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ORIGINAL ARTICLE

Comparison of three different options for immediate treatment of painful temporomandibular disorders: a randomized, controlled pilot trial

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ABSTRACT

Objective: The purpose of this study was to compare the short-term effectiveness of three different types of immediate, non-pharmacological intervention for alleviation of the painful symptoms of temporomandibular disorders (TMD).

Material and methods: Thirty-six patients (mean age 41.6 ± 16.7 years, 25 females) diagnosed with non-dysfunctional painful TMD received counselling and subsequently were randomly allocated to three treatment groups: patients in Group A received prefabricated oral splints with water-filled elastic pads (Aqualizer®), those in Group B were provided with vacuum-formed co-polyester oral splints and those in Group C were given appointments to receive Michigan-type hard splints. Clinical examination was conducted, at baseline and after 2 weeks, by use of the RDC/TMD. Current pain intensity was determined by evaluation of graded chronic pain status (GCPS) on a numerical rating scale (NRS). Active maximum mouth opening without pain (AMMOP) was also measured. Paired sample *t*-tests and one-way analysis of variance with a significance level of $p \leq 0.05$ were conducted.

Results: After 2 weeks, overall mean current pain was reduced by 41.95% ($p < 0.001$). Current pain reduction was significant for Group B (66.6%, $p < 0.001$) but not for Groups A (37.88%, $p = 0.56$) and C (22.29%, $p = 0.26$). After 2 weeks, current pain level for Group B was significantly lower than that for Group C ($p = 0.041$). Overall, there was a statistically significant increase of AMMOP ($p = 0.01$).

Conclusion: All therapeutic options were pain-reducing. The results from this study suggest that cost-effective and time-effective intervention of counselling combined with use of a vacuum-formed splint is a favourable option for initial, short-term treatment of painful TMD.

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Introduction

According to epidemiologic studies, TMD is most commonly diagnosed on the basis of myofascial pain,[1–3] i.e. Group I according to the Research Diagnostic Criteria for Temporomandibular Disorders, or RDC/TMD.[4]

The multitude of treatment or management approaches for the relatively small group of symptoms is indicative of the lack of consensus regarding understanding of the pathophysiological mechanisms underlying TMD.

With regard to management of patients with painful TMD, studies show that most dentists prefer splints as the first therapeutic option.[5,6] A variety of types of laboratory-fabricated splint are available, ranging from hard to soft and from occlusal adjusted to unadjusted. Although all these devices consistently result in pain relief, the relief does not seem superior to that achieved by use of alternative treatment options.[7,8] Hard stabilization splints are the most preferred treatment option in this context,[9,10] although many other types of intervention are currently in use among clinicians.[7,11]

Splints are, presumably, less effective at reducing pain of chronic (dysfunctional) TMD resulting from central sensitization phenomena.[12,13] For non-dysfunctional painful TMD, fabrication of acrylic resin appliances is time-consuming, because of the technical steps necessary; these cannot, therefore, be used for immediate, initial treatment of painful TMD. This is extremely important to clinicians and patients, because patients usually expect immediate treatment of their problem on the basis of appropriate diagnosis. In this context, flexible vacuum-formed splints could have a decisive time advantage; evidence of their pain-reducing effectiveness is still lacking, however.

A prefabricated splint system, called Aqualizer®, is also available; this was introduced to address the scarcity of therapy for immediate, non-pharmacological treatment of TMD-related pain. This device contains a flexible fluid layer that prevents tooth-to-tooth contact and, consequently, controls the vertical dimension of occlusion. Use of this hydrostatic oral splint is indicated for TMD-related pain,[14] and it could also be used as an immediate, short-term option for

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treatment of TMD pain, although its effectiveness is currently unknown.

Because the pain-reducing efficacy of some non-pharmacological options (vacuum-formed or prefabricated splints) suitable for immediate treatment of TMD is unknown, the main purpose of this study was to compare the short-term (2 weeks) pain-reducing effects of three types of non-pharmacological, immediate intervention, i.e. prefabricated splints, vacuum-formed splints and counselling alone. Counselling and self-treatment have been shown to have pain-reducing effects comparable with those of different splints in previous studies,[15,16] thus, the study hypothesis was that all three types of intervention would have similar short-term effects.

Material and methods

Subjects

This clinical trial was conducted from 2009 to 2011 in the University Clinic of Heidelberg, Germany. The study sample was recruited from consecutive patients seeking treatment for non-odontogenic facial pain at the Department of Prosthodontics. All participants were thoroughly informed about the study by their examiners, and all gave their written consent before commencement of the study. The protocol was approved by the Ethics Committee of the Medical Centre of the University of Heidelberg (ref. no.: S-416/2009), and was in accordance with the latest version of the World Medical Association's Declaration of Helsinki.[17]

Inclusion criteria

Participants eligible for the study were selected in accordance with pre-set criteria. Included were adult patients of both genders in need of acute treatment for painful non-chronic (i.e. non-dysfunctional) TMD-related pain, diagnosed by use of the RDC/TMD. Patients with pain of myogenic, arthrogenic or combined origin were included. In contrast, patients with chronic (i.e. dysfunctional) facial pain or facial pain of dental, systemic (e.g. rheumatoid arthritis), traumatic (facial trauma or surgery) or neuropathic origin, patients with missing teeth leaving a gap >5 mm or with more than three consecutive missing back teeth, and patients needing dental treatment were excluded from the study. Other exclusion criteria were severe bruxism, as reported by the patients or their partners, pregnancy and previous active treatment for painful TMD within the last month, except for use of analgesics. Graded chronic pain status (GCPS),[18] as included in the German version of the RDC/TMD,[19] was used for grading of pain. Patients with a GCPS value of 3 or 4, indicative of disabling chronic pain, were not eligible for the study.

Assessment methods and study protocol

Thirty-six patients who met all the inclusion criteria, diagnosed with non-dysfunctional painful TMD by use of the RDC/TMD by calibrated examiners, gave their written, informed consent to participation in the study. All patients were examined on the basis of the same criteria, and custom alginate impressions of both dental arches and bite registrations were obtained from all patients after examination but before allocation to a study subgroup. For all patients diagnosed with TMD, their disease and its multifactorial aetiology were explained, and they were given advice on how to reduce stress on their masticatory system by avoiding extreme movements of the jaw (e.g. yawning) and by avoiding chewing hard food or chewing gum. All patients in extreme pain were allowed to use common over-the-counter analgesics, the type, amount and frequency of which were to be reported on recall.

Each study participant was then randomly assigned to one of three treatment groups (A, B and C). A statistician not involved in the study had provided consecutively numbered sealed envelopes with one random assignment in each. The envelopes were opened in sequence by the principal investigator after an eligible patient had given his/her written informed consent to participation in the study and had been examined.

Patients allocated to Group A received, immediately, a prefabricated oral splint with water-filled elastic pads (Aqualizer®; Dentrade International, Köln, Germany). Patients were instructed to wear the splint during sleep and for at least 6 h a day. Patients assigned to Group B received, at the same appointment but after waiting for $\sim$1 h, an individualized vacuum-formed oral splint, made from 1.5-mm-thick co-polyester film (Erkodent, Pfalzgrafenweiler, Germany), fabricated on the patient's study casts, always by the same technician, in a dental laboratory. These patients were also instructed to wear the splint during sleep and for at least 6 h a day. Patients in Group C were the waiting-list group, and would, after the normal counselling described above, receive a Michigan-type hard acrylic oral splint after 2 weeks. This is the usual time needed for this kind of treatment in an average dental surgery in Germany, because of the necessary technical and bureaucratic procedures.

A follow-up appointment was arranged 2 weeks after the first examination, i.e. at the end of the active study period. During this appointment, all patients were examined again, by use of the RDC/TMD, by a calibrated examiner unaware of their allocation and of the diagnosis at the first examination. At this point the study was complete, and patients in Groups A and B still experiencing pain and patients in Group C were further treated by use of the usual treatment protocol of the Department of Prosthodontics of the University Clinic of Heidelberg, which includes medication, use of oral appliances and physiotherapy.

Pain intensity was rated on a numeric rating scale (NRS), which the patients completed at each appointment. Because of the short duration of the study, current pain intensity, only, was assessed as primary outcome. A secondary outcome was active maximum jaw opening without pain.

Statistics

The sample characteristics and all measures of outcome were reported descriptively. Pain-intensity data were tested for

normality by use of the Shapiro–Wilk test. Pain intensity as rated on the NRS was compared between the two time points (day of first examination and after 14 days) by use of the *t*-test for paired samples. At each time (T1 and T2) the three groups were compared for pain intensity by use of one-way analysis of variance (ANOVA) with the Tukey adjustment for multiple comparisons (for the post-hoc tests). The significance level was set at $p \leq 0.05$. All statistical analysis was performed by use of the software SPSS 20.0 (Chicago, IL). To estimate the sample size necessary for further clinical trials, *post-hoc* power analysis was performed with G*Power (version 3.1.9.2).

Results

The mean age [±standard deviation (SD)] of the study sample was 41.58 (±16.68) years, and twenty-five patients (69.4%) were female. More demographic characteristics of the sample are presented in Table 1. RDC/TMD results at baseline for the patients in the diagnostic subgroups are listed in Table 2. All patients completed the study without complications and were included in the assessment. Of the ten patients initially taking analgesics, only three continued to take these during the 2-week period of this trial.

Table 1. Detailed demographic sample characteristics at baseline.

Patient No.	Age (in years)	Gender	Study group	Diagnosis (Axis I of RDC/TMD)	Pain duration (in weeks)
#1	52	Male	A	Myofascial pain	24
#2	24	Female	C	Myofascial pain with limited opening Arthralgia bilaterally	24
#3	25	Male	A	Myofascial pain	63
#4	47	Male	B	Arthralgia on the left side	24
#5	44	Female	C	Myofascial pain with limited opening	4
#6	71	Male	B	Myofascial pain Arthralgia bilaterally	40
#7	47	Female	A	Myofascial pain with limited opening	104
#8	38	Female	A	Myofascial pain with limited opening Disk displacement without reduction without limited opening on the right side Arthralgia on the right side	156
#9	45	Female	B	Myofascial pain with limited opening Arthralgia on the left side	44
#10	24	Female	C	Myofascial pain with limited opening	144
#11	22	Female	C	Myofascial pain with limited opening	0.43 (3 days)
#12	62	Female	B	Myofascial pain	2
#13	48	Female	C	Myofascial pain with limited opening Disk displacement without reduction with limited opening bilaterally Arthralgia on the right side	40
#14	21	Female	A	Myofascial pain with limited opening	16
#15	33	Female	A	Myofascial pain with limited opening Disk displacement with reduction bilaterally	96
#16	63	Female	B	Myofascial pain Arthralgia on the left side	20
#17	45	Male	B	Myofascial pain	4
#18	41	Female	C	Myofascial pain Arthralgia on the left side	28
#19	72	Female	A	Myofascial pain Disk displacement with reduction on the left side	1
#20	58	Female	C	Myofascial pain with limited opening Arthralgia on the right side	12
#21	52	Female	A	Myofascial pain with limited opening Arthralgia on the right side	160
#22	27	Female	B	Myofascial pain with limited opening	1
#23	50	Female	B	Myofascial pain	1
#24	28	Female	C	Myofascial pain with limited opening	16
#25	34	Female	B	Myofascial pain	24
#26	18	Female	C	Myofascial pain with limited opening Disk displacement with reduction on the right side	24
#27	32	Male	A	Myofascial pain	24
#28	20	Female	A	Myofascial pain	104
#29	65	Female	C	Myofascial pain Arthralgia on the right side	144
#30	55	Male	B	Myofascial pain Disk displacement with reduction on the left side	24
#31	55	Female	C	Myofascial pain	24
#32	75	Male	A	Arthralgia on the right side	2
#33	23	Female	A	Myofascial pain with limited opening	8
#34	31	Male	B	Myofascial pain with limited opening Disk displacement without reduction without limited opening on the left side Arthralgia bilaterally	12
#35	26	Male	B	Myofascial pain with limited opening Arthralgia on the right side	96
#36	24	Male	C	Myofascial pain	16

A = counselling + aqualizer, B = counselling + individualized vacuum-formed splint, C = counselling.

Mean current pain intensity for the whole sample, obtained by use of the NRS on the day of the first examination, was 5.03 (±2.29) with a median of 5.0. Current pain intensity was normally distributed at both time points (Shapiro–Wilk test, $p > 0.05$). Current pain in the three groups did not differ significantly at baseline (one-way ANOVA, $p = 0.91$).

After 2 weeks, current pain for the whole sample was reduced by 41.95% from 5.03 (±2.29) to 2.92 (±2.48) with a median of 3.0 points on the NRS. This reduction was statistically significant (*t*-test for paired samples, $p < 0.001$) and remained statistically significant when analysed, by use of the same test, separately for Group B (66.6%, $p < 0.001$), but not for Group A (37.88% reduction, $p = 0.56$) or Group C (22.29% reduction, $p = 0.26$), as is apparent from Figure 1.

Current pain at recall was compared for the three groups by one-way ANOVA. Statistically significant differences were observed among the three groups ($p = 0.05$); after the post-hoc tests the differences remained significant solely for the comparison between Groups B and C ($p = 0.04$) but not for the other two comparisons ($p > 0.05$). GCPS results for the whole sample and for each group at both time points are listed in Table 3.

Average (±SD) maximum active jaw opening without pain was 34.29 (±10.41) mm at baseline. There was, overall, a statistically significant increase at the second examination (39.26 ± 11.47 mm; paired Student's *t*-test, $p = 0.01$).

Table 2. Summary of demographic sample characteristics.

Participants	*N*	Group A	Group B	Group C	Mean age (SD)	Pain duration in weeks (SD)
Male	11	4	6	1	43.91 (18.12)	27.25 (30.35)
Female	25	8	6	11	39.93 (16.30)	48.23 (56.18)
Total	36	12	12	12	41.58 (16.68)	42.98 (51.33)

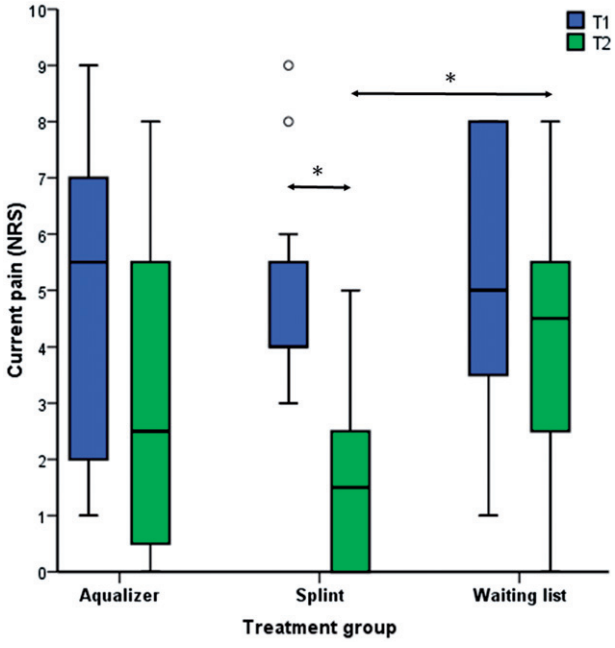

Figure 1. Box plots of current pain intensity for each treatment group at both time points. T1 = baseline, T2 = 2-weeks later, *$p < 0.05$.

Discussion

This study was the pilot phase of a randomized, controlled, single-blind clinical trial of the effectiveness of three different options for acute non-pharmacological treatment of painful non-chronic TMD. The sample was selected, on the basis of strict criteria, to be representative of most new TMD patients treated at first-grade settings in Germany. The ages of the patients and the gender distribution within the sample (69.4% female patients) are comparable with those for other samples of TMD patients in other studies [20,21] although the percentage of female patients was much higher in some studies.[16,22]

Pain is a major symptom of TMD, and is the reason most patients seek treatment.[23] Pain intensity on the NRS is often used, and is recommended (IMMPACT statement) as a measure of pain severity and treatment success.[24] A thorough clinical examination of the stomatognathic system, to identify the origin of the pain in a standardized manner, is necessary, and should be conducted by a dentist. Use of a standardized diagnostic procedure (RDC/TMD) by calibrated examiners ensured the validity of the diagnoses and of patient selection in this study with regard to pain origin and intensity.

After proper diagnosis of painful TMD, there is usually a need for immediate and, ideally, non-pharmacological treatment. Thus, the therapeutic approaches compared in this work were common cost-effective and time-effective options available in routine dental practice in Germany for immediate treatment of TMD patients as alternatives to NSAID, which patients usually take without seeking advice and may be associated with side-effects.

The time-consuming procedure needed for fabrication of a hard acrylic splint in a dental laboratory, which usually takes ~2 weeks, is an obstacle to use of this kind of splint for immediate treatment. Other alternatives to NSAID as treatment options, for example cognitive behavioural therapy, physiotherapy, or trigger point injections, were not included, because of their high cost, the lack of standardization of the intervention or their unavailability at many first-grade treatment settings.

Taking into account that, on average, a reduction of ~30% in the NRS is a clinically important difference,[25] all three treatment options seemed effective at reducing pain intensity, but, because of the small sample size, did not reach significance for Groups A and C. Post-hoc sample size estimation

Table 3. Current pain NRS values for the sample and treatment groups at both time points.

	Group A		Group B		Group C		Total	
Current pain	T1	T2	T1	T2	T1	T2	T1	T2
Mean (SD)	4.83 (2.76)	3.0 (2.70)	5.0 (1.81)	1.67 (1.78)	5.25 (2.38)	4.08 (2.50)	5.03 (2.29)	2.92 (2.48)

T1 = baseline, T2 = 2 weeks later.

revealed that for Group B (vacuum-formed splint) 21 subjects and for Group A 50 subjects would have been necessary to reach the desirable power level of 0.8.

Counselling, in terms of diagnosis (i.e. putting the patients' disease in context), explanation of the origin and prognosis of the disease (and, as a consequence, removing any fear of malignancy or incurable disease) and self-management therapy, has been shown to be effective.[26] At the beginning of this study the patients were also advised to avoid muscle stress (e.g. to avoid chewing hard food or gum) and excessive movement of the jaws (e.g. yawning). The therapeutic effect of counselling for Group C does not contradict the results of another clinical trial [16] which concluded that, in the long term, counselling or self-care alone has the same effect as use of a soft or hard appliance.

Vacuum-formed splints, although not used as an immediate therapeutic option in this study, have been reported not to differ from hard acrylic splints with regard to patient perception,[27] and seem to perform very well in reduction of masticatory muscle pain in the short term.[15,28] In a previous study, vacuum-formed occlusal splints reduced facial myalgia by 25.4% within 2 weeks;[29] this is slightly less than in our study, possibly because dysfunctional pain patients were not specifically excluded from that study. Other randomized clinical trials of vacuum-formed splints found no improvement in the short-term [30] for 'usual pain intensity' (derived from the modified SSI, which is not directly comparable with pain intensity on the NRS).

A trend toward reduction of pain intensity was also observed for the hydrostatic splint, but the effect was less than for the vacuum-formed splint. Research results for similar populations are insufficient for comparison of this result; the trend could, nevertheless, be of importance for low-income patients, because of its greater availability and much lower cost. It is, in addition, not easy to explain the different effectiveness observed for Groups A and B. According to current understanding of motor unit (MU) recruitment inside the masseter,[31] insertion of splints causing (even small) vertical changes of jaw position induce significant modification of MU recruitment. This, in turn, might unload dysfunctional MU and accelerate natural healing by the muscle's own stem cells (satellite cells).[32] It might, however, be speculated that the 'duty-time' of the prefabricated soft splint was somehow smaller, because of frequent removal of the appliances during the initial two or three nights until the patients were used to the splint (reports from patients support this assumption).

The improvement in symptoms and signs after treatment may also be attributed to regression to the mean and the natural course of the disease. The placebo effect is, moreover, another important factor when considering the effects of treatment, and it is sometimes difficult to assess its contribution to the results of clinical trials, although placebo-controlled studies [33] have excluded a pure placebo effect.

A review [34] has concluded that use of occlusal appliances to manage localized masticatory myalgia, arthralgia or both, is sufficiently supported by the literature. The results of this study suggest that immediate splint therapy has a positive, clinically significant effect on reduction of pain in the muscles, better than that of counselling alone. In this study, moreover, significant improvement of mouth opening was observed after insertion of the splints. This finding corroborates the outcome of previous studies which found an improvement of 7.4 mm in mouth opening after splint therapy.[35,36]

It must also be remarked that sample size in this pilot study may not be sufficient to reveal differences between pain intensity as a result of use of hydrostatic splints. As reported above, however, according to the post-hoc evaluation of effect size in this study the group size needed to be $n = 21$ to enable detection of differences between the groups at recall with a power of 0.8. With regard to the strict selection criteria (non-dysfunctional and not previously treated patients with painful TMD), it was not considered feasible to continue this study in a third-grade health-care setting. Furthermore, the small number of participants limits the generalizability of the results. Another possible disadvantage of the study design could be the unknown influence of different expectations of the different treatments. Nevertheless, the patients on the waiting list received active treatment,[15,16] i.e. expert counselling and self-treatment instructions on how to reduce stress on their masticatory system. This, with the fact that all patients knew about the good prognosis of their disease, may have reduced differences between their expectations, and the authors believe patient expectations had no significant effect on outcome.

TMD tends to be a persistent, recurrent pain condition which usually exceeds the 2-week period of this clinical trial. The outcome of treatment by use of occlusal appliance therapy has been reported to be effective after 4–8 weeks.[37–39] A 2-week period could thus be regarded as quite short for assessment of the effectiveness of splint therapy for patients with TMD; it may, however, be sufficient for examination of the initial effects of treatment, as shown in this study.

Of the 10 patients initially taking analgesics, only three continued to take these during the 2-week period of this trial. This positive result can be ascribed to the expert counselling and immediate splint intervention, and emphasizes the usefulness of this initial TMD treatment.

Conclusions

The outcome of this clinical study suggests that patient counselling combined with a splint, with good cost-effectiveness and time-effectiveness (in the regional context of the study) and almost no side effects, seems to be a good immediate short-term option for amelioration of the signs and symptoms of painful TMD.

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Disclosure statement

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

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