CLINICAL

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THE TREATMENT OF RHIZOARTHROSIS WITH COLLAGEN MEDICAL DEVICE SMALL JOINTS

SUMMARY

Rhizoarthrosis is a very widespread disease; it affects 20% of the adult population and represents about 10% of all osteoarthritic locations; it is more frequent in females than in males (4:1 ratio). The initial symptom is TM pain followed by difficulty in performing daily activities such as turning a key or opening a bottle. The treatment is initially conservative with the application of immobilization braces and the simultaneous use of chondroprotectors. If this treatment is not effective, before undertaking the definitive surgical treatment, infiltrative therapy with Collagen may be considered. Collagen MDs improve the mechanical qualities of the joint capsule by restoring the anisotropic characteristics of the tissue with an evident positive effect on the "joint hypermobility stabilisation", movement, pain and quality of life.
– The purpose of this trial is to evaluate the efficacy of the endo- and peri-articular injection of MD-Small Joints in patients suffering from rhizoarthrosis before undergoing definitive surgical therapy.
In this clinical study, 22 patients (3 M; 19 F) were included and assessed for 10 weeks with the DASH, VAS scales and Grind Test.
The treatment was well tolerated, and no side effects were observed. The improvement obtained was approximately 60-80% of all rating scales. This trial shows that clinical improvement is directly proportional to the reduction in joint laxity and is therefore a function of the effectiveness of MD-Small Joints on joint collagen.

KEY WORDS **RHIZOARTHOSIS, COLLAGEN MEDICAL DEVICE, MD-SMALL JOINTS, HAND PAIN, DASH, VAS, GRIND TEST, COLLAGEN**

RHIZOARTHROSIS

Rhizoarthrosis (RA) is a type of arthritis that affects the **trapeziometacarpal (TM) joint**. The etymology of the term 'rhizoarthrosis' is Greek: *rizos* means "root"; this joint, in fact, is located at the root of the thumb.

– RA is a widespread condition; it affects **20%** of the adult population (Barra *et* Al., 2003) and represents approximately **10%** of all osteoarthritic localisations in the human body (Sollazzo *et* Al., 2006). RA is more frequent in females than males (4:1 ratio) and generally occurs between the fifth and sixth decades of life.

In women, it frequently begins at menopause, while in men it is more related to overuse phenomena (Bonola *et* Al., 1981).

The TM joint plays a key role in normal thumb function: all gripping actions overload the TM joint because the axis of the thumb exerts force and acts as a fulcrum on this joint.

This force transmits a radial stress at the base of the metacarpal, which, over time, causes a reduction in the tension of the capsuloligamentous system (Bernardini, 2018), resulting in joint hyperlaxity and subluxation of the first metacarpal.

• The preternatural movement of the bone heads alters the joint surface; there is a progressive thinning of the cartilage and subsequent onset of pain and arthritis. Symptomatology is bilateral in 50% of cases.

FUNCTIONAL ANATOMY

The TM joint can be considered the most complex joint of the human body as it allows the thumb to perform volo-volar pincer grips with the long fingers; in other words, it allows the hand to perform its most distinctive function: opposition, that is, prehension (Caroli, 1996).

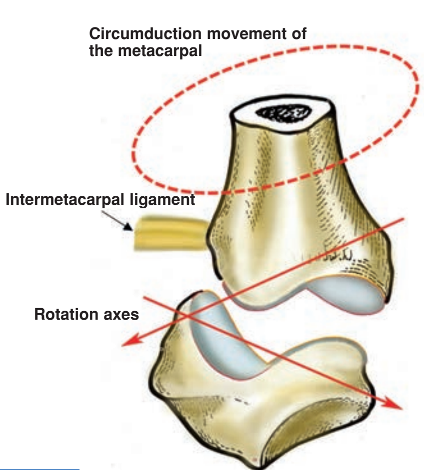


FIG. 1

Trapeziometacarpal joint.

Kapandji (1971) defined the TM joint as a reciprocal interlocking or saddle-shaped joint and compared it to a rider in the saddle with perfectly matching torus-shaped contact surfaces (Bonola *et* Al., 1981).
The movements take place on two perpendicular axes and their combination allows for a true circumduction, conditioned by the intermetacarpal ligament, which acts as a pivot (FIG. 1,2).
The structures that support and stabilize this joint are the capsule, the extracapsular ligaments and the intrinsic and extrinsic muscles.
The capsuloligamentous structures of the TM joint are extremely important, both in providing stability and in guiding the complex movements of the thumb.
The joint capsule is very lax and fits along the contour of the articular surfaces of the trapezium and the base of the metacarpal. This laxity is determined by the fact that the first metacarpal must allow for ample movement and rotation of the metacarpal along its own longitudinal axis (Caroli, 1996).

▶ Ligaments of the capsule

The ligamentous system is equally important because, in addition to ensuring the stability of the TM joint, its maximum tension allows stopping the various movements of the first metacarpal bone, assisted by the fascial and muscular structures in this function.
It should also be noted that the TM ligaments, through their insertion, help to guide the movements of the thumb and mainly those of axial rotation.
A number of thickenings depart from the joint capsule, giving rise to the following ligaments:

- the dorsoradial ligament (DRL) or Arnold's external trapeziometacarpal ligament stops abduction and favours rotation in pronation of the metacarpal joint;
- the dorsoulnar ligament (DUL) or Arnold's internal trapeziometacarpal ligament, which is very thick and wide, stops the retroposition movement and favours rotation in supination of the metacarpal;
- the anterior oblique ligament (AOL). Some authors describe two portions of this ligament: a superficial one and a deep one (beak ligament), which is particularly important in stabilising the TM joint in the degrees of maximum abduction and retroposition movement of the thumb;
- the fibrous, thick and short intermetacarpal ligament (IML): it stretches between the base of the first and second metacarpals; this ligament stops the abduction movement of the first metacarpal.

  The IML is crucial because its loosening causes external subluxation of the base of the first metacarpal, which, as explained below, is one of the most important causes of **joint instability** (Caroli, 1996) (FIG. 2).

▶ Motor muscles of the thumb

As indicated by Kapandji (1971), the TM joint works in compression as a joint. The intrinsic thenar muscles allow the first metacarpal to orient in all directions of space, as if it were a pile whose orientation can be changed by changing the tension of the cables. According to the author, the muscular components provide support to joint coaptation in all positions, resulting from the synergistic activation of agonist and antagonist muscles (Brunelli *and* Brunelli, 1996).

Mobility is the essential opposition function of the thumb; it is enabled by nine motor muscles:

- Four extrinsic or long muscles located in the forearm. Three are for grip opening movements: The *extensor pollicis longus, extensor pollicis brevis,* and *abductor pollicis longus;* and one for power grip: *flexor pollicis longus.* As a reminder, the extrinsic muscles are the motor muscles for power gripa;

- **DRL = Dorsoradial Ligament**
- **DUL = Dorsoulnar Ligament**
- **AOL = Anterior Oblique Ligament *(beak ligament)***
- **IML = Intermetacarpal Ligament**

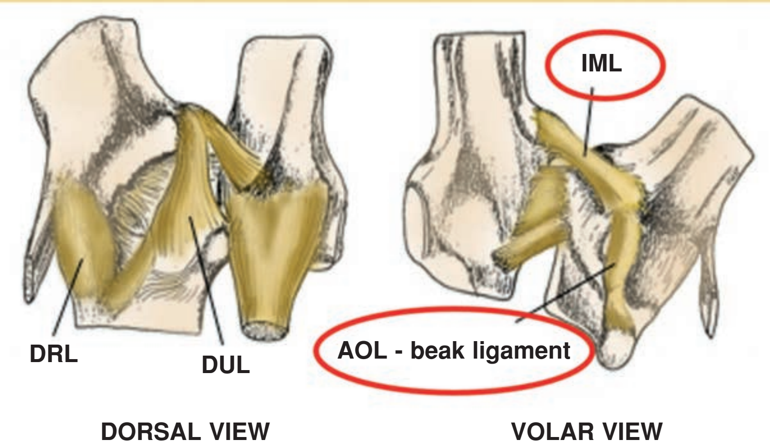


FIG. 2

Ligaments of the trapeziometacarpal joint.

- Intrinsic muscles located in the thenar eminence and first interosseous space; they provide for precision and coordination during different grips and opposition.
  – The external group is composed of three muscles (*opponens pollicis*, *abductor pollicis brevis*, and *flexor pollicis brevis*) that have a synergistic function of thumb opposition.
  – The internal group consists of the adductor and first palmar interosseous muscles.
  These are crucial for gripping/holding objects, because they also perform their action on the **MP (metacarpophalangeal)** and **IP (interphalangeal) joints** (flexion of the former and extension of the latter), making the opposition grip with the index finger more effective.

Opposition is not a fixed movement: indeed, there is a range of oppositions that execute a great variety of grips and actions according to the number of fingers involved and their mode of association (Kapandji, 1971).

- Bi-digital grips give the classic pincer grips between the thumb and index finger; there are 3 types: terminal, subterminal, and subterminolateral.

– The terminal opposition grip is the finest and most precise because it makes it possible to firmly grasp a small object or pick up a very thin object.
The thumb opposes the nail surface of the index finger with the fingertip.
In this grip, as the metacarpal wedges into the trapezius, it protects the joint capsule from any tensional forces and avoids degenerative effects on the joint (FIG. 3).
– The subterminal grip is the most recurrent and instinctive one: the thumb and the index finger oppose each other with the palmar face of the fingertip and this way can grip objects of different calibre, even thin ones, such as a sheet of paper or a pencil.
In this grip, a significant tensive force is created radially at the base of the metacarpal that stretches the joint capsule and the intermetacarpal ligament, making them increasingly lax over time.

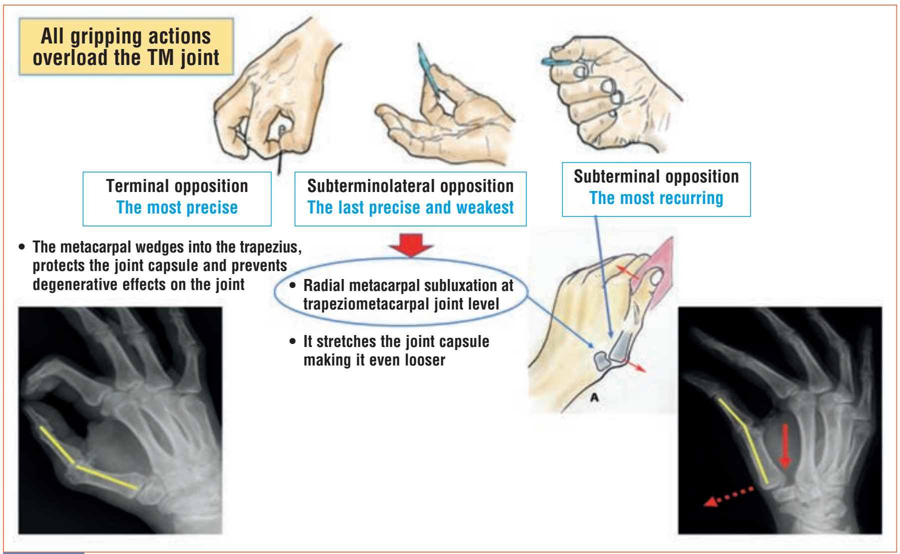


FIG. 3

Effects of grip on the trapeziometacarpal joint.

This laxity produces joint instability, the cause of radial subluxation of the metacarpal and joint degenerative processes.
– The subterminolateral grip is the least fine and weakest compared to the previous ones.
The palmar aspect of the pulp of the thumb rests on the external aspect of the first phalanx of the index finger, creating, in this case too, great radial tension at the base of the metacarpal resulting in the tendency of the TM joint to develop subluxation (Kapandji, 1971).

- The cause of RA always lies in TM joint **instability**.

It can be primary or secondary (TAB. 1).

In ligamentous hyperlaxity, instability is due to an excessive range of motion.
In this case, the palmar ligament (beak ligament) is of great importance, as it limits the hyperextension of the metacarpal and, above all, the intermetacarpal ligament between the base of the first and second metacarpals, which counters the subluxation of the first metacarpal radially, without limiting other movements (FIG. 2).
Laxity and/or degeneration of this ligament produce abnormal TM joint movements, with incongruity of the articular surfaces rapidly triggering degeneration.
– Another known cause that Brunelli (2007) considers to be the most frequent is instability due to the absence of ab-

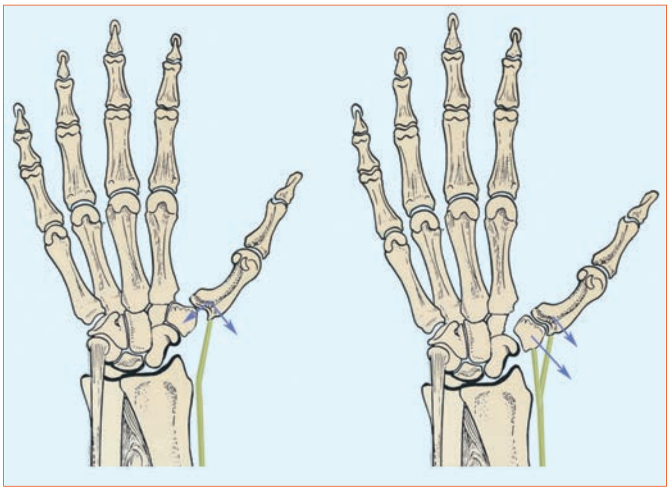
PRIMARY INSTABILITY	SECONDARY INSTABILITY
Hypoplasia of the trapezium, abnormal obliquity of its saddle	Traumatic capsular ligament lesion
Congenital capsular ligament laxity	Outcome of fracture of the trapezium or the base of the first metacarpal
Muscle imbalance due to the absence of insertion of one of the APL tendons on the trapezium	Operational stress due to repetitive work with strong thumb adduction
Muscle hypotonia of the non-dominant hand in elderly people	

TAB. 1

Causes of the trapeziometacarpal joint instability.

FIG. 4

Instability due to the absence of intersection of *abductor pollicis longus* in the trapezium. – Tensive forces.



ductor pollicis longus **(APL)** insertion on the trapezium. In cases where the APL has distal double insertion on the trapezium and on the base of the first metacarpal, with each contraction of the APL the entire thumb-metacarpal-trapezium column shifts in abduction, maintaining normal trapeziometacarpal joint relationships.
Conversely, if there is no insertion on the trapezium, all abductor force is exerted on the base of the first metacarpal, causing significant subluxation tension with a deleterious shear effect on, and cartilage damage, of the TM joint (FIG. 4).
– Repeated stress (overuse) is another frequent cause of TM joint arthritis; the TM joint is subjected to a considerable workload, as it is involved in approximately 50% of all actions of the hand.

FIG. 5

Subluxation of the first metacarpus.

It is possible to distinguish some activities and habitual gestures that favour the deterioration of the articular surfaces: the repeated prehension of small objects exerts radial stress on the TM joint that does not allow the base of the metacarpal to stay in contact with the articular surface of the trapezium (FIG. 3).
The luxation force transmitted on the metacarpal can be multiplied up to 12-120 times (Cooney *and* Chao, 1977).

SYMPTOMATOLOGY

TM joint instability is often asymptomatic; over time, pain develops, leading the patient to consult a physician.
– The most frequent clinical picture is initially represented by an annoying pain localised at the base of the thumb that appears when active movements in radial abduction such as grips or pincer movements are performed, and/or passive movements in rotation-opposition such as turning a key, unscrewing a cap, turning a handle, writing with a thin pen or even just buttoning a shirt (Dias *et* Al., 2006).
The patient complains of decreased hand strength and mobility.
Later, the pain appears even at rest, at night, and may radiate to the wrist and forearm. In more advanced stages, pain is spontaneous and is associated with bone crepitus due to joint laxity.

– The patient does not "use" the thumb well to avoid pain: over time, this causes muscle weakness in the stabilisation structures of the TM joint; the metacarpal loses the ability to slide on the trapezium along the adduction-abduction axis, in addition to which there is a radial shift of the base of the metacarpal.

The loss of congruence between the bone heads affects the mechanical stability of the joint: it results in dislocation, consequently decreasing movement amplitude (Pomerance, 1995). During abduction movements, the joint capsule is stretched.
Some capsular fibres are weakened, leading to the dorsal subluxation of the base of the metacarpal; therefore, when the *adductor pollicis* and *flexor pollicis brevis* muscles contract, they pull the distal part of the metacarpal toward the palm.
The result is a "tilt" of the articular surface at the base of the metacarpal on the saddle of the trapezium.

- This tilt, though imperceptible, is the cause of the pain.

That is why, in cases of RA, holding and turning a key, lifting a cup or writing are actions that cause pain: in fact, these actions, although with movements that require little articulation, stress the TM joint and its means of containment (Dias *et* Al., 2006).

– The prevalent clinical signs are:
- deformation and swelling at the base of the first metacarpal (FIG. 5), caused by a combination of dislocation, joint inflammation, and osteophyte formations;
- 1st ray in adduction, more common in advanced stages;
- pain on palpation;
- positive axial compression test or Grind test: the axial load on the trapezium, together with the rotation of the metacarpal, trigger pain at the base of the thumb;
- TM joint dislocation, with or without rotation, which causes stretching of the capsule, which, if inflamed, is painful.

As the disease progresses, TM joint subluxation produces a radial deviation of the MP of the thumb due to the contracture in adduction of the first metacarpal, which is followed by a flexion of the IP, generating a picture of "Z-thumb". This is an expression of one of the most compromised pictures of RA in which, in addition to the TM joint, the MP in hyperextension and IP in flexion are involved.

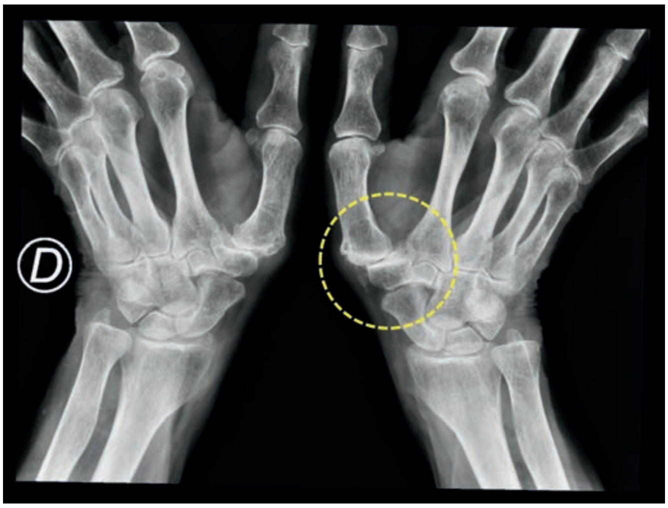


FIG. 6

Stress view.

RADIOGRAPHIC PICTURE – THE EATON-LITTER CLASSIFICATION

RA can be diagnosed through a careful physical examination.
X-rays of the thumb in 3 planes and the particular stress view of the basal joint are necessary to confirm the diagnosis.
The view for the basal joint under stress, when performed correctly, provides an excellent image for assessing the degree of TM joint subluxation.
In this 30° oblique view, the patient is asked to press the tips of the thumbs against each other while the X-ray is being performed (FIG. 6).

X-rays should always be interpreted in relation to the patient's clinical situation. Often, patients with very compromised radiographic pictures report very little or no pain; others with negative or insignificant X-rays may present severe functional deficits with significant impact on daily and/or work activities. There is no indication for MRI and/or ultrasound; only CT may be useful as an additional preoperative investigation.

– Eaton and Glickel (Glickel, 2001) described a method for classifying pathological changes in RA based on the appearance in standard radiographic views and those under stress.
This method has also proven to be useful in medical planning and, if needed, surgery.
– At present, the most widely used classification is the Eaton-Littler classification modified by Brunelli (Barra *et* Al., 2003) which includes both the radiographic picture and clinical picture (TAB. 2).

RHIZOARTHROSIS – CONSERVATIVE TREATMENT

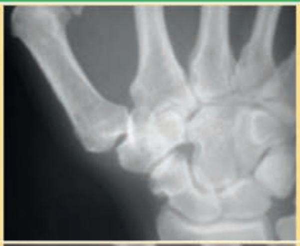
Treatment in all stages of the disease is initially conservative.
– The first step is the application of an immobiliser at night and possibly during the day for 2-3 weeks (Swigart *et* Al., 1999); the reduction in joint head movement and friction leads to decreased pain and stiffening of the capsuloligamentous structures with reduced subluxation (Pomerance, 1995).
This can be associated to chondroprotectors that achieve their maximum therapeutic effectiveness if the joint is immobilised; in fact, since there is no wear effect, the cartilage can regenerate (Towheed *et* Al., 2005).
The synergy of these two measures can ensure a good outcome.
Conservative treatment requires early diagnosis of the degenerative process (Towheed *et* Al., 2005) because it is more effective, especially in the early stages (1st and 2nd).
The goals of conservative treatment are:

- to reduce pain at the base of the thumb, both at rest and while performing routine daily activities;
- avoid TM joint overload by teaching the patient correct prehension modes and favouring gripping with terminal opposition (FIG. 3);
- provide TM joint stability with the immobiliser while simultaneously reducing radial metacarpal subluxation.

– Corticosteroid injections act on pain; they are sometimes used when the pain is unbearable (Pellegrini, 1992; Swigart *et* Al., 1999). These injections, if repeated, are less and less effective and irreparably damage the articular cartilage (Burton *and* Pellegrini, 1986; Swigart *et* Al., 1999).

RHIZOARTHROSIS – TREATMENT WITH MD-SMALL JOINTS

If initial conservative treatment does not produce positive effects, endo- and periarticular injection therapy may be considered before resorting to definitive surgical treatment.
The anatomical structures forming the containment/stabilisation system are: the joint capsule, ligaments and fibrous membranes that provide "direct seal", while the tendons and muscles provide "indirect seal".
• The extra-articular structures are made of Type I collagen (COL1): the quantity and quality of this triple helix macroprotein ensure optimal and repeated physiological articular movement over time.
– With ageing, all the COL1 forming the peri- and intra-articular structures undergoes important qualitative/quantitative changes (discrepancy between neofibrillogenesis and fibrillolysis) with progressive depletion and/or damage of adequate COL1, so that the articular bone heads are more mobile along the

STAGE	X-RAY	CLINICAL SIGNS	ACCESSORY ELEMENTS
1		TM joint subluxation is less than 1/3 Subchondral sclerosis begins to develop along with initial diastasis of the articular heads Instability, initial pain	Subluxation of the base of the first metacarpal under stress in abduction or in semeiologic manoeuvres (dynamic) Possible hypoplasia of the trapezium on X-ray examination
2		Subluxation is greater than 1/3 The capsule begins to be quite loose The first osteophytes of more than 2 mm in size appear Frequent pain on exertion Modest functional limitation	Instability Joint space narrowing, modest arthritic signs Osteophytes
3		The joint space is greatly reduced and sclerosis is increasingly evident Constant and stronger pain, stiffness Functional limitation Crepitus on palpation of the base of the thumb associated with more or less obvious deformities	Continuous pain Severe limitation
4		Severe anatomical and radiographic alterations resulting in functional impotence TM joint rigidity Severe functional limitation	Decreased pain related to stiffness, sometimes absent

TAB. 2

Eaton-Litter classification modified by Brunelli.

physiological excursion planes and are no longer firmly held in place. Hypermobility of the joints leads to abnormal support with consequent inflammation, first, and then degeneration of articular cartilage, the prime mover towards arthritic degeneration (Milani, 2019).

• In short: according to physiological biomechanics, the incorrect positioning of two contiguous joint heads forming a joint causes wear, pain and difficult movement. The tenocyte, a very specialised fibrocyte, is the cell that produces COL1; it also synthesizes matrix **Proteoglycans (PGs)** and Metalloproteinases (MMPs) (Bernardini, 2018) involved in the degradation of old or damaged fibres by the inflammatory/traumatic process.

– The primary event in the arthritic process is to be found in the reduction and alteration of PGs: mechanical, chemical or cytological factors lead to the depolymerization of the chains of Glycosaminoglycan (GAGs), which, by breaking, cause the decreased resistance of the articular cartilage matrix.

– As a consequence of these events, the collagen fibres that are not adequately protected by the matrix also break into fragments; the cartilage thus loses its elasticity and wears out (Scagliati, 1995).

All extra- and intra-articular structures are fundamentally made of collagen, hence the usefulness of deriving therapeutic means that allow the physician to counter osteo-arthro-myofascial pathologies (Stone *et* Al., 1997; Milani, 2010; 2013; 2019).

MD-Small Joints

Guna Collagen Medical Devices are injectable products (p.a., i.a., s.c., i.d., i.m.) consisting of collagen of porcine origin (porcine collagen is the most similar and akin to human collagen) and one or more ancillary substances characterised by a particular tropism for the various and specific anatomical districts to which the collagen can be conveyed with greater effectiveness and specificity (Milani, 2013; 2019).

Guna Collagen Medical Devices provide collagen in the form of tropocollagen, which is assembled to collagen in the presence of the enzyme lysine hydroxylase, at the level of the extracellular matrix (ECM); it therefore acts as a bioscaffold (Milani, 2010).

– The deposition of neosynthesized collagen fibres in the damaged area secondary to loco-regional injection of the MDs produces a significant improvement in the mechanical qualities of the injured tissue; in particular, the anisotropic characteristics are restored. **Anisotropy** is a mechanical property of collagen: it describes the ability of its fibres to propagate tensile forces in a single preferential direction.

Due to the orientation of the collagen fibres in a single direction, proper mechanical support is achieved for optimal function (Milani, 2019).

– Guna Collagen Medical Devices improve the histological make-up of anatomical structures in which collagen is present and provide a mechanical support (bioscaffold) with a clear positive effect on the stabilisation of joint hypermobility, movement, pain, and quality of life; they have a restructuring, repairing and remodelling action and contribute to the containment of the physiological deterioration of joints and tissues to counterbalance the effects due to various causes including ageing, postural defects, chronic concomitant diseases, traumas and injuries (Various Authors, 2011).

– In addition to collagen, **MD-Small Joints** contains *Viola odorata*, an ancillary substance that is indicated – inter alia – in rheumatic pain of the wrist joints radiating to the forearm (Various Authors, 2011).

MATERIALS AND METHODS

Twenty-two patients (3 M; 19 F) suffering from RA were included in this clinical trial.
In 4 patients the pathology was bilateral; in this study, the most compromised side was considered.

– All patients were tested with the **DASH** questionnaire to assess loss of function (values 0 to 100; 100 = maximum disability), the VAS Scale (values 1 to 10), and the **Grind test** to assess capsuloligamentous laxity (G0 = no joint laxity; G1 = scarce laxity; G2 = lax; G3 = very lax).

– The mean age of the patients was 61.2 years (min. 44, max. 78): 12 patients in stage 2 and 10 patients in stage 3; 10 patients had maximum laxity G3, 5 had minor laxity G2, 7 had minimal laxity G1, and none G0.
All patients at the time of inclusion had decreased strength and functional limitation of the first ray. As regards laterality, 7 patients (33%) had RA in the nondominant hand.
This high percentage is explained by the fact that the nondominant hand, in many activities, must maintain a static grip for a long time thus resulting in severe overuse phenomena.
For example, suffice it to think of a patient who holds a sheet of metal or other material with strength in order to work it with the dominant hand.
In elderly patients, however, it is often due to muscular hypotonia of the nondominant hand: this explains how important the tendons and muscles, namely the structures involved in “indirect gripping”, are.

The mean **DASH** was **50.72** at the first visit with a minimum of 16.5 and a maximum of 75.25; the mean **VAS** was **7.14** at the first visit with a minimum of 5 and a maximum of 9; the mean Grind test was **2.25** with a minimum of 1 and a maximum of 3 (TAB. 3).

	Age (years)	DASH	VAS	Grind test
Mean	**61.22**	**50.72**	**7.14**	**2.25**
Minimum	44	16.5	5	1
Maximum	78	75.25	9	3

TAB. 3
Patient assessment at inclusion.

– After one week of home therapy (low dose medicaments), patients began outpatient treatment with **MD-Small Joints** (1 vial = 2 mL), to which 0.5 mL of lidocaine 2% was added. Intra-articular injection was performed with 0.7-0.8 mL (i.e., the average capacity of the TM joint); the remaining amount (approx. 1.0 mL) in the periarticular site (FIG. 7).
In addition, approx. 0.5 mL were used for a second periarticular injection at the level of the 1st commissure in order to attack the deep part of the capsule between the first and second metacarpals, but above all to inject the intermetacarpal ligament in order to stabilise it and reduce the conflict due to its laxity (FIG. 2,8).
Injections were administered 3 or 4 times a week; the 4th or 5th were administered after 2 weeks.
In 8 patients, further treatment was required after another 2 weeks.

– Some patients experienced an exacerbation of symptoms after the 1st or 2nd administration; in 6 cases, therapy had to be temporarily suspended, but at the follow-up of the following week the worsening had completely regressed; in some cases, there was a clinical and

FIG. 7
Intra- and periarticular infiltration.

FIG. 8
Infiltration of the 1st commissure.

Weeks	0	1	Δ Week 1	2	3	4	5	6	7	8	9	10	Δ	%
DASH	**50.72**	39.87	21.39%	29.71	24.54	18.00	18.25	20.18	16.50	18.75	14.75	**8.13**	**42.59**	**83.97**
VAS	**7.14**	6.60	7.56%	5.06	4.44	3.85	3.60	4.20	4.29	2.80	3.33	**3**	**4.14**	**57.98**
Grind test	**2.25**	2	11.11%	1.367	1.233	0.923	1.111	0.714	0.8	0.667	0.5	**0.5**	**1.75**	**77.7**

TAB. 4

DASH, VAS, and Grind test values before and after treatment (10 follow-ups).

psychological improvement, so that treatment was resumed in all patients (no drop-out).

No patients required NSAIDs.
Only one patient, who was very anxious, was given anaesthesia in the superficial branch of the radial nerve, prior to the procedure described, to eliminate the pain of the i.a. and p.a. injections.
The addition of a minimal amount of lidocaine 2% resulted in significant patient compliance.
Case series confirmed the higher incidence of RA in the female gender.

RESULTS

This study enrolled: **1)** patients who had pain at stages that were too early to consider surgical treatment; **2)** non-responders to previous therapies, such as steroid therapy; **3)** patients who, despite having a surgical indication, refused surger.
In any case, it is believed that the earlier this treatment is initiated, the better the chance of an effective clinical response.

– Analysis of the DASH, VAS, and Grind test values showed that after the first week of treatment with low dose medicaments, there was a **21.39%** improvement in the DASH value, **7.56%** improvement in the VAS value, and **11.11%** improvement in the Grind test value. These data demonstrate the effectiveness of this preliminary therapeutic time (TAB. 4).

• Evaluating then the difference from the beginning to the end of the therapy, it can be seen that the DASH value decreased by **42.59 points** (**83.97%** increase in function); pain, according to the VAS Scale, decreased from **7.14** to **3** with a delta of **4.14** and consequently a **57.98%** decrease, while laxity went from a Grind test of **2.25** to a Grind test of **0.5** (**1.75**- point improvement), i.e., an increase in capsuloligamentous tension of **77.7%** (TAB. 4).

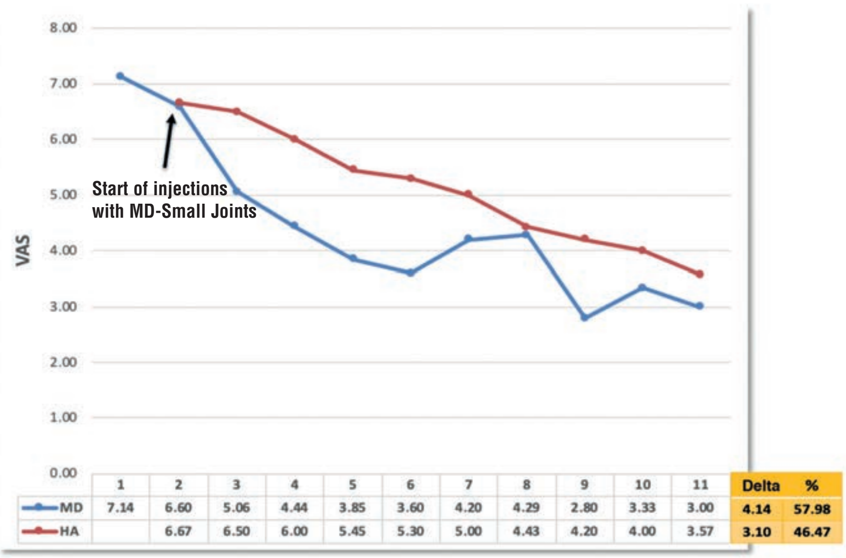


FIG. 9

VAS comparison: MD-Small Joints *vs* Hyaluronic Acid.

MD-SMALL-JOINTS VS HYALURONIC ACID

Intra-articular injection treatment with hyaluronic acid **(HA)** has been and still is another cornerstone of RA therapy, used by physiatrists and hand surgeons (Strass *et* Al., 2009; Volpi *et* Al., 2009; Iannitti *et* Al., 2011).
– Comparing the values obtained with MD-Small Joints with those obtained in a similar study carried out by the author (Brunato, 2012) on 51 patients treated with 3 intra-articular injections of HA administered 3 weeks apart, the following differences were recorded: at 10 weeks the VAS dropped from 6.67 to 3.57.
The difference was **3.10** points versus **4.14** points for MD-Small Joints, demonstrating a greater efficacy in pain control of **1.4 points** for MD-Small Joints (**+ 11,51%**) vs HA.
What is most striking is the early and marked decrease in pain from the first weeks of treatment with MD-Small Joints compared to HA (FIG. 9).
– Comparing the DASH values, the reduction was 42.59 points with MD-Small Joints compared to 27.51 points with HA, an improvement in hand function of **+ 25.7%**.
With MD-Small Joints, daily work activity, as verified with the DASH question-

naire, was maintained with significantly less pain (FIG. 10).

Converting all the values measured by DASH, VAS, and Grind test **to a scale of 10** shows that the improvement in DASH and VAS values is directly proportional to the decrease in Grind test, i.e., the reduction in joint laxity.
The recovery of joint tension is the result of the direct effect of injections with MD-Small Joints on the capsuloligamentous structures and in particular on the intermetacarpal ligament.

This is the clinical observational demonstration that local injection of MD-Small Joints restores the anisotropy of collagen and produces a significant and immediate improvement in the mechanical qualities of the damaged tissue, whence the clinical improvement of RA (FIG. 11).

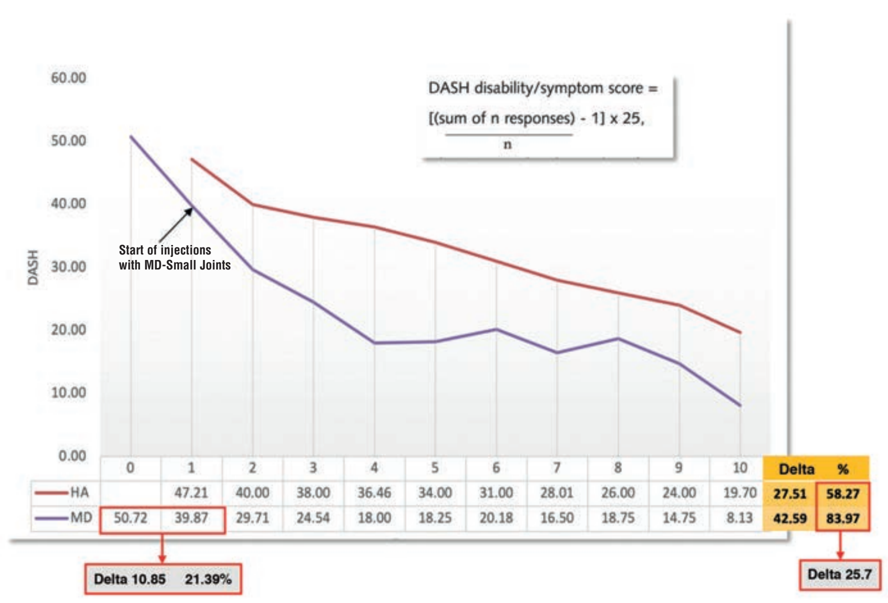


FIG. 10

DASH comparison: MD-Small Joints *vs* Hyaluronic Acid.

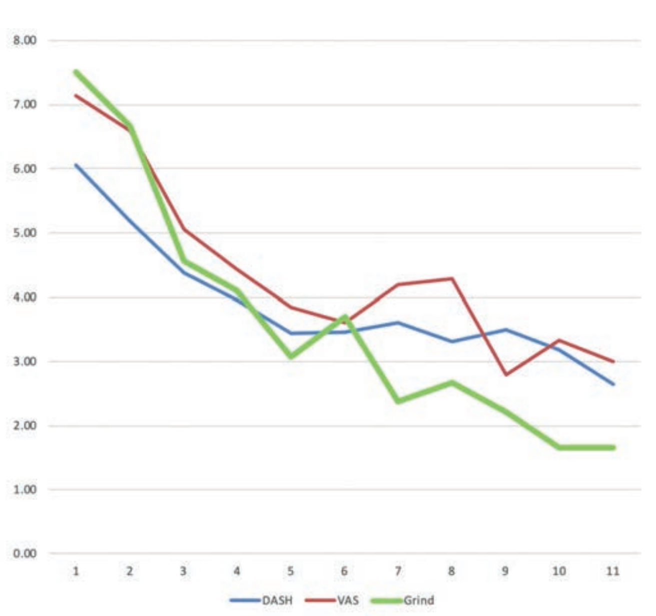


FIG. 11

Comparison of DASH and VAS values as a function of Grind test values.

DISCUSSION

Injection treatment of RA with Collagen Medical Device Small Joints significantly improved patients' symptoms in very few weeks; most importantly, pain clearly decreased, from the outset, as a result of the rapid reduction in joint laxity, proving to be more effective than HA therapy.

Most authors (Dias *et* Al., 2006) consider treating RA with immobilisation and taking NSAIDs for 2-3 months; if symptoms do not regress, surgery should be considered.
Corticosteroid injections act on pain and may be indicated when conservative therapy has not been effective (Pellegrini, 1992; Swigart *et* Al., 1999), but repeated injections have been found to have decreasing efficacy, in addition to irreparably damaging the capsule and articular cartilage (Burton *and* Pellegrini, 1986; Swigart *et* Al., 1999).
HA treatment has been shown to be less effective.

▶ MD-Small Joints has proven to be effective in delaying surgery, providing patients with rapid clinical improvement and an expectation of slowing down the pathology; all this in the absence of side effects and with excellent tolerability. ■

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