

scientific report

MIG

THERAPY





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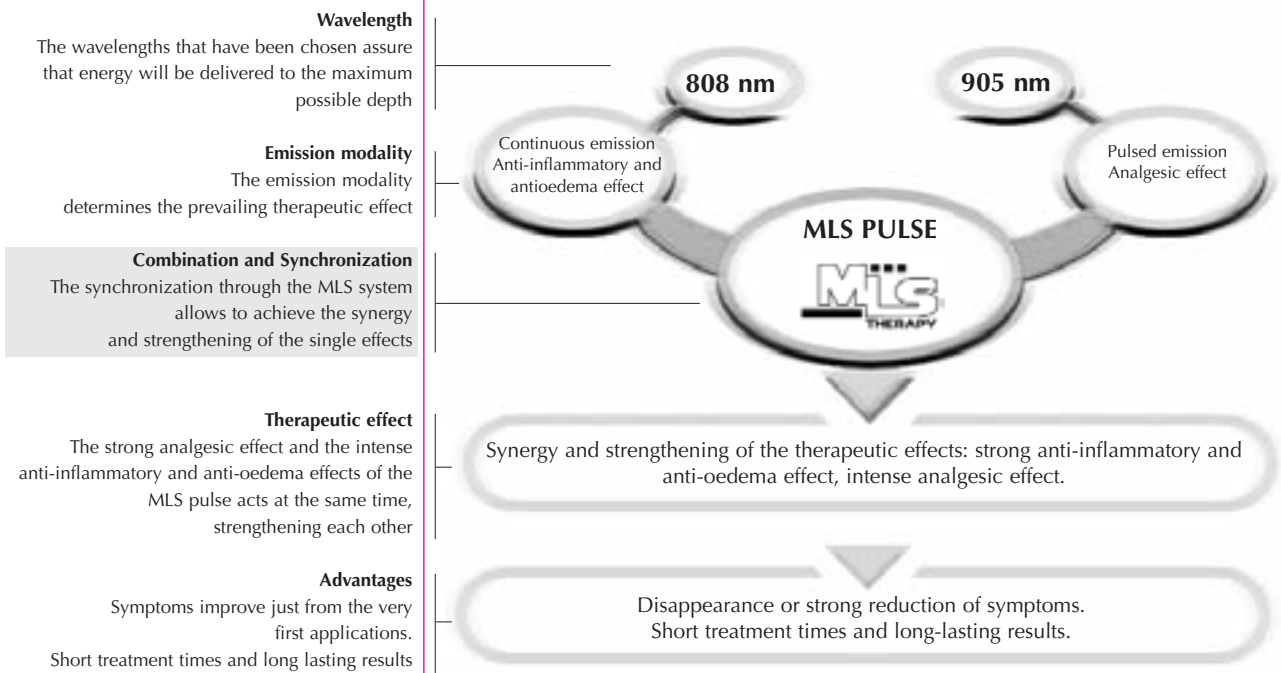
INTRODUCTION

MLS Therapy is a new therapy for treating pain, inflammation and oedema and for repairing superficial lesions. It was developed in order to overcome the limits of traditional Laser therapy, based on the use of diode lasers. Currently, no diode Laser is able to induce strong anti-inflammatory, anti-oedema and analgesic effects contemporarily and within a short period of time. Continuous Laser emissions act fast on inflammation, stimulating blood and lymphatic circulation and inducing fast re-absorption of fluid build-ups; however, they only have a secondary effect on pain, which is diminished after reducing the inflammatory process. Pulsed Laser emissions, on the other hand, have a practically immediate effect on pain, since they are able to induce analgesia, interfering with the very transmission of the pain impulse to the higher brain centres, but they are less effective at treating inflammation and oedema, only achieving results after a long period of application. MLS therapy is able to overcome the limit imposed by selecting one of the two emission types, since it is based on the characteristic therapeutic properties of a new Laser pulse. It uses an MLS pulse, a combined, synchronized emission of continuous and pulsed Laser emissions with different infrared wavelengths. The patented control system that generates the MLS pulse synchronizes the two emissions. Thanks to this characteristic synchronization, the various therapeutic effects – anti-inflammatory and anti-oedema of the continuous emission and analgesic of the pulsed emission – not only take place at the same time, but reciprocally reinforce each other.



Because of this, MLS therapy is able to guarantee effectiveness and short treatment times when treating numerous osteo-muscular system diseases and when repairing superficial lesions.

Main features of the MLS pulse and MLS Therapy.



MLS Therapy has been developed and tested following a strict course of biomedical and clinical research. In fact, the effectiveness of the combination of the emissions making up the MLS pulse was initially tested in vitro on cellular cultures, then in vivo on animals, and finally by means of controlled clinical trials run by major state-of-the-art health structures for treating traumatic or degenerative painful diseases.



The course of MLS Therapy research and testing.

In vitro studies

Padua University (Italy)

The combination of the MLS pulse emissions is able to induce a dose-independent stimulation of HeLa cultured cells

In vivo studies

Turin University (Italy) - Sao Paulo University (Brasil)

Italian Ministry for the Instruction the University and the Research

MLS emissions increase the speed of post-surgery neuromuscular regeneration in experimental models

Clinical studies

CHRONIC LUMBAGO

Padua University

Orthopaedic Rehabilitation Service

30 patients

High effectiveness of MLS Therapy in treating the pathology

CERVICAL DISTORTION

CeMuRNI Padua University

20 patients

The specific MLS synchronization assures a greater therapeutic effectiveness with respect to the combined emission only

VARIOUS OSTEO/MUSCULAR TENDINOUS PATHOLOGIES

Laser Centre - Cartigliano - ITALY

128 patients

MLS Therapy is effective to treat shoulder pain, lumbago, lumbosciatica, carpal or metatarsal tunnel syndrome and tension headache.

SHOULDER PAIN

University of Padua - CeMuRNI

72 patients

MLS Therapy, applied as a monotherapy, shows a greater effectiveness than the traditional contact Lasertherapy

The first part of this Report discusses the indications and benefits possible with MLS Therapy.

The second part is dedicated to the discussion of the theoretical principle underlying the effectiveness of the MLS pulse and the way in which it interacts with cells and tissues. Finally, the report gives a detailed account of the in vivo and in vitro research results and the outcome of clinical trials carried out on patients, which led to medical approval of the treatment.





INDICATIONS

Patient targeted response.

- *lumbago*
- *sciatica*
- *lumbosciatica*
- *epicondylitis*
- *periarthritis*
- *tendonitis*
- *gonalgia*
- *myositis*
- *arthrosis*
- *degenerative processes*
- *sprained joints*
- *bursitis*
- *trauma*
- *bruising*
- *effusions*
- *muscular strains and sprains*
- *injuries, burns*
- *venous oedema*
- *varicose ulcers*
- *bedsores*

MLS Therapy is a therapeutic technique that is particularly suitable for treating numerous diseases, including some that pose a considerable challenge for the patient and doctor due to their frequency and nature.

Indications for MLS Therapy can include:

- muscular/skeletal system trauma (strains, sprains, etc.)
- degenerative illnesses of articular or neuromuscular origin
- painful conditions of various origin
- inflammatory conditions, including those affecting the elderly
- oedema due to circulatory stasis, reduced lymphatic drainage or trauma
- superficial lesions of various origin

Patients affected by specific problems such as lumbago, sciatica, lumbosciatica, epicondylitis, periarthritis, tendonitis, gonalgia, myositis, arthrosis, degenerative processes, sprained joints, bursitis, trauma, bruising, effusions, muscular strains and sprains, injuries, burns, venous oedema, varicose ulcers and bedsores will experience fast relief and certain benefits following application of MLS Therapy.

MLS Therapy is non-invasive, painless and can be applied successfully to patients of any age. Patients with special therapeutic requirements (patients with pacemakers, pregnant women and diabetics) should consult their doctor before treatment.



ADVANTAGES

Shorter treatment times, longer lasting results and the possibility to treat greater numbers of patients.

MLS Therapy makes it possible to obtain a considerable number of therapeutic benefits. In fact, the MLS pulse provides combined analgesic, anti-inflammatory and anti-oedema action. Since it is particularly effective at combating all the processes underlying the problem, it provides a particularly fast solution. At the same time, its action on the painful symptoms is reinforced by the combined effect.

Overall, the application of MLS Therapy guarantees the following benefits:

- extremely short treatment times
- reduction and disappearance of pain, including nervous pain, within a very short space of time
- strong anti-inflammatory effect
- fast healing from strains and sprains
- fast recovery of structural integrity of damaged muscles
- fast resolution of oedematous states
- immediate improvement of local circulation
- fast repair of superficial lesions, such as cuts, ulcers and tissues.

These benefits mean complete patient satisfaction, thanks to a response targeted at complete problem solving.

The shorter treatment times mean that the doctor saves time, enabling him/her to dedicate more time to treating additional patients.





PRINCIPLE OF ACTION

The MLS impulse is extremely effective at inducing a therapeutic response.

The idea that light has curative properties is widespread in modern culture, aware of the fact that light has been considered a source of life since ancient times.

Light is essential to almost all life forms: plants draw their life energy directly from solar radiation by means of photosynthesis.

It regulates the biological rhythms – sleep, waking – of the majority of living beings, who are able to perceive it thanks to specific photoreceptors.

Today it has been scientifically proved that certain light emissions are able to effectively transfer energy to animal cells and tissue. Areas subject to a poor metabolism recover full activity and the ailing tissue is cured following treatment.

However, some light emissions are more effective than others.

Not all light emissions are of the same quality nor do they have the same therapeutic effect. In fact, each light emission has precise physical parameters that establish how the electromagnetic field associated with it “vibrates”. These parameters also play a fundamental role in determining whether the emission is able to transfer its energy to the tissue or not.

The analysis of clinical literature describing the results obtained with light emissions developed up to now, has highlighted that the extent of the therapeutic effect – after passing a threshold energy dose



characteristic to the tissue and problem to be treated – depends on some fundamental parameters: the coherence of the emissions used, their wavelength and the way in which they supply energy over time (or rather the form of the energy impulse used).

Biomedical research and clinical trials able to demonstrate the therapeutic potential of the emission used, have led to the identification of the most efficient emission parameters.

MLS therapy is possible thanks to the identification of an extremely effective wave form.

The synergic effects of MLS Therapy are obtained thanks to physical characteristics peculiar to the MLS pulse.

It involves an extremely sophisticated light emission, which transfers the electromagnetic field energy to tissue in an extremely efficient manner: it is a light impulse of superior biological and therapeutic quality, which is generated by a combined, synchronized continuous and pulsed emission system involving several wavelengths. The MLS pulse was developed on the basis of the most recent information available in clinical literature, and the results of detailed scientific research, which demonstrated the greater induction effectiveness of the primary biochemical and bioelectrical effects of its component emissions.



THE PRINCIPLES BEHIND THE MLS IMPULSE.

1) The MLS emission is coherent.

Scientific studies on the therapeutic effects of light emissions demonstrate that a greater therapeutic effect is obtained if the emission is coherent. One of the most widely accepted hypotheses for explaining this mechanism is that the light/biological membrane interaction generates a coherent biolaser emission (if the incidental light is coherent), due to the existence of conduction bands in these sub-cellular structures containing free charges (e).

2) The MLS pulse wavelengths guarantee the deepest possible action,

based on scientific findings on the capacity of coherent light to penetrate biological tissues (epidermis, dermis and subcutaneous tissue).

In fact, it is well known that the depth reached by the light emission depends on the incidental radiation wavelength.

The reason lies in the presence of specific superficial chromophores that present areas of maximum absorption in correspondence to particular wavelength intervals, which will therefore be filtered and not reach the deepest tissue layers, and that are transparent in other areas of the electromagnetic spectrum.

The interval between 600 and 1200 nm is known as the 'therapeutic window' because there are no chromophores in this range able to filter the light emission: the wavelengths of the emissions making up the MLS pulse fall into this precise interval, meaning that they are able to reach the deepest anatomical structures that are often involved in the ailments that MLS Therapy is most suitable for treating. Other wavelengths would not have the same effect.



3) The MLS impulse is a synchronized combination of two unique emission modes, continuous and pulsed, so as to be able to obtain the therapeutic effects belonging to each mode.

The continuous emission (light is emitted in a constant fashion over time, or in pulses in the order of milliseconds), in fact, guarantees an intense anti-inflammatory and anti-oedema effect, because it is able to stimulate the circulation and lymphatic drainage considerably, and because it is able to interact with the synthesis and degradation of inflammation mediators.

The inflammation and oedema are destined to diminish considerably and heal completely after a very short period of treatment. The pulsed emission (the light is issued in short pulses, lasting a matter of nanoseconds) has an effect on pain transmission: the action takes place at the level of the superficial nociceptors and, thanks to the depth of action of the emission used, on the afferent nervous fibres. The rest potential is restored more quickly after the generation of the action potential: this is translated into an increase of the cell and nervous fibre's stimulation threshold and, consequently, a reduction in the feeling of pain. Moreover, the contemporary activation of the proprioceptive channels (A-alpha and A-beta fibres), which are subject to greater myelination and therefore able to conduct the nervous stimulus more quickly, induces a pain block on the level of Rolando's gelatinous substance – as indicated by the gate theory – which is replaced by kinesthesia. The analgesic effect obtained is immediate and long lasting.

4) The real innovation behind the MLS pulse lies in the synchronization of the emissions that make it up. Through the synchronization of the component emissions, the MLS pulse is able to provide an intense and immediate therapeutic effect on both the inflammatory processes, and on the painful symptoms accompanying them.

This is due to the fact that the anti-inflammatory and anti-oedema



effects of the continuous emission and the analgesic effect of the pulsed emission reinforce each other, thanks to the synchronization of the emissions. Moreover, the overall way in which energy is supplied through the MLS pulse, together with the net reduction in treatment times, guarantees that there is no risk of addiction. Here is an example of how the combined Laser emission is more efficient: it is well known that the Laser acts on the oedema-contraction-pain trio. It is equally true that, by eliminating one of the causes, the other two tend to return to normal. In the case of a patient with a sprained ankle, who is experiencing pain and difficulty in moving and placing weight on his/her foot due to the swelling and oedema, treatment with MLS Therapy will provide an immediate analgesic effect, whilst also providing a strong anti-inflammatory and anti-oedematous action at the same time, by means of vasodilation and re-absorption of the irritant substances (prostaglandins, bradykinins, histamine, K^+ , Ca^{++} and H^+ ions). From the very first application, the patient will regain partial mobility following the reduction of the swelling, the oedema and the pain, and will be able to place weight on his/her foot.





NEW MLS THERAPY

MLS Therapy restores cellular bioelectrical and biochemical balance.

The emissions that make up the MLS pulse are able to act selectively and in synergy on the two mechanisms of biochemical and bioelectrical homeostasis.

Intuitively, one can imagine that the variable rhythm induced by the MLS impulse makes it possible to recruit the most satisfactory energy mix for the cell and is able to act at a cellular level, based on the induction and maintenance of the resonance between the vibrations of the incidental electromagnetic field, and the transition frequencies from the fundamental energy levels to the stimulated energy levels, and therefore active energy, of the structures and molecules able to perceive the stimulus.

This effect could be compared to pushing a swing. A strong initial impulse is needed to start it up, but, once it is moving, a less intense impulse is all that is needed to maintain the motion, as long as it is given at the right frequency, in keeping with the oscillation frequency of the swing.



CELLULAR BIOCHEMICAL AND BIOELECTRICAL BALANCE.

The key to understanding how MLS Therapy works lies in the knowledge of the primary events that take place on a cellular level, and which guarantee maintenance of an optimal state of well being for the cell and the tissue that it is part of.

Cells are always actively involved, from a biochemical point of view, in breaking down nutrients that come from the circulatory system and in transforming the energy that is released from the fission of the carbon-carbon links into energy stored in the cellular energy exchange molecule: ATP (Adenosine triphosphate).

ATP is then consumed in order to provide for all the cell's metabolic requirements, for the synthesis of new compounds, such as protein, and for maintaining the difference in ionic concentration between the two sides of the cellular membrane.

Any process that alters the balance between ATP formation (through glycolysis, the citric acid cycle and oxidative phosphorylation) and break down in the various metabolic processes, leads to a pathological condition in the cell, and therefore in the tissue, in which reduction of the messenger RNA, corresponding protein synthesis and reduction of the membrane potential may be observed.

This leads to biochemical imbalance and bioelectrical alteration.

From a biochemical point of view, the cell passes from optimal energy conditions to lower energy conditions, where part of the available energy is used to combat the pathological process, such as synthesizing signal molecules that were not needed before.

In fact, it is well known that in inflammatory processes, a considerable quantity of ions, especially Ca^{++} , and local pro-inflammatory mediators, such as histamine, is released. Part of the energy may also be 'diverted' in order to repair any



structural tissue damage. If this variation to the cellular energy conditions is associated with a short supply of nutrients and oxygen from outside, due to localized microischemia situations such as those that occur in the case of degenerative illness or damage to the muscular/skeletal system, it is likely that the disease will become chronic because the cell is unable to return to its optimal energy conditions.

The bioelectrical alteration of the membrane potential has further negative effects, mainly due to the local modification of the conformation of the transmembrane carriers that become less efficient in carrying out their function of transporting nutrients inside the cell, and excreting catabolites produced by the various enzymatic reactions.

If the fall in membrane potential on a cellular level leads to an insufficient cellular nutrients supply, a reduction in ATP synthesis may be observed in the mitochondrion, due to a lower proton gradient and reduced efficiency of the respiratory chain components (which, in their turn, are lacking in the final electron acceptor, O_2 , if an ischemic situation is present).

Once again, a vicious circle may arise that corresponds to the worsening of the disease, if the ATP supply coming from the mitochondrion is below the quantity required for maintaining the action of the Na/K pump and the other active carriers present on the cellular membrane.

In the particular case of excitable cells, such as superficial nociceptors and neurons whose axons contribute to forming afferent nociceptive fibres, the reduction in membrane potential and the reduced efficiency in restoring the action potential cause a reduction in the action potential trigger threshold, or rather have the effect of reducing the pain perception threshold.



From the above, it is clear that an effective curative strategy must aim to restore the cell's biochemical and bioelectrical balance.

It is clear that both the biochemical and bioelectrical balance can be restored by returning the cells, and particularly the specific molecular and structural substrata, to optimal energy conditions by means of a direct energy transfer.

However, this transfer must not be thermal – in order to avoid breaking down the sensitive cellular substrata, and because heat is not in itself a form of energy that can be directly used by the cell – and must be targeted at the cellular structures where it is most opportune for the energy to be transferred.



The experiments and considerations that we show on the next pages demonstrate that, because of its physical characteristics, the MLS pulse is able to guarantee maximum energy transfer efficiency by interacting with the cellular and ultra cellular structures and the reactive molecules responsible for maintaining the basic metabolism.

It is able to quickly and completely restore an optimal biochemical and bioelectrical balance by means of efficient energy transfer. Use of the MLS pulse makes it possible to recruit intracellular photoreceptors immediately and restore higher energy conditions to the cell.

Thanks to the MLS pulse, the cell is initially reactivated and then kept in these energetically active conditions, in which the primary biochemical and bioelectrical balance restorative effects can take place in the final therapeutic effect.

These effects are obtained at the same time, within a very short space of time, and above all in synergy.

All in all, this is what guarantees the possibility to reduce treatment times considerably and obtain the long lasting results unique to MLS Therapy.





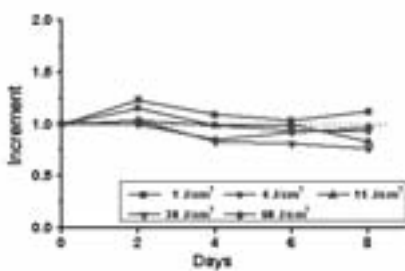
BIOMEDICAL RESEARCH

The biomedical research results that made MLS Therapy possible.

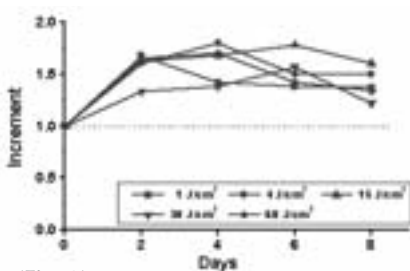
The MLS pulse is generated by a combined, synchronized, continuous and pulsed emission system, involving several coherent emissions with characteristic different wavelengths. It was developed on the basis of the results of specific scientific research carried out in order to investigate the biological effects of the combination of the component emissions.

This research was the result of ASA' s collaboration with two of the most important Italian universities in the field of biomedical research.

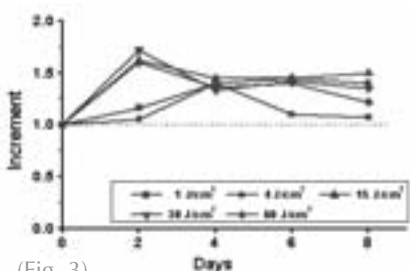
A study on in vitro cellular lines was carried out at the University of Padua Biology Department, while research was carried out into experimental in vivo models at the University of Turin Biology Department. The second trial was sponsored by the Italian Ministry of Education and Research (MIUR), indicating the strictness and seriousness with which it was planned and carried out, and by the Anatomy Department at the Federal University of Sao Paolo (Brazil).



(Fig. 1)



(Fig. 2)



(Fig. 3)

IN VITRO RESEARCH

The variation of cellular growth increase in a standard model system (HeLa cells) was measured after radiation with continuous emissions only, pulsed emissions only and, finally, combined emissions (continuous + pulsed). The measurement was made with different doses of energy density (J/cm^2) in order to highlight possible response dose-dependency.

The decision to measure the increase in cellular growth was made because this parameter is particularly sensitive to the cell's metabolic activity: when it is in optimal energy conditions, the replication increases because all the fundamental biomolecular mechanisms, the DNA replication, RNA transcription and protein synthesis take place at the best possible rhythm.

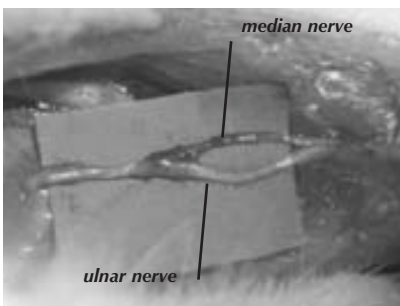
The first result obtained is represented in (figure 1), showing the relative increase of cellular growth in relation to time, at different doses, as measured on HeLa cells treated with continuous emissions only at 808 nm. This type of emission on its own has no effect on the cellular growth.

However, when the HeLa cells were treated with a pulsed emission only, biostimulation was induced, but the effect was heavily dose-dependent and unstable over time (figure 2).

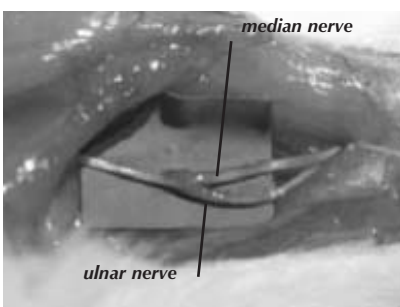
A very different effect is obtained when the HeLa cells are treated with a combination of the two emissions (figure 3).

In fact, it can be seen that the combined emission is able to induce cellular metabolism stimulation in a way that is substantially independent from the dose and completely stable over time.

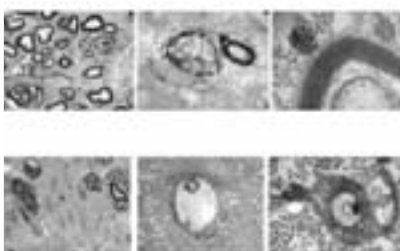
The in vitro research demonstrates that the combined emission guarantees the greatest biostimulation effect as regards both extent and duration. This fundamental result led to an in vivo study, in order to check whether the in vitro results would be confirmed on an animal model too.



(Fig. 4a)



(Fig. 4b)



(Fig. 5)

IN VIVO RESEARCH

The in vivo trials were carried out on rat, assessing the extent of nervous regeneration and the consequent restoration of muscle functions following lateral neurotomy (an operation that involves resecting the ulnar nerve from the median nerve and then rejoining them), after radiation with continuous emission only, pulsed emission only and combined emission.

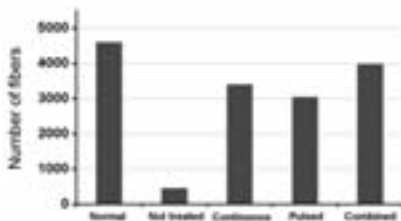
The nervous regeneration was assessed directly by means of visual examination and then by transmission electronic microscopy.

The recovery of the muscular mass was measured in terms of the weight of the muscle innervated by the median nerve.

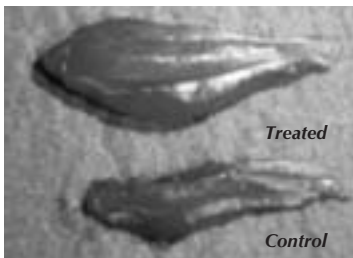
Finally, the muscular function recovery was assessed using the grasping test, which predicts the amount of weight the test animal can support with the limb that has undergone the operation.

The nervous regeneration stimulation obtained in animals treated with combined emission is extremely significant. As can be seen in these photos, even a simple visual examination makes it possible to see how the median nerve in the treated animals is subject to optimal regeneration (figure 4a: nerve regeneration in untreated animals; figure 4b: nerve regeneration in animals treated with the combined emission).

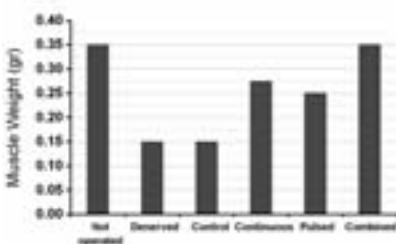
The electronic microscopy confirms the extent of nervous regeneration obtained in animals treated with the combined emission. On a subcellular level, the restoration of the physiological number of organelles, mainly mitochondria, in the cells of the animals treated with this kind of emission was observed. Meanwhile, at the level of the nerve, the practically complete re-myelination is evident (figure 5). Finally, the count of the number of nervous fibres regenerated shows how the recovery – in animals treated with the combined Laser emission – is almost complete, while a smaller degree of stimulation is observed with the other two types of



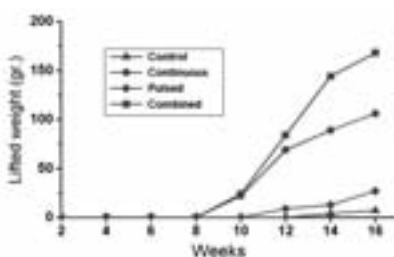
(Fig. 6)



(Fig. 7)



(Fig. 8)



(Fig. 9)

emission (figure 6).

The nervous regeneration and recovery of fibre myelination are followed by the restoration of the nerve’s conduction capacity, and by the recovery of the innervated muscle contraction capacity, which returns to receiving the nervous stimulus correctly again.

In fact, in untreated animals the innervated muscle becomes atrophic because it is not stimulated to contract correctly, while in Laser treated animals it recovers its trophic factor in a more or less evident fashion depending on the stimulus used (figure 7).

In correspondence to the greater nervous regeneration obtained thanks to the combined emission, the recovery of the muscular mass in animals treated with this kind of stimulus is complete, a result which even amazed the researchers who carried out this trial (figure 8).

Muscular function recovery through grasping test.

The consequence of the complete muscular mass recovery and the almost total innervation recovery in animals treated with the combined Laser emission is reflected in the greater muscular function recovery, assessed using the grasping test. An increasing weight is fastened to the foot of the animal that has undergone the nerve resection and has then been treated with the Laser, in order to assess the muscle’s contractile capacity. As can be seen in figure 9, the muscle of animals treated with the combined emission regained a considerable contractile capacity, unlike that of the animals treated with the other two emission modes.



CONCLUSIONS

These results demonstrate a very important fact: the combined emission represents a stimulus that the cell perceives as 'different' from the two separate emissions. In other terms, the combined emission is a biologically 'new' stimulus that is able to induce a characteristic effect, which cannot be obtained when the two emissions are used separately. The combined emission provides dose-independent and stable biostimulation.

The results also confirm the extreme effectiveness of the MLS pulse in transferring energy to cells and tissues in an optimal fashion, where 'optimal' means an energy transfer able to elicit the maximum biological response.





CLINICAL CONFIRMATION

The outcomes of four clinical trials will be illustrated below in the form of scientific articles, thereby enabling those in the sector to appreciate the severity with which MLS Therapy was validated in a medical environment.

These four trials were carried out in order to check the effectiveness of MLS Therapy in treating some of the commonest osteo/muscular/tendinous problems.

The first trial was a controlled trial on the treatment of chronic lumbago of a mechanical nature, carried out at the University of Padua Orthopaedic Clinic, the second was a clinical trial on the treatment of traumatic cervicalgia (whiplash) carried out at the Physiatric Department, Abano Terme Nursing Home, in collaboration with the CeMuRni (the University of Padua's Multidisciplinary Centre for the use of non-ionizing radiation), the third was a clinical trial on the treatment of various osteo/muscular/articular problems performed at the Laser therapy centre run by Dr. Tasca, Cartigliano, Italy, a specialist in the sector, and the fourth trial was a controlled, comparative study with traditional Laser therapy, also performed at the CeMuRni.

The results of these clinical trials demonstrate that MLS Therapy is an extremely effective therapeutic approach for the problems indicated, which occur frequently and are difficult to resolve, consuming considerable public funds.



MLS Therapy has also been proven to guarantee shorter treatment times and long lasting results.

These trials confirm what is already known to the now numerous MLS Therapy users. Further clinical trials are currently underway in order to expand the range of indications of this new approach and examine its therapeutic potential in more detail.



TREATING CHRONIC LUMBAGO WITH MLS THERAPY. A CONTROLLED TRIAL.

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Department of Surgery

Orthopaedic Rehabilitation Service

University of Padua Hospital

This trial assessed the effectiveness of MLS Therapy in treating chronic lumbago. 30 patients affected with the illness were subjected to monotherapy with MLS Therapy, monitoring painful symptoms through the use of the Visual Analogue Scale (VAS). The results were compared with the progress of symptoms recorded in a homogeneous control group as regards numbers and composition. After 10 treatment sessions, a significant reduction in painful symptoms was observed and a fair amount of mobility was recovered. The above results confirm the effectiveness of MLS Therapy in treating chronic lumbago of a mechanical nature.

Introduction

Lumbar pain is a symptom of variable etiology that is very widespread amongst the adult population, especially young adults in industrialized countries. Numerous epidemiological studies have been carried out over recent years, with varied findings as regards the incidence and social impact of this disease. This lack of accurate data is linked to the different sources of information, the very definition of lumbar pain, the various forms of behavior of sufferers depending on insurance systems and, finally, the different treatments used in different countries. In order to get a clear picture of the capacity of this phenomenon, it will be useful to provide some information on the prevalence of the disease, especially in the work environment, and its consequent economic impact. In Great Britain, for example, 46% of a random sample of the general population claims to have suffered from lumbago at least once in their lives. Also in Great Britain, there were 15 million medical visits for lumbago in 1993, leading to 1.5 million spinal X-rays, one million patients treated with rehabilitative physiotherapy, 100,000 hospital admissions, 30,000 day-hospital days and 24,000 surgical operations. Lumbago costs the country an estimated 520 million Euro/year.

The disease also has extremely high social costs. In fact, the statistics drawn up by the British social security institute indicate 81 million



paid sick days due to backache in 1991-92, with an estimated increase to 106 million days per year by 2002-2003 (Waddell G, 1996; Andersson GB, 1999).

Laser therapy plays an extremely important role in the field of physiotherapy used on a daily basis in outpatient departments, since the biological effects of the Laser light provide an analgesic, anti-inflammatory and biostimulating effect (England S et al., 1989; Ernst E et al., 1993; Gam A et al., 1993; Tuner J and Hode L, 2002). The difficulty in conducting random controlled trials (RCTs) (Beckermann et al., 1992) on such a widely prescribed therapy, leads to a lack of coherent data in literature, also because of the absence of indications on the physical parameters used (wavelength, frequency, dosage, application method, treatment duration) (Brosseau L. et al, 2000; Vasseljien O. et al, 1992).

However, it was found that modulating the wave shape plays a fundamental role in patient response to the therapy, and that certain types of Laser pulses are able to provide greater therapeutic effects (Corti L et al., 2003; Fortuna D et al., 2002). This trial was planned in order to assess the effectiveness of Laser therapy using a specific Laser pulse, known as the MLS pulse (Multiwave Locked System), obtained through the combination and synchronization of two different Laser emissions, on a homogeneous sample of subjects affected with chronic lumbago of a mechanical nature.

Population and Methodology

30 subjects with an average age of 39.63 were involved in the trial (DS 3.54 years, range 29-47), including 13 men and 17 women. In order to be admitted to the study, patients had to have been suffering from the pain for more than three weeks and the pain had to be due to lumbago of a mechanical nature.



Clinical protocol	
N° sessions	10
Individual session duration	2 min
Treatment parameters	
Pulse repetition frequency	700 Hz
Dose supplied	2.02 J/cm²

Table 1: Clinical protocol and treatment parameters

During the initial check-up, all the patients were subjected to a cognitive investigation of the pain symptoms using the “Visual Analogue Scale” (VAS), and therefore to a specific objective evaluation.

All the patients started exclusive physiotherapy immediately using MLS therapy supplied by the MIX5 (ASA, Arcugnano, Italy) device, able to supply the MLS pulse. There were ten consecutive sessions (table 1), each lasting 2 minutes, using a pulse repetition frequency of 700 Hz, a total quantity of energy supplied per session of 39.67 J and an energy dose of 2.02 J/cm². The multidiode applicator, with a 5 cm diameter, is positioned on the lower back, focusing on the multifidi muscles, since these are the main muscles involved in chronic mechanical lumbago.

At the end of treatment, all the subjects were re-assessed using the same methods, after an average space of 15 days (DS 1; range 14-16) from the initial assessment. The pain was also assessed using a binary ordinal scale expressed in: improvement of the symptoms (positive result) and stasis or worsening of the symptoms (negative result). A second group of 30 subjects, matching the first group as regards age, sex and pathology, was also recruited. The subjects in this second group were given traditional therapy around 15 days after the initial assessment. Immediately before starting treatment, they were subjected to another check-up using the same methods. The control group was necessary in order to assess any modifications linked to the natural course of the disease, and the reproducibility of the data, or rather a methodological error; because of this, the VAS scale was administered to each subject twice within the space of an hour during the check-up.

In order to assess the progress of the painful symptoms of the subjects treated, the data collected by the VAS scale was monitored on a daily basis, before each session.

All 30 subjects in the study group were forbidden to take any other

form of treatment, such as drugs, physio/kinesitherapy, etc.

The results were statistically analysed using ANOVA tests for measurements, repeated before and after treatment (pre and post), of the variable in question (VAS) with one and two group factors: the group and the outcome. Average differences of $p < 0.05$ were also considered significant.

Results

In the control group, the variance analysis (ANOVA) did not find any significant differences in the average VAS values during the two evaluations carried out within a short space of time. In fact, the values were 6.88 for the second evaluation and 7.02 during the first ($p = 0.51$). Consequently, the average differences between the two measurements were not significantly above 0, thereby excluding the existence of a systematic error in the measurement technique.

The extent of agreement of the measurement pairs was expressed using the coefficient of repeatability, or rather 2DS of the measurement pairs, which was equivalent to 0.41 (figure 1).

In fact, rather than a causal error in the measurement method, finding a difference in absolute value above the repeatability coefficient represented a real modification in the variable measured.

In the control group, no significant different in the average VAS values was found between the evaluation carried out immediately before the start of treatment and the evaluation carried out initially, around 15 days earlier: 6.79 v. 7.02 ($p = 0.43$); this means that the course of the disease itself did not have any effect on the painful symptoms. As regards the pain reported at the end of treatment by the study group, comprising a total of 30 subjects, 25 (83.3%) reported a "positive result" expressed as an improvement in the

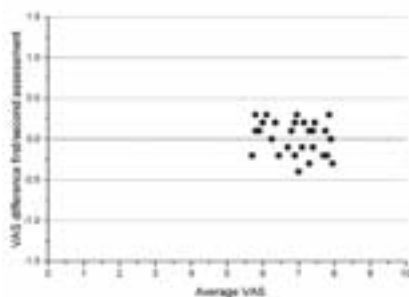


Figure 1: Control group. Difference between VAS score at first and second assessment.

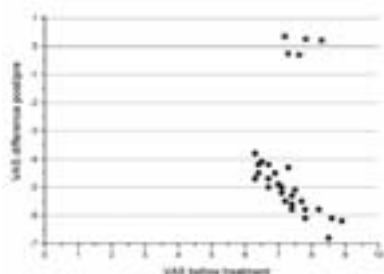


Fig. 2: Difference between post-treatment VAS and pre-treatment VAS on the basis of the pre-treatment VAS score.

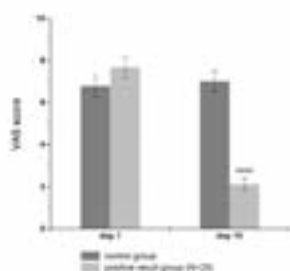


Fig. 3: Average VAS scores relative to the control group and the group treated with MLS Therapy (positive result subgroup, No. 25) measured on day 1 and day 15.

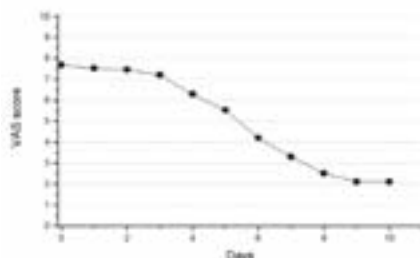


Fig. 4: Positive result subgroup: daily progress of average VAS score.

symptoms, while 5 (16.7%) reported a “negative result”.

The results relative to each subgroup are illustrated in the diagram in figure 2, where the circles represent the VAS differences of the “positive result” subgroup and the squares the differences of the “negative result” subgroup. In particular, 3 of the latter subjects recorded a stasis of symptoms and 2 stated that the symptoms had got worse.

In the “negative result” subgroup, the post treatment values did not change significantly ($p = 0.62$) with respect to before the treatment, respectively equalling 7.71 and 7.46; none of the individual variations had an absolute value above the coefficient of repeatability.

In the “positive result” subgroup, the average post treatment values fell significantly ($P < 0.0001$) with respect to before the treatment, falling from 7.69 to 2.12 (figure 3); the individual values diminished in all 25 subjects, in keeping with or more than the coefficient of repeatability.

The daily progress of the painful symptoms (expressed as average VAS score in the “positive result” subgroup) during treatment with MLS Therapy is represented in figure 4, where it can be seen that the most significant changes are concentrated in the period between the fourth and eighth day.

Conclusions

MLS therapy is particularly effective in treating chronic lumbago of a mechanical type, ensuring a high percentage of success (83.3% of patients treated) in the reduction of painful symptoms, even in consideration of the fact that this treatment was applied as a monotherapy. The reduction in painful symptoms was extremely



significant and was obtained with a reduced number of applications, each of which was particularly brief.

It can therefore be surmised that MLS Laser therapy is able to offer a good chance of reducing or resolving the painful symptoms of chronic lumbago using a “non-operator dependent” method able to reproduce the same effect.



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MLS THERAPY TREATMENT OF CERVICAL DISTORTION.

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This study assessed the effectiveness of MLS Therapy treatment on post-traumatic cervical distortion. 20 patients affected with the disease were recruited and then treated with MLS Therapy. The results, based on an assessment of the subjective (VAS scale) and objective (articular mobility) parameters, confirm the therapeutic value of this new method. A comparison with existing results in literature regarding the effectiveness of the combined, unsynchronized emission demonstrates that the specific MLS synchronization leads to a synergy of the component emissions' therapeutic effects, guaranteeing shorter treatment times and particularly long-lasting results.

Introduction

Neck pain linked to “whiplash” as the result of a road traffic accident is caused by the distortion of the cervical column. The term “whiplash” does not indicate a clinical diagnosis, but a damaging or potentially damaging mechanism. Recent years have seen an increase in the number of people suffering from this problem, despite the fact that the number of road traffic accidents has fallen. Up to 5% of people involved in accidents will suffer from persistent, disabling neck pain. While men are the most likely to suffer from the problem, women are actually the most likely to suffer from persistent pain.

While this condition should be interpreted as a disease affecting the soft tissues and muscles, the damage to the cervical column is actually difficult to comprehend, as the symptoms are often unrelated to the findings of the objective examination and often only arise some time after the accident. It is supposed that these symptoms are due to the mechanical misalignment of the cervical column that occurs at the moment of the trauma.

The most common situation is a collision, when the vehicle is hit from behind and pushed forward. The passenger's body comes into contact with the seat back and becomes one with the vehicle, following the forward thrust.



Kaneoka and Ono (1999) used a special cineradiographic technique to study the movement of the cervical column of some volunteers subjected to collisions at a speed of 4 km/h.

They found three distinct models of movement for the cervical column after impact. During the flexion/extension movement, the vertebra in position C6 initially rotates backwards before the upper vertebrae. This means that the cervical column initially demonstrates a flexed position. When C6 reaches the maximum rotational angle, C5 is forced to extend. The upper segments bend while the lower ones extend, and the cervical column assumes a typical "S" shape. In this position, the C5-C6 segment performs a "book opening" movement around an instantaneous rotation axis shifted towards the other.

The cervical column is therefore forced to move by the lower vertebrae. This movement is completely different to that of normal extension and is probably linked to the appearance of the typical symptoms: cervicalgia, stiffness, reduced upper spine mobility, headache, dizziness, and cognitive and psychological symptoms such as irritability, tiredness, anxiety, insomnia, attention deficit and concentration problems.

Cervicalgia and headache occur in the majority of cases within one week from the accident, getting worse over the next three months.

A characteristic of the whiplash syndrome is the discrepancy between the persistence of the painful symptoms, and the lack of any specific structural damage. It seems that this long term persistence of the symptoms is linked to the severity of the cervical distortion and, in part, to certain factors preceding the trauma (past cranial trauma and headaches), as well as the initial post-traumatic reaction (for example, disturbed sleep or psychological alterations). The best treatment for this problem is still a matter of debate.



In fact, various different approaches of both a conservative and active nature have been tried, including immobilization, physiotherapy and drugs, although the outcome is always uncertain and variable (Verhagen A. et al, 2004).

For some time now, it has been well known that Laser therapy can be used successfully in the treatment of numerous muscular/articular pathologies (Bjordal JM, 2003; Hakguder A et al., 2003). Clinical practice has provided indications that particular infrared emissions, characterized by specific energy supply methods, are able to provide specific therapeutic effects.

It has been observed that continuous emissions have a prevalently anti-inflammatory effect, while pulsed emissions have a more marked analgesic effect (Tuner J. and Hode L., 2002).

During an earlier study, we aimed to assess the effectiveness of the combination of two emission types in the treatment of post-traumatic cervicgia, aiming to superimpose the two therapeutic effects (Corti L. et al, 2003). We found that this combination is effective in reducing painful symptoms and improving patient mobility, although a high number of sessions and fairly long treatment times were required.

Recently, we observed an accumulation of indications from a large number of public and private centres regarding the effectiveness of new MLS Therapy in treating various osteo/muscular/tendinous pathologies. This therapy uses a particular kind of pulse (the MLS pulse) achieved through the synchronization of specific continuous and pulsed infrared Laser emissions, using a characteristic patented control system. The effectiveness of this pulse would seem to lie in the correlation between the specific synchronization pattern and the synergy of the component emissions' therapeutic effects. This study aims to assess these indications under stricter conditions.



It assesses the effectiveness of MLS Therapy treatment of post-traumatic cervical distortion, as this is a problem that is notoriously difficult to resolve, comparing the results with those obtained when treating the same pathology with a combined, unsynchronized emission (Corti L. et al, 2003).

Materials and Methods

The study group consisted of 20 patients with cervical distortion caused by a road traffic accident, 12 men and 8 women, aged between 30 and 41 (average = 33).

Cervical distortion was diagnosed following the standard spinal X-ray procedure. In some cases, the patient’s condition was also assessed using dynamic radiography and an MRI of the cervical region. The initial distribution of the entity of symptoms presented the usual dispersion due to the fact that traumas of an equal intensity to the sympathetic system can influence the individual response.

The MLS Therapy treatment was administered using the MIX5 device (ASA srl, Arcugnano, Italy).

MLS Therapy was administered once a day for a total of 10 treatment sessions. Each session involved a single application of MLS Therapy lasting no more than 2 minutes (table 1). The therapy was applied by positioning the characteristic multidiode applicator in the proximity of a single point in the cervical region, corresponding to the joint between C2 and C3, in order to irradiate a circular area with a 5 cm diameter. During the first 3-4 sessions, a pulse repetition frequency of 500 Hz was used, while during the last 6-7 sessions, the frequency was increased to 1000 Hz, in keeping with the authors’

Clinical protocol	
N° sessions	10
Individual session duration	1 min and 22 sec (first 3-4 sessions)
	1 min and 10 sec (remaining sessions)
Treatment parameters	
Pulse repetition frequency	500 Hz (first 3-4 sessions)
	1000 Hz (remaining sessions)
Dose supplied	1.27 J/cm² (first 3-4 sessions)
	1.29 J/cm² (remaining sessions)

Table 1: Clinical protocol and treatment parameters



personal experience and the results of the earlier study (Corti L. et al, 1988; Corti L. et al, 2003). Doses equivalent to 1.27 J/cm² were given during the first 3-4 sessions and 1.29 J/cm² during the last 6-7 sessions. These doses were chosen on the basis of the research team's clinical experience, and do not differ in any way from those found in other case histories (Corti L et al, 1988; Corti L et al, 1991; Corti L et al, 2003), which indicate 1 J/cm² as the reference dose for acute analgesic therapy.

MLS Therapy was associated with massotherapy after the fifth session. In cases with more intense painful and functional symptoms, the therapy was also associated with acupuncture, stretch and spray after the fifth session.

The painful symptoms were assessed using the VAS scale (visual analogue scale) at the end of each MLS Therapy session and one month after the end of treatment. The objective assessment was carried out by measuring the patient's ability to twist his/her head in degrees after treatment. In all cases, we also monitored the specific symptoms of cervical distortion in addition to pain, such as nausea, tinnitus, dizziness, etc.

The statistical significance of the results was analysed following standard procedures (t-test and post-hoc ANOVA if necessary).

Results

At the end of the treatment with MLS Therapy, we observed a consistent improvement of the painful symptoms in all the patients. The average VAS score fell from an initial value of 8 to an average value of 2 ($p < 0.0001$) at the end of the tenth and last treatment session (figure 1). It is particularly significant that the most consistent

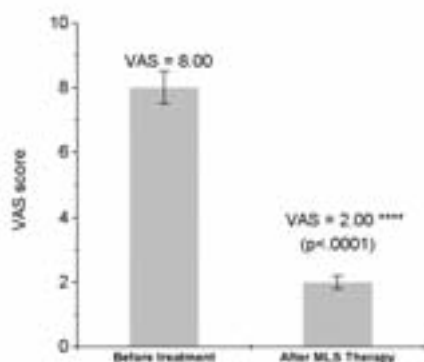


Figure 1. VAS score before and after MLS therapy.

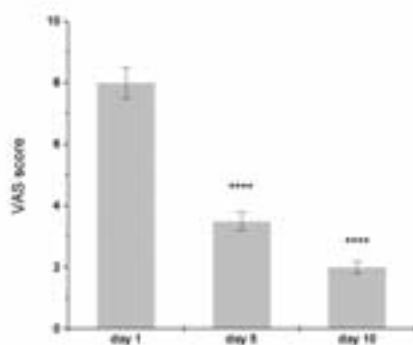


Figure 2. VAS score before treatment, at the fifth session, and after completion of treatment with MLS therapy.

reduction in the VAS score was observed within the first 5 sessions. In fact, the average score at the end of the fifth treatment sessions was 3.5, falling further still during the following five sessions to reach an end value of 2 (figure 2).

In 2 cases only, a slight worsening of the painful symptoms was observed during the first session, but this was resolved in the following sessions. This initial rebound effect should be attributed to the usual vessel and sympathetic system stimulation following the energy supply that reactivates the primary processes at the level of the various tissue components. One month later, the average score recorded using the VAS was annulled thanks to continuing treatment with other therapies: rehabilitation and resolution of persisting factors such as malocclusion or earlier pathologies.

The improvement in painful symptoms was accompanied by an improvement in articular mobility. At the end of treatment, an improvement in the patient’s ability to twist his/her neck was recorded in 60% of cases.

5 patients suffered from nausea and dizziness in association with pain and stiffness. These symptoms improved quickly, in keeping with reduction in painful symptoms.

Discussion

The results described in this article highlight the effectiveness of MLS Therapy in treating a problem that often fails to respond to traditional treatments, such as cervicgia caused by whiplash syndrome. It is very important to note the fact that the application of this new method led to an extremely significant result by the fifth treatment session, after a reduced number of applications and



administration of MLS Therapy as a monotherapy (we should remember that it was only associated with other treatments from the sixth session onwards).

The therapy was also found to be effective in all the cases treated. The unsurprising initial heterogeneity of the sample as regards symptoms is due to different individual reactions that usually occur in the case of trauma at the level of the sympathetic system, but is not very significant as regards the quality of the results, since the chosen assessment parameters are the most reliable and secure possible.

It is particularly interesting to compare the results obtained in this study with those of the aforementioned study (Corti L. et al, 2003), in which the same pathology is treated by supplying the same energy doses, but using a combined, unsynchronized emission.

In fact, it was found that, with treatment times of around 10 times shorter (from 20 to less than 2 minutes) and with the same overall number of sessions, MLS Therapy makes it possible to obtain a faster and more consistent reduction in painful symptoms (figure 3), consequently accelerating the patient's recovery of mobility.

In fact, the VAS score is significantly lower at the fifth session ($p < 0.001$) – proving that it acts faster – and at the end of treatment ($p < 0.01$), showing that the MLS pulse is able to induce a more marked pain relief effect at the end of treatment than that obtained using the simple combined emission.

We can therefore conclude that the type of emission used, which only differs from the combined emission in the specific MLS synchronization, is able to provide a considerably greater therapeutic effect. The results of this study demonstrate how specific MLS synchronization of the continuous and pulsed emissions is able to induce the synergic reinforcement of the anti-inflammatory and

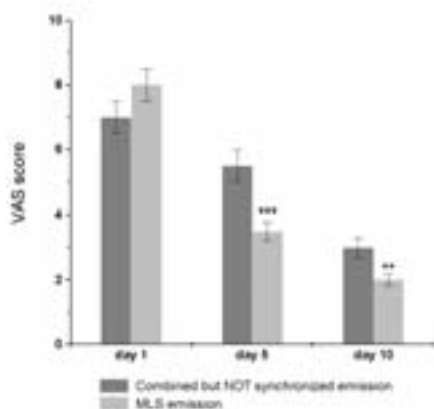


Figure 3. Comparison of VAS score progress following treatment with combined, unsynchronized emission and with MLS emission.



analgesic therapeutic effects of the two emissions, and this reinforcement cannot be obtained by merely superimposing the two emission types.

Subsequent analysis of these results in view of the definition of which energy stimulus is effectively efficient in inducing biostimulation and restoring the cell's metabolic balance (biochemical and bioelectrical), leads us to believe that the particular modulation of a Laser pulse, associated with a specific combination of wavelengths and emission modes, represents a stimulus of superior quality from a biological point of view. In other terms, one can surmise from the results that there are Laser pulses (such as the MLS pulse) that are 'perceived' by the cell as more effective, although supplying the same amount of energy.

It can therefore be affirmed that this specific modulation provides the energy supply with a peculiar 'quality' that makes it easier to absorb and able to exercise its therapeutic effect to a greater extent. This result, supported by detailed trial data, is in line with findings on cellular culture (Squizzato F. et al, in 2003), on laboratory animals (Gigo Benato D et al., in press) and with the results of some literature analyses (Fortuna D. et al, 2003).

In conclusion, this study demonstrates that MLS Therapy has a significant therapeutic effect on the inflammatory and oedematous process and on the pain transmission mechanism by a synergic and simultaneous action. This contributes to ensuring greater patient benefits and a consistent reduction in treatment times.



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MLS THERAPY TREATMENT OF VARIOUS OSTEO/MUSCULAR/TENDINOUS PATHOLOGIES.

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This study aimed to investigate the effectiveness of MLS Therapy treatment on various osteo/muscular/tendinous pathologies. 128 patients aged between 18 and 82 were treated with MLS Therapy for shoulder pain, lumbago, lumbosciatica, carpal or metatarsal tunnel syndrome and tension headache. Following treatment, significant remission of the painful symptoms was observed in all cases treated. The results confirm the therapeutic validity of the new MLS Therapy, as long as certain fundamental criteria are respected when establishing the therapeutic protocol.

Introduction

Some osteo/muscular/tendinous pathologies are a source of considerable social costs due to their incidence amongst the population and their debilitating symptoms.

The extent of the phenomenon and its consequent economic impact increase with the prevalence of the pathology, especially in the workplace. In order to provide a clear picture of the extent of the problem, we have provided some information regarding the incidence of some of the pathologies covered by this study.

Chronic lumbago

Chronic lumbago is a syndrome of variable etiology, second only to widespread respiratory diseases as the cause of time off work.

In Great Britain, 46% of a random sample of the general population claims to have suffered from lumbago at least once in their lives. This leads to an estimated cost of 620 million Euro/year. It is estimated that paid sick days due to back pain will increase to 106 million by 2002-2003 (Waddell G., 1996; Andersson G.B., 1999).

Lumbosciatica

Lumbosciatica is also a syndrome of variable etiology, characterized by pain that spreads from the lumbar area to the buttocks and lower limbs, following a lateral or posterior course. The most widespread causes are a prolapsed intervertebral disc and contraction of the



Pathology	N° patients
Shoulder pain (PHS)	36
Lumbago	28
Lumbosciatica	32
Carpal tunnel syndrome	12
Metatarsal tunnel syndrome	10
Tension headache	10
	128

Table 1: Patient distribution by pathology.

ileopsoas muscles. The pathology strikes both sexes in the same way, affecting around 7% of Italian adults (Various Authors, 2003)

Carpal tunnel syndrome

Carpal tunnel syndrome is caused by compression of the median nerve at the height of the wrist, caused by enlargement of the tendon due to inflammation inside the tunnel. Compression of the median nerve causes pain, lack of feeling and tingling in the first three fingers of the hand. If the pathology is not treated early, it may lead to permanent disability. It is estimated that, in the United States, around 3-4% of the total population may develop the syndrome every year, with a consequent demand for treatment and temporary inability to work (Tanaka S. et al, 1994). Data regarding the Italian population is substantially similar (Mondelli M. et al, 2002).

Tension headache

Sporadic tension headaches occur in around 30 per cent of the general population, while 5% suffer from this problem recurrently (at least one episode per week). Prevalence varies from 34-65% in men to 36-86% in women. Typical neurological symptoms include painful pressure on head and neck muscles, the discovery of painful points corresponding to muscles during palpation, and contraction of the masseter and trapezius muscles. The intensity of the pain is slight-average and never completely disabling.

Its characteristics do not vary over time or according to age. In its episodic form, the headache lasts from 30 minutes to seven days (less than one day in most cases). In its chronic form, the pain lasts from months to years and is only subject to one or two day interruptions. In 90 per cent of cases the pain is bilateral, strong, coercive and non-pulsating. The regions affected are usually the nape and the forehead. The pain may however extend to the occipital, parietal and frontal regions, and sometimes even to the shoulders. The accompanying symptoms include paracsis,



dizziness and slight neck stiffness (especially if the pain has spread to the neck). Pain is the only symptom in the episodic form, while chronic forms may be associated with photo/phonophobia, irritability, anorexia and nausea.

Periarthritis humeroscapularis (shoulder pain)

The term periarthritis humeroscapularis indicates a condition of periarticular inflammation that is really caused by a combination of different pathologies. It affects around 1-2% of the total population (van der Windt DA. et al, 1995). This pathology can also lead to painful, debilitating symptoms and considerable reduction of articular mobility, with consequent problems for the patient in performing even the simplest daily activities.

For all the above pathologies, pharmacological treatment targeted at reducing the painful symptoms and/or treating the inflammatory process may be more or less effective depending on the case and the pathological etiology. The problem of undesirable side effects, which are always present, is particularly significant in specific patient categories, such as the elderly, who may be less tolerant to pharmacological treatment, making this type of approach more problematic.

Clinical practice has recognized Laser therapy as a possible alternative or adjuvant. In fact, the effectiveness of Laser radiation, with suitable emission parameters, has been demonstrated in inducing analgesia, reducing the inflammation and reducing oedema. Clinical evidence on the subject (Tuner J. and Hode L, 2002) leads us to surmise that certain wavelengths and emission methods are able to provide specific therapeutic effects. Approaches that combine different infrared emissions and different emission modes (continuous and pulsed) are particularly interesting.



Clinical protocol	
N° sessions: 6	Shoulder pain Tension headache Carpal and metatarsal tunnel
N° sessions: 8	Lumbago Lumbosciatica
Standard treatment protocol (fixed duty cycle)	
Shoulder pain (PHS)	2 min <i>point app. duration</i> 900 Hz <i>pulse rep. frequency</i> 2.16 J/cm ² <i>dose supplied</i>
Lumbago Lumbosciatica	3 min <i>point app. duration</i> 900 Hz <i>pulse rep. frequency</i> 3.24 J/cm ² <i>dose supplied</i>
Carpal tunnel syndrome	2 min <i>point app. duration</i> 900 Hz <i>pulse rep. frequency</i> 2.16 J/cm ² <i>dose supplied</i>
Metatarsal tunnel syndrome	2 min <i>point app. duration</i> 900 Hz <i>pulse rep. frequency</i> 2.16 J/cm ² <i>dose supplied</i>
Tension headache	2 min <i>point app. duration</i> 400 Hz <i>pulse rep. frequency</i> 1.81 J/cm ² <i>dose supplied</i>
Analgesic treatment protocol (variable duty cycle) - very acute/acute stage	
All	1-5 min <i>point app. duration</i> 5 Hz <i>pulse rep. frequency</i> 0.085-0.423 J/cm ² <i>dose supplied</i>
Treatment protocol for pathologies in chronic or ingrained stage	
All	1 min <i>point app. duration</i> CW (continuous wave) 2.23 J/cm ² <i>dose supplied</i>

Table 2: Clinical protocol and treatment parameters.

These approaches have demonstrated (Corti L. et al, 2003) interesting biostimulation properties, already suggested by previous in vitro and in vivo studies (Gigo Benato D. et al, 2003; Squizzato F. et al, in press).

Innovative MLS Therapy appears to be particularly promising. In fact, in addition to combining specific continuous and pulsed infrared Laser emissions, it synchronizes them using a specific patented system, thereby creating a characteristic energy emission temporal pattern. The previous clinical results described in this report, together with those obtained in other centres where MLS Therapy is used on a regular basis, indicate that in the treatment of certain common pathologies affecting the muscular system, this synchronization synergizes the therapeutic analgesic and anti-inflammatory/anti-oedema effects, reducing treatment times and increasing the effectiveness of the therapy.

The scope of this study is therefore to investigate the effectiveness of MLS Therapy on some common pathologies, and, in the event of a positive result, to identify the optimal treatment parameters on the basis of the phase of the pathology (very acute/acute or chronic/ingrained).

Population and Methodology

128 patients aged between 18 and 82 (average age 40), including 62 men and 66 women, suffering from the pathologies indicated in table 1, were treated with MLS Therapy using the MIX5 device (ASA srl, Arcugnano, Italy).

The effectiveness of the treatment was assessed by means of a subjective examination (VAS scale) at the end of each session.



The treatment was administered to each patient on a daily basis, on weekdays. The number of treatments varied depending on the pathology being treated (from a minimum of 6 to a maximum of 8 sessions, see table 2). The patients were normally treated using standard treatment parameters (pre-set in the device) established on the basis of the available clinical literature (Bjordal J.M., 2003; Tuner J. and Hode L, 2002). The therapy was only adapted to the individual patient's response if necessary (reduction of the VAS during the first two sessions to below 1.5), depending on the phase of the pathology (very acute/acute or chronic/ingrained), respectively opting for more marked analgesic treatment targeted at direct action on the pain transmission mechanism or more aggressive treatment in order to facilitate the resolution of more ingrained pathologies.

The author, being experienced in acupuncture, optionally performed the treatment also on acupuncture points.

In patients suffering from an acute or very acute stage of the pathology, we decided to apply MLS Therapy following a protocol based on the administration of low energy doses at a low frequency. This was possible because the device in question allows the operator to modify the duty cycle from fixed to variable, making the dose dependent on the pulse repetition frequency. In the case of pathologies in a chronic or ingrained stage, we applied a protocol based on the administration of energy doses similar to those applied in standard protocols, supplied in a shorter space of time.

The treatment parameters used in the various cases are indicated in table 2. A brief description follows of the practical treatment method using the multidiode applicator supplied with the MIX5 device.

Before each application, the skin in the area in question was cleaned thoroughly using a bland disinfectant solution.

Shoulder pain.

Application in front of and behind the joint, with particular attention to painful points detected during the check-up, focusing on active



trigger points. The applicator was positioned at the centre of the local pain. As a reference, the anterior points of acupuncture IC 14, 15, 16; TR 14 and the posterior points IT 9, 10, 11, 12, 13 were taken into account.

Lumbago.

Treatment of the lumbar region, on both sides of the spinal column, especially at the level of the lower margins of the spinal apophyses of L2-L5 and to the sides of the sacrum. Treatment of four additional points per side, two in a distal direction starting from the articulation between L3 and L4 and two in a distal direction starting from the articulation between L5 and S1.

Lumbosciatica.

Treatment on points corresponding to the lower margins of the spinal apophyses from L1 to S1, to the right or left of the spine depending on the sciatic nerve involved. Application to 8 points along the sciatic nerve (with reference to the acupuncture points V36, 37, 40, 55, 56, 57, 60).

Carpal tunnel.

Treatment on two points above the plica of the wrist, on the plica, and on two points at the level of the palm of the hand (reference to points MC5-8).

Metatarsal tunnel.

Treatment at the level of the metatarsus with reference to acupuncture points F3-4, VB 40-41.

Tension headache.

Treatment of the active trigger points on the trapezius muscle and the masseters.



Pathology	Initial VAS	Final VAS
Shoulder pain (PHS)	8.50	2.00
Lumbago	6.50	2.00
Lumbosciatica	7.50	2.00
Carpal tunnel syndrome	6.00	2.00
Metatarsal tunnel syndrome	6.50	2.00
Tension headache	8.50	2.00
	7.63	2.00

Table 3: Initial and final VAS scores in relation to the pathology in question, and overall averages before and after treatment. The overall averages (in bold) are pondered averages for the number of patients in each class.

The average VAS scores relative to each group of patients (for each specific pathology) were calculated before starting MLS treatment and after completion of the entire therapy cycle. These values were compared using t tests and ANOVA when necessary.

Results

At the end of the treatment sessions, a significant reduction ($p < 0.0001$) in the VAS score was observed in all patients, from an average of 7.63 to an average of 2.00 (Figure 1). In the case of some pathologies (shoulder pain, tension headache), the reduction - in terms of absolute difference - was even more significant (see table 3).

In 70% of patients, independently of the pathology, we also observed a reduction in the VAS score from the initial value to what would be the final post-treatment score by the end of the fourth session. For these patients, the treatment was continued for a further 2-4 sessions in order to keep the trial conditions homogenous, but it is unlikely that stopping treatment would have led to a fresh outbreak of the symptoms.

Discussion

The results of this study extend the indications for MLS Therapy and suggest its general validity for many other osteo/muscular/tendinous pathologies.

In fact, MLS Therapy proved itself to be particularly effective in the treatment of all the pathologies considered, using the protocols initially established on the basis of earlier clinical experience. These protocols guaranteed an excellent result in the majority of cases treated.



The fact that some patients suffering from particularly intense painful symptoms, especially deriving from pathologies at an acute stage, found particular relief when the treatment parameters were modified in order to provide an MLS Therapy protocol with a marked analgesic effect (changing duty cycle from fixed to variable and reducing the pulse repetition frequency), demonstrates how important it is to be able to adapt the therapy to the individual patient’s response and also on the basis of the neurogenic pain component.

It is therefore important that the MLS Therapy tool employed, as is the case of the one used in this trial, makes it possible to cater for this requirement in cases where it is necessary to apply this type of protocol.

Although this trial was performed on a limited number of patients, the results lead us to believe that MLS Therapy is an extremely valid approach for treating the pathologies in question, in terms of ease of application, absence of side effects, effectiveness and speed in reducing the painful symptoms.

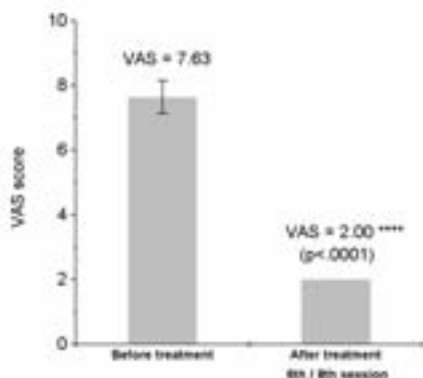


Fig. 1: Average VAS scores before start of treatment and after completion of treatment with MLS therapy.



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MLS LASER THERAPY TREATMENT OF SHOULDER PAIN: A CONTROLLED COMPARATIVE STUDY.

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Shoulder pain (periarthritis humeroscapularis) is a widespread problem that is difficult to resolve, as well as having a varied etiology.

This trial evaluated the effectiveness of treating this pathology with MLS Therapy, applied as a monotherapy, comparing the results with those obtained using traditional contact Laser therapy, in the presence of a suitable control group.

The results demonstrated that MLS Therapy is highly effective in inducing a fast reduction of painful symptoms and that this effect is greater than that obtained using traditional Laser therapy.

Introduction

The term “periarthritis” is commonly used to describe a range of painful situations in the shoulder region, including the impingement syndrome, acute and chronic calcific tendonitis, subacromial bursitis and adhesive capsulitis.

These are complex and multifactorial clinical scenarios, which cause pain and reduced mobility.

These pathologies are most commonly found in classic cases where the limb is subjected to excessive strain, either during work or following intense physical activity. Periarthritis is a strain-related pathology that affects the extra rotary muscles of the upper limb (supraspinatus, infraspinatus, teres minor) or the synovial bursae (subacromial, subcoracoid and subscapular). In some athletes, the shoulder is put through considerable strain and may be subject to repeated micro traumas. In the long term, these may determine a painful syndrome that is often the cause of a suspension of sports or work activity. The pain is frequently localized on the anterior/lateral face of the shoulder, tending to spread along the front face of the arm. Following the application of pressure, a strong pain in correspondence to the bicipital groove may arise. The painful symptoms also worsen when the joint is moved. In order to understand how the different clinical scenarios develop, we need to bear in mind some important anatomical/functional aspects. Firstly, there is a zone of greater wear in correspondence to the insertion of



the supraspinatus muscle, which is particularly delicate due to repeated trauma of the humerus head against the front margin of the acromion when raising and lowering the arm.

This trauma is responsible for lots of local painful situations (“impingement symptoms”). The long head of the biceps tendon is subjected to considerable wear, especially in proximity to the greater tuberosity and at the point where it enters the bicipital groove. There are also zones of precarious vascularization in correspondence to the supraspinatus tendons and the long head of the biceps. The so-called “critical zone”, a portion of the supraspinatus tendon situated around 1 cm away from the insertion of the greater tuberosity, is very vulnerable.

This poorly vascularized zone may become ischaemic during movement when subjected to anomalous pressure.

Complex mechanisms may also lead to the occurrence of calcification, which frequently affects the supraspinatus tendon, followed by the infraspinatus, the teres minor and the subscapular in that order. Calcification may increase in volume, infiltrating the fibres of the nearby tendons and raising the floor of the subacromial bursa. The tendon may therefore break under the floor of the bursa or inside the bursa itself. This creates communication between the bursa and the articular cavity, which can be clearly seen in arthrography. At the same time, alterations may affect the adjacent bone structures, which may be subject to sclerosis, osteophytosis and atrophy.

The standard treatment for shoulder periarthrititis, at least in the early stages, is essentially conservative and involves reduction of physical activity, pharmacological therapy with FANS, either generally or locally, and physiotherapy (Laser therapy, ionophoresis, T.E.N.S. or diadynamic currents, ultrasound therapy). Kinesitherapy is targeted at restoring joint mobility, especially in the clinical forms of frozen shoulder; restoring mobility makes it possible to reinforce the results achieved by medical and physical therapy while muscular



strengthening exercises aim to strengthen the weakened muscular groups. In our last study we highlighted the effectiveness of traditional Laser therapy in treating shoulder periarthritis, both through point treatment and by scanning the zone to be treated. Some recent studies, including those featured in this scientific report, have highlighted the effectiveness of MLS Therapy in treating various osteo/muscular/tendinous pathologies.

In particular, its greater effectiveness in terms of pain relieving speed has been highlighted in comparison to that of traditional Laser therapy for the treatment of cervicgia caused by whiplash.

We wanted to extend the comparison of the effectiveness of MLS Therapy and traditional Laser therapy to the treatment of periarthritis humeroscapularis, another pathology that is difficult to resolve.

Patients and methods

72 patients suffering from shoulder pain due to strain, including 38 men and 34 women, were randomly divided into 3 groups of 24 patients each. These groups were respectively treated with traditional contact Laser therapy, traditional scanning Laser therapy and MLS Therapy. Each patient underwent ten treatment sessions, whatever the therapy type (one application per day for 10 consecutive days). The painful symptoms were assessed using the VAS scale (visual analogue scale) at the end of each session.

The dimension of the calcifications was assessed using ultrasound (probe for small parts at 7.5 – 10 MHz).

The point therapy was performed using the IDEA TS device (ASA Srl, Arcugnano, Italy) equipped with a continuous emission hand piece, 808 nm, P_{max} 500 mW. The treatment was performed on local points of pain and any active trigger points identified by means of palpation.



Device	IDEA TS	COMBY TS D	MIX5
Therapy	Contact	Scanning	MLS
Wavelength	808	808+905	MLS Pulse
Time (mm:ss)	00:10	02:53	01:14
Frequency (Hz)	700	700	700
Dose (J/cm ²)	1.2	1.2	1.2

Table 1: Emission features of the devices used and treatment parameters.

The scanning treatment was administered using the Laser COMBY TS model D system (ASA Srl, Arcugnano, Italy), evenly covering the anterior and posterior region of the shoulder. Finally, MLS Therapy was performed using the MIX5 system (ASA Srl, Arcugnano, Italy), administering the energy in the front zone and in the rear zone of the joint.

The same energy dose was supplied in all 3 cases (1.2 J/cm²) and the same Laser pulse repetition frequency was used (700 Hz).

The emission characteristics of the devices and the application parameters are described in table 1.

All three therapeutic methods were applied as monotherapies, without the aid of pharmacological treatment or physio/kinesitherapy.

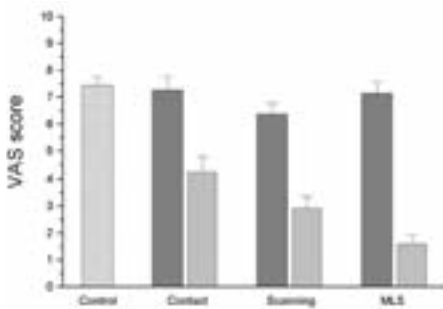
A second control group was also recruited, involving the same number of patients (72), age distribution, sex, and initial average pain intensity as assessed using the VAS scale. This group was subjected to objective painful symptom examinations at the same time as the first group and was then treated with MLS Therapy after 10 days had passed, when treatment on the first group had come to an end. This was done in order to monitor variations in the course of the painful symptoms due to the natural evolution of the disease. The treatment methods and parameters were the same as those described for the study group.

The painful symptoms of each group were assessed using the VAS scale at 15, 30 and 60 days from the end of treatment.

Results

Painful symptoms

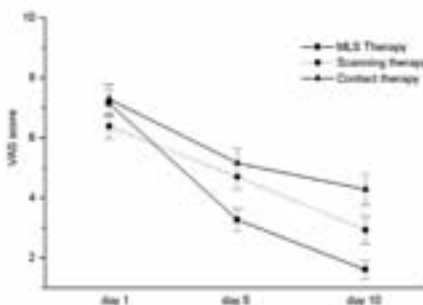
All three therapeutic methods proved to be effective with respect to the control group, guaranteeing statistically significant pain relief (see figure 1 and table 2). The two traditional techniques (contact/scanning) were not found to be equally effective. In fact,



(Fig. 1)

Therapy	Day 1	Day 5	Day 10
Control group	7.29±0.45	7.37±0.41	7.45±0.32
Contact	7.27±0.51	5.15±0.49	4.27±0.52
Scanning	6.37±0.41	4.69±0.43	2.92±0.46
MLS	7.14±0.44	3.26±0.38	1.60±0.32

Table 2: Average VAS score measured at day1, day 5, day 10 of treatment



(Fig. 2)

scanning with the combined emission was found to be slightly more effective in terms of pain relief speed compared to the contact Laser therapy (figure 2). However, the increase in pain relief speed obtained using MLS Therapy was highly significant and much faster than the traditional treatments. The percentage of patients for whom MLS therapy was effective was particularly high (84%). The follow up at 15, 30 and 60 days confirms that the results are long-lasting.

Calcification dimensions

As far as regards the calcification dimensions, all three types of Laser treatment led to a significant reduction of approximately the same entity.

Conclusions

This study demonstrates that the new MLS Therapy is a valid tool for treating shoulder pain, since it makes it possible to reduce painful symptoms within a shorter space of time than traditional contact or scanning Laser therapy. The results obtained in the follow up at 15, 30 and 60 days from the end of the treatment confirm that the results obtained are long lasting and not due to a transitory effect of temporary analgesia. The success rate (84%) appears to be particularly important in consideration of the fact that MLS Therapy was not associated with other types of physical, pharmacological or manipulative treatment.



CLINICAL RESULTS IN THE TREATMENT OF ANKLE AND KNEE DISTORTION PATHOLOGIES WITH MLS THERAPY

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Keywords: MLS VAS pain distortion
knee ankle

ABSTRACT

The aim of this study is to evaluate the effectiveness of MLS (Multiwave Locked System) Therapy on osteo-musculotendinous pathologies previously not considered, such as trauma to the knee and ankle. The knee is a complex joint, extremely exposed to trauma and degenerative lesions; while the ankle bears the body weight and is thus very vulnerable and subject to sprains.

Of the 28 patients included in this study, 11 had knee trauma, 18 had ankle trauma. A 10-day treatment with the M6 system (ASA, Arcugnano, Vicenza) was scheduled, making automatic execution of the therapy possible. The VAS scores before MLS Therapy, those before therapy but after palpation, and those right after treatment are compared through t-test.

The results confirm the effectiveness of MLS Therapy in the remission of painful symptoms and in recovery of functionality in a short time, so as to allow, in many cases, for the suspension of therapy before completing the 10 sessions foreseen by protocol.

INTRODUCTION

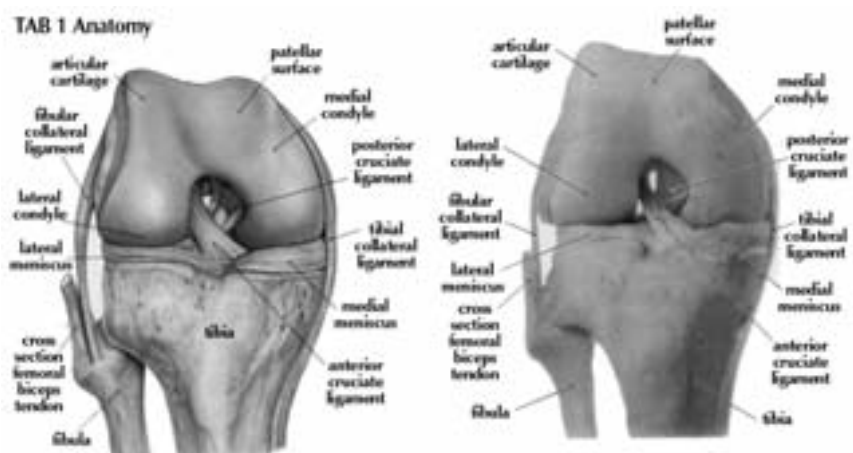
It has been known for some time that laser therapy successfully treats numerous musculoarticular pathologies (Bjordal JM. et al. [1]; Hakguder A. et al. [2]) playing an important role in the physical therapy used in daily medical practice (England S. et al. [8]; Ernst E. et al. [9]; Gam A. et al. [10]; Tuner J. et al. [3]).

In particular, it has been observed that continuous emission has an



anti-inflammatory effect and pulsed emission has a prevalently analgesic effect (Tuner J. [3]); while, in a previous study on treatment of post-traumatic cervicalgia, it has been shown that the combination of the two types of emission represents an effective way of obtaining the overlapping of both therapeutic effects (Corti L., et al. [4]). Thanks to the control system that generates the MLS impulse, MLS therapy takes another step ahead: through synchronization of continuous and pulsed emission, the analgesic, anti-inflammatory and anti-edema effects are strengthened synergically with each other. These results are in line with previous cell culture and laboratory animal studies, where we can see how particular types of laser impulses are able to exercise greater therapeutic effects (Squizzato F. et al. [5]; Gigo-Benato D. et al. [6]; Fortuna D. et al. [7]). The aim of our research was to expand the case histories relative to MLS Therapy, evaluating its effectiveness on osteo-musculotendinous pathologies as of yet not taken into consideration, such as knee and ankle trauma.

The knee joint extends from between the distal end of the femur and the proximal end of the tibia and is protected in front by the knee-cap, which eases the muscles' job during flexion and extension movements. The bony surfaces are covered by a layer of cartilage which eases their reciprocal sliding. The knee has two menisci, medial and lateral. The menisci are cartilaginous structures serving both for increasing stability and for absorbing blows and loads, acting like proper shock





absorbers. Finally, the ligaments are fibrous structures connecting the joint ends: the anterior cruciate ligament with the posterior cruciate ligament forms the central pivot of the knee, essential for the knee's stability as it prevents anterior translation of the tibia in respect to the femur. Thanks to the help of the articular capsule, which contains the synovial fluid, and the muscles, the ligaments allow movement.

We have specifically emphasized the effectiveness in terms of pain remission, confirming the validity of this therapeutic approach in reduced treatment time.

The knee

Because of its anatomy, the knee joint is the most exposed to trauma and degenerative lesions.

It is a complex joint which subjects the bone, capsule, meniscus, ligament and myotendinous structures to considerable stress; an incorrect movement while practicing sports, a sudden functional overload of the knee, a contrast with the foot set on the ground can produce acute lesions.

The most common traumas are due to sudden rotation of the tibial plate with the foot set on the ground.

They provoke lesions in the menisci, the cruciate ligaments, the collateral ligaments or sprains. In our study we present the most frequent cases regarding gonalgia from knee sprains, the diagnoses range also to contusions, meniscal alterations, tendonitis, lesions to the ligaments, apophysitis.

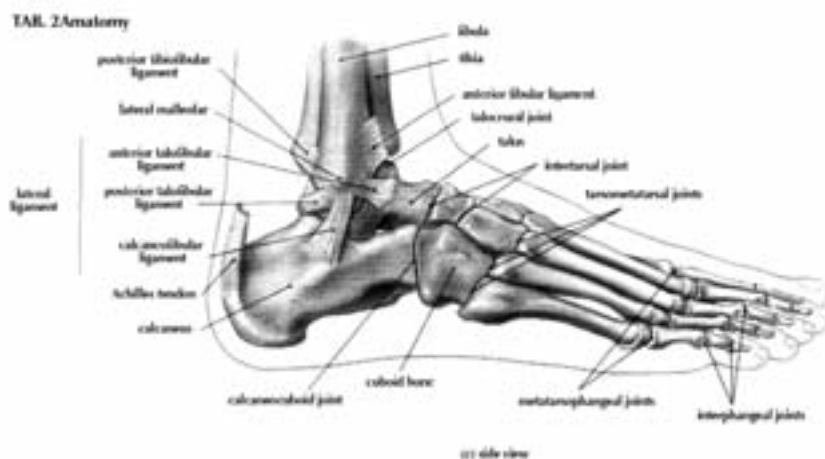
Sprain is due to a "closed" lesion, or one without tearing of the skin, of a joint that is rotated violently beyond the normal limits of its mobility. This abrupt movement leads to an incomplete and temporary dislocation of the bone heads involved.

The speed of the movement and return to its normal position, even if it doesn't generally provoke bone lesions, does not prevent, however, a serious sprain or even the breaking of the ligaments that stabilize the joint itself.

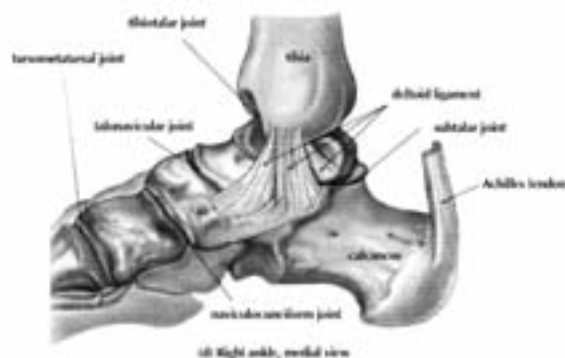
The symptoms of pain and fast developing local swelling are due to this mechanism of straining and laceration.



The foot is a sophisticated structure made of 26 bones, joined by 33 joints reinforced by more than 100 ligaments. The weight of the body passes to it through the ankle or talocrural joint, formed by the articulations between the tibia, fibula and talus. The articular capsule of the ankle joint extends between the distal surfaces of the tibia, the medial malleolar, the lateral malleolar, and the talus. The ligaments extend between all these bones, strong fibrous cords whose rupture, following more serious sprains, implies a greater articular play with subsequent instability. The main ligaments are the medial deltoid ligament and the three lateral ligaments. The malleolars, supported by these ligaments and held together by the tibiofibular ligaments prevent the ankle joint from slipping sideways.



Ankle and foot joints. Side view (Martini FH et al. [11])



Ankle and foot joints. Medial view (Martini FH et al. [11])

The ankles are very vulnerable and thus subject to sprains. A sprained ankle comes about because of heavy stress involving the ligaments. The most common sprain mechanism is an internal rotation movement of the ankle. When this unusual movement is faster and stronger than can be contrasted by the muscles, the ligaments will be subject to an excessive traction leading to damage to the ligaments. This damage can be more or less complex depending on the number of ligaments involved and the extent and



seriousness are quantified in three degrees: first degree sprains consist of a sprain of the ligaments without breaking; second-grade sprains include a partial break of the ligaments, nevertheless leaving joint stability intact; finally, third-degree sprains are the most serious and means there is complete breaking of the ligaments, leading to instability.

Also in the case of the ankle the traumas examined in our study have different etiologies: tibiotarsal sprain with lesions of the ligaments, contusions of the malleolars, plantar fasciitis of the calcaneus insertion of the foot, metatarsal fracture, tendonitis, partial lacerations of the ligaments, tenosynovitis, capsulitis.

Just as for the shoulder and elbow joints, individual tendons can develop degenerative pathological processes linked to functional overload. One of the most common kinds of tendonitis, found in some cases of this clinical study, is tendonitis of the Achilles tendon. The Achilles tendon originating from the muscles of the posterior leg space, inserts in the calcaneus; its task is to transmit the force originating in these muscles to the skeleton and it is constantly involved during walking, running and jumping.

The main symptom is pain along the length of the tendon sometimes felt in the calcaneus region, initially tied to physical effort, but after a while also at rest.

MATERIALS AND METHODS

Admitted to the study were patients coming for physiotherapy and rehabilitation for the consequences of trauma to the knee or ankle. 28 patients participated, 17 with ankle trauma, 11 with knee trauma. The patients were treated daily, on weekdays, for a total of 10 sessions altogether. During the first 5 sessions MLS Therapy was applied as monotherapy. In the following 5 sessions MLS Therapy was accompanied by electrostimulation in order to favour muscle recovery, with an identical protocol for all the patients.

The MLS Therapy equipment used for this study is the M6 system



(ASA, Arcugnano, Vicenza). M6 makes automatic execution of MLS Therapy in Multitarget form possible. Thanks to its robotized head, illumination is performed by automatic shift on the treatment zone of a target area illuminated simultaneously.

The applicator is positioned above the area to be treated (100cm²), at a distance of approximately 20 cm, trying to guarantee as far as possible that the patient does not move his leg during treatment.

The applicator is positioned above the area to be treated (100cm²), at a distance of approximately 20 cm (measurable with the ultrasound sensor with which the equipment is supplied).

In this study treatment with MLS Therapy was performed at a constant frequency of 700 Hz per 10 minutes at an intensity of 50%. The total energy emitted was 481.5 J, which corresponds to a dose of 4.8 J/cm².

Assessment of the outcome was made by VAS (Visual Analogue Scale) at three different moments of each session: the value of spontaneous pain was evaluated before the start of MLS Therapy (T1), pain after palpation before the onset of therapy (T2) and pain at the end of therapy (T3).

In some cases the articular functionality before the onset of therapy and at the end of the entire 10-session cycle was evaluated. In particular, the extent of articular excursion of the knee was studied: with the patient lying down and the knee flexed the distance between heel and buttocks was measured (normal extension corresponds to about 5°).

The VAS data at T1 (before MLS Therapy), Ts (before MLS Therapy after palpation), T3 (right after MLS Therapy) were compared through t-test. The minimum level of significance was set at 0.05. The data were analyzed with Origin software (Microcal), version 7.0.

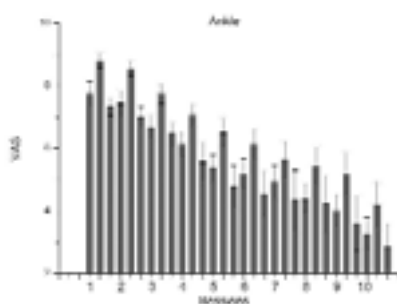


Fig. 1 Average VAS score before MLS Therapy (T1), before MLS Therapy after palpation (T2), right after MLS Therapy (T3).

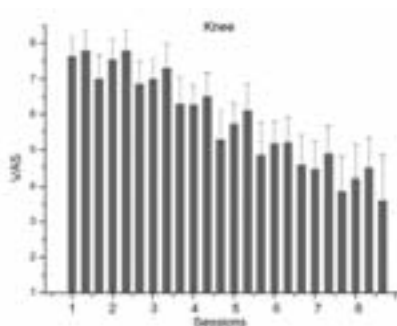


Fig. 2 Average VAS score before MLS Therapy (T1), before MLS Therapy and after palpation (T2), right after MLS Therapy (T3).

RESULTS

At the end of treatment MLS Therapy for all 28 patients the results for the VAS score show a clear improvement in passing from the first to the tenth session. In the case of the ankle the results relative to the VAS show a clear and constant improvement from session to session. In passing from T1 to T2 of each session we notice a worsening of the VAS, due to palpation of the painful area. As we can see from the graph in figure 1 (Session 1, VAS (T1) = 7.75 ± 0.37 , N =16; session 10, VAS (T3) = 2.850 ± 0.41 , N =7) the difference between the average VAS value at time T1 at the first session and the average VAS value at time T3 at the tenth sitting is statistically significant ($p < 0.00001$). At time T2 of each session (VAS evaluation after palpation) we observe a slight worsening of the painful symptoms due to palpation of the painful area; a value which, in any case, diminishes at every session in a statistically significant way (Session 1 VAS(T2) = 8.81 ± 0.25 , N =16; session 10, VAS (T2) = 4.20 ± 0.74 , N = 10; $p = 3.05E-7$).

From figure 1 we can see that the error of the average VAS value grows with the number of sessions; the increase in errors is due to the fact that many patients ended the treatment before the ten applications. To demonstrate this, the statistical analysis of the data is significant ($p < 0.0001$) comparing the averages at the first and the fifth sessions, calculated on the VAS values of 16 patients: at session 1, VAS (T1) = 7.75 ± 0.37 , N =16; at session 5, VAS (T1) = 5.37 ± 0.44 , N =16.

In the case of the knee, remission of pain obtained in patients with MLS Therapy is less significant. Nevertheless, to show the effectiveness of MLS Therapy in relatively short times, only two of the eleven patients treated completed the ten sessions.

For this reason statistical analysis is made between the VAS values obtained in the first eight sessions (Fig. 2) obtaining significant results with the comparison of the averages at time T1 of the first



session and at time T3 of the eighth session ($p < 0.01$): S1, T1, VAS = 7.63 ± 0.53 , N = 11; S8, T3, VAS = 3.6 ± 1.2 . If, instead, the t-test is made between the VAS at session 1 and the VAS at session 5, all the patients are included: S1, T1, VAS = 7.63 ± 0.53 , N = 11; S5, T1, VAS = 5.72 ± 0.58 , N = 11 ($p < 0.01$).

DISCUSSION

The results of this study broaden the therapeutic confines of MLS Therapy demonstrating its effectiveness in the remission of painful symptoms and in the recovery of functionality, both in patients with ankle trauma and those with knee trauma

The remission of pain is in fact statistically significant in both cases, considering also the fact that most of the patients start with an elevated VAS score (20% patients, VAS = 10). In patients with ankle trauma the result corresponds to five 'stars', on the basis of the decimals separating the p-value from 1 ($p < 0.00001$); the patients with knee trauma show more modest but statistically significant results ($p\text{-value} < 0.01$).

In the last four sessions, in both cases, VAS error increases; this is due to the fact that many patients terminated their treatment cycle after the fifth session. Suspension of treatment before ten sessions signifies that the therapy is effective in times which are even briefer than those foreseen.

For some patients articular functionality has also been evaluated at the end of the ten sessions by measuring the degrees of the extent of articular excursion of the knee: in 75% of the cases recovery of functionality results at 60%.

This study has demonstrated that the new MLS Therapy represents a valid instrument even for the effectiveness in short treatment.



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MLS THERAPY TREATMENT OF ACUTE SHOULDER PAIN IN INFLAMMATORY PROCESSES OF THE ROTATOR CUFF

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Keywords: MLS, shoulder, pain, VAS, SSRS, rotator, cuff

ABSTRACT

Shoulder pain is a complex pathology due to pathological processes involving the glenohumeral joint, the acromioclavicular joint, the ligaments or the supporting tendons. In this paper we illustrate the efficacy of MLS (Multiwave Locked System) Therapy in the treatment of acute shoulder pain in inflammatory processes involving the rotator cuff. Twenty patients underwent monotherapy treatment with MLS Therapy using the MIX5 system (ASA, Arcugnano, Vicenza). After an initial clinical-anamnestic examination, subjective and objective evaluations of the pain symptomatology are made right before treatment, after 10 days of application and after 30 days. At the end of MLS Therapy treatment the data are compared with each other using t-test: the results relative to the VAS ($p < 0.0001$) and to the SRQ and SSRS parameters show a statistically significant improvement and, as already demonstrated previously, confirm MLS Therapy as one of the best solutions for rapidly reducing pain symptoms in many muscle-tendon diseases, guaranteeing long-lasting benefits from the results.

INTRODUCTION

Shoulder pain is a complex pathology with a multiple etiology. Felt at the inner shoulder, this pain is due to pathological processes involving the glenohumeral and acromioclavicular joints, the ligaments or the supporting tendons. The complex movement of the shoulder is the result of the movement of four joints: the scapulohumeral, the acromioclavicular, the sternoclavicular and the



Tab. 1 – The scapulohumeral joint is the most mobile of the human body: it has three degrees of movement which allow the upper limb to be oriented in relation to the three planes of space (sagittal, frontal, horizontal). Nevertheless, we must remember that the scapular glenoid does not completely contain the head of the humerus; stability is guaranteed by the glenoid labrum which increases its surface and covers it. The rotator cuff muscles, together with the superior, middle, and inferior glenohumeral ligaments and the tendon of the biceps long head, contribute to maintaining the humeral head inside its joint cavity; if this did not happen the head of the humerus would dislocate at every movement.

scapulothoracic. In order for the shoulder to function well, all four of these joints must move simultaneously and in synchrony.

There are about 30 muscles surrounding the shoulder, allowing its movement; in particular, the muscles making up the “rotator cuff” are responsible for the external and internal rotation of the shoulder: the supraspinatus (abductor), subscapular (internal rotator), infraspinatus and teres minor (external rotators).

These structures, together with the long head of the brachial biceps and the subacromion-deltoid bursa, fall between the humeral head and an arc above it consisting of: acromion (a postero-anterior projection of the scapula), the coracoid process (an anterior projection of the scapula), and the coracoacromial ligament, which

subacromial bursa
acromion
supraspinatus
acromioclavicular joint
coracoacromial ligament
infraspinatus
coracoid process
long head of biceps
teres minor
subscapularis

joins the two protuberances. Inflammation of these structures causes “degenerative syndrome of the rotator cuff”.

Pathologies involving the rotator cuff derive typically from excessive use of the shoulder and can arise following physical activity. In the case of “throwing” sports (such as volley ball), they originate from an inflammation of the tendons due to harmful mechanisms of overload



caused by movements that are repeated excessively (microtraumas) or performed too intensely. The causing factors are extrinsic or intrinsic, such as defects in the length or angle of the limbs, postural imbalance. The problem originates from a bad relationship of force between the elevator/depressor muscles and the internal/external muscles that during movement generate a conflict between the tendon and the bony wall above them; this perpetuates damage to the tendon, making it degenerate until there is a partial or complete break. The use of laser as a therapeutic instrument is quite widespread and has been used successfully for some time in treating numerous muscle-joint pathologies (Bjordal JM, et al. [1]; Hakguder A, et al. [2]) as it is able to stimulate the different cell processes at the tissue level, which translates into remission of pain, diminution of edema, inhibition of the inflammatory process (Tuner J, et al. [3]; England S, et al. [5]; Ernst E, et al. [6]; Gam A, et al. [7]).

Furthermore, it has been known for some time that continuous laser emissions act quickly on inflammation while the pulsations have a practically immediate effect on pain (Tuner J. [3]). Recent studies show that the combination of the two types of emission results in an overlapping of the therapeutic effects (Corti L. et al. [4]).

MLS Therapy further enhances these therapeutic effects by achieving a linked and synchronized emission of different continuous and pulsated laser emissions with different infrared wavelengths.

The aim of the study presented in this report is to evaluate the efficacy of MLS Therapy in the treatment of acute shoulder pain in inflammatory processes involving the rotator cuff, avoiding, in this case, concomitant pharmacological therapy.

As already demonstrated in recent studies, MLS Therapy has shown its effectiveness in the treatment of many muscle-tendon diseases and represents one of the best solutions for reducing pain in the shortest time possible, guaranteeing long-lasting benefits.



MATERIALS AND METHODS

Population

This study includes 20 patients, 7 males and 13 females, with a mean age of 59 (range: 45-78 years), suffering from painful shoulder due to inflammatory processes involving the rotator cuff.

The inclusion criteria for the study call for the presence of pain in the shoulder, with or without functional limitations, in the absence of complete lesions of the rotator cuff (shown by ultrasound or NMR), fractural or degenerative pathologies, and a history of recurring dislocations. The patients begin monotherapy treatment with MLS Therapy in the absence of concomitant or recent oral or infiltrative NSAIDS or corticosteroids.

Equipment

The equipment used for this study is the MIX5 D system (ASA, Arcugnano, Vicenza), equipped with a multidiode applicator with a fixed sight and 5 continuous and pulsated laser heads guided by the MLS system. The MLS emission of the applicator covers a Target Area of 5 cm in diameter, capable of optimizing the homogeneous and simultaneous activation of several photoreceptors and of a broad tissue volume. Homogenous coverage of the zone to be treated is important for minimizing energy loss through scattering, guaranteeing that all the tissue responds promptly to the therapy.

Methodology

One session per day is effected, for 10 days (5 days a week for two weeks) on the target area corresponding to the site of the diagnosed lesion. The evaluation methods call for an initial clinical-anamnestic examination, followed by the subjective and objective evaluations of the painful symptoms through the use of the VAS (Visual Analogue Scale), of the SSRS (Subjective Shoulder Rating Scale) test and the SRQ (Shoulder Rating Questionnaire) test in three phases: prior to the beginning of the entire MLS Therapy cycle, at the end of the cycle and 30 days after the end of therapy.



The VAS, for the evaluation of painful symptoms, is a straight line of 10 cm with the two ends corresponding to “no pain” – equal to 0 – and with the maximum pain possible, or the maximum experienced – equal to 10 -.

The SRSS (Bonaiuti D. [8]) represents the patient’s appraisal of the condition of his own shoulder. The SRSS, in contrast to most specific measurement scales for the shoulder, also includes evaluation of instability. It attributes the main importance to articularity (35 points), rather than to function (10+5) or to instability (15 points). Pain is not evaluated on the basis of intensity (as with the VAS scale) but in relation to frequency, length and the circumstances in which it is felt. The highest score for a shoulder with no problems is 100. The lowest score is 0.

Objective evaluation is effected through a clinical exam of flexion, abduction, internal rotation, external rotation and administration of the SRQ scale (Bonaiuti D. [8]). The latter is evaluated by a questionnaire for evaluating the severity of the correlated symptoms and the functional state of the shoulder.

It includes pain, everyday, sports, and free-time activity, satisfaction with the work, and the areas of improvement. The highest score for a shoulder with no problems is 100; the lowest is 0.

After the first evaluation (T1) follows MLS Therapy with a constant frequency of 700Hz per 5 minutes. All together 55.01 Joules are emitted, equal to a dose of 2.8 Joule/cm² with an intensity of 50%.

The second evaluation (T2) is effected immediately at the end of the 10-session cycle, using the same evaluative instruments.

Finally, the third evaluation (T3) is obtained with a new administration of the evaluation tests 30 days from the end of the last MLS Therapy session.



Data analysis

The data from T1 (beginning of therapy), T2 (end of therapy), T3 (30 days after the end of therapy) are compared through t-test.

The lowest level of significance is set at 0.05. The data are analyzed with Origin software (Microcal), version 7.0.

T-test is an appropriate analysis every time we want to compare the averages (A) of two groups (a, b) and estimate if the averages of two groups are statistically different from each other.

T-test compares two averages keeping in mind how much the average found between the two groups differs from the real average (valid assumptions assuming that the distribution of the terms of the population follows a normal or Gaussian pattern); this evaluation is linked to the probability of error that we are willing to accept and depends on the standard deviation of our samples.

The parameter representing the analysis of the t-test is the p-value, or significance level, which is calculated in the following way: $p\text{-value} = \frac{Ma - Mb}{SE(Ma - Mb)}$ The numerator is represented by the difference of the averages of the two groups; the denominator, instead, refers to the standard error of this difference.

The standard error depends in turn on the standard deviation that measures how much the single values differ from the mean.

In our case, group a, for example, is represented by the average of the VAS of the patients of the patients in time T1 and group b by the average of the VAS of the patients at time T2: $p\text{-value} = \frac{VAS1 - VAS2}{SE(VAS1 - VAS2)}$.

To give another example, group a is represented by the average of the SRQ of the patients at time T2 and group b by the average of the SRQ of the patients at time T3: $p\text{-value} = \frac{SRQ2 - SRQ3}{SE(SRQ2 - SRQ3)}$. The p-value represents the probability that the difference observed between the two averages is casual.

Typically, a value of p-value equal to 0.05 (or 5%) is used: a p-value

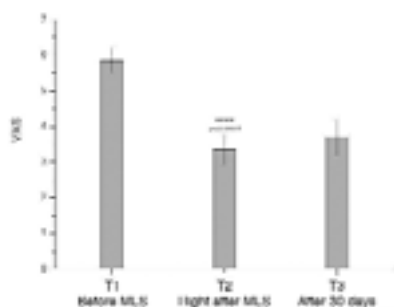


Fig. 1 Average VAS score before MLS treatment (T1), right after MLS treatment (T2), 30 days after treatment (T3).

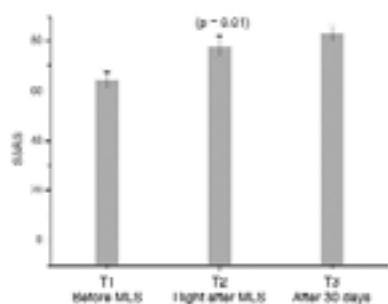


Fig. 2 Average SSRS score before MLS treatment (T1), right after MLS treatment (T2), 30 days after treatment (T3).

equal to 0.05 tells us we have a 5% possibility that the difference between the two averages is casual. Therefore, in our case, if in the comparison between VAS1 and VAS2 $p < 0.05$, we can say that VAS1 and VAS2 are statistically different from each other, in other words VAS1 is significantly different from VAS2.

RESULTS

At the end of treatment with MLS Therapy the results relative to the VAS scale show a clear improvement in the passage from T1 to T2, as we can see in the graph in figure 1 (VAS1 = 5.85 ± 0.37 , N=20; VAS2 = 3.35 ± 0.41 , N=20): the difference between the two values is statistically significant ($p = 5.48E-5$).

Upon follow up after 30 days the result obtained at T2 remains stable in time (VAS3 = 3.7 ± 0.49 , N=20): the mean VAS at T2, in fact, is not significantly different from that at T3 ($p = 0.59$), even if there is a slight worsening of the painful symptoms.

Regarding the SRSS test we notice a significant improvement from T1 to T2, as shown by the graph in figure 2 (SSRS1 = 64.4 ± 3.23 , N=20; SSRS2 = 77.95 ± 3.95 , N=20): the difference between the two values is statistically significant ($p = 0.01$).

At 30 days (SSRS3 = 82.8 ± 3.24 , N=20) the result obtained remains stable: the value of SSRS2 is not significantly different from that of SSRS3 ($p = 0.35$), rather, it continues to increase, witness of a further improvement.

The results of the SRQ test show roughly the same pattern: there is a significant improvement from T1 to T2 as can be seen in figure 3 (SRQ1 = 44.25 ± 3.76 , N=20; SRQ1 = 55.8 ± 3.47 , N=20): the difference between the two values is statistically significant ($p = 0.03$). At 30 days the result obtained at T2 remains stable at T3 (SRQ3 = 60.05 ± 3.31 , N=20): the value of SRQ2 is not significantly different from that of SRQ3 ($p = 0.38$) and here, too, there continues to be improvement.

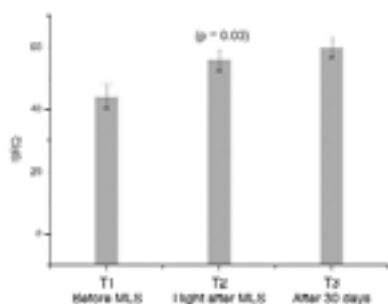


Fig. 3 Average SQR score before MLS treatment (T1), right after MLS treatment (T2), 30 days after treatment (T3).

DISCUSSION

The results of this research highlight the effectiveness of MLS Therapy in the treatment of pain of the shoulder and, in particular, of the inflammatory processes involving the rotator cuff.

At the end of treatment with MLS Therapy the results relative to the VAS and to the SRQ and SSRS parameters show a statistically significant improvement; the VAS bears witness to a considerable improvement: the result corresponds to four ‘stars’ based on the decimals separating the p-value from 1 ($p < 0.0001$).

The analysis made at 30 days after the end of treatment show a slight worsening of the VAS, not – however – statistically significant. Nevertheless, the VAS at a month after treatment is not comparable with the data found before treatment: the worsening may represent an almost functional process due to the resumption of motor activity of the shoulder and arm involved, without recording the true quality of the pain. To demonstrate this, the results of the SSRS and SRQ scales are significant; at 30 days from the end of treatment there is a slight improvement indicative of the persistence of the benefits of this therapy.

In this study we wanted to examine the path of the painful symptomatology through subjective as well as objective measure. VAS is a one-dimensional instrument that quantifies what the patient subjectively perceives as pain or as relief in the whole of their physical, psychological and spiritual variables without, however, distinguishing which of these components has the greater role. SRSS and SRQ are specific tests for pathologies involving the shoulder, known internationally, which extend the evaluation of the pain to multiple determining factors.



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