The Efficacy of Appliance Therapy in Patients with Temporomandibular Disorders of Mainly Myogenous Origin. A Randomized, Controlled, Short-Term Trial

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Aims: *To compare the short-term efficacy of treatment with a stabilization appliance compared with that of a non-occlusal, control appliance in patients with temporomandibular disorders (TMD) of mainly myogenous origin.* ***Methods:*** *A randomized, controlled trial was performed with 60 patients suffering from myofascial pain. Patients were randomly assigned to a treatment or a control group. The treatment group was treated by means of a stabilization appliance and the control group by means of a non-occlusal appliance. Symptoms and signs were registered before and after 10 weeks of treatment.* ***Results:*** *Improvement of overall subjective symptoms was reported in both groups, but significantly more often in the treatment group than in the control group (*P = *.000). The prevalence of daily or constant pain showed a significant reduction in the treatment group (*P = *.028) compared with the control group. There was a significant decrease in the number of tender masticatory muscles in the treatment group (*P = *.018) compared with the control group.* ***Conclusion:*** *The results of this short-term evaluation suggest that the stabilization appliance is more effective in alleviating symptoms and signs in patients with TMD of mainly myogenous origin than a control, non-occlusal appliance. The stabilization appliance can therefore be recommended for the therapy of these patients.*

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Occlusal appliances are commonly used in the treatment of patients with temporomandibular disorders (TMD), and their effectiveness in reducing symptoms has been reported to vary between 70% and 90%.[1] Nevertheless, as the demand for evidence-based dentistry has increased, the efficacy of occlusal appliances for the treatment of TMD has been questioned. For instance, Major and Nebbe[2] concluded from their review that splint therapy has not been demonstrated to be the treatment of choice to manage joint pain. The review by Marbach and Raphael[3] was also not able to identify evidence for their long-term efficacy. They therefore recommended in another study[4] that appliances should not be used for musculoskeletal facial pain. Furthermore, a recently published systematic review of randomized controlled trials on the occlusal treatment of TMD concluded that occlusal splints may be of some benefit in the treatment of TMD and that there is an obvious need for well-designed controlled studies to analyze the current clinical practices.[5] Indeed, the few randomized controlled studies that have been published have led to inconclusive results.[6–9] In 2 of these studies, performed on patients recruited through a newspaper announcement, no difference in

pain improvement was found with the use of either an occluding or a non-occluding appliance.[6,8] On the contrary, a third randomized controlled trial comprising patients referred for treatment of TMD of mainly arthrogenous origin reported that both symptoms and signs improved significantly with a stabilization appliance than with a control, non-occlusal appliance.[9] A further problem, as reported by Dao and Lavigne in a comprehensive literature review,[10] is the fact that it is still largely unknown how splints work. Therefore, the authors concluded that oral splints should be used as an adjunct for pain management rather than as a specific treatment modality.

Because of these diverse opinions, there obviously is a strong need for further randomized controlled trials (RCTs) to identify if a stabilization appliance is really effective. The aim of this RCT was therefore to compare the short-term efficacy of a treatment with a stabilization appliance with that of a control, non-occlusal appliance in patients with TMD of mainly myogenous origin. The null hypothesis was that the treatment outcome with a stabilization appliance does not differ from that of a control, non-occlusal appliance.

Materials and Methods

Subjects

Sixty patients were selected from 926 patients referred for treatment of TMD, over a period of approximately 2 years, to the Department of Stomatognathic Physiology, Faculty of Odontology, Malmö University. All patients referred for TMD pain (338) were clinically screened; 272 (80%) patients with TMD pain were excluded because they did not fulfill the inclusion criteria, and 6 (1.7%) declined to participate in the study. According to a power calculation made before the beginning of the study, a total of 60 patients provides a statistical power slightly above 90% for obtaining a statistically significant difference in a 2-tailed test at the 5% level if the true success probabilities in the 2 groups are 30% and 70%, respectively.

Patients included in the study had a history of pain from the masticatory muscles, which was verified by interview and clinical examination. The clinical diagnosis was myofascial pain with or without limited opening according to the Research Diagnostic Criteria for TMD.[11] Inclusion criteria were pain of muscular origin with or without limited opening, including a complaint of pain associated with localized areas of tenderness to palpation in masticatory muscles, combined with self-assessed myofascial pain of at least 40 mm on a 100-mm visual analog scale (VAS).[12,13] Exclusion criteria were temporomandibular joint (TMJ) pain verified by interview and clinical examination, previous treatment for TMD, use of complete dentures, or a history of psychiatric disorders or symptoms related to disease in other components of the stomatognathic system (eg, toothache, neuralgia).

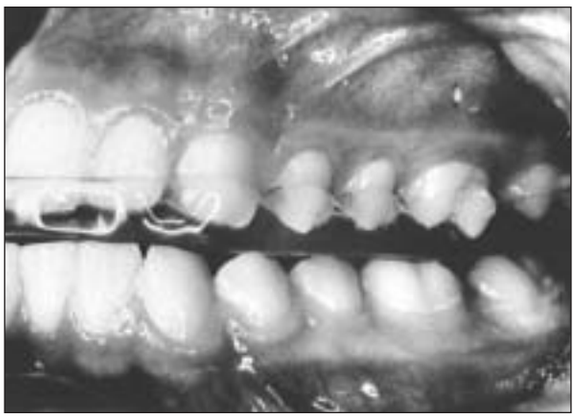
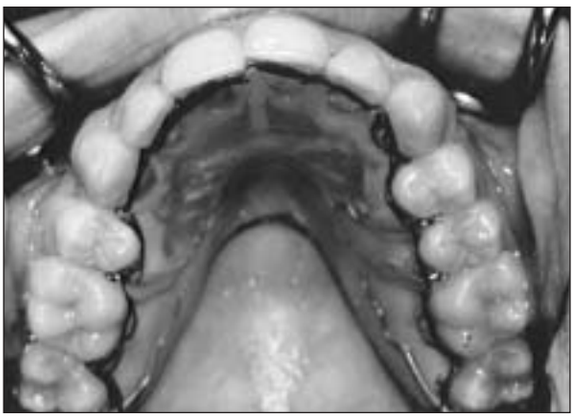
The patients were informed about the lack of a clear-cut cause of their myofascial pain and about contributing factors.[14] They were reassured and informed about the nature of TMD and the relationship between muscle fatigue, muscle pain, and the psychophysiologic aspects of stress and how to self-monitor TMD symptoms. All participants gave their consent. The study was approved by the ethic committee of Lund University.

Experimental Methods

The study was performed as a RCT similar to a previous study on the efficacy of occlusal and non-occlusal appliances in the treatment of patients with TMD of mainly arthrogenous origin.[9] Patients were randomly allocated to 1 of the 2 groups: a treatment (T) group treated with a stabilization appliance or a control (C) group treated with a control, non-occlusal appliance. One independent person carried out the randomization by using 10 series of consecutively numbered, sealed, opaque envelopes. Each envelope contained a treatment specification.[15] This procedure was repeated until 60 patients were found for the study.

One specialist in stomatognathic physiology performed the screening, history-taking, clinical examination, reassurance, and information gathering before treatment, as well as the evaluation after the treatment. Another specialist in stomatognathic physiology, who was not involved in the examination at baseline and at follow-up, delivered and adjusted the appliance. The first specialist, thus, had no information as to which group the patients belonged.

During the first visit, patients filled out a standardized questionnaire and were examined clinically, and impressions were taken for the construction of the appliance. At the second visit, the occlusal appliance was delivered and adjusted. A second adjustment was made 2 weeks later and no further adjustment was performed during the following 8 weeks except for single patients due to reason of comfort. After 10 weeks of treatment, the patients filled out a questionnaire and were reexamined clinically to evaluate the treatment outcome. All patients had the same number of visits.

Figs 1a and 1b Lateral view of a stabilization appliance *(a)*, and occlusal view of a control, non-occlusal appliance for the control group *(b)*.

The questionnaire used before treatment included questions about pain duration, intensity, and frequency. The pain intensity was recorded on a VAS scale with the endpoints "no pain" and "very severe pain." The patients had to register both the worst pain experienced and the pain felt at the time of the examination. The intensity of myofascial pain also was registered on a 5-point verbal scale as follows: 0 = no pain, 1 = slight pain, 2 = moderate pain, 3 = severe pain, 4 = very severe pain. Frequency of myofascial pain was registered 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. Reported pain at rest as well as during mandibular movements was also registered. The questionnaire used after treatment included some additional questions, including an evaluation of improvement of overall subjective symptoms according to a 6-point verbal scale: 0 = symptom-free, 1 = much better, 2 = better, 3 = unchanged, 4 = worse, 5 = much worse. The treatment outcome was judged as positive when the patient reported improvement of overall subjective symptoms. In addition, the patients were asked to rate the pain intensity on a VAS on which the initial pain intensity was marked.[12,13] They were also asked to report any kind of discomfort associated with the appliance therapy, how often they used the occlusal appliance (0 = every night, 1 = several nights a week, 2 = when necessary, 3 = not at all), and if they were satisfied to have been assigned to a treatment modality by randomization.

The clinical examination, performed before and after treatment by the same examiner, included measurements of mandibular movements, pain during nonguided mandibular movements, registration of clicking and/or crepitation, locking, and lateral and/or posterior tenderness of the TMJ. The following muscles were palpated manually: the anterior and posterior temporalis muscles, the attachment of the temporalis muscle, the deep and superficial portions of the masseter, the medial and lateral pterygoids, and the posterior portion of the digastric muscle. 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[16] was also noted.

The stabilization appliance (Fig 1a) had a smooth, flat surface with supporting teeth in contact and was adjusted to centric relation that was achieved by chin-point guidance. The appliance also had a canine-protected articulation to avoid mediotrusion interferences during laterotrusion. At protrusion, the appliance had contacts between canines. The control, non-occlusal appliance (Fig 1b) was designed with a palatal coverage and clasps on one of the molars on each side of the maxilla; thus, the appliance did not cover the occlusal surface and therefore did not alter the intermaxillary relationship.[9] Patients were instructed to use the appliances during the night for a period of 10 weeks.

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 groups. For comparison within groups, the McNemar test was used for categorical variables

Table 1 Demographic Data of the 60 Myofascial Pain Patients Before Treatment

	T group (n = 30)	C group (n = 30)	Total (n = 60)
Gender			
Females	25	27	52
Males	5	3	8
Age (y)			
Mean	31	28	29
Min–max	14–54	14–56	14–56
< 20	4	7	11
20–40	19	18	37
> 40	7	5	12
Ethnicity			
Scandinavia	24	24	48
Other European countries	2	2	4
Asia	2	2	4
Latin America	2	2	4
Marital status			
Married	11	12	23
Adolescent living in family	3	7	10
Divorced	4	4	8
Never married	12	7	19
Highest level of education			
Elementary school	4	7	11
High school	16	16	32
College	10	7	17
Duration of myofascial pain (mo)			
Median	36	24	27
Min–max	4–420	1–120	1–420
Duration of myofascial pain			
< 6 mo	1	2	3
≥ 6 mo	29	28	57

T = treatment group, C = control group.

and Wilcoxon signed-rank test was used for the variables measured on an ordinal scale. Differences at the 5% level of probability were considered statistically significant.[15]

Results

Before Treatment

The demographics data are shown in Table 1 and the symptoms and signs before and after treatment in Tables 2 and 3. There were no differences in ethnicity, symptoms, and signs between T and C groups before treatment ($P > .05$).

Ninety-five percent of all patients reported myofascial pain with a duration of ≥ 6 months. The VAS mean value for the worst myofascial pain was 73 mm for all patients, 75 mm for those of the T group (SD = 18.6), and 71 mm for those of the C group (SD = 17.6), the difference being not statistically significant ($P > .05$).

Seventy-two percent of all patients reported daily or constant myofascial pain (Table 2). Forty-seven percent of the patients in the T group and 57% of the patients in the C group reported severe or very severe myofascial pain. Only 10% of all patients had a mouth-opening capacity < 40 mm. Forty-two percent of the patients had more than 2 painful mandibular movements. Tenderness to palpation of ≥ 3 masticatory muscle sites was found in 88% of the patients. According to Helkimo's Clinical Dysfunction Index,[16] 38% of the patients had severe dysfunction (Table 3).

After Treatment

Within the groups. The symptoms improved with statistical significance in both groups ($P < .05$), but the signs improved significantly only in the T group (Tables 2 and 3). In both groups, a statistically significant reduction was found in the number of patients with daily myofascial pain (T group $P = .000$ and C group $P = .006$), in the number of patients reporting moderate to very severe myofascial pain (T group $P = .000$ and C group $P = .016$), in the number of patients reporting severe or very severe myofascial pain (T group $P = .002$ and C group $P = .001$), in the level of the worst myofascial pain experienced as marked on the VAS (T group $P = .000$ and C group $P = .027$), and in the number of patients with myofascial pain during mandibular movements (T group $P = .000$ and C group $P = .004$). The worst pain had a VAS value of 41 mm (SD = 28.7) in the T group and 56 mm (SD = 30.1) in the C group.

After treatment, the following parameters decreased significantly only in the T group: the myofascial pain marked on the VAS ($P = .000$), the number of patients with myofascial pain at rest ($P = .000$), the number of patients with ≥ 4 tender sites of the masticatory muscles ($P = .022$), and the number of patients with myofascial pain during 2 to 4 mandibular movements ($P = .012$).

There were no significant differences within the groups regarding mouth-opening capacity or reciprocal clicking. None of the patients had locking in the TMJ before treatment, but after 10 weeks of treatment, 2 patients in the C group presented locking in the TMJ at follow-up (Table 3).

Between the groups. Positive treatment outcomes were found in both groups at the follow-up for both symptoms (Table 2) and signs (Table 3). Improvement of overall subjective symptoms was reported by 97% of the patients in the T group and by 53% in the C group, with a statistically significant difference between the groups (chi-square $P = .000$).

Table 2 No. of Patients with Symptoms of Myofascial Pain Before and After Treatment with Appliances in the 2 Patient Groups

	Before				After			
	T group		C group		T group	C group	Statistical test	Significance level between
Symptoms	n	%	n	%	n	n	(chi-square)	groups
Frequency of myofascial pain								
Never	0	0	0	0	12	5	4.0	.045
Rarely	0	0	0	0	5	3		NS
Once a month	0	0	0	0	2	4		NS
Once every second week	1	3	2	7	3	2		NS
Once a week	0	0	0	0	1	2		NS
Twice a week	1	3	0	0	2	0		NS
3–4 times a week	5	17	8	27	2	4		NS
Daily or constantly	23	77	20	66	3	10	4.8	.028
Intensity of myofascial pain								
No pain	0	0	0	0	11	4		NS
Slight	1	3	1	3	6	4		NS
Moderate to very severe	29	97	29	97	13	22	5.6	.018
Severe or very severe	14	47	17	57	2	4		NS
Pain at rest	24	80	19	63	7	13		NS
Pain during mandibular movements	29	97	30	100	12	21	5.5	.020
Awareness of clenching/grinding	24	80	25	83				
Improvement of overall subjective symptoms								
Better to symptom free					29	16	15.0	.000
Much better to symptom free					18	9	5.5	.020
VAS (mean, mm)								
In the examination situation	33		26		14	27		NS
Worst	75		71		41	56		NS
50% reduction of worst myofascial pain patients					13	5		NS

T = treatment group, C = control group, NS = not significant.
The dichotomous variables used in the chi-square test are transformed from variables measured on an ordinal scale.

None of the patients received additional treatment for TMD during the 10 weeks of appliance therapy. Twenty-three percent of the patients in the T group and 30% of the patients in the C group reported discomfort with the appliance. Eighty-three percent of the patients in the T group and 77% of the patients in the C group reported to have used the appliance several nights a week or every night. Eighty-seven percent of the patients in the T group and 43% of those in the C group were satisfied with the randomization process, the difference being statistically significant (chi-square = 6.6, $P = .010$).

Discussion

The null hypothesis of this randomized controlled trial performed on TMD patients with mainly myogenous pain was rejected, as symptoms and signs improved more in the group treated by means of a stabilization appliance than in the group treated by means of a control, non-occlusal appliance. These results are in agreement with those of another randomized controlled trial conducted by Ekberg et al[9] on patients referred for treatment of TMD of mainly arthrogenous origin, that reported 83% improvement with the stabilization appliance. The findings, however, disagree with those by Dao et al[8] and Rubinoff et al[6] who found that a stabilization appliance was not superior to a control, non-occlusal appliance in relieving myofascial pain as well as signs and symptoms. It is difficult, however, to compare the results of these 3 studies, as the 3 populations were not described in a comparable manner and probably also did not match for signs and symptoms. For instance, in our study, the patients had requested treatment for TMD pain, whereas in the study by Dao et al,[8] patients were recruited both by announcements in the local newspapers and by referrals. We think it is more appropriate only to include patients demanding treatment for TMD. Also, the pretreatment pain intensity was evaluated differently in the 2 studies. In our study, patients rated the worst pain that, on average, corresponded to 73 mm on the VAS, whereas patients in the earlier study rated the postexercise pain intensity to about 40 mm on the VAS. These differences seem to indicate that the studies did not include the same type of myofascial pain patients.

Table 3 No. of Patients with Signs of Myofascial Pain Before and After Treatment with Appliances in the 2 Patient Groups

	Before				After			
	T group		C group		T group	C group	Statistical test (chi-square)	Significance level between groups
Signs	n = 30	%	n = 30	%	n = 30	n = 30		
Maximal opening capacity								
< 40 mm	2	7	4	13	0	5		.020
Pain during mandibular movements								
0	12	40	11	36	17	17		NS
1	4	13	8	27	8	5		NS
2–4	14	47	11	37	5	8		NS
Masticatory muscles								
0					4	2		NS
1–3 tender sites	8	27	2	7	13	6		NS
≥ 4 tender sites	22	73	28	93	13	22	5.6	.018
Degree of tenderness								
2	27	90	25	83	24	20		NS
3	3	10	5	17	2	8		NS
TMJ								
Lateral tenderness	0	0	0	0	4	6		NS
Posterior tenderness	0	0	0	0	0	3		NS
Reciprocal clicking	14	47	12	40	13	11		NS
Crepitations	0	0	0	0	1	1		NS
Locking	0	0	0	0	0	2		NS
Clinical Dysfunction Index								
I	6	20	0	0	14	6	4.8	.028
II	11	37	20	67	10	14		NS
III	13	43	10	33	4	10		NS

T = treatment group, C = control group, NS = not significant.
The dichotomous variables used in the chi-square test are transformed from variables measured on an ordinal scale.

It is also difficult to compare our results with those of Rubinoff et al,[6] who did not find that an occluding appliance better relieved symptoms and signs than a non-occluding appliance. The present study instead reported differences as far as frequency and intensity of myofascial pain, pain during mandibular movements, maximal opening capacity < 40 mm, and registered pain in ≥ 4 tender sites of the masticatory muscles. The study by Rubinoff et al[6] did not, however, present single symptoms and signs. The positive efficacy of the stabilization appliance on the intensity of myofascial pain in our study was nonetheless in line with the results by Turk et al,[7] who found significant short-term (6 weeks) effects on pain, comparing an intraoral appliance with biofeedback/stress management in TMD.

Previous retrospective studies[17,18] have reported that patients with TMD of mainly myogenous origin respond less well to treatment than patients with TMD of mainly arthrogenous origin. This difference in treatment outcome has been related to the fact that myogenous patients are more psychologically distressed than arthrogenous patients.[19–24] In our 2 prospective studies, no such differences in treatment outcome between myogenous and arthrogenous patients could be found. Surprisingly, in this short-term evaluation of myofascial pain patients, we found an effect on tenderness to palpation of the masticatory muscles that was not seen in our previous study.[9]

Patients were instructed to use their appliances every night, and 77% to 83% of the patients reported that they used their appliances at least several nights a week. In other studies, patients were instructed to wear the appliance day and night.[6–8] Davies and Gray[25] found no advantage of any particular pattern of splint use in patients with "pain dysfunction syndrome." The results of that study and the present study therefore suggest that it is sufficient to wear the stabilization appliances only at night.

The randomized design of the present study, as well as the matching of the patients as far as symptoms and signs before treatment, provide validity to the comparison of the treatment effects of the 2 appliances. Of course, an improvement of symptoms and signs after treatment is not necessarily due to the specific therapeutic modality used. Spontaneous remission, natural fluctuation of the condition, as well as the placebo effect[26,27] can also contribute to a positive treatment outcome. Because of the lack of a control group without treatment, it was impossible to determine how these and other factors could have

contributed to the treatment success. Nevertheless, our results showed that the stabilization appliance was more effective for TMD of mainly myogenous origin than was the non-occlusal, control appliance. It is unlikely that the difference observed between the groups was due to chance alone. Therefore, the stabilization appliance can be recommended as a short-term treatment modality for TMD of mainly myogenous origin. It is our belief that patients with myofascial pain in general will benefit from stabilization appliance therapy unless the patient's general health has an influence that is too heavy on the myofascial pain.

As TMD tends to be a chronic, recurrent pain condition,[28] the true treatment outcome cannot be assessed after only 10 weeks, which was the time of therapeutic evaluation in this study. Thus, patients will be followed and evaluated from a longer perspective.

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