

# 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:  $61.13 \pm 9.43$  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 ( $\chi^2=1139.767$ ;  $df=171$ ,  $p=0.001$ ). 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).

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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 çiğnemekte zorluk çektiniz mi?
2. Dişlerinize veya takma dişlerinize yemek kaçtı mı?
3. Takma dişlerinizin yerine tam oturmadığını hissediyor musunuz?
4. Ağzınızda acı duydunuz mu?
5. Dişlerinizde, ağzınızda veya takma dişlerinizde bir sorun olduğu için yemek yerken rahatsızlık duydunuz 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 farkında olarak mı yaşıyorsunuz?
10. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle bazı yemekleri yemekten çekindiniz mi?
11. Takma dişlerinizle ilgili sorun nedeniyle yemek yiyemediğiniz oluyor mu?
12. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle yemek yemeyi yarıda bıraktığınız oldu mu?
13. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle üzülüyor musunuz?
14. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle utanıyor musunuz?
15. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle dışarı çıkmaktan kaçındığınız oldu mu?
16. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle eşinize veya ailenize karşı daha az hoşgörülü 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 başkaları ile birlikte olmaktan zevk almadığınız oluyor mu?
19. Dişleriniz, ağzınız veya takma dişlerinizle ilgili bir sorun nedeniyle genelde hayatın daha az tatmin edici olduğunu düşünüyor musunuz?

**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: Ender, 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 confirma-

tory 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  $\leq 3$ ), a root-meansquare error of approximation (RMSEA, acceptable value  $\leq .08$ ), goodness of fit index (GFI, acceptable value  $\geq .85$ ) and comparative fit index (CFI, acceptable value  $\geq .90$ ). 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-

dard of 0.70. 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 limita-

tion, 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-treat-

**Table 1.** The distribution of the demographic data of the participants.

		n	%
<b>Gender</b>	Women	58	55.8
	Men	46	44.2
<b>General Health</b>	Poor	12	11.6
	Moderate	45	43.2
	Good	47	45.2
<b>Marital status</b>	Single	27	25.9
	Married	77	74.1
<b>Living status</b>	Alone	17	16.3
	With the family	87	83.7
<b>Working status</b>	Retired	83	79.8
	Working	21	20.2
<b>Monthly income level</b>	Low	23	22.1
	Moderate	30	28.9
	High	51	49.0
<b>Educational level</b>	University	15	14.4
	High school	34	32.7
	Middle school or under	55	52.9

**Table 2.** Cronbach's coefficient alpha values and test-retest reliability of the OHIP-EDENT-T.

		OHIP EDENT-T Mean±Standard Deviation	Corrected item total correlation (n=104)	Test-retest (ICC) (n=35)	95 % CI
<b>Physical impact</b>	Functional limitation	3.65±2.88	0.813	0.793	0.453-0.815
	Physical pain	4.19±3.67	0.714	0.645	0.417-0.793
	Physical disability	2.37±2.84	0.819	0.630	0.501-0.823
<b>Psychological impact</b>	Psychological discomfort	2.16±2.22	0.765	0.684	0.449-0.804
	Psychological disability	1.01±1.71	0.883	0.859	0.531-0.897
<b>Social impact</b>	Social disability	0.64±1.79	0.841	0.724	0.597-0.876
	Handicap	0.57±1.42	0.839	0.786	0.550-0.861
	Total OHIP-EDENT-T	14.59±13.09	0.890	0.749	0.567-0.896



ment baseline for edentulous patients. Although the present study did not record pre-treatment scores, the enormous 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 convergent validity of the OHIP-EDENT-T. Previous studies evaluating 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 considered to be correlated by reducing them to smaller number of basic dimensions. However, even though OHRQoL is generally recognized by the scientific literature to be a multidimensional construct that includes physical and psychological 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 domains, He and Wang (17), Shrestha et al. (21) and Montero et al. (20) reported 5 relevant domains – with relevancy referring to factors with eigenvalues of >1. Possebon et al. (36) is the first study in the literature to report the confirmatory factorial analysis of the OHIP-EDENT instrument. Accordingly, a model was presented with 3 factors comprised of 19 sub-factors. Similarly, the present study found 3 relevant domains 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 conducted, so that the final translation could not be compared with previous versions. In addition, sensitivity and responsiveness 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.

**Türkçe Özet:** Konik-ışınli bilgisayarlı tomografi (kıbt) kullanılarak molar dişlerde kök kanal uzunluğu ölçümü: iki boyutlu ve üç boyutlu yöntemlerin karşılaştırılması. Amaç: Bu çalışmada amaç, büyük azı dişlerinin 2 boyutlu (2D) ve 3 boyutlu (3D) konik-ışınli bilgisayarlı tomografik (KİBT) yöntemleri ile gerçekleştirilen kök kanal uzunluğu ölçümlerinin, gerçek kök kanal uzunluklarıyla uyumunun incelenmesidir. Gereç ve yöntem: 24 büyük azı dişe ait 70 kök kanalı KİBT ile tarandı ve kök kanalları eğimlerine göre "Düz", "Aşırı krvatürlü" ve "Birden fazla krvatüre sahip" olarak sınıflandırılmıştır. 2D ölçümler, uygun bir KİBT kesitinde, kök kanalının foramen apikalesi ile ilgili kanalın tüberkül tepesi referans alınarak yapılmıştır. 3D ölçümler, aynı referans noktaları arasında düzenli aralıklarla ilerleyen aksiyal kesitler içerisinde gerçekleştirilmiştir. KİBT ile ölçüm yöntemlerinin tekrarlanabilirlik ve güvenilirlik analizinde Sınıf İçi Korelasyon Katsayısı kullanılmıştır. Gerçek kök kanal uzunluğu ve KİBT ile kök kanal uzunluğu ölçümleri arasındaki farkların kabul edilebilir sınırlar dahilinde ( $\pm 0,5$  mm) olup olmadığı ki-kare ve McNemar testleri ile değerlendirilmiştir. Bulgular: Her iki yöntemin de tekrarlanabilir olduğu ve mükemmel güvenilirlik sağladığı gözlemlendi. Bununla birlikte, 3D yöntemi ile elde edilen ölçümler % 85,7 oranla kabul edilebilir sınırlar dahilinde bulunmuştur ve 2D yöntemi ile arasındaki fark istatistiksel olarak anlamlı bulunmuştur ( $p < 0,05$ ). "Birden fazla krvatüre sahip" kök kanallarında, 3D yöntemi ile yapılan kök kanal uzunluğu ölçümleri 2D metodundan daha güvenilir bulunmuş-

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

	Factor 1: Physical impact	Factor 2: Psychological impact	Factor 3: Social impact
<b>Factor 1:</b>			
Physical impact			
1. Chewing difficulty	0.651		
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		
<b>Factor 2:</b>			
Psychological impact			
8. Worried		0.784	
9. Self-conscious		0.671	
13. Upset		0.717	
14. Been embarrassed		0.434	
<b>Factor 3:</b>			
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
<b>Total Score</b>	0.734	0.590 to 0.831*
<b>Subscales</b>		
<b>Physical impact</b>	0.711	0.560 to 0.820*
<b>Psychological impact</b>	0.742	0.650 to 0.816*
<b>Social impact</b>	0.645	0.541 to 0.735*

tur. "Düz" kök kanalları için 2D yöntemi "Aşırı kurvatürlü" kök kanallarına kıyasla gerçek kök kanal uzunluğuna önemli ölçüde yakın sonuçlar vermiştir ( $p < 0.05$ ). Sonuç: 3D yöntemi ile 2D yöntemine kıyasla daha doğru kök kanal uzunluğu ölçümleri elde edilebilir. Hali hazırda mevcut bir KIBT görüntüsü varsa, büyük ağız dişlerinde kök kanal uzunluklarının tedaviye başlamadan önce belirlenmesinde alternatif olarak kullanılabilir. Anahtar Kelmeler: Konik-ışınlı bilgisayarlı tomografi, Kök kanalı, İki boyutlu, Üç boyutlu, Endodonti

**Ethics Committee Approval:** This study was approved by the Ethics Committee of Istanbul University Faculty of Medicine (Approval No. 18205).

**Informed Consent:** Informed consent was obtained from all participants.

**Peer-review:** Externally peer-reviewed.

**Author contributions:** CB and OG participated in designing the study. ÖE and KBK participated in generating the data for the study. ÖE participated in gathering the data for the study. ŞÇD participated in the analysis of the data. CB, OG, KBK and ŞÇD wrote the majority of the original draft of the paper. KBK participated in writing the paper. CB, OG, ŞÇD have had access to all of the raw data of the study. CB has reviewed the pertinent raw data on which the results and conclusions of this study are based. CB, OG, ÖE, KBK and ŞÇD have approved the final version of this paper. ŞÇD guarantees that all individuals who meet the Journal's authorship criteria are included as authors of this paper.

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