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Effects of Occlusal Splints on Temporomandibular Disorders and Well-Being Among Fibromyalgia and Bruxism Patients: A Quasi-Experimental Study

Maria Esteve * and Juan Ignacio Rosales Leal

Stomatology Department, School of Dentistry, University of Granada, 18071 Granada, Spain; irosales@ugr.es
* Correspondence: mariaestevero@gmail.com

Abstract: Background: The purpose of this study was to investigate the effect of occlusal splints on temporomandibular disorders (TMDs) and well-being in patients with fibromyalgia and bruxism. This experimental study assessed the impact of Michigan-type occlusal splints on TMDs and well-being in fibromyalgia and bruxism patients and healthy individuals. Methods: This quasi-experimental study assesses the impact of an intervention on TMD symptoms and overall well-being in patients with fibromyalgia and bruxism. A total of 266 participants were divided into three groups: bruxism with fibromyalgia (ABFG, n = 37), sleep bruxism with fibromyalgia (SBFG, n = 53), awake bruxism without fibromyalgia (ABG, n = 45), sleep bruxism without fibromyalgia (SBG, n = 85), and a healthy control group (HG, n = 46). All participants received a rigid acrylic occlusal splint and counseling on behavioral changes. Pre- and post-treatment questionnaires measured various variables, including jaw function (JFLS-8), anxiety (GAD-7), oral health impact (OHIP-14), well-being (WHO-5), sleep quality (PSQI), and symptoms such as bruxism, TMJ pain, headaches, and jaw locking. Results: The study demonstrated that occlusal splints significantly improved various outcomes in patients with bruxism and fibromyalgia. For the ABFB, significant reductions were observed in JFLS-8, GAD-7, OHIP-14, and PSQI and increases in WHO-5 scores ($p < 0.001$). Similar improvements were noted in the SBFB. The ABG group showed significant changes in JFLS-8, OHIP-14, and WHO-5, but not in GAD-7 or PSQI. Furthermore, SBG exhibited significant improvements across all measures except WHO-5. Patients in the HG showed only slight changes in PSQI. Additionally, significant reductions in the prevalence of TMJ pain, headaches attributed to TMJ, and jaw locking were noted across the bruxism groups. Conclusion: This study finds that occlusal splints significantly enhance symptoms of TMD and enhance overall well-being, especially in patients with fibromyalgia. Significant improvements were observed in JFLS-8, GAD-7, OHIP-14, PSQI, and WHO-5 scores, alongside a marked reduction in the prevalence of TMJ pain, TMJ-related headaches, and jaw locking. This highlights occlusal splints as an effective therapeutic option for managing both physical and psychological symptoms in fibromyalgia patients. However, the benefits for healthy individuals were minimal, suggesting a need for further research on long-term effects and treatment optimization.

Keywords: prosthodontic; occlusion; clinical; rehabilitation; appliance

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1. Introduction

Temporomandibular disorder (TMDs) is one of the leading causes of seeking dental care, aside from dental pain. As a result, dental practitioners must be well-versed in identifying the risk factors of patients most susceptible to TMDs, ensuring accurate

diagnosis, and selecting the most effective management strategies for optimal treatment outcomes [1]. TMDs refers to a range of conditions involving pain and/or dysfunction of the masticatory muscles and temporomandibular joints [1]. The key symptoms include pain, restricted jaw movement, and joint noises during jaw function [1]. While TMDs are not life-threatening, it can significantly affect a person's quality of life, particularly when symptoms become chronic, as management can be complex and often necessitates a multidisciplinary approach [1]. Mandibular functional limitations in chewing and mobility are key clinical manifestations of TMDs [2]. Thus, early identification and intervention of these limitations can significantly enhance patients' quality of life [2].

TMDs are often comorbid with primary headaches [3]. Notably, the prevalence of headaches rises in correlation with the number of TMDs symptoms [4]. Studies have shown that 56.5% of individuals with one TMDs symptom experience headaches, while the prevalence increases to 65.1% in those with two symptoms, and further to 72.8% in individuals presenting with three or more TMDs symptoms [4]. According to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMDS), a headache attributed to TMDs is defined as a headache in the temple area that is secondary to pain-related TMDs [4]. This headache is affected by jaw movement, function, or parafunction and can be replicated during provocation testing of the masticatory system [5].

Psychosocial disorders and impairments play a crucial role in the development of TMDs [6]. The prevalence of psychosocial factors is notably higher in TMDs patients, with anxiety being a significant comorbidity [6]. Anxiety can influence pain perception and trigger the release of neurotransmitters linked to parafunctional habits [7]. Additionally, it may contribute to hyperactivity in the masticatory muscles, leading to joint overload and exacerbating TMDs symptoms [7]. Moreover, TMDs can have a significant impact on oral health, directly affecting individuals' daily lives, personal experiences, socio-cultural environments, and mental well-being [8]. The discomfort and limitations caused by TMDs can influence not only physical functioning but also emotional functioning and social interactions [8]. The consideration of the biopsychosocial effects of oral health and disease on patients' lives is gaining prominence [9]. It is increasingly recognized that the management of conditions like TMDs should adopt a patient-centered approach, incorporating psychological evaluation rather than focusing solely on physician-centered technical parameters [9]. Health encompasses not only the absence of disease but also the presence of physical, psychological, and social well-being [10]. These aspects can be effectively assessed through social indicators, global self-assessments, and multi-item surveys to provide a holistic view of patient care [10].

These symptoms may be accentuated in patients with bruxism, as the repetitive jaw-muscle activity associated with clenching or grinding of the teeth can further aggravate pain and discomfort, potentially worsening both TMD and sleep disturbances [11]. This activity may be present in patients with fibromyalgia, as it is a chronic condition that causes widespread pain and sensitivity, fatigue, and other symptoms such as sleep disturbances or general discomfort [12]. Well-being is a multidimensional construct that includes physical, psychological, and social aspects of health [12]. In patients with chronic pain conditions such as TMD and fibromyalgia, well-being can be assessed using validated scales, which have been widely used in research on chronic pain and quality of life [12]. It is a central sensitization syndrome, characterized by chronic musculoskeletal pain, affecting approximately 5% of the global population [13]. Several studies have highlighted the common presence of a painful condition associated with TMDs and fibromyalgia [13]. This syndrome involves a combination of factors that predispose individuals to, and trigger, TMDs, which may account for the high prevalence of TMDs signs and symptoms in these patients [14]. Bruxism can occur during sleep as an activity of the masticatory muscles, particularly

during the N1 sleep stage, including brief daytime naps, and may be rhythmic (phasic) or non-rhythmic (tonic) [15]. It is associated with morning headaches, and some studies have highlighted its effect on insomnia [16]. On the other hand, daytime bruxism is described as masticatory muscle activity during wakefulness, characterized by repeated or prolonged contact of opposing teeth and/or jaw clenching or thrusting. It is not considered a motor disorder in otherwise healthy populations [17].

Sleep disturbances are recognized as a risk predictor for developing painful TMD [18]. There is a proportional and bidirectional relationship between sleep quality and TMD pain, as pain can disrupt sleep, and poor sleep, in turn, exacerbates pain [18]. TMDs affect up to 15% of adults, with as many as 90% of TMDs patients reporting poor sleep quality [19]. Insomnia and sleep apnea are the two most common forms of sleep disturbances observed in individuals with TMDs [19].

To prevent the negative effects of sleep bruxism, stabilizing and occlusal splints can be used [20]. These splints eliminate occlusal interferences, relax the masticatory and neck muscles through passive stretching, improve occlusal and neuromuscular stabilization, and reposition the mandibular condyles and articular discs [20]. In addition to occlusal splint, treatment for bruxism may involve various therapeutic options, such as patient education about harmful habits, biofeedback, muscle relaxation exercises, short-term medications, botulinum toxin injections, psychotherapy (including stress reduction, lifestyle changes, hypnosis), electrical methods, and correction of speech pattern disturbances [21,22].

However, few studies have explored the combination of these variables and pathologies in patients with fibromyalgia and bruxism. Both bruxism and fibromyalgia are conditions that may lead to increased pain sensitivity and muscular hyperactivity, which can contribute to the onset and exacerbation of TMD symptoms. The combination of fibromyalgia and bruxism is especially important to study because both conditions may share underlying mechanisms like central sensitization and disrupted pain regulation. They belong to a group of disorders known as central sensitization syndromes—which also includes conditions such as irritable bowel syndrome, chronic fatigue syndrome, and migraine. These syndromes often overlap in the same patients and can make symptoms worse when they occur together. Looking at this comorbidity helps us better understand why some people experience more severe or complex TMD symptoms [18]. Additionally, the presence of bruxism in individuals with fibromyalgia has been linked to increased muscle tension, which may further aggravate TMD symptoms [11]. Given these physiological connections, investigating the impact of occlusal splints in these specific groups is crucial to understanding potential therapeutic approaches. It would be valuable to investigate whether the use of an unloading splint could offer an effective solution for these patients. Therefore, the aim of this study was to evaluate the impact of splint therapy on TMDs symptoms and overall well-being in patients with fibromyalgia and bruxism.

2. Materials and Methods

2.1. Study Design

This is a quasi-experimental study with an experimental design which measures the effect of an intervention on TMDs symptoms and overall well-being in patients with fibromyalgia and bruxism. Diagnostic criteria for the assessment of temporomandibular disorders were used in a clinical context with patients with bruxism, fibromyalgia and bruxism, and a healthy group, which was used as a comparison group. This design was selected due to the ethical considerations associated with withholding treatment from symptomatic patients seeking care. The study was approved by the Ethics Committee of the University of Granada (Approval Code: 4492). All participants gave informed consent prior to inclusion.

2.2. Participants

A total of 266 participants were included in this study; all patients in this study were patients who came to the dental clinic. Participants were assigned to one of the following groups: awake bruxism with fibromyalgia (ABFG, n = 37), sleep bruxism with fibromyalgia (SBFG, n = 53), awake bruxism without fibromyalgia (ABG, n = 45), sleep bruxism without fibromyalgia (SBG, n = 85), and the rest of participants were assigned to the healthy group (HG, n = 46), that is, the control group. Participants in the healthy group did not meet diagnostic criteria for bruxism, fibromyalgia, or TMDs. Occasional mild symptoms, such as joint sounds or transient discomfort, were not exclusion criteria, as they are common in routine dental evaluations and not indicative of pathology.

To participate in this study, the following inclusion criteria were considered: (a) the age of each participant had to range from 25 to 70 years old, and (b) participants had to give informed consent to voluntarily take part in the study. Also, (c) for the bruxism categorization, patients with possible sleep bruxism, and/or possible wakefulness bruxism were selected. Finally, (d) the fibromyalgia group diagnosis for the participants was based on the revised ACR 2016 criteria [23]. Those diagnosed with fibromyalgia according to the ACR 2016 criteria were assessed by me based on their interview responses. These criteria are a combination of the ACR 2010 and 2011 criteria, serving as diagnostic criteria when used in clinical settings, but also as classification criteria when used for research purposes, or for those already diagnosed with this syndrome, the diagnosis had been made by their primary care physicians or rheumatologists in specialized centers and was confirmed by the study team through a review of medical records and the application of relevant questionnaires. However, the following exclusion criteria were considered: (a) edentulous individuals (complete loss of all natural teeth) and (b) pregnant women.

2.3. Procedures

All patients received therapy with rigid acrylic upper occlusal splint habit counseling and standardized behavioral recommendations. The occlusal splint was constructed after an occlusal registration and subsequent occlusal adjustment by the doctor. Patients were advised to wear the splint only at night while sleeping. All patients also received beneficial behavioral changes and were given a printed version of instructions on relaxation techniques, sleep hygiene, diet modification, thermotherapy, and pain management, as well as avoidance of dental clenching. In addition, the participants completed a questionnaire for the assessment of temporomandibular disorders, bruxism, and overall well-being before and after performing the treatment using a Michigan-type splint. The second phase of questionnaires were conducted after 1 month of treatment following the use of the Michigan-type splint based on prior research suggesting that early improvements in TMD symptoms can be detected within this timeframe [24]. Specifically, this questionnaire had 8 sections. (1) Jaw functional scale 8 (JFLS-8) [25]; (2) generalized anxiety disorder 7 (GAD-7) [26]; (3) oral health impact profile 14 (OHIP-14) [27]; (4) world health organization well-being index (WHO-5) [28]; (5) Pittsburgh sleep quality index (PSQI) [29]; (6) sleep bruxism [30]; (7) awake bruxism [30]; (8) joint sounds [5]; (9) temporomandibular joint pain [5]; (10) headache attributed to temporomandibular joint [31]; (11) headache attributed to bruxism [31]; and (12) jaw locking [5]. Then, the following sections contained categorical variables with specific questions to measure additional TMD, bruxism, and overall well-being, based on the patient's testimony and clinical examination. Specifically, the following variables were measured.

Probable sleep bruxism, according to the Standardized Tool for the Assessment of Bruxism (STAB) [32] and positive responses (i.e., "yes" answer) to any of the following

bruxism questions [30]: "(a) Are you aware that you clench at night?; (b) Has anyone told you that you clench or grind your teeth at night?; (c) Do you wake up with a headache?"

Probable awake bruxism was diagnosed using the STAB (21) and based on a positive response to the following question: 'Are you aware of clenching or grinding your teeth during the day?

Joint sounds [5], if affirming the following question: "Have you had any noise(s) in the joint when moving or using the jaw?"

Temporomandibular joint pain [5]: The participant had to confirm that pain in the jaw, temple, ear, or front of the ear is always present or comes and goes. Also, the individuals had this disorder if answering yes to the following question: "Did any of the following activities affect (i.e., did the pain improve or worsen) the pain in your jaw or temple on either side? Chewing hard or difficult-to-grind foods; Open the mouth or moving the jaw sideways or forward; Oral habits such as keeping teeth together, clenching, grinding, or chewing gum; Other jaw activities such as talking, kissing, or yawning".

Headache attributed to temporomandibular joint [31], if confirming headaches involving the temple area or any of the following activities changing the individual's headache (making it better or worse) located in the temples on either side: (a) Chewing hard or difficult to grind foods; (b) Open the mouth or move the jaw sideways or forward; (c) Oral habits such as keeping teeth together, clenching or grinding teeth or chewing gum; (d) Other jaw activities such as talking, kissing or yawning.

Headache attributed to bruxism [31] if confirming headaches when waking up.

Jaw locking [5] according to positive responses (i.e., "yes" answer) to the following questions: (a) "Have you ever had your jaw locked, even for a moment, so that you could not fully open your mouth (even if it was for a moment and then unlocked)?"; (b) Was that jaw locking severe enough that it limited your mouth opening and interfered with your ability to eat?; (c) Did you open your mouth wide, did your jaw lock, even for a moment, so that you could not close your mouth from that wide-open position?; (d) When your jaw was in a fully open position, did you have to do anything such as rest, move, push or maneuver your jaw to get your mouth to close?

2.4. Statistical Analysis

First, descriptive statistics were calculated for the numeric variables (i.e., JFLS-8, GAD-7, OHIP-14, WHO-5, and PSQI) as mean and standard deviation (mean $\pm$ SD) and for the categorical variables as frequency count and percentage of prevalence in each group (i.e., fibromyalgia and healthy group). These descriptive statistics were obtained before and after the intervention. Then, a non-parametric test (Wilcoxon test) was used to compare pre-and post-test differences in each variable and group in all numeric variables. Cohen's d was calculated to measure the effect size (ES), which was interpreted as follows: 0–0.19 (trivial effect), 0.20–0.49 (small effect), 0.50–0.79 (moderate effect), and 0.80 or higher (large effect) [33]. In addition, the McNemar–Bowker test was used to compare pre-and post-test differences in the categorical variables. The level of significance set at $p \leq 0.05$ for all the analyses. All statistical analyses were conducted using IBM SPSS Statistics software, version 29.0 (IBM Corp., Armonk, NY, USA).

3. Results

Table 1 shows the differences in pre and post-occlusal splint intervention in ABFG, SBFG, ABG, SBG, and HG in JFLS-8, GAD-7, OHIP-14, WHO-5, and PSQI.

The intervention had a significant effect on all variables in the ABFG. The mean score significantly decreased in JFLS-8 ($p < 0.001$, ES = 1.54), GAD-7 ($p < 0.001$, ES = 1.69), OHIP-14 ($p < 0.001$, ES = 3.52), and PSQI ($p < 0.001$, ES = 2.01) in addition to increasing scores for

WHO-5 ($p < 0.001$, ES = 1.15). When it comes to the SBFG, it also showed significant changes in JFLS-8 ($p < 0.001$, ES = 1.71), GAD-7 ($p < 0.001$, ES = 1.69), OHIP-14 ($p < 0.001$, ES = 2.61), PSQI ($p < 0.001$, ES = 2.18), and WHO-5 ($p < 0.001$, ES = 1.10). Regarding the ABG, it also showed significant changes in JFLS-8 ($p < 0.001$, ES = 0.98), OHIP-14 ($p = 0.02$, ES = 0.51), and WHO-5 ($p = 0.01$, ES = 0.35). However, no significant changes were observed in GAD-7 ($p = 0.21$, ES = 0.21) or PSQI ($p = 0.17$, ES = 0.16). When it comes to the SBG, it also showed significant changes in JFLS-8 ($p < 0.001$, ES = 1.04), GAD-7 ($p < 0.001$, ES = 0.62), OHIP-14 ($p < 0.001$, ES = 1.15), and PSQI ($p < 0.001$, ES = 0.36). On the other hand, no significant changes were observed in WHO-5 ($p = 0.59$, ES = 0.06). For HG, significant changes were only observed in PSQI ($p = 0.01$, ES = 0.25). There were no significant differences in JFLS-8 ($p = 0.07$, ES = 0.16), GAD-7 ($p = 0.52$, ES = 0.06), OHIP-14 ($p = 0.22$, ES = 0.17), or WHO-5 ($p = 0.07$, ES = 0.25).

Table 1. Differences pre- and post-occlusal splint intervention in JFLS-8, GAD-7, OHIP-14, WHO-5, and PSQI.

Group	Variables	Pre	Post	*p*	ES
Awake bruxism with fibromyalgia	JFLS-8	17.19 ± 12.09	3.3 ± 3.99	<0.001	1.54
	GAD-7	14.14 ± 3.93	7.70 ± 3.70	<0.001	1.69
	OHIP-14	32.70 ± 2.66	14 ± 7.03	<0.001	3.52
	WHO-5	5.19 ± 2.66	8.84 ± 3.62	<0.001	1.15
	PSQI	15.81 ± 2.37	11.11 ± 2.31	<0.001	2.01
Sleep bruxism with fibromyalgia	JFLS-8	18.13 ± 11.85	3.11 ± 3.70	<0.001	1.71
	GAD-7	13.34 ± 3.84	6.91 ± 3.76	<0.001	1.69
	OHIP-14	30.77 ± 7.57	11.75 ± 7	<0.001	2.61
	WHO-5	6.77 ± 3.73	10.77 ± 3.55	<0.001	1.10
	PSQI	15.64 ± 2.43	10.57 ± 2.22	<0.001	2.18
Awake bruxism without fibromyalgia	JFLS-8	8.53 ± 9.61	1.58 ± 2.78	<0.001	0.98
	GAD-7	7.44 ± 4.97	6.43 ± 4.74	0.21	0.21
	OHIP-14	14.53 ± 8.83	10.53 ± 6.72	0.02	0.51
	WHO-5	12.60 ± 5.01	10.78 ± 5.42	0.01	0.35
	PSQI	8.78 ± 3.78	8.22 ± 3.27	0.17	0.16
Sleep bruxism without fibromyalgia	JFLS-8	8.47 ± 10.02	0.93 ± 2.24	<0.001	1.04
	GAD-7	7.31 ± 4.47	4.78 ± 3.63	<0.001	0.62
	OHIP-14	15.21 ± 8.61	6.71 ± 5.90	<0.001	1.15
	WHO-5	12.61 ± 4.99	12.89 ± 4.45	0.59	0.06
	PSQI	8.84 ± 3.73	7.59 ± 3.18	<0.001	0.36
Healthy group	JFLS-8	2.15 ± 5.11	1.46 ± 3.48	0.07	0.16
	GAD-7	4.07 ± 4.56	3.78 ± 4.38	0.52	0.06
	OHIP-14	6.35 ± 6.98	5.33 ± 4.78	0.22	0.17
	WHO-5	14.74 ± 4.93	13.65 ± 4.54	0.07	0.23
	PSQI	5.78 ± 2.49	5.22 ± 1.99	0.01	0.25

Note: JFLS-8: Jaw functional limitation scale; GAD-7: General Anxiety Disorder-7; OHIP-14: Oral Health Impact Profile-14; WHO-5: World Health Organization Well-Being Index; PSQI: Pittsburgh Sleep Quality Index (PSQI).

Table 2 shows the prevalence (%) of temporomandibular disorders pre- and post-occlusal splint intervention in ABFG, SBFG, ABG, SBG, and HG.

A significant reduction in the prevalence of TMJ pain ($p < 0.001$), headache attributed to TMJ ($p < 0.001$), and jaw locking ($p < 0.001$) was found in ABFG. However, no significant changes were observed in joint sounds ($p = 0.63$) and headache attributed to bruxism ($p = 1.00$). When it comes to SBFG, significant differences were observed in the following variables: TMJ pain ($p < 0.001$), headache attributed to TMJ ($p < 0.001$), and jaw locking ($p < 0.001$). On the other hand, no significant changes have been observed in joint sounds

($p = 0.13$), and headache attributed to bruxism ($p = 0.13$). For the ABG, significant differences were observed in all variables: joint sounds ($p = 0.02$), TMJ pain ($p < 0.001$), headache attributed to TMJ ($p < 0.001$), headache attributed to bruxism ($p = 0.01$), and jaw locking ($p < 0.001$). Regarding the SBG, significant differences were observed in all variables: joint sounds ($p = 0.02$), TMJ pain ($p < 0.001$), headache attributed to TMJ ($p < 0.001$), headache attributed to bruxism ($p < 0.001$), and jaw locking ($p < 0.001$). Finally, in HG, there were significant changes in TMJ pain ($p < 0.001$), headache attributed to TMJ ($p < 0.001$), and jaw locking ($p < 0.001$). Nevertheless, no significant changes were found for joint sounds ($p = 0.63$) or headache attributed to bruxism ($p = 0.33$).

Table 2. Frequency (count, n) and prevalence (%) of temporomandibular disorders and well-being pre- and post-occlusal splint intervention.

Group	Variable	Pre	Post	*p*
Awake bruxism with fibromyalgia	Joint sounds	23 (62.2%)	21 (56.8%)	0.63
	TMJ pain	37 (100%)	22 (59.5%)	<0.001
	Headache attributed to TMJ	37 (100%)	24 (64.9%)	<0.001
	Headache attributed to bruxism	36 (97.3%)	35 (94.6%)	1.00
	Jaw locking	17 (45.9%)	1 (2.7%)	<0.001
Sleep bruxism with fibromyalgia	Joint sounds	35 (66%)	30 (56.6%)	0.13
	TMJ pain	53 (100%)	27 (50.9%)	<0.001
	Headache attributed to TMJ	52 (98.1%)	31 (58.5%)	<0.001
	Headache attributed to bruxism	52 (98.1%)	47 (28.7%)	0.13
	Jaw locking	24 (45.3%)	1 (1.9%)	<0.001
Awake bruxism without fibromyalgia	Joint sounds	22 (48.89%)	15 (33.3%)	0.02
	TMJ pain	37 (82.2%)	20 (44.44%)	<0.001
	Headache attributed to TMJ	39 (86.67%)	19 (42.22%)	<0.001
	Headache attributed to bruxism	35 (77.77%)	26 (57.68%)	0.01
	Jaw locking	13 (28.89%)	1 (0.02%)	<0.001
Sleep bruxism without fibromyalgia	Joint sounds	43 (50.6%)	23 (27.1%)	<0.001
	TMJ pain	67 (78.8%)	18 (21.2%)	<0.001
	Headache attributed to TMJ	68 (80%)	22 (25.9%)	<0.001
	Headache attributed to bruxism	74 (87.11%)	29 (34.1%)	<0.001
	Jaw locking	18 (21.2%)	1 (1.2%)	<0.001
Healthy group	Joint sounds	12 (26.1%)	10 (21.7%)	0.63
	TMJ pain	18 (39.1%)	7 (15.2%)	<0.001
	Headache attributed to TMJ	26 (56.5%)	10 (21.7%)	<0.001
	Headache attributed to bruxism	17 (37.0%)	12 (26.1%)	0.33
	Jaw locking	8 (17.4%)	0 (0.0%)	0.01

Note: TMJ = temporomandibular joint.

4. Discussion

The aim of this study was to analyze the effect of an occlusal splint intervention on TMDs and overall well-being in five specific groups: (1) patients with awake bruxism and fibromyalgia, (2) patients with sleep bruxism and fibromyalgia, (3) patients with awake bruxism without fibromyalgia, (4) patients with sleep bruxism without fibromyalgia, and (5) a group of healthy individuals without bruxism or fibromyalgia. The variables analyzed included measures of mandibular function, anxiety, oral health, well-being, sleep quality, and specific TMJ symptoms, such as joint noises, and temporomandibular pain. The occlusal splint intervention resulted in significant positive effects in ABFB, SBFB, ABG, and SBG. While HG also showed improvements after treatment, these were less pronounced compared to the other groups. The findings of this study suggest that occlusal splints may contribute to improvements in TMD symptoms and psychological well-being in patients

with bruxism and fibromyalgia. However, given the study design, these results should be interpreted with caution. The observed benefits may be partially explained by other factors such as behavioral counseling and patient expectations.

Firstly, in the ABFB group, the occlusal splint intervention showed significant improvement in multiple TMD-related symptoms, including TMJ pain, joint noises, mandibular locking, and reductions in JFLS-8 scores. These results suggest that the use of splints may alleviate the overload on the TMJ in patients exhibiting both bruxism and fibromyalgia. Molina-Torres et al., in their study comparing laser therapy on pain trigger points and the use of stabilization splints, concluded that both can be effective therapeutic treatments for reducing pain symptoms and the clicking sounds associated with TMD in patients with fibromyalgia [34]. Additionally, this group showed an improvement in both psychological and physical well-being, as reflected in the scores of the GAD-7, OHIP-14, WHO-5, and PSQI questionnaires. Although some of these tools may assess related domains, each was selected for its validated focus on a distinct construct—such as sleep quality, emotional well-being, or functional limitations—allowing for a more comprehensive interpretation. However, it is important to consider that the intervention also included behavioral recommendations. This raises the possibility that improvements were partially influenced by factors such as sleep hygiene, stress management, and relaxation techniques. Prior research by Raphael and Marbach (2001) highlighted that patients with widespread pain did not significantly benefit from occlusal splints, whereas those with localized pain did [35]. This contrasts with our findings, which showed improvements even in patients with fibromyalgia. One possible explanation is that we used a different splint design, and all patients also received behavioral guidance as part of the treatment. These additional elements, along with differences in patient selection and context, may have contributed to the more favorable outcomes observed in our study. Thus, patient context, differences in methodology, and the multifactorial nature of the intervention may explain the difference in our results from those of previous studies reporting limited effects in similar populations.

Secondly, for the SBFB group, the intervention also resulted in significant improvements in TMD-related symptoms, particularly in TMJ pain, mandibular locking, and reductions in JFLS-8 scores. Improvements in GAD-7, OHIP-14, WHO-5, and PSQI scores also reflected enhancements in overall well-being and sleep quality. This is consistent with prior studies, such as Gomes et al., which demonstrated that the use of splint therapy in the treatment of sleep bruxism creates a biomechanical balance between the physiological load and that generated by stress [24]. This suggests that such treatment may lead to the stabilization of bruxism by reducing deformations and deviations in the TMJ, thereby decreasing the load on the joint [24].

Patients in the ABG also exhibited significant improvements in mandibular function, as indicated by JFLS-8 scores, along with enhancements in oral health and overall well-being (as measured by OHIP-14 and WHO-5). However, the improvements in anxiety (GAD-7) and sleep quality (PSQI) did not reach statistical significance in this group. This may be partly due to the relatively small sample size in this subgroup. This suggests that while the splint has a positive impact on certain aspects of TMD and overall well-being, the effects may be less pronounced concerning anxiety reduction and sleep improvement in patients with bruxism without fibromyalgia. This finding supports studies such as that by Ainoosah et al., which observed that adjustable splints, such as full-occlusion biofeedback splints, were more effective in reducing episodes of sleep bruxism, improving patient-reported symptoms, and enhancing overall well-being [36]. Although our study showed smaller changes in the WHO-5 well-being test, positive post-treatment changes were still observed [36].

In the SBG, the intervention led to significant improvements in JFLS-8, GAD-7, OHIP-14, and PSQI. However, the WHO-5 did not show statistically significant changes. These results suggest that for patients with sleep bruxism, the occlusal splint may be beneficial in alleviating specific TMD symptoms and improving physical aspects, but its impact on overall well-being may be limited in comparison to other groups. This finding supports research by Garstka et al., who indicated that the combination of splint use with behavioral and physiotherapy interventions could maximize benefits for patients with bruxism and TMD [37].

Finally, in the HG, significant improvements were only observed in PSQI after the use of the occlusal splint, while other variables, such as JFLS-8, GAD-7, and WHO-5, did not show statistically significant changes. This suggests that while the use of splints may enhance certain aspects of sleep in healthy individuals, their impact on other aspects of well-being and mandibular function is minimal in the absence of TMD or evident bruxism. These findings align with studies highlighting the importance of combining splint use with additional interventions for those without apparent mandibular or bruxism-related issues. Although WHO-5 scores slightly decreased in this group, the change was not statistically significant. This may reflect a lack of perceived benefit from the splint in asymptomatic individuals or discomfort from using an unnecessary device. While occlusal splints are generally safe, minor side effects such as occlusal changes or patient dissatisfaction may occur, particularly when no clinical indication is present. On the other hand, we concur with the statements made by Minakuchi et al., in their study, which highlights that for some patients, using the splint at night represents a safe and relatively effective management approach to reduce the frequency and intensity of bruxism [21].

Finally, it is important to acknowledge some limitations of this study. Specifically, the first limitation is the small sample size of registered patients. Another limitation is that bruxism was assessed using self-reported questionnaires rather than instrumental diagnostic tools, such as polysomnography or electromyography. This may lead to an overestimation of bruxism prevalence, and future studies should aim to validate self-reported data with objective measures. The assessment of well-being was based on self-reported questionnaires, and its improvements may be indirectly related to pain reduction rather than a direct effect of the intervention. Future research should explore additional dimensions of well-being beyond self-reported questionnaires. Moreover, there is a lack of a control group that did not take part in an intervention, since this research was conducted in a clinical context in which every patient that comes to the clinic seeks treatment. A quasi-experimental design was chosen for ethical reasons, as withholding treatment in a clinical setting was not appropriate. While this limits causal inference, it reflects real-world practice. Additionally, the duration of the follow-up was limited to one month. Although this timeframe was chosen based on previous studies suggesting early symptom improvements, it is possible that a longer follow-up (e.g., three to six months) could reveal different patterns of response or sustained benefits. We also acknowledge that expectancy or placebo effects may have influenced some subjective outcomes, such as perceived anxiety or well-being.

5. Conclusions

The study demonstrates that occlusal splints significantly improve symptoms related to TMDs and overall well-being, particularly in patients with fibromyalgia (ABFB and SBFB groups). Significant reductions were observed in JFLS-8, GAD-7, OHIP-14, PSQI, and increases were seen in WHO-5, highlighting the multifaceted benefits of occlusal splints for this population. Notably, the intervention also led to a marked decrease in the prevalence of TMJ pain, headaches attributed to TMJ, and jaw locking among fibromyalgia

patients, underscoring the potential of occlusal splints as an effective therapeutic option for managing both physical and psychological symptoms in this vulnerable group. Overall, splint therapy affects TMDs and associated symptoms in patients with fibromyalgia and bruxism, but benefits for healthy individuals are minimal. Further studies may explore the long-term effects and optimize treatment protocols.

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