

endoret® (prgf®)

Endogenous Regenerative Technology

OSTEOARTHRITIS

ONLY ENDORET HAS DEMONSTRATED EFFICACY IN TWO CLINICAL TRIALS OF LEVEL I AMONG ALL PLASMA RICH IN GROWTH FACTORS (2) (3) (4) (5)

ENLOA⁽¹⁾

ENDORET® LONG TERM TREATMENT FOR OSTEOARTHRITIS

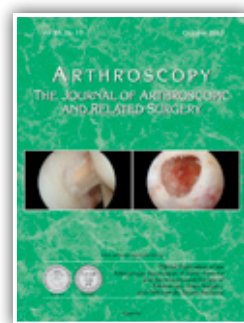
Randomized clinical trial for the evaluation of Endoret (prgf) versus Durolane (Hyaluronic Acid) as a treatment of knee osteoarthritis

UP TO 83% OF THE PATIENTS TREATED WITH ENDORET EXPERIENCED PAIN REDUCTION

60% of the patients continue referring **less pain*** one year after treatment with Endoret

Endoret is safe and **significantly superior to Durolane (Hyaluronic Acid)** both at 24 and 48 weeks

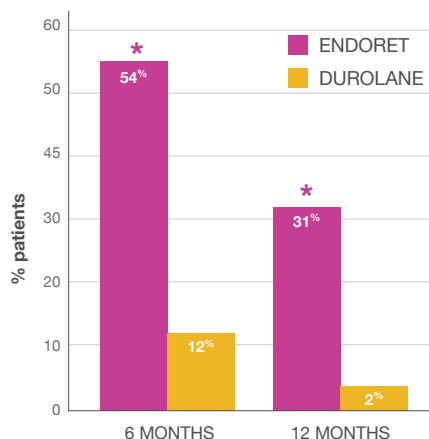
*At least 30% pain reduction



% OF PATIENTS WITH **HIGH** PAIN[§] REDUCTION AFTER TREATMENT.

* p<0.05%

§ Reduction of 50% in WOMAC Index



(1) Vaquerizo V, Plasencia MÁ, Arribas I, Seijas R, Padilla S, Orive G, Anitua E. Comparison of Intra-Articular Injections of Plasma Rich in Growth Factors (PRGF-Endoret) Versus Durolane Hyaluronic Acid in the Treatment of Patients With Symptomatic Osteoarthritis: A Randomized Controlled Trial. *Arthroscopy*. 2013 Oct;29(10):1635-43. doi: 10.1016/j.arthro.2013.07.264.

(2) Anitua E, Sánchez M, Oribe G, Padilla S. A biological therapy to osteoarthritis treatment using platelet-rich plasma. *Expert Opin. Biol. Ther* (Early online).

(3) Anitua E, Sánchez M, Zalduendo MM, de la Fuente M, Prado R, Orive G, Andía I. Fibroblastic response to treatment with different preparations rich in growth factors. *Cell Prolif*. 2009;42:162-170.

(4) Anitua E, Sánchez M, Nurden AT, Zalduendo MM, de la Fuente M, Azofra J, Andía I. Platelet-released growth factors enhance the secretion of hyaluronic acid and induce hepatocyte growth factor production by synovial fibroblasts from arthritic patients. *Rheumatology (Oxford)*. 2007;46:1769-1772.

(5) Anitua E, Sanchez M, De la Fuente M, Zalduendo MM, Orive G. Plasma rich in growth factors (PRGF-Endoret) stimulates tendon and synovial fibroblasts migration and improves the biological properties of hyaluronic acid. *Knee Surg Sports Traumatol Arthrosc*. 2012.

ABSTRACT

Víctor Vaquerizo, M.D., Miguel Ángel Plasencia, Ph.D., Ignacio Arribas, Ph.D., Roberto Seijas, M.D., Sabino Padilla, Ph.D., Gorka Orive, Ph.D., and Eduardo Anitua, M.D., D.D.S., Ph.D.

Knee Comparison of Intra-Articular Injections of Plasma Rich in Growth Factors (PRGF-Endoret) Versus Durolane Hyaluronic Acid in the Treatment of Patients With Symptomatic Osteoarthritis: A Randomized Controlled Trial.

Arthroscopy. 2013 Oct;29(10):1635-43. doi: 10.1016/J.Arthro.2013.07.264.

PURPOSE

The purpose of this study was to compare the efficacy and safety in a randomized, clinical trial of 3 injections of PRGF-Endoret (BTI Biotechnology Institute, Vitoria, Spain) versus one single intra-articular injection of Durolane hyaluronic acid (HA) (Q-MED AB, Uppsala, Sweden) as a treatment for reducing symptoms in patients with knee osteoarthritis (OA).

METHODS

Ninety-six patients with symptomatic knee OA were randomly assigned to receive PRGF-Endoret (3 injections on a weekly basis) or one infiltration with Durolane HA. The primary outcome measures were a 30% decrease and a 50% decrease in the summed score for the pain, physical function, and stiffness subscales of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Lequesne scores from baseline to weeks 24 and 48. The percentage of OMERACT-OARSI (Outcome Measures for Rheumatology Committee and Osteoarthritis Research Society International Standing Committee for Clinical Trials Response Criteria Initiative) responders was also documented. As secondary outcomes, pain, stiffness, and physical function by use of the WOMAC and the Lequesne score were considered and overall safety of the injection themselves.

RESULTS

The mean age of the patients was 63.6 years. Treatment with PRGF-Endoret was significantly more efficient than treatment with Durolane HA in reducing knee pain and stiffness and improving physical function in patients with knee OA. The rate of response to PRGF-Endoret was significantly higher than the rate of response to HA for all the scores including pain, stiffness, and physical function on the WOMAC, Lequesne index, and OMERACT-OARSI responders at 24 and 48 weeks. Adverse events were mild and evenly distributed between the groups.

CONCLUSIONS

Our findings show that PRGF-Endoret is safe and significantly superior to Durolane HA in primary and secondary efficacy analysis both at 24 and 48 weeks; provides a significant clinical improvement, reducing patients' pain and improving joint stiffness and physical function with respect to basal levels in patients with knee OA; and should be considered in the treatment of patients with knee OA.

LEVEL OF EVIDENCE

Level I, multicenter randomized controlled clinical trial.