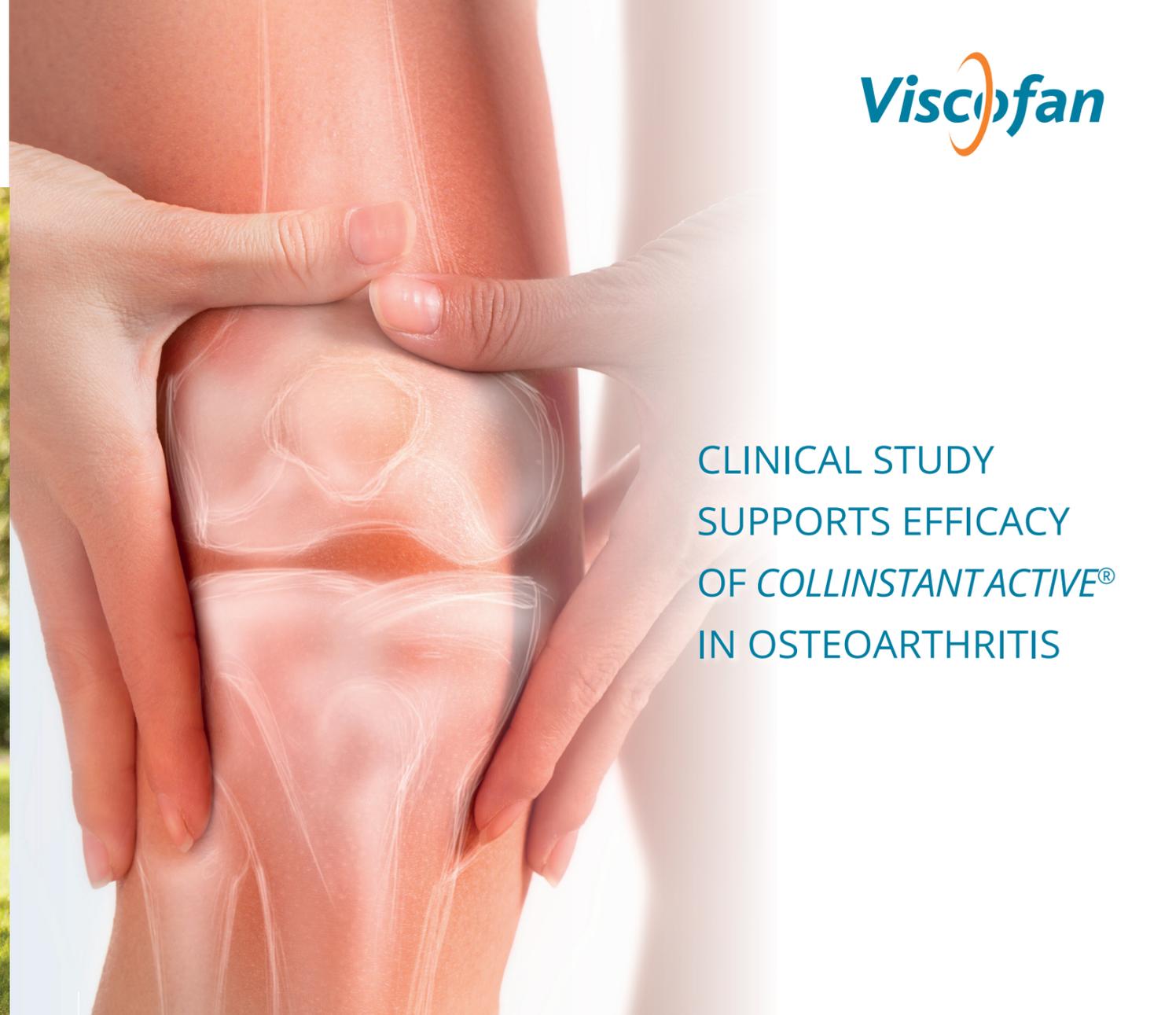




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CLINICAL STUDY
SUPPORTS EFFICACY
OF *COLLINSTANTACTIVE*[®]
IN OSTEOARTHRITIS

WHITE PAPER

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SUMMARY

- Randomized, double-blind, placebo-controlled clinical trial evaluated the efficacy of *COLLInstant active*[®] collagen peptides in combination with vitamin C as dietary supplement in the treatment of grade 2 and 3 osteoarthritis patients with moderate to severe pain.
- *COLLInstant active*[®] & vitamin C was effective in reducing pain, inflammation, and analgesic use, while at the same time increasing joint function and overall quality of life.
- Daily food supplementation with *COLLInstant active*[®] collagen hydrolysate and vitamin C may reduce pain and increase joint function in patients with osteoarthritis.

OSTEOARTHRITIS – A GLOBAL BURDEN

Osteoarthritis (OA) is a multi-cause degenerative process that affects the joint as a functional unit, causing pain, stiffness and impaired movement with a notorious impact on the quality of life. OA is a pathology that generates great healthcare impact and shows a high prevalence among elderly where it is the single most common cause of disability.¹ Pain control and general management of the disease are the most pressing issues for therapists in order to improve quality of life for OA patients.

~500 million people worldwide suffer from osteoarthritis.

In Spain, osteoarthritis is the main cause of permanent disability and the third cause of temporary working place disability.

(Source: Osteoarthritis Foundation International)

Past clinical studies have shown that collagen hydrolysate as a dietary supplement can improve joint function and activity-related pain in patients with mild OA symptoms^{2,3,4}.

In 2020, researchers of the Gala Servicios clinicos in Badajoz/Spain conducted a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy of *COLLInstant active*[®] collagen hydrolysate as food supplement in the treatment of grade 2 and 3 osteoarthritis patients with moderate to severe pain⁵.

STUDY OBJECTIVES

The main objective of the study was to determine the clinical efficacy of the oral dietary supplement with collagen peptides in reducing pain and improving joint function after six months of treatment. In addition, analgesic use and overall efficacy of the supplement were evaluated.

KEYWORDS

Osteoarthritis, joint pain, joint inflammation, collagen food supplement, collagen hydrolysate, collagen peptides.

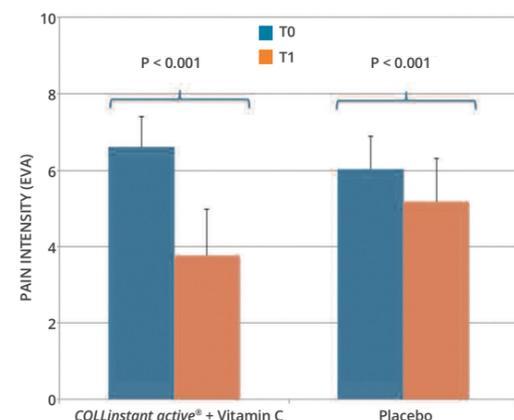


CLINICAL STUDY SUPPORTS EFFICACY OF *COLLInstant active*[®]

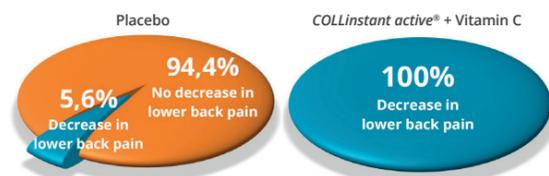
Daily food supplementation with collagen hydrolysate and vitamin C reduces pain and increases joint function in patients with osteoarthritis

Pain intensity decreased

All patients of the experimental group (100%) reported a decrease in pain intensity versus only 58,6% of the patients in the placebo group. The graph below shows the mean values of pain intensity, measured with VAS scale, at baseline (T0) and six months after treatment (T1) in patients of the control group and the experimental group. Error bars represent the standard deviation of the sample of each group.

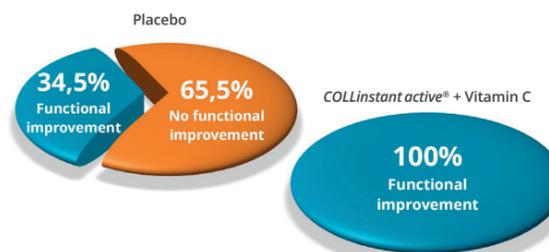


Treatment with *COLLInstant active*[®] and vitamin C was particularly effective in reducing lower back pain: all patients from the experimental group reported a decrease in pain intensity versus only 5,56% of patients in the placebo group (percentages assessed with the VAS scale).



Joint function improved

Joint function improved in all patients of the experimental group (100%) and was significantly lower in the placebo group (34,5%). In addition, although disability decreased over the course of the study in both groups, this improvement was significantly greater in patients in the experimental group (percentages assessed with the Lequesne index for knee OA).



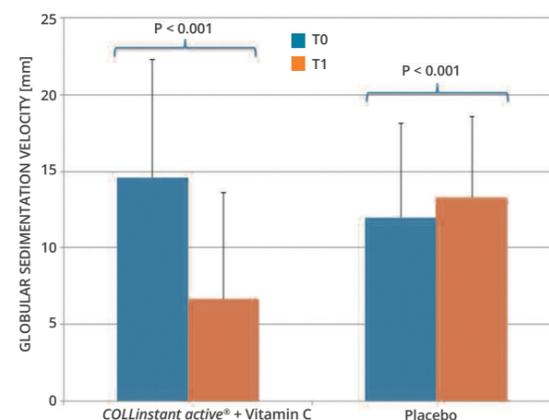
Use of analgesics dropped

The number of patients taking analgesics for OA pain was halved between T0 and T1 visits in the placebo group, but dropped considerably to one-fifth of the original number in the experimental group.

Biochemical inflammation marker declined

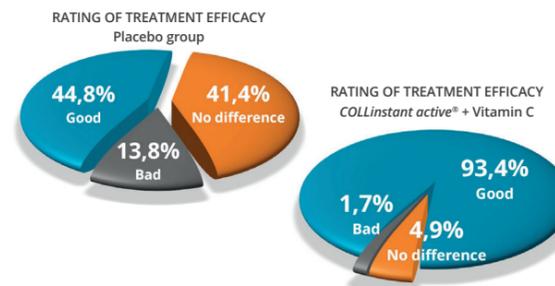
There was a significant reduction in C-reactive Protein (CRP) in the experimental group while the values did not vary in the placebo group between T0 and T1. The Erythrocyte Sedimentation Rate (ESR) dropped significantly in the experimental group but increased in the placebo group, indicating ongoing inflammation.

The graph below shows mean ESR values at baseline (T0) and six months after treatment (T1) in the control and experimental group. Error bars represent the sample standard deviation of each group.



Treatment efficacy confirmed

In a general assessment, 93,4 % of the experimental group confirmed the efficacy of the treatment with *COLLInstant active*[®] & vitamin C versus 44,8% of the control group.



Supplement rated tolerable and acceptable

No adverse effects occurred in both patient groups, and the acceptability of experimental and placebo food supplements was rated good almost unanimously (98,3%).

METHODS

Patient inclusion: 120 patients ≥ 30 years of age with grade 2 and 3 osteoarthritis and moderate to severe pain were included in the study. 61 individuals were assigned to the experimental (active treatment) study group, and 59 to the control (placebo) group (equal sex ratio). Patients were randomized 1:1 stratified by age, sex, BMI and OA location to receive either experimental or placebo treatment.

Study regime: All patients in the experimental group received 1 sachet / day, containing 10 g hydrolyzed collagen (*COLLInstant active*[®]), 80 mg vitamin C and sweeteners as powder for suspension to be taken orally once per day („chondroprotectors“). The sachets of the placebo group contained sweetener only („placebo“).

Data collection: Primary endpoints of the study were pain intensity on the visual analog scale (VAS) and functional assessment using the Lequesne index between the baseline period (T0) and the final period (T1) after six months of treatment. Additional data were collected using the WOMAC questionnaire score for knee and hip OA, the WOOS questionnaire score for glenohumeral OA, the Neck Disability Index (NDI) questionnaire score, the Oswestry Disability Index score and low back pain scale, and the SF-36 Quality of Life Questionnaire score (physical health status SF-36 PH and mental health status SF-36 MH).

CONCLUSIONS

The authors of the study observed a medium- to long-term healthcare benefit in OA patients treated with chondroprotectors in terms of a decrease in pain and inflammation and an increase in mobility and quality of life. While the anti-inflammatory effects may be in part attributed to vitamin C, the trial results support that the daily administration of *COLLInstant active*[®] collagen peptides can improve joint function and reduce pain intensity. During the osteoarthritic process, a number of cellular events and mediators lead to chondrocyte apoptosis and a degradation of the extracellular matrix of cartilage, resulting in a significant loss of collagen. The current body of literature suggests that a daily intake of collagen peptides can stimulate and facilitate natural collagen synthesis, thereby promoting the regeneration of collagenous tissues^{2,3,4}.

This study has demonstrated the efficacy of 10 g *COLLInstant active*[®] & vitamin C as a daily OA treatment. With its high acceptance as soluble, easy-to-use powder, collagen hydrolysate is an effective nutritional supplement to support the maintenance of joint health and mobility and to improve quality of life in OA patients.