

## **OSTEOARTHRITIS**

ONLY ENDORET® TECHNOLOGY HAS DEMONSTRATED EFFICACY IN TWO CLINICAL TRIALS OF LEVEL I AMONG ALL PLASMA RICH IN GROWTH FACTORS

### **ENTROA**(1)

# ENDORET® TECHNOLOGY TREATMENT FOR OSTEOARTHRITIS



Randomized clinical trial for the evaluation of ENDORET® Technology compared to Hyaluronic acid in the treatment of symptomatic osteoarthritis of the knee.

ENDORET® TECHNOLOGY
DECREASES SIGNIFICANTLY
THE PAIN AND THE RIGIDITY
OF THE OSTEOARTHRITIS
OF THE KNEE (2) (3) (4) (5)

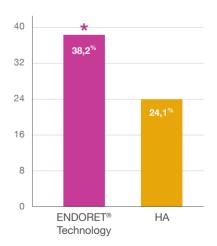
70% OF PATIENTS IMPROVE WITH ENDORET® TECHNOLOGY(1)

During the study period, ENDORET®
Technology reduced pain more and
more effectively while the efficacy of
hyaluronic acid was gradually reduced.

None of the patients treated with ENDORET® Technology presented adverse reactions to the treatment.

% OF PATIENTS WITH A SIGNIFICANT REDUCTION IN PAIN<sup>2</sup> 6 MONTHS AFTER TREATMENT

- \* p<0.05%
- <sup>a</sup> Defined as a reduction of 50% on the WOMAC Index



(f) Sanchez Mr, P2 N, P2



# ABSTRACT

Mikel Sánchez, Ph.D., Nicolás Fiz, Ph.D., Juan Azofra, Ph.D., Jaime Usabiaga, Ph.D., Enmanuel Aduriz Recalde, Ph.D., Antonio Garcia Gutierrez, Ph.D., Javier Albillos, Ph.D., Ramón Gárate, Ph.D., Jose Javier Aguirre, Sabino Padilla, Ph.D., Gorka Orive, Ph.D., and Eduardo Anitua, M.D., D.D.S., Ph.D.

A Randomized Clinical Trial Evaluating Plasma Rich in Growth Factors (PRGF-Endoret) Versus Hyaluronic Acid in the Short-Term Treatment of Symptomatic Knee Osteoarthritis.

#### **PURPOSE**

This multicenter, double-blind clinical trial evaluated and compared the efficacy and safety of PRGF-Endoret (BTI Biotechnology Institute, Vitoria-Gasteiz, Spain), an autologous biological therapy for regenerative purposes, versus hyaluronic acid (HA) as a short-term treatment for knee pain from osteoarthritis.

#### **METHODS**

We randomly assigned 176 patients with symptomatic knee osteoarthritis to receive infiltrations with PRGF-Endoret or with HA (3 injections on a weekly basis). The primary outcome measure was a 50% decrease in knee pain from baseline to week 24. As secondary outcomes, we also assessed pain, stiffness, and physical function using the Western Ontario and McMaster Universities Osteoarthritis Index; the rate of response using the criteria of the Outcome Measures for Rheumatology Committee and Osteoarthritis Research Society International Standing Committee for Clinical Trials Response Criteria Initiative (OMERACT-OARSI); and safety.

#### **RESULTS**

The mean age of the patients was 59.8 years, and 52% were women. Compared with the rate of response to HA, the rate of response to PRGF-Endoret was 14.1 percentage points higher (95% confidence interval, 0.5 to 27.6; P .044). Regarding the secondary outcome measures, the rate of response to PRGF-Endoret was higher in all cases, although no significant differences were reached. Adverse events were mild and evenly distributed between the groups.

#### CONCLUSIONS

Plasma rich in growth factors showed superior short-term results when compared with HA in a randomized controlled trial, with a comparable safety profile, in alleviating symptoms of mild to moderate osteoarthritis of the knee. Level of Evidence

Level I, randomized controlled multicenter trial.