S. Boccaccio

CLINICAL

TREATMENT OF HIP OSTEOARTHRITIS WITH MD-HIP – CLINICAL AND FUNCTIONAL EVALUATION USING A GAIT ANALYSIS SYSTEM

SUMMARY

In Italy, 8% of all forms of osteoarthritis (OA) are localised at the acetabulofemoral joint, with considerable impairment of quality of life due to pain and lameness, and consequent reduction of movement. Conventional medical treatment of OA is based on the use of analgesics, NSAIDs, corticosteroids and physiotherapy.
– In this observational study, 15 patients (mean age = 62 years) with grade II-III hip OA according to the Kellgren-Lawrence Scale were enrolled and treated solely with the MD-HIP medical device (2 vials = 4 mL/treatment) injected subcutaneously into the periarticular and peritrochanteric regions once a week for 4 consecutive weeks.
Evaluations were performed at the beginning of therapy (T0) and at one week after the 4th and last treatment session (TF).
Results obtained:
– NRS (Numeric Rating Scale): from 7.26 at T0 to 0.8 at TF;
– ROM (Range of Motion): from 78° at T0 to 88° at TF;
– WOMAC (Western Ontario and McMaster Universities Arthritis Index) scale: from 52.05 at T0 to 15.88 at TF;
– Support phase: from 62.77 at T0 to 59.74 at TF;
– Flight phase: from 37.38 at T0 to 40.28 at TF;
– Propulsion: from 6.05 at T0 to 6.81 at TF;
– Gait quality: from 91.95 at T0 to 97.08 at TF.
The values of the last 4 parameters considered were obtained using the BTS G-Walk analyser.
The statistical significance of all the results obtained ($p < 0.01$) and the absence of side effects show that MD- HIP is an effective and highly reliable tool for the treatment of hip OA.

KEY WORDS

HIP OSTEOARTHRITIS, MEDICAL DEVICE, MD-HIP, GAIT ANALYSER

https://stiwell.medel.com/orthopaedics/hip-arthrosis

INTRODUCTION

Osteoarthritis (OA) is a chronic, debilitating disease with a multi-factorial aetiology; the major causes of this complex condition include age, obesity, metabolic disorders, inflammatory diseases, and genetic factors.

– In Italy, approximately 5 million patients suffer symptomatic forms of OA, characterised predominantly by pain and reduced joint mobility.
Conventional conservative treatment aims to reduce pain and increase the joint's range of motion using analgesics, NSAIDs, steroidal anti-inflammatories, and physiotherapy (1).

8% of all forms of OA are localised at the acetabulofemoral joint that, as in all other forms of OA, is characterised by pain and a reduced range of motion (lameness), resulting in an impaired quality of life.

The osteoarthritic process is characterised by a vicious circle that results in the degradation of the articular cartilage matrix **(ACM)** and chondrocyte death, causing changes in the neosynthesis of collagen-rich ACM, whose function is to absorb the mechanical stress placed on the joints.

– The 2003 EULAR (European League Against Rheumatism) Guidelines (2) in-

GENDER	AGE	SIDE
F	77	R
F	65	R
M	50	R
M	50	L
F	67	L
F	69	L
F	57	R
F	43	L
M	73	L
M	72	R
F	63	R
F	72	R
F	71	L
M	54	R
F	47	R

TAB. 1

dicate, among the treatment options for OA, the use of SySADOA (Symptomatic Slow-Acting Drugs for OsteoArthritis) able to modify the evolution of OA.
Of these options, in recent years the use of hyaluronic acid **(HA)** has become popular due to its synovial fluid viscosupplementation properties, which make it possible to restore the biological and organoleptic properties of the normal HA present inside the joint capsule, which, in the case of OA, is deficient (3).

HA is used in certain forms of OA, such as osteoarthritis of the knee and shoulder.

When HA is used in hip OA, ultrasound guidance is used to obtain optimal control of the position of the needle, as the hip is a deep joint and, therefore, it is more difficult to reach (4).

– Of the various treatment options for OA, in order to reduce the cartilage degradation process, it is necessary to consider products containing collagen, which can be administered both in hydrolysed form via the oral route, and – far more effectively – by injection (5).

Lastly, although many studies have investigated the effects of these treatments before and after local injection, very few have evaluated them in terms of gait quality (6).

PURPOSE OF THE STUDY

The purpose of this observational study was to evaluate the outcomes of use of **MD-HIP** medical device for injection containing collagen in the treatment of **hip osteoarthritis**.
– The primary outcome was the evaluation of the pain and functional parameters;
– The secondary outcome was the correlation of these data with gait quality.

MATERIALS AND METHODS

Between January and October 2020, we enrolled **15 consecutive patients** with hip OA referred to our Physical Medicine & Rehabilitation Unit. Patient characteristics are provided in TAB. 1:

- 10 F
- 5 M
- mean age: 62 years
- right hip OA: 9 pat.
- left hip OA: 6 pat.

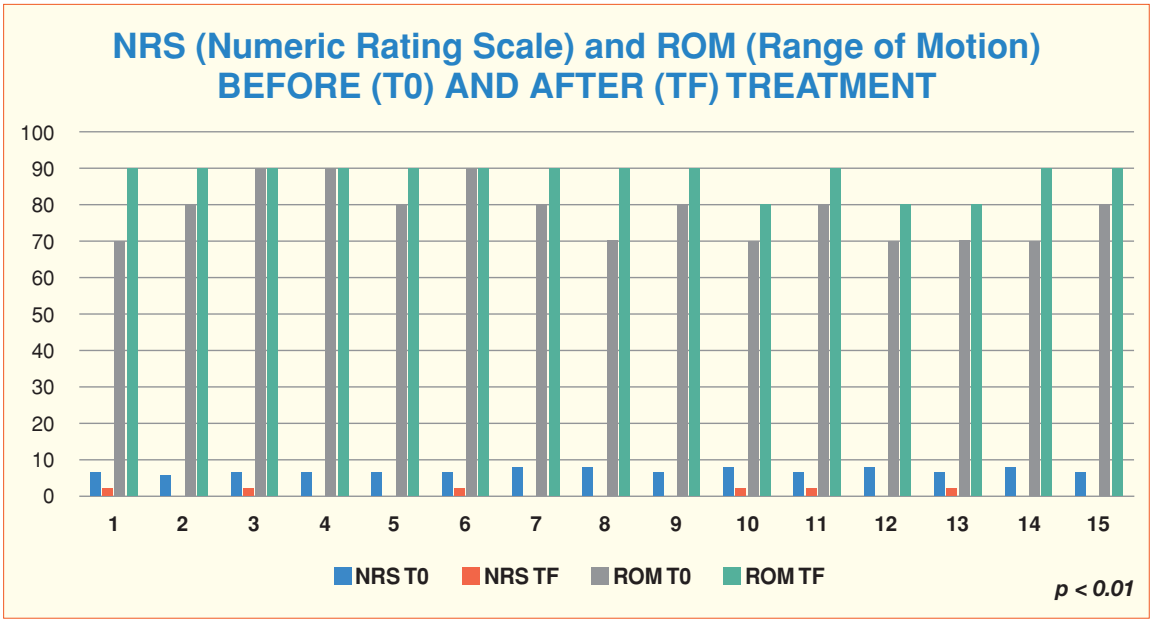
Each patient was assessed before the injection **(T0)** and 5 weeks later **(TF)**, one week after the last treatment session.

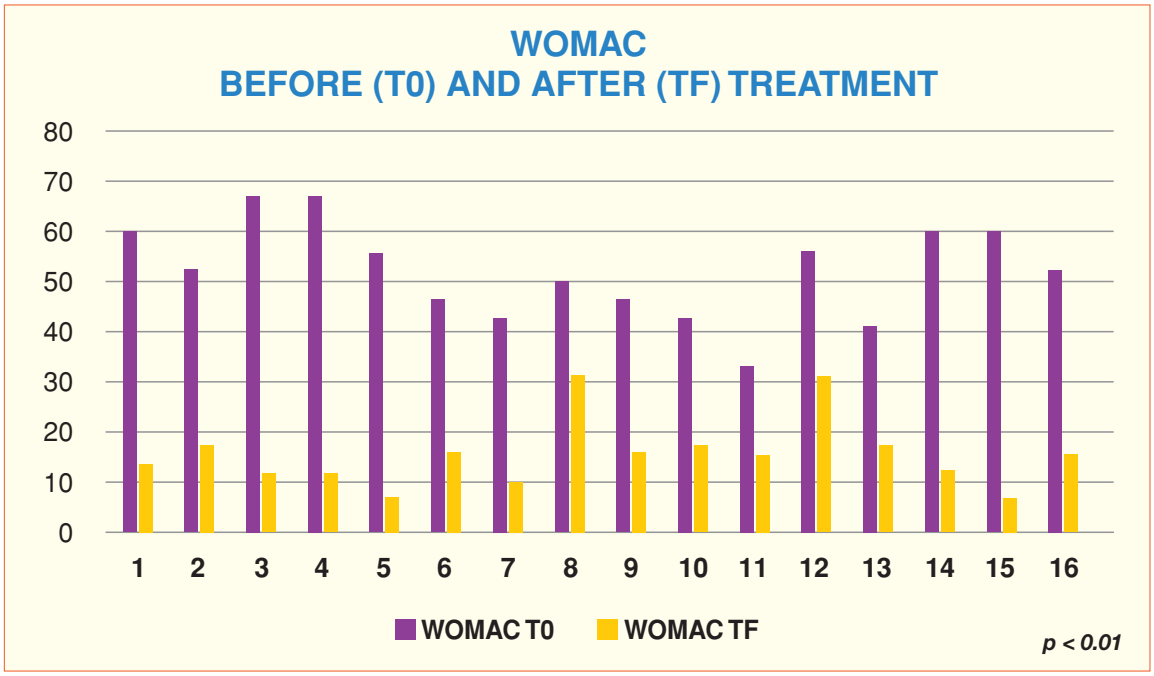
The study inclusion and exclusion criteria are indicated below.

– Inclusion criteria:

- age between 40 and 80 years;
- grade II-III hip OA defined by radiographic grading using the Kellgren-Lawrence Scale (7);
- absence of pharmacological treatments for active OA;
- good treatment compliance in all steps of the study.

TAB. 2





TAB. 3

– Exclusion criteria:
- poor treatment compliance;
- presence of other conditions involving the acetabulofemoral joint such as tumours, necrosis of the head of the femur, dysplasia; patients eligible for hip replacement surgery;
- patients who received steroids in the previous 6 months;
- anti-coagulant therapy;
- active skin infections or disease at the treatment site.

– Treatment was carried out solely with **MD-HIP** (Guna Spa, Milan - Italy), a medical device for injection containing collagen, developed specifically for the hip joint.
The chosen injection route was **subcutaneous**; the injection sites were **1)** the periarticular region of the hip, and **2)** the peritrochanteric regions.
– During each treatment session, patients were injected **2 vials** of MD-HIP (4 mL).
The sessions were once-weekly for **4 consecutive weeks** (total of 8 vials injected).
The final assessment was performed one week **after** the last treatment session (week 5).
The assessments were carried out using:
- the **NRS** (Numeric Rating Scale) for the **pain evaluation**;
- the **WOMAC** (Western Ontario and McMaster Universities Arthritis Index) scale for the **functional assessment**;
- **Gait analysis** using the **BTS G-Walk** analyser [BTS Bioengineering, Garbagnate Milanese, Milan - Italy].

The WOMAC (8) scale is used to assess the conditions of patients with hip or knee OA.

The test rates the main aspects of the condition, such as pain, joint stiffness and function of the considered joint.
The score is the sum of the 3 groups of questions with 5 possible answers to choose from to rate pain, stiffness and functional limitation of activities of daily living such as going up stairs, lying down on and getting up from a bed, walking, etc.
• The BTS G-Walk gait analyser consists of a wireless system connected to a computer.

This instrument consists of 1) a triaxial accelerometer, 2) a magnetic sensor and 3) a triaxial gyroscope positioned at L5. BTS G-Walk analyses a number of gait parameters, such as speed, cadence and symmetry index and therefore provides valuable information on pelvic movements on three axes.

In this study, the parameters considered were:
- propulsion, to assess functional recovery;
- the support phase (normal value: 58.98 +/- 1.97) and the flight phase (normal value: 40.03 +/- 3.56), to evaluate gait quality in relation to pain;
- the gait quality index.

INJECTION TECHNIQUE

Each treatment was administered with a 16 mm 25 G needle, via the subcutaneous route.

– The injection sites were the periarticular region, with injections perpendicular to the skin plane, and the peritrochanteric region with the needle slanted to an angle of about 30° to the skin plane.

The subcutaneous route was used considering the specific tropism and trophism of MD-HIP for the acetabulofemoral joint.

The injection treatment was also expanded to the peritrochanteric region as we believe that these patients also have a concomitant functional stress-induced

tendinopathy of the greater trochanter insertion site that contributes to the symptoms experienced.

STATISTICAL ANALYSIS

For data analysis, we calculated the mean with its pre- and post-treatment variations and, using an appropriate programme, the achievement of statistical significance, using a comparison of means test.

RESULTS

The analysis of the results showed a considerable decrease/ increase in both the clinical and functional values.
– The NRS (Numeric Rating Scale), values, used to rate pain, and ROM (Range of Motion), showed a significant decrease in the former, with a mean value of **7.26** at **T0** and of **0.8** at **TF**, and an increase in the range of motion for femur flexion in relation to the pelvis, with a mean value of **78°** at **T0** and of **88°** at **TF** (TAB. 2).
– The functional indices, evaluated using the WOMAC scale, showed a significant improvement with a mean value of **52.05** at **T0** and of **15.88** at **TF** (TAB. 3).
– For the gait quality analysis, the indices considered were **1)** the flight phase; **2)** the support phase, to be correlated with pain; **3)** propulsion, to be correlated with speed and therefore the extension of the acetabulofemoral joint; **4)** the gait quality index as a general assessment index considering various parameters.

– The analysis of these data showed a decrease in the mean support phase value from **62.77** at **T0** to **59.74** (normal value: 58.98 +/- 1.97) at **TF** and – consequently – an increase in the flight phase from a mean value of **37.38** at **T0** to **40.28** at **TF**.
In both cases this variation achieves statistical significance ($p < 0,01$).

These changes show an improvement in gait quality, to be correlated with an improvement in propulsion (from **6.05** at **T0** to **6.81** at **TF**) and a reduction in pain at weightbearing and walking [detected by means of the reduction in the mean NRS values at TF (see before)], which, in turn, indicates the better flexion-extension of the hip associated with the increase in ROM [mean of the TF values equal to 88° (see before)] and of the gait quality with a mean value of **91.95** at **T0** and of **97.08** at **TF** ($p < 0.01$) (TAB. 4).

DISCUSSION

The purpose of this study was to evaluate treatment with MD-HIP in patients with grade II or III hip osteoarthritis according to the Kellgren-Lawrence Scale.

OA is currently common in Italy, where it is estimated to affect approximately 5 million people.
In approximately 8% of cases, the disease involves the hip joint.

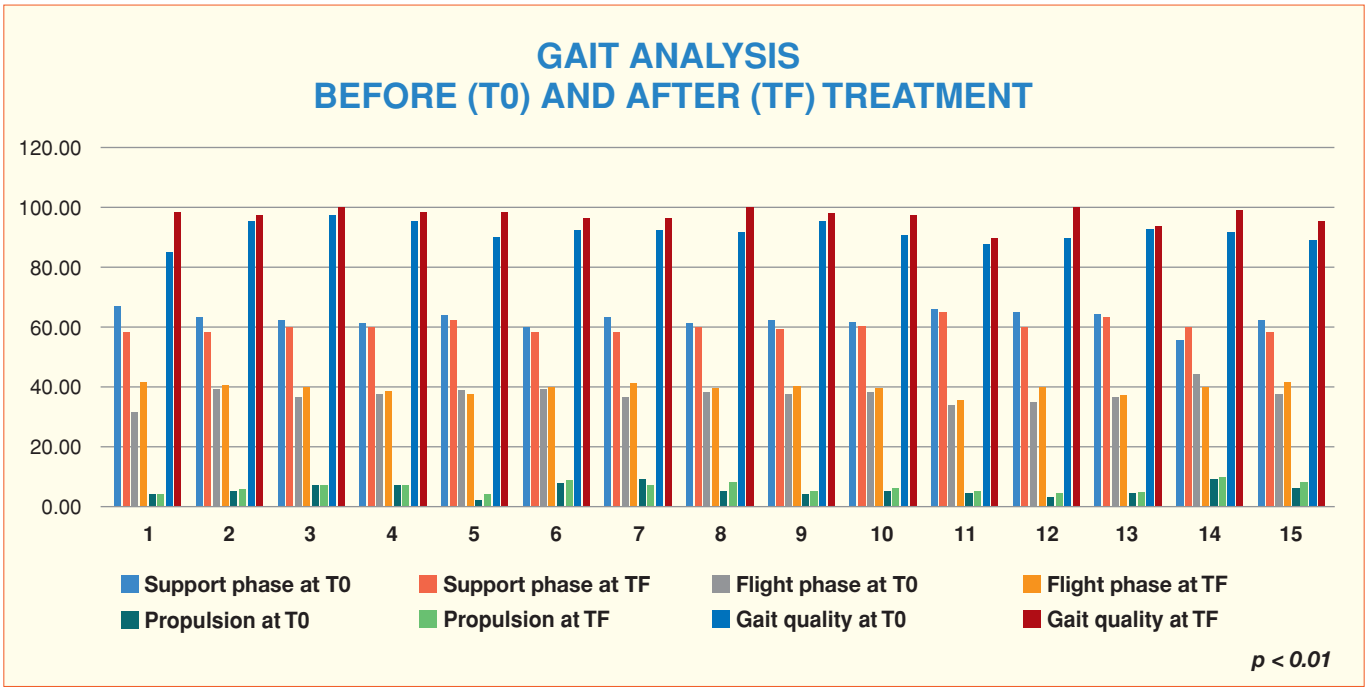
Hip OA is characterised by pain, decrease in the joint's range of motion lameness and gait defects that, in the most severe cases, requires joint replacement surgery.

Conventional treatments aim to increase the range of motion of the joint and reduce pain and they rely mainly on the use of anti-inflammatory drugs and physical therapies.

In our trial, we only injected a medical device containing collagen (MD-HIP) via the subcutaneous route.
The injection sites were periarticular and peritrochanteric.

The former (periarticular sites), because

TAB. 4



MD- HIP contains an active substance that provides specific trophism for the acetabulofemoral joint.
The latter (peritrochanteric sites), because we noticed that, in order to compensate, these patients develop a tendinopathy of the peritrochanteric and gluteus medius muscles that exacerbates the symptoms experienced.

– The results obtained show a clear improvement in the clinical and functional status.

As regards the primary outcome, there was a significant reduction in pain as well as an increase in the joint's range of motion.

The functional improvement was also evident, as rated by both patients and the WOMAC Scale, as well as by means of gait analysis, with an improvement in the support phase and speed.

CONCLUSIONS

The purpose of our study was to evaluate the treatment of hip OA using Collagen Medical Device-HIP (MD-HIP).

All patients were evaluated using reference clinical and functional scales and with a highly-innovative gait analyser.

– The data showed a significant improvement in the values after 4 consecutive weeks of treatment with MD-HIP, injected via the subcutaneous route.

These variations achieved statistical significance.

– Gait analysis represents an optimum system for evaluating the results achieved.

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author

Dr. Salvatore Boccaccio
– Physical Medicine and Rehabilitation Specialist
– Senior House Officer
U.O.C. Medicina Fisica e Riabilitazione [Physical and Rehabilitation Medicine Unit] P.O. A. Rizza, ASP Siracusa

Syracuse, Italy