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Comparative Effectiveness of Digitally and Conventionally Fabricated Occlusal Splints with Low-Power Laser Therapy in Treating Temporomandibular Disorders

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Abstract

Introduction: Temporomandibular disorder (TMD) is common, and occlusal splints (OSs) and low-power laser (LPL) therapy are effective conservative treatments. This study aims to compare the effectiveness of conventionally and digitally fabricated OS, with and without LPL, in treating TMD patients.

Methods: Forty patients diagnosed with TMDs were randomly assigned to four treatment groups. The first group received LPL therapy in conjunction with digitally fabricated OS. The second group was treated with LPL therapy and conventionally fabricated OS. The third group received digitally made OS without LPL, and the fourth group was provided with conventionally fabricated OS without LPL. Patients' pain levels were evaluated using a Visual Analog Scale (VAS) before treatment (pre-treatment) and at 1 week, 1 month, and 3 months post-treatment. The Association of Dental Research (IADR) scale was used to measure mouth opening and mandibular movements. Additionally, the physical characteristics of the OS were assessed over the 3-month period, including their resistance to failure, color change, and the level of patient satisfaction with the treatments.

Results: There were no statistically significant differences in color change or failure rates between conventionally and digitally fabricated occlusal splints after three months ($P>0.05$). Likewise, patient satisfaction levels did not differ significantly between the two splint types ($P>0.05$). However, the conventionally fabricated splints required significantly more adjustment points and a longer delivery time ($P<0.05$). All four treatment groups experienced a significant reduction in pain intensity following the interventions ($P<0.05$). Additionally, the group receiving low-power laser therapy with digitally fabricated splints demonstrated greater improvements in all three movement parameters ($P<0.05$).

Conclusion: The use of a combined treatment approach, involving a digitally-fabricated OS and LPL therapy could yield greater benefits for patients with TMDs in terms of pain reduction and functional improvements.

Keywords: Temporomandibular disorders, Occlusal splint, Laser therapy, Low-Level laser

Introduction

Oral and facial pain (OFP) conditions including TMDs are among the most commonly encountered issues in clinical practice. TMDs encompass a wide range of musculoskeletal and neuromuscular disorders affecting the temporomandibular joint and associated structures.[1] The etiology of TMDs is multifactorial, with both physical and psychosocial factors playing roles. While physical causes can be broadly categorized as either arthrogenic or myogenic in origin, the signs and symptoms of TMDs may often resemble those of other OFP conditions.[2] Establishing an accurate physical diagnosis are crucial for developing an appropriate treatment plan, but this can be challenging in some cases. Obtaining a detailed patient history including any history of trauma or previous pain episodes, is an essential part of the diagnostic process.[3] TMDs are estimated to affect between 5% and 15% of the adult population, although TMD-related symptoms have been reported in as many as 50% of adults.[4] Recent evidence suggests that the prevalence of TMDs may be increasing in recent years.[5] A comprehensive systematic review and meta-analysis in 2021 reported a pooled prevalence of 31% for TMDs in adults and 11% in children and adolescents.[6] Initial management of TMDs often involves the use of various medications, such as analgesics, non-steroidal anti-inflammatory drugs, anxiolytics, and anti-depressants.[7] Occlusal Splints (OS), also known as night guards, orthotics appliances, or oral appliances are a

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commonly prescribed non-invasive treatment option with minimal risks. The use of OS has resulted in the reduction of muscle tension, activity, and pain intensity, as well as an increase in maximum mouth opening in patients with TMDs.[8,9]

Despite the widespread adoption of various treatment approaches for TMDs, the effectiveness of these methods remains uncertain. This uncertainty underscores the need for further research to determine the most appropriate treatment options for patients. One promising modality is Low-Level Laser Therapy (LLLT), which is believed to facilitate tissue healing and diminish inflammation through several mechanisms. For instance, LLLT enhances cellular metabolism and promotes ATP production, thereby supporting tissue repair. Additionally, it exhibits anti-inflammatory properties by lowering levels of pro-inflammatory cytokines, which alleviates pain and swelling.[10] Moreover, LLLT can modulate pain pathways, effectively reducing nociceptive signaling and improving pain thresholds. [11] LLLT has been demonstrated to promote tissue healing, reduce inflammation, and alleviate pain, making it a relevant and effective intervention for patients experiencing TMD-related symptoms.[12-14] Conventionally OS and digitally manufactured OS share similar mechanisms but differ in their fabrication processes, affecting effectiveness and patient comfort. Conventionally fabricated splints, made from heat-cured acrylic, redistribute occlusal forces to alleviate strain on the temporomandibular joint (TMJ) and associated muscles. This helps reduce muscle hyperactivity and parafunctional habits like bruxism, leading to decreased pain and improved jaw function. In contrast, digitally manufactured splints utilize advanced technologies such as 3D printing and computer-aided design (CAD) for precise customization based on detailed scans of the patient's mouth. This superior fit enhances comfort and compliance while potentially improving therapeutic outcomes.[15,16]

The present study aimed to investigate and compare the outcomes of two treatment modalities for TMDs: conventionally fabricated occlusal splints (OS) and digitally manufactured OS, both used in conjunction with LLLT. Additionally, the study examined some physical properties of these two types of splints, such as resistance to breakage and color stability. The null hypothesis was that there was no significant difference between the physical characteristics of the two types of OS, and also between their effects with or without the combination of the low-level laser in mandibular movement improvement.

Methods and Materials

Patients

This randomized clinical trial enrolled 40 patients diagnosed with TMDs, adhering to well-defined inclusion and exclusion criteria to ensure a robust study population. The sample size for this study was influenced by prior research, which indicated that a minimum of 40 participants per group is necessary to detect clinically meaningful differences in treatment outcomes for TMDs. This prior research established a target power of 0.80 and an alpha level of 0.05, guiding our calculation. The inclusion criteria for the study stipulated a diagnosis of TMD based on the established research diagnostic criteria for this condition.[17] Participants were included if they reported or presented with at least one of the three cardinal signs or symptoms of TMD: jaw pain, limited mouth opening, or TMJ noise. Exclusion criteria encompassed a range of medical conditions and treatment histories. Participants with systemic rheumatic, neurologic/neuropathic, endocrine, or immune/autoimmune diseases, as well as those with a history of radiation treatment to the head and neck, TMJ surgery, or recent jaw trauma within the last two months, were excluded. Additionally, individuals with non-TMD orofacial pain disorders and pregnancy, or those unable to participate due to language barriers or mental/intellectual incompetence were not eligible. The use of narcotic pain medication, muscle relaxants, steroid therapy, or nonsteroidal anti-inflammatory drugs (unless discontinued for specified periods) also disqualified potential participants. Lastly, any ongoing dental treatments, the presence of dentures, contraindications for imaging, or the inability or unwillingness to provide informed consent were additional grounds for exclusion. Demographic data, including the participants' age, gender, and educational status, were collected and recorded. The study protocol was approved by the ethics committee of Shahid Beheshti University of Medical Sciences, with the assigned research ethical code IRCT20220706055400N1. All enrolled patients were provided with a comprehensive explanation of the research methodology and were required to sign a written informed consent form.

Study groups

The patients were divided into four treatment groups, with 10 subjects assigned to each group. The treatments administered in the respective groups were as follows: group 1: LPL therapy combined with digitally fabricated OS, group 2: LPL therapy used in combination with conventionally made OS, group 3: digitally produced OS as the sole treatment, and group 4: conventionally fabricated OS provided as the primary intervention. Before any intervention, the participants were given a TMD questionnaire based on the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) and the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD).[8] We specified that the translated versions of the questionnaires used in this study were validated for the population studied prior to their implementation. We conducted a thorough review of the literature and consulted with experts in the field to confirm

that the translated questionnaires maintain their reliability and validity when applied to our specific population. In addition, a previously trained clinician conducted a clinical examination that included the palpation of the masticatory muscles and temporomandibular joints (TMJs), the evaluation of mandibular movements using a specific ruler and periodontal probe, and the use of a stethoscope to check for clicking sounds in the TMJs; the following items were analyzed: frequency of headache, fatigue, difficulty in chewing, presence of habitual parafunctions such as bruxism and clenching, and patients' psychological state. To assess parafunctional behaviors, including bruxism, we asked participants to complete a validated self-report questionnaire detailing the frequency, duration, and intensity of bruxism episodes, as well as associated symptoms like jaw pain and dental wear. Additionally, participants recorded their bruxism occurrences in a daily diary over two weeks, providing real-time data for a more accurate assessment. The clinician also noted the presence or absence of splint fracture or discoloration, and patients' satisfaction with the occlusal splint (OS) was recorded after three months. For this purpose, participants completed a structured questionnaire designed to evaluate their satisfaction with OS and the overall treatment experience. The questionnaire included items related to pain relief, ease of use, comfort, and perceived effectiveness of the treatment. This multi-faceted assessment approach ensures a thorough evaluation of both clinical and parafunctional aspects, enhancing the rigor and reliability of our study findings. A similar process was followed for the second group (laser therapy + conventional splint) and the fourth group (conventional splint only), but in these cases, the conventional splints were fabricated using heat-cured acrylic polymethyl methacrylate (Figure 1).

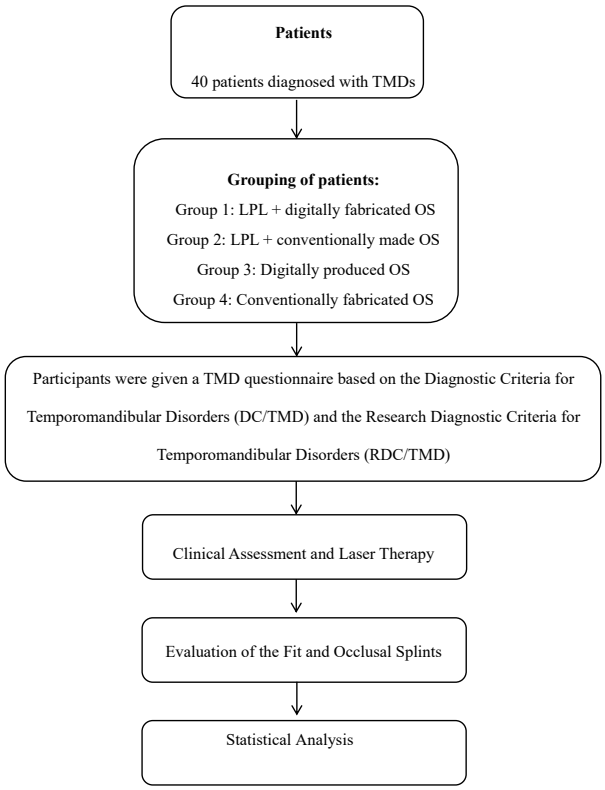

Figure 1. A flowchart illustrating the study design

Clinical Assessment and Laser Therapy

The study protocol involved a comprehensive clinical examination of the participants. This included an assessment of the masticatory muscles in terms of pain or spasm, as well as an examination of the temporomandibular joint for any pain, sounds, or deviations in movement. The presence of clenching and bruxism (teeth grinding) symptoms was also determined.[18,19] The range of jaw movements was measured using a ruler and a standard manual probe, the University of North Carolina-15 (UNC15) probe. The pain levels were assessed in the masseter, temporal, and sternocleidomastoid muscles (middle part) using a numerical pain scale from 0 (no pain) to 10 (worst imaginable pain), as reported by the subjects on a visual analog scale (VAS).[20-23] The GaAlAs diode laser device (Diode D5; 808 nm, LAMBDA; Italy) was measured with a power of 300 mW, energy density of 7.89 J/cm2 , and spot size of 0.38 cm2, and it was used to irradiate 10 s per point, resulting in a total energy of 3J per point (3J divided by 0.38 = 7.89 J/cm2). The laser was applied to the beginning, middle, and end of the masseter muscle, the anterior part of the temporalis muscle, and the middle part of the sternocleidomastoid muscle, with each application lasting 10 seconds. The laser therapy was administered twice a week for a total of 12 sessions.[18,19] During the laser application, the patients were positioned with the Frankfurt plane parallel to the floor, and the active tip of the laser device was covered to prevent infection. The laser was applied to the patient's skin, which was cleaned with 70% alcohol, and both the patient and the operator used protective glasses. The evaluation of the patients involved assessing the pain intensity using the VAS scale and the number of mandibular movements based on the scale of the International Association of Dental Research (IADR). These assessments were performed before the study, one week after the laser therapy sessions, and approximately three months after the completion of the laser therapy.[20-23]

Evaluation of the Fit and Occlusal Splints

After the completion of the laser therapy sessions, alginate impressions (Zhermack, Padoua, Italy) were made for each patient, and casts were prepared using dental stone (type IV dental stoneExtra hard, USA). An anterior jig made with self-polymerizing acrylic (Acrosun, Iran) was used to create a 2 mm posterior separation, and a wax (Beta Dent, Iran) record was made to capture the correct central relation of the patient. The same impression and

record-making process was also performed for the groups receiving only OS. For the first and third groups (laser therapy + OS, and OS only), the casts and wax records were scanned using a 3D scanner (Shining 3D, China), and OS were fabricated using 3D printing (Envision TEC, Germany) with a printable resin (eSUN DM100 Dental Model Resin, Iran). The OS were then delivered to the patients, and the necessary adjustments were made to ensure optimal fit, as determined by pressure point checks using compression silicone washers (Kulzer, Germany) and articulating paper. The time required for the OS delivery session was recorded using a wristwatch. The patients were instructed to wear the OS for at least 6 hours per day, typically during sleep. Evaluations using the VAS and IADR scales were performed before the treatment and one week, one month, and three months after the OS delivery.

Statistical Analysis

The study utilized SPSS version 23.0 for all analyses. Various statistical tests were employed to evaluate the data, including tests for comparing nominal and ordinal qualitative variables and quantitative variables. The Shapiro-Wilk test was conducted to assess data normality. Non-parametric tests were used for comparisons due to non-normal distribution. One-way ANOVA analyzed dependent variables at baseline, with a significance level (α) set at 0.05 for all analyses.

Results

Splint Characteristics and Patient Satisfaction

Table 1 compares the distribution of the frequency of color change in splints, the distribution of splint adjustment points, the distribution of splint failure after three months, and the satisfaction of patients with the treatments received in each group. The results show that the compared groups had statistically significant differences in terms of the number of adjustment points ($P < 0.05$).

Comparison of Treatment Outcomes

The study first assessed the equality of the baseline dependent variables across the 4 treatment groups using one-way ANOVA. The results showed significant baseline differences for pain intensity ($P = 0.001$), left jaw movements ($P = 0.044$), and right jaw movements ($P = 0.047$). However, there were no significant baseline differences for maximum mouth opening ($P = 0.397$) or forward jaw movements ($P = 0.124$). To account for these baseline differences, the analysis focused on the changes from baseline within each group, rather than the absolute values. Table 2 presents the comparisons of the changes in pain intensity, maximum mouth opening, and forward movements over time within each study group. Table 3 provides the pairwise comparisons of these changes between all recorded time points for all groups. Finally, Figures 1, 2 and 3 display the mean and standard deviation of the study variables over time for the different treatment groups.

Pain Intensity

The analysis of changes in pain intensity from baseline revealed a statistically significant difference between the 4 treatment groups at the 1-week assessment point ($P < 0.001$). Pairwise comparisons using the Bonferroni method showed that group CL had significantly greater reductions in pain compared to groups C ($P < 0.001$), D ($P = 0.006$), and DL ($P = 0.015$), indicating the CL group experienced the most substantial pain relief. Furthermore,

Table 1. Distribution of the frequency of color change in splints, splint adjustment points, splint failure after three months, and the satisfaction of patients with the treatments received in each group

Variable		Digital	Conventional	*P*-value
Color change of splint types	No	6(85.7%)	3(42.9%)	0.089
	Yes	1(14.3%)	4(57.1%)	
Splint failure rate after three months	No	4(57.1%)	7(100%)	0.001*
	Yes	3(42.9%)	0(0.0%)	
Patient satisfaction with treatment	1	0(0.0%)	1(14.3%)	0.382
	2	(14.3%)1	(28.6%)2	
	3	3(42.9%)	2(28.6%)	
	4	3(42.9%)	2(28.6%)	
The number of points that needed to be adjusted in the splints	3	(28.6%)2	(0.0%)0	0.0004*
	4	(57.1%)4	(14.3%)1	
	5	1(14.3%)	0(0.0%)	
	6	0(0.0%)	2(28.6%)	
	7	0(0.0%)	3(42.9%)	
	8	0(0.0%)	1(14.3%)	

*Statistical Significance level = 0.05

Table 2. Comparison of the changes made in pain intensity, maximum mouth opening over time, and the number of forward movements

Variable	Group	Before	1 Week later	1 Month later	Three Months later	One-week changes compared to baseline	One-month changes compared to baseline	Three-month changes compared to baseline
Pain Intensity	Laser + Digital Splint (DL)	3.14 ± 2.97	2.38 ± 2.00	1.915 ± 1.00	0.57 ± 1.512	1.14 ± 1.676	2.14 ± 2.795	3.24 ± 1.862
	Laser + Conventional Splint (CL)	0.90 ± 7.86	0.48 ± 1.71	2.34 ± 4.86	1.512 ± 5.57	0.90 ± 6.14	2.24 ± 3.00	3.52 ± 1.899
	Digital splint (D)	2.22 ± 3.43	2.38 ± 3.00	1.25 ± 0.71	0.76 ± 0.29	0.53 ± 0.43	1.38 ± 2.71	2.46 ± 3.89
	Conventional Splint (C)	2.63 ± 2.71	2.57 ± 2.57	1.70 ± 1.29	0.79 ± 0.43	0.37 ± 0.14	1.51 ± 1.43	2.98 ± 2.35
Maximum Mouth Opening	Laser + Digital Splint (DL)	42.57 ± 5.8	6.00 ± 47.00	6.04 ± 50.14	50.71 ± 6.849	4.43 ± 3.457	7.57 ± 3.101	8.14 ± 4.337
	Laser + Conventional Splint (CL)	4.60 ± 44.7	4.54 ± 44.71	4.53 ± 44.71	4.54 ± 44.71	0.58 ± 0.00	0.58 ± 0.00	0.57 ± 0.00
	Digital splint (D)	6.29 ± 48.6	6.52 ± 48.71	5.76 ± 49.29	6.024 ± 49.43	0.38 ± 0.14	1.49 ± 0.71	1.57 ± 0.86
	Conventional Splint (C)	9.32 ± 46.7	9.32 ± 46.71	10.59 ± 47.57	10.69 ± 47.86	0.00 ± 0.00	1.46 ± 0.86	1.67 ± 1.14
Progressive Movements	Laser + Digital Splint (DL)	7.0 ± 2.380	1.902 ± 9.4	1.380 ± 9.29	9.43 ± 1.99	2.43 ± 1.13	2.29 ± 1.25	2.43 ± 0.97
	Laser + Conventional Splint (CL)	1.49 ± 6.29	1.496 ± 6.3	1.512 ± 6.43	1.512 ± 6.43	0.00 ± 0.00	0.37 ± 0.14	0.37 ± 0.14
	Digital splint (D)	2.57 ± 8.57	2.573 ± 8.57	2.138 ± 8.14	2.116 ± 8.14	0.00 ± 0.00	0.95 ± 0.29	0.97 ± 0.43
	Conventional Splint (C)	1.34 ± 6.14	1.345 ± 6.14	1.345 ± 6.14	1.345 ± 6.43	0.000 ± 0.00	0.577 ± 0.00	0.951 ± 0.29
Lateral movements (right and left)	Laser + Digital Splint (DL)	6.29 ± 1.28	2.215 ± 8.71	1.484 ± 7.93	8.5 ± 1.87	2.42 ± 1.33	1.64 ± 1.25	2.21 ± 1.47
	Laser + Conventional Splint (CL)	1.93 ± 7.8	2.110 ± 7.93	2.015 ± 7.86	1.880 ± 7.93	0.378 ± 0.14	0.345 ± 0.07	0.244 ± 0.14
	Digital splint (D)	2.46 ± 9.3	2.410 ± 9.36	2.809 ± 9.64	2.841 ± 9.71	0.189 ± 0.07	1.625 ± 0.35	1.618 ± 0.42
	Conventional Splint (C)	1.27 ± 8.4	1.272 ± 8.43	1.185 ± 8.71	1.205 ± 9.07	0.000 ± 0.00	0.566 ± 0.28	0.988 ± 0.64

Table 3. *P*-value of the pairwise comparison of the pain intensity, maximum mouth opening over time, lateral movements (right and left), and the number of forward movements between all of the recorded time points for all groups

Variable	Time 1	Time 2	Splint Digital Group (D)	Laser + conventional splint (CL)	Laser + Digital Splint (DL)	8Conventional splint(C)
Pain Intensity	3 Months	One Month	0.836	0.408	0.679	0.535
		1 week	0.023*	0.023*	0.098	0.062
		Before	0.004*	0.062	0.013*	0.038*
	One Month	1 week	0.038*	0.147	0.214	0.214
		Before	0.007*	0.007*	0.038*	0.147
	One Week	Before	0.535	0.0025*	0.408	0.836
Maximum Mouth Opening	3 Months	One Month	0.552	0.836	0.918	0.775
		1 week	0.2447	0.178	0.062	0.553
		Before	0.663	0.178	0.001*	0.4710
	One Month	1 week	0.44	0.255	0.078	0.3620
		Before	0.387	0.255	0.001*	0.088
	One Week	Before	0.295	0.99	0.121	0.0762
Progressive Movements	3 Months	One Month	0.215	0.65	0.836	0.96
		1 week	0.296	0.48	0.918	0.379
		Before	0.096	0.478	0.003*	0.186
	One Month	1 week	0.076	0.1258	0.918	0.753
		Before	0.336	0.3578	0.005*	0.148
	One Week	Before	0.712	0.369	0.004*	0.387
Lateral movements (right and left)	3 Months	One Month	0.332	0.342	0.408	0.44
		1 week	0.113	0.098	0.918	0.668
		Before	0.554	0.145	0.003*	0.41
	One Month	1 week	0.660	0.66	0.352	0.763
		Before	0.088	0.778	0.03*	0.382
	One Week	Before	0.0569	0.542	0.002*	0.601

*Statistical Significance level = 0.05

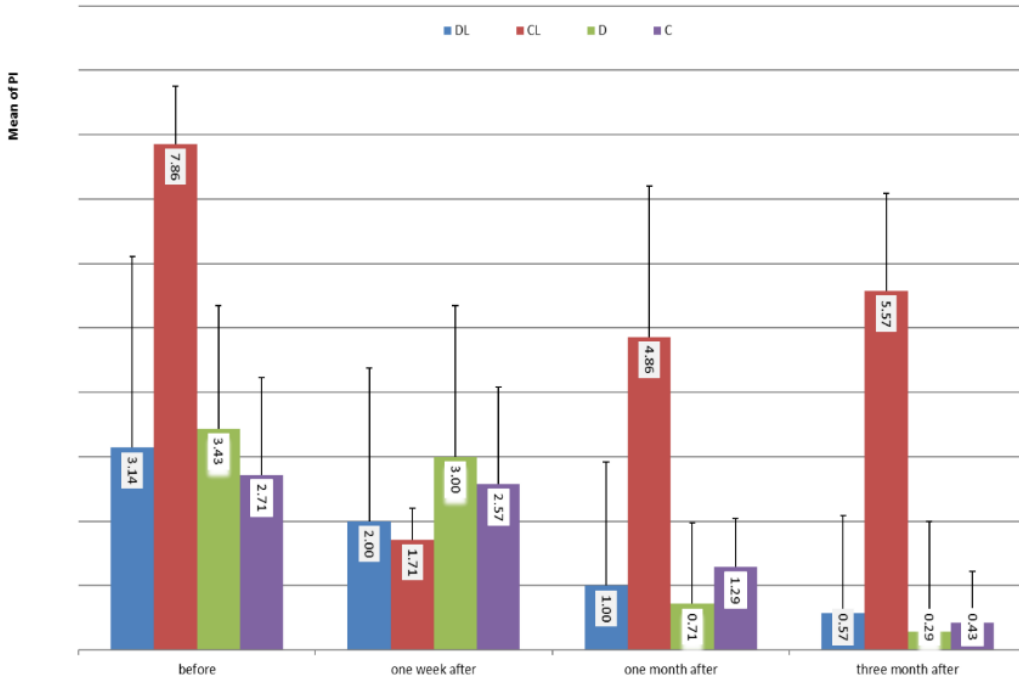

Figure 2. Mean and standard deviation of the pain intensity

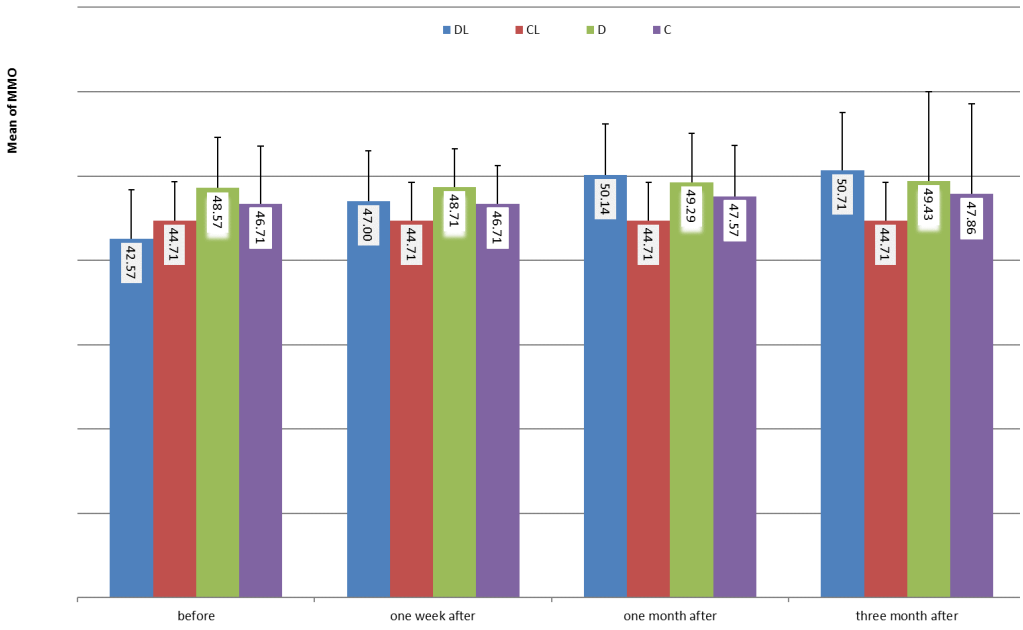

Figure 3. Mean and standard deviation of maximum mouth opening over time

within-group analyses using the Friedman test indicated that pain intensity changes over the measurement time points were statistically significant for all 4 treatment groups (Tables 2 and 3) (Figure 2).

Maximum Mouth Opening and Jaw Movements

The study results showed statistical significance in the changes of maximum mouth opening, jaw forward movements, and lateral jaw movements between the four treatment groups (C, CL, D, and DL) at different time points (one week, one month, and three months compared to baseline). For maximum mouth opening, there were significant differences between the changes of one week, one month, and three months compared to baseline, with *P*-values of 0.001, < 0.001, and < 0.001, respectively, across the four groups. Pairwise comparisons using the Bonferroni test revealed significant differences between groups C and DL ($P = 0.004$), CL and DL ($P = 0.005$), and D and DL ($P = 0.020$), with the DL group demonstrating the greatest increase in maximum mouth opening. Within-group analysis using the Friedman test showed statistically significant differences in maximum mouth opening over

time in groups C ($P=0.033$) and DL ($P=0.001$). For jaw forward movements, there were significant differences between the changes of one week ($P=0.0001$), one month ($P=0.001$), and three months ($P=0.001$) compared to the baseline across the four groups (Figure 3). Pairwise comparisons using the Bonferroni method revealed significant differences between DL and CL ($P=0.0001$), D and DL ($P=0.0001$), and DL and C ($P=0.0001$), with the DL group showing the greatest increase in jaw forward movements. For lateral jaw movements (right and left), there were significant differences between the changes of one week, one month, and three months compared to baseline, with *P*-values of <0.001, 0.04, and 0.019, respectively (Figure 4). Pairwise comparisons using the Bonferroni test showed significant differences between C and DL ($P=0.001$), D and DL ($P=0.002$), and CL and DL ($P=0.010$), with the DL group demonstrating the most significant increase in lateral jaw movements. Within-group analysis using the Friedman test showed a statistically significant difference in lateral jaw movements over time in the DL group ($P=0.003$).

Discussion

The results of this study demonstrated several significant findings. Regarding splint characteristics and patient satisfaction, there were statistically significant differences between the groups in the number of splint adjustment points required. For the comparison of treatment outcomes, baseline differences were accounted for by analyzing the changes from baseline. Pain intensity showed a statistically significant reduction at 1 week in the CL group compared to the other three groups. Maximum mouth opening and the range of jaw movements (forward, lateral right and left) showed the greatest improvements in the DL group compared to the other groups at multiple timepoints. Within-group analyses also revealed significant increases in range of motion outcomes over time in the DL group. Overall, the digitally fabricated splints used in combination with low-power diode laser therapy (DL group) demonstrated superior clinical outcomes compared to the other treatment approaches evaluated.

In a randomized clinical trial, the findings indicated that the improvement of pain and mouth opening in the treatment groups was better than that in the control group, and in the low-power laser therapy group, it was better than that in the OS.[24] In addition, it has been shown that laser therapy, compared to placebo or other minimally invasive methods, has a good effect on pain in patients with temporomandibular disorder [24]. Also, with the aim of evaluating and comparing the effectiveness of OS and low-level laser therapy in 40 patients with TMJ pain, it has been shown that the patients of the OS group had a statistically significant improvement in mouth opening, and the patients of the laser therapy group had a significant improvement in reducing pain.[25] Therefore, both methods are somehow effective in the improvement of patients, so it is necessary to investigate the effectiveness of the combination of these two approaches.

Previous studies on patients with chronic closed lock from disc displacement without TMJ reduction have shown that the combined treatment of OS and laser therapy resulted in significant improvements in VAS scores and mouth opening compared to single treatments of each approach.[26] However, another study evaluating the comparison of using low-power laser therapy along with splint therapy versus splint therapy alone for the treatment of TMDs found that adding laser therapy did not increase long-term improvements, though it did reduce pain in

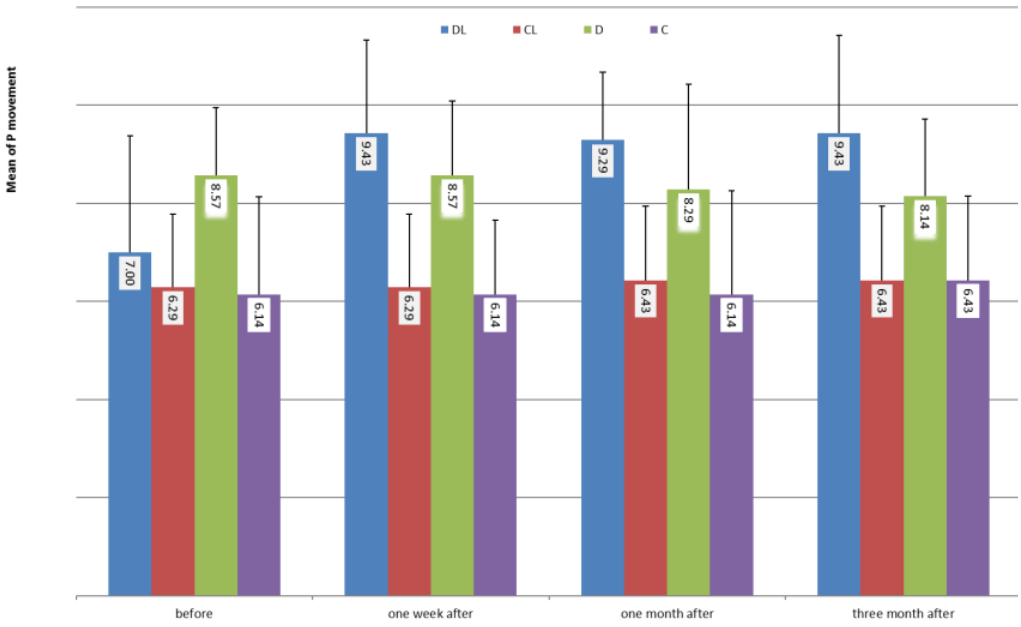

Figure 4. Mean and standard deviation of lateral movements (right and left), and the number of forward movements for different groups over time

the first weeks.[27] The present study found similar results, with a significantly greater decrease in pain intensity at 1 week in the OS + low-power laser group compared to the other three groups, but no significant differences in pain reduction at 1 month and 3 months. This suggests that the short-term effects of the combined approach may be greater than the long-term effects. Some conflicting results have been reported, with one study finding laser therapy ineffective for treating myogenic problems.[28] This may be related to differences in treatment duration, laser power/wavelength, and the specific application site (TMJ versus masticatory muscles). Overall, reviews of previous studies indicate that the combined treatment of low-power laser with OS is preferable to splint treatment alone for TMD patients.[29] Additionally, digital splints have been shown to affect pain intensity better than conventional splints.[30]

In the present study, while there was no significant difference in healing factors including pain between the two groups that only used OS, the comparison of all groups showed a greater improvement in pain in the group that received low-power laser therapy combined with a digital splint. The difference between the digital splint + laser group and the conventional splint + laser group can be attributed to the method of splint fabrication. Using a digital approach for creating the splint offers advantages such as eliminating human errors, saving time, and higher levels of predictability compared to conventional molding and casting techniques.[31] Therefore, the digital splint approach appears preferable even when not combined with laser therapy. The results of the present study indicate that the combination of digitally fabricated OS treatment with low-power laser therapy can improve pain, maximum mouth opening, forward movements, and lateral movements of the jaw. This combined approach may increase patient satisfaction with the treatment and encourage them to receive this form of therapy. Interestingly, the present study found no significant difference in patient satisfaction after three months between the groups receiving digitally fabricated and conventionally made OS. However, the study did identify differences in the accuracy and compatibility of the OS with the oral environment, as measured by the number of adjustment points required during the delivery session. Specifically, the average number of adjustment points was significantly higher for the conventional splint group compared to the digital splint group, likely due to the greater precision of the digital manufacturing process. Since this study compared not only the combined approach of OS with laser therapy versus OS alone but also the methods of splint fabrication, the authors recommend future randomized clinical trials with larger sample sizes to obtain more reliable results. Additionally, they suggest studies with longer follow-up times, as well as an examination of specific laser treatment variables, such as wavelength, irradiation time, muscle type, and number of sessions, given their potential impact on treatment outcomes.

Our study does have some limitations that should be acknowledged. One notable limitation is the relatively small sample size of 40 patients, which, although sufficient to detect clinically meaningful differences, may limit the generalizability of the findings. Future research could benefit from larger, multi-center trials to enhance the external validity of the results. Additionally, the study's reliance on self-reported measures for bruxism and patient satisfaction may introduce bias; incorporating objective measures could provide a more comprehensive assessment of treatment efficacy. Furthermore, the follow-up period of three months may be insufficient to evaluate the long-term effects of the interventions. Extended follow-up would allow for a better understanding of the durability of treatment outcomes. The potential influence of confounding variables, such as lifestyle factors or concurrent treatments, was not extensively controlled, which could affect the results. Future studies should aim to standardize participant characteristics and control for these variables. Lastly, exploring the mechanisms of action in greater detail, particularly how different types of splints interact with laser therapy, could yield insights for optimizing treatment protocols. Addressing these limitations in future research will enhance the understanding of TMD management and improve clinical practices.

Conclusion

The findings of this study suggest that the combined approach of using a digitally fabricated OS along with low-level laser therapy may be the preferred method for treating patients with TMD. This combined treatment demonstrated greater improvements in pain and functional factors compared to using an OS alone. Beyond the benefits of the combined therapy, the study also identified the advantages of the digital splint fabrication process over the conventional approach. Digitally made splints exhibited fewer manufacturing errors and required fewer adjustment points during delivery, resulting in faster treatment procedures. This increased accuracy and efficiency of the digital splint method could further contribute to improved patient outcomes and satisfaction. Overall, the results of this study support the adoption of the digital splint and laser therapy combination as an effective, reliable, and preferred approach for managing TMD patients in clinical practice. The superior precision and speed of the digital fabrication process, combined with the synergistic effects of laser therapy, make this a compelling treatment option worthy of further investigation and implementation.

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Competing Interests

The authors declare no conflict of interest.

Ethical Approval

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