



# OVOMET® Health Efficacy Study



CONFIDENTIAL

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**OVOMET® Health: egg membrane for the treatment of knee and hip associated joint pain and stiffness. A human efficacy pilot study.**

**Abstract**

OVOMET Health, natural egg membrane manufactured by Eggnovo S.L., is a food supplement that contains naturally occurring protein and glycosaminoglycans essential for healthy joints. OVOMET Health was evaluated for efficacy in the treatment of persistent knee and/or hip pain and stiffness associated with osteoarthritis. Thirty patients were recruited and assigned to receive 300 mg of OVOMET Health daily for 50 days. The assessment, made at days 10, 20, 30, 40 and 50 after the beginning of the treatment was based on Western Ontario and McMaster Universities (WOMAC) Osteoarthritis. The patients experienced a gradual and significant decrease in pain, stiffness and an improvement in function since the first 10 days of the beginning of the treatment until the end of the study.

This study concludes that OVOMET Health is an effective and safe alternative for the treatment of pain and stiffness associated with hip and/or knee osteoarthritis. Daily supplementation with 300 mg of OVOMET Health reduced significantly both, pain, stiffness and improved function along the study.

## **Introduction**

Osteoarthritis (OA) is one of the most common forms of joint disease and is a top cause of disability in older people. It is a chronic condition in which the material that cushions the joints, the cartilage, breaks down. This causes the bones to rub against each other, producing stiffness, pain and loss of joint movement. About 70 % of people over the age of 70 have evidence of osteoarthritis (1). There is no cure for the disease but some treatments attempt to slow disease progression. Many nutrition supplements have been used for treatment of OA such as glucosamine, chondroitin sulphate and hyaluronic acid among others.

OVOMET Health is an all natural egg membrane manufactured by Eggnovo S.L. via a patented process (ES 2327087 B2 and ES 2181580 B1) in a sustainable and environmentally friendly manner without the use of chemicals. The egg membrane, the egg's placenta, is a natural ingredient obtained from the inner membrane that covers the shell of the egg. Eggshell membranes are composed of fibrous proteins such as collagen type I (2), glucosamine (3), hyaluronic acid (4), glycosaminoglycans like dermatan sulphate and chondroitin sulphate (5), and other components including lysozyme (6), ovotransferrin (7) and desmosine and isodesmosin (8). Eggshell membrane is recommended by the NHPD (Natural Health Products Directorate of Canada) to help relieve the joint pain associated with processes of osteoarthritis, as well as to help reduce the stiffness and joint pain.

OVOMET Health contains naturally the above cited components, all of them being important constituents of joints and playing a crucial role in their health, mobility and flexibility. OVOMET Health ensures the supply of nutrients necessary for the repair of joints together with anti-inflammatory compounds of natural origin. OVOMET Health consumption prevents healthy joints by the intake of a natural product.

The goal of the present study is to assess the effectiveness of a 50 days treatment with OVOMET Health in improving function and reducing knee and/or hip joint pain and stiffness. The results are presented herein.

## **Materials and Methods**

### **Product composition**

OVOMET Health is manufactured by Eggnovo S.L. in Villatuerta, Spain. OVOMET Health is a natural egg membrane powder from avian source that has a naturally occurring unique composition containing various essential molecules for healthy joints such as:

- Hyaluronic acid (> 4%)
- Collagen (types I, V y X) (> 25%)
- Chondroitin sulphate (> 5%)
- Glucosamine (> 2%)
- Dermatan sulphate (> 1%)
- Keratan sulphate (> 1%)
- Lysozyme (> 1%)

### **Study design**

The treatment consisted in the intake once daily of OVOMET Health provided in 300 mg capsules stored in closed containers at room temperature. The capsule was taken by mouth along with water or juice daily in the morning. Thirty subjects were enrolled in a period of 50 days, with assessments at days 0, before the beginning of the study, and days 10, 20, 30, 40 and 50 following the onset of the treatment.

All subjects 18 years of age or older with known symptomatic osteoarthritis of the knee and/or hip were considered for enrolment in the study. In order to be eligible, patients must have been diagnosed with osteoarthritis and have had persistent pain associated with osteoarthritis with a baseline score of at least 2 in pain on WOMAC questionnaire. Subjects agreed to replace current pain relief medications with OVOMET Health treatment after a 7-day washout period. Ibuprofen and paracetamol were allowed for pain relief rescue, if necessary. Subject recorded the time, name and amount of painkiller taken. Patients were excluded if they had a known allergy to eggs. Subjects who met all of the eligibility criteria were enrolled to participate.

The assessment was based on the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index for hip and knee (9). The WOMAC Index has been extensively validated and has been translated and linguistically validated in over 65 alternate-language forms (10). It consists of five questions addressing the severity of joint pain, two questions addressing joint stiffness and 17 questions addressing limitations in performing physical activities, function (10). The questionnaire is a standardized measure which captures the patient's own perspective of their joints health status.

Subjects were also instructed to record any changes in overall health, as well as any discomfort associated with the ingestion of the capsules. Treatment assessment points (days 10, 20, 30, 40 and 50) were compared to pre-treatment assessment (day 0, baseline).

## Statistical analysis

Repeated measures ANOVA was performed to assess statistical differences with the baseline. Statistical significance was accepted at an  $\alpha$  value of  $< 0.05$ . SPSS (version 22) was used for all statistical analyses.

## Results

The study was carried out between September 2014 and January 2015. A total of 30 subjects were recruited and enrolled in the trial. The average age of enrolled patients in the present study was  $54.56 \pm 2.25$  years and 52% of them were women (Table 1). From the enrolled patients, 10 did not complete the treatment or did not answer all the WOMAC questionnaires and therefore, were not available for further analysis.

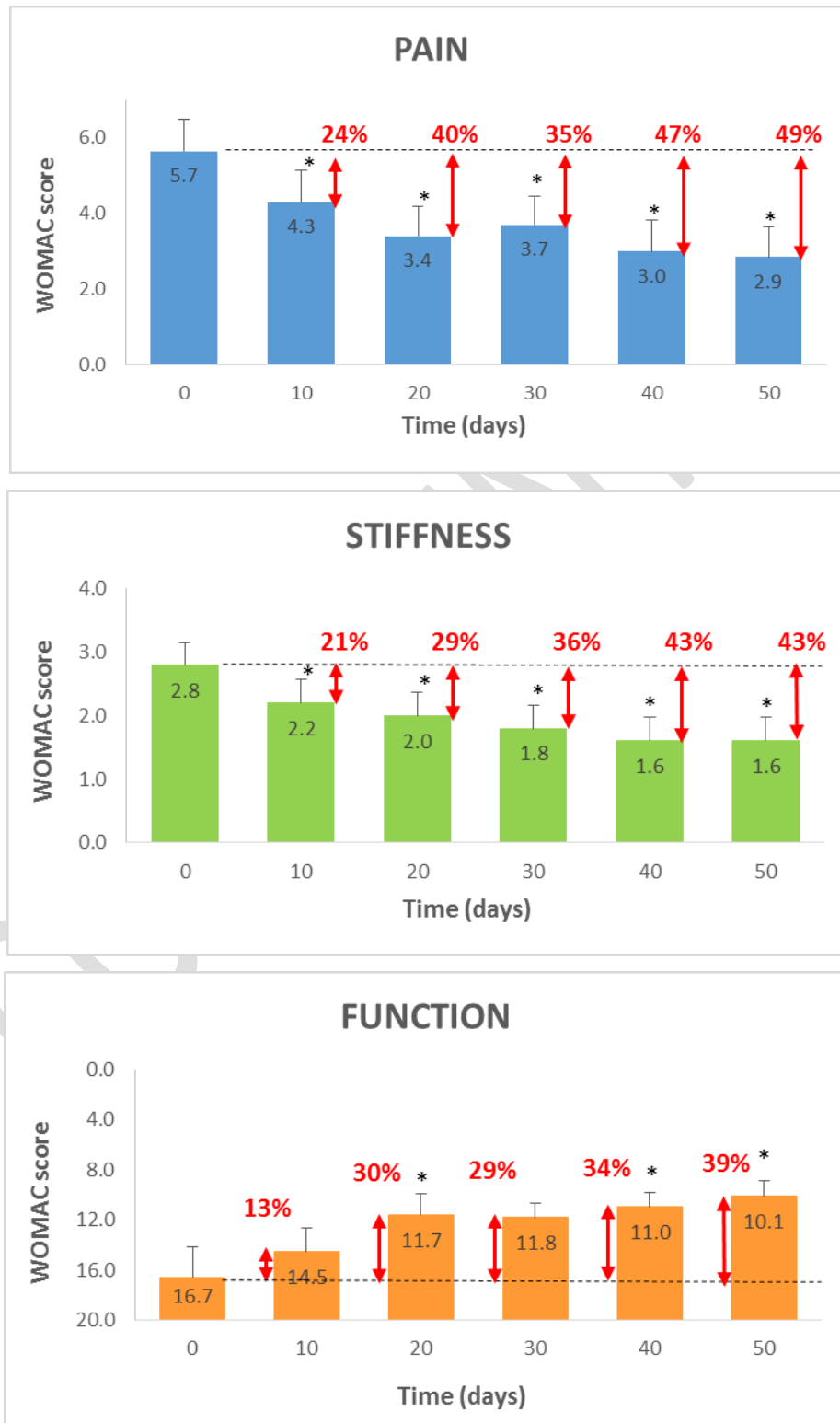
A significant decrease was observed in either pain, stiffness and function all over the study based on ANOVA results. Focusing on comparisons between the baseline and the different assessment points, a significant and gradual decline in pain was observed since the first 10 days of OVOMET Health intake until reaching almost a 50% of pain decrease at the end of the study (Figure 1). An alike pattern was observed in stiffness, getting a 43% of significant stiffness reduction the day 50 after the beginning of the treatment. Similarly, a gradual significant function improvement was measured, achieving almost a 40% of function recovery the last day of OVOMET Health intake (Figure 1).

**Table 1.** Descriptive data of patients with hip and/or knee osteoarthritis.

Descriptive data of the sample	
	patients
Sex, women %	51.72
Age, mean (EE)	54.56 (2.25)

In the first 10 days of OVOMET Health intake, half of the patients experienced a 10% of pain decrease and 30% of the subject had a 50% of pain reduction (Table 2). After 50 days of treatment, 70% of patients experienced a 50% of pain reduction and 35% of subjects perceived a 75% of pain decrease (Table 2). Regarding stiffness, in the first 10 days of treatment 45% of the patients had a 10% of stiffness decline and 10% of subjects had a 75% of drop. As the study progressed, the decline in stiffness was sharper reaching a 50% of decrease in 60% of the patients at day 50 after the intake of OVOMET Health. At this time point, 25% of patients exhibited a 75% of stiffness decline (Table 2). In function, half of the subjects felt a 10% of improvement as soon as at day 10 after the beginning of the treatment (Table 2). At the same time point, 10% of patients experienced a 75% of function improvement. This rapid function increase was enhanced throughout the study, reaching at day 50 a 75% of recovered function in 25% of the patients while more than half of the patients improved a 50% in function (Table 2).

**Figure 1.** The effects of the treatment with OVOMET Health in hip and/or knee pain, stiffness and function in osteoarthritic patients.



**Table 2.** The percentages of decrease in pain, stiffness and function after 50-days of treatment with OVOMET Health.

		10 days (patient %)	20 days (patient %)	30 days (patient %)	40 days (patient %)	50 days (patient %)
<b>Pain decrease (%)</b>	<b>75%</b>	5	15	10	35	35
	<b>50%</b>	30	50	45	60	70
	<b>10%</b>	50	65	65	75	75
<b>Stiffness decrease (%)</b>	<b>75%</b>	10	15	20	30	25
	<b>50%</b>	20	25	40	55	60
	<b>10%</b>	45	50	55	65	70
<b>Function increase (%)</b>	<b>75%</b>	10	15	15	25	25
	<b>50%</b>	20	30	30	45	55
	<b>10%</b>	50	65	60	70	75

Summarising, osteoarthritic patients experienced a gradual and significant improvement in hip and/or knee pain, stiffness and function after the treatment with OVOMET Health. The effects were evident since the first 10 days of intake and gradual throughout the studied period.



## **Discussion-Conclusion**

OA is one of the most common forms of joint disease and is a substantial cause of disability in older people. The present research was designed to evaluate the efficacy of OVOMET Health in the treatment of subjects suffering from knee and hip pain associated with osteoarthritis.

Patients experienced a rapid response (10 days) for all WOMAC scores. The intake of OVOMET Health showed a significant improvement in knee and hip pain, stiffness or function since the first 10 days of treatment. As the trial progressed, there was a gradual significant improvement of osteoarthritis symptoms and at the end of the study, 70%, 60% and 55% of patients had a 50% of improvement in pain, stiffness and function symptoms, respectively. So, OVOMET Health showed a double benefit for patients: a rapid response (10 days after the beginning of the treatment) and a gradual and progressive improvement response along the treatment.

From the current results it can be presumed that the use of OVOMET Health does have potential as a treatment for hip and knee joint pain and stiffness. Moreover, the absence of reported adverse effects make OVOMET Health a remarkable choice when dealing with a condition that requires long-term treatment such as for instance OA.

This study concludes that OVOMET Health is a viable, effective and safe alternative for the treatment of pain and stiffness associated with hip and knee osteoarthritis. Daily supplementation with 300 mg of OVOMET Health significantly reduced pain and stiffness and improved function since the day 10 after the beginning of the treatment. The observed gradual significant improvement of the symptoms within the 50-days study period made us expect that a longer treatment with OVOMET Health would trigger greater improvement in function and a bigger decrease in pain and stiffness.

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