Reliability and validity of the Turkish version of oral health impact profile for edentulous subjects

Purpose
The validated translations of the OHIP-EDENT exist in different languages; however, there is no reliable and validated Turkish translation. The present study was conducted to evaluate the reliability and to validate the Oral Health Impact Profile in edentulous subjects translated to Turkish (OHIP-EDENT-T).

Materials and Methods
The study sample included 104 conventional complete denture wearers (58 women and 46 men, mean age: 61.13 ± 9.43 years). The original English version of OHIP-EDENT was translated into Turkish using a forward-backward method and applied to the subjects. The reliability of the OHIP-EDENT-T was evaluated using internal consistency and the test–retest method. Validity was determined as construct and convergent validity. The construct validity of OHIP-EDENT-T was assessed using exploratory and confirmatory factor analysis.

Results
The Cronbach's alpha value for OHIP-EDENT-T was 0.890. The intraclass correlation coefficient (ICC) was 0.749 for the OHIP-EDENT-T total score, and ICCs for the subscales ranged from 0.630 (95% CI = 0.501-0.823) to 0.859 (95% CI = 0.531-0.897), indicating good to excellent agreement. The Kaiser-Meyer-Olkin value for sampling adequacy was 0.820 and results of Bartlett's sphericity test indicated statistical significance ($\chi^2=1139.767; \text{df}=171, p=0.001$). This showed that factorial analysis could be applied to the data set. The three-factor structure of the scale explained 81.1% of the observed variance. The agreement of the three-factor solution was further tested with confirmatory factor analysis, and the fit index was found to be acceptable (chi-square fit test=1.449, RMSEA=0.040, GFI=0.94, CFI=0.93).

Conclusion
Within the limitations of this study, it can be concluded that OHIP-EDENT-T is a valid and reliable instrument for evaluating the quality of life of edentulous patients.

Keywords: Oral-health related quality of life, OHIP, OHIP-EDENT, Edentulous, Complete denture

Introduction
The increase in the life expectancy has been associated with tooth loss (1). In Turkey, the prevalence of edentulism is on the rise (2) and this affects the main functional activities of edentulous patients (3). The Oral Health-Related Quality-of-Life (OHRQoL) is a multi-dimensional construct that aims to collect information concerning the patient’s subjective assessment of his/her oral health, including functional as well as psycho-social well-being, sense of self, expectations and treatment satisfaction (4). Although both fixed and removable implant-supported prostheses have been reported to increase OHRQoL and patient satisfaction when compared to complete dentures (CDs) (5), CDs continue to be the most common treatment option for edentulism (6).
OHRQoL scales are score-based tools for evaluating the effect of dental treatment on oral health and quality-of-life (7-11). One of the most popular OHRQoL instruments, the Oral Health Impact Profile (OHIP) provides a detailed analysis of OHRQoL based on the conceptual model of oral health described by Locker that utilizes the World Health Organization (WHO) International Classification of Impairments, Disabilities and Handicaps (12-14). The OHIP comprises of 49 questions grouped under 7 subdomains, namely: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. OHIP is a reliable and valid instrument, however, it is also long and difficult to complete (15,16). A shorter, more patient-friendly 14-item version of the (OHIP-14), developed by Slade (14), covers the same 7 domains as the original OHIP. This version demonstrated acceptable validity, therefore, it is less time-consuming for researchers and easier to complete for patients. However, some parts of the OHIP-14 are inappropriate for CRDP wearers and the floor effect limits its ability to detect improvements in CRDP wearers following clinical intervention (16). To address these issues, Allen and Locker (16) implemented the OHIP-EDENT, a 19-statement version that covers the same domains as the OHIP, that can detect changes in OHRQoL before and after insertion of new CRDPs. Since the OHIP-EDENT can be used to evaluate negative impacts specifically related to edentulous patients, it can provide additional data that might be useful in developing effective interventions for edentulous patients (17).

Validated translations of the OHIP-EDENT exist in Portuguese, Japanese, Spanish, Chinese and Nepalese; however, there is no reliable and validated Turkish translation (17-21). Therefore, recent studies on the edentulous Turkish population have used the Turkish version of the OHIP-14, which has been noted as a limitation (22-26). Therefore, the aim of the present study was to translate the OHIP-EDENT into Turkish and to assess the reliability and validity of this translated version (OHIP-EDENT-T).

Patients and Methods

Participants and eligibility criteria

This study was approved by the Ethics Committee of the Istanbul University Faculty of Medicine (Approval No. 18205), and written informed consents were obtained from all participants. Based on a recommended minimum of 5-10 patients per item for instrument analysis (27) (i.e. 95 participants for the 19-item questionnaire), and adding 10% to account for possible drop-outs, 104 edentulous individuals (58 female, 46 male, age range: 39-87 years; mean age: 61.13 ± 9.43) were recruited consecutively among patients attending the Istanbul University, Faculty of Dentistry, Department of Prosthodontics for CD treatment. To be included in the current study, the subjects had to be adult, consent to participate, be born, raised and educated within the national borders of Turkey, and have the cognitive skills and literacy to complete the study forms. Individuals who were unable to understand the OHIP-EDENT-T questions were not invited to the study.

Complete dentures

Conventional maxillary and mandibular dentures were fabricated using standard prosthetic method that involved balanced articulation with anatomic acrylic resin teeth (Enigma; Davis Schottlander & Davis, Tonawanda, NY, USA) and maximal extension of the denture borders using functional impression methods by 5 prosthodontists who were blinded to the study protocol (28).

Translation

The original OHIP-EDENT questionnaire comprises of 19 items grouped under 7 domain as follows: 1-functional limitation (3 items), 2- physical pain (4 items), 3- psychological discomfort (2 items), 4-physical disability (3 items), 5-psychological disability (2 items), 6- social disability (3 items) and 7-handicap (2 items) (17). Participants rate the frequency with which their daily activities are affected by oral health-related problems associated with denture use on a scale of 0-4 (0: Never, 1: Hardly ever, 2: Occasionally, 3: Fairly often, 4: Very often). OHRQoL impairment is characterized by the the sum of the individual items that ranges from 0 to 76. Higher scores indicate greater impairment. The OHIP-EDENT was translated into Turkish by a dentist fluent in both English and Turkish. The translated version (OHIP-EDENT-T) was reviewed by six other dentists, and the conceptual equivalence between the original inventory and the translated version was checked by an independent, professional translator who has back-translated the scale (8).

Questionnaire administration

Following an average of 4-week of functional adaptation and adjustment period during which the subjects wore the same dentures, The OHIP-EDENT-T (Figure 1), the global question (see convergent validity section below) and a demographic form were handed out to the patients. Subjects filled the forms alone in a quiet room in the morning hours with no time restriction. 35 randomly selected participants were re-tested after two weeks.

Reliability

Internal consistency of the OHIP-EDENT-T was assessed by calculating Cronbach’s alpha values. Test-retest reliability was evaluated by calculating intraclass correlation coefficients (ICC) and 95% confidence intervals (CI) for the OHIP-EDENT-T. Cronbach’s alpha values range from 0.0-1.0, with a value of 0.7 or higher considered reliable (29). Intra-class correlation (ICC) scores that indicate varying levels of agreement were interpreted as follows: <0.40: poor to fair; 0.41-0.60: moderate; 0.61-0.80: good; >0.80: excellent (30).

Validity

Construct validity of the OHIP-EDENT-T was assessed using exploratory factorial analysis. Bartlett’s sphericity and Kaiser-Meyer-Olkin (KMO) tests were conducted to explore possible significant correlations among the OHIP-EDENT-T items, with factor loadings of >0.40 considered significant (31).
1. Dişlerinizde, ağzınızda veya takma dişlerinizde bir sorun olduğu için yemek çılgınlıkta zorluk çektin mi?
2. Dişlerinize veya takma dişlerinize yemek kaçtı mı?
3. Takma dişlerinizin yerine tam oturmadığını hissediyor musunuz?
4. Ağzınızda acı duyduğunuz mu?
5. Dişlerinizde, ağzınızda veya takma dişlerinizde bir sorun olduğu için yemek yerken rahatsızlık duyduğunuz mu?
6. Ağzınızda acıyan yerler var mı?
7. Takma dişleriniz rahatsızlık verdi mi?
8. Dişlerinizle ilgili sorunuz var mı?
9. Dişleriniz, ağzınız veya takma dişlerinizin farklıda olmak için yaşiyorsunuz?
10. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle bazı yemekleri yemeken çekindiniz mi?
11. Takma dişlerinizle ilgili sorun nedeniyle yemekyi yiyemediğiniz oluyor mu?
12. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle yemek yerken yapırdığınızı bazı şeyler oluyor mu?
13. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle üzülüyorsunuz?
14. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle utanıyorsunuz?
15. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle dışarı çıkmaktan kaçındınız mı?
16. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle eşi nezi de olmama için kastedildiniz daha az hoşgörüllü müsünüz?
17. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle başkalarını rahatsız ediyor musunuz?
18. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle başkalarını birlikte oynamaya zevk almadığınız oluyor mu?
19. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle genelde hayatınız daha az tatmin edici olduğunu düşünüyorsunuz?

Figure 1. Turkish translation of the OHIP-EDENT (OHIP-EDENT-T). The rating scale for each item is as follows:
0: Hiç bir zaman, 1: Enden, 2: Bazen, 3: Sık, 4: Çok sık.

Convergent validity

In line with previous studies, after responding to the OHIP-EDENT-T, participants were asked an extra-global question (“Are you satisfied with the use of complete dentures”) with 5 possible responses (1=very satisfied, 2=satisfied, 3=fair, 4=dissatisfied, 5=very dissatisfied) in order to examine convergent validity (17,21). The convergent validity was assessed by examining the correlation between OHIP-EDENT-T subscale scores and the global question, with correlation levels rated as follows: <0.20: poor; 0.21-0.40: fair; 0.41-0.60: good; 0.61-0.80: very good; >0.81: excellent (32).

Statistical analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS Inc., Release 15.0 for Windows, Chicago, IL, USA). In addition, the factorial model according to the results of exploratory factor analysis was verified by confirmatory factor analysis (IBM SPSS Amos 21.0; IBM Corp, Armonk, NY, USA). The current study used the following fit indexes: chi-square fit test (acceptable value ≤ 3), a root-meansquare error of approximation (RMSEA, acceptable value ≤ .08), goodness of fit index (GFI, acceptable value ≥ .85) and comparative fit index (CFI, acceptable value ≥ .90). The confidence level was set to 95% and p<0.05 was considered significant.

Results

Demographic data of participants was presented in Table 1.

Reliability

Table 2 shows the internal consistency of the multi-item scales. Cronbach’s alpha for the OHIP-EDENT-T total score was 0.890. Cronbach’s alpha values for the subscales ranged from 0.714 for “Physical pain” to 0.883 for “Psychological disability.” All subscales exceeded the minimum reliability stan-
The ICC was 0.749 for the OHIP-EDENT-T total score, and ICCs for the subscales ranged from 0.630 (95% CI = 0.501-0.823) to 0.859 (95% CI = 0.531-0.897), which indicates good to excellent agreement.

**Validity**

As KMO value for sampling adequacy was 0.820 and Bartlett’s sphericity test indicated statistical significance ($\chi^2=1139.767$; df=171, p=0.001) factorial analysis could be applied to the data set. The results of factor analysis for all subscales are given in Table 3. Factor loadings were above 0.40 for all items. 81.1% of total variance was explained by three factors, namely: Physical impact (Functional limitation, Physical pain, Physical disability); Psychological impact (Psychological discomfort, Psychological disability); and Social impact (Social disability, Handicap). OHIP-EDENT-T total and subscale scores significantly correlated with the global question ($rs: 0.645-0.742$), demonstrating good to excellent convergent validity (Table 4).

When the fit index values were examined, the current study have found that the results were acceptable and in good agreement. The results from the fit indexes were; for chi-square fit test 1.449, for RMSEA 0.040, for GFI 0.94, for CFI 0.93.

**Discussion**

The OHIP-EDENT questionnaire has become the gold standard for reporting patient centered quality of life in edentulous patient (33). The questionnaire has been translated into Portuguese, Japanese, Spanish, Chinese and Nepalese and the reliability of these culturally-adapted versions have been evaluated (17-21). However, the present study is the first to examine the reliability and validity of a Turkish version of the OHIP-EDENT, the OHIP-EDENT-T.

Previous studies have reported that the Cronbach’s alpha values for the OHIP-EDENT varied between 0.785 and 0.972 (17,21). This inconsistency, such as the one between Nepali as well as Chinese versions of the OHIP-EDENT, have been attributed to the differences in sample sizes (17, 21). Cronbach’s coefficient alpha of OHIP-EDENT-T was 0.89, which indicates that this scale is able to measure a theoretical construct with good internal consistency and to reliably detect changes in the OHRQOL of edentulous subjects. The corrected item-total correlation coefficients were above 0.20 which shows the consistency of the items in the scale.  Good internal consistency was further clarified by ICC values (0.749; (95% CI =0.567-0.896), indicating test-retest reliability remains stable over time.

Previous studies evaluating the OHRQOL of new denture wearers have reported OHIP-EDENT scores of 14.91 and 16.23. The present findings demonstrated that the mean OHIP-EDENT-T score was 14.59, which is in accordance with those reported previously (19,34). A systematic review and meta-analysis of the baseline OHIP-EDENT scores determined 28.63 (95% CI, range: 21.93-35.34) to be the pre-treatment mean OHIP-EDENT-T score.
ment baseline for edentulous patients. Although the present study did not record pre-treatment scores, the enor-

mous difference between the baseline OHIP-EDENT scores reported by meta-analysis and the post-treatment scores calculated in the present study suggest that improvements in OHRQoL related to prosthetic treatment were measurable by the OHIP-EDENT-T (33).

The current study measured both construct and conver-
gent validity of the OHIP-EDENT-T. Previous studies evalu-
ating the OHIP-EDENT used different methodologies for assessing validity, the exploratory factor analysis being the most common (17,20,21,35,36). The main purpose of factor analysis is to facilitate the understanding and interpretation of the relationships between numerous variables consid-
ered to be correlated by reducing them to smaller number of basic dimensions. However, even though OHRQoL is gen-
erally recognized by the scientific literature to be a multi-
dimensional construct that includes physical and psychologi-
cal factors as well as social well-being, there is no consensus regarding its specific factorial characteristics (37). Results of the exploratory factor analysis of OHIP-EDENT data varied among studies: Souza et al. (35) reported 4 relevant do-
mains, He and Wang (17), Shrestha et al. (21) and Montero et al. (20) reported 5 relevant domains – with relevancy refer-
ing to factors with eigenvalues of >1. Possebon et al. (36) is the first study in the literature to report the confirmatory factor analysis of the OHIP-EDENT instrument. Accord-
ingly, a model was presented with 3 factors comprised of 19 sub-factors. Similarly, the present study found 3 relevant do-
mains for the OHIP-EDENT-T.

This study has a number of strengths, first of which is the wide socio-demographic range of the study population. In addition, the simple language of the questionnaire and scale makes the survey easy to apply and easy to evaluate. In terms of limitations, de novo development was not con-
ducted, so that the final translation could not be compared with previous versions. In addition, sensitivity and respon-
sonsiveness of the OHIP-EDENT-T could not be evaluated, since this would require a longitudinal study.

Conclusion

Within the limitations of this study, it may be concluded that the OHIP-EDENT-T is a valid and reliable instrument for evaluating the OHRQoL of edentulous patients.

Table 3. Exploratory factor analysis of OHIP-EDENT-T.

| Subscale                        | Factor 1: Physical impact | Factor 2: Psychological impact | Factor 3: Social impact |
|---------------------------------|---------------------------|-------------------------------|------------------------|
| Physical impact                 |                           |                               |                        |
| 1. Chewing difficulty           | 0.561                     |                               |                        |
| 2. Food catching                | 0.455                     |                               |                        |
| 3. Dentures not fitting         | 0.515                     |                               |                        |
| 4. Aching sensation             | 0.586                     |                               |                        |
| 5. Uncomfortable to eat         | 0.782                     |                               |                        |
| 6. Sore spots                   | 0.873                     |                               |                        |
| 7. Uncomfortable dentures       | 0.471                     |                               |                        |
| 10. Avoids eating              | 0.582                     |                               |                        |
| 11. Unable to eat               | 0.765                     |                               |                        |
| 12. Interrupts meals            | 0.503                     |                               |                        |
| Psychological impact            |                           |                               |                        |
| 8. Worried                      | 0.784                     |                               |                        |
| 9. Self-conscious               | 0.671                     |                               |                        |
| 13. Upset                       | 0.717                     |                               |                        |
| 14. Been embarrassed            | 0.434                     |                               |                        |
| Social impact                   |                           |                               |                        |
| 15. Avoided going out           | 0.749                     |                               |                        |
| 16. Less tolerant               | 0.724                     |                               |                        |
| 17. Irritable                   | 0.859                     |                               |                        |
| 18. Unable to enjoy company     | 0.881                     |                               |                        |
| 19. Life unsatisfying           | 0.481                     |                               |                        |
| % variance                      | 45.5                      | 25.4                          | 10.2                   |
| Total variance (%)              | 81.1                      |                               |                        |

Table 4. Convergent validity of the OHIP-EDENT-T: correlations between subscale scores with global oral health rating (Spearman’s rank correlation coefficient. * p < 0.01).

| Subscale          | Rs     | 95 % CI          |
|-------------------|--------|------------------|
| Total Score       | 0.734  | 0.590 to 0.831*  |
| Subscales         |        |                  |
| Physical impact   | 0.711  | 0.560 to 0.820*  |
| Psychological impact | 0.742 | 0.650 to 0.816*  |
| Social impact     | 0.645  | 0.541 to 0.735*  |
Informed consent was obtained from all participants. Committee of Istanbul University Faculty of Medicine (Approval No. 18205).

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