

Comparative Study On Therapeutic Outcome Of Phonophoresis Vs Normal Ultrasound Therapy Advised In Plantar Fasciitis: A Prospective Study

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Abstract: -

Plantar fasciitis is the chief cause for irritation in plantar fascia. Plantar fascia is a non- elastic, thick, multi-layered connective tissue that origin at the medial tuberosity of the heel as well as surrounding perifascial structures. Conservative treatment opinion for plantar fasciitis is mainly to reduce the pain which includes rest, cryotherapy, compression and elevation of foot, soft tissue and joint manipulation, TENS (transcutaneous electrical nerve stimulation), extracorporeal shock wave therapy (ESWT), muscle strengthening, insoles. Patients are advised to use MCR footwear, Stretching and strengthening exercises are important to improve the functional ability and muscle weakness of foot and tightness of Achilles tendon, and therapeutic ultrasound is most advised to relieve pain. This thesis objective is to study the therapeutic outcome of phonophoresis using diclofenac sodium gel. And to provide better evidence in treatment plantar fasciitis. The statistical results and outcome measures according to VAS- Visual Analogue Scale and FAAM – Foot and Ankle Ability Measurement Scale showed phonophoresis has better therapeutic outcome that is in relieving pain and improving ability of foot.

Keywords: - phonophoresis, plantar fasciitis, FAAM scale, VAS scale, ultrasound therapy, diclofenac gel.

Date of Submission: 03-02-2024

Date of Acceptance: 13-02-2024

I. Introduction:

Plantar fasciitis is the chief cause for irritation in plantar fascia. Plantar fascia is a non- elastic, thick, multi-layered connective tissue that originates at the medial tuberosity of the heel as well as surrounding perifascial structures. 11% to 15% of all foot pain is involved with this plantar fasciitis. The other synonyms for this condition are policeman heel, painful heel syndrome, runner's heel, sub calcaneal pain, calcaneal prostatitis, calcaneal enthesopathy, calcaneodynia, and calcaneal spur syndrome¹.

Although plantar fasciitis is an inflammatory process, it is a degenerative disorder of plantar fascia. It is misnamed as plantar fasciitis, as it is a degenerative condition the appropriate terminology is “*plantar fasciosis*”².

Plantar fascia anatomy:

Plantar fascia is also called as “plantar aponeurosis”. Plantar fascia is a fibro-elastic connective tissue with irregular collagen fibers with minimum elastin properties. It is made up of longitudinal dense connective tissue. This plantar fascia is a connective tissue which is firmly connected to plantar muscle and skin⁹. The plantar fascia is rich in hyaluronan. It originates from medial tuberosity of the calcaneus bone. It posteriorly attaches to medial tuberosity of calcaneus and runs into the metatarsophalangeal joints (MTP) and proximally attached to flexor digitorum brevis.

Plantar fascia has three distinct structural components

- the medial component,
- the central component (plantar aponeurosis),
- and the lateral component

Anteriorly plantar fascia is divided into five segments one for each toe.

Plantar fasciitis: -

Plantar fasciitis is an exhausting condition with severe pain in the heel region. It is an inflammatory condition which is caused due to overstretching of plantar fascia. The most common symptom is pain which is more severe in taking a few steps in early morning. The pain gradually fades after a few more steps. The pain is insidious in onset and gradually aggravates in time¹³.

Pain occurs due to irritation in pain fiber on repeated trauma in plantar fascia. Local inflammatory reactions occur due to the release of inflammatory substances like substance p, glutamate and sensitivity of nociceptor is increased¹⁴.

Plantar fascia acts as the main stabilizer in the medial longitudinal arch of foot. It helps to reduce the stress and acts against ground reactive, motion forces. Plantar fasciitis is caused due to excessive stretch and excessive load on the band in the foot. Due to stress on the band, small tears occur in the fascia mainly in the region where it connects to anterior calcaneus¹⁵.

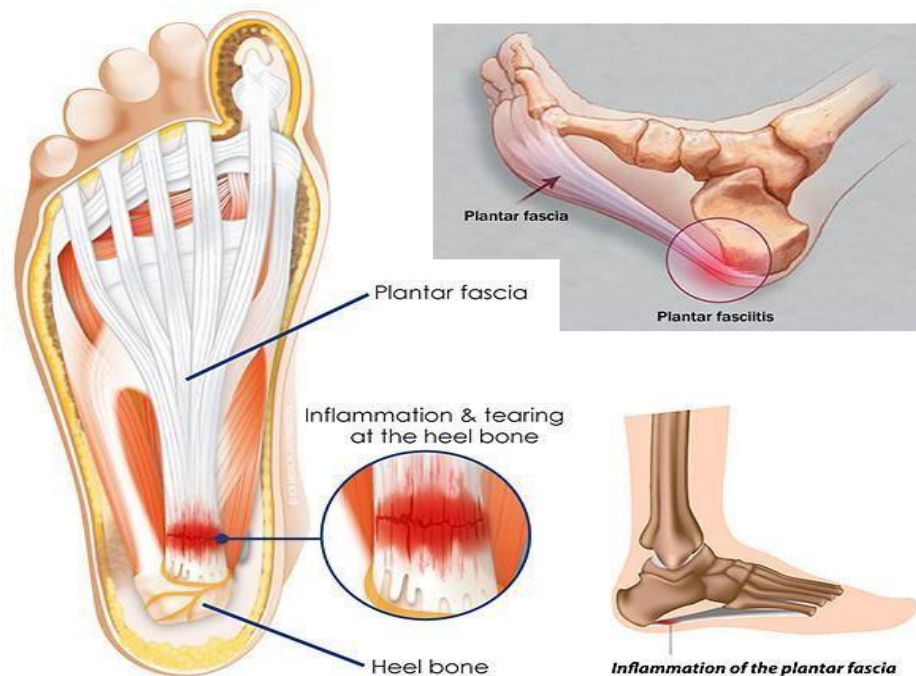


Figure 1.1:- Mechanism of plantar fasciitis

SIGNS AND SYMPTOMS: -

- stabbing pain usually occurs with first few steps in the early morning
- pain gradually reduces after few more steps
- pain is present in the bottom of the foot near heel region
- pain is severe when patient hobbles around
- it may occur on other regions of sole of the foot
- Tenderness is present

AETIOLOGY AND RISK FACTORS: -

Policemen, military personnel, runners, athletes, obese personnel, Anatomical risk factors like excessive femoral anteversion, muscle weakness, lateral tibial torsion, plantar fascia shortening, muscle imbalance. Other risk factors include excessively worn footwear, use of improper footwear, walking barefoot, excessive weight bearing activity and overtraining.

DIAGNOSIS: -

Plantar fasciitis is mainly diagnosed by physical examination and based on the history of the patient. Pain present on the first step in the early morning is the classical feature of plantar fasciitis and is used to distinguish it from other conditions of heel pain. Pain in plantar fasciitis is usually unilateral but nearly 30% of patients show bilateral pain. Patients should be further questioned about the past history, severity of pain and duration of pain for confirmatory

diagnosis¹⁶. Diagnosis can be made clinically with tenderness at the medial tuberosity of the calcaneus on palpation and pain worsens with dorsiflexion of toes and foot.

MANAGEMENT:

NON -PHARMACOLOGICAL MANAGEMENT: -

Conservative treatment opinion for plantar fasciitis is mainly to reduce the pain which includes rest, cryotherapy, compression and elevation of foot, soft tissue and joint manipulation, TENS (transcutaneous electrical nerve stimulation), extracorporeal shock wave therapy (ESWT), muscle strengthening, insoles. Patients are advised to limit the biomechanical deviation that is caused by structural abnormalities^{1,10}. Patients are advised to use MCR footwear, Stretching and strengthening exercises are important to improve the functional ability and muscle weakness of foot and tightness of Achilles tendon, and therapeutic ultrasound is most advised to relieve pain.

PHONOPHORESIS: -

Phonophoresis is a type of ultrasound therapy. It allows the topically applied medication to enter into the tissue.

It is defined as movement of medication through the skin membrane into the subcutaneous tissue under the influence of ultrasound waves²².

PHARMACOLOGICAL MANAGEMENT: -

ANTI-INFLAMMATORY MEDICATION:

Topical and oral NSAID's (Non-Steroidal Anti- Inflammatory) medication are most common in the treatment of plantar fasciitis.

Short term steroid injections are used. But there is limited evidence to support the steroid injection because it may cause further rupture of plantar fascia and regeneration of plantar fat pad. Majorly used oral pharmacological agents are NSAID's like paracetamol, aceclofenac, diclofenac, ibuprofen etc., and topical diclofenac gel is commonly used. In severe pain conditions opioid analgesics are used. Most commonly used opioid analgesics is tramadol.

Aim:

The aim of this study is to compare the efficacy and tolerability of phonophoresis using Diclofenac sodium gel and normal aqua gel in ultrasound massage recommended in patients with plantar fasciitis.

Objectives:

- The objective of this research is to study the therapeutic outcome of phonophoresis using diclofenac sodium gel.
- To compare therapeutic outcome in two groups of patients receiving phonophoresis using diclofenac gel and normal ultrasound therapy.
- To provide better evidence in treatment plantar fasciitis.

II. MATERIALS AND METHODS:

SAMPLE AND SAMPLE SIZE:

In our study 60 randomized subjects were recruited. Due to possibilities of drop outs, 54 subjects agreed to participate in the study. In which four subjects were discontinued due to their unavailability and unwillingness in the study. 50 subjects participated in the study by attending all the sessions.

The sample size required for the study was calculated by the following formula $n = \frac{1.96 \times p \times q^2}{d^2}$

d^2

where,

n = sample size

1.96 is constant fraction error

p = prevalence of previous study

q = (1-p)

d = absolute error

Subjects were taken and divided into 2 groups

Group-A: receiving ultrasound therapy using diclofenac gel (25 subjects)

Group-B: receiving ultrasound therapy without any pharmacological agents (25 subjects) which includes all the inclusion and exclusion criteria described below:

Inclusion criteria: -

- Above 18 years patients
- Plantar fasciitis with or without calcaneal spur.

- Consent and compliance with all aspects of the study protocol, methods, providing data during follow-up contact.

Exclusion criteria: -

- Patient is not on any oral analgesics
- Patients with open wound in area of receiving ultrasound treatment
- Subject who does not provide full consent
- Patients with cast or any supportive devices
- Subjects involving in any other ongoing research studies
- Subjects having foot cracks
- Subject is allergic to topical diclofenac gel

Outcome measures:

Physical examination includes palpitation is done and tenderness is checked at medial calcaneal tuberosity. Differential diagnosis was made among the other pathological conditions having the similar symptoms. A positive Tinel sign, a positive neurodynamic test, and the absence of numbness or burning pain were employed in the differential diagnosis of TTS to rule out the pathology.

Pain during the first few steps in the morning and during the day times is measured by using VAS. Patients were asked to assess the intensity of pain on VAS which has scoring from 0 to 10. VAS is the easiest method to assess the intensity of pain.

To assess the function and ability of foot and ankle FAAM scale is used in our study. The FAAM scale has 29 items. It is divided into 2 subgroups. Activities of daily living subscale (21 items), Sports subscale (18 items). Each item has four options which score between 0 to 4.

Scoring is given according to the response of the subject. The calculation of two sub groups in FAAM is done separately. According to the percentage we get after calculation, the ability and function of foot and ankle is determined.

Therapeutic ultrasound:

In our study the subjects were treated with 10 min of therapeutic ultrasound at frequency of 1 MHz and continuous current at a pulse intensity of 1 to 1.5W/cm² depending on the severity of the condition (The therapist lessened the intensity when the patient's sensitivity level was too high and the procedure hurt them). The researchers wanted to increase therapeutic effects (both thermal and non-thermic) in the target tissue because earlier experiments had found no effect of ultrasound^{3,27}. The authors chose the continuous mode in order to maximize the thermic effect, which is also in line with the general advice for chronic diseases.

Both the groups received 5 to 10 sessions of ultrasound therapy based on relieving of pain. Group-A received ultrasound therapy (phonophoresis) with diclofenac gel and group- B received ultrasound therapy without diclofenac gel. All adverse events reported by patients during the study period were recorded by the therapists. Throughout the study the subjects were blinded (single blinded) whether they are receiving therapeutic ultrasound along with diclofenac gel or receiving therapeutic ultrasound without diclofenac gel.

III. Results: -

Tab- 5.1: Distribution Based on occupation of subject:

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S.no	Occupation	No. Of subjects	Percentage (%)
1.	Farmer	9	18%
2.	Conductor	3	6%
3.	Police	5	10%
4.	Security person	7	14%
5.	Gardener	6	12%
6.	Employee	6	12%
7.	Others	14	28%
	TOTAL	50	100%

Fig-5.1: Distribution based on VAS scoring before and after USG treatment with diclofenac gel (phonophoresis)

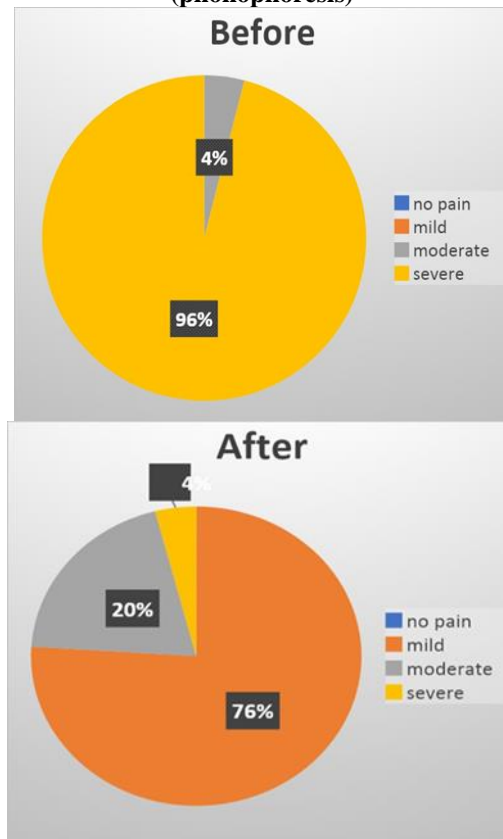


Fig-5.2: Distribution of subjects based on VAS scoring in USG treatment without diclofenac gel

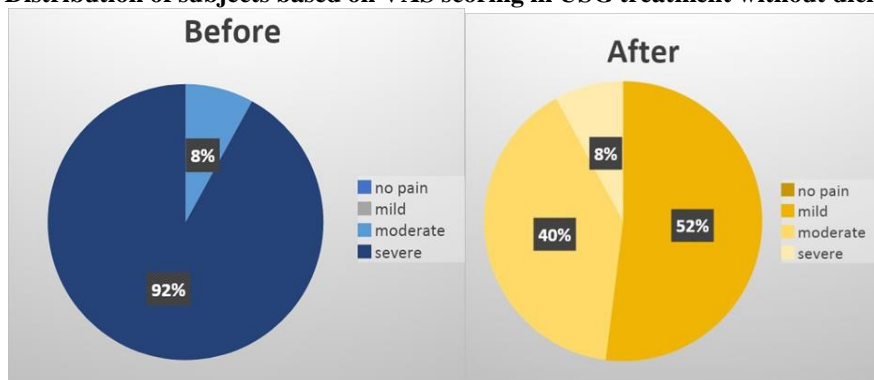


Fig-5.3: Distribution based on FAAM scale results before and after USG treatment with diclofenac gel (phonophoresis)

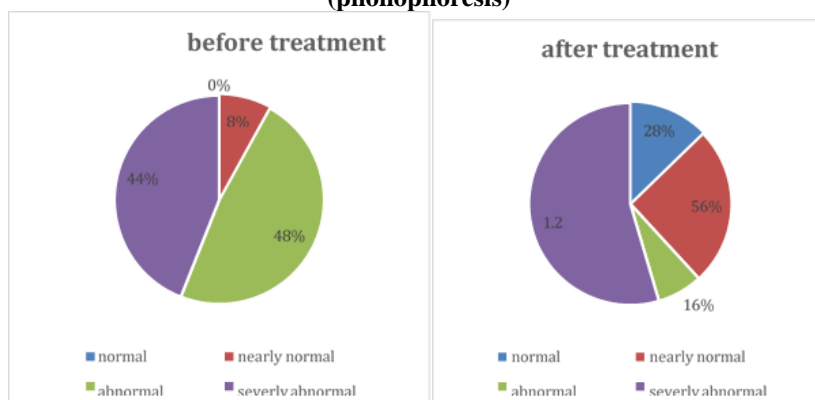
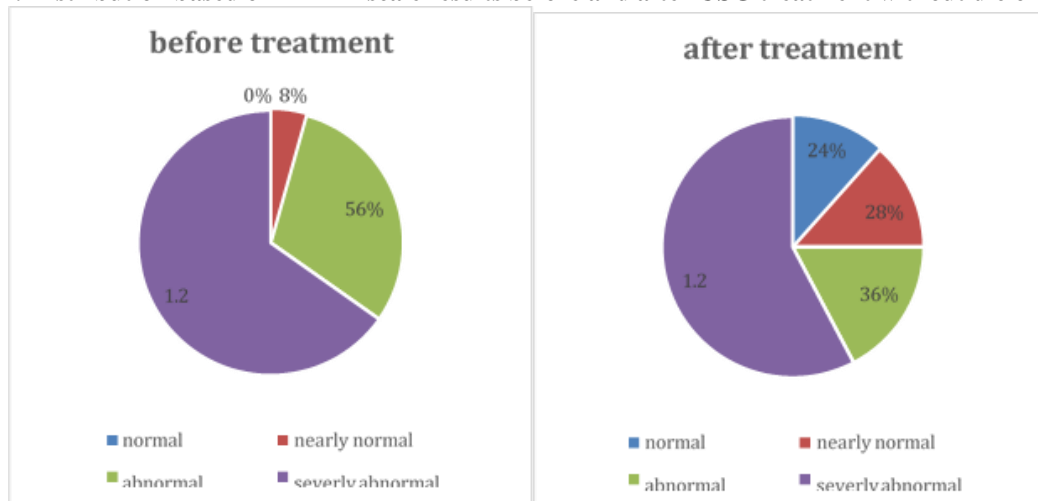


Fig-5.4: Distribution based on FAAM scale results before and after USG treatment without diclofenac gel



In phonophoresis According to VAS, before treatment 24 (96%) subjects had severe pain, while 1 (4%) subject had moderate pain. After treatment (phonophoresis) 19 (76%) of subjects had mild pain, 5 (20%) subjects had moderate pain, 1 (4%) subject had severe pain even after phonophoresis. The complete description about score of VAS of phonophoresis in both before and after treatment and comparative charts are shown in figure 5.1

In USG therapy without diclofenac gel, according to VAS before treatment 23 (92%) had severe pain and 2 (8%) subjects had moderate pain. After treatment in USG therapy without any therapeutic agent 13 (52%) subjects had mild pain, 10 (40%) subjects had moderate pain and 2 (8%) subjects had severe pain even after treatment. The complete description about score of VAS in USG therapy without diclofenac gel, before and after treatment and comparative charts are shown in figure 5.2

In USG treatment with diclofenac gel (phonophoresis), level of function of foot based on FAAM scale in the participants before treatment are 12 (48%) subjects showed abnormal, 11 (44%) subjects showed severely abnormal, while 2 (8%) subjects showed nearly normal. After treatment, 14 (56%) subjects showed nearly normal, 7 (28%) subjects showed normal and 4 (16%) subjects showed abnormal. The complete description about score of FAAM of phonophoresis in both before and after treatment and comparative charts are shown in figure 5.3

In USG treatment without diclofenac gel level of function of foot based on FAAM scale in the participants before treatment are 14 (56%) subjects showed abnormal, 9 (36%) subjects showed severely abnormal, while 2 (8%) subjects

showed nearly normal. After treatment, 9 (36%) showed abnormal ,7 (28%) subjects showed nearly normal, 7 (28%) subjects showed nearly normal and 6 (24%) subjects showed normal, 3 (12%) showed severely abnormal. The complete description about score of FAAM of USG therapy without diclofenac gel in both before and after treatment and comparative charts are shown in figure 5.4

Table-5.5 Statistical analysis of phonophoresis:

S.no.	Phonophoresis	mean	Standard deviation
1.	VAS before treatment	8	± 0.009
2.	VAS after treatment	3	± 0.113
3.	FAAM before treatment	66	± 0.138
4.	FAAM after treatment	35	± 0.112

Table-5.6 Statistical analysis of normal ultrasound therapy:

S.no	Ultrasound therapy	mean	Standard deviation
1.	VAS before treatment	8	†_0.009
2.	VAS after treatment	4	± 0.017
3.	FAAM before treatment	65	± 0.137
4.	FAAM after treatment	46	†_0.204

Table-5.7 Results of ANOVA:

S.no	Results	F- value	P- value
1.	VAS between phonophoresis and normal ultrasound therapy	6.807	0.012
2.	FAAM between phonophoresis and normal ultrasound therapy	3.839	0.054

Table-5.8 Statistical analysis of FAAM questionnaire in phonophoresis:

S.NO	FAAM questionnaire	Before treatment		After treatment	
		Mean	Standard Deviation	Mean	Standard deviation
1	standing	0	0	0	0
2	walking on even ground	5	0	5	± 4.79
3	walking on even ground without shoe	5	± 6.44	5	± 5.29
4	walking uphill	5	± 7.10	5	± 6.08
5	walking down hills	5	± 8.24	5	± 6.55
6	going up stairs	5	± 7.68	5	± 4.63
7	going down stairs	5	± 6.48	5	± 6
8	walking on uneven ground	5	± 5.14	5	± 5.19
9	stepping up and down curbs	5	± 3.16	5	± 6.08
10	squatting	5	± 4.79	5	± 3.39
11	coming up on your toes	5	± 5	5	± 5.43
12	walking initially	5	± 4.84	5	± 5
13	walking 5min or less	5	± 5.14	5	± 5.38
	walking approximately 10 min	7	± 6.20	5	± 4.69
15	walking 15 mins or greater	5	± 6.85	5	± 6.04
16	home responsibilities	5	± 4.18	5	± 3.80
17	activities of daily living	5	± 4.79	5	± 2.91
18	personal care	5	± 4.69	5	± 3.67
19	light to moderate work (standing / walking)	5	± 4.58	5	± 3.60
20	heavy work (push /pull/ climbing/ carrying)	5	± 5.56	5	± 4.63
21	recreational activities	5	± 3.74	5	± 3.74
22	running	5	± 6.04	5	± 3.60
23	jumping	5	± 6.96	5	± 4.52
24	landing	5	± 5.24	5	± 6.40
25	starting and stopping quickly	5	± 4.24	5	± 3.16
26	cutting / lateral movement	5	± 3.31	5	± 3.93
27	ability to perform activity with your normal technique	5	± 2.82	5	± 2.54
28	ability to participate in your desired sport as long as you like	5	± 3.80	5	± 4.12

Table-5.9 Statistical analysis of FAAM questionnaire in normal ultrasound therapy

S.no	FAAM questionnaire	Before treatment		After treatment	
		Mean	Standard Deviation	Mean	Standard Deviation
1	standing	3.8	± 4.54	5	± 5.74
2	walking on even ground	5	± 8	4.8	± 4.54
3	walking on even ground without shoe	5	± 6.55	5	± 7.14
4	walking uphill	5	± 7.14	5	± 5.83
5	walking down hills	5	± 6.48	5	± 5.74
6	going up stairs	5	± 7.14	7	± 6.55
7	going down stairs	5	± 6.04	5	± 5.04
8	walking on uneven ground	5	± 4.69	5	± 4.84
9	stepping up and down crubs	5	± 3.74	3.8	± 4.81
10	squatting	5	± 4.47	5	± 3.80
11	coming up on your toes	5	± 4.06	5	± 7.28
12	walking initially	5	± 5.65	5	± 5.74
13	walking 5min or less	5	± 6.74	5	± 5.43
14	walking approximately 10 min	5	± 5.70	5	± 6
15	walking 15 mins or greater	5	± 5.91	5	± 5.65
16	home responsibilities	5	± 1.73	5	± 4.84

IV. Discussion: -

- By comparing the study's beginning and end, all outcome indicators showed statistically significant improvement which is shown in table-1 and table-2. Results are similar to **Yigal katzap et.al, (2018) “Additive Effect of Therapeutic Ultrasound in the Treatment of Plantar Fasciitis: A Randomized Controlled Trial”¹** in terms of pain improvement over time, in both groups. Another study looked at stretching as a possible treatment method. However, because numerous therapy modalities were used concurrently, it is impossible to determine which modality helped reduce the symptoms. In our study, by using one-way ANNOVA between two groups p- value for VAS and FAAM scale between two groups is 0.012 and 0.054 respectively. Which shows that strong presumption.
- According to **Pfeffer G, et.al, (1999) “Comparison of custom and prefabricated orthoses in the initial treatment of proximal plantar fasciitis”**. It can be found that efficacy of stretching in one of its groups, with the other groups using 1 of 4 different shoe inserts, in terms of pain relief over time.
- According to **Starkey C. (2004) “Therapeutic Modalities”**. Some studies showed that phonophoresis may be effective treatment modality. Before being absorbed by the subcutaneous tissues, the phonophoresis media travel transdermally through the enzymatic barrier of the stratum corneum and epidermis. It may take longer for medications that are absorbed through the epidermis to diffuse into deeper tissues because they may be stored in the subcutaneous tissues.³⁰
- According to **Nussbaum E. (1996) “The influence of ultrasound on healing tissues”**. The size of cavitation depends on the ultrasonic properties, and low- intensity, high-frequency, and pulsed ultrasound have a lower bubble formation limit. Additionally, a frequency of 3 MHz may have produced different results than 1 MHz, which was frequently used by researchers on relatively peripheral tissues like the Achilles tendon and patellar tendon. To identify the factors (duty cycle, intensity, and frequency) that are more efficient for the transportation of medications, more study is required.³¹

V. Conclusion:

- The current study seems to be the first study done to focus on comparison of phonophoresis vs normal ultrasound therapy in treatment of plantar fasciitis.
- In our study we observed that phonophoresis has better therapeutic outcome than normal ultrasound therapy.
- The statistical results and outcome measures according to VAS- Visual Analogue Scale and FAAM – Foot and Ankle Ability Measurement Scale showed phonophoresis has better therapeutic outcome that is in relieving pain and improving ability of foot.
- We conclude that phonophoresis using diclofenac gel is better treatment when compared to normal USG treatment. And phonophoresis is the beneficial remedy in plantar fasciitis treatment.

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