Original Article

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Effects of soft occlusal appliance therapy for patients with masticatory muscle pain

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Background: The options for stabilization appliance therapy for masticatory muscle pain include soft occlusal and hard stabilization appliances. A previous study suggested that hard stabilization appliance therapy was effective for patients with local myalgia who developed long facets on their occlusal appliances. The objective of this study was to identify patients in whom a soft occlusal appliance should be used to treat masticatory muscle pain by analyzing the type of muscle pain present and patient factors that influenced the effectiveness of this treatment.

Methods: The study included 42 patients diagnosed with local myalgia or myofascial pain according to the Diagnostic Criteria for Temporomandibular Disorders Diagnostic Decision Tree. The analysis of patient factors included variables believed to be associated with temporomandibular disorders. First, a temporary screening appliance was used for 2 weeks to assess each patient for bruxism during sleep. Soft appliance therapy was then started. For each patient, the effectiveness of the appliance was evaluated according to the intensity of tenderness during muscle palpation and the treatment satisfaction score at one month after starting treatment.

Results: Data from 37 of the 42 patients were available for analysis. Twenty-five patients reported satisfaction with the appliance. In logistic regression analysis, the odds ratio for reduction of facet length was 1.998. Nineteen patients showed at least a 30% improvement in the visual analog scale score. The odds ratio for local myalgia was 18.148.

Conclusion: Soft appliance therapy may be used in patients with local myalgia. Moreover, patients who develop short facets on the appliance surface are likely to be satisfied with soft appliance therapy. Soft appliance therapy may be appropriate for patients with local myalgia who develop short facets on their occlusal appliance.

Keywords: Bruxism; Myalgia; Myofascial Pain Syndromes; Soft Appliance; Temporomandibular Joint Disorders.

INTRODUCTION

While occlusal stabilization appliance therapy has long been used to treat masticatory muscle pain, controversy remains regarding its efficacy, with some studies reporting its effectiveness [1-3] and others concluding a lack of significant effect [4,5]. There are also no clear standards regarding the choice and use of occlusal appliance therapy for patients with masticatory muscle pain. The options for stabilization appliances include soft occlusal appliances and hard stabilization appliances. Although hard stabilization appliance therapy is currently recommended [6], soft appliances are frequently used in the clinical setting [7,8]. Some studies have reported that these appliances relieve masticatory muscle pain [9-13].

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In a previous study, we analyzed the patient factors and conditions influencing the change in pain using the visual analog scale (VAS) and patient satisfaction following hard stabilization appliance therapy for masticatory muscle pain. We found that (1) a significantly higher proportion of patients whose VAS scores did not improve had myofascial pain rather than local myalgia, (2) both patients with improved VAS scores and those who were satisfied had significantly long facets on their occlusal appliances, and (3) patients with a high 9-item Patient Health Questionnaire (PHQ-9) score for depression were less satisfied the with hard appliance and those with a high 15-item Patient Health Questionnaire (PHQ-15) score for somatic symptoms showed less improvement in their VAS score following hard appliance therapy.

The objectives of this study were to analyze the type of muscle pain and patient factors influencing the effectiveness of soft appliances in the treatment of masticatory muscle pain, to identify patients in whom a soft appliance should be used, and to identify differences between soft and hard appliance therapies.

METHODS

1. Subjects

The study subjects were patients who presented with orofacial pain at the Tokyo Dental College Suidobashi Hospital between January and October 2017 and were diagnosed with local myalgia or myofascial (spreading or referred) pain according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) diagnostic decision tree. The exclusion criteria were age < 18 years; moderate or severe systemic disease (American Society of Anesthesiologists physical status class III or above), missing free-end, temporomandibular joint pain, failure to attend hospital appointments, condition deterioration necessitating a switch to a different splint, and improvement before starting occlusal splint therapy. Forty-two (8 men, 34 women) of 47 eligible patients agreed to participate and provided written informed consent. The study protocol was approved by the ethics committee of Tokyo Dental College (ethical clearance number 756).

2. Assessments

During the initial examination, we assessed the range of pain-free mouth opening, the number of tender points on muscle palpation, the intensity of tenderness at the most tender point during muscle palpation (using VAS), the presence or absence of anterior tooth guide, attrition with dentin exposure (defined as attrition of the upper and lower teeth was consistent and luster was present), awareness of sleep bruxism (SB), awareness of awake bruxism, muscle fatigue on waking, torus palatinus or torus mandibularis, and scalloping of the tongue. The temporalis (anterior, middle, and posterior) and masseter (origin, body, and insertion) muscles were palpated on both sides. The palpation pressure was 1 kgf for 2 s with the finger pressure calibrated before palpation using an algometer to standardize the pressure. To differentiate the types of myalgia involved, whether local myalgia or myofascial pain, the pressure duration was increased to 5 s. Myofascial pain was defined as the presence of spreading or referred pain, while local myalgia was defined as the presence of neither condition.

Other patient factors investigated included sleep duration, snoring or apnea, smoking, daily alcohol consumption, daily caffeine consumption, daily duration of computer use, and scores on three self-administered questionnaires, that is, PHQ-9, PHQ-15, and 7-item Generalized Anxiety Disorder (GAD-7) assessment for anxiety, which are used during DC/TMD axis II screening.

3. Temporary screening appliance

To screen each patient for SB and, if present, to determine whether it was the clenching type (based on short wear facets) or grinding/mixed type (based on long wear facets), a temporary screening appliance was made from autopolymerizing resin (Facet Resin, GC Corporation, Tokyo, Japan) for use at night. This resin

Fig. 1. Occlusal facets present on the appliance. After 2 weeks, the surface texture was assessed, and the lengths of the facets formed by the mandibular canines were measured.

was selected because it combines sufficient strength with the appropriate degree of abradability (for facet formation). The appliance position was adjusted with canine guidance by grinding. In addition, the appliance contacted all the teeth equally on the centric occlusion. The appliance was adjusted repeatedly over several days until the subject ceased to experience any discomfort. After the adjustment was complete, a marker (Facet Resin Marker, GC Corporation) was applied to allow for easy observation of the surface texture of the appliance. After 2 weeks, the surface texture was assessed and the lengths of the facets formed by the mandibular canines were measured. Fig. 1 shows the length of the facets.

4. Analysis of heart rate variability

After 5 min of rest in a quiet, temperature-controlled room, the subjects performed a simple standing test that included sitting for 2 minutes, standing upright for 2 minutes, and then sitting again for 1 min. During the test, the brachial blood pressure and pulse rate were measured with 1-min intervals oscillometrically using blood pressure and an electrocardiogram device (Kiritsu Meijin®; Crosswell, Kanagawa, Japan). Power spectral analysis of variability in the R-R interval reveals both low (0.04–0.15 Hz) and high-frequency (0.15–0.4 Hz) spectral components. Evidence suggests that high-frequency (HF) power is largely a function of parasympathetic nervous activity in the heart. Low frequency (LF) power is used, most often normalized for total power, as a representative index of sympathetic activity in the heart [14,15]. The following variables were evaluated: the coefficient of component variation for high frequency ($CCVHF = \sqrt{HF}/AVG(RR) \times 100$, related to parasympathetic activity), the ratio of LF to HF (LF/HF, related to sympathetic activity); the coefficient of variation of the R-R interval (CVRR, related to autonomic nervous system activity); and heart rate (HR) [16,17].

5. Soft appliance therapy

After screening, a soft occlusal appliance was provided for use at night. The soft appliance was 2 mm in thickness, designed to cover the entire maxillary dentition, and was adjusted by tapping until it contacted all teeth equally. The subjects were required to attend appointments at the hospital for adjustment every 2 weeks.

6. Evaluation of effectiveness of occlusal appliance therapy

One month after the start of treatment, the effectiveness of the occlusal appliance was evaluated using the VAS score indicating the intensity of tenderness during muscle palpation, The treatment satisfaction score was also measured. A VAS score $\geq$ 30% or a score that was lower after treatment than before was considered an improvement, while any other score was considered a lack of improvement [18]. Treatment satisfaction was self-assessed as (1) greatly worsened, (2) worsened, (3) no change, (4) improved, or (5) greatly improved. Scores of 1, 2, or 3 indicated dissatisfaction, while scores of 4 or 5 indicated satisfaction.

7. Statistical analysis

We compared the patients who exhibited improvement to those who did not, and those who expressed satisfaction to those who did not in terms of multiple patient factors at baseline. Chi-squared tests were used to compare sex, presence or absence of myofascial pain, presence or absence of anterior tooth contact, attrition with dentin exposure, awareness of awake bruxism, torus palatinus or torus mandibularis, scalloping of the tongue, snoring or apnea, smoking, daily alcohol consumption, and daily caffeine consumption between groups. Mann–Whitney U tests were used to compare age; baseline VAS score (before treatment); number of tender points; and 9-item Patient Health Questionnaire, PHQ-15, and GAD-7 scores before and after standing measurements of HR, CVRR, CCVHF, and LF/HF. Student's t-tests were used to compare sleep duration at baseline, daily duration of computer use, range of pain-free mouth opening, and facet length (in the canine region of the screening appliance).

Variables that differed significantly in any of these comparisons were entered into a logistic regression analysis to identify factors predictive of improvement in VAS scores and factors associated with satisfaction. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 24.0 (IBM Corp., Armonk, NY, USA). P-values < 0.05 were considered statistically significant.

Wilcoxon signed-rank tests were used to compare the changes in VAS scores and the number of tender points between before and after soft appliance therapy.

The target sample size in this case-control study was 37 patients as this number was deemed sufficient for detecting differences with a power of 0.8 based on the results of our previous study [19].

RESULTS

Five of the 42 patients who consented to participate in the study were excluded due to failure to attend a

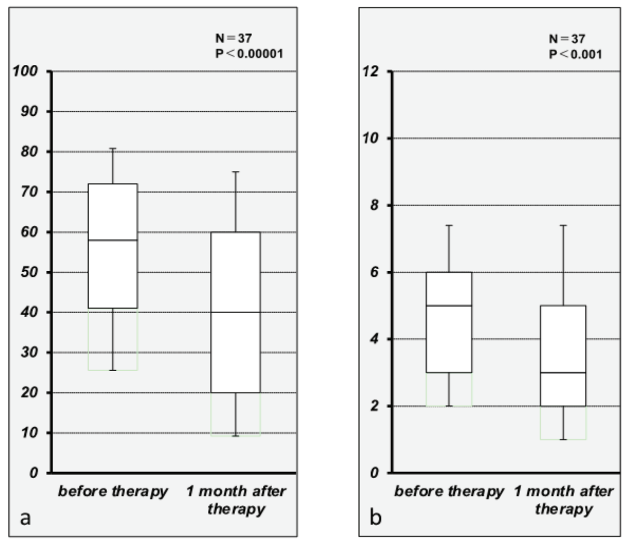

Fig. 2. The VAS scores and tender points before and after treatment. The VAS scores and the numbers of tender points before and 1 month after soft appliance therapy. (a) The VAS scores were significantly improved. (b) The number of tender points was significantly improved.

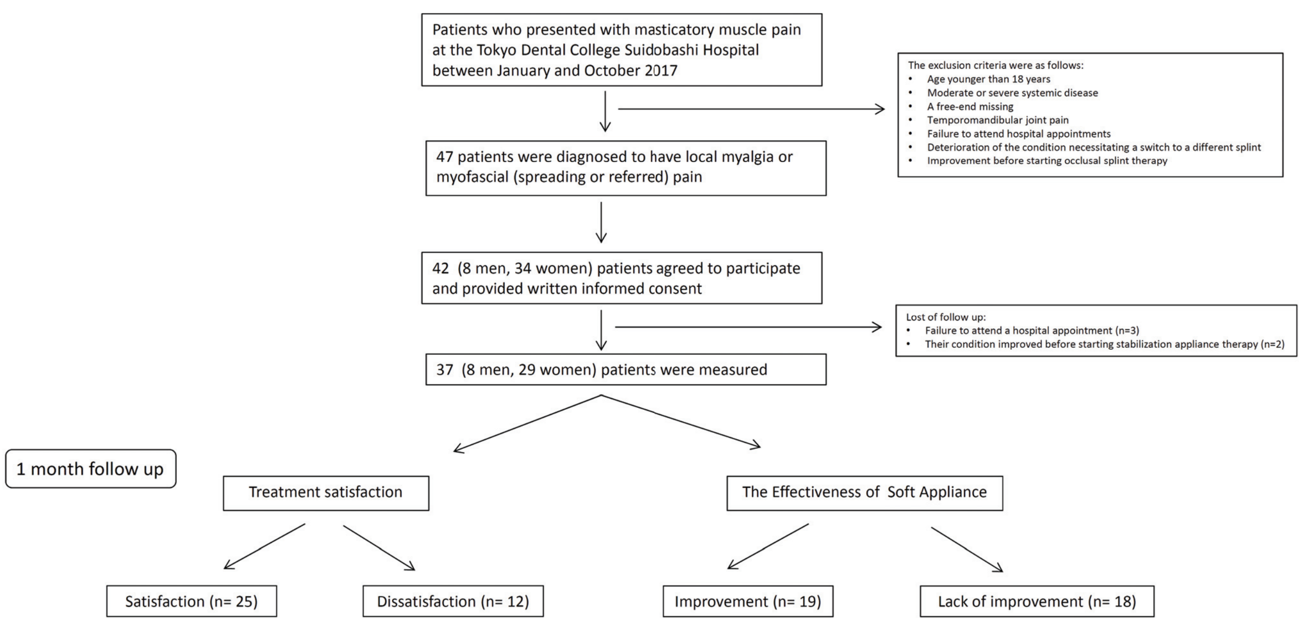

Fig. 3. The flow diagram of this study.

Table 1. Satisfied and dissatisfied groups

Factors	Satisfied	Dissatisfied	P value
Number of cases	25	12	
Male/Female	4/21	4/8	0.231
Age (years)	53.2 ± 12.7	47.6 ± 12.0	0.678
Local myalgia/myofascial pain	12/13	2/10	0.066
Mouth opening range (mm)	41.3 ± 5.6	45.1 ± 6.7	0.066
VAS (before therapy, mm)	51.9 ± 20.7	63.6 ± 19.9	0.041*
Tender points (before therapy)	4.5 ± 2.4	5.1 ± 2.3	0.222
Anterior tooth guide (yes/no)	13/12	4/8	0.286
Tooth wear (attrition) (yes/no)	21/4	12/0	0.142
Tooth grinding (during sleep) (yes/no)	8/17	5/7	0.711
Awake bruxism (yes/no)	16/9	5/7	0.192
Torus mandibularis/palatinus (yes/no)	9/16	6/6	0.416
Tongue scalloping (yes/no)	15/10	8/4	0.695
Snoring or apnea (yes/no)	4/21	2/10	0.959
Smoking (yes/no)	1/24	2/10	0.186
Daily alcohol consumption (yes/no)	5/20	3/9	0.729
Daily caffeine consumption (yes/no)	17/8	4/8	0.127
Sleep duration (hours)	6.3 ± 1.1	6.3 ± 0.6	0.505
Computer use (hours)	2.8 ± 3.5	4.5 ± 3.8	0.096
PHQ-9	7.8 ± 4.3	9.3 ± 8.9	0.568
PHQ-15	7.3 ± 4.6	7.7 ± 6.0	0.513
GAD-7	6.8 ± 4.6	7 ± 5.2	0.464
HR difference (before and after standing)	5.9 ± 6.4	7.1 ± 3.1	0.226
CVRR difference (before and after standing)	1.9 ± 2.1	1.8 ± 1.2	0.534
CCVHF difference (before and after standing)	-0.2 ± 0.7	0.1 ± 0.2	0.069
LH/HF difference (before and after standing)	5.9 ± 12.7	3.9 ± 7.4	0.508
Facet length (mm)	2.7 ± 1.8	4.6 ± 2.1	0.007*

*P < 0.05

VAS, visual analog scale; PHQ-9, 9-item Patient Health Questionnaire; PHQ-15, 15-item Patient Health Questionnaire; GAD-7, 7-item Generalized Anxiety Disorder; HR, heart rate; CVRR, coefficient of variation of the R-R interval; CCVHF, coefficient of component variation for high frequency, LH/HF, ratio of LF to HF.

hospital appointment (n = 3) or because their condition improved before starting stabilization appliance therapy (n = 2). Thus, the analysis included 37 patients (eight men, 29 women) with a mean age of 48.3 ± 15.2 years. The mean ages of the men and women were 50.4 ± 11.3 and 53.9 ± 13.1 years, respectively. The VAS scores (P < 0.00001) and the number of tender points (P < 0.001) improved significantly following soft appliance therapy (Fig. 2). Fig. 3 illustrates the flow diagram of the study design.

1. Satisfaction versus dissatisfaction

Twenty-five patients (67.5%) reported satisfaction (four men, 21 women; mean age 53.2 ± 12.7 years), while 12 patients reported dissatisfaction (four men, eight women; mean age 47.6 ± 12 years).

The VAS score at baseline was significantly higher in the satisfied patients than that in the dissatisfied patients (P = 0.041). The facet length in the satisfied group was significantly shorter than that in the dissatisfied group (P = 0.007; Table 1). Logistic regression analysis of these factors showed an odds ratio for satisfaction with the reduction of facet length of 1.998 (Table 2).

2. Improvement versus lack of improvement

Improvement was evident in 19 (51.3%) patients (four men, 15 women; mean age 56.8 ± 14 years) but not in the remaining 18 patients (four men, 14 women; mean

Table 2. Factors contributing to patient satisfaction

Factors	OR	95%CI	P value
VAS	1.046	0.998–1.096	0.06
Facet length	1.998	1.128–3.539	0.018

OR, odds ratio; CI, confidence interval; VAS, visual analog scale.

Table 3. Improvement and lack of improvement groups

Factors	Improvement	Lack of improvement	P value
Number of cases	19	18	
Male/female	4/15	4/14	0.931
Age (years)	56.8 ± 14	49.1 ± 11.2	0.03*
Local myalgia/myofascial pain	11/8	3/15	0.009*
Mouth opening range (mm)	41.8 ± 5.8	44.1 ± 6.9	0.126
VAS (before therapy)	50.8 ± 21.1	61.0 ± 19.9	0.071
Tender points (before therapy)	4.5 ± 2.6	4.7 ± 2.1	0.371
Anterior tooth guide (yes/no)	11/8	6/12	0.134
Tooth wear (attrition) (yes/no)	14/5	17/1	0.117
Tooth grinding (during sleep) (yes/no)	7/12	5/13	0.556
Awake bruxism (yes/no)	13/6	8/10	0.142
Torus mandibularis/palatinus (yes/no)	7/12	6/12	0.823
Tongue scalloping (yes/no)	12/7	11/7	0.897
Snoring or apnea (yes/no)	3/16	3/15	0.942
Smoking (yes/no)	1/18	2/16	0.515
Daily alcohol consumption (yes/no)	5/14	3/15	0.476
Daily caffeine consumption (yes/no)	11/8	10/8	0.419
Sleep duration (hours)	6.4 ± 1.2	6.2 ± 0.7	0.28
Computer use (hours)	3.2 ± 3.9	3.6 ± 3.4	0.261
PHQ-9	6.9 ± 3.8	9.8 ± 6.7	0.275
PHQ-15	5.9 ± 4	9.1 ± 5.4	0.038*
GAD-7	5.6 ± 4	8.8 ± 5.2	0.028*
HR difference (before and after standing)	5.9 ± 3.4	6.7 ± 2.9	0.218
CVRR difference (before and after standing)	1.7 ± 1.5	2 ± 1.2	0.254
CCVHF difference (before and after standing)	-0.1 ± 0.3	-0.1 ± 0.3	0.378
LH/HF difference (before and after standing)	6.1 ± 14.3	3.9 ± 2.1	0.269
Facet length (mm)	2.6 ± 2.0	4.0 ± 2.0	0.024*

*P < 0.05
VAS, visual analog scale; PHQ-9, 9-item Patient Health Questionnaire; PHQ-15, 15-item Patient Health Questionnaire; GAD-7, 7-item Generalized Anxiety Disorder; HR, heart rate; CVRR, coefficient of variation of the R-R interval; CCVHF, coefficient of component variation for high frequency, LH/HF, ratio of LF to HF.

age 49.1 ± 11.2 years).

The patients who had improved were significantly older than those who did not (P = 0.03). Myofascial pain was significantly more common in patients who did not improve than in those who did improve (P = 0.009). Furthermore, the PHQ-15 and GAD-7 scores were significantly higher in the patients who did not improve than in those who did improve (P = 0.038 and P = 0.028, respectively). Facet lengths in the patients who improved were significantly shorter than those in patients who did not (P = 0.024 L; Table 3). Logistic regression analysis showed an odds ratio for improvement of local myalgia of 18.148 (Table 4).

DISCUSSION

Masticatory muscle pain in TMD develops as a result

Table 4. Factors contributing to pain improvement

Factors	OR	95% CI	P value
Age	0.956	0.885–1.032	0.247
Local myalgia/Myofascial pain	18.148	1.564–210.595	0.02
PHQ-15	1.003	0.789–1.277	0.978
GAD-7	1.268	0.934–1.723	0.128
Facet length	1.536	0.917–2.572	0.103

OR, odds ratio; CI, confidence interval; PHQ-15, 15-item Patient Health Questionnaire; GAD-7, 7-item Generalized Anxiety Disorder.

of the complex interaction of multiple factors; thus, control groups should ideally comprise of patients with TMD who fulfill diagnostic criteria similar to those used in the treatment groups (with regards to axes I and II of the DC/TMD). However, ensuring consistency in these criteria is extremely difficult. Therefore, we did not include a control group. Instead, we divided the patients according to the treatment effect and investigated the differences in patient factors between these groups. Therefore, a limitation of this study was the lack of investigation of the placebo effect.

In the present study, local myalgia was improved by 18-fold compared to myofascial pain on the VAS. Myofascial pain is characterized by deep or spreading pain and is associated with factors such as central sensitization, impaired peripheral blood flow (hypoxia), and the pain-inducing action of nerve growth factors that can result in sensitivity to palpation or tenderness as a result of pressure, sometimes with referred pain [20]. A recent study showed that autonomous contractions of the fascia may be induced by enhanced sympathetic activity and are caused by the release of calcium [21]. These studies have also identified myofascial pain and local myalgia as distinct entities. A previous study reported a 50-fold improvement in local myalgia compared to myofascial pain when a hard appliance [19]. Myofascial pain is a condition different from local myalgia. Local myalgia is caused by muscle fatigue; thus, soft and hard appliances are likely to be more effective for local myalgia than for myofascial pain. The existence of psychosocial risk factors and the potential involvement of central hyperalgesia must be considered when managing myofascial pain. This study has a limited patient observation period and observed few side effects or complications of discomfort. However, the evaluation was performed after 1 month, which was defined as the observation period for this study. Thus, long-term side effects or discomfort from the soft appliance are also possible.

The shorter facets of soft appliances led to high levels of patient satisfaction. However, a study using a similar method reported that the use of a hard appliance with long facets was also associated with a high level of satisfaction [19]. These results are in contrast with our finding that patients Please check this unitwith a short facet type were more likely to be satisfied with a soft appliance, while patients with a long facet type were more likely to be satisfied with a hard appliance. These findings suggest that a soft appliance works without hindering short facets while a hard appliance works without hindering the long facets. Thus, unencumbered SB may enhance patient satisfaction. Although excessive SB may cause muscle pain. One study reported that patients with muscle pain showed less muscle activity during sleep compared to the controls [22] and another report reported decreased muscle activity if pain was present [23]. These findings have led to negative opinions regarding the onset of muscle pain attributed to excessive SB in recent years. If SB is regarded as an opportunity to dissipate stress during sleep, then allowing SB to proceed unhindered may yield greater comfort.

Stabilization appliance therapy currently involves the use of various devices in clinical practice, with the stabilization-type hard appliance preferred for occlusion and temporomandibular joints [24]. Previous reports showed that soft appliances increased muscle activity and produced more subjective muscle fatigue compared to hard appliances [6] and, thus, these devices were not recommended [25]. However, these reports do not describe the mitigation of pain or perceived patient satisfaction with the use of a soft appliance. Pain and muscle tenderness were significantly decreased in patients who wore a soft appliance compared to controls [10] and 74% of patients who used a soft appliance reported decreases muscle pain [13]. Furthermore, a previous study demonstrated similar reductions in muscle tenderness between soft and hard appliances and no significant difference in VAS pain scores between the two devices [11]. These reports and our present results suggest that the use of soft appliances may need to be reconsidered in the treatment of muscle pain.

Psychosocial factors affect the risk of chronic masticatory muscle pain in TMD [26-28]. Recent studies have shown that the PHQ-15 is a valuable tool for evaluating somatic symptoms, and the tool is recommended in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) [29]. Studies of somatic symptoms and masticatory muscle pain in TMD have reported a strong association between a high score on the PHQ-15 and TMD development [30]. The GAD-7 is a valuable screening tool for anxiety. A recent study reported that patients with masticatory muscle pain in chronic TMD tended to have higher rates of depression and anxiety compared to those in the control patients [28,31]. Thus, it is important to consider whether anxiety may cause chronic pain to become severe. We found no difference in PHQ-15 and GAD-7 scores between patients who improved and those who did not or between satisfied and dissatisfied patients. Nevertheless, the PHQ-15 and GAD-7 are considered to be essential in the management of masticatory muscle pain in TMD.

A relationship between myofascial TMD and the autonomic nervous system has been reported, with decreased parasympathetic nervous activity and increased sympathetic nervous activity during sleep [32]. Patients with chronic TMD also showed increased HR and autonomic nervous dysfunction, including decreased parasympathetic nervous activity [33]. However, the autonomic nervous system failed to predict or contribute to the incidence of masticatory muscle pain in TMD [34]. We observed no difference in autonomic nervous system activity between patients who improved and those who did not or between satisfied and dissatisfied patients; however, we did not distinguish between myalgia and myofascial pain. Our findings suggest the need to investigate HR variability in patients with myofascial pain.

In conclusion, the results of this study suggested that patients with local myalgia responded better to soft appliance therapy compared to hard appliance therapy. Patients who developed short facets were likely to be satisfied with a soft appliance rather than a hard appliance. Therefore, a soft appliance may be appropriate for patients with local myalgia who develop short facets on their occlusal appliances.

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AUTHOR CONTRIBUTIONS

Kosuke Kashiwagi: Writing - original draft
Tomoyasu Noguchi: Writing - original draft
Ken-ichi Fukuda: Writing - original draft

CONFLICTS OF INTEREST: The authors declare that there is no conflict of interest regarding the publication of this paper.

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