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# Effect of stabilization splint therapy on pain during chewing in patients suffering from myofascial pain

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**SUMMARY Masticatory myofascial pain (MFP) condition is a musculoskeletal disorder that compromises the functional capacities of the masticatory system. As such, the incorporation of an intensive chewing test as a discriminatory exercise for the diagnosis of this condition and evaluation of treatment success has considerable potential. Various splint designs have been used successfully, which have posed a question of whether the therapeutic effect of the splint is a placebo or has some other curative properties. The purpose of this study was to evaluate the efficacy of the stabilization appliance to reduce signs and symptoms in MFP patients and to compare the pain experience during the chewing test between two groups of patients, with and without splints. Myofascial pain patients ($n = 37$) who reported exacerbation of pain in function participated in the study. Patients perfomed a 9-min chewing test, followed by 9-min rest and marked their pain intensity on a visual analogue scale every 3 min. Of the 37 patients, 21 received a stabilization flat occlusal splint for night use and 16 were equally monitored clinically without a splint. At the end of 8 weeks, a second clinical examination and chewing test were performed. Student's *t*-test was used to analyse differences between study groups. Analysis of variance and covariance (ANCOVA) with repeated measures was applied to analyse the effect of treatment. Level of pain at baseline prior to the chewing test (P0) was introduced as a co-variant. At baseline both groups showed relatively high scores of pain intensity and did not show any significant differences among the collected variables. At the end of the experiment, the splint group had a statistically significant reduction in pain intensity, in mean muscle sensitivity to palpation and in the pain experience during the chewing test compared with no change in the controls. A stabilization splint has a therapeutic value beyond its placebo effects. Thus, it should be an integral part of the treatment modalities in MFP disorder patients. An intensive chewing test is an effective tool to evaluate the treatment modality efficacy in MFP patients.**

**KEYWORDS: temporomandibular disorder, myofascial pain, stabilization splint, chewing, occlusal appliance, oro-facial pain**

## Introduction

Myofascial pain (MFP) is a temporomandibular disorder (TMD) categorized as a functional disorder of the muscles of mastication (Okeson, 1996). It is characterized by a dull, aching, radiating pain that becomes aggravated with jaw movement and function, and may involve limited mouth opening (Dworkin & LeResche, 1992).

One treatment option for MFP is an occlusal stabilization splint, which are beneficial in reducing symptoms (up to 70–90%) in patients with TMD. However, there is no agreement concerning their action mechanism (Clark, 1988; Okeson, 1993). Moreover, there are contradictory reports regarding the efficacy of splint therapy in MFP patients. The subjective outcome of splint therapy including non-occluding placebo splints for the treatment of MFP patients has been studied (Greene & Laskin, 1972). Following the use of non-occluding placebo splints, 40% of the patients reported some relief. Of all patients included in their

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study, 26% reported no change in symptoms, regardless of the splint design used.

In another study (Rubinoff, Groos & McCall, 1987) the efficacy of hard acrylic flat splint versus non-occluding splint serving as a control was studied, among MFP and internal derangement patients. The subjective and objective parameters revealed no statistical significant effect for the flat splint after 6 weeks of treatment. In two other studies (Johansson *et al.*, 1991; List *et al.*, 1992) of MFP and internal derangement patients, the flat splint was more effective, both subjectively and objectively, when compared with the control group.

Dao *et al.* (1994a) studied three groups of MFP patients: one group received a flat occlusal splint for 24 h; the second, a non-occluding splint for 24 h; and the third, a flat occlusal splint for 30 min prior to a functional chewing test. Pain intensity and unpleasantness were recorded at rest and after experimental mastication of 3 min. The results indicated that the variables measured were unrelated to the type of treatment. Thus, the effects of a flat splint inserted for 30 min prior to the experiment or a non-occluding splint for 24 h, both reduced symptoms similar to that of the group treated with a flat occluding splint for 24 h. The non-specific effect of the treatment could be attributed to the placebo effect of the splints. The study did not use a control group without a splint to evaluate the natural course of the disorder. This is particularly important when studying the effect of treatment in MFP patients as they exhibit a cyclic fluctuation of symptoms and a high rate of spontaneous remission (Stohler, 1999).

The diagnosis MFP is based on the report of pain level and disability on the clinical examination of mouth opening, and tenderness to palpation of the masticatory muscles (Dworkin & LeResche, 1992). Theoretically, since MFP is a musculoskeletal disorder, it is related to the functional demands and functional manipulation upon examination (Okeson, 1995). In a clinical study, a functional chewing test of 3 min exacerbated pain in most MFP patients but had no effect on asymptomatic subjects (Dao, Lund & Lavigne, 1994b).

Based on all of these findings, there is a need for a more specific detection of the effect of splint therapy on MFP patients experiencing pain exacerbation in chewing. The incorporation of an intensive chewing test could be helpful in the diagnostic process, as well as in the evaluation of any treatment efficacy when the functional performance occurs.

The objectives of this study were to evaluate the efficacy of the stabilization appliance in reducing signs and symptoms in MFP patients, and to compare the pain experience during the chewing test between patients treated with the stabilization appliance and controls without any appliances.

## Subjects and methods

The study population comprised 37 individuals extracted from a large body of patients referred for treatment at the TMD Clinic, Tel-Aviv University. All were diagnosed as suffering from a MFP disorder according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) (Dworkin & Leresche, 1992). The inclusive criteria for participating in the study were between 16 and 45 years, masticatory muscle pain present for at least 6 months at a frequency of at least four times a week, sensitivity to palpation in at least two sites of the masseter and/or temporalis muscles, natural dentition with no more than one missing tooth per quadrant, no evidence of carious lesions or periodontal disease, and an increase in masticatory muscle pain during a chewing test of at least 15 mm on a visual analogue scale (VAS).

Exclusive criteria were temporomandibular joint disease or disorder diagnosed clinically or radiologically, chronic disease or continuous use of medication, history of trauma to the facial or cervical regions, and previous treatment related to their disorder during the last 6 months.

All patients gave their informed consent to participate in the study.

Patients were divided into two age- and gender-matched groups. The experimental splint group consisted of 21 patients (16 females and five males, mean age $30{\cdot}3 \pm 9{\cdot}12$), who received treatment with a Michigan type stabilization appliance for night use (Okeson, 1993). The control group consisted of 16 patients (13 females and three males, mean age $27{\cdot}5 \pm 6{\cdot}65$) who did not receive an appliance.

All patients underwent a personal interview and were provided with a detailed explanation of their disorder, its cyclic nature and possible aetiology. Both groups were examined clinically at the same time intervals. Clinical examination at the beginning (S-1) and at the end of the experiment (S-6) was conducted by the same examiner who was unaware of the patient group affiliation.

*Experimental design*

At the first visit (S-1) all patients filled out the RDC/TMD questionnaire and were then examined clinically by a single faculty member. In addition to the scores recommended in the RDC/TMD index, the arithmetical mean value for the eight sites of the superficial muscles of mastication (origin and insertion of the masseter muscle – right and left, the anterior and middle portion of the temporalis muscle – right and left) was also calculated.

Patients were then requested to perform an experimental chewing exercise modified from Dao *et al.* (1994b) as follows:

**(1)** Initially, patients were asked to indicate on VAS, ranging from 0 to 100, their pain intensity at rest (P0).

**(2)** Patients were then requested to chew half a leaf of green casting wax, gauge 28* for 9 min.

**(3)** In the process of chewing, patients were requested to indicate their pain intensity on VAS, at 3, 6 and 9 min.

**(4)** At the end of 9 min of chewing, patients were instructed to hold their jaw at rest for an additional 9 min.

**(5)** During the rest period, patients were again requested to mark their pain intensity on VAS every 3 min, e.g. 12, 15 and 18 min from the beginning of the experiment. Each of the requested VAS recordings was provided on a separate page to avoid possible bias by former recordings. At the end of the first session, impressions for a stabilization splint were taken from the patients in the experimental group.

At the second session, 2 weeks later, the experimental group received the stabilization appliance and the controls were only re-examined. At sessions 3, 4 and 5, at 2-week intervals, all patients were seen, minor adjustments of the stabilization appliance were performed in the study group and patient support and encouragment to both groups was given. At the end of 8 weeks (S-6), a second clinical examination and a similar chewing test were performed.

Student *t*-test was used to analyse differences between study groups (splint versus control) regarding their signs and symptoms and patient characteristics according to RCD/TMD, and the value change in each clinical variable between S-1 and S-6. Analysis of variance and covariance (ANCOVA) with repeated measures was applied to analyse the effect of treatment (S-1 versus S-6) of the group (splint versus control), mode of activity during the chewing test (chewing phase versus resting phase), and effect of time during the chewing test on pain intensity. The level of pain at baseline prior to the chewing test (P0) was introduced as a covariant. The level of significance was set at $P < 0{\cdot}05$.

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## Results

*Comparison between study groups at baseline (S-1)*

Splint versus control group at baseline (S-1) regarding patient characteristics and all collected clinical and self-report variables, revealed no significant differences (Tables 1 and 2).

For both groups, the variables describing pain intensity showed relatively high scores. The mean present pain was $59{\cdot}57 \pm 27{\cdot}73$ for the splint group and $46{\cdot}00 \pm 26{\cdot}23$ for the control group. The mean maximal pain was $78{\cdot}00 \pm 20{\cdot}17$ in the splint group versus $71{\cdot}06 \pm 22{\cdot}95$ in the control group and the calculated pain intensity was $65{\cdot}18 \pm 23{\cdot}02$ for the splint group and $56{\cdot}88 \pm 22{\cdot}80$ for the control group. The total duration of pain, including periods of remission and exacerbation, according to the patient's report was long-term: $28{\cdot}48 \pm 28{\cdot}99$ months for the splint group and $34{\cdot}81 \pm 28{\cdot}37$ for the control group. However, in both groups the degree of disturbances in daily social and family activity caused by the pain was not high.

As expected, Axis II parameters indicated a moderate degree of depression and somatization in both groups.

The clinical variables of active and passive mouth opening (AMO, PMO) were in the normal range with no differences between groups. The mean muscle sensitivity (MMS) was elevated in both groups, in accordance to the inclusive criteria of the study.

**Table 1.** Characteristics calculated from the finding of the RCD/TMD score

| | Splint group | Control group |
|---|---|---|
| Pain duration (months) | $28{\cdot}48 \pm 28{\cdot}99$ | $34{\cdot}81 \pm 38{\cdot}37$ |
| Pain intensity (VAS) | $65{\cdot}18 \pm 23{\cdot}02$ | $56{\cdot}88 \pm 22{\cdot}80$ |
| Disability score | $39{\cdot}80 \pm 34{\cdot}85$ | $22{\cdot}43 \pm 21{\cdot}61$ |
| Depression score | $0{\cdot}740 \pm 1{\cdot}386$ | $0{\cdot}828 \pm 0{\cdot}578$ |
| Somatization score | $0{\cdot}674 \pm 0{\cdot}554$ | $0{\cdot}868 \pm 0{\cdot}733$ |
| Somatization without pain items score | $0{\cdot}557 \pm 0{\cdot}573$ | $0{\cdot}622 \pm 0{\cdot}711$ |

**Table 2.** Clinical signs and symptoms at initial examination (S-1), at the end of the study (S-6) and the value-change (Δ) in each variable during 8 weeks of follow-up

| Signs and symptoms | | Splint group | Control group | *P*-value* |
|---|---|---|---|---|
| Present pain (VAS) | S-1 | 59·57 ± 27·73 | 46·00 ± 26·23 | |
| | S-6 | 29·62 ± 22·63 | 41·25 ± 30·34 | |
| | ΔS | 30·24 ± 32·19 | 4·75 ± 17·23 | 0·0083 |
| Active mouth opening (mm) | S-1 | 43·33 ± 11·19 | 48·31 ± 4·69 | |
| | S-6 | 48·24 ± 8·14 | 50·19 ± 5·59 | |
| | ΔS | −4·90 ± −6·11 | −1·87 ± −3·70 | |
| Passive mouth opening (mm) | S-1 | 48·76 ± 8·56 | 52·44 ± 5·94 | |
| | S-6 | 51·24 ± 8·07 | 53·81 ± 6·68 | |
| | ΔS | −2·48 ± −2·94 | −1·38 ± −2·28 | |
| Difference passive–active | S-1 | 5·43 ± 4·20 | 4·12 ± 3·22 | |
| | S-6 | 3·00 ± 1·82 | 3·81 ± 2·64 | |
| | ΔS | 2·43 ± 3·93 | 0·31 ± 2·96 | |
| Mean muscle sensitivity (points) | S-1 | 1·78 ± 0·57 | 1·82 ± 0·53 | |
| | S-6 | 1·09 ± 0·64 | 1·72 ± 0·57 | 0·0042 |
| | ΔS | 0·68 ± 0·80 | 0·09 ± 0·39 | 0·0102 |

**P*-value according to Student's *t*-test.

*Effect of mode of treatment approach on patients' subjective report and clinical signs*

The patients' clinical signs and symptoms as recorded at the end of the study (S-6) and their change in value when compared with those recorded at the beginning (Δ = S6-S1) for each variable are presented in Table 2. The present pain decreased by 30·24 ± 32·19 in the splint group compared with only 4·75 ± 17·23 in the control group ($P = 0·0083$).

The clinical variables of AMO and PMO, which were in the normal range with no difference between the groups at the beginning of the study, showed a slight increase at the end in both groups, with no statistical difference between them. The MMS decreased to a lower level in the splint group compared with the control group (1·09 ± 0·64 versus 1·72 ± 0·57, $P = 0·0042$). The difference in value between S-1 and S-6 favoured the splint treatment mode: MMS decreased by 0·68 ± 0·80 in the splint group while in the control group it decreased by only 0·09 ± 0·39 ($P = 0·0102$).

*Effect of treatment approach on the chewing test*

Pain intensity during the chewing test at initial examination (S-1) and at the end of the study (S-6) are presented in Fig. 1 for the splint group and in Fig. 2 for the control group.

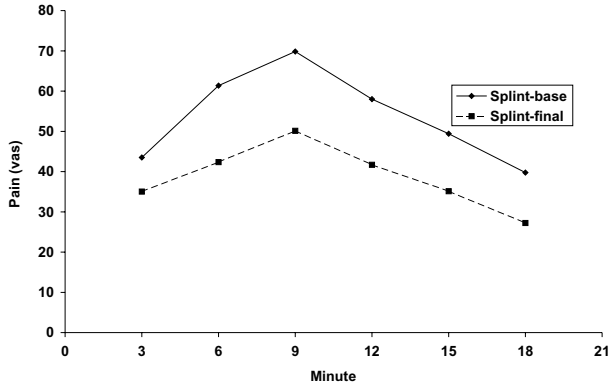


**Fig. 1.** Chewing test at the beginning and end of the study (splint group).

The ANCOVA with repeated measures, while the covariance was pain level at baseline prior to the chewing test, showed the following: (i) A main effect of time from the initial examination to the end of the study (S-1 versus S-6) ($P = 0·0031$). (ii) An interaction between the time (S-1 versus S-6) and treatment approach (splint versus control) ($P = 0·0036$). The pain level during the chewing test decreased significantly following the use of the splint, while in the control group the pain level remained the same at the two chewing tests (at S-1 and

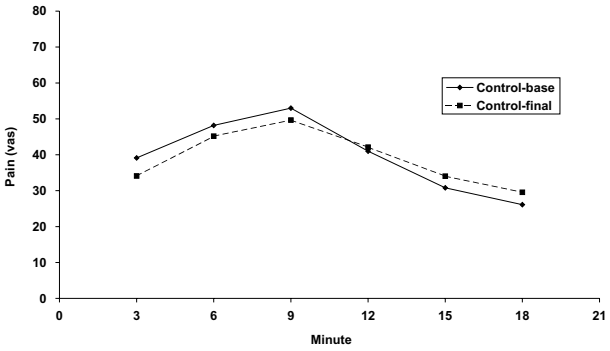


**Fig. 2.** Chewing test at the beginning and end of the study (control group).

S-6). (iii) A main effect of activity during the chewing test (chewing phase versus resting phase) ($P = 0{\cdot}0049$). (iv) An interaction between activity and the effect of time during the chewing test ($P < 0{\cdot}001$). Pain increased during the chewing phase and decreased during the resting phase. This effect was unrelated to the time between the initial examination to the end of the study or to the treatment approach.

## Discussion

The present study design included two groups of MFP patients with no temporomandibular joint involvement. All patients had pain at rest that exacerbated in function. This indicated that the group was relatively homogeneous, unlike the report of Dao *et al*. (1994a) whose group did not have a uniform reaction. Like other musculoskeletal conditions, such as low back pain, a provocation of aggressive movement is likely to provoke increased pain. It was conceivable to assume that the incorporation of an intensive chewing exercise would raise pain intensity. Musculoskeletal disorders are usually of a cyclic nature and most often remissions are spontaneous (Stohler, 1999). In chronic MFP conditions, patients normally request an active treatment intervention. Splint treatment is an efficient, reversible, and non-invasive modality in which its attributes are not fully understood and are considered, to a large extent, to be a placebo (Clark, 1988; Okeson, 1993; Schiffman, 1995; Dao & Lavigne, 1998). To estimate their value, it is strongly suggested to incorporate a chewing test as described in the present study. As it poses increased functional demands on the masticatory muscles, it may possess the potential to discriminate between the placebo effect and other processes that occur, which allow a better masticatory performance. It also allows an instantaneous pain report on VAS, which is easier to determine than one from memory.

In the experimental group three clinical findings strengthened the assumption that the treatment efficacy of the stabilization splint was remarkable for the duration of this experiment when compared with the control group. Reduction in pain intensity (VAS), MMS and level of pain experienced during the chewing test on VAS was significant in the splint group at the end of the experimental period compared with the controls who did not show any reduction in these parameters.

Several studies report the superiority of the flat stabilization appliance when compared with a no treatment control group, without chewing tests and in mixed TMD populations (Lundh *et al*., 1985, 1988; Johansson *et al*., 1991; List *et al*., 1992). However, other studies question the validity of the stabilization splint as a treatment modality and claim that even non-occluding splints are equally beneficial (Rubinoff *et al*., 1987; Dao *et al*., 1994a; Schiffman, 1995; Dao & Lavigne, 1998; Stohler, 1999). These studies did not incorporate a control group without a splint and did not test pain behaviour under increased functional load, such as experimental chewing. One study found a placebo beneficial effect of splints under increased functional demands of 3-min duration (Dao *et al*., 1994a). In our opinion, the short chewing task and the possible mixed group as far as reaction to the chewing effort (pain elevation or reduction; Dao *et al*., 1994b) may be responsible for the contradiction with the present study results.

In our study, the pain decrease in the experimental group during the chewing test as compared with the control group may be unrelated to the specific appliance design. It needs to be shown whether a similar pain decrease will occur with non-occluding splints or other splint designs, as favourable treatment effects have been shown in other studies (Lundh *et al*., 1985; Dao *et al*., 1994a). If this occurs, it may be assumed that the mechanism of action is unrelated to the appliance design but to other aspects associated with the appliances, such as a change in the cognitive awareness and behavioural modification (Okeson, 1993) of the patients. This leads to the assumption that in a true placebo design, the control group should not receive any appliance in the oral cavity.

It was assumed that under significant functional demands as requested during a 9-min chewing, the placebo component of the splint would be less significant. During this tiring masticatory performance, consumption of considerable energy imposes a strain on the muscle tissue. In an MFP patient a sensitive muscle should not react with a remarkable reduction in pain levels unless the healing process has started. The incorporation of a non-splint control group allows us to negate a spontaneous recovery, which is characteristic to the cyclic behaviour of the MFP disorder (Stohler, 1997; Magnusson, Egermark & Carlsson 2000). A similar study incorporating an extended experimental chewing test in a group of patients wearing non-occluding splints is underway. It will allow us to further evaluate the relative contribution of the splint presence and design to the recovery processes. Our assumption is that in the presented study conditions, the beneficial therapeutic effect of the stabilization appliance is beyond a placebo effect.

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