RegenPRP™ Therapy

The safe & effective leucocyte-reduced Platelet-Rich Plasma for

tendinopathies

regenlab® ™ TISSUE ENGINEERING SPECIALISTS

RegenLab® is a leading innovator of medical products for the preparation of platelet-rich plasma (PRP).

RegenLab® provides expertly designed & patented Medical Devices for platelet-rich plasma preparations, CE certified and registered by most national agencies worldwide.

RegenLab® remains committed to providing products of the highest quality and safety, as well as protecting customers through enforcement of its intellectual property rights.

1/ What is RegenPRP™ ?

RegenPRP™: the standardised leucocyte-reduced platelet concentrate prepared with RegenLab® technology that provides an autologous reservoir of growth factors.

1.1 - PLATELETS

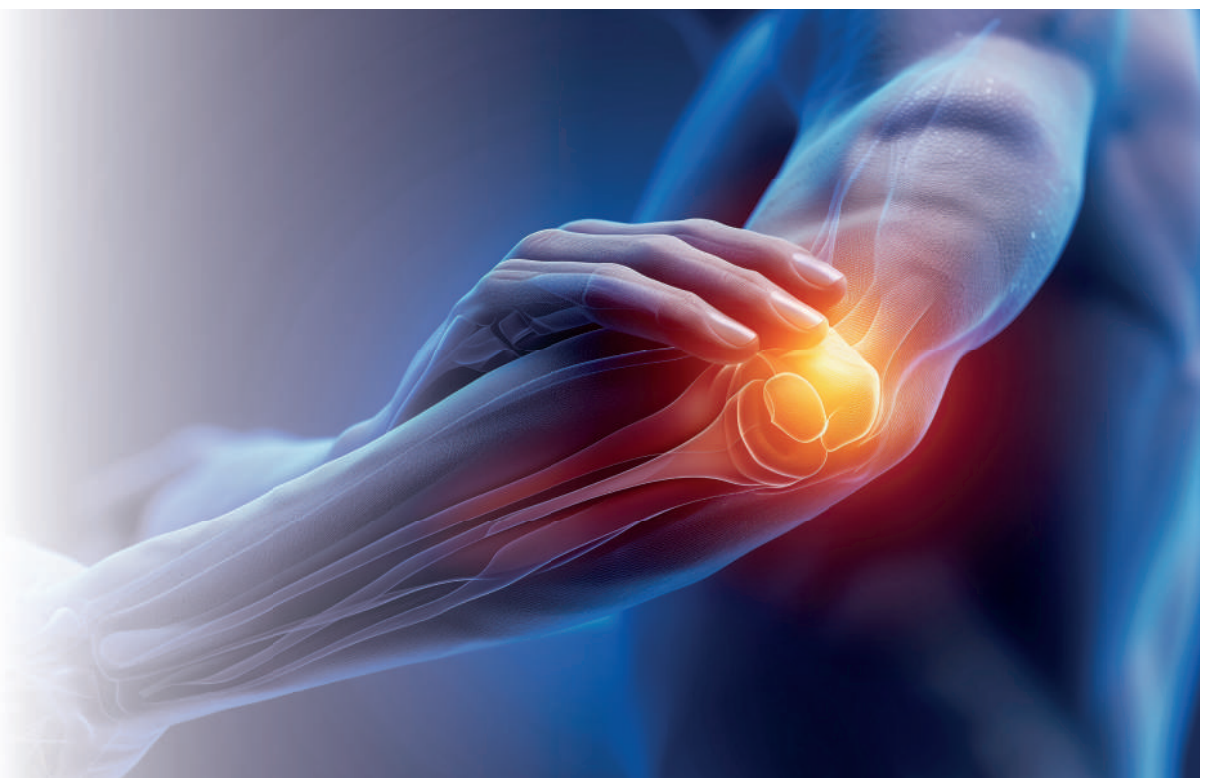
In addition to their role in haemostasis, platelets are key factors in tissue repair mechanisms.[1] They provide essential growth factors, such as FGF, PDGF, TGF-β, EGF, VEGF, IGF, which are involved in stem cell migration, differentiation and proliferation. Platelet growth factors also stimulate fibroblasts and endothelial cells to induce the deposition of new extracellular matrix and neo-vascularisation, respectively.

1.2 - PLASMA

Plasma contains many factors essential for cell survival including nutrients, vitamins, hormones, electrolytes, growth factors (such as IGF and HGF), and proteins. Among the plasma proteins, the molecules involved in the coagulation process allow the formation of the fibrin polymer that serves as a scaffold for cell migration and new tissue generation.[2]

1.3 - PLATELET-RICH PLASMA (PRP)

- Proven role in the healing of tissues, with key roles in cell migration, proliferation and differentiation
- Mechanism of action comprises anti-inflammatory activity and induction of cell-signalling cascades
- Key role in the synthesis of new extracellular matrix for tissue regeneration



1. Fountain, J. H. and S. L. Lappin (2019). Physiology, Platelet, StatPearls Publishing, Treasure Island (FL).
2. Mathew, J. and M. Varacallo (2019). Physiology, Blood Plasma, StatPearls Publishing, Treasure Island (FL).

2/ Technology Platform for Standardised Autologous Regenerative Medicine

2.1 - TECHNOLOGY ADVANTAGES

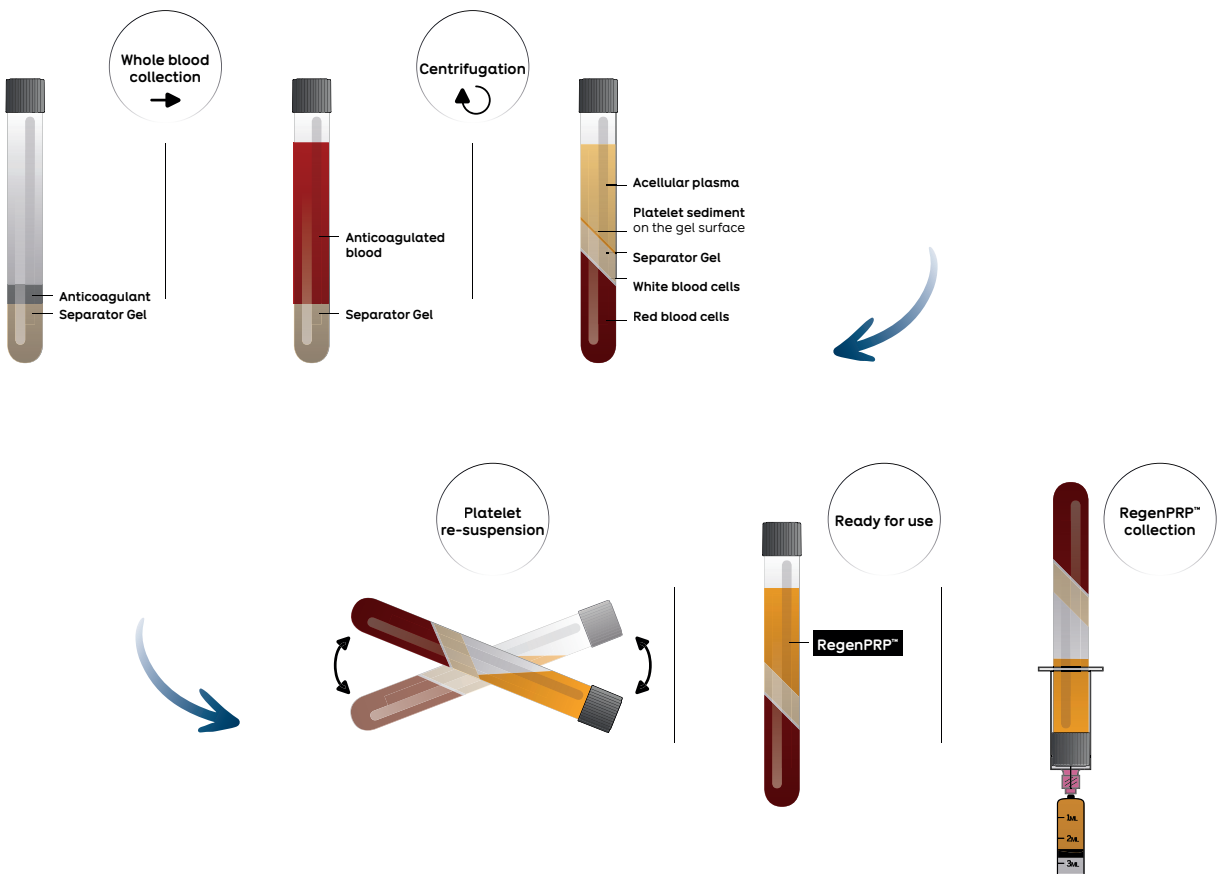
- User-independent standardised preparation
- Minimum volume of blood required
- Safe closed-circuit system
- Mechanical separation of PRP using a chemically inert separator gel with a single centrifugation at a relative centrifugal force of 1500 x g
- Pharmaceutical grade solution of sodium citrate allowing a reversible anticoagulation
- Anticoagulation may be reversed to obtain RegenPRP™ in different jellified forms, such as injectable gel, fibrin glue, fibrin clot or suturable fibrin membrane by adding Autologous Thrombin Serum (ATS prepared with RegenATS™ device), either alone or combined with a calcium solution
- Minimal learning curve and ease of use
- Operationally and clinically efficient process
- Facilitates and streamlines routine practice

2.2 - BIOLOGICAL ADVANTAGES

- RegenPRP™ is standardised, leucocyte-reduced and easily reproducible
- RegenLab® specific separator gel technology guarantees minimal variability
- Platelet recovery > 80%
- High platelet quality. Viable & functional platelets
- Full plasma recovery. No loss of plasma growth factors and fibrinogen
- Leucocyte-reduced PRP. Specific depletion of pro-inflammatory granulocytes, leaving mainly lymphocytes and monocytes
- Virtually no red blood cells

2.3 - SCIENTIFIC ADVANTAGES

- Demonstrated safety and efficacy
- Evidence-based outcomes for numerous therapeutic indications
- Large number of clinical studies, with over 200 publications



3/ Clinical evidence

3.1 - RegenPRP™ for tendinopathies

RegenPRP™ has been evaluated for several tendinopathies including:

- Chronic tendinopathies
- Non-insertional tendinopathies compared to enthesopathies
- Achilles and patellar tendinopathies
- Rotator cuff tendinopathies
- Gluteal tendinopathies
- Plantar fasciitis

3.1.1 - Achilles tendinopathies : Salini 2015[3]

OBJECTIVE

Evaluate the use of RegenPRP™ for the treatment of recalcitrant non-insertional Achilles tendinopathies and investigate whether positive outcomes depend on the age of the patients.

PROTOCOL

Retrospective study on 44 patients who had failed to respond to conservative treatment.
Patients received a total of 3 treatments at weekly intervals. RegenPRP™ (~ 4 ml) was injected at several sites into the degenerated tendon area. Injections were performed in sterile conditions, without anaesthesia and under ultrasound control.
Functional evaluation of Achilles tendon was performed using Victorian Institute of Sports Assessment-Achilles questionnaire (VISA-A) at baseline and at 1, 3, 6 and 12 months after the treatment. Patients were divided according to their age in two cohorts (Young <55-year-old; Elderly >55-year-old) (Fig. 1).

RESULTS

A constant and significant increase of the VISA-A score was observed for both patient groups during the whole length of the follow up, although better outcomes were seen in younger patients.

CONCLUSION

When injected into tendon lesions, RegenPRP™ showed good outcomes in patients suffering from recalcitrant Achilles non-insertional tendinopathies.

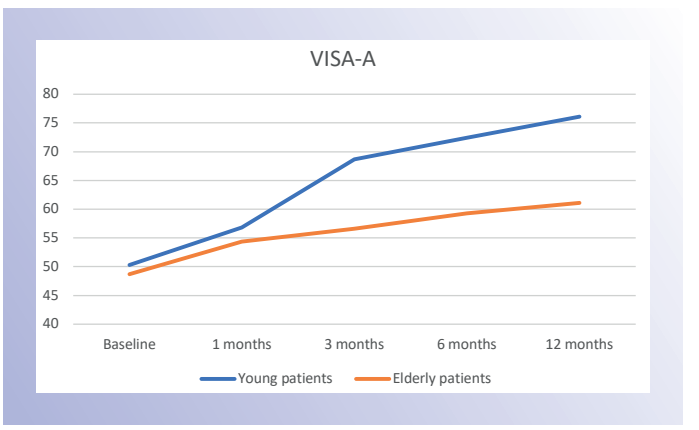


Figure 1: Evolution of VISA-A score in patients treated with RegenPRP™, stratified according to their age group.

Improvement of Achilles tendon functionality after RegenPRP™ treatment was sustained for the 12 months of follow up.

3. Salini V, Vanni D, Pantalone A, Abate M. Platelet Rich Plasma Therapy in Non-insertional Achilles Tendinopathy: The Efficacy is Reduced in 60-years Old People Compared to Young and Middle-Age Individuals. Frontiers in aging neuroscience 2015;7:228..

3.1.2 - Achilles and patellar tendinopathies : Crescibene 2015[4]

OBJECTIVE

Examine the effect of RegenPRP™ in chronic Achilles and patellar tendinopathies.

PROTOCOL

Case series study on 21 patients suffering from chronic tendinopathy for at least 6 months: 14 cases of Achilles tendinopathy and 7 cases of patellar tendinopathy. All patients were sportspeople not responding to conventional treatments.

Patients received a total of 3 infiltrations at weekly intervals. RegenPRP™ was injected half in the tendon lesion and half in the peritendinous area under US control with local anaesthesia (Fig. 2).

In addition, patients followed a personalized rehabilitation program for one month.

Functional evaluation was performed using the VISA questionnaire for Achilles (VISA-A) and patellar tendon (VISA-P) at baseline, at the end of the treatment cycle (3 weeks) and at 12- and 24-months follow-up (Fig. 3). A numeric rating scale was also used to measure subjective pain.

RESULTS

A significant improvement of the VISA scores was observed at the end of the treatment cycle at 3 weeks. The benefice was sustained all along the two years of follow-up period (Fig. 3) and accompanied by a significant reduction in pain ($p<0.01$).

Ultrasound scans performed at the end of the follow up showed a visible reduction in tissue irregularity in 86% of infiltrated tendons.

CONCLUSION

At the end of the follow-up, patients demonstrated a complete functional recovery and no longer complained of pain.
In addition, RegenPRP™ treatment was well tolerated and without adverse events.

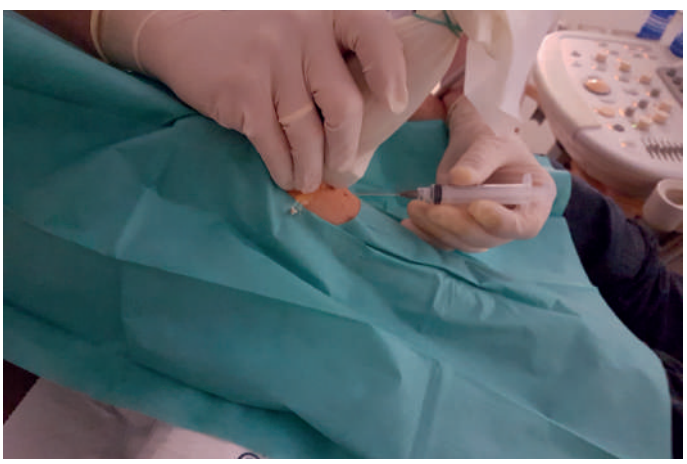


Figure 2: Ultrasound controlled injection of RegenPRP™ in Achilles tendinopathies. ©Dr. Adam

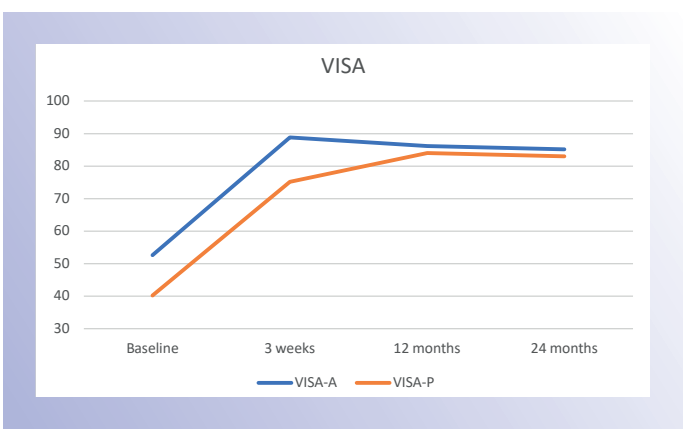


Figure 3: VISA evaluation of Achilles (VISA-A) and patellar (VISA-P) tendinopathies

4. Crescibene, A., Napolitano, M., Sbano, R., Costabile, E., and Almolla, H.. Infiltration of Autologous Growth Factors in Chronic Tendinopathies. Journal of blood transfusion 2015, 924380.

3.1.3 - Elbow tendinopathies : Le Coz 2011[5]

OBJECTIVE

Examine the effect of RegenPRP™ in twenty-two elbows with tendinitis (epicondylitis n=19 and chronic tricipital tendinitis n=3) after failure with at least two usual treatments.

PROTOCOL

Case series study on 22 patients with elbow tendinopathy not responding to conventional treatments for 3 to 18 months.

Intra-tendinous injections of RegenPRP™ were performed by peppering (point-by-point and nappage) technique, without local anaesthesia. Ten patients received 1 injection, 9 patients received 2 injections and 3 patients received 3 injections.

Evaluation of pain was performed one- and two-months after the last injection. Follow up examination was performed after 9 to 22 months.

RESULTS

Nineteen patients (86%) presented good (5 patients) or very good (14 patients) results after receiving RegenPRP™ treatment (Fig. 4).
No relapse was seen over time and patients rated “good” at follow-up became “very good” over time.

No adverse events were reported apart from transient local pain during or after PRP injection.

CONCLUSION

RegenPRP™ treatment resulted in long-term improvement of elbow tendinopathies not responding to conventional treatment.

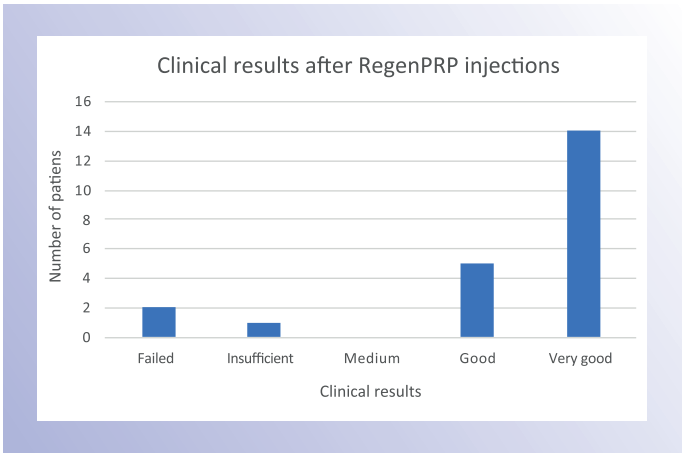


Figure 4: Clinical results after receiving RegenPRP™ injections for treating elbows tendinitis. Good or very good results were seen in 86% of the patients.

RegenPRP™ infiltration is a valid option for patients with chronic tendinopathy who did not benefit from other treatments

5. Le Coz J. Traitement de 22 cas de tendinites du coude, rebelles aux traitements classiques, par injection de plasma riche en plaquettes (PRP). Journal de Traumatologie du Sport 2011;28:83-9.

Regen Lab SA is an ISO13485 : 2016 and MDSAP certified medical device manufacturer

This brochure is provided as an educational tool for Regen Lab's product users. The preparation of RegenPRP™ must be performed by a physician (or a qualified person under the supervision of the physician) trained on the equipment and procedure, and according to the instructions for use.

The treatment with RegenPRP™ must be performed by a qualified physician therapeutic outcomes are patient-specific. The physician should assess, based on his personal experience and data from the literature, whether the treatment is suitable for the patient. The contents of this brochure do not constitute a recommendation for specific treatment.

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