Oral parafunctional behaviours: acute versus chronic painful Temporomandibular disorders

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DEDICATION

This work is dedicated to my parents Mr. Naresh Kumar, Mrs. Madhu Bala and my brother Sachin Rana for their endless love, encouragement and support throughout my Master's program.

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LIST OF ABBREVIATIONS

TMJ	Temporomandibular Joint
TMD	Temporomandibular Disorders
PTMD	Painful Temporomandibular Disorders
ACTION	Acute Chronic Transition
RDC/TMD	Research Diagnostic Criteria for Temporomandibular Disorders
DC/TMD	Diagnostic Criteria for Temporomandibular Disorders
M and F	Males and Females
B and G	Boys and Girls
AV	Ana Velly
MG	Mervyn Gornitsky
ZD	Zovinar Der Khatchadourian
FS	Firoozeh Samim
JGH	Jewish General Hospital
MGH	Montreal General Hospital
OD	Oral Diagnosis
GCPS	Graded Chronic Pain Scale
CPI	Characteristic Pain Intensity
IASP	International Association for the Study of Pain
PHQ-8	Patients Health Questionnaire-8
GAD-7	Generalized Anxiety Disorders-7
OR	Odds Ratio
CI	Confidence Interval

HR	Hazard ratio
OBC	Oral behaviour checklist
GAD-7	Generalised Anxiety disorder
PSS	Perceived Stress Scale
NIH	National Institute of Health
MFP	Masticatory myofascial pain

ABSTRACT

Aim. This case-control study was designed to investigate the association of oral parafunctional behaviours in chronic painful temporomandibular disorders (PTMD) relative to the acute PTMD.

Methods. Participants with PTMD were recruited from four different sites: (i) dental clinic of the Jewish General Hospital; (JGH); (ii) Oral Diagnosis (OD) clinic of McGill University, Faculty of Dentistry; (iii) Montreal General Hospital (MGH), Montreal, Quebec, Canada; and (iv) the Dental Specialty Group, in Ottawa, Ontario, Canada. Pain classification based on the International Association of the Study of Pain (IASP) was used to classify PTMD participants in acute (< 3 months) or chronic (≥ 3 months) groups. The validated Oral Behaviour Checklist, General Anxiety Disorder (GAD-7) and Patient Health Questionnaire (PHQ-9) were used to assess the oral parafunctional behaviours, anxiety and depression, respectively. The association between oral parafunctional behaviours and PTMD was assessed using unconditional logistic regression analysis.

Results. A total of 284 participants accepted to participate in this study; 48 (17%) were included in the acute PTMD group and 236 (83.1%) in the chronic group. The majority of both groups were females ($P = 0.23$). Results from the crude logistic analysis showed that participants with chronic PTMD were more likely to present high odds of OBC1 (OR = 2.43, $P = 0.04$) compared to acute PTMD participants. A strong association was found with OBC2 score (OR = 4.12, P = 0.0004). These associations remained in the multivariable analyses when adjusted for potential confounders; OBC1 (OR = 3.07, $P = 0.01$), and OBC2 (OR = 4.71, $P = 0.0005$). The sensitivity analysis also showed that these results were not biased by pain intensity or patients' recruitment location OBC1 (OR = 3.07, $P = 0.01$), and OBC2 (OR = 4.71, $P = 0.0005$).

Conclusion. Relative to acute PTMD, chronic PTMD is associated with oral parafunctional behaviours. This association was not confounded by demographic characteristics, psychological symptoms, pain severity or patients' recruitment location. This result suggests that these behaviours contribute to the transition from acute to chronic PTMD.

ABSTRAIT

Objectif. Cette étude cas-témoins a été conçue pour étudier le lien entre les comportements parafonctionnels oraux dans les troubles temporo-mandibulaires douloureux chroniques (DPMT) et les DMP aiguës.

Méthodes Les participants atteints de MPT ont été recrutés dans quatre sites différents: (i) la clinique dentaire de l'Hôpital général juif; (HGJ); (ii) la clinique de diagnostic oral (OD) de la faculté de médecine dentaire de l'Université McGill; (iii) l'hôpital général de Montréal (Hôpital général de Montréal), Montréal, Québec, Canada; et (iv) le groupe de spécialité dentaire, à Ottawa, Ontario, Canada. Une classification de la douleur basée sur l'Association internationale pour l'étude de la douleur (IASP) a été utilisée pour classer les participants PTMD dans les groupes aigus (<3 mois) ou chroniques (≥ 3 mois). La liste de contrôle validée sur le comportement oral, le trouble d'anxiété générale (GAD-7) et le questionnaire sur la santé du patient (PHQ-9) ont été utilisés pour évaluer les comportements parafonctionnels oraux, l'anxiété et la dépression. L'association entre les comportements parafonctionnels oraux et la PTMD a été évaluée à l'aide d'une analyse de régression logistique inconditionnelle.

Résultats. Au total, 284 participants ont accepté de participer à cette étude. 48 (17%) ont été inclus dans le groupe PTMD aigu et 236 (83.1%) dans le groupe chronique. La majorité des deux groupes étaient des femmes (p = 0.23). Les résultats de l'analyse logistique brute ont montré que les participants atteints de PTMD chronique étaient plus susceptibles de présenter des probabilités élevées de CBO1 (OR = 2.43, P = 0.04) par rapport aux participants de PTMD aigus. Une forte association a été trouvée avec le score OBC2 (OR = 4.12, P = 0.0004). Ces associations sont restées dans les analyses multivariées après ajustement pour les facteurs de confusion potentiels; OBC1 (OR = 3.07, P = 0.01) et OBC2 (OR = 4.71, P = 0.0005). L'analyse de sensibilité a également

montré que l'intensité de la douleur ou le lieu de recrutement des patients (OBC1 (OR = 3,07, P = 0,01) et OBC2 (OR = 4,71, P = 0,0005) n'étaient pas biaisés dans ces résultats.

Conclusion. Par rapport à la DPM aiguë, la DMPT chronique est associée à des comportements para fonctionnels oraux. Cette association n'est pas confondue avec les caractéristiques démographiques, les symptômes psychologiques, la gravité de la douleur ou le lieu de recrutement des patients. Ce résultat suggère que ces comportements contribuent à la transition de la PTMD aiguë à chronique.

PREFACE

This thesis has followed a manuscript based thesis style. The manuscript in this thesis discusses the association of oral parafunctional behaviours among chronic PTMD relative to the acute PTMD participants. Starting with a brief introduction of the topic in first chapter, the second chapter provides review of literature in the field of temporomandibular disorders, evaluation of temporomandibular disorder and commonly associated risk factors with PTMD. The third chapter will explain the study objectives and hypotheses based on prior knowledge of the literature. Chapter five will further discuss the methodology of the study, followed by the manuscript in chapter five. Furthermore, chapter six represents the comprehensive discussion including some methodological considerations, strengths and limitations. Chapter seven presents concise conclusions of this work. The last two chapter, seven and eight will discuss the clinical relevance and the knowledge translation respectively.

CONTRIBUTION OF THE AUTHORS

Manuscript:

Oral parafunctional behaviours: acute versus chronic painful Temporomandibular disorders.

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Lamin Juwara, MSc. Ph.D. candidate helped with the statistical analysis and writing of the manuscript.

CHAPTER 1. INTRODUCTION

Temporomandibular disorders (TMDs) is a collective term used to describe musculoskeletal conditions characterized by pain in the muscles of mastication and temporomandibular joint or both (1). The common signs and symptoms include tenderness in the muscles upon palpation, pain with the range of motion or limitation of the jaw on opening followed by interference with vital functions such as eating, swallowing and speaking (2). Results from the telephone survey conducted among the general population of the province of Québec, Canada, shows that 30% of the population self-reported the frequent episodes of TMD jaw pain. The prevalence of cases reporting frequent episodes in the range of 'quite often' or 'very often' was estimated at 7% with more than 69% of the participants experiencing moderate to severe pain (3). Eighty-five percent of the cost of treating TMD is associated with the treatment of the patients who complain of persistent pain (4).

Many studies in the past have identified the potential risk factors that can contribute to the painful TMD; including psychological factors, (5-11) trauma, (9, 12-15) genetic, (16-18), comorbidities (9, 12, 19) and oral parafunctional behaviours associated with chronic PTMD (4, 9, 20-24). The common treatment of PTMD includes splint therapy, pharmacologic therapy, and behavioural management. Regardless of the treatment given to the patients, the majority of these patients will continue to suffer from PTMD (7). Thus, it is essential to prevent acute PTMD from becoming chronic PTMD, which is hard to manage relative to the acute PTMD.

Therefore, Dr. Ana Miriam Velly initiated Acute to Chronic TMD Transition (ACTION) project in 2015. The overall goal of this project is to identify the risk factors implicated in the transition from acute to chronic painful TMD. Our project is in agreement with the statement given by National Institutes of Health (NIH) "we do not fully understand how acute progresses to chronic

pain at any level, from molecular to behavioural" (25). The current study is the third part of the ACTION project, and this study aims to assess the association of oral parafunctional behaviours among chronic PTMD relative to the acute PTMD participants.

The following section provides an overview of the epidemiology of TMD, screening, diagnosis and potential risk factors that can contribute to PTMD.

CHAPTER 2. LITERATURE REVIEW

2.1 Epidemiology of Temporomandibular Disorders

2.1.1 Prevalence of painful temporomandibular disorders

"It is the proportion of the individuals in a population who have the disease at a specific instant and provides an estimate of the probability that an individual will be at a point in time" (26). The formula for calculating prevalence (P) is:

$$P = \frac{\text{number of existing cases of a disease}}{\text{Total population}} \text{ at a given point of time}$$

It is further classified into three different types. The first type is period prevalence that represents the number of cases that have the disease or the condition within a population at any point during a specified period (26). The second type is point prevalence defined as the status of the disease in a population at a specific point of time in their lives. Lifetime prevalence is a general term, which measures the cumulative frequency of an outcome at any time during the individual's past (26).

Table 1 summarizes the results of previous studies on the prevalence of painful TMD, including the eleven studies. Von Korff *et al.,* in 1988, assessed the period prevalence using a self-reported questionnaire and a telephone interview over six months. Patients were recruited from the Health Maintenance Organization, USA, and the total number of patients included were 1,016 participants (80.3%) with ages ranging from 25 to 44 years. Results suggested that the prevalence of facial pain at six months was 12%, and more females presented facial pain (15%) compared to males (8%). Females more commonly sought treatment for painful TMD (58.4%) than males (41.6%) (27).

A telephone survey was conducted including 897 French-speaking individuals from the province of Québec, Canada, to assess the prevalence of self-reported TMD jaw pain (participation rate of 64%). All the participants were above 18 years of age. TMD-related pain was self-reported by 30% of the population and prevalence among females was almost twice as high as that of males (9% vs. 5%) (3).

Another cross-sectional study was conducted in Iran, and eligible participants with ages ranging from 18 to 65 years were recruited from six healthcare bases in Mashhad to assess the prevalence of myofascial pain. Results showed that 151 women with the mean age of 31.05 years completed the entire questionnaire for the study (participation rate 95%). Prevalence of myofascial pain calculated was 9.93% using the RDC/TMD criteria to classify the myofascial pain (28).

The prevalence of TMD was assessed at three-month using self-reported instrument based on the U.S National Health Interview Survey (NHIS) from non-Hispanic whites and non-Hispanic blacks. Results showed that a total of 30, 978 people, 17, 498 females and 13, 480 males with the age of ≥18 years, were included in the study. The overall prevalence of TMD pain was 4.6 % and more specifically for women 6.3% and men 2.8%. In non-Hispanic white women up to age 50, the prevalence was approximately 7% to 8%, but it decreased after age 55 (29).

Furthermore, the prevalence of myofascial temporomandibular disorders was assessed among a community in the New York, USA and the study-estimated prevalence of myofascial subtype of TMD (M-TMD) at six-month periods. Out of 19,586 females, 2,000 participants were invited for the RDC/TMD examination, and 782 participants accepted and completed the clinical examination using RDC/TMD. Prevalence of the M-TMD was found to be 10.5% (clinical examination) and 10.1% (telephone survey) and was significantly higher among young women (30).

A telephone survey was conducted in an Italian population and 2,005 individuals ranging in age from 15 to 70 years were included in the study population. All the participants were asked about common TMD signs and symptoms such as difficulty with jaw pain, jaw movement and joint sounds using RDC/TMD. Results show that of the study population, 8.1% reported limitation of jaw movements, 5.1% reported jaw pain, 33.3% reported joint sounds and 36.2% of this population had painful TMD (31).

Another cross-sectional survey conducted by Karibe *et al.* (2015) assessed the association of TMD symptoms and other orofacial pain conditions including 1,415 subjects with the age group of 11 to 15 years. The questionnaire consisted of six questions out of which three questions were regarding TMD symptoms (i.e. jaw pain, TMJ sounds and limited jaw opening) during last three months, based on the RDC/TMD criteria. Results showed that TMD symptoms were reported by 12.9 % of the participants who were included in the study (32).

The prevalence of painful TMD was assessed among adolescents in Norway using a cross-sectional study design. The study population includes 562 participants recruited from four different dental clinics in Rogaland country, Norway. Participants who responded positively to the two screening questions then underwent the clinical examination to confirm the TMD diagnosis. Results noted that 7% of the individuals experienced painful TMD, and the majority were female; F: M; 3:1 (33).

A recent cross-sectional study shows that the prevalence of signs and symptoms of Temporomandibular disorders (TMD) in adolescence. Nine hundred and thirty-four adolescents with the age of 10-14 years were included. Prevalence of TMD symptoms was 34.9%, and the most frequently associated symptoms reported were headache and neck ache (20.9%) followed by joint sounds (18.5%) (35).

Table 1. Summary of Prevalence of painful TMD

Authors, year	Study design	Study population	Age (in years)	Sample size (n)	Prevalence	Condition	Assessment
Von Korff *et al.*, 1988	Survey	Patients at Health Maintenance Organization in Seattle,USA	≥ 18	1,016	12%	Facial pain	Self-reported questionnaire/ telephone interview
Goulet *et al.*, 1995	Cross-sectional	Province of Québec	≥ 18	897	5%	TMD pain	Telephone survey/ self-reported questionnaire
Scmitter *et al.*, 2007	Cross-sectional	Six health care bases in Mashhad	18-65	171	9.93%	Myofascial pain	Self-reported questionnaire/ clinical examination RDC/TMD
Isong *et al.*, 2008	Survey	General population, USA	≥ 18	30,987	4.6%	TMD pain	Telephone survey
Janal *et al.*, 2008	Survey	Households, USA	18-75	782	10.5%	Myofascial pain	Telephone survey/ examination RDC/TMD
Slade *et al.*, 2011	Cohort	Four different clinics, USA	18-44	3,263	10.1%	TMD symptoms	Telephone/interview/ clinical examination/RDC/TMD
Mobilio *et al.*, 2011	Survey	Households in Municipality of Ferrara, Italy	15-70	2,005	5.1%	Painful TMD	Telephone survey
Karibe *et al.*, 2015	Cross-sectional	Randomly selected Japanese children and adolescents	11-15	1415	12.9%	TMD symptoms	RDC/TMD symptom questionnaire
Ostensjo *et al.*, 2017	Cross-sectional	Four dental clinics in Rogaland County, Norway	13-19	560	7.2%	Painful TMD	Self-reported questionnaire
Gillborg *et al.*, 2017	Cross-sectional	Randomly selected population of southern Sweden	20-89	6300	11%	TMD pain	Self-reported questionnaire
Bertoli *et al.*, 2018	Cross-sectional	Brazilian adolescents	10-14	326	10.3%	Myofascial pain	Self-reported questionnaire

2.1.2 Incidence of Temporomandibular Disorders

"It is the number of new events or cases of the disease that develops in a population at risk during a specific time interval" (26). There are two types of incidence: cumulative incidence and incidence rate or density

Cumulative incidence (CI) is the proportion of people who become diseased during a defined period and is calculated as:

$$CI = \frac{\text{number of new cases of a disease during a given period}}{\text{Total population at risk}}$$

"Incidence rate (IR) is the more precise estimate of the impact of exposure in a population that utilizes all available information" (26). It is considered as a measure of the instantaneous rate of development of disease in the population and is defined as:

$$IR = \frac{\text{number of new cases of a disease during a given period}}{\text{Total person-time of observation}}$$

Table 2 summarizes results of longitudinal studies that assessed TMD incidence. Von Korff *et al.* conducted a longitudinal study with the sample size of 1,016 individuals who were interviewed from a large health maintenance organization, Group Health Cooperative of Puget Sound (GHC). Eight hundred and three participants remained eligible for the follow-ups when re-interviewed after three years after the initial interview. Results showed that females (7.7%) experienced higher onset rates of TMD pain compared to males (4.8%), and the reported cumulative incidence rate of painful TMD was 6.5% (6).

Table 2. Incidence of painful TMD							
Authors, Year	**Study Design**	**Study population**	**Age**	**Sample Size**	**Dropout rate**	**Incidence (%)**	**Assessment**
Von Korff *et al.*,1993	Cohort	No TMD-related symptom	18+	1,016	15%	Cumulative (6.5)	Questionnaire
Kamisaka *et al.*, 2000	Cohort	No TMD-related symptom	20+	367	40%	Cumulative (6.1)	Questionnaire
LeResche *et al.*, 2007	Cohort	No TMD-related symptoms	11-17	1996	51%	Cumulative (6.8)	Questionnaire/telephone interview/clinical examination
Marklund *et al.*, 2007	Cohort	No TMD-related symptoms	18 - 48	371	17%	Annual (12)	Questionnaire/clinical examination
Nilsson *et al.*, 2007	Cohort	Painful TMD	12-19	2,255	10%	Annual (2.9)	Clinical examination/ questionnaire
Slade et al., 2013	Cohort	Painful TMD	18-44	2,737	16%	Annual (3.9)	Telephone interview/ clinical examination (RDC/TMD)

Another four-year longitudinal study was conducted by Kamisaka *et al.* with a sample size of 672 randomly selected citizens of Okayama City who were requested to answer a self-administered questionnaire four years after completing the initial one. TMD symptoms assessed and six symptoms compared for clenching habits, history of extrinsic trauma, sleep disturbance and family history of TMD. The incidence of TMD symptoms ranges from 6.1% (TMD pain) to 12.9% (TMJ noises). Females had a 2.81:1 increased risk of reporting the TMD pain relative to the men ($P< 0.01$) (36).

A one-year prospective cohort study conducted among university students to investigate the incidence and prevalence of temporomandibular disorders. The study population consisted of 371 dental students examined at the start of education and out of which after one-year 308 were re-examined. A questionnaire and clinical examination forms used to assess the TMD signs and symptoms. Results show that a 1-year incidence of TMD signs or symptoms was 12% with no statistically significant difference between men and women (37).

The three-year longitudinal study was carried out by Nilsson *et al.* (2007) that included an adolescent age group of 12 to19 years from all public dental service clinics in Ostergotland, Sweden. Individuals who visited the clinics for annual examinations were eligible for the study. Self-reported methods used to assess TMD-related pain and dysfunction. Overall, the annual incidence of TMD pain among 2,255 participating adolescents was 2.9%. Incidence among girls was significantly higher (4.5%) than in boys (1.3%) (38).

A large prospective cohort study conducted to find the risk of first-onset of TMD in the USA. Recruitment sites included participants from four different sites from the year 2006 to 2008 and followed up for 5.2 years to find those who developed the temporomandibular disorder (TMD). Eligible patients who did not have painful TMD with ages ranging from 18 to 44 years

recruited. After a 3-month interval, participants asked to complete a self-reported screening questionnaire to assess the TMD signs/symptoms. Those reporting positive signs/symptoms were invited for clinical examination and diagnoses were confirmed using the RDC/TMD clinical examination form. Out of 2,737 initially, TMD-free people, when followed over a period (median = 2.8 years/person), 260 people developed first-onset TMD with the annual incidence rate of 3.5% per annum (12).

2.2 Temporomandibular Disorder Evaluation

2.2.1 Temporomandibular pain screening instrument

Table 3 shows the long version of TMD pain screening instrument purposed by Gonzalez (39).

Table 3. Temporomandibular pain disorder screening instrument.

1. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?
   a. No pain b. From very brief to more than a week, but it does stop.
   c. Continuous

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

3. In the last 30 days, did the following activities change any pain (that makes it better or makes it worse) in your jaw or temple area on either side?
   A. Chewing hard or tough food
      a. No b. Yes
   B. Opening your mouth or moving your jaw forward to the side
      a. No b. Yes
   C. Jaw habits such as holding teeth together, clenching, grinding or chewing gum
      a. No b. Yes
   D. Other jaw activities such as talking, kissing or yawning
      a. No b. Yes

Note: Items 1 through 3A constitute the short version of the screening instrument, and Items 1 through 3D constitute the long version. An “a” response 0 points, a “b” response 1 point and a “c” response 2 points.

The most recent TMD pain-screening instrument developed by Gonzalez *et al*. consists of short (three-item) and long (six-item) versions and exhibited excellent validity in identification of participants with pain-related TMD (sensitivity; 99%) and healthy control participants (specificity; 97%) (39).

2.2.2 Temporomandibular Disorder Diagnosis

Many diagnostic instruments that include Helkimo's Index, Symptom Severity Index (SSI), Craniomandibular Index (CMI), and Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), and Diagnostic Criteria (DC/TMD), have been established for the diagnosis of TMD. The most recent and more commonly used instruments are RDC/TMD and DC/TMD.

2.2.2.1 Research Diagnostic Criteria (RDC/TMD)

The Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD), published in 1992, was the first step toward diagnosis, and the author advised that further research was needed to make it more valid and to improve the clinical utility. RDC/TMD divided into two parts; Axis I includes physical assessment and diagnostic protocol; and Axis II includes evaluation of psychological status, pain-related disability and parafunctional behaviour in TMD (40).

Axis I is further sub-grouped into three different categories: muscle disorder, disc displacement and joint disease. The first TMD subgroup, muscle disorder, has two subcategories of its own. Group I a; myofascial pain, includes the pain in the muscles of mastication or on palpation at least in three places, one of which aligns with the reported pain. Similarly, group I.; myofascial pain with limited mouth opening refers to pain in the jaw area and muscles of mastication that result in jaw limitation functions. The group I b; Disc displacement categorizes

by three types of abnormal mandibular function. Type I is disc displacement with reduction with no pain, presence of the clicking sounds on opening or closing. Type II is disc displacement without reduction with a limited opening with no pain up to ≤ 35mm during the unassisted opening and no clicking. Last is type III, disc displacement without reduction without limited opening, with pain beyond the mouth opening of 35mm or more during the unassisted opening. The third group is joint diseases that are further divided into three types; a) arthralgia b) osteoarthritis c) osteoarthrosis (41-43). Axis II also has four subgroups: physiological assessment, pain-related disability, TMD pain, and related parafunctional behaviours. RDC/TMD Axis I diagnostic algorithms was compared to the standard diagnosis, and the validation project shows that Axis I has excellent diagnostic accuracy for detection of myofascial pain and arthralgia, whereas diagnostic accuracy for detecting the disc displacements and degenerative joint disorders is not adequate. Validity and reliability of RDC/TMD Axis II instruments were good for checking the psychosocial and pain-related disability (42).

2.2.2.2 Diagnostic Criteria (DC/TMD)

RDC/TMD was the initial step made for the TMD diagnosis but, as authors advised, this needed to be assessed for the content validity (40). Thus, the multisite validation project (2008-2011) was conducted to test the validity of the Axis I and concluded that these diagnostic criteria need some modification and recommendations (44).

The DC/TMD tool also has an Axis I and Axis II. Axis I is for physical assessment and includes muscle disorders, TMJ disorders and headache attributed to TMDs. Muscle disorders have four subtypes: myalgia; tendonitis; myositis; and spasm. Myalgia includes three subcategories: local myalgia; myofascial pain and myofascial pain with a referral. TMJ disorders

include arthralgia, disc displacement with reduction, disc displacement with reduction with intermediate locking, disc displacement without reduction with a limited opening, disc displacement without reduction without limited opening, osteoarthritis, osteoarthrosis, luxation, psychological status, and psychosocial functioning (46)

Table 4. AXIS I assessment protocol (physical diagnosis for pain-related and joint-related TMDs)

Validated Axis I pain-related TMD diagnosis	
Disorder	Sensitivity, Specificity
Myalgia	90%, 99%
Myofascial pain with referral	86%, 98%
Arthralgia	89%, 98%
Headache attributed to TMD	89%, 87%
Validated Axis I TMJ diagnosis	
Disorder	Sensitivity, Specificity
Disc displacement with reduction	38%, 98%
Disk displacement without reduction with limited opening	80%, 97%
Disk displacement without reduction without limited opening	54%, 79%
Degenerative joint disease	55%, 61%
Subluxation	98%, 100%
TMJ; Temporomandibular joint, TMD; Temporomandibular joint disorders	

Table 5. Clinical and Research application of selected DC/TMD Axis I and Axis II tests

	Axis I: Physical Diagnosis		Axis II: Psychological States	
	Pain diagnosis	Joint diagnosis	Distress and pain disability	
Application	Clinical or research		Clinical	Clinical or research
Screening test	TMD pain screener	DC/TMD for disc displacements, degenerative joint disease and subluxation	PHQ-4, GCPS	PHQ-9, GAD-7, PHQ-15 and GCPS
Confirmatory test	DC/TMD for myalgia, arthralgia and headache attributed to TMD	MRI (disc displacements), CT(Degenerative disorders), Panoramic radiographs, MRI or CT for subluxation	Combination with the mental health provider	Psychiatric or behavioural medicine interview
Patient Health Questionnaire-4(PHQ-4), Graded chronic pain scale (GCPS), Patient Health Questionnaire-9(PHQ-9), Generalised Anxiety disorder-7(GAD-7), Patient Health Questionnaire-15 (PHQ-15)				

Table 4 describes the specificity and sensitivity of the different diagnoses of TMD and Table 5 describes the Axis I, Axis II tools, and their clinical and research application (45)

2.3 Risk Factors for Temporomandibular Disorders

The risk factor is the exposure of an individual to the characteristics that modify the likelihood of developing the disease. Previous studies have already demonstrated the potential risk factors: trauma, psychological factors, age, sex, comorbidities and oral parafunctional behaviours (10) (47). The following is a description of the risk factors demonstrated by other studies.

2.3.1 Trauma

Many studies have demonstrated the role of trauma in the etiology of the TMDs (15). A total of 727 symptomatic patients were included in the study, and the data was collected using interviews, clinical examinations and self-administered questionnaires between the January 1983 and May 1984 including the age group of 17 to 70 years old. Results indicated that out of 727 patients, 66 did not report sign or symptoms of TMJ dysfunction. The majority of the patients were female (86%) out of which 83% of women and 17% of men reported acute intrinsic trauma to the head or neck, whereas extrinsic trauma was reported by 284 patients to head and neck, 21% reported whiplash injury, out of which 128 reported this injury as the precipitating factor of their TMJ dysfunction symptoms. Nine patients (1%) reported oral surgery as a cause of their TMJ dysfunction symptoms. The results of this study suggest that trauma to head and neck may contribute to the development of TMJ disorders (15).

Another study conducted by Pullinger *et al.* (1991) to evaluate the history of trauma in the diagnostic group of temporomandibular disorder patients (n=230). Diagnoses were divided into

different groups: (1) disc displacement with reduction DD; (2) disc displacement without reduction; (3) osteoarthrosis (OA) with prior derangement history; (4) primary OA; (5) myalgia; and (6) subluxation. Trauma history characterized in TMD patient groups: group 1 (63%); group 2 (79%); group 3 (44%); group 4 (53%); group 5 (54%) with the ($p<0.001$) compared with 13% and 18% of asymptomatic (n = 61) and symptomatic (n = 161) student control subjects. The high prevalence of trauma was noted among the myalgia group. DD with reduction and without reduction has a high prevalence among patients with a history of motor vehicle accidents. Results suggest that trauma can be both cumulative and a precipitating event in TMDs (48).

A retrospective study conducted by Probert TC et al. (1994), analyzed the records from the Transport Accident Commission (TAC) of Victoria, Australia. The patients who received the treatment for temporomandibular pain dysfunction disorder (TMPD) were identified. Out of 20, 673 subjects, 0.4% of subjects with mandibular fractures and 0.5% of subjects with whiplash injuries presented for treatment an associated TMPD. Majority of the patients were female relative to men (5:2). Results also showed that 75% of individuals reported symptoms of TMPD immediately after the accident and approximately 96% within two months of the accident (49).

Furthermore, a retrospective study conducted to investigate the hypothesis that a patient with a history of trauma or non-temporomandibular joint surgery might report increased pain-related TMD. The study sample consisted of 609 (78%) females and 169 (22%) males. Based on the history of the trauma and surgeries, 37 % had a history of injuries and trauma ranging in number from 1 to 5; 56% of the subjects reported 1 to 10 major surgeries. The Wilcoxon rank sum test showed that a group of subjects with histories of surgery had significantly greater pain severity ($P = .001$) and higher pain frequency ($P < .001$). These results demonstrated that patients with TMD

reporting histories of previous traumas and non-TMJ surgeries had significantly greater pain intensity and frequency of TMD symptoms (50).

A case-control study was conducted by Velly *et al.* to find contributing factors to chronic myofascial pain. From 282 patients, 178 were diagnosed with chronic myofascial pain (MFP). Results from the crude analysis showed that individuals with history of trauma present a high likelihood of having chronic MFP (OR=2.10; 95% CI: 1.04.50) and, when adjusted for psychological symptoms (anxiety, depression, somatization), trauma remains associated with chronic MFP (OR=2.08; 95% CI: 1.03; 4.40) (9).

A longitudinal study was conducted to demonstrate if jaw injury and the third molar removal may precipitate events in TMD patients and the association of jaw injury with temporomandibular disorders (TMD). A total of 2,374 first-year university students were approached. Results showed jaw injury was significantly associated with the TMD, and the odds ratios reported were: group 2 (OR=2.25); group 3 (OR = 2.47); group 6 (OR = 3.38); and group 7 (OR = 2.01). Individuals with a history of third molar extraction also have a high likelihood of present TMD (OR = 1.81) (13).

The OPPERA (Orofacial pain: prospective evaluation and risk assessment) project used a prospective cohort study design to investigate the risk factor responsible for the first onset of the TMD. The study population of 2,737 was enrolled from four US study sites in the year 2006 to 2008 and followed up for 5.2 years to see how many of them developed the temporomandibular disorder. Out of 2,737 initially TMD-free people, results showed that injury due to prolonged opening was predictive of the first onset of TMD and a lifetime history of external injury to jaw (OR = 1.29; 95% of CI: 0.85 to 1.95), lifetime history of jaw injury due to yawning (OR = 1.09;

95% of CI: 0.51 to 2.31). Lifetime history of jaw injury due to prolonged opening (OR = 1.94; 95% of CI: 1.02 to 3.67) was not associated with the TMD (12).

2.3.2 Psychological factors

Many studies have demonstrated that psychological factors play an essential role in the etiology of the TMD. It was recognized that anxiety and depression might be an etiological factor in some cases. However, anxiety or depression may result from a TMD.

A prospective cohort study was conducted and a sample of adult patients enrolled from large health maintenance organizations. This sample was reinterviewed three years after the initial interview. Of the total, 803 patients were reinterviewed. Depressive symptoms were measured using Symptom Checklist 90 – revised, and they did not find any significant association of depressive symptoms and the TMD. The odds ratio reported for the first onset of selected pain symptoms adjusted for age, gender and educational status; depression severity and TMD pain; normal (OR = 1.00), moderate (OR = 1.17), severe (OR = 1.60) (6).

A five-year prospective cohort study was conducted and for the psychological measures, comparable patterns for changes in depression and anxiety were observed. The high-improvement pain group was the only group to show marked psychological improvement over the five years, consistent with a large amount of change in their pain from baseline to 5 years. The low-improvement and same pain groups displayed patterns for all three psychological variables that were intermediate between the high-improvement and the worse groups, concerning both changes over time and relationship (7).

Furthermore, Steed *et al.* conducted a study to find the degree to which pretreatment stress and psychological dysfunction is related to presenting pain and intracapsular symptom levels. Data

was collected from the pre- and post-treatment from two practices, one in Ottawa, Canada, and the other in Indianapolis, Indiana, USA. The study used a standardized measure of symptom severity. The TMJ scale quantifies both the physiological and psychological symptoms, and several subscales are also particularly useful; global scale (GS), two pain scale-based on palpation pain (PP), another on static pain report (PR) and joint dysfunction scale (JD). The study population consisted of patients who completed the pretreatment and posttreatment study, 239 in Indianapolis and 322 in Ottawa. Results show that pretreatment psychological factors and stress do seem to be moderately and significantly related to presenting pain levels and overall TMD levels and also treatment outcome was not related to psychological symptoms (8).

Another prospective cohort study design and this study aimed to assess the catastrophizing and depression effect on the progression of pain intensity and disability scores in TMD pain patients at the 18-month follow up. Among 570 patients, 480 subjects responded to the follow-up and the mean age was 36.02 years. Results from the crude linear regression model showed depression ($\beta = 5.89$, 95% of CI 4.00 to 7.78, $P < 0.0001$), multivariable model including all the covariates, depression ($\beta = 2.49$, 95% of CI 0.06 - 4.32, $P = 0.08$). Catastrophizing was correlated with the depression ($r = 0.42$, $P<0.0001$). Crude and multivariable models analyses of the predictors of the progression of clinically significant pain GCPS from the progression of pain cohort for depression reveals; crude model depression (OR = 1.36, 95% of CI 1.04 to 1.79, $P = 0.03$), in multivariate model (OR = 1.04, 95% of CI 0.74 to 1.45, $P = 0.83$). So the results from this study show that depression was positively related to characteristic pain intensity, onset and progression of the TMD pain (10).

A prospective cohort study was conducted among healthy individuals with an age of 18 to 34 years to find psychological characteristics associated with pain sensitivity and its influence risk

of first-onset TMD. Data was collected using completed psychological questionnaires and underwent quantitative sensory testing to determine pain sensitivity. A sample size of 171 participants was followed up for three years. The depression, perceived stress, and mood were found to be associated with pain sensitivity and also increases the risk of TMD ($P < 0.05$) (11).

2.3.3 Oral Parafunctional behaviours

Most of the studies conducted related to oral parafunctional behaviours remain focused on bruxism (clenching and grinding) or the other behaviours are covered to a lesser extent. Following is the summary of the studies that show oral parafunctional behaviour as a potential risk factor for the development of the TMD.

The cross-sectional data was analyzed from the prospective cohort study to see the association of oral parafunctional habits and mandibular dysfunction. Nursing students from the University of Minnesota School of Nursing were invited to participate. A total of 269 students took part in this study and 250 completed the questionnaire and the clinical examination part. Participants indicated their frequency of involvement with each oral habit using the visual analogue scale (VAS). The questionnaire consisted of 16 oral parafunctional habits that included questions related to chewing on only one side, touching/holding teeth together, clenching or grinding during waking hours, clenching or grinding during sleep, biting nails, tongue, cheeks, lips or objects, holding jaw forward, holding jaw rigid and holding tongue against lower teeth, and the oral habit index was calculated using this questionnaire. The highest reported daily and weekly behaviour was touching/holding teeth together (39%) and chewing gum (87%). Individuals with muscle or joint disorder subjects and muscle/joint disorder subjects had the highest levels of parafunctional habits with the latter significantly higher ($P<0.01$) than normal subjects (51).

The aforementioned case-control study by Velly *et al.* (2003) shows that univariate analyses suggest that clenching-only (OR = 3.0, 95% of CI = 1.43 - 6.31) and clench-grind (OR = 6.07, 95% of CI = 2.45 – 14.51) was associated with the chronic MFP. This association remains the same when adjusted for anxiety and depression for clench only (OR = 2.77, 95% of CI = 1.14 - 6.70) and clench - grind (OR = 8.90, 95% of CI = 2.97-27.60) (9).

Another study shows that higher EMG value during clenching was associated with more pain for both the temporalis and masseter muscles. The study sample consisted of fourteen individuals ranging from 21 to 35 years of age. All the patients received the diagnosis for TMD or myofascial pain using Research Diagnostic Criteria (RDC/TMD). Half of the subjects (4 males, three females) were assigned to the Decrease training group, while the remaining half (4 males, three females) were assigned to the Increase training group. EMG activity during training was collected in 1-min epochs. The mean of twenty-minute training sessions was calculated, representing the participant's performance during the training session. The pain was significantly higher in the group which engaged in the experimental clenching task. Two of the seven subjects who engaged in clenching were diagnosed with myofascial pain following training, while none of the seven subjects who were asked to decrease the activity of the temporalis and masseters were diagnosed with any TMD pain-related disorder following training. Findings suggest that parafunctional activity increases pain and can lead to a diagnosis of TMD or other pain (52).

A case-control tudy was conducted including Japanese university students ranging in age from 18 to 26 years. Participants completed the self-reported questionnaire, including oral parafunction. The multiple regression model adjusted for age and gender demonstrated that chewing on one side caused an increased risk of TMJ noise (OR = 1.54, $P < 0.001$), TMJ pain (OR = 1.54, $P < 0.001$) and impaired mouth opening (OR = 2.00, $P < 0.001$). Tooth clenching also increase the risk of

TMJ noise (OR = 1.86, $P < 0.001$), TMJ pain (OR = 1.79, $P = 0.001$) and impaired mouth opening (OR = 1.88, $P < 0.001$). Findings suggest significant associations between parafunctional activities and TMD symptoms (53).

The case-control study further shows similar results and found a statistically strong relationship between clenching and muscle palpation findings, as well as between sensitivity in the mandibular joints and positive muscle palpation findings (54).

A cross-sectional study conducted by F. Sato *et al.* in 2006, they named the oral parafunctional behaviour as teeth contacting habits (TCH) to investigate ID. TCH is associated with the perpetuation of the chronic pain of TMD patients. A sample size of 508 patients has selected out of which 229 patients whose pain continued for more than four months were selected. Results showed that 50.4% of whole 508 participants responded "yes" to the question for TCH, although those 229 patients with chronic pain were 49.0% (improved) and 54.6 % (not improved). Patients with TCH and have pain for more than four months were less likely to show improvement in pain on the first visit (OR = 1.944, p = 0.043). Unilateral chewing (OR = 2.802) was also found to be associated with TCH (OR = 2.195). Half of the chronic patients with TMD had TCH. TCH can contribute to the prolongation of TMD pain (55).

Furthermore, van der Meulen, M. J., *et al.* (2006) conducted a study consisting of two cohorts of TMD pain patients, the first cohort comprising 303 patients and the other 226 patients. The questionnaire consisted of the 12-item oral parafunction questionnaire and Research Diagnostic Criteria Axis II questionnaire, which includes a characteristic pain intensity score (CPI). Relationships between oral parafunctions and CPI were examined and adjusted for age and gender. They did not find any clinically significant relationships between different types of self-reported oral parafunctions and TMD pain complaints (56).

The effect of prolonged tooth clenching on masticatory muscle pain was studied in 2010, and it was hypothesized that late-onset soreness might develop depending on the clenching force. Perceived pain, fatigue and pressure-pain thresholds of masseter and temporalis muscles were assessed before, immediately after and one day after the tasks. Masseter pressure-pain threshold decreased immediately after (-13.7%; $p = 0.050$) and one day after (-22.0%; $p = 0.006$) the 7.5% task. The temporalis pressure threshold decreased one day after the 7.5 % task (-14.6%; $p = 0.003$). They concluded that low-level tooth clenching in healthy women induces a delayed soreness of the jaw elevator muscles (23).

A case-control study was conducted by A. Michelotti *et al.* (2010) to assess the oral parafunctional behaviours as a risk factor and more specifically to determine whether daytime clenching/grinding and nail-biting are risk factors for different subgroups of temporomandibular disorders. The case group included 557 patients, and the control group included 111 healthy patients. Results from the logistic regression analysis shows that daytime clenching/grinding was a significant risk factor for myofascial pain (OR = 4.9, 95% of CI; 3.0 – 7.8) and for disc displacement (OR = 2.5, 95% CI: 1.4 – 4.3), whereas nail biting was not associated with the TMD (57).

The Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) project, represents a case-control study that includes 1,633 controls and 185 cases with chronic, painful TMD, who completed oral behaviour checklists (OBC) and received clinical examinations. Odds ratios were calculated, and models adjusted for a location as well as age, sex and race. Results showed that compared to controls, for TMD cases with parafunctional behaviours, the odds of TMD was elevated 17-fold (OR = 16.8, 95% of CI = 8.6 to 32.9) among people in the upper tertile (oral behaviour checklist sum score; 25-62), relative to people in the lowest tertile (oral behaviour

checklist sum score; 17-24), demonstrating that oral parafunctional behaviours are strongly associated with the chronic TMD (47).

In a population-based cross-sectional survey conducted by Karibe *et al*. in 2015, 1,415 subjects with ages ranging from 11 to 15 years self-reported their TMD symptoms, headache, neck pain, and toothache, and completed questionnaire scales that assessed 15 daily activities. Results from the multivariate logistic regression showed that odds of TMD symptoms in subjects frequent diurnal clenching were OR = 3.69, P = 0.011 and concluded that diurnal clenching was strongly associated with TMD symptoms (32).

Another study was conducted using a self-reported questionnaire, oral behaviour checklist (OBC), patient health questionnaire (PHQ-9) and generalized anxiety disorder (GAD-7) among a study population of 94 subjects. Results demonstrated that waking state oral parafunctional behaviours were statistically significantly associated with the presence of the TMD diagnosis and also individuals with pain-related TMD diagnosis had a statistically significantly higher mean OBC score (58).

A case-control study aimed to analyze the frequency, amplitude and duration of daytime clenching episodes in patients with masticatory muscle pain and pain-free individuals was conducted by I. Cioffi *et al.* in 2017. The study sample consisted of 15 women suffering from masticatory muscle pain (MP group) recruited and matched for age to a control group composed of 18 TMD-free individuals (CTR group). Patients were asked to complete a questionnaire at the beginning of the study; the Oral Behavior Checklist (OBC), the State-Trait Anxiety Inventory (STAI), and the Somatosensory Amplification Scale (SSAS). Results from the study show that individuals with masticatory muscle pain have an increased frequency of both high- and low-intense daytime clenching episodes (59).

The frequency of oral behaviours in patients with temporomandibular disorders (TMD) and a control group without TMD was evaluated using the case-control study design. The total number of 260 controls and 260 subjects with TMD completed the oral behaviour checklist (OBC). Results from stepwise regression analysis demonstrated that frequent expression of holding, tightening, or tense muscles is associated with 10.83 times ($P<0.05$) higher risk of TMD, grinding teeth together during waking hours with 4.94 times ($P<0.05$) higher risk, and sustained talking with 2.64 times ($P<0.05$) higher risk of TMD (60).

The cross-sectional study was conducted among the children and adolescents to investigate the risk factor associated with the TMD. A total of 1,800 questionnaires were distributed among pupils of schools. The study population was divided into two samples: children with ages ranging from 7 to 12 years (answered by parents) and adolescents aged 13 to18 years (self-report). Oral habits (viz., chewing gum, and/or biting on nails, pens/pencils, and/or lips/cheeks) and bruxism were found to be associated with pain-related TMDs in both the groups (61).

Most recently, a case-control study was conducted to investigate the effect of anxiety, somatosensory amplification and facial pain on self-reported oral behaviours. The participants were asked to fill out the following questionnaires: State-Trait Anxiety Inventory, the Somatosensory Amplification Scale, the Oral Behavior Checklist (OBC) and the TMD-Pain Screener. Total of 255 university students filled out the self-reported facial TMD pain (pain group; 47 subjects) and without pain (control group; 208 subjects,) using a web survey. Results Trait anxiety, somatosensory amplification, and OBC scores were greater in pain than the control group (p <0.05). Trait anxiety was positively associated with the frequency of oral behaviours, as measured with the OBC ($p < 0.05$). A significant effect of the interaction study group, trait anxiety

(p = 0.028) on OBC scores was found. Thus, individuals with high anxiety have more likelihood of presenting oral behaviours more frequently (62).

Based on the literature review and results presented above, unfortunately, there is no study to the best of our knowledge that had studied the association of the oral parafunctional behaviour among chronic PTMD patients relative to the acute PTMD patients, whereas some studies showed the association of TMD among chronic TMD patients relative to the non-TMD population. It will be interesting to see the association of oral parafunctional behaviours among chronic PTMD relative to the acute PTMD.

CHAPTER 3. STUDY OBJECTIVES AND HYPOTHESES

Many studies demonstrated that oral parafunctional behaviours are common among TMD patients relative to healthy individuals. Further, cohort studies showed that oral parafunctional behaviours increase the risk of TMD. Self-care management and splint therapy are commonly advised treatment for the management of oral parafunctional behaviours in TMD patients. Regardless of the treatment received, the majority of the patients complains of persistent pain. Thus, it is important to identify the factors that contribute to the acute-chronic pain transition.

The current case-control study aimed to assess the association of oral parafunctional behaviours among chronic PTMD patients relative to the acute PTMD.

3.1. Specific study objectives and study hypotheses:

1. To assess the association between oral parafunctional behaviours and chronic PTMD relative to the acute PTMD.

Null hypothesis: There is no association between oral parafunctional behaviours and chronic PTMD relative to acute PTMD. Chronic PTMD individuals did not present a higher odd of oral parafunctional behaviours in comparison to acute PTMD individuals.

2. To evaluate if the association between oral parafunctional behaviour and chronic PTMD were confounded by psychological symptoms (anxiety and depression), age, sex, site of recruitment, and pain intensity.

Null hypothesis: The association between oral parafunctional behaviours and chronic PTMD is not confounded by the psychological symptoms (anxiety and depression), age, sex, recruitment site, and pain intensity.

3. To evaluate if the association between oral parafunctional behaviour and chronic PTMD was modified by depression symptoms.

Null hypothesis: Depression symptoms are not modifying the association between oral parafunctional behaviour and chronic PTMD.

CHAPTER 4. METHODOLOGY

This clinically based case-control study from the ACTION program aimed to identify the association of oral parafunctional behaviours in chronic painful TMD patients relative to acute painful TMD patients. The methodology of the case-control study outlined in this chapter includes ethics, study design, study population, data collection and statistical analysis.

4.1 Ethics

This clinically based case-control study is part of a prospective cohort study, which was approved by the Research Ethics Committees, McGill University Institutional Review Board in Montreal, Quebec, Canada (approval number A12-M113-14A) and by the Dental Speciality Group, Ottawa, Ontario, Canada (approval number 240-400).

4.2 Eligibility and Recruitment

Potential patients recruited from four different sites: (i) the dental clinic of the Jewish General Hospital (JGH); (ii) the oral diagnosis (OD) clinic of McGill University, Faculty of Dentistry; (iii) Montreal General Hospital (MGH), Montreal, Quebec, Canada; and (iv) Dental Specialty Group, in Ottawa, Ontario, Canada during the time period from October 2015 to the present date. Eligibility criteria included age from 18-80 years, not pregnant, capable of speaking and reading French or English, no acute pain caused by dental disease (e.g. pulpitis, severe periodontal disease), ear infection, neurological disorders, atypical pain, acquired immune deficiency syndrome (AIDS), neoplasms and chronic systemic diseases affecting the joints. Patients who were mentally impaired, blind, and deaf or mute and those with physical handicaps, preventing them from answering the questionnaires were not eligible.

All patients underwent extra-oral and intra-oral clinical examinations and received the diagnosis for painful TMD-based DC/TMD by a certified dentist after signing a consent form (44). The intra-oral examination included a full dental examination to rule out the possibility of pain due to any other dental etiology.

Both groups include patients diagnosed with painful TMD and are classified into acute and chronic groups based on chronic pain defined by the International Association for the Study of Pain (IASP) as "pain which has persisted beyond normal tissue healing time," which in the absence of other criteria is taken to be three months. Acute TMD-related pain was defined as pain with onset less than three months or more (63) (11), whereas chronic was defined as pain that persists beyond the normal time of healing, which in the absence of any other criteria is taken to be three months (64, 65).

4.3 Exposure Assessment

The DC/TMD instruments used to assess the primary and secondary aim.

4.3.1 Oral Behaviour Checklist (OBC)

The Oral Behaviour Checklist (OBC) is a 21-item questionnaire, employing five response options (0–4) and consists of two parts (45). The first part includes sleep oral parafunctional behaviours (SOPH): (i) clench or grinds teeth when asleep, based on any information you may have; (ii) sleep position that puts pressure on your jaw. The OBC's five response options for SOPH are 'none of the time' '<1 Night/per month', '1-3 Night/per month', '1-3 Nights/per week' and '4-7 nights/week', which are equivalent to the scores 0, 1, 2, 3, 4, respectively. The second section includes a list of 19 potentially parafunctional behaviours that occur during the day. Such

behaviours may strain the jaw, such as: kissing, playing a wind instrument, singing, holding a telephone between the shoulder and chin, smoking, leaning with chin on one's hand, and chewing or biting on hard food. The responses to these items are 'none of the time,' 'a little of the time,' 'some of the time,' 'most of the time,' 'all of the time,' and were numbered 0, 1, 2, 3, 4, respectively (45).

The validity of the OBC was checked by Van der Meulen *et al*. shows the test-retest reliability of OBC was excellent (ICC = 0·86, P < 0·001). Concurrent validity was good: the correlation between the OBC and Oral Parafunctions Questionnaire (OPQ) was high (r = 0·757, P < 0·001) (66). Richard Ohrbach and his team also assessed the validity and reliability of the OBC for the waking hour parafunctional behaviour and demonstrated that the OBC has good reliability with the test-retest reliability coefficient greater than 0.8 and good validity (67). The sum scores of the endorsed frequencies were calculated (68).

4.4 Potential confounders

4.4.1 Psychological symptoms

The Patient Health Questionnaire (PHQ-8) consists of 8 items assessing the patient's depressed mood. The total sum of all the item's individual scores was computed (8). The sensitivity and specificity of a PHQ-8 for the major depressive disorder were calculated at 100% and 95%, respectively; for any other depressive disorder the sensitivity and specificity were 70% and 98 (9).

Generalized Anxiety Disorder (GAD-7) is a validated questionnaire that comprises seven items. Similar to the PHQ-8, the total sum score of all the items was computed. Robert L. Spitzer and his team checked the validity of the instrument, and at a cut-off point, the GAD-7 had a

sensitivity (89%) and specificity (82%) Cronbach's (α) = 0.92 that shows the good validity and internal consistency of the instrument (10).

The scoring cut-offs for the GAD-7 and PHQ-8 questionnaires assessing anxiety and depression respectively were: 0-4 indicates that a person is not anxious or depressed; 5-9 indicates mild; 10-14 moderate; and 15–27 indicates severe anxiety or depression (8).

4.4.2 Other factors

Other factors adjusted for the confounding effects were; age, sex, pain intensity and recruitment site; JGH, MGH, McGill clinic, Ottawa dental clinic.

4.5. Statistical Analysis

Chi-square and Student's t-test were used to test statistical differences between PTMD groups relative to their sex, age, depression and anxiety.

Univariate and multivariable unconditional logistic regression analyses were applied to assess the primary aim. The crude model includes the sum score of the OBC as the independent variable and the study groups (i.e. acute or chronic PTMD) as the dependent variables. The multivariable model included anxiety, depression, age, and sex variables to evaluate if they confounded the association between oral parafunctional behaviours and PTMD. Confounders were chosen based on prior knowledge of their relationship with the oral parafunctional behaviours and evaluated through a change of estimate criterion between the adjusted and crude effects.

Also, we created four interaction factors to assess if the association between PTMD and OBC were modified by age, sex, anxiety and depression. The interaction term was kept in the model only if the significance level of the regression coefficient was equal to or lower than 0.10.

The odds ratio (OR) and the 95% confidence intervals (95% CI) were estimated. All statistical tests were done at an alpha level of 0.05 (2-tailed). Further, imputation was performed on missing data using the Multiple Imputation by Chained Equations (MICE). We repeated the crude and adjusted analysis considering the imputation data. Statistical analyses were performed using the SAS version (version 9.4; SAS Institute, Cary, NC).

Further, we utilized multiple imputations for handling missing values. For multiple imputations, we used the mix package in the R statistical package (version 3.3.0) (69). Ten imputed data sets were fitted and then analyzed using the MIANALYZE procedure in SAS.

CHAPTER 5. MANUSCRIPT

Oral parafunctional behaviours: acute versus chronic painful temporomandibular disorders

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Abstract

Aim. This case-control study was to investigate the association of oral parafunctional behaviours in chronic painful temporomandibular disorders (PTMD) relative to the acute PTMD.

Methods. Participants with PTMD were recruited from four different sites: (i) dental clinic of the Jewish General Hospital; (JGH); (ii) Oral Diagnosis (OD) clinic of McGill University, Faculty of Dentistry; (iii) Montreal General Hospital (MGH), Montreal, Quebec, Canada; and (iv) the Dental Specialty Group, in Ottawa, Ontario, Canada. Pain classification based on the International Association of the Study of Pain (IASP) was used to classify PTMD participants in acute (< 3 months) or chronic (≥ 3 months) groups. The validated Oral Behaviour Checklist, General Anxiety Disorder (GAD-7) and Patient Health Questionnaire (PHQ-9) were used to assess the oral parafunctional behaviours, anxiety and depression, respectively. The association between oral parafunctional behaviours and PTMD was assessed using unconditional logistic regression analysis.

Results. Two hundred eighty-four participants accepted to participate in this study; 48 (17%) were included in the acute PTMD group and 236 (83.1%) in the chronic group. The majority of both groups were females ($P = 0.23$). Results from the crude logistic analysis showed that participants with chronic PTMD were more likely to present high odds of OBC1 (OR = 2.43, $P = 0.04$) compared to acute PTMD participants. A strong association was found with OBC2 score (OR = 4.12, $P = 0.0004$). These associations remained in the multivariable analyses when adjusted for potential confounders; OBC1 (OR = 3.07, $P = 0.01$), and OBC2 (OR = 4.71, $P = 0.0005$). The sensitivity analysis also showed that these results were not biased by pain intensity or recruitment location: OBC1 (OR = 3.07, $P = 0.01$) and OBC2 (OR = 4.71, $P = 0.0005$).

Conclusion. Relative to acute PTMD, chronic PTMD is associated with oral parafunctional behaviours. This association is not confounded by demographic characteristics, psychological symptoms, pain severity or patients' recruitment location. This result suggests that these behaviours contribute to the transition from acute to chronic PTMD.

Introduction

Temporomandibular disorders (TMD) encompasses musculoskeletal conditions characterized by pain and dysfunction in the muscles of mastication or the temporomandibular joints or both.(40, 70, 71) The prevalence of painful TMD (PTMD) ranges from 5% to 12% (29, 35, 72).

There are various risk factors for TMD, including psychological factors (5-11), trauma (9, 12-15), genetic (16-18) and comorbidities (9, 12, 19). Previous studies also demonstrated that oral parafunctional behaviours are associated with chronic PTMD (4, 9, 20-24). Oral parafunctional behaviours broadly defined as oral, masticatory, and facial behaviours that do not serve any functional purpose (73). Self-care management and oral splints are commonly recommended by dentists to manage oral parafunctional behaviours (74, 75). However, regardless of the treatment received, PTMD commonly remains (4, 7). Thus, it is crucial to prevent PTMD from becoming chronic, as chronic pain is more difficult to manage compared with acute pain in TMD. Therefore, it is needed to identify the risk factors that contribute to this transition. The prevention of these risk factors could lower the transition risk.

The Acute-Chronic Transition pain (ACTION) prospective studies endeavour to discover the determinants for the risk of acute to chronic painful TMD transition. This goal is in line with the NIH statement: “we do not fully understand how acute progresses to chronic pain at any level, from molecular to behavioural” (76). Given the previous studies findings, the role of oral parafunctional behaviours on the transition risk warrants closer examination.

The results of this study are restricted to the baseline assessment of oral parafunctional behaviours in a large ACTION cohort of people with acute or chronic painful TMD. The primary

aim of this study is to characterize differences in oral parafunctional behaviours between acute and chronic PTMD.

Methodology

Study design and study population

This clinically based case-control study was approved by the Research Ethics Committees, McGill University Institutional Review Board in Montreal, Quebec, Canada (approval number A12-M113-14A) and by the Dental Speciality Group, Ottawa, Ontario, Canada (approval number 240-400).

The PTMD sample was recruited from four different sites: (i) Dental clinic of the Jewish General Hospital (JGH); (ii) The Oral Diagnosis (OD) clinic of McGill University, Faculty of Dentistry; (iii) Montreal General Hospital (MGH), Montreal, Quebec, Canada; and (iv) the Dental Specialty Group, in Ottawa, Ontario, Canada. The inclusion criteria for participation in study required the diagnosis of PTMD diagnosis (muscle and/or joint pain) and age from 18-80 years. Patients were excluded if they presented: (i) acute pain caused by dental disease (e.g. pulpitis, severe periodontal disease), neurological disorders, and cancer. Patients who were not able to provide informed consent or did not understand English or French were also excluded. The recruitment began on September 1, 2017, and ended on January 31, 2019. The diagnosis of PTMD was determined by clinical examination using the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) protocol (44).

Participants were classified in acute or chronic PTMD groups based on the definition of chronic pain by the International Association for the Study of Pain (IASP) as "pain which has persisted beyond normal tissue healing time," which in the absence of other criteria is three months

(63). Thus, acute PTMD was defined as pain lasting less than three months, whereas chronic was defined as the pain lasts for three months or more (77).

Oral parafunction behaviours assessment

Oral parafunction behaviours were assessed with the Oral Behaviour Checklist (OBC). The reliability of OBC is excellent, and its validity is good ($r = 0{\cdot}76$, $P < 0{\cdot}001$) (45, 66) (8) (78).

The first part of this instrument assesses the occurrence of sleep-related oral parafunctional behaviours during sleep (i.e., clenching or grinding teeth when asleep and being in a sleep position that puts pressure on your jaw). For each item, participants were asked to report on the frequency over the last month, using responses: 'None of the time' '<1 Night/per month', '1-3 Night/per month', '1-3 Nights/per week,' and '4-7 nights/week', which are equivalent to the scores 0, 1, 2, 3, 4, respectively. The second section includes a list of 19 potential parafunctional behaviours that occur during the day: grinding, clenching, pressing, holding, pressing tongue, placing, biting, chewing gum, holding the jaw in a rigid position, playing a musical instrument, kissing, playing a wind instrument, sustained talking, eating between meals, singing, holding a telephone between the shoulder and chin, smoking, leaning with the chin on one's hand, and chewing or biting on hard food. The patient was asked to report the frequency over the past month for each item, using responses: 'None of the time', 'A little of the time', 'Some of the time', 'Most of the time', and 'All of the time' (score range 0–4). Based on DCTM protocol, the OBC cut-offs for sum of OBC are: 1) 0-16; 2) 17-24; and 3) 25-62 (68).

Assessment of potential confounders and effect modifiers

Potential confounders or effect modifiers were age, sex, anxiety, and depression symptoms. Depression symptoms were assessed by the valid Patient Health Questionnaire (PHQ-8). The validity of this instrument is excellent for major depressive disorders (specificity 95%, sensitivity 100%) and good for other depressive disorders (sensitivity 70%, specificity 98%) (9). The Generalized Anxiety Disorder (GAD-7), used to assess anxious mood and behaviour, is also a valid (sensitivity 89%, specificity 82%) and reliable ($\alpha = 0.92$) instrument (8). The cut-offs for the PHQ-8 are: scores of 0-5 indicate mild depression, 6-10 moderate depression, 11-15 moderately severe depression and 16-20 presents severe depression; for the GAD-7: 0-5 indicates mild anxiety, 6-10 moderate anxiety, 11-15 severe anxiety (68).

Statistical Analysis

Chi-square and Student's t-test were used to test statistical differences between PTMD groups relative to their sex, age, depression and anxiety.

Univariate and multivariable unconditional logistic regression analyses were applied to assess the primary aim. The crude model includes the sum score of the OBC as the independent variable and the study groups (i.e. acute or chronic PTMD) as the dependent variables. The multivariable model included anxiety, depression, age, and sex variables to evaluate if they confounded the association between oral parafunctional behaviours and PTMD. Confounders were chosen based on prior knowledge of their relationship with the oral parafunctional behaviours and evaluated through a change of estimate criterion between the adjusted and crude effects.

In addition, we created four interaction factors to assess if the association between PTMD and OBC were modified by age, sex, anxiety and depression. The interaction term was retained in

the model only if the significance level of the regression coefficient was equal to or lower than 0.10. The odds ratio (OR) and the 95% confidence intervals (95% CI) were estimated. All statistical tests were done at an alpha level of 0.05 (2-tailed). Further, imputation was performed on missing data using the Multiple Imputation by Chained Equations (MICE). We repeated the crude and adjusted analysis considering the imputation data. Statistical analyses were performed using the SAS version (version 9.4; SAS Institute, Cary, NC). Further, we utilized multiple imputations for handling missing values. For multiple imputations, we used the mix package in the R statistical package (version 3.3.0) (69). Ten imputed data sets were fitted and then analyzed using the MIANALYZE procedure in SAS.

Sensitivity analysis

Multivariable unconditional logistic regression analysis was performed to assess if the primary result was biased by the location where participants were recruited and/or by their pain intensity. Thus, the multivariable model included the same covariates used in the primary analysis plus the location where they were recruited and mean of pain intensity (current, worse, and average).

Results

In total, 319 potential patients were invited to participate in the study. Out of these, seven refused (participation rate 97.8%) and 28 (0.99%) were not eligible. The main reasons for non-participation were the lack of time and lack of interest. The most common reasons for exclusion were dental pain, age less than 18, and not understanding English or French (Figure 1).

From the remaining 284 participants, 48 (17%) present acute PTMDs and 236 (83.1%) chronic PTMDs. Figure 2 illustrates that the acute/chronic patients' ratio of the study groups was similar across all recruitment locations ($P = 0.26$).

Table 1 shows the distribution of oral parafunctional behaviours and covariates between acute and chronic PTMD participants. Most of them were female in either group ($P = 0.23$), and no statistically significant difference was found in their mean age ($P = 0.88$). No statistically significant difference was found in the pain intensity average for the acute (mean = 55.21, SD = 22.43) and the chronic (mean = 57.74, SD = 20.76, $P = 0.42$) groups.

Figure 1. Patient's enrollment flowchart

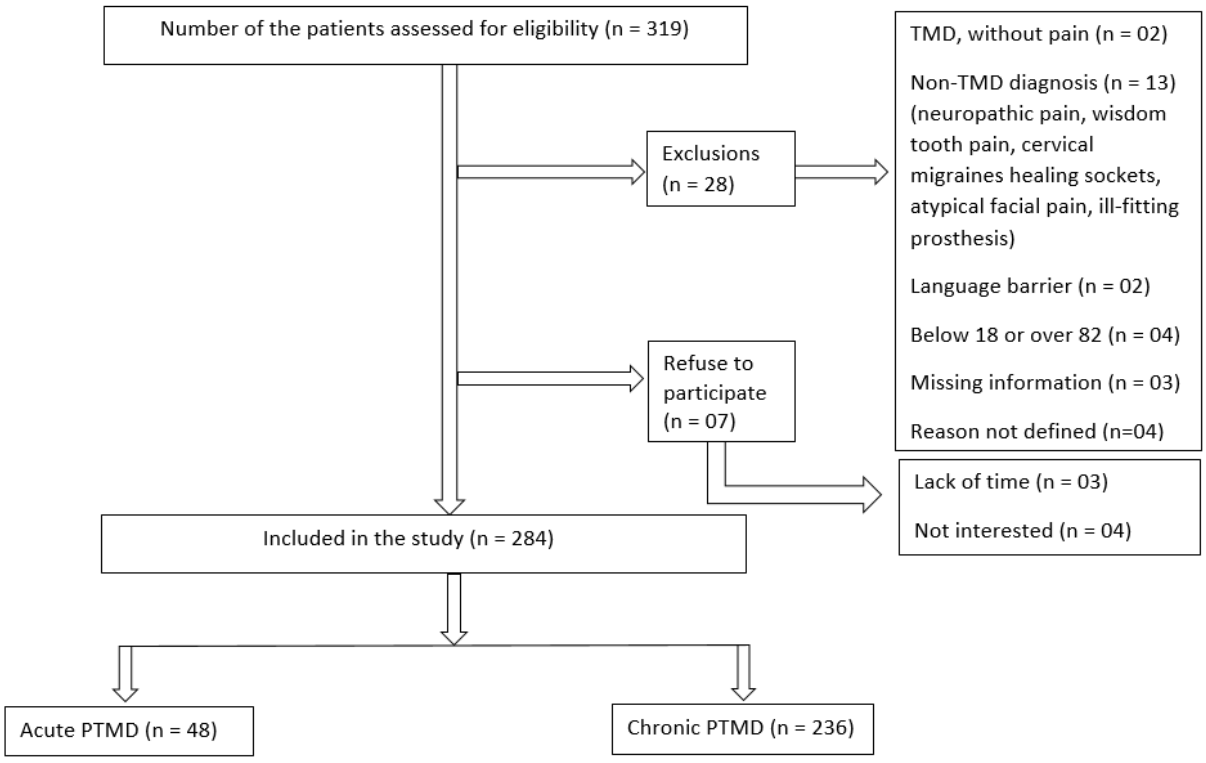


Table 1 shows the primary analysis. The crude logistic analysis showed that participants with chronic PTMD were more likely to present greater odds of OBC1 (OR = 2.43, $P = 0.04$) compared to acute PTMD participants. A strong association was found between OBC2 score and chronic PTMD (OR = 4.12, $P = 0.0004$). These associations remained in the multivariable analyses adjusted for potential confounders; OBC1 (OR = 3.07, $P = 0.01$), and OBC2 (OR = 4.71, $P = 0.0005$). Furthermore, these associations were not modified by depression symptoms (OBC1 $P = 0.85$; OBC2 $P = 0.92$). No significant associations with anxiety, sex, and age were noted in the crude or multivariable analysis.

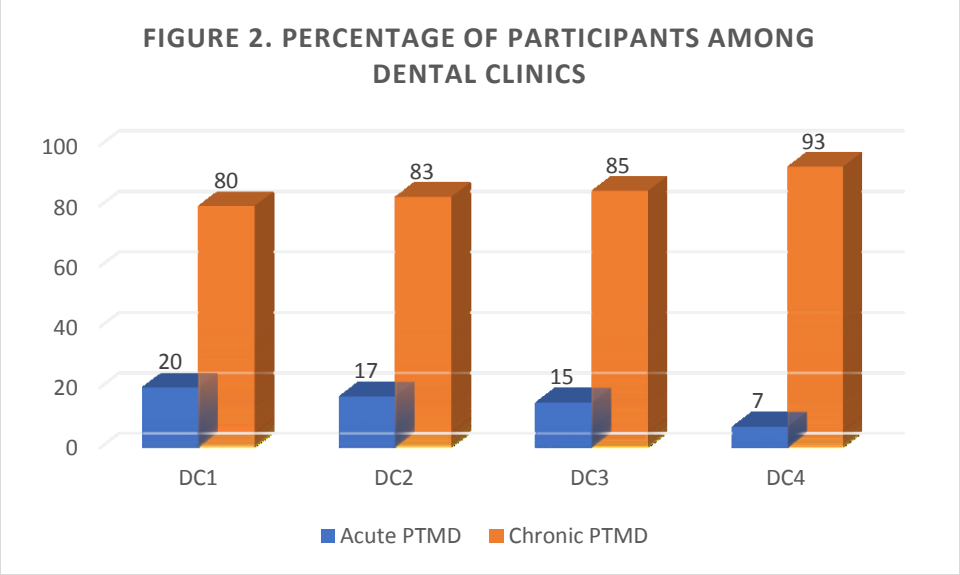
Table 7. Crude and adjusted OR and 95% of CI for the association of oral parafunctional behaviours between acute and chronic PTMD

Factors	Category	Acute/ Chronic (n)	OR (95% of CI) Crude	OR (95% of CI) Multivariable	OR (95% of CI) Imputation
Oral parafunctional behavior	OBC0	17/34	1 (referent)	1 (referent)	1 (referent)
	OBC1	13/67	2.43 (1.06 - 5.57)**	3.07 (1.27 - 7.42)**	2.73 (1.15 – 6.46)**
	OBC2	15/131	4.12 (1.88 - 9.05)**	4.71 (1.97 - 11.29)**	4.67 (1.98 –11.02)**
Sex	Male	14/50	1 (referent)	1 (referent)	1 (referent)
	Female	34/186	1.53 (0.76 - 3.07)	1.89 (0.87 – 4.10)	1.82 (0.86 – 3.84)
Age	Mean	43.54/43.13	1.00 (0.98 -1.02)	1.01 (0.99 – 1.03)	1.01 (0.99 – 1.03)
Anxiety symptoms	0	32/147	1 (referent)	1 (referent)	1 (referent)
	1	16/89	1.21 (0.63 – 2.33)	0.54 (0.23 - 1.25)	0.59 (0.27–1.33)
Depression symptoms	0	39/152	1 (referent)	1 (referent)	1 (referent)
	1	9/84	2.39 (1.10–5.18)**	3.61 (1.34 – 9.72)**	3.07 (1.21 – 7.80)**

Abbreviations: OR; Odds Ratio, CI; Confidence interval

[a] Simple logistic regression analysis, [b] Multivariate logistic regression analysis including age, sex, depression and anxiety OBC0 is the sum of score from 0 to less than 17; OBC1 is the sum of score from 17 to less than 25, and OBC2 is the sum of score from 25 or more.** $P<0.05$

As participants were recruited from different dental clinics, we assessed if the greater odds among chronic cases were biased by the location where they were recruited. This analysis was also adjusted by pain severity since it was possible that patients with greater pain severity remember more about those habits. The multivariable model showed that the results remained similar. Participants with chronic PTMD were more likely to present the score of OBC1 (OR = 2.89) and OBC2 (OR = 3.65, *P* = 0.04) than the acute PTMD participants, regardless the clinic they were recruited, their pain intensity, psychological symptoms and demographics. No significant interactions were found between depression and oral parafunctional regardless of the frequency of the oral parafunctional behaviour (depression and OBC1, $p = 0.68$; depression and OBC2, $p = 0.82$).



Discussion

Previous studies showed that oral parafunctional behaviours modify the risk of TMD ((12). Other studies also found an association between chronic PTMD and oral parafunctional behaviours (12, 55, 79). Cairns *et al.* suggested that oral parafunctional behaviours can injure the masticatory muscle and therefore increase the risk of TMD (80).

This case-control study demonstrated that the odds of oral parafunctional behaviours are higher among chronic PTMD relative to acute PTMD participants (Tables 1 and 2). There is no study, to the best of our knowledge that have assessed the association of oral parafunctional behaviours and acute and chronic PTMD patients. Furthermore, we found that this association is not confounded by participants' sex, age, psychological symptoms, pain intensity or recruitment location. Moreover, depression symptoms did not modify the association of oral parafunctional behaviours and chronic PTMD.

In addition, in this study, similar to others, we also found that higher levels of depression were more common among chronic than acute PTMD participants, whereas anxiety was not associated with chronic PTMD (81-83).

We did not find a significant difference in the percentage of sex and mean age between acute and chronic painful PTMD. These results partially agree with the Garofalo *et al.* study that found that females were more frequently found in the chronic group, but no mean age difference was found between groups (82, 84).

In our case-control study, we speculated that patients with chronic PTMD might be more aware of oral parafunctional behaviours than the acute PTMDs. Thus the acute participants may have under-reported these behaviours. To reduce the potential for recall bias, some methodological procedures were applied. Participants were not informed about the specific aims of the study and

were thereby not unduly influenced in the completion of the questionnaire. The misclassification bias was also limited by using a validated questionnaire. Also, the analysis was adjusted by psychological symptoms and pain intensity, since patients with greater anxiety and/or depression symptoms or pain severity could be more aware of these habits. Finally, this analysis was also adjusted by the patients' recruitment location since this covariate could be correlated with the report of oral behaviours.

Several limitations need to be considered. First, there is a chance of misclassification of the acute and chronic PTMD groups, since this classification was based on self-reported pain duration. To minimize the chance of misclassification, we used the chronic pain definition proposed by the IASP, (64, 65) and the analysis was adjusted by covariates that could modify this classification (e.g. psychological symptoms, pain intensity and location); participants with severe pain intensity or depression could remember more about the duration of their pain than those with mild pain and/or without depression symptoms. Second, there is a chance of PTMD misdiagnosis. To reduce this bias, all participants received a clinical examination following the DC/TMD protocol (68).

As participants were recruited from specialized pain and general dental clinics, this allowed us to increase the generalization of the results and decrease the chance selection bias associated specifically to a given dental clinic because of the referral pattern.

In conclusion, the current results indicate that relative to acute PTMD, oral parafunctional behaviours are associated with chronic PTMD. This relationship is strong among frequent oral habits. Furthermore, this association was not confounded by demographic characteristics, psychological symptoms or pain severity. A cohort study, however, is needed to determine if the oral parafunctional behaviours contribute to the transition from acute to chronic PTMD.

CHAPTER 6. DISCUSSION

This section discusses the summary of the results, strengths as well as the clinical significance and the knowledge translation.

6.1 Summary of the results

Studies have shown that oral parafunctional behaviours are common among the chronic PTMD relative to the non-TMD population. Baseline case-control analysis from the OPPERA study evaluated oral parafunctional behaviours as a potential risk factor for the chronic TMD (47). Velly *et al.* demonstrated that clenching was associated with chronic masticatory myofascial pain (MFP), regardless of participants' demographics, psychological symptoms or how the participants were informed about these habits. Leketas *et al.* in 2017 support that certain oral parafunctional behaviours, such as holding, tightening or tensing muscles, grinding teeth together during walking hours and sustained talking are more common among chronic TMD than healthy controls (60).

Furthermore, cohort studies also found that oral parafunctional behaviours increase the risk of TMD (HR = 1.75, CL = 1.28, 2.39) as well as its persistence (85).

The results of this case-control study showed that chronic PTMD participants have a higher likelihood of presenting oral parafunctional behaviours relative to the acute PTMD. No study to the best of our knowledge has compared the likelihood of oral parafunctional behaviours among chronic PTMD relative to the acute PTMD participants. The results were not confounded by psychological factors (anxiety and depression symptoms), age and sex-based, neither by location were recruited or their pain intensity.

Depression symptom was more common among the chronic PTMD patients relative to the acute cases, whereas anxiety symptoms were not associated with chronic PTMD. These findings are consistent with the other findings where an acute pain is characterized by anxiety symptoms

and chronic pain dominated by depression symptoms. Gatchel *et al.*, results showed that patients with chronic TMD (78%) were more likely to have significant signs of depression symptoms comparative to the acute TMD patients, whereas anxiety symptoms found to be more common among the acute TMD (47 to 53 percent) relative to the chronic TMD (81). Same results were found by the other studies also where they noted the high level of depression symptoms among chronic PTMD group relative to the acute (86).

We did not find a significant association of age or sex with the chronic PTMD, what is in harmony with the other studies; Glaros *et al.* did not find a significant difference of age and sex among chronic TMD group (84). Our findings disagreed with the results from other studies where they showed that the females are at a greater likelihood of presenting with the chronic PTMD (9) (87) and are at higher risk of developing the chronic PTMD (82).

6.2 Methodological considerations

6.2.1 Bias

It is defined as an error in an epidemiologic study that results in an incorrect estimate of the association between exposure and risk of disease (26). Evaluating the role of bias in any study conduct is a necessary step in interpreting the study results (26). Thus, it is important to design and conduct each study in a way that every possibility of introducing bias has been predicted to minimize the bias. Types of bias expected and the measure we used to minimize those are discussed below.

6.2.1.1. Selection Bias

Selection bias can result from the way individuals are selected for the study. A number of factors like diagnosis and referral of individuals can contribute to the selection bias. To minimize this, we used the DC/TMD criteria for the diagnosis and the patient were recruited from the four different dental sites to reduce the selection bias specific to the referral.

6.2.1.2 Information Bias

Information bias result from differences in the way data on exposure or outcome is obtained from the various study groups (26). To minimize the chances of misclassification, participants were classified into the acute or chronic PTMD group based on the basis of definition of chronic pain given by IASP based on which chronic pain is defined as "pain without apparent biological value that has persisted beyond the normal tissue healing time, which in the absence of any other pain criteria is taken to be 3 months" (63) (11). Furthermore, all participants received the clinical examination based on the DC/TMD protocol to decrease the chance of misdiagnosis. Additionally, it was used to validate and reliable questionnaires to assess pain intensity, oral parafunctional habits and psychological symptoms to decrease the chance of information bias.

To prevent or minimize recall bias, the multivariable analyses were adjusted by covariates that could modify the recall of oral parafunctional behaviours; pain intensity and psychological symptoms. The analyses were also adjusted by the location where participants were recruited to decrease the chance of selection bias.

6.2.2 Effect of confounders

Confounding is the mixing of the effect of exposure under study on the disease with that of the third factor (26). The third factor must be associated with the exposure and independent of

that exposure, be a risk of for the disease. Confounding can lead to overestimate or underestimate of the true association between exposure and disease and can even change the direction of the effect. Therefore, it is important to control the confounding factors. In the current case-control analysis, we used the multivariate model to adjust for potential confounders as age, sex, anxiety and depression symptoms based on the prior knowledge of confounding factors. The sensitivity analysis adjusted for the location where participants were recruited and pain intensity.

6.3 Strengths and limitations

This case-control study has many strengths; (i) all the instruments used in the study were validated; (ii) TMD diagnosis was made by TMD specialist/dentist that help to reduce chances of misdiagnosis; (iii) we used the multivariate model to adjust for the potential confounders; (iv) recruitment from the four different sites that help to reduce the chances of selection bias (v); and participation rate is high (97.8%).

Several measures used to overcome the limitations, as there were chances of misclassification; we used the chronic pain definition given by IASP to classify the acute and chronic PTMD groups (64). Furthermore, we adjusted the analysis for potentially confounding factors like age, sex, pain intensity, recruitment site, anxiety and depression based on the prior knowledge of the literature.

CHAPTER 7. CONCLUSIONS

The following conclusions can be drawn from the results of the current case-control analysis:

a) Chronic PTMD participants have higher odds of presenting with oral parafunctional behaviours relative to acute PTMD participants;

b) Oral parafunctional behaviours were more common among chronic PTMD participants relative to acute PTMD participants;

c) These associations were not biased by participant's demographics, psychological symptoms, pain intensity or the recruitment site;

d) Depression symptoms did not modify the association between chronic PTMD and oral parafunctional behaviour.

CHAPTER 8. CLINICAL RELEVANCE

PTMD is the second most common chronic pain after back pain. It is among one of the most common reasons why patient seeks treatment in dental settings. Splint therapy, pharmacotherapy and the self-management are commonly used to manage pain in PTMD patients. Regardless of the treatment received, at least 30% of patients complain of persistent pain. Therefore, it is important to treat PTMD before it becomes chronic. As stated by NIH, however, we do not know how acute pain progresses to chronic pain, there is a crucial need for identifying risk factors that implicated in the painful transition from acute to chronic.

The current study is the part of the large prospective cohort study ACTION aimed to identify the risk factors implicated in the pain transition from acute to chronic PTMD. Our study results suggest that oral parafunctional behaviours can contribute to the transition from acute to chronic PTMD.

CHAPTER 9. KNOWLEDGE TRANSLATION

Results of the case-control study was presented in the form of oral or poster presentation at national and international conferences; International Association for Dental Research (IADR, 2019, abstract accepted), International Association of study of pain (IASP, 2018), Canadian pain society (CPS 2018, 2019), McGill Research day (2018, 2019), McGill Pain day (2018, 2019) and Network for Oral and Bone Health Research (RSBO) (2018, abstract submitted for 2019). The manuscript for the first paper is to be sent for publication in July 2019.

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CHAPTER 11. APPENDIX

Consent forms and Questionnaires

ACTION PROGRAM BASELINE QUESTIONS FOR TEMPOROMANDIBULAR DISORDERS

Hospital	Patient Number	Initials	

Day	Month	Year

Please answer the following questions:

1. How old are you? _____ *years old*

2. Do you have pain in temple, face, jaw joint, or jaws once a week or more often?

☐ Yes ☐ No

3. Do you have pain when you open your month wide or chew, once a week or more often?

☐ Yes ☐ No

4. In the last 30 days, on average, how long did any pain in your jaw or temple area on either side last?

☐ No pain

☐ From very brief to more than a week, but it does stop

☐ Continuous

5. In the last 30 days, did you have pain or stiffness in your jaw on wakening?

☐ Yes ☐ No

6. 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. ☐ 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 or chewing gum. ☐ Yes ☐ No

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

7. Have you ever had pain in your jaw, temple, in the ear, or in front of the ear on either side?

   ☐ Yes ☐ No

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

   ___ Year(s) ___ Month(s)

9. How would you rate your facial pain right now?
   Please rate your pain by circling the number that tells how much pain you have right now.

No pain										Pain as bad as it could be
0	1	2	3	4	5	6	7	8	9	10

10. 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".

No pain										Pain as bad as it could be
0	1	2	3	4	5	6	7	8	9	10

11. 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)

No pain										Pain as bad as it could be
0	1	2	3	4	5	6	7	8	9	10

12. 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

13. In the last 30 days, how much has facial pain interfered with your daily activities? Use a scale where 0 is "no interference" and 10 is "unable to carry on any activities".

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

14. 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”.

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

15. 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”.

No interference										Unable to carry on any activities
0	1	2	3	4	5	6	7	8	9	10

16. How would you describe the duration of this pain in your jaw, temple, ear, or in front of the ear since it first began? *(Select ONE response)*

- ☐ Persistent – continuous pain since initial onset
- ☐ Recurrent – more than one bout of pain, with periods of no pain
- ☐ One time – a prior episode of pain that has ended

17. 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? (Select ONE response)

- ☐ No pain
- ☐ Pain comes and goes
- ☐ Pain is always present

18. In the last 30 days, how many days per month have you had this pain in your jaw, temple, in the ear, or in front of the ear? *(Select ONE response)*

- ☐ Less than 1 day
- ☐ 1 day or more, but less than 15 days
- ☐ 15 days or more, but not continuous
- ☐ Continuous

19. On average, how long does a single episode of this pain in your jaw, temple, in the ear, or in front of the ear last? *(Select ONE response)*

- ☐ Less than 30 minutes per episode
- ☐ 30 minutes to less than 2 hours per episode
- ☐ 2 hours to less than 4 hours per episode
- ☐ 4 hours to 72 hours (3 days) per episode
- ☐ More than 3 days to 7 days per episode
- ☐ More than 7 days of continuous pain per episode

20. In the last 30 days, have you had any headaches?

☐ Yes ☐ No

If you answered NO to question 20, skip to Question 24.

21. How many years or months ago did your headache first begin?

___ Year(s) ___ Month(s)

22. In the last 30 days, rate the intensity, on average, of your headache? *(Select ONE response)*

- ☐ Mild to moderate
- ☐ Moderate to severe

23. Where is the headache located? *(Mark ALL that apply)*

- ☐ Temple
- ☐ Front of head
- ☐ Top of head
- ☐ Back of head
- ☐ Behind the eyes or inside the head

24. In the last 30 days, have you had any jaw joint noise(s) when you moved or used your jaw?

☐ Yes ☐ No

25. Have you ever had your jaw lock or catch, even for a moment, so that it would not open ALL THE WAY?

☐ Yes ☐ No

If you answered NO to question 25, skip to question 29.

26. Was your jaw locked or caught severely enough to limit your jaw opening and interfere with your ability to eat?

☐ Yes ☐ No

27. Is your jaw currently locked or limited so that your jaw will not open ALL THE WAY?

☐ Yes ☐ No

28. At any time in your life, 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?

☐ Yes ☐ No

29. What treatments did you receive for your pain?

☐ Dental extraction

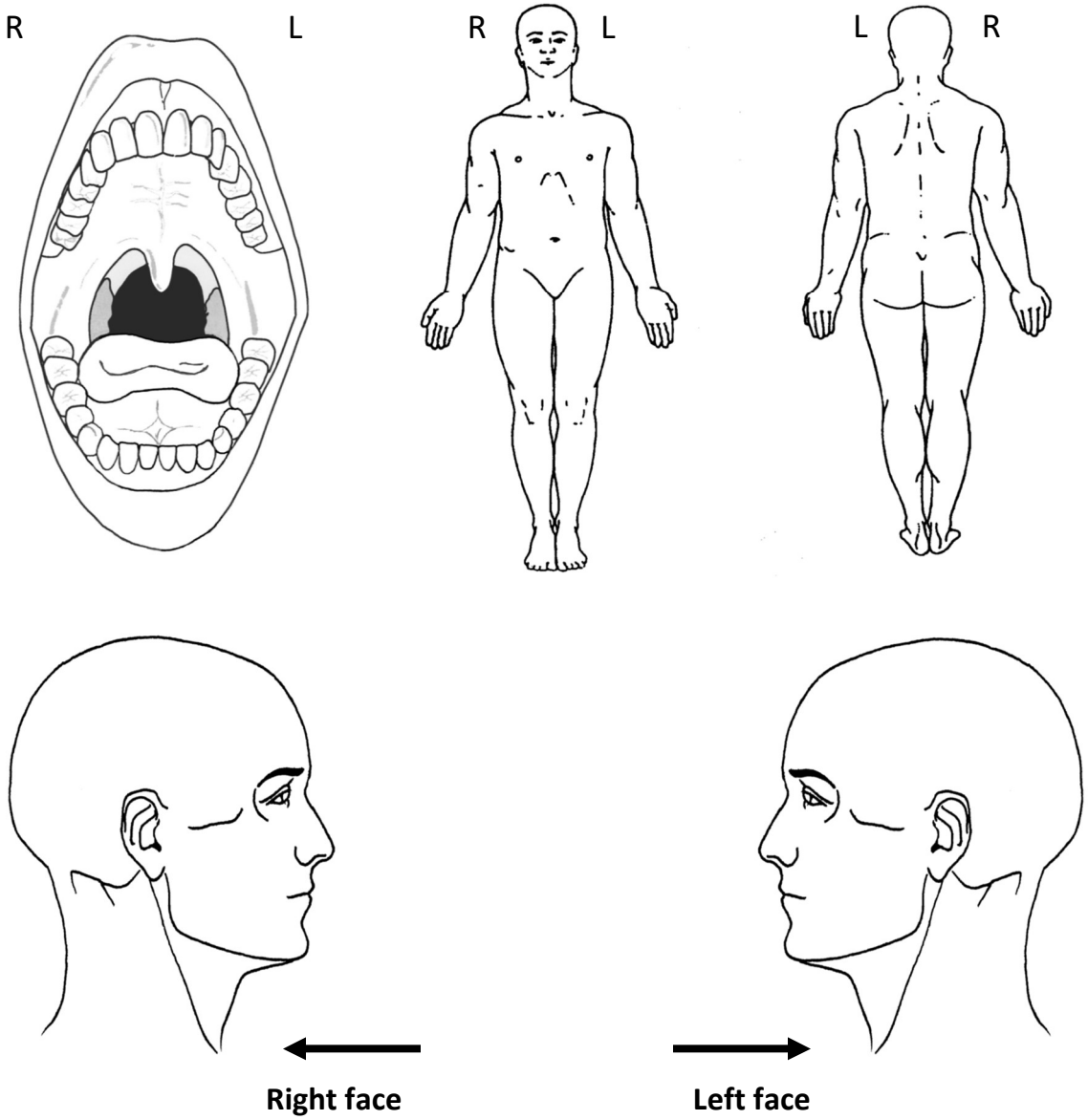
☐ Orthodontics treatment

30. Do you have:

Condition	*Yes*	*No*	*Medication for condition*
a. Diabetes	☐	☐	
b. Allergies (Penicillin/Medication)	☐	☐	
c. Thyroid problem	☐	☐	
d. Rheumatic fever	☐	☐	
e. High blood pressure	☐	☐	
f. Low blood pressure	☐	☐	
g. Smoking (per day)	☐	☐	
h. Asthma	☐	☐	
i. Heart problems	☐	☐	
j. Pain in arms	☐	☐	
k. Pain in legs	☐	☐	
l. Pain in chest	☐	☐	
m. Pain in neck	☐	☐	
n. Pain in back	☐	☐	
o. Pain in abdomen	☐	☐	

31. Pain Diagram

Indicate the location of ALL of your different pains by shading in the area, using the diagrams that are most relevant. If there is an exact spot where the pain is located, indicate the pain with a solid dot (●)*. If your pain moves from one location to another, use arrows to show the path.*



32. On which side of the face is the pain more severe?

☐ Left side ☐ Right side ☐ Both sides equally

33. Using the scale below, please indicate the degree to which you have these feelings.

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
A. Feeling nervous, anxious or on edge	0	1	2	3
B. Not being able to stop or control worrying	0	1	2	3
C. Worrying too much about different things	0	1	2	3
D. Trouble relaxing	0	1	2	3
E. Being so restless that is hard to sit still	0	1	2	3
F. Becoming easily annoyed or irritable	0	1	2	3
G. Feeling afraid as if something might happen	0	1	2	3

34. Using the scale below, please indicate the degree to which you have these feelings.

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
A. Little interest or pleasure in doing things.	0	1	2	3
B. Feeling down, depressed, or hopeless.	0	1	2	3
C. Trouble falling or staying asleep, or sleeping too much.	0	1	2	3
D. Feeling tired or having little energy.	0	1	2	3
E. Poor appetite or overeating.	0	1	2	3
F. Feeling bad about yourself – or that you are a failure or have let yourself or your family down.	0	1	2	3
G. Trouble concentrating on things, such as reading the newspaper or watching television.	0	1	2	3
H. Moving or speaking so slowly that other people could have noticed or the opposite - being so fidgety or restless that you have been moving around a lot more than usual.	0	1	2	3

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐	☐	☐	☐

35. Please answer the following questions about yourself by indicating the extent of your agreement:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
A. In uncertain times, I usually expect the best.					
B. It's easy for me to relax					
C. If something can go wrong for me, it will.					
D. I'm always optimistic about my future.					
E. I enjoy my friends a lot.					
F. It's important for me to keep busy.					
G. I hardly ever expect things to go my way.					
H. I don't get upset too easily.					
I. I rarely count on good things happening to me.					
J. Overall, I expect more good things to happen to me than bad.					

36. Have you undergone any tooth extraction?

☐ Yes ☐ No

If you answered "Yes", for what reason?

☐ Because of pain ☐ Do not remember ☐ Not because of pain

37. Have you received any orthodontics treatment?

☐ Yes ☐ No

If you answered "Yes", for what reason?

☐ Because of pain ☐ Do not remember ☐ Not because of pain

38. Write down the number corresponding to your choice in the right hand column.

Included: ☐ **Yes** ☐ **No**

0 = No chance of dozing
1 = Slight chance of dozing
2 = Moderate chance of dozing
3 = High chance of dozing

Situation	Chance of dozing
Sitting and reading	
Watching TV	
Sitting inactive in a public place (e.g. a theather or a meeting)	
As a passenger in a car for an hour without a break	
Lying down to rest in the afternoon when circumstances permit	
Sitting and talking to someone	
Sitting quietly after a lunch without alcohol	
In a car, while stopped for a few minutes in traffic	

39. Write your response (*Yes* or *No*) in the right hand column.

Questions	Yes or No
S- Snoring: Do you snore loudly (louder than talking or loud enough to be heard through closed doors)?	
T- Tired: Do you feel tired, fatigued, or sleepy during daytime?	
O- Observed: Has anyone observed you stop breathing during sleep?	
P- Blood Pressure: Do you have or are you being treated for high blood pressure?	
B- BMI: Body mass index > 35	
A- Age: Age over 50 years old?	
N- Neck: Neck circumference or collar size > 40 cm?	
G- Gender: Male gender?	

40. The Fatigue Severity Scale (FSS) is a method of evaluating the impact of fatigue on you.

This tool allows assessing the impact of fatigue on you. This is a short questionnaire that asks youto rate your level of fatigue. It contains nine statements that rate the severity of your fatigue symptoms.

Read each statement and circle a number from 1 to 7, based on how accurately it reflects your condition during the past week and the extent to which you agree or disagree that the statement applies to you.

A low value (e.g., 1) indicates strong disagreement with the statement, whereas a high value (e.g., 7) indicates strong agreement. It is important to surround a number (1-7) for each question.

During the past week, I have found that:	**Disagree ⟷ Agree**						
My motivation is lower when I am fatigued.	1	2	3	4	5	6	7
Exercise brings on my fatigue.	1	2	3	4	5	6	7
I am easily fatigued.	1	2	3	4	5	6	7
Fatigue interferes with my physical functioning	1	2	3	4	5	6	7
Fatigue causes frequent problems for me.	1	2	3	4	5	6	7
My fatigue prevents sustained physical functioning.	1	2	3	4	5	6	7
Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3	4	5	6	7
Fatigue is among my three most disabling symptoms.	1	2	3	4	5	6	7
Fatigue interferes with my work, family, or social life.	1	2	3	4	5	6	7
					Total :		

41. The Insomnia Severity Index has seven questions. For each question:

Please CIRCLE the number that best describes your answer.

Please rate the CURRENT (i.e. LAST 2 WEEKS) SEVERITY of your insomnia problem(s).

Insomnia Problem	None	Mild	Moderate	Severe	Very Severe
1) Difficulty falling asleep	0	1	2	3	4
2) Difficulty staying asleep	0	1	2	3	4
3) Problems waking up too early	0	1	2	3	4

4) How SATISFIED/DISSATISFIED are you with your CURRENT sleep pattern?

Very satisfied	Satisfied	Moderately satisfied	Dissatisfied	Very Dissatisfied
0	1	2	3	4

5) How NOTICEABLE to others do you think your sleep problem is in terms of impairing the quality of your life?

Not at all Noticeable	A Little	Somewhat	Much	Very Much Noticeable
0	1	2	3	4

6) How WORRIED/STRESSED are you about your current sleep problem?

Not at all Worried	A Little	Somewhat	Much	Very Much Worried
0	1	2	3	4

7) To what extent do you consider your sleep problem to INTERFERE with your daily functioning (e.g. daytime fatigue, mood, ability to function at work/daily chores, concentration, memory, etc.) CURRENTLY?

Not at all Interfering	A Little	Somewhat	Much	Very Much Interfering
0	1	2	3	4

To be completed by researcher only

Diagnosis: _____

_____

_____

_____

Treatment received during baseline appointment: _____

_____

_____

_____

Additional notes: _____

_____

_____

_____

_____

_____

_____

_____

The Oral Behavior Checklist

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

	Activities During Sleep	None of the time	< 1 Night /Month	1-3 Nights /Month	1-3 Nights /Week	4-7 Nights/ Week
1	Clench or grind teeth **when asleep**, based on any information you may have	☐	☐	☐	☐	☐
2	Sleep in a position that puts pressure on the jaw (for example, on stomach, on the side)	☐	☐	☐	☐	☐
	Activities During Waking Hours	**None of the time**	**A little of the time**	**Some of the time**	**Most of the time**	**All of the time**
3	Grind teeth together **during waking hours**	☐	☐	☐	☐	☐
4	Clench teeth together **during waking hours**	☐	☐	☐	☐	☐
5	Press, touch, or hold teeth together other than while eating (that is, contact between upper and lower teeth)	☐	☐	☐	☐	☐
6	Hold, tighten, or tense muscles without clenching or bringing teeth together	☐	☐	☐	☐	☐
7	Hold or jut jaw forward or to the side	☐	☐	☐	☐	☐
8	Press tongue forcibly against teeth	☐	☐	☐	☐	☐
9	Place tongue between teeth	☐	☐	☐	☐	☐
10	Bite, chew, or play with your tongue, cheeks or lips	☐	☐	☐	☐	☐
11	Hold jaw in rigid or tense position, such as to brace or protect the jaw	☐	☐	☐	☐	☐
12	Hold between the teeth or bite objects such as hair, pipe, pencil, pens, fingers, fingernails, etc	☐	☐	☐	☐	☐
13	Use chewing gum	☐	☐	☐	☐	☐
14	Play musical instrument that involves use of mouth or jaw (for example, woodwind, brass, string instruments)	☐	☐	☐	☐	☐
15	Lean with your hand on the jaw, such as cupping or resting the chin in the hand	☐	☐	☐	☐	☐
16	Chew food on one side only	☐	☐	☐	☐	☐
17	Eating between meals (that is, food that requires chewing)	☐	☐	☐	☐	☐
18	Sustained talking (for example, teaching, sales, customer service)	☐	☐	☐	☐	☐
19	Singing	☐	☐	☐	☐	☐
20	Yawning	☐	☐	☐	☐	☐
21	Hold telephone between your head and shoulders	☐	☐	☐	☐	☐

Hôpital			No. Patient	Initiales	
Jour	**Mois**	**Année**			

S'il-vous-plaît répondez aux questions suivantes:

1. Quel âge avez-vous? _____ *ans*

2. Avez-vous mal à la tempe, au visage, aux mâchoires, ou aux articulations des mâchoires, une fois par semaine ou plus souvent?

☐ Oui ☐ Non

3.Avez-vous des douleurs lorsque vous ouvrez votre bouche ou mâcher, une fois par semaine ou plus souvent?

☐ Oui ☐ Non

4. Au cours des 30 derniers jours, quelle était la durée de toute douleur que vous avez peut-être ressentie dans la/les mâchoire/s ou au niveau de la/des tempe/s?

☐ Pas de douleur

☐ De très brève durée à plus d'une semaine, mais ça s'arrête

☐ Continue

5. Ces 30 derniers jours, avez-vous eu de la douleur ou rigidité dans votre mâchoire au réveil?

☐ Oui ☐ No

6. Ces 30 derniers jours, est-ce-que les activités suivantes ont changé la douleur (c'est-à-dire, s'est améliorée, s'est empirée) à la mâchoire, à la tempe, à l'oreille, ou devant l'oreille des deux côtés?

A. Mâcher de la nourriture dure. ☐ Oui ☐ Non

B. Ouvrir la bouche, ou bouger la mâchoire en avant en avant ou sur le côté. ☐ Oui ☐ Non

C. Des habitudes de fonction telles que maintenir les dents serrées, ou mâcher de la gomme. ☐ Oui ☐ Non

D. D'autres activités telles que parler, embrasser ou bailler. ☐ Oui ☐ Non

7. Avez-vous déjà eu de la douleur à la mâchoire, la tempe, dans l'oreille ou en avant de l'oreille d'un côté ou de l'autre?

   ☐ Oui ☐ Non

8. Il y a combien d'années ou de mois qu'a débuté, pour la première fois, votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille?

   ___ Année(s) ___ Mois

9. Veuillez encercler le numéro qui décrit le mieux le niveau de douleur faciale que vous ressentez en ce moment.
   Utilisez une échelle de 0 à 10, où 0 indique «aucune douleur» et 10 indique «la pire douleur possible».

   Aucune douleur — La pire douleur possible
   0 1 2 3 4 5 6 7 8 9 10

10. Quel est le chiffre qui décrit la plus forte douleur faciale que vous avez ressentie au cours des 30 derniers jours.
    Utilisez la même échelle, où 0 indique « aucune douleur » et 10 indique «la pire douleur possible».

    Aucune douleur — La pire douleur possible
    0 1 2 3 4 5 6 7 8 9 10

11. Quel est le chiffre qui décrit le niveau de douleur faciale que vous avez ressenti en général au cours des 30 derniers jours.
    Utilisez la même échelle, où 0 indique «aucune douleur» et 10 indique «la pire douleur possible».

    Aucune douleur — La pire douleur possible
    0 1 2 3 4 5 6 7 8 9 10

12. Ces 30 derniers jours, combien de jours avez-vous été empêché(e) de faire vos activités habituelles tel que emploi, école/cours, ou travaux ménagers par votre douleur faciale? (*tous les jours = 30 jours*)

    ___ Jours

13. Jusqu'à quel point votre douleur faciale a interféré avec vos activités quotidiennes des 30 derniers jours.*Utilisez une échelle de 0 à 10, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».*

    Aucune interférence — Incapable d'exécuter les activités quotidiennes
    0 1 2 3 4 5 6 7 8 9 10

14. Jusqu'à quel point votre douleur faciale vous a empêché de prendre part à des activités sociales, familiales et récréatives au cours des 30 derniers jours. *Utilisez la même échelle, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes».*

Aucune interférence										Incapable d'exécuter les activités quotidiennes
0	1	2	3	4	5	6	7	8	9	10

15. Jusqu'à quel point votre douleur faciale vous a empêché de faire votre travail au cours des 30 derniers jours (incluant les taches domestique)? *Utilisez la même échelle, où 0 indique «aucune interférence» et 10 indique «incapable d'exécuter les activités quotidiennes»*.

Aucune interférence										Incapable d'exécuter les activités quotidiennes
0	1	2	3	4	5	6	7	8	9	10

16. Quel énoncé s'applique à la durée de cette douleur à la mâchoire, tempe, oreille, ou en avant de l'oreille depuis son apparition? (Choisir une seule réponse)

- ☐ Persistante - une douleur continue depuis le début
- ☐ Récurrente - plus d'un épisode de douleur, avec des périodes sans douleur
- ☐ Une fois - un épisode de douleur qui s'est terminé

17. Au cours des 30 derniers jours, laquelle des propositions suivantes décrit le mieux votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille d'un côté ou de l'autre? (Choisir une seule réponse?

- ☐ Aucune douleur
- ☐ La douleur qui vient et disparaît
- ☐ La douleur est toujours présente

18. Au cours des 30 derniers jours, combien de jours avez-vous eu votre douleur à la mâchoire, tempe, dans l'oreille ou en avant de l'oreille? (Choisir une seule réponse)

- ☐ Moins de 1 jour
- ☐ Un jour et plus, mais moins de 15 jours
- ☐ 15 jours et plus, mais pas continuellement
- ☐ Continuellement

19. En moyenne, combien de temps dure un seul épisode de votre douleur à la mâchoire, tempe, dans l'oreille, ou en avant de l'oreille ? (Choisir une seule réponse)

- ☐ Moins de 30 minutes par épisode
- ☐ 30 minutes à moins de 2 heures par épisode
- ☐ 2 heures à moins de 4 heures par épisode
- ☐ 4 heuresà 72 heures (3 jours) par épisode
- ☐ Plus de 3 jours à to 7 parépisode
- ☐ Plus de 7 jours à continuellement par épisode

20. Au cours des 30 derniers jours, avez-vous eu des maux de tête?

☐ Oui ☐ Non

Si vous avez répondu NONà la question 20, passez à la question 24.

21. Il y a combien d'années ou de mois que votre mal de tête débuté pour la première fois?

___ Année(s) ___ Mois

22. Au cours des 30 derniers jours, évaluez l'intensité en moyenne de votre mal de tête à la tempe. (Choisir une seule réponse)

- ☐ Légère à modérée
- ☐ Modérée à sévère

23. Où est le mal de tête situé?*(Cochez TOUT ce qui s'applique)*

- ☐ Tempe
- ☐ Front
- ☐ Dessus de la tête
- ☐ Arrière de la tête
- ☐ Derrière les yeux ou à l'intérieur de la tête

24. Au cours des 30 derniers jours, avez-vous eu des bruits dans l'articulation de la mâchoire lorsque vous bougez ou utilisez votre mâchoire?

☐ Oui ☐ Non

25. Avez-vous déjà eu la mâchoire bloquée ou coincée au point de ne pouvoir l'ouvrir COMPLÈTEMENT?

☐ Oui ☐ Non

Si vous avez répondu NON à la question 25, passez à la question 29.

26. Est-ce-que le blocage ou coincement de votre mâchoire était suffisamment sévère pour limiter son ouverture et interférer avec votre capacité à manger?

☐ Oui ☐ Non

27. Est-ce que votre mâchoire est actuellement bloquée ou limitée au point de ne pouvoir l'ouvrir COMPLÈTEMENT?

☐ Oui ☐ Non

28. À n'importe quel moment de votre vie lorsque vous avez ouvert la bouche grande, avez-vous déjà eu la mâchoire bloquée ou coincée, même pour un instant, au point de nepouvoir la fermer de cette position grande ouverte?

☐ Oui ☐ Non

29. Quels traitements avez-vouz reçus contre la douleur?

☐ Extraction dentaire

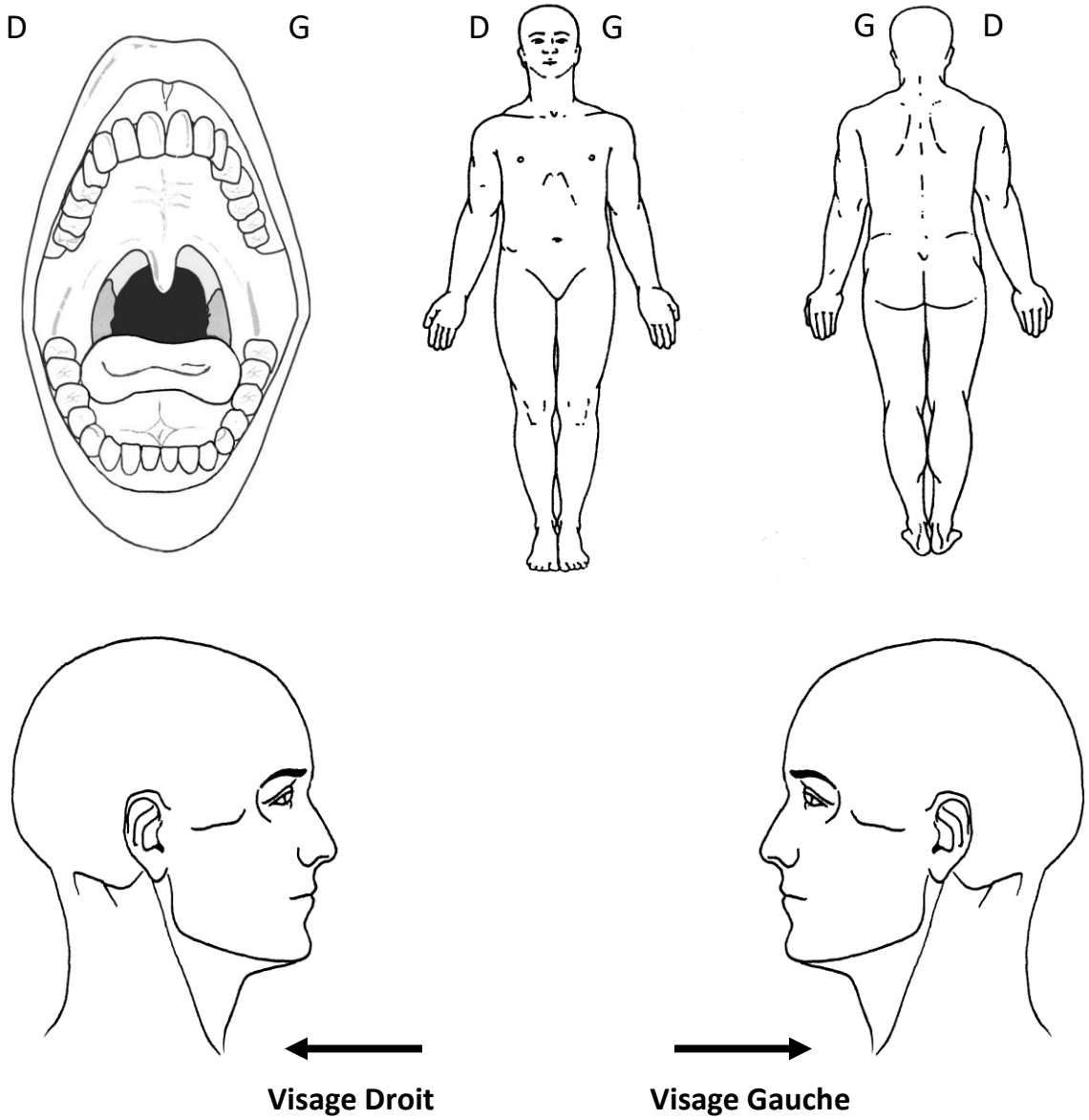
☐ Traitement orthodontique

30. Avez-vous ces conditions suivantes?

Condition	*Oui*	*Non*	*Médicament(s) pour la condition*
a. Diabète	☐	☐	
b. Allergies (Pénicilline/Médicaments)	☐	☐	
c. Problème de thyroïde	☐	☐	
d. Fièvre rhumatismale	☐	☐	
e. Haute pression sanguine	☐	☐	
f. Basse pression sanguine	☐	☐	
g. Fumez-vous? (nombre par jour)	☐	☐	
h. Asthme	☐	☐	
i. Problème cardiaque	☐	☐	
j. Douleur aux bras	☐	☐	
k. Douleur aux jambes	☐	☐	
l. Douleur à la poitrine	☐	☐	
m. Douleur au cou	☐	☐	
n. Douleur au dos	☐	☐	
o. Douleur à l'abdomène	☐	☐	

31. Diagramme de douleur

Indiquez l'emplacement de TOUTES vos douleurs différentes en colorant la zone, sur lesillustrations appropriées. S'il ya un endroit précis où la douleur est localisée, indiquer la douleur avec un point solide (●). *Si votre douleur bouge d'un endroit à un autre, utilisez des flèches pour indiquer la trajectoire.*



32. De quel côté du visage la douleur est-elle plus sévère?

☐ Côté gauche ☐ Côté droit ☐ Les deux côtés également

33. En utilisant l'échelle ci-dessous, s'il-vous-plaît indiquez la mesure dans laquelle vous avez ces sentiments.

Au cours des 14 derniers jours, à quelle fréquence avez-vous été dérangé(e) par les problèmes suivants?	Jamais	Plusieurs jours	Plus de la moitié des jours	Presque tous les jours
A. Sentiment de nervosité, d'anxiété ou de tension.	0	1	2	3
B. Incapable d'arrêter de vous inquiéter ou de contrôler vos inquiétudes.	0	1	2	3
C. Inquiétudes excessive à propos de tout et de rien.	0	1	2	3
D. Difficulté à se détendre.	0	1	2	3
E. Agitation telle qu'il est difficile de rester tranquille.	0	1	2	3
F. Devenir facilement Contrarie(e) ou irritable.	0	1	2	3
G. Avoir peur que quelque chose d'épouvantable puisse arriver.	0	1	2	3

34. En utilisant l'échelle ci-dessous, s'il-vous-plaît indiquez la mesure dans laquelle vous avez ces sentiments.

Au cours des 14 derniers jours, à quelle fréquence avez-vous été dérangé(e) par les problèmes ou états suivants?	Jamais	Plusieurs jours	Plus de 7 jours	Presque tous les jours
A. Peu d'intérêt ou de plaisir à faire des choses	0	1	2	3
B. Se sentir triste, déprimé(e) ou désespéré(e)	0	1	2	3
C. Difficultés à s'endormir ou à rester endormi(e), ou trop dormir	0	1	2	3
D. Se sentir fatigué(e) ou avoir peu d'énergie	0	1	2	3
E. Peu d'appétit ou trop manger	0	1	2	3
F. Mauvaise perception de vous-même – ou vous pensez que vous êtes un perdant ou que vous n'avez pas satisfaits vos propres attentes ou celles de votre famille	0	1	2	3
G. Difficultés à se concentrer sur des choses tel que lire le journal ou regarder la télévision	0	1	2	3
H. Vous bougez ou parlez si lentement que les autres personnes ont pu le remarquer. Ou au contraire – vous êtes si agité(e) que vous bougez beaucoup plus que d'habitude	0	1	2	3

Si vous avez cochez au moins un des problèmes nommés dans ce questionnaire, répondez a la question suivante : Dans quelle mesure ce(s) problème(s) a-t-il (ont-ils) rendu difficile votre travail, vos taches à la maison ou votre capacité a bien vous entendre avec les autre?

☐ Pas du tout difficile ☐ Plutôt difficile ☐ Très difficile ☐ Extrêmement

35. S'il-vous-plaît répondez aux questions suivantes sur vous-même en indiquant la mesure de votre accord :

	Totalement en désaccord	Plutôt en désaccord	Neutre	Plutôt d'accord	Totalement d'accord
A. Dans les moments d'incertitude, je m'attends habituellement au mieux					
B. J'ai de la facilitéà me relaxer					
C. S'il y a des chances que ça aille mal pour moi, ça ira mal					
D. Je suis toujours optimiste face à mon avenir					
E. J'apprécie beaucoup mes amis(e)s					
F. C'est important pour moi de me tenir occupé(e)					
G. Je ne m'attends presque jamais à ce que les choses aillent comme je le souhaite					
H. Je ne me fâche pas très facilement					
I. Je m'attends rarement à ce que de bonnes choses m'arrivent					
J. Dans l'ensemble, je m'attends à ce qu'il m'arrive plus de bonnes choses que de mauvaises					

36. Avez-vousdéjà subi une extraction dentaire?

☐ Oui ☐ Non

Si vous avez répondu « Oui », pour quelle raison?

☐ Parce que j'avais mal ☐ Je ne m'en souviens pas ☐ Pas à cause de la douleur

37. Avez-vous déjà eu un traitement orthodontique?

☐ Oui ☐ Non

Si vous avez répondu « Oui », pour quelle raison?

☐ Parce que j'avais mal ☐ Je ne m'en souviens pas ☐ Pas à cause de la douleur

38. Écrivez le numéro correspondant à votre choix dans la colonne de droite.

Inclu: ☐ **Oui** ☐ **Non**

0 = Aucun risque de m'assoupir ou de m'endormir
1 = Faible risque de m'assoupir ou de m'endormir
2 = Risque modéré de m'assoupir ou de m'endormir
3 = Risque élevé de m'assoupir ou de m'endormir

Situations	Scores (0, 1, 2 ou 3)
Lire en position assise	
Regarder la télévision	
Être assis(e) inactif(ve) dans un lieu public (par exemple théâtre, réunion etc.)	
Être assis(e) en tant que passager(ère) dans un véhicule pour une période d'une heure sans arrêt	
Être étendu(e) l'après-midi lorsque les circonstances le permettent	
Être assis(e) en parlant avec quelqu'un	
Être assis(e) tranquille après un repas sans boisson alcoolique	
Dans une voiture arrêtée quelques minutes a un feu de circulation ou dans la circulation	

39. Inscrivez votre réponse (*Oui* ou *Non*) dans la colonne de droite.

Questions	Oui ou Non
Ronflements **Ronflez**-vous **fort** (suffisamment fort pour qu'on vous entende à travers une porte fermée ou pour que votre partenaire vous donne des coups de coude parce que vous ronflez) ?	
Fatigue Vous sentez-vous souvent **fatigué(e)**, **épuisé(e)** ou **somnolent(e)** pendant la journée (comme par exemple s'endormir au volant) ?	
Observation Quelqu'un a-t-il **observé** que vous **arrêtiez de respirer** ou que **vous vous étouffiez/suffoquiez** pendant votre sommeil ?	
Tension Êtes-vous atteint(e) d'**hypertension artérielle** ou êtes-vous traité(e) pour ce problème ?	
Indice de Masse Corporelle supérieur à 35 kg/m^2 ?	
Âge supérieur à 50 ans?	
Tour de cou important (mesuré au niveau de la pomme d'Adam) Pour les hommes, votre tour de cou est-il supérieur ou égal à 43 cm ? Pour les femmes, votre tour de cou est-il supérieur ou égal à 41 cm ?	
Sexe = Masculin?	

40. Fatigue Severity Scale (FSS) des troubles du sommeil.

Cet outil permet d'évaluer l'impact de la fatigue sur vous. Il s'agit d'un court questionnaire qui vous demande de mesurer votre niveau de fatigue. Il contient neuf affirmations qui mesurent la sévérité des symptômes de votre fatigue.

Lisez chaque affirmation et entourez un nombre de 1 à 7 qui semble correspondre à votre état de fatigue durant la semaine dernière.

• Une valeur basse (1) indique que vous n'êtes pas d'accord avec l'affirmation, tandis qu'une valeur haute (7) indique que vous êtes d'accord avec l'affirmation proposée.

• Il est important d'entourer un nombre (1 à 7) pour chaque question.

Durant la semaine passée, j'ai trouvé que :	**Pas d'accord ⟷ D'accord**						
Ma motivation est plus basse quand je suis fatigué (e)	1	2	3	4	5	6	7
Les exercices me demandent des efforts	1	2	3	4	5	6	7
Je suis facilement fatigué(e)	1	2	3	4	5	6	7
La fatigue interfère avec mes fonctions physiques	1	2	3	4	5	6	7
La fatigue me cause souvent des problèmes	1	2	3	4	5	6	7
Ma fatigue empêche certaines fonctions physiques	1	2	3	4	5	6	7
La fatigue m'empêche de mener à bien certaines obligations et responsabilités	1	2	3	4	5	6	7
La fatigue est parmi mes 3 symptômes les plus handicapants	1	2	3	4	5	6	7
La fatigue interfère avec mon travail, ma famille ou ma vie sociale	1	2	3	4	5	6	7
					Total :		

41. L'Indice de gravité Insomnia a sept questions. Pour chaque question:

S'il-vous-plaît encerclez le numéro qui décrit le mieux votre réponse. Veuillez noter la SÉVÉRITÉ COURANTE (à savoir, 2 dernières semaines) de votre problème d'insomnie .

Problème d'insomnie	Aucune	Légère	Moyenne	Élevée	Extrême
1) Difficulté à s'endormir	0	1	2	3	4
2) Difficulté à rester endormi(e)	0	1	2	3	4
3) Problème de réveil trop tôt le matin	0	1	2	3	4

4) À quel point êtes-vous SATISFAIT(E) / INSATISFAIT(E) de votre sommeil actuel ?

Très satisfait(e)	Satisfait(e)	Neutre	Insatisfait(e)	Très insatisfait(e)
0	1	2	3	4

5)À quel point considérez-vous que vos difficultés de sommeil sont APPARENTES pour les autres en termes de détérioration de la qualité de vie ?

Aucunement	Légèrement	Moyennement	Extrêmement	Très Extrêmement
0	1	2	3	4

6) À quel point êtes-vous INQUIET(ÈTE) / PRÉOCCUPÉ(E) à propos de vos difficultés de sommeil actuelles ?

Aucunement	Légèrement	Moyennement	Extrêmement	Très Extrêmement
0	1	2	3	4

7) À quel point considérez-vous que vos difficultés de sommeil PERTURBENT votrefonctionnement quotidien (ex. : fatigue, concentration, mémoire, humeur) ACTUELLE?

Aucunement	Légèrement	Moyennement	Extrêmement	Très Extrêmement
0	1	2	3	4

À compléter par le/la chercheur/e

Diagnosis: _____

_____

_____

_____

Treatment received during baseline appointment: _____

_____

_____

_____

Additional notes: _____

_____

_____

_____

_____

_____

_____

_____

Faculté de médecine dentaire
Université Laval

CLINIQUE DE DESORDRES TEMPOROMANDIBULAIRES

Dossier # : _____

Nom: _____ **Date :** _____

HABITUDES ORALES

Activités durant le sommeil	Pas du tout	< 1 nuit / mois	1-3 nuits / mois	1-3 nuits / sem.	4-7 nuits / sem.
1. Serrer ou grincer des dents en dormant, basé sur n'importe quelle information vous pouvez avoir	☐	☐	☐	☐	☐
2. Dormir dans une position qui met une pression sur votre mâchoire (ex. : sur le ventre ou le côté)	☐	☐	☐	☐	☐

Activités durant les heures d'éveil	Pas du tout	Un peu	Partie du temps	Plupart du temps	Tout le temps
3. Grincer des dents durant le jour	☐	☐	☐	☐	☐
4. Serrer les dents ensemble durant le jour	☐	☐	☐	☐	☐
5. Presser, toucher ou garder les dents ensemble à d'autre moments qu'en mangeant (i.e. contact entre les dents du haut et du bas)	☐	☐	☐	☐	☐
6. Crisper, serrer ou raidir les muscles sans serrage ou mettre les dents ensembles	☐	☐	☐	☐	☐
7. Tenir ou envoyer la mâchoire vers l 'avant ou sur le côté	☐	☐	☐	☐	☐
8. Presser la langue fortement contre les dents	☐	☐	☐	☐	☐
9. Placer la langue entre les dents	☐	☐	☐	☐	☐
10. Mordre, mâchouiller ou jouer avec la langue, les joues ou les lèvres	☐	☐	☐	☐	☐
11. Tenir ou garder la mâchoire rigide ou raide pour l'immobiliser ou la protéger	☐	☐	☐	☐	☐
12. Tenir entre les dents ou mordre des objets tel que crayon, stylo, doigt, ongle, cheveux, pipe	☐	☐	☐	☐	☐
13. Mâcher de la gomme	☐	☐	☐	☐	☐
14. Jouer un ou des instruments de musique qui utilise la bouche ou la mâchoire (tel que la flûte, violon, corps, trompette, saxophone)	☐	☐	☐	☐	☐
15. Appuyer la mâchoire sur la main tel que mettre le menton dans sa main	☐	☐	☐	☐	☐
16. Mastiquer la nourriture sur un côté seulement	☐	☐	☐	☐	☐
17. Manger entre les repas (aliments qui demandent à être mastiquer)	☐	☐	☐	☐	☐
18. Parler continuellement (ex. : enseigner, vendre, service à la clientèle)	☐	☐	☐	☐	☐
19. Chanter	☐	☐	☐	☐	☐
20. Bailler	☐	☐	☐	☐	☐
21. Tenir le téléphone entre l'épaule et la tête	☐	☐	☐	☐	☐

Centre universitaire de santé McGill | McGill University Health Centre

Hôpital général juif | Jewish General Hospital

McGill

Consent Form

Transition from acute to chronic painful temporomandibular disorders: A prospective cohort study

You are being invited to participate in a study regarding transition from acute to chronic Temporomandibular Disorder 'called TMD', a type of facial pain. You have been selected as we are interested in understanding what may predict health wellbeing associated with facial pain. You have the right to know about the purposes and procedures that are be used in this study and to be informed about its potential benefits, risks and any discomfort that may occur. There is no compensation for your participation. Before you agree to take part in this study, it is important that you read the information in this consent form. You should ask as many questions as you need to in order to understand what you will be asked to do. Your participation is voluntary.

Purpose of this study:

The purpose of this study is to identify the possibilities of having a TMD-related pain and determine the factors associated with this facial pain.

Procedures:

If you agree to participate in our study, you will be asked to do the following:

- You will be invited to complete a questionnaire on the day of your dental appointment (today), and at 3 and 6 months after this first interview. If you cannot do so, we will ask you to complete it at a later time and mail it back to us in a postage-paid envelope that will be provided to you. If you cannot return this questionnaire, a telephone interview will then be conducted by the research assistant. The completion of the questionnaire may take on average 10 to 20 minutes. The 3 and 6 months follow-up interviews take less than five minutes to complete and can be done either by telephone or via an online survey. If you choose the online survey, you will be entered in a bi-annual draw to win one of five $20 Amazon gift cards after all questionnaires have been completed.
- Allow us to collect saliva (5-10 ml) on the day of the first interview. To collect the saliva, the research assistant will ask you to spit into a sterilized centrifuge tube. No hospitalization is required for this purpose. The duration of saliva collection will take a maximum of 10 minutes. Saliva samples will be used to assess if the composition of the saliva is related to TMD-related pain.
- The research team will ask you about your general health using a brief questionnaire. We will see if you have high blood pressure, diabetes, thyroid problem, allergy, and asthma. We will do that to see if these factors may predict health wellbeing associated with facial pain.
- The questions which are going to be asked in the study will help to identify the individuals with TMD, as well as to measure the level of pain and disability related to this condition. Other questions will evaluate the level of general health and psychological characteristics (e.g., anxiety and depression).

Risks, Disadvantages and Side-Effects:
You will be interviewed by the research assistant. If you feel uncomfortable to answer any of the questions, you are free to stop or skip that question and move on to the next one. This interview will take a maximum of 20 minutes of your time.

Benefits:
There is no direct benefit to participate in this study. However, this study will provide the medical and dental community with more definitive evidence of factors that may increase the chance of this type of facial pain. The results of this study may contribute to the development of personalized programs to improve TMD pain management.

Voluntary participation / withdrawal:
Your participation in this study is voluntary. Whether you accept or decline to participate in this study, your future dental care and your patient-doctor relationship will not be affected in any way. You may choose to participate now and decide to stop your participation at any time. If you decide to withdraw from the study, all information obtained about you up to the point of your withdrawal will be kept to preserve the scientific integrity of the study. Upon your withdrawal, you can request to have your saliva samples destroyed.

Confidentiality:
While you take part in this research study, the researcher in charge and study staff will collect and store personal identifiable information about you in a file for the purpose of the research study. Only information necessary for the research study will be collected.

All information and saliva sample obtained about you during this study will be treated confidentially within the limits of the law. Thus, to protect your identity, your name and identifying information will be replaced with a code (numbers). The link between the code and your identity as well as the study file will be kept under the responsibility of Dr. Velly and will be held in a locked drawer in Dr. Velly's office at the Dental Department of the Jewish General Hospital. No information that discloses your identity will be allowed to leave the institution.

The saliva sample will be stored in the saliva freezer at the Lady Davis Institute of the Jewish General Hospital under the responsibility of Drs. Gornitsky, Schipper and Velly. Your sample will be stored until the saliva is used for study analysis. The remaining saliva sample will be destroyed in the laboratory of Dr. Hyman Schipper at the Lady Davis Institute, 10 years after the completion of the study. The sample will only be used for the purposes described in this consent form. The Lady Davis Institute requires a pass for entry, the door to the lab is locked and the results of the samples will be kept in a locked drawer with information being codified. Computer information is restricted by a password.

The result of the analysis will be kept confidential and will not be placed anywhere in your file. Also, you will not be identified in any published report. A copy of this consent form will not be placed in your medical record file and a copy will be given to you.

For the purpose of monitoring this research, your research study file as well as your medical records identifying you could be checked by a person authorized by the Research Ethics Committee of the Jewish General Hospital or the Institutional Review Board of McGill University. This person is obliged to respect your privacy.

For safety purposes, and in order to communicate information that is required in order to protect your well-being, Dr. Velly, the principal researcher of this study will keep your personal information including your name, contact information, the date when your participation in the study began and when it ended separate from the research documents.

You have the right to look at your study file in order to check the information gathered about you and to correct it, if necessary, as long as the study researcher or the institution keeps this information.

Contact information:

If you have any question about this study, please contact Dr. Ana Velly: 514-340-8222 ext. 22932, 3755 Cote St. Catherine Road, room A-017, Montreal, Quebec H3T 1E2. For any question regarding your rights as a research participant, please contact Rosemary Steinberg (Jewish General Hospital), local commissioner of complaints and quality of service, at 514-340-8222 ext. 25833 or Pascale Valois (Montreal General Hospital), local commissioner of complaints and quality of service, at 514-934-1934 ext. 44285

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Hôpital général juif | Jewish General Hospital

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Statement of Consent:

I have read the previous information and my questions were answered to my satisfaction. A copy of this signed consent form will be given to me. My participation is voluntary and I can withdraw from the study at any time without giving reasons. It will not affect my dental care now or later. I do not give up any of my legal rights by participating in this study. I understand that I will be contacted by the research assistant at the first appointment and after three and six months.

I agree to participate in this study.

_____

Printed name of participant

_____ _____

Signature of Subject Date

Contact information: _____

_____

Printed name of person obtaining consent

_____ _____

Signature of Person Obtaining Consent Date

Centre universitaire de santé McGill | McGill University Health Centre

Hôpital général juif | Jewish General Hospital

McGill

Formulaire de consentement

Transition de la douleur aiguë à la douleur chronique liée aux désordres temporomandibulaires: Une étude de cohorte prospective

Vous êtes invité à participer à une étude concernant la transition de la douleur aigue à la douleur chronique liée aux désordres temporomandibulaires, nommés « DAM », un type de douleur au visage. Vous avez été sélectionné car nous sommes intéressés à comprendre ce qui peut prédire le bien-être en santé lié à la douleur faciale. Vous avez le droit de connaître le but et les procédures de cette étude, et d'être informé sur ses potentiels avantages et risques, ainsi que tout inconfort qui peuvent être encourus. Il n'y a aucune rémunération pour participer à cette étude.

Avant d'accepter de prendre part à cette étude, il est important que vous lisiez l'information dans ce formulaire de consentement. Vous devriez poser autant de questions nécessaires afin de comprendre ce que vous serez invité à faire. Votre participation est volontaire.

But de l'étude:

L'objectif de cette étude est de déterminer les possibilités d'avoir de la douleur liée aux désordres temporomandibulaires et de déterminer les facteurs associés à cette douleur au visage.

Procédures:

Si vous acceptez de participer à notre étude, vous serez demandé de faire ce qui suit:

- Vous serez invité à compléter un questionnaire le jour de votre rendez-vous (aujourd'hui), 3 et 6 mois après ce premier entretien. Si vous ne pouvez pas le compléter, nous vous demanderons de le faire ultérieurement et de nous renvoyer le questionnaire dans une enveloppe prépayée que nous vous fournirons. Si vous ne pouvez pas nous retourner ce questionnaire, une entrevue téléphonique sera alors effectuée par l'assistant de recherche. L'achèvement du questionnaire peut prendre en moyenne de 10 à 20 minutes. Le suivi de 3 et 6 mois prennent moins de cinq minutes à compléter et peuvent être effectués par téléphone ou par sondage électronique. Si vous choisissez le sondage électronique, vous serez inscrit à un tirage au sort semestriel pour gagner une de cinq cartes cadeaux d'une valeur de $20 sur Amazon, lorsque vous auriez complété tous les questionnaires.
- Permettez-nous de recueillir de la salive (5-10 ml) le jour de la première entrevue. Afin de collecter la salive, l'assistant de recherche vous demandera de cracher dans une éprouvette stérilisée. Aucune hospitalisation ne sera nécessaire à ces fins. La durée de la collecte de salive prendra un maximum de 10 minutes. Les échantillons de salive seront utilisés afin d'évaluer si la composition de la salive est liée à cette douleur.

- L'équipe de recherché vous posera des questions sur vos la santé en général en utilisant un bref questionnaire. Nous vérifierons si vous avez de l'hypertension, le diabète, des problèmes de thyroïde, des allergies ou de l'asthme. Nous ferons cela afin de voir si ces facteurs peuvent prédire le bien-être en santé associé à la douleur au visage.
- Les questions qui seront posées lors de cette étude aideront à l'identification des individus atteints de DAM, ainsi que de mesurer le niveau de douleur et d'incapacité lié à cette condition. D'autres questions évalueront le niveau de la santé en général et les caractéristiques psychologiques (ex. anxiété et dépression).

Les risques, inconforts et effets secondaires:
Vous aurez des entrevues avec l'assistant de recherche. Si vous n'êtes pas confortable à répondre à certaines questions en particulier, vous êtes libres d'arrêter ou de sauter la question et de passer à la suivante. Cette entrevue prendra un maximum de 20 minutes de votre temps.

Avantages:
Il n'y a aucun avantage direct à participer à cette étude. Cependant, cette étude fournira à la communauté médicale et dentaire des preuves plus définitives sur les facteurs qui peuvent augmenter les chances de cette douleur au visage. Ces résultats peuvent contribuer au développement de programmes personnalisés pour améliorer la gestion de la douleur liée aux désordres temporomandibulaires.

Participation volontaire / retrait:
Votre participation à cette étude est volontaire. Indépendamment de si vous accepter ou refuser de participer à cette étude, vos futurs soins dentaire et votre relation dentiste-patient ne seront affectés en aucune façon. Vous pouvez choisir de participer maintenant et d'arrêter à tout moment. Si vous décidez de vous retirer de cette étude, toutes informations recueillies jusqu'au moment de votre retrait seront gardées afin de protéger l'intégrité scientifique de l'étude. Après votre retrait, vous pouvez demander à ce que vos échantillons de salive soient détruits.

Confidentialité:
Durant votre participation à cette étude, le chercheur responsable et le personnel impliqué dans l'étude collecteront et conserveront des informations personnelles pouvant vous identifier dans un dossier aux fins de l'étude. Seules les informations nécessaires à l'étude de recherche seront recueillies.

Toutes les informations et échantillons de salive obtenus de vous au cours de cette étude seront traités confidentiellement dans les limites de la loi. Ainsi, afin de protéger votre identité, votre nom et informations d'identification seront remplacés par un code (chiffres). Le lien entre le code et votre identité ainsi que le dossier d'étude seront maintenus sous la responsabilité du Dr. Velly, et seront conservés dans un tiroir verrouillé dans le bureau du Dr. Velly au département dentaire de l'Hôpital général juif. Aucune information révélant votre identité ne sera autorisé à quitter l'établissement.

L'échantillon de salive sera conservé dans un congélateur contenant des échantillons de salive à l'Institut Lady Davis de l'Hôpital général juif, sous la responsabilité des Drs. Gornitsky, Schipper et Velly. Votre échantillon sera conservé jusqu'à ce que la salive soit utilisée pour des analyses. Le reste de l'échantillon de salive sera détruit dans le laboratoire du Dr. Hyman Schipper à l'Institut Lady Davis, 10 ans après la fin de l'étude. L'échantillon de salive sera utilisé uniquement aux fins des objectifs décrits dans ce formulaire de consentement. L'Institut Lady Davis nécessite un laissez-passer pour y accéder, la porte du laboratoire est verrouillée, et les résultats des échantillons seront conservés dans un tiroir fermé à clé avec les informations codifiées. Les informations sur l'ordinateur sont limitées par un mot de passe.

Le résultat de l'analyse sera maintenu confidentiel et ne sera pas placé dans votre dossier. En outre, vous ne serez identifié dans aucun rapport publié. Une copie de ce formulaire de consentement ne sera pas placée dans votre dossier médical, et un exemplaire vous sera remis.

Aux fins de surveillance de cette étude, votre dossier de recherche ainsi que vos dossiers médicaux vous identifiant peuvent être vérifiés par une personne autorisée par le comité d'éthique de l'Hôpital général juif ou le comité d'examen institutionnel de l'Université McGill. Cette personne est tenue de respecter votre vie privée.

Pour des raisons de sécurité, et afin de communiquer des informations qui sont nécessaires pour protéger vos données, Dr. Velly, chercheur principal de cette étude, gardera vos informations personnelles, y compris votre nom, vos coordonnées, les dates auxquelles votre participation à l'étude a commencé et a fini séparées des documents de recherche.

Vous avez le droit de consulter votre dossier d'étude afin de vérifier les informations recueillies sur vous et de les corrigées, si nécessaire, tant que le chercheur ou l'institution conserve ces renseignements.

Contacts :

Si vous avez des questions au sujet de cette étude, s'il vous plaît contacter Dr. Ana Velly: 514-340-8222 poste 22932, 3755 Côte Ste. Catherine Road, room A 017, Montréal, Québec H3T 1E2. Pour toute information concernant vos droits à titre de participant à une étude de recherche, veuillez contacter Rosemary Steinberg (Hôpital général juif), commissaire locale aux plaintes et à la qualité du service, au 514-340-8222 poste 25833 ou Pascale Valois (Hôpital général de Montréal), commissaire locale aux plaintes et à la qualité du service, au 514-934-1934 poste 44285.

Déclaration de consentement:

J'ai lu les informations et mes questions ont été répondues à ma satisfaction. Une copie de ce formulaire de consentement signé me sera remise. Ma participation est volontaire et je peux me retirer de l'étude à tout moment sans donner de raisons, sans que cela affecte mes soins médicaux maintenant ou plus tard. Je ne renonce à aucun de mes droits légaux en participant à cette étude. Je comprends que je serai contacté par l'assistante de recherche au premier rendez-vous et après trois et six mois.

Je suis d'accord pour participer à cette étude.

_____

Nom du participant

_____ _____

Signature du participant Date

Coordonnées : _____

_____

Nom de la personne obtenant le consentement

_____ _____

Signature de la personne obtenant le consentement Date