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Evaluation of pain intensity of the masticatory muscles after occlusal appliance and combined therapy: a 6-months follow-up pilot study

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Masticatory muscle pain (MMP) is a common type of orofacial pain. Occlusal appliance (OA) is contemplated as a first-line conservative approach for chronic MMP, however, integrated biopsychosocial approaches such as counseling and self-care therapies (CSG) are also considered essential**. Aim:** This pilot study aimed to compare the use of a combined therapy (GSG + OA) and solely OA treatment on pain intensity related to chronic MMP over a 6-month follow-up. **Methods:** For this, 20 patients diagnosed with chronic MMP using the Diagnostic criteria for temporomandibular disorders (DC/TMD) were divided into 2 groups (n=10) and treated with OA or combined therapy (CoT; OA + CSG). Electromyographic muscle activity (EMG), visual analogue scale (VAS) and pressure pain threshold (PPT) were recorded at baseline, 1, 3 and 6 months after treatment. Data was collected and statistical analysis were applied at a significance level of 5%. **Results:** Results showed no significant differences at baseline among groups for any assessment. VAS showed that both treatments decreased subjective pain in volunteers over time, but no significant differences among both groups were observed at any evaluation time. For electromyography, CoT and OA presented no significant differences throughout the experiment neither on relaxed muscle position or maximum volunteer contraction. Finally, a significantly higher PPT for CoT was found for all muscles at the last assessment point ($p<0.05$). **Conclusion:** These findings suggest that both treatments are effective for the reduction of pain perception (VAS) in patients with chronic MMP. However, the addition of CSG to an OA therapy may be more beneficial for the improvement of tenderness on the same patients, at least in a long-term basis (> 3 months). Notwithstanding, a larger study should be performed to substantiate these findings.

Keywords: Facial pain. Myofascial pain syndromes. Occlusal splints.

Introduction

Temporomandibular disorders (TMDs) embrace a range of painful and non-painful conditions involving the temporomandibular joint (TMJ), masticatory muscles, and associated structures[1-3]. Among TMDs, masticatory muscle pain (MMP) is one of the most common types of orofacial pain conditions[4] and , in chronic states, is frequently associated with symptoms like TMJ sounds and uncoordinated mandibular movements, which affect the social, vocational, and emotional life of patients[3,5].

Even though numerous treatments such as pharmacotherapy, physiotherapy, oral appliances (OA), botulinum toxin, surgical approaches, and counseling and self-care therapies (CSG) are widely used to treat chronic MMP, they usually have a high, but not total, success rate[1,6,7]. Within these treatments, systematic reviews confirmed an effective performance of OA to control pain related to different TMDs[8,9] and to decrease the frequently associated psychosocial impairments[10,11]. For these reasons, OA is contemplated as a first-line conservative approach for chronic MMP, although it involves clinical and laboratorial steps, which represent a manufacturing cost that may differ depending on the employed material[12-15]. However, even though OA is stablished as a beneficial treatment for chronic MMP at a short-term basis (< 3 months), its benefits seemed to be equalized or even lesser than other therapeutic modalities at a long-term (> 3 months)[16]. Moreover, few studies have reported the short- or long-term effects of solely OA as a treatment for chronic MMP[17], since it is usually associated to other therapies[14,18,19].

On the other side, it is well known that emotions play an important role in the perception of pain and are contemplated as perpetuating factors[20,21]. Focusing only on a mechanical approach may be insufficient to promote long-term control of the pain associated to TMDs, since negative emotions are frequently involved causing anxiety, depression, stress and fatigue[22]. Negative emotional states of patients are often present in severe clinical conditions, significantly affecting the progression of chronic pain[21,23]. For these reasons, integrated biopsychosocial approaches with conservative and reversible characteristics such as CSG, which involves self-care strategies and behavioral therapies, are essential in the treatment of chronic TMDs[24]. CSG are used to stimulate patients to change their behavior and stress[11], and are contemplated as very powerful tools in the control of chronic MMP.

Although both therapies (OA and CSG) have been broadly studied, the possible benefits on improving pain intensity that CSG may offer to an exclusively OA treatment for chronic MMP, whether at short- (< 3 months) or/and at a long-term basis (> 3 months), are still not completely elucidated. Therefore, this pilot study aimed to compare the benefits of a combined therapy (CoT; GSG + OA) versus OA on pain intensity of chronic MMP over a 6-months period. We assumed that a CoT will be more effective to control the pain associated to chronic MMP than OA itself at short and long-term assessments.

METHODOLOGY

Patients

The present study was approved by the Ethics Committee of the Piracicaba Dental School, University of Campinas, São Paulo, Brazil (CAAE# 70654317.2.0000.5418). All

patients received a consent form before involvement. A total of 112 female patients who attended to the clinics of the Piracicaba Dental School - UNICAMP, São Paulo, Brazil were evaluated using the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD)[25] by an experienced examiner.

Patients diagnosed with chronic MMP (myofascial pain on masticatory muscles lasting > 3 months) greater than 50mm in the visual analogue scale (VAS), and under contraceptive intake (in an attempt to control hormonal imbalance and better standardize our sample) were included for this experiment. Exclusion criteria (figure 1) comprised patients with a history of face or TMJ trauma, probable diagnosis of bruxism (clinical findings + self-report), partial removable or total prosthesis users, daily use of anti-inflammatory, analgesic or myorelaxant treatment, patients with unrealistic expectation for treatment results, presence of arthritis, osteoarthritis, diabetes, fibromyalgia or neurological disorders, presence of primary headache diagnosed by the International Classification of Headache Disorders questionnaire[26], and those who did not agreed to sign the consent form.

After applying inclusion and exclusion criteria, 20 patients were randomly allocated into two different groups (n=10) using the random allocation software[27]: CoT, with patients treated with CSG and OA; and OA, with patients treated with OA only.

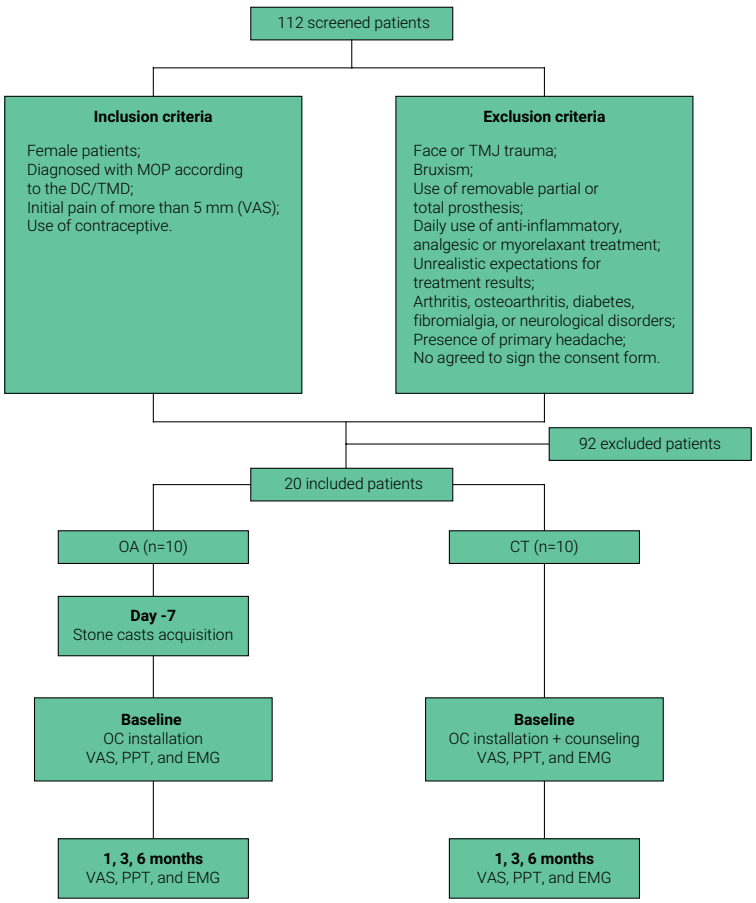

Figure 1. Flowchart of the study showing the screened patients, inclusion and exclusion criteria, enrolled patients, and sequence of treatments application and assessment.

Treatments

All treatments were performed by an experienced clinician who was not involved in the outcomes assessment.

Counseling and self-care techniques (CSG)

For CSG, patients received extensive verbal and written instructions from the same clinician (table 1). The aim of the therapy was to learn about the anatomy and physiology of the stomatognathic system as well as the etiology and prognosis of TMDs. Also, patients received self-care strategies to control parafunctions and relieve pain (*e.g.* practicing physical exercises and how to relax jaw muscles), along with information to improve sleep (*e.g.* reducing alcohol or coffee consumption before sleeping, maintain a regular sleep schedule, among others), correct body posture, and the importance of dietary habits[17,28]. Counseling was reinforced every time the patient returned for evaluation and with weekly mobile text message reminders.

Table 1. Counseling and self-care strategies given to the patients.

Instructions provided to the patients
• Explanation about anatomy and physiology stomatognathic system
• Explanation about the genesis and evolution of MMP
• At rest position of jaw, there should be no contact of teeth
• Exercise regularly
• Use relaxation techniques during stressing situations (*e.g.* deep breathing and progressive muscle relaxation)[29]
• Try to avoid hard food and eat small pieces at each time
• Avoid parafunctional habits (biting things, nails, leaning on the jaw, etc)
• Reduce alcohol or coffee consumption before sleeping
• Maintain regular sleep schedule

Occlusal Appliance (OA)

To make the OA, maxillary and mandibular stone casts were obtained from the patients one week before baseline session. Both casts were mounted on a semi-adjustable articulator in a position of maximal intercuspidation and considering a 3mm posterior disocclusion. The OA consisted in a rigid 3-mm flat splint covering all maxillary teeth, made of transparent thermo-polymerized acrylic resin (Vipicril Plus, Vipi®, Brazil). OA was adjusted to the centric position of each patient´s jaw and using a bilateral balanced occlusion design (*i.e.* simultaneous contacts on all teeth during excursive movements)[30]. Patients received the OA and were instructed to use it every night while sleeping. Baseline was considered as the day patients received the splint and follow-up period started after the splint installation. Adjustments were made every time they were required until a comfortable fit of the OA and the correct centric position were achieved.

Outcomes

Assessments were performed by an experimenter who was blinded to treatment assignments. Outcomes (pain intensity and muscle electric activity) were measured in all participants at four different times, as described in figure 1: baseline (before application of the corresponding treatment), and 1, 3- and 6-months following OA installation and/or after providing counselling instructions to the patients.

Visual Analog Scale (VAS)

VAS consists of a 100 mm horizontal line in which the left end is labeled with the words "no pain" and the right end is written "worst pain imaginable". Volunteers had to mark a point on the line according to the level of their current pain. The media of VAS from all patients in a group was considered for data analysis[7].

Pressure pain threshold (PPT)

A digital algometer with 1 cm2 circular at rod (Kratos DDK-20. São Paulo, Brazil) was used to assess PPT by a single calibrated operator (Kappa = 0.89). Pressure was applied perpendicular to the surface of the skin with relaxed muscles at a rate of 0,3kg/ cm2 according to the following muscle sequence: right anterior temporal (RT), right masseter (RM), left masseter (LM), and left anterior temporal (LT) muscle; after 5 min, a second series of stimuli were applied at inverse order. Pressure stopped when patients started to feel pain-like perceptions[31].

Electromyography (EMG)

The ADS 1200 (Lynx Electronic Technology Ltd, Sao Paulo, Brazil) equipment with eight channels was used to record the electromyographic signal of the evaluated muscles. The electrodes were fixed in the most prominent part of the muscle at maximal contraction; also, a personalized acetate plate was elaborated for each patient in order to locate the electrodes in the same muscle part every time.

The relaxed muscle position (RMP) and maximum volunteer contraction (MVC) were evaluated. To record maximum electrical muscle activity a Parafilm M (American National Can, Chicago, IL, USA) was bitten bilaterally in the molar region for five seconds. This process was recorded for three different times and the arithmetic mean was calculated[32].

The softwares Lynx AqDa- dos 7.02 and Lynx AqD Analysis 7.0 (Lynx Electronic Technology Ltd, Sao Paulo, Brazil) were used for the acquisition of simultaneous signals and to process the root mean square (RMS) values, expressed in mV.

Statistical Analysis

The results were analyzed using the Analysis of variance (ANOVA) for repeated measures (RM) to test the effect of time (4 periods) and treatment (OA and CoT) on the assessed outcomes (VAS, PPT, and EMG), followed by Tukey´s multiple comparisons test to compare the paired inter-groups effect. Intra-group analysis was assessed using one-way ANOVA RM, followed by Tukey´s multiple comparisons test. All data

was processed using the Jamovi® statistic software, version 1.2 (The Jamovi Project, 2020). The significance level of 5% was set for all data.

RESULTS

The sample was composed of women with a mean age of 27±4 years, diagnosed with MMP according to the DC/TMD. VAS-baseline values showed no differences among groups.

Post-treatment assessments of VAS (Figure 2) showed that both, OA and CoT, decreased pain intensity in volunteers over time (1, 3 and 6 months). In addition, we observed no significant differences among both groups (CoT and OA) at any evaluation period (p=0.56; effect size £0.10).

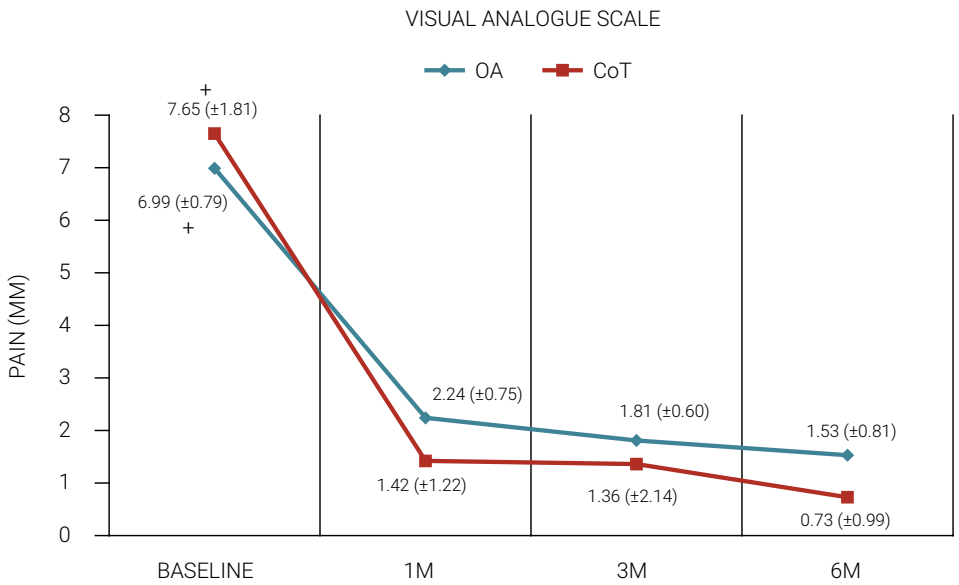

Figure 2. Visual Analogue Scale (VAS). Occlusal appliance (OA) and combined therapy (CoT) decreased pain intensity assessed by VAS after 1 month and maintained up to 6-months. Mean ± standard deviation; +=p<0.001 within group (one-way ANOVA followed by Tukey´s multiple comparisons test). However, no significant differences were found among groups throughout the experiment (p>0.05; two-way repeated measures ANOVA followed by Tukey´s multiple comparisons test).

For electromyography, the relaxed muscle position (RMP) and maximum volunteer contraction (MVC) of muscles were evaluated. The within group analysis showed no differences on OA or CoT over-time (p>0.05; one-way repeated measures ANOVA followed by Tukey´s multiple comparisons test). Additionally, CoT and OA groups presented no significant differences among them throughout the experiment (*i.e.* from baseline to 6-month assessment) neither on RMP (p>0.05; effect size=0.13) nor MVC (p>0.05; effect size= 0.16), as observed in Figure 3.

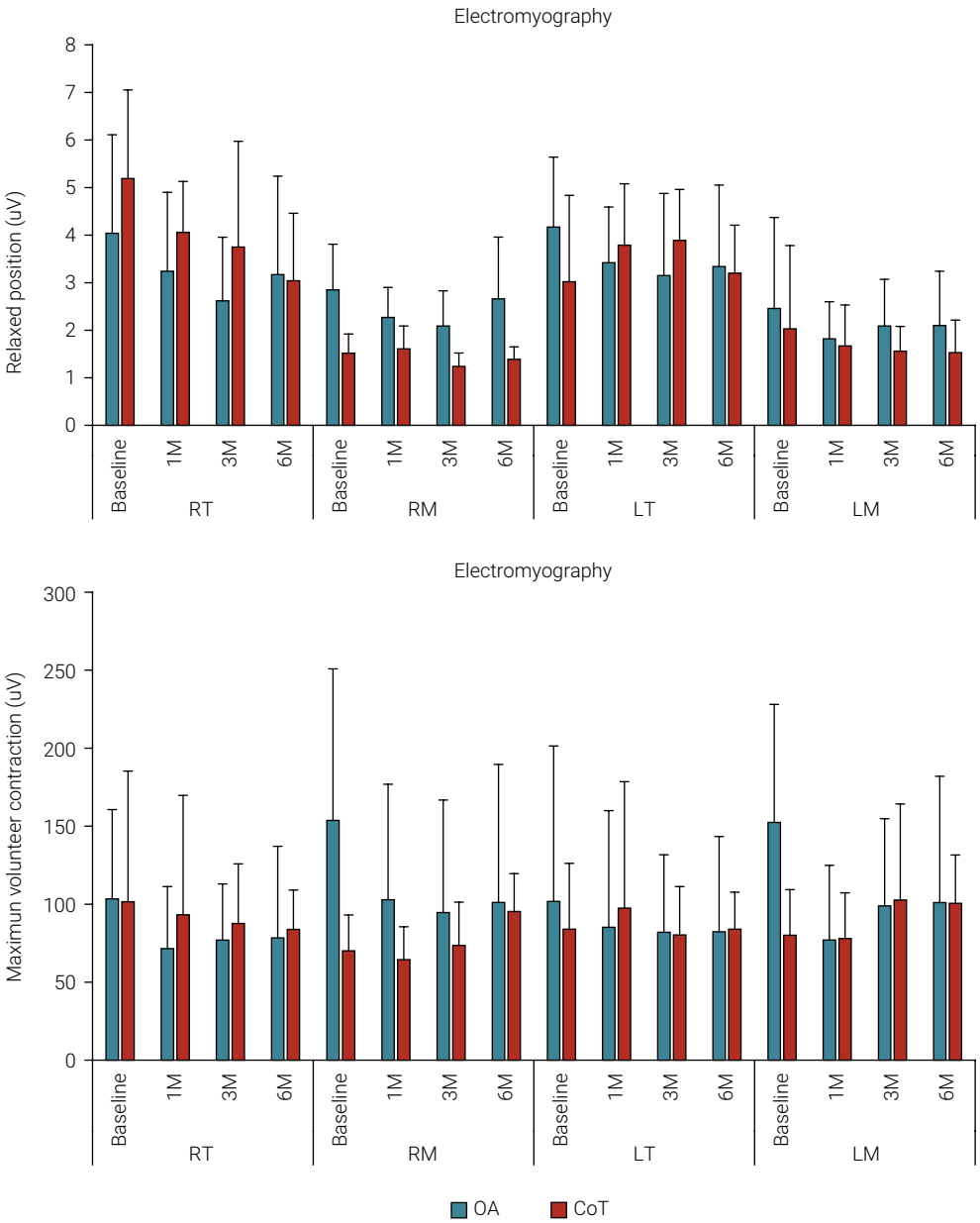

Figure 3. The electromyographic assessment of masseter and temporalis muscles showed no significant differences within groups (p>0.05; one-way repeated measures ANOVA followed by Tukey´s multiple comparisons test). Among groups comparisons also showed no differences (p>0.05; three-way repeated measures ANOVA followed by Tukey´s multiple comparisons test) neither on (A) relaxed muscular position nor (B) maximum volunteer contraction. OA, occlusal appliance; CoT, combined therapy; RT, right temporalis; RM, right masseter; LT, left temporalis; LM, left masseter.

Regarding PPT (Figure 4), CoT, but not OA, showed a significant relieve of tenderness after 3 months on the left side muscles (p<0.01; one-way repeated measures ANOVA followed by Tukey´s multiple comparisons test) and an improvement in all muscles after 6 months (p<0.05; one-way repeated measures ANOVA followed by Tukey´s

multiple comparisons test). Moreover, overall differences among groups were found (p<0.001; effect size = 0.28). The statistical analysis showed no differences between treatments at baseline or at 1-month assessment. However, after 3 months, differences became notorious with higher PPT values for CoT rather than OA, and a clear significant difference on the left temporalis and masseter among groups (p<0.05; LT: 1.37± 0.11 for CoT vs 0.73± 0.12 for OA; and LM: 1.53±0.24 for CoT vs 0.73±0.13 for OA). Finally, a significantly higher PPT for CoT over OA was found for all muscles at the last assessment point (p<0.05; RT: 1.02± 0.29 for CoT vs 0.79± 0.23 for OA; and RM: 0.95±0.27 for CoT vs 0.77±0.95 for OA; LT: 1.92± 0.07 for CoT vs 0.76± 0.18 for OA; and LM: 1.79±0.17 for CoT vs 0.73±0.16 for OA).

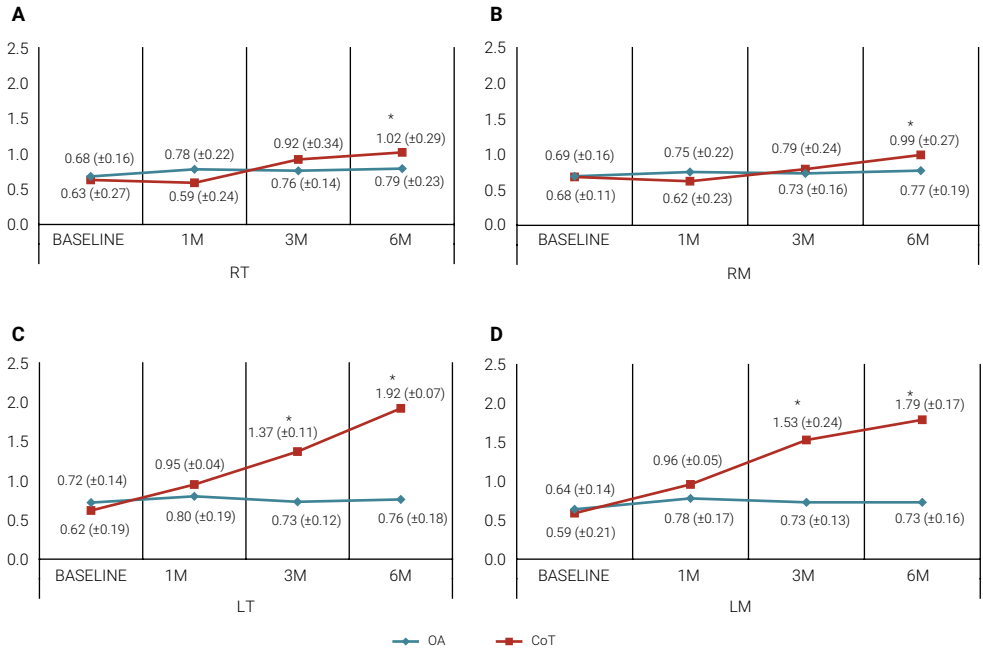

Figure 4. Pressure pain threshold (PPT) of (A) right temporalis (RT), (B) right masseter (RM), (C) left temporalis (RM), and (D) left masseter (LM). Mean ± standard deviation; *=P<0.5 among inter-group paired variables (three-way repeated measures ANOVA followed by Tukey´s multiple comparisons test). OA, occlusal appliance; CoT, combined therapy.

DISCUSSION

In this pilot study, we aimed to compare the effectiveness of an OA treatment against CoT (OA plus CSG) on the reduction of pain intensity related to chronic MMP, over a 6-month evaluation period. Our results suggested that both therapeutic approaches (OA and CoT) had a similar positive effect on pain perception (VAS) throughout the 6-month follow-up. However, significantly higher PPT values can be seen after 6 months just for CoT, which may suggest a positive influence of CSG over a solely OA therapy for the improvement of tenderness on patients with chronic MMP, at least at a long-term evaluation.

Both, OA and CSG, had previously demonstrated a positive effect for the treatment of pain related to TMDs, including MMP[16,28]. However, different from previous studies[14,17-19], we assessed the benefits of including CSG to a solely OA approach on patients with chronic MMP. It is important to consider that CSG is a non-invasive treatment that can be used by any health-care professional, because of its simple technique that requires no ample experience and no profound knowledge of psychological domains[28]. Additionally, CSG is a low-cost strategy with proven beneficial effects when used alone[17,33] or in combination with other treatments like physical therapy[34].

Similar to our results, other studies have shown an improvement on reported pain (VAS) after the use of OA[16], CSG[14,17] or CoT (*i.e.* different types of OA plus CSG)[18,19]. On the other side, the results of PPT from our study suggested no improvement on tenderness for solely OA, and an improvement just on the left-side muscles for CoT after 3 months. These findings are comparable to the ones presented by Conti et.al 2012, where none of the assessed groups (full coverage splint plus CSG, anterior trigeminal inhibitory nociceptive device plus CSG, and CSG alone) showed an increase on PPT levels at 3-month evaluation[19]. The different effects among these two pain-rating methods (VAS and PPT) may be due to their weak correlation for assessing pain intensity in myogenic-TMD populations[35,36], proving that VAS may not be an adequate PPT predictor.

Additionally, following the aforementioned results, it may be suitable to suggest that both, OA and CSG, have a higher impact on patient´s perception of pain rather than on the physiological domain, at least in a short-term basis (< 3 months). As it is known, pain is a complex and multidimensional experience that receives influence from physiological, emotional, and cognitive dimensions[37]. For this reason, it is difficult to describe pain intensity based just on a self-reported scale (VAS) or a mechanically-stimulated pain test (PPT) without assessing other pain domains (*e.g.* cognitive or emotional), which is a limitation of our pilot study.

Interestingly, we found a significant long-term (>3 months) improvement on PPT for CoT compared to solely OA. It is important to remark that few studies have reported long-term effects of CSG or OA as singular treatments, as they are usually studied together or in combination with other therapies[14,16,28]. Truelove et al.[14], 2006, observed no differences among two CoT groups (conventional flat plane acrylic splint plus CSG, and soft vinyl splint plus counseling) and CSG alone after a 12-month evaluation period. It was concluded that OA provides no additional benefits to CSG and makes the treatment more expensive[14]. Additionally, a systematic review and metanalysis concluded that OA may have a higher short-time benefit for reducing pain related to TMDs when compared to other therapeutic modalities. Though, this effect seemed matched or even lesser than other therapies at a long-term[16]. The better performance of CoT may be attributed to the knowledge and, consequently, better control and awareness of the possible causes related to MMP, which are shown during CSG. For these reasons, the concomitant use of CSG and OA (*i.e.* CoT) may be more favorable than a merely OA intervention for chronic pain of the masticatory muscles, at least at a long-term basis.

Regarding EMG, our results showed no differences within and among groups over time on electric muscle activity for RMP and MVC muscle positions. Previous

experiments evaluated OA electromyographic effects of masticatory muscles and found a decreased electromyographic activity[8,38,39]. However, with the exception of one study[39], this reduction is frequently transient and may be attributed to the presence of an unusual object inside the mouth (*e.g.* the OA) which produces an avoidance conduct[13].

Finally, some shortcomings need to be reported. First, the use of a small sample size is clearly a limitation of this pilot, so larger studies are required to substantiate the results from this experiment. Second, our sample was restricted to a female population, due to their higher prevalence of TMDs[3]. Also, the use of contraceptives was an attempt to avoid unstable pain periods associated with hormonal fluctuation throughout menstrual cycle[40]; however, since hormones play an important role on pain outcomes from myofascial pain patients[41], different results in other populations cannot be disregarded. Third, pain is a multidimensional experience[42] with highly prevalent psychosocial impairments[5], so the assessment of cognitive and emotional features should be considered in future experiments.

CONCLUSION

The use of OA and CoT seems to have a similar positive effect on patient´s perception of pain over a 6-month evaluation period. However, even though both treatments reported a slightly, but no significant, improvement on tenderness at a short-term basis (< 3 months), the use of a CoT presented an increased beneficial effect after 6 months on patients diagnosed with chronic MMP.

Due to the aforementioned reasons and considering that CSG is a no-cost simple treatment modality, its concomitant use with OA therapy may be a better option for patients suffering from chronic MMP rather than OA alone. Yet, larger studies including different populations and assessing other pain dimensions should be encouraged.

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