**PROTOCOL TITLE:** Does the VerTouch Device Improve Insertion Site Identification for Lumbar Neuraxial Procedures when Compared to Palpation or Ultrasound Guided Site Selection? A Prospective Randomized Controlled Trial

**PRINCIPAL INVESTIGATOR:**

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## STUDY SUMMARY:

| | |
|---|---|
| Investigational Agent(s) (Drugs or Devices) | Intuitap VerTouch Device |
| IND / IDE / HDE # | |
| Indicate Special Population(s) | Children<br>Children who are wards of the state<br>Adults Unable to Consent<br>Cognitively Impaired Adults<br>Neonates of Uncertain Viability<br>x Pregnant Women<br>Prisoners (or other detained/paroled individuals)<br>Students/Employees |
| Sample Size | 120 |
| Funding Source | Intuitap Medical |
| Indicate the type of consent to be obtained | x Written<br>Verbal/Waiver of Documentation of Informed Consent<br>Waiver of HIPAA Authorization<br>Waiver/Alteration of Consent Process |
| Site | Lead Site (For A Multiple Site Research Study)<br>Data Coordinating Center (DCC) |
| Research Related Radiation Exposure | Yes<br>x No |
| DSMB / DMC / IDMC | Yes<br>x No |

**OBJECTIVES:**
Is there an identifiable difference in the number of insertions and redirections of the needle for a lumbar neuraxial procedure when the VerTouch device is used, instead of palpation (current gold standard) or ultrasound guidance (US), for the identification of the procedural insertion site?

**Null Hypothesis:**
There is no difference in the number of insertions and redirections of the needle for a lumbar neuraxial procedure when the VerTouch device is used.

**BACKGROUND:**
**Literature:**
Neuraxial procedures are performed across a myriad of clinical scenarios. From spinal anesthesia for caesarian sections, to epidural anesthesia for labor pain and abdominal surgery, to lumbar punctures and lumbar drain placements for the diagnosis and management of neurologic illness, accessing the spinal cord and surrounding structures is commonplace in many busy hospitals. Anesthesiologists, neurologists, neurosurgeons, emergency physicians, and other providers learn and perform neuraxial access with meticulous precision and attention to detail to avoid damaging the spinal cord. The best-in-breed methods for ensuring safety continue to rely on provider experience and palpation (using the fingers) of the back and surrounding landmarks. Some practitioners use ultrasound, which is bulky, costly, and requires yet additional training. As such, the safety of these procedures has plateaued. They are not unsafe by any means – the rates of complications can be as low as in the single digits of percentage when performed by an experienced provider. A new device (the VerTouch), holds promise to reduce the complication rate for the first time in years, as well as allow providers with significantly less training to achieve the same, low complication rate.

VerTouch incorporates tactile sensing—a form of electronic palpation—to detect spinal landmarks, analogous to those sensed during manual palpation. This technology is most prevalent in robotics, but has recently been applied as a clinical-imaging tool in breast, prostate, and other soft-tissue applications. The device comprises an array of pressure sensors—also known as force-sensing resistors—which, when pressed against the back, measure the distribution of mechanical stress across the compressed tissue. These data are processed and communicated to the device's display as a full-color, 2D pressure map of patient anatomy. Regional differences in elasticity/hardness are observed as gradations between deep blue (for areas of low firmness) to red (for areas of higher firmness, e.g. bone).

In this project we aim to compare the VerTouch device to palpation and US techniques used to identifying the anatomic landmarks and optimal location for neuraxial access. In a previous feasibility study completed here at Northwestern University (NU) in Prentice Women's hospital (stu#: 00207454), the researchers showed that when VerTouch was used to mark a site prior to the neuraxial procedure, and the site marked was eventually used for the procedure, the success rate of the procedure with minimal needle manipulation was greater than historical data for the gold standard palpation technique. Additionally, the provider confidence in the information provided by the device was greater than 95% (abstract and/or submitted manuscript for this study can be provided on request). The proposed RCT herein will be a prospective comparison

of the now proven VerTouch device to the gold standard of palpation and the commonly cited US techniques.

**SIGNIFICANCE:**
Thousands of neuraxial procedures are completed daily with over 12,000 done at Prentice Women's hospital last year. These procedures are not without difficulty and complication. The gold standard of palpation and blind advancement of the needle toward the spine can result in multiple insertions of the needle into the skin and redirections of the trajectory of that needle after insertion to avoid the bones of the spine protecting the spinal column. These insertions and redirections are not only time consuming while the patient is in an uncommon position, but they also cause discomfort and possibly lasting pain days after the procedure. In addition to the patient dynamics, when anatomical or positioning issues result in difficult neuraxial procedures the common teaching is to attempt US guided access. Unfortunately, not many proceduralist are trained in this modality and the additional materials needed to perform the procedure with US take time to gather and further prolong the procedure. Additionally, though the cost of US technology is getting more reasonable, it is still rather expensive and a barrier to utilization by many facilities around the country and the world. Often, after many attempts, the proceduralist accepts failure of the procedure and refers the patient to the interventional radiology (IR) or pain medicine specialist for completion of the procedure using radiation to visualize the spine. Note, this is not an option for pregnant women who are not eligible for radiation due to fetal concerns.

The VerTouch offers a non-invasive, untethered, and non-radiation producing device that allows for the visualization of the underlying structures of the spine to determine ideal needle placement for neuraxial procedures. The output on the screen can also be visualized by other providers or senior proceduralist for assistance with best course of action for the procedure. The device does not cause discomfort to the patient and does not require any additional materials to be functional.

This study has the potential to show that the VerTouch is more effective than palpation and as effective as US at defining the location for neuraxial procedure initiation and eventual success. If the VerTouch device is capable of improving the consistency of success of neuraxial procedures, while minimizing need for costly and cumbersome US technology and decreasing referral to radiation requiring procedures, the benefit to patients and proceduralists would be exponential.

**STUDY ENDPOINTS:** The primary endpoint is the combined total number of insertions or redirection of the needle being used for the procedure.
The endpoint is when all the subjects for each arm have been recruited and completed study procedures.

**STUDY INTERVENTION(S) / INVESTIGATIONAL AGENT(S):**
We will use the VerTouch device which we have shown to be a non-significant risk device (IDE). It is comprised of a non-invasive pressure sensor that is gently pushed against the back, with a screen that reads out the pressure being applied across the device. Areas of higher pressure are suggestive of bony areas, whereas areas of lower pressure are more likely tissue. The application of the device to the body is less obtrusive than ultrasound, which is commonly used, because this device does not use any gel or other medium.

The device will be stored in a locked space only accessible to the proceduralist or research personnel authorized to prepare the device for use. The device is self-contained and powered by an internal rechargeable battery. The device will only be at the bedside for those subjects that

have been recruited to participate. In order to maintain blinding, even if the device is not used for the recruited patient it will be at the bedside to ensure the observers are not un-blinded.

**PROCEDURES INVOLVED:**

The study participants will be recruited in two parallel cohorts – pregnant patients and non-pregnant patients. Pregnant patients tend to be healthy and without comorbidities, and the providers (anesthesiologists) that perform the neuraxial procedure tend to have significant experience. Non-pregnant patients tend to require neuraxial access for diagnostic or therapeutic purposes (i.e. not for the relief of labor pains), and therefore have comorbidities. Additionally, these providers (ER, neurology, etc.) tend to do far less of these procedures. Together, these two tracks provide the breadth of neuraxial access and therefore maximally determine early feasibility of this device.

For both pregnant and non-pregnant patients, the study procedure is the same. Eligible patients will be identified by chart review of various elements of the electronic medical record, as follows:

**Labor & Delivery**: Patients will be identified in communication with the OB anesthesia team that maintains an “electronic tracking board” in the interdisciplinary workroom in Prentice. Only patients early in labor, who are in relatively low amounts of pain and distress, will be approached by OB Anesthesia research nurses about the study. If the patient agrees to participate in the study she will be randomized that time to one of the three arms (palpation, US, or VerTouch).

**Lumbar Puncture**: Patients scheduled to undergo diagnostic or therapeutic lumbar puncture will be identified by appointment schedule and chart review. If a patient is determined to be eligible for the study by the provider responsible for the procedure the patient will be approached once availability of the study team is confirmed. The study team will arrange to be present for the procedure at the scheduled appointment time. The proceduralist or study team member will consent the patient, and if the patient agrees to participate in the study he/she will be randomized that time to one of the three arms (palpation, US, or VerTouch).

**Randomization:**
Prospective, randomized, controlled, observer blinded trial in patients undergoing neuraxial procedures for diagnostic, therapeutic, primary surgical anesthesia or labor pain management.

Group #1: VerTouch utilized for identification of site for labor epidural or spinal anesthesia procedure

Group #2: Ultrasound (US) utilized for identification of site for labor epidural or spinal anesthesia procedure

Group #3: Control group, palpation utilized for identification of site for labor epidural or spinal anesthesia procedure

Group #4: VerTouch utilized for identification of site for lumbar puncture procedure

Group #5: Ultrasound (US) utilized for identification of site for lumbar puncture procedure

Group #6: Control group, palpation utilized for identification of site for lumbar puncture procedure

Participants will be randomized to treatment groups based on a random computer-generated schedule (https://www.randomizer.org). Proceduralists will not be blinded to randomization, however blinded research personnel will observe the procedure after site determination and collect all outcome measures in this study.

For groups 1-3, on request of neuraxial procedure the research nurse and proceduralist willh proceed to the patient's room with all normal supplies in addition to the VerTouch and US machine designated for this study. The research nurse will then un-blind to proceduralist to the patient's group and site identification will proceed. Regardless of the group, the proceduralist will make a mark at the site identified for the procedure using a chlorhexidine safe surgical marking pen. After completion of marking, the research nurse will notify the observer that they may enter the room to observe the procedure and collect the relevant data. Observers will be limited to 3observers, and additionally inter-observer variability will be minimized using video corroboration of at least 10 procedures.

If one of the blinded study observers is not readily available due clinical responsibilities, the research nurse will video record the procedure per protocol. The procedure video will be reviewed by the blinded observer and the number of redirections and reinsertions will be counted and relayed to the research nurse for completion of data collection.

For groups 4-6, once the patient is in the procedural suite the proceduralist will be un-blinded. He/she will proceed to mark the patient with the appropriate modality determined by the group number. After marking, the proceduralist will allow the research observer to enter the room to observe the procedure and collect the relevant data. Observers will be limited to 3 observers, and additionally inter-observer variability will be minimized using video corroboration of at least 10 procedures.

All standard procedures for neuraxial procedures will be followed (standard practice) after site determination including time out, skin prep, hemodynamic monitoring, post-procedure instruction etc.

Zoomed in audio-less video of the procedure sight will be collected during at least 10 of the procedures, at each site, for inter-observer variability determination. If the subject has any identifying marks in or near the procedure site or refuses video capture of the procedure no video or images will not be collected in that subject. If the blinded observer is not present and the procedure cannot be recorded for any of the above reasons, the patient will be removed from the study.

Data collected on the VerTouch device will only be associated with the subject number when collected from device for technical evaluation of pressure sensor performance.

If US is used the provider chooses to save an image of the anatomy visualized the research nurse or staff will save that image under the subject number for post-hoc analysis of anatomy identified and image quality achieved.

**DATA AND SPECIMEN BANKING**

We will collect and data including reason for procedure, type of procedure, any anatomical issues affecting procedure (including but not limited to: scoliosis, positioning, BMI, paralysis), and age. The video/images collected will allow us to compare the observer variability.

**SHARING RESULTS WITH PARTICIPANTS**
Results will not be shared with participants.

**STUDY TIMELINES**
The individual will participate in the study for the duration of the procedure, which is usually approximately half an hour. It will take approximately one year to enroll all participants, and approximately 3 months to perform data analysis.

**INCLUSION AND EXCLUSION CRITERIA**

Inclusion criteria are any adult patients undergoing a neuraxial procedure. Necessary to this is the inclusion of pregnant women who make up a significant fraction of neuraxial procedures.

Exclusion criteria are those patients who do not speak English, have a plastic allergy, or are unable to consent.

Other special populations (individuals who are not yet adults, prisoners, vulnerable populations) will also be excluded.

If it is impossible to take a photograph that does not include identifying marks on the back (i.e. a birthmark or tattoo) the patient will be excluded from the video portion of the study

**VULNERABLE POPULATIONS**
Pregnant women will be included in the study because they make up the primary population that will benefit from the success of this device. As otherwise young and healthy females, they also represent a group that, if a serious adverse effect of neuraxial access were to occur, could result in significantly lifelong morbidity.

The device has been tested on cadavers, 5 healthy subjects to prove sensor function, 8 healthy subjects who did not undergo a procedure to prove limited congruence with palpation, and 10 healthy subjects that did not undergo procedure to prove feasibility of functional design.

At this time the device needs to be tested in a setting where patients are undergoing procedures, and that is the purpose of this study. It is critical that the study contain pregnant women in the population as they receive the highest rate of neuraxial procedures, have significantly different anatomy than the general population and stand to gain the most from the success of the device. If this device were to be successful in identifying the optimum needle placement for epidural placement in pregnant women, this could one day significantly reduce the discomfort and possible side effects of neuraxial procedures in pregnant women. Notably, a relatively large percentage (up to 5%) of women will experience a significant headache after neuraxial access due to “blind” needle guidance. This can be debilitating, especially in the setting of labor and birth. This non-invasive, inexpensive device holds promise to one day reduce this morbidity and therefore significantly improve the experience of these women during the birth of their child.

HRP 412 has been reviewed

**PARTICIPANT POPULATION(S)**

| Accrual Number: | Category/Group: (Adults/Children Special/Vulnerable Populations) | Consented: Maximum Number to be Consented or Reviewed/Collected/Screened | Enrolled: Number to Complete the Study or Needed to Address the Research Question |
|---|---|---|---|
| Local | Pregnant Women | 60 | 60 |
| | Adults | 60 | 60 |
| Study-wide | | | |
| | | | |
| Total: | | 120 | 120 |

**RECRUITMENT METHODS**
Patients will be identified by the anesthesiology team by chart review after the team has been alerted to the need for pain management and approached in person to be recruited.

The source of participants will be Prentice Women's Hospital and NM (Galter, Feinberg, Lavin) pavilions.

**COMPENSATION FOR PARTICIPATION IN RESEARCH ACTIVITIES**
There will be no compensation for participation.

**WITHDRAWAL OF PARTICIPANTS**
Patients can withdraw from the study at any time and their data will be deleted, and in no way will this impact their care since the study explicitly does not affect the standard of care. The study team will notify the PI by secure NM or NU email if a subject withdraws from the study.

**RISKS TO PARTICIPANTS**
No significant risk to the patient exists with the utilization of the VerTouch device. The materials on the device that come in contact with the patient are similar or the same as those that make up the US probes used in current state. The device is non-invasive and does not generate radiation or any other emission that would affect he patients skin or underlying tissues.

**POTENTIAL BENEFITS TO PARTICIPANTS**
While there is no direct benefit to participants, we do hope that this will benefit pregnant and non-pregnant patients in the future who are undergoing neuraxial procedures. Our previous feasibility study did suggest that the use of the VerTouch may represent an improvement on the current gold standard of palpation.

**DATA MANAGEMENT AND CONFIDENTIALITY**

Based on the feasibility study data collected and published earlier this year at our institution the incidence of first insertion success when utilizing the VerTouch device is 90.1%. Using historical data from studies comparing Ultrasound to Palpation the first insertion success rates are 62.9 and 43.6%, respectively. When utilizing the anticipated incidence of first insertion success for the VerTouch device and Ultrasound to complete a sample size calculation, given Type 1 and Type 2 error are 0.05 and 80%, respectively, each group must contain 38 patients. Therefore, when including the control "palpation" group, the total population needs to be 114 patients. We plan to recruit 120 patients, 40 in each group, to ensure appropriate sample size and allow unknown possible exclusions of recruited patients."

All photographs will be maximally zoomed in. If it is impossible to take a video that does not include identifying marks on the back (i.e. a birthmark or tattoo) no image will be taken. Data will be stored in REDcap using NM password protected computers for data entry.
Data in REDcap is backed up nightly using NM servers which are only accessible to the NM IT administrator. Data in REDcap and pictures/videos will be destroyed 5 years after the completion of the study.

Statistical analysis: Data will be compared between groups using the chi2 statistic or the Fisher's exact test. A $P < 0.05$ will be required to reject the null hypothesis.

**PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS**
**N/A** (minimal risk study)

**PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS**
Patients in this study, whether undergoing neuraxial access for a disease-state or for the treatment of labor pains, will certainly be under some amount of stress. Having a needle placed into one's back, as is the case for neuraxial procedures, can be stress provoking. Extra care will be taken to approach them during a quiet moment when the clinical team has finished their evaluation. It will be emphasized that in no way will this impact their care, and in fact can help future patients undergo these procedures more quickly and safely to minimize their stress.

**COMPENSATION FOR RESEARCH-RELATED INJURY**
**N/A**

**ECONOMIC BURDEN TO PARTICIPANTS**
There is no cost to the patient to be in this study.

**CONSENT PROCESS**

Consent will take place in Prentice Women's Hospital 8th floor Labor and Delivery unit at a time mutually convenient to the clinical team, patient, and research team. Subjects will also be recruited from Galter, Lavin and Feinberg pavilions (numerous medical units). They will be offered to contemplate their participation up until 10 minutes prior to the time of their neuraxial procedure (if any less than 10 minutes were available for application of the VerTouch device prior to the clinical procedure, this would risk rushing the clinical procedure). REDcap electronic consent will be utilized to decrease the number of times the paper consent would be touched. Multiple

times throughout the process, the participant will be reminded that this in no way affects their standard of care and that participation can be withdrawn at any time.

**NON-ENGLISH SPEAKING PARTICIPANTS**
**N/A**

**WAIVER OR ALTERATION OF CONSENT PROCESS**
**N/A**
**PROTECTED HEALTH INFORMATION (PHI AND HIPAA)**
Does the study involve the creation, use, or disclosure of Protected Personal Health Information?

- Will a HIPAA Authorization be obtained from for all participants? Yes
-
- Name
- Age (years)
- Date of procedure
- Telephone numbers
- Medical Record Numbers
- Email address

**QUALIFICATIONS TO CONDUCT RESEARCH AND RESOURCES AVAILABLE**

The PI has 10 plus years clinical research experience. Prentice Women's Hospital cares for over 12,000 women a year for childbirth. Over 90 percent request pain management using Anesthesiology services for epidural catheter placement for pain relief. The research team includes 8 nurse clinicians in the Anesthesia care team who will assist the PI during the study period.

In the event of an inadvertent dural puncture the study team and PI will contact the anesthesiology team to follow up with the subject for the next 5 days to assess for complications.

**MULTI-SITE RESEARCH N/A**