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# Translation and Validation of the Malay Version of Oral Health Impact Profile for Temporomandibular Disorders

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## ABSTRACT

Most prior oral health-related quality of life (OHRQoL) research concerning temporomandibular disorders (TMDs) had utilised generic OHRQoL measures. This study aimed to translate and validate the Malay version of Oral Health Impact Profile for TMDs (OHIP-TMDs), a TMDs-specific OHRQoL tool, for use in Malay literate populations. The translation and cross-cultural adaptation of the OHIP-TMDs into the Malay language were implemented according to the international guidelines. A convenience sample of 243 subjects completed the Malay OHIP-TMDs (OHIP-TMDs-M) as well as the Malay Short Oral Health Impact Profile (S-OHIP-M), Global Oral Health ratings (GOH-M) and Fonseca Anamnestic Index (FAI-M). The OHIP-TMDs-M was re-administered to a subset of 40 subjects after two weeks for test-retest reliability. Concurrent, convergent and discriminative validity were assessed using Spearman's rank correlation, Kruskal Wallis and Mann-Whitney U tests with significance level set at $p < 0.05$. The OHIP-TMDs-M was found to have excellent internal consistency (Cronbach's alpha = 0.98) and test-retest reliability (intraclass correlation coefficient = 0.99, $p < 0.001$). A strong and positive correlation with S-OHIP-M ($rs = 0.74$) was observed, and OHIP-TMDs-M scores differed significantly between subjects with disparate GOH-M ratings ($p < 0.001$). Furthermore, the OHIP-TMDs-M was able to discriminate between subjects with and without TMDs. The OHIP-TMDs-M was found to have excellent reliability and good validity. It is a promising tool for assessing TMDs-specific OHRQoL in Malay literate populations.

***Keywords:*** *Cross-cultural adaptation; oral health-related quality of life; psychometric testing; temporomandibular disorders; translation*

 

## INTRODUCTION

Temporomandibular disorders (TMDs) are a group of conditions affecting the temporomandibular joints, masticatory muscles and surrounding structures (NIDCR, 2019). TMDs affect about 12% of the general population and more females (Manfredini *et al.*, 2011; NIDCR, 2019). Signs and symptoms of TMDs typically increase during adolescence and peak during middle age (Lövgren *et al.*, 2016). In addition to orofacial pain and headaches, other TMDs signs/symptoms include TMJ noises and locking, limited or abnormal jaw movements as well as otologic complaints like ear fullness, tinnitus, vertigo and hearing loss (De Toledo *et al.*, 2017). Pain and dysfunction associated with TMDs can negatively impact the oral health-related quality of life (OHRQoL) of patients more than that caused by other oral conditions (Dahlström & Carlsson, 2010). There was a strong correlation between TMD symptoms and low OHRQoL whose clinical signs and symptoms included orofacial, neck and head pain, sleep disturbance, depression and stress (He & Wang, 2015). However, both non-surgical and surgical interventions to treat TMDs had been shown to improve OHRQoL of patients who suffered from the conditions (Song & Yap, 2018).

The OHRQoL can be described as "a multi-dimensional construct that reflects people's comfort when eating, sleeping and engaging in social interaction; their self-esteem; and their satisfaction with respect to their oral health" (US-DHHS, 2000). By embracing the biopsychosocial effect of oral health and diseases on patients' lives, new prospects for dental practice, education and research were established including the paradigm shift from objective clinician-centric to subjective patient-relevant disease management outcomes (Song & Yap, 2018). OHRQoL can be evaluated using social indicators, global self-ratings and multiple-item surveys (Slade, 2002). Multiple-item surveys are frequently used and can be generic or condition-specific in nature. Almost all prior OHRQoL research concerning TMDs had utilised generic measures of which the Oral Health Impact Profile (OHIP) is the most popular (Dahlström & Carlsson, 2010). The OHIP is founded on Locker's conceptual framework for oral health and comprises of seven domains, namely functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap (Locker, 1988). Generic OHRQoL measures are, however, not constructed to capitalise on impacts associated with specific diseases and typically have higher "floor effects" (i.e., no impact) as certain items surveyed may not be common or applicable (Sischo & Broder, 2011). Consequently, Durham *et al.* (2011) developed a TMDs-specific OHRQoL measure (i.e., OHIP-TMDs) to address this deficiency.

The OHIP-TMDs was derived from the original 49-item OHIP and comprised of 22 items of which 20 were from the original OHIP and two from qualitative research on patients with TMDs. As it has fewer items than the original OHIP, scoring complexity, administration time, and cost are reduced considerably (Yule *et al.*, 2015). Although the OHIP-TMDs had been translated into Chinese and validated (He & Wang, 2015), it is currently still not available in the Malay language. Malay language is a major language in Southeast Asia and is spoken by about 290 million people in Malaysia, Indonesia, Brunei and Singapore (Guillemin *et al.*, 1993). As many in Southeast Asia do not speak English and may only be conversant in Malay, it is prudent that the Malay language version of the OHIP-TMDs to be developed. Thus, the objectives of this study were to translate and cross-culturally adapt the English OHIP-TMDs into the Malay language for use in Malay literate populations, and to assess the psychometric properties of the Malay OHIP-TMDs (OHIP-TMDs-M).

## MATERIALS AND METHODS

Ethics approval for the study was attained from the Medical Ethics Committee, Faculty of Dentistry, Universiti Malaya prior to starting this study [Ref. No.: DF OS1701/0008(L)]. The translation and cross-cultural adaptation procedures were based on the following international guidelines: (a) Guidelines for cross-cultural adaptation of health-related measured (Guillemin *et al.*, 1993), (b) Guidelines for establishing cultural equivalency of instruments (Ohrbach *et al.*, 2013), and (c) Consensus-based standards for the selection of health measurement instruments (COSMIN) checklist (Mokkink *et al.*, 2010).

### Translation and Cross-Cultural Adaptation Process

The translation and cross-cultural adaptation process involved the following phases:

#### *Forward translation*

The forward translation team consisted of a qualified English language professional and a dental expert who independently translated the English OHIP-TMDs into Malay. The forward translation team was effectively bilingual and Malay was their mother tongue. As the English expert had no knowledge of TMDs or the study concept, a mixed perspective was achieved when generating the two independent translations as both lay and medical language with its cultural nuances were incorporated (Sousa & Rojjanasrirat, 2011).

#### *Synthesis and resolution of discrepancies*

A meeting between the researchers and forward translators was held to discuss the forward translations of the OHIP-TMDs. Following the discussion, the independent translations were subsequently combined to form a common forward translation. Any discrepancies in word choices were recorded and resolved by consensus of the forward translation team.

#### *Backward translation*

The synthesised common Malay translation was then translated back into English by a separate backward translation team consisting of another two language experts whose mother tongue was Malay. These two translators were blinded to the original English OHIP-TMDs.

#### *Expert committee review and revision*

An expert committee for the translation and cross-cultural adaptation of OHIP-TMDs was established comprising four dental experts from the disciplines of oral and maxillofacial surgery, dental public health, and prosthodontics. The expert committee examined the forward and backward translations, identified any discrepancies including semantic, idiomatic, experiential and conceptual equivalence (Ohrbach *et al.*, 2013), and produced the pre-final instrument through consensus.

#### *Testing of the pre-final OHIP-TMDs-M*

The pre-final instrument was tested on 10 randomly selected patients who attended the Oral and Maxillofacial Clinical Sciences Clinics either for follow up or treatment related to oral and maxillofacial surgery. They were asked to answer the questionnaires independently. Time taken to answer the questionnaires was noted and feedback on the instructions, wording and content of the questionnaires was subsequently sought from the subjects. Each subject was interviewed on their thoughts of what each question meant and the chosen response. These were then analysed to ensure that the pre-final OHIP-TMDs-M was confined to its equivalence in an applied setting and inappropriate items or items with errors were identified. Problematic items were reviewed and revised by the expert committee as needed so that the item intention was best reflected. The final version of the OHIP-TMDs-M was ultimately generated by the expert committee.

## Psychometric Testing of the OHIP-TMDs-M

### *Study design*

A cross-sectional study conducted to assess the psychometric properties of the OHIP-TMDs-M. A convenience sampling was used to recruit the samples. In our study, the subjects consisted of individuals who came to seek for treatment at Faculty of Dentistry, Universiti Malaya, their accompanying persons, staff of the dental faculty, university students in the campus and sellers in the shops at the hospital. Data collection took place from January 2017 to January 2018. To be included in the study, subjects must be aged 18 years old and above, able to read/comprehend the Malay language and give consent. In addition, for subjects with TMDs, they need to have pain in the TMJs or masticatory muscles either at rest or during function, have clinically diagnosed TMDs and/or treatment and/or be undergoing treatment or follow up for TMDs. Subjects with TMD were registered TMD patients who attended Oral & Maxillofacial Clinical Sciences Clinics for TMD follow up and/or treatment. Subjects with organic pathology around the TMJ area, history of orofacial trauma, psychiatric disorders, illiteracy and problems understanding the Malay language were excluded. Sample size was calculated based on the optimal subject to item ratio of 10 subjects per item in the measure (Terwee *et al.*, 2007; He & Wang, 2015). As the OHIP-TMDs consisted of 22 items, the minimum sample size needed to conduct this study was 220. The samples size for test-retest were derived from formula of intraclass correlation coefficient (ICC) test using PASS software (NCSS, LLC, USA). Alpha and power were set at 0.05 and power of 90% respectively, a minimum 30 samples was calculated which are sufficient to detect the value of 0.5 of ICC (Bujang & Baharum, 2017). For test-retest purposes, 40 subsamples (20 normal and 20 with TMD) were identified during the first questionnaire administration and they were given the same sets of questionnaires after two weeks later (He & Wang, 2015; Terwee *et al.*, 2007).

### *Questionnaires administered*

The questionnaires administered to the subjects comprised of demographic data, the Malay versions of OHIP-TMDs (OHIP-TMDs-M), Short Oral Health Impact Profile (S-OHIP-M), Global Oral Health ratings (GOH-M) and the Fonseca Anamnestic Index (FAI-M).

The OHIP-TMDs-M comprised the same seven domains as the original OHIP. Each item is rated on a 5-point Likert scale (0 = never to 4 = very often). Domain and total severity scores are calculated by adding the item scores for the domain and all items respectively. Total severity scores for the 22 items ranged from 0 to 88. S-OHIP-M was developed to be used as a descriptive and discriminative measure in population oral health survey Malaysia and validated by Saub *et al.* (2005). It consists of 14 items that are also grouped into the seven domains which was similar domain with OHIP-TMDs-M as both instruments were originally based on validated OHIP developed by Slade & Spencer (1994). The word "denture" was, however, replaced with "jaw" as it was more relevant to the present study. The responses were scored on the similar 5-point Likert scale. Domain scores were again calculated by adding item scores for the different domains. Total severity scores were computed by adding the scores for all 14 items and ranged from 0 to 56. For both OHIP-TMDs-M and S-OHIP-M, higher severity scores indicated greater impact and poorer OHRQoL (Durham *et al.*, 2011).

The GOH-M was adapted from Saub *et al.* (2005) and contained three items pertaining to perceived oral/jaw health status (GOH1), perceived satisfaction with oral/jaw health (GOH2), and perceived need for oral/jaw treatment (GOH3). GOH1 and GOH2 were scored on a 5-point Likert scale (1 = excellent or very satisfied

to 5 = very poor/dissatisfied). Scoring for GOH3 were 0 = do not know, 1 = no, and 2 = yes. The FAI-M consisted of 10 items that assess jaw movements, facial pain, TMJ sounds, parafunctional habits, perceived malocclusion and emotional stress associated with TMDs (Natu *et al.*, 2018). It is a simple and low-cost patient-reported TMDs screening tool that has high accuracy, sensitivity and specificity for identifying TMDs particularly masticatory muscle disorders (Berni *et al.*, 2015). Responses were scored on a 3-point scale (0 = no, 5 = sometimes, and 10 = yes). The total scores for the 10 items ranged from 0 to 100 and allowed for the categorisation of TMDs into no (0 to 15 points), mild (20 to 40), moderate (45 to 65), and severe (70 to 100).

### *Conduct of study*

The study was conducted in a non-clinical setting with the researchers present to address any doubts or queries concerning the study. Participants were informed of the study objectives, provided with a patient information sheet, and signed informed consent was obtained before starting the survey. The OHIP-TMDs-M was re-administered to a subset of 40 subjects (20 with and 20 without TMDs) after two weeks for test-retest reliability assessment. The collated questionnaires were reviewed and screened for missing or uncompleted items prior to data entry.

## Statistical Analysis

The data were first cleaned by running frequency distributions for individual items of each questionnaire. Subjects with more than 20% of items missing from each questionnaire were excluded from the analysis. Mean (SD) and/or median (IQR) and percentages were computed for continuous and categorical data, respectively. Statistical analysis was conducted using Statistical Package for Social Sciences version 22 software (IBM Corporation, Armonk, NY, USA). The significance level was set at $p < 0.05$.

### *Reliability testing*

The internal consistency of OHIP-TMDs-M was assessed using Cronbach's alpha coefficient. Cronbach's alpha is a function of the average intercorrelations of items and the number of items in the scale. An instrument is considered to have adequate internal consistency if it had a Cronbach's alpha value of more than 0.70 (Zucoloto *et al.*, 2014). Test-retest reliability was assessed by ICC using a two-way random effect model. Test-retest reliability was considered poor, fair to good, and excellent if the ICC values are < 0.40, between 0.40 and 0.75, and > 0.75 respectively (Rosner, 2011).

### *Validity testing*

Concurrent validity assesses how well an instrument measures up to a well-established one. For this purpose, the OHIP-TMDs-M was compared with the S-OHIP-M in terms of correlations between total and domain scores of OHIP-TMDs-M and S-OHIP-M using Spearman's rank correlation. Spearman's correlation coefficient (*rs*) which indicates the strength and direction of correlation ranged from 0 (no correlation) to ±1 (perfect correlation), with higher positive scores indicating superior concurrent validity (Aishvarya *et al.*, 2014).

Construct validity examines how well an instrument measures what it claims to be measuring. In this study, two types of construct validity, namely convergent and discriminative validity, were determined (Saub *et al.*, 2005). Convergent validity refers to the observed association between two instruments measuring the same construct. OHIP-TMDs-M was compared against the GOH-M. The following three hypotheses were evaluated: (a) subjects with perceived

poorer oral/jaw health status would have higher OHIP-TMDs-M scores, (b) subjects who are less satisfied with their oral/jaw health would have higher OHIP-TMDs-M scores, and (c) subjects with perceived oral/jaw treatment needs would have higher OHIP-TMDs-M scores. As the data were not normally distributed (Kolmogorov-Smirnov test, $p < 0.05$), Kruskal-Wallis test was used for intergroup comparisons of OHIP-TMDs-M severity scores for each GOH item.

For discriminative validity testing, the ability of OHIP-TMDs-M to distinguish between subjects with (total FAI-M scores ≥ 20 points) and without TMDs (total FAI-M scores ≤ 15 points) was assessed. As data were not normally distributed (Kolmogorov-Smirnov test, $p < 0.05$), Mann Whitney U-test was used. It was hypothesised that subjects with TMDs would have higher total OHIP-TMDs-M scores than those without TMDs.

## RESULTS

### Translation and Pre-Final Version Testing

Forward and backward translations of the English OHIP-TMDs into the Malay language did not pose any difficulties. Testing of the pre-final OHIP-TMDs-M on the 10 clinical subjects also revealed no problematic items with subjects affirming that the items were easy to understand.

### Psychometric Testing of the OHIP-TMDs-M

Of the 252 subjects recruited, nine were excluded as they did not answer more than 20% of the questionnaires. The final sample of 243 participants consisted of 83

**Table 1** Socio-demographic characteristics of the subjects ($n = 243$)

| Characteristic | *n* | % |
|---|---|---|
| Age/year | | |
| 18–30 | 175 | 72.0 |
| 31–40 | 55 | 22.6 |
| 41–50 | 6 | 2.5 |
| 51–60 | 5 | 2.1 |
| > 60 | 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 |

with TMDs and 160 without TMDs. The sociodemographic characteristics of the subjects are shown in Table 1. The majority of subjects were female (72.0%), aged between 18 to 30 years old (72.0%), of the Malay race (72.0%), and had a diploma/college education (42.8%).

### *Reliability testing*

The Cronbach alpha value for total OHIP-TMDs-M score was 0.98, and the values varied from 0.83 (social disability) to 0.95 (psychological disability) for the various domains (Table 2). The ICC for total OHIP-TMDs-M score was 0.99 and ranged from 0.97 to 0.99 for the different domains. All correlations were statistically significant ($p < 0.001$) and the 95% confidence interval boundaries are reflected in Table 2.

### *Validity testing*

Concurrent validity testing was done by correlating total scores and domain scores between OHIP-TMDs-M and S-OHIP-M. A positive and strong correlation ($rs = 0.74$) was observed ($p < 0.001$) respectively in Table 3.

Convergent validity testing was performed by comparing total OHIP-TMDs-M scores between GOH ratings (i.e., poor/very dissatisfied to excellent/very satisfied; or yes, no, and uncertain). Significant associations were observed between OHIP-TMDs-M scores and the different GOH-M ratings ($p < 0.001$). Bonferroni post hoc test was used to assess for significant between-group differences in median total scores for each of the associations (Table 4). For GOH1, mean and median total scores ranged from 4.5 to 62.5 and 1.0 to 64.0, respectively. For GOH2, mean total scores varied from 6.1 to 41.2 while median total scores ranged from 0.5 to 42.0. Subjects with perceived poor oral/jaw health status or who were very dissatisfied with their oral/jaw health had higher total OHIP-TMDs-M scores. Lastly for GOH3, mean and median total scores ranged from 6.4 to 30.5 and 2.0 to 34.0, respectively. Subjects with perceived oral/jaw treatment needs had notably higher OHIP-TMDs-M scores than those with no treatment needs.

**Table 2** Internal consistency and test-retest reliability of the OHIP-TMDs-M

| Parameters | Internal consistency ($n = 243$) | Test-retest reliability ($n = 40$) | |
|---|---|---|---|
| | Cronbach's alpha | ICC | 95% CI |
| Total OHIP-TMDs-M | 0.98 | 0.99 | 0.98–0.99 |
| Functional limitation Items 1–2 | 0.84 | 0.99 | 0.98–0.99 |
| Physical pain Items 3–7 | 0.90 | 0.97 | 0.95–0.99 |
| Psychological discomfort Items 8–11 | 0.90 | 0.99 | 0.96–0.99 |
| Physical disability Items 12–13 | 0.93 | 0.99 | 0.96–0.99 |
| Psychological disability Items 14–18 | 0.95 | 0.99 | 0.95–0.99 |
| Social disability Items 19–20 | 0.83 | 0.98 | 0.93–0.98 |
| Handicap Items 21–22 | 0.89 | 0.98 | 0.92–0.98 |

Discriminative validity testing was done by comparing total OHIP-TMDs-M scores between subjects with and without TMDs. Median (IQR) scores for subjects without TMDs were 1.5, whereas the scores were 25.0 for those with TMDs (Table 5). Median total scores were significantly higher in subjects with TMDs compared to those without TMDs ($p < 0.001$).

**Table 3** Concurrent validity test for the OHIP-TMDs-M: Correlation of total and domain scores between OHIP-TMDs-M and S-OHIP-M

| OHIP-TMDs-M | S-OHIP-M* | Correlation coefficient descriptor | *p*-value |
|---|---|---|---|
| Total | 0.74 | High positive relationship | < 0.001 |
| Domain 1: Functional limitation | 0.60 | Moderate positive relationship | < 0.001 |
| Domain 2: Physical pain | 0.49 | Low positive relationship | < 0.001 |
| Domain 3: Psychological discomfort | 0.42 | Low positive relationship | < 0.001 |
| Domain 4: Physical disability | 0.74 | High positive relationship | < 0.001 |
| Domain 5: Psychological disability | 0.65 | Moderate positive relationship | < 0.001 |
| Domain 6: Social disability | 0.66 | Moderate positive relationship | < 0.001 |
| Domain 7: Handicap | 0.41 | Low positive relationship | < 0.001 |

Note: *Spearman Rho's correlation coefficient; level of significance $p < 0.05$

**Table 4** Convergent validity OHIP-TMDs against GOH

| Parameters | Rating | *n* | OHIP-TMDs-M | | *p*-value[1] |
|---|---|---|---|---|---|
| | | | Mean score (SD) | Median score (IQR) | |
| GOH 1 Perceived oral/jaw health status | Excellent[a] | 24 | 4.50 (7.1) | 2.00 (6.0) | <0.001 |
| | Very good[b] | 70 | 5.00 (8.8) | 1.00 (7.0) | |
| | Good[a,b] | 113 | 14.4 (14.4) | 9.00 (22.0) | |
| | Average[a,b] | 32 | 34.0 (20.1) | 37.0 (33.0) | |
| | Poor[a,b] | 4 | 62.5 (20.1) | 64.0 (23.0) | |
| GOH 2 Perceived satisfaction with oral/jaw health | Very Satisfied[a] | 40 | 6.10 (11.1) | 0.50 (8.0) | <0.001 |
| | Satisfied[b] | 116 | 7.10 (10.4) | 2.00 (11.0) | |
| | Moderate[a,b] | 75 | 24.8 (19.2) | 24.0 (34.0) | |
| | Dissatisfied[a,b] | 10 | 41.2 (16.4) | 42.0 (18.0) | |
| | Very Dissatisfied | 2 | 38.0 (21.2) | 38.0 (0.0) | |
| GOH 3 Perceived need for oral/jaw treatment | Yes[a] | 55 | 30.5 (21.5) | 34.0 (35.0) | <0.001 |
| | No[a] | 124 | 6.40 (9.6) | 2.00 (9.0) | |
| | Do not know[a] | 64 | 14.9 (15.0) | 9.00 (24.0) | |

Note: [1]Kruskal-Wallis test, level of significant $p < 0.05$; [a,b]Median differences were statistically significant following Bonferroni correction.

**Table 5** Discriminative validity test for the OHIP-TMDs-M: Comparison of total OHIP-TMDs-M scores between subjects with and without TMDs based on the FAI-M

| Parameter | Groups | *n* | Median score (IQR) | *p*-value[1] |
|---|---|---|---|---|
| OHIP-TMDs-M | Without TMDs | 160 | 1.5 (8.0) | < 0.001 |
| | With TMDs | 83 | 25.0 (31.0) | |

Note: [1]Mann Whitney U test; level of significance $p < 0.05$

## DISCUSSION

### Translation and Pre-Final Version Testing

This study translated and cross-culturally adapted the English OHIP-TMDs into the Malay language and assessed the psychometric properties of the OHIP-TMDs-M. Translation and cross-cultural adaptation are important processes that must be completed before the OHIP-TMDs can be used on Malay speakers in Southeast Asia. To ensure a diversified perspective (both lay and medical) on the items, the forward translation team consisted of an "uninformed" language and an "informed" dental expert (Sousa & Rojjanasrirat, 2011). Agreements with the usual spoken Malay language was thus accomplished. Similarly, the back translation team comprised of another two "uninformed" language experts who also had no prior knowledge of the original English OHIP-TMDs. Translations were all conducted independently to minimise biases (Sousa & Rojjanasrirat, 2011). The expert committee scrutinised the various translations for linguistic and other equivalences to derive the pre-final version. The pre-final version of the questionnaire must be understood by a 12-year-old (approximately a grade six level of reading) (Beaton *et al.*, 1998). Testing of the pre-final version was conducted on 10 clinical subjects. It is recommended that at least 6 to 10 subjects are required for "pre-testing" to obtain inputs on wording and content of the items (Arredondo *et al.*, 2012). Testing of the pre-final version allowed for a last check prior to psychometric characterisation in a larger subject sample. No major difficulties were encountered for all the 22 items during translation, cross-cultural adaptation and testing of the pre-final version of the OHIP-TMDs-M.

### Psychometric Testing of the OHIP-TMDs-M

A cross-sectional design and convenience sampling technique was employed to assess the psychometric properties of the OHIP-TMDs-M. Subjects were recruited from individuals seeking dental treatment or presenting at the Faculty of Dentistry, Universiti Malaya. Based on the information released by Department of Statistics Malaysia (2017), the estimated distribution of ethnic groups in Malaysia were Malays (68.8%), Chinese (23.2%), Indians (7.0%) and others (1.0%). This race distribution was corroborated by that observed in our study with Malays forming the majority of subjects (72.0%) and others constituting the least (1%). The percentage of Indians (14.8%) was, however, marginally higher than Chinese (12.0%). Regardless of race, all subjects were fluent in the Malay language as it was the national language.

#### *Reliability testing*

For internal consistency testing, the Cronbach's alpha value for total OHIP-TMDs-M was 0.98 and the values ranged from 0.83 to 0.95 for the different domains. These values were higher than the minimum value of 0.70 specified for good internal consistency. For the clinical setting, a higher threshold value of 0.90 may be warranted (Bland & Altman, 1997). This was met by total OHIP-TMDs-M as well as all domains with the exception of functional limitation. A lower Cronbach's alpha value (< 0.70) was

also observed for the functional limitation domain of the Chinese OHIP-TMDs (He & Wang, 2015). Functional restrictions are not the primary reason for the perception of lower OHRQoL in patients with TMDs, and may account in part for the slightly inferior Cronbach's alpha value for this domain (Rodrigues *et al.*, 2015). For test-retest reliability testing, the time period between repeated OHIP-TMDs-M administrations was two weeks. This was adequately long to avoid recall and sufficiently short to preclude clinical fluctuations (Terwee *et al.*, 2007). The ICC ranged from 0.97 to 0.99 for total OHIP-TMDs-M and the various domains. The level of clinical significance was thus excellent as reliability coefficient was > 0.75 and close to 1.0 (Cicchetti, 1994; Rosner, 2011). Test-retest ICC for the English and Chinese versions of the OHIP-TMDs was similarly high with coefficients of 0.81 and 0.89, respectively (He & Wang, 2015; Yule *et al.*, 2015). Based on the aforementioned, it was determined that the OHIP-TMDs-M has excellent reliability.

### *Validity testing*

For concurrent validity testing, the S-OHIP-M was used for comparison as it is the most commonly used Malay instrument for assessing OHRQoL. The S-OHIP-M had been cross-culturally adapted and validated for the Malaysian adult population (Saub *et al.*, 2005; 2007). Furthermore, it is also connected to health-related quality of life that has inferences for a person's self-perceived well-being (Mohamed *et al.*, 2017). Results of Spearman's test showed a significant, positive and strong correlation ($rs$ = 0.74) between total OHIP-TMDs-M and total S-OHIP-M (Terwee *et al.*, 2007). In terms of domain scores, the correlation between OHIP-TMDs-M and S-OHIP-M domains showed positive and strong/very strong correlations (Table 3). The condition specific OHIP-TMDs-M was thus inter-related to the generic S-OHIP-M despite containing proportionately more TMDs pertinent items (Yule *et al.*, 2015). While the S-OHIP-M can be used for different oral diseases including other orofacial pain conditions, the OHIP-TMDs-M can only be used for TMDs related surveys.

For convergent validity testing, internationally adopted or nationally tested instruments should be employed for confluence (Bullinger *et al.*, 1993). The GOH ratings were selected as they had been used for validating the S-OHIP-M as well as the Chinese OHIP-TMDs (Saub *et al.*, 2005; He & Wang, 2015). These subjective global ratings of oral health had been related to the multidimensional aspects of OHRQoL (Krisdapong & Sheiham, 2014). All three hypotheses were confirmed as subjects with professed poorer oral/jaw health status, lower oral/jaw health satisfaction and greater oral/jaw treatment needs had higher total OHIP-TMD-M scores. For discriminative validity testing, the OHIP-TMDs-M was able to differentiate between subjects with and without TMDs as determined by the FAI. The FAI is widely used in both community and clinical TMDs related studies (Jain *et al.*, 2018; Natu *et al.*, 2018; Özdinç *et al.*, 2020). It has been shown to be congruent with other instruments for identifying TMDs including the Helkimo index, American association of orofacial pain questionnaire and jaw symptom and oral habit questionnaire (Pastore *et al.*, 2018). Mean and median total OHIP-TMDs-M scores of subjects with TMDs were greater 5.4 and 16.6 folds than those with no TMDs. Findings of both the convergent and discriminative validity authenticated the construct validity of the OHIP-TMDs-M.

## Limitations of the Present Study

While results indicated that the OHIP-TMDs-M has excellent reliability and good validity, the present study had some limitations. First, a convenience sampling technique was used to recruit the subjects. Although random sampling in preferable where possible, the use of convenience sampling in a cross-cultural adaptation study was deemed acceptable as long as the sample is relevant. In our study, the index was

culturally adapted for use among patients with TMDs, and thus it was tested including patients with TMDs and some non-TMDs samples. The use of non-random sampling in this type of study was relatively common and considered to be adequate (Clark & Watson, 1995). Second, for construct validity testing, additional psychometric evaluation including confirmatory factor analysis could be performed (He & Wang, 2015). Future study on the instrument should consider undertaking confirmatory factor analysis in order to confirm the factors existed for use in the local setting. For discriminative validity testing, the clinical subtypes of TMDs, i.e. TMJ disorders and/or masticatory muscle disorders, were not specified. Future studies could use internationally accepted standards like the Diagnostic Criteria for TMDs (DC/TMD) (Schiffman *et al*., 2014) and could provide insights on the specificity and sensitivity of the OHIP-TMDs-M.

## CONCLUSION

The OHIP-TMDs was successfully translated and cross-culturally adapted into the Malay language. The Malay version of the OHIP-TMDs (OHIP-TMDs-M) was empirically shown to have excellent internal consistency and test-retest reliability. Furthermore, it had good concurrent and convergent validity when measured to the S-OHIP-M and GOH-M. The OHIP-TMDs-M was also able to discriminate between subjects with and without TMDs. In view of its excellent reliability and good validity, the OHIP-TMDs-M is a promising tool for assessing TMDs-specific OHRQoL in Malay literate populations.

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