A Randomized Clinical Trial of Intraoral Soft Splints and Palliative Treatment for Masticatory Muscle Pain

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Thirty subjects seeking treatment for masticatory muscle pain at a university-based TMJ clinic were randomly assigned to soft-splint, palliative-treatment, and no-treatment groups. After 4 to 11 weeks of treatment, subjects were evaluated for changes from their baseline levels of symptoms, maximum pain-free opening, pain thresholds measured by a pressure algometer, and occlusal contacts. With the use of the multivariate analysis of variance and analysis of covariance, the results suggest that the soft-splint group had statistically significant improvement ($P < .01$), the palliative-treatment group had improvement that was not statistically significant, and the no-treatment group had a slight aggravation of symptoms. The soft-splint group had fewer occlusal contact changes assessed with shimstock compared to the palliative-treatment and no-treatment groups. The findings of this study suggest that the soft splint is an effective short-term treatment for reducing the signs and symptoms of masticatory muscle pain in patients, and the soft splint does not cause occlusal changes.

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Soft splints and palliative treatment have been suggested as treatments that can be provided at the initial examination for patients with masticatory muscle pain.[1,2] Palliative treatment involves a self-care program that patients follow based on instructions they receive from their provider. The American Academy of Orofacial Pain[1] suggested that the success of a palliative treatment program is dependent on the patient's motivation, cooperation, and compliance and on the rapport of the patient with the practitioner. No randomized clinical trial evaluating the efficacy of palliative treatment for masticatory muscle pain could be found in the literature. Randolph et al[3] reported a retrospective study that compared 15 patients who were provided with palliative treatment and 95 patients who were provided with palliative treatment in addition to splint therapy. In telephone interviews 1 to 7 years later, 60% of the patients who had received only palliative treatment reported few recurrent symptoms; 70% of the patients who had received both palliative treatment and conservative treatment also reported few recurrent symptoms. Hodges[4] reported that 75% of patients who were provided with palliative treatment were pain free or comfortable with their problem and management.

Soft splints have been advocated for patients with temporomandibular disorders (TMD).[2,5–18] However, there are few trials that have evaluated efficacy, and outcomes have been variable.[13,19,20]

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Soft splints can be made for the maxillary or mandibular arches and are easily constructed. These appliances are often inserted immediately at the initial examination, which may be desired for a patient who has an acute sprain or acute muscle spasm or who needs a badly worn or broken splint replaced.[6,10,21]

Soft splints have been used as interim appliances until acrylic-resin splints could be provided.[10–12] These appliances have also been suggested as prognostic tools to evaluate whether an acrylic-resin splint would be advantageous. Harkins et al[12] found that 93% of the 42 patients who were given soft splints and reported a reduction in their symptoms also reported good to excellent results with a subsequent acrylic-resin splint used during the next 3 to 6 months.

A high degree of patient acceptance has been reported with soft splints. The soft, resilient material may help dissipate some of the heavy loading that occurs during parafunctional activity.[8,11,14,15] Block et al[17] found that after 6 weeks of using soft splints, 74% of 19 patients had complete or almost complete remission of their TMD symptoms. Harkins et al[12] found that 74% of the patients who wore a soft splint had a reduction in facial myalgia, and 74% had a reduction in or elimination of temporomandibular joint (TMJ) clicking. Many other case reports of soft splint efficacy are presented in the literature.[2,5,7–11,13,14,18]

Nevarro et al[19] and Okeson[20] are cited as evidence for the ineffectiveness of soft splints.[22] Nevarro et al[19] reported a randomized clinical trial comparing maxillary hard acrylic-resin and resilient occlusal splints (n = 20). No quantifiable outcome measures were used, but six of 10 subjects with the hard appliance reported symptom remission. Two additional subjects reported partial symptom remission. In the group using resilient occlusal splints, six of 10 subjects reported additional morning soreness. Okeson[20] investigated the effect of soft occlusal splints as compared with hard stabilization appliances on nocturnal electromyographic (EMG) activity, a measure of nocturnal bruxism, which is often thought to be a contributor to masticatory muscle pain. In a repeated measurement (A-B-A-C-A) design, 10 asymptomatic subjects who admitted they were bruxers were treated with nocturnal use of hard and soft occlusal splints. The soft splint was significantly less effective in reducing nocturnal EMG activity; in fact, five of the 10 subjects had a significant increase in EMG activity.

Occlusal changes were observed in patients who wore soft splints in studies by Singh et al[23] and Harkins et al[12]; Singh et al[23] apparently used unadjusted soft splints, and Harkins et al[12] used preformed soft splints that did not have lingual flanges.

There is a need for a randomized clinical trial assessing palliative treatment and soft splints in the treatment of masticatory muscle pain. In the present study, soft splints and palliative treatment were compared with a no-treatment approach (control) for changes in a modified Symptom Severity Index (SSI), maximum pain-free opening, pain threshold measured by a pressure algometer, and occlusal contacts for subjects with masticatory muscle pain.

Materials and Methods

This study identified patients who had complaints of orofacial pain and clinical evidence of a masticatory muscle origin to their pain. Because no workable consensus has been reached regarding the classification of specific masticatory muscle pain disorders,[24] subjects were simply identified as having "masticatory muscle pain" as the source of the pain complaint. The medical history and clinical examination were used to rule out other sources of pain, such as dental, metabolic, and neurologic disorders.

Thirty consecutive consenting subjects from the TMJ and Craniofacial Pain Clinic at the University of Minnesota, Minneapolis, MN, who met the inclusion/exclusion criteria were enrolled. The following criteria were used for inclusion:

1. The subject's pain complaint was aggravated by jaw function (eg, eating or talking) or parafunctional habits (eg, clenching or grinding the teeth). This criterion was based on patient history.
2. The subject's pain complaint was duplicated and/or aggravated by palpation of the muscles of mastication. This criterion was based on clinical examination.
3. The subjects were between the ages of 18 and 60.

The following criteria were used for exclusion:

1. The subject's pain complaint was aggravated by clinical loading of the temporomandibular joint (TMJ). This criterion was based on clinical examination.
2. The subject's pain complaint was aggravated by TMJ clicking and/or catching. This criterion was based on history and clinical examination.
3. Concurrent major psychiatric disease was present. This criterion was based on patient history.
4. The subject was unwilling to accept a random assignment to one of the three treatment groups.

These criteria were designed to identify subjects with pain from the masticatory muscles and to rule out TMJ intra-articular sources of pain.[25,26] None of the subjects was receiving any other treatment or medications at the outset of the study. The subjects were assessed for baseline measurements by one of two calibrated, blinded examiners and were randomly assigned to one of three treatment groups. Randomization was made in blocks to maintain equal group sizes. The age of the subjects ranged from 19 to 51. The mean ages of the soft-splint, palliative-treatment, and no-treatment groups were 34, 36, and 31 years, respectively. The duration of the study for each subject was about 6 weeks, and the final evaluations were with the same independent, blinded examiner who performed the initial evaluation.

Subjects assigned to the soft-splint group received a soft splint fabricated from their mandibular cast and adjusted to provide complete mandibular arch coverage that had evenly distributed bilateral posterior contacts with light or no contact on the anterior teeth when in the centric position. Anterior guidance provided posterior separation in excursive movements, and the vertical dimension was increased from intercuspal position by approximately 1 mm. This was accomplished by vacuum suctioning a warmed sheet of 0.150-inch (3.8-mm) thick resilient mouth guard material (Dentiform mouth guard material 0.150, IDE Interstate, Amityville, NY) over the mandibular cast. The occlusal surface of the splint was evenly warmed with an alcohol torch (Alcohol-torch, Hanau, IDE Interstate) and inserted in the subject's mouth. A functional imprint was developed in centric, lateral, and protrusive excursions, using bilateral centric relation manipulation.[27] A carbide bur was used to remove the excess material from the imprint to develop the desired occlusal pattern.[11] The soft splint was then polished with pumice and disinfected, and the subject was told to wear the splint 24 hours a day, except when eating meals.

Subjects assigned to the palliative-treatment group received verbal and written instructions on self-care for their masticatory muscle pain. These instructions included applying moist heat or ice, eating a soft diet, decreasing oral parafunctional habits, decreasing caffeine consumption, modifying sleeping posture, and using over-the-counter medications, as needed.

Subjects assigned to the no-treatment group received neither palliative treatment nor a soft splint. Patients normally wait 4 to 6 weeks for their insurance company to process and authorize treatment recommendations.

The following standardized questionnaire and examination measures were used to evaluate changes for each subject: *(1)* a modified SSI[28]; *(2)* maximum pain-free opening[29]; *(3)* muscle-pain threshold assessed with a pressure algometer[30]; and *(4)* occlusal contact changes assessed with shimstock.[31] Reliability and validity of these outcome measures have been previously demonstrated.[28–31]

Maximum pain-free opening was measured in millimeters at the subject's maximum incisor-to-incisor pain-free opening.[29] The muscle-pain threshold was measured with a PAMP II pressure algometer (0.13-inch^2 palpation rod) at a rate of 30% of the maximal force (10 lb) per second (77 psi maximal pressure) on the anterior temporal muscle and on the superior and inferior areas of the masseter muscle.[30]

Occlusal contacts were evaluated by determining changes in the number of maxillary teeth that held shimstock (GHM Hanel-Medizinal, Nurtingen, Germany) with opposing mandibular teeth on closure in the intercuspal position.[31]

Prior to initiating the study, the two examiners were calibrated. Trial measurements were taken of five subjects to establish interrater reliability. The intraclass correlations for maximum pain-free opening and muscle-pain threshold were 0.91 and 0.97, respectively. There was good agreement between the two raters for the assessment of shimstock occlusal contact; there was only one tooth contact disagreement for the 72 teeth checked.

The four null hypotheses tested in this study were:

1. There is no difference among the treatment responses of the three groups in reduction of symptoms as measured with the modified SSI.
2. There is no difference among the treatment responses of the three groups in terms of an increase in maximum pain-free opening.
3. There is no difference among the treatment responses of the three groups in terms of an increase in pain threshold of the anterior temporal muscle and the superior and inferior areas of the masseter muscle, as measured by the pressure algometer.
4. There is no difference in occlusal contact changes among the three groups, as assessed with shimstock.

Pearson's correlation coefficients were calculated between each pair of dependent variables to determine if any were significantly correlated ($r \geq .5$). The interdependent variables were then tested as a set using a multivariate analysis of variance to test the null hypotheses that there were no differences among the soft-splint, palliative-treatment, and no-treatment groups. Wilk's lambda (Λ) was

Table 1 Initial Mean Measures and Standard Deviations

	Soft splint Mean (SD)	Palliative Mean (SD)	No treatment Mean (SD)
Modified Symptom Severity Index	61.8 (10.8)	61.2 (16.3)	60.7 (21.0)
Maximum pain-free opening (mm)	37.5 (6.8)	39.9 (10.9)	40.3 (6.3)
Pressure algometer score (psi)	31.3 (11.8)	35.7 (14.9)	41.0 (21.2)

Table 2 Final Mean Measures and Standard Deviations

	Soft splint Mean (SD)	Palliative Mean (SD)	No treatment Mean (SD)
Modified Symptom Severity Index	32.7 (19.9)	49.4 (18.3)	63.4 (20.1)
Maximum pain-free opening (mm)	42.4 (6.2)	41.0 (12.4)	40.0 (7.1)
Pressure algometer score (psi)	45.3 (12.7)	35.2 (15.1)	38.1 (22.8)

Table 3 Initial Mean Measures and Standard Deviations

	Soft splint Mean (SD)	Palliative Mean (SD)	No treatment Mean (SD)
Modified Symptom Severity Index	−29.1 (22.5)*	−11.8 (17.0)	2.7 (9.1)
Maximum pain-free opening (mm)	4.9 (5.0)*	1.1 (2.5)	−0.3 (2.6)
Pressure algometer score (psi)	14.0 (4.6)*	0.5 (6.4)	−2.9 (4.7)
Contact changes	1.3 (1.1)	2.0 (1.9)	1.9 (0.9)

*$P < .01$

used to determine if there was a statistically significant difference among groups for the set of interdependent variables.

An analysis of covariance (ANCOVA) was used to test the null hypotheses that there were no differences among the three groups for the modified SSI, maximum pain-free opening, and muscle-pain threshold. Time was used as the covariant as the duration of treatment varied in the clinical setting. An ANCOVA was also used to test the null hypothesis that there were no differences in occlusal contact changes among the groups. Time was again assigned as the covariant. For the dependent variables that were found to have a statistically significant difference, comparisons between specific pairs of groups were made using Student-Newman-Keul's multiple comparisons test.

Results

Two of the 30 study subjects did not return for their final evaluations. One subject moved, and the second subject, a member of the palliative-treatment group, said that she was asymptomatic and refused to return for fear that the final evaluation might cause her symptoms to return. After 30 subjects had entered the study, two additional subjects were sequentially added to the study and assigned to the groups in the order that the dropouts were originally assigned. This enabled 10 subjects in each group to complete the study.

The duration of treatment ranged from 4 to 11 weeks. The mean duration for the soft-splint, palliative-treatment, and no-treatment groups were 6.3, 6.9, and 6.7 weeks, respectively.

The three groups were evaluated to determine if there was a statistically significant difference in *(1)* age, *(2)* the length of time between evaluations, *(3)* baseline SSI scores, *(4)* baseline measurement of maximum pain-free openings, and *(5)* baseline reading of muscle-pain threshold scores. There was no statistically significant difference among the groups for these potential confounding factors and baseline measures.

The mean baseline and final measures for each group are summarized in Tables 1 and 2. Table 3 shows mean changes in the measures from baseline to final. Pearson's correlation coefficients sug-

gested that the dependent variables for the modified SSI, the maximum pain-free opening, and the muscle-pain threshold were moderately correlated (r ranged from .57 to .64). Therefore, a multivariate analysis of variance (MANOVA) with Λ was performed for these dependent variables. This set of dependent variables was found to have a statistically significant difference among the groups ($P = .0001$).

An ANCOVA and a Student-Newman-Keul's multiple comparisons test were used to test the null hypotheses that there were no differences among the three groups for each of the four dependent variables. Time as the covariant had no statistically significant effect on the outcome. Statistically significant differences were found among the three groups for change in the modified SSI ($F = 8.42$, $df = 2$, $P < .01$), maximum pain-free opening ($F = 6.16$, $df = 2$, $P < .01$), and muscle-pain threshold ($F = 27.99$, $df = 2$, $P < .001$). The Student-Newman-Keul's multiple comparisons among groups revealed that the three dependent variables for the soft-splint group were significantly different than those from the other two groups ($P < .05$). There was no statistically significant difference in occlusal contact changes among the groups ($F = 0.65$, $df = 2$, $P = .5297$).

There was considerable variation among individuals in the duration of treatment. Therefore, a regression analysis was done to test the effect of time on the four outcome measurements for the three groups. The interaction between time and group had no effect on the outcome. Pearson's correlation coefficient was calculated for duration of treatment with each of the four outcome measures. The calculations showed that there were no statistically significant differences: modified SSI, $r = .01804$; maximum pain-free opening, $r = .10338$; muscle-pain threshold, $r = -.11405$; and occlusal contact changes, $r = .11399$.

Discussion

The modified SSI assesses the general subjective severity of pain and includes the sensory intensity, affective intensity, duration, frequency, and tolerability of the chief complaint. The results are raw scores from 0 to 100.[28] The modified SSI scores were significantly reduced for the group treated with the soft splints, reflecting a patient perception of improvement in muscle pain with this treatment. Although the group treated with palliative management improved (the mean SSI score changed from 61.2 to 49.4), the improvement was not statistically significant. Compared with the untreated control group, the change in SSI score may reflect nonspecific treatment effects related to the doctor-patient interaction.[32] The untreated control group realized no improvement in mean SSI score with a baseline score of 60.7 and a final score of 63.4. This finding is consistent with those of Harkins et al,[12] who found that the symptoms in their control group did not change appreciably over a shorter term of 10 to 20 days.

Maximum pain-free opening has been recommended as an outcome measurement in TMD clinical trials[29] and has recently been shown to be a highly reliable clinical sign.[33,34] The increase in maximum pain-free opening in the soft-splint group was significantly greater than that in the other two groups. The mean increase of 4.9 mm compares favorably with the average increase of 5.3 mm reported by Okeson et al[29] in an assessment of patient treatment with a hard acrylic-resin maxillary occlusal splint worn full-time, except when eating, throughout a 4-week period.

Change in muscle-pain threshold has been shown to be a reliable outcome measure in clinical trials on TMD.[30,35] The soft-splint group exhibited a mean increase in muscle-pain threshold that was significantly greater than the other two groups. Schiffman et al[30] compared masticatory muscle–pain thresholds of patients with myofascial pain syndrome and those of asymptomatic subjects. The average difference found with the PAMP II pressure algometer on the corresponding sites for females was 39.7, compared to our soft-splint group's mean change of 14.0. As has been reported previously, it seems that patients successfully treated for muscle pain typically exhibit lower thresholds than subjects with no history of myofascial pain.[30]

All three outcome measures in this study suggested that significant improvement resulted in the soft-splint group compared to the palliative-treatment and control groups. Although the duration of treatment varied from 4 to 11 weeks, there was no statistically significant difference among the mean lengths of the treatment periods for the three groups. There was also no statistically significant time interaction identified with the regression analysis and no statistically significant correlation between an individual's duration of treatment and any of the outcome measures. These findings suggest that the observed improvement was likely due to differences in treatment effectiveness.

It has been suggested that the soft occlusal surface of the soft splint may contribute to occlusal changes.[23] The results of the present article suggest that over the time period of this study, such occlusal

changes did not occur. It is possible that past reports of occlusal contact changes with these soft appliances may be due to the occlusal design of the appliance. It has often been reported that these appliances cannot be adjusted with the same care as hard acrylic-resin appliances and are often not adjusted at all.[36] The method described in the literature[11] can provide improved occlusal adjustment of the soft occlusal splint.

Most previous clinical reports regarding the use of soft occlusal splints and palliative treatment have not used quantifiable outcome measures. Outcomes have been reported as the percentage of subjects who report subjective improvement. Therefore, no direct comparison with these results can be made. The percentage of subjects reporting improvement in this study does compare favorably with other studies. Ninety percent of the subjects in the soft-splint group of the present study reported improvement; Clark's review[36] reported 70% to 90% clinical success for the traditional complete arch stabilization appliance. Harkins et al[12] reported that 74% of their patients who were provided with a prefabricated soft splint to use for 10 to 20 days had a decrease in facial myalgia. Block et al[17] reported 74% of their patients had complete or almost complete remission of their nonspecific TMD symptoms after wearing a soft splint for 6 weeks. Palliative treatment, although not resulting in a statistically significant difference from no treatment in terms of the quantifiable outcome measures, provided 90% of the subjects with reported improvement. This is comparable to the results reported by Randolph et al[3] and Hodges.[4]

Results of two previously reported studies contrast with our findings and suggest little efficacy of soft occlusal splints in the treatment of TMD. In the randomized clinical trial of Nevarro et al,[19] it is unclear how often the subjects wore the appliances. In addition, the weekly adjustment of the resilient splint "consisted of a mock adjustment since it is not possible to properly adjust this type of occlusal splint." The resultant lack of occlusal stability of the resilient appliances may have resulted in reduced efficacy.

Okeson's nocturnal EMG comparison[20] of hard and soft occlusal splints reported significantly less effect with soft appliances. Three observations related to this outcome can be made. First, the treatment effect of soft occlusal splints may not be a result of reduced nocturnal EMG activity. Although there is some evidence that hard occlusal splints can reduce nocturnal EMG activity, there is considerable variation in response. A reduction in symptoms may be unrelated to effect on nocturnal EMG activity.[37,38] Second, the response of symptomatic patients may be different than that of the asymptomatic subjects in the study by Okeson. Third, the acknowledged differences in the occlusal adjustment methods for the soft and hard splints in Okeson's study may have affected the outcome. Although Okeson[20] adjusted the soft appliances "until the patient reported that during light closure all mandibular teeth contacted the splint evenly," there are obvious differences in the occlusal scheme of the two appliances shown in his paper. It is possible that the occlusal scheme resulting from our adjustment method may provide better balance, which could improve the effect of the soft occlusal splint.

At the final evaluation of the present study, subjective opinions were solicited. Subjects were asked: *(1)* What did you dislike about your soft splint? *(2)* What improvements do you think could be made with it? *(3)* Do you want to have an acrylic-resin occlusal splint fabricated or continue to use the soft splint?

Features of the soft splint that the participants disliked were varied. Three of the 10 subjects reported that the soft splint was too bulky. This report was also the most common complaint that Harkins et al[12] received. Two subjects said that it interfered with speech. Two subjects had comments that related to the porosity of the vinyl; one subject, a farmer, found that if he wore the splint while working in areas with a foul odor, the splint retained the odor. The other subject, who was a heavy smoker and coffee drinker, believed that cigarette smoke and coffee discolored his splint.

The subjects generally recommended improvements to correct the undesirable features, ie, "make the splint less bulky." All but one of the subjects desired to continue using the soft splint rather than change to an acrylic-resin splint.

Within the limits of this randomized clinical trial, this study suggests:

1. Soft splint treatment is significantly more effective than palliative treatment or no treatment.
2. Treatment with a soft splint does not appear to produce occlusal changes.
3. Occlusal adjustment of the soft splint may play a role in its treatment efficacy.

The results suggest that the soft splint is an effective short-term treatment for reducing the signs and symptoms of masticatory muscle pain and that it does not result in short-term occlusal changes. There was some suggestion of palliative treatment being more effective than no treatment, but this was not statistically significant. Future

research is needed to further investigate the effect of occlusal adjustment on soft and hard occlusal splints, to determine the long-term effect of these appliances, to compare the efficacy of the soft splint with that of the hard occlusal splint, and to determine the most appropriate usage regimen for these appliances.

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Resumen

Estudio Clínico a Azar de Férulas Blandas Intraorales en el Tratamiento Paliativo del Dolor Muscular Masticatorio

Treinta personas que buscaban tratamiento para el dolor muscular masticatorio en una clínica de origen universitario dedicada a las articulaciones temporomandibulares (ATM), fueron asignadas al azar a diferentes modalidades de tratamiento: férulas blandas, tratamiento paliativo, o sin tratamiento. Después de 4 a 11 semanas de tratamiento, las personas fueron evaluadas para determinar los cambios en los síntomas detectados en la visita inicial, la máxima apertura sin dolor, los umbrales de dolor a la presión medidos con un algómetro, y los contactos oclusales. Por medio del uso del análisis de varianza multivariado y el análisis de covarianza, los resultados indican que el grupo de la férula blanda mejoró, lo cual se consideró estadísticamente significativo ($P < 0,01$); el grupo con tratamiento paliativo mejoró, pero no se consideró estadísticamente significativo; y en el grupo que no recibió tratamiento los síntomas se agravaron levemente. El grupo con la férula blanda tuvieron menos cambios en los contactos oclusales al ser evaluados con una hoja metálica (shimstock) en comparación a las personas del grupo que recibieron tratamiento paliativo y las que no recibieron tratamiento. Los hallazgos de este estudio indican que la férula blanda es un tratamiento de corta duración y efectivo en la reducción de los signos y síntomas de pacientes que padecen dolor muscular masticatorio; además la férula no produce cambios oclusales.

Zusammenfassung

Ein randomisierter klinischer Versuch mit weichen Aufbissschienen und palliativer Behandlung bei Schmerzen in der Kaumuskulatur

Dreissig Subjekte, die eine auf Kiefergelenke spezialisierte Universitätsklinik aufgesucht hatten zur Behandlung von Schmerzen in der Kaumuskulatur, wurden zufällig einer der folgenden drei Gruppen zugeordnet: 1. Behandlung mit weicher Aufbissschiene, 2. palliative Behandlung, 3. keine Behandlung. Nach vier bis elf Wochen wurden die Subjekte untersucht auf Veränderungen ihrer Symptome: maximale schmerzfrei mögliche Mundöffnung, Schmerzschwelle (Druckalgometer), okklusale Kontakte. Die Gruppe, die eine weiche Schiene trug, schien—nach multivariate Analyse und Kovarianzanalyse—eine statistisch signifkante Verbesserung aufzuweisen ($P < 0,01$), die Gruppe mit Palliativtherapie zeigte eine Verbesserung, die keine statistische Signifikanz erlangte und die Gruppe ohne Therapie schliesslich hatte eine leichte Aggravation der Symptome. Die Gruppe mit der weichen Schiene wies weniger Veränderung der okklusalen Kontaktsituation auf als die beiden andern Gruppen (Beurteilung mit Shimstockfolie). Die Resultate dieser Studie besagen, dass die weiche Aufbissschiene ein wirksames Kurzzeittherapiemittel zur Behandlung von Patienten mit Schmerzen in der Kaumuskulatur sein kann und dass durch diese Therapie die okklusale Kontaktsituation nicht verändert wird.