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GUNA COLLAGEN MEDICAL DEVICES

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ABSTRACT BOOK

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INDEX

FOREWORD

This Abstract Book is a collection of clinical cases treated with collagen infiltrations and presented during national and international Medical Congresses.

They constitute real-world evidence on the use of Guna Collagen Medical Devices for the injection treatment of various musculoskeletal pathologies.

The contents of this Abstract Books are organized by anatomical region for easy consultation.

Guna Collagen Medical Devices are **CE-marked class III Medical Devices** containing **type I collagen**. They can be administered through intra-articular, extra-articular (subcutaneous, intradermal, intramuscular) injections, or mesotherapy.

Each 2ml vial of a Guna Collagen Medical Device contains collagen of swine origin and additional ingredients of mineral or plant origin, or vitamins, specific for each item of the range.

They are available in packs of 5 or 10 sterile vials.

LITERATURE REVIEW ON COLLAGEN

Collagen type I for injectable use in the treatment of musculoskeletal disorders: a literature overview.

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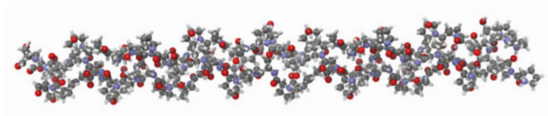
Introduction

Musculoskeletal disorders (MSDs) affect 15-20% of the population, and in the 70% of cases they cause chronic pain. The incidence and the prevalence of MSDs are increasing worldwide following the global aging of population, thus determining growing suffering and costs. Musculoskeletal conditions are also the highest contributor to the global need for rehabilitation. [Cieza A., et al . The Lancet, 2021]
Many MSDs are characterized by a quantitative and/or qualitative alteration of collagen. The imbalance between degradation and synthesis processes of collagen, influenced by proinflammatory cytokines and reactive oxygen species (ROS), is responsible for the progressive histological and functional weakening of musculoskeletal system structures, such as tendons. As a matter of fact, tendons' mechanical properties are strongly influenced by the composition of the extracellular matrix (ECM), mainly made up of type I collagen [Bosman FT, et al. J Pathol. 2003; Kannus P,. Scand J. Med. Sci Sports 2000]. Tissue-engineering strategies involve the use of scaffolds, cells and/or bioactive factors to promote tendon regeneration through a natural process (in case of damaged or lost tissue) [Randelli F, et al. Cells 2020].
During the onset of Osteoarthritis (OA), an acute inflammatory process is established, and pro inflammatory factors cause the degradation of ECM, including collagen. [Hunter DJ, et al. Lancet 2019]. For this reason, intra-articular collagen injections have been investigated as a possible symptomatic adjuvant or stand-alone treatment for OA and as a cost-effective solution compared with HA. [Martin Martin LS, et al. BMC Musculoskelet Disord. 2016].
The interactions between muscle cells and ECM play a key role in the reparative processes of muscle tissue, especially when it's subjected to mechanical stress. Quantitative or qualitative alterations of collagen at the ECM level can become the cause of inappropriate muscle regeneration, favoring, or supporting pathological processes [Thorsteinsdóttir S, et al. Dev Biol. 2011].
Considering the increase of clinical evidences and studies on regenerative collagen [Giarda F, et al. MR Volume 39 – N.1 – Marzo 2023], our aim is to provide an updated overview of the literature on the use of collagen-based medical devices (CMD) in the musculoskeletal field.



The structural unit of collagen is characterized by the presence of three polypeptide chains with a left-handed orientation, coiled to form a right-handed triple helix.

Materials and Methods

Using PubMed, Web of Science and EMBASE, we identified relevant papers published up to April 2023 concerning the use of CMD in the treatment of musculoskeletal disorders.

Results

In vitro exposure: The results of the in vitro studies by Randelli F. et al. on the use of type I collagen preparations, in the form of injectable CMD on human tenocytes obtained from healthy fragments of the gluteus minimus tendon, show that the tenocytes cultured on MD-Tissue, compared to controls, have a higher proliferation rate and higher migration potential. [Randelli F, et al. Cells. 2018] This therapeutic approach also influences the collagen turnover pathways and represents an input involving mechanotransduction phenomena, proposing itself as a bio-scaffold with a reparative and regenerative action. [Randelli F, et al. Cells. 2020].

Clinical evidence: The results of the seven studies which evaluated the effects of intra-articular collagen injections for knee OA showed that the intra-articular administration of collagen may stimulate chondrocytes to produce hyaline cartilage and hinder the normal inflammatory response leading to fibrous tissue formation, reducing symptoms and improving functionality. The use of type-I collagen as an intra-articular treatment for knee OA was found not only to be effective, but also safe with negligible side effects. [Tarantino D, et al. IJERPH 2023].
Intra and peri-articular infiltration of type I collagen was also found to be effective in patients with coxarthrosis (Kellgren-Lawrence I and II). Some clinical trials had in fact demonstrated statistically significant results in reducing pain and improving function, with lasting effects up to 3 months [Tivchev P. Bulgarian Journal of Orthopedics and Trauma 2012; Giovannangeli F. PRM 2017; Milano E. PRM 2018]
In a pilot study, infiltrative collagen was shown to be effective in reducing pain and improving function in subjects affected by lateral epicondylitis, one and three months after treatment. The 50 enrolled patients were treated with a series of five injections at weekly intervals. (Corrado B, et al. Muscle Ligaments and Tendons Journal 2019)
In a randomized, controlled, single-blind study of 43 patients, the use of injectable type I collagen in the treatment of myofascial pain within masseter muscles was compared with the intramuscular injection of lidocaine and saline. The results showed a significant reduction of pain intensity in muscle activity, quantified by surface electromyography, in all groups for both variables analyzed. However, the most consistent improvements were observed in the subgroup treated with collagen type I. [Nitecka-Buchta A, et al. Pain Res Manag 2018]

Discussion and Conclusion

Analyzing the literature available to date, porcine derived type I collagen is proposed as a promising approach in the treatment of pain and functional recovery related to musculoskeletal pathologies. No significant side effects have ever been reported in previous studies. However, the actual literature shows a span of studies that vary in methodology, samples analyzed, pathologies treated, and outcomes evaluated. Discrepancies between studies still do not allow to draw conclusive considerations, however CMD could represent a novel safe and cost-effective approach to musculoskeletal disorders. Further studies are needed to more precisely define the indications and limitations of the method.

NECK

12° I.S.Mu.L.T. Congress
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PORCINE COLLAGEN TYPE I FOR THE TREATMENT OF CERVICAL PAIN SYNDROME RELATED TO ZYGAPOPHYSEAL JOINT INVOLVEMENT.

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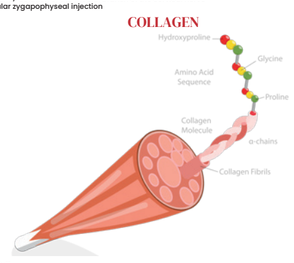
INTRODUCTION:

Chronic cervicalgia associated with degenerative problems of the cervical spine is a frequent and difficult-to-treat condition.
Involvement of the posterior zygapophyseal facet joints is considered the main source of pain in up to 70 % of cases.
The most common interventional techniques available are invasive:

- Anaesthetic blocking of the medial branch of the cervical nerve
- Radiofrequency ablation of the medial branch of the cervical nerve
- Intra-articular zygapophyseal injection



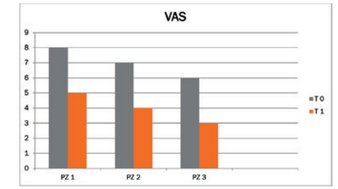
METHODS:

The study involved 3 patients referred to the physiatric outpatient clinic for persistent cervicalgia for more than 6 weeks, associated with muscle stiffness and joint limitation, resistant to analgesic and systemic anti-inflammatory therapy.
Gender: 1 M, 2 F
Age, 86 yrs, 47 yrs, 38 yrs.
All patients underwent an imaging examination with MRI without contrast of the cervical spine for diagnosis and exclusion of neoplastic pathology.

The Segmental Objective Examination showed:

- Limitation of the cervical P-ROM to medium levels in two cases, to initial levels in one case
- Presence of muscle contracture and trigger points at the level of the middle trapezius muscle
- Positive Extension-Rotation test for accentuation of pain related to the posterior interapophyseal facet joints

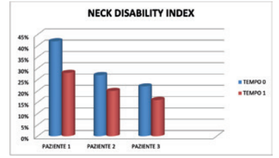
The patients were assessed at time zero, at the start of treatment, and at time 1, one week after the end of treatment.
The Visual Analogic Scale (VAS) for pain and the Neck Disability Index Questionnaire (NDIQ) for cervicalgia-related disability were administered.
The site of the zygapophyseal facet joints at levels C3-C4, C4-C5, C5-C6, C6-C7, was revealed using ultrasound with a 12 Hz linear probe, and marked.
Total injection sessions 5. In each weekly session the patients were treated with MD-NECK collagen administered by periarticular mesotherapy. 13 mm 28G needle, 4 points on each side of the neck infiltrated freehand to a depth of 13 mm at the level of the bilaterally identified zygapophyseal joints (total 4 ml).
At the level of the most painful trigger points of the middle trapezius muscle, 3 + 3 injections per side were performed in the first 3 sessions, subcutaneous mesotherapy with a 13 mm 28G needle with Tr14 in vials (total 4 ml).



VAS	T 0	T1
PZ 1	8	5
PZ 2	7	4
PZ 3	6	3

RESULTS:

All patients reported progressive clinical improvement.
The VAS was reduced in all patients:
VAS 8 -> 5
VAS 7 -> 4
VAS 6 -> 3
The NDI improved in all patients:
21 (42%) severe disability -> 14 (28%) moderate disability
12 (27%) moderate disability -> 9 (20%) minimal disability
11 (22%) moderate disability -> 8 (16%) minimal disability
Periarticular injection treatment with MD-NECK, a class III medical device made from porcine collagen type I, is a useful, safe and easy-to-use restorative and regenerative solution.
Collagen can reduce joint pain and inflammation and promote bioregeneration processes.
In this study, joint treatment with type I collagen was combined with treatment of the cervicoscapular myofascial inflammatory component with the Tr14 complex to accelerate the patients' functional recovery.



NECK DISABILITY INDEX	T0	T1
PZ 1	21 (42%) severe disability	14 (28%) moderate disability
PZ 2	12 (27%) moderate disability	9 (20%) minimal disability
PZ 3	11 (22%) moderate disability	8 (16%) minimal disability

CONCLUSIONS:

Injection treatment with MD-NECK type I porcine collagen using an ultrasound-assisted periarticular mesotherapy technique is a safe and effective practice that can be used as a valuable tool for the treatment of a difficult, high-prevalence, chronic disease with few conservative solutions available.

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OZONE THERAPY WITH COLLAGEN-BASED FOCAL INJECTIONS ON A PATIENT WITH SEVERE CERVICALGIA

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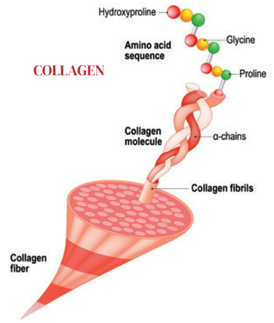
INTRODUCTION:

Effectiveness of the therapeutic combination of Ozone Therapy and Collagen-Based Focal Infiltration on patients with severe neck pain
Neck pain (Cervicalgia) is one of the most common disorders worldwide, with around 75% of the population having once throughout their lifetime.
The incidence rate varies by gender. It happens more frequently in females, especially those between 40 and 60.
Following lower back pain and depression, neck pain is now the third main health issue leading to absenteeism.



CLINICAL CASE:

A 51-year-old female, a bank clerk, came to our outpatient clinic of San Raffaele Hospital (Milan, Italy) in October 2023, complaining about severe neck pain, causing her an unacceptable change in her quality of life in the past few months.
She underwent a right mastectomy due to breast cancer (2015) and cycles of post-interventional chemotherapy with radiotherapy.
On 23rd July 2023, she went to the Accident and Emergency of Fidenza Hospital (Parma, Italy) for severe cervical pain, bilateral ear pain, subjective dizziness and tremours on the upper limbs.She had a cervical X-ray showing no vertebral fracture but spondyloarthritis with moderate physiological curve reduction. The brain CT is normal. A&E discharged her with the prescription of NSAIDs and muscle relaxant (Dicloreum+Thiocolchicoside) for one week; however, without benefit.

For the persistence of unstopping pain, the patient had a cervical MRI without contrast showing:

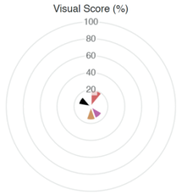
- On the C5-C6 level, the disc protrusion causes the anterior epidural closure and mild reduction in the width of the conjugation foramina (more on the right to the left).
- On the C6-C7 level, the disc protrusion presents medio-posteriorly and slightly compressing the dural sac (Thecal sac).

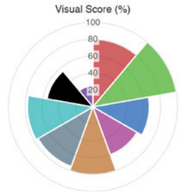
During the Neurosurgical visit, she underwent a peridural infiltration without benefit. Therefore, she was prescribed Gabapentin, Tizanidin, Dexamethasone, Tramadol, and Oxycodone by oral administration; still, the pain was not totally under control.
During medical examination, visit, she had an intense muscle contraction on the trapezoid and both the superficial and deep cervical paravertebral muscles. Combining Ozone Therapy and Collagen-Based Focal Infiltration may meet the therapeutic requirement.
The programme for this patient consists of the following on the trapezoid and cervical paravertebral muscles:

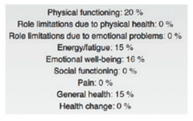
- Ten times Ozone Therapy:
  - O2 / O3 concentration: 5 - 8 µg in the syringe of 50 mL and the needle of 27 Gauge
- Ten times Collange-Based Focal Infiltration:
  - 1 vial of Guna MD-Muscle of 2mL in the syringe of 5 mL and the needle of 27 Gauge

NB: Current therapy:

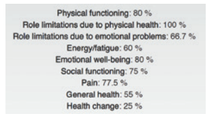
- 1 packet of Magnesium Pidolate per day for a month
- 4 drops of Clonazepam before sleep



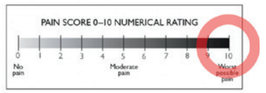




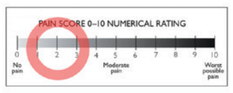
SF-36 Pre-Treatment



SF-36 Post-Treatment



NRS – Pre Treatment



NRS – Post Treatment

CONCLUSIONS:

This clinical case demonstrates the effectiveness of combining ozone therapy and collagen-based focal infiltration treatment with Guna MD-Muscle in a patient with severe neck pain and functional limitation due to intense muscle contraction.

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SHOULDER

SIMFER
SOCIETÀ ITALIANA DI MEDICINA FISICA E RIABILITATIVA
The Italian Society of Physical and Rehabilitation Medicine

CALCIPHIC TENDINOSIS: a new infiltrative therapeutic opportunity based on porcine collagen.

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Centro Polispecialistico Pacini s.r.l.

Introduction

Calcific tendinosis is the chronic suffering of a tendon, characterised by the degeneration of the normal tendon structure. Calcium deposits reduce the elasticity and mobility of the tendons involved, which, by becoming stiffer, are more prone to become inflamed when stressed.
The aim of this case report is to prevent tissue damage in the shoulder by infiltrative therapy with type I porcine collagen, as an alternative to other conservative therapies such as PRP (more investigative and expensive) or non-conservative therapies such as surgery.
Type I collagen is the most abundant protein present in the connective tissue that surrounds and protects the peri-articular compartment, such as tendons and ligaments. Its exogenous supplementation by infiltration strengthens and repairs damaged structures, giving greater elasticity and resistance.

Materials and Methods

One 58-year-old patient suffering from calcific tendinosis of the right shoulder (supraspinatus and long head of the biceps) with functional limitation and chronic stiffness in the investigated planes of movement was treated. A musculotendinous ultrasound was performed before and after the infiltrative treatment. Prior to starting the infiltrative cycle with collagen, the patient was treated with a focal shock wave cycle.
A course of 5 infiltrations of MD-TISSUE was performed (1 infiltration per week for 5 weeks), using a 25 mm 26G needle in the peri-lesional site.
Pain was assessed by means of a VAS scale, initial value (T0) 8 and final value (T1) 1-2.
During the treatment, a progressive subjective/clinical improvement of the pain symptoms and mobility of the right shoulder associated with a physiokinesitherapy cycle with stretching was observed. MD-TISSUE is a class III medical device that has a mechanical scaffold effect and an antioxidant role due to the presence of its excipients (vitamin C/B1, B2, B6 and magnesium gluconate).
Follow-up was performed at 3 months with reported stable VAS 1-2 pain and no reported anti-inflammatory intake. The follow-up at 6 months confirmed the absence of pain symptoms.

Figure 1:*Image of calcific shoulder tendinosis*

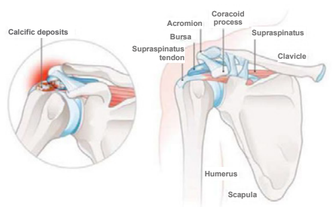
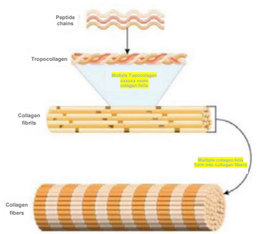


Figure 2:*Triple helix collagen*



Results

MD-TISSUE enabled an improvement in tendon fibre quality and improved tendon mobility in sliding, a significant reduction in pain and an improvement in joint mobility associated with physiokinesitherapy.
The efficacy of type I porcine collagen meant that there was no need for cortisone infiltration. The benefit of the latter must be weighed against the risk of a possible delay in the healing process and is only useful in cases of acute and not chronic pain, as was the case with this patient.

Conclusions

Infiltrative treatment with type I porcine collagen promoted homeostasis, remodelling and tissue repair by acting as an active scaffold in the extracellular membrane. It was able to repair the damage, improving the functionality of the compromised structures.
GUNA MD-TISSUE is a regenerative, restorative, useful, safe, easy-to-use, side-effect-free and cost-effective therapeutic treatment compared to other infiltrative therapies. It may prove to be a treatment that can be combined with a course of instrumental treatment with focal shock waves. The latter can reduce calcification, while collagen can improve and restore tissue integrity and realign fibres.

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Grottaferrata INI

THERAPEUTIC OUTCOME IN PATIENTS WITH ROTATOR CUFF INJURY: INJECTION TREATMENT WITH PORCINE COLLAGEN TYPE I

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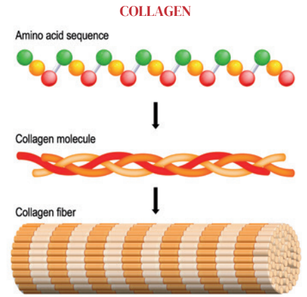
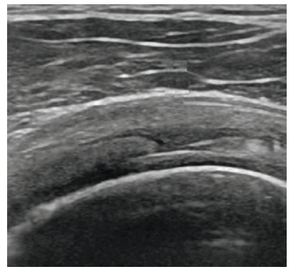
INTRODUCTION:

Rotator cuff injury is generally associated with lacerations or tears of the tendon tissue that can cause detachment from the bone surface. This type of injury can occur for various reasons, including traumatic events, incorrect movements, excessive loads or impact on the shoulder. The most common cause of a cuff tear is degeneration of the tendon tissue, caused by wear of the tendons over time. Symptoms of rotator cuff injury include shoulder pain that can radiate to the elbow, limitation of joint movement, reduced function and possible muscle weakness. It is essential to diagnose this condition correctly in order to determine the most appropriate treatment.
The aim of this work was to evaluate the effect of injection treatment with 2 ml collagen (Guna MD-TISSUE) at the tendon and muscle lesions, revealed by muscular- skeletal ultrasound.



METHODS:

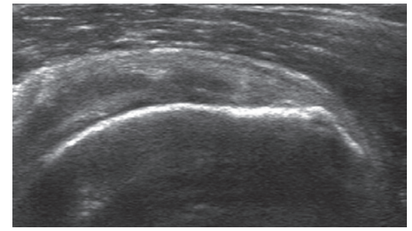
Three patients (aged 52, 58 and 80) with rotator cuff lesions who came to our attention through visits at the Outpatient Physical Rehabilitation Medicine Clinic were enrolled.
A Medical examination and diagnostic investigations (NRS assessment scale, Constant Scale, laboratory tests, ESR, CRP, haemochromocytometric, electrophoretic protidogram, ultrasound evaluation of the injured shoulder) were performed for each patient.
All patients underwent ultrasound-marked peri-tendon and peri-lesion injection with a Samsung HS-40 system and power Doppler of 2 ml of the class III medical device porcine collagen type I (GUNA MD-TISSUE) using a 25-mm long, 25 Gauge needle.
The procedure was repeated once a week for 5 consecutive weeks.



Before treatment

RESULTS:

Patients who underwent injections of GUNA MD-TISSUE showed, statistically, a significant reduction in pain from 8 to 5 (NRS), a reduction in inflammatory parameters, evidenced by power doppler, and a progressive recovery to the performance of daily living activities, thanks to restoration of the functional component of the treated joint.



After treatment

CONCLUSIONS:

Porcine collagen type I MD TISSUE injections have proven to be a safe and effective therapy compared to other injection therapies such as corticosteroids which have a short-term action only on acute pain with the risk of damage to tendon structures.
Porcine collagen type I, acting as an extracellular matrix bio-scaffold on connective tissues that have suffered damage or wear, stimulates the synthesis of new collagen, repairs and regenerates tissues leading to functional healing. It is a new, cost-effective and regenerative therapeutic solution.

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TREATMENT OF SHOULDER INSTABILITY IN A YOUNG FEMALE WITH EHLERS-DANLOS SYNDROME

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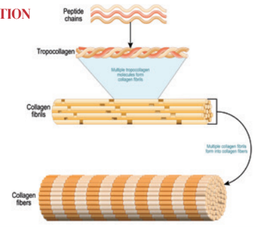
INTRODUCTION:

The Ehlers-Danlos syndrome (EDS) is a group of diseases majorly affecting collagen formation. The symptoms and severity vary from patient to patient, including skin hyperelasticity, joint hypermobility, and collagen malformation causing soft tissue disorder.
According to the specific diagnostic criteria issued by the Ehlers-Danlos Society in 2017, EDS can be subdivided into 13 types: Classical EDS (cEDS, I), Hypermobile EDS (hEDS, III), Vascular EDS (vEDS, IV), Kyphoscoliosis EDS (kEDS, VI), Arthrochalasia EDS (aEDS, VII A&B), Dermatosparaxis EDS (dEDS, VII C), etc. Among these subtypes, the Hypermobile EDS (hEDS, III) is one of the most common in patients.
Joint hypermobility means the joint(s) of the patients can reach an incredible action compared to the average, caused by ligament and tendon weakness due to collagen malformation. This symptom appears widely in many subtypes of EDS. To keep normal motor function, the weak tendons and ligaments crave further energy and materials to maintain joint stability. Therefore, it raises inflammation, pain, and dysfunction at or around the joints and, in the later phase, globally. Patients suffer not only frequent joint dislocation and sub-dislocation but also general weakness and tiredness.
Up to now, there is no disease-specific treatment for any EDS subtypes. To the present, the most applicable treatment is the multi-discipline symptom and supportive treatment.
Since collagen is the fundamental component of connective tissue, and Ehlers-Danlos Syndrome is a disease with the changes in the genes affecting the structure and function of collagen and related connective tissue proteins, the use of injection and oral administration of collagen may bring about better symptom management by its mechanical properties as a bioscaffold of the extracellular matrix to stabilise the articulation.
This clinical case report demonstrates the efficacy of collagen-based treatment.

COLLAGEN FORMATION



CLINICAL CASE:

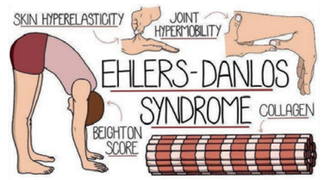
A 29-year-old female came to our physiatric outpatient clinic with long-term frequent sub-dislocations and dislocations on the mandibular and shoulders.
In 2018, she had her first episode of shoulder dislocation while she was trying to carry a heavy suitcase in the airport. She used to be sporty, fast walking three times and amateur badminton twice per week.
In 2022 summer, she had sub-dislocation on the shoulders bilaterally during her work. Since then, she has suffered from multiple sub-dislocations and dislocations on the shoulders. Later in autumn, she experienced numerous monolateral mandibular sub-dislocations and dislocations.
Days before Christmas in 2022, she was diagnosed with Ehlers-Danlos Syndrome with a genetic test, classified as Hypermobile type.
In April 2023, she underwent a physiatric visit for severe bilateral shoulder, worse on the left to the right, instability due to Ehlers-Danlos Syndrome (1).

The treatment was indicated as follows:

- Ten times of physiotherapy sessions:
  Twice a week, for 5 weeks
  Exercises to stabilize the scapula and rebuild the shoulder's muscular balance by strengthening the muscles.
  Improve the joint control to achieve the full recovery of the joint function.
- Ten times of porcine type I collagen injections:
  Intra-articular once a week for 5 weeks; peri-articular once a week for 5 weeks (Guna MD-Shoulder) (2)
- Compliments supply:
  1 flacon per day orally with collagen (5,000 mg), hyaluronic acid (200 mg), vitamin C and Manganese.
- Pharmacological treatment:
  Etoricoxib 60 mg 1 tablet daily for 2 weeks

A bilateral shoulder ultrasound was requested and carried out one week after the visit, with findings of:

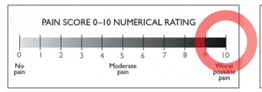
BILATERAL SHOULDER ULTRASOUND:
Parts linear probe, highlighted, in correspondence with the left acromioclavicular joint, a hint of acromioclavicular misalignment due to a very slight cranial displacement of the lateral end of the clavicle.
On the left, the head of the humerus is partially misaligned concerning the glenoid cavity.
On the right, thinned and non-homogeneous infraspinatus tendon in the absence of full-thickness lesions.



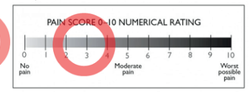
RESULTS:

The entire treatment was well tolerated (NRS from 10 to 3).
The scales at the end of therapy show the following scores:

NRS (pre)



NRS (post)



CONCLUSIONS:

The combination of collagen (oral and intra-articular/peri-articular) and targeted physiotherapy shows effectiveness in pain management and recovering shoulder joint stability. This injective collagen protocol could be a novel, valid and well tolerated therapy, without side effect, for this type of patients that needs a safety management.

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2. COLLAGEN STRUCTURE AND STABILITY Matthew D. Shoulders1 and Ronald T. Raines1,2 Ronald T. Raines: raines@biochem.wisc.edu

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COMPARISON OF THE COMBINED INTRAMUSCULAR INJECTION TREATMENT OF OZONE/COLLAGEN THERAPY AND THE INTRAMUSCULAR INJECTION TREATMENT OF OZONE THERAPY FOR CHRONIC LOW BACK PAIN DUE TO DISCOPATHY

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Introduction Any innervated structure of the spine can cause low back pain: muscles, ligaments, the dura mater, nerve roots, zygapophysial joints, the fibrous annulus and the fascial system.
The rationale for using ozone therapy to treat chronic low back pain in discopathies is based on the combination of anti-inflammatory action and acceleration of the dehydration process of the disc's cartilage tissue.
The fascial system, i.e. the collection of all collagen-based tissues, represented by a three-dimensional network throughout the body, is also involved in the aetiology of pain.
The deep thoraco-abdominal fascia is involved in chronic lumbar symptoms: microstructural changes in collagen and structural changes in connective tissue are described.
Type I collagen administered by local intramuscular injection provides the necessary substrate to positively remodel the connective tissue that makes up the thoraco-abdominal fascia.
The aim of the study is to highlight the complementary nature of the two therapies when it comes to controlling lower back pain symptoms in discopathies.

Materials and Methods Twenty male and female patients, aged between 38 and 79 years, with an average age of 58 years were enrolled in the study.
Patients with lower back pain with for more than six months investigated with an MRI of the lumbosacral spine and evidence of a discopathy were included in the study.
Exclusion criteria: acute radicular signs in the lower limbs; active and/or ongoing oncological pathologies, cognitive impairment and patients reluctant to provide the informed consent. Inclusion criteria: A lumbosacral MRI with an evidence of disc herniation or multiple disc protrusions, persistent lower back pain for at least six months, NSAID and painkiller therapy that has been discontinued for at least two weeks, cortisone therapy that has been discontinued for at least two months.

Figure 1: *injection of type I porcine collagen.*

Table 1: *Evaluation and follow-up of patients with ROM, VAS and the Roland-Morris questionnaire*

Patient assessment and follow-up	
T0	Before the first injection
T1	After the last injection
T2	One month after the last injection

The patients were divided into two groups: group A (OT only) and group B (OT + type I porcine collagen + Hamamelis). All patients (A+B) were treated with paravertebral intramuscular injections of O2O3 at a concentration of 10 ug. The total volume injected in each treatment corresponds to 20ml split into four injection points (5ml per point). Needle used: 23G 32 mm. All patients were treated twice a week for a total of 8 consecutive infiltration treatments. Twenty minutes after the lumbar IM administration of O2O3, patients in group B were subjected to an intramuscular injection of type I porcine collagen + Hamamelis, 1 2-ml vial split over 4 injection sites. Needle used: 27G 1 9 mm.

Results The patients in group B described greater control over the pain symptoms (VAS scale) and joint recovery at the end of the treatment cycle, and a greater stability of the results obtained in the control at one month than in group A.

Figure 2A

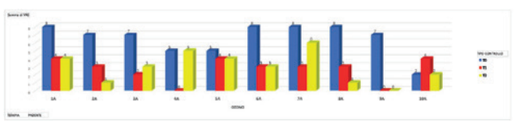

Figure 2B

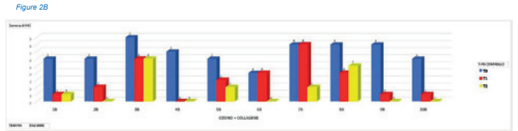

Figure 2C

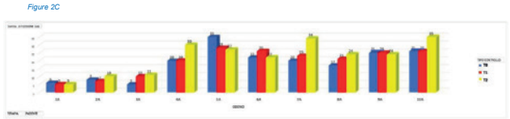

Figure 2D

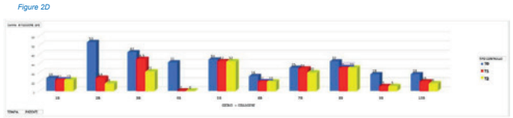

Figure 2: *Graphic representation of results; reduction in VAS in the two groups of patients (Fig. 2A and 2B) and after combined OT + type I porcine collagen therapy (Fig. 2B); greater consolidation of the results obtained in the one-month follow-up after the end of treatment with combined OT + type I porcine collagen therapy (Fig. 2B). Greater joint recovery with the combination therapy and further improvement at the one-month follow-up (Fig. 2D) compared to the group treated with OT alone (Fig. 2C)*

Conclusions

The ultrasound-observed connective tissue disorganisation and microstructural alterations of the collagen tissue can be treated by stimulating a positive remodelling of the tissue constituting the thoraco-abdominal fascia. The infiltrative administration of type I porcine collagen and Hamamelis Virginiana provides the necessary substrate for remodelling and acts synergistically with ozone therapy with improved expected results.

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ULTRASOUND-GUIDED INJECTIONS OF PORCINE COL1 IN TENDINOPATHY: A CASE SERIES

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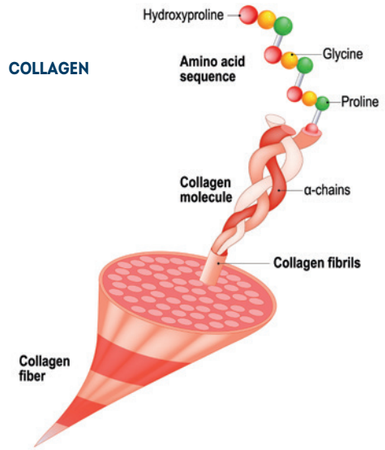
INTRODUCTION AND PURPOSE:

Lateral epicondylitis (LE), also known as tennis elbow, is a frequent painful elbow syndrome due to tendinopathy of the common extensor tendon at the lateral epicondyle of the humerus. It is a chronic inflammatory condition caused by repeated micro-traumas and excessive overload of the extensor carpi radialis brevis muscle.
It affects approximately 1-3% of the population and is frequent in racket sports (e.g., tennis, squash), gymnastics, fitness, and weight lifting. Artists, musicians, electricians, mechanics and other professions that require frequent and repeated movements of the wrists and elbow are also affected.
Lateral epicondylitis is one of the main causes of absence from work and poorer performance by athletes.
Conservative treatment of LE includes: rest, physical therapy, braces, patches, NSAIDs, shock waves (ESWT), laser, infiltration therapy (corticosteroids, hyaluronic acid, botulinum toxin, PRP, autologous stem cells). The effectiveness of infiltration treatments is variable and they present some critical issues. For example, corticosteroids are useful in BT, but have little or no effectiveness in LT, while PRP or autologous stem cells are expensive and difficult-to-use methods.
A new alternative solution in LE management is porcine COL1, which, besides being cost-effective, allows tissue remodelling. A 2018 study by Randelli et al. (16) demonstrated the biological rationale, according to which porcine COL1 can induce the proliferation and migration of tenocytes, thus promoting tendon repair.
The aim of this study was to evaluate the effectiveness of porcine COL1 infiltrations in patients with chronic LE tendinopathy of the elbow (between 2022 and 2023), in terms of pain reduction and improvement of function.

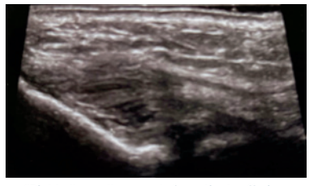


METHODS:

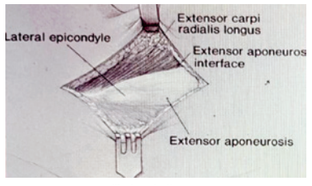
Twenty patients (2 professional tennis players, 5 professional padel players, 3 weightlifting athletes, 10 heavy manual workers) with chronic lateral extensor tendinopathy, evaluated by ultrasound and PRTEE (Patient Rated Tennis Elbow Evaluation) questionnaire, were enrolled.
Patients were treated with cycles of 5 ultrasound-guided infiltrations at weekly intervals.
Intratendinous infiltrations of porcine collagen type I (MD-TISSUE Guna 2 ml) were performed using a 55 mm, 26 Gauge needle.
Two patients did not respond to treatment with collagen infiltrations and underwent surgery; both were professional athletes who play Padel and tennis, respectively.
One patient was surgically treated with NIRSCHL procedure for lateral release of the epicondyles and tangential resection of the epicondyle.
In the other patient, lateral release was performed, i.e., the collateral ligament was reconstructed with the transposition of the local extensor fascia septum.

RESULTS:

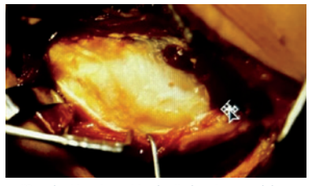
After the infiltration cycle, all patients reported a reduction in pain (assessed with VAS scale from 9 to 0), recovery of function and return to work and sporting activities.
Follow-ups were carried out at 1, 3, and 6 months by clinical evaluation and ultrasound.
There was strong evidence ($p<0.001$) of a statistically significant main effect across multiple clinical observations. Ultrasound showed an improvement in the structural integrity of the tendon. The MD TISSUE porcine collagen infiltrated into the intratendinous site acted on the degeneration of the tendon fibres, stimulating the synthesis of new collagen, restoring tendon structure and avoiding the need for surgery in most of the treated patients.



"Right elbow ultrasound of a patient suffering from lateral epicondylitis."



"Lateral elbow: extensor origin."



"Surgical treatment typically involves excision of the area of tendinitis, debridement of the local tissue bed, and reattachment of the tendon origin as indicated."

CONCLUSIONS:

Infiltrations of Guna MD TISSUE based on porcine collagen type I have proven to be a safe and effective therapy compared to other infiltration therapies with corticosteroids, for instance, which act only on acute pain with the risk of damage to the tendon structures, and a cost-effective reparative and regenerative therapy, which is quick to use compared to PRP.
Porcine collagen type I is among the novel regenerative therapeutic solutions.
It acts as an ECM scaffold on connective tissues that have suffered damage or wear, stimulates the synthesis of new collagen, repairs/regenerates tissues leading to functional healing, and allows a quicker return to sports activity.
Guna's type I porcine collagen allows to act on the reparative and regenerative phase, with a biological response that made it possible to speed up return to the sportive activity.

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FINGERS - HAND

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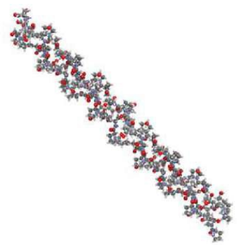
CASE SERIES: INFILTRATIVE TREATMENT WITH TYPE I PORCINE COLLAGEN IN PATIENTS WITH RHIZOARTHROSIS

DR.MIRISOLA GABRIELE, DR. MANGONE GIUSEPPE, DR. SCARSELLI MATTEO

Introduction

Rhizoarthrosis is arthrosis of the trapeziometacarpal joint, which is located at the base of the thumb and allows the first finger to bend.
It is one of the most common degenerative joint diseases affecting mainly post-menopausal women. It is caused by weakening of the palmar oblique trapeziometacarpal ligament, which can cause pain and difficulty when gripping objects and twisting.
Conservative therapies include the use of infiltrative corticosteroids, orthoses and anti-inflammatory drugs; if ineffective, surgery may be necessary (arthrodesis, arthroplasty, trapeziectomy).

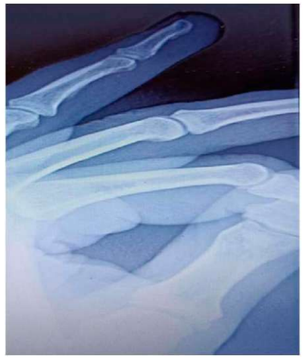


Materials and methods

Collagen has been found as an application in the management of this pathology, delaying or avoiding the surgical approach.
Collagen is a protein that makes up the extracellular matrix (ECM) and confers stress and load resistance to the tissues where it is present. It has been shown to be effective in reducing pain and recovering functionality.
Physiologically, from the age of 40, there is an imbalance between the production and degradation of collagen.
Therapy with MD-SMALL JOINTS involves the infiltration of type I porcine collagen into the affected area, which is effective in stimulating collagen synthesis and creating a bioactive scaffold that strengthens intra- and periarticular structures by reducing pain, increasing mobility and improving joint stability.
We recruited 4 patients with painful joints who were administered 5 ultrasound collagen infiltrations for each joint on a weekly basis.
Pain, disability and joint stability were assessed at T1 (first infiltration) and T2 (one week after the last infiltration session).
No adverse effects or periprocedural complications were reported.

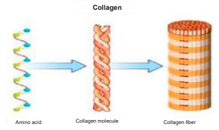
Results

The degree of arthrosis was assessed by means of the "Grinding test"; the "Crank test" was used while pain was assessed by means of the NRS scale; the degree of disability was assessed by means of the Quick-DASH questionnaire.
The results showed a 22% improvement in pain relief and 11.4% improvement in disability after treatment. In addition, the number of positive grinding crank tests decreased during the treatment period.



Conclusions

In summary, MD-SMALL JOINTS therapy based on the infiltration of type I porcine collagen can be a treatment solution for rhizoarthrosis. This conservative approach can be useful for patients of all ages, pregnant women and patients with rare diseases, as the class III medical device poses no adverse risks to the patient and does not cause any cartilage or bone damage. However, further studies are needed to assess the long-term effectiveness of this therapy.



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The use of type I collagen in the treatment of symptomatic rhizoarthrosis: preliminary results

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Introduction

Osteoarthrosis of the trapeziometacarpal (TM) joint, better known as rhizoarthrosis, is a condition that affects around 20% of the population over the age of 50. Symptoms are bilateral in 50% of cases. A considerable role in the pathogenesis is represented by TM instability, which may be secondary to ligamentous hyperlaxity or to repeated radial stress of the base of the I metacarpal bone, conditioning an increase of the luxating force and progressive relaxation of the capsular ligamentous apparatus. More specifically, a loosening of the intermetacarpal ligament, stretched between the base of the I and II metacarpal bones and limiting the abduction movement of the I finger, determines the progressive external subluxation of the base of the I metacarpal bone, resulting in the incongruence of the articular surfaces and the progression of the degenerative phenomena [1]. Clinically, patients present with localised pain at the base of the first toe, accentuated by active movements in radial abduction and/or passive movements in rotation-opposition, which may lead to a variable degree of strength deficit and functional limitation at rest and during activities, with a subsequent negative impact on quality of life [2].
In vitro studies have proven the ability of type I collagen for infiltrative use to work within collagen turnover pathways, acting as a bio-scaffold with a reparative and regenerative action, while several in vivo works have shown improvements in terms of pain reduction and increased functionality following its intra- and peri-articular infiltrative use in the early stages of arthrosis located in different T3 joint districts.The aim of this study is to evaluate the possible efficacy and safety of using collagen-based medical devices in the treatment of symptomatic rhizoarthritis.

Materials and methods

- ❑ Thirteen people [mean age 60.4 years; 11Fs, 2Ms] presenting a clinical picture of symptomatic rhizoarthrosis were enrolled, six of whom had bilateral symptoms.
- ❑ Patients did not undergo physical therapy or other local infiltrative treatments in the three months prior to recruitment. Each subject was given five intra-articular and peri-articular infiltrations in the trapeziometacarpal joint, on a weekly basis, under ultrasound guidance with a 27G x 4mm needle.
- ❑ The VNS scale at rest (VNS-R) and during movement (VNS-A) was administered to quantify pain symptoms and the DASH questionnaire was used as an index of the functional impact of the pathology.
- ❑ All measurements were taken before starting the treatment (T0), during each infiltrative session (T1-T4), at one month (T5) and at three months (T6) after the end of the treatment, to analyse the onset and duration of any improvements.

Results

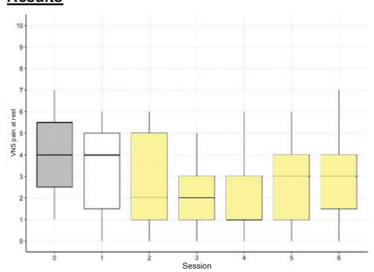

Figure 1

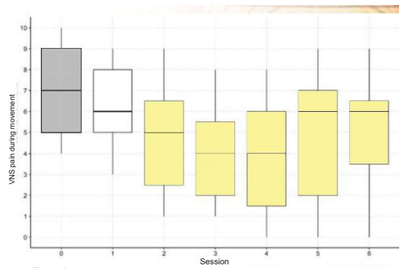

Figure 2

Graphical representation of pain trends during the observation period. Figure 1 shows the VNS values at rest and Figure 2 shows the VNS values during movement. Sessions that differ significantly from session 0 (in grey) are highlighted in yellow

- Our results showed a **statistically significant effect of the F0-F6 session ($F_{6,108}$ = 8,42; p < 0.001),** indicating that there are significant differences in the value of VNS-R in the different evaluation sessions, in particular:
The VNS-R score in the session **was significantly higher than in sessions 2 (p = 0.036), 3 (p < 0.001), 4 (p < 0.001), 5 (p < 0.001) and 6 (p = 0.022).**

- The VNS-A results substantially replicate the VNS-R ones, with a **statistically significant session effect.**

- DASH in session 0 is **significantly lower compared to the one collected in sessions 4 (p < 0.001), 5 (p < 0.0357) and 6(p < 0.0092).**

Conclusions

Infiltrative treatment using type I collagen medical devices may be **a viable alternative in the management of symptomatic rizoarthritis,** in view of its safety, ease of use and observed efficacy. However, further evidence is needed to better define the indications and limitations of the method.

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COLLAGEN-BASED INFILTRATIVE THERAPY IN THE REHABILITATION PATHWAY OF BILATERAL RHIZOARTHROSIS.

Filippo Valgimigli[1]

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Introduction

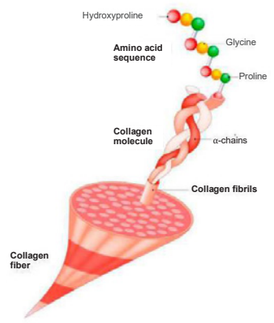
Rhizoarthrosis is an arthritic condition that affects the joint at the base of the thumb, between the trapezius bone of the carpus and the first metacarpus, which allows the first finger of the hand to perform flexion, extension and bending movements to the other fingers.
It affects 20% of the adult population and accounts for about 10% of arthritic localisations; it is more frequent in women than in men (4:1 ratio).
In women, it frequently begins during the menopause, while in men it is more related to overuse. The causes may be repetitive stress on the joint and ligament laxity.
Treatment is initially conservative with the application of immobilisers and the simultaneous use of chondroprotectors. If this treatment is unsuccessful, infiltrative therapy with cortisone, hyaluronic acid and collagen can be used before proceeding to surgery.
The aim of the study is to evaluate the efficacy of peri-articular infiltrations with GUNA MD-SMALL JOINTS collagen in a patient with bilateral rhizoarthrosis, in terms of pain reduction and improved mobility.

Materials and Methods

A 70-year-old female patient with a radiographic diagnosis of bilateral rhizoarthrosis was treated with five infiltrations of MD-SMALL JOINTS once a week for three consecutive weeks, followed by a further two sessions at monthly intervals with two vials per session.
The peri-articular route of administration was performed at the base of the thumb bilaterally, using a 13mm 26G needle. No drugs and/or infiltrative medical devices were added, nor was physiotherapy or immobilisation with a brace carried out.
MD-SMALL JOINTS is a class III medical device based on type I porcine collagen and viola odorata that has a mechanical bioscaffold effect, protects against wear and tear, reduces pain and improves the mobility of small joints.

Figure 1:*Hand Osteoarthrosis*

Figure 2:*Triple helix collagen*



Results

A 50% reduction in inflammation, swelling and pain was reported by the patient after the first three infiltrations, 80% after the fourth and 100% after the fifth according to the NRS (Numerical Rating Scale of pain). At the same time, joint mobility improved, enabling the patient to perform their normal daily movements.
Collagen used intra- and peri-articularly is effective in controlling pain symptoms, improving function and reducing joint instability.

Conclusions

After evaluating the decision to only perform this therapy and not to use the night brace, a very satisfactory result was found both in terms of the durability of the therapeutic effect and the patient's compliance. The doctor's high safety of use of the medical device should also be emphasised.

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Trigger finger ultrasound-guided infiltrative treatment with collagen. Initial clinical evidence.

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2. Specialist Rehabilitation Unit, 'Luigi Sacco' Hospital, ASST Fatebenefrateili Sacco, Milan.
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Introduction

Tenosynovitis of the finger flexor tendons, in most cases associated with the clinical condition described as 'trigger finger', is one of the most common causes of hand disabilities. It causes pain and difficulty in daily living and work activities, afflicting some *2%* of the world's population with a prevalence of up to 10% in diabetic patients. It mainly affects adult women in the dominant hand, particularly involving the third and fourth fingers. Flexor tenosynovitis occurs when the A1 pulley becomes thickened, preventing the tendons from moving freely during bending-extension movements. The difficulty in extending the affected finger when flexed is characteristic; the movement loses fluidity and a 'jerk' occurs, which is sometimes painful. The inflammatory state and hypervascularisation can be detected by an ultrasound, even on an outpatient basis. Treatment options may be conservative or surgical, depending on the severity of the condition. No standardised conservative protocols are currently available, although several infiltrative algorithms with therapeutic substances are reported in the literature. The aim of this in-depth methodological study is to illustrate the use of a class III medical device based on type I porcine collagen *(e.g. MD-Tissue)* by infiltration in clinical pictures of trigger finger.

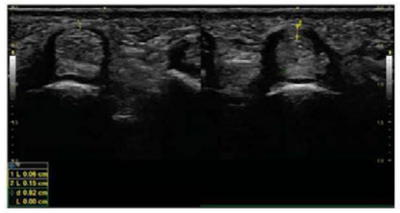

Figure 1:A short-axis ultrasound image of the A1 pulley in a physiological situation (left) and in a pathological situation (right) in which the fibrous thickening characteristic of trigger finger is visible and measurable.

Materials and Methods

After clinical and ultrasound diagnosis (Figure 1), written informed consent is collected from the patient to inform them of the risks of the method, as per hospital practice. The patient is placed lying down on the couch for protection in the event of any vaso-vagal reactions, with their hand in the supine position. After properly disinfecting the skin with *10%* iodopovidone solution *(e.g. Betadine)* the infiltrative procedure is performed using a high-frequency probe for studying small joints (18 MHz) with sterile probe covers. We recommend the *in-plane technique*, with a probe and needle (22G gauge, length 32 mm) placed alongside one another to observe the needle and ensure it reaches the injection site properly [Figure 2]. The peri-tendon injection is given at the site of perceived 'snapping', targeting the tendon sheath. The uniform distribution of the device along the tendon is possible thanks to the procedure being shown via the ultrasound **(Figure 3).**

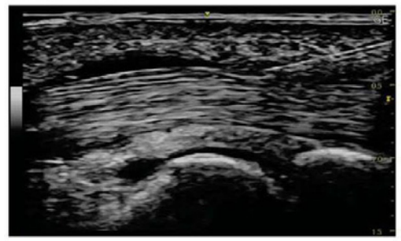

Figure 2:A long-axis ultrasound image obtained during an infiltrative procedure. The needle tip in the INP ion technique is shown on the right and the injected medical device collection on the left.

Results

Following treatment, the treated patients (3) reported a progressive improvement in the perception of pain and stiffness in the affected finger (rating scales used: *Quinnell classification, NRS).* In view of the patients' clinical response, subsequent booster sessions were proposed with up to 3 infiltrations in total.

Figure 3:A short-axis ultrasound image obtained following the peri-tendon injection procedure. A hypoechogenic halo surrounding the tendon component is displayed, indicating a correct and uniform distribution of the medical device.

Conclusions

The infiltrative treatment of trigger finger with porcine collagen-based medical devices *(e.g. MD-Tissue)* is a safe medical practice, free of contraindications and easily performed with ultrasound guidance in an *outpatient setting.* Further studies will be needed to prove the efficacy of this treatment in hand flexor tenosynovitis by enrolling a larger cohort and setting up defined study protocols.

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RECURRENCE OF DE QUERVAIN IN MUSICIAN: COMBINED FOCUSED SHOCK WAVE TREATMENT AND INFILTRATION THERAPY USING INFILTRATIVE PORCINE COLLAGEN

ALBERTO FORMIS
Physiatrist - Head of Unit San Clemente Mantova

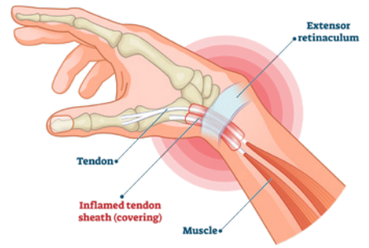
Fondazione Teresa Camplani
S. CLEMENTE Nursing Home

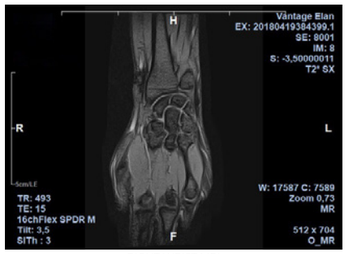
AIM

Description of the clinical case of a musician - bass player suffering from relapsing De Quervain syndrome.

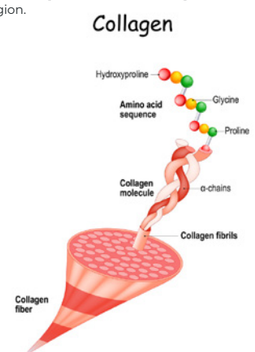
METHOD

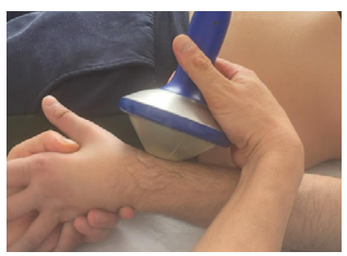
Patient aged 30, right-handed, bass player, surgically treated in 2017. Following the failure of conservative physiotherapy for tenolysis on the abductor pollicis longus (APL) and extensor pollicis brevis (EPB), the patient underwent an MRI on the right wrist one year later. This showed normal representation of the triangular fibrocartilage with fibro-cicatricial results in the integuments along the course of the 1st compartment of the extensors in the region of the radial metaphysis resulting from previous surgery. The thickness and structure of the tendons of the APL and EPB muscles were within limits.
The patient came to our attention in January 2022 due to persistent, debilitating painful symptoms in the area of radial styloid and positive Finkelstein sign. He reported that the disorder occurred approximately 30 minutes after the start of activity, with persistent pain, albeit reduced, in the following hours despite rest.
In light of this condition, an indication was given for a cycle of focused shock waves (4) followed by a cycle (5) of peritendinous infiltrative sessions using porcine collagen type I Guna MD-Tissue (class III medical device) one month later. The patient underwent 4 focused shock wave sessions (ESWT) at weekly intervals - 2000 pulses per session - with an average energy flux density (EFD) of 0.10- 0.18 mmJ/mm2 - Frequency 6-8 Hz) using EMS equipment (piezoelectric generator) - all sessions were carried out by the same practitioner; the subject then underwent 5 infiltration sessions using Guna Collagen through an ultrasound-guided technique in the peritendinous region.





RIGHT WRIST MRI





RESULTS

The ESWT treatment was well tolerated; during a check-up one month after completion of the ESWT, the patient reported a significant reduction in painful symptoms during use (NRS 8 > 5), while the pain when at rest had completely regressed. After the infiltrative cycle the patient reported almost complete regression of the symptoms (NRS 2).

CONCLUSION

The proposed combined therapy of ESWT and Md-Tissue infiltration proved effective and safe in the treatment of persistent painful symptoms following surgery for De Quervain syndrome.

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COLLAGEN TYPE I INJECTION TREATMENT IN MEDIAL GASTROCNEMIUS MUSCLE INJURY

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2. Head of Physical and Rehabilitation Medicine at the Istituti Clinici Zucchi di Monza Gruppo San Donato, Via Bartolomeo Zucchi, 24, 20900 Monza, MB Italy.

INTRODUCTION:

Muscle injuries are among the most frequent injuries occurring in the sports community, and those to the gastrocnemius muscle, such as the one in our clinical case, are some of the most common injuries.
In this case study, an in-depth examination of injuries was carried out, including description, causes and physiology of healing, classification, physical and instrumental therapies, and rationale for the use of injectable type I collagen to speed up the repair and functional healing of the muscle and the return to sporting activity. Collagen type I is the most abundant protein in the body and a constituent of soft tissues: tendons, ligaments, muscles.

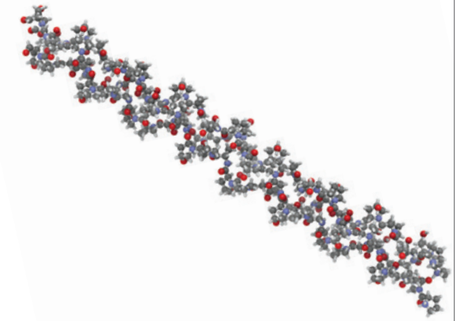
OBJECTIVE:

To share, by using a clinical case, the epidemiology, aetiology, diagnostic criteria, and therapeutic interventions for the gastrocnemius muscle injury.

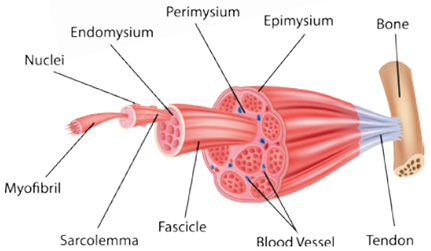
MATERIALS AND METHODS:

The patient enrolled was a 24-year-old male professional cyclist who came to our consultation for stabbing pain in the posterior left thigh arose during daily training. He was suspected of GRADE I°/II° GASTROCNEMIC LESION due to strain and showed local oedema, muscle tension, stiffness, pain on locoregional palpation and during mobilisation and contraction. After ultrasound confirmation of a grade I° muscular lesion in the 3° medial gastrocnemius, it was decided to proceed with functional rest, 8 sessions of Human TECAR therapy on alternate days and local collagen injections.

After 7 days, the patient underwent 3 ultrasound-guided injections of collagen type I MD-Muscle (1 vial of 2ml) at weekly intervals. The injections were administered intramuscularly at the level of the lesion in the medial gastrocnemius, with a 22G x 3.50'' – 0.7mm x 90mm needle and by ultrasound approach. The pain assessment scale was the VAS (Visual Analogue Scale) of initial and final pain at one month after the end of the injection cycle. Follow-up pain assessment at 3 and 6 months was also useful.
In terms of pain reduction, the outcome values were assessed with VAS scale from initial point 8 (T0), to intermediate point 4 (T1), to final point 0 (T2). Follow up were done at 3 months (T3) and 6 months (T4).



Structure of Skeletal Muscle

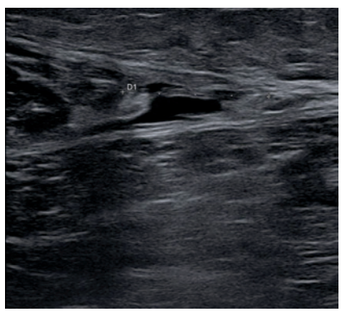


RESULTS:

The patient reported progressive improvement in pain and function of the affected limb after the treatment with physical therapy and rest combined with Collagen type I injections. Three weeks after the injury occurred ultrasound scans showed no trace of scarring, which could have caused discomfort in the performance and resumption of professional sporting activity. The patient therefore resumed his athletic activity. The perfect *restitutio ad integrum* accelerated recovery time, avoiding excessive retraining of the muscle during its daily physiological movement. Porcine type I collagen allowed to contain muscular scarring, which usually prevents physiological contraction and release movement.

CONCLUSIONS:

The injection treatment with **GUNA MD-MUSCLE** made with **porcine type I collagen** is a useful, safe, and easy-to-use reparative treatment. Collagen injections can be used in combination with physical therapies. In addition, the synergic use with TECAR therapy methodology can accelerate the reabsorption of the perilesional oedema, facilitating targeted deposition of collagen. **MD-MUSCLE** significantly reduced pain, had antioxidant and anti-inflammatory activity and promoted homeostasis, remodelling and tissue repair, by acting as an active scaffold at the level of the extracellular membrane. Further studies will be necessary to prove effectiveness on a wider number of cases.



Ultrasound imaging of Medial Gastrocnemius grade I/II with local oedema and thinning of muscle fibers.

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EFFECTS OF COMBINED APPLICATION OF PRP AND GUNA KNEE COLLAGEN IN THE TREATMENT OF MODERATE OSTEOARTHRITIS OF THE KNEE. PILOT STUDY.

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INTRODUCTION

Multiple basic and clinical studies supporting the beneficial effects of individual PRP and collagen IA application in the treatment of OA of the knee. Potentially this two forms of treatment could have synergic effect.

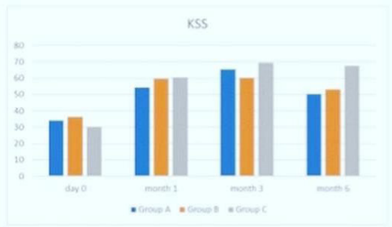
METHOD

- Prospective trial , 60 patients
- Radiographically confirmed (Kellgren-Lawrence grade 2 and 3 OA)
- Previously untreated, randomly assigned to three groups (n=20 patients per group)

GROUP	TREATMENT
A	PRP
B	MD-KNEE
C	PRP + MD-KNEE

- IA application under ultrasound guidance; three time an interval of three weeks in each group
- All patients were evaluated by Knee Society Score (KSS) and Visual Analogue Scale (VAS) for pain, before the treatment and in 1, 3 and 6 months after the treatment

RESULTS



CONCLUSION

The study shows that combined PRP and GUNA collagen administration have benefitial long-term effects in the treatment of moderate knee OA symptoms.

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TENDONITIS OF THE BICEPS FEMORIS MUSCLE TREATED WITH TYPE-1 COLLAGEN-BASED MESOTHERAPY

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2. IRCCS Istituto Auxologico Italiano, Department of Biomedical Science for Health-University of Milan, Milan, Italy

Introduction The tendon is a fibrous connective tissue that enables a muscle to fit onto a bone; it is mainly made up of collagen fibres that give it its high strength and, to a lesser extent, elastin fibres that give it its minimal elasticity. Tendonitis is an inflammation of the tendon that causes pain and local swelling, if this condition is not treated it can damage the fibres that comprise the tendon.
Therapeutic approaches include:
- infiltrative corticosteroids, oral and topical NSAIDs
- physical therapies (laser, tecar, ultrasound)

The aim of the study is to share the aetiology, diagnostic criteria and innovative therapeutic interventions based on infiltrative collagen as an option to the usual approaches through the management of a clinical case.

Materials and Methods The patient identified for the study is a 75-year-old woman, who underwent surgery on 12/06/2018 for a right total knee replacement implant, resulting from gonarthrosis. A few years after the surgery, the patient began to complain of pain in the postero-lateral section of her right knee, even at night. Upon physical examination, she presented pain on palpation at the distal insertion of the biceps femoris muscle and along its course for about 4-5 cm cranially.
The ultrasound confirmed a picture of tendinitis in the hamstring muscle. The patient underwent an infiltrative cycle with type I collagen MD-TISSUE, a cycle of 6 sessions at weekly intervals. During the procedure, a 13 mm 26G needle was inserted freehand at a depth of 2.5 mm. Type I collagen is the most abundant protein in the body and is the main component of soft tissues, tendons, ligaments and muscles. In this case report, the use of infiltrative collagen via mesotherapy allowed the tendon to be supplemented of its main element in a non-invasive and easily managed outpatient approach.

Figure 1: *Ultrasound of the posterior knee region*

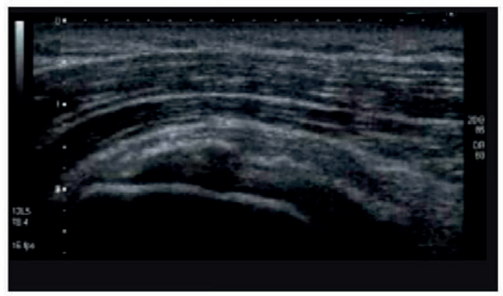
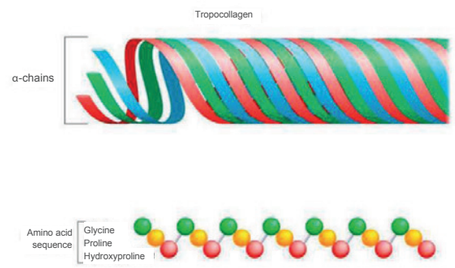


Figure 2: *Triple helix collagen*



Results The patient reported progressive improvement in both subjective and objective pain after treatment with type I collagen. Pain was assessed with the VAS scale at TO and T1, i.e. at 1 week after the last infiltration. Assessing this pain scale showed an improvement in symptomatology from a VAS at TO of 7 to a VAS at T1 of 2.
Conclusions: Periarticular infiltration treatment with MD-TISSUE, a class III medical device made from porcine collagen type I, is a useful, safe and easy-to-use restorative and regenerative solution. Collagen, acting as a bio-scaffold at the level of the extracellular membrane, significantly reduced pain, enhancing the anti-inflammatory activity. It also led to a reduction in oedema, promoting the realignment of fibres, the remodelling of damaged tissue and tissue repair.

Conclusions

Periarticular infiltration treatment with MD-TISSUE, a class III medical device made from porcine collagen type I, is a useful, safe and easy-to-use restorative and regenerative solution. Collagen, acting as a bio-scaffold at the level of the extracellular membrane, significantly reduced pain, enhancing the anti-inflammatory activity. It also led to a reduction in oedema, promoting the realignment of fibres, the remodelling of damaged tissue and tissue repair.

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PAINFUL KNEE PROSTHESIS: CAN INFILTRATIVE PORCINE COLLAGEN TYPE I HELP US?

CASE REPORT

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Vita-Salute San Raffaele University
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San Donato Group

INTRODUCTION

Infiltrative porcine collagen type I in the treatment of tendinopathy, arthropathy, inflammatory diseases and painful scarring has been extensively studied and is widely used in clinical practice. The safety and success of these treatments has enabled an extension of its indications to other unusual situations such as excessive tendon and ligament tension.

METHODS

A 55-year-old patient with a knee prosthesis, after the first few weeks when the acute phase had passed, experienced medial pain if the two knees were in contact, especially in his preferred lateral position when sleeping at night. The X-ray showed, in addition to the obvious malposition of the tibial plateau which protruded medially by approximately 2mm, an initial calcification at the insertion of the medial collateral, probably due to chronic inflammation. During a clinical examination the patient reported that the site of pain was not precisely at the palpatory marker of the protruding tibial plateau, but instead at the proximal insertion of the medial collateral, therefore at a site at some distance from the implant and extracapsular. The use of GUNA MD-Tissue infiltrative collagen was therefore recommended, administered in 5 x 4ml infiltrations at one-month intervals, to be performed at the proximal insertion of the medial collateral.

RESULTS

There was a gradual but continuous reduction in pain: the patient was already feeling huge benefits after the third session of infiltration. The value on the VAS scale decreased from 7 to 2, and no reactions or adverse events were reported at the six-month follow-up.

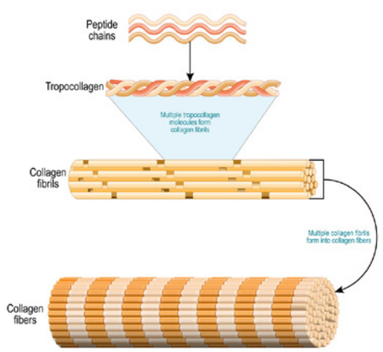
DISCUSSION

Many studies (Randelli F. et al.) have shown that infiltrative porcine collagen can affect the human collagen turnover pathway and facilitate the process of fibroblast migration. Specifically, the infiltrative compound seems able to enhance the expression of an inhibitor gene of some metalloproteases (MMP-1, MMP-2) responsible for collagen degradation. The increased gene expression occurred after the first 24 hours, with an up-regulation after 72. The increase in collagen in the ligaments therefore results from the inhibition of its degradation by specific proteases.

CONCLUSIONS

Infiltrative porcine collagen type I has enabled us to relieve painful symptoms caused by malpositioning of prostheses associated with excessive tension in the medial collateral, which would otherwise require replacement of the prosthesis.

COLLAGEN FORMATION



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POSTER NO. 208

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SOCIETÀ ITALIANA DI MEDICINA FISICA E RIABILITATIVA
The Italian Society of Physical and Rehabilitation Medicine

CASE SERIES ON INFILTRATIVE TREATMENT WITH PORCINE COLLAGEN IN PATIENTS WITH POST-TRAUMATIC ANKLE ARTHROSIS

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Introduction

Arthrosis is a chronic arthropathy characterised by the destruction and potential loss of articular cartilage together with other ligamentous and joint changes, including bone hypertrophy (the formation of osteophytes). Symptoms include gradually developing pain aggravated or triggered by activity, stiffness lasting < 30 minutes on awakening after inactivity and occasional joint swelling. Osteo-ligamentous trauma or instability secondary to it or to another cause often leads to arthrotic changes.
Post-traumatic ankle arthrosis accounts for the majority of causes of degenerative tibio-tarsal arthropathy.
It occurs in most intra-articular ankle injuries, often proving refractory to various types of infiltrative therapies, even with the correct rehabilitation and orthotic course.
The current therapeutic solutions used in the management of post-traumatic ankle arthrosis are divided into conservative and non-conservative. A conservative approach is indicated in the literature as opposed to a surgical approach.
Conservative approaches include:

- infiltrative corticosteroids in the acute phase of the disease
- moulded insoles and braces in the early stages of the disease
- anti-inflammatory drugs in the acute and chronic phases of the disease
- medical devices for infiltrative use (hyaluronic acid, mesenchymal cells, PRP, collagen) in the acute and chronic phases of the disease

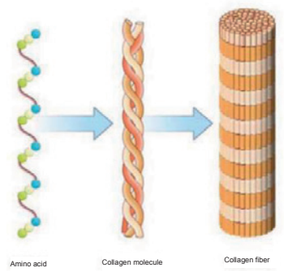
The surgical approach, when pain becomes acute and the treatments described above are no longer effective, is to resort to an ankle arthrodesis or total ankle replacement. The latter offers better long-term functionality than ankle arthrodesis according to a recent study.
The aim of this study is to evaluate the efficacy of type I porcine collagen infiltration using GUNA MD-SMALL JOINTS.
Collagen is one of the most abundant proteins in many living organisms because it plays a connective role in biological structures. It is also the most abundant protein in the extracellular matrix (ECM). The ECM is a non-cellular component within all tissues/organs and acts as a structural scaffold that can direct cell adhesion, cell migration, and regulate cell growth and metabolism.
The three polypeptide triple helix chains of GLY, PRO and HYP stabilised by interchain hydrogen bonds give the molecule high resistance to stress and tissue loading. From the age of 40, there is an imbalance between the production and degradation of collagen, which is why it is important to stimulate its synthesis through infiltration.

Materials and Methods

Five patients between 40 and 72 years of age were recruited, with a total of 5 painful post-traumatic TT joints, who complained of intense pain, stiffness and a feeling of instability upon examination. All patients (with Kellgren Lorenz arthrosis grade II/III) underwent a treatment protocol involving a course of 5 ultrasound infiltrations of type I porcine collagen (GUNA MD-SMALL JOINTS). Infiltrations were performed weekly with a 23G x1" no. 16 (0.6x25mm) gauge needle. The clinical evaluation and questionnaire were performed at the initial visit preceding the first infiltration (T0) and one week after the last infiltration, i.e. 6 weeks after the first infiltration (T1). Follow-up is ongoing for evaluation at 3 months (T2) and 6 months (T3) from T0.

***Figure 1** : Foot x-ray*

***Figure 2:**Triple helix collagen*



Results

Magnitudes of pain, disability, joint stability, support type (with podoscope) were assessed using the numeric pain scale (NRS) and the AOFAS questionnaire.
After the collagen infiltration cycle, an overall improvement of 19.8% was observed in patients with post-traumatic ankle arthrosis. The NRS scale showed an average reduction of 2.9 points, indicating a significant decrease in the patients' perceived pain. However, it is important to emphasise that these results make up a short-term assessment. Further follow-ups at 3 months (T2) and 6 months (T3) are currently underway to assess the effectiveness and duration of the benefits obtained.

Conclusions

The use of type I porcine collagen infiltration with GUNA MD-SMALL JOINTS has proven to be an effective therapeutic approach for the treatment of post-traumatic ankle arthrosis, as it induces fibroblasts to produce more autologous collagen and increases the stability of the ankle joint.
The results showed a significant reduction in pain and related symptoms in treated patients. Due to its high biocompatibility, GUNA MD-SMALL JOINTS is an excellent therapeutic option for patients of all ages/affected by rare diseases and pregnant women. The Class III medical device does not cause any cartilage damage and does not form any micro-deposits.
These results indicate that collagen infiltrations could be a viable alternative to conventional infiltrative therapies for the treatment of post-traumatic ankle arthrosis. However, further studies are needed to assess the long-term effectiveness of this approach and to confirm the benefits observed in this case series. Evaluation of the treatment from baseline data at 3 months and 6 months will make it possible to determine the duration of positive effects and provide further information on possible long-term relapses.

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The use of collagen-based medical devices in the treatment of Morton's neuroma: a case series

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Introduction Morton's neuroma is a compressive neuropathy of the common plantar digital nerve. The conservative approach is the first recommended treatment option, frequently involving infiltrative therapies based on ethanol, sclerosants or cortisone. (1) These latter in particular have proven effective in reducing pain, mainly in the short term, with uncommon but non-negligible side effects. (2) Previous work has demonstrated the potential of collagen-based medical devices in facilitating homeostasis and tissue repair, behaving as an active biological scaffold on the extracellular membrane, with no significant side effects yet reported. (3) There are no previous studies that describe the infiltrative use of porcine collagen type I in the treatment of Morton's Neuroma. The aim of this case series is to assess their efficacy in reducing pain and improving function in the short to medium term.

Materials and Methods Three female patients, aged between 51 and 62 years and suffering from symptomatic, radiologically-demonstrated Morton's neuroma, were enrolled. The patients were given three injections, at weekly intervals, of porcine collagen type I (2ml) added to 2ml of 2% lidocaine hydrochloride using a 26G (13mm) needle. The infiltrations were carried out via dorsal access, in the distal intermetatarsal spaces, with indirect ultrasound guidance (Figure 1). The results, in terms of improved function and pain control, were assessed using the AOFAS (American Orthopaedic Foot and Ankle Society) questionnaire, and according to the VNS (Visual Numeric Scale) for pain (assessed both at rest and during activity), administered before, during (T0, T1 and T2), and on completion of 6 months of treatment (T3-5; Table 1).

Figure 1: injection of porcine collagen type I.

Treatments and follow-up of patients	
T0	Before first injection
T1	Before second injection
T2	Before third injection
T3	Check-up after 1 month of treatment
T4	Check-up after 2 months of treatment
T5	Check-up after 3 months of treatment

Table 1: Treatments and follow-up of patients. The three applications coincided with the first three follow-ups at points T0, T1 and T2.

Statistical analysis was performed using the PRISM Graphpad 6.0 software, with two-way ANOVA analysis using the Bonferroni comparative test, taking the T0 follow-up time as the point of comparison. Values of $p<0.05$ were considered to be significant.

Results During the observation period, all patients treated experienced a significant reduction in painful symptoms when at rest as early as one week after the first session, with a gradual improvement, in terms of both pain and function, reported in the subsequent follow-ups (Figure 2). There was a significant reduction in pain, even during activity, reaching values clearly lower than those initially reported (Figure 2). The average score on the AOFAS scale gradually increased from 58.67/100 to 82.67/100 (T0 vs T3; Figure 2A) showing statistical significance even between patients and maintaining the improvement in function at six months (T5: average value 85.33/100: CI: 75.00-91.00; **p=0.0002**; Figure 2A). The average resting VNS score for pain went from 8.00/10 to 2.33/10 in resting conditions (T0 vs T3; T5: average value 3/10: CI: 1.00-3.00; **p<0.0001**; Figure 2B), and from 9.00/10 to 3.33/10 during activity (T0 vs T3), with further reductions found at the final, six month check-up (T5: average value 3.00/100: CI: 2.00-5.00; **p=0.0004**; Figure 2C). Two patients experienced moderate pain (2/10) only during activity, and one patient reported pain of mild intensity at rest (3/10) and medium intensity during activity (5/10). None of the patients reported pain resulting from the treatment, and no local or systemic adverse events were reported.

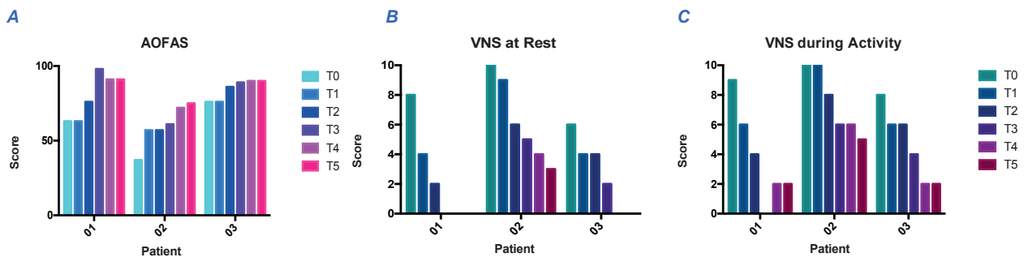

Figure 2: Graphical representation of results; Results of AOFAS score in the three patients (Figure 2A) and results of VNS score at rest (Figure 2B) and during activity (Figure 3C). Figure 2A Two-way ANOVA test (p=0.0002); Figure 2B Two-way ANOVA test (p<0.0001); Figure 2C Two-way ANOVA test (p=0.0004).

Conclusions

Collagen-based medical devices for infiltrative use are proposed as a safe, effective, easily applied option in the treatment of pain and functional limitation resulting from Morton's neuroma. However, further studies with a larger number of cases and experimental assays in the preclinical and clinical phases are required to better understand the mechanism of action and confirm its potential for use in compressive neuropathy.

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THE TREATMENT OF ACHILLES TENDINOPATHY USING INFILTRATIVE PORCINE COLLAGEN TYPE I IN PATIENTS WITH DIABETES: CASE SERIES

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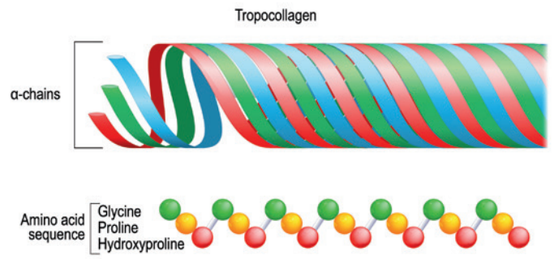
INTRODUCTION

Achilles tendinopathy is one of the most common syndromes caused by overuse and one of the most limiting in terms of function, in that it restricts daily activities. The causes are multifactorial and currently still controversial. Among the most common causes we have tendinosis of the tendon, which often leads to rebellious pain; it is not easily treated by traditional therapies and requires frequent infiltrative therapies using NSAIDS or expensive "regenerative" treatments. In patients for whom cortisone is contraindicated, we have proposed the use of infiltrative collagen, achieving good results at medium follow-up.

MATERIALS AND METHODS

A cohort of 13 patients with diabetes were subjected to infiltrative treatments using porcine collagen type I from March 2021 to January 2023. All patients were suffering from degenerative tendinopathy of the Achilles tendon resistant to other conservative treatments. None of the patients had known allergies. The infiltrative cycle involved the infiltration of 2ml GUNA MD-Tissue collagen in 5 sessions at one-week intervals. The infiltrations were performed using a 25mm 23G insulin needle around the tendon insertion and along its proximal course. The patients attended follow-up consultations 1 month and 6 months after the last infiltration, to assess the VAS and clinical parameters.

COLLAGEN



RESULTS

A significant reduction in VAS was noted in all patients even after the second infiltration. There were no adverse reactions or local reactions at the injection sites. After six months the patients were able to perform normal daily activities without the aid of devices or drugs.

DISCUSSION

Some studies, including a recent one (Romsaco et al.), have analysed biochemical processes resulting from the injection of porcine collagen type I on cultures of human fibroblasts, comparing them with "untreated" fibroblasts. The fibroblasts grown with collagen developed a different morphology in the first 24 hours, with cellular rearrangements that ensured better proliferation, cellular migration and collagen production. All this occurs due to a so-called "mechanotransduction", i.e. the cell's ability to convert extracellular mechanical signals (collagen injected from the outside) into intracellular biochemical signals (gene neoexpression).

CONCLUSIONS

The use of infiltrative porcine collagen type I in degenerative tendinopathy may be a valid alternative to traditional treatments, especially for patients for whom cortisone drugs or other infiltrative drugs are contraindicated Given the cost-effective benefits of the product, the supporting literature and lack of proven side effects, the use of infiltrative collagen can for all intents and purposes be recommended as a first line of treatment in these cases.

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INFILTRATION TREATMENT USING PORCINE COLLAGEN TYPE I ON ANTERIOR PERONEAL ASTRAGALIC LIGAMENT INJURIES IN SPORTS PATIENTS: A CASE SERIES

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Dr Ennio Lopresti, Physiatrist, Department of Rehabilitation at Clinica San Martino, Lecco

INTRODUCTION:

Lesions of the peroneal astragalic ligament are common among athletes in sports that involve a high risk of injury (football,basketball,skiing,athletics).The anterior peroneal astragalic ligament (LPAA) is the main ligament that laterally stabilises the tibiotarsal joint and the one most frequently subject to injury.
This case series,conducted on athletes aims to assess the reparative effects of collagen combined with laser therapy on LPAA injuries and to achieve optimal management of these lesions that enables reathletisation and quicker return to play.
We use a regenerative injection therapy based on porcine COL I (GUNA MD-TISSUE) for the management of partial lesions of LPAA

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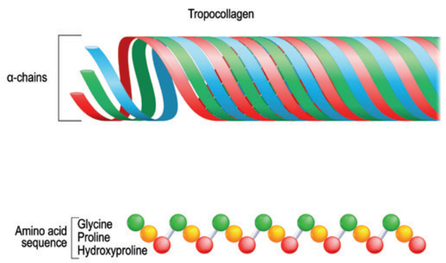
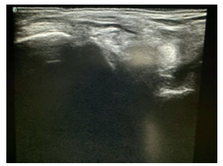
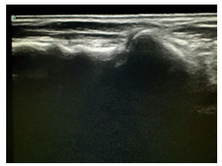


METHODS:

6 Patients (3 runners,2 football players,1 gymnast) with recent ankle sprains resulting from sporting events. An ultrasound was performed to highlight and ascertain the extent of the injury to the LPAA.
All patients presented distractive lesions but no complete lesion (mild/moderate degree); the joint structures that had been subjected to stress presented clinically with an anterior drawer sign and slightly positive or negative astragalic tilting.
Pain upon palpation was experienced in the anterior region of the peroneal malleolus with,in some cases, some remaining swelling in the perimalleolar area and functional limitation.
3 patients had a VAS score of 9, 3 score of 7.
The patients were given 10 laser therapy sessions combined with manual draining therapy and proprioceptive exercises, undertaken during infiltration with 2 ml porcine COL I Guna MD-TISSUE.
Cycle:2 infiltrations a week for 4 weeks by the peri and intra-ligament route under ultrasound guidance, 25 G,20 mm needle.



PAA tendon after injury



PAA tendon after collagen injections

RESULTS:

Follow-ups were carried out 1 month and 3 months after completion of the treatment, with a reported reduction in pain on palpation of the anterior peroneal astragalic ligament, and a negative drawer test in all 6 cases.
On completion of the infiltration cycle the patients reported: an improvement in pain (reduced VAS, final score was 2), stability of the joint which, combined with training in the gym to obtain correct load distribution, enabled a quicker, more effective return to competitive activity.
The check-up ultrasound performed 3 months after the last infiltration showed evidence of restoration and realignment of new ligament fibres.

Infiltration therapy using Guna MD-TISSUE, a bioscaffold based on porcine collagen type I, enabled the repair and healing of the damaged tissue during the proliferative phase, and leads to the healing of the ligament and functional restoration during the remodelling phase.

CONCLUSIONS:

Type I collagen is a fundamental structural component of ligaments and therefore played a crucial role in the tissue regeneration. This therapy, which acts on the biology of anterior peroneal astragalic ligament repair, has proven safety and cost-effectiveness, and avoids the need for surgery or more invasive treatment. Type I collagen played a vital role in the synthesis of new collagen, realigning damaged fibres and strengthening the connective tissue during remodelling and repair. For sports patients with anterior peroneal astragalic ligament injuries, this innovative therapy has improved the clinical picture, with rapid recovery of function and return to play.

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MUSCLES

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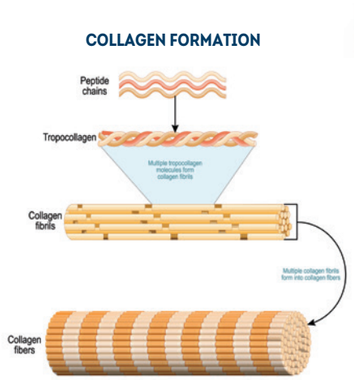
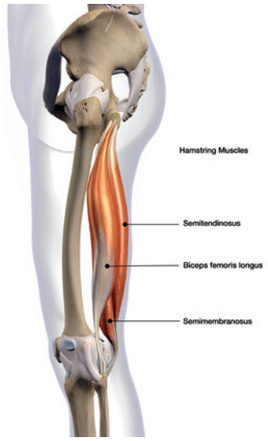
EFFICIENCY AND SAFETY OF COLI INJECTIONS FOR TREATMENT OF HAMSTRING TENDINOPATHY

SARINO RICCIARDELLO MATTEO BALDASSARRI, DIEGO GHINELLI, LUCA PERAZZO, ROBERTO BUDA
Hospital VILLA LAURA BOLOGNA

INTRODUCTION AND PURPOSE:

Hamstring injuries are one of the most common types of injuries affecting athletes and sportive people. Despite this, the optimal management of hamstring muscle injuries is not well defined. The main symptom of proximal hamstring tendinopathy (PHT) is lower gluteal pain, especially during running or prolonged sitting. Traditional treatment methods for PHT are by the majority comparable to those of other tendinopathies: they include rest and ice for symptoms relief in the initial phase, reduction or pause of sports activity, nonsteroidal anti-inflammatory drugs (NSAIDs), soft tissue mobilization, physiotherapy and continuous home exercise program focusing on progressive eccentric hamstring strengthening and core stabilization. Novel therapeutic approaches are recognized including shockwave (SWT) and ultrasound (US) therapy, ultra-sound-guided corticosteroid injection and Platelet rich plasma (PRP) injection. US-guided corticosteroid injection of the tendons heath is used in PHT. However detrimental effects such as slowed long-term tissue healing caused by inhibition of collagen linkage, incomplete healing and recurrent injury have been reported. Additionally, symptoms often recur after initial good short-term results. Collagen injections (COLI) represent a novel biological approach to treat tendinopathies and musculotendinous reconstructions; they are also considered a cost effective, easy to use and regenerative solution. Purpose of the study is to determine the efficacy of an ultrasound-guided GUNA porcine collagen type I injection in the treatment of patients with PHT.



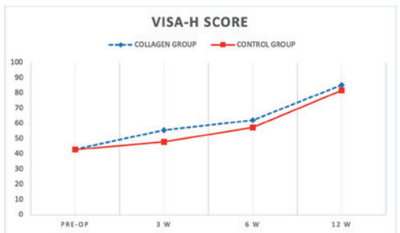


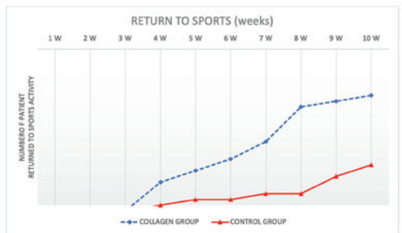
METHODS:

Twenty-eight patients diagnosed with an acute hamstring injury were randomly allocated to ultrasound-guided GUNA porcine collagen type I injection with needle of 21G (COLL group) combined with a rehabilitation program, or to a rehabilitation program only. The primary outcome of this study was time to return to play. In addition, changes in pain severity and pain interference scores over time were examined. Administration of n. 2 injections of 4ml of MD-MUSCLE (performed weekly under ultrasound guidance confirmed on magnetic resonance imaging (MRI). Pain, function and sporting activity were tested with the Victorian Institute of Sport Assessment-Proximal Hamstring Tendons (VISA-H) questionnaire, administered before injections and at 8-weeks follow-up.

RESULTS:

The study sample consisted of 20 males and 8 females with a mean age of 30.2 years. Patients in the COLL group achieved full recovery significantly earlier than controls (P = .02). The mean time to return to sport was 56.7 ± 7.0 days and 72.5 ± 20.6 days for the COLL and Rehabilitation group, respectively (t (22) = 2.50, P = .02).
Both groups started with similar VISA-H scores (mean: 43.90); after with 6- week post-injection COLL group VISA-H scores (mean: 62.14) otherwise Rehabilitation group had lower results (mean : 57.34), no statistically significant difference was found (p = 0.14). When performing separate analyses for patients with mild (n = 9), moderate (n = 16) or marked (n = 4) PHT, no statistically significant difference was found in pre-and post-injection VISA-H scores for any of the groups (p = 0.86, p = 0.13, p = 0.28 respectively), although patients with moderate or marked degree improved faster.





CONCLUSIONS:

The protocol used in patients with PHT, carrying out the infiltrations of MD-Muscle collagen combined with a dedicated rehabilitation program, was significantly more effective in the treatment of femoral biceps lesions than the rehabilitation program alone. The injection treatment with the Guna medical device based on type I porcine collagen represents a valid reparative therapy, useful, safe, easy to use and cost-effective. Collagen can be associated with physical therapies, accelerating the regenerative process. In addition, the use of the ultrasound guidance facilitates the targeted deposition of collagen, compared to the freehand approach. MD-Muscle significantly reduced pain by exerting an antioxidant and anti-inflammatory activity. It promotes homeostasis, remodeling and repair of tissues, by acting as an active scaffold at the level of the extracellular membrane.
Guna's type I porcine collagen allows to act on the reparative and regenerative phase, with a biological response that made it possible to speed up return to the sportive activity.

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GUNA medical device

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