Efficiency of occlusal appliance therapy in secondary otalgia and temporomandibular disorders

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In clinical practice, it is commonly assumed that occlusal splints have therapeutic value in the treatment of temporomandibular disorders (TMD), but the evidence based on randomized controlled trials is scarce. This study evaluated the short-term (10-week) efficacy of a stabilization splint in subjects with recurrent secondary otalgia and active TMD treatment need using a randomized, controlled, double-blind design. Thirty-six subjects were randomly allocated to the two treatment groups: the stabilization splint and the control splint group. After 10 weeks' treatment, the intensity of secondary otalgia, measured on a VAS scale (from 0 to 100 mm), decreased statistically significantly in the stabilization splint group (t 2.12; *P* 0.006), but not in the control group. Improvement in active TMD treatment need in subjects showing moderate or severe signs and symptoms of TMD was reported significantly more often in the stabilization splint group than in the control splint group (χ^2 5.71; *P* .017). A statistically significant decrease in the Helkimo clinical dysfunction index was seen in the subjects with stabilization splint (Z −2.63; *P* .009), but not in the subjects with control splint. The results indicate that the use of a stabilization splint is beneficial with regard to secondary otalgia and active TMD treatment need. □ *Active TMD treatment need; clinical trial; control splint; secondary otalgia; stabilization splint*

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In clinical practice, it is commonly assumed that occlusal splints have therapeutic value in the treatment of temporomandibular disorders (TMD). This belief is based on several reports of a successful outcome achieved with these appliances (1–10). However, most of these studies have not been based on the principles essential for randomized, controlled trials (RCTs) (11). Forssell et al. (11) published a meta-analysis showing that evidence for occlusal therapy in TMD treatment is scarce. They found only 14 RCT studies on occlusal appliances, many of which had clear shortcomings in study design. One well-designed study of myofascial pain patients treated with an occlusal appliance showed that the effect of a stabilization splint was non-specific and gave no better result than a non-occluding palatal splint (12). On the other hand, in a recent RCT study, Ekberg et al. (13) reported a different result. According to them, the different outcome of these two studies could be due to different origins of pain. In their first study concerning occlusal appliances, Ekberg et al. included TMD patients with pain of arthrogenous origin, while Dao et al. (12) treated TMD patients with pain of myogenous origin. Later, Ekberg et al. reported good treatment outcome results in patients with stabilization splints in TMD of myogenous origin as well (14).

Otalgia and other aural symptoms seem to be common in connection with TMD, and are generally explained as referred pain from the masticatory muscles, temporomandibular joints or from the neck region. We have earlier found secondary otalgia (otalgia without infection or trauma) in 40–48% of subjects with moderate or severe signs and symptoms of TMD (15). In that study, the subjects with otalgia more often had masticatory muscle and joint tenderness on palpation than the subjects without otalgia. In addition, the mean number of visits to a physician because of otalgia in subjects with moderate or severe signs and symptoms of TMD was 14 times as high as that in the subjects with no TMD treatment need (15).

In the literature, we have found only a few previous reports on treatment of otalgia in connection with TMD (16, 17). Koskinen et al. (16) based their conclusions on a follow-up study without controls. Keersmaekers et al. (17) used a control group consisting of TMD patients without otalgia. Both studies showed that treatment of TMD decreased otalgia in TMD patients. However, these investigations were neither randomized nor blinded.

In the present study, we set out to test the effect of a stabilization splint in subjects with secondary otalgia in connection with moderate or severe signs and symptoms of TMD in a RCT study. The null hypothesis was that a stabilization splint is not more effective than a control splint in the treatment of secondary otalgia or TMD.

Subjects and methods

The questionnaires of the present study were mailed to the subjects from March 1999 to August 2000 in Jyväskylä, Finland. The study was approved by the Ethics Committee of the Central Hospital in Jyväskylä, Central Finland. A total of 2500 subjects in the age groups 25-, 35-, 45-, 55-

and 65-years (equal numbers of men and women) were randomly selected by including every tenth of the names in alphabetical order drawn from the database of the municipal administrative court in Jyväskylä.

The first step in the study was to send a questionnaire about otalgia to all 2500 subjects (Fig. 1). In this questionnaire, secondary otalgia was defined as pain inside or around the ear without any known disease explaining the pain in the ear (18). Altogether 1720 subjects (69%; ♂ 785, ♀ 935) completed the questionnaire and returned it.

The second step was to mail a written description of the clinical study along with an invitation to participate in stomatognathic and otorhinolaryngologic examinations and interviews, to the subjects ($n = 152$) who reported occurrence of recurrent secondary otalgia at least once a month during the preceding 6 months. Informed consent was obtained from all the subjects. A total of 100 subjects (66%) participated in all clinical examinations and interviews. An experienced otologist (SK) performed a standardized otolaryngologic examination and interview to rule out primary otalgia. The otologic examination included evaluation of maxillary sinuses with ultrasound, evaluation of mobility of ear drums by acoustic tympanometer, and bilateral inspection and palpation of the ventral, dorsal and lateral neck. According to the otorhinolaryngologic examination and interview, nine subjects had primary otalgia and were excluded from the otorhinolaryngologic and dental analyses. All the subjects in the present study ($n = 36$) fulfilled the criteria of secondary otalgia. In the analysis of dropouts ($n = 52$), no differences in age (χ^2 2.3; P .677) or gender (χ^2 0.5; P .485) were found compared to those who participated.

In the third step, an experienced clinician (MK) performed the standardized interviews and clinical stomatognathic examinations. The clinical examination included measurement of mandibular movements, pain during guided and non-guided mandibular movements, registration of temporomandibular joint (TMJ) sounds (clicking and/or crepitation), locking, and lateral and/or posterior tenderness of the TMJ. The following muscles were palpated: the anterior and posterior temporal muscle, the attachment of the temporal muscle, the deep and superficial portion of the masseter, the medial and lateral pterygoid, and the posterior portion of the digastric muscle. The degree of muscle tenderness was evaluated according to a 4-point scale (0 = no tenderness, 1 = tenderness reported by the subject, 2 = tenderness with a palpebral reflex, 3 = withdrawal reaction).

The comprehensive interview was performed after the clinical examination to minimize examination bias and included 17 questions concerning symptoms of TMD and symptoms related to TMD. The frequency of headache was estimated in the interview on a 4-point scale (1 = never or seldom, 2 = once a month, 3 = 2 to 4 times a month, 4 = at least twice a week). Facial pain was defined as pain in the facial region (excluding headache, ear and tooth pain). Intensity of facial pain was reported by the subject using a scale from 0 to 10 (0 = no pain, 10 = maximal pain).

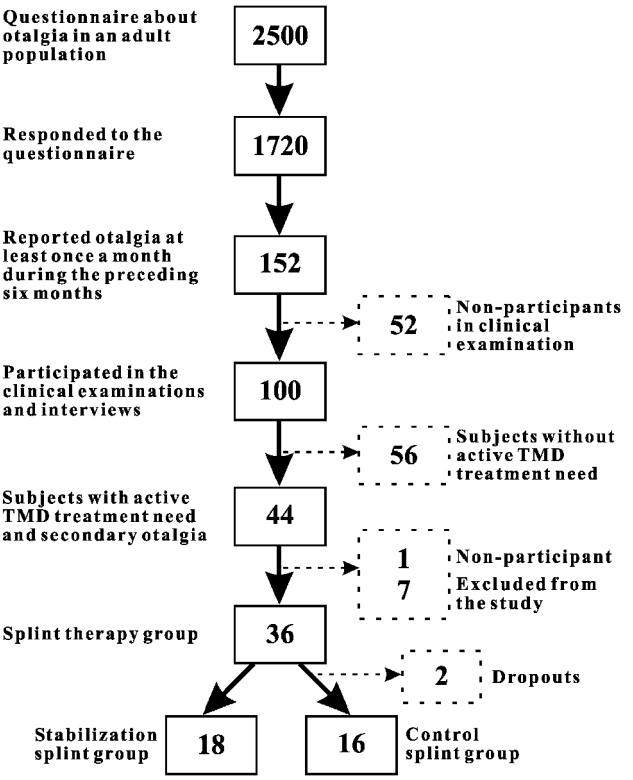

Fig. 1. Selection of subjects with secondary otalgia occurring at least once a month during the preceding 6 months for the splint therapy groups.

On the basis of the clinical examination and interview, the subjects were divided into three diagnostic subgroups according to their signs and symptoms: mainly arthrogenous, mainly myogenous or combined arthrogenous and myogenous TMD. This was based on the criteria defined by De Leeuw et al. (19), as well as the corresponding guidelines of the American Academy of Orofacial pain (20). The clinical dysfunction score according to Helkimo (21) was calculated (D_i 0 = no signs, D_i I = mild signs, D_i II = moderate signs, D_i III = severe signs of TMD).

The subjects estimated the intensity of secondary otalgia by drawing a vertical line on the visual analog scale, the VAS (0 mm–100 mm, 0 mm = no pain, 100 mm = the most intensive pain you can imagine). In the same way, the subjects also estimated the impact of secondary otalgia on daily living (0 = not interfering, 100 = impossible to live a normal life), concentration (0 = not interfering, 100 = impossible to concentrate) and sleeping (0 = not interfering, 100 = impossible to sleep).

The subjects were then classified according to Kuttila et al. (15) into active ($n = 44$) and no TMD treatment need groups ($n = 56$) (Fig. 1). A subject was considered to belong to the active TMD treatment need subgroup if he/she was suffering from signs and symptoms of TMD prompting him/her to seek medical help, or was estimated as needing

Table 1. Distribution of subjects in the splint groups before treatment according to some background factors and clinical TMD diagnostic subgroups ($n = 36$). Two subjects in the control splint group were lost during the study

Variable	Stabilization splint ($n = 18$)	Control splint ($n = 18$)
Gender		
Men	6	3
Women	12	15
Age (years)		
Mean age	45	47
Range	25–65	25–65
Duration of otalgia		
6 months–2 years	14	12
Over 2 years	4	6
Frequency of otalgia		
At least once a month	10	9
At least once a week	4	4
Daily	4	5
Intensity of otalgia		
VAS < 40	13	14
VAS 40	5	4
TMD diagnostic subgroups		
Myogenous	8	4
Arthrogenous	2	4
Combined	8	10
Bruxism	14	15
Headache twice a month	8	9
Neckache twice a month	18	15

care for TMD by an experienced clinician. A subject was considered to belong to the no treatment need subgroup if there were no signs and symptoms of TMD treatment need. The subjects who had earlier received any treatment for their TMD as well as the subjects with complete dentures, a history of psychiatric disorder, or symptoms of neuralgias or toothache ($n = 7$) were excluded. A total of 36 subjects with active TMD treatment need fulfilled the criteria of secondary otalgia and agreed to participate in the splint treatment study with a double-blind set-up. Informed consent was obtained from all the subjects. The distributions of gender and age, duration, frequency and intensity of otalgia, and diagnostic subgroup, bruxism, headache and neckache in different splint groups before treatment are given in Table 1.

Finally, the subjects were randomly allocated to the splint treatment group and the control group (Fig. 1) by randomizing the first splint type by lot and, thereafter, alternating stabilization splint and control splint treatment for the consecutive subjects. The subjects in the treatment group were treated with a stabilization splint, and those in the control group with a non-occluding, thin palatal splint (13). Another dentist trained in stomatognathic physiology (ESN) installed and adjusted the flat stabilization splints in centric relation with canine guidance and without any mediotrusion contacts during lateral slides. Protrusion was symmetric, without molar or premolar contacts. Within 2 weeks, the same dentist checked and readjusted the splint. The check-up was also performed in the control group.

Two subjects in the control group left the study. One felt the splint was too uncomfortable and the other had continuous symptoms of respiratory infection during the follow-up period and needed medical care. Of the remaining 34 subjects, 18 (♂ 6, ♀ 12, mean age 45 years) wore a stabilization splint and 16 (♂ 3, ♀ 13, mean age 48 years) a palatal control splint during the night for 10 weeks (13). At the end of the study period, the subjects were re-examined by the same clinician (MK) who examined them before the treatment without knowing the type of splint used. She also classified the subjects into active or no TMD treatment need subgroups once again. In addition, the intensity of secondary otalgia and its impact on daily living, concentration and sleeping were estimated without showing the initial VAS scores to the subjects. The intensity of facial pain, the frequency of headache and the Helkimo clinical dysfunction index were estimated as before, after the trial.

Statistical analyses consisted of the χ^2-test and Student's t test to determine the significance of differences between the groups. For comparison within groups, the paired samples t test, the Wilcoxon signed-ranks test and the binomial test were used (SPSSWIN 10.0). The differences in the occurrence of the studied variables were considered statistically not significant (NS) if $P > .05$, almost significant if $.05 \geq P > .01$, significant if $.01 \geq P > .001$, and highly significant if $.001 \geq P$.

Results

Secondary otalgia

An improvement of otalgia was found in 15 subjects (83%) in the stabilization splint group after the 10-week follow-up, while the corresponding figure in the control group was 10 (63%). The difference between the groups was statistically not significant. Within the stabilization splint group, the difference in the number of subjects with improvement of secondary otalgia compared to the number with no change or worsening of otalgia was statistically significant (binomial test, P.008). In the control splint group, no statistically significant difference was seen between the frequency of the subjects with and those without improvement of otalgia (P.454) (Fig. 2).

The intensity of otalgia decreased in the stabilization splint group from a VAS score of 34 to 17 (t 3.13; P.006), but no decrease was seen in the control splint group (t 1.61; P.129). Furthermore, the subjects with stabilization splint reported a statistically significant improvement in their concentration ability (t 3.23; P.005) contrary to the subjects with control splint.

Facial pain and headache

In the stabilization splint group, 15 of the subjects (83%) reported a decrease in intensity of facial pain, while the corresponding figure in the control splint group was 9 (56%). The improvement was statistically significant within

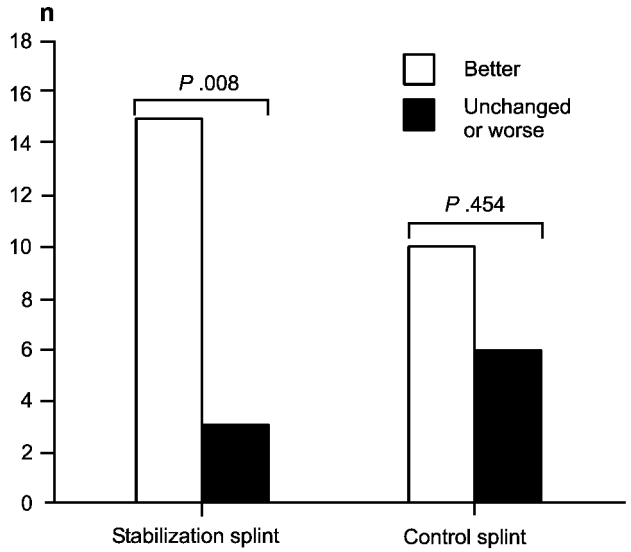

Fig. 2. Treatment outcome of secondary otalgia in the stabilization ($n = 18$) and control splint groups ($n = 16$).

the stabilization splint group (Z −3.1; P .002) and almost significant within the control splint group (Z −2.0; P .049), but not between the groups (χ^2 4.6; P .052). In some subjects, a simultaneous decrease was observed in facial pain and secondary otalgia. In the stabilization splint group, 16 subjects reported facial pain at the base line and all reported a decrease in the intensity of facial pain at the 2nd examination. Of these subjects, 81% also reported a decrease in the intensity of otalgia. In the control splint group, 15 subjects reported facial pain at baseline and 9 of them reported a decrease in the intensity of facial pain at the 2nd examination. Of these subjects, 67% also reported a decrease in the intensity of otalgia. Among the 6 subjects without a decrease in the intensity of facial pain, 3 reported a decrease in the intensity of otalgia, but the other 3 did not.

The frequency of headache within the groups decreased statistically significantly in the subjects with stabilization splint (Z −2.7; P 0.007), but not in the subjects with control splint (Z −1.5; P .133).

TMD signs

After 10 weeks' treatment, the difference in the change in number of painful mandibular movements (decrease versus no change or increase) between the splint groups was statistically almost significant (Table 2). The mean number of muscles tender to palpation decreased statistically significantly in the stabilization splint group, but not in the control group (Table 2). The number of subjects in the stabilization splint group with at least 4 muscles tender to palpation decreased statistically significantly after treatment (Wilcoxon signed rank test: Z −3.00; P .003), but a similar decrease was not seen in the control splint group (Wilcoxon signed rank test: Z −1.73; P .083) (Table 2). The degree of tenderness on muscle palpation decreased statistically significantly from grade 3 to grade 2 or less in the subjects with stabilization splint (t 3.28; 95% CI 1.3–5.8), but did not decrease in the subjects with control splint (t 2.22; 95% CI 0.09–4.2).

Active TMD treatment need

After 10 weeks' treatment, the number of subjects with no TMD treatment need was significantly higher in the

Table 2. Signs before and after treatment in splint groups (stabilization splint $n = 18$, control splint $n = 16$). Fisher's exact test ([a]) was used for comparison between groups. Wilcoxon signed rank test ([b]) and paired t-test ([c]) were used in for comparison within the groups

	Stabilization splint			Control splint		
	Before *n*	After *n*	*P*	Before *n*	After *n*	*P*
Change in number of painful mandibular movements between groups						.043[a]
Decrease		7			1	
No change or increase		11			15	
Masticatory muscles						
Mean no. of muscles tender on palpation	8.6	5.1	.004[c]	7.8	5.7	.042[c]
No. of subjects with at least 4 muscles tender on palpation	18	9	.003[b]	13	10	NS[b]
Temporomandibular joint						
Tenderness on TMJ palpation						
Only lateral	8	7	NS[b]	8	7	NS[b]
Lateral and posterior	1	1		1	2	
Joint sounds			NS[b]			NS[b]
No sounds	5	5		5	6	
Clicking	9	10		5	8	
Crepitation	3	2		3	1	
Reciprocal clicking	1	1		3	1	
Helkimo clinical dysfunction index			.009[b]			NS[b]
D_i I	0	4		2	1	
D_i II	8	9		8	6	
D_i III	10	5		6	9	

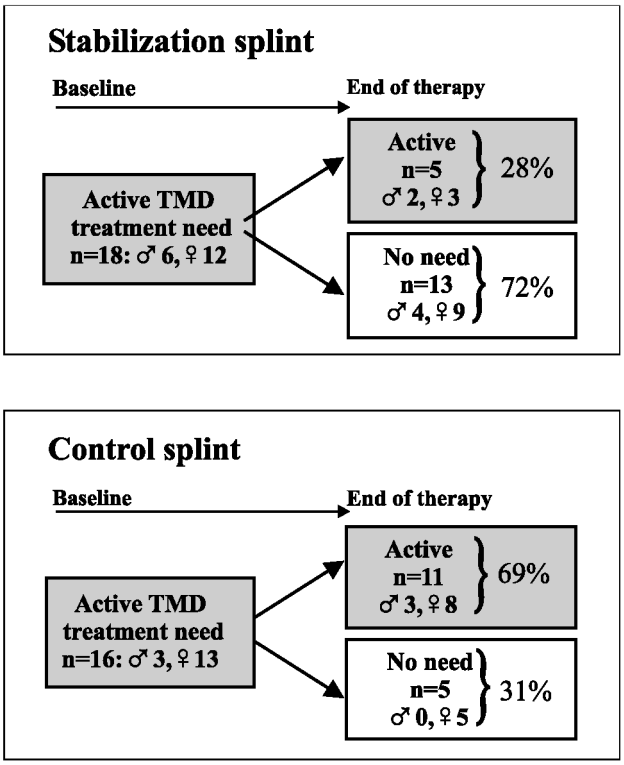

Fig. 3. Change in TMD treatment need from active to no treatment need in the splint groups: stabilization splint was more effective than a control splint in decreasing TMD treatment need (χ^2 5.7; P.017).

stabilization splint group than in the control splint group (13 vs 5, χ^2 5.71; P.017) (Fig. 3). However, a significant improvement in TMD treatment need was observed within both groups (stabilization splint: Z −3.61; $P < .001$, control splint group Z −2.4; P.014). The change from active TMD treatment need to no TMD treatment need was not associated with gender.

Discussion

Treatment with a stabilization splint showed a positive outcome in terms of both secondary otalgia and TMD treatment need. With regard to otalgia, the decrease was significant within the groups but not between the groups. This may be due to the relatively low intensity of the secondary otalgia at baseline. In a patient material, the VAS score of secondary otalgia would probably have been higher, but we examined and treated subjects in a randomly selected non-patient population although the subjects showed moderate or severe signs and symptoms of TMD. In our opinion, the improvement of otalgia in this trial may indicate that pain in the auricular area is often referred pain from the temporomandibular joint and associated structures.

The result regarding TMD is in good agreement with the results of Ekberg et al. (13, 14). Our results differ from those of Dao et al. (12), who reported no differences in treatment outcome between the stabilization and control splint groups. The origin of pain differed in our study compared to the study by Ekberg et al. (13) and the study by Dao et al. (12): Dao et al. investigated TMD patients with pain of mainly myogenous origin, Ekberg et al. TMD patients with pain of mainly arthrogenous origin. Most of our subjects in this investigation had mainly a combined type of signs and symptoms of TMD. Our results are in line with those of Ekberg et al. regarding many individual signs of TMD, but there are also some differences. In the study by Ekberg et al. concerning arthrogenous TMD patients, neither the tenderness on palpation of the masticatory muscles nor the degree of muscle tenderness showed any significant reduction, as they did in our study. When Ekberg et al. investigated TMD patients with mainly myogenous origin of TMD, they obtained results similar to ours with regard to number of tender muscles (14). The Helkimo clinical dysfunction index decreased statistically significantly in Ekberg's and our study.

The most commonly used methods for measuring the intensity of pain are verbal and numerical rating scales or the VAS. The VAS provides a simple, efficient and minimally intrusive measure of pain intensity. In contrast to other pain measurement methods, it is appropriate to use the VAS to estimate the percentage differences between measurements from independent samples of subjects such as, for example, in our study, the intensity of secondary otalgia in two different splint groups. On the other hand, there is also a major disadvantage of the VAS: it assumes that pain is a unidimensional experience although pain is much more than its intensity. According to the study by Magnusson et al. (22), the behaviour rating scale was found to be more useful than the VAS in TMD patients. However, the intensity of pain measured with the VAS is a dimension of pain widely used in clinical and research settings (23).

In order to study a randomly selected group of subjects with secondary otalgia and moderate or severe signs and symptoms of TMD, a thorough selection procedure had to be used. In the present study, the age and gender standardized prevalence of secondary otalgia was 6%, and a mailed questionnaire about otalgia successfully reached 152 subjects with secondary otalgia. One hundred of them gave their consent to participate in both stomatognathic and otolaryngologic examinations and interviews. Owing to the strict inclusion criteria and for other reasons, only 36 subjects participated in the clinical trial. Despite the small number of subjects, a statistically significant difference between the groups could be observed with regard to TMD treatment need. Throughout the study, blinding was given the highest priority. Two different investigators participated, one carried out the evaluations and examinations, while the other was responsible for the treatment procedure.

Our results are in line with our earlier results regarding the close connection between secondary otalgia and TMD

treatment need. In our earlier longitudinal study (24), we showed that 7–9% of adults had active treatment need for TMD with moderate or severe signs and symptoms of TMD. Among the subjects with active treatment need, 40–49% also reported secondary otalgia during the interview. In the present study, we first estimated the prevalence of secondary otalgia by means of a questionnaire on a population level (result 6%) and then classified the subjects with secondary otalgia into subgroups of active treatment need for TMD and no treatment need. In the present study, 44% of the subjects with secondary otalgia were classified as having active TMD treatment need. On the whole, we have shown in two different population studies, that TMD is closely connected to secondary otalgia.

The stabilization splints are still not a definitive treatment method but an adjunct or symptomatic treatment. However, they seem to be effective according to the studies published after the publication of the review by Dao and Lavigne (25). The effect of a stabilization splint on pain is related to the biomechanics of musculoskeletal tissues, such as the physical interactions between the condylar head, disc, fossa, retrodiscal tissue, ligaments and muscles during functioning (26). In addition, the placebo effect may influence the subjective sensation of pain during and after a treatment period. Although spontaneous remission and natural fluctuation in signs and symptoms of TMD may influence the treatment outcome, Ekberg et al. (27) found that the long-term results were in line with their earlier short-term results concerning pain in arthrogenous TMD patients treated with a stabilization appliance. As early as 1972, Greene and Laskin stated that any kind of splint probably affects the masticatory muscles (1). It may be possible that the control splint influences the subject's awareness of jaw habits and functioning of the tongue and, in this way, also the muscles and TM joint, although in principle the control splint does not alter the intermaxillary relationship. Moreover, the thickness of the palatal plate of the control splint may affect treatment outcome: a thick palatal appliance could bring about an improvement in the myofascial pain dysfunction (MPD) syndrome (28). In our study, as in the study by Ekberg et al., the subjects wore a palatal control splint with a thin palatal plate to minimize any possible effect of the control splint.

In conclusion, the results of this short-term evaluation suggest that the stabilization splint is more effective in the alleviation of secondary otalgia emanating from TMJ and associated structures, as well as of active TMD treatment need, facial pain and headache, than the palatal control splint.

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