Freshly Isolated Adipose-Derived Stem Cells for the Treatment of Achilles Tendinopathy: A Randomized Prospective Clinical Trial

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Introduction/Purpose: 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: To test this hypothesis, patients affected by non-insertional Achilles tendinopathy (range 18-55 y/o) were prospectively enrolled in this clinical 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 were also evaluated by ultrasound and magnetic resonance before treatment and after 4 and 6 months.

One-way analysis of variance (ANOVA) with Bonferroni’s correction will be used to compare data. P values < 0.05 was considered statistically significant. Statistical analysis was performed by GraphPad Prism v5.0 software. The study was approved by an external Ethical Committee (ID:24bis 12MS. All the patients signed a specific informed consent before being enrolled in the study.
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 (p < 0.05). In SVF patients these improvements were faster, with significantly results 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.

Conclusion: PRP and SVF are safe and effective treatments for Achilles tendinopathy. However, SVF allowed to obtain faster results, thus allowing to consider this treatment for patients requiring to come back to sport earlier. Despite the very promising findings in both in vitro and pre-clinical studies on the use of adipose-derived stem cells in the tendon settings, literature still lacks of clear evidences about their clinical efficacy. Our, randomized controlled clinical trial demonstrates that freshly isolated adipose stem cells are able to exert a beneficial effect on Achilles tendinopathy, representing an important step towards the future clinical application of this approach.

- Achilles tendinopathy
- platelet rich plasma (PRP)
- adipose-derived mesenchymal stem cells (ASCs), either expanded or used directly within the stromal vascular fraction (SVF),
- non-insertional Achilles
• VAS Pain
• VISA-A
• AOFAS
• SF-36 forms
• 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
• PRP and SVF are safe and effective treatments for Achilles tendinopathy. However, SVF allowed to obtain faster results, thus allowing to consider this treatment for patients requiring to come back to sport earlier.

REFERENCES

