

Predictors of obturator functioning and satisfaction in Turkish patients using an obturator prosthesis after maxillectomy

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Objective. The aim of this study was to determine the sociodemographic, behavioral, and clinical factors affecting obturator function and satisfaction using the obturator functioning scale (OFS) in maxillectomy patients rehabilitated with obturator prostheses.

Study Design. The study sample consisted of 41 maxillectomy patients. The OFS was translated into Turkish and adapted for assessing obturator functioning and patient satisfaction among Turkish patients. Data were collected from patients' medical records and self-completed questionnaires, including the Turkish version of the OFS, sociodemographic and behavioral characteristics. Descriptive statistics, Mann-Whitney U test, Spearman's correlation coefficient, and backward stepwise multiple linear regression were used for data analysis.

Results. Internal consistency (Cronbach's alpha = 0.85) and test-retest reliability (intraclass correlation coefficient = 0.86) were acceptable for the OFS. The most frequently reported problem was "difficulty chewing." Bivariate analysis revealed significant differences in total OFS scores in terms of surgery type, defect size, and education level, except for the other clinical and sociodemographic characteristics and behavioral factors. Education level and surgery type were found to be the most important predictors of patient satisfaction and functioning of the obturator.

Conclusions. The Turkish version of the OFS might be a useful tool for clinicians to identify patients who are at risk for poor functioning of the obturator, lack of satisfaction, and unmet needs. (Oral Surg Oral Med Oral Pathol Oral Radiol 2017;■■■:■■-■■)

In recent years, health-related quality of life (HRQOL) and treatment satisfaction have been progressively acknowledged as patient-reported outcome measures in the prosthetic rehabilitation of patients with head and neck cancer.^{1,2}

After resection of maxillofacial tumors, patients have to deal with orofacial functional problems and emotional issues that might have significant negative effects on the HRQOL of patients and their caregivers. In the management of maxillary defects, obturator prosthesis is the most widely used noninvasive approach to restore the patient's oral functions, aesthetics, and resocialization.³⁻⁵

There are several studies examining patients' HRQOL and its relationship to obturator functioning.⁴⁻¹¹ However, to our knowledge, there are no published studies evaluating the functioning of the obturator and the satisfaction of Turkish patients with obturator prostheses after total maxillectomy. In previous studies, generic HRQOL measures were commonly used in combination with HRQOL measures for head and neck cancer, and HRQOL measures specific for oral health were used for assessing the treatment outcomes of oral rehabilitation. A recent consensus report on orofacial rehabilitation¹² and a structured

review of studies reporting specific functions in patients with head and neck cancer states that more sensitive and specific measures are needed for assessing the impacts of oral rehabilitation on patients' HRQOL because the existing measures seem to lack the discriminating ability to measure the effects of oral rehabilitation on HRQOL in these cases.¹³ Recognizing the importance of oronasal functions on HRQOL outcomes, the obturator functioning scale (OFS) was developed at the Memorial Sloan Kettering Cancer Center with the aim to assess the self-reported functioning of and satisfaction with the obturator prosthesis in maxillectomy patients.¹⁰ Besides clinical parameters, using this subsite and performance-based specific HRQOL measure may provide useful information about patients' unmet needs and expectations, as well as the effectiveness of the prosthodontic treatment.¹³

Reconstruction with a prosthetic obturator is the most preferred method in Turkey. Our institutional experience has indicated that many patients are dissatisfied with their obturator prostheses and its poor functionality. It is known that evaluation of HRQOL and functional outcomes after prosthetic rehabilitation of patients with head and neck cancer is critical for optimal patient care and

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Statement of Clinical Relevance

This study aimed to investigate the causes of problems with chewing and swallowing, food leakage, and speech problems in patients with head and neck cancer and to increase the quality of life of these patients by proposing solutions to these problems.

comprehensive evaluation of treatment options.¹⁴ Thus, this pilot study aimed to determine the sociodemographic and clinical factors affecting functioning of and satisfaction with obturator prostheses using the OFS in Turkish patients rehabilitated with maxillary obturator prostheses after maxillectomy.

MATERIALS AND METHODS

Forty-one patients who had undergone maxillectomy and been rehabilitated with obturator prostheses at the Prosthodontics Clinic of a dental teaching hospital in Istanbul, Turkey, were recruited to participate in this cross-sectional study. Patients were selected consecutively during their annual checkup visits to our hospital between January 4 and April 30, 2014.

The inclusion criteria for maxillectomy patients were (1) age 18 years or over; (2) use of a definite obturator prosthesis for at least 6 months; (3) having a clinically and functionally acceptable prosthesis, according to the criteria defined by Beumer et al.,¹⁵ including consideration of efficiency of mastication, air and liquid leakage into the nasal cavity, and speech; (4) being disease-free at the time of the questionnaire; and (5) an adequate level of literacy to complete the questionnaire instruments.

Exclusion criteria were (1) history of mental illness; (2) inability or unwillingness to consent; (3) less than 1 year since surgical resection; and (4) having an implant-retained prosthesis.

Procedure

The study was approved by the Ethics Committee of the Istanbul Faculty of Medicine and conducted in accordance with the principles of the Helsinki Declaration. All patients were informed about the scope of the study by a clinic assistant (A.B.). Informed consent was obtained from each subject who agreed to participate before he or she filled out the questionnaires. After completion of the dental prosthetic examination by a trained clinic assistant (A.B.), data were collected via face-to-face interviews with a trained research assistant (M.O.K.) in the clinic's waiting room. Of the 54 potentially eligible patients who had had a maxillectomy, 41 (76%) were eligible for this study. Reasons for the exclusion of 13 patients were presence of an ongoing or recurrent disease ($n = 3$), inadequate literacy level ($n = 4$), mental handicap ($n = 1$), having an implant-retained prosthesis ($n = 3$), and refusal to participate ($n = 2$).

Data acquisition

Data were collected from responses to a questionnaire with 2 sections. The first section comprised sociodemographic (gender, age, educational level, employment status, family monthly income) and clinical variables (type of tumor, stage of disease, size of maxillectomy defect,

degree of resection, condition of premorbid dentition, type of surgery, and radiotherapy).

The second section consisted of the Turkish version of the OFS, which was developed by Kornblith et al.¹⁰ to assess patient satisfaction with the functioning of the obturator. The OFS comprised 15 items in 3 subscales: (1) eating problems; (2) speech problems; and (3) other problems, such as dry mouth, numbness of the upper lip, difficulties with inserting the obturator, and avoidance of social life. Response categories ranged from 1 (not at all—a little difficult) to 5 (very much—extremely difficult). Scores were transformed on a scale from 0 to 100. Higher scores indicated worse obturator functioning and poorer patient satisfaction.

At the time of this study, no Turkish translation of the OFS was available. On the basis of standard recommendations,¹⁶ the process of cross-cultural adaptation involved several steps: translation from English to Turkish; an initial meeting of the expert panel to produce the first Turkish version; pilot-testing in a convenience sample of 25 patients; a second meeting of the expert panel to produce a new consensus version; back-translation to English; and re-evaluation by the expert panel members. The OFS was translated from English to Turkish by 2 native Turkish-speaking translators experienced in translation of health questionnaires. In the first meeting, the expert panel consisted of researchers and translators who examined the 2 versions of the OFS to determine a semi-final translation for testing. This was then reviewed to ensure that the final translation was fully comprehensible and to verify the cross-cultural equivalence of the source and final versions. In addition, the face and content validity of the scale were examined by the expert panel to assess clarity of wording of items. This version was then pilot-tested on a convenience sample of 25 patients who had undergone maxillectomy and oral rehabilitation at our clinic to ensure sensitivity to local culture and choice of appropriate wording. In the second meeting, modifications were made according to comments from the patients and the expert panel members to clarify the content of the questionnaire.

In our study, the internal consistency of scale was tested for the entire sample of patients. Minimum sample size for Cronbach's alpha coefficient was calculated by using Bonnett's formula¹⁷: $N = (2k[k-1])(z_{\alpha/2} + z_{\beta})^2 / \ln([1-p_k]/[1-\tilde{p}_k])^2 + 2$. In this formula, k (15) is the number of OFS items, p_k is the lowest acceptable Cronbach's alpha value (0.70), and \tilde{p}_k (0.88) is a planning value obtained from previous research¹⁸; $z_{\alpha/2}$ and z_{β} are points on the standard normal distribution exceeded with probability $\alpha/2$ and β , respectively. Twenty-three patients would be required for testing $H_0: p_k = 0.70$ against a 2-sided alternative at $\alpha = 0.05$ with power of 0.80, where $k = 13$ and $\tilde{p}_k = 0.88$.

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