Short-term Effectiveness of a Prefabricated Occlusal Appliance in Patients with Myofascial Pain

Maria Nilner, DDS, PhD
Professor

EwaCarin Ekberg, DDS, PhD
Associate Professor

Department of Stomatognathic Physiology
Faculty of Odontology
Malmö University
Malmö, Sweden

Marika Doepel, DDS
Specialist in Clinical Dentistry, Assistant
Department of Prosthodontics
Faculty of Medicine, Institute of Dentistry
University of Turku
Turku, Finland

Johanna Andersson, DDS
General Practitioner
Public Dental Health
Malmö, Sweden

Kirsi Selovuo, DDS
Private Practice
Turku, Finland

Yrsa Le Bell, DDS, PhD
Docent
Graduate Programme in Clinical Dentistry
Faculty of Medicine, Institute of Dentistry
University of Turku
Turku, Finland

Correspondence to:
Professor Maria Nilner
Department of Stomatognathic Physiology
Faculty of Odontology
Malmö University
Carl Gustavsvägen 34
SE-20506 Malmö, Sweden
Fax: +46 40 6658420
E-mail: maria.nilner@od.mah.se

Aims: *To compare the short-term effectiveness of a stabilization appliance with a prefabricated occlusal appliance in myofascial pain patients in a randomized controlled trial.* ***Methods:*** *Sixty-five patients at 2 centers were assigned to a stabilization appliance group (S group, n = 33) or a prefabricated appliance (Relax) group (R group, n = 32). The patients had been suffering from temporomandibular disorder (TMD) pain for 3 months to 40 years. The patients were examined for symptoms and signs of temporomandibular disorders according to the Research Diagnostic Criteria for TMD and treated by a general practitioner. Treatment outcomes regarding pain, registered on a visual analog scale, and overall ratings of pain, registered on a verbal scale, were evaluated at 6- and 10-week follow-up appointments, and the data from the groups were compared statistically.* ***Results:*** *The main treatment outcome in the 2 groups was a positive improvement of overall symptoms without any statistically significant differences between groups at either 6 or 10 weeks. At the 6-week follow-up, 72% of all patients reported a 30% reduction of the worst pain, and 55% of the patients reported a 50% reduction of the worst pain, whereas at the 10-week follow-up, the percentages were 69% and 61%, respectively. According to the verbal scale, 85% of all patients reported themselves to be "better," "much better," or "symptom-free" at the 6-week follow-up, and 83% reported this at the 10-week follow-up.* ***Conclusion:*** *The effectiveness of the prefabricated occlusal appliance seemed to be the same as that of the stabilization appliance. The prefabricated appliance can therefore be recommended as a short-term therapy in adult patients with myofascial pain.* J OROFAC PAIN 2008;22:209–218.

Key words: myofascial pain, occlusal appliances, pain, randomized controlled trial, temporomandibular disorders

Occlusal appliances are commonly used in the treatment of patients suffering from temporomandibular disorders (TMD).[1–3] In 4 recently published systematic reviews including randomized controlled trials (RCT), conflicting conclusions were reached on the efficacy of occlusal appliance therapy. In the studies by Forssell et al,[4] Forssell and Kalso,[5] and Al-Ani et al,[6] more well-designed studies were called for. However, Türp et al[7] concluded that, based on the currently best available evidence, most patients with masticatory muscle pain will be helped by the use of a stabilization splint.

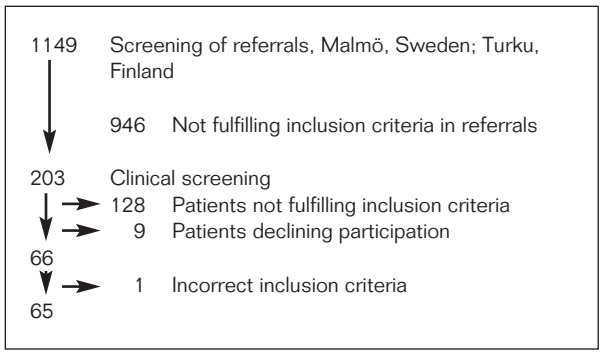

Fig 1 Selection of patients referred for treatment of TMD.

Although the reviews[4–7] have led to equivocal results regarding the evidence of appliance therapy, the conclusions of the RCTs themselves regarding treatment outcome have been positive. A study by Dao et al[8] concluded that patients suffering from myofascial pain could not be differentiated from control groups regarding treatment outcome after 8 weeks. All 3 groups reported a positive treatment outcome. Ekberg et al,[9–12] however, found a better treatment outcome with stabilization appliance therapy compared to a control appliance in patients suffering from TMD of both myogenous and arthrogenous origin in short-term as well as long-term studies.

Most studies have been performed by well-trained TMD clinicians, and thus the effectiveness has not been tested. General practitioners often claim that adjustment of a stabilization appliance is a difficult and time-consuming procedure.[13] Because of the prevalence of TMD pain in the general population of 6% to 12%,[14–16] there is a need for the general dental practitioner to treat patients with TMD. The large size of a stabilization appliance may sometimes affect the comfort and thereby the compliance of the patient.[10,12]

A new type of oral appliance, the Nociceptive Trigeminal Inhibition (NTI), which engages the central incisors, was introduced some years ago,[17] but because of its negative effects on occlusion and the risk of swallowing or aspiration,[18,19] the NTI appliance was not accepted as a treatment modality in Sweden. However, general practitioners found the NTI appliance to be an easy treatment modality, not least for the comfort of the patients.

A new prefabricated appliance, Relax (Unident), has been developed. Relax covers the anterior maxilla from canine to canine with an occlusal plateau. This new appliance should be compared with a well-accepted occlusal appliance. According to the aforementioned reviews, the most tested appliance is the stabilization appliance.

The aim of this RCT was therefore to evaluate the short-term effectiveness of the Relax appliance and compare it with that of a stabilization appliance in patients with myofascial pain. The hypothesis of this study was that the treatment outcome with the prefabricated occlusal appliance, Relax, is similar to that obtained with a stabilization appliance.

Materials and Methods

The study was performed during the period February 2005 to August 2006 as a multicenter study in Malmö, Sweden, and Turku, Finland. The patients were selected from 1,149 patients referred for treatment of TMD to the Department of Stomatognathic Physiology, Faculty of Odontology, Malmö University, Sweden, and the Department of Stomatognathic Physiology, Faculty of Medicine, Turku University, Finland. On the basis of the information in the referrals, 203 patients were clinically screened according to the inclusion and exclusion criteria. The progress of the study is presented in Fig 1. Of the 9 patients who declined to participate, 8 reported that they were unable to follow the schedule of appointments, and 1 was undergoing dental treatment. A total of 66 patients initially met the inclusion and exclusion criteria, but during treatment, 1 patient was rediagnosed with arthrogenous pain and thus excluded from the study.

According to a power calculation made before the beginning of the study, the inclusion of at least 22 patients in each group would provide a statistical power slightly above 90% for obtaining statistical equivalence. Equivalence means within 15 units in a 2-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 the group treated with a stabilization appliance.
The inclusion criteria of the study were:

- Age ≥ 18 years
- Pain of muscular origin with or without limited opening, according to the Research Diagnostic Criteria (RDC) for TMD of Dworkin and LeResche[16]
- Self-assessed worst myofascial pain of at least 4 on a graded numeric rating scale (NRS) (scale of 0 to 10)
- Duration of pain at least 3 months

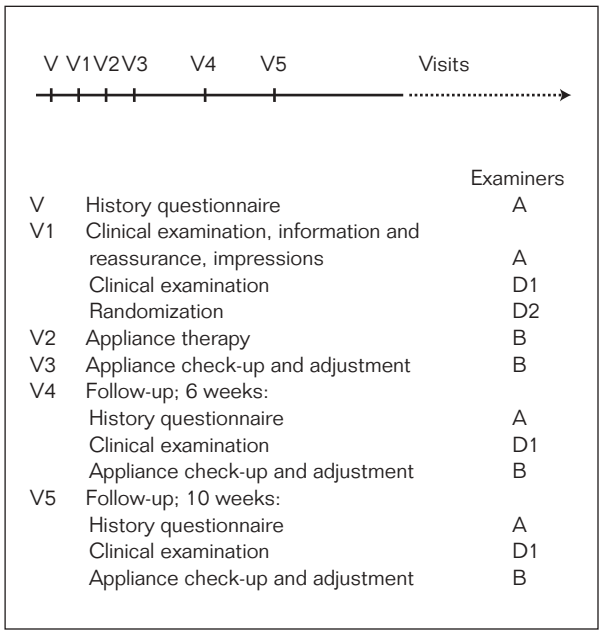

Fig 2 Visits (V) before treatment and at 6- and 10-week follow-ups performed by dentists A and B and a dental assistant (D_1). Randomization was done by an independent person (D_2).

Exclusion criteria were:

- Temporomandibular joint pain verified by interview or clinical examination
- Presence of complete dentures
- Symptoms related to disease in other components of the stomatognathic system (eg, toothache, neuralgia)
- Whiplash diagnosis
- Diagnosed systemic muscular or joint disease (eg, fibromyalgia, rheumatoid arthritis)
- A history of psychiatric disorders
- Periodontal problems
- Previous treatment with an occlusal appliance
- Presence of idiopathic orofacial pain

The study was performed as an RCT. Patients were randomly allocated to 1 of 2 groups: one group was treated with a prefabricated appliance, Relax (R), and the other was treated with a stabilization appliance (S). One independent person (D_2) at each clinic carried out the randomization by using 10 series of consecutively numbered, sealed, opaque envelopes. Each envelope contained a treatment specification. The last series included 6 envelopes (3 for each treatment modality). This randomization procedure was repeated until 66 patients were included in the study. One patient was later eliminated because of incorrect inclusion criteria. To compensate for probable dropouts, the number of patients recruited was greater than the sample size originally planned.

The history-taking and the clinical examination were performed, and reassurance and information were given before treatment, by 1 dentist (Dentist A). The patients were informed about the lack of a clear-cut cause of their myofascial pain and about contributing factors. They were reassured and informed about the nature of TMD and the relationship between muscle fatigue, muscle pain, the psychophysiologic aspects of stress, and how to self-monitor TMD symptoms. All participants gave their written consent. The study was approved by the ethical committee of Lund and Turku universities.

A history questionnaire,[16] including a 1-week pain diary, was completed by the patients. To exclude odontogenic reasons for the orofacial pain, a panoramic radiographic examination was performed. The treatment with an occlusal appliance was performed by a second dentist (Dentist B) (Fig 2). The people designated as Dentist A at both centers were calibrated to the RDC/TMD. Dentist A at each clinic had no information as to which group the patients belonged. Dentist B, a general practitioner at both clinics who was not involved in the examination at baseline or at follow-ups, delivered, adjusted, and evaluated the use and wear of appliances.The general practitioners were instructed and trained together for half a day to handle the prefabricated appliance.

Before treatment and at the 6- and 10-week follow-up appointments, a trained dental assistant (D_1) performed a clinical examination, which included registration of opening capacity and

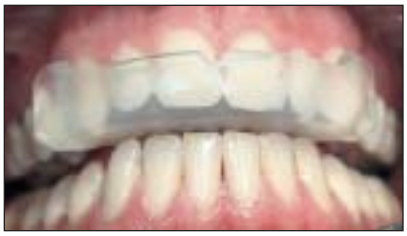

Fig 3a *(above)* Relax appliance, frontal view.

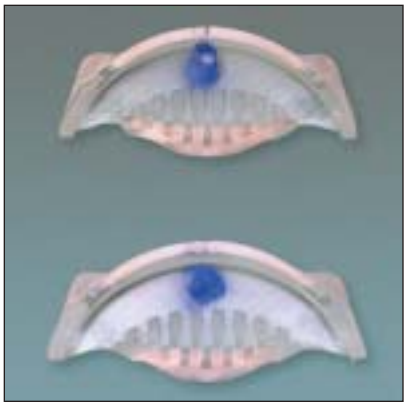

Fig 3b *(right)* Relax appliance, inner view, in 2 sizes.

Fig 3c Relax appliance fitted with inner material.

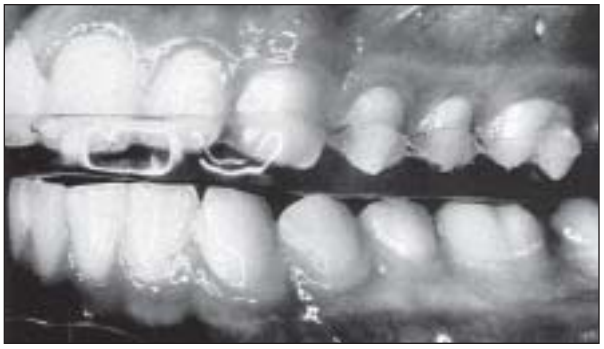

Fig 4 Stabilization appliance.

recording of pressure pain threshold (PPT) with an electronic algometer (Somedic). The tip of the algometer had a surface of 1 cm^2 and a rate of pressure increase of approximately 30 kPa per second. The PPT was determined as the point at which a stimulus applied to the skin changed from a sensation of pressure to one of pain. PPTs were assessed bilaterally at the masseter and the anterior temporalis muscle.[20] The PPT was recorded twice on each side at an interval of 2 minutes, and the mean value of the 2 recordings was used as the baseline value. The order of assessments was the same for all recordings, starting with the muscles on the right side, then the left side, and ending with the reference point.

The prefabricated Relax appliance (methylmethacrylate) included a front plateau that covered the edges of the incisors and canines with a palatal extension of about 1 cm (Fig 3). The frontal plateau allows both occlusal and articulation contacts. The buccal side of the appliance has 2 extensions that widen the dimension of the appliance and make removal easy. The appliance is individually fitted with self-curing silicone material (polyvinyl siloxane) inside the appliance, which is adhered to the appliance with an adhesive. Adjustment of the appliance aims to achieve contacts in centric relation. In lateral excursions, contacts on the canines or frontal group and symmetric contacts at protrusion were achieved.

The stabilization appliance (Fig 4) had a smooth, flat surface, with supporting teeth in contact, and was adjusted in centric relation. The appliance also had canine-protected articulation or group contacts of frontal teeth to avoid mediotrusion interferences during laterotrusion. At protrusion, the appliance had bilateral, symmetric contacts between canines.

The patients were instructed to use the appliance at night. The occlusal appliances were made, adjusted, and dispensed by the general practitioner. Comfort, patient acceptance, and function of the appliance were checked within 2 weeks, and the same procedure was repeated at the 6- and 10-week follow-up visits by the general practitioner.

Daily pain intensity during 1 week at rest, on mouth opening, and during chewing was recorded on a visual analog scale (VAS) with the endpoints "no pain" and "very severe pain,"[21] in addition to the history questionnaire used before treatment and for the 6- and 10-week follow-up appointments. Frequency of myofascial pain was recorded according to the following 9-point verbal scale: 0 = never; 1 = rarely; 2 = once a month; 3 = once every second week; 4 = once a week; 5 = twice a week; 6 = 3 to 4 times a week; 7 = daily; 8 = constantly.

At the follow-up appointments, improvement in overall subjective symptoms was measured according to a 6-point verbal rating scale: 0 = symptom-free; 1 = much better; 2 = better; 3 = unchanged; 4 = worse; 5 = much worse. The patients were asked to report any kind of discomfort associated with the appliance therapy and how often they used the appliance (0 = every night; 1 = several nights a week; 2 = when necessary; 3 = not at all).

Table 1 Demographic Data of the 65 Myofascial Pain Patients Before Treatment

	R (n = 32)	S (n = 33)
Gender		
Female	27	31
Male	5	2
Age (y)		
Mean	37	36
Median	38	36
Min–max	20–63	18–71
< 20	0	4
20–40	19	17
> 40	13	12
Ethnic origin		
Scandinavia	28	24
Other European countries	3	6
Asia	1	3
Latin America	0	0
Marital status		
Married	20	20
Divorced	4	4
Never married	8	9
Highest level of education		
Elementary school	4	4
High school	18	18
College	10	11

R = Relax appliance; S = stabilization appliance.

Table 2 Distribution of Reported Myofascial Pain, Awareness of Parafunctions, and Registered Palpatory Tenderness of the Masticatory Muscles Before Treatment

	R (n = 32)	S (n = 33)
Duration of myofascial pain (mo)		
Mean	80	50
Median	36	36
Min–max	3–480	6–240
3 to 6 mo	1	0
≥ 6 mo	31	33
NRS at the examination		
Mean	4.0	5.2
Median	3.5	5.0
NRS worst		
Mean	7.9	7.4
Median	8.0	8.0
NRS on average		
Mean	5.6	5.8
Median	5.0	5.0
Frequency of myofascial pain		
One time	2	1
Recurrent	16	19
Persistent	14	13
Awareness of clenching/grinding		
Daytime	22	22
Nighttime	27	22
Palpatory tenderness in masticatory muscles		
Mild to moderate	30	30
Moderate to severe	18	25
Severe	18	24

NRS = numeric rating scale; R = Relax appliance; S = stabilization appliance.

The treatment outcome measures of the study for both groups were (*1*) improvement in overall symptoms, (*2*) 50% and 30% reduction[22] in pain according to the VAS scale, and (*3*) improvement according to the verbal scale after treatment.

Statistical Analyses

The chi-square test was used for comparison of the distribution of variables in different groups of patients on a nominal scale, and the Mann-Whitney *U* test compared the variables measured on an ordinal scale. These tests were used to determine the significance of differences between groups. For comparison within groups, the McNemar test was used for categorical variables, and the Wilcoxon signed ranks test was used for the variables measured on an ordinal scale. Differences at the 5% level of probability were considered statistically significant.

Results

Before Treatment

The demographic data are shown in Table 1. There were no differences found in age, gender, ethnicity, or other demographic data between the R and S groups.

Symptoms and signs are presented in Table 2. Ninety-eight percent of all patients reported myofascial pain with a duration of 6 months or more; 2% of patients had pain for 3 to 6 months. The median NRS value for the worst myofascial pain was 7.7 for all patients. Awareness of clenching and/or grinding during the daytime was reported by 68% of all patients; at night, the corresponding figure was 75%. All patients reported tenderness to palpation of masticatory muscles, with 94% of patients reporting this tenderness as mild to moderate and 67% reporting it as moderate to severe.

Table 3 Diagnoses According to RDC/TMD in 2 Patient Groups at Baseline

Diagnosis	R (n = 32)	S (n = 33)	Total (n = 65)
Myofascial pain			
Without limited opening	21	22	43
With limited opening	11	11	22
Disc displacement			
With reduction	6	10	16
Without reduction	0	0	0
With limited opening	0	0	0
Without limited opening	0	0	0
Arthralgia/osteoarthritis	0	0	4
Osteoarthrosis	3	1	4

R = Relax appliance; S = stabilization appliance.

Table 5 Frequency of Use, Additional Adjustment, and Wear of the Appliances at 6 and 10 Weeks

	6 weeks		10 weeks	
	R (n = 32)	S (n = 33)	R (n = 32)	S (n = 33)
Frequency of use				
Every night	28	28	26	21
Several nights/wk	2	3	1	5
When necessary	2	2	5	6
Additional adjustment of appliance				
Yes	17	21	11	17
Wear				
Slight	6	6	7	7
Moderate	0	0	0	0
Severe	0	1	0	0

R = Relax appliance; S = stabilization appliance.

Table 4 Improvement of Myofascial Pain at 6 and 10 Weeks

	6 weeks		10 weeks		Significance level
	R (n = 32)	S (n = 33)	R (n = 32)	S (n = 33)	
Overall subjective symptoms					
"No change" to "worse"	4	6	4	6	NS
"Better" to "symptom-free"	28	27	27	26	NS
"Much better" or "symptom-free"	10	9	13	12	NS
Reduction of worst reported pain (VAS)					
By 30%	23	24	23	22	NS
By 50%	18	18	21	18	NS

Chi-square test.
R = Relax appliance; S = stabilization appliance; NS = not significant.

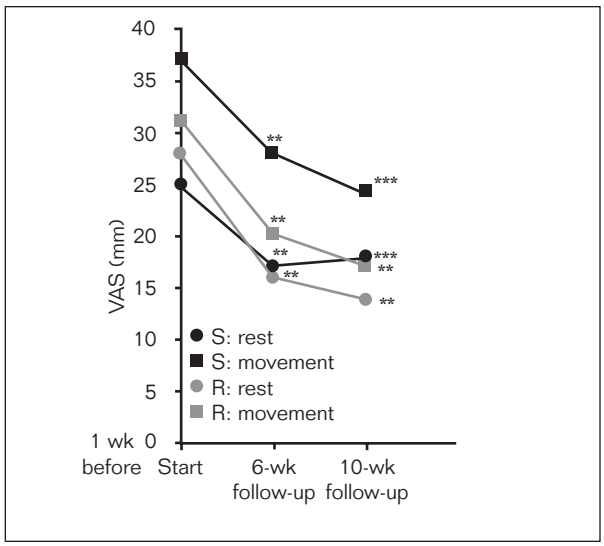

Fig 5 Mean daily pain registration for a 1-week period on VAS at rest and on movement (opening, chewing) in both groups, assessed before the start of treatment and before the 6- and 10-week follow-ups. Wilcoxon signed ranks test: $^{**}P < .01$; $^{***}P < .001$.

The diagnoses of the patients are presented in Table 3. All patients had a diagnosis of myofascial pain, 25% had a disc displacement, and only a few had a diagnosis of osteoarthrosis. No differences were found in the subdiagnosis of TMD between the R and S groups.

After Treatment

During the 10 weeks of appliance therapy, none of the patients received either additional treatment or another occlusal appliance for TMD. One patient in the S group did not participate in the 10-week follow-up because of orthodontic treatment.

Between Groups. The main treatment outcome in both groups was a positive improvement in overall subjective symptoms without any statistically significant differences between the groups R and S at both 6 and 10 weeks (Table 4). At the 6-week follow-up, 72% of all patients reported a 30% reduction of the worst pain, and 55% of the patients reported a 50% reduction of the worst pain. The 10-week follow-up results showed per-

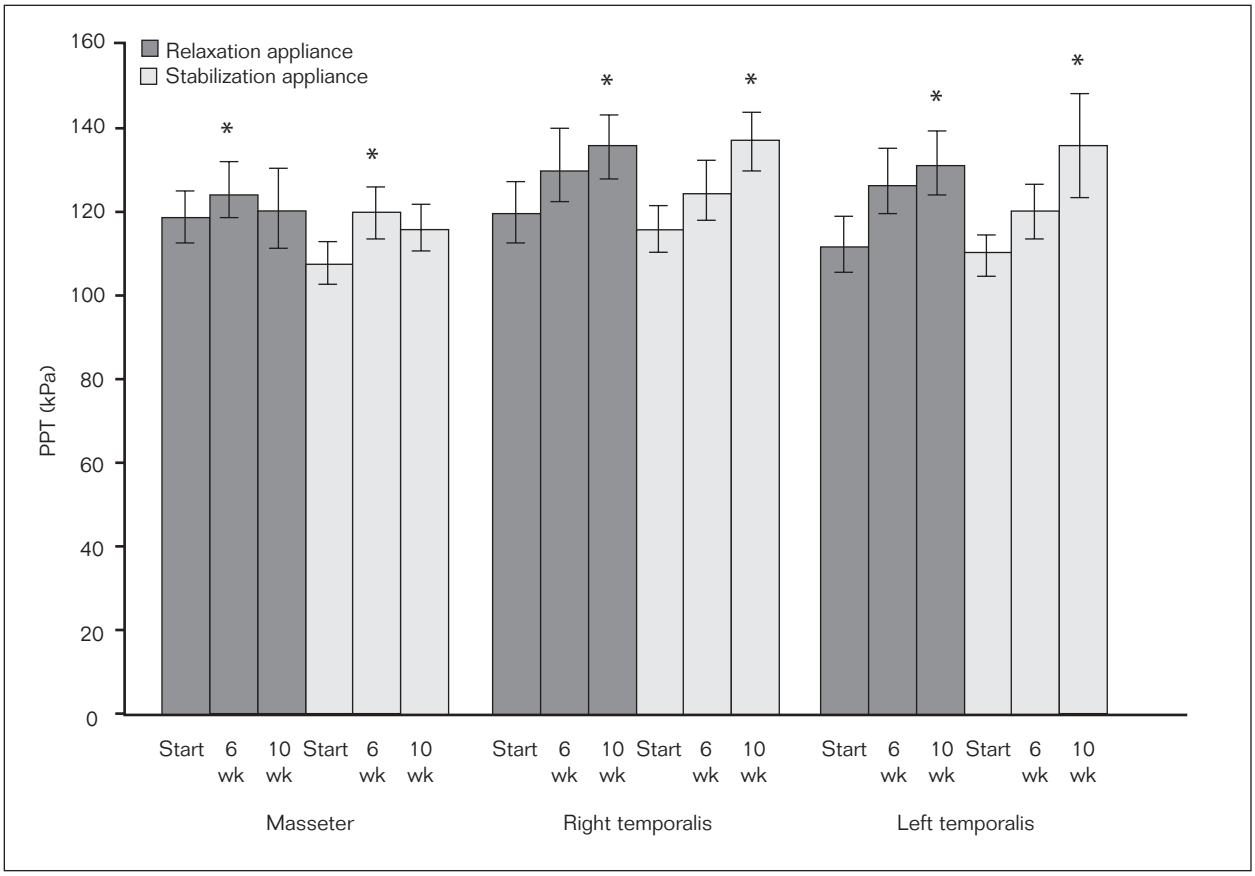

Fig 6 Algometer registration (pressure pain threshold and SD in kPa) in both groups at baseline and at 6- and 10-week follow-ups. Wilcoxon signed rank test: $*P < .05$.

centages of 70% and 61%, respectively. According to the verbal scale, 85% of all patients reported themselves to be "better," "much better," or "symptom-free" at the 6-week follow-up, and 83% reported this at the 10-week follow-up.

At the 6-week follow-up, 94% of all patients reported that they used their appliances several nights a week or more; the percentage was the same for both groups. By 10 weeks, this had fallen to 84% in the R group and 81% in the S group (Table 5). At the 10-week follow-up, 13% in both groups used their appliance only when necessary.

Additional adjustment of the appliance was needed in the R group for 53% of the patients at 6 weeks and for 34% at 10 weeks. In the S group, 64% needed an adjustment at 6 weeks and 53% needed one at 10 weeks. These differences between the groups were not statistically significant. Severe wear was found in 1 appliance in the S group. Eighty percent of all appliances in both groups showed no wear at 6 or 10 weeks.

Within Groups. The registered pain (VAS) at rest and on movements (opening and chewing) had improved at both follow-up appointments, with statistical significance in both groups ($P < .05$) (Fig 5). No statistically significant difference was found regarding opening capacity within the groups at 6 and 10 weeks.

Statistically significant changes in the values of the algometer registrations were found. The differences found in both groups were on the right side of the masseter muscle at the 6-week follow-up ($P = .016$) and on both sides of the anterior temporal muscle at the 10-week follow-up ($P = .003$) (see Fig 6).

Discussion

The hypothesis that a similar treatment outcome could be achieved with the prefabricated occlusal appliance, Relax, and a stabilization appliance was confirmed in this RCT. There was no difference in treatment result between the groups regarding the outcome measures. The treatment outcomes in both groups were positive, and the outcome of patients

with myogenous pain was somewhat (10%) poorer than has earlier been reported in an RCT.[11] In the present study, the treatment was performed by a general practitioner, and in the earlier study it was performed by specialists. Differences in treatment outcomes between specialists and general practitioners are one reason for carrying out an effectiveness study.

The prefabricated occlusal appliance, Relax, has an occlusal plane similar to that of the so-called relaxation splint. The relaxation splint is an interocclusal appliance introduced in Sweden in the 1960s, a modification of the Hawley plate. The splint has a front plateau that covers the edges of the incisors and canines, which allows occlusal contacts. In contrast to the stabilization appliance, the relaxation splint covers the palate and is retained by clasps. The prefabricated Relax appliance, which extends from canine to canine, is individually fitted with a silicon material and differs from the relaxation splint mainly in its smaller size and only partial coverage of the palate.

Few clinical trials have studied the effect of the relaxation appliance. Dahlström and Haraldson[23,24] reported that the clinical signs of TMD patients improved significantly in a stabilization splint group compared to a relaxation splint group after 6 weeks. Siegert and Gundlach[25] found that the stabilization appliance gave better relief of TMD signs and symptoms compared to the relaxation splint. The stabilization appliance in that study was made in the mandible and the patients were advised to use their appliances as much as possible except when eating, whereas in the studies by Dahlström and Haraldson,[23,24] the appliances were used only at night. Since the relaxation splint and the Relax appliance differ in their design, the results are not directly comparable. In addition, the studies by Dahlström and Haraldson[23,24] and Siegert and Gundlach[25] did not fulfill rigid requirements on blinding, and too few individuals were studied.

Recently, a new splint design was introduced, the NTI appliance. The NTI appliance covers the maxillary incisors and allows point contact with the mandibular incisors. The appliance is adjusted to prevent contact of the canines during lateral excursions and is claimed to reduce tooth clenching and grinding through a "nociceptive trigeminal inhibition tension suppression system."[17] The proposed mechanism of action of the NTI appliance would be that overloading of the periodontal ligament of the mandibular incisors will cause activation of nociceptive afferents which, by means of reflex pathways, will inhibit the jaw-closing muscles.[17] The hypothesis that decreased electromyographic (EMG) activity is related to an improvement in TMD pain problems was recently tested.[26] The results showed a strong inhibitory effect on EMG activity in jaw-closing muscles during sleep of the NTI appliance but not of a stabilization appliance. A similar decrease in EMG activity can be hypothesized with the use of Relax. Jokstad et al[18] showed that the efficacy of the NTI appliance was the same as that of a stabilization appliance. On the other hand, Magnusson et al[19] found in their study, which compared the NTI appliance to a stabilization appliance, that all the examined variables (reported symptoms, frequency of symptoms, change in use of analgesics, and change in clinical signs of TMD) were in favor of the stabilization appliance. The results are difficult to compare, since the study of Magnusson et al was a pilot study with 30 participants and did not include statistical analyses. The present results are in accordance with those of Jokstad et al.[18] However, this study is not fully comparable with the 2 discussed here, since the design of the Relax appliance differs from that of the NTI appliance.

The present study design does not address the specific effect of the occlusal appliances, which to date is not known.[5,6,27] Several factors potentially influenced by stabilization appliance therapy have been suggested, for example, alteration of the occlusal condition, increased vertical dimension, cognitive awareness, or an increase of peripheral input to the central nervous system. Similar factors could also apply to the effect of the Relax appliance. An improvement in symptoms and signs after treatment may also be attributed to regression to the mean, natural fluctuation, or the placebo effect.[28] Several studies have shown a better treatment outcome with a stabilization appliance compared to a control appliance that covers only the palate, both in the short term and in the long term.[9–12] Raphael and Marbach[29] concluded that "the majority of the best-designed research studies do not support the efficacy of intraoral appliances" and "intraoral appliances do not reduce pain intensity." However, Dao and Lavigne[27] drew contradictory conclusions from essentially the same data and stated that "the results of controlled clinical trials lend support to the effectiveness of the stabilization appliance in the control of myofascial pain." A recent review[3] concluded that the use of occlusal appliances in managing localized masticatory myalgia, arthralgia, or both is sufficiently supported by evidence in the literature. The authors suggested that occlusal appliances, when used for TMD, work as behavioral interventions and not as medical devices that

produce effects via physical changes in the position of the mandible.

Interesting results regarding the efficacy of splint therapy have recently been published by Truelove et al.[30] In that study, 200 subjects diagnosed with TMD were randomized into 3 groups: the first group was treated with conservative, dentist-prescribed self-care (jaw relaxation, reduction of parafunction, thermal packs, nonsteroidal anti-inflammatory drugs, passive opening stretches, and suggestions about stress reduction) without any intraoral appliance, whereas the other 2 groups included either a conventional flat-plane hard acrylic splint or a soft vinyl splint (low-cost athletic mouth guard), in addition to the other treatment measures in their treatment regimen. The authors concluded that the traditional splint therapy offered no benefit over the soft vinyl splint therapy, and also that neither splint therapy provided any greater benefit over self-care treatment without splint therapy. The self-care treatment, however, was extensive and included several treatment modalities. Because a treatment regime has been found to give better results than single treatments[31] in treating TMD signs and symptoms, the lack of difference between the groups was not surprising.

Pressure algometry has been found to have acceptable intraobserver and interobserver reliability in quantifying tenderness to palpation.[32] The assessments in this study were made with linearly increasing pressure and with duplicate recordings, which have been found to give a more reliable result than single recordings.[33,34] The present study showed similar PPT values at baseline versus those found in patients with local myalgia.[35] The PPT values in the present study increased in the same way in both groups, indicating similar improvements in PPT.

The Relax appliance is an easy means of providing a patient with an occlusal appliance. A single clinical visit is required, and there are no laboratory costs. It was the experience of the general practitioners in our effectiveness study that the Relax appliance was easier to adjust for the patient (and the need for adjustments was decreased compared to the stabilization appliance). To prevent appliance-induced malocclusion, the Relax appliance is not recommended for patients with open bite, and it should be used only at night.

It is concluded that from a short-term perspective, the prefabricated occlusal appliance Relax seems to be as effective as the stabilization appliance, and it can therefore be recommended for nighttime use as a short-term treatment modality in adult patients with myofascial pain. The true treatment outcome cannot be assessed after only 10 weeks, but the effectiveness of the Relax appliance will be followed and evaluated in a long-term study.

References

1. Glass EG, McGlynn FD, Glaros AG. A survey of treatments for myofascial pain dysfunction. Cranio 1991;9:165–168.
2. Glass EG, Glaros AG, McGlynn FD. Myofascial pain dysfunction: Treatments used by ADA members. Cranio 1993;11:25–29.
3. Kreiner M, Betancor E, Clark GT. Occlusal stabilization appliances: Evidence of their efficacy. J Am Dent Assoc 2001;132:770–777.
4. Forssell H, Kalso E, Koskela P, Vehmanen R, Puukka P, Alanen P. Occlusal treatments in temporomandibular disorders: A qualitative systematic review of randomized controlled trials. Pain 1999;83:549–560.
5. Forssell H, Kalso E. Application of principles of evidence-based medicine to occlusal treatment of temporomandibular disorders: Are there lessons to be learned? J Orofac Pain 2004;18:9–22.
6. Al-Ani MZ, Davies SJ, Gray RJM, Sloan P, Glenny AM. Stabilisation splint therapy for temporomandibular pain dysfunction syndrome [review]. Cochrane Database Syst Rev 2004;1:CD002778.
7. Türp JC, Komine F, Hugger A. Efficacy of stabilization splints for the management of patients with masticatory muscle pain: A qualitative systematic review. Clin Oral Invest 2004;8:179–195.
8. Dao TT, Lavigne GJ, Charbonneau A, Feine JS, Lund JP. The efficacy of oral splints in the treatment of myofascial pain in the jaw muscles: A controlled clinical trial. Pain 1994;56:85–94.
9. Ekberg EC, Vallon D, Nilner M. Occlusal appliance therapy in patients with temporomandibular disorders. A double-blind controlled study in a short-term perspective. Acta Odontol Scand 1998;56:122–128.
10. Ekberg EC, Nilner M. A 6- and 12-month follow-up of appliance therapy in TMD patients: A follow-up of a controlled trial. Int J Prosthodont 2002;15:564–570.
11. Ekberg EC, Vallon D, Nilner M. The efficacy of appliance therapy in patients with temporomandibular disorders of mainly myogenous origin. A randomised, controlled, short-term trial. J Orofac Pain 2003;17:133–139.
12. Ekberg EC, Nilner M. Treatment outcome of appliance therapy in temporomandibular disorder patients with myofascial pain after 6 and 12 months. Acta Odontol Scand 2004;62:343–349.
13. Lindfors E, Magnusson T, Tegelberg Å. Treatment with interocclusal appliances. Swed Dent J 2006;30:123–134.
14. Von Korff M, Dworkin SF, Le Resche L, Kruger A. An epidemiologic comparison of pain complaints. Pain 1988 Feb;32(2):173–183.
15. Lipton JA, Ship J, Larach-Robinson D. Estimated prevalence and distribution of reported orofacial pain in the United States. J Am Dent Assoc 1993;124:115–121.
16. Dworkin SF, LeResche L. Research Diagnostic Criteria for Temporomandibular Disorders: Review, Criteria, Examinations and Specifications, Critique. J Craniomandib Disord 1992;6:300–354.
17. Shankland WE II. Migraine and tension-type headache reduction through pericranial muscular suppression: A preliminary report. Cranio 2001 Oct;19(4):269–278.

18. Jokstad A, Mo A, Krogstad BS. Clinical comparison between two different splint designs for temporomandibular disorder therapy. Acta Odontol Scand 2005;63: 218–226.
19. Magnusson T, Adiels AM, Nilsson HL, Helkimo M. Treatment effect on signs and symptoms of temporomandibular disorders—Comparison between stabilisation splint and a new type of splint (NTI). A pilot study. Swed Dent J 2004;28:11–20.
20. Svensson P, Arendt-Nielsen L, Nielsen H, Larsen JK. Effect of chronic and experimental jaw muscle pain on pain-pressure thresholds and stimulus-response curves. J Orofac Pain 1995;9:347–356.
21. Seymor RA, Simpson JM, Charlton JE, Phillips ME. An evaluation of length and endphase of visual analogue scales in dental pain. Pain 1985;21:177–185.
22. Farrar J, Young J Jr, LaMoreaux L, Werth J, Poole RM. Clinical importance of changes in a chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94:149–158.
23. Dahlström L, Haraldson T. Immediate electromyographic response in masseter and temporal muscles to bite plates and stabilization splints. Scand J Dent Res 1989;97: 533–538.
24. Dahlström L, Haraldson T. Biteplates and stabilization splints in craniomandibular dysfunction. A clinical and electromyographic comparison. Acta Odontol Scand 1985;43:109–114.
25. Siegert R, Gundlach KKH. Stabilisationsschiene versus Entspannungsbehelf zur Behandlung myofazialer Schmerzen. Dtsch Zahnärztl Z 1989;44:17–19.
26. Baad-Hansen L, Jadidi F, Castrillon E, Thomsen PB, Svensson P. Effect of nociceptive trigeminal inhibitory splint on electromyographic activity in jaw closing muscles during sleep. J Oral Rehabil 2007;34:105–111.
27. Dao TTT, Lavigne GJ. Oral splints: The crutches for temporomandibular disorders and bruxism? Crit Rev Oral Biol Med 1998;9:345–361.
28. Greene SG, Laskin ML. Splint therapy for the myofascial pain-dysfunction (MPD) syndrome: A comparative study. J Am Dent Assoc 1972;84:624–628.
29. Raphael K, Marbach JJ. Evidence-based care of musculoskeletal facial pain. Implications for the clinical science of dentistry. J Am Dent Assoc 1997;128:73–79.
30. Truelove E, Hanson-Huggins K, Mancl L, Dworkin S. The efficacy of traditional, low-cost and nonsplint therapies for temporomandibular disorder. J Am Dent Assoc 2006;137:1099–1107.
31. Feine JS, Lund JP. An assessment of the efficacy of physical therapy and physical modalities for the control of chronic musculoskeletal pain. Pain 1997 May;71:5–23.
32. Jensen K. Quantification of tenderness by palpation and use of pressure algometers. In: Friction JR, Awad E (eds). Advances in Pain Research and Therapy, vol 17: Myofascial pain and fibromyalgia. New York: Raven Press, 1990:165–181.
33. Ohrbach R, Gale EN. Pressure pain thresholds in normal muscles: Reliability, measurement effects and topographic differences. Pain 1989;37:257–263.
34. Isselée H, De Laat A, Lesaffre E, Lysens R. Short-term reproducibility of pressure pain thresholds in masseter and temporalis muscles of symptom-free subjects. Eur J Oral Sci 1997;105:583–587.
35. Ernberg H, Hedenberg-Magnusson B, Alstergren P, Kopp S. Pain, allodynia, and serum serotonin level in orofacial pain of muscular origin. J Orofac Pain 1999;13:56–62.