DEVELOPMENT AND VALIDATION OF MALAY VERSION OF FONSECA ANAMNESTIC INDEX (FAI) & ORAL HEALTH IMPACT PROFILE FOR TEMPOROMANDIBULAR DISORDER (OHIP-TMD)

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ORIGINAL LITERARY WORK DECLARATION

Name of Candidate : Muzaffar Bin Apipi

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Title of Research Report : Development and Validation of Malay Version of Fonseca Anamnestic Index and (FAI) and Oral Health Impact Profile for Temporomandibular Disorder (OHIP-TMD)

Field of Study : Oral & Maxillofacial Surgery

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DEVELOPMENT AND VALIDATION OF MALAY VERSION OF FONSECA ANAMNESTIC INDEX (FAI) AND ORAL HEALTH IMPACT PROFILE FOR TEMPOROMANDIBULAR DISORDER (OHIP-TMD)

ABSTRACT

Objectives: This research aims to translate and validate Malay version of Fonseca Anamnestic Index (FAI), a 10-item temporomandibular disorder (TMD)-screening tool and Oral Health Impact Profile for TMD (OHIP-TMD), a 22-item TMDs-specific version of the Oral Health Impact Profile (OHIP). **Methods**: Translation of FAI and OHIP-TMD was done via forward and backward translation in sequential approach following guidelines for cross-cultural adaptation. A total of 243 convenience samples which consists of 160 non-TMD and 83 with TMD completed the questionnaires. A subsample of 40 subjects (20 non TMD, 20 TMD) were administered questionnaires twice with 14 days interval for test-retest analysis. Psychometric properties assessment involved were reliability and validity analysis. **Results**: A response rate of 96.4% was recorded (243 of 252 subjects), nine subjects were excluded due to more than 20% incomplete answer. FAI & OHIP-TMD were found to be reliable with Cronbach's alpha obtained for FAI was 0.90 & OHIP-TMD was 0.98. Test-retest consistency: ICC using a two-way random effect model with absolute agreement calculated for both FAI & OHIP-TMD obtained 0.99. For validity analysis, concurrent validity, convergent validity, discriminative validity and construct (hypothesis) test were performed. Concurrent validity test conducted using Spearman's coefficient rank correlation with short version of Oral Health Impact Profile- Malay version (S-OHIP M) for both questionnaires shown a significant result, positive value of > 0.70. Convergent validity test with 3 global oral health rating: perceived oral health status, perceived oral health satisfaction and perceived need of treatment conducted using Kruskal-Wallis test for both questionnaires obtained significant result, p-value were < 0.001 (< 0.050) and had confirmed six hypotheses.

Discriminative validity test conducted using Mann- Whitney U test proved that both FAI & OHIP-TMD significantly able to distinguish non-TMD with TMD group with p-value were 0.001 (< 0.050) and confirmed two hypotheses. All eight-construct validity (hypothesis) tested were confirmed. **Conclusions**: Malay Version of FAI & OHIP-TMD are reliable and valid for Malaysian population based on psychometric properties assessment conducted.

Keywords: Temporomandibular disorder (TMD), FAI, OHIP-TMD, cross-cultural adaptation (CCA), Malay version.

PEMBANGUNAN DAN VALIDASI VERSI BAHASA MELAYU INDEKS *ANAMNESTIC FONSECA* (IAF) DAN PROFIL KESAN KESIHATAN MULUT BAGI GANGGUAN TEMPOROMANDIBULAR (PKKM-GTM)

ABSTRAK

Objektif : Penyelidikan ini bertujuan untuk menterjemahkan dan validasi versi Bahasa Melayu Indeks *Anamnestic Fonseca* (IAF), alat pengesan gangguan temporomandibular (GTM) 10 soalan dan Profil Kesan Kesihatan Mulut bagi Gangguan Temporomandibular (PKKM-GTM), 22 soalan TMDs- versi khusus Profil Kesan Kesihatan Mulut (PKKM). **Kaedah**: Terjemahan IAF dan PKKM-GTM berjaya dilakukan menerusi terjemahan ke hadapan dan ke belakang dalam pendekatan berurutan mengikut garis panduan untuk penyesuaian silang budaya. Sejumlah 243 sampel mudah yang terdiri daripada 160 bukan GTM dan 83 GTM telah menyelesaikan soal selidik. Subsampel sebanyak 40 subjek (20 bukan GTM, 20 GTM) diberi soal selidik dua kali dengan selang 14 hari untuk analisis *test-retest*. Penilaian sifat psikometrik yang terlibat adalah analisis *reliability* dan *validity*. **Keputusan**: *Response rate* direkodkan adalah 96.4% (243 daripada 252 subjek), sembilan subjek dikecualikan kerana jawapan tidak lengkap lebih daripada 20%. IAF & PKKM-GTM boleh dipercayai dengan *Cronbach's alpha* yang diperolehi untuk IAF adalah 0.90 & PKKM-GTM adalah 0.98. Konsistensi *test-retest*: ICC menggunakan *two way effect model* dengan *absolute agrrement* dikira untuk kedua-dua IAF & PKKM_GTM dan nilai diperolehi 0.99. Bagi analisis *validity*, *concurrent validity, convergent validity, discriminative validity and construct*(hipotesis) *validity* telah dijalankan. Ujian *concurrent* yang dijalankan menggunakan *Spearman's coefficient rank correlation* dengan versi pendek Profil Kesan Kesihatan Mulut dalam bahasa Melayu (*S-OHIP (M)*) untuk kedua-dua soal selidik menunjukkan hasil yang signifikan, nilai positif > 0.70. Ujian *convergent* dengan 3 *global oral health rating*: status kesihatan mulut dirasakan, kepuasan kesihatan mulut yang dirasakan dan keperluan rawatan yang

dijalankan menggunakan ujian *Kruskal wallis* untuk kedua-dua soal selidik memperoleh keputusan yang signifikan, nilai p <0.001 (<0.050) dan telah mengesahkan enam hipotesis. Ujian d*iscriminative validity* yang dijalankan menggunakan ujian *Mann-Whitney U* membuktikan bahawa kedua-dua IAF & PKKM-GTM dapat membezakan bukan GTM dengan kumpulan GTM dengan p-nilai adalah 0.001 (<0.050) dan mengesahkan dua hipotesis. Semua lapan *construct* (hipotesis) *validity* yang diuji telah disahkan. **Kesimpulan**: Versi Melayu IAF & PKKM-GTM adalah dipercayai dan sah digunakan penduduk Malaysia berdasarkan penilaian sifat psikometrik yang dijalankan.

Kata kunci: Gangguan temporomandibular (GTM), IAF, PKKM-GTM, penyesuaian silang budaya, versi Bahasa Melayu

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This report has plenty of room for improvement and far form perfection due to my limited knowledge, understanding, language.

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LIST OF SYMBOLS AND ABBREVIATIONS

TMD	:	Temporomandibular disorder
FAI	:	Fonseca Anamnestic Index
FAI (M)	:	Malay version of Fonseca Anamnestic Index
OHIP-TMD	:	Oral Health Impact Profile for Temporomandibular Disorder
OHIP-TMD (M)	:	Malay version of Oral Health Impact Profile for Temporomandibular Disorder
S-OHIP (M)	:	Short version of Oral Health Impact Profile Malay Version
GOH	:	Global Oral Health
TMJ	:	Temporomandibular joint
AAOP	:	American Academy of Orofacial Pain
CCA	:	Cross-cultural adaptation

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CHAPTER 1: INTRODUCTION

1.1 Introduction

Temporomandibular disorder (TMD) is a generally perceived term for pain and/or dysfunction that affecting the temporomandibular joint, masticatory muscles and related structures. The most common clinical findings include temporomandibular joint pain and clicking, masticatory muscles pain with restricted movement or deviated or dislocated jaw, headaches and some time with earaches (Fricton, 2014; Okeson, 2008b).

Multifactorial in etiology make TMD a complex disease. Identifying these factors are challenging and crucial as it is part of treatment. Many conditions that contributes to TMD includes excessive muscle function or parafunctional habits, physical trauma, hormonal factors, structural changes within the joint, traumatic occlusion, psychological discomfort and sleep disorder (Lei, Fu, Yap, & Fu, 2016; Liu & Steinkeler, 2013; Pandarakalam & Khalaf, 2014; A. U. Yap, Chua, Dworkin, Tan, & Tan, 2002; A. U. Yap, Chua, & Tan, 2004)

Based on multiple studies and surveys conducted, TMD has a wide range of prevalence between 1% to 75% people with signs and/or symptoms in different population in the west and some Asian countries, with peak occurrence in 20-40 year of age are more affected (Manfredini et al., 2011; NIDCR, 2018; Okeson, 2008b). The wide range of prevalence probably resulted from diversification in study designs, sampling techniques, measurement tools and different diagnostic criteria for TMD.

Although many methods have been applied in assessing TMD including a questionnaire, patient's history, clinical physical examination, diagnostic instruments and psychological evaluation, nevertheless no agreement has been reached on the best method to be used. Helkimo's indexes (1974) was developed as a global epidemiologic survey which classifies patients based on five most commonly observed signs and symptoms into

different anamnestic dysfunction index (Clark, Delcanho, & Goulet, 1993; P. C. A. Conti, Ferreira, Pegoraro, Conti, & Salvador, 1996). However, it has its limitations of being an inappropriate tool clinically for individual patient diagnosis. With regards to that, Dworkin and Leresche in 1992 created the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) which can provide a physical diagnosis based on clinical examination and identify other characteristics of patients which can influence their expression and treatment of TMD simultaneously (Schiffman et al., 2014). Although RDC-TMD was further revised into DC-TMD in 2013, the requirement of patient's presence for the study makes it impractical in large-scale population studies (Bonini, Campos, Carrascosa, Bonafé, & Maroco, 2014).

In order to carry out a study in a large non-patient population, a self-administered questionnaire serves as a suitable instrument due to its speed, low cost and simplicity (Bonini et al., 2014; Oliveira, Dias, Contato, & Berzin, 2006). Moreover, it eliminates the influence of examiner towards the patients and reduces variability in measures. Therefore, Fonseca Anamnestic Index (FAI) is proposed as an alternative in collecting epidemiological data. Even though FAI consist of ten questions only, it is a fast and short survey that follows the characteristics of a multidimensional evaluation. The ten questions include checking for pain in temporomandibular joint, head, back, while chewing, parafunctional activities, limited movements, joint clicking, the perception of malocclusion and feeling of emotional stress (Campos, Carrascosa, Bonafé, & Maroco, 2014; Oliveira et al., 2006). Many studies had used FAI to assess the prevalence and severity of TMD in a population, mainly Brazilian population (Berni, Dibai-Filho, & Rodrigues-Bigaton, 2015; Bonini et al., 2014; Pedroni, De Oliveira, & Guaratini, 2003; Pires, de Castro, Pelai, de Arruda, & Rodrigues-Bigaton, 2018; Rodrigues-Bigaton, de Castro, & Pires, 2017). The original FAI questionnaire is in Portuguese language and has

been translated to other languages e.g. English which widely used in the Brazilian population.

In order to effectively assess the prevalence and severity of TMD in the Malaysian population particularly for the Malaysia National Health Survey, a *Bahasa Malaysia* (Malay) translated version of the FAI is needed. Hence, the objective of this study is to develop the Malay version of the Fonseca Anamnestic Index for use in Malaysian populations. Besides that, this study also aims to determine the reliability and validity of the Malay version FAI.

The present perspective for TMD is complex and multifactorial in nature. It is an integration of biological, psychological and social factors which includes stressful and emotional activities, structural abnormalities, traumatic injuries, malocclusion and different condition of arthritis or viral infection. Pain is the most common reason for patients to look for treatment. It usually occurs in the masticatory muscles, the pre-auricular area and the temporomandibular joints. Other than that, restricted and deviated jaw movement, temporomandibular joint sounds during function and recurrent headaches are also commonly observed.

Measurement of oral health related quality of life (OHRQoL) is generally accepted as a means of characterizing the effects of oral disorders on the quality of life of a population. John MT et al. (2007) explained that it is feasible to compare the impact of different oral conditions on daily life by using OHRQoL instruments (John, Reiβmann, Schierz, & Wassell, 2007). There is a strong correlation between TMD symptoms and the impact on the quality of life with clinical signs and symptoms including orofacial, neck and head pain, sleep disturbance, depression and stress (He & Wang, 2015). Apart from that, functional disability in normal daily movements involving the jaw such as eating, biting, speaking and kissing are also observed (He & Wang, 2015). Persisting and recurrent

symptoms serve as a source of stress which can affect the psychological state and social well-being of a person.

Some of the standard tools used for such measurement are the Oral Health Impact Profile (OHIP) and Oral Impact on Daily Performance (OIDP). They are, however, criticized for being too broad, containing unnecessary items and hence unable to evaluate the impact of particular oral disorder on the quality of life (He & Wang, 2015). Many researchers suggest developing a condition-specific instrument that can accurately assess the impact of TMD on people. This condition specific instrument which will contain lesser items can reduce the scoring complexity, administrating time and cost (Yule et al., 2015). Hence, Durham and his partners (2011) proposed the Oral Health Impact Profile for TMDs (OHIP-TMD). This shortened version consists of 22 items, 20 items obtained from the original OHIP with addition of two new items (Durham et al., 2011; Yule et al., 2015). Currently, He and Wang (2015) have successfully translated the English OHIP-TMD into Chinese version and culturally adapted it to the Chinese mainland population (He & Wang, 2015).

Due to social, economic and cultural differences, a strict psychometric assessment must be achieved before OHIP-TMD can be used in other areas. Therefore, there is a need to translate and validate OHIP-TMD into our national language, *Bahasa Malaysia* (Malay language) for a better assessment of TMD on the quality of life of the Malaysian population. That being the case, the objective of this study is to develop the Malay version of the OHIP-TMD for use in Malaysian populations and to determine the reliability and validity of the OHIP-TMD.

1.1.1 Aim

The aim is to translate and validate Malay Version of Fonseca Anamnestic Index (FAI) and Oral Health Impact Profile for Temporomandibular disorder (OHIP-TMD).

1.1.2 Objectives

1. To develop the Malay version of the FAI and OHIP-TMD for use in Malaysian population
2. To determine the reliability and validity of the Malay version of FAI and OHIP-TMD (FAI (M) and OHIP-TMD (M))

1.2 Rationale and Relevance of Research

Cross-cultural adaptation of validated health related instruments is an alternative to developing a new instruments or questionnaire for a certain disease. Psychometric properties assessment is crucial before applying a tool which was validated in other population. In Malaysia, we have yet to develop an assessment screening tool and oral health impact profile assessment tool specific for TMD. This initiate us as part of healthcare service provider to translate these necessary tools which will have great impact in detecting this serious health condition earlier, to understand TMD distribution in Malaysian population and to deliver best treatment for TMD patient.

The Malay version of the FAI questionnaire and OHIP-TMD are valuable for research purpose, in screening of TMD and to evaluate the impact on quality of life in Malaysian population.

CHAPTER 2: LITERATURE REVIEW

Temporomandibular disorder (TMD) is a clinical condition which may present with pain and dysfunction of temporomandibular joint, mastication muscles and adjacent tissues. This condition most commonly gives rise to notable pain & noise over the temporomandibular joint and occasionally limited jaw movement (Bagheri & Jo, 2008; Hupp, Tucker, & Ellis, 2014). The complexity of its etiology, contributing factor and predisposing factor give a challenge in treating TMD.

2.1 TEMPOROMANDIBULAR DISORDER EPIDEMIOLOGY

According to the National Institute of Dental and Craniofacial Research in year 2018, TMD present in 5-12 % of the population with a higher prevalence in the younger population (NIDCR, 2018). Moreover, it is twice more likely to occur in females than in males (Bevilaqua-Grossi, Chaves, de Oliveira, & Monteiro-Pedro, 2006). Persistent pain caused by TMD has a significant impact on an individual's daily activities, quality of life and psychological state. Patients with TMD suffer from a variety of pain including headaches, earaches, pain during mouth opening, mastication, at rest, and pain in temporal and masseter muscles (Bagis, Ayaz, Turgut, Durkan, & Özcan, 2012). de Magalhães Barros (2009) stated that the quality of life of individuals with TMD is severely affected by orofacial pain, regardless of gender (de Magalhães Barros, Seraidarian, de Souza Côrtes, & de Paula, 2009). There is a relation between the severity of TMD and the impact on the quality of life of individuals with TMD seeking treatment (P. C. R. Conti, Pinto-Fiamengui, Cunha, & Conti, 2012). An early diagnosis and treatment measures for TMD is vital as its severity progresses with time.

2.2 TEMPOROMANDIBULAR DISORDER ETIOLOGY

The etiology of TMD is complex and multifactorial yet largely unresolved. The anatomical relationship that are closely related with TMD are disturbances or changes in dental occlusion, masticatory muscles and temporomandibular joints. Okeson in 2008 stated that, under normal conditions the masticatory system works as usual, until a certain sort of situation occurred which considerably disrupts the normal masticatory function. The condition exceeds the individual's physiological tolerance and turns symptomatic (Okeson, 2008b).

Current understanding of joint biomechanics, neuromuscular physiology, psychological disorder and pain mechanism point out that the nature of TMD is complex and related to biological, behavioral, environmental, social and cognitive influences alone or in combination which gives rise to sign and symptoms of TMD (Bagheri, Bell, & Khan, 2012).

2.2.1 Local Factors

Local factors associated with TMD includes occlusal disharmony, trauma, parafunctional habits such as bruxism, and constant deep pain input (Manfredini & Lobbezoo, 2010; Okeson, 2008b).

2.2.2 Systemic Factors

Systemic factors which are associated with TMD include emotional stress, psychological factors, genetics, gender, diet, hormonal changes, osteoarthritis, rheumatoid arthritis, autoimmune disorder (Gauer & Semidey, 2015; A. U. J. Yap, Tan, Chua, & Tan, 2002).

2.3 CLASSIFICATION OF TEMPOROMANDIBULAR DISORDER

TMD can be generally classified into intraarticular or articular (within the joint) and extraarticular or nonarticular (surrounding musculatures) (Gauer & Semidey, 2015; Miloro, Ghali, Larsen, & Waite, 2004).

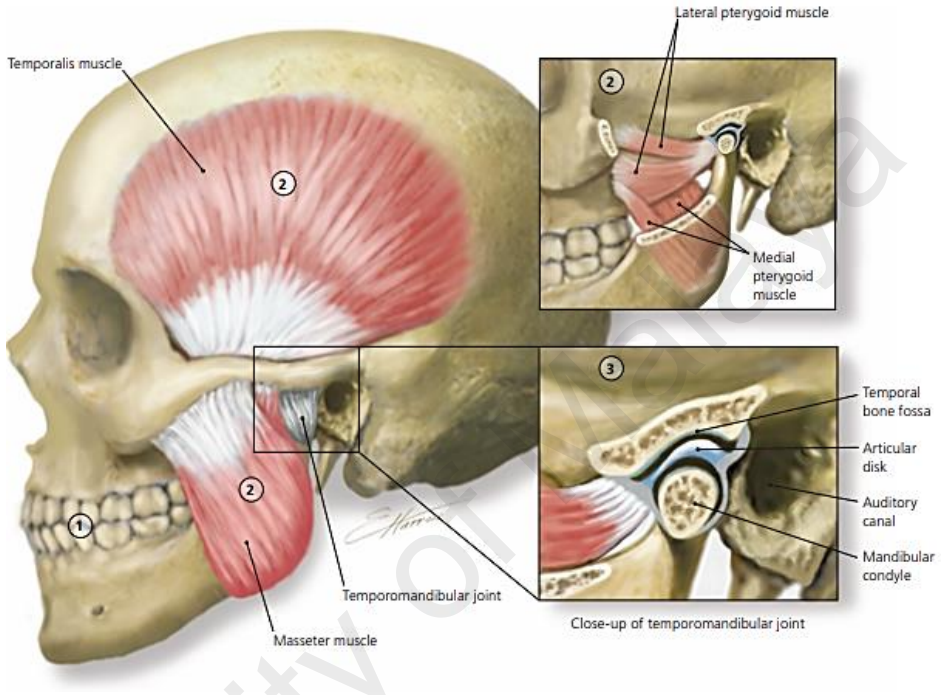

Figure 2-1 Classification of TMD. Extraarticular and intraarticular in origin (Gauer & Semidey, 2015)

Anatomy of the temporomandibular joint and the structures in Figure 2.1 play an important role for jaw movement. Disturbances may originate from either part of it or combination of structures. The most common musculoskeletal conditions inherent in TMD are:

1. Teeth and mandible. Dental occlusion in normal position is a 1 to 2 mm overbite. Bruxism seen by presence of teeth attrition. Mouth opening less than 30 to 35 mm is considered abnormal.

2. Muscles of mastication. TMD findings may include spasm and/or tender muscles of mastication: masseter, temporalis and/or pterygoid muscles. Palpation during clenching helps identify the specific muscles.

3. Temporomandibular joint (TMJ). The TMJ is a gliding joint that consist of mandibular condyle and temporal bone fossa. The ligamentous capsule, articular disk, and retrodiscal tissue are components which allow for smooth joint movement. Examination of the joint by palpating anterior to the tragus bilaterally could identify any abnormality. Clicking and popping is quite common and may occur if articular disk has slipped anterior to the condylar head (click) but then is reposition in proper position (pop) (Gauer & Semidey, 2015).

Another classification by Bell was further modified by Okeson in 2008. It separated TMDs into four broad categories having a similar sign and symptoms clinically : (1) masticatory muscle disorders, (2) TMJ disorders, (3) chronic mandibular hypomobility disorders, and (4) growth disorders (Okeson, 2008b).

Latest, American Academy of Orofacial Pain (AAOP) classified TMD as in table below:

Table 2.1 Classification of TMDs by AAOP, 2013. Adapted from (De Rossi, Greenberg, Liu, & Steinkeler, 2014)

AAOP diagnostic classification of TMDs	
Diagnostic criteria	Diagnosis
Cranial bones (including the mandible)	Congenital and developmental disorders: aplasia, hypoplasia, hyperplasia, dysplasia (eg, first and second branchial arch anomalies, hemifacial microsomia, Pierre Robin syndrome, Treacher Collins syndrome, condylar hyperplasia, prognathism, fibrous dysplasia) Acquired disorders (neoplasia, fracture)
TMJ disorders	Deviation in form Disc displacement (with reduction; without reduction) Dislocation Inflammatory conditions (synovitis, capsulitis) Arthritides (osteoarthritis, osteoarthrosis, polyarthritides) Ankylosis (fibrous, bony) Neoplasia
Masticatory muscle disorders	Myofascial pain Myositis spasm Protective splinting Contracture

This classification is useful in determining best treatment option according to cause of TMD.

2.4 SIGNS & SYMPTOMS OF TEMPOROMANDIBULAR DISORDER

The complexity of TMD gives rise to various clinical manifestation. Patients may present with signs and symptoms of pain from temporomandibular joint (TMJ), earache which related to pain in the TMJ, joint sound like clicking or crepitus in the temporomandibular joint, bruxism, chewing difficulty resulted from pain or tenderness in the muscles of mastication of TMJ, limited mouth opening, headache related to pain over temporalis muscles (Florencio et al., 2017; Moore, 2011; NIDCR, 2018).

Based on the classification of articular & nonarticular TMD, signs and symptoms can easily be grouped into its origin. In nonarticular disorders most of it appears as myofascial pain focused on the muscles of mastication and some groups of muscle of the head and neck region (Bagheri et al., 2012). Almost more than half of TMD involved myofascial pain. This also includes chronic conditions for instances fibromyalgia, strain of the muscle, and myopathies. Myofascial pain and disturbance are speculated as a result of clenching, bruxism, or other parafunctional activities which give rise to mastication muscle strain, spasm, pain, later leading towards functional restriction (Miloro et al., 2004). Emotional stress does influence clenching and bruxism, leading to myofascial pain (Okeson, 2008b). Symptoms include chronic pain of the mastication muscles, pain which radiate to the ears, neck, and head.

Articular disorders of TMD is either inflammatory or noninflammatory joint pathology. Inflammatory articular changes occur in rheumatoid arthritis (RA), seronegative spondylopathies, such as ankylosing spondylitis, psoriatic arthritis, gout, and infectious arthritis. Noninflammatory articular disk condition includes osteoarthritis, joint damage secondary to trauma or surgery, or other cartilage or bone disorders (Liu & Steinkeler, 2013). Theoretically, the mechanism of articular disorders is derived from imbalance of anabolic and catabolic cytokines. These changes initiate an inflammatory environment. It subsequently forms oxidative stress, free radicals, and ultimately damage the joint (Okeson, 2008b).

Internal derangement concerns the changes between relationship of the disk and the condyle. TMJ disc displacement is occurred when the articular disc is displaced from its usual functional position between the head of the condyle and the glenoid fossa of the temporal bone (Ahmad & Schiffman, 2016). Disk displacements are classified as disk displacement with reduction or without reduction (Fig. 2.2).

The mechanism of disk displacement with reduction, explained in Figure 2.2.

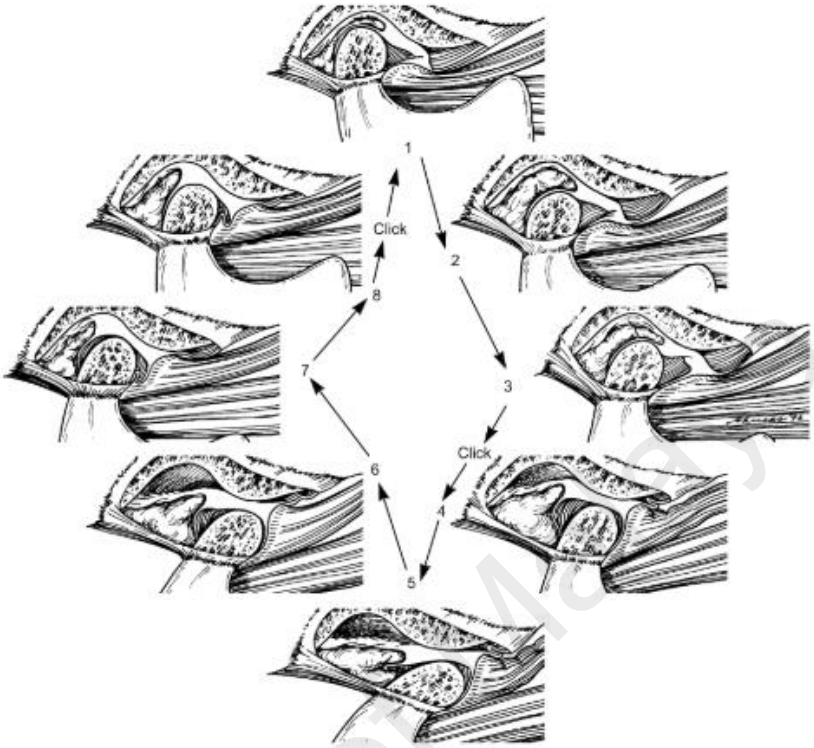

Figure 2-2 Disk displacement with reduction. Adapted from Okeson, 2008 (Okeson, 2008a, 2008b)

In position 1, the posterior border of the disc which has been thinned, allowing activity of the superior lateral pterygoid to dislocate the disc anteriorly (and medially). Between positions 3 and 4, a click is felt as the condyle moves across the posterior border of the disk. Normal condyle–disc function occurs during the remaining opening and closing movement until the closed joint position is approached. A second click usually heard once the condyle moves from the intermediate zone over the posterior border of the disk (between positions 8 and 1) (Okeson, 2008a)

The fibrocartilage disc usually will be displaced anteromedially but rarely may be displaced laterally or posteriorly. Anatomically, disk displacement with reduction is interference between the mandibular condyle with the articular disk during jaw opening or closing. This interference may generate clicking, popping, or crepitus in the joint, which can be associated with discomfort. Clicking alone, however, is not diagnostic of

articular disk displacement. During disk displacement with reduction, the condyle meets the posterior aspect of the disk, which then reduces to its proper position between the condyle and glenoid fossa. Articular disk displacement is associated with TMD. A study by Tallents et al. (1996) found that magnetic resonance imaging (MRI) evidence of disk displacement were observed in 84% of symptomatic patients with TMD and 33% of asymptomatic patients (Tallents, Katzberg, Murphy, & Proskin, 1996). MRI findings, however, should not solely dictate treatment because disk displacement may occur in asymptomatic patients.

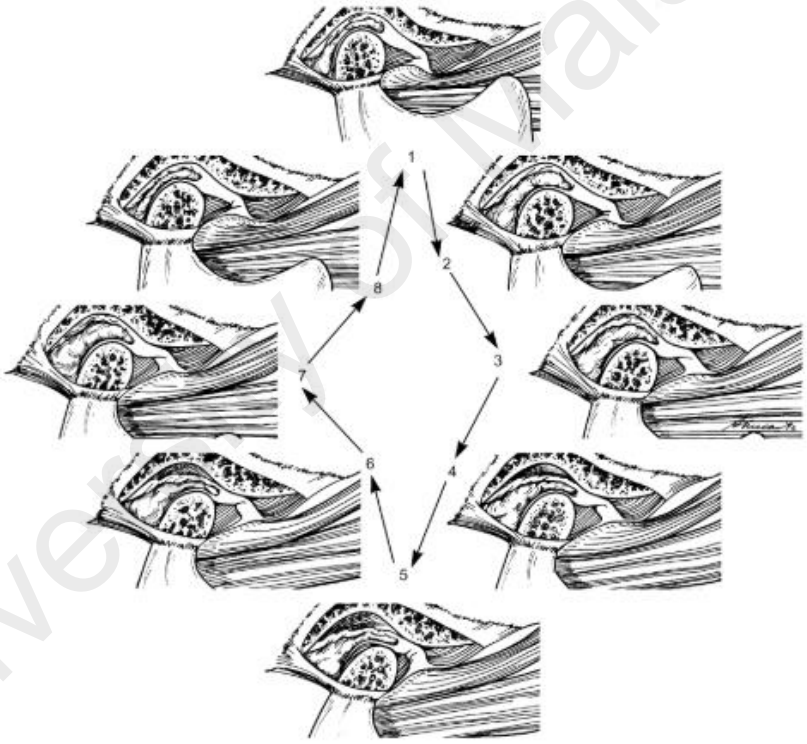

Figure 2-3 Disc dislocation without reduction (closed lock)(Okeson, 2008a, 2008b)

As the elasticity of the superior retrodiscal lamina is lost or morphologic changes of the disc, recapturing of the disc becomes more difficult. When the disc is not reduced, the forward translation of the condyle forces the disc further displaced anteriorly, as in Figure 2.3. This is clinically called a ‘‘closed lock’’ because the disc is dislocated and it limits the mouth opening (Okeson, 2008b).

2.5 EVALUATION, CLINICAL EXAMINATION AND IMAGING

2.5.1 History Taking and Examination

Thorough history taking and clinical examination systematic clinical examination is crucial in making accurate diagnosis. The fundamental components of thorough head and neck examinations with focusing on TMD signs and symptoms must performed is described in Table 2.2 (Dym & Israel, 2012):

Table 2.2 History taking and examinations. Adapted from Dym & Israel, 2012

History taking and Examinations:
• Chief complaint • History of present illness Chronology of onset Description of any trauma Factors that increase symptoms / Exacerbating factors Factors that improve symptoms / Alleviating factors • Patient's medical and dental histories Prior history of joint dysfunction Has this individual ever been treated for a similar problem What were the results of that treatment? Are any comorbid systemic disorders present? • Findings of the clinical examination include the following: Muscles of the mastication, neck and shoulders Conditions found within the oral cavity that might be contributing to the patient's pain complaints (ie, an evaluation of the soft tissues, periodontium, and teeth) Myofunctional and/or parafunctional habits Mandibular range-of-motion measurements Auscultation of the TMJs during movement Radiologic findings

A positive sign is defined as any clinical finding associated with TMD. Symptoms refer to any TMD associated complains by the patient. Signs that are present but unknown to the patient are called subclinical (Okeson, 2008b).

The physical examinations involve are summarized in Table 2.3.

Table 2.3: Physical examination by Stern & Greenberg, 2013 (Stern & Greenberg, 2013)

Physical Examination		
System	Physical Examination	Examples of related disease
General appraisal	Asymmetry, swelling, tremors, posture Palpation of extraoral soft tissues such as lymph nodes and salivary glands	Neoplastic disease Dyskinesia Cervical spine disorders Multiple sclerosis
Musculoskeletal evaluation	Palpation of cervical and muscles of mastication. Palpation (and auscultation) of the TMJs for joint noises and their time of occurrence, tenderness, and swelling Measuring mandibular range of vertical and lateral movements Inspect for corrected and uncorrected deviations, maximum opening with comfort, with pain, and passive range of motion (assisted opening) and signs of parafunction	Primary or secondary myalgia Myofacial pain Chronic widespread pain Localized arthritis Rheumatoid osteoarthritis Polyjoint osteoarthritis Disc displacement with or without reduction
Neurologic evaluation	Cranial nerve screening	CNS neoplasia Multiple sclerosis Secondary trigeminal neuralgia Chronic daily headaches Acute trigeminal neuritis

Table 2.3 continued

Vascular evaluation	Compression of temporal and carotid arteries	Temporal arteritis Trigeminal neuralgia caused by vascular compression
Ear, nose, and throat	Ear discharge, external lesions, swelling of parotid, external auditory canal examination by trained clinician, palpation of the maxillary and frontal sinuses, and visualization of oropharynx	Sinusitis Acute otitis media Neoplastic disease Parotid disease
Intraoral evaluation	Dental and periodontal examination Soft tissue condition (ulceration, mass, and infection) Stability of maxillomandibular relationship, and signs of parafunction	Vesiculobullous and ulcerative disease Dental disorders Periodontal disease

(Stern & Greenberg, 2013)

2.5.2 Diagnostic Imaging

TMD is usually associated with abnormal alterations in the components of the temporomandibular joint. A research by Khojastepour, Vojdani & Forghani (2017), recognized marked alterations of condylar bone in TMD patients as compared to normal individual. They observed changes in condylar bone, including articulate surface became flat, eroded surface, subcortical cyst (Ely cyst), subcortical sclerosis, generalized sclerosis, and marginal bony overgrowth (osteophyte) (Khojastepour, Vojdani, & Forghani, 2017)

Variety of imaging modalities are available to assist in diagnosis of TMD. One basic routine radiograph is the panoramic radiographic which must be taken in patients who are suspected to have TMD as a screening modality in identifying odontogenic disease and other disorders that maybe the source of TMD. Other basic plain radiographs may be used for the evaluation of TMJ namely lateral transcranial view, transpharyngeal view and transmaxillary anterior posterior view (White & Pharoah, 2004).

According to Bagheri & Jo (2008), TMJ arthrogram (injected dye fluoroscopy into superior joint space) is another imaging option capable of displaying the disk dynamic feature and to evaluate disk perforation. It is a minimally invasive procedure. TMJ arthrograms used to assess the position of the disc, but it is technically sensitive and not easily available in most facilities (Bagheri & Jo, 2008).

In the TMJ evaluation, cone beam computed tomography (CBCT) has been extensively used as an imaging method. It has been observed to have superior reliability and precision in the identification of condylar cortical changes as compared to panoramic radiograph and help in diagnosis of TMD (de Boer, Dijkstra, Stegenga, de Bont, & Spijkervet, 2014). In addition, it uses smaller dose than the conventional CT imaging for hard tissue structure assessment (Bagheri et al., 2012). de Boer et al. (2014), suggest that cone-beam CT should be considered as an integral imaging in the presence of limitation of jaw function, movement, and pain in the TMJ on palpation and when the articular eminence is not visible on panoramic (de Boer et al., 2014). Axial CT scan is capable in providing images of confined hard and soft tissue (Bagheri & Jo, 2008).

The articular disc is thin and small in nature making it difficult to assess on CT scan slices. Magnetic resonance imaging MRI is the gold standard for TMD/TMJ assessment, especially prior to surgical intervention. This method is safe for patients as it avoids use of ionizing radiation. MRI gives precise information of the articular disc and mastication muscle, allowing visualization of inflammatory condition and effusions. MRI is useful to evaluate the position, shape, signal of the disk, joint effusion, the marrow signal of the condyle, the presence of loose bodies within the joint, pannus formation in the case of inflammatory arthritides and any osseous changes. According to Hunter & Kalathingal in 2013, proton density (PD) and T2-weighted sequences which acquired in corrected

sagittal and coronal views with the use of TMJ surface coils were mentioned as an imaging protocol that could be applied in TMJ MRI (Hunter & Kalathingal, 2013)

2.6 SCREENING & DIAGNOSTIC TOOLS

2.6.1 Helkimo Index

In 1974, Martti Helkimo created a tool which consist of the anamnestic index (Ai) and clinical dysfunction index (Di) for screening of TMD used in epidemiological study in Finland. For each individual an index was calculated which determined the degree of dysfunction, as judged from both indexes (M. Helkimo, 1974).

The anamnestic index (Ai) is obtained from the interview with the individual, based on yes-no questionnaires which later graded into Ai0 : asymptomatic, AiI : mild symptoms, AiII : severe symptoms (M. I. Helkimo, Bailey, & Ash, 1979).

The clinical dysfunction index (D,) is an evaluation of the masticatory function. It is based on five symptoms; limitation in range of movement of the mandible and TMJ function, pain during mandibular movement, tender on palpation over the TMJ and the muscle of mastication. Each of these five symptoms was judged according to a scale of severity using 0: no symptom, 1: mild symptom or 5: severe points. The scores awarded for the five symptoms were afterward added together. Each individual thus had a total dysfunction score ranging from 0 to 25 points. The higher the score, the more severe the dysfunction.

Table 2.4 Helkimo Ai & Di, 1974 (M. Helkimo, 1974)

Anamnestic dysfunction Index, A_i	
A_i O	denotes complete absence of subjective symptoms of dysfunctions of the masticatory system (i.e. symptoms mentioned under A_i I and A_iII)
A_i I	denotes mild symptoms such as temporomandibular joint (TMJ) sounds (clicking and crepitation), feeling of stiffness or fatigue of the jaws
A_iII	denotes severe symptoms of dysfunction. One or more of following symptoms were reported in the anamnesis: difficulty in opening the mouth wide, locking, luxations, pain on movements, facial and jaw pain
Clinical dysfunction Index, D_i	
D_i O	denotes absence of the clinical symptoms, or which the index is built up
D_i I	denotes mild symptoms of dysfunction. 1 – 4 of the following symptoms were recorded: deviations of the mandible in opening and/or closing movement> 2mm from a straight (sagittal) line, TMJ sounds (clicking or crepitation), tenderness to palpation of the masticatory musculature in 1 – 3 palpation sites, tenderness to palpation laterally over the TMJ, pain in the association with 1 movement of the mandible, maximal mouth opening 30 – 39 mm, horizontal movements 4 – 6 mm
D_i II	denotes at least one severe symptom combined with 0 – 4 mild symptoms or 5 mild symptoms only. The severe symptoms may be any of the following: locking/luxation of TMJ, tenderness to palpation in 4 sites or more of the masticatory musculature, tenderness to palpation posteriorly of the TMJ, pain in 2 or more movements of the jaw, maximal mouth opening < 30 mm, one or more horizontal movements < 4 mm
D_i III	denotes 2 – 5 of the severe symptoms possibly combined with any of the mild symptons

2.6.2 Fonseca Anamnestic Index (FAI)

The FAI was constructed in Portuguese language and used to assess the severity of signs and symptoms of TMD in Brazilian population. This questionnaire is based on Helkimo anamnestic index which is used to classify the severity of TMD either it is mild, moderate or severe.

Table 2.5: Fonseca Anamnestic Index (FAI) questionnaire (Campos et al., 2014; Rodrigues-Bigaton et al., 2017)

Question	Answer		
	No	Sometime	Yes
1. Do you have difficulty opening your mouth wide?			
2. Do you have difficulty moving your jaw to the sides?			
3. Do you feel fatigue or muscle pain when you chew?			
4. Do you have headaches?			
5. Do you have neck pain or stiff neck?			
6. Do you have ear aches or pain in that area (temporomandibular joint)?			
7. Have you ever noticed any noise in your temporomandibular joint while chewing or opening your mouth?			
8. Do you have any habits such as clenching or grinding your teeth?			
9. Do you feel that your teeth do not come together well?			
10. Do you consider yourself a tense (nervous) person?			

It is made up of a ten item/question with responses of "yes" (10 points), "sometimes" (5 points) and "no" (0 points). The total of the score dictate the classification of the severity of TMD: 0 to 15 points means absence of TMD, 20 to 45 points as mild TMD, 50 to 65 points as moderate TMD; and 70 to 100 points as severe TMD (Bevilaqua-Grossi et al., 2006; Rodrigues-Bigaton et al., 2017) (Table 2.6)

Table 2.6: Severity of FAI classification (Pires et al., 2018)

Points	Severity
Total between 0 and 15 points	No TMD
Total between 20 and 45 points	Mild TMD
Total between 50 and 65 points	Moderate TMD
Total between 70 and 100 points	Severe TMD

Based on Helkimo's (1974), Fonseca developed this anamnestic questionnaire that classifies TMD signs and symptoms as light, moderate or severe, or non-TMD. A study by Fonseca himself in 1992 on TMD patient, achieved a reliability of 95% with a good correlation with Helkimo's index ($r = 0.6169$, $p < 0.050$) (Pedroni et al., 2003). According to Pedroni et al, 2003, advantages of FAI are self-administered, fast application time, and low cost (Pedroni et al., 2003). Another extra benefit of the FAI is the reduction of influence from the examiner during the survey and less variability in the measures (Campos et al., 2014).

According to Rodrigues-Bigaton et al. (2017), FAI could be extensively used by health practitioners to assess patients with myogenous TMD. It is cheap, quick, and easy to use even via the phone with excellent accuracy, sensitivity, and specificity to assess individual with myogenous TMD (Rodrigues-Bigaton et al., 2017).

2.6.3 Other Instruments to assess Temporomandibular Disorder

2.6.3.1 Research Diagnostic Criteria of Temporomandibular Disease (RDC/TMD)

Another tool/instrument named Research Diagnostic Criteria for Temporomandibular Disorder (RDC/TMD), edited by Samuel F Dworkin and Linda LeResche, was published in 1992. The RDC/TMD is a tool used to diagnose TMD and the preferred instrument in

cases of myogenous disorder which comprised of two components (Khoo, Jin Yap, Chan, & Bulgiba, 2008; Rodrigues-Bigaton et al., 2017):

(1) Axis I of the RDC/TMD

Records clinical physical findings which are divided into 3 groups: muscle disorders, disc displacements, and other joint conditions (arthralgia, osteoarthritis, and osteoarthrosis).

(2) The Axis II RDC/TMD

Consists of several components derived from self-reported ratings on Likert scales and endorsement of symptoms or limitations on categorical scales. The profile measures perceived pain intensity, pain-related disability, resulting limitations, depression, and nonspecific physical symptoms suggesting somatization tendencies.

A study by John, Dworkin, & Mancl in 2005, shown a reliability fair to good (John, Dworkin, & Mancl, 2005). The Malay translation of RDC/TMD is available (Khoo et al., 2008).

2.6.3.2 Diagnostic Criteria/Temporomandibular Disorder

DC/TMD is an improved tool which is a redefined version of RDC/TMD. It includes Axis I- physical diagnosis screening questionnaire to identify pain-related TMD as well Axis I diagnostic algorithms. This most common pain related TMD is component of a thorough classification framework for TMD Taxonomic (Schiffman et al., 2014).

The new DC/TMD is a comprehensive adjunct to a well-developed clinical reasoning skill, thorough history and the clinical examination. The purpose of this diagnostic protocol is to provide a physical diagnosis and concurrently identify other pertinent features of the patient that would affect the expression and management of the disorders (Schiffman et al., 2014). Nonetheless, the physical assessment requires the presence of the patient and thus impractical on a large sample.

2.7 IMPACT OF TMD ON QUALITY OF LIFE

Every disease has a certain impact on patient's life. One study reported 98.7% of TMD patients demonstrated that TMD has an impact on their quality of life (de Magalhães Barros et al., 2009). A comparison by John et al. in 2007 proven that TMD correlated much higher impacts compared to the normal population (means for all diagnoses were 32.8 to 53.7 versus 15.8 in the general population)(John et al., 2007). This large-scale study has proven that TMD greatly impacts the the quality of life associated with oral health.

2.7.1 Oral Health Impact Profile – Temporomandibular Disorder (OHIP-TMD)

Multiple diseases present related to oral region, giving rise to multiple new tools and instrument either to help in screening, diagnosing and monitoring treatment outcome. Recently, health-related assessment tools vastly developed and adapted for either generic or specific disease to guide in assessing progression or worsening of patient's condition.

In the oral health domain, various studies attempt to identify the best instruments to be used. There is no clear guideline for usage of either generic or disease specific health status measure to be applied in oral health. Generic health status tools are not sensitive to oral health outcomes and it have possibility of poor discriminant and responsiveness of change properties (Allen, 2003; Allen, McMillan, & Locker, 2001). Hence, disease specific measures proven capable in detecting subtle changes producing better responsiveness (Allen, 2003).

Slade and Spencer in 1994, developed a validated tool named Oral Health Impact Profile (OHIP) which were used to a scale the social impact of oral disorders related to oral health outcomes (G. D. Slade & Spencer, 1994). This tool has been shown to have high Cronbach's alpha, 0.70-0.83 and test-retest reliability Intraclass Correlation Coefficient (ICC) of 0.42-0.77 which demonstrated its stability.

A condition-specific measure in respect to TMD, Durham et al, 2011 created Oral Health Impact Profile (OHIP-TMD), a more responsive tools in TMD population which obtained from OHIP-49 using a qualitative and quantitative mixed-method (Durham et al., 2011). Twenty item were originated from OHIP-49. Another two items were obtained from a qualitative TMD research (Durham et al., 2011). OHIP-TMD is grouped into seven domains:

1) the functional limitation (items 1-2)
2) physical pain (items 3-7)
3) psychological discomfort (items 8-11)
4) physical disability (items 12-13)
5) psychological disability (items 14-18)
6) social disability (items 19,20)
7) handicap (items 21,22)

The response is a five-point Likert format: never, hardly ever, occasionally, fairly often, very often (equivalent to scores of 0-4) (He & Wang, 2015). According to Yule *et. al.* in 2015, this questionnaire could detect responses to the standard problem-based items of OHIP-49 based on the same five-point ordinal response, Likert-scale. A higher score indicates a poorer quality of life (Yule et al., 2015).

2.8 CROSS-CULTURAL ADAPTATION (CCA)

Each country has their own languages and cultures which need to be addressed in developing or even in adapting validated questionnaires, instruments or tools prior to application in respective population. Cross-cultural adaptation is compulsory for any instrument to be used in different country and population to obtain equivalence between the original source and target versions of it. The word "cross-cultural adaptation" is used to represent a process that addresses problems at both language (translation) and cultural

adaptation issues in the preparation of a questionnaire before being use in a different population (D. E. Beaton, Bombardier, Guillemin, & Ferraz, 2000).

Based on guidelines by Orbach et al. in 2009, there are three approaches to establish an instrument to second language (Table 2.7):

Table 2.7: Approaches in developing instrument in second language (Ohrbach, Bjorner, Jezewski, John, & Lobbezoo, 2013)

Approach	Definition
Sequential	A completed instrument in a source language is used to produce an adaptation in target language via translation, back-translation, and equivalency
Parallel	A single set of items appropriate to the measurement of the construct in each of the development process is done based on international discussions of each item from relevant cultural input which are present during the instrument development
Simultaneous	An assumption is made that both universal as well as culture specific assessments are required, and so a given version of the instrument in a particular language is comprised of both general items that exist in all language versions as well as items specific to that culture, in relation to the respective construct

The sequential approach is the most commonly used approach (Ohrbach et al., 2013).

Guidelines of CCA for health related measures recommended by Guilleman et al. in 1993 (Guillemin, Bombardier, & Beaton, 1993), which then further revised by Beaton et al. 1998 and approved by American Academy of Orthopaedic Surgeons (AAOS) are summarised in Figure 2.4:

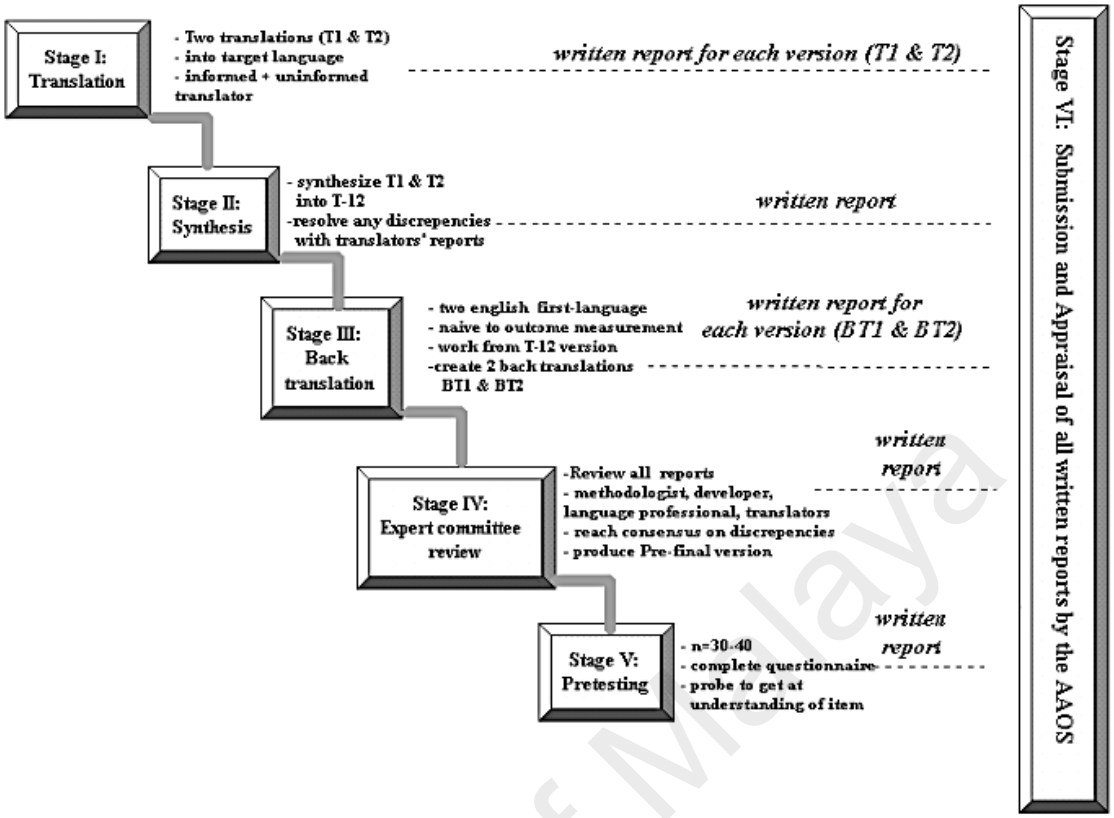

Figure 2-4 Recommended Cross-cultural Adaptation for the approval of AAOS (D. Beaton et al., 1998)

2.8.1 Stage I: Initial Translation

Cross-cultural adaptation begins with a forward translation. A minimum of two forward translations is recommended to compare and compensate each translations discrepancies and differences in wording. The translator should consist of independent individual, bilingual with preferable first language is the target language. It is advisable to involve more than one translator in the process to offer a combination of views (D. Beaton et al., 1998; Epstein, Santo, & Guillemin, 2015; Schmidt & Bullinger, 2003)

2.8.2 Stage II: Synthesis of Translation

Synthesis of common translation (T-12) which derived from first (T1) and second translator (T2) version is conducted by referring to original instrument and recorded by an observer. Any issues addressed and agreements made are then recorded in the written

report. This stage requires the translation to be determined by consensus of all involved rather than single opinion (D. Beaton et al., 1998).

2.8.3 Stage III: Back Translation

Back translation is conducted by translator appointed is/are totally blind to the original version. This process provide validity checking by magnifying inconsistencies or conceptual errors and any unclear wording of the translation. Similar rule applies whereby minimum two translators are needed. These two translations (BT1 and BT2) are constructed by two different persons which the source language (English) is their first language.

The two translators should be blind from the idea of the study preferably individual without a medical background in order to prevent bias, and to induce unanticipated interpretation of the items in the forward translation questionnaire (T-12) therefore improving the likelihood of detecting any inadequacy (D. Beaton et al., 1998).

2.8.4 Stage IV: Expert Committee

The composition of the expert committee is essential to obtained cross-cultural equivalence. This composition should constitute methodologists, health professionals, language professionals and translators (forward and backward translators). The original developers of the questionnaire should be associated together with the expert committee during this stage. This committee is responsible to rectify and merge all versions of the questionnaires to come to consensus and produce pre-final version prior to field testing. The material at the disposal to the committee includes the original questionnaire, and each translation (T1, T2, T12, BT1, BT2) together with corresponding written reports (which explain the rationale of each decision at earlier stages).

According to Guilleman et al in 1993, decisions will need to be made by this committee to achieve equivalence between the source and target version in four areas (Guillemin et al., 1993):

(1) *Semantic equivalence:* the meaning of the items is the same in both cultures

(2) *Idiomatic equivalence:* Colloquialisms, or idioms, are difficult to translate. The committee may have to formulate an equivalent expression in the target version.

(3) *Experiential equivalence:* Items are seeking to capture and experience of daily life, however; often in a different country or culture, a given task may simply not be experienced (even if it is translatable).

(4) *Conceptual equivalence:* domains have the same relevance, meaning and importance regarding the explored concept in both cultures (Epstein et al., 2015).

The committee will have to rearranged and organized all versions of questionnaire, to produce final questionnaire which should be able to understand by a 12-year-old boy as the general recommendation for questionnaires (D. Beaton et al., 1998).

2.8.5 Stage V: Test of The Pre-Final Version

The final integral part of adaptation process is the pretest of the final version to target population whose mother tongue is the target language (Sousa & Rojjanasrirat, 2011). Pre-field methods are particularly suitable to collect information on how respondents proceed when answering the questions. Often, the focus is on single questions rather than the whole questionnaire. They include expert group reviews and cognitive interviews such as think aloud interviews, probing, respondent debriefings, confidence ratings, paraphrasing, sorting, vignette techniques, and analyses of response latencies. One

method sometimes described in the literature as a pre-field method is the use of focus groups or clinical sample, that we treated in the design of the questionnaire, since it is more closely related to a preliminary analysis and the development of concepts than to the actual testing of a draft questionnaire. Nevertheless, focus groups or clinical sample might also play a role in pre-field testing. Focus groups or clinical sample typically require one or more facilitators/researchers and several participants (6-10) who provide insight into the measure's wording and content (Epstein et al., 2015; Ohrbach et al., 2013). According to Beaton et al, 2002, ideally pre-testing should include 30-40 participants of target population.

The findings of this phase are summarized and presented for evaluation to the AAOS or the appropriate committee. It enables investigators determine whether the question idea and purposes can be consistently understood by the participants and how the investigator designed. This stage does not address the construct validity, reliability or item response patterns which are also crucial in defining a successful cross-cultural adaptation. It only helps provides some measure of quality in the content validity.

Approval of translated version of the questionnaire does not require any additional testing for the retention of the psychometric properties of the questionnaire but is highly recommended to be performed. This is in keeping with other guidelines for the translation and adaptation of other measures (D. Beaton et al., 1998; Epstein et al., 2015).

2.8.6 Stage VI: Submission of Documentation to the AAOS or Related Committee for Appraisal

The final stage in the adaptation process is submission of all reports and forms to the AAOS or related committee that will verify the recommended stages or protocol were followed accordingly. This committee will not alter the content, as it will be assuming that by following this process a reasonable translation has been achieved. Once the

appraisal is complete, the committee will either approved, requests for clarification, or not approve.

In the case of the second response, the applicants/researchers will have the opportunity to resubmit their application with the necessary revisions. If the finalized questionnaire is approved, the adapted version will be considered the "authorized" translation and will be made available to others who might be able to make use of it (D. Beaton et al., 1998).

2.9 RELIABILITY & VALIDATION OF TRANSLATED VERSION: PSYCHOMETRIC PROPERTIES

Cross-cultural adaptation does play important part in ensuring a consistency in the content, and face validity between source/original version and target versions of a questionnaire. Most of original version questionnaire have tested the reliability and validity of their questionnaire, hence it is advisable for the resultant version to have the same properties.

It is highly recommended that after an adaptation process, investigators or researchers ensure that the new version has demonstrated the statistical and psychometric measurement properties needed for the intended application and to include the results of that analysis in the final report (D. Beaton et al., 1998; D. E. Beaton et al., 2000; Sousa & Rojjanasrirat, 2011).

2.9.1 RELIABILITY & VALIDATION

Table 2.8 describes psychometric properties in concise and statistical assessment necessary for each of properties related to health related questionnaire development or translation adopted based on Mateen et al in 2017 (Mateen et al., 2017).

Table 2.8 Psychometric Properties & Measurements (Mateen et al., 2017)

Psychometric properties	Definition/Description	Measurements
Reliability: "The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. using different sets of items health related questionnaires outcome (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater); or by the same persons (i.e. raters or responders) on different occasions (intra-rater)"		
•	Internal consistency: The degree to which items in a scale/outcome measure or a subscale of that measure are homogeneous, and the extent to which they measure various aspects of the same construct	Cronbach-α calculated per dimension AND Cronbach-α between .70 and .95 considered excellent
•	Test-retest consistency: The degree to which a scale/outcome measure is stable and produces similar results when administered at 2 different time points, on the same individual, with no interceding intervention	Intraclass Correlation Coefficient (ICC) ≥ 0.70 or weighted kappa at least ≥0.70
•	Inter-rater consistency: The degree to which a scale/outcome measure is stable and produces similar results when conducted by two different administrators (inter), on the same individual, with no interceding intervention	Omitted from the quality criteria, as the vast majority of outcome measures were patient reported
•	Measurement error: The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured	Minimally Important Changes (MIC) -Smallest detectable changes (SDC) OR MIC outside the Limits of Agreement (LOA) OR convincing arguments that the Standard Error Measurement (SEM) is acceptable

Table 2.8 Psychometric Properties & Measurements continued

Psychometric properties	Definition/Description	Measurements
Validity	: Degree to which an instrument measures the construct(s) it purpose to measure	
	• Content and face: The degree to which the domain/concept of consequence is sampled (content)/looks as though is sampled (face) by the items in the scale/ outcome measure	A clear description is provided of the measurement aim, the target population, the concepts that are being measured, and the item selection AND target population and (investigators OR experts) were involved in item selection
	• Criterion (concurrent): The degree to which the scores of a health related-patient reported outcome instrument are an adequate reflection of a criterion standard ("gold standard")	Convincing arguments that criterion standard is criterion AND correlation with criterion standard ≥70
	• Criterion (predictive): The degree to which a scale/outcome measure can forecast a specific outcome at later time points	Any appropriate mathematical method for demonstrating predictive relation [not part of the quality assessment]
	• Construct validity (hypothesis testing): Whether a scale performs as hypothesized by a priori defined relations/ constructs	Specific hypotheses were formulated AND at least 75% of the results are in accordance with these hypotheses
	• Construct validity (structural): The extent to which a factor analysis supports the interrelation between a set of items on a scale and the domains or the constructs theoretically measured by the scale or by subscale structure	Factor analyses performed on adequate sample size (4-10 subjects per variable, and minimum 100 subjects in total

Table 2.8 Psychometric Properties & Measurements continued

Psychometric properties	Definition/Description	Measurements
	• Construct validity (cross-cultural): The degree to which the performance of the items on a translated or culturally adapted instrument are an adequate reflection of the performance of the items of the original version of the instrument	Confirmatory factor analysis of the translated tool, based on: (1) at least 2 forward translations from the source language that yield a pooled forward translation; (2) at least 1 backward translation to the source language that results in another pooled translation; and (3) a review of translated versions by lay and expert panels with revisions
Others	• Responsiveness: The extent to which a scale has the ability to assess clinically important change over time.	Standardized coefficient of responsiveness reported and suggestive of moderate to high responsiveness (eg, Cohen d [effect size] and SRM>0.5. OR Guyatts Responsiveness Ratio (RR) >1.96 OR Receiver Operating Characteristics (ROC) Area Under Curve (AUC)≥.70)

Another guideline for assessment of health-related measurement is the COSMIN (COnsensus-based Standard for the selection of health Measurement Instruments) which aims to improve the selection of health measurement instruments. The relationship of all psychometric properties explained in Figure 2.5:

Figure 2-5 Taxonomy of COSMIN taxonomy of relationships of measurement properties (Mokkink et al., 2010)

The COSMIN is a detailed guide developed for the validation, cross-cultural adaptation, and critical evaluation of studies that aim to evaluate measurement instruments in the area of health which could be used as a guidance in questionnaire development or validation (Rodrigues-Bigaton et al., 2017).

An international Delphi Study conducted by Mokkink et al, in 2010 had developed the COSMIN checklist which is meant for evaluation of the methodological quality of a study on the measurement properties of a health-related patient-related outcome (HR-PRO) instrument. These checklist includes psychometric properties listed (Mokkink et al., 2010) :

1. Internal consistency
2. Reliability
3. Measurement error
4. Content validity
5. Structural validity
6. Hypothesis testing
7. Cross-cultural validity
8. Criterion validity
9. Responsiveness
10. Interpretability

The primary indicator of the measurement of a questionnaires or instruments are the reliability and validity of the specific measures (Kimberlin & Winterstein, 2008). A correct test should be implemented and carried out with regards to available systematically reviewed guidelines to measure the psychometric properties which is an important part of research quality.

CHAPTER 3: METHODOLOGY

This study is a cross sectional study which consists of two main phases:

1) Translation of FAI & OHIP-TMD into Malay Version

2) Psychometric assessment of Malay version of FAI & OHIP-TMD

3.1 TRANSLATION OF FAI & OHIP-TMD INTO MALAY VERSION

The questionnaires that were being translated are:

1) Fonseca Anamnestic Index (FAI) – English Version

2) Oral Health Impact Profile for Temporomandibular Disorder (OHIP-TMD) – English Version

3.1.1 Development, Translation and Cross-Cultural Adaptation

Translation & Validation phases were based on three guidelines Guidelines of cross-cultural adaptation of health-related measures proposed by Guillemin et al. in 1993 (Guillemin et al., 1993), Guidelines for Establishing Cultural Equivalency of Instruments (Ohrbach et al., 2013) & COSMIN checklist (Mokkink et al., 2010). The phases were described in flowchart Figure 3.1.

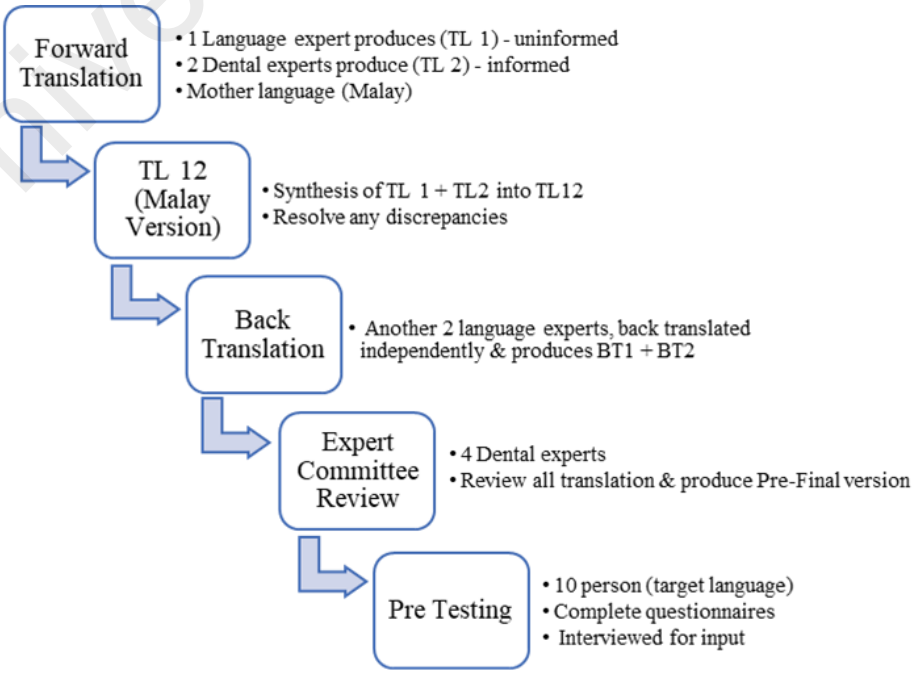

Figure 3-1 Translation Phase of FAI & OHIP-TMD

3.1.2 Forward Translation

The English Version (source language) of Fonseca Anamnestic Index (FAI) & Oral Health Impact Professional for Temporomandibular Disorder (OHIP-TMD) were forward translated to Malay (target language).

Forward translators team consists of one qualified English language expert which produced first translation (TL1) & two dental experts which produced another translation (TL2) independently. The three translators were bilingual individuals which Malay language were their mother tongue. The language expert was naïve to the questionnaire concept while the two dental experts were aware of the study concept. This was to have a mix perspective in generating two translations that contain words and sentences that cover both the medical and the usually spoken language with its cultural nuances (Sousa & Rojjanasrirat, 2011). Both translations were combined and finalized to a translation.

3.1.3 Synthesis of Translation

TL1 and TL2 (forward translation) was then combined and form a finalized single forward translation. Any discrepancies were recorded and addressed. The final translation (TL-12) was then subjected to back translation by the backward translation team. The element that was taken to account were conceptual equivalence, conversational and common language and specific terms which fits the target culture and language.

3.1.4 Back Translation

TL-12 which was the forward translation was then being translated back into source language which was in English by two individual translators independently which later produced backward translation 1 (BT1) and backward translation 2 (BT2). These two translators were two different language experts from forward translation team whose mother tongue were target language (Malay) but both did not have any information and

idea of the questionnaire/instruments being translated as to avoid bias and displaying imperfections in it (D. E. Beaton et al., 2000).

Beaton et al. (1998), mentioned that back translation to the source language is considered as a part of validity check as it is presented gross inconsistencies or conceptual errors of translations (D. Beaton et al., 1998). Although the forward and backward translation design is the most common technique used for cross-cultural research, this methodological steps have not been applied uniformly (Epstein et al., 2015).

3.1.5 Expert Committee Review, Revision and Consolidation

The expert committee for this study composed of 4 dental experts, from three different backgrounds, Oral & Maxillofacial Surgery, Dental Public Health and Prosthodontic. This committee identified any discrepancies between both forward and backward translation and comes with a conclusion compiled which forms a pre-final instrument. The pre-final instrument should represent the most cultural equivalence supported by inputs from every perspective (D. E. Beaton et al., 2000).

The committee was responsible to review the content of the instruments with respect to the four types of equivalences namely semantic, idiomatic, experiential, and conceptual, and make it able to be understood by a 12-year-old native speaker of the target language. These four types of equivalences must be established for an instrument to be used cross-culturally (Ohrbach et al., 2013). In our study, the forward and back translation were analysed and examined thoroughly as consolidation prior to constructing the pre-final Malay version of FAI & OHIP-TMD.

3.1.6 Pre-Testing

The final stage of adaptation process was pre-test. Initial step in validation is the testing of pre-final version to target population. According to Epstein et al. in 2015, focus groups

usually will involve one or more facilitators and several participants (6-10) who provide input into the wording and content of the measure (Epstein et al., 2015).

In this study, we recruited 10 convenience clinical subjects to whom the pre-final version was pre-tested. Each subject was instructed to answer the pre-final questionnaire of Malay version of FAI & OHIP-TMD and they were interviewed instantly after to probe every individual thought of what each questionnaire item meant and the selected answer. Both the meaning of the items and responses are then analysed. This was to assure that the adapted version (pre-final version) still confined to its equivalence in an applied situation. The distribution of responses was analysed to look for a high proportion of missing items or single responses.

According to Ohrbach et al. (2013), the expected outcome of this stage is to identify inappropriate items and items with errors and provide recommendations for how the problematic items can be improved (Ohrbach et al., 2013). Problematic items were reviewed by the expert committee as needed and further revised by the translators and the committee so that the item intention was best reflected.

3.2 PSYCHOMETRIC PROPERTIES ASSESSMENT

Psychometric properties were assessed by field-testing the FAI(M) & OHIP-TMD(M) to the clinical subjects. Reliability and validity analysis were conducted according to data obtained by using IBM SPSS Statistical Version 22.

3.2.1 Study Design

The present study used cross-sectional design and data was collected from January 2017 until January 2018 to assess Malay version of FAI and OHIP-TMD psychometric properties.

3.2.2 Sample Population

Study subjects were convenience sample recruited consists of students of University Malaya, patients who were registered to Faculty of Dentistry, University Malaya and members of the public which fulfilled the inclusion & exclusion criteria of this study.

3.2.3 Study Location

This study was conducted in Faculty of Dentistry, University of Malaya.

3.2.4 Sample Size

The sample size were calculated based on the subject to item ratio whereby 5 to 10 subject were required per item in a single measures or instrument (He & Wang, 2015; Terwee et al., 2007). The most number of item was in OHIP-TMD questionnaire which consist of 22 items. Hence, the minimum amount of subject needed to conduct this study is 110.

3.2.5 Sample Selection Inclusion Criteria

The inclusion criteria for this study were:

a) Age 18 year old and above

b) Ability to understand and comprehend Malay language questionnaire

c) For TMD subject: Presence of pain in the jaw, TMJ area and adjacent structure either at rest or during jaw movement – clinically diagnosed and supported with Axis-1 DC/TMD Pain Screener and/or TMD patient who is treated or follow up in Faculty of Dentistry, University of Malaya in year 2016 until 2018

d) For non TMD subject: patient or public who registered and/or present in Faculty of Dentistry in year 2016 until 2018 who did not have TMD signs and symptoms

3.2.6 Sample Selection Exclusion Criteria

The exclusion criteria for this study are:

a) Subject presence with organic pathology related to temporomandibular joint (TMJ) area or history of trauma

b) Illiteracy and having problems understanding Malay language

c) Diagnosed with psychiatric disorders

d) Inability to give consent

3.2.7 Study Tools

There were multiple questionnaires involved and administered in this study:

1. Demographic questionnaires:
   (a) gender (male, female)
   (b) age (18 – 30-year-old, 31-40 year old, 41-50 year old, 51-60 year old, >60 year old)
   (c) races (Malay, Chinese, Indian, Kadazan/Iban/others)
   (d) level of education (Primary school, Secondary school, Diploma/Colleague, Degree, Postgraduate/PhD)
2. Malay version of FAI (FAI (M)) consists of 10 items with 3 answers (no, sometime, yes)
3. Malay version of OHIP-TMD (OHIP-TMD (M)) consists of 22 items with 5 Likert scale answers option (never, hardly ever, occasionally, fairly often, very often)
4. Global Oral Rating (GOH) questionnaires:
   (a) GOH 1: perceived oral/jaw health status (excellent, good, fair, poor, very poor)

(b) GOH 2: perceived satisfaction with oral/jaw health (very satisfied, satisfied, moderate, dissatisfied, very dissatisfied)

(c) GOH 3: perceived need for oral/jaw treatment (yes, no, don't know)

5. Malay version of Short Oral Health Impact Profile (S-OHIP-TMD) consists of 14 items with 5 Likert scale answers (never, hardly ever, occasionally, fairly, often, very often)

3.2.8 Conduct of the Study

Psychometric properties assessment of FAI (M) & OHIP-TMD (M) involved data collection and data analyses. All convenience subjects were recruited and the final translated Malay version of FAI & OHIP-TMD were administered along with demographic, GOH rating and S-OHIP (M).

Initially, all subject was explained regarding the study concept. Patient information sheet (PIS) and informed consent were provided with the questionnaires. The subject was called to a non-clinical setting room and given 15 minutes to complete the questionnaires and investigators were present during the session for any doubt or queries concerning the study. The subject was instructed to read carefully the PIS and signed the informed consent once they fully understood prior completing the questionnaires.

To carry out test-retest analysis, 40 subsamples were selected and consists of 20 non TMD and 20 TMD subjects. Test-retest was carried out 2 weeks (14 days) after first administration of questionnaires. All data collected were well kept for data entry and analysis later.

3.2.9 Data Analyses

All collected data were reviewed and screened for any missing or incomplete answer. All data were labelled prior data entry into the computer for the ease of analyses. Data were entered into computer using IBM SPSS Statistical Analysis version 22 prior analyses.

The data were screened by assessing the frequency distribution of each item in the questionnaire. Following Slade & Spencer (1997) suggestion, missing data more than 20% of the items (two or more for FAI, 4 or more for OHIP-TMD, 3 or more for S-OHIP (M)) were excluded from analyses (G. Slade, 1997). For continuous data, mean and standard deviation (s.d) were calculated while for categorical data, median and percentage were calculated based on the data. Each study tool was calculated based on their scoring system.

3.2.9.1 Fonseca Anamnestic Index (FAI) and Scoring

This questionnaire is a tool for screening and assessing the severity of TMD, based on their signs and symptoms.

It consists of 10 items with three responses yes (10 points), sometimes (5 points), no (0 points). The score was calculated by the sum of the points of all items and classified (Berni et al., 2015) as:

1) Absence of signs and symptoms of TMD (0-15 points)
2) Mild TMD (20-45 points)
3) Moderate TMD (50-65 points)
4) Severe TMD (70-100 points)

In this study, we used the total score for data analyses for ease of assessing the severity of TMD as to compared to severity score with OHIP-TMD and S-OHIP (M).

3.2.9.2 Oral Health Impact Profile for Temporomandibular Disorder (OHIP-TMD) and Scoring

OHIP-TMD is a tool which is condition-specific measure for TMD, which derived from OHIP-49 using a mixed-method qualitative and quantitative (Durham et al., 2011). It consists of 22 items and grouped into seven domains (Durham et al., 2011):

1) the functional limitation (items 1-2)
2) physical pain (items 3-7)
3) psychological discomfort (items 8-11)
4) physical disability (items 12-13)
5) psychological disability (items 14-18)
6) social disability (items 19,20)
7) handicap (items 21,22)

The response is a five-point Likert format: never (0), hardly ever (1), occasionally (2), fairly often (3), very often (4) (He & Wang, 2015). There are three methods to calculate OHIP-derived questionnaire (Allen & Locker, 1997):

1) Prevalence of impact: percentage of participants reporting 1 or more impacts "very often" or "often"
2) Severity of Impact: Additive (ADD score); calculated by adding up the response codes for each item. The ADD score could range from 0 to 88 for OHIP-TMD
3) Extent of impact: Simple count (SC score); calculated by summing the number of items reported as "very often" and "often". The SC score could range from 0 to 22 for OHIP TMD.

We used the ADD score for this study to assess the severity of impact. The higher the OHIP-TMD score, it reflects a poorer quality of life (Yule et al., 2015).

3.2.9.3 Global Oral Health (GOH) Rating and Scoring

Global Oral Rating (GOH) questionnaires used in present study were adapted from Saub et al. in 2005 (Saub, Locker, & Allison, 2005) were:

1) GOH 1: perceived oral/jaw health status: excellent (1 point), good (2 point), fair (3 point), poor (4), very poor (5 point),
2) GOH 2: perceived satisfaction with oral/jaw health; very satisfied (1 point), satisfied (2 point), moderate (3 point), dissatisfied (4 point), very dissatisfied (5 point),
3) GOH 3: perceived need for oral/jaw treatment; yes (2 point), no (1 point), don't know (0 point)

3.2.9.4 Short Oral Health Impact Profile – Malay version (S-OHIP (M))

S-OHIP (M) developed by Saub et al. in 2005 were used for concurrent validity in our study. It contains 14 items which are grouped similar subscale as original OHIP-49 by Slade & Spencer (1994) (Saub et al., 2005):

1) the functional limitation (items 1, 2)
2) physical pain (items 3, 4)
3) psychological discomfort (items 5, 6)
4) physical disability (items 7, 8)
5) psychological disability (items 9, 10)
6) social disability (items 11,12)
7) handicap (items 13, 14)

The response is described in a five-point Likert format: never, hardly ever, occasionally, fairly, often, very often (equivalent to scores of 0-4). There are two scoring method available: additive score (ADD) and simple count scores (SC). The ADD score adding total score of 14 items ranging from 0 to 56. Another method, SC score calculated by number of item response recorded as 'often' and 'very often' with a range of score of 0 until 14. A greater score represent poorer oral health related quality of life (OHRQoL) (Saub et al., 2005).

In this study, we had modified every 14 items by replacing the word 'denture' with 'jaw'. This was suggested by our study committee so that it more relevant to our study interest and with permission from the original S-OHIP (M)'s author prior modification. We used the ADD score for this study to assess the severity of impact similar conduct with the OHIP-TMD.

3.2.10 Reliability & Analysis

Internal consistency was conducted using Cronbach's alpha coefficient as a measure of internal consistency, calculated using IBM SPSS Statistical Software version 22. Cronbach's alpha is a function of the average intercorrelations of items and the number of items in the scale. A score of more than 0.70 considered having adequate consistency (Zucoloto, Maroco, & Campos, 2014)

Test-retest reliability is applied to 40 subsample of total 243 subjects to complete a second questionnaire 2 weeks after initial administration. Intraclass correlation coefficient (ICC) using two way random effect model with absolute agreement was performed using IBM SPSS Statistical Software version 22. The ICC descriptors values of reliability designated by poor (<0.40), fair to good (0.40 - 0.75) , excellent (> 0.75) (Rosner, 2011).

3.2.11 Validity & Analysis

Concurrent validity test is to measure how well a new instrument compares to a well established tool. In concurrent validity, we apply FAI (M) & OHIP-TMD (M) against Short Version of OHIP- Malay version (S-OHIP (M)) which was already adapted and validated & it is the nearest comparatively related to our area of study (Saub, Locker, Allison, & Disman, 2007).

Spearman's Rho correlation is used to assess concurrent validity in between this questionnaires. A higher score expresses a high correlation is obtained and it indicates good concurrent validity (Aishvarya et al., 2014). The score varies from 1 (perfect correlation) to 0 (absolute no correlation). Spearman's correlation test evaluates the overall correlation between items, considering values >0.20 to be considered as the existence of proper correlation (Rodrigues-Bigaton et al., 2017).

Hinkle et al (2003) described an interpretation of correlation coefficient results in details (Hinkle, Wiersma, & Jurs, 2002) (Table 3.2) :

Table 3.1 Correlation Coefficient Interpretation (Hinkle et al., 2002)

Size of Correlation	Interpretation
0.90 to 1.00 (-0.90 to –1.00)	Very high positive (negative) correlation
0.70 to 0.90 (-0.70 to -0.90)	High positive (negative) correlation
0.50 to 0.70 (-0.50 to -0.70)	Moderate positive (negative) correlation
0.30 to 0.50 (-0.30 to -0.50)	Low positive (negative) correlation
0.00 to 0.30 (0.00 to -0.30)	Little if any correlation

Construct Validity is a test used to measure how well an instrument measures up to it claims (Ohrbach et al., 2013). Currently, there is no 'gold standard' related to TMD condition, hence construct validity was evaluated. The construct validity involved were convergent and discriminative test (Saub et al., 2005).

For convergent validity, FAI (M) & OHIP-TMD (M) were analyzed against Global Oral Health (GOH) Questionnaire which consists of three general question on oral health status, which adopted from Saub et al. in 2005, includes:

1) GOH 1: perceived oral/jaw health status: excellent (1 point), good (2 point), fair (3 point), poor (4), very poor (5 point)
2) GOH 2: perceived satisfaction with oral/jaw health; very satisfied (1 point), satisfied (2 point), moderate (3 point), dissatisfied (4 point), very dissatisfied (5 point)
3) GOH 3: perceived need for oral/jaw treatment; yes (2 point), no (1 point), don't know (0 point) (Saub et al., 2005)

These global questions used to reflect subjects' general oral health and TMJ conditions in general. The hypotheses tested were:

1) those who were having poor oral health status would be more likely to have higher FAI (M) score than those who were good or excellent
2) those who were having poor oral health status would be more likely to have higher OHIP-TMD (M) score than those who were good or excellent
3) those who not satisfied with their oral/jaw health status would be more likely to have higher FAI (M) score than those who satisfied
4) those who not satisfied with their oral/jaw health status would be more likely to have higher OHIP-TMD (M) score than those who satisfied
5) those who need for dental treatment more would be more likely to have higher FAI (M) & OHIP-TMD (M) than those who not required treatment

6) those who need for dental treatment more would be more likely to have higher OHIP-TMD (M) than those who not required treatment

The higher the score, the poorer the oral health status. Kruskal-Wallis test is used for analyses based on the distribution of the data which is nonparametric, non normally distributed and to compare outcome which more than 2 groups (Rosner, 2011). The null hypothesis states that the population medians are all equal. P-value less than 0.050 represent statistically significant difference in between normal subject and TMD.

In discriminative validity, we were assessing whether FAI (M) & OHIP-TMD (M) could discriminate non-TMD from TMD population. Data obtained demonstrated non normal distribution, hence Mann Whitney-U test was used to evaluate this property (Rosner, 2011). The bigger the U-value, the lesser differences in between two groups, with a p-value of less than 0.050 is considered significant. The hypotheses were:

1) TMD subject should have higher FAI (M) score as compared to non TMD
2) TMD subject would have a higher OHIP-TMD (M) score as compare to non TMD

3.3 ETHICAL APPROVAL AND FUNDING

The ethical approval for this study was obtained from Medical Ethics Committee, Faculty of Dentistry, University of Malaya on 22 December 2016 (Ethics Committee/IRB Reference Number: DF OS1701/0008(L)) (Appendix A).

The funding of this study was obtained from Dental Research Management Center (DRMC) under Dental Postgraduate Research Grant, Faculty of Dentistry, University of Malaya (DPRG/01/17).

3.4 INFORMED CONSENT

The subjects that were recruited in this study consists of individuals who fulfilled the inclusion and exclusion criteria. They were given a brief explanation of the study and they were asked to read the Patient Information Sheet (PIS) document carefully prior to participation (Appendix B).

Afterward, once the patient fully understood and agreed to be part of this study, the written informed consent form (Appendix C) was signed and personally dated by the subject and by the investigator who conducted the informed consent discussion and data collection session.

CHAPTER 4: RESULTS

4.1 TRANSLATION

The English version of FAI & OHIP-TMD were successfully translated to Malay language via forward and backward translation according to the translation protocol for this study. There were no marked item or word changes in forward and backward translation comparatively. The final translations of FAI & OHIP -TMD were then pre-tested to 10 convenience clinical subject and feedbacks obtained described that the questionnaires were easy to understand. The final Malay version of FAI & OHIP-TMD were as attached in Appendix E and G respectively.

4.2 PSYCHOMETRIC ANALYSIS

In this study, a total of 252 initial subjects were involved and consisted of 165 normal (non-temporomandibular disorder non-TMD) subject and 87 subjects which presented with temporomandibular disorder (TMD). Nine from total subjects were excluded as they did not answer in more than 20% of questionnaires. Finally, a total 243 subjects participated consisting of 160 non-TMD subjects and 83 TMD subjects. TMD were identified & diagnosed clinically and supported by using Axis-1 DC/TMD Pain Screener. A response rate of 96.4% was recorded.

As for test-retest reliability assessment, 40 subsamples (20 normal and 20 TMD) were selected randomly, and they are given the same sets of questionnaires at interval time of 2 weeks between first and second administrations (He & Wang, 2015; Meulen, Lobbezoo, Aartman, & Naeije, 2014; Terwee et al., 2007)

4.3 SAMPLE CHARACTERISTICS

A convenience subjects of 243 consists of 68 males, and 175 females. Most of the subject is in a range of age 18 to 30-year-old which composed 72.0 % of subjects. As Malaysia is a multiracial country, there was a presence of various races involved in this

study includes of Malay (72.0%), Chinese (12.0%), Indian (14.8%) and others such as Iban, Kadazan (1.2%) of total subjects. Majority of the subjects' educational level were diploma/college level with 42.8% subjects (Table 4.1).

Table 4.1 Characteristic of subjects (N=243)

Characteristics		n	Percentage
Age	18-30-year-old	175	72.0
	31-40-year-old	55	22.6
	41-50-year-old	6	2.5
	51-60-year-old	5	2.1
	>60-year-old	2	0.8
Gender	Male	68	28.0
	Female	175	72.0
Race	Malay	175	72.0
	Chinese	29	12.0
	Indian	36	14.8
	Others	3	1.2
Education Level	Primary School	3	1.2
	Secondary School	52	21.4
	Diploma/College	104	42.8
	Degree	79	32.5
	Postgraduate/PhD	5	2.1

4.4 RELIABILITY ANALYSIS

There are 2 questionnaires being analyzed for psychometric properties which consist of Malay version of FAI & OHIP-TMD (FAI (M) & OHIP-TMD (M)).

4.4.1 FAI Reliability

The highest correlation for each item in the construct was between 0.31 and 0.90, except for FAI (M) item number 5, which falls below 0.3 (Table 4.2). The lowest

Corrected Item-Total Correlation value was 0.31(Table 4.3). The reliability test for FAI (M) conducted resulted a Cronbach's alpha of 0.90 (Table 4.4)

Table 4.2 FAI (M) Inter-Item Correlation Matrix

	FAI1	FAI2	FAI3	FAI4	FAI5	FAI6	FAI7	FAI8	FAI9	FAI10
FAI1	1.000	.869	.703	.422	.079	.677	.667	.372	.701	.480
FAI2	.869	1.000	.638	.404	.049	.654	.626	.358	.713	.426
FAI3	.703	.638	1.000	.534	.299	.660	.523	.394	.623	.527
FAI4	.422	.404	.534	1.000	.579	.538	.379	.324	.382	.495
FAI5	.079	.049	.299	.579	1.000	.296	.156	.127	.182	.376
FAI6	.677	.654	.660	.538	.296	1.000	.525	.413	.618	.509
FAI7	.667	.626	.523	.379	.156	.525	1.000	.402	.569	.420
FAI8	.372	.358	.394	.324	.127	.413	.402	1.000	.338	.456
FAI9	.701	.713	.623	.382	.182	.618	.569	.338	1.000	.526
FAI10	.480	.426	.527	.495	.376	.509	.420	.456	.526	1.000

Table 4.3 FAI (M) Mean scores, corrected item-total correlation and Cronbach's alpha if item deleted

	Mean scores	Standard Deviation (SD)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
FAI 1	2.1	3.4	0.78	0.88
FAI 2	1.8	3.3	0.74	0.88
FAI 3	2.4	3.1	0.76	0.88
FAI 4	3.4	3.2	0.61	0.89
FAI 5	2.5	3.0	0.31	0.91
FAI 6	2.0	2.9	0.76	0.88
FAI 7	2.7	3.9	0.66	0.89
FAI 8	1.5	2.7	0.48	0.90
FAI 9	1.7	2.9	0.73	0.88
FAI 10	1.9	2.8	0.64	0.89

Test – retest was performed on 40 subsamples. The test-retest was conducted using ICC absolute agreement and obtained a score of 0.97 (Table 4.4). There was a significant correlation in between pre and post test, p-value of <0.001 with 95% confidence interval, lower bound of 0.98 and upper bound of 0.99, using a two-way mixed effects model (Table 4.4).

Table 4.4 Internal Consistency and Test–retest Reliability of the FAI (M)

Scale	Internal Consistency Cronbach's Alpha n-=243	ICC n=40	ICC (95%CI) n=40
Total Score	0.90	0.99	0.98-0.99
FAI 1	0.88	0.96	0.84-0.96
FAI 2	0.88	1.00	-
FAI 3	0.88	0.99	0.97-0.99
FAI 4	0.88	0.97	0.88-0.97
FAI 5	0.91	0.92	0.75-0.92
FAI 6	0.88	0.99	0.96-0.99
FAI 7	0.89	0.97	0.89-0.97
FAI 8	0.90	0.99	0.95-0.99
FAI 9	0.88	0.98	0.94-0.98
FAI 10	0.89	0.91	0.71-0.91

4.4.2 OHIP-TMD (M) Reliability

The highest correlation for each item in the construct was between 0.43 and 0.87 (Table 4.5). The lowest Corrected Item-Total Correlation value was 0.72 (Table 4.6). The reliability test for OHIP-TMD (M) conducted resulted a Cronbach's alpha of 0.98 (Table 4.7).

Test – retest was performed on 40 subsamples. The test-retest was conducted using ICC absolute agreement and obtained a score of 0.99 (Table 4.7). There was a significant correlation in between pre- and post-test, p-value of <0.001 with 95% confidence interval, lower bound of 0.98 to upper bound 0.99, using a two-way mixed effects model (Table 4.7).

Table 4.5 OHIP-TMD (M) Inter-Item Correlation Matrix

	TMD 1	TMD 2	TMD 3	TMD 4	TMD 5	TMD 6	TMD 7	TMD 8	TMD 9	TMD 10	TMD 11	TMD 12	TMD 13	TMD 14	TMD 15	TMD 16	TMD 17	TMD 18	TMD 19	TMD 20	TMD 21	TMD 22
TMD1	1.000	.720	.557	.696	.568	.811	.536	.718	.745	.774	.725	.796	.695	.616	.620	.642	.623	.568	.614	.688	.564	.631
TMD2	.720	1.000	.632	.874	.524	.757	.672	.627	.675	.703	.643	.676	.710	.518	.517	.591	.491	.486	.538	.728	.514	.565
TMD3	.557	.632	1.000	.647	.723	.604	.724	.537	.427	.556	.640	.475	.525	.661	.618	.694	.641	.658	.684	.625	.666	.668
TMD4	.696	.874	.647	1.000	.590	.742	.672	.646	.634	.710	.669	.675	.719	.529	.535	.601	.534	.499	.562	.719	.537	.564
TMD5	.568	.524	.723	.590	1.000	.603	.714	.519	.418	.571	.670	.473	.464	.674	.642	.700	.675	.667	.652	.568	.663	.654
TMD6	.811	.757	.604	.742	.603	1.000	.612	.734	.772	.818	.765	.849	.817	.632	.578	.628	.600	.614	.635	.812	.591	.616
TMD7	.536	.672	.724	.672	.714	.612	1.000	.570	.470	.584	.668	.498	.569	.714	.618	.728	.635	.651	.692	.633	.639	.720
TMD8	.718	.627	.537	.646	.519	.734	.570	1.000	.769	.759	.746	.735	.667	.637	.697	.677	.660	.650	.664	.689	.614	.591
TMD9	.745	.675	.427	.634	.418	.772	.470	.769	1.000	.839	.754	.826	.741	.576	.654	.613	.599	.539	.582	.743	.567	.581
TMD10	.774	.703	.556	.710	.571	.818	.584	.759	.839	1.000	.848	.835	.765	.672	.703	.706	.688	.657	.730	.814	.668	.658
TMD11	.725	.643	.640	.669	.670	.765	.668	.746	.754	.848	1.000	.738	.698	.760	.773	.798	.788	.772	.787	.756	.722	.745
TMD12	.796	.676	.475	.675	.473	.849	.498	.735	.826	.835	.738	1.000	.861	.607	.611	.609	.585	.605	.636	.768	.534	.562
TMD13	.695	.710	.525	.719	.464	.817	.569	.667	.741	.765	.698	.861	1.000	.579	.513	.560	.542	.543	.599	.815	.498	.527
TMD14	.616	.518	.661	.529	.674	.632	.714	.637	.576	.672	.760	.607	.579	1.000	.739	.861	.783	.780	.739	.632	.690	.783
TMD15	.620	.517	.618	.535	.642	.578	.618	.697	.654	.703	.773	.611	.513	.739	1.000	.829	.847	.755	.816	.605	.815	.775
TMD16	.642	.591	.694	.601	.700	.628	.728	.677	.613	.706	.798	.609	.560	.861	.829	1.000	.845	.792	.762	.656	.731	.796
TMD17	.623	.491	.641	.534	.675	.600	.635	.660	.599	.688	.788	.585	.542	.783	.847	.845	1.000	.752	.747	.618	.818	.775
TMD18	.568	.486	.658	.499	.667	.614	.651	.650	.539	.657	.772	.605	.543	.780	.755	.792	.752	1.000	.758	.653	.742	.739
TMD19	.614	.538	.684	.562	.652	.635	.692	.664	.582	.730	.787	.636	.599	.739	.816	.762	.747	.758	1.000	.708	.786	.761
TMD20	.688	.728	.625	.719	.568	.812	.633	.689	.743	.814	.756	.768	.815	.632	.605	.656	.618	.653	.708	1.000	.678	.669
TMD21	.564	.514	.666	.537	.663	.591	.639	.614	.567	.668	.722	.534	.498	.690	.815	.731	.818	.742	.786	.678	1.000	.799
TMD22	.631	.565	.668	.564	.654	.616	.720	.591	.581	.658	.745	.562	.527	.783	.775	.796	.775	.739	.761	.669	.799	1.000

Table 4.6 OHIP-TMD (M) Mean scores, Corrected Item-Total Correlation

	Mean scores	Standard Deviation (SD)	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
OHIP-TMD 1	0.8	1.1	0.81	0.98
OHIP-TMD 2	0.7	1.0	0.77	0.98
OHIP-TMD 3	0.7	1.0	0.74	0.98
OHIP-TMD 4	0.8	1.0	0.78	0.98
OHIP-TMD 5	0.6	0.9	0.72	0.98
OHIP-TMD 6	0.9	1.1	0.85	0.98
OHIP-TMD 7	0.5	0.8	0.76	0.98
OHIP-TMD 8	0.9	1.0	0.81	0.98
OHIP-TMD 9	0.8	1.1	0.79	0.98
OHIP-TMD 10	0.6	0.9	0.88	0.98
OHIP-TMD 11	0.6	0.9	0.90	0.98
OHIP-TMD 12	0.8	1.1	0.82	0.98
OHIP-TMD 13	0.7	1.1	0.78	0.98
OHIP-TMD 14	0.5	0.8	0.81	0.98
OHIP-TMD 15	0.5	0.9	0.82	0.98
OHIP-TMD 16	0.5	0.9	0.85	0.98
OHIP-TMD 17	0.5	0.8	0.81	0.98
OHIP-TMD 18	0.6	0.8	0.79	0.98
OHIP-TMD 19	0.5	0.9	0.83	0.98
OHIP-TMD 20	0.6	0.9	0.85	0.98
OHIP-TMD 21	0.5	0.9	0.79	0.98
OHIP-TMD 22	0.5	0.8	0.81	0.98

Table 4.7 Internal Consistency and Test–retest Reliability of the OHIP-TMD (M)

Scale	Internal Consistency Cronbach's Alpha coefficient n-=243	ICC n=40	ICC (95%CI) n=40
Total Score	0.98	0.99	0.98-0.99
Functional Limitation OHIP-TMD 1- 2	0.84	0.99	0.98-0.99
Physical Pain OHIP-TMD 3-7	0.90	0.97	0.95-0.99
Psychological discomfort OHIP-TMD 8-11	0.90	0.99	0.96-0.99
Physical disability OHIP-TMD 12-13	0.93	0.99	0.96-0.99
Psychological disability OHIP-TMD 14-18	0.95	0.99	0.95-0.99
Social disability OHIP-TMD 19-20	0.83	0.98	0.93-0.98
Handicap OHIP-TMD 21-22	0.89	0.98	0.92-0.98

4.5 VALIDITY

4.5.1 Concurrent Validity

Concurrent validity test was conducted using S-OHIP (M) which already cross-cultural adapted to Malaysian population and the closest instrument/tool to compare with FAI (M) & OHIP-TMD (M).

Validity test in this study was conducted following the non-parametric analysis as the descriptive data were non normally distributed. The Kolmogorov-Smirnov test (p-value < 0.050) and visual inspection of histogram and Q-Q plot showed FAI (M) and OHIP-TMD (M) data were non-normally distributed with FAI (M) skewness of 0.9 (SE=0.2) and kurtosis of -0.1 (SE=0.3) and OHIP-TMD (M) skewness of 0.9 (SE=0.3) and kurtosis of 0.9 (SE=0.3)

Concurrent validity test was conducted using Spearman rank correlation between FAI (M) and S-OHIP (M). There was a significant correlation seen with p-value < 0.001 (Table 4.8). There was a strong linear relationship correlation in between FAI (M) and S-OHIP (M) with correlation coefficient positive value, r_s of 0.71.

Table 4.8 Correlation of FAI (M) and S-OHIP (M)

			FAI (M)	S-OHIP (M)
Spearman's rho	FAI (M)	Correlation Coefficient	1.000	0.711(**)
		Sig. (2-tailed)	.	<0.001
		N	243	243
	S-OHIP (M)	Correlation Coefficient	0.711(**)	1.000
		Sig. (2-tailed)	<0.001	.
		N	243	243

** Correlation is significant at the 0.010 level (2-tailed)

Concurrent validity test was conducted using Spearman rank correlation between OHIP-TMD (M) and S-OHIP (M). There was a significant correlation with p-value of <0.001 (Table 4.10). There was positive strong linear relationship correlation in between OHIP-TMD (M) and S-OHIP (M) with correlation coefficient value, r_s of 0.74 (Table 4.9).

Table 4.9 Correlation of OHIP-TMD (M) and S-OHIP (M)

			OHIP-TMD (M)	S-OHIP (M)
Spearman's rho	OHIP-TMD (M)	Correlation Coefficient	1.000	.740(**)
		Sig. (2-tailed)	.	<0.001
		N	243	243
	S-OHIP (M)	Correlation Coefficient	.740(**)	1.000
		Sig. (2-tailed)	<0.001	.
		N	243	243

** Correlation is significant at the 0.010 level (2-tailed)

4.5.2 Construct Validity

Two kinds of construct validity test were conducted. There were convergent and discriminative test.

4.5.2.1 Convergent Validity

Convergent validity test were conducted using Kruskal Wallis test as the data was non parametric and to compare more than two groups in each global oral health questionnaire (GOH) outcomes.

Table 4.10 Association between FAI (M) and Global Oral Health (GOH) Rating

		N	FAI (M) Mean Score (S.D)	P-value*
GOH 1 Perceived oral/jaw health status	Excellent	24	8.1 (9.5)	<0.001
	Good	70	10.3 (12.4)	
	Fair	113	24.2 (21.0)	
	Poor	32	43.9 (27.2)	
	Very Poor	4	70 (11.5)	
GOH 2 Perceived satisfaction with oral/jaw health	Very Satisfied	40	8.5 (10.9)	<0.001
	Satisfied	116	12.7 (15.1)	
	Moderate	40	38.0 (24.3)	
	Dissatisfied	10	48.0 (15.5)	
	Very Dissatisfied	2	55.0 (14.1)	
GOH 3 Perceived need for oral/jaw treatment	Yes	55	38.1 (25.5)	<0.001
	No	124	11.3 (15.1)	
	Don't know	64	28.8 (21.7)	

*Kruskal Wallis test

Based on table 4.10, the p-value of Kruskal Wallis test for FAI (M) and GOH 1, GOH 2 and GOH 3 were all < 0.001, which was less than 0.050. The mean score of FAI (M) was increased as the respondents perceived oral health status changed from excellent to very poor. Those respondents who perceived a need for dental treatment and were not satisfied with their oral health had a significant higher mean FAI score (Table 4.10).

Table 4.11 Association between OHIP-TMD (M) and Global Oral Health (GOH) Rating

		N	OHIP-TMD(M) Mean Score (S.D)	P-value*
GOH 1 Perceived oral/jaw health status	Excellent	24	4.5 (7.1)	<0.001
	Good	70	5.0 (8.8)	
	Fair	113	14.4 (14.4)	
	Poor	32	34.0 (20.1)	
	Very Poor	4	62.5 (20.1)	
GOH 2 Perceived satisfaction with oral/jaw health	Very Satisfied	40	6.1 (11.1)	<0.001
	Satisfied	116	7.1 (10.4)	
	Moderate	40	24.8 (19.2)	
	Dissatisfied	10	41.2 (16.4)	
	Very disssatisfied	2	38 (21.2)	
GOH 3 Perceived need for oral/jaw treatment	Yes	55	30.5 (21.5)	<0.001
	No	124	6.4 (9.6)	
	Don't know	64	14.9 (15.0)	

*Kruskal Wallis test

Based on table 4.11, the p-value of test for OHIP-TMD (M) against GOH 1, GOH 2 & GOH 3 was < 0.001, which is less than 0.050. The mean score of OHIP-TMD (M) increased as the respondents perceived oral health status changed from excellent to very poor. Those respondents who perceived a need for dental treatment and were not satisfied with their oral health had a significantly higher mean OHIP-TMD (M) score (Table 4.11).

4.5.2.2 Discriminative Validity

Discriminative validity was conducted using Mann-Whitney U Test. The data in this was nonparametric, as for discriminative, we compared normal or non-TMD subject and TMD subject using Mann Whitney U test.

Table 4.12 Discriminative Validity in between non TMD and TMD groups

	Group	N	Mean Score (S.D)	Sum of Ranks	P- value*
FAI (M)	Healthy/Non TMD	160	10.1 (12.2)	13795.5	<0.001
	TMD	83	44.8 (20.7)	15674.5	
OHIP-TMD (M)	Healthy/Non TMD	160	5.6 (8.4)	14065.0	<0.001
	TMD	83	30.5 (18.2)	15581.0	

*Mann Whitney U test

Discriminative validity test for FAI (M) (Table 4.12) showed sum ranks of 13795.5 in normal subject and 15674.5 in subject with TMD. The mean score of FAI (M) was higher in TMD group. In the Mann-Whitney U test, the p-value is 0.001, which is less than 0.050. Hence there is significant difference in between normal subject and subject with TMD.

Discriminative validity test for OHIP-TMD (M) (Table 4.12) showed sum ranks of 14065.0 in normal/non-TMD subject and 15581.0 in subject with TMD. The mean score of OHIP-TMD (M) was higher in TMD group. In the Mann-Whitney U test, the p-value is 0.001, which was less than 0.050. Hence there is significant difference in between normal subject and subject with TMD.

CHAPTER 5: DISCUSSIONS

5.1 TRANSLATION

Cross cultural adaptation and synthesis of Malay version of FAI & OHIP-TMD were conducted via forward and backward translation following the translation protocol of this study. Three main reference guidelines for the whole process were Guidelines of cross cultural adaptation of health related measures proposed by Guilleman et al. in 1993 (Guillemin et al., 1993), Guidelines for Establishing Cultural Equivalency of Instruments (Ohrbach et al., 2013) and COSMIN checklist (Mokkink et al., 2010).

Forward translation team consists of one language expert (uniformed) and two dental experts (informed) which produced 2 separate translations respectively and later being concluded to a single forward translation version. Our protocol applied that the forward translation team were bilingual, whose native language were Malay language. They were from two distinct background, health related personnel and language expert. This was to ensure that we obtained a mix perspective and views on the items of the questionnaires not only from medical aspect but also to equivalence it to the usual spoken language (Sousa & Rojjanasrirat, 2011).

Back translation team in our protocol consists of two language experts with similar background, bilingual, but their native language is Malay. They are both have no prior knowledge of the original questionnaires (blinded) and they produced two independent translations separately. This was carried out as to reduce biases (Guillemin et al., 1993). Sousa & Rojjanasrirat, (2011) emphasized that a well-qualified translators chosen for back translation is key in producing high quality back translations (Sousa & Rojjanasrirat, 2011). The sort of experts engaged in the translation process can also affect the result of a translation (Van Widenfelt, Treffers, De Beurs, Siebelink, & Koudijs, 2005). Back translation should be comparable to the content and purpose of the initial items,

instructions and answer categories. One must keep in mind to not solely based on the back translation as the only method of translation (Hambleton, 2001).

Expert committee team of this study consists of four dental experts with three different specialties were involved in synthesizing the Malay version of FAI & OHIP-TMD. All forward and backward translations were reviewed and examined in detail for all type of equivalence (Semantic, Idiomatic, Experiential and Conceptual) until consensus was reached in producing the pre-final version. General recommendations for questionnaires were followed by making sure that the pre-final questionnaire would be understood by the equivalent of a 12-year-old (roughly a grade six level of reading) (D. Beaton et al., 1998).

Pre-testing was done to 10 convenience clinical subjects and they were interviewed immediately after they answered the pre-final version. Arredondo et al. (2012), proposed a number of 6 to 10 subjects for pre testing is vital to provide input on the wording and content of the item (Arredondo, Mendelson, Holub, Espinoza, & Marshall, 2012). Pre-testing served as final assessment for any discrepancies of wording and understanding of the whole questionnaires involved in present study which were Malay version of FAI & OHIP-TMD. All subjects for pre-testing could completed the given questionnaires with no issue arise either in wording or concept of the study, as they commented it as straight forward and easy to understand.

5.2 STUDY DESIGN AND SAMPLE POPULATION

5.2.1 Study design

A cross sectional study design was used in this study. This design is an appropriate for this study as one of the main objective is to assess the psychometric properties of FAI (M) and OHIP-TMD (M) prior application to Malaysian population which were conducted in a specific period of time (Mann, 2003).

5.2.2 Sample

The sample in this study were selected using non random sampling, convenience technique which individuals who are the easiest to recruit, consists of individuals seeking dental treatment in Faculty of Dentistry, University Malaya and public present in University of Malaya (Kelley, Clark, Brown, & Sitzia, 2003).

A total of 252 convenience subjects initially recruited. They were required to answer all questionnaires given: sociodemographic, Malay version of FAI, OHIP-TMD, S-OHIP and GOH rating. All subjects strictly followed the inclusion and exclusion criteria. Nine subjects which were not answering the questionnaires given completely were excluded. Finally, 243 subjects which consist of 160 non-TMD subjects and 83 TMD subject were considered with response rate of 96.4%. The possibility of high response rate was likely due to well given instructions by the investigator and the questionnaires itself were easy to understand.

5.2.3 Sample size calculation

The sample size were calculated based on the subject to item ratio whereby 5 to 10 subject are required per item in a single measures or instrument and this was to ensure stability of variance-covariance matrix in analysis (He & Wang, 2015; Terwee et al., 2007). The most number of item was in OHIP-TMD questionnaire which consist of 22 items, therefore, the minimum subject required is 110. We successfully recruited more than the minimum suggested. A total of 243 convenience subjects obtained from period of January 2017 until Januari 2018.

5.2.4 Characteristics of Sample Population

This study involved patients aged more than 18-year-old who public or patient present in Faculty of Dentistry, University Malaya. The minimum age was selected for ease of study and fitness for informed consent taking. The most age range which represents the

sample population were aged in between 18 to 30-year-old with more than half of total sample (72.0%). This was due to the convenience sample which mostly contributed by individuals who were student and present in University Malaya during the research data collection period.

Based on Department of Statistics Malaysia, estimated major ethnic groups distribution in Malaysia in year 2017 are *Bumiputera* (Malay) (68.8%), Chinese (23.2%), Indians (7.0%) and others (1.0%) (Mahidin, 2017). Our study reflected almost similar race distributions with Malay (72.0%), Chinese (12.0%), Indian (14.8%) and others (1.0%), except Indian had a higher percentage than Malaysian distribution.

In the present study, most of subject had received tertiary education with a total of 183 (75.3%). This was likely due to most of the subject involved in this study were convenience subject of University Malaya population, either student or staff.

5.3 RELIABILITY ANALYSIS

Reliability test which was performed for in this study are:

1) Internal consistency by using Cronbach alpha calculation
2) Test-retest consistency by using Intraclass Correlation Coefficient (ICC)

5.3.1 Reliability of FAI (M)

FAI (M) internal consistency test obtained a Cronbach's alpha of 0.90. Minimum Cronbach's alpha of 0.70 is required to show a good internal consistency and as for clinical setting a higher value are needed, with a minimum value of 0.90 (Bland & Altman, 1997). Mateen et al. (2017) described that Cronbach alpha between 0.70 and 0.95 are considered excellent (Mateen et al., 2017). Hence, internal consistency of FAI (M) was accepted as excellent.

Test-retest consistency were performed on data of 40 subsample who were recalled and repeated the same questionnaires after 2 weeks (14 days) following the first administration. ICC using absolute agreement was conducted and FAI (M) obtained a score of 0.97, which is more than 0.70 that which considered as 'minimum accepted' reliability (Mokkink et al., 2010; Terwee et al., 2007). Guidelines agreed by Cicchetti & Sparrow (1981), Fleiss (1981) and Landis & Koch (1977) stated that when the reliability coefficient is below 0.40, the level of clinical significance is poor; when it is between 0.40 and 0.59, the level of clinical significance is fair; when it is between 0.60 and 0.74, the level of clinical significance is good; and when it is between 0.75 and 1.00, the level of clinical significance is excellent (Cicchetti, 1994; Landis & Koch, 1977). The test-retest using ICC of FAI (M) shown an excellent result.

Internal consistency and test-retest consistency indicated that FAI (M) was reliable and stable based on the tests conducted.

5.3.2 Reliability of OHIP-TMD (M)

The reliability test for OHIP-TMD (M) conducted results a Cronbach's alpha of 0.98. Minimum Cronbach's alpha of 0.70 is required to show a good internal consistency and as for clinical setting a higher value are needed, with a minimum value of 0.90 (Bland & Altman, 1997). Mateen et al (2017) described that Cronbach alpha between 0.70 and 0.95 are considered as excellent (Mateen et al., 2017). This result demonstrated that OHIP-TMD (M) have a good internal consistency. He and Wang (2015) obtained a Cronbach alpha of 0.92 which was similar to our finding (He & Wang, 2015).

Test-retest consistency were performed on data of 40 subsamples who were recalled and repeated the same questionnaires after 2 weeks following the first administration. ICC using absolute agreement was conducted and OHIP-TMD (M) obtained a score of 0.97, which is more than 0.70 that considered 'minimum accepted' reliability (Mokkink

et al., 2010; Terwee et al., 2007). ICC score of 0 denote no reliability, while score 1 denote perfect reliability (Weir, 2005). There is significant correlation in between pre- and post-test p-value of <0.001 with 95% confidence interval, lower bound of 0.98 to upper bound 0.99, using a two-way mixed effects model. The guidelines state that, when the reliability coefficient is below 0.40, the level of clinical significance is poor; when it is between 0.40 and 0.59, the level of clinical significance is fair; when it is between 0.60 and 0.74, the level of clinical significance is good; and when it is between 0.75 and 1.00, the level of clinical significance is excellent (Cicchetti, 1994; Landis & Koch, 1977). The result demonstrated that OHIP-TMD (M) have a good internal consistency. This finding is similar with study by Yule et al. (2015) and He and Wang (2015) which obtained test retest ICC of 0.81 and 0.89 respectively (He & Wang, 2015; Yule et al., 2015)

Internal consistency and test-retest consistency indicated that OHIP-TMD (M) was reliable and stable based on the tests conducted.

5.4 VALIDITY ANALYSIS

Validity test in this study conducted following the non-parametric analysis as the descriptive data were non-normally distributed. A Kolmogorov–Smirnov test was applied in this study where the goal is to compare two unknown distributions & have more power than methods based on means, and it comparable with methods based on robust measures of location (Wilcox, 2005). It also showed to be more powerful than chi-square test for any sample size (Lilliefors, 1967; Massey Jr, 1951).

The Kolmogorov-Smirnov test (p-value < 0.050) and visual inspection of histogram and Q-Q plot showed FAI (M) and OHIP-TMD (M) data were non-normally distributed (Chinna & Choo, 2016; Razali & Wah, 2011).

5.4.1 Concurrent Validity

Concurrent validity test was conducted in this study as there was no "gold standard" instrument to assess TMD. There is S-OHIP(M) which already cross-culturally adapted to Malaysian population and considered as the closest instrument to compare with FAI (M) & OHIP-TMD (M) with respect to oral health related assessment (Saub et al., 2005). There was a modification in this study whereby the word 'denture' in every 14 items in S-OHIP (M) were replaced with the word 'jaw' as agreed by study committee and the original author of S-OHIP (M). The purpose was to relate it more towards the interest of the study which were concerning of specific measure of FAI and OHIP-TMD that related to the temporomandibular disorder.

Spearman's coefficient of rank correlation test is generally used to measure the degree of correspondence between rankings also considered as a measure of association between the samples and an estimate of the association between X and Y in the continuous bivariate population (Gibbons & Chakraborti, 2011). It usually adopted when assumption of bivariate normal distribution is not tenable (Artusi, Verderio, & Marubini, 2002). The data in our study was non normally distributed, hence Spearman's rank correlation coefficient test was used in this study for concurrent validity test in to evaluates correlation between FAI (M), OHIP-TMD (M) and S-OHIP (M).

5.4.1.1 Association in between FAI (M) and S-OHIP (M)

Concurrent validity test conducted using Spearman rank correlation was performed. There was significant correlation with p-value < 0.001, which was less than 0.010. There was a positive strong linear relationship correlation in between FAI (M) and S-OHIP (M) with correlation coefficient was positive value, r_s of 0.71 more than 0.70 (Terwee et al., 2007). This value fall in between range of +0.70 to +0.90 which considered as high positive correlation (Hinkle et al., 2002). Therefore, it is convinced that FAI (M) was

significantly correlated in the same purpose with S-OHIP (M) and had a good concurrent validity. This result also consistent with Fonseca (1992), which demonstrated FAI and Helkimo's index obtained moderate positive correlation ($r = 0.62$, $p < 0.050$) in assessing TMD (Pedroni et al., 2003).

5.4.1.2 Association of OHIP-TMD (M) and S-OHIP (M)

Concurrent validity test conducted using Spearman rank correlation. There was significant correlation with p-value of < 0.001, less than 0.010. There was a positive strong linear relationship correlation in between OHIP-TMD (M) and S-OHIP (M) with correlation coefficient value, r_s of 0.74 more than 0.70 (Terwee et al., 2007). This value fall in between range of +0.70 to +0.90 which considered as high positive correlation (Hinkle et al., 2002). Therefore, it is convinced that OHIP-TMD (M) was significantly correlated with in the same purpose with S-OHIP (M) and had a good concurrent validity.

5.4.2 Convergent Validity

Convergent validity is usually used to describes how closely a measure is related to other measures of the same construct to which it should be related. It is optimal for convergent validity to use either internationally available instrument or nationally well-tested instruments for validation purposes (Bullinger, Anderson, Cella, & Aaronson, 1993). The GOH rating was adopted from studies conducted by Saub et al. (2005) and He & Wang (2015) (He & Wang, 2015; Saub et al., 2005). The association between the global oral health (GOH) rating with FAI (M) and OHIP-TMD (M) scores using Kruskal Wallis test were calculated to assess for convergent validity.

5.4.2.1 Association of FAI (M) and Global Oral Health (GOH) Rating

The p-value of Kruskal Wallis test for FAI (M) against GOH 1, GOH 2 & GOH 3 was significant with a value of < 0.001, which is less than 0.050. This provides evidence of construct validity. Thus, mean score of FAI (M) was increased as the respondents

perceived oral health status changed from excellent to very poor. Those respondents who perceived a need for dental treatment and were not satisfied with their oral health had significantly higher mean FAI score. Overall, there were a significant correlations of FAI (M) with all GOH rating questionnaires and thus proved that it closely measures similar construct.

The hypotheses testing for FAI (M) were: 1) those who were having poor oral health status would be more likely to have higher FAI (M) score than those who were good or excellent; 2) those who not satisfied with their oral/jaw health status would be more likely to have higher FAI (M) score than those who satisfied; 3) those who need for dental treatment more would be more likely to have higher FAI (M) score than those who not required treatment. All hypotheses were strongly accepted based on the convergent validity results.

5.4.2.2 Association of OHIP-TMD (M) and Global Oral Health (GOH) Rating

The p-value of test of Kruskal Wallis test for OHIP-TMD (M) against GOH 1, GOH 2 & GOH 3 is < 0.001, which was less than 0.050. This provides evidence of construct validity Thus, mean OHIP-TMD (M) score increased as the respondents perceived oral health status changed from excellent to very poor. Those respondents' who perceived a need for dental treatment and were not satisfied with their oral health had significant higher mean OHIP-TMD (M) score. Overall, there are significantly correlations of OHIP-TMD (M) with all GOH rating questionnaires and thus proved that it closely measures the similar construct.

The hypotheses testing for OHIP-TMD (M) were :1) those who were having poor oral health status would be more likely to have higher OHIP-TMD (M) score than those who were good or excellent; 2) those who not satisfied with their oral/jaw health status would be more likely to have higher OHIP-TMD (M) score than those who satisfied; 3) those

who need for dental treatment more would be more likely to have higher OHIP-TMD (M) than those who not required treatment. All hypotheses were strongly accepted based on the convergent validity results.

5.4.3 Discriminative Validity

Discriminative validity is mostly concerned with how well the scale can distinguish between groups with known differences. As for discriminative test, we compared the score of normal/non-TMD group with TMD group. Our hypothesis was: TMD subjects will have higher score as compared to non TMD subjects in both FAI (M) and OHIP-TMD (M) questionnaires. In this study, we used Mann Whitney U test for discriminative validity. This test is normally used to obtain a relationship in a nonparametric of two independent samples test (Rosner, 2011).

5.4.3.1 Discriminative Test of FAI (M) in between non-TMD and TMD

Discriminative validity test for OHIP-TMD (M) (Table 4.16) showed sum ranks of 14065.0 in normal/non-TMD subject and 15581.0 in subject with TMD. In the Mann-Whitney U test, the p-value is 0.001, which is less than 0.050. Hence there is significant difference in sum rank FAI (M) between normal subject and subject with TMD. The hypothesis testing for FAI (M) was: TMD group should have higher FAI (M) score as compared to non TMD group. This hypothesis was strongly supported by the findings of this test.

5.4.3.2 Discriminative Validity Test of OHIP-TMD in between non-TMD and TMD

Discriminative validity test for FAI (M) (Table 4.16) showed sum ranks of 13795.5 in normal subject and 15674.5 in subject with TMD. In the Mann-Whitney U test, the p-value is 0.001, which is less than 0.050. Hence there is significant difference in between normal subject and subject with TMD. The hypothesis testing for OHIP-TMD (M) was:

TMD group should have higher OHIP-TMD (M) score as compared to non TMD group. This hypothesis was strongly supported by the findings of this test.

5.5 LIMITATION OF STUDY

5.5.1 Translation process

Ideally, the translator is suggested to be a bilingual individual with native language is the source language (Ohrbach et al., 2013). Due to fund constraint, we recruited two translators from local language expert (mother tongue is Malay language) for back translation.

Pre-testing conducted in this study was limited to a minimum of 10 participants only. Few studies used more participant for pre-testing process, as this possible to relate with an insufficient feedback in the cultural representative to the wording prior synthesis of final translation of FAI & OHIP-TMD.

5.5.2 Sample

A convenience sampling technique conducted in this study did not sufficiently represent the Malaysian population in view of its multiracial and variety of ethnics in Malaysia. A reach to wider range of population for instances in rural and urban whereby both populations involved would be able to reflect a better generalizable of Malaysian population

5.5.3 Psychometric Assessment

Based on Guidelines proposed by Terwee et al. (2007) and Mateen et al. (2017), more psychometric assessment was suggested to be conducted which is confirmatory factor analysis, as a part of construct validity test. The time constraint limits us to conduct this analysis.

5.6 Future Study

There are few recommendations for further study:

1. To test FAI (M) and OHIP-TMD (M) to a wider population with different backgrounds such as urban and rural, more races and ethnics in Malaysia, different level of educations.
2. To use a validated Malay version of Diagnostic Criteria for Temporomandibular Disorder (DC/TMD) for better concurrent validity tools which are more specific for TMD as compared to S-OHIP (M) which are more general oral health assessment.
3. To assess the psychometric properties of FAI (M) & OHIP-TMD (M), by additional factor analysis on both instruments.
4. To do cross cultural adaptation of English version of FAI & OHIP-TMD for English preferred-Malaysian population.
5. To apply FAI (M) for assessment Malaysian population as it a cheaper form of screening for population based survey.
6. To assess responsiveness to change in perceive oral health status of the OHIP-TMD (M) for clinical outcome assessment application.

CHAPTER 6: CONCLUSION

1. The FAI and OHIP-TMD have been successfully developed and translated into Malay versions via forward-backward translation
2. Psychometric properties assessment conducted shown statistically significant results and sufficiently demonstrated that FAI (M) and OHIP-TMD (M) were valid and reliable for use by Malaysian population.

REFERENCES

Ahmad, M., & Schiffman, E. L. (2016). Temporomandibular Joint Disorders and Orofacial Pain. *Dental Clinics of North America*, *60*(1), 105-124.

Aishvarya, S., Maniam, T., Karuthan, C., Sidi, H., Nik Jaafar, N. R., & Oei, T. P. (2014). Psychometric properties and validation of the Satisfaction with Life Scale in psychiatric and medical outpatients in Malaysia. *Compr Psychiatry*, *55*, S101-S106.

Allen, P. F. (2003). Assessment of oral health related quality of life. *Health and Quality of Life outcomes*, *1*(1), 40.

Allen, P. F., & Locker, D. (1997). Do item weights matter? An assessment using the oral health impact profile. *Community dental health*, *14*(3), 133-138.

Allen, P. F., McMillan, A. S., & Locker, D. (2001). An assessment of sensitivity to change of the Oral Health Impact Profile in a clinical trial. *Community dentistry and oral epidemiology*, *29*(3), 175-182.

Arredondo, E. M., Mendelson, T., Holub, C., Espinoza, N., & Marshall, S. (2012). Cultural Adaptation of Physical Activity Self-Report instruments. *Journal of Physical Activity and Health*, *9*(s1), S37-S43.

Artusi, R., Verderio, P., & Marubini, E. (2002). Bravais-Pearson and Spearman correlation coefficients: meaning, test of hypothesis and confidence interval. *The International Journal of Biological Markers*, *17*(2), 148-151.

Bagheri, S. C., Bell, R., & Khan, H. (2012). *Current Therapy in Oral and Maxillofacial Surgery*. St. Louis, Missouri: Elsevier Saunders.

Bagheri, S. C., & Jo, C. (2008). *Clinical Review of Oral and Maxillofacial Surgery*. St. Louis, Missouri: Mosby Elsevier.

Bagis, B., Ayaz, E. A., Turgut, S., Durkan, R., & Özcan, M. (2012). Gender Difference in Prevalence of Signs and Symptoms of Temporomandibular Joint Disorders: A Retrospective Study on 243 Consecutive Patients. *International journal of medical sciences*, *9*(7), 539-544.

Beaton, D., Bombardier, C., Guillemin, F., & Ferraz, M. B. (1998). Recommendations for the cross-cultural adaptation of health status measures. *New York: American Academy of Orthopaedic Surgeons*, 1-9.

Beaton, D. E., Bombardier, C., Guillemin, F., & Ferraz, M. B. (2000). Guidelines for the Process of Cross-Cultural Adaptation of Self-Report Measures. *Spine*, *25*(24), 3186-3191.

Berni, K. C., Dibai-Filho, A. V., & Rodrigues-Bigaton, D. (2015). Accuracy of the Fonseca anamnestic index in the identification of myogenous temporomandibular disorder in female community cases. *Journal of Bodywork & Movement Therapies, 19*(3), 404-409.

Bevilaqua-Grossi, D., Chaves, T. C., de Oliveira, A. S., & Monteiro-Pedro, V. (2006). Anamnestic Index Severity and Signs and Symptoms of TMD. *CRANIO®, 24*(2), 112-118.

Bland, J. M., & Altman, D. G. (1997). Statistics notes: Cronbach's alpha. *British Medical Journal, 314*(7080), 572.

Bonini, J. A. D., Campos, D., Carrascosa, A. C., Bonafé, F. S. S., & Maroco, J. (2014). Epidemiology of severity of temporomandibular disorders in Brazilian women. *Headache, 28*, 147-152.

Bullinger, M., Anderson, R., Cella, D., & Aaronson, N. (1993). Developing and evaluating cross-cultural instruments from minimum requirements to optimal models. *Quality of life research, 2*(6), 451-459.

Campos, J. A. D. B., Carrascosa, A. C., Bonafé, F. S. S., & Maroco, J. (2014). Severity of temporomandibular disorders in women: validity and reliability of the Fonseca Anamnestic Index. *Brazilian oral research, 28*(1), 16-21.

Chinna, K., & Choo, W. Y. (2016). *Statistical analysis using SPSS* (3rd Edition ed.): Pearson Malaysia.

Cicchetti, D. V. (1994). Guidelines, Criteria, and Rules of Thumb for Evaluating Normed and Standardized Assessment Instruments in Psychology. *Psychological assessment, 6*(4), 284-290.

Clark, G., Delcanho, R., & Goulet, J.-P. (1993). The Utility and Validity of Current Diagnostic Procedures for Defining Temporomandibular Disorder Patients. *Advances in dental research, 7*(2), 97-112.

Conti, P. C. A., Ferreira, P. M., Pegoraro, L. F., Conti, J. V., & Salvador, M. C. (1996). A Cross-Sectional Study of Prevalence and Etiology of Signs and Symptoms of Temporomandibular Disorders in High School and University Students. *Journal of Orofacial Pain, 10*(3), 254-262.

Conti, P. C. R., Pinto-Fiamengui, L. M. S., Cunha, C. O., & Conti, A. C. d. C. F. (2012). Orofacial pain and temporomandibular disorders- the impact on oral health and quality of life. *Brazilian oral research, 26*(SPE1), 120-123.

de Boer, E. W. J., Dijkstra, P. U., Stegenga, B., de Bont, L. G. M., & Spijkervet, F. K. L. (2014). Value of cone-beam computed tomography in the process of diagnosis and management of disorders of the temporomandibular joint. *British Journal of Oral and Maxillofacial Surgery, 52*(3), 241-246.

de Magalhães Barros, V., Seraidarian, P. I., de Souza Côrtes, M. I., & de Paula, L. V. (2009). The Impact of Orofacial Pain on the Quality of Life of Patients with Temporomandibular Disorder. *Journal of Orofacial Pain, 23*(1).

De Rossi, S. S., Greenberg, M. S., Liu, F., & Steinkeler, A. (2014). Temporomandibular Disorders: Evaluation and Management. *Medical Clinics of North America, 98*(6), 1353-1384.

Durham, J., Steele, J., Wassell, R., Exley, C., Meechan, J., Allen, P., & Moufti, M. A. (2011). Creating a patient-based condition-specific outcome measure for Temporomandibular Disorders (TMDs): Oral Health Impact Profile for TMDs (OHIP-TMDs). *Journal of oral rehabilitation, 38*(12), 871-883.

Dym, H., & Israel, H. (2012). Diagnosis and Treatment of Temporomandibular Disorders. *Dental Clinics of North America, 56*(1), 149-161.

Epstein, J., Santo, R. M., & Guillemin, F. (2015). A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. *Journal of clinical epidemiology, 68*(4), 435-441.

Florencio, L. L., de Oliveira, A. S., Carvalho, G. F., Dach, F., Bigal, M. E., Fernandez-de-Las-Penas, C., & Bevilaqua-Grossi, D. (2017). Association Between Severity of Temporomandibular Disorders and the Frequency of Headache Attacks in Women With Migraine: A Cross-Sectional Study. *J Manipulative Physiol Ther, 40*(4), 250-254.

Fricton, J. R. (2014). Temporomandibular Disorders. In M. J. Aminoff & R. B. Daroff (Eds.), *Encyclopedia of the Neurological Sciences (Second Edition)* (Vol. 4, pp. 409-413). Oxford: Academic Press.

Gauer, R. L., & Semidey, M. J. (2015). Diagnosis and Treatment of Temporomandibular Disorders. *American family physician, 91*(6), 378-386.

Gibbons, J. D., & Chakraborti, S. (2011). Nonparametric Statistical Inference. In *International encyclopedia of statistical science* (pp. 977-979): Springer Berlin Heidelberg.

Guillemin, F., Bombardier, C., & Beaton, D. (1993). Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *Journal of clinical epidemiology, 46*(12), 1417-1432.

Hambleton, R. K. (2001). The next generation of the ITC Test Translation and Adaptation Guidelines. *European Journal of Psychological Assessment, 17*(3), 164.

He, S. L., & Wang, J. H. (2015). Validation of the chinese version of the oral health impact profile for TMDs (OHIP-TMDs-C). *Medicina Oral Patología Oral y Cirugia Bucal*, e161-e166.

Helkimo, M. (1974). Studies on function and dysfunction of the masticatory system. *Acta odontologica scandinavica, 32*(4), 255-267.

Helkimo, M. I., Bailey, J. O., & Ash, M. M. (1979). Correlations of electromyographic silent period duration and the Helkimo dysfunction index. *Acta odontologica scandinavica, 37*(1), 51-56.

Hinkle, D. E., Wiersma, W., & Jurs, S. G. (2002). *Applied statistics for the behavioral sciences* (5th edition ed.): Boston : Houghton Mifflin.

Hunter, A., & Kalathingal, S. (2013). Diagnostic imaging for temporomandibular disorders and orofacial pain. *Dental Clinics, 57*(3), 405-418.

Hupp, J. R., Tucker, M. R., & Ellis, E. (2014). *Contemporary Oral and Maxillofacial Surgery* (6th edition ed.). St Louis, Missouri: Elsevier Mosby.

John, M. T., Dworkin, S. F., & Mancl, L. A. (2005). Reliability of clinical temporomandibular disorder diagnoses. *Pain, 118*(1-2), 61-69.

John, M. T., Reiβmann, D. R., Schierz, O., & Wassell, R. W. (2007). Oral Health-Related Quality of Life in Patients with Temporomandibular Disorders. *Journal of Orofacial Pain, 21*(1).

Kelley, K., Clark, B., Brown, V., & Sitzia, J. (2003). Good practice in the conduct and reporting of survey research. *International Journal for quality in health care, 15*(3), 261-266.

Khojastepour, L., Vojdani, M., & Forghani, M. (2017). The association between condylar bone changes revealed in cone beam computed tomography and clinical dysfunction index in patients with or without temporomandibular joint disorders. *Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology, 123*(5), 600-605.

Khoo, S.-P., Jin Yap, A. U., Chan, Y. H., & Bulgiba, A. M. (2008). Translating the Research Diagnostic Criteria for Temporomandibular Disorders into Malay: evaluation of content and process. *Journal of Orofacial Pain, 22*(2).

Kimberlin, C. L., & Winterstein, A. G. (2008). Validity and reliability of measurement instruments used in research. *American Journal of Health-System Pharmacy, 65*(23), 2276-2284.

Landis, J. R., & Koch, G. G. (1977). The measurement of observer agreement for categorical data. *biometrics, 33*(1), 159-174.

Lei, J., Fu, J., Yap, A. U., & Fu, K.-Y. (2016). Temporomandibular disorders symptoms in Asian adolescents and their association with sleep quality and psychological distress. *CRANIO®, 34*(4), 242-249.

Lilliefors, H. W. (1967). On the Kolmogorov-Smirnov test for normality with mean and variance unknown. *Journal of the American statistical Association, 62*(318), 399-402.

Liu, F., & Steinkeler, A. (2013). Epidemiology, Diagnosis, and Treatment of Temporomandibular Disorders. *Dental Clinics of North America, 57*(3), 465-479.

Mahidin, M. U. (2017). Press Release Current Population Estimates, Malaysia, 2016-2017. Available from Goverment of Malaysia Department of Statistics Malaysia Retrieved 14th July 2017 https://www.dosm.gov.my

Manfredini, D., Guarda-Nardini, L., Winocur, E., Piccotti, F., Ahlberg, J., & Lobbezoo, F. (2011). Research diagnostic criteria for temporomandibular disorders: a systematic review of axis I epidemiologic findings. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics, 112*(4), 453-462.

Manfredini, D., & Lobbezoo, F. (2010). Relationship between bruxism and temporomandibular disorders: a systematic review of literature from 1998 to 2008. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology, 109*(6), e26-e50.

Mann, C. (2003). Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emergency medicine journal, 20*(1), 54-60.

Massey Jr, F. J. (1951). The Kolmogorov-Smirnov Test for Goodness of Fit. *Journal of the American statistical Association, 46*(253), 68-78.

Mateen, B. A., Doogan, C., Hayward, K., Hourihan, S., Hurford, J., & Playford, E. D. (2017). Systematic Review of Health-Related Work Outcome Measures and Quality Criteria-Based Evaluations of Their Psychometric Properties. *Archives of physical medicine and rehabilitation, 98*(3), 534-560.

Meulen, M., Lobbezoo, F., Aartman, I., & Naeije, M. (2014). Validity of the Oral Behaviours Checklist: correlations between OBC scores and intensity of facial pain. *Journal of oral rehabilitation, 41*(2), 115-121.

Miloro, M., Ghali, G., Larsen, P., & Waite, P. (2004). *Peterson's principles of oral and maxillofacial surgery* (Vol. 1): PMPH-USA.

Mokkink, L. B., Terwee, C. B., Patrick, D. L., Alonso, J., Stratford, P. W., Knol, D. L., . . . De Vet, H. C. (2010). The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Quality of life research, 19*(4), 539-549.

Moore, U. J. (2011). *Principles of Oral and Maxillofacial Surgery* (6th edition ed.): John Wiley & Sons.

NIDCR, N. I. o. D. C. R. (2018). Prevalence of TMJD and its Signs and Symptoms _ National Institute of Dental and Craniofacial Research. Retrieved February, 2018, from National Insitute of Health https://www.nidcr.nih.gov/research/data-statistics/facial-pain/prevalence

Ohrbach, R., Bjorner, J., Jezewski, M., John, M., & Lobbezoo, F. (2013). Guidelines for establishing cultural equivalency of instruments. *New York: University at Buffalo*.

Okeson, J. P. (2008a). The Classification of Orofacial Pains. *Oral and Maxillofacial Surgery Clinics of North America, 20*(2), 133-144.

Okeson, J. P. (2008b). *Management of Temporomandibular Disorders and Occlusion* (6th Edition ed.). St. Louis, Missouri: Mosby Inc., Elsevier.

Oliveira, A. S. d., Dias, E. M., Contato, R. G., & Berzin, F. (2006). Prevalence study of signs and symptoms of temporomandibular disorder in Brazilian college students. *Brazilian oral research, 20*(1), 3-7.

Pandarakalam, C., & Khalaf, M. W. (2014). Temporomandibular Disorders. In *Reference Module in Biomedical Sciences*: Elsevier.

Pedroni, C., De Oliveira, A., & Guaratini, M. (2003). Prevalence study of signs and symptoms of temporomandibular disorders in university students. *Journal of oral rehabilitation, 30*(3), 283-289.

Pires, P. F., de Castro, E. M., Pelai, E. B., de Arruda, A. B. C., & Rodrigues-Bigaton, D. (2018). Analysis of the accuracy and reliability of the Short-Form Fonseca Anamnestic Index in the diagnosis of myogenous temporomandibular disorder in women. *Brazilian Journal of Physical Therapy*.

Razali, N. M., & Wah, Y. B. (2011). Power comparisons of shapiro-wilk, kolmogorov-smirnov, lilliefors and anderson-darling tests. *Journal of statistical modeling and analytics, 2*(1), 21-33.

Rodrigues-Bigaton, D., de Castro, E. M., & Pires, P. F. (2017). Factor and Rasch analysis of the Fonseca anamnestic index for the diagnosis of myogenous temporomandibular disorder. *Brazilian Journal of Physical Therapy, 21*(2), 120-126.

Rosner, B. (2011). *Fundamentals of biostatistics* (7th Edition ed.). Boston: Brooks/Cole, Cengage Learning.

Saub, R., Locker, D., & Allison, P. (2005). Derivation and validation of the short version of the Malaysian Oral Health Impact Profile. *Community dentistry and oral epidemiology, 33*(5), 378-383.

Saub, R., Locker, D., Allison, P., & Disman, M. (2007). Cross-cultural adaptation of the Oral Health Impact Profile (OHIP) for the Malaysian adult population. *Community dental health, 24*(3), 166-175.

Schiffman, E., Ohrbach, R., Truelove, E., Look, J., Anderson, G., Goulet, J.-P., . . . Svensson, P. (2014). Diagnostic criteria for temporomandibular disorders (DC/TMD) for clinical and research applications: recommendations of the International RDC/TMD Consortium Network and Orofacial Pain Special Interest Group. *Journal of oral & facial pain and headache, 28*(1), 6.

Schmidt, S., & Bullinger, M. (2003). Current issues in cross-cultural quality of life instrument development. *Archives of physical medicine and rehabilitation, 84*, S29-S34.

Slade, G. (1997). The Oral Health Impact Profile In: Slade GD, ed. *Measuring Oral Health and the Quality of Life*, 93-104.

Slade, G. D., & Spencer, A. J. (1994). Development and evaluation of the oral health impact profile. *Community dental health, 11*(1), 3-11.

Sousa, V. D., & Rojjanasrirat, W. (2011). Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. *Journal of evaluation in clinical practice, 17*(2), 268-274.

Stern, I., & Greenberg, M. S. (2013). Clinical Assessment of Patients with Orofacial Pain and Temporomandibular Disorders. *Dental Clinics of North America, 57*(3), 393-404.

Tallents, R., Katzberg, R., Murphy, W., & Proskin, H. (1996). Magnetic resonance imaging findings in asymptomatic volunteers and symptomatic patients with temporomandibular disorders. *The Journal of Prosthetic Dentistry, 75*(5), 529-533.

Terwee, C. B., Bot, S. D., de Boer, M. R., van der Windt, D. A., Knol, D. L., Dekker, J., . . . de Vet, H. C. (2007). Quality criteria were proposed for measurement properties of health status questionnaires. *Journal of clinical epidemiology, 60*(1), 34-42.

Van Widenfelt, B. M., Treffers, P. D., De Beurs, E., Siebelink, B. M., & Koudijs, E. (2005). Translation and cross-cultural adaptation of assessment instruments used in psychological research with children and families. *Clinical child and family psychology review, 8*(2), 135-147.

Weir, J. P. (2005). Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. *Journal of strength and conditioning research, 19*(1), 231.

White, S., & Pharoah, M. (2004). Oral radiography principles and interpretation. In *Diagnostic Imaging of the temporomandibular joint* (5th ed., pp. 538-550): St. Louis: CV Mosby Company.

Wilcox, R. (2005). Kolmogorov–smirnov test. *Encyclopedia of biostatistics*.

Yap, A. U., Chua, E., Dworkin, S. F., Tan, H., & Tan, K. B. (2002). Multiple pains and psychosocial functioning/psychologic distress in TMD patients. *International Journal of Prosthodontics, 15*(5).

Yap, A. U., Chua, E., & Tan, K. B. (2004). Depressive symptoms in Asian TMD patients and their association with non-specific physical symptoms reporting. *Journal of oral pathology & medicine, 33*(5), 305-310.

Yap, A. U. J., Tan, K. B. C., Chua, E. K., & Tan, H. H. (2002). Depression and somatization in patients with temporomandibular disorders. *The Journal of Prosthetic Dentistry, 88*(5), 479-484.

Yule, P. L., Durham, J., Playford, H., Moufti, M. A., Steele, J., Steen, N., . . . Ohrbach, R. (2015). OHIP-TMDs: a patient-reported outcome measure for temporomandibular disorders. *Community Dent Oral Epidemiol, 43*(5), 461-470.

Zucoloto, M. L., Maroco, J., & Campos, J. A. D. B. (2014). Psychometric properties of the Oral Health Impact Profile and new methodological approach. *Journal of dental research*, *93*(7), 645-650.