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and past incumbent of the
chair of Plastic Surgery-
University of Tel Aviv
P.O.B. 2338, Savyon, 56530 Israel
e-mail: ikaplan90@gmail.com

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Contents

4

A measure of post-operative satisfaction after application of Mphi therapeutic laser for pain management in patients with surgical extraction of impacted third molars.

N. Doan, L. Nguyen-Pham, S. Cokim

9

A comparison of effects of therapy with the NIR laser diode and MLS[®] laser system.

M. Kimlickova, Y. Efremova, E. Blaskova, V. Navratil1, L. Navratil

15

Successful treatment for neuropathic pain with MLS[®]: a case study.

S.R. Olmos

19

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

T. Viliiani

A measure of post-operative satisfaction after application of Mphi therapeutic laser for pain management in patients with surgical extraction of impacted third molars.

N. Doan^{1,2,3}, L. Nguyen-Pham¹, S. Cokim¹

¹School of Dentistry and ²Department of Biomedical Engineering the University of Queensland, Brisbane, Queensland, Australia

³Private practice, Brisbane, Queensland, Australia

ABSTRACT

This study aim to assess the efficacy of a MLS[®] Mphi therapeutic laser as an adjunct management of postoperative pain, swelling, and trismus related the surgical extraction of impacted third molars using visual analogue scale (VAS) and satisfaction outcome measure. A cohort of 42 impacted wisdom patients, each underwent surgical extraction of 4 extractions under local anesthetic, were selected for a double-blind, randomized, controlled clinical trial. The two groups of patients were divided into control and study group, each of 21 patients, match my age and sex. Immediately after the extraction procedure, the experimental group received one off 1.27 J/cm² of energy density intraorally using Mphi laser while the control

group received sham radiation. The degree of postoperative pain, swelling, trismus, and dry socket was registered for both groups at day one, day 7 (one week) and day 28 (4 weeks). Only those normal patients with 4 impacted wisdom teeth required flap approach, and had complete clinical data were included in this study. Using visual analogue scale (VAS = 0 to 10), the study group revealed to have less: pain, swelling, bleeding and speech impairment and had better overall satisfaction at one day and one week than the control counterpart (*P<0.05). No significant difference in pain at 1 months. The study group showed a less dry socket than the control group without statistical significance. All participants in the both groups required analgesics, however,

the study group required less pain killer than the control group between day one to day seven. At one week, the study group had less moderate trismus and more mild trismus compare to the control group (P<0.05). The application of ASA Mphi laser in the postoperative management of pain in surgical wisdom teeth extraction statistically produced early stage of satisfaction as well as reduced postoperative pain, swelling, bleeding, speech impairment, analgesics use and trismus.

INTRODUCTION

Surgical removal of impacted lower third molars is the most common oral surgery procedure. In spite of better and innovative surgical technology post-surgical complications are still happening. Trauma related inflammation is the main feature associate in most of wisdom teeth extractions couple with pain, swelling, trismus and dry socket. Therefore, management of these complications is of paramount importance to ensure superior outcomes and better patients' satisfaction. The worse post-operative pain most commonly occurs around 3 to 5 hours after surgery, especially, when anesthetics wear off. This type of pain normally persists for another 2 to 3 days, and gradually reduce its intensity toward day 7, and is commonly managed by analgesia such as NSAID while therapeutic application of LLLT has received varied results [1]. Currently there is an innovative method for control of post-operative complications in impacted wisdom tooth extractions through the application of Multiwave-Locked System laser such as Mphi laser. The unique feature of MLS[®] Laser Therapy is the patented wave technology, combining dual wavelengths and both continuous (808 nm enhanced anti-inflammatory and anti-edema effects) and pulsed (905 nm enhance analgesic effects) waves, making it an efficient laser for treating pain and inflammation, especially, in post-operative dental extraction pain [2]. Mphi laser has many therapeutic indications: sprains, muscle tears, tendinitis,

brachial neuralgia, craniofacial pain, bursitis, lumbago, arthritis, articular pain, edema, and hematoma. MLS[®] Laser Therapy exert its bio-stimulation effects through its anti-inflammatory and analgesic properties of the 808 nm and 905 nm emissions of the laser [2]. These bio-stimulation effects are very beneficial in management of complications such as pain in wisdom teeth extraction.

Research on LLLT is extensive, to date more than 4,500 articles listed on PubMed on LLLT and over than 1,480 papers discussed pain associated with wisdom teeth extraction. Systemic review on the application of LLLT in pain management and wisdom teeth extractions [1] showed mixed results due to multiple inconsistencies in classification of wavelengths, outcome measures, study methods, recording techniques, degree of wisdom teeth impaction, and duration of surgery.

The marginal benefit of LLLT is of many folds less time taken for quality tissue repair and this is accomplished through a surge of microcirculation in the irradiated area, which consecutively nourish tissue while reducing edema by relieving the equilibrium of hydrostatic filtration and absorption pressures [3].

Mphi MLS[®] laser provides a new spectrum for research as it is a combined and synchronous wavelength technology. Study on the use of Mphi laser on treatment of craniofacial pain showed promising results [2, 4].

Satisfaction is one of the outcome measure used in this study. It may be considered as a way to quantify patients' experiences at the conclusion of a treatment with emphasis on patients' understanding, viewpoints and assessment. Satisfaction in this study was recorded as the proportion of happiness at the end of the procedure [5]. To determine patient satisfaction, the study uses McGill questionnaire on a visual analogue scale (VAS) [6].

Visual Analogue Scale (VAS) was also used to define patients' post-operative pain [5].

A common post wisdom teeth extraction complication is dry socket or alveolar osteitis.

Dry socket occurs more often in lower more wisdom teeth. The complaint has usually been depicted by disintegrated or impeded recovery accompanying with disintegration or displacement of the blood clot in the healing socket. A typical feature of dry socket is a lasting and burning pain sensation in and around the extraction location around 3 to 7 day after the surgical extraction that is not simply alleviated by analgesics. As Mphi laser has a bio-stimulatory and analgesic property, it will be interesting to see its effect on alveolar osteitis prevalence in this study.

This study aim to assess the efficacy of a MLS[®] Mphi therapeutic laser as an adjunct management of postoperative pain, swelling, bleeding, speech impairment, and trismus related to surgical extraction of impacted third molars using visual analogue scale (VAS) and satisfaction outcome measure.

MATERIALS AND METHODS

The study was conducted in a private location using a double-blind, randomized, controlled clinical trial using Mphi laser as an adjunct post-operative management. The study group consisted of 21 women and 21 men with mean age of 19.0 (+12.7) with age range from 17-25 years of age. Patients were recruited from a private dental clinic in Brisbane Queensland. The protocols for laser treatment were identical for all members of a same study group. The screening clinical assessment to select patients consisted of clinical exam with the use of intra-oral camera, Joint Vibration Analysis (JVA), Cone Beam Computed Tomography (CBCT) or Orthopantograms. All selected patients must have four impacted wisdom teeth of similar degree of impaction as confirmed in clinical screening assessment.

A cohort of 42 impacted wisdom patients underwent surgical extraction of 4 impacted wisdom extraction under local anesthetic were selected for a double-blind, randomized, controlled clinical trial using Mphi laser as an adjunct post-operative management. Neither the patients nor the operator knew which group the patients

belong to. The two groups of patients were randomly divided into control and study group, each of 21 patients, match by age and sex.

The laser therapy was delivered using a Multiwave-Locked System (MLS[®]) a NIR laser (model Mphi, ASA laser, Vicenza, Italy) which is considerably distinctive from other laser supply systems: it mixes and synchronizes a pulsed emission at 905 nm and a continuous split emission at 808 nm wavelength with output power up to 1.1W - Peak Power 25W.

MLS[®] Mphi laser therapy was used for the study group with the following protocols: upper and lower wisdom teeth region- 16 seconds for each extraction site at an intensity of 25% and a frequency of 1500 Hz, time used for each application is 4 seconds, and dosage of 1.27 J/cm² at 4 locations buccal, lingual, distal and occlusal aspect of the extraction sites. Total of 2.5 J applied (Figure 1). The control group received sham radiation and standard management. The degree of postoperative pain, swelling, and trismus was registered for both groups at day one, day 7 (one week) and day 28 (4 weeks) by the same two reviewers. Only those patients with complete clinical data were included in this study.

A. Visual Analogue Scale (VAS) assessment of Post-operative Pain

To establish patient satisfaction, the study assign McGill questionnaire on a visual analogue scale (VAS) ranges from 1 to 10 of which 1 as having no pain and 10 is the worst pain (Fig. 2).

B. Measures of Post-operative Satisfaction

The patients were requested to document their overall satisfaction on sensation of discomfort on a visual-analogue-scale with 0% being totally unsatisfied and 100% being completely satisfied (Fig.3). The VAS scores were recorded for both sides at day one, day seven (one week), day 28 (one month). The VAS scores attained were evaluated for statistical significance.

C. Prevalence of dry socket

When the patients of the two study groups returned at day 7 for review or comeback earlier if dry socket pain was severe then the patient will be registered on the dry socket list.

D. OraStretch® ROM scales to evaluate trismus

Trismus is one of the common complication after wisdom teeth extraction. To quantify trismus this study employed OraStretch® ROM vertical scales. The OraStretch® ROM scales were exclusively devised for patients with sternly restricted openings. The elongated ruler design permit for measurement of the minutest openings as low as 3mm. Here trismus is classified into 3 categories: severe if maximal opening is less than or equal to 15 mm; moderate if it is ≤ 25 mm; and mild if it is ≤35 mm. Any vertical opening ≥35 mm is considered normal.

E. Statistical analysis

One way analysis of variance was performed for statistical significance.

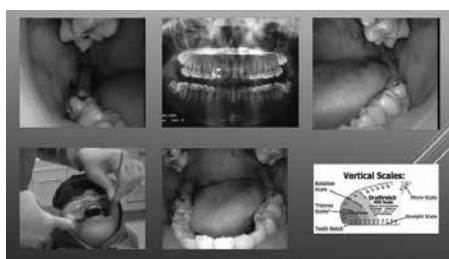


Figure 1: Views of a patient after four wisdom teeth extractions then Mphi laser treatment at extraction sites. The OraStretch scales were used to measure trismus. (From CranioRehab.com)

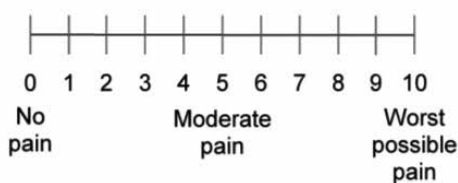


Figure 2: Pain assessment using Visual Analogue Scale

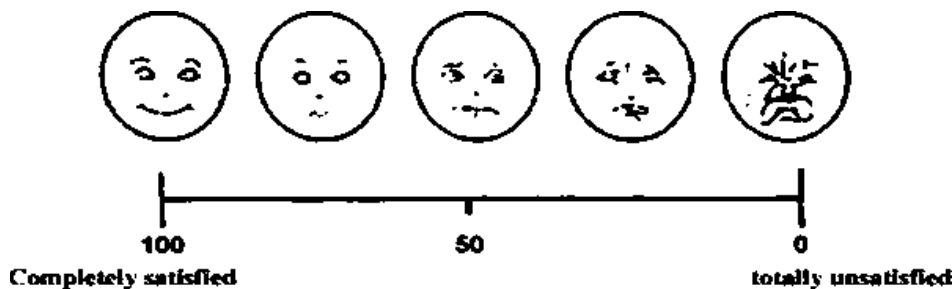


Figure 3: A measure of overall satisfaction

RESULTS

From all the recruited dental patients at a private dental practice, a total of 42 patients 10 males and 11 females of similar age range having 168 extracted wisdom of similar degree of impaction were recorded. All selected patients had the procedure done under local anesthetics. Of 42 patients treated, all patients had flap raised on every tooth extracted. All the extracted sockets were closed using 3/0 resorbable suture, of which none required scheduled removal though some patients might had ask to trim part of their suture to reduce irritation to lips and tongue. No patients failed to return for review at one week and one month.

Using *visual analogue scale* (VAS=0 to 10), study group had less: pain, swelling, bleeding, speech impairment, less days of taking analgesics and had better overall satisfaction at day one and week one than the control counterpart [Fig. 4, (*P<0.05)]. The experienced pain was significantly less in the study group compared to the control group with [5.7 (±1.75) vs 8.9 (±2.83) (*P<0.05)].

Swelling was significantly less in the study group compared to the control group with [5.4 (±1.35) vs 9.3 (±2.37) (*P<0.05)].

Bleeding was significantly less in the study group compared to the control group with [5.4 (±1.35) vs 7.8 (±1.64) (*P<0.05)].

Speech impairment was significantly less in the study group compared to the control

group with [6.5 (±1.78) vs 3.1 (±1.26) (*P<0.05)].

Days of taking analgesics was significantly less in the study group compared to the control group with [3.4 (±0.43) vs 5.8 (±0.23)]

Compare the control vs study group, percentage (%) of Overall Satisfactions were statistically significant at 1 day [(52.5 (±8.43) vs 94.5 (±7.35), *P<0.05) and 1 week [61.5 (±17.34) vs 94.1 (±11.12), *P<0.05] but not at 1 month [94.1 (±11.12) vs 93.2 (±9.76)].

Though there were two female patients in the control group developed dry socket. However, the cases were too small to have any statistical significance.

At one week, the study group had less moderate trismus [(38.1(±10.79) vs 66.7(±19.51) and more mild trismus (61.9 (±19.51) vs 23.8 (±10.75) *P<0.05] compare to the control group. No difference at the degree of pain at 1 month (P>0.05). [Fig. 4].

		Control group Sham laser treated	Test group MLS® laser treated	Overall results
Number of wisdom teeth extracted		21x4	21x4	168
Number of patients failed to return for review		0	0	0
Extraction method		Surgical with flap	Surgical with flap	
Type of analgesia		Local anesthetics	Local anesthetics	Local anesthetics
Prevalence of dry socket (1 week)		2(2.4%)	0.0%	2.4%
Visual Analogue Scale (0 = lowest and 10= highest)	Pain	8.9 (±2.83)*	5.7 (±1.75)*	7.6(±2.29)
	Swelling	9.3 (±2.37)*	5.8 (±1.92)*	7.6 (±2.15)
	Bleeding	7.8 (±1.64)*	5.4 (±1.35)*	6.6 (±1.50)
	Speech impairment	6.5 (±1.78)*	3.1 (±1.26)*	4.9(±1.22)
Days taking analgesics		5.8 (±0.23)*	3.4 (±0.43)*	4.2 (±0.33)
Percentage (%) of Overall Satisfaction (Visual Analogue Scale 0 = lowest and 100 = highest)	1 day	52.5 (±8.43)*	94.5 (±7.35)*	77.8(±7.89)
	1 week	61.5 (±17.34)*	94.1 (±11.12)*	77.8 (±14.28)
	1 month	89.9 (±11.8)	93.2 (±9.76)	89.55 (±10.78)
Trismus measurement using OraStretch® Vertical ROM scales (mm): Severe≤15 mm, Moderate≤25mm, Mild≤15mm	Day 1	0	0	0
	Week 1			
	Severe	9.5 (±8.82)	0	4. (±8.82)
	Moderate	66.7(±19.51)*	38.1 (±10.79)*	52.3 (±14.62)
	Mild	23.8 (±10.75)*	61.9 (±19.51)*	42.9 (±15.71)
	1 Month			
	Severe	0	0	0
	Moderate	0	0	0
	Mild	9.5 (±1.5)	0	4.7(±1.81)

Figure 4: Overall results

Statistical significance: *P<0.05

DISCUSSION

This study has showed that application of Mphi laser in wisdom teeth extractions is a minimal invasive novel technique that can deliver a fairly good outcomes in compared with traditional care approaches. It has also strengthened the notion that the uses of MLS® laser can give a foreseeable result with notable efficiency and efficacy in oral surgery such as those seen in surgical wisdom teeth extraction.

Visual analogue scales (VAS) are employed extensively for pain evaluation, yet it is subjective, but stay valuable instrument for quantifying subjective data, if it is utilised properly. In this study, it showed the exceptional satisfaction of the laser study group to the control counterpart.

Quantification of trismus can be arbitrary, the use of OraStretch® ROM scales has simplified this assessment significantly.

Low-level laser therapy (LLLT) has earned considerable recognition [7]. Research have revealed that LLLT amplifies the rate and quality of wound healing and has an inclusive definite impact on the inflammatory processes [8]. Though the published literature on the effects of LLLT on pain in wisdom teeth extraction received mixed results, Bjordal et al's study [9] illustrated that "0.37-0.96 J/cm² laser had no effect on eliminating symptoms but 6-7 J laser reduced pain to a greater degree". This study employed 4 lots of laser applications each of 4 seconds, and dosage of 1.27 J/cm² at 4 locations buccal, lingual, distal and occlusal aspect of the extraction sites. Total of 2.5 J applied. Therefore, the energy density used in the MLS® Mphi exceeded 0.37-0.96 J/cm². The outcome of this study illustrated pain, bleeding, swelling, trismus and speech impairment all were reduced with the use of Mphi laser. This clearly demonstrated that synchronous MLS® of Mphi laser did showed the anti-inflammation, anti-edema and analgesic effects in complication of wisdom teeth extraction.

It was discovered that continuous-mode diode Low Level Laser Therapy (LLLT) of

808 nm wavelength enhances speed of wound healing and decreases inflammation contrasted to Alvogyl and SaliCept [10]. This study has demonstrated that Mphi laser help to reduce incidence of dry socket in two female patients ($P > 0.05$). However, due to small sample size, the result did not yield a statistical significance. Certainly, further study with larger sample size is essential for achieving a significant outcome.

In term of overall satisfaction, patients appeared to be more satisfied in the initial phase of the treatment, and not at the later one when the extractions wound were almost healed then satisfaction rate showed to be of no difference.

CONCLUSION

This study showed that application of Mphi laser after wisdom teeth extraction is a least invasive, effective, and innovative technique that can deliver a slightly better early stage satisfaction result as compare to the traditional care approach in impacted wisdom teeth extraction. Use of therapeutic MLS® laser rendered less complications such as pain, swelling, bleeding, trismus and speech impairment. VAS and OraStretch® ROM scales are good means to quantify the effect of Mphi laser on wisdom teeth extraction complications. Further studies with larger sample sizes are required to validate the measuring outcomes.

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A comparison of effects of therapy with the NIR laser diode and MLS[®] laser system.

M. Kimlickova¹, Y. Efremova¹, E. Blaskova², V. Navratil¹,
L. Navratil^{1, 2}

¹Department of Health Care Disciplines and Population Protection, Faculty of Biomedical Engineering, Czech Technical University in Prague, Czech Republic

²The Medical Devices Therap Tilia, Prague, Czech Republic

ABSTRACT

Laser therapy can be applied as a rehabilitation treatment in patients affected by musculoskeletal diseases. The target of the present study was an assessment of therapeutic effects achieved applying laser therapy to treat three different musculoskeletal disorders: arthrosis, vertebrogenic algesic syndrome (VAS) and enthesopathy. Two different sources were compared: a single wavelength (830 nm), pulsed NIR laser (BLT2000) and a dual wavelength (808 nm, continuous emission, and 905 nm, pulsed emission) NIR laser (Multiwave Locked System - MLS[®]). Moreover, as regards the MLS[®] source, the efficacy of two different doses was compared. Not only therapeutic effects but also the comfort of the patient associated with the therapeutic procedures here evaluated was considered.

INTRODUCTION

Musculoskeletal disorders are likely to be the most frequent problems which can adversely affect the quality of life in patients. In particular, pain is a very limiting factor in day life. Among the many different types of physical therapies

offered to the patients to alleviate the symptoms due to musculoskeletal diseases, laser therapy can be particularly useful due to its analgesic effect.

The effects of laser radiation on the target tissue is obtained through the conversion of light energy to different forms of energy. In the organism, the mechanism of light energy conversion to other forms of energy, with achieving desirable biological effects, has not yet been exactly described.

In the tissues, cells are sensitive to laser irradiation. As a consequence of the activation of signal cascades, the processes of apoptosis, cytoskeleton rearrangement, transcription regulation and cytokine synthesis can be triggered. Based on literature, mitochondria play the principal role in the mechanisms underlying laser effect [1]. The function of mitochondria is to supply energy for cell functions, since the synthesis of adenosine triphosphate occurs within them due to cell respiration. For laser treatment, suitable physical parameters must be chosen, which will make possible the penetration of sufficient radiation energy into the tissue without immediate prevalence of thermal effects. In this way, it is possible to provide

therapeutic effects avoiding side effects. It is also necessary to take into account optical properties of tissues, particularly of the skin, in which water, melanin and haemoglobin are present in sufficient amounts. It is thus possible to state that optical characteristics of tissues, through which the laser beam propagates during its application, also play their specific roles. In agreement with current knowledge verified by objective clinical studies, including histological examinations, laser can be reasonably applied either under conditions of the continuous regimen or at a frequency not exceeding 50 Hz. Higher values are no more effective in therapy, since the cell is not capable of response in the manner required [1]. At the onset of using the high power therapeutic lasers, opinions concerning the suitable density of energy applied were considerably modified. Due to the power of diodes in low power lasers, which typically does not exceed 400 mW, the usual energy density is of 8 to 10 J/cm² in many indications [2,3,4]. By using high power laser sources, the value is increased by factors of ten to fifty [5,6].

It has been hypothesized that a way for transfer of information among individual cells during the irradiation is based on GAP junctions (connexons), the bystander effect [1].

Laser therapy is widely used for the treatment of musculoskeletal disorders, most frequently on patients with diagnoses of arthrosis, vertebrogenic algesic syndrome (VAS) and disorder of soft tissues (enthesopathy) [2,3,6,7,8,9,10].

In the present study, two different laser sources were compared for their effectiveness when applied to the treatment of musculoskeletal disorders. Moreover, one of the laser sources was tested for its effectiveness when applied with two different doses.

MATERIALS AND METHODS

The clinical study was carried out at the

healthcare facility THERAP TILIA, Praha. Based on the most frequent occurrence of selected diagnoses in the field of musculoskeletal disorders, we collected three groups of patients affected by arthrosis, vertebrogenic algic syndrome (VAS) and enthesopathy, respectively. We monitored and compared the therapeutic effects of a laser apparatus from the company BTL (BTL Health Technique a.s., Brno, Czech Republic) and those of a dual wavelength MLS® laser (MLS®, ASA srl, Arcugnano, Italy). In the latter case, two different doses were considered.

The BTL 2000 apparatus consists of a source emitting radiation with 830 nm wavelength, 200 mW power, operating in pulsed regimen with 10 Hz frequency. The Multiwave Locked System (MLS®) laser emits radiation with 808 nm wavelength in the continuous regimen and 905 nm wavelength in the pulsed regimen. Maximum power is 1.1 W. Within each of the three different groups, three subgroups of patients were randomly selected.

The patient group A was treated by using the MLS® apparatus with parameters set by the manufacturer, 1500 Hz, 9.62 J/cm². The laser treatment was applied four times at intervals of seven days.

The patient group B experienced laser therapy by using the MLS® apparatus, but with altered physical parameters of the therapy based on our many years' experience. In the beam, we set a frequency of 10 Hz and the application time was chosen in such a way that the area treated was exposed to an energy density of 30 J/cm². Similarly as in the first group of patients, we applied laser four times at intervals of seven days.

The patient group C experienced a treatment performed by BTL laser source. The laser emits radiation with 830 nm wavelength in the pulsed regimen 10 Hz, the area treated was exposed to an energy density of 6 J/cm².

In this group of patients, 12 applications

three times a week were prescribed. The benefit of the treatment was always evaluated during each visit associated with a session of laser therapy. The last evaluation was implemented 7 days after the last laser application. In all the patients, we also evaluated negative feelings in course of therapy.

RESULTS

In the three groups, laser therapy was tested, in particular, for its analgesic effect. Pain perception is a subjective symptom, thus, the following four-point scale was employed for the effect assessment:

- 1 - Vanishing of problems
- 2 - Considerable improvement
- 3 - Moderate improvement
- 4 - Unaltered condition (no improvement of the condition).

Parameters summarized in Tables 1 to 3 show that, in our study, patients in

a broad age range (17-81 years) were represented.

Results summarized in Table 1 demonstrate that in all the three groups of patients, the expected therapeutic effect was achieved and the parameters under monitoring, i.e. pain which limited the activity of patients, decreased. In terms of subjective feelings of patients in all the groups, there was a considerable improvement of the problems.

Table 1: Results of MLS® therapy with the use of parameters set by the manufacturer (group A).

Diagnosis	Sex	MLS®					
		Age		Number of applications		Therapeutic effect	
		n	x ± SD	n	x ± SD	n	x ± SD
Arthrosis	men	2	36.5 ± 6.5	2	3.5 ± 0.5	2	2.5 ± 0.5
	women	2	44.0 ± 9.0	2	4.0 ± 0	2	2.0 ± 0
	total of	4	40.3 ± 8.7	4	3.8 ± 0.4	4	2.3 ± 0.4
VAS	men	7	51.6 ± 16.7	7	3.9 ± 0.3	7	2.6 ± 0.7
	women	19	54.3 ± 15.7	19	3.8 ± 0.4	19	2.4 ± 0.5
	total of	26	53.6 ± 16.0	26	3.8 ± 0.4	26	2.4 ± 0.6
Enthesopathy	men	3	49.0 ± 7.3	3	3.7 ± 0.5	3	2.3 ± 0.5
	women	4	70.3 ± 11.5	4	3.5 ± 0.5	4	2.5 ± 1.1
	total of	7	61.1 ± 14.5	7	3.6 ± 0.5	7	2.4 ± 0.9

VAS - vertebrogenic algic syndrome

Diagnosis	Sex	MLS®					
		Age		Number of applications		Therapeutic effect	
		n	x ± SD	n	x ± SD	n	x ± SD
Arthrosis	men	0	---	0	---	0	---
	women	2	63.5 ± 1.5	2	4.0 ± 0	2	2.5 ± 0.5
	total of	2	63.5 ± 1.5	2	4.0 ± 0	2	2.5 ± 0.5
VAS	men	9	55.2 ± 16.9	9	3.9 ± 0.3	9	2.4 ± 0.7
	women	26	58.9 ± 16.7	26	3.9 ± 0.3	26	2.4 ± 0.5
	total of	35	58.0 ± 16.8	35	3.9 ± 0.3	35	2.3 ± 0.6
Enthesopathy	men	1	65.0 ± 0	1	4.0 ± 0	1	3.0 ± 0
	women	4	49.0 ± 8.6	4	4.0 ± 0	4	2.8 ± 0.8
	total of	5	52.2 ± 10.0	5	4.0 ± 0	5	2.8 ± 0.7

VAS – vertebrogenic algic syndrome

Table 2: Results of MLS® therapy with the use of parameters set by the user (group B). The laser emits radiation with 808 nm wavelength in the continuous regimen and 905 nm wavelength in the pulsed regimen 10 Hz, the area treated was exposed to an energy density of 30 J/cm².

Table 2 demonstrates that the treatment conditions applied in this group were also effective. However, considering the therapeutic effects versus the different diseases, interesting differences were observed. In patients belonging to VAS and arthroses groups, there was a considerable improvement of the problems. In the group of enthesopathies, there was an only moderate improvement of pain in the patients monitored.

Results summarized in Table 3

documenting the effect after the BTL application also show a therapeutic benefit in the treatment of VAS and enthesopathies. Minimum effects were observed in the treatment of arthroses; there was no pain relief in women. However, the low number of subjects should be taken into account. In the groups of VAS and enthesopathies, the resulting therapeutic effects were comparable to those obtained by MLS® therapy.

The results demonstrated that the

therapeutic effect is quite similar after the application of the three different cycles of therapy. Differences monitored at the end of therapies in the three groups studied (A, B, C) were not statistically significant. Nevertheless, the data show that in the treatment of arthroses MLS® therapy resulted more effective than BTL.

However, data reported in tables 1 to 3 highlighted a very important difference among the therapies, concerning the number of applications needed to obtain the desired therapeutic effect. It may be observed that a number of treatment sessions ≤ 4 was sufficient to obtain a significant improvement of patient status by applying MLS® therapy, while a number of sessions 10 was required by applying BTL apparatus. Therefore the pain relief was achieved much faster applying MLS® therapy. The differences between the two groups treated by MLS® therapy with different doses (J/cm²) was not significant.

DISCUSSION

The patients were randomly included into our study. As mentioned above, patients in a wide range of age (17-81) were accepted. The comparison of the therapeutic effect according to the age will be a target of our further studies with providing sufficient representation of subjects in narrower ranges of age within the framework of the diseases considered. It is expected that the age plays an important role in the response to therapy, considering that physiological processes in tissues are affected in the course of laser therapy.

A comparison between the therapeutic benefits obtained by application of MLS® laser and BTL demonstrated that a significant improvement of symptoms was reached in both cases, but it required a number of MLS® treatment sessions ≤ 4, while a number of sessions 10 was applied in the case of the BTL apparatus. Therefore the pain relief was achieved

Diagnosis	Sex	LLT					
		Age		Number of applications		Therapeutic effect	
		n	x ± SD	n	x ± SD	n	x ± SD
Arthrosis	men	16	55.8 ± 11.4	16	14.4 ± 3.0	16	2.6 ± 1.0
	women	2	59.0 ± 0	2	10.0 ± 0	2	4.0 ± 0
	total of	18	56.1 ± 10.8	18	13.9 ± 3.1	18	2.8 ± 1.0
VAS	men	8	47.5 ± 12.1	8	12.5 ± 2.5	8	2.5 ± 1.1
	women	6	24.3 ± 6.9	6	13.3 ± 2.4	6	2.3 ± 0.5
	total of	14	37.6 ± 15.3	14	12.9 ± 2.5	14	2.4 ± 0.9
Enthesopathy	men	6	29.7 ± 11.1	6	10.0 ± 0	6	2.3 ± 0.5
	women	14	30.6 ± 8.8	14	13.6 ± 2.3	14	2.6 ± 1.0
	total of	20	30.3 ± 9.6	20	12.5 ± 2.5	20	2.5 ± 0.9

VAS – vertebrogenic algic syndrome

Table 3: Results of BTL therapy (group C).

much faster applying MLS® therapy. Our results concerning the possibility of using laser therapy in the treatment of arthroses are in agreement with those presented by other authors. Ohkuni et al. [2], analysing results based on two-years monitoring, observed significant analgesic effects in chronic Joint pain after a four-week therapy (2 sessions/week) with a NIR laser source (power 1 W and wavelength 830 nm). Significant therapeutic benefit in terms of analgesic effects in the pain due to knee joint

arthrosis was described by Soleimanpour et al. [3], who applied a NIR laser with power 30 mW, wavelength 890 nm and energy density 6.6 J/cm². Recently some papers described the application of high power lasers in the treatment of lateral epicondylitis [8,9]. In patients with knee joint osteoarthritis, Kheshie et al. [5] compared the therapeutic effects of high power laser (HIRO 3.0), low power laser (830 nm, 800 mW, energy density 50 J/cm²) and placebo. The therapy was supplemented by physical

exercise in all the groups. The results demonstrated statistically significant differences between the laser application and placebo; the difference between HILT and LLLT was not statistically significant, though better results were observed with HIRO 3.0.

Ohkuni et al. [6] irradiated the sacroiliac joint in a pilot study of 9 patients for analgesic purposes (power of 1 W, wavelength of 830 nm, energy density of 20 J/cm²). They demonstrated analgesic effect and improvement in the blood circulation in ligaments maintaining the sacroiliac articulation.

There are fairly beneficial therapeutic effects of laser in the treatment of enthesopathies, which holds for both low power and high power types. The benefit in the treatment of lateral epicondylitis was already mentioned above [8,9] and similar results were also obtained in the treatment of myofascial pain. Demirkol et al. [3] compared the results of laser treatments in the temporomandibular joint movement disorder, characterized by myofascial pain, with the use of a splint, laser (Nd:YAG 1.064 nm, 250 mW, 8 J/cm²) and placebo. The authors observed no statistically significant differences between the treatment with the therapy associated to the splint or laser. In our work published in 2014 [11], we observed beneficial effects of laser (830 nm, 200 mW, 10 Hz, 4 J/cm²) in the treatment of pain in the dysfunction of the temporomandibular joint.

A recent research [12] compared the effects of high power laser therapy (pulsed Nd:YAG laser supplemented by therapeutic physical exercise) in myofascial pains of the musculus trapezius to controls (application of placebo laser + therapeutic physical exercise). In addition to pain, the authors evaluated further 15 parameters (for example, the range of motion in the head rotation, flexion, and neck spine extension). The results demonstrated statistically significant beneficial effects of

the high power laser application.

An interesting study on a rat model investigated the effects of laser treatment (laser diode, wavelength 830 nm, power of 50 mW and energy density of 6 J/cm²) on Achilles tendon inflammation induced by mechanical trauma [10]. The effect of laser treatment was compared to that of the anti-inflammatory drug Diclofenak and non-treated controls. The degree of the inflammation was verified based on the number of inflammatory cells, amount of types I and III collagen fibres and tensile strength of the tendon and tendon elasticity. The results unambiguously demonstrated that the effects of phototherapy and anti-inflammatory drug are comparable, both the therapeutic effects being highly statistically significant. After laser irradiation, the tendon elasticity was even higher compared to the healthy tendon. The experiment was implemented in animals. Thus, the results were not affected by the patient subjectivity, as is the case of clinical studies.

A further study [13] investigated the effect of laser therapy on fatigue and strength of a spastic muscle. The spasticity occurs as a result of a cerebrovascular event. The muscle performance was considered based on electromyography and the muscle fatigue was evaluated from the lactate concentration. A laser diode with 100 mW power and 808 nm wavelength was used. The muscle was irradiated on 30 points by a total energy of 120 J. After laser irradiation, intensive physical exercise was implemented with the help of a moto-splint. The laser application significantly increased muscle force and reduced lactate concentration in blood serum.

In an in vitro study [14], sixteen samples of Sprague-Dawley rat Achilles tendon were irradiated in culture medium. Then, the status of the tissue was evaluated by a series of analytical tests characterizing cell activity (number of living cells, percentage

of Ki-67 NO production, PCNA activity (PCNA antigens are auxiliary proteins for DNA polymerase in the nucleus) and expression of cyclins A, B1, D1 and E. The samples were exposed to four different energy densities: 1, 1.5, 2 and 2.5 J/cm². Laser irradiation enhanced tenocyte proliferation, NO production, PCNA regulation and production of the cyclins A, B1 and E. It was, however, impossible to establish any clear dependence on the energy density.

The antiinflammatory effect of Low Level Laser Therapy (LLLT, 830 nm wavelength, 30 mW power, 4 J/cm² energy density) was unambiguously demonstrated in a study [4] performed by using mouse paw edema as a model. The inflammation was induced by a carrageenan administration. A number of selected parameters (size of oedema based on the amount of extravascular plasma proteins at the oedema site, intracellular production of free radicals, hydroperoxide concentration (LOOH) and reduced glutathione in the blood plasma) was simultaneously monitored to evaluate the effect of laser irradiation. Control groups were administered with bradykinin or prostaglandin E2, instead of laser application.

Other authors [15] demonstrated the effect of a NIR laser (MLS® laser source, two simultaneous emissions with 808 nm and 905 nm wavelengths, 195 mW and 230 mW power, 1000 Hz and 2000 Hz frequency, respectively) on erythrocytes. The total energy applied to the erythrocytic suspension ranged between 1.5 and 15 J. Changes in membranes were evaluated with the help of a fluorescence spectropolarimeter. The results demonstrated changes in the structure and function of erythrocytic membranes and fluidity.

A widely discussed issue concerns the number of laser therapy sessions needed to obtain the therapeutic effect and also the interval between the individual

applications. Both in terms of public health care and quality of life of the single patient, the time and number of sessions required to obtain the benefits is very important. In this study, we demonstrated that the same therapeutic results were obtained with a mean of 4 therapeutic sessions in the case of MLS® therapy versus a mean of 12 sessions of BTL therapy. Thus, the former therapy strongly reduced the length of the rehabilitation period, that means time saving for patients and the medical facility, enhanced treatment comfort for the patient and early return to work and normal activities.

Negative side effects of the therapy have been observed in none of the patients participating in the study. The study supported our many-years clinical experience of work with therapeutic lasers, suggesting that laser effect is characterized by its rapid onset and persists for long periods of time [16, 17, 18, 19].

CONCLUSION

In the study presented here, we demonstrated important benefits due to laser therapy in rehabilitation care, particularly due to its analgesic effects. Technically different types of laser sources were tested (MLS® and BTL). The results demonstrated benefits from both types of laser, but there was a very significant difference in the number of applications needed. MLS® system induced significant therapeutic effects with only 4 sessions against 12 with BLT. This difference enhances the patient comfort and speeds up rehabilitation.

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Successful treatment for neuropathic pain with MLS®: a case study.

S.R. Olmos

President of the American Academy of Craniofacial Pain and Founder of the TMJ & Sleep Therapy Centres International.

ABSTRACT

Recent reports show that nearly half of adult Americans are living with chronic pain and one quarter are at high risk of obstructive sleep apnea (OSA), a sleep breathing disorder (SBD). The relationship between chronic pain and sleep is well documented. However, patients seeking treatment for pain symptoms have historically been treated independently from those seeking treatment for SBDs.

The purpose of this paper is to highlight the benefits of the MLS® laser system for the treatment of typical neuralgia of the lingual nerve and the comorbidity of chronic pain and sleep related breathing disorders.

A 66 year-old male was referred to our office for the relief of left mandibular episodic facial pain neuralgia. The patient had refractory treatment relief from two different anti-convulsant medications directed from different neurologists. The patient was screened in our office and referred to a Board Certified Sleep Physician and found positive for OSA (obstructive sleep apnea). The patient was treated with OAT (oral appliance therapy), MLS® laser and CPAP. The patient had complete elimination of his chronic pain and discontinued his medications and continues to be free of pain two years later.

These results establish the efficacy of the

MLS® laser in the treatment of neuropathy and in combination with the treatment of OSA and bruxism as a mechanism for nerve entrapment demonstrates a long-term cure.

INTRODUCTION

Classical trigeminal neuralgia (TN) is a disease of severe stabbing neuropathic facial pain of the second and third divisions of the trigeminal nerve [1]. It is estimated that 1 in 15,000 people suffers from trigeminal neuralgia; however, numbers may be significantly higher due to frequent misdiagnosis [2]. The incidence is greatest in people over 50 years of age and women more frequently than men [3].

It has also been reported that 26% of the American population were at high risk of obstructive sleep apnea (OSA), a sleep breathing disorder (SBD), indicating as many as one in four Americans could benefit from an evaluation for OSA [4]. In the same report, 57% of obese individuals were at high risk for OSA. Obesity is defined as a BMI (body mass index) of 30 or greater.

This case study seeks to demonstrate a long-term cure for trigeminal neuralgia utilizing low-level laser therapy and treatment for OSA.

This case demonstrates relief of chronic facial pain of the mandibular division of the trigeminal nerve as it innervates the muscles of mastication (see Figure 1).

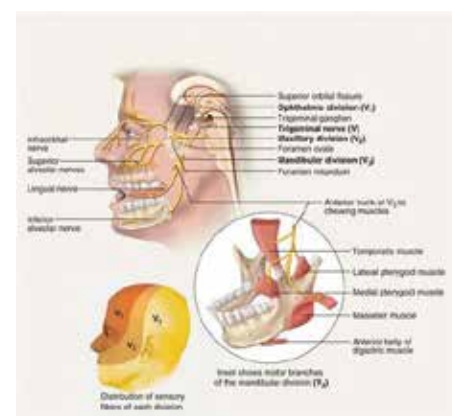


Figure 1

Trigeminal neuropathy can have many origins such as a neoplastic growth compressing the nerve as it leaves the pons and before it leaves the cranium through either the foramen rotundum (maxillary division, blue arrow) or foramen ovale (mandibular division, green arrow), see Figure 2. Tumours, usually posterior fossa meningiomas or neuromas, are found in 2% of patients who present with typical TGN [5]. Surgical excision is indicated for these conditions as diagnosed via MRI.

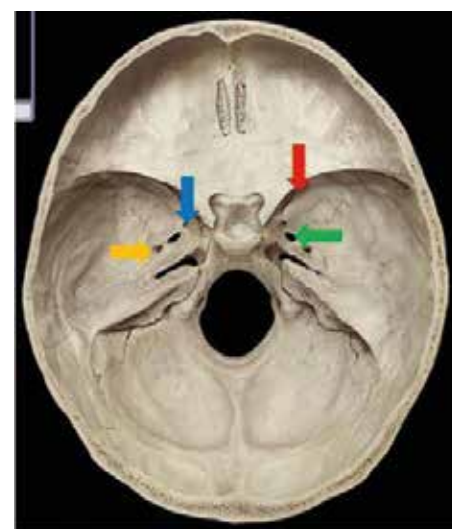


Figure 2

Another source of trigeminal neuralgia can

be enlargement of the middle meningeal artery that can compress the mandibular division as it leaves the skull through the foramen ovale. The middle meningeal artery is a branch of the maxillary artery in the infratemporal fossa. It enters the skull through the foramen spinosum (yellow arrow Figure 2), and is within the dura mater lining the cranial cavity. The critical abnormality is vascular contact at the dorsal root entry zone, rather than more distally; such is seen in 3–12% of trigeminal nerves at autopsy [6,7]. Brain Surgery (microvascular decompression), is necessary to treat this condition.

The most common source of trigeminal neuralgia is peripheral entrapment of the nerve by the muscles it innervates or mechanical trauma (injury). There is damage to the myelin sheath that lowers the capacitance of the nerve that lowers its' threshold for conduction. So there is a spontaneous transmission of pain in a sensory nerve by contractions of the muscles it innervates or a structure that it passes through. It has been my experience that mandibular trigeminal neuralgia is often present in combination with a movement disorder termed bruxism. Bruxism is an exacerbation of normal rhythmic masticatory muscle activity that results in wear of dentition and muscle pain disorders. The brain is stimulated by a variety of factors including pain, medications and sleep-related breathing disorders [8].

Treatment for trigeminal neuralgia is usually medicinal. Membrane stabilizing drugs, anti-convulsants, centrally acting muscle relaxants individually or in combination are used. Dosages are increased over time as tolerance, metabolism of the drugs increase and their effectiveness decreases. When maximum dosage for each individual drug has been reached it is lowered and an additional drug is combined until maximum dosage is reached and a third drug or new combination is tried. Commonly used drugs are Tegretol (carbamazepine), Neurontin (gabapentin), Lamictal (lamotrigine),

Clonopin (clonazepam), Baclofen, (Lyrica (Pregabalin).

The clinical efficacy of low level laser therapy (LLLTL) in the treatment of neuropathic pain is well established in many studies [9-19]. This is a very important tool for the treatment of nerve injuries as all other treatments are palliative while the laser therapy is truly therapeutic.

CASE STUDY

A man 66-year-old was referred to our office for the relief of left mandibular episodic facial pain neuralgia by an oral maxillofacial surgeon. His chief complaints were chronic pain (four years) when chewing, jaw and facial pain. He had spontaneous shooting pain on the left side of his face. He said he could relate it to a novocaine injection and tooth implant. He was currently being treated with carbamazepine 100 mg four times daily, but the pain was not controlled. He had previously been treated with gabapentin 300 mg three times per day until it became ineffective. He sometimes took alcohol and sedatives for pain relief or

sleeping.

Positive findings from his health history were high blood pressure, stroke, asthma, hepatitis, and frequent awakenings at night. Our clinical findings at time of examination were: BMI 31.07, B.P. 166/100, Pulse 64, Respirations 16, Temperature 98.2. Orthopedic mandibular ranges of motion were 56 mm without pain, left and right lateral movements of 10 mm, and 9 mm of protrusion. Dental examination demonstrated molar class one occlusion, with 4 mm of overjet and overbite, with worn dentition (bruxism), see Figure 3.



Figure 3

Oral evaluation demonstrated Mallampati class 4, furrowed tongue, coating of the tongue (indicating mouth breathing from nasal obstruction), and scalloping of the tongue, which are both indicative of a sleep-related breathing disorder, see Figures 4 and 5.



Figure 4



Figure 5

There were no positive findings for muscle, tendon and ligament palpation. Imaging utilizing CBCT (cone beam computed tomography) demonstrated a significant cant of the mandible to the left side (affected side) and was confirmed with photograph of patient with tongue blade, see Figures 6 and 7. This indicates that the elevator muscles or muscles of mastication are shorter on the left than right. When muscles are shorter than their resting length they have greater resting tonus or tension.



Figure 6



Figure 7

Nasal obstruction was observed from the iCAT CBCT, with deviation of the septum to the left with nasal soft tissue hypertrophy, see Figure 8. The oropharyngeal airway appeared to be within normal dimensions while awake, however it did not measure how much it can collapse while asleep, see Figure 9.



Figure 8



Figure 9

The diagnosis for this patient was trigeminal neuralgia with suspected sleep-related breathing disorder, nasal obstruction, nasal valve compromise, and bruxism. The treatment plan consisted of:

1. Decompression appliance therapy, see Figure 10, (night orthotic that prevents mandibular retrusion, reduces clenching forces and opens nasal valve), for cant correction and leveling of the occlusal plane utilizing the phonetic or sibilant



Figure 10

phoneme registration [20] and reducing of oropharyngeal airway collapse while sleeping with combined use of weekly treatments with a dual wavelength, high power IR laser (Multiwave Loked System (MLS®) laser, Mphi, ASA srl, Vicenza, Italy) see Figure 11, using the following treatment parameters: 50% intensity, frequency of 100 Hz, for 2-3 minutes utilizing energy of 30 joules and carbamazepine 100 mg four times per day. Treatment time 10-12 weeks and re-evaluation.

2. Referral to sleep physician for diagnostic PSG (polysomnography).
3. Referral to ENT physician for evaluation and treatment of nasal obstructions.

TREATMENT RESULTS

At four weeks of the combined treatment of decompression, carbamazepine and weekly applications with the Mphi laser the facial pain and jaw pain had resolved and the pain when chewing had reduced between 40-50%. The unique synergistic use of two wavelengths of energy (808 and 905) using both pulsed and continuous (chopped) application is superior to either pulsed or continuous laser systems. The laser was used from the peripheral point of the innervation of the masseter nerve working back centrally towards its' origin. Laser radiation can stimulate biochemical reactions and repair processes [21,22]. Since the damaged nerve has low threshold and is easily stimulated to transmit nociception/pain, it is necessary to keep the patient on medication to control the nerve while it is being healed. Once the nerve healing is complete and it retains its' normal threshold or capacitance the need for medications is unnecessary.



Figure 11

At eight weeks of combined therapy and weekly applications of the Mphi laser the pain when chewing was resolved as well as the facial and jaw pain. At this point I recommended reduction of the carbamazepine dosage by one third and continued reduction until elimination of the drug or return of pain symptoms. The patient finally agreed to have a sleep study (PSG), and I wrote the prescription for referral.

At eleven weeks he had an attended sleep study (PSG) and the results were overall moderate apnea with an AHI of 26.0 and a REM AHI of 40.4 (severe). He had zero (0) stage 3 delta wave restorative sleep and his lowest oxygen desaturation was 82%. His periodic limb movement (PLM) index was 21.4. He was diagnosed with obstructive sleep apnea and PLM disorder.

At re-evaluation at 13 weeks of treatment the patient had completely weaned off all medications and was symptom free. He chose not to treat his OSA and his PSG testing was performed without the decompression appliance. He found that he had a slight tingling of the same injured nerve when he did not wear his oral decompression appliance for three nights. It was explained to the patient the severe health risks of untreated OSA.

This article demonstrates the relationship between trigeminal nerve injury and muscle contraction disorders such as those found in patients with sleep-related breathing disorders. Most importantly it demonstrates the value of laser therapy utilizing the unique delivery of the Mphi laser system on healing injured nerves. This is the most remarkable tool that I have seen in my 30 years of treating chronic pain disorders.

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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.

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