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Research article

Validation of the "obturator functioning scale" for Chinese-speaking patients with obturator prostheses after cancer-related maxillectomy

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ABSTRACT

Objective: The Obturator Functioning Scale (OFS) is a scale without formal measures of validity in any language. This study aimed to translate and adapt the OFS from English to Chinese and check its reliability and validity in Chinese-speaking patients with obturator prostheses after cancer-related maxillectomy.

Abbreviations: OFS, Obturator functioning scale; UW-QOL, University of Washington quality of life scale; OFS-Ch, Chinese version of the OFS; QOL, Quality of life; PSS-HN, Performance status scale for head and neck; EORTC QLQ-H&N35, European organisation for research and treatment of cancer quality of life questionnaire-head and neck 35; FACT-H&N, Functional assessment of cancer therapy-head and neck scale; CFA, Confirmatory factor analysis; RMSEA, Root mean square error of approximation; SRMR, Standardized root mean square of residuals; NFI, Normed fit index; IFI: incremental fit index, TLI; Tucker-lewis index, CFI; Comparative fit index, EFA; Exploratory factor analysis, KMO; Kaiser–meyer–olkin, M0; Kornblith model, CR; Composite reliability, AVE; Average variance extracted, M1; Model 1, 3-Factor model.

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Methods: The 15-item Chinese preversion of the OFS was completed by 133 patients in three tertiary stomatological hospitals. Of these, 41 completed it again one week after the first measurement. The patients also completed the Chinese version of the University of Washington quality of life scale (UW-QOL, Version 4).
Results: Item 12 ("upper lip feels numb") was deleted to achieve a better statistical fit. The 14-item Chinese version of the OFS (OFS-Ch) demonstrated high internal consistency (Cronbach's alpha = 0.908). The test-retest reliability coefficients for most items exceeded 0.90, indicating substantial reproducibility. Confirmatory factor analysis found that the scale consisted of three correlated factors: 1) eating (four items), 2) speech (five items), and 3) other problems (five items). This explained 70.2 % of the total variance using exploratory factor analysis. The scale was significantly convergent and discriminant and could validly discriminate between patients with Brown I and IId maxillary defects.
Conclusions: Our results showed that the OFS-Ch scale is a valid tool for evaluating oral dysfunction and satisfaction with appearance for patients with the obturator prosthesis and identifying those at risk of poor obturator function in clinical settings.

1. Introduction

Cancer-related maxillectomies are relatively uncommon [1,2]. However, patients with maxillary defects may suffer from severe aesthetic and functional disabilities, such as significant facial disfigurement, impaired masticatory function, hypernasal speech, leakage of foods and liquids into the nasal cavity and difficulty swallowing [3]. Oronasal and oro-antral communications are the most significant changes occurring after surgical removal of maxillary tumours; they profoundly affect the patient's social interaction and quality of life (QOL) [4,5]. Obturator prostheses remain a common approach and the "gold standard" to occlude areas of the resected maxilla [6], which can dramatically improve speech intelligibility, communication performance and QOL [7].

Several prominent standardised questionnaires, such as the University of Washington QOL scale (UW-QOL) [8], the Performance Status Scale for Head and Neck (PSS–HN) [9], the European Organisation for Research and Treatment of Cancer Quality of Life questionnaire-Head and Neck 35 (EORTC QLQ-H&N35) [10], and the Functional Assessment of Cancer Therapy-Head and Neck Scale (FACT-H&N) [11], are widely used to evaluate the functional disability of patients with head and neck cancer. However, none pay specific attention to hypernasality, nasal fistula, noticeable clasps, or difficulty inserting the obturator, which were attributed to maxillectomy and the ensuing restoration with obturator prostheses.

The Obturator Functioning Scale (OFS) was developed by Kornblith et al. [7] at the Memorial Sloan Kettering Cancer Centre in 1996. The OFS was designed to evaluate the impact of obturator prosthesis on maxillectomy patients' eating, speech and cosmetic satisfaction, but free of the confounding psychological issues of facial disfigurement [7]. The scale consists of 15 questions, split into three subscales: 1) the eating subscale (three items), 2) the speech subscale (five items), and 3) other questions (seven items), including appearance, mouth dryness, and so on. The items were rated on a 5-point Likert scale ("not at all", "a little difficult", "somewhat difficult", "very difficult", "extremely difficult"), ranging from 1 to 5, with higher scores reflecting greater difficulties with obturator functioning [7].

Excellent internal consistency was reported for use in English. The internal consistency for the total scale, the eating subscale, and the speech subscale were 0.86, 0.82, and 0.87, respectively [7]. Similar results were also reported after it was translated into Greek [12], Turkish [13], Arabic [14], and Chinese languages [15]. However, the OFS remains a scale without formal measures of validity in any language until now, partly because maxillary cancer is a relatively rare tumour with high mortality [2]. In fact, the number of samples in these studies involved in measuring the reliability of OFS is within the range of 30–57 patients [7,12–15], not meeting the criterion with a minimum of five participants per scale item to evaluate the construct validity [16].

When we began the retrospective study in 2019, He et al. [15] had not published their work regarding the reliability of OFS in the Chinese language. A forward-backward approach following the translation guidelines was used to develop a Chinese version of the OFS (OFS-Ch). This study aimed to validate the OFS-Ch in a series of patients with cancer-related maxillectomy.

2. Materials and methods

2.1. Design and participants

A cross-sectional study was conducted over two years, from December 2019 to December 2021, in three tertiary stomatological hospitals—the Peking University School and Hospital of Stomatology, Tianjin Stomatological Hospital and Stomatological Hospital of Tianjin Medical University. The medical records were reviewed for patients who underwent maxillectomy due to a primary and untreated malignant tumour and were reconstructed using conventional obturator prostheses between April 2007 and December 2020. Patients with a time since surgery of less than 12 months, recurrent disease in the follow-up or having an implant-retained prosthesis were excluded. The study was conducted in accordance with the principles of the Helsinki Declaration. The Ethics Committee of Tianjin Stomatological Hospital (ChiCTR2100050477) approved the retrospective study. Informed consent was obtained from the patients for the publication of their cases.

2.2. Translation and cultural adaptation

At the time of this study, no Chinese translation of the OFS was available. The OFS-Ch scale was developed and adapted according to translation guidelines using a forward-backward approach. Considering the arbitrariness of the use of the OFS, for example, adding, deleting or revising items without any measure of reliability in previous studies [6,14,17–20], we merged the English versions reported by Kornblith et al. [7] in 1996 and by Artopoulou et al. [12] in 2017. In Kornblith's original English version, the two items regarding swallowing in the eating problems subscale were "Leakage when swallowing liquids" and "Leakage when swallowing foods". The corresponding two items were "nasal leaking when swallowing liquids" and "nasal leaking when swallowing foods" in Artopoulou's version. We accepted the latter since nasal fistula was a frequent complaint [19], and the problem could be expressed more precisely by "nasal leaking" than "leakage". We abandoned the item "Trouble with hearing", which was added in Artopoulou's version to maintain consistency with Kornblith's original version.

Therefore, a 15-item English version was translated by two teams of bilingual doctors for forward translation. The first Chinese version was confirmed by integrating the results of the two teams. A pilot test in a convenience sample of seven patients was conducted to identify difficulties in understanding the scale. Then, a new consensus version was produced in a second expert panel meeting with modifications according to the patients' comments. This version was taken as the template for backward translation. Two independent bilingual translators produced two separate backward translations from the forward translation without looking at the original English version of the questionnaire. Finally, translators and researchers discussed discrepancies and differences between all these versions, revised all the translations and merged them into a 15-item Chinese preversion of OFS (Table 1).

Table 1
OFS original and Chinese version (preview version). The 15 items are shown after the process of translation and cultural adaptation.

Original OFS	Chinese preview version of OFS
Eating problems subscale	进食问题子量表
1. Difficulty in chewing foods Not at all difficult; A little difficult; Somewhat difficult; Very much difficult; Extremely difficult	1 你觉得咀嚼食物困难吗? 根本不困难; 稍微有点困难; 中等程度困难; 比较困难; 极其困难
2. Nasal leakage on swallowing liquids Not at all; A little; Somewhat; Very much; Extremely	2. 你吞咽液体(如酒、水、饮料等)时会从鼻孔漏出吗? 根本不漏; 很少会漏; 有时会漏; 经常会漏; 总是会漏
3. Nasal leakage on swallowing foods Not at all; A little; Somewhat; Very much; Extremely	3. 你吞咽食物时会从鼻孔漏出吗? 根本不漏; 很少会漏; 有时会漏; 经常会漏; 总是会漏
Speech problems subscale	**说话问题子量表**
4. Voice different from before surgery Not at all; A little; Somewhat; Very much; Extremely	4. 与手术前相比,你说话的声音有改变吗? 根本没有改变; 稍微有点改变; 有中等程度改变; 改变比较大; 改变极大
5. Difficulty in talking in public Not at all difficult; A little difficult; Somewhat difficult; Very much difficult; Extremely difficult	5. 在公共场合时,你讲话有困难吗? 根本不困难; 稍微有点困难; 中等程度困难; 比较困难; 极其困难
6. Speech is nasal Not at all; A little; Somewhat; Very much; Extremely	6. 你说话时有鼻音吗? 根本没有鼻音; 稍微有一点鼻音; 有中等程度鼻音; 鼻音比较严重; 鼻音极其严重
7. Difficulty pronouncing words Not at all difficult; A little difficult; Somewhat difficult; Very much difficult; Extremely difficult	7. 某些字的发音很费劲吗? 根本不费劲; 稍微有点费劲; 一般费劲; 比较费劲; 极其费劲
8. Speech is difficult to understand Not at all difficult; A little difficult; Somewhat difficult; Very much difficult; Extremely difficult	8. 你说话时别人会听不懂吗? 根本不会; 很少会; 有时会; 经常会; 总是会
Others	**其他问题**
9. Mouth feels dry Not at all; A little; Somewhat; Very much; Extremely	9. 你口干吗? 根本不口干; 稍微有点口干; 中等程度口干; 口干比较严重; 口干极其严重
10. Dissatisfaction with looks Not at all; A little; Somewhat; Very much; Extremely	10. 你对自己的外貌不满意吗? 非常满意; 挺满意; 还算满意; 比较不满意; 非常不满意
11. Clasps on front teeth are noticeable Not at all; A little; Somewhat; Very much; Extremely	11. 你觉得前牙区的卡环碍眼吗? 根本不碍眼; 稍微有点碍眼; 中等程度碍眼; 比较碍眼; 极其碍眼
12. Upper lip feels numb Not at all; A little; Somewhat; Very much; Extremely	12. 你觉得上嘴唇有麻木吗? 根本不麻木; 稍微有点麻木; 中等程度麻木; 比较麻木; 极其麻木
13. Avoidance of family/social events Not at all; A little; Somewhat; Very much; Extremely	13. 你会避免参加家庭聚会或社交活动吗? 根本不会; 很少会; 有时会; 经常会; 总是会
4. 1Difficulty inserting obturator Not at all difficult; A little difficult; Somewhat difficult; Very much difficult; Extremely difficult	14. 你觉得戴赝复体困难吗? 根本不困难; 稍微有点困难; 中等程度困难; 比较困难; 极其困难
15. Upper lip looks funny Not at all; A little; Somewhat; Very much; Extremely	15. 你觉得上嘴唇的外形奇怪吗? 一点也不奇怪; 稍微有点奇怪; 中等程度奇怪; 比较奇怪; 非常奇怪

Abbreviations: OFS, obturator functioning scale.

2.3. Data acquisition

Information about demographic data (gender, age, education level, marital status, and employment status) and clinical variables (histopathology, postoperative radiotherapy, and Brown's new classification of maxillary defect [21]) were collected from the participants. A total of 133 patients were recruited to complete the 15-item Chinese preversion of the OFS by a single trained interviewer during a telephone interview. To assess the criterion validity of OFS-Ch, patients were also asked to simultaneously complete the Chinese version of UW-QOL (Version 4) [22]. The UW-QOL included 15 items with 3–5 Likert-scaled response options. The questionnaire and single-item measurement scores ranged from 0 (worst) to 100 (best), with higher scores representing a better QOL [8,23]. To determine the test-retest reliability of the OFS-Ch scale, 41 patients were asked to complete the 15-item Chinese preversion of the OFS twice within one week.

2.4. Data analysis

Data entry and analyses were performed using the Statistical Package for the Social Sciences (SPSS) 17.0 software package (SPSS Inc., Chicago, IL, USA) for Windows. The significance was set at a p-value of less than 0.05. Descriptive statistics were used to summarise the sociodemographic and clinical characteristics. The mean with range was used for continuous variables, and the frequency with percentages for categorical variables.

Considering the 15 items of the OFS, 75 to 150 participants should be required according to the sample size guidance that 5–10 participants per scale item would be suitable to establish sufficient evidence of scale validity and reliability [16]. In this study, a total sample size of 133 was considered appropriate for testing the proposed model.

Internal consistency reliability was determined by Cronbach's coefficient α for the total scale and each subscale. A coefficient of over 0.7 indicated acceptable internal consistency [16,24]. Test-retest reliability was evaluated by calculating Spearman's correlation between the first and second assessments on 41 patients. A correlation coefficient of 0.8 would act as a recommended threshold value [25]. Since good reliability is the prerequisite of construct validity [26], the internal consistency reliability of the 15-item Chinese preversion of the OFS was first calculated before we started evaluating validity.

Then, the dimensionality of the 15-item, 3-factor model proposed by Kornblith et al. [7] was tested with confirmatory factor analysis (CFA) using Amos software version 26.0. The goodness-of-fit of the model was evaluated using several parameters: the Chi-square (χ^2), degrees of freedom (df), Root Mean Square Error of Approximation (RMSEA), Standardised Root Mean Square of Residuals (SRMR), Normed Fit Index (NFI), Incremental Fit Index (IFI), Tucker-Lewis Index (TLI), and Comparative Fit Index (CFI). If the value of χ^2/df is < 3, the model fit is acceptable; a value < 2 is considered an adequate fit [27]. A value of RMSEA less than 0.05 indicates a close fit, values in the range of 0.05–0.08 a fair fit, values in the range of 0.08–0.10 a mediocre fit, and values greater than 0.10 a poor fit [28]. A cutoff value close to 0.08 for SRMR is considered a relatively good fit [28]. Regarding these fit indexes (NFI, IFI, TLI, and CFI), a value above 0.9 is acceptable according to conventional cutoff criteria [28]. These fit indices for the model using the statistical criteria with a threshold in each were summarised in Table 2 [29].

An exploratory factor analysis (EFA) was conducted using principal components analysis with varimax rotation, following the Kaiser–Meyer–Olkin (KMO) measure of sampling adequacy and Bartlett's Test of Sphericity. A value of the KMO index between 0.8 and 0.9 is considered good, and a value larger than 0.9 is considered very good [30]. The number of factors retained in the scale was determined by the Eigenvalues >1 and the visual inspection of the scree plot.

The results of CFA indicated that the Kornblith model (M0) did not fit the data obtained from the Chinese participants. However, the goodness-of-fit of the model could be improved by eliminating items, since the standardised regression weights (factor loadings) of items 9 (0.329) and 12 (0.286) were less than 0.40 [31]. We deleted item 12 but retained item 9 because the factor loading of the latter was greater than 0.40 in the succeeding EFA. Then, an EFA was performed on the 14-item scale to produce a multidimensionality model M1, which was further tested using CFA.

The composite reliability (CR) and average variance extracted (AVE) were used to evaluate the convergent validity. Generally, the values of AVE of each latent variable >0.7 and the values of CR of each latent variable >0.5 indicated acceptable convergent validity [29]. The discriminant validity can be evaluated by comparing the square root of AVE for any two constructs and the correlation estimate between the same construct [29]. If the square root of the AVE of one latent variable was larger than any of the correlation coefficients between itself and the other latent variables, we concluded that the dimension had discriminant validity [32].

Table 2
Threshold measures for fit indices model.

Index	Threshold	
	Good fit	Acceptable fit
Chi-square/degrees of freedom (χ^2/df)	$1 \leq \chi^2/df \leq 2$	$2 \leq \chi^2/df \leq 3$
Root Mean Square Error of Approximation (RMSEA)	$\leq$0.05	0.05 $<$ RMSEA $\leq$0.80
Standardized Root Mean Square of Residuals (SRMR)	$\leq$0.05	0.05 $<$ SRMR $\leq$0.80
Normed Fit Index (NFI)	$\geq$0.95	$\geq$0.90
Incremental Fit Index (IFI)	$\geq$0.95	$\geq$0.90
Tucker-Lewis Index (TLI)	$\geq$0.95	$\geq$0.90
Comparative Fit Index (CFI)	$\geq$0.95	$\geq$0.90

Known-group validity was determined using test scores to distinguish between individuals from different groups [26]. In our study, the scores of the scale of two subgroups (patients with Brown I or Brown IId maxillary defect) were compared using the Mann–Whitney test. The Chinese version of the UW-QOL was used as the criterion for assessing criterion-related validity because of the lack of a gold standard. The criterion-related validity was studied using bivariate correlation analysis to compute the Spearman correlation coefficients (lower than 0.40 were considered weak, between 0.40 and 0.70 as moderate and greater than 0.70 as strong [30]) between the OFS factors and the items of UW-QOL.

3. Results

3.1. Patient characteristics

The baseline demographic characteristics for the patients enrolled in the study are shown in Table 3. The total number of patients was 133, of which 48.1 % were male. The patients ranged in age between 22 and 96 years, with a mean age of 56.5 at the time of data collection. Of the total sample, 72.1 % had an elementary or high school level of education. Most participants in the sample were married (89.4 %), without comorbidity (69.9 %), unemployed/retired (57.9 %), diagnosed with squamous cell carcinoma (58.7 %), and without postoperative radiotherapy (60.9 %). Of the 133 patients, 17 were classified as Brown I (12.8 %), 1 (0.8 %) as Brown IIa, 99 (74.7 %) as Brown IIb, 3 (2.2 %) as Brown IIc, and 13 (9.8 %) as Brown IId.

3.2. Construct validity of the OFS-Ch

The 15-item Chinese preversion of the OFS is shown in Table 1. The results of evaluating the dimensionality of the 15-item OFS questionnaire using CFA and EFA are shown in Tables 4 and 5.

According to the results of the initial CFA, the model originally hypothesised by Kornblith [7] of 15 items and three factors, M0, did not fit the data obtained from Chinese participants (Table 5). The $\chi^2/df = 3.188 > 3$; SRMR $= 0.109 > 0.08$; RMSEA $= 0.129 > 0.10$; TLI $= 0.818 < 0.9$; CFI $= 0.849 < 0.9$; IFI $= 0.851 < 0.9$; and NFI $= 0.797 < 0.9$, indicating substantial mismatch. To improve the goodness-of-fit of the model, item 12 ("upper lip feels numb") was deleted because its factor loading was less than 0.4 both at the CFA (0.286) and EFA (0.389) (Table 4).

An EFA on the 14-item OFS-Ch (Supplementary Table 1) produced a 3-factor structure (M1, Table 6). In model M1, the KMO index was satisfactory, with the value = 0.863, and Bartlett's Test of Sphericity showed a highly significant ($\chi^2 = 1272.29$, df = 91, p-value

Table 3
Demographic characteristics of the study participants.

Characteristics	All cases ($n = 133$)
Mean age, years (range)	56.5 (22–96)
<65 years (%)	90 (67.7)
Male (%)	64 (48.1)
General condition (%)	
Comorbidity	40 (30.1)
No Comorbidity	93 (69.9)
Marital status (%)	
Single	5 (3.8)
Married	119 (89.4)
Divorced/Widowed	9 (6.8)
Employment status (%)	
Unemployed/Retired	77 (57.9)
Full/Part-time	56 (42.1)
Education level (%)	
Illiterate	3 (2.3)
Elementary (≤9 years)	49 (36.8)
High school (10–12 years)	47 (35.3)
College (>12 years)	34 (25.6)
Pathological diagnosis (%)	
Squamous cell carcinoma	78 (58.7)
Adenoid cystic carcinoma	27 (20.3)
mucoepidermoid carcinoma	14 (10.5)
Other cancers	14 (10.5)
Treatment modality (%)	
Surgery	81 (60.9)
Surgery + radiotherapy	52 (39.1)
Brown classification of maxillary defect	
I	17 (12.8)
IIa	1 (0.8)
IIb	99 (74.4)
IIc	3 (2.2)
IId	13 (9.8)

Table 4
Descriptive statistics of the items of the original OFS in the adaptation for a sample of Chinese cancer-related maxillectomy patients. The factor loadings of the original model M0 by EFA and CFA were shown.

OFS (original version)		Descriptive Statistics			Cronbach's coefficient		Factor loadings			
	[a]Item	Mean	SD	Skew	[b]Alpha	[c]Alpha	CFA, M0, k = 15	EFA, M0, k = 15		
								Factor 1	Factor 2	Factor 3
Eating	1. Difficulty in chewing foods	1.96	1.18	0.982	0.659	0.892	0.693			0.523
	2. Nasal leakage on swallowing liquids	2.20	1.25	0.746		0.898	0.539			0.714
	3. Nasal leakage on swallowing foods	1.57	1.00	1.843		0.897	0.528			0.771
Speech	4. Voice different from before surgery	1.79	1.05	1.211	0.949	0.886	0.908	0.881		
	5. Difficulty in talking in public	1.53	0.79	1.396		0.890	0.905	0.887		
	6. Speech is nasal	1.65	1.00	1.387		0.888	0.891	0.838		
	7. Difficulty pronouncing words	1.65	1.06	1.507		0.889	0.892	0.875		
	8. Speech is difficult to understand	1.58	0.93	1.380		0.888	0.845	0.790		
Others	9. Mouth feels dry	1.61	1.09	1.749	0.786	0.899	0.329			0.593
	10. Dissatisfaction with looks	1.68	1.03	1.737		0.894	0.848		0.826	
	11. Clasps on front teeth are noticeable	1.57	0.88	1.614		0.895	0.807		0.832	
	12. Upper lip feels numb	1.26	0.64	2.868		0.904	**0.286**			**−0.389**
	13. Avoidance of family/social events	1.90	1.24	1.128		0.897	0.617		0.623	
	14. Difficulty inserting obturator	1.59	1.04	1.790		0.899	0.607		0.709	
	15. Upper lip looks funny	1.72	0.85	1.087		0.897	0.727		0.775	

The Kaiser–Meyer–Olkin (KMO) and Bartlett's sphericity test were performed to determine whether the data was suitable to be analyzed using EFA. In the model M0, a KMO measure of 0.857 indicated adequate sampling adequacy. The Bartlett's Test of sphericity showed a highly significant (χ^2 = 1307.15, df = 105, p value < 0.0001). χ^2, Chi-square; df, degrees of freedom.

[a]Item, the numbering in original scale; OFS, obturator functioning scale; SD, Standard Deviation; M0, the model proposed by Kornblith et al. [7].

[b]Alpha, Alpha of each factor.

[c]Alpha, Alpha if the item was deleted; CFA, confirmatory factor analysis; EFA, exploratory factor analysis; k: the number of items in the tested model.

Table 5
The goodness-of-fit of dimensionality models of the OFS using CFA in the process of adaptation to the Chinese population.

Model	χ2 (df)	χ2/df	NFI	IFI	TLI	CFI	SRMR	RMSEA [90%CI]
M0 (k = 15)	277.390 (87)	3.188[a]	0.797	0.851	0.818	0.849	0.109	0.129 (0.112–0.146)
M1 (k = 14)	218.765 (74)	2.956[a]	0.835	0.885	0.856	0.883	0.078	0.122 (0.103–0.141)
M1-modification (k = 14)	99.819 (64)	1.560[a]	0.925	0.972	0.959	0.971	0.056	0.065 (0.039–0.089)

Abbreviations: CFA, confirmatory factor analysis; k: the number of items in the tested model; M0, request for 3 factors with k = 15 items (same model proposed by Kornblith et al. [7]); M1, 3-factor model with 14 item after the item 12 was deleted; M1-modification, the model that has the best fit through the CFA, error covariance was added between some of items according to the modification indices to M1; χ^2, Chi-square; df, degrees of freedom; NFI, Normed Fit Index; IFI, Incremental Fit Index; TLI, Tucker-Lewis Index; CFI, Comparative Fit Index; SRMR, Standardized Root Mean Square of Residuals; RMSEA, Root Mean Square Error of Approximation; CI, confidence interval.

[a] $P < 0.01$.

<0.001). The analysis explained 70.2 % of the scale's total variance, with the first factor accounting for 30.702 %, the second factor 23.980 % and the third factor 15.526 %. The OFS items that loaded more robustly onto the first factor were related to speech (items 4–8). The second factor, composed of items 10, 11, and 13–15, was associated with appearance, social interaction and inserting obturator. The third factor concerned eating and dry mouth, which comprised items 1–3 and 9. We denominated factor 1 "Speech", factor 2 "Others", and factor 3 "Eating". The factor loadings for each item are presented in Table 6. The two communalities had values of 0.484 and 0.494; all others were between 0.527 and 0.861.

The dimensionality of the 14-item, 3-factor model (M1) produced by EFA was further tested with CFA. The goodness-of-fit statistics of model M1 (The χ^2/df = 2.956 < 3; SRMR = 0.078 < 0.08, in Table 5) was superior to a greater extent than M0. However, it still displayed an unsatisfactory fit (RMSEA = 0.122 > 0.10; TLI = 0.856 < 0.9; CFI = 0.883 < 0.9; IFI = 0.885 < 0.9; and NFI = 0.835 < 0.9, in Table 5). Inspection of the modification indices suggested adding error covariance between OFS1 and OFS2 (namely, items 1 and 2), OFS1 and OFS3, OFS1 and OFS4, OFS2 and OFS10, OFS4 and OFS13, OFS4 and OFS14, OFS5 and OFS7, OFS6 and OFS8, OFS6 and OFS10, OFS8 and OFS13 (Fig. 1). These modifications resulted in a significant improvement in the fit indices. The goodness-of-fit statistics were χ^2/df = 1.560 < 2; SRMR = 0.056 < 0.08; RMSEA = 0.065 < 0.08; TLI = 0.959 > 0.95; CFI = 0.971 > 0.95; IFI = 0.972 > 0.95; and NFI = 0.925 > 0.9 (Table 5). The standardised factor loadings for each item were in the range of 0.487–0.926 ($P < 0.001$, Table 7 and Fig. 1).

3.3. Convergent validity and discriminant validity of the 14-item OFS-Ch

In convergent validity, the CR for each dimension ranged from 0.809 to 0.948, which was higher than the recommended threshold

Table 6
Exploratory factor analysis of the OFS Scale (M1, 14 items).

	Factor 1	Factor 2	Factor 3	Communality
1. Difficulty in chewing foods			0.521	0.527
2. Nasal leakage on swallowing liquids			0.825	0.749
3. Nasal leakage on swallowing foods			0.834	0.754
4. Voice different from before surgery	0.865			0.861
5. Difficulty in talking in public	0.895			0.857
6. Speech is nasal	0.837			0.821
7. Difficulty pronouncing words	0.879			0.838
8. Speech is difficult to understand	0.780			0.782
9. Mouth feels dry			0.613	0.494
10. Dissatisfaction with looks		0.822		0.742
11. Clasps on front teeth are noticeable		0.835		0.735
13. Avoidance of family/social events		0.621		0.484
14 .Difficulty inserting obturator		0.726		0.561
15. Upper lip looks funny		0.772		0.624
Eigenvalue	4.298	3.357	2.174	
Percentage of explained variance (%)	30.702	23.980	15.526	

In the model M1, the Kaiser–Meyer–Olkin (KMO) index was satisfactory with the value = 0.863; and Bartlett's sphericity test showed a highly significant ((χ [2] = 1272.29, df = 91, p value < 0.001).
Abbreviations: χ^2, Chi-square; df, degrees of freedom; OFS, obturator functioning scale.

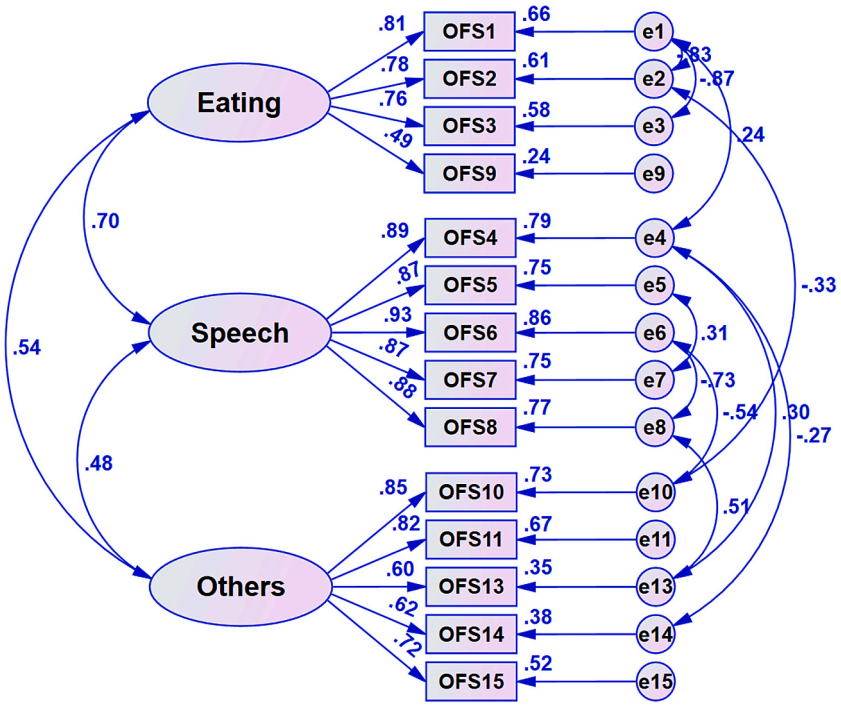

Fig. 1. Three-factor model (M1) of the 14-item Chinese version of the OFS. OFS1-15 corresponded to the item 1–15, respectively.

value of 0.7 (Table 7). In addition, the AVE for each factor is between 0.532 and 0.786, which was higher than the standard 0.5 (Table 7). These results indicated that each factor of the OFS had adequate convergent validity.

This study observed a significant correlation among the three factors ($P < 0.01$, Table 8). In addition, the correlation coefficients between any of the two factors were smaller than the corresponding square root of AVE for each factor (Table 8), indicating adequate discriminant validity.

3.4. Known-group validity of the 14-item OFS-Ch

The scores between the Brown I and IId maxillary defect groups were compared per item, and the results are shown in Table 9. Statistically significant differences for each item in the eating and speech factors were found between the two groups ($P < 0.05$), indicating good known-group validity. No significant difference was observed for each item in the factor of other questions between

Table 7
The convergent validity of the OFS Scale (M1, 14 items).

Construct	Item	Estimate	S.E.	*Z* value	*P* value	Standardized factor loadings	CR	AVE
Eating	OFS1	1.000				0.815	0.809	0.523
	OFS2	1.045	0.161	6.479	***	0.783		
	OFS3	0.809	0.131	6.157	***	0.759		
	OFS9	0.562	0.117	4.810	***	0.487		
Speech	OFS4	1.000				0.890	0.948	0.786
	OFS5	0.743	0.049	15.226	***	0.867		
	OFS6	1.018	0.058	17.459	***	0.926		
	OFS7	0.993	0.065	15.250	***	0.868		
	OFS8	0.863	0.059	14.724	***	0.879		
Others	OFS10	1.000				0.852	0.846	0.529
	OFS11	0.833	0.077	10.891	***	0.816		
	OFS13	0.850	0.114	7.476	***	0.595		
	OFS14	0.755	0.097	7.790	***	0.616		
	OFS15	0.708	0.077	9.246	***	0.722		

OFS, obturator functioning scale; CR, composite reliability; AVE, average variance extracted; S.E., standard error; OFS1-15 corresponded to the item 1–15, respectively; ***$P < 0.001$.

Table 8
The discriminant validity of the OFS Scale (M1, 14 items).

	Eating subscale	Speech subscale	Others subscale
Eating subscale	–	0.698[a]	0.542[a]
Speech subscale	0.698[a]	–	0.478[a]
Others subscale	0.542[a]	0.478[a]	–
Square root of AVE	0.723	0.835	0.736

OFS, obturator functioning scale; AVE, average variance extracted.
[a]$P < 0.01$.

Table 9
Known-group validity of the OFS Scale (M1, 14 items).

		Brown I maxillary defect ($n = 17$)		Brown IId maxillary defect ($n = 13$)		
Construct	Items	Mean ± SD	Median (range)	Mean ± SD	Median (range)	*p* value
Eating	OFS1	1.18 ± 0.39	1 (1–2)	3.00 ± 1.35	4 (1–5)	**< 0.001**
	OFS2	1.00 ± 0.00	1 (1–1)	2.23 ± 1.17	2 (1–5)	**< 0.001**
	OFS3	1.00 ± 0.00	1 (1–1)	1.31 ± 0.48	1 (1–2)	**0.016**
	OFS9	1.18 ± 0.39	1 (1–2)	2.46 ± 1.66	2 (1–5)	**0.017**
Speech	OFS4	1.29 ± 0.59	1 (1–3)	2.31 ± 1.18	2 (1–4)	**0.007**
	OFS5	1.18 ± 0.39	1 (1–2)	2.08 ± 1.26	2 (1–4)	**0.021**
	OFS6	1.00 ± 0.00	1 (1–1)	2.23 ± 1.36	2 (1–4)	**0.001**
	OFS7	1.06 ± 0.24	1 (1–2)	2.15 ± 1.41	1 (1–4)	**0.008**
	OFS8	1.18 ± 0.53	1 (1–3)	2.08 ± 1.12	2 (1–4)	**0.005**
Others	OFS10	1.12 ± 0.33	1 (1–2)	1.84 ± 1.34	1 (1–5)	0.066
	OFS11	1.12 ± 0.33	1 (1–2)	1.61 ± 0.96	1 (1–4)	0.074
	OFS13	1.53 ± 0.80	1 (1–4)	1.77 ± 1.36	1 (1–5)	0.883
	OFS14	1.29 ± 0.77	1 (1–4)	2.23 ± 1.59	1 (1–5)	0.063
	OFS15	1.59 ± 0.62	2 (1–3)	2.00 ± 1.00	2 (1–4)	0.277

Bold values indicate $P < 0.05$; OFS1-15 corresponded to the item 1–15, respectively.

the two groups.

3.5. Criterion validity of the 14-item OFS-Ch

The correlation coefficients of scores among the factors of the OFS scale (M1, 14 items) and the UW-QOL items were computed and are presented in Table 10. Generally, the between-instrument correlations were higher for the same or similar domains than across different or nonsimilar domains. For example, the coefficient between the factor "speech" of OFS and the item "speech" of UW-QOL was 0.636, which is higher than the coefficients between this factor and any other items of UW-QOL. None of the factors of the OFS showed a correlation coefficient >0.3 for "pain" and "taste", indicating a weak correlation among them. Surprisingly, although the "eating" factor showed a moderate correlation (Spearman's rho = −0.469, $P < 0.01$) with "chewing" of the UW-QOL, a weak correlation (Spearman's rho = −0.293, $P < 0.01$) was found between this factor and "swallowing". In addition, the "eating" factor also showed a moderate correlation (Spearman's rho = −0.453, $P < 0.01$) with "speech". The factors of other questions in the OFS showed a

Table 10
Spearman's correlation coefficients among the factors of the OFS scale (M1, 14 items) and the 12 items of UW-QOL.

OFS	UW-QOL											
	Pain	Appearance	Activity	Recreation	Swallowing	Chewing	Speech	Shoulder	Taste	Saliva	Mood	Anxiety
Eating	−0.045	−0.373[b]	−0.322[b]	−0.368[b]	−0.293[b]	**−0.469**[b]	**−0.453**[b]	−0.266[b]	−0.238[b]	**−0.576**[b]	−0.299[b]	−0.167
Speech	−0.231[b]	−0.387[b]	−0.281[b]	−0.302[b]	−0.320[b]	−0.372[b]	**−0.636**[b]	−0.249[b]	−0.192[a]	−0.307[b]	−0.188[a]	−0.077
Others	−0.248[b]	**−0.662**[b]	**−0.439**[b]	**−0.633**[b]	−0.336[b]	−0.347[b]	−0.325[b]	−0.382[b]	−0.118	−0.193[a]	**−0.553**[b]	**−0.519**[b]

OFS, obturator functioning scale; UW-QOL, the University of Washington quality of life scale.
[a] $P < 0.05$.
[b] $P < 0.01$.

moderate correlation with “appearance” (Spearman’s rho = −0.662, $P < 0.01$), “activity” (Spearman’s rho = −0.439, $P < 0.01$), “recreation” (Spearman’s rho = −0.633, $P < 0.01$), “mood” (Spearman’s rho = −0.553, $P < 0.01$), and “anxiety” (Spearman’s rho = −0.519, $P < 0.01$) in the UW-QOL.

3.6. Reliability of the OFS

The Cronbach’s coefficient alpha of the 15-item questionnaire (M0), the eating subscale (three items), the speech subscale (five items), and other question subscales (seven items) were 0.902, 0.659, 0.949, and 0.786, respectively (Table 4). After eliminating item 12, the Cronbach’s coefficient alpha of the 14-item OFS-Ch (M1), the eating subscale (four items), the speech subscale (five items), and other question subscales (five items) were 0.908, 0.724, 0.949, and 0.834, respectively (Table 11), indicating excellent internal consistency. The loss of any single item did not significantly affect the total Cronbach’s alpha, ranging from 0.889 to 0.903. The corrected–item to total correlation coefficients varied from 0.462 to 0.786. The inter-item correlations were positive and are shown for each item in Fig. 2.

Regarding the test-retest reliabilities, the Spearman correlation coefficients for most items were larger than 0.90, except for items 1 (0.827) and 15 (0.895), indicating excellent reproducibility over time.

4. Discussion

The validation of the OFS into Chinese is essential, since the language was used by over 1400 million speakers. Although the incidence of maxillary cancer is relatively rare, the absolute number of patients in the Chinese-speaking population should not be underestimated, considering China’s huge population base. Knowing the benefits and limitations of an obturator prosthesis in restoring the specific functional and aesthetic issues resulting from a maxillectomy would contribute to optimising the function of the obturator prosthesis for improved QOL in these patients [12]. In addition, the validation of the OFS into Chinese will allow international cross-cultural comparison.

In this study, the OFS-Ch was congruent with Kornblith’s original OFS [7] in format, content and scoring system, except for items 2 and 3, where the word "leakage" was replaced by "nasal leaking" since nasal fistula was a frequent complaint [19]. This problem could be expressed more precisely by "nasal leaking" than "leakage". During the translation, both translators thought that the word "funny" in item 15 could not be translated directly into Chinese because the equivalent word ("滑稽的, 可笑的") in Chinese often referred to the action or behaviour, not configuration. The word "funny" was modified to "strange" and translated into Chinese as "奇怪的".

Validity means the ability of a scale to evaluate what it was designed to measure. Construct validity, the most critical validity index, means how a specific scale relates to previous expectations or theories. According to the original English version, the 15 items of OFS were hypothesised to measure disability from three dimensions (M0): eating (three items), speaking (five items), and other problems (seven items) [7]. However, this construct has not been verified in any languages. According to Artopoulou [12], a 16-item Greek version of the OFS was classified into five dimensions: eating (three items), speaking (five items), appearance (five items), inserting obturator (one item) and other problems (two items). However, item 12 ("upper lip feels numb ") was unrelated to the patient’s appearance. In addition, the authors only assessed the reliability of the Greek version of the OFS, not its validity [12].

In this study, the cross-cultural validity of the OFS-Ch was established by testing the hypothesis that the structure of the translated scale was consistent with the original English version (M0). However, item 12 was ultimately deleted to achieve a better statistical fit. Three factors were extracted from the 14-item OFS-Ch by EFA, which explained 70.2 % of the total OFS-Ch variance. The ensuing CFA verified the 3-factor structure (M1) produced by the EFA after considering the logical correlations between items. Adequate convergent

Table 11
Internal consistency and test–retest reliability of the OFS Scale (M1, 14 items).

Construct	Items	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	[a]Alpha	[b]Alpha	Test-retest reliability, r
Eating	OFS1	22.053	78.944	0.636	0.724	0.896	0.827**
	OFS2	21.812	80.593	0.513		0.902	1.000**
	OFS3	22.444	83.355	0.511		0.901	0.926**
	OFS9	22.406	83.107	0.476		0.902	1.000**
Speech	OFS4	22.226	77.994	0.786	0.949	0.889	0.988**
	OFS5	22.481	82.479	0.736		0.894	0.988**
	OFS6	22.368	79.250	0.755		0.891	0.990**
	OFS7	22.368	79.083	0.716		0.892	0.989**
	OFS8	22.436	79.990	0.772		0.891	0.931**
Others	OFS10	22.331	81.708	0.586	0.834	0.898	0.960**
	OFS11	22.444	83.915	0.558		0.899	0.983**
	OFS13	22.113	80.434	0.530		0.901	0.932**
	OFS14	22.421	83.791	0.462		0.903	0.960**
	OFS15	22.293	84.966	0.514		0.900	0.895**

[a] Alpha, Cronbach’s coefficient alpha of each factor.
[b] Alpha, Cronbach’s coefficient alpha if the item was deleted; r, Spearman correlation coefficient. OFS1-15 corresponded to the item 1–15, respectively.

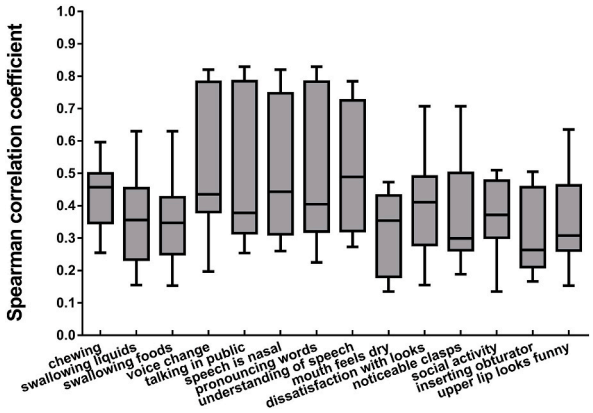

Fig. 2. Inter-item correlations for the 14-item OFS. Each box and whisker summarise 13 correlations of one item with the other 13 items.

validity and discriminant validity were also confirmed for M1. Our study showed that the best option for adapting the original OFS to the Chinese-speaking population was a 14-item questionnaire fitting into three moderately correlated factors: “eating” (including items 1–3 and 9), “speech” (including items 4–8), and “other problems” (including items 10, 11, and 13–15).

In the original English version, item 9 (dry mouth), which was thought to have a possible adverse effect on the fit or functioning of the prosthesis by the designer, was listed in the dimension of other problems. In our study, item 9 was classified into the factor of “eating”, indicating a strong relationship between “dry mouth” and the oral functions of “chewing” and “swallowing”. Item 9 was also related to the factor of “speech” in the EFA, but it was deleted from the dimension due to the factor loading <0.5. Therefore, the factor of “eating”, comprising item 9, did not contradict the original hypothesis of the designer. On the contrary, the results indicated that a dry mouth might impact the “chewing” and “swallowing” functions by exerting an unfavourable effect on the prosthesis.

Our study showed a good known-group validity for “eating” and “speaking”. However, the “other problems” factor did not support the known-group validity. The possible reasons might be: (1) the sample size was not large enough since the total number of patients was 30 in the two groups, and (2) these items were expected to be similar after the different extent of maxillectomy and the ensuing restoration with obturator prostheses in nature as a previous study had reported [12]. However, in our previous study of patients with Brown IIb defects, the group with submental flap reconstruction reported significantly higher scores than those with conventional obturation rehabilitation in “other problems” ("avoidance of family/social events" and "upper lip looks funny") [5]. The results indicated that “other problems” also had a good known-groups validity if the fundamental differences existed in the two groups.

There are some limitations concerning this study that should be addressed in the future. First, the most obvious one was the representativeness of the sample, composed only of patients with Brown I and II defects. However, the intent was to include a broader sample of patients with Brown III and IV defects. Second, this was a retrospective study, and we could not assess responsiveness, which measures the ability of the OFS-Ch to detect clinical change over time and after clinical intervention. Third, the results were preliminary. It is necessary to apply the instrument in the clinic to establish an optimal cutoff point and see its evolution after the rehabilitation of oral function by obturator prostheses.

5. Conclusions

This study was the first to explore the construct validity of the OFS for patients with obturator prostheses after cancer-related maxillectomy. Our results demonstrated that the 14-item OFS-Ch had good reliability and validity. Therefore, in clinical settings, it is a useful screening tool for assessing Chinese-speaking patients with oral dysfunction after maxillectomy and identifying those at risk for poor function of the obturator.

Data availability statement

Data available on request from the authors.

CRediT authorship contribution statement

Jian-Wei Shang: Writing – original draft, Formal analysis, Data curation. **Yuan-Yuan Tian:** Data curation. **Zhao-Yuan Xu:** Formal analysis, Data curation. **Xiao-Ming Liu:** Supervision, Investigation. **Ye Cao:** Project administration, Methodology. **Lei Sui:** Project administration, Methodology. **Chi Mao:** Supervision, Project administration, Methodology. **Yong-Sheng Zhou:** Supervision, Project administration, Methodology. **Chen-Lu Liu:** Writing – original draft, Conceptualization. **Hong-Qiang Ye:** Supervision, Funding acquisition, Formal analysis, Conceptualization. **Ying-Bin Yan:** Writing – review & editing, Supervision, Funding acquisition, Formal analysis, Conceptualization.

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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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e31071.

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