and optimal angulation would 1) decrease procedure time by increasing first past success when used as a guide to the thoracic epidural space; and 2) increase needle accuracy when compared to traditional ultrasound landmark based techniques, we will ask an observer (i.e. anesthesiologist) to document following:

A. *the time to procedure completion starting from skin puncture to time at which the Tuohy needle is withdrawn;*
B. *the number of needle movements (in any direction/re-direction);*
C. *number of skin punctures made;*
D. *patients' pain score during the procedure using the numeric rating scale (NRS);*
E. *any complications during the procedure such as paresthesias, dural punctures;*
F. *the need for patient controlled analgesia (PCA) in PACU (constituting failure of epidural).*

Lastly, the patient will be asked to rate their level of overall discomfort during the procedure on a scale of 0-10 (0 – being no pain/no discomfort and 10 being worst possible pain/extreme discomfort) at its conclusion. Similarly, the regional anesthesiologists will be given a questionnaire regarding ease of use and limitations of the technique. Our survey strategy will help to validate study results, and enable optimization and implementation of the novel technology.

Knowledge Translation

The success of this proposal will lead to implementation of a new objective tool, validation of which will create an accessible, low-cost piece of technology that will reduce patient morbidity and increase procedure success rate. This 'state-of-the-art' technology can be used for alternate procedures such as peripheral nerve block in patients that cannot be easily positioned for live ultrasound techniques (e.g. trauma patients). The HoloLens can be applied at institutions with a unique but potentially anatomically difficult population such as the obstetric and trauma population. Specifically, at the outset, we aim to apply HoloLens locally at Trauma Bay, Sunnybrook Health Sciences Centre. In aggregate, the proposed study will generate a knowledge-based cost-effective approach that can be used as a teaching and clinical tool around the world where resources are at a minimum.

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