RegenPRP™ Therapy

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

osteoarthritis

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 efficacy in tissue healing, 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
- Growing body of evidence to support PRP as a treatment for osteoarthritis (OA)[3]

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).
3. Oeding, J. F., N. H. Varady, F. W. Fearington, A. Pareek, S. M. Strickland, B. U. Nwachukwu, C. L. Camp and A. J. Krych (2024). «Platelet-Rich Plasma Versus Alternative Injections for Osteoarthritis of the Knee: A Systematic Review and Statistical Fragility Index-Based Meta-analysis of Randomized Controlled Trials.» Am J Sports Med: 3635465231224463

2/ Technology Platform for Standardised Autologous Regenerative Medicine

2.1 - TECHNOLOGY ADVANTAGES

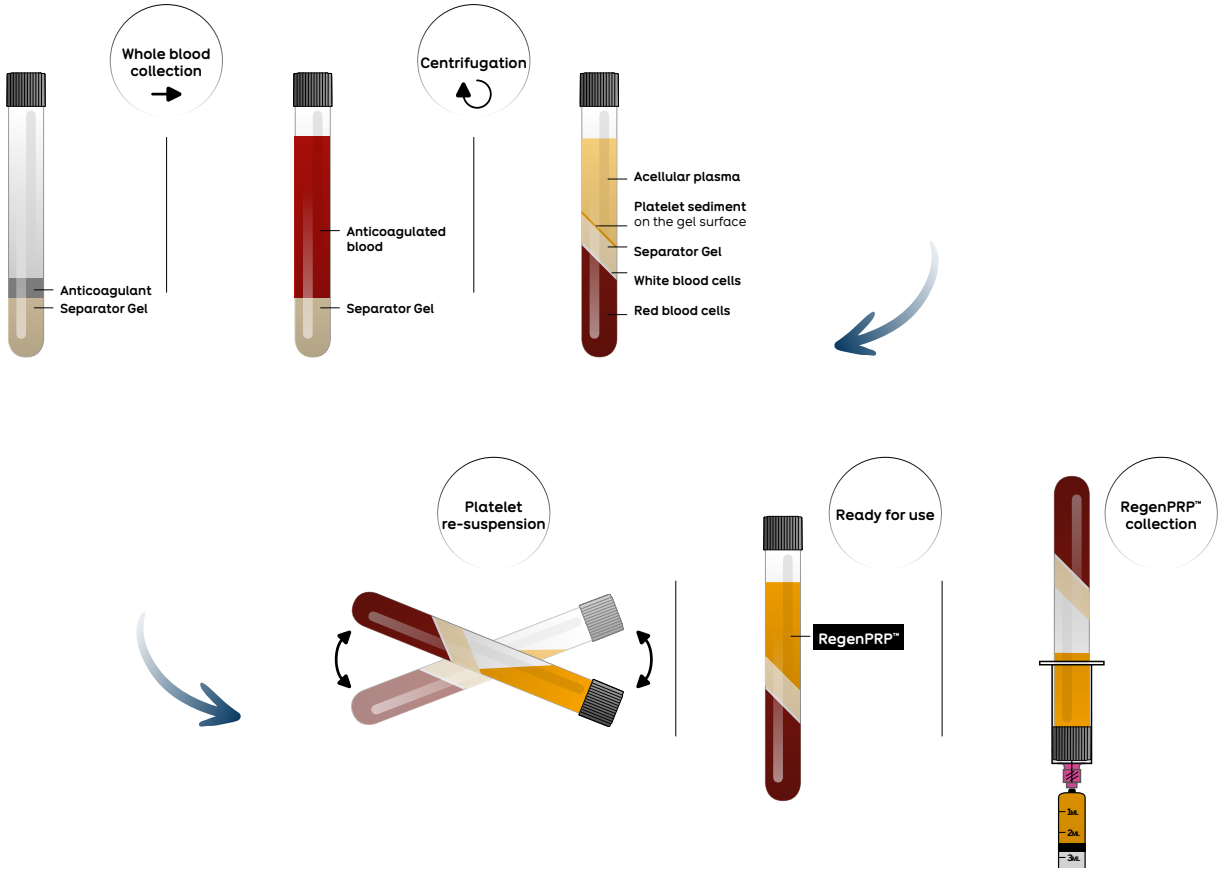
- User-independent standardised preparation
- Minimum volume of blood required
- Safe closed-circuit system
- Mechanical separation of PRP using a chemically inert separator gel with a single centrifugation at a relative centrifugal force of 1500 x g
- Pharmaceutical grade solution of sodium citrate 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 knee OA : Lin 2019[4]

OBJECTIVE

Prospective, randomised, double-blind study to compare the efficacy of intra-articular injections of either RegenPRP™ or Hyaluronic Acid (HA) or normal saline (NS) solution for knee OA.

NUMBER OF PATIENTS TREATED AND CHARACTERISTICS

53 patients diagnosed with osteoarthritis, Ahlbäck Grade I-III, were randomly assigned to 3 treatment groups (PRP, HA or NS).

TREATMENT

3 weekly injections of either RegenPRP™ (31 knees), HA (29 knees), or NS (27 knees).
Follow-up: WOMAC and IKDC scores were recorded at 1, 2, 6 and 12 months

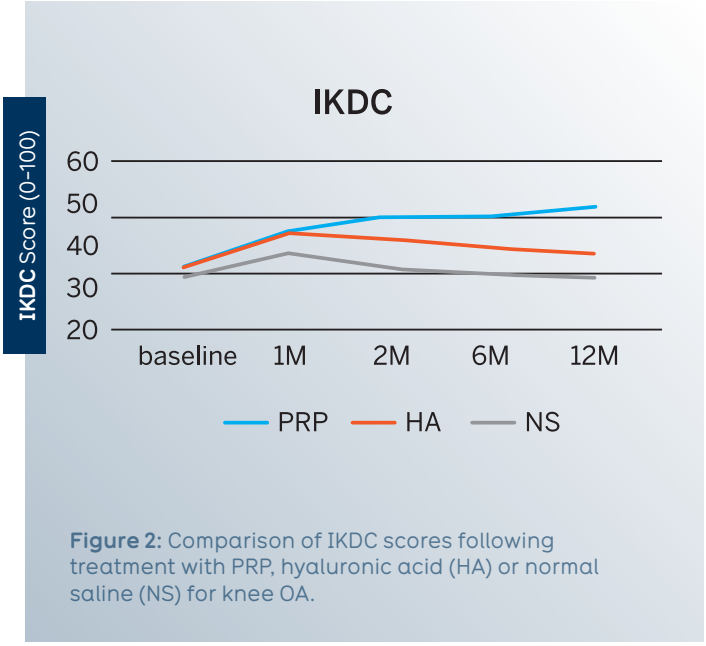


Figure 2: Comparison of IKDC scores following treatment with PRP, hyaluronic acid (HA) or normal saline (NS) for knee OA.

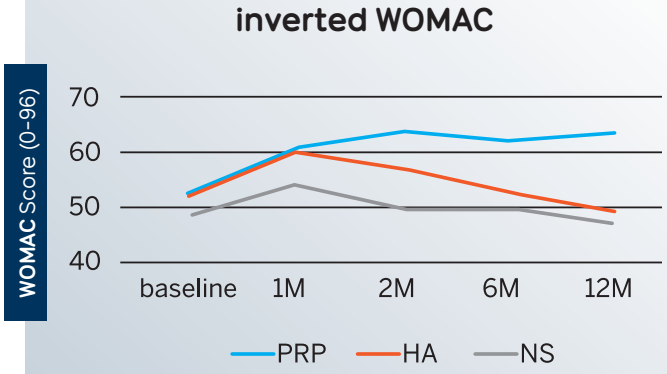


Figure 1: Comparison of WOMAC scores following treatment with PRP, hyaluronic acid (HA) or normal saline (NS) for knee OA.

In this study WOMAC score was assessed with an internet-based (www.orthopaedicscores.com) functional outcome questionnaires for which a higher score means a better outcome, in opposition with usual WOMAC scoring for which the higher scores are linked with the poorer outcomes.

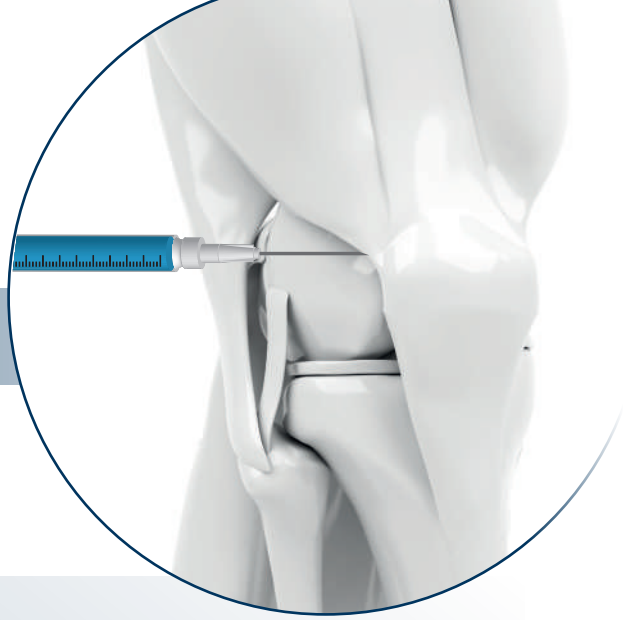
RESULTS

All groups showed statistically significant improvement in both scores at 1 month.

Sustained improvement up to 12 months for both WOMAC and IKDC scores was observed only in the PRP group, whereas both the HA and NS groups showed declining scores after the first month. (Fig.1 & Fig. 2)

The improvement was sustained at 12 months only in the PRP group

4. Lin, K.-Y., et al. (2019). «Intra-articular injection of platelet-rich plasma is superior to hyaluronic acid or saline solution in the treatment of mild to moderate knee osteoarthritis: a randomised, double-blind, triple-parallel, placebo-controlled clinical trial.» Arthroscopy 35(1): 10100106-117.



Significant improvement in function and pain at all time points, up to 12 months, compared to baseline.

OBJECTIVE

Evaluate the effects of RegenPRP™ on joint functionality and pain in knee OA patients.

NUMBER OF PATIENTS TREATED AND CHARACTERISTICS

72 patients with knee OA, Kellgren-Lawrence Grade 2 or 3

PROTOCOL

Patients had a total of 3 treatment sessions, with a RegenPRP™ injection given every 21 days. Patients were evaluated before the treatment and at 1, 3, 6 and 12 months from the last injection using the WOMAC, VAS at rest and VAS in movement scores.

RESULTS

Patients showed a significant improvement in function and pain at all time points compared to baseline, which lasted for almost one year. (Fig. 3 & Fig. 4)

A breakdown analysis of the items on the WOMAC score indicated that there was a significant improvement in the pain and function score until the third month, after which it did not improve further but was sustained.

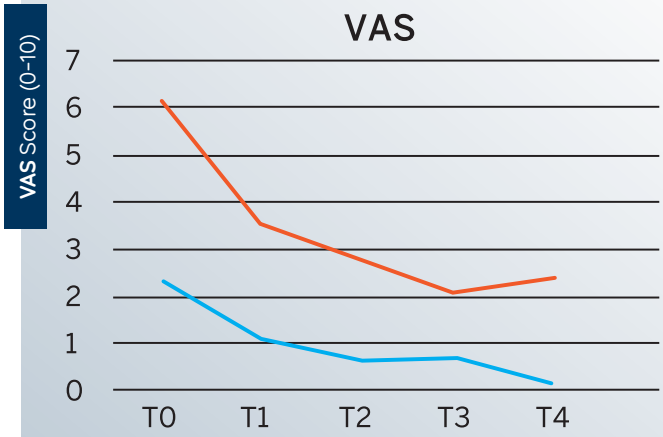


Figure 3: VAS scores at rest, VAS scores in movement before the treatment (T0) and at 1, 3, 6 and 12 months after the treatment (T1, T2, T3 and T4 respectively).

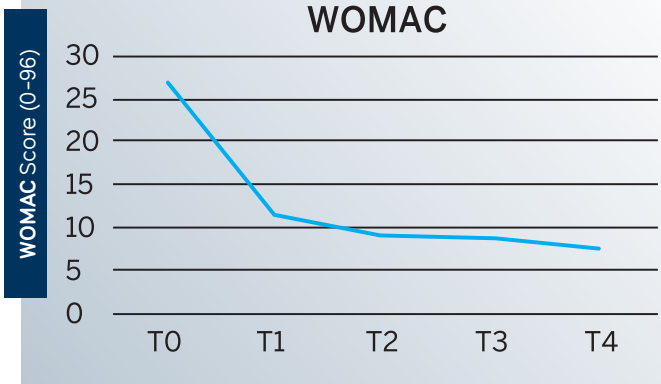


Figure 4: WOMAC scores before the treatment (T0) and at 1, 3, 6 and 12 months after the treatment (T1, T2, T3 and T4 respectively).

5. Mangone, G., et al. (2014). «Infiltrative treatment with Platelet Rich Plasma (PRP) in gonarthrosis.» Clin Cases Miner Bone Metab 11(1): 67-72.

3.3 - RegenPRP™ for knee OA : Chen 2017[6]

OBJECTIVE

Prospective study to evaluate the effectiveness of RegenPRP™ in treating patients with minor to moderate knee OA (grades 1 to 3 on the Ahlbäck scale) combined with supra-patellar bursitis.

NUMBER OF PATIENTS TREATED AND CHARACTERISTICS

24 elderly patients (> 65 years of age, 14 female and 10 male patients).

PROTOCOL

Aspiration of synovial fluid (SF) followed by intra-articular knee joint injection of RegenPRP™ were performed in three treatment sessions with a monthly interval.
The SF volumes, protein concentrations and Lequesne functional index values were evaluated at each injection (Baseline, M1, M2) and at the follow up time periods, 3 and 6 months after the last treatment session (M5, M8).

RESULTS

3 monthly PRP injections resulted in significant decreases of supra-patellar bursa SF volume and its total protein concentration (Fig. 5).
Proteomic analysis showed a decrease of proteins associated with inflammation, and an increase in markers associated with attenuation of cartilage degeneration.
These findings are associated with significantly improved index of knee OA severity (Fig. 6).
The improvement was maintained during the 6 month-follow-up (Fig.5 & Fig.6).

After receiving 2 monthly PRP injections, the rheology of synovial fluid started to change with significant drops in total protein concentrations.

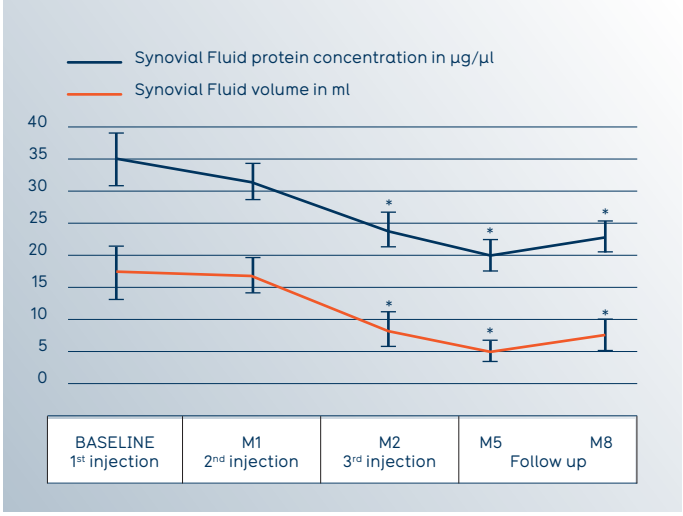


Figure 5: Differences in synovial fluid protein concentrations and volumes before and after PRP injections.
*: significant statistical differences at the time of 3rd PRP injection (M2, patients have received 2 PRP injections), and at 3 and 6 months after the completion of the 3rd PRP injection (M5, M8) when compared with the first 2 PRP injections ($p < 0.05$). Values expressed as mean ± standard error of means (SEM).

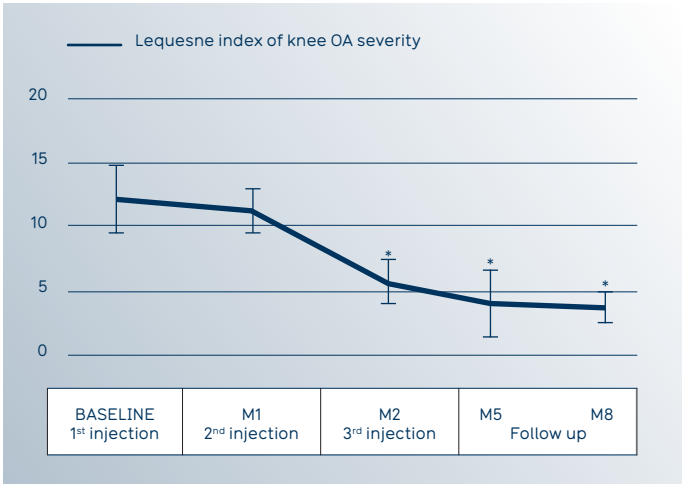


Figure 6: Status of knee pain and knee OA severity evaluated with Lequesne Index
*: significant statistical differences at the time of 3rd PRP injection (M2, patients have received 2 PRP injections), and at 3 and 6 months after the completion of the 3rd PRP injection (M5, M8) as compared with the first 2 PRP injections ($p < 0.05$). Values expressed as mean ± standard error of means (SEM).

6. Chen CPC, Cheng CH, Hsu CC, Lin HC, Tsai YR, Chen JL. The influence of platelet rich plasma on synovial fluid volumes, protein concentrations, and severity of pain in patients with knee osteoarthritis. Experimental gerontology 2017;93:68-72.

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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