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## ABSTRACT

Osteoarthritis of the hip is a commonly observed disease in outpatient clinics dedicated to musculoskeletal pain management. The non-surgical therapeutic tools at our disposal are few and not always effective, especially in the advanced stages of the disease, in which joint damage is considerable.

In recent years, joint injection therapy with hyaluronic acid has become common, using an ultrasound-guided technique to improve the safety and appropriateness of the injection.

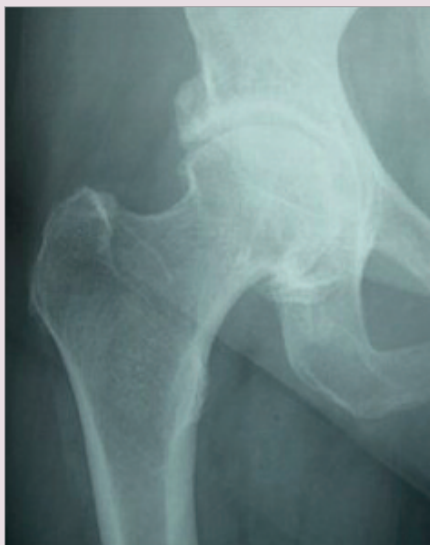
In literature, data on the efficacy of this treatment are more than encouraging.

– The combined use of hyaluronic acid and Collagen Medical Device MD-HIP via intra-articular and peri-articular injections are a valuable therapeutic tool in the treatment of hip osteoarthritis.

– This study aimed to assess its effectiveness on pain, functionality, tolerability, and safety.

## KEY WORDS

**COLLAGEN MEDICAL DEVICE, HYALURONIC ACID, MD-HIP, OSTEOARTHRITIS, PAIN, REHABILITATION, INJECTION, ULTRASOUND**



<https://www.boneclinic.com.sg/orthopaedic-conditions/hip-pain/hip-osteoarthritis/>

# THE ROLE OF MD-HIP IN ULTRASOUND-GUIDED INJECTION THERAPY IN OSTEOARTHRITIS OF THE HIP

## INTRODUCTION

Osteoarthritis (OA) is the most common arthritic condition and the main cause of disability amongst the elderly population.

– The hip is the second most commonly affected joint, with a prevalence range between 3% and 11% in the population over 35 years of age.

OA of the hip is characterised by the progressive de-structuration of the joint

cartilage. Clinically, it presents a progressive increase in pain symptoms associated with joint movement, leading to a loss of segmental function and alteration of motor dynamics.

At the current time, both the pharmacological (NSAIDs, cortisones, low dose medicines and herbal remedies) and non-pharmacological (rehabilitation, physiotherapy, acupuncture) treatment options aim to control pain symptoms, improve the consequent disability and, where possible, restrict the structural damage to the affected joint.

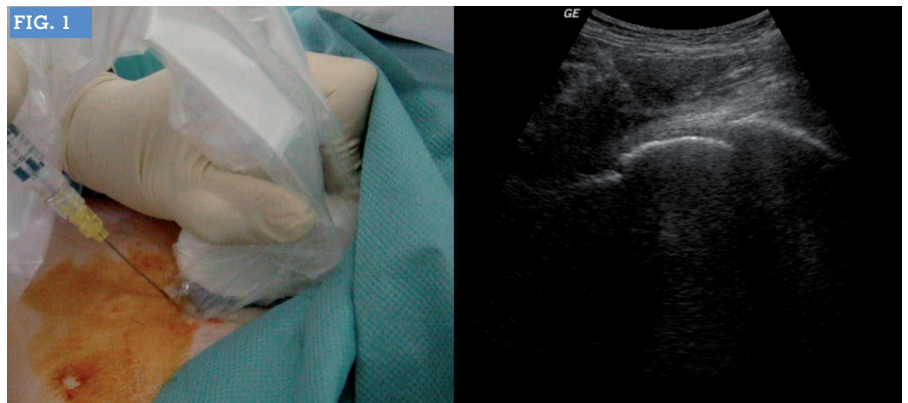
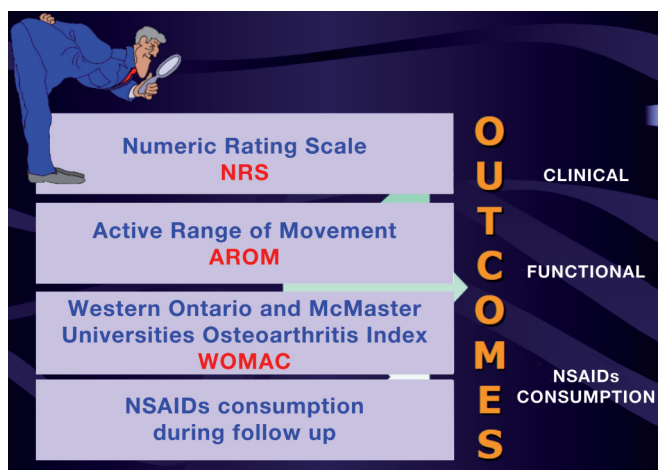


FIG. 1

TAB. 1



– Over the past 15 years, intra-articular injection therapy with hyaluronic acid (HA) has become increasingly extensively used worldwide, supported by the good results obtained in certain investigational clinical studies on the reduction of pain and improvement in joint function, making it possible to postpone the need for hip replacement surgery by several years.

HA is a high-molecular-weight glycosaminoglycan, constituted by a sequential repetition of glucuronic acid and N-acetylglucosamine.

In joints affected by OA, the concentration and molecular weight of physiological HA undergo a 33 - 50% reduc-

tion, with an obvious reduction in its effectiveness in protecting the joint.

Intra-articular viscoinduction and viscosupplementation are based on HA's physiological capacity to restore synovial fluid to an optimum viscosity and elasticity and its natural joint-protecting function, overcoming the loss of HA and stimulating its endogenous production, as well as controlling the production and activity of the pro-inflammatory mediators and matrix metalloproteinases.

– **Guna Collagen Medical Devices (MDs)** constitute a significant part of the possible options and therapeutic solutions for

the treatment of painful and dysfunctional musculoskeletal conditions, such as OA.

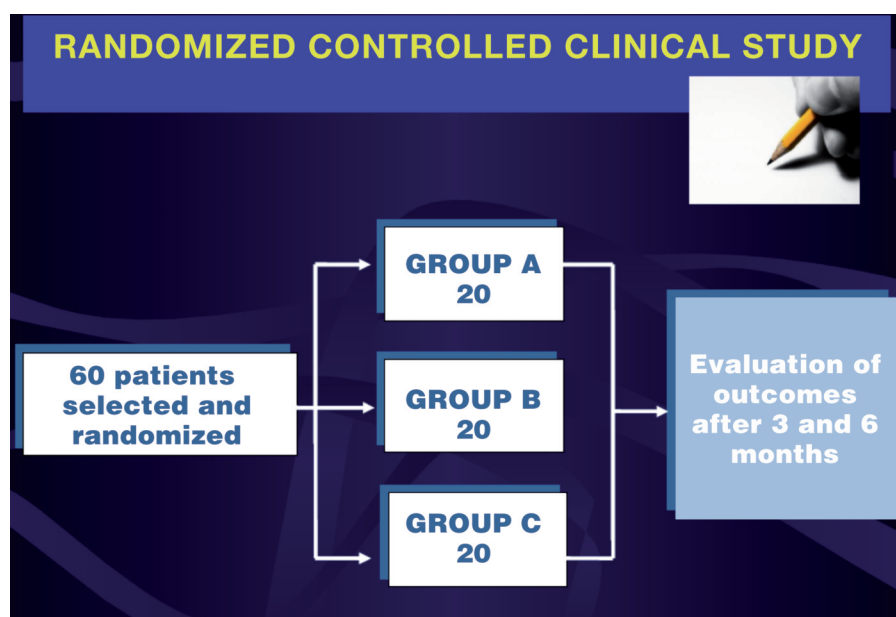
– With their porcine collagen content and ancillary substances of natural origin (vehicular excipients), they allow a **new structuring of the intra-articular tissues** (ligaments and joint cartilage) and **extra-articular tissues** [ligaments, joint capsule, tendons (which are primarily constituted by collagen) and muscles], providing a mechanical scaffold to favour the best arrangement of the damaged collagen fibres and to counter any joint laxity that may cause pain.

– In addition, the Guna Collagen MDs improve the viscoelastic properties of the intra-articular fluid, thanks to the cementing function of the collagen fibres of the proteoglycans of the extracellular matrix.

**HA + Guna Collagen MD combination therapy** is even more interesting considering the most recent physiopathological hypotheses regarding OA, according to which it is precisely the **extra-articular segment**, which is far more-richly vascularised, that is the *primum movens* of the pathological process.

– The aim of this study was to evaluate the therapeutic efficacy of **HA + MD combination therapy** in **osteoarthritis of the hip**.

TAB. 2



**PATIENTS AND METHODS**

This clinical study involved patients of both genders (51-77 years of age), who referred to the University Physical Medicine and Rehabilitation Unit - Turin - Italy for hip joint pain. The following inclusion criteria were used:

- diagnosis of primary OA for more than 12 months, according to *American College of Rheumatology* criteria;
- Kellgren-Lawrence radiological clas-

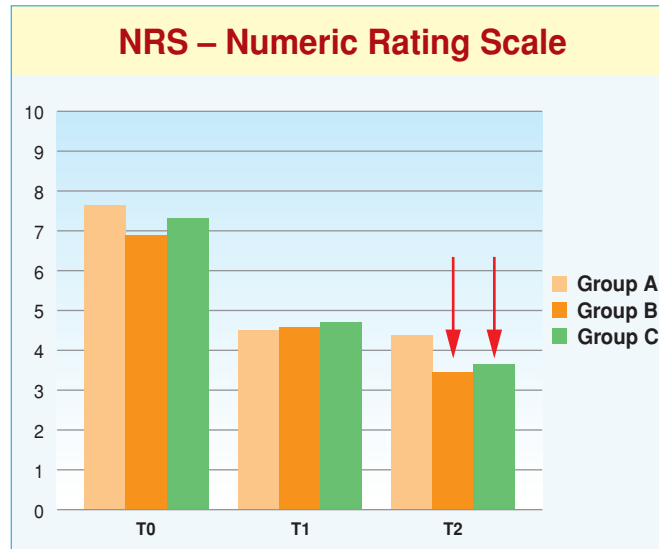
sification: **grades II-III**;

- moderate-severe pain with Numerical Rating Scale (NRS): score > 5, without taking NSAIDs;
- walking possible for intermediate distances (> 50 m), without aids.

Patients satisfying any of the following criteria were excluded from the study:

- diagnosis of RA, chondrocalcinosis, psoriasis, metabolic bone disease, gout, active phase infections;
- OA with rapid impairment, significant or congenital dysplasia of the acetabulum or head of the femur;
- symptomatic bilateral OA of the hip;
- previous injections of HA and/or intra-articular or oral cortisone therapy taken in the month prior to inclusion;
- mental illness;
- oral anticoagulant therapy, pregnancy, obesity;
- orthopaedic or neurological conditions compromising ability to walk.

Having received specific information on the potential risks of intra-articular therapy and having given their written informed consent – the enrolled patients



TAB. 3

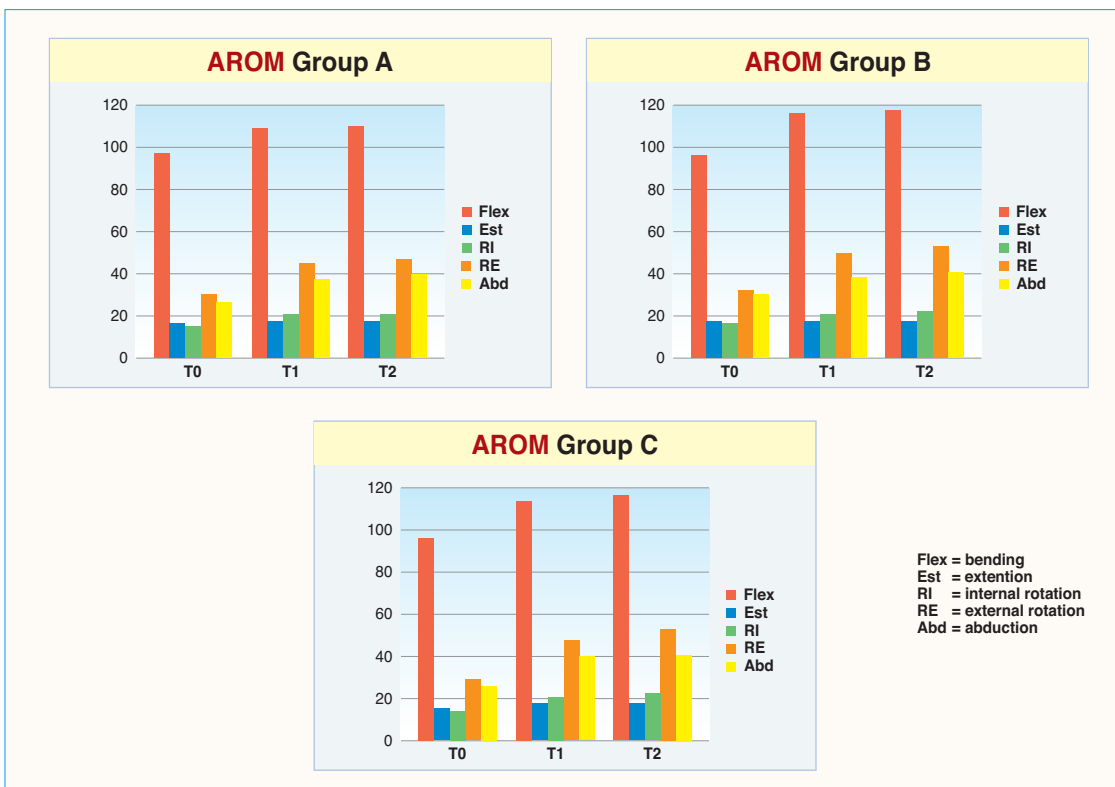
were randomised to one of three Groups (A, B, C).

– **Group A** received a cycle of 3 intra-articular injections of high-molecular-weight HA (MW 500-700,000, 20 mg/2mL, **Hyalubrix**, Fidia Farmaceutici Spa) at 10-day intervals.

– **Group B** received a cycle of 3 intra-articular injections of high-molecular weight HA (MW 500-700,000, 20

mg/2mL, **Hyalubrix**) and peri-capsular injections of **MD-Hip** (Guna Spa - Milan) (2 ampoules) at T0, T14 and T35, alternated with 2 peri-/intra-capsular injections with **MD-Hip** (2 ampoules) at T7 and T21.

– **Group C** received a cycle of 2 intra-articular injections of high-molecular weight HA (MW 500- 700,000, 20 mg/2mL, **Hyalubrix**) and peri-capsular injections of **MD-Hip** (2 ampoules) at T7 and T14, alternated with 2 peri-/intra-



TAB. 4

Flex = bending  
 Est = extension  
 RI = internal rotation  
 RE = external rotation  
 Abd = abduction

capsular injections with **MD-Hip** (2 ampoules) at T0, T14 and T35.

The patients included in the 3 Groups were also trained, by means of a short cycle of specific group rehabilitation sessions (*Hip School*), to correctly perform an exercise protocol to be repeated at home as self-treatment, at least 3 times a week.

The peri- and intra-articular injection treatment was administered under ultrasound guidance, using a Convex 3.5-MHz transducer with a standard technique (FIG. 1).

A number of clinical studies published in literature agree on the fact that multiple articular injection treatment does

not present a higher risk of adverse events or post-hip replacement infections than single articular injection.

Clinical and functional outcomes were measured at **3** and **6 months** from the first injection treatment.

The following were quantified:

- 1) pain using the NRS;
- 2) active range of movement (AROM) of the hip;
- 3) functional capacities;
- 4) pain using the WOMAC Index (*Western Ontario and McMaster Universities Osteoarthritis Index*), a multidimensional tool evaluating 17 functional patient activities, in addition to the 5 influenced by pain and the 2 items regarding joint stiffness.

In addition, any use of NSAIDs by the patients throughout the entire follow-up period and the occurrence of any adverse events was also recorded (TAB. 1).

## RESULTS

The study was conducted on **60 patients** who met the inclusion and exclusion criteria and were randomised, stratified by gender and age, in the order of 20 subjects to each treatment Group (Group A, B, and C) (TAB. 2).

No patient abandoned the study before the 6-month follow-up.

– Pain measured using the NRS had dropped in all 3 treatment Groups at the 3-month visit (T1) and to an even greater extent at 6 months (T2) in Groups **B** and **C** (TAB. 3).

– The active range of movement (AROM) progressively improved on all spatial planes in all 3 Groups (TAB. 4).

By plotting a graph of the sum of the articular gain obtained by patients in the single Groups at 3 and 6 months, a higher, progressive increase in *articular gain* is observed for Groups **B** and **C** (TAB. 5).

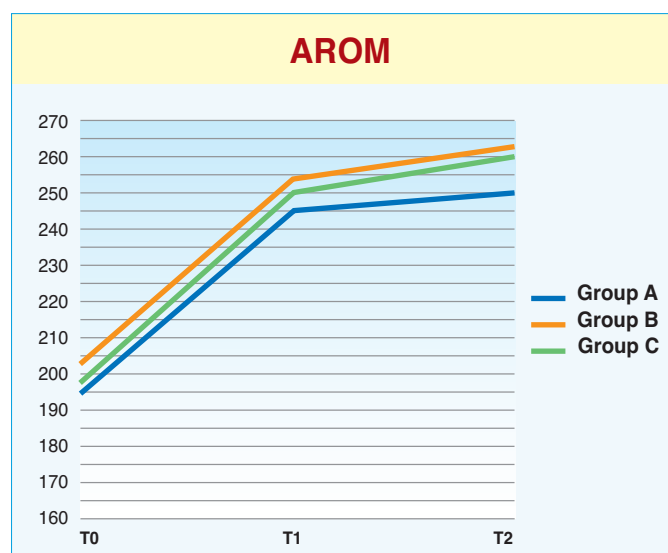
The WOMAC global score showed an improvement in functional activities for all patients, especially amongst Group **B** patients at the 6-month visit (TAB. 6).

By breaking the WOMAC index down into its 3 main items (*pain score, stiffness score, function score*), the function score increased progressively at both 3 and 6 months in Groups **B** and **C** (TAB. 7).

In the 3 Groups, there was a modest and homogeneous increase in the use of NSAIDs over time (TAB. 8).

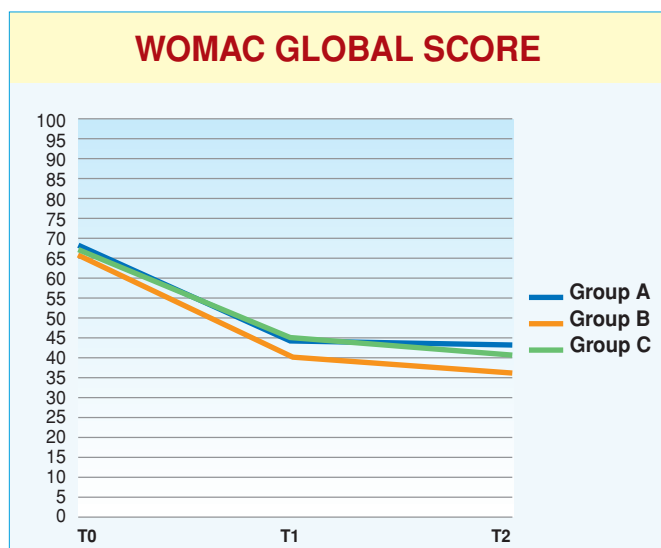
No adverse events were recorded.

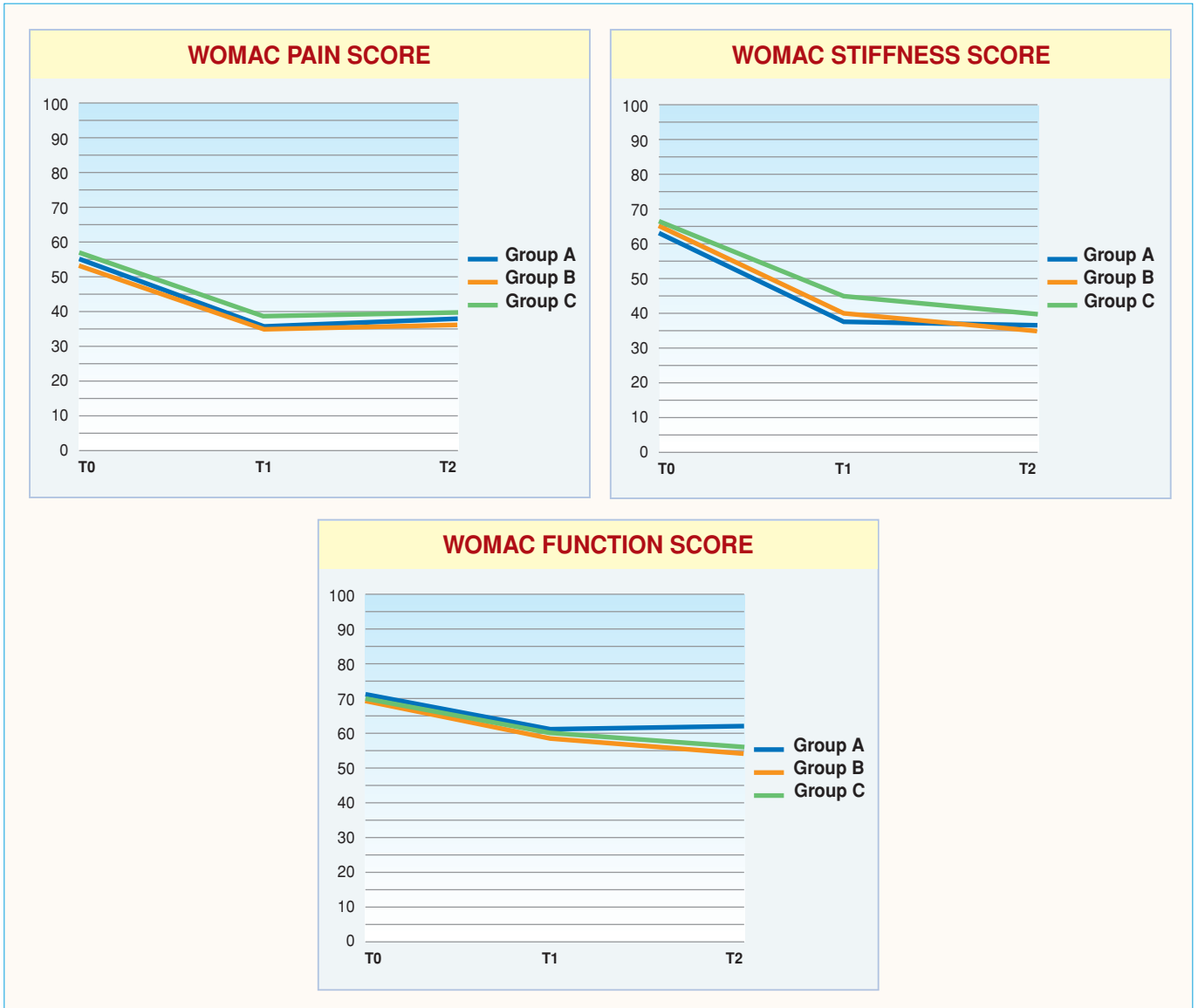
– All patients included in the study showed good compliance as regards performance at least three times a week of the home exercise programme that they had been taught (TAB. 9).



TAB. 5

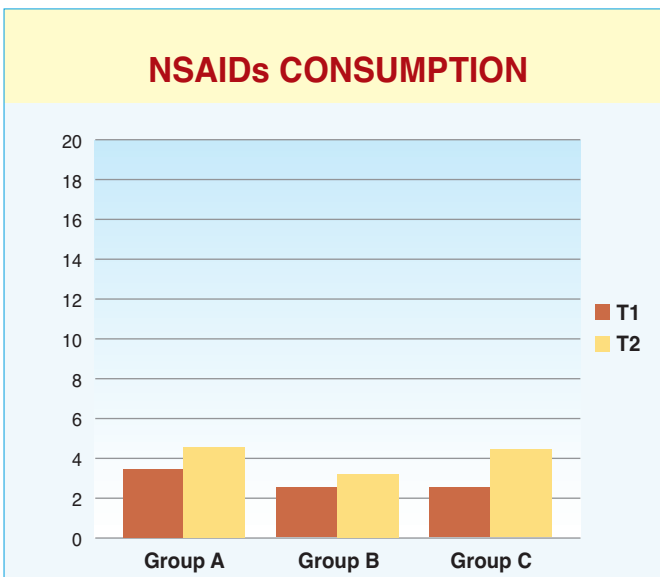
TAB. 6



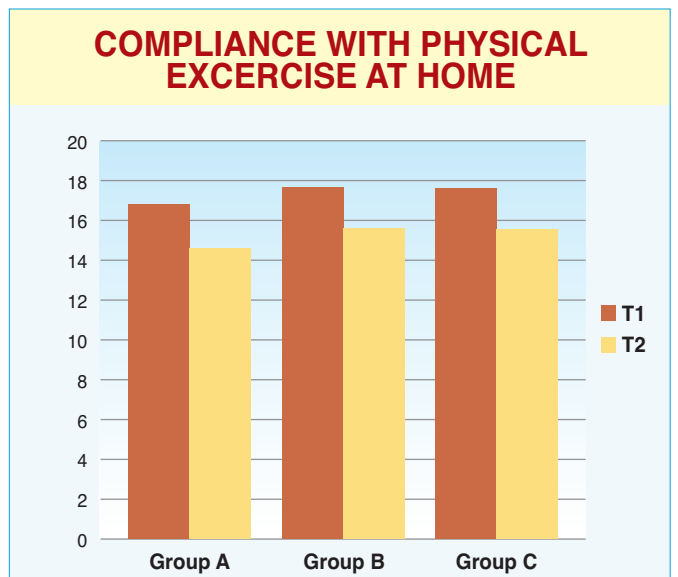


TAB. 7

TAB. 8



TAB. 9



## CONCLUSIONS

The results obtained in this controlled, randomised, clinical study conducted on a homogeneous population with symptomatic osteoarthritis of the hip were those hypothesised during the initial study design phase.

– **HA + MD-Hip** combination therapy makes it possible to obtain a **more significant** and **longer-lasting** improvement in terms of **pain**, **overall range of movement** of the hip and, above all, its **function** than with treatment with HA alone.

The use of MD-Hip fills an unmet therapeutic need, making it possible to obtain **better clinical results**, by acting on the **periarticular tissues** that play a crucial role in the pathogenesis of osteoarthritic conditions.

– Moreover, this combination therapy also makes it possible to reduce the number of articular injections of HA, without compromising the therapeutic result, especially with regard to daily activities.

– As has already been highlighted several times in literature, good compliance in performing a specific home exercise programme with a certain constancy affects the final therapeutic result.

– During the clinical study, MD-Hip did not show any negative side effect and was seen to have an excellent safety profile. ■

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