Title: The Effect of Vibratory Anesthesia on Patient Pain Perception in Corticosteroid Injections of the Upper Extremity (NCT07553273)

Faculty Sponsor/Principal Investigator:
John J. Faillace, MD FAAOS

Funding Sponsor:
University of Texas Medical Branch Department of Orthopaedic Surgery and Rehabilitation

Address:
2.316 Rebecca Sealy
301 University Blvd., Route 0165
Galveston, Texas 77555-0165

Phone Number: (409) 747-5700

Student Researchers:
Katelyn Cole, B.S.
Alice Lee, B.A.
Joshua Lui B.S.

Protocol version date: 7/23/25

1. **Introduction and Purpose:**

In-clinic injections of corticosteroids are common for various pathologies of the hand, wrist, and elbow. The use of these anti-inflammatory injections can reduce inflammation and alleviate symptoms associated with compression neuropathies as well as osteoarthritis which can delay or eliminate the need for surgical intervention. In addition to the risks inherent to corticosteroid injections (CSI) on the underlying skin and soft tissue, such as pigment changes and atrophy, injectional pain at the site of needle insertion is also common[1].

Pain associated with CSI can be a barrier to patients being willing to trial or continue treatment with this minimally invasive treatment option. Currently, corticosteroid injections for inflammatory conditions of the upper extremity are performed with either vapocoolant spray topical anesthesia or without anesthesia. Vapocoolant spray itself can cause some patient discomfort while spray is being applied due to cooling affect. Vibration anesthesia has been shown to be an effective method of reducing pain during injections[2]. The aim of this study is to evaluate how vibratory anesthesia affects pain perception for injections of the hand, wrist, and elbow. This study will assess patient-reported pain experienced during the injection with and without anesthetic (vibratory or vapocoolant). We will compare perceived pain scores for participants undergoing injections with vibratory anesthesia to participants undergoing injections without any anesthesia as well as with vapocoolant spray. We will also compare patient discomfort related to anesthesia method. We hypothesize the patient-reported perceived pain scores with both vibration and vapocoolant spray anesthesia will be statistically significantly decreased compared to scores without anesthesia. Secondly, we hypothesize the patient-reported perceived pain scores for subjects having vibratory anesthesia will be either be statistically significantly decreased or non-inferior when compared to those to those undergoing injections with vapocoolant spray topical anesthesia. Lastly, we predict patient discomfort related to application of anesthesia method will be statistically significantly decreased in the vibration anesthesia group.

Primary study endpoint:
Measuring the effect of topical anesthesia on pain associated with corticosteroid injection pain in the hand, wrist, and elbow.

Secondary study endpoint
To determine effect of vibratory anesthesia compared to vapocoolant spray anesthesia and no anesthesia on hand, wrist, and elbow corticosteroid injection pain.

The study risks are reasonable in relation to the potential benefits because the vibratory anesthesia tool poses no greater pain risk compared to no anesthesia or vapocoolant spray and it does not exacerbate natural history of hand or wrist pathologies.

2. Background and rationale:

Prior studies have shown the use of vibratory anesthesia to reduce patient pain during injections of the eyelids, face, and oral cavity.[1-4] However, little research exists regarding its application for pain reduction in corticosteroid injections of the upper extremity. The current standard of care for pain reduction during in-clinic injections of the upper extremity is for the injector to apply vapocoolant spray prior to injection. Vibratory anesthesia is hypothesized to reduce pain by decreasing the transmission of peripheral pain receptor signals to the brain[2]. Topical anesthesia is often desired for pain reduction of the corticosteroid injections for the upper extremity, as many participants with upper extremity tendinopathies and nerve compression syndromes suffer from hypersensitivity to the area and hyperalgesia[5-6].

Prior research has investigated the use of vibratory anesthesia to decrease the pain of digital blocks, which anesthetize the finger away from the site of injury or pathology[7], but scarce research has been performed to assess pain modulation by vibratory anesthesia for corticosteroid injections at the site of the pathology or trigger points in the upper extremity. Our proposed study aims to assess the efficacy of vibratory anesthesia for injections of the upper extremity in a manner that poses no additional risk to the patient than the current standard practice and may aid in decreasing discomfort associated with anesthesia itself.

The Digivibe device is an FDA approved device by Suthe Dermal that uses pulsed vibrations to activate the larger A-beta nerve fibers thus interfering with pain signals. This device has a circular shape that allows clinicians to inject through the device into the area surrounded by pain blocking vibrations[8]. The use of the Digivibe device for the purposes of this study is within the marketing approval and registration of its FDA registration and classification.

3. Concise Summary of Project:

This study is a prospective, randomized cohort with three arms. Patients will be assigned to one of three cohorts. In order to standardize efficacy of reduction of injection pain only patients who are receiving bilateral injections will be eligible to participate in this study.

Participants will receive bilateral injections and will be randomized to receive a combination of two of the three options listed below (one on each side):

a. no anesthesia
b. vapocoolant spray topical anesthetic prior to injection
c. vibration anesthesia using the Digivibe device throughout the duration of the injection.

Randomization will occur via the randomization tool on the RedCap survey platform. Each patient that voluntarily consents to the participate in this study will complete an identical Numeric Pain Rating Scale (NPRS) to assess patient reported pain (0 being none 10 being worst possible pain):

1. Related to the method of anesthesia

2. Pain related to injection

Patients will be recruited into the study until each cohort has at least 165 participants. This study is proposed to last for one year.

Participants in the vibratory or vapocoolant spray anesthesia cohorts will not incur any additional cost related to the anesthesia or injection. None of the participants will incur any research-related costs. The participants will not be subject to any new conditions or consequences from early exit, withdrawal of consent, or voluntary non-participation in this study.

4. **Study Procedures:**

At the time of clinic visit, patients deemed eligible by study personnel will be consented for voluntary participation in the research study. Participants will then be randomized via a random generator into one of the three cohorts.

Each cohort will receive two injections with one of the following combinations of anesthetic treatments:

1. Limb A: no anesthesia and Limb B: vapocoolant spray topical anesthetic prior to injection
   OR
2. Limb A: no anesthesia and Limb B: vibration anesthesia using the Digivibe device throughout the duration of the injection.
   OR
3. Limb A: vapocoolant spray topical anesthetic prior to injection and Limb B: vibration anesthesia using the Digivibe device throughout the duration of the injection.

Each injection will consist of 1.5cc of volume constituted by 0.5cc 40% triamcinolone acetonide, 0.5cc 2% lidocaine, and 0.5cc 0.5% bupivacaine injected at the site standard for their clinical diagnosis via 25-gauge syringe in bilateral extremities.

Participants will complete post-injection numeric pain rating scales assessing perceived pain after syringe disposal.

All injections will be given under semi sterile conditions per clinic standard prepped with: ChloraPrep® Frepp® 2% Chlorhexidine Gluconate/70% Isopropyl Alcohol

For participants receiving no anesthesia: no anesthesia will be administered before the injection and injection will be administered. After typical disposal of injection syringe, participant will complete post-injection numeric pain rating scale assessing pain of injection.

For participants receiving vibratory anesthesia: vibratory anesthesia will be administered throughout the duration of the injection. The circular part of the device will be applied directly to the surface of the skin. At the center of the circle is where the injection will be given, and the vibration will be turned on throughout the duration of the injection. After typical disposal of injection syringe, participant will complete post-injection numeric pain rating scale assessing pain of injection.

For participants receiving vapocoolant spray anesthesia: vapocoolant spray anesthesia will be applied until the skin blanches, which is the standard clinical use. Corticosteroid injection will be given. After typical disposal of injection syringe, participant will complete post-injection numeric rating score.

Each subject's participation will encompass approximately twenty-minutes including informed consent, completion of numeric pain rating scales (anesthetic application discomfort and post-injection)

application of anesthetic method, and injection to bilateral injection sites. Participants cannot participate more than once in the study. No biological samples are to be collected from any participant.

In accordance with the Food and Drug Administration Amendment Act of 2007 (FDAAA) and The International Committee of Medical Journal Editors (ICMJE) member journals trials-registration policy as a condition for publication, this study will be registered in the public trials registry ClinicalTrials.gov pending IRB approval, which is sponsored by the National Library of Medicine. Results will be published to ClinicalTrial.gov when available but will not identify individual participants, under privacy and confidentiality issues. All research personnel is in the process of completing the required Clinical Trials trainings.

5. Sub-Study Procedures:

There will be no sub-study procedures for this research

6. **Criteria for Inclusion of Subjects:**

Inclusion criteria:

- Any patient of the Principal Investigator, Dr. John Faillace, who has clinically diagnosed bilateral arthritis, tendinopathy, arthropathy, or compression neuropathy of the hand, wrist, or elbow where treatment with corticosteroid injection is indicated.
- Participants who voluntarily consent to participate in the study and sign consent forms.
- Participants who complete all numeric pain rating scales
- Patients aged ≥ 18 years old

7. **Criteria for Exclusion of Subjects:**

Exclusion criteria:

- Participants who opt out of the study or withdraw consent
- Participants who are determined to be without capacity to consent to study participation or injection procedure by principal investigator
- Participants with inability to complete numeric pain rating scales
- Participants with known allergies to triamcinolone acetonide, lidocaine, or bupivicaine
- Participants without clinically diagnosed bilateral arthritis, tendinopathy, arthropathy, or compression neuropathy of the hand, wrist, or elbow.
- Participants where treatment with corticosteroid injection is not indicated bilaterally.
- Patients ≤ 18 years old

8. **Sources of Research Material:**

Digivibe vibratory anesthesia devices, numeric pain rating scales, vapocoolant spray, and consent forms will be provided by the UTMB Department of Orthopaedic Surgery and Rehabilitation. Demographics, including age, sex, clinical diagnoses, as well as scores from the numeric pain rating scales will be entered into a password protected data sheet only accessible to UTMB personnel through UTMB OneDrive will be used for data analysis and interpretation throughout the duration and at the conclusion of the study.

9. Recruitment Methods and Consenting Process:

Potential subjects will be patients of the Principal Investigator. Each participant must consent to participation and completion of the injection pain questionnaire. All potential subjects will be recruited during the clinic visit if they have a clinical diagnosis eligible for participation.

A trained research assistant or other qualified researcher will ask the subject whether he/she is willing to participate in the study. Potential subjects will not be approached by a member of the research team until they have shown an interest in the study with their provider first. If the subject answers in the affirmative, the assistant will explain the procedures and risks/benefits of the study in greater detail and commence the informed consent process. Only IRB-approved staff will obtain consent from prospective subjects to be included in the database. Completed informed consent forms will be kept in a locked filing cabinet in the study coordinator's office.

Consent will include elaboration of information collected during research process, which includes age, sex, clinical diagnosis, numeric pain rating scale scores. Potential subjects will be reassured that they will receive care in accordance with standard practice for their respective clinical diagnosis regardless of decision to participate in study. Participants will be reassured that inclusion in either cohort will not affect natural history or modulate effect of corticosteroid on their respective clinical diagnosis, but may have influence on pain perception of procedure. Participants will have option to withdraw consent at any time during process. Non-English speaking subjects will be consented with official translating services provided through University of Texas Medical Branch.

10. **Potential Risks:**

Every subject will undergo injections using clean technique that is typical/standard of care for in-clinic injections. All injections will be administered by the Principal Investigator, or other appropriately medically trained staff-person with medical doctorate.

There are no known long-term risks of vibratory anesthesia or vapocoolant spray anesthesia. Short term risks may include brief discomfort related to application of anesthesia. Neither have been shown to be associated with enhanced pain, discomfort, or progression of clinically diagnosed compression neuropathy, arthropathy, tendinopathy, or arthritis. There is currently no known risk that vibratory anesthesia or vapocoolant spray have enhanced pain perception compared to injection without anesthesia.

Participation in injections without anesthesia has risk is short-lived pain associated with corticosteroid injection as compared to no anesthesia cohort that will terminate at conclusion of injection.

The potential risk of loss of data confidentiality is minimal. All reasonable efforts will be made to protect participants' data however there is a minimal risk that data may be lost or inadvertently disclosed. Data will be de-identified and cannot be linked to any participant names or personally identifiable information, data storage is password protected, and access to data is limited to authorized personnel only. In the event of a data breach or loss, participants will be notified and steps will be taken to mitigate any potential harm.

11. **Subject Safety and Data Monitoring:**

No personally identifiable data will be included on the numeric pain rating scales. Participants are informed of numeric pain rating scales and allowed to opt out without penalty or risk of receiving inadequate treatment for clinical diagnosis. All data will be de-identified and cannot be linked to any participant identifiable information, data storage will be password protected, and access to data is limited to authorized personnel only. Participant consent forms will be stored in a locked file cabinet in the department of orthopaedic surgery and rehabilitation.

12. **Procedures to Maintain Confidentiality:**

All data will be de-identified and stored on password protected data sheet using UTMB OneDrive. Access to data is limited to authorized personnel only. Participant consent forms will be stored in a locked file cabinet in the department of orthopaedic surgery and rehabilitation. Badge access and/or key access is required to access the department after hours. None of the data collected during the study will be disclosed to outside entities.

13. **Potential Benefits:**

The potential benefit of the research to the subjects is decreased perception of injection pain. Potentially, the research will provide data to suggest vibratory anesthesia causes less injectional pain than vapocoolant spray or injections without anesthesia.

14. **Biostatistics:**

Pain scores will be treated as continuous numeric measures, assessed for normality of the distribution, and potentially transformed to an improved approximation of normality if appropriate. Principal analysis will be by analysis of variance relating pain score to treatment group, with differences among groups assessed by Tukey-adjusted contrasts. Secondary analyses will add surgery type as a covariate in the model, allowing an interaction with treatment group, and differences among groups will be assessed by surgery type. Alpha will be set at .05, for a 95% level of confidence.

Data will be analyzed by UTMB Statistician Dr. Daniel Jupiter Department of Biostatistics and Data Science, Department of Orthopaedic Surgery and Rehabilitation Associate Program Director, dajupite@utmb.edu upon study completion.

15. References

1. Pace CS, Blanchet NP, Isaacs JE. Soft Tissue Atrophy Related to Corticosteroid Injection: Review of the Literature and Implications for Hand Surgeons. J Hand Surg Am. 2018;43(6): 558-563

2. Pooja Sharma, Craig N. Czyz, Allan E. Wulc, Investigating the Efficacy of Vibration Anesthesia to Reduce Pain From Cosmetic Botulinum Toxin Injections, Aesthetic Surgery Journal, Volume 31, Issue 8, November 2011, Pages 966–971, https://doi.org/10.1177/1090820X11422809

3. Fayers T, Morris DS, Dolman PJ. Vibration-assisted anesthesia in eyelid surgery. Ophthalmology. 2010;117:1453-1457.

4. Sharma P, Czyz CN, Wulc AE. Investigating the efficacy of vibration anesthesia to reduce the pain from cosmetic botulinum toxin injections. Aesthet Surg J. 2011;31(8):966-971

5. Smith KC, Comite CL, Balasubramanian S, Carver A, Liu JF. Vibration anesthesia: a noninvasive method of reducing discomfort prior to dermatologic procedures. Dermatol Online J. 2004;10:1.

6. Nanitsos E, Vartula R, Forte A, Dennison PJ, Peck CC. The effect of vibration on pain during local anaesthesia injections. Aust Dent J. 2009;54:94-100.

7. Lundeberg T, Nordemar R, Ottoson D. Pain alleviation by vibratory stimulation. Pain. 1984;20:13-23.
8. Goldfarb CA, Gelberman RH, McKeon K, Chia B, Boyer MI. Extra-articular steroid injection: early patient response and the incidence of flare reaction. J Hand Surg Am. 2007;32(10):1513-1520

9. Pedersen C, Miller M, Xu KT, Carrasco L, Smith C, Richman PB. Use of Dental Vibration Tool to Reduce Pain from Digital Blocks: A Randomized Controlled Trial. Reg Anesth Pain Med. 2017;42(4):458-461

10. “How It Works.” Suthe Dermal, 21 May 2024, suthedermal.com/science-behind-digivibe/.