

## **Study of the Safety of PM Tendon Rescue to Treat Symptoms of Tendinopathy: a randomized, double-blinded, placebo-controlled trial**

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### **Abstract:**

**Background:** Tendinitis is defined as the inflammation of a tendon, generally resulting from an injury. When an injury occurs, the tendon also experiences tendinosis, micro-tearing of the connective tissue that makes up the tendon. These combined conditions evolve into the condition of tendinopathy. The standard treatment for this condition involves anti-inflammatory agents, but they rarely resolve the issue in the long-term.

**Methods:** Subjects were randomly chosen to receive either the test or the placebo for the duration of the two-week treatment phase during which they assessed their symptoms on a daily basis. The treatment phase is compared to baseline and return to baseline phases before and after the treatment phase, thus allowing for observations over the course of the study.

**Results:** Three test subjects reported side effects during the application phase of the study. One placebo subject reported a side effect during treatment.

**Conclusion:** The results suggest that Peaceful Mountain Tendon Rescue is as safe as a water-based placebo gel with two weeks of treatment. It would be beneficial to compare Peaceful Mountain Tendon Rescue with the current treatments for tendinopathy in a future study.

### **Background:**

Tendinopathy, otherwise known as tendinitis, is one of the most common diagnoses in both occupational and sports-related injuries. Chronic injuries, such as tendonitis, account for about 48% of reported occupational illnesses and 30-50% of sports-related injuries (1). Tendinopathy is most commonly the result of repetitive movement and the overuse of a tendon. Tendinopathy collectively describes tendonitis, which is inflammation of the tendon, and tendinosis, which is a slow-healing series of micro-tears to the tendon. Following an injury of the tendon, both tendonitis and tendinosis may occur, causing general pain, tenderness, and swelling in the area of the injury (2).

The common treatment for tendinopathy is rest of the injured area, the application of ice to reduce swelling, and anti-inflammatory pain relievers. Anti-inflammatory agents such as corticosteroids and NSAIDs (non-steroidal anti-inflammatory drugs), which include ibuprofen, ketoprofen, and Aleve, are commonly recommended for treatment of tendinopathy (3, 4, 5). However, these treatments do not promote the healing process of the tendon, and research has failed to show these methods as effective in the long-term. Physical therapy is another method commonly used to conservatively treat tendonopathy (5). Adherence to a treatment regimen, however, can be difficult for many subjects, and compliance is often not adequate to maintain remission. The most beneficial treatment of tendinopathy is one that includes not only anti-inflammatory, and analgesic agents, but also connective tissue-regenerating agents that will treat the symptoms of both tendonitis and tendinosis. If the inflammation is reduced, the body's natural mechanism to facilitate repair of the damaged collagen fiber is thwarted. Weakness of the tendon then results from the micro-tears that remain. As the tendon is continuously used, rupture of the tendon may occur.

The product to be tested, Peaceful Mountain Tendon Rescue, is administered topically in gel form according to a specified protocol. The solution is an herbal gel that contains agents with analgesic, blood-flow enhancing, 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 tendinitis in any joint region, and to be at least 18 years of age. Subjects were not allowed to use anti-inflammatory medications or any other medications during the trial period. If a subject presented with bilateral tendinitis, only one joint was 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 2-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 elbow 3 times daily. At the fourth 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 fifth 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.

The data from 21 subjects (9 placebo, 12 test) were analyzed by looking at test and placebo subject's average reduction in reported symptom severity on a scale from 1-9 with 1 being no symptoms present, and 9 being the most severe symptoms. Student's paired, one or two tailed t-test was used to determine if the average weekly change was significant in each group separately. The average percent change was also calculated. The baseline characteristics for the test and placebo groups were calculated (Table 1).

<b>Variable</b>	<b>Test (n=12)</b>	<b>Placebo (n=9)</b>
Age in years	45 (± 8)	36 (±19)
Period of symptoms in months- (range)	49 (2-192)	37 (2-60)
No. of women (%)	9 (75)	6 (67)
Location		
Shoulder- No. (%)	0 (0)	4 (44)
Elbow- No. (%)	8 (67)	2 (22)
Knee- No. (%)	1 (8)	2 (22)
Wrist- No. (%)	1 (8)	1 (11)
Ankle- No. (%)	1 (8)	0 (0)
Hip- No. (%)	1 (8)	0 (0)

**Table 1** Baseline characteristics of participants. Values are averages (±standard deviation) unless otherwise stated.

## **Results:**

### **Outcome**

#### **Week 1**

One test subject reported an increase in stiffness immediately after application of the gel. This side effect only lasted for the first week of treatment.

#### **Week 2**

Two test subjects reported side effects during the second week of treatment. One reported an increase in sensitivity after applying the gel. This sensitivity lasted for approximately 15 minutes after application. Another test subject reported bruising where the gel was applied. One placebo subject reported staining of the skin where the gel was applied. None of these side effects continued after application of the gel was stopped.

## **Discussion:**

The side effects may not be from the properties of the gel. One test subject reported bruising in the area where the gel was applied. It is unknown if this was a result of using the gel or from rubbing the area too hard when the gel was applied. These results suggest that Peaceful Mountain Tendon Rescue is safe with minimal side effects and is comparable to a placebo gel for 2 weeks of treatment.

It would be beneficial to compare Peaceful Mountain Tendon Rescue to the current treatments for tendinitis including NSAIDs and corticosteroids.

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