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Manual Physical Therapy and Exercise Versus Electrophysical Agents and Exercise in the Management of Plantar Heel Pain: A Multicenter Randomized Clinical Trial

Plantar heel pain is commonly referred to as "plantar fasciitis"; however, recent research suggests that the condition manifests itself as a noninflammatory degenerative process, thus the term "fasciosis" may be more appropriate.[22] Lemont and colleagues[22] reviewed the histological findings of 50 patients with heel pain. The findings revealed that none of the samples exhibited any evidence of inflammation but, rather, degenerative changes in the fascia.[22] Perhaps this is the reason why corticosteroid injections have been found to be ineffective and, in fact, often result in serious side effects, including plantar fascia ruptures.[1,34] Considering the ongoing debate regarding proper nomenclature, for the purpose of this study we will use the term "plantar heel pain" to refer to the presentation of our clinical population.

It has been reported that approximately 1 in 10 individuals will develop chronic heel pain and nearly 2 000 000 Americans are affected annually.[8,9,11,30] Patients with plantar heel pain often report that pain is located along the medial border of the plantar fascia to its insertion at the medial tuberosity of the calcaneus.[7] The pain is worse in the morning when taking the first few steps after getting out of

● **STUDY DESIGN:** Randomized clinical trial.

● **OBJECTIVE:** To compare the effectiveness of 2 different conservative management approaches in the treatment of plantar heel pain.

● **BACKGROUND:** There is insufficient evidence to establish the optimal physical therapy management strategies for patients with heel pain, and little evidence of long-term effects.

● **METHODS:** Patients with a primary report of plantar heel pain underwent a standard evaluation and completed a number of patient self-report questionnaires, including the Lower Extremity Functional Scale (LEFS), the Foot and Ankle Ability Measure (FAAM), and the Numeric Pain Rating Scale (NPRS). Patients were randomly assigned to be treated with either an electrophysical agents and exercise (EPAX) or a manual physical therapy and exercise (MTEX) approach. Outcomes of interest were captured at baseline and at 4-week and 6-month follow-ups. The primary aim (effects of treatment on pain and disability) was examined with a mixed-model analysis of variance (ANOVA). The hypothesis of interest was the 2-way interaction (group by time).

● **RESULTS:** Sixty subjects (mean [SD] age, 48.4 [8.7] years) satisfied the eligibility criteria, agreed to participate, and were randomized into the EPAX (n = 30) or MTEX group (n = 30). The overall group-by-time interaction for the ANOVA was statistically significant for the LEFS (P = .002), FAAM (P = .005), and pain (P = .043). Between-group differences favored the MTEX group at both 4-week (difference in LEFS, 13.5; 95% CI: 6.3, 20.8) and 6-month (9.9; 95% CI: 1.2, 18.6) follow-ups.

● **CONCLUSION:** The results of this study provide evidence that MTEX is a superior management approach over an EPAX approach in the management of individuals with plantar heel pain at both the short- and long-term follow-ups. Future studies should examine the contribution of the different components of the exercise and manual physical therapy programs.

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● **KEY WORDS:** *iontophoresis, manipulation, mobilization, plantar fasciitis, plantar fasciosis*

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bed, after prolonged sitting, or at the beginning of a workout.[12] The pain pattern lessens during a day of ordinary activity, but increases as the activity intensifies and may linger after the increased intensity has ceased.[32] These symptoms can lead to considerable functional limitations and prolonged disability.[7,24] Plantar heel pain is a common clinical condition treated by physical therapists.

Interventions such as iontophoresis, ultrasound, mobilization/manipulation, and therapeutic exercise are utilized by physical therapists to manage patients with plantar heel pain; however, these have varying levels of evidence in regard to their effectiveness.[15,27] Of these interventions, iontophoresis, with either dexamethasone or acetic acid, and stretching of the gastrocnemius muscle and/or plantar fascia are recommended based on moderate evidence.[15,27] However, the available evidence indicates that the effects do not endure beyond the short term, with differences between groups disappearing beyond 3 months in most trials.[15,27] Despite the lack of convincing evidence in support of these modalities for the long-term management of plantar heel pain, clinicians continue to use iontophoresis, stretching, strengthening, ultrasound, and cryotherapy.[9-11,15]

Only weak evidence exists to support the use of manual therapy interventions and therapeutic exercise in the patient population with plantar heel pain.[27,41] No randomized trials of manual therapy interventions have been reported. Young et al[41] reported the outcomes of a series of 4 patients with heel pain who were managed with manual physical therapy, which was augmented by therapeutic exercise. Although all patients received 7 or fewer treatments in physical therapy, they all reported a clinically meaningful reduction in pain and improvement in function. However, a cause-and-effect relationship cannot be inferred from a case series; therefore, further research is warranted to compare the effectiveness of the "traditional modalities" approach[15] to an approach incorporating

manual physical therapy and therapeutic exercise. The purpose of this study is to determine if the combination of manual physical therapy and exercise is more effective than an electrophysical modalities and exercise approach (iontophoresis, ultrasound, cryotherapy, and stretching) in patients referred to physical therapy with plantar heel pain.

METHODS

IN THIS MULTICENTER INTERNATIONAL trial, we recruited consecutive patients over a 16-month period (from October 2006 to January 2008). Patients presenting to physical therapy at 1 of 2 outpatient orthopaedic physical therapy clinics (Rehabilitation Services of Concord Hospital, Concord, NH, and School of Physiotherapy Clinics, University of Otago, Dunedin, New Zealand) with a primary report of plantar heel pain were screened for eligibility criteria. Inclusion criteria required patients to be between the ages of 18 and 60 years, with a primary report of plantar heel pain and a Lower Extremity Functional Scale (LEFS) score of less than or equal to 65. Patients were excluded if they exhibited any red flags to manual therapy interventions (ie, tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged history of steroid use, severe vascular disease, etc), had prior surgery to the distal tibia, fibula, ankle joint, or rearfoot region (proximal to the base of the metatarsals), had insufficient English language skills to complete all questionnaires, or were unable to comply with treatment and follow-up schedule. All patients reviewed and signed a consent form approved by The Human Investigations Committee, Concord Hospital, Concord, NH and the Lower South Regional Ethics Committee, Dunedin, New Zealand prior to participation.

Therapists

Six physical therapists (mean [SD] age, 36.8 [8.5] years) participated in the examination and treatment of all patients

in this study. All participating physical therapists underwent training provided by 1 of the investigators, which included studying a manual of standard procedures with the operational definitions of each examination and treatment procedures used in this study and practical training sessions. Participating therapists had a mean of 14.8 years (SD, 8.0 years; range, 1-21 years) of clinical experience.

Examination Procedures

All patients provided demographic information and completed a number of self-report measures, followed by a standardized history and physical examination at baseline. Self-report measures included the LEFS, the Foot and Ankle Ability Measure (FAAM), the Numeric Pain Rating Scale (NPRS),[20] and the Beck Anxiety Index (BAI). The BAI is an anxiety index consisting of 21 questions, each with a Likert scale response ranging from 0 (not at all) to 3 (severely ["It bothered me a lot"]). Higher scores indicate greater levels of anxiety. The BAI has exhibited strong internal consistency, test-retest reliability, and correlation with the Hamilton Anxiety Rating.[2] All patients underwent a standardized physical examination to assess physical impairments.

Outcomes Measures Patients completed all outcome measures at baseline, 4-week, and 6-month follow-up periods. The primary outcome measure used in this study was the patients' perceived level of disability as a result of their plantar heel pain, as measured by the LEFS at 6-month follow-up. The LEFS is a lower extremity functional scale consisting of 20 questions and a highest possible score of 80.[3] Higher scores indicate greater levels of function. The LEFS has been shown to have excellent validity, test-retest reliability, and responsiveness to change in patients with lower extremity disorders.[3,25,40] The LEFS is a commonly used outcome measure in patients with plantar heel pain.[33] As the minimal clinically important difference (MCID) has been reported to be 9 points,[3] we excluded pa-

tients with a score of greater than 65 to avoid a ceiling effect.

Patients also completed the FAAM, a region-specific self-report questionnaire with demonstrated validity, reliability, and responsiveness to change.[25,26] The FAAM has 2 subscales: the activities of daily living (ADL) subscale and the sport subscale. The ADL subscale consists of 21 questions, each with a Likert response scale ranging from 4 (no difficulty) to 0 (unable to do the activity). Individuals may also mark "N/A" in response to any of the activities listed. Items marked as "N/A" are not scored. The scores on each item were totaled. The number of questions with a response was multiplied by 4 to get the highest potential score. If all questions were answered, the highest possible score was 84. The total score for the items was divided by the highest possible score and multiplied by 100 to obtain a percentage. Higher scores indicate higher levels of function.[26] The MCID for the FAAM ADL subscale is 8 points.[25,26] An 11-point NPRS (0, no pain; 10, worst imaginable pain) was used to measure pain intensity. Numeric pain scales have been shown to be reliable and valid.[13,18-21,31] The MCID for the NPRS is 2 points.[14]

Additionally, at 4 weeks and 6 months patients also completed a 15-point global rating of change (GRC) question, based on a scale described by Jaeschke et al,[17] to rate their own perception of improved function. The scale ranges from –7 (a very great deal worse) to zero (about the same) to +7 (a very great deal better). Intermittent descriptors of worsening or improving are assigned values from –1 to –6 and +1 to +6, respectively. The use of a retrospective GRC as an outcome measure represents a credible option in the absence of an external gold standard and continues to be a common, feasible, and useful method for assessing outcomes.[16,35-37] The MCID for the GRC is arbitrary, although it has been reported that scores of +4 and +5 are indicative of moderate changes in patient status.[17] All outcome measures were collected by a researcher blinded to the patient's group assignment.

Randomization Following the baseline examination, patients were randomly assigned to receive either manual physical therapy and exercise (MTEX) or a program of electrophysical agents and exercise (EPAX). Concealed allocation was performed by using a computer-generated randomized table of numbers created prior to the beginning of the study. Individual, sequentially numbered index cards with the random assignment were prepared. The index cards were folded and placed in sealed opaque envelopes. A researcher, who was blinded to the baseline examination findings, opened the envelope and proceeded with treatment according to the group assignment.

Interventions

Patients in both groups were treated 2 times per week for 2 weeks, followed by 1 time per week for 2 weeks, for a total of 6 visits over 4 weeks.

Electrophysical Agents and Exercise Treatment Approach (EPAX) We considered iontophoresis with dexamethasone and stretching of the gastrocnemius muscle and/or plantar fascia to be commonly used therapies based on current available evidence.[15,27] Despite the lack of convincing supporting evidence, clinicians continue to use other modalities for the management of heel pain, such as intrinsic foot muscle strengthening, ultrasound, and cryotherapy[9-11,15]; so we also included these in the standardized EPAX protocol to enhance external validity. All patients in the EPAX group received therapeutic ultrasound (3 MHz, 1.5 W/cm^2, 100-Hz frequency, 20% duty cycle for 5 minutes), as it has been suggested that ultrasound may enhance skin permeability, hence transdermal drug penetration,[4,5] followed by iontophoresis with dexamethasone (dose, 40 mA-min). All patients were also instructed in stretching techniques directed at the soleus and gastrocnemius muscles and the plantar fascia, and strengthening exercises for the intrinsic muscles of the foot.[42] Patients were instructed to perform the exercises 3 times daily during the course

of the study (4 weeks). At the completion of each treatment session, ice was applied to the plantar fascia over its proximal insertion at the medial calcaneal tubercle for a period of 15 minutes.[15] Patients were also instructed to perform all ADL that did not increase symptoms and to avoid activities that aggravated symptoms.

Manual Physical Therapy and Exercise Approach (MTEX) All patients in this group were treated with 5 minutes of aggressive soft tissue mobilization directed at the triceps surae and the insertion of the plantar fascia at the medial calcaneal tubercle[12,41] and rearfoot eversion mobilization[41] (**APPENDIX A**). The MTEX approach also included an impairments-based manual therapy approach directed at the hip, knee, ankle, and foot.[41] Appropriate technique selection was determined through the clinical decision making of the treating therapists: for example, if restricted ankle dorsiflexion was noted at the clinical examination, anteroposterior talocrural joint mobilization or distraction manipulation was indicated; if restricted hip joint rotation was noted at the clinical examination, mobilization of the hip joint was indicated; and so forth, as indicated in **APPENDIX A**.[41] Specific techniques that clinicians were instructed to use are outlined in **APPENDIX A**. In addition, all patients in the MTEX group were instructed to perform an ankle eversion self-mobilization exercise and manual soft tissue mobilization of the plantar fascia at home to augment the manual physical therapy techniques performed in the clinic, and were also instructed to perform the gastrocnemius and soleus stretches, identical to the EPAX group (**APPENDIX B**). Patients were also instructed to perform all ADL that did not increase symptoms and to avoid activities that might aggravate symptoms.

Sample Size

The sample size estimation was performed using SPSS statistical software (SPSS Inc, Chicago, IL). The calculations were based on detecting a 10-point difference in the LEFS (9 points is the MCID) referenced at

the 6-month follow-up, assuming a standard deviation of 14 points, 2-tailed, an alpha level equal to .05, and 80% power. This generated a sample size of 25 subjects per group. Allowing for a conservative dropout rate, we recruited 60 subjects into the study. This sample size predicted greater than 80% power to detect both statistically significant and clinically meaningful changes in the LEFS.

FIGURE 1. Flow-diagram of subject recruitment and retention. Abbreviations: EPAX, electrophysical agents and exercise; LEFS, Lower Extremity Functional Scale; MTEX, manual physical therapy and exercise.

TABLE 1	Baseline Variables: Demographics, Outcome Measures, Selected Physical Impairments*		
Variable	**EPAX Group (n = 30)**	**MTEX Group (n = 30)**	***P* Value**
Age (y)	47.4 ± 9.3	49.5 ± 8.0	.37[†]
Gender (n female)	22 (73%)	20 (67%)	.79[‡]
Duration of symptoms (d)	268.0 ± 237.8	255.4 ± 190.2	.83[†]
NPRS (0-10, lower is better)	4.6 ± 1.6	4.8 ± 1.9	.59[†]
LEFS (0-80, higher is better)	51.1 ± 10.8	47.8 ± 14.3	.30[†]
FAAM (0-84, higher is better)	57.3 ± 12.2	57.2 ± 16.4	.98[†]
BAI (0-63, higher is worse)	5.5 ± 4.5	5.8 ± 3.7	.81[†]
BMI (kg/m^2)	33.1 ± 7.6	30.5 ± 5.4	.15[†]
Taking medications at the start of the study (n)	7 (23%)	6 (20%)	.98[‡]

Abbreviations: BAI, Beck Anxiety Index; BMI, Body Mass Index; EPAX, electrophysical agents and exercise; FAAM, Foot and Ankle Ability Measure; LEFS, Lower Extremity Functional Scale; MTEX, manual physical therapy and exercise; NPRS, Numeric Pain Rating Scale.
* Values expressed as mean ± SD, except where otherwise indicated.
† Independent-samples t tests.
‡ Chi-square tests.

Data Analysis

Descriptive statistics, including frequency counts for categorical variables and measures of central tendency and dispersion for continuous variables were calculated to summarize the data. Baseline demographic data were compared between treatment groups using independent *t* tests for continuous data, and chi-square tests of independence for categorical data to assess the adequacy of the randomization. The primary aim (effects of treatment on pain and disability) was examined with a 2-by-3 mixed-model analysis of variance (ANOVA), with treatment group (EPAX versus MTEX) as the between-subjects variable and time (baseline, 4 weeks, 6 months) as the within-subjects variable. Separate ANOVAs were performed with the LEFS, the FAAM, and the NPRS as the dependent variable. For each ANOVA, the hypothesis of interest was the 2-way interaction (group by time). Planned pairwise comparisons were performed examining the difference between baseline and follow-up periods using the Bonferroni equality at an alpha level of .05. An intention-to-treat analysis was conducted, with missing data substituted by the last value carried forward.

Additionally we dichotomized patients as having experienced a successful outcome using a cut score of +5 on the GRC. It has been reported that scores of +4 and +5 are indicative of moderate changes in patient status and scores of +5 have been previously used as a measure of success in clinical research.[6] We then calculated the numbers needed to treat (NNTs) and 95% confidence intervals (CIs) at both the 4-week and 6-month follow-up periods.

RESULTS

ONE HUNDRED ONE CONSECUTIVE patients were screened for possible eligibility criteria. Sixty patients (mean ± SD age, 48.4 ± 8.7 years; 70% female) satisfied the eligibility criteria,
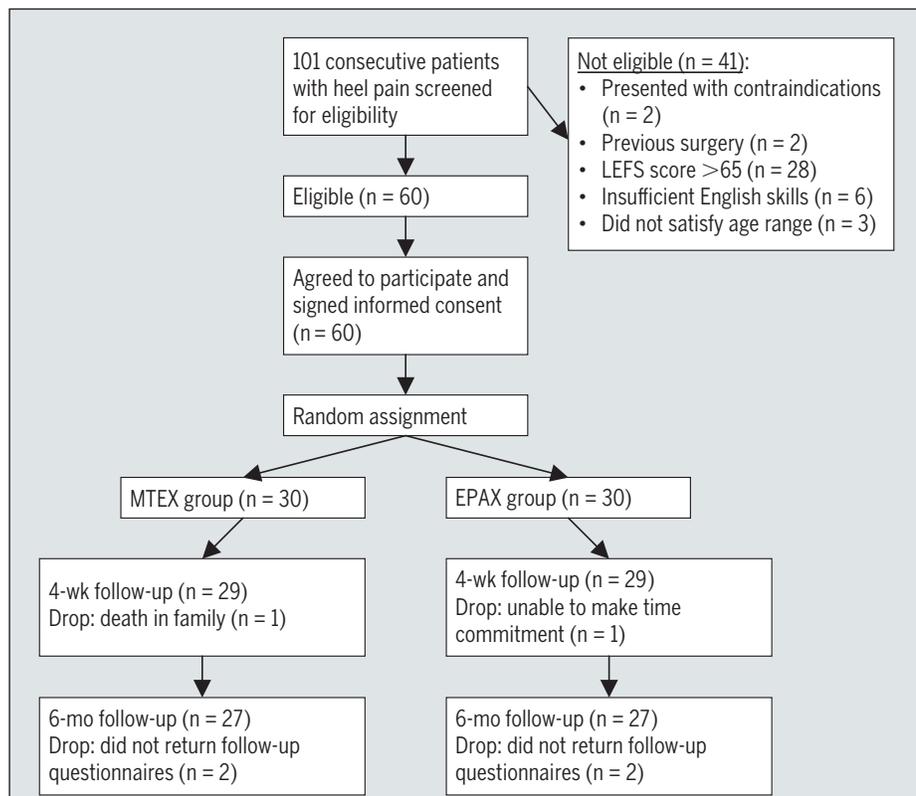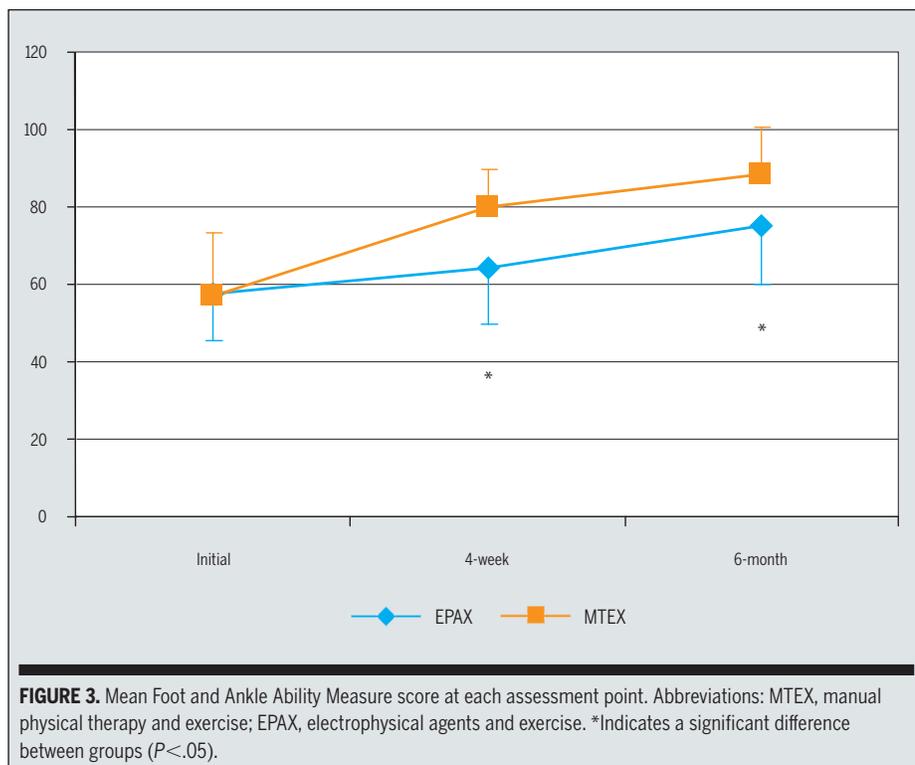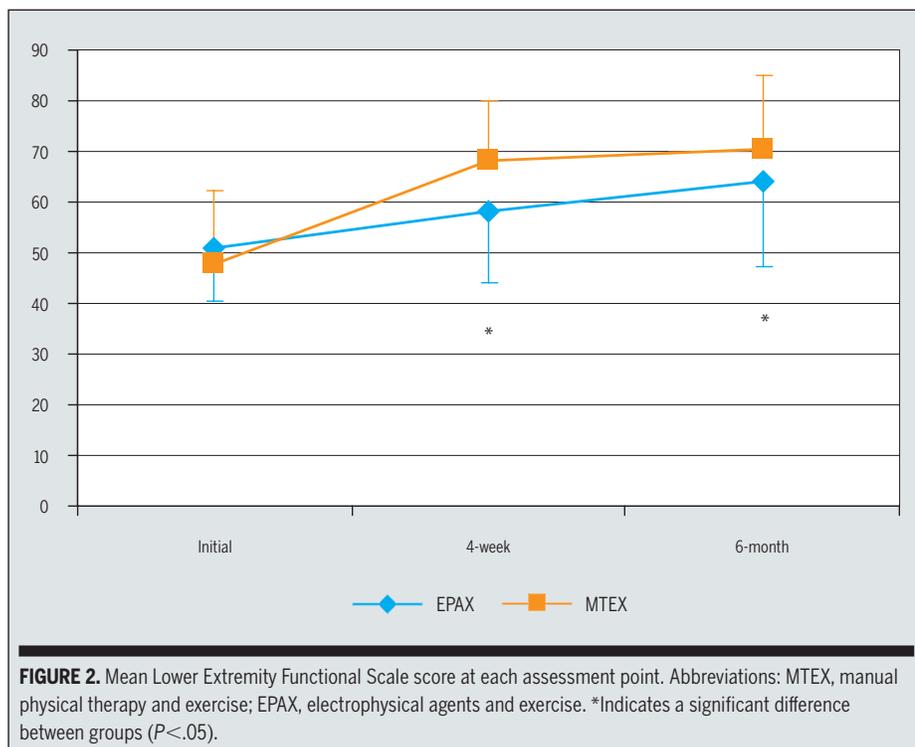
FIGURE 2. Mean Lower Extremity Functional Scale score at each assessment point. Abbreviations: MTEX, manual physical therapy and exercise; EPAX, electrophysical agents and exercise. *Indicates a significant difference between groups (*P*<.05).

FIGURE 3. Mean Foot and Ankle Ability Measure score at each assessment point. Abbreviations: MTEX, manual physical therapy and exercise; EPAX, electrophysical agents and exercise. *Indicates a significant difference between groups (*P*<.05).

agreed to participate, and were randomized into the EPAX (n = 30) and MTEX (n = 30) groups. The reasons for ineligibility can be found in **FIGURE 1**, which provides a flow-diagram of subject recruitment and retention. Baseline characteristics between the groups were similar for all variables (*P*>.05) (**TABLE 1**). A total of 58 (97%) patients completed the 4-week follow-up, and a total of 54 (90%) patients completed the 6-month follow-up (**FIGURE 1**). There was not a significant difference in dropout rates between the groups at either the 4-week or 6-month follow-up period.

The overall group-by-time interaction for the mixed-model ANOVA was statistically significant for the LEFS (*P* = .002), FAAM (*P* = .005), and pain (*P* = .043). Between-group differences revealed that the MTEX group experienced both significant and clinically meaningful improvements over the EPAX group, as measured by difference in the LEFS at both the 4-week (13.5 points [95% CI: 6.3, 20.8]) and 6-month (9.9 points [95% CI: 1.2, 18.6]) follow-up periods (**FIGURE 2**). Similarly, significant and clinically meaningful between-group differences in the FAAM favored the MTEX group at both follow-up periods (13.3% [95% CI: 4.6, 22.0] and 13.6% [95% CI: 3.2, 24.1], respectively) (**FIGURE 3**). The MTEX group had significantly larger NPRS improvement at the 4-week follow-up period (−1.5 points; 95% CI: −0.4, −2.5), but the between-group differences were no longer significant at the 6-month follow-up (**FIGURE 4, TABLE 2**).

Both groups showed some clinically meaningful change over time; however, the EPAX group estimates for change in LEFS and NPRS at 4-week follow-up did not reach the MCID for those outcome measures (**TABLE 2**). Additionally, patients in the MTEX group exhibited significantly (*P*<.05) higher scores on the GRC at both the 4-week and 6-month follow-up periods (mean difference between groups of 1.7 [95% CI: 0.4, 3.0] and 1.4 [95% CI: 0.3, 2.5], respectively). The MTEX group reported a mean GRC rating of "moderately better" at 4 weeks, while the EPAX group reported a GRC of "a little bit better." At 6 months, the MTEX group reported their symptoms as being a "great deal better," while the EPAX group reported that their symptoms were "moderately better." The NNTs were 4 (95% CI: 1.9, 12.8) at the 4 week-follow-up and 4 (95% CI: 1.9, 14.2) at the 6-month follow-up.

DISCUSSION

THE RESULTS OF OUR STUDY SHOW that both groups demonstrated a significant improvement over time. However, the results also suggested that the combined-treatment approach, consisting of manual physical therapy and exercise, provides greater clinical benefits in terms of function than an approach using electrophysical agents and common exercise in managing patients with plantar heel pain. Furthermore, the magnitude of this benefit is important, as noted by the difference in functional scores (LEFS and FAAM), which surpassed the MCID for both measures and was maintained at 6-month follow-up. Clinicians can be confident that treating patients with heel pain using the MTEX approach is likely to result in clinically meaningful improvements in pain and function, because the 95% CI for within-group change over time excludes the MCID for all outcome measures at both time points.[29] Additionally, the NNT at both follow-up periods was 4. This suggests that clinicians would need to treat 4 patients with MTEX to experience 1 successful outcome superior to the EPAX approach.[29] Any NNT under 5 indicates an effective treatment.[28]

The present results indicate that the group receiving iontophoresis with dexamethasone, ultrasound, and cryotherapy, combined with stretches of the triceps surae and intrinsic foot muscle exercises, experienced improved function and pain. Similarly, Gudeman and colleagues[15] demonstrated that the addition of iontophoresis of dexamethasone to "other traditional modalities" led to superior outcomes when compared to placebo iontophoresis in the short term. These effects were not maintained at a 4-week follow-up.[15] There is biological evidence suggesting that what was once referred to as plantar fasciitis may in reality not be an inflammatory process. It seems reasonable that other management strategies may have better outcomes than those directed specifically at reducing inflammation. This may be the reason why
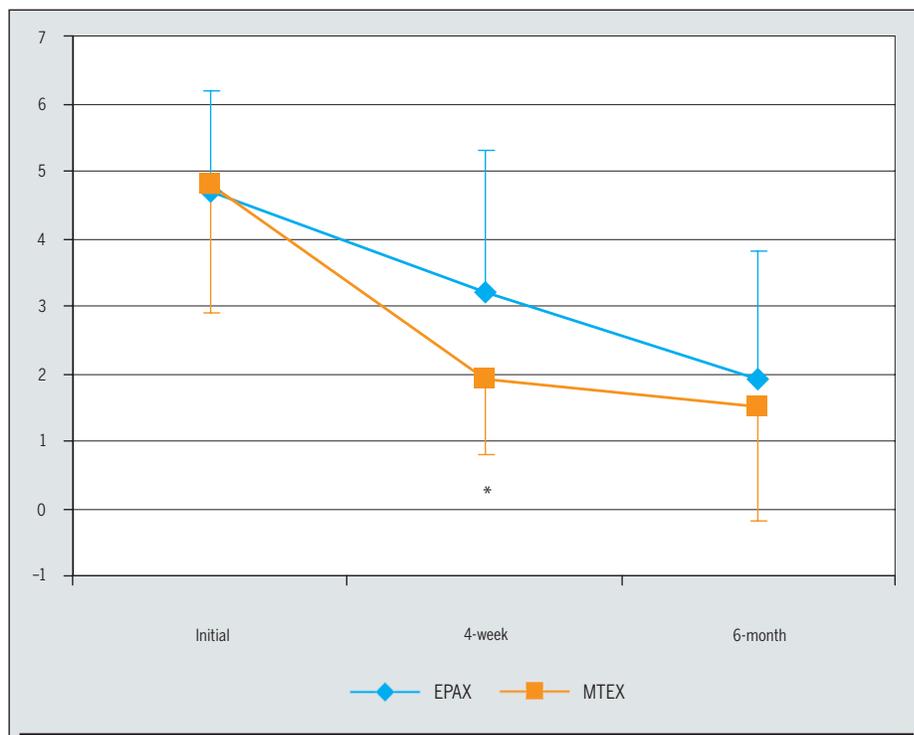

FIGURE 4. Mean Numeric Pain Rating Scale scores at each assessment point. Abbreviations: MTEX, manual physical therapy and exercise; EPAX, electrophysical agents and exercise. *Indicates a significant difference between groups (*P*<.05).

TABLE 2	PAIRWISE COMPARISONS AT EACH PERIOD		
Variable	**EPAX Group***	**MTEX Group***	**Between-Group Differences†**
LEFS (0-80, higher is better)			
Baseline to 4 wk	7.5 (3.1, 12.0)	21.0 (15.1, 26.9)	13.5 (6.3, 20.8), *P* = .001
Baseline to 6 mo	12.9 (7.8, 18.0)	22.8 (15.6, 30.1)	9.9 (1.2, 18.6), *P* = .027
FAAM (0-84, higher is better)			
Baseline to 4 wk	8.9 (3.6, 14.3)	22.2 (15.1, 29.4)	13.3 (4.6, 22.0), *P* = .004
Baseline to 6 mo	17.9 (12.9, 23.1)	31.6 (22.2, 41.1)	13.6 (3.2, 24.1), *P* = .012
NPRS (0-10, lower is better)			
Baseline to 4 wk	−1.4 (−0.8, −2.2)	−2.9 (−2.1, −3.7)	−1.5 (−0.4, −2.5), *P* = .008
Baseline to 6 mo	−2.8 (−1.9, −3.7)	−3.4 (−2.3, −4.4)	−0.6 (0.8, −1.9), *P* = .39

Abbreviations: EPAX, electrophysical agents and exercise; FAAM, Foot and Ankle Ability Measure; LEFS, Lower Extremity Functional Scale; MTEX, manual physical therapy and exercise; NPRS, Numeric Pain Rating Scale.
* Values represent mean difference from baseline to follow-up (95% confidence interval).
† Values represent difference between EPAX group values and MTEX group values (95% confidence interval), and P value.

the group receiving manual therapy and exercise in our study experienced greater improvements in disability and pain. In our study, the MTEX approach, as compared to the EPAX approach, resulted in better outcomes that were statistically and clinically meaningful at both the 4-week (function and pain) and 6-month (function only) follow-ups.

The findings in our MTEX group are similar to those reported in a case series by Young et al,[41] who found that patients with plantar heel pain who were treated with manual therapy using an impair-

ment-based approach experienced clinically meaningful improvements in pain. The mechanism underlying the added benefit of manual physical therapy cannot be determined by the current study design. The MTEX protocol included a first level of standardized interventions, then a second level of interventions that utilized an impairments-based approach. The impairments-based component left the selection of interventions to the decision making of the treating therapists, based on indications gained from a standardized clinical examination. Hence, we cannot be certain which specific manual therapy and exercise techniques would be most advantageous for this population. However, all patients in this group received aggressive soft tissue mobilization directed at the triceps surae and the insertion of the plantar fascia at the medial calcaneal tubercle,[12,41] and rearfoot eversion mobilization[41] plus gastrocnemius and soleus stretches (**APPENDICES A** and **B**).[15,27] Future studies should investigate which specific manual techniques and exercises are most essential for maximizing outcomes in this population.

It is possible that the subjects in the MTEX group benefited from improved gait and weight-bearing mechanics produced by addressing musculoskeletal impairments throughout the lower extremity.[39,41] The inclusion of an impairment-based component to our MTEX approach is consistent with contemporary manual physical therapy practice.[39,41] We refer the reader to recent literature discussing the relevance of regional interdependence to optimizing management of musculoskeletal disorders.[23,38,39,41] Where therapists in this trial found impairments of the hip or knee regions and provided interventions to treat those impairments, it must be noted that we do not advocate these interventions as treatment for plantar heel pain; they are treatment for impairments of hip or knee function. Interventions to other regions of the locomotor system may be indicated when clinical examination reveals impairments and there is evidence sup-

porting the biological plausibility that the presence of such impairments may result in abnormal stresses on plantar foot structures during weight-bearing function.[39,41] We contend that resolving impairments found elsewhere may help relieve abnormal stresses on the plantar fascia, thereby aiding resolution of the plantar heel pain. However, our MTEX protocol included interventions to treat the plantar heel region directly, and we believe this should be the primary focus of intervention.

Recently published clinical practice guidelines focusing on the management of patients with plantar heel pain[27] concluded that there is only minimal evidence to suggest that manual therapy is effective for the management of heel pain. We believe that the findings of the current study may enhance these recommendations. However, the same guidelines[27] also suggested that moderate evidence exists for the use of night splints and strong evidence for the use of orthotics for the management of heel pain. Because we did not compare a treatment approach of manual therapy and exercise to that of night splinting or orthotics, no inferences can be made as to which would be more effective. Future studies should compare the outcomes achieved by these interventions. Furthermore, it appears that both groups reached a plateau in terms of improvements in pain and function when the interventions were withdrawn. Perhaps delivering the interventions for more than 6 visits would have led to further improvements in pain and function. However, future studies are necessary to test this hypothesis. Additionally, we did not successfully collect enough data on home exercise compliance to allow for analysis. Such data would be helpful in the interpretation of the outcomes and compliance (or lack thereof) that might have an impact on the results of the study. Strengths of this study include an adequate sample size to detect between-group differences and a very low dropout rate. Additionally, in this international trial, data were collected at 2 clinical

sites from 2 countries, which enhances the generalizability of the results.

CONCLUSION

IN THIS INTERNATIONAL MULTICENTER trial, we found manual physical therapy and exercise to be superior to electrophysical agents and exercise in the management of patients with plantar heel pain. We found both approaches to demonstrate benefits; however, the magnitude of the benefit was more substantial with manual physical therapy and exercise, with between-group differences in function persisting at long-term follow-up. Future studies should seek to identify which specific manual therapy techniques and exercises are most effective, and compare the combination of manual physical therapy and exercise against other conservative management strategies for the treatment of plantar heel pain. ◉

■ KEY POINTS

FINDINGS: A combination of manual physical therapy and exercise is superior to a combination of ultrasound, iontophoresis, and exercise for the management of patients with plantar heel pain.
IMPLICATIONS: Physical therapists should consider using a manual therapy and exercise approach in the management of patients with plantar heel pain.
CAUTION: Compliance with the home exercise program may have had an impact on the results.

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APPENDIX A

MANUAL THERAPY
MANUAL PHYSICAL THERAPY AND EXERCISE GROUP
Foot and Ankle Region

Intervention	Details	Figures
Plantar fascia and flexor hallucis longus stretch and tissue mobilization Indication: plantar soft tissue restriction, thickening or degeneration	Patient is in a prone position with the knee extended. Calcaneus is held in eversion while maintaining talocrural dorsiflexion. The first ray and toes are stretched into dorsiflexion, while the operator's thumb glides proximal and distal along the path of the plantar fascia and flexor hallucis longus. Depth of soft tissue mobilization is determined by patient tolerance and reactivity. Stretch/mobilization is performed for approximately 3 min.	
Lateral glide/eversion rearfoot mobilization Indication: ankle joint rearfoot complex restriction	The tibia, fibula, and talus are stabilized against the table. The therapist then uses the opposite thenar eminence to grasp the calcaneus. A mobilizing force is directed through the therapist's arm and thenar eminence to the medial calcaneus.	
Rearfoot distraction manipulation Indication: talocrural joint motion restriction	The therapist grasps the dorsum of the patient's foot with interlaced fingers and provides firm pressure with both thumbs in the middle of the plantar surface of the forefoot, then engages the restrictive barrier by dorsiflexing and everting the ankle and applying long axis distraction. The therapist pronates, everts, dorsiflexes the foot to fine-tune the barrier. The therapist then applies a high-velocity, low-amplitude thrust in a caudal direction. If the therapist feels that the distraction is not occurring at the talocrural joint, the thrust is attempted again, with more pronation/eversion and "scooping" motion at the rearfoot/subtalar joint before the distraction manipulation.	
Anterior-to-posterior talocrural mobilization, method 1 Indication: talocrural joint dorsiflexion restriction	The therapist uses one hand to firmly stabilize the lower leg at the malleoli. The therapist then grasps the anterior, medial, and lateral talus with the other hand and applies an anterior-to-posterior oscillatory mobilization force to the talus.	
Anterior-to-posterior talocrural mobilization, method 2 Indication: talocrural joint dorsiflexion restriction	The clinician grasps and supports the arch of the foot and applies a stabilizing force (anterior-to-posterior-directed force) over the anterior talus. A belt (padded) is placed over the patient's distal posterior tibia and fibula and around the clinician's buttock region. The patient is guided into dorsiflexion of the involved ankle, while, simultaneously, the clinician produces a posterior-to-anterior-directed force to the distal leg by leaning backwards/pulling on the belt. The forces and direction of motion and stabilization should be adjusted until the patient experiences a pain-free motion of ankle dorsiflexion.	

APPENDIX A (CONTINUED)

Foot and Ankle Region (continued)

Intervention	Details	Figures
Distal tibiofibular mobilization (anterior-posterior to the distal fibula) Indication: tibiofibular joint restriction	The therapist places the distal leg of the patient at the edge of the table, the therapist's thigh is used to stabilize the patient's foot (move into progressive dorsiflexion). The therapist grasps and stabilizes the distal tibia with one hand. The therapist places the thenar eminence over the lateral malleolus and uses his/her body to impart an anterior-to-posterior-directed mobilizing force through the arm and thenar eminence.	
Cuboid manipulation Indication: intertarsal joint restriction	The tips of the thumbs are placed over the medial plantar surface of the cuboid. The knee is flexed to 90°, with the ankle in neutral. The knee is then passively extended as the ankle is plantar flexed with slight supination of the subtalar joint. A thrust force is applied to the cuboid with both thumbs.	
Intertarsal mobilization Indication: intertarsal joint restriction	With the patient prone the therapist stabilizes the dorsum of the patient's foot on his/her flexed knee (which is resting on the plinth). The therapist then identifies the target tarsal bone and performs a plantar-to-dorsal mobilization using the hypothenar eminence.	
Tibialis posterior stretch Indication: tibialis posterior complex restriction, thickening or degeneration	Patient is in a prone position with knee flexed to 90°. The ankle is held in dorsiflexion and the calcaneus in eversion. The therapist assesses the dorsiflexion end feel, while ensuring calcaneal eversion is maintained. Bilateral comparison should be performed and compared. The therapist maintains a stretch for approximately 60 s.	

Knee Region		
Intervention	**Details**	**Figures**
Knee flexion progression with valgus and internal rotation Indication: tibiofemoral joint flexion restriction	The therapist stabilizes the patient's thigh and knee against his/her body, while grasping the patient's ankle. The therapist gently brings the patient's heel towards the buttock to the restrictive barrier. The patient's heel is then brought slightly lateral, while simultaneously internally rotating the tibia. Oscillatory mobilizations are performed through a 12- to 25-cm range of movement.	
Knee flexion progression with varus and external rotation Indication: tibiofemoral joint flexion restriction	The therapist stabilizes the patient's thigh and knee against his/her body, while grasping the patient's ankle. The therapist gently brings the patient's heel towards the buttock to the restrictive barrier. The patient's heel is then brought slightly medial, while simultaneously externally rotating the tibia. Oscillatory mobilizations are performed through a 12-to-25-cm range of movement.	
Knee extension mobilizations Indication: tibiofemoral joint extension restriction	The therapist places the heel of one hand over the proximal tibia while the opposite hand supports the lower leg. An oscillatory mobilization is performed in an anterior-to-posterior direction over the proximal tibia.	
Patellofemoral joint mobilizations Indication: patellofemoral joint restriction	The therapist grasps the inferior and lateral aspects of the patella using the index finger and web space of the thumb. The heel of the therapists opposite hand is placed on the superior pole for caudal mobilizations and the inferior pole for cephalad mobilizations. Oscillatory mobilizations are performed in the target direction.	
Proximal tibiofibular joint posterior-to-anterior manipulation Indication: tibiofibular joint restriction	The therapist places the second metacarpo-phalangeal (MCP) joint in the popliteal fossa, then pulls the soft tissue laterally until the MCP is firmly stabilized behind the fibular head. The therapist uses his/her other hand to grasp the foot and ankle, and externally rotates the leg and flex the knee to the restrictive barrier (the therapist should feel firm pressure from the fibular head over the palmar aspect of the MCP). Once at the restrictive barrier, the therapist applies a high-velocity, low-amplitude thrust through the tibia (direct the patient's heel towards the ipsilateral buttock).	

APPENDIX A (CONTINUED)

	Hip Region	
Intervention	**Details**	**Figures**
Caudal glide progression Indication: hip joint flexion restriction	The therapist uses a mobilization belt placed firmly in the patient's hip "crease." The therapist flexes the patient's hip to the restrictive barrier. The therapist uses his/her body to apply a caudally directed force to the proximal thigh and performs an oscillatory passive accessory mobilization force. The amount of hip flexion, rotation, and adduction/abduction can be varied to find the position of optimal mobilization.	
Anterior-to-posterior progression Indication: hip joint flexion, adduction, or internal rotation restriction	The therapist places the patient's lower extremity with the hip in a position of flexion, adduction, and internal rotation. The therapist uses his/her body to impart an oscillatory, passive mobilizing force to the posterolateral hip capsule through the long axis of the femur. The therapist progresses the technique by adding more flexion, adduction, and/or internal rotation.	
Posterior-to-anterior mobilization in flexion, abduction, and external rotation Indication: hip joint extension, abduction or external rotation restriction	With the patient in prone, the therapist brings the patient's hip into varying degrees of flexion, abduction, and external rotation. The therapist contacts the proximal hip and uses his/her body to impart an oscillatory, passive mobilizing force in a posterior-to-anterior direction. The therapist varies the vector of the mobilizing force, dependent on stiffness and the patient's symptoms. If the patient has extremely limited hip motion, start with a pillow under the patient's ipsilateral trunk to decrease the amount of hip abduction required. Progress to lying flat on the table when able.	
Internal rotation in extension Indication: hip internal rotation joint restriction	The therapist flexes the patient's knee to 90° and ensures that the hip is in neutral or slight adduction. The hip is internally rotated until the contralateral ilium raises approximately 2 to 5 cm from the table. The therapist stabilizes the lower leg and imparts an oscillatory, passive mobilizing force through the contralateral pelvis. Note: if the patient experiences knee discomfort, the therapist should grasp the distal thigh and place his/her forearm along the medial aspect of the patient's tibia.	

APPENDIX B

HOME EXERCISE PROGRAM

HOME EXERCISE INSTRUCTIONS

This exercise handout contains a picture and description of the exercises you will be doing during physical therapy and at home during your participation in this study.

In addition to performing these exercises, you should maintain your usual activities within the limits of your pain. Continue to do all activities that do not increase your symptoms and avoid activities that aggravate your symptoms. You do not have to discontinue all other forms of exercise during your participation in this study (eg, jogging, walking, etc). However, please do not begin any new forms of exercise during your participation in this study and do not add any exercises to this program unless instructed by your physical therapist. You should not experience any significant increase in your pain while performing these exercises. Discontinue these exercises if they cause you significant increased pain, and notify your physical therapist.

Component	Procedure	Duration and Frequency	Illustration
Stretch 1	In standing, with your involved foot furthest away from the wall, lean forward, while keeping your heel on the floor and knee bent. Lean forward until you feel a stretch in the calf and/or Achilles region.	Perform this exercise at home 3 times daily for 2 repetitions holding each for 30 s.	
Stretch 2	In standing, with your involved foot furthest away from the wall, lean forward while keeping your heel on the floor and the back knee straight. Lean forward until you feel a stretch in the calf and/or Achilles region.	Perform this exercise at home 3 times daily for 2 repetitions holding each for 30 s.	
Ankle eversion self-mobilization	Stabilize your leg with your arm as shown. Your stabilizing hand should wrap around the very end of your leg, just above your ankle. Use your other hand to grasps the back part of your foot and push towards the floor.	Perform in an on-off fashion 30 times, repeat 3 times.	
Self-stretching and mobilization of plantar fascia and flexor hallucis longus	Cross the affected leg over the nonaffected leg. While placing your fingers over the base of your toes, pull the toes back towards your shin until a stretch is felt in your plantar fascia. With your other hand, mobilize the plantar fascia and flexor hallucis longus from your heel towards your toes. Start gently at first then work deeper as tolerated.	Perform for 3 to 5 min.	