

Medical Device containing porcine collagen and ancillary substances in injection treatment for plantar fasciitis

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Key words

Plantar fasciitis, porcine collagen, ancillary substances, Medical Devices.

Abstract

Although cortisone injections can reduce the inflammation of plantar fasciitis, there are certain potentially serious issues associated with their administration in the heel area. In the clinical cases described, considering the duration of the symptoms (about one year in clinical case 1), the efficacy of the treatment with porcine collagen and ancillary substances correlates well with the short time to improvement in pain symptoms, as shown by the decrease in the NRS (Numerical Rating Scale) score, the swift return to occupational activities and the ultrasound findings of normalisation at the insertion of the plantar fascia. At one-year follow-up, the patients did not report any further episodes of pain. Two of the ten cases treated are described here in greater detail.

Introduction

The term “plantar fasciitis” is used to define an inflammatory process involving the plantar fascia (also known as the plantar aponeurosis), the band of fibrous tissue that runs from the medial part of the calcaneus to the metatarsal ligaments. This inflammation usually occurs at the calcaneal insertion (i.e. at the base of the calcaneus, which is less well vascularised), and can be associated with a calcaneal spur, a spike-shaped bone formation that protrudes towards the toes from the medial process of one or both calcanei. Plantar fasciitis can be caused by degenerative changes in the plantar aponeurosis due to repeated microtraumas, which cause an inflammation of the bone (periostitis) secondary to traction of the microtears, or excessive strain on the plantar fascia. This condition is common among athletes (marathon runners, basketball and football players and other athletes who play sports in which the lower limbs are subject to great stress) [1].

According to the national guidelines for the diagnostic imaging of the musculoskeletal system [2]:

Calcaneal spurs are common incidental findings. The cause of the pain can rarely be identified by x-ray.

Ultrasound (US), nuclear medicine (NM) and magnetic resonance (MRI) techniques are more sensitive in revealing inflammatory processes, but should only be used in selected cases. Most patients are treated on the basis of their clinical signs without requiring diagnostic imaging investigations.

Clinical presentation

Plantar fasciitis presents with the gradual onset of pain inside the heel, which causes gait changes in which most of the weight is borne by the forefoot. In the event of a plantar fascia tear, the subject feels an acute “tearing” pain and is no longer able to walk.

The pain symptoms are highly characteristic: upon waking, the subject feels an excruciating pain and is barely able to move, a situation that only improves when the subject has walked, even just a short distance. Calcaneal spur is a mainly degenerative condition, caused primarily by osteoarthritis or the chronic evolution of plantar fasciitis; however, unlike the latter, it can be asymptomatic.

Treatment and care

Plantar fasciitis rarely resolves spontaneously. The immediate treatment usually consists in local application of ice, accompanied by use of a silicone heel pad that acts as a shock absorber. In less severe cases, physical therapy (tecar therapy, massage, ultrasound, laser) combined with stretching of the plantar fascia, Achilles' tendon and calf muscles, as well as use of suitable insoles and local anti-inflammatory injections can be effective. A new therapy was recently introduced, consisting in injections of autologous conditioned plasma (ACP). Calcaneal spurs are treated in much the same way. Therapy can also include treatment with shock waves, which may reduce the symptoms and yield good results; however, this procedure can result in bruising, swelling, pain, numbness and tingling, and is not always effective. When the condition is severe, or is refractory to the treatments described above, the available options include a surgical procedure, known as plantar fascia release (in which incisions are performed making it possible to release and stretch the plantar fascia). When a calcaneal spur is present, it will be removed during the same procedure. Recovery time is approximately 6 months. Unfortunately, recurrences are common and the problem may represent a few months later. However, many of these recurrences can be attributed to carelessness during the postoperative period (which is delicate in these cases) or a premature return to sports activities, which are often resumed even before the pain symptoms have fully regressed [3,4]. Two of the ten cases treated are described below.

Clinical case 1

58-year-old male patient, a warehouse manager, weight 98 kg, height 173 cm. Approximately 6 years ago, the patient experienced pain in his heel, which was treated with ultrasound. Arthroscopic treatment for a meniscal tear. Right hip replacement. Right retinal detachment. No allergies reported. The pain symptoms returned about a year ago. They recently became worse, with intense pain on waking (> on the left), for which he "could barely move", and which subsided partly after walking. (Figure 1). Manual loosening manoeuvres were performed and physiotherapy exercises and static and dynamic baropodometric analyses were prescribed. Injection, using a mesotherapy needle, of 2 vials of MD-MUSCLE (collagen + Hypericum; GUNA S.p.a Milan, Italy). + 2 vials of MD-MATRIX (collagen + citric acid and nicotinamide;

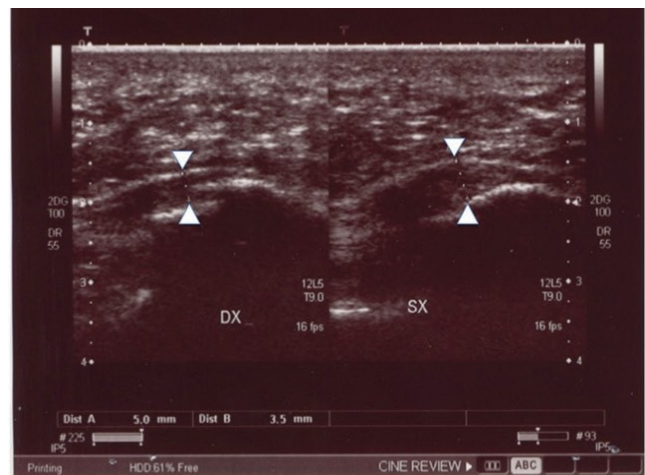


Fig. 1: Pretreatment ultrasound scan, clinical case 1: The ultrasound study shows a thickening and enhanced hypoechoogenicity of the calcaneal insertion of the plantar fascia, which is more pronounced on the left, consistent with fasciitis (the arrows indicate the thickness of the tendon at the insertion).

Procedure: x-ray of the right and left feet, ultrasound scan of right and left calcanei

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The x-rays of the right and left foot (full material on CD) did not show any focal bone lesions.
 Bilateral ossification of the calcaneal insertion of the Achilles' tendon.
 Bilateral plantar calcaneal bone spur.
 Mural calcifications along the arterial vascular axes.

The ultrasound study revealed a thickening and enhanced hypoechoogenicity of the calcaneal insertion of the plantar fascia, which is more pronounced on the left, consistent with fasciitis.

Fig. 2 – Dynamic baropodometric analysis, clinical case 1: weight-bearing changes in which more weight is put on the left foot.

GUNA S.p.a Milan, Italy). Decrease in NRS score from 10 to 7. Prescription of sublingual palmitoylethanolamide (PEA) 600 mg bid. Insoles prescribed on the basis of the baropodometric analysis (Figures 2 and 3). Three further injections, using a mesotherapy needle, administered to the heel with: 2 vials of MD-MUSCLE + 2 vials of MD-MATRIX. NRS = 6.5 (26.05.2011) Injections administered, using a mesotherapy needle, to the heel with 2 vial of MD-MUSCLE + 2 vials of MD-MATRIX + 1 vial of MD-POLY (collagen + drosera; GUNA S.p.a Milan, Italy) + perimalleolar injection: Decrease in NRS score from 6 to 3 (28.06.2011). Continued sublingual PEA 600 mg bid for 4 weeks. Follow-up ultrasound scan (Figure 4): 14.07.2011 (NRS=2).

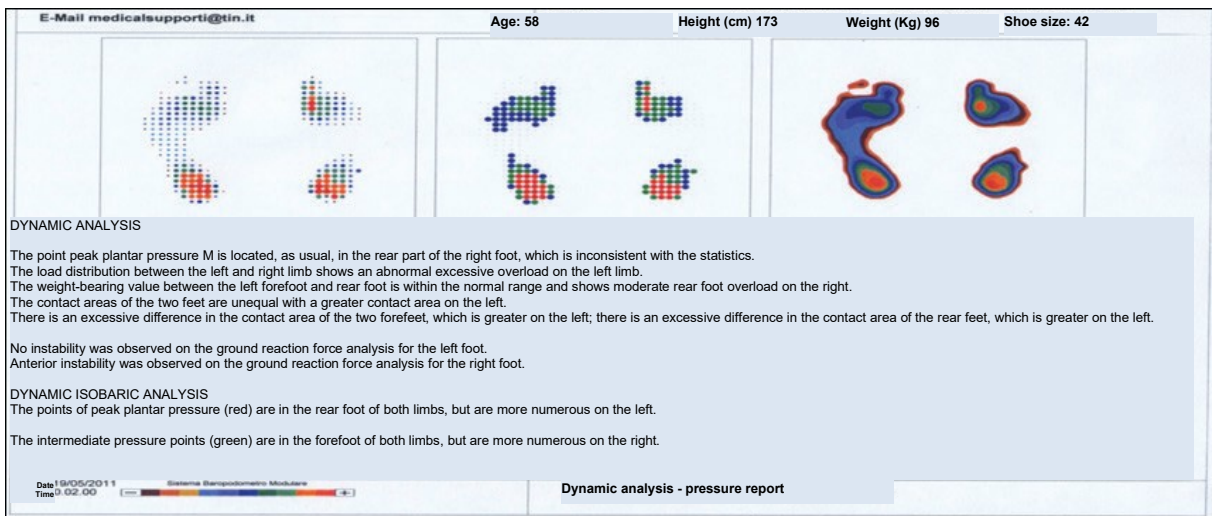


Fig. 3 Static baropodometric analysis, clinical case 1: abnormal distribution between forefoot and rear foot, with excessive weight-bearing on the forefoot.

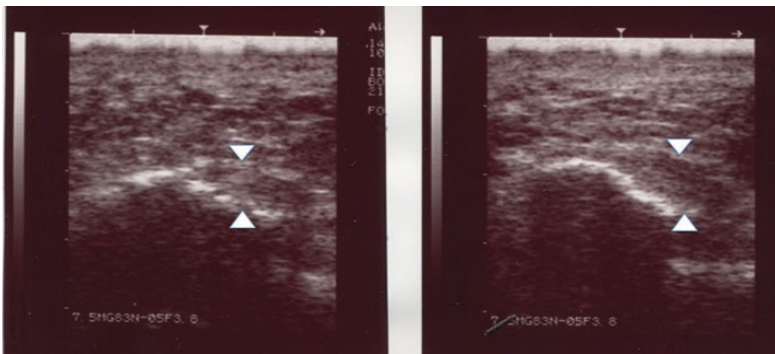


Fig. 4 Ultrasound scan, clinical case 1: the follow-up ultrasound scan shows the normalisation of the calcaneal insertion of the plantar fascia. There is no evidence of overdilatation of the bursae.

The follow-up ultrasound scan of the left calcaneus shows the normalisation of the calcaneal insertion of the plantar fascia. There is no evidence of overdilatation of the bursae.

Clinical case 2

Female patient, works in an office, weight 80 Kg, height 165 cm, appendectomy, right shoulder rotator cuff tear, haemorrhoidectomy, atrial septal defect with mild ectasia of the thoracic aorta, hypothyroidism (Levothyroxine sodium 50 µg 3 days + 75 µg 4 days a week + Zn, Mg, Se, I and vitamin E, D, B1, B2, B6 and B12 supplementation 3 days a week).

Sudden onset of intense pain in the right plantar area exacerbated by walking and on account of which the patient "could barely move". The laterolateral weight-bearing x-ray of the right foot showed a "reduction of the longitudinal arch under weight-bearing conditions. No focal bone lesions observed. Plantar calcaneal osteophyte". The ultrasound study revealed "thickening and enhanced hypoechoogenicity of the plantar fascia consistent with fasciitis" (Figure 5).

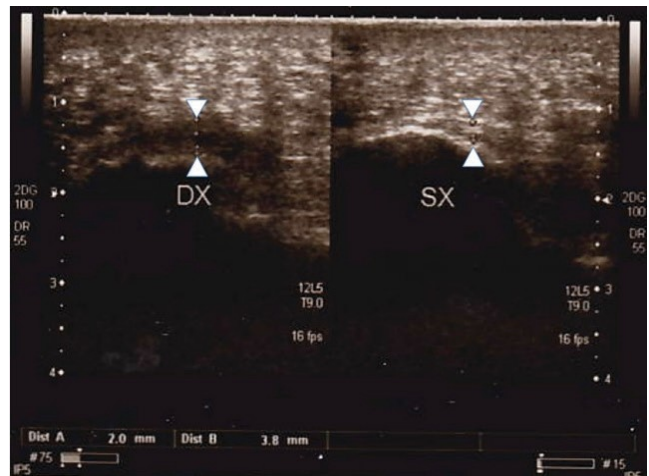


Fig. 5 Pretreatment ultrasound scan, clinical case 2: Thickening and enhanced hypoechoogenicity of the calcaneal insertion of the plantar fascia consistent with fasciitis.

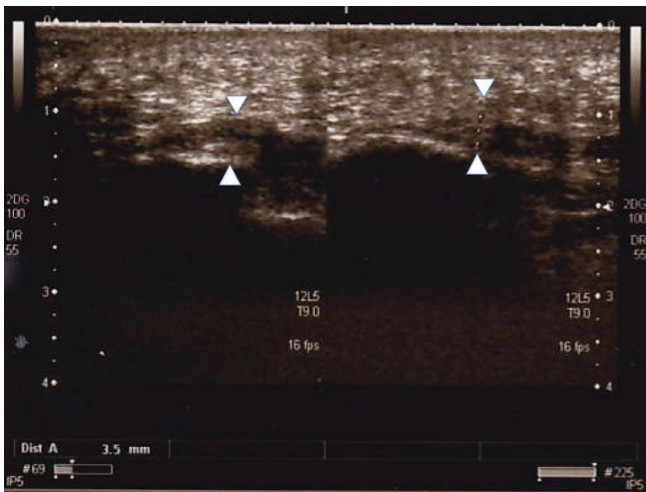


Fig. 6 Follow-up ultrasound scan after 12 days, clinical case 2: Reduction in the hypoechoogenicity at the insertion of the right plantar fascia

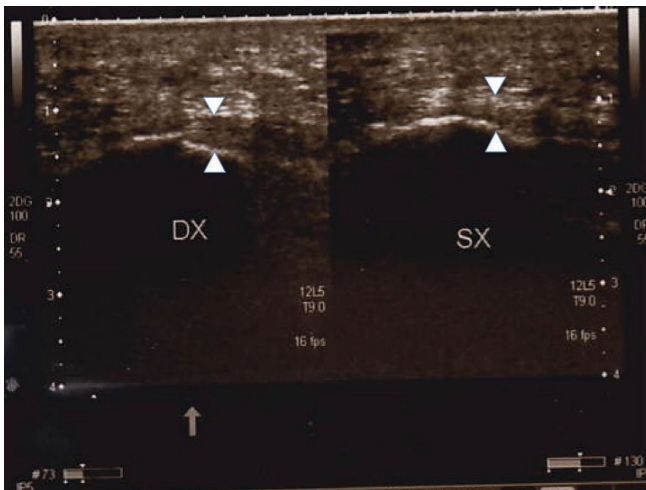


Fig. 7 Follow-up ultrasound scan after 20 days, clinical case 2: Normalisation of the ultrasound findings for the calcaneal insertion of the right plantar fascia.

Manual loosening manoeuvres were performed and physiotherapy exercises and static and dynamic baropodometric analyses were prescribed. Injection with mesotherapy needle of 2 vials of MD-MUSCLE + 2 vials of MD-MATRIX. Decrease in NRS score from 10 to 7. Prescription of sublingual palmitoylethanolamide (PEA) 600 mg bid. Follow-up ultrasound after 12 days "Reduction in the hypoechoogenicity at the insertion of the plantar fascia" (Figure 6). Injection, with mesotherapy needle, in the heel with: 2 vials of MD-MUSCLE + 2 vials of MD-MATRIX. VAS = 6. Further injection with mesotherapy needle in the heel with 2 vials of MD-MUSCLE + 2 vials of MD-MATRIX + 1 vial of MD-POLY: decrease in NRS score from 6 to 2. Continued sublingual PEA 600 mg bid for four weeks. Follow-up ultrasound scan after 20 days: "Normalisation of the ultrasound findings for the plantar fascia" (Figure 7).

Discussion

The collagen used is of porcine origin, that most similar to the collagen present in the human body, contaminant-free, with standardised molecular weight and chemical and physical characteristics and it can be used for periarticular, intra-articular, intramuscular and intradermal administration [5]. The "ancillary substances" or carriers (Hypericum, Citric acid, Nicotinamide, Drosera), were chosen on the basis of various criteria, such as conventional use, dedicated literature, clinical studies and quality profiles. They permit a better, more targeted "in situ" positioning of the collagen, in order to improve the histological condition of the anatomical structures, in which it is present, and of the collagen itself, as well as to provide a mechanical support with evident positive effects on the stabilisation of joint mobility, pain and quality of life.

The availability of Collagen Medical Devices for local injection is a decisive factor in the repair process that follows anti-inflammatory intervention. The slack articular-support elements cause local nociceptor stimulation, as well as excessive tension and stress, which explains why reinforcing these structures has a regenerative, as well as an analgesic, effect. [6]

The contribution of PEA warrants more thorough investigation. Although it was initially thought to play a primarily anti-inflammatory role, by down-modulating inflammatory mediator release by the mast cells and macrophages, it is now thought to play a key role in regulating the processes underlying the neurogenic and neuropathic pain, as well as being involved in protection mechanisms such as ALIA (Autacoid Local Injury Antagonism). Although cortisone injections can reduce the inflammation of plantar fasciitis, there are certain potentially serious issues associated with their administration in the heel area. The two issues that are cause for concern are the atrophy of the plantar fat pad and fascial tear. Both occur in a very small percentage of patients, but can cause a worsening in the pain symptoms in the heel. Although steroid injections and iontophoresis can lead to a significant improvement in the foot pain that accompanies in plantar fasciitis, both approaches warrant further investigation. As observed by Crawford and Gudeman, steroid therapy for plantar fasciitis plays a significant role in short-term therapy [7; 8]. However, a series of complications have been reported, including plantar fascia tear, plantar fat pad atrophy, lateral plantar nerve injury secondary to injection, calcaneal osteomyelitis and, with iontophoresis, burning of the skin below [8; 9-14].

Conclusions:

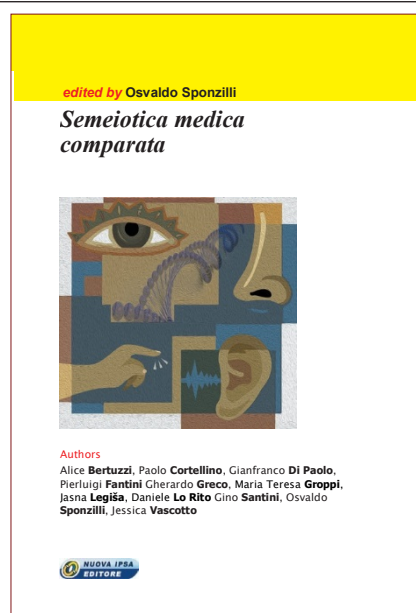
In clinical case 1, considering the duration of the symptoms of about one year, the efficacy of the treatment correlates well with the short time to improvement in pain symptoms, as shown by the decrease in the NRS score, the swift return to occupational activities and the ultrasound finding of a normalisation of the insertion of the plantar fascia.

At one-year follow-up, the patient did not report any further episodes of pain. In clinical case 2, the sudden onset of the symptoms and their rapid resolution, as confirmed by ultrasound, show the efficacy of the treatment described. At one-year follow-up, the patient did not report any further episodes of pain. The treatment was well tolerated with a complete absence of undesirable effects and adverse reactions.

References

- Cluett J. Plantar fasciitis. Disponibile a: <http://orthopedics.about.com/od/footankle/a/fasciitis.htm>.
 La diagnostica per immagini Ministero della Salute. Disponibile a: www.salute.gov.it/imgs/c_17_pubblicazioni_1164_allegato.pdf.
 Craig C Y. Plantar Fasciitis Treatment & Management. Disponibile a: <http://emedicine.medscape.com/article/86143-treatment>.
 van de Water AT, Speksnijder CM. Efficacy of taping for the treatment of plantar fasciosis: a systematic review of controlled trials. *J Am Podiatr Med Assoc.* 2010;100(1):41-51.
 Urgelles LA. Inflammation-New trends in assessment and control at the physiological level. *Physiological Regulating Medicine* 2011;1:37-41.
 Ottaviani M. Trattamento delle patologie articolari con collagen medical devices. – studio clinico su 257 pazienti. *La Med. Biol.*, 2014;3:11-21.
 Crawford F, Atkins D, Young P, Edwards J. Steroid injection for heel pain: evidence of short-term effectiveness. A randomized controlled trial. *Rheumatology (Oxford).* 1999;38(10):974-7.
 Gudeman SD, Eisele SA, Heidt RS Jr, Colosimo AJ, Stroupe AL. Treatment of plantar fasciitis by iontophoresis of 0.4% dexamethasone. A randomized, double-blind, placebo-controlled study. *Am J Sports Med.* 1997;25(3):312-6.
 DeMaio M, Paine R, Mangine RE, Drez D Jr. Plantar fasciitis. *Orthopedics.* 1993;16(10):1153-63.
 Acevedo JI, Beskin JL. Complications of plantar fascia rupture associated with corticosteroid injection. *Foot Ankle Int.* 1998;19(2):91-7.
 Sellman JR. Plantar fascia rupture associated with corticosteroid injection. *Foot Ankle Int.* 1994;15(7):376-81.
 Leach R, Jones R, Silva T. Rupture of the plantar fascia in athletes. *J Bone Joint Surg Am.* 1978;60(4):537-9.
 Snow DM, Reading J, Dalal R. Lateral plantar nerve injury following steroid injection for plantar fasciitis. *Br J Sports Med.* 2005;39(12):e41; discussion e41.
 Gidumal R, Evanski P. Calcaneal osteomyelitis following steroid injection: a case report. *Foot Ankle.* 1985 Aug;6(1):44-6.

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Semeiotics comes from Greek and means *study of signs*. Indeed, it concerns the study of clinical signs and symptoms. In his writings, Hippocrates, the father of medicine, described a very thorough clinical examination, including auscultation, palpation, percussion and, above all, the collection of even the slightest clue that can be of use when formulating a diagnosis: the hues of the skin, changes in emotional and psychological behaviour, muscle contractions, secretions and excretions. This method of investigation was based primarily on fully-comprehensive observation; it focused on the individual, the person presenting the disease and the corresponding symptoms. Hippocrates' art was the art of observing, diagnosing and treating.

Over the past 50 years, medical schools have abandoned the study of semeiotics to may way for instrumental investigations and technology, resulting in doctors no longer being able to grasp the subjective and objective signs of imbalance and disease. This book aims to recover all the semeiological methods pertaining to the various forms of medicine, in order to acquire an integrated semeiotics that allows the reader to rediscover the true essence of medicine. An objective that it achieves by balancing the holistic approach that characterises complementary medicine with “technological” clinical practice. This integration can give new life to a form of medicine that is more humane and global, in the truest sense of the word, a form of medicine that respects the individual biography that always goes hand-in-hand with the biopathology of an individual in a state of suffering.

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