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Ultrasound-guided collagen injections for treatment of plantar fasciopathy in runners: A pilot study and case series

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ABSTRACT

Background. Plantar fasciopathy is a frequent source of foot pain in athletes, and it is caused by the degeneration of the proximal insertion of the plantar fascia, usually triggered by repetitive microtrauma. Type I porcine collagen was shown to enhance tendon repair in vitro, and collagen injections are currently used to treat different tendinopathies. The aim of this study is to verify the effectiveness of collagen injections on pain and function in runners with plantar fasciopathy. Methods. Runners, who have been suffering from plantar fasciopathy for at least 6 months, were treated with a series of 4 ultrasound-guided type I porcine collagen injections, at weekly intervals. The Visual Analogue Scale, American Orthopedic Foot and Ankle Society-Ankle Hindfoot score and pressure algometry were used to verify the effects of collagen injections at 1-month and 3-month follow-up. Results. Compared to baseline, minor ($p \geq .05$) and major ($p \leq .001$) improvements on pain and function were registered at 1-month and 3-month follow-up, respectively. Conclusion. This is the first study that evaluates the effectiveness of collagen injections in the treatment of plantar fasciopathy in runners. Despite the limitations of this study, the positive findings could represent the starting point for further clinical trials.

Keywords: Plantar fasciitis; Plantar fasciopathy; Chronic plantar fasciitis; Athletes; Runners; Collagen injections.

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INTRODUCTION

Plantar fasciopathy (PF) is a musculoskeletal condition that affects the plantar fascia, which is a thick band made by connective tissue that runs from the calcaneal tuberosity forward to the heads of the metatarsal bones, helping to maintain the stability and the arch of the foot (Hormozi et al., 2011; Petraglia et al., 2017). The plantar fascia is divided into three cords, with the central one being the thickest and the most often injured (Meyer et al., 2018). PF was formerly known as "plantar fasciitis", but this term is obsolete, since inflammation is absent in this condition. Nowadays PF is considered a degenerative pathology, more similar to tendinopathy and to a chronic disease, which involves the site of the attachment of the plantar fascia at the medial tubercle of the calcaneus (Petraglia et al., 2017).

PF is a common cause of foot pain in adults, usually a plantar-medial heel pain, typically after a long weight-bearing phase, and it usually worsens the patients' quality of life (Alrashidi et al., 2016; Irving et al., 2008). It has been reported that 10% of people may suffer from symptoms of PF during their lifetime (Monteagudo et al., 2018; Riddle et al., 2003). PF affects both sexes, ranging from sedentary individuals to athletes, with women being affected slightly more often than men (Orchard, 2012; Taunton et al., 2002). The peak incidence of PF occurs in people aged between 45 and 65 years (Riddle and Schappert, 2004). PF is experienced in both recreational and elite athletes and is reported in different sports (Orchard, 2012). A recent review concerning ankle and foot injuries in sport pointed out that PF is mainly reported in runners (Sobhani et al., 2013). The incidence of PF in runners ranges from 4.5 to 10%, and represents the third most frequently experience running-related musculoskeletal injuries (Lopes et al., 2012). A recent prospective study analysed the novice running-related injuries, revealing that PF accounts for about 5% (Nielsen et al., 2014). In ultra-marathon runners PF has an incidence of about 11% (Hoffman and Krishnan, 2014). In runners, PF seems to be associated with overuse, training errors, and improper or excessively worn footwear (Rompe, 2009).

Diagnosis of PF is essentially clinical (Oliva et al., 2017). The cardinal symptom of PF is the intense and acute heel pain localized primarily where plantar fascia attaches to the anterior calcaneus (Petraglia et al., 2017). A runner typically reports a sensation of pain over the plantar aspect of the foot, typically worse with initial morning ambulation and improved during the course of a run, with worsening pain after discontinuation of activity (Tenforde et al., 2016). Foot stiffness and heel swelling are also present (Goff and Crawford, 2011). The Windlass test can be performed to confirm the diagnosis, although it has a low sensitivity (De Garceau et al., 2003).

In the case of uncertain diagnosis or when patient presents a persistent heel pain, instrumental analysis can be performed (Petraglia et al., 2017). Diagnostic imaging is recommended when patient suffers of persistent heel pain after 4-6 months of conservative approaches or in case of atypical symptoms or signs (Neufeld and Cerrato, 2008). Plain radiography, magnetic resonance imaging (MRI), diagnostic ultrasonography (US), nerve conduction study and bone scans can be carried out for differential diagnosis (Petraglia et al., 2017). US is a very useful, non-invasive, well-tolerated and reliable tool to confirm the diagnosis (Alrashidi et al., 2016; Lim et al., 2016). It can be used for follow-up and monitoring the improvement after initiation of therapy (Alrashidi et al., 2016). US features of PF include a thickened (> 4 mm) and hypoechoic aponeurosis close to its calcaneal attachment (Elias et al., 2013). Shear wave elastography (SWE) allows quantitative assessment of the stiffness of the plantar fascia and can highlights the classic alterations of PF (Corrado et al., 2019; Schillizzi et al., 2020; Vola et al., 2018). Contrary to popular belief, recent studies have demonstrated no correlation between fascial thickness and degree of symptoms (Meyer et al., 2018).

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The crucial aims of PF management are the reduction of pain, the improvement of quality of life, including both the return to daily physical activity and physical fitness (; (Petraglia et al., 2017). Around 90% of patients with PF will find that their symptoms resolve within 12 months with conservative treatment (Crawford and Thomson, 2003), but about one tenth of cases may fail to respond to it. The first level of treatment would include the use of non-steroidal anti-inflammatory drugs (NASAIDs), specific physical exercises (such as stretching of the plantar fascia), foot insoles, night splints, ice massage, and patient's instructions to lose weight, activity modifications, and not to use flat shoes or walk barefoot (Akınoğlu and Köse, 2018; Celik et al., 2016; Cinar et al., 2018; Huffer et al., 2017; Lim et al., 2016, 2016; Montesano et al., 2020; Oliva et al., 2017; Palermi et al., 2020; Sirico et al., 2018). Other treatment options are local injections of corticosteroids (CSs) (Gurcay et al., 2017), anaesthetic, and botulinum toxin (Ahmad et al., 2017); extracorporeal shock wave therapy (Corrado et al., 2019; Hsu et al., 2018; Reilly et al., 2018); ultrasound scanning; radiofrequency ablation (Akınoğlu and Köse, 2018; Ozan et al., 2017); cryopreserved human amniotic membrane injections (Hanselman et al., 2015); prolotherapy (Kim and Lee, 2014; Ryan et al., 2009); ozone injections (Bahrami et al., 2019); hyaluronic acid injections (Kumai et al., 2018); platelet-rich plasma injections (PRP) (Chen et al., 2019; Franceschi et al., 2014; Singh et al., 2017; Sirico et al., 2017; Soraganvi et al., 2019); and surgical, such as endoscopic release (Al-Ashhab et al., 2018; Bernhard et al., 2018; Oliva et al., 2017). However, as yet, there is no consensus regarding the optimal treatment method (Corrado et al., 2019, Eftekharsadat et al., 2016; Kiter et al., 2006; Say et al., 2014).

To our knowledge, only one study by Kim et al. (Kim et al., 2016) explored the effects of collagen injections for PF after unsuccessful conservative treatment with NSAIDs, night splints, and stretching exercises for at least 3 months, reporting an increased tissue elasticity after treatment. Given the degenerative nature of PF, that encompasses collagen degeneration, the rationale behind the use of collagen injections is that collagen is a major extracellular matrix component in tendons and ligaments, and it contributes to the entrapment, local storage, and delivery of growth factors and cytokines. Collagen also plays an important role in organ development, wound healing, and tissue repair (Hay, 1981). Injectable collagen is used to treat different tendinopathies (Corrado et al., 2020; Corrado et al., 2019), because of its ability to stimulate synthesis, maturation and secretion of endogenous type I collagen (Randelli et al., 2018).

The aims of this prospective pilot study and case series are: (a) to evaluate the effectiveness of US-guided collagen injections in the treatment of PF in a group of runners, and (b) to examine the feasibility of such an intervention that is intended to be used in a larger scale and higher quality studies.

No studies on the effectiveness of collagen injections in treating PF in runners have been published to date.

MATERIALS AND METHODS

This is a prospective observational pilot study carried out at the Federico II University Hospital of Naples, Italy. The subjects of our study were all outpatients, enrolled from September 2019 to November 2019. The patients were non-professional marathon runners who have been suffering from PF for at least 6 months. All patients underwent US and X-ray before the enrolment.

The inclusion criteria were: age > 18 years, pain over the plantar aspect of the foot (typically worse with initial morning ambulation and improved while running), sharp pain elicited by palpation of the medial plantar calcaneal region, a positive Windlass test, US evidence of increased plantar fascia thickness, and lack of therapy in the last 6 months.

The exclusion criteria were: previous foot and ankle surgery, inflammatory arthritis, X-ray evidence of heel spur, and previous fractures, bone tumours or osteonecrosis of the ankle and foot.

After a full and clear description of the study protocol, all the enrolled patients were invited to sign the informed consent. The study was carried out in accordance with the principles of the Declaration of Helsinki and met the ethical standards of the local ethics committee.

Ten patients were enrolled (7 males and 3 females), with an average age of 34 ± 8 years. Regarding the treatment, four US-guided injections of 2 ml porcine type I collagen were planned once a week. All injections were performed by a single physician with over ten years of experience. There is strong evidence that the accuracy of US guidance is greater than that of palpation guidance (Hall, 2013). Injections were performed with the patients lying face down on the examination table. A 22-gauge needle was inserted with a medial approach under US guidance, aligned to the long axis of the US transducer. The needle was directed anteriorly to the insertion of the plantar fascia on the calcaneal bone, in the region of the maximal thickness of the fascia. When the tip of the needle was seen in the correct position, then collagen was slowly injected.

Patients were invited to not rest after each injection, but only to avoid foot and ankle overloading for 24 hours. Patients were advised to interrupt their sporting activities during the treatment and until the last follow-up. No other treatment was associated with collagen injections.

Patients were evaluated at the time of enrolment (T0), one month (T1) and three months (T2) after the last injection. Pain was assessed using the 10 cm-Visual Analogue Scale (VAS) and the pressure algometry. Assessment of function was conducted using the Italian version of the American Orthopedic Foot and Ankle Society – Ankle-Hindfoot (AOFAS-AH) score.

Pressure algometry is a semiquantitative method used to evaluate the pain threshold in tissues. The pressure algometry has been validated to determine pain threshold (Walton et al., 2011; Ylinen et al., 2007), and it has been found repeatable and stable (Frank et al., 2013). The pressure algometer used in this study was a Force Dial™ FDK 20 (Wagner Instruments, Greenwich USA). The pressure was measured in kilogram per square centimetre (Kg/cm^2). The measurement was conducted on the most sensitive point of the plantar fascia. The algometer contact head was aligned perpendicularly to the skin and the pressure gradually increased until the patient reported pain (i.e. pain tolerance). This process was repeated three times at the same point on the plantar fascia, then an average of the three readings was recorded. Higher algometer scores indicated greater pressure threshold and less tenderness, and vice versa.

The AOFAS-AH score comprises nine questions and covers three categories: pain (40 points), function (50 points) and alignment (10 points), for a total of 100 points. Although it has yet to be validated, the AOFAS-AH is one of the most widely-used score in clinical studies concerning ankle and foot, and it remains in use at a substantially higher rate than other scales that have been validated (Leigheb et al., 2016).

Results were calculated as mean and standard deviation. Statistical significance was analysed by one-way nonparametric ANOVA (Kruskal Wallis test). The confidence interval was established at 95% ($p < .05$). Statistical analysis was performed using IBM SPSS version 20 for Windows.

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RESULTS

Means and standard deviations of VAS, pressure algometry, and AOFAS-AH are listed in Table 1.

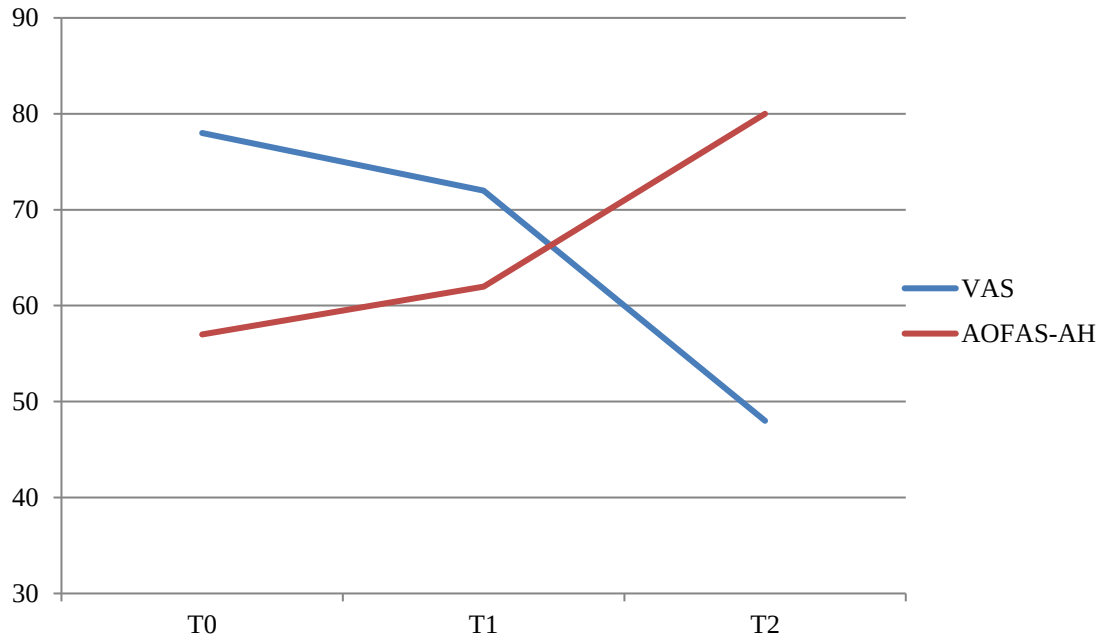
Table 1. Means and standard deviations of VAS, pressure algometry, and AOFAS-AH at different follow-up times.

Outcome measures	T0	T1	T2
VAS 0-10	7.8 ± 0.79	7.2 ± 0.63 Δ = 7.7% p = .98	4.8 ± 0.79 Δ = 38.5% p < .001
Pressure algometry kg/cm^2	4.45 ± 0.29	4.65 ± 0.26 Δ = 4.5% p = .11	5.2 ± 0.2 Δ = 16.9% p < .001
AOFAS-AH 0-100	57.4 ± 4.09	62.3 ± 3.74 Δ = 8.5% p = .19	80.8 ± 3.26 Δ = 40.8% p < .001

Note: VAS = Visual Analogue Scale; AOFAS-HF = American Orthopedic Foot Ankle Society – Hind Foot; Δ = relative delta.

At the baseline, mean scores of VAS, pressure algometry, and AOFAS-AH were 7.8, 4.45 Kg/cm^2, and 57.4, respectively.

At 1-month follow up, evaluation of VAS and pressure algometry showed a not statistically significant improvement in pain relief (mean VAS score = 7.2; mean algometry score = 4.65 Kg/cm^2). Regarding the improvement of function, the average AOFAS-AH at T1 was 63.3, and even in this case the difference was not statistically significant (p = .19).



Note: VAS = Visual Analogue Scale; AOFAS-HF = American Orthopedic Foot Ankle Society – Hind Foot.

Figure 1. Trends of VAS and AOFAS-AH over time.

At 3-month follow up, improvement in pain and function became greater and statistically significant. The average scores of VAS, pressure algometry, and AOFAS-AH were 4.8, 5.2 Kg/cm^2, and 80.8, respectively ($p < .001$). Trends of VAS and AOFAS-AH over time are shown in Figure 1.

No adverse event was reported after collagen injections, except for some cases of burning sensation at the injection site which resolved spontaneously in a few hours.

DISCUSSION

PF is a common cause of heel pain and foot impairment in both élite and recreational athletes. Different approaches are available for the treatment of PF, either conservative and surgical. Approximately 90% of patients with PF can be successfully treated without surgery (Monteagudo et al., 2018).

Injections are one of the several conservative interventions used to treat PF, with CSs and PRP being the most commonly administered drugs.

Several studies showed that CSs injections provide pain relief in the short term, but they do not provide a long-lasting effect (no more than one month) and could carry some risk of complications such as plantar fascia rupture and plantar fat pad atrophy (David et al., 2017; Tatli and Kapasi, 2009).

PRP injections seem to be a safer modality when compared to CSs injections, and it was suggested that PRP affects collagen catabolism and irregular vascularization in chronic PF (Monto, 2013). A recent systematic review pointed out that PRP injections were associated with improved pain and function at 3-month follow-up (Singh et al., 2017). However, adverse event rates and costs of PRP injections for the treatment of PF have not been properly analysed.

To our knowledge, in the current scientific literature only one study by Kim et al. reported the outcomes of collagen injections for treating PF, but not in athletes (Kim et al., 2016). Kim and colleagues evaluated the effectiveness of a series of three collagen injections in the treatment of PF using US elastography. Patients showed significantly increased strain ratios in their calcaneal insertions after collagen injections, proving the regenerative effect of such a therapy (Kim et al., 2016).

In our pilot study, we wanted to evaluate the effectiveness of collagen injection therapy in a group of ten runners affected by chronic PF (four injections of type I porcine collagen, once a week).

A direct comparison of results is possible only with the study by Kim et al., even if the assessment tool is a little bit different. In the study by Kim et al., the pain relief was assessed using the 100 mm-VAS three months after the last collagen injection (Kim et al., 2016). The mean 100 mm-VAS scores were, before and after treatment, respectively 71.8 and 43.9. A 38.9% reduction of the pain score was registered. In our study, the mean VAS scores were 7.8 and 4.8 at T0 and T2 (3-month follow-up), respectively. We observed a 38.5% reduction of the pain after treatment. Therefore, the results between our study and the one by Kim and colleagues are totally comparable (M. Kim et al., 2016).

Our results can be also compared with those of different injectable therapies frequently used for the management of PF.

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Jain et al. aimed to compare the efficacy of PRP to traditional CS injection in the treatment of chronic PF at three, six and twelve months after injection (Jain et al., 2015). Patients were assessed using the 10 cm-VAS for pain and the AOFAS-AH score for function.

The CSs group had a pre-treatment average score of 8.27 and 56.70 for VAS and AOFAS-AH respectively, while the PRP group had a pre-treatment average score of 8.30 e 58.63 for VAS and AOFAS-AH respectively. At three months post-treatment, the VAS and AOFAS-AH average scores improved, respectively, to 2.83 and 86.37 as regards to the CS group, and improved, respectively, to 3.50 and 83.70 as regards to the PRP group.

Comparing our results with those achieved by Jain et al., we can state that collagen injections at 3-month follow-up reach the same pain relief and function restoration similar to those of PRP injections (Jain et al., 2015).

Mahindra et al. compared the effects of PRP and CSs injections in the treatment of chronic PF. Patients were assessed using the 10 cm-VAS for pain and the AOFAS-AH score before injection, at three weeks, and at 3-month follow-up (Mahindra et al., 2016).

Mean VAS score in the PRP and CSs groups decreased, respectively, from 7.44 and 7.72 at the pre-injection time to 3.76 and 2.84 at 3-week follow-up and, respectively, to 2.52 and 3.64 at 3-month final follow-up. Mean AOFAS-AH score in the PRP and CSs groups improved, respectively, from 51.56 and 55.72 at the pre-injection time to 83.92 and 86.6 at 3-week follow-up and, respectively, to 88.24 and 81.32 at the final 3-month follow-up. The authors concluded that PRP injection is as effective or more effective than CSs injection in treating chronic PF.

In comparison to our findings, we can state that CSs are slightly more effective for pain relief and functional improvement in the short term compared to PRP and much more effective compared to collagen but, at an intermediate term, PRP and collagen are more effective than CSs, especially regarding the disability reduction.

Summarizing, CSs injection resulted in short-term benefit (no more than 1 month) with an associated increased risk of rupture of the plantar fascia and fat pad atrophy especially if frequently repeated, whereas PRP injections were associated with improved pain and function at 3-month follow-up even if no clear information regarding adverse event rates or costs have been provided until now.

In our pilot study, adverse events were not observed neither during nor after the treatment, and the cost-benefit ratio was judged positive by the enrolled patients.

The preliminary findings of our study let us suppose that collagen injections are useful for treating PF. Since collagen is a structural protein of the plantar fascia, injectable collagen works not just healing, but also restoring the tissue's native function. Endogenous collagen synthesis, maturation, and secretion are also stimulated by injectable collagen, thus favouring plantar fascia repair. The effectiveness at the intermediate term and the lack of side effects could be explained on the basis of the above-mentioned reasons.

The present study has some limitations: (a) a small sample, (b) the lack of a control group, and (c) the short follow-up time. However, it should be highlighted that this is a pilot study and that is, to our knowledge, the only study on the effectiveness of collagen injection therapy for PF in athletes.

In conclusion, our pilot study pointed out that a series of four type I porcine collagen US-guided injections, at weekly intervals, is able to reduce significantly pain symptoms and to improve function in a group of 10 runners with PF at 3-month follow-up.

Higher quality studies with a greater number of patients are needed to confirm our preliminary studies and draw more definitive conclusions on the role of collagen injections in the management of PF.

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