Effectiveness of a novel hydrolyzed collagen formulation in treating patients with symptomatic knee osteoarthritis: a multicentric retrospective clinical study.

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Introduction

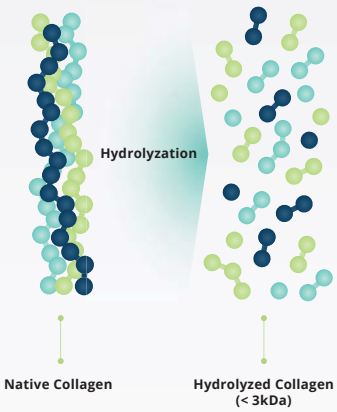
Knee osteoarthritis (OA) is a musculoskeletal disorder that has high economic and social costs and may have a heavy impact on the patients' quality of life. In patients aged <60 years, knee OA has a prevalence of about 10% in men and 13% in women.

Pharmacological treatments, such as oral or topical administration of non-steroidal anti-inflammatory drugs, are effective only on a short-term basis, and their prolonged use has several adverse effects.

OA causes structural, cellular and biochemical changes in the affected joints. Inflammation leads to progressive degradation of the components of the extracellular matrix (ECM), including collagen. Thus, the effect of administration of exogenous collagen has been investigated.

A novel collagen formulation (CHondroGrid®, CG) consisting in low molecular weight hydrolyzed bovine collagen for intra- and peri-articular injection has been placed on the market as a medical device.

Hydrolyzation is a cleaving process obtained through enzymes and chemico-physical agents, that leads to collagen peptides having a different range of molecular weight and size.



As peptides are significantly smaller than the whole molecule, they easily diffuse into liquids.

Therefore, they can be easily injected into the intra- and peri-articular spaces where, by diffusion, they spread all over the articular and tendon and ligament surfaces.

CHondroGrid® could act as a mechanical and structural reinforcement of weakened and/or damaged collagen matrix.

Aim of the study

This retrospective and multicentric study aims to assess CHondroGrid® safety and performance in reducing symptoms in 70 patients suffering from knee osteoarthritis.

Patients and treatment

Patients included in the study:

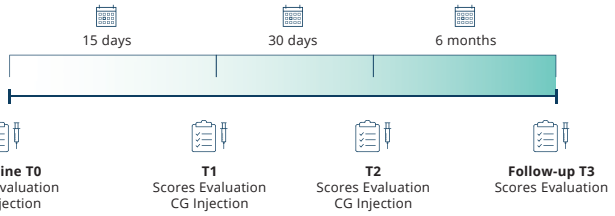
- Suffered from Kellgren Lawrence grade 1 to 4 knee OA
- BMI < 30
- Treated by administering three intra-articular CG injections (4 mg/2 mL)

Measurements

- **Lequesne score** (severity for osteoarthritis)
- **VAS** scores (subjective pain) at rest and moving
- **WOMAC** scores (pain, stiffness and physical function)

Scores were recorded at **T0, T1, T2, T3** (Follow-up).

Study time-line

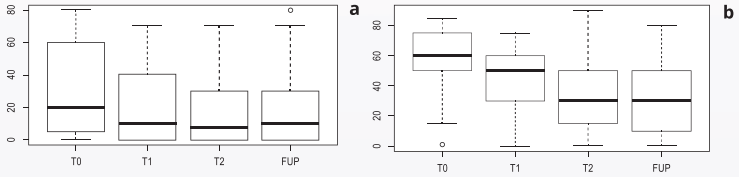


Patients Baseline Characteristics

Parameter	Age	BMI	KL Scores (1,2,3,4)	M/F	Diabetes	Cardiovascular Disorders	Metabolic Disorders
Mean ± SD or Y/N (%/%)	57.1±14.5	24.6±2.9	25 (35.7) 31 (44.3) 11 (15.7) 3 (4.3)	37/33 (52.8/47.2)	3/67 (4.5/95.5)	11/59 (15.7/84.3)	7/63 (10/90)

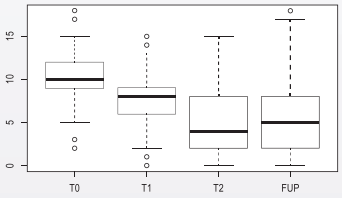
Results

Figure 1: **VAS scores** measured at rest (**a**) and while moving (**b**)



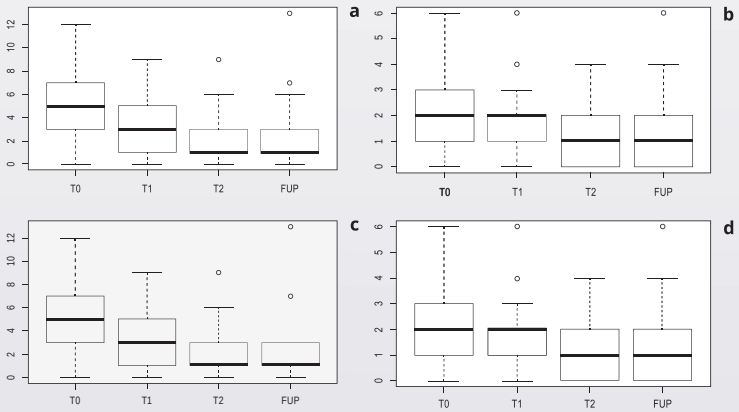
Median VAS at rest and moving decreased significantly after both CG injections and was stable at follow-up.

Figure 2: **Lequesne scores**



Median Lequesne decreased significantly after the first injection, decreased further after the second injection and slightly increased at the 6-month follow-up.

Figure 3: **WOMAC** pain (**a**), stiffness (**b**), physical function (**c**) subscores and total WOMAC score (**d**).



For all scores, median values at T1 are significantly lower than those at baseline, and median values at T2 are significantly lower than those a T1. For all scores, median values at the 6-month follow-up were not significantly different than that at T2.

Conclusions

Indicate that CHondroGrid® is a safe and effective short-term adjuvant in the treatment of symptomatic knee OA by intra-articular injection;

Do not provide indications concerning long-term effects of intra-articular injections;

Further controlled prospective studies should be carried out to investigate if intra-articular CG injection may be more beneficial than other non-pharmacological treatments already available in the clinical practice.