



M. Ottaviani

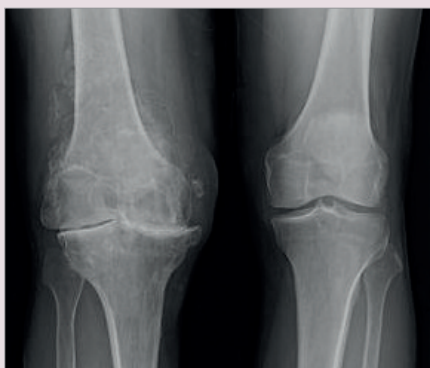
SUMMARY

Collagen is the main extracellular structural protein to be found in the connective tissue and bone tissue of most animals. In humans aged about 50 years its synthesis begins to reduce, with consequent cartilage and tendon degeneration and inevitable development of osteoarthritis and tendonitis. Since these degenerative conditions are very common and evolve towards pain and joint stiffness, there is an urgent need for tools that allow practitioners not only to limit this degenerative evolution, but also, in certain cases, to induce its regression.

This clinical study was conducted on 257 patients with joint and tendon disorders (impingement syndrome, shoulder tendinopathy, hip arthritis, knee arthritis, trapeziometacarpal osteoarthritis, Achilles' tendinopathy) frequently reflected in clinical evidence, such as pain and joint stiffness; they were all treated exclusively with local injections of Guna Collagen Medical Devices.

The data were collected through self-assessment scales, validated by the WHO and the results showed that Guna Collagen MD can give a useful contribution to containing the problems associated with joint degeneration.

PAROLE CHIAVE GUNA COLLAGEN MEDICAL DEVICES, COLLAGEN, OSTEOARTHRITIS, TENDINOPATHY, PAIN



<http://www.georgeackermanmd.com/knee-osteoarthritis.html>

TREATMENT OF JOINT CONDITIONS WITH GUNA COLLAGEN MEDICAL DEVICES – CLINICAL STUDY ON 257 PATIENTS

INTRODUCTION

Collagen is a glycoprotein characterised by a structure in which a simple **basic module** is repeated: collagen molecules join together to form a collagen fibril; a union in which each molecule overlaps with that above by one quarter of its length.

This creates a kind of *wall*, in which the

individual bricks that make it up are staggered in order to achieve considerable resistance to both incident tangential and perpendicular forces (FIG. 1).

– This characteristic arrangement gives the collagen significant sturdiness in terms of **resistance**, **extensibility** and **incompressibility**, whilst guaranteeing **plasticity**, **flexibility**, allowing **torsion**

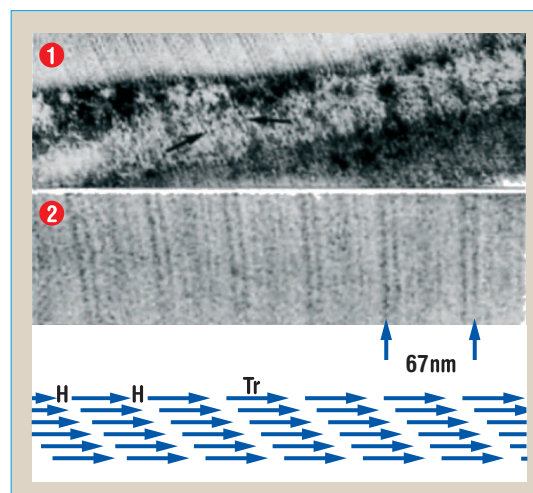


FIG. 1

Structure of collagen.

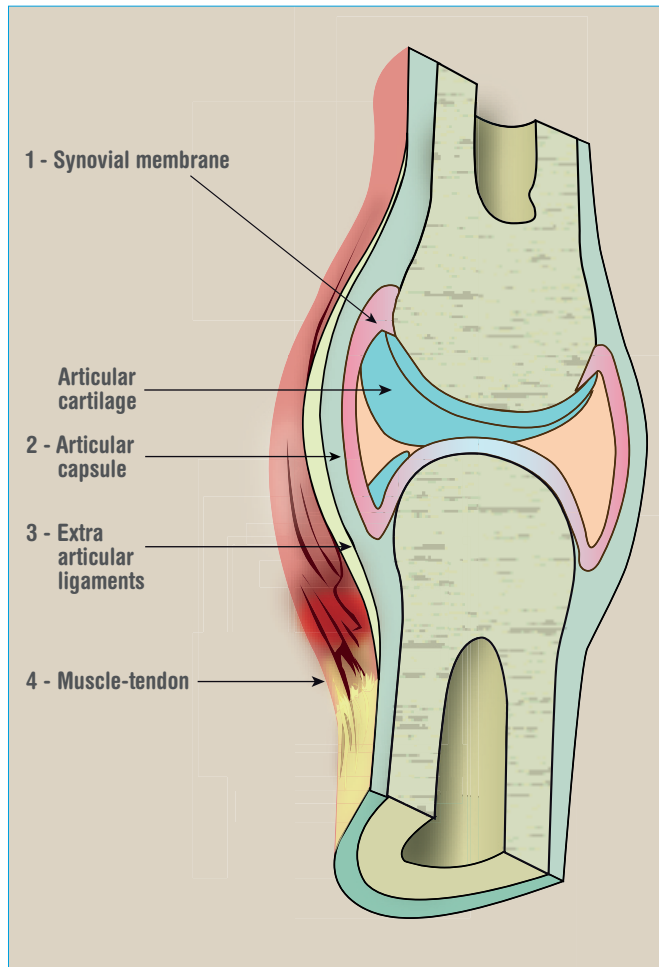
1: Sugars bound to collagen.

Relationship between sugar (black precipitations) and the density of collagen fibrils (ME 112.000X);

2: Section of a collagen fibril (ME 240.000X).

A cycle of 67 nm (670 Å) forms on the base of collagen molecules, each of which is staggered by ¼ of their length.

FIG. 2
Extra-articular
containment
system.



and **great resistance** to load.

In order to be functional, almost all joints must possess two, apparently contradictory, characteristics: stability and mobility.

The **articular stabilisation** systems consist of the structures pertaining to both the **extra-articular component** and the **intra-articular component**; collagen is

present in abundance in both of these structures.

– The extra-articular component consists of ligaments, the articular capsule, tendons and muscles; the intra-articular component is formed of ligaments (for the knee and hip joints only) and of joint cartilage (FIG. 2).

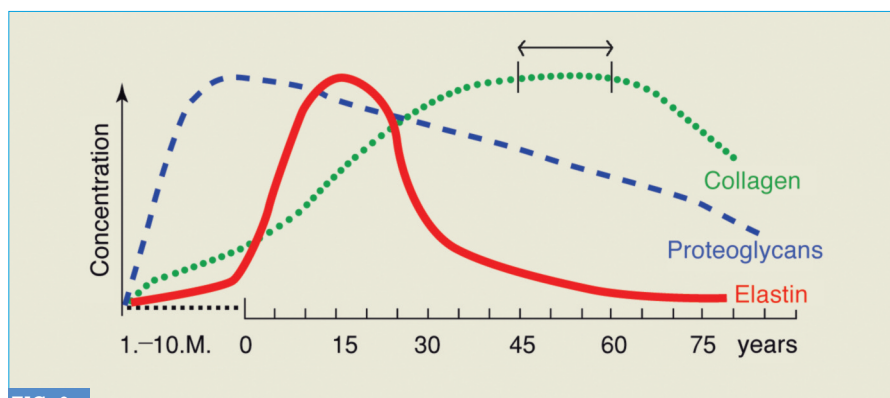


FIG. 3
Age-related biosynthesis of collagen, proteoglycans, and elastin.

One of the most important causes of joint pain is the **laxity** of the intra- and extra-articular stabilisation structures; lax containment systems result in **articular hypermobility**, especially in non-physiological directions and at non-physiological angles that, on the one hand, lead to greater, early wear of the containment systems themselves and, on the other, cause progressive cartilage degeneration.

The mechanical support provided by collagen represents an effective natural scaffolding.

– In humans, the biosynthesis of collagen starts to decrease at 55-60 years of age (FIG. 3);

From this age onwards, there is a quantitative and qualitative deterioration in the joint structures. More specifically, in the musculoskeletal system, the cartilage surfaces become thinner and degenerate to osteoarthritis, whereas the tendinous and ligamentous structures become less elastic and progress to tendinoses and tendinopathies of varying severities. Often in musculoskeletal conditions, the instrumental diagnostic evidence (x-ray, ultrasound, etc.) is not consistent with the clinical findings.

The term **Osteoarthritis state** is used to indicate physiological age-related articular ageing; it is a parapsychological condition that does not cause any clinical situation and is often incidentally observed during imaging studies performed for other reasons (e.g. injury). However, when osteoarthritis makes itself felt by causing the characteristic onset symptoms, such as *stiffness* and joint pain, we talk about osteoarthritis disease. Osteophytes are irregular beak- or crest-shaped proliferations of bone tissue that form in the vicinity of joints affected by a number of pathological processes, but above all in the presence of osteoarthritis. Their presence can involve disorders of various types, with restrictions to joint movement or the compression and irritation of nearby structures, in particular, nerve branches and tendon insertions. Osteophytes are the

bone tissue's attempt to increase the surface area of the heads of the articular bones damaged by osteoarthritis, in an attempt to stabilize the joint (FIG. 4).

In addition, it is common for ultrasound scans and MRI studies to show complete or multiple tendon damage, despite the presence of little or no signs and symptoms; conversely, in other cases, the tendon is intact but the patient experiences very severe pain and functional impairment.

As regards the tendinous-ligamentous sub-system, an anatomopathological distinction can be made between tendinites or tenosynovitis, tendinoses and tendon injuries of various degrees.

– Tendinites or tenosynovites are inflammatory states of the tendon and possibly also of its sheath, with or without peritendinous effusion; they may be a consequence of either a traumatic event or a functional overload.

When the repair process of the affected element starts in the presence of inflammation, the scar tissue that forms is a connective tissue that is devoid of the characteristics of elasticity and resistance that are typical of native tendons; this makes the structure more prone to partial or complete tears.

– For this reason, an inflammatory process affecting a tendinous or ligamentous structure should not be underestimated, rather it should be kept under close observation and resolved as soon as possible.

Also on the basis of our experience we can undoubtedly state that clinical and diagnostic evidence are not always consistent. In Italy, osteoarthritis accounts for **72.6%** of all rheumatic diseases and is responsible for **70%** of cases of chronic pain. The potential therapeutic approach to osteoarthritis, and tendinopathy, can be of different types:

- educational
- pharmacological
- rehabilitative
- surgical.

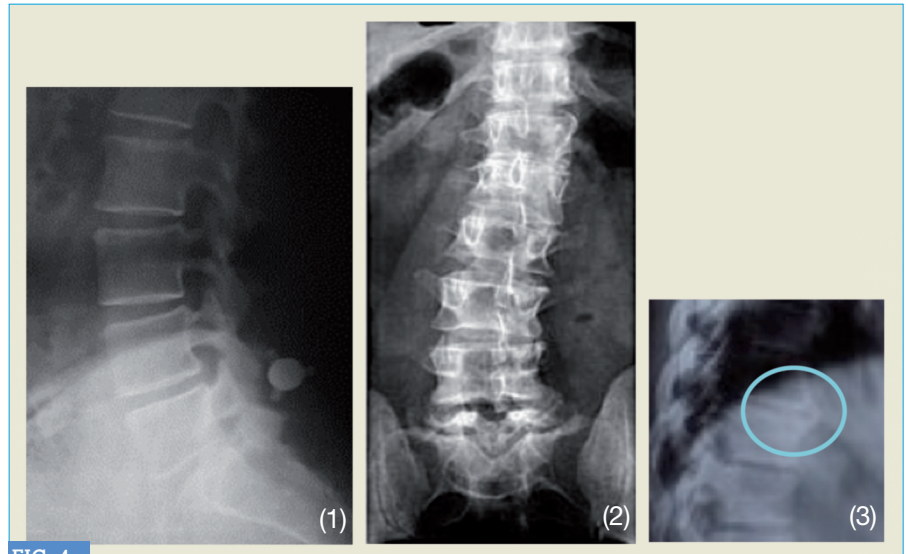


FIG. 4

X-ray of the L-S spine of an individual with severe low back pain without osteoarthritic skeletal alterations (1); of a L-S spine with significant radiological signs of osteoarthritic degeneration (2) in an asymptomatic patient; osteophytes (3).

The educational approach is represented by an improvement in quality of life including health education intervention, the use of braces, where necessary, and weight loss, when appropriate.

The conventional medicinal products used to treat osteoarthritis and tendinopathies (NSAIDs, Coxibs, Paracetamol, Steroids, and Opioids) have a symptomatic action and are used on both systemic and local levels (e.g. intra-articular steroid injections).

There are other medicinal products, whose real efficacy is not recognised by all Authors, which are thought to exert a slow chondroprotective action, these are: glucosamine sulphate, chondroitin sulphate, and hyaluronic acid.

The local use – and therefore – the intra-articular injection of hyaluronic acid boosts its efficacy; this kind of treatment is referred to as “visco-supplementation” and it has **only** a lubricating and shock-absorbing action.

Until just a few years ago, osteoarthritis was considered a progressive degenerative disease; subsequently, a prevention campaign against the progression of osteoarthritis with the use of “Cartilage integrators”, was started.

– For some years now, it possible to state

that osteoarthritis is a process that is, at least in part, reversible.

Given the ongoing rise in the population's average age, it goes without saying that having access to tools able to maintain high quality of life standards despite *chrono-aging* is an important breakthrough.

Guna Collagen Medical Devices are products for local injection constituted by **collagen** of porcine origin (porcine tissues have a very high collagen content) and a substance known as an *an-cillary* or vehicle, of plant or mineral origin, characterised by a particular tropism for the specific articular segments.

A tangential filtration process, combined with sterilisation and control of the molecular weight, makes it possible to obtain a pure product with standard chemical and physical characteristics.

The availability of Guna Collagen Medical Devices for local injection is a determining factor in the repair process that follows anti-inflammatory intervention.

Lax joint support elements cause local nociceptor stimulation and excessive tension and stress: which explains why the reinforcement of these structures is **analgesic** as well as **regenerative**.

AREA	M	F	Total N.	Age - average	Age - range
SHOULDER, UPPER LIMB	30%	70%	147	53,5	34-78
KNEE	66%	34%	53	67,5	55-82
HIP	30%	70%	30	67	53-78
ACHILLES	20%	80%	27	43,3	32-63

TAB. 1

General caseload. Patient distribution according to gender and age.

– These characteristics translate directly into organoleptic properties: collagen is a **tissue structurer** (structural protein) and also possesses lubricating qualities.

– These bases form the significant difference between the properties of collagen and those of hyaluronic acid.

The latter is a lubricant (high viscosity) only of the articular cavity, that acts on the intra-articular component **only**, primarily in the large joints.

Collagen **also** and **primarily**, acts on the structures of the extra-articular component (capsule, ligaments, tendons) of small, medium, and large joints.

In addition, hyaluronic acid is efficacious in cases of modest and intermediate clinical severity, whereas collagen is also efficacious in those cases in which the patient's mobility is more severely

impaired: it replaces the *bricks* where the *wall* had crumbled.

– Guna Collagen Medical Devices can be used alone or in home combinations with conventional or Physiological Regulating Medicine (PRM) products as **Guna-Arthro**, **Guna-Flam**, **Guna-Anti IL 1**, **Guna-Interleukin 10**; the treatment programme may also include other systemic pharmacological and rehabilitation treatments.

MATERIALS AND METHODS

A total of **257 patients** (36.5% M; 63.5% F) were enrolled in this clinical study. The mean age was 58.7 years, with a range of 32-82 years.

TAB. 1 shows the joint segments considered and treated and the corresponding epidemiological characteristics of the caseload.

More specifically, because of the type of assessment scale used, the "Shoulder and upper limb (SUL)" Group included **124** patients with problems relating to the shoulder alone (rotator cuff syndrome, with possible tendon lesions); the remaining **23** had a number of other conditions, such as trapeziometacarpal osteoarthritis, epicondylitis and ganglion cysts of the wrist (U.L.). It was consequently decided to analyse the results of these two sub-Groups independently (FIG. 5).

As far as the "Knee" Group was concerned, all **53** treated cases were classified as stage I, II and III osteoarthritis of the knee using the Kellgren-Lawrence radiological scale.

In the "Hip" Group, the treated hip joint(s) were affected by mild and moderate primary hip osteoarthritis (stage I and II); in this Group (**30** patients), patients were considered holistically, and only patients with a normal physique were included, so that the needle used was able to reach the pericapsular area.

In the "Achilles" Group, all the cases treated were mono- or bilateral Achilles' tendinopathies; **11** cases of tendonitis in the same area with ultrasound-documented exudate were also treated.

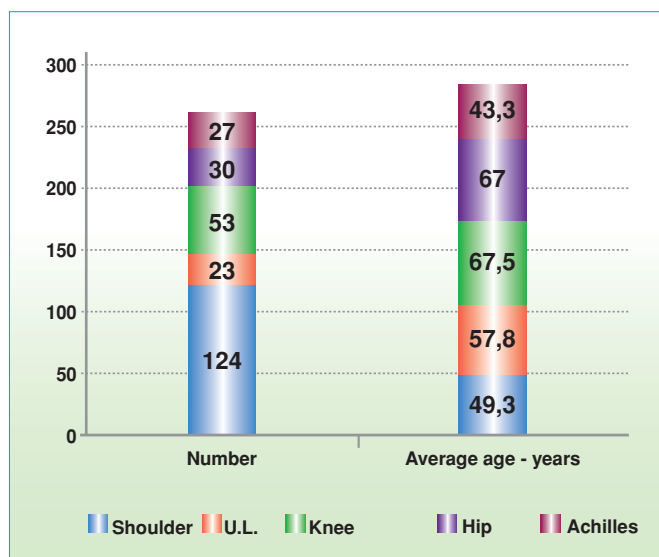
All patients were told about the type of treatment that they were being offered and the main differences that it would have compared to a similar injection therapy with hyaluronic acid or Guna Collagen MDs. They all signed the informed consent form.

The clinical and symptomatic findings of the patients enrolled were collected using assessment questionnaires validated by the WHO, more specifically:

- the Pain symptom was measured using a five-point visual-analogue scale (VAS), in which "0" = no pain and "5" = unbearable pain;
- D.A.S.H. (Disability for Arm, Shoulder and Hand) for the shoulder, elbow, hand, and wrist (range 0-100, in which 0 = no disability) (TAB. 2);
- O.K.S. (Oxford Knee Score) for the knee (range 48-0, in which 48 = no disability) (TAB. 3);
- O.H.S. (Oxford Hip Score) for the

FIG. 5

General caseload.
– Number and mean age of patients included in the study per individual condition considered.



hip (range 48-0, in which 48 = no disability) (TAB. 4);

- V.I.S.A.-A (Victorian Institute of Sport Assessment – Achilles) for the Achilles' tendon (range 68-0, in which 68 = no disability) (TAB. 5).

The questionnaires were filled out by patients; the dedicated questionnaire was administered at the **first visit** and at the **end of treatment**.

Patients were administered **intra-articular** (shoulder, elbow, wrist, hand and knee), **pericapsular** (hip) and **local** (tendons) injections **with the appropriate and specific MDs**; 5 cc disposable syringes were used, with 23G x 1-1/2 - mm 0.60 x 40 needles for the hip, knee, and shoulder injections and 26G x 1/2 - mm 0.40 x 16 needles for hand, wrist, elbow, and foot injections.

Before administration, the skin was disinfected using a liquid product containing quaternary ammonium salt.

– In those segments in which administration was intra-articular, sterile surgical gloves were used and the injection area was disinfected thoroughly using sterile gauze soaked in surgical Betadine. In certain segments that are particularly rich in pain-sensitive nerve terminations, spray “ice” was used for analgesic purposes. The injections were administered **twice-weekly for 5 consecutive weeks** (total = 10 injections).

– The patients treated for chronic degenerative diseases (knee osteoarthritis, hip osteoarthritis, trapeziometacarpal osteoarthritis and one case of severe Achilles' tendinopathy in a semi-professional dancer) continued with **maintenance therapy** (1 session a month for 6 consecutive months, then every 3 months). In no case was it suggested for the pharmacological therapy to be suspended or varied; patients taking NSAIDs or Paracetamol were asked to use this therapy only when absolutely necessary. The evolution of the pain symptom in particular was monitored in the 8 patients who were taking opioid analgesics, in order to gradually reduce the posology of these drugs.

RESULTS

All the patients included in this study completed the treatment. None of them reported any side effect after the administration of the Guna Collagen Medical Devices. In those patients on antiplatelet or dicoumarol therapy, small areas of ecchymosis were observed at the injection site, but it reabsorbed rapidly without requiring any particular intervention.

All patients considerably **reduced** their use of conventional medicinal products and in **75% ≈** of all cases their administration was not considered necessary.

– Of the 8 patients on treatment with opioid analgesics, 3 continued taking these medicinal products, albeit at considerably lower doses, whereas the remaining 5 gradually discontinued their use.

Generally speaking, the pain symptoms started to subside from the **4th or 5th administration**; however, in cases of subacromial impingement and Achilles' or elbow tendinopathy the positive effects on pain were observed later.

In the osteoarthritic forms, affecting both the knee and the hip joint, the first effect reported by patients was a sensation of a **greater range of joint motion**; this sensation was perceived by patients after the first 2 - 3 sessions.

One particularly complex case was that of a male patient with polycythaemia, with concomitant severe osteoarthritis of the knee, hip and shoulder joint and significant functional impairment.

This was the case in which the improvement assessed by the questionnaires used in the study was poor; however, considering the initial clinical situation, it can be said that this was the patient who was most satisfied with the treatment received.

– We initially treated the shoulder alone and only subsequently, at the patient's insistence, also treated the knees. At a later date, we will decide if and when to treat the hips.

► Pain

The pain assessment scale showed a reduction from **3.06** (initial mean value including all the cases analysed) to a final value of **1.34**.

– The variation in the pain experienced in the various segments is shown in FIG. 6.

Shoulder and upper limb Group (FIG. 7)

D.A.S.H. is an assessment questionnaire that considers a number of everyday situations facing the patient (disability concerning movements of the shoulder, hand, and elbow). The worst score is 100 and describes an extremely invalidating situation; a normal situation coincides with a score of 0.

In the caseload managed in this study regarding conditions of the **Shoulder**, the score dropped from an initial average of **78.7** to a final score of **17.3**.

As far as the **Upper limb Group** is concerned, from the initial mean of **66.8** the score dropped to **18.2**.

– In this case, the use of the D.A.S.H. questionnaire proved to be a disputable choice, as it pooled the results for a number of different segments. In the future, we intend to use a dedicated score, such as the *Oxford Shoulder Score* to assess shoulder function.

Knee Group

O.K.S. (The Oxford Knee Score) is an assessment scale including different common situations of everyday life.

The patient is invited to reply with regard to the 4 months prior to completion of the questionnaire; for obvious time reasons, post-treatment completion refers to the time at which it is filled out.

A score of 0 coincides with the most impaired situation, whereas a score of 48 coincides with a condition of full function. Of the 53 patients included (FIG. 8), the average initial score was **13.6**, whereas a score of **35.8** was achieved at the end of treatment.

D.A.S.H.

This questionnaire asks about your symptoms as well as your ability to perform certain activities. Please answer every question, based on your condition in the last week. If you did not have the opportunity to perform an activity in the past week, please make your best estimate on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1	Open a tight or new jar	1	2	3	4	5
2	Write	1	2	3	4	5
3	Turn a key	1	2	3	4	5
4	Prepare a meal	1	2	3	4	5
5	Push open a heavy door	1	2	3	4	5
6	Place an object on a shelf above your head	1	2	3	4	5
7	Do heavy household chores (e.g., wash walls, wash floors)	1	2	3	4	5
8	Garden or do yard work	1	2	3	4	5
9	Make a bed	1	2	3	4	5
10	Carry a shopping bag or briefcase	1	2	3	4	5
11	Carry a heavy object (over 10 lbs).	1	2	3	4	5
12	Change a lightbulb overhead	1	2	3	4	5
13	Wash or blow dry your hair	1	2	3	4	5
14	Wash your back	1	2	3	4	5
15	Put on pullover sweater	1	2	3	4	5
16	Use a knife to cut food	1	2	3	4	5
17	Recreational activities which require little effort (e.g., cardplaying, knitting, etc...)	1	2	3	4	5
18	Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g golf, hammering, tennis, etc...)	1	2	3	4	5
19	Recreational activities in which you move your arm freely (e.g., playing freestyle, badminton, etc...)	1	2	3	4	5
20	Manage transportation needs (getting from one place to another)	1	2	3	4	5
21	Recreational activities which require considerable effort (e.g. push-ups, shaking a spray can, etc...)	1	2	3	4	5
22. During the past week, to what extent has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? (circle number)						
NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY		
1	2	3	4	5		
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? (circle number)						
NO LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE		
1	2	3	4	5		
		NONE	MILD	MODERATE	SEVERE	EXTREME
24	Arm, Shoulder or hand pain	1	2	3	4	5
25	Arm, Shoulder or hand pain when you performed any specific activity	1	2	3	4	5
26	Tingling (pins and needles) in your arm, shoulder or hand	1	2	3	4	5
27	Weakness in your arm, shoulder or hand	1	2	3	4	5
28	Stiffness in your arm, shoulder or hand	1	2	3	4	5
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? (circle number)						
NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP		
1	2	3	4	5		

30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem (circle number)

NONE	MILD	MODERATE	SEVERE	EXTREME
1	2	3	4	5

The following questions ask about the impact of your arms, shoulder or hand problem on your ability to work. Please circle the number that best describes your physical ability in the past week.

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	EXTREME DIFFICULTY	UNABLE
Did you have difficulty:						
31	Using your usual technique for your work?	1	2	3	4	5
32	Doing your usual work because of arm, shoulder or hand pain?					
33	Doing your work as well as you would like?					
34	Spending your usual amount of time doing your work?					
The following questions relate to the impact of your arms, shoulder or hand problem on playing your musical instrument or sport or both. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you. Please circle the number that best describes your physical ability in the past week.						
Did you have difficulty:						
35	Using your usual for playing your instrument or sport?	1	2	3	4	5
36	Playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
37	Playing your musical instrument or sport as well as you would like?	1	2	3	4	5
38	Spending your usual amount of time practicing or playing your instrument or sport?	1	2	3	4	5
Thank you for filling in this form.						

TAB. 2

– D.A.S.H. (Disability for Arm, Shoulder and Hand) Questionnaire.

O.K.S. - OXFORD KNEE SCORE**NEW OXFORD KNEE SCORE QUESTIONNAIRE**

Please answer the following 12 questions. Please only consider how you have been getting on during the past four weeks

<p>1. How would you describe the pain you have usually from your knee?</p> <p>None – 4 Very mild – 3 Mild – 2 Moderate – 1 Severe – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>	<p>8. Have you been able to do your own household shopping on your own?</p> <p>Yes, easily – 4 With little difficulty – 3 With moderate difficulty – 2 With extreme difficulty – 1 No, impossible – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>
<p>2. Have you had any trouble with washing and drying yourself all over because of your knee?</p> <p>No trouble at all – 4 Very little trouble – 3 Moderate trouble – 2 Extreme difficulty – 1 Impossible to do – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>	<p>9. For how long have you been able to walk before the pain from your knee became severe (with or without a stick)?</p> <p>No pain, even after more than 30 minutes – 4 16-30 minutes – 3 5-15 minutes – 2 Around the house only – 1 Unable to walk at all – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>
<p>3. Have you had any trouble getting in and out of a car or using public transport because of your knee?</p> <p>No trouble at all – 4 Very little trouble – 3 Moderate trouble – 2 Extreme difficulty – 1 Impossible to do – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>	<p>10. Have you been able to walk down a flight of stairs</p> <p>Yes, easily – 4 With little difficulty – 3 With moderate difficulty – 2 With extreme difficulty – 1 No, impossible – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>
<p>4. If you were to kneel down could you stand up afterwards?</p> <p>Yes, easily – 4 With little difficulty – 3 With moderate difficulty – 2 With extreme difficulty – 1 No, impossible – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>	<p>11. After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your knee?</p> <p>Not at all painful – 4 Slightly painful – 3 Moderately painful – 2 Very painful – 1 Unbearable – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>
<p>5. Have you been limping when walking because of your knee?</p> <p>Rarely/never – 4 Sometimes or just at first – 3 Often, not just at first – 2 Most of the time – 1 All of the time – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>	<p>12. How much pain from your knee interfered with your usual work (including housework)?</p> <p>Not at all – 4 A little bit – 3 Moderately – 2 Greatly – 1 Totally – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>
<p>6. Have you felt that your knee might suddenly give way or let you down?</p> <p>Rarely/never – 4 Sometimes or just at first – 3 Often, not just at first – 2 Most of the time – 1 All of the time – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>	<p>13. Have you been troubled by pain from your knee in bed at night?</p> <p>No nights – 4 Only 1 or 2 nights – 3 Some nights – 2 Most nights – 1 Every night – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>
<p>7. Could you kneel down and get up afterwards?</p> <p>Rarely/never – 4 Sometimes or just at first – 3 Often, not just at first – 2 Most of the time – 1 All of the time – 0</p>	<p>Score</p> <div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div>		

TAB. 3

– O.K.S. (Oxford Knee Score) Questionnaire.

O.H.S. - OXFORD HIP SCORE**OXFORD HIP SCORE**

Please answer the following 12 questions.

During the past 4 weeks...

1. How would you describe the pain you usually have in your hip?

- 4) None
3) Very mild
2) Mild
1) Moderate
0) Severe

2. Have you been troubled by pain from your hip in bed at night?

- 4) No nights
3) Only 1 or 2 nights
2) Some nights
1) Most nights
0) Every night

3. Have you had any sudden, severe pain- 'shooting', 'stabbing', or 'spasms' from your affected hip?

- 4) No days
3) Only 1 or 2 days
2) Some days
1) Most days
0) Every day

4. Have you been limping when walking because of your hip?

- 4) Rarely/never
3) Sometimes or just at first
2) Often, not just at first
1) Most of the time
0) All of the time

5. For how long have you been able to walk before the pain in your hip becomes severe (with or without a walking aid)?

- 4) No pain for 30 minutes or more.
3) 16 to 30 minutes
2) 5 to 15 minutes
1) Around the house only
0) Not at all

6. Have you been able to climb a flight of stairs?

- 4) Yes, easily
3) With little difficulty
2) With moderate difficulty
1) With extreme difficulty

7. Have you been able to put on a pair of socks, stockings or tights?

- 4) Yes, easily
3) With little difficulty
2) With moderate difficulty
1) With extreme difficulty
0) No, impossible

8. After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?

- 4) Not at all painful
3) Slightly painful
2) Moderately painful
1) Very painful
0) Unbearable

9. Have you had any trouble getting in and out of a car or using public transportation because of your hip?

- 4) No trouble at all
3) Very little trouble
2) Moderate trouble
1) Extreme difficulty
0) Impossible to do

10. Have you had any trouble with washing and drying yourself (all over) because of your hip?

- 4) No trouble at all
3) Very little trouble
2) Moderate trouble
1) Extreme difficulty
0) Impossible to do

11. Could you do the household shopping on your own?

- 4) Yes, easily
3) With little difficulty
2) With moderate difficulty
1) With extreme difficulty
0) No, impossible

12. How much has pain from your hip interfered with your usual work, including housework?

- 4) Not at all
3) A little bit
2) Moderately
1) Greatly
0) Totally

TAB. 4

– O.H.S. (Oxford Hip Score) Questionnaire.

TAB. 5
– V.I.S.A.-A (Victorian
Institute of Sport
Assesment- Achilles
tendon)
Questionnaire.

V.I.S.A.-A

IN THIS QUESTIONNAIRE, THE TERM PAIN REFERS SPECIFICALLY TO PAIN IN THE ACHILLES TENDON REGION

1. For how many minutes do you have stiffness in the Achilles region on first getting up?

100 mins 0 mins **POINTS**

0 1 2 3 4 5 6 7 8 9 10

2. Once you are warmed up for the day, do you have pain when stretching the Achilles tendon fully over the edge of a step? (keeping knee straight)

strong severe pain no pain **POINTS**

3. After walking on flat ground for 30 minutes, do you have pain within the next 2 hours?

strong severe pain no pain **POINTS**

4. Do you have pain walking downstairs with a normal gait cycle?

strong severe pain no pain **POINTS**

5. Do you have pain during or immediately after doing 10 (single leg) heel raises from a flat surface?

strong severe pain no pain **POINTS**

6. How many single leg hops can you do without pain?

0 10 **POINTS**

7. Are you currently undertaking sport or other physical activity?

0 ☐ Not at all **POINTS**

4 ☐ Modified training ± modified competition

7 ☐ Full training ± competition but not at same level as when symptoms began

10 ☐ Competing at the same or higher level as when symptoms began

At the end of the treatment, patients were offered the chance to continue with maintenance therapy: all the patients agreed to continue the treatment, saying that they were satisfied and confident. The improvements achieved were maintained in the following months. In some cases, further improvements were seen; however, in order to quantify these data, the situation must be evaluated on a case-by-case basis.

Hip Group

O.H.S. (The Oxford Hip Score) is an assessment scale for hip joint function. The patient must answer regarding his/her every day motor performance. Once again, patients were invited to answer the end-of-treatment questionnaire, by entering their replies at the

time of assessment. Full joint integrity coincides with a score of 48 points, whereas a clinical situation of maximum impairment coincides with a score of 0.

It is important to remember that the patients in this Group presented radiographic evidence of a stage I or II condition, the phases of the disease in which pain and functional impairment emerge.

In this Group, the mean score decreased from an initial value of **10.2** (indicating somewhat severe general impairment) to a final score of **37.2** (FIG. 9).

Achilles' Group

This Group of patients, suffering from an inflammation of the Achilles' tendon, answered the Victorian Institute of Sport

Assessment (V.I.S.A.-A) questionnaire, which refers to the Achilles' tendon alone and provides a score of between 0 and 68 points; the latter value refers to a condition of complete and perfect function.

In this case, as shown by the data in FIG. 10, the score increased from an initial value of **21.0**, to a final value of **54.0** points.

The patients in this Group had an ultrasound study, with a finding of effusion between the tendon folds.

– As ultrasound is a non-invasive imaging technique, at the end of treatment the patients had a follow-up ultrasound scan, to show the reabsorption of the signs of inflammation (FIG.11).

CONCLUSIONS

All the treated patients declared that they were satisfied with the result achieved.

– There were no drop outs, despite the fact that the treatment lasted 5 - 6 weeks. As far as all of the assessment questionnaires as a whole are concerned, there was a considerable, statistically significant, subjective improvement.

To this we must add the objective improvement, confirmed by imaging studies (follow-up ultrasound) for those patients with Achilles' tendon conditions, and clinically by range of joint motion tests.

After the first 3 - 4 administrations, almost all patients in the Shoulder, Hip and Knee Groups, expressed their surprise at the feeling of greater joint freedom.

The Hip Group was the Group that expressed the greatest and earliest satisfaction with the treatment. From a percentage standpoint, the best result was achieved in the Achilles' Group: this can be attributed to the fact that this Group was constituted by patients with the lowest average age and that in which the condition was not secondary to an overload or degenerative process. The members of this Group and the Shoulder Group were not offered any maintenance therapy. A single addition-

al administration was required in just two cases, both in the Shoulder Group. For the patients in the Hip, Knee and Upper Limb Groups (in the latter, for cases of trapeziometacarpal osteoarthritis only) the treatment is still on-going. Administration is once-monthly for the first six months.

Subsequently, if stable remission is achieved, the treatment is administered once every two months and, later, once every three months.

Having been thoroughly informed of the role played by locally-administered collagen (Guna Collagen MDs), the patients readily understood that their attention to symptoms is fundamental to a successful outcome of treatment, in order to achieve long-lasting results.

– Another positive aspect of treatment with Guna Collagen MDs is the rapid effect on pain, even and above all in patients on dicoumarol anti-coagulant therapy, who cannot take NSAIDs or steroids.

A positive and somewhat rapid response was also observed in those patients with heavy pharmacological regimens due to comorbidities.

It is important to note that, in most of the cases observed in this study (as is the case for the majority of patients referred to a physiatrist), the patient was referred after at least two months of attempts using conventional pharmacological therapy (NSAIDs, Steroids, Paracetamol) without achieving any stable result. Their body was therefore intoxicated.

– The toxins from conventional anti-inflammatory drugs accumulate above all in the structures comprising the musculoskeletal system.

– Even subjects on heavy chronic pharmacological treatment (steroids, oral hypoglycaemic agents, insulin, anticoagulants), the positive response to therapy was achieved without any interference with their ongoing chronic therapies. ■

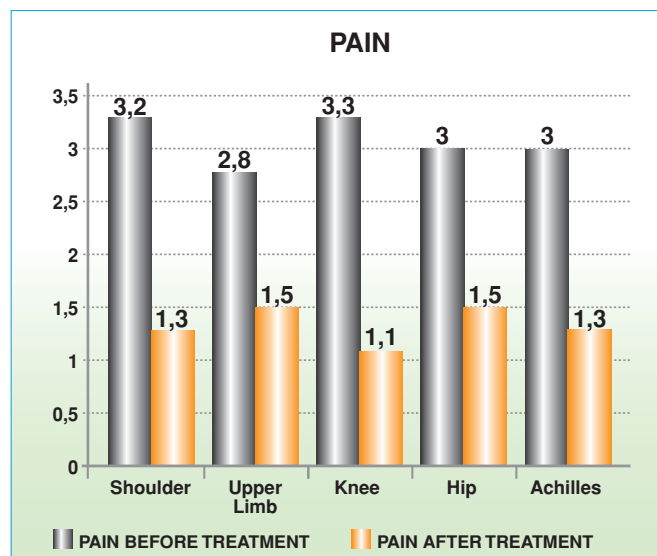


FIG. 6

Variation in the pain symptoms pre- and post-treatment in the different Groups treated with Guna Collagen MDs.

FIG. 7

Results of the analysis of the data collected using the D.A.S.H. questionnaire for conditions affecting the shoulder and upper limb (elbow, wrist, and hand).

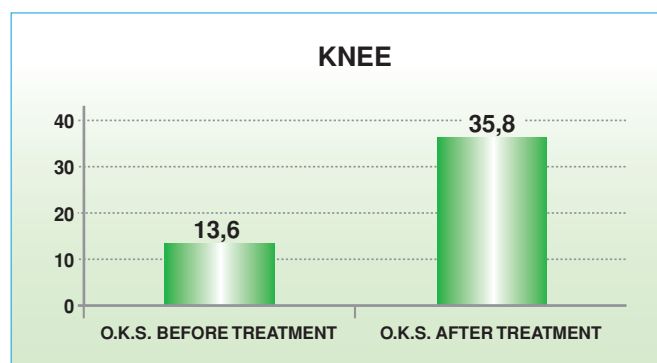
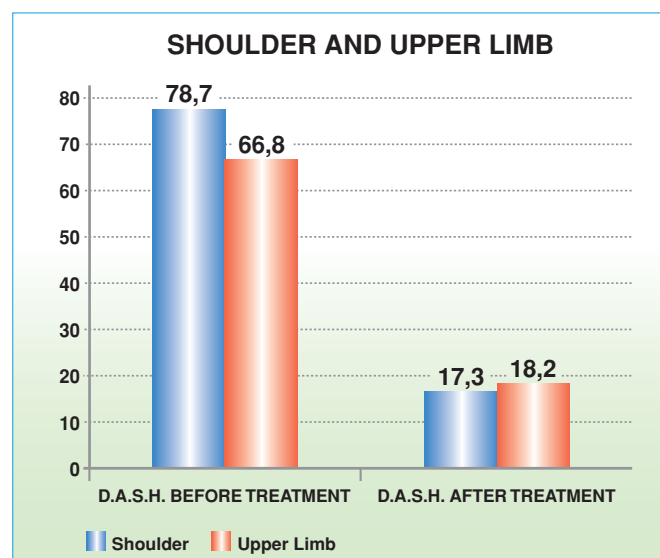


FIG. 8

Results of the analysis of the data collected using the O.K.S., for knee conditions.

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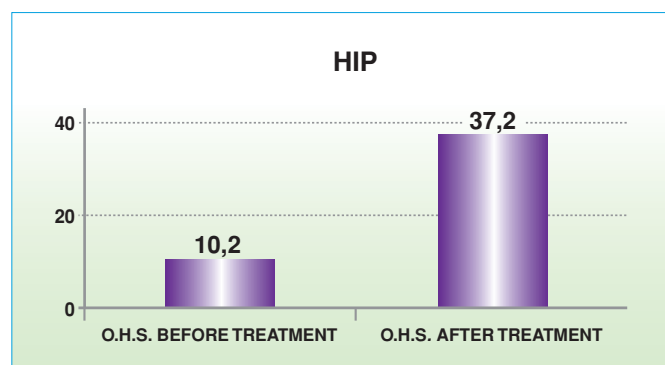


FIG. 9

Results of the analysis of the data collected using the O.H.S., for hip conditions.

FIG. 10

Results of the analysis of the data collected using the V.I.S.A.-A, for Achilles' tendon conditions.

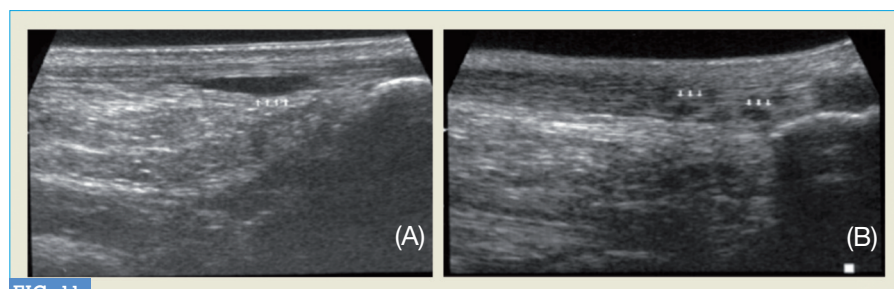
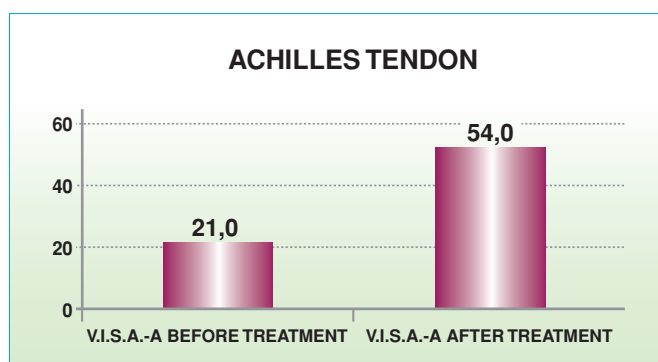


FIG. 11

(A) Achilles' tendon in the presence of effusion in the peritendineum; (B) The effusion is no longer visible. A situation of chronic tendinosis persists, with microcalcifications.

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author

Dr. Morena Ottaviani, MD

– Physical Medicine and Rehabilitation specialist

C.M.R. - Centro Medico Riabilitativo
Via Francolano, 121

I – 16030 Casarza Ligure (GE)