Effects of the bite splint 15-day treatment termination in patients with temporomandibular disorder with a clinical history of sleep bruxism: a longitudinal single-cohort study

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Objective. The aim of this study was to assess the effects of bite splint (BS) treatment termination in patients treated for temporomandibular disorder (TMD) and sleep bruxism (SB).
Study Design. This longitudinal single-cohort study assessed 30 patients (29.5 ± 7.8 years old, 86.7% women) who were successfully treated with BS for SB and TMD for 30 days to 6 months prior to termination of the use of BS. The Research Diagnostic Criteria for TMD Axes I and II, Sleep Assessment Questionnaire, Beck Depression Inventory, and BiteStrip were used to assess TMD signs and symptoms, sleep disorders, depression, and SB at baseline and after 15 days of BS disuse.
Results. TMD symptoms, including the disability points, characteristic pain intensity, and present pain at rest, increased significantly ($P < 0.05$). After 15 days of BS termination, there were no significant differences in SB and depression levels, sleep quality, and TMD signs.
Conclusions. In patients with TMD and SB, BS treatment cessation is not recommended. (Oral Surg Oral Med Oral Pathol Oral Radiol 2012;114:740-748)

Sleep bruxism (SB), according to the International Classification of Sleep Disorders, is a sleep movement characterized by grinding or clenching of the teeth.[1] This dental movement is produced by rhythmic or tonic sustained contractions of the masseter muscles or other muscles of mastication, also known as rhythmic masticatory muscle activity.[2,3] As a consequence of SB, bruxers may appear with tooth grinding, muscle pain, temporomandibular joint pain (TMJ), and mandibular locking, as well as masseter hypertrophy, masticatory muscle fatigue, and headaches, among other symptoms.[4,5] However, whether SB causes muscle pain, particularly morning headaches, remains controversial because bruxism events do not correlate positively with pain.[6,7]

The diagnosis of SB is made subjectively by the report of tooth grinding by the bed partner, as well as by the degree of tooth grinding (as evidenced by tooth wear) present at the time of examination.[3] However, the intraoral examination for evaluation of tooth grinding cannot determine whether the patient is still grinding his or her teeth, whether the grinding took place in the past and is no longer occurring, or whether the tooth wear is the result of the process of natural wear, as seen in aging.[8,9]

Polysomnography is considered the available gold standard for the diagnosis of SB; however, because of its cost and the difficulty involved in spending the night in a sleep laboratory, which differs from a home environment, this examination is difficult to carry out.[1,2,6] To circumvent this problem, portable electromyo-

Statement of Clinical Relevance

In successfully treated patients with temporomandibular disorder (TMD) with sleep bruxism, 15-day interruption of bite splint use increased TMD symptoms, but did not affect depression, sleep scores, or TMD signs. The findings suggest a clinical benefit from bite splint use in these patients.

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graphic appliances for the masticatory muscles have been used. Among them, the BiteStrip, a disposable appliance that measures electromyographic (EMG) activity of the masseter muscle, can be used as a validated screening method for SB.[10-12]

Symptomatic treatment of SB is based on tooth protection by the continuous use of a bite splint (BS). Nevertheless, there is insufficient evidence to confirm BS effectiveness over SB activity reduction, particularly considering the fact that its myorelaxation effect is short term only, and the continuous use of the appliance might be of questionable value.[13] Similarly, the available literature shows that the BS does not differ from placebo in the treatment of temporomandibular disease (TMD) pain.[14-16] Thus, it is of interest to assess the consequences of a 15-day termination of treatment with a BS in patients with TMD and a clinical history of SB who have been treated successfully with BS. If the BS has an effect on both SB and TMD pain, the cessation of appliance use could lead to an increase in SB and subsequently a relapse in pain, which could justify the continuous use of the BS. Alternatively, if signs and symptoms remain improved following cessation of treatment with the BS, cessation of the use of the BS, or intermittent/as-required use once symptoms of pain have subsided, would be justified.

Therefore, this single-cohort longitudinal study was designed to assess the effects of a 15-day termination period of treatment with a BS in patients with TMD and a clinical history of SB who have been treated successfully with a BS for 1 to 6 months. In addition, we hypothesize that if an increase in pain levels is observed, other correlates of pain such as depression, somatization, and sleep disturbances will also relapse.

MATERIAL AND METHODS

Inclusion and exclusion criteria

To be selected for this investigation, subjects had to have appeared with a chief complaint of SB and TMD at the Orofacial Pain Clinic of the Faculty of Dentistry at the Pontifical Catholic University of Rio Grande do Sul, Brazil. A preliminary diagnosis of SB was based on a clinical history questionnaire. The inclusion criteria for SB treatment included the following: (1) history of tooth grinding of at least 3 episodes per week reported by the bed partner for the past 6 months; (2) clinical presence of excessive tooth wear associated with bruxism; and (3) masseter muscle hypertrophy.[1,2,6] Patients also had to be in the age range of 20 to 45 years old to obviate age as a confounding factor in the EMG readings.[17] Exclusion criteria included the following: (1) fewer than 3 nights of reported SB per week, (2) outside the age range, and (3) clinical history of functional (e.g., depression, anxiety) or sleep (e.g., apnea, insomnia) disorders.[18]

TMD inclusion criteria required the patient to present with a self-report of TMJ pain or masticatory muscle pain, particularly aggravated by function.[6,7] Other inclusion criteria for TMD included the following: (1) successfully treated in this pain clinic such that patients exhibited total or partial remission of the symptoms of TMD (i.e., $\leq$3 on a 10-point scale in "present pain at rest" [question 7 of the Research Diagnostic Criteria for TMD (RDC/TMD)] Axis II), and (2) have posterior support (5 teeth or more) and mouth opening of at least 35 mm to allow for construction and retention of the BS.[19] The exclusion criteria were based on reported risk factors for TMD such as (1) relevant skeletal abnormalities (severe Angle's Class II or III, CR-CO slide greater than 4 mm, uni- or bilateral crossbites, and cleft palate), (2) orthodontic treatment finished $<$2 years prior to the study, (3) periodontal disease with tooth mobility, (4) presence of restorations with risk of fracture, (5) clinical history of systemic diseases or conditions requiring chronic medication (such as diabetes or arthritis), (6) pregnancy, and (7) use of medication affecting the central nervous system (e.g., anxiolytics, antidepressants, and anticonvulsants).[19-22]

The information above was collected by clinical examination and history reported by patients. The consent form, which was signed by all patients, was approved by the Ethics and Scientific Committee of the Faculty of Dentistry (Protocol 004/09) and the São Lucas Hospital Ethics Committee of the Pontifical Catholic University of Rio Grande do Sul (Protocol 09/04694), which is recognized by the National Research Council and by the Office for Human Research Protection, following the guidelines of the Helsinki Declaration.

Study protocol and questionnaires

The complete examination, including sociodemographic variables, clinical history, and clinical examination of all patients with SB and TMD pain treated with the BS, was performed at baseline (T1). The selected patients with SB who were treated with the BS were examined both at baseline (T1) and at the 15-day follow-up (T2). The intraoral examination, the presence of wear facets and indentations on the tongue and mucosa, and occlusal support were analyzed at T1 only.[19,20]

The following questionnaires were used at T1 and T2: (1) the Brazilian Portuguese validated version of the Beck Depression Inventory (BDI) as a chronic pain correlate, (2) specific items of the RDC/TMD Axes I and II for traditional signs and symptoms of TMD as well as psychosocial variables, and (3) the Sleep Assessment Questionnaire (SAQ).[21-25]

The most reproducible items of the RDC/TMD Axis I were chosen: (1) maximum mouth opening, (2) right and left lateral excursions, and (3) protrusion.[24] Additionally, we performed tests for sensitivity to palpation on the masseter and temporalis muscles, as well as in the posterior submandibular zone. The right and left TMJs were also palpated (extraauricular approach) to assess for joint sounds. In these palpation measurements, considering their known low reproducibility, we collapsed the original 4-item scales into dichotomous outcomes (positive/negative) to increase reproducibility.[19,21] All measurements, with the use of either a millimeter ruler or palpation, were performed according to the examination guidelines of the RDC/TMD Axis I.[24]

For the RDC/TMD Axis II, the following essential items were selected. For pain intensity assessment in the long as well as in the short term, 2 items were selected. The first item was the characteristic pain intensity (CPI), which is a compound score of 3 self-completing questions assessing pain intensity (questions 7 to 9) asking about present pain at rest, the worst pain in the past 6 months, and the average pain in the past 6 months. Each question includes 1 ordinal scale ranging from 0 to 10, with 0 meaning "no pain" and 10 "pain as bad as could be." The second item is question 7, or "present pain at rest," which is the first question of the CPI. These 2 items were chosen to assess pain at rest for the past 6 months as well as pain at rest at the time of examination to compensate for fluctuation of pain over time, which is seen in patients with chronic TMD.[24] Pain at rest has also been shown to be a good predictor of treatment outcome for TMD.[21]

Other items of Axis II, which measure the impact of chronic pain on daily life including psychosocial measures, were also selected: (1) chronic pain grade (CPG), (2) disability points (DP), (3) depression, and (4) nonspecific physical symptoms, including and excluding pain items. Depression and nonspecific physical symptoms, including and excluding pain, have also been shown to be good correlates of chronic pain.[21-24] The CPG is a compound ordinal score (0, I, II, III, or IV). It combines the results of the DP, which measures the impact of chronic pain on activities of daily living, with the pain intensity measured by the CPI. Patients can be scored according to the following criteria: (1) 0 = no pain in the prior 6 months, (2) I = low disability and low intensity, (3) II = low disability and high intensity, (4) III = moderately limiting, and (5) IV = severely limiting.[24]

The BDI was included to assess the level of depression in our sample.[23] Volunteers answered the 21-question questionnaire. Each question was composed of 4 alternatives, with scores ranging from 0 to 3, with a maximum score of 63. Depression was assessed using 2 methods to improve sensitivity and specificity of identification of this condition and because it is also known that different depression scales sometimes yield different results. Specifically, the BDI and the RDC/TMD Axis II were used.[23,24] The SAQ, which has been validated against polysomnography, was included as a screening method for sleep disorders. The SAQ is a short, 17-item questionnaire. Each question was composed of 5 alternatives, with scores ranging from 0 to 4, with a maximum score of 68.[25] Depression and sleep have been shown to be good predictors of treatment outcome for patients with TMD and are also present in many other chronic pain conditions, such as irritable bowel syndrome.[21,22]

Self-administered questionnaires, such as the BDI, the RDC Axis II, and the SAQ, were applied by the same trained examiner. Similarly, the clinical examination following the RDC/TMD guidelines for Axis I was performed by another single trained examiner blinded to the results of the self-administered questionnaires. To assure blinding, patients were asked to not inform the clinical examiner about characteristics of their pain (e.g., spontaneous, particular symptoms). In this regard, it was postulated that should the clinical examiner become aware of the patients' symptoms, this awareness could bias the clinical examination using the RDC Axis I model in search of signs for TMD.

BiteStrip

A portable EMG appliance (BiteStrip) was used to assess SB. The BiteStrip was used on the left masseter at T1 and T2 for the purpose of measuring masseter activity, thereby screening for SB. This step was important to minimize misconstruing other orofacial events (e.g., coughing, face rubbing, head scratching, lip movements, yawning, sleep talking, swallowing, grunting, grimacing, and excessive movement of the lip or tongue) as SB episodes.[10,12,26] The BiteStrip is similar to a portable surface EMG device and has a computer chip that registers the number of contractions of the masseter muscle during a 5-hour period (e.g., during sleep). This EMG device was placed on the left masseter only and employed according to the manufacturer's instructions.[27] After the test was completed, the display showed a 4-scale ordinal categorical score representing the number of bruxism episodes during 5 hours of sleep (0 = no bruxism: up to 39 episodes; 1 = mild bruxism: 40-74 episodes; 2 = moderate bruxism: 75-124 episodes; 3 = severe bruxism: equal to or greater than 125 episodes; and E = error message). According to the manufacturer, contractions that exceed 30% of the maximum voluntary clenching muscle activity were considered an SB episode.[27] The BiteStrip

has been shown to be a cost-effective and moderately valid screening device for SB, particularly with regard to the dichotomous finding of the absence or presence of SB (κ agreement index = 0.71). This device is not as sensitive for the assessment of the intensity of muscle contraction or, in this case, SB (weighted κ = 0.51).[12]

BS

The BS, also known as the Michigan-type BS, was made with hard, heat-activated acrylic. It has a flat surface with multiple contacts on the anterior and posterior teeth and canine guidance.[14] The waxing and processing were carried out in the same laboratory (Monteiro Orthodontic Laboratory Ltd., Porto Alegre, RS, Brazil). The low-temperature processing method was chosen to prevent thermal shrinkage, which has been reported as the major cause of alterations in denture-base resin. The flask was kept in a water bath at 70°C for 24 hours. After completion of processing, the flasks were bench-cooled for 4 hours at room temperature (24 ± 1°C). Specimens were removed from the mold by being deflasked 15 minutes later and stored in 37°C water.[28]

Confounders, sample size calculation, and statistical analysis

The data collected were organized and analyzed using SPSS software (Statistical Package for the Social Sciences; version 17 for Windows, SPSS Inc., Chicago, IL). The formula for the sample size calculation for a single sample was $n = Z^2_{1-\alpha/2}\, P(1-P)d^2$, in which P is the anticipated proportion of bruxism (5%), $Z_{1-\alpha/2} = 1.96$ for a 2-sided test at the 0.05 level, and d is the absolute precision of 8% (95% confidence interval). A sample size of 28 individuals was reached. The following tests were used: (1) the Kolmogorov–Smirnov test for normality assessment, (2) the paired Student *t* test for continuous variables, (3) the Wilcoxon rank-signed test for nonparametric and ordinal variables, and (4) the McNemar test for dichotomous variables. The type I error was set at 5%, type II at 20%, and statistical power at 80%. In addition, the Spearman correlation was determined at baseline between "pain at rest" and the BDI, SAQ, and BiteStrip scores. In this single-cohort (before-and-after) design, the patients were their own controls; therefore, it was not necessary to control confounders for both SB and TMD.[29,30]

RESULTS

Population

The initial sample, which met the inclusion criteria for SB and TMD diagnosis, was composed of 60 patients. However, only 30 met all of the inclusion/exclusion criteria and volunteered for the study (response rate of 50%), thus making up the final sample size. The initial sample size calculation was 28, but was increased to 30 to compensate for drop-outs. Patients were excluded for not being in the age range (n = 15), for still having spontaneous TMD pain greater than 3 on a 10-point scale following treatment (n = 7), and for not agreeing to participate (n = 8). Prior to inclusion in our study, the time that it took SB patients for a total or partial remission of TMD-related symptoms after the treatment with BS ranged from 30 days to 6 months, but the great majority (i.e., 90%) improved within the first 60 days following initiation of treatment with the BS.

Table I. Social and demographic variables

Independent variables	*(n = 30)*
Educational level (%)	
Elementary school completed	6.7
High school not completed	3.3
High school completed	20
Undergraduate education not completed	20
Graduate education completed	13.3
Postgraduate education	36.7
Sex (%)	
Female	86.7
Male	13.3
Age in years	
Average (SD)	29.5 (7.8)
Occlusal grinding pattern (%)	
Light or no grinding	13.3
Grinding in enamel	36.7
Grinding in dentin in isolated spots	43.3
Dentin exposure in an area >2 mm^2	6.7
Angle's classification (%)	
Class I	60
Class II	20
Class III	20
Guidance on lateral excursion (%)	
Canines	46.7
Anterior teeth	10
Anterior–posterior teeth	26.7
Posterior teeth	16.7
Guidance on protrusive movement (%)	
Canines	6.7
Anterior teeth	73.3
Anterior–posterior teeth	6.7
Posterior teeth	13.3

The majority of the sample was composed of females (most of child-bearing age) and patients with postsecondary education. Most had occlusions that could be classified as being Angle's Class I and had canine guidance on lateral and anterior guidance on protrusive movements, respectively. Almost half had grinding patterns on enamel and dentin, with slightly over one third having grinding on enamel only, whereas only 6.7% had dentin exposure >2 mm^2 (Table I).

Normality testing

Normality testing of the continuous variables, measured by the Kolmogorov–Smirnov test (n = 30), was

Table II. Before and after analysis of the continuous parametric variables

	Before (n = 30), average (SD)	*After (n = 30), average (SD)*	*Student's paired t test*
Maximum mouth opening (mm)	52.7 (6.3)	52.2 (6.3)	NS
Sleep Assessment Questionnaire	16.1 (10.0)	15.9 (9.9)	NS
Characteristic pain intensity	39.2 (25.4)	49.6 (28.9)	$P = 0.03$*
Pain at rest (question 7 of the RDC/TMD Axis II)	2.2 (2.2)	3.9 (3.1)	$P = 0.006$†

RDC/TMD, Research Diagnostic Criteria for temporomandibular disorder.
*$P < 0.05$.
†$P < 0.01$.

performed. The following continuous-variable data distribution differed significantly from the normal curve ($P < 0.05$): (1) left lateral excursion, (2) right lateral excursion, (3) protrusion, and (4) the BDI. Such variables could not be analyzed using parametric tests; therefore, they were analyzed with the nonparametric Wilcoxon signed-rank test.[30] The other continuous variables did not differ significantly from the normal curve (nonsignificant at $P < 0.05$) and the Student paired *t* test was used.

Results before and after the 15-day treatment termination with the BS

The differences between T1 and T2 for maximum mouth opening and the SAQ were not statistically significant. The CPI showed a significant increase in pain after treatment termination of the BS. This included present pain at rest, which is assessed by question 7 of the RDC/TMD Axis II, a finding that was highly significant (Table II). In relation to present pain at rest, 63.3% of patients had an increase in pain, pain in 23.3% of patients remained unchanged, and 13.3% of patients had a reduction in pain following cessation of treatment. All patients, including those who did not experience an increase in pain (i.e., 36.6%), were retreated with the BS after the 15-day treatment-cessation period.

The differences in protrusion and lateral excursive movements, both right and left, between T1 and T2 were not statistically significant, nor were the findings for the BDI. In addition, T1 and T2 did not differ for the following: (1) the BiteStrip, (2) the nonspecific physical symptoms, pain items included and excluded, and (3) depression measured by Axis II of the RDC/TMD. In contrast, the CPG classification and DP were both statistically significant ($P = 0.05$ and $P < 0.01$, respectively; Table III).

The findings reported here demonstrate a moderately positive correlation between pain at rest scores with the scores for the BDI ($r = 0.434$, $P = 0.017$). A low positive correlation between present pain at rest with the BiteStrip scores ($r = 0.117$, $P = 0.538$) was also found. In addition, a highly positive correlation between present pain at rest with SAQ scores ($r = 0.62$, $P = 0.000$) was revealed. Finally, the SB subjects in this sample showed borderline scores consistent with the presence of sleep disorders as measured by the SAQ (16.1 ± 10, cut-off point = 17).[25]

Significant alterations were not found with respect to TMJ noises on either the left or the right side. Similarly, there were no differences in sensitivity to palpation in the masseter and temporalis muscles, as well as those in the posterior submandibular zone. Nevertheless, despite not being significantly different, there was a tendency toward increased pain on palpation for all sites (Table IV).

DISCUSSION

The main objective of this single-cohort longitudinal study was to assess the effects of treatment termination of BS for 15 days in patients with TMD and a clinical history of SB. Importantly, these patients also had to have responded well to treatment with the BS within 30 days to 6 months. Secondarily, we wanted to determine whether any increases in pain parameters that might occur following termination of treatment with the BS might also be associated with an increase in associated correlates of pain including depression, somatization, and sleep disturbances. Our findings support the benefit of BS in treatment of these patients.

Main results before and after the 15-day treatment termination with the BS

The differences between T1 and T2 in the CPI and in present pain at rest assessed by question 7 of the RDC/TMD Axis II (TMD symptoms) included a significant increase in pain symptomatology after the BS treatment termination of 26.5% ($P < 0.05$) and 77.2% ($P < 0.01$), respectively. In addition, there was an increase in 26.6% (almost significant, $P = 0.05$) in the chronic pain grade classification and in 30% ($P < 0.01$) in the DP, confirming that there was a propensity toward an increase in both short-term and long-term assessment of TMD pain (symptoms), as well as in pain disability.[21,22,24] This finding strongly contrasted with the available literature, which indicated that BS did not differ from placebo in the treatment of TMD pain.[14-16]

Table III. Before and after analysis of the continuous nonparametric and ordinal variables

Independent variables	*(N = 30)*	*Wilcoxon signed-rank test*
Left lateral excursion	Reduced (negative sign), N = 9 Increased (positive sign), N = 10 No change (equal sign), N = 11	NS
Right lateral excursion	Reduced (negative sign), N = 10 Increased (positive sign), N = 11 No change (equal sign), N = 9	NS
Protrusion	Reduced (negative sign), N = 9 Increased (positive sign), N = 14 No change (equal sign), N = 7	NS
Beck Depression Inventory	Reduced (negative sign), N = 15 Increased (positive sign), N = 8 No change (equal sign), N = 7	NS
BiteStrip	Reduced (negative sign), N = 5 Increased (positive sign), N = 11 No change (equal sign), N = 14	NS
Disability points	Reduced (negative sign), NN = 0 Increased (positive sign), N = 8 No change (equal sign), N = 22	0.007†
Chronic pain grade classification	Reduced (negative sign), N = 1 Increased (positive sign), N = 9 No change (equal sign), N = 20	NS ($P = 0.05$)
Depression	Reduced (negative sign), N = 16 Increased (positive sign), N = 11 No change (equal sign), N = 3	NS
Nonspecific physical symptoms (including pain items)	Reduced (negative sign), N = 13 Increased (positive sign), N = 13 No change (equal sign), N = 4	NS
Nonspecific physical symptoms (excluding pain items)	Reduced (negative sign), N = 11 Increased (positive sign), N = 10 No change (equal sign), N = 9	NS

Number of patients (N) with increased scores (positive sign), reduced scores (negative sign), and no change (equal sign).
*$P < 0.05$ (2-tailed).
†$P < 0.01$ (2-tailed).

One problem with randomized controlled trials for chronic pain is the influence of the placebo effect, which might account for 60% of the overall success rate, masking the true treatment effect of intraoral appliances. The placebo effect might be an explanation for why no treatment has been proven the best for TMD thus far.[15,16] In addition, previous TMD trials did not report the presence or absence of SB among TMD patients.[14-16] This single-cohort research design was intended to eliminate the placebo effect as a confounding factor, considering that the treatment had already taken place.[30] However, this approach would require the termination of an ongoing treatment (management) for SB and TMD. Because of this ethical issue, this study was designed on the assumption that there is actually no correlation between SB and pain and that oral appliances have minimal effects on both SB and TMD, as demonstrated repeatedly in the literature.[6,15,16,31-36] Taken in combination, the interruption of treatment would have predicted no increasing effect on either SB or TMD signs and symptoms.

Our study design accounted for the fact that SB concurrent with morning headaches has been linked to some forms of sleep apnea, which might be aggravated by the use of a BS.[13,37,38] We thus excluded patients with a clinical history of sleep breathing disorders to avoid any possible risk to their health. Also, considering that the only proved effect of BS is protection against tooth wear and to minimize harmful effects to the patients, we also excluded any patient with restorations with risk of fracture and those who were nonresponders (pain at rest greater than 3 on a 10-point scale) after treatment with BS.[13,21,22] However, because of the unexpected return of TMD symptomatology, the study, which was initially designed to last 30 days, had to be interrupted after 2 weeks, and all patients had to resume BS use.

Secondary results before and after 15-day treatment termination with the BS

The differences in the following RDC/TMD Axis I clinical examination items were nonsignificant (TMD signs): (1) maximum mouth opening, (2) protrusion, and (3) lateral excursive movements, both right and left, between T1 and T2. Significant alterations were not found in TMJ noises on both sides, as well as the

Table IV. Before and after analysis of nominal variables. Palpation sensitivity of the masticatory muscles and temporomandibular joint (TMJ) sounds

Independent variables	*Before (N = 30)*	*After (N = 30)*	*McNemar test*
Right TMJ sounds			
Absent = 0	16	15	NS
Present = 1	14	15	
Left TMJ sounds			
Absent = 0	16	14	NS
Present = 1	14	16	
Masseter (palpation sensitivity)			
Absent = 0	7	4	NS
Present = 1	23	26	
Temporalis (palpation sensitivity)			
Absent = 0	10	5	NS
Present = 1	20	25	
Posterior submandibular zone (palpation sensitivity)			
Absent = 0	12	8	NS
Present = 1	18	22	

The original scores (0 to 4) were collapsed into dichotomous scores (0 or 1) to increase reproducibility.

palpation sensitivity of the masseter and temporalis muscles and posterior submandibular zone. However, there was a propensity toward an increase in palpation sensitivity in all structures, which might have been significant if the study had not been interrupted or if the sample size was larger. These findings also agree with previous research indicating that TMD signs are poorer risk indicators and treatment outcome predictors of TMD than symptoms.[21,39] However, these results must be analyzed with care considering that they were collected in a specialized clinic in a small group of patients, and further studies must be undertaken to determine whether the findings hold up in a primary care center.[30]

Similarly, there were no significant differences between T1 and T2 for known correlates of chronic pain regarding the following: (1) nonspecific physical symptoms pain items included, (2) nonspecific physical symptoms pain items excluded, and (3) depression measured by Axis II of the RDC/TMD. The results for the BDI and SAQ were also nonsignificant. This contrasts with the available literature, which shows that the pain correlates of sleep and depression are good risk indicators and good treatment outcome predictors of TMD patients.[21,39] In addition, we found a moderate Spearman correlation between pain at rest and BDI scores, which agrees with previous studies.[24,40,41] Finally, the borderline scores for sleep disorders found for SB subjects, as well as the high correlation between present pain at rest with SAQ scores, agree with previous studies that sleep disorders increase the risk of developing and perpetuating pain, not only in TMD but also in other chronic pain conditions such as irritable bowel syndrome.[21,22,39] One explanation for these conflicting results is the fact that because of the short-term nature of our study and the known correlation among chronic pain, sleep, depression, and nonspecific physical symptoms, it is possible to presume that these other pain correlates would have increased in the long term.

The BiteStrip also yielded a nonsignificant difference between T1 and T2. It is important to stress the fact that the BiteStrip was used in this investigation to screen for SB as well as for assessment of activity of the masseter muscle. Therefore, the data shown here should be tested against actual polysomnography in future studies.[10,12,26] In addition, the low association between present pain at rest with the BiteStrip scores found in this study is in agreement with a recent finding suggesting that sleep bruxers with lower frequencies of orofacial activities were more at risk of reporting pain and that it might not be possible to correlate levels of pain with the amount of bruxism activity, as has been reported by others.[6,20,31,32]

Population

Reports regarding the prevalence of bruxism have yielded highly variable data ranging from 5% to 90%. This finding makes it virtually impossible to calculate a representative sample with 100% precision. Nevertheless, the sample size used in this investigation was similar (i.e., from 20 to 30 subjects) to the population sizes used in other recent experimental and observational studies regarding bruxism. This alone would seem to bolster the external validity of the data reported in this study.[1,2,19,20,37] In the literature, the male/female proportion was close to 50% in most studies, confirming that gender difference has not been reported for pain-free bruxers.[1,2,12,26] However, our study showed a predominance of women (86.7%), which was similar to that found for TMD patients.[7,21,22,24] This may have occurred because our sample was composed of sleep bruxers who presented with TMD symptomatology upon arrival in our clinic, contrasting with pain-free bruxers in other studies.[2,6,19,20,26] Additionally, our average age (29.5 years old) was also similar to that reported for both bruxers and TMD patients, which helps confirm that the prevalence of bruxism is higher (8%-13%) in young adults from 20 to 40 years of age, even in different societies.[2,21,22,24,37,39,42] In our sample, only 6.7% of patients had severe grinding with dentin exposure >2 mm^2, confirming that the severity of grinding is not higher among bruxers than in the average adult population (3%-7%) and that little relationship exists between tooth grinding pattern and bruxism behavior. The amount of grinding varies according

to factors such as age, gender, tooth location, and awake versus SB.[8,9,43,44]

Methodological limitations and suggestions for future studies

In our single-cohort (before-and-after) design, the patient was the control of himself/herself, and it was not necessary to control for SB and TMD confounders such as sex, age, or socioeconomic and craniometric measures.[30] It might have been possible to add a separate control group that continued to receive treatment, creating a parallel, randomized controlled trial, but it would have been extremely difficult to match both groups considering that all confounders for TMD and SB must have been controlled at the same time in the design stage. This approach would have drastically reduced our sample size. Also, it would have been possible to control these variables in the analysis stage, but this would have required a large sample size. Nevertheless, these alternative methodological strategies may be attempted in future studies.

We considered our baseline (T1) as the moment just prior to termination of treatment. We were not able to include the records prior to treatment itself, either because they were not available or, when they were, because they were often performed by a different examiner (noncalibrated), which would have contaminated our sample. Future research that includes baseline records prior to treatment is encouraged. This longitudinal single-cohort study assessed patients who have been treated successfully with BS for SB and TMD within a time frame of 30 days to 6 months, which was the time required for partial or total remission of TMD pain. However, it is not known whether the relapse of TMD pain observed after treatment termination seen in the current study would apply to patients treated for longer periods of time.

An intriguing finding of our study was that objective signs of TMD and SB remained improved, whereas the subjective symptoms (pain) returned. However, there was a propensity toward an increase in palpation sensitivity in all structures, which might have been significant if the treatment had been interrupted for a longer period of time. Similarly, pain correlates such as sleep, depression, and nonspecific physical symptoms were not affected by treatment termination, but might be in a longer follow-up.

The reasons for the relapses noted in spontaneous pain, in both long- and short-term assessment, following cessation of BS therapy remain unclear, particularly because the BiteStrip results remained unchanged. Given the above argument regarding the difficulty of correlating bruxism and pain, however, this finding might not be particularly surprising. In addition, the tendency toward increased pain in the TMJ following palpation is in agreement with a recent study, which found that severe SB increases the risk of developing clicking in the TMJ by about 3.4-fold, especially in females.[7] One possible explanation might be the load transmitted to the TMJ from the clenching/grinding of teeth, which in theory would be partially absorbed by the BS hard acrylic or resilient material, but this is highly speculative at this time and must be tested in future studies.[13]

CONCLUSIONS

The results of this study showed that a 15-day treatment termination in the use of the BS in patients with a history of SB and TMD led to a significant increase in values obtained from long- and short-term assessments of pain at rest.

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