# Iontophoresis of 0.4 % Dexamethasone Versus low Energy Extracorporeal Shock Wave Therapy in the Treatment of Chronic Plantar Fasciitis

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## ABSTRACT

***Background:*** *Planter Fasciitis is the development of pain in the bottom of the heel due to injury in the planter fascia that covers the bottom of the foot. It causes heel pain in active as well as sedentary adults of all ages. The injury is more likely to occur in persons who are obese or on those who are on their feet most of the day. It is also a common injury in the running sports. This study was applied to compare the effect of low energy extracorporeal shock wave to Iontophoresis of the 0.4 Dexamethasone in the treatment of those patients with chronic plantar Fasciitis.* ***Methods:*** *Twenty –six participants aged 18 to 65 years diagnosed as having chronic planter Fasciitis were randomly assigned to two treatment groups, all the patients receiving stretching exercises in addition to 5 min pulsed US 1.1 w/cm$^2$ for six times over two weeks. In addition to that, the patients in group A treated by low energy Extracorporeal shock wave therapy twice over the two weeks (one in the first session and the second after one week from the beginning of treatment), while the patients in group B treated by Iontophoresis of 0.4% Dexamethasone for six times over two weeks. The outcome of the treatment measured after one week from the last session and as follow up after three months of the treatment by VAS in addition to Maryland foot score (P<0.05).* ***Results:*** *Low energy Extracorporeal shock wave therapy and Iontophoresis of 0.4% Dexamethasone provided significant improvement in the visual analogue scale and also improvement according to Maryland foot score but between the two groups there was no significant difference (P>0.05) in the visual analogue scale and in the Maryland foot score after the treatment by one week and after three months from the treatment.* ***Conclusions:*** *Low energy extracorporeal shock wave therapy and Iontophoresis of 0.4% Dexamethasone are successful treatment modalities for the plantar Fasciitis. Iontophoresis treatment is coast effective compared to the low energy extracorporeal shock wave therapy and also during application there is no pain that may be associated after application of the shock therapy so the Iontophoresis may be the first treatment choice according to these results.*

## INTRODUCTION

Plantar Fasciitis commonly causes inferior heel pain and occurs in up to 10 percent of the regular population and represents the fourth most injury to the lower limb. The condition affects active and sedentary adults of all ages. Plantar Fasciitis is more likely to occur in persons who have overload on the foot or who have limited ankle dorsiflexion[7].

On the other hand, there is a direct relationship between plantar Fasciitis and the patients with high body mass index[2,4]. Females appear to be affected more than males with this condition. Experts believe that the pain is caused by acute or chronic injury to the origin of the plantar fascia from cumulative overload stress[22].

Diagnosis of the planter Fasciitis is based on the patient's history and on results of the physical examination. Patients typically presents with inferior heel pain on the weight bearing and the pain often persist for months or even years. Pain associated with plantar Fasciitis may be throbbing, searing, or piercing, especially with the first few steps in the morning or after period of inactivity. The discomfort often improves after further ambulation but worsen with continued activity, often limiting daily activities. Walking barefoot, on toes, or upstairs may exacerbate the pain. The patient usually has tenderness around the medial calcaneal tuberosity at the planter opneurosis[6,8,9].

Understanding of the anatomy and the mechanics of the foot accepting that there are physiologic limits to the amount of the stress soft tissue can sustain and that helps to explain why the planter Fasciitis happens and that also may helps to design a successful rehabilitation

program and gives clues for early identification of who is at risk in time to initiate preventive measures[18].

Diagnostic imaging is not helpful in diagnosing plantar Fasciitis, but it should be considered if another diagnosis is strongly suspected. According to several small case-control studies that compared patients with and without plantar Fasciitis, thicker heel opneurosis, identified by ultrasonography, is associated with plantar Fasciitis[9].

On the other hand, radiography may provide important significant information in showing of calcification in the soft tissues around the heel or osteophytes on the anterior calcaneus (i.e., heel spurs)[9]. Fifty percent of patients with plantar Fasciitis and up to 19 percent of persons without plantar Fasciitis have heel spurs. The presence or absence of the heel spurs is not helpful in diagnosing plantar Fasciitis[9,19]. Bone scans can show increased uptake at the calcaneus, and magnetic resonance imaging can show thickening of the plantar fascia. However, the accuracy of these tests remains inconclusive[9].

There is a professional consensus that 70-90% of plantar Fasciitis patients can be managed by non-operative measures. When conservative treatment fail, surgical plantar fasciotomy with or without heel spur removal and neurolysis of the branch of the lateral plantar nerve have been employed[3].

Recent systematic reviews, have evaluated the effectiveness of the low energy extracorporeal shock wave therapy in the management of the chronic plantar Fasciitis. The action of the low-energy extracorporeal shock-wave treatment (ESWT) is the result of process called cavitation, which is defined as the formation and movement of bubbles in a fluid. Strong forces exerted in the region of the moving bubble cause mechanical tissue disruption. The repair of mechanical tissue disruption is the theoretical basis for the neovascularisation process and subsequent pain relief following the application of (ESWT)[4,10].

In order for ESWT to be therapeutic, the energy should focus at the point of existing pathology. As a therapeutic option for patients with chronic plantar fasciitis (ESWT) has been recommended; 1000 to 2000 shock waves of an energy flux density (ED) from 0.01 to 0.4 $mJ/mm^2$ are usually applied two to three times at two weeks intervals[10].

The analgesic effect of ESWT was first described by Dahmen et al., It has given relief of pain in 50% to 80% of patients with improvement in function depending on the severity of the pain. Some study believe that the pain relieve effect of the l(ESWT) therapy in addition to the stretch effect of stretching exercises and the application of the ultrasonic is one of the most effective protocol in the treatment of the chronic plantar Fasciitis[3].

On the other hand, iontophoresis is a process that uses bipolar electric fields to propel molecules across intact skin and into underlying tissue[12]. Iontophoretic drug delivery for the condition of plantar Fasciitis provides and alternative to hypodermic injection of corticosteroids, with increased comfort of the patient and decreased the systematic side effect of the corticosteroids drugs[17]. It allows a short term administration and avoids the associated discomfort of the needle insertion at already tender area of the tissue. Avoiding the use of a hypodermic needle also prevent further tissue trauma and eliminate the risk of infection at the injection site[12]. Also the risk of potential necrosis and/or fascia weakening associated with injection of corticosteroids is eliminated. Plantar Fasciitis is usually a very well localized condition, appropriate for electrode placement over the affected site[16]. There are many reports indicating that this mode of drug delivery can be useful and iontophoresis with Dexamethasone appear to be effective in treating inflammation in several areas of the body. Dexamethasone Sodium phosphate is a corticosteroid medication. It is useful for reducing inflammation associated with musculoskeletal injuries[16,17]. By inhibiting cytokines, Dexamethasone work as anti-inflammatory, analgesic, and immunosuppresser. In addition to that, it inhibits the migration for scavenger white blood cells to the site of inflammation. Like other corticosteroids, Dexamethasone stimulates the synthesis of enzymes required to decrease the inflammatory response[15,16,17].

In application of iontophoresis, the Dexamethasone sodium phosphate iontophoresis solution is a preservative-free aqueous solution. The preservative-free solution produce better outcomes than preserved solution, as a preserved solution may contain positively charged ions (which compete with the negatively charged Dexamethasone)[19].

Many authors reported that, the combination between applications of iontophoresis with Dexamethasone sodium phosphate in addition to the stretching exercises for the calf muscles with using of ultrasonic waves on the plantar fascia may be one of the most effective non-operative ways in the treatment of the planter Fasciitis[17,16,19].

The purpose of this study was to determine if there was a significant difference between the application of iontophoresis with Dexamethasone Sodium Phosphate and the application of low energy Extracorporeal shock wave in the treatment of the patient with plantar Fasciitis. We hypothesized that there is no significant difference between the application of iontophoresis with Dexamethasone Sodium phosphate and low energy extracorporeal shock wave in the level of pain according to the visual analogue scale and the score of Maryland foot scale in the patient with plantar Fasciitis.

## SUBJECTS, MATERIALS AND METHODS

### Subjects

Twenty -six patient (Thirteen men, thirteen women) with a confirmed diagnosis of chronic plantar Fasciitis were randomly assigned to two treatment group as shown in the following table (Table 1).

***Table (1):***

| | Men (n = 13) | | | Women (n = 13) | | |
|---|---|---|---|---|---|---|
| | Mean | SD | Range | Mean | SD | Range |
| Age (years) | 40.15 | 9.7 | (22 - 61) | 39.2 | 8.7 | (28 - 63) |
| Mass (Kg) | 77.6 | 15.2 | (69.0 - 83.3) | 78.2 | 13.6 | (70.5 - 81.2) |

Inclusion Criteria:

The criterion for entry into the study was heel pain localized to the site of insertion of the planter fascia and intrinsic muscles of the medial calcaneal tuderosity on the anterior medial aspect of the heel for more than six months. The severity of the pain was recorded and a low pain score is not an exclusion criterion. The location of the pain was tested by exerting pressure on the heel.

Exclusion Criteria:

The exclusion criteria include dysfunction of knee, other foot disorder, local arthritis, generalized polyarthiritis, rheumatoid arthritis, ankylosing spondylitis, neurologic abnormalities, and nerve entrapment syndrome, history of heel operation, the age of patient out the range of the sample in the study, pregnancy, an infection, and tumor.

Before participation all patients signed consent form and were randomly assigned to two treatment groups (group A and group B), all the patients received stretching exercises for the calf muscles for 10 min and application of US 1.1 W/cm$^2$ for 5 min for six times over two weeks (day after day). In addition to that, the patients in group A were treated by (ESWT) wave therapy in the first session and another time after the first week of treatment. On the other hand, patients in group B were treated by Iontophoresis of 0.4% Dexamethasone for every session (six sessions over two week on day after day basis).

### Materials

Patients in Group A were treated by application of the (ESWT) by an experimental device (Siemens Osteostar; Siemens AG, Erlangen, Germany) characterized by the integration of an electromagnetic shock wave generator in a mobile fluoroscopy unit. By means acoustic lens, the focus of the shock-wave source is just the center of the C-arm.

On the hand, patient on group B were treated by Iontophoresis with Dexamethasone using COMBI-500 Electrotherapy Unit (Combi-500 produced by Gymna Uniphy-Belgium), and also we used the same machine in application of US for all patients who participated in that study by using the large head 4 inch.

**Methods**

For Evaluation:

In the first session and after the patient signed the consent form, every patient was asked to localize the area of pain and determine the level of pain using the (VAS).

After that the patient determined his feet functional ability by using Maryland foot score.

For Treatment:

All the patients participated in the study were randomly distributed to 2 groups (Group A and Group B). All the patient were treated by passive stretching exercises for calf muscles and hamstring for 10 min by the same therapist, after that the patient were treated by US waves application for 7 minutes on the site of pain, mainly the pain localized in the site of insertion of the plantar fascia on the medial calcaneal tuberosity on the anterior medial aspect of the heel, pulsed US applied with 1 MHz frequency and intensity of 1.1 W/cm$^2$. These parameters of US application recommended for this condition by M, Steinborn 2007. In Addition to that, patients in group (A), were treated by (ESWT) twice over the two weeks (one in the first treatment session and the second after one week from he beginning of the treatment). On the other hand, all patients in group (B) were treated by Iontophoresis of 0.4% Dexamethasone with the regular sessions for 20 min every session on regular basis day after day for two weeks.

After that every patient determined the level of pain on the (VAS) and the functional ability using Maryland foot score. These readings collected at the end of the last session, after three months.

## RESULTS

The aim of this study was to compare the effect of the application of (ESWT) versus Iontophoresis of 4% Dexamethasone in the treatment of the chronic Plantar Fasciitis. Our hypothesis was that there was no significant difference between the two treatment methods in the treatment of those patients. We measured the changes in the score of (VAS) and the Maryland foot score before and after the application of the both methods by one week and three months after the last session and the difference between these two treatment methods. Paired t-test was used to analysis for the outcomes from this study.

**Pain:**

On average, the pre-treatment pain level was 6.5±0.5 while one week after the treatment the average of pain in group (A) was 4.6±0.4 and in the group (B) 4.5±0.4.

After three months the average of pain in group (A) was 3.9±0.4 and in group (B) was 3.8±0.4 (P<0.001) table (2) Figure (1).

***Table (2): Average of pain pre treatment and after by one week and three months in both groups.***

| | | Range | SD | Mean | P[b] |
|---|---|---|---|---|---|
| Pre treatment | | 5 to 8 | 0.5 | 6.5 | < 0.001 |
| After one Week | (A) | 4 to 6 | 0.4 | 4.6 | |
| | (B) | 3 to 5 | 0.4 | 4.5 | |
| After Three Months | (A) | 2 to 5 | 0.4 | 3.9 | |
| | (B) | 2 to 5 | 0.4 | 3.8 | |

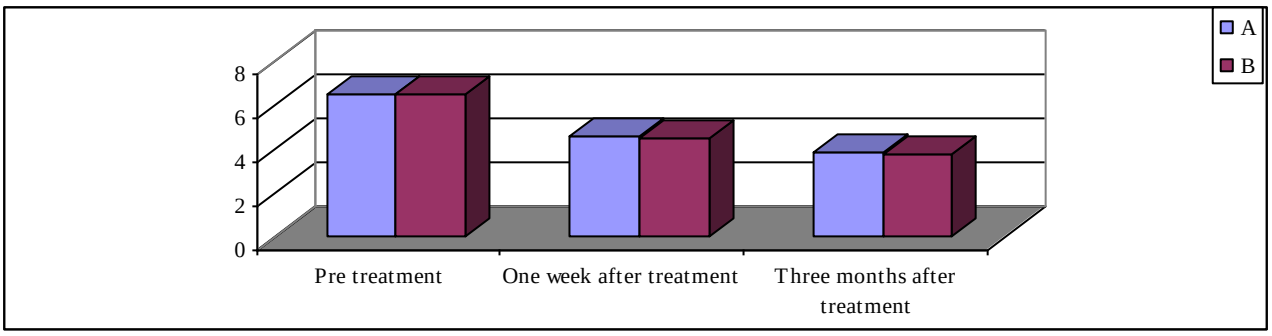


***Fig. (1): Average of pain pre treatment and after by one week and three months in both groups.***

**Maryland Foot Score:**

The functional activities of the patients were measured by using Maryland foot score. It was found that, on average, the pre-treatment score was 35 ± 15 while one week after treatment, the average score in group (A) was 52 ± 17 and in group (B) was 54 ± 19. Three months after treatment, the average score in group (A) was 80 ± 12 while in group (B) was 82 ± 13. (P<0.001) table (3) Figure (2).

***Table (3): Average of Maryland foot score pre-treatment, one week and three months after treatment in both groups.***

| | | Range | SD | Mean | P[b] |
|---|---|---|---|---|---|
| Pre treatment | | 20 to 39 | 15 | 35 | < 0.001 |
| After one Week | (A) | 49 to 59 | 17 | 52 | |
| | (B) | 50 to 61 | 19 | 54 | |
| After three Months | (A) | 79 to 91 | 12 | 80 | |
| | (B) | 80 to 90 | 13 | 82 | |

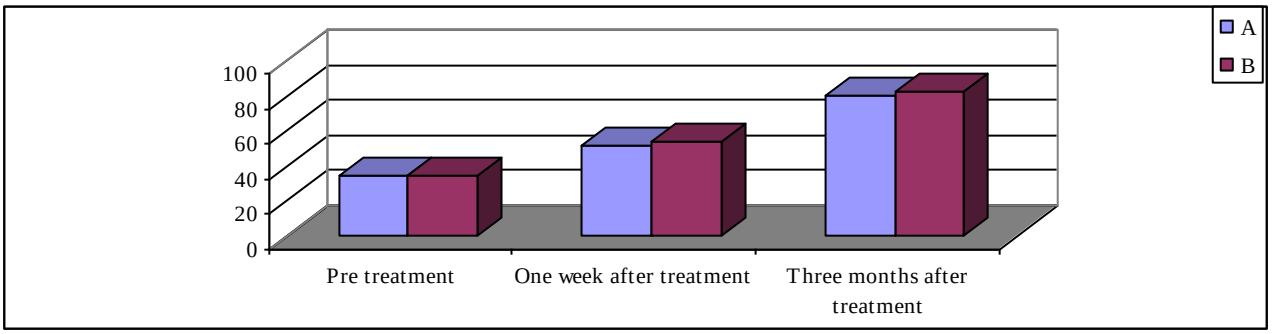


***Fig. (2): Average of Maryland foot score pre-treatment, one week and three months after treatment in both groups.***

## DISCUSSION

Planter Fasciitis is a common disorder that affects a wide range of people specially the obese subjects and also some athletes as the runners. Various types of treatment used to treat those patients. The most effective two types of treatment used with those patients are the Iontophoresis with Dexamethasone 4% and the ESWT. Using the questioner applied on the physical therapy centers on west California about the most effective modalities that used with the patient with planter fasciites, it was found that the application of ESWT and application of the 4% Dexamethasone iontophoresis were the most effective modalities used with those patients[1,5,11]. In the study that applied by (Riviere) who measure the changes in the thickness of the plantr fascia as a measure of subside of inflammation in the patient with plantr Fasciitis he reported that by application of ESWT once per week

for two weeks he found the thickness of the plantr fascia decrease about 25% and he found the same reduction in the thickness when he applied iontophoresis with 4% Dexamethasone but he did not report the effect on the pain score or the functional activity of the patient. On the other hand, some authors found that in the comparison between the application of extracorporeal shock-wave and the application of Dexamethasone 4% iontophoresis on the chronic planter Fasciitis patient, they found that the score of pain by using (VAS) reduced with the application of Iontophoresis Dexamethasone 4% more than the application of ESWT one week after treatment[13,14,20,21]. The difference in the result between this study and the previous study may be returned as this study follow the changes in the pain scale by using VAS one week and also three months after the treatment as the effect of the application of extracorporeal shock-wave may need more time to begin the process of revascularization on the affected area. Many author recommend the use of ESWT as the last stage of non-invasive treatment, they suggested that the patient who complain from planter Fasciitis from more than 6 months and not responding to the other non invasive treatment may be indicated to ESWT[16,22]. On the other hand, the high coast of application of Extracorporeal shock-wave may be one of the main reasons that limit the usage of this technique in the treatment of chronic planter Fasciitis.

**Limitations:**

While the present study appears to have clinical implications, some limitation needs to be addressed. The sample size was notably small (n= 26), and increase in the sample is recommended for further study. Also increase the time for the follow up of those patients to be one year may help to provide more information in the comparison between these 2 types of treatment.

**Conclusion:**

In the treatment of the patient with chronic planter Fasciitis both ESWT and application of Iontophoresis with 4% Dexamethasone are effective in the treatment in those patients as the pain score decrease and the functional activities improved. The application of the iontophoresis with 4% Dexamethasone may be preferred as the coast of application of extracorporeal shock-wave is high.

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## الملخص العربي

### الإدخال ألايوني للديكساميثازون 0.4٪ مقابل العلاج بالموجات التصادمية منخفضة الطاقة في علاج الالتهاب المزمن للفافة الاخمصية

التهاب اللفافة الاخمصية يعرف بأنه الإحساس بالألم في الجزء السفلي من الكعب ومتدال ي باطن القدم وذلك بسبب الإصابة في اللفافة الاخمصيه التي تغطي الجزء السفلي من القدم . هذه الإصابة تسبب آلام الكعب في البالغين النشطين وكذلك في الأشخاص الذين لا يقومون بأي أنشطة رياضية من جميع الأعمار . تكثر احتمالات الإصابة في الأشخاص الذين يعانون من السمنة المفرطة أو أولئك الذين يقفون على أقدامهم معظم اليوم . وأيضا هذه الإصابة تعتبر شائعة في الرياضات التي تتطلب الجري لفترات طويلة . تم تطبيق هذه الدراسة لمقارنة تأثير الموجات التصادمية منخفضة الطاقة من خارج الجسم مقابل ا لإدخال الأيوني للديكساميثازون 0.4٪ في علاج هؤلاء المرضى المصابين بالتهاب اللفافة الأخمصية المزمن . وقد شارك في هذه الدر اسة ستة وعشرون مشاركا تتراوح أعمارهم بين 18 إلى 65 سنة شخصت أعراضهم على أنها التهاب مزمن للفافة الأخمصية وقد وزعت هذه العينة عشوائيا إلى مجموعتين ، كل المرضى الذين يشاركون في هذه الدراسة يطبق عليهم تمرينات تمدد لمده عشر دقائق بالإضافة إلى 5 دقائق موجات فوق الصوتية بشدة 1,1 وات لكل سنتيمتر مربع وبتردد 50 % بواقع ثلاث جلسات أسبوعياً (يوم بعد يوم) لمده أسبوعين . بالإضافة إلى ذلك ، فإن المرضى في المجموعة (أ) سيتم علاجهم بالموجات التصادمية منخفضة الطاقة مرتين (أول تطبيق للموجات التصادميه في الجلسة الأولى والتطبيق الثاني بعد أسبوع من آخر جلسة علاجية) في حين أن المرضى في المجموعة الثانية تلقت العلاج بالإدخال الأيوني للديكساميثازون 0.4% بواقع ست جلسات خلال أسبوعيً . تقاس نتائج العلاج على النحو التالي بعد أسبوع واحد من الجلسة الأخير ة ثم بعد ثلاثة أشهر . لقياس تأثير هذه الطرق العلاجي ة يستخدم مقياس شده الألم بالإضافة إلى استخدام المقياس الوظيفي للقدم (ميريلاند) ($P < 0.05$) . وقد أوضحت النتائج تحسن كبير في حده الألم لدي هؤلاء المرضى وأيضا تحسين لوظيفة القدم وفقا للمقياس الوظيفي للقدم (ميريلاند) ولكن بين المجموعتين لم يكن هناك فرق إحصائي ( $P > 0.05$) في كل من درجه تحسن الألم والتحسن الوظيفي للقدم وفقا للمقياس الوظيفي للقدم (ميريلاند) بعد أسبوع وبعد ثلاثة أشهر من العلاج . الاستنتاجات : كل من الإدخال الأيوني للديكساميثازون 0.4% و العلاج بالموجات التصادمية منخفضة الطاقة اثبت نجاحه في علاج التهاب اللفافة الأخمصية . ولكن من منظور آخر وهو تكلفة العلاج التي يتحملها المريض فقد وجد أن العلاج عن طريق ا لإدخال الأيوني لليكساميسازون 0.4% يعتبر اقل تكلفه بالمقارنة بالعلاج عن طريق استخدام الموجات التصادمي ة منخفضة الطاقة ، وأيضاً تتميز طريقه العلاج بالإدخال الأيوني للديكساميثازون 0.4٪ لا يصاحبها الالم التي من الممكن أن يشعر بها المريض عن طريق تطبيق العلاج بالموجات التصادمية منخفضة الطاقة .