Received: 4 February 2023 | Revised: 18 April 2023 | Accepted: 7 September 2023

DOI: 10.1111/joor.13593

JOURNAL OF ORAL REHABILITATION WILEY

ORIGINAL ARTICLE

Occlusal splint and combined multiwave locked system laser therapy demonstrated differential patient-reported outcomes and clinical parameters: A randomized controlled trial in patients with temporomandibular disorder

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Funding information
Grants for Development of New Faculty Staff, Ratchadaphiseksomphot Endowment Fund, Chulalongkorn University, Grant/Award Number: DNS 64_067_32_005_1

Abstract

Purpose: To evaluate the impact of occlusal splint plus laser therapy (OS + LT) compared with OS alone on the patient-reported outcomes and clinical parameters of patients with temporomandibular disorders (TMDs).

Methods: Twenty-three patients with TMDs were randomly assigned to two treatment approaches: OS and OS + LT (multiwave locked system). The two outcomes were clinical parameters (mouth-opening distances, number of muscles and TMJs with pain) and patient-reported outcomes (pain score and oral health-related quality of life [OHRQoL] determined using the 14-item oral health impact profile [OHIP-14]). The outcomes were measured at four time points: baseline, 2 weeks, 1 and 3 months after treatment. According to DC/TMD Axis I classification, the participants were diagnosed as having pain only and pain with intraarticular joint disorder. Adjusting for age and sex, the outcome changes were analysed using generalized estimating models at a 5% significance level.

Results: The pain-free mouth-opening distance of the patients who received OS + LT continuously increased from 2 weeks to 3 months. However, the value was significantly increased at 3 months in patients who received OS alone. The unassisted mouth-opening distance significantly increased after 3 months in both groups. In both treatment approaches, the number of muscles and TMJs with pain, as well as the pain and OHIP-14 scores gradually decreased from baseline to 3 months.

Conclusions: The patients who received OS and OS + LT demonstrated better OHRQoL and clinical parameters during 3 months after treatment. An improvement in the pain-free mouth-opening distance at 2 weeks was found only in OS plus LT group; however, this difference may not be clinically significant.

KEYWORDS
laser therapy, muscle of mastication, occlusal splint, oral health impact profile, oral health-related quality of life, temporomandibular disorder

1 | INTRODUCTION

Temporomandibular disorders (TMDs) is a term comprising musculoskeletal and neuromuscular conditions involving the temporomandibular joints (TMJs), masticatory muscles, associated tissues, as well as physical and psychosocial conditions.[1] About 30%–40% of the general adult population present with mild-to-severe signs and symptoms of TMDs.[2,3] The TMDs' signs and symptoms include pain, impaired jaw function, malocclusion, TMJ sounds and a limited range of mouth opening.[4] Although TMDs are not life-threatening conditions, they have a negative impact on daily living activities.[5] Currently, a conservative approach is preferable because it is less aggressive than surgical treatment, and is considered the first treatment choice for patients with mild to moderate TMD stages.[6,7] Conservative approaches for treating TMDs include patient education and self-care instruction, an occlusal splint (OS) and physical therapy such as laser treatment.[6,8]

The Michigan-type OS is the most widely used design with canine guidance that allows for unrestricted movement in a centric occlusion.[9] The clinical purposes of an OS are to create freedom in centric, stabilize the TMJs, relax the masticatory muscles and prevent further tooth wear due to parafunctional activities.[7] Previous clinical studies reported the effectiveness of OS in increasing the range of motion, reducing TMD pain and anxiety, and improving the oral health-related quality of life (OHRQoL) of patients with TMDs.[10–13] Although a meta-analysis revealed that short-term OS therapy improves TMD symptoms, its long-term effectiveness was not demonstrated.[14] Another systematic review concluded that OS therapy alone did not improve TMD symptoms or quality of life.[15] Moreover, a network meta-analysis demonstrated that combined treatment approaches, including physiological, psychological and dental treatment, produced the maximum improvement in TMD symptoms.[16]

Low-level laser therapy (LT) has been used as a conservative approach for treating TMD symptoms. The laser produces monochromatic and coherent single-wavelength light.[17] However, few studies have reported the efficacy of low-level LT in reducing pain and increasing mandibular motion.[18–20] Subsequently, the multiwave locked system (MLS) laser was introduced. MLS is a form of LT that combines a synchronized continuous dual wavelength of 808 and 905 nm and uses pulse and continuous laser beams. These components reduce pain, inflammation and oedema.[21] A previous animal study demonstrated that MLS laser induced spinal cord injury recovery and tissue repair.[22] Clinical studies in humans demonstrate the advantages of MLS in reducing chronic neck and shoulder pain.[23,24] However, to our knowledge, there is limited clinical evidence on the efficacy of the MLS laser in treating patients with TMDs.

The primary and secondary objectives of this randomized controlled trial study were to evaluate the efficacy of an OS plus LT compared with an OS alone on the patient-reported outcomes and clinical parameters in TMD patients at 2 weeks, 1 and 3 months after treatment. The null hypothesis was that the patient-reported outcomes and clinical parameters would not differ between the TMD patients who received an OS plus LT and those who received an OS alone.

2 | MATERIALS AND METHODS

The present study was a two-armed parallel single-blinded randomized controlled trial study. The outcome assessor was blinded to the type of TMD treatment received by the participants. The study protocol was approved by the Human Research Ethics Committee at the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand (HREC-DCU 2021-034). The study was registered with the Clinical Trials Registry (identification number TCTR20220512001), and the procedures were performed in full accordance with the Helsinki Declaration. The participants were verbally informed about the study protocol, and provided written informed consent before participating in the study.

2.1 | Participants and sample size estimation

The participants were recruited from the patients (18–65 years old) who attended the Occlusion and Orofacial Pain Clinic, Chulalongkorn University Dental Hospital from November 2021 to April 2022. Eligible participants were the patients presenting with pain-related TMDs, including myalgia, myofascial pain or arthralgia, with or without intraarticular joint disorders, such as disc displacement with or without reduction. They had TMDs' signs and symptoms during the past 30 days, but had not received any TMD treatment. The exclusion criteria were patients having degenerative joint diseases, cognitive impairment or other causes of oro-facial pain, such as dental caries and periodontal diseases.

At baseline, the participants were classified according to their clinical diagnosis of TMDs into two subgroups: pain only and pain with the intraarticular joint disorder (combined symptoms), based on the DC/TMD Axis I classification.[25] The pain-only group consisted of the patients with regional pain, whereas the patients with pain and history of limited mouth opening and masticatory disturbance, with or without TMJ noise, were categorized as having pain with intraarticular joint disorders.

The sample size was estimated using G*Power software with statistical analyses comprising the *F*-test and ANOVA–repeated measures, within factors. Using an input effect size $f=0.25$, α error = 0.05, power = 0.80, number of groups = 2 and number of measurements = 4, a total sample size of 20 was calculated. Thus, based on having two groups, 10 samples per group were determined. When a potential 10% drop-out rate was included, each group required at least 11 samples.

2.2 | Randomization process

Randomization was performed using computer-generated numbers (Excel® 2010; Microsoft). Each number was put in a sealed envelope, and the participants ($N=23$) were randomly allocated into two groups with an allocation ratio of approximately 1:1. The participants with odd and even numbers were allocated to the control

and experimental group, respectively. An investigator (P.P.) who was not involved in the treatment outcome evaluation generated the allocation sequence, and assigned the participants to the control and experimental groups.

2.3 | Interventions

TMD treatment was provided using two conventional approaches: OS (control) and OS plus LT (experimental group). The treatments and OS adjustments were performed by an investigator with 10 years of clinical experience who did not participate in the outcome determination (P.P.).

The flat-plane occlusal splints with canine guidance were made with clear-type heat-cured acrylic resin as previously described.[26] Impressions were taken using an irreversible hydrocolloid impression material (Jeltrate; Dentsply), and Type III dental stone was poured into the impression within 15 min to create the master casts. The maxillomandibular relationship was recorded at centric relation using folded pink wax (Pinnacle modelling wax; Dentsply Sirona). The casts were mounted on a Type II articulator (DeTREY rational Articulator; Dentsply). Wax patterns were created with a 2-mm average thickness in the molar region, and heat-cured by the same technician and laboratory using the lost-wax technique. After processing, the OS was finished and delivered to the participants. Occlusal adjustments were performed at centric relation and maximum intercuspation. Equal contact at the occlusal plane of the OS was provided for the lower teeth. The participants were instructed to wear the OS every night while sleeping. The OS was readjusted during the follow-up visits at 2 weeks, 1 and 3 months after delivery.

LT was performed using a Multiwave Locked System (MLS laser; Mphi laser, ASA Srl.). The laser treatment was applied twice a week for 2 weeks. During the laser application, the dentists and patients wore goggles in compliance with the International Standard CEI IEC 825-1. The application site was cleaned with 70% alcohol. The MLS laser therapy was applied using two modes: TMJ and muscle modes. The MLS laser probe was positioned perpendicular to the TMJ and the tender muscles. The laser was applied at similar locations on the left and right sides. For the TMJ mode, a laser pulse repetition with a frequency of 350 Hz, a dose of 2.51 J/cm^2 and 50% intensity was applied on the TMJ location for 30 s during mouth opening and another 30 s during mouth closing. For the muscle mode, a laser pulse repetition with a frequency of 350 Hz, a dose of 2.79 J/cm^2 and 50% intensity was used. The laser was scanned over the tender muscles for 1 min. The procedures were repeated twice on the TMJ location and the tender muscles.

Similar self-care instructions were given verbally and in written form through a leaflet to both groups by the investigator who provided the TMD treatment (P.P.). The self-care instructions comprised eating a soft diet with slow chewing stroke and smaller bite, avoiding firm sticky food, limiting the range of mouth opening to pain-free extent, using hot or cold compression, relaxing jaw muscles and maintaining proper head, neck and back postures during both daytime activities and sleep.[27] For the OS plus LT group, the MLS laser therapy was administered only during the first 2 weeks of the study, and the participants did not receive any additional self-care motivation during the treatment period.

2.4 | Outcome assessment

The primary outcome was patient-reported outcomes assessed using a pain rating scale and their OHRQoL. The participants rated their pain intensity using a 10-point numerical rating scale, of which a score of 0–10 indicated no pain to the worst pain. The OHRQoL was assessed using the Thai version of the 14-item Oral Health Impact Profile (OHIP-14) questionnaire.[28] The OHIP-14 determined the frequency of the impacts on seven domains: functional limitation, physical pain, physical disability, psychological discomfort, psychological disability, social disability and handicap. The participants gave responses on the frequency of the problem using a 5-point ordinal scale (0-never, 1-hardly ever, 2-occasionally, 3-fairly often and 4-very often). The sum of the item scores was the OHIP severity score, ranging from 0 to 56; a higher score indicated more negative impacts on their oral health problems.[29]

The secondary outcome was the clinical parameters that comprised the mouth-opening distance (mm) and the number of locations around the masticatory system with pain. The mouth-opening distance was measured at three conditions: pain-free, unassisted and assisted mouth opening. Unassisted mouth opening was measured at the maximum distance regardless of pain or discomfort, whereas assisted mouth opening was performed with the assistance of the investigator. Three measurements were performed on each participant with 10-minute resting interval using a ruler from the incisal edge of the right maxillary incisors to the mandibular central incisors. The number of muscles and TMJs with pain were counted on the left and right sides on two occasions; during function (mouth opening and excursion) and palpation. The examined locations were the temporalis muscles, masseter muscles, lateral pterygoid muscles, temporalis tendons, as well as the posterior mandibular and submandibular regions on the left and right sides. The total score of each occasion ranged from 0 to 14 locations. The accuracy of range of motion assessment was evaluated in 10 TMD patients who were not included in the present study. The results showed an intraclass correlation coefficient ranging from 0.88 to 0.99, indicating good intra-examiner reliability.

The outcomes were assessed by an investigator (P.V.) with more than 30 years of clinical experience at baseline (T0), and at the follow–up visits 2 weeks (T1), 1 month (T2) and 3 months (T3) after treatment.

2.5 | Data analysis

The data were analysed using STATA version 13.0 (StataCorp LP) at a 5% significance level. Descriptive statistics were used to

determine the percentages, means (standard deviations [SD]), and median (first quartile [Q1], third quartile [Q3]). Analytical statistics was performed based on an intention-to-treat analysis. A generalized estimating equation (GEE) analysis was used to evaluate the effects of each treatment approach on the outcomes across time points, and the models were adjusted for age and sex. A GEE model with a Gaussian distribution and an identity link function assuming an exchangeable working correlation structure was used to assess the changes in mouth-opening distances, pain score and OHIP-14 score between the four time points. A GEE model with a Poisson distribution and log link function assuming an exchangeable working correlation structure was used to assess the changes in OHIP-14 prevalence between time points.

3 | RESULTS

The study began with 23 TMD patients, and the retention rate was 100%. The consort flow diagram is demonstrated in Figure 1. The baseline characteristics of the participants in the two treatment groups are presented in Table 1. The mean age of the participants was 29.1 (±11.8) years old (range 19–61 years old), and the male:female ratio was 1:2.3. Based on the DC/TMD Axis I clinical diagnosis, 60.9% of the participants had pain only. The other 39.1% were diagnosed as having pain with the intraarticular joint disorder.

The clinical parameter outcomes are demonstrated in Tables 2 and 3. In the participants who received OS plus LT, the pain-free mouth-opening distance continuously increased from 2 weeks to 3 months. In contrast, this distance significantly increased at 3 months in the participants who received OS alone (Table 2). The patients' unassisted mouth-opening distance significantly increased after 3 months in both groups. However, a significantly increased assisted mouth-opening distance at 3 months was found only in the participants who received OS alone. The number of muscles and TMJs with the pain gradually decreased after receiving either treatment approach (Table 3).

The patient-reported outcomes are presented in Table 4. In both treatment approaches, the pain and OHIP-14 scores gradually decreased from baseline through 3 months.

4 | DISCUSSION

The present study evaluated the efficacy of an OS plus LT compared with an OS alone on the patient-reported outcomes and clinical parameters of TMD patients at 2 weeks, 1 month and 3 months after treatment. Both treatment approaches significantly increased the patients' pain-free and unassisted mouth-opening distances and improved their OHRQoL. During 3 months after treatment, two treatment approaches reduced the pain levels and decreased the number of muscles and TMJs with pain on palpation and those with pain when in function. Interestingly, a significant improvement in the pain-free mouth-opening distance at 2 weeks was found only in the OS plus LT group. Based on these results, the null hypothesis was rejected.

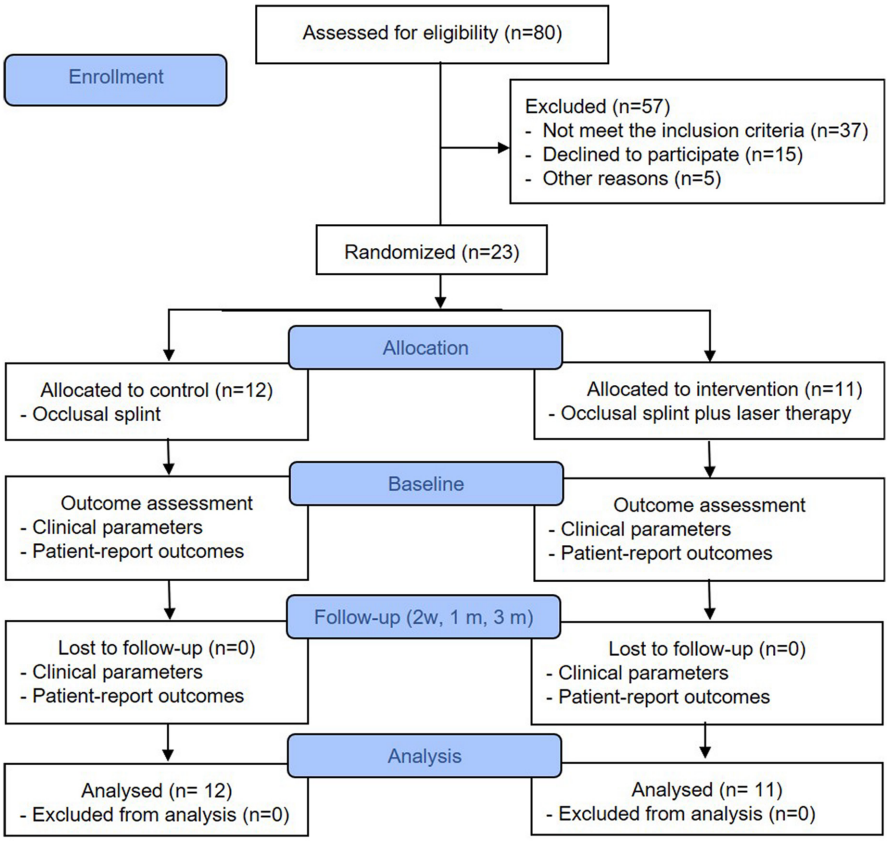

FIGURE 1 Consort flow diagram of the study.

TABLE 1 Baseline characteristics of the participants ($N = 23$).

Characteristics	Overall	Treatment approaches	
		Splint ($n = 12$)	Splint + laser ($n = 11$)
Age (years)			
Mean (±SD)	28.5 (±11.0)	26.0 (±7.1)	31.2 (±14.0)
Sex (%)			
Male	30.4	33.3	27.3
Female	69.6	66.7	72.7
Diagnosis (%)			
Pain	60.9	58.3	63.6
Pain with internal disc derangement	39.1	41.7	36.4
Functional outcome at baseline: mean (±SD)			
Mouth-opening distance(mm)			
Pain-free	37.3 (±7.8)	36.9 (±8.0)	37.6 (±7.7)
Unassisted	42.0 (±7.5)	41.4 (±7.6)	42.5 (±7.6)
Assisted	44.6 (±7.0)	44.0 (±6.2)	45.3 (±7.7)
Number of locations with pain (ranges 0–14): median (Q1, Q3)			
Pain during function (jaw opening and excursion)	2 (1, 2)	2 (1, 2)	2 (1, 2)
Pain on palpation	4 (3, 7)	4 (2, 5)	5 (3, 7)
Patient-reported outcome at baseline: mean (±SD)			
Pain score (ranges 0–10)	3.9 (±2.9)	3.6 (±2.2)	4.1 (±2.5)
OHIP-14 score (ranges 0–56)	12.4 (±7.8)	10.7 (±7.3)	14.3 (±8.1)

TABLE 2 Mean (SD) of the mouth-opening distances (mm).

Time	Pain-free mouth opening (mm): mean (SD)		Unassisted mouth opening (mm): mean (SD)		Assisted mouth opening (mm): mean (SD)	
	Splint ($n = 12$)	Splint + laser ($n = 11$)	Splint ($n = 12$)	Splint + laser ($n = 11$)	Splint ($N = 12$)	Splint + laser ($N = 11$)
Baseline	36.6 (10.7)[a]	32.4 (11.5)[a]	41.4 (9.5)[a]	40.6 (7.5)[a]	45.7 (6.9)[a]	45.1 (8.0)[a]
2 weeks	38.4 (7.9)[a]	37.3 (7.4)[b]	43.8 (7.6)[a]	43.2 (8.1)[a]	45.5 (7.5)[a]	45.9 (8.0)[a]
1 month	38.5 (9.4)[a]	39.4 (7.0)[b]	43.2 (8.4)[a]	43.1 (6.7)[a]	45.4 (7.9)[a]	45.2 (7.1)[a]
3 months	40.7 (9.1)[b]	42.7 (8.0)[c]	44.3 (7.4)[b]	47.0 (7.3)[b]	46.5 (6.5)[a]	48.3 (7.9)[b]

Note: Different alphabetical letters indicated significant difference between time points ($p < .05$).

TABLE 3 Median (Q1, Q3) of the number of muscles and temporomandibular joints (TMJs) with pain.

Time	Number of muscles and TMJs with pain when function: median (Q1, Q3)		Number of muscles and TMJs with pain on palpation: median (Q1, Q3)	
	Splint ($n = 12$)	Splint + laser ($n = 11$)	Splint ($n = 12$)	Splint + laser ($n = 11$)
Baseline	2 (1, 2)	2 (1, 2)	5 (2.5, 8.5)	7 (4, 12)
2 weeks	1.5 (0.5, 2)	2 (1, 2)	4 (2, 4.5)	5 (3, 7)
1 month	2 (0.5, 3)	2 (0, 2)	3 (0.5, 6)	4 (1, 6)
3 months	0 (0, 1.5)	1 (0, 2)	3 (1, 4.5)	3.5 (0, 9)

In our study, the patients with TMD were 19–61 years old, with a higher proportion of females. This is comparable to the general population in which TMD occurs when individuals are 20–40 years old with a higher prevalence in females.[30,31] This supports the generalizability of our findings to the TMD population. In accordance with several studies in TMD patients,[12,32,33] the OHIP-14 was used

TABLE 4 Mean (SD) of the pain and total oral health impact profile (OHIP) scores.

Time	Pain score: mean (SD)		OHIP-14 score: mean (SD)	
	Splint ($n=12$)	Splint + laser ($n=11$)	Splint ($n=12$)	Splint + laser ($n=11$)
Baseline	4.7 (1.4)[a]	4.6 (1.6)[a]	15.5 (6.9)[a]	17.3 (6.7)[a]
2 weeks	3.8 (1.9)[a]	3.9 (2.6)[a]	10.8 (5.5)[b]	15.0 (10.2)[b]
1 month	3.2 (2.2)[a]	3.3 (2.2)[a]	6.8 (4.5)[c]	11.3 (6.2)[c]
3 months	1.8 (1.8)[b]	2.8 (2.8)[b]	3.7 (3.0)[d]	9.0 (5.9)[d]

Note: Different alphabetical letters indicated significant difference between time points ($p<.05$).

as an OHRQoL indicator because it can detect the efficacy of TMD treatment. Several LT protocols have been used for treating patients with temporomandibular disorders.[34,35] However, it remains unclear which protocol is the most effective in treating TMD patients. In our study, the 2-week laser therapy was employed with 3 months of follow-up because we hypothesized that LT could be an adjunctive treatment that provides a long-term treatment effect.

The present study demonstrated that OS therapy increased the pain-free and unassisted mouth-opening distances. It also decreased the number of muscles and TMJs with pain on palpation and those with pain when in function. However, the pain-free mouth-opening distance significantly increased from 2 weeks to 3 months after receiving OS plus LT. In contrast, a significant change in the pain-fee mouth-opening distance after receiving OS alone was found at 3 months. As supported by Melchoir et al.,[36] OS therapy alone and OS plus low-level LT increased the amount of jaw movement after 5 weeks; however, the OS plus low-level LT resulted in a greater improvement in pain intensity level and TMJ noise reduction. However, the effectiveness of OS therapy in treating TMD is currently unresolved. A meta-analysis demonstrated that OS therapy reduced pain intensity, decreased muscle tenderness and increased mouth-opening distance during short-term use. However, its long-term benefits 3 months after therapy were not demonstrated.[14] A previous systematic review also revealed that OS therapy alone did not improve TMJ clicking or quality of life.[15] A network meta-analysis demonstrated a significant improvement in TMD symptoms in the patients who received combined treatment approaches, such as OS and counselling.[16] From our findings, although OS plus LT may result in a better functional outcome during short-term follow-up, it is possible that this minor difference may not be clinically significant.

There are different functional mechanisms between the OS and LT when treating the TMD. The OS alters the patients' TMJ position and optimizes the occlusal force distribution, which prevents over-function of the muscles of mastication and creates an occlusal stability.[7,26] In the study, the MLS laser was used due to its multiple wavelengths, which provide synergistic effects through a wider range of mechanism.[21–23] The pulse component induces the release of endogenous opioid, including endorphin and enkephalin, resulting in an analgesic effect by reducing the velocity of nerve transmission. Meanwhile, the continuous component stimulates adenosine triphosphate production and increases blood and lymphatic circulation, which helps restoring biochemical and bioelectrical imbalances via direct energy transfer, resulting in reduced inflammation and oedema. Previous case reports consistently demonstrated positive effects of the MLS in reducing pain associated with functional overload-induced muscular contracture in athletes,[37] severe pain caused by disc herniation at lumbar region[38] and myofascial pain in the cervical region.[39] Thus, the MLS laser might be an adjunctive treatment for conventional OS therapy.

The patient's pain level and the OHRQoL gradually improved from 2 weeks to 3 months, with a significant OHRQoL change at 2 weeks in both treatment approaches. Our results are in accordance with Kokkola et al.,[12] the pain and OHIP scores gradually improved over 1 year of TMD treatment after receiving OS therapy or masticatory muscle exercise plus counselling. In the present study, the pain level reduced in accordance with the better OHRQoL. Also, both patient-reported outcomes conformed with the improved clinical parameters. However, the improvement in the clinical parameters was delayed compared with the patient-reported outcomes. The explanation for these results might be that the patients' perception depended on a physical function and was affected by the psychological and social conditions of an individual.

In the present study, the assisted mouth-opening distance was relatively stable after treatment, possibly because each individual has their threshold level and fixed range of motion or due to a permanent anatomical change such as disc displacement without reduction. Therefore, the patient-reported outcomes and some clinical parameters, including the pain-free and unassisted mouth-opening distances, are suggested as indicators to determine the efficacy of TMD treatment. Based on our results, the MLS laser could be an adjunctive therapy to enhance the recovery from TMD symptoms, compared with providing OS therapy alone. To determine the efficacy of TMD treatment, dentists should focus on clinical parameters, and assess the OHRQoL of an individual for holistic care.

The present study has some limitations. Although TMD is a self-limiting disease whose signs and symptoms can improve over time without any treatment, our study did not have a control group that did not receive any treatment. This was because the patients attending our clinic expected some TMD management and intervention. Although physiotherapy has been reported as an effective management strategy for TMD, the protocols are different between muscular and intraarticular disorders.[40] Therefore, physiotherapy-only group was not included as a control in this study. Because none of

the patients participating in our study presented with degenerative joint disease or subluxation, these diseases were not included in our study. Furthermore, this study used only the MLS laser system. Thus, the generalizability of the findings is limited to specific TMD subgroups and a single laser system. The treatment option analysis did not consider the treatment cost and the number of dental visits, which could be factors that affect a patient's decision to choose this treatment option. Moreover, this study did not evaluate certain variables, such as psychosocial condition and pain-related disability, which may have an impact on the effectiveness of TMD treatment. Additional studies are needed using a follow-up duration of more than 3 months to determine the long-term effect of the OS and LT approaches for treating TMD symptoms. The treatment outcomes between the patients with muscle and TMJ problems should be investigated for precise treatment recommendations. A cost-effectiveness analysis is suggested to determine whether the additional LT cost is worth the improved oral health outcome.

5 | CONCLUSION

During 3 months after receiving OS alone or OS plus LT, the patients with TMD had better OHRQoL and clinical parameters, including their mouth-opening distance, as well as the number of muscles and TMJs with pain. An improvement in the pain-free mouth-opening distance at 2 weeks was found only in OS plus LT group; however, this difference may not be clinically significant.

AUTHOR CONTRIBUTIONS

PP: conceptualization, supervision, methodology, investigation, validation, writing—original draft preparation, reviewing and editing. PV: conceptualization, supervision, investigation, validation, writing—reviewing and editing. NL: conceptualization, supervision, methodology, formal analysis, visualization, writing—original draft preparation, writing—reviewing and editing.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge Dr. Kevin Tompkins for language revision of this manuscript.

FUNDING INFORMATION

This study was supported by the Grants for Development of New Faculty Staff, Ratchadaphiseksomphot Endowment Fund, Chulalongkorn University [grant number DNS 64_067_32_005_1].

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/joor.13593.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Potewiratnanond P, Vanichanon P, Limpuangthip N. Occlusal splint and combined multiwave locked system laser therapy demonstrated differential patient-reported outcomes and clinical parameters: A randomized controlled trial in patients with temporomandibular disorder. *J Oral Rehabil*. 2023;00:1-8. doi:10.1111/joor.13593