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Effect of low-level LASER therapy versus CAD/CAM Michigan splint on patients with Temporomandibular Muscle Disorders: a randomized clinical trial

Efeito da terapia LASER de baixa potência versus placa de Michigan CAD/CAM em pacientes com Distúrbios Temporomandibulares musculares: um ensaio clínico randomizado

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ABSTRACT

Objective: This study aimed to evaluate the efficacy and sustainability of using low level LASER therapy and CAD/CAM Michigan splint on improving the range of mandibular movements, muscle activity and reducing the pain. **Material and Methods:** 56 female patients were randomly divided into two groups. **Group A:** Patients received applications of low-level LASER therapy using semiconductor InGaAsp diode LASER type 940 nm with continuous mode of operation, applied for 180 sec per session for 12 sessions. **Group B:** Patients received Michigan splint of 2 mm thickness constructed on their upper teeth, the splint was 3D digitally printed. Electromyography was used to evaluate muscle activity, visual analogue scale was used to evaluate the pain intensity, ARCUS digma facebow was used to evaluate range of mandibular movements, and maximum mouth opening was taken using a millimeter ruler. They were measured before the beginning of the treatment, and at three and six month follow-up periods. **Results:** The results revealed that both low-level LASER therapy and Michigan splint reduce the myofascial pain, improved the range of the mandibular movements, and the muscles activity, but the effect of the low-level LASER therapy was more profound and sustainable. After 6 months from the beginning of the treatment, changes in masseter muscle activity (P= 0.001; effect size= 1.757), pain intensity (P= 0.003; effect size= 3), and range of mandibular movement (P= 0.001, effect size= 1.729) differed significantly between the two groups. **Conclusions**: Low-level LASER therapy had a better and more sustainable effect on reducing the pain intensity and improving the muscle activity as well as the mandibular movement when compared to Michigan splint.

KEYWORDS

Electromyogram; Low level LASER therapy; Michigan splint; Muscle disorders; Myofascial pain; Temporomandibular disorders.

RESUMO

Objetivo: Este estudo teve como objetivo avaliar a eficácia e a durabilidade do uso da terapia LASER de baixa potência e da placa de Michigan CAD/CAM na melhora da amplitude dos movimentos mandibulares, atividade muscular e redução da dor. **Material e Métodos:** 56 pacientes do sexo feminino foram divididos aleatoriamente em dois grupos. **Grupo A:** os pacientes receberam aplicações de terapia LASER de baixa potência utilizando diodo semicondutor InGaAsp LASER tipo 940 nm em modo contínuo de operação, aplicado por 180 segundos por sessão durante 12 sessões. **Grupo B:** os pacientes receberam a placa de Michigan com uma espessura de

2 mm confeccionada sobre a arcada superior, a placa foi impressa digitalmente em 3D. A eletromiografia foi utilizada para avaliar a atividade muscular, a escala visual analógica foi utilizada para avaliar a intensidade da dor, o arco facial ARCUS digma foi utilizado para determinar a amplitude dos movimentos mandibulares e a abertura máxima da boca foi medida com uma régua milimétrica. Todas as medidas foram realizadas antes do início do tratamento e nos períodos de acompanhamento de três e seis meses. **Resultados:** Os resultados revelaram que tanto a terapia LASER de baixa potência como a placa de Michigan reduziram a dor miofascial, aumentaram a amplitude dos movimentos mandibulares e melhoraram a atividade muscular, mas o efeito da terapia LASER de baixa potência foi mais profundo e duradouro. Após 6 meses do início do tratamento, as alterações na atividade do músculo masseter (P= 0. 001; tamanho do efeito= 1,757), intensidade da dor (P= 0,003; tamanho do efeito= 3), e amplitude de movimento mandibular (P= 0,001, tamanho do efeito= 1,729) diferiram significativamente entre os dois grupos. **Conclusão:** A terapia com LASER de baixa potência teve um efeito melhor e mais duradouro na redução da intensidade da dor e na melhora da atividade muscular, bem como do movimento mandibular, quando comparada à placa de Michigan.

PALAVRAS-CHAVE

Distúrbios musculares; Distúrbios temporomandibulares; Dor myofascial; Eletromiograma; Placa de Michigan; Terapia LASER de baixa potência.

INTRODUCTION

Temporomandibular disorders (TMDs) are a collective term used to describe a group of musculoskeletal conditions occurring in the temporomandibular region. These conditions are associated with pain in the muscles of mastication, the temporomandibular joint, or both, that are usually found during palpation and function [1].

TMDs are classified into intra-articular disorders and muscle disorders. Intra-articular disorders include disc displacement with or without reduction, arthritis, and arthralgia, while muscle disorders are further classified into local myalgia where the pain is confined into palpated areas of the muscle, myofascial pain where the pain spreads through the entire muscle, and myofascial pain with referral where it spreads also to adjacent structures [2]. Although myofascial pain is considered the predominant type of TMDs, it is very difficult for it to be properly evaluated despite its great impact on the patients' quality of life [2-4]. Limitation in the mandibular movements is also a common finding in patients suffering from TMDs, it affects their normal daily functions as their ability to eat properly and function without pain. Moreover, the patient will be either complaining of limited mouth opening that is most probably related to abnormal muscle activity, or the sudden feeling that their jaw gets stuck, and this is probably related to internal disc derangement [4,5]. Other signs and symptoms also related to TMDs include clicking sounds, headaches, and tension in the muscles of the back of the neck and the shoulders [5,6].

Variable treatment modalities have been introduced by different specialties for the management of TMDs, including physiotherapy, surgery, and the use of intraoral appliances [7]. Physiotherapy includes physical exercises, manual therapy technique, ultrasound, LASER, and transcutaneous electrical nerve stimulation (TENS) [8-10]. Surgical interventions include open joint surgeries and less invasive procedures as joint lavage and lysis [11]. The use of intraoral appliances includes stabilization splints (SS), anterior repositioning splint, and bite planes [12,13].

SS is a full coverage removable intraoral occlusal splint worn over the maxillary or the mandibular teeth, to reduce the amount of tooth contact preventing the tooth wear, while providing the patient with an ideal occlusal scheme, free from interference [13,14]. It is very effective in reducing pain especially in cases of patients suffering from muscle hyperactivity [14]. SS is a conservative treatment approach for TMDs, yet the durability of its effect on muscles activity and pain level is still controversial and there is lack of strong evidence for its long-term effect. As a lot of studies have proven that the effect of the SS lasts only as long as the patient wears it, and that it is mostly used as a diagnostic tool to identify the etiology of the TMD [15].

Low-level LASER therapy (LLLT), biostimulation, or photobiomodulation is a type

of therapy that has become recently popular in the management of a wide variety of medical and dental conditions, such as wound healing, tissue repair and prevention of further damage and tissue death, relief of inflammation, pain, and edema in chronic diseases and injuries, as well as relief of neurological pain [16]. LLLT is non-invasive, painless, and can be easily administered [17,18]. LLLT reduces prostaglandins(PGE2), interleukins(IL1), tumor necrosing factors, plasminogen activator, histamine and acetylcholine levels, neutrophil cell influx, hemorrhagic formation, COX-2 expression, cell apoptosis. It also improves microcirculation [19,20], and inhibits the transmission at the neuro muscular junction [21-23], which in turn helps in the reduction of chronic pain and improves the muscles' function.

But would the use LLLT for pain management and function improvement sustain its effect for a longer period when compared with the SS or would it be considered another conservative and reversible treatment option for myofascial pain associated with TMDs?

So, we conducted this study to compare the long-term effect of these two conservative non-invasive techniques used in the management of pain related TMDs, and to determine which one of them would sustain its effect after the end of the treatment. The null hypothesis was that there is no difference between the long-term effect of both techniques on the muscle function improvement and pain relief.

MATERIALS AND METHODS

Institutional research board (IRB) approval and trial registration

This study was approved by Ethics committee of scientific research of Faculty of Dentistry, Ain Shams university, with approval code: FDASU-REC IR112207, and registered at www.clinicaltrials.gov with reference no. NCT05901701.

Sample size calculation

Sample size calculation was performed using G*Power version 3.1.9.7 based on the results of a previous study [24]. A power analysis was designed to have adequate power to apply a two-sided statistical test to reject the null hypothesis that there is no difference between groups. By adopting an alpha level of (0.05) and a beta of (0.2), i.e., power = 95% and an effect size (d) of (1.09) calculated based on the results of a previous study. The predicted sample size (n) was (46), i.e., 23 samples per group. For treatment of TMJ problem and detect for difference between two modalities.

Recruitment and selection criteria

From the outpatient clinic of oral and maxillofacial department, Faculty of dentistry, Ain Shams university, dentulous patients suffering from the following DC/TMD signs and symptoms of myofascial pain were selected; pain in the muscles of mastication (temporalis and masseter) that affects the jaw movements and get worse with function. On palpation of the involved muscles, a palpable painful taut bands were noticed, in association with referred pain to other areas beyond the point of palpation but within the bulk of the palpated muscle, this hyperirritable spots were considered trigger points and three of them were chosen to apply the LLLT on it later, other signs and symptoms manifested as headache, periauricular pain or pain in the TMJ, teeth wear that appears in the form of multiple smooth shiny facets, teeth mobility, and malocclusion. Taking into consideration that any patient who suffered from one of the following criteria was excluded; pregnant females, breast feeders, patients having pacemakers, heart disease, tumors, general connective tissue disease e.g., Rheumatoid arthritis, psychiatric disorders, skeletal morphology as class II or III, TMJ clicking sounds, local skin infection over the masseter or temporalis, symptoms that may be referred to other disorders of orofacial region (tooth ache, trigeminal neuralgia, migraine), or patients using medications such as Muscle relaxant, Steroids, Dopamine precursors like L dopa and Aminoglycoside.

From the selected patients, fifty-six participants met the selection criteria and managed to complete the treatment and follow up to take part in this clinical trial. The age range of the selected patients was from 35 to 55 y, they were suffering from the previous signs and symptoms from 6 months up to 2 years.

Study design

Blocked randomization technique was used to divide the patients into two equal groups (28

per each) using sealed envelopes, the person who was in charge for randomization was blinded to the group allocation of the patients. The outcome assessors also didn't know the allocated groups, and the patients were instructed not to mention their groups to the assessors. Three operators were involved in the assessment process, one for the assessment of the muscle activity using the EMG, another one for the assessment of the mandibular movement using ARCUS digma and the maximum mouth opening using graduated ruler, and the last one for the assessment of the pain intensity using VAS. Each outcome was assessed by the same operator through the entire process for all the patients. The Consolidated Standards of Reporting Trials (CONSORT) specifications were applied.

Intervention

In the first group patients received LLLT, while in the second group the patients received 2mm thickness maxillary hard occlusal splints (Michigan splints).

For the LASER group, diode LASER (Epic 10, Biolase, USA) with wavelength 940nm was used after calibration using a LASER power sensor and meter. First the skin was cleaned with 70% alcohol gel, according to the facial template the trigger points were determined. The deep tissue hand piece with spacer was locked at the 25 mm notch to deliver the LASER beam with spot size of 25 mm to the target tissue (Figure 1), and then the diode LASER machine (940 nm) was adjusted to the required parameters, pain therapy mode, with the power output 4W, for 30 seconds, with continuous mode of emission. Total energy of 120J, power density 1.6 W/cm^2, and effective dose 48 J/Cm^2 were received by each trigger point. Three points were chosen on the temporalis and masseter area. Two of them were located on the body of the masseter muscle below the ala tragus line, and one over the insertion of the temporalis below the hairline . Any synthetic clothes at the field where the LASER beam passed were removed. Both the patient and the operator wore their protective goggles specific for 940 nm diode LASER wavelength. The hand piece was held in intimate contact, and at 90^o with the patient's skin (Figure 2), the foot control was pressed to allow the LASER beam to be released. Each patient received a total of twelve sessions for six weeks, two sessions per week.

Figure 1 - Deep tissue hand piece with a spacer attached at the 25 mm spot size notch.

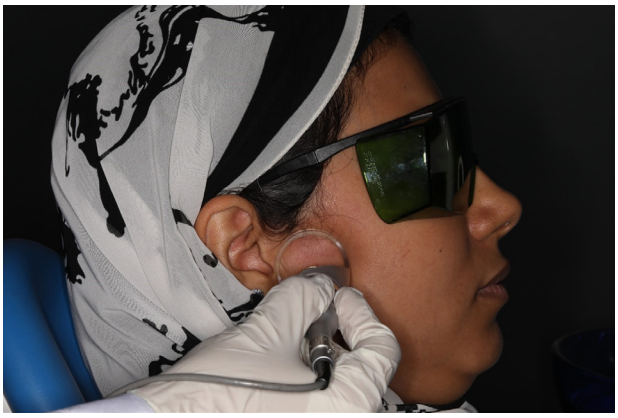

Figure 2 - LASER beam directed to the trigger point using deep tissue hand piece.

For the splint group, maxillary and mandibular impressions were done using heavy consistency polyether impression material (Identium Heavy – kettenbach, USA.) in a proper sized stock tray, and then poured immediately using type III dental stone (Gypsano Lab Dental Stone, Gypsano, UAE.). The maxillary cast was mounted on the semi-adjustable articulator (Bio-Art, Dentaltix, Madrid, Spain) by means of a face bow record and centric occluding relation record was taken to mount the lower cast.

On the articulator the incisal post was adjusted to allow 2 mm vertical separation between the posterior teeth, a protrusive record was taken from the patient and used to adjust the protrusive and lateral condylar guidance on the articulator. The articulator with the casts mounted on it was scanned using desktop scanner (Planmeca plan scan, Texas, USA), and both protrusive and lateral condylar guidance values were introduced to the virtual articulator on the software (8 Exocad software 2.4). Virtual designing of the splint was done with the following criteria, flat occlusal

surface to achieve contact with only the working cusps of all the mandibular posterior teeth, and in the canines' area it had two occlusal ramps to create separation of the posterior teeth during the eccentric mandibular movement, it extended on the hard palate in the form of horseshoe while labially and buccally it ended 2mm below the incisal edge and across the height of the contour of the posterior teeth. The splint was printed using a 3D printer (Phrozen printer, Phrozen Tech Co. Ltd, Taiwan) and liquid resin (NextDent Ortho Clear, NextDent, Soesterberg, Netherlands). The splint (Figure 3) was checked in the patient mouth for retention, and proper disocclusion of the posterior teeth during lateral and protrusive movements using articulating paper placed at the area of the canine ramps and asking the patient to protrude the mandible and move from one side to other side, till un-interrupted V-shape was produced on the canine ramps. The patients were instructed to gradually wear off the splint after 3 months but told to wear it if their discomfort returns which is often at times of stress.

Assessment

Before the beginning of the treatment, and at three and six months after the beginning of the treatment, changes in muscle activity, mandibular movement, mouth opening range, and pain intensity were assessed.

The change in muscle activity was assessed using EMG (Dantec "keypoint", Apline Biomed, Denmark), first the patient was seated upright with unsupported head to allow the muscles to relax, then the patient was instructed to look forward and perform maximum clenching in centric occlusion to locate both masseter and temporalis muscles, each muscle was palpated to identify the trigger points, three trigger points in the masseter and temporalis area were selected and marked on each side. These points were transferred to a clear celluloid template which is positioned on the face with the aid of a window cut at the ala of the nose, to help reposition the template each time during EMG measuring in the follow up periods and in the upcoming LASER treatment sessions. The ala tragus line was also drawn on the template to aid in the repositioning process.

The EMG ground electrode was positioned on the forehead and the active electrodes were positioned on the trigger points, first the active electrodes were positioned over the trigger points of the right masseter temoralis muscle area then the patient was asked to chew a 1cm cube of carrot on the right side for 30 seconds, and the readings were recorded, then the same process was repeated for the left masseter, right and left temporalis.

The range of mandibular movements was assessed using ARCUS digma (ARCUS digma II, Kavo, Germany), first the upper face bow was secured to the upper arch using rubber base material to the bite fork and the spatial orientation of the maxillary arch was recorded while the patient was sitting upright. The para-occlusal clutch was prepared and attached to the patient's mandibular teeth (Figure 4). The patient was asked to perform the required mandibular movements which are the protrusive, lateral right and left border movements, to record maximum range of motion. The horizontal condylar inclination was calculated and displayed on the screen.

The maximum mouth opening (MMO) of the patients was recorded between the incisal edges of the upper and lower central incisors using a graduated ruler.

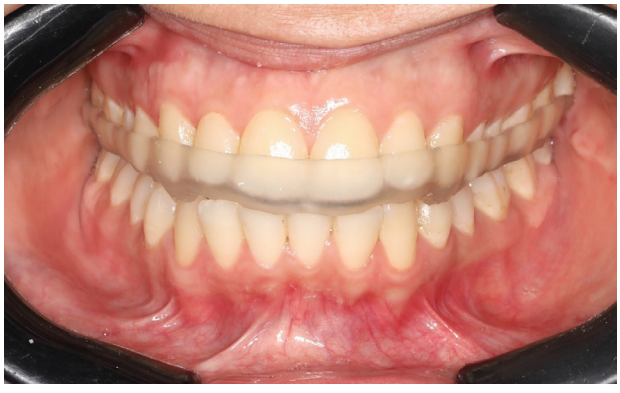

Figure 3 - Intraoral frontal view of Michigan splint.

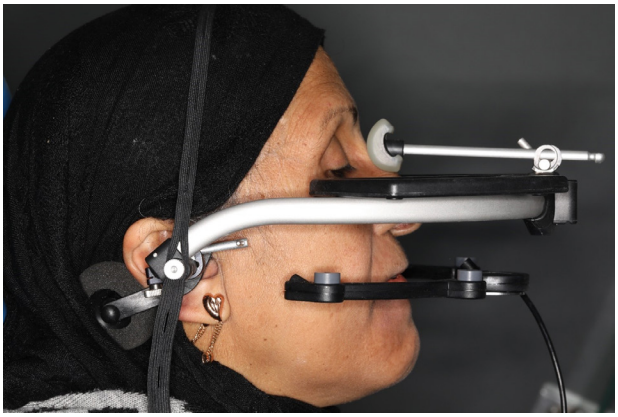

Figure 4 - ARCUS Digma facebow secured to the patient head to assess the mandibular movements.

The visual analogue scale is a widely used subjective measurement tool for the assessment of the severity of a certain pain in patients. The degree of pain intensity was recorded using a 10 cm scale that represents the spectrum from no pain to the worst pain. In this study the patients were asked to express the degree of pain they were experiencing using this scale. This was done before the beginning of treatment after 3 and 6 months.

After the assessment of the effect of the two treatment modalities during the three and six months follow up periods was done, data were collected.

Data analysis

All the patients involved in both groups continued the treatment and showed up for the follow up records, The four outcomes for the two treatment modalities were statistically analyzed to evaluate the significant difference between the baseline and post operative readings.

The numerical data for the 56 patients was collected and explored for normality by checking the distribution using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). All data showed non-normal (non-parametric) distribution except for MMO data which showed normal (parametric) distribution.

Parametric data were presented as mean, standard deviation (SD) values while non-parametric data were presented as median and range values. For parametric data, repeated measures ANOVA test was used to compare between the groups as well as to study the changes by time within each group. Bonferroni's post-hoc test was used for pair-wise comparisons when ANOVA test is significant.

For non-parametric data, Mann-Whitney U test was used to compare between the two groups. Friedman's test was used to study the changes by time within each group. Dunn's test was used for pair-wise comparisons when Friedman's test is significant. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS

Regarding the EMG (Table I) and VAS (Table II) records, pair-wise comparisons between time periods in each group revealed that, for the LLLT group there was statistically significant decrease in the muscles' activity and pain intensity in both three and six months readings, while in the splint group there was statistically significant decrease in the muscles' activity for both masseter and temporalis muscles and pain intensity at the three months follow up period when compared with the baseline data followed by non-statistically significant change at the six months follow up reading.

When the two groups were compared with each other, there was no statistically significant difference in the masseter muscle activity and pain intensity at the baseline data and at the three months follow up period, but when compared at the six months follow up period the splint group

Table I - Descriptive statistics and results of Mann-Whitney U test for comparison between muscle activities (Microvolt) in the two groups and Friedman's test for the changes within each group

Muscle	Time	LLLT (n = 56 muscles)		SPLINT (n = 56 muscles)		*P*-value	*Effect size (d)*
		Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Masseter	Pre-operative	218 (107-553) ^{A}	172.6 (57.2)	191 (89.7-239) ^{A}	172.6 (57.2)	0.057	0.844
	3 months	139 (81.7-169) ^{B}	131.1 (30.3)	137.5 (75.1-174) ^{B}	131 (30.3)	0.977	0.012
	6 months	82.7 (56-143) ^{C}	133.2 (30)	132 (78.6-170) ^{B}	133.2 (30)	0.001*	1.757
	P-value	<0.001*		0.001*			
	Effect size (w)	0.924		0.549			
Temporalis	Base line	215.5 (124-318) ^{A}	212.7 (60)	234.5 (154-450) ^{A}	249.5 (79.3)	0.402	0.347
	3 months	148.5 (105-242) ^{B}	154.6 (38.8)	143 (58.7-210) ^{B}	144.7 (40.6)	0.840	0.083
	6 months	119 (99.3-200) ^{C}	132.5 (35.2)	137.5 (70.2-289) ^{B}	145.6 (55.2)	0.544	0.249
	P-value	<0.001*		0.001*			
	Effect size (w)	0.924		0.632			

*Significant at $P \leq 0.05$. Different superscripts in the same column indicate statistically significant change by time.

Table II - Descriptive statistics and results of Mann-Whitney U test for comparison between pain (VAS) scores in the two groups and Friedman's test for the changes within each group

Time	LLLT (n = 28 patients)		SPLINT (n = 28 patients)		*P*-value	*Effect size (d)*
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Pre-operative	5 (4-8) ^{A}	5.5 (1.6)	5.5 (4-8) ^{A}	5.8 (1.5)	0.621	0.28
3 months	2.5 (1-3) ^{B}	2.3 (0.8)	3 (1-3) ^{B}	2.5 (0.8)	0.652	0.233
6 months	1 (0-1) ^{C}	0.7 (0.5)	3.5 (2-5) ^{B}	3.5 (1)	0.003*	3
P-value	0.002*		0.009*			
Effect size (w)	1		0.78			

*Significant at P ≤ 0.05. Different superscripts in the same column indicate statistically significant change by time. e same column indicate statistically significant change by time.

Table III - Descriptive statistics and results of Mann-Whitney U test for comparison between horizontal condylar inclination (°) in the two groups and Friedman's test for the changes within each group

Time	LLLT (n = 56 joints)		SPLINT (n = 56 joints)		*P*-value	*Effect size (d)*
	Median (Range)	Mean (SD)	Median (Range)	Mean (SD)		
Pre-operative	18 (-14.9-24.5) ^{B}	14.3 (11.5)	12.5 (1.9-23.1) ^{B}	13.1 (6)	0.225	0.511
3 months	29.4 (2-41.6) ^{A}	25.8 (11.8)	20.5 (2.7-39) ^{A}	20.6 (9)	0.069	0.8
6 months	32.8 (11.8-45.7) ^{A}	31.7 (9.9)	15.7 (2.6-25.4) ^{A}	15.8 (6.3)	0.001*	1.729
P-value	<0.001*		<0.001*			
Effect size (w)	0.924		0.924			

*Significant at P ≤ 0.05.Different superscripts in th.

Table IV - Descriptive statistics and results of repeated measures ANOVA test for comparison between MMO (cm) in the two groups and the changes within each group

Time	LLLT (n = 28 patients)		SPLINT (n = 28 patients)		*P*-value	*Effect size (Partial Eta squared)*
	Mean	SD	Mean	SD		
Pre-operative	3.2 ^{C}	0.22	3.32 ^{C}	0.47	0.591	0.03
3 months	3.75 ^{B}	0.21	4.08 ^{A}	0.5	0.165	0.183
6 months	4.15 ^{A}	0.23	3.92 ^{B}	0.5	0.319	0.099
P-value	<0.001*		0.001*			
Effect size (Partial Eta squared)	0.828		0.805			

*Significant at P ≤ 0.05. Different superscripts in the same column indicate statistically significant change by time.

showed a higher level of muscle activity and pain intensity which were statistically significant.

For the temporalis muscle, it was found that there was no significant difference in the muscle's activities in both groups either in the baseline data or in both follow up periods.

Regarding the change in the range of the horizontal mandibular movement (Table III), pair-wise comparisons between time periods in each group revealed that, within both groups there was statistically significant increase in the horizontal condylar inclination in the three months readings when compared to the baseline data, followed by non-statistically significant change at the six months follow up reading.

When the two groups were compared with each other, there was no statistically significant difference at the baseline data and at the three months follow up period, but when compared at the six months follow up period the splint group showed a lower level of horizontal condylar inclination which was statistically significant.

As for the MMO (Table IV), pair-wise comparisons between time periods in each group revealed that, within the LLLT group there was statistically significant increase in the MMO in both three and six months readings, while in the splint group there was statistically significant increase in the MMO at the three months follow up period when compared with the baseline data

followed by statistically significant decrease at the six months follow up reading but still statistically significant higher when compared with the baseline data.

When the two groups were compared with each other, there was no statistically significant difference at the baseline data and at the three and six months follow up periods.

DISCUSSION

Both LLLT and Michigan occlusal splint are considered effective conservative non- invasive techniques in the management of pain related TMDs, but the main objective of an effective treatment modality is to be sustainable, so this study aimed to evaluate whether the effect of both treatments would be sustainable or not after the patients stop the treatment.

In this study LLLT caused a significant difference in the EMG readings, and VAS records between the baseline data, and the three months follow up records, and also between the three and six months follow up records. This may be attributed to the therapeutic biostimulatory effect of low level LASER on the cells which improves the cells functions, increases the production of ATP [21-23], which in turn increases the activity of (Na^+/Ca^{2+}) exchanger protein, that is responsible for controlling the Ca^{2+} level, by removing one Ca^{2+} ion from the cell in exchange with 3 Na^+ ions into the cell, controlling the Ca^{2+} level is important for normal muscle contraction [16]. This occurs in conjunction with the improvement in the microcirculation and the inhibition in the transmission at the neuromuscular junction, leading to muscle relaxation [20-23].

Many studies have proven that the use of LLLT in treatment of TMDs causes improvement in both function and pain relief. The study done by Venezian et al. [25] to evaluate the effect of diode LASER (780 nm) in the management of myofascial pain by using the VAS, showed that there was a reduction in the pain level in both temporalis and masseter muscles, yet there was no significant change in the EMG records before and after the treatment. Mazzetto et al. [26] stated that when LLLT was applied to four points around the lateral pole of the condyles has proven to be effective in reducing the myofascial pain and improving the range of the mouth opening. The insignificant change in the readings of the temporalis muscle can be attributed to the limited area available for the admission of laser below the hair line.

There was significant improvement in the horizontal mandibular movement and the range of MMO, indicating that the use of LLLT with the suggested protocol had a profound effect on the involved muscles caused by its anti-inflammatory and pain-relieving effect, and this coincides with the results of previous studies [26-28].

In the group of patients that received the Michigan splint, there was an improvement in the EMG readings, VAS records and horizontal jaw movement readings at the three months follow up period when compared to the baseline data, but on comparing the three months follow up data with the six months recorded data, there was no statistically significant change and this is properly linked to the discontinuity of using the splint after the three months records were done.

Many researches have reported that the use of Michigan occlusal splint has proven its effectiveness in the relief of muscle pain over time [27-30], but the exact hypothesis for the improvement in muscle activity and pain relief is still controversial. As some studies [30-33] suggest that the relief of the pain was caused by the elimination of the occlusal discrepancies leading to “interference free” occlusion, while others [31,34] adopted the concept of the cognitive theory, that the use of the splint change the oral environment affecting the available space for the tongue, making the patients aware of their habit and conscious about the position of the mandible, also being aware of the presence of a foreign object intraorally causes alteration in the peripheral sensory input to central nervous system (CNS) decreasing the CNS induced bruxism, but when the patient accommodates to the splint, they usually show symptoms of bruxism [35]. Another theory suggested that the increase in the vertical dimension of rest results in muscle relaxation [31,36].

Although the use of splints is very effective in reducing myofascial pain, several studies reported that it has short term effect. Kuzmanovic Pficer et al. [37], this meta-analysis study included thirty three randomized control trials that compared between the SS with other treatment modalities, it proved that the SS has positive short-term effect on the reduction of pain and improvement of the mandibular movement,

but in the long-term follow up there was no significant difference between the SS group and the control group, and this is also supported by the findings in this study, as there was no significant difference between the three and six months EMG, VAS and horizontal condylar guidance records for the splint group when the patient ceases to use the splint after 3 months from the beginning of the treatment.

CONCLUSION

The null hypothesis was rejected due to the significant difference between the two groups as LLLT had a better and more sustainable effect on reducing the pain intensity and improving the muscle activity as well as the mandibular movement when compared to Michigan splint.

Based on the findings of this study it has been showed that the use of LLLT has a more profound and sustainable effect in the management of muscle pain and in the improvement of the mandibular movements in cases with TMDs when compared to Michigan splint.

Author's Contributions

AMSF: Conceptualization, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing, Resources. RMG: Visualization, Supervision, Project Administration. DEB: Formal Analysis, Investigation, Resources, Data Curation, Writing – Review & Editing.

Conflict of Interest

All authors declare that they have no conflicts of interest.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of: Ethics committee of scientific research, Faculty of Dentistry, Ain Shams university, the approval code is: FDASU-REC IR112207, and registered at www.clinicaltrials.gov with reference no. NCT05901701.

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