

## Treatment of Achilles Tendinopathy with Autologous Adipose-derived Stromal Vascular Fraction: Results of a Randomized Prospective Clinical Trial

Laura de Girolamo, PhD, Miriam Grassi, Marco Viganò, Carlotta Perucca Orfei, Umberto Alfieri Montrasio, Federico Usuelli, MD

Galeazzi Orthopaedic Institute, Milan, Italy.

**Objectives:** Achilles tendinopathy commonly occurs in both active and inactive persons. It consists in the development of pain and inflammation in the early phases, with progression to the development of fibrotic tissue and degeneration of tendon matrix. Current conservative treatment approaches do not provide sustained satisfactory results, particularly in active patients, although platelet rich plasma (PRP) injection have shown to be effective in many cases. The therapeutic effect of adipose-derived mesenchymal stem cells (ASCs), either expanded or used directly within the stromal vascular fraction (SVF), have demonstrated to possess significant anti-inflammatory and immunomodulatory effects, mediated by the release of active factors, and thus potentially useful in the treatment of tendinopathy.

**Methods:** Patients affected by non-insertional Achilles tendinopathy (range 18-55 y/o) were prospectively enrolled in this controlled study, and randomly assigned either to single PRP injection group (GPSIII kit, Biomet, USA) (n=28 tendons) or single adipose tissue SVF (FastKit, Corios, Italy) (n=28 tendons) injection group. All patients were assessed clinically pre-operatively and at 15, 30, 60, 120 and 180 days from treatment, using VAS Pain, VISA-A, AOFAS and SF-36 forms. Patients also underwent to US and MRI before treatment and then at 4 and 6 month-follow-ups. An aliquot of SVF of each patient was analyzed in vitro for mesenchymal stem cells (MSC) content, viability, proliferation rate, differentiation potential and immunomodulatory ability. Sample size of the study was calculated with a power analysis based on VISA-A score. All the results are expressed as mean  $\pm$  standard deviation. A Wilcoxon test for paired data was performed to compare variables before and after surgery.

**Results:** Population background data and pre-operative scores were similar in the two groups ( $p>0.05$ ). At final follow up both patients group showed significantly improvements in all the scores in comparison to baseline ( $p<0.05$ ). In SVF patients these improvements were faster, with significantly better scores with respect to pre-injection level already starting 15 days after treatment. Indeed at this time point a significant difference between groups in term of VAS, AOFAS and VISA-A score was observed ( $p<0.05$ ), with better results in the SVF group. After 6 months MR and ultrasounds showed an improvement of clinical signs in both groups, without relevant differences. No side effects were observed in neither groups. In vitro analysis showed a modest content of MSCs in the SVF samples; however these cells were able to efficiently proliferate and differentiate, and to exert good immunomodulatory effect in an in vitro inflammatory model.

**Conclusion:** Both PRP and SVF are safe and effective treatments for Achilles tendinopathy. However, SVF allowed to obtain faster results, thus allowing to consider this treatment particularly suitable for patients requiring to come back to physical activities sooner.

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