

Testing with pulsed and continuous emission Ultrasounds

Clinical trial for serious pathologies of the
musculoskeletal apparatus treated by electro-medical
ultrasound device Sirio

Appendix A

Dr. Cristiano Cecchetelli, Surgeon specialized in Sport Medicine,
Sonographer, Traumatologist

Dr. Emanuel Paleco, Biologist with Master degree in Sport Science,
Electro-medical Technologies, Nutrition

Results update

Six months after the issuing the first results of the clinical trial we sum up the new results achieved with the electro-medical device Sirio.

We have tested the effectiveness of Sirio on a group of 50 patients, aged between 18 and 70, both males and females, with musculoskeletal problems in acute, sub-acute and chronic phase. We have tried to confirm the antalgic and inductors effects of the inflammatory response, described in the literature of the preliminary study.

Especially we have tested 21 patients with chronic pathologies and 29 patients with acute and sub acute pathologies.

Each session lasted on average 15-20 minutes; the type of hand probe to be used and of the ultrasound power output employed have been evaluated each time from patient to patient according to the area to treat, to the pursued physical effect and to the compliance-tolerability showed by the patients.

After each session the following data have been gathered in appropriate forms: the type of treatment carried out (probe used, time and power output), the immediate post treatment effects, as subjective sensation of diminishing painful symptomatology reported by the patient, as objective improvement of the joint functionality and as objective reduction of a joint oedematous swelling.

The intervals among treatments and the patient enrollment criteria were the same described in the clinical trial.

Among the chronic pathologies the most treated problems were: lumbar sciatica pains, cervical pains, rotator cuff impingement syndromes, knee, heel and ankle chronic pains.

Among the acute pathologies the most treated problems were: muscle distractions and contractures, tendon pains and sprains.

Achieved results

The results achieved have been evaluated taking into consideration:

- the sensations reported by the patient of reduction of the algic symptomatology;
- the objective improvement of the articular functionality;
- the objective reduction of edemas.

	Acute and sub acute problems Pathology and area	N° of sessions	Clinical response	Evaluation and result
1	Tendinopathy with lesion of the right shoulder supraspinatus tendon	4	+ antalgic effect + tissue regeneration	++
2	Tendinopathy with lesion of the right shoulder supraspinatus	4	+ antalgic effect + tissue regeneration	++
3	Meniscus pain of the anterior horn External meniscus right side	6	+ antalgic effect + antiphlogistic effect	++
4	Left ankle sprain	6	+ appearance of the hematoma + algic reduction	++
5	Left ankle sprain	3	+ appearance of the hematoma - algic reduction	+-
6	1° degree muscle distraction strain involving the right great adductor	6	+ antalgic effect + tissue regeneration	++
7	Meniscus pain of the anterior horn External meniscus left and right sides	6	+ antalgic effect + antiphlogistic effect	++
8	Tendon pain of the right epicondyle	6	+/- slight improvement	+/-
9	Heel pain, right foot	4	+ antalgic effect	++
10	Enthesitis of the patellar tendon, right knee	6	+ appearance of the hematoma + algic reduction	++
11	Muscle strain, right pectoral major (upper lateral part)	5	+ antalgic effect + tissue regeneration	++
12	Bilateral Achilles tenosynovitis	6	+ appearance of the hematoma + algic reduction	++
13	1° degree muscle injury, Right medial gemellus muscle	8	+ antalgic effect + tissue regeneration	++
14	Left ankle sprain	8	+ prompt restart of sport activity	++
15	1° degree muscle injury, Sartorius muscle, right thigh	10	+ antalgic effect + tissue regeneration (ultrasound scan)	++
16	Heel pain, Left and right foot	9	+/- slight improvement	+/-
17	Rotator cuff, right shoulder	3	+/- improvement in the mobility	++
18	Rotator cuff, right shoulder	8	+ improvement in the mobility	++
19	Impingement syndrome, right shoulder	8	++ clear articular improvement	++
20	Sub acute tendinopathy, flexor tendon of the right hand	4	+ Edema reduction and recovery of functionality	++
21	Insertion hamstring tendinopathy	6	Pain reduction and functionality improvement in the beginning, then stable clinical picture	+/-
22	2° degree muscle injury (sub acute)	4	Pain reduction	++
23	Posterior tibial tendinopathy and plantar fasciitis	6	-- unchanged clinical picture of the posterior tibial tendon, + slight symptom reduction on the fascia	--
24	Chronic Achilles tendinopathy (acute phase)	4	Edema reduction, partial pain reduction	+/-
25	2° degree muscle injury	3	Recovery of mobility and hematoma reduction	++

26	1° degree muscle injury	4	Pain reduction	++
27	Pes anserine tendinopathy	6	Pain and edema reduction during the first week followed by a gradual recovery of functionality with the rehabilitative therapy	+ -
28	Knee sprain with meniscus pain	5	Pain and edema reduction, improvement in the articular mobility	++
29	Lumbar contracture	1	++ Pain reduction	++
	Chronic problems Pathology and area	N° of sessions	Clinical response	Evaluation and result
30	Lumbar sciatica	5	+ + antalgic effect	++
31	Arthritis, right knee	4	+ antalgic effect + articular mobility	++
32	Complete injury of the supraspinatus, infraspinatus and subscapular tendinopathy	4	+ + antalgic effect	++
33	Lumbar sciatica	4	+ + antalgic effect	++
34	Tendinopathy of the insertion of infraspinatus	4	+ + antalgic effect	++
35	Meniscus pain, right knee	5	+ antalgic effect + articular mobility	++
36	Arthrosis, right shoulder	2	+ + antalgic effect	++
37	Hip arthrosis	2	+ + antalgic effect	++
38	Lumbar sciatica	2	+ + antalgic effect	++
39	Cervical pain	3	+ + antalgic effect	++
40	Lumbar sciatica	2	+ + antalgic effect	++
41	Lumbar sciatica	6	+ + antalgic effect	++
42	Arthritis, right shoulder	4	+ - antalgic effect	+ -
43	Lumbar discopathy	6	+ - antalgic effect	+ -
44	Rotator cuff arthritis	4	+ antalgic effect - articular mobility	+ -
45	Cervical pain	4	+ - antalgic effect	+ -
46	Cervical pain	4	+ - antalgic effect	+ -
47	Cervical pain	6	+ + antalgic effect	++
48	Lumbar sciatica	2	+ + antalgic effect	++
49	Rotator cuff arthritis	4	+ antalgic effect - articular mobility	+ -
50	Cervical pain	6	+ + antalgic effect	++

Number of treated patients: 50 (21 in chronic phase and 29 in acute and sub acute phase); total number of treatments: 230.

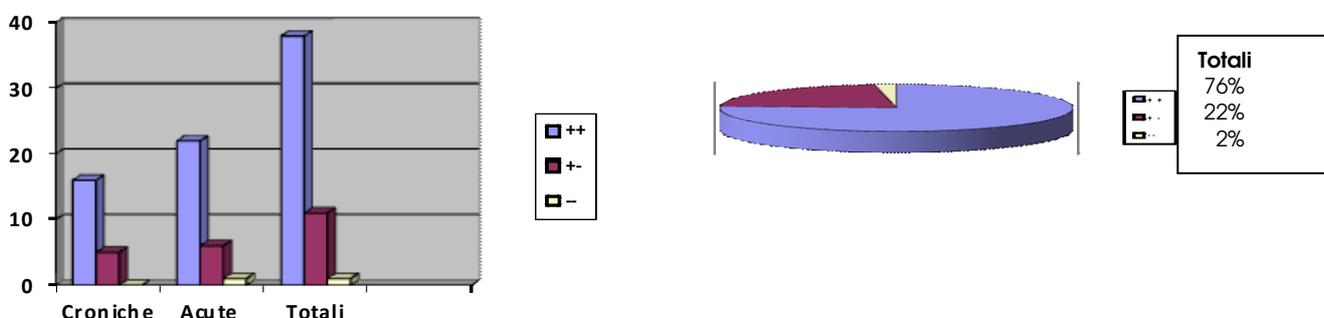
The treatments were divided in effective(++), if the problem were solved, partially effective (+-), if the problems were partially solved, and not effective(--).

Number of patients with chronic problems: 21 divided in 16(++) and 5(+ -)

Number of patients with acute and sub acute problems: 29 divided in 22(++), 6(+ -) and 1(--).

Total number of patients: 50 divided in 38(++), 11(+ -) and 1(--).

Average number of treatment per patient= $240/50= 4.8$ treatment/pt.



Conclusions

According to the results achieved, Sirio has been confirmed to be an effective therapy for some acute and sub acute affections (which are reported above) of the musculoskeletal system. Besides it has proved to be equally effective even on chronic problems achieving an immediate result and performing its antalgic effect since the first treatment, without produce important side-effects.

In the light of these results the study will continue with new patients in order to confirm with more numerous scientific evidences Sirio effectiveness in treating acute, sub-acute and chronic problems of the musculoskeletal system.