Oral behaviours and masseter activity in patients with masticatory muscle pain

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ABSTRACT

Background: Myogenous pain of the chewing muscles is a subgroup of temporomandibular disorder (TMD). It is a complex condition not fully understood at this time. One possible causal factor of myogenous TMD may be overloading of the jaw joint and muscles as a result of prolonged low-level clenching. This includes behaviours such as clenching and grinding, which may be observed during awake hours. The use of wireless surface electromyography (EMG) allows for the collection of objective data regarding jaw muscle activity in the habitual environment.

Methods: Female patients (N = 27, mean age 27.0 ± 6.3 years) diagnosed with myalgia or myofascial pain with referral were age matched with TMD-free controls (N = 26, mean age 28.0yrs ± 6.5 years). A single examiner completed a standardised TMD examination on all participants to confirm eligibility for the study. Participants were fitted with a minimally invasive wireless EMG sensor on the skin surface overlying the masseter muscle on their preferred chewing side. Participants wore the EMG sensors while awake, over two consecutive days. Maximum voluntary contraction (MVC) was identified as peak bite force. Contraction episodes were detected at four thresholds: 3 x minimum root mean square (RMS) at rest, 3% MVC, 5% MVC, 10% MVC.

Results: The vast majority of the participants in the patient group had myofascial pain affecting the masseter muscles. Maximum opening was decreased in the patients compared to controls. The Oral Behaviour Checklist (OBC) summary score was higher in patients than controls (p < 0.01). MVC was 1124.7 ± 550.8 μV in the patient group and 1202.5 ± 424.5 μV in the control group (p = 0.559). The frequency, duration and amplitude of masseter contraction episodes were calculated. Most masseter contraction episodes of both patients and controls were of relatively low amplitude (< 10% MVC) and short duration (< 10 seconds). There was no significant
difference in the number of episodes per hour between groups. A significant difference in total contraction time % was found between groups ($p = 0.039$) with a tendency to longer contractions in the patient group. No significant association was found between self-reported parafunction and masticatory muscle activity.

Conclusion: Patients with myogenous TMD reported a higher level of parafunction. Patients and controls have a similar level of number of contractions during waking hours but the contractions are longer. The OBC may not be a reliable tool for assessing wake-time parafunction.
THESIS OUTLINE

This research project focuses on the association of masticatory muscle activity and muscle-related temporomandibular disorders. For convenience of future publications, this study is presented in six chapters in the format of a *Hybrid Thesis*. As such, a degree of overlap between the chapters is inevitable. The thesis is organised as follows:

**Chapter 1 – Review of the Literature**

A general overview of temporomandibular disorders and oral parafunctional behaviour is presented in the first chapter. This includes a review of the literature on the epidemiology and psychosocial impact of the condition, current understanding of the aetiology, and methods of assessment of masticatory muscle activity.

**Chapter 2 – Core Materials and Methods**

The methodological details of the present study are presented in the second chapter. The chapter presents an overview of the study design, participant recruitment, specialised equipment used, examination procedure and data analysis.

**Chapter 3 – Questionnaire and Clinical Findings in a Sample of Females with Myogenous TMD Pain**

The clinical findings of the study are presented in the third chapter along with a comparison of self-reported oral behaviours in the patient and control groups.
Chapter 4 – Masticatory Muscle Activity in Patients with Myogenous TMD Pain

The electromyographic findings of masticatory muscle activity in patients with myogenous TMD-related pain and healthy age-matched controls is presented in the fourth chapter.

Chapter 5 – Future Research Directions

The fifth and final chapter of this work summarises the study’s conclusions and possible avenues to be investigated in the future.

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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CNS</td>
<td>Central nervous system</td>
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<tr>
<td>CPI</td>
<td>Characteristic pain intensity</td>
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<tr>
<td>DC-TMD</td>
<td>Diagnostic Criteria for Temporomandibular Disorders</td>
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<td>EMA</td>
<td>Ecological momentary assessment</td>
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<tr>
<td>EMG</td>
<td>Electromyography</td>
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<td>GCPS</td>
<td>Graded Chronic Pain Scale</td>
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<td>IS</td>
<td>Interference score</td>
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<tr>
<td>MMA</td>
<td>Masticatory muscle activity</td>
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<td>MVC</td>
<td>Maximal voluntary contraction</td>
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<td>OBC</td>
<td>Oral Behaviour Checklist</td>
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<td>OHIP</td>
<td>Oral Health Impact Profile</td>
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<td>OHRQoL</td>
<td>Oral health-related quality of life</td>
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<td>OPPERA</td>
<td>Orofacial Pain: Prospective Evaluation and Risk Assessment</td>
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<tr>
<td>PCB</td>
<td>Printed circuit board</td>
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<tr>
<td>RLD</td>
<td>Right leg drive</td>
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<tr>
<td>RMS</td>
<td>Root mean square</td>
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<tr>
<td>SEM</td>
<td>Standard error of the mean</td>
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<tr>
<td>STROBE</td>
<td>Strengthening the reporting of observational studies in epidemiology</td>
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<tr>
<td>TMD</td>
<td>Temporomandibular disorder</td>
</tr>
<tr>
<td>TMJ</td>
<td>Temporomandibular joint(s)</td>
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I. REVIEW OF THE LITERATURE

Introduction
Epidemiology
Psychosocial Impact of TMD
Aetiology of TMD
Parafunctional Behaviour
Study Objectives

References
1.1 INTRODUCTION

Temporomandibular disorder (TMD) is a collective term given to a broad range of conditions that involve the muscles of mastication, temporomandibular joints (TMJ) and the associated bony and soft tissue structures (Okeson, 1996; Liu and Steinkeler, 2013). Symptoms of TMD typically include pain of the masticatory muscles and/or TMJ, altered jaw function, pain on chewing, reduced range of movement of the mandible, locking and joint noises. In addition to these symptoms, patients may also report headaches, dizziness, ear ache or ringing in the ears (Glaros and Lausten, 2003). The overwhelming majority of patients seeking treatment do so for relief of TMD-related pain (Dworkin et al., 1990).

1.2 EPIDEMIOLOGY

TMD is the second most common musculoskeletal condition resulting in pain, following chronic lower back pain. The prevalence of TMD reported in the literature varies greatly. A systematic review reported a low prevalence of TMD signs in the general population with a prevalence of 9.7% for masticatory muscle pain, 11.4% for disc displacement disorders, and 2.6% for arthralgia/osteoarthritis (Manfredini et al., 2011). The inconsistency in prevalence data is unlikely due to variations in the populations studied and more likely due to a lack of homogeneity in the diagnostic criteria applied in different investigations prior to the introduction of standardised diagnostic criteria (Manfredini et al., 2011). Moreover, high prevalence values in some studies may be attributed to the inclusion of mild signs and symptoms. Severe pain and dysfunction are less common (Murray et al., 1996). The incidence for first onset TMD is approximately 4% (Slade, et al., 2013a). The treatment need in the general population is approximately 15% (Al-Jundi et al., 2008).
There are more females than males seeking treatment for TMD with a ratio of 3.3 between genders (Manfredini et al., 2011). This gender distribution is consistent with other painful musculoskeletal and non-musculoskeletal disorders which also show a female predominance (Gran, 2003; Fillingim, 2017). Multiple mechanisms have been proposed to explain these sex differences: differences in endogenous opioid function, cognitive/affective influences, social factors and the effects of sex hormones (Fillingim 2017). With regard to sex hormones, studies in both animals and humans have suggested a sexual dimorphism with an increased number of estrogen and progesterone receptors in the articular tissues of females (Milam et al., 1987; Abubaker et al., 1993). The theory of hormonal influence is supported by the age distribution of TMD, with a pattern of onset after puberty and a decrease in prevalence following menopause. For instance, signs and symptoms of TMD occur equally in younger boys and girls with the gender difference becoming apparent after puberty (Magnusson et al., 1985). Moreover, there is a higher risk of painful TMD in patients receiving estrogens or taking oral contraceptives (LeResche et al., 1997).

Longitudinal epidemiologic studies showed the benign nature of TMD: signs and symptoms fluctuate over time, may resolve spontaneously and progression to a severe condition occurs very rarely (Magnusson et al., 1985; Magnusson et al., 1993; Könönen et al., 1996; Magnusson et al., 2000).

Unlike other chronic joint conditions, the prevalence of TMD decreases in elderly patients (Carlsson, 1999), and signs and symptoms of TMD are mild (Tzakis et al., 1994).

1.3 PSYCHOSOCIAL IMPACT OF TMD

Oral health-related quality of life (OHRQoL) is a well-accepted way of describing the impact of a disease condition on perceived oral health. The
Oral Health Impact Profile (OHIP) is one of the most widely used OHRQoL instruments. A number of studies have assessed the effect of TMD on OHRQoL. John et al. (2007) found that patients with a diagnosis of TMD, regardless of the diagnosis, had a considerably impaired OHRQoL: the mean OHIP score for all diagnoses was 42.9, when compared to 15.8 for the general population, with higher values meaning lower OHRQoL.

Of the various TMD conditions, disc displacement with reduction has the least effect on the OHRQoL (John et al., 2007). Indeed, this condition is frequently pain-free, although joint sounds may be heard. Increasing levels of disability, i.e. higher Graded Chronic Pain Scale (GCPS) scores were associated with a decreased OHRQoL (John et al., 2007). Barros et al. (2009) found that 98.7% of the patients referred for TMD treatment at a Brazilian University reported some negative impact of TMD while 57% reported that TMD pain and dysfunction impacted daily activities. Similar findings were reported by Murray et al. (1996) who found in a cohort of new patients referred to a Canadian facial pain research unit that 50% could ignore the pain or carry on with daily activities despite pain, 27% reported that the pain interfered with their ability to concentrate, while the remaining 23% found the pain to be debilitating, requiring them to undertake only simple tasks or take rest. These studies show that TMD pain may have a significant negative impact on the quality of life and the ability to perform daily activities. This is not surprising and reflects individual differences in coping with pain.

1.4 AETIOLOGY OF TMD

The aetiology of TMD has been the subject of many publications and many theories have been suggested in the past. A substantial step forwards in the understanding of TMD aetiology has been provided by the “Orofacial Pain: Prospective Evaluation and Risk Assessment” (OPPERA) study (Slade et al., 2013b). This evaluated risk factors for the onset of TMD in 2,737 participants.
followed for 3 years. This study clearly indicated that TMDs have a multifactorial aetiology, *i.e.* that they are due to the interplay of different factors consistent with the biopsychosocial model of disease. Variables of the health status domain made the greatest contribution to TMD incidence, followed closely by psychological and clinical orofacial domains (Fillingim et al., 2011). Genetic factors were also concurring. Interestingly, a previous epidemiological study reported similar risk factors for TMD onset already at early adolescence (LeResche et al., 2007). The OPPERA study also showed that oral parafunction (*e.g.* clenching the teeth during wakefulness or holding the jaw rigid) was the single most significant predictor of TMD (Ohrbach et al. 2014), confirming the results of previous studies consistently showing that self-reported tooth clenching are associated with myogenous TMD pain; (Gramling et al., 1997; Macfarlane et al., 2001). Of notes is the apparent low association between self-reported bruxism/wake-time parafunction and painful TMD (Van der Meulen et al., 2006). Nevertheless, the risk of developing masticatory muscle pain is 4-5 times higher in individuals with the habit of keeping the teeth in contact during wake-time than in those without (Huang et al., 2002; Michelotti et al., 2010; Reissmann et al., 2017).

### 1.5 PARAFUNCTIONAL BEHAVIOUR

Parafunctional oral behaviours are those behaviours not related with the “normal” function of the masticatory system. The most known parafunction is bruxism, which is defined as a repetitive jaw-muscle activity characterized by clenching or grinding of teeth and/or by bracing or thrusting of the mandible (Lobbezoo et al., 2013). The disorder may occur in sleep (sleep bruxism) and while awake (wake-time parafunction). It is important to differentiate sleep bruxism from wake-time parafunction. Sleep bruxism is related to sleep architecture and in particular to microarousal (Lavigne et al.,
2003; Macaluso et al., 1998), while wake-time parafunction is most likely a behaviour related to psychosocial factors such as stress, anxiety and depression (Manfredini and Lobbezoo, 2009; Khawaja, et al., 2015b). Beside their different aetiology, sleep bruxism and wake-time parafunction differ also for the way muscles contract. Sleep bruxism is characterized by medium intensity contractions that on average last 10-15 sec (Kato et al., 2001; Lavigne et al., 2001) while wake-time parafunction seems to be expressed by longer-lasting, low-intensity contractions (Fujisawa et al., 2013).

1.5.1 ASSESSMENT AND EPIDEMIOLOGY

Unlike sleep bruxism, there is little objective information on the prevalence of wake-time parafunction assessed in habitual environments in healthy subjects and TMD patients. Assessment of parafunctional activity uses questionnaires, ecological momentary assessment (both of which are subjective) and electromyographic recording of elevator muscles. The estimated prevalence of wake-time parafunction using a questionnaire varies between 22% and 31% (Manfredini et al., 2013). Questionnaires are inevitably linked to recall bias, which may limit the validity of prevalence data collected in this manner. The Oral Behaviour Checklist (OBC) is a validated questionnaire used in many studies, including the OPPERA project, to assess for the presence of self-reported parafunctional habits (Markiewicz et al., 2006; Ohrbach et al., 2008). The OBC is a 21-item questionnaire which yields a score 0-84 depending on the self-perceived frequency of various oral behaviours.

Ecological momentary assessment (EMA) is a technique by which a subject is reminded several times over the study period to report the presence/absence of a behaviour – for instance, tooth contacts (Chen et al., 2007; Glaros et al., 2016; Bracci et al., 2018). This approach allows subjects to recall the behaviour close to the time of its occurrence and
decreases/eliminates the recall bias. In the study by Chen et al. (2007), participants were alerted every 20 minutes during the day to check and report whether their teeth were in contact over 10 days. While this is a better alternative to retrospective self-reporting questionnaires, this study does not provide a detailed understanding of muscle activity throughout the day.

The paucity of information on parafunctional activities when awake may be ascribed to practical difficulties of using portable EMG recorders, which may be wired and may interfere with common activities. The development of portable, wireless EMG devices allows for such behaviours to be assessed in a natural environment.

Objective data on masticatory muscle activity (MMA) (frequency, intensity, duration) can be gained through the use of surface electromyography (EMG). EMG detects muscle activity and can provide accurate data on oral behaviours over an extended period of time. Perhaps due to the obtrusive nature of EMG equipment, most of the long-term studies have focused on night time masticatory muscle activity (Miguel et al., 1992; Gallo et al., 1999). Raphael et al. (2013) reported background masticatory muscle electromyographic activity was elevated during sleep in women with myogenous TMD pain. There is limited data on the association of objectively recorded masticatory muscle activity during wake-time in healthy subjects and myogenous TMD pain patients. This lack of information was the basis for this study.

1.5.2 WAKE-TIME PARAFUNCTION AND TMD

Knowledge on wake-time parafunction is limited in comparison to that on sleep bruxism. Both forms have been associated with a higher risk of TMD. More recent observations seem to favour the role of wake-time parafunction in the aetiology of TMD, although it is possible that in the aetiology cascade,
sleep bruxism and wake-time parafunction are not independently associated but interact additively, i.e. the presence of each one amplifies the effect of the other one (Reissmann et al., 2017).

The role of wake-time parafunction in the aetiology of masticatory muscle pain is biologically plausible. Indeed, repetitive, long-lasting, low-level muscle contractions, as they likely occur also during wake-time parafunction in myogenous TMD patients, are a significant risk factor for work-related muscle pain (details in Palla (2014) and Palla and Farella (2010)). It is hypothesized that during these muscle contractions small (Cinderella) motor units become fatigued and damaged leading, in turn, to a localized inflammation with release of inflammatory mediators (Hägg, 1991). These sensitize the muscle nociceptors (Furquim et al., 2015).

In healthy individuals these changes usually resolve and are not able to trigger longer lasting and self-perpetuating masticatory muscle pain (Takeuchi et al., 2015), although opposite results were reported by Glaros and Burton (2004). Independently of these seemingly contradictory results, wake-time parafunction alone is not a sufficient cause to trigger a clinical condition. Whether it will lead to muscle overuse and persistent pain likely depends upon the interplay of local (the frequency of long-lasting muscle contractions, the capacity for motor units substitution or rotation, the flexibility in spatial muscle activation and the adaptation capacity of the muscle tissue), genetic and psychosocial factors (fear-avoidance beliefs, somatization, anxiety and catastrophizing) (Palla, 2014), that are involved in the individual adaptation/modulation of pain conditions as reported by the OPPERA study (Slade et al. 2013b).

That wake-time parafunction can be considered a risk factor for myogenous TMD is supported also by the observation that prolonged submaximal muscle contractions are observed in TMD patients. For instance, Glaros et
al. (2005) reported more frequent tooth contact and a higher intensity of
contact in patients with TMD-related pain than in pain-free subjects.
Similarly, non-functional tooth contacts were nearly four times more
frequent in patients with masticatory muscle pain than in controls (Chen et
al., 2007). Moreover, subjects with wake-time parafunction have a 4-5 times
higher risk of developing masticatory muscle pain than individuals without
it (Huang et al., 2002; Michelotti et al., 2010; Reissmann et al., 2017). The
fact that wake-time parafunctional activity does not differ between male and
female could be considered evidence contradicting the involvement of this
behaviour in the aetiology of TMD as more females than males suffer of
painful TMD. However, this discrepancy could be explained by a higher
susceptibility of females than males for muscle pain.

Electromyographic recordings of muscle activity during waketime also
indicate an association between painful TMD and masticatory muscle
activity during waketime. Cioffi et al. (2016) reported that female patients
with masticatory myalgia had an increased frequency of wake-time muscle
contractions compared to healthy females during mental and practical
ability tasks. A series of daytime recordings using portable EMG recorders in
which the activity of the masseter and temporal muscles were recorded in
the natural environment during wake time reported an overall longer
contraction time in patients with TMD (with or without pain) than in
controls. The largest difference was found to be for low-intensity
contractions that lasted on average 59 and 20 minutes in patients with and
without disc displacement, respectively (Iwasaki et al., 2015; Iwasaki et al.,
2017; Khawaja et al., 2015a). Shorter average duration was recorded in
another study (Iwasaki et al., 2015). Also in subjects with self-reported
daytime clenching, the largest number of contractions episodes are of low-
intensity (Fujisawa et al., 2013). It must however be underlined that
association does not mean causality. To indicate a cause-effect relationship the association must fulfil several conditions as reported by Hill (1965).

1.6 STUDY OBJECTIVES

Due to the paucity of EMG recordings of the elevator muscles during wake-time in the natural environment, in particular in patients with myogenous TMDs, the aim of this study was to record the electromyographic activity of a masseter muscle during wake-time in the natural environment in a group of healthy individuals and patients with myogenous TMD matched for age and gender. A secondary aim of this study was to investigate the association between self-reported oral parafunction and masticatory muscle activity. Specifically, the goal was to investigate whether there is a difference in the frequency, duration and magnitude of masseter muscle contractions between the two groups and whether the level of activity was correlated to the OBC summary score.

The tested hypothesis was that myogenous TMD patients contract the muscles for a longer period of time, in particular that they have a greater frequency of long-lasting, low-amplitude contraction episodes than healthy individuals, and that participants with a higher OBC summary score have a higher level of MMA.
1.7 REFERENCES


2. CORE MATERIALS AND METHODS

Study Design
Setting
Participants
Study Procedure
Data Analysis
Statistical Analysis
Data Storage
Funding
Ethical Approval
Māori Consultation

References
2.1 STUDY DESIGN

An observational case-control study was designed according to the STROBE guidelines (Elm et al., 2007).

2.2 SETTING

This study was conducted at the University of Otago, Dunedin. Participants were recruited and data were collected between August 2017 and June 2018.

2.3 PARTICIPANTS

2.3.1 SAMPLE SIZE AND POWER

The required sample size was estimated using previous data on mean duration of masticatory contraction episodes per day (2.7 ± 1.0 sec; Michelotti et al., 2005). Setting type I error to 0.05 and type II error at 0.2 (i.e. 80% power), a sample of 30 participants per group would allow detection of a small-to-medium effect size (Cohen’s d ≤ 0.7).

2.3.2 PARTICIPANT RECRUITMENT AND SELECTION CRITERIA

Participants were recruited for the study by: 1) contacting patients on the Faculty of Dentistry TMD waiting list; 2) e-mail advertising distributed to University of Otago and Otago Polytechnic staff and students; 3) a number of advertisements on the ‘Otago University Postgraduate Society’ Facebook page; 4) fliers placed around the University of Otago campus and; 5) word of mouth.

Inclusion criteria were female patients in the age range 18-50 years with a painful myogenous TMD. The control group included individuals without a past or present history of TMD and headache (in the month preceding the
examination) and on examination, free of signs of TMD except for a pain-free disc displacement with reduction.

Both patients and control individuals were excluded from the study if they were: undergoing orthodontic treatment with fixed appliances; missing five or more permanent teeth (excluding third molars); using full fixed or removable dental prostheses; had any present orofacial inflammatory conditions; rheumatological conditions; neurological disorders and/or neurological motor disorders; acute psychiatric conditions; primary headache form; craniofacial syndromes including cleft lip and/or palate; were habitual users of drugs influencing the activity of the central nervous system (CNS), and; if they self-reported any skin allergy to plaster adhesive.

As TMD predominantly affects females, only females were included to avoid variability due to gender. The age range selected was broad enough to include prevalence peaks of TMD between 20-40 years (Leresche and Drangsholt, 2008). The upper limit was set at 50 years because an increased prevalence of inflammatory-degenerative joint disorders could be expected above this age (Manfredini et al., 2010).

Participants undergoing orthodontic treatment were excluded because of the known reduction in maximal bite force during fixed appliance treatment (Alomari and Alhaija, 2012). Participants with more than 5 missing teeth were excluded due to the association between decreased occlusal contacts and bite force (Bakke, 2006). Maximal bite force is significantly greater in dentate subjects than in denture wearers and therefore, participants with removable or fixed dentures were excluded (Haraldson et al., 1979). Participants with orofacial inflammatory, rheumatologic disorders and primary headache form were excluded so not to confound TMD diagnosis. Participants with neurologic conditions and neuromotor disorders were excluded due to a possible effect on central pain processing and muscle
regulation. Those with acute psychiatric conditions and habitual users of drugs, such as muscle relaxants and sedatives, were excluded because of their effect on the central nervous system. Finally, participants with self-reported allergies to plaster adhesive were excluded due to the exposure of such adhesives during the EMG stage of the study.

All participants provided informed written consent prior to participation in the study and received a $50 supermarket voucher upon completion of the study.

2.4 STUDY PROCEDURE

This study consisted of three phases: screening, clinical examination and EMG data collection.

2.4.1 SCREENING

First contact with participants from the TMD waitlist was by phone call followed by e-mail. The first contact with all other participants was by e-mail. Participants were sent a Participant Information Sheet and asked to complete an electronic form (Google® Form) which included the demographics questionnaire, the DC-TMD Symptom Questionnaire and the Graded Chronic Pain Scale v2.0 (Von Korff et al., 1992; Schiffman et al., 2014). The responses to electronic forms were screened prior to appointments being scheduled. Patients were recruited first and controls were age-matched +/- 3yrs to the patients and recruited.

2.4.2 CLINICAL EXAMINATION

At initial appointment, informed written consent was obtained from the study participants. A thorough history was collected including initial onset, location, characteristics, severity, triggers, frequency and duration of pain. A single investigator (DR) performed a standardised clinical examination to
clinically evaluate and assess eligibility of participants for inclusion in the study.

The clinical examination included recording of maximum (pain free, assisted and unassisted) mouth opening, maximum lateral and protrusive excursions. Familiar pain (pain that is like or similar to the pain the patient has been experiencing) during these tasks was noted. Joint noises (clicking or crepitation) during opening and closing, lateral and protrusive excursions were checked and recorded if present. The temporal and masseter muscles, TMJs and supplemental muscles were palpated and associated pain recorded, including if the pain was localised or referred. Digital pressure for clinical examination was not calibrated.

Patients were those diagnosed with masticatory muscle pain, which included “myofascial pain” and “myofascial pain with referral”. For the purpose of this study, the group “myofascial pain” also included the diagnosis “local myalgia” following the DC-TMD guidelines for diagnosis (see Appendix 6.9, Schiffman et al., 2014, Ohrbach et al. 2014).

Participants with no TMD-related pain were eligible as controls. That is, they needed to confirm lack of TMD pain or headaches in the past month, and absence of TMD signs on clinical examination.

Approximately 20 individuals who received the Participant Information Sheet either did not respond, indicated they did not want to participate, or were unavailable to participate in the study. Some 5 individuals indicated interest in the study but missed their clinical examination appointment and were not followed up. Of the individuals examined, 4 were not included in the study: 2 were not eligible for the control group due to headaches or migraines, and 2 were not eligible for pain group due to the lack of myogenous TMD diagnosis (had arthrogenous conditions only).
2.4.3 EMG DATA COLLECTION

2.4.3.1 EMG EQUIPMENT

Wireless EMG device

A small wireless EMG device developed at the University of Otago was used for this study. The device was small and minimally invasive, weighing 4.1 g and measuring 28x35 mm (Figure 2.1). The device housed a printed circuit board (PCB) which electrically connected all the device components and was powered by a disposable 3V lithium battery (CR2032, Energizer, Town and Country, Missouri). EMG activity was sampled at 1000 Hz using a programmable gain right leg drive amplifier (AD81291, Texas Instruments, Dallas, Texas), low-pass filtered using a cut-off frequency of 432 Hz (antialiasing filter) and AD converted with a 24-bit resolution. The data were down sampled to 8 Hz by computing root mean square (RMS) power in non-overlapping 125ms rectangular windows. The RMS data (24 bit) were then wirelessly transmitted in packets of four data every 500 ms to a dedicated android based smart phone via the Bluetooth Low Energy (BLE) protocol.

Figure 2.1 – Wireless EMG device
**Electrodes**

Custom-made disposable Ag/AgCl surface electrodes (SPES Medica, Genova, Italy) were used in the study. The electrodes were arranged in a triangular configuration with distance of 20mm between the active electrodes. The right leg drive (RLD) was at a distance of 23.5mm to the active electrodes. The electrodes had snap connectors that allowed connection to the wireless EMG device.

**Smartphone application**

An Android smartphone application (app) called EMG Guard™ was developed for visualisation, calibration and logging of EMG activity. The recorded data was transmitted to a smartphone via Bluetooth or ANT+. The app was designed to be user-friendly and allowed the investigator to set threshold values for detection of contraction episodes (see below) prior to the start of the recording session. The EMG data received from the device was stored in the internal memory of the smartphone.

**Accelerometer**

An accelerometer (GENEActiv, Activinsights, Kimbolton, UK) was used to collect body activity data, however the results from this are not presented in this thesis.

**2.4.3.2 EMG PROTOCOL**

Following confirmation of eligibility in either group, participants were able to choose to commence EMG data collection on the same day or reschedule to another day within two weeks if this was more convenient to them. The EMG activity during wake-time was recorded on two consecutive days.

The device was fitted on the participants’ preferred chewing side. For participants lacking a preferred side, the right-hand side was selected.
Prior to placement of the device, the skin surface was prepared with an abrasive gel (Nūprep™, Weaver and Company, Aurora, CO, USA) to lower skin impedance at the electrode site. The gel was scrubbed on the skin overlying the masseter for approximately one minute by the participant. The gel was removed from the skin surface with medical grade gauze. Thereafter, the skin was further cleaned with an isopropyl alcohol swab.

The masseter muscle was palpated to determine position and orientation of the electrodes. The EMG device was placed so the active electrodes were along the masseter long axis, and the RLD electrode pointing back towards the ear (see Figure 2.2). Once positioned on the skin surface, the EMG device was linked to the smartphone via the app and recording was commenced (Figure 2.3 a-d).

![Figure 2.2](image) – Wireless EMG device on the skin surface overlying the masseter muscle
**Figure 2.3** a-f - EMG Guard Android smartphone application screenshots showing connection via Bluetooth or ANT+ (a), beginning an EMG recording (b), the dashboard view showing live RMS detected (c), calibration mode in which the peak prolonged contraction was selected as MVC (d), User Mode used by participant, shows real time visualisation of EMG signal detected and buttons to log activity (e), exit user mode to save and stop recording (f).
First, the maximum voluntary clenching (MVC) and EMG activity at rest, while keeping the teeth slightly in contact, were recorded. To register the EMG at MVC participants were asked to perform three to five maximal clenches with an aligner tray seater (Chewies™, Dentsply, York, PA, USA), placed between the posterior teeth on the same side as the sensor. MVC were separated by rest intervals of approximately 15 seconds (Figure 2.3a-d). The peak EMG activity, excluding obvious outliers that varied by more than 30%, produced during maximal voluntary contraction (MVC) was selected. To record the EMG level at rest, participants were asked to allow their face muscles to relax completely with their teeth apart for approximately 20 seconds.

Thereafter, participants were instructed in the use of the smartphone, of the app and how to stop and save the recording (Figure 2.3 e-f). Safe removal of the device from the skin surface and storage in a sealed container was also carefully explained.

Participants were asked to wear and leave the EMG device on for approximately 12 hours, during daytime. They were also asked to log activities on the app such as eating, sleeping, and ‘other’ user-defined activity such as running, cycling or strenuous exercise, and not to actively alter behaviours (such as eating or exercise) during the period of EMG recording. Care was taken to avoid any verbal instructions to the participants that would sensitise them or alter oral behaviours during the recording.

Participants returned the following morning and the whole process was repeated and the device recalibrated.

Following the second recording day, participants were asked to complete the Oral Behaviour Checklist on Google Forms™ (Markiewicz et al., 2006; Ohrbach et al., 2008). This questionnaire was provided at the end of EMG
recording in order to minimise the risk of bias by sensitising the participants to these behaviours.

2.4.4 TREATMENT AND FOLLOW UP OF PATIENTS

After participating in the study, TMD patients were internally referred to the Discipline of Oral Medicine for ongoing treatment and care.

2.5 DATA ANALYSIS

2.5.1 QUESTIONNAIRE AND CLINICAL EXAMINATION DATA

GCPS and OBC questionnaire data was scored as per DC-TMD Scoring Manual for Self-Report Instruments (Ohrbach and Knibbe, 2017).

2.5.2 CONTRACTION EPISODES

The EMG data recordings were downloaded from the smartphones. These recordings were plotted using a script in R™ software (v3.3.1, R Foundation for Statistical Computing, Vienna, Austria) and were used in subsequent analysis for quality check of recordings.

Raw EMG data from the device were imported into MatLab_R2016b (MathWorks, Natick, Massachusetts, USA) for computation of contraction episodes statistics. A contraction episode was defined as a signal above a defined threshold which could contain sub-threshold signal portions shorter than a stand-by time to of 5 sec (Gallo et al., 1999; Farella et al., 2005). The number, amplitude and duration of contraction episodes detected by the EMG device were calculated as previously described (McNee et al., 2013) using a threshold of 3x “minimum at rest”, 3% MVC, 5% MVC and 10% MVC. ‘Minimum at rest’ was defined as the lowest root mean square (RMS) value during a 10sec ‘rest’ period. Thrice the minimum at rest was found to be indicative of a low-level clench.
The number of contraction episodes per hour (ep/hour) was calculated at each threshold. Total contraction time was defined as the sum of the duration of all contraction episodes above a defined threshold (e.g. 3% MVC). Relative contraction time was defined as the total contraction time divided by the total recording time and was reported as a percentage.

2.6 STATISTICAL ANALYSIS

Statistical analyses were performed using SPSS (version 20.0, IBM Corporation, Chicago, Illinois, USA).

Data were firstly analysed with conventional descriptive statistics. If not specified otherwise, variability was expressed as a standard error of the mean (± SEM). Data were then analysed using a linear mixed model. This analysis was used to investigate whether features of contraction episodes differed between patients and controls. The mixed model response variables were “Episode per hours”, and “Relative Contraction Time”. The variables “day”, and “group” were entered as fixed factors, while the variable “individual” was entered as random term. Multiple analyses were run for contraction episodes assessed for the four different thresholds. Where appropriate, Bonferroni corrected post-hoc multiple comparisons were run. The significance level was set at 0.05.

2.7 DATA STORAGE

2.7.1 STORAGE OF QUESTIONNAIRES AND EXAMINATION FORMS

Hard copy consent and examination forms were kept in secure storage within the Faculty of Dentistry, University of Otago. These questionnaires will be retained for up to 10 years at the above location. The electronic forms completed by the participants were stored on the Google Drive cloud server. These forms will be saved on the secure cloud server for up to 10 years. Only
the investigators involved in this study were able to access these questionnaires.

2.7.2 STORAGE OF EMG DATA

EMG data files were downloaded from smartphone internal storage and were stored on a secure hard drive within the Faculty of Dentistry, University of Otago. These may be accessed by the investigators for follow up on this study.

2.8 FUNDING

The study was supported by the New Zealand Dental Association Research Foundation (RF 8.08 2016).

2.8.1 DONATIONS

Energizer New Zealand donated 200 CR2032 batteries for use in this study.

2.9 ETHICAL APPROVAL

This study was approved by the University of Otago Ethics Committee in December 2016 (reference HI6/125) – see Appendix 6.1.

2.10 MĀORI CONSULTATION

Consultation with the Ngāi Tahu Research Consultation Committee was completed in December 2016 – Appendix 6.2.
REFERENCES


3. QUESTIONNAIRE AND CLINICAL FINDINGS IN A SAMPLE OF FEMALES WITH MYOGENOUS TMD PAIN

Abstract
Introduction
Study Aims
Materials and Methods
Results
Discussion
Conclusion

References
3.1 ABSTRACT

Aims: The aim of the present study was to describe the features of temporomandibular (TMD) signs in females with myogenous orofacial pain, and to investigate whether the level of self-reported parafunctional behaviours differed between females with myogenous TMD pain and healthy controls.

Methods: Females students and staff members from the University of Otago and Otago Polytechnic were recruited by e-mail and social media advertising as well as paper flyers placed around campus. Patients were also recruited from the Faculty of Dentistry TMD waitlist. DC-TMD Symptom Questionnaire, Graded Chronic Pain Scale (GCPS) and Oral Behaviour Checklist (OBC) were completed online using Google Forms™. A standardised examination was conducted by a single investigator and patients allocated to a myogenous pain or pain-free group.

Results: Myofascial pain without referral was the most common diagnosis affecting 89.7% of the patients. Myofascial pain with referral was found in the remaining 10.3%. Of the patients with myofascial pain, 81.5% reported familiar pain in the masseter and temporal muscles on palpation while the remaining patients reported familiar pain only in the masseter muscle. A joint click was detected in 37.0% of the patients compared to 7.7% in the controls ($p < 0.001$). Maximum unassisted and assisted opening was significantly higher in controls ($54.0 \pm 6.4$mm and $55.5 \pm 6.2$mm) than patients ($46.9 \pm 6.4$mm and $51.0 \pm 5.0$mm) ($p < 0.01$). Patients self-reported a higher frequency or number of oral behaviours with the average OBC summary score differing with statistical significance ($31.0 \pm 8.7$ vs. $21.7 \pm 10.8$, $p = 0.001$). The GCPS score was $1.67 \pm 0.73$ in patients and $0.12 \pm 0.33$ in controls.
**Conclusion:** Females with myogenous orofacial pain had distinct clinical features consisting of muscle tenderness to palpation, limited jaw function and joint sounds. In addition, they had significantly higher level of self-reported wake-time parafunctions.
3.2 INTRODUCTION

Temporomandibular disorder (TMD) is a term that encompasses a range of conditions affecting the masticatory muscles and/or the temporomandibular joint (TMJ) (Liu and Steinkeler, 2013). TMD is commonly characterised by pain, joint sounds and altered function (Dworkin and LeResche, 1992) and most commonly affects females with a peak occurrence between 20 and 40 years of age (Leresche and Drangsholt, 2008). The “Orofacial Pain: Prospective Evaluation and Risk Assessment” (OPPERA) study (Slade et al., 2013) provides strong evidence that TMDs have a multifactorial aetiology, i.e. that they are due to the interplay of different factors consistent with the biopsychosocial model of disease. Variables of the health status domain made the greatest contribution to TMD incidence, followed closely by psychological and clinical orofacial domains (Fillingim et al., 2011). Genetic factors were also concurring.

The OPPERA study also showed that parafunction was the single most significant predictor of TMD (Ohrbach et al. 2014). Parafunctional behaviours are activities conducted during the day such as clenching, grinding, nail/lip/cheek biting – all of which fall outside the normal physiological functioning of the stomatognathic system (Ohrbach et al., 2008). These parafunctional oral behaviours have the potential of overloading muscles and joints (Winocur et al., 2006). An association between parafunctional behaviour and TMD has been reported in several studies as reported in Chapter 1.4 “Aetiology of TMD”. However, an association is not proof of causality. The pain reduction upon habit reversal therapy, such as reduction of tooth contacts, seems to support this association too, (Glaros et al., 2007), although pain remission can occur for several reasons (Palla et al., 2014).
Oral parafunctions are measured using questionnaires, Ecological Momentary Assessment or electromyography. A commonly used questionnaire is the Oral Behaviour Checklist (OBC) which has been proposed as an instrument to measure self-reported parafunctional behaviours (Markiewicz et al., 2006; Ohrbach et al., 2008).

3.3 STUDY AIMS

The aim of this study was to 1) describe the features of temporomandibular (TMD) signs of females with myogenous orofacial pain, and 2) and to investigate whether the level of self-reported parafunctional behaviours differed between females with myogenous TMD orofacial pain and matched healthy controls.

3.4 MATERIALS AND METHODS

Comprehensive details of methodology relating to participant recruitment, questionnaires, clinical examination and data analysis are presented in Chapter 2 – Core Methods and Materials.

A total of 65 participants expressed interest in the study. Of these, 58 were clinically examined and 5 were found to be ineligible based on the inclusion and exclusion criteria. The final study sample comprised 53 female subjects in total. This included 27 women suffering from masticatory muscle pain and 26 controls who were matched for age and gender to the patient group.

3.5 RESULTS

3.5.1 DEMOGRAPHIC CHARACTERISTICS

The demographic data of all participants is presented in Table 3.1
Table 3.1 - Characteristics of the studied groups

<table>
<thead>
<tr>
<th></th>
<th>No. Patients (%)</th>
<th>No. Controls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Female</td>
<td>27 (100.0)</td>
<td>26 (100.0)</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-20</td>
<td>3 (11.1)</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>21-30</td>
<td>16 (59.3)</td>
<td>16 (61.5)</td>
</tr>
<tr>
<td>31-40</td>
<td>7 (25.9)</td>
<td>7 (26.9)</td>
</tr>
<tr>
<td>41-50</td>
<td>1 (3.7)</td>
<td>1 (3.8)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NZ European</td>
<td>23 (85.2)</td>
<td>9 (34.6)</td>
</tr>
<tr>
<td>Māori</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Asian (incl. Indian)</td>
<td>3 (11.1)</td>
<td>11 (42.3)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (3.7)</td>
<td>6 (23.1)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>13 (48.1)</td>
<td>7 (26.9)</td>
</tr>
<tr>
<td>Living with partner</td>
<td>6 (22.2)</td>
<td>8 (30.8)</td>
</tr>
<tr>
<td>Married</td>
<td>7 (25.9)</td>
<td>7 (26.9)</td>
</tr>
<tr>
<td>Separated or divorced</td>
<td>0 (0.0)</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (3.7)</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>University Student</td>
<td>16 (59.3)</td>
<td>18 (69.2)</td>
</tr>
<tr>
<td>University Staff</td>
<td>6 (22.2)</td>
<td>8 (30.8)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (18.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Recruitment method</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMD Waitlist</td>
<td>7 (25.9)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Email</td>
<td>17 (63.0)</td>
<td>18 (69.2)</td>
</tr>
<tr>
<td>Social media</td>
<td>1 (3.7)</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>Flyer</td>
<td>1 (3.7)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Word of mouth</td>
<td>1 (3.7)</td>
<td>6 (23.1)</td>
</tr>
<tr>
<td><strong>All combined</strong></td>
<td>27</td>
<td>26</td>
</tr>
</tbody>
</table>

\(^a\) \chi^2 \text{ test: } p = 0.001

\(^b\) \chi^2 \text{ test: } p = 0.006
Patients (27.0 ± 6.3 years) and controls (28.0 ± 6.5 years) did not differ significantly for age ($p = 0.856$) and marital status ($p = 0.416$). However, the two groups were not matched for ethnicity ($p = 0.001$). New Zealand European constituted the majority of the patient group. Asian ethnicities (including Indian, Chinese, Japanese and Korean) made up 11% of the patients and 42% of the controls.

The majority of participants in both groups were undergraduate or postgraduate university or polytechnic students. Five patients were not affiliated with the university/polytechnic and were recruited from the TMD waiting list at the Faculty of Dentistry at the University of Otago. E-mail advertising was effective in recruiting over two thirds of the participants for both groups. Word of mouth was effective for the recruitment of almost a quarter of the control group and the participants recruited by this method heard about the study from friends who had participated in the study.

3.5.2 CLINICAL EXAMINATION FINDINGS

Of the 30 individuals examined for inclusion in the pain group, 27 could be recruited. Two were excluded as they were found to have pain not related to the masticatory muscles: one had arthralgia only and the other a primary headache form. The third one was excluded as she had no previous history of jaw pain but was experiencing an acute flare up due to occlusal dysesthesia.

28 individuals were assessed for inclusion in the control group but 2 were excluded due to regular headaches within the month preceding the study. None of the 26 controls had any TMD-related pain on clinical examination.

As mentioned in chapter 2.4.2 “Clinical Examination”, ‘localised myalgia’ and ‘Myofascial pain without referral’ were not differentiated in the clinical exam and are collectively termed ‘myofascial pain’ for the purpose of this study.
In 24 (88.8%) of the patients, palpation caused a pain localized within the palpated muscle (myofascial pain) and in the remaining 3 (11.1%) the pain spread beyond the boundary of the muscle (myofascial pain with referral). Some 23 (85.2%) of the pain patients reported familiar pain on palpation in the masseter and temporal muscles, while the remaining 4 (14.8%) individuals only in the masseter muscle.

Joint noises were detected during clinical examination in 12 patients (10 with clicks, of which 2 had intermittent locking, and 2 with crepitus) and 5 controls (2 with clicks, 3 with crepitus). More patients self-reported TMJ noises in the DC-TMD Symptom Questionnaire than controls: 23 patients and 5 controls had self-reported joint noise(s) in the past month (χ² test; p < 0.001).

The average maximum pain-free opening was 38.4 ± 7.1mm in patients, and 15 (55.6%) of these had limited pain-free mouthing (<40mm). The average maximum unassisted and assisted mouth opening was significantly greater in controls than in patients (p ≥ 0.005) – Figure 3.1. Eight (30.8%) of the controls reported discomfort on maximum unassisted opening. However, they reported that this was not painful nor a familiar sensation, as they normally did not open that wide.

![Figure 3.1](image.png)

**Figure 3.1** – Mean and standard error of maximum mouth opening in patients and controls.
3.5.3 GRADED CHRONIC PAIN SCALE AND ORAL BEHAVIOURS CHECKLIST

Participants completed the GCPS online up to 8 weeks prior to the clinical examination. Patients had an average characteristic pain intensity (CPI) score of 49.1 ± 15.9 and those of the control group of 3.2 ± 10.7. The interference score (IS) was 30.6 ± 23.4 for the pain group and 0.6 ± 3.3 for the control group. The overall CGPS was 1.7 ± 0.7 for the pain group and 0.1 ± 0.3 for the control group. The distribution of CGPS scores of the groups is shown in Table 3.2.

Table 3.2 – GCPS scores for patients and controls

<table>
<thead>
<tr>
<th>GCPS</th>
<th>No. Patients (%)</th>
<th>No. Controls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0 (0.0)</td>
<td>23 (88.5)</td>
</tr>
<tr>
<td>1</td>
<td>13 (48.1)</td>
<td>3 (11.5)</td>
</tr>
<tr>
<td>2</td>
<td>10 (37.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>3</td>
<td>3 (14.8)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>4</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

All combined 27 26

The OBC summary score was significantly higher for the pain group than for the control group (31.0 ± 8.7 and 21.7 ± 10.8 respectively; \( p = 0.001 \)) (patients \( N = 26 \), controls \( N = 26 \), Figure 3.2). One participant from the pain group did not complete and return the OBC despite multiple attempts to contact them.
The frequency distributions of the self-reported oral behaviours during waking hours is presented in Table 3.3 and Figure 3.3. In the table, the OBC Summary Score is dichotomised into low (1-24) and high (25-84). The frequency distribution of “high” and “low” scores differed significantly between groups \((p = 0.005)\), with 21 out of the 26 patients having an OBC summary score above 24. Patients had a slightly higher mean score for most oral behaviours except for leaning with hand on jaw, eating between meals, singing, and holding the telephone between the head and shoulders (OBC items 15, 17, 19 and 21).

Table 3.3 – Oral behaviour summary score

<table>
<thead>
<tr>
<th>Oral Behaviour Summary Score *</th>
<th>Pain Group (%)</th>
<th>Control Group (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>5 (19.2)</td>
<td>16 (61.5)</td>
</tr>
<tr>
<td>High</td>
<td>21 (80.8)</td>
<td>10 (38.5)</td>
</tr>
<tr>
<td>All combined</td>
<td>26</td>
<td>26</td>
</tr>
</tbody>
</table>

*\(\chi^2\) test: \(p = 0.005\)
Figure 3.3 – Self-reported oral behaviours during waking hours in patients and controls. Data were compared by Mann-Whitney U Test; * $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$
3.6 DISCUSSION

As expected, patients had some distinct features including masticatory muscle pain on palpation and a limited range of jaw function when compared to age-matched controls. In addition, jaw sounds (clicking and crepititation) were more common in the pain group.

The OBC is an instrument that has been proposed in order to assess oral parafunction (Markiewicz et al., 2006; Ohrbach et al., 2008). Patients reported a higher OBC summary score than controls, indicating that during wake-time, they had a more pronounced parafunctional behaviour than healthy controls. The OBC summary scores reported by patients and controls in this study were comparable to those reported by Cioffi et al. (2016) for females with myogenous TMD and healthy controls. The OPPERA study found that only an OBC summary score of 25 or more was associated with predicting the risk of first onset of TMD pain (Ohrbach et al., 2011). In the present study, 21 out of the 26 pain patients who completed the OBC had a score in this range. Interestingly, 10 out of the 26 controls had an OBC summary score of 25 or more. This relatively high proportion of healthy controls with a high OBC score may be due to the relatively high proportion of students in the group. Various studies have shown a concerning rate of stress, depression and anxiety in university students (Regehr et al., 2013), and these disorders are associated with wake-time oral parafunctional behaviours (Khawaja et al., 2015). Moreover, there is an established link between emotional stress and parafunctional behaviours (Ohrbach and Michelotti, 2018).

Limitations of the study included the clinical examination by a single examiner, the convenience sampling of the study group and the time lag between the completion of the Symptoms Questionnaire and Graded
Chronic Pain Scale and the clinical examination. While a clinical examination performed by a single examiner may warrant that the examination is conducted in all subjects in the same manner it also increases the risk of bias in the selection process.

It is known that non-chronic myogenous TMD pain may resolve spontaneously. The majority of the pain patients had a GCPS score of I or II, that is, they had a low disability (only 4 of the 27 patients were found to have a GCPS score of III and none had a score of IV). Therefore, it cannot be excluded that the characteristic pain intensity recorded when the patient filled the GCPS did not correspond to the value at the beginning of the study, due to the time lag between the filling of the GCPS and the clinical examination/the beginning of the EMG recording (as much as eight weeks, although usually two weeks).

Initially, the patients were planned to be recruited solely from the Faculty of Dentistry TMD waiting list. However, due to a lack of interest from patients on the waiting list (that had been referred for TMD management by their general medical practitioners or family dentists) the net was cast wider. E-mail advertising was found to be the most effective means of advertising for both groups. As a convenience sample was used, the results of this study cannot be extrapolated to the myogenous TMD pain “population” at large. This sampling method may also be responsible for the relatively low pain intensity reported by the patients, although the mean CPI score of patients in this study was comparable to that reported by Cioffi et al. (2016) for female with myogenous TMD.
3.7 CONCLUSION

Females with myogenous TMD had a greater OBC summary score than healthy matched controls, indicating a higher degree of wake-time parafunction. Of note is that a third of the controls also had a ‘high’ OBC summary score.
3.8 REFERENCES


4. MASTICATORY MUSCLE ACTIVITY IN PATIENTS WITH MYOGENOUS TMD PAIN

Abstract
Introduction
Materials and Methods
Results
Discussion
Conclusions

References
4.1 ABSTRACT

**Aims:** The aim of the present study was 1) to collect objective data on masticatory muscle activity during wake-time in the habitual environment in females with myogenous temporomandibular disorder (TMD) and age-matched pain-free controls, 2) to compare the features of masticatory muscle activity between the two groups, and 3) investigate the association between self-reported oral parafunction and masticatory muscle activity.

**Methods:** Female participants (N = 27, mean age 27.0 ± 6.3 years) diagnosed with myofascial pain with and without pain referral were age and gender matched with controls free of TMD-pain (N = 26, mean age 28.0 ± 6.5 years). A single examiner completed a standardised TMD examination on all participants, to confirm eligibility for the study. Participants wore a minimally invasive, wireless EMG device attached to the skin overlying the masseter muscle. Participants wore the EMG sensors whilst awake, over two consecutive days. Maximum voluntary contraction (MVC) was identified as peak bite force. Contraction episodes over 5 seconds duration were detected at four thresholds: 3x minimum EMG activity at rest, 3% MVC, 5% MVC, 10% MVC. The frequency, duration and amplitude of masseter contraction episodes were calculated and compared between the two groups by means of mixed model analysis.

**Results:** MVC was 1124.7 ± 550.8μV in the pain group and 1202.5 ± 424.5μV in the control group (p = 0.559). Most masseter contraction episodes of both patients and controls were of relatively low amplitude (< 10% MVC) and short duration (<10 seconds). There was no significant difference in the number of episodes per hour between groups (p > 0.05). A significant difference in total contraction time was found between groups (p = 0.039) with a tendency to longer contractions in the pain patients. There was a significant interaction between the factors “group” and “threshold” (p =
suggesting that the difference of relative contraction time varied across thresholds, being more pronounced for low-level activity. No significant association was found between the level of self-reported parafunction and both the number of contraction episodes per hour or the relative contraction time.

**Conclusion:** Patients with myogenous TMD pain have a similar number of masseter muscle contractions during wake-time as age-matched pain-free controls but the contractions are longer in the myogenous TMD patients. Masseter muscle contractions are not significantly associated with self-reported levels of oral behaviours and parafunctions.

**4.2 INTRODUCTION**

Temporomandibular disorder (TMD) manifest by pain in the muscles of mastication and/or the temporomandibular joint (TMJ), joint noises, and/or limited range of functional jaw movements (Golstein, 1999; Liu and Steinkeler, 2013). Females are more frequently affected with, and are more likely to seek treatment for TMD than males (Lipton et al., 1993; Carlsson, 1999; Poveda-Roda et al., 2007). TMD-related pain is the primary symptom in those seeking treatment (Dworkin et al., 1990; John et al., 2007). The prevalence of TMD symptoms reported in the literature is highly variable but a systematic review reported a prevalence of 9.7% for masticatory muscle pain in the general population (Manfredini et al., 2011).

It is widely accepted that TMD has a multifactorial aetiology with an interplay of patient health, psychological, genetic and biomechanical (parafunction) factors (LeResche et al., 2007; Fillingim et al., 2011; Ohrbach et al., 2014). The “Orofacial Pain: Prospective Evaluation and Risk Assessment” (OPPERA) study (Slade et al., 2013) has provided valuable insight into the aetiology of the condition. The OPPERA study showed that
self-reported oral parafunction was one of the strongest predictor of TMD (Ohrbach et al., 2014). Parafunctional behaviours such as tooth grinding and tooth clenching habits are clinically associated with masticatory muscle tenderness (Okeson, 1996; Glaros and Burton, 2004; Winocur et al., 2006; Chen et al., 2007; Michelotti et al., 2010; Ohrbach and Michelotti, 2018). The results presented in Chapter 3 show that patients with myogenous TMD pain have a higher level of self-reported parafunction compared to healthy controls. Wake-time parafunction differs from sleep bruxism and seems to be characterised by prolonged, low-level contractions (Fujisawa et al., 2013).

Most studies on wake-time parafunction rely on questionnaires and Ecological Momentary Assessment (EMA) (see chapter 1.5.1 “Assessment and Epidemiology”). Questionnaires are invariably susceptible to recall bias which limits the validity of such data. EMA is a better alternative to questionnaires but still does not provide detailed understanding of muscle activity throughout the day.

Objective data on masticatory muscle activity (MMA) can be obtained through the use of surface electromyography (EMG). EMG studies during wake-time are limited but have shown an association between painful-TMD and masticatory muscle activity. Cioffi et al., (2016) reported female patients with masticatory muscle myalgia had an increased frequency of contractions compared to healthy females when performing standardised tasks. While a number of studies have assessed wake-time muscle activity in patients with various TMD conditions such as disc displacement (Iwasaki et al., 2015; Iwasaki et al., 2017), myalgia/arthralgia (Khawaja et al., 2015), there is thus far limited data on the association between MMA while awake in myogenous TMD patients and healthy subjects. To date, the association between MMA (collected by EMG in the natural environment) and self-reported parafunction has not been investigated.
4.3 STUDY AIMS

The aims of the present study were: 1) to collect objective data on masticatory muscle activity during wake-time in the natural environment in females with myogenous TMD and age-matched pain-free controls, 2) to compare the features of masticatory muscle activity between the two groups and 3) investigate the relationship between self-reported oral parafunction and EMG activity.

4.4 MATERIALS AND METHODS

This study was approved by the Ethics Committee of the University of Otago, Dunedin, New Zealand.

Methodological details pertaining to participant recruitment, questionnaires, clinical examination, electromyography, study procedure and analysis can be found in Chapter 2 - Core Material and Methods.

4.5 RESULTS

Masseter muscle activity was recorded for a total of 696.6 hours in the patient group and of 644.6 hours in the control group, with a mean recording length of 12.4 hours per day in both groups \((p > 0.05)\) (Table 4.1). Some data was lost due to failure of the device connectivity to the smartphone via Bluetooth/ANT+. The percentage of missing data during recording was similar between patients and controls \((6.3\% \text{ and } 5.1\% \text{ respectively, } p > 0.05)\). The mean MVC was slightly lower in the patient group, but the difference between groups was not statistically significant \((p > 0.05)\). The minimum and average EMG activity at rest were comparable between the groups \((p > 0.05)\).
Table 4.1 – Characteristics of the EMG recordings averaged over the two recording days by study groups.

<table>
<thead>
<tr>
<th></th>
<th>Patients (mean ± SEM)</th>
<th>Controls (mean ± SEM)</th>
<th>F-value a</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recording time (hours/day)</td>
<td>12.4 ± 1.3</td>
<td>12.4 ± 1.6</td>
<td>0.01</td>
<td>0.939</td>
</tr>
<tr>
<td>Missing data (%)</td>
<td>6.3 ± 6.2</td>
<td>5.1 ± 5.6</td>
<td>0.74</td>
<td>0.395</td>
</tr>
<tr>
<td>Maximum voluntary contraction (μV)</td>
<td>1124.7 ± 550.8</td>
<td>1202.5 ± 424.5</td>
<td>0.35</td>
<td>0.559</td>
</tr>
<tr>
<td>Minimum activity at rest (μV)</td>
<td>11.0 ± 0.6</td>
<td>11.1 ± 0.5</td>
<td>1.10</td>
<td>0.299</td>
</tr>
<tr>
<td>Average activity at rest (μV)</td>
<td>13.5 ± 0.6</td>
<td>13.6 ± 0.6</td>
<td>0.22</td>
<td>0.645</td>
</tr>
</tbody>
</table>

* Results analysed using a mixed model analysis

The mean number of contraction episodes of the masseter muscle varied with the thresholds used for episode detection. It ranged from around 600 episodes per recording day with a 10% threshold, to over 1,100 episode per recording day, with the lowest threshold (3x minimum activity). Descriptive statistics for contraction episode counts is presented in Table 4.2.

Table 4.2 – Episode count averaged over the two recording days in patients and controls.

<table>
<thead>
<tr>
<th></th>
<th>Patients (Mean ± SEM)</th>
<th>Controls (Mean ± SEM)</th>
<th>F-value a</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Episodes per day</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3x minimum</td>
<td>1127.4 ± 56.6</td>
<td>1132.3 ± 58.7</td>
<td>0.32</td>
<td>0.576</td>
</tr>
<tr>
<td>3% MVC</td>
<td>1087.8 ± 62.6</td>
<td>1123.6 ± 64.9</td>
<td>0.61</td>
<td>0.437</td>
</tr>
<tr>
<td>5% MVC</td>
<td>924.9 ± 53.3</td>
<td>869.2 ± 55.3</td>
<td>0.24</td>
<td>0.628</td>
</tr>
<tr>
<td>10% MVC</td>
<td>608.9 ± 47.2</td>
<td>517.3 ± 48.9</td>
<td>5.89</td>
<td>0.019</td>
</tr>
</tbody>
</table>

* Mixed model analysis

The distribution of all contraction episodes collected from all study group participants during the two recording days, according to their amplitude and duration is given in Figure 4.1. Episodes were mostly of low amplitude and short duration. The episodes are skewed by different thresholds. The distribution of episodes by length is shown in Figure 4.2.
Figure 4.1 – 3D Histograms showing the counts, amplitude and duration of all contraction episodes between controls (blue) and patients (green)
Note that the proportion of longer episodes was slightly, but consistently higher in patients than in controls, especially for low levels of detection thresholds.

**Figure 4.2 a-d** – Relative proportion of masseter contraction episodes lasting longer than 2, 5, 10, 20 and 30 seconds

Note that the proportion of longer episodes was slightly, but consistently higher in patients than in controls, especially for low levels of detection thresholds.
The number of contraction episodes per hour was calculated for each threshold. The number of contraction episodes per hour was slightly higher in the patients at each of the tested thresholds but the difference was not significant ($p > 0.05$). The number of episodes per hour by study group is presented in Figure 4.3 and Table 4.3.

Figure 4.3 – Box plot showing the number of masseter contraction episodes per hour at various thresholds by study group.

Table 4.3 – Masseter contraction episodes per hour at various thresholds by study group

<table>
<thead>
<tr>
<th>Episodes per hour $^a$</th>
<th>Patients (Mean ± SEM)</th>
<th>Controls (Mean ± SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3x minimum</td>
<td>99.3 ± 4.9</td>
<td>96.3 ± 5.1</td>
</tr>
<tr>
<td>3% MVC</td>
<td>94.0 ± 5.2</td>
<td>95.7 ± 5.4</td>
</tr>
<tr>
<td>5% MVC</td>
<td>81.3 ± 4.6</td>
<td>74.3 ± 4.8</td>
</tr>
<tr>
<td>10% MVC</td>
<td>54.6 ± 4.3</td>
<td>44.2 ± 4.4</td>
</tr>
</tbody>
</table>

$^a$ All differences $p > 0.05$

A significant difference in relative contraction time was found between groups, with the myogenous TMD group having a longer contraction time than the control group ($F = 4.47$, $p = 0.039$). There was a significant interaction between the factors “group” and “threshold”, suggesting that the
difference of relative contraction time varied across thresholds, and was more pronounced with lower detection thresholds (Figure 4.4). Post hoc tests revealed that the differences between groups were most pronounced for episodes above 3% MVC and 5% MVC ($F \geq 4.19, p \leq 0.05$). For low detection thresholds (3x minimum, 3% MVC, 5% MVC), the difference in relative contraction time between groups ranged from 4% to 10% with a smaller difference of only 1% at the 10% MVC threshold (Table 4.4).

![Figure 4.4](image)

**Figure 4.4** – Relative contraction times of masseter muscle contractions by groups and by thresholds.

<table>
<thead>
<tr>
<th></th>
<th>Patients (Mean ± SEM)</th>
<th>Controls (Mean ± SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative contraction time (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3x minimum</td>
<td>24.5 ± 1.8</td>
<td>21.0 ± 1.9</td>
</tr>
<tr>
<td>3% MVC</td>
<td>32.0 ± 3.2</td>
<td>22.1 ± 3.4</td>
</tr>
<tr>
<td>5% MVC</td>
<td>19.6 ± 2.3</td>
<td>13.2 ± 2.4</td>
</tr>
<tr>
<td>10% MVC</td>
<td>8.7 ± 0.9</td>
<td>7.5 ± 0.9</td>
</tr>
</tbody>
</table>

*a p < 0.05*
Regardless of their status (patient or control), all participants were grouped according to the reported level of oral parafunctions. Participants with a lower self-reported parafunction (OBC summary score 0-24) had a similar number of contraction episodes per hour to those with a higher level of self-reported parafunction (OBC summary score 25-84) - Figure 4.5.

**Figure 4.5** - Number of episodes per hour by self-reported parafunction

There was a trend to lower relative contraction time in participants with low self-reported parafunction but this difference was not statistically significant ($p > 0.05$) – Figure 4.6.
Figure 4.6 – Relative contraction time by self-reported parafunction
4.6 DISCUSSION

This study aimed to compare masticatory muscle activity in females with myogenous TMD and healthy pain-free age-matched controls whilst awake and in the habitual environment, and to investigate the association between self-reported oral behaviours and EMG data.

The EMG level at MVC and at rest position were not found to be significantly different between groups. The number of contraction episodes was similar in patients and controls, and episodes were mostly of short duration and low amplitude. Surprisingly, there was no significant difference in the number of contraction episodes between patients and controls. This finding contradicts results of Ecological Momentary Assessment studies that reported a higher frequency of tooth contacts and more muscle tension in TMD pain patients than in healthy controls (Chen et al., 2007; Glaros et al., 2005). This discrepancy is likely due to differences in the recording technique and in the study populations. Even if ecological momentary assessment reduces the risk of recall bias, only continuous EMG recording can detect when the masseter muscle contracts and, therefore, EMG recording should be regarded as the “gold standard” for assessing wake-time masseter activity.

There was a significant difference in the relative contraction time with a longer relative contraction time in patients than controls, especially for contractions at low-intensity level. This finding supports the results by Khawaja et al. (2015) who also reported a longer contraction time (larger duty factor) in patients with TMD (with or without pain) than in controls. Unfortunately, the present study design does not allow us to answer questions on whether long-lasting masticatory muscle contractions are a cause of TMD or secondary phenomena of having TMD. The “Cinderella hypothesis” (Hägg, 1991) postulates that type I muscle fibres (“Cinderella motor units”) can fatigue during prolonged low-level contractions, becoming
damaged, thus leading to local inflammation and subsequent nociceptor sensitisation and muscle pain. Palla and Farella (2010) reported the presence of Cinderella motor units in the masseter muscle during prolonged low-amplitude clenching tasks performed at 4-6% MVC. However, it remains to be demonstrated whether the duration of the low-level contractions recorded in this study could be sufficient to trigger a myogenous pain. Comparison with recordings from the trapezius muscles in patients with work-related trapezius myalgia suggest that much longer low-intensity contractions episodes are associated with pain (Østensvik et al., 2009; Hanvold et al., 2012; Hanvold et al., 2013). It must, however, be emphasised once again that prolonged low-intensity contractions are not sufficient to lead to muscle pain and muscle pain is generally accepted as the result of the interplay of different factors (Palla, 2014; Ohrbach and Michelotti, 2018).

No significant association was found between the OBC scores and the frequency of contraction episodes. The number of episodes per hour were similar in those (regardless of patient or control status) who self-reported a low level of parafunction and those who self-reported a high level of parafunction. There was tendency to a higher relative contraction time in those with a high OBC summary score, indicating longer contractions, but the difference was not statistically significant. Thus, the results of this study, which to our knowledge is the first in which the OBC was tested against continuous EMG recording of the masseter muscle activity, seem to not support the validity of the OBC. Some authors have advocated educating patients on what is meant by behaviours such clenching and grinding and repeating the self-reports after the patient has been asked to monitor their behaviours over a 1- or 2-week period for increased accuracy (Lobbezoo et al. 2018).
Contrary to our expectation, MVC values did not differ significantly between patients and controls. Previous research has suggested that MVC is lower in TMD patients, and can be reduced by experimental induction of pain (Lund et al., 1991; Svensson et al., 1998; Wang et al., 2000). That MVC values were similar between groups in this study may be ascribed to the fact that patients had generally low-to-moderate pain levels (see below).

The duration of recording was similar and comparable between days and groups. Two consecutive days of recording may have been insufficient to allow subjects to “forget” the recording device, i.e. it cannot be excluded that the individuals undergoing recording changed their habits, although they were instructed not to do so. Furthermore, despite care being taken to avoid verbal dialogue or instruction that sensitised the patient, a possible Hawthorne Effect cannot be excluded.

This study has several shortcomings, the first one being the use of surface EMG which, in spite of likely being the best method to record the masseter muscle contraction behaviour in the habitual environment, is not free of limitations. Indeed, surface EMG recordings are less accurate than recordings with intramuscular fine-wire electrodes (Chapman et al., 2010), because the intramuscularly recorded EMG signal is not contaminated by crosstalk from other muscles (Mangun et al., 1986), which is the case with surface EMG devices especially when recording low-intensity contractions. During these recordings, the signal could have been contaminated by cross-talk from other facial muscles (e.g. buccinator). In addition, analytical pattern recognition algorithms were not applied to differentiate between different oral behaviours. Thus, these shortcomings do not allow the conclusion that all contractions episodes corresponded to parafunctional activity. Further studies are necessary in order to assess which threshold level allows the best recognition of parafunctional activity. This evaluation would
likely require combined simultaneous registration of tooth contacts and EMG. Although physical activity data was collected, it was not analysed in this study. Periods of self-reported activity such as eating and physical activity were also not excluded or analysed separately.

A further limitation of this study was the lack of bite force measurement such as that used by Iwasaki et al. (2015) for calibration of the EMG as an alternative to MVC, as such a measurement would circumvent the need for calculations reliant on MVC to determine the contraction episodes and relative contraction time.

Maximum voluntary contraction is a measure routinely used for calibration in EMG studies. Though efforts were taken to standardise the collection of MVC in study participants, the MVC was found to be highly variable between individuals. This is not altogether surprising given the degree of individual variation in the size and form of the masseter muscle.

Missing data is another limitation of this study. The use of a wireless EMG device introduced the need for a smartphone to act as a data recorder. The continuous recording of data relied on the smartphone being in range of the EMG device. Despite the instruction to carry the smartphone on their person or to remain within a 3m radius of the smartphone, there were inevitably instances of the phone falling out of range of the EMG device. In such instances, the last outcome was carried forward. Any sequence of missing data greater than the threshold to detect a contraction episode (5sec) was discarded to minimise the effect of the missing data. Not only was the amount of missing data in this study relatively low (approximately 5% of total recording time) but it was not different between the two groups. Therefore, it is safe to assume that this shortcoming has unlikely affected the results.
Another shortcoming relates to the fact that not enough patients and controls could be recruited to meet the target of 30 participants per group to achieve 80% statistical power. Although the Faculty of Dentistry services the greater Otago area, with a population of just under a quarter of a million (Subnational population estimates: At 30 June 2017, Stats NZ), the number of successful recruits from the Faculty’s TMD waiting list was low. Due to the length of the waiting list, many participants reported spontaneous resolution of their symptoms since the referral was made. Perhaps due to the large student population and the transient nature of the TMD pain, many patients on the waiting list were no longer living in Dunedin or no longer affected by TMD pain when asked to participate in the study. Others were not interested in the study because they did not want to wear a device visible on their face. There was a significant difference in the ethnicity of participants between groups, though it is not known whether there is a difference in bite force or MMA between Asian and Caucasian populations. Because of the difficulty in recruiting participants for the pain group, we were unable to exclude mild patients (i.e. with low GCPS score). In fact, the pain group consisted almost entirely of patients with mild pain of limited disability and small impact on routine activities (see Chapter 3). No information was collected on pain levels during the electromyographic recording. The final patient sample largely consisted of students that may not be representative of the general TMD pain population. Students also constituted the majority of the control group – of these, most were postgraduate students who were perhaps under psychological stress during their studies.
4.7 CONCLUSIONS

Female patients with myogenous TMD pain had a similar number of masseter contraction episodes during wake-time as healthy subjects. However, the contraction episodes, especially those at low-intensity, lasted longer in the pain patients than in the controls. Self-reported oral parafunction, i.e. the OBC score, did not correlate with the number of contraction episodes, raising doubts about the validity of the OBC for assessing wake-time parafunction.
4.8 REFERENCES


Slade GD, Fillingim RB, Sanders AE, Bair E, Greenspan JD, Ohrbach R, et al. (2013). Summary of findings from the OPPERA prospective cohort study of


5. FUTURE RESEARCH DIRECTIONS
This study used a wireless EMG device to record masseter muscle activity of myogenous TMD patients and healthy controls. We believe EMG is the gold standard for recording masticatory muscle activities as it does not suffer from the limitations of EMA approaches and self-report surveys of oral parafunctional behaviours. That the device is wireless means that participants can go about daily activities with minimal or no interference.

In the future, the present study should be replicated using a larger sample and for a longer period of time. Future research should include patients with more severe and chronic TMD as well as healthier controls, such as the exclusion of joint noises or even distant past history of TMD. Future studies may also use pattern recognition algorithms to distinguish between oral behaviours.

The use of the wireless recording and smartphone monitoring will facilitate large scale studies. An exciting opportunity exists whereby development of the smartphone app could allow participants to receive real time biofeedback in the form of a vibration of the phone to indicate muscle activity to raise awareness of parafunctional behaviours and promote habit reversal.
6. APPENDICES

Ethical Approval
Māori Consultation
Funding
Advertising
Participant Information Sheets
Participant Consent Forms
Participant Questionnaires
Clinical Examination Form
Diagnostic Decision Tree
6.1 ETHICAL APPROVAL

H16/125

20 December 2016

Professor M Farella
Department of Oral Sciences
Faculty of Dentistry

Dear Professor Farella,

I am again writing to you concerning your proposal entitled “Jaw muscle overload as a possible cause of orofacial pain”, Ethics Committee reference number H16/125.

Thank you to Divya Ramanan, student investigator on the above project, for her emails of 8th and 19th December 2016 addressing the issues raised by the Committee.

On the basis of this response, I am pleased to confirm that the proposal now has full ethical approval to proceed.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

http://www.otago.ac.nz/healthandsafety/index.html

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:
gary.witte@otago.ac.nz
jo.farrondediaz@otago.ac.nz

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

The Human Ethics Committee (Health) asks for a Final Report to be provided upon completion of the study. The Final Report template can be found on the Human Ethics Web Page http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html

Yours sincerely,

[Signature]

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

cc. Professor W M Thomson  Department of Oral Sciences
6.2 MĀORI CONSULTATION

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE
TE KOMITI RAKAHAU KI KAI TAHU

Tuesday, 01 November 2016.

Professor Mauro Farella,
Faculty of Dentistry - Department of Oral Science,
DUNEDIN.

Tēnā koe Professor Mauro Farella,

Jaw muscle overload as a possible cause of orofacial pain and headache

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 01 November 2016 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee considers the research to be of importance to Māori health.

As this study involves human participants, the Committee strongly encourage that ethnicity data be collected as part of the research project. That is, the questions on self-identified ethnicity and descent, these questions are contained in the latest census.

The Committee suggests dissemination of the findings to relevant Māori health organisations, for example the National Māori Organisation for Dental Health, Oranga Nīho and to Professor John Broughton and Malcolm Dacker, who are involved in Māori Dental Health, University of Otago.

We wish you every success in your research and the committee also requests a copy of the research findings.

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Paketaraki
Te Rūnanga o Moeraki
This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 01 November 2016 to 1 May 2018.

Nāhaku noa, nā

Mark Brunton
Kaiwhakahaere Rangahau Māori
Research Manager Māori
Research Division
Te Whare Wānanga o Otago
Ph: +64 3 479 8738
Email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:

*Te Rūnanga o Oākou Incorporated*
*Kāti Huirapa Rūnanga ki Puketāraki*
*Te Rūnanga o Moeraki*
6.3 FUNDING

ADVICE OF RESEARCH FUNDING GRANT APPLICATION AS ASSESSED BY THE BOARD,
OF THE NEW ZEALAND DENTAL RESEARCH FOUNDATION
NZDA HOUSE, WEDNESDAY 29 July 2016

Date of Advice
11 August 2016

Name of Applicant/s
Farella M, Ramanan D, Polonowita A, Hamilton J, Paila S

Reference
RF8.08 2016

Title of Research
Jaw muscle overload as a possible cause of orofacial pain and headache.

Amount Awarded
$12,350

Condition/s of Award
Funding of this project is subject to ethics approval being obtained and in accordance with the reporting conditions as follows. A payment of $12,350 will be made on the receipt of an invoice for such. Progress Reports are required by 1 June 2017 and annually thereafter (see General Comments). A Final Report (and a copy of any publications) is required at the completion of the project on 30 September 2018. Copies of any publications after this date are also to be provided.

General Comments
The project ranked sufficiently for the Board to agree to award $12,350 subject to the payment conditions. For administrative convenience Progress Reports are to be submitted to Research and Enterprise, ‘Centre for Innovation’, University of Otago by 15 May 2017 and annually thereafter. Publications should acknowledge funding support from the NZ Dental Research Foundation.

Signed: Richard Jeffries (Chair, New Zealand Dental Research Foundation Board)

YOU ARE REQUIRED TO SUBMIT A PROGRESS REPORT TO RESEARCH AND ENTERPRISE, UNIVERSITY OTAGO BY 15 MAY 2017 TO ENSURE REPORTS ARE RECEIVED BY NZDRE BY 1 JUNE 2017
(Please email your report to – research@otago.ac.nz)

The Principal Researcher should sign, date and return a COPY of this advice notice (in the panel below) to acknowledge conditions and enable payment of the Award. If the Principal Researcher is a post-graduate student then the student’s supervisor should sign and return this form. Thank you.

Name: ________________________ Signed: ________________________ Date: __/__/2016

Principal Researcher OR Student Supervisor
6.4 ADVERTISING

6.4.1 FACEBOOK ADVERTISING

Admin please delete this if it is inappropriate on this page!

I am a postgrad dental student looking for some participants for my research. I am looking for females aged 18-50yrs. I need (A) some cases with ongoing jaw pain and also (B) some controls with no history of jaw pain.

As part of the research we are collecting EMG data (electrical activity) of the masseter muscle - the jaw muscle in front of your ear that people clench when they’re angry! This involves wearing a wireless electric sensor (seen in picture) for 12 hours during the day for 2 consecutive days.

For taking part in this research, you receive a $50 New World voucher and if you are in the case group you will also receive some advice on the management of the jaw pain.

If you are interested in being a case or a control, or know someone who might be please PM me or email jawstudy.otago@gmail.com for a participant information sheet

Thanks for reading 😊
Hi everyone,

We are still looking for some participants for my Jaw study at the Faculty of Dentistry. For the study, we are collecting data on jaw muscle activity during the day. To do this we use a skin surface sensor which detects the underlying muscle’s activity. You would need to wear this sensor for 2 days for ~ 12 hours each day while awake.

We are still looking for some cases but now mostly need controls.
To be eligible, you must be: female, 18-50yrs old, not currently undergoing orthodontic treatment.
Cases should have had some jaw muscle pain in the last month.
Controls should have no jaw muscle pain or head aches in the last month.

You will receive a $50 NEW WORLD SUPERMARKET VOUCHER for participating.

If you or someone you know might be interested, please email jawstudy.otago@gmail.com
6.4.2 E-MAIL ADVERTISING

Dear all,

At the Faculty of Dentistry, we are conducting a study aiming to assess jaw muscle contractions of individuals with jaw muscle pain (pain in the jaw, temple, in the ear or in front of the ear). We are now looking for study participants, both cases with pain and pain-free controls to be used for comparison.

The study involves the wearing of a wireless sensor on the face (masseter muscle - on the bottom corner of your cheek). The sensor will record your muscle activity throughout the entire day. This recording occurs over two consecutive days. The patch is relatively small and compatible with all daily activities except swimming and showering.

To be eligible for this study you must:
- Be female
- Be between the ages of 18-50yr old
- Be able to attend 3 appointments, the first one lasting 40 min and subsequent 15 min, at the dental school (310 Great King Street, North Dunedin)

Cases with pain must have experience some jaw muscle pain within the last month. Pain-free controls must not have had any jaw pain or headache for the past month.

As a thank you for your participation, you will receive a $50 supermarket voucher, as well as a timely appointment with one of our colleagues for a consultation regarding your jaw pain (controls won't need this consultation).

If you are interested in participating in this study, please e-mail jawstudy.otago@gmail.com

I look forward to hearing from you,

Kind regards,

Divya

Divya Ramanan BDS
DClinDent Candidate (Orthodontics)
Jaw muscle overload as a possible cause of orofacial pain

Jaw muscle overuse is thought to lead to chronic jaw muscle pain. Approximately 1 in 10 of people suffer from jaw pain but this condition is not clearly understood. Very little is known about jaw muscle activity during the day.

This study aims to compare jaw muscle activity in patients with jaw pain to those without. We will record jaw muscle activity over two consecutive weekdays with the use of surface electromyography sensor (see picture) placed on the skin overlying the maseter jaw muscle. By participating in this study you will help us to better understand a condition that affects many people throughout life.

We require cases (people with jaw muscle pain) and controls (those without jaw pain) and you may be eligible for this study if you:

- Are female
- Are aged 18-50 years
- Are not currently undergoing orthodontic treatment
- Are not missing more than 5 permanent teeth
- Do not wear removable or fixed dentures
- Can attend 3 appointments at the School of Dentistry
- Are willing to wear the sensor for 2 consecutive days, while awake ~ 12 hours each day

You will receive a $50 New World voucher for participating.

Participation in this study requires you to attend three appointments:

Day 1) 45mins – clinical examination to determine eligibility for either group and to place the sensor

Day 2) 15mins – to place the sensor back on

Day 3) ~5mins – to return equipment and collect the voucher

To participate in this study, please email: jawstudy.otago@gmail.com
Primary Investigator: Mauro Farela, Discipline of Orthodontics, Ph 479 7068

This project has been reviewed and approved by the University of Otago Human Ethics Committee. Reference: H16/125
6.5 PARTICIPANT INFORMATION SHEETS

6.5.1 PATIENTS

Participant Information Sheet (Cases)

<table>
<thead>
<tr>
<th>Study title:</th>
<th>Jaw muscle overload as a possible cause of orofacial pain</th>
</tr>
</thead>
</table>
| Principal investigator: | Professor Mauro Farella  
Department of Oral Sciences  
Head of Discipline - Orthodontics |
| | Contact phone number: 03-4797068 |

Thank you for showing an interest in this research project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you and we thank you for considering our request.

Introduction

It has been suggested that jaw muscle overload may contribute to chronic painful orofacial conditions affecting ~10% of the population. There is little known about jaw muscle activity during the day and we hope to learn more with this study.

What is the aim of this research project?

The aim of this study is to compare jaw muscle activity in patients with facial pain and those without with the use of an electromyography (EMG) sensor placed on the skin surface above the masseter muscle. The small, wireless sensor (see picture below) can be worn by participants for several hours without interfering with routine tasks. This will give us valuable information on muscle activity during waking hours.

Who is funding this project?

This projection is funded by a grant from the New Zealand Dental Association Research Fund.

Who are we seeking to participate in the project?

We are initially seeking to recruit patients who have been referred to the TMD clinic within the Faculty of Dentistry. To qualify patients must:

- Aged between 18-50 years
- Be diagnosed at the consultation with jaw muscle pain
- Give written consent to participate in this study

Patient do not qualify for this study if they:

- Undergoing orthodontic treatment
- Are missing 5 of more teeth (excluding wisdom teeth)
- Wear fixed or removable full dentures
- Have a beard and are unwilling to shave it
- Have a significant allergy to plaster adhesive
- Have any rheumatological, neurological or psychiatric disorders (depression, anxiety, PTSD are not excluding conditions)

Participants in this study will need to present for three appointments, the first ~45mins, then ~15mins followed by a short appointment to return the equipment and collect the voucher.

If you participate, what will you be asked to do?

As a participant, you will be required to wear a small electromyography sensor for two consecutive days (for at least 12 hours while awake). The skin surface will be prepared with an exfoliating gel prior to placement of the patch. The EMG sensor is calibrated by asking you to bite firmly. Once calibrated, the device is ready to go. The device is not waterproof so it is advisable that you shower on the morning of your first and second appointments. The sensor will detect electric signals from the masseter muscle and transmit this information to a smartphone which you will need to keep on or near you for the duration of the study. You will be asked to register specific activities such as eating, and exercise. We will also place an accelerometer on your hip or wrist. This can be worn under clothes if you choose. This will help us better understand the data collected.

The sensor transmits the electric signals from the jaw muscle to a smartphone which will be provided. You will need to keep this phone on or near you for the duration of the recordings. You will be asked to register specific activities such as eating, and exercise and also will be asked to wear an accelerometer which looks like a watch on your wrist. This will help us better understand the data collected. Upon completion of the recording and return of equipment, you will receive a $50 supermarket voucher to reimburse you for travel costs and your time. Please be aware that participation in this study is voluntary and you can refuse to participate. Participants can withdraw from the study until data collection starts. After this time, data collected is anonymised and added to other data collected in the study. Please be aware that participation in this study is voluntary and refusal to participate will not in any way effect your care. Participants can withdraw from the study until data collection starts. After this time, data collected is anonymised and added to other data collected in the study.

Is there any risk of discomfort or harm from participation?

The exfoliating gel used can be slightly irritating to those with sensitive skin types though is generally well tolerated. There may be mild discomfort of the skin immediately after preparation but this be short-lasting.
What specimens, data or information will be collected, and how will they be used?

Following the three days of data collection period, the information will be downloaded from the smartphone in the form of a digital spreadsheet. The data collected will indicate the size, frequency and duration of muscle contractions throughout the recording period. This data will be analysed to see if patients with TMD have different jaw muscle activity than pain-free patients. This data will be anonymised and stored on a secure computer. Only the investigators in this study will have access to this information. This data will be held by the investigators following the completion of the study and used in the development of other related studies.

Should you be interested in learning more about your own muscle activity, this information can be provided on request in the form of a series of graphs and brief written description.

The results from this study will be part of a Doctor of Clinical Dentistry (Orthodontics) thesis.

What about anonymity and confidentiality?

As mentioned above, the anonymous data collected is stored in a secure computer accessible only by the investigators of the study.

Following completion of the study in mid-late 2018, a summary of results from the study will be mailed to the participants.

If you agree to participate, can you withdraw later?

You may withdraw from participation in the project at any time and without any disadvantage to yourself.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

Professor Mauro Farella (Head of Discipline – Orthodontics, Primary Investigator); Ph 03-4797068 or

Divya Ramanan (Postgraduate Student and Student Investigator), at the same phone number.

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Participant Information Sheet (Controls)

<table>
<thead>
<tr>
<th>Study title:</th>
<th>Jaw muscle overload as a possible cause of orofacial pain</th>
</tr>
</thead>
</table>
| Principal investigator: | Professor Mauro Farella  
Department of Oral Sciences  
Head of Discipline - Orthodontics |
| | Contact phone number:  
03-4797068 |

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you and we thank you for considering our request.

**Introduction**

It has been suggested that jaw muscle overload can lead to chronic painful orofacial conditions affecting ~10% of the population. There is little known about jaw muscle activity during the day and we hope to learn more with this study.

**What is the aim of this research project?**

The aim of this study is to compare jaw muscle activity in patients with facial pain and those without, with the use of an electromyography sensor placed on the skin surface above the muscle. The small, wireless sensor (see picture below) can be worn by participants for several hours without interfering with routine tasks. This will give us valuable information on muscle activity during awake hours.

**Who is funding this project?**

This projection is funded by a grant from the New Zealand Dental Association Research Fund.

**Who are we seeking to participate in the project?**

We are seeking to recruit participants for our control group. To qualify patients must:

- Be aged between 18-50 years
- Not have any facial and/or headache over the past 3 months
- Give written consent to participate in this study

Patient do not qualify for this study if they:

- Are currently undergoing orthodontic treatment
- Are missing 5 or more teeth (excluding wisdom teeth)
- Wear fixed or removable full dentures
- Have a beard and are unwilling to shave it
- Have a significant allergy to plaster adhesive
- Have any rheumatological, neurological or psychiatric disorders
  (depression, anxiety, PTSD are not excluding conditions)

Participants in this study will need to present for three appointments, the first ~45mins, the second about ~15mins followed by a very short appointment to return the equipment and collect your voucher.

**If you participate, what will you be asked to do?**

As a participant, you will be required to wear a wireless electromyography sensor for two consecutive days (you can remove it at night time). The skin surface will be prepared with an exfoliating gel prior to placement of the patch. A brief exam will assess the size, position and orientation of the masseter jaw muscle. The EMG sensor is calibrated by asking you to bite with maximum force. Once calibrated, the device is ready to go. The device will record your muscle activity throughout the day. You can remove it at night before you sleep. In the morning, you will return for the second appointment where the patch will be placed again. Again, you can take it off when you sleep. You will then return on the third day to return the equipment and to collect your voucher. The device is not waterproof so we advise you take a shower on the morning before the first and second appointment.

The sensor transmits the electric signals from the jaw muscle to a smartphone which will be provided. You will need to keep this phone on or near you for the duration of the recordings. You will be asked to register specific activities such as eating, and exercise and also will be asked to wear an accelerometer which looks like a watch on your wrist. This will help us better understand the data collected.

Upon completion of the recording and return of equipment, you will receive a $50 supermarket voucher to reimburse you for travel costs and your time. Please be aware that participation in this study is voluntary and you can refuse to participate. Participants can withdraw from the study until data collection starts. After this time, data collected is anonymised and added to other data collected in the study.

**Is there any risk of discomfort or harm from participation?**

The exfoliating gel used can be slightly irritating to those with sensitive skin types, though it is generally well tolerated. There may be mild discomfort of the skin immediately after preparation but this be short-lasting.
What specimens, data or information will be collected, and how will they be used?

Following the three days of data collection period, the information will be downloaded from the smartphone in the form of a digital spreadsheet. The data collected will indicate the size, frequency and duration of muscle contractions throughout the recording period. This data will be analysed to see if patients with TMD have different jaw muscle activity than pain-free patients. This data will be anonymised and stored on a secure computer. Only the investigators in this study will have access to this information. This data will be held by the investigators following the completion of the study and used in the development of other related studies.

Should you be interested in learning more about your own muscle activity, this information can be provided on request in the form of a series of graphs and brief written description.

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Any questions?

If you have any questions now or in the future, please feel free to contact either:

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Divya Ramanan (Postgraduate Student and Student Investigator), at the same phone number.

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
PARTICIPANT CONSENT FORMS

Jaw muscle overload as a possible cause of orofacial pain.

Principal Investigator: Professor Mauro Farella (mauro.farella@otago.ac.nz; 03-4797068)

CONSENT FORM FOR PARTICIPANTS
Following signature and return to the research team this form will be stored in a secure place for ten years.

Name of participant:..........................................................

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. I have had sufficient time to talk with other people of my choice about participating in the study.
3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project prior to commencing participation without disadvantage.
6. I know that as a participant I will be required to complete a number of questionnaires, and be able to attend three appointments on consecutive days. I understand that I will need to wear a surface EMG sensor. This will be protected by a waterproof dressing but I understand I must take care to minimise risk of damage to the sensor and other equipment provided for the duration of my participation in the study.
7. I know that the questionnaire will explore the nature of my facial pain condition to ascertain classification, severity, chronicity; psychological factors such as stress, anxiety,
quality of sleep; oral habits such as awareness of clenching grinding; demographic information. If the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s), and/or may withdraw from the project without disadvantage of any kind.

8. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.

9. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for at least ten years.

10. I understand that the results of the project may be published and be available in the University of Otago Library, but I agree that any personal identifying information will remain confidential between myself and the researchers during the study, and will not appear in any spoken or written report of the study.

11. I know that there is no remuneration offered for this study, other than a $50 supermarket voucher to compensate for travel costs.

Signature of participant: 
Date: 

Name of person taking consent: 
Date: 


6.7 PARTICIPANT QUESTIONNAIRES

6.7.1 DEMOGRAPHICS QUESTIONNAIRE

Section 1 - Demographic Information

*Required

Email address *
Your email address

What is your gender? *
Choose

What is your age, in years? *
Your answer

What is your current marital status?
- Married
- Living with partner
- Separated or divorced
- Single
- Other:

What is your ethnicity?
- New Zealand European
- Maori
- Chinese
- Indian
- Other:

What is your current occupation? (e.g. Student)
Your answer
6.7.2 DC-TMD SYMPTOM QUESTIONNAIRE

Diagnostic Criteria for Temporomandibular Disorders
Symptom Questionnaire

Patient name __________________________ Date __________________

PAIN

1. Have you ever had pain in your jaw, temple, in the ear, or in front of the ear on either side? □ No □ Yes
   If you answered NO, then skip to Question 5.

2. How many years or months ago did your pain in the jaw, temple, in the ear, or in front of the ear first begin? _______ years _______ months

3. In the last 30 days, which of the following best describes any pain in your jaw, temple, in the ear, or in front of the ear on either side?
   □ No pain
   □ Pain comes and goes
   □ Pain is always present
   Select ONE response.
   If you answered NO to Question 3, then skip to Question 5.

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

   A. Chewing hard or tough food □ No □ Yes
   B. Opening your mouth, or moving your jaw forward or to the side □ Yes □ No
   C. Jaw habits such as holding teeth together, clenching/grounding teeth, or chewing gum □ Yes □ No
   D. Other jaw activities such as talking, kissing, or yawning □ Yes □ No

HEADACHE

5. In the last 30 days, have you had any headaches that included the temple areas of your head? □ No □ Yes
   If you answered NO to Question 5, then skip to Question 8.

6. How many years or months ago did your temple headache first begin? _______ years _______ months

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

   A. Chewing hard or tough food □ Yes □ No
   B. Opening your mouth, or moving your jaw forward or to the side □ Yes □ No
   C. Jaw habits such as holding teeth together, clenching/grounding, or chewing gum □ Yes □ No
   D. Other jaw activities such as talking, kissing, or yawning □ Yes □ No
### JAW JOINT NOISES

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>R</th>
<th>L</th>
<th>DNK</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>In the last 30 days, have you had any jaw joint noise(s) when you moved or used your jaw?</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### CLOSED LOCKING OF THE JAW

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>R</th>
<th>L</th>
<th>DNK</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Have you ever had your jaw lock or catch, even for a moment, so that it would not open ALL THE WAY?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>If you answered NO to Question 9 then skip to Question 13.</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Was your jaw lock or catch severe enough to limit your jaw opening and interfere with your ability to eat?</td>
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</tr>
<tr>
<td>11</td>
<td>In the last 30 days, did your jaw lock so you could not open ALL THE WAY, even for a moment, and then unlock so you could open ALL THE WAY?</td>
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<tr>
<td></td>
<td><strong>If you answered NO to Question 11 then skip to Question 13.</strong></td>
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<td></td>
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</tr>
<tr>
<td>12</td>
<td>Is your jaw currently locked or limited so that your jaw will not open ALL THE WAY?</td>
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</tr>
</tbody>
</table>

### OPEN LOCKING OF THE JAW

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>R</th>
<th>L</th>
<th>DNK</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>In the last 30 days, when you opened your mouth wide, did your jaw lock or catch even for a moment such that you could not close it from this wide open position?</td>
<td></td>
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<td></td>
<td><strong>If you answered NO to Question 13 then you are finished.</strong></td>
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<tr>
<td>14</td>
<td>In the last 30 days, when your jaw locked or caught wide open, did you have to do something to get it to close including resting, moving, pushing, or maneuvering it?</td>
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</tbody>
</table>
GRADED CHRONIC PAIN SCALE

Graded Chronic Pain Scale Version 2.0

1. On how many days in the last 6 months have you had facial pain? ______ Days

2. How would you rate your facial pain RIGHT NOW? Use a scale from 0 to 10, where 0 is “no pain” and 10 is “pain as bad as could be”.

<table>
<thead>
<tr>
<th>No pain</th>
<th>Pain as bad as could be</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
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<tr>
<td>1</td>
<td>2</td>
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<td>2</td>
<td>3</td>
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<td>9</td>
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<tr>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

3. In the LAST 30 DAYS, how would you rate your WORST facial pain? Use the same scale, where 0 is “no pain” and 10 is “pain as bad as could be”.

<table>
<thead>
<tr>
<th>No pain</th>
<th>Pain as bad as could be</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
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<td>1</td>
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<td>10</td>
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</tbody>
</table>

4. In the LAST 30 DAYS, ON AVERAGE, how would you rate your facial pain? Use the same scale, where 0 is “no pain” and 10 is “pain as bad as could be”. [That is, your usual pain at times you were in pain.]

<table>
<thead>
<tr>
<th>No pain</th>
<th>Pain as bad as could be</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
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<td>1</td>
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<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

5. In the LAST 30 DAYS, how many days did your facial pain keep you from doing your USUAL ACTIVITIES like work, school, or housework? (every day = 30 days) ______ Days

6. In the LAST 30 DAYS, how much has facial pain interfered with your DAILY ACTIVITIES? Use a 0-10 scale, where 0 is “no interference: and 10 is “unable to carry on any activities”.

<table>
<thead>
<tr>
<th>No interference</th>
<th>Unable to carry on any activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

7. In the LAST 30 DAYS, how much has facial pain interfered with your RECREATIONAL, SOCIAL AND FAMILY ACTIVITIES? Use the same scale, where 0 is “no interference: and 10 is “unable to carry on any activities”.

<table>
<thead>
<tr>
<th>No interference</th>
<th>Unable to carry on any activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>

8. In the LAST 30 DAYS, how much has facial pain interfered with your ABILITY TO WORK, including housework? Use the same scale, where 0 is “no interference: and 10 is “unable to carry on any activities”.

<table>
<thead>
<tr>
<th>No interference</th>
<th>Unable to carry on any activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>9</td>
<td>10</td>
</tr>
</tbody>
</table>
### 6.7.4 ORAL BEHAVIOUR CHECKLIST

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 [x] response for each item and do not skip any items.

<table>
<thead>
<tr>
<th>Activities During Sleep</th>
<th>None of the time</th>
<th>&lt; 1 Night/Month</th>
<th>1-3 Nights/Week</th>
<th>1-3 Nights/Week</th>
<th>4-7 Nights/Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Clench or grind teeth when asleep, based on any information you may have</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>2 Sleep in a position that puts pressure on the jaw (for example, on stomach, on the side)</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

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

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# 6.8 CLINICAL EXAMINATION FORM

## DC/TMD Examination Form

**Patient**

**Examiner**

### Date filled out (mm-dd-yyyy)

#### 1a. Location of Pain: Last 30 days (Select all that apply)

<table>
<thead>
<tr>
<th>RIGHT PAIN</th>
<th>LEFT PAIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ None</td>
<td>○ None</td>
</tr>
<tr>
<td>○ Temporal</td>
<td>○ Temporal</td>
</tr>
<tr>
<td>○ Other m. muscles</td>
<td>○ Other m. muscles</td>
</tr>
<tr>
<td>○ Non-mast structures</td>
<td>○ Non-mast structures</td>
</tr>
<tr>
<td>○ Masseter</td>
<td>○ Masseter</td>
</tr>
<tr>
<td>○ TMJ</td>
<td>○ TMJ</td>
</tr>
</tbody>
</table>

### 1b. Location of Headache: Last 30 days (Select all that apply)

| ○ None | ○ Temporal | ○ Other |
|○ None | ○ Temporal | ○ Other |

### 2. Incisal Relationships

<table>
<thead>
<tr>
<th>Horizontal Incisal Overjet</th>
<th>Vertical Incisal Overlap</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ If negative mm</td>
<td>○ If negative mm</td>
</tr>
</tbody>
</table>

### 3. Opening Pattern (Supplemental; Select all that apply)

| ○ Straight | ○ Corrected deviation |
|○ Straight | ○ Corrected deviation |

### 4. Opening Movements

#### A. Pain Free Opening

<table>
<thead>
<tr>
<th>mm</th>
</tr>
</thead>
</table>

#### B. Maximum Unassisted Opening

<table>
<thead>
<tr>
<th>mm</th>
</tr>
</thead>
</table>

#### C. Maximum Assisted Opening

<table>
<thead>
<tr>
<th>mm</th>
</tr>
</thead>
</table>

#### D. Terminated? ○ ○

### 5. Lateral and Protrusive Movements

#### A. Right Lateral

<table>
<thead>
<tr>
<th>mm</th>
</tr>
</thead>
</table>

#### B. Left Lateral

<table>
<thead>
<tr>
<th>mm</th>
</tr>
</thead>
</table>

#### C. Protrusion

<table>
<thead>
<tr>
<th>mm</th>
<th>○ If negative</th>
</tr>
</thead>
</table>

### Uncorrected Deviation

<table>
<thead>
<tr>
<th>○ Right</th>
<th>○ Left</th>
</tr>
</thead>
</table>

---

99
6. TMJ Noises During Open & Close Movements

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Right TMJ</th>
<th>Left TMJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>Close</td>
<td>Patient</td>
</tr>
<tr>
<td>Click</td>
<td>Crepitus</td>
<td></td>
</tr>
</tbody>
</table>

7. TMJ Noises During Lateral & Protrusive Movements

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Right TMJ</th>
<th>Left TMJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>Close</td>
<td>Patient</td>
</tr>
<tr>
<td>Click</td>
<td>Crepitus</td>
<td></td>
</tr>
</tbody>
</table>

8. Joint Locking

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Right TMJ</th>
<th>Left TMJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>While Opening</td>
<td>Patient</td>
<td>Pain</td>
</tr>
<tr>
<td>Wide Open Position</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Muscle & TMJ Pain with Palpation

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Right Side</th>
<th>Left Side</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1 kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporals (posterior)</td>
<td>Pain</td>
<td>Familiar Pain</td>
</tr>
<tr>
<td>Temporals (middle)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporals (anterior)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Masseter (origin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Masseter (body)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Masseter (insertion)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMJ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral pole (0.5 kg)</td>
<td>Pain</td>
<td>Familiar Pain</td>
</tr>
<tr>
<td>Around lateral pole (1 kg)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Supplemental Muscle Pain with Palpation

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Right Side</th>
<th>Left Side</th>
</tr>
</thead>
<tbody>
<tr>
<td>(0.5 kg)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior mandibular region</td>
<td>Pain</td>
<td>Familiar Pain</td>
</tr>
<tr>
<td>Submandibular region</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral pterygoid area</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporals tendon</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Diagnoses

<table>
<thead>
<tr>
<th>Pain Disorders</th>
<th>Right TMJ Disorders</th>
<th>Left TMJ Disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Disc displacement (select one)</td>
<td>None</td>
</tr>
<tr>
<td>Myalgia</td>
<td>...with reduction</td>
<td>Disc displacement (select one)</td>
</tr>
<tr>
<td>Myofascial pain with referral</td>
<td>...with reduction, with intermittent locking</td>
<td>...with reduction, with intermittent locking</td>
</tr>
<tr>
<td>Right Arthralgia</td>
<td>...without reduction, with limited opening</td>
<td>...without reduction, with limited opening</td>
</tr>
<tr>
<td>Left Arthralgia</td>
<td>...without reduction, without limited opening</td>
<td>Degenerative joint disease</td>
</tr>
<tr>
<td>Headache attributed to TMD</td>
<td>Subluxation</td>
<td>Degenerative joint disease</td>
</tr>
</tbody>
</table>

12. Comments

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6.9 DIAGNOSTIC DECISION TREE

Pain-Related TMD and Headache

HISTORY

Start at each blue-outline box

Regional pain [SQ3] AND Pain modified by jaw movement, function, or parafunction [SQ4]

Examiner confirmation of pain location [E1a] [Yes = Mast muscles] [Yes = TMJ]

(1) Familiar pain from: jaw opening [muscle, E4] OR masticatory muscle palpation (2 secs) [muscle, E9]; AND (2) Confirm location [E1a]

Investigate other pain diagnoses

Investigate other pain diagnoses


Examine confirmation of headache in temporalis area [E1b]

Familiar headache from: jaw opening OR excursive movement, OR temporalis muscle palpation [temporalis, from E4, E5, OR E9]

Headache not better accounted for by another headache diagnosis [Symptom review]

Myalgia

Myofascial pain

Local myalgia

Myofascial pain with referral

Arthralgia

Notes: 2 secs palpation is sufficient for myalgia; 5-secs is required for subtypes

Diagnosis of Myalgia or Arthralgia

Headache of any type in temporal region [SQ5] AND Headache modified by jaw movement, function, or parafunction [SQ7]

Version 5/20/2014 (text revision)
Diagnostic Criteria for Temporomandibular Disorders (DC/TMD): Diagnostic Decision Tree

**Intra-articular Joint Disorders**

- **Current TMJ noises by history [SQ8]**
- **Noise detected by patient during examination [E6 OR E7]**

  - **Opening & closing click [E6]**
  - **[Opening or closing click [E6] AND Excursive or protrusive click [E7]]**

  - **Current intermittent locking with limited opening [SQ11=yes & SQ12=no]**

  - **MAO ≥ 40mm (including overbite) [E4C]**

  - **Prior jaw locking in closed position [SQ9] AND Interference in mastication [SQ10]**

- **Degenerative Joint Disorder**

  - **Current TMJ noises by history [SQ8]**
  - **Noise detected by patient during examination [E6 OR E7]**

  - **Crepitus detected by examiner [E6 OR E7]**

  - **Degenerative joint disease**

- **Investigate other diagnoses**

**Imaging Clinical Diagnosis**

- **Disc displacement with reduction**
- **Disc displacement without reduction, with limited opening**
- **Disc displacement with reduction, with intermittent locking**
- **Disc displacement without reduction without limited opening**

- **Confirm by MRI when indicated**

**Version 5/20/2014 (text revision)**