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ORIGINAL ARTICLE

Headache: short- and long-term effectiveness of a prefabricated appliance compared to a stabilization appliance

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Abstract

Objective. To compare the short- and long-term effectiveness of a prefabricated occlusal appliance with that of a stabilization appliance when treating headache in patients with myofascial pain. ***Material and methods.*** Sixty-six patients, 94% of whom suffered concomitantly from headache, at two centres for Stomatognathic Physiology in Sweden and Finland were included in a randomized controlled trial. History questionnaires and clinical examination according to the Research Diagnostic Criteria for Temporomandibular Disorders were used at baseline and at 10-week and 6- and 12-month follow-ups. Patients were randomly assigned to either a prefabricated (R) or a stabilization appliance (S) group. ***Results.*** There were significant decreases in the frequency and intensity of headache in both groups at all follow-ups, without statistically significant differences between groups. At baseline, 23 patients in both groups reported recurrent-continuous headache and, at 12 months, seven in the R group and four in the S group. The mean intensity (numeric rating scale) of headache prior to treatment decreased significantly at 12 months from 5.3 to 2.1 in the R group and from 6.1 to 2.9 in the S group. At the 12-month follow-up, 56% of patients in the R group reported a 30% reduction in intensity of headache and 50% a 50% reduction. In the S group, corresponding values were 39% and 36%, respectively. Non-specific physical symptoms were significantly associated with frequency of headache at baseline and at 6 months, and with depression at 6 and 12 months. ***Conclusion.*** The effectiveness of the prefabricated appliance seems to be similar to that of the stabilization appliance in the treatment of headache in patients with myofascial pain in both the short and long term.

Key Words: *Headache, long-term follow-up, myofascial pain, occlusal appliances, temporomandibular disorders*

Introduction

Tension-type headaches (TTHs) can be frequent and severe, and cause great invalidity to those suffering from them [1]. The diagnosis of the disease relies exclusively on the symptoms, which are not as distinct as in migraine. According to the International Classification of Headache Disorders (ICHD) [2], TTH is divided into subcategories of infrequent episodic, frequent episodic (ETTH), and chronic tension-type (CTTH) headache, which have similar clinical features. In a Danish population study [3], only 16% of patients with TTH had contacted a general practitioner because of headache, compared with 56% of migraineurs, but when the data were corrected for the markedly higher prevalence of TTH, the total use of medical services was in fact 54% higher for TTH. This supports the fact that TTH is one of the most costly diagnoses, causing roughly three times more sick leave than migraine [3]. The symptoms of TTH are indistinct and the cause is often considered mixed.

Headache, especially TTH, has been reported as a complaint in ≈40–70% of patients suffering from temporomandibular disorders (TMDs) [4,5]. Both headache and TMDs are prevalent conditions in the general population, and headache seems to be one common symptom associated with TMDs.

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Several clinical and epidemiological studies have demonstrated an association between headache and TMDs [4,6–8]. It has also been shown that occlusal treatment of TMDs can reduce overall headache, TTH, and combination headache [6,9–14]. However, the exact relationship between TMDs and headache is largely unknown. In a recently published study by Ballegaard et al. [15], the authors indicated that a high proportion of headache patients have significant disability because of ongoing chronic TMD pain, and they emphasized the importance of examination of the masticatory system in headache sufferers.

Occlusal therapy including occlusal appliances has been reported to have a positive treatment effect in TTH, in both the short and long term [6,11,16]. According to Ekberg et al. [13] and Ekberg and Nilner [14], the stabilization appliance seemed to have a positive effect on the frequency of TTH in patients with TMD pain of both arthrogenous and myogenous origin.

In a recent randomized controlled trial (RCT) [17], the effectiveness of treatment with a prefabricated occlusal appliance was compared in the short term to that with a stabilization appliance in patients suffering from TMDs of mainly myogenous origin. The results showed a similar treatment outcome in both groups, as regards both symptoms and signs, with no difference between the groups.

The aim of this study was to evaluate the effectiveness of a prefabricated appliance compared to that of a stabilization appliance regarding the frequency and intensity of headache in myofascial pain patients, in both a short- and long-term perspective.

The study hypothesis was that the decreases in frequency and intensity of headache would be similar in patients with myofascial pain treated with a prefabricated appliance or a stabilization appliance in both the short and long term.

Material and methods

Material

The research was carried out as an RCT during the period February 2005 to May 2007 as a multicentre study in Malmö and Turku. Sixty-six patients (aged ≥18 years) with myofascial pain, diagnosed according to Dworkin and LeResche [18], were followed at 10 weeks and 6 and 12 months. The patients were selected from 203 eligible patients referred for treatment of TMDs to the Department of Stomatognathic Physiology, Faculty of Odontology, Malmö University and the Department of Stomatognathic Physiology, Faculty of Medicine, Turku University (Figure 1). A more detailed description of the subjects and demographic data, as well as of inclusion and exclusion criteria, has been presented previously [17]. According to a power calculation, made using the original sample of myofascial pain patients before the beginning of the study, the inclusion of at least 22 patients in each group would provide a power slightly above 90% for obtaining statistical equivalence. Equivalence means within 15 units in a two-tailed test at the 5% level if the true success probability in the group treated with a prefabricated appliance is the same or differs from that of the group treated with a stabilization appliance [17]. All participants gave their written consent. The study was approved by the Ethics Committees of Lund and Turku Universities [permission Nos. H4 846/2004 (Lund) and 19.10.2004 §305 (Turku)].

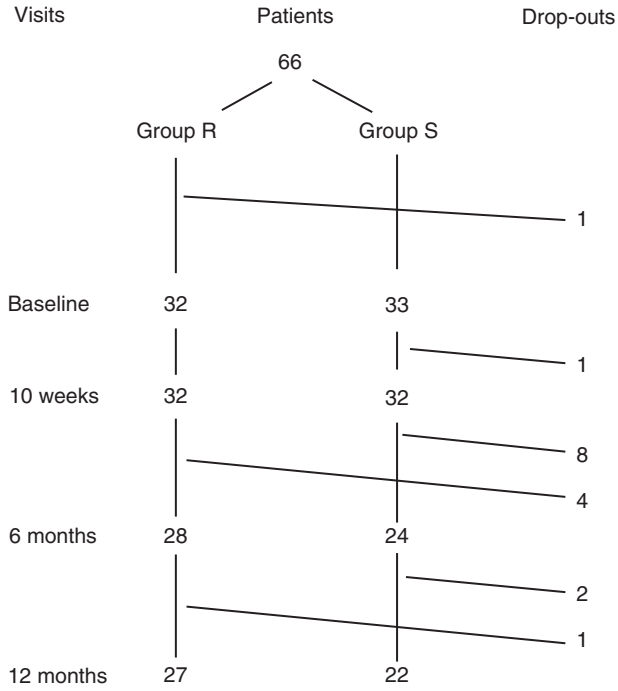

Figure 1. Distribution of TMD patients at baseline and at the 10-week, 6- and 12-month follow-ups in both patient groups. R = prefabricated appliance, S = stabilization appliance.

Randomization and occlusal appliances

After the baseline examination, patients were randomly allocated to one of two groups: one group were treated with a prefabricated appliance, Relax (R group; Figure 2a), and the other with a stabilization appliance (S group; Figure 2b), as thoroughly described previously [17]. The randomization procedure was repeated until 66 patients were included in the study. At both centres a general practitioner not involved in the examination adjusted and delivered the appliances. The design of the study, as well as the delivery, adjustment, and instructions for use of the appliances, have also been described previously [17]. After 10 weeks, the patients were instructed to use the appliance when needed. At the 10-week follow-up, patients not satisfied with the treatment outcome

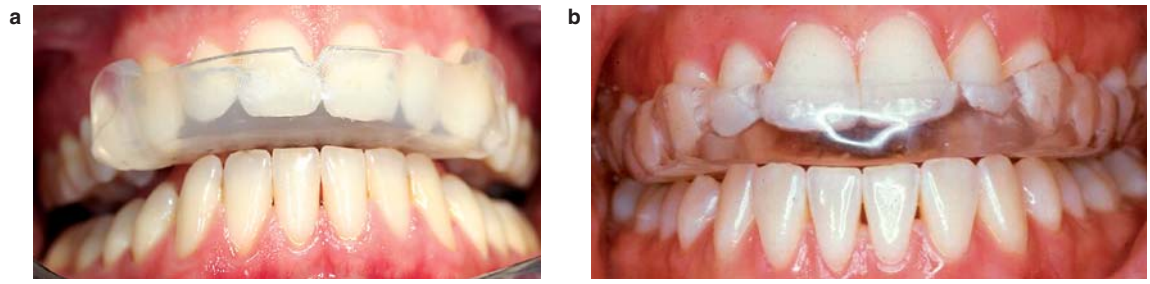

Figure 2. Frontal views of (a) prefabricated appliance, (b) stabilization appliance.

were offered another appliance and/or additional treatment.

Study design and questionnaires

History questionnaires and clinical examinations according to Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) [18] were completed at baseline and at 6- and 12-month follow-ups. A single examiner at each university, who was blinded to the treatment groups, performed all clinical examinations and gave information and counselling. The examiners were calibrated in accordance with the RDC/TMD. Treatment assignment was concealed from the examiner using sealed envelopes. When the participants were evaluated, a dental nurse distributed the questionnaires and instructed them not to discuss the treatment with the examiner. A more thorough description of the study design has been presented previously [17].

The pretreatment questionnaire included four questions about both the occurrence and frequency of headache during the preceding 6 months on a verbal scale, as follows: 1 = continuous; 2 = recurrent; 3 = rarely. Patients reporting recurrent headache specified it as follows: 1 = once a month; 2 = once a week; 3 = at least 15 times a month. For statistical analyses, the groups with no headache and rare headache were combined into one group, as were the groups with recurrent and continuous headache. The intensity of both headache and myofascial pain during the preceding 6 months was assessed on a numeric rating scale (NRS) [19] with the endpoints 0 and 10, while intensity of headache during the month prior to the follow-ups was registered on a visual analog scale (VAS) [20] with the endpoints 0 and 100 mm. For statistical analysis and comparison with NRS baseline data, the VAS was changed to a scale from 0 to 10 using the following conversion rules: 0–4 mm = 0; 5–14 mm = 1; 15–24 mm = 2. . .; 95–100 mm = 10.

Changes in psychological data, depression and non-specific physical symptoms (NSPhS) were assessed using the Symptom Check List-90-Revised [18], which includes 20 questions indicating depression and 12 indicating NSPhS, with the classifications normal, moderate, and severe.

Before treatment and at the 6- and 12-month follow-ups, a trained dental assistant performed a clinical examination including registration of unassisted mouth opening capacity without pain and maximal assisted opening, and recording of pain pressure threshold (PPT) bilaterally at the masseter and the anterior temporalis muscle using an electronic algometer (Somedic AB, Farsta, Sweden).

Awareness of grinding or clenching during the day and at night, and pain from the neck and shoulders were registered. The patients also answered questions about self-assessed stress on a verbal scale: little; to some extent; and much. At the different follow-ups the patients were asked about the frequency of their use of the appliance by means of a verbal scale, as follows: every night; several nights a week; or when necessary.

Treatment outcome measures

The primary outcome measures were the reported frequency and intensity of headache.

Statistical analysis

The chi-square test was used for comparison of the inter-group distribution of variables measured on a nominal scale, and the Mann–Whitney U-test for variables measured on an ordinal scale. For comparison within groups, the McNemar test was used for dichotomic variables, and Wilcoxon's signed rank test for analyzing changes between baseline data and follow-up measurements and for those variables measured on an ordinal and continuous scale. The Mann–Whitney U-test was used for analyzing the difference in change between the groups. Differences at the 5% level of probability were considered statistically significant. Statistical analyses were done using SPSS 16.0 software (SPSS Inc, Chicago, IL).

Results

For up to 10 weeks of appliance therapy, none of the patients expressed a need for or demanded additional treatment or another occlusal appliance for TMDs.

One patient in the R group was excluded due to a wrong diagnosis. One patient in the S group did not participate in the 10-week follow-up because of ongoing orthodontic treatment. After the 10-week follow-up, two patients in the R group and four in the S group requested another appliance. In the S group, one patient was diagnosed with cancer and could no longer participate. In both groups, one patient did not want to participate any longer, and one patient from each group requested additional treatment. One patient in the S group had moved. These 14 patients were considered drop-outs. Between the 6- and 12-month follow-ups, two patients in the S group and one in the R group dropped out due to illness, requested another treatment, or refused to participate. These three patients were also considered drop-outs (Figure 1). When comparing the drop-outs with those completing the study, no differences between the two groups could be found at baseline regarding either headache or demographic data.

Frequency of headache

There were no statistically significant differences in frequency of headache between the groups at baseline. Twenty-nine out of 32 patients in the R group and 32/33 in the S group, 94% in total, reported suffering from headache at baseline. The majority, 72% in the R group and 70% in the S group, reported their headache to be 'recurrent/continuous'. In both groups, 28/39 patients in total reported recurrent headache, with a headache frequency of <15 times a month.

The frequency of headache decreased statistically significantly ($P \leq 0.01$) compared to baseline at all follow-ups in both groups (Table I). There were no differences at baseline, or at follow-ups, between the groups.

Intensity of headache

At baseline, the mean intensity (NRS) of headache during the 6 months prior to the start of treatment was 5.3 in the R group and 6.1 in the S group. At the 12-month follow-up, the intensity had decreased to 2.1 in the R group and to 2.9 in the S group. The decrease was significant ($P < 0.001$) in both groups at every follow-up, without a significant difference between the groups (Figure 3). In an intent-to-treat analysis, at the 10-week follow-up, 58% of all patients reported a 30% reduction in intensity of headache and 43% reported a 50% reduction. The 12-month follow-up results showed corresponding values of 48% and 43%, respectively (Table II).

Mouth-opening capacity

Mouth opening showed no statistically significant differences between or within the groups during the follow-up period. The unassisted mouth-opening capacity without pain (mean of both groups) increased from 41.8 mm at baseline to 43.7 mm at 12 months, while the assisted mouth-opening capacity remained similar at baseline (53 mm) and 12-month follow-up.

Emotional functioning and headache

In a per-protocol analysis, the NSPhS score was significantly associated with frequency of headache at baseline and at the 6-month follow-up (Figure 4a). A statistically significant association between frequency of headache and depression score at the 6- and 12-month follow-ups was observed (Figure 4b).

Algometer registrations/headache

A statistically significant increase in PPT was found in both groups on the right side of the anterior temporal muscle at the 10-week follow-up, and on the left side at all follow-ups. Furthermore, there was a statistically significant difference in PPT in the S group on the right side of the anterior temporal muscle between baseline and the 6-month follow-up ($P \leq 0.05$). No

Table I. Reported frequency of headache at baseline and at the 10-week, 6- and 12- month follow-ups.

	Baseline		10 weeks		6 months		12 months	
Frequency	R(n = 32)	S(n = 33)	R(n = 32)	S(n = 32)	R(n = 28)	S(n = 24)	R(n = 27)	S(n = 22)
No headache	3	1	6	4	5	2	4	1
Rarely	6	9	12	18	14	17	16	17
Recurrent								
Once a month	2	7	2	3	2	2	0	2
Once a week	11	8	5	5	2	2	4	1
≥15 times a month	7	4	4	2	3	0	2	0
Continuous	3	4	3	0	2	1	1	1

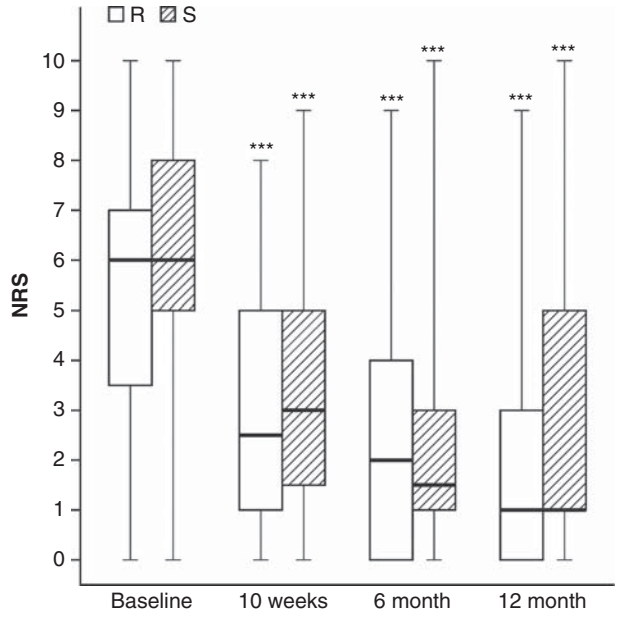

Figure 3. Intensity of headache on the NRS (median and interquartile range) assessed at baseline and compared to the 10-week and 6- and 12-month follow-ups. R = prefabricated appliance, S = stabilization appliance.$^{***}P \leq 0.001$ (Wilcoxon signed ranks test).

statistically significant changes in PPT of the masseter muscle could be found in either group.

Influencing factors

At the 6-month follow-up, 39% of patients in the R group reported that they used their appliance several nights a week or more, compared with 25% in the S group. By 12 months, use had decreased to 33% in the R group and to 14% in the S group. At the 12-month follow-up, 33% in the R group and 50% in the S group used their appliances when necessary.

At baseline, 17 patients in the R group and 27 in the S group reported overall stress to some or a great extent. The intensity of myofascial pain assessed using the NRS was 5.7 in the R group and 5.8 in the S group, while pain in the neck and shoulders occurred in 29 and 31 patients in the R and S groups, respectively. None of the above-mentioned factors were found to be associated with the decrease of headache outcome in either group. The same outcome was found regarding social factors, such as sick leave, general health, social status, and educational level, reported by the patients.

Discussion

The aim of this study was originally to compare the effectiveness of a prefabricated occlusal appliance with that of a stabilization appliance in treating patients with myofascial pain. Since patients with this diagnosis often suffer from headache it is of interest to evaluate the short- and long-term effectiveness of the prefabricated appliance, with respect to headache.

The frequency and intensity of headache decreased in both the short and long term in patients with myofascial pain. The frequency of headache changed significantly in both groups from recurrent/continuous to none/rarely at both the 6- and 12-month follow-up. This is well in line with the results of Ekberg and Nilner [14] on patients with TMDs of myogenous origin and concomitant TTH. They reported a reduction in the number of patients who experienced headache at least once a week, and an improvement in headache in patients treated with a stabilization appliance.

Our results are in line with earlier reports focusing on the association between headache and TMDs. As early as 1980, Magnusson and Carlsson [21] found the prevalence of recurrent headaches in a group of TMD patients to be higher than that in a group of dental patients. A reduction in the frequency of recurrent headache after TMD treatment was found. The authors concluded that patients consulting for recurrent headache should undergo functional examination of the masticatory system and that headache patients with clinical signs of TMDs should receive stomatognathic treatment. Forssell et al. [6] compared patients suffering from migraine, muscle contraction and combination headache and TMDs treated with occlusal adjustment to controls treated with mock adjustment. They concluded that "occlusal therapy can reduce both frequency and intensity in patients with muscle contraction and combination headache". Shokker et al. [9] reported a significant decrease in both the intensity and frequency of headache in 23 chronic headache patients also diagnosed with craniomandibular disorders and treated by a dentist. Another 25 patients were treated by a

Table II. Reported reduction of headache at the 10-week, 6- and 12- month follow-ups.

	10 weeks P^a		6 months		12 months		
Reduction	R(n = 32)	S(n = 33)	R(n = 28)	S(n = 24)	R(n = 27)	S(n = 22)	
By 30%	20	18	16	16	18	13	NS
By 50%	14	14	14	14	16	12	NS

[a]Chi-square test.

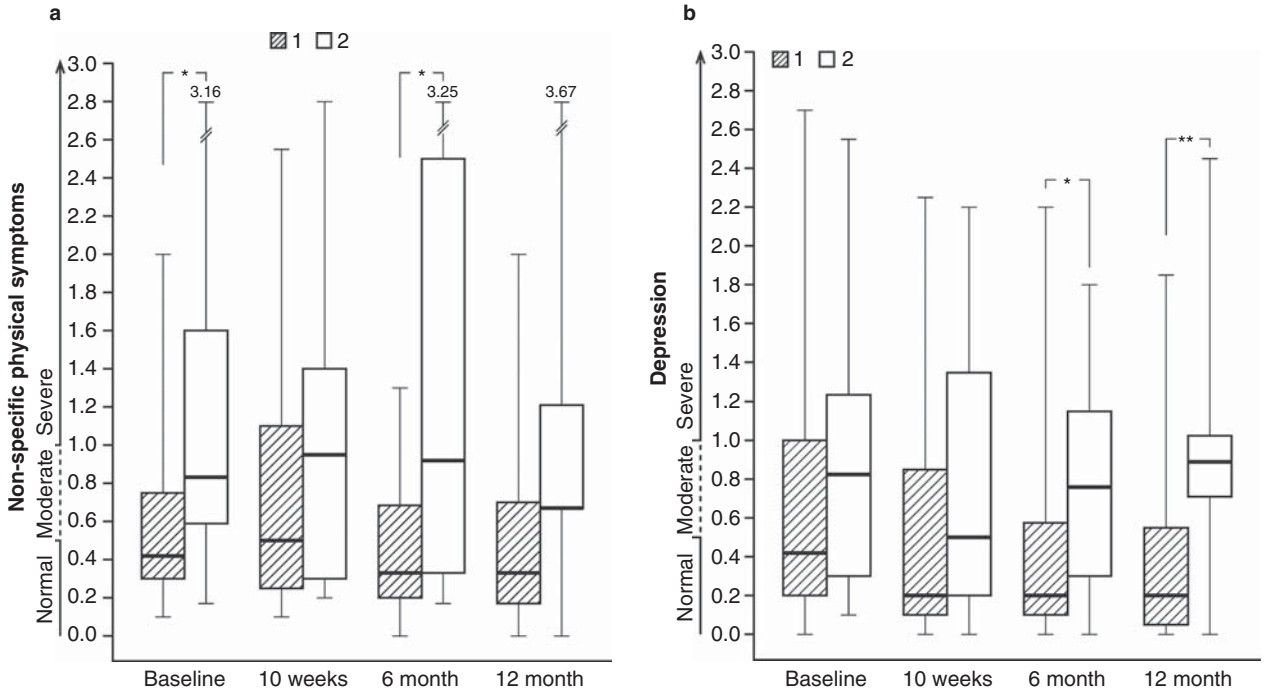

Figure 4. (a) Difference in scores (median and interquartile range) for NSPhS between patients with no/rare headache and recurrent/continuous headache in the R and S groups together. 1 = no/rare headache; 2 = recurrent/continuous headache. $^{*}P \leq 0.05$ (Mann–Whitney U-test). (b) Difference in scores (median and interquartile range) for depression between patients with no/rare headache and recurrent/continuous headache in the R and S groups together. 1 = no/rare headache; 2 = recurrent/continuous headache. $^{*}P \leq 0.05$, $^{**}P \leq 0.01$ (Mann–Whitney U-test).

neurologist. The occlusal treatment included mainly stabilization splint therapy and was reported to be superior when compared to the pharmacological treatment. The working mechanisms of the appliances are not known. However, the incorporation of an appliance seems to be beneficial for the patient [22].

In a review by Svensson [23] it was concluded that myofascial TMDs and TTH disorders overlap and seem to share many of the same pathophysiological mechanisms. He suggested that orofacial pain and headache specialists should collaborate to improve diagnostic techniques and management strategies for TMDs and TTH. Also, Ballegaard et al. [15] reported recently on the overlap between primary headaches and TMDs. Their study included headache patients referred to a headache centre. The patients were diagnosed according to the ICHD-II [2] by neurologists. Sixty per cent of the patients had more than one headache diagnosis: migraine was the most prevalent single diagnosis (15.2%), followed by TTH (11.1%). The patients were examined according to the RDC/TMD and a TMD diagnosis (Axis I) was identified in 56.1% of them. Facial pain according to the RDC/TMD Axis II chronic pain grade classification was reported by 82.8% of patients. In a study by Shokker et al. [8], the results indicated that there is a close relationship between TMDs and recurrent headache, irrespective of the neurological diagnosis of the headache. In our study, the main symptom of the patients was myofascial pain of myogenous origin, and 94% suffered concomitantly from headache. Although a headache diagnosis according to the ICHD was not defined in our material, it is probable that the patients suffered mostly from TTH, and more precisely from ETTH, since 28/39 patients reporting recurrent headache had a headache frequency of <15 times a month and, in the RDC/TMD questionnaire, no-one reported suffering from migraine or receiving ongoing medication for migraine.

Ekberg and Nilner [14], in their study on the treatment outcome of appliance therapy in patients with TMDs of myogenous origin, found that a 30% improvement in muscles tender to palpation was a factor which influenced a positive treatment outcome of TTH pain. In their material of 100 chronic headache patients referred to a neurologist, Shokker et al. [8] found that 55 exhibited craniomandibular pain during examination of the stomatognathic system. They concluded that this suggested a possible relationship between headache and the condition of the masticatory muscles. In spite of the fact that we found some significant increase in pain pressure thresholds in both groups, such a connection was not found in our study. We registered the muscle tenderness in two muscles on both sides of the face using an algometer, while Ekberg and Nilner palpated five sites on each side of the face, which might explain the discrepancy between the results. A difficulty in comparing different studies is that some report on TMD patients with concomitant headache referred to a specialist in

stomatognathic physiology, while others report on headache patients with the signs and symptoms of TMDs referred to a neurologist.

Another type of frontal intra-oral device, the Nociceptive Trigeminal Inhibition Tension Suppression System (NTI-tss), was introduced by Shankland [24] and aimed mainly at reduction of TTH and migraine. Its specific design, with a single, pinpoint contact on the occluding element, is intended to suppress the intensity of parafunctional pericranial muscular activity by taking advantage of the jaw-opening reflex. This concept has been criticized by Magnusson et al. [25], who found in their pilot study comparing the NTI-tss with a stabilization splint, that the stabilization splint was superior for all variables, including treatment of headache. Jokstad et al. [26] found no differences in treatment efficacy of either TMDs or headache between the two splints. Later, Stapelmann and Türp [27] concluded in their review that evidence from RCTs suggests that the NTI-tss device may be successfully used for the management of bruxism and TMDs. Owing to the risk of undesired effects, the use of the NTI-tss device should be questioned.

TMD patients have been reported to be more distressed than healthy individuals [28]. In an earlier study [14], any kind of stressful life events seemed to influence the treatment outcome of headache at 12-month follow-up. Using the same instrument in this study did not show any association between stressful life events and treatment outcome. A validated questionnaire might have revealed some associations. Several studies have reported on cognitive behaviour and depression and NSPhS as important factors in the treatment outcome of TMDs [29]. In a longitudinal study of TMD patients, NSPhS were found to be an important factor for the development of myofascial pain [30]. In the present study, no consistent associations between frequency of headache and NSPhS and depression could be found. To our knowledge there is no other study reporting on these symptoms in association with headache in myofascial pain patients over a long-term follow-up period.

A limitation of this study is the high number of drop-outs after the 10-week follow-up. Drop-outs are a common problem in clinical long-term follow-up studies. However, to compensate for drop-outs, we included more patients than the original power calculation demanded. In addition, despite the many drop-outs, analyses showed no difference between the drop-outs and those who completed the study regarding the frequency and intensity of headache and demographic data. Another shortcoming of the study was using an NRS at baseline but a VAS at follow-ups when assessing the intensity of headache. However, this was corrected by converting the VAS to an NRS.

The results of this study suggest that the prefabricated appliance seems to have the same effectiveness as the stabilization appliance on headache in patients with myofascial pain in both a short- and long-term perspective. Suffering from TTH is a major financial burden in society today [3], considering both medication and absence from work. From a health point of view, the prefabricated appliance might offer an economical treatment option.

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