ACP Tendo – Plant derived human collagen scaffold combined with ACP for the treatment of tendinopathy

A European Case Series

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Vergenix STR – scaffold ▶ **ACP Tendo Growth Factor Depot** ◀ **ACP – Autologous Growth Factors**

Introduction

ACP Tendo is a novel treatment approach for tendinopathy where Autologous Conditioned Plasma (ACP) is combined with a scaffold material, Vergenix STR. ACP falls into the group of Platelet Rich Plasmas (PRPs) and is produced from a small volume of the patient's blood containing elevated levels of growth factors[1] which play a crucial role in tissue regeneration.[2,3] Prior to injection it is combined with Vergenix STR, a recombinant human collagen Type I produced in tabacco plants. This scaffold material offers several advantages in regards to biocompatibility, safety and structure compared to tissue-derived collagen.[4,5,6]

In vivo a fibrin-collagen clot is formed at the injection site releasing growth factors over a prolonged time and serving as a scaffold for cell ingrowth (Figure 1). This technology provides a unique biological treatment option for tendinopathy. Not only does it provide optimised scaffolding, but it is the only option on the market offering a single injection with a prolonged growth factor release.

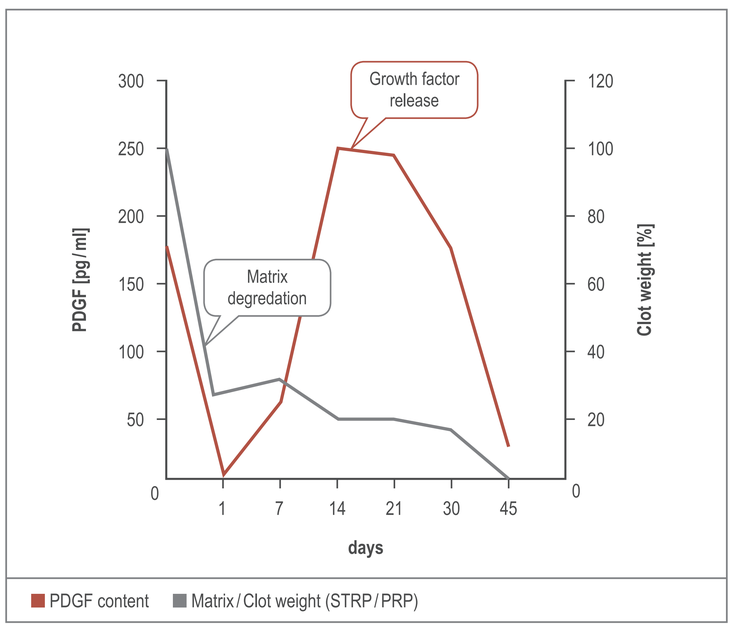

Figure 1: Time course of growth factor release in an animal model. Rats were treated with a subcutaneous injection of Vergenix STR / PRP (platelet rich plasma) and growth factor content was measured by ELISA at different time points over the course of several weeks. Clot degradation was measured by clot weight. Red graph: PDGF content, grey graph: clot weight

Objectives

Safety and effectiveness of ACP Tendo was evaluated in a European case series for the treatment of tendinopathy in different locations.

Methods

24 patients in 9 different sites were treated with a single injection of ACP Tendo for following indications:

- Rotator Cuff: Partial ruptures of the supraspinatus
- Achilles Tendon: Tendinopathy
- Other foot and ankle tendon pathologies:
  Peroneal Tendon Rupture / Tendinopathy, Tibialis Tendon
- Common Extensor Tendon: Epicondylitis

Standard patient-reported outcomes questionnaires for pain and function, according to the respective indication, were administered at standard time points postoperatively using the online Surgical Outcomes System™ (Arthrex SOS™). Results were reported from pre-treatment out to 6 months post-treatment. The number of patients included in the individual study modules and the follow-up time points is shown in Table 1.

	Rotator Cuff	Achilles Tendon	Misc. Foot and Ankle	Common Extensor Tendon
Number of Patients treated with ACP Tendo	n=7	n=6	n=6	n=5
Number of Patients at follow-up time points				
2 weeks	n=7	n=5	n=6	n=4
6 weeks	n=7	n=6	n=6	n=4
3 months	n=4	n=6	n=6	n=3
6 months	n=1	n=3	n=3	n=1

Table 1: Number of patients included into the study modules and the respective follow-up examinations

Conclusion

This European case series shows that ACP Tendo offers a promising new treatment option for chronic tendinopathy. In all treatment groups, patient-recorded-pain decreased after a mere 2 weeks and continued along this trend up to the last follow-up at 6 months.

Functionality in the Rotator Cuff and Common Extensor Tendon Group increased over the study period, almost achieving pre-symptom levels after 6 months. The treatment combines both the advantages of autologous growth factors from ACP as well as the optimized scaffold properties of the Vergenix STR. The prolonged release of grwoth factors at the injury site makes it an innovative biological single-injection treatment option for tendinopathy as well as an option as a biological adjunctive in tendon reconstructions.

More patients and more scores are needed to evaluate long-term success

Results

Patient pain recorded using the VAS score decreased in all groups from pre-treatment to 6 month follow-up time-point (Figure 2). No adverse events were recoreded in any of the groups.

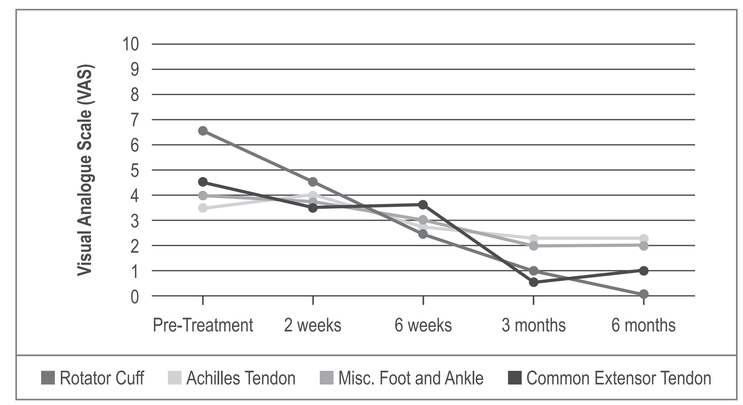

Figure 2: VAS Pain Score of patients treated with ACP Tendo for various indications.

Regarding patients with partial ruptures of the supraspinatus or epicondylitis, improvement in functionality was recoreded using the SANE questionnaire. Both groups showed an increase in the SANE from pre-treatment to 3 and 6 months follow-up time-points (Figure 3).

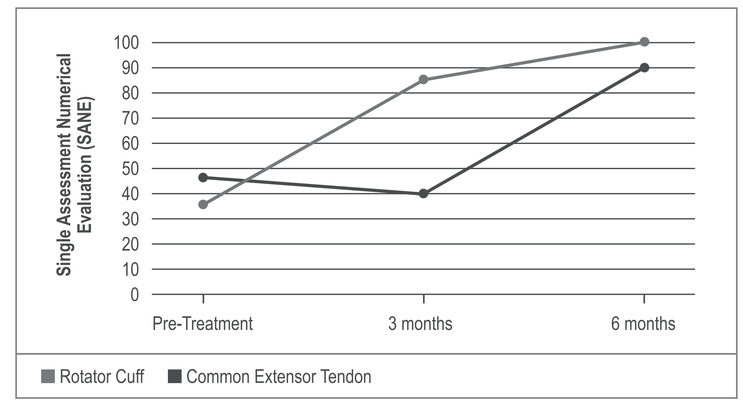

Figure 3: SANE Score of Rotator Cuff and Common Extensor Tendon patients treated with ACP Tendo.

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