

Safety and efficacy of Laserpuncture with MLS® laser – Mphi type – in spinal pain: additional clinical observations.

T. Viliani

Prato Recovery and Rehabilitation Unit, ASL Toscana Centro.

ABSTRACT

The paper reports the results of a study which continues a previous clinical research about effectiveness and safety of laserpuncture with laser MLS® in patients with spinal pain. 41 outpatients with chronic spinal pain were enrolled and treated, twice a week, for 4-8 sessions. The points to treat were chosen following the rules of classical acupuncture. VAS/NRS before treatment was 7.5 ± 2 , while at the end of treatment it was 3.4 ± 1 , and at 1 month follow-up remained at value 3.2 ± 0 . No side effect occurred. The PIGC score also showed good results on quality of life. The present data confirm our previous results about safety and efficacy of laserpuncture with MLS® laser.

INTRODUCTION

This work is part of a research line about the clinical effects of stimulation of acupuncture points using laser instruments, technique which is called "laserpuncture", in particular on musculoskeletal pain.

Studies about this method began in the 70s, together with the spreading use and demonstrations of effectiveness of classic acupuncture. In fact, in parallel to the

classical method of skin stimulation with needles, the research was extended to other methods of stimulation which could be less invasive and safer [1]. The laserpuncture consists in treating acupoints with the laser light beam and is defined as "traditional stimulation of acupuncture points with laser irradiation at low intensity, which does not induce heat". The work in literature and recorded on medical databases shows that it represents an effective method of stimulating points. Two recent reviews with meta-analysis [2,3] have addressed the effects of laser acupuncture in the treatment of musculoskeletal pain: in the correctly performed studies and where adequate dosage was used, positive effects were found, considering the pain as the primary outcome.

The stimulation of acupoints by laser beam causes effects which are similar, although not completely identical, to classical acupuncture, both in clinical and neuro-molecular reactions. The effects of laserpuncture are partly due to the peripheral nerve stimulation in specific anatomical areas (NAU: Acupuncture Neural Unit ") [4], with modulation of

afferent input on second-order spinal neurons, partly to stimulation of interstitial and fascial tissue, and in part are related to the endogenous opioid analgesia, through central mechanisms [5,6]. Experimental studies with interesting results and observations have been performed on animal models [7,8].

The cited reports suggest that laserpuncture can be even more effective than traditional acupuncture. In fact, the laserpuncture could combine the effects of acupuncture to the biostimulating effects of the laser beam. The "photo-bio-stimulation", that is the trigger function of the specific laser wavelengths on acupoints, can cause biochemical, electrochemical and structural changes at cellular level, which are specific of laser light (and not of the needle), triggering additional factors that can affect the outcome of the disease. However it is still unclear the mechanism of action of laserpuncture, that does not act through mechanical stimulation, it shares exactly the ways of pain modulation by acupuncture needles.

From the clinical point of view the laserpuncture seems equivalent to the puncture needle [9].

The acupuncture point irradiated by laser beam needs adequate energy to elicit physiological effects at the cellular level (photobiomodulation): the key point of laserpuncture is precisely the dosage applied. In the two reviews cited the irradiation is applied with a minimum output power of 10 mW and an energy dose of at least 0.5 J/point.

The International Associations of laser therapy provide some recommendations: the World Association for Laser Therapy (WALT) [10] suggests using doses ranging from 2 to 16 Joules for laser treatments, while the Australian Medical Acupuncture College establishes [11] that "the energy density for optimal laserpuncture and biostimulation, based on the current clinical experience, is 4 J/cm²". Nevertheless instrumental technical parameters to be used in this practice are

still in doubt and there are still no official guidelines for laserpuncture.

The most important determinant of the effectiveness of laserpuncture is the depth of action, so you can compare the needle action, and the technical parameters have recently been detailed [12]. The depth of action of the laser beam depends (in addition to the characteristics of tissue and patient) on different parameters, such as: wavelength, dosage, beam intensity, dose range (which in the literature varies between 0.001 J/cm² and 10 J/cm²), continuous or pulsed emission mode.

Experimental data indicate that good results are achieved when two wavelengths are combined, thanks to dual-wavelength lasers [13]. A paper reports the possibility of using high-intensity lasers to reproduce the stimulation of the needle [14].

From the current state of the art, it appears that to achieve a therapeutic effect with laserpuncture the optimum power of the laser radiation should be between 5-500mW, and the wavelength between 600 and 1000 nm.

Red radiation (600-700 nm) has a skin penetration lower than IR radiation. Therefore, red wavelengths are indicated for the treatment of the surface points (points "Jing Well"), which are found for example at the tip of the fingers and feet, and for auricular points, while IR wavelengths (800-1000), which have greater penetration, are given to the points on the arms, legs, back, and "Ashi" points.

The optimal frequency of stimulation for the laserpuncture is very low (10 Hz) and continuous mode or pulsed evoke different reactions [15].

Another important parameter is the processing time of each point, which is a function of power, and of the type of pathology. In general, the higher the power of the laser the lower the treatment time, more time is required for the treatment of joint pain compared to the soft tissues and more time in chronic conditions with respect to the acute ones. The dose is

expressed in J/cm² (density) and $1J = 1W \times \text{sec}$. Knowing the type of laser we have, we can calculate the application time needed. To decide the dosage on the point, the radius of the area in cm² must be taken into account. For laserpuncture it is necessary to keep the handpiece in contact with the skin, and a beam diameter of a few millimeters.

Acupuncture points are thus treated with different doses, depending upon the location and depth of the point to be treated, in literature prevailing doses from 0.2-0.5 J/cm² up to 4-8 J/cm², with different exposure times, based on the type of laser. The dose must be adjusted in relation to the assessment of the disease and the individual response. A laser of 5-20 mW directed on the skin does not produce pain or heat, or other sensations.

The laser acupuncture finds applications in acute and chronic painful conditions, neck pain and lumbago, shoulder pain, pain from osteoarthritis of the hip, knees, hands, feet, epicondylitis, carpal tunnel syndrome, and in general in all the fields of application of somatic, auricular and microsystems acupuncture. Laser in physiotherapy is considered secure and safe. The use of laserpuncture has greatly increased in recent years due to its painless nature and the absence of side effects [16,17,18,19].

Many types of laser equipments were used in the time to stimulate the acupuncture points, with different wavelengths (which correspond to different depths of action), in particular with emission at 632.8 nm

(Helium Neon), 810.0 nm (diode Gallium / Aluminium / Arsenide), 904.0 nm (diode Gallium / Arsenide), 10600 nm (CO₂), 1064 nm (diode Nd:YAG). The Multiwave Locked System (MLS®) [21,22], is a diode laser that differs from the others by its synchronized dual emission, differing for both wavelength and emission mode: continuous emission (808 nm) and pulsed emission (905 nm). The continuous emission has a prevailing anti-inflammatory effect, while the pulsed emission has a predominant analgesic effect: the

synchronized emission causes a reinforcing effect between the two actions, resulting in rapid physiological effects and symptoms. Relating to laserpuncture the continuous radiation simulates the continuous effect of the presence of the needle, while the pulsed allows a greater depth of action and the biostimulating effect. The effect of the MLS® pulse laser was initially tested in vitro on cell cultures, then in vivo in animals and then on controlled clinical trials [20].

Laser MLS® already has given multiple demonstrations of experimental and clinical efficacy against many musculoskeletal diseases and it has established protocols, on the basis of experimental and clinical data. Our previous research [23] analyzed the clinical effects of laserpuncture with MLS®, showing positive results in absence of side effects.

The aim of the present study was to confirm the safety, feasibility and efficacy of laserpuncture via laser instrument MLS®, Mphi type. The study is a continuation of our previous research, with focus on the spinal area.

MATERIALS AND METHODS

41 adult patients were treated on an outpatient basis, 29 F and 12 M, aged between 32 and 94 years, for a total of 212 seats, (average 6 sessions / pts.) They were suffering from back pain, in the cervical, thoracic or lumbar tract, present for at least 3 months, with VAS ≥ 5. 20 pts. had neck pain, 12 low back pain, 9 pts. suffered from dorsal back pain.

Before treatment, all patients were informed of the technical and specific nature of the laser beam and expressed written consent to treatment.

The main evaluation parameter was pain, which is the most important and debilitating symptom in spinal column troubles: for pain assessment, we used the Visual Analogue Scale (VAS), in its numerical form (NRS, Numerical Rating Scale) the only one universally accepted tool for assessing pain, which is a typically subjective symptom and

unquantifiable by operators.

The VAS-NRS scale was administered to the subjects before and at the end of treatment and then at follow-up at 1 month, made via telephone interview. Differently from the previous study, to evaluate the quality of life, at the beginning and end of the sessions was also used the PGIC (Patient Global Impression of Change) (24). It is a score which evaluates, according to the subjective judgment of the patient, change in terms of activity limitation, symptoms, emotional reactions, and other expressions of the quality of life related to the condition of pain. Each dimension has 7 levels: 1. No change or worsening of the condition, 2. Almost unchanged 3. Better, but not significantly 4. Better, but the change did not make the difference, 5 moderately better, with a slight but significant change, 6 better, with a significant change that has made a real difference 7. Big improvement with marked difference of the pain condition.

The treatment was done on an outpatient basis. The patients were treated 2 times / week, for a total of 6-8 sessions (minimum 4 sessions, maximum 8 sessions)

The treatment was performed with Laser Multiwave Locked System, Mphi, with contact handpiece, program adapted specifically for laserpuncture.

The machine consists of two laser sources, with wavelength 808 nm and 905nm. The source with 808 nm has a maximum power of 1000 mW, continuous emission, variable frequency from 1 Hz to 2Khz, while the source 905 nm has a maximum power of 25 W and frequency modulated from 1 Hz to 2kH. Manually adjusting the output parameters can provide the J/cm² exactly dosed, to customize the treatment in relation to the disease and to the location of the chosen points. The intensity of the treatment was set to 50% of the maximum power of the MLS® source.

The points of laserpuncture were chosen using the same rules of selection of classical acupuncture. The ray of light generated from the apparatus was applied directly

to the skin, at the level of the specific acupoints, according to the meridians and the syndromes identified in Traditional Chinese Medicine and on the trigger points ("ASHI" points in acupuncture). The treatment was performed by a physician experienced in acupuncture (experience of 22 years of acupuncture). For the considered diseases the acupuncture points were chosen primarily on 3 meridians (gall bladder, urinary bladder and governor vessel) based on the location of the pain.

Laser acupuncture treatment protocol used: As in our previous study on ASHI points and deep points delivered energy was 8.4 J / cm², while on the most superficial or very sensitive points, the energy was up to 0.5 J / cm². In any case the frequency was always set to 10 Hz. The treatment, for purposes of study, was globally simplified and "standard" point groups were used for each disease according to the clinical syndrome, apart from the treatment on the points ASHI (painful points) that were clearly different from patient to patient.

For patients suffering from neck pain: 10 UB (Urinary Bladder), 20 GB (Gall Bladder), 21 GB, 15 and 16 TH (Triple Heater), and painful points. At the lower limbs bilaterally 59-60 UB, 34-38 GB, 3 Ki (Kidney) or 3 LV (Liver). 3 SI (Small Intestine) bilateral on upper limbs.

For patients with low back pain: sensitive points on the inner branch of the Urinary Bladder meridian, from 21 UB to 34 UB, axial points of the GV (Governor Vessel), 2-3-4-5 GV, ASHI points, branch points on the outer side of the meridian bladder (50-54 UB) and 30 GB . On the lower limbs, bilaterally: 40 UB 59-60 UB, 3 Ki, and 34-38 GB, 3 SI bilaterally on upper limbs.

For patients suffering from back pain: sensitive points on the inner branch of the Bladder meridian, from 11 UB to 19 UB, axial points of GV, ASHI points, lateral points on the external branch of the Urinary Bladder meridian (41-50 UB). On the lower limbs, bilaterally: 40 UB, 60-62 UB, 3 R, and 3 SI bilaterally on the upper limbs bilateral.

RESULTS

Initial VAS-NRS average of patients group was 7.5 ± 2.4 (range 10-5), and at the end of the treatment it was found 3.4 in average (range 0-7, comprising also unchanged patients). At follow-up one month later, the pain sensation measured by VAS-NRS was 3.2 Positive changes in PGIC score were reported by 31/41 patients (75% of patients treated).

PGIC Score	Pts. number (tot. 41)
Level 1	6
Level 2	1
Level 3	3
Level 4	2
Level 5	6
Level 6	13
Level 7	10

PGC: 1. No change or worsening of the condition, 2. Almost unchanged 3. Better, but not significantly 4. Better, but the change did not make the difference, 5 moderately better, with a slight but significant change, 6 better, with a significant change that has made a real difference 7. Big improvement with marked difference of the pain condition.

As in the rest of the literature analyzed, there has been no local adverse event reported, such as erythema, itching or burn. There has been no adverse events of general type.

DISCUSSION AND CONCLUSIONS

The data of the present study confirm the extreme security of laserpuncture with Laser MLS®, because no patients had no general neither local adverse reactions. In relation to the effectiveness we can confirm the positive judgement. Several of enrolled patients had underlying serious spine troubles as cervical stenosis or previous spinal surgery, so the gravity of the situation justifies that the

result is not changed by some of them. It is very difficult to compare our results to other laserpuncture studies because we used an MLS® device, which simultaneously dispenses two different wavelength with two different emission modalities, which is not the case of the other studies.

Compared to the classical needle acupuncture, as reported in literature, we can do the following considerations, as assessed to date:

1) Although the numerical data and the studies are still quantitatively minor, the effects of the laser beam appear to be similar, from the clinical point of view, to those of classical acupuncture.

2) The laserpuncture is confirmed as a safe technique, non-invasive, non-binding for the patient, thus avoiding the complications of skin puncture, and can be practiced even in patients with needles fair.

REFERENCES

- Whittaker P, Laser acupuncture: past, present, and future. *Lasers Med Sci* 2004, 19:69-80.
- Baxter GD, Bleakley C, McDonoug S. Clinical Effectiveness of Laser Acupuncture: a Systematic Review. *J Acupunct Meridian Stud* 2008;1(2):65–82.
- Law D, McDonough S, Bleakley C, Baxter GD, Tumilty S. Laser Acupuncture for Treating Musculoskeletal Pain: A Systematic Review with Meta-analysis. *J Acupunct Meridian Stud* 2015;8(1):2e16.
- Zhang ZJ, Wang XM, Mc Alonan G. Neural Acupuncture Unit: A New Concept for Interpreting Effects and Mechanisms of Acupuncture. *Evidence-Based Complementary and Alternative Medicine*. 2012, Article ID 429412, 23 pages, doi:10.1155/2012/429412.
- Hagiwara S, Iwasaka H, Okuda K, Noguchi T. GaAlAs (830 nm) low-level laser enhances peripheral endogenous opioid analgesia in rats. *Lasers Surg Med* 2007, 39:797–802.
- De Morais NC, Barbosa AM, Vale ML, Villaverde AB, de Lima CJ, Cogo JC, Zamuner SR. Anti-inflammatory effect of low-level laser and lightemitting diode in zymosan-induced arthritis. *Photomed Laser Surg* 2010,28:227–232.
- Marques VI, Cassu RN, Nascimento FF, Tavares RCP. Laser Acupuncture for Postoperative Pain Management in Cats. *Evidence-Based Complementary and Alternative Medicine*. Volume 2015, Article ID 653270, 6 pages, <http://dx.doi.org/10.1155/2015/653270>.
- Erthal V, da Silva MD, Cidral-Filho FJ, Santos AR, Nohama P. ST36 laser acupuncture reduces pain-related behavior in rats: involvement of the opioidergic and serotonergic systems. *Lasers Med Sci*. 2013 Sep;28(5):1345-51. doi: 10.1007/s10103-012-1260-7. Epub 2013 Jan 5.
- Dorsher PT, Clinical Equivalence of Laser Needle to Metal Acupuncture Needle in Treating Musculoskeletal Pain: A Pilot Study. *Medical Acupuncture*. March 2010, 22(1): 11-17. doi: 10.1089/acu.2009.0724
- WALT. Recommended treatment doses for Low Level Laser Therapy, 2010. <http://waltza.co.za/documentation-links/recommendations/dosage-recommendations/>(accessed Sep 2013).
- Australian Medical Acupuncture College, Position statement on laser acupuncture, 2012, <http://www.chiro.org/acupuncture/FULL/Position Statement on Laser Acupuncture.shtml>.
- Litscher G, Opitz G. Technical Parameters for Laser Acupuncture to Elicit Peripheral and Central Effects: State-of-the-Art and Short Guidelines Based on Results from the Medical University of Graz, the German Academy of Acupuncture, and the Scientific Literature. *Evidence-Based Complementary and Alternative Medicine*, 2012, Article ID 697096, 5 pages doi:10.1155/2012/697096.
- Chow R, Yan W, Armati P. Electrophysiological Effects of Single Point Transcutaneous 650 and 808nm Laser Irradiation of Rat Sciatic Nerve: A Study of Relevance for Low-Level Laser Therapy and Laser Acupuncture. *Photomedicine and Laser Surgery*, Volume 30, Number 9, 2012Pp. 530–535.
- Zereto JL, Sasaki KM, Toda K. High-intensity laser for acupuncture-like stimulation. *Lasers Med Sci*, 2007, 22:37-41.
- Hsieh CW, Wu JH, Hsieh CH, Wang QF, Chen JH. Different Brain Network Activations Induced by Modulation and Nonmodulation Laser Acupuncture. *Evidence-Based Complementary and Alternative Medicine*, 2011, Article ID 951258, 8 pages doi:10.1155/2011/951258
- Weber M, Fussgänger-May T, Wolf T. "Needles of Light": A New Therapeutic Approach. *Medical Acupuncture*, Volume 19, Number 3, 2007, 141-151
- Baxter GD, Bleakley C, McDonough S. Clinical Effectiveness of Laser Acupuncture. A Systematic Review. *J Acupunct Meridian Stud* 2008;1(2):65–82.
- Ruth M, Weber M, Zenz M. Laser acupuncture for chronic back pain. A double-blind clinical study. *Schmerz* 2010;24:485–93. doi: 10.1007/s00482-010-0966-3.
- Glazov G, Yelland M, Emery J. Low-dose laser acupuncture for non-specific chronic low back pain: a double-blind randomized controlled trial. *Acupunct Med*. 2014 Apr;32(2):116-23. doi: 10.1136/acupmed-2013-010456.
- Huang Y, Sharma SK, Carroll J, Hamblin MR. Biphasic dose response in low level light therapy. An update. *Dose-Response*, 2011, 9:602–618.
- Pagnutti S, MLS® Lasertherapy Scientific Report and Scientific Studies. ASA Research Centre.
- MLS® LASER GUIDE, ASALaser.
- Viliani T, Laserpuncture with MLS® (Multiwave Locked System) system Mphi: safety and clinical efficacy in joint disease, preliminary data. *Energy for Health*, 2014, 13: 14-17.
- Hurst H, Bolton J, Assessing the clinical significance of change scores recorded on Subjective outcome measures. *J. Manipulative Physiol Ther* 2004, 27:26-35.