Techniques and Considerations for Ultrasound Guided Placement of an Injectable Peripheral Nerve Stimulator

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Introduction

Ultrasound technology advancements over the past few decades have enabled its usage in medical applications beyond diagnostic imaging. Conventional imaging modalities (i.e., fluoroscopy) are limited, as they do not allow for soft tissue visualization and expose patients, clinicians, and their staff to ionizing radiation.

Ultrasound-guided injection has become a standard practice, allowing clinicians to view soft tissue structures and peripheral non-axial neural targets. Visualization of soft tissue structures using ultrasound also allows closer proximity targeting when placing stimulators for a range of peripheral anatomical structures, as neural anatomy can vary between patients.

Here we present optimized methods for ultrasound-guided placement of an injectable peripheral nerve stimulator in benchtop, pig cadaver, and human cadaver models.

Methods

Porcine and human cadaveric models (Surgical Training and Research Core, CWRU, Cleveland, OH; Anatomy Core, CWRU, Cleveland, OH) were used to develop methods for device injection. A benchtop model consisted of 3D printed bones with blood vessels and nerves constructed of tubing and nylon rope encased in high density (~30% w/v) gelatin.
3 ultrasound machines were used to visualize and confirm the location of nerve targets, the delivery system, and device upon delivery: a handheld high frequency linear scanner L15HD3 (Clarius, Burnaby, CA), a standard Acuson VF8-3 (ProvidianMedical, Tampa, FL), and a high frequency Vevo 3100 (FUIJIFILM, Toronto, ON).
Injectable electrodes, Injectrodes®, and delivery systems were provided by Neuronoff Inc. (Cleveland, OH), for which the delivery needle has an outer diameter of 18g (1.27mm).

Figure 1: Ultrasound probes used in this study. A: Clarius L15HD3; B: Acuson VF8-3; C: Vevo 3100 MX700. A and B are clinical units, whereas C is a research use only ultra-high frequency system capable of visualizing nerve fascicles.

Benchtop Model

For initial procedure development a benchtop model high density gelatin model was manufactured. To increase utility of the model, 3D printed resin bones, nerves made from braided nylon, blood vessels from teflon tubing, and powdered silica (to increase backscattering) were added to the gelatin molds. Under ultrasound, the model provided a familiar view that was then employed as a training tool during procedure development to enable clinicians to train each other - or in the case of this study provide research staff with the training necessary to do ultrasound guided placements onto a peripheral nerve.

Figure 2: A gelatin model of the wrist with embedded anatomical components used to training both visualization of the needle and placement of the injectable electrode. Shown here is the Clarius L15HD3 using an in-plane approach.

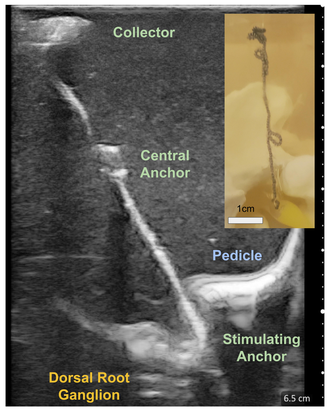

Figure 3: Visualization (Clarius L15HD3) of an injectable electrode placed in a gelatin model, where the hyperechoic backscattering agent (silica powder) highlights the characteristic acoustic shadow cast by the device. Modeled bone and nerve anatomy is also seen. An image of an injected electrode placed in such a semi-clear gel is provided in the insert.

Porcine Model

To develop the ultrasound guided placement procedure beyond the constraints of a benchtop model, post-mortem (within 4 hours of euthanasia) porcine posterior tibial nerve (PTN) was targeted.
Target identification was achieved via traditional methods used in nerve block procedures, and skin markings used to plan the procedure. Ultrasound was used to identify an entry site ~4cm proximal to the target and to prepare a delivery path to minimize tissue damage during placement. The tip of the delivery needle was guided under ultrasound to the target and twisted to confirm location and proximity (Figure 4 below). While in-plane and out-of-plane techniques resulted in successful placement of the Injectrode within the retinaculum of the pig tibial nerve, out of plane placement was preferred as the end of the needle tip as well as the nerve were more readily identified. In-plane imaging was then performed to confirm the placement and fully visualize the device and nerve (Figure 5 below)

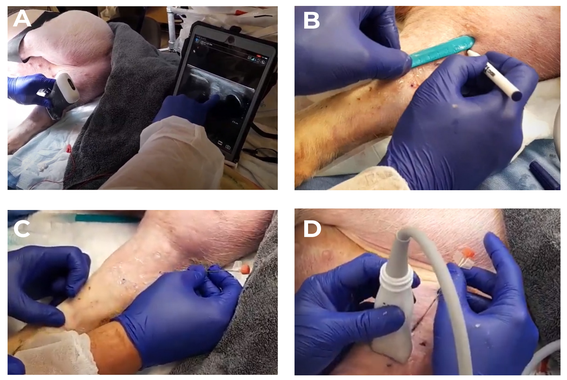

Figure 4: A) Visualization of overall anatomy to plan entry site, followed by B) markings of both entry site and target. C) Insertion of injection needle at entry site followed by D) out-of-plane imaging (Vevo 3100 MX700) of the needle to advance towards the PTN prior to placement of the electrode.

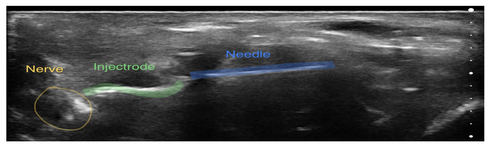

Figure 5: In-plane ultrasound image (Clarius L15HD3) of the injectable electrode exiting the injection needle onto the porcine posterior tibial nerve. Cut-downs (not shown here) were performed to confirm placement location.

Human Cadaveric Model

Following successful procedure development in the porcine model, the same approach was used to place devices onto the human PTN in cadavers and train other clinicians on the procedure (shown on right, Vevo 3100 ultrasound).
The overall approach remained unchanged between the two models, with human lower limb anatomy allowing for a broader selection of potential entry sites, which will separately require optimization in the future clinical implementation of this technology and procedure.

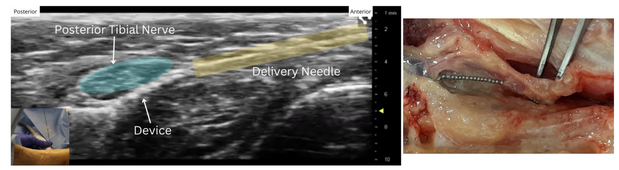

Figure 6: Ultrasound (Vevo 3100 MX450) visualization of the device exiting the delivery needle during injection, flexibly conforming to the PTN. Cut-down (right) confirmed accurate placement on the target.

Conclusions

- 2 to 15 MHz ultrasound (standard clinical frequencies) was sufficient to visualize the target, delivery needle, and device.
- Real-time visualization through ultrasound reduces the risk of soft tissue damage during placement, allows for precise Injectrode placement with close proximity to a desired target, and builds upon familiar principles of nerve block procedures.
- The Injectrode device and placement needle appear hyperechoic under ultrasound.
- The Injectrode displays a large acoustic shadow which helps users identify device location.
- The combination of benchtop and cadaveric models allowed for effective training of other clinicians and research scientists in the use of the procedure.

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