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Temperature Controlled High Energy Adjustable Multi-Mode Emission Laser Therapy in the Treatment of the Chronic Low Back Pain

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Abstract

Temperature controlled high energy adjustable multi-mode emission laser therapy (THEAL) is a new physiotherapy method recently introduced in the treatment of musculoskeletal disorders. The first published clinical trials show an excellent clinical response in the treatment oflow back pain (LBP). In view of various protocol modulation modes, we wanted to verify the effect of a protocol that provided contextual administration of different wavelengths.

We administered to twenty patients a treatment that consisted of ten sessions of Temperature controlled High Energy Adjustable multi-mode emission Laser therapy (THEAL) (iLux XP/ Ixyon, Mectronic Medicale, Italy), with the simultaneous delivery of 650nm, 810nm and 1064nm wavelengths.

The patients have been monitored during different follow-ups(FUs)to check the remission of pain, using Visual Analog Scale (VAS) for pain, Roland Score for functional recovery with and OswestryScore for regression of disability. Already at the end of the treatment after 10 days, and at subsequent FUs time at 1, 2, 4 and 12 months, a significant improvement was noticed for all these scores.

These clinical results are consistent with the expected biological effects for each wavelengththat we have administered. The 810nm has a strong affinity for modulating no receptive pain, 650nm wavelengths have a marked anti-inflammatory effect and 1064nm has a decontracting action on muscles.

The possibility to use a High Energy Laser with adaptive modulating emission and thermal control of biological tissue (THEAL) allows an optimized energy delivery with good local compliance. The concomitant administration of these wavelengths would therefore enable action on the various pathogenic noxa: radicular pain, local inflammation and reactive muscle response.

Keywords: Highintensity; High energy; Laser therapy; Low back pain; Wavelength; Thermal control

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Introduction

In recent years, researchers and clinicians have begun administering High Energy Laser therapy in treatment of various musculoskeletal disorders [1-4]. The results were very satisfactory, justifying the interest in deepening the knowledge on this treatment [5]. The first novelty in the use of High Energy (Level) Lasers compared to Low Energy (Level) Lasers lies in the ability to determine a greater energy transfer. A thermal control is necessary to modulate the High EnergyLaser for optimizing the metabolic action of the delivered energy.

At this point, the new goal of clinical research is to allow simultaneous administration of different wavelengths. In fact, based on the previous work, it is known that each wavelength, interacting with different chromophores, determines different biological effects. The 650nm wavelength interacts with the connective tissue and induces an anti-inflammatory response [6,7]. The 810nm wavelength interacts with the nerve fibers and causes a modulation effect of the root pain [8]. The 1064nm wavelength interacts with the muscle tissue and causes a decontracting action [9].

The possibility of simultaneously carrying out a bio-stimulation that is specific to nerve fibers,

connective tissue, muscle beams, inflammatory and peripheral edema tissues, and local microcirculation, is the basis of the new high-energy laser therapy with administration of more than one wavelength. Thistherapy mode, taking advantage of a thermo-control and modulation of the wavelengths mechanism, allow to optimize the energy supply in relation to the tissue thermal thresholdof each patient.

The aim of our study was to improve pain and disability in chronic lumbar pain, regardless of etiology (arthritic, root pain, etc). Chronic low back pain is occurs due to amechanical overload of the functional unit, consisting of the vertebral body and intervertebral disc [10]. Compression on nerve fibers results in the development of a neuropathic peripheral lesion with neuropathic and no receptive pain [11]. Perilesional inflammation, due to the presence of inflammation cytokines and soft tissue edema, triggers additional lesions on nerve fibers. The para-vertebral muscles, in response to the local overload, contract, becoming a further trigger of pain and district disturbance. In this clinical picture, it is necessary to administer a therapy that can work simultaneously on each of the tissues involved, thus resetting the specific biological imbalance. Therefore, the purpose of this clinical study is to check in the patients with chronic lumbar pain the therapeutic efficacy of this type of High Energy Laser Therapy, THEAL Therapy, in the medium term.

Materials and Methods

We have drawn a prospective observational clinical study in which we recruited patients with chronic low back pain(LBP) for at least 12 weeks and>18 years of age. The study was approved by the Local Ethics Committee. Patients were informed and authorized to be included in the study. Patients with a contraindication to laser therapy (cancer, infection, pregnancy) were excluded.Patients were evaluated using VAS scales for pain [12], Roland disability score, Morris Disability Questionnaire [13] and Oswestry Low Back Pain [14]. The evaluation time was at the time of recruitment (T0), at the end of treatment (T1), at 1 month(T2), at 2 months (T3), at 4 months (T4) and at 12 months (T5). The data was expressed as mean and standard deviation. The two-time comparison was done using the student's t-test for paired sample, placing statistical significance for $p < 0.05$.

Treatment mode

The patients were treated withTemperature controlled High Energy **A**djustable multi-mode emission Laser therapy (THEAL THERAPY, iLux XP/ Ixyon, MectronicMedicale, Italy). We used a super-pulse stochastic emission (E^2C), characterized by the randomness of the impulses emitted with a frequency varying between 20Hz to 70 Hz and a super-pulsed non stochastic emission (AntInf) with a frequency in the range 15Hz to 40Hz. The patients received THEAL therapy a simultaneous adjustable combination of 650nm (E^2C), 810nm (E^2C) and 1064nm (AntInf), thermo-controlled and adjusted. Each patient was treated five times a week, for a total of ten sessions. The power was set constantly at 5 Watt. The spot size was 1 cm^2. The patient was placed in a prone position on the treatment couch with hip and knee extended and the ankle in maximal extension. The treatment surface area was lumbar para-vertebral zone in correspondence with the affected spinearea. We measured the two sides of this zone and we calculated the corresponding surface. In a single session, each patient was treated with THEAL therapy using a dosage of 50 J per each cm^2 of this painful area at the level of the column. The spinal region was scanned with a 45°inclination lateral to facet articular joints and moving from cranio-caudal to caudo-cranial direction. The remaining area was treated carrying out the treatment following the direction of the muscle fibers with an inclination of 90° of the handpiece. For eye protection from the laser beam, all subjects wore protective darkened glasses. Patients were advised to notperform any other physical or pharmacological therapies during the study period.Patients have been advised to suspend work or sports activities that include repeated movements in flexion or torsion of the spine or handling loads greater than 15kg. It was instead strongly advised against prolonging the complete suspension from work or absolute rest in bed.

For each patient a standardized schedule was compiled. The file included the following data: sex, age, weight, height, body mass index (BMI), time, smoking habit, vertebral region involved in disease (from L1 to S1), pain surface (LBP with or without leg pain), pain side (right/left/bilateral), joules, scores for each scale. The compiled schedules were put into a database built with FileMaker Pro Software and the data were analyzed using Stata MP12 Statistic Software. For categorical variables we evaluated absolute frequency and proportion.Scores obtained for each scale were expressed as mean +/- standard deviation for each evaluation time. The recorded scores were compared with the T0 value with the t-student test for paired samples, placing the significance for $p<0.05$.

Results

In the study we treated twentypatients with an average age of 60%, 80% were women, 20% were smokers, BMI was 27.5kg/cm^2. The mean onset of low back pain was 20 weeks (+/- 8weeks). In relation to previous work, 30% made a move with the important engagement of the trunk. The location of the spine pathology was thus distributed: 10% L1-L2, 10% L2-L3, 60% L4-L5, 20% L5-S1.Seventy percenthad an irradiation of the root pain of the lower limbs. Treatment has an average administration of 1031+/-578.5 Joule. No drop-outs occurred. Pain, measured with VAS scale, showed a significant reduction from T0 at all subsequent evaluation times ($p<0.001$) (Table 1). Functional limitation, monitored by Roland Score, showed significant improvement from T0 at subsequent evaluation times ($p<0.001$) (Table 1). Disability, assessed by Oswestry Score, significantly decreased from T0 to subsequent follow up ($p<0.001$) (Table 1).

Discussion

The study verified the efficacy of Temperature controlled High Energy Adjustable multi-mode emission Laser therapy (THEAL) in LBP treatment at all the follow ups. Patients showed improvement in pain, functional recovery and disability remission. These evident results, already at the end of the treatment, have presented a further progressive improvement up to the last one-year follow-up.

The novelty of our protocol is the use of a High Energy Laser with adaptive modulation of each wavelength. Besides, tissue thermal control allows high energy lasers to be dispensed without thermal risks.The choice to simultaneously administer different wavelengths guarantees the benefits of each of them.In treatment of LBP, THEAL therapy proved to be efficacious, though generally until now only low energy laser has been used [14-17]. The user high energy laserfor skeletal muscle disease has only been recently adopted [18]. The clinical experience is mainly for tendinopathies [18]. As regards LBP the preliminary data of two studies have advanced the indication for treatment of LBP using High Laser Therapy. In study of Fiore

Table 1: Mean scores +/- standard deviation of different scales at different evaluation times. The comparison of the results with respect to the T0 value was affected with t-student test for paired samples.

	T0	T1	T2	T3	T4	T5
VAS	7.5 +/-1.6	3 +/- 1.8	2.8 +/- 1.9	3.1 +/- 2.3	2.4 +/- 1.9	0.9 +/- 1.9
Comparison to T0		p=0.0001	p<0.0001	p=0.0007	p=0.0001	p<0.0001
Roland disability score	16.5 +/- 2.7	7.2 +/- 4.9	8.9 +/- 7.1	8.9 +/- 6.7	6.6 +/- 5.8	5 +/- 5.3
Comparison to T0		p<0.0001	p=0.003	p=0.004	p=0.0003	p=0.0002
OswestryLow Back Pain	43.8 +/- 12.7	25.1 +/- 13.4	23 +/- 14.4	19.1 +/- 12	16.7 +/- 12.2	13.6 +/- 11.6
Comparison to T0		p=0.001	p=0.001	p=0.0008	p=0.0004	p=0.0002

(T0: recruitment; T1: end of treatment, on average after 10 days; T2: one month; T3: at 2 months; T4: At 4 months; T5: at 12 months).

et al. [4]. Theclinical improvement was demonstrated at the end of treatment (at 3 weeks), but there was no medium or long term FUs. In the study of Osti et al. [3] the high energy laser and TECAR combined therapy showed a clinical improvement at 8 weeks, but it is not possible to quantify the benefit of Laser and TECAR therapy independently. In our previous study we used the high energy laser and we had already started analyzing which wavelengths could be more compliant [2]. They found that 810nm showed good affinity for LBP within 4 months of re-evaluation.

The use of high energy laser therapy in a new method in rehabilitation and the protocols differ according to physical parameters. Remind thebiological effects of laser: bio-stimulation [19], modulation of inflammation [20] and of pain [21-23] and angiogenesis [24]. In previous studies that verified the efficacy of High Energy Laser Therapy in skeletal muscle disease, the treatment protocols differed according to wave length, power and pulse/continue mode. Santamato et al. [19] administered a laser with a wave length 1064nm, a 6 W and continuous mode. Fiore et al. [4] used a laser with a 1064nm, a 5 W and pulse mode. In our previous work we administered a laser therapy with simultaneous three wave lengths(810nm, 980nm and 1064nm),13 W and continuous mode[1]. Osti et al. [3] chose simultaneous emission of three wave lengths (810nm, 980nm to 1064nm), with maximum power of 12 W and pulse modality alternated with continuous modality. In our work we chose to study more deeply the clinical effects of administrationcontextuallyof different wave lengths. In clinical practice, power andpulse/continuousmodeare modulated during the treatment or at different cycles of treatment according to the thermic perception of the patients. Instead, the wave length is predefined and determined by the device. Technological advances are providing the physician to make it possible to choose from time to time which wavelengths to administer.Furthermore, the administration can be carried out singularly or simultaneously, and the quota of each can be regulated. It thus becomes interesting to understand how to modulate the physical parameters in relation to different pathologies.

We chose to study only the wave lengths most used in skeletal muscle treatment. The present trial studied specifically the influence of different wavelengths of high level laser therapy for the treatment of acute LBP with or without leg pain. Varying the wavelength, within the "therapeutic window" between 600nm to1200nm, and varying also the specificity of the target tissue, the depth of action and possible interference of chromophores on clinical-therapeutic effect [7]. The biological effects of each wavelength showed to be efficacious for management of LBP. The affinity between laser 650nm and collagen is responsible for anti-inflammatory effect on connective and muscle tissue [6]. The reduction of penetration capacity due to chromophores interference, in particularly of melanin and hemoglobin, justifies a local action in the surface [7]. 810nm laser therapy has good capacity to modulate nociceptive pathways [8]. At this wave length, the laser is able to reach the tissues in depth decreasing in chromophoresresorption (melanin and Hb) [9]. The laser 1064nm is able to develop anti-inflammatory effect on muscle tissue. It is able to avoid the scattering effect caused by tissue chromophores (melanin e la ossi-Hb), acting more deeply[9].

The clinical improvement found in our patients could be interpreted as the summery of the effects of each wavelength. 810nm wavelength recovers nerve fiber, acting on the first cause of LBP and ensuring a functional recovery. It induces a pain remission with a great efficacy in terms of recovery disability. 650nm laser therapy acts on the surface decreasing muscle contracture, which represents secondary cause of LBP. 1064nm laser therapy induces an anti-inflammatory effect, mainly on muscle tissue. Also this action can be understood as a controlling effect on a secondary component of the pathology, but no less important.

In conclusion, the results of this experience support the efficacy of the use of THEAL therapy in the treatment of chronic low back pain. Additional trials will be useful to standardize the protocol. But the first two conclusions we can already draw are that: the simultaneous administration of multiple wavelengths is a winning strategy, because it allows toexploit the beneficial biological effects of each wavelength. In addition, clinical improvements have been persistent over time, confirming that the action induced by this therapy is able to reset inflammatory mechanisms responsible for pain and disability.

The weakness of this study is the lack of a placebo group, unauthorized by our ethics committee. Furthermore, there is not a control group. However, the previous experiences published in literature showed the effectiveness of this therapy [1-4]. This new study focused on the potential for simultaneous administration of different wavelengths of a High Energy Laser.In addition, there is no magnetic resonance monitoring that would allow to verify the local biological effects of the therapy. The strengths of the study are the medium-term follow-up and the non-invasiveness of patient monitoring methods. The data from this study put in the hands of orthopedists, physiatrists and physiotherapists an excellent tool for the treatment of low back pain. New studies will allow us to test how to integrate this therapeutic method into a rehabilitation path, integrated with therapeutic exercises and pharmacological therapy.

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