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# Treatment of Plantar Fasciitis by Iontophoresis of 0.4% Dexamethasone

## A Randomized, Double-Blind, Placebo-Controlled Study*

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## ABSTRACT

Plantar fasciitis is a common problem in running sports. This study was undertaken to determine whether iontophoresis of dexamethasone in conjunction with other traditional modalities provides more immediate pain relief than traditional modalities alone. Forty affected feet were randomly assigned to one of two groups. Group I feet were treated with traditional modalities and placebo iontophoresis. Group II feet received the traditional modalities plus iontophoresis of dexamethasone. Both groups were treated six times over 2 weeks. The subjects' clinical course was assessed using the Maryland Foot Score. At the conclusion of treatment, Group II patients had significantly greater improvement than Group I patients (increase on Maryland Foot Score of 6.8 ± 5.6 for Group II and 3.1 ± 4.1 for Group I). However, at followup 1 month after completion of treatment there was no significant difference between groups (increase of 5.6 ± 8.0 for Group I and 7.4 ± 6.3 for Group II). These results suggest that although traditional modalities alone are ultimately effective, iontophoresis in conjunction with traditional modalities provides immediate reduction in symptoms. Based on these results, iontophoresis of dexamethasone for plantar fasciitis should be considered when more immediate results are needed (i.e., performance athletes and active patients).

Plantar fasciitis is a common cause of heel pain in athletes as well as those not involved in sports. It is caused by overload to the plantar fascia at its origin into the calcaneus, resulting in microtears in the fascia near or at the fascia-bone interface.[7,17,24] Symptoms of plantar fasciitis include gradual onset of pain at the origin of the plantar aponeurosis and 1 cm distal to this area. Patients often report that pain is worse after periods of inactivity and decreases after warmup and as activity progresses. Plantar fasciitis is common in runners, an incidence of approximately 10% has been reported.[16] It is also seen in the nonathletic community among the overweight population and those who spend long periods standing.

On physical examination, the pain is typically reproduced with dorsiflexion of the metatarsophalangeal joints and palpation of the fascial band. A tight heel cord with restricted ankle dorsiflexion is seen in 70% of patients with unilateral plantar fasciitis.[1] Other possible causes of heel pain should be ruled out including stress fractures, inflammatory arthritides, and entrapment of the nerve to the abductor digiti quinti muscle or the medial calcaneal branches.

Initial conservative treatment of plantar fasciitis can include a spectrum of modalities, including orthoses to address the biomechanical causes, nonsteroidal antiinflammatory drugs, stretching and strengthening techniques, ultrasound, friction massage, and night splints. Generally, several modalities are combined to provide reduction of inflammation and symptoms.[30]

Correction of abnormalities of the foot is essential in the treatment of plantar fasciitis. Heel pads or heel cups may be useful in the immediate relief of chronic symptoms.[27] Correction of forefoot abnormalities and hindfoot instability is also fundamental.[26] Orthotic shoe inserts are effective to this end. A stretching and strengthening program of the gastrocnemius muscle, Achilles tendon, and the plantar fascia is also essential to the rehabilitation of this

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disorder, especially in athletes but also in the nonathletic population. These stretches should be designed to decrease the strain on the origin of the plantar fascia during exercise.[27,30] Night splints can also be used in the treatment of plantar fasciitis.[26,29] Ryan[26] recommends use of posterior night splints as an alternative when conservative treatment is not working but before invasive treatment is undertaken. When conservative treatment fails, treatment often progresses to steroid injection[30] and, if no relief is afforded, surgical release.[19,20,25,28]

Iontophoresis of corticosteroids has been discussed as an additional treatment modality for plantar fasciitis.[9] Iontophoresis is a process in which ions in solution are transferred through the intact skin via electrical potential using bipolar electrodes. Positive ions are carried through the skin at the positive electrode and negative ions are carried through at the negative electrode. Ionizable materials in solution, such as dexamethasone sodium phosphate, will migrate toward the poles of opposite charge. Superimposed on this normal migration, a direct (galvanic) current enhances and intensifies the movement of ions.

To our knowledge, no published report has evaluated iontophoresis for the treatment of plantar fasciitis. However, several investigators have reported findings that support the hypothesis that iontophoresis is a clinically effective method of administering antiinflammatory medications for other overuse clinical situations.[3,8,12] Delacerda[8] treated shoulder girdle myofascial syndrome with iontophoresis of dexamethasone and found patients had greater range of pain-free abduction compared with patients treated with orally administered muscle relaxants and analgesic medication or hot pack and ultrasound. Bertolucci[3] conducted a double-blind investigation of iontophoresis versus placebo on shoulder tendinitis and found that patients who were under 45 years of age reported improvement after iontophoresis treatments. Similarly, Harris[12] reported that 75% of 50 patients treated with iontophoresis for various musculoskeletal inflammatory conditions had excellent to good outcomes based on restored range of motion, improved function, and decreased pain. Additional support for the clinical effectiveness of iontophoretically administered dexamethasone comes from two case reports. One described successful treatment of a patient with an acute anterior disk dislocation of the temporomandibular joint.[5] The other reported on a patient with rheumatoid arthritis of the knees.[13]

The purpose of this prospective, double-blind, placebo-controlled study was to determine whether iontophoresis of dexamethasone will reduce a patient's plantar fasciitis symptoms, thus proving to be an effective treatment for plantar fasciitis.

## MATERIALS AND METHODS

In this prospective, double-blinded, placebo-controlled study, subjects were randomly assigned to one of two groups. Group I feet were treated with traditional modalities alone. As a placebo, these Group I patients had iontophoretic electrodes attached to the plantar aspect of the foot, but only phosphate buffered saline was administered. Group II feet received the traditional modalities plus iontophoresis of 0.4% dexamethasone sodium phosphate USP.

All patients signed informed consent forms and were examined at the initial visit by one of two physicians (SAE or SDG) to determine whether the diagnostic inclusion and exclusion criteria were met. Exclusion criteria included history of diabetes, foot tumor, or foot trauma such as a fracture. Additional tests, such as bone scan or electromyography were ordered as needed to rule out other causes of heel pain. Radiographs were taken of all patients to rule out any unusual causes of heel pain such as calcaneal cyst or stress fracture. Before beginning treatment, an independent, blinded investigator administered status testing to provide a pretreatment baseline. The status testing involved the use of the Maryland Foot Score (MFS).[23] The MFS assesses both pain and function of the foot on a 100-point scale and quantifies pain, gait, stability, support, limp, motion, and ability to climb stairs.

During the 2 weeks of treatment, patients in both groups received six treatments of iontophoretically administered dexamethasone or placebo.[14,15] For Groups I and II, iontophoresis was performed using the Phoresor II Iontophoresis Drug Delivery System (IOMED, Inc., Salt Lake City, Utah). Current of up to 4.0 mA was applied, depending on each patient's sensitivity. The total charge delivered was 40 mA over 20 minutes.

In addition to iontophoresis, a physical therapist implemented the traditional modalities of ice (20 minutes), a stretching program for the plantar fascia and gastrocnemius-soleus muscle complex, and a program for strengthening the extrinsic muscles for both groups. Patients in each group received six sessions of therapy over a 2- to 3-week period at the time of the iontophoresis of dexamethasone or placebo. All subjects received instructions for a home exercise program and an orthosis (a viscoelastic heel). Patients were directed to follow the REST protocol (Resume Exercise below the Soreness Threshold) so that although sports activity was not specifically restricted, strenuous exercise was unlikely.

After the completion of the six treatments, the blinded investigator again administered physical examination and status testing to determine any change in symptoms. Finally, at approximately 4 weeks after completion of treatment, physical examination and status testing were performed for followup.

After six treatments and a 1-month followup, subjects learned their group assignment. Group I (placebo) subjects who were still experiencing symptoms were given the option to receive formal treatment of iontophoresis with dexamethasone following the Group II protocol. However, none of the subjects asked for additional treatment.

## RESULTS

Thirty-nine patients (32 women and 7 men; mean age, 42.1 ± 13.6 years) with a total of 44 affected feet were recruited for the study and randomly assigned to one of the two groups. Three patients (four feet) were eliminated

TABLE 1
Mean Maryland Foot Score and *P* Values at Each Interval by Treatment Group

| Group | Score | Difference Pre-Post | Difference Pre-FU | Difference Post-FU |
|---|---|---|---|---|
| Control ($N = 20$) | | | | |
| Pre | 83.4 ± 7.9 | +3.0 | +5.1 | +2.1 |
| Post | 86.4 ± 7.8 | $P = 0.004$ | $P = 0.009$ | $P = 0.181$ |
| Followup | 88.5 ± 7.1 | | | |
| Treatment ($N = 20$) | | | | |
| Pre | 78.6 ± 5.8 | +6.8 | +7.4 | +0.6 |
| Post | 85.4 ± 5.5 | $P < 0.001$ | $P = 0.009$ | $P = 0.530$ |
| Followup | 86.0 ± 7.9 | | | |

subsequent to enrollment for the following reasons: a fifth metatarsal fracture, noncompliance with the protocol (wearing of bilateral night splints), and withdrawal to pursue holistic treatment. Using random assignment, there were 20 feet in Group I and 20 feet in Group II. The treatment groups were compared using an independent-groups *t*-test to determine any initial differences. There were no significant differences in height (mean, 169.49 ± 3.3 cm) or weight (mean, 81.81 ± 46.9 kg) between the two groups. In addition, there were no initial significant differences before treatment between groups for any of the evaluative measures employed in the study.

Mean MFS values for each group at the various time intervals are shown in Table 1. Group II patients had significantly greater improvement between pretreatment and immediate posttreatment than Group I patients, with an increase of 6.8 ± 5.6 for Group II and 3.0 ± 4.1 for Group I. At the 1-month followup there was no significant difference between groups (5.1 ± 8.0 for Group I and 7.4 ± 6.3 for Group II). The difference in the increase (control versus treatment groups) between pre- and posttesting was statistically significant ($P = 0.022$), but the difference in the increase between pre- and follow-up testing was not significant ($P = 0.434$). Because the significant difference after treatment was observed early in the protocol, the last 17 feet enrolled were tested in the middle of treatment, after the third treatment administration of iontophoresis or placebo. The results for these feet are in Table 2. A significant difference as measured by the MFS was observed between the pretreatment and midtreatment interval (mean difference, Group I = 0.3 ± 3.3 and Group II = 7.4 ± 5.5; $P = 0.014$).

The data in Table 3 show that, overall, 95% of patients (38 of 40) in this protocol had excellent or good results at the 1-month followup according to the MFS, and only 5% (2 of 40) had fair results. No patients had "failure" results. This is consistent with other reports in the literature.[22]

## DISCUSSION

A majority of patients respond well to conservative treatment for plantar fasciitis.[2,11,19] However, the average recovery time is 6 weeks and, in many cases, symptoms can persist for 3 to 6 months.[6,19,28] If operative intervention is required, an athlete can be out of training or a patient may be unable to work for 4 to 12 months or more depending on the length of time that conservative treatment is performed.[6,19,20,28] Because most patients do well with conservative treatment, the goal for any new treatment for this disorder should work toward minimizing recovery time in a cost-effective manner (Table 4).

Traditional treatment modalities for plantar fasciitis should work initially toward the resolution of symptoms— or relief of inflammation and pain—with a long-term goal of alleviating the biomechanical factors that caused the disor-

TABLE 2
Mean Maryland Foot Score and *P* Value at Each Interval by Treatment Group for Subsample

| Group | Score | Difference Pre-Int | Difference Pre-Post | Difference Pre-FU | Difference Int-Post | Difference Int-FU | Difference Post-FU |
|---|---|---|---|---|---|---|---|
| Control ($N = 6$) | | | | | | | |
| Pre | 81.7 ± 8.7 | | | | | | |
| Intermediate | 82.0 ± 9.9 | +0.3 | +4.5 | +5.5 | +4.2 | +5.2 | +1.0 |
| Post | 86.2 ± 9.9 | $P = 0.005$ | $P < 0.001$ | $P = 0.003$ | $P = 0.312$ | $P = 0.466$ | $P = 0.948$ |
| Followup | 87.2 ± 7.6 | | | | | | |
| Treatment ($N = 9$) | | | | | | | |
| Pre | 77.9 ± 6.0 | | | | | | |
| Intermediate | 85.3 ± 7.4 | +7.4 | +9.1 | +9.2 | +1.7 | +1.8 | +0.1 |
| Post | 87.0 ± 4.7 | $P = 0.828$ | $P = 0.020$ | $P = 0.690$ | $P = 0.012$ | $P = 0.189$ | $P = 0.786$ |
| Followup | 87.1 ± 7.8 | | | | | | |

TABLE 3
Raw Maryland Foot Scores Prestudy and at Followup

| Group | Excellent (90–100) | | Good (75–90) | | Fair (50–74) | | Failure (<50) | |
|---|---|---|---|---|---|---|---|---|
| | PRE | FU | PRE | FU | PRE | FU | PRE | FU |
| Control | 3 | 11 | 12 | 8 | 5 | 1 | 0 | 0 |
| Treatment | 1 | 7 | 14 | 12 | 5 | 1 | 0 | 0 |
| Total | 4 | 18 | 26 | 20 | 10 | 2 | 0 | 0 |

TABLE 4
Cost of Treatment Modalities and Iontophoresis

| Modality | Approximate cost |
|---|---|
| Home stretching prescribed by physical therapist | $40.00–$60.00 |
| Commercial home stretching program | $30.00–$60.00 |
| Shoe inserts—orthoses | $25.00–$40.00 |
| Shoe inserts—heel cup | $30.00/pair |
| Night splints | $90.00–$120.00 |
| Injection | $85.00–$115.00 |
| Ultrasound | $47.00 |
| Friction massage | $39.00 |
| Iontophoresis | $35.00–$40.00 per treatment |

der. To this end, traditional modalities have included ice, oral nonsteroidal antiinflammatory drugs, shoe inserts, a stretching-strengthening program, ultrasound, friction massage, night splints, and steroid injection.

In this study, patients who underwent iontophoresis experienced greater immediate relief of symptoms than those treated with traditional modalities alone (as indicated by MFS scores). In the subsample, this difference was observed as early as the third iontophoresis administration (1 week). However, by 1 month after completion of the modalities there is no longer a significant difference. These results suggest that, although traditional modalities alone are ultimately effective, iontophoresis in conjunction with traditional modalities provides immediate relief of symptoms.

The advantages of using iontophoresis include the following. 1) Iontophoresis is a noninvasive and painless procedure for the local administration of antiinflammatory medications. 2) Iontophoresis of corticosteroids yields local tissue concentrations that are lower than those achieved with injection but greater than those achieved with oral administration[10] and therefore is considered to be both safe and effective. 3) Treatment with iontophoresis may represent a cost saving for patients and their insurers. Prolonged physical therapy for recalcitrant cases of plantar fasciitis and missed work days may be avoided when iontophoresis is added to the traditional modalities of treatment. In this study, as few as three treatments were sufficient to provide immediate relief of symptoms.

Complications of iontophoresis have been noted. Maloney et al.[21] reported adverse effects in 26 patients, although all effects were mild and resolved without treatment. Prolonged erythema under the negative electrode (remaining until the patient left the office, but resolving within 24 hours) occurred after eight procedures. During iontophoresis, a tingling, stinging, burning, or pulling sensation was noted under the electrode in nine cases and was especially apparent at the start of current administration or if the amperage was turned up rapidly. A metallic taste was noted by patients during nine procedures when the electrode was placed on the face.

The iontophoretic complication causing the most concern among practitioners is the burning of underlying skin. There were no such occurrences in the Maloney et al. study. Bezzant et al.[4] reported one incident of superficial burning of the skin. No complaints or complications are reported in the current study. Complications of steroid injection into the plantar fascia, including necrosis of the fat pad, have been reported,[18] but the effect of dexamethasone administered iontophoretically to the plantar fascia has not been investigated.

The use of iontophoresis for the treatment of plantar fasciitis may be a cost-effective modality to add to the treatment of plantar fasciitis because it can shorten the length of time a patient must undergo therapy or time away from work. However, this study did not address how soon patients returned to work. Once a patient's symptoms are relieved and he or she feels confident with the exercises, the patient can be released to a home exercise program. Each patient in this study underwent traditional physical therapy for the treatment of plantar fasciitis. This treatment consisted of ice, stretching and strengthening exercises, and a heel cup. This traditional treatment costs, on average, $80.00 per visit. Adding iontophoresis to this treatment brings the cost of treatment per visit up to $115.00. However, since iontophoresis can reduce the overall number of times a patient must be seen in therapy, its effectiveness offsets the $35 charge per visit.

The initial scope of this study was very specific: is the use of iontophoresis of dexamethasone an effective method of treatment for plantar fasciitis. Our results indicate that it is effective for specific treatment goals. Because the end result of function is the same if iontophoresis is or is not used, we recommend its use for patients who need an immediate reduction of symptoms, i.e., the elite athlete. Although this modality of iontophoresis will initially reduce the symptoms of plantar fasciitis, it is still imperative that patients undergo traditional modalities of physical therapy and rest and address the underlying cause of the disorder.

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