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Characteristics of Piano Level Laser Therapy (PLLT™) Using Novel 1064 nm Laser Handpiece Technology

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ABSTRACT

Both types of the photo-biomodulation (PBM) therapy, the low-level laser therapy (LLLT) characterized by minimal temperature elevations of not more than 0.1 to 0.5°C, and as well the high-intensity laser therapy inducing temperature changes of several degrees C, are increasingly being used for the reduction of inflammation, wound healing and pain management.

In this paper we report on a novel 1064 nm laser handpiece technology (MarcCo™) that enables PLLT™ (Piano Level Laser Therapy), characterized by the application of either low-level or high-level laser therapy with a stamping or brushing delivery technique. The unique capability of the MarcCo™ technology to deliver highly collimated and homogeneous beam profiles with very large spot sizes represents a significant improvement in the field of tissue stimulation.

Key words: Photobiostimulation, PBM, Piano Level Laser Therapy, PLLT, LLLT, HILT, Nd:YAG, Genova, MarcCo.

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I. INTRODUCTION

Photobiomodulation therapy (PBM), sometimes referred as low-level laser therapy (LLLT), has been increasingly used for the reduction of inflammation, wound healing and pain management [1]. It is usually performed by low-energy lasers (also known as cold lasers or class III lasers). By definition, PBM uses irradiation intensities that induce minimal temperature elevations (not more than 0.1 to 0.5°C), if any. PBM acts through various means – affecting cellular mechanisms via Cytochrome C Oxidase activation in mitochondria, activating photosensitive receptors on the cell membrane, as well as affecting extracellular signaling molecules [1]. The treatments with the most clinical evidence for the positive effects of PBM include wound healing and pain management.

In the area of pain management, lasers with powers slightly higher than typically used during PBM have been proven to be even more effective [2-8]. Higher powers enable deeper penetration of therapeutic light intensities that can reach muscles and tendons, as well as act directly on nerves to inhibit pain signals. This type of therapy has been referred to as high-intensity-level therapy or HILT, mainly to differentiate from PBM, as high-powered (class IV) Nd:YAG (1064 nm) lasers are commonly used with HILT. During HILT several hundreds of Joules of energy are delivered to the treated area [2-7]. HILT has been traditionally performed using relatively small ($d = 5$ mm) laser spot sizes, with the whole treatment area irradiated using manual brushing with a fast scanning speed to cover 1 to 5 cm in 1 s [2]. By repeating transverse and longitudinal brushing until the laser beam covers the whole treated area (typically 25-150 cm^2), it is possible to achieve approximately homogeneous irradiation of the treated tissue, even when the output laser beam is diverging (i.e., increasing in size with distance away from the handpiece) and the beam profile has a standard bell-shaped Gaussian profile.

Therapy using high-energy intensities is characterized by tissue temperature changes of several degrees, and has proven to be a painless and effective method for temporary relief of muscle and joint pain and stiffness, arthritis pain or muscle spasm, temporary increase in local blood circulation and/or promoting the relaxation of muscle [8].

One important disadvantage of HILT over PBM is that it requires repetitive manual scanning (i.e., brushing) of the small (5 mm) beam over the treated area in order to deliver the desired higher energy dose. A more desirable method of delivery would be the stamping technique, since with this method the outcome does not depend on the practitioner's experience and attention. With the stamping technique, the handpiece is held in a fixed position over the treated handpiece spot-size area until the exact required energy dose is delivered, after which it is then moved to an adjacent spot to be irradiated. This process is consecutively performed until the entire treated body area is covered.

The advantages of the stamping technique become more pronounced when performing treatments with a large handpiece spot size. This is because with a large spot size, the entire body can be covered in shorter time. However, as opposed to PBM treatments, delivering higher energy doses with the stamping technique requires a beam profile that is i) collimated (i.e., with the beam spot size not affected by the distance from the treated tissue) and ii) homogeneous (i.e., flat-top, top-hat); both of these requirements represent a significant technical challenge.

In recent years, however, a special Genova™ handpiece (manufactured by Fotona, d.o.o.) has been developed that delivers a collimated top-hat beam profile with a relatively large spot size of d = 10 mm [9-15]. This handpiece has enabled a PLLT – Piano Level Light Therapy modality that is characterized by the ability to deliver both low-level and high-level intensities using larger spots in stamping mode, as well as the ability to work in the brushing mode.

In this paper we report on a newer and more significant developmental step in the field of PLLT. Recently, a novel class of handpieces has been developed that has overcome the technical challenges involved in delivering homogeneous beams with extremely large spot sizes. These MarcCo™ laser handpieces (manufactured by Fotona, d.o.o.) are characterized by a highly collimated and homogeneous beam profile with a uniform intensity for a wide range of handpiece spot sizes (d ≈ 10 - 50 mm). The MarcCo™ large spot size and uniform beam-handpieces allow the user to deliver laser energy to the treated tissue in a "stamping" mode using both low-level and high-level energy intensities. This brings forward the possibilities of easily combining photobiomodulation and pain-relief protocols, which would usually require two separate devices. It also allows for fast, high-intensity laser therapies using the stamping protocol because of the large spot sizes available.

The MarcCo™ handpiece technology can be used with a number of laser wavelengths in addition to 1064 nm, including 670, 810, and 980 nm. However, in this paper we focus only on the PLLT therapy based on the 1064 nm wavelength.

Results are presented as the measurements of changes in skin temperature (ΔT) after the application of the stamping PLLT™ therapy using MarcCo™ handpieces with different spot sizes.

Fig. 1.: MarcCo™ handpiece technology – MarcCo L (bottom), MarcCo M (middle) and MarcCo S (top)

Further, a comparison of calculated parameters for stamping and brushing PLLT™ is made, based on a comparison of the results with the published temperature changes as measured for HILT therapy using the brushing technique [2].

A clinical case is also presented, where PLLT™ therapy in two different modalities was successfully used to treat a patient with neuralgic amyotrophy.

II. MATERIALS AND METHODS

a) In vivo skin temperature measurements

A pulsed Nd:YAG laser (LightWalker® ATS, Dynamis SP) with MarcCo S (d = 10 mm), MarcCo M (d = 24 mm) and MarcCo L (d = 43 mm) handpieces (all manufactured by Fotona, d.o.o.) was applied over the patient's forearm as shown in Fig. 2. The following laser parameters were used: 1064 nm wavelength, pulse duration of 100 μs, frequency of 30 Hz, and average spot area power density ($P_S = P/S$; where $S = \pi d^2/4$) within the laser spot (d) of 1.0 W/cm² or 1.8 W/cm². The laser handpiece was held at a fixed position, and the maximal temperature increase $\Delta T = (T_{max} - T_{initial})$ was measured by the end of the irradiation sequence of t_{ir} = 60 s or 120 s on four of the authors' arms with a thermal video camera FLIR.

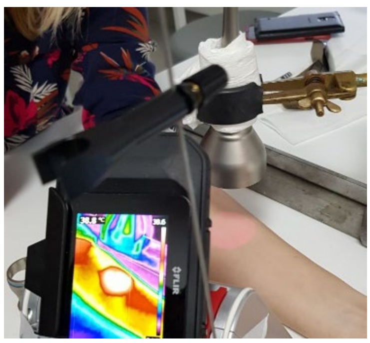

Fig. 2.: Experimental set-up. The largest spot size (43 mm) handpiece is shown. When using the stamping technique, the handpiece is held fixed at the same position until the total laser dose has been delivered.

b) Clinical example of PLLT therapy

A 52-year-old male patient with paresis and pain in the right shoulder was diagnosed with neuralgic amyotrophy by a neurologist. The patient had severely impaired shoulder abduction and flexion - he could not lift his arm by more than 90 degrees and could not brush his teeth using his right arm. He had been prescribed NSAID therapy, B1 and B6 vitamin supplementation and light shoulder exercise. The initial acute pain subsided with treatment, but discomfort in the area and partial paresis had remained. Despite the therapy, there was little progress on the range of shoulder movement 3 months after the initial diagnosis. At that point, the PLLT therapy using the MarcCo L handpiece was performed.

The patient received three combined therapy sessions using MarcCo L handpieces. In the first pass, the stamping technique was performed using "cold" PLLT settings for photobiomodulation – MSP pulse (100 µs), P = 3 W (resulting in the spot power density $P_s = P/(\pi d^2/4 = 0.21$ W/cm²), 10 Hz, with 1 minute treatment duration per spot. In the second pass, higher "warm" PLLT settings that already cause mild heating of the tissue were used, aimed at pain relief – MSP pulses 8 W (P_s = 0.55 W/cm²), 60 Hz, in stamping mode, where the handpiece was held at each spot from 1 to 2 minutes, depending on patient tolerance. Three laser sessions were performed with 2-day intervals. The patient had gained back full range of motion and functionality of the affected arm following the three PLLT treatments. For a demonstration of improvement, see the photos in Fig. 6 that were taken immediately after the third session. When the patient was interviewed via telephone six months following the PLLT procedure, he still had full range of motion, which remained unchanged since the PLLT treatment. While the pain in his shoulder subsided, he still felt slight discomfort only when performing more intense physical activities using his right arm.

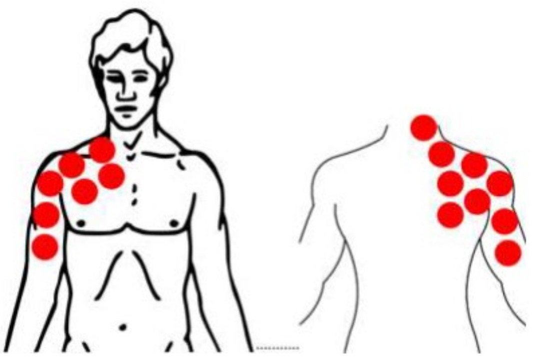

Fig. 3.: Treated area in the clinical case, using the MarcCo L handpiece and stamping technique.

In this clinical case, both the non-thermal bio-modulation and thermal pain management PLLT modes were utilized to treat a condition where partial paresis was accompanied by pain. The PLLT dual-modality laser treatment has shown to be effective in both regaining movement and reducing pain in the affected shoulder.

III. RESULTS

c) Temperature measurements

Figure 4 shows the measured ΔT for different MarcCo™ spot sizes (S, M and L) and power densities, averaged over the results on four subjects, as a function of the irradiation time. As can be seen from Fig. 5, the rate of temperature increase (in ΔT/s) is higher for larger spot sizes.

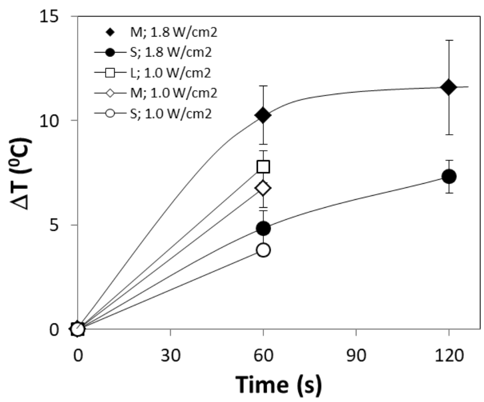

Fig. 4.: Measured temperature increases as a function of irradiation time (t_{ir}) during stamping PLLT for different spot size MarcCo™ handpieces and spot power densities (P_S). It should be noted that when using recommended PLLT protocols (See Tables 1 and 2) the resulting temperature increase is below 3⁰C.

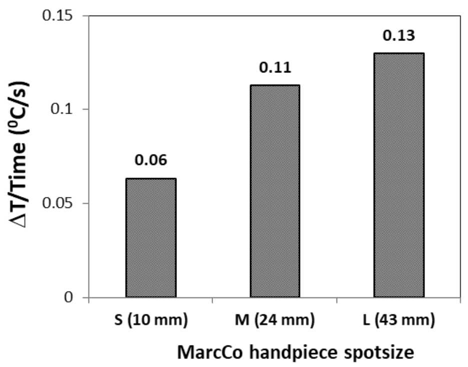

Fig. 5. Measured temperature increase rates during stamping PLLT for the same spot power density of P_S = 1.0 W/cm² and different spot size MarcCo™ handpieces.

d) Clinical case of PLLT

The outcome of the PLLT treatment using a protocol as described in the Methods and Materials section, of a patient diagnosed of neuralgic amyotrophy, is presented in Fig. 6. Before the treatment, the patient could not lift his arm by more than 90 degrees and was not able to brush his teeth using his right arm.

Fig. 6.: Patient before (above) and immediately after 3 treatments (below) using the MarcCo L dual mode PLLT treatment. The patient was instructed to lift the arm to his maximum ability. Before the treatment, the patient could not lift his arm by more than 90 degrees and was not able to brush his teeth using his right arm. The treatment protocol is described in the Methods and Materials section.

IV. DISCUSSION

Our measurements show that larger treatment sizes result in higher temperature increases ΔT for the same delivered energy density F (See Fig. 4). This observation must be considered when performing PLLT™ with a brushing or stamping protocol.

The skin temperature increase during the therapy performed with the brushing technique has been reported in ref. [2]. In this study, the front thigh area (A = 15 cm × 10 cm = 150 cm^2) was exposed to the Nd:YAG laser operated with a d = 5 mm spot size at about P = 3 W average power. This resulted in a relatively high spot power density of $P_S = P/(\pi d^2/4)$ = 20.4 W/cm^2, however, this parameter is relatively unimportant when using the brushing technique. The important parameter is the effective power density (P_A) delivered over the overall manually scanned treatment area A. During the studied brushing treatment, the total treated area was A = 150 cm^2, with total E = 3000 J delivered to this area in t_{ir} = 900 s, resulting in $P_A = E/(A \times t_{ir})$ = 0.02 W/cm^2.

In order to be able to compare the published temperature results as obtained using the brushing technique [2], and the measured temperature increases using the stamping technique in this study, we introduce the heating rate $R = \Delta T/(P_A \, . \, t_{ir})$ (in ^{0}C cm^2/J), representing the temperature increase per delivered energy density F (in J/cm^2). Note that for the stamping technique, the complete package of energy per spot is delivered during the single-spot irradiation time, therefore, the effective power density is calculated over the spot size area (S) and not the total treatment area (A), thus in the case of stamping mode, $P_S = P_A$. Total treatment time for the stamping technique was calculated by multiplying the spot treatment duration with the number of spots needed to cover the total treatment area.

Figure 7 shows the dependence of the heating rate R as it follows from the stamping PLLT data shown in Fig. 4, and from the published temperatures for the brushing therapy [2].

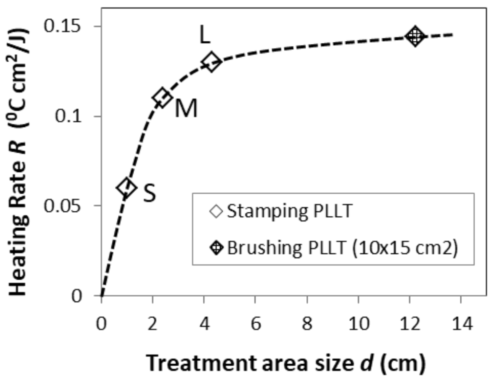

Figure 7.: Dependence of the heating rate R on the treatment area size d. The symbols S, M and L represent MarcCo™ handpieces with stamping area sizes d = 10, 24 and 43 mm. For the scanned treatment area A = 10 x 15 cm^2, a representative size d = A$^{1/2}$ = 12.3 cm was taken. The corresponding heating rate was calculated from R = 2.6^{0}C/(900 s x 0.02 W/cm^2) = 0.14 ^{0}C cm^2/J.

As can be seen from Fig. 7, the heating rates as obtained for the stamping PLLT and the heating rate for the brushing PLLT™ follow the same dependence on the treatment area size.

The measured average temperature increase during the standard brushing therapy is ΔT = 2.6 ± 1.4^{0}C [2]. The treatment area and laser parameters as described in ref [2] were used for the calculation of other parameters for brushing PLLT. The irradiation times for Fotona handpieces were calculated from t_{ir} = 2.6 ^{0}C/(P_A x R). The treatment area power density (P_A) is calculated from the average laser power (P) and treatment area (A) as $P_A = P/A$. For the stamping protocol, the spot size area S was used in treatment area power density calculations, while for the brushing protocol, the total treated area was used in treatment area power density calculations. The total stamping treatment time was calculated as the time required to successively "stamp" the total treated area of 150 cm^2.

It should be noted that the brushing and stamping PLLT must result in the same skin temperature increase to be considered substantially equivalent in terms of their efficacy and safety. This requirement is supported by the observation that the skin cooling time is on the order of ten minutes [15], which is longer or comparable to the irradiation times of the brushing or stamping treatments.

Using the above criteria for the calculation of treatment parameters, we obtain the following stamping and brushing PLLT treatment protocols for different laser handpieces, as shown in Table 1 below. For completeness, a comparison is made also for some of the other handpieces available with Fotona devices: R30-Y and Genova™ (available with LightWalker® and XPulse®) and R34 (available with Dynamis).

As can be seen from Table 1, when performing a brushing protocol, the handpiece spot size is relatively unimportant for the final outcome since the smaller beam (provided $d < A$) is rapidly scanned over the larger treatment area and the effective power density ($P_A = P/A$) depends only on the average laser power (P) and the treatment area A, and not on the spot size d. For the exemplary brushing protocol according to the protocol studied in refs. [2, 6], the effective power density (P_A = 0.02 W/cm^2), the treatment duration ($t_{ir} \approx 900$ s), the delivered energy ($E \approx 3000$ J) and the final temperature increase (ΔT = 2.6 ^{0}C) are approximately the same regardless of the handpiece spot size (See Table 1). Also, much lower spot power densities are required for larger spot sizes to achieve the same temperature increase – this means that brushing with larger spot sizes is expected to result in a more homogeneous energy distribution, with a reduced risk of locally administering too high intensities due to human error.

V. CONCLUSIONS

The novel MarcCo™ handpiece technology improves the ease of use and provides a better control of the delivery of the desired energy dose for both the brushing or stamping delivery method.

As shown in the clinical case performed in the stamping mode, MarcCo™ handpieces coupled with high-performance Fotona 1064 nm (Nd:YAG or diode) laser platforms such as LightWalker®, SkyPulse® and Dynamis™ offer unique possibilities for combining "cold" and as well "warm" pain management PLLT protocols in a single treatment session, using a single device.

The large MarcCo™ spot sizes allow the practitioner to perform low-level (cold) and high-level (warm) therapies in the very controlled stamping manner. The advantage of the stamping protocol as compared to the brushing protocol for treating larger areas is the higher control of the delivered energy density since it does not depend on the experience and attention of the practitioner performing the manual brushing.

On the other hand, when performing the PLLT

Table 1: Exemplary brushing and stamping PLLT treatment protocols for different handpieces available on Fotona platforms, including 3 MarcCo™ handpieces, calculated to deliver an equivalent temperature increase to a treatment area of 150 cm^2, as specified in HILT references [2, 6].

	Reference data		Calculated parameters for Fotona handpieces											
Handpiece/device	HIRO 3, ASA Alayat et. Al. (2)	Hilthera, Jeisys, Khan et. al. (6)	**MarcCo S**	**Genova**	**R30-Y / R34-T**	**R30-Y / R34-T**	**MarcCo M**	**MarcCo L**	**MarcCo S**	**Genova**	**R30-Y / R34-T**	**R30-Y / R34-T**	**MarcCo M**	**MarcCo L**
Treatment technique	**Brushing mode**		**Brushing mode**						**Stamping mode**					
Total treated area (cm^2)	150	150*	150	150	150	150	150	150	150	150	150	150	150	150
ΔT (^{0}C)	2.6	2.8	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6	2.6
Spotsize d (mm)	5	5	10	11	15	20	24	43	10	11	15	20	24	43
Spotsize area (cm2)	0.2	0.2	0.79	0.95	1.77	3.14	4.52	14.51	0.95	0.79	1.77	3.14	4.52	14.51
Heating Rate R (^{0}C cm^2/J)	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.06	0.06	0.08	0.1	0.11	0.13
Spot power density P_S (W/cm^2)	20.4	6.4	3.8	3.3	1.8	1.0	0.7	0.2	1.5	1.5	1.3	1.3	0.9	0.2
Effective power density P_A (W/cm^2)	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	1.50	1.50	1.34	1.30	0.90	0.23
Laser power (W)	3.6	12.5	3.0	3.1	3.1	3.1	3.2	2.9	1.2	1.4	2.4	4.1	4.1	3.3
Irradiation time (s)	900	900	934	889	901	887	880	960	29	29	24	20	26	87
Total treatment time (s)	**900**	**900**	**934**	**889**	**901**	**887**	**880**	**960**	**5520**	**4562**	**2060**	**955**	**871**	**899**
Total delivered energy E(J)	**3000**	**3000**	**2786**	**2786**	**2786**	**2786**	**2786**	**2786**	**6500**	**6500**	**4875**	**3900**	**3545**	**3000**

treatment in a brushing mode, the large MarcCo™ handpiece spot sizes make it easier for the practitioner to cover the area in a more homogenous manner.

The PLLT stamping technique is especially advantageous for i) MarcCo™ laser beam spot sizes of $d \geq 20$ mm, where the stamping and brushing treatment protocols result in similar P_A, t_{ir}, E and ΔT (see Table 1), and ii) when addressing trigger/pain points with MarcCo™ spot sizes $d \leq 10$ mm.

The optimal settings for MarcCo™ handpieces in low-level ("cold") PLLT mode and high-level ("warm") PLLT mode for pain management PLLT are shown in Table 2 below. The stamping mode is recommended for both types of therapies since all treatment body areas, from trigger points and small lesions to large body areas, can be effectively covered with the stamping technique utilizing the available range of MarcCo™ handpiece sizes.

Table 2: Recommended 1064 nm PLLT stamping treatment protocols for MarcCo™ handpieces on Fotona platforms for low-level (cold) and high-level (warm) PLLT performed using the stamping technique.

	"cold" PLLT - photobiomodulation			"warm" PLLT - pain management		
	Spot power density W/cm^2	Frequency (Hz)	Time per spot (s)	Spot power density	Frequency	Time per spot
MarcCo S	0.6	10	60	1.5	30	60-120*
MarcCo M	0.2	10	60	0.6	30	60-120*
MarcCo L	0.2	10	60	0.5	30-60	60-120*

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