PAIN MANAGEMENT IN CERVICAL CHRONIC MYOFASCIAL PATHOLOGIES: MDS LOCAL THERAPY *VS* CONVENTIONAL TREATMENT – RESULTS OF A COHORT, CONTROLLED CLINICAL TRIAL

Authors: Hermann G.F., Rivkina T., Lavino D.
Responsible of the trial: Dr. G.F. Hermann – Republic of S. Marino

SUMMARY
This controlled clinical trial refers the treatment of 196 patients suffering from chronic muscle-tensive neck pain. The patients were divided into 2 homogeneous Groups, one treated with medical devices (COLLAGEN Neck + COLLAGEN Muscle + COLLAGEN Neural) *vs.* those treated with pharmacological therapy (*Ketoprofen*).
The results show better results of the devices treatment: comparable quantitative effects but higher qualitative effects (35.8% *vs*. 21.1% of very good results). The injections of 3 MDs (COLLAGEN Neck + COLLAGEN Muscle + COLLAGEN Neural) treating pain and improving performances on the three levels of space presents no incidence of adverse effects and offers a therapy option which is safe, effective and personalized with the appropriate medical device.
KEY WORDS: Muscle-tensive pain, Medical devices.

INTRODUCTION

Muscle tensive cervicodynia is a pathology with an enormous social impact (*Yelin et al., 1986*). It causes loss of considerable number of working days in various professional fields including those which require body work with exposure to climate changes (*Hollander and Yeostros, 1963*) and weight lifting (*Walker-Bohe and Cooper, 2005*) or those which require a sedentary activity such as sitting in front of a computer (*Treatster et al., 2006*) for long time or as car driving. The conventional therapy is mostly based on the local or systemic use of NSAIDs and on physical rehabilitation. The repeated use of NSAIDs is potentially dangerous: they are the first commonly prescribed drug with serious adverse reactions (*Coste et al., 1995*)

PATIENTS AND METHODS
This study enrolled 196 patients [81 M (41.3%): 115 F (58.7%)] between 22 and 53 years of age.
They all referred the appearance of the symptoms somewhere between 6 and 12 months prior to the enrolment.
Excluded patients were the ones with radiographic evidence of heavy arthrosic arthropathy (Haas scale III, IV) or with symptoms of radicular compression or fibromyalgia in accordance with the definition of the American College of Rheumatology (ACR) (1996), or with a medical history of allergies to drugs or gastrointestinal, hepatic, renal pathologies, or cancer.

- Group A – Allopathic
87 patients (44,4% of the total number of patients included in the study; 31 M and 56 F) between 25 and 53 years of age, were treated in the pain points and in the trigger points (TPs) of the cervical muscles (Fig. 1) with *Ketoprofen* two 2ml vials (100 mg each) with a 4mm 27G needle.

- Group B – MDs
109 patients (55,6% of the total number of patients included in the study; (50M and 59F) between 22 and 52 years of age, were treated with Collagen Neck 1 vial + Collagen Muscle 1 vial + Collagen Neural 1 vial (MDs cocktail).

Collagen Neck is a medical device specific for the neck vertebra treatment. It is effective locally creating a collagen barrier that smoothes the friction between cervical vertebral disks, so releasing the pain and the muscle spasm.

Collagen Muscle is for muscle spasms. It is locally effective as it potentiates the histological structure at the muscle tendineous junctions so that it tonifies the physiological tonic reflex muscle contraction through the muscle-tendon system (Gamma Circle)

Collagen Neural helps repolarizating the nerve suffering from hypoxia (and therefore pain) caused by spasm of the muscles carrying the nerve, as it increases the viscosity of the matrix tissue where it is injected.
The application is done bilaterally, paravertebral, along the cervical vertebras, 3cm from the Back Medial Line, from the 3rd to the 7th cervical vertebra (total number of vertebrae treated: 5). Total number of infiltrations: 10. Average quantity per infiltration: 0.5-0.6 ml of the MDs cocktail. The site of application is made sterile; the needle is inserted in the same manner as for the intra-articular, but it reaches 3-4 mm depth, without reaching the vertebral cervical disk capsule or vertebral cervical ligaments.
Other material for treatment:
1) Syringes: 10cc
2) Materials for aseptic skin preparation: sterile gloves, Iodine solution, alcohol solution, sterile gauze pads, ethyl chloride spray for skin.
Number of applications: 10 for each patient belonging to the Group A or the Group B, once a week for 10 weeks in succession (total duration of the therapy: 2,5 months)

- Highly significant comparability (homogeneity) between the 2 test Groups before treatment (TAB.1):
1) Average age (not shown in TAB.1):
- Group A = 44.6 years
- Group B = 45.2 years
2) Pain
- Group A = 13.4
- Group B = 13.8
3) Dizziness
- Group A = 2.0
- Group B = 2.2
4) Neck movement, measured in angle degrees
- Group A = 248.6°
- Group B = 250.7°
5) Number of trigger points
- Group A = 3.2
- Group B = 3.7

Since both Groups are homogeneous (number, sex, age, symptomatology), the results are comparable. The clinical trial - therefore – complies with homogeneity criteria for the compared Groups.

EVALUATION
The final evaluation (follow up = 4-6 weeks after the last treatment) was carried out according to subjective 1) and objective 2) parameters as well as the incidence of adverse effects.

1) SUBJECTIVE PARAMETERS
Two parameters were considered:
1a) Cervico neck pain: at re-awakening and stress-induced. For the evaluation of the pain symptomatology, the Scott and Huskisson (1976) Visual Analogic Scale (VAS) (score from 0 to 10) was used and the sum of the parameters at re-awakening and stress-induced were evaluated within a range of 0-20.
The VAS (unidimensional subjective method) is more useful for the evaluation of chronic pain in comparison with the Verbal Rating Scale (VRS; Keele, 1948), the Numerical Rating Scale (NRS; Donnie, 1978), the Analogue Chromatic Continuous Scale (ACCS; Grossi, 1983).

Recently, Ottaviani (2008) proposed the Roland-Morris Low Back Pain and Disability Questionnaire modified for cervical pain. Nevertheless, the above mentioned Questionnaire it is not easily understandable for all people.

1b) Dizziness was evaluated according to the following point values:
- 0: absent
- 1: subjective attack of dizziness provoked by rapid postural variations
- 2: subjective attack of dizziness provoked by even minimal and slowly executed postural variations
- 3: sense of instability in orthostatism.

2) OBJECTIVE PARAMETERS
Two parameters were considered:
2a) The myofascial TPs of the superior and inferior trapezius on the more painful side, index of the muscle-tensive component:
- 0: TP absent
- 1: TP present (solid nodule) but not painful
- 2: TP present and painful upon deep palpation
- 3: TP present and painful upon superficial palpation.

2b) Total articular range, expressed in degrees (total: 300°) based on the parameters of normalcy according to Cipriano (2003):
- flexoextension: 90° (45° + 45°)
- rotations: 120° (60° + 60°)
- lateral inclinations: 90° (45° + 45°).

ADVERSE EFFECTS
Classified according to the following values:
- 0: no adverse effects
- 1: temporary local skin reaction in one or more points of injection
- 2: temporary organ disorder which did not interfere with the therapy course
- 3: organ disorders which required treatment withdrawal.

RESULTS
Results were collected according to a score system (Zenker *et al*., 2002) that considered all examined points : the subjective profile 1) objective aspects 2) adverse effects.

1) SUBJECTIVE PARAMETERS
(maximum points =10):
1a) Pain = reduction in the Scott-Huskisson Visual Analogic Scale (VAS):
- at least 0-3 degrees: *0 points*
- at least 4-7 degrees: *3 points*

- at least 8 degrees: *6 points*.
1b) Dizziness = reduction with respect to the initial valuation:
- unchanged: *0 points*
- 1 level: *2 points*
- at least 2 levels: *4 points*.

2) OBJECTIVE PARAMETERS
(maximum points =10):
2a) Neck joint movement = total increase in the three directions:
- 20°: *0 points*
- between 20° and 50°: *3 points*
- > 50°: *6 points*.
2b) Trigger Points
- persistence of non-painful TP before the treatment: *0 points*
- persistence of painful TP: *0 points*
- persistence of non-painful TP: *3 points*
- TP disappeared: *4 points*.

The valuation of the trigger areas and TPs was deliberately differentiated, as reported in literature (Wachter and Prien, 1988). We observed that total eradication is quite difficult to achieve.

3) ADVERSE EFFECTS
- effects which caused the treatment withdrawal (drop out) : 0 points
- transitory disorder which did not alter the continuation of the therapy: 2 points
- temporary local reaction in one or more injection site : 4 points
- No adverse effects: 6 points.

The comprehensive valuation of the results was as follows: null: *0 - 7 points* low: *8 – 14 points* good: *15 – 21 points* very good: *22 – 26 points*

4-6 weeks after the last treatment, 84 patients of Group A (3 dropped out in the course of the therapy) and the 109 patients of Group B (no drop-outs) were re-evaluated for the following parameters:

1) Pain
- Group A = 6.2
- Group B = 4.1
2) Dizziness
- Group A = 1.2
- Group B =
0.4 SCORES
- Group A = 6.1
- Group B = 7.1
---
3) Neck joint movement in degrees
- Group A = 273.5°
- Group B = 285.5°
4) Trigger points
- Group A = 2.3
- Group B = 0.6

SCORES
- Group A = 6.0

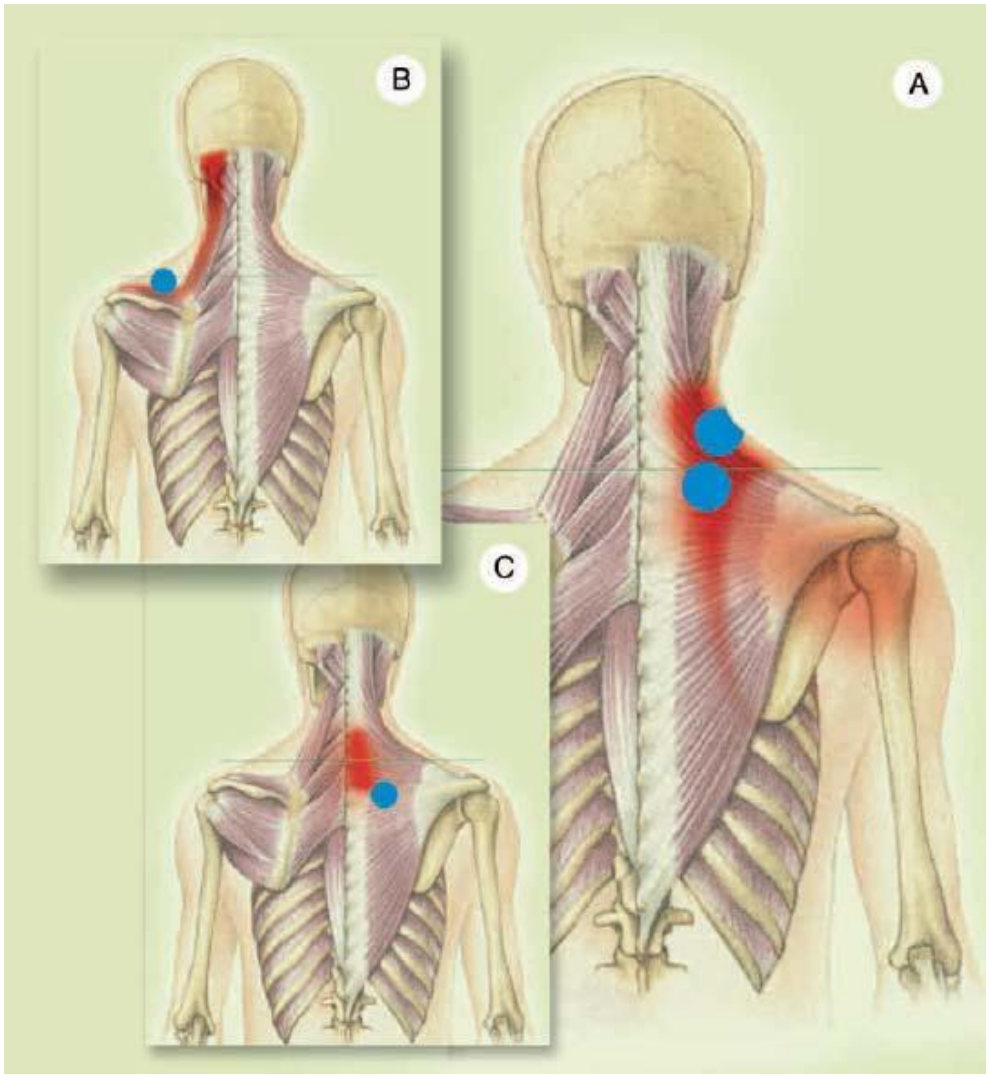
- Group B = 5.6 5)
Adverse effects
- Group A = 14
- Group B =
6 POINTS
- Group A = 5.5
- Group B = 5.9

TOTAL SCORES
- Group A = 17.6
- Group B = 18.6

The differences between the 2 Groups before and after therapy are shown for the following parameters: PAIN (TAB.2), DIZZINESS (TAB.3), NECK MOVEMENTS (TAB.4), TRIGGER POINTS (TAB.5), and ADVERSE EFFECTS (TAB.6).
- The comprehensive results of the therapy are shown in TABLES 7 and 8.

DISCUSSION – CONCLUSIONS
The results of the conventional therapy *vs.* MDs treatment for pain management in cervical chronic myofascial TPs confirm the efficacy of both anti-pain therapies compared in 2 very homogenous groups of patients: in both groups, a highly positive response with regards to pain and neurovegetative symptoms was obtained (conventional therapy : 85,7%; MDs therapy: 85,4%). Major differences were founded in the tolerability of the treatment (Tab. 6). In particular, the 4 transitory local reactions of the MDs Group were represented by small erythematous reaction corresponding to the points of injection, appearing immediately after the first session and resolving itself after ½ -1 hour spontaneously. The observed transitory local reactions occurred differently in the traditional therapy Group: a larger number (12) was observed and the reaction occurred in 9 out of 12 (75%) cases after the first or 2nd session.
This controlled clinical study demonstrates that MDs are effective in the treatment of pain and of neurovegetative phenomena of cervical origin, practically without local and/or systemic negative side effects and can be comparable in quantitative effects, to its traditional treatment counterpart.

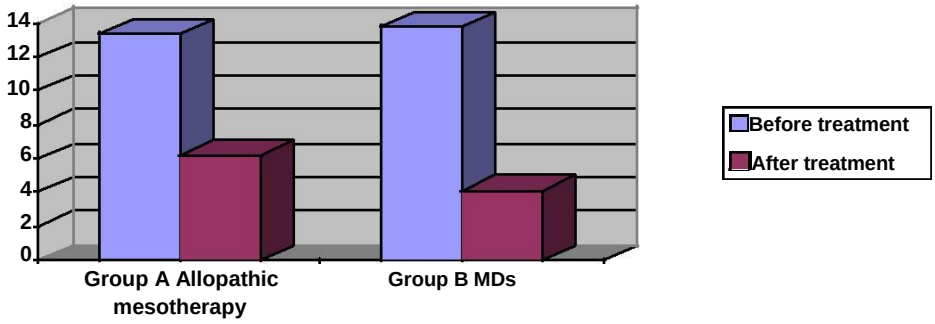
Fig. 1



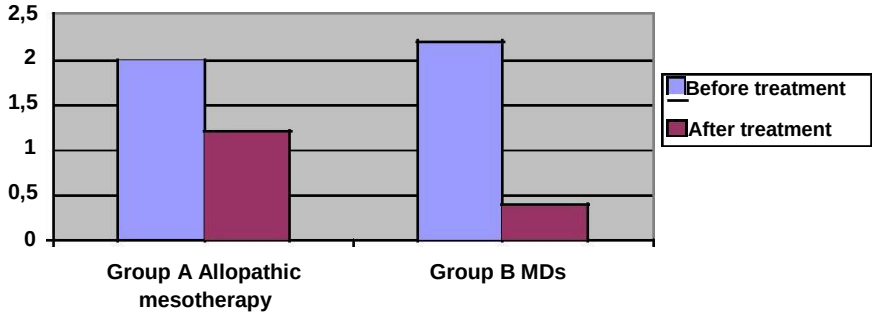
TAB.1: Average parameter values before treatment. These values show the comparability between Group A = Traditional and Group B = MDs

PARAMETER	GROUP A	GROUP B
PAIN	13,4	13,8
DIZZINESS	2,0	2,2
NECK MOVEMENT	248,8*	250,7*
TRIGGER POINTS/ZONES	3,2	3,7

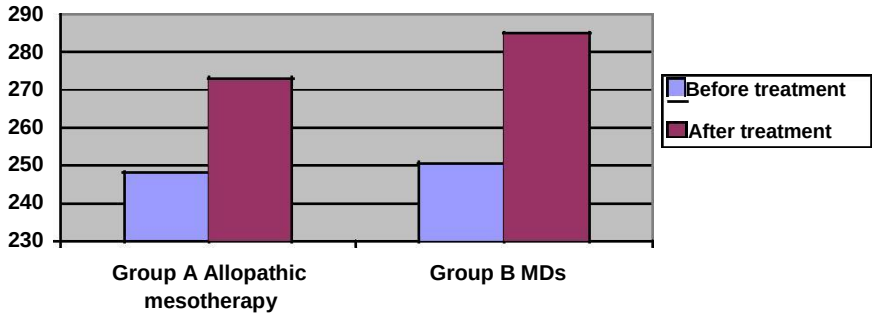
TAB. 2: Pain. Comparison between the 2 Groups before and 4 weeks after the last treatment.



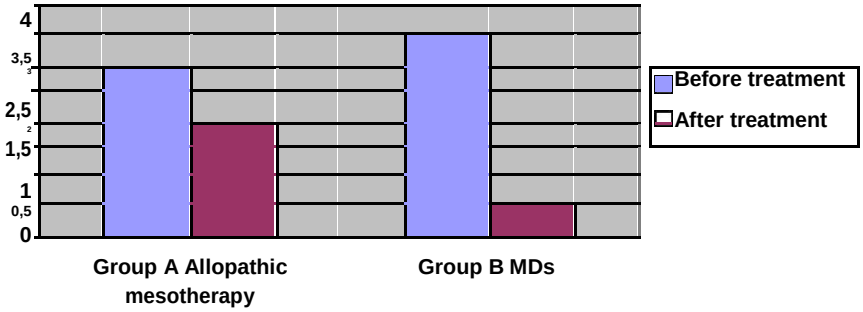
TAB. 3: Dizziness. Comparison between the 2 Groups before and 4 weeks after the last treatment.



TAB. 4: Neck movement.
Comparison between the 2 Groups before and 4 weeks after the last treatment



TAB. 5: Trigger Points/Zones.
Comparison between the two groups before and 4 weeks after the last treatment.



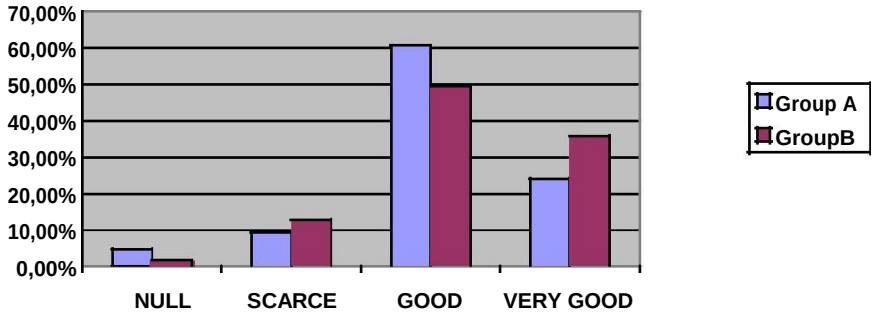
TAB. 6: Adverse effects in the 2 Groups

LOCAL OR GENERAL REACTION	GROUP A n. of patients	%	GROUP B – MDs n. of patients	%
NONE	67	77	105	96.3
LOCAL TEMPORARY REACTION IN ONE OR MORE INJECTION POINTS	12	13.8	4	3.7
TEMPORARY ORGANIC PATHOLOGY WITH CONTINUATION OF THE THERAPY	5	5.7	0	0
ORGANIC PATHOLOGY WITH INTERRUPTION OF THE THERAPY	3	3.5	0	0
TOTAL	87	100	109	100

TAB. 7 :

RESULT	GROUP A – n. of patients	%	GROUP B – MDs n. of patients	%
NULL	4	4.8	2	1.8
SCARCE	8	9.5	14	12.8
GOOD	51	60.7	54	49.6
VERY GOOD	21	24.1	39	35.8
TOTAL	84*	100	109	100
*3 drop out patients in the included 87				

TAB. 8



REFERENCES

Yelin E.H., Henke C.J., Epstein W.V. – Work disability among persons with musculoskeletal conditions. Arthritis Rheum, 1986 Nov; 29(11): 1322-1333.
Hollander J.P., Yeostros S.Y. – The effect of simultaneous variations of humidity and barometric pressure on arthritis. AIBS Bulletin, Vol. 13, 3 (Jun 1963); 24-8.
Walker-Bohe J., Cooper M. – Hard work never hurt anyone: or did it? Ann Rheum Dis., 2005; 64:1391-1396.
Treaster D., Marras W.S., Burr D., Sheedy J.E., Hart D. – Myofascial trigger point development from visual and posture stressors during computer work. J. Electroneur. Kinesiol., 2006 Apr; 16(2); 115-24.
Coste J., Hanotin C., Leutenegger E. – Prescription of non-steroideal anti-inflammatory agents and risk of iatrogenic adverse effects: a survey of 1072 French general pratictioners. Therapie, May-Jun, 50(3): 265-70; 1995.

THERAPY OF CERVICAL SPINE PATHOLOGY WITH MEDICAL DEVICES COLLAGEN NECK + COLLAGEN MUSCLE
Authors: Hermann G.F., Rivkina T., Ruocco
A. Responsible of the trial: Dr. G.F. Hermann
Republic of S. Marino

A Cohort study lasting 3 months was performed on 10 patients affected with chronic cervical pain.
Subjects treated: 10 (6 F; 4 M)
Age: between 53 and 62 years.
The diagnosis for all patients was cervical disc arthrosis with painful trigger points of neck muscles
The exclusion criteria: disc herniation with neurological signs, neurogenic pain, pain caused by neoplastic or autoimmune illness
Symptomatology: neck pain at rest as well as in movement associated to muscular contraction and movement limitation.

Treatment: 10 mesotherapy sessions once a week. The site of application is done paravertebral bilaterally from the 4th to 7th cervical vertebral.
Remedies: Collagen Neck (2 ampoules) + Collagen Muscle (2 ampoules)

Analysis modality:
Pain evaluation by means of VAS scale (Visual Analogic Scale – Scott and Huskisson)
Joint function evaluation of Flexion, Extension, Rotation by means of goniometrical numerical scale Flexion, Extension, Rotation: *range* 0° / 90°

Evaluation of muscular contraction:
Improvement:
Absent = 0
Slight = 1
Moderate = 2
Good = 3

PATIENT – GENDER – AGE			Pain - VAS		Joint mobility		Improvement of muscular contraction
			Before	After	Before	After	
B.A.	M	54	7	3	40°	70°	3
D.A.	M	58	7	3	45°	75°	3
B.N.	M	60	8	4	35°	60°	2
G.C.	M	55	8	3	50°	70°	3
C.V.	F	53	6	4	35°	65°	3
R.G.	F	56	5	1	45°	80°	3
L.V.	F	49	9	4	30°	60°	3
M.A.	F	59	6	4	40°	75°	3
A.C.	F	62	7	2	40°	70°	3
T.B.	F	56	6	1	50°	75°	3

Final result of the therapy

Therapeutic response was very good for pain, articular mobility and muscle contractility.

Tolerance
Very good.

Side effects
None.

In one case (C.V.) a paradoxical effect was observed: slight increase of muscle contracture after the infiltration (lasted 6-8 hours), that disappeared spontaneously. We believe that this effect has been produced by the mechanical effect of the needle in the cervical muscles.

REFERENCES

Milani L. – Agopuntura e Patologia Viscerale. Collana Scientifica di Medicina Tradizionale. Cleup-Unicopli; 1978. Italian
Sola A.E. – Myofascial trigger points pain in the neck and shoulder girdle. Northwest Med. 54: 980-984; 1955 (p. 983). Travell J.G., Daltz S.H. – The myofascial genesis of pain. Postgrad Med., 11: 425-434; 1986.
Travell J.G., Simons D.G. – Myofascial Pain and Dysfunction. The Trigger Point Manual. Williams & Wilkins, Baltimore/London; 1983.

USE OF THE MEDICAL DEVICE (MD) SHOULDER *VS* ULTRASOUND THERAPY IN THE TREATMENT OF **THE** IMPINGEMENT (SUBACROMIAL SYNDROME)

Authors: Hermann G.F., Rivkina T. – Republic of S. Marino

SUMMARY

This clinical trial was carried out on 50 patients suffering from shoulder pain caused by impingement (subacromial syndrome). The patients were divided into two Groups (Group A; Group B) homogeneously in number, gender and average age.

Group A patients received both a treatment with COLLAGEN SHOULDER + physiokinesitherapic treatment. Group B received an ultrasound local treatment + a physiokinesitherapic treatment. The rehabilitation shoulder program was the same for both Groups of patients.

Group A treatment was well accepted, tolerated, with no negative side effects and the painful symptomatology improved; the use of NSAIDs was not necessary and a better recovery of the shoulder articular mobility was obtained. The difference with the results in the 2 Groups is very clear.

INTRODUCTION

Shoulder pain always comes with a limitation in the *range* of movement; it is a widespread clinical condition with a high economic and social incidence for health expenses and absences from work for a number of professional categories. Neer (1972) has published a complete layout on the matter concerning the shoulder pathology describing it as *impingement*.

PATIENTS AND METHODS

Aim of this controlled clinical trial is to compare the effectiveness of local injections with MDs *vs* Ultrasound therapy, both of them in association with kinesiotherapy in order to treat the subacromial impingement syndrome. 50 patients have been included in this clinical trial (19 M; 31 F – average 58 and 54 years old respectively) suffering from shoulder pain.

ESCLUSION CRITERIA
Patients suffering from pain in the shoulder due to arthrosic or arthritic origin, fractures and dislocations, shoulder pain due to cervical origin.

The patients included have been divided into 3 Subgroups (1, 2, 3) according to the pain onset: 1 – acute pain: less than 15 days
2 – sub-acute pain: between 15 days and 7 weeks
3 – chronic pain: more than 7 weeks
►GROUP A: 25 patients (16 F; 9 M – average 55.8 and 53.7 years respectively)
Group A1 (acute pain): 30%
Group A2 (sub-acute pain): 40%
Group A3 (chronic pain): 30%.

Patients underwent – twice a week for 4 consecutive weeks – periarticular infiltrations with the medical device (COLLAGEN) SHOULDER, with a loose disposable needle 0.4x20mm 27G into the local painful trigger points and into the local main acupoints LI (Large Intestine) 15 and LI16.
►GROUP B: 25 patients (15 F; 10 M – average 57.4 and 53.2 years respectively) Group B1 (acute pain): 16%
Group B2 (sub-acute pain): 40%
Group B3 (chronic pain): 44%.
All patients belonging to Group B underwent Ultrasound therapy (1MHZ, 2 WATT/cm^2 for 10 minutes) on the painful local zones (Ebenbichler *et* Al., 1999; Gam *et* Al., 1998).
Both Group A and Group B underwent a kinesiologic rehabilitating treatment (daily sessions for 15 days).
In Tables 1, 2 the scores of each patient (Group A, Group B) are shown before the treatments.

TAB 1 – Group A (MD Shoulder + Kinesiotherapy) score before treatment.

	No.	M-F	Age	VAS	Flex	Ext	Abd	ER	IR	Jobe	Neer	Yocum	Palm up
A1	1	M	45	7	***		**	**	**	YES	YES	YES	
	2	M	52	7	***	YES	***	*	**	YES	YES	YES	YES
	3	M	48	6	*		**		*	YES	YES	YES	YES
	4	F	46	7	**				*	YES	YES	YES	
	5	F	56	6	**		**		*	YES	YES	YES	YES
	6	F	53	6	***	YES	***	*	**	YES	YES	YES	
	7	F	55	7	**		*	*		YES	YES	YES	YES
	8	F	58	6	**			**		YES	YES	YES	YES
A2	9	M	50	5	**		*		**		YES	YES	YES
	10	M	59	5	*			*		YES	YES	YES	
	11	F	48	6		YES	**	*	*	YES	YES	YES	YES
	12	F	51	6				*		YES	YES	YES	
	13	F	52	5		YES	*	**		YES	YES	YES	YES
	14	F	54	5	*				*	YES		YES	YES
	15	F	57	6	*	YES	**	*			YES	YES	YES
	16	F	58	5	**				*	YES	YES	YES	YES
	17	F	59	5	*		*			YES		YES	YES
	18	F	61	6	*	YES			*	YES	YES	YES	YES
A3	19	M	63	4	*						YES	YES	YES
	20	M	59	4			*			YES	YES	YES	
	21	M	55	5	**	YES					YES	YES	YES
	22	M	58	5				*		YES	YES	YES	
	23	F	60	5			*			YES		YES	YES
	24	F	62	4				*		YES		YES	YES

	25	F	63	4						YES	YES	YES	YES

TAB 2 – Group B (Ultrasound therapy + Kinesiotherapy) score before treatment.

	No.	M-F	Age	VAS	Flex	Ext	Abd	ER	IR	Jobe	Neer	Yocum	Palm up
B1	1	M	44	6			**	***	**	YES	YES	YES	
	2	M	47	7	***		**	**	*	YES	YES	YES	YES
	3	M	56	7	*		**	*	**	YES	YES	YES	YES
	4	F	46	6			*	**	*	YES	YES	YES	
B2	5	M	43	5	**		**		*	YES	YES	YES	YES
	6	M	46	5			*			YES	YES	YES	
	7	M	54	5	**	YES			**		YES	YES	YES
	8	M	63	6					*	YES		YES	YES
	9	M	62	6			*				YES	YES	YES
	10	F	44	6	*		*			YES	YES	YES	YES
	11	F	55	5				*		YES		YES	YES
	12	F	58	5	**	YES	*	**	*	YES	YES	YES	
	13	F	59	6				*			YES	YES	YES
	14	F	60	6	*					YES	YES	YES	YES
	15	F	62	5	*	YES	**		*	YES	YES	YES	YES
	16	F	64	5				*	*		YES	YES	YES
B3	17	M	53	4			*		*	YES	YES	YES	
	18	M	64	3				*		YES		YES	YES
	19	F	50	4	*		**	**		YES	YES	YES	
	20	F	54	4					*	YES		YES	
	21	F	61	4	**		*	*		YES	YES	YES	
	22	F	63	4						YES		YES	
	23	F	64	3	*					YES	YES	YES	YES
	24	F	65	3			*		*	YES		YES	YES
	25	F	56	4				*		YES		YES	YES

FINAL EVALUATION
SUBJECTIVE PARAMETER
Shoulder pain quantifiable on the basis of the Visual Analogical Scale (VAS - Scott & Huskisson) (from 0 to 10). OBJECTIVE PARAMETERS
JOINT MOVEMENT
Flexion (Flex): < 90°; 90°-120°;
>120° Extension (Ext): Yes; No
Abduction (Abd): < 90°; 90°-120°;
>120° External rotation (ER): <45°; >45°
Internal rotation (IR): <45°; >45°.
Positive results to Jobe, Neer, Yocum, Palm up tests (specific shoulder mobility test) Side effects: Yes; No
NSAIDs consumption during the treatment (Yes; No)

RESULTS
GROUP A
►SUBJECTIVE
PARAMETERS: PAIN (TAB. 3):
A1: in quite every case, marked reduction of the pain symptom from "*painful*" to "*soft*" (from 6.5 to 2 VAS) A2: Pain is reduced by 75% (from 5.5 to 1.5 VAS)
A3: 80% pain reduction (from 4.5 to 1 VAS). ►OBJECTIVE PARAMETERS:
JOINT MOVEMENTS:
A1: Optimal recovery in patients with a very damaged articularity;
A2 and A3: No important alteration in the articular limitations have been registered; however articular limitations were moderate since the beginning.
CONFLICT TEST:
A1, A2 and A3: marked homogenous alteration in the 3 subgroups.
SIDE EFFECTS: 2 local and temporary "*erythematous reactions*" have been registered near the infiltration points; their onset has been noticed after the first session and they spontaneously disappeared in 6-8 hours.
NSAIDs: none.

GROUP B
►SUBJECTIVE
PARAMETERS: PAIN (TAB. 4):
B1: no symptom alteration
B2 and B3: 50-60% important reduction (respectively from 5.5 to 2.1 and from 3.5 to 1.4 VAS).

►OBJECTIVE PARAMETERS:
JOINT MOVEMENTS
B1, B2 and B3: small variations (> in B3) in patients with a moderate-severe
damage. CONFLICT TESTS:
B1, B2 and B3: marked homogenous alteration in the 3
subgroups. SIDE EFFECTS: none.
NSAIDs: 32% of patients has associated the treatment with a pharmacological therapy involving NSAIDs in order to limit pain, partially worsened by the kinesiotherapic physical exercises.
Tab. 5, 6 show results o in both Groups after treatment.

TAB 5 – Group A (MD Shoulder + Kinesiotherapy) after treatment.

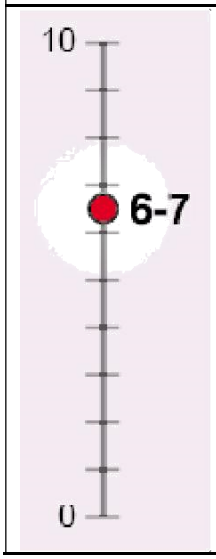
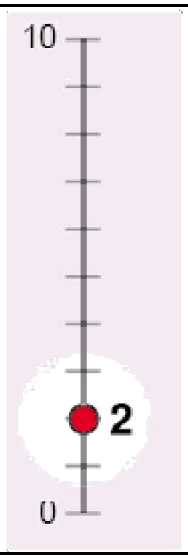
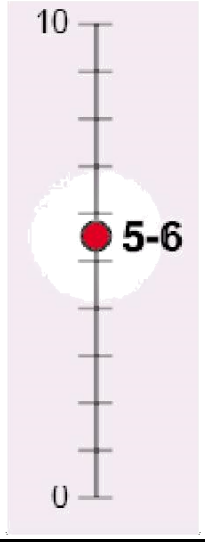
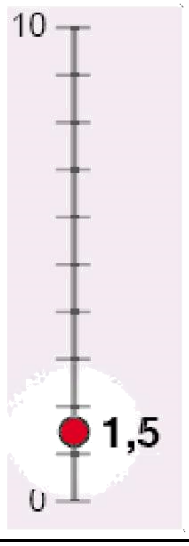
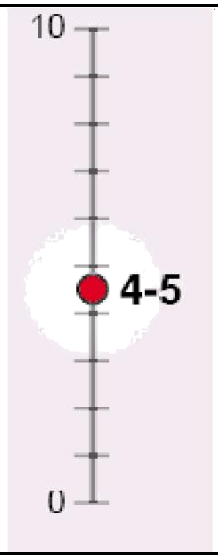
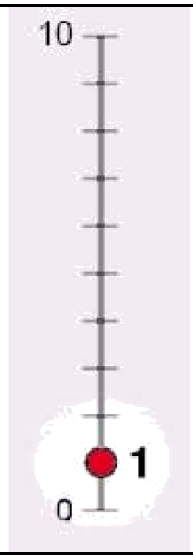
	No.	M-F	Age	VAS	Flex	Ext	Abd	ER	IR	Jobe	Neer	Yocum	Palm up	e. coll.	NSA IDs
A1	1	M	45	2			*					YES		NO	NO
	2	M	52	2	*				*	YES	YES	YES		NO	NO
	3	M	48	1									YES	NO	NO
	4	F	46	2								YES		YES*	NO
	5	F	56	3					*				YES	NO	NO
	6	F	53	2	*		*			YES		YES		NO	NO
	7	F	55	2										NO	NO
	8	F	58	2										NO	NO
A2	9	M	50	3	*		*					YES	YES	NO	NO
	10	M	59	2							YES	YES		NO	NO
	11	F	48	2				*						YES*	NO
	12	F	51	1										NO	NO
	13	F	52	1				*		YES		YES	YES	NO	NO
	14	F	54	1					*					NO	NO
	15	F	57	2										NO	NO
	16	F	58	1	*							YES	YES	NO	NO
	17	F	59	1			*						YES	NO	NO
	18	F	61	2	*				*	YES		YES		NO	NO
A3	19	M	63	1									YES	NO	NO
	20	M	59	1										NO	NO
	21	M	55	2								YES		NO	NO
	22	M	58	1				*		YES		YES		NO	NO
	23	F	60	1										NO	NO
	24	F	62	1				*				YES	YES	NO	NO
	25	F	63	1										NO	NO

TAB 6 – Group B (Ultrasound therapy + Kinesiotherapy) after treatment.

	No.	M-F	Age	VAS	Flex	Ext	Abd	ER	IR	Jobe	Neer	Yocum	Palm up	e. coll.	NSAIDs
B 1	1	M	44	6			*	**	*	YES	YES	YES		NO	
	2	M	47	7	*		**	*	*			YES	YES	NO	YES
	3	M	56	7	*		*	*	**	YES		YES	YES	NO	YES
	4	F	46	6			*	*	*					NO	
B 2	5	M	43	3	*		*	*	*	YES		YES	YES	NO	YES
	6	M	46	2			*				YES	YES		NO	
	7	M	54	2	*	YES		*	*		YES	YES	YES	NO	
	8	M	63	3								YES	YES	NO	YES
	9	M	62	2			*						YES	NO	
	10	F	44	2	*		*			YES		YES	YES	NO	
	11	F	55	2								YES		NO	
	12	F	58	1	*	YES	*	*	*	YES		YES		NO	YES
	13	F	59	2								YES		NO	
	14	F	60	3	*						YES	YES	YES	NO	YES
	15	F	62	2	*	YES	*		*	YES		YES	YES	NO	YES
	16	F	64	2				*					YES	NO	
B 3	17	M	53	2								YES		NO	
	18	M	64	1									YES	NO	
	19	F	50	1	*			*		YES		YES		NO	
	20	F	54	1								YES		NO	
	21	F	61	2			*			YES	YES	YES		NO	YES
	22	F	63	2								YES		NO	
	23	F	64	2								YES		NO	
	24	F	65	1						YES		YES	YES	NO	
	25	F	56	1									YES	NO	

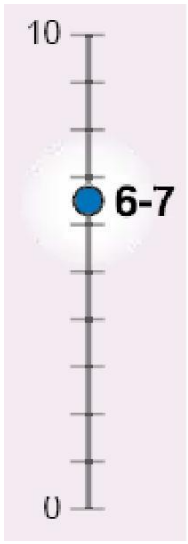
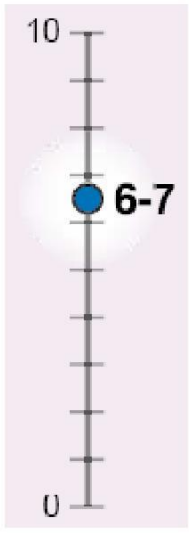
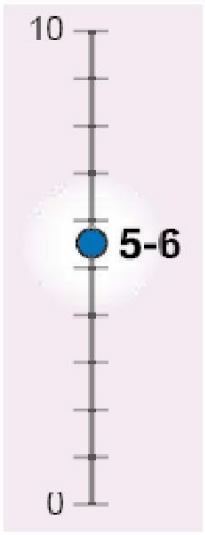
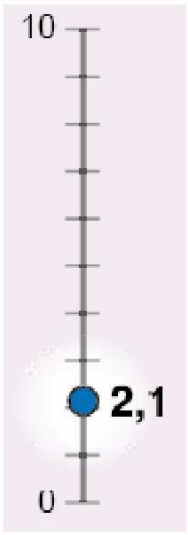
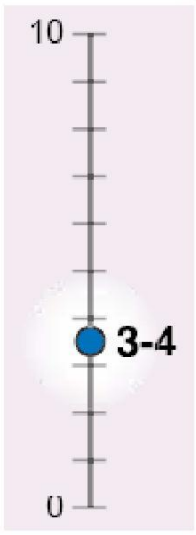
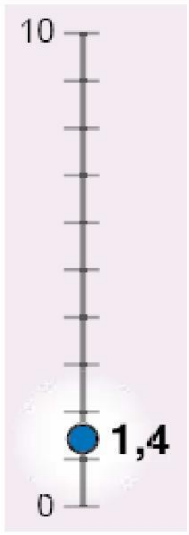
DISCUSSION
Tab. 3, 5 and 7 highlight that the best results for the Group A (MD) have been registered in patients with an intense pain symptomatology and with a severe functional limitation while Group B patients being in acute phase did not relieved their pain nor their joint movements (Tab. 4, 6 and 7).
Only 2 local temporary herythematous reactions have happened in Group A near the infiltration points, however they spontaneously disappeared in 6-8 hours.
- We can state that the medical device COLLAGEN SHOULDER is effective and has no side effects in the treatment of acute and chronic shoulder pathology.

Tab. 3 – Pain evaluation. Group A = Collagen Shoulder + Kinesiotherapy.

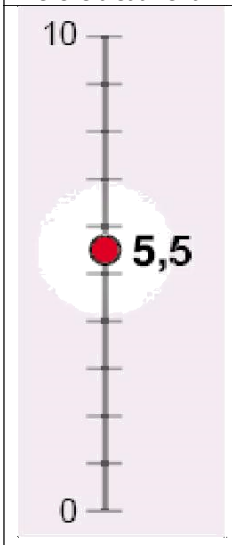
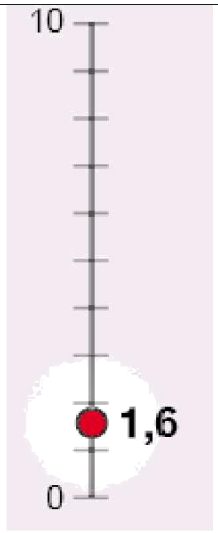
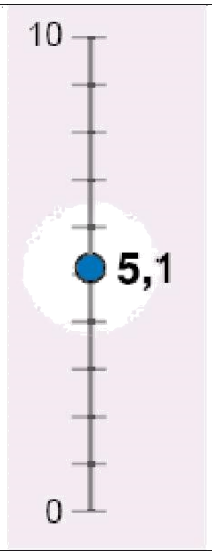
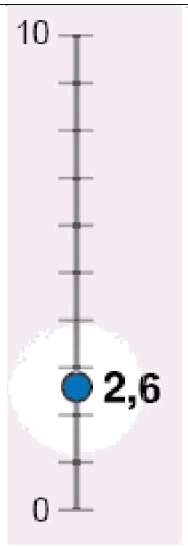
Pain evaluation Group A = Collagen Shoulder + Kinesiotherapy					
GROUP A1		GROUP A2		GROUP A3	
Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
					

Tab. 4 – Pain evaluation. Group B = Ultrasound therapy + Kinesiotherapy.

Pain evaluation Group B = Ultrasound therapy + Kinesiotherapy		
GROUP B1	GROUP B2	GROUP B3

Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
					

Tab. 7 – Average evaluation of the alteration before and after the treatment. Average evaluation of the pain alteration before and after the treatment

GROUP A		GROUP B	
Before treatment	After treatment	Before treatment	After treatment
			

REFERENCES

BERRY H., FERNANDES L., CLARK R.J., HAMILTON E.B.D. – Clinical study comparing acupuncture, physiotherapy, injection, and oral anti-inflammatory therapy in shoulder-cuff lesion. The Lancet 1980; Jan 26: 208-09.

EBENBICHLER G.R., ERDOGMUS C.B., RESCH K., FUNOVICS M.A., KAINBERGER F., BARISANI G., ARINGER M. – Ultrasound theraphy for calcific tendinitis of the shoulder. N Engl J Med, 340: 1533-38, 1999.

GAM A.N., WARMING S., LARSEN L.H., JENSEN B., HOYDALSMO O., ALLON I., ANDERSEN B., GOTZSCHE N., MATHIESEN B. – Treatment of myofascial trigger points with ultrasuond combined with massage and exercise -a randomised controlled trial. Pain 1998, 77: 73-79.

NEER C.S. – Anterior acromioplasty for the chronic impingement syndrome in the shoulder. J. Bone Joint Surgery, 54-A, 1972.

NEER C.S. – Impingement lesions. Clin. Orthop., 173: 70-77, 1983.

TREATMENT OF SHOULDER PERIARTHRITIS WITH MEDICAL DEVICES
Authors: Hermann G.F., Rivkina T., Ruocco A.
Responsible of the trial: Dr. G.F. Hermann
Republic of S. Marino

SUMMARY

The aim of the present study is to assess the use of medical devices in the treatment of pain due to periarthritis with 2 medical devices, COLLAGEN SHOULDER and COLLAGEN POLY.

INTRODUCTION

Periarthiritis is a chronic deseases quite common in aged people. Patientr refers paina and lose of movement. As standard therapy FANS and cortison medicaments are used, that are known for the frequent side effects. So it is useful to look for other treatments that could be used when patients cannot undergo FANS therapy. This study has also the aim to assess the area of the MD treatments.

Under the diagnosis of shoulder periarthritis there is a group of pathological changes affecting the joint capsule and/or the peri-articular tissue, expecially the sub.acromial bursa, the sheath of the long head of the biceps, the supraspinatus tendon.

SYMTOMATOLOGY
Pain both at rest and in movement of shoulder and superior limb, functional limitation in movements.
INCLUSION CRITERIA
Tendinitis of shoulder cuff rotator muscles and/or the *caput longus* of the biceps with signs of periarthritis

EXCLUSION CRITERIA
Dislocations, bone lesions, total or partial lacerations of the shoulder cuff rotator muscles and tendons.

PATIENTS AND METHODS
10 patients (5F; 5M), aged between 50 and 60 year old, suffering from scapular-humeral (shoulder) periarthritis, have been included into a 2 months observational trial.

Treatment: 8 local injection sessions, once a week using insulin needle into local painful trigger points[1] (average of treated trigger points: 4).
MDs used: Medical device: COLLAGEN SHOULDER (1 ampoule = 2 ml) + COLLAGEN POLY (1 ampoule = 2 ml), peri-articular (1 ml of cocktail in each periarticular trigger point).
Trial method:
- Pain evaluation (by means of the Visual Analogic Scale - VAS)
- Evaluation of the articular functionality in abduction and flexion-extension by means of the numeral goniometric scale; *range* = 0° / 45° / 90°./130°/180°.
- Circumduction evaluation:
Possible to 20% - (1)
Possible to 40% - (2)
Possible to 60% - (3)
Possible to 80% - (4)

Patients	Pain (VAS Scale)	Functional limitation in	Circumduction

[1] Positive trigger point needs to be painful to a 4 Kg/cm^2 pressure applied by the examiner's digit, that is to say when the applied thumb pressure is sufficient to blanch the nail-bed of the doctor's thumb when he/she presses firmly on the part.

and age			flexion/ extension and abduction			
	Before	After	Before	After	Before	After
R.A. – 46	6	4	50°	120°	1	2
P.A. – 48	6	4	55°	145°	1	3
C.L. – 51	5	3	60°	130°	2	3
O.S. – 44	7	5	45°	110°	1	2
L.V. – 54	7	4	50°	125°	1	3
B.G. – 51	7	3	35°	170°	2	4
S.V. – 47	7	4	45°	120°	2	3
M.C. – 53	6	2	80°	180°	2	4
G.C. – 46	6	3	90°	160°	2	3
S.B. - 52	6	1	70°	180°	2	4

Improvements have been very good concerning both pain and functional limitation of flexion-extension and circumduction.

Final results of the therapy: very good therapeutic response for pain, articular mobility and muscular contracture.
Tolerance: excellent.
Side effects: none.
This observational trial results highlight that the medical devices COLLAGEN SHOULDER + COLLAGEN POLY are effective for the pathology here studied. The components of their formulations act on the shoulder joint improving the tropism of: 1) articular cartilage; 2) articular capsule; 3) rotators shoulder cuff.

MEDICAL DEVICE FOR CHRONIC ANKLE PAIN: TREATMENT ON 70 PATIENTS
Authors: Hermann G.F., Rivkina T., Ruocco A.
Responsible of the trial: Dr. G.F. Hermann
Republic of S. Marino

Summary
70 patients suffering from chronic ankle pain of different origin have been treated with the medical device (COLLAGEN) SMALL JOINTS.
The evaluation criteria for resetting the mobility of the tibio-tarsal joint has been the difference of the total angle extension range (extension and flexion) between the normal (healthy) joint and the distorted one of the same patient.
Patients have been treated weekly for 10 times and evaluation was performed after the 4th and the 9th week.
Key words: ankle pain, Medical device, COLLAGEN Small Joints, tibio-tarsal joint

Introduction
The ankle is one of the most common sites for acute musculoskeletal injuries. Acute ankle trauma is responsible for 10 to 30 percent of sports-related injuries in sports.
Ankle sprains may be mainly classified into 2 groups: complicated and uncomplicated. Uncomplicated ankle sprains are treated without surgery, while complicated need surgery.

Chronic pain of the ankle may develop after an injury not completely recovered, tarsal tunnel syndrome as well. This is a result of nerve compression at the ankle as the nerve passes under the *flexor retinaculum*.
Also arthritis – as rheumatoid arthritis, reactive arthritis, gouty arthritis, ankylosing spondylitis, psoriatic arthritis – can involve the ankle area.
These diseases generally are not induced by trauma injury, develop gradually and are associated with pain, swelling, stiffness and sometimes warmth in the involved ankle.

The aim of the present study is the evaluation of the use of COLLAGEN Small Joints associated or not to other MDs according to different sessions in chronic ankle pain.

Material and Methods

Seventy two patients with chronic ankle pain have been enrolled according to the following inclusion criteria: Age over 40 years old
Ankle pain due to bone fracture at least 6 months before the treatment
Ankle pain due to arthritis and/or rheumatic diseases.

The exclusion criteria were:
Secondary pain due to present or previous bone fracture in the last 3 months
Concomitant administration of anti-inflammatory or antipain drugs (es. Cortisone, NSAIDs, ASA)

The administration of NSAIDs has not been considered as far, as pain was still the main symptom.

The treatment was based on the use of the medical device COLLAGEN SMALL JOINTS in the ankle joint alone or associated with other adequate MDs in order to optimize the anatomic functionality.

The intra-articular application provides a collagen barrier that makes movement easier and not painful, the walking more confident, strengthens the bone edges and lights the pain. Together with collagen other biochemical ingredients with antiaging activity for joints and matrix tissue ar present in COLLAGEN SMALL JOINTS.

10 treatments were performed once a week for 10 consecutive weeks, according to the following scheme:

1st week – 1st session treatment: COLLAGEN SMALL JOINTS via intraarticular treatment COLLAGEN MUSCLE + COLLAGEN POLY + COLLAGEN NEURAL via periarticular	6th week – 6th session treatment: COLLAGEN SMALL JOINTS via periarticular
2nd week – 2nd session treatment: COLLAGEN SMALL JOINTS via intraarticular treatment COLLAGEN MUSCLE + COLLAGEN POLY + COLLAGEN NEURAL via periarticular	7th week – 7th session treatment: COLLAGEN SMALL JOINTS via periarticular
3rd week – 3rd session treatment: COLLAGEN SMALL JOINTS via intraarticular treatment COLLAGEN MUSCLE + COLLAGEN POLY + COLLAGEN NEURAL via periarticular	8th week – 8th session treatment: COLLAGEN SMALL JOINTS via periarticular
4th week – 4th session treatment: COLLAGEN SMALL JOINTS via intraarticular treatment COLLAGEN MUSCLE + COLLAGEN POLY + COLLAGEN NEURAL via periarticular	9th week – 9th session treatment: COLLAGEN SMALL JOINTS via periarticular
5th week – 5th session treatment: COLLAGEN SMALL JOINTS via intraarticular treatment COLLAGEN MUSCLE + COLLAGEN POLY+ COLLAGEN NEURAL via periarticular	10th week – 10th session treatment: COLLAGEN SMALL JOINTS via periarticular

At each session just one side of the ankle was treated via intraarticular, while the periarticular application was performed in 2- 3 different points bilaterally. The patients was recommended a period of rest of at least 3 hours after the treatment (FIG. 1).

Data collecting

At the first visit, patients were registered for: age, height, weight, duration of disease.

Patients data				
F	M	Average age	Height (cm)	Weight (kg)
45 (64,3%)	25 (34,7%)	67,3 years	173,2	97,2

Before each treatment the following data were collected:

Pain intensity, according to a 3 value scale

Pain scale	
0	No pain
1	Light/moderate
2	Strong/severe

Joint mobility: the value has been identified as the difference between the total angle (flexion + extension) of the two joints (affected and healthy) and measured with goniometer (error +/- 3°). 0 score means equal mobility between the 2 joints (error +/- 10°)

Evaluation criteria

The evaluation criteria consist in the value reached at the 10th treatment for pain intensity and joint mobility.
Pain: the treatment is evaluated as effective, if pain decreases from 2 (1st visit) to 1 or 0 (9th visit)
Mobility: The treatment is positive if the difference between the total angle of both sides decreases of 10°, at the end of the treatment.

Results

Joints mobility (differences between total angles) show good improvement already from the 4th – 5th treatment. At the 8th treatment the improvement is generally stable (Tab. 1).
Pain symptoms improved as well and at the 6th - 7th treatment – generally – the value is stable.

Results at the 9th visit	
Difference between angle movement of both sides decreased of 10 degrees	Patients 58 (positive) (82,8%)
Difference between angle movement of both sides did not decrease	Patients 12 (negative) (17,2%)

Results at the 9th visit	
Pain symptoms – Number of patients with no pain symptoms	Patients 61 (87,1%) (no pain)
Pain symptoms – Number of patients that accused no pain decrease.	Patients 9 (12,9%) 1-2 according to the Pain Scale

Tab. 1

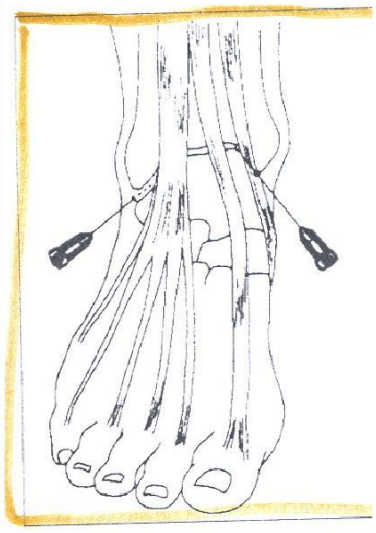
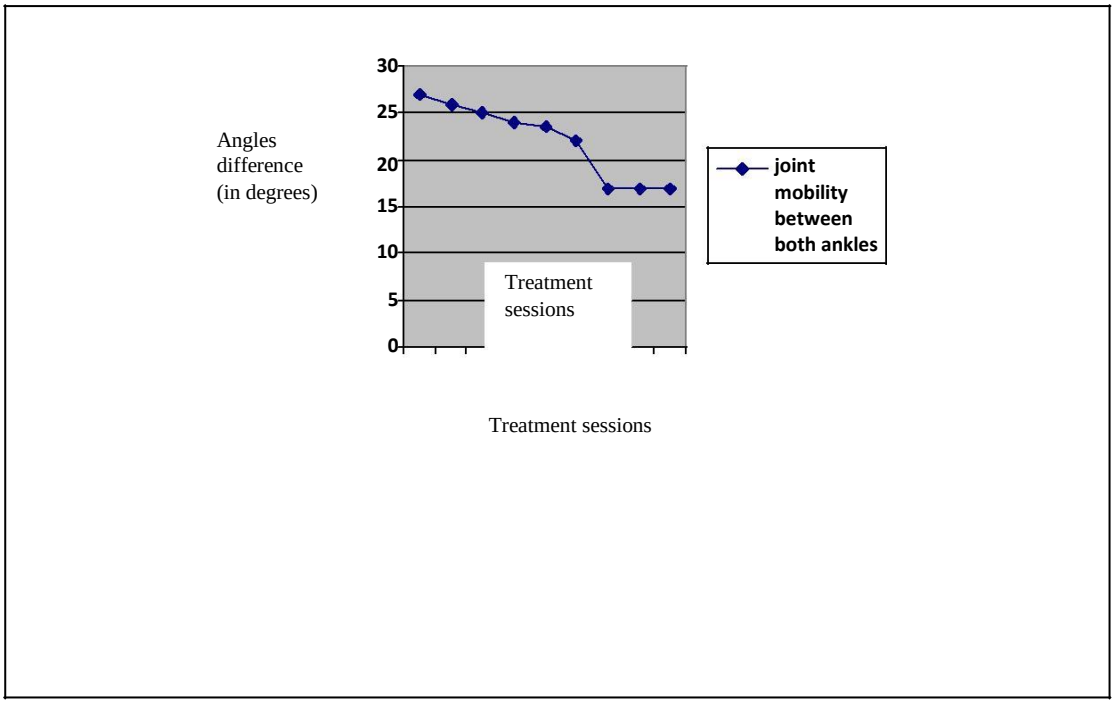


Fig. 1
Medial application. A 22 gauge needle is placed about 4 cm proximal and lateral to the distal end of the medial malleolus. The flexor hallucis longus tendon is just lateral to this point.
The needle is directed 45° posteriorly, slightly upward, and laterally.

Lateral application. A 22 gauge needle is placed about 1 cm proximal and medial to the distal end of the lateral malleolus.
The needle is directed 45° posteriorly, slightly upward, and medially

Fig. 2 – Evaluation of Joint Mobility.



Conclusions

This clinical trial on 72 patients affected from chronic ankle pain shows that the treatment above mentioned (MDs applied, modality of application and timing) is effective. No side negative effects have been observed. Therefore the treatment is safe, simple to carry out and effective, for a pathology that usually requires the use of anti-inflammatory drugs and/or of physical and rehabilitative therapy that should last long.

ANTIAGING TREATMENT OF COLLAGEN TISSUE
AN OBSERVATIONAL MULTICENTRIC CLINICAL TRIAL
AUTHOR: De Bellis M., Hermann G.F., Rivkina T.
Responsible of the trial : Hermann G.F. - Republic of S. Marino

INTRODUCTION

Chronological aging of the skin is the result of a mixture of biological, biochemical and molecular events established by the genetic code of each individual (chronoaging). Other environmental chemical and physical factors contribute to aging and these are of varying importance in determining its type and severity (photoaging).
Chronoaging and photoaging have a significant impact on the alteration of some physiological cutaneous mechanisms, not only as independent events, but also as synergic factors.
Chronoaging affects all the structure of the tegumental system: at the epidermis level, one can see a reduction in mitoses, a tendency towards premature keratinisation, the dispersion of melanocytes, and a reduction in Lagerhans cells. The dermis shows a loss of thickness and thinning out of the vascular support: the collagen fibres are fragmented; the elastic fibres are disorganized; the interstitial subastance (matrix) tends to become uniform, and there are lower number of fibroblasts.
The reduction in collagen type I synthesis is clearly linked to age.
The connective tissue lay down in the extracellular matrix that is not just a supportive tissue but a very specialized and organized structure, where all changes in the internal and external environment affect the cell mechanism via the interstitial substance (matrix).
When chronoaging and photoaging changes affect the fibrillar connective tissue in the dermis, skin aging is clearly visible in loss of elasticity and turgidity and appearance of wrinkles.

PATIENTS AND METHODS

This cohort clinical study evaluated the effectiveness of COLLAGEN TISSUE in the treatment of wrinkles and skin slackening via a series of subjective and objective clinical indicators.
340 patients of both sexes (289F – 51M) aged between 35 and 75 (F) and between 40 and 70 (M), were included into the study that lasted 1 year. They wee divided into 5 different age ranges (F) and 3 different age ranges (M). All patients attending the clinics of the medical doctors taking part in the study were included, without exclusion criteria.
The period of the study lasted 6 months (from Sept. 2004 to Feb. 2005).
The treatment consisted of 8 sessions on a weekly basis.
3.8% of the patients dropped out of the treatment after the first few sessions, for reasons that were not dependent on the program.
The application method was done as linear infiltration 1 cm apart, which was parallel to the skin surface in the medium and medium-deep dermis layers, or wrinkles infiltrations, according to the *tunneling* technique.

RESULTS

The results were evaluated before and after the specific treatment via the subjective classification of the visual and tactile characteristics of the wrinkles and the slackening of the face and neck tissues.
Mild reactions to the treatment were observed in 8 cases (2.3%) with slight erythema in the injection site, which disappeared spontaneously after a few minutes.
The results of the treatment with COLLAGEN TISSUE are shown in FIGG. (*see later*).
Six months after the end of the treatment, all Clients had been contacted by phone. We could visit directly 200 of them for a overall evaluation of the treatment. The treatment was still performing well and some Clients decided to make one single reinforcement treatment.
The other Clients contacted y phone expresses their good satisfaction for the treatment.

CONCLUSIONS

This observational cohort clinical study has shown that COLLAGEN TISSUE is highly effective and has high levels of tolerability in the treatment of all types of wrinkles, especially linear periocular and perilabial wrinkles, in Group A and B, in particular, there was a considerable reduction ranging up to the disappearance of wrinkles; in Groups C, D and E (patients from 35 to over 70) there was a steady improvement, from the index “obvious” to the index “slight”.
The treatment is safe and not painful, with long-lasting results.

COMMENTS
The activity of MD TISSUE is surely due to the replacing of the epidermis broken or absent collagen fibers with new collagen (substitute mechanic effect) and to the supplementation of biochemical ingredients in low dose that give texture to the local extracellular matrix.

FIG. 1 – Group A (female patients – 30-40 years old), before (B) and after (A) therapy; no. = 37.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	35	36	34	36	17	27	34	36	23	25
Slight	2	1	3	1	18	10	2	1	11	9
Obvious	0	0	0	0	2	0	1	0	3	3

FIG. 2

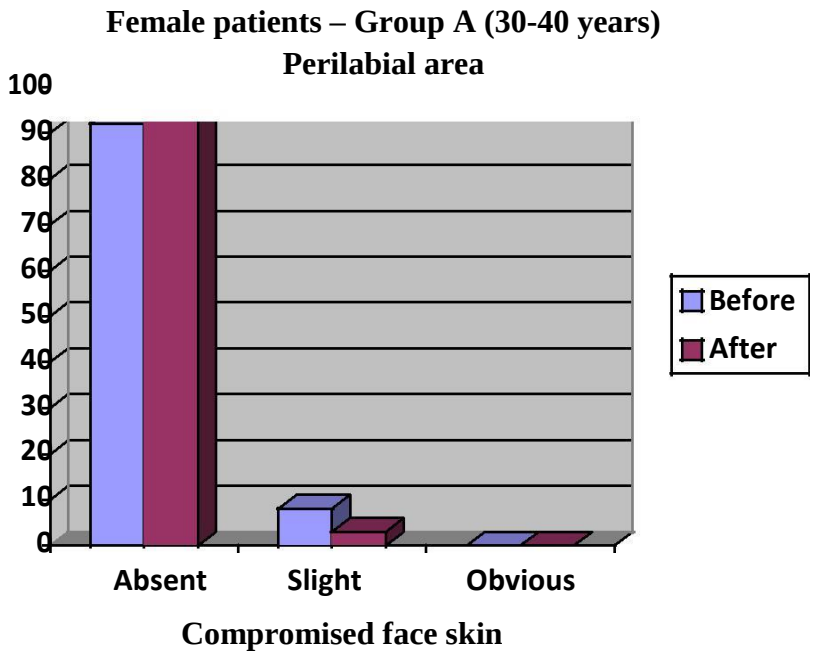


FIG. 3

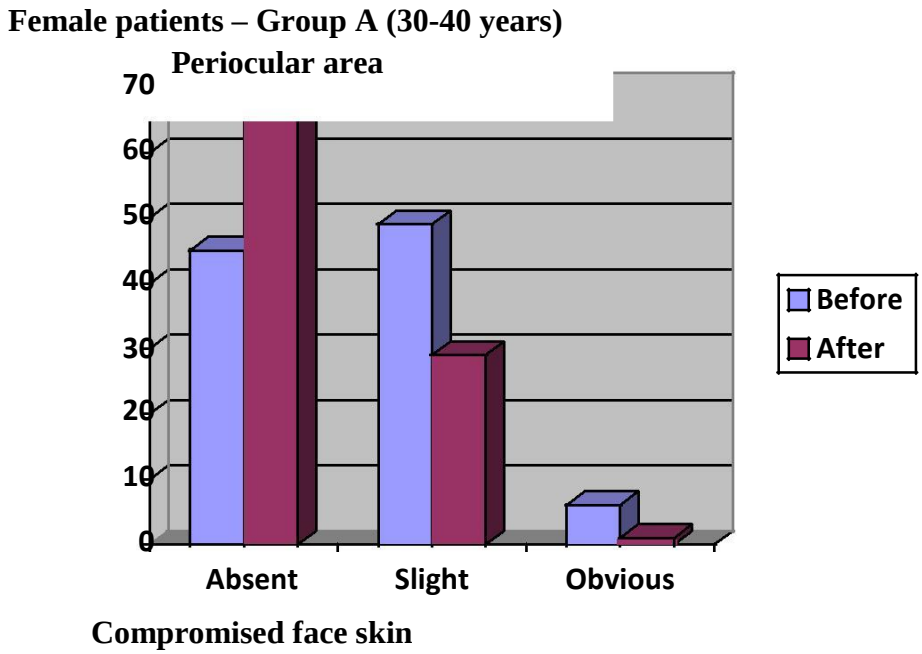
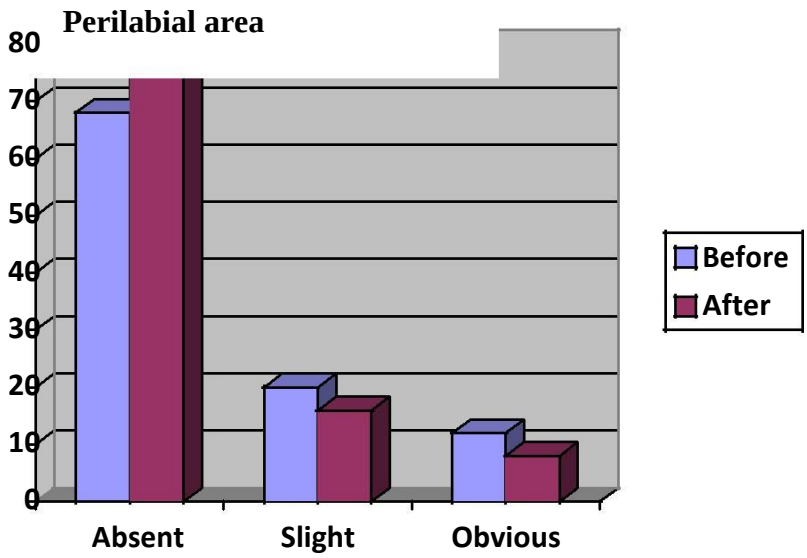


FIG. 4 – Group B (female patients – 40-50 years old), before (B) and after (A) therapy; no. = 48.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	43	45	32	39	14	27	30	34	24	25
Slight	3	2	9	7	22	13	15	13	17	18
Obvious	2	1	7	2	12	8	3	1	7	5

FIG. 5

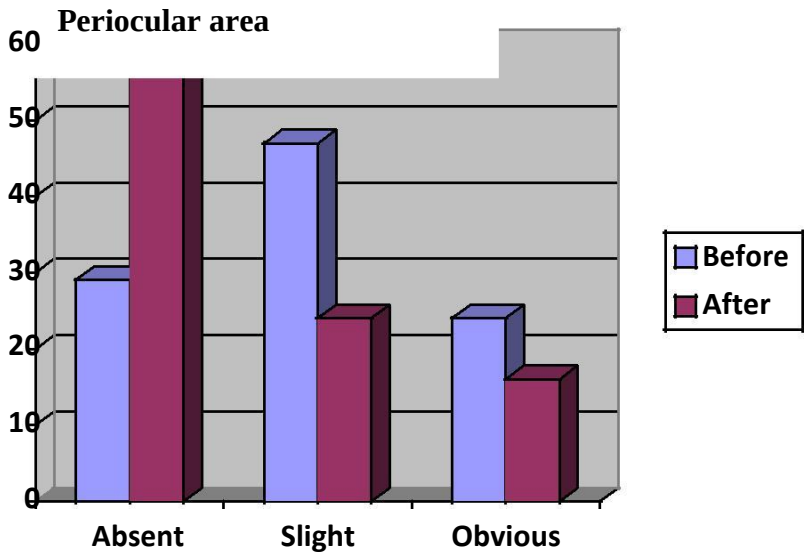
Female patients – Group B (40-50 years)



Compromised face skin

FIG. 6

Female patients – Group B (40-50 years)



Compromised face skin

FIG. 7 – Group C (female patients – 50-60 years old), before (B) and after (A) therapy; no. = 94.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	67	73	24	37	3	5	1	0	0	1
Slight	17	13	55	47	63	67	49	54	48	51
Obvious	10	8	15	10	28	22	44	40	46	42

FIG. 8

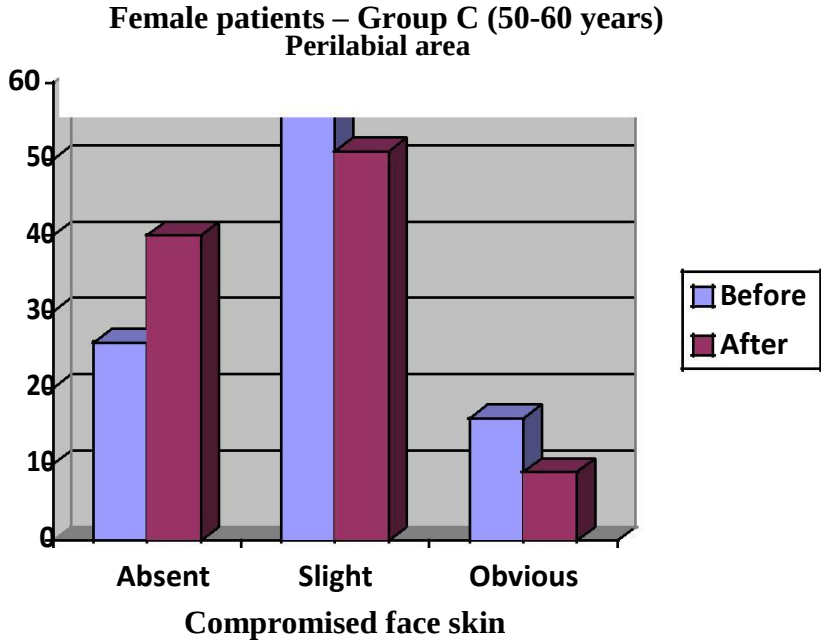

Female patients – Group C (50-60 years)
Perilabial area
60
50
40
30
20
10
0
Absent
Slight
Obvious
Compromised face skin
Before
After

FIG. 9

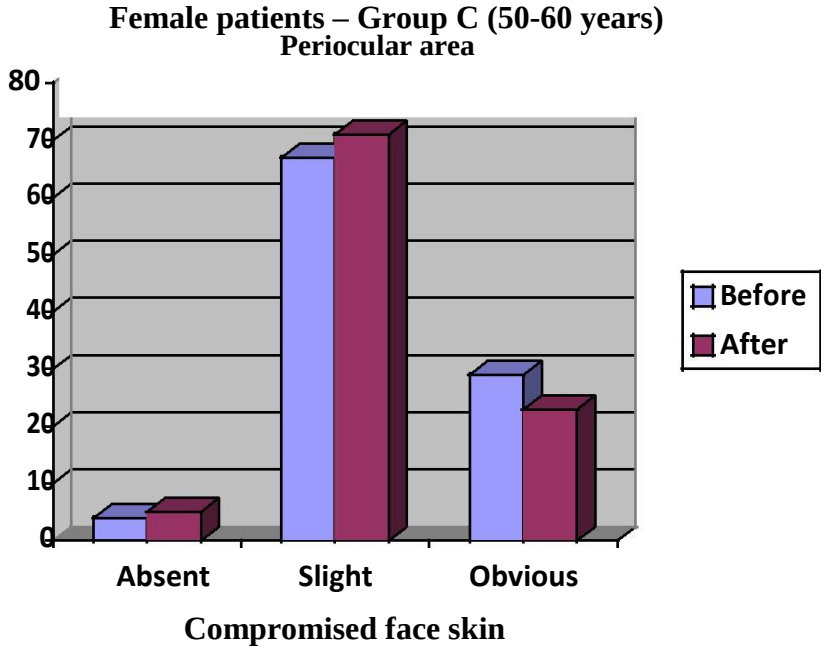

Female patients – Group C (50-60 years)
Periocular area
80
70
60
50
40
30
20
10
0
Absent
Slight
Obvious
Compromised face skin
Before
After

FIG. 10 – Group D (female patients – 60-70 years old), before (B) and after (A) therapy; no. = 58.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	9	14	0	0	0	0	1	1	0	0
Slight	26	22	27	33	26	33	29	30	28	31
Obvious	23	22	31	25	32	25	29	28	30	27

FIG. 11

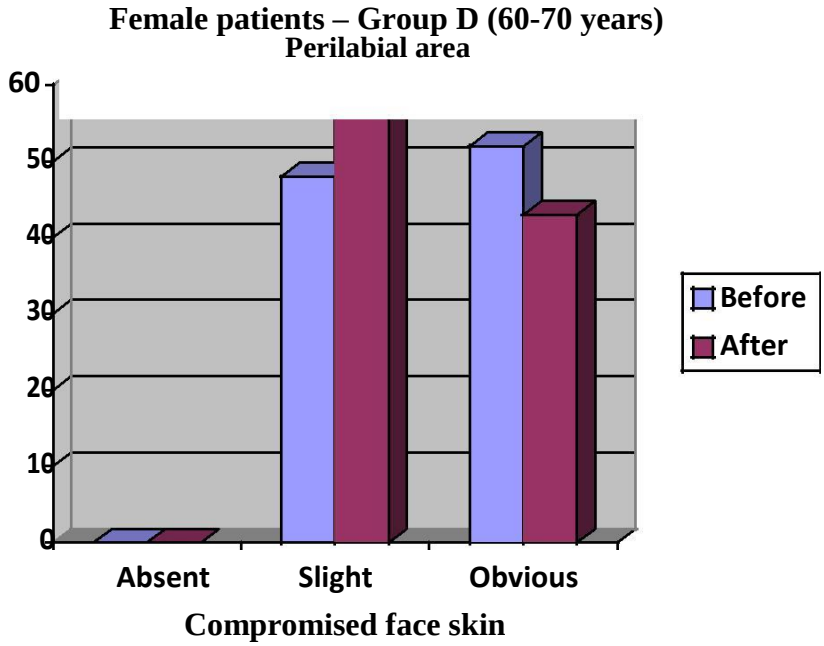

Female patients – Group D (60-70 years)
Perilabial area
60
50
40
30
20
10
0
Absent
Slight
Obvious
Before
After
Compromised face skin

FIG. 12

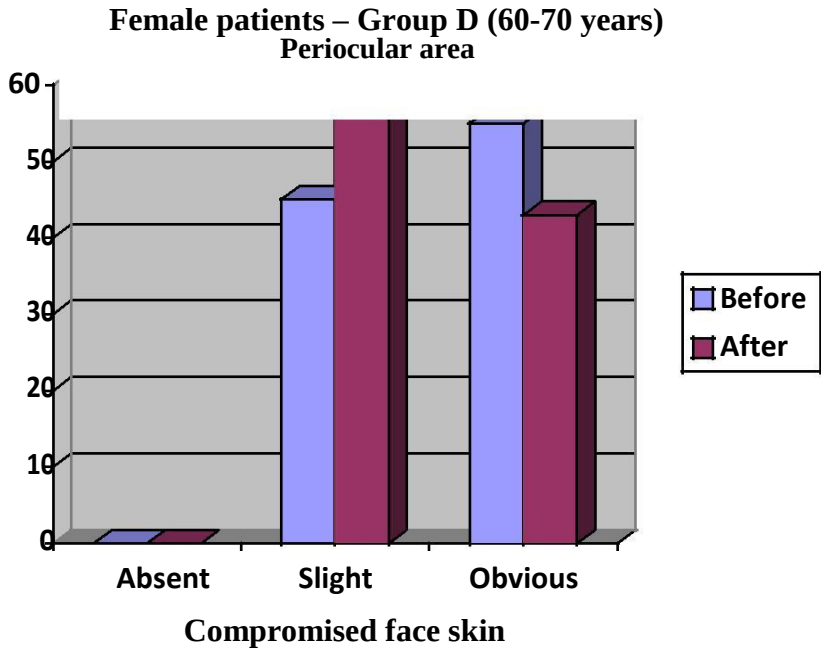
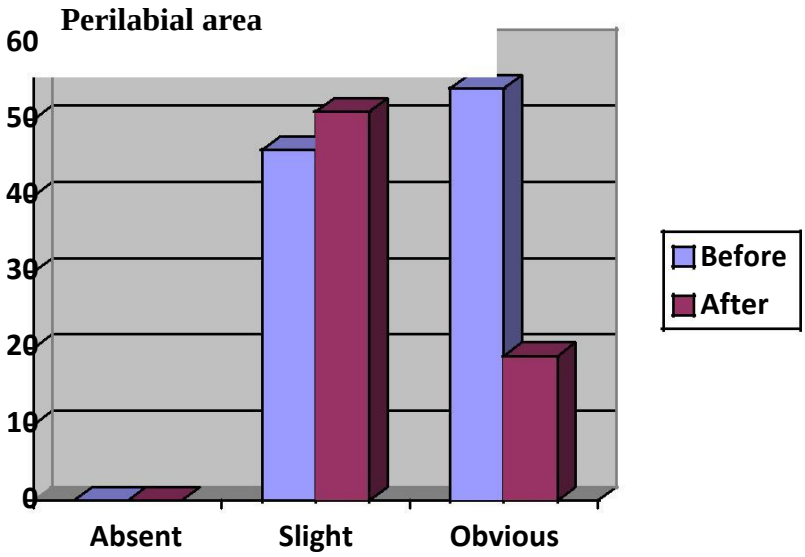

Female patients – Group D (60-70 years)
Periocular area
60
50
40
30
20
10
0
Absent
Slight
Obvious
Before
After
Compromised face skin

FIG. 13 – Group E (female patients – >70 years old), before (B) and after (A) therapy; no. = 52.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	2	2	1	0	0	0	0	0	0	0
Slight	25	28	23	27	24	26	24	24	22	22
Obvious	25	22	28	25	28	26	28	28	30	30

FIG. 14

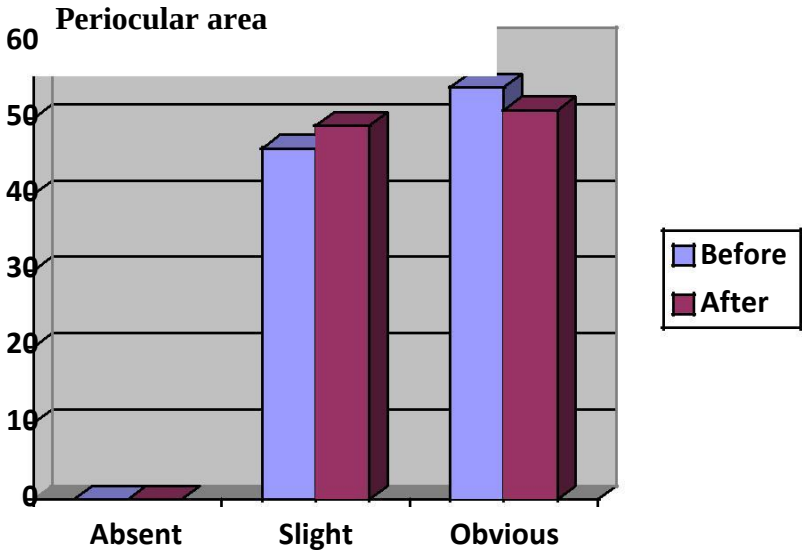
Female patients – Group E (>70 years)



Compromised face skin

FIG. 15

Female patients – Group E (>70 years)



Compromised face skin

FIG. 16 – Group B (male patients – 40-50 years old), before (B) and after (A) therapy; no. = 25.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	21	22	19	21	9	11	19	20	18	20
Slight	3	2	3	3	11	10	5	5	6	5
Obvious	1	1	3	1	5	4	1	0	1	0

FIG. 17 – Group C (male patients – 50-60 years old), before (B) and after (A) therapy; no. = 22.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	12	13	11	13	8	8	12	13	12	12
Slight	7	8	7	6	10	11	8	7	8	9
Obvious	3	1	4	3	4	3	2	2	2	1

FIG. 18 – Group D (male patients – 60-70 years old), before (B) and after (A) therapy; no. = 5.

WRINKLES Compromised face skin (visual and tactile characteristics)	Cheek (Glyphic wrinkles) No. patients		Perilabial area No. patients		Periocular area No. patients		Forehead area No. patients		Eyebrow area No. patients	
	B	A	B	A	B	A	B	A	B	A
Absent	1	1	1	2	1	1	1	1	1	1
Slight	2	3	2	3	3	3	2	3	3	4
Obvious	2	1	2	0	1	1	2	1	1	0

FIG. 19 – Global evaluation on the treatment: results.

Evaluation	Very poor No. (%)	Poor No. (%)	Acceptable No. (%)	Good No. (%)	Excellent No. (%)
Doctor's evaluation	0 (0)	0 (0)	0 (0)	105 (31)	235 (69)
Patient's evaluation	0 (0)	0 (0)	0 (0)	95 (28)	245 (72)

FIG. 20 – Global evaluation on tolerability.

Evaluation	Very poor No. (%)	Poor No. (%)	Acceptable No. (%)	Good No. (%)	Excellent No. (%)
Doctor's evaluation	0 (0)	0 (0)	0 (0)	3 (1)	337 (99)
Patient's evaluation	0 (0)	0 (0)	0 (0)	10 (3)	330 (97)

SAFETY AND EFFICACY OF A MEDICAL DEVICE IN COUNTERACTING COLLAGEN AGING

Authors: Intong lra.,Kishi Generao Fb., Villarama-Cellona Cd.
University of the Philippines, Philippine General Hospital Manila

Sedentary lifestyle, incorrect diet, drug abuse, concomitant disorders, psycho-emotional stress, etc. can lead to an accumulation of toxins in the matrix tissue of the dermis, that affects the collagen tissue as well. The collagen becomes worn out and the appearance of the affected area becomes loose without turgidity.
Quite when legs and arms are affected, movements become stiff as the intoxicated tissue compromise also the joints.

Several methods can improve this situation, generally appropriate diet and physical activities. Further a local supplementation of new collagen that induce a cleaning of the detoxified matrix can speed the anti-aging activities.

A useful tool is the medical device COLLAGEN MATRIX that is made of collagen and biochemical compounds that support the matrix tissue, without interfering with other concomitant treatments that the patients may undergo.

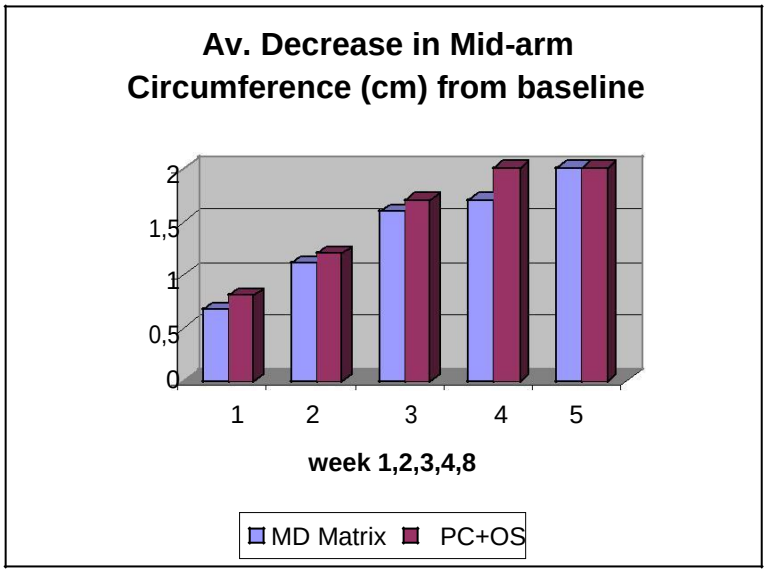
PATIENTS AND METHODS

This clinical study has the aim to collect evidence of the use of COLLAGEN MATRIX.
40 female subjects, aged 25-45 years, complaining of loose tissue in the upper arms and with stiff movement of the shoulder joints were recruited.
Exclusion criteria:
Underlying dermatologic, neurologic, musculoskeletal or vascular diseases in both arms, concomitant diagnosis of shoulder joints diseases
pregnancy
thyroid problems
hypercoagulable states, or recent cancer

20 subjects received a treatment of Phosphatidil choline plus Organic silica, PC+OS, 20 received COLLAGEN MATRIX.
The treatment consisted into the application of 1 vials of product into the subcutaneous of bilateral upper arms, evenly distributing it over the affected area.
The study lasted 8 weeks and treatment was done at week 1,2,3, and 4. The subjects mid upper arm circumferences were measured at week 1,2,3,4, and 8.
Subjects were also asked to report any adverse events.
Organic silica is rich in silica is associated with plant extracts and enzyme.
Collagen Matrix is formulated with collagen extract and biochemical compounds (vitamins) in low doses in order to act locally on the matrix tissue.

RESULTS
The following data was collected according to a 0-10 score scale:
Injection site erythema score (Objective)
Injection site pain score (Subjective).
The for each subject the average Decrease in Mid-arm Circumference (cm) from their corresponding baseline was reported.

RESULTS



No significant differences or abnormalities between treatments at baseline, week 3 and 8.
Remarkably the effect of MD Matrix continued up to the 8th week, although treatment was stopped after 4 weeks.

Injection site pain resulted to be tolerant and a few slight injection site erythema were noted.

The PC +OS treatment showed the following side effects:
- 1 Post-Inflammatory Hyperpigmentation that was resolved after a month.
- 2 Slight Erythema developed erythematous macules on the sites of injection

Common adverse events were hematomas, warmth, pruritus, heaviness that were resolved into 1-2 days.

COMMENTS

PC+OS and MD MATRIX are comparable in efficacy, though MD MATRIX showed no adverse reaction and long lasting results.

EFFECTS OF THE MEDICAL DEVICE MD THORACIC *VS* ULTRASOUND THERAPY ON MOBILITY AND THORACIC PAIN IN HYPERKYPHOTIC PATIENTS AT THE MEDIUM TRACT LEVEL (T5, T6, T7)

Authors: Hermann G.F., Rivkina T. – Republic of S. Marino

SUMMARY

This clinical trial has been carried out on 26 hyperkyphotic patients at the medium tract level (T5 – T6 – T7, the most common clinical condition of the disease). They were showing pain and functional limitation concerning dorsal backbone movements due to hyperkyphosis of different origin.

Patients have been subdivided into 2 homogenous Groups (1; 2) at random as for number, gender, average age, level of kyphosis (± 1).

Group 1 has been treated with the medical devices MD Thoracic + MD Muscle + MD Neural (2 ampoules each) by means of biweekly paravertebral infiltrations into the area of the maximum kyphotic curvature (generally from T4 to T10).

Group 2 has been treated with Ultrasound therapy (1MHz, 2 WATT/cm^2 for 10 minutes) twice a week for 15 consecutive weeks. Both treatments have been well tolerated and have not shown any negative side effect. The painful symptomatology (Scott-Huskisson scale) has improved in both Groups (a decrease as regards the initial value: Group 1 = 48.2%; Group 2 = 52.5%) while results on the dorsal backbone mobility have been registered only in Group 1 (+25% as regards the initial values). Treatment with NSAIDs (Non Steroidal Anti-Inflammatory Drugs) or ASA (Acetylsalicylic Acid) was not necessary in both Groups during the observation and clinical trial period.

INTRODUCTION

Dorsal kyphosis is an accentuation of the standard physiological curvature of the dorsal rachis both visible to the naked eye and at x-ray examination.

The hyperkyphotic curvature forces the person to adopt a closure attitude at the rib cage level causing, this way, a limitation of the ribcage itself during the inspiratory phase of respiration.

Medium tract hyperkyphosis is the most widespread form of the pathology, together with compensation lumbar hyperlordosis. Postural rehabilitation should not be only a localized corrective intervention, but it should act on the whole rachis readjustment. All the correction tools aim readjustment the tone of the paravertebral long thoracic muscles so as to reduce as much as possible the wrong rachis positions.

At this point, a reference to the Law of Borelli and Weber Fick is fundamental: "*the length of the fibers is proportional to the shortening obtained by their contraction and this is equal to the half of the fibers length*". On the long term, the thoracic hyperkyphosis causes a progressive adaptation and consequent stiffening of the ligaments. Postural deflexions of the physiologic positioning are caused by and alteration of the morpho-functional unity: muscles – ligaments – tendons – intervertebral disk – joints between articular processes. Whenever an effective therapy for the reduction of kyphosis is needed, an action on these elements is required.

PATIENTS AND METHODS

This clinical trial aims at comparing the effectiveness of the local injective therapy with the 3 MDs (COLLAGEN THORACIC + COLLAGEN MUSCLE + COLLAGEN NEURAL – selected for their characteristics of intervention on the abovementioned morpho-functional unity) *vs* Ultrasound therapy.

All the patients have been included *at random* (total number: 26), depending on the arrival date at the first consultation. Every patient underwent a motor rehabilitation as well to recover his/her vertical structure.

Patients have been divided into 2 homogeneous Groups:

Group 1: 13 pz (8M, 5F; average age: 38.5 years; average degree of kyphosis: 39°)

Therapy: COLLAGEN THORACIC 2 ampoules + COLLAGEN MUSCLE 2 ampoules + COLLAGEN NEURAL 2 ampoules (6 ml total).

Paravertebral infiltrations (laterally, 2 cm from the Posterior Median Line) from T5 to T7 included, twice a week (with an interval of at least 2-3 days), of 0.5 ml- MDs cocktail using an insulin needle for 10 consecutive times.

COLLAGEN Thoracic is a medical device specific for the thoracic area. It is locally effective creating a collagen barrier that smoothes the friction between the thoracic intervertebral disk and the latero-vertebral joints improving – this way – movement and pain.

Group 2: 13 pz (10M, 3F; average age: 41.3 years; average degree of kyphosis: 41°)

Therapy: Ultrasound therapy 1MH, 2WATT/cm^2 for 10-12 minutes, twice a week for 15 consecutive weeks. EVALUATION

The final evaluation has been carried out at the beginning of the 10th session for Group 1 and at the beginning of the 15th session of therapy for Group 2, according to 2 prefixed parameters: a) pain; b) thoracic rachis movement.

Pain, being an objective parameter, has been evaluated according to a 10 degrees Linear Scale: 0 = *no pain*; 10 = *maximum endurable pain* (Visual Analogic Scale – Scott and Huskisson).

Pain (Tab. 1)

Average pain <u>before</u> treatment

Group 1: 5.6

Group 2: 5.9

Average pain <u>after</u> treatment

Group 1: 2.9 (2.7 decrease, 48.2% as regards the initial value)

Group 2: 3.1(2.8 decrease, 52.5% as regards the initial value).

Having set (*intention to treat*) that the difference between the 2 treatments (Group 1; Group 2) would have been statistically significant only for a 10% decrease, because the difference between Group 1 (52.8%) and Group 2 (48.2%) is 4.6%, we can state that the efficacy of the therapies applied to Group 1 and o Group 2 is overlapping and that both therapies are extremely targeted to the symptom pain in hyperkiphotic patients.

Rachis movement (TAB. 2)
The evaluation of the mere rachis movement is quite difficult and not free from psycho-emotional influences on the patient side. Since all the patients included in this clinical trial were not suffering from pathologies jeopardizing the flexor functionality of lumbar and cervical rachis (thus considered to be within the standard), the evaluation has been carried out on the rachis bending (flexion) *in toto*. From this evaluation, only the thoracic bending function would have came out, measured in degrees as regards to the vertical line passing through the maximum dorsal curvature (standard average: 45°).
Flexion average in degrees before treatment
Group 1: average degree of kyphosis = 30° ≈ (between 28° and 32°)
Group 2: average degree of kyphosis = 36° ≈ (between 34° and 38°).
Flexion average in degrees after treatment
Group 1: 42° ≈ (between 40° and 44°)
Group 2: 35° ≈ (between 33° and 37°).

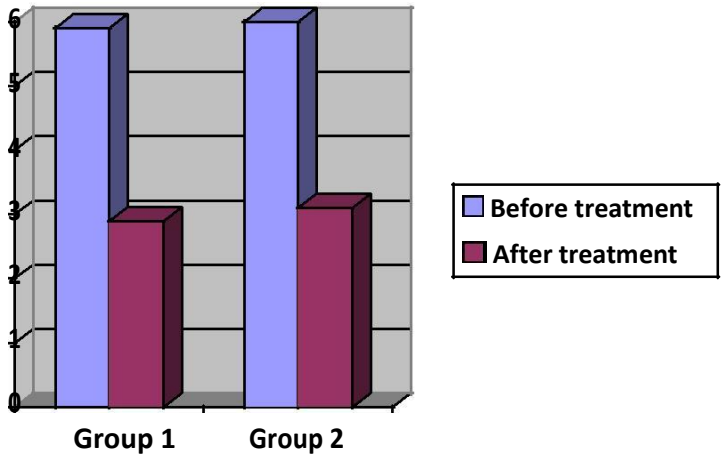
These data highlight that in Group 1 there has been a clear improvement in the flexor movement (+12°, that is +27% as regards to the initial values), while in Group 2 no joint functionality improvement has been registered (before treatment: 36°; after therapy: 35°).

CONCLUSIONS

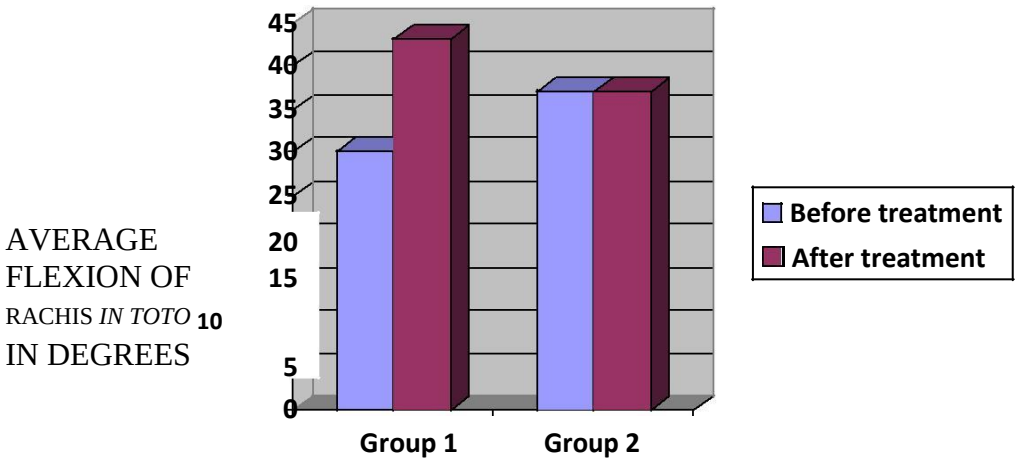
This clinical trial carried out for 45 days shows that the medical devices Collagen Thoracic + Collagen Muscle + Collagen Neural are as effective as the Ultrasound therapy on the symptom pain (TAB. 1) but definitely more effective compared to Ultrasound therapy in the rachis movement *in toto* in adulthood patients suffering from thoracic hyperkyphosis of the medium tract (TAB. 2).

The clear improvement of rachis pain and mobility are most likely due to MDs application that affects not only symptoms but mainly the trophic improvement as well, due to the supplementation of substances that support the entire morpho-functional unit affected with the dorsal hyperkyphosis.

PAIN EVALUATION



FLEXION EVALUATION



TREATMENT OF LOW BACK PAIN AND LUMBAGO-SCIATICA IN ATHLETES

Authors: Hermann G.F., Rivkina T. – Republic of S. Marino

SUMMARY
In this clinical trial, the positive effects of the therapy with the Medical Device (MD) Lumbar + Collagen Muscle + Collagen Neural on 2 pathologies caused by functional overload are described. These pathologies (simple low back pain; low back pain + ischiatic pain) frequently affect the lumbar spine, especially in sportsmen. Ninety two athletes (60 M; 32 F) aged between 18 an 32 years (average 22), suffering from low back pain, lumbar pain + ischiatic pain with different levels of objective and subjective severity, took part to this trial.

INTRODUCTION
Athletes are at great risk of sustaining a lumbar spine injury due to physical activity. Whatever the sport (skiing, basketball, football, ice skating, running, golf or tennis), the spine undergoes stress, absorption of pressure, twisting, turning, and even bodily impact. This strenuous activity puts a strain on the back that may cause injury to even the most fit athletes. Although the entire spine is used when playing sports, it is estimated that 5-10 percent of all sports injuries are related to the lumbar spine. Many cases of low back pain in athletes can be traced to a specific event or trauma: others are brought by repetitive minor injuries that result in microtraumas.

The diagnosis has been carried our through a clinical examination that included: observation, anamnesis, inspection, palpation, functional examination, serologic examination (in 45% of the included patients), differential diagnosis (that represented also the exclusion criteria – *see later*).

- INCLUSION CRITERIA
Athletes referring low back pain related to sport activity were included (musculoligamentous strain, presence of trigger points, spondylosis, spondlylolisthesis).

- EXCLUSION CRITERIA
Lumbar pain not directly related to sports activities has been excluded from the present study: disk injuries, herniated disk, projected thoracic pain, referred pain from internal organs.

PATIENTS AND METHODS
The athletes included in this trial practiced the following sports:
42 soccer, 12 athletics, 8 handball, 4 basketball, 10 swimming, 2 artistic gym, 6 karate, 4 ice skating, 4 skiing.

GROUP A: Athletes with low back pain only enrolled in this trial were 82 (89% of all patients included).
GROUP B: Athletes with low back pain + slight sciatica were 10 (11% of all the patients included) (Fig. 1).

GROUP A
Athletes with a low back pain (n° 82) had been treated with the medical device Collagen Lumbar - 2 ampoules + Collagen Muscle - 1 ampoule + Collagen Neural - 1 ampoule (cocktail in the same syringe: 8 ml); in order to help movement and soothe local pain, collagen supplementation together with trace elements was done reinforcing the disk collagen, that is the main substance constituting the intervertebral disc, and is often fissured or anyway altered in its own anatomic structure in athletes or elderly people.

GROUP B
Athletes with low back pain associated to slight sciatica (no. 10) had been treated with the medical device Collagen Lumbar - 1 ampoule + Collagen Muscle - 1 ampoule + Collagen Ischial - 2 ampoules (cocktail in the same syringe: 8 ml) for the above mentioned conditions. The use of Collagen Ischial in these patients is aimed at the reinforcement of the *perineurium* creating therefore a better conductivity of the ischiatic nerve suffering from ischemia due to contraction of the satellite muscle.

The sterile ampoules are mixed together and injected via periarticular (next to the joint capsules).

Preparation for Injection
Materials for aseptic skin preparation: Sterile gloves, Iodine solution Alcohol solution, Sterile gauze pads, Ethyl chloride spray for skin (optional).
Syringes: 10cc
Joint technique: the periarticular application needs a 22 G needle. The site of application must be sterile; the needle is inserted in the same manner as for the intraarticular, but it reaches 4 mm depth, without perforating the joint capsule.

For the patients of GROUP A, the application of the MDs, has been once a week, and the scheme of treatment, the following:
From week 1 to week 5: Collagen Lumbar (2 ampoules) + Collagen Muscle (1 ampoule) + Collagen Neural (1 ampoule) x treatment
From week 6 to week 10: Collagen Lumbar (2 ampoules) x treatment.

The application area is along the lumbar vertebras from L2 to L5, both side paravertebral. Infiltration per point 0,5-1 ml. The treatment has been associated with sleeping in hard bed and the pillow under the neck or the knees in order to promote muscle relaxing with proper spine position.

For the patients of GROUP B, the applications of the MDs has been once a week, and the scheme of treatment, the following:
From week 1 to week 5: MD Lumbar (1 ampoule) + Collagen Muscle (1ampoule) + Collagen Ischial (2 ampoules) x treatment.
From week 6 to week 10: MD Ischial (2 ampoules) x treatment.
Same application area, same associated treatment as patients of GROUP A.

For the evaluation of efficacy, objective and subjective parameters have been considered.

Evolution of some clinical parameters				
	After 3 weeks	After 6 weeks	After 9 weeks	After 12 weeks (follow-up: 72% of all patients included)
Pain at rest	↓	↓	↓	→
Pain on movement	→	↓	↓	↓
Pain after physical effort	→	→	→	↓
Pressure pain on spinal apophysis and/or in paravertebral region	→	→	↓	↓
Irradiated pain	→	↓	→	↓
Muscle hypotrophy	→	→	→	→
Muscle contracture	→	→	↓	↓
Limitation of spine joints	→	→	↓	↓
Limitation of lumbar joints	→	→	→	↓

During the two years of the trial, it was possible to observe that 28% of athletes treated came back due to the reappearance of the pathology 8-9 months after the last treatment. The reappearance of the symptoms has always been related to an excessive effort of the lumbar spine due to an intensive training and agonistic activity.
The tolerability has been complete. None of the 92 athletes treated has presented side effects that are in general present in quite high percentage in athletes treated with pharmacological conventional therapy (NSAIDs, cortisone, ASA).

At the 12th week (2 weeks after the end of the last treatment) the follow-up was carried out for the 72% of all the patients included). It was possible to demonstrate that the administration of the MDs leads to a clear and progressive reduction of pain at rest, on movement, at digitopressure and irradiated in case of lumbar sciatica, just after the first 2-3 applications (Figg. 2, 3).

Conclusions
The use of the MDs, used in this trial, has allowed to get 83% of positive results in the therapy of low back pain and low back + ischial pain in young athletes. The MDs have given good results that justify their use, and have produced no side effects. The MDs used in this clinical trial monitored for a period of two years proved significative effectiveness and full tolerability.

Fig. 1 Patients grouping

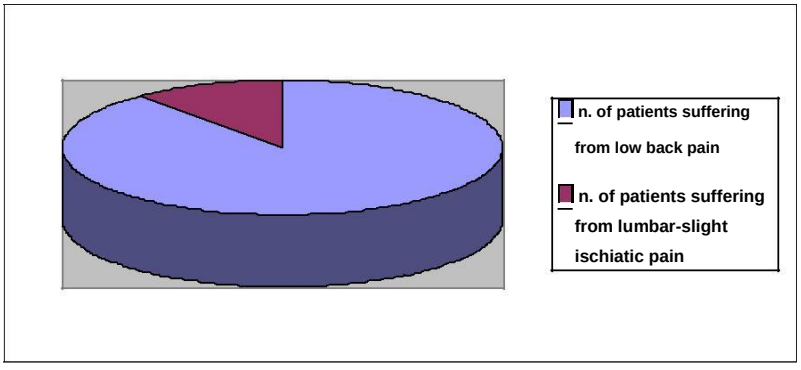


Fig. 2 - GROUP A: low back pain.

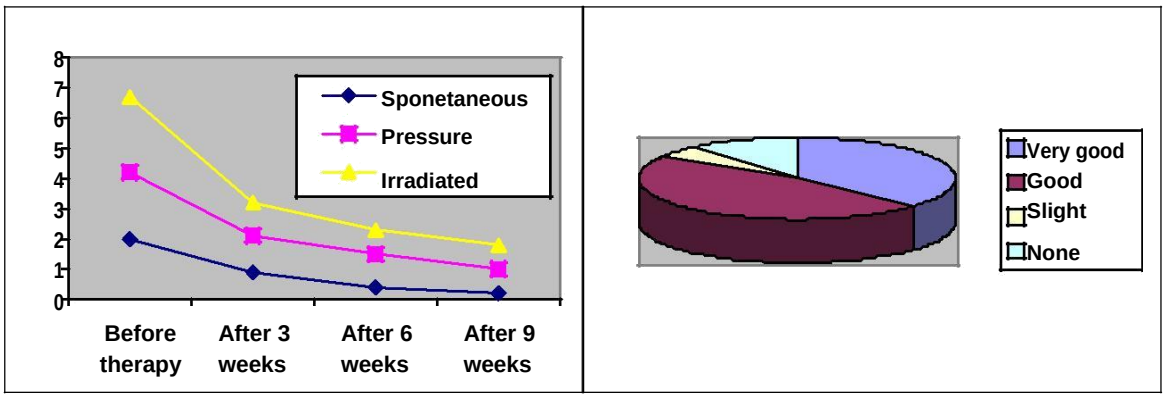
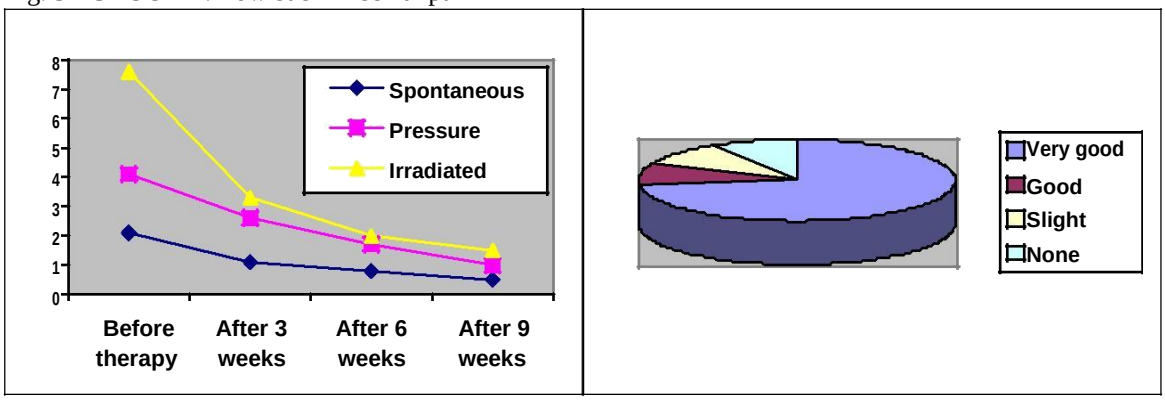


Fig. 3 - GROUP B: Low back + ischial pain



THERAPY WITH MD HIP + MD MUSCLE *VS* ELECTROACUPUNCTURE IN PAIN MANAGEMENT AND IMPROVEMENT OF COXO-FEMORAL ARTICULAR FUNCTIONALITY – RESULTS OF A COHORT, RANDOMIZED CONTROLLED CLINICAL TRIAL

Authors: Hermann G.F., Rivkina T., Ruocco A. – Republic of S. Marino

SUMMARY

Coxarthrosis is the localization of the chronic degenerative arthrophaty of the hip joint. Frequently, it is a severe and disabling disease. Its causes are both anatomical and mechanical. Clinical symptoms include pain while walking, functional constrains and joint deformities. These constraints have negative consequences on walking, causing pain which leads to disability and muscle spasms. In order to test the effectiveness of the medical devices COLLAGEN HIP + COLLAGEN MUSCLE, a controlled, randomized clinical trial has been carried out. The clinical trial meets the criteria of homogeneity, identifies a primary objective and dimensions of the sample in accordance with statistical criteria of reliability. The results show that the treatment with COLLAGEN HIP + COLLAGEN MUSCLE injected together near the coxo-femoral capsule articulation is 50% more effective than the Electroacupuncture in specific standardized local Acupoints. The infiltration of COLLAGEN HIP + COLLAGEN MUSCLE produced no side effect (only 4 small superficial hematomas, spontaneously healed in 10-15 days).

KEY WORDS: COXARTHROSIS, HIP MOVEMENT IMPROVEMENT, COLLAGEN HIP, COLLAGEN MUSCLE, ACUPUNCTURE

INTRODUCTION

Coxarthrosis is the localization of chronic degenerative arthropaty of the hip joint. It is a severe and disabling disease (1, 2, 3, 4) with causes that are both anatomical and mechanical. Clinical symptoms include pain while walking, functional constrains and joint deformity. Pain is due to the load but may also be induced by groin palpitation (many trigger points) or passive joint mobilization. The constrains have negative consequences on walking, causing pain which leads to limping and muscle spasm, which limits further muscle movement.

PATIENTS AND METHODS

In order to verify the therapeutic effectiveness of COLLAGEN HIP + COLLAGEN MUSCLE, a cohort, randomized, controlled trial has been carried out. The trial meets the criteria of homogeneity, identifies a primary objective and dimensions the sample in accordance with statistical criteria of reliability.

1) Country: Italy – 1 orthopedic and rheumatology clinic, 1 orthopedic and acupuncture clinic,
1 general practice clinic.
2) Number of patients recruited: 129 [55 M (43%); 74 F (57%)].
3) Patients' age: average = 54.8 years. Min: 42.3; Max: 68.5.
4) Pathology: coxalgia caused by 1st and 2nd degree primary coxarthrosis acc. to Hubbard.
5) Inclusion criteria:
- 5.1) Primary coxarthrosis clinically evidenced and diagnosed on the basis of algic symptoms of the hip joint reported by the patients.
- 5.2) 1st and 2nd degree coxarthrosis (X-rays).
- 5.3) Enduring pain for at least 4 months without signs of acute inflammation.
6) Exclusion criteria:
- 6.1) Secondary coxarthrosis
- 6.2) Relapsing coxarthrosis
- 6.3) Patients previously treated with corticosteroids during the 6 months prior to recruitment.
- 6.4) Slight pain.
7) Random, according to the patient's recruitment time.
8) Treatment:
- Group A: COLLAGEN HIP 2 vials + COLLAGEN MUSCLE 2 vials (cocktail = 8ml) – 66 patients [27 M (41%); 39 F (59%) – Average age = 56.2].

Ten weekly sessions for 10 consecutive weeks in 4 selected points (FIG. 1) with a 4cm 30 G needle to reach the selected articular capsule points. 2 ml of cocktail per point.

- Group B: Electroacupuncture – 63 patients [28 M (44.5%); 35 F (55.5%) – Average age = 53.5] (FIG. 2).

Ten weekly sessions of electrostimulated acupuncture for 10 consecutive days into the points highlighted in Fig. 2. Electric contents; BL54(+)/ GB 29 (-), GB 30 (+)/ GB 27 (-), GB 28 (+)/ ST 31 (-), SP 12 (+)/GB 31 (-). Disposable nickel-free needles (SH 0.25 x 25 mm GT) electrostimulated for 25 minutes at high frequency (300Hz) – low variable progressive intensity depending on individual sensitivity.

EVALUATION
CRITERIA PATIENTS
- All patients were evaluated according to
A) Osteoarthritis Index questionnaire (Western Ontario and Mac Master Universities – WOMAC). The WOMAC Index is self administered and assesses the amplitude of pain, disability and joint stiffness. The WOMAC Index Questionnaire is designed to evaluate patient's conditions according to 3 criteria:
1) Pain – *5 items* – Each item is scored on a scale from 0 (no problem/pain) to 10 (foreseeable problem/worst pain). 2) Stiffness – *2 items*.
3) Physical functionality – *7 items*.
B) SF – 36 Questionnaire, the most widespread and best-known patient oriented questionnaire about the general health status.
2) DOCTORS
- Clinical evaluation (hip extrarotation, tight extension, bending of tight and pelvis, evaluation of the ability to walk on a flat floor).

THERAPEUTIC EFFECTIVENESS

See TAB. 1 – The 2 Groups had the same WOMAC Index at T0 (clinical homogeneity): 5.5 for Group A and 5.1 for Group B (clinical homogeneity). The differences between the 2 Groups begun from the 2nd week of treatment (after the 3rd session) and became evident starting from the 6th week of treatment (after the 7th session). In Group B, the Womac Index at the 7 th session was 3.5, while it was 3.4 10 days after the end of the 10th session. In Group A, the WOMAC Index was 3.0 at the 7th session, while it was 2.2 10 days after the end of the 10th session.

SIDE EFFECTS

Group A = 4 events: small superficial hematomas spontaneously healed in 10-15 days.

Group B = 7 events: small superficial hematomas spontaneously healed in 10-15 days (different points have been treated).

CONCLUSIONS

By comparing the effectiveness of COLLAGEN HIP + COLLAGEN MUSCLE infiltrations *vs* Electroacupuncture, the two treatments were shown to be effective in reducing chronic pain from primary coxarthrosis with a greater and more rapid statistically significant improvement for the patients in Group A (exact Fisher test $p < 0.01$): in fact the WOMAC score in Group A is 3.3 meanwhile in Group B it is 1.7.

- On the basis of what above, we can state that COLLAGEN HIP + COLLAGEN MUSCLE can be injected in proximity of the coxo-femoral articular capsule to successfully treat chronic pain from primary coxarthrosis with no negative side effects.

The improvement is progressive from the 1st to the 10 th weekly session. This treatment is well tolerated and can also be used to control acute and secondary coxarthrosis pain.

REFERENCES
1) Radin E.L. - Aetiology of osteoarthritis. Clin Rheum Dis 1976; 2: 509-522.
2) Danielsson L., Lindberg H., Nilsson B. – Prevalence of coxarthrosis. Clin Orthop 1984; 191:110-115.
3) Kelsey J. - Epidemiology of musculoskeletal disorders. Monographs in epidemiology and biostatistics. Oxford: Oxford University Press; 1982.
4) Typpo T. - Osteoarthritis of the hip: radiological findings and etiology. Ann Chir Gynaecol, 1985; 74: 5-38.

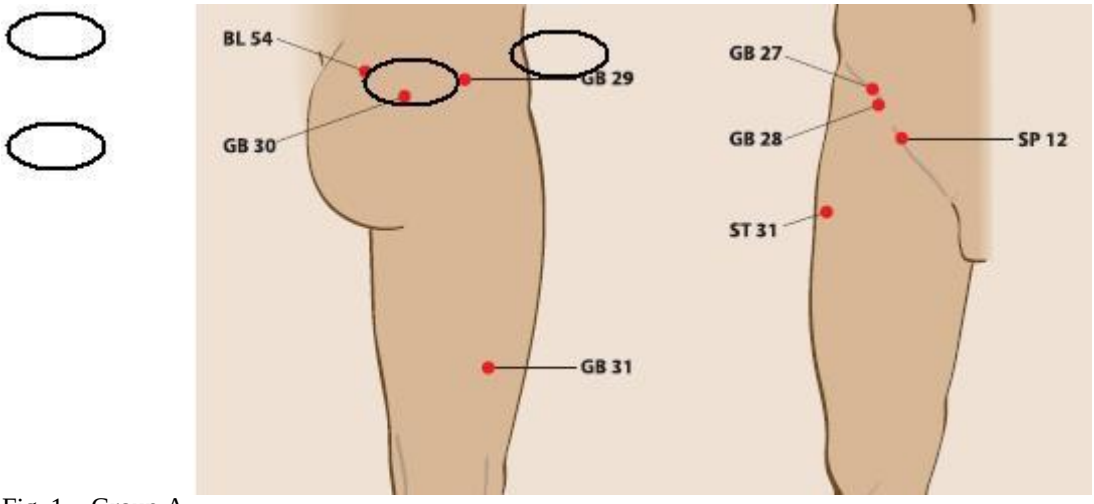


Fig. 1 – Group A –
Points infiltrated with COLLAGEN HIP (2 vials) + COLLAGEN MUSCLE (2 vials).

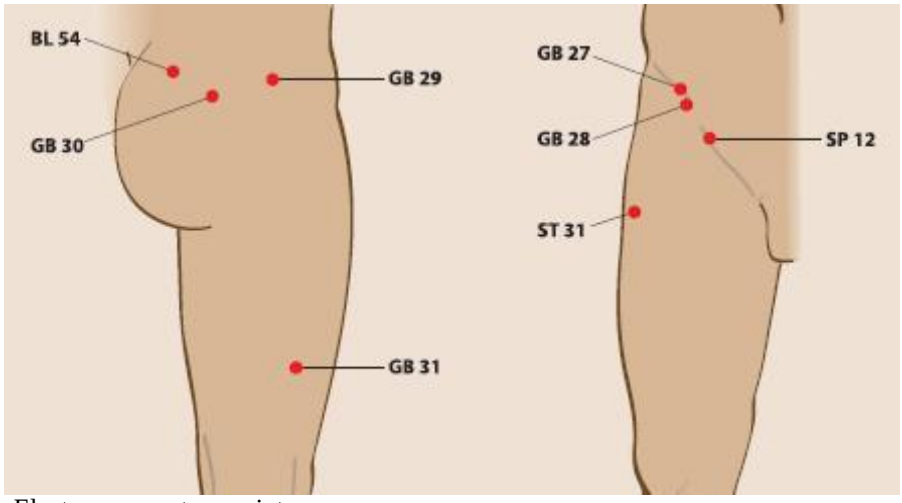
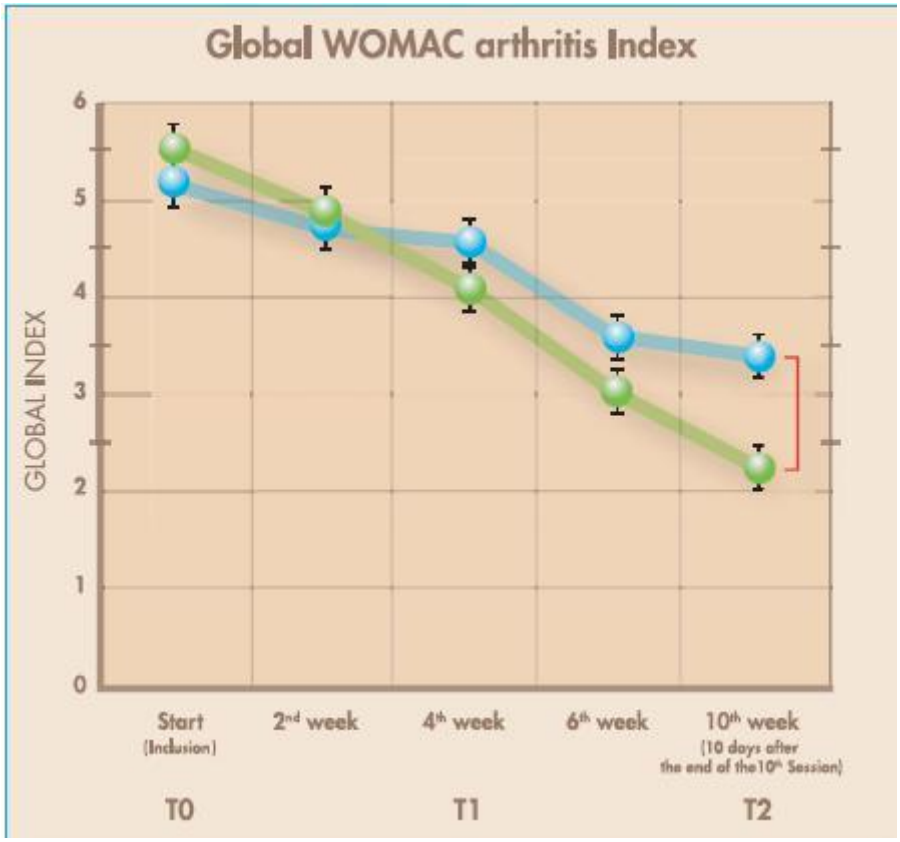


Fig. 2 – Group B - Electroacunpunture points.



Tab. 1
Green line – COLLAGEN HIP + COLLAGEN MUSCLE ampoules injected into selected Acupoints
Blue line – Electoacupuncture.

USE OF THE MEDICAL DEVICE KNEE IN THE TREATMENT OF MILD AND MODERATE GONARTHROSIS – AN OPEN CLINICAL TRIAL

Authors: Hermann G.F., Rivkina T., Ruocco A.
Responsible of the trial : Hermann G.F. - Republic of S. Marino

INTRODUCTION

Within the orthopedic pathologies, gonarthrosis is the most diagnosed type of arthrosis hitting limbs.
Usually, gonarthrosis is asymptomatic for a long time until the latent form evolves into a knee painful clinical form. Apart from the distinction between primary or secondary arthrosis, the symptomatic treatment consists of physical measures, electrotherapy, mechanic therapy, physiotherapy, NSAIDs administration and intra-articular cortisone.
- At an international level, the administration of NSAIDs (Non-Steroideal Anti-Inflammatory Drugs) prevails. NSAIDs administration is in many occasions problematic because it causes a general failure in the prostaglandins or COX 1,2 also involved in physiological processes synthesis. Moreover, due to NSAIDs side effects, it is advisable to consider alternative therapeutic methods, such as de the Medical Device (MD) KNEE.

MATERIALS AND METHODS

17 patients have been included in this trial. All of them were suffering from gonarthrosis of different severity (mild in 8 patients, moderate in 6 patients, severe in 3).
2/3 of the patients were F and 1/3 M (aged between 49 and 81 years). The 3 patients affected by severe gonarthrosis were part of the higher age bracket (76, 80, 83 years of age).
The clinical symptomatology has been evaluated on the basis of 4 parameters: 1) muscular stiffness; 2) pain at the beginning of a movement; 3) pain during the loading; 4) permanent pain.

Gonarthrosis evaluation and classification have been carried out according to the standard radiographic criteria [anterior and posterior X-Rays and 2 lateral X-Ray of the knee (r; l)]. The improvement parameters considered have been: 1) march movement; 2) objective evaluation of the articular functionality; 3) pain at rest and in movement.

TREATMENT

Being a chronic pathology, all the patients have been treated with the COLLAGEN KNEE by intrarticular administration for the first 2 sessions while for the remaining 10 sessions by periarticular administration.

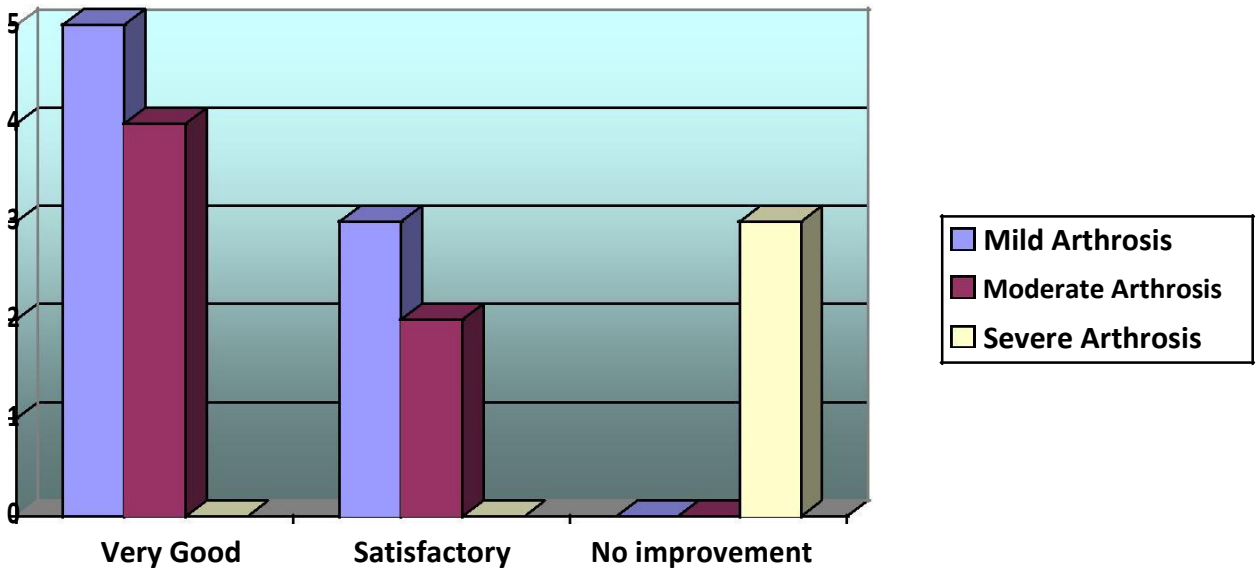
The intrarticular infiltration has been carried out with 1 ampoule of COLLAGEN KNEE while periarticular infiltrations with 2 ampoules of COLLAGEN KNEE. The treatments took place once a week (total period of treatment = 3 months). The pericapsular (periarticular) infiltration has been done into the painful pressure points (2 kg/cm^2) (trigger points) and into medial and lateral collateral ligament insertions. A clinical analysis has been carried out for every patients in order to evaluate the functional condition. The report analysis has been carried out by means of an objective clinical test concerning articular functionality (objective) and a *patient-oriented* questionnaire for pain evaluation (subjective).

Patients have been warned to resort to the pharmacological therapy they were using before the inclusion into this clinical trial (mainly NSAIDs, ASA) only in case of real need and not on the basis of a fixed medical plan (as before their inclusion in the trial).

TOLERABILITY

No evidence of side effects caused by the intrarticular and periarticular injection of COLLAGEN KNEE. RESULTS

The results of the therapy are shown in Tab. 1. These data highlight that very good and good results have been registered in 9 patients (53%), all of them being affected by mild or moderate arthrosis while satisfactory results have been registered in 5 patients suffering from mild and moderate arthrosis. On the other hand, for 3 patients no improvement has been noticed and they were part of the Group severe arthrosis.



Tab. 1

It has to be highlighted that the 3 patients not benefiting of any improvement were in the higher bracket age, and have been affected by a severe arthrosis for more than 6 years.

- Only these 3 patients needed the conventional (their usual before this treatment) pharmacological therapy. Moreover, it has to be mentioned that 2 out of these 3 patients were listed to undergo a surgical intervention to replace their knee, while 1 out of 3 (the oldest) already underwent a prosthesis surgery concerning the other knee.
- Very good and satisfactory results have been registered in 82% of the patients. We believe these positive results are due to COLLAGEN KNEE, mainly to the peculiarity to improve joint cartilage trophism and the trophism of tissues containing collagen (crossed ligaments, collateral knee ligaments, articular capsule, tendons) of the morpho-functional unit making up the knee.

MILD AND MODERATE GONARTHROSIS THERAPY WITH THE MEDICAL DEVICES: COLLAGEN KNEE + COLLAGEN POLY

Authors: Hermann G.F., Rivkina T., Ruocco A.
Responsible of the trial : Hermann G.F. - Republic of S. Marino

Patients
10 patients have been treated (7F; 3M), aged 45 - 60 years, divided into 2 Groups (Group 1 = 4 patients = mild symptomatology; Group 2 = 6 patients = moderate symptomatology).
Pathology:
Femoral and tibial chronic-degenerative pathology, mild and moderate patellar
pathology. Exclusion criteria:
Lesions concerning bones, menisci, and
ligaments. Symptomatology:
Pain: 1) at rest; 2) during knee movements and functional limitations in flexion and extension.
Treatment:
10 sessions, once a
week. MDs used:
Medical device: MD KNEE 1 vial + MD POLYARTHRITIS 1 vial (cocktail = 4
ml). Trial method:
- Pain evaluation (by means of the VAS = Visual Analogic Scale, 1-10)
- Evaluation of the articular functionality in flexion and extension by means of the numeral goniometric scale; *range* in flexion-extension = 0° / 45° / 90°. The 10 patients included in this trial have been divided into 2 Groups (Group 1; Group 2) on the basis of the symptomatology severity measured during the first clinical examination.

Group 1 (mild symptomatology)
(10 sessions)

Patient		Pain			Articular range of flexion -extension		
Name	Age	Before	After	Difference	Before	After	Difference
P.A.	45	5	2	3	55°	80°	25°
C.A.	60	6	3	3	40°	75°	35°
G.C.	57	6	2	4	50°	90°	40°
F.L.	58	7	2	5	35°	75°	40°
Average		6	2.25	3.75	45°	80°	35°

Group 1: 4 patients suffering from a mild degenerative pathology.
Good results both for pain and articular functionality.
The alteration in the articular range (difference between the evaluation before and after) is not affected by the patient's age. The average difference of the pain scale (VAS) is 3.75 while the average difference of the articular range of flexion-extension is 35% that is +78% compared to the initial value.
Group 2 (moderate symptomatology)
(10 sessions)

Patient		Pain			Articular range of flexion -extension		
Name	Age	Before	After	Difference	Before	After	Difference
P.G.	64	8	6	2	30°	65°	35°
G.A.	61	7	5	2	45°	65°	25°
T.A.	62	6	4	2	55°	70°	15°
F.C.	59	7	5	2	50°	60°	10°
B.D.	64	7	5	2	55°	76°	20°
G.U.	65	8	6	2	60°	76°	15°
Average		6.8	4.8	2	49°	68.3°	20°

Group 2: 6 patients suffering from a moderate degenerative pathology.

The result on pain symptomatology and on articular functionality is good.
The alteration in the articular range (difference between the evaluation before and after) is not affected by the patient's age. The average difference of the pain scale (VAS) is 2 while the average difference of the articular range of flexion-extension is 20° that is +40.8° compared to the initial value.

CONCLUSIONS
From this clinical trial, it emerges:
All the patients included have been helped by the periarticular infiltration of COLLAGEN KNEE + COLLAGEN POLYARTHRITIS;
The best results have been registered in patients affected by mild gonarthrosis;
The treatment is well tolerated and no relevant side effect has been registered.