Effectiveness of a Prefabricated Occlusal Appliance in Patients with Temporomandibular Joint Pain: A Randomized Controlled Multicenter Study

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Aims: To evaluate the effectiveness of a prefabricated appliance and compare it to the effectiveness of a stabilization appliance in patients with temporomandibular joint (TMJ) pain. **Methods:** This randomized, controlled multicenter study comprised 48 patients diagnosed with TMJ arthralgia according to the Research Diagnostic Criteria for Temporomandibular Disorders. The effectiveness of a prefabricated appliance (Relax), worn by half of the patients (referred to as the R group), was compared to the effectiveness of a stabilization appliance, worn by the other half of patients (S group). Treatment outcome was assessed according to the recommendations by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) on an intent-to-treat basis. To analyze the differences between groups, the chi-square test and the Mann-Whitney *U* test were used, while the Friedman analysis of variance (ANOVA) on ranks was used for the analyses between baseline data and follow-up measurements, all with a significance level set at $P < .05$. **Results:** There were no differences between the groups at baseline. A 30% reduction of pain intensity was reported by 62.5% of the R group and 58.3% of the S group at the 10-week follow-up; 58% and 50.3%, respectively, at the 6-month follow-up; and 41.7% in both groups at 12 months. At the 12-month follow-up, pain intensity had decreased and physical function had improved in both groups ($P < .005$ and $P < .016$, respectively), without significant group differences. Emotional function (depression and nonspecific physical symptoms) did not change. Overall improvement of "better" to "symptom-free" was observed in 67% of the R group and 58% of the S group. No side effects occurred. **Conclusion:** The effectiveness of the prefabricated appliance seems to be similar to that of the stabilization appliance in alleviating TMJ pain. Since the prefabricated appliance requires only one visit for construction, it is convenient for both the general practitioner and for the patient. *J Oral Facial Pain Headache 2014;28:128–137. doi: 10.11607/ofph.1216*

Key words: *arthralgia, headache, long-term follow-up, occlusal appliance, temporomandibular disorders*

Conditions affecting the temporomandibular joint (TMJ) or the masticatory muscles and associated structures, such as teeth, ears, cheeks, and forehead, are often collectively referred to as temporomandibular disorders (TMD). These conditions are usually described as a sensation of a dull, steady pain overlying the TMJs and muscles.[1] TMD pain is frequently accompanied by restricted mouth opening capacity, pain upon chewing, muscle soreness, and headache.

The prevalence of TMD has been reported to be approximately 10% to 15% of the adult population[2–5] and 1.5 to 2 times higher among women than men.[6,7] The latter is in concordance with other orofacial conditions, such as trigeminal neuralgia, burning mouth syndrome, and atypical odontalgia.[8–11]

Pain is a subjective unpleasant experience.[12] However, the impact of chronic pain involves not only an unpleasant sensory experience, but also an emotional one in which feelings of failure, misery, guilt, alienation, and even depression may occur.[13,14] This may explain why psychological suffering, impaired social relations, chronic fatigue syndrome, and recurrent sick leave frequently accompany TMJ pain. Subsequently, this may lead to frequent use of health care, analgesics,[15,16] and, hence, to a decreased quality of life.[14,17–19]

Patients suffering from TMD experience pain and tenderness in the joint capsule and/or the synovial lining of the TMJ as well as pain in the joint during maximum unassisted opening, during assisted opening, or during jaw movement. In a recent study, approximately 16% of the adult population (22% of women and 10% of men) reported pain from the TMJ during the last month.[20] When subgroups of consecutive TMD patients were examined, approximately 67% to 86% of the patients with arthralgia also suffered from myalgia.[21–23]

Occlusal appliances are commonly used in the treatment of TMD, and their use in managing TMD pain conditions is supported by evidence in the literature.[24–27] For many years, the stabilization appliance has been the main appliance recommended for the treatment of TMD pain. However, most of the previous studies have been efficacy studies performed at specialty clinics by dentists with a high degree of experience and competence, ie, conducted under ideal conditions. In general practice, a more varied degree of competence in managing TMD pain can be expected. Therefore, there is a need for effectiveness studies to measure the degree of beneficial effect of treatment provided in general practice, ie, not under ideal conditions.[28] Hence, it is of interest to find easier procedures that can be used by general practitioners for fabricating an appliance with effectiveness sustainable in the long term. Previous studies from the authors' group have compared the effectiveness of a prefabricated occlusal appliance with the traditional stabilization appliance in myofascial pain and headache. The effectiveness of the prefabricated appliance seemed to be similar to that of the stabilization appliance both in short-term and long-term evaluation.[29–31] However, the effectiveness of the prefabricated appliance on TMJ pain has not been evaluated.

Consequently, the aim of this study was to evaluate the effectiveness of a prefabricated appliance and to compare it with the effectiveness of the stabilization appliance in patients with TMJ pain. The null hypothesis was that the treatment outcome of the prefabricated appliance would not differ from that of the stabilization appliance regarding the outcome domains recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).

Materials and Methods

Study Design

This randomized, controlled trial (RCT) was conducted from October 2008 to December 2011 as a multicenter study. The three participating centers were the Department of Orofacial Pain and Jaw Function, Faculty of Odontology, Malmö University, Sweden; the Section of Orofacial Pain and Jaw Function, Department of Dental Medicine, Karolinska Institutet, Sweden; and the Department of Stomatognathic Physiology, Institute of Dentistry, Faculty of Medicine, University of Turku, Finland. The methods and selection of participants were approved by the regional ethical review boards in Lund, Sweden (452/2008) and in Turku, Finland (17.12.2007 §425). The study followed the guidelines of the Declaration of Helsinki, and all participants gave their written consent.

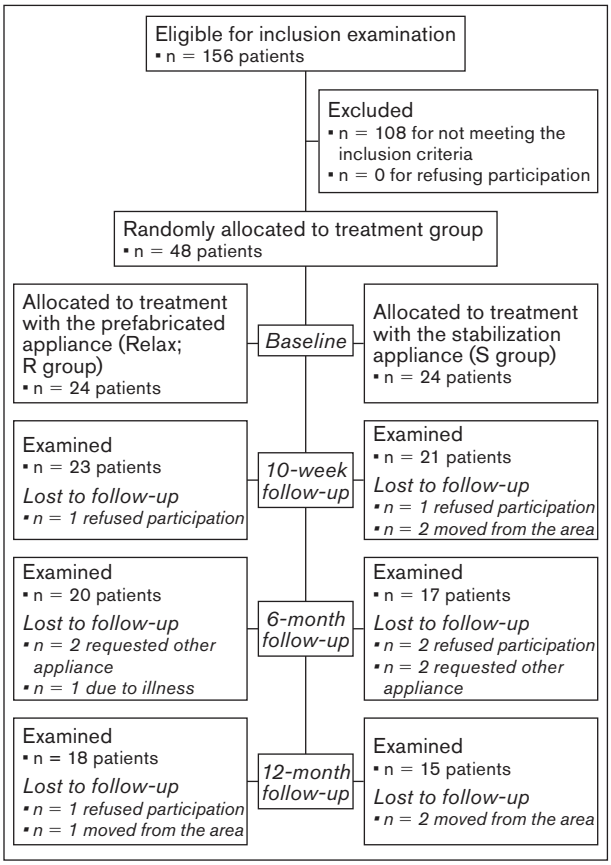


Fig 1 Flowchart of the selection of participants from the patients referred for treatment of TMD.

Patients

Based on the information given on 1,274 referrals for TMD, 156 patients with a main complaint of TMJ pain were subjected to a screening (see next page). Forty-eight patients, 16 at each center (45 women and 3 men) were found eligible and were included in this study; none declined participation (Fig 1). According to the power calculation, inclusion of 22 patients in each group would be sufficient to detect a statistically significant difference of 30% between interventions at a significance level of 5% with a power of 90%. In order to compensate for dropouts, two additional patients were included in each group.

The inclusion criteria for the patients were: age ≥ 18 years; a diagnosis of arthralgia or osteoarthritis of the TMJ according to the Research Diagnostic Criteria for TMD (RDC/TMD)[32]; self-assessed worst TMJ pain during the last 6 months of at least 4 on a 0 to 10 graded numeric rating scale (NRS); and duration of pain ≥ 3 months. The included patients had one or several co-diagnoses of: myofascial pain with or without limited opening; disc displacement with or without reduction; osteoarthrosis in the contralateral TMJ; and episodic or chronic tension-type headache.

The exclusion criteria for the patients were: presence of complete dentures; neuropathic pain or neurologic disorders (eg, myasthenia gravis, orofacial dystonia); pain of dental origin; whiplash-associated disorder; diagnosed systemic muscular or joint diseases (eg, rheumatoid arthritis, fibromyalgia); history of psychiatric disorders; severe malocclusions as well as frontal open bite from canine to canine; periodontal problems; and previous treatment with an occlusal appliance.

Study Protocol

The study comprised six visits: *(1)* screening for study participation and alginate impressions; *(2)* delivery of appliance; *(3)* first check of the delivered appliance after 2 weeks; *(4)* follow-up at 10 weeks; *(5)* follow-up at 6 months; and *(6)* follow-up at 12 months.

The screening (baseline) included a questionnaire that comprised a general health questionnaire, the RDC/TMD Axis II questionnaire, and a 1-week pain diary (described below in section on "Pain intensity"). The questionnaire was sent to the patient at least 1 week before the screening examination, and the patient was instructed to bring the completed questionnaire to the screening visit. No patient forgot to bring the completed questionnaire. In addition, a clinical examination according to the RDC/TMD Axis I was performed, which also included registration of the occlusion as well as vertical and horizontal overbite. Finally, a panoramic radiograph was taken to exclude pain of dental origin. No patients were excluded for odontogenic reasons.

The follow-ups included a questionnaire that also comprised the 1-week pain diary that was completed by the patient beforehand and handed over at the visit. In addition, the follow-ups included registration of occlusion, vertical and horizontal overbite, unassisted mouth opening, wear of the appliance, and use and adverse events of the appliance.

An orofacial pain specialist (Dentist A) at each center performed the clinical examinations, took impressions, and retrieved the questionnaires. All three Dentists A were calibrated in the RDC/TMD examination technique to a gold standard examiner (ECE) in the course of a day. At each center, one general practitioner (Dentist B), not involved in the examinations, adjusted and delivered the appliances and evaluated their use and wear. All three Dentists B were instructed and trained for a day to handle the appliances in the same manner.

Dentists A were blinded to group assignment, and the patients as well as Dentists B were instructed not to reveal to Dentists A the type of appliance that they had been using. The type of appliance was not revealed to any Dentists A during the entire study, since impressions were taken for all patients and Dentists A and B never met the patients together.

Randomization

Each patient was randomized to receive either the prefabricated appliance (Relax, Unident), consequently referred to as the R group, or a stabilization appliance, referred to as the S group. For each center, 16 consecutively numbered, opaque, sealed envelopes containing a note with the treatment (8 for each treatment) were made and placed in a larger envelope. For each patient, an independent person at each center randomly drew an envelope and handed it to Dentist B. This was repeated until 16 patients at each center were included.[29]

Treatment

Prefabricated Appliance. The prefabricated appliance covers the edges of the incisors and canines and has a palatal extension of approximately 1 cm. A single visit to the dentist is required and no dental technician has to be involved. The frontal plateau of the Relax appliance allows occlusal contacts. The prefabricated appliance (polymethylmetacrylate) was individually fitted with a self-curing silicone material (polyvinyl siloxane) and was adjusted to achieve stable occlusal contacts in centric relation. The lateral articulation was on the canines or the frontal group, while the jaw protrusion was achieved with bilateral, symmetric contacts.

Stabilization Appliance. The stabilization appliance (methylmetacrylate) had a flat, smooth surface against the opposing teeth and was adjusted to achieve stable occlusal contacts in centric relation. The lateral articulation was on the canines or the frontal group, while the jaw protrusion was achieved with bilateral, symmetric contacts on the canines or the frontal group. Mediotrusive contacts were eliminated. This appliance requires at least two visits to the dentist and also the involvement of a dental technician for fabrication.

The patients were instructed to wear the appliance every night for the first 10 weeks and thereafter when needed. Use (0 = every night; 1 = several nights a week; 2 = when necessary; 3 = not at all) and wear (0 = no; 1 = slight; 2 = moderate; 3 = severe) were checked within 2 weeks and again at the 10-week,

6-month, and 12-month follow-ups by Dentist B. The appliances were adjusted when needed at every follow up by Dentist B.

Treatment Outcome Measures

The IMMPACT recommends six core domains to be evaluated in RCTs: participant disposition, pain intensity, physical functioning, emotional functioning, participant ratings of overall improvement, and adverse events.[33,34] The change in weekly pain intensity (see below) from baseline was the primary outcome measure. The other domains recommended by IMMPACT served as secondary outcome measures.

Pain Intensity. A 1-week pain diary was used for daily assessment of pain at jaw opening. This comprised seven visual analog scales (VAS), 0 to 100 mm, with the endpoints marked "no pain" (0) and "unbearable pain" (100). The patients were instructed to assess the pain intensity every evening during the week preceding each visit (screening and follow-ups). For each patient, the average pain intensity during the week (mean of 7 days) was calculated and used for the statistical analyses (hereafter called weekly pain intensity). Several repeated assessments have been shown to be a more valid measure of pain intensity than a single assessment.[35] A 30% pain reduction was used, as recommended by IMMPACT,[34] and considered clinically significant.[36]

Physical Functioning. Physical functioning was classified using the Graded Chronic Pain Scale (GCPS),[15] which is included in the RDC/TMD Axis II questionnaire.[32] The severity scale is divided into two parts, one assessing pain intensity and the other assessing limitations in physical functioning due to pain. For physical functioning, a disability score (DP 0 to 6) is calculated and combined with the pain intensity score (0 to 100) and graded as follows: grade 0 = no TMD pain in the previous 6 months; grade I = low disability ($<$ 3 DP) and low-intensity pain ($<$ 50); grade II = low disability ($<$ 3 DP) and high-intensity pain ($>$ 50); grade III = high disability and moderately limiting (3 to 4 DP regardless of pain intensity); grade IV = high disability and severely limiting (5 to 6 DP regardless of pain intensity).

Limitation in jaw function was assessed over time with the Jaw Function Limitation Scale (JFLS-20),[37] which replaced the Jaw Disability Checklist in the RDC/TMD Axis II questionnaire.[32] The JFLS-20, consisting of three constructs (mastication, vertical jaw mobility, and emotional expression), is determined by 20 questions recorded on a numeric rating scale rated from 0 to 10 (0 = no limitation and 10 = maximal limitation) and reported as summary scale scores.

In addition, the maximum voluntary mouth-opening capacity including the vertical overbite was assessed in millimeters with a ruler.

Emotional Functioning. The changes in emotional functioning, ie, depression and nonspecific physical symptoms (NSPhS), were assessed using the modified Symptom Checklist-90-Revised (SCL-90-R) instrument in the RDC/TMD Axis II questionnaire.[32] This includes 20 questions indicating depression and 12 questions indicating NSPhS. The total score was calculated (0 to 4). The presence of depression was classified as normal ($<$ 0.535), moderate (0.535 to 1.105), or severe ($>$ 1.105), while the classification for NSPhS was normal ($<$ 0.5), moderate (0.5-1), or severe ($>$ 1).[32]

Overall Improvement. The overall improvement was assessed by the patient on a 6-point rating scale: 0 = symptom-free; 1 = much better; 2 = better; 3 = unchanged; 4 = worse; 5 = much worse.

Adverse Events. To estimate any adverse events, the number of tooth contacts in centric occlusion and vertical overbite (mm) was assessed. In addition, checks were made of changes in tooth sensitivity and/or of the presence of occlusal trauma in the mandibular anterior teeth, since the prefabricated appliance only covers the edges of the incisors and canines in the maxilla.

Statistical Analyses

The statistical analyses were performed using SigmaPlot software version 11.0 (Systat software Inc).

For analyses of differences between groups in the distribution of variables on a nominal scale, the χ^2 test was used, while the Mann-Whitney *U* test was used for analyses of group differences for variables on an ordinal scale. The Friedman´s analysis of variance (ANOVA) on ranks with Dunn´s test as a post-hoc test was used for analyses of changes between baseline data and follow-up measurements. Since three different centers took part in the study, the effect of "place of treatment" was also analyzed. The significance level was set at $P < .05$.

Results

There were no significant differences between the three centers for any of the study outcomes, and hence the results are presented for the entire group.

The demographic data are shown in Table 1. No differences were found between the groups regarding any demographic data, such as sex, age, ethnic origin, marital status, and highest level of education.

Pain variables and awareness of clenching/grinding retrieved from the RDC/TMD Axis II questionnaire at baseline are presented in Table 2. There were no significant differences between the groups. All patients in both groups reported mild to moderate tenderness to digital palpation of the TMJ.

Table 1 Demographic Data of 48 Patients with TMJ Pain Before Treatment with a Prefabricated Appliance (R)* or Stabilization Appliance (S)

	R (n = 24)	S (n = 24)
Sex		
Female	23	22
Male	1	2
Age (y)		
Mean	40	41
Median	39	41
Range	21–71	19–73
< 20 y	0	1
20–40 y	13	11
> 40 y	11	12
Ethnic origin		
Scandinavia	21	19
Other European countries	0	3
Asia	3	1
Africa	0	1
Marital status		
Never married	4	7
Married	17	15
Divorced	3	2
Highest level of education		
Elementary school	5	3
High school	7	9
College	12	12

*Relax appliance.

Table 2 Pain Variables and Awareness of Parafunctions, Retrieved from the RDC/TMD Axis II Questionnaire in 48 Patients with TMJ Pain Before Treatment with a Prefabricated Appliance (R)* or Stabilization Appliance (S)

	R (n = 24)	S (n = 24)
Duration of TMJ pain (mo)		
Mean (SD)	40 (53)	57 (76)
Median (IQR)	12 (46)	24 (47)
Range	3–180	5–240
3–6 mo	4	3
≥ 6 mo	20	21
Frequency of TMJ pain		
Recurrent	17	10
Persistent	7	14
Current TMJ pain intensity (NRS 0–10)†		
Mean (SD)	4.2 (2.3)	5.1 (1.5)
Median (IQR)	4.5 (2.0)	5.0 (2.0)
Worst TMJ pain intensity last 6 mo (NRS 0–10)†		
Mean (SD)	7.8 (1.7)	7.2 (2.0)
Median (IQR)	7.5 (2.5)	8.0 (2.0)
Average TMJ pain intensity last 6 mo (NRS 0–10)†		
Mean (SD)	5.8 (1.6)	6.1 (1.2)
Median (IQR)	6.0 (2.5)	6.0 (2.0)
Awareness of clenching/grinding		
Daytime	1	1
Nighttime	3	5
Both daytime and nighttime	11	12

*Relax appliance.
†Retrieved from the Graded Chronic Pain Scale.
SD = standard deviation; IQR = interquartile range (75th percentile minus 25th percentile); NRS = numeric rating scale.

Table 3 presents the diagnoses of the patients. All patients had a diagnosis of arthralgia in one or in both of the TMJs. Sixty-seven percent of the patients also had a diagnosis of myofascial pain.

Analyses of the dropouts revealed no differences in TMJ pain, physical functioning, emotional functioning, or demographic data compared to the patients who completed the study.

After Treatment

Primary Treatment Outcome. The median weekly pain intensities are shown in Fig 2. The pain intensity decreased significantly with time in both groups (Friedman test; $P < .005$), but there were no significant differences between groups at any time point.

At the 10-week follow-up, 62.5% of the patients in the R group and 58.3% in the S group reported a 30% reduction in weekly pain intensity (intent-to-treat analysis). At the 6-month follow-up, the corresponding frequencies were 58.3% and 50%, respectively, and at the 12-month follow-up they were 41.7% in both groups. None of these figures differed significantly between groups.

Secondary Treatment Outcomes. *Physical Functioning.* There were no differences in GCPS severity between the two groups at baseline. There was a significant change to a lower-severity grade in GCPS at the 10-week, 6-month, and 12-month follow-ups, both in the R group and the S group separately (Friedman test; $P < .001$), but there were no differences between the groups (Table 4).

There were no statistically significant differences at baseline between the groups concerning JFLS-20 scores. A statistically significant decrease in limitation scores in all three constructs of JFLS-20 (ie, mastication, vertical jaw mobility, and emotional expression) was observed with time in both groups (Friedman test; $P < .001$), but there were no differences between the groups (Table 4).

The maximum unassisted mouth opening increased with time in both groups (Friedman test; R group $P < .016$ and S group $P < .001$). There were no significant differences between the groups at any time point (Table 4).

Emotional Functioning. At baseline, most patients had severe scores for depression and moderate to severe scores for NSPhS. Neither the scores for depression nor for NSPhS changed significantly with time, although the NSPhS score tended to decrease with time in the S group (Friedman test; $P = .053$). None of the scores differed significantly between the groups at baseline or at any follow-up (Fig 3).

Overall Improvement. At the 10-week follow-up, intention-to-treat analysis showed that 58% of the patients in the R group reported to be "better," "much better," or "symptom-free." The corresponding

Table 3 Diagnoses According to RDC/TMD in 48 Patients with TMJ Pain Before Treatment with a Prefabricated Appliance (R)* or Stabilization Appliance (S)

	R (n = 24)	S (n = 24)
Arthralgia (IIIa)		
One side	13	9
Both sides	9	13
Osteoarthritis (IIIb)		
One side	2	2
Both sides	0	0
Myofascial pain	15	16
Disc displacement with reduction (IIa)		
One side	5	5
Both sides	1	0
Disc displacement without reduction (IIb) with limited opening		
One side	1	3
Both sides	1	2

*Relax appliance.
RDC/TMD = Research Diagnostic Criteria for Temporomandibular Disorders.

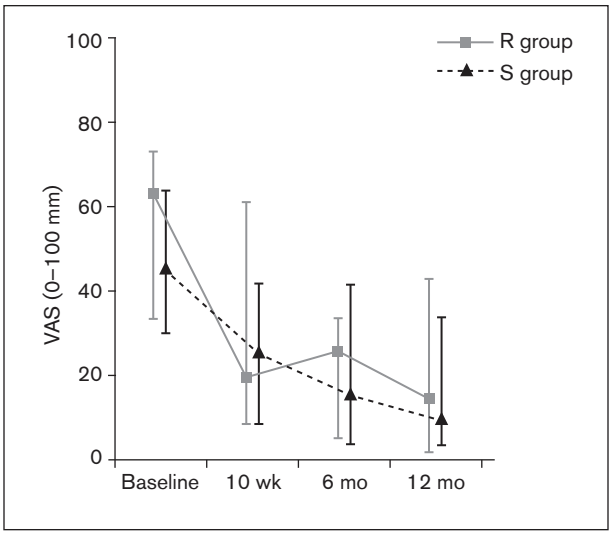


Fig 2 Median (IQR; interquartile range) differences in average weekly pain intensity at the 10-week as well as at the 6- and 12-month follow-ups (0–100 mm visual analog scale) during jaw opening compared with baseline are shown for both the group treated with the prefabricated appliance Relax (R group) and the group treated with a stabilization appliance (S group). The decrease in pain intensity was significant for both groups at all follow-up visits. (Significant difference compared to baseline [Dunn's test; $P < .05$].) There were no significant differences between the groups at any follow-up.

Table 4 Distribution of Physical Functioning Assessed with the Graded Chronic Pain Scale (GCPS) and Median (IQR) Limitation in Jaw Function Assessed with the Jaw Function Limitation Scale (JFLS) and as Maximum Unassisted Mouth Opening (MUMO) Before (Baseline) and 6 and 12 Months After Treatment with a Prefabricated Appliance (R)* or Stabilization Appliance (S) in 48 Patients with TMJ Pain

	Baseline		10 wk		6 mo		12 mo	
	R (n = 24)	S (n = 24)	R (n = 23)	S (n = 21)	R (n = 20)	S (n = 17)	R (n = 18)	S (n = 15)
GCPS								
Grade 0	0	0	0	0	0	0	2	2
Grade I	6	8	11	9	13	13	10	9
Grade II	11	12	10	9	3	3	3	4
Grade III	5	2	2	2	0	1	2	0
Grade IV	2	2	0	1	0	0	1	0
JFLS								
Mastication	21.5 (12.0)	16.5 (23.0)	9.0 (15.5)	4.5 (17.5)	1.5 (26.0)	3.0 (13.5)	2.5 (9.0)	0 (4.0)
Jaw mobility	10.5 (11.0)	12.0 (14.0)	12.0 (20.5)	3.5 (15.0)	1.0 (11.0)	1.5 (8.5)	1.0 (6.0)	0 (2.0)
Emotional	14.0 (28.0)	15.0 (28.5)	9.5 (31.5)	5.0 (18.0)	0.5 (13.5)	2.0 (9.0)	0.5 (12.0)	0 (4.0)
MUMO (mm)	46.0 (11.0)	42.0 (10.5)	48.5 (13.3)	39.0 (11.0)	50.5 (10.0)	49.5 (7.8)	51.0 (11.0)	50.0 (9.0)

*Relax appliance.
Grade 0 = no disability, Grade I = low disability and low intensity pain, Grade II = low disability and high intensity pain, Grade III = high disability and moderately limiting, Grade IV = high disability and severely limiting. There was a significant improvement in physical function for all variables at all follow-ups compared to baseline (Dunn's test; $P < .05$), except for MUMO at 10 weeks in the S group, but no significant difference between groups.

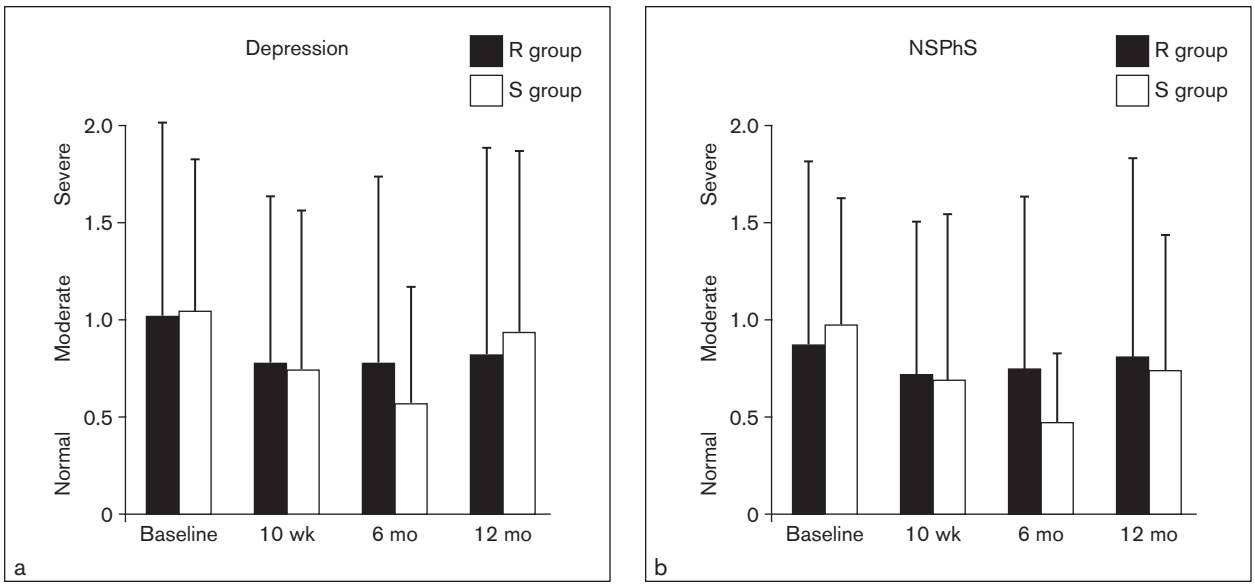
percentage in the S group was 71%. At the 6- and 12-month follow-ups, these results were 58% and 67%, respectively, in the R group, while in the S group they were 63% and 58%, respectively. There were no significant differences between groups (Table 5).

Adverse Events. No adverse events were reported. In the R group, the mean number of occlusal contacts was 17 at baseline and at the 10-week and 6-month follow-ups. At the 12-month follow-up, the mean number of occlusal contacts increased to 18. However,

Table 5 Overall Improvement of TMJ pain 10 Weeks, 6 Months, and 12 Months After Treatment with a Prefabricated Appliance (R)* or Stabilization Appliance (S) in 48 Patients with TMJ Pain

	10 wk		6 mo		12 mo	
Overall improvement	R (n = 23)	S (n = 21)	R (n = 20)	S (n = 17)	R (n = 18)	S (n = 15)
"No change" to "Worse"	9	4	6	2	2	1
"Better" to "Symptom-free"	14	17	14	15	16	14
"Better"	8	8	5	7	4	6
"Much better" or "Symptom-free"	6	9	9	8	12	8

*Relax appliance.
There were no significant differences between the groups at any follow-up..



Figs 3a and 3b Median differences in scores **(a)** for depression and **(b)** for nonspecific physical symptoms (NSPhS) compared with baseline are shown for both the group treated with the prefabricated appliance Relax (R group) and the group treated with a stabilization appliance (S group). Depression scores are classified as normal (< 0.535), moderate (0.535–1.105), and severe (> 1.105), and the NSPhS scores are classified as normal (< 0.5), moderate (0.5–1), and severe (> 1). There were no significant changes in depression score or in NSPhS. There were no differences between the groups at any time points.

this finding was related to one patient who had received fixed prosthodontics resulting in an increased number of occlusal contacts. In the S group, the mean number of occlusal contacts was 16 at baseline and at all follow-up visits. None of the patients' mandibular anterior teeth showed any sign of change in sensitivity or of occlusal trauma (eg, increased attrition, mobility, enamel fractures, etc) in any of the groups.

The mean vertical overbite did not change in any of the groups, and no patients presented a change in vertical overbite during the study period.

Additional Outcome Measures. *Use of Appliance.* At the 10-week follow-up, all patients reported that they used their appliance several nights per week or more. Compliance at the 6-month follow-up was 75% in both groups (intention-to-treat analysis). At the 12-month follow-up, the use of the appliance for several nights per week or more decreased to 60% in the R group and 69% in the S group. The remaining patients only used their appliance when needed. There were no significant differences in the frequency of use between the groups.

Adjustments and Wear. In the R group, additional adjustment of the appliance was needed for two of the patients after 10 weeks, for six patients after 6 months, and for three patients after 12 months. In the S group, eight of the patients needed adjustment after 10 weeks, one patient after 6 months, and three patients after 12 months. There was a significantly higher need of adjustment of the appliance in the R group after 6 months (Mann Whitney *U* test; $P = .035$), but no other differences were found between the groups. Only one appliance in each group showed signs of moderate wear at the 6- and 12-month follow-ups, and severe wear was only found in one appliance in the S group at the 12-month follow-up.

Discussion

The expected outcome of this study from testing the null hypothesis was that the effectiveness of the prefabricated appliance Relax did not differ from a stabilization appliance in patients with self-reported TMJ pain and a diagnosis of arthralgia. The pain intensity decreased both in the short term and long term in both groups, without differences between the groups. In both groups, a 30% pain reduction was achieved by approximately 60% of the patients (intention-to-treat analysis) at the 10-week follow-up and by almost 42% of the patients at the 12-month follow-up. Thus, the null hypothesis was accepted.

Previous results from both short- and long-term effectiveness studies of the prefabricated appliance Relax are in line with those of the present study. They showed that approximately 60% of the patients with myofascial pain and headache received a substantial pain reduction after 6 weeks and 12 months. They also showed that the effectiveness of the prefabricated appliance is similar to the stabilization appliance.[29–31] Further, in other studies investigating the effect of a stabilization appliance on TMJ pain, there was a reduction in TMJ pain in 50% of the patients both at short-term and long-term follow-ups,[38,39] which is also in line with the effect of the stabilization appliance found in the present study.

Very few studies have investigated appliances covering only the maxillary frontal teeth. These studies reported that stabilization appliances were superior to such appliances for decreasing TMD signs and symptoms[40] as well as for their effect on electromyographic activity in the healthy masseter and temporal muscles.[41] Also in another study on myofascial pain, the stabilization appliance was reported to be superior to an appliance covering only the maxillary frontal teeth for subjective pain relief and signs of TMD (Helkimo's Index).[42] The above-mentioned results are in contrast with the present study's results. However, this difference in results might be explained by several factors. The most important factor is that these previous studies do not fulfill the requirements described by Consolidated Standards of Reporting Trials (CONSORT).[43] In a recent systematic review, these earlier studies did not reach level 1 criteria, meaning that selection bias, measurement bias, and comparison group bias might have affected the outcome.[25] Further, the design of the appliance used in the present study differed from the earlier studies. The prefabricated appliance had no full palatal covering, extended from canine to canine, and was individually fitted in a silicone material, whereas the appliances used in the earlier studies covered the palate, were retained by clasps on the molars, and had a front plateau covering the edges from canine to canine. Other studies using an appliance covering only the central incisors reported contradictory results. In one study, the appliance covering only the central incisors had similar treatment effects as the stabilization appliance for reducing self-reported TMD-related pain and headache, as well as muscle tenderness upon palpation and improvement of jaw opening.[44] However, in another study, the stabilization appliance was reported superior to the appliance covering only the central incisors for influencing subjective signs and symptoms of TMD.[45]

The significant change to a lower GCPS severity grade in both groups at all follow-ups was not surprising, since similar results have been reported in previous studies—both in a study investigating the effectiveness of the prefabricated Relax appliance on myofascial pain[30] and in a study investigating the efficacy of different treatment modalities, such as dentist-prescribed self-care treatment or dentist-prescribed self-care treatment plus either a stabilization appliance or a soft vinyl splint.[46] Also, jaw functioning was significantly improved in both groups. On all three constructs of the JFLS-20, there was an improvement with significantly decreased scores, which also was reported by Doepel et al.[30]

Further, in spite of the pain relief, there was no change in any of the emotional functioning scores during any of the follow-ups in this study. This is in contrast to the authors' previous study of patients with myofascial TMD pain,[30] where the NSPhS and depression scores were significantly decreased. One explanation could be differences in the NSPhS and depression scores between the dropouts and the patients that remained in this study. However, the NSPhS and depression scores amongst the dropouts did not differ from those who completed this study. A more plausible explanation might be differences in the patient samples between the studies. On the other hand, the results from the present study are similar to a previous study that tested different types of treatment, including occlusal appliances and behavioral therapy, in which there was no change in any of the emotional functioning scores during any of the follow-ups.[47]

When using partial-coverage appliances, there is always a risk that occlusal changes might occur.[45] However, in concordance with the authors' previous study of patients with myofascial pain,[30] there was no change in either the number of occlusal contacts or in the vertical overbite in any of the groups, although almost two-thirds of the patients still used their appliances at the 12-month follow-up. This might be explained by differences in the design between the Relax appliance and other partial-coverage appliances covering only the central incisors.[45]

In both groups, 75% of the patients continued to use their appliance several nights per week or more at the 6-month follow-up. This is in line with the reported frequency of use in the authors' previous study comparing the short-term effect on myofascial pain (approximately 80% in both groups),[29] but slightly higher than a previous study focusing on headache, in which 59% of the patients in the R group and 41% in the S group continued to use their appliance after 6 months.[31] The frequency of use is also in line with other studies using both resilient[48] as well as stabilization appliances,[39,49,50] where approximately 50% to 70% of the patients continued to use their appliances several nights per week or more.

Effectiveness studies are important for the general practitioner due to their clinical relevance. However, all of the 44 RCT studies that Fricton and coworkers identified in a recent review article on occlusal appliances as treatment modalities for TMD were efficacy studies.[25] One of the strengths of the present study was its design, which adhered to the established and validated criteria by the Research Triangle Institute for designing effectiveness studies.[51] The study also followed the recommendations by IMMPACT and CONSORT; it was a randomized, controlled multicenter study with both calibrated and blinded examiners and calibrated general practitioners.

Some limitations of this study also need to be addressed. First, no natural history group to control for time effect was included. However, the main aim was not to evaluate the effectiveness of appliance therapy in general for patients with TMJ pain, but to compare the effectiveness of the prefabricated appliance with that of the stabilization appliance. Therefore, this study cannot answer any question about the specific effect of occlusal appliances, nor about the effect of occlusal appliances compared to behavior-modifying therapy or other treatment approaches. Another limitation is that two-thirds of the patients had a co-diagnosis of myofascial pain, which might have influenced the results. However, previous studies have shown that patients with pure TMJ pain are very rare,[21–23,39] and to minimize any such effect, all patients included should have pain located to the TMJ as their main complaint. Finally, compliance was only based on self-report, so these data must be interpreted with caution.

Dropouts are common in clinical long-term follow-up studies. The high number of dropouts at the 6-month and 12-month follow-ups is a limitation of this study. However, this does not seem to have affected the results, since no differences at baseline in any of the IMMPACT domains could be noted between the patients participating during the entire study and the patients not present at the follow-ups. Another limitation is that not all types of adverse events were registered, eg, discomfort, sickness, or decubitus.

Conclusions

This study showed that the effectiveness of the prefabricated appliance seems to be similar to that of the stabilization appliance in alleviating TMJ pain, both in the short term and long term. Since the appliance is prefabricated, it requires only a single visit for the construction, which makes it convenient both for the general practitioner and the patient. Therefore, it can be recommended for the treatment of patients with TMJ pain when used only during sleep.

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