

Prospective Randomized Trial of Electrolysis for Chronic Plantar Heel Pain

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Abstract

Background: Chronic plantar heel pain (CPHP) is a common condition with high prevalence rates and a projected cost of treatment of US\$192 to US\$376 million. There are several therapeutic approaches and there is increased interest in treatments aimed at the regeneration of tissues with poor healing potential. Our purpose was to investigate the effectiveness of ultrasound-guided percutaneous needle electrolysis in chronic plantar heel pain.

Methods: A total of 73 patients with a clinical and ultrasonographic diagnosis of plantar heel pain unrelated to systemic inflammatory disease who had not received any other treatment in the previous 6 months on the affected foot were randomly allocated to receive either ultrasound-guided percutaneous needle electrolysis of the fascia (experimental group, n = 39) or placebo puncture (control group, n = 34). The primary outcome was pain scored with an 11-point numeric pain rating scale (0 = no pain, 10 = maximum pain). Secondary outcomes were function and disability measured by the 21-item activities of daily living subscale of the Foot and Ankle Ability Measure questionnaire, and fascia thickness measured by ultrasound. Outcomes were measured at 1, 12, and 24 weeks.

Results: The mixed-model analysis of covariance observed significant group × time interactions from all variables: pain in numeric pain rating scale ($P < .001$), FAAM Activities of Daily Living Subscale scale ($P < .002$), and ultrasonographic measures of the plantar heel ($P < .002$). Patients in the experimental group had better results posttreatment at 12 and 24 weeks compared with the control group.

Conclusion: With chronic plantar heel pain, ultrasound-guided percutaneous needle electrolysis improved pain and function. This treatment may also decrease fascia thickness.

Level of Evidence: Level I, randomized controlled trial.

Keywords: heel pain, plantar heel pain, plantar fasciitis, plantar fasciosis, heel spur syndrome, painful heel syndrome, electrolysis

Introduction

Chronic plantar heel pain (CPHP) is a common condition with high prevalence rates,¹⁸ and a projected cost of treatment of US\$192 to US\$376 million.³⁵ The pathophysiology of CPHP is unclear, but it is thought to be multifactorial.^{10,21,32}

The most common primary source of pain is plantar fasciopathy, also described as plantar fasciitis (PF).²⁹ Although the term *fasciitis* suggests acute inflammation, current research indicates that PF is more of a chronic degenerative process or fasciosis than an inflammatory process.²⁹ In fact, histologic findings have shown fragmentation and degeneration of the fascia rather than inflammation.³²

PF is commonly reported in both athletic and nonathletic populations.²⁴ It is estimated that CPHP affects about 10%

of runners, and contributes to 15% of foot impairments.⁸ In the United States, 7% of people older than 65 years report tenderness in the heel region.¹⁴ Patients frequently experience plantar medial heel pain, which is more intense during

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the initial steps and following prolonged weightbearing.³⁹ PF can be diagnosed by clinical examination alone²⁴; however, imaging modalities including ultrasonography and magnetic resonance imaging can aid in diagnosis and rule out other causes of heel pain.²³ Ultrasonography is the most widely reported imaging modality used to diagnose PF, and thicknesses of >4.0 mm are diagnostic for PF.²⁶

Several therapeutic approaches have been reviewed for the management of CPHP.^{11,12,20} The main goals of treatment are pain relief and restoration of function. A systematic review showed that physical therapy, stretching, anti-inflammatory drugs, and steroidal injections were effective in improving pain outcomes.⁴ There is increased interest in treatments aimed at the regeneration of tissues with poor healing potential (eg, platelet-rich plasma therapy, percutaneous needle tenotomy, dry needling, acupuncture, and percutaneous needle electrolysis [PNE]).^{36,37}

Ultrasound-guided PNE is a minimally invasive technique that induces an inflammatory response through a nonthermal electrolytic reaction. This controlled response facilitates an increased cellular activity that can lead to the regeneration of injured tendons, and does not damage healthy tissue because of the different resistance to current flow.^{4,12,20} PNE has proven effectiveness in the treatment of tendinopathy with good results in the supraspinatus and the extensor tendon at its attachment on the lateral epicondyl.^{6,37}

To our knowledge, no randomized clinical trial has investigated the effects of PNE in CPHP. We hypothesized that PNE could also be effective in connective tissue with similar pathophysiology and histopathology to tendinopathy, such as the plantar fascia. The purpose of this study was to evaluate the clinical effect of ultrasound-guided PNE in CPHP at 1, 12, and 24 weeks posttreatment versus CPHP patients who received placebo treatment. We also aimed to determine whether PNE affected the plantar fascia thickness.

Methods

This parallel, group-blinded, randomized, placebo-controlled trial was carried out in a university clinic. All study procedures were approved by the university ethics committee, and took place from November 2014 to September 2016. Seventy-three participants were randomly assigned to the experimental group or the control group. All participants provided written informed consent before enrollment. All participants were informed that they had a 50% chance of receiving sham puncture over PNE, and that the principal investigator was blinded to the type of intervention given, but that they would receive the same active post-intervention treatment.

Participants

A total sample of 80 patients was recruited from 3 orthopedic surgeons in our health area that offered to the patients

an experimental treatment as an option for their pathology. Patients aged 18 to 65 years were included if they had experienced unilateral heel pain for at least 3 months, and were diagnosed with CPHP by physical examination and ultrasonography. The acceptable criteria for diagnosing CPHP by physical examination included insidious onset of sharp pain under the plantar heel surface upon weightbearing after a period of nonweightbearing, heel pain that increased in the morning with the first steps and decreased with slight levels of activity such as walking.²⁴ The acceptable criteria for diagnosing CPHP by ultrasonography included plantar fascia thicker than 4 mm measured at a standard location where the fascia crosses the anterior aspect of the inferior calcaneal border, as well as a decrease in echogenicity.²³

Patients were excluded if they had any of the following: foot deformity, suspected nerve entrapment (ie, Baxter's nerve, tarsal tunnel syndrome), any systemic disease that could have induced foot pain, sensory disorder, current skin or soft tissue infection near the injection site, previous injections in the plantar fascia for pain management or continued physical therapy interventions for the foot region in the previous 6 months, history of ever being treated with ultrasound-guided PNE on any part of the body, or previous operative treatment of the affected foot. Subjects were not excluded if they had occasionally taken drugs for pain relief (acetaminophen, metamizole, or NSAIDs) or some kind of physical therapy intervention for less than 1 week and never in the last week before enrollment.

A total of 80 patients with CPHP were enrolled. Of these patients, 7 were excluded on the basis of the exclusion criteria; 1 patient had diabetes mellitus, and 6 had been treated for PF in the previous 6 months (5 with physical therapy and 1 with a corticosteroid injection). Hence, 73 patients were randomly assigned to the experimental group (n = 39) or the control group (n = 34). Figure 1 shows the flow chart of the study process. The 2 groups had similar baseline characteristics for all variables (Table 1). Of the 34 patients allocated to the control group, 5 were lost to follow-up; 1 did not complete the treatment and 4 were excluded at the 12-week follow-up (1 had received corticosteroid treatment, and 3 withdrew because of a lack of treatment efficacy). In the experimental group, 1 patient was excluded at the 12-week follow-up for having received physical therapy.

Interventions

Participants were randomly allocated to the ultrasound-guided PNE group (experimental group) or the sham intervention group (control group). Each treatment day, participants received one intrafascial puncture with an acupuncture needle (diameter 0.35 mm, length 40 mm); depending on the grouping, the patients were then either administered 28 mC of cathodal PNE (EPTE v2; Ionclinics,

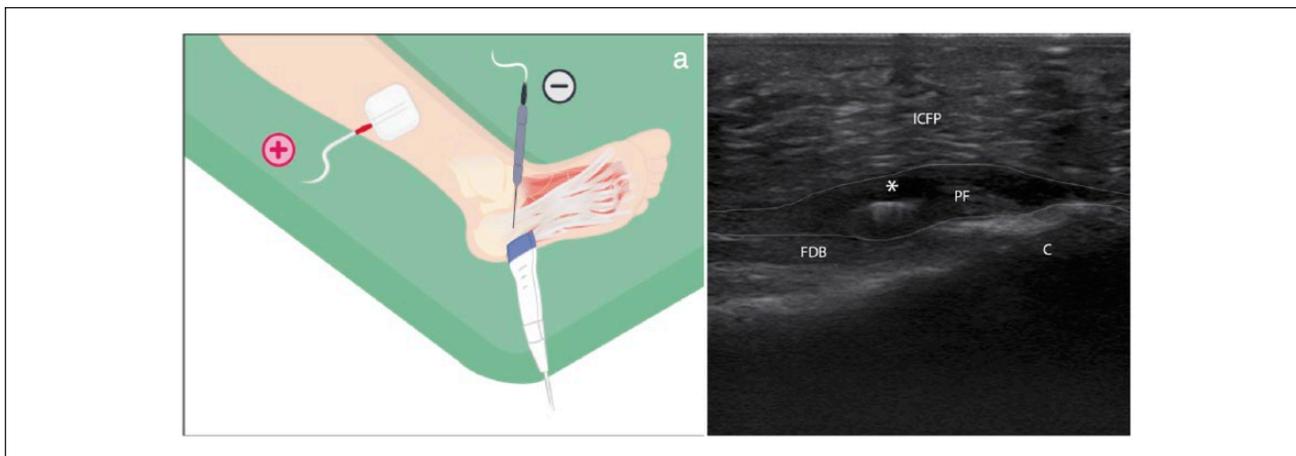


Figure 1. (A) Schematic representation of the ultrasound-guided heel puncture. Short-axis in-plane approach. (B) Sagittal ultrasonographic image obtained over the posterior insertion of the plantar fascia in a 42-year-old patient with chronic plantar heel pain. Note the hyperechogenic gas produced by the electrolysis chemical reaction (*). C, calcaneus; FDB, flexor digitorum brevis; ICFP, infracalcaneal fat pad; PF, plantar fascia.

Table 1. Demographic and Baseline Characteristics of the Intention-to-Treat Populations.^a

Characteristics	US-Guided PNE Group, Mean (SD) (n = 38)	Placebo Group, Mean (SD) (n = 29)
Age, y	45.1 (11.4)	46.6 (11.1)
No. (%) of females	23 (60.5)	19 (65.5)
BMI	29.2 (3.5)	28.7 (4.4)
Heel pain (NPRS) when taking the first steps in the morning	7.0 (1.4)	6.4 (1.4)
FAAM activities of daily living subscale	43.2 (10.1)	43.2 (10.2)
Plantar fascia thickness, mm	6.4 (0.9)	6.3 (1.0)

Abbreviations: BMI, body mass index; FAAM, Foot and Ankle Ability Measure; NPRS, numeric pain rating scale; PNE, percutaneous needle electrolysis; SD, standard deviation; US, ultrasound.

^aP > .05 for all variables.

Valencia, Spain), or placebo (using the same device modified to administer no electrical current) at the affected plantar fascia region. The ultrasonographic monitor was turned off once the needle was inserted into the affected area, so the clinical investigator could not see the hydrogen gas produced by the electrolytic reaction as a hyperechogenic dense mass, thereby blinding the clinician as to whether PNE or placebo was being administered. Once the electrical current had been administered, the needle was removed. Patients in both groups received the same active postinjection treatment, which consisted of an exercise program.³¹ In the control group, although other authors have previously used depth-sham electroacupuncture methods,⁹ there was a low risk of bias because none of the participants had ever previously experienced the electrical sensation produced by PNE (as specified in the exclusion criteria).

For the active procedure, patients were placed in supine position and antiseptic measures were applied with chlorhexidine 1%, sterile transmission gel, and transducer covers. An

ultrasound probe (Mindray M7; Mindray Medical Intl Ltd, Shenzhen, China) with a variable frequency (6-14 MHz) linear array transducer (L 14-6 s; Mindray Medical Intl Ltd, Shenzhen, China) was placed under the calcaneus in a short-axis view. One ultrasound-guided in-plane puncture was made from the medial part of the calcaneus, through the skin, and advanced under continuous ultrasound guidance through the fat pad and into the affected area of the proximal plantar fascia at the end of the medial calcaneal tubercle. An anodic plate was placed proximal to the calf muscles (Figure 2). The treatment was repeated once a week for 5 weeks.

Randomization and Treatment Allocation

An investigator (A.F.R.) who had no contact with the participants generated the random number sequence and handed the device to the clinical investigator for the therapeutic procedure. Treatment allocation was done in a 1:1

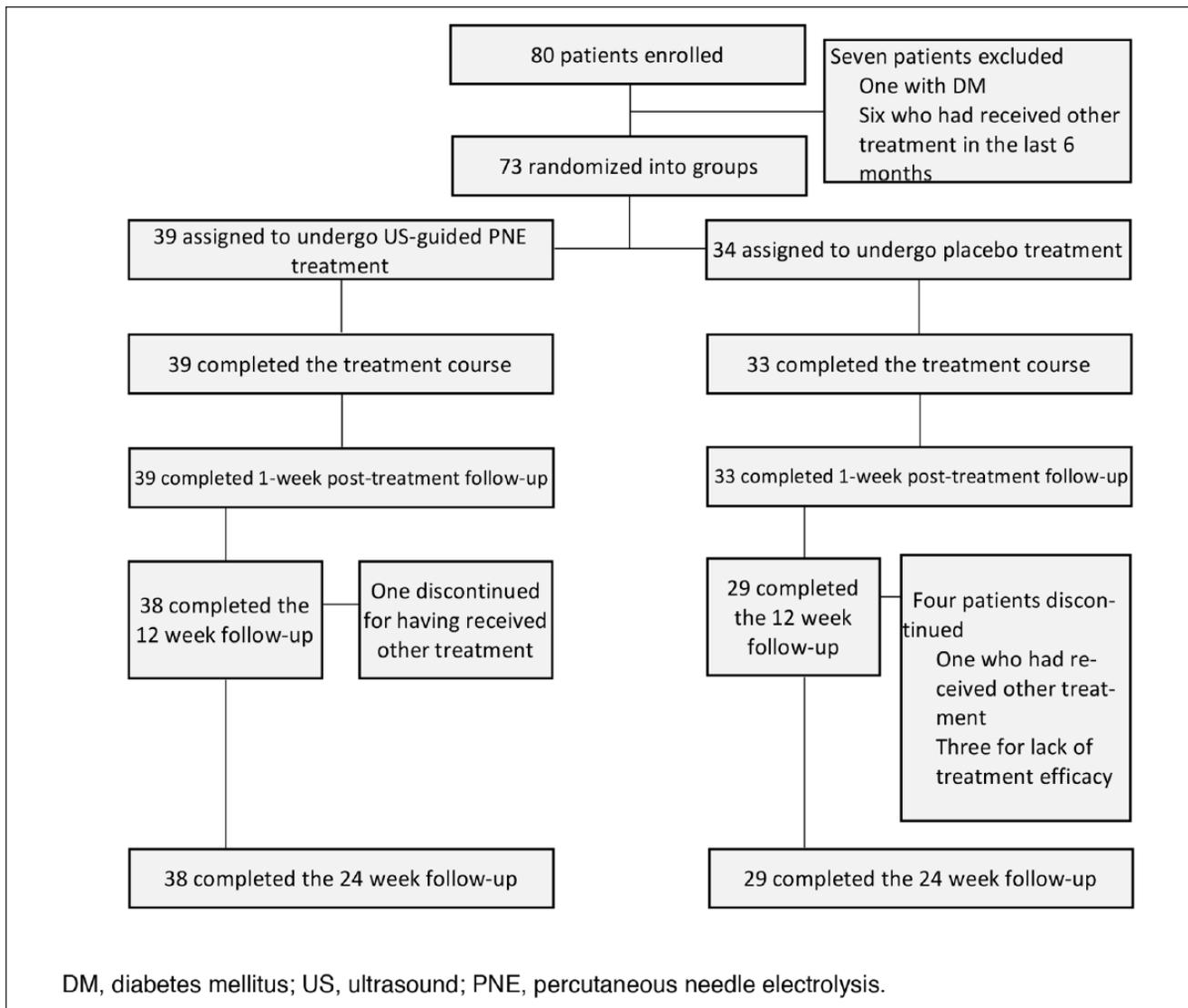


Figure 2. Flow chart of the study process.

DM, diabetes mellitus; PNE, percutaneous needle electrolysis; US, ultrasound.

manner in permuted blocks of 4 to 8 stratified by treatment center using a computer-generated randomized list; thus, the patients and the clinical investigator were blinded to the intervention. The randomization table was kept in a password-protected computer file. The punctures were performed by a clinical investigator (S.T.D.) with 10 years of experience in conducting injection procedures. Clinical outcomes and ultrasonographic measures were made by a third investigator (T.F.R.), who was a sonographer with 8 years of experience.

Sample Size Determination

The sample size was calculated based on previous studies, which indicated that 34 participants per group would

provide 80% power to detect a minimal clinically important difference of 2 points on the numeric pain rating scale (NPRS)¹⁶ assuming an alpha level of 0.05 and a 10% loss to follow-up.

Primary Outcomes

The primary outcome was “first step” pain measured by an 11-point NPRS (0 = no pain, 10 = maximum pain) at baseline and at 1, 12, and 24 weeks posttreatment.

Secondary Outcomes

The secondary outcomes were function and plantar fascia thickness at baseline and at 1, 12, and 24 weeks

Table 2. Outcome Measures of Foot Pain, Function, and Plantar Fascia Thickness in Participants With Plantar Heel Pain Treated With Percutaneous Needle Electrolysis or Placebo.

	Baseline	1 wk Posttreatment	3 mo Posttreatment	6 mo Posttreatment	P Value
Mean level of heel pain (NPRS, 0–10)					
CG	6.4 ± 1.4 (5.9-7.8)	6.1 ± 1.4 (5.3-7.1)	4.8 ± 1.6 (4.4-5.3)	3.7 ± 1.6 (3.1-4.4)	.001
EG	7.0 ± 1.4 (6.2-7.8)	2.1 ± 1.2 (1.2-3)	1.1 ± 0.9 (0.3-1.9)	0.4 ± 0.6 (0.1-0.9)	
FAAM activities of daily living subscale					
CG	43.2 ± 10.2 (37.1-44.3)	44.7 ± 9.7 (36.8-42.9)	52.3 ± 11.6 (47.3-61)	61.8 ± 12.7 (58.1-65.1)	.002
EG	43.2 ± 10.2 (36.9-44.1)	72.1 ± 7.9 (66.4-78.5)	78.2 ± 5.5 (71.8-81.1)	82 ± 2.9 (73.9-87.8)	
Ultrasound measurements of plantar fascia thickness (mm)					
CG	0.6 ± 0.1 (0.3-0.8)	0.6 ± 0.1 (0.3-0.8)	0.7 ± .1 (0.3-0.8)	0.7 ± 0.1 (0.3-0.7)	.03
EG	0.6 ± 0.1 (0.3-0.8)	0.6 ± 0.1 (0.4-0.8)	0.6 ± 0.1 (0.3-0.7)	0.6 ± 0.1 (0.3-0.8)	

posttreatment. Function was measured by the 21-item activities of daily living (ADL) subscale of the Foot and Ankle Ability Measure (FAAM) questionnaire. Item score totals range from 0 to 84, with each item scored on a 5-point Likert-type scale (4 to 0) from “no difficulty at all” to “unable to do.” Plantar fascia thickness was measured by diagnostic ultrasonography at the location where the fascia crosses the medial calcaneal tubercle; at this location, the measurement technique has been shown to have good intra-rater reliability, with the 95% limits of agreement ranging from -0.7 mm to 0.5 mm.⁴⁰ Adverse events associated with the intervention were recorded, such as postinjection pain, soft tissue infection, and nerve injury from needle penetration.

Statistical Analyses

Statistical analysis was performed using SPSS software, version 22.0 (SPSS, Chicago, IL), and was conducted in the intention-to-treat population. When data were missing, the last value recorded for each patient was used. Baseline demographic and clinical variables were compared between the 2 groups using independent Student *t* tests for continuous data and χ^2 tests of independence for categorical data. Our primary evaluation included mixed-model repeated measures analyses of covariance; this evaluation used time as the within-subject factor and group as the between-subject factor and was adjusted for baseline outcomes for evaluation of between-group differences in all outcomes. We used χ^2 tests to compare self-perceived improvement and success rate at 12 and 24 weeks in both groups.

Results

No adverse events were reported in association with the trial intervention. The mixed-model analysis of covariance observed significant group \times time interactions for all variables: pain as assessed by the NPRS ($P < .001$), function as assessed by the FAAM ADL subscale ($P < .002$), and ultrasonographic measurements of the plantar heel

thickness ($P < .002$). The experimental group exhibited greater decreases in all 3 variables at 1, 12, and 24 weeks posttreatment compared with the control group. Table 2 summarizes the baseline and posttreatment data as well as within-group differences.

At 1 week posttreatment, the average numeric pain rating scale (NPRS) score in the experimental group was reduced by 4.9 points (69.9%), which was a significantly greater reduction than that in the control group of 0.4 points (5.9%). Furthermore, the between-group difference of more than 4 points or 60% is clinically relevant, as a difference of 2 points or 30% is the established limit for clinical relevance.^{15,33} The mean difference between groups in pain relief remained significant at 12 and 24 weeks posttreatment. The superiority of ultrasound-guided PNE compared with placebo was also supported by the 21-item activities of daily living (ADL) subscale of the Foot and Ankle Ability Measure (FAAM) results, which improved by 28.9 points at 1-week posttreatment in the experimental group compared with 1.4 points in the control group; this between-group difference reached the minimal clinically important difference established by Martin et al.²⁵ The mean difference between groups in function remained significant at 12 and 24 weeks. Ultrasonographic measurements indicated that the treatment probably had a biological effect on the plantar fascia tissue, as there was a significant decrease in the plantar fascia thickness in the experimental group at 24 weeks compared with baseline; however, this may not represent a true decrease in plantar fascia thickness, as discussed below.

Discussion

The present study investigated the effectiveness of ultrasound-guided PNE in CPHP. Ultrasound-guided PNE was effective in the short term (0-3 months) and the intermediate term (3-6 months), providing better pain relief and improvement of functional disability than placebo. The latest published reviews on CPHP treatment include evidence for the benefits of manual therapy, stretching, taping, foot orthoses, and night splints^{5,7,24,28}; furthermore, there is weak

evidence for the efficacy of low-level laser therapy and phonophoresis with ketoprofen gel, and conflicting evidence for electrotherapy with 0.4% dexamethasone or 5% acetic acid delivered via iontophoresis, acupuncture, or trigger point dry needling.^{5,7,24,28} The Cochrane Review concluded that there is low quality evidence for short-term pain relief following corticosteroid injection (CI) with placebo or no treatment.¹²

A recent review by Tsikopoulos et al³⁶ reported that micronized dehydrated human amniotic/chorionic membrane (mDHACM) is the best injection option in the short term, and botulinum toxin A is the most likely to relieve pain intensity in the first 0 to 6 months after treatment. Extracorporeal shock wave therapy can be considered as a treatment option before operative management.¹⁷ Operative interventions are suggested for CPHP resistant to conservative options, but surgery can be associated with prolonged healing and did not prove superior to conservative treatment.^{11,13,30}

To our knowledge, no clinical trial has investigated the effects of PNE in CPHP. Promising results have been reported in trials investigating PNE for chronic lateral elbow epicondylitis,³⁷ patellar tendinopathy,^{1,2} and subacromial pain syndrome,⁶ but further evidence is needed. As plantar fasciopathy is the most common cause of CPHP, and its pathology may be similar to tendinopathy, the application of PNE may be effective. Iborra-Marcos et al published a retrospective study comparing the effectiveness of corticosteroid injection (CI) versus percutaneous electrolysis for the treatment of plantar fasciitis demonstrating that both techniques were effective, providing excellent visual analog scale pain and Foot and Ankle Disability Index results at 12 months.¹⁹ The exact mechanism by which PNE exerts its effects remains to be elucidated, but both mechanical and biochemical effects are currently proposed.⁶ In our study, the control group improvements in the NPRS and FAAM ADL subscale might be partly explained by this mechanical effect and by the placebo effect, but the superior results in the experimental group suggest the importance of the biochemical effect of the electrolysis. Abat et al³ and Valera-Garrido et al³⁸ demonstrated that the application of electrolysis initiates an inflammatory response and promotes wound healing in collagenase-induced tendinopathy and in healthy rat tendons.

Fusiform thickening of the plantar fascia is a well-established feature of PF. CPHP patients are more than 100 times more likely to have abnormally thickened plantar fascia (>4 mm) compared with asymptomatic controls.³⁹ The present results of a reduction in plantar fascia thickness at 24 weeks are encouraging, and may be due to the hypothesized stimulation of the tendon biology.³⁸ However, our results showing a decrease in plantar fascia thickness of 0.3 mm from baseline in the experimental group may not represent a true improvement, as the intrarater reliability of the measurement

was not investigated in detail. One study reported 95% limits of agreement of -0.7 mm to 0.5 mm.⁴⁰ McMillan et al²⁷ concluded that changes in thickness greater than -0.7 mm represented true improvement. According to these criteria, we cannot conclude that true improvements in fascia thickness were achieved in our study.

A major finding of our trial was that the clinical outcomes achieved with PNE treatment did not decline over time. We consider this a very important finding, as it indicates that PNE is not just a good treatment option regarding pain relief and improvement in functionality in the short term. PNE is in some way affecting plantar fascia tissue regeneration, and achieved even better results after 3 and 6 months of follow-up. In contrast, other injection therapies, such as corticosteroids or mDHACM, have reported good results in pain relief and functional improvement in the short term (up to 2 months) but not in the intermediate term (2-6 months).³⁶

In our opinion, the current theoretical model of plantar fasciopathy as a degenerative process^{8,22} requires different and new therapeutic approaches aimed at the regeneration of tissues with poor healing potential, and our results indicate that treatment with PNE is promising. In order to give orientation to clinicians about when to use this new therapy the authors recommend using it when conservative treatment fails.

Strengths and Limitations

The design of this trial was rigorous, incorporating adequate statistical power, placebo control, and blinding of the participants, the clinician carrying out the injections, and the clinician who performed the ultrasonographic measurements and evaluated the test results. The implementation of an exercise program was also undertaken to better represent normal clinical practice. One potential limitation in the blinding of the participant and the clinician was that the patients can feel some pain when electrolysis is applied. Furthermore, only 1 clinician performed the intervention and only 1 clinician performed the ultrasonographic measurements. These factors may limit the generalizability and external validity of the trial findings, and should be considered carefully. Another limitation is that we did not record the degree of pain felt by the patients during the intervention. Both groups felt some pain, as any injection in which a needle is inserted into damaged tissue is painful, but it may have been useful to compare the degree of pain felt in the control and the experimental groups, as pain is a potential reason for withdrawal from treatment. However, none of our patients withdrew from the study because of pain. It is also necessary to consider the associated placebo effect, which is related to the device itself but also to the intervention and the physician. The pure treatment effect is not distinguishable from this placebo effect, so both are clinically used together.^{17,34} The small sample size and lack of

generalizability to other populations are other limitations that must be considered.

Conclusions

Ultrasound-guided PNE was safe and effective for CPHP in the short term (0-3 months), and was even better at the intermediate term (3-6 months), achieving better results than placebo in pain relief and improvement in functional disability. These findings are relevant for clinical practice, as clinicians may consider using this new treatment in CPHP patients. We cannot conclude that true improvements in fascia thickness were achieved in our study.

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Declaration of Conflicting Interests

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