Surface Electromyographic Changes in Response to Oral Orthotic Device Therapy in Subjects with Masseter and Temporalis Muscle Pain

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Donavon Khosrow K. Aroni

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THESIS COMMITTEE

Thesis Advisor

Noshir Mehta, D.M.D., M.S.

Associate Dean for Global Relation, Professor

Department of Public Health and Community Service

Tufts University School of Dental Medicine

Committee Members

George Maloney, D.M.D., M.Ac.

Professor, Faculty

Craniofacial Pain Center

Tufts University School of Dental Medicine

Egilius L.H. Spierings, M.D., Ph.D.

Consulting Neurologist & clinical professor

Craniofacial Pain Center

Tufts University School of Dental Medicine

Leopoldo L. Correa, B.D.S., M.S.

Associate professor, Diplomate AADSM

Craniofacial Pain Center

Tufts University School of Dental Medicine

Tofool Alghanem, D.D.S., M.S.

Assistant Professor

Department of Public Health and Community Service

Tufts University School of Dental Medicine

ABSTRACT

Objectives. The purpose of this study was to assess the association between the change in muscle electrical activity of the masseter and temporalis muscles at mandibular rest position and the change in the pain level, from pre-treatment to post-treatment with oral orthotic devices in patients with temporomandibular disorders (TMD) of myogenous origin.

Methods. In this prospective clinical trial, 26 subjects (mean age 36.5 and SD 16.69) seeking TMD treatment were selected to participate in this study. Subjects were diagnosed with asymmetrical bilateral TMD of myogenous origin following Diagnostic Criteria (DC/TMD) Axis I. Subjects were treated for 30 days with custom fabricated upper and lower, hard oral orthotic devices modified by creating uniform occlusal contacts. The custom fabricated upper device was designed with minimized posterior occlusal contacts to be used during sleep. The lower custom fabricated device also was designed with balanced posterior occlusal contacts to be used during the day (approximately 2-3 hours in the morning and 3-4 hours in the afternoon). Surface electromyography (sEMG) of bilateral masseter and anterior temporalis muscles was performed before treatment and four weeks after oral orthotic device therapy. The association between the change in muscle electrical activity of the masseter and temporalis muscles at mandibular rest position and the change in the pain level, from pre-treatment to post-treatment, was assessed. The collected data were statistically analyzed using a mixed model to determine the association between changes in pain and changes in muscle activity.

Results. There was no significant association between changes in pain and sEMG pre and post treatment.

Conclusion. Despite a noticeable decrease in pain, sEMG findings of this study were not supportive of significant differences in sEMG activity of masseter and temporalis muscles of patients with asymmetrical bilateral myofascial pain.

Key words. Temporomandibular Disorder; Surface electromyography; Diagnostic criteria; Myofascial pain;

DEDICATION

This paper is dedicated to my family for their unwavering support by helping me so that I can help others.

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TABLE OF CONTENTS

DEDICATION v
ACKNOWLEDGMENTS vi
TABLE OF CONTENTS vii
LIST OF FIGURES viii
LIST OF TABLES x
LIST OF ABBREVIATIONS xi
LIST OF SYMBOLS xii
Introduction 2
Aim and Hypothesis 7
Research Design 8
Materials and Methods 10
Statistical Analysis 16
Results 17
Discussion 21
Conclusion 24
References 25
APPENDICES 28
Appendix A: Tables 29
Appendix B: Figures 40
Appendix C: Illustarations 63

LIST OF FIGURES

Figure 1. Flow chart of the study protocol

Figure 2. Masseter and temporalis muscles illustration

Figure 3. Flow chart of the study protocol jaw position EMG capture

Figure 4. Pre-treatment sEMG at rest

Figure 5. Post-treatment sEMG at rest

Figure 6. Pre-treatment sEMG with teeth at point contact

Figure 7. Post-treatment sEMG with teeth at point contact

Figure 8. Pre-treatment sEMG at MVC

Figure 9. Post-treatment sEMG at MVC

Figure 10. Pain level of the side with worse pain

Figure 11. Pain level of the side with a lesser pain

Figure 12. Group NRS pre and post-treatment

Figure 13. Temporalis EMG of the side with worse pain at rest

Figure 14. Temporalis EMG of the side with a lesser pain at rest

Figure 15. Masseter EMG of the side with worse pain at rest

Figure 16. Masseter EMG of the side with a lesser pain at rest

Figure 17. Temporalis EMG of the side with worse pain at MVC

Figure 18. Temporalis EMG of the side with a lesser pain at MVC

Figure 19. Masseter EMG of the side with worse pain at MVC

Figure 20. Masseter EMG of the side with worse pain at MVC

Figure 21. Temporalis pre and post treat. EMG at point contact

Figure 22. Masseter pre and post-treatment EMG at point contact

Figure 23. Pre and post-treatment mean EMG muscle groups

LIST OF TABLES

Table 1. Subject timeline

Table 2. Pain index

Table 3. Combined temporalis & masseter EMG at rest

Table 4. Combined temporalis & masseter EMG at MVC

Table 5. Temporalis muscle EMG at rest

Table 6. Masseter muscle EMG at rest

Table 7. Temporalis muscle EMG at MVC

Table 8. Masseter muscle EMG at MVC

Table 9. Temporalis EMG with teeth at point contact

Table 10. Masseter EMG with teeth at point contact

LIST OF ABBREVIATIONS

TMD - Temporomandibular Disorder

TMDS - Temporomandibular Disorder Syndrome

MPS - Myofascial Pain Syndrome

DC - Diagnostic Criteria

NRS - Numeric Rating Scale

EMG - Electromyogram / Electromyograph

sEMG - Surface Electromyogram

IRB - Institutional Review Board

ICF - Informed Consent Form

TUSDM - Tufts University School of Dental Medicine

MVC - Maximum Voluntary Clenching

POC - Percentage Overlapping Coefficient

SD - Standard Deviation

LIST OF SYMBOLS

µV – Microvolts

Surface Electromyographic Changes in Response to Oral Orthotic Device Therapy in Subjects with Masseter and Temporalis Muscle Pain

Introduction

Temporomandibular disorder (TMD) is a complex and broad clinical term covering a heterogeneous group of physical disorders of hard and soft tissues (jaw joint, bone, nerves, ligaments, fascia, and muscles) that prevent the masticatory system from properly working.[1] This diverse group of pathophysiology is characterized by classic defining clinical features of pain, jaw noise, limited and/or altered range of motion that could cause restricted jaw function. Patients with TMD may present one or more of these characteristics. Pain as a delineate feature of TMD is the primary reason for patients seeking care. The number of patients referred by different medical providers, including physicians to dentists, has increased.[2] Temporomandibular disorder is considered the most common non-odontogenic orofacial pain and presents with the presence of other related concurrent symptoms. These symptoms include: neuralgia, toothache, earache, and headache and neck pain.[3]

Temporomandibular disorder is classified into various categories by the National Institute of Dental and Craniofacial Research, part of the National Institutes of Health (NIH).[4] The Diagnostic Criteria for Temporomandibular joint Disorder (DC/TMD) system assists in the classification of clinical findings based on physical examination (axis I) with three categories including 1- muscle disorder; 2- disc displacement; and 3- arthralgia, arthrosis, arthritis. The psychological status of the patient is considered (Axis II).[5,6,7]

Myofascial pain syndrome (MPS) is reported as the most common form of TMD.[8] It presents with subjective pain in the muscles of mastication. In clinical research, following DC/TMD makes the diagnosis of TMD-myofascial pain more consistent. Myofascial pain syndrome (MPS) refers to a chronic pain of soft-tissue and results from irritable foci (trigger

points) within skeletal muscles, their ligaments and fascial constriction. Focal point tenderness, hardening of the muscle and reproduction of pain upon trigger point palpation, referred pain, pseudo-weakness of the affected muscle and limited range of motion are among the characteristic features of MPS.[9]

It may also present sign and symptoms of stomatognathic muscular alteration. Masseter and temporalis muscles are two of the masticatory muscles and are positioned superficially. This characteristic makes it easy to evaluate their clinical presentation in different jaw positions.

In general, TMD is not completely understood, and the precise etiology of myofascial pain is unknown. Multiple studies have indicated several underlying factors of myofascial pain. Macrotrauma and microtrauma have been identified as underlying factors of MPS in the form of physical overloading of the masticatory muscles, occlusal interferences and nocturnal bruxism. Emotional stress and psychiatric illness are also reported as being among systemic factors contributing to these symptoms.

Multiple factors influencing the neuromuscular control of body posture, including neck, head, or mandible position, may affect the bite force. Myogenous pain associated with TMD may be linked to abnormal contraction, hyperactivity, or fatigue of masticatory muscle. Pain reported in the jaw joint region, while less frequent, is also reported as relatively common. Head and neck pain are reported in approximately 10-20% of the population and approximately 10% of patients over age 18 report pain in the temporomandibular joint (TMJ) area.[10,11]

Evidence-based dentistry guides decision-making by encouraging proper assessment,

diagnosis, and treatment planning based on the best current evidence. Quantitative and objective clinical assessment of the symptoms should support the evidence-based diagnostic protocols and treatment standards. This will allow better differentiation among several clinical diagnoses.[12] Multiple studies have explained the force of masticatory muscles using the biomechanical models[13,14,15] and some used electromyogram to assess the muscle activity.[16,17]

Intramuscular or surface electromyography (EMG) can be used in this decision-making for deeper understanding via quantitative and objective assessment of myogenous symptoms in the stomatognathic apparatus. It is a technique for evaluating and recording the electrical activity produced by skeletal muscles.[18] An electromyogram is utilized to capture and record the muscular electrical potentials generated by muscle cells. It analyzes the signals to detect biomechanical movement of body parts, activation level and recruitment order.[19] These features enable the utilization of EMG in evaluating masticatory muscle activity for diagnosis, monitoring the progression of the disease, and measuring the therapeutic effects of the treatment.

Multiple studies have indicated lower bite force measurements in patients with TMD in comparison with non-symptomatic controls.[20,21,22] Impaired stomatognathic function and perceived postural changes in the mandible and decreased electromyographic activity of the masticatory muscles have been reported in patients with TMD. The effect of experimentally induced muscle pain has indicated an inhibitory effect on jaw muscle activity.[22] Biomechanical TMJ loading models explain the effect on masticatory muscle forces[13,14,15] by different factors including orofacial pain, age, occlusion and gender.[19,23-31] Consideration of these factors prevents extrapolation of complex clinical contexts in the

clinical evaluation of patients. Further EMG studies of masticatory muscles are required to substantiate these findings in subjects with myogenous TMD pain.

Oral orthotic devices, also known as occlusal splints, have been indicated as one of the most commonly used and primary methods to manage and treat TMD-myofascial pain symptoms.[8,32,33] The impact of oral orthotic device on the masticatory muscles is significant. These devices alter the muscle activity significantly and lead to a more physiologically stable neuromuscular repositioning of the mandible.[8] Other TMD treatment methods used in conjunction with occlusal splints include pharmacological intervention, physical therapy, relaxation techniques, and biobehavioral intervention and self-care treatment.[33]

Pain severity of the TMD is typically selected for determining the relative benefit of the study interventions. Pain measurement methods are not strictly standardized between studies, but defining significant clinical changes and successful outcomes could offer a reasonable comparison. Patients with low or mild pain level may not pursue treatment or may not find the therapeutic clinical interventions result enough to report. This could explain why almost all pain studies are limited to moderate or severe pain. Most positive studies favoring stabilization appliances used a baseline pain level of moderate to severe in order to avoid ceiling effect in studies with too low pain levels at baseline.[34]

In addition to subjectively reported symptoms, a quantitative and objective evaluation is important for proper diagnosis of patients with facial pain related to TMD. The quantitative EMG characteristics of masticatory muscles can be analyzed for additional assessment of the symptoms and objective diagnosis. This study was designed for further

assisting practitioners in the utilization of sEMG as a diagnostic aid, monitoring the effectiveness of conventional management and treatment.

The current body of literature does not provide enough evidence to support integrating new technology in the clinic to treat patients. The goal of this study was to evaluate the utilization of sEMG in the assessment of masseter and temporalis muscle pain. This study also evaluated the effect of using oral orthotic devices for masseter and temporalis muscle pain on the sEMG activity and pain level.

Aim and Hypothesis

A) **Aim**

The primary aim of the study is to assess the association between the change in muscle electrical activity of the masseter and temporalis muscles at mandibular rest position and the change in the pain level, from pre-treatment to post-treatment with oral orthotic devices.

B) **Hypothesis**

This study will evaluate the following hypothesis:

There is a positive association between change in sEMG activity and change in pain level of the masseter and temporalis muscles, before and after treatment with oral orthotic devices.

Research Design

This study was a single center, single-arm, prospective, controlled clinical trial. The participants in this study were recruited and selected from patients who attend the Craniofacial Pain Center at Tufts University School of Dental Medicine, complaining of TMD with myofascial pain. All subjects were selected according to DC/TMD Axis I myogenous pain group[5,6,7] (DC/TMD is being used for a comprehensive assessment of reliability and validity of the diagnostic classification system to identify and distinguish TMD cases).

Inclusion and exclusion criteria were considered to select the subjects for this study. This study was designed to be completed in four clinical visits. (Figure 1)

Patients were scheduled for the second visit for fitting of the oral orthotic devices and capturing sEMG. Prior to fitting of oral orthotic devices, sEMG was performed according to BTS TMJOINT manufacturer, using commercially available wireless BTS FREEEMG unit (BTS SpA Viale Forlanini, 40 Garbagnate M.se (MI) I-20024 Italy btsbioengineering.com) in second visit. The sEMG activity was recorded with jaw at rest position (presence of freeway space), with teeth at first pint of contact, and centric occlusion (in a sustained MVC avoiding any facial or orbicular expression or jaw or head movement allowing the natural intercuspation of the teeth). This step was repeated three times in a row for the sEMG recording and then the average value of these three attempts was recorded. (Figure 3)

After completion of sEMG recording, subjects received the upper and lower oral orthotic devices following the clinical treatment protocol. Subjects were returned to the clinic for visit three after two weeks. This was first follow-up visit after fitting of the oral devices as a standard clinical visit. The fourth and final visit, also a standard clinical visit, was scheduled

for two weeks after the previous follow-up visit. During the fourth visit the sEMG recording captured as it was done during second visit.

Materials and Methods

This study was a single center, single-arm, prospective, controlled clinical trial. A power calculation was conducted using nQuery Advisor (Version 7.0). Assuming a correlation of 0.5 between change in pain and change in muscle activity, a sample size of n=26 was adequate to obtain a type I error rate of 5% and a power of 80%. The participants in this study were females and males age ≥ 18 years old and selected from patients complaining of TMD with myofascial pain. All subjects were selected according to DC/TMD Axis I myogenous pain group[5,6,7]

Inclusion and exclusion criteria were considered to select the subjects for this study. Inclusion Criteria were as follows: age 18 or older; all subjects presented with pain at the time of the initial evaluation upon muscle palpation (master and temporalis) using a palpometer/algometer to apply standardized pressure (2 lbs.) to assess pain; and score of 5 or greater in facial pain on a NRS scale (with score between 0-10) reporting average discomfort over the last 7 days.

Exclusion Criteria were as follows: any injury caused by trauma or tumors of head and neck; arthrogenic pain according to DC/TMD[5]; psychiatric disorders according to DC/TMD (Axis II); odontogenic tooth pain and periodontal pathology based on clinical and radiographic examinations; generalized muscle pain or a central or peripheral neurological disorder that may influence the sEMG records, patients with full/partial removable dentures; significant systemic disease that may be pain producing in muscles; subjects on opioid pain medications (NSAID and acetaminophen allowed on an as needed basis); subjects on prescribed medications that affect the muscle activity (e.g., muscle relaxants such as metaxalone, flexeril); and subjects who are participating in another health-related research study affecting pain and muscle activity.

Subject Withdrawal/Termination Criteria were also considered for this study. These criteria were: subjects with development of any systemic disease that may be pain producing in muscles during the study period; any injury caused by trauma to the head and neck during the study period; subjects with development of odontogenic tooth pain and periodontal pathology during the study period, subjects reporting taking opioid during the study; subjects who were experiencing an unanticipated adverse therapeutic effect (allergy to the materials); subjects who were deciding to stop participating in the study; and subjects who could not comply/tolerate using the oral orthotic devices.

Subjects were selected from patients who attend the Craniofacial Pain Center at Tufts University School of Dental Medicine (TUSDM) for a standard clinical visit, and no deviation from the proposed treatment occurred due to the study requirements. This study was designed to be completed in four clinical visits.

During the initial visit, the patient completed consultation, demographic information and comprehensive medical history and history of present illness (e.g., cause, duration, treatments, and history of trauma in the past six months). Review of panoramic radiograph (one is taken if the patient does not have a current radiograph), head/neck and oral examination, DC/TMD evaluation, patient discomfort scale (NRS including facial discomfort) and alginate impressions of both upper and lower arches (taken to make models for orthotic devices) also completed during first clinical visit. Upon completing the standard clinical visit, qualified patients were informed about the study. (Table 1)

All participating subjects were provided with the detailed explanation of the study protocol approved by Institutional Review Board (IRB). All subjects signed the written IRB approved

Informed Consent Form (ICF), ensured that they understand the study, certifying their willingness to participate in the study.

Muscle palpations performed using a palpometer/algometer (pressure gauge) to apply standardized pressure (2 lbs.) to masseter and temporalis to assess pain. The NRS form was completed according to the subjective pain sensation. All subjects were instructed to refrain from NSAID and/or acetaminophen use for 24 hours prior to Visit 2. (In order to be sure the serum half-life of the medication has been exitded and to avoid its possible effects on the data collection.)

Patients were scheduled for the second visit for fitting of the oral orthotic devices and capturing sEMG. Prior to fitting of oral orthotic devices, sEMG was performed using BTS FREEEMG unit. Commercially available BTS TMJOINT used for dental occlusion functional analysis incorporating surface electromyographic analysis to measure the differential influence of the neuromuscular alterations induced by occlusal function. Standardization of the sEMG recording technique performed according to manufacturer to avoid any variability between visit 2 and 4 (i.e., position of the probes, conductance of the skin, muscle cross-talk, age and gender).

Patients seated in the dental chair in an upright position and head in a natural position without head support. Facial skin was cleaned with an alcohol swab; four disposable 8 mm silicon electrodes were located in place and positioned parallel to the direction of muscle fibers of anterior temporalis and masseter muscles on both sides by palpating the muscles. (Figure 2)

A plastic shield guide was marked, using anatomical landmarks, with the site of the electrodes positions to help with the positioning of the probes at the same location during visit 4. A set-

up test done for all subjects. The Set-up test is a calibration test and all the trials acquired after this test compared with the Set-up test. The sEMG software automatically calculates the indices considering the ratio between the set-up test and tests without cotton rolls.

The patients asked to clench for five seconds with two cotton rolls placed between the two arches, one for each side (on molar and pre-molar teeth). This step is a reference for standardization. Since different jaw positions cause different muscle function, the electromyographic activities of both masseter and temporalis muscles were collected at three different mandibular positions.

The sEMG activity was recorded with jaw at rest position (presence of freeway space), with teeth at first pint of contact, and centric occlusion (in a sustained MVC avoiding any facial or orbicular expression or jaw or head movement allowing the natural intercuspation of the teeth). Subjects were asked to clench their teeth for five seconds then rest for ten seconds. This step was repeated three times in a row for the sEMG recording. The average value of these three attempts was recorded. The recorded values of sEMG activity at rest, point contact, and MVC expressed as a percentage of the activity recorded during the standardization test. (Figures 4-9)

After completion of sEMG recording, subjects received the oral orthotic devices. The upper device was modified by creating an anterior platform so that the opposing dentition (canine to canine) occlusal contacts occlude uniformly. Bilateral posterior point contacts were also provided in the area of first or second molar. Subject were in the supine position in a dental chair with head placed on the headrest and provided pillow in a most subjective comfortable position.

The lower custom fabricated device constructed so that only three bilateral posterior contacts (from the second premolar to the first/second molar) allowed without static and dynamic anterior contacts. Subjects were seated in the dental chair in an upright position without head support with the trunk in an erect posture and head in a natural position. Lower oral orthotic device modified in this body position. All occlusal contacts were even and occlude simultaneously with the occluding surface of the device. Subjects were asked to wear the upper device while sleeping. Subject were asked to wear the lower device during the day (approximately 2-3 hours in the morning and 3-4 hours in the afternoon). They were asked not to eat with these devices.

Subjects were returned to the clinic after two weeks for visit three (first follow-up visit after fitting of the oral devices) as a standard clinical visit. Based on the review of subjective symptoms and clinical evaluation and examination, necessary adjustment and modification of the devices were done by modifying occlusal contact as needed. Eligibility and subject withdrawal criteria were reviewed during visit three and four to ensure that the subject still qualifies for the study.

The fourth and final visit, also a standard clinical visit, was scheduled for two weeks after the previous follow-up visit. Set-up test and sEMG assessment of the bilateral masseter and anterior temporalis muscles were performed as at visit two. The sEMG activity with jaw at rest position (no teeth contact), point contact, and MVC on natural intercuspation of the teeth were recorded. (Figure 23)

Analysis and index calculation of the collected data performed by dental contact analyzer software according to BTS TMJOINT manufacturer using commercially available wireless

BTS FREEEMG unit (BTS SpA Viale Forlanini, 40 Garbagnate M.se (MI) I-20024 Italy btsbioengineering.com).

Descriptive statistics (e.g., means and standard deviations) were calculated. A mixed model used for the analysis of the association between changes in pain and changes in muscle activity. A p-value of less than .05 considered statistically significant.

Statistical Analysis

A power calculation was conducted using nQuery Advisor (Version 7.0). Assuming a correlation of 0.5 between change in pain and change in muscle activity, a sample size of n=26 was adequate to obtain a type I error rate of 5% and a power of 80%.

The followings are different analysis techniques considered to calculate these indices:

To determine symmetric distribution of the muscular activity determined by occlusion, the EMG waves of paired muscles were compared by computing a Percentage Overlapping Coefficient (POC, unit: 0% - 100%).[35,36]

The mean total muscle activities for the four investigated muscles (right and left masseter, right and left temporalis) were computed as the areas of the standardized EMG potentials (normalized r.m.s. amplitude) over time (unit: μV / μVs %).[35,36] Calculating mean surface EMG activity for existence of differences between the left and right assessed. This calculation will assess any difference in the surface EMG activity of muscles of the sides with different pain levels.

To determine ratios of the right side to the left side different muscular activation, the asymmetry index (SAI) between the sides was calculated.[37] The difference in surface EMG activity between muscles on the right side to the left side were assessed for each paired muscles. All the sEMG assessed by dental contact analyzer software according to BTS TMJOINT manufacturer. This finding assessed the sEMG activity relation to the pain level on the same side.

SAS version 9.2 was used in the analysis.

Results

A total of 26 study subjects (20 females [76.92%] and six males [23.03%] with different ethnicity) were selected, according to DC/TMD, with a complaint of moderate to severe pain. Pre-treatment NRS on the side with worse pain ranged from 5-8 and the mean score recorded as 6.34 with standard deviation (SD) of 0.98. Post-treatment NRS ranged from 0-5 and the mean score recorded as 2.58 with SD of 1.24. (Table 2)

With muscles of mastication at rest, comparing pre and post-treatment sEMG parameters of temporalis and masseter muscles with worse pain, most findings were not significantly different at the study population level. (Table 3)

Pre-treatment sEMG parameters of temporalis muscle at rest on the side with worse pain showed a mean activity of 5.18 µV*sec. with SD of 1.80 µV*sec. and range of 8.16 µV*sec. Post-treatment sEMG parameters of temporalis muscle at rest on the side with worse pain showed a mean activity of 5.18 µV*sec. with SD of 1.86 µV*sec. and range of 8.42 µV*sec. (Figure 13) The sEMG parameters of temporalis muscle at rest on the side with a lesser degree of pain showed pre-treatment mean of 4.72 µV*sec., SD of 1.17 µV*sec. and range of 5.95 µV*sec. (Figure 14) Post-treatment sEMG parameters of temporalis muscle at rest on the side with a lesser pain showed a mean of 4.85 µV*sec. with SD of 1.06 µV and range of 4.25 µV*sec. (Table 6)

At the population study level, pre-treatment masseter muscle sEMG parameters of the side with worse pain at rest indicated a mean of 4.46 µV*sec., SD of 0.83 µV*sec. and range of 3.77 µV*sec. (Figure 15) Post-treatment sEMG parameters of the masseter muscle at rest on the side with worse pain showed a mean of 4.35 µV*sec. with SD of 0.63 µV*sec and range

of 2.40 µV*sec. The sEMG parameters of the masseter muscle at rest on the side with a lesser degree of pain showed pre-treatment mean of 4.34 µV*sec., SD of 0.72 µV*sec. and range of 2.95 µV*sec. (Figure 16) Post-treatment sEMG parameters of the masseter muscle at rest on the side with a lesser pain showed a mean of 4.44 µV*sec. with SD of 0.72 µV*sec. and range of 3.28 µV*sec. (Table 7)

The same set of sEMG activity recording of the temporalis and masseter muscles was recorded during MVC. A very high variable findings were shown between pre and post-treatment sessions at both individual and the population study level.

Pre-treatment temporalis muscle sEMG parameters of the side with worse pain at MVC indicated a mean of 65.99 µV*sec., SD of 52.11 µV*sec. and range of 221.01 µV*sec. Post-treatment sEMG parameters of temporalis muscle at MVC of the side with worse pain showed a mean of 60.48 µV*sec. with SD of 32.68 µV*sec and range of 127.86 µV*sec. (Figure 17) The sEMG pre-treatment parameters of temporalis muscle on the side with a lesser degree of pain at MVC showed a mean of 57.95 µV*sec., SD of 42.59 µV*sec. and range of 143.88 µV*sec was recorded. (Figure 18) Post-treatment sEMG parameters of temporalis muscle on the side with a lesser pain at MVC showed a mean of 55.82 µV*sec. with SD of 33.21 µV and range of 148.65 µV*sec. (Table 8)

Pre-treatment masseter muscle sEMG parameters at MVC of the side with worse pain indicated a mean of 73.31 µV*sec., SD of 58.70 µV*sec. and range of 253.26 µV*sec. Post-treatment sEMG parameters of the masseter muscle at MVC on the side with worse pain showed a mean of 69.68 µV*sec. with SD of 46.86 µV*sec and range of 184.37 µV*sec. (Figure 19) Pre-treatment sEMG parameters of the masseter muscle at MVC on the side with a lesser degree

of pain showed a mean of 67.84 µV*sec. with SD of 55.73 µV*sec. and range of 209.6 µV*sec. (Figure 20) Post-treatment sEMG parameters of the masseter muscle at MVC on the side with lesser pain showed a mean of 66.84 µV with SD of 53.92 µV and range of 175.33 µV*sec. (Table 9)

Pre-treatment temporalis muscle sEMG parameters of the side with worse pain with teeth at point contact indicated a mean of 7.97 µV*sec., SD of 4.37 µV*sec. and range of 17.72 µV*sec. Post-treatment sEMG parameters of temporalis muscle, with teeth at point contact, of the side with worse pain showed a mean of 7.98 µV*sec. with SD of 4.06 µV*sec and range of 16.59 µV*sec. (Figure 21) The sEMG pre-treatment parameters of temporalis muscle on the side with a lesser degree of pain with teeth at point contact showed a mean of 7.73 µV*sec., SD of 5.81 µV*sec. and range of 30.98 µV*sec was recorded. Post-treatment sEMG parameters of temporalis muscle on the side with a lesser pain with teeth at point contact showed a mean of 7.01 µV*sec. with SD of 3.78 µV and range of 18.9 µV*sec. (Table 10)

Pre-treatment masseter muscle sEMG parameters of the side with worse pain with teeth at point contact indicated a mean of 6.62 µV*sec., SD of 3.25 µV*sec. and range of 14.65 µV*sec. Post-treatment sEMG parameters of the masseter muscle of the side with worse pain with teeth at point contact showed a mean of 6.02 µV*sec. with SD of 2.70 µV*sec and range of 11.15 µV*sec. (Figure 22) Pre-treatment sEMG parameters of the masseter muscle of the side with a lesser degree of pain with teeth at point contact showed a mean of 6.46 µV*sec. with SD of 3.20 µV*sec. and range of 16.13 µV*sec. Post-treatment sEMG parameters of the masseter muscle of the side with lesser pain with teeth at point contact showed a mean of 5.75 µV with SD of 1.52 µV and range of 6.22 µV*sec. (Table 11)

The pain level improvement is statistically significant during this study period. Pre-treatment pain NRS of the side with worse pain indicated a mean of 6.38, SD of 0.94 and range of 3. Post-treatment pain NRS of the side with worse pain showed a mean score of 2.58 with SD of 1.24 and range of 5. The side with lesser pain of the participating subjects indicated pre-treatment pain NRS with mean of 2.81, SD of 2.38 and range of 7. It also indicated post-treatment pain NRS with the mean score of 1.19, SD of 1.44 and range of 5. (Figure 12)

Discussion

In spite of an abundance of research in the field, the current body of literature poorly supports the diagnostic and therapeutic approaches involved in the treatment of TMD. The impact of muscle activity and muscle pain on a patient with TMD-myofascial pain has long been a field of interest for practitioners. Current literatures support different theories to explain muscle pain, muscle hyperactivity and pain adaptation models.[38]

The evolving science of pain has revealed a multitude of subjective features as well as underlying mechanisms involved in the pain process. Hence not all pain is treated in the same manner. Nociceptors can be activated and sensitized by different stimuli (e.g. mechanical stimuli such as trauma or overloading and endogenous inflammatory mediators) that trigger pain perception. Myofascial pain is one such pain entity and with muscle pain as a major medical problem, it draws attention of care providers for better understanding of the causes, proper management, and treatment.

In dentistry, few studies have highlighted the clinical significance of the EMG parameters, and have provided inconsistent results as well. There are multiple influencing factors (e.g. body posture and emotional stress and relaxation state) affecting neuromuscular control of jaw position. Some of the neck muscles with increased sEMG parameters have been linked to jaw muscle pain.[31] Other studies reported an association between muscle activity and bite force which results in lower muscle activity in patients diagnosed with TMD-myofascial pain syndrome.[17,21,27] A more recent investigation with attempt to detect differences in sEMG activity of the patient with unilateral TMD-myofascial pain, denied any finding or link between the symptomatic and asymptomatic muscles.[39]

This study was designed to investigate the association between the change in muscle electrical activity of the masseter and temporalis muscles at mandibular rest position and the change in the pain level, from pre-treatment to post-treatment with oral orthotic devices. To enhance the internal validity of this study, it was reasonable to set the inclusion and exclusion criteria for congruity of the group. Following this criteria in turn affected the sample size of the study and is considered one of the limitations of the study design. Another limiting factor of this study was to include subjects with asymmetrical bilateral face pain, and the results may not be extrapolated to patients with unilateral TMD-myofascial pain symptoms. Long term follow up care and assessment of the symptoms with further analysis of the data may provide stronger support for this study findings. All measures were considered to minimize inherent noise for assessment purposes and to obtain reproducible standard EMG recording at pre and post-treatment sessions.[40]

In this investigation, we examined whether pain equated to sEMG parameters and characteristics in subjects with asymmetrical bilateral TMD-myofascial pain symptoms. The sEMG parameters and pain levels were collected, according to protocols used in the research setting, before and after all subjects were treated with oral orthotic devices. Participating subjects selected according to set inclusion and exclusion criteria without any prior related treatment for the past two years.

Combined sEMG parameters of the side with worse pain indicated the followings. At the group level, pre-treatment sEMG parameters of masseter and anterior temporalis muscles at mandibular rest position indicated the mean score of 56.23 μV*sec. with SD of 11.43 μV*sec. and a range of 51 μV*sec. Post-treatment sEMG parameters of masseter and anterior

temporalis muscles at mandibular rest position indicated the mean score of 57.57 µV*sec. with SD of 11.16 µV*sec. and range of 55 µV*sec. (Table 3)

Pre-treatment sEMG parameters of masseter and anterior temporalis muscles with teeth at point contact indicated the mean score of 83.8 µV*sec. with SD of 30.24 µV*sec. and a range of 154 µV*sec. Post-treatment sEMG parameters of masseter and anterior temporalis muscles with teeth at point contact indicated the mean score of 77.92 µV*sec. with SD of 24.34 µV*sec. and a range of 115 µV*sec. (Table 4)

Pre-treatment sEMG parameters of masseter and anterior temporalis muscles at MVC indicated the mean score of 768.50 µV*sec. with SD of 508.36 µV*sec. and a range of 1755 µV*sec. Post-treatment sEMG parameters of masseter and anterior temporalis muscles at MVC indicated the mean score of 728.77 µV*sec. with SD of 458.23 µV*sec. and a range of 1634 µV*sec. (Table 5)

Correlation analysis was conducted to evaluate the association between change in pain, with the change at rest, and change in MVC. The analysis changes of NRS with rest sEMG parameters correlation coefficient is -0.139 and the p-value of 0.50. This analysis also indicates changes of NRS with MVC sEMG parameters correlation coefficient as -0.220 and the p-value of 0.28. No associations were found to be significant at the alpha 0.05 level in this group of subjects. At the individual level, difference between pre-treatment and post-treatment pain level on the side with worse pain was significant. (Figures 10) The pain level difference between pre-treatment and post-treatment on the side with lesser pain was also significant at the individual level. (Figure 11) At the group level, difference between pre-treatment and post-treatment pain level on the side with worse pain was also significant. (Figures 12)

Conclusion

Within limits of this study, there is not enough evidence to support the hypothesis. Despite a significant improvement in pain level, our study did not find a positive association between changes in sEMG activity and change in pain level of the masseter and temporalis muscles, before and after treatment with oral orthotic devices. Standardized methodology to capture EMG plays an important role to achieve accurate data. Limitation of these standardized methodology in capturing sEMG used in the current literatures, has to be considered as the possible underlying factor. Considering these limitations, further studies needed prior to conclude different pain theories including different pain mechanisms, pain adaptation, centrally mediated pain mechanism, and also protective functional activation of the muscles

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APPENDICES

Appendix A: Tables

Appendix B: Figures

Appendix C: Illustrations, data, links

Appendix A: Tables

Appointment Procedures	Visit 1	Visit 2	Visit 3	Visit 4
Standard of care procedures for visit	X	X	X	X
Informed Consent Form	X			
Evaluate inclusion/exclusion criteria	X			
Palpometer rating	X			X
Patient Discomfort Scale	X	X	X	X
Evaluate eligibility and withdrawal criteria		X	X	X
EMG		X		X
Handout/Collect Diary		X	X	X
Adverse Event Assessment		X	X	X
Stipend		X		X

Table 1. Subject Timeline

NRS from 0-10	Pre-treat. Side with worse pain	Post-treat. Side with worse pain	Pre-treat. Side with a lesser pain	Post-treat. Side with a lesser pain
Mean	6.38	2.58	2.81	1.19
SD	.094	1.24	2.38	1.44

Table 2. Pain index

Temporalis & Masseter	**Pre-treat. EMG Side with worse pain at Rest**	**Post-treat. EMG Side with worse pain at Rest**
Mean	56.23	57.58
SD	11.43	11.16

Table 3. Combined temporalis & masseter EMG at rest

Temporalis & Masseter	**Pre-treat. EMG Side with worse pain at MVC**	**Post-treat. Side with worse pain at MVC**
Mean	768.50	728.77
SD	508.36	458.23

Table 4. Combined temporalis & masseter EMG at MVC

Temporalis & Masseter	**Pre-treat. EMG Side with worse pain, teeth at point contact**	**Post-treat. Side with worse pain, teeth at point contact**
Mean	83.08	77.92
SD	30.24	23.34

Table 5. Combined temporalis & masseter EMG with teeth at point contact

Temporalis at Rest	Pre-treat. Side with worse pain at rest EMG	Post-treat. Side with worse pain at rest EMG	Pre-treat. Side with a lesser pain at rest EMG	Post-treat. Side with a lesser pain at rest EMG
Mean	5.18	5.18	4.72	4.85
SD	1.8	1.86	1.17	1.06

Table 6. Temporalis muscle EMG at rest

Masseter at Rest	Pre-treat. Side with worse pain at rest EMG	Post-treat. Side with worse pain at rest EMG	Pre-treat. Side with a lesser pain at rest EMG	Post-treat. Side with a lesser pain at rest EMG
Mean	4.46	4.35	4.34	4.44
SD	0.83	0.63	0.72	0.72

Table 7. Masseter muscle EMG at rest

Temporalis at MVC	Pre-treat. Side with worse pain at rest EMG	Post-treat. Side with worse pain at rest EMG	Pre-treat. Side with a lesser pain at rest EMG	Post-treat. Side with a lesser pain at rest EMG
Mean	65.99	60.48	57.95	55.82
SD	52.11	32.68	42.59	33.21

Table 8. Temporalis muscle EMG at MVC

Masseter at MVC	Pre-treat. Side with worse pain at rest EMG	Post-treat. Side with worse pain at rest EMG	Pre-treat. Side with a lesser pain at rest EMG	Post-treat. Side with a lesser pain at rest EMG
Mean	73.31	69.68	67.84	66.84
SD	58.70	46.86	55.73	53.92

Table 9. Masseter Muscle EMG at MVC

Temporalis EMG, teeth w/ Point Contact	**Pre-treat. Side with worse pain at point contact EMG**	**Post-treat. Side with worse pain at point contact EMG**	**Pre-treat. Side with a lesser pain at point contact EMG**	**Post-treat. Side with a lesser pain at point contact EMG**
Mean	7.97	7.98	7.73	7.01
SD	4.37	4.06	5.81	3.78

Table 10. Temporalis EMG with teeth at point contact

Masseter EMG, teeth w/ Pint Contact	Pre-treat. Side with worse pain at point contact EMG	Post-treat. Side with worse pain at point contact EMG	Pre-treat. Side with a lesser pain at point contact EMG	Post-treat. Side with a lesser pain at point contact EMG
Mean	6.62	6.02	6.46	5.75
SD	3.25	2.70	3.20	1.52

Table 11. Masseter EMG with teeth at point contact

Appendix B: Figures

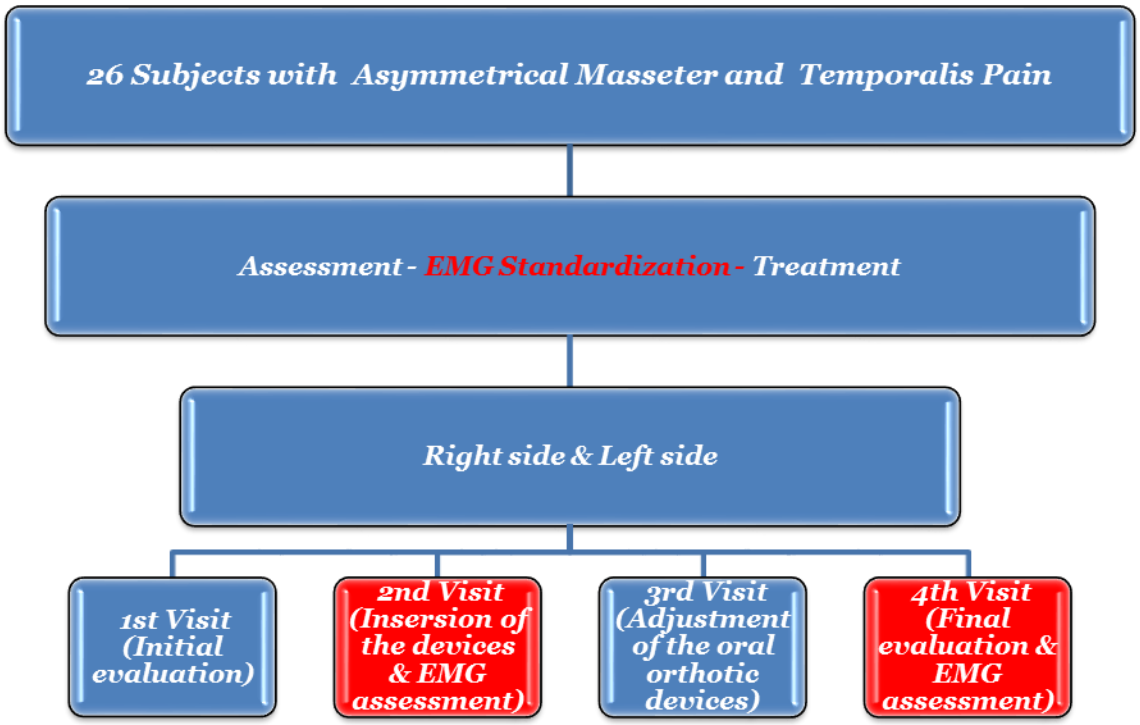


Figure 1. Flow chart of the study protocol

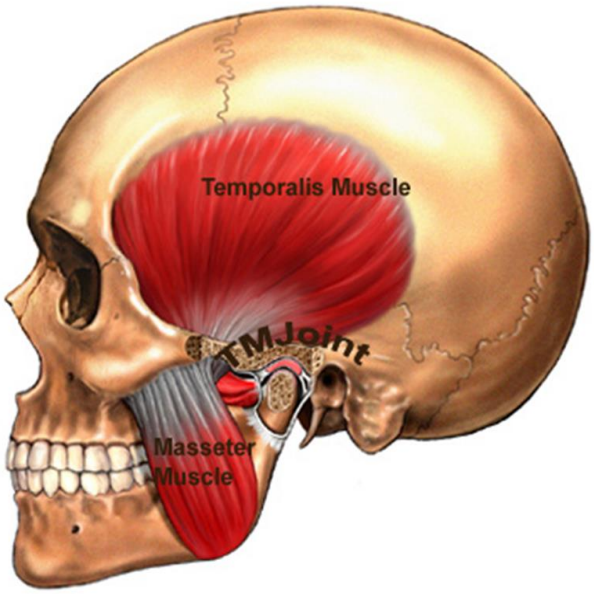


Figure 2. Masseter and temporalis muscles

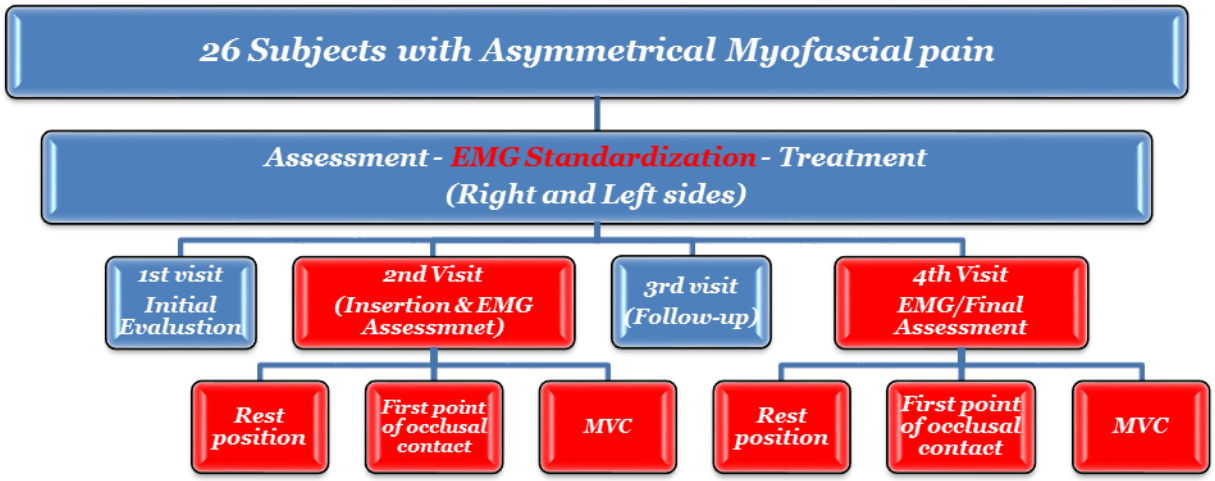


Figure 3. Flow chart of jaw position EMG capture

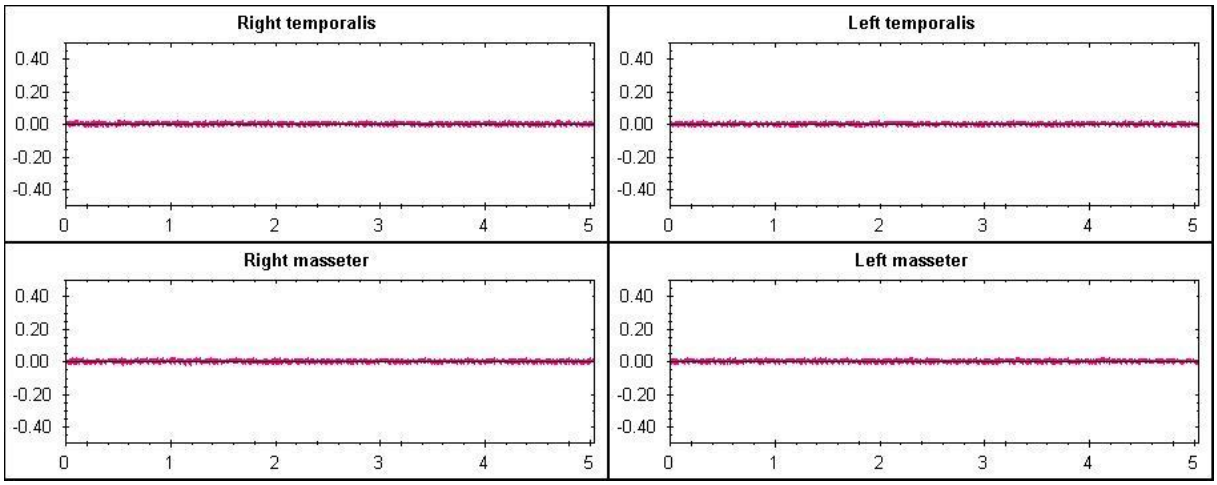


Figure 4. Pre-treatment sEMG at rest

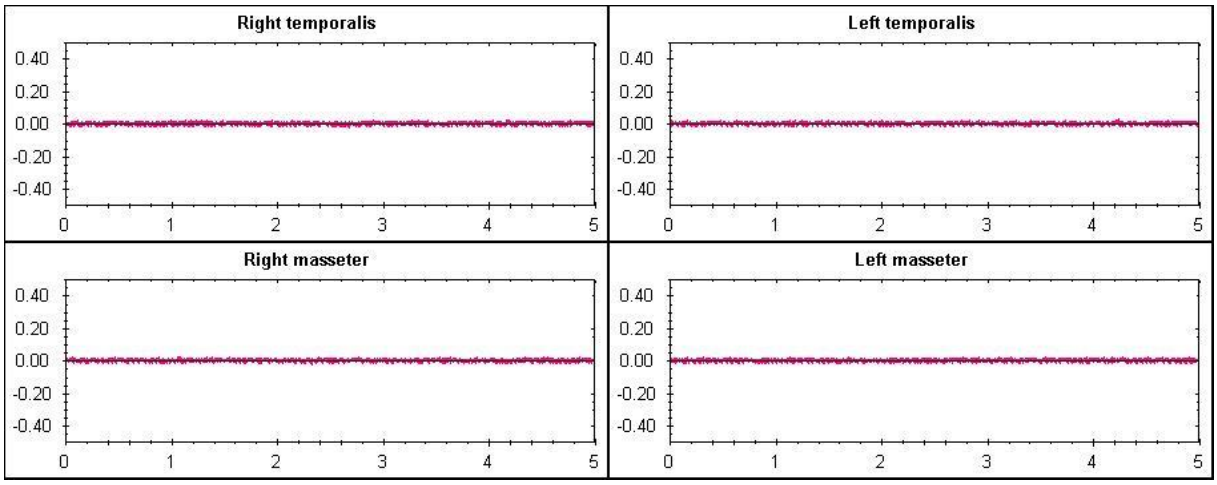


Figure 5. Post-treatment sEMG at rest

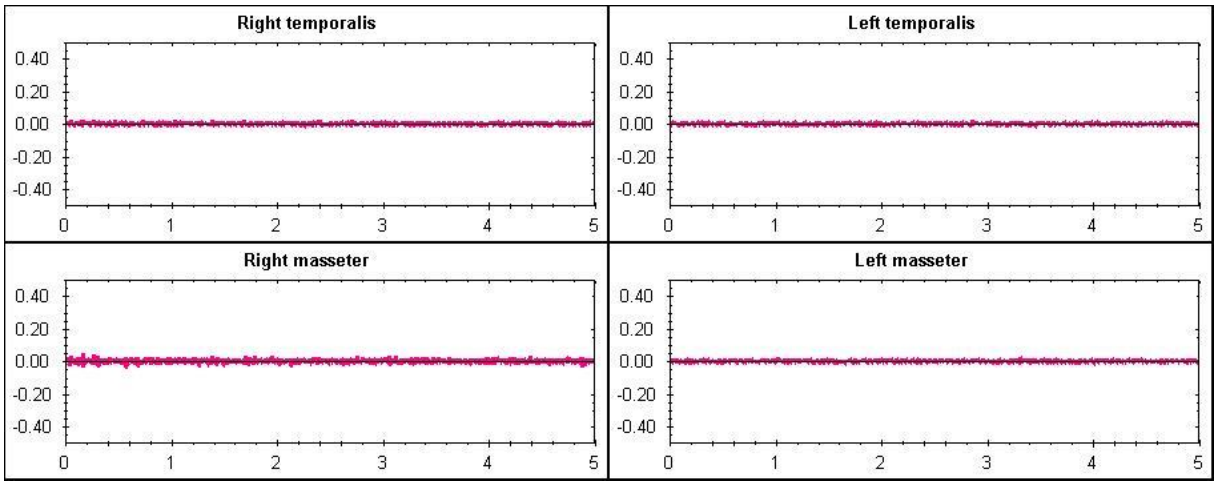


Figure 6. Pre-treatment sEMG with teeth at point contact

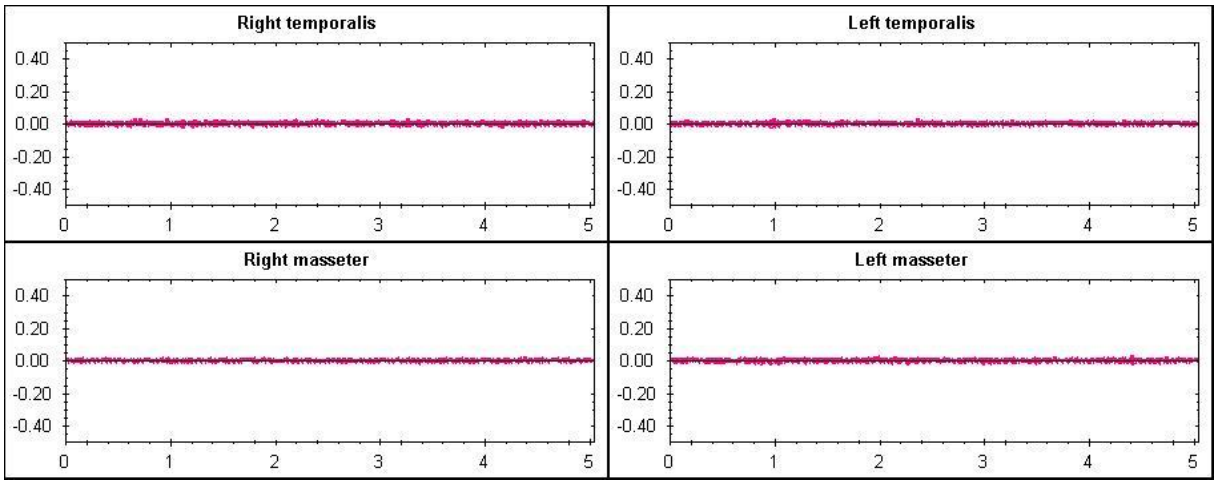


Figure 7. Post-treatment sEMG with teeth at point contact

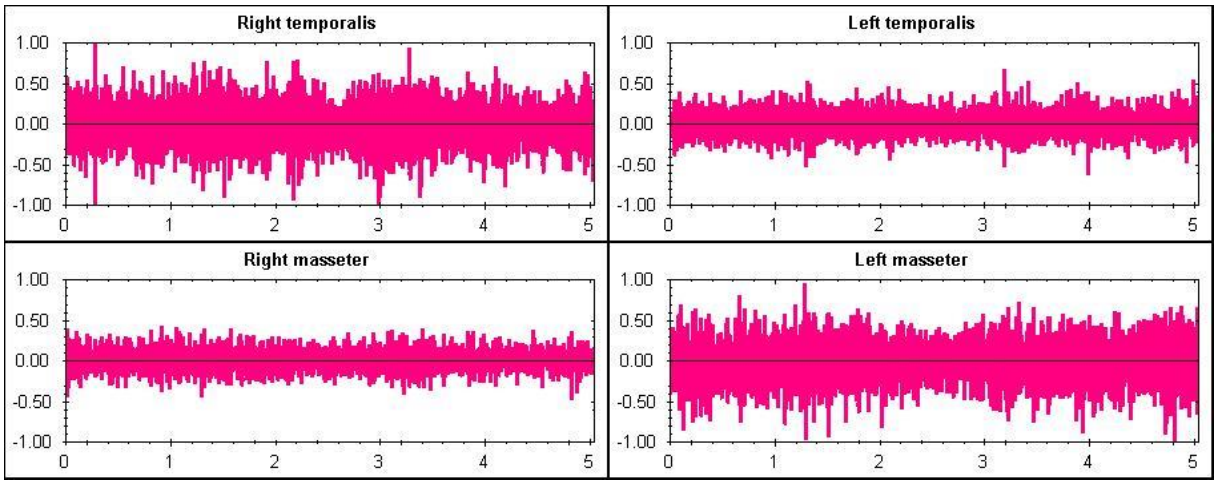


Figure 8. Pre-treatment sEMG at MVC

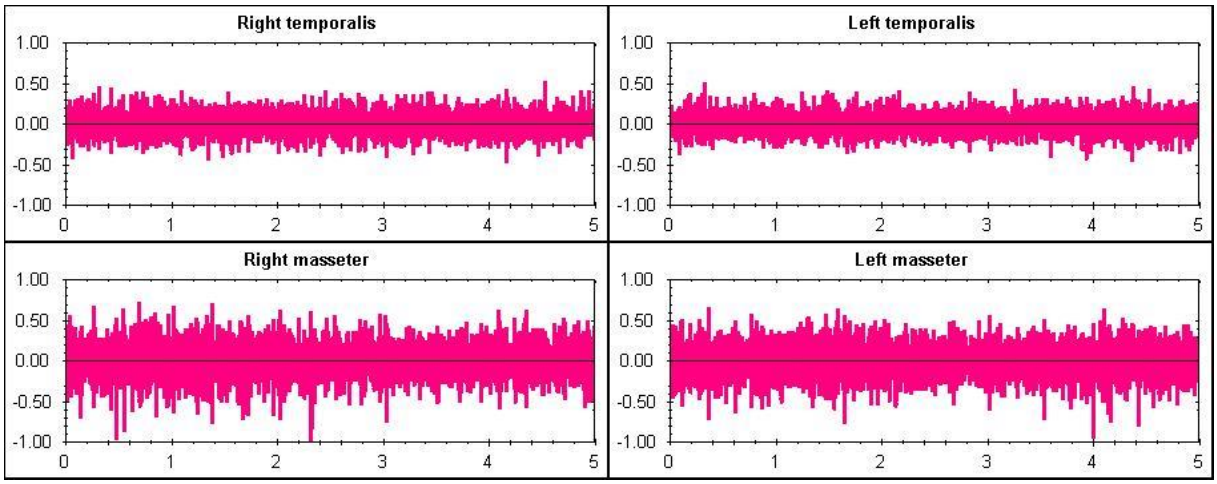


Figure 9. Post-treatment sEMG at MVC

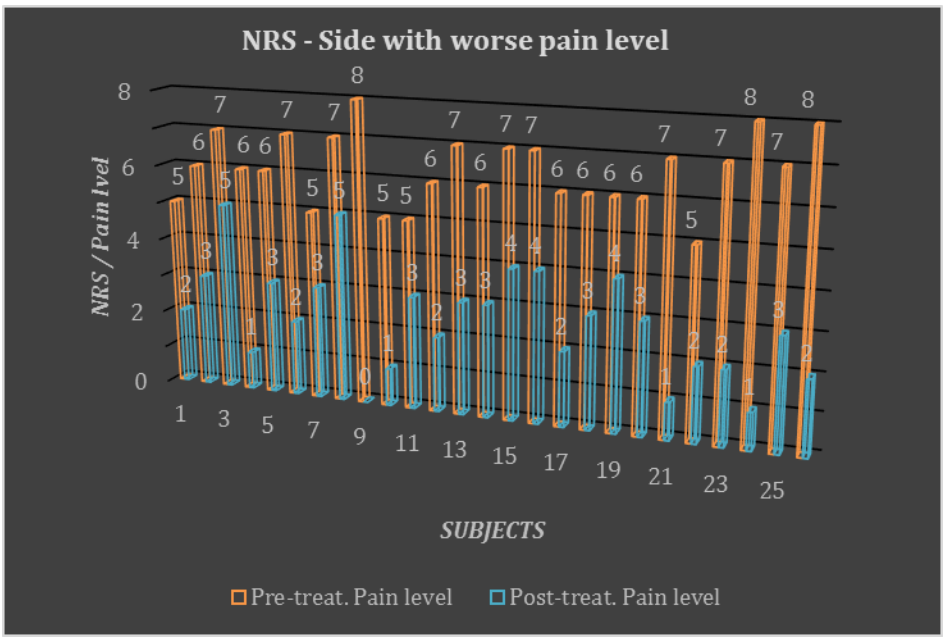


Figure 10. Pain level of the side with worse pain

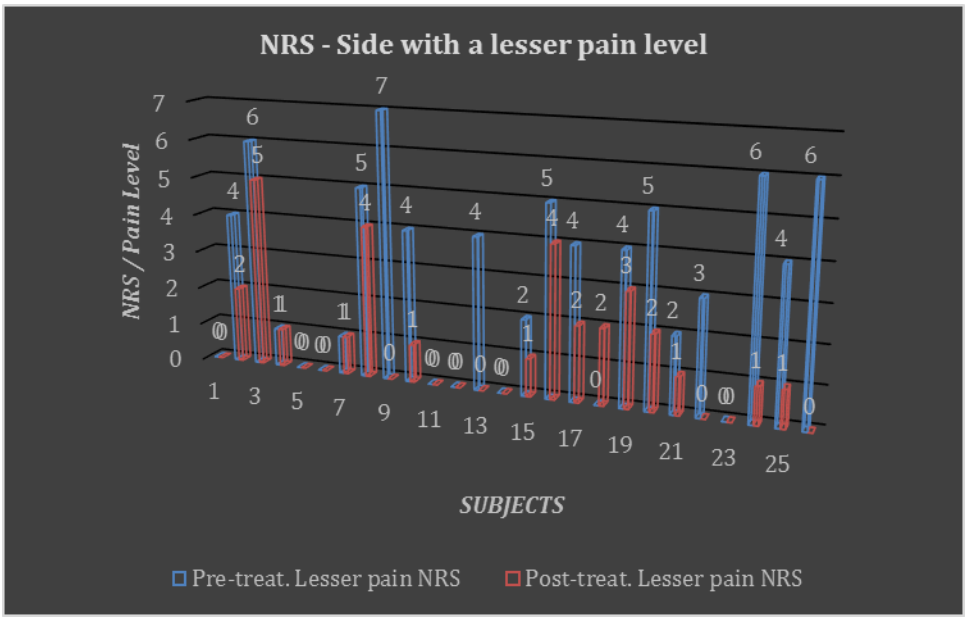


Figure 11. Pain level of the side with a lesser pain

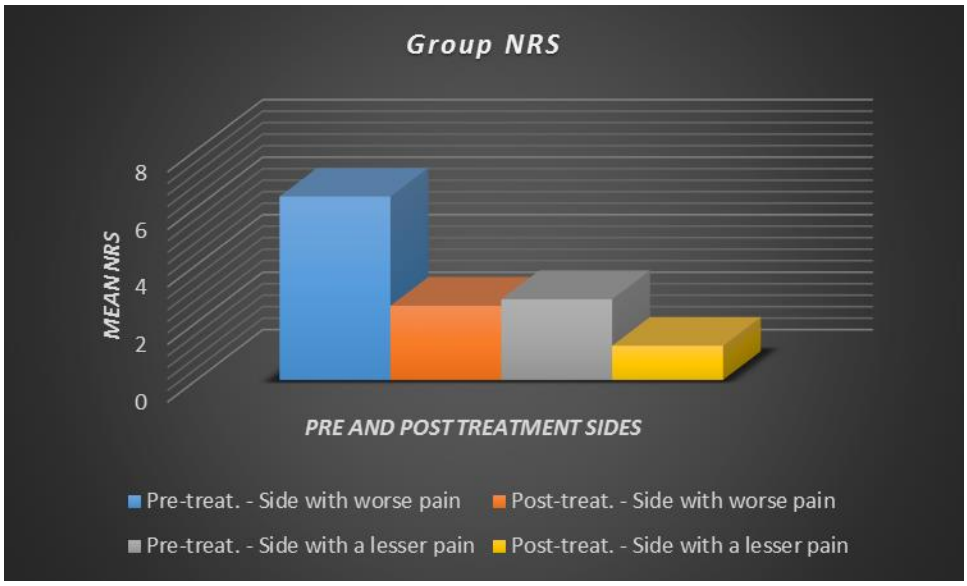


Figure 12. Group NRS pre and post-treatment

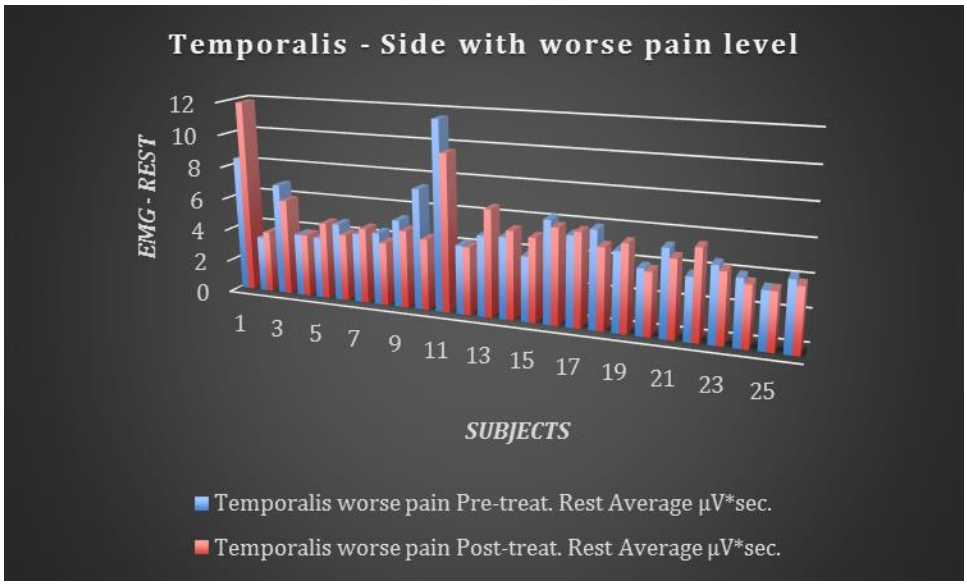


Figure 13. Temporalis EMG of the side with worse pain at rest

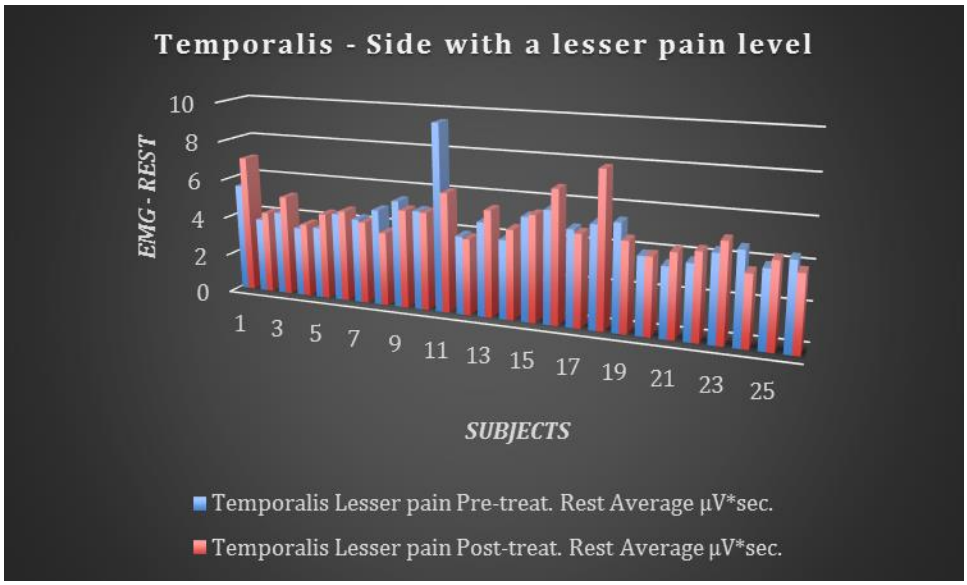


Figure 14. Temporalis EMG of the side with a lesser pain at rest

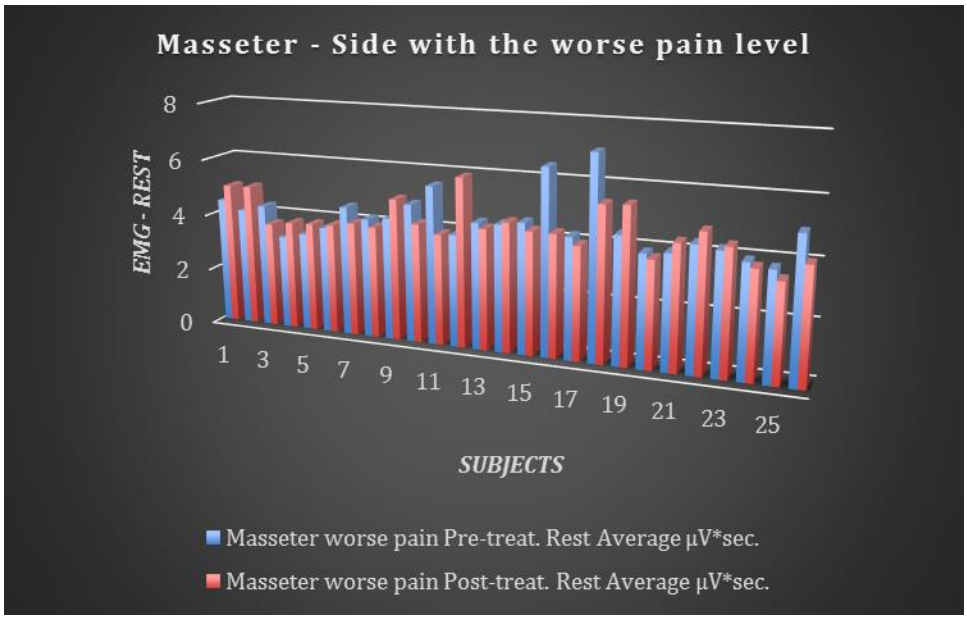


Figure 15. Masseter EMG of the side with worse pain at rest

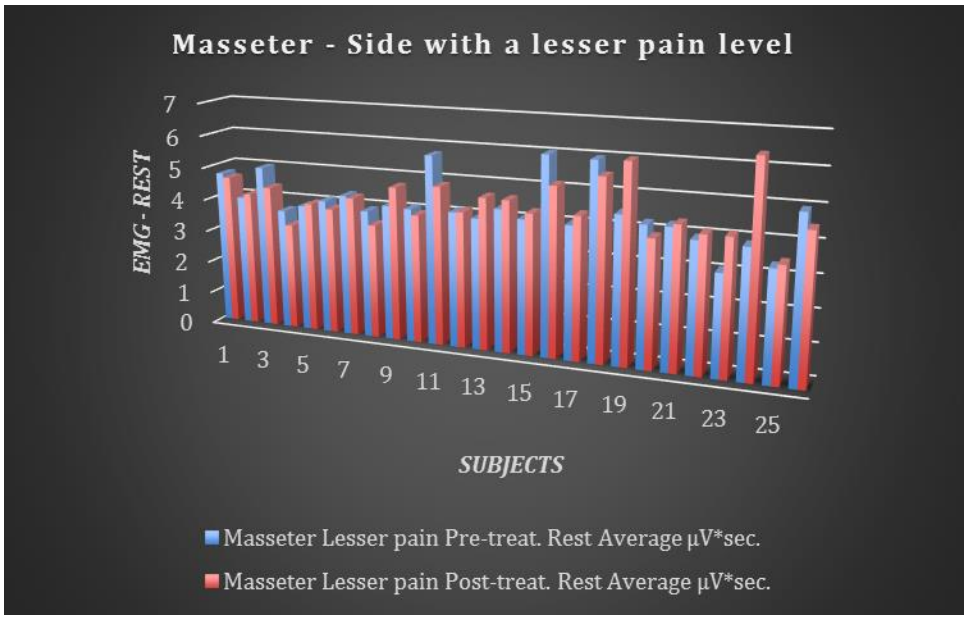


Figure 16. Masseter EMG of the side with a lesser pain at rest

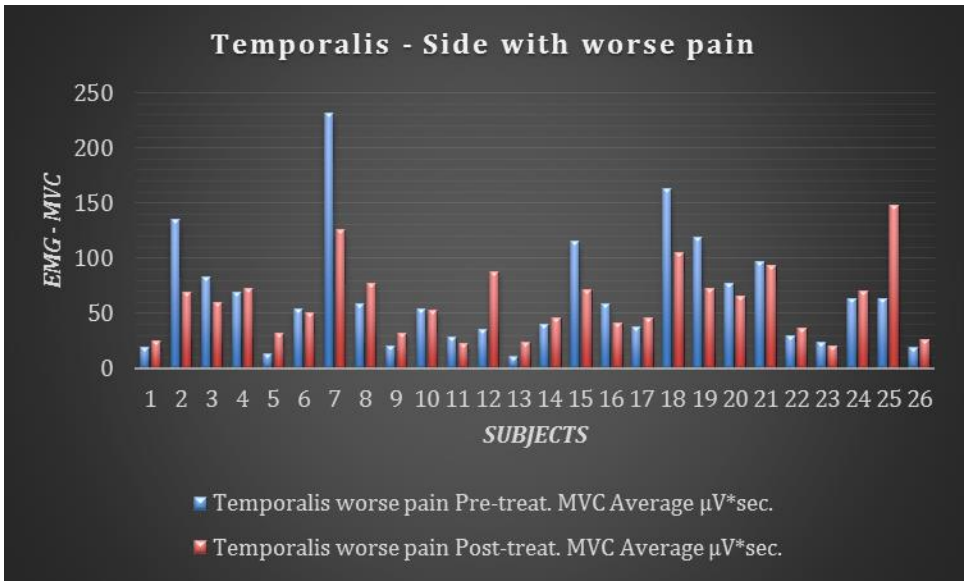


Figure 17. Temporalis EMG of the side with worse pain at MVC

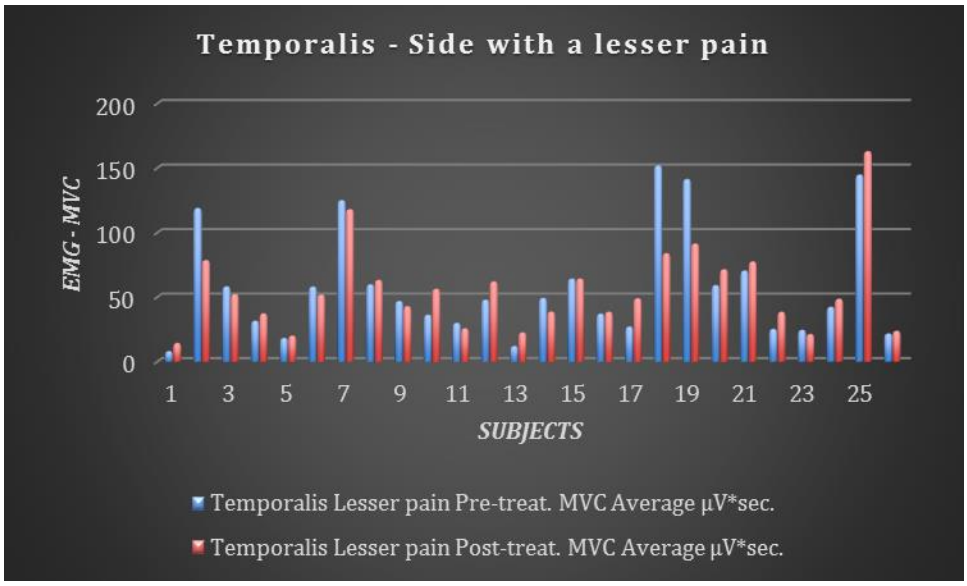


Figure 18. Temporalis EMG of the side with a lesser pain at MVC

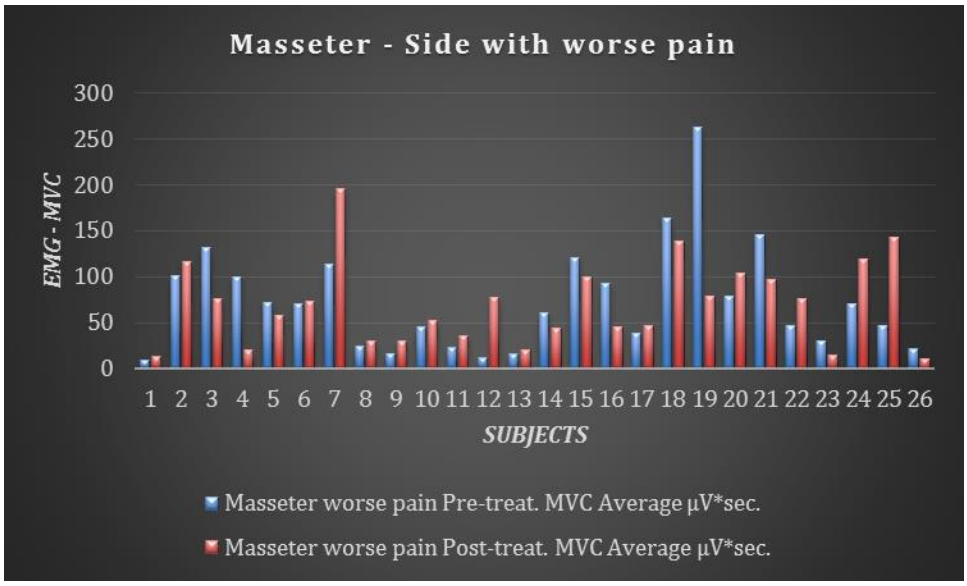


Figure 19. Masseter EMG of the side with worse pain at MVC

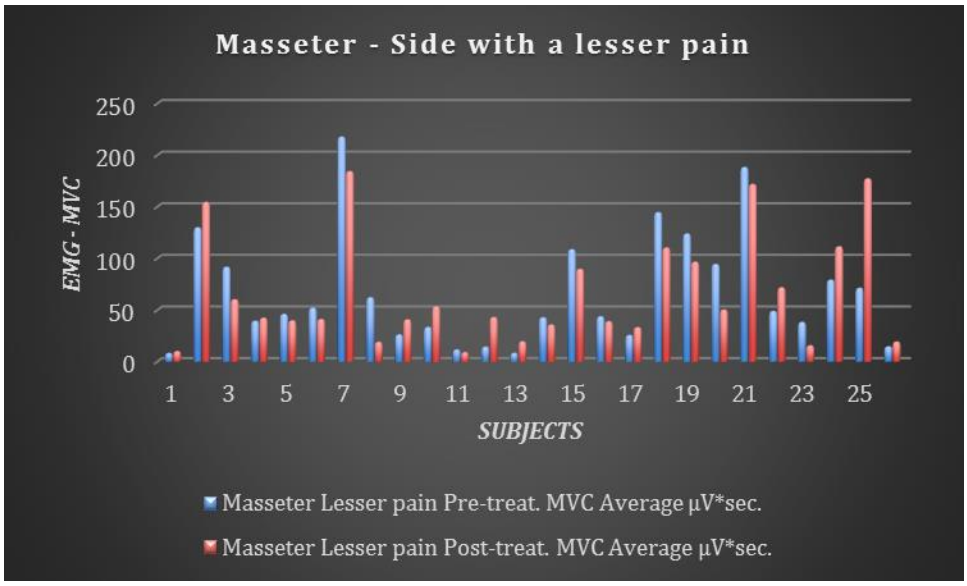


Figure 20. Masseter EMG of the side with a lesser pain at MVC

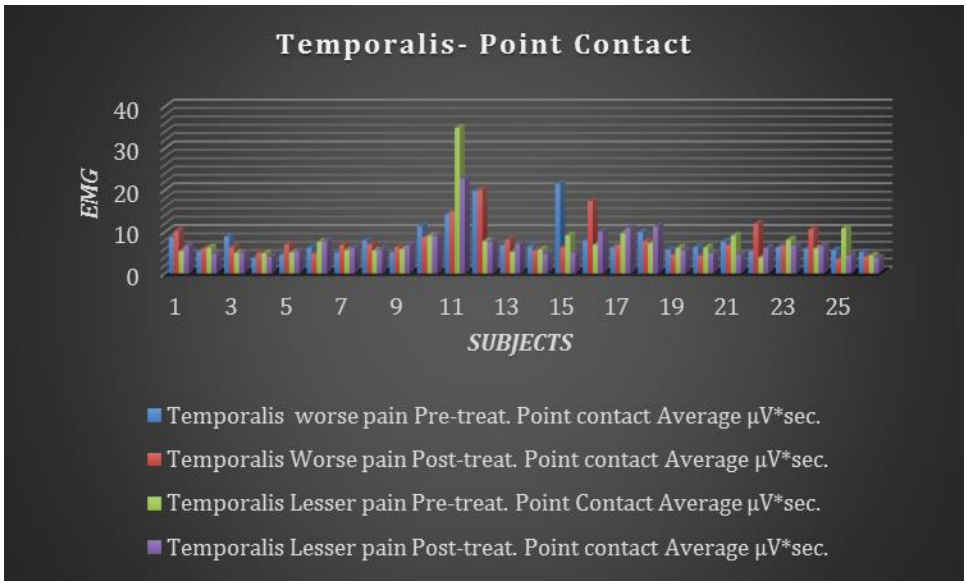


Figure 21. Temporalis pre and post-treatment EMG at point contact

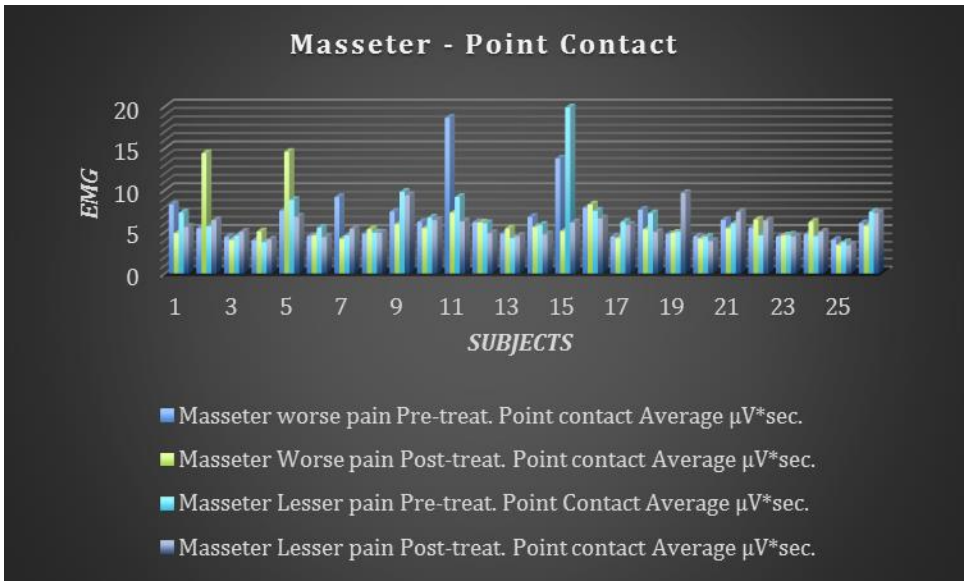


Figure 22. Masseter pre and post-treatment EMG at point contact

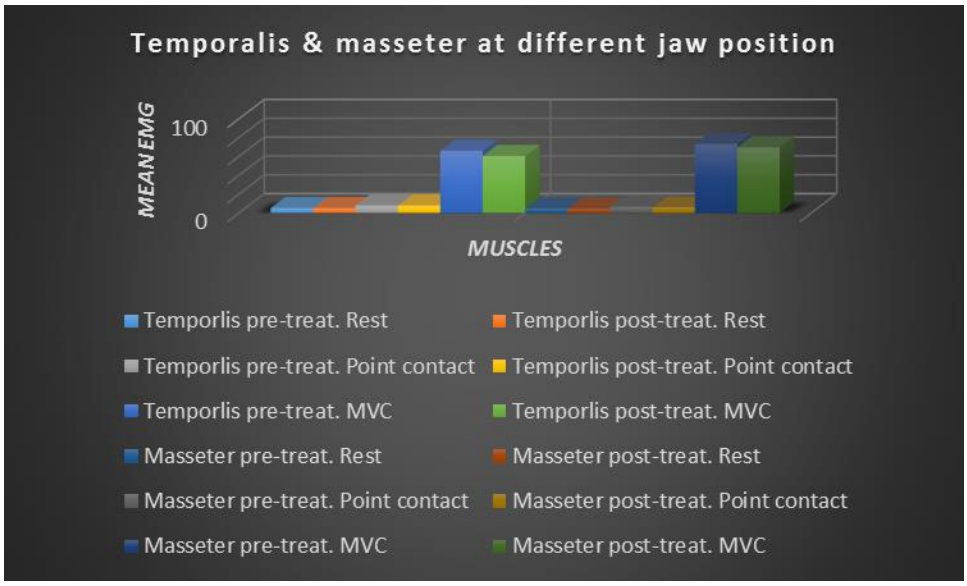


Figure 23. Pre and post-treatment mean EMG muscle groups

Appendix C: Illustarations

Case contents

- Receiving Unit

- Probes Kit available in 2 versions:
  - POC4: include 4 wireless probes*
  - POC6: include 6 wireless probes*

*(identificative labels available in 4 different colors)

- Probes Charger (AC adapter included)

	Temporalis worse pain Pre-treat. Rest Average µV*sec.	Temporalis worse pain Post-treat. Rest Average µV*sec.	Temporalis Lesser pain Pre-treat. Rest Average µV*sec.	Temporalis Lesser pain Post-treat. Rest Average µV*sec.
1	8.42	11.91	5.55	7.03
2	3.45	3.82	3.84	4.22
3	6.91	5.96	4.29	5.15
4	3.88	3.88	3.58	3.8
5	3.82	4.75	3.69	4.44
6	4.79	4.16	4.52	4.69
7	4.31	4.66	4.34	4.22
8	4.47	3.9	4.91	3.77
9	5.39	4.78	5.47	5.03
10	7.41	4.39	5.06	5.01
11	11.61	9.67	9.5	6.09
12	4.24	4.18	3.99	3.89
13	4.97	6.58	4.8	5.43
14	5.01	5.42	4.03	4.57
15	3.99	5.14	5.27	5.4
16	6.28	5.86	5.7	6.74
17	5.5	5.74	4.87	4.69
18	5.96	4.99	5.22	7.86
19	4.84	5.34	5.4	4.57
20	3.99	3.85	3.92	3.94
21	5.3	4.74	3.55	4.25
22	3.81	5.5	3.81	4.4
23	4.61	4.31	4.41	5
24	4.04	3.71	4.67	3.61
25	3.5	3.49	3.93	4.34
26	4.26	3.93	4.44	3.87
Max. Value	11.61	11.91	9.5	7.86
Min. Value	3.45	3.49	3.55	3.61
Range	8.16	8.42	5.95	4.25
Median	4.7	4.75	4.48	4.57
Mean	5.18	5.18	4.72	4.85
SD	1.80	1.86	1.17	1.06
Variance	3.23	3.47	1.38	1.13

Temporalis worse pain Pre-treat. Point contact Average µV*sec.	Temporalis Worse pain Post-treat. Point contact Average µV*sec.	Temporalis Lesser pain Pre-treat. Point Contact Average µV*sec.	Temporalis Lesser pain Post-treat. Point contact Average µV*sec.	Temporalis worse pain Pre-treat. MVC Average µV*sec.	Temporalis worse pain Post-treat. MVC Average µV*sec.	Temporalis Lesser pain Pre-treat. MVC Average µV*sec.	Tempo Lesser pain Po treat. MVC Averag µV*sec
8.64	10.21	5.35	6.71	19.39	24.82	7.88	14.19
5.24	6.05	6.22	4.69	134.85	68.86	118.79	78.36
8.86	6.26	4.96	4.98	82.51	59.85	58.1	52.12
3.78	4.98	4.87	4.04	69.16	72.83	31.4	37.13
4.49	6.95	5.03	5.32	13.06	32.09	18.11	19.88
6.21	4.77	7.6	7.78	54.26	50.2	57.92	51.7
4.95	6.78	5.58	6.07	231.44	125.99	124.91	117.86
7.87	7	5.48	5.7	58.08	77.18	59.69	63.1
5.07	6.38	5.86	6.69	20.83	32.44	46.72	42.76
11.27	8.77	9.03	8.94	53.42	53.04	36.12	56.24
14.18	14.83	34.83	22.66	28.9	22.72	29.77	25.56
19.78	20.08	7.75	7.6	35.51	87.72	47.75	61.87
6.76	8.09	5.13	7.04	10.43	23.37	11.89	22.37
6.53	5.58	5.73	4.69	39.62	45.49	49.12	38.53
21.5	6.26	9.15	5.03	115.01	70.98	64.12	64.13
7.87	17.26	6.91	10.02	58.57	40.98	36.95	38.39
6.25	6.87	9.63	10.85	37.47	46.06	26.93	48.88
9.92	7.83	7.3	11.29	163.45	105.37	151.76	83.8
5.68	4.52	6.16	5.51	118.96	72.33	141.25	91.24
6.29	4.29	6.28	4.82	77.2	65.71	59.03	71.35
7.66	6.83	9.07	4.43	96.32	92.85	70.37	77.35
5.41	11.86	3.85	6.14	29.54	36.41	25.1	38.33
6.33	6.72	8.09	6.65	23.43	20.39	24.37	21.14
5.95	10.61	6.02	6.54	62.99	70.51	42.2	48.49
5.61	3.49	10.79	4.34	62.85	148.25	144.77	162.84
5.1	4.08	4.29	3.76	18.59	26.08	21.58	23.62
21.5	20.08	34.83	22.66	231.44	148.25	151.76	162.84
3.78	3.49	3.85	3.76	10.43	20.39	7.88	14.19
17.72	16.59	30.98	18.9	221.01	127.86	143.88	148.65
6.31	6.81	6.19	6.105	56.17	56.45	47.235	50.29
7.97	7.98	7.73	7.01	65.99	60.48	57.95	55.82
4.37	4.06	5.81	3.78	52.11	32.68	42.59	33.21
19.06	16.52	33.73	14.30	2715.32	1067.66	1813.55	1102.85

Masseter worse pain Pre-treat. Rest Average µV*sec.	Masseter worse pain Post-treat. Rest Average µV*sec.	Masseter Lesser pain Pre-treat. Rest Average µV*sec.	Masseter Lesser pain Post-treat. Rest Average µV*sec.
4.46	5	4.75	4.63
4.15	5.01	4.03	4.16
4.35	3.72	5.02	4.41
3.31	3.83	3.72	3.28
3.48	3.86	3.93	4.01
3.77	3.89	4.14	3.9
4.57	4.02	4.36	4.3
4.21	3.95	3.94	3.52
4.31	5	4.16	4.74
4.86	4.2	4.12	3.95
5.56	3.91	5.78	4.87
3.95	5.94	4.14	4.16
4.43	4.25	4.01	4.65
4.45	4.54	4.35	4.63
4.58	4.31	4.11	4.3
6.5	4.3	6.04	5.16
4.25	3.97	4.06	4.35
7.08	5.42	5.98	5.53
4.46	5.46	4.49	6.01
3.92	3.75	4.26	3.89
4.01	4.37	4.26	4.35
4.37	4.81	3.95	4.13
4.25	4.4	3.09	4.13
3.96	3.78	3.89	6.39
3.8	3.45	3.36	3.48
5.02	4.06	4.97	4.5
7.08	5.94	6.04	6.39
3.31	3.45	3.09	3.28
3.77	2.49	2.95	3.11
4.33	4.225	4.14	4.325
4.46	4.35	4.34	4.44
0.83	0.63	0.72	0.72
0.69	0.39	0.51	0.52

Masseter worse pain Pre-treat. Point contact Average µV*sec.	Masseter Worse pain Post-treat. Point contact Average µV*sec.	Masseter Lesser pain Pre-treat. Point Contact Average µV*sec.	Masseter Lesser pain Post-treat. Point contact Average µV*sec.	Masseter worse pain Pre-treat. MVC Average µV*sec.	Masseter worse pain Post-treat. MVC Average µV*sec.	Masseter Lesser pain Pre-treat. MVC Average µV*sec.	Masseter Lesser pain Post-treat. MVC Average µV*sec.
8.28	4.85	7.3	5.58	9.14	12.79	8.13	9.9
5.42	14.41	5.66	6.4	100.63	115.96	129.87	154.55
4.39	4.03	4.54	5.01	131.4	76.12	91.58	60.2
3.98	5.04	3.75	4.08	99.98	20.08	39.36	42.3
7.53	14.57	8.81	6.81	72.19	58.05	45.97	39.69
4.5	4.58	5.49	4.37	70.73	72.84	51.96	41
9.16	4.17	4.59	5.36	113.26	195.31	217.73	184.27
4.77	5.32	4.91	4.9	23.8	29.6	62.12	18.93
7.42	5.92	9.79	9.39	16.4	29.53	26.07	40.73
6.18	5.44	6.7	6.39	44.93	51.67	33.36	53.51
18.63	7.29	9.17	6.24	22.31	36.11	11.56	8.94
6.16	6.11	6.03	4.84	11.35	77.68	14.29	42.99
4.78	5.4	4.25	4.51	15.31	20.08	8.35	19.46
6.77	5.58	5.83	4.69	59.89	43.29	42.67	35.74
13.76	5.09	19.88	6.12	120.53	99.93	108.71	89.61
7.89	8.26	7.51	6.6	92.77	45.2	43.7	38.91
4.45	4.25	6.19	5.84	38.55	46.06	25.58	33.17
7.63	5.3	7.22	4.99	164.27	138.66	144.51	110.28
4.73	4.88	5.02	9.64	262.4	78.05	123.85	96.54
4.46	4.2	4.4	3.9	78.22	103.27	94.33	50.25
6.42	5.42	6.02	7.38	144.97	96.88	188.27	171.82
5.45	6.46	4.58	6.34	46.11	76.51	48.86	71.69
4.44	4.56	4.64	4.45	30.13	14.37	38.12	15.52
4.72	6.2	4.48	5.02	69.63	119.56	79.14	111.46
4.04	3.42	3.75	3.42	46.38	143.08	71.2	177.25
6.04	5.72	7.38	7.25	20.88	10.94	14.56	19.16
18.63	14.57	19.88	9.64	262.4	195.31	217.73	184.27
3.98	3.42	3.75	3.42	9.14	10.94	8.13	8.94
14.65	11.15	16.13	6.22	253.26	184.37	209.6	175.33
5.745	5.36	5.745	5.47	64.76	65.445	47.415	42.645
6.62	6.02	6.46	5.75	73.31	69.68	67.84	66.84
3.25	2.70	3.20	1.52	58.70	46.86	55.73	53.92
10.53	7.28	10.24	2.32	3445.20	2195.96	3105.60	2906.94

Pre-treat. All muscles w/ Cotton	Post-treat. All muscles w/ Cotton	Pre-treat. Worse pain NRS	Post-treat. Worse pain NRS	Pre-treat. Lesser pain NRS	Post-treat. Lesser pain NRS
559	1613	5	2	0	0
1667	1582	6	3	4	2
1662	1247	7	5	6	5
1148	1247	6	1	1	1
826	691	6	3	0	0
1052	1342	7	2	0	0
2063	1910	5	3	1	1
647	864	7	5	5	4
1249	727	8	0	7	0
457	571	5	1	4	1
471	709	5	3	0	0
802	1103	6	2	0	0
329	866	7	3	4	0
1197	1323	6	3	0	0
1396	1135	7	4	2	1
901	848	7	4	5	4
1289	878	6	2	4	2
1451	1237	6	3	0	2
1198	945	6	4	4	3
1513	1471	6	3	5	2
1837	1183	7	1	2	1
631	700	5	2	3	0
384	328	7	2	0	0
673	635	8	1	6	1
1461	1677	7	3	4	1
1003	672	8	2	6	0
2063	1910	8	5	7	5
329	328	5	0	0	0
1734	1582	3	5	7	5
1100	1024	6	3	3.5	1
1071.77	1057.85	6.38	2.58	2.81	1.19
477.90	394.77	0.94	1.24	2.38	1.44
228386.26	155846.22	0.89	1.53	5.68	2.08

Pre-treat. pain score side w/ worse pain using Palpometer	Post-treat. pain score side w/ worse pain using Palpometer	Pre-treat. pain score side w/ lesser pain using Palpometer	Post-treat. Pain score side w/ lesser pain using Palpometer
4	0	0	0
6	0	2	1
6	2	5	3
5	1	0	0
6	0	0	0
6	0	0	0
5	1	0	0
7	2	3	1
7	0	5	0
4	0	2	0
3	0	0	0
5	1	0	0
6	1	1	0
7	3	0	0
6	1	1	0
5	2	2	2
6	1	3	0
5	1	0	1
4	1	2	2
6	1	2	0
8	0	0	0
4	0	2	0
6	0	0	0
7	0	3	0
6	2	2	0
7	1	3	0
8	3	5	3
3	0	0	0
5	3	5	3
6	1	1.5	0
5.65	0.81	1.46	0.38
1.20	0.85	1.56	0.80
1.44	0.72	2.42	0.65

Subjects	Pre-treat. Rest Average µV*sec.	Pre-treat. Point contact Average µV*sec.	Pre-treat. MVC Average µV*sec.	Post-treat. Rest Average µV*sec.	Post-treat. Point Contact Average µV*sec.	Post-treat. MVC Average µV*sec.
1	71	86	143	99	79	169
2	49	66	1452	59	89	1382
3	64	69	1044	59	58	641
4	44	48	659	44	51	512
5	44	79	443	52	89	427
6	51	72	732	48	66	644
7	53	69	1894	52	67	1803
8	49	72	550	45	65	532
9	56	86	438	58	83	357
10	63	100	545	54	90	604
11	95	202	278	70	157	272
12	50	102	341	58	104	822
13	54	62	139	63	73	253
14	53	75	508	63	65	477
15	55	134	1161	56	68	840
16	76	98	674	67	129	536
17	56	97	456	56	81	503
18	71	95	1779	71	95	1350
19	57	65	1646	59	77	1090
20	48	64	855	47	51	848
21	51	83	1382	52	66	1163
22	51	55	435	56	74	523
23	52	76	363	53	64	195
24	50	64	793	61	83	998
25	44	69	1022	45	42	1756
26	55	72	249	50	60	251
Max. Value	95	202	1894	99	157	1803
Min. Value	44	48	139	44	42	169
Range	51	154	1755	55	115	1634
Median	53	73.5	604.5	56	73.5	570
Mean	56.23	83.08	768.50	57.58	77.92	728.77
SD	11.43	30.24	508.36	11.16	24.34	458.23
Variance	130.58	914.39	258430.66	124.49	592.63	209977.30

http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfrl/rl.cfm?lid=15421&lpcd=DYJ

Biocryl polymer resin

Product 1	Product 2
Thermal Forming Material Biocryl Form-X; GREAT LAKES BIOCRYL; Invisacryl; Invisacryl Ultra; MOUTHGUARD MATERIAL; Smart Moves Safety Data Sheet: http://www.greatlakesortho.com/content/files/msds/021-023%20Splint%20Biocryl.pdf	Biocryl Polymer Resin Safety Data Sheet: http://www.greatlakesortho.com/content/files/msds/040-017%201lb%20Clear%20Biocryl%20Polymer.pdf

Health history questioner
http://dental.tufts.edu/wp-content/uploads/cranio_3-HealthHistoryPartI.pdf
http://dental.tufts.edu/wp-content/uploads/cranio_4-HealthHistoryPartII_revised.pdf

Tufts UNIVERSITY
School of Dental Medicine

DISCOMFORT SCALE

Patient Name:_____ Date:_____

These are discomfort scales. For each part of the body there are two horizontal rows, one for the left and one for the right. Please report the average discomfort over the last seven days by circling a rating from "0" to "10" which best reflects your discomfort. If you have discomfort on both sides, circle both rows.

	SIDE	NONE	→								SEVERE
Bite Symptoms or Bite Changes	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
TMJ pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
TMJ sounds	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Headaches	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Facial Pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Eye Symptoms	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Ear Pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Stuffy Ear or Ringing Sounds	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Neck Pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Arm/Hand/Finger Numbness, tingling or pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Upper Back Pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Lower back Pain	*Left*	0	1	2	3	4	5	6	7	8	9	10
	Right	0	1	2	3	4	5	6	7	8	9	10
Overall Pain Score:		0	1	2	3	4	5	6	7	8	9	10

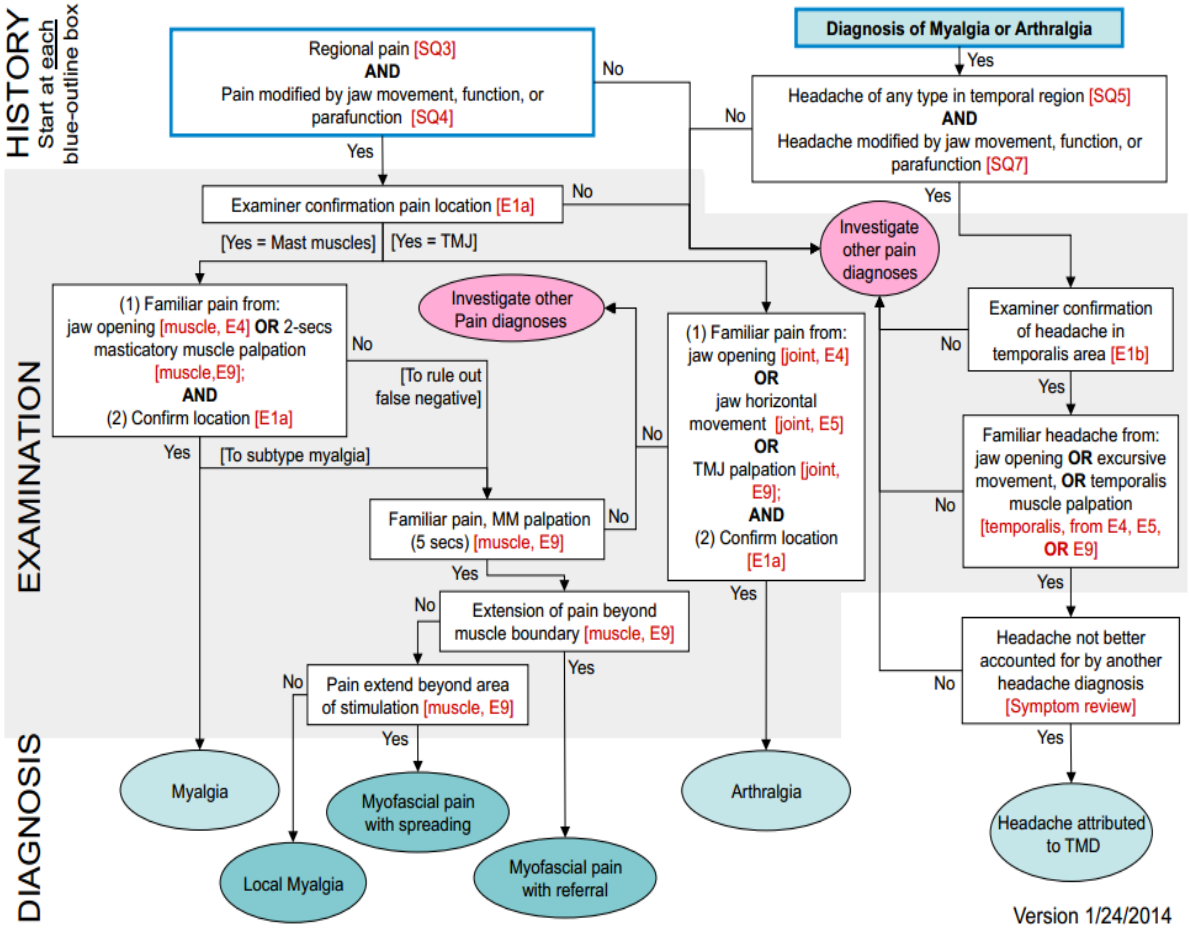
Changes since last visit:

Patient's Signature:_____

Craniofacial Pain Headache and Sleep Center
1 Kneeland Street #601 Boston, MA 02111 Telephone:(617) 636-6817 / Fax: (617) 636-3831

Diagnostic Criteria for Temporomandibular Disorders (DC/TMD): Diagnostic Decision Tree

Pain-Related TMD and Headache



Diagnostic Criteria for Temporomandibular Disorders (DC/TMD): Diagnostic Decision Tree