

PCCA Lipoderm®

Achilles Tendonitis: Pain Management by Compounding

SUMMARY: Currently there is no standard pharmacological therapy with clear evidence to treat Achilles tendonitis. The purpose of this case study is to evaluate the effectiveness of a transdermal formula using Lipoderm® in managing Achilles tendonitis associated pain in two patients. The Victorian Institute of Sports Assessment-Achilles Questionnaire (VISA-A) was used to evaluate the clinical outcome. Following application of the compounded formula, the total VISA-A scores improved from below 10 points to greater than 50 points in both patients, with overall severity of symptoms decreased from 10 and 9 before treatment, to 2 and 1 after treatment, respectively, in these two patients. This case study demonstrated an effective and safe option for pain management in Achilles tendonitis patients by using this compounded formula.

Submitted by: Jim Perry, Compounding Pharmacist at District Drugs & Compounding Center, Rock Island, IL

Introduction:

Achilles tendonitis, also known as Achilles tendinopathy, is inflammation of the tendon and is always associated with acute or chronic pain. The lifetime incidence of Achilles tendonitis in competitive athletes is 24%, and the risk is even higher in runners [1]. Achilles tendonitis also occurs in people with a sedentary lifestyle, with possibility of 5.6% in non-athletes [2].



Figure 1. Anatomy of the Achilles tendon (yellow) and Achilles tendonitis (red).

The Achilles tendon is where the gastrocnemius (calf) muscle and soleus muscle converge and inserts on the calcaneus. Contraction of the muscles pulls the Achilles tendon to cause the foot to plantarflex to allow standing on the tip of toes or pointing the toes (Figure 1.) [2]. Therefore, inappropriate footwear, poor running mechanics, obesity and other factors stressing the tendon can link to an increased risk of Achilles tendonitis. The region at 2 to 6 cm above insertion point of the Achilles tendon is most susceptible to injury and associated with most pain (Figure 1, red) [2]. In addition to pain, swelling, warmth, tenderness and stiffness are the common clinical presentations of Achilles tendonitis, resulting in impairment of physical function and daily life.

The goal of therapy for acute and chronic Achilles tendonitis is to relieve pain and regain function. Treatment

generally consists of rest, ice, a short course of NSAIDs and tendon support. Resistance exercise is usually included in chronic tendonitis therapy [3]. While a number of local injection therapies have been used, such as glucocorticoid injection, platelet-rich plasma injection, etc., so far there is no clear evidence to support the efficacy of any of the pharmacological therapies [3]. Surgery is necessary in some cases.

The purpose of this case study is to present the effectiveness of a compounded formula (Table 1.) in managing pain and minimizing impairment resulted from Achilles tendonitis in two patients.

Rx	
Diclofenac sodium	5 g
Lidocaine USP	2 g
Ethoxy diglycol	10 mL
Base, PCCA Lipoderm®	q.s.

Table 1. Compounded formula for Achilles tendonitis (PCCA formula 13583).

Methodology:

The Victorian Institute of Sports Assessment – Achilles Questionnaire (VISA-A) was implemented to evaluate the symptoms and impact on physical activity of using the compounded formula in Achilles tendonitis management. The VISA-A is a patient self-administered questionnaire containing 8 questions. Three necessary domains are covered by the questions: pain, functional status and activity. The maximum score is 100, meaning completely asymptomatic in all three domains. The minimum score is 0, indicating the worst pain and the greatest limitation of physical activity. Generally an Achilles tendonitis patient will not achieve higher than 70 on the VISA-A scale [4].

Two patients were evaluated by orthopedic doctors and were diagnosed with acute Achilles tendonitis separately. They were instructed to complete the VISA-A retrospectively before and after treatment. Patients were also asked to score their overall severity of symptoms on a 0-10 scale. Written informed consent was obtained from these patients for publication of this case study.

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I. VISA-A	Patient #1		Patient #2	
	Before	After one month	Before	After 8 weeks
1. Pain on first getting up	≥100 min	10 min	90 min	10 min
2. Pain when stretching the Achilles tendon	Pain score 8/10	Pain score 1/10	Pain score 9/10	Pain score 1/10
3. Pain after walking for 30 min	Pain score 9/10	Pain score 1/10	Pain score 10/10	Pain score 1/10
4. Pain walking downstairs in normal gait	Pain score 9/10	Pain Score 5/10	Pain score 9/10	Pain score 2/10
5. Pain during 10 (single leg) heel raises	Pain score 7/10	Pain score 1/10	Pain score 9/10	Pain score 1/10
6. Number of single leg hops without pain	0	5	0	2
7. Current physical activity level	Not at all	Very little	Not at all	Not at all
8. Pain / duration of Achilles tendon loading activity	Sever pain / 0 min	Some pain / 1-10 min	Sever pain / 0 min	No pain / 1-10 min
Total score /100	7	52	4	53
II. Overall severity of symptoms /10	10	2	9	1

Table 2. Clinical outcomes of Achilles tendonitis before and after treatment reported by two patients using VISA-A and overall severity scale.

Case Report:

Patient #1, LC, is a 71-year-old female who presented with pain in one foot for a month. She was initially treated with ice pack and oral NSAIDs, but the pain was not under control. She was diagnosed with unilateral Achilles tendonitis and was started on the transdermal compound. She was instructed to apply 1 to 2 pumps (0.5-1g) to tendonitis area 3 to 4 times daily as monotherapy. After one month, her pain was significantly relieved and the patient was able to resume some activities. Patient's VISA-A score improved from 7 points before treatment, very severe impairment, to 52 points after treatment, meaning tolerable pain in daily physical activities (Table 2). Her self-reported severity of symptoms went from the most severe symptoms, 10 points, down to 2 points, suggesting very minor symptoms. The patient was very pleased with the outcome and the severe pain hasn't recurred since discontinuing the compound.

Patient #2, JJ, is a 66-year-old female who was diagnosed with acute Achilles tendonitis. Her treatment failed with Voltaren® gel 1% initially, and she was later prescribed this compound. After applying 3 to 4 times daily for 8 weeks, the patient's pain level during daily life dramatically decreased, despite no change in her physical activity level. This patient's VISA-A score improved from 4 to 53, suggesting that she was able to resume the majority of her daily life within 8 weeks, considering her sedentary lifestyle. Overall severity of symptoms was reported as 9 before treatment, and only 1 after treatment.

No adverse reactions were reported by the patients.

Discussion and Conclusions:

Achilles tendonitis frequently causes pain and disability, yet is difficult to treat, requiring prolonged rehabilitation with a high risk of recurrence. The etiology of Achilles tendonitis is multifactorial and complicated. No standard treatment is

currently available. Recent studies have identified non-resolving inflammation as a feature of Achilles tendonitis^[5, 6]. Effective pain control in the acute phase associates with better leg function recovery. In this formula, topical diclofenac at 5% is the key component to target inflammation in these two patients. Topical diclofenac at 10% has been shown to significantly improve symptoms of Achilles tendonitis in a small randomized controlled trial^[7]. However, FDA-approved diclofenac gel is only available at 3% or lower, which was the dose patient JJ failed on. The compounded formula gives flexibility to apply sufficient strength based on the patients' response. Moreover, in combination with lidocaine, it can provide synergistic effect in pain control. Lipoderm was the transdermal vehicle to deliver the active ingredients. It is an industry-leading base used in a number of pain management formulations. As a result, this compounded formula successfully helped two Achilles tendonitis patients, who were suffering from severe pain and had both failed conventional therapies, achieve relief from pain. Transdermal delivery of diclofenac and lidocaine by Lipoderm may provide a novel and effective therapy for Achilles tendonitis treatment, and also sheds light on the personalized, anti-inflammatory approach in developing new therapies.

References:

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