Brazilian Dental Science

unesp
UNIVERSIDADE ESTADUAL PAULISTA
"JÚLIO DE MESQUITA FILHO"
Instituto de Ciência e Tecnologia
Campus de São José dos Campos

CC BY

ORIGINAL ARTICLE

DOI: https://doi.org/10.4322/bds.2022.e3401

Thermoformed occlusal splints for the treatment of masticatory muscle pain: a clinical trial

Placas oclusais termoplásticas para o tratamento da dor muscular mastigatória: um ensaio clínico

Diego De Nordenflycht[1], **Javier Salinas**[1], **Lisa Armstrong**[2]

1 - Universidad Andres Bello, Facultad de Odontologia, Viña del Mar, Chile
2 - Private practice, Viña del Mar, Chile

ABSTRACT

Objective: Compare the clinical effectiveness of custom thermoformed occlusal splints (OS) alongside behavioral and self-care therapy (BST) in the management of myalgia of the masticatory muscles. **Material and methods:** A controlled clinical trial was conducted with a total of 46 subjects with a diagnosis of myalgia according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD). All subjects were treated with BST at the beginning of the study and were then randomized into four groups: behavioral and self-care control group; Thermoformed Tough-elastic splint group; Thermoformed Soft-elastic splint group, and non-occlusive splint group. Follow-ups were carried out at 2, 6, and 10 weeks, where it was evaluated: pain in the masticatory muscles, mandibular range of motion, mandibular functional limitation, and occlusal discomfort. Data were analyzed with Doornik and Hansen, Shapiro–Wilk, and ANOVA at $p=0.05$. **Results:** All the variables showed significant improvement ($p<0.05$) from the first follow-up and were maintained later. BST control group, as well as groups with BST associated with OS, were able to reduce pain and increase the mandibular range of motion without significant differences between them ($p>0.05$), while the Thermoformed Tough-elastic splint was the most efficient in terms of the mandibular functional limitation. The occlusal discomfort decreased over time, but without statistically significant differences in terms of time and design of OS. **Conclusion:** The addition of thermoformed OS to behavioral and self-care therapy does not have a significant impact on myalgia of the masticatory muscles.

KEYWORDS

Myalgia; Occlusal splint; Self-care; Temporomandibular joint disorders; Thermoformed splint.

RESUMO

Objetivo: Comparar a eficácia clínica das Placas Oclusais (PO) termoplásticas personalizadas associadas à Terapia Cognitiva Comportamental (TCC) na condução da mialgia dos músculos mastigatórios. **Material e Métodos:** Foi realizado um ensaio clínico controlado randomizado com um total de 46 participantes com um diagnóstico de mialgia de acordo com os Critérios de Diagnóstico das Desordens Temporomandibulares (DC/TMD). Todos os participantes foram tratados com a TCC, no início do estudo, e foram, depois, randomizados em quatro grupos: grupo controle Terapia Congnitivo Comportamental; grupo de placa termoplástica dura-soft, grupo de placa termoplástica soft, e grupo de placa sem cobertura oclusal. Foram realizados controles com 2, 6, e 10 semanas, onde foi avaliado: dor nos músculos mastigatórios, amplitude de movimento mandibular, limitação funcional mandibular, e desconforto oclusal. Os dados foram analisados com Doornik e Hansen, Shapiro-Wilk, e ANOVA a $p=0,05$. **Resultados:** Todas as variáveis mostraram melhora significativa ($p<0,05$) desde o primeiro controle e se mantiveram posteriormente. O grupo de controlo da TCC, bem como os grupos com TCC associada a PO, foram capazes de reduzir a dor e aumentar a amplitude de movimento mandibular sem diferenças significativas entre eles ($p>0,05$), enquanto que, a placa termoplástica dura-soft, foi a mais eficiente em termos da limitação mandibular funcional. O desconforto oclusal diminuiu ao longo do tempo, mas, sem diferenças estatisticamente

significativas em termos de tempo e design da PO. **Conclusão:** A inclusão da Terapia Cognitivo Comportamental à PO termoplástica não tem um impacto significativo na mialgia dos músculos mastigatórios.

PALAVRAS-CHAVE

Mialgia; Placa oclusal; Autocuidado; Disfunção Temporomandibular; Placa oclusal termoformada.

INTRODUCTION

Temporomandibular disorders (TMD) encompass a group of musculoskeletal and neuromuscular conditions that involve the temporomandibular joints (TMJ), masticatory muscles and associated tissues, and they have been identified as a major cause of non dental pain in the orofacial region [1]. One of the most prevalent conditions is myalgia of the masticatory muscles, which involves three possible clinical diagnoses according to the diagnostic criteria for temporomandibular disorders (DC/TMD): local myalgia, myofascial pain, and myofascial pain with referral [2]. Although multiple possibilities have been proposed for the treatment of TMD, most recognized standards prioritize reversible interventions over invasive ones [3]. Occlusal splints (OS), either alone or in combination with other treatment modalities, is the most common dental management strategy for both myalgia of the masticatory muscles, as well as for TMD in general [4-6]. Systematic reviews have shown positive effects on pain intensity, reduction of chronic pain, and jaw movements improve [7]. Although recent evidence indicates that multimodal therapy consisting of counseling therapy plus hard stabilization OS may produce the maximum improvement for TMD patients [8], soft or resilient appliances are frequently used by dentists in the clinical setting [9,10] therefore it is important to evaluate its clinical effectiveness. However, no conclusive results have been found on the type or design of OS to alleviate the symptoms of TMD [3,5]. Satisfactory results in improving TMD symptoms (pain score, range of motion, tenderness in masticatory muscles) have been found for resilient OS in the short [11] and long term [12], and consistent results compared to stabilization OS have been found [13,14]. As OS therapy is not specific and the mechanisms underlying its effectiveness are not fully understood [15], it opens the possibility of implementing different designs, inexpensive, and simpler forms of OS, which may be capable of generating relief of pain and function improvement in TMD patients [14].

On the other hand, there is consensus that treatment focused on patient education, behavioral changes, and self-care should be considered as a central component for the treatment of TMD [16-18]. Studies show significant improvements in the reduction of pain and increased mandibular ranges of motion in subjects treated with behavioral and self-care therapy (BST) alone or in combination with OS [14,19-23]. Therefore, BST can be considered as an initial and essential component for the TMD management due to their effectiveness and immediacy, important elements considering that these patients suffer a disabling and painful condition.

Due to the above, BST and thermoformed OS could have an important advantage over other treatment alternatives due to the possibility of being implemented within a short period of time, with low-cost equipment, and even without the involvement of a dental technician, however there is still a lack of evidence to support its effectiveness. Therefore, the aim of this research was to compare the clinical effectiveness of thermoformed OS together with BST in the management of myalgia of the masticatory muscles.

MATERIAL AND METHODS

Study design

A randomized controlled clinical trial was conducted at the Dental Clinic of Andrés Bello University (Viña del Mar, Chile). The study subjects were recruited from the universe of patients seeking treatment for jaw pain at the University Dental Clinic. All subjects were informed about the study by their operator and gave their written consent before starting the study. The protocol, design, and implementation were approved by the Scientific Ethics Committee

of the Faculty of Dentistry of Andrés Bello University, Viña del Mar, Chile (Folio No. 033, 2017) that was in accordance with the latest version of the Declaration of Helsinki. This trial is registered at the US National Institutes of Health (ClinicalTrials.gov) #NCT04588636.

Sample size calculation

The sample size was calculated according to a confidence level of 95% and a statistical power of 80%. Based on the previous study by Niemelä et al. [20], it was determined that the variance of the main variable (masticatory muscle pain) of the reference group was 2.6. The pain variable was measured on the visual analog scale (VAS), where a minimum clinically relevant difference was considered if a 3.5 point decrease was achieved on the VAS scale with respect to treatment, a reference that was also considered in this study. According to the above, the necessary number of participants needed for each group was 9 and adjusted for possible losses to 11.

Inclusion and exclusion criteria

Adults of both sexes were included, who needed treatment for TMD-related myalgia of the masticatory muscles, diagnosed using the DC/TMD protocol. Patients with painless arthrogenous TMD (such as disc displacement with reduction or subluxation) concomitant with the masticatory muscle pain were considered acceptable to include in the study. A total of 77 subjects were examined, of which 46 men and women, without distinction of gender, were eligible and included in the study; none rejected their participation. The subjects' inclusion criteria were: aged between 18 and 40 years, the presence of masticatory muscles myalgia according to DC/TMD criteria. The exclusion criteria were: arthrogenous TMD that involve joint pain, limited mouth opening or crepitus; history of TMD treatment; recent history of facial or cervical trauma; ongoing orthodontic treatment; abnormal dental mobility; subjects with loss of more than two teeth other than third molars and/or premolars due to orthodontic indication; subjects with systemic musculoskeletal diseases or who are under analgesic treatment; subjects with a diagnosed intellectual disability who cannot express their will to participate in scientific research as established by law No. 20,584 of Chile [24].

Randomization and interventions

After meeting the inclusion and exclusion criteria, the subjects were assigned to one of four treatment groups following simple randomization procedures through a computationally generated sequence, "list randomizer" [25]. The four groups formed were:

- Behavioral and self-care therapy control group (BST control group): This group consisted of 12 subjects who received verbal and written information on the etiology and prognosis of TMD. In addition, advice on habits and behavior changes, relaxation techniques, sleep hygiene, diet modification, thermotherapy, encouragement to practice social and aerobic activities, and how to prevent risk factors and bad habits;
- Thermoformed Tough-elastic splint (TES group). This group consisted of 12 subjects who received BST in combination with a thermoformed tough-elastic occlusal splint vacuum-formed from individual thermoforming blanks of 2 mm thick polyethylene terephthalate (Biolon, Dreve, Unna, Germany) (Figure 1a, 1b and 1c);
- Thermoformed Soft-elastic splint (SES group). This group consisted of 12 subjects who received BST in combination with a thermoformed soft-elastic occlusal splint vacuum-formed from 3 mm thick thermoforming blanks of ethyl vinyl acetate (Drufosoft, Dreve, Unna, Germany) (Figure 1d, 1e and 1f);

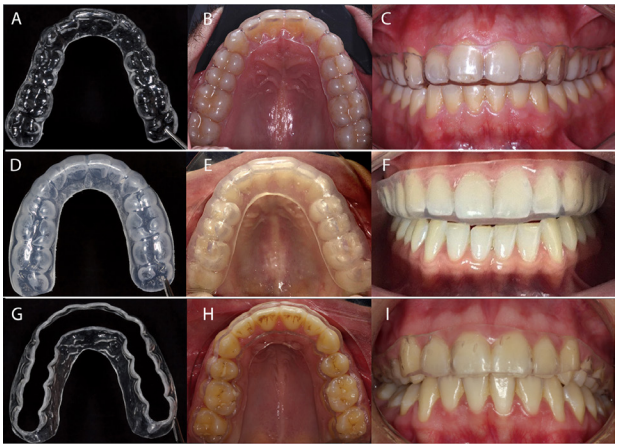

Figure 1 - Referential clinical images of occlusal splints: Thermoformed Tough-elastic splint (A), from occlusal (B) and front (C) views; Thermoformed Soft-elastic splint (D), from occlusal (E) and front (F) views; Non-occlusive splint (G), from occlusal (H) and front (I) views.

- Non-occlusive splint group (NOS group). This group consisted of 10 subjects who received BST in combination with a non-occlusive splint from thermoforming blanks of rigid polyethylene terephthalate 2 mm thick (Biolon, Dreve), from which the occlusal surfaces and incisal edges were cut allowing the usual occlusal contact (Figure 1g, 1h and 1i).

Occlusal splints were made with a generic design, without customization and without control of the vertical dimension. Then, they were adjusted in the mouth to verify their retention, alleviate areas of compression, and ensure the presence of simultaneous and bilateral contacts. Exclusive use during sleep, hygienic care of the device, and indications in case of pain/discomfort were indicated.

Sequence of interventions and blinding

To protect the blinding of the study, it was carried out by two operators: A (examiner) and B (therapist). Treatment of the subjects consisted of 5 sessions: (1) diagnosis of recruited subjects and maxillary teeth impression was taken by operator A; (2) BST instruction and delivery of OS by operator B; (3) first control and BST instruction reinforcement at 2 weeks; (4) second control and BST reinforcement at 6 weeks; (5) third control, removal of OS (if it corresponds to 10 weeks), and it is encouraged to continue with BST. All controls were performed by operator A in order to achieve a double-blinding (Figure 2). To assure this, all subjects were told that operator A cannot know which treatment was delivered, so

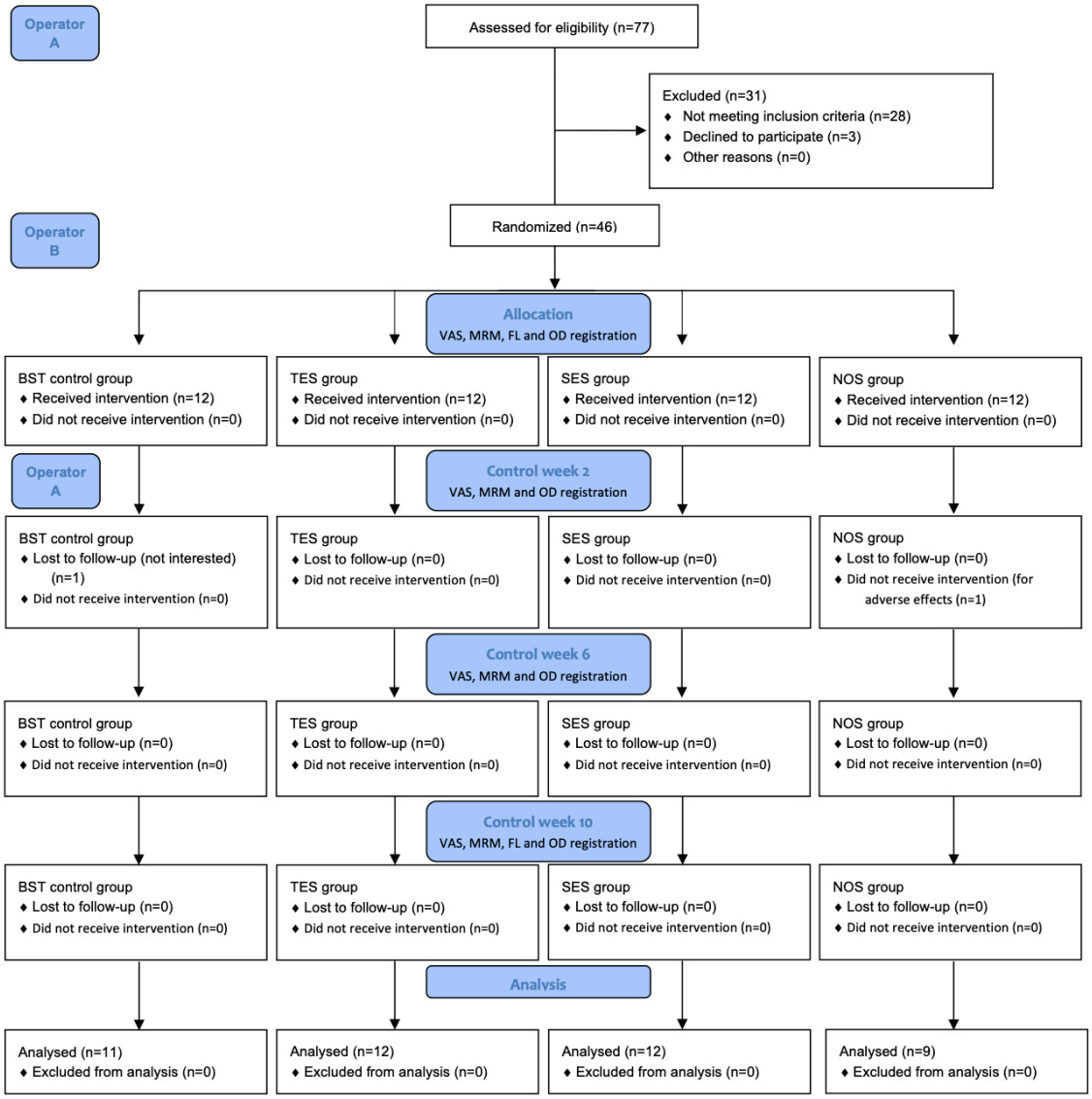

Figure 2 - Flow chart of participant selection of subjects referred for TMD treatment. BST: behavioral and self-care therapy; TES: Thermoformed Tough-elastic splint ; SES: Thermoformed Soft-elastic splint; NOS: non-occlusive splint; VAS: visual Analog Scale; MRM: mandibular range of motion; FL: functional limitation; OD: occlusal disconformity.

that in case of complications, they should contact operator B. Operator B randomly delivered the treatment among subjects selected by operator A after the initial examination, being themself in charge of contacting them and delivering the corresponding treatment.

Assessment methods

The initial evaluation was carried out following the symptom questionnaire and clinical examination guidelines according to the DC/TMD protocol [26] in order to determine the involvement of axis I. Additionally, the jaw functional limitation scale (JFLS-20) of axis II of the DC/TMD [27] was applied. An intraoral clinical examination was also performed to exclude dental causes of pain. The following variables were analyzed:

- *Masticatory muscle pain (MMP)*: pain intensity was measured using the visual analog scale (VAS); subjects were asked to mark the level of pain according to their current perception at the moment of the examination. This was applied in the initial evaluation, and weeks 2, 6, and 10;
- *Mandibular range of motion (MRM)*: autonomous and comfortable maximum mouth opening, without feeling pain and not-assisted by the operator, measured in millimeters from incisal edge to incisal edge of anterior teeth, compensating the overbite [26]. This was applied in the initial evaluation, and weeks 2, 6, and 10;
- *Jaw functional limitation (JFLS-20)*: the assessment of functional limitation (FL) in terms of mastication, movements, communicational, and global limitation that the subject presents was achieved with the survey of jaw functional limitation scale (JFLS-20) of the DC/TMD [27]. This was applied in the initial evaluation and week 10.
- *Occlusal discomfort (OD)*: the evaluation of adverse effects or discomfort of subjects associated with occlusal splint during treatment was done using a visual analog scale (VAS). It was applied in weeks 2, 6, and 10;

Statistical analysis

Demographic sample characteristics were descriptively reported. Data were tested to determine normality using Shapiro–Wilk and Doornik–Hansen tests, data that were parametric, so they were analyzed with a mixed ANOVA test for the variables masticatory muscle pain, mandibular range of motion, functional limitation, and occlusal discomfort. The level of significance was established at $p=0.05$. All statistical analysis was performed using the SPSS version 17 software (IBM, Chicago, IL, USA).

RESULTS

The data that support the findings of the study are openly available in Open Science Framework (OSF.io). CONSORT 2010 checklist is available at [28]. The study was initiated with 46 subjects that met the inclusion criteria, and 44 of them completed the 10 weeks treatment. Descriptive statistics are shown in Table I. Two patients voluntarily decided to discontinue the study during the week 2 follow-up. One belonged to the BST control group who was not interested in continuing the follow-up; the other patient belonged to the NOS group who decided to withdraw due to the discomfort generated by the device, who was instructed to stop using the OS. Both patients were recommended to continue with the indications made in behavioral and self-care therapy.

- *Masticatory muscle pain.* Means of MMP are shown in Table II. The results showed statistically significant MMP reduction for all groups between baseline and week 2, which continued during weeks 6 and 10. No statistically significant differences were found between groups that used OS (TES, SES or NOS) and the BST control group ($p > 0.05$);
- *Mandibular range of motion.* Means of the MRM are shown in Table II. The results showed a statistically significant increased range of opening for all groups between baseline and week 2. No statistically significant differences were found between groups that used OS (TES, SES or NOS) and the BST control group ($p > 0.05$);
- *Jaw functional limitation.* The mean, standard deviation, and p-values for JFLS-20 are shown in Table II. A statistically significant reduction ($p < 0.05$) in the JFLS-20 was observed in all groups at 10 weeks. However, when comparing the OS groups with the BST control group, only the

Table I - Descriptive statistics, distribution of subjects by gender, mean age and age ranges

		BST control group	TES group	SES group	NOS group	Total	%
N° patients	Initial	12	12	12	10	46	
	Final	11	12	12	9	44	
Gender	Female	8	8	10	9	34	77.27
	Male	3	4	2	0	10	22.73
Age	Average	22.7	23.8	26.1	23.4	24.02	
	Median	23	24	24.5	21	23.1	
	Range	20–25	18–29	18–40	18–40	18–40	

BST: behavioral and self-care therapy; TES: Thermoformed Tough-elastic splint; SES: Thermoformed Soft-Elastic occlusal splint; NOS: non-occlusive splint.

Table II - Means (SD) for masticatory muscle pain, mandibular range of motion, mandibular functional limitation and occlusal discomfort per time and groups

		BST control group	TES group	SES group	NOS group	p-values (between groups per week)
MMP	Baseline	4.82 (2.32)¶	5.00 (1.04)*	4.42 (1.00)§	4.78 (1.79)#	nS
	Week 2	3.09 (1.92)¶	3.08 (1.62)*	2.92 (1.78)§	3.11 (1.69)#	nS
	Week 6	2.73 (1.79)¶	2.00 (1.65)*	2.25 (1.29)§	2.33 (1.50)#	nS
	Week 10	1.71 (1.01)¶	1.42 (1.00)*	1.50 (0.80)§	1.78 (0.67)#	nS
Between groups (BST control group x OS groups) at week 10			p = 0.775	p = 0.528	p = 0.953	
MRM	Baseline	37.18 (7.24)¶	43.25 (8.86)*	39.33 (9.8)§	39.22 (10.31)#	nS
	Week 2	41.18 (6.74)¶	46.83 (8.99)*	42.83 (10.33)§	41.33 (9.06)#	nS
	Week 6	42.18 (7.36)	47.50 (9.11)	45.50 (9.31)	43.33 (8.72)	nS
	Week 10	44.09 (6.39)	49.92 (7.01)	45.50 (10.59)	44.22 (6.30)	nS
Between groups (BST control group x OS groups) at week 10			p = 0.093	p = 0.551	p = 0.6	
JFLS-20	Initial	2.39 (1.59)¶	1.16 (1.26)*	1.79 (1.39)§	2.82 (2.09)#	
	Final	0.76 (0.56)¶	0.28 (0.27)*	0.68 (0.88)§	0.77 (0.78)#	
	Difference	1.63 (1.35)	0.87 (1.03)	1.11 (0.91)	2.05 (1.90)	
Between groups (BST control group x OS groups) at week 10			p = 0.047	p = 0.335	p = 0.491	
OD	Week 2		3.33 (1.72)	3.00 (1.86)	3.22 (2.68)	nS
	Week 6		2.83 (1.59)	2.83 (1.95)	3.33 (3.00)	nS
	Week 10		2.17 (1.70)	2.58 (2.31)	2.00 (1.80)	nS

MMP: Masticatory muscle pain (VAS). MRM: mandibular range of motion (in mm). JFLS-20: jaw functional limitation scale. OD: occlusal discomfort. nS: non-significant. BST: behavioral and self-care therapy. TES: Thermoformed Tough-elastic splint. SES: Thermoformed Soft-Elastic splint. NOS: non-occlusive splint. Same symbols (¶, *, §, #) indicates statistically significant differences (p<0.05) within groups along time for each variable

TES group obtained statistically significant improvements assessed at week 2 (Table II);

- *Occlusal discomfort*. It was observed that OD decreases over time, but without statistically significant differences (p >0.05) according either to the time or the OS used (TES, SES or NOS).

DISCUSSION

The present clinical trial compared the clinical effectiveness of custom thermoformed occlusal splints alongside behavioral and self-care therapy in the management of myalgia of the masticatory muscles over 10 weeks. All the variables showed significant improvement from baseline to the first follow-up and were maintained later. The BST control group, as well as groups with OS were able to reduce pain and increase the mandibular range of motion, while the TES group turned out to be the most efficient in improving the mandibular functional limitation.

Masticatory muscle pain reduction was obtained in all groups, which was statistically

significant from the second week of treatment, also observed at weeks 6 and 10 (Table II). In addition, no statistically significant differences were found between the BST control group and the groups that intervened with OS, for which suggests that the addition of OS to the BST does not have a significant impact for the subjects in the management of myalgia of the masticatory muscles. Similar results were found in other clinical trials that compare hard, soft and non-occlusive OS [14] and hard versus soft OS [13]. Nor were statistically significant differences were not found between treatment groups with different OS materials, concluding that the splint material has no impact on its effectiveness when used for TMD pain which is in accordance with recent meta-analysis [8].

According to the consensus of the Initiative on methods, measurement, and pain assessment in clinical trials (IMMPACT), it is important to assess outcomes in clinically meaningful rather than statistically significant terms [29] given that statistically significant differences often do not have a clinical representation, where percentages of improvement close to 15% in the evaluation of pain, are interpreted by the subjects as insignificant [30]. However, it is rare to find large differences in the results between two treatment modalities, especially in painful TMD management, where the success rate of the various therapeutic approaches is high [31]. Considering the above, pain intensity measurements were considered clinically significant when there was at least a 30% reduction in pain scores, as recommended by IMMPACT [29]. That being said, all groups showed a statistically significant reduction in pain intensity scores and, at the same time, were above or very close to achieving a clinically significant reduction, presenting a decrease of 30.9% for the BST control group, 35.8% for the TES group, 29.2% for the SES splint group, and 30% for the NOS group, between baseline and week 10.

Although the effects of OS could not be discarded, the pain reduction observed during the follow-up can be attributed to the behavioral and self-care therapy which is based on basic elements of cognitive behavioral therapy, relaxation techniques, reinforcement of desired behaviors and withdrawal from unwanted behaviors, home physiotherapy, and non-prescription pharmacological therapy [32], which efficiency for treating myogenous TMD have been previously documented [33], and is expected that most TMD patients will respond well in four to six weeks [34]. Self-care contribution to patient health goes beyond pain reduction since it has shown to improve the mobility and psychological aspects, and impact directly on well-being and oral health related quality of life (OHRQoL) [35] in TMD patients, but its clinical success depends fundamentally on the subject's adherence to it, which is directly related to positive speech, a hopeful message, and constant follow-up by a trained practitioner.

Mandibular range of motion increased in all groups. Authors found statistically significant increases for all groups between baseline and week 2, which continued during weeks 6 and 10 without statistically significant differences between groups. Therefore, apparently no additional benefit was obtained by incorporating an OS in the BST treatment, which results are consistent with previous reports [17,19,36]. Seifeldin and Elhayes found that the maximum mouth opening significantly increased in patients using soft OS in the fourth month, which may be due to the supposed idea that resilient material may help to distribute the heavy functional occlusal forces and hastened relief from muscle spasms [13].

Regarding jaw functional limitation, a statistically significant reduction in JFLS-20 scores was found in all study groups, although the comparison between groups show that only the combination of BST and Thermoformed Tough-elastic splint compared to the BST control group achieved a statistically significant difference ($p=0.047$). The JFLS-20 is an organ-specific instrument for assessing functional status of the masticatory system that has exhibited good reliability and validity for 3 constructs assessing limitations in mastication, jaw mobility, and verbal and emotional expression [37]. Despite its usefulness in clinical practice and research, few studies on the treatment of TMD have reported its application. Significant JFLS-20 scores reduction have been reported in patients with arthrogenic TMD using resilient OS but without significant differences versus other treatments in the follow-up [38]. While other reports non-significant difference in JFLS-20 scores between improvement and non-improvement patients treated with resilient OS in patients with sub-acute and chronic TMD [39]. Other reports found non-significant JFLS-20 scores reduction using

stabilization OS splints for chronic TMD [40] and masticatory myofascial pain [41], which suggest that OS therapy that can reduce pain and improve range of motion, may not be better that other treatments to improve mastication and verbal and emotional expression in patients with myogenic TMD. Present results are presumptively explained by the successful combination of good adherence to behavioral therapy and the biomechanical effect of Tough-elastic material used in the appliance, but this assumption requires further research.

Occlusal discomfort decreased with the passage of time, although no significant differences were observed between groups. Similarly, Nilsson et al. found minimal reports of discomfort in patients using soft or non-occlusive OS, without significant differences between them in the short term [11]. This may be explained by the fact that subjects gradually adapted to the use of the OS, reporting some uncomfortable but tolerable sensations. Among the adverse effects of the use of the OS, the subjects reported hypersalivation, sensations of pressure on the teeth, and abnormal perception of the occlusion during the first minutes after its removal. All of these have been reported in the literature and described as minor, transitory, and reversible [5].

There are some limitations to this study that should be considered: (1) the final thickness of the OS was not assessed since elastic thermoformed OS are simpler and cheaper (but very popular) forms of occlusal devices compared to stabilization splints; this can be considered a limitation since it is known that the OS should have at least 2 to 3 mm of thickness at the posterior region [42,43]. (2) The lack of a negative control group (without intervention) does not allow to determine if the improvement on variables assessed are the result of the treatments (BST or OS) or, in some degree, product of spontaneous remission or "regression to the mean" that characterizes TMDs natural course [44]. (3) It appears necessary to define a minimum value of pain intensity as an inclusion criteria, since with the inclusion of subjects with very low pain intensity the sensitivity to find clinically significant improvements may be lost, but this would require a large universe of patients. (4) The absence of history of TMD treatment and masticatory pain in the last 30 days were considered indicators of acute (or first onset) myogenous TMD but the present study lacks of reliable criteria to differentiate acute and chronic pain patients (e.g. International Association for the Study of Pain chronic pain definition [45]); this is important since although transition from acute to chronic TMD pain is common [46], acute TMD typically represent simpler cases that can be managed by a single clinician with self-care, but chronic TMD are more complex and should be managed interdisciplinary [34].

CONCLUSION

Current results show that thermoformed occlusal splints (Tough-elastic, Soft-elastic or non-occlusive) do not produce an additional benefit to behavioral and self-care therapy in the management of myalgia of the masticatory muscles in the short-term. Considering the limitations of the present study, occlusal splints should not be discarded as treatment for myogenic TMDs, although authors suggest that initial management of patients with myalgia of the masticatory muscles should be based on behavioral and self-care therapy.

Authors' Contributions

DDeN: Conceptualization, Methodology, Writing – Review & Editing, Visualization, Supervision. JS: Conceptualization, Software, Formal Analysis, Investigation, Data Curation, Writing – Original Draft Preparation. LA: Conceptualization, Software, Formal Analysis, Investigation, Data Curation, Writing – Original Draft Preparation.

Conflict of interest

There are no conflicts of interest.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Regulatory Statement

Nil.

REFERENCES

1. de Leeuw R, Klasser GD. Orofacial pain: guidelines for assessment, diagnosis, and management. United Kingdom: Quintessence Publishing; 2018.

2. Schiffman E, Ohrbach R, Truelove E, Look J, Anderson G, Goulet JP, et al. Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications: recommendations of the International RDC/TMD Consortium Network* and Orofacial Pain Special Interest Group†. J Oral Facial Pain Headache. 2014;28(1):6-27. http://dx.doi.org/10.11607/jop.1151. PMid:24482784.

3. Roldán-Barraza C, Janko S, Villanueva J, Araya I, Lauer HC. A systematic review and meta-analysis of usual treatment versus psychosocial interventions in the treatment of myofascial temporomandibular disorder pain. J Oral Facial Pain Headache. 2014;28(3):205-22. http://dx.doi.org/10.11607/ofph.1241. PMid:25068215.

4. Türp JC, Komine F, Hugger A. Efficacy of stabilization splints for the management of patients with masticatory muscle pain: a qualitative systematic review. Clin Oral Investig. 2004;8(4):179-95. http://dx.doi.org/10.1007/s00784-004-0265-4. PMid:15179561.

5. List T, Axelsson S. Management of TMD: evidence from systematic reviews and meta-analyses. J Oral Rehabil. 2010;37(6):430-51. http://dx.doi.org/10.1111/j.1365-2842.2010.02089.x. PMid:20438615.

6. Conti PCR, de Alencar EN, da Mota Corrêa AS, Lauris JR, Porporatti AL, Costa YM. Behavioural changes and occlusal splints are effective in the management of masticatory myofascial pain: a short-term evaluation. J Oral Rehabil. 2012;39(10):754-60. http://dx.doi.org/10.1111/j.1365-2842.2012.02327.x. PMid:22672361.

7. Zhang S-H, He K-X, Lin C-J, Liu XD, Wu L, Chen J, et al. Efficacy of occlusal splints in the treatment of temporomandibular disorders: a systematic review of randomized controlled trials. Acta Odontol Scand. 2020;78(8):580-9. http://dx.doi.org/10.1080/00016357.2020.1759818. PMid:32421379.

8. Al-Moraissi EA, Farea R, Qasem KA, Al-Wadeai MS, Al-Sabahi ME, Al-Iryani GM. Effectiveness of occlusal splint therapy in the management of temporomandibular disorders: network meta-analysis of randomized controlled trials. Int J Oral Maxillofac Surg. 2020;49(8):1042-56. http://dx.doi.org/10.1016/j.ijom.2020.01.004. PMid:31982236.

9. Gnauck M, Helkimo M, Magnusson T. Routines for interocclusal appliance therapy among general dental practitioners in a Swedish county. Swed Dent J. 2012;36(3):125-32. PMid:23230806.

10. Candirli C, Korkmaz YT, Celikoglu M, Altintas SH, Coskun U, Memis S. Dentists' knowledge of occlusal splint therapy for bruxism and temporomandibular joint disorders. Niger J Clin Pract. 2016;19(4):496-501. http://dx.doi.org/10.4103/1119-3077.183310. PMid:27251967.

11. Nilsson H, Limchaichana N, Nilner M, Ekberg EC. Short-term treatment of a resilient appliance in TMD pain patients: a randomized controlled trial. J Oral Rehabil. 2009;36(8):547-55. http://dx.doi.org/10.1111/j.1365-2842.2009.01973.x. PMid:19604318.

12. Nilsson H, Vallon D, Ekberg EC. Long-term efficacy of resilient appliance therapy in TMD pain patients: a randomised, controlled trial. J Oral Rehabil. 2011;38(10):713-21. http://dx.doi.org/10.1111/j.1365-2842.2011.02210.x. PMid:21434963.

13. Seifeldin SA, Elhayes KA. Soft versus hard occlusal splint therapy in the management of temporomandibular disorders (TMDs). Saudi Dent J. 2015;27(4):208-14. http://dx.doi.org/10.1016/j.sdentj.2014.12.004. PMid:26644756.

14. Alencar F Jr, Becker A. Evaluation of different occlusal splints and counseling in the management of myofascial pain dysfunction. J Oral Rehabil. 2009;36(2):79-85. http://dx.doi.org/10.1111/j.1365-2842.2008.01913.x. PMid:18976268.

15. Klasser GD, Greene CS, Lavigne GJ. Oral appliances and the management of sleep bruxism in adults: a century of clinical applications and search for mechanisms. Int J Prosthodont. 2010;23(5):453-62. PMid:20859563.

16. Liu F, Steinkeler A. Epidemiology, diagnosis, and treatment of temporomandibular disorders. Dent Clin North Am. 2013;57(3):465-79. http://dx.doi.org/10.1016/j.cden.2013.04.006. PMid:23809304.

17. Nagata K, Maruyama H, Mizuhashi R, Morita S, Hori S, Yokoe T, et al. Efficacy of stabilization splint therapy combined with non-splint multimodal therapy for treating RDC/TMD axis I patients: a randomized controlled trial. J Oral Rehabil. 2015;42(12):890-9. http://dx.doi.org/10.1111/joor.12332. PMid:26174571.

18. van Grootel RJ, Buchner R, Wismeijer D, van der Glas HW. Towards an optimal therapy strategy for myogenous TMD, physiotherapy compared with occlusal splint therapy in an RCT with therapy-and-patient-specific treatment durations. BMC Musculoskelet Disord. 2017;18(1):76. http://dx.doi.org/10.1186/s12891-017-1404-9. PMid:28183288.

19. Truelove E, Huggins KH, Mancl L, Dworkin SF. The efficacy of traditional, low-cost and nonsplint therapies for temporomandibular disorder: a randomized controlled trial. J Am Dent Assoc. 2006;137(8):1099-107, quiz 1169. http://dx.doi.org/10.14219/jada.archive.2006.0348. PMid:16873325.

20. Niemelä K, Korpela M, Raustia A, Ylöstalo P, Sipilä K. Efficacy of stabilisation splint treatment on temporomandibular disorders. J Oral Rehabil. 2012;39(11):799-804. http://dx.doi.org/10.1111/j.1365-2842.2012.02335.x. PMid:22809314.

21. De la Torre Canales G, Manfredini D, Grillo CM, Guarda-Nardini L, Machado Gonçalves L, Rizzatti Barbosa CM. Therapeutic effectiveness of a combined counseling plus stabilization appliance treatment for myofascial pain of the jaw muscles: A pilot study. Cranio. 2017;35(3):180-6. http://dx.doi.org/10.1080/08869634.2016.1168071. PMid:27077259.

22. Eliassen M, Hjortsjö C, Olsen-Bergem H, Bjørnland T. Self-exercise programmes and occlusal splints in the treatment of TMD-related myalgia-Evidence-based medicine? J Oral Rehabil. 2019;46(11):1088-94. http://dx.doi.org/10.1111/joor.12856. PMid:31286551.

23. Melo RA, de Resende CMBM, Rêgo CRF, Bispo ASL, Barbosa GAS, de Almeida EO. Conservative therapies to treat pain and anxiety associated with temporomandibular disorders: a randomized clinical trial. Int Dent J. 2020;70(4):245-53. http://dx.doi.org/10.1111/idj.12546. PMid:32153038.

24. Chile. Ley 20,584. Regula a los derechos y deberes que tienen las personas en relación con acciones vinculadas a su atención en salud. Santiago, Chile: Ministerio de Salud; Subsecretaría de Salud Pública; 2012.

25. Random.ORG. List randomizer [Internet]. 2021 [cited 2021 aug 12]. Available from: https://www.random.org/lists/

26. Ohrbach R, Gonzalez Y, List T, Michelotti A, Schiffman E. Diagnostic criteria for temporomandibular disorders (DC/TMD) Clinical Examination Protocol. Version 2 June 2013 [Internet]. 2013 [cited 2017 may 12]. Available from: www.rdc-tmdinternational.org

27. Ohrbach R, Gonzalez Y, List T, Michelotti A, Schiffman E. Diagnostic criteria for temporomandibular disorders: assessment instruments. Version 15 May 2016 [Internet]. 2016 [cited 2017 may 12]. Available from: www.rdc-tmdinternational.org

28. Salinas J, Armstrong L. Behavioral therapy and self-care vs thermoformed occlusal splints in the treatment of masticatory muscles pain: a controlled clinical trial. Charlottesville: Center for Open Science/OSF Home; 2021. http://dx.doi.org/10.17605/OSF.IO/9XTMD

29. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT

recommendations. J Pain. 2008;9(2):105-21. http://dx.doi.org/10.1016/j.jpain.2007.09.005. PMid:18055266.

30. Ekblom A, Hansson P. Pain intensity measurements in patients with acute pain receiving afferent stimulation. J Neurol Neurosurg Psychiatry. 1988;51(4):481-6. http://dx.doi.org/10.1136/jnnp.51.4.481. PMid:3259976.

31. Manfredini D, Piccotti F, Ferronato G, Guarda-Nardini L. Age peaks of different RDC/TMD diagnoses in a patient population. J Dent. 2010;38(5):392-9. http://dx.doi.org/10.1016/j.jdent.2010.01.006. PMid:20100537.

32. Story WP, Durham J, Al-Baghdadi M, Steele J, Araujo-Soares V. Self-management in temporomandibular disorders: a systematic review of behavioural components. J Oral Rehabil. 2016;43(10):759-70. http://dx.doi.org/10.1111/joor.12422. PMid:27487973.

33. de Freitas RFCP, Ferreira MÂF, Barbosa GAS, Calderon PS. Counselling and self-management therapies for temporomandibular disorders: a systematic review. J Oral Rehabil. 2013;40(11):864-74. http://dx.doi.org/10.1111/joor.12098. PMid:24102692.

34. Fricton J. Myogenous temporomandibular disorders: diagnostic and management considerations. Dent Clin North Am. 2007;51(1):61-83, vi. http://dx.doi.org/10.1016/j.cden.2006.10.002. PMid:17185060.

35. Figueiró C, Knorst JK, Fensterseifer CK, Folchini S, Milanesi JM, Bernardon Silva T, et al. Changes in oral health-related quality of life after self-care treatment in patients with myofascial pain. Cranio. 2021;1-7. http://dx.doi.org/10.1080/08869634.2021.1922229. PMid:33928869.

36. Michelotti A, Iodice G, Vollaro S, Steenks MH, Farella M. Evaluation of the short-term effectiveness of education versus an occlusal splint for the treatment of myofascial pain of the jaw muscles. J Am Dent Assoc. 2012;143(1):47-53. http://dx.doi.org/10.14219/jada.archive.2012.0018. PMid:22207667.

37. Ohrbach R, Larsson P, List T. The jaw functional limitation scale: development, reliability, and validity of 8-item and 20-item versions. J Orofac Pain. 2008;22(3):219-30. PMid:18780535.

38. Ekici Ö, Dündar Ü, Gökay GD, Büyükbosna M. Evaluation of the efficiency of different treatment modalities in individuals with painful temporomandibular joint disc displacement with reduction: a randomised controlled clinical trial. Br J Oral Maxillofac Surg. 2022;60(3):350-6. http://dx.doi.org/10.1016/j.bjoms.2021.08.001. PMid:34756640.

39. Emshoff RD, Bertram A, Stigler RG, Schnabl D. Early responses to 3 mm resilient stabilization appliance therapy for sub-acute and chronic temporomandibular disorder pain predict 12-months follow-up outcomes. Cranio. 2022;40(1):72-8. http://dx.doi.org/10.1080/08869634.2019.1677301. PMid:31601160.

40. Gikić M, Vrbanović E, Zlendić M, Alajbeg IZ. Treatment responses in chronic temporomandibular patients depending on the treatment modalities and frequency of parafunctional behaviour. J Oral Rehabil. 2021;48(7):785-97. http://dx.doi.org/10.1111/joor.13173. PMid:33797785.

41. Lindfors E, Magnusson T, Ernberg M. Effect of therapeutic jaw exercises in the treatment of masticatory myofascial pain: a randomized controlled study. J Oral Facial Pain Headache. 2020;34(4):364-73. http://dx.doi.org/10.11607/ofph.2670. PMid:33290442.

42. Lin S-L, Wu S-L, Ko S-Y, Yen CY, Yang JW. Effect of flat-plane splint vertical thickness on disc displacement without reduction: a retrospective matched-cohort study. J Oral Maxillofac Surg. 2017;75(8):1627-36. http://dx.doi.org/10.1016/j.joms.2016.12.047. PMid:28157490.

43. Bilir H, Kurt H. Influence of stabilization splint thickness on temporomandibular disorders. Int J Prosthodont. 2022;35(2):163-73. http://dx.doi.org/10.11607/ijp.6923. PMid:35507529.

44. Greene CS, Manfredini D. Treating temporomandibular disorders in the 21st Century: can we finally eliminate the 'Third Pathway'? J Oral Facial Pain Headache. 2020;34(3):206-16. http://dx.doi.org/10.11607/ofph.2608. PMid:32870949.

45. Nicholas M, Vlaeyen JWS, Rief W, Barke A, Aziz Q, Benoliel R, et al. The IASP classification of chronic pain for ICD-11: chronic primary pain. Pain. 2019;160(1):28-37. http://dx.doi.org/10.1097/j.pain.0000000000001390. PMid:30586068.

46. Sabsoob O, Elsaraj SM, Gornitsky M, Laszlo E, Fricton JR, Schiffman EL, et al. Acute and chronic temporomandibular disorder pain: a critical review of differentiating factors and predictors of acute to chronic pain transition. J Oral Rehabil. 2022;49(3):362-72. http://dx.doi.org/10.1111/joor.13283. PMid:34800343.

Diego De Nordenflycht
(Corresponding address)
Universidad Andres Bello, Facultad de Odontologia, Viña del Mar, Chile
Email: diego.den@gmail.com

Date submitted: 2022 Jan 31
Accepted submission: 2022 May 31