Laser Therapy and Occlusal Stabilization Splint for Temporomandibular Disorders in Patients With Fibromyalgia Syndrome: A Randomized, Clinical Trial

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ABSTRACT

Context • Patients with fibromyalgia syndrome (FMS) report frequent and severe symptoms from temporomandibular disorders (TMDs). The appropriate treatment of TMDs remains controversial. No studies have occurred on the efficacy of therapy with a laser or an occlusal stabilization splint in the treatment of TMDs in patients with FMS.

Objective • The study intended to investigate the therapeutic effects of laser therapy and of an occlusal stabilization splint for reducing pain and dysfunction and improving the quality of sleep in patients with TMDs and FMS.

Design • The research team designed a single-blinded, randomized clinical trial.

Setting • The study took place in the research laboratory at the University of Granada (Granada, Spain).

Participants • Participants were 58 women and men who had been diagnosed with FMS and TMDs and who were referred from the clinical setting.

Intervention • Participants were randomly assigned to the occlusal-splint or the laser group. The laser group received a treatment protocol in which laser therapy was applied to the participant's tender points, and the occlusal-splint group underwent a treatment protocol in which an occlusal stabilization splint was used. Both groups underwent treatment for 12 wk.

Outcomes Measures • Pain intensity, widespread pain, quality of sleep, severity of symptoms, active and passive mouth opening, and joint sounds were assessed in both groups at baseline and after the last intervention. The measurements used were (1) a visual analogue scale (VAS), (2) the Widespread Pain Index (WPI), (3) the Symptom Severity Scale (SSS), (4) the Patient's Global Impression of Change (PGIC), (5) the Pittsburgh Quality of Sleep Questionnaire Index (PSQI), (6) an assessment of the number of tender points, (7) a measurement of the active mouth opening, (8) a measurement of the vertical overlap of the incisors, and (9) the measurement of joint sounds during mouth opening and closing.

Results • The group X time interaction for the 2×2 mixed analysis of variance found no statistically significant differences between the 2 treatment groups: (1) VAS, $P = .591$; (2) WPI, $P = .112$; (3) SSS, $P = .227$; (4) PGIC, $P = .329$; (5) number of tender points, $P = .107$; (6) right and left clicking sounds in the jaw joint during palpation at mouth opening, $P = .723$ and $P = .121$, respectively; and (7) right and left clicking sounds in the jaw joint during palpation at mouth closing, $P = .743$ and $P = .698$, respectively. Compared with baseline, the laser treatment showed significant improvements on several outcomes, including the VAS, $P < .001$; WPI, $P = .003$; and SSS, $P = .001$. Overall, the study found an average improvement in symptoms from baseline of 21% , $P < .001$, based on the PGIC.

Conclusions • Laser therapy or an occlusal stabilization splint can be an alternative therapeutic treatment for reducing pain symptoms and the clicking sound for TMDs in patients with FMS. (*Altern Ther Health Med.* 2016;22(5):23-31.)

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Fibromyalgia syndrome (FMS) is a chronic pain condition affecting soft tissues, which is characterized by generalized musculoskeletal pain that is associated with persistent fatigue, generalized morning stiffness, nonreparative sleep, headaches, irritable bladder, dysmenorrhea, restless legs, an undefined pattern of numbness, tingling, and intolerance to exercise.[1] Patients with FMS report frequent and severe symptoms of temporomandibular disorders (TMDs).

FMS patients show a significantly longer duration of general body pain than of TMDs, which indicates that FMS begins in other parts of the body and extends to the temporomandibular region. FMS has a significant effect on the progression of TMDs pain, and it represents a risk factor for progression of chronic orofacial pain.[2]

TMDs are a heterogeneous group of conditions affecting the temporomandibular joint, masticatory muscles, and associated structures. The disorders are frequently associated with chronic pain. Structural factors, especially occlusion and psychological factors, are among the most important etiological considerations that have been associated historically with the pathology.[3]

In the United States, the prevalence of TMDs is estimated to be between 5% and 15%. The National Institute of Dental and Craniofacial Research has estimated that TMDs cost an average of $4 billion annually.[4] Similarly to FMS, most of the studies evaluating TMD differences between genders have shown a greater prevalence of TMD symptoms in women.[5] It is a disease related to the female gender, because women are 3 times more affected than men.[6]

Presently, the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) index, which has been proposed by Dworkin and LeResche, is accepted as the best and most widely used classification for TMDs. Those authors adopted a multidimensional perspective in the evaluation of TMDs, which incorporates the study of chronic pain based on the parallelism found between patients with TMDs and patients with other chronic pain syndromes.[7,8]

The appropriate treatment of TMDs remains controversial. Several treatments have been used, including the occlusal splint, relaxation therapy, educational therapies, pharmacological interventions, and physiotherapy.[9,10] Occlusal splints have been used as an important modality for the management of TMDs, with the most common category being a stabilization splint. A reduction in muscle activity, an increase in the vertical dimension of occlusion, improvement in occlusal stability, a placebo effect, and cognitive alterations are listed as possible beneficial effects of the occlusal splint.[10]

Although a range of physiotherapy modalities exist for TMDs management, laser therapy is more frequently used than others, because of its conservative and analgesic nature and its anti-inflammatory effects in the target tissue.[11] The mechanisms involved in the pain reduction and therapeutic effects from the laser include a release of endogenous opioids that enhances cell respiration and tissue healing, decreases inflammation, and increases vasodilatation and pain threshold.[11,12]

In general, treatment with lower-level laser therapy has had a positive psychological effect for chronic patients.[13] However, researchers have been able to draw no definitive conclusions on the efficacy of lower-level laser therapy for the treatment of TMDs because many methodological differences have existed among the studies regarding the number and duration of treatments and the type of laser beam. Those differences prevent the creation of standardized guidelines for effective treatment with lower-level laser therapy.[9]

Previous studies have shown controversial results on the efficacy of laser therapy in the management of TMDs. Meta-analyses performed by McNeely et al[14] and Pretrucci et al[15] did not demonstrate beneficial effects for laser therapy on the pain that TMDs can cause. In addition, no studies have occurred on the efficacy of therapy with a laser or an occlusal stabilization splint in the treatment of TMDs in patients with FMS. The purpose of the current study was to investigate the therapeutic effects of laser therapy and of an occlusal splint for reducing pain, improving the quality of sleep, decreasing dysfunction, and diminishing joint sounds in patients with TMDs and FMS.

METHODS

A single-blinded, randomized clinical trial was conducted.

Participants

The research team recruited females and males who had been diagnosed with FMS previously to the recruitment from their rheumatologist, according to the criteria of the American College of Rheumatology,[15] and with TMDs, based on the RDC/TMD.[7] Seventy-four consecutive patients who attended the clinical of dentistry from the University of Granada and AGRAFIM (association of fibromyalgia from the city of Granada, Spain) were screened for eligibility, and 58 patients met the criteria.

Inclusion criteria were (1) an FMS diagnosis, (2) the presence of TMDs, (3) a pretreatment visual analog score (VAS) score of >30 mm, (4) pain of muscle origin that was confirmed by palpation, (5) availability for the study's schedule, and (6) willingness to attend the evening sessions of therapy.

Exclusion criteria were (1) a history of recent trauma, (2) use of therapeutic cointerventions during treatment, (3) an indication for surgical treatment of the temporomandibular joint, (4) physical or mental illness that

precluded attendance at therapy sessions, (5) pain attributable to a confirmed neck pain condition, (6) acute infection, and (7) the presence of a collagen vascular disease.

Informed consent was obtained from all participants, and the study was conducted according to the 2008 modification of the Helsinki Declaration and to current Spanish legislation covering clinical trials (Royal Decree 2008). The study was approved by the Bioethics Committee of Granada (Granada, Spain).

Procedures

At baseline, patients provided demographic and clinical information about their ages, professions, times of diagnosis, and educational levels and about the drugs that they were taking at the time of the study.

Patients were allocated to either a laser group or an occlusal-splint group, 29 participants to each group. Stratified, balanced randomization was performed to guarantee a balance between the groups in the type of medication that they were receiving for FMS symptoms. The groups were balanced for type of medication received, using a stratification system that generates a sequence of letters for each combination of categories. Sequences were derived from a table of correlatively ordered permutations of the letters A and B in groups of 6, with each letter appearing 3 times (AAABBB, ABABAB, etc). The sequences assigned to patients were placed in envelopes containing the allocation to each study group.

All outcome measures were completed by participants in both groups at baseline and immediately after the last intervention (ie, at the end of the 12 wk of the study) by an assessor blinded as to the treatment allocation of the participants. Inclusion criteria were administered to all potential participants, and the outcomes measures were evaluated only to the 58 people who were included.

Interventions

The patients in the laser group received treatments at a peak power of 80 W, with an average power of 50 mW, a pulse-repetition rate of 1.500 Hz, a pulse length of 1 μs, and a dose of 3 J/cm^2 for 2 minutes per point. The laser therapy was applied to the tender points that had been selected during the first examination (when outcomes measures were collected at baseline), using the Láser (Enraf-Nonius Ibérica SA, Madrid, Spain). Patients underwent laser therapy for 12 weeks, receiving 1 session per week.

The occlusal-splint group received stabilization-splint therapy. The occlusal splints were fabricated in a laboratory of the Faculty of Dentistry at the University of Granada. The protocol was as follows: (1) an impression of the maxilla was made with chromatic alginate, Phase Plus from Zhermack (Rovigo, Italy); (2) the working models were emptied into a plaster stone type IV, the Elite Rock by Zhermack; (3) the occlusal splints were fabricated with terephthalic-acid polyester that was 3 mm thick, Clear Model 120 from Dentaflux (Ripoll, Madrid, Spain); it was used in a molding machine with a thermoplastic vacuum plate, the Machine by Dentaflux. After obtaining the occlusal splint, each patient agreed to wear it during sleep every night, for an average of 8 hours per night, for the 12 weeks of treatment.

Outcome Measures

The measurements used were (1) a VAS, (2) the Widespread Pain Index (WPI), (3) the Symptom Severity Scale (SSS), (4) the Patient's Global Impression of Change (PGIC), (5) the Pittsburgh Quality of Sleep Questionnaire Index (PSQI), (6) an assessment of the number of tender points, (7) a measurement of active mouth opening, (8) a measurement of the vertical overlap of the incisors, and (9) the measurement of joint sounds during mouth opening and closing.

Visual Analogue Scale. The intensity of pain as shown on a VAS was defined as the primary outcome. A 100-mm VAS was used for determining pain intensity, the scores on which could range from 0 = no pain to 100 = very severe pain.

Widespread Pain Index. The index was used to assess the pain threshold and the extent of the pain.[16] The WPI is a part of the ACR 2010 and the modified 2010 criteria. The WPI score is between 0 and 19. This index involves a checklist of 19 areas of the body. If the patient has felt pain in the specific area in the past 7 days, a check is made and a score 1 is given.

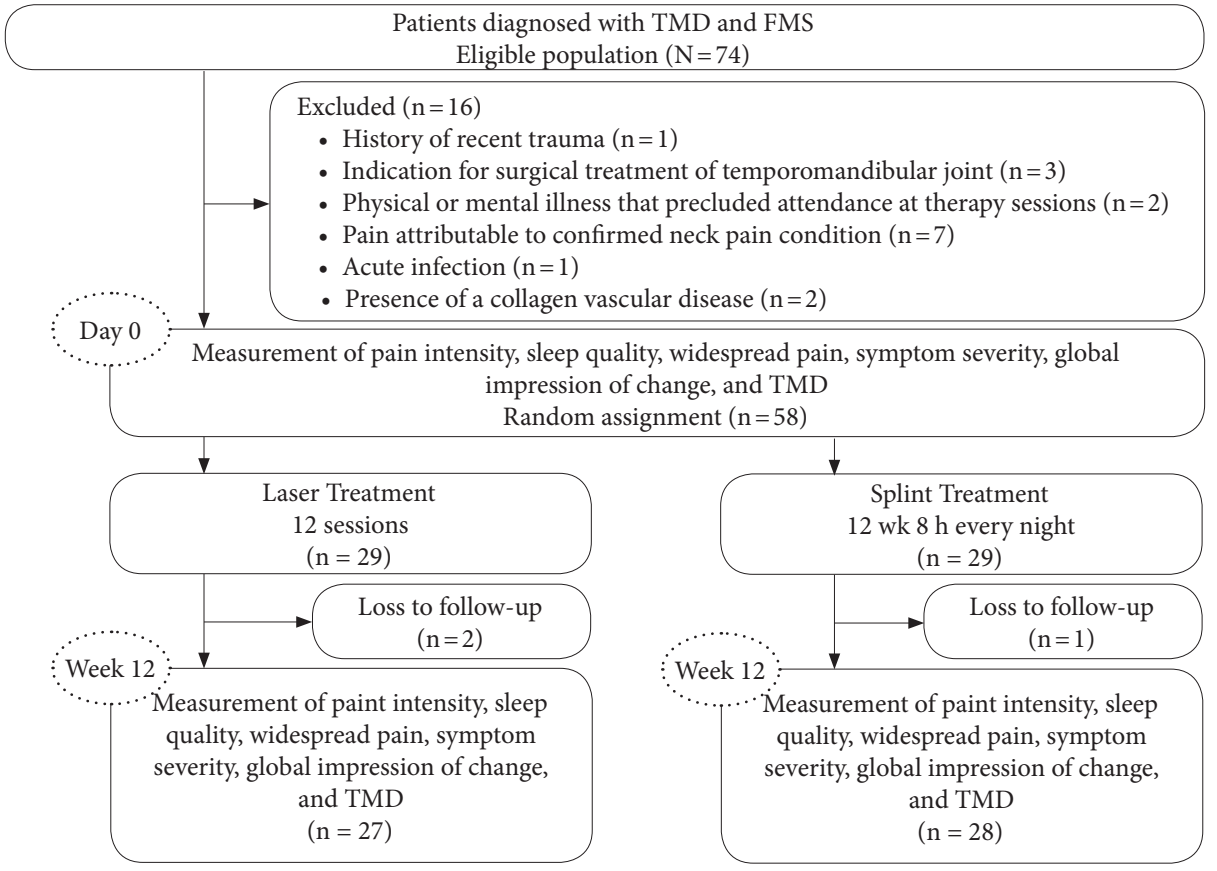
Symptom Severity Scale. The scale is used to assess the severity of symptoms in people with current or previous FMS and in individuals for whom the criteria have not yet been applied. The WPI is a part of the ACR 2010 criteria. The questionnaire is especially useful in the longitudinal evaluation of patients with a marked symptomatic variability as a quantitative measure of symptom severity.[15,16] The SSS considers the severity of symptoms in 4 categories unrelated to pain (including fatigue, cognitive problems, etc). There are rated on a scale from 0 to 3 for a total possible score of 12.

Global Impression of Change. Clinically important improvement was assessed with a modified, 5-point version of the PGIC. Participants were asked to score the change on the following scale: much improved, slightly improved, no change, slightly worsen, and much worse.[17]

Pittsburgh Quality of Sleep Questionnaire Index. The questionnaire was used to study participants' quality of sleep. It comprises 24 items, with the patient responding to 19 of the items and with an individual living in the same dwelling or hospital room responding to the remaining 5 items. Scores are obtained on each of 7 components of sleep quality: (1) subjective quality, (2) sleep latency, (3) sleep duration, (4) habitual sleep efficacy, (5) sleep perturbations, (6) use of hypnotic medication, and (7) daily dysfunction. Each component is scored from 0 to 3, with 0 = no problems and 3 = severe problems. All scores are summed to determine the total score, by adding the component scores, which can range from 0 to 21. The reliability coefficient of the PSQI is 0.78.[17,18]

Number of Tender Points. A minimum of 0 and a maximum of 36 points were assessed by palpation of a possible 18 points on both sides, including (1) 3 points on the joint capsule—lateral, posterior, and superior; (2) 3 points on

Figure 1. Flow Diagram of Participants In the Course of the Study



Abbreviations: TMD, temporomandibular disorder; FMS, fibromyalgia syndrome.

the masseter—anterior, inferior, and deep; (3) 3 points on the temporal—anterior, deep middle, and origin); (4) 2 points on the pterygoid—medial and lateral; (5) 3 points on the sternocleidomastoid—upper, middle, and lower); (6) 2 points on the trapezius—origin and upper; (7) 2 points on the splenius capitis muscles.[17]

Active and Passive Mouth Opening. The participant was asked to open her or his mouth as much as possible for the measurement of the active mouth opening without pain and the maximal active mouth opening. The maximal, passive mouth opening was measured after the application of downward pressure on the mandible by the patient's second and third finger.

Vertical Overlap of the Incisors. The overlap was measured by a ruler (Helios-Preisser, Gammertingen, Germany) and recorded in mm for the parameters.[19,20]

Joint Sounds During Mouth Opening and Closing. The clicking was assessed with the examiner's left index finger on the right joint and right finger on the preauricular area. The fingertip was placed anteriorly to the tragus of the ear. The participant was asked to open his or her mouth slowly as much as possible. After each closing, the participant had to place his or her teeth in contact at a maximal intercuspal position. Participants opened and close their mouths 3 times. The total number of sounds was recorded for both sides.[21]

Statistical Analysis

Data were analyzed with SPSS software (version 20.0, IBM, Armonk, NY, USA) and the analyses were conducted following the intention-to-treat analysis by forwarding the last value assessed as the posttreatment value. The number of participants was estimated by a sample calculation that considered a difference of at least 36 units, with a value of $\alpha = 0.05$ and $\beta = 0.08$, defining the smallest size for each group as 18 patients.[22] The sample size was increased to a total of 58 participants to allow for a loss to follow-up of up to 40%.

Baseline demographic and clinical variables were examined between both groups using the independent Student *t* test for continuous data and χ^2 tests of independence for categorical data. A separate, 2×2, mixed-model analysis of variance (ANOVA) was performed, with time pre- and postintervention as the within-participants factor, and the group occlusal splint or laser was used to determine the effects of the treatment on pain, dysfunction, global impression of change, and quality of sleep. Effect sizes were calculated using Cohen's *d* coefficient for all variables. An effect size of <0.2 reflects a negligible difference, one between ≥0.2 and ≤0.5 a small difference, one between ≥0.5 and ≤0.8 a moderate difference, and one ≥0.8 a large difference. The hypothesis of interest was the group X time interaction, at an a priori, α-level equal to 0.05.

Table 1. Demographic Characteristics of Both Groups

Characteristics	Occlusal-Splint Group (n = 29) n, mean, or %	Laser Group (n = 29) n, mean, or %	*P* Value
Gender, female/male, n	28/1	27/2	.242
Age, y, mean ± SD	51.79 ± 7.79	51.00 ± 8.32	.840
Profession, %			
Housewife	60.71	70.13	.109
Business	14.28	11.11	.429
Administrative staff	25	18.51	.203
Time since diagnosis of FM, %			
1–5 y	10.71	3.70	.038[a]
6–10 y	35.71	29.62	.288
11–15 y	28.57	44.44	.018[a]
16–20 y	17.85	14.81	.477
>20 y	7.14	7.40	1.000
Time since diagnosis of TMD, %			
1–5 y	17.85	22.22	.203
6–10 y	25	37.03	.109
11–15 y	21.42	14.81	.171
16–20 y	17.85	14.81	.477
>20 y	17.85	11.11	.132
Educational level, %			
Primary studies	67.85	62.96	.288
Higher education	32.14	37.03	.288

[a]*P* < .05 (95% confidence interval).

Abbreviations: FM, fibromyalgia; TMD, temporomandibular disorder.

RESULTS

Fifty-eight patients, with a mean age of 51 ± 8 years and 94% female and 6% male, satisfied all the eligibility criteria, agreed to participate, and were randomly assigned to the laser (n = 29) and occlusal-splint (n = 29) groups. The reasons for ineligibility are found in Figure 1, which provides a flow diagram of patient recruitment and retention. One participant in the occlusal-splint group and 2 participants in the laser group dropped out. Characteristics at baseline between groups are shown in Table 1.

Table 2 shows the mean scores with the standard deviations before and after the 2 interventions for the WPI, SSS, VAS, PGIC, PSQI, number of tender points, active and passive mouth opening, and joint sounds. Table 3 shows the mean scores with their respective 95% confidence intervals and Cohen's *d* effect sizes for the same measures.

WPI and SSS. The laser group showed statistically significant postintervention improvements on the WPI (*P* = .003) and the SSS (*P* = .001). The occlusal-splint group also showed statistically significant postintervention improvements on the WPI (*P* = .004) and the SSS (*P* = .001).

VAS and PGIC. The laser group showed statistically significant postintervention improvements in the VAS (*P* < .001) and the PGIC (*P* = .001). The occlusal-splint

Table 2. Statistical Differences Within Groups for WPI, SSS, VAS, PGIC, PSQI, Number of Tender Points, Active and Passive Mouth Opening, and Joint Sounds

Outcome	Occlusal-Splint Group (n = 29) Preintervention Mean ± SD	Occlusal-Splint Group (n = 29) Postintervention Mean ± SD	*P* Value	Laser Group (n = 29) Preintervention Mean ± SD	Laser Group (n = 29) Postintervention Mean ± SD	*P* Value
WPI	15.62 ± 2.89	13.45 ± 4.16	.004[a]	15.59 ± 3.50	14.62 ± 3.75	.003[a]
SSS	9.72 ± 1.93	8.07 ± 2.82	.001[a]	9.72 ± 2.99	8.69 ± 3.04	.001[a]
VAS	76.55 ± 14.71	66.55 ± 21.92	.005[a]	78.62 ± 20.13	70.69 ± 19.07	.001[a]
PGIC	4.41 ± 0.87	3.48 ± 1.18	.003[a]	4.45 ± 0.78	3.83 ± 0.54	.001[a]
PSQI	16.00 ± 3.17	13.69 ± 4.05	.001[a]	14.07 ± 4.38	13.45 ± 4.68	.007[a]
No. of tender points	11.86 ± 2.31	6.76 ± 1.53	.001[a]	11.69 ± 2.24	7.24 ± 1.81	.001[a]
Active mouth opening without pain	27.34 ± 5.15	30.03 ± 5.08	.001[a]	26.10 ± 5.22	27.45 ± 5.27	.001[a]
Maximal active mouth opening	37.17 ± 6.23	38.41 ± 6.29	.001[a]	34.72 ± 5.04	35.34 ± 5.29	.001[a]
Maximal passive mouth opening	40.79 ± 6.13	42.47 ± 6.16	.001[a]	38.34 ± 5.32	39.24 ± 5.74	.001[a]
Right clicking sound during palpation when opening	0.28 ± 0.46	0.10 ± 0.31	.023[a]	0.31 ± 0.47	0.17 ± 0.38	.043[a]
Left clicking sound during palpation when opening	0.21 ± 0.41	0.17 ± 0.38	.573	0.45 ± 0.51	0.24 ± 0.44	.031[a]
Right clicking sound during palpation when closing	0.24 ± 0.44	0.03 ± 0.19	.012[a]	0.34 ± 0.48	0.17 ± 0.38	.023[a]
Left clicking sound during palpation when closing	0.21 ± 0.41	0.03 ± 0.19	.023[a]	0.41 ± 0.50	0.21 ± 0.41	.012[a]

[a]*P* < .05 (95% confidence interval).

Abbreviations: WPI, Widespread Pain Index; SSS, Symptom Severity Scale; VAS, visual analog scale; PGIC, Patient's Global Impression of change; PSQI, Pittsburgh Quality of Sleep Questionnaire Index; SD, standard deviation.

Table 3. Changes in Scores for the 2 Groups for the WPI, SSS, VAS, PGIC, PSQI, Number of Tender Points, Active and Passive Mouth Opening, and Joint Sounds

Outcome/Group	Within-group Score Changes Means (95% CI)	Between-group Differences in Score Changes Means (95% CI)	Effect Sizes (Cohen's *d*)
WPI			
Occlusal-splint group	2.172 (0.764 to 3.581)	-1.172 (-3.255 to 0.911)	0.614
Laser group	0.966 (0.369 to 1.562)		0.267
SSS			
Occlusal-splint group	1.655 (0.722 to 2.588)	-0.621 (-2.161 to 0.920)	0.696
Laser group	1.034 (0.574 to 1.495)		0.341
VAS			
Occlusal-splint group	10.000 (3.334 to 16.666)	-4.138 (-14.947 to 6.671)	0.546
Laser group	7.931 (3.817 to 12.045)		0.404
PGIC			
Occlusal-splint group	0.931 (0.339 to 1.523)	-0.345 (-0.829 to 0.139)	0.907
Laser group	0.621 (0.363 to 0.878)		0.937
PSQI			
Occlusal-splint group	2.310 (1.215 to 3.406)	0.240 (-2.063 to 2.546)	0.639
Laser group	0.620 (0.184 to 1.057)		0.137
No. of Tender Points			
Occlusal-splint group	5.103 (4.543 to 5.663)	-0.483 (-1.363 to 0.397)	0.659
Laser group	4.448 (3.850 to 5.046)		0.200
Active Mouth Opening Without Pain			
Occlusal-splint group	-2,689 (-3.145 to -2.233)	2.586 (-1.384 to 5.310)	0.525
Laser group	-1.344 (-1.701 to -0.988)		0.256
Maximal Active Mouth Opening			
Occlusal-splint group	-1.241 (-1.522 to -0.960)	3.068 (0.009 to 6.128)	0.198
Laser group	-0.620 (-0.948 to -0.292)		0.119
Maximal Passive Mouth Opening			
Occlusal-splint group	-1.655 (-1.981 to -1.329)	3.206 (0.076 to 6.337)	0.269
Laser group	-0.896 (-1.355 to -0.438)		0.162
Right Clicking Sound During Palpation When Opening			
Occlusal-splint group	0.172 (0.026 to 0.319)	-0.069 (-0.253 to 0.115)	0.471
Laser group	0.138 (0.004 to 0.271)		0.327
Left Clicking Sound During Palpation When Opening			
Occlusal-splint group	0.034 (-0.089 to 0.158)	-0.069 (-0.285 to 0.147)	0.100
Laser group	0.207 (0.020 to 0.394)		0.445
Right Clicking Sound During Palpation When Closing			
Occlusal-splint group	0.207 (0.050 to 0.364)	-0.138 (-0.297 to 0.021)	0.677
Laser group	0.172 (0.026 to 0.319)		0.391
Left Clicking Sound During Palpation When Closing			
Occlusal-splint group	0.172 (0.026 to 0.319)	-0.172 (-0.341 to -0.004)	0.602
Laser group	0.207 (0.050 to 0.364)		0.438

Note: An effect size of <0.2 reflects a negligible difference; between ≥0.2 and ≤0.5, a small difference; between ≥0.5 and ≤0.8, a moderate difference; and ≥0.8, a large difference.

Abbreviations: WPI, Widespread Pain Index; SSS, Symptom Severity Scale; VAS, visual analogue scale; PGIC, Patient's Global Impression of Change; PSQI, Pittsburgh Quality of Sleep Questionnaire Index.

group also showed statistically significant postintervention improvements in the VAS ($P = .005$) and the PGIC ($P = .003$).

PSQI. The laser group and occlusal splint both showed statistically significant postintervention improvements on the PSQI, with $P < .001$ and $P < .007$, respectively.

Number of Tender Points. The laser group and occlusal-splint group both showed statistically significant postintervention improvements in the number of tender points, with $P < .001$ for each group.

Active and Passive Mouth Opening. The laser group showed statistically significant postintervention improvements in the measurements for active mouth opening ($P = .001$), maximal active mouth opening ($P = .001$), and maximal passive mouth opening ($P = .001$). The occlusal-splint group also showed statistically significant postintervention improvements in in the measurements for active mouth opening ($P = .001$), maximal active mouth opening ($P = .001$), and maximal passive mouth opening ($P = .001$).

Joint Sounds. The laser group showed statistically significant postintervention improvements in the occurrence of the right clicking sound in the jaw joint during palpation when opening ($P = .043$), of the left clicking sound in the jaw joint during palpation when opening ($P = .031$), of the right clicking sound in the jaw joint during palpation when closing ($P = .023$), and of the left clicking sound in the jaw joint during palpation when closing ($P = .012$). The occlusal-splint group showed statistically significant postintervention improvements in the occurrence of the right clicking sound in the jaw joint during palpation when opening ($P = .023$), of the right clicking sound in the jaw joint during palpation when closing ($P = .012$), and of the left clicking sound in the jaw joint during palpation when closing ($P = .023$). The group didn´t show a significant difference in the left clicking sound in the jaw joint during palpation when opening.

Group X Time Interaction. The 2×2 mixed-model ANOVA with repeated measurements showed group X time interactions that were statistically significant on the PSQI ($F = 8.617$; $P = .005$), for the measurement of active mouth opening without pain ($F = 22.677$; $P = .001$); for the measurement of maximal active mouth opening ($F = 8.656$; $P = .005$); and for the measurement of maximal passive mouth opening ($F = 7.631$; $P = .008$).

The group X time interaction for the 2×2 mixed ANOVA did not find a statistically significant result on the VAS ($F = 0.293$; $P = .591$); on the WPI ($F = 2.610$; $P = .112$); on the SSS ($F = 1.493$; $P = .227$); on the PGIC ($F = 0.969$; $P = .329$); for the measurement of the right clicking sound in the jaw joint during palpation when opening ($F = 0.127$; $P = .723$); for the measurement of the left clicking sound in the jaw joint during palpation when opening ($F = 2.482$; $P = .121$); for the measurement of the right clicking sound in the jaw joint during palpation when closing ($F = 0.109$; $P = .743$); for the measurement of the left clicking sound in the jaw joint during palpation when closing ($F = 0.121$; $P = .698$); and for the number of tender points ($F = 2.684$; $P = .107$).

DISCUSSION

For TMDs in patients with FMS, the results of the current randomized clinical trial have suggested that treatment with laser therapy or an occlusal stabilization splint for 12 weeks result in similar outcomes in widespread pain, severity of symptoms, pain intensity, global impression of change, number of tender points, and joint sounds. However, the occlusal stabilization splint treatment showed major improvements in sleep quality, active mouth opening without pain, maximal active mouth opening, and maximal passive mouth opening in comparison with laser therapy.

Many studies have shown that laser therapy can be effective in reducing pain from TMDs. However, those studies have suggested that the effectiveness of laser therapy is more accentuated with the use of higher irradiation protocols, a larger number of sessions, and greater frequency of application.[23-26] Nevertheless, several studies have shown controversial results on the efficacy of laser therapy in the management of TMDs.[14,15]

The many methodological differences among the studies, especially regarding the number, duration, wavelength, and frequency of laser applications, prevent development of standardized guidelines for effective treatment of TMDs with laser therapy.[27-30] The occlusal-splint group in the current study exhibited a more moderate effect size than patients in the laser group on the WPI and the SSS.

The widespread pain associated with fibromyalgia can play a significant role in the chronicity of patients with TMDs. The presence or absence of widespread pain may help to define the specific circumstances under which oral splints should be prescribed for patients with myofascial face pain. The results of the current study cannot be compared to other studies that link a conservative treatment of the stomatognathic system to general health parameters that have been recorded in patients with fibromyalgia.

Raphael and Marbach[31] have concluded that patients with widespread pain and myofascial face pain who received an active splint did not experience improvements, whereas patients with local pain who received the active splint did. It is likely that the multiple symptoms of FMS, such as widespread pain, fatigue, sleep disturbances, and so forth may be the result of the high somatization scores in FMS.[32] The relationship of comorbidity between TMDs and FMS may indicate the existence of some form of central sensitization sharing neurochemical events.[33]

Both groups exhibited significant statistical differences after intervention for pain intensity and number of tender points. Previous studies have reported that an elevated percentage of FMS patients had pain or tenderness upon palpation of the temporomandibular joint.[34,35] Studies have not documented that individuals with myofascial face pain who are given occlusal stabilization splints to wear and who are provided with education for behavioral changes, reported earlier significant improvements compared with individuals who received an anterior-device, nociceptive trigeminal inhibition system or counseling for behavioral changes and

self-care.[10] It has been hypothesized that occlusal splints have a cognitive awareness component, likely related to changes in the tongue position during sleep due to the presence of a foreign object in the oral cavity. Pain reduction is often produced by the development of consciousness of the position and of the potentially harmful use of the jaw and of changes in the intramuscular recruitment pattern.[10,35]

In our study, an important finding was the high percentage of patients who were responsive to the treatment, including those in the occlusal-splint group who had decreased their VAS value by at least 65% versus a 44% decrease in the laser group. Those results are similar to those obtained through the treatment for TMDs with an occlusal splint and electromyography control.[36]

Laser therapy has an analgesic, anti-inflammatory, antiedematous, and biostimulatory effect, which has proven to be effective in reducing pain and muscle tension in patients with TMDs.[11,23] Previous studies have focused on the immediate effects of laser therapy.[37,38] Those studies have evaluated pain symptoms after each session. However, several studies have demonstrated the cumulative effects of laser therapy.

In the current study, a significant reduction of pain occurred after 12 sessions of laser therapy. Those results agree with the findings of Hara et al[39] who found an accumulative effect for laser therapy after 12 laser applications, but the significant improvements in pain were not observed after 6 applications. Kato el al[36] had observed that the positive effects of laser treatment were achieved after 8 sessions, and the immediate effect was not significant regarding pain reduction. In addition, in a study about the efficacy of low-level laser therapy for the treatment of myogenous temporomandibular joint disorder, the laser group experienced a 36% increase in mouth opening after 12 laser applications, indicating the effectiveness of laser therapy in promoting mandibular range of motion in TMDs patients.[11]

An interesting finding in the current study was that the occlusal-splint group showed a greater improvement in quality of sleep as compared to the laser group. The association between pain symptoms and sleep disturbances has been reported in patients with TMDs and FMS. In fact, sleep disorders in FMS may be due to a pre-sleep pain condition. It is possible that improvements in sleep can lead to less pain in the morning.[40] The negative effects associated with poor sleep are the first factor that predicts pain in individuals with fibromyalgia.[40] The moderate effect size of occlusal decompression therapy versus laser therapy can be justified by the fact that the occlusal splint was worn during sleep every night, because it is a bite splint.

In the current study, both groups showed a small effect size for the measurement of maximal active and passive mouth opening and of the right and left clicking sounds in the jaw joint during palpation when opening the mouth. The effects in the occlusal-splint group were similar to those obtained by stabilization splints in the treatment of temporomandibular joint, pain-dysfunction syndrome.[41]

The current research team recognizes some limitations of the current study. First, only a single physiotherapist performed the treatments. It is possible that the therapist's personal skills might have biased the results. Second, a placebo control group was not included. Third, the research team did not assess the results during a follow-up period after the intervention. The findings, however, have provided relevant preliminary data that can guide future interventions in patients with FMS and TMDs. Further studies are now needed to analyze interventions in relationship to specific psychological circumstances.

CONCLUSION

In the current study, laser therapy and occlusal stabilization splint therapy exhibited similar decreases in widespread pain, severity of symptoms, pain intensity, global impression of change, number of tender points, and clicking sounds during palpation when opening and closing the mouth for patients with TMD disorders and FMS. Based on the results of the current study, laser therapy or an occlusal stabilization splint can be an alternative therapy for reducing pain symptoms and clicking sounds for TMDs in patients with FMS. Futures studies are now needed to research multiple therapeutic approaches commonly used in the management of FMS- and TMD-related symptoms.

AUTHOR DISCLOSURE STATEMENT

The authors declare that they have no potential conflicts of interest with respect to the research, authorship, and/or publication of the manuscript.

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