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Comparison of the effects of a conventional physiotherapy with Multiwave Locked System laser in glenohumeral joint peritendinitis: a randomised trial.

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ABSTRACT

Objectives: To evaluate the therapeutical effects of Multiwave Locked System (MLS®) laser and the combined therapy of microwave diathermy and interference current, in patients with glenohumeral joint peritendinitis.

Design: This was a prospective, randomised, parallel, single center trial.

Setting: Outpatient Hospital Clinic

PARTICIPANTS: A sample of 76 patients with glenohumeral joint peritendinitis

Methods: The patients were randomized into 2 groups in a 1:1 ratio: a group was treated with MLS® Laser Therapy (group A) and a group with microwave diathermy and interferential current therapy (group B). The primary outcome was the reduction of pain according to Shoulder Pain and Disability Index (SPADI). Secondary outcomes were improvements of shoulder's movement (goniometry) and the reduction of pain, through the visual analogue scale (VAS). An intragroup and an intergroup analysis were performed.

Results: Both treatments demonstrated statistically significant intragroup differences. The intergroup analysis showed a greater improvement of MLS® Laser Therapy in terms of pain reduction at the end of the treatment and at the mid-term follow-up visit.

Conclusion: Both therapies have been demonstrated to be effective and safe. The application of MLS® laser treatment presented more effective and durable therapeutic effects.

Key words: Glenohumeral joint – Tendinitis - Laser therapy - Diathermy.

LAY ABSTRACT

The purpose of the present investigation is to evaluate the therapeutical effects, in terms of pain reduction and mobility improvement, of Multiwave Locked System (MLS®) laser energy treatment and the combined therapy of microwave diathermy and interference current. A total of 76 patients were recruited for the study. They were split into two groups: Group A received eight sessions of MLS® laser; Group B – 10 sessions of microwave diathermy and interferential current. All the patients were evaluated at baseline prior to starting treatment (T0), after completion of the therapeutic course (T1), and on the 45th day from baseline (T2). The intergroup analysis showed a greater improvement of MLS® Laser Therapy in terms of pain reduction at the end of the treatment and at the mid-term follow-up visit. It also presented more effective and durable therapeutic effects.

INTRODUCTION

Glenohumeral joint peritendinitis is one of the most common shoulder diseases [1, 2], that affects people who practice sports as well as repetitive activities related to work or to everyday life [3].

Moreover, peritendinitis of rotator cuff muscles aggravates with ageing [4] and affects more than 80% of the people over 80 years of age [5]. According to its definition, tendinitis suggests that tendon injury is accompanied by an inflammatory response [6-9].

The glenohumeral joint peritendinitis affects rotator cuff tendons, most commonly, of *m. supraspinatus*. This damage can vary from a simple tendinopathy to degenerative alterations, even to their partial or complete rupture. On the other hand, the glenohumeral joint peritendinitis very often leads to a secondary adhesive glenohumeral joint capsulitis (frozen shoulder), due to a pain-induced disturbed movement mechanism [10].

It appears as an evolution of an initially controlled inflammatory process, starting after a traumatic

moment and evolving towards an abnormal uncontrolled fibrosis [11, 12]. Its origin should be considered a severe medical failure, as glenohumeral joint function is not always completely restored in some patients [13].

Approximately 40% of the rotator cuff tendinopathy patients fail to respond to conservative management [14,15] and more than one half of the patients report a reiterating and permanent pain in the long term [16]. The rotator cuff tendinopathy is widely common and represents a considerable socio-economic burden because of work loss and treatment costs [17].

Investigations on the effects of Multiwave Locked System (MLS®) lasers have shown the possibility to influence immediately the disease pathogenesis [18-25] and the opportunity to use the therapeutic lasers in any phase of disease stage. Such characteristics make the MLS® Laser Therapy a suitable application in the treatment of glenohumeral joint peritendinitis [13].

Therapeutic modalities, local microwave diathermy and interferential current are commonly used for the glenohumeral joint peritendinitis. They can help in the restriction of the degeneration processes through a restoration improvement [25] and a reduction of tissue neovascularization that is related to tendinopathy pathogenesis [6]. Diathermy exerts several biological effects such as metabolic function enhancement, deep tissue temperature elevation, and blood microcirculation improvement.

As a result, from these effects, pain reduces and joint movement volume increases. The contraindications for the usage of this modality include the application on metal [26], metabolic imbalance and pacemakers [14]. The therapy with interferential currents consists in the application of an alternating medium-frequency current (4000 Hz) modulated at a low frequency (0-250 Hz). One of the advantages of the interferential currents over the low-frequency ones consists in their capacity to penetrate into the human organism despite the skin resistance. Another advantage of the interferential current is its capacity to generate low frequency current in deep tissues in the area of treatment.

In the literature available, several theoretical physiological mechanisms such as the 'gate control' theory, enhanced circulation, pain reduction, nervous conductivity blockade and placebo have been proposed to support the analgesic effects of the interferential current [27,28].

MATERIALS AND METHODS

This prospective, randomised, parallel, single centre trial was conducted at the St. Marina University Hospital of Varna. The scientific research has been conducted in accordance with the principles set forth in the Helsinki Declaration and received the permission from the Commission on Ethics of Scientific Research, appointed at the Medical University of Varna - protocol № 98 / 26.11.2020. Data were collected in a group of patients (n=76) with acute glenohumeral joint peritendinitis. The researchers have received permission from the hospital authority to conduct the trial in the hospital.

All the enrolled subjects gave their consent to participate at the study and filled the informed consent.

Patients with the following conditions have been included: diagnosis of glenohumeral joint peritendinitis verified by means of a physical examination, clinical manifestations such as palpable pain in the projection of the insertions of the affected muscles, reduced joint active flexion, abduction and external rotation, no physical therapy and/or laser treatment during the period after pain onset.

Patients with the following conditions have been excluded: a diagnosed shoulder-complex bone fracture, a proved rupture of the tendon of *m. supraspinatus* or another tendon of the rotator cuff muscles and of *m. biceps brachii*, history of pain symptoms lasting longer than one week or chronically relapsing complaints in the affected shoulder, a consulting examination by orthopaedist requiring any surgical intervention, applications of corticosteroid preparations or other drugs after pain onset, any comorbidity creating contraindications for laser treatment such as systemic neoplastic, infectious and autoimmune diseases as well as for conventional physical therapy, a preceding surgical intervention in the affected shoulder, a fifth and sixth skin type after Fitzpatrick, an incapacity to understand and observe the study protocol, patients who refused to sign the informed consent concerning the therapeutic procedures, patients who refused to participate to the study due to personal reasons, a pregnancy state.

After patients have passed an initial assessment of inclusion / exclusion criteria they were randomised into 1 of 2 groups in a 1:1 ratio. A group was treated with the MLS® Laser Therapy – group A – while the other with a combination of microwave diathermy and interferential current therapies – group B. The principal investigator generated the distribution sequence (by software platform GraphPad), enrolled the participants, and assigned participants to interventions (Figure 1).

Interventions

The MLS® is a type of near infrared class IV high power laser distinguished by two simultaneous emissions. The two types of laser sources emit radiations of different wavelengths, peak power and emission regime. The first one is a pulsed diode laser at 905 nm with a pulse duration of 100 ns and a peak power of 25 W. The second diode laser emits a radiation wavelength at 808 nm in a constant regime (max power 1W for each diode) or in "frequenced" regime with a repetition frequency up to 2000Hz and a fixed duty cycle of 50%.

The patented system of synchronized sources enables their combined application with a total average power up to 1.1W or 3.3W, depending on the laser applicator (heandpiece), a peak power of 25W, a modulation frequency of 1-2000 Hz or continuous.

The MLS® Laser Therapy device used in this study is M6 (ASA srl -Arcugnano, Italy), equipped with both a robotized multidiode head (up to 3,3W), able to perform automatic scanning treatments, and an MLS® handpiece (up to 1,1W), aimed to perform manual point to point or scanning treatments.

Each treatment included two stages: the scanning of the frontal and dorsal shoulder area of 93 cm^2 each with a robotized multidiode head (Figure 2-1) and a point-by-point process with the manual handpiece with 7 points of 3,14 cm^2 area each were treated (Figure 2-2), for a total area of 21,98 cm^2.

The two different parameter settings used, based on the application mode, are reported in the Table I. The therapeutic plan included eight sessions divided within two working weeks. In the first week each patient underwent to a daily treatment for a total of five days and five procedures, while in the second week, a daily procedure was performed every second day for a total of three procedures.

The therapeutic method used in group B included ten sessions divided within two working weeks, every day each patient received one application of microwave electromagnetic field and one of interferential currents.

The microwave electromagnetic field (Figure 3-1) has been used with the following parameters setting: wavelength of 12,6 cm and frequency of 2375 MHz, microwave intensity of 0,56 W/cm^2, power of 40-70 W or less, session duration of 10-15 minutes and subjective dosage - athermic with gradual increase up to oligothermic that is felt as a very slight heat. For the interferential currents (Figure 3-2) has been used a four-pole method with the following parameters: alternating current, sinusoid impulse, bearing frequency of 4000 Hz, alternating frequency of 90-100 Hz, session duration of 15 min and subjective dosage - up to the sensation of running current.

Sample size calculation

A convenient sample of patients with peritendinitis of glenohumeral joint participated in this study.

The relationship between significance, power, sample size and effect size is used to make sample size calculation. To avoid Type II error, or false negatives it is generally accepted we should aim for a power of 0,8. Our calculations were made using a significance level alpha = 0.05 and the test has 80% power, and if assumed a medium effect size of 0.5, it is needed a sample size of about 32 patients in each group. A total of 76 patients fulfilled the inclusion criteria and were enrolled in the study.

Randomisation procedure

all enrolled subjects were randomly allocated either to group A or B using online generated sequence for random distribution (1:1). The software platform used was GraphPad (https://www.graphpad.com/quickcalcs/randomize1.cfm).

It randomly scrambles a set number of participants among a set number of treatment slots, so each treatment always gets assigned the same number of participants. The random allocation sequence has been created by the leading author – Dr. Panayotova. She was also responsible for the enrollment of the participants and for the procedure assignment.

Primary outcome measures

For evaluation of the functional status and of pain during the follow-up we used the Shoulder Pain and Disability Index (SPADI). It is a self-administered questionnaire that consists of two dimensions, one for pain and the other for functional activities. The pain dimension consists of five questions regarding the severity of an individual's pain. Functional activities are assessed with eight questions designed to measure the degree of difficulty an individual has with various activities of daily living that require upper-extremity use.

The patient is asked to circle the number from 0 to10 scale that best describes the pain or disability. The total score is measured as a percentage and is equal to the sum of points collected from all answers to the 13 questions divided by the maximum number of 130 points multiplied by 100. The means of the two subscales are averaged to produce a total score ranging from 0 (best) to 100 (worst). Minimum Detectable Change (90% confidence) = 13 points (29). All the patients were

evaluated in three different moments: at baseline prior to starting treatment (T0), after completion of the therapeutic course (T1), and on the 45th day from baseline (T2).

Secondary outcome measures

In order to objectify the functional improvement an anglemetry of glenohumeral joint has been used. An eventual increase of range of motion (ROM) corresponds to the patient's improvement. The movements evaluated were: flexion (F), abduction (Abd) and external rotation (ER), (Figure 4). Other parameters included in the study were the assessment of spontaneous and palpable pain, according to the visual analogue scale (VAS_s, VAS_p). This is a measuring instrument that attempts to measure a characteristic or relationship that is considered not to be easily measurable directly. (30) VAS is a straight horizontal line with a fixed length, usually 100 mm. The patient notes the degree of spontaneous pain (no movement in the affected joint) and pain on palpation in the projection of the insertion of m. infraspinatus. When reporting the results for every 10 mm of the line correspond to the following points and levels of pain: 0 - no pain, 1-2 - mild pain, 3-4 - moderate pain, 5-6 - severe pain, 7-8 - a lot severe pain, 9-10 - unbearable pain. A minimum clinically important difference of 1.37 cm has been determined for a 10-cm pain VAS in patients with rotator cuff disease evaluated after 6 weeks of nonoperative treatment. (31) As a palpation spot we chose, due to its high recurrence rate, the insertion of the supraspinatus muscle. For that the greater tubercule of the humerus has to be identified and the palpation pressure should be applied to its proximal – lateral – anterior aspect. The patients were evaluated in three different moments: at baseline prior to starting treatment (T0), after completion of the therapeutic course (T1), and on the 45th day from baseline (T2).

Statistical methods

Continuous variables are summarized as mean ± SD, and categorical variables are reported as frequencies or percentages. The Shapiro-Wilk test was used to analyse the normal distribution of the variables. Continuous variables were compared using Student t tests or Wilcoxon rank sum tests if the data were not normally distributed. Categorical variables were compared using chi-square tests or Fisher exact tests if >25% of the cells in the contingency table had expected frequencies <5. A p value <0.05 was considered to indicate statistical significance for all analyses. Cohen's D (standardized mean difference) was used. This is one of the most common ways to measure effect size.

Two statistical analyses were performed: an intragroup analysis, to evaluate, for both therapeutic methods, the differences of each parameter in the three different evaluation moments and an intergroup analysis, to compare the outcomes obtained through the two different therapeutic methods.

In the intragroup analysis Friedman's and Wilcoxon's nonparametric tests and the paired T-test have been run, while in the intergroup analysis the Mann-Whitney's nonparametric test was used.

Statistical analyses were performed using SPSS software.

RESULTS

A total of 78 patients were enrolled between November 2020 and September 2021. After patients have passed an initial assessment of inclusion / exclusion criteria 76 of them were randomised by software platform either to the MLS® group (n=38) or to the microwave electromagnetic field and interference currents group (n=38). 2 of the patients have been excluded due to not meeting the inclusion criteria. All the enrolled patients completed the 45th day follow-up visit. Baseline data were obtained for all the patients. The average age at baseline was 45.7±10.2 years, and 52.6% were men. In the 60.5% of the cases was treated the right shoulder. At baseline, the difference from the normal of the anglemetry of humeral joint was 28°±24° for the flexion, 32°±27° for abduction and 34°±27° for external rotation. The baseline value spontaneous VAS was 3.1±2.8, palpatory VAS was 4.8±2.0 and SPADI was 57.4%±22.6%. There were no differences in the demographic, physical and pain evaluation between the 2 groups thus resulting homogeneous each other (Table II).

In Table III are reported the results of the intragroup statistical analysis. As shown, for the patients treated with the MLS® Laser Therapy, a significant difference of the mean values calculated in correspondence of the three time points have been found in the humeral joint movement analysis (Figure 5) - flexion, abduction and external rotation - and in the pain and functional evaluation analysis - VAS and SPADI scores. Such improvement trend is significant even at the mid-term follow-up visit. Only the differences concerning the spontaneous pain, according to VAS, between T1 and T2 values, resulted not statistically different (p-value = 0,058) (Figure 5). It is reasonable to consider this aspect related to the great initial improvement the patients achieved after the treatment cycle completion,

the low initial VAS_s value (2.8 ± 3.0 cm) and the marginal improvement obtained at follow-up.

For the patient treated with microwave electromagnetic field and interferential currents (MW_IT), there is a statistically significant difference in the mean values of the palpatory and spontaneous pain according to VAS, as well as in the percentage SPADI scores (Figure 5). As a consequence of chance, the differences between After and D45th scores were found for humeral joint flexion (p-value = 0,658), abduction (p-value = 0,285) and external rotation (p-value = 0,166) (Figure 5). This is due to the fact that these patients achieved a maximal and long-lasting improvement after treatment completion, too. In the cases of statistically significant differences between the T1 and T2 mean values confirm a trend of improvement that continue even after the end of the treatment cycle.

The intergroup analysis results are reported in Table IV and represented in Figure 6. The two groups have been compared at the end of the treatment cycle and at the follow-up. One half of the parameters present a statistically significant difference of the mean values in favour of the treatment method used in laser MLS® group (A). After treatment completion, MLS® Laser Therapy group resulted statistically different from the MW_IT group (B) in terms of: spontaneous pain (0.6cm vs 1.1cm, p = 0.016), palpatory pain (2.2cm vs 3.7cm, p < 0.000) and SPADI score (23.5% vs 35.9%, p-value = 0.003); a greater improvement seems achievable through the MLS® Laser Therapy. The two groups result not statistically different in terms of improvement of ROM of the glenohumeral joint movements.

At the mid-term follow-up visit, 45 days after the beginning of the therapy, it is reported a significant difference between the two groups in favour of the MLS® treatment group in terms of shoulder flexion (5.9° vs. 8.29°, p = 0.009), palpatory pain according to VAS (1.1cm vs. 3.2cm, p < 0.000) and percentage SPADI scores (17.6% vs. 31.4%, p < 0.000).

Cohen's D, or standardized mean difference, is one of the most common ways to measure estimated effect size. The measurement estimated effect size was used if the data were normally distributed (SPADI and VAS_p). Standardized mean difference is as follows: VAS_p T0 Group A 0.87, VAS_p T1 Group A 1,52, VAS_p T2 Group A 0,79, VAS_p T0 Group B 0.81, VAS_p T1 Group B 0.86, VAS_p T2 Group B 0,37, SPADI T0 Group A 1,61, VSPADI T1 Group A 1,65, SPADI T2 Group A 0,65, SPADI T0 Group B 1.82, SPADI T1 Group B 1.62, SPADI T2 Group B 0,33.

DISCUSSION

The findings of our study showed a statistically significant decrease in pain and an improvement of the shoulder functionality with both therapeutic methods. MLS® laser group demonstrated to be superior in reducing palpatory pain according to VAS scale and percentage of disability according to SPADI, and showed similar improvement in ROM compared to the combined microwave diathermy and interference current group.

Our results are in accordance with Eslamian et al 2012 (32) where a LLLT at 830nm was applied with similar dosage (4J/cm^2) and combined with conventional physiotherapy demonstrating superiority over routine physiotherapy from the view of decreasing pain and improving the patient's function, but no additional advantages were detected in increasing shoulder joint range of motion in comparison to other physical agents.

A recent systematic review including 11 studies and involving 486 participants (33), report that the results of using LLLT to improve pain and function in shoulder tendinopathies are controversial. Only 45% of the 11 studies included showed a statistically significant decrease in pain; and only 1 of the 6 studies that assessed functional outcomes observed a statistically significant improvement. However, the results obtained in our study with the application of MLS® Laser Therapy seem to strengthen the evidence in favor of laser therapy in improving function and ROM as well as pain. This could depend on the characteristics of the laser emission and the setting dose applied in our study.

This hypothesis seems to be confirmed by another systematic review with meta-analysis based on 17 randomized controlled trials (RCTs) focused on LLLT treatment effects in shoulder tendinopathy (34). This review underlined that trials performed with inadequate laser doses were ineffective across all outcome measures. The same review confirms that adequate laser doses (according to WALT guidelines) can offer clinically relevant pain relief both alone and in combination with physiotherapy interventions, while secondary outcome measures of shoulder function were only significantly in favor of LLLT when used as monotherapy.

On the other hand, the strong biological effects of the MLS®: anti-inflammatory, anti – oedema and analgesic, have been explained at a cellular level by Monici and team in a proteomic study published in 2013.(35) It was conducted on muscle cells (myoblasts) and has proven that MLS® treatment induces an in-

crease of anti-inflammatory protein NLRP 10. That protein inhibits the activity of caspase-1 and the protein complex PYCARD, which promotes the maturation of the inflammatory cytokines interleukin-1 β (IL-1β) and interleukin 18 (IL-18). Therefore, in turn, NLPR 10 inhibits the production of pro-inflammatory interleukins IL-1β and IL-18, reducing inflammation.

These evidences support our findings that MLS® Laser Therapy, used as monotherapy, is an effective tool for reducing pain and improving overall function.

Previous investigations on the effect of MLS® lasers have shown the possibility to influence immediately the disease pathogenesis and to be applied in any phase of the disease stage. This suggests an early use of the MLS® Laser Therapy as primary option in comparison with conventional physical therapy. The latter is associated with higher therapeutical risks, especially when applied in the early stage of the disease. Investigations on the effects of MLS® Laser Therapy applied with different settings (frequency, power, dosage) on this disease, as well as the comparison of MLS® laser with other common physical factors, could be of further interest. According to our clinical practice, including the research work, all the tender / trigger palpation points could be eliminated in up to 3 sessions which is an excellent demonstration of the analgesic effect of the MLS®. The effect manifests within seconds of treatment and even if a recurrence of the tender / trigger point is sometimes observed, if treated for a second time it is permanently resolved.

With the exception of patients contraindicated or at risk for treatment with laser therapy or with microwave diathermy and interferential current, with due precautions the potential side effects and harms to study participants are minimal. Unintended effects in each group such as exacerbation of existing pain symptoms, headache and dizziness may occur, and they are a manifestation of individual intolerance to the microwave diathermy. [36] During the course of the study, no severe adverse events have been observed in both groups. Regardless of the initial pain intensity and ROM limitation, both treatment protocols resulted well tolerated by the patients.

Despite the current scientific research publications [13, 18, 37-40], further researches on the MLS® Laser Therapy in glenohumeral joint peritendinitis patients are desirable.

A limit of the current study is that it is not blinded and further studies comparing sham and real MLS® Laser Therapy could better prove the therapeutic effects of laser treatment. Another limitation is the 45 days follow–up as in the clinical practice the glenohumeral peritendinitis is known as a disease with high recurrence percentage. A three or even six months follow – up will provide a better reference to that matter.

CONCLUSIONS

Our clinical experience supports the conclusion that both therapeutic methods used - MLS® laser treatment and combined physical complex of microwave diathermy and interferential current - are suitable as a common protocol for routine clinical practice in the patients with glenohumeral joint peritendinitis. Both treatments have shown to improve the joint movement and to reduce the pain, and in both groups no adverse events happened during the course of the study. In particular, one half of the registered clinical parameters presented a statistically significant difference of the mean values in favour of the treatment method used in laser therapy group (A). The application of the MLS® Laser Therapy treatment enabled a successful and long-lasting influence on these patients. The applicability of the method depends on the personnel training and the availability of an MLS® laser device. This modern monotherapy option needs to be further evaluated but it can be considered a valid alternative to any other combined double or triple physical therapies.

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NOTES

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Authors' contributions. - All authors contributed equally to the manuscript and have read and approved the final version of the manuscript.

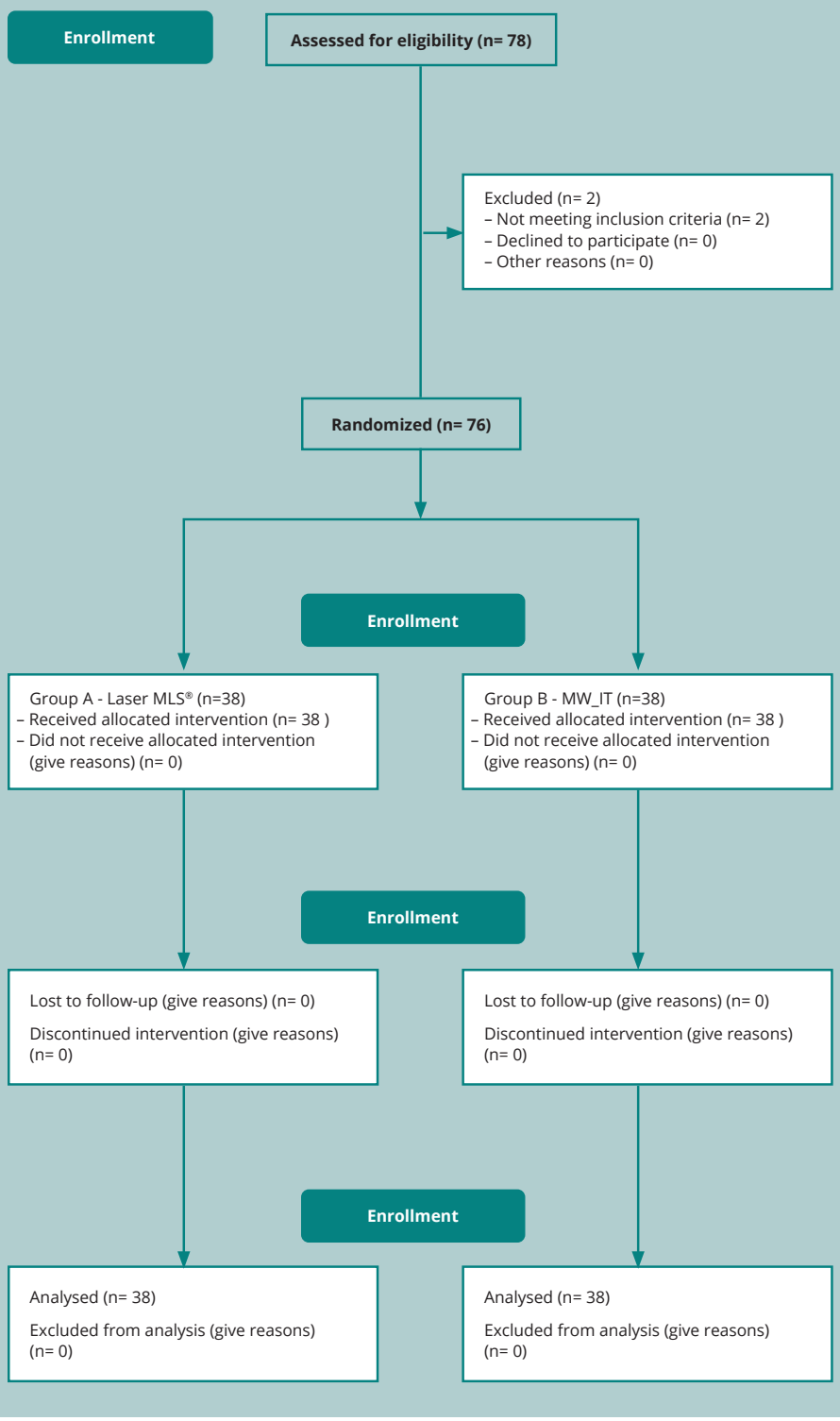
APPLICATION MODE	Frequency (Hz)	Intensity (%)	Mean Power (W)	Total Area (cm^2)	Time (min)	Energy (J)	Energy Dose (J/cm^2)
Scanning - Robotized multi-diode head	700	50	~1	186	8	480	2,57
Point-by-Point Manual handpiece	700	50	0,3	21,98	8	144	6,56

Table I. MLS® therapy protocol used.

VARIABLE		Group A - Laser MLS® (n=38)	Group B - MW_IT (n=38)	*p-Value*
Age (yrs)		48 ± 8.10	43.5 ± 11.55	NS
Male		19 (53)	21 (58)	NS
Shoulder-Side: Right		22 (61)	24 (66)	NS
Anglemetry of Humeral Joint (°)				
	Flexion	30 ± 26.6	26.5 ± 22.6	NS
	Abduction	38.7 ± 33.2	26.3 ± 18.7	NS
	External Rotation	39.7 ± 28.0	28.7 ± 26.4	NS
Pain - Visual Analogue Scale (mm)				
	VAS_spontaneous	2.8 ± 3.0	3.4 ± 2.6	NS
	VAS_palpatory	4.5 ± 1.8	5.1 ± 2.2	NS
	SPADI (%)	49.2 ± 20.8	65.5 ± 21.5	NS
				Values are mean ± standard deviation (SD) or n (%)

Table II. Demographic, physical and pain variables at Baseline.

Figure 1.1. CONSORT flow diagram



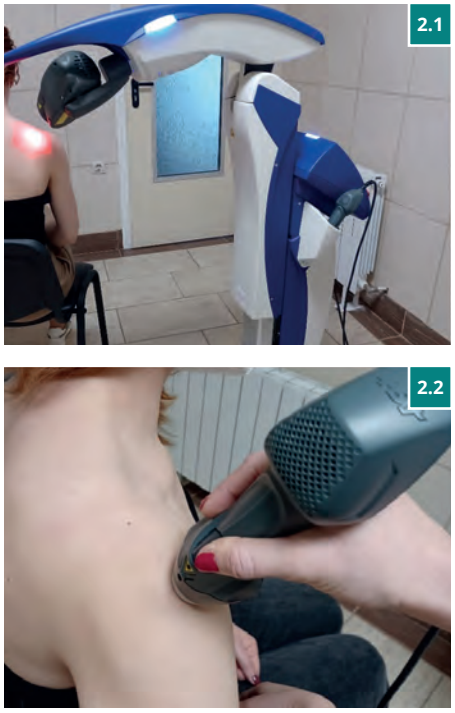


Figure 2. - Group A - MLS® M6 laser therapy application treatment: (2.1) robotized scanning mode, (2.2) manual point-by-point headpiece mode.

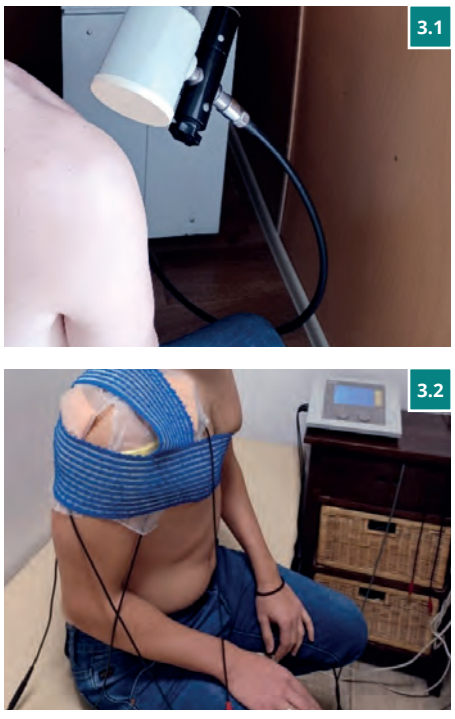


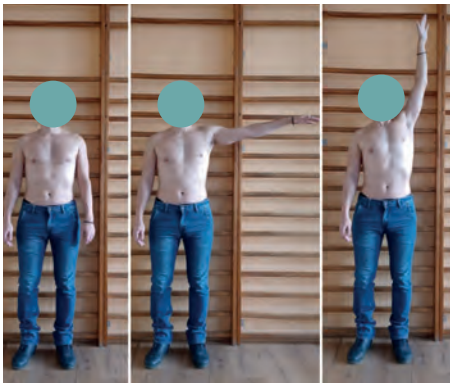
Figure 3. - Group B – combination of microwave electromagnetic field (3.1) and interference currents (3.2).

VARIABLES	Group A – Laser MLS® Mean (SD) ; Min-Max	*p-Value* T1-T0 / T2-T1 / T2-T0	Group B - MW_IT Mean (SD) ; Min-Max	*p-Value* T1-T0 / T2-T1 / T2-T0
Flexion (°)				
T0	30 (27) ; 0-100	0,000	26.5 (22) ; 0-90	0,000
T1	9.3 (22) ; 0-90	0,003	8.7 (13) ; 0-70	**0,658**
T2	5.92 (17) ; 0-70	0,000	8.3 (13) ; 0-70	0,000
Abduction (°)				
T0	38.7 (33) ; 10-150	0,000	26.3 (19) ; 10-100	0,000
T1	12.6 (25) ; 0-110	0,007	8.2 (12) ; 0-60	**0,285**
T2	7.8 (19) ; 0-80	0,000	7.1 (13) ; 0-60	0,000
External Rotation (°)				
T0	39.7 (28) ; 0-90	0,000	28.7 (26) ; 0-90	0,000
T1	12.8 (22) ; 0-80	0,020	11.3 (20) ; 0-75	**0,166**
T2	8.8 (18) ; 0-60	0,000	7.1 (13) ; 0-60	0,000
VAS_spontaneous (cm)				
T0	2.8 (3) ; 0-10	0,000	3.4 (3) ; 0-10	0,000
T1	0.61 (2) ; 0-8	**0,058**	1.1 (1) ; 0-6	0,002
T2	0.26 (1) ; 0-5	0,000	0.7 (1) ; 0-5	0,000
VAS_palpatory (cm)				
T0	4.5 (2) ; 0-7	0,000	5.1 (2) ; 0-10	0,000
T1	2.2 (2) ; 0-10	0,000	3.7 (2) ; 0-7	0,014
T2	1.1 (1) ; 0-5	0,000	3.2 (2) ; 0-7	0,000
SPADI (%)				
T0	49.2 (21) ; 12-94	0,000	65.5 (22) ; 11-99	0,000
T1	23.5 (21) ; 1-78	0,000	35.9 (19) ; 3-69	0,000
T2	17.6 (18) ; 0-70	0,000	31.4 (21) ; 0-70	**0,050**

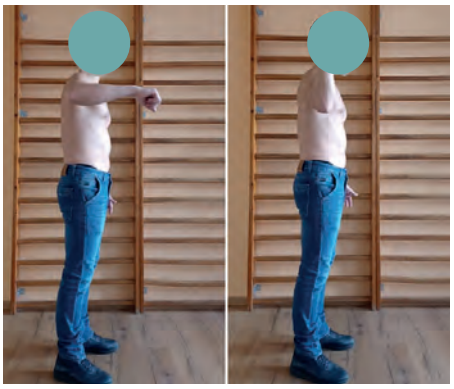
Table III. Intra-group statistical analysis of the assessment indicators used in both groups at Baseline (T0), at the end of the treatment cycle (T1) and at the follow-up visit, 45 days since the beginning of the treatment (T2).

VARIABLE	Group A – Laser MLS® Mean (SD)	Group B - MW_IT Mean (SD)	*p-Value*
Flexion (°)			
T1	9.3 (22) ; 0-90	8.7 (13) ; 0-70	**0,658**
T2	5.92 (17) ; 0-70	8.3 (13) ; 0-70	0,000
Abduction (°)			
T1	12.6 (25) ; 0-110	8.2 (12) ; 0-60	**0,285**
T2	7.8 (19) ; 0-80	7.1 (13) ; 0-60	0,000
External Rotation (°)			
T1	12.8 (22) ; 0-80	11.3 (20) ; 0-75	**0,166**
T2	8.8 (18) ; 0-60	7.1 (13) ; 0-60	0,000
VAS_spontaneous (cm)			
T1	0.61 (2) ; 0-8	1.1 (1) ; 0-6	0,002
T2	0.26 (1) ; 0-5	0.7 (1) ; 0-5	0,000
VAS_palpatory (cm)			
T1	2.2 (2) ; 0-10	3.7 (2) ; 0-7	0,014
T2	1.1 (1) ; 0-5	3.2 (2) ; 0-7	0,000
SPADI (%)			
T1	23.5 (21) ; 1-78	35.9 (19) ; 3-69	0,000
T2	17.6 (18) ; 0-70	31.4 (21) ; 0-70	**0,050**

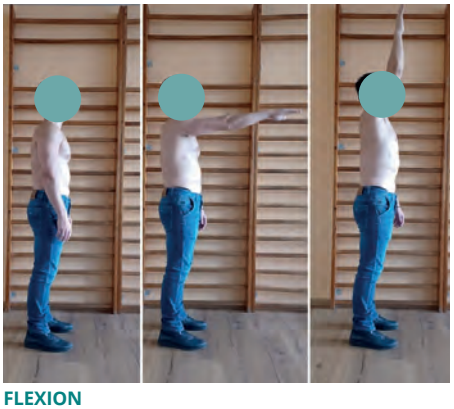
Table IV. Inter-group statistical analysis of the assessment indicators used in both groups at Baseline, at the end of the treatment and at the follow-up visit, 45 days since the treatment start



ABDUCTION



INTERNAL ROTATION



FLEXION

Figure 4. - Evaluation of Aglemetry of humeral joint flexion, abduction and external rotation.

Figure 5.

Mean values with 95% confidence interval (CI) of the clinical parameters evaluated at Baseline, in correspondence of the last treatment (T1) and after 45 days since the first treatment (T2) - difference from the normal of the glenohumeral Flexion, Abduction and External Rotation - assessment of spontaneous and palpatory pain according to the visual analog scale (VAS_s, VAS_p) and of functional status and pain through the Shoulder Pain and Disability Index (SPADI).

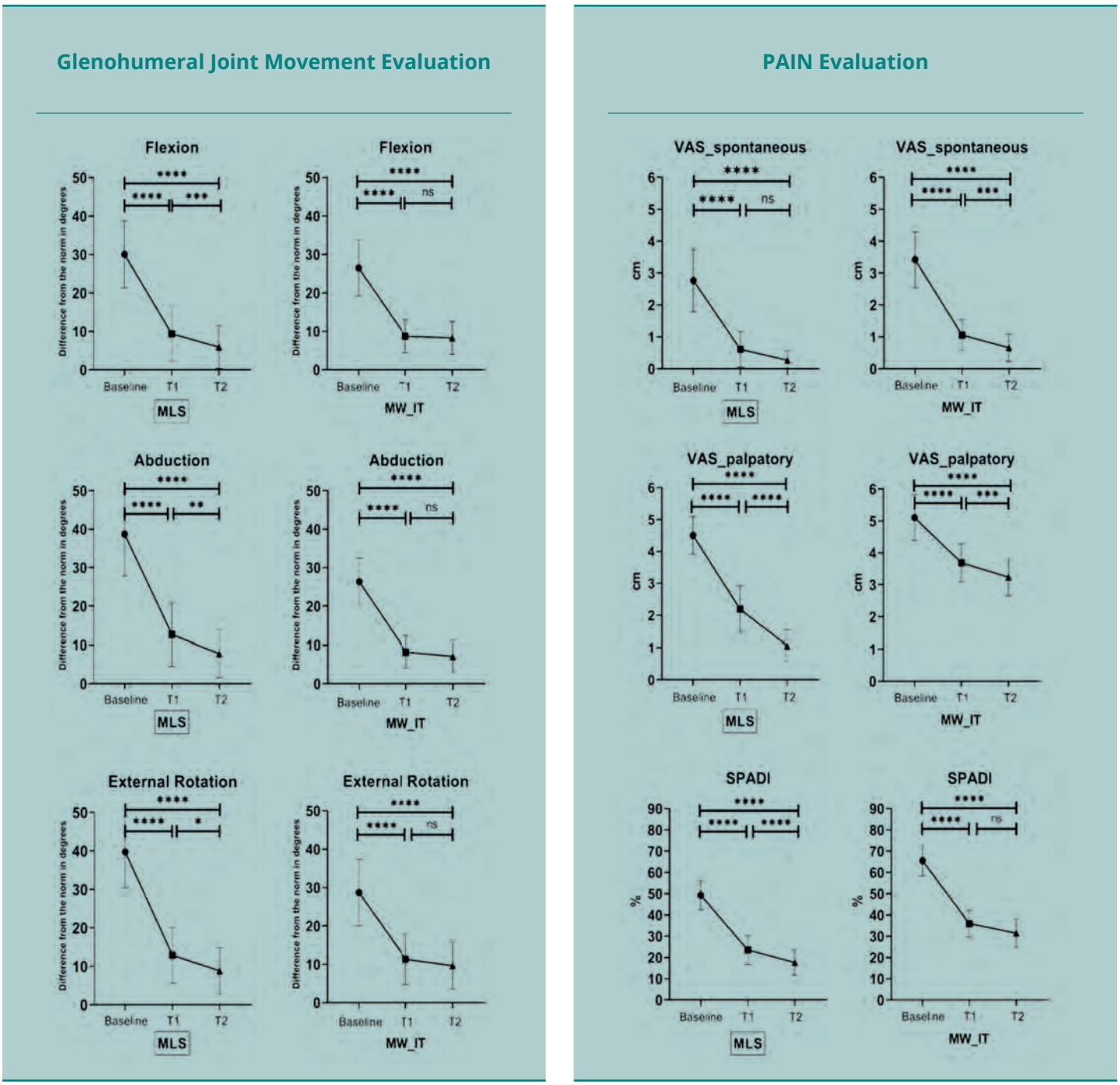
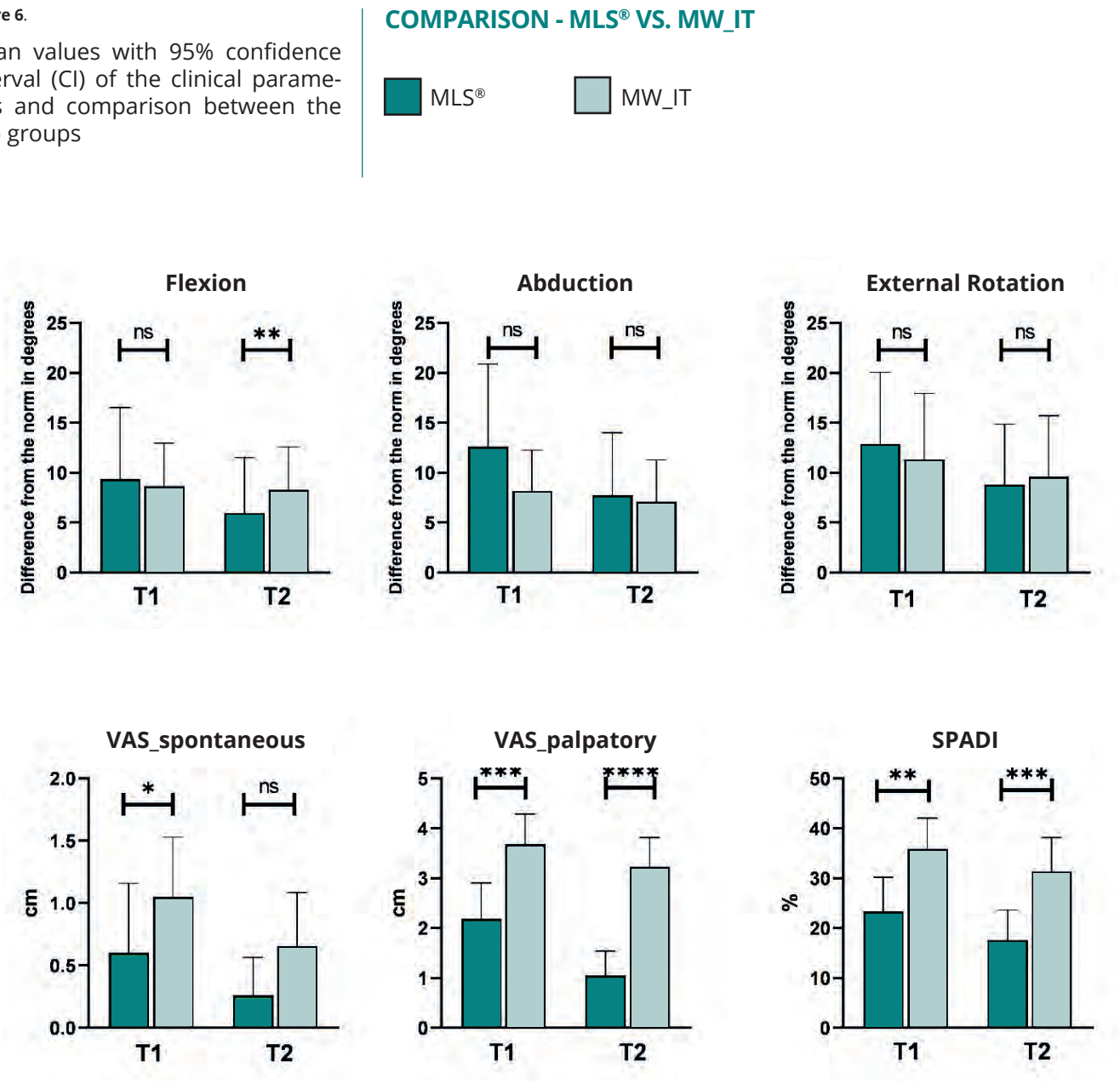


Figure 6.

Mean values with 95% confidence interval (CI) of the clinical parameters and comparison between the two groups



NOTES

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Authors' contributions. - All authors contributed equally to the manuscript and have read and approved the final version of the manuscript.

Integrated new therapy to usual care in management of not healing wounds and post-surgical ulcers.

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INTRODUCTION

Managing foot ulcers in diabetes pose significant challenges and financial burdens on healthcare systems, and impact morbidity, mortality, and quality of life.

In light of this, wound management principles such as debridement and wound bed preparation, alongside novel technologies, designed to alter wound physiology for facilitating healing, are essential when attempting to heal a chronic diabetic foot ulcer. [1-2]

If Standard Care remains a target of our actions, novel methods and therapies may improve outcomes.

Particular attention should be given to post-surgical lesions that do not heal in the first instance.

Advanced medications, skin grafting (autologous, engineered or from a cadaveric donor), and physical therapies are available to enhance tissue regeneration, each with its own mechanisms. At the San Jacopo Hospital DF UNIT in Pistoia (Italy), we use the following integrated protocol to improve wound healing in various conditions:

- Surgical treatment (debridement, minor amputations, evacuation of abscesses)
- Standard treatment of infections (antibiotic therapy, antiseptics)
- Vascular access (diagnosis and possibly revascularization) to improve blood flow.

Finally, we are trying to improve outcomes with some new approaches such as Vacuum Assisted Closure Therapy (VAC) and physical therapies.

Among physical therapies for treating of diabetic foot ulcers, laser therapy has demonstrated potential and promising outcomes. [3-6]

The Multiwave Locked System (MLS®) Laser Therapy is well known for its capacity to allow analgesic, antiinflammatory, anti-oedema and tissue repair effects in superficial and deep tissues through cellular and molecular mechanisms demonstrated in studies conducted with in vitro and animal models. [7, 8, 9]

Based on the literature concerning the mechanisms of action of MLS® technology and its specific features, we have ascertained its appropriateness, for addressing patient issues, within our department.

MATERIALS AND METHODS

We have collected three different clinical cases in which MLS® Laser Therapy applied by a M8 device (ASA Srl, Italy) was used as an adjuvant treatment to our integrated protocols for improving wound healing in the treatment of foot ulcers in diabetic patients.

The MLS® - M8 Laser is a class IV laser therapy system that allows the emission of near-infrared (NIR) beams with wavelengths of 808 nm - 905 nm, spatially overlapped and synchronized, with continuous (or frequenced) and pulsed emission respectively, average power of 3.5W and a peak power of 75W.

The device is designed with a robotic head that allows automatic scanning of the anatomical area to be treated with homogenous energy delivery over a target area from 20 cm^2 to 900 cm^2.

During each session, two distinct laser treatments were administered covering an area of 20 cm^2.

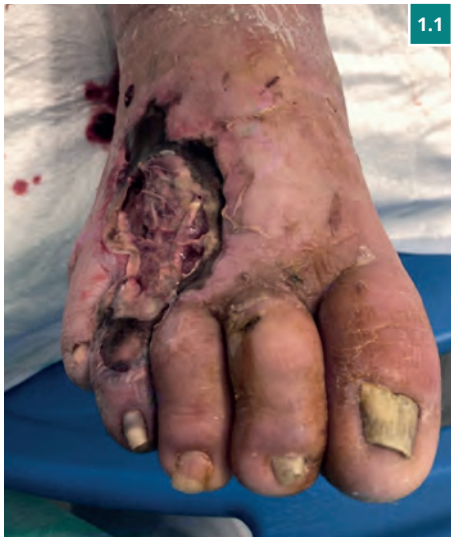
The first treatment aimed to induce an anti-edema effect through modulation of inflammation and improvement of endothelial function, whereas the second treatment was designed to have a biostimulating effect to modulate the tissue healing. Please refer to the following table for the specific parameters utilized.

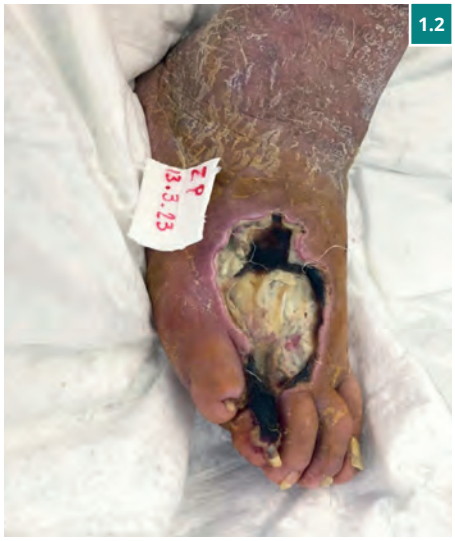
Treatments	Modulation	Frequency (Hz)	Intensity (%)	Dose (J/cm²)	Treatment time (min:sec)
1	FPW*	2000	100	10	01:33
2	FPW*	1500	100	2	00:20

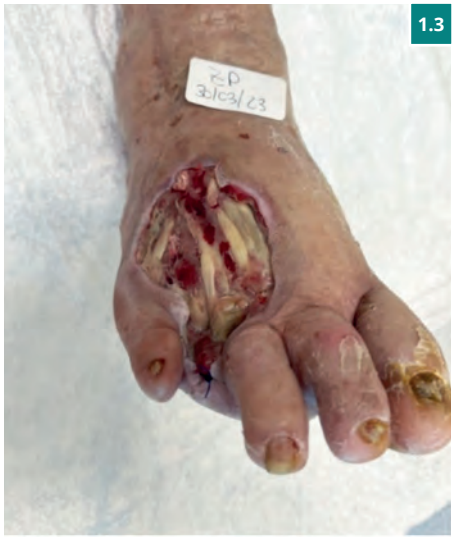
(*) FPW – Frequenced Wave: the 808 nm wavelength is emitted in a frequenced modality, combined, and synchronized with the 905 nm wavelength emitted in a pulsed modality.

CASE REPORT 1

In March 2023, a 62-year-old male patient with newly diagnosed type 2 diabetes (HbA1c 12.8%, bad metabolic control) and peripheral vascular disease came to our clinic. Upon examination, a foot abscess accompanied by critical limb ischaemia was diagnosed (Figure 1.1 and 1.2). Treatment started with abscess evacuation, and two days later, right leg femoral and anterior tibial artery angioplasty was performed. The post-operative lesion on the outer surface of the right foot was still present after two weeks and showed slow healing and slow tissue regeneration (refer to Figure 1.3). After two weeks, the patient started to receive MLS® Laser Therapy twice a week to facilitate the formation of an optimal lesion bed for a subsequent scheduled skin graft from a cadaver donor. (Refer to Figure 1.4, 1.5). Following skin grafting procedure (Figure 1.6), in addition







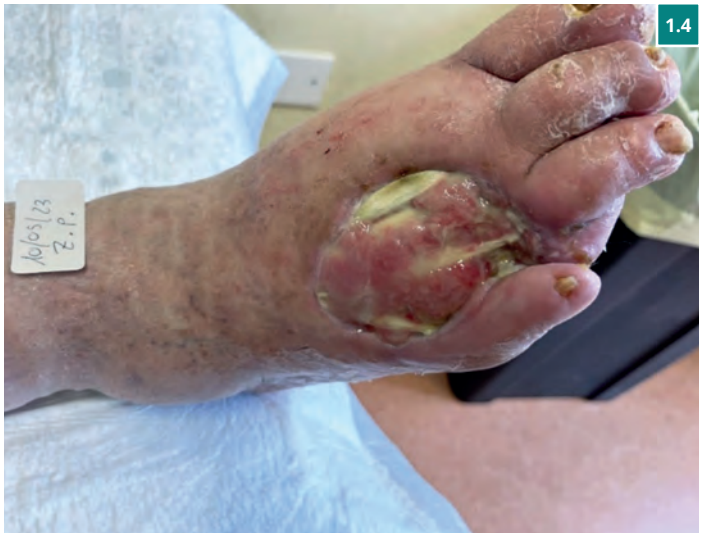


Figure 1.1, 1.2, 1.3: Evolution of the lesion during the hospitalisation; after more than 3 weeks, the wound showed a slow evolution in terms of tissue regeneration.

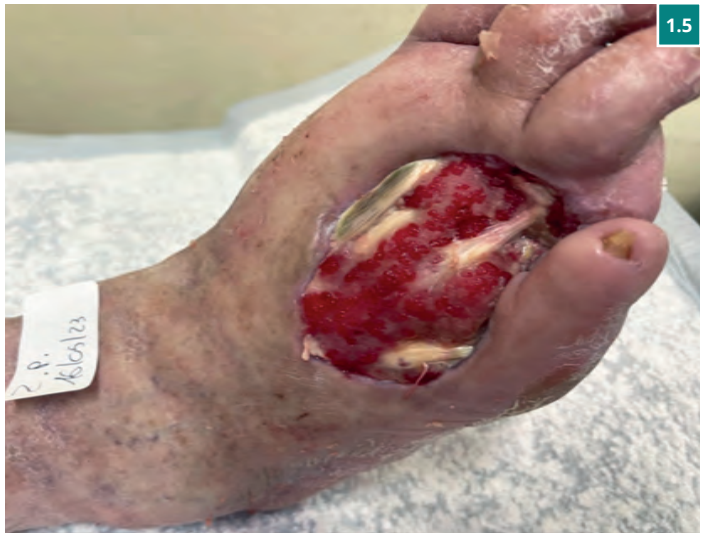
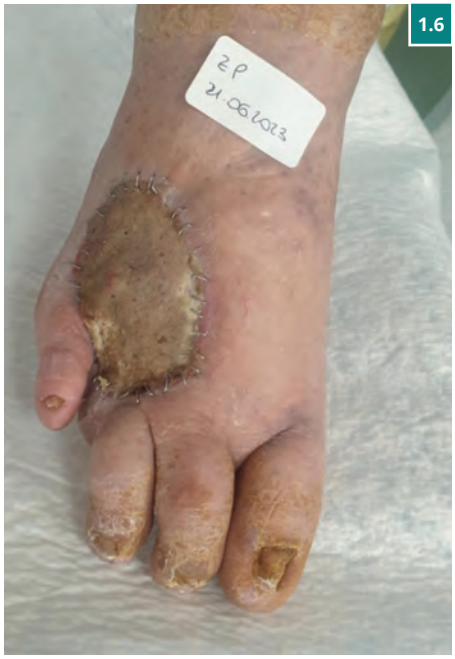


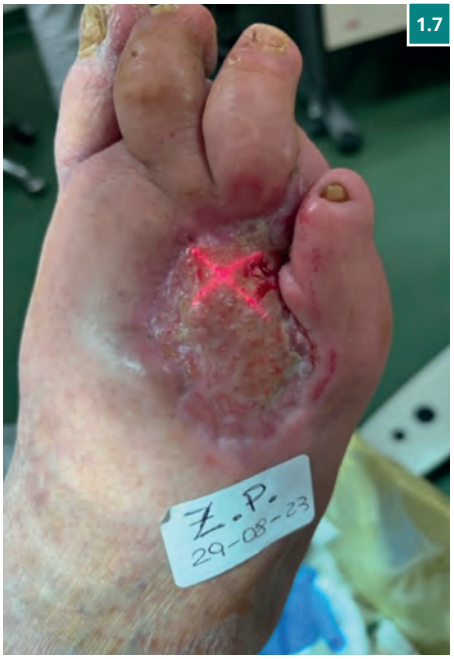
Figure 1.4, 1.5: Wound evolution during laser therapy for lesion bed preparation prior to skin grafting procedure.

to standard wound care laser therapy was continued . At each session the two specific treatment protocols previously described were applied to the lesion area to stimulate edema resorption and healing mechanisms. The treatments were performed with a fixed pointer and with doses of 10 and 2 J/cm^2, respectively.

After sixty-nine days from the skin grafting procedure and eighteen laser sessions, the treatment results were very satisfactory, the post-operative lesion was in an excellent state of development and showed clear re-epithelialisation signs.

(Figure 1.7)

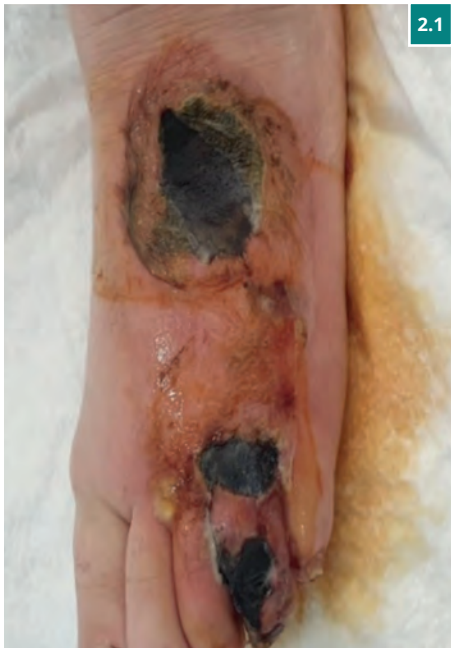


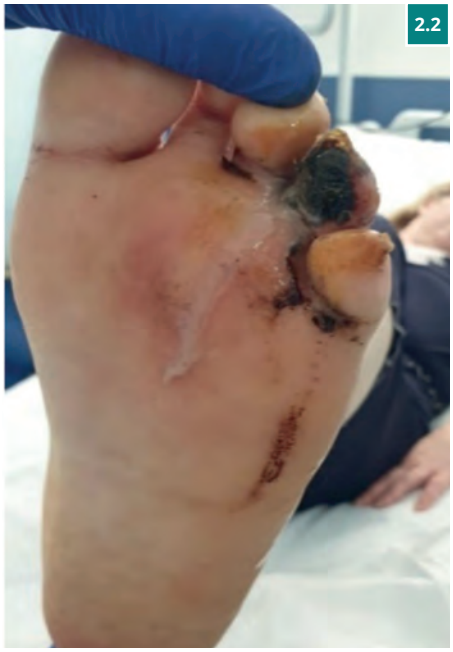


Figures 1.6, 1.7: Lesion after skin grafting and at the end of the evaluation.

CASE REPORT 2

On March 15th, 2023, a 48-year-old female patient , had access to emergency department (ED) for wet gangrene of the left foot and glycemic decompensation in newly diagnosed diabetes mellitus (HbA1c 15.5% and no other chronic complication of diabetes) (see Figures 2.1, 2.2). We performed excarectomy, evacuation of a dorsal abscess and initial forefoot plantar fasciitis and IV toe amputation. The patient underwent intravenous antibiotic therapy and local antiseptic dressings. Following reduction of clinical signs of infection, the negative wound pressure therapy (NWPT) was applied. (Figure 2.3)





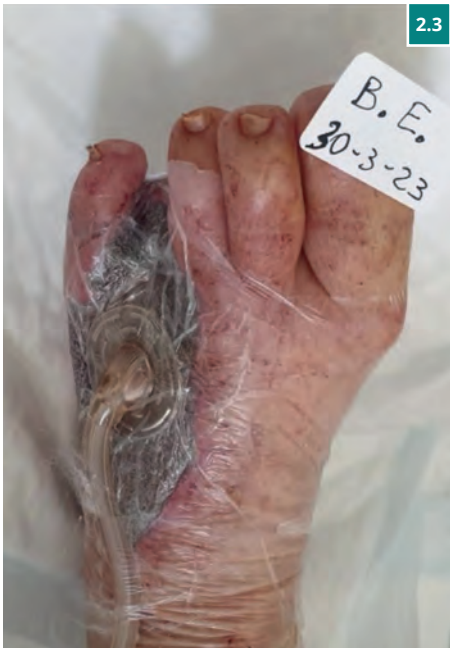


Figure 2.1,2.2, 2.3:
Left and central photos show the left foot gangrene at ED. Right photo shows the NWPT: a specific dressing was placed over the wound and connected to a vacuum pump. The negative pressure removes the excess exudate, increases blood flow, and promotes the growth of healthy tissue.

Every 4 days, for three weeks, the patient underwent MLS® Laser Therapy, dressing change and NPWT re-application, to prepare the lesion bed for skin grafting. At each session specific treatment protocols were applied to the lesion area to stimulate edema resorption and healing mechanisms. The treatments were performed with a fixed pointer and with doses of 10 and 2 J/cm^2, respectively. There were increasing signs of wound bed granulation as treatment progressed. (Figure 2.4 & 2.5)

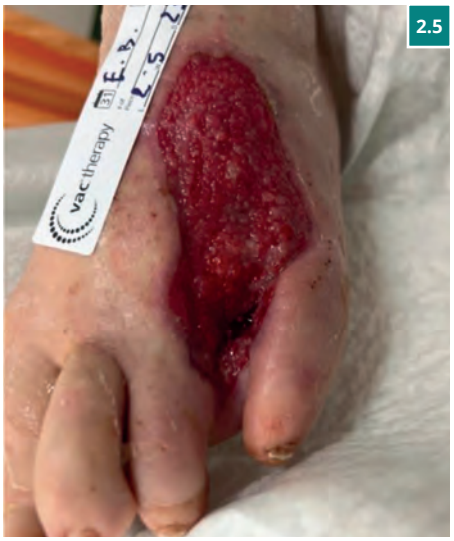
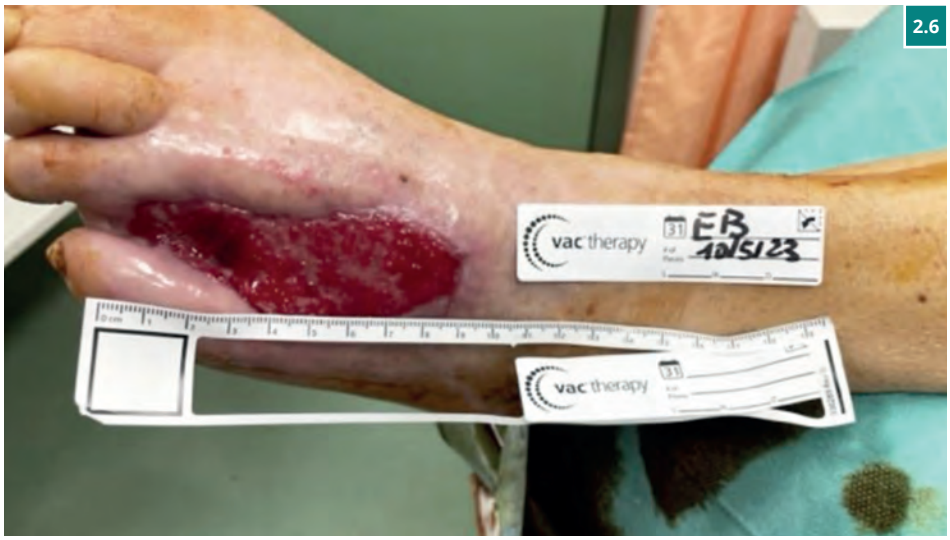


Figure 2.4, 2.5: Lesion bed preparation with MLS® Laser Therapy.



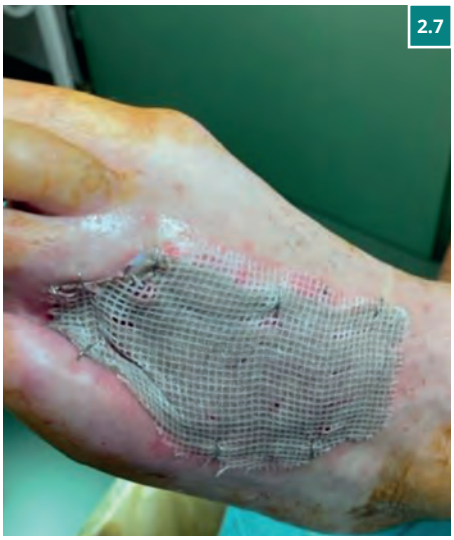


Figure 2.6, 2.7: lesion condition before and immediately after skin grafting, wound area (~8cm x 2cm).

After forty days from the beginning of NWPT therapy and eleven MLS® laser sessions, the patient underwent to skin grafting from cadaveric donor. (Figures 2.6, 2.7)

Subsequently, every four days during dressing change, the area of the lesion and the surrounding tissue were treated with MLS® Laser Therapy using the protocols described above.

As the patient received laser therapy alongside standard treatments, objective improvements were recorded. These included a notable and progressive acceleration of wound healing and clear signs of re-epithelialisation. (Figure 2.8, 2.9).

The efficacy of the therapy is based on its ability to improve the condition of the wound prior to tissue transplantation and to accelerate the healing process.

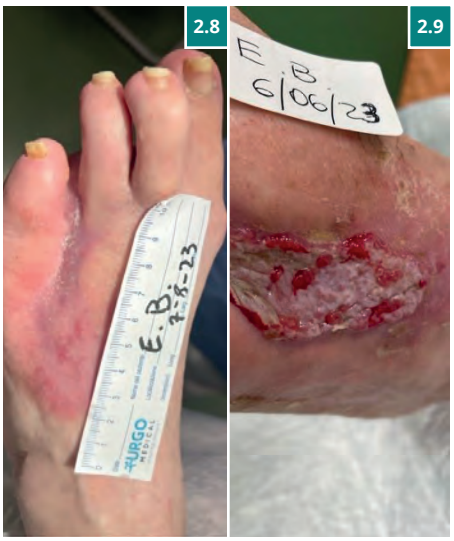


Figure 2.8, 2.9:
The images show the post-operative lesion during the laser therapy and at the final evaluation - complete healing of the wound.

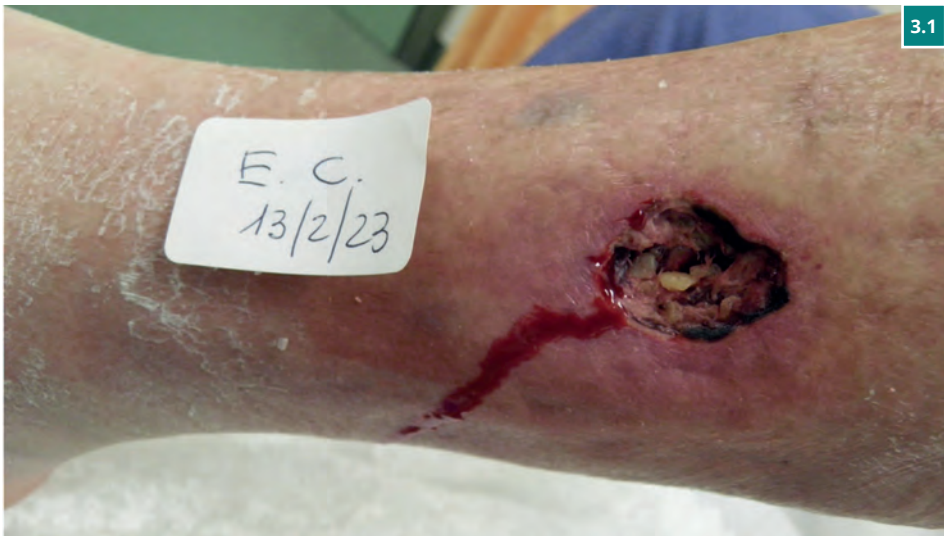
CASE REPORT 3

In February 2023, a 77-year-old male with type 2 diabetes (diabetes duration 37 years), peripheral vascular disease, chronic kidney disease and laser treated retinopathy, came to our clinic. After experiencing a blunt trauma to the middle third of his left lower limb, a lesion emerged and quickly progressed into an abscess with an intramuscular fistulous tract. The patient underwent evacuation of the purulent material and toilet of the lesion while receiving antibiotic therapy. Following this, in addition to standard wound care, a session of MLS® Laser Therapy, with the two specific protocols previously described, was administered every 3 days for a total of 10 sessions.

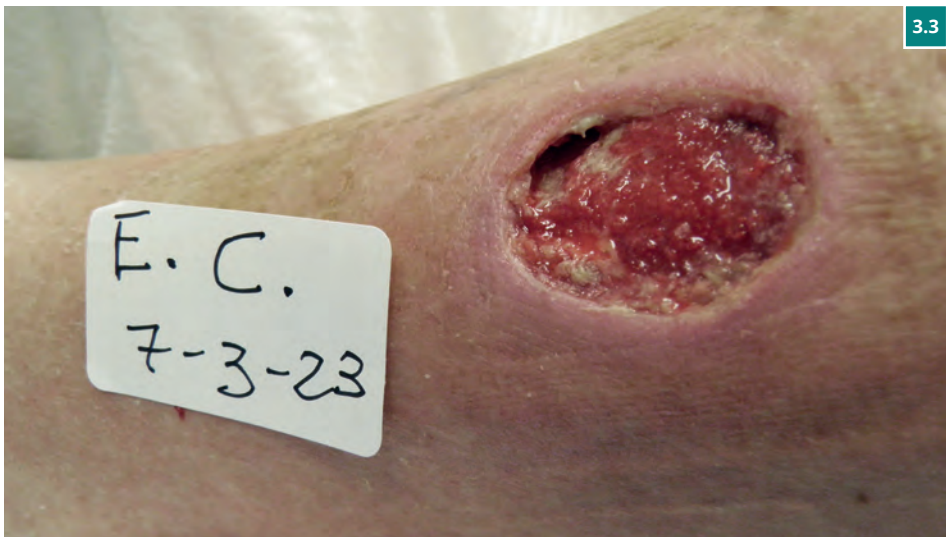
In the meantime, the patient underwent concurrent angioplasty for the superficial femoral artery and peroneal trunk in the left lower limb.

The progression of the lesion from initial examination to final assessment is shown in the images below. (Figures 3.1-3.5; Table 1). A rapid closure and re-epithelialization of the lesion was noted.

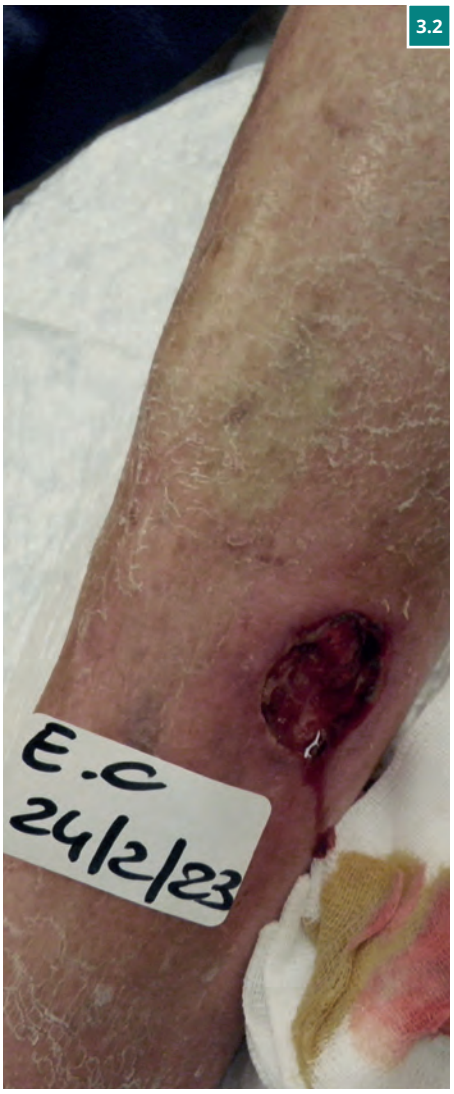
DATE	DAYS	Lesion Area (cm^2)	Lesion Depth (cm)	Lesion Volume (cm^3)	Area Reduction since Baseline (%)	Volume Reduction since Baseline (%)
13 Feb 2023	0	20 (5cmx4cm)	1.5	30	-	-
24 Feb 2023	11	16 (4cmx4cm)	0.5	8	20 %	73 %
07 Mar 2023	22	12 (4cmx3cm)	0.2	2.4	40 %	92 %
20 Jul 2023	157	0	0	0	100 %	100 %



3.1



3.3



3.2

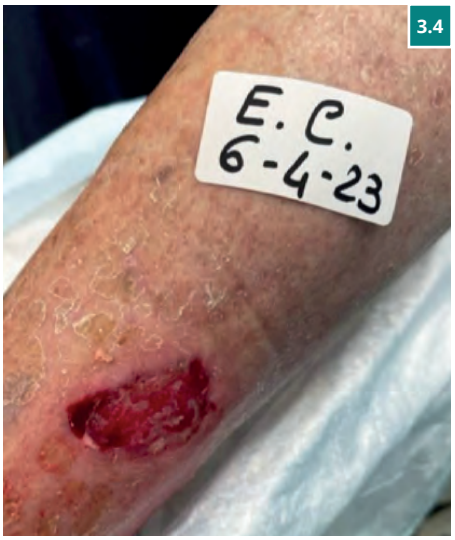
DISCUSSION AND CONCLUSIONS

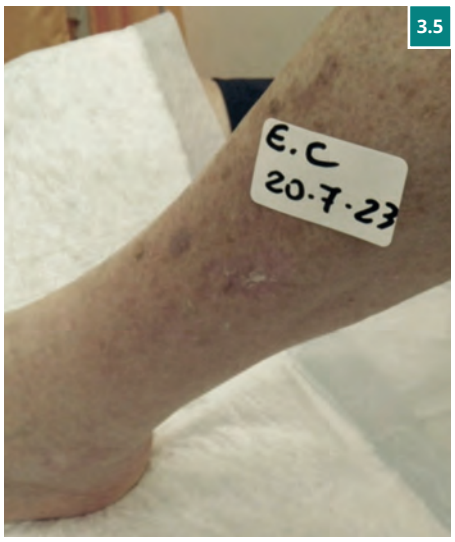
Based on our clinical experience, the integration of guidelines based standard wound with innovative therapeutic methods like MLS® Laser Therapy has demonstrated remarkable efficacy in enhancing and accelerating the wound healing process. Specifically, its role in achieving an ideal wound bed for cadaveric tissue transplantation has been noteworthy.

Notably, in the aforementioned cases, the expected healing time was significantly reduced. These outcomes are in agreement with the results of *in vitro* studies aimed at investigating the mechanisms underlying the therapeutic effects of the MLS® laser source.

These studies demonstrated that MLS® emission is capable of promoting neoangiogenesis, improving cell energy metabolism, modulating inflammation and, consequently, regulating fibroblast activation [9, 10]. The therapy offers additional benefits because of its easy-to-use application and reduced treatment time compared to traditional methods. The findings here presented show the potential of this therapy and establish a sound basis for future research.

Figures 3.1, 3.2, 3.3, 3.4, 3.5:
Progressive healing of the ulcer.





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High Intensity Laser Therapy (HILT) versus Extracorporeal Shockwave Therapy (ESWT) in the treatment of noncalcifying tendinopathies of the rotator cuff: a retrospective study.

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ABSTRACT

Instrumental physical therapies are extensively used in clinical practice to manage tendinopathies. However, there is still a lack of scientific evidence to support their efficacy.

This retrospective study evaluated the short- and long-term effectiveness of High Intensity Laser Therapy (HILT) and Extracorporeal Shockwave Therapy (ESWT) in treating non-calcific rotator cuff tendinopathy.

The study included twenty patients divided into two groups. Group A (n=10) treated daily with HILT for one week, whereas Group B (n=10) received ESWT once a week for four weeks. The principal outcome of the study was the degree of pain reduction using the numeric rating scale (NRS). Moreover, mobility, shoulder strength, and functional improvement were assessed via the Constant-Murley questionnaire and the Disability of the Arm, Shoulder and Hand (DASH) questionnaire.

The results of the study indicated noteworthy improvements in the Constant-Murley scale scores, DASH questionnaire and NRS scores after both HILT and ESWT treatment. However, the outcomes of HILT laser therapy were found significant at first follow-up and the effects remained almost consistent over the three-month follow-up period. On the other hand, ESWT resulted in more gradual clinical improvement over time, with significant outcomes visible at three months.

In conclusion, HILT and ESWT have been demonstrated to be effective therapies for patients with non-calcific rotator cuff tendinopathy. However, HILT laser therapy resulted in more rapid clinical improvement.

INTRODUCTION

Shoulder pain is the third most common cause of musculoskeletal disorder resulting in pain and functional limitation of the upper limb (1). Among the various causes, the rotator cuff tendinopathy is the most common (65%) and the incidence ranges from 5% to 40% (2). This wide range is due to the initial asymptomatic phase in which the structural alterations of the tendon matrix are clinically silent (3-5). Cuff tendinopathy predominantly affects people over 50 years of age, although it is also frequent in overhead athletes, such as volleyball, water polo, basketball, baseball, tennis (6-7), and workers who overload the shoulders with repetitive movements (8), maintaining incorrect postures for prolonged periods or subjected to vibrations (9-11). The most affected structure is the tendon of the supraspinatus muscle (80%), followed by infraspinatus (15%) and subscapularis (5%). The etiology of rotator cuff tendinopathy is multifactorial, and the responsible factors can be either intrinsic or extrinsic (12-13). Intrinsic factors include age, gender, biomechanical abnormalities, joint laxity, reduced muscle strength and elasticity, metabolic diseases (obesity, diabetes, hyperlipidemia), cardiovascular diseases, and rheumatic diseases; the extrinsic factors include the intake of tenotoxic drugs such as ciprofloxacin, steroids, statins, and oral contraceptives. Histologically, rotator cuff tendinopathy is characterized by the appearance of a degeneration of collagen fibers, reduction of the content of Type I collagen with increase of the content of Type III (reparative), considerable variability in cell density, increased extra-cellular matrix without clear signs of inflammation (14). Clinically it manifests with increasing pain in the anterior and lateral region of the shoulder and functional limitation (loss of strength and movement); in

severe cases, the execution of normal activities of daily living is compromised (15). Treatment is essentially conservative and involves rest/modification of activities (how to avoid performing overhead movements), non-steroidal anti-inflammatory drugs, personalized rehabilitation plan, injections, and the use of physical therapies. The surgical referral is indicated only after six months of conservative treatment or in cases in which shoulder function worsens during appropriate nonsurgical treatment.

Instrumental physical therapies are widely exploited in clinical practice for the management of tendinopathies; however, the scientific evidence in support of many of these treatments are often lacking. In this context, both Laser therapy and shock wave therapy have been shown to be a successful therapy in reducing the pain and improve joint function in patients with rotator cuff tendinopathy (16-21). In details, Laser therapy acts through various biological effects such as the photo-thermal effect, the photo-mechanical effect, and the photochemical effect. It is therefore able to reduce pain, inflammation, and edema, allowing for an earlier onset of tissue healing and earlier initiation of rehabilitation treatment. In particular, studies on the effect of low-level laser therapy – (LLLT) (16,17) or High intensity laser therapy - (HILT) (18-20) in patients with non-calcific tendinopathy of the rotator cuff, have demonstrated good efficacy and safety. Three randomized controlled trials of the effect of high-power laser therapy were conducted in noncalcifying tendinopathy of the rotator cuff. Elsodany et al. have shown that Nd:YAG laser therapy associated with therapeutic exercise is more long-term efficacy (3-month and 6-month follow-up) compared to therapeutic exercise alone in decreasing pain and in improving ROM and shoulder function in a sample of 60 patients affected by non-calcifying tendinopathy of the rotator cuff (18). Santamato et al. and Pekyavas et al. have instead demonstrated the greater effectiveness of HILT in the short term compared to other classic treatments of non-calcific tendinopathy of the rotator cuff (ultrasound therapy, kinesio-taping and exercise therapeutic) in reducing pain and in improving joint function and muscle strength (19, 20).

Moreover, extracorporeal shock wave therapy (ESWT) has been advanced as a possible alternative treatment in those patients with no results with traditional conservative management (22). It is believed that shockwave therapy alleviates pain due to insertional tendinopathy by the induction of neovascularization and improvement of blood supply to the tissue and initiating repairs of the chronically inflamed tissues by tissue regeneration. A shock wave is a non-linear type of 15-20 MHz frequency pressure wave with an around 10 μs rise time. These soundwaves define a positive and negative phase, producing at the tissue interface, the cavitation effect, namely the formation of bubbles and their subsequent implosion with the genesis of a second wave (23). The propagation wave, through direct mechanical perturbation polarizing membrane cells, increases the density of the tissue and, therefore radical production, cell proliferation and growth factors formation (24). It is an economic and noninvasive physical therapy with good clinical effects and had been proved to be beneficial in calcific tendinosis; however, the treatment efficacy in not calcific tendinosis of rotator cuff remains controversial (25). Thus, the aim of the study was to evaluate the short- and long-term efficacy of HILT and ESWT in the treatment of tendinopathy of the rotators cuff.

MATERIALS AND METHODS

The study has been conducted in 2019 at the U.O.C. "Orthopedic Rehabilitation" of the Padua Hospital.

Population

We included patients, aged between 18 and 80 years, with clinical and instrumental diagnosis (Ultrasounds or MRI) of non-calcific tendinopathy of the rotator cuff. Inclusion criteria: shoulder pain during overhead movements; symptoms for at least 3 months not responsive to NSAIDs and/or physiotherapy; pain on the insertion of the rotator cuff tendons and positivity to clinical tests for rotator cuff disease; reduced shoulder range of motion (ROM). Exclusion criteria: complete or partial rupture > 50% of the tendons of the rotator cuff diagnosed by ultrasound or MRI; presence of tendon calcifications on ultrasound evaluation; pregnancy or breastfeeding; cancer; acute rheumatic diseases; coagulation disorders; significant shoulder trauma in the last 6 months.

Study Design

A retrospective analysis evaluated patients treated with (HILT) Group A and (ESWT) Group B. Group A received a cycle of 4 laser sessions each day for a week; while the patients in the Group B received 4 ESWT sessions, once a week for 4 weeks. Each HILT session lasted approximately 15 minutes divided into an initial phase, an intermediate phase, and a final phase. The initial and final phases (fluence 810-1320 mJ/cm^2-frequency of 30-40 Hz-total energy of 3000 J) were performed

with a slow scanning mode (speed of about 10 cm every 2 seconds) using a standard handpiece with spacer, along the course of the rotator cuff, upper trapezius, deltoid, and pectoral muscles. In the intermediate phase (fluences 360-610 mJ/cm^2, frequency 15-17 Hz) the painful points (trigger and tender points) were treated with a fixed handpiece equipped with a spacer, perpendicular to the painful point for a duration of about 5-7 seconds. Both the operator and the patient wore specific laser light protection goggles. HILT was delivered using the Hiro 3 device, a Nd:YAG laser with a wavelength of 1064 nm and a pulsed emission that is part of the Hilterpia® (ASA S.r.l.)

ESWT sessions had an average duration of 15 minutes during which 1600 strokes were delivered at a frequency of 4 Hz. The energy applied was adjusted based on the patient's tolerance, however reaching a maximum level not exceeding 0.15 mJ /mm^2. The shock wave generator was MODULITH® SLK, (StorzMedical, MODULITH® SLK). After applying a transparent and odorless gel to the skin surface of interest, which facilitates the propagation of the waves to the biological tissues, the therapeutic head was positioned using ultrasound guidance to focus the shock wave beam precisely on the target area.

Clinical Outcomes

The principal outcome was the pain reduction through the numeric rating scale (NRS); moreover, we analyzed the Constant-Murley questionnaire and the Disability of the Arm, Shoulder, and Hand (DASH) questionnaire to evaluate mobility, shoulder strength and functional improvement.

The Constant-Murley evaluate the assessment of pain, strength, and joint function of the upper limb. This scale is constituted by four parameters: two subjective (pain and daily activities) and two objectives (active mobility and strength). The degree of pain reported by the patient is evaluated on a scale from 0 to 15; the ability to perform normal activities of daily living on a scale from 0 to 20; the articular excursion evaluates intra- and extra- rotation, anterior elevation, and abduction with a score ranging from 0 to 10, for a total of up to 40 points; finally, the strength of the shoulder is measured on a scale from 0 to 25. The measurement of strength consists in asking the patient to keep the arm in 90° abduction for 5 seconds with a weight ranging from 0.5 kg to 12.5 Kg. Every 0.5 kg corresponds to a point on the scale. The total score ranges from 0 to 100 and is given by the sum of the scores of the individual parameters. A higher score indicates a better patient functionality.

DASH investigates the difficulties that the patient encounters in carrying out the activities of daily living (ADL). It is questionnaire made of 30 questions each of which is assigned a score from 1 to 5. A higher score indicates a higher is the disability/ difficulty during daily activity.

For both groups, were evaluated the data collected at baseline visit before treatment (T0), at the end of treatment cycle (T1), and at 3 months follow-up visit (T2).

Statistical Analysis

The data were entered in an EXCEL sheet and analyzed with the SAS 9.4 program (AS Institute Inc., Cary, NC, USA) for Windows. The quantitative variables were analyzed descriptively reporting as mean and standard deviation, while for the qualitative variables the number and percentage of subjects in each category were reported. The verification of the normality of the quantitative variables was carried out with the Shapiro-Wilk test. The comparison between groups was carried out with the Wilcoxon test of the sum of the ranks in the case of quantitative variables with non-normal distribution (age), with the analysis of variance for repeated measures in the case of the evaluation scales used, with the exact test Fisher's in the case of qualitative variables. The result of the analysis of variance was expressed with the value of the statistical significance p for the effects of treatment group, time and for the interaction group-time.

The withing group and between group comparison at each time was carried out with the Student's t test and the result is expressed with the value of the statistical significance p, the estimate of the difference between the means and the relative confidence interval at 95%. The level of statistical significance was set at 5%.

RESULTS

Twenty patients have been included in the study, aged between 47 and 69 years (average age 57.95 years). Group A (n=10, mean age 58.2 years old, F:M ratio =7:3); Group B (n=10, mean age 57.7 years old, F:M ratio = 8:2). No statistical difference was encountered between the two groups for the distribution of the gender variable (Fisher exact test p = 1.000) and for the distribution of the age variable (Wilcoxon rank sum test p=0.9093).

Both groups had a significant improvement in the Constant-Murley scale score. Patients in the HILT group showed an increase of 15.0 points at T1 ($p < 0.0001$) and 15.8 points at T2 ($p = 0.0002$). Patients in

the ESWT group showed an increase of 9.2 points at T1 (p = 0.0045) and 18.1 points at T2 (p < 0.0001). (See Figure 1)

DASH questionnaire decreased significantly (p < 0.001) in both group at the end of the treatment cycle and at the three-month follow-up compared to T0. Patients in the HILT group presented a decrease of 14.7 points at T1 (p < 0.0001) and of 15.1 points at T2 (p < 0.0001). Patients in the ESWT group presented a decrease of 10.3 points at T1 (p < 0.0008) and of 16.9 points at T2 (p < 0.0001). (See Figure 2)

NRS score decreased in both groups at the end of the cycle and at the three-month follow-up compared to T0. Patients in the HILT group showed a decrease in pain of 2.0 points at T1 (p < 0.0001) and of 1.5 points at T2 (p < 0.0002). Patients in the ESWT group showed a decrease of 0.3 points at T1 (p = 0.2624) and of 1.6 points at T2 (p = 0.0001). (See Figure 3)The between group difference in Constant-Murley and the DASH scores was not significant both T1 and T2. At T1, group A showed a higher decrease in NRS compared to group B.

All the evaluations registered during the study have been reported in the following table.

	ESWT (N°=10)	**HILT (N°=10)**		
	Mean (SE)		MD	p-value
Constant-Murley				
T0	51.3 (6,9037)	49.1 (6,9037)	2,2	NS
T1	60,5 (5,3393)	64,1 (5,3393)	-3,6	NS
T2	69,4 (4,7418)	64,9 (4,7418)	4,5	NS
	P≤ 0,001	**P≤ 0,001**		
DASH				
T0	87,2 (4,7011)	89,4 (4,7011)	-2,2	NS
T1	76,9 (4,6410)	74,7 (4,6410)	2,2	NS
T2	70,3 (4,4995)	74,3 (4,4995)	-4	NS
	P≤ 0,001	**P≤ 0,001**		
NRS				
T0	6,7 (0,3342)	7,0 (0,3342)	-0,3	NS
T1	6,4 (0,3367)	5,0 (0,3367)	1,4	**0,0087**
T2	5,1 (0,2728)	5,5 (0,2728)	-0,4	NS
	P≤ 0,001	**P≤ 0,001**		

SE = standard Eror; **MD** = mean different.

DISCUSSION

Rotator cuff tendinopathy is among the most common causes of painful shoulder and its prevalence is 2.8%-3% in the general population (26). Age of over 50 years and female gender represent relevant risk factors. In line with those expectations, the study population analyzed presented a mean age of 57.95 years (57.7 years in the ESWT group and 58.2 years in the HILT group, p = NS) and a prevalence of women 3 times higher than men (15 women and 5 men). The treatment of rotator cuff tendinopathy is mainly conservative; however, to date, the most effective approach has not yet been defined. Physical therapies in combination with exercise have shown important synergistic effects. Among the most recent technologies, HILT (18) and ESWT (27) have shown interesting results in the treatment of rotator cuff tendinopathy. ESWT stimulate tissue healing through upregulation of inflammatory cytokine receptors and afferent pain receptors, promote cell proliferation, neo-angiogenesis, and extracellular matrix synthesis (28). Their efficacy in the treatment of musculoskeletal problems is proven (29-30).

The HILT laser utilized have a primarily photomechanical action, resulting in cytoskeleton remodeling and changes in the concentrations of cytoskeleton proteins such tubulin, vimentin, and actin (31-32). This laser also appears to increase the formation of important extracellular matrix components such as collagen, fibronectin, and aggrecans (32), fibronectin fibril rearrangement (33), and cell differentiation (34). These effects lead to changes in cell-matrix interactions and this influences important cellular processes such as: spreading, adhesion, motility. Hilterapia® is used for the treatment of numerous musculoskeletal disorders (35-36-37); due to its important anti-inflammatory, anti-edema, antalgic, and biostimulating effects (38), it has proven to be a successful therapy in reducing pain and improving joint function in patients with rotator cuff tendinopathy, both in the short and long term (18, 19, 20).

The results of our study showed a functional improvement, assessed by clinical scales, of both groups. In particular, there was a statistically significant higher score in the Constant-Murley scale, and a reduction of the pain during the activity of daily living. Moreover, both groups reported a reduction of the DASH score, and an improvement of the upper limb function. Furthermore, we found a statistical improvement of the shoulder pain, assessed by NRS scale. In details, both groups, treated with HILT and ESWT showed a reduction of the pain at the end of the treatment and at the three months follow-up. Interestingly, we found a between group difference at the end of the therapy, with a higher improvement of the shoulder pain in patients treated with HILT.

However, this difference is no longer detected at three months, with ESWT also showing a significant improvement.

Regarding the HILT therapy, our findings are consistent with those of Elsodany and colleagues, who evaluated the short- and long-term therapeutic effects of HILT laser therapy treatment on 60 patients with rotator cuff tendinopathy.

Their results demonstrated an important effect of HILT laser treatment on pain reduction in conjunction with a physiotherapy compared with physiotherapy only (18). Regarding ESWT our results confirm the conclusions of Galasso et al. that showed, in a study of 20 patients with non-calcific tendinopathy of the supraspinatus, the higher effect of ESWT therapy compared to placebo, in reducing pain symptoms and improving joint function (39). We are aware that our study is not free of limitations. In particular, the number of patients could affect the generalizability of the results and further studies are requested to confirm our results.

CONCLUSION

In both the short and long term, HILT and ESWT have been demonstrated to be effective therapies for patients with non-calcific rotator cuff tendinopathy. However, HILT laser therapy resulted in more rapid clinical improvement at the end of the cycle, and that these effects were almost constant at the three-month follow-up, whereas ESWT resulted in more gradual clinical improvement over time, with significant results at three months.

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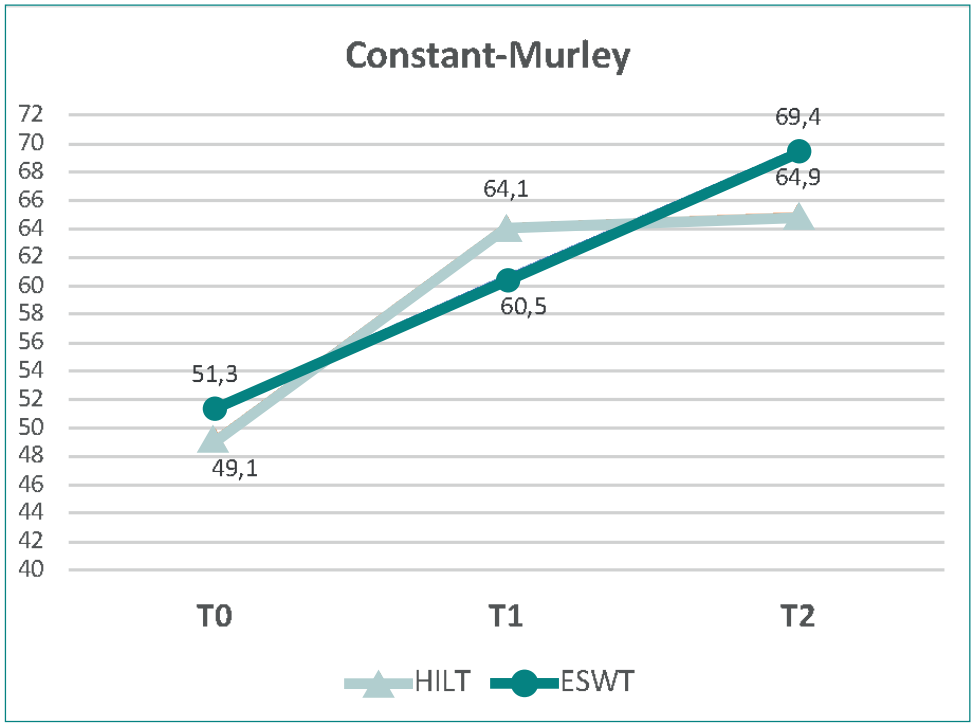


Figure 1
Representation of Constant-Murley scale scores over time for the two groups: HILT and ESWT.

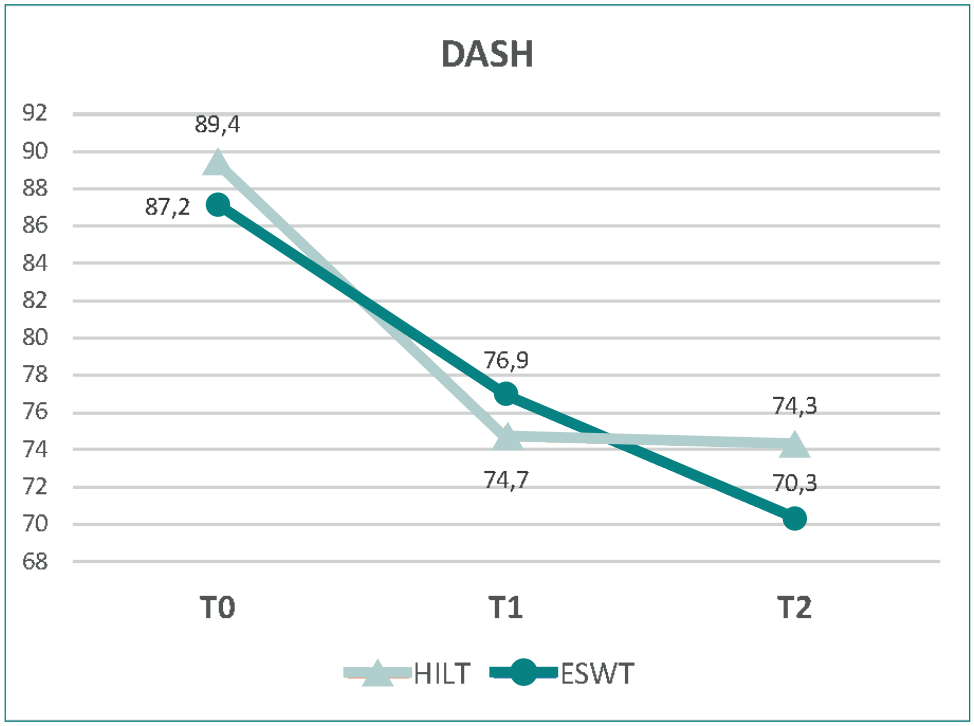


Figure 2
Representation of the DASH scores over time for the two groups: HILT and ESWT.

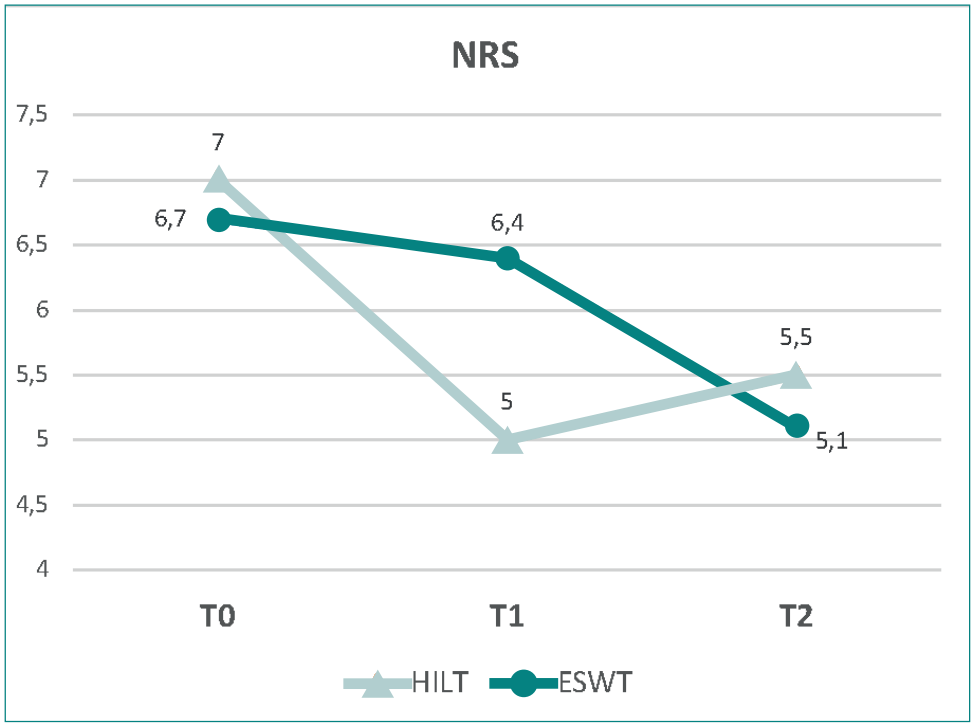


Figure 3
Representation of the NRS scores over time for the two groups: HILT and ESWT.

Application of low-intensity, low-frequency pulsed electromagnetic fields (PEMF) in the treatment of osteoarthritic dogs – observational study.

Dr.ssa Sisti Valentina Maria

ABSTRACT

This paper reports the findings of an observational study investigating the efficacy of pulsed electromagnetic fields (PEMF) in treating osteoarthritis (OA). OA is a degenerative joint condition which mainly affects a significant number of older dogs, leading to discomfort and reduced mobility. magnetotherapy has become a more widely accepted complementary intervention in veterinary medicine in the alleviation of pain and enhancement of joint functionality.

In this study, an analysis was conducted on a representative sample of ten dogs afflicted with OA, which were subjected to magnetotherapy treatments, two sessions per weeks, for a duration of six weeks. The principal indicators of interest included the degree of pain on palpation and the degree of lameness, joint mobility, muscle circumference and the dogs' level of participation and happiness. Validated assessment instruments were employed, and clinically significant data was gathered.

The observational study produced evidence showing a notable reduction in joint pain and an improvement in joint mobility for dogs treated with magnetotherapy. Additionally, pet owners reported an increase in their pets' participation and happiness levels.

This study provides encouraging evidence for magnetotherapy's effectiveness as a therapeutic option for treating joint pain in dogs.

INTRODUCTION

Osteoarthritis in dogs

Osteoarthritis (OA) in dogs is an extremely vast and complex pathology belonging to the orthopedic field. It occurs with extreme frequency in daily outpatient practice. Epidemiological studies report an incidence of OA in dogs ranging between 8% and 20%.

The most significant data of recent scientific research now set aside the old theories according to which OA is a form of senescence or joint wear exclusively of elderly subjects.

The new theories on the pathogenesis of these adult/elderly subjects are currently based on the conception that mediators with a destructive value characterize OA, which act in constructive interaction thanks to self-amplifying mechanisms capable of defeating substances with anabolic and reparative activity.

In this context, free radicals assume significant importance and seem to be the cause of the degenerative and inflammatory alterations characteristic of arthrosis in dogs of a certain age. We therefore speak of multifactorial etiology characterized by multiple risk factors.

According to the etiopathogenesis, arthropathies are divided into inflammatory: infectious (bacterial, viral, fungal) and non-infectious (immune-mediated erosive and non-erosive); and non-inflammatory, with consequent effects on their primary localization and symptomatology. Inflammatory arthropathies primarily affect the articular components, the synovium, the ligaments and secondarily the cartilage and subchondral bone. In non-inflammatory (non-neoplastic) forms, on the contrary, the tissues involved are cartilage and bone.

Inflammatory arthropathies are also generally polyarticular (shoulder, elbow, hip), but immune-mediated ones have instead a symmetrical bilateral involvement (carpus and tarsus). The symptoms appear variable. There is lameness in relation to the degree of chronicity of the lesion.

If the OA is of inflammatory origin, there is the presence of swollen, warm, and painful joints, with the risk, in the case of bacterial forms, of hesitating in edematous formations inside the limb and osteomyelitis caused by the erosion of the cartilage matrix induced by patho-

genic enzymes or released by leukocytes destroyed by bacteria. Instead, deformation of the joints characterizes the OA of immune-mediated origin; the periarticular soft tissues weaken to the point of sometimes causing rupture of ligaments or tendon supports. In any case, among the different clinical forms, pain is the main manifestation related to the types of osteoarthritis.

OA involves all dogs' races without distinction and affects all age groups. Bacterial or tick-borne forms can easily affect even young subjects.

To arrive at a precise diagnosis, therefore, in addition to an accurate anamnesis, an in-depth clinical examination and the support of instrumental diagnostic investigations such as: radiographic examinations, arthrocentesis, arthroscopy, culture and serological tests are required.Thanks to increasingly in-depth knowledge about the etiopathogenesis of OA and increasingly innovative diagnostic techniques, we are moving towards a combined medical therapy.

These are different interventions but with a synergistic effect to act on three main objectives: (1) to intervene on the causes that have caused the arthritic degeneration; (2) interfere with the pathogenetic mechanisms that represent the biological substrate of the disease; (3) act to counteract the emerging symptomatology at whatever stage it is.

The primary cause is often treated with surgical therapies to correct the biomechanics of the joint and to try to recover its functionality.

For the other two objectives, a multimodal treatment is used instead, consisting of the integration of different therapies such as: nutritional control both in preventive and therapeutic form: aimed at reducing excess weight that could affect the diseased joints; rehabilitation physiotherapy; pharmacological treatment understood as "pain-oriented" symptomatic therapies (eg: NSAIDs) and "disease-oriented" ones (eg: chondroprotectors).

Physiotherapy rehabilitation is now considered an effective complement to surgical and pharmacological treatments for OA in dogs. It is capable of pursuing six important objectives: 1) improve joint function, correcting alterations and re-educating the patient to walk; 2) reduce muscle contractures and stimulate the trophism of the myotenoligamentous apparatus due to periods of reduced motor activity; 3) increase proprioceptive abilities and exploit the plasticity of the nervous system; 4) stimulate the blood and lymphatic system; 5) enhance muscle trophism; 6) decrease pain.

The application methods are numerous and are often linked to the aptitudes of the veterinary surgeon who performs them, to his availability of space, time, and economics.

Among the often-used rehabilitation treatments we find active/passive therapeutic exercises and instrumental techniques: magnetotherapy, laser therapy, TECAR therapy, shock waves, ultrasound therapy, neuromuscular electrostimulation.

Magnetotherapy

The use of magnetic fields dates to Egyptian times. We have considerable evidence of its use also from the Roman period and the Middle Ages.

Magnetotherapy is defined by Steiss (1997) as "a form of physical therapy which, by exploiting the interaction between a magnetic field and the body, regulates the electrochemical balance of the cell, restoring the correct membrane permeability; thanks to its bio-regenerating action, it stimulates tissue regeneration and accelerates repair phenomena".

Not all magnetic fields are the same, a clear distinction is made between constant ones and those that vary over time or pulsating; in general, it is the latter that are used for therapeutic purposes. The effect of magnetotherapy on organisms would be realized at the level of neurovegetative and cellular metabolic regulation.

The pulsed magnetic fields induce micro-currents which, causing ion exchanges in the cell membranes, restore the correct membrane potential (unbalanced in the case of a pathological cell).

From this restored electrochemical balance of the cell, a correct membrane permeability follows.

The bio-stimulating effect ultimately modulates and accelerates tissue regeneration and repair.

Dragone L. (2015) summarizes the effects of magnetotherapy on the body in: increase in cellular permeability; ionization of protoplasmic molecules and increase of the polarization level; increased permeability to calcium; piezoelectric effect on the bone and stimulation of fibrocartilage calcification; inhibition of bone resorption and earlier callus formation; increased action of osteoblasts; cartilage stimulation; analgesic effect.

By intervening on certain parameters such as the intensity of the field, the frequency of the impulses and the duration of exposure of the body to the pulsed magnetic field, different effects can be achieved: analgesic, anti-inflammatory, biostimulant and repairing.

The fields of application of magnetotherapy are many:

– Treatment of fractures, osteoarthritis, arthritis, consolidation delays
– Inflammatory processes
– Contractures and muscle spasms
– Vascular alterations
– Pain
– Neurological pathologies (Steiss,1997)

Among the various applications of magnetotherapy, the best known and most studied is the one on the bone. Several studies have shown that magnetotherapy is able to accelerate and/or reactivate the phenomena of bone healing, promoting the proliferation of osteoblasts, local neo-vascularization, and mineralization of the fibrocartilaginous callus (Dragone, 2015; Auer et al., 1983; Carlucci et al., 1978).

Some studies in human medicine have instead questioned the pain-relieving power of this technique (McCarthy et al., 2006), minimizing the encouraging results brought to light by recent clinical studies conducted on the subject. Recent scientific works have been able to confirm how low intensity and frequency pulsed magnetic fields can influence the behavior of different cell types: nerve, endothelial, connective tissue, and muscle. Colciago et al. (2019) analyzed in vitro the biological responses to EMF exposure on cells of the peripheral nervous system. In this work, the effects of electromagnetic fields on cultures of rat Schwann cells (SC) (taken from the sciatic nerve) regarding their viability, proliferation, migration capacity and specific myelin markers were studied.

Research has shown that the exposure of these cells to electromagnetic fields does not cause toxic stimuli, morphological changes or influence their migration and myelinating capacity. On the contrary, prolonged, and repeated exposure over time to low intensity and frequency PEMF fields induces increased proliferation in SCs. Therefore, the use of PEMF could represent a useful tool to improve the regenerative capacities of myelin producing SCs affecting peripheral nerves with significant consequences on the fields of application in medicine, both in preventing degeneration and in promoting nerve regeneration. Although the use of pulsed electromagnetic fields in osteoarticular pathologies is very extensive in daily clinical practice, the underlying mechanisms of action remain partly unknown and complex to reconstruct due to the multiple interactions between the different biological tissues. Unfortunately, the bibliography on this subject is scarce. Some publications on works conducted on osteoblasts (De Mattei M et al., 1999), osteoclasts (Chang K et al., 2003) and on cultures in liquid medium of fibroblast-like cells derived from human peripheral blood mononuclear cells date back to the 1980s (Gómez-Ochoa et al., 2010); however, these works are not sufficient to explain the anti-inflammatory effect of magnetic fields on osteoarthritis processes. In the 2017 Biochemistry and Biophysics Report, a comparative study between electromagnetic fields and low-level laser therapy conducted on mitogen-activated protein kinases is cited in which the powerful healing effect that electromagnetic fields emerge, through the stimulation of protein kinase pathways.

At the end of this article, there is even talk of such a high biological stimulation effect on cells due to magnetic fields, that a moderate use is recommended in terms of time and frequency of use. The need arises to further investigate the effects of magnetotherapy in veterinary medicine as this sector unfortunately does not have enough scientific evidence. Considering the above premises, the present prospective observational study aims to describe and evaluate the effects of low-frequency and intensity pulsed electromagnetic fields (PEMF) in dogs with osteoarthritis.

MATERIALS AND METHODS

The study was conducted between September 2021 and September 2022, at: the Rehabilitation Physiotherapy department of the Teaching Hospital of the School of Veterinary Medical Sciences of Camerino, the Futuravet facility (second level) of Tolentino and the Veterinary Clinic (associated studio) of Posatora (AN). Before starting data collection, informed consent was obtained from the owner of each subject.

Population

All patients diagnosed with OA were evaluated by clinical and instrumental examination (radiography) regardless of joint involved, age, race, and weight; the patient were in pharmacological wash-out for at least two weeks. The degree of severity of the pathology was defined based on the radiographic examination, using the Kellgren-Lawrence classification scale.

This scale identifies five degrees of severity: not appreciable, doubtful, minimum, moderate, and severe; we start from a perfect joint, then as we continue along the ladder we see a reduction of the joint space, bone sclerosis, important bone deformation, disappearance of the cartilage and formation of osteophytes.

Study Design

Each patient underwent two magnetotherapy sessions a week distrib-

uted equidistantly from each other for a total of twelve sessions. The patients did not undergo any further medical treatments during the physiatric treatment cycle. For the application of low intensity and frequency pulsed electromagnetic fields (PEMF), the portable device PMT QS (ASA Srl, Arcugnano) was used, equipped with Flexa applicators (36 x 21 x 2 cm (L x P x H) - 1.2 kg), programmable frequency from 0.5 to 100 Hz and variable magnetic field intensity from 5% to 100% (from ~2.5 to ~40 Gauss).

Figure 1.1. Patient Whiskey - Example of application of PEMF magnetotherapy at low intensity and frequency.

The handpieces were placed directly in contact with the anatomical site of the arthrotic lesion by taking advantage of the appropriate elastic bands.

The treatment was delivered without requiring any predetermined position of the patient. All patients were treated with the following protocol and device settings: the clinical protocol has thus been set up based on the clinical practice of the center and is conceived in such a way as to initially obtain an analgesic, vascular stimulation, and therefore anti-inflammatory effect; and subsequently by an increasingly bio stimulating effect. The subjects were evaluated at the baseline visit (T0) and at the end of the sixth session (T1) and the twelfth session (T2) of treatment.

	FREQUENCY (HZ)	INTENSITY (%)	TIME (MIN)
First 3 sessions			
Phase 1	40	33	25
Phase 2	70	33	25
Next 5 sessions			
Phase 1	100	10	25
Phase 2	60	100	25
Last 4 sessions	95	50	45

Clinical Outcomes

The following parameters were evaluated for each patient: pain on palpation, degree of lameness, level of participation and happiness, circumference of ipsilateral and contralateral muscle masses, range of motion (ROM) of the treated joint.

Pain on palpation

By palpation and manipulation of the limb, the different consistency of the muscles, the possible presence of contractures, crackles, or points of evident pain (trigger points) that limit the load or the joint ROM of the patient were evaluated. The degree of pain on palpation was measured using a scale of values (Knap et al., 2008) with a score from 0 to 4:

0 = no sign of pain on palpation
1 = mild pain on palpation
2 = moderate pain on palpation
3 = intense pain on palpation
4 = the subject is in so much pain that the limb cannot be palpated

Degree of lameness

Lameness, a clinical symptom characterized by irregular gait, was assessed by physical examination using a scale of values ranging from 0 to 5 (Knap et al., 2008):

0 = normal gait
1 = slight lameness
2 = evident lameness without subtracting the limb from the load
3 = severe lameness without removal of the limb from weight bearing
4 = severe lameness with intermittent unloading of the limb
5 = severe lameness with continuous removal of the limb from weight bearing

Level of Participation and Happiness

This qualitative parameter was evaluated by objective clinical examination during visits and by feedback received from the owner.

A scale of values ranging from 0 to 5 was used:

0 = impatience
1 = distrust
2 = fair
3 = good
4 = excellent
5 = complete

Range Of Motion (ROM)

The degree of joint mobility was evaluated using an arm goniometer, consisting of two arms hinged together. The reference arm remains fixed while the other has been rotated according to the movement of the joint under examination, the pin is applied to the motor center of the joint. Before proceeding with the measurements, to limit possible errors, the subject was expected to be sufficiently relaxed. The subject was placed in standing position or in lateral recumbency. Each measurement was repeated three times and the mean value was taken. For each patient, the joint angles of maximum flexion and maximum extension of the joint subject to OA were measured. In the case of patients with carpal OA, maximal external rotation was evaluated.

Circumference of muscle masses

The measurement of the circumference of the articular masses always took place in the same landmarks, for the anterior limb the point was located on the middle third of the humerus while for the rear limb on the middle third of the femur. A specific meter called Girthometer was used to measure muscle mass. This instrument consists of a tape equipped with a spring and relative dynamometer which allows the same force to be applied during measurements. To reduce the measurement error also in this case, the measurement was repeated three times and the mean value was taken. Each measurement was compared to that of the contralateral muscle.

Statistical analysis

A descriptive statistical analysis of all relevant variables was performed. Continuous variables were summarized by number of patients (N), mean, standard deviation, minimum, maximum. Categorical variables were summarized by number (N) and percentage of patients (%). Differences for all clinical outs were calculated for each patient at the sixth and twelfth treatments using the baseline visit as a reference.

The significance level of the statistical tests was set at 0.05. Parametric tests (e.g., Student's t-test) were used to analyze continuous variables; when the continuous variables are not normally distributed, the corresponding non-parametric tests have also been performed (e.g., Wilcoxon's signed-sum ranks test).

RESULTS

Ten patients of varying breed and size with a mean weight of 24.5 ± 12.1 kg (Min = 11.4 kg and Max = 45.0 kg) and age of 10.0 ± 3.0 years (Min = 4.0 years, Max = 13.5 years) were enrolled.

At the baseline visit, the population had a degree of osteoarthritis of severe degree in 70% of cases, of moderate degree in 20% of cases and of minimal degree in the remaining 10%. The anatomical sites affected by osteoarthritis and treated were the hip (3 cases), the elbow (2 cases), the spine (3 cases), the shoulder (1 case) and the carpus (1 case).

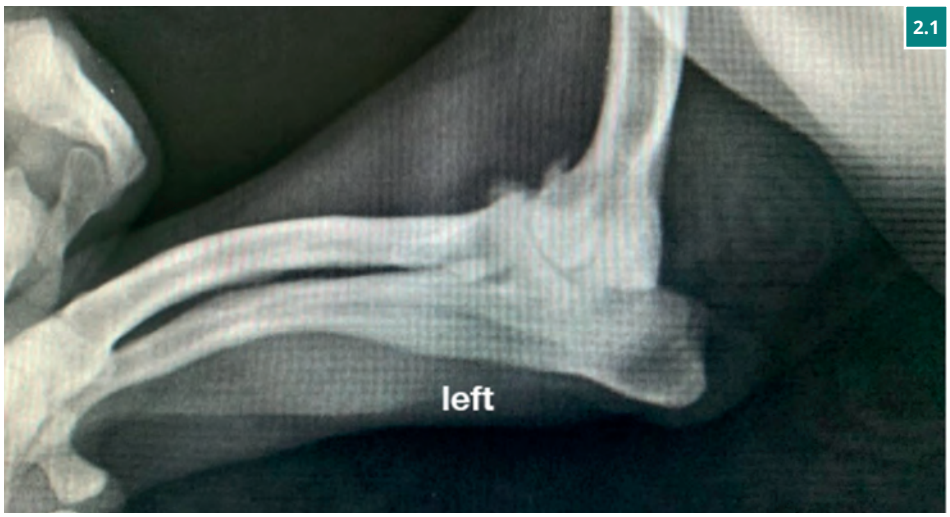


Figure 2.1. Patient Whiskey – radiographic image of left elbow, severe osteoarthritis with osteophytosis cranial to the radial head and humeral condyles with deformation of the condylar joint profile. Pro curvature of radium and ulna.

The degree of pain on palpation detected was 2.7 ± 1.3 (Min = 0, Max = 4), while the degree of lameness was evaluated equal to 1.9 ± 1.1 (Min = 0, Max = 4).

At the baseline visit, the mean level of participation and happiness found in the subjects was 2.4 ± 2.0 (Min = 0, Max = 5) points.

The measurements of the circumference of the muscle of the ipsilateral limb and its contralateral limb, the degree of flexion, extension and external rotation of the treated limb are shown in Table 1. In the middle of the treatment cycle (T1), after 6 sessions of PEMF magnetotherapy, the pain on palpation was reduced by an average of 1.5 ± 0.8 points, equal to 52.5% ± 25.8% ($p < 0.05$).

The degree of lameness decreased by 1.1 ± 0.5 points equal to a reduction of 60.0% ± 30.9% ($p < 0.05$).

The mean level of participation and happiness increased significantly by 1.4 ± 1.7 points from the baseline

Table 1. Ipsilateral/contralateral Muscle Circumference and Range of Motion of the Treated Joint of the Baseline Visit Population.

	Mean	SD	Min	Max
Muscle circumference Limb (cm)				
Ipsilateral				
Hip	30,7	6,8	24	40
Elbow	23,5	6,5	17	30
Column	33,7	6,1	26	41
Shoulder	28,0	0,0	28	28
Carpus	18,5	0,0	18,5	18,5
Controlateral				
Hip	33,2	7,1	26,5	43
Elbow	26,0	7,0	19	33
Column	36,7	7,0	29	46
Shoulder	32,0	0,0	32,0	32,0
Carpus	20,0	0,0	20,0	20,0
Range of Motion (°)				
Flexion				
Hip	55,7	4,9	50	62
Elbow	47,5	2,5	45	50
Shoulder	58,3	6,2	50	65
Carpus	20,0	0,0	20,0	20,0
Extension				
Hip	129,3	14,0	111	145
Elbow	144,0	4,0	140	148
Column	121,3	24,5	92	152
Shoulder	145,0	0,0	145,0	145,0
External Rotation				
Carpus				
	13	0,0	13	13

Table 2. Mean value and standard deviation of monitored parameters before, during and at the end of the treatment cycle.

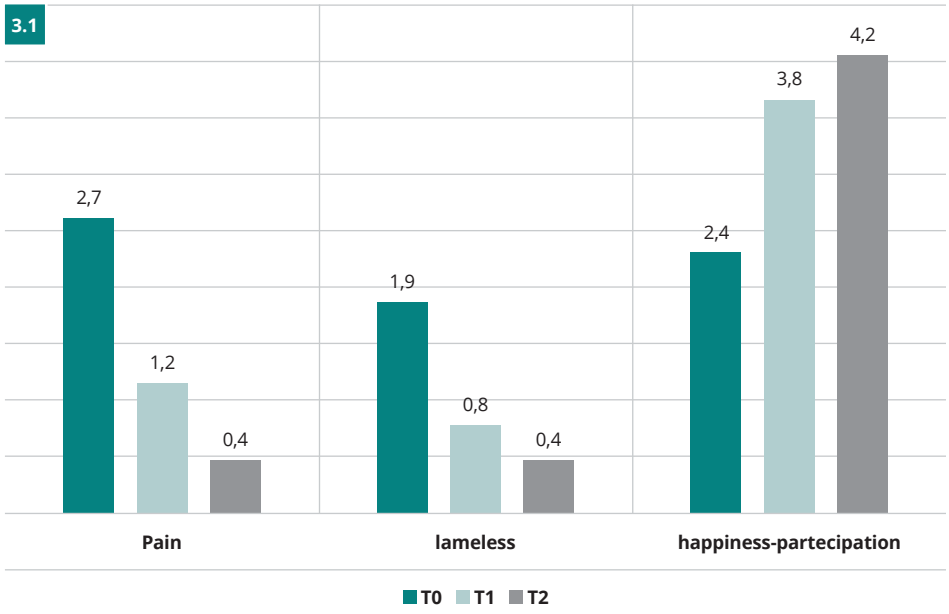
	T0 Mean (SD)	**T1** Mean (SD)	**T2** Mean (SD)
Pain	2,7 (1,3)	1,2 (0,7)	0,4 (0,5)
Lame	1,9 (1,1)	0,8 (0,7)	0,4 (0,5)
Happiness-Participation	2,4 (2,0)	3,8 (1,1)	4,2 (0,9)
Limb Circumference (cm)			
Ipsilateral			
Hip	30,7 (6,8)	33 (6,5)	34,5 (6,6)
Elbow	25,3 (6,5)	25,3 (7,2)	26,3 (7,25)
Column	33,7 (6,1)	37,3 (4,2)	38,7 (4,5)
Shoulder	28 (0)	30 (0)	31 (0)
Carpus	18,5 (0)	20 (0)	22,5 (0)
Controlateral			
Hip	33,2 (7,1)	34 (7,3)	34,7 (6,8)
Elbow	26 (7)	26 (7)	26,3 (7,2)
Column	36,7 (7)	38,7 (5,3)	39 (4,2)
Shoulder	32 (0)	32 (0)	32 (0)
Carpus	20 (0)	22 (0)	22,5 (0)
Range of Motion (°)			
Flexion			
Hip	55,7	46,5 (13,8)	41,8 (10,6)
Elbow	47,5 (2,5)	39,5 (5,5)	35 (5)
Column	58,3 (6,2)	45,3 (11,6)	39 (9,4(
Shoulder	52 (0)	48 (0)	42 (0)
Extension			
Hip	129,3 (14)	143 (9,2)	155 (8,2)
Elbow	144 (4)	149,5 (2,5)	162 (4)
Column	121,3 (24,5)	133,7 (15,6)	142,3 (14,3)
Shoulder	145 (0)	150 (0)	158 (0)
External Rotation			
Carpus			
	13 (0)	11 (0)	6,5 (0)

Figure 3.1. Degree of pain, lameness and level of Participation and Happiness found in the population under examination at the Baseline visit (T0) after 6 sessions (T1) and after 12 sessions (T2) of PEMF magnetotherapy.

value ($p < 0.05$). The muscle circumference of the treated limb was increased on average by 9.2% ± 6.3%, while that of the contralateral limb by 3.8% ± 5.3%.

The degrees of flexion and extension were evaluated separately for: hip, elbow, spine and shoulder (see Table 2); on average compared to baseline, the degree of flexion decreased by 19% ± 14%, while that of extension by 9.1% ± 8.4%. The degree of external rotation was evaluated in only one individual, at T1 it resulted decreased by 15% compared to T0.

At the end of the treatment cycle (T2) compared to baseline, pain on palpation decreased by 2.3 ± 1.2 points



equal to a reduction of 83% ($p < 0.05$); the degree of lameness improved on average by 1.5 ± 0.8 points equal to 79.7% ($p < 0.05$), while the level of happiness-participation increased by 1.8 ± 1.9 points.

The muscle circumference of the treated limb was increased by 14.6% ± 7.9% while that of the contralateral muscle by 6% ± 7%. As regards the mobility of the hip, elbow, spine and shoulder joints, flexion increased on average by 28% ± 11% while extension decreased by 17.3% ± 10.3%. Carpal mobility as assessed by external rotation measurement increased by 50%.

The results obtained in the middle and at the end of the treatment cycle are shown in Table 2.

DISCUSSION

Patients treated with low-intensity and low-frequency PEMF magnetotherapy showed a significant reduction in pain, lameness, participation, and happiness, both in the middle of the treatment cycle and at its end, compared to the data measured at the baseline visit.

This was also found in an ever-greater availability, malleability, and willingness of the subjects to undergo PEMF magnetotherapy and this is an indication of clinical positivity.

The increase in joint mobility found during this study is a comforting fact. Regardless of the result achieved at the end of the twelve sessions, it expresses a positive response from the patient to the treatments and suggests the possibility of being able to further improve joint mobility if the subject undergoes a longer and/or maintenance cycle of magnetotherapy.

Although evaluated in only one subject, even the slightest correction of the rotated carpus in valgus suggests a positive interference of the PEMFs with the osteo-articular structures.

It should be remembered that the clinical improvement observed may in part have been influenced by the following factors:

1- Managing the patient at home. After taking a treatment, the owners should manage the patient according to certain rules such as: warm and dry environment; controlled motor activity (avoid jumping, jerking and sudden movements); contained diet for the achievement of normal weight. Underestimating one of these aspects could not allow the achievement of the desired result, in fact it could be the reason for an, albeit minimal, exacerbation of the initial condition, as has been found in some enrolled patients.

2- The protocol used. The one chosen for this work was defined based on previously obtained results and is the one that is applied in the clinical practice of the center.

It has been standardized for all patients to avoid a bias if it is customized for each patient. However, it is believed that an adjustment, at each session, of the therapy to the physiological and clinical condition of the patient can lead to obtaining the best results.

This study has demonstrated how it is possible with non-conventional conservative therapy alone to control the clinically appreciable symptoms caused by arthritic processes such as: pain, lameness, degree of happiness-participation, joint mobility, muscle rebalancing. PEMF therapy, used in a controlled and constant manner, can be indicated, both for acute treatment and for long-term maintenance, to counteract arthritic phenomena, allowing patients, especially geriatric subjects, to achieve a better state of well-being, balance, and tranquility.

Although the small number of patients studied, from the results obtained PEMF magnetotherapy has brought improvements regardless of the degree of severity found or the anatomical district affected.

Further investigations, in larger populations, are needed to further validate the obtained results. Furthermore, it would be interesting to study the benefits of the integrated application of PEMF with other physiatric methods such as: laser therapy, neuro-muscular electrostimulation, passive manual techniques, and active exercises in a more or less controlled manner carried out in succession. This therapeutic approach could provide an additional stimulus for all the anatomical districts involved and a strengthening of the mechanism of action of the PEMF therapy itself.

CONCLUSIONS

In this observational study, PEMFs proved to be a valuable therapeutic tool in the treatment of OA in dogs. The treated patients, regardless of the degree of severity, age or anatomical site treated, reported an improvement in pain symptoms, an improvement in mobility and quality of life.

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3. Gmünder FK, Cogoli A. Effect of space flight on lymphocyte function and immunity. In: Fregly MJ, Blatteis CM, eds. Handbook of Physiology. Oxford:University Press, 1996, vol. 2, pp 799-813.

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