Official Title: Infracalcaneal Peppering Injection Technique for Chronic Plantar Fasciitis: Protocol for a Parallel Randomized Clinical Trial

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Study Title: Infracalcaneal Peppering Injection Technique for Chronic Plantar Fasciitis: Protocol for a Parallel Randomized Clinical Trial

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Background, Rationale and Context

Plantar fasciitis is one of the most common causes of foot pain in adults. Plantar fasciitis demonstrates a lifetime prevalence rate of 10% and accounts for 1 million provider visits in the United States annually (1). In 2007, an estimated $284 million was spent on medical treatments for this condition (2).

Briefly, from an anatomical perspective, the plantar fascia is *not* inert. This thick band of tissue (*aponeurosis*) on the underside of the foot comprises three bands (i.e., medial, central, and lateral) that connect the calcaneus to the toes, has intimate involvement with the Achilles tendon, and acts as both a dynamic shock absorber as well a secondary support structure of the arch (3). As the toes extend during the stance phase of gait, the plantar fascia tightens, creating a *windlass mechanism* (4) that results in elevation of the foot arch, inversion of the hindfoot, and, consequently, external rotation of the leg. The plantar fascia is actually well innervated and together with the intrinsic foot musculature plays a *critical role* in both proprioception and stability, serves to stabilize the arch, and provides dynamic sensory and motor control to the foot (3). Thus, when the plantar fascia becomes irritated or *unhealthy*, this can have detrimental effects on an individual's ability for both standing and walking, which for most is *essential* for living. Unfortunately, the etiology of plantar fasciitis is still poorly understood despite numerous studies on this condition (5).

Thought to have primarily a *mechanical* origin, plantar fasciitis and its development is multifactorial, but *strongly associated* in individuals with an increased BMI (7) and/or decreased ankle joint dorsiflexion (i.e. calf muscle tightness) (8). The diagnosis of plantar fasciitis is usually based on *clinical criteria alone*, with pain localized to the medial tubercle of the calcaneus (i.e. its origin or *enthesis*) considered pathognomonic and is the most widely reported clinical sign. Most patients with plantar fasciitis report *plantar heel pain* after standing up from bed in the morning and/or after they have been seated for a prolonged time. Typically, the heel pain improves somewhat with ambulation but could intensify by day's end with prolonged walking or standing. Patients will oftentimes compensate with their gait to avoid placing direct pressure on the heel. Imaging plays a limited role in routine clinical practice, though may be useful to rule out other causes of heel pain when in doubt (6). As in other musculoskeletal disorders, plantar fasciitis has shown associations with increased levels of depression, stress, and anxiety and may have a significant negative impact on foot-specific and general health-related quality of life (9-10).

In terms of management, conservative therapy (e.g. stretching and/or strengthening exercises, self-myofascial release, NSAIDs, taping, arch supports, supportive shoes, rest, immobilization, etc. to name a few) is still viewed as the mainstay of treatment (11).

Interestingly, evidence on long-term prognosis of plantar fasciitis appears equivocal and no one treatment is superior to the others. Though most experts tout plantar fasciitis as a self-limiting condition (12), some *chronic* sufferers report continued issues with this disorder *5-15 years* from initial onset of symptoms (13), contributing to further ambivalence associated with this disorder. Surgery, typically performed by partially cutting the plantar fascia at the heel, can be offered in recalcitrant cases as a last resort. This *invasive* intervention is of course not without risks, including possible incomplete relief of symptoms (or, worse yet, *more pain* than before surgery), nerve damage, and permanent changes in foot shape (i.e. flat foot). Moreover, plantar fasciitis surgery in the US can cost $10,000 or more (which varies by geography, surgeon's fees, facility costs, and other services such as anesthesia and follow up care) (14).

Lying within the conservative-surgical treatment spectrum for plantar fasciitis is local corticosteroid injection (CSI) therapy (15), a *minimally invasive intervention* that is relatively quick and easy for the clinician to perform in the *outpatient clinical setting*. A targeted plantar fascia injection typically combines both corticosteroid (CSI) and a local anesthetic (LA) as the substance infused (i.e. *injectate*). Administration of a CSI near the irritated plantar fascia has documented evidence of providing pain relief for up to 1 month only (16). A randomized trial performed as far back as 1956 showed *no statistical difference* between CSI and placebo (i.e., saline) with 6-18 months of follow-up recorded (17). Yet, to this day, a CSI is essentially the only immediate intervention that can be proffered in the outpatient clinic by providers that third-party payers (at least in the United States) will compensate for. In point of fact, 73% of surveyed orthopaedic surgeons *preferred CSI* to treat heel pain (18), *yet* its own preeminent foot association, the American Orthopaedic Foot and Ankle Society (14), advocates for its *judicious* use for fear of deleterious side effects, including fat pad atrophy (20) and possible rupture (21). The ambiguity surrounding corticosteroid *injection* as therapy is further substantiated from histopathologic studies involving plantar fasciitis (22-24), which *failed to demonstrate any inflammatory process*, calling into question the rationale on the use of corticosteroids altogether, which are used primarily for their potent anti-inflammatory effects (18). Reasonably, the terminology plantar *fasciitis* is perhaps a misnomer given the *degenerative* (rather than inflammatory) findings uncovered (24), which some investigators refer to as plantar *fasciosis* or plantar *fasciopathy*, given the similar tissue pathology seen in other musculoskeletal tendon disorders, or *tendinopathies* (25-28, 31).

While there have been several prospective investigative studies on CSI for plantar fasciitis, there is vagueness on injection method. There are essentially two described techniques (29): single injection (how CSI is traditionally administered) or *peppering* injection, the latter initially described in 1964 (30) as a technique for lateral epicondylitis, a form of chronic tendinopathy involving the arm. Injection *peppering* is thought to disrupt the chronic degenerative process by provoking bleeding and *inflammation* to promote healing (31). Several study trials involving the injection method for lateral epicondylitis highlights that it is the *physical needling of the pathologic site* (i.e. *peppering*) as opposed to the *injectate* that incites healing (30-34). Thus, a *peppering injection* performed for plantar fasciitis, though just hypothetical, would act similarly via repeatedly fenestrating the pathologic site and *opening holes on several spots* rather than a single spot (33) to stimulate hematoma formation and subsequent healing. To our knowledge, only two previous investigative studies have disclosed its use for plantar fasciitis (35, 36). Likewise, the medical evidence on injection therapy for plantar fasciitis also shows imprecision on both the approach (i.e. medial or plantar heel) and target (i.e. superficial to, deep to, or into the plantar fascia) to inject, just as long as it is deposited *close to* the plantar fascia origin (*enthesis*) (19, 25, 37-39). Though ultrasound guidance can provide more real-time accuracy of where the injectate infiltrates, it shows no superiority to traditional palpation guided injection therapy (36).

Our research team considers corticosteroid injection a nebulous and insufficient treatment option for plantar fasciitis sufferers. If *first do no harm* is the physician's axiom, then

CSI's continued utilization altogether for this tricky pathology should be questioned. Our investigative team has exposed a knowledge gap and posits a challenge to the existing CSI treatment paradigm for plantar fasciitis via an alternative minimally invasive infracalcaneal peppering injection technique being non-inferior to traditional CSI, with the premise that it is the needle rather than the steroid administered that is beneficial for the patient.

Successful completion of our proposed pilot study addresses a critical knowledge gap in the treatment of chronic plantar fasciitis and breaches the translational roadblock of clinical implementation. The results from this rigorous pilot study will provide the framework for our anticipated full-scale efficacy trial with the potential of affording the clinician an upgraded evidenced-based treatment option that has been demonstrated to be safe, effective, and reproducible.

Objectives

1. Assess feasibility of infracalcaneal peppering injection technique with and without CSI in the management of patients with chronic plantar fasciitis.
    a. Feasibility of recruitment, randomization, retention, patient and physician time constraints, and tolerability of treatment will be assessed. Clear quantitative benchmarks and a number needed to treat will be achieved for planned utilization in a subsequent full-scale efficacy trial.
2. Assess the efficacy of infracalcaneal peppering injection with and without CSI for reduction in pain utilizing two validated patient reported outcomes measures (PROMs): the Visual Analog Scale (VAS) and Foot Function Index (FFI), administered at baseline, then at 2, 4, 8, and 12 weeks. Minimal Important Difference (MID) calculations for both VAS and FFI PROMs, specifically for plantar fasciitis, have already been investigated/established and will be used as a reference.
    a. Greater than 75% of these PROMs from ALL cumulative target dates will be captured, providing a target number needed to treat (NNT) to conduct a full-scale efficacy trial investigation.

Methods and Measures

Design: A randomized, double-blind placebo-controlled pilot study at one single institution

Setting: Atrium Health Wake Forest Baptist Department of Orthopaedic Surgery-Podiatry Services practice located in High Point, North Carolina

Subject Selection Criteria

Inclusion Criteria

- Men and women 18 years of age and older
- Patient reported history of plantar heel pain *and* confirmed clinical tenderness of pain with direct palpation of the medial calcaneal tubercle on baseline exam
- Diagnosis of chronic plantar fasciitis, defined for study purposes as symptoms greater than or equal to 6 weeks in duration

Exclusion Criteria

- Individuals less than 18 years of age
- Pregnancy

- History of receiving a local heel injection (i.e. CSI or other injectate) within the last 3 months
- Prior heel trauma or surgery
- Allergy to local corticosteroid or local anesthesia

Sample Size

We estimate the sample size required to answer the research question to be 50 participants.

Interventions and Interactions

Once both informed consent and enrollment have been verified, initial evaluation by the PI will be conducted on participants, and baseline assessments will be performed. The assessments include:

- Documentation of participant age at enrollment along with information on sex/gender, race, and ethnicity to ensure the study involves Inclusion of Individuals across the Lifespan
- History and physical exam
- Calculated BMI
- Documentation of referral patterns (PCP, self, or other referral)
    - If from PCP or other, documentation of what information/work-up was provided (e.g. told they have "heel spur", given NSAIDs, exercises, etc.)
- Clinical confirmation/diagnosis of plantar fasciitis (pain at medial calcaneal tubercle)
- Dolorimeter readings of PPT # (pressure algometer)
- Documentation of subjective reporting of first-step pain (yes/no)
- Foot posture score
- Heel tenderness score
- Initial X-ray (notation and measurement of heel spur) of the symptomatic foot/heel will be performed, if not already completed
- Initial diagnostic musculoskeletal US (PF thickness and echogenicity; fat pad thickness)
- Patient completed baseline self-assessment of both "general heel pain" and "first step pain" (VAS PROM)
- Patient completed baseline self-assessment of foot function (FFI PROM)

At this point, the patient will be block allocated to their study arm, having been randomized in a double-blind fashion by the clinical coordinator. This individual will facilitate safe record-keeping and the processes required to maintain the double-blind design of this study. We will specifically conduct the study in a permuted block design to ensure a 1:1 ratio for the two treatment intervention groups. The study arms are as follows:

- Group 1 - CSI/LA injection
- Group 2 - LA/Saline injection

A nurse or staff member will open a previously prepared and sealed opaque envelope (prepared beforehand by the clinical coordinator) labeled with the participant ID of the patient, which will be unique to the individual and different from their MRN. In this envelope, they will discover the patient's assigned treatment arm. The nurse or staff member will then prepare the syringe with the assigned treatment arm. Once the syringe is filled with the designated substance, the syringe will be wrapped with opaque tape or dark Coban wrap to conceal the contents in the

syringe for both the PI and study participant. The participant's skin will be sterilely prepped with alcohol.

The PI will then administer the injection using an infracalcaneal needle peppering technique as follows:

1. The hypodermic needle is inserted using infracalcaneal injection approach.
2. The hypodermic needle is withdrawn while at the same depositing injectate.
3. The hypodermic needle is redirected without emerging from the skin.

The PI will perform steps 1-3 standardly 20-25 times. Following the completion of the injection and clinical observation, the patient will receive home care and follow-up instructions which will include the standardized teaching of 3 exercises (calf stretching, plantar fascia specific stretching, and plantar fascia loading exercise). Patients will be sent home with an exercise diary to record when and if they complete the instructed exercises with directions to bring the diary to the next visit. Patients will receive 1 phone call between this visit and the next to check in on their exercise progress and remind them to complete the exercise diary.

The patient will be seen at follow-up visit #1 for evaluation and management 2 weeks post-treatment intervention. At this visit, the following assessments will be completed:

- History and physical exam
- Patient self-assessment of both "general heel pain" and "first step pain" (VAS PROM)
- Patient self-assessment of foot function (FFI PROM)
- Dolorimeter readings of PPT # (pressure algometer)
- Heel tenderness score
- Review of the exercise diary

A new exercise diary will be given to the patient. The recommended exercises will be instructed again. Patients will be encouraged to bring the diary to their next visit. To increase compliance, patients will receive 1 phone call to check in on their exercise progress and remind them to complete the exercise diary.

The patient will return for follow-up visit #2 for evaluation and management 4 weeks post-treatment intervention. At this visit, the following assessments will be completed:

- History and physical exam
- Patient self-assessment of both "general heel pain" and "first step pain" (VAS PROM)
- Patient self-assessment of foot function (FFI PROM)
- Dolorimeter readings of PPT # (pressure algometer)
- Heel tenderness score
- Review of the exercise diary

A new exercise diary will be given to the patient. The recommended exercises will be instructed again. Patients will be encouraged to bring the diary to their next visit. The patient will be called 1 time to remind them to complete their exercise diary between visits.

The patient will return for follow-up visit #3 for evaluation and management 8 weeks post-treatment intervention. At this visit, the following assessments will be completed:

- History and physical exam
- Patient self-assessment of both "general heel pain" and "first step pain" (VAS PROM)
- Patient self-assessment of foot function (FFI PROM)
- Dolorimeter readings of PPT # (pressure algometer)
- Heel tenderness score

- Review of the exercise diary

A new exercise diary will be given to the patient. The recommended exercises will be instructed again. Patients will be encouraged to bring the diary to their next visit. The patient will be called 1 last time to remind them of their exercise diary and encourage them to complete it.

The follow-up visit #4 will be the final study visit. This visit will occur 12 weeks post-treatment intervention. At this visit, the following assessments will be completed:

- History and physical exam
- Patient self-assessment of both “general heel pain” and “first step pain” (VAS PROM)
- Patient self-assessment of foot function (FFI PROM)
- Dolorimeter readings of PPT # (pressure algometer)
- Heel tenderness score
- Review of the exercise diary
- Final diagnostic musculoskeletal US (PF thickness and echogenicity; fat pad thickness)
- Exit survey

Evaluation Schedule Summary

Procedures	Screening -42 to -1 days	Injection day 0	Week 2 +/- 3 days	Week 4 +/- 3 days	Week 8 +/- 3 days	Week 12 +/- 3 days
Review Study Procedures, Informed Consent, and Privacy Authorization	x	x				
Eligibility Criteria for Study Entry	x	x				
Patient Demographics	x					
Patient Medical/Surgical History	x	x				
Height, Weight, and Vital Signs	x	x	x	x	x	x
Foot & Ankle Physical Exam	x	x	x	x	x	x
Presentation of Exercise Therapy (targeted stretching and strengthening)	x	x	x	x	x	x
Clinical Observation	x					
X-ray of Affected Foot	x					
Ultrasound of Affected Foot	x					x
Randomization		x				
Study Therapeutic Treatment Intervention (infracalcaneal needle peppering injections)		x				
Evaluation of Injection Site		x	x	x	x	x

Subject Self-Assessments - VAS PROM (for both general heel pain and first step pain) - FFI PROM	x	x	x	x	x	x
Exercise Diary & Instruction of the 3 Exercises		x	x	x	x	x
Foot Posture	x	x				
Heel Pressure Threshold using Dolorimeter	x	x	x	x	x	x
Heel Tenderness Score	x	x	x	x	x	x
Exit Survey						x

*Not on schedule: reminder phone call between study visits to encourage exercise diary completion and compliance.

Outcome Measure(s)

Patient Assessments

- Heel Tenderness VAS PROM
- First Step Pain VAS PROM
- FFI PROM
- Exercise Diary
- Exit Survey at completion of study

Physician Assessments

- Baseline and subsequent foot and ankle physical exam, heel pressure threshold, and heel tenderness score
- X-ray and ultrasound imaging
    - Our research team will be the first to examine musculoskeletal ultrasound imaging obtained both before and after an infracalcaneal peppering injection in participants with chronic plantar fasciitis. Musculoskeletal ultrasound has become more established in the medical literature as a reliable objective measure of plantar fasciitis, with thickness measurements >4.0mm correlating with clinical symptoms (40). Musculoskeletal ultrasound's utility here would enable our investigators to assess for any quantifiable tissue changes associated with our intervention.

Patient Retention

Every effort will be made to retain patients in the study to ensure complete data collection. During the study consent process, potential study participants will be educated regarding the importance of full participation in all visits. Patients will be reminded of their upcoming appointment via phone call or email. Patients will also be reminded about their follow-up visits at all clinic visits.

Patient/study participant compensation will occur at certain study visits. Study participants will receive a paid total of $100.00 if all scheduled study visits are completed.

Study Visit #1 – injection day	$20.00
Study Visit #2 – 2 weeks post-treatment intervention	No payment. Next payment at 4-week follow-up study visit (visit #3).
Study Visit #3 – 4 weeks post-treatment intervention	$40.00
Study Visit #4 – 8 weeks post-treatment intervention	No payment. Next payment at 12-week follow-up study visit (visit #5).
Study Visit #5 – 12 weeks post-treatment intervention	$40.00

Analytical Plan

Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

All patients ages 18 years and up with a diagnosis of plantar heel pain will be screened for inclusion into the study. The study will be conducted in accordance with the current IRB-approved clinical protocol; ICH GCP Guidelines adopted by the FDA; relevant policies, requirements, and regulations of the clinical test site IRB; and applicable federal agencies.

Patients who meet the inclusion criteria will be asked to participate in the research study and provided ample time and encouragement to ask questions and discuss the study with others (medical providers, family, friends, etc.). A copy of the informed consent form will be provided to the patient. The study team will answer all questions.

Subjects may withdraw from the study at any time for any reason at their request. Otherwise, participants will be followed as per the protocol. Attempts will be made to collect clinical data from withdrawn subjects. There will be no replacement of subjects who withdraw from the study.

Subject Recruitment Methods

The study will recruit patients who present to the Atrium Health Wake Forest Baptist Department of Orthopaedic Surgery-Podiatry Services practice located in High Point, North Carolina with symptoms of plantar heel pain. In order to approach patients that have received care at this practice in the past, we will create an i2b2 query to result a list of patients seen by Dr. Jones and diagnosed with plantar fasciitis within the last 3 years (11/1/2020 – 11/1/2023). These patients will be contacted by the study coordinator to introduce the study, gauge their interest, and begin the pre-screening process if they opt in to doing so.

Additionally, the study will be listed on Be Involved and study flyers will be distributed and posted. A social media ad will also be distributed on Facebook and Instagram with information about the study and a link to the Be Involved web page. Interested potential subjects will be contacted via telephone or email and be asked to complete a pre-screening questionnaire. We will utilize a REDCap survey in instances where the potential subject prefers email communication to conduct the pre-screening questionnaire. Study flyers will have a QR code

available for interested individuals to scan and easily access the REDCap pre-screening questionnaire.

All completed questionnaires and personal identifying information collected via Be Involved, both for recruited subjects and those who have declined participation, will be kept securely by the select study personnel. This information will remain in a password protected file and only be accessed on a secure network.

Study Screening and Enrollment

Potential study participants will be screened in the Orthopaedic Surgery-Podiatry Services Practice. Patients with plantar heel pain who meet the study inclusion criteria will be told about the study and will be asked if they would like to participate. The study will be described, and the requirements for study participation will be explained. Potential study participants will be encouraged to ask questions about the study and to find out what is involved in study participation. Patients who agree to participate will be asked to provide informed consent. No study related procedures will occur until after the informed consent is obtained. Following completion of informed consent, the study procedures will begin.

Informed Consent

Signed informed consent will be obtained from each subject in the privacy of a closed clinical examination room. A study team member will discuss the study with patients who meet study entry criteria and will obtain consent while the patients are in the clinic following their visit. Each study participant will receive a copy of the signed informed consent form.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, fully minimizing the collection of any information that could directly identify subjects and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file and stored separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed six years after closure of the study by shredding any paper documents and deleting information from computer files, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with computer data being password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

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Appendix

1. Data Collection Sheet
2. VAS PROM
3. FFI PROM
4. Exercise Diary
5. Exit Survey