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Evaluation of masticatory muscle response to clear aligner therapy using ambulatory electromyographic recording

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Introduction: Patients undergoing clear aligner therapy (CAT) report muscle tenderness and produce wear facets on their aligner trays. However, little is known about the masticatory muscle response to clear aligners. Here, we measured the activity of the masseter during CAT using ambulatory electromyography. We also explored whether psychological traits modulate the masticatory muscle response to CAT. **Methods:** Using portable data loggers, we recorded the electromyographic (EMG) activity in the right masseter muscle of 17 healthy adults without temporomandibular disorder (16 females, 1 male; mean age ± standard deviation, 35.3 ± 17.6 years) commencing treatment with CAT over 4 weeks, under the following conditions: week 1 without aligners (baseline), week 2 with a passive aligner (dummy), week 3 with their first active aligner (active1), and week 4 with their second active aligner (active2). We used a mixed-effect model to test differences in EMG activity over the 4-weeks and a general linear model to test the effect of psychological traits on EMG activity. **Results:** The EMG activity of the masseter increased significantly with aligners compared with baseline. The largest relative increase in EMG activity was seen during the dummy (152%; $P<0.001$) and active1 (155%; $P<0.001$) stages. During active2, the activity of the masseter decreased significantly toward baseline levels. Participants' trait anxiety was positively associated with increases in EMG activity ($P=0.027$). **Conclusions:** CAT is associated with a transient increase in masticatory muscle activity, possibly because of an increase in wake-time parafunctional tooth clenching. Temporomandibular disorder-free patients adapt well to CAT as the masticatory muscle activity decreases toward baseline levels after 2 weeks. (Am J Orthod Dentofacial Orthop 2021;159:e25-e33)

Clear aligner therapy (CAT) has seen rapid growth and advancements over the past several years, making it a popular treatment modality in contemporary orthodontics.[1] This trend is largely because of the growing demand among prospective patients for esthetic treatment alternatives to traditional brackets and wires.[2,3] The primary advantages of CAT over traditional fixed-edge appliances are its esthetics,[2,3] removability,[4] and comfort.[5-8]

The muscles of mastication are capable of adapting to the various functional demands imposed on them.[9] These adaptive changes include altering their physical size, fiber properties, muscle activity, and force of contraction.[10-12] However, despite the rising popularity of CAT, little is known about the response of masticatory muscles to clear aligners.

A few studies have shown that patients undergoing CAT have increased frequency of wake-time tooth clenching episodes,[13] report jaw muscle tenderness,[13] and produce wear facets on their aligner trays.[14] In contrast, orthodontic treatment with a fixed appliance

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can lead to patients avoiding tooth contact to reduce tooth pain related to orthodontic tooth movement. Repetitive clenching on aligners might be an acquired behavior acting as a conditioning stimulus to reduce the perception of the orthodontic nociceptive stimuli.[15] Indeed, similarly to plastic wafers,[16] clenching on the aligners could induce a temporary displacement of the teeth and promote blood flow through the compressed areas of the periodontal ligament; thus, preventing the accumulation of proalgesic mediators in the periodontal ligament space and promoting pain relief.[17]

There is substantial evidence of a positive association between awake bruxism—repetitive masticatory muscle activity involving tooth clenching—and impaired mood.[18,19] For example, awake bruxism is highly prevalent in anxious individuals,[20,21] and experimental tooth clenching reduces salivary cortisol concentrations.[22] Therefore, tooth clenching may be a maladaptive coping mechanism to manage stress.

Surface electromyography (sEMG) is an objective method for measuring the activity of a muscle of interest through the placement of electrodes over the skin. Its simplicity and noninvasive nature have brought widespread use to researchers in dentistry for both basic science and clinical studies.[23] For instance, sEMG has been used to study temporomandibular disorder (TMD),[24,25] detect muscle hyper- and hypoactivity,[26,27] imbalance,[28] and fatigue.[29-32]

Current literature about the response of masticatory muscles to CAT during wakefulness is limited to patients' self-report.[13] In this study, we aimed to evaluate the masticatory muscle response to CAT using ambulatory sEMG during the daytime. We also explored whether the masticatory muscle response to CAT is modulated by psychological traits. It was hypothesized that (1) patients subjected to CAT would have a transient increase in masseter muscle activity, (2) that this increase in masseter activity is related to orthodontic tooth movement, and (3) is dependent on psychological traits.

MATERIAL AND METHODS

Subjects aged 17 years or older with a plan to undergo CAT, were recruited from the graduate orthodontic clinics at the University of Toronto (Toronto, Ontario, Canada) and the University of Western Ontario (London, Ontario, Canada). Ethics approval was obtained from the corresponding Research Ethics Boards at each Institution, and informed consent was acquired from each subject before entering the study.

Each potential participant completed an initial screening questionnaire using the TMD-Pain screener.[33] In addition, each subject underwent a preliminary TMD examination at each center according to the diagnostic criteria for TMD clinical protocol.[34] Exclusion criteria consisted of current TMD or orofacial pain, current use of muscle relaxants or other medications affecting masticatory muscle activity, presence of any systemic disorders affecting motor behaviors and pain perception, and daily use of any analgesics.

Seventeen subjects were recruited (16 females, 1 male; mean age ± standard deviation, 35.3 ± 17.6 years). All participants were treated using Invisalign clear aligners (Align Technology, San Jose, Calif), made of the latest generation of multilayer thermoplastic polyurethane-based material, SmartTrack (Align Technology). Using the ClinCheck Pro software (Align Technology), the first stage of aligners for all participants consisted of maxillary and mandibular aligners programmed with no active tooth movements (passive aligners). Active tooth movements were programmed for the subsequent stages at the standard rate recommended by the ClinCheck Pro algorithms. All participants had Class I or mild Class II malocclusion with mild to moderate crowding or spacing in the maxillary and mandibular dental arches (nonextraction cases). Chewies to improve aligner seating and intermaxillary elastics were not used.

Baseline questionnaires

To determine the effect of psychological traits and self-reported parafunctional oral behaviors on masticatory muscle activity during CAT, we asked each participant complete the Oral Behavior Checklist (OBC),[35] the State-Trait Anxiety Inventory,[36] the Somatosensory Amplification Scale (SSAS),[37] and the Beck Depression Inventory (BDI).[38]

The OBC includes 21 items assessing the awareness and self-reported frequency of oral behaviors on a 5-point scale (range of scores, 0-84).[35] The State-Trait Anxiety Inventory includes 20 items to assess state anxiety and 20 statements to assess trait anxiety on a 4-point scale (range of scores for each subscale, 20-80).[36] For this study, only trait anxiety was used. The SSAS includes 10 statements investigating participants' sensitivity to bodily sensations on a 5-point scale (range of scores, 10-50), and it is an estimate of bodily hypervigilance.[39,40] The BDI investigates 21 depressive symptoms, scored between 0 and 3 (range of scores, 0-63).[38]

Study design

The study design is depicted in Figure 1. We recorded the electromyographic (EMG) activity in the right masseter muscle of subjects commencing treatment with CAT over 4 weeks, with sampling done 3 d/wk (day 1, day 3, and day 5 of each week). EMG data were

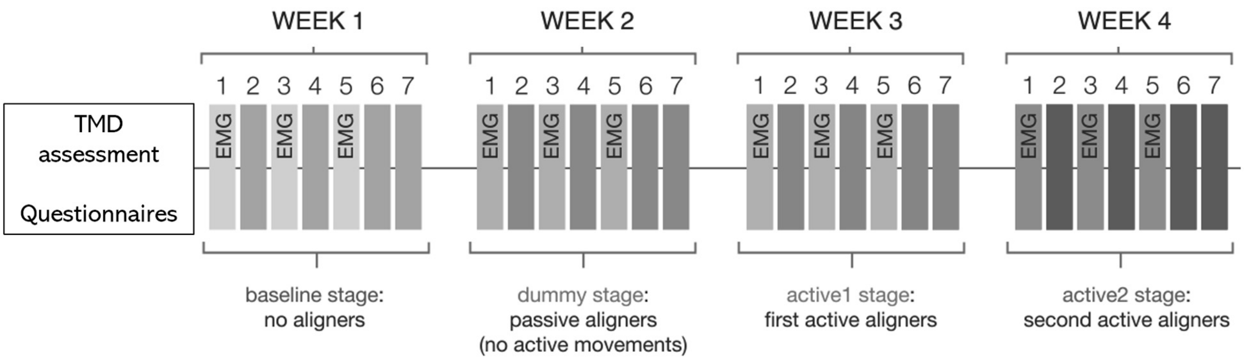

Fig 1. Research design.

collected before the start of CAT with no aligners (week 1, baseline stage), for 1 week while participants were wearing a passive aligner (week 2, dummy stage), for 1 week while participants were wearing their first active aligner (week 3, active1 stage), and finally for 1 week with their second active aligner (week 4, active2 stage).

Surface electromyography

Participants were given a kit containing a portable EMG device (MicroEMG; OT Bioelettronica, Turin, Italy), disposable bipolar self-adhesive concentric EMG electrodes (Code 2.0; Spes Medica, Genova, Italy) with a radius of 2 cm, rectangular electrodes (3.5 × 4 cm, Red Dot; 3M, Saint Paul, Minn), disposable batteries, secure digital (SD) cards, and alcohol pads. The kit also contained a personalized calendar to help remind participants of which day they had to perform the EMG recording and a paper diary. The SD cards were labeled; that is, they reported the date on which they had to be used.

Before starting the experiment, each participant received detailed instructions and demonstrations on the proper usage of the EMG device. A video tutorial, as well as a procedure manual and checklist, were also provided.

In summary, participants were instructed as following: (1) not to use make-up on the day of the EMG recording (and to shave for male participants); (2) to insert a new battery and a new SD card in the device before the daily EMG recording; (3) to rub their right cheek with the alcohol pads provided for at least 20 seconds before using the EMG device; (4) to place the EMG electrode on the right cheek and the device on the right clavicle (Fig 2); (5) to start the recording by pressing the red button on the device in the afternoon of the predetermined recording day; (6) to clench their teeth in maximum intercuspation and at their maximum voluntary contraction for 3 times lasting 3 seconds each, and separated by 5-second intervals, at the beginning of each recording session; (7) to stop the recording after 4 hours by pressing the same red button; (8) to store the SD card and dispose of the battery; and (9) to repeat procedures 1-8 at the next recording day, as reported in their calendar.

Participants were asked to place the concentric electrode on the right masseter muscle, along a line projecting from the mandibular angle to the lateral canthus of the eye, approximately 20 mm above the mandibular angle,[41] and to connect the electrode to the device. The electrode was located on the most prominent belly of the muscle as evaluated by palpation during maximum voluntary contraction (ie, the part of the muscle which closely approximates the largest muscle "bulge" when they clenched; Fig 2).

The device was connected to a reference electrode (3.5 × 4 cm, Red Dot; 3M) on the middle point of the right clavicle (Fig 2). The concentric ring systems of the electrodes show higher spatial selectivity with respect to the traditional detection systems and reduce the problem of electrode location because they are insensitive to rotations and reduce EMG cross talk.

To reduce artifacts during EMG recordings, we instructed all participants to avoid exercising, chewing, and eating during recording sessions. If these activities did occur, participants were instructed to record the time of the corresponding day in the diary.

Before starting the 4-week recording, the operator carefully checked that the participant could place the electrodes and perform the EMG recording correctly. All participants were asked to try the procedures beforehand at our clinics. Specifically, we asked them to position both the electrode on the masseter and the EMG device and complete a recording lasting a few minutes. All participants were informed that they could contact the investigators if they had questions regarding the use of the device, or for any technical reason.

Fig 2. EMG portable data logger. **A,** Location of the concentric electrode on the right masseter; **B,** device positioned on the right clavicle; **C,** device and electrode in place.

Participants returned their kit to the research unit at the end of week 4. After that, a TMD examination was performed.[34] All participants received financial compensation for participating in this study.

EMG signal processing

EMG signals were sampled at 1024 Hz, amplified, and bandpass filtered between 10-550 Hz. All EMG raw data were downloaded from the SD cards, sorted, and imported in a worksheet including the day of recording (day 1, day 3, or day 5), condition (baseline, dummy, active1, or active2), and subject identification number, using a custom-made computer algorithm. This algorithm was written using macros for Microsoft Excel using Visual Basic programming language (version 16.0; Microsoft Corp, Redmond, Wash).

Using software (OTBioLab; OT Bioelettronica), 2 operators (T.L. and J.T.) visualized and processed all the EMG signals recorded during the experiments, identified and removed EMG artifacts on the basis of information provided by the participants and careful examination of all EMG signals. The operators were trained by an investigator (I.C.) with over 15 years of experience in EMG data analysis. Any disagreement between the operators was resolved by the senior investigator (I.C.). Finally, EMG data were standardized across participants and conditions by computing z-scores.

Statistical analysis

A generalized linear mixed-effect model with Bonferroni-corrected Wilcoxon paired signed rank test was used to test differences in EMG z-scores between the different experimental conditions (baseline, dummy, active1, and active2), and between recording days (day 1, day 3, day 5) of each condition. The interaction day of recording by condition was tested and included in the model since it was statistically significant. Therefore, the fixed factors included in the final statistical model were the recording day, the experimental condition, and their interaction. The participant identification number was included as a random factor.

A general linear model was used to test the effect of behavioral (OBC) and psychological factors (trait anxiety, SSAS, BDI) on the EMG relative changes from baseline EMG measurements. The statistical significance was set at P <0.05. The statistical analysis was conducted using SPSS (version 24; IBM, Armonk, NY) by a single operator (I.C.).

On the basis of a previous study,[42] 16 participants were required to detect a 10% change in EMG activity with the Invisalign appliance, with a large effect size (d = 0.85), alpha and beta error set at 0.05 and 0.1, respectively.

RESULTS

There were no participant dropouts during the experimental period. The compliance of the participants in the research protocol was satisfactory. Over the 4-week experimental period, the expected recording time was 48 hours over 12 days (4 weeks, 3 d/wk, 4 h/d). The average EMG wear time of the participants was 45.93 ± 14.60 hours. No participant developed symptoms of TMD after the 4-week recording.[34]

Masseter muscle activity increases with CAT

The EMG activity of the masseter during the 4 experimental conditions is reported in Figure 3, *A*. The activity of the masseter was affected by the experimental condition (F = 130.14; P <0.001), the recording day (F = 6.95; P = 0.001), and the interaction condition by day (F = 13.41; P <0.001).

The activity of the masseter considerably increased while wearing the aligners compared with baseline. Relative to the baseline, the largest relative increase in EMG activity was recorded during the dummy (152%; P <0.001) and active1 (155%; P <0.001) conditions, while the least relative increase was during active2 (62 %; P <0.001). There was no difference in EMG activity

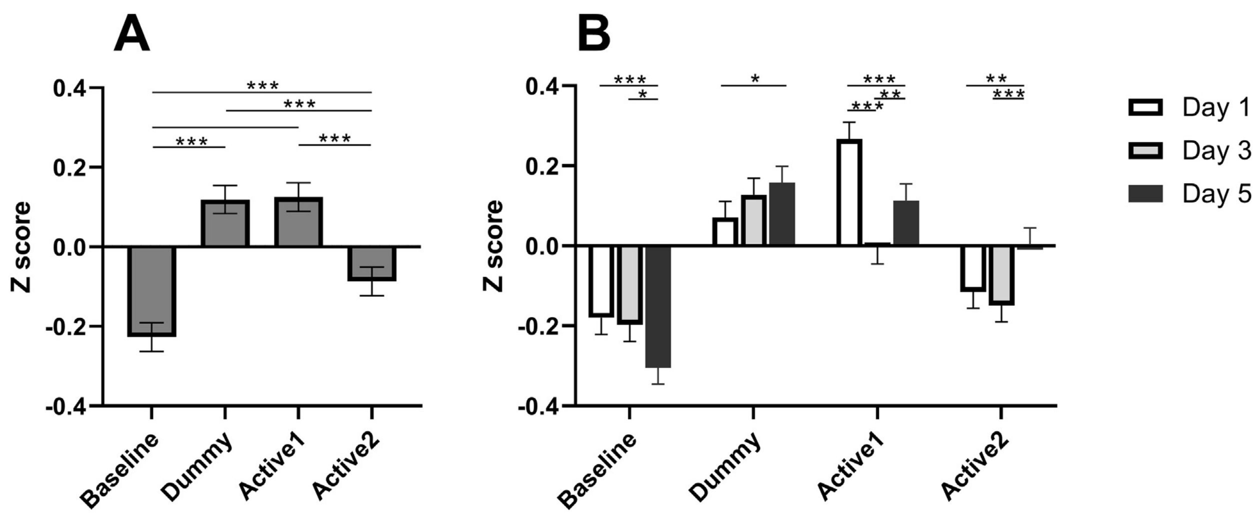

Fig 3. A, Mean EMG activity of the masseter ± standard errors of the mean during the 4 experimental conditions; **B,** during each recording day. Significant difference at **P* <0.05, ***P* <0.005, and ****P* <0.001.

between the dummy and active1 conditions ($P = 0.751$). The activity of the masseter decreased significantly from active1 to active2 ($P < 0.001$).

Daily EMG trajectories are reported in Figure 3, *B*. At baseline, the EMG activity decreased significantly from day 1 to day 5 ($P = 0.001$), and from day 3 to day 5 ($P = 0.007$). No differences were found between day 1 and day 3 ($P = 0.638$).

During the dummy condition, the EMG activity increased from day 1 to day 5 ($P = 0.035$). No differences were found between day 1 and day 3 ($P = 0.214$), and between day 3 and day 5 ($P = 0.395$).

During active1, the EMG activity decreased from day 1 to day 3, and increased from day 3 to day 5 (all $P < 0.001$). During active2, the EMG activity increased from day 1 to day 5 ($P = 0.003$), and from day 3 to day 5 ($P = 0.002$). No differences were found between day 1 and day 3 ($P = 0.350$).

The masseter response to CAT is dependent on anxiety and self-reported oral behaviors

The participants' mean (± standard deviation) scores of OBC, trait anxiety, SSAS, and BDI were 29.8 ± 10.9, 30.5 ± 5.5, 9.3 ± 5.1, and 2.7 ± 3.1, respectively.

Trait anxiety scores were positively associated with an increase in EMG activity ($\beta = 75.04$; $P = 0.027$). Both SSAS and BDI were not associated with EMG relative changes ($P = 0.471$ and $P = 0.202$, respectively). OBC scores were associated with a decrease in EMG activity ($\beta = -34.12$; $P = 0.011$).

DISCUSSION

In this study, we measured the EMG activity of the masseter muscle in healthy subjects undergoing CAT. After having collected data for 1 week while participants did not wear aligners (baseline), we recorded the activity of participants' right masseter while they wore passive aligners (dummy stage) and 2 active aligners (active1 and active2) for the other 3 weeks—1 week for each condition. In line with our hypothesis, we found that the activity of the masseter increased with CAT. However, contrary to our hypothesis, orthodontic tooth movement did not contribute significantly to the increase in masseter activity. Indeed, we did not find statistically significant differences between the dummy and active1 stage. The main difference, in theory, between the passive aligner and the first aligner is the introduction of orthodontic tooth pain, via orthodontic tooth movement.[8] Therefore, our study suggests that the mere presence of an aligner itself is the major contributing factor to changes in masseter activity, rather than the actual tooth pain from orthodontic tooth movement.

The current knowledge of the effect of CAT on daytime masticatory muscle activity is extremely limited. In a recent study involving 43 adolescents and adults aged 13-51 years, Brien[13] found that about 66% of participants submitted to CAT reported tooth clenching during the day, after 2 weeks of treatment. However, that study used self-reports, which makes it difficult to draw conclusions. Indeed, it is often difficult for patients to identify tooth clenching episodes.[43] Nonetheless, our study is in agreement with Brien's[13] findings. Indeed, we measured a 152% increase from baseline to the dummy stage, and a 155 % and 62% increase from baseline to active1 and active2, respectively. Our results indicate that patients adapted well to the aligners: after an initial increase, the masseter activity decreased toward the baseline levels during active2. Interestingly, the EMG activity increased progressively from day 1 to day 5 during the dummy condition, whereas during active 1 and active 2 it decreased from day 1 to day 3 and then increased again on day 5. This change may be explained by an initial avoidance behavior developed by participants in response to the active aligners, which ceased after day 3 when participants increased their muscle activity.

Although it is possible that the increased activity of the masseter with aligners was due to increased muscle tone and/or increased frequency of tooth clenching, it is unlikely that it was determined by increased functional activities (eg, chewing and swallowing). Participants were instructed not to chew while wearing the aligners and during the recordings, and all EMG signals were visually inspected. Although wearing the appliance may have increased the salivary flow rate,[44] we could not identify and remove swallowing episodes from the recorded signals. However, patients commonly reported salivary flow to resume to a normal rate after 3 to 4 days from aligner delivery. Therefore, although it is possible that an increased frequency of swallowing affected the recordings during the dummy condition, it is unlikely that the increased masseter activity observed during active1 and active2 stages were due to an increased frequency of swallowing.

Nonetheless, this explanation relies on participants' self-reports and not a quantitative measurement of saliva flow rates. In addition, the introduction of a foreign object into the oral cavity (such as the aligner) can cause an initial disturbance and possibly lead to occlusal hypervigilance, with increased oral behaviors, such as tooth clenching.[45] Occlusal hypervigilance is a term that describes the tendency to increase occlusal perceptions and heighten attention on changes to the dentition. Patients with occlusal hypervigilance may continuously check their occlusion and selectively focus on detecting changes to their occlusion.[45] This continuous monitoring may result in repetitive tooth-to-tooth contacts and clenching as a way to detect and search for possible threats in the oral cavity.[45,46] However, our general linear model did not reveal any association between participants' somatosensory amplification—an estimate of hypervigilance—and EMG relative changes.

To the best of our knowledge, this is the first study measuring the activity of the masseter during CAT using surface electromyography during wakefulness. Therefore, we cannot make direct comparisons with other studies. However, several authors have investigated the effect of occlusal splints on masticatory muscle activity. Although some studies have shown that occlusal splints contribute to reducing masticatory muscle load, the effect of occlusal splints on the muscles of mastication is still controversial.[47,48] Notably, the response of masticatory muscles to an occlusal splint has been reported to be affected by the type of material used. Al-Quran and Lyons[49] found that hard splints led to decreased EMG in both the masseter and the temporalis. Differently, soft splints produced a slight increase in the activity of both muscles, but particularly the masseter muscle. Similar results were found by Okeson.[50] The Invisalign aligners used in the study were made of a material with some degree of elasticity. However, it is difficult to compare the SmartTrack (LD30; Align Technology) material to the resin used for hard or soft splints. SmartTrack (Align Technology) is a polymer made of a multilayer aromatic thermoplastic polyurethanes/polyester. This material has been advertised to improve the elasticity of the aligners compared with the previous materials (Proceed30 and Exceed30).[51] To produce orthodontic forces, it is certainly more elastic than the resin used to fabricate hard occlusal splints commonly used in patients with TMD. However, studies comparing the material properties of aligners to occlusal splints are lacking. The aligners used in this study are neither rigid as conventional occlusal splints nor soft as over the countersoft silicon splints, and they are much thinner (about 0.3 mm thick as reported by the manufacturer) than occlusal splints. Recently, Manfredini et al[52] evaluated the masticatory muscle response to clear removable thermoplastic orthodontic retainers during sleep. The retainers were reported to be made of the same material that is commonly used to build clear aligners. The authors did not find a significant effect of the retainers on masticatory muscle activity during sleep. Differently, Castroflorio et al[53] reported that CAT was associated with an increase in masseter phasic contraction related to sleep bruxism during the first and third months of treatment.

Similarly, subjects wearing rigid occlusal splint increased phasic contractions after 3 months of treatment. However, the response of the masticatory muscles to clear aligners during sleep may be significantly different from wake-time, as the neurobiological mechanisms regulating jaw muscle contraction during sleep and wake-time are different.[54] Of interest, the response of the masseter to occlusal splints is dependent on their thickness. Manns et al[55] showed that hard resin occlusal splint increasing the vertical dimension by 1.1 mm decreased the activity of the masseter significantly less than splints altering the vertical dimension by an average of 4.25 and 8.25 mm. Therefore, it is likely that thin clear aligners do not decrease the activity of the muscles of mastication. Instead, they likely increase it as found in the current study and reported previously by Brien et al[13] and Castroflorio et al.[53]

We showed that both trait anxiety and OBC were predictors for EMG activity. Participants' trait anxiety was positively associated with EMG activity. In agreement with previous reports showing a significant effect of anxiety on masticatory muscle activity,[20,21,46] orthodontic treatment with CAT may lead to a greater increase in the masticatory muscle activity of anxious subjects. Of interest, OBC scores were negatively associated with EMG relative change with aligners; that is, subjects with low OBC scores presented a greater increase in EMG activity with the aligners. This highlights the fact that querying patients about a history of parafunctional activity often does not yield an accurate response, as many patients may not be aware of their oral habits.

There were some limitations to this study. First, we could not isolate parafunctional tooth clenching episodes from the EMG signals, as done previously.[21,56] To do so, we should have standardized the EMG data using the maximum voluntary contraction of each participant recorded during each day. Although we asked participants to perform 3 clenches at maximum voluntary contraction at the beginning of each recording day, not all of them did do so. Therefore, because we could not standardize the data using the maximum voluntary contraction in all participants, we computed z-scores. A z-score, or standard score, is a measure of how many standard deviations below or above the mean a raw score is. Therefore, it is logical to assume that higher z-scores corresponded to parafunctional tooth clenching and lower z-score to minimal muscle activity. Second, as we did not aim to test gender differences, our study was not designed to test gender differences in EMG activity. Of note, participants were predominantly female except for a single male, limiting the generalizability of the study to only female subjects. Third, we did not measure the frequency of swallowing during the different experimental phases. These measurements would have required additional electrodes and/or a microphone, which could have made the ambulatory recording extremely challenging for participants.

CONCLUSIONS

Although CAT leads to an initial avoidance behavior after the first 48 hours of treatment, it determines a transient increase in masticatory muscle activity, which subsides after 2 weeks. Psychological factors, such as trait anxiety, play a significant role in the individual adaptation to CAT. Further studies are needed to determine whether the response of masticatory muscle to CAT differs between males and females and the short-and long-term effects of CAT on patients at risk for TMD or with a former TMD history.

AUTHOR CREDIT STATEMENT

Johnny Tran and Tiantong Lou contributed to the study design, recruitment of participants, data collection, analysis and interpretation, and drafting of the manuscript. Tommaso Castroflorio and Ali Tassi contributed to the conceptualization of the research study and study design, data interpretation, and writing. Iacopo Cioffi contributed to the conceptualization of the study and study design, data analysis and interpretation, and writing. He was the coordinator of the multisite research. All authors approved the manuscript.

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