Effects of Anxiety and Daytime Clenching on Orthodontic Pain Perception

by

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Abstract

Objectives: This study assessed the relationship between anxiety and oral parafunctional behaviours in individuals with and without orofacial pain; and whether the relationship between anxiety and orthodontic tooth pain is dependent upon wake-time tooth clenching.

Methods: The State-Trait Anxiety Inventory (STAI), Oral Behaviour Checklist (OBC) and TMD-Pain Screener were completed by 255 students with (n=47, 24.8±4.2 years) and without (n=208; 26.0±4.8 years) TMD pain. STAI score distribution was examined and 45 volunteers (26.0±3.4 years) with low-, intermediate-, and high-anxiety were recruited and submitted to experimental orthodontic-tooth-movement.

Results: A significant effect of the interaction group*trait anxiety on OBC scores was found (p=0.028). A significant effect of the interaction clenching*study group*day on tooth-pain was found (p<0.001).

Conclusion: The relationship between anxiety and oral parafunctional behaviours is affected by concurrent TMD pain. The relationship between anxiety and orthodontic tooth pain experienced during experimental orthodontic-tooth-movement is dependent on the frequency of wake-time tooth clenching.

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1 Background and Literature Review

Pain is an unpleasant and emotional experience associated with actual or potential tissue damage (Burket et al. ; IASP). Perception of pain is highly personal and the reported degree of pain is not always correlated with the amount of tissue injury. For instance, concurrent inflammation or abnormalities in peripheral and/or central nociceptive pathways may alter pain perception. Stimuli that do not usually provoke pain may result in a painful response (allodynia), and painful stimuli may determine an exaggerated pain response (hyperalgesia) (Jensen and Finnerup 2014).

Pain is a complex and subjective experience that unfortunately is a common clinical symptom that accompanies orthodontic interventions (Krishnan 2007; Shi et al. 2015). It is considered by patients the worst component of orthodontic treatment and is responsible for individuals refraining from seeking orthodontic treatment, discontinuing care, or terminating treatment early. It has been reported that approximately 95% of orthodontic patients will experience some degree of pain and that 8-30% of such patients will, as a result, terminate orthodontic treatment (Krishnan 2007; Sergl et al. 1998). This is of concern because orthodontic pain, which is tooth pain produced during orthodontic treatment, can attenuate patient compliance (Ukra et al. 2011), that is the willingness to cooperate during treatment, and ultimately compromise treatment effectiveness (Cozzani et al. 2015; Krishnan 2007). Indeed, an increased level of compliance has been observed in patients who have less pain during orthodontic treatment (Albino et al. 1991).

Orthodontic pain is mainly related to the application of force to induce tooth movement, which results in the compression of the periodontal ligament supporting tissue, leading to pressure, acute ischemia, inflammation and edema in the periodontal ligament space (Jones and Richmond 1985). With the periodontal tissues and vessels under pressure eliciting an immediate change in blood flow, pro-algesic chemical mediators and noxious agents such as prostaglandins, histamine, serotonin and substance P are released from free nerve endings and induce pain and sensitivity (Giannopoulou et al.

2006; Krishnan 2007).   Many of these free nerve endings that terminate in the orofacial tissues originate from primary afferent fibres of the fifth cranial nerve, the trigeminal nerve (Sessle 2011).   The stimulation of nociceptive free nerve endings via noxious agents results in the subsequent activation of small-diameter, slow-conducting (A-delta and C-fibre) primary afferent fibres.   Such fibres have their primary afferent cell bodies residing in the trigeminal ganglion, in Meckel's cave, and transmit electrical signals to the central nervous system for sensory-discriminative interpretation of the location, quality, intensity and duration of the noxious stimulus (Sessle 2011).   Both an immediate and delayed painful response secondary to orthodontic force application has been previously described (Burstone 1962).   The former has been attributed to the initial response to compression of the immediate surrounding periodontal ligament and the latter to hyperalgesia of the periodontal ligament related to the release of pro-algesic mediators (Krishnan 2007).

A means for accurate measurement of pain stands critical to its evaluation and various methods have been utilized to measure and evaluate pain in orthodontic patients and the somatosensory changes occurring in the trigeminal locations during orthodontic treatment.   A number of traditional surveys with pre-tested patient interviews or questionnaires have been used to evaluate the intensity and the quality of pain such as Visual Analogue Scales (VAS) (Linacre 1998), McGill Pain Questionnaire (MPQ) (Melzack 1975), Verbal Rating Scales (VRS) (Jones and Chan 1992a; Jones and Chan 1992b).   Most studies utilized ratings with VAS, where the respondent is to mark a location on the line that correlates with the amount of pain experienced.   This is advantageous as it provides the respondent with a rating scale bound by minimum constraints through freedom of indicating the exact intensity of pain and maximum opportunity for personal expression (Krishnan 2007).

Quantitative sensory testing (Arendt-Nielsen and Yarnitsky 2009), a non-invasive psychophysical testing method in which different modalities (mechanical, thermal, electrical, and chemical) are applied to a specific location has been also largely used to study the somatosensory changes occurring during and after orthodontic treatment and

to provide a better understanding of the neurobiological mechanisms related to orthodontic pain (Bucci and Michelotti 2018; Simmons 1994).

A wide array of orthodontic procedures elicits varying degrees of pain (Cioffi et al. 2016; Cioffi et al. 2012b; Erdinc and Dincer 2004; Michelotti et al. 1999; Tecco et al. 2009). Of such, even the simplest orthodontic procedure being the placement of orthodontic elastomeric separators to create minimal space for subsequent orthodontic band placement can elicit mild pain in some patients and immediate acute pain in others (Michelotti et al. 1999). The reason for this variability in orthodontic pain perception has been the focus of several studies (Brown and Moerenhout 1991; Cioffi et al. 2012b; Marques et al. 2014).

Psychological traits, such as anxiety, can influence the inter-individual variability of orofacial pain sensitivity (Al-Harthy et al. 2015; Klages et al. 2006; Reissmann et al. 2014). Orofacial pain is defined as pain localized to the region located superior to the neck, anterior to the ears, and inferior to the orbits, and is inclusive of pain of dental and non-dental origin, as well as pain of the temporomandibular joint or temporomandibular disorders (TMDs) (Shephard et al. 2014), which represents a heterogeneous group of musculoskeletal and neuromuscular conditions involving the temporomandibular joint complex, and surrounding muscular and osseous components (Slade et al. 2016). Trait anxiety is a mood disorder that has been defined as a general pattern of worry and physical dysregulation that is characteristic of an individual (Spielberger 1983). It has been associated with a greater pain experience in patients submitted to orthodontic treatment (Cioffi et al. 2016). Anxiety plays a role in influencing the perception of orthodontic pain and reported pain may be associated with the patient's attempt to translate feelings of anxiety into a physical problem manifested as pain (Beck et al. 2014; Cioffi et al. 2012b; Krishnan 2007; Spielberger 1983). Increased anxiety was demonstrated in individuals undergoing orthodontic treatment with prolonged pain when compared to individuals undergoing orthodontic treatment with short pain duration (Bergius et al. 2008). Furthermore, orthodontic pain has been reported to be greater in

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individuals with moderate to severe anxiety as compared to individuals with low levels of anxiety (Cioffi et al. 2016).

Anxiety has also been shown to play an important role in exacerbating pain-related fear (Asmundson and Taylor 1996), which in turn, has been demonstrated to possess a critical role in promoting avoidance behaviour (Asmundson and Taylor 1996; McCracken et al. 1993; McCracken et al. 1992; Waddell et al. 1993). Anxiety is a state that revolves around a future-oriented source of threat that is intangible and is manifested through hypervigilance, which involves attentive environmental scanning for potential sources of danger and is associated with the preventative behaviour of avoidance (Murphy et al. 1997). In contrast, fear is characterized as an adaptive behavioural response to a threat that is definite, discernible and immediate (Dymond et al. 2015; Rachman 1998). The fear-avoidance model is largely dependent on how an individual interprets pain. For instance, if the pain is catastrophically misinterpreted as significant injury/pathology, it will result in increased fear of pain and subsequent avoidance of physical movement that is presumed to worsen the current situation (Crombez et al. 2012). Hence, both avoidance and hypervigilance seemingly function to protect the body from further injury by providing it time to heal (Crombez et al. 2012).

The contribution of anxiety to wake-time clenching and oral parafunctional behaviours has been verified by several authors (Endo et al. 2011; Manfredini and Lobbezoo 2009; Michelotti et al. 2012) who showed that individuals with increased anxiety present an increased frequency of wake-time clenching episodes. This also applies to trait anxiety, which refers to a general pattern of worry and physical dysregulation (Michelotti et al. 2012; Spielberger 1983).

Oral parafunctional behaviours collectively refer to any activity in the mouth that deviates from the expected jaw functional demands of mastication, swallowing, communication or breathing (Ohrbach et al. 2008). This is inclusive of sleep-related oral parafunctions such as sleep bruxism (Manfredini et al. 2013) as well as awake-related oral parafunctions such as wake-time tooth clenching, also known as awake

bruxism (Glaros and Williams 2012). It has been determined that the former involves masticatory muscle activity during sleep that is characterized as rhythmic (phasic) or non-rhythmic (tonic), whereas the latter consists mostly of centric or clenching episodes with tooth contact, bracing, or thrusting of the mandible (Ohrbach et al. 2008).

Awake bruxism is characterized by repetitive isometric contractions of the jaw elevator muscles and clenching of teeth (Lobbezoo et al. 2013). Experimental studies have shown that sustained wake-time clenching elicits jaw muscle fatigue and pain in healthy subjects (Farella et al. 2010), is associated with TMD and contributes to incidence of TMD (Michelotti et al. 2010; Slade et al. 2016), and may be related to tooth wear (Diracoglu et al. 2011; Pigno et al. 2001). High levels of anxiety are also characteristics of individuals reporting temporomandibular pain (Fillingim et al. 2013; Michelotti et al. 2012; Pallegama et al. 2005; Reiter et al. 2015). Therefore, concurrent orofacial pain may heighten the relationship between anxiety and oral behaviors.

The perception of pain is also influenced by somatic awareness. Somatosensory amplification refers to the tendency to perceive a given normal somatic sensation (such as heat, cold, touch, pressure, etc.) as intense, noxious and disturbing (Barsky et al. 1988). Amplification of somatic sensations involves bodily hypervigilance, which is characterized by a heightened attention to the body and a selective focus on detected sensations, which increases their perception (Barsky et al. 1988). Clinical experience suggests that individuals with bodily hypervigilance also may present with occlusal hypervigilance, which is an increased occlusal perception and heightened attention to changes in one's dental occlusion (Palla and Klinenberg 2015). People with occlusal hypervigilance present with a selective focus on detecting occlusal sensations, and continuously check their occlusion (Palla and Klinenberg 2015). It is possible that oral behaviours involving repetitive tooth-to-tooth contact and clenching may serve to scan the intraoral environment in search of possible threats, such as occlusal interferences or changes into dental occlusion during orthodontic treatments, and may be more prevalent in individuals with greater somatosensory amplification.

2   Statement of Problem

During orthodontic treatment, the associated teeth present with both hyperalgesia and allodynia due to the application of orthodontic forces. Wake-time clenching may contribute to an increased orthodontic pain experience by producing tooth micro-trauma in the periodontium, which stimulates and promotes the release of peripheral inflammatory mediators (Abd-Elmeguid and Yu 2009; Krishnan 2007), and the stimulation of free nerve endings. This, in turn, could result in increased pain perception during several stages of orthodontic treatment. Since anxiety and the frequency of wake-time clenching are correlated, this can be expected mainly in individuals with increased anxiety (Cioffi et al. 2016). Although the contribution of oral parafunctional behaviors, specifically wake-time clenching, to orofacial and temporomandibular pain has been consistently verified (Khawaja et al. 2015; Michelotti et al. 2010; Sierwald et al. 2015), it is to our knowledge that the role of oral parafunctional behaviours in relation to anxiety and orthodontic pain perception has only been minimally investigated as it is possible that individuals with higher anxiety have more frequent wake-time clenching episodes (Cioffi et al. 2012a; Khawaja et al. 2015) and that these, in turn, may result in additional microtrauma (Dejak et al. 2005; Greenberg 2006) and increased tooth pain during orthodontic tooth movement (Horinuki et al. 2015). With that said, the increased frequency of clenching episodes in patients with greater anxiety could theoretically overload the periodontal ligament during orthodontic treatment and contribute to a greater pain experience. Indeed, a previous study has shown that the frequency of wake-time clenching correlates positively with orthodontic pain (Cioffi et al. 2016). Therefore, parafunctional tooth clenching may play a role in the relationship between anxiety and orthodontic pain. Indeed, theoretically, a greater frequency of clenching episodes in anxious individuals may result in overstimulation of the periodontal ligament and contribute to greater orthodontic pain perceived by anxious patients. However, the fear-avoidance model suggests that an acute orthodontic pain may trigger fear-avoidance behaviour in individuals with high levels of anxiety, which may contribute to reducing parafunctional tooth clenching and orthodontic pain intensity over time as a result of reduction in stimulation of the periodontal ligament. Therefore, it is still unclear

whether and how orthodontic pain is affected by wake-time tooth clenching and how anxiety and tooth clenching interact to affect orthodontic pain. A better understanding of the roles of anxiety and parafunctional behaviours on orthodontic pain will allow clinicians to better tailor treatment strategies for the management of pain during orthodontic treatment, especially in those people who are anxious towards orthodontic procedures.

3   Objective of Study

The aims of this study were:

1. To assess the general relationship between anxiety, somatosensory amplification and oral parafunctional behaviours in a large sample of individuals with and without orofacial pain.

2. To assess whether the relationship between anxiety and orthodontic pain is dependent upon wake-time tooth clenching.

4   Hypothesis

It was hypothesized that:

1. Both anxiety and somatosensory amplification are positively associated with the frequency of oral parafunctional behaviours, and the extent of such relationship is dependent on the presence of concurrent orofacial pain.

2. The relationship between anxiety and tooth pain is dependent on the frequency of wake-time tooth clenching during experimentally induced orthodontic tooth movement.

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Currently, the possible role of oral parafunctions on orthodontic pain perception is completely unknown. The following series of three self-contained chapters will explore the possible effects of wake-time clenching and anxiety on orthodontic pain. Such information may be useful for clinicians to better manage patient compliance and to better tailor their treatment strategies in those individuals who may be more sensitive to orthodontic pain during orthodontic treatment. This will eventually contribute to reduce treatment time and healthcare costs.

The first chapter will examine the relationship between pain and orthodontic patient compliance. The second chapter will dissect the effects of trait anxiety, somatosensory amplification, and facial pain on self-reported oral behaviors. Finally, the third chapter will analyze how wake-time tooth clenching affects the relationship between trait anxiety and orthodontic pain.

5 Chapter One

5.1 Pain and Orthodontic Patient Compliance: a Clinical Perspective[1]

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5.1.1 Abstract

The success of orthodontic treatment relies on four key components: the diagnostic and clinical skills of the orthodontist, favourable biologic characteristics of the patient (bone turnover, craniofacial morphology, stage of growth, etc.), patients' willingness to cooperate during treatment and to follow all treatment recommendations (i.e. patient compliance), and the use of an appropriate and effective orthodontic appliance. According to clinical realms and research evidence, patient compliance is a core issue as it can strongly affect the objectives and results of orthodontic treatment and length of time a patient must wear orthodontic appliances. However, patient compliance still remains the weakest link in the chain because it is the least predictable aspect from an orthodontic treatment-planning context.

Patients frequently report orthodontic pain during different phases of orthodontic treatment, and it has been considered one of the main reasons for discontinuing care or terminating treatment early. According to research evidence, orthodontic pain strongly affects patient compliance, and thus compromises treatment effectiveness and efficiency. Reduced patient compliance results in increased treatment time and additional costs to both the healthcare provider and patient, and unfortunately, the most advanced orthodontic appliances and diagnostic modalities are unable to overcome this issue.

This article aims to summarize the available research evidence concerning patients' painful response to orthodontic procedures, and to help clinicians to detect individuals who might be at risk for reduced compliance during orthodontic treatment.

Keywords: orthodontic pain, patient compliance, anxiety, orthodontic treatment

5.1.2 Orthodontic patient compliance

Nowadays orthodontics has achieved unbelievable goals. Thanks to the application of novel and highly accurate technologies, the orthodontic diagnostic process has changed for the better, and currently almost every orthodontist is provided with very accurate information, appliances, and tools that contribute to the improvement in orthodontic diagnosis, treatment-planning and therapy [1-4]. Although technologic advances have increased the quality and the predictability of orthodontic treatment, the success of every orthodontic therapy still relies on four old-fashioned key components: the diagnostic and clinical skills of the orthodontist, favourable biologic characteristics of the patient (bone turnover, craniofacial morphology, stage of growth, etc.), patients' willingness to cooperate during treatment and to follow all treatment recommendations (i.e. patient compliance), and the use of an appropriate and effective orthodontic appliance.

An underestimated rival that is patient compliance during orthodontic treatment constantly threatens the power of modern orthodontics. Compliance can be defined as the degree to which patients conform to a given healthcare provider's advice and prescription [5] (e.g. wearing intraoral elastics, maintaining impeccable oral hygiene, keeping scheduled appointments). It is often defined as patients' adherence to treatment, which is the willingness to accept a prescribed therapeutic regimen [6], and it is established through concordance with the healthcare provider [7]. According to clinical realms and research evidence, patient compliance is a core issue as it can strongly affect the objectives and results of orthodontic treatment and length of time a patient must wear orthodontic appliances [8]. Nonetheless, patient compliance still remains the weakest link in the chain because it is the least predictable aspect from an orthodontic treatment-planning context. Indeed, no technologic device can well predict patient compliance, and orthodontists are still keen to find an answer to that age-old question: can we predict patient compliance?

Compliance is known to be dependent upon patient psychosocial and physiological factors, as well as a given patient's relationship with his or her orthodontist [9]. The

scientific evidence currently available has casted doubts on some variables orthodontists usually take into consideration in attempting to predict compliance. In a study by Mandall and co-workers, age, gender, concerns about the malocclusion, and socioeconomic status were not found to affect compliance-related variables [10]. Patient compliance was assessed by evaluating the number of appliance breakages, oral hygiene, and missed appointments in 144 patients ranging between 11 and 19 years old. Baseline assessments consisted of the oral aesthetic subjective impact assessment (OASIS), which included questions to assess the degree of concern patients feel because of their malocclusion, "utility scores", which are an expression of individual well-being, and the Townsend score, which evaluated socioeconomic status.

The great majority of orthodontic patients will claim that braces hurt. While pain is only temporary for a bulk of these patients, some of them are likely to experience pain for longer durations of time. In light of this, we are aware that the latter are less likely to obey treatment recommendations as a result of their painful experience. The effect of pain on patient compliance was carefully investigated by Sergl and coworkers, who tested the effect of psychosocial variables on pain induced by different orthodontic appliances in a study sample of 84 individuals (age 12.8 ± 4.1 years) [11]. The pain ratings were collected every day for the initial 17 days, and at 14, 90 and 180 days post-placement or post-delivery of orthodontic appliances. It was determined that fixed appliances elicited the greatest scores for pain. A significant negative correlation between pain and tooth sensitivity experienced during orthodontic treatment and an individual's perception on the severity of their malocclusion was also found (i.e. individuals who possessed a greater perception on the severity of their malocclusion adapted faster and reported less pain). Finally, and more importantly, reduced levels of compliance (as assessed by a series of questionnaires) and treatment acceptance were shown in individuals who experienced greater levels of pain during treatment. Hence, the authors concluded that the amount of initial pain and discomfort is correlated to treatment acceptance and compliance in the long-term, and that the acceptance of treatment and patient compliance might be assessed in advance through the evaluation

of patient's pain reports over time. These results are of major importance when considering the prevalence of pain and discomfort experienced during treatment.

5.1.3 Orthodontic treatment and pain

Almost 70% percent of orthodontic patients report pain during orthodontic treatment. Furthermore, 25% to 42% of them have prolonged pain duration. Interestingly, only 15% of patients report pain to be insignificant. Discomfort and painful experience have been reported by patients to affect their cooperation during treatment, and up to 10-20% of orthodontic patients interrupt orthodontic therapy early because of the pain experience [12-15]. Orthodontic pain is mainly related to release of peripheral inflammatory mediators in the periodontal ligament during orthodontic tooth movement. Prostaglandin-E2, interleukin 1-beta (IL-1β) and substance P were shown to increase after experimental orthodontic tooth movement [16]. Pain perception appears approximately 2 to 3 hours after orthodontic procedures, and has been shown to peak after 24 hours, and decrease after 72 hours [17] with a high degree of interindividual and intraindividual variation.

There exists a non-linear relationship between age, gender, psychological state, and cultural background with pain perception following placement of orthodontic appliances [18]. Bergius and co-workers analyzed the individual psychological variables that might be related to prolonged orthodontic pain experience [14]. After having inserted orthodontic separators between the molars of patients to be submitted to orthodontic therapy, the authors divided the study sample (55 subjects aged 12 to 18 years) in two groups: those who had no pain after seven days, and those who still presented with pain. The higher median score for pain in the *pain group* was 58 mm (0-100 mm visual analogue scale (VAS)) at day 1, whilst it was 31 mm in the *no pain group.* These results suggest that, after being subjected to the same stimulus, those who reported an initial greater degree of pain will likely experience pain for a longer period of time. A greater number of females were present in the *pain group* whilst individuals with higher motivation for treatment were more frequent in the *no pain group*. The latter group also

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demonstrated lower dental anxiety scores. The regression analysis showed that low motivation for treatment, elevated levels of dental fear and anxiety, and low activity temperament were associated with increased pain experience and could be considered important factors for predicting a persistent painful response during treatment.

In the last decade, several authors have analyzed pain reports of patients submitted to orthodontic treatment in order to understand which bracket appliances, archwires or procedures were less painful. Pringel and co-workers [19] wanted to know whether the method of archwire ligation influences pain intensity during treatment. They recruited 52 individuals for their randomized clinical trial comparing Damon 3 Ormco and Tru Straight bracket appliances. Both groups were treated with a Copper Ni-Ti round 0.014-inch archwire. The regression analyses failed to find a significant effect of the bracket appliance on maximum pain reports. The average difference in mean maximum pain was 11 mm on a 0-100 mm VAS. This value was not significant and well below the value of 20 mm used for the sample size calculation. Interestingly, the Little irregularity index was also not significantly associated with mean peak pain reports. Cioffi and co-workers [20] tested the effect of the wire alloy on pain reports. They compared the pain elicited by round superelastic versus heat-activated 0.016-inch archwires in their randomized controlled trial involving 30 subjects (age range of 11 to 26 years) and concluded that thermal archwires resulted in less pain during treatment. Also, in this case, the degree of crowding was not found to influence pain reports. Shalish and coworkers compared the disturbances determined by labial (conventional GAC 0.022 x 0.028 brackets), lingual (3M™ Unitek™ Incognito™), and Invisalign® appliances [21]. The degree of pain, oral dysfunction, influence on general activities, and oral symptoms were evaluated over a 14-day period using numeric rating scales. Lingual appliances were able to elicit the greatest pain scores over the observation period. Labial appliances determined, on average, reduced pain scores in comparison to other appliances. Interestingly, Invisalign® patients reported the lowest scores for oral symptoms (e.g. such as sores on the tongue, cheeks, or lip). Therefore, it is likely that dental pain was the main contributor of the pain scores within the Invisalign® group. The lingual appliance was associated with higher levels of severe pain and analgesic

consumption, the greatest oral and general dysfunction, and the most difficult and longest recovery. Although this study provides novel and important information, it did not include a psychological assessment of patients, which is a variable that may account for large interindividual differences in pain reports.

In their systematic review, Long and coworkers evaluated the effects produced by lingual and labial appliances on pain, prevalence of caries, difficulty in speech, treatment duration, and oral hygiene [22]. Six studies (four controlled clinical trials and two randomized clinical trials) with low to medium risk of bias were included. A meta-analysis was conducted using four selected studies. The authors concluded that the overall pain experience was not affected by the bracket type, and greater levels of pain in the region of the tongue was elicited by the use of lingual appliances, while greater disturbances were produced in cheeks and lips by labial appliances.

5.1.4 Can we predict patient painful response to orthodontic procedures and patient compliance?

Pain is a subjective experience that involves physiological peripheral and central modulation, with emotion and cognition both playing major roles in influencing this experience [23]. Firestone and co-workers assessed whether patient's pain anticipation is a predictor of orthodontic pain [24]. Patients were questioned about the appearance of their teeth before treatment, appearance of their face, expectations of treatment, expectations about pain, how strongly pain influences their social life and leisure, and frequency of headaches [23]. They compared these results to patients' reports after 7 days of active orthodontic therapy. There was no statistical difference between anticipated pain statements and maximum pain reports during treatment, and between anticipated disruption of daily life and actual interference determined by orthodontic treatment. Moreover, the frequency of headaches was found to be a predictor of pain and daily disruption. The authors concluded that patients who anticipated a greater effect of pain on their leisure activities reported higher levels of pain and more disruption of their daily lives as a result of pain. These results let us hypothesize that anxiety, that

is a feeling of worry, nervousness, or unease about something with an uncertain outcome, which is strongly affected by future prospects, may play a major role in influencing orthodontic pain experience.

Anxiety has been reported to be strongly associated with orthodontic pain ratings. Beck and co-workers [25] demonstrated that dental anxiety and pain catastrophizing, which is considered a maladaptive coping strategy that intensifies the experience of pain, and depression are strongly associated with the pain response. In their experimental study, they submitted participants to experimental pain by placing two orthodontic separating rings, one mesial and one distal to the permanent mandibular right first molar tooth. Pain reports were assessed using six VAS over the next 48 hours. The respondents were divided into groups following the distribution of pain scores (i.e. *high pain* repondents: ten participants above the 90th percentile with a peak VAS score of 8.00 cm or higher, and *low pain* respondents: ten participants below the 10th percentile with a score of 0.55 cm or lower). Dental anxiety and pain catastrophising scores (PCS) were assessed. All these scores were greater in *high pain* respondents as compared to *low pain* respondents. Increases of one unit in PCS magnification and dental anxiety scores determined a relative risk of being *high pain* responders of 1.60 and 1.14, respectively. Interestingly, electrical pain thresholds measured at incisors did not differ between groups. This suggests that central cognitive mechanisms might have greatly contributed to pain modulation in the study samples.

The effect of anxiety on orthodontic pain has been further verified in combination with somatosensory amplification [26], an individual characteristic linked to an increased perception of bodily sensations. Somatosensory amplification refers to the tendency to perceive a given somatic sensation as intense, noxious and disturbing [27]. Somatosensory amplification is correlated with several indices of general distress including anxious and depressive symptoms [26]. In their clinical experiment, Cioffi and co-workers induced experimental orthodontic pain by using orthodontic separators in two groups of individuals with high versus low combined scores of somatosensory amplification and trait anxiety [28]. Individuals with high combined scores demonstrated

a heightened pain perception over 5 days, and presented decreased pressure pain thresholds at masticatory muscle locations. The greatest difference between groups was found 24 hours after the placement of orthodontic separators. Finally, an increased frequency of parafunctional daytime clenching episodes [29] was found in individuals with greater pain scores. However, it is still unknown whether and how clenching episodes may contribute to the orthodontic pain experience.

5.1.5 Can we reduce patient's anxiety during treatment?

Since patient anxiety significantly contributes to the experience of pain, strategies aimed at reducing anxiety might diminish the subjective perception of pain. Wang and co-workers assessed whether cognitive behavioral therapy (CBT) could be effective in reducing orthodontic pain [30]. The CBT intervention was delivered immediately after initial archwire placement. The CBT interventions involved guided imagery, activity pacing, relaxation training, assistance in tackling pain-related anxiety, and problem solving [31]. The intervention group was compared to a group submitted to ibuprofen medication, in which patients received 300 mg of ibuprofen at 6, 12, and 24 hours after initial archwire placement. Finally, a control group with no intervention was also recruited (in this group participants received routine diet and oral hygiene instructions only). The authors did not find significant between-group differences (ibuprofen vs. CBT) and concluded that modulation of individual psychological factors can be as effective as pharmacological interventions in reducing pain during treatment. In a study by Cozzani and co-workers, the effects of a structured phone call versus a non-structured text message on pain reports was tested [32]. The phone call aimed to thank the patient for participating in the study and for having attended the previous orthodontic appointment, to explain possible reasons for pain or discomfort, to encourage appropriate dental hygiene, to recommend adequate use of analgesics, and to stress the importance of a positive attitude towards orthodontic treatment. Both procedures determined a significant reduction in pain reports as compared to a control group, who did not receive any intervention. Hence, the authors concluded that a post-procedure

phone call might reduce the perception of pain. It was also likely that the decrease of individual anxiety due to the intervention might have influenced the perception of pain.

Bartlett and co-workers performed a similar study [33]. They assessed the effects of a structured phone call versus an attention-only one. The structured phone call aimed to retrieve information about a patient's wellbeing, whether pain and discomfort were present, and to reassure that the patient's reaction was within normal limits. Furthermore, it promoted the necessity of sustained oral hygiene, the need for a soft diet, and the importance of maintaining a positive attitude. The attention-only phone call included a brief gesture of thanks for participating in the study and functioned as a notice of how to properly complete the questionnaire about pain. Both interventions were accompanied by pain reports that were significantly lower as compared to the control group, who did not receive a phone call. No differences were found between the two interventions. Hence, the content of the phone call did not play a significant role on the outcome of pain.

These studies allow us to hypothesize that even the nocebo or placebo effects of words and gestures should be considered when dealing with orthodontic patients. According to Olshansky and co-workers [34], *"A cold, uncaring, disinterested and emotionless physician will encourage a nocebo response. In contrast, a caring, empathetic, physician fosters trust, strengthens beneficent patient expectations, and elicits a strong placebo response."* The extent to which words and patient information are able to determine a nocebo effect has been clearly described by Aslaksen and co-workers [35], who were able to reverse topical analgesia determined by a mixture of lidocaine and prilocaine by nocebo information. This hyperalgesic nocebo suggestion was mediated by an increase in blood systolic pressure and stress.

5.1.6   Conclusion

Orthodontic pain influences patient compliance. In order to possibly reduce the painful response to orthodontic treatment, and in the attempt to enhance patient compliance,

clinicians should take into consideration a set of procedures that can be easily and safely performed and incorporated to routine clinical settings other than simply always resorting to the prescription of pain medications.

First and foremost, it would be advisable to perform a thorough assessment of a given patient's psychological factors in order to identify specific characteristics, such as anxiety, which are known to be related to a more heightened painful experience. Secondly, assessment of patient expectations about treatment and pain/impairment secondary to orthodontic treatment is highly recommended. The research evidence suggests that pain anticipation is a strong predictor of pain response during treatment. Those who anticipate greater discomfort are likely to have a more intense and prolonged pain experience. Thirdly, improvement in verbal and non-verbal communication skills and the simultaneous attempt to reduce nocebo effects, while enhancing placebo effects is critical. Finally, incorporation of close patient follow-up (e.g. phone calls, apps, diaries) for monitoring patient symptoms will result in an enhanced orthodontist-patient relationship and, in turn, stronger compliance.

5.1.7 Conflict of interest

The author confirms that he has conflict of interest.

5.1.8 References

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6 Chapter Two

6.1 Effects of Trait Anxiety, Somatosensory Amplification, and Facial Pain on Self-Reported Oral Behaviors[2]

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6.1.1 Abstract

Oral behaviors are activities like gum chewing, teeth clenching and biting of objects that go beyond normal functioning demands and contribute to the onset of temporomandibular disorders (TMD). Somatosensory amplification refers to the tendency to experience somatic sensations as intense, noxious, and disturbing and is related to bodily hypervigilance. Clinical experience suggests that individuals with bodily hypervigilance also present with occlusal hypervigilance, and continuously check their occlusion. This study aimed at investigating whether somatosensory amplification and trait anxiety, a characteristic correlated with hypervigilance, are associated with a greater incidence of oral behaviors, and verifying how self-reported facial TMD pain affect this relationship.

The State-Trait Anxiety Inventory, the Somatosensory Amplification Scale, the Oral Behavior Checklist (OBC) and the TMD-Pain Screener Questionnaire were filled out by 255 university students with self-reported facial TMD pain (PAIN group; 47 subjects, 24.8±4.2 years) and without pain (CTR group; 208 subjects, 26.0±4.8 years) using a web survey.

Trait anxiety, somatosensory amplification and OBC scores were greater in the PAIN than CTR group (all $p<0.05$). Trait anxiety and somatosensory amplification were positively associated with the frequency of oral behaviors, as measured with the OBC (all $p<0.05$). A significant effect of the interaction study group*trait anxiety ($p=0.028$) on OBC scores was found.

Individuals with greater trait anxiety and somatosensory amplification have more frequent oral behaviors. The relationship between anxiety and oral behaviors is affected by concurrent facial pain. Clinicians should evaluate patients' anxiety and somatosensory amplification before starting dental treatment.

Keywords: oral parafunctional behaviors, awake bruxism, trait anxiety, somatosensory amplification, temporomandibular joint disorders

6.1.2 Introduction

Oral behaviors are activities like gum chewing, teeth clenching and biting of objects, which deviate from functional activities [1]. These activities need to be carefully evaluated in the clinical setting because they are known to be predictors of temporomandibular disorders (TMD) [2].

Awake bruxism is an oral behavior characterized by repetitive clenching of teeth [3]. Experimental studies have shown that sustained wake-time clenching elicits jaw muscle fatigue and pain in healthy subjects [4], contributes to TMD onset [5,6] and tooth wear [7-8]. The contribution of anxiety to oral behaviors and wake-time clenching has been largely verified. Anxious individuals have frequent oral behaviors and wake-time clenching episodes [9-12]. However, high levels of anxiety are also a characteristic of individuals with facial pain [11,13-15]. Therefore, it is not clear whether the relationship between anxiety and wake-time clenching is due to the higher prevalence of painful TMD in individuals with frequent self-reports of clenching episodes. Somatosensory amplification refers to the tendency to perceive a given normal somatic sensation (such as heat, cold, touch etc.) as intense, noxious and disturbing [16]. Amplification of somatic sensations involves bodily hypervigilance, which is characterized by a heightened attention to the body and a selective focus on detected sensations [16]. Clinical experience suggests that individuals with bodily hypervigilance also may present with occlusal hypervigilance, which is an increased occlusal perception and heightened attention to changes in one's dental occlusion [17]. People with occlusal hypervigilance present a selective focus on detecting occlusal sensations, and continuously check their occlusion [17]. Oral behaviors involving repetitive tooth-to-tooth contact and clenching may serve to scan the intraoral environment in search of possible threats such as occlusal interferences, and be more prevalent in individuals with greater somatosensory amplification.

This study aimed at investigating whether increased levels of trait anxiety and somatosensory amplification are associated with a greater incidence of oral behaviors.

A second aim was to verify how self-reported facial pain affects this relationship. It was hypothesized that: 1. Both anxiety and somatosensory amplification are positively associated with the frequency of oral behaviors, and 2. The relationship between anxiety and oral behaviors is influenced by concurrent facial pain.

6.1.3 Materials and methods

Two hundred fifty-five students (161 females, 94 males; mean age±SD = 25.8±4.7 years) at the University of Toronto participated in a web-survey with five online questionnaires. The survey included a modified version of the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) demographics questionnaire [18], the TMD-Pain Screener Questionnaire [18-19], the State-Trait Anxiety Inventory [20], the Oral Behavior Checklist [1,21], and the Somatosensory Amplification Scale [16]. The validity of these questionnaires has been tested in different settings [1,16,19-23]. Incentive for individuals to fully complete the web-survey was established through a lottery system that led to the awarding of gift cards. The following inclusion/exclusion criteria were used: current students studying at the University of Toronto with a valid University of Toronto email address.

The *TMD-Pain Screener questionnaire* (Figure 12-5) investigates about the presence of pain in the jaw or temple area in the last 30 days. Specifically, subjects were asked if they had pain in the jaw or temple area, pain or stiffness in the jaw on awakening, and whether oral activities affected any pain in the jaw or temple area. A score ranging from 0 to 2 points is attributed to each answer with a total score ranging from a minimum of 0 to a maximum of 7 points [19].

The *State-Trait Anxiety Inventory* includes 20 items for assessing state anxiety (Figure 12-6) and 20 for assessing trait anxiety (Figure 12-7). Trait anxiety includes constructs such as *"I feel pleasant"*, "*I feel nervous and restless*", "*I feel like a failure*", etc. Participants indicated how they generally feel by choosing among the following options: "*almost never*", "*sometimes*", "*often*", or *"almost always"*. Each answer is ranked as a

score from 1 to 4 with a total score ranging from a minimum of 20 to a maximum of 80 [20].

The *Oral Behaviors Checklist* (OBC) (Figure 12-8) includes 21 items assessing awareness and the self-reported frequency of waking-state oral behaviors [21]. The reliability and validity of the OBC in detecting waking-state oral parafunctions has been previously demonstrated [1,21]. Participants reported the daily frequency for each oral behavior listed in the questionnaire by choosing among the following options: *"none of the time"*, "*a little of the time*", *"some of the time"*, "*most of the time*", or "*all of the time*". Each answer is ranked as a score from 0 to 4 with a total score ranging from a minimum of 0 to a maximum of 44 [21].

Other than computing the total OBC score for each subject, a partial score (OBC6) was calculated by summing the OBC items 3, 4, 5, 10, 12, and 13 (i.e. #3: *grinding teeth together during waking hours*; #4: *clenching teeth together during waking hours*; #5: *pressing, touching, or holding teeth together other than eating*; #10: *biting, chewing, or playing with tongue, cheeks, or lips*; #12: *holding objects between teeth or biting objects such as hair, pipe, pencils, pens, fingers, etc.*; #13: *use of chewing gum*) with a total score ranging from a minimum of 0 to a maximum of 24 [22-23]. The rationale for using these items was that these oral activities are characterized by pressing attitudes against soft tissues, objects, or teeth, and may account for oral behaviors involving repetitive tooth-to-tooth contact and clenching.

The *Somatosensory Amplification Scale* (SSA) (Figure 12-9) [16] includes 10 statements investigating participants' sensitivity to bodily sensations, such as *"Sudden loud noises really bother me"*, "*I am often aware of various things happening within my body*", *"I can sometimes hear my pulse or my heartbeat throbbing my ear"*, etc. Participants could answer among the following options: *"not at all"*, *"a little"*, "*moderately*", "*quite a bit*", or *"extremely".* Each answer is ranked as a score from 0 to 4 with a total score ranging from a minimum of 0 to a maximum of 40 [16].

6.1.4 Website for research survey

A website was used to collect the measurements. The website was designed for access from desktop or laptop computers, tablets and mobile phones and was advertised by use of flyers, social-media networking and student newsletters including a Quick Response code linked to the website. The website included a set of multiple-choice questionnaires with answers inserted by the participant through the use of radio buttons, and was structured to check for the completeness of the answers. A confirmation message after the completion of the survey was generated, including an identification (ID) that was linked to the lottery system. The web-survey accepted one attempt (one fully completed survey) from each and every registered participant. All collected data was encrypted, protected and stored in a comma-separated values (CSV) worksheet. Informed consent was obtained on-line.

6.1.5 Statistical analysis

Based on the TMD-Pain Screener scores [9], two study groups were constructed. One group included people with scores ≥3 (group reporting facial pain, PAIN group), and the other comprised of participants with scores <3 (no facial pain, CTR group).

Pearson coefficients (r) and coefficients of determinations (r^2) were computed to test correlations and associations between the study variables (Trait Anxiety, OBC, OBC6, SSA) in both groups. Non-parametric tests (Mann-Whitney) were used to test between– groups (PAIN vs. CTR) in trait anxiety, OBC, OBC6, and SSA scores.

Contingency tables (2x5) were constructed to examine the distribution of the items included in the Oral Behaviors Checklist (questions 1-21) in both the study groups. The Chi-squared test was used to determine whether there was a significant association between the frequency of OBC items and the study groups. Standardized residuals were also computed. The Chi-squared test was also used to test whether the gender distribution was similar between groups.

In order to test the concurrent effect of gender, trait anxiety, SSA, and pain (study group: PAIN vs. CTR) on oral behaviors, two mixed-effect regression models were constructed. OBC and OBC6 scores were included as dependent variable. Trait anxiety and SSA scores were included in the model as covariates. Gender and the study group (PAIN vs. CTR) as fixed factors. All the interactions between independent variables were tested and retained in the models when statistically significant ($p < 0.05$). Data were analysed using SPSS version 24.0 (IBM).

6.1.6 Results

The PAIN group comprised 47 individuals (33 females, 14 males; mean age±SD = 24.8±4.2 years). The CTR group included 208 subjects (128 females, 80 males; mean age±SD = 26.0±4.8 years).

6.1.6.1 Between-groups comparisons

Median scores for trait anxiety, oral behaviors (OBC and OBC6), and somatosensory amplification (SSA) are reported in Figure 6-1. Trait anxiety and SSA were greater in the PAIN than CTR group ($p = 0.001$ and $p = 0.003$, respectively). OBC and OBC6 scores were higher in the PAIN than CTR group (all $p < 0.001$). Most of the OBC items were more prevalent in the PAIN group (all $p < 0.05$) than the CTR group (see Table 6-1). OBC scores were greater in female than in male individuals ($p < 0.05$).

6.1.6.2 Correlations and associations between trait anxiety, oral behaviors (OBC and OBC6) and somatosensory amplification (SSA)

In the PAIN group, trait anxiety was moderately correlated to SSA ($r = 0.519$, $p < 0.001$; $r^2 = 0.27$), moderately correlated to OBC ($r = 0.586$, $p < 0.001$; $r^2 = 0.34$), and moderately correlated to OBC6 ($r = 0.436$, $p = 0.001$; $r^2 = 0.19$) scores. SSA was significantly, but moderately correlated to OBC ($r = 0.352$, $p < 0.001$; $r^2 = 0.12$) and weakly correlated to OBC6 ($r = 0.270$, $p = 0.033$; $r^2 = 0.07$).

In the CTR group, trait anxiety was weakly correlated to SSA (r=0.242, p<0.001; r^2=0.06), weakly correlated to OBC (r=0.290, p<0.001; r^2=0.08), and weakly correlated to OBC6 (r=0.298, p=<0.001; r^2=0.09). SSA was significantly, but weakly correlated to OBC (r=0.263, p<0.001; r^2=0.07) and weakly correlated to OBC6 (r=0.211, p<0.001; r^2=0.04).

6.1.6.3 Mixed effect regression models

A significant main effect of gender (p=0.039), trait anxiety (p<0.001), SSA (p=0.002), and of the interaction group*trait anxiety (p=0.028) on OBC scores was found (Table 6-2). Figure 6-2 depicts the interaction effect in the regression model. A significant main effect of gender (p=0.045), trait anxiety (p<0.001), SSA (p=0.032) and the study group (p=0.002) on OBC6 scores was also determined (Table 6-2).

6.1.7 Discussion

This study investigated the prevalence of oral behaviors in university students and tested the association between trait anxiety, somatosensory amplification and oral behaviors. In addition, it evaluated whether facial TMD pain affected this relationship.

For this study, we used the TMD-Pain Screener Questionnaire [19] to detect individuals with facial TMD pain. The specificity and sensitivity of the TMD-Pain Screener Questionnaire for detecting painful TMD versus healthy controls have been reported to be 99.1% and 96.9%, respectively [19]. Therefore, this questionnaire is a valid tool to identify individuals with painful TMD. Similarly, the Oral Behaviors Checklist was shown to be valid (as compared to surface electromyography) for detecting wake-time oral parafunctional behaviors [1], as it effectively predicts these activities in the natural environment [24].

The prevalence of facial TMD pain was 18% (21% in females and 15% in males). This finding is consistent with a recent study reporting the prevalence of TMD pain in Finnish students to be 25.9% in women and 11.4% in men [25]. Differently from our study, other investigators found a higher prevalence of TMD symptoms (approximately 38-40%) in students [26-27]. Discrepancies between the studies may be due to the method used to detect TMD. In our report, we used the TMD-Pain Screener Questionnaire, which investigates the presence of painful TMD and does not account for non-painful TMD (e.g. temporomandibular joint clicking). Therefore, the presence of TMD may be underestimated in our sample.

Our study has confirmed that oral behaviors and painful TMD are associated [2,5,22]. Clenching and grinding (OBC items 1,3,4), holding the teeth together (item 4), tensing the jaw muscles or holding the jaw in a rigid position (items 6, 7, 11), pressing the tongue against the teeth (item 9), playing with the tongue, cheeks or lips (item 10), and using chewing gum (item 13) were more frequent in individuals with facial TMD pain than pain-free individuals. These activities require a sustained and repetitive contraction of the jaw muscles, which may result in muscle overload, local ischemia, and pain [28-29].

Trait anxiety was measured by using the State-Trait Anxiety Inventory [20]. The reliability of this questionnaire has been shown to be high [20,30]. Trait anxiety was positively associated with oral behaviors, similarly to other studies reporting that the frequency of oral behaviors is increased in subjects with a more anxious personality disposition [9-12].

Somatosensory amplification scores were within the ranges reported previously [22]. The relationship between somatosensory amplification and oral behaviors has been minimally investigated so far [12,22]. Our study demonstrated a positive association between these constructs. Somatosensory amplification is related to bodily hypervigilance, which is a heightened perception of somatic sensations. Clinical realms reveal that patients with occlusal hypervigilance continuously check their occlusion [17].

Specific oral behaviors characterized by repetitive tooth-to-tooth contact, tongue-to-teeth contact, and clenching may serve to scan the intraoral environment in search of possible threats, such as occlusal interferences or changes into dental occlusion during orthodontic treatments.

The relationship between somatosensory amplification, trait anxiety and oral behaviors is heightened in individuals with concurrent facial TMD pain. Trait anxiety was found to be greater in individuals with facial pain than the pain-free group. The relationship between anxiety and TMD has been subject of several studies, which used different scales [15,22,31-34] with contrasting results. A recent study examining TMD patients showed that the association between TMD and anxiety is dependent on the severity of TMD [15]. Our regression model showed a significant interaction effect between trait anxiety and facial pain, which suggests that pain has an additive effect on the relationship between anxiety and oral behaviors: people with high levels of trait anxiety present a greater frequency of oral behaviors if pain is present (Figure 6-2).

In agreement with previous reports [22,35], somatosensory amplification was slightly greater in people reporting facial pain than pain-free individuals. This result suggests that concurrent pain heightens somatic bodily sensations and contributes to hypervigilance [36]. The stronger relationship we found between somatosensory amplification and oral behaviors in individuals with facial TMD pain contributes to explain the general framework that links painful temporomandibular disorders to increased occlusal awareness [17]. In a previous study, it was shown that individuals with TMD continued to clench their teeth and in some cases increased their parafunctional activities when exposed to experimental changes to their dental occlusion [38]. Differently, healthy individuals reduced the frequency of tooth contacts when exposed to the same condition [38].

In agreement with previous reports [5,39], in our study oral behaviors were found to be gender-related and to be more frequent in females. However, due to the greater number

of female participants in the current study, it is possible that this finding has been overestimated.

This study has some limitations. Firstly, the sample analysed is composed of university students with a limited age range that may be not representative of the general population. Furthermore, the majority of our sample consisted of dental students, which may be aware of wake-time tooth clenching episodes more in comparison to lay people. Secondly, ethnic, racial, and cultural factors have been reported to influence anxiety and related disorders [40]. Our survey included more than ten different races and ethnicities. We decided not to include this data in the statistical analysis. Indeed, controlling for these variables may have significantly affected the power of our investigation. Thirdly, we used the TMD-Pain Screener Questionnaire [18,19] to detect individuals with TMD pain, but did not examine the participants clinically. Although this questionnaire has very high sensitivity and specificity (>0.95) [19] in detecting painful TMD, it cannot account for a clinical diagnosis. Additionally, the TMD pain screener is able to inform only about painful TMD and does not account for non-painful TMD. Hence, the effect of non-painful TMD on the outcome measures could not be estimated. Also, we did not measure the severity of facial pain, which could also have affected trait anxiety and oral behaviors in our sample. Moreover, it may be argued that including both somatosensory amplification and trait anxiety as predictors in the regression model may account for multi-collinearity. Somatosensory amplification and trait anxiety were positively correlated [12], as reported previously [41]. However, the correlation between these variables was found to be weak to moderate (r=0.321, p<0.001) and could have not have affected the analysis [42]. Finally, our results indicate that the facial pain group had more frequent clenching activities during sleep than the pain-free group. Nonetheless, the validity of the oral behaviors checklist for the assessment of sleep bruxism is limited.

6.1.8 Conclusion

In conclusion, this study has shown that both somatosensory amplification – an estimate of bodily and occlusal hypervigilance – and trait anxiety are positively associated with oral behaviors, and that concurrent facial pain heightens the relationship between trait anxiety and oral behaviors. Clinicians should gather information about patient's psychological traits before starting dental treatments. Indeed, oral behaviors may cause jaw muscle overloading and pain, favour orthodontic relapse, and compromise patient's adaptation to dental rehabilitations, thereby increasing the risk of failure during treatment.

6.1.9 Acknowledgments

6.1.10   Compliance with ethical standards

6.1.10.1 Conflict of Interest

6.1.10.2 Funding

6.1.10.3 Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

6.1.10.4 Informed consent

For this study was obtained on-line from all individual participants included in the study. The study was reviewed and approved by the University of Toronto Research Ethics Board (protocol #32797).

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6.1.12 Figures and tables
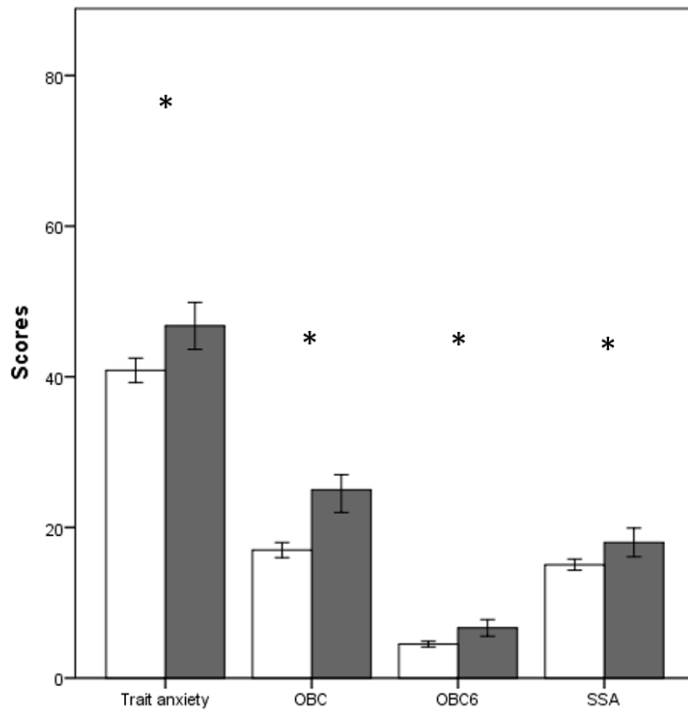
Figure 6-1. Median values (+/- 95% confidence intervals) for Trait Anxiety, OBC, OBC6, and SSA in both groups. White: CTR group, Grey: PAIN group. *Between groups significant differences at p<0.05.
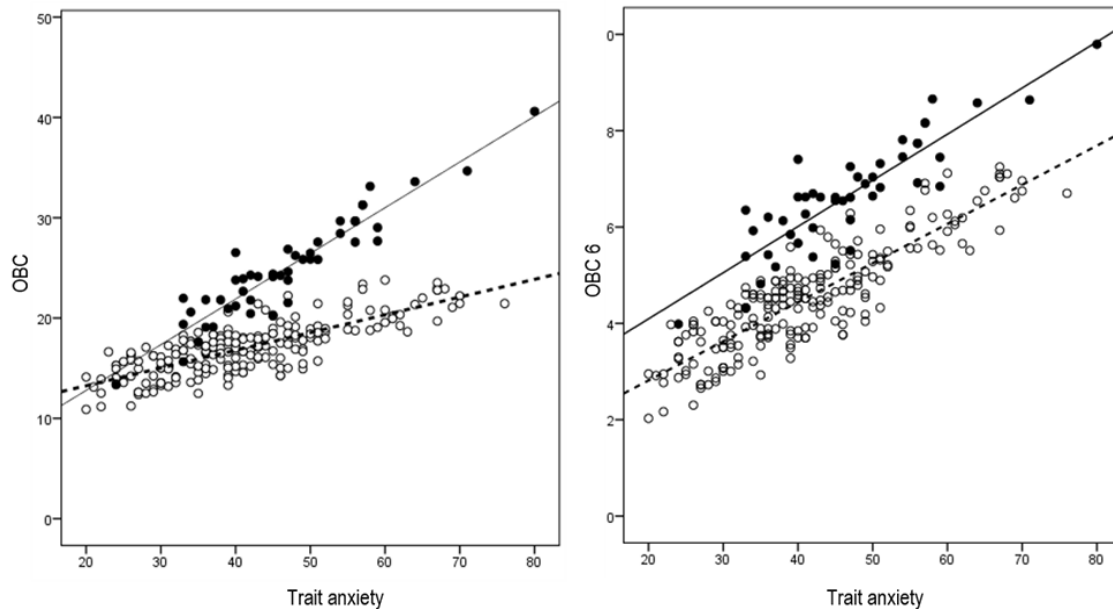
Figure 6-2. Scatter plots with regression lines showing the relationship between Trait Anxiety and OBC (predicted values) and Trait Anxiety and OBC6 (predicted values) in both groups. White: CTR group, Grey: PAIN group.

Table 6-1. Frequency of oral behaviours in the study groups (PAIN vs. CTR). Standardized residuals are reported between squared brackets. Bold type: statistically significant.

	None of the time	< 1 night/month	1-3 nights/ month	1-3 nights/ week	4-7 nights/ week
Clench or grind teeth when asleep, based on any information you may have	99 CTR (48.1%) [0.8]	27 CTR (13.1%) [0.9]	40 CTR (19.4%) [-0.1]	19 CTR (9.2%) [-0.5]	21 CTR (10.2%) [-1.7]
P<0.001	13 PAIN (27.7%) [-1.7]	1 PAIN (2.1%) [-1.8]	10 PAIN (21.3%) [0.2]	7 PAIN (14.9%) [4.0]	16 PAIN (34.0%) [3.5]
Sleep in a position that puts pressure on the jaw (for example, on stomach, on the side)	70 CTR (34.0%) [0.9]	10 CTR (4.9%) [0.3]	8 CTR (3.9%) [-0.3]	26 CTR (12.6%) [-0.5]	92 CTR (44.7%) [-0.5]
P=0.081	7 PAIN (14.9%) [-1.9]	1 PAIN (2.1%) [-0.7]	3 PAIN (6.4%) [-0.7]	9 PAIN (19.1%) [1.0]	27 PAIN (57.4%) [1.0]

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Grind teeth together during waking hours	155 CTR (75.2%) [0.6]	36 CTR (17.5%) [-0.5]	11 CTR (5.3%) [-1.3]	4 CTR (1.9%) [-0.4]	0 CTR (0%) -
P=0.004	26 PAIN (55.3%) [-1.3]	12 PAIN (25.5%) [1.0]	9 PAIN (19.1%) [2.7]	0 PAIN (0%) [-0.9]	0 PAIN (0%) -
Clench teeth together during waking hours	93 CTR (45.1%) [0.9]	79 CTR (38.3%) [0.3]	27 CTR (13.1%) [-1.6]	7 CTR (3.4%) [-0.4]	0 CTR (0%) -
P<0.001	11 PAIN (23.4%) [-1.9]	15 PAIN (31.9%) [-0.6]	18 PAIN (38.3%) [3.3]	3 PAIN (6.4%) [0.8]	0 PAIN (0%) -
Press, touch, or hold teeth together other than while eating (that is, contact between upper and lower teeth)	79 CTR (38.3%) [1.0]	85 CTR (41.3%) [0.5]	34 CTR (16.5%) [-0.6]	8 CTR (3.9%) [-2.2]	0 CTR (0%) -
P<0.001	8 PAIN (17%) [-2.0]	14 PAIN (29.8%) [-1.0]	12 PAIN (25.5%) [1.2]	13 PAIN (27.7%) [4.6]	0 PAIN (0%) -
Hold, tighten, or tense muscles without clenching or bringing teeth together	142 CTR (68.9%) [1.3]	42 CTR (20.4%) [-0.6]	16 CTR (7.8%) [-1.6]	6 CTR (2.9%] [-0.8]	0 CTR (0%) -
P<0.001	15 PAIN (31.9%) [-2.6]	15 PAIN (31.9%) [1.4]	13 PAIN (27.7%) [3.3]	4 PAIN (8.5%) [1.6]	0 PAIN (0%) -
Hold or jut jaw forward or to the side	160 CTR (77.7%) [0.5]	37 CTR(18.0%) [0.2]	7 CTR (3.4%) [-1.7]	2 CTR (1.0%) [-0.7]	0 CTR (0%) -
P=0.001	29 PAIN (61.7%) [-1.0]	7 PAIN (14.0%) [-0.4]	9 PAIN (19.1%) [3.5]	2 PAIN (4.3%) [1.5]	0 PAIN (0%) -
Press Tongue forcibly against teeth	148 CTR (71.8%) [0.6]	43 CTR (20.9%) [-0.4]	15 CTR (7.3%) [-0.5]	0 CTR (0%) [-1.6]	0 CTR (0%) -
P=0.001	25 PAIN (53.2%) [-1.6]	13 PAIN (27.7%) [-0.8]	6 PAIN (12.8%) [1.1]	3 PAIN (6.4%) [3.3]	0 PAIN (0%) -
Place tongue between teeth	154 CTR (74.8%) [1.0]	40 CTR (19.4%) [-0.9]	9 CTR (4.4%) [-1.1]	3 CTR (1.5%) [-0.5]	0 CTR (0%) -
P=0.001	21 PAIN (44.7%) [-2.0]	17 PAIN (36.2%) [2.0]	7 PAIN (14.9%) [2.3]	2 PAIN (4.3%) [1.1]	0 PAIN (0%) -
Bite, chew or play with your tongue, cheeks or lips	90 CTR (43.7%)	69 CTR (35.5%)	36 CTR (17.5%)	11 CTR (5.3%)	0 CTR (0%)

	[1.0]	[0.2]	[-1.1]	[-1.0]	-
	9 PAIN (19.1%)	14 PAIN (29.8%)	17 PAIN (36.2%)	7 PAIN (14.9%)	0 PAIN (0%)
P=0.001	[-2.2]	[-0.4]	[2.3]	[2.0]	-
Hold jaw in rigid or tense position, such as to brace or protect the jaw	179 CTR (86.9%)	25 CTR (12.1%)	2CTR (1.0%)	0 CTR (0%)	0 CTR (0%)
	[0.8]	[-0.8]	[-1.8]	[-1.3]	-
	28 PAIN (59.6%)	11 PAIN (23.4%)	6 PAIN (12.8%)	2PAIN (4.3%)	0 PAIN (0%)
P<0.001	[-1.7]	[1.7]	[3.7]	[2.7]	-
Hold between the teeth or bite objects such as hair, pipe, pencils, pens fingers, fingernails, etc.	132 CTR (64.1%)	47 CTR (22.8%)	21 CTR (67.7%)	6 CTR (2.9%)	0 CTR (0%)
	[0.2]	[0.5]	[-0.8]	[-0.2]	-
	28 PAIN (59.6%)	7 PAIN (14.9%)	10 PAIN (21.3%)	2 PAIN(4.3%)	0 PAIN (0%)
P=0.151	[-0.3]	[-1.0]	[1.8]	[0.4]	-
Use chewing gum	55 CTR (26.7%)	73 CTR (35.4%)	60 CTR (29.1%)	18 CTR (8.7%)	0 CTR (0%)
	[-0.9]	[0.3]	[0.9]	[-0.3]	-
	31 PAIN (44.7%)	14 PAIN (29.8%)	6 PAIN (12.8%)	6 PAIN (12.8%)	0 PAIN (0%)
P=0.029	[1.8]	[-0.5]	[-1.8]	[-0.7]	-
Play musical instruments that involves use of mouth or jaw (for example, woodwind, brass, string instruments)	189 CTR (91.7%)	13 CTR (6.3%)	2 CTR (1%)	2 CTR (1%)	0 CTR (0%)
	[-0.2]	[0.7]	[0.3]	[-0.3]	-
	46 PAIN (97.9%)	0 PAIN (0%)	0 PAIN (0%)	1 PAIN (2.1%)	0 PAIN (0%)
P=0.261	[0.4]	[-1.6]	[-0.6]	[0.6]	-
Lean with your hand on the jaw, such as cupping, or resting the chin in the hand	37 CTR (18%)	70 CTR (34%)	70 CTR (34.0%)	29 CTR (14.1%)	0 CTR (0%)
	[0.9]	[0.0]	[-0.3]	[-0.5]	-
	2 PAIN (4.3%)	16 PAIN (34%)	19 PAIN (40.4%)	10 PAIN (21.3%)	0 PAIN (0%)
P=0.094	[-1.9]	[0.0]	[0.6]	[1.0]	-
Chew food on one side only	82 CTR (39.8%)	66 CTR (32.0%)	31 CTR (15.0%)	27 CTR (13.1%)	0 CTR (0%)
	[1.1]	[-0.1]	[-1.2]	[-0.3]	-
	7 PAIN (14.9%)	16 PAIN (34.0%)	16 PAIN (34.0%)	8 PAIN (17.0%)	0 PAIN (0%)
P=0.002	[-2.3]	[0.2]	[2.5]	[0.6]	-
Eating between meals	15 CTR (7.3%)	75 CTR (36.4%)	88 CTR (42.7%)	28 CTR (13.6%)	0 CTR (0%)
	[0.5]	[0.2]	[0.2]	[-0.9]	-
	1 PAIN (2.1%)	15 PAIN (31.9%)	18 PAIN (38.3%)	13 PAIN (5.1%)	0 PAIN (0%)
P=0.083	[-1.1]	[-0.4]	[-0.4]	[2.0]	-
Sustained talking (for example, teaching, sales, customer service	70 CTR (34.0%)	94 CTR (45.6%)	28 CTR (13.6%)	14 CTR (6.8%)	0 CTR (0%)
	[0.2]	[0.2]	[-0.2]	[-0.6]	-
	14 PAIN (29.8%)	19 PAIN (40.4%)	8 PAIN (17.0%)	6 PAIN (12.8%)	0 PAIN (0%)
P=0.480	[-0.4]	[-0.4]	[0.5]	[1.2]	-
Singing	128 CTR (62.1%)	62 CTR (30.1%)	14 CTR (6.8%)	2 CTR (1.0%)	0 CTR (0%)
	[0.6]	[-0.6]	[-0.4]	[-0.3]	-
	21 PAIN (44.7%)	20 PAIN (42.6%)	5 PAIN (10.6%)	1 PAIN (2.1%)	0 PAIN (0%)
P=0.172	[-1.3]	[1.2]	[0.8]	[0.6]	-
Yawning	16 CTR (7.8%)	131 CTR (63.6%)	45 CTR (21.8%)	14 CTR (6.8%)	0 CTR (0%)
	[0.6]	[0.3]	[-0.7]	[-0.2]	-

P=0.191	1 PAIN (2.1%) [-1.2]	26 PAIN (55.3%) [-0.6]	16 PAIN (34.0%) [1.4]	4 PAIN (8.5%) [0.4]	0 PAIN (0%) -
Hold telephone between your head and shoulders	116 CTR (56.3%) [0.0]	72 CTR (35.0%) [-0.2]	18 CTR (8.7%) [0.6]	0 CTR (0%) [-0.9]	0 CTR (0%) -
P=0.074	26 PAIN (55.3%) [-0.1]	19 PAIN (40.4%) [0.5]	1 PAIN (2.1%) [-1.3]	1 PAIN (2.1%) [1.9]	0 PAIN (0%) -

Table 6-2. Results from the regression models. Bold type: statistically significant.

Independent variables	OBC F value (p value)	OBC6 F value (p value)
Group	0.803 (0.371)	**9.846 (0.002)**
Gender	**4.309 (0.039)**	**4.068 (0.045)**
Trait anxiety	**22.434 <0.001)**	**18.813 (<0.001)**
SSA	**9.687 (0.002)**	**4.639 (0.032)**
Group* Trait anxiety	**4.914 (0.028)**	-

7 Chapter Three

7.1 Wake-Time Tooth Clenching Affects the Relationship Between Trait Anxiety and Orthodontic Pain[3]

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Running title: anxiety, wake-time clenching, and orthodontic pain perception

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7.1.1 Abstract

Tooth pain experienced during orthodontic treatment is reported to be mild to moderate, but significantly affects patient compliance. Orthodontic pain has been reported to be greater in patients with moderate to severe anxiety as compared to those with low levels of anxiety. Increased levels of anxiety are associated with a greater frequency of wake-time tooth clenching, an oral parafunctional behavior that is characterized by repetitive isometric contractions of the jaw elevator muscles. The increased frequency of clenching episodes in patients with greater anxiety could overload the periodontal ligament during orthodontic treatment and contribute to a greater pain experience. The aim of this study was to assess whether the relationship between anxiety and orthodontic pain is dependent upon wake-time tooth clenching. It was hypothesized that the relationship between anxiety and tooth pain is dependent on the frequency of wake-time tooth clenching during experimentally induced orthodontic tooth movement.

Two hundred fifty-five students filled in the State-Trait Anxiety Inventory (STAI) through a web-survey. The distribution of trait anxiety (STAI) scores was examined. Forty-five healthy volunteers (31F, 14M; mean age±SD = 26.0±3.4 years) with low (<20th percentile of STAI distribution; LA; n=14), intermediate (between 20th and 80th percentile of STAI distribution; IA; n=17), and high (>80th percentile of STAI distribution; HA; n=14) trait anxiety were recruited and submitted to the experimental intervention. Orthodontic elastomeric separators were positioned between the permanent mandibular molars on either the right of left side to induce an experimental orthodontic tooth movement. Tooth pain and wake-time tooth clenching were rated three times a day (10:00, 16:00 and 22:00) for five days on Visual Analogue Scales (VAS; 100 mm). With regard to clenching, participants were asked to report how much they clenched their teeth in the last six hours (left endpoint: "*none of the time*"; right endpoint: "*most of the time*"). Pressure pain thresholds (PPTs) were measured at the thenar eminence (extra-trigeminal location) and the anterior temporalis and superficial masseter (trigeminal location) in both sides before and after the intervention. Relative changes in PPTs were calculated (PPT post-intervention – PPT pre-intervention).

At masseter, IA individuals had a positive relative change in PPTs after the intervention, which was greater than LA (P=0.045) and HA (P=0.001) groups. No effect of gender on PPT changes was found (P=0.703). At temporalis, the relative change in PPTs was not dependent on the study group (P=0.248), but was affected by gender and increased only in male individuals (P=0.021). At the thenar eminence, the relative change in PPTs was affected by the interaction gender*study group (P=0.019). HA males had a greater and positive PPT relative change as compared to HA females (P=0.001), who had a negative relative change.

The intervention determined tooth pain, which was maximal at day one and minimum at day six (all P<0.05). A significant effect of the interaction day*study group*clenching on tooth pain was found (P<0.001). In the first day, HA individuals had similar tooth pain as LA group (P≥0.05). After day two, individuals of the HA group presented a greater reduction in both tooth pain levels and frequency of clenching as compared to LA (all P<0.05).

Tonic painful stimuli in the trigeminal region determine somatosensory alterations in both the muscles of mastication and at extratrigeminal locations. The relationship between anxiety and tooth pain experienced during experimental orthodontic tooth movement is dependent on the frequency of wake-time clenching episodes. Individuals with high trait anxiety reduce the frequency of clenching episodes in response to a painful stimulus in the periodontal ligament. This avoidance behavior contributes to a reduced pain experience after two days.

Keywords: oral behaviors, awake bruxism, trait anxiety, orthodontic pain

7.1.2 Introduction

Pain is an unpleasant and emotional experience associated with actual or potential tissue damage [1-2]. Pain is a complex and subjective experience that unfortunately is a common clinical symptom that accompanies orthodontic interventions [3-4]. It is mainly related to the application of orthodontic force to induce tooth movement, which results in compression of the supporting periodontal ligament tissue eliciting inflammation [5]. This results in the release of noxious agents and pro-algesic chemical mediators from free nerve endings thus increasing pain and sensitivity [3,6]. Orthodontic tooth pain is concerning as it is can attenuate patient compliance and compromise the effectiveness of orthodontic therapy [7]. Also, it is responsible for individuals refraining from seeking orthodontic treatment, discontinuing care, or terminating treatment early [3,8]. Orthodontic pain (or generally any other pain in the body) can be affected by several factors including psychological factors, such as, for instance, trait anxiety, which has been linked to orthodontic pain in previous research [9].

Trait anxiety is a mood disorder that has been defined as a general pattern of worry and physical dysregulation that is characteristic of an individual [10]. It has been associated with a greater pain experience in patients submitted to orthodontic treatment [9]. However, it is also known that trait anxiety is a characteristic that is highly prevalent in subjects with highly frequent oral behaviors such as wake-time tooth clenching [11]. Oral parafunctional behaviours are activities that deviate from functional behaviours such as chewing and swallowing [12]. Among these oral parafunctional behaviors there is wake-time tooth clenching [13-14], which is characterized by repetitive and sustained tooth-to-tooth contacts determined by the contraction of the elevator muscles.

Psychological factors such as trait anxiety and wake-time tooth clenching may interact to affect orthodontic pain. Indeed, an increased frequency of clenching episodes may overstimulate the periodontal ligament of anxious individuals and be associated with a higher pain experience. On the other hand, anxiety has also been shown to play an important role in exacerbating pain-related fear [15], which in turn, has been demonstrated to possess a critical role in promoting avoidance behaviour [15-18].

Therefore, it is still not clear how anxiety and wake-time clenching interact to affect orthodontic pain perception.

The aim of this longitudinal study was to test whether the relationship between anxiety and tooth pain is dependent on the frequency of wake-time tooth clenching and to assess how anxiety and wake-time tooth clenching interact to affect orthodontic pain.
It was hypothesized that the relationship between anxiety and tooth pain is dependent on the frequency of wake-time tooth clenching during experimentally induced orthodontic tooth movement, and that the motor response to an orthodontic painful stimulus is different between individuals reporting high vs. low levels of trait anxiety.

7.1.3 Materials and methods

Two hundred fifty-five students (161 females, 94 males; mean age±SD = 25.8±4.7 years) at the University of Toronto (St. George Campus) filled in the State-Trait Anxiety Inventory (STAI, form Y, trait version) [10] through a web-survey. The STAI includes 20 items for assessing state anxiety and 20 for assessing trait anxiety. Trait anxiety includes constructs such as "*I feel pleasant*", "*I feel nervous and restless*", "*I feel like a failure*", etc. Participants indicated how they generally feel by choosing among the following options: "*almost never*", "*sometimes*", "*often*", or "*almost always*". Each answer is ranked as a score from 1 to 4 (Spielberger 1983). Based on the web-survey, forty-five healthy volunteers (31 females, 14 males; mean age±SD = 26.0±3.4 years) with low (<20th percentile of trait anxiety distribution; n=14; Group LA), intermediate (between 20th and 80th percentile; n=17; Group IA), and high (>80th percentile; n=14; Group HA) trait anxiety were recruited.

The following exclusion criteria was used: current orthodontic treatment, active psychiatric disorders, use of medication acting on the Central Nervous System, habitual analgesic consumption, pain in the orofacial district, any systemic disease that could affect peripheral and central pain perception, presence of fixed extended (equal or more than three teeth) or complete/partial removable dentures. The choice of the previously

stated exclusion criteria is based on the fact that pain sensitivity could be altered in individuals with current painful conditions [19], individuals with a reduced number of natural teeth might be less sensitive to the experimental condition due to a reduced degree of sensitivity to occlusal changes [20], and to avoid psychiatric or pharmacological influences on individual pain ratings.

The three study groups (Groups HA, IA, and LA) were evaluated for the effects produced by a temporary, minimal, and fully reversible experimental tooth movement determined by the application of orthodontic elastomeric separators (American Orthodontics, X-Ring Separators) to the mesial and distal interproximal contacts of a permanent mandibular first molar to induce an experimental orthodontic tooth movement [21-22]. A custom-made pain diary was provided to participants to monitor three variables (tooth pain, perceived stress, and frequency of tooth clenching) with visual analogue scales (VAS) logged three times per day (10:00, 16:00, 22:00) over the course of five days. VAS Ratings were from 0 mm to 100 mm with construct-relevant end-points. For instance, *"no pain"* would be at the 0 mm end-point and *"the worst ever pain"* would be at the 100 mm end-point. With regard to clenching, participants were asked to report how much they clenched their teeth in the last six hours (with left endpoint indicating *"none of the time"* and right endpoint indicating "*most of the time"*). Finally, participants would return to clinic on day six for PPTs and separator removal.

Before and after the experimental procedure, pressure pain thresholds (PPTs) were determined for each subject utilizing an electronic algometer (Medoc Wagner Inc.) with a rubber tip (1 cm^2) at the thenar eminence which refers to a group of muscles on the palm of the hand at the base of the thumb (extra-trigeminal location), anterior temporalis (trigeminal location) and superficial masseter (trigeminal location) muscles bilaterally following a previously published protocol [23]. The PPTs were distinguished as the point at which the pressure stimulus altered from a pressure sensation to a pain sensation. The PPTs were measured at each site four times with one-minute interval between trials. Data was collected before and after the 5-day experiment in order to test whether

the orthodontic tooth pain could have influenced pain sensitivity in both trigeminal and extra-trigeminal areas.

7.1.4 Statistical analysis

The psychophysical measurements (pressure pain thresholds - PPTs) were reduced at each time point by computing the mean of the trials obtained at each PPT muscle location, after having discarded the first trial. To evaluate whether PPTs changed differently in the study groups after the 5-day experiment, a mixed effect model was used. Relative changes in PPT values were considered as dependent variables for the respective models, while study group and gender were used as independent variables. First order interactions between study group and gender were tested and retained in the model if statistically significant. A second set of multiple regression analyses were used to evaluate PPT changes from baseline.

A mixed effect model was used to test the effect of the intervention (placement of separators) on tooth pain in extreme groups (HA vs. LA). Study group, VAS scores for clenching and perceived stress, and day were used as independent variables. Statistical significance was set at p value of <0.05. Data were analyzed using SPSS version 24.0 (IBM).

7.1.5 Results

The relative percentage change (increase or decrease) in PPTs after the experimental procedure was assessed at the superficial masseter, anterior temporalis, and thenar eminence muscle bilaterally. Results from the mixed-effects regression models are reported in Table 7-1. At the superficial masseter muscle (trigeminal location), the changes in PPTs determined by the intervention were dependent on the study group (P=0.011) and are reported in Figure 7-1. PPTs relative changes were positive in both the IA and LA group, being the change greater in the IA group (P=0.045) than the LA group. Conversely, PPT relative changes were negative in the HA group and significantly differed from the IA group (P=0.001). IA individuals had a positive relative

change in PPTs after the intervention, which was greater than LA (P=0.045) and HA (P=0.001) groups. No effect of gender on PPT relative changes was found (P=0.703). At temporalis (Figure 7-2), the relative change in PPTs was not dependent on the study group (P=0.248), but was affected by gender and increased only in male individuals (P=0.021). At the thenar eminence (Figure 7-3), the relative change in PPTs was affected by the interaction gender*study group (P=0.019). HA males had a greater and positive PPT relative change as compared to HA females (P=0.001), who had a negative relative change. The intervention determined tooth pain (Figure 7-4), which was maximal at day one, and minimum at day six in all groups (all P<0.05). Results from the mixed-effects regression models are reported in Table 7-4 and a significant main effect of study group (p<0.001), clenching (p=0.001), gender (p=0.002), stress (p<0.001), and of the interaction of day*study group*clenching (p<0.001) on tooth pain was found.

In the first day, HA individuals had tooth pain similar to the LA group (p≥0.05). After day two, individuals of the HA group presented a greater reduction in both tooth pain levels and frequency of clenching as compared to LA (all P<0.05). The intervention determined an increase in the frequency of wake-time tooth clenching (Figure 7-5), which was maximal at day one with no difference between groups. Furthermore, we found that the decrease in wake-time tooth clenching was significant between day one and day two (p<0.05), but a greater reduction in tooth clenching was recorded in the HA group, which suggests a greater degree in avoidance behaviour in HA individuals.

7.1.6 Discussion

Gender or sex differences in clinical and experimental pain conditions have been previously described [20] with females demonstrating higher pain sensitivity via lower tolerance to pressure pain under some experimental conditions [24]. It has also been reported that, from a clinical standpoint, pain is more prevalent in females, who are also likely to experience pain more severely [25-26].

For this study, the change in PPT in both extra-trigeminal and trigeminal locations via orthodontic intervention in the trigeminal location were investigated and evaluated. It was found that inducing a stimulus in the trigeminal area via orthodontic intervention elicited significant changes in both trigeminal, as reported in previous studies [27-28]. Interestingly, in some participants, significant changes were found at extra-trigeminal areas.

Pressure pain threshold (PPT) at the thenar eminence (extra-trigeminal location) demonstrated a significant interaction between gender and study group. This suggests that the effect of study group (level of trait anxiety) on the PPT change at extra-trigeminal locations is dependent on gender. Although no differences were observed between males and females in the LA group, a significant difference was noted in the high anxiety (HA) study group. The change in PPT at extra-trigeminal locations was negative in female individuals with HA after the intervention suggesting that anxious females reduced their PPT becoming more sensitive, while the change in PPT at extra-trigeminal locations was positive in male individuals with HA after the intervention suggesting that HA males increased their PPT becoming less sensitive. Therefore, when submitting patients to orthodontic procedures, female individuals with HA became more sensitive at extra-trigeminal locations. This may be explained by the mechanism of eliciting pain in areas associated with the trigeminal nerve that secondarily functioned to sensitize the rest of the body (extra-trigeminal locations) [29-30]. Conversely, in male individuals with HA, there was a protective effect where repeated painful events experienced by male individuals resulted in an increased tolerance to pain. In healthy male individuals, this was the expected outcome, as continuous pain induction for five days will initiate adjustment of pain-associated mechanoreceptors, which manifest clinically as an increase in tolerance to pain [31]. Therefore, our study suggests that orthodontic treatment in female patients with HA may result in such patients developing a general increase in pain sensitivity. However, further studies with greater sample sizes are needed to address this question more specifically. In comparison, individuals with chronic pain lack the ability to adjust, which results in a reduction of PPT and ultimately a decreased tolerance to pain and the development of allodynia, which is

mostly due to central sensitization phenomena, which were not present in our study sample made of healthy participants.

PPT at the masseter muscle (trigeminal location) failed to exhibit an interaction with gender, but displayed an effect of study group. Individuals with HA whether male or female demonstrated a decrease in PPT after the intervention at the masseter muscle. Contrastingly, PPT at the temporalis muscle (trigeminal location) failed to exhibit an interaction with study group, but displayed an effect of gender with only male individuals becoming less sensitive and female individuals demonstrating no change. For the temporalis muscle, it seems that level of trait anxiety has no role in change in PPT after the intervention. A plausible explanation on why an effect of study group was seen only in the masseter muscle and not in the temporalis muscle could be that the former is in closer proximity to the location of the elastomeric separator or that the motor response of induced clenching in the first two days secondary to elastomeric separator placement may have sensitized the masseter muscle more than the temporalis muscle. Hypersensitivity and hyposensitivity of orofacial structures to mechanical stimuli via PPT after orthodontic tooth movement has been examined by previous studies [21,32]. A highly significant, although small, decrease in the PPT of the masseter and temporalis muscles were found in healthy subjects 24 hours after exposure to an experimentally-induced orthodontic tooth pain secondary to orthodontic separators. This suggests that periodontal noxious stimuli may elicit neuroplastic changes in the central and peripheral nervous system [21]. A plausible explanation is that the application of orthodontic separators creates a peripheral inflammatory condition that stimulates the activity of nociceptive specific neurons in the trigeminal nucleus caudalis [33]. In another study, it was found that subjects demonstrated a significant alteration in the posture of the craniocervical axis secondary to a history of orthodontic treatment and this may account for differential interpretation of nociceptive signals by the trigeminal complex [32]. In a previous study [34], the effect of occlusal interferences on the PPT of the masseter and temporalis muscles in healthy subjects has been examined and it was found that neither the active nor the dummy occlusal interference resulted in significant changes in PPT of the masseter and anterior temporalis muscles. This suggests that healthy subjects were

able to adapt effectively to the occlusal interference without eliciting any associated somatosensory alterations. With that said, it can be postulated that neuroplastic changes are more likely a manifestation of the transient inflammatory pain secondary to orthodontic tooth movement rather than alterations in occlusion [27].

It has been previously established that experimentally induced orthodontic pain is greater in individuals with higher trait anxiety [9] and clenching oral parafunctional behaviours are more frequent in individuals with higher trait anxiety [9,35]. However, up to the present time, the function of oral parafunctional behaviours with respect to trait anxiety and orthodontic pain perception has been marginally explored. It was hypothesized that the relationship between trait anxiety and tooth pain is dependent on the frequency of wake-time tooth clenching during experimentally induced orthodontic tooth movement. It was found that the trait anxiety study groups each demonstrated a different response to tooth pain. This was also affected by clenching suggesting that trait anxiety and clenching interact with each other to affect tooth pain. It is conceivable that individuals with higher anxiety have more frequent wake-time clenching episodes [9,35] and these, in turn, may elicit further microtrauma [36-37] and manifest as increased tooth pain during orthodontic tooth movement [38]. Immediately after orthodontic intervention, in the first day, HA individuals had tooth pain similar to the LA group. Interestingly, this relationship does not hold true 48 hours after intervention. After day two, the group with HA had a greater decrease in pain (mean tooth pain) as compared to the group with LA. This finding also corresponded with a greater decrease in oral parafunctions (mean clenching) in the group with HA when compared to the group with LA, thus indicating an interaction and suggestion of a greater degree in avoidance behaviour in HA individuals. In other words, two days after orthodontic intervention, individuals with HA may have experienced less pain than individuals with LA as a result of a decrease in oral parafunctions in individuals with HA. Specifically, the drop in tooth pain was noted between day two and day three, whereas the drop in wake-time tooth clenching was noted between day one and day two, which suggests the likelihood of an avoidance behaviour that occurs before the reduction in tooth pain is manifest. This phenomenon may be attributed to the fundamental role anxiety has in

aggravating pain-related fear [15] which, in turn, has been revealed to possess a critical role in avoidance behaviour [16-18]. Moreover, anxiety may be manifested through hypervigilance, which is associated with focused environmental scanning for potential sources (orthodontic intervention) of danger (tooth pain) that, in turn, may trigger the preventative behaviour of avoidance [39]. This confirms our hypothesis in that the relationship between trait anxiety and tooth pain is dependent on clenching or oral parafunctional behaviours, and that the motor response to a painful stimulus depends on individual anxiety levels.

From a clinical standpoint, STAI (trait anxiety) [10] and OBC (oral parafunctional behaviours [12,40] questionnaires completed chair-side by a patient prior to orthodontic intervention provides baseline data that can be utilized to estimate affect on predicted tooth pain secondary to orthodontic intervention. This study confirms that trait anxiety alone cannot predict tooth pain. Trait anxiety interacts with oral parafunctional behaviours to affect orthodontic pain.

There are a few limitations to this study. Firstly, the sample assessed is composed entirely of university students with a limited age range that may not be representative of the general population. Secondly, ethnic, racial, and cultural factors have been reported to influence PPTs [41]. In general, when compared with individuals of European descent, African-Americans tend to exhibit lower pain tolerance and report greater pain sensitivity to experimental pain stimuli [42-43]. Additionally, psychosocial factors such as anxiety and hypervigilance may contribute to differences in pain sensitivity between ethnicities [42,44-45]. Nevertheless, although our study sample included university students from a multitude of different races and ethnicities, we decided not to include them in the statistical analysis for reasons attributed to a limited sample size as controlling for this may have significantly affected the power of our investigation. Also, in this study we used paper-based diaries, which could have increased the chances of recall bias [46-47]. Interestingly, experimental changes in the dental occlusion have been shown to determine neuroplastic changes in the primary somatosensory cortex (S1) and motor cortex (M1) in animal models [48]. Therefore, it could be possible that

such changes are present also in humans subjected to changes in the dental occlusion. Therefore, Magnetic Resonance Imaging (MRI) may be used to scan the brain of volunteers submitted to the experimental model before and after the intervention. This assessment will characterize the neuroplastic changes occurring in the somatosensory cortex of these individuals and allow for assessing whether the neuroplastic changes occurring in the brain following an experimental fully reversible modification of the intra-oral environment (orthodontic elastomeric separators) producing orthodontic pain are dependent on the level of anxiety of the individual.

7.1.7 Conclusion

Tonic painful stimuli in the trigeminal region determine somatosensory alterations in both the muscles of mastication and at extratrigeminal locations in patients with increased anxiety levels. The relationship between anxiety and tooth pain experienced during experimental orthodontic tooth movement is dependent on the frequency of wake-time clenching episodes. Individuals with high trait anxiety reduce the frequency of clenching episodes in response to a painful stimulus in the periodontal ligament.

The reduction in clenching frequency could likely be seen as a fear-avoidance behaviour suggesting that acute orthodontic pain may trigger a fear-avoidance behaviour in individuals with high levels of anxiety. This may contribute to reducing parafunctional tooth clenching and orthodontic pain intensity over time, because of a reduced stimulation of the periodontal ligament.

7.1.8 Acknowledgments

7.1.9 References

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7.1.10 Figures and tables

Superficial Masseter
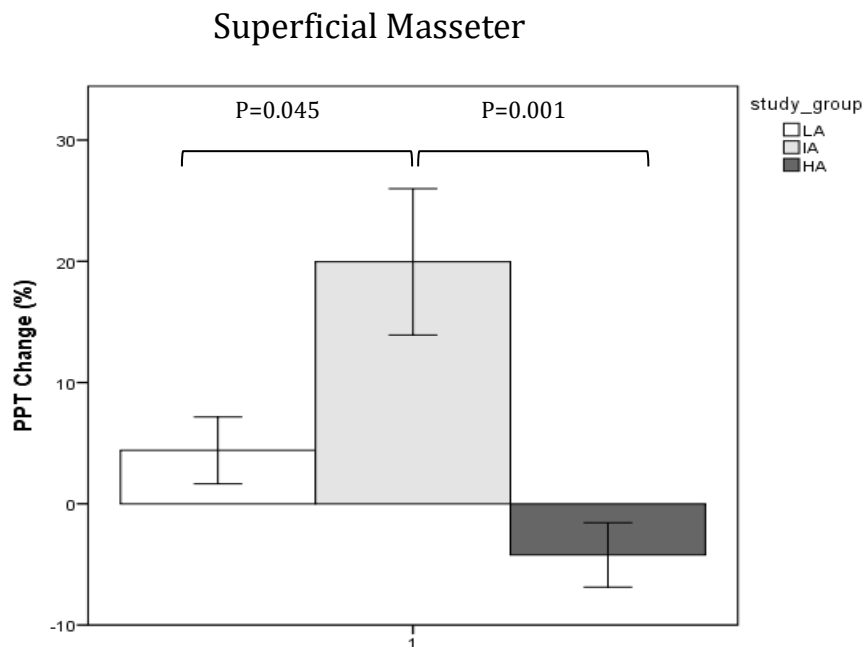
Figure 7-1. Pressure Pain Threshold (PPT) at the superficial masseter muscle (trigeminal location). Error bars indicate the standard error of mean.

Table 7-1. Results from the regression models with dependent variable of PPT change at the superficial masseter muscle (trigeminal location). Bold type: statistically significant.

Independent variables	PPT Change at Masseter Muscle F value (p value)
Gender	0.147 (0.703)
Group	**4.766 (0.011)**

Anterior Temporalis

P=0.021
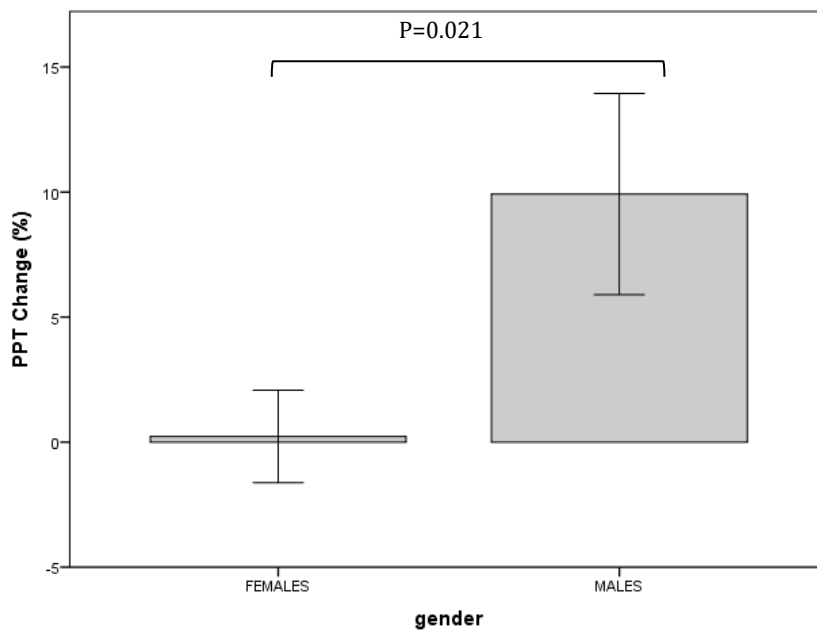
Figure 7-2. Pressure Pain Threshold (PPT) changes at the anterior temporalis muscle (trigeminal location). Error bars indicate the standard error of mean.

Table 7-2. Results from the regression models with dependent variable of PPT change at the anterior temporalis muscle (trigeminal location). Bold type: statistically significant.

Independent variables	PPT Change at Temporalis Muscle F value (p value)
Gender	5.491 (0.021)
Group	1.420 (0.248)

Thenar Eminence
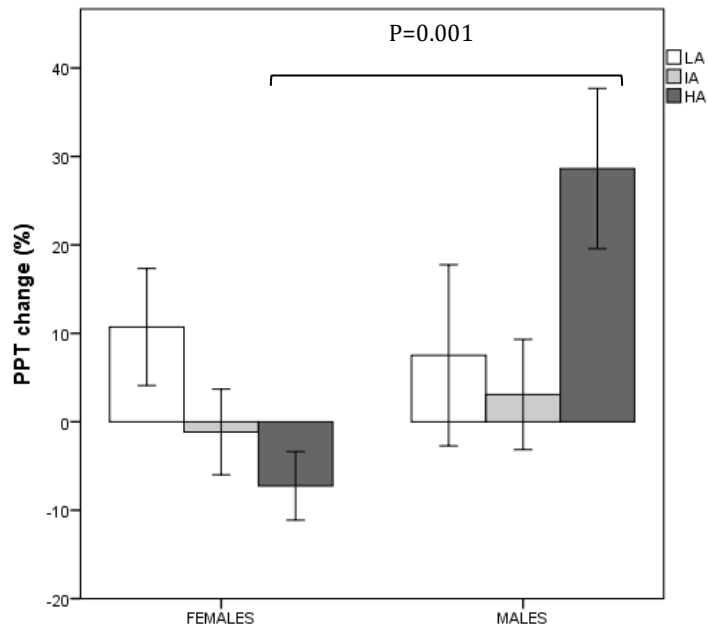
Figure 7-3. Pressure Pain Threshold (PPT) change at the thenar eminence (extra-trigeminal location). Error bars indicate the standard error of mean.

Table 7-3. Results from the regression models with dependent variable of PPT change at the thenar eminence (extra-trigeminal location). Bold type: statistically significant.

Independent variables	PPT Change at Thenar Eminence F value (p value)
Gender	4.068 (0.047)
Group	0.885 (0.417)
Gender*Group	**4.166 (0.019)**
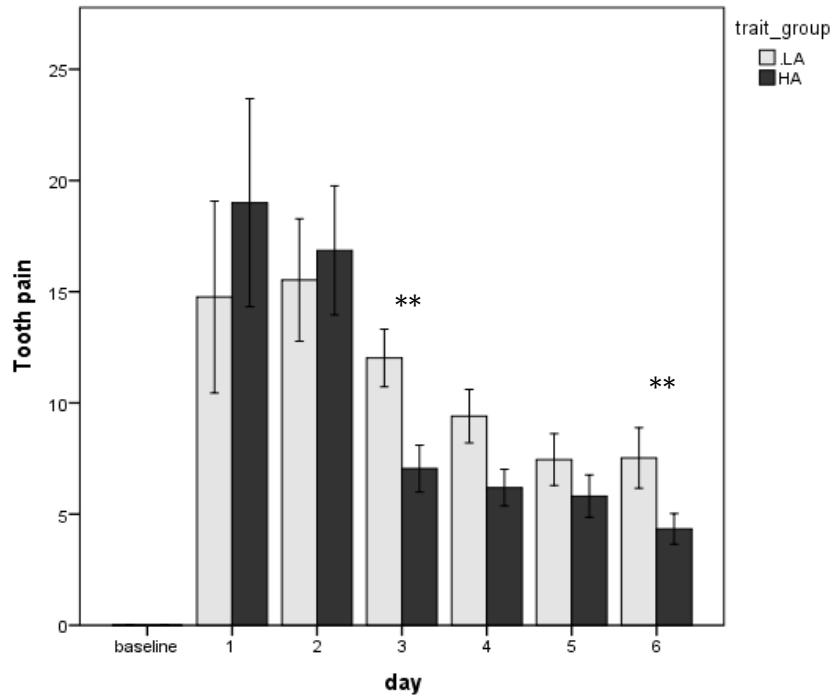
Figure 7-4. Intervention determined tooth pain over a six-day span with low anxiety (LA) group in light grey and high anxiety group (HA) in black. Error bars indicate the standard error of mean.
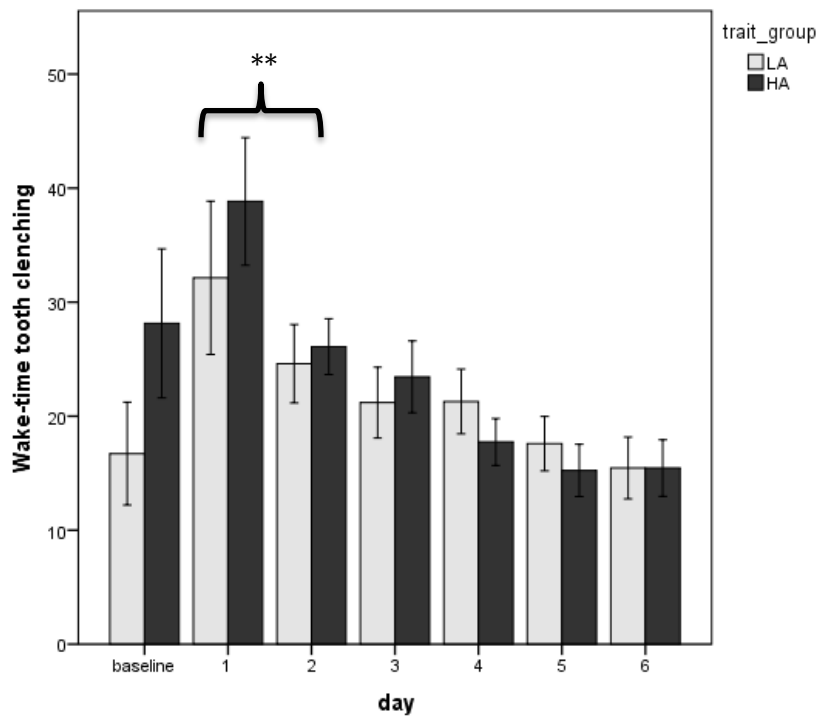
Figure 7-5. Wake-time tooth clenching over a six-day span with low anxiety (LA) group in light grey and high anxiety group (HA) in black. A significant change was found between day 1 and 2. Error bars indicate the standard error of mean

Table 7-4. Results from the regression models with dependent variable of tooth pain. Bold type: statistically significant.

Independent variables	Tooth Pain F value (p value)
Day	2.077 (0.067)
Trait group	**14.518 (<0.001)**
Clenching	**11.987 (0.001)**
Gender	**9.923 (0.002)**
Stress	**22.508 (<0.001)**
Day*Trait group*Clenching	**3.198 (<0.001)**
Trait group*Gender	3.193 (0.075)

DAY: #__/5   TIME OF SEP PLACEMENT: NAME:

TOOTH PAIN (How severe is your tooth pain today? Place a vertical mark on the line below to indicate how bad you feel your tooth pain is today)

10:00AM   1————————————————1
            0   VAS (mm)   100

04:00PM   1————————————————1
            0   VAS (mm)   100

10:00PM   1————————————————1
            0   VAS (mm)   100

TOOTH CONTACT/FREQUENCY OF CLENCHING (How often did you clench or hold your tooth together in the last six hours? (0 – none of the time, 100 – most of the time)

10:00AM   1————————————————1
            0   VAS (mm)   100

04:00PM   1————————————————1
            0   VAS (mm)   100

10:00PM   1————————————————1
            0   VAS (mm)   100

PERCEIVED STRESS (How severe is your perceived stress today? Place a vertical mark on the line below to indicate how bad you feel your perceived stress is today)

10:00AM   1————————————————1
            0   VAS (mm)   100

04:00PM   1————————————————1
            0   VAS (mm)   100

10:00PM   1————————————————1
            0   VAS (mm)   100

Figure 7-6. Custom-made pain diary to monitor three variables (tooth pain, perceived stress, and frequency of tooth clenching) with visual analogue scales (VAS) logged three times per day (10:00, 16:00, 22:00) over the course of five days.

8   General Discussion

Patients report orthodontic pain during various points of their orthodontic therapy, and it has been considered one of the main etiological factors for discontinuation of care or early termination of treatment (Cozzani et al. 2015; Krishnan 2007). Based on current literature, patient compliance is strongly attenuated by orthodontic pain, and thus compromises the effectiveness and efficiency of orthodontic therapy (Ukra et al. 2011). Reduced patient compliance surmounts to prolonged treatment duration, which amounts to supplemental costs to both the healthcare provider and patient. It is unfortunate that this issue still stands amidst the widespread availability of the most innovative orthodontic diagnostic and treatment modalities. Therefore, it would be advantageous if the healthcare provider were able to utilize some robust means to detect individuals who may be prone to reduced compliance during orthodontic therapy.

The web-survey was a retrospective study that assessed the general relationship between trait anxiety, somatosensory amplification, and facial pain on self-reported frequency of oral parafunctional behaviors. It investigated the prevalence of oral behaviors in university students and tested the association between trait anxiety, somatosensory amplification and oral behaviors. In addition, it evaluated whether facial pain affected this relationship. It is known that oral behaviors and painful TMD are associated (Cioffi et al. 2017; Michelotti et al. 2010; Ohrbach et al. 2013) since such behaviors require a sustained and repetitive contraction of the jaw muscles, which may result in muscle overload, local ischemia, and pain (Delcanho et al. 1996; Suzuki et al. 2016). Trait anxiety was found to be positively associated with oral behaviors, which follows the concept that the frequency of oral behaviors is increased in subjects with a more anxious personality disposition (Cioffi et al. 2016; Endo et al. 2011; Manfredini and Lobbezoo 2009; Michelotti et al. 2012). Our study also demonstrated a positive association between the constructs of somatosensory amplification and oral behaviors. Furthermore, the survey confirmed that the relationship between somatosensory amplification, trait anxiety and oral behaviors is heightened in individuals with concurrent facial TMD pain. Specifically, our regression model showed a significant

interaction effect between trait anxiety and facial pain, which suggests that pain has an additive effect on the relationship between anxiety and oral behaviors: people with high levels of trait anxiety present a greater frequency of oral behaviors if pain is present. Moreover, the stronger relationship we found between somatosensory amplification and oral behaviors in individuals with facial TMD pain contributes to explain the general framework that links painful temporomandibular disorders to increased occlusal awareness (Palla and Klinenberg 2015).

The longitudinal behavioural study evaluated the relationship between anxiety and orthodontic pain using a longitudinal experiment to analyze how wake-time tooth clenching affects the relationship between trait anxiety and orthodontic tooth pain that has been experimentally induced. This allowed for interpretation of whether orthodontic pain is dependent on the frequency of wake-time tooth clenching during experimentally induced orthodontic tooth movement. It was found that trait anxiety and tooth clenching interact with each other to affect orthodontic pain. Specifically, two days after orthodontic intervention, individuals with HA experienced less pain than individuals with LA as a result of a decrease in oral parafunctions in individuals with HA. Particularly, the drop in tooth pain was noted between day two and day three, whereas the drop in wake-time tooth clenching was noted between day one and day two, which suggests the likelihood of an avoidance behaviour that occurs before the reduction in tooth pain is manifest. This phenomenon may be attributed to the fundamental role anxiety has in aggravating pain-related fear (Asmundson and Taylor 1996) which, in turn, has been revealed to possess a critical role in avoidance behaviour (McCracken et al. 1993; McCracken et al. 1992; Waddell et al. 1993).

9   Conclusions

This research has demonstrated that anxiety and jaw muscle motor response to changes in dental occlusion interact to affect orthodontic pain perception. The relationship between anxiety and tooth pain experienced during experimental orthodontic tooth movement is dependent on the frequency of wake-time clenching

episodes. Individuals with high trait anxiety reduce the frequency of clenching episodes in response to a painful stimulus in the periodontal ligament. This avoidance behavior contributes to a reduced orthodontic pain experience.

Additionally, tonic painful stimuli in the trigeminal region may determine somatosensory alterations in both the muscles of mastication and at extratrigeminal locations, especially in those reporting high levels of anxiety.

It is known that orthodontic pain influences patient compliance. Therefore, in order to mitigate the painful experience secondary to orthodontic therapy, and in turn enhance patient compliance, clinicians should contemplate to conduct a complete evaluation of a given patient's psychological factors in order to identify specific characteristics, such as anxiety, which can affect the perception of pain during treatment. From a clinical standpoint, STAI (trait anxiety) (Spielberger 1983) and OBC (oral parafunctional behaviours) (Markiewicz et al. 2006; Ohrbach et al. 2008) questionnaires completed chair-side by a patient prior to orthodontic therapy can provide baseline data that may be used to estimate affect on predicted tooth pain secondary to orthodontic intervention.

10   Future Directions

Neuroplasticity is defined as the ability of the Central Nervous System (CNS) to assume adaptations both structurally and functionally in response to novel experiences (Warraich and Kleim 2010) and can be detected in humans with functional Magnetic Resonance Imaging (fMRI) (Kleim and Jones 2008). Experimental changes in the dental occlusion have been shown to determine neuroplastic changes in the primary somatosensory cortex (S1) and motor cortex (M1) in animal models (Avivi-Arber et al. 2015). Hence, future extensions of this study plan to utilize Magnetic Resonance Imaging (MRI) to scan the brain and the masticatory muscles of participants before and after an experimental orthodontic tooth movement. This will permit determining whether the neuroplastic changes that occur in the brain following an experimental and fully-

reversible modification of the intra-oral environment (via application of orthodontic elastomeric separators) producing orthodontic tooth pain are dependent on the level of anxiety of the individual.

11   References

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12 Appendices

12.1 Ethics Approval

UNIVERSITY OF TORONTO

OFFICE OF THE VICE-PRESIDENT, RESEARCH AND INNOVATION

PROTOCOL REFERENCE # 32797

June 2, 2016

████████████████████████

FACULTY OF DENTISTRY   FACULTY OF DENTISTRY

Dear ████████████

Re: Your research protocol entitled, "Effects of anxiety and daytime clenching on orthodontic pain perception"

ETHICS APPROVAL	Original Approval Date: June 2, 2016 Expiry Date: June 1, 2017 Continuing Review Level: 2

We are writing to advise you that the Health Sciences Research Ethics Board (REB) has granted approval to the above-named research protocol, for a period of one year. Ongoing research under this protocol must be renewed prior to the expiry date.

Any changes to the approved protocol or consent materials must be reviewed and approved through the amendment process prior to its implementation. Any adverse or unanticipated events in the research should be reported to the Office of Research Ethics as soon as possible.

Please ensure that you submit an Annual Renewal Form or a Study Completion Report 15 to 30 days prior to the expiry date of your current ethics approval. Note that annual renewals for studies cannot be accepted more than 30 days prior to the date of expiry.

If your research is funded by a third party, please contact the assigned Research Funding Officer in Research Services to ensure that your funds are released.

Best wishes for the successful completion of your research.

Yours sincerely,

████████████

REB Chair

Research Oversight and Compliance Office - Human Research Ethics Program
McMurrich Building, 12 Queen's Park Crescent West, 2nd Floor, Toronto, ON M5S 1S8 Canada
Tel: +1 416 946-3273 ● Fax: +1 416 946-5763 ● ethics.review@utoronto.ca ● http://www.research.utoronto.ca/for-researchers-administrators/ethics/
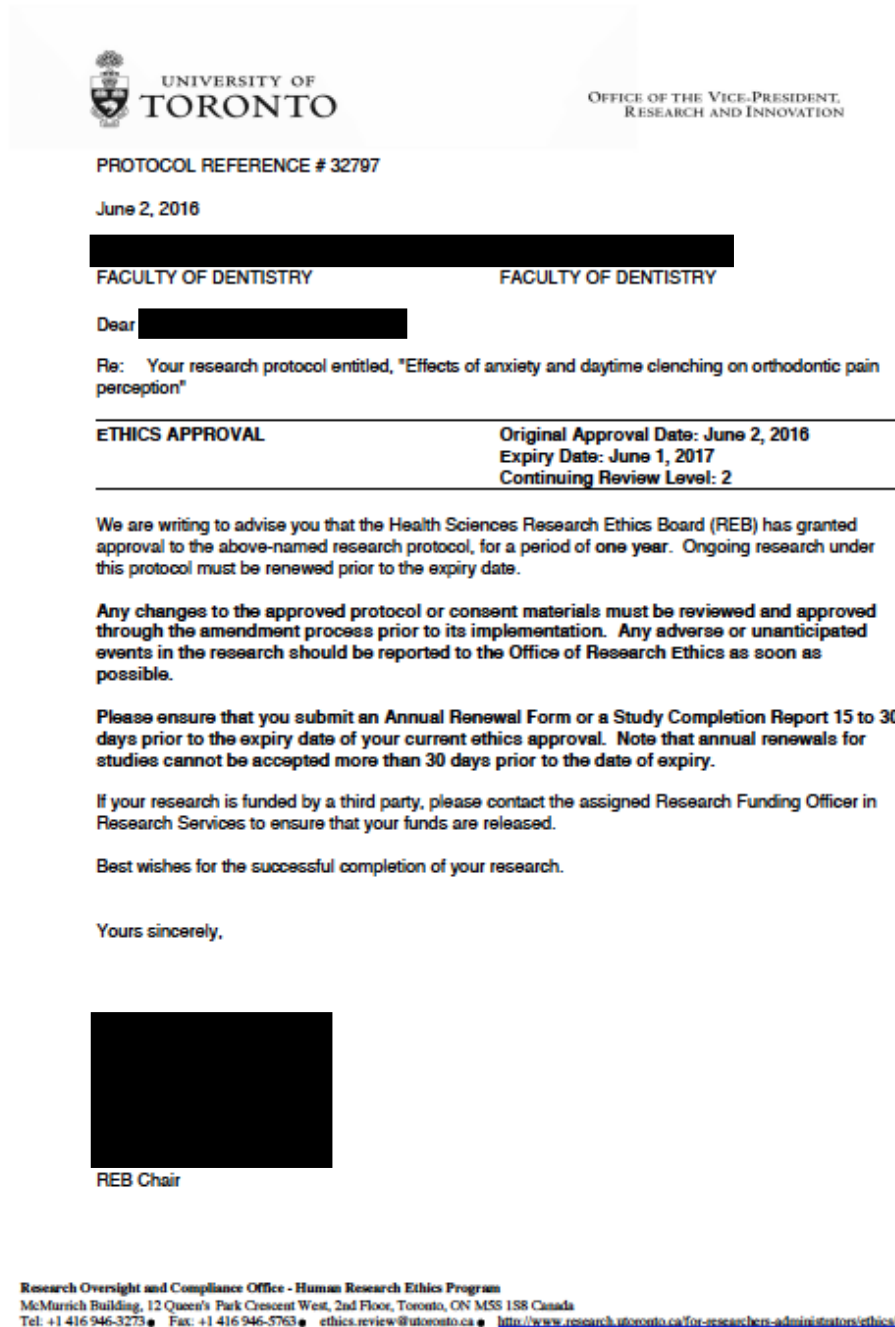
Figure 12-1. Ethics Approval from the Health Sciences Research Ethics Board (REB) from the University of Toronto.

12.2 Web-Survey Questionnaires

Diagnostic Criteria for Temporomandibular Disorders
Demographics (*questions modified or added by the investigators)

1. What is your current marital status?
   ☐ Married
   ☐ Living as married
   ☐ Divorced
   ☐ Separated
   ☐ Widowed
   ☐ Never married

2. What is your ethnicity*?
   ☐ Canadian
   ☐ French
   ☐ English
   ☐ German
   ☐ Scottish
   ☐ Irish
   ☐ Italian
   ☐ Ukrainian
   ☐ Dutch (Netherlands)
   ☐ Chinese
   ☐ Jewish
   ☐ Polish
   ☐ Portuguese
   ☐ South Asian (e.g., East Indian, Pakistani, Sri Lankan, etc.)
   ☐ Norwegian
   ☐ Welsh
   ☐ Swedish
   ☐ First Nations (North American Indian)
   ☐ Métis
   ☐ Inuit
   ☐ Other - Specify

3. What is your race? Mark all that apply*.
   ☐ Aboriginal/First Nations
   ☐ White
   ☐ South Asian (e.g., East Indian, Pakistani, Sri Lankan, etc.)
   ☐ Chinese
   ☐ Black
   ☐ Filipino

Figure 12-2. Questionnaire 1: Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Demographics Questionnaire (RDC/TMD). An asterisk indicates questions modified or added by the investigator. Page 1/3.

☐Latin American
☐Arab
☐Southeast Asian (e.g., Vietnamese, Cambodian, Malaysian, Laotian, etc.)
☐West Asian (e.g., Iranian, Afghan, etc.)
☐Korean
☐Japanese
☐Other

4. What is the highest grade or level of schooling that you have completed?*
☐Less than high school diploma or its equivalent
☐High school diploma or a high school equivalency certificate
☐College, CEGEP or other non-university certificate or diploma
☐University certificate or diploma below the bachelor's level
☐Bachelor's degree (e.g., B.A., B.Sc.)
☐University certificate, diploma, degree above the bachelor's level

5. What is your family's current annual household income? Please include all sources of income for all family members such as wages, salaries, investments, etc*.
☐No income
☐$15,000-$29,999
☐$30,000-$49,999
☐$50,000-$79,999
☐$80,000 -$99,999
☐$100,000 -$119,999
☐$120,000 or more

6. Do you have any neurologic or metabolic disorders?
☐Yes
☐No
☐Maybe/Unsure

7. Do you habitually use any of the following analgesics*?
☐NSAIDs (i.e., Advil, Motrin, Nuprin, Aleve, Naprosyn, Celebrex)
☐Acetaminophen (i.e., Tylenol, Paracetamol)
☐Opioids (i.e., codeine, fentanyl, hydrocodone, methadone)
☐Anti-epileptics (i.e., Clonazepam, Gabapentin, Lamotrigine, Phenytoin)

8. Do you have fibromyalgia or recurrent headaches?
☐Yes
☐No
☐Maybe/Unsure

9. Do you have any of the following pre-existing orofacial pain?
☐Dental
☐Periodontal
☐Joint/TMJ
☐Muscle/Myofascial

Figure 12-3. Questionnaire 1: Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Demographics Questionnaire (RDC/TMD). An asterisk indicates questions modified or added by the investigator. Page 2/3.

☐None

10. Do you have any of the following pre-existing pain elsewhere in the body?
☐Head
☐Neck
☐Shoulder
☐Back
☐Chest
☐Thorax
☐Abdomen
☐Umbilicus
☐Upper Limb
  ☐Arm
  ☐Elbow
  ☐Forearm
  ☐Wrist
  ☐Hand
  ☐Fingers
☐Pelvic
☐Lower Limb
  ☐Thigh
  ☐Knee
  ☐Leg
  ☐Calf
  ☐Ankle
  ☐Foot
  ☐Toes
☐Elsewhere
☐None

11.   Did you have braces?*
  ☐No
  ☐Yes
  ☐I have braces now
  ☐I will have them soon

12. Do you have a removable or fixed dental prosthesis (bridge with at least three teeth)?*
  ☐No
  ☐Yes

Figure 12-4. Questionnaire 1: Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) Demographics Questionnaire (RDC/TMD). An asterisk indicates questions modified or added by the investigator. Page 3/3.

TMD-PAIN SCREENER

1. In the last 30 days, which of the following best describes any pain in your jaw or temple area on either side?

    a.   No pain
    b.   Pain comes and goes
    c.   Pain is always present

2. In the last 30 days, have you had pain or stiffness in your jaw on awakening?
    a.   No
    b.   Yes

3. In the last 30 days, did the following activities change any pain (that is, make it better or make it worse) in your jaw or temple area on either side?

    A.   Chewing hard or tough food
        a.   No
        b.   Yes

    B.   Opening your mouth or moving your jaw forward or to the side
        a.   No
        b.   Yes

    C.   Jaw habits such as holding teeth together, clenching/grinding, or chewing gum
        a.   No
        b.   Yes

    D.   Other jaw activities such as talking, kissing, or yawning
        a.   No
        b.   Yes

Items 1-3A represent the short screener, and items 1-3D represent the long screener. An 'a' response is 0 points, a 'b' response is 1 point, and a 'c' response is 2 points. See publication for scoring cutoffs.

Gonzalez YM, Schiffman E, Gordon SM, Seago B, Truelove ET, Slade G, Ohrbach R (2011). Development of a brief and effective temporomandibular disorder pain screening questionnaire: reliability and validity. JADA 142:1183-1191.

Figure 12-5. Questionnaire 2: The TMD-Pain Screener (Schiffman et al. 2014).

DIRECTIONS:

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

	NOT AT ALL	SOMEWHAT	MODERATELY SO	VERY MUCH SO
1. I feel calm.	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

Figure 12-6. Questionnaire 3: The State-Trait Anxiety Inventory (STAI): state anxiety version (Spielberger 1983).

DIRECTIONS

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe how you generally feel.

	ALMOST NEVER	SOMETIMES	OFTEN	ALMOST ALWAYS
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am "calm, cool, and collected"	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn't matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Figure 12-7. Questionnaire 3: The State-Trait Anxiety Inventory (STAI): trait anxiety version (Spielberger 1983).

The Oral Behavior Checklist

How often do you do each of the following activities, based on **the last month**? If the frequency of the activity varies, choose the higher option. Please place a (√) response for each item and do not skip any items.

	Activities During Sleep	None of the time	< 1 Night /Month	1-3 Nights /Month	1-3 Nights /Week	4-7 Nights/ Week
1	Clench or grind teeth **when asleep**, based on any information you may have	☐	☐	☐	☐	☐
2	Sleep in a position that puts pressure on the jaw (for example, on stomach, on the side)	☐	☐	☐	☐	☐

	Activities During Waking Hours	None of the time	A little of the time	Some of the time	Most of the time	All of the time
3	Grind teeth together **during waking hours**	☐	☐	☐	☐	☐
4	Clench teeth together **during waking hours**	☐	☐	☐	☐	☐
5	Press, touch, or hold teeth together other than while eating (that is, contact between upper and lower teeth)	☐	☐	☐	☐	☐
6	Hold, tighten, or tense muscles without clenching or bringing teeth together	☐	☐	☐	☐	☐
7	Hold or jut jaw forward or to the side	☐	☐	☐	☐	☐
8	Press tongue forcibly against teeth	☐	☐	☐	☐	☐
9	Place tongue between teeth	☐	☐	☐	☐	☐
10	Bite, chew, or play with your tongue, cheeks or lips	☐	☐	☐	☐	☐
11	Hold jaw in rigid or tense position, such as to brace or protect the jaw	☐	☐	☐	☐	☐
12	Hold between the teeth or bite objects such as hair, pipe, pencil, pens, fingers, fingernails, etc	☐	☐	☐	☐	☐
13	Use chewing gum	☐	☐	☐	☐	☐
14	Play musical instrument that involves use of mouth or jaw (for example, woodwind, brass, string instruments)	☐	☐	☐	☐	☐
15	Lean with your hand on the jaw, such as cupping or resting the chin in the hand	☐	☐	☐	☐	☐
16	Chew food on one side only	☐	☐	☐	☐	☐
17	Eating between meals (that is, food that requires chewing)	☐	☐	☐	☐	☐
18	Sustained talking (for example, teaching, sales, customer service)	☐	☐	☐	☐	☐
19	Singing	☐	☐	☐	☐	☐
20	Yawning	☐	☐	☐	☐	☐
21	Hold telephone between your head and shoulders	☐	☐	☐	☐	☐

Figure 12-8. Questionnaire 4: The Oral Behavioural Checklist (OBC) (Markiewicz et al. 2006).

Somatosensory Amplification Scale.(SSAS)					
	Not at all	A little	Moderately	Quite a bit	Extremely
Sudden loud noises really bother me	0	1	2	3	4
I hate to be too hot or too cold	0	1	2	3	4
I have a low tolerance for pain	0	1	2	3	4
I am often aware of various things happening within my body	0	1	2	3	4
Sudden loud noises really bother me	0	1	2	3	4
I am a quick to sense the hunger contractions in my stomach	0	1	2	3	4
When someone else coughs,it makes me cough too	0	1	2	3	4
I can't stand smoke,smog,or pollutants in the air	0	1	2	3	4
I can sometimes hear my pulse or my heartbeat throbbing in my ear	0	1	2	3	4
Even something minor,like an insect bite or a splinter,really bothers me	0	1	2	3	4
When I bruise myself,it stays noticeable for a long time	0	1	2	3	4

Figure 12-9. Questionnaire 5: Somatosensory Amplification Scale (SSAS) (Barsky 1992).

Would you like to be contacted for further research studies?
YES / NO
Do you give the consent to use the data collected by means of the web survey for future studies?
YES / NO

Figure 12-10. Questionnaire 6: Data retention and participation to future research studies

12.3 Custom-Made Self-Report Pain Diary

DAY 1*

TOOTH PAIN (How severe is your tooth pain today? Place a vertical mark on the line below to indicate how bad you feel your tooth pain is today)

10:00   0   1————————————1   VAS (mm)   100

16:00   0   1————————————1   VAS (mm)   100

22:00   0   1————————————1   VAS (mm)   100

OCCLUSAL DISCOMFORT (How severely is your mouth bothered by the separators?) Place a vertical mark on the line below to indicate how bad you feel your occlusal discomfort is today)

10:00   0   1————————————1   VAS (mm)   100

16:00   0   1————————————1   VAS (mm)   100

22:00   0   1————————————1   VAS (mm)   100

TOOTH CONTACT/FREQUENCY OF CLENCHING How often did you clench or hold your teeth together in the last six hours (0 none of the time, 100 most of the time)

10:00   0   1————————————1   VAS (mm)   100

16:00   0   1————————————1   VAS (mm)   100

22:00   0   1————————————1   VAS (mm)   100

PERCEIVED STRESS (How severe is your perceived stress today? Place a vertical mark on the line below to indicate how bad you feel your perceived stress is today)

10:00   0   1————————————1   VAS (mm)   100

16:00   0   1————————————1   VAS (mm)   100

22:00   0   1————————————1   VAS (mm)   100

NOTES
10:00
16:00
22:00

Figure 12-11. Self-report tooth pain, occlusal discomfort, tooth contact/frequency of clenching, and perceived stress.

12.4 Website Disclaimer, Privacy Code and Patient Consent

WEBSITE DISCLAIMER

Welcome to this Web survey!

Thank you for agreeing to take part to this research.

This survey aims to evaluate the relationship between oral parafunctional behaviours (tooth clenching, grinding, gum chewing etc.) and anxiety, and to recruit volunteers with specific characteristics, who will be contacted to participate in a clinical research study. The questionnaire will assess the frequency of your oral parafunctional behaviours and some psychological aspects. You will answer also general questions concerning your ethnicity, health, use of medication, income, that are known to be related to individual pain sensitivity. We kindly ask you to give accurate and honest answers to help us with our research.

This survey should take not more than 20 minutes to be completed. Please be assured that the survey is anonymous and all answers you provide will be kept in the strictest confidentiality. This website uses SSL Encryption to protect any data you send during the survey process. The browser will display a message informing you that you are entering a secure area. The message appearing depends on whether your Internet browser preferences have been set to show this or not. You will be required to insert your email address to receive an ID and to participate. Your email will be kept confidential and will not be released to any third person for commercial or other purposes.

You will be allowed to leave the multiple-choice questionnaires at any moment, and to complete them at a later session (for instance at a different hour of the same day or on a different day entirely) by using your email and password for login. Upon successful completion of the survey, an email will be sent to you confirming such completion. The system will accept one attempt (one fully completed web survey) from each and every registered participant with an U of T email.

By giving your response to the survey, you will be entered into a prize drawing:

15 gift cards valued at $20 CAN each (coffee gift card)
10 gift cards valued at $50 CAN each (coffee gift card)
3 gift cards valued at $100 CAN each (participant's choice of on-line store gift card)

Our goal is to receive 300 completed surveys. The drawing will take place at the conclusion of the survey period, and winners will be notified immediately. The investigators will follow the 1:10 ratio rule (1 prize, 10 participants) if the number of participants in the web survey exceeds the target of 300.

After having completed the survey (PART 1 of the research study), we will assess if you are eligible for our clinical research study (PART 2 of the research study), which aims to evaluate the effects of parafunctional oral habits (daytime clenching, grinding etc.) and anxiety on orthodontic pain sensitivity. You may be contacted to participate in the clinical phase of the study and express your willingness or refusal to participate. Participation in research is voluntary. You can choose to participate in the whole study (Part 1 and Part 2), part of the study (Part 1) or choose not to participate at all.

Further instructions will be sent to you by email if you are eligible for our clinical research.

In consideration of the disclosure of Information by the participants to the principal investigator authoring this web survey (the Receiving Party), the receiving party hereby agrees:

1. To hold the Information in strict confidence and to take all reasonable precautions to protect such information. All data will be stored in a remote server and transferred to the Faculty of Dentistry, University of Toronto

2. Not to disclose any personal information to any third parties

Figure 12-12. Website disclaimer for web survey evaluating the relationship between oral parafunctional behaviours and anxiety, and to recruit volunteers with specific characteristics. Page 1/2.

3. Not to make any use whatsoever at any time of such information except to conduct the current research study as described above.

At the end of the web-survey, you will be asked to give the consent to having the data collected from the web survey to be retained for future studies, and if you are willing to be contacted for future research studies different from these listed in the present disclaimer.

A summary of the results of the current research study can be requested by sending an email to █████████

The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study-related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team.

Contact information:

█████████

You can contact the Office of Research Ethics of the University of Toronto if you have questions about your rights as a research participant-(ethics.review@utoronto.ca - phone 416 946 3273).

☐ By accessing and using this website, you expressly acknowledge that you have read and understood this "Disclaimer" page and agree, on behalf of yourself, if applicable, to be bound by its terms. Please click next to accept to participate to the survey and begin

[Start the Web-based Evaluation Start Test]

Figure 12-13. Website disclaimer for web survey evaluating the relationship between oral parafunctional behaviours and anxiety, and to recruit volunteers with specific characteristics. Page 2/2.
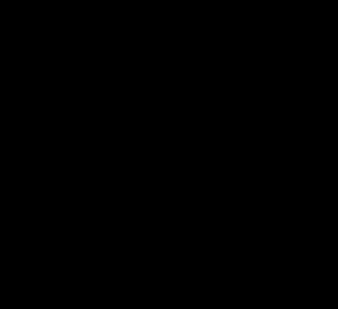
UNIVERSITY OF TORONTO
FACULTY OF DENTISTRY

PRIVACY CODE FOR THE FACULTY OF DENTISTRY, UNIVERSITY OF TORONTO

INTRODUCTION

Privacy of personal information is an important principle in the provision of quality dental care to our patients. We understand the importance of protecting your personal information. We are committed to collecting, using and disclosing your personal information responsibly. We also try to be as open and transparent as possible about the way we handle your personal information.

We have tried to make our office Privacy Code as easy to understand as possible. To ensure that you see how we are complying with the federal privacy legislation, the *Personal Information and Protection and Electronic Documents Act* (PIPEDA), our Privacy Code is organized to follow the Act's ten interrelated principles that are the foundation of PIPEDA.

DEFINITIONS

Collection – The act of gathering, acquiring or obtaining personal information from any source, including third party sources by any means

College – Royal College of Dental Surgeons of Ontario

Consent – A voluntary agreement with what is being done or is being proposed to be done. Consent can either be express or implied. Express consent may be given explicitly, either orally or in writing.

Disclosure – Making personal information available to others besides the dentist or the dental team.

Legislation – The *Regulated Health Professions Act* (RHPA), Schedules attached, *Dentistry Act*, Regulations made under these Acts, and By-laws of the College, and the *Personal Information Protection and Electronic Documents Act* (PIPEDA)

Member – A member of the Royal College of Dental Surgeons of Ontario and this includes a health profession corporation

Faculty – The Faculty of Dentistry and when referencing access to information, to the Privacy Information Officer, and the Faculty of Dentistry

Patient – An individual about whom the dentist collects personal information in order to carry out prognosis, diagnosis, and treatment, including controlled acts

Personal Information – Information about a patient that is recorded in any form, and this includes: the patient's name, address, telephone number, social insurance number, fax number, e-mail address, gender, marital status, children, date of birth, occupation, medical records, health records, insurance company, insurance coverage, history, occupation, place of work, employer

RHPA Procedural Code - The Health Professions Procedural Code, Schedule 2 to the *Regulated Health Professions Act (RHPA)* **PIPEDA PRINCIPLES**

Principle 1: Accountability
Any dentist in this Faculty is responsible for information collected by him/her, or under his/her direction, and under his/her control.

Accountability for this Faculty's compliance rests with the designated individual or individuals, even though others in the Faculty may be responsible for the day-to-day collection and processing of personal information.

The identity of the individual designated by the Faculty to oversee the compliance, the Privacy Information Officer, will be made known upon request.

This Faculty is responsible for information in our possession or custody, including information that has been transferred to a third party for processing. We will use contractual or other means to provide a comparable level of protection while the information is being accessed and/or processed by that third party.

Our Faculty will implement policies and practices to give effect to the principles, including:
- implementing policies to protect personal information;
- establishing procedures to receive and respond to complaints and inquiries;
- training staff about privacy policies and practices;
- developing information to explain privacy policies and procedures.

124 Edward Street   Toronto Ontario   M5G 1G6   FAX (416) 979-4936   1/4

Figure 12-14. Privacy Code for the Faculty of Dentistry at the University of Toronto. Page 1/4.

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Principle 2: Identifying Purposes for Collecting Information

The purposes for which personal information is collected in this Faculty will be identified before or at the time the information is collected.

This Faculty collects personal information for the following purposes:

- to deliver safe and efficient patient care
- to identify and to ensure continuous high quality service
- to assess your health needs
- to provide health care
- to advise you of treatment options
- to enable us to contact you
- to establish and maintain communication with you
- to offer and provide treatment, care and services in relationship to the oral and maxillofacial complex and dental care generally
- to communicate with other treating health-care providers, including specialists and general dentists who are the referring dentists and/or peripheral dentists
- to allow us to maintain communication and contact with you to distribute health-care information and to book and confirm appointments
- to allow us to efficiently follow-up for treatment, care and billing
- for teaching and demonstrating purposes on an anonymous basis
- for research and publication purposes on an anonymous basis to complete and submit dental claims for third party adjudication and payment
- to comply with legal and regulatory requirements, including the delivery of patients' charts and records to the College in a timely fashion, when required, according to the provisions of the *Regulated Health Professions Act*
- to comply with agreements/undertakings entered into voluntarily by the member with the Royal College of Dental Surgeons of Ontario, including the delivery and/or review of patients' charts and records to the College in a timely fashion for regulatory and monitoring purposes
- to deliver your charts and records to the dentist's insurance carrier to enable the insurance company to assess liability and quantify damages, if any
- to prepare materials for the Health Professions Appeal and Review Board (HPARB)
- to invoice for goods and services
- to process credit and debit card payments
- to collect unpaid accounts
- to assist this office to comply with all regulatory requirements
- to comply generally with the law

This Faculty will identify the purposes for which personal information is collected, at or before the time of collection. We will only collect that information necessary for the identified purposes.

When personal information has been collected and is to be used or disclosed for a purpose not previously identified, the new purpose will be identified prior to its use or the disclosure. Your consent is required before the information can be used or disclosed for that purpose.

Faculty staff collecting personal information will be able to explain to you the purpose for which the information is being collected.

When you sign the Patient Consent Form, you will be deemed to understand and accept this office's collection, use and disclosure of your information for the specified purposes.

Principle 3: Consent

This Faculty will seek informed consent for the collection, use and/or disclosure of personal information, except where it might be inappropriate to obtain your consent, and subject to some exceptions set out in law.

Consent is required for the collection of personal information and subsequent use or disclosure of that information.

In order for the principles of consent to be satisfied, our office has undertaken reasonable efforts to ensure that you are advised of the purposes for which information is being used, and that you understand those purposes. Once consent is obtained, we do not need to seek your consent again, unless the use, purpose or disclosure changes.

Existing protocols for electronic submissions of dental claims require a signature on file. Specific consent may be required for additional requests from insurers. This shall be collected at the time, or in conjunction, with predeterminations for extensive services, providing the scope of information released is disclosed. If there is any doubt, information shall be released directly to you for review and submission.

Consent for the collection, use and disclosure of personal information may be given in a number of ways, such as:

- signed medical history form;
- signed introductory questionnaire;
- taken verbally over the telephone and then charted;
- e-mail;
- written correspondence.

You may withdraw consent upon reasonable notice.

Figure 12-15. Privacy Code for the Faculty of Dentistry at the University of Toronto. Page 2/4.

Principle 4: Limiting Collection of Personal Information

The collection of personal information by our office shall be limited to that which is necessary for the purposes identified in this Privacy Code.

Principle 5: Limiting Use, Disclosure and Retention

Personal information shall not be used or disclosed for purposes other than those for which the information is collected, except with your express consent, or as required by law.

Our Faculty has protocols in place for the retention of personal information.

Retention of information records is defined and referenced in College's Guidelines on Dental Recordkeeping.

In destroying personal information, our Faculty has developed guidelines to ensure secure destruction in accordance with the College's Guidelines on Dental Recordkeeping.

Principle 6: Accuracy of Personal Information

This Faculty endeavours to ensure that your personal information is as accurate, complete, and as up-to-date as necessary for the purposes that it is to be used.

The extent to which your personal information shall be accurate, complete and up-to-date will depend upon the use of the information, taking into account the interest of our patients.

Information shall be sufficiently accurate, complete and up-to-date to minimize the possibility that inappropriate information is used to make a decision about you as our patient.

Principle 7: Safeguards for Personal Information

Our Faculty has taken appropriate measures to safeguard your personal information from unauthorized access, disclosure, use or tampering.

Safeguards are in place to protect your personal information against loss or theft, as well as unauthorized access, disclosure, copying, use or modification.

Your information is protected, whether recorded on paper or electronically.

Our staff and students are aware of the importance of maintaining the confidentiality of personal information.

Care is used in the care and destruction of personal information to prevent unauthorized access to the information even during disposal and destruction.

Principle 8: Openness about Privacy

Our Faculty will make readily available to you specific information about our Faculty policies and practices relating to the management of personal information.

This information includes:
- a Patient Information Sheet that outlines the name of the Privacy Information Officer who is accountable for our Faculty privacy policies. This is the person to whom you can direct any questions or complaints. The Information Sheet also describes how to access your personal information held in this office;
- a copy of our Patient Consent Form that explains how this Faculty collects, uses and discloses your personal information;
- our office Privacy Code

Principle 9: Patient Access to Personal Information

Upon written request and with reasonable notice, you shall be informed of the existence, use and disclosure of your personal information, and shall be given access to that information.

Upon written request and with reasonable notice, our Faculty will advise you whether or not we hold personal information about you.

Our Faculty shall allow you access to this information.

Upon written request and with reasonable notice, our Faculty shall provide you with an accounting of how your personal information has been used, including third party disclosures. In providing this information, we will attempt to be as specific as possible.

When it is not possible to provide a list of the organizations or individuals to which there has been disclosure about you, we will provide you with a list of such organizations or individuals to which we may have disclosed information about you. Disclosure of probabilities in these cases would satisfy this requirement.

We will respond to your request within a reasonable period of time, and at minimal or no cost to you. The request for information will be provided or made available in a form that is generally understandable.

Figure 12-16. Privacy Code for the Faculty of Dentistry at the University of Toronto. Page 3/4.

The dentist will comply with the regulations of his/her College that define patient access to records.

You are free to challenge the accuracy and completeness of the information and seek to have it altered, amended, or changed. This process is explained in the Patient Information Sheet.

When a challenge is not resolved to your satisfaction, we will record the substance of the unresolved challenge.

When appropriate, the existence of the unresolved challenge shall be transmitted to third parties having access to the information in question. This disclosure may be appropriate where a dentist has been challenged about a change to a service date or services rendered under consideration for insurance benefits.

Principle 10: Challenging Compliance
You shall be able to challenge compliance with these principles with the Faculty's Privacy Information Officer who is accountable within the dental office for the dentist's compliance. Our Faculty has in place procedures to receive and respond to your complaints or inquiries.

This information, including the name of our Faculty's Privacy Information Officer, is included in the Patient Information Sheet, available on request.

The procedures are easily accessible and simple to use.

Our Faculty has an obligation to inform our patients who make inquiries about how to access the privacy complaint process in our Faculty, and about how to access that process. This information is outlined in the Patient Information Sheet.

The Privacy Information Officer in our Faculty will investigate each and every complaint made to the office in writing.

If a complaint is found to be justified, the Privacy Information Officer will take appropriate measures, including, if necessary, amending any office policies and practices.

Patients will be provided with information about how to contact the Privacy Commissioner of Canada to forward any unresolved complaint. This information is included in the Patient Information Sheet, available on request.

Figure 12-17. Privacy Code for the Faculty of Dentistry at the University of Toronto. Page 4/4.

PATIENT CONSENT FORM:
FOR COLLECTION, USE AND DISCLOSURE
OF PERSONAL INFORMATION

Privacy of your personal information is an important part of our Faculty providing you with quality dental care. We understand the importance of protecting your personal information. We are committed to collecting, using and disclosing your personal information responsibly. We also try to be as open and transparent as possible about the way we handle your personal information. It is important to us to provide this service to our patients.

In this office, Dr. James Posluns, Director of Clinics acts as the Privacy Information Officer.

All staff members who come in contact with your personal information are aware of the sensitive nature of the information that you have disclosed to us. They are all trained in the appropriate uses and protection of your information.

Attached to this consent form, we have outlined what our office is doing to ensure that:

- only necessary information is collected about you;
- we only share your information with your consent;
- storage, retention and destruction of your personal information complies with existing legislation, and privacy protection protocols;
- our privacy protocols comply with privacy legislation, standards of our regulatory body, the Royal College of Dental Surgeons of Ontario, and the law.

Do not hesitate to discuss our policies with me or any member of our staff.

Please be assured that every staff person in our office is committed to ensuring that you receive the best quality dental care.

How Our Office Collects, Uses and Discloses Patients'
Personal Information

Our office understands the importance of protecting your personal information. To help you understand how we are doing that, we have outlined here how our office is using and disclosing your information.

This Faculty will collect, use and disclose information about you for the following purposes:

- to deliver safe and efficient patient care
- to identify and to ensure continuous high quality service
- to assess your health needs
- to provide health care
- to advise you of treatment options
- to enable us to contact you
- to establish and maintain communication with you
- to offer and provide treatment, care and services in relationship to the oral and maxillofacial complex and dental care generally
- to allow us to maintain communication and contact with you to distribute health-care information and to book and confirm appointments
- to allow us to efficiently follow-up for treatment, care and billing
- for teaching and demonstrating purposes on an anonymous basis
- for research and publication purposes on an anonymous basis
- to complete and submit dental claims for third party adjudication and payment
- to comply with legal and regulatory requirements, including the delivery of patients' charts and records to the Royal College of Dental Surgeons of Ontario in a timely fashion, when required, according to the provisions of the *Regulated Health Professions Act*
- to comply with agreements/ undertakings entered into voluntarily by the member with the Royal College of Dental Surgeons of Ontario, including the delivery and/or review of patients' charts and records to the College in a timely Fashion for regulatory and monitoring purposes
- to deliver your charts and records to the dentist's insurance carrier to enable the insurance company to assess liability and quantify damages, if any

Page 1 of 4

Figure 12-18. Patient Consent Form: for collection, use and disclosure of personal information at the Faculty of Dentistry, University of Toronto. Page 1/2.

- to prepare materials for the Health Professions Appeal and Review Board (HPARB)
- to invoice for goods and services
- to process credit or debit card payments
- to collect unpaid accounts
- to assist this office to comply with all regulatory requirements
- to comply generally with the law
- to communicate with other treating health-care providers, including specialists and general dentists who are the referring dentists and/or peripheral dentists and physician

The Faculty of Dentistry, University of Toronto, and its students and residents may use anonymous patient treatment records and other patient clinic information, including, for example, diagnostic information, x-rays and photos of treatment outcomes for academic and accreditation purposes such as teaching, publication and examinations, including those undertaken after graduation and/or outside the University of Toronto. Photos of treatment outcomes may show the patient's face.

By signing the consent section of this Patient Consent Form, you have agreed that you have given your informed consent to the collection, use and/or disclosure of your personal information for the purposes that are listed. If a new purpose arises for the use and/or disclosure of your personal information, we will seek your approval in advance.

Your information may be accessed by regulatory authorities under the terms of the *Regulated Health Professions* Act(RHPA) for the purposes of the Royal College of Dental Surgeons of Ontario fulfilling its mandate under the RHPA, and for the defence of a legal issue.

Our Faculty will not under any conditions supply your insurer with your confidential medical history. In the event this kind of a request is made, we will forward the information directly to you for review, and for your specific consent.

When unusual requests are received, we will contact you for permission to release such information. We may also advise you if such a release is inappropriate.

You may withdraw your consent for use or disclosure of your personal information, and we will explain the ramifications of that decision, and the process.

Page 2 of 4

Figure 12-19. Patient Consent Form: for collection, use and disclosure of personal information at the Faculty of Dentistry, University of Toronto. Page 2/2.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Dear Student,

We would like to kindly invite you to take part in a study evaluating the effects of anxiety and oral parafunctions behaviours (daytime clenching, grinding etc.) on orthodontic pain sensitivity.
You have been selected from a pool of participants involved in a web survey because of your answers.
Our goal is to recruit at least 56 participants to the experimental phase.

We would like to monitor the discomfort/pain produced by a simple, routine dental procedure (that is the placement of orthodontic elastomeric separators) over a short duration of time – five days, and to assess the characteristics of your masticatory (chewing) muscles by using two electronic devices.

You will be involved with the following **nine** procedures:

- Dental visit **and clinical examination**
- Electromyographic test
- Measurement of pressure pain thresholds
- Placement of orthodontic elastomeric separators between molars
- Report of your pain/discomfort/**tooth clenching**/stress for five days in a diary
- Measurement of pressure pain thresholds
- Orthodontic elastomeric separators removal
- **Dental visit and clinical examination, and debriefing**

Dental Visit

An expert orthodontist (Dr. Iacopo Cioffi) and an orthodontic resident (Dr. Jeffrey Chow) will assess the function of your masticatory (chewing) muscles by palpation, and evaluate your oral hygiene status and your occlusion (bite). We will further examine the soft tissues of the head and neck, as well as the inside of the mouth. The dental exam will be performed in the clinical research space of the research supervisor at the Faculty of Dentistry. This will require approximately 5-10 minutes of your time. If we find a dental/oral condition (for example, cavities) that requires treatment or observation, we will refer you to your dentist or to the University of Toronto, Faculty of Dentistry dental clinic (124 Edward Street). The examination will be performed thoroughly and systematically to ensure that no components are missed. The dental exam will be repeated at the end of the experimental phase.

Figure 12-20. Consent to participate in Phase II: Clinical Experimental Procedure. Page 1/5.

Electromyographic Test

We will use an electronic device to assess the behaviour of your masticatory (chewing) muscles while you read a magazine. Plastic probes (see image on left) will be placed onto your cheeks. We will apply a conductive gel on your skin prior to positioning the probes. The probes will be positioned on your cheeks and temples and stay in place through conductive stickers (electrodes). It is possible that after the procedure your cheeks and temples will present with an impression of the electrodes. This will disappear in a few minutes following the procedure. Allergies are rare. Rest assure that this exam is totally harmless. You **will not** experience any electrical shocks and/or discomfort during this test. This test will take approximately 30 minutes of your time.

Measurement of Pressure Pain Thresholds

This test will measure your pressure pain threshold. We will press your cheeks and temples with a special instrument called an algometer, which is similar to the rubber tip of the eraser-end of a pencil. Pressure will be placed with said instrument onto the surface of your cheek and temple. This will continue until the point in time where you indicate and decide that the pressure sensation has changed into a discomforting sensation. The instrument will be withdrawn immediately. We will do three tests for each cheek and temple. This test will require approximately 20 minutes.

Positioning of Orthodontic Separators Between your Molars.

We will place orthodontic elastomeric separators (two separators in the upper dental arch and two in the lower dental arch) between your molar teeth, which may result in a slight discomfort. This procedure requires only a few seconds in the majority of cases. In some people, this may cause mild temporary tooth pain, which will decrease day by day. This is the most common procedure in orthodontics and is completely reversible. Additionally, we will require you monitor your tooth pain, occlusal discomfort (how severely your mouth is bothered by the separators) and perceived daily stress by using a custom-made diary according to our instructions for five consecutive days. We kindly ask you to avoid the use of analgesics (pain medication) and to take note of the time/day of consumption if needed for other conditions. Also, please report the name and dosage of the medication you used. After five days, the orthodontic elastomeric separators will be removed. However, if for any reason, you can at any time request the removal of the orthodontic elastomeric separators or stop the study entirely. You can also remove the orthodontic elastomeric separators by yourself using a toothpick. Allergies are rare (latex allergy in normal population is low, under 1%). If you swallow an orthodontic elastic separator, it will be expulsed in the feces.

Figure 12-21. Consent to participate in Phase II: Clinical Experimental Procedure. Page 2/5.

Separators removal and debriefing

After five days, you will be asked to return to our clinical orthodontic department with your diary to have the pressure pain threshold test repeated. Afterwards, the orthodontic elastomeric separators will be removed.

Possible risks

The procedures used in this study (pressure pain thresholds and surface electromyography) are known to be safe and are routinely used in clinical and research settings.
Orthodontic elastomeric separators are regularly used to assess tooth pain perception in research studies. They are commonly placed between molars prior to starting orthodontic treatment to create a minimal space to allow for placement of molar bands. The procedure of separator insertion by an orthodontist using dental floss is safe. Public Informative videos (examples) are available here: https://www.youtube.com/watch?v=41ozsPnxkiA ; https://www.youtube.com/watch?v=6ixDYdcccEl
A minimal space opening between the molars is expected to show up at day 5. The space will close spontaneously after separators removal.

Orthodontic separators are known to produce a mild and short-lasting discomforting experience. However, patients tolerate this very well. The majority of research studies using separators to induce tooth pain report pain that is mild but with high inter-individual variability. At any time, you are free to withdraw from the study and to remove the separators by using a toothpick or you can request us to remove them for directly you.

The event of swallowing orthodontic separators by adult individuals is rare. If this is the case, they will be expulsed in the feces.
In rare cases, separators can cause severe gingival inflammation. If it is this case, you will be prescribed and directed to use a 0.12% chlorhexidine mouth-rinse. If inflammation continues to persist, the investigators will refer you to the dental clinic at the University of Toronto, Faculty of Dentistry for appropriate management. Allergies are quite rare (latex allergy in normal population is low at less than 1%).

Possible benefits

Currently, the possible role of oral parafunctions on orthodontic pain perception is completely unknown. Understanding the effects of daytime clenching on orthodontic pain may be useful for clinicians to possibly identify those patients who may be at risk for increased pain sensitivity. This will allow for better tailoring of orthodontic treatment strategies for such patients. Participants will also benefit from the vigilant assessment of their teeth and intraoral soft tissues, and be appropriately referred to their dentist or to the dental clinic at the University of Toronto, Faculty of Dentistry if the presence of any dental/oral condition(s) is/are detected that is in need of treatment and/or observation.

Would you like to take part in this study?

We would like to kindly invite you to take part in this study. Participation in research is entirely voluntary. You may decide to participate or to not participate in this study.

Figure 12-22. Consent to participate in Phase II: Clinical Experimental Procedure. Page 3/5.

COMPENSATION AND WITHDRAWAL

You may refuse to participate or withdraw at any moment without any repercussions. If you agree to participate in this study, upon successful completion (at the end of the five day duration), we will give you a gift card valued (participant's choice of an on-line store) at $100.00 CAN for your participation.
If you decide to withdraw after day three, a gift card of a minimum of $50.00 CAN will be provided for your participation.
Your compensation for this investigational testing will be managed as follows:

1) Baseline assessments + day1+day2+day 3 = $50.00 gift card (separators are in your mouth up and until the end of day three)
2) Baseline assessments + day1+day2+day 3+day 4 = $70.00 gift card, (separators are in your mouth up and until the end of day four)
3) Baseline assessments + day1+day2+day 3+day4+day5+final assessments = $100.00 gift card (separators are in your mouth up and until the end of the study)

Note that there is no reimbursement of travel or parking costs.

We kindly ask you to contact us as soon as possible if you lose a separator: the investigators ███████ ██ will arrange an appointment within hours in order to let you continue to be in the study.

Privacy Statement

We are committed to protecting your personal information and respecting your privacy. Personal information is defined as any details that will enable you to be identified, such as ID numbers, telephone numbers, address, email address etc. When designing and executing our research, it is our policy to take all necessary steps to ensure that personal information you provide is processed fairly and lawfully. Only authorized staff has access to personal information and they are obliged to respect its confidentiality. We do not sell, rent or exchange any personal information supplied by you to any third party. Nor do we use any of the information you provide for direct marketing or other non-research activities.

All the information you will provide will be property of the Faculty of Dentistry at the University of Toronto. Only the investigators listed in this document will have access to the data. Your personal data will be stored at the Faculty of Dentistry.

In obtaining your cooperation to participate in the survey, we undertake not to mislead you in any way about the nature of the research we are conducting, the way in which the data is collected and the use that will be made of the survey results. All of the information that you provide will be treated as confidential and together with your research data will only be used for this or other research purposes. Your comments will not be identified as belonging to you; instead they will be combined with those gathered from other survey participants, and will be analyzed as part of a group.

We do not use any of the information you provide for direct marketing or other non-research activities. If we ask you for personal information that enables you to be identified - e.g. your name, ID numbers, email address or telephone number, we will clearly state why we are asking for it and for your permission to use it for that purpose. For example, it might be to contact you for other research studies.

The research study you are participating in may be reviewed for quality assurance to make sure that the required laws and guidelines are followed. If chosen, (a) representative(s) of the Human Research Ethics Program (HREP) may access study-related data and/or consent materials as part of the review. All information accessed by the HREP will be upheld to the same level of confidentiality that has been stated by the research team.

Figure 12-23. Consent to participate in Phase II: Clinical Experimental Procedure. Page 4/5.

Your participation is entirely voluntary. You are entitled to ask that part, or all, of the record of your involvement in research be deleted or destroyed. If you decide to withdraw from the study you can ask us to withdraw the data used for research as well.

The results of this research study will be an object of publication or research presentations. You can request a summary of the research results to the investigators, who will be pleased to send it to you by email. Please contact ███████████████████████████████████

This research is economically supported by the research funds of the Research Supervisor and by the Faculty of Dentistry, University of Toronto.

You can contact the Office of Research Ethics at ethics.review@utoronto.ca or 416-946-3273 if you have questions about your rights as participant
Contact information of the investigators:

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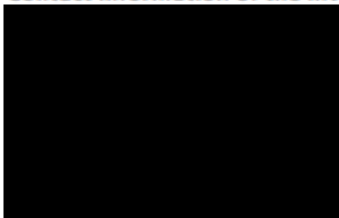
PLEASE, FILL IN THE FOLLOWING SECTION

I voluntarily consent to participate in this study and
have received a signed copy of this form to take home with me

YES ( )   NO ( )
My research data can be kept in case I decide to withdraw from the study
YES ( )   NO ( )
I give my consent for use of my research data for further/future research studies
YES ( )   NO ( )
I would like to be contacted for participation with other research studies
YES ( )   NO ( )

Name: _____ Surname: _____
Phone Number: _____ Email Address: _____
☐ I agree   ☐ I disagree   Signature: _____

Figure 12-24. Consent to participate in Phase II: Clinical Experimental Procedure. Page 5/5.

12.5 Recruitment Flyer

UNIVERSITY OF TORONTO
FACULTY OF DENTISTRY

Research study - Orthodontics

Are you studying at U of T? Can you help us with our research?
We would like to evaluate the relation between individual psychological traits, oral parafunctional behaviours (daytime tooth clenching, grinding, etc.), and pain sensitivity

If you would like to participate, please register for and complete this web survey that will require approximately 20 minutes of your time. You will be invited to answers general questions assessing your health, frequency of oral parafunctional behaviours, and your anxiety.

http://www.orthowebresearch.com

By participating in the web survey, you will be entered in a draw for the following prizes:

15 gift cards valued at $20 each (coffee company gift card)
10 gift cards valued at $50 each (coffee company gift card)
5 gift cards valued at $100 each (participant's choice of on-line store gift card)

We will assess your answers. Selected individuals will be contacted for participation in the clinical phase of the study. If you are selected, you will be asked to wear orthodontic separators (refer to pictorial image below) for five days and to report your discomfort/pain/stress. Before placing the orthodontic separators, we will record the activity of your masticatory muscles and assess their sensitivity to pressure stimuli. We will compensate you for your time spent participating in this clinical investigation with a 100 dollars gift card. You may choose to participate in the web survey only and refuse to take part into the clinical phase.
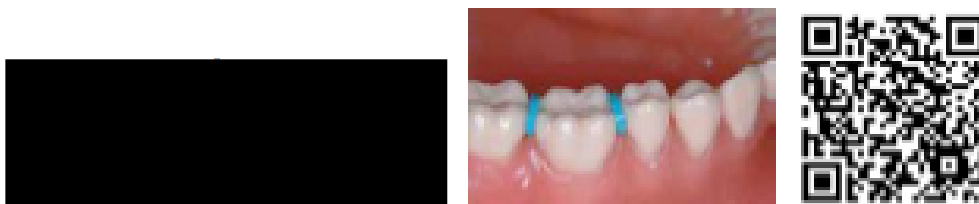

Figure 12-25. Recruitment flyer used to invite participants to complete a web-survey to assess the relation between oral parafunctional behaviours and trait anxiety in a large sample of individuals. This flyer has also been advertised through the use of Facebook.

12.6 Medical History Questionnaire

UNIVERSITY OF TORONTO
FACULTY OF DENTISTRY

Medical Questionnaire

Please paste label:

For office use only. Date: _____
Perio _____ Surgery _____ Endo _____
Crown _____ Bridge _____ Amal/Resin _____
P/Dent _____ F/Dent _____
Implants _____
Other _____ C/D 1-2-3-4 _____ MHO _____
Comments: _____
_____
Radiographs: Pt to obtain x/rays; reassess _____
FMS _____ Pan _____ Special procedures _____
Pan + B/W _____ Pan + selected periapicals __+___
Other_____
Screening signature: _____

Have you ever been a patient at this Faculty?   Yes _____   No _____

To provide the best possible care for our patients, all patients must fill out this questionnaire completely. Please answer the following questions as accurately as possible. If you have any questions or doubts, please check (√) the "Not sure/Maybe" choice.

	Yes	No	Not Sure/ Maybe
1. Are you being treated for any medical condition at the present or have you been treated Within the past year? If so, why?_____	___	___	___
2. Was your last medical check-up within the past one year?	___	___	___
3. Has there been any change in your general health in the past year?..............	___	___	___
4. Are you taking any medications or non-prescription drugs of any kind?......... IF YES, LIST _____	___	___	___
5. Do you have any allergies? (e.g. Hayfever, Latex/Rubber) _____	___	___	___
6. Have you ever had peculiar or adverse reaction to any medicines or injections? (e.g. penicillin, aspirin, local anaesthestics, "dental freezing").......	___	___	___

7. Do you have or have you ever had any of the following?
Please check off (√) all that apply.

___ any heart problem	___ heart murmur	___ blood pressure problem
___ chest pain	___ heart transplant	___ rheumatic fever
___ angina	___ heart surgery	___ mitral valve problems
___ heart attack	___ artificial heart valve/valve repair	___ congenital heart disease
___ stroke	___ infection of the heart (endocarditis)	(from birth or early childhood)
___ shortness of breath	___ heart failure/CHF	

☐ NONE OF THE ABOVE

	Yes	No	Not Sure/ Maybe
8. Do you have any condition that could affect your immune system, e.g. Leukemia, AIDS, HIV infection?	___	___	___
9. Do you have any tendency to bruise easily or bleed for a prolonged period of time after a cut?	___	___	___
10. Have you ever been hospitalized for any illnesses or operations? .... Please explain: _____	___	___	___

PLEASE TURN OVER

Figure 12-26. Medical Questionnaire for the Faculty of Dentistry, University of Toronto. Page 1/2.

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Chart #_____

11. Do you have, or have you ever had, any of the following?
    Please check off (√) all that apply.

___ hepatitis   ___ lung disease   ___ steroid therapy   ___ arthritis, type_____
___ jaundice   ___ tuberculosis   ___ diabetes   ___ seizures
___ liver disease   ___ asthma   ___ stomach ulcers   ___ kidney disease
___ bone strengthening pills e.g. Actonel, Prolia   ___ prosthetic joint   ___ cancer
    (type) _____   ___ thyroid problems
    (how long)_____

☐ NONE OF THE ABOVE

	Yes	No	Not Sure Maybe
12. Do you take any blood thinners (eg. Coumadin, Pradax, Xarelto, Eliquis, Clopidogrel, Aspirin, or other)?.. If so, what is the name of the blood thinner? _____	___	___	___
13. Are there any conditions or diseases not listed above that you have or have had?... If so, what? _____	___	___	___
14. Are there any diseases or medical problems that run in your family? (e.g. Diabetes, cancer or heart disease?)..			
15. Do you or did you smoke? If so, how much? _____	___	___	___
16. Do you drink alcoholic beverages on a regular basis?	___	___	___
17. Do you use recreational drugs (such as cocaine or amphetamines)?..............	___	___	___
18. Are you nervous during dental treatment?..	___	___	___
19. How nervous are you? (Indicate by marking the scale below). NOT AT ALL – 1 – 2 – 3 – 4 – 5 – VERY ANXIOUS	___	___	___
20. If you are nervous, would you like us to consider additional techniques, along with "freezing", to help you?			
21. Have you ever had any serious trouble with any previous dental treatment?..	___	___	___
22. For women only, are you pregnant? .... If so, what is the expected delivery date? _____	___	___	___

CONSENT FORM: I ACKNOWLEDGE that the information given above is true to the best of my knowledge. Should there be any change to my present health status in the future, I will advise the Faculty. I have been informed that my physician may be contacted by letter, fax or telephone in order to complete details of my medical history. I hereby consent to my physician providing the Faculty of Dentistry, University of Toronto with any information in this regard which may help ensure safe dental treatment. Finally, I hereby acknowledge that dental treatment may be delayed until all medical information required by the Faculty of Dentistry is received.

Date: _____ Patient Signature: _____Witness Signature: _____

Medical Doctor's Name: _____Medical Doctor's Phone #: _____

Medical Doctor's Address: _____

Specialist Doctor's Name: _____ Specialist Doctor's Phone #: _____

Specialist Doctor's Address: _____

Figure 12-27. Medical Questionnaire for the Faculty of Dentistry, University of Toronto. Page 2/2.