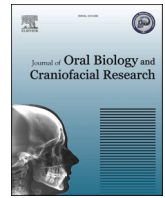




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Reliability and validity of a Hindi version of the Oral Health Impact Profile (OHIP-EDENT-H) for edentulous subjects: A Cross-Sectional study

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ABSTRACT

Aim: The study aimed to translate the OHIP-EDENT into Hindi and assess its validity and reliability.

Methods: The study included 150 participants whose demographic information was collected using the Modified Kuppuswamy Socio-economic Scale. The Oral Health Impact Profile in Edentulous (OHIP-EDENT) was translated into Hindi using the standard forward-backward method. Test-retest reliability was assessed using the Intra-class Correlation Coefficient (ICC) and internal consistency using Cronbach's alpha. The Kaiser-Meyer-Olkin (KMO) test and Bartlett's test of sphericity coefficient were used to conduct Exploratory Factor Analysis (EFA) and confirm the Construct validity. To establish Convergent validity, the relationship between the global question and the OHIP-EDENT-H subscale scores was observed.

Results: The data was analyzed with a confidence level of 95 %, and statistical significance was interpreted as a p-value of less than 0.05. The Cronbach's alpha score for OHIP-EDENT-H was 1.00, indicating high internal consistency. The corrected item-total correlations ranged from 0.665 to 0.923, and the total ICC score was 0.763, demonstrating good reliability. The subscales' intra-class correlation coefficient values ranged from 0.968 to 0.997, indicating high reliability. However, items 4, 6, 13, 17, 18, and 19 had factor loadings below the acceptable threshold of 0.40 in the factor analysis. Additionally, the total and subscale scores of the OHIP-EDENT-H showed significant correlations with global question, with correlation coefficients ranging from 0.665 to 0.923.

Conclusion: The Hindi version of OHIP-EDENT is a reliable and valid tool for evaluating the OHRQoL of Hindi-speaking edentulous individuals.

List of Abbreviations:

Abbreviation	Definition
OHIP- EDENT	Oral Health Impact Profile in Edentulous
OHRQoL	Oral Health-Related Quality of Life
GOHAI	Geriatric Oral Health Assessment Index

1. Introduction

Edentulism is a debilitating dental condition resulting in the complete loss of teeth, which can cause significant distress to the affected person.¹ It has been reported that the total prevalence of edentulism is approximately 16.3 % in India.² The traditional full denture is the usual

option for edentulous patients due to its affordability and easy maintenance.³ Rehabilitating edentulous patients involves addressing their functional, aesthetic, psychological, and social needs. Successful outcomes depend on tailored strategies that prioritize individual needs and preferences.⁴

The concept of Quality of Life (QoL) is subjective and differs across cultures. In India, there hasn't been a sufficient description of Oral Health-Related Quality of Life (OHRQoL), so there is a need for conceptual research. Using models from other cultures may be inaccurate and not address important cultural factors. It is crucial to use culturally sensitive approaches for accurate and relevant measurement of QoL.⁵ Its significance lies in dental research, measuring clinical outcomes for patients and providing valuable guidance for dental public health administration and policy-making.⁶

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Questionnaire surveys are frequently used to assess OHRQoL. The Oral Health Impact Profile (OHIP) is a widely used tool for this purpose. The OHIP initially consists of 49 components that are categorized into seven subscales based on Locker's 1988 model.⁷ A shorter version, OHIP-14, is also widely utilized to save time.⁸ In 2002, Allen F. and Locker D. developed a 19-question version of OHIP-EDENT in English, tailored for patients with no teeth. This tool helps evaluate how dental health affects the overall quality of life of individuals with a prosthesis. It encompasses seven subscales addressing handicaps, functional limitations, pain, psychological discomfort, and physical and psychological disability.⁹ However, OHIP-14 was unable to accurately detect changes in individuals without teeth following clinical intervention due to the "floor effect."¹⁰ This effect occurs when participants score the minimum possible value on a questionnaire, making it hard to discern any further changes. Consequently, OHIP-EDENT became the preferred tool for edentulous subjects worldwide.

When conducting global research on the quality of life, it's crucial to culturally adapt health status indicators. This is especially important when using foreign instruments on individuals from diverse cultural backgrounds who speak different languages. Doing so helps guarantee that consistent data can be collected globally for multicenter and multinational research.¹¹

The Hindi-speaking, diverse population faces challenges in using the OHIP-EDENT instrument due to differences in language, culture, and socioeconomic conditions. A comprehensive psychometric evaluation is necessary for adaptation. The OHIP-EDENT questionnaire has been validated in multiple languages, such as Chinese, Nepali, Japanese, Turkish, Portuguese, Serbian, Croatian, and Bosnian.^{11–17}

Hence, this study aims to translate the original OHIP-EDENT questionnaire into Hindi and validate the reliability and validity of the Hindi translation.

2. Materials and methods

The institutional ethics committee approved the study with reference number SVIEC/ON/Dent/BNPG21/D22062. The study has also been registered with the Clinical Trials Registry of India (CTRI) under registration number CTRI/2022/06/043605. All participants were provided with an information sheet outlining the study protocol, and their informed consent was obtained.

2.1. Sample size

Based on the literature, it is suggested to have 5–10 individuals per item to analyze any tool or questionnaire.¹⁸ With 19 items in the questionnaire, at least 95 participants were required for the analysis. Consequently, a mean of 7.5 was calculated, and a minimum sample size of 150 participants (including 5 % non-responses) was considered for this study.

2.2. Inclusion and exclusion criteria

The study enrolled participants who were 50 years of age or older, in good overall health, and able to understand Hindi. The participants were chosen from the Department of Prosthodontics at the Dental College and Hospital. After a period of physiological adjustment and adaptation, all participants had been using the same dentures for at least a month. The study excluded individuals with partial dentures or single complete dentures. Furthermore, those who declined to sign the consent form were not considered for inclusion in the study.

This study included 150 individuals who wear full dentures, with an average age of 59.22 ± 9.95 years. Of these individuals, 39.3 % were females and 60.7 % were males. The participants' socioeconomic status was assessed using a modified version of the Kuppuswamy Socioeconomic Scale (2022).¹⁹ The demographic information of the participants was analyzed to explore any potential correlation between

socioeconomic status and the satisfaction scores obtained using the OHIP-EDENT H scale.

The OHIP-EDENT English questionnaire was translated into Hindi using the forward-backward method proposed by Guillemin et al.²⁰ Participants responded to all 19 items using a 5-point Likert scale (0 = never; 1 = seldom; 2 = fairly often; 3 = often; 4 = very often). A higher OHIP-EDENT-H summary score indicates a lower satisfaction level for the participant.

The OHIP-EDENT-H questionnaire underwent evaluation for reliability and validity using various parameters. Test-retest reliability was assessed using the intra-class correlation coefficient (ICC), and internal consistency was measured using Cronbach's alpha. To test the reliability, an additional 30 participants were asked to complete the same questionnaire after a 2-week interval.¹¹

To ensure the validity of the study, exploratory factor analysis (EFA) was used. Before conducting EFA, Bartlett's test of sphericity coefficient and KMO tests were performed to verify significant correlations. Additionally, convergent validity was assessed by examining the relationship between the global question "In general, how would you rate your satisfaction with the use of complete dentures?" and the scores on the Hindi version of the OHIP-EDENT subscale. To assess this relationship, Spearman's correlation (r_s) was considered.

2.3. Statistical analysis

The data was gathered and entered into Microsoft Excel Version 13 for analysis. It underwent statistical analysis using IBM Statistical Package for Social Science version 21. Frequency and percentage were utilized for categorical data, while mean and standard deviation were computed for continuous data. The chi-square proportion test was used to evaluate the proportion of different participants' responses. For reliability analysis, Cronbach's alpha and ICC were calculated. Spearman correlation was employed to measure the correlation between the global question and domains. EFA was conducted for validation. All statistical analyses were carried out with a 95 % confidence interval ($p < 0.05$).

3. Results

The study assessed the demographics and socioeconomic status of 150 participants using the modified Kuppuswamy Socio-economic Scale (2022). The participants had varying levels of education and were

Table 1
Demographic details of participants (n = 150); based on the Modified Kuppuswamy Socio-economic Scale (2022).

	CATEGORY	PERCENT (%)	P VALUE
TOTAL PARTICIPANTS (Age: 59.22 ± 9.95)	Males	60.7	
	Females	39.3	
^b EDUCATION	A	0.00	^a 0.001
	B	4.00	
	C	10.00	
	D	12.67	
	E	18.00	
	F	18.67	
	G	36.67	
^b OCCUPATION	A	0.7	^a 0.001
	B	14.7	
	C	33.3	
	D	46.7	
	E	2.0	
	F	1.3	
	G	1.3	

^a Significant ($P < 0.05$).

^b Education and Occupation Categories A-G as given in original scale (2022).

engaged in diverse occupations (Table 1). Analysis of the distribution based on total monthly family income revealed that 61.34 % of the participants earned between 46,475/- and 92,950/- (Table 2). Table 3 shows the percentage of participants in different socioeconomic status categories according to the Modified Kuppaswamy Scale (2022). Additionally, 76 % of the participants belonged to the upper and lower middle classes. Table 4 presents the relationship between the participants' socioeconomic status and their satisfaction level. The Spearman's correlation value between the global question and the socioeconomic status of each participant was -0.659 ($p < 0.05$), indicating that as socioeconomic status decreases, satisfaction level increases (Table 5).

Table 6 demonstrates the OHIP-EDENT-H factor analysis results, mean scores, and Cronbach's alpha values. The Cronbach's alpha for the total OHIP-EDENT score was 1.00. The values for the subscales ranged from 0.971 for "item 9" to 1.00 for "items 1, 2, 5, and 14". The reliability standard for each subscale was greater than 0.70.

3.1. Reliability

The internal consistency of the multi-item scales is shown in Table 7. The corrected item-total correlations ranged from 0.665 for "handicap" to 0.923 for "functional limitation." All items met the recommended minimum correlation threshold of 0.20. The test's reliability was assessed by 30 additional participants who repeated it after two weeks. Mean values with 95 % confidence intervals were calculated. The subscale's ICC values ranged from 0.968 (95 % CI = 0.946–0.981) to 0.997 (95 % CI = 0.996–0.998), indicating excellent agreement. Overall, these results indicate that OHIP-EDENT-H has good reliability.

3.2. Validity

Bartlett's test of sphericity produced a result of 5282.013 with 190 degrees of freedom, and a p-value less than 0.001. The KMO test resulted in a value of 0.947, indicating significant correlations and allowing us to proceed with the factor analysis. The factor analysis results for each subscale can be found in Table 6. These results were obtained through EFA to assess the construct validity. All items, except for 4, 6, 13, 17, 18, and 19, had factor loadings above 0.40. The data in Table 8 shows a significant association between OHIP-EDENT-H and the global question, with correlation coefficients ranging from 0.665 to 0.923. This indicates good to excellent convergent validity, signifying a high level of agreement between the two measures.

4. Discussion

The OHIP EDENT has gained popularity as a valuable tool for assessing the quality of life of edentulous patients undergoing different types of prosthetic treatments.²¹ It is crucial to measure the influence of oral health on quality of life to evaluate the effectiveness of diverse treatments such as traditional full dentures, fixed and removable

Table 2

Total monthly income of participants based on the Modified Kuppaswamy Socio-economic Scale (2022).

		FREQUENCY	PERCENT	P VALUE
TOTAL MONTHLY FAMILY INCOME (SCORE)	≤ 9307	2	1.33	^a 0.001
	9308–27,882	10	6.67	
	27,883–46,474	21	14.00	
	46,475–69,534	52	34.67	
	69,535–92,950	40	26.67	
	92,951–1,85,894	22	14.67	
	$\geq 1,85,895$	3	2.00	
	Total	150	100.0	

^a Significant ($P < 0.05$).

Table 3

Distribution of participants according to the Modified Kuppaswamy Socio-economic Scale (2022).

		FREQUENCY	PERCENT	P VALUE
SOCIO-ECONOMIC STATUS	Upper	3	2.00	^a 0.001
	Upper Middle	50	33.33	
	Lower Middle	64	42.67	
	Upper Lower	21	14.00	
	Lower	12	8.00	
	Total	150	100.0	

^a Significant ($P < 0.05$).

implant therapy, overdentures, and implant-supported obturators.^{22–25}

The OHIP-EDENT has been translated into several languages including Chinese, Nepali, Japanese, Turkish, Portuguese, Serbian, Croatian, and Bosnian, and has been assessed for reliability and validity.^{11–17} India ranks highest in the world's population, with 43.6 % of people speaking Hindi.^{26,27} Therefore, it is important to translate the OHIP-EDENT into Hindi for clinical and research purposes.

In this study, the OHIP-EDENT questionnaire was translated from its original language to Hindi using standard procedures recommended in the literature. Respondents used a five-point Likert scale, unlike the three-point scale utilized in the Brazilian version. An individual's socioeconomic status significantly impacts their QoL, health, social standing, and class. We analyzed demographics using the modified Kuppaswamy socio-economic scale (2022) to ensure participants from various socioeconomic classes were included, increasing the study's external validity. Regardless of their level of education and occupation, all participants easily understood and responded to the Hindi translation of the questionnaire.

The total score for OHIP-EDENT-H displayed a high level of internal consistency reliability with a Cronbach's alpha coefficient of 1.00, and each domain showed a coefficient alpha greater than 0.70. Additionally, all the item-total correlations were notably higher than the recommended value of 0.2, indicating strong internal consistency reliability of OHIP-EDENT-H.

It is important to wait a significant amount of time between administering tests to ensure that the results are reliable and not influenced by memory bias or any significant changes in the person being tested.¹¹ In this study, the researchers used EFA to examine and correlate the different domains of the OHIP-EDENT-H scale with each other. The study also evaluated the convergent validity of the scale by examining the correlation between the global question and the questions in all seven domains. The findings of the study align with previous research in the field.^{11,12,14}

Except for items 4, 6, 13, 17, 18, and 19, all other items showed strong associations with their respective factors. It's worth noting that among the participants, experiencing "pain and sore spots in the mouth" (indicated in questions 4 and 6) was not commonly reported as a reason for dissatisfaction with their prostheses. Furthermore, participants expressed less concern about questions related to "being upset with the prosthesis," "avoiding going out," "not being able to enjoy others' company," and "not being able to enjoy life satisfactorily."

The results are consistent with a study conducted by Mathur et al. on the Hindi version of the GHQAI scale.²⁸ The study found that a greater number of individuals from India reported more challenges related to their physical functioning compared to psychological and handicap domains. This observation could be connected to prioritizing necessities over psychosocial factors in developing nations. In our study, we had a higher number of male participants (60.7 %), who are generally perceived to be less concerned about their appearance in social settings. Consequently, these participants experienced more significant impacts

Table 4
Comparison of the global question and socio-economic status.

			GLOBAL QUESTION					Total	P Value
			Not at all	Probably	Sometimes	Sometimes	Most of the Time		
SOCIO-ECONOMIC STATUS	Upper	N	0	0	0	0	3	3	^a 0.001
		%	0.0 %	0.0 %	0.0 %	0.0 %	100.0 %	100.0 %	
	Upper Middle	N	1	0	0	18	31	50	
		%	2.0 %	0.0 %	0.0 %	36.0 %	62.0 %	100.0 %	
	Lower Middle	N	5	7	20	11	21	64	
		%	7.8 %	10.9 %	31.3 %	17.2 %	32.8 %	100.0 %	
	Upper Lower	N	7	7	5	0	2	21	
		%	33.3 %	33.3 %	23.8 %	0.0 %	9.5 %	100.0 %	
	Lower	N	10	0	2	0	0	12	
		%	83.3 %	0.0 %	16.7 %	0.0 %	0.0 %	100.0 %	
TOTAL	N	23	14	27	29	57	150		
	%	15.3 %	9.3 %	18.0 %	19.3 %	38.0 %	100.0 %		

^a Significant (P < 0.05).

Table 5
Correlation of global questions with socioeconomic status.

CORRELATIONS					
	Global Question	Correlation	Socio-Economic Status	Confidence Interval	
				Lower	Upper
Spearman's rho			-0.659	-0.741003	-0.557631
		p Value	0.000		
		N	150		

Table 6
Range, mean scores, Cronbach's alpha, and factor analysis results for the OHIP-EDENT H.

	ITEM	MEAN	S.D.	CRONBACH'S ALPHA	FACTOR LOADING
FUNCTIONAL LIMITATION	1. Difficulty chewing	3.59	1.41	1.00	0.868
	2. Food catching	3.77	1.36	1.00	0.773
	3. Dentures not fitting	3.71	1.44	0.996	0.822
PHYSICAL PAIN	4. Painful aching	4.38	1.01	0.996	0.394
	5. Uncomfortable to eat	3.61	1.49	1.00	0.861
	6. Sore spots	4.33	1.10	0.982	0.301
	7. Uncomfortable dentures	3.53	1.45	0.995	0.862
PSYCHOLOGICAL DISCOMFORT	8. Worried	3.50	1.45	0.996	0.843
	9. Self-conscious	4.27	1.19	0.971	0.422
PHYSICAL DISABILITY	10. Avoid eating	3.49	1.44	0.995	0.863
	11. Interrupt meals	3.57	1.48	0.996	0.837
	12. Unable to eat	3.77	1.43	0.979	0.808
PSYCHOLOGICAL DISABILITY	13. Upset	3.56	1.44	0.987	0.363
	14. Been embarrassed	4.41	1.07	1.00	0.459
SOCIAL DISABILITY	15. Less tolerant of others	4.18	1.27	0.972	0.708
	16. Irritable with others	4.41	1.10	0.996	0.836
	17. Avoid going out	4.33	1.14	0.995	0.254
HANDICAP	18. Unable to enjoy company	4.19	1.27	0.986	0.278
	19. Life unsatisfying	4.15	1.31	0.991	0.307

*Significant (P < 0.05).

in terms of their functional limitations and physical disabilities.

The current questionnaire uses simplified language for easier administration and assessment. The study's strengths include a thorough and systematic approach to translating and validating the OHIP-EDENT questionnaire into Hindi. A sample size of 150 participants and the use of established statistical methods such as ICC, Cronbach's alpha, and EFA, as well as assessment of Convergent Validity, add robustness to the study. The inclusion of demographic data using the Modified Kupswamy Socio-economic Scale provides additional context and aids in

understanding the study population.

The study acknowledges the potential limitations of its findings, as it was conducted with a specific population. The exclusion of certain demographic groups or specific oral health conditions may limit the broader applicability of the OHIP-EDENT-H questionnaire. Additionally, conducting a longitudinal study and using Confirmatory Factor Analysis (CFA) to assess the sensitivity and responsiveness of the OHIP-EDENT-H over time could have provided valuable insights into its usefulness for finding changes in OHRQoL among edentulous individuals.

Table 7

Test-retest reliability and Internal consistency of the OHIP- EDENT H.

SUBSCALES	CORRECTED ITEM-TOTAL CO- RELATIONS (n = 180)	TEST- RE TEST (ICC) (n = 30)	CONFIDENCE INTERVALS
Functional limitation	0.923	0.997	0.996–0.998
Physical pain	0.901	0.987	0.981–0.991
Psychological discomfort	0.904	0.968	0.946–0.981
Physical disability	0.902	0.975	0.962–0.983
Psychological disability	0.915	0.978	0.964–0.987
Social disability	0.711	0.985	0.977–0.990
Handicap	0.665	0.983	0.972–0.990

ICC intra-class correlation coefficient.

AGREEMENTS: <0.40 = fair; 0.41–0.60 = moderate; 0.61–0.80 = good; >0.80 = excellent.

Table 8

Convergent validity of the OHIP-EDENT H.

SUBSCALES	r _s	CONFIDENCE INTERVALS
Functional limitation	0.923	0.90–0.94
Physical pain	0.901	0.87–0.93
Psychological discomfort	0.904	0.87–0.93
Physical disability	0.902	0.87–0.93
Psychological disability	0.915	0.88–0.94
Social disability	0.711	0.62–0.78
Handicap	0.665	0.56–0.75

Spearman's rank correlation coefficient (r_s); CORRELATIONS: <0.2 = Poor; 0.41 and 0.60 = fair; 0.61 and 0.80 = very good; <0.80 = excellent.

It may be beneficial to explore potential cultural and linguistic nuances that could impact the interpretation of the OHIP-EDENT-H among Hindi-speaking individuals in future studies, thus improving the questionnaire's overall applicability. Additionally, future research could concentrate on validating the Hindi version of the Oral Health Impact Profile (OHIP-EDENT-H) in various regions of India to ensure its relevance across diverse cultural and socio-economic backgrounds.

Qualitative research, conducted through individual interviews, group discussions, or observations, can provide valuable insights into the experiences, attitudes, and perceptions of the Hindi-speaking edentulous population regarding psychosocial factors. This approach complements the quantitative data obtained from the OHIP-EDENT-H questionnaire and can help uncover challenges that may not be fully captured through quantitative measures alone.

Furthermore, it would also be beneficial to conduct comparative studies between the OHIP-EDENT-H and other existing tools to evaluate its effectiveness in capturing the unique challenges and experiences of edentulous patients in the Indian context.

The study's findings have significant implications and improve both clinical assessment and research efforts. Having a validated Hindi version of the OHIP-EDENT questionnaire is a valuable tool for assessing the cultural aspects of OHRQoL of Hindi-speaking edentulous patients in clinical settings. Healthcare professionals can use this tool to better understand how edentulism affects different aspects of patients' lives, and then customize efficient interventions and treatment plans to improve patient care outcomes.

5. Conclusion

The Hindi version of OHIP-EDENT has demonstrated strong reliability and validity when used with the edentulous Hindi-speaking population. Therefore, the OHIP-EDENT-H is a dependable and valid tool for evaluating the OHRQoL of Hindi-speaking edentulous individuals.

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Contribution details

Dr. Saruchi Saxena, Role (Definition of intellectual content, investigation, manuscript writing, etc.), acquisition of data, analysis and interpretation of data, Drafting the article or revising it critically for important intellectual content; Dr Neerja Mahajan (Professor and P.G guide): Role (Concepts, Design, manuscript writing, etc.), Conception and design, analysis and interpretation of data, Drafting the article or revising it critically for important intellectual content; Dr. Vineet Vinay: Analysis and interpretation of data Drafting the article or revising it critically for important intellectual content.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper"

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