Evaluation of the short-term effectiveness of education versus an occlusal splint for the treatment of myofascial pain of the jaw muscles

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ABSTRACT

Background. The authors conducted a clinical trial to compare the effectiveness of an education program with that of an occlusal splint in treating myofascial pain of the jaw muscles across a short period.

Method. The authors assigned 44 patients randomly to two treatment groups; 41 patients completed the study. The first group (four male, 19 female; mean [standard deviation {SD}] age, 31.4 [14.0] years) received information regarding the nature of temporomandibular disorder (TMD) and self-care measures, whereas the second group (five male, 13 female; mean [SD] age, 31.1 [8.8] years) received an occlusal splint. One of the authors evaluated each patient every three weeks during a three-month treatment period. Treatment outcomes included pain-free maximal mouth opening, spontaneous muscle pain, pain during chewing and headache.

Results. After three months, changes in spontaneous muscle pain differed significantly between the education and occlusal splint groups ($P = .034$; effect size = 0.33). Changes in pain-free maximal mouth opening did not differ significantly between groups ($P = .528$; effect size = 0.20). Changes of headache and pain on chewing did not differ significantly between groups ($P \geq .550$, effect size ≤ 0.10).

Conclusions. During a short period, education was slightly more effective than an occlusal splint delivered without education in reducing spontaneous muscle pain in patients with TMD. Pain-free mouth opening, headache and pain during chewing were not significantly different between the two treatments.

Key Words. Education; occlusal splint; myofascial pain; randomized controlled clinical trial.
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Myofascial pain is the most common temporomandibular disorder (TMD).[1-3] The main symptoms of this condition are pain, limited jaw movements or a combination of the two, and they usually are aggravated by function. No specific therapies have been proven to be more effective than others, and conservative and reversible therapies (such as self-care, education and splints) have been advocated to reduce pain and improve jaw function at least as much as have invasive and irreversible treatments.[1-3]

Occlusal splints are the most popular treatment modality for TMD.[4] Investigators have described various types of occlusal splints with different designs, indications and functions.[4-6] Nevertheless, the most common design is the full-arch, flat-plane maxillary stabilization splint. Researchers in several trials have reported that occlusal splints are clinically successful.[7-10] Occlusal splint therapy can provide centric relation occlusion, eliminate posterior interferences, provide anterior guidance on anterior teeth, reduce neuromuscular activity and establish stable occlusal relationships with

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uniform tooth contacts throughout the dental arch.[4,11] Nevertheless, the mechanism of action of occlusal splints is still unknown. Results from several studies in which investigators compared stabilization splints with nonocclusal splints failed to show any statistically significant difference for any of the outcomes measured.[4,6,12-15] A possible working mechanism of occlusal splints could be based on nonspecific effects linked to the patient-doctor relationship, the patient's education and the patient's expectations.[4,16]

Investigators have hypothesized that an education program emphasizing reduction of jaw muscle activity would be as successful as an occlusal splint given to the patient without much further information.[17-23] Consequently, the aim of our study was to compare, by means of a randomized clinical trial, the effectiveness of an education program with that of occlusal splint therapy for the treatment of myofascial pain of the jaw muscles across a short period.

METHODS

Participants. One hundred ninety-eight consecutively seen patients seeking treatment for orofacial pain were referred to the Clinic for Temporomandibular Disorders and Orofacial Pain of the University of Naples Federico II across nine months. The patients underwent a routine stomatognathic examination to detect signs and symptoms of TMD. A dentist (A.M.) who was trained in TMD diagnosis according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD)[24] performed a clinical and functional examination of each patient.

Inclusion criteria were myogenous pain and report of ongoing pain, either recurrent or constant, for a duration of more than three months (diagnostic categories Ia and Ib in the RDC/TMD), as well as absence of objective evidence of joint pathology or dysfunction. To be included in this clinical trial, participants had to report at baseline having spontaneous muscle pain greater than 30 millimeters on a visual analog scale (VAS). Exclusion criteria were disk displacement with or without reduction (diagnostic category II of the RDC/TMD); arthrogenous TMD with pain or radiographic alterations in the temporomandibular joints (diagnostic category III of the RDC/TMD); other orofacial pain conditions; other TMD treatments performed in the preceding three months; neurological or psychiatric disorders or both; history of or current abuse of pain medication; and use of an occlusal splint in the preceding year.

Forty-four consecutively seen patients with myogenous TMD (10 men and 34 women; age range, 18-53 years; mean [standard deviation {SD}] age, 31.2 [11.8] years) met the inclusion and exclusion criteria. We assigned the patients to two treatment groups by means of a balanced block randomization. The first group consisted of 23 patients (four men and 19 women; age range, 20-53 years; mean [SD] age, 31.4 [14.0] years) who received education only. The second group consisted of 21 patients (six men and 15 women; age range, 18-49 years; mean [SD], 30.3 [11.4] years) who received occlusal splints but no further information. A second examiner (G.I.) who was masked as to the patient's treatment performed the baseline assessment and, three months after the start of treatment, collected data again (still masked as to each participant's treatment).

During the entire study period, no participants received any other form of treatment—including drugs, physical therapies or occlusal adjustments—other than that assigned to their group. We obtained written informed consent from all participants before they entered the study.

Treatments. ***Education.*** Participants in the education group received general information about self-care of jaw musculature. The home exercise program in the education group was focused on habit-reversal techniques.[25-27] The clinician (S.V.) reassured the patient by explaining the problem, the suspected etiology and the good prognosis for this benign disorder. He explained the normal jaw muscle function, emphasizing that overuse of these muscles could be one of the causes of their pain. He told the participants to pay close attention to their jaw muscle activity, to avoid their usual oral habits and excessive mandibular movements, and to follow a soft diet. The clinician instructed them to keep the muscles relaxed by holding the mandible in its postural position (teeth apart) and not in occlusion, because occlusion requires unintentional muscle contraction.[28] The clinician determined mandibular rest position by asking the participants to pronounce the letter "N" several times and to hold the tongue behind the maxillary incisors, with the lips in slight contact. Furthermore, he requested that the participants practice what they learned at home and during their common activities by using visual aids to alert them to tooth contact, as well as by holding the mandible in a relaxed position. He also informed the participants about the relationship between chronic

ABBREVIATION KEY. RDC/TMD: Research Diagnostic Criteria for Temporomandibular Disorders. **TMD:** Temporomandibular disorder. **VAS:** Visual analog scale.

pain and psychosocial stress.

Occlusal splint. The participants in the other group received an occlusal splint as the only treatment. The occlusal splint used in this study was the stabilization (Michigan) splint.[29] This is a rigid splint constructed for the maxillary arch, including all of the maxillary teeth, with a flat occlusal plane. A technician constructed it under the direction of the clinician (S.V.) with minimal increase in vertical dimension, and the clinician adjusted it so that the opposing dentition occluded uniformly, evenly and simultaneously with the occluding surface of the splint in centric occlusion. Coverage of the labial surfaces and buccal surfaces of the maxillary teeth provided frictional retention for the splint. The splint extended approximately 10 mm into the palate beyond the palatogingival margin. The clinician instructed participants to use the splint only during sleep.

Procedure. For all participants, the clinician (S.V.) took accurate alginate impressions of both arches and an interocclusal record with a wax wafer. After one week, the participants in the occlusal splint group received the occlusal splint accurately adjusted in the centric occlusion, and the participants in the education group received an explanation of the etiology and of the good prognosis for TMD, as well as information about self-care for the jaw musculature. The same clinician (S.V.) administered both therapies.

All participants received written instructions about their own treatment program (that is, counseling or occlusal splint instructions), and the clinician (S.V.) told them to continue with the prescribed therapy throughout a three-month period even if they were pain free. The clinician who provided the therapy evaluated each participant every three weeks during the whole treatment period. The length of each visit was about 15 minutes. After the clinician obtained the history and conducted the clinical examination, he asked the participants in the education group about their compliance and reinforced their motivation; he evaluated participants in the occlusal splint group to determine any need for adjustment of the device to eliminate local irritation of the soft and hard oral tissues and to adjust the occlusal surface so that mandibular teeth would touch the splint evenly and simultaneously.

Three months after the start of treatment, the baseline examiner (G.I.) collected data again while being masked as to each participant's treatment.

Assessments. ***Pain.*** One of the examiners (G.I.) assessed spontaneous muscle pain, pain during chewing and headache by using three separate 100-mm horizontal VASs.[30,31] The left endpoint of each scale indicated no pain or headache at all, and the right endpoint indicated the worst pain or headache imaginable.

During the assessment of pain during chewing, the examiner asked participants to chew bilaterally for 60 seconds a stick of chewing gum. Participants reported any pain on the scale immediately after completing the task (according to the method reported by Farella and colleagues[32]).

Pain-free maximal mouth opening. The clinician conducting the assessments (G.I.) measured maximal "pain free" opening as the distance between the maxillary and mandibular incisal edges and added the overbite measurement. We defined "pain free" as the maximum distance the participant could open his or her mouth without experiencing any additional pain and discomfort.

Statistics. Preliminary analyses consisted of descriptive statistics, normality tests and tests for homogeneity of variances. The outcome measurements were maximum pain-free mouth opening, spontaneous muscle pain, pain during chewing and headache. We analyzed the outcome measures by means of repeated-measurements analysis of variance, using time (before and after) as the within-participant factor and treatment group (education and splint) as the between-participant factor. We performed baseline and post hoc multiple comparisons by means of paired and unpaired t test for interval data and by means of Fisher exact tests for proportions. All tests were two-tailed. We set the α level at .05. We performed post hoc power analyses, considering the smallest detectable differences of 5 mm for jaw opening and of 28 mm for VASs.[33] We performed all calculations by using a commercial statistical software package (SPSS Version 5.0 for Windows, SPSS, Chicago).

RESULTS

Three participants (one male, two female) (6.8 percent), all from the occlusal splint group, dropped out of the study. Hence, 23 participants in the education group and 18 participants in the occlusal splint group completed the study. The table summarizes participants' baseline characteristics, according to both treatment group and whether they completed the study. Baseline characteristics did not differ significantly between the two groups ($P \geq .05$).

Overall, pain-free maximal mouth opening did not differ between treatment groups ($F = 0.99$; $P = .325$), but changed significantly over

TABLE

Pretreatment data*† for all participants.

CHARACTERISTIC	PARTICIPANT DATA, ACCORDING TO TREATMENT GROUP AT BEGINNING OF STUDY		PARTICIPANT DATA, ACCORDING TO STUDY COMPLETION STATUS	
	Education (n = 23)	Occlusal Splint (n = 21)	Completed (n = 41)	Dropped Out (n = 3)
Age, in Years*	30.2 (13.0)	30.3 (11.4)	30.4 (12.0)	31.8 (11.0)
Sex				
Male	4	6	9	1
Female	19	15	32	2
Mouth Opening, in Millimeters*	43.2 (6.3)	41.5 (7.9)	42.5 (7.1)	41.6 (5.5)
Spontaneous Muscle Pain*‡	41.6 (19.4)	39.1 (20.2)	39.9 (20.4)	40.8 (19.3)
Pain During Chewing*‡	44.8 (23.3)	49.6 (28.9)	47.1 (26.7)	46.7 (24.6)
Headache*‡	33.3 (19.6)	33.9 (21.1)	33.7 (19.2)	32.3 (20.7)

* Data are shown as means (standard deviations). Mean values were compared by using an unpaired Student *t* test. Ratios were compared by means of the Fisher exact test.
† None of the *P* values was significant.
‡ According to score on a 100-mm visual analog scale.

time ($F = 12.1$; $P = .001$). The effect of treatment on pain-free maximal jaw opening did not differ significantly between the two groups (interaction time × treatment group; $F = 0.41$; $P = .528$; effect size = 0.20) (Figure 1). Post hoc analysis revealed that the test for this interaction term had 58 percent power.

VAS scores for spontaneous muscle pain did not differ between treatment groups ($F = 0.25$; $P = .623$) and did not change significantly across time ($F = 1.7$; $P = .197$). The effect of treatment on spontaneous muscle pain score, however, was significantly different between the two groups (interaction time × treatment group; $P = .034$; effect size = 0.33). Post hoc tests revealed that spontaneous muscle pain changed significantly across time in the education group ($P = .017$) but not in the occlusal splint group ($P = .540$). Pain during chewing and headache scores were not significantly influenced by time, treatment group and effect of treatment ($F \geq 1.1$; $P \geq .106$; effect size ≤ 0.10) (Figure 2). The power of these statistical tests was 70 percent or greater.

DISCUSSION

In this study, three participants (6.8 percent) did not complete the trial and the scheduled therapeutic protocol. This percentage of dropouts is lower than that in other clinical studies.[18,34] The three participants who dropped out were assigned to the occlusal splint group, and their reason for dropping out was the splint's cost.

Changes in spontaneous muscle pain differed significantly between treatment groups, with reduced pain levels found only in the education group across a short period. To the best of our knowledge, this is the first randomized controlled trial in which investigators evaluated the efficacy of an occlusal splint prescribed with a minimum amount of information about treatment, including any other form of education and self-care. For instance, it is possible that unlike the participants in the education group, the participants in the occlusal splint group clenched their jaws during the treatment period. Therefore, teaching patients that the overuse of the jaw muscles could be the major cause of their pain may be more effective than the simple use of an occlusal splint.

In support of this hypothesis, investigators in a previous study found that habit reversal was as effective as a splint therapy for TMD-related pain.[26] This finding could confirm that the key to achieving a good outcome in TMD management seems to be success in educating the patient about the disorder to enhance self-care. Some research findings indicate that self-management programs in TMD have long-term positive effects.[25] On the other hand, investigators in several studies found a statistically significant association between daytime clenching or grinding and myofascial pain,[35-39] confirming that clenching or grinding is an important risk factor for myofascial pain.[37,39] Explanations for the association between clenching and myofascial pain can be found in the literature. In participants experiencing myalgia, investigators have found that either muscular fibers are damaged[40] or blood supply is reduced.[41] In particular, the perfusion of

the masseter muscle is reduced statistically significantly in people performing voluntary isometric contractions.[42] Furthermore, investigators in previous electromyographic studies identified a range of minimal muscular activity in the first 3 to 4 mm of mouth opening, confirming that a jaw posture with a few millimeters of interocclusal resting space involves a great reduction of masticatory muscle activity and supporting the validity of clinical advice to patients to keep the teeth apart.[28]

Another possible explanation could be that, contrary to participants in the occlusal splint group, participants in the education group received extensive information and considerable patient-doctor interaction. Therefore, participants' improvement could be linked to the positive effects of psychophysiological mechanisms associated with education and reassurance and mediated by each participant's coping skills, mood and emotional state. With this type of chronic disorder, education and reassurance are powerful tools for remission.[4]

Results from studies regarding patient education compared with those of studies regarding other rehabilitation treatment modalities show that enforcing patients' responsibilities, and thereby addressing psychosocial factors, can yield better results.[26,27,43] This has been found in TMD research as well. Indeed, Dworkin and colleagues[44,45] concluded that carefully structured minimal interventions emphasizing self-management of TMD may offer real benefit to a substantial number of patients with myogenous TMD. Addressing both dental and psychological factors by means of stress management results in a better long-term outcome than does using an intraoral splint alone. On the other hand, different kinds of occlusal splints combined with education are able to reduce the myofascial pain.[15] Experimental evidence indicates the influence of the medical context on specific neural systems.[46] This factor could explain the great benefit of education and reassurance in the treatment of chronic conditions such as TMD.[4]

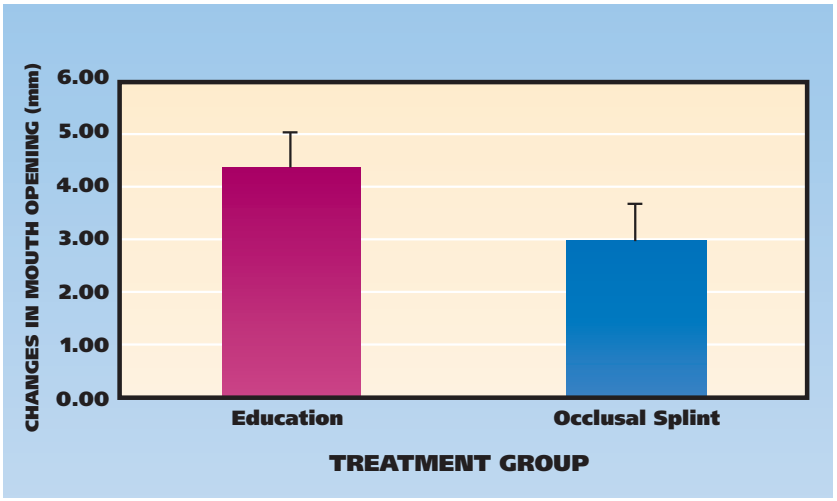

Figure 1. Changes in pain-free maximal jaw opening (measured in millimeters on a visual analog scale) experienced by participants in the two treatment groups (education and occlusal splint). The whiskers represent standard deviations. There were no statistically significant differences ($P > .05$). mm: Millimeters.

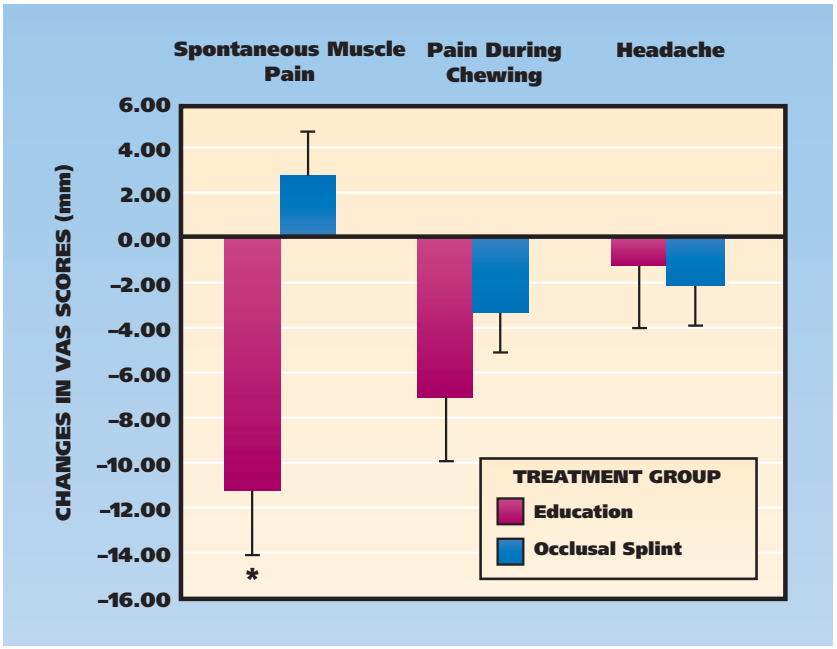

Figure 2. Relative changes in visual analog scale (VAS) scores for spontaneous muscle pain, pain during chewing and headache. The whiskers represent standard deviations; the asterisk indicates a statistically significant difference ($P < .05$). mm: Millimeters.

To be included in this clinical trial, participants had to report spontaneous muscle pain greater than 30 mm on a VAS at the baseline. Using this threshold, we selected a sample of patients with TMD who had moderate to severe pain; therefore, one cannot extrapolate the findings to a general TMD population, which also

includes participants with slight or mild pain. The effect of the occlusal splint or the education might be different in patients with TMD who are experiencing less intense pain.

Our trial lacked a nontreatment or placebo control group, so we cannot discard the possibility that a natural reduction of pain occurred in some participants.[47] Furthermore, we did not ask the participants to complete a daily diary of their pain, so we did not investigate the influence of the treatment modalities on the frequency of pain.

CONCLUSIONS

Our findings show that during a short period, education was slightly more effective than an occlusal splint in treating spontaneous muscle pain. The treatments did not have significantly different effects in terms of pain-free mouth opening, headache and pain during chewing. Therefore, our findings indicate that for successful management of myofascial pain, education of patients regarding self-care as well as extensive communication between patient and doctor may be more effective than an occlusal appliance. The long-term effects of both treatment protocols should be evaluated in future studies. ■

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