Occlusal appliance therapy in patients with temporomandibular disorders

A double-blind controlled study in a short-term perspective

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Stabilization appliances are commonly used in the treatment of temporomandibular disorders (TMD), although the treatment effects are not fully understood. This study evaluated the short-term efficacy of a stabilization appliance in patients with TMD of arthrogeneous origin, using a randomized, controlled, and double-blind design. Sixty patients were assigned to two equally sized groups: a treatment group given a stabilization appliance and a control group given a control appliance. Improvement of overall subjective symptoms was reported in both groups but significantly more often in the treatment group than in the control group ($P = 0.006$). Frequency of daily or constant pain showed a significant reduction in the treatment group ($P = 0.02$) compared with the control group. The results of this short-term evaluation showed that both the stabilization appliance and the control appliance had an effect on temporomandibular joint (TMJ) pain. It is improbable that the difference observed between the groups is due to chance alone. □ *Clinical trial; control appliance; stabilization appliance; temporomandibular joint pain*

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Occlusal appliances are commonly used in the treatment of patients with temporomandibular disorders (TMD) and have been reported to improve signs and symptoms in these patients (1–3). However, the treatment effects of the stabilization appliance are not fully understood. Several factors influencing the effects have been discussed, such as reduced postural activity in the elevator muscles and elimination or alteration of the influence of the noxious proprioceptive input from occlusal interferences (4–6). Other factors discussed in relation to the treatment effects are the changes of the condyle–fossa relationship, the placebo effect, and the effect of the stabilization of the occlusion as well as an increase in the vertical dimension (7).

In an early study by Greene & Laskin (8), 40% of patients with myofascial pain-dysfunction syndrome showed an improvement when treated with a nonocclud-ing splint. Rubinoff et al. (9) found both nonoccluding and occluding appliances effective in ameliorating subjective symptoms in myofascial pain patients, but the occluding appliance used was reported to be more effective in relieving clinical signs.

Most studies evaluating the effects of treatment with a stabilization appliance do not take diagnoses into consideration. Wilkinson et al. (10) found nocturnal appliances more effective in treating patients suffering from myogeneous pain than those with arthrogeneous pain. Patients with more arthrogeneous sources of pain benefited from continuous appliance use.

In a controlled study of myofascial pain patients treated with stabilization or control appliances, Dao et al. (6) found a positive treatment outcome but no differences between the groups regarding the effect on pain.

Few controlled studies investigating the effect of stabilization appliance therapy are available, and knowledge about the treatment effects in specific diagnostic groups is lacking. The purpose of this double-blind controlled study was therefore to investigate the short-term effect of treatment with a stabilization appliance compared with a control appliance in patients with TMD of arthrogeneous origin. The null hypothesis was that a stabilization appliance is no better than a control appliance.

Materials and methods

Subjects

The 60 patients who participated were selected from the 1904 patients referred for treatment of TMD during a period of 3 years to the Department of Stomatognathic Physiology, Centre for Oral Health Sciences, Lund University. All patients referred for TMD pain (718) were clinically screened. Ninety percent of the patients with TMD pain were excluded because they did not fulfill the inclusion criteria, and 1% of the patients declined to participate in the study. Before the start of the study a power calculation was made. The total of 60 patients gives our study a statistical power slightly above 90% for obtaining significance in a two-tailed test at the 5% level if the true success probabilities in the two groups are 30% and 70%, respectively. Originally, 66 patients were selected. Of the 6 dropouts, 2 moved from the area and 4 did not follow the schedule of appointments for the study (Fig. 1).

Patients included in the study had a history of

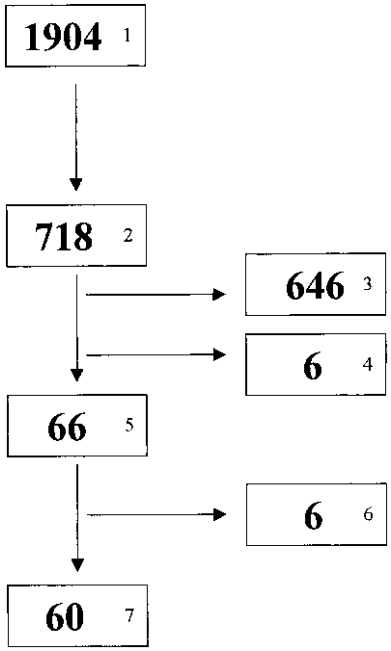

Fig. 1. The selection of patients referred for treatment of temporomandibular disorders (TMD) for inclusion in the study. 1: screening of referrals; 2: clinical screening of TMD pain patients; 3: patients not fulfilling the inclusion criteria; 4: patients declining to participate in the study; 5: patients fulfilling the inclusion criteria; 6: patients excluded from the study (2 moved from the area, 4 did not follow the schedule of appointments for the study); 7: patients included in the study.

temporomandibular joint (TMJ) pain, which was verified by interview and clinical examination. The clinical diagnosis was capsulitis/synovitis (3). None of the patients had earlier had any treatment for their TMD. After receiving information about the project, all participating patients gave their consent. The patients were informed about the lack of an unambiguous cause of TMJ pain and about contributing factors (3). To determine the most effective appliance for TMJ pain relief, two different designs of appliances were presented to the patients.

Inclusion criteria were pain localized to the TMJ region and lateral and/or posterior tenderness to palpation of the TMJ combined with self-assessed TMJ pain of at least 40 mm on a 100 mm visual analog scale (VAS) (11, 12).

Exclusion criteria were previous treatment with occlusal appliances, use of complete dentures, a history of psychiatric disorders or symptoms referred to diseases in other components of the stomatognathic system (e.g. toothache, neuralgia), and acute TMJ pain requiring pharmacologic management.

Methods

The study was performed with a double-blind design with one specialist in stomatognathic physiology performing the screening, history-taking, and clinical examination as well as evaluation after the treatment. Another specialist in stomatognathic physiology delivered and readjusted the appliances for the patients without any other involvement in the treatment. The first specialist thus had no information about which group the patients belonged to.

The steps of the study are shown in Table 1. The patients filled out a standardized questionnaire, and a clinical examination was performed. Impressions were taken for appliance therapy. The patients were randomly assigned to one of the two groups: treatment or control. The randomization was carried out by one independent person, using 10 series of consecutively numbered sealed opaque envelopes. Each envelope contained a treatment specification (13). This procedure was repeated until 60 patients were found for the study. Table 2 shows the age and sex distribution in the treatment and control groups. At the third visit the occlusal appliance was delivered, and a readjustment was made 2 weeks later. The treatment outcome was evaluated 10 weeks after the start of treatment (Table 1). This visit incorporated a questionnaire and a clinical examination. All patients had the same number of visits.

The questionnaire used before treatment included questions about intensity of TMJ pain according to a VAS with the endpoints 'no pain' and 'very severe pain'. The patients had to register both the worst TMJ pain experienced and the TMJ pain in the examination situation on the VAS. The intensity of TMJ pain was also registered on a verbal scale as follows: 0 = no, 1 = slight, 2 = moderate, 3 = severe, 4 = very severe. Frequency of TMJ pain was registered according to the following verbal scale: 0 = never, 1 = rarely, 2 = once a month, 3 = once every second week, 4 = once a week, 5 = twice a week, 6 = 3–4 times a week, 7 = daily, 8 = constantly. Duration of TMJ pain was assessed as follows: 0 = no pain, 1 = a couple of minutes, 2 = some hours, 3 = a full day, 4 = constant. Reported pain at rest as well as during mandibular movements was registered. The questionnaire used after treatment was the same as before treatment with some additional questions, including an evaluation of overall changes in severity of symptoms according to a 6-point verbal scale: 0 = symptom-free, 1 = much better, 2 = better, 3 = unchanged, 4 = worse, 5 = much worse. After treatment the patients registered changed pain at rest

Table 1. Sequence of steps for the two patient groups in the study. Visits 1, 2, and 5 were performed by one examiner and visits 3 and 4 by another examiner

Visit no.	Procedure(s)
1	Clinical screening of patients.
2	Questionnaire and clinical examination. Impressions for occlusal appliance. Randomization.
3	Patient receives occlusal appliance after adjustment.
4	Readjustment of occlusal appliance (2 weeks after visit 3).
5	Evaluation of treatment outcome (10 weeks after visit 3). Questionnaire and clinical examination.

as well as during mandibular movements as follows: 0 = no, 1 = much less, 2 = less, 3 = unchanged, 4 = worse, 5 = much worse. The patients were also asked to complete an assessment of pain in which their initial scores of pain on the VAS were marked (12). Any kind of discomfort associated with the appliance therapy was registered.

The clinical examination included measurements of mandibular movements, pain during non-guided mandibular movements, registration of TMJ sounds (clicking and/or crepitation), locking, and lateral and/or posterior tenderness of the TMJ. The following muscles were palpated: the anterior and posterior temporal muscle, the attachment of the temporal muscle, the deep and superficial portion of the masseter, the medial and lateral pterygoid, and the posterior portion of the digastric muscle. The muscles were palpated manually before and after treatment by the same examiner. The degree of tenderness was evaluated according to a 4-point scale: 0 = no tenderness, 1 = tenderness reported by the patient, 2 = tenderness with a palpebral reflex, 3 = tenderness with a defense reaction. The clinical dysfunction score according to Helkimo (14) was noted.

The patients in the treatment group were given a stabilization appliance; see Fig. 2a. The stabilization appliance had a smooth flat surface with all supporting teeth in contact. The endpoint on the appliance was centric relation achieved by chin-point guidance. At laterotrusion a cuspid rise was placed on the appliance to prevent mediotrusion interferences. At protrusion the appliance had contacts between cuspids. The patients in the control group were given a control appliance designed with a palatal coverage and clasps on the maxillary teeth. The control appliance did not interpose between the occluding teeth and therefore did not alter the intermaxillary relationship (Fig. 2b). Both groups were instructed to use the appliances during the night for a period of 10 weeks.

The study was approved by the Ethics Committee of Lund University.

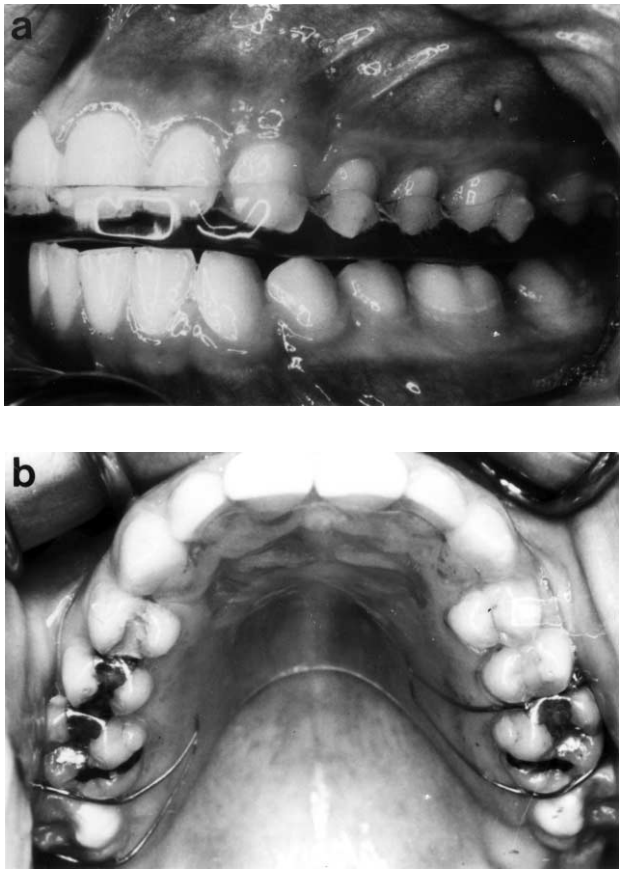

Fig. 2a. Lateral view of the stabilization appliance used in the patients in the treatment group. 2b. Occlusal view of the control appliance used in the patients in the control group.

Statistical analysis

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 was used for the variables measured on an ordinal scale. These tests were used to determine the significance of differences between the groups. For comparison within groups the McNemar test was used for categoric variables, and Wilcoxon's signed-rank test was used for variables measured on an ordinal scale. Differences at the 5% level of probability were considered statistically significant.

Results

Before treatment

The distribution of duration of TMJ pain in months is presented in Table 2. The mean value for the worst TMJ pain rated on the VAS was 77 mm for all patients, 76 mm for the treatment group, and 78 mm for the control group. Nearly all patients reported moderate, severe, or very severe TMJ pain (Table 3).

Thirty-five percent of the patients had a reduced mouth-opening capacity (<40 mm). The mean value of the maximum mouth-opening capacity was above 40 mm in both groups. Two-thirds of the patients had more than two painful mandibular movements. Tenderness to palpation of more than 4 sites in the masticatory muscles was found in 93% of the patients. According to Helkimo's clinical dysfunction index, 64% of the patients had severe dysfunction (Table 3).

After treatment

Within groups. A statistically significant improvement of overall subjective symptoms was reported in both groups ($P < 0.001$). In the treatment group there was a statistically significant reduction in the number of patients reporting moderate to very severe TMJ pain ($P = 0.002$). There was

Table 2. Distribution of the 60 patients in the 2 patient groups before treatment according to sex, age, and duration of temporomandibular joint (TMJ) pain

	Treatment group ($n = 30$)	Control group ($n = 30$)	Total ($n = 60$)
Females	26	29	55
Males	4	1	5
Mean age (years)	31	30	30
Age range (years)	13–76	15–72	13–76
TMJ pain duration (months)			
Median	24	14	18
Range	3–360	2–120	2–360
Duration of TMJ pain < 6 months	3	7	10
Duration of TMJ pain ≥ 6 months	27	23	50

a statistically significant decrease in level of the worst TMJ pain experienced as marked on the VAS in the treatment group ($z = -4.0$, $P = 0.001$) as well as in the control group ($z = -2.9$, $P = 0.0034$). The TMJ pain marked on the VAS in the reexamination situation showed a statistically significant reduction within the treatment group ($z = -3.1$, $P = 0.002$). Pain in the TMJ at rest decreased significantly in the treatment group ($P = 0.0001$) and in the control group ($P = 0.003$). Reported TMJ pain during movements decreased significantly in the treatment group ($P < 0.0001$) as well as in the control group ($P = 0.02$).

After 10 weeks of treatment, 50% of the patients in the treatment group had no tenderness to palpation of the TMJ, and the corresponding value for the control group was 30%; there was a significant difference within the treatment group ($P = 0.001$) as well as within the control group ($P = 0.004$). Tenderness to palpation of the masticatory muscles showed no significant reduction within the groups regarding the number of tender sites in the masticatory muscles or the degree of muscle tenderness. There were no significant differences within the groups regarding mouth-opening capacity or TMJ sounds. The number of patients with locking in the TMJ increased from three to seven in the control group and decreased from two to one in the treatment group.

Between groups. Positive treatment outcomes were found at the 10-week follow-up regarding both symptoms and signs in the group treated with a stabilization appliance and in the group treated with a control appliance. Improvement of overall subjective symptoms was reported by 83% of the patients in the treatment group and 50% in the control group. The comparisons between the two groups are presented in Table 4.

Thirty-three percent of the patients in the control group and 7% of those in the treatment group reported exacerbation of TMJ pain when using the appliance. The difference between the groups was significant (chi-square = 6.7, $P = 0.01$). No patient received additional treatment for symptoms of TMD during the 10 weeks of appliance therapy.

Discussion

The null hypothesis of this double-blind controlled study of TMJ pain patients was rejected. The study showed a better treatment outcome, as regards both symptoms and signs, in the group treated with a stabilization appliance than in the group treated with a control appliance. The results were in contrast to those of Dao et al. (6), who found no differences between groups treated with stabilization and control appliances regarding the effect on pain. There was, however, a difference in origin of the pain between these two studies.

To study a group of patients with TMD of arthrogeneous origin with pain, a thorough selection procedure had to be used. In this screening procedure, many patients with pain of myogeneous origin were found, as well as

Table 3. Number of patients with symptoms and signs of temporomandibular joint (TMJ) pain before treatment in the two patient groups

	Treatment group ($n = 30$)		Control group ($n = 30$)	
	n	%	*n*	%
Symptoms				
Frequency of TMJ pain				
Rarely	2	7	2	7
Once a month	1	3	0	0
Once every second week	0	0	0	0
Once a week	0	0	0	0
Twice a week	0	0	3	10
3–4 times a week	3	10	3	10
Daily or constant pain	24	80	22	73
Intensity of TMJ pain				
Slight	2	7	2	7
Moderate to very severe pain	28	93	28	93
Worst TMJ pain at VAS ≥ 40 mm*	30	100	30	100
Pain at rest	18	60	19	63
Pain during movements	26	87	25	83
Signs				
Maximal opening capacity < 40 mm	11	37	10	33
Pain during mandibular movements				
1	5	17	5	17
2–4	20	66	20	66
Masticatory muscles				
Degree of tenderness				
2	19	63	16	53
3	10	33	14	47
1–3 tender sites	3	10	0	0
>4 tender sites	26	87	30	100
TMJ				
Only lateral tenderness	23	77	24	80
Lateral and posterior tenderness	7	23	6	20
Reciprocal clicking	9	30	13	43
Locking	2	7	3	10
Crepitation	6	20	5	17
Clinical dysfunction index				
I	0	0	0	0
II	12	40	10	33
III	18	60	20	67

* VAS = visual analog scale.

Table 4. Correlation of symptoms and signs of temporomandibular joint (TMJ) pain after treatment in the two patient groups

	Treatment group ($n = 30$)	Control group ($n = 30$)	Statistical test (chi-square)	Significance level
Symptoms				
Frequency of TMJ pain				
Never	2	1		
Rarely	6	2		
Once a month	1	0		
Once every second week	2	2		
Once a week	1	0		
Twice a week	4	2		
3–4 times a week	4	4		
Daily or constant pain	10	19	5.4	$P = 0.02$
Intensity of TMJ pain				
No pain	4	2		
Slight	7	2		
Moderate to very severe	19	26	5.4	$P = 0.02$
50% reduction of worst TMJ pain on VAS*	11	6		NS
Decreased worst TMJ pain on VAS	23	21		NS
Reported decreased pain at rest	29	22	6.4	$P = 0.01$
Reported decreased pain during mandibular movements	15	22		NS
Change of overall subjective symptoms				
Symptom-free–better	25	15	7.5	$P = 0.006$
Unchanged–much worse	5	15		
Signs				
Maximal opening capacity < 40 mm	8	10		NS
Pain during mandibular movements				
0	8	4		
1	10	2		
2–4	12	24	9.2	$P = 0.002$
Masticatory muscles				
Degree of tenderness 2	17	17		NS
3	9	11		NS
Tender sites 1–3	4	4		NS
≥4	20	24		NS
TMJ				
Only lateral tenderness	9	18	4.3	$P = 0.04$
Lateral and posterior tenderness	6	3		NS
Reciprocal clicking	10	12		NS
Locking	1	7		NS
Crepitation	5	5		NS
Clinical dysfunction index				
I	4	2		NS
II	14	8		NS
III	12	20	4.3	$P = 0.04$

* VAS = visual analog scale.

patients with arthrogeneous pain rated less than 40 mm on the VAS. However, of the 66 selected patients fulfilling the inclusion criteria, only 6 dropped out.

In spite of the improvement, the worst reported TMJ pain after treatment was ≥40 mm on the VAS in two-thirds of the patients in both groups. One explanation for the reported improvement could be that after treatment these patients did not experience their worst TMJ pain as frequently as before treatment. Linton & Gotestam (15) found a general tendency for patients to overestimate the baseline pain intensity on the VAS scale. To avoid problems with memory of pain on the VAS scale, the patients' initial scores were shown (12). Since Magnusson et al. (16) found that a verbal scale was significantly better than a VAS scale when recording memory of pain, we considered the subjective evaluation of the TMJ pain in our study reliable.

All patients in our study had a diagnosis of capsulitis/synovitis before treatment. Since muscular pain can explain tenderness on lateral TMJ palpation, there is a risk of incorrect diagnosis. However, the randomization resulted in almost the same number of patients with only lateral tenderness, and thus the results of the study were not confounded.

Regarding treatment of TMD of arthrogeneous origin, Scholte et al. (17) and De Leeuw et al. (18) showed in their retrospective studies that patients with craniomandibular disorders (CMD) responded better to treatment if the CMD was of mainly arthrogeneous origin than if it was of mainly myogeneous origin. This could be one explanation

for the difference in results between our study and that by Dao et al. (6). One should also keep in mind that spontaneous remission and natural fluctuation of the condition can be important factors for a positive treatment outcome. Our results, however, still showed a better outcome in the treatment group than in the control group.

The placebo effect is another important factor when considering the treatment effects, and it is sometimes difficult to assess in clinical trials, especially in a study like this. As soon as any kind of appliance is inserted intraorally, there will probably be an effect on the masticatory muscles (8), thereby making it impossible to introduce a placebo appliance. This study included a comparison of treatment outcomes between two groups of patients treated with two different appliances, incorporating the placebo effect equally in the two groups. Regarding reported improvement, our study was even more successful than that by Greene & Laskin (8), who reported 40% improvement with the nonoccluding appliance.

In contrast to our findings Rubinoff et al. (9) found no difference between an occluding and a nonoccluding appliance in relieving signs. In the present study differences were found in signs before and after treatment: joint tenderness, and registered pain during more than two mandibular movements. The design of the studies differed, as did the diagnoses of the patients.

Regarding TMJ tenderness, differences were found in lateral tenderness in the treatment group before and after treatment. It seems that the group treated with a stabilization appliance experienced a positive treatment effect on pain and/or tenderness in the TMJ. One should be aware, however, that this lateral tenderness may include tenderness in the deep portion of the masseter muscle.

The treatment outcome of occlusal appliance therapy has been reported to be good after 4–8 weeks (8, 9, 19). To make comparison possible between our study and that by Dao et al. (6), the same duration of treatment, 10 weeks, was used. No differences between groups were found by Dao et al. (6), and all pain ratings decreased significantly with time, which encouraged us to use the same period of treatment.

The use of Helkimo's index in clinical studies has been questioned because of its limited sensitivity to small changes in the condition (20) and limited assessment of functional impairment (21). In our study Helkimo's index was used merely to describe the severity of the dysfunction in the two groups and to enable the reader to compare the dysfunction index with that of patients in other studies.

The double-blind and controlled design of this study, as well as the similarity between treatment and control groups with regard to symptoms and signs before treatment, makes the comparison of the treatment effects of the two appliances reliable. The results of this short-term evaluation showed that both the stabilization appliance and the control appliance had an effect on TMD pain. It is improbable that the difference observed between the groups is due to chance alone.

The true outcome in chronic TMD cannot be seen at 10 weeks. The effects of the treatment with the two different appliances will be followed and evaluated in a longer perspective.

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