

## **Study of the Safety of Peaceful Mountain Tendon Rescue to Treat Symptoms of Plantar Fasciitis: a randomized, double-blinded, placebo-controlled trial**

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### **Abstract:**

**Background:** Plantar fasciitis is defined as pain and inflammation caused by tearing the plantar fascia, generally due to excessive weight bearing or use. The standard of care typically includes anti-inflammatory agents, but the problem does not usually resolve with this type of therapy.

**Methods:** Subjects were randomly chosen to receive either the test or the placebo for the three-week treatment phase during which they completed daily symptom assessments. The treatment phase is compared to baseline and return to baseline phases in order to assess change.

**Results:** One subject reported side effects during each treatment week for the test group where as 3 subjects reported side effects in the placebo group. All side effects were mild and were only present during treatment.

**Conclusion:** The results suggest that Peaceful Mountain Tendon Rescue is as safe if not safer than a placebo gel when used for 3 weeks.

### **Background:**

Plantar fasciitis, a repetitive strain injury affecting the inferior aspect of the heel, is caused by excessive loading of the plantar fascia due to a naturally pronating foot, or fallen arch<sup>1</sup>. The constant strain on the connective tissue results in a series of micro-tears, which fail to heal for the tears are constantly being reopened by even cautious locomotion<sup>2</sup>. Symptoms present as localized tenderness on the inferior anteromedial aspect of the calcaneus, which is the origin of the tendonous band<sup>1</sup>. Prevalence of the condition is higher in runners, women, and in the middle aged and elderly. Obesity, occupational stress, and shoes with poor cushioning are factors that can increase one's risk of developing symptoms<sup>2</sup>.

The medical standard of care for plantar fasciitis consists of, depending on severity, regimens of stretching, night splints, orthotic devices, corticosteroid injections, and a variety of surgical methods for crippling cases<sup>2,3</sup>. The condition is frequently self-limiting, but treatment seems to hasten this recovery little, if at all<sup>3</sup>. As the condition resolves, orthotic devices can be very expensive, and corticosteroid injections for pain can cause permanent fat pad atrophy<sup>2</sup>. Regardless of severity, an alternative to corticosteroid injection and over the counter pain remedies would give those suffering symptoms a means to control pain without the severe side-effects.

The product to be tested is an herbal gel, Peaceful Mountain Tendon Rescue, which is administered topically according to this specified protocol. The herbal gel contains agents with anti-inflammatory and tissue-regenerating properties.

### **Methods:**

Subjects were recruited from local advertisements such as flyers and newspapers and study visits were held at the Klearsen Corporation clinical research department. Subjects were required to have a history of plantar fasciitis in at least one foot, and to be at least 18 years of age. Subjects were not allowed to use anti-inflammatory medications or any other inconsistent medications during the trial period. If a subject presented with bilateral plantar fasciitis, both feet were assessed and treated.

Following a comprehensive screening questionnaire and upon consented enrollment, subjects were randomly assigned to either the placebo or the test groups. Subjects were required to attend weekly visits at the clinic to complete weekly side effect surveys and to have the gel tube weight assessed. At the first clinic visit, each subject completed a side effect survey and was instructed complete daily surveys for the

duration of the trial. During the first week of the trial, the subject did not apply any treatment, therefore, this is referred to as the Baseline Phase. The 3-week Treatment Phase began following the second visit where the subjects were given the gel tube that had been randomly assigned to them. They were instructed to liberally apply the gel to the affected foot 3 times daily. At the fifth visit, the subjects were instructed to discontinue the use of the gel and to continue completing daily side effect surveys for the last week, the Return to Baseline Phase, of the study. At the sixth and final visit, the subjects completed a final weekly side effect survey and were informed of whether they had been given the test or the placebo.

## **Results:**

### **Outcome**

When analyzed, the test and placebo groups had similar baseline characteristics except for the duration of the condition. Table 1 shows the average baseline characteristics for the test and placebo groups.

<b>Variable</b>	<b>Test (n=14)</b>	<b>Placebo (n=13)</b>
Age in years ( $\pm$ standard deviation)	50 ( $\pm$ 10)	49 ( $\pm$ 10)
Period of symptoms in months- (range)	42 (3-120)	14 (6-60)
No. women (%)	13 (93)	9 (69)
Foot affected		
Right- No. (%)	4 (28)	4 (31)
Left- No. (%)	5 (36)	2 (15)
Both- No. (%)	5 (36)	7 (54)
Pre-disposing factors		
Sudden weight gain- No. (%)	2 (14)	1 (8)
Obesity- No. (%)	1 (7)	0 (0)
Use of shoes with poor cushioning- No. (%)	5 (36)	6 (46)
Increased running distance- No. (%)	3 (21)	0 (0)
Change in walking or running intensity- No. (%)	1 (7)	4 (31)
Achilles tendon tightness- No. (%)	2 (14)	4 (31)
Occupation involving prolonged weight bearing- No. (%)	4 (29)	4 (31)

**Table 1** Baseline characteristic of participants. Values are averages unless otherwise stated.

During the study one test subject and 3 placebo subjects reported side effects (Fig 1). One test subject reported dry skin each week of treatment. The placebo subjects reported a rash on the hand the first and second week of treatment, staining of the skin the second week of treatment, and dry skin the second and third week of treatment. All of these side effects can be considered skin irritation.

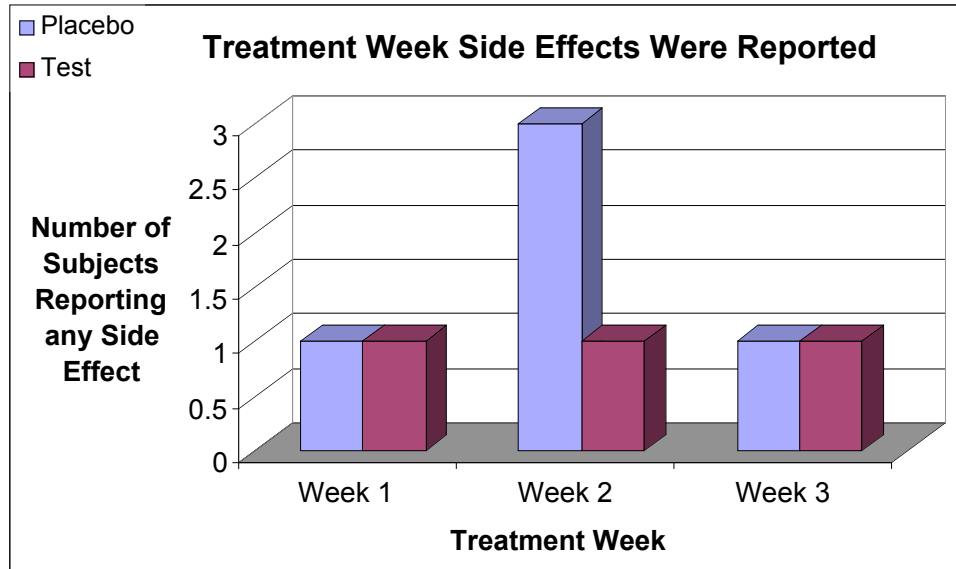


Fig 1. The number of test and placebo subjects that reported side effects during each week of treatment.

**Discussion:**

Skin irritation was the only side effects reported in both groups. Dry skin was the only side effect reported by a test subject. This side effect was also seen in the placebo group, suggesting that the active ingredients may not be causing the dry skin but the nature of a water based gel. These side effects were considered mild and only last during treatment. This test suggests that Peaceful Mountain Tendon Rescue is safer than a placebo when used for 3 weeks.

**References:**

1. Buchbinder, R. Plantar fasciitis. *New England Journal of Medicine*. 350: 2159-66.
2. Singh, D., Angel, J., Bentley, G., & Trevino, S. G. Fortnightly review: Plantar fasciitis. *British Medical Journal*. 7101: 172-5.
3. Barrett, S. L., and O'Malley, R. Plantar fasciitis and other causes of heel pain. *American Family Physician*. 1999.
4. Rammelt, S., and Zwipp, H. Calcaneous fractures: facts, controversies and recent developments. *International Journal of the Care of the Injured*. 35: 443-461.
5. Kennedy, J. G., et al. An outcomes assessment of intra-articular calcaneal fractures, using patient and physician's assessment profiles. *International Journal of the Care of the Injured*. 34: 932-936.
6. Trevino, S., and Baumhauer, J. F. Tendon injuries of the foot and ankle. *Clinics in Sport Medicine*. 11(4): 727-738.