

Plantar Fasciitis

PCCA Lipoderm® ActiveMax™

SUMMARY: Plantar fasciitis, also known as painful heel syndrome, results from the inflammation of a foot ligament. A male physician with plantar fasciitis was suffering from heel pain and was walking with a cane because of this condition. Following unsuccessful treatments, the patient was dispensed a transdermal compounded medication including a combination of topical drugs in Lipoderm® ActiveMax™. In just 7 days, the patient's condition improved from the worst possible pain to pain-free, as demonstrated by the research instruments SF-MPQ and NRS.

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Introduction:

The plantar fascia is a long and thin fibrous ligament that lies across the feet, beneath the skin, connecting the heel to the toes and supporting the arch of the feet. When this ligament becomes irritated and inflamed it causes pain on the bottom of the heel. This condition is named plantar fasciitis (Figure 1), also known as painful heel syndrome, and it is estimated to affect more than 3 million people per year in the United States and to cost third-party payers between \$192 and \$376 million¹⁻³.

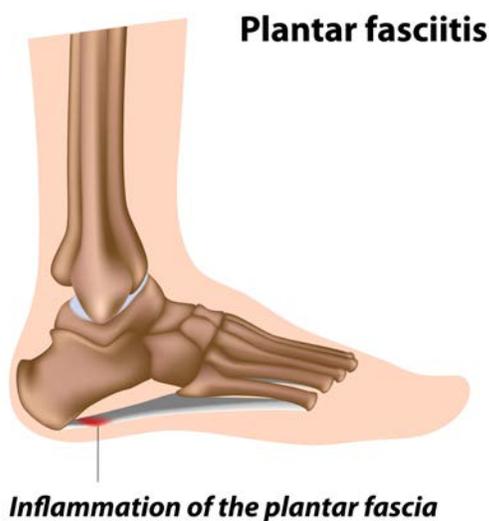


Figure 1. Illustration of the plantar fascia and plantar fasciitis.

Plantar fasciitis is the most common cause of heel pain in adults and, although of unknown etiology, there are risk factors that are likely to contribute to this condition, such as: new or increased activity; repetitive impact activity; obesity; high arch of the foot; and tight calf muscles^{1,3}. When disregarded, plantar fasciitis may become a chronic condition⁴. More than 90% of patients improve their condition with non-surgical treatment, which commonly includes stretch exercises, supportive orthotics, and nonsteroidal anti-inflammatory drugs (NSAIDs).

The purpose of this case study is to discuss the successful management of plantar fasciitis in an adult male with a transdermal compounded medication.

Case Report:

A 43-year-old male suffering from plantar fasciitis visited a compounding pharmacy limping and with unbearable pain because of his condition. The patient is a physician who works long hours, sometimes over 12 hours/day, and spends part of his working hours standing. The patient suspects that his condition, which initiated 10 days before, is the result of his demanding professional life. The patient tried several medications to alleviate the pain but none was effective. He started with ibuprofen 800 mg tablets TID, then added omeprazole 40 mg tablets BID because of stomach pain and a potential stomach ulcer, followed by Voltaren® Gel. He did not try narcotics because of his medical profession. The patient reported that, despite the medications, his pain kept growing and his condition evolved, in just 10 days, from some difficulties walking to walking with a cane and Abeo® orthotics biomechanical footwear.

The compounding pharmacist recommended an alternative transdermal pain medication including the NSAIDs diclofenac sodium and ibuprofen, and the muscle relaxants cyclobenzaprine HCl and magnesium chloride⁵ in Lipoderm® ActiveMax™, a transdermal compounding base with proprietary liposomal components that are likely to increase the permeation of drugs⁶ (Table 1). The patient was advised to apply the cream three times a day and to flex/stretch the feet at bedtime and in the morning.

Rx
Diclofenac Sodium 10%
Ibuprofen 2%
Cyclobenzaprine HCl 2%
Magnesium Chloride 5%
Base, PCCA Lipoderm® ActiveMax™

Table 1. PCCA Formula 12547: Diclofenac Sodium 10%, Ibuprofen 2%, Cyclobenzaprine HCl 2% and Magnesium Chloride 5% Cream (Lipoderm® ActiveMax™).

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Methodology:

The patient's self-reported heel pain, before and after treatment with the transdermal compounded medication, was assessed by two adapted research instruments: the short-form McGill Pain Questionnaire (SF-MPQ) and the Numeric Rating Scale (NRS).

The SF-MPQ is a short questionnaire that has been validated for the measurement of pain. It consists of 15 descriptors (11 sensory and 4 affective) which are scored on an intensity scale from 0 (none) to 3 (severe). Three pain subscales may be derived from this assessment by adding the individual scores obtained for selected descriptors, as follows: sensory pain (descriptors 1-11), affective pain (descriptors 12-15) and overall pain (descriptors 1-15)⁷. The Present Pain Intensity (PPI) is an additional evaluative category of the overall pain that consists in five verbal descriptors associated to a numerical value, from 0 (no pain) to 5 (excruciating pain). The PPI may be used alone or combined with the scores obtained from the sensory and affective pain. The original SF-MPQ also includes a Visual Analogue Scale (VAS), which was substituted in this case study by an adapted NRS. Permission was obtained to use the SF-MPQ for the purposes of research: *copyright R. Melzack 1984, 1987*.

The NRS is a generic, unidimensional assessment that consists of a segmented, 11-point intensity scale (from 0 to 10); it is commonly used to assess pain. The raw change and percent change are calculated taking into account the baseline and endpoint scores selected by the patient⁸.

Results and Discussion:

The patient scored the NRS, PPI and 11 descriptors in the SF-MPQ, before and 7 days after treatment with the transdermal compounded medication. Before treatment, the patient scored 10 in the NRS (worst possible pain) and 5 in the PPI (excruciating pain). Regarding the SF-MPQ, the patient scored 3 (severe pain) for 8 sensory descriptors and 3 affective descriptors. After treatment, the patient scored 0 in the NRS, PPI and all SF-MPQ descriptors. These results demonstrate that the patient's condition improved from the worst possible pain to pain-free, in just 7 days.

Following the first application of the transdermal compounded medication at bedtime, the patient felt immediate relief when he woke up in the morning and did not even take the ibuprofen / omeprazole.

After 3 days of treatment, the patient called the compounding pharmacist to thank him for the "magic foot cream." According to the patient's report, the pain continued to fade from day 3 until the end of the treatment at day 7, when the patient was considered pain-free. Although the patient was still using the Abeo[®] orthotics biomechanical footwear, the cane was no longer necessary as he could walk normally again.

Conclusions:

The patient's self-reported heel pain from plantar fasciitis was reduced to zero in 7 days only following the application of PCCA Formula 12547. The transdermal base Lipoderm[®] ActiveMax[™] is likely to have facilitated the skin permeation of the topical drugs, potentially contributing to greater potency from synergistic effects⁶. There is a need for pain control in plantar fasciitis, a debilitating condition that affects the patient's quality of life, and transdermal compounded medications allow for unique customized treatment options.

References:

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