

Fortigel® collagen peptides

A new option in the conservative treatment of osteoarthritis?

by Gelita

Previous preclinical studies carried out in recent years showed that collagen peptides are adsorbed by the body in intact form, accumulate in cartilage tissue, stimulate the collagen and proteoglycan production and have a positive effect on cartilage metabolism and on the progression of osteoarthritis (Flechtenhar K (2009) Chronic joint disease *Nutrafoods* 8(3) 23-29).

Last April Gelita researchers, in collaboration with clinicians from the *Tufts Medical Center* (Boston, MA, US) and the *Beth Israel Deaconess Medical Center* (Boston, MA, US) published the results of a study showing, for the first time in humans, that oral administration of a formulation of collagen hydrolysate (Fortigel®) had a direct and positive influence on cartilage structure (McAlindon TE et al (2011) Change in knee osteoarthritis cartilage detected by delayed gadolinium-enhanced magnetic resonance imaging following treatment with collagen hydrolysate: a pilot randomized controlled trial. *Osteoarthritis and Cartilage* 19 399-405).

Composition and technical specifications

The technical specifications of Fortigel® are reported in *Table 1*. Fortigel® is free of fat, carbohydrates, and purines; 1g has an energy value of 3.5 kcal (15 kJoule).

The new clinical study

The study carried out was a prospective, randomized, placebo-controlled, double-blind pilot trial on 30 patients (mean age 60 years) suffering from mild gonarthrosis. The goal of the study was to identify structural changes in the joint cartilage, by the evaluation of the cartilage proteoglycan content using a special MRI technique (dGEMRIC). The study participants were given a daily dose of 10g Fortigel® or a placebo over a period of 48 weeks.

In spite of the pilot features of the study and the small number of patients, the results showed that the administration of Fortigel® resulted in a positive effect on cartilage structure with a trend to increase in proteoglycan density within the joint cartilage (*Fig 1*).

While in the untreated placebo group, observed for over a year, progressive loss of cartilage substance occurred, degeneration of the extracellular matrix in the *verum* group decreased in a statistically significant manner in the medial and lateral tibial cartilage after 24 weeks of treatment.

This particular zone is subject to considerable mechanical stress through pressure and shear force. It is quite possible that the cartilage metabolism in this zone is increased so that the cartilage tissue becomes more receptive to stimulation by collagen peptides than other regions, where the trend was still present although it did not reach statistical significance.

This study thus represents the missing link between preclinical studies with a focus on the mode of action and clinical studies setting out to confirm efficacy on patients.

Table 1 Analytical specification of Fortigel®

Physical and chemical properties

Appearance	white powder
Odour	neutral
Taste	neutral
Dry substance (%)	91-96
Protein content dry substance (%)	97-100
Ash (%)	< 0.8
Peroxides (ppm)	<10
Viscosity mPa.s	3.5-5
pH	5.4-6.3
Solubility	freely soluble

Heavy Metals (ppm)

Arsenic	≤ 0.7
Cadmium	≤ 0.1
Chromium	≤ 1.0
Copper	≤ 2.0
Mercury	≤ 0.02
Lead	≤ 0.5
Zinc	≤ 10
Sulphur dioxide	≤ 10

Microbiological properties

Total viable aerobic count (cfu/g)	< 1.000
Anaerobic sulphite-reducing bacteria (cfu/g)	<10
<i>Salmonella</i> (/25g)	neg
<i>Escherichia coli</i> (/10 g)	neg

Shelf life 5 years

Storage under dry and odourless conditions

Safety

Fortigel® was well tolerated over the 48 weeks of treatment: there were no adverse event reports related to treatment.

Applications and dosage

Fortigel® is suitable for protein enrichment in dietary supplements and functional foods. It can be used in patients suffering from osteoarthritis as it represents a possible causal therapy for the condition, and in healthy persons for disease prevention. The suggested dose is 10 g/day.

For information

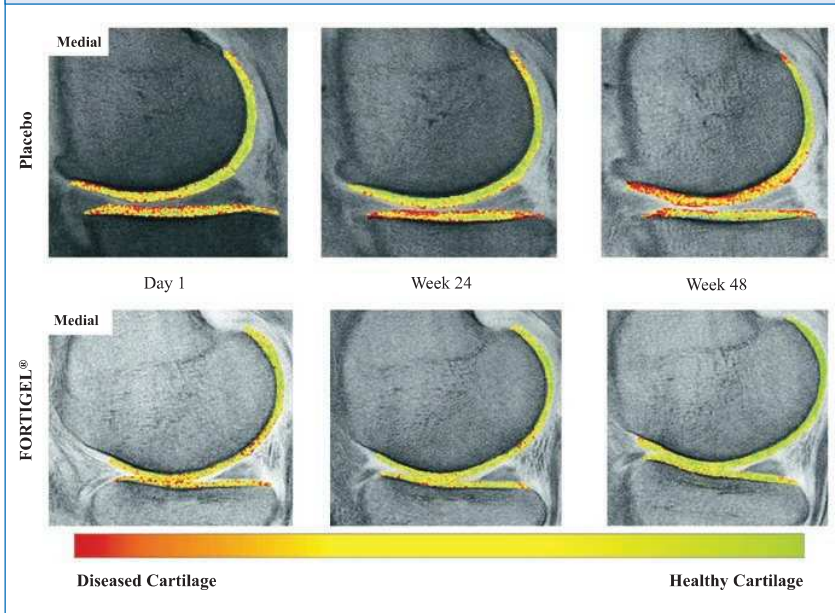
Martin Walter

tel +49 6271 84 2147

email martin.walter@gelita.com

web www.GELITA.com

Figure 1 Representative dGEMRIC images of knee cartilage in the placebo and Fortigel®-treated groups over time



Gelita in a nutshell

Gelita is the leading company for manufacturing and marketing collagen proteins. Coordinated from its headquarters in Eberbach, Germany, Gelita provides customers around the world with products of the highest standard, comprehensive technical expertise and sophisticated solutions. More than 20 sites and a global expert network ensure that state-of-the-art know-how is always available for customers. More than 135 years of experience in the field of collagen proteins are the basis of Gelita's performance. A strong requirement for innovation is the driving force of the family-owned company that is always looking for new solutions for food, pharmaceutical, health & nutrition as well as for technical applications. Besides the traditional use of collagen proteins as natural stabilizers and emulsifiers for countless products, Gelita has intensified its research in developing solutions for physical mobility, calorie management and beauty from within.