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Efficacy of stabilization splint treatment on the oral-health related quality of life – a randomized controlled one-year follow-up trial

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Running title: Splint treatment in temporomandibular disorders

Summary

The aim of this randomized controlled trial was to assess the efficacy of stabilization splint treatment on the oral health-related quality of life (OHRQoL) during a one-year follow-up. Originally, the sample consisted of 80 patients (18 men, 62 women) with temporomandibular disorders (TMD) who had been referred to the Oral and

Maxillofacial Department, Oulu University Hospital, Finland, for treatment. Patients were randomly designated into splint (n = 39) and control group (n = 41). Patients in the splint group were treated with a stabilization splint. Additionally, patients in both groups received counseling and instructions on masticatory muscle exercises. The patients filled in the Oral Health Impact Profile-14 (OHIP-14) questionnaire before treatment and at 3 months, 6 months and 1 year. At total, 67 patients (35 in the splint group vs. 32 in the control group) completed the questionnaire at baseline. The outcome variables were OHIP prevalence, OHIP severity and OHIP extent. Linear mixed-effect regression model was used to analyze factors associated with change in OHIP severity during the one-year follow-up, taking into account treatment time, age, gender, and group status. OHIP prevalence, severity and extent decreased in both groups during the follow-up. According to linear mixed-effect regression, decrease in OHIP severity did not associate significantly with group status. Compared to masticatory muscle exercises and counseling alone, stabilization splint treatment was not more beneficial on self-perceived OHRQoL among TMD patients over a one-year follow up.

Keywords: temporomandibular disorders, TMD, oral health-related quality of life, treatment, stabilization splint, RCT

Introduction

Temporomandibular disorders (TMD) can be described as different forms of dysfunction and pain in the masticatory system, i.e., structures related to masticatory muscles, temporomandibular joints (TMJs) or both. Reduced jaw mobility, muscle or TMJ pain and TMJ sounds (clicking, crepitation) are the most common signs and symptoms of TMD. Even though the etiology of TMD is not fully understood, it is known to be multifactorial. (1)

TMD are very common among the population (2–4). The prevalence rate of symptoms varies from 25 to 50% while the prevalence of clinical signs varies from 40 to 90% (3). The risk for TMD signs and symptoms is higher among women than men. There is also a difference in the prevalence of TMD between age groups: young and middle-age adults suffer more often from pain and other symptoms of TMD as compared to children, adolescents and the elderly (3–4).

Stabilization splint (SS) is an oral appliance which is one of the most commonly used noninvasive treatment methods for TMD (1). Some short-term randomized controlled trials (RCTs) have found evidence of the pain-relieving effect of SS versus other treatment methods or no treatment on TMD pain, both of arthrogeneous and myogenous origin (5–7). On the other hand, some studies have shown that there is only a small or no additional benefit on TMD pain relief with SS treatment versus placebo, control splints (e.g. non-occluding splint) or other treatment methods (e.g. acupuncture, counseling, masticatory muscle exercises) (8–10).

The most severe outcome of chronic pain, as TMD-related pain conditions most often are, is a decreased or deterioration of the quality of life. Previous studies with patient samples have pointed out the substantial negative impact of TMD on the oral health-related quality of life (OHRQoL) (11–14). TMD may associate with OHRQoL through multiple ways, such as pain, depression and somatization and frequent dental attendance (15–17). One of the most commonly used instruments to evaluate OHRQoL is the Oral Health Impact Profile (OHIP), which has seven dimensions: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap (18). All these dimensions are based on the conceptual model of oral health (19).

More RCTs are needed to evaluate the outcome of the SS treatment methods used for TMD. To gather reliable, high-quality evidence on the efficacy of the treatment of TMD, the patient's point of view should be assessed (21). Most studies concerning the efficacy of SS therapy on TMD have used the intensity of pain (21) as the main outcome variable. It has been shown that OHRQoL gives more information about the impact of the oral condition or disease on patient's everyday life and its quality as compared to clinical measures of disease or mere pain intensity (19–20). Thus, it is reasonable to use OHRQoL as outcome measure when evaluating the efficacy of SS in treatment of TMD. In the literature, evidence concerning the efficacy of SS treatment on OHRQoL perceived by the TMD patients is still scarce. Based on the previous studies, it can be hypothesized that OHRQoL improves during the treatment in TMD patients, and that SS have no beneficial effect on OHRQoL as compared to mere masticatory muscle exercises. The aim of this RCT was to evaluate the effectiveness of SS therapy on the OHRQoL among TMD patients during a one-year follow-up, based on RCT.

Materials and methods

Design of the study

The sample of the present RCT study consisted originally of 80 patients (18 men/62 women) who had been referred to the Oral and Maxillofacial Department, Oulu University Hospital, Finland, for treatment of TMD-related facial pain. The patients were examined between March 2008 and August 2010. The inclusion criteria for the study were as follows: (1) clinically diagnosed TMD according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) (24), (2) minimum 20 years of age, and (3) lack of long-term general diseases, like rheumatoid arthritis, that may affect the TMJs or the masticatory muscles (10).

Using computer-generated random numbers, the patients were randomly assigned to two sub-groups: splint group and control group (Fig. 1). Patients in the splint group (n = 39) received SS treatment, counseling and instructions on masticatory muscle home exercises. The control group (n = 41) were counseled and instructed on masticatory muscle home exercises without the SS treatment. The mean age of the patients in the splint group was 42.6 years (SD 13.4 years) and in the control group 44.0 years (SD 13.1 years). The gender distributions were 83.8% women versus 16.2% men in the splint group and 73.2% women versus 26.8% men in the control group. A thorough description of the material is presented in a previous publication (10).

Data collection

The primary outcome was OHRQoL. All patients in both groups were clinically examined, and information on OHRQoL, using a Finnish translation of the 14-item Oral Health Impact Profile (OHIP-14), was collected at four time points: before treatment (baseline), and 3 months, 6 months and 1 year after the baseline. The number of patients who completed the questionnaire was as follows: 67 patients (control group n = 32, splint group n = 35) at baseline, and 39 (control group n = 19, splint group n = 20) at 3 months, 35 (control group n = 13, splint group n = 22) at 6 months, and 43 (control group n = 14, splint group n = 29) at one-year follow-up. All the data collections were performed by the same dentist specialized in stomatognathic physiology (KS) who was not aware of the group status of the patients.

The Finnish version of the OHIP-14 has been used earlier in a nationally representative survey to obtain population estimates for prevalence, extent and severity (23). The frequency of each impact was asked during the preceding month on an ordinal five-point scale. The responses were coded as follows: 0='never', 1='hardly ever', 2='occasionally', 3='fairly often' and 4='very often'. Higher OHIP scores indicate worse and lower scores indicate better OHRQoL. For cases with one or two missing OHIP items, values were imputed using the item's sample mean. In the case of more than two missing values the response was excluded from the study. Three outcome variables of OHIP were formed. The OHIP prevalence was evaluated as the percentage of participants reporting one or more items as 'fairly often' and 'very often' (FoVo), and 'occasionally', 'fairly often' and 'very often' (OFoVo). The OHIP FoVo and OFoVo extent scores were calculated as the sums of ordinal responses on items reported FoVo or OFoVo (range 0–14). The OHIP severity score was calculated by summing the ordinal values for 14 items (range 0–56).

Treatment procedures

The stabilization splints were made of heat-cured acrylic by the same dental technician. The occlusion of the splint was defined in the centric relation occlusion using wax (Astynax ®). The patients were instructed to use the splint every night during the study. Night-time splint use is generally recommended based on Finnish Current Care Quidelines. Day-time use is in most cases impossible due to working at day-time. All the patients in both groups (except for those having TMJ clicking) were instructed to perform a standardized program for masticatory muscle exercises as described by Carlsson and Magnusson (24). At the beginning of the training program, active mouth openings, laterotrusive movements and protrusive movements were performed. The mandible was held in the maximal positions for a few seconds on each movement. Thereafter, these movements were made towards resistance (using the patient's own fingers). After jaw exercises, the patients were suggested to open the jaw wide, stretching it with fingers a few times for 10–20 s. These movements were repeated 7–10 times per training session, and the sessions were performed 2–3 times per day. Patients with jaw hypermobility were instructed to press the tongue against the palatinum, during the opening. Patients having TMJ clicking were instructed to make opening movements from the anterior jaw position (where clicking was noted) to maximum mouth opening. The movements were repeated 30 times per day. The patients received written instructions, and the movements were also demonstrated by the dentist before the treatment, and reprised if necessary.

The instructions for masticatory muscle exercises were given by the same dentist (KS) at the first visit. At every examination, the patients were reminded to use the splint and/or to perform the exercises on a regular basis. The

stabilization splint treatments were performed by two other dentists who were instructed on the treatment method. This study was approved by the ethical committee of Oulu University Hospital (statement 29/2007). The study is reported in line with CONSORT guidelines.

The flow chart of the study is presented in Figure 1. Some patients were referred to other treatment, switched groups or dropped out due to missed visits during the trial. The time the patients had remained in their original groups was included in the follow-up. Two patients in the splint group dropped out of the trial; one did not attend any of the check-ups and the other was offered other treatment, i.e., orthognathic surgery. In addition, during the one-year follow-up, altogether 16 patients interrupted their attendance in the trial or did not show up for their follow-up appointment. Sixteen controls were transferred from the control group to the splint group because of their symptoms and need of treatment. Thirteen patients (10 patients in the splint group and three in the control group) were treated with arthrocentesis of the TMJ during the study.

Statistical analyses

OHIP prevalence, severity and extent were calculated for both study groups at every follow-up time point. Statistical significances between the groups in OHIP prevalence were analyzed using chi-square test, in OHIP severity using Student's t-test, and in OHIP extent using Mann-Whitney U Test. Linear mixed-effect regression model was used to analyze factors associated with change in OHIP severity during the one-year follow-up, taking into account treatment time (one year vs. baseline, 3 months and 6 months), age, gender, and group status (splint vs. control group). The data were analyzed using SPSS software, version 22.0.

Results

A drop-out analysis showed no significant differences in age, gender, OHRQoL or facial pain intensity at baseline between those who had dropped out vs. those who had stayed in the study group during the follow-up (Table 1). OHIP prevalence and extent scores with both OFoVo and FoVo cut-points and OHIP severity for both groups in all follow-up periods are presented in Table 2. There were no statistically significant differences between the groups in any of the OHIP variables during the study.

The percentage distribution of the OFoVo responses for each OHIP-14 item can be seen in Figure 2 (at baseline for the total study sample). The items in the physical pain dimension were reported most frequently (painful aching 74.6% and uncomfortable eating any foods 71.7%). More than half of the patients reported the items in the psychological discomfort dimension (been self-conscious 53.7% and felt tense 55.2%) and the item in the psychological disability dimension (difficult to relax 53.7%). After one-year follow-up, the results were as follows: the items in the physical pain dimension (painful aching 67.4% and uncomfortable eating any foods 53.5%) and the items of the psychological discomfort dimension (been self-conscious 41.9% and felt tense 41.9%). Last, the item of psychological disability dimension (difficult to relax) was reported by 32.6% of the patients after one year of follow-up; this item exhibited the most considerable change from baseline to one-year follow-up. (Fig. 3)

According to linear mixed-effect regression, time point was the only factor that associated statistically significantly with OHIP severity scores, which were highest at baseline. Group status was not associated with the change or rate of change of OHIP severity (Table 3).

Discussion

The results of this RCT showed that during treatment, OHRQoL decreased among TMD patients during the one-year follow-up. The SS treatment did not offer significant benefit on OHRQoL compared with masticatory muscle exercises alone, as no statistically significant differences were shown between the splint group and the control group in any of the OHIP variables. Additionally, the group status did not associate with the OHIP-14 severity based on linear mixed effects model. The lack of statistical differences between the groups after one-year follow-up can be due to that both methods, the SS treatment and masticatory muscle exercise, alone are effective. One possible explanation could also be the placebo effect. There were several patients who were referred to other treatment, switched groups or dropped out due to missed visits, which may also have affected on the results.

This RCT is a novel study in this area: to our knowledge, there are no previous RCTs on the impact of TMD treatment in relation to OHRQL. Alajbeg et al. (25) conducted a pilot study evaluating the changes in pain intensity and self-perceived OHRQoL among thirty TMD patients during SS treatment. They hypothesized that the treatment response is different depending on the clinical subtypes of TMD pain (myogenous or TMJ origin) or pain chronicity (acute or chronic pain). In contrast to our study, the follow-up time was shorter (6 months) and there no control group. The results by Alajbeg (25) showed that during the 6-month SS therapy there were statistically significant changes in pain intensity, as evaluated with VAS (Visual Analogue Scale) and in OHRQoL, as evaluated with OHIP-14. However, they reported that pain type (acute or chronic) or TMD pain subtype (muscular or joint) showed no significant differences in improvement rates. More RCTs are needed considering the effect of SS therapy in relation to OHRQoL.

A cross-sectional study (23), as part of the comprehensive nationwide Health 2000 Survey in Finland, investigated the prevalence and severity of OHRQoL (as evaluated using OHIP-14) among Finnish adult population aged 30 years or over. Based on the study, the OHIP prevalence levels were 35.1% for OFoVo and 10.3% for FoVo, and the mean OHIP severity was 4.02 (95% CI 3.83–4.21). These levels are considerably lower than those in the present study, thus indicating that the OHRQoL among TMD patients is much poorer than among general adult population in Finland. Additionally, based on the present study, the OHIP values did not achieve the same levels as in normal population during either of the treatments (the SS treatment or mere counseling and masticatory muscle exercises). The results of the present study support the earlier findings on

OHRQoL among TMD patients (11–12, 15–16). Papagianni et al. (26) have pointed out that TMD pain seems to have a more significant impact on patients' everyday life than tooth wear or edentulousness. Almoznino et al. (14) have shown that TMD patients suffer more from impaired OHRQoL compared to controls. According to their study, TMD patients showed worse scores in OHIP-14 in the following domains: physical pain, psychological discomfort, physical disability and psychological disability. The mean OHIP-14 severity was 12.50 ± 8.14 in the TMD group and 9.58 ± 10.00 in the control group. Similar OHIP profiles were also seen in our study. Physical pain (painful aching and uncomfortable eating any foods) was the most frequently reported OHIP dimension in the total study sample, psychological discomfort (been self-conscious and felt tense) being the second most frequently reported. These results support the bio-psychosocial model in the background of TMD (27). Also, TMD associate with impaired OHRQoL through multiple ways, linked with depression and somatization (14–15). Further clinical trials with more individualized treatment programs that also take the psychosocial aspects into account are needed.

Other studies have reported changes in OHRQoL among patients with malocclusion and TMD during occlusal rehabilitation. Silvola et al. (28) found that during treatment (orthodontic or surgical-orthodontic), the mean OHIP severity (n = 51) decreased from 17.6 (baseline) to 4.1 (after treatment). This is considerably lower compared to the corresponding values found in the present study after treatment. On the other hand, the OHIP prevalence for FoVo was 70.6 % before and 9.8% after the orthodontic or surgical-orthodontic treatment. In the present study, the most significant changes in the mean scores of OHIP-14 dimensions were observed in psychological discomfort and physical pain dimensions, thus indicating that besides pain and discomfort, psychological problems, such as poor self-consciousness, feeling tense and difficulty to relax, are strongly linked with symptomatology of TMD patients, and may also relieve the most during the treatment. These changes may be due to the actual effect of the treatment received, the placebo effect, or possibly due fluctuation in stress condition during the follow-up.

The study design and a relatively long follow-up time were the strengths of this RCT. The instruments used, i.e. RDC/TMD criteria and OHIP-14, are valid and standardized in the assessment of TMD and OHRLQoL. OHIP-14 has been shown to have good reliability, validity and precision (29). While The RDC/TMD Axis II criteria used in the assessment of pain chronicity and psychosocial factors are TMD/chronic pain-specific, OHIP is a more generic way for assessing aspects of oral health-related quality of life (such as functional limitation and psychosocial discomfort and disability). As population level information is available for OHIP-14, comparison of the results provide important information in the assessment of treatment response.

The limitations of the study were the changes in group status and the lack of OHIP-14 data due to missing completed questionnaires (Fig. 1). Additional RCT studies with larger patient samples and more individualized treatments are needed to evaluate the treatment outcome of TMD. Changes in group status due to drop-outs and switching groups often cause problems during a long follow-up period, as was the case in the present study. The power of the data was naturally impaired by these changes, which is why the treatment time of each patient was considered in the analysis. It should also be noted that it is difficult to control the use of the splint as well performing the masticatory muscle exercises, especially during a long follow-up.

The present study results showed that neither age, gender, nor the group status did associate with the OHIP severity, the only associating variable with the OHIP-14 severity over one-year follow-up was the time point, i.e. the baseline. One of the characteristics of the TMD signs and symptoms is fluctuation, which may at least partly also explain the variations in the OHIP values in the present study. In an earlier study with the same sample, the VAS on pain intensity also fluctuated during the treatment in the same manner (30). On the other hand, the fluctuation of TMD pain may also be linked with the changes among the OHIP items. In addition, the fact that patients in both the groups received counseling, enrolled in a study in the perception of receiving treatment may have had a "white coat" or placebo effect.

Conclusion

Based on the present RCT, SS treatment did not show any beneficial effect on self-perceived OHRQoL compared to mere counseling and masticatory muscle exercises as OHRQoL. improved during the one-year follow-up regardless of the treatment received, thus supporting our hypothesis. Of the OHIP dimensions, psychological discomfort and physical pain decreased during the follow-up. Further studies with larger samples are needed to evaluate the effect of SS treatment on OHRQoL among TMD patients.

Acknowledgements

This study has been approved by the Ethical Committee of Northern Ostrobothnia Hospital District.

Conflict of interests

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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Tables

Table 1. Comparison between patients who dropped-out and stayed in their original groups (splint vs. control groups) according to Oral Health Related Quality of Life (OHRQoL) and gender, age and facial pain VAS-scale in splint and control groups at baseline.

Baseline	Drop-outs			Stayed			p*
	Splint (n=8)	Control (n=19)	Total (n=27)	Splint (n=27)	Control (n=13)	Total (n=40)	
Gender (% of women)	75.0	68.4	70.4	81.5	84.6	82.5	.243
Age (years, mean SD)	47.0(14.8)	41.0(13.4)	42.8(13.8)	41.2(12.8)	50.9(9.9)	44.4(12.6)	.664**
OHIP ofovo[a] prevalence (%)	87.5	94.7	92.6	96.3	84.6	92.5	.989
OHIP fovo[a] prevalence (%)	62.5	73.7	70.4	88.9	61.5	80.0	.365
OHIP ofovo[b] extent	4.8(4.3)	5.0(3.2)	4.9(3.5)	5.8(3.2)	5.4(3.9)	5.7(3.4)	.372**
OHIP fovo[b] extent	3.6(3.9)	2.8(2.8)	3.1(3.1)	2.9(2.4)	2.7(3.0)	2.8(2.6)	.974**
OHIP severity[c] (mean SD)	16.3(14.7)	15.7(10.8)	15.9(11.8)	17.9(9.8)	16.2(12.0)	17.4(10.5)	.486**
Facial pain VAS (mean SD)	3.4(3.2)	4.3(2.4)	4.0(2.6)	5.6(2.6)	3.9(2.6)	5.1(2.7)	.142**

[a]percentage of the subjects reporting at least one OHIP-14 impact
[b]number of OHIP-14 impacts reported (range 0-14)
[c]the sum of OHIP-14 impacts reported (range 0-56)
*between total values by chi-square statistics or Fisher's Exact Test
**by Mann-Whitney U Test

Table 2. The Oral Health Impact Profile (OHIP-14) prevalences and means (standard deviation, SD) of OHIP severity and extent in splint and control groups at different follow-ups including impacts occurring 'fairly often' or 'very often' (FoVo) and 'occasionally', 'fairly often' or 'very often' (OFoVo).

Time point	Prevalence[a] (%)						Extent[b] mean (SD)						Severity[c] mean (SD)		
	OFoVo			FoVo			OFoVo			FoVo					
	Splint	Control	p*	Splint	Control	p*	Splint	Control	p**	Splint	Control	p**	Splint	Control	p***
Baseline (n = 67)	94.3	90.6	0.569	82.9	68.6	0.176	5.54 (3.48)	5.16 (3.46)	0.627	3.06 (2.78)	2.78 (2.81)	0.576	17.57 (10.89)	15.94 (11.14)	0.546
3 months after (n = 39)	85.0	78.8	0.662	50.0	47.4	0.869	3.70 (83.13)	4.89 (4.08)	0.478	1.65 (1.90)	1.95 (2.64)	0.967	12.05 (8.84)	14.84 (11.63)	0.403
6 months after (n = 35)	81.8	76.9	0.726	59.1	46.2	0.458	5.09 (4.39)	3.69 (3.43)	0.408	2.41 (3.17)	1.08 (1.50)	0.287	15.95 (13.05)	11.46 (9.02)	0.282
1 year after (n = 43)	86.2	78.6	0.525	51.7	64.3	0.437	4.14 (3.85)	3.50 (3.53)	0.555	1.72 (2.43)	1.86 (2.21)	0.624	13.17 (10.68)	11.86 (9.75)	0.699

[a]percentage of the subjects reporting at least one OHIP-14 impact
[b]number of OHIP-14 impacts reported (range 0-14)
[c]the sum of OHIP-14 impacts reported (range 0-56)
*by chi-square statistics
**by Mann-Whitney U Test
***by Student's t-test

Table 3. Linear mixed effects models for the association between gender, age, group status and follow-up time point and Oral Health Impact Profile (OHIP-14) severity over one-year follow-up.

Baseline predictors	Model with main effects			Model with main effects and interaction		
	Coefficient	95%CI	p-value	Coefficient	95%CI	p-value
Gender (ref. male)						
Female	-4.41	-10.30–1.48	0.140	-4.22	-10.08–1.63	0.155
Age	0.05	-0.13–0.23	0.590	0.051	-0.13–0.23	0.586
Group (ref. control)						
Splint	1.67	-3.13–6.47	0.490	1.85	-4.19–7.89	0.546
Time point (ref. 1 year)						
Baseline	4.54	2.11–6.98	0.000	4.58	0.39–8.76	0.032
3 months	0.55	-2.19–3.28	0.692	1.46	-2.99–5.91	0.516
6 months	0.35	-2.41–3.11	0.801	-2.78	-5.02–4.46	0.908
Group*time (ref. I year)						
Splint group*baseline				<0.01	-5.18–5.19	0.999
Splint group*3 months				-1.60	-7.32–4.12	0.580
Splint group*6 months				0.96	-4.91–6.83	0.746

Figure legends

Figure 1. Flow chart of the study. The numbers surrounded by medium grey circles describe the missing patients of the OHIP-14 data from the questionnaire. Sixteen patients in the control group switched to the splint group during the study. One patient was referred for surgical treatment, one did not attend any follow-ups. Sixteen others dropped out during the trial.

Figure 2. Percentage distribution of patients scoring ‘occasionally’, ‘fairly often’ and ‘very often’ (OFoVo) responses to each OHIP-14 item at baseline for the total study population (n = 67).

Figure 3. Percentage distribution of patients scoring ‘occasionally’, ‘fairly often’ and ‘very often’ (OFoVo) responses to each OHIP-14 item after one-year follow-up for the total study population (n = 43).