

UNIVERSIDADE DE SÃO PAULO  
FACULDADE DE ODONTOLOGIA DE BAURU

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**Clinical, somatosensory and psychosocial characterization of  
patients with painful temporomandibular joint clicking:  
a cross-sectional study**

**Caracterização clínica, somatossensorial e psicossocial de  
pacientes com estalido doloroso da articulação  
temporomandibular: um estudo transversal**

BAURU  
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Tese constituída por artigos apresentada à Faculdade de Odontologia de Bauru da Universidade de São Paulo para obtenção do título de Doutor em Ciências no Programa de Ciências Odontológicas Aplicadas, na área de concentração Reabilitação Oral.

Orientador: Prof. Dr. Paulo César Rodrigues Conti

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## ERRATA

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*“São Gabriel com Maria, São Rafael com Tobias, São Miguel com todas as hierarquias, abre para nós estas vias!”*

*Maria Porta do Céu*



## ABSTRACT

### **Clinical, somatosensory and psychosocial characterization of patients with painful temporomandibular joint clicking: a cross-sectional study**

Characterize patients with painful temporomandibular joint (TMJ) clicking can help to understand the arthralgia mechanisms in cases of TMJ clicking and to formulate a better clinical approach. The presented study aimed to characterize patients with painful TMJ clicking. Ninety individuals, equally divided into three groups, composed the sample: patients with painful TMJ clicking (n=30); patients with painless TMJ clicking (n=30); and, control group (n=30). Clinical data included: oral behaviors (OBs) (unilateral chewing; chewing gum; nail biting; bite foreign objects; lean with your hand on the jaw; sleep in a position that puts pressure on the jaw); sleep bruxism (SB); awake bruxism (AB); and, malocclusion. Somatosensory data included: mechanical pain threshold (MPT), wind-up ratio (WUR), pressure pain threshold (PPT), and the conditioned pain modulation (CPM) paradigm. Psychosocial data were formulated on the basis of some questionnaires: Pittsburgh Sleep Quality Index (PSQI); Pain Vigilance and Awareness Questionnaire (PVAQ); Pain Catastrophizing Scale (PCS); Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK/TMD); Perceived Stress Scale (PSS); and, The State-Trait Anxiety Inventory (STAI). A 5% significance level was used for all statistical tests. Patients with painful TMJ clicking showed a significant association with specific OBs (lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; and, nail biting); presence of AB; higher values of MPT and WUR; lower PPT; less efficient CPM; and, higher scores of PSQI, PVAQ, PCS, and TSK/TMD when compared to the other groups ( $p < 0.05$ ). Patients with painless TMJ clicking showed a significant association with the OBs of chewing gum and nail biting; presence of AB; lower PPT; and, higher scores of PVAQ and TKS/TMD only when compared to the control group ( $p < 0.05$ ). No significant difference among groups was found for other OBs (unilateral chewing and bite foreign objects), BS, malocclusion, PSS, and STAI data. It can be concluded that patients with painful TMJ clicking were characterized by a significant association with specific harmful OBs, AB, a somatosensory gain of function (more sensitive) to mechanical pain tests and impaired CPM in the TMJ area, poor sleep quality along with higher levels of hypervigilance, pain catastrophizing, and kinesiophobia.

Keywords: Temporomandibular Joint. Temporomandibular Joint Disc. Pain.

## RESUMO

Caracterizar pacientes com estalido doloroso da articulação temporomandibular (ATM) pode ajudar a entender os mecanismos da artralgia em casos de estalido da ATM e a formular uma melhor abordagem clínica. O presente estudo teve como objetivo caracterizar pacientes com estalido doloroso da ATM. Noventa indivíduos, igualmente divididos em três grupos, compuseram a amostra: pacientes com estalido doloroso da ATM (n = 30); pacientes com estalido indolor da ATM (n = 30); e grupo controle (n = 30). Os dados clínicos incluíram: hábitos orais (HOs) (mastigação unilateral; mascar chiclete; roer unhas; morder objetos estranhos; apoiar a mandíbula na mão; e, dormir em uma posição que exerça pressão sobre a ATM); bruxismo do sono (BS); bruxismo da vigília (BV); e má oclusão. Os dados somatossensoriais incluíram: limiar de dor mecânica (LDM), somação temporal (ST), limiar de dor a pressão (LDP) e a modulação de dor condicionada (MDC). Os dados psicossociais incluíram os questionários: Índice de qualidade de sono de Pittsburgh (IQSP); Questionário de Vigilância e Consciência da Dor (QVCD); Escala de Catastrofização da Dor (ECD); Escala Tampa de Cinesiofobia para distúrbios temporomandibulares (ETC/DTM); Escala de Estresse Percebido (EEP); e Inventário de Ansiedade Traço-Estado (IATS). Um nível de significância de 5% foi utilizado para todos os testes estatísticos. Pacientes com estalido doloroso da ATM apresentaram uma associação significativa com HOs específicos (apoiar a mandíbula na mão; dormir em uma posição que exerça pressão sobre a ATM; mascar chiclete; e roer unhas); presença de BV; valores mais altos de LDM e ST; menor LDP; MDC menos eficiente; e maiores escores de IQSP, QVCD, ECD e ETC/DTM quando comparados aos outros grupos ( $p < 0,05$ ). Pacientes com clique indolor da ATM apresentaram uma associação significativa com os HOs de mascar chiclete e roer unhas; presença de BV; menor LDP; e maiores escores de QVCD e ETC/DTM somente quando comparados ao grupo controle ( $p < 0,05$ ). Não foram encontradas diferenças significativas entre os grupos para os outros HOs (mastigação unilateral e morder objetos estranhos), BS, má oclusão, EEP e IATS. Pode-se concluir que pacientes com estalido doloroso da ATM foram caracterizados por uma associação significativa com HOs prejudiciais específicos, BV, ganho de função somatossensorial (mais sensível) a testes mecânicos de dor e MDC prejudicado na área da ATM, má qualidade do sono e maiores níveis de hipervigilância, catastrofização e cinesiofobia.

Palavras-chave: Articulação Temporomandibular. Disco da Articulação Temporomandibular. Dor.

## LIST OF ABBREVIATIONS AND ACRONYMS

AB	Awake Bruxism
AM	Ante Meridiem
ANOVA	Analysis of Variance
CI	Confidence Interval
CPM	Conditioned Pain Modulation
CS	Conditioning Stimulus
DDWR	Disc displacement with Reduction
EMA	Ecological Momentary Assessment
MPT	Mechanical Pain Threshold
MRI	Magnetic Resonance Imaging
NRS	Numerical Rating Scale
OB	Oral Behavior
PCS	Pain Catastrophizing Scale
PPT	Pressure Pain Threshold
PM	Post Meridiem
PSQI	Pittsburgh Sleep Quality Index
PSS	Perceived Stress Scale
PVAQ	Pain Vigilance and Awareness Questionnaire
RCP-MI	Retruded Contact Position to Maximum Intercuspatation
QST	Quantitative sensory testing
RDC/TMD	Research Diagnostic Criteria for Temporomandibular Disorders
REBEC	Brazilian Registry of Clinical Trials
SB	Sleep Bruxism
SD	Standard Deviation
STAI	The State-Trait Anxiety Inventory
TMDs	Temporomandibular Disorders
TMJ	Temporomandibular Joint
TS	Test Stimulus
TSK/TMD	Tampa Scale for Kinesiophobia for Temporomandibular Disorders
VAS	Visual Analog Scale
WUR	Wind-up Ratio

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# 1

## INTRODUCTION



## INTRODUCTION

Temporomandibular disorders (TMDs) are a group of disorders involving the temporomandibular joint (TMJ), the masticatory muscles, and the associated structures.<sup>1</sup> The main disorders related to TMJ are internal derangements and inflammatory disorders.<sup>2</sup> TMJ internal derangements are a group of disorders related to an abnormal positional relationship between the disc and the condyle, articular eminence, and/or mandibular fossa.<sup>3</sup>

The most common internal derangement is the TMJ disc displacement with reduction (DDWR) that corresponds to 40,92% of TMDs diagnoses.<sup>4</sup> In DDWR, when the mouth is closed, the articular disc is displaced in relation to the condyle and, when the mouth is open, the disc returns to the intermediate area between the condyle and the articular tubercle.<sup>5</sup> DDWR is probably the most common cause of TMJ clicking, defined as a sound event that occurs when the disc is displaced and repositioned during mandibular movements.<sup>6, 7</sup> TMJ clicking corresponding to 30.7% of clinical signs of TMD and is one of the most common complaints of patients.<sup>8</sup>

Despite the fact that TMJ clicking is usually painless, some patients can present concomitant joint pain that starts or is intensified at the opening clicking moment,<sup>9</sup> possibly due to compression of the bilaminar zone and TMJ inflammation, characterizing a painful TMJ clicking.<sup>5, 6</sup> Arthralgia is the TMJ inflammation that generates pain that is affected by jaw movement, function, or parafunction<sup>2</sup>. Alone, arthralgia corresponds to 26.5% of TMD diagnosis.<sup>10</sup>

TMJ pain is one of the most common reasons for a patient to seek a TMD specialist.<sup>1</sup> Regarding TMJ clicking, most patients do not seek treatment until pain develops.<sup>11</sup> However, the correlation between pain and disc position is not fully understood.<sup>12</sup> A study compared, by using magnetic resonance imaging, TMJ morphology between patients with painful TMJ clicking and painless TMJ clicking. Disc and mandibular condyle morphologies; articular eminence morphology and inclination; size of the mandibular fossa; joint space size; joint effusion; bone marrow of the mandibular condyle; and the relative signal intensity of retrodiscal tissue were evaluated. No significant differences were detected between groups, and no anatomic characteristics influenced the presence of pain in TMJ clicking.<sup>13</sup> Perhaps, an analysis including variables from outside of the intraarticular point of view (such as clinical, somatosensory, and psychosocial data) can contribute to characterize the patient with painful TMJ clicking.

To study the clinical variables of TMD patients is always important once some conditions, like TMJ clicking and arthralgia, are related to excessive biomechanical forces

applied to TMJ that are usually present in the patient daily activities;<sup>14</sup> only after understand the patients clinical behavior will be possible to establish an appropriate approach.<sup>15</sup>

Besides that, especially when pain is involved, such as in the painful TMJ clicking, it is also important to interpret which are the pain mechanisms related to the condition and how the body of the patient understands and processes painful stimuli; these data allow compounding the patient somatosensory profile.<sup>9</sup> Quantitative sensory testing (QST) is a reliable tool to formulate a somatosensory profile.<sup>16, 17</sup> QST is a standardized method of seven tests measuring thirteen parameters that systematically assess the clinical manifestations and somatosensory abnormalities of the peripheral and central nervous systems, evaluating myelinated A-fibers (A-beta and A-delta fibers) and unmyelinated C fibers.<sup>18</sup> Regarding the QST, mechanical pain tests (such as mechanical pain threshold, wind-up ratio, and pressure pain threshold) are the most important in patients with TMJ pain.<sup>19</sup> Along with the standard QST, the conditioned pain modulation (CPM) paradigm is often used to assess the human descending pain inhibition system, composing a significant portion in the individual somatosensory profile, and it is also usually deficient in individuals with TMJ pain.<sup>20</sup>

Likewise, psychosocial factors have an important influence on TMD patients that usually present psychosocial impairment and a high prevalence of psychological disorders that increase the frequency of clinical complaints.<sup>21</sup> Self-report of TMJ clicking are more frequent in care-seeking patients that also have greater non-specific physical symptoms, with a propensity to somatization and with the heightened awareness of their own body image.<sup>22</sup> In fact, psychosocial factors are so relevant in patients with TMJ clicking complaints that can influence clinical pain and QST responses.<sup>23</sup>

So, besides to characterize the patient with painful TMJ clicking, an analysis including clinical, somatosensory, and psychosocial variables may help to understand why arthralgia occurs concomitant in only some cases of TMJ clicking and to formulate a better clinical approach.



# 2

## ARTICLES



## ARTICLES

The articles presented in this thesis were written according to the Brazilian Oral Research and to the Journal of Oral Rehabilitation instructions and guidelines for article submission, respectively.

- ARTICLE 1 – Oral Behaviors, Bruxism, Malocclusion and Painful Temporomandibular Joint Clicking: Is There Any Association?
- ARTICLE 2 – Somatosensory and Psychosocial Profile of Patients with Painful Temporomandibular Joint Clicking.



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**ARTICLE 1**

The present article was written according to the Brazilian Oral Research instructions and guidelines for article submission.

**ORAL BEHAVIORS, BRUXISM, MALOCCLUSION AND PAINFUL TEMPOROMANDIBULAR JOINT CLICKING: IS THERE ANY ASSOCIATION?**

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## **ORAL BEHAVIORS, BRUXISM, MALOCCLUSION AND PAINFUL TEMPOROMANDIBULAR JOINT CLICKING: IS THERE ANY ASSOCIATION?**

### **ABSTRACT**

The present cross-sectional aimed to determine if there is an association between specific oral behaviors, sleep bruxism, awake bruxism, and painful temporomandibular joint (TMJ) clicking. Ninety individuals, divided into 3 groups, composed the sample. Group 1 (n=30): patients with painful TMJ clicking; Group 2 (n=30): patients with painless TMJ clicking; and, Group 3 (n=30): control group. The following clinical data were studied: oral behaviors (unilateral chewing; chewing gum; nail biting; bite foreign objects; lean with your hand on the jaw; and, sleep in a position that puts pressure on the jaw); sleep bruxism; awake bruxism (including the frequency in 10 days period, evaluated by ecological momentary assessment); and malocclusion. All tests were performed with a 5% significance level. Group 1 had the higher frequencies and a significant association with the behaviors of lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; nail biting; and, awake bruxism ( $p<0.05$ ). Chewing gum, nail biting and awake bruxism were associated with Group 2 only when compared to Group 3 ( $p<0.05$ ). No significant difference among groups was found for other behaviors (unilateral chewing and bite foreign objects), sleep bruxism, and all malocclusion ( $p>0.05$ ). It can be concluded that patients with painful TMJ clicking had a higher frequency with a statistically significant association with some specific harmful behaviors (lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; and, nail biting) and awake bruxism.

**KEYWORDS:** Temporomandibular joint. Temporomandibular joint disc. Pain.

## INTRODUCTION

Temporomandibular disorders (TMDs) are a group of disorders involving the masticatory muscles, the temporomandibular joint (TMJ), and the associated structures<sup>1</sup>. The main TMJ-related disorders are internal derangements and inflammatory disorders<sup>2</sup>. Disc displacement with reduction (DDWR) is the most common internal derangement and corresponds to about 41% of TMD clinical diagnoses<sup>3</sup>. In this condition, when the mouth is closed, the articular disc is displaced in relation to the condyle and, when the mouth is open, the disc returns to its original position in the intermediate area between the condyle and the articular tubercle<sup>2, 3</sup>. Clinically, DDWR is related to TMJ clicking, that occurs when the disc is displaced and repositioned during mandibular movements<sup>3, 4</sup>. TMJ clicking corresponding to 30.7% of clinical signs of TMD and is one of the most common complaints of patients<sup>5</sup>.

Although TMJ clicking it is usually painless, in some patients, pain can be a comorbid symptom, characterizing a more serious condition such as painful TMJ clicking, in which pain located in the TMJ area and surrounding tissues occurs or is intensifying at the click moment, possibly due to a compression of bilaminar zone and TMJ inflammation<sup>2, 3, 6, 7</sup>. Arthralgia is the inflammation of the joint capsule and/or of the TMJ synovial lining, generating pain and sensitivity<sup>2</sup>. Alone, arthralgia corresponds to 26.5% of TMD diagnosis<sup>8</sup>, and the presence of TMJ clicking increases the relative risk of developing arthralgia<sup>9</sup>.

In part, the etiology of TMJ clicking and arthralgia are, directly or indirectly, related to biomechanical forces applied to TMJ, exceeding the adaptive capacity of the individual<sup>2, 10</sup>. Alone, both conditions have been investigated in association to oral behaviors, bruxism, and malocclusion in an attempt to establish a causal relationship and possible treatment strategies<sup>5, 11-13</sup>. However, no study addressed these factors in patients with painful TMJ clicking (DDWR plus arthralgia, in the same TMJ). This information may help to improve the understanding of this condition and to formulate a better clinical approach.

Therefore, the present study aims to determine if there is an association between oral behaviors, bruxism, malocclusion, and painful TMJ clicking. The null hypothesis is that the variables studied would not present any difference.

## METHODS

This research was approved by the Research Ethics Committee of the Bauru School of Dentistry, University of São Paulo, Bauru, São Paulo, Brazil (CAAE: 88592018.0.0000.5417/ N<sup>o</sup>: 2.725.838) and it was registered at the Brazilian Registry of Clinical Trials (REBEC: RBR-4j5g96). All individuals were informed about the research purposes and signed a free informed consent form. This cross-sectional study was conducted following the Helsinki Declaration and the recommendations of the Strengthening the Reporting of Observational Studies in Epidemiology (Strobe) guidelines<sup>14</sup>.

The sample size calculation was performed using G\*Power 3.1.9.2 software (Düsseldorf, Germany). The following parameters were considered: a) test power of 0.8; b) 0.016 significance level, considering the multiple comparisons of three families of variables: oral behaviors, bruxism and

malocclusion. Thus, according to Bonferroni's correction in which the standard alpha error of 0.05 is divided by the number of families of comparisons, the level of significance adopted in the calculation was 1.6%<sup>15</sup>; and, c) effect size of 0.4 for the analysis of variance test (ANOVA) with only one inter-subject factor, i.e., groups ( $n = 3$ ). Thus, the total sample size was 90 individuals equally divided into three groups: group 1 was composed of 30 patients (22 females, 8 males, a mean age of  $33.4 \pm 13.53$  years) with unilateral painful TMJ clicking (DDWR plus arthralgia, in the same TMJ); group 2 was composed of 30 patients (22 females, 8 males, a mean age of  $32.8 \pm 13.56$  years) with unilateral painless TMJ clicking (only DDWR); and group 3 (control group) was composed of 30 asymptomatic individuals (22 females, 8 males, a mean age of  $31.36 \pm 10.64$  years) with no TMJ clicking and no arthralgia. The individual was considered the unit of observation. The study design and sample formation were based on a previous investigation studying the anatomy of the TMJ to understand the concomitance presence of arthralgia and DDWR<sup>7</sup>.

The sample was obtained from Brazilian individuals, over 18 years old, that consecutive seeking regular dental treatment (control group) or presenting with complaint of clicking and/or pain in TMJ area at the Bauru School of Dentistry, Orofacial Pain Clinics, from September, 2018 to July, 2019. A single examiner (R.L.P.), specialist, and professor of TMD and Orofacial Pain, conducted all clinical examinations. The patients were then allocated in one of the groups according to the clinical examination, based on the official Portuguese version of the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) - Axis I<sup>1</sup>.

Individuals were excluded if they had any pain different from arthralgia, such as myofascial pain; with TMJ sound different from clicking (crepitation or terminal thud); who had any previous surgical intervention in the TMJ; with systemic conditions such as fibromyalgia, osteoarthritis and autoimmune arthritis like rheumatoid arthritis or any degenerative joint disease; wearing removable dental prostheses; individuals ongoing orthodontic treatment; or, in continuous use of medications such as analgesics and anti-inflammatory drugs. The following clinical data were studied: oral behaviors (OBs), sleep bruxism (SB), awake bruxism (AB), and malocclusion.

### ***Oral Behaviors***

OBs, previously reported in the literature as related to TMJ pain and/or TMJ noise<sup>5, 11</sup>, were evaluated (based on the last month) by a self-report questionnaire based on The Oral Behaviors Checklist<sup>16</sup>. Five OBs were studied during wakefulness: unilateral chewing; chewing gum; nail biting; bite foreign objects (e.g. pen); and, lean with your hand on the jaw, such as cupping or resting the chin in the hand. There were 5 possible answers: none of the time, a little of the time, some of the time, most of the time, and all of the time. Also, it was investigated if the individual sleep in a position that puts pressure on the jaw (for example, on stomach, on the side) (in the same side of TMJ complaint) and how often (none of the time, <1 night/month, 1 to 3 nights/month, 1 to 3 nights/week, and 4 to 7 nights/week). For analyses, OBs were evaluated dichotomously: present or absent. The OB was considered as



"present" (i.e., individual with that OB) when the frequency was "most of the time" or "all of the time" or "1 to 3 nights/week" or "4 to 7 nights/week"<sup>5, 11, 16</sup>.

### ***Sleep Bruxism***

Considering the diagnostic grading system, the presence of "Probable SB" was based on a positive self-report with a positive clinical inspection<sup>17</sup>. To be considered as "Probable SB" the individual should answer "yes" to the question: Have you been told or do you notice that you grind your teeth or clench your jaw while sleeping at night (with the frequency of at least 1–3 nights/week)?; and, in the clinical inspection should be present an incident of abnormal tooth wear (visible wear within the enamel or visible wear with dentin exposure and loss of clinical crown height of  $< 1/3$ ) - in this study the examination consisted of the inspection of the last present molar in the right mandibular dental arch<sup>18</sup>.

### ***Awake Bruxism***

Considering the diagnostic grading system, the presence of "Probable AB" was based on a positive self-report with a positive clinical inspection<sup>17</sup>. To be considered positive to the presence of "Probable AB" the individual should answer "yes" to the question: During the day, do you do repetitive or sustained tooth contact and/or bracing or thrusting of the mandible (with the frequency of at least "most of the time")?; in the clinical inspection was used the same parameter describe for SB<sup>18</sup>.

The frequency of AB was studied by an instrumental assessment (ecological momentary assessment [EMA]). As EMA, a free app for smartphone called No Clenching® (Live iDeas, Palhoça, Santa Catarina, Brazil) in the Portuguese version (*Desencoste seus dentes*®) was used. This system sends alert during the day to collect data on self-reported AB. The software was programmed to send 12 alerts/day, every hour, from 9.00 AM to 9.00 PM. The individuals were instructed to answer, "yes" or "no", on real time in every alert, if they were doing any AB activity (teeth contact; teeth clenching; teeth grinding; bracing). All these possible conditions were previous explained to the participants. Participants were also taught to discard the alert if it happened while performing functional activities, such as eating or talking. Data were recorded over a ten days period, gathering 120 answers, but for statistical analysis, only the first 100 answers were considered (individuals with less than 100 answers were excluded). After the observation period, the software generated a report, sent to the researcher via email, by the participants. To evaluate the frequency of AB, all individuals were asked to use the EMA, even without the positive self-report of activity in the anamnesis.

### ***Malocclusion***

The following malocclusion conditions were investigated, based on clinical inspections protocols adopted in previous studies<sup>13, 19</sup>: anterior open bite (present/absent); posterior cross-bite (present/absent); overbite (normal/ $\geq 4$  mm); overjet (normal/ $\geq 5$  mm); canine guidance (present/absent); mediotrusive

and/or laterotrusive interferences (present/absent); retruded contact position to maximum intercuspatation (RCP-MI) slide (normal/ $\geq 2$  mm);  $\geq 5$  missing posterior teeth (present/absent).

### ***Statistical Analysis***

All data were tabulated, submitted to descriptive analysis, and were assessed for normal distribution with the Kolmogorov-Smirnov test. A chi-square test was used to compare the presence of categorical variables (OBs; SB; AB; and occlusal features) among groups. One-way analysis of variance (ANOVA) test was used to compare the frequency of AB. The ANOVA test was followed by post hoc Tukey's test. A 5% significance level was used for all tests. Data were analysed using SPSS Statistics 25.0 software (IBM®, New York, USA).

## **RESULTS**

The descriptive data (frequency distribution) for OBs, SB, AB, and malocclusion are shown in Table 1. In the comparison among all groups, patients with painful TMJ clicking had a higher frequency with a statistically significant association with the OBs of lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; nail biting; and, AB ( $p < 0.05$ ). Patients with painless TMJ clicking had a significant association with the use of chewing gum, nail biting and AB, only when compared to a control group ( $p < 0.05$ ). The other OBs (unilateral chewing and bite foreign objects), BS, and all malocclusion features showed no significant difference ( $p > 0.05$ ) among groups (Table 1).

Regarding the frequency of AB, evaluated by EMA, all individuals of the sample answered the app at least 100 times, and therefore, no one was excluded from this analysis. Group 1 (painful TMJ clicking) had a higher mean of frequency of "Yes" answers of AB activity,  $37.43 \pm 33.75$  (range 0-91); followed by group 2 (painless TMJ clicking),  $22.40 \pm 24.59$  (range 0-88); and, group 3 (control group),  $5.17 \pm 6.05$  (range 0-23). Considering the total sample ( $n=90$ ), there were 21.67% of positive responses on real time report of AB activity. Significant differences ( $p < 0.05$ ) in frequencies of "Yes" answers of AB activity among groups were found (Table 2).

## **DISCUSSION**

The present study found that lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; nail biting; and, AB, have a significant association with patients with painful TMJ clicking when compared to patients with painless TMJ clicking and to the control group. SB and malocclusion were not related to this condition. Thus, the null hypothesis should be partially rejected.

Only specific OBs previously reported in the literature as related to TMJ pain and/or TMJ noise were evaluated. In the present study, four OBs showed a statistically significant difference among groups. The behaviors of lean with your hand on the jaw and sleep in a position that puts pressure on

the jaw were reported, respectively, by 37.8% and 42.2% of the individuals (considering the total sample); also, both were significantly associated only with painful TMJ clicking (Table 1). Similar findings were reported previously, when the same OBs were positively related to TMJ pain and TMJ clicking, individually<sup>11</sup>, although higher frequencies were found. The association between these OBs and painful TMJ clicking may support the hypothesis that compressive activities over the TMJs could be a contributing factor to the internal derangement of the joint by increasing the intra-articular pressure<sup>20</sup>. Also, high intra-articular pressure of the TMJ can result in changes in the composition and volume of the synovial fluid and contribute to the production of inflammatory mediators<sup>21</sup>.

In the comparison among all groups, use chewing gum and nail biting were OBs associated with painful TMJ clicking. Besides that, these two OBs were also associated with painless TMJ clicking, but only when compared to the control group (Table 1). The OB of chewing gum was one of the most prevalent OB (42.2% of the entire sample); in fact, the association this OB with painful TMJ clicking and with painless TMJ clicking was not surprising, since a higher incidence of TMJ clicking and arthralgia in individuals with chewing gum habit had already been reported<sup>22-24</sup>, with a potential contributing factor for these conditions<sup>22</sup>. Possibly this can be explained by the fact that the high compressive forces within the joint due to the intense use of chewing gum contribute to squeeze the disc off the condyle and increase the sensitivity of retrodiscal tissues<sup>25</sup>. Nail biting is one of the most persistent OB. A study showed that the report in childhood of nail biting was a predictor of the same OB 20 years later<sup>26</sup>. Nail biting was reported by 40% of the individuals (considering the total sample), similar to a previous study (48%)<sup>27</sup>. An experimental study suggested that the TMJ is loaded more heavily during incisor biting than during molar chewing<sup>28</sup>. Also, incisal clenching has been reported to reduce anterior joint space and to increase disc compression<sup>29</sup>. These factors can explain the association between TMJ pain/clicking, and nail biting found in this study.

Unilateral chewing was reported by 22.2% of individuals (considering the total sample) without significant difference among groups or association with TMJ pain/clicking. These results differ from the study of Yalçın et al.<sup>30</sup> (2017), that found a higher frequency (45.6%) of unilateral chewing with a significant association with TMD. Differences in methodologies may explain the divergence of the results: in the study of Yalçın, et al.<sup>30</sup> (2017) the frequency was not considered to establish the presence of the OB, only the simple report of the patient; in addition, no specific group of TMD was evaluated. To bite foreign objects was also not significantly associated with any group, and only 10% of the sample was considered positive to this OB. Possibly the overlapping of other OBs of a similar nature (such as the use of chewing gum and nail biting) that presented higher prevalence, may explain the low frequency and the results of this variable.

SB is a masticatory muscle activity during sleep<sup>17</sup>. In this study, 30% of the individuals present a positive diagnostic of "Probable SB", with a similar prevalence among groups (Table 1). This similarity in prevalence, together with the fact that no instrumental assessment for SB was made, may have contributed to the absence of a significant association between SB and painful TMJ clicking.

Anyway, this result is in accordance with previous studies that found no significant association between the presence of disc displacements<sup>31</sup>, arthralgia<sup>32</sup>, and self-report of SB.

AB is a masticatory muscle activity during wakefulness<sup>17</sup>. Among adults, the prevalence of AB has been reporting range between 22-30%<sup>33</sup>. In this study, 37.8% of the individuals present a positive diagnostic of "Probable AB". In a study with a seven-day observation period, the frequency of real time report of AB activity in a sample of healthy young adults was 28.3% (being teeth contact and jaw clenching the most frequent activities)<sup>34</sup>. Considering EMA, in the total sample, there were 21.67% of positive responses on real time report of AB activity, however, there was no differentiation among the various AB activities. It is interesting to point, that even in individuals with a negative self-report of AB, had some positive answers to AB in the app. This fact underscores the importance of collecting real time data at multiple recording points during the day, in the self-environment of the individual, provided by EMA, for a more reliable evaluation of AB. Patients with painful TMJ clicking presented a higher mean of frequency of "Yes" answers of AB activity ( $37.43 \pm 33.75$ ), than patients with painless TMJ clicking ( $22.40 \pm 24.59$ ), and, than the control group ( $5.17 \pm 6.05$ ). In the comparison among all groups, the presence of a positive diagnostic of " Probable AB" and the frequency of "Yes" answers of AB activity were significantly associated with painful TMJ clicking. These two variables were also associated with painless TMJ clicking only when compared to the control group (Table 1). These results agree with the literature, since AB has already been reported as a significant risk factor for disc displacement<sup>35</sup>, increasing also the risk for TMJ pain on jaw movement<sup>36</sup>. A possible reason for the relationship between TMJ clicking, TMJ pain and AB can be obtained from studies by finite element models, where an abnormal distribution of stresses in the disc because of prolonged clenching is found, and this may facilitate disc displacement in symptomatic TMJs<sup>37</sup>; furthermore, relatively high stresses were observed in the retrodiscal tissues throughout clenching<sup>38</sup>, reducing TMJ nutrient levels and producing an overload that could lead to severe damage to TMJ disc itself<sup>39</sup> .

In the present study, eight malocclusion features were addressed and none of them showed any significant difference among groups, thus confirming that other factors (ie, oral behaviors, bruxism activities) are more relevant to TMJ pain be a comorbid symptom in patient with TMJ clicking. Also, these results are in accordance with previous studies, using multiple logistic regression analysis, that suggest that there is no clinically relevant association between malocclusion and TMJ clicking or TMJ arthralgia<sup>13, 19</sup>.

In this study was found an association of OBs (lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; and, nail biting) and AB with painful TMJ clicking. Based on that, clinically, maybe it is important to evaluate the presence of these factors on patients with painful TMJ clicking, to include the control of these factors in the management of this condition. However, all results should be interpreted carefully. Limitations of the present investigation include the restricted population without gender pairing; a well-filtered sample once that all other TMD conditions were excluded so that it was possible studied just DDWR plus arthralgia, without interferences; no TMJ

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image exam was performed, so it is not possible to affirm that there was no other intra-articular pathology, such as some degenerative joint disease, that could be contributing to TMJ pain/clicking; also, no polysomnographic records to evaluate SB; and the study design (cross-sectional), which makes it impossible to establish a cause-effect relationship. Ideally, prospective studies should be conducted in the future. The present results collaborate with the literature that suggests that the answer to why arthralgia is present in some cases of TMJ clicking is not in the anatomy of the TMJ itself<sup>7,40</sup>, and clinical, somatosensorial and psychosocial variables may be just as or even more important in painful TMJ clicking.

## **CONCLUSIONS**

In view of the results and limitations of this study, it can be concluded that patients with painful TMJ clicking had a higher frequency with a statistically significant association with the behaviors of lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; nail biting; and, awake bruxism. Sleep bruxism and malocclusion were not related to this condition.

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**Table 1. Descriptive data for oral behaviors, bruxism and malocclusion plus p-value of chi-square test (frequency).**

Variables		Painful TMJ clicking (n=30)	Painless TMJ clicking (n=30)	Control group (n=30)	Total (n=90)	<i>p</i> -value
Lean with your hand on the jaw	Present	18 (60.0%) <sup>A</sup>	10 (33.3%) <sup>B</sup>	6 (20.0%) <sup>B</sup>	34 (37.8%)	0.005*
	Absent	12 (40.0%) <sup>A</sup>	20 (66.7%) <sup>B</sup>	24 (80.0%) <sup>B</sup>	56 (62.2%)	
Sleep in a position that puts pressure on the jaw	Present	20 (66.7%) <sup>A</sup>	11 (36.7%) <sup>B</sup>	7 (23.3%) <sup>B</sup>	38 (42.2%)	0.003*
	Absent	10 (33.3%) <sup>A</sup>	19 (63.3%) <sup>B</sup>	23 (76.7%) <sup>B</sup>	52 (57.8%)	
Use chewing gum	Present	21 (70.0%) <sup>A</sup>	12 (40.0%) <sup>B</sup>	5 (16.7%) <sup>C</sup>	38 (42.2%)	< 0.001*
	Absent	9 (30.0%) <sup>A</sup>	18 (60.0%) <sup>B</sup>	25 (83.3%) <sup>C</sup>	52 (57.8%)	
Nail biting	Present	20 (66.7%) <sup>A</sup>	12 (40.0%) <sup>B</sup>	4 (13.3%) <sup>C</sup>	36 (40.0%)	< 0.001*
	Absent	10 (33.3%) <sup>A</sup>	18 (60.0%) <sup>B</sup>	26 (86.7%) <sup>C</sup>	54 (60.0%)	
Unilateral chewing	Present	7 (23.3%) <sup>A</sup>	6 (20.0%) <sup>A</sup>	7 (23.3%) <sup>A</sup>	20 (22.2%)	0.938
	Absent	23 (76.7%) <sup>A</sup>	24 (80.0%) <sup>A</sup>	23 (76.7%) <sup>A</sup>	70 (77.8%)	
Bite foreign objects	Present	3 (10%) <sup>A</sup>	4 (13.3%) <sup>A</sup>	2 (6.7%) <sup>A</sup>	9 (10.0%)	0.905
	Absent	27 (90%) <sup>A</sup>	26 (86.7%) <sup>A</sup>	28 (93.3%) <sup>A</sup>	81 (90.0%)	
Sleep Bruxism	Present	10 (33.3%) <sup>A</sup>	8 (26.7%) <sup>A</sup>	9 (30.0%) <sup>A</sup>	27 (30.0%)	0.957
	Absent	20 (66.7%) <sup>A</sup>	22 (73.3%) <sup>A</sup>	21 (70.0%) <sup>A</sup>	63 (70.0%)	
Awake Bruxism	Present	19 (63.3%) <sup>A</sup>	11 (36.7%) <sup>B</sup>	4 (13.3%) <sup>C</sup>	34 (37.8%)	< 0.001*
	Absent	11 (36.7%) <sup>A</sup>	19 (63.3%) <sup>B</sup>	26 (86.7%) <sup>C</sup>	56 (62.2%)	
Anterior open bite	Present	1 (3.3%) <sup>A</sup>	2 (6.7%) <sup>A</sup>	0 (0.0%) <sup>A</sup>	2 (2.2%)	0.770
	Absent	29 (96.7%) <sup>A</sup>	28 (93.3%) <sup>A</sup>	30 (100.0%) <sup>A</sup>	88 (97.8%)	
Posterior cross-bite	Present	5 (16.7%) <sup>A</sup>	3 (10.0%) <sup>A</sup>	2 (6.7%) <sup>A</sup>	10 (11.1%)	0.592
	Absent	25 (83.3%) <sup>A</sup>	27 (90.0%) <sup>A</sup>	28 (93.3%) <sup>A</sup>	80 (88.9%)	
Overbite	Normal	12 (40.0%) <sup>A</sup>	17 (56.7%) <sup>A</sup>	19 (63.3%) <sup>A</sup>	48 (53.3%)	0.212
	≥4 mm	18 (60.0%) <sup>A</sup>	13 (43.3%) <sup>A</sup>	11 (36.7%) <sup>A</sup>	42 (46.7%)	
Overjet	Normal	23 (76.7%) <sup>A</sup>	25 (83.3%) <sup>A</sup>	27 (90.0%) <sup>A</sup>	75(83.3%)	0.439
	≥5 mm	7 (23.3%) <sup>A</sup>	5 (16.7%) <sup>A</sup>	3 (10.0%) <sup>A</sup>	15 (16.7%)	
Canine guidance	Present	13 (43.3%) <sup>A</sup>	16 (53.3%) <sup>A</sup>	18 (60.0%) <sup>A</sup>	47 (52.2%)	0.468
	Absent	17 (56.7%) <sup>A</sup>	14 (46.7%) <sup>A</sup>	12 (40.0%) <sup>A</sup>	43 (47.8%)	
Mediotrusive and/or laterotrusive interferences	Present	12 (40.0%) <sup>A</sup>	8 (26.7%) <sup>A</sup>	8 (26.7%) <sup>A</sup>	28 (31.1%)	0.472
	Absent	18 (60.0%) <sup>A</sup>	22 (73.3%) <sup>A</sup>	22 (73.3%) <sup>A</sup>	62 (68.9%)	
RCP-MI slide	Normal	22 (73.3%) <sup>A</sup>	21 (70.0%) <sup>A</sup>	24 (80.0%) <sup>A</sup>	67 (74.4%)	0.754
	≥2 mm	8 (26.7%) <sup>A</sup>	9 (30.0%) <sup>A</sup>	6 (20.0%) <sup>A</sup>	23 (25.6%)	
≥5 missing posterior teeth	Present	2 (6.7%) <sup>A</sup>	1 (3.3%) <sup>A</sup>	0 (0.0%) <sup>A</sup>	3 (3.3%)	0.770
	Absent	28 (93.3%) <sup>A</sup>	29 (96.7%) <sup>A</sup>	30 (100.0%) <sup>A</sup>	87 (96.7%)	

\* Difference statistically significant. Different capital letters represent statistical significance difference among groups. RCP-MI: retruded contact position to maximum intercuspation slide

**Table 2. Comparison of frequencies of "Yes" answers of AB activity among groups**

<b>Groups comparison</b>	<b>Difference of means of "Yes" answers of AB activity</b>	<b><i>p</i>-value</b>
Group 1 x Group 2	15.03	0.049*
Group 1 x Group 3	32.26	< 0.001*
Group 2 x Group 3	17.23	0.020*

\* Difference statistically significant. Group 1: painful TMJ clicking; Group 2: painless TMJ clicking; Group 3: control group.

**ARTICLE 2**

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**ARTICLE 2 - Somatosensory and Psychosocial Profile of Patients with Painful Temporomandibular Joint Clicking.**

Poluha RL, De la Torre Canales G, Bonjardim LR, Conti PCR. Somatosensory and psychosocial profile of patients with painful temporomandibular joint clicking. *J Oral Rehabil.* 2020 Aug 19. doi: 10.1111/joor.13081. Epub ahead of print. PMID: 32813889. Available at: <<https://onlinelibrary.wiley.com/doi/full/10.1111/joor.13081>>. Accessed on: November 21, 2020.



# 3

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## **DISCUSSION**



## DISCUSSION

To the best of our knowledge, these are the first studies that aimed to characterize the patients with painful TMJ clicking (trying to compose a clinical, somatosensory, and psychosocial profile), when compared to patients with painless TMJ clicking and with a control group.

Compiling the two studies, the results showed that in the clinical profile, patients with painful TMJ clicking had an important association with specific oral behaviors (lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; and, nail biting) and awake bruxism. Sleep bruxism and malocclusion were not related to this condition. In the somatosensory profile, individuals with painful TMJ clicking showed a significant somatosensory gain of function (being more sensitive) to mechanical pain tests (mechanical pain threshold [MPT]; wind-up ratio [WUR]; and pressure pain threshold [PPT]) and had an impaired (less efficient) conditioned pain modulation (CPM) paradigm in the TMJ area. In the extra-trigeminal site (thenar muscle) there was no difference in any parameters related to the somatosensory profile. As for the psychosocial profile, patients with painful TMJ clicking showed a significantly poor sleep quality along with higher levels of hypervigilance, pain catastrophizing, and kinesiophobia. No significant association with stress and anxiety were found.

In part, the etiology of arthralgia and TMJ clicking are related to biomechanical forces applied to TMJ that surpass the individual adaptive capacity.<sup>2, 12</sup> All the oral behaviors with significant results reported in the first study have in common the effect of increasing intra-articular pressure. High intra-articular pressures are a contributing factor to TMJ internal derangement since it favors disc displacement and increases the sensitivity of the retrodiscal tissues.<sup>24-26</sup> Besides that, this high intra-articular pressure can modify the composition and volume of the synovial fluid and also contribute to the generation of inflammatory mediators, usually presents in arthralgia.<sup>27</sup> This same line of reasoning can be extended to the awake bruxism variable, in which studies showed an abnormal stress distribution in the articular disc and in the retrodiscal tissues throughout clenching, this could facilitate disc displacement and possibly lead to damage of TMJ tissues.<sup>28-30</sup>

TMJ internal derangements and inflammatory disorders are usually associated with somatosensory abnormalities, with patients being more sensitive to mechanical pain tests.<sup>31, 32</sup> Also, it is known that the trigeminal innervation areas (such as TMJ) usually shows a weaker inhibitory pain control than other body regions.<sup>33</sup> So, considering the results reported in the second study, was not surprising that patients with painful TMJ clicking demonstrated to have

a significant somatosensory gain of function (considering MPT, WUR, and PPT) and a less efficient CPM, in TMJ area. The phenomena of peripheral and central sensitization help to explain the reported somatosensory profile of patients with painful TMJ clicking.<sup>34, 35</sup> It is important to highlight here that the QST exams were imported from the neuropathic evaluation to the TMD field, so some limitations are still present and adaptations are necessary. Although the QST battery consists of seven tests measuring thirteen parameters, only mechanical pain tests seem to be reliable and relevant in painful TMD conditions.<sup>36</sup> Also, methodological difficulties are still present regarding the CPM paradigm (such as the variability of unverified and standardized protocols; and, without references values for the results).<sup>37</sup> So future studies are necessary to establish the best somatosensorial evaluation protocol considering the particularities of the trigeminal nervous system and TMD conditions.

In the same way, psychosocial factors have been shown important in patients with TMJ clicking complaints, besides influencing clinical pain conditions.<sup>23</sup> The results of the second study showed that patients with painful TMJ clicking had a significantly poor sleep quality along with higher levels of hypervigilance, pain catastrophizing, and kinesiophobia. Once these patients had a painful condition and taking into account that sleep and pain have an important relationship with mutual negative influence,<sup>28</sup> impaired sleep quality is expected. Also, it is important to point out that painful TMJ clicking is a pain condition evoked/influenced by the movement (open mouth);<sup>39</sup> conditions like this are usually related to excessive attention to pain, magnification of the symptoms and fear of movement.<sup>22, 40, 41</sup> These factors help to explain the psychosocial profile found in patients with painful TMJ clicking.

Clinically, based on the characterization of the patients with painful TMJ clicking, it can be suggested treatment plan to this condition must include the identification and control of harmful oral behaviors and awake bruxism. Also, the mechanism-based management should address strategies to reduce, especially, peripheral sensitization and improved endogenous pain modulation. Moreover, to a complete approach, the treatment has to contemplate important psychosocial factors related to these patients. However, it is important to keep in mind caution when judging all the present findings, once the two studies have limitations such as: the restricted population without gender pairing; no TMJ image exam was performed; also, only some quantitative sensory testing were analysed.

Studies that aim the characterization of patients and conditions, with an analysis including clinical, somatosensory, and psychosocial data, appear to have a wide field of applicability in the TMD literature.<sup>42</sup> Composing the most complete patient and condition profile possible may have a direct reflex in the treatment plan, once that different clinical



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conditions (even if equally painful) can present different pain mechanisms; and, even patients with the same condition can have completely different abnormalities generating the condition and the pain process<sup>36</sup> and, therefore, will need a different approach.<sup>43</sup> So, these data can help to formulate mechanism-based personalized management for each condition, for each patient, and even understand why some patients won't respond to classical treatments and became refractory.<sup>44, 45</sup> Future research should keep characterizing different TMD diagnoses to improve the knowledge of the conditions and the formulation of the treatment plans.

Although the study design (cross-sectional) do not allow to establish any definitive cause-effect relationship, it is possible to hypothesize that concomitant occurrence of TMJ arthralgia in only some cases of TMJ clicking of patients with DDWR is due to the higher frequency in these patients of harmful oral behaviors and awake bruxism, that increase the intra-articular pressure in an environment already sensitized with lower pain thresholds, in a patient with a deficient descending pain inhibition system, and with a several negatives alterations in specific psychosocial aspects; all of these, in a level beyond the individual adaptive capacity. Once most patients with TMJ clicking usually postpone seeking treatment until the clicking truly disturbs or there is a concomitant presence of pain, it is important to futures studies to elucidated factors that could interfere in the chance of a patient present painful TMJ clicking.



**4**

**CONCLUSION**



## **CONCLUSION**

In view of the results and limitations of the studies, it can be concluded that patients with painful TMJ clicking were characterized by a significant association with specific oral behaviors (lean with your hand on the jaw; sleep in a position that puts pressure on the jaw; use chewing gum; and, nail biting); presence of awake bruxism; a significant somatosensory gain of function to mechanical pain tests (MPT; WUR; and PPT) and an impaired CPM in the TMJ area; poor sleep quality along with higher levels of hypervigilance, pain catastrophizing, and kinesiophobia.



# 5

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**APPENDIX**



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**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN THESIS**

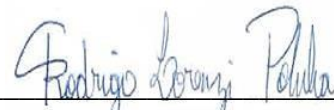
We hereby declare that we are aware of the article “**Oral Behaviors, Bruxism, Malocclusion and Painful Temporomandibular Joint Clicking: Is There Any Association?**” will be included in the thesis of the student **Rodrigo Lorenzi Poluha** was not used and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, November 23, 2020

Rodrigo Lorenzi Poluha

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Author



Signature

Giancarlo De la Torre Canales

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Author

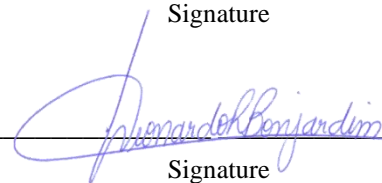


Signature

Leonardo Rigoldi Bonjardim

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Author



Signature

Paulo César Rodrigues Conti

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Author



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**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN THESIS**

We hereby declare that we are aware of the article “**Somatosensory and Psychosocial Profile of Patients with Painful Temporomandibular Joint Clicking**” will be included in the thesis of the student **Rodrigo Lorenzi Poluha** was not used and may not be used in other works of Graduate Programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, November 23, 2020

Rodrigo Lorenzi Poluha

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Author



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Signature

Giancarlo De la Torre Canales

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Author



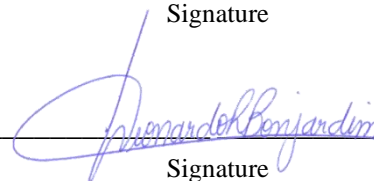
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Leonardo Rigoldi Bonjardim

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Paulo César Rodrigues Conti

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**7**

**ANNEXES**



**ANNEX A. Ethics Committee approval, protocol number.**

USP - FACULDADE DE  
ODONTOLOGIA DE BAURU DA  
USP



**PARECER CONSUBSTANCIADO DO CEP**

**DADOS DO PROJETO DE PESQUISA**

**Título da Pesquisa:** CARACTERIZAÇÃO ESQUELÉTICA, SOMATOSENSORIAL E PSICOSSOCIAL DE PACIENTES COM ESTALIDO DOLOROSO DA ARTICULAÇÃO TEMPOROMANDIBULAR: UM ESTUDO TRANSVERSAL

**Pesquisador:** Paulo César Rodrigues Conti

**Área Temática:**

**Versão:** 2

**CAAE:** 88592018.0.0000.5417

**Instituição Proponente:** Universidade de Sao Paulo

**Patrocinador Principal:** Financiamento Próprio

**DADOS DA NOTIFICAÇÃO**

**Tipo de Notificação:** Outros

**Detalhe:** Carta resposta e Versão Assinada.

**Justificativa:** Atendendo à solicitação do parecer de aprovação recentemente emitido a este

**Data do Envio:** 23/06/2018

**Situação da Notificação:** Parecer Consubstanciado Emitido

**DADOS DO PARECER**

**Número do Parecer:** 2.768.073

**Apresentação da Notificação:**

o mesmo do parecer N°2.725.838

**Objetivo da Notificação:**

o mesmo do parecer N°2.725.838

**Avaliação dos Riscos e Benefícios:**

o mesmo do parecer N°2.725.838

**Comentários e Considerações sobre a Notificação:**

Apesar de aprovado por este CEP, ficou pendente a assinatura no documento de resposta às pendências pelo responsável pela pesquisa, que agora foi apresentada adequadamente.

**Endereço:** DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9  
**Bairro:** VILA NOVA CIDADE UNIVERSITARIA    **CEP:** 17.012-901  
**UF:** SP                      **Município:** BAURU  
**Telefone:** (14)3235-8356    **Fax:** (14)3235-8356    **E-mail:** cep@fob.usp.br

USP - FACULDADE DE  
ODONTOLOGIA DE BAURU DA  
USP



Continuação do Parecer: 2.768.073

**Considerações sobre os Termos de apresentação obrigatória:**

Apesar de aprovado por este CEP, ficou pendente a assinatura no documento de resposta às pendências pelo responsável pela pesquisa, que agora foi apresentada adequadamente.

**Conclusões ou Pendências e Lista de Inadequações:**

Aprovado

**Considerações Finais a critério do CEP:**

O CEP FOB-USP acata por unanimidade o parecer APROVADO emitido pelo relator sobre o envio de carta de respostas devidamente assinada pelo pesquisador responsável.

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

Tipo Documento	Arquivo	Postagem	Autor	Situação
Outros	RESPOSTA_AO_CEP_ASSINADA.pdf	23/06/2018 17:17:01	Paulo César Rodrigues Conti	Postado

**Situação do Parecer:**

Aprovado

**Necessita Apreciação da CONEP:**

Não

BAURU, 12 de Julho de 2018

Assinado por:  
Ana Lúcia Pompéia Fraga de Almeida  
(Coordenador)

Endereço: DOUTOR OCTAVIO PINHEIRO BRISOLLA 75 QUADRA 9  
Bairro: VILA NOVA CIDADE UNIVERSITARIA CEP: 17.012-901  
UF: SP Município: BAURU  
Telefone: (14)3235-8356 Fax: (14)3235-8356 E-mail: cep@fob.usp.br

**ANNEX B. Patient's informed consent exoneration.**

## Universidade de São Paulo Faculdade de Odontologia de Bauru

Página 1 de 2

Departamento de Prótese Dentária e Periodontia

### TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

O (A) Sr/Sra. está sendo convidado a participar da pesquisa “**CARACTERIZAÇÃO ESQUELÉTICA, SOMATOSENSORIAL E PSICOSSOCIAL DE PACIENTES COM ESTALIDO DOLOROSO DA ARTICULAÇÃO TEMPOROMANDIBULAR: UM ESTUDO TRANSVERSAL**” com orientação do Professor Dr. Paulo César Rodrigues Conti. Esta pesquisa tem como objetivo identificar os fatores associados a presença de dor articular em pacientes com estalido da articulação temporomandibular (ATM). Este estudo clínico envolverá 84 participantes, os quais serão divididos igualmente em 3 grupos: Grupo 1 terá 28 participantes com estalido da ATM, mas sem dor articular; Grupo 2 terá 28 participantes com estalido da ATM e dor articular; Grupo 3 terá 28 participantes totalmente assintomáticos sem queixas ou relatos de dor/estalos na ATM. A formação dos grupos e o diagnóstico de dor e estalido na ATM serão feitos através de um exame físico padrão para quadros de distúrbios temporomandibulares. Em seguida, cada participante será convidado a responder alguns questionários que fornecerão informações sobre hábitos orais, hipervigilância, catastrofização, qualidade do sono, estresse e ansiedade. Em seguida serão realizados testes de sensibilidade, através de aparelhos que medem a sua percepção de dor por meio de testes de pressão e a sua modulação de dor perante mudança de temperatura. Para todos os exames serão utilizados equipamentos amplamente seguros. No entanto, há de se considerar um risco mínimo e algum possível desconforto durante a realização dos testes de sensibilidade, como uma leve sensação de pressão e/ou picada. A avaliação do (a) Sr./Sra. com esta sequência de testes e exames pode ser benéfica, pois podemos diagnosticar algum tipo de alteração neurológica e/ou articular. Uma vez diagnosticada alguma destas alterações, você será orientado a buscar um serviço especializado de acordo com o problema encontrado. Todos os exames serão realizados em uma única sessão com duração média de uma hora e trinta minutos. Nenhuma dessas avaliações trará qualquer tipo de dano físico (apenas um pequeno desconforto relacionado ao teste de sensibilidade como relatado anteriormente), moral ou material para o (a) Sr/Sra. As informações fornecidas serão mantidas confidenciais, respeitando sua privacidade. Os resultados obtidos serão analisados e publicados em meios de informação científicos, sem a sua identificação, de qualquer forma. O (A) Sr/Sra. não terá nenhum gasto ou ganho financeiro por participar na pesquisa e também não correrá risco algum além de um leve incomodo proveniente dos testes realizados. Caso haja algum dano decorrente de sua participação nesta pesquisa, será lhe garantido o direito à indenização, bem como haverá o ressarcimento de qualquer possível gasto por participar da pesquisa. Você é livre para deixar de participar a qualquer momento sem nenhum prejuízo. Caso não concorde em participar desta pesquisa, sua vontade será respeitada, seu nome será preservado e você não será penalizado física ou psicologicamente por isso, pois não é de nosso interesse causar constrangimentos ou danos à sua imagem. Uma via deste Termo de Consentimento Livre e Esclarecido ficará com você e outra conosco. Qualquer dúvida a respeito da pesquisa poderá entrar em contato com Rodrigo Lorenzi Poluha, e-mail: [rodrigopoluha@gmail.com](mailto:rodrigopoluha@gmail.com), telefone (42) 999459674. Para reclamações e denúncias faça contato pelo Comitê de Ética e Pesquisa desta faculdade pelo telefone (14) 3235-8356 ou e-mail: [cep@fob.usp.br](mailto:cep@fob.usp.br).

Rubrica do Participante da Pesquisa:

Rubrica do Pesquisador Responsável:



## Universidade de São Paulo Faculdade de Odontologia de Bauru

Departamento de Prótese Dentária e Periodontia

Pelo presente instrumento que atende às exigências legais, o Sr. (a)

portador da cédula de identidade \_\_\_\_\_, após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, ciente que responderão apenas aos questionários propostos, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA e FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Cap. III, Art. 9º do Código de Ética Odontológica (Res. CFO-118/2012)), ou (Cap. IV, Art. 23. do Código de Ética da Fonoaudiologia (Res. CFFa nº 490/2016)) – para outras profissões verificar o Código de Ética do sigilo profissional correspondente).

Por fim, como pesquisador(a) responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e IV.4, este último se pertinente, item IV.5.a e na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em duas vias igualmente válidas (uma via para o participante da pesquisa e outra para o pesquisador) que serão rubricadas em todas as suas páginas e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Bauru, SP, \_\_\_\_\_ de \_\_\_\_\_ de \_\_\_\_\_.

\_\_\_\_\_  
Assinatura do Participante da Pesquisa

\_\_\_\_\_  
Nome/Assinatura do Responsável Principal

**O Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução CNS nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

**Horário e local de funcionamento:**

Comitê de Ética em Pesquisa

Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **14hs às 17 horas**, em dias úteis.

Alameda Dr. Octávio Pinheiro Brisolla, 9-75

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