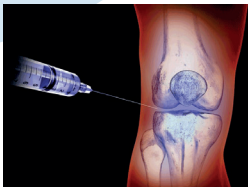
Clinical Sheet

CHONDROGRID: A PILOT CLINICAL STUDY

The intra-articular administration of hydrolyzed collagen as a possible arthrosis treatment addressing both function and symptoms.



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Arthrosis is an inflammatory condition that affects the joints; the most frequently affected areas are the hand, hip and knee. Knee arthrosis, in particular, affects approximately 10% of men and 13% of women over 60. The condition is associated with pain, swelling and impaired function of the joint. To date, there is no cure for knee arthrosis and treatment, which only addresses the symptoms of the condition, must continue for the rest of the patient's life. The pharmacological approach to the symptoms of arthrosis entails topical and/or oral administration of non-steroidal anti-inflammatory drugs (NSAIDs), or the intra-articular injection of corticosteroids. Topical treatment has limited effectiveness and requires several applications; treatment by oral administration of NSAIDs, as well as intra-articular injections of corticosteroids, can only last for a limited period of time and have a number of side effects, especially – as is the case with this condition – if it extends over several years. The interest of clinicians in alternative, non-pharmacological therapies for the treatment of the symptoms of arthrosis is quite significant: their application, in fact, may reduce the use of medicinal products, and in some cases, in less severe arthrosis and in combination with physiotherapy, eliminate it altogether. The possible non-pharmacological alternatives include, other than viscosupplementation, the intra-articular injection of hydrolyzed collagen, as described in this sheet.

Materials

All patients involved in the study were treated with CHondroGrid (Bioteck), a device made from low-molecular-weight hydrolyzed collagen. CHondroGrid is indicated for the treatment of painful symptoms and loss of functionality in the main joints (knee, shoulder, hip, wrist and ankle), either caused by degenerative conditions or due to trauma or excess load. Treatment entails performing three intra-articular injections, the second 15 days after the first and the third 30 days after that. The action mechanism is based on the ability of hydrolyzed collagen to diffuse in the synovial fluid and to evenly spread on the surface of the damaged joint, reinforcing the cartilage matrix.

CHondroGrid, in fact, is able to perform a mechanical action of direct reinforcement of the weakened and/or deteriorated structures, improving mobility and contributing to reducing the painful symptoms in the joint.

Parameter	Mean ± SD or Y/N (%/%)
Age (years)	58.1±11.1
Weight (Kg)	76.5±14.1
Height (cm)	173.7±9.0
BMI (Kg/m2)	25.2±3.3
KL score 1,2,3,4 (%)	4 (20); 11 (55); 3 (15); 3 (10)
M/F (%)	14/6 (70/30)
Diabetes Y/N (%)	2/18 (10/90)
Cardiovascular disorders Y/N (%)	7/13 (35/65)
Metabolic disorders Y/N (%)	4/16 (20/80)
Concomitant treatment Y/N (%)	11/9 (55/45)

Fig. 1 – *Distribution of the subjects according to their baseline characteristics.*

	Baseline (before first injection)	T1 (15 days after first injection)	T2 (30 days after first injection)	FUP (about 6 months after first injection)	FUP vs Baseline (%)
Time (days)	N/A	14.5.1±2.0	22.9±11.2	172.1±22.7	N/A
VAS at rest	6 (22.5)	0 (6.25)	0 (5)	0 (10)	-100.0%
VAS when moving	50 (23.25)	30 (27.75)	21 (21.25)	22.5 (20)	-55.0%
Lequesne Index	9 (3.25)	7 (5.25)	3.5 (5.25)	5 (5)	-44.0%
WOMAC (pain)	4.5 (3.25)	2 (3.0)	1 (2.25)	1 (2.25)	-77.8%
WOMAC (stiffness)	2 (2.25)	2 (2.25)	1 (2.25)	0.5 (1.25)	-75.0%
WOMAC (physical function)	18 (13.0)	13.5 (12.5)	5 (10.25)	5 (7)	-72.2%
WOMAC (Total)	23.5 (14.5)	17 (15.75)	8 (13.75)	6.5 (9.25)	-72.3%

Fig. 2 – *Values of the parameters covered by the study at the various time points and their percentage reduction compared to the baseline. All parameters decreased significantly, with values exceeding 50%, with the exception of the Lequesne index, which however decreased by 44%.*

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Results

The sheet summarizes a retrospective pilot study concerning the clinical data of 20 patients affected by knee arthrosis, the severity of which ranged from 1 to 4 on the Kellgren Lawrence scale, treated with intra-articular injections of CHondroGrid at two Italian hospitals.

The study excluded all data concerning patients who suffered from conditions that might have interfered with the assessment of the symptoms and functionality, such as rheumatoid arthritis and fibromyalgia, or who presented with a knee infection, as well as the data concerning patients with BMI ≥ 30. The study also excluded the data concerning patients who, in the three months before treatment with CHondroGrid, had been treated with oral corticosteroids, or had received intra-articular injections of corticosteroids, NSAIDs, hyaluronic acid or other formulas. The data of patients who had undergone surgery in the 6 months before the study were also excluded.

The medical records included the AP weight-bearing X-rays of the joint before treatment (baseline), and the Lequesne index, the WOMAC score, the subjective VAS score measured both at rest and in motion at the baseline, following each injection and 6 months after the third injection (follow-up). The medical records also needed to report any adverse events associated with the use of the device, to allow its safety profile to be assessed.

The distribution of the subjects by baseline characteristics is shown in the table of Figure 1, while the trend of functional scores over time is summarized in the table of Figure 2 and in the figures below. Following treatment with CHondroGrid, all the parameters covered by the study significantly decreased as of the very first injection; they further decreased following the second injection and then remained unchanged over time, showing a possible long-lasting effect of the treatment with CHondroGrid on the symptoms of arthrosis. The study did not find any side effects associated with the use of the device.

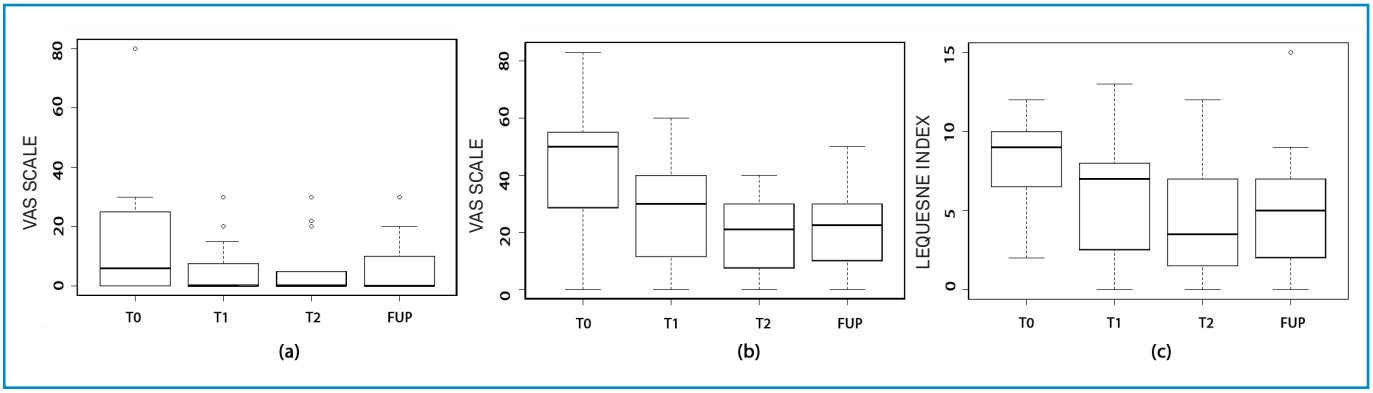

Fig. 3 – *Reduction of the pain at rest (a), during movement (b) and of the Lequesne index following treatment with CHondroGrid. The reduction is significant already from the first injection, it increases after the second injection and then remains unchanged over time during the follow-up period.*

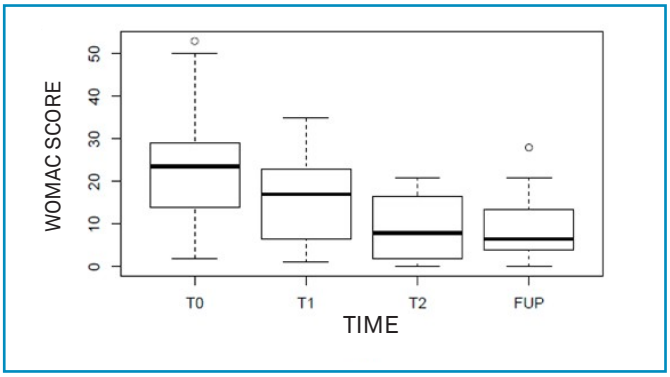

Fig. 4 – *Reduction of the total WOMAC score. The reduction is significant already from the first injection, it increases after the second injection and then remains unchanged over time during the follow-up period. The scores relating to pain, rigidity and function show a similar trend (not shown).*

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