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 operator feel and skill. However, this is highly influenced by patient body habitus where obese patients or those with anatomical variations or spinal abnormalities can prove 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, secondary 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. 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. US landmarks can be done with thoracic epidurals, but 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 image of the US image as an 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. This technology presents a unique opportunity where we can 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. This alongside three-dimensional object recognition allows for a variety of potential uses in anaesthesiology. In other words, it is possible to provide an accurate live road map for the needle path under the patient's skin. Thus when the operator locates the anatomical landmarks using an US for a neuraxial technique, a holographic needle trajectory can be instantaneously created and remains on the patient even after the US probe is placed at rest.

Objectives:

The objectives of this study are to assess whether a Hololens application allowing 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, 2) increase needle accuracy when compared to traditional ultrasound landmark-based techniques.

Hypothesis:

We hypothesize that using Hololens for neuraxial anesthetic techniques will decrease procedure time and increase needle accuracy.

Methodology and Evaluation:

In collaboration with medical content, software and engineering experts, we have designed the first model of a live holographic anatomical marking system using Microsoft Hololens. The prototype will be piloted on a 3D printed see-through thoracic spine phantom by four experienced staff regional-anesthesiologists who will determine the accuracy of the holographic trajectory.

A thoracic spine ultrasound phantom was constructed utilizing open source 3D anatomy files from the BodyParts3D library, which was created from whole body MRI images with 2mm slice thickness of a healthy male volunteer. A container and associated parts were designed using AutoDesk Fusion 360 and 3D printed using a Creality CR-10S from PLA. When filled with compatible gel (Azad Mashari, 2016) and covered with a layer of surgical glove material (to obscure the location of the spine with the opaque gel) and covered with a layer of surgical glove material (to obscure the location of the spine with the opaque gel), the model has interlaminar acoustic windows and depth characteristics compatible with population averages when viewed with a portable ultrasound. 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.

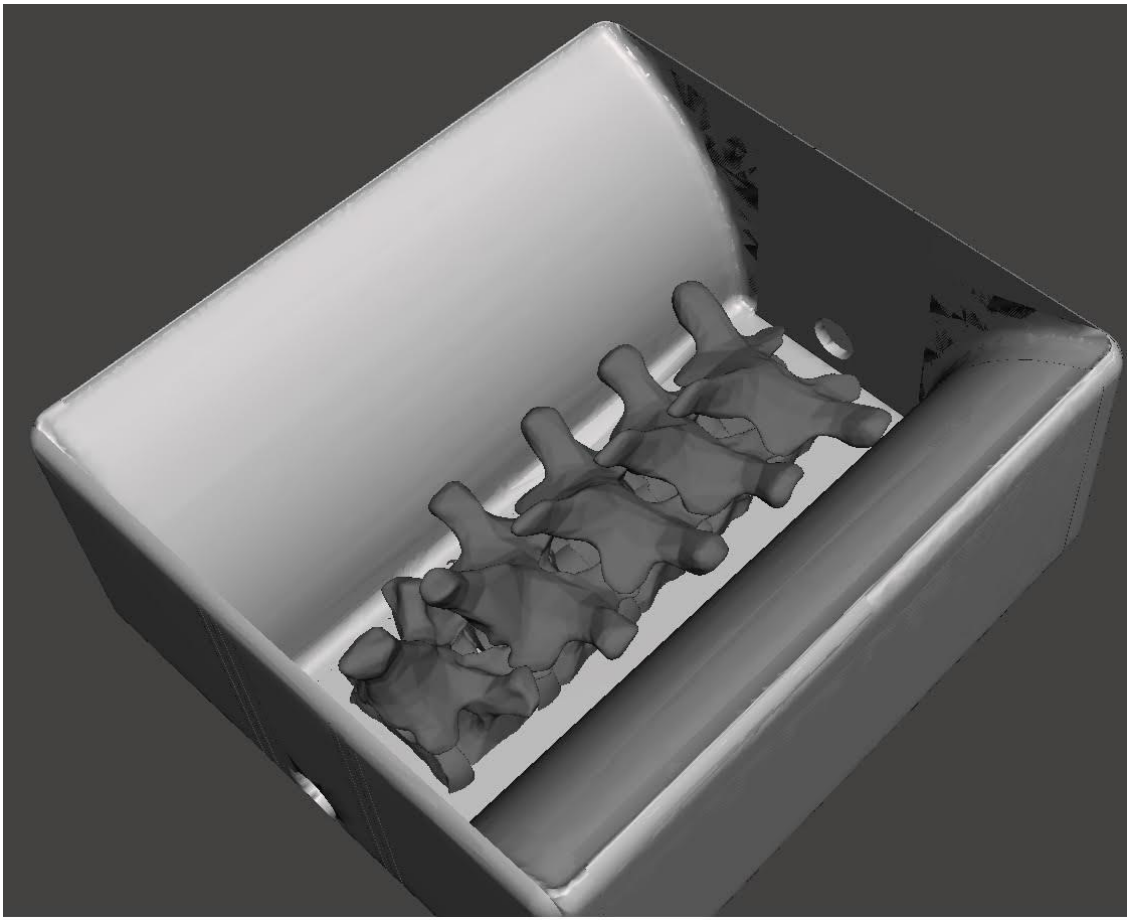

Figure 1: 3D Model of Thoracic Spine Ultrasound Phantom

Prior to the start of the study, the four expert anesthesiologists will practice needle insertion by attempting needle insertion 20 times each, or until they felt comfortable with the system, while wearing the Microsoft Hololens.

Local research ethics approval will be sought prior to patient recruitment. Only patients who meet inclusion criteria will be approached for participation in this study.

Inclusion Criteria:

- > 18 years of age
- Patients scheduled for the following types of surgical procedures:
    - General procedures: Splenectomy, Ventral hernia, Whipple, Pancreatectomy, Gastrectomy, Minor resection,
    - Urological procedures: Nephrectomy, Cystectomy
    - Vascular procedures: Open abdominal aortic aneurysm, Aortic bifemoral bypass
    - Gynecologic Oncology procedures: Total abdominal hysterectomy/Bilateral salpingo-oophorectomy +/- omentectomy and +/- lymph node dissection

Exclusion Criteria:

- Lack of patient consent
- Laparoscopic procedures
- Contraindication to epidurals

Based on a previous study using live US, we will recruit 84 patients undergoing thoracic epidural procedure and randomize them to one of two groups: 1) US-guided thoracic epidural technique (control) or 2) Hololens-assisted thoracic epidural technique (intervention). The block room at Sunnybrook Health Sciences Centre is staffed daily with 10 regional anesthesiologists in a rotating manner. Four of the experienced regional anesthetists who is comfortable with the Microsoft hololens as mentioned above will perform thoracic epidurals for this study as they are trained in the US-guided thoracic epidural technique, and each will perform 21 epidurals in total (11 maximum for each group).

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 system 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, the needle will then be inserted by following the holographic trajectory overlaid on the patient's back.

Outcome measures:

In order to address our first objective of whether the Hololens application, allowing a holographic marking of the needle insertion site and optimal angulation, would decrease procedure time by increasing first past success when used as a guide to the thoracic epidural space:

1) An observer will document the time to procedure completion starting at skin puncture to time at which the Tuohy needle is withdrawn.

In answering our second objective of whether the Hololens application would increase needle accuracy when compared to traditional ultrasound landmark based techniques:

1) An observer will document the number of needle a) manipulations (in any direction/re-direction) and b) the number of punctures made. Patients' pain score during the procedure will be captured using the numeric rating scale (NRS). Lastly any complications during the procedure such as paresthesias, dural punctures and the need for patient controlled analgesia (PCA) in PACU will also be documented.

A questionnaire regarding the patients' level of discomfort during the procedure will be administered to the patient upon completion of the procedure. Similarly, the regional anesthesiologists will be given a questionnaire regarding ease of use and limitations of both techniques.

Sample Size Calculation:

Based on historical data in the literature and from our own institution, mean thoracic epidural catheter placement requires 10 minutes with a standard deviation of 3 min. A reduction in procedure time of 2 minutes (20% relative reduction) would be considered a meaningful reduction in the context of patient comfort and operating room efficiency. With a 2 sided type I error rate of 5% and power 80%, 36 participants per group (72 total) will be required but we will recruit 84 patients to compensate for potential withdraws, so each of the four anesthesiologists complete an equal number of thoracic epidurals.

Statistical analysis:

The primary outcome (1st pass success as measured by time to epidural placement) will be analyzed as follows. It will initially be assessed for normality visually and with the Shapiro-Wilk test. If normally distributed, data will be analyzed with the independent samples t-test. If the assumption of normality is violated, the Mann-Whitney U test for non-parametric data will be utilized. Inferential testing will be 2 sided and $p < 0.05$ will be considered significant.

Secondary outcomes that are continuous in nature (number of skin punctures, number of needle manipulations, 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.

Knowledge Translation:

With the validation of this tool, it creates an accessible, low-cost piece of technology that will reduce patient morbidity and increase procedure success rate. This technology can easily be used for alternate procedures as well such as peripheral nerve block in patients that cannot be easily positioned for live ultrasound techniques (e.g., trauma patients). As such, it can be applied locally at institutions presented with a unique but potentially anatomically difficult population such as the obstetric and trauma population at Sunnybrook Health Sciences Centre. Furthermore, as a teaching and clinical tool, this can be used around the world where resources are at a minimum.

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