

Reduction in parafunctional activity: a potential mechanism for the effectiveness of splint therapy

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SUMMARY Interocclusal splints may be an effective modality in the management of temporomandibular disorders (TMD), but there is little evidence regarding the mechanism by which splints work. This study tested the hypothesis that pain reduction produced by splints is associated with reduction in parafunctional activity. In a two-group, single-blinded randomized clinical trial, patients diagnosed with myofascial pain received full coverage hard maxillary stabilization splints. Patients were instructed to maintain or avoid contact with the splint for the 6 weeks of active treatment. Patients who decreased the intensity of tooth contact were expected to show the greatest alleviation of pain, and those who maintained or increased contact were expected to report lesser reductions in pain. Experience-sampling methodology was used to collect data

on pain and parafunctional behaviours at pre-treatment and during the final week of treatment. Patients were reminded approximately every 2 h by pagers to maintain/avoid contact with the splint. The amount of change in intensity of tooth contact accounted for a significant proportion of the variance in pain change scores. Patients who reduced tooth contact intensity the most reported greater relief from pain. Splints may produce therapeutic effects by reducing parafunctional activities associated with TMD pain.

KEYWORDS: temporomandibular disorders, pain, parafunction, treatment, splint, experience sampling

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Introduction

Intraoral orthotic or splint therapy is the most common therapeutic approach used to treat patients diagnosed with temporomandibular disorders (TMD) (1). There is general consensus that splints are useful in the conservative treatment of TMD (2–5), although the mechanism of efficacy is not fully understood. Practitioners use many different types of splints (e.g. stabilization, repositioning, distraction) fabricated from both hard and soft materials. Some of the rationales for use of an interocclusal splint have included management of pain and dysfunction of the masticatory muscles, modification of intermaxillary relationships and occlusal force distribution, reduction of parafunctional activity, removal of occlusal interferences, changing intracapsular structural relationships in the TMJ, and control of tooth wear and mobility (6).

Behavioural and psychological treatment modalities have also been used successfully to treat patients with TMD pain. A meta-analysis of the efficacy of biofeedback-based relaxation approaches reported larger treatment effects in patients who received these approaches compared with those assigned to placebo-control or no-treatment groups (7). Approaches using cognitive-behavioural methods have also reported encouraging results (8, 9), particularly in patients at risk for more refractory pain (10), and there is evidence that a combined splint and behavioural treatment condition may improve treatment relief when compared with either modality offered alone (11).

There is some evidence that parafunctional activities are an important etiological factor in TMD pain. Experimental studies show that both sustained maximal (12–15) and low-level clenching (16) increases

pain, and can lead to a diagnosis of myofascial pain or arthralgia in otherwise pain-free individuals (16–19). If parafunctions can cause TMD symptoms, it may be reasonable to expect that TMD patients have a higher rate of parafunctions than non-pain individuals. When experience-sampling methods (ESM) were used to compare TMD patients to a group of non-TMD controls, the patients with pain reported more frequent and intense contact than non-pain controls (20, 21). The hallmark of ESM is the collection of repeated momentary assessments from participants in their natural environments (22). The focus on momentary phenomena and immediate responding reduces various recall biases common to traditional self-report techniques.

Treatments targeting parafunctions decrease TMD pain. Some studies have used habit reversal (23, 24) to increase a patient's awareness of unwanted behaviour (i.e. parafunctions), develop an alternative to the unwanted behaviour (e.g. relaxation of the masticatory muscles), and substitute the alternative for the unwanted behaviour. Studies that use this technique to decrease parafunctions have reported success in reducing TMD pain (25–28). Some evidence suggests that patient groups using either habit reversal techniques or splints both experience significant relief from pain (29).

Splints are foreign objects in the mouth, and they may change oral tactile stimuli, decrease the oral volume space for the tongue, and make the patients conscious about the position and potentially harmful use of their jaws (30). This can cause patients to reduce or stop parafunctional activity. In their review of placebo-appliance controlled studies and studies that used non-treatment control groups published since 1995, Kreiner, Betancor, and Clark (31) concluded that 'occlusal appliances, when used for TMDs, work as behavioral interventions and not as medical devices that produce effects via physical changes in the position of the mandible... The behavioral effect of an occlusal appliance likely is... induced by both wearing a device and being in a study.' (p. 776). The reported efficacy of splints may be related to their impact on parafunctions rather than to various dental and joint mechanics.

This study examined the effect of parafunctions on the effectiveness of splint therapy for patients with myalgia and/or arthralgia. The fundamental hypothesis of the study was that reduction in parafunctional activity would account for a significant and meaningful proportion of the variability in pain reduction. Experience-sampling methods were used to assess

parafunctions and pain at pre-treatment and at the end of treatment.

In this randomized, 6-week trial, patients diagnosed with myofascial pain and/or arthralgia received stabilization splints. Patients were randomly assigned to one of two treatment groups in which they were instructed to avoid contact with the splint or to maintain light contact with the splint. A modification of ESM techniques was used to encourage patients to adhere to their assigned instructions throughout the study. The two treatment groups were given different sets of instructions to try to maximize differences in oral/tooth contact behaviours during the active phase of treatment. Based on the experimental hypothesis and assuming that patients strictly adhered to their treatment instructions, patients in the avoid contact group should have less pain than those in the maintain contact group at the end of treatment. In case patients did not strictly adhere to their treatment instructions, an analysis of the data by actual behaviour change should show that those who decreased tooth contact the most would experience the greatest relief from pain.

Methods

Subjects

Patients from a tertiary care center for the treatment of facial pain, located within a dental school, were given an opportunity to participate. In addition, advertisements to recruit subjects were printed in the region's largest circulation newspaper, announced on a commercial radio station, and e-mailed to every faculty, staff member, and student of the University of Missouri-Kansas City.

To be included in the study, patients had to meet all of the following criteria: (i) receive a diagnosis of myofascial pain and/or arthralgia according to the Research Diagnostic Criteria (RDC) for TMD (32); (ii) Have at least six natural teeth in each quadrant; (iii) be between the ages of 18 and 70 years; and (iv) live in the Kansas City metropolitan area. Patients who met any of the following criteria were excluded from the study: (i) any other TMD diagnosis according to the RDC, such as disk displacement, osteoarthritis, or osteoarthrosis of the TMJ; (ii) any systemic condition associated with widespread pain (e.g. fibromyalgia); (iii) any obvious dental decay or periodontal disease to which facial pain could be attributed; (iv) history of any condition whose

symptoms overlapped with TMD (e.g. migraine); (v) history of moderate to severe head or neck injury; (vi) previous experience with interocclusal splint therapy in the 6 months prior to the initial examination; and (vii) currently wearing orthodontic appliances.

Screening examination

Sixteen muscle sites accessible extraorally and four muscle sites accessible intraorally were palpated according to the techniques described in the RDC. Patient report of pain during muscle palpation was scored on a 0 to 3 scale, with 0 signifying no pain and 3 signifying severe pain. Pain in the TMJ was also determined by palpation and rated on a 0–3 scale. The presence of sound in the TMJ during vertical opening, closing, lateral excursion, and protrusion was determined by palpation, supplemented by auscultation. Pain-free unassisted mandibular opening and maximum unassisted opening were measured in mm. A panoramic radiograph was taken to assess for the presence of any gross pathology in the TMJ.

Splint fabrication and use

Maxillary flat plane acrylic interocclusal splints were fabricated on stone casts mounted on a Hanau semi-adjustable articulator in centric relation. The splint was fabricated with 2 mm thickness of acrylic between the maxillary and mandibular posterior teeth. The splint was adjusted to create uniform point contact of the centric cusps against the splint on all occluding posterior teeth. Anterior teeth were in light point contact or were discluded slightly. In excursive movements, contact with the centric cusps was uniform. A slight anterior and canine rise was achieved in protrusive functions, where possible. Patients were instructed to insert the splint for 20 h a day, somewhat less than the recommendations received by many TMD patients in the United States (1, 33), and to take it out during meals. Each was instructed to return to the clinic for adjustment of the splint after 2 weeks of use.

Experience-sampling methodology

Experience-sampling methodology (ESM) was used to obtain self-report data from participants. Subjects carried pagers in this study. The pagers were one-way devices that beeped or vibrated when contacted. A custom-programmed executable (exe) derived from

the Paradox® database (Version 8)* was used to place calls to pagers. The mean time between calls was 120 min, with a 40-min window of variability within which a specific call could be placed; a specific call to a subject could occur up to 20 min earlier or up to 20 min later than would be expected on a fixed, invariant schedule. The variability of calls was based on a random number generator that produced an equal distribution of values on either side of the expected call time. Variability in calling schedules reduced the possibility that subject behaviour would be affected by the anticipation of a call at a fixed point in time.

At pre-treatment and during the last week of treatment, subjects were instructed to fill out a pre-printed 3" × 5" card each time they were paged, unless doing so would jeopardize their safety. Subjects were asked to report on intensity of tooth contact, pain in the jaw, face or head, and pain in other parts of the body. Because some TMD patients report low levels of tooth contact but also report chronic 'tightness' in the masticatory muscles or report that they 'set' their jaws, subjects were asked to report on tension in the jaw, face and head. Intensity of tooth contact was recorded on a four-point scale (no contact to strong clenching), while the remaining variables were recorded on an 11-point (0–10) scale. The anchors for the pain measures were 'No pain' and 'Severe pain' and the anchors for the tension measure were 'Completely relaxed' and 'Extremely tense'.

During the other weeks of treatment, patients continued to carry pagers, and they did not fill out the pre-printed cards when they were paged. However, they were instructed to check tooth contact each time they were paged and to strive to follow the treatment instructions each had received in response to a page.

Pain diaries

During the pre-treatment and treatment weeks, patients were instructed to complete pain diaries four times a day: morning, noon, evening, and bedtime. Facial/jaw pain was recorded on a four-point scale where 1 represented no pain and 4 reflected the severe pain.

Group assignment

Patients were randomly assigned to either an Avoid Contact or Maintain Contact group. Individuals in the

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'Avoid Contact' group were told that the paging messages were a reminder for them to avoid any contact with the splint; individuals in the 'Maintain Contact' group were told that the paging messages were a reminder for them to rest the lower jaw against the splint with light tooth contact. All patients were also given instruction sheets consistent with their group assignment.

Dentists

Two dentists were used in the study. The treating dentist delivered the splint, provided treatment instructions to all patients at the time the splint was delivered, and performed all adjustments of the splint. The examining dentist, blinded to the patient's group assignment, performed all the tasks described in the screening and follow-up examinations.

Procedure

All patients signed an informed consent document approved by the university's Institutional Review Board. After completion of the screening examination, the examining dentist took impressions and bite registrations. All patients were asked to cease use of analgesic medications until the end of the study. Patients were then given a pager and copies of the eight-item pager questionnaire card. Each received instructions on the use of the pager and cards. Patients also received pain diary forms to complete.

After 1 week, patients returned to the clinic to return the pager data and to have the occlusal appliance inserted and adjusted by the treating dentist. After the splint was inserted and adjusted, a third investigator gave a sealed envelope containing the group assignment to the treating dentist. The treating dentist provided instructions to each patient appropriate to their group assignment. Patients were told to return to the clinic after 2 weeks of using the splint for follow up. Patients were reminded to follow the instructions they received each time they were paged and to complete the pain diary four times daily.

During the last (sixth) week of treatment, patients were instructed to fill out the pager questionnaires as they had in the pre-treatment week. After the sixth week, patients returned to the clinic for the final examination, performed by the blinded examining

dentist. At this visit, subjects also turned in the pagers, pager questionnaire data and pain diaries.

Outcome data and plan for statistical analysis

The key measures taken from the pager data were those concerning facial pain and intensity of tooth contact. For levels of pain and parafunctions obtained from the pager cards, descriptive statistics were computed for each patient. Pain was measured on an 11-point scale, and parafunctional activity was assessed as the mean intensity of tooth contact measured on a four-point scale. Degree of change was expressed as the slope of a best-fit regression line between data collected at pre-treatment and during the last week of treatment for tooth contact and separately for pain. For the pain diary, descriptive statistics were calculated by patient for each week.

Two sets of analyses were carried out. The first set examined actual change in behaviour and its relationship to pain reduction. To examine this hypothesis, an analysis of covariance was carried out, using the slope of the regression line representing change in intensity of tooth contact behaviour (as derived from the pager cards) as the covariate, group assignment as the independent variable, and the slope of the regression line representing change in pain as the dependent variable. If change in intensity of tooth contact were importantly related to pain relief, the covariate would account for a significant and meaningful proportion of the variance in pain reduction scores, and the group factor would not be significant. The second set of analyses was based on the assumption that patients actually followed the instructions provided by the treating dentist; i.e. all patients in the avoid contact group reduced tooth contact and all patients in the maintain contact group maintained or increased contact. The study was originally powered to detect a 20% difference between groups with a sample size of 20. Parafunction data, pager data on pain and pain diary data were subjected to a repeated measures analysis of variance. For all analyses, alpha was set to 0.05.

Results

Table 1 presents demographic data on enrolled subjects. The typical patient was a woman in her forties, with some college education, who reported chronic facial pain (i.e. pain greater than six months). Groups did not

Table 1. Demographic characteristics of patients

Group	Subjects enrolled	Female, male	Age (years)	Education (years)	Pain duration (years)
Avoid	5	4,1	45.0 (5.5)	14.4 (2.2)	9.4 (8.4)
Maintain	9	8,1	39.1 (12.6)	14.8 (2.6)	9.0 (6.3)

Figures in parentheses are standard deviations.

Table 2. Pain and parafunction data obtained from experience-sampling methods

Group	Tooth contact intensity*					Facial pain [†]				
	Pre-treatment		End of treatment		Change [‡]	Pre-treatment		End of treatment		Change [‡]
	Mean	s.d.	Mean	s.d.		Mean	s.d.	Mean	s.d.	
Avoid	2.04	0.62	1.28	0.22	-0.77	2.55	1.92	1.48	0.85	-1.13
Maintain	1.79	0.57	2.02	0.50	0.21	2.96	1.23	1.86	1.11	-1.18

*Tooth contact intensity recorded on a 1–4 scale.

[†]Facial pain recorded on a 0–10 scale.

[‡]Change in tooth contact intensity and facial pain, expressed as the mean of the unstandardized coefficients derived from regression analyses carried out for each subject between pre-treatment and the final treatment week.

differ statistically on any of the demographic variables. Two patients, one from each group, dropped out because of dissatisfaction with treatment. Two more patients, both from the Maintain group, failed to return for a final examination; both reported they were using the splint at the end of the study.

Table 2 presents tooth contact and facial pain data obtained from ESM. Most subjects completed the pager questionnaire within 3 min of contact. The degree of change in intensity of tooth contact was calculated as the coefficient of the least-squares regression line (calculated for each subject) between tooth contact and facial pain data at pre-treatment and at the end of treatment. Table 2 also shows the unstandardized coefficients generated by this analysis. Negative coefficients reflect a reduction in intensity of tooth contact or pain, while positive coefficients reflect an increase. The degree of reduction or increase in tooth contact intensity is reflected by the magnitude of these coefficients. All of the patients assigned to the Avoid group reported reduced intensity of tooth contact, and four of the six patients assigned to the Maintain group reported increased intensity of tooth contact. Groups did not differ significantly at baseline for either tooth contact intensity or pain.

A repeated measures analysis of covariance was performed on the unstandardized coefficients representing pain reduction, using the values representing

change in tooth contact intensity as the covariate. This analysis showed a significant Covariate effect, $F(1,7) = 8.35$, $P < 0.05$, partial eta-squared = 0.544, and no significant Group effect. Reduction in intensity of parafunctions accounted for a significant and meaningful proportion of the variance in pain reduction scores.

A repeated measures analysis of variance was conducted on the mean tooth contact intensity data per subject. This analysis showed a significant Time by Group interaction, $F(1,8) = 12.32$, $P < 0.01$, partial eta-squared = 0.606, and no significant Group or Time effects. An analysis of variance was also conducted on the coefficients representing the degree of change in tooth contact intensity that were created from regression analyses utilizing the multiple pre-treatment and end of treatment values. This analysis showed a significant Group effect, $F(1,8) = 10.96$, $P < 0.05$, partial eta-squared = 0.58, indicating that groups overall differed in tooth contact intensity. A repeated measures analysis of variance performed on mean facial pain data showed a significant effect for Time, $F(1,8) = 8.07$, $P < 0.05$, partial eta-squared = 0.502. A similar analysis conducted on the pain diary data also showed a significant effect for Time, $F(5,30) = 4.54$, $P < 0.01$, partial eta-squared = 0.431. Individuals assigned to the Avoid group reported greater decreases in tooth contact intensity during the treatment period than Maintain

group participants. Patients assigned to the maintain group increased the proportion of time in tooth contact from 50.7% (s.d. = 34.8) to 62.7% (s.d. = 35.7), and patients assigned to the avoid group reduced the proportion of time in tooth contact from 66.1% (s.d. = 23.9) to 22.0% (s.d. = 15.5), a significant Group \times Time interaction, $F(1,8) = 7.68$, $P < 0.05$, partial eta-squared = 0.681. Both groups reported significant reductions in facial pain from pre-treatment to the end of treatment.

Discussion

The general hypothesis that reduction in parafunctions accounts for a significant and meaningful proportion of the change in pain can be answered two ways. One method is to assume that patients followed the instructions provided to them. That is, all the Avoid subjects actually decreased the intensity of tooth contact, and all the Maintain subjects actually increased tooth contact intensity. If this assumption is correct, repeated measures analyses are reasonable and appropriate strategies for examining the data.

However, the data generated in this study show that not all the Maintain subjects increased tooth contact intensity. When the impact of changes in patient behaviour on pain reduction is examined, the data show that those who decreased intensity of tooth contact the most also tended to report the greatest relief from pain. This effect is illustrated in Fig. 1. When group data are considered without reference to changes in patient behaviour, the results show reduction in pain for both the Avoid and Maintain groups, and no differences between groups.

Our study showed that occlusal splints are an effective modality to treat TMD pain and that intervening with patient's behaviour by targeting parafunctional activity enhances the efficacy of splint therapy for TMD patients. As with all clinically oriented trials, the study had some limitations and raised new questions. The first issue is sample size and representativeness. A considerable number of people were screened before selection into the study. Many were eliminated because they had TMD diagnoses other than myofascial pain and arthralgia or because they had other chronic pain problems. An additional group was eliminated because they had recent treatment experience with splints. The patients selected may not be representative of all individuals who complain of TMD symptoms. We

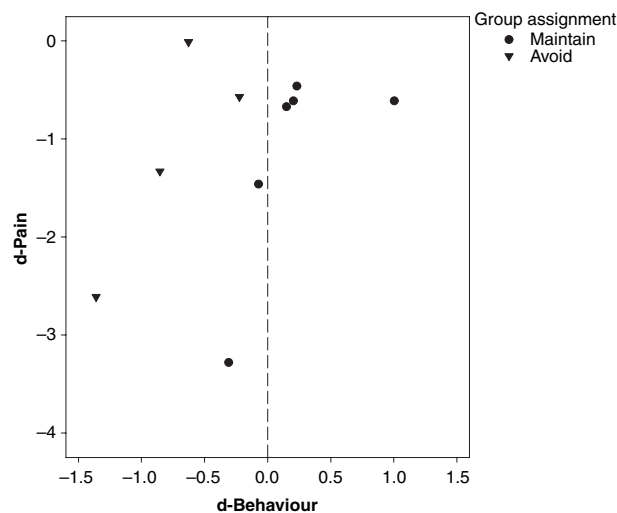


Fig. 1. Scatterplot showing changes in tooth contact behaviour with changes in pain. Changes in tooth contact behaviour are reported on the X-axis. Negative values indicate reduction in tooth contact behaviour from baseline. Changes in reported pain are reported on the Y-axis. More negative values indicate greater reduction in pain.

did not monitor analgesic medication use directly. The drop-out rate was relatively high, especially considering the original sample size. The treatment period was relatively short, and it would be desirable to collect long-term outcome data. A replication using larger sample size would increase confidence that the findings reported here were not a statistical aberration.

Because the ESM technique relied on pagers to trigger data recording and checking of tooth contact, patients enrolled in the study had to be limited to residents of the Kansas City metropolitan area, the coverage area of the pager company. The advantages of ESM approaches using pagers are that the technology is inexpensive, robust, and relatively insensitive to the 'insults' of daily life. Pager coverage and rental costs may be more advantageous for providers and patients who live in urban areas rather than rural areas. Personal data assistants may be substituted for pagers at a higher cost and greater sensitivity to careless handling of the device.

Changes in tooth contact intensity could have been short-lived, especially in the Maintain group, only lasting for a short period of time after being paged. If splints are (inadvertent) behaviour change devices, as suggested by Kreiner *et al.* (31), some of the patients in the Maintain group may have terminated contact shortly after being reminded by the pager. The amount

of force exerted by each patient on the splint could have varied as well, although it is likely that patients were very consistent in their own definitions of 'light contact' (34). We also do not know the validity of the responses entered on the pager cards. However, during the pre-treatment week and the sixth week of treatment, patients also recorded the time they were paged. When the times entered on the cards were compared with calling times recorded by the computer dialling programme, the data showed a close correspondence between the two data sets. These findings increase confidence that the data reported on the cards were accurate.

Many studies suggest that stabilization splints can reduce facial pain (35–40), and our results are consistent with these studies. However, many studies on the efficacy of splints focus on the fabrication and design of the splint and do not provide sufficient information on the instructions given to patients. There are few studies describing how dentists use splints with their patients (1, 41), and virtually nothing on the instructions that they give to patients. A dentist who inserts a splint with little explanation of its mechanism of action or weak instructions to patients may limit the effectiveness of the device. In our view, dentists should present splints as a 'cueing' device to remind patients to reduce tooth contact and muscle tension. Dentists should explain that tooth contact requires activation of the masticatory muscles, that simple contact can easily double the activity of the temporalis and masseters (17, 18, 42), and that more intense contact (i.e. 'clenching') can increase the activity of these muscles even further. Dentists could also describe how individuals who have TMD pain report high levels of tooth contact (20, 21) compared with non-TMD individuals. These data could provide a rationale for instructing patients to decrease the activity of the masticatory muscles and for describing the splint as a 'reminder' that they should strive to avoid tooth contact and reduce masticatory muscle tension. In short, it may be beneficial to encourage patients to change their own parafunctional behaviours with the aid of the splint, rather than to describe the splint as the sole agent responsible for pain reduction.

Conclusion

The outcome of this study showed that splints are effective in reducing the intensity of pain for patients with jaw pain and pain in the masticatory muscles.

Groups did not differ in the degree of pain reduction reported by patients. The data also showed that change in behaviour is important in the outcome of splint therapy. Virtually all patients reported reduced pain, and those who reduced intensity of tooth contact the most tended to report the greatest reduction in pain. These findings are consistent with the hypothesis advanced by Kreiner *et al.* (31) that the efficacy of splints may reflect a combination of non-specific effects of being in treatment with the specific effects of reduction in parafunctions. Clinicians who target parafunctional tooth contact and other patient behaviours may enhance the outcome of splint therapy for pain.

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