

Laserpuncture with MLS[®] (Multiwave Locked System) system Mphi: safety and clinical efficacy in joint disease, preliminary data.

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ABSTRACT

The article discusses preliminary results of laser acupuncture with Multiwave Locked System in osteoarticular diseases. Laser acupuncture is a modern technique to stimulate acupoints without needling. The effects of laserpuncture on 67 adult outpatients are discussed. Laser acupuncture showed to be a safe and painless tool to manage osteoarticular pain. Parameters, dosages and modality are discussed: laserpuncture needs lower frequency and lower dosage than other laser's therapy protocols. Our results suggest that laserpuncture with MLS[®] could be a good non-pharmacological treatment in the management of chronic pain.

INTRODUCTION

Acupuncture is considered an excellent tool for non-pharmacological treatment and control of pain in osteoarthritic disease: mechanisms of action are well known and have been studied for decades by the

international scientific community [1,2]. Acupuncture uses the stimulation of specific points on the body, which vary according to the situation, to get through local and general reactions, a reaction of reduction of pain and to facilitate recovery. The most classic form of point stimulation uses needles (characteristic and very thin needles). The acupuncture point was recently defined as NAU ("Neural Acupuncture Unit"), which corresponds to a set of concentrated neuronal and neuroactive components, present in the skin, muscle and connective tissue [3,4].

Explained from the point of view of Western medicine acupuncture is a technique of peripheral sensory stimulation (via activation of peripheral A-delta and C fibers) applied at specific points, acupuncture points and/or trigger points, which activates the nerve pain pathways, causes the release of pain-killing substances and causes a rebalancing of muscle contractility and of sympathetic nervous system. The WHO documents,

milestones in the literature on acupuncture, show the pathological situations in which acupuncture has proven to be effective, mainly in headache, knee pain, back pain, cervicgia, epicondylitis, shoulder pain, rheumatoid arthritis [5,6].

The use of laser light to stimulate the acupuncture points is carried out by about 3 decades [7]. In the scientific literature (PubMed), there are over 500 works on laser - acupuncture, which show that it is a form of effective points stimulation. Laserpuncture consists in the treatment of acupoints with the laser light beam and it is defined as "stimulation of traditional acupuncture points with low intensity laser irradiation, which does not induce heat". In the Western world it is little known that pioneers doctors of laserpuncture are just from China.

The light beam generated by the laser device is directly applied to the skin at the level of trigger points (acupuncture "ASHI" points) and to the specific acupoints and meridians according to the syndromes identified by Traditional Chinese Medicine. The points of laserpuncture are in fact selected using the same selection rules of classical acupuncture. The scientific literature on laser acupuncture is quite extensive although not conclusive, and it is not yet clear whether there are differences between laser puncture and needle puncture [8-10]. The stimulation of acupoints with a laser beam seems to have an effect similar to classic acupuncture, both at clinical and neuro-molecular level. The effects of laserpuncture are in fact partly due to peripheral nerve stimulation, to the modulation of afferent input on second-order neurons and spinal analgesia increase by endogenous opioid, through the action of central mechanisms. The laser also acts at the cellular and local level with evidence of modulation of immune processes. Some reports suggest that laserpuncture can be even more effective than traditional acupuncture. In fact, the laserpuncture combines the effects of acupuncture to the effects of biostimulation of the laser beam.

The "photo-bio-stimulation" of specific laser wavelengths on the acupoint can cause biochemical changes, electrochemical and structural properties at the cellular level, triggering additional factors on the outcome of the disease.

However, many questions still remain, mainly related to the instrumental parameters to be used in the technical practice. There are recognized international organizations that offer laser therapy recommendations. For example The "World Association for Laser Therapy" (WALT) [11] suggests doses ranging from 2 to 16 Joules for laser treatments. The "Australian Medical Acupuncture College" established [12] that "the energy density for optimal laserpuncture and biostimulation, based on current clinical experience, is 4 J/cm²". The most important determinant of the effectiveness of laserpuncture is the depth of action, and the technical parameters have been recently established [13]. The depth of action of the beam depends (besides the characteristics of the subject) on wavelength, dosage, beam intensity, energy density, dose range (which varies in the literature between 0,001 J/cm² and 10 J/cm²), continuous or pulsed laser emission. Tuner and Hode, both appraised researchers on laser therapy, have recently stated that "dose is a very complicated issue. It is a matter of wavelength, power density, type of tissue, condition of the tissue, chronic or acute problem, pigmentation, treatment technique, and so forth" [14]. Still Tuner and Hode say "anyone who studies the literature carefully can become confused. Some wavelengths achieve the best effects on This and That, while others have poorer effects or none at all. Some doses lead to beneficial effects, but when the dose is increased, the effects wear off. If we treat a condition, some of the parameters we want to influence may be affected, but perhaps not all. If we administer treatment from a distance, we do not get the same effects as if we treat analysis or in contact with pressure. Some frequencies produces effects

on pain, others on edema. What are we to believe? And what do we do to find the best dose, wavelength, and so forth?".

Good experimental data seem achieved when two different wavelengths are combined together, with a so-called two-color laser [15]. The continuous emission simulates the continuous presence of the needle, while the pulsed emission allows a greater depth of action and a bio-stimulating effect. Only recent research has begun to explore the possibility of using high-intensity laseracupuncture to replay the stimulation of the needle [16]. At the state of the art today, the optimal power of the laser beam in the laser acupuncture lies between 5-500mW, and the therapeutic effect of laser-puncture is obtained for wavelengths between 600 and 1000 nm. With the red laser (600-700 nm) there is a little of penetration through the skin and is usable to treat the surface points (Jing Well points) like those of the tip of the fingers and toes, while the IR laser (800-1000) are used for the deeper points, on the arms, legs, trunk and ASHI points.

A laser beam of 5-20 mW directly on the skin produces no pain, no heat or other sensations. The optimal frequency of stimulation for the laserpuncture is very low (10 Hz) and continuous or pulsed emission mode evokes different reactions [17]. The other parameter is the treatment time of each point, which is a function of the laser power and of the type of disease. In general, the higher the laser power the shorter is the treatment time, more time is needed for the treatment of joint pain compared to the soft tissues and more time is needed in chronic conditions compared to acute situations. The dosage is expressed in J/cm² (density): 1W = 1J/sec. Knowing the type of laser we can calculate the necessary time of application. To decide about the dose one must take into account the diameter of the area in cm². For laserpuncture we requires the handpiece in contact with the skin, with a few millimeters

beam diameter. The acupuncture points are then treated with different doses depending upon the location and depth of the point to be treated. In the literature dosages vary from 0.2-0.5 J/cm² up to 4-8 J/cm², with time exposure variables based on the laser type. The dose must be adjusted in relation to the assessment of the disease and the individual response. Laser acupuncture is applied in acute and chronic painful conditions, neck pain and low back pain, shoulder pain, joint pain from osteoarthritis of the hip, knee, hand, foot, epicondylitis, carpal tunnel syndrome, and in general in all the fields of application of somatic, auricular and microsystems acupuncture. Use of laserpuncture has greatly increased in recent years due to its painless nature and the absence of side effects [18-20].

The laser physiotherapy is considered to be a secure and non-hazardous tool. Many types of lasers have been used over time to stimulate acupuncture points. A new laser is the Multiwave Locked System (MLS®) [21,22], in which the laser diode differs from the other for the simultaneous emission of two wavelengths, different for both wavelength and for emission modes: a continuous emission of 808 nm, and a 905 nm pulsed emission.

The continuous emission has a prevalent anti-inflammatory effect, while the pulsed emission has a predominant analgesic effect: the synchronized double emission causes a reinforcing effect between the two actions, resulting in rapid physiological effects and symptoms relief. The effect of the MLS® pulse was initially tested in vitro on cell cultures, afterwards in vivo in animals and finally on controlled clinical trials.

The laser MLS® has multiple demonstrations of experimental and clinical effectiveness in many diseases and musculoskeletal affections, using established protocols on the basis of experimental and clinical data.

RATIONALE OF THE STUDY

The present study concerns the safety, feasibility and effectiveness of

laserpuncture, using the MLS® laser instrument, type Mphi.

- 1) The first objective was to evaluate the safety of treatment with laserpuncture using MLS® (in terms of adverse reactions, side effects, both local or general effects).
- 2) The second objective was to evaluate the clinical efficacy of the treatment and the degree of patient satisfaction.

CASE STUDIES AND METHODS

67 adults patients were treated on an outpatient basis, 28 M and 39 F, mean age 64 aa (range 35-78 aa.) for a total of 402 sessions (mean 6 sessions/patient). The patients suffered from acute or chronic muscle-skeletal diseases, in painful phase: 18 neck pain, 16 low back pain, 13 knee pain, 14 shoulder, 6 arthrosis / arthritis hands.

Before treatment, all the patients were informed of the technique and the specificity of the laser beam, and expressed written informed consent to treatment. The evaluation parameter, which tests the most important symptom in all painful conditions was the Visual Analogue Scale (VAS). It was administered to the subjects before treatment, after 3 laser sessions, at the end of treatment and at follow-up three months after, by telephone interview which consists of four response options: 1 - not satisfied, 2- not very satisfied, 3 - satisfied, 4 - very satisfied.

The treatment was done on an outpatient basis. The patients were treated 3 times / week, every other day, for 2 weeks, for a total of 6 sessions.

The treatment was carried out with laser Multiwave Locked System, Mphi model, with handle in contact, tailored specifically for laserpuncture. The instrument dispense simultaneously two laser rays, with 808 nm and 905 nm wavelength.

The source of 808 nm has a maximum power of 1,000 mW, continuous emission frequency ranging from 1 Hz to 2Khz , while the 905 nm source has a maximum

power of 25 W and frequency adjustable from 1 Hz to 2kHz. By manually adjusting the parameters it is possible to give the exactly measured J/cm², to tailor treatment according to the disease and the site of the chosen points. The intensity of the treatment was set to 50% of the maximum power of the source MLS®.

Treatment protocol used:

For all diseases, ASHI points and points deep the energy delivered was 4-8 J/cm², while on the most superficial or very sensitive points, we limited to an energy up to 0.5 J/cm². In any case the frequency was always set to 10 Hz. The treatment, for purposes of study, has been globally simplified: "standard" groups of points for each disease were used, while only a few other points were customized in relation to the syndrome and involved meridians.

For patients with neck pain also with shoulders irradiation, with frequent flare-ups of chronic pain relieved by rest and heat: 10 UB, 20 GB, 11 UB, 21 GB, 15 and 16 SJ, and the painful points. The lower extremities bilaterally 59-60 UB, 34-38 GB, Kid 3 or 3 Liv, plus 3 SI in the upper limb .

For patients with low back pain: the sensitive points on the internal branch of the Urinary Bladder meridian, from 21 UB to 34 UB, axial points of DUmai, ASHI points , lateral points on the external branch of the Urinary bladder meridian (50- 54 UB) and 30 GB. On the lower limbs, bilateral: 40 UB, 59-60 UB, 3Kid, and 34-38 GB, plus 3 SI for the upper limb. Patients with knee pain: always ASHI points, then 34 GB, 34 ST, 35 ST, 36 St, 10 Kid, 9 SP, 8 Kid, 8 Liv, and " eye of the knee ", and ro Ting point. Limbs below 60 UB, 3 Kid, 3 Liv.

For patients with shoulder pain syndrome: ASHI points, and items related to the

meridians involved, depending on the pain of the involved movement (anteflexion, retroflexion, abduction, rotation).

Generally 11/10/13 SI, SJ 13-14, 15 LI, 21 GB, bilateral distal point 38 St.

For patients with arthrosis / arthritis in the hand, depending on the affected joint: Lu 9-10 on the thumb, on thumb and index LI points 2-3-4-5, and 2-3-4-5 SI on wrist and little finger. "Extra meridian" points in the palmar surface of the proximal interphalangeal joints, face dorsal interdigital tissue, the dorsal surface of each finger on the proximal interphalangeal joint were treated. In any case the point 4 LI was treated.

RESULTS

Average initial VAS value of patients was 7.4 ± 2.9 (range 4.6-8.1), after 3 sessions it was 5.6 (range 4.9-6.3), and at the end of treatment was found to be 3.2 (range 1.2-4.3). At follow-up three months the pain as measured by VAS was 2.3 (see Fig. 1).

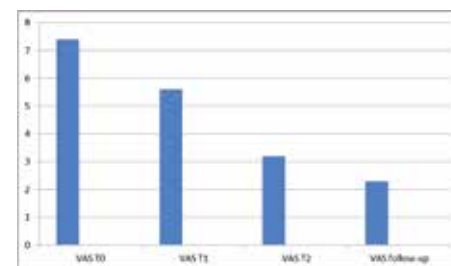


Figure 1 Trend of pain measured with Visual Analogue Scale: before treatment (T0), after 3 sessions (T1), at the end of treatment after 6 sessions (T2), and control at three months.

We found an improvement in variable 61/67 patients (91,04% of patients). At follow-up, the patients answers showed 6 pts.(8,9%) as not satisfied of the treatment, 7 pts. (10,4%) were a little satisfied, 22 pts. (32,8%) said to be satisfied, and 32 pts. (47,7%) resulted very satisfied (see table).

Patient's opinion	Number (tot. 67)
Not satisfied	6 (8,9 %)
A little satisfied	7 (10,4 %)
Satisfied	22 (32,8%)
Very satisfied	32 (47,7%)

Table 1: Follow-up telephone questionnaire answers of the treated patients.

No patients reported adverse events, neither local nor general.

DISCUSSION

Although for many years laserpuncture has been used as an alternative to classical acupuncture and there are empirically found interesting results, clinical studies on laserpuncture are relatively few. The most recent publications focus on the effects of brain and autonomic system by the stimulation of certain single points with laserpuncture, getting exciting effects, but still far from the clinic. Furthermore, since the laser instrument market is in continuous innovation, studies concern always new lasers with different emission frequencies and different powers. While reading literature it is difficult to orient ourselves in the standard parameters to be used; probably more than one type of laser is useful to effectively stimulate acupoints, with agreement, however, on the use of low-frequency stimulation and low power.

Our data confirm the results of other studies on the clinical efficacy of laserpuncture [20,23,24]. We obtained a reduction in VAS, from a pre-treatment value of 7.4 ± 2.9 to a value of 2.3 at follow-up to three months. Patient satisfaction has been remarkable: the answers were a 19.5 % non/ little satisfied, and 80.5 % of satisfied/ very satisfied.

In our study we used a laser (MLS®,

Mphi) with a dual source which allows a simultaneous emission of two different wavelengths, always in the range of wavelength that were considered effective in the scientific literature. It is possible that this type of stimulation, while allowing a continuous stimulation (such as that of the needle) and a stimulation pulse (which allows to a greater depth of action of the radius) will lead to greater clinical efficacy of the treatment.

The combined emission represents a stimulus that the cell perceives as "different" in the two separate emissions, i.e. a stimulus that induces new and particular characteristic effects, and that cannot otherwise be obtained when the two emissions are used separately.

As in the rest of the literature reviewed, no adverse events occurred.

CONCLUSIONS

The high number of sessions and the clinical variability of the cases treated by laserpuncture allow to first detect the extreme security of MLS®, as no patient had general adverse or skin reactions. In relation to the effectiveness we can give a positive opinion. Probably with further research and discussion on the most appropriate dosages, the results may be even better. Compared to the classical acupuncture we can identify, as measured to data, that the effects of the laser beam appear to be comparable, from the clinical point of view, to the classical acupuncture. Laserpuncture is a safe, non-invasive treatment, non-binding for the patient, thus avoiding the complications of skin puncture. The laser-acupuncture could achieve greater popularity, as acceptable also by patients with needle fear.

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