Treatment outcome of appliance therapy in temporomandibular disorder patients with myofascial pain after 6 and 12 months

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Aim: To compare the long-term effect of treatment with a stabilization appliance (group T) and treatment with a control appliance (group C) in temporomandibular disorder (TMD) patients with myofascial pain. *Methods:* In this controlled trial, 60 patients (mean age 29 years) with myofascial pain were evaluated after 10 weeks of treatment with either a stabilization appliance or a control appliance. All 60 patients were then assigned to 1 of 3 groups according to demand for treatment. Seventeen patients from group C requested another appliance and were given a stabilization appliance, thus creating a mixed group (group M). *Results:* A significant difference in improvement of overall subjective symptoms in an intent-to-treat analysis between groups T and C was found at the follow-ups. In a survival analysis of treatment compliance, a significant difference was found between groups T and C. At the 6- and 12-month follow-ups, a significant reduction in myofascial pain, as measured on a visual analog scale, was found in all three groups. A significant decrease in frequency and intensity of myofascial pain was found in group T at the follow-ups. A significant decrease in number of tender sites on the masticatory muscles was found in group T at the follow-ups. *Conclusion:* The results support the conclusion that the positive treatment outcome obtained by use of a stabilization appliance to alleviate the signs and symptoms in patients with myofascial pain persisted after 6 and 12 months. Most patients in groups T and M reported positive changes in overall subjective symptoms in this trial. We therefore recommend use of the stabilization appliance in the treatment of TMD patients with myofascial pain. □ *Myofascial pain; stabilization appliance and long-term follow-up; temporomandibular disorders*

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The effect of occlusal appliance (OA) therapy in patients with temporomandibular disorders (TMD) has been presented in several review articles (1–6), in some of which (1, 2, 4) studies other than randomized controlled trials (RCTs) have been incorporated. Other reviews have included RCTs with different qualities, although in two of these (3, 5) attempts were made to adhere to strict rules of inclusion for RCTs. Even though these latter studies included RCTs, the conclusions reached on the efficacy of OA therapy were conflicting.

In one well-performed study (7), the authors concluded that the treatment group could not be differentiated from the control group regarding treatment outcome after 10 weeks. In some well-performed RCTs (8, 9), however, a good effect has been found with OA therapy in patients suffering from TMD of both arthrogenous and myogenous origin. A major difference between the study by Dao et al. (7) and studies by Ekberg et al. (8, 9) was in use of the OA; the patients in the Dao et al. study used it day and night, while those in the Ekberg et al. studies (8, 9) used it only at night-time.

Marbach & Raphael (1) concluded in a review that there might be some short-term effect but no long-term effect of OAs. One year later, in an article (10) on future directions in the treatment of chronic musculoskeletal facial pain, these authors stated that most controlled studies concluded that appliances were ineffective. They did not recommend appliance therapy for musculoskeletal facial pain owing to the lack of long-term effectiveness.

To improve our knowledge of the effect of appliance therapy on patients with TMD of mainly arthrogenous origin in a long-term perspective, we performed a 6-month and 12-month follow-up study (11). This was a follow-up of the RCT we had presented earlier (8), and the signs and symptoms of TMD in 74% of the group treated with a stabilization appliance were found still to be alleviated after 12 months. Most patients in the control group requested treatment with a stabilization appliance during the trial due to a negative outcome and/or discomfort from use of the control appliance.

We studied the efficacy of appliance therapy in patients with TMD of mainly myogenous origin in another RCT (9). The treatment outcome in the treatment group was significantly better than in the control group after 10 weeks of treatment; 97% of the patients in the treatment group versus 53% in the control group reported improvement. We tracked this positive treatment outcome in the long-term perspective.

The hypothesis was that the positive treatment outcome would not persist in a longer perspective. The purpose of this follow-up was therefore to investigate the long-term effects of treatment with a stabilization appliance com-

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pared with a control appliance in patients with TMD of mainly myogenous origin.

Materials and methods

Subjects

Sixty patients (52 F and 8 M, mean age 29 ± 2 years) suffering from myofascial pain (12) were followed up at 10 weeks, 6 months, and 12 months. A statistical power calculation had revealed that 60 patients equated with a statistical power of slightly above 90% for obtaining significance in a two-tailed test at the 5% level if the true success probabilities of overall subjective symptoms was 70% in the treatment group (group T) and 30% in the control group (group C).

The age and sex distribution of the patients who were randomly assigned to the T and C groups has been presented previously (8). An independent person performed the randomization using 10 series of consecutively numbered, sealed, opaque envelopes. Each envelope contained a treatment specification. This procedure was repeated until 60 patients were found for the study.

At the follow-ups, some patients had their appliances adjusted when needed or when they requested another appliance. All of the patients in group T were satisfied with readjustments and requested no other treatment. Seventeen patients in group C requested the other appliance. The 60 TMD patients with myofascial pain formed three groups: group T comprised 30 patients who had been treated with a stabilization appliance; group C, 12 patients who had been treated with a control appliance; and a mixed group (group M), 18 patients who had been treated first with a control appliance and then with a stabilization appliance. After evaluation at the 6-month follow-up, 2 more patients in group C who requested a different appliance were given a stabilization appliance and then assigned to group M. One patient from this group dropped out before the 6-month follow-up due to refusal to participate (Fig. 1).

Experimental methods

In this study, the treatment outcome was evaluated after 10 weeks, 6 months, and 12 months with a questionnaire and a clinical examination. The TMD specialist (A) who performed the baseline examination and evaluated treatment outcome was blinded to which OA therapy the patient was receiving. Another TMD specialist (B) not involved in the examinations or assessments of the results handed out and adjusted the appliances.

The questionnaire used at baseline and at the follow-ups included questions about the frequency of myofascial pain to be rated on a 9-point verbal scale as follows: never, rarely, once a month, once every second week, once a week, twice a week, 3–4 times a week, daily, or constantly. The intensity of myofascial pain was registered according to the following 5-point verbal scale: no pain, slight, moderate, severe, and very severe. At the start, the patients registered their worst myofascial pain on a visual analog scale (VAS). At the follow-ups, the pain registrations were made on a VAS where their initial scores were shown (13, 14). Changes in pain at rest and/or during mandibular movements were also reported. The overall change in severity of symptoms was registered in accordance with a 6-point verbal scale: symptom-free, much better, better, unchanged, worse, much worse. A report of symptom-free, much better, and better was judged to be a positive treatment outcome. The patients were asked how they used their appliance: every night, several nights a week, when necessary, or not at all. Discomfort connected with use of the appliance was registered along with any additional treatment.

The clinical examination at baseline and 6 and 12 months after treatment included registration of maximal opening capacity, pain during mandibular movements, temporomandibular joint (TMJ) sounds, and lateral and/or posterior tenderness of the TMJ. The following muscles were palpated: the temporal, the masseter, and the lateral pterygoid, and the submandibular and posterior mandibular regions. The muscles were palpated at baseline and at the follow-ups by the same examiner, and the number of tender sites was registered. These clinical variables have been found to be reliable with kappa values from acceptable to good levels (15, 16).

After the baseline examination, patients in group T were given a stabilization appliance and patients in group C a control appliance. The control appliance had palatal coverage and clasps on the maxillary teeth, and the appliance did not interpose between occluding teeth. The designs of the appliances have been described previously (8). During the 10-week treatment period, patients were told to use the appliances every night. At the follow-ups,

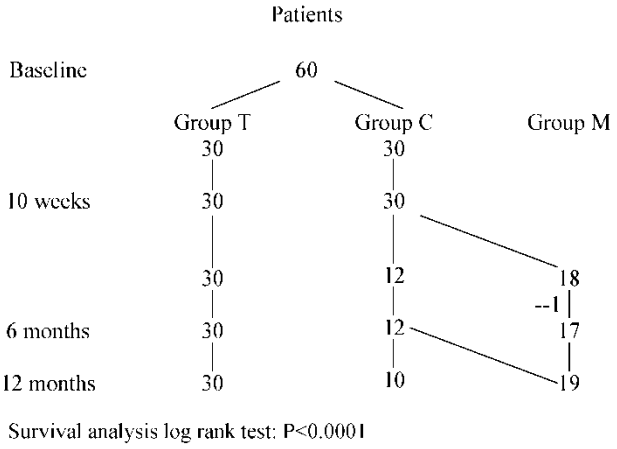
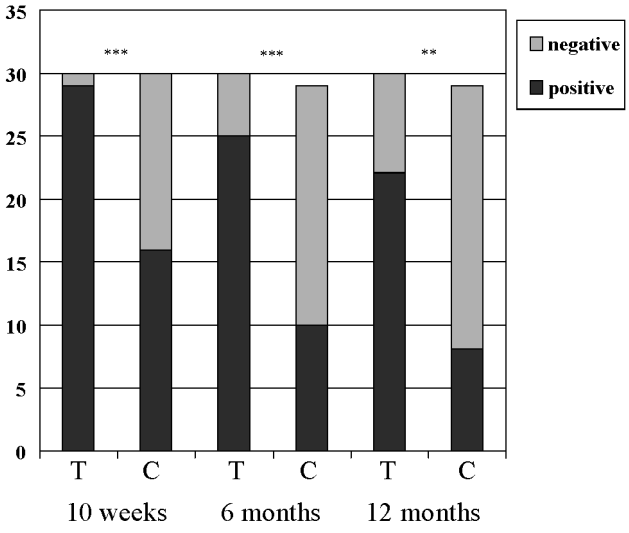


Fig. 1. Distribution of patients at baseline, at the 10-week evaluation, and at the 6- and 12-month follow-ups in all patient groups (T = treatment group, C = control group, M = mixed group). One patient from group M dropped out after the 10-week evaluation.

however, they were told to use the appliances when necessary. The results from the 10 weeks' follow-up have been presented in detail earlier (9).

Statistical analysis

The chi-square test was used for comparison of treatment outcome on a nominal scale to determine whether the differences between groups T and C were significant. For evaluation of treatment compliance between groups T and C a survival analysis log rank test was used. The McNemar test was used to compare the distribution of categorical variables and Wilcoxon's signed-rank test was used for variables measured on an ordinal scale. These tests were used to determine the significance of differences within groups. Differences at the 5% level of probability were considered statistically significant. The Bonferroni test was used to correct categorical variables and adjust *P*-values to avoid mass significance.



Chi-square test. **P*<0.05, ***P*<0.01, ****P*<0.001.

Fig. 2. Number of patients reporting a change in overall subjective symptoms on a verbal scale in the treatment group (T) and in the control group (C) at the 10-week evaluation and at the 6- and 12-month follow-ups. The change in overall subjective symptoms was judged to be positive when the patient reported being better, much better, or symptom-free. The change in overall subjective symptoms was judged to be negative when the patient reported being unchanged, worse, or much worse. Only one patient had dropped out from group C at the 6- and 12-month follow-ups.

Results

The 6-month follow-up

After the 10-week period of treatment, 17 patients in group C requested another appliance; these patients were therefore considered drop-outs. In an intent-to-treat analysis comparing groups T and C in regard reported improvement of overall subjective symptoms, a significant difference was found between groups T and C ($P < 0.0001$) (Fig. 2). Six patients in group T reported total remission of their myofascial pain.

At baseline, 23 patients in group T suffered from daily or constant myofascial pain. This number decreased significantly ($P < 0.0001$) to 6 patients at the 6-month follow-up. The number of patients in group T reporting the intensity of myofascial pain to be moderate or higher decreased significantly from 29 to 14 patients ($P < 0.0001$), and among those in group T who registered their pain to be severe or very severe from 14 to 3 patients ($P = 0.03$). In group T, the number of patients reporting pain at rest decreased significantly from 24 to 5 ($P < 0.0001$) and of those reporting pain during mandibular movements from 29 to 16 ($P < 0.0001$).

The number of tender sites on the masticatory muscles was also significantly reduced at this follow-up in group T ($P < 0.0001$) (Table 1). Table 1 presents results from the clinical examination.

Eighty-three percent of the patients in group T ($n = 30$) and 82% in group M ($n = 17$) reported an improvement in overall subjective symptoms. Of the 12 patients in group C, 83% reported improvement.

A statistically significant decrease from baseline in the levels of the worst experienced myofascial pain as marked on the VAS was found in all three groups (Fig. 3). A reduction of 30% or more was found in 60% of the patients in group T, 83% in group C, and 47% in group M.

The 12-month follow-up

Because 2 more patients in group C requested a different appliance after the 6-month follow-up, 19 patients were considered drop-outs. In comparisons of groups T and C regarding reported improvement in overall subjective symptoms in an intent-to-treat analysis, a significant difference was found ($P = 0.003$) (Fig. 2). In a survival analysis, the relative rate of non-compliance was 2.0 in relation to the number of patients, and that was significant ($P < 0.0001$, $\chi^2 = 29.476664$) (Fig. 1). Seven patients in group T reported remission of their myofascial pain.

The number of patients in group T who suffered from daily or constant myofascial pain decreased significantly ($P < 0.0001$) from 23 to 3. The number of patients in group T who reported the intensity of myofascial pain to be moderate or higher decreased significantly ($P < 0.0001$) from 29 to 15 and from 14 to 1 among those who registered their pain as severe or very severe ($P = 0.01$). In group T, pain at rest decreased significantly in 19 of the 24 patients ($P < 0.0001$) who reported this, while pain during

Table 1. Number of patients with signs of temporomandibular disorders at baseline and at the 6- and 12-month follow-ups in the three patient groups (T = treatment group, C = control group, M = mixed group)

Signs	6 months						12 months					
	T (n = 30)		C (n = 12)		M (n = 17)		T (n = 30)		C (n = 10)		M (n = 19)	
	Baseline	After	Baseline	After	Baseline	After	Baseline	After	Baseline	After	Baseline	After
Maximal opening capacity <40 mm	2	1	1	1	3	1	2	0	1	1	3	1
Maximal opening capacity (mean, mm)	47	49	52	54	47	50	47	49	51	53	48	51
Pain during mandibular movements												
0	12	17	7	10	3	9	12	17	7	5	5	10
1	4	9	3	0	5	6	4	8	1	3	5	5
2–4	14	4	2	2	9	2	14	5	2	2	9	4
Masticatory muscles												
Tender sites (mean, *s*)	7 (±4)	4 (±3)***	6 (±3)	3 (±3)	8 (±2)	6 (±3)*	7 (±4)	4 (±3)***	6 (±3)	3 (±2)	8 (±2)	5 (±4)*
TMJ												
Lateral and/or posterior tenderness	0	0	0	1	0	4	0	4	0	1	0	6
Reciprocal clicking	14	8	6	7	6	5	14	9	5	4	7	5
Locking	0	0	0	0	0	0	0	0	0	0	0	0
Crepitation	0	0	0	0	0	0	0	0	0	0	0	0

s = standard deviation.
McNemar test, Wilcoxon's signed-rank test, Bonferroni test: * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

mandible movements decreased significantly in 13 of the 29 patients ($P < 0.0001$).

The number of tender sites on the masticatory muscles was also significantly reduced in group T (Table 1).

Seventy-three percent of the patients in group T ($n = 30$) and 68% in group M ($n = 19$) reported improvement in their overall subjective symptoms. All 10 patients in group C reported improvement.

A statistically significant decrease from baseline in the levels of the worst experienced myofascial pain as marked on the VAS was found in all three groups (Fig. 2). A reduction of 30% or more was found in 60% of the patients in group T, 68% in group C, and 63% in group M.

Use of appliances and side effects

Sixty-seven percent of all patients reported that they used their OA at least several times a week at the 6-month follow-up. At the 12-month follow-up, this figure had decreased to 47%. Fifteen percent of all patients did not use their OA at all at the 6-month follow-up compared to 10% at the 12-month follow-up.

During the trial, 20% of the patients in group T, 10% in group C, and 11% in group M reported discomfort with the OA: feelings of queasiness, tightness from the appliance, tenderness in the teeth, mouth dryness, increasing pain, or decreased mouth opening capacity.

Additional treatment

Only one patient in group T reported additional treatment for TMD at the 6-month follow-up and none from the other groups. The patient had had acupuncture, and at the 12-month follow-up had also received physical therapy.

Discussion

The hypothesis of this study was rejected because 70% or more of the patients in group T reported an improvement in their overall subjective symptoms at the 10-week, 6-month, and 12-month follow-ups. Twenty-three percent of the patients in group T reported total remission at the 12-month follow-up. All of these patients except one had also reported the same at the 6-month follow-up. It has been stated that the treatment outcome in clinical studies differs from that in randomized controlled trials in that the clinical studies report better treatment outcomes (17). It is interesting to note that the results from our study are comparable to those of clinical studies in which 70% to 90% of the patients reported reduction in symptoms. In our study, however, high figures were found for relief of symptoms in a long-term perspective. It was obvious in Fig. 1 that survival rate for the stabilization appliance was higher than for the control appliance. Other long-term follow-ups have reported similar results (19–21). The

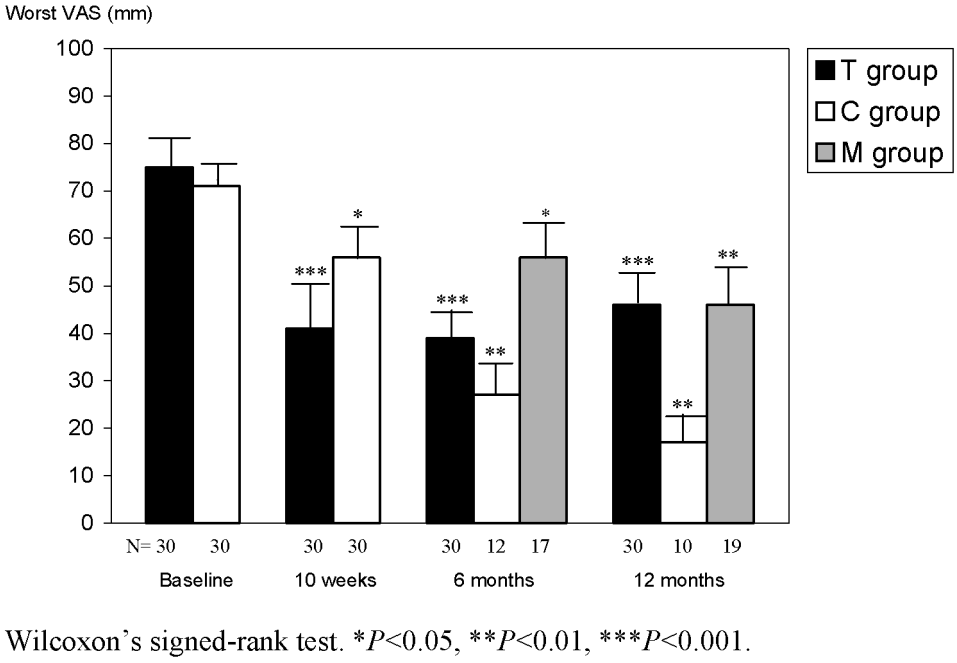


Fig. 3. Mean values and standard deviation of the level of the worst experienced myofascial pain registered on VAS at baseline, after 10 weeks, and after 6 and 12 months in all patient groups (T = treatment group, C = control group, M = mixed group).

cognitive treatment used in two of these studies, however, gave even better results.

Although the goal per se is not to encourage use of an OA for more than 6–8 weeks, it is still of interest to study a group of patients suffering from chronic myofascial pain and their need to use an OA. Not many studies evaluate the long-term results of treatment with an OA (11, 19–21), one reason being that it is time-consuming, but it could also be that OA therapy is primarily designed as short-term treatment. Patients suffering from chronic pain, though, have a great and prolonged demand for treatment and care.

Only 2% of the patients failed to complete the full course of this controlled trial, making the within-group comparisons of the appliances reliable. Solely in group C was there a change of appliance, since none of the patients from group T requested treatment with another appliance. With this controlled trial it was not possible to follow the original design, as it would have been unethical not to accede to the patients' requests for a different appliance.

For the best possible result in treatment with a stabilization appliance, the occlusal surface should be periodically adjusted to compensate for changes in the relation between maxilla and mandible due to pain, muscle activity, or alterations in the structural relations of the soft tissues (22). However, not every patient needed his or her appliance adjusted.

This trial showed that the beneficial effect on the subjective symptoms 'frequency of myofascial pain' and 'intensity of myofascial pain' and the clinical sign 'number of tender masticatory muscles' registered after the 10-week period of treatment (9) remained essentially unchanged within group T throughout this trial. This is in line with another long-term follow-up in patients with TMD of mainly arthrogenous origin (11), where the decrease in number of tender masticatory muscles was not registered until the 12-month follow-up, indicating that it takes longer to reduce muscle tenderness in patients with TMJ pain.

It has to be kept in mind that spontaneous remission (23) and natural fluctuations in condition, as well as the placebo effect (24), are factors important for a positive treatment outcome. Owing to the design of this controlled trial, group C consisted of patients with a positive treatment outcome at the follow-ups. It is emphasized, though, that group C decreased markedly in number. The positive outcome in this group corresponded more to a placebo effect than to a specific therapeutic effect at both the 6- and 12-month follow-ups, as only 10 patients out of the original 30 had a positive treatment outcome at the 12-month follow-up.

A statistically significant reduction in the mean of the worst myofascial pain registered on the VAS was found in all three groups at all follow-ups; this corresponded well with the results for treatment of TMJ pain (11). Continuous registration on the VAS was not made. However, the patients were evaluated several times during the year, making the pain registration on the VAS of value. These pain registrations should be seen in the perspective of treatment of chronic pain patients. The validity of the

VAS estimates made by patients with chronic pain has previously been reported to be unsatisfactory (25). The explanation was that reliability of the VAS is low for measurements of pain relief because chronic pain patients have difficulty recalling a previous pain experience. Carlsson (25) recommended using complementary indices of pain relief when assessing the efficacy of treatment. At the start of our study, all except three patients reported their pain to be chronic (6 months or more), which should be taken into consideration when evaluating the treatment outcome registered on the VAS in our study. We chose a pain reduction of 30% on the VAS to be clinically relevant, as presented by Farrar et al. (26). A 30% reduction of pain in long-term follow-ups of treatment with OA has previously been reported (20, 21).

Although the patients suffered from chronic myofascial pain, most reported a positive change in overall subjective symptoms. Approximately 50% of the patients reported use of their OA several times a week. No other recommendation was made regarding use of the OA except when needed after the first 10 weeks. It appears that the patients who suffered from chronic myofascial pain benefited from their OA.

One patient reported additional treatment, which was well in line with another long-term controlled trial of treatment with OA (11). In the study by Dao et al. (7), five patients reported other treatments at the short-term follow-up. In contrast to our study, Dao et al. recommended use of the OA day and night.

The result of this controlled trial in a long-term perspective was contrary to the hypothesis. The stabilization appliance was effective in alleviating both signs and symptoms in patients with myofascial pain. At the 10-week follow-up, many patients in group C reported a negative treatment outcome, complained about discomfort associated with the control appliance, or both, which left a small C group. Most patients in groups T and M reported a high rate of positive change in their overall subjective symptoms. We therefore recommend the stabilization appliance in the treatment of TMD patients with myofascial pain.

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