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Contents

The affect of MLS therapy on nerve conduction parameters in developing diabetic sensory peripheral neuropathy.

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ABSTRACT

The MLS laser is composed of an 808nm continuous emission laser and a 905nm pulsed emission laser that are synchronized. The purpose of this study was to determine the effect of the MLS laser on the injured tibial and peroneal nerves in diabetic sensory neuropathy. The sural nerve was chosen as an untreated control nerve.

A controlled prospective study was performed on ten patients with documented type 2 diabetes and peripheral sensory neuropathy. Nerve conduction parameters were determined prior to therapy and reevaluated post therapy. The course of therapy was three weeks. F-wave chronodispersion (Fc) measurements at the completion of the study showed significant improvement with this therapy. Peroneal Fc went from 8.99ms to 6.19ms (p=.015). Tibial Fc went from 10.30ms to 6.97ms (p=.001). The MLS laser therapy produced objective improvement in nerve function for persons with developing diabetic sensory neuropathy.

INTRODUCTION

As the prevalence of diabetes mellitus continues to rise throughout the world, so do the complications associated with this disease. Neuropathy is a common and serious complication associated with diabetes. The peripheral sensory type of diabetic neuropathy (DPN) is implicated as a causal factor in the development of foot ulcerations, infections and amputations. The loss of sensation in DPN has been shown to be a key component in the formation of foot ulcerations [1]. DPN is part of a triad of neuropathy, deformity and trauma that predispose the individual to pedal ulceration. Removal of one or more of the causal pathways is a goal in the prevention of foot ulcer development and healing of existing wounds [2]. In the United States, the cost associated with treating the sequelae of diabetic neuropathy is in the billions of dollars [3]. Often research and treatment are aimed at providing symptomatic pain relief. However, sensory restoration, not pain relief, is needed to interrupt the causal pathway leading to foot ulceration in DPN. Novel treatments have been tried that attempt to provide healing of the injured peripheral nerve. Subjective responses to these treatments have been published. Unfortunately, little objective evidence of reparation of the peripheral nerve in response to treatment has been demonstrated [4].

The MLS laser is a novel treatment for a variety of maladies causing pain and inflammation. The MLS laser is characterized by an 808 nm continuous emission laser and a 905 nm pulsed emission laser that are synchronized. In vitro and in vivo research has shown a beneficial effect of this technology on peripheral nerve injury [5]. Nerve conduction studies (NCS) are an objective measurement of peripheral nerve function. This controlled prospective pilot study was devised to look at the effect of the MLS laser on NCS parameters in developing DPN.

MATERIALS AND METHODS

Study subjects were taken from a cohort the author previously studied regarding the characteristics of developing diabetic sensory polyneuropathy [6]. 10 subjects were enrolled in this MLS laser pilot study.

Prior to inclusion in the study, subjects completed a subjective neuropathy screening questionnaire which was a modification of the Michigan neuropathy screening instrument. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Local IRB approval was obtained for the study design and informed consent was obtained from all subjects.

Exclusion criteria for the group included

any evidence of coronary artery disease or peripheral arterial disease including past surgical or medical intervention, claudication symptoms, rest pain or ischemia associated ulceration history. Exclusion criteria also included any disease diagnosis that may cause peripheral nerve dysfunction. The list of diseases were: thyroid disorders, vitamin B12 or folate deficiency, seronegative or seropositive spondyloarthropathy, hepatic or renal disease, lumbosacral pathology, toxin exposure including chemotherapeutic agents, familial polyneuropathy, any existing diagnosis of neuromuscular disorders, history of chronic alcohol abuse, previous medical or surgical intervention for peripheral nerve pathology or previous back or extremity surgery.

Inclusion criteria for the experimental group included a mandatory diagnosis of type 2 diabetes for less than 10 years prior to the test date. Subjects additionally had to be willing to discontinue their medications for symptomatic treatment of neuropathic pain for twenty-four hours prior to sensory testing. All included subjects provided pertinent medical histories and laboratory work along with their list of prescription and over-the-counter medications. All ten subjects were diagnosed with DPN according to the guidelines from the 1988 San Antonio Joint Consensus Statement requiring an elimination of confounding factors with a multiplicity of signs and symptoms. Additional factors monitored included age, height, weight, BMI and hemoglobin A1c.

NCS was performed on the tibial, peroneal and sural nerves of the left lower extremity. A single certified technician administered all of the testing. Testing was performed according to the manufacturer's instructions for the Neurometrix® NCS equipement. The tibial and peroneal nerves were treated with the MLS laser and the sural nerve

INDIVIDUAL PRE AND POST TREATMENT NCS RESULTS

#	1	2	3	4	5	6	7	8	9	10	Mean	p =	Ref. range
Ht	65	64	61	60	65	72	66	65	70	71	66		
Sex	F	F	F	F	F	M	F	F	M	M			
Age	58	82	64	39	64	63	74	39	64	49	59.6		
BMI	31.6	25.7	46.1	24.4	33.3	29.8	29.0	22.6	33.7	30.4	30.7		<25
A1c	7.8	6.3	11.3	11.0	7.1	7.7	6.8	7.0	6.9	6.1	7.8		4.0-5.7
pPFc	4.73	9.77	A	A	2.93	8.59	15.56	9.85	14.88	5.59	8.99		
3PFc	0.43	10.16	6.64	7.03	0	0.98	12.77	6.96	12.96	5.26	6.19	0.015	<18.05
pTFc	12.11	4.30	A	6.25	6.45	14.84	16.80	10.16	16.48	4.98	10.30		
3TFc	8.40	1.76	A	2.54	6.05	9.57	10.62	6.20	12.41	5.15	6.97	0.001	<14.49
pPA	1.42	2.79	0.25	1.84	1.41	3.67	0.44	2.26	0.96	1.60	1.67		
3PA	2.61	2.68	1.03	1.85	0.97	3.51	0.74	2.12	1.14	1.67	1.83	0.30	>1.15
pTA	4.53	2.54	A	3.04	2.63	3.04	2.88	2.41	2.90	4.74	3.19		
3TA	3.98	3.87	A	3.00	2.54	2.67	3.02	3.66	2.77	4.64	3.35	0.49	>1.41
pSV	42.73	A	A	A	50.50	46.29	A	43.66	38.70	57.84	46.62		
3SV	39.68	A	A	A	46.29	42.73	A	45.82	34.56	48.80	42.98	0.24	variable
pSA	6.09	A	A	A	4.92	9.27	A	2.22	6.04	1.76	5.05		
3SA	5.08	A	A	A	7.81	10.48	A	1.80	5.58	7.95	6.45	0.34	>3.39

Legend:
(subject number),
Ht (height inches),
BMI (body mass index),
A1c(hemoglobin A1c),
pPFc(pre treatment peroneal Fc),
3PFc(post treatment peroneal Fc),
pTFc (pre treat-ment tibial Fc),
3TFc (post treatment tibial Fc),
pPA (pre treatment peroneal CMAP),
3PA (post treatment peroneal CMAP),
pTA(pre treatment tibial CMAP),
3TA(post treatment tibial CMAP),
pSV(initial sural CV),
3SV(3rd week sural CV),
pSA(initial sural ampli-tude),
3SA(3rd week sural amplitude),
Ref. range(normal reference range),
A(absent).

was not treated. In this way, the sural nerve acted as an internal control.
Treatment was administered three times per week for 3 weeks. Each treatment session consisted of 1.50 J/cm2 (2.5 min) at the tarsal tunnel, 1.5 J/cm2 (2.5 min) at the fibular neck, and 4.00 J/cm2 at the dorsal foot. NCS parameters were taken prior to the first treatment and immediately following the final treatment. Statistical analysis was computed with mean, standard deviation, paired t-testing and p-value computation.

RESULTS

All subjects completed the full course of therapy and returned for post study NCS evaluation. None of the study subjects reported any adverse reaction to the therapy.
The means are as follows: age 59.6 years (39-82), height 66 inches (60-72), weight 191 lbs (125-252), A1c level 7.8% (6.3-11.3). All ten subjects had a diagnosis of type 2 diabetes. Seven subjects were female and three were male. None of the enrolled subjects took medication for pain.
Individual results are reported in table I. F-wave chronodispersion (Fc) for the peroneal nerve pre treatment was 8.99ms. Post treatment the Fc was 6.19ms yielding a p- value of .015. Fc for the tibial nerve was 10.30ms pre treatment and 6.97ms post treatment. This yielded a p-value of .001. The amplitudes (CMAP) of the peroneal and tibial nerve pre and post treatment did not reach a $p<.05$. Similarly, the p values for the untreated sural nerve (CMAP and conduction velocity (CV) were followed) did not reach a $p<.05$. The sural nerve CMAP and CV was not obtainable 40% of the time leading to less reliable evaluation; however, the CVs were generally slower at the end of the study and the CMAPs were slightly increased.

DISCUSSION

NCS are objective, quantitative and reproducible evaluations of the function of peripheral nerves. Reproducibility of nerve conduction requires consistency of methods, including electrode locations, distances, and temperature [7]. These parameters are well controlled and permit reproducible results with the Neurometrix® testing equipment [8]. F-wave latencies are the most reproducible, with only a 2-3% variation. CMAPs have the lowest reproducibility (10-15% variation) and CV and distal latency are intermediate (4-7% variation) [9]. F-waves are the most sensitive measure of diabetic neuropathies [10].
Fc is a measure of the variability of conduction in different axons in the whole nerve. This makes Fc uniquely useful for detecting even mild abnormalities. For the relative diagnostic sensitivity of all F-wave parameters, Fc is the most often abnormal parameter. Fc is ideally suited for monitoring the treatment of DPN [11]. F-waves have been used as frequently as every two weeks to follow peripheral nerve healing in previously published studies. In this study, tibial ($p=.001$) and peroneal ($p=.015$) Fc improved significantly ($p<.05$) over 3 weeks. This improvement is much greater than the published 2-3% variation. This finding is indicative of nerve healing.
CMAP provides an indication of the number of functioning axons in a nerve and the amount of muscle that is still innervated. CMAPs and CVs are dependent upon the persistent myelinated fibers in the nerve conducting the applied stimulus [7]. An injured nerve will heal at approximately 1mm per day. Because of the relatively slow healing of the peripheral nerve, no change in the CMAP or CV over the course of a 3 week treatment is expected. The length of these nerves being tested would lead one to expect months not weeks of healing before the CMAP or CV would be profoundly affected. While CMAP did increase in both the tibial ($p=.49$) and peroneal ($p=.30$) nerves, it was within the reported 15% variability associated with this parameter.
The sural nerve served as the control in this study. Sural nerve CV did trend slower, but fell within the 7% published variation rate. In the same way, the sural CMAP results pre and post study fell within the published 15% variation rates. The control was statistically unchanged. Previous evaluation of sensory loss in DPN found the axonal pathology is not entirely length dependent and not purely of metabolic cause. An anatomic component for sensory loss was implied [6]. The anatomic regions chosen for application of MLS laser therapy were the tarsal tunnel, fibular neck region and dorsal foot. These regions represent anatomic sites predisposed to peripheral nerve entrapment and damage in DPN [12,13,14].
The small sample size, short period of treatment and immediate follow up are limitations of this pilot study. Future research should look at variable treatment parameters with the MLS laser and the effect of this promising therapy over a longer period of time. Evaluation of the NCS parameters over months instead of weeks should yield more dramatic improvements in the CMAP and CV of the treated nerves if regeneration and healing of the nerve fibers persists.

CONCLUSIONS

MLS laser therapy applied to the tibial and peroneal nerves in persons with documented DPN will lead to objective improvement in nerve function as demonstrated by NCS evaluation. A reasonable expectation is that this improvement in function will lead to improved sensibility in the feet. Improved sensibility interrupts the causal pathway leading to ulceration, infection and amputation. In this pilot study, MLS therapy appears to be uniquely capable of healing the injured nerve in DPN and shows great promise in the battle against the devastating sequelae of this disease.

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The MLS therapy in postural myofascial pain and postraumatical of the neck.

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ABSTRACT

Myofascial pain is a common cause of chronic syndromes, not only of orofacial district, but also any other district; such painful syndromes often mimic other disorders, in relation to their location, and are still often be denied or underestimated. Myofascial pain is usually in an area known as Trigger points (TrPs). Laser therapy has been often proposed for the treatment of pain and disability management of various disorders. In comparison to the classical laser therapy, MLS therapy has several special characteristics: it combines laser emissions with two wavelengths (808 and 905 nm), one in the continuous mode (808 nm, with a maximum power of 1W), and the other one in a pulsed mode (905 nm, with a peak power of 25 W). The advantage of this laser system consists in better propagation inside the tissue respect to other wavelengths and in the possibility of increasing the emitted energy. The aim of the study was to analyze the efficacy of MLS in patients with myofascial pain. 30 patients with myofascial pain in the cervical region were enrolled in the study. The patient's evaluation included Visual Analogue Scale (VAS) and Neck Pain Disability Questionnaire that is a multidimensional questionnaire assessment of pain, disability and cognitive-behavioural aspects linkable to cervicalgia. The symptoms of pain was evaluated through the VAS scale, at the end of each session of MLS therapy and after one month after the end of treatment. Pain relief was good in both cases. MLS therapy has proven to be very effective in post traumatic myofascial pain. Myofascial postural pain needs a series of actions such as postural gymnastics that might improve the result.

INTRODUCTION

Myofascial pain is without a doubt the most common cause of chronic syndromes, not only of orofacial district, but also any other district. Such painful syndromes often mimic other disorders, in relation to their location, and are still often be denied or underestimated. Myofascial pain is usually in an area known as Trigger points (TrPs), a hypersensitive point within a skeletal muscle, painful to palpation and compression [1-2] . The TrP arise from cycles of sarcomerical contractions with increased metabolic activity and local ischemia. These phenomena are maintained by the release of various substances such as lactate, prostaglandin E2, bradykinin, substance P, potassium and hydrogen ion and initiated by an excessive release of acetylcholine [3-4]. The pathophysiology of myofascial pain in the orofacial complex is being connected to a wide range of factors, which may cause or facilitate the dysfunction of muscle fibers or overlap with it: among them are the malocclusions, physiological factors; changes in posture (e.g. in front of the computer, watching tv, or even sleeping), past trauma (neck distorsion for exemple), reumatological, endocrine, nutritional disorders, anaemia, avitaminosis, stress [5-6].

In comparison to the classical laser therapy, the MLS therapy has several special characteristics: it combines laser emissions with two wavelengths (808 and 905 nm), one in the continuous system (808 nm, with a maximum power of 1W), and the other one in a pulsed system (905 nm, with a maximum power of 25 W) [7-8].The advantage of this combination consists in better penetrability and in the possibility of increasing the emitted energy. Therefore, the pulsing system combines the stimulating effect on microcirculation with the advantage of an increased top power, but they have a low average energy, and the combination to a continuous laser wave secures an appropriate energetic intake. The synchronizing of the two wavelengths may transfer the energy towards the cellular sublayer in a more efficient manner than the emission of a single component. Thus, the MLS impulse has bigger antiphlogistic, bio-stimulating and analgesic effects than

a continuous emission or a pulsed one, used separately or in combination, but unsynchronized. Enjoying the advantage of a bigger divergence of the diodes irradiation cones, the multidiode laser may have a spot of big dimensions – 50 mm. its wavelength and the energetic transfer method in relation to time.
MLS therapy creates the conditions for the achievement of numerous therapeutic effects, as it has an anti-inflammatory, anti-edematous, and analgetic action, which eventually leads to rapid ameliorations [9-10].

MATERIALS AND METHODS

30 patients with myofascial pain were selected. 14 posttraumatical and 16 postural. 18 males and 12 females, aged between 23 and 71 years (mean = 45).
The diagnosis of cervical distortion was formulated according to the standard procedure of spine radiography. In some cases the state of patients was evaluated through dynamic radiography and MRI of the region.

Exclusion criteria were: therapy with oral anticoagulants, non compliant patients (cognitive impairment or psychiatric disorder), skin diseases. The patients' evaluation included history and clinical examination, VAS (11-12) and Neck Pain Disability Questionnaire [13].
In many diseases, predominantly post-traumatic and degenerative affecting cervical spine is important to assess the presence and degree of involvement of cervical nerve structures. In the presence of a cervical pain of possible neurological origin you can use different clinical trials that indicate whether the relevant radicular pain (i.e. from a nerve root), or trunkular (i.e. from a nerve trunk) and if there are signs of a mechanical compression of the root itself. So we used some test:
Foramen Compression Test. Indicates the compression of one or more cervical roots at the level of the foramen of conjugation. Running with the patient sitting tilt your head to one side and the examiner applies pressure on the head with both hands. It is good when the pressure causes a pain radiated to upper limb on the side where the head is flexed.
Test of distraction. The patient sitting, the examiner raises his head with both hands (a hand under her chin and the other below the occiput) with a traction. It is good when traction exerted reduces pain radiated to upper limb.
Test of the brachial plexus stretching. Patient supine, the examiner fix the shoulder of the limb to be tested in JAWS, abduce and extends the arm holding the elbow bent, the forearm supine and extending the elbow. When the final position induces a pain radiated to upper limb is significant. The test is primarily a radiculopathy on the roots C5-C7 or a problem at the expense of the cervical plexus. To increase the sensitivity of the test you may ask the patient to turn his head from the side while rotating to the side looked reduces symptoms. The test is very effective and is almost always positive whenever there is the slightest been irritant of the roots. So it is especially useful in clinical cases where a shoulder pain radiated, is moderately mild cervicalgia coexists and you are unable to resolve if the disease is attributable to cervical or scapular-humeral belt.

Depression Test of the shoulder. The patient is sitting, the examiner with one hand pushing down on the shoulder and the other tilt the head to the opposite side. The Test is positive when the action produces ipsilateral cervical pain radiated to upper limb.

SCORE	INTERPRETATION OF THE OSWESTRY LBP DISABILITY QUESTIONNAIRE
0-20% Minimal Disability	Can cope w/ most ADL's. Usually no treatment needed, apart from advice on lifting, sitting, posture, physical fitness and diet. In this group, some patients have particular difficulty with sitting and this may be important if their occupation is sedentary (typist, driver, etc.)
20-40% Moderate Disability	This group experiences more pain and problems with sitting, lifting and standing. Travel and social life are more difficult and they may well be off work. Personal care, sexual activity and sleeping are not grossly affected, and the back condition can usually be managed by conservative means.
40-60% Severe Disability	Pain remains the main problem in this group of patients by travel, personal care, social life, sexual activity and sleep are also affected. These patients require detailed investigation.
60-80% Crippled	Crippled Back pain impinges on all aspects of these patients' lives both at home and at work. Positive intervention is required.

Interpretation of disability scores (from original article) / Fairbanks CT, Couper C, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire Physio Ther 1980;66:271-273./

PROTOCOL	
N° of session	10
Time for single session	3min. (first 3-4 session) 3min. (the other session)
PARAMETER OF TREATMENT	
Frequency	700Hz (first 3-4 session) 1500 Hz (the other session)
Density of the dose	3,0 J/cm^2 . (first 3-4 session) 3,5 J/cm^2 (the other session)

Table 1 Protocol of treatment

VAS	pre MLS	After MLS	at 30 days
Myofascial pain postraumatical	8	2	2
Myofascial pain postural	7	4	2

Table 2 - Vas before and after MLS

BEFORE MLS	AFTER 30 DAYS
20 patients Moderate Disability	
10 patients Severe Disability	30 Minimal Disability

Table 3 - Score of Neck Pain Disability Questionnaire

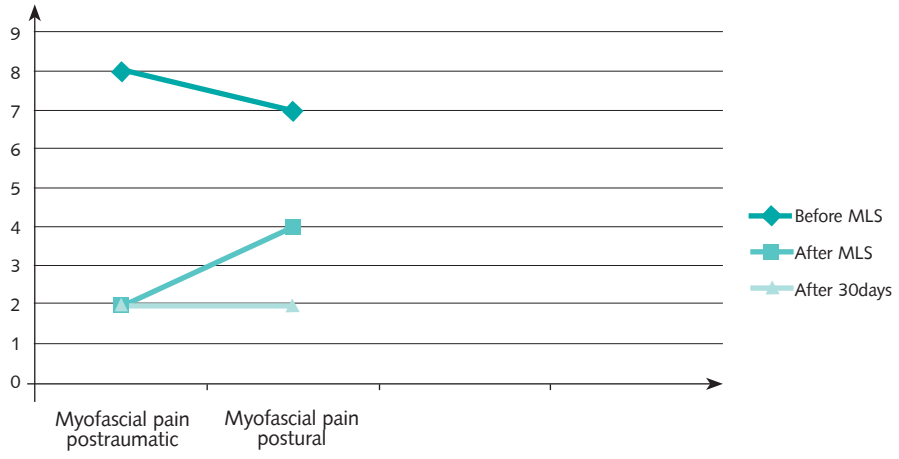

Fig. 1 - The graphic of the results

The assessment of the results was based on quantification of pain with the Visual analogue scale (VAS), on the objectivity, on the amount of pain medications-anti-inflammatories hired and hours of nighttime sleep, dizzying descriptive symptoms. The symptoms of pain was evaluated through the VAS scale, at the end of each session of MLS therapy and after one month after the end of treatment.

Finally was used Neck Pain Disability Questionnaire, as validated in Italian language, such as multidimensional questionnaire assessment of pain, disability and cognitive-behavioural aspects linkable to cervicalgia.

TREATMENT

We use a MLS laser device (M6 ASA-Arcugnano, Vicenza). The treatment performed five time in the week and we applied the original program of the laser. The laser is very simple to use especially on the neck have disomogeneos field. The table 1 reproduce the protocol.

RESULTS

All the patients had a good response to the MLS therapy. The choice of two doses in treatment was dictated by the possible exacerbation of symptoms the first sessions. The figure 1 and the table 1 show the results.

Neck Pain Disability Questionnaire:

Before the treatment there were 20 patients in Moderate Disability (20/40%) the other in Severe Disability. At 30 days after the MLS therapy all the patients go to the Minimal Disability score.Tab.2

15 patients (50%) had positive the tests for the neck pain (Foramen Compression Test, Test of distraction, Test of the brachial plexus stretching, Depression Test of the shoulder). After MLS only 3(10%) had the tests positive.

DISCUSSION

The results described in this article is to highlight the effectiveness of MLS Therapy in the treatment of a disease often does not respond to traditional treatments such as myofascial pain. It is extremely important the fact that the application of this method has achieved significant results already after the first four-five sessions of treatment and in all cases the treaties (the initial and not surprisingly slight inhomogeneities in sample found symptoms is due to the different individual response that usually you register in the system-level trauma sympathetic but it is not relevant for the purposes of the goodness of the results obtained, because the metrics chosen are considered the most reliable and secure). The two groups have had a good overall result. The slightly smaller because the postural therapy has solved the symptom but not the cause that is more difficult to control. The association or the continuation with postural might be a solution for better results [14-18].

There are no data on the durability of response but it is assumed that the post-traumatic group have had greater success. It can therefore be concluded that the issuance is used, which differs from that combined only for specifying synchronization MLS, is able to exercise a significantly greater therapeutic effect. The findings of this study show that the specific emissions continue synchronization and MLS pulsed is capable of inducing synergistic enhancement of therapeutic effects and their analgesic anti-inflammatory drug respectively of the two issues and that such expansion do not get with the superposition of two types of issue.

In conclusion, this study shows that the MLS Therapy exerts a significant therapeutic effect for contemporary and synergistic action on both edemigen and inflammatory process on transmission mechanism of pain. This helps to ensure a greater benefit to the patient, and ensures a consistent decrease in stroke treatment. With regard to physical therapy with other principals the answer seems faster, with undoubted advantage in drug consumption and recovery of hours of sleep.

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Application of MLS laser on muscular contracture caused by functional overload in a young athlete - case report.

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ABSTRACT

Myalgic fatigue (or muscular contracture caused by functional overload) is clinically detected as an unpleasant feeling of one or more muscles, that appears within 24 hours after exercise and disappears in 5-7 days. In athletes, often the muscular contracture is not due to pathological alterations of muscle metabolism, but rather to a condition of lack of training, as typically happens at the beginning of the training season or after a period of enforced rest due to trauma or injury. Laser therapy has long been widely used to treat muscle pain and contracture, and recently it has also been proposed to prevent injuries from overwork in athletes. The aim of this study was to evaluate the efficacy of an advanced IR laser system, the MLS laser, in combination with the other components of standard therapy for the treatment of muscular contracture. MLS system is a laser device with special characteristics: it is equipped with synchronized combination of continuous and pulsed emissions. The first one (that may emit also in pulsed mode) with λ=808 nm and maximum power of 1W, the other one with λ=905 nm and peak power of 25W. Here we report the case of a 16 years old athlete in good health state and with no previous muscle injury. The athlete reported a rectus femoris pain after a work of multiple running on 200 meters. After 3 days of MLS treatment, associated with mobilization of the muscle, stretching and eccentric contraction exercise, the athlete reported negative clinical examination for pain and muscle contracture and was available to work with the team. Studies are in progress to confirm our findings increasing the number of cases and also evaluating the efficacy of MLS laser therapy on different types of injury.

INTRODUCTION

Myalgic fatigue (or muscular contracture caused by functional overload) is clinically detected as an unpleasant feeling of one or more muscles, that appears within 24 hours after exercise and disappears in 5-7 days. The diffusely painful muscle is sensitive to palpation and inefficient during exercise. The symptoms are of varying severity and the quantification of exercise intolerance is difficult. The ensuit fatigue protects the muscle against further exercise which might be harmfull.

In athletes, often the muscular contracture is not due to pathological alterations of muscle metabolism, but rather to a condition of lack of training, as typically happens at the beginning of the training season or after a period of enforced rest due to trauma or injury [1].

Muscular contracture begins as a result of a single concentrated physical exercise that exceeds the adaptation of muscle structure, or as a result of series of repeated physical exercises (for example during training at the beginning of a season). Therapy currently in use is composed of instrumental therapy (tecar and/or laser therapy) and a light mobilization of the muscle (cyclette with a low load or tapis roulant at low speed) both aimed at reducing inflammation and at increasing muscle vascularity, all associated with a physiotherapic protocol (stretching and eccentric contraction exercise). During the preseason of ACF Fiorentina young athletes, we used MLS laser therapy in combination with the other components of classical therapy for muscular contracture to assess the benefits of this kind of treatment on prognosis.

Laser therapy has long been widely used to treat muscle pain and contracture, and recently it has also been proposed to prevent injuries from overwork in athletes [2,3].

Although many studies have demonstrated the effectiveness of laser therapy in promoting vascularization through controlled vasodilation [4], reducing pain [5-7] and inflammation [8-10], the results reported in the literature do not allow to draw on clear indications on the therapeutic

efficacy and the appropriateness of application of the different treatment parameters. This variety of results and often conflicting indications is largely due to the equally wide variety of laser sources and treatment parameters used in the studies.

In fact the interaction between laser radiation and tissue is highly dependent on the optical properties of the treated tissue, the characteristics of the source (wavelength, power, continuous or pulsed mode emission) and the treatment parameters chosen (frequency of the pulses, fluence, exposure time). In this study we used as the laser source an MLS laser with near infrared (NIR) emissions and treatment parameters specifically setted for muscle contracture.

MATERIALS AND METHODS

16 years old athlete in good health state and with no previous muscle injury was included in our study. The athlete reported a rectus femoris pain after a work of multiple running on 200 meters in the morning; the muscle appeared painful and contracted in absence of lesions on ultrasound examination. Athlete was treated with a MLS laser device provided by ASA s.r.l. (Arcugnano, Vicenza, Italy). This instrument has special characteristics: it combines the laser emission of two diodes with different wavelengths, one (λ = 808nm) may emit in continuous and in pulsed mode, in the first case with a power P = 1.1W, in the second with an average power Pa = 0.55W and a maximum frequency of 2000Hz. The other one (λ = 905 nm) may emit only in pulsed mode with a maximum frequency of 2000Hz and an average power Pa = 60mW. In pulsed mode, pulse repetition frequencies of the two diodes are the same.

For the treatment we used the following parameters (muscle contracture program): 700 Hz frequency, 2 min exposure, 39,67 J energy delivered by handpiece.

The treatment protocol was always carried out under the threshold of pain reported by the athlete

	FIRST DAY	SECOND DAY	THIRD DAY
Morning	Cyclette 15′ Low resistence Mild tecar-therapy 20′ Laser-therapy (muscle contracture program)	Ultrasound (contracture) Cyclette 20′ Low-mild resistence Tecar-therapy with massage 20′ Laser-therapy (muscle contracture program)	Tecar-therapy with massage 20′ Laser-therapy (muscle contracture program) CPW mode Eccentric contraction exercise: quadriceps 4x10. Eccentric contraction exercise: rectus femoris 4x10. Stretching 30″x5 Run 10′x2 - changes of direction - technique with ball.
Afternoon		Cyclette 20′ Mild resistence Tecar-therapy with massage 20′ Laser-therapy (muscle contracture program) Stretching 30″x3 Eccentric contraction exercise: quadriceps 3x10. Eccentric contraction exercise: rectus femoris 3x10. Stretching of quadriceps and rectus femoris 30″x3	Laser-therapy (muscle contracture program 700 Hz 2 minuti 50% intensità 39,67 J) CPW mode Training with team.

We added to the classical rehabilitation protocol the MLS laser therapy according to this model

RESULTS

The athlete was available to work with the team after 3 days of treatment.

We joined the athlete to the team according to subjective symptoms and to the clinical examination negative for pain and muscle contracture.

DISCUSSION

The prognosis of a muscle contracture is 5-7 days as usually found in clinical experience. The athlete treated according to the new protocol was cured in just 3 days of therapies with no recurrence or new muscle injury. We should note that the injury occurred during the preseason, so the athlete was subjected to treatment twice a day rather than once, as often happens during the season.

However, the result is very encouraging. Studies are in progress to confirm our findings increasing the number of cases and also evaluating the efficacy of MLS laser therapy on different the types of injury.

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Physical treatment of post traumatic gonalgia by NIR laser therapy: a case report.

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ABSTRACT

In this paper we present a case report that refers to a female patient, aged 54, who suffered from post-traumatic knee pain. The clinical case described was part of a clinical trial whose purpose was to investigate the therapeutic effects of NIR laser therapy on knee pain.

The laser source was a Multiwave Locked System (M6 device) provided by ASA s.r.l. (Arcugnano, Vicenza, Italy). The instrument consisted of two assembled laser diodes with synchronized emissions at 808 and 905 nm, respectively. The patient was treated 3 times weekly, for a total of 10 treatments. The patient's pain, both before and after each session, was measured by using VAS scale, in order to evaluate the effect of the laser therapy. The data obtained show that, during the treatment, the patient had a progressive improvement in pain relief. At 60 days follow-up, it was observed that the effect of laser therapy persisted. The results we obtained in this study indicate that, with the chosen laser source (MLS) and treatment parameters, NIR laser therapy had beneficial effects on knee pain.

INTRODUCTION

Gonalgia, or knee pain, is a common problem, which requires medical examinations and treatments, both in sportsman and in non-sportsman [1]. It is a symptom that can be due to many different causes: it can occur in young persons hurting after a distortive trauma (with related joints or menisci lesions), in elderly persons suffering for knee arthrosis, in athletes with an inflamed rotular tendon (jumper knee), in teenagers feeling pain at the tibial apophysis (Osgood - Schlatter disease). More specifically, according to their etiology, the patellofemoral disorders are distinguished with the classification of Merchant [2].

Obviously symptoms can be more or less acute, depending on their gravity, on which structure of the knee has been affected, on the type of pathology which caused gonalgia. In general it is possible to distinguish between acute pain, usually as a consequence of a trauma, and chronic pain.

The difficulties in diagnostic classification of knee pain and subsequent treatment are related to the nonspecificity of subjective and objective symptoms [3].

Since many years, laser therapy has been widely used to control pain in different musculoskeletal conditions. Despite its widespread use, the results of the experimental and clinical studies are conflicting. In particular, relatively few controlled clinical studies on laser therapy applied for the treatment of knee pathologies have been reported and the findings from these studies are also contradictory [4, 5]. The results obtained from the trial of Stelian et al. suggest that laser treatment may be useful in reducing the pain and disability associated with knee osteoarthritis [4]. In contrast, in a double blind, placebo controlled study on the efficacy of LLLT on knee pain, no difference between the actively and the placebo treated groups was detected [5]. Since the results following the application of laser therapy show a significant variability, also according to the laser source and the treatment parameters used, we evaluated the effect of the MLS laser on knee pain. Here, we report the particular case of a female patient, 54 years old, who suffered from severe post-traumatic knee pain.

MATERIALS E METHODS

The patient, a cook, aged 54 years, female, belonged to a group of several patients, males and females of different ages, that were recruited for the trial from our outpatients aid physiotherapy. Patients presented a generalized pain of the knee. Inclusion criteria was based on pathology, pain symptoms reported and treatability with laser therapy. Exclusion criteria were: other physical instrumental therapies, except for electrical stimulation for muscle reinforcement o strengthening of the district considered (ex. femoral quadriceps in pathologies of the knee), as this physical therapy has not analgesic and

biostimulation effect on joint tissues. The patient that we present in this case report turned to us following a post-traumatic knee pain.

Patient was treated with ASA M6 laser device provided by ASA s.r.l. (Arcugnano, Vicenza, Italy). The instrument consist of two assembled laser diodes, with synchronized emissions at 808 and 905 nm, respectively. The diode with = 808nm may emit in continuous mode, with a power P = 1.1W, or pulsed mode with an average power Pa = 0.55W and a maximum frequency of 2000Hz.

The diode = 905 nm is characterized by a pulsed emission with a maximum frequency of 2000Hz and an average power Pa = 60mW.

Therefore, the MLS emission can occur in different modes, according to the operator's choice:

Continuous Mode (Continuous Mode Operation, CW): diode with λ = 808 nm, continuous emission and diode with λ = 905 nm, pulsed emission. Pulsed mode (Pulsed Mode operation): diode with λ = 808nm, pulsed emission with pulses repetition frequency f808 (Max value 2000Hz) and diode with λ = 905nm, pulsed emission with pulses repetition frequency f905 = f808.

When frequency changes, the emission features allow the average power of the 905nm diode emission to change, while the average power of the 808nm diode emission does not change. In fact, when the frequency changes the 808nm diode emission duration changes in proportion, in this way the average power remains the same, while the temporal distribution of the released energy changes. With the same emission time (and spot sizes), the whole energy (808nm + 905nm) changes when the set frequency changes.

In the present case, the following treatment parameters have been applied: 2 min time exposure, 900 Hz frequency, 72,45 J energy delivered.

SCALA VAS										
Session	1°	2°	3°	4°	5°	6°	7°	8°	9°	10°
Pre-therapy pain	4	4	4	4	3	3	2	2	1	0
Post-therapy pain	4	4	4	3	3	3	2	1	0	0

Table I: Visual Analogue Scale (VAS)

Patient was also subjected to a progressive personalized functional rehabilitation, consisting of passive mobilization, assisted or active at natural load.

The protocol consisted in 10 sessions (3 sessions per week) and in the drafting of a specific patient form prepared by ASA S.r.l. and optimized by outpatient of Dr. Caruso.

The patient form reported:

1. the progressive number of session,
2. personal data of patient (personal details, profession, etc...),
3. the beginning and end of sessions,
4. pathology (location and cause),
5. indication of the instrumental tests provided for the initial evalutation,
6. a table for indicating the parameters set during the sessions,
7. a second table for the evaluation of the patient (pain and muscle strength),
8. a section dedicated to the ongoing evaluation
9. diagrams for the anatomical location of the point of treatment.

Treatment was carried out on a Bobath bed, electrically adjustable in height, which made the treatment even more versatile for the use of MLS device which has a swivel head on one arm also adjustable for height and angle.

The room used was dedicated to laser therapy, with doors closed and monitored by the operator. Patient and therapist wore for the entire duration of the session appropriate protective eyewear provided by ASA s.r.l. Where necessary, regions adjacent to the treated area were shielded with charge material (lymph node regions, etc..).

The patient's evaluation was performed during treatment sessions. In each session, the sensation of pain reported by patient, both before treatment and at the end of it, was assessed. Patient was reassessed after 60 days to evaluate the post-treatment course. The evaluation of pain was made through the visual analogue scale (VAS).

PATIENT

Sex, age: F, 54

Profession: cook

Treatment start: 24/5/2011

Treatment end : 4/7/2011

Sessions: 10

Pathology: post-traumatic knee pain

Follow-up: the patient was reassessed 60 days after the end of treatment. Result was the same, except for occasional relapse in their efforts.

RESULTS

The patient subjected to M6 laser treatment showed a marked improvement in knee pain. At the beginning of treatment the patient reported a knee pain that can be placed at level 4 on the VAS scale. During the 10 sessions pain progressively decreased to level 0 (Table 1). At the end of the therapy the patient did not complain of any pain, as well as at 60 days follow-up, except for occasional relapse during intense efforts.

DISCUSSION

Acute or chronic pain, is an unpleasant subjective sensory experience and is the leading cause of functional limitation in patients who have undergone trauma.

Pain may resolve in a few days or may persist over time and then determine actual degenerative tissue anatomy as a result of alterations in the recruitment and muscle control. When pain interest one of the joints of the lower limb, as in the case report, also determines changes of deambulation, posture and functional limitations that affects negatively on the recovery [6, 7].

In the present study, the patient had a marked improvement in the knee pain until the complete disappearance at the end of treatment and at 60 days follow-up.

Possible contributing factors related to the results, such as the absence of work efforts, must be examined. These factors can have favoured the disappearance of pain acutely. The patient performs a job where she needs to maintain an orthostatic position for long periods and submit the knee to intense and continuous efforts.

CONCLUSION

The instrument used in this case report belongs to the group of NIR, class IV laser systems and seems to be very effective in the treatment of pain caused by trauma, also thanks to the in depth effect of biostimulation. Furthermore, activation of the microcirculation and anti-edema action, are effective when pain is predominantly inflammatory.

A further advantage of MLS therapy, is the control of heat produced in the tissues by the treatment. The control of the heat minimizes the contraindications to the use. For these reasons, NIR laser therapy, administered by a M6 laser device, may play an important role in the treatment of acute pain and its effectiveness has been reported by our patient.

Finally, it is hoped a large-scale research to obtain scientifically significant results on the effectiveness of this device in pain syndromes of different tissues.

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High Intensity Pulsed Nd:YAG Laser in painful knee osteoarthritis: the biostimulating protocol.

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ABSTRACT

Laser therapy is a widely used instrumental methodology in the physiotherapy treatment of osteoarthritis pain. High Intensity Laser Therapy (HILT, Nd:YAG laser) in last years proved to be effective in painful Knee Osteoarthritis (KO), due to its high intensity and to the
depth reached by the laser ray. Several HILT protocols are available to treat this condition, in relation to the phase of the disease and to the clinical data of the patient.

Aim of this study was to analyze the clinical efficacy and the safety of HILT, using a biostimulating protocol in patients with symptomatic KO.

34 out-patients with symptomatic KO (II-III Kellgren-Lowrence Scale stage) were enrolled and randomized to treatment (16 patients, Group A) or to waiting list (18 patients, Group B). The study is an open-label, before and after study. The treatment consisted in HILT biostimulating treatment (10 sessions, three time a week) for Group A and no treatment for Group B. The patients were assessed by WOMAC Scale, before treatment (t0), after treatment (t1) and after 4 months (t2). At the same time intervals were assessed the patients in the waiting list.

HILT-treated patients showed a highly statistically significant improvement between t0 and t1 in WOMAC scale, and the improvement was maintained at follow-up (t2), while the patients in the waiting list showed a worsening tendency. No side effect was found in the treated group.

The HILT treated patients showed good clinical results, in pain and functional items. We conclude that this HILT protocol seems a good medical instrument for pain control in KO and for improvement of patient's quality of life.

INTRODUCTION

High Intensity Laser Therapy (HILT) is a powerful laser-therapy, which showed interesting results in osteoarthritis pain treatment [1,2,3,4]. Knee OA pathogenesis is characterized by the combination of flogistic and degenerative aspects, which clinically presents as phases of acute and intense pain over a chronic degenerative background [5,6].

The prevalence of knee pain and of symptomatic knee OA is increasing [7]. The longitudinal, population-based US study (Johnston County Osteoarthritis Project, 2008) conducted on 3.068 participants found that nearly half of the adult's sample will develop symptomatic knee OA, in at last one knee by age 85 years, suggesting similar risks in the general US population. Knee OA is the most frequent form of lower extremity OA and it has a profound clinical and public health burden [8,9]. Disability and functional impairment is mostly determined by pain [10], and pain reduction, together with the control of the disease progression are the two main targets of the therapeutic approach. Among physiotherapy treatments, Low Level Laser Therapy (LLLT) is widely proposed as an effective alternative treatment for arthritis and especially knee osteoarthritis, though there is weak evidence to support EBM recommendation of low level laser therapy for short term treatment of OA [11]. The effects of laser therapy are due to its photo-chemical, photothermal and photo-mechanical actions, and the therapeutic efficacy are related to its antiflogistic, antalgic, antioedema and biostimulating effects [12,13].

In particular the laser's biostimulating effect is due to the facilitation of tissues repair, by increasing the cells metabolic activity and microcirculation activation.

In last ten years high powerful therapeutic lasers were developed. In particular some studies [14,15] indicate that High Intensity Laser Therapy (HILT), a Nd:YAG laser application modality, can be very effective in pain and flogosis control, due to its intense and deep effects [16,17]. HILT Hero 3 is a powerful laser instrument with a pulsed beam and high frequency (wavelength 1064 nm) which reaches very high peak power (1-3 kW).

HILT can provide an homogeneous distribution of the ray into the deep tissue, such as the intraarticular space, and the light intensity is able to activate the main biologic mechanisms involved in antalgic therapy, and likely, in repearing and regenerative therapy. Beyond the photo-thermal effect, which is one of the most important effects in laser-therapy, more complex biological and cellular reactions must be considered [18]. A distinguishing characteristic of HILT is its capability to produce photomechanical effects on the treated tissues, due to the very short duration and the very high intensity of the impulse. This phenomenon can produce important therapeutical effects, because such stimulation can trigger biological signals to promote repair and tissue regeneration, together with vascular and lymphatic system activation: previous researches [18,19,20] showed that Nd:Yag laser radiation leads to cellular cytoskeleton reorganization in endothelial, mesenchimal and connective cells, and to their stimulation to extra-cellular matrix production, similarly to mechanical stimulus. Nd:YAG laser stimulation favours extra-cellular matrix production and its assembly, it induces connective cells differentiation and endothelial layers formation, thus promoting tissue repair processes ("regenerative effect").

In knee painful OA more than one treatment protocol are available with this kind of high intensity laser. It is possible to treat pain, using a specific sequential protocol, applied on the joint, on the surrounding tissue and over the muscle tender-trigger points. This treatment showed interesting results, in knee OA and in other joints problems. [2,3,4,14,15]

AIM OF THE STUDY

The present study was an open-label, before-after clinical trial. The aim was to evaluate the clinical and functional efficacy of the HILT treatment, using a biostimulating protocol, in patients affected by symptomatic knee osteoarthritis.

MATERIAL AND METHODS

Patients. Patients suffering for symptomatic KO were recruited for this trial from outpatients of the Recovery and Rehabilitation Agency (AOU Careggi, Firenze). Patients with symptomatic KO, aged were included. Informed consensus was obtained. Inclusion criteria required the presence of symptomatic KO (following ACR criteria [21]), II-III stade of Kellgren-Lawrence Scale [22] on the radiological evaluation. Exclusion criteria were: therapy with oral anticoagulants, non compliant patients (cognitive impairment or psychiatric disorder), neoplastic pathology, and presence of deep vein thrombosis. The patients' evaluation included history and clinical examination.

Initial assessment (t0), before treatment, included WOMAC Scale [23] The patients were randomized in two groups, following the method of random number table.

Treatment. After randomization the patients underwent two different treatments: Group A was treated with High Intensity Laser Therapy (ten sessions, on alternate days), see Table I, whilst Group B was in the waiting list for the treatment. The treated patients were reassessed at the end of the treatment (t1) and after 4 months (t2). The untreated patients were assessed at the same intervals. HILT technique was performed by manual scansion and contact grip, which is used to treat deep organs. We used linear scansion, according to the knee specific access areas (optical windows). Each session provides maximal fluencies and frequencies (fluency 1430-1780 mJ/cm2; frequency 25-30 Hz), with slow scansion in six optical windows, 500 J/window, 3000 J/session. Data analysis. Data of patients were compared by Student t-Test.

RESULTS

Thirty-four patients, for a total of 41 knees, were included in the analysis. 16 and 18 patients respectively were treated with HILT treatment (Group A) or waiting list (Group B). All the patient but two (one in Group A, and one in Group B) finished the study. Baseline data of the two Groups are explained in table II. Mean age was 65.5 years (range: 46-78) and 67, 2 years (range: 45-80) for Group A and Group B respectively, while the proportion of male (M) and female (F) patient was 6 M, 10 F and 6 M, 12 F respectively. WOMAC Scale values at t0 were 41.4 ±9 (Group A) and 40.5 ±5 (Group B).

At t1 the treated group showed greatly different results in the scales points: Group A changed WOMAC values from 41.4 ± 9 to 17.5 ± 5 ($p < 0.001$), whilst Group B WOMAC values were not varied from 40.5 ±5 to 38 ± 2 (p = n.s.), see Table III. At follow-up (4 months) Group A substantially maintained the improvement, with a slight regression: WOMAC scale showed little but statistically significant variations at t2: 24.8 ± 7, while Group B showed a worsening score (t2 = 43.5 ± 1). WOMAC sub items related with pain, stiffness and function were analysed too, see Table IIIa.

These items showed the same tendency of total WOMAC scale scores (see Table IIIa and Table IIIb). At t2 this results showed a regression, which resulted statistically significant (t2 vs. t1 $p<0.005$), but the improvement between t0 and t2 remained highly significant (see Figure 1). In figure 2 is shown the different course of sintomathology in the treated vs. the untreated patients 99, 8% of the Group A patients were improved and 1 patient (0, 2%) was not varied. At follow-up the clinical effects were maintained in 75% of the subjects, while in 25% there was a regression. No HILT-treated patient showed side effects.

HILT treatment protocol (GroupA): pulsed high power laser, Nd:YAG, λ1064nm, (HIRO 3 ASAlaser), for 10 sessions, on alternate days, biostimulating program. This program is articulated in one phase, with low manual scansion and contact grip. Linear scansion was used, according to specific access areas (optical windows). Each session provides maximal fluencies and frequencies (fluency 1430-1780 mJ/cm2; frequency 25-30 Hz), in six optical windows, 500 J/window, 3000 J/session.

Table I: HILTerapia Treatment protocol

DISCUSSION

The data about HILT efficacy in osteo-articular diseases are increasing [1,14,15, 24, 25, 26]. Our study tested the clinical efficacy of the biostimulating laser protocol. Previous studies demonstrated the significant effects using antalgic protocol, which is technically different, as it uses different manual scansion and doses [1,2,3,4].

Our study showed a relevant short-term efficacy of this technique on knee pain reduction and on stiffness and function improvement. The effect was especially evident at the end of the treatment, where it pertains 99, 8% of the pts., and it is maintained by 75% of the subjects after 4 months.

This intense and powerful treatment, achieved a rapid pain control, in almost all the patients. In respect of previous researches [3,4] this antalgic effect was even more likely and evident.

Nevertheless a percentage of the treated subject (25%) showed a certain regression at follow-up. This data was not predictable in relation to the rationale of the study. A merely speculative explanation could be that photomechanical effect is the main responsible of the antalgic response, but that our treatment duration was not till

	Pats. number	Mean age	sex	WOMAC Scale
GROUP A	16 (21 knees)	65.5±1	10 F, 6 M	41.4 ±9
GROUP B	18(20 knees)	67.2± 3	12 F, 6 M	40.5 ±5

Table II: Groups baseline characteristics

	WOMAC Scale - t0	WOMAC Scale - t1	WOMAC Scale - t2
GROUP A	41.4 ± 9	17.5 ± 5	24.8 ± 7
GROUP B	40.5 ±5	38.6 ±2	43.5±1

Table III:
WOMAC Scales Values at t0, t1 and at the follow-up (t2) of the two Groups

WOMAC	t0	t1	p-value
Total (0-96)	41,4 ± 9	17,5 ± 5	p<0.001
Pain	6,8	3,1	p<0.005
Stiffness	3,9	1,2	p<0.001
Function	30,8	13,8	p<0.001

Table III A:
WOMAC Scale Values (total and sub-items) before treatment (t0), at the end of treatment (t1) in the HILT treated group

WOMAC	t0	t1	p-value
Total	17,5 ± 5	24,8 ± 7	p<0.005
Pain	3,1	4,5	p.n.s.
Stiffness	1,2	2,4	p.n.s.
Function	13,8	16,1	p.n.s.

Table III B:
WOMAC scale Values (total and sub-items) at the end of treatment (t1) and at follow-up (four months)(t2) in the HILT treated Group

WOMAC	t0	t1	p-value
Total	41,4 ± 9	24,8 ± 7	p<0.001
Pain	6,8	4,5	p<0.005
Stiffness	3,9	2,4	p<0.005
Function	30,8	16,1	p<0.001

Table III C:
WOMAC scale Values (total and sub-items) before treatment (t0) and at follow-up (t2) four months) in the HILT treated group

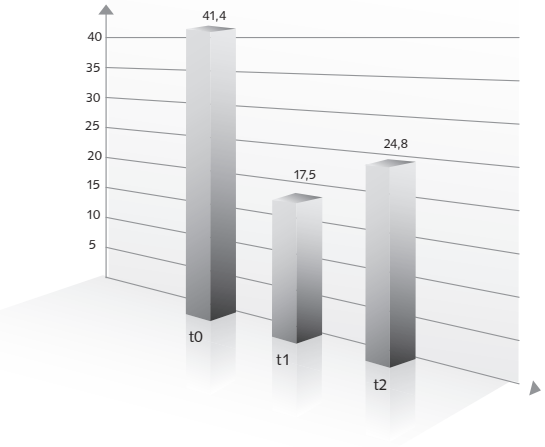

Figure 1: Results of the HILT- treated patients

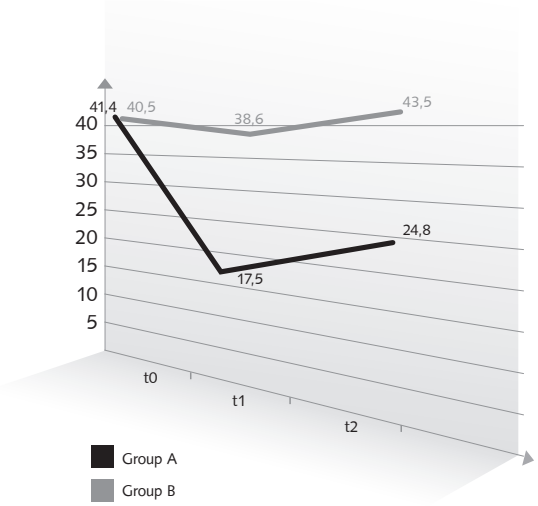

Figure 2: Course of sintomathology in the treated vs. the untreated patients, according to WOMAC scale (Group A: Hilterapia, Group B: no treatment): the untreated group did not improve, rather it got worse.

sufficient to stimulate more permanent cellular reactions, eventually more than ten sessions are needed to reach this result. We are aware that this study has got some limits. Firstly we do not have the prove of the molecular intra-articular effects: we cannot demonstrate the stimulation of the connective cells, but only clinical effects. Secondly it has small numbers of patients and there is not a control group of differently treated patients (i.e. placebo laser therapy).
So the work must go on: as several researches found HILT efficacy, we need to increase the patients population and to find standard therapy programmes regarding the dose and duration of the laser therapy to optimize the treatment.
Different HILT regimes were applied in painful Knee OA, with different doses and duration [1,2,3,4] and it seems that these various HILT therapy regimes were all safe and effective methods in the treatment of knee OA.

CONCLUSIONS

In conclusion, this study revealed that a short-period application of HILT biostimulating protocol is more effective in pain reduction and in functional ability improvement than no treatment in patients with symptomatic knee OA. Thus, HILT can be an important instrument in pain control contributing to the long-term management of chronic painful knee. The study confirms the safety of the technique.

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