Protocol Title: The Effect of Vibratory Anesthesia on Patient Pain Perception in Corticosteroid Injections of the Upper Extremity
IRB Number: #24-0303
Approval Date: 29-Jul-2025
Sponsor: University of Texas Medical Branch Department of Orthopaedic Surgery
Principal Investigator: John J Faillace, MD FAAOS
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The University of Texas Medical Branch at Galveston
Minimal Risk Consent Form

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Please read this consent form carefully, and do not hesitate to contact the principal investigator with any questions or concerns you may have before deciding whether to participate. Taking part in this research study is voluntary. You do not need to participate, and you may stop at any time.

Your doctor is a research investigator in this study. Your doctor is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor. Choosing not to participate in this research study will not affect your medical care.

The key information that follows can help you learn more about this research study. It can also help you decide whether or not to take part in the research. Please read the entire consent form or have someone read it with you. If there is anything that you do not understand, please talk to the study doctor or team to have your questions answered before signing the consent form.

Voluntary Participation & Right to Withdraw:	Your decision to be in this study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time
Purpose	The principal investigator and collaborators are investigating the effect of vibratory anesthesia on pain perception during corticosteroid injections of the hand, wrist, and elbow. Secondly, the investigators are investigating if vibratory anesthesia significantly decreases pain of corticosteroid injection compared to injections without anesthesia or injections with the vapo-coolant spray. The vibratory anesthesia will be measured through the Digivibe device, an FDA registered Class 1 device. The most important risk of participation in this study is injectional pain.
Key Reasonable Foreseeable Risks and Discomforts	Risks or discomforts from this research include injectional pain that should not exceed the time it takes to administer the injection.

Reasonable Expected Benefits	Benefits to you by participating in this study include a potential decrease in the pain of corticosteroid injections.
Length of Participation	Your participation in this study will last for the length of this visit.
Procedures	If you choose to participate in this study, you will be asked to receive your standard treatment: corticosteroid injections to each arm. The injections to each arm will be two of three options: no anesthesia, vapo-coolant spray anesthesia, vibratory anesthesia.

***** This overview only includes some of the information you need before deciding whether to take part. Additional details are given in the full consent document, which can be found on the following pages. Be sure to review the rest of this consent form before deciding about participation.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have either an arthropathy, arthritis, tendinopathy, or compression neuropathy of the hand, wrist, or elbow and are receiving treatment with corticosteroid injection.

Study Summary:
The principal investigator and collaborators are investigating the effect of vibratory anesthesia on pain perception during corticosteroid injections of the hand, wrist, and elbow. Secondly, the investigators are investigating if vibratory anesthesia significantly decreases pain of corticosteroid injection compared to injections without anesthesia or vapo-coolant spray. The most important risk of participation in this study is injectional pain.

The following things you should know about this research study:

- The purpose of the study is to investigate vibrational anthesesia's effects on corticosteroid injection pain. If you choose to participate, you will be asked to complete a post-injection numeric pain rating scale of your actual pain experienced during the injection. This will take approximately 20 minutes.
- Risks or discomforts from this research include injectional pain that should not exceed the time it takes to administer the injection.
- The study will potentially decrease the pain of corticosteroid injections.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

Please take your time to read this entire form and ask questions before deciding if you want to take part in this research project.

DETAILED RESEARCH CONSENT

What is the purpose of this research study?
The purpose of the study is to investigate the effects of vibrational anesthesia on pain of corticosteroid injections for tendinopathies, arthropathies, or compression neuropathies of the hand, wrist, and elbow

How many people will take part in this study?
About 165 people will take part in this study at UTMB.

What procedures are involved as part of this research study?
As part of your standard medical treatment, you are receiving corticosteroid injections to bilateral upper extremities. Once you agree to participate in this study and you sign this consent form, you will be asked to complete the following tests and procedures. You will receive two injections total, one in each arm. These two injections that you receive will be determined randomly based on a random generator within the RedCap survey system in one of these combinations:

1. No anesthesia and vapocoolant spray topical anesthetic prior to injection
2. No anesthesia and vibration anesthesia using the Digivibe device throughout the duration of the injection.
3. Vapocoolant spray topical anesthetic prior to injection and vibration anesthesia using the Digivibe device throughout the duration of the injection.

If chosen to be in one of the Digivibe groups, the device will be used on the skin. There is a circular part of the device that is applied directly to the surface of the skin and vibrates, and the injection will be made within the circular part.
You will be asked to sign this consent form and complete the outlined procedures. After your injection is completed, you will complete a numeric pain rating scale regarding the comfort of the anesthesia you receive. The administration of both corticosteroid injections are part of your standard medical care, but use of topical anesthetic in one or both limbs is being done only because you are taking part in this research study. This visit should take no longer than 20 minutes.

What are the possible risks for choosing to participate in this research study?
The risks of participation in this study include injectional pain. This pain is part of normal standard pain that comes with an injection. No other pain is associated with the device. Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What are the potential benefits for participating in this research study?
The potential benefits for participating in this research study is decreased pain during your injection. Your participation may also potentially benefit society by providing information on how vibration effects injectional pain.

Will I be reimbursed for participating in this research study?
There will be no reimbursement for participation in this study.

Is there an alternative treatment/procedure?
The alternative is not to participate in the study.

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if you do not complete the injection pain questionnaire. Other reasons you may be removed from the study without your consent:

- The sponsor cancels the research.
- The researchers believe that participation in the research is no longer safe for you.

How will my information be protected?
All results obtained in this study will be kept confidential and only available to the research study team. Your individual information will not be reported, only the results of all participants as a group. The pain scale questionnaire will contain no personal information about you.

How will my privacy be protected?
We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

The research team will know your identity and that you are in the research study. Other people at UTMB, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety. If you think this study might affect your clinical care, please inform your doctor.

People outside of UTMB may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form; however, people outside UTMB who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

Who can I contact with questions about this research study?

If you have any questions, concerns or complaints before, during or after the research study, or if you need to report a research-related injury or bad side effect, you should immediately contact Dr. John J. Faillace at (409) 747-5700.

This study has been approved by the UTMB Institutional Review Board (IRB). If you have any complaints, concerns, input or questions regarding your rights as a subject participating in this research study or you would like more information about the protection of human subjects in research, you may contact the IRB Office at irb@utmb.edu.

Do I have to participate?
Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled.

CONSENT TO PARTICIPATE:
The purpose of this research study, procedures to be followed, risks and benefits have been explained to you. You have been given the opportunity to ask questions, and your questions have been answered to your satisfaction. You have been told who to contact if you have additional questions. By signing this form, you are confirming that you have read this consent form and voluntarily agree to participate as a subject in this study.

Signature of Subject	Date
Printed name of Subject	

Interpreter Statement (if applicable):

Using language that is understandable and appropriate, I have discussed this project, and the items listed above with the subject.

Signature of Person Obtaining Consent	Date and Time of Consent Obtained
Printed Name of Person Obtaining Consent	

Interpreter Statement (if applicable):

I have interpreted this consent form into a language understandable to the participant and the participant has agreed to participate as indicated by their signature on the associated short form:

Printed Name of Interpreter	Signature of Interpreter

Date and Time of Consent Obtained