



# Prospective Clinical Pilot Study to Evaluate the Effect of Prosthodontic Rehabilitation on Psychological Status and Quality of Life in Maxillectomy Patients: An Indian Experience

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**Abstract** The purpose of the study was to assess psychological status (PS) and quality of life (QOL) before surgical resection of maxilla (T0), 2 weeks after resection (T1), 2 weeks after use of intermediate obturator (T2), before (T3) and 12 weeks after use of definitive obturator (T4). 20 participants, planned for resection of maxilla and subsequent prosthodontic rehabilitation were enrolled. Assessment was done using Hospital Anxiety and Depression Scale (HADS) (HADS-A: anxiety and HADS-D: depression) for PS, World Health Organization Quality of Life BREF (WHOQOL-BREF) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire- Head and Neck Module (EORTC QLQ-H&N35) for QOL, and obturator functioning scale (OFS) for obturator functioning. Six cases were dropped out. Highest HADS-A score was observed presurgically ( $18.7 \pm 1.1$ ) and highest HADS-D score at T1 ( $18.5 \pm 1.8$ ). After rehabilitation, HADS-A and HADS-D decreased significantly ( $P < 0.01$ ). Least WHOQOL-BREF

score was observed at T1, followed by a consistent, significant rise after rehabilitation at all time intervals ( $P < 0.01$ ). Highest EORTC QLQ-H&N 35 score was observed at T1, with significant reduction ( $P < 0.001$ ) after rehabilitation for all questions, except those related to sexual wellness ( $P = 1$ ). Highest OFS were observed at T2 ( $3.1 \pm 10.3$ ) and least at T4 ( $1.9 \pm 0.2$ ). QOL and PS decline after maxillectomy. Patient education and rehabilitation with obturator leads to improvement in QOL and PS probably due to restored oral functions, and improved health of soft tissue. Both parameters improved with enhanced obturator quality and time.

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## Introduction

Adverse effects of head and neck cancer are associated with physical debilitation and mental stress attributed to the event of occurrence of cancer, therapeutic intervention (surgical, radiotherapy, and chemotherapy), functional impairment and the social ostracism [1–4]. The aim of rehabilitation of patients with maxillectomy is to maintain oral and nasal functions. Obturator prosthesis satisfactorily fulfils the aim. Additionally, obturator prosthesis offers the advantage of immediate rehabilitation together with permitting surveillance of re-occurrence of cancer, if any [2, 4–7].

The incidence of head and neck cancer is high [2, 8, 9]. Advances in diagnosis, therapy, and rehabilitation have enabled an increase in life span of individuals. The increased life expectancy must, however, be accompanied by improved quality of life (QOL) and reduced psychological stress. Certain tools have been used in previous studies to evaluate QOL and psychological status (PS) of patients with somatic illness and head and neck cancer [10–23]. World Health Organization Quality of Life BREF (WHO QOL-BREF) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire- Head and Neck Module (EORTC QLQ-H&N35) are widely used, self-administered tools for QOL assessment [10, 11, 13, 14, 17, 23]. Hospital Anxiety and Depression Scale (HADS) has a domain for anxiety (HADS-A) and a domain for depression (HADS-D) [12, 15, 16, 19]. This tool is used to assess psychological status (anxiety and depression) in patients with somatic illness. In maxillectomy patients, to assess the performance of obturator prosthesis, obturator functioning scale (OFS) has been used in the past [8, 18, 21, 22].

Literature is replete with studies related to head and neck cancer diagnosis, therapy, treatment modalities, survival and life expectancy subsequent to therapy [18–25]. However, there is dearth of literature on QOL and PS following prosthodontic rehabilitation in patients who have undergone maxillectomy as a treatment modality due to head and neck cancer in India. The paucity of literature related to the issue with reference to India is even more glaring. The current study was designed with the objective to assess QOL (through WHO QOL-BREF and EORTC QLQ-H&N 35 scores), psychological status (through HADS-A and HADS-D scores), and prosthesis functioning (through OFS) in patients planned for maxillectomy and rehabilitation with obturator prosthesis at various observation intervals in participants reporting to a tertiary dental centre in India. The secondary objective was to correlate the change that would occur after 2 weeks of use of intermediate obturator (T2) and after 12 weeks of use of

definitive obturator (T4) in the 4 dependent variables namely PS (as observed thru HADS score), QOL (as assessed in WHO and EORTC score), and in OFS. The study thus has two null hypotheses: (1) There is no statistically significant difference in WHO QOL-BREF scores, EORTC QLQ-H&N 35 Score, HADS-A, and HADS-D scores before maxillectomy, after maxillectomy, and after rehabilitation with intermediate and definitive obturator prosthesis; and (2) There is no statistically significant difference between functioning of intermediate obturator at 2 weeks of use, just before insertion of definitive obturator, and 12 weeks after use of definitive obturator.

## Material and Methods

The prospective clinical study was conducted on subjects with history of oral cancer, planned for maxillectomy, and referred for prosthodontic rehabilitation in dental outpatient department of a tertiary care centre in India, during August 2017 to October 2018. Convenience sample size of 20 participants was chosen. Participants were selected following the inclusion and exclusion criteria. Ethical clearance was obtained from the institution's Ethical Committee (Ref. No. IECPG-208/23.08.2017). The study was registered in Clinical Trial Registry—India (CTRI) (Reg. No. CTRI/2018/04/013,164). There was no restriction on selection of participants based on age, gender, type of cancer, and site of maxillary resection. Participants having completely edentulous arch, co-existent mid-facial defects, bilateral maxillectomy, involvement of mandible or tongue, defects of soft palate only, history of airway diseases were excluded from the study. The participants were asked to sign the informed consent form. Six participants were dropped from the study. Out of the six participants, one participant was lost due to death, three participants did not report during the study, surgical closure was done for one participant, and resection was extended to include mandible in one participant. All the enrolled participants were educated about the treatment procedure, consequences of surgery, exercises to overcome trismus and use of trismus screw, and prosthodontic rehabilitation. The participants included had almost full complement of teeth in the non resected portion of maxillary arch and in the mandibular arch. Surgical, intermediate and definitive obturator prosthesis were fabricated and used by the participants at various stages of healing of the defect. QOL and PS of the participants were assessed before surgery (T0), 2 weeks after surgery (T1), 2 weeks after insertion of intermediate obturator (T2), just before insertion of definitive obturator (T3), and 12 weeks after the insertion of definitive obturator (T4). Obturator functioning

assessment was done at 2 weeks after insertion of intermediate obturator (T2), just before insertion of definitive obturator (T3), and 12 weeks after the insertion of definitive obturator (T4).

PS was assessed using Hospital Anxiety and Depression Scale (HADS) [12]. There are 7 questions in the anxiety and depression domain of HADS questionnaire. Least score value possible for response of each question in each domain is 0, representing absence of abnormality. Maximum score value for response of each question in each domain is 3, and the same represents maximum anxiety or maximum depression. Thus the maximum score achievable in each domain is 21 and minimum score possible is 0 (zero).

QOL was assessed using World Health organization Quality Of life—BREF (WHOQOL—BREF) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire—Head & Neck module (EORTC QLQ—H&N35) questionnaires [10, 11]. The WHO QOL-BREF evaluates the QOL of patients based on 26 questions, spread over four domains. Questions about physical status of health are included in domain 1, psychological status are included in domain 2, social relationship are mentioned in domain 3, and environment are mentioned in domain 4. Improved QOL is represented through a higher score [10]. EORTC QLQ-H&N 35 consists of 35 questions assessing the symptoms and side effects of cancer treatment, oral functions, social activity, body image and sexuality. Higher score in this questionnaire signifies poor QOL [11].

Obturator functioning was assessed through an interview using the Obturator Functioning Scale (OFS) [4]. OFS is used by the operator to assess speech, ability to eat and esthetic satisfaction subsequent to use of an obturator prosthesis. The scale consists of 15 questions, each answered on a 5 point Likert Scale.

The collected data was tabulated in excel sheet and analyzed using statistical package for social science (Stata 14.0; StataCorp LLC). Descriptive statistics was applied and quantitative variables were assessed for normality by Shapiro–Wilk test. To determine change in patient's QOL, PS, and obturator performance at different time points, repeated measure ANOVA with Bonferroni post hoc adjustments was used for intragroup comparison at different time intervals ( $\alpha = 0.05$ ). To determine the correlation coefficient between change in the QOL, PS, and OFS observed at T2 and T4, Spearman Correlation Coefficient was used ( $\alpha = 0.05$ ).

## Results

The average age of 14 patients who completed the study was 42.7 years (range of 19–65 years). There was an equal distribution of male and seven female participants in the

study. Thirteen patients had received radiotherapy. The details have been presented in Supplementary Table 1. Descriptive data for anxiety and depression domain of HADS has been shown in Table 1. On comparison, there was a statistically significant change in the observations of anxiety score and depression score at different time periods ( $P < 0.001$  for HADS-A and HADS- D) as seen in Table 2. Maximum anxiety score was observed just before the surgical resection (T0). The scores reduced consistently at different time periods of observation. The least anxiety score was observed at T4 (12 weeks after delivery of definitive obturator). The comparison of scores before surgery and 12 weeks after use of definitive obturator was statistically significant ( $P < 001$ ). Maximum score for depression was observed at T1. There was a significant reduction in scores for depression after the use of prosthesis (both intermediate and definitive). Least score for depression was observed at 12 weeks after the use of definitive obturator prosthesis (T4). The change between presurgical scores of depression and use of definitive obturator at 12 weeks was statistically significant ( $P < 001$ ).

Descriptive data for WHOQOL—BREF score can be appreciated in Table 3. For all the four domains, the score prior to the surgery (T0) was highest. A drastic drop, with least value, was observed in all four domains at T1. Least value was observed for physical health status, followed by psychological status, environment status, and social status. After insertion of the prosthesis there was a consistent rise of scores at all observed time intervals. Maximum value of score was observed at T4 for all four domains after rehabilitation. The scores at T4 for all domains were, however, still less than scores at T0. It was also noted that at T4, the rise in scores was maximum in the physical domain. Comparative analysis of WHOQOL-BREF questionnaire scores has been shown in Table 4. The changes observed at the different time intervals were significant for all the four domains ( $P < 001$ ). Comparison of scores observed at T0 and at T4 was statistically significant for all the 4 domains: physical health status ( $P = 0.01$ ), psychological status ( $P < 001$ ), social status ( $P < 001$ ), and environment ( $P < 0.001$ ).

Statistical analysis of EORTC QLQ-H&N 35 questionnaire scores is shown in Table 5. Highest score was observed at 2 weeks after surgery. Significant reduction of scores ( $P < 0.001$ ) was observed after prosthodontic rehabilitation by intermediate obturator, just before delivery of definitive obturator, and 12 weeks after use of definitive obturator for all questions except for questions related to sexual wellness ( $P = 1$ ).

Results of obturator functioning scale have been shown in Table 6. Highest Scores were observed at T2 and least for T4. Comparison of the scores at T2 and T4 revealed a

**Table 1** Descriptive data of Hads-A and Hads-D score at different time intervals

	T0 Mean ± SD	T1 Mean ± SD	T2 Mean ± SD	T3 Mean ± SD	T4 Mean ± SD
HADS—A	18.7 ± 1.1	15.3 ± 1.9	11.5 ± 1.9	6.6 ± 2.9	4.4 ± 2.1
HADS—D	11.7 ± 3.0	18.5 ± 1.8	13.9 ± 1.6	7.4 ± 3.7	4.5 ± 2.4

T0: Observation time just before surgery

T1: Observation done at 2 weeks after surgery

T2: Observation done at 2 weeks after delivery of intermediate obturator

T3: Observation done just before delivery of definitive obturator

T4: Observation done at 12 weeks after delivery of definitive obturator

HADS-A: Hospital Anxiety and Depression Scale for Anxiety

HADS-D: Hospital Anxiety and Depression Scale for Depression

**Table 2** Comparison of Hads-A and Hads-D Score at different time intervals from baseline

Variable	Comparison between T0 and T1	Comparison between T0 and T2	Comparison between T0 and T3	Comparison between T0 and T4
HADS-A	$P < .002$ CI = [−1.1, −5.7]	$P < .001$ CI = [−5.2, −9.2]	$P < .001$ CI = [−9.1, −15]	$P < .001$ CI = [−11.9, −16.7]
HADS-D	$P < .001$ CI = [−8.8, −4.8]	$P < .001$ CI = [−5.0, −0.5]	$P < .001$ CI = [−1.2, −7.3]	$P < .001$ CI = [−4.8, −8.8]

T0: Observation time just before surgery

T1: Observation done at 2 weeks after surgery

T2: Observation done at 2 weeks after delivery of intermediate obturator

T3: Observation done just before delivery of definitive obturator

T4: Observation done at 12 weeks after delivery of definitive obturator

HADS-A: Hospital Anxiety and Depression Scale for Anxiety

HADS-D: Hospital Anxiety and Depression Scale for Depression

significant difference ( $P < .001$ ). Significantly reduced scores at T3 were observed when compared with scores at T2 ( $P < .001$ ). A comparison between T3 to T4 was also statistically significant ( $P < .001$ ).

A positive and linear correlation was observed between the change in scores for all the dependent variables just before insertion of definitive obturator (T3) and 12 weeks after use of definitive obturator (T4) as seen in Table 7. Statistically significant correlation was observed between change in scores for OFS and HADS-D ( $P < .001$ ,  $r = 0.7$ ), physical health status domain of WHO-BREF and HADS-A score ( $P = .01$ ,  $r = 0.6$ ), physical health status domain and psychological domain of WHO—BREF scores ( $P = 0.02$ ,  $r = 0.5$ ), EORTC QLQ-H&N 35 score and environmental domain of WHO—BREF scores ( $P = 0.02$ ,  $r = 0.6$ ), and social domain of WHO-BREF and anxiety domain of HADS-A ( $P < 0.001$ ,  $r = 0.9$ ).

## Discussion

The results of the study reject both the null hypothesis. A statistically significant difference in WHO QOL-BREF scores, EORTC QLQ-H&N 35 Score, and HADS scores before maxillectomy, after maxillectomy, and after rehabilitation with intermediate and definitive obturator prosthesis was observed. A statistically significant difference between functioning of intermediate obturator at 2 weeks of use, just before insertion of definitive obturator, and 12 weeks after use of definitive obturator was also observed.

Highest score in anxiety domain of HADS-A was observed presurgically probably due to the apprehension associated with the treatment and surgical intervention [16, 19]. After the use of obturator prosthesis, there was a decrease in anxiety scores. Preoperative education provided in detail to the participants regarding treatment can be the possible reason for reduction of scores. Least score

**Table 3** Descriptive data of Whoqol-Bref questionnaire score at different time intervals

Domains	T0 Mean ± SD	T1 Mean ± SD	T2 Mean ± SD	T3 Mean ± SD	T4 Mean ± SD
Domain1	62.7 ± 8.9	6.2 ± 11.5	25.8 ± 12.1	39.2 ± 9.3	56.5 ± 9.3
Domain2	63.1 ± 6.8	22.9 ± 7.4	33.6 ± 11.7	42.3 ± 8.8	51.3 ± 9.6
Domain3	69.4 ± 12.4	47.2 ± 14.7	47.9 ± 15.5	49.3 ± 15.6	49.3 ± 17.9
Domain4	67.4 ± 9.2	23.7 ± 7.8	35.1 ± 10.1	39.8 ± 8.3	48.1 ± 9.5

T0: Observation done just before surgery

T1: Observation done at 2 weeks after surgery

T2: Observation done at 2 weeks after delivery of intermediate obturator

T3: Observation done just before delivery of definitive obturator

T4: Observation done at 12 weeks after delivery of definitive obturator

Domain 1: Physical health

Domain 2: Psychological

Domain 3: Social relationship

Domain 4: Environment

SD: Standard deviation

**Table 4** Comparison of Whoqol-Bref questionnaire scores at different time intervals from baseline

Variable	Comparison between T0 and T1	Comparison between T0 and T2	Comparison between T0 and T3	Comparison between T0 and T4
Domain 1	$P < .001$ CI = [-47.3, -65.7]	$P < .001$ CI = [-27.2, -46.5]	$P < .001$ CI = [-17.6, -29.3]	$P = .01$ CI = [-2.4, -10.05]
Domain 2	$P < .001$ CI = [-33.7, -46.8]	$P < .001$ CI = [-22.2, -36.7]	$P < .001$ CI = [-17.2, -24.4]	$P < .001$ CI = [-7.1, -16.4]
Domain 3	$P < .001$ CI = [-10.6, -33.7]	$P < .001$ CI = [-10.4, -32.5]	$P < .001$ CI = [-9.1, -31.1]	$P < .001$ CI = [-8.5, -31.7]
Domain 4	$P < .001$ CI = [-37.3, -50.2]	$P < .001$ CI = [-26.5, -38.0]	$P < .001$ CI = [-22.6, -32.60]	$P < .001$ CI = [-14.8, -23.6]

T0: Observation done just before surgery

T1: Observation done at 2 weeks after surgery

T2: Observation done at 2 weeks after delivery of intermediate obturator

T3: Observation done just before delivery of definitive obturator

T4: Observation done at 12 weeks after delivery of definitive obturator

Domain 1: Physical health

Domain 2: Psychological

Domain 3: Social relationship

Domain 4: Environment

was observed 12 weeks after the use of definitive obturator due to favourable response to a well designed prosthesis.

Maximum HADS-D score was observed immediately after surgery, thus implying maximum state of psychological state of depression. The same can be attributed to loss of a part of body as perceived by the patient [4, 16, 19]. After the use of obturator, a gradual reduction of scores was observed. Least score for depression was observed at 12 weeks after use of definitive obturator

prosthesis. The possible reason for the same can be replacement of the missing part of the oral cavity by the prosthesis, thus restoring near normal function. The improved design and quality of prosthesis, together with a phase of adaption may also account for the same.

Observations of WHO QOL-BREF score revealed maximum reduction of scores post surgically, thus implying poorest quality of life before rehabilitation. Loss of functional living tissue, associated physical discomfort,

**Table 5** Descriptive data of Eortc Qlq-H&N35 score at different time intervals

QN	Questions	T0 Mean ± SD	T1 Mean ± SD	T2 Mean ± SD	T3 Mean ± SD	T4 Mean ± SD	P value
1	Have you had pain in your mouth?	2.3 ± 0.7	4.0 ± 0.01	2.9 ± 0.2	2.1 ± 0.5	1.8 ± 0.3	< .001
2	Have you had pain in your jaw?	2.5 ± 0.5	4.0 ± 0.6	2.9 ± 0.6	2.1 ± 0.5	1.8 ± 0.3	< .001
3	Have you had soreness in your mouth?	2.1 ± 0.6	4.0 ± 0.01	2.9 ± 0.2	2.1 ± 0.3	1.9 ± 0.2	< .001
4	Have you had a painful throat?	2.2 ± 0.6	3.9 ± 0.2	2.9 ± 0.6	2.1 ± 0.3	1.8 ± 0.3	< .001
5	Have you had problems swallowing liquids?	2.2 ± 0.8	3.1 ± 0.6	2.7 ± 0.4	2.1 ± 0.5	1.9 ± 0.2	< .001
6	Have you had problems swallowing pureed food?	2.2 ± 0.6	3.8 ± 0.3	2.1 ± 0.3	1.9 ± 0.2	1.8 ± 0.3	< .001
7	Have you had problems swallowing solid food?	2.1 ± 0.8	3.9 ± 0.2	2.1 ± 0.3	1.9 ± 0.2	1.5 ± 0.5	< .001
8	Have you choked when swallowing?	2.0 ± 0.8	3.9 ± 0.2	2.7 ± 0.4	2 ± 0.4	1.9 ± 0.2	< .001
9	Have you had problems with your teeth?	2.7 ± 1.1	3.7 ± 0.7	2.7 ± 0.4	2.5 ± 0.6	1.9 ± 0.2	< .001
10	Have you had problems opening your mouth wide?	2.2 ± 0.6	3.1 ± 0.8	3 ± 0.5	2.4 ± 0.6	1.8 ± 0.3	< .001
11	Have you had a dry mouth?	2.3 ± 0.7	2 ± 0.6	3.1 ± 0.5	2.3 ± 0.4	2 ± 0	< .001
12	Have you had sticky saliva?	2.3 ± 0.4	3.6 ± 0.7	1.5 ± 0.5	2 ± 0.4	2 ± 0.4	< .001
13	Have you had problems with your sense of smell?	2.2 ± 0.6	2.7 ± 0.6	1.9 ± 0.2	1.9 ± 0.2	1.6 ± 0.4	< .001
14	Have you had problems with your sense of taste?	2.2 ± 0.6	3.6 ± 0.4	2.9 ± 0.2	2.1 ± 0.3	2 ± 0	< .001
15	Have you coughed?	2.2 ± 0.6	3.9 ± 0.2	2.7 ± 0.4	2.0 ± 0.2	1.9 ± 0.2	< .001
16	Have you been hoarse?	2.3 ± 0.8	4 ± 0.01	3 ± 0.01	2.5 ± 0.5	2 ± 0.2	< .001
17	Have you felt ill?	2.2 ± 0.5	4 ± 0.01	3 ± 0.01	2.1 ± 0.3	1.8 ± 0.3	< .001
18	Has your appearance bothered you?	2.2 ± 0.7	3.8 ± 0.5	2.9 ± 0.2	2.5 ± 0.5	2 ± 0.01	< .001
19	Have you had trouble eating?	2.2 ± 0.7	4 ± 0.01	2.8 ± 0.3	1.9 ± 0.2	1.9 ± 0.2	< .001
20	Have you had trouble eating in front of your family?	2.0 ± 0.6	4 ± 0.01	2.3 ± 0.4	2.1 ± 0.3	1.7 ± 0.4	< .001
21	Have you had trouble eating in front of other people?	2.4 ± 0.6	4 ± 0.01	3.2 ± 0.4	2.7 ± 0.4	2 ± 0.01	< .001
22	Have you had trouble enjoying your meals?	2.6 ± 0.6	4 ± 0.01	3.0 ± 0.2	2.5 ± 0.5	2 ± 0.6	< .001
23	Have you had trouble talking to other people?	2.3 ± 0.6	4 ± 0.01	3.0 ± 0.2	2.3 ± 0.4	1.9 ± 0.01	< .001
24	Have you had trouble talking on the telephone?	2.8 ± 0.6	4 ± 0.01	3.1 ± 0.3	3 ± 0.2	2.2 ± 0.4	< .001
25	Have you had trouble having social contact with your family?	2.5 ± 0.5	3.6 ± 0.4	2.7 ± 0.4	2.1 ± 0.3	1.9 ± 0.2	< .001
26	Have you had trouble having social contact with friends?	2.5 ± 0.8	3.5 ± 0.6	2.8 ± 0.3	2.3 ± 0.4	2 ± 0.01	< .001
27	Have you had trouble going out in public?	2.4 ± 0.7	4 ± 0.01	3 ± 0.2	2.6 ± 0.4	2 ± 0.01	< .001
28	Have you had trouble having physical contact with family or friends?	2.1 ± 0.8	3.6 ± 0.7	2.5 ± 0.5	2.1 ± 0.3	2 ± 0.01	< .001
29	Have you felt less interest in sex?	2.8 ± 0.5	2.7 ± 0.6	2.6 ± 0.4	2.5 ± 0.4	2.5 ± 0.5	.1
30	Have you felt less sexual enjoyment?	2.9 ± 0.4	2.6 ± 0.4	2.6 ± 0.4	2.5 ± 0.5	2.5 ± 0.5	.1
31	Have you used pain-killers?	1.5 ± 0.5	2 ± 0.01	2.1 ± 0.3	1 ± 0.01	1 ± 0.01	< .001
32	Have you taken any nutritional supplements (excluding vitamins)?	1.2 ± 0.1	1.3 ± 0.4	1 ± 0.01	1 ± 0.01	1 ± 0.01	< .001
33	Have you used a feeding tube?	1.2 ± 0.4	2 ± 0.01	1 ± 0.01	1 ± 0.01	1 ± 0.01	< .001
34	Have you lost weight?	1.8 ± 0.3	2 ± 0.01	2 ± 0.01	1.3 ± 0.4	1 ± 0.01	< .001
35	Have you gained weight?	2 ± 0.7	1 ± 0.01	1 ± 0.01	1.6 ± 0.4	2 ± 0.01	< .001
Total Score	73 ± 23.6	105.8 ± 29.5	83 ± 23.15	59.7 ± 31.2	51.8 ± 27.2	< .001	

QN: Question Number

T0: Observation time just before surgery

T1: Observation done at 2 weeks after surgery

T2: Observation done at 2 weeks after delivery of intermediate obturator

T3: Observation done just before delivery of definitive obturator

T4: Observation done at 12 weeks after delivery of definitive obturator

EORTCQOL H&amp;N-35 = European Organization of Research and Treatment of Cancer Quality of Life head and neck modules

**Table 6** Descriptive and comparative data of obturator functioning score (Ofs) at different time points

	T2 Mean ± SD	T3 Mean ± SD	T4 Mean ± SD	P value	Comparison At Different Time Intervals between different groups		
					T2 and T3	T2 and T4	T3 andT4
OFS score	3.1 ± 0.3	2.6 ± 0.3	1.9 ± 0.2	< .001	P < 001 CI = [−6.2, −10.5]	P < 001 CI = [−15.4, −21.2]	P < 001 CI = [−7.8, −11.9]

OFS: Obturator Functioning Scale

T2: Observation at 2 weeks after delivery of intermediate obturator

T3 = Observation just before delivery of definitive obturator

T4 = Observation at 12 weeks after delivery of definitive obturator

CI = Confidence Intervals

and the inability to perform daily activities of life are the possible causes contributing to the same. Marked reduction of scores was noted in the physical status domain (domain 1). Associated oral pain, inadequate sleep, generalized indisposition, and reduced capacity to work soon after surgery can be the contributory factors for the same. After the insertion of obturator prosthesis, the scores improved in all four domains. The most noticeable improvement was observed in the physical status domain (domain 1). The improvement with intermediate obturator was less than that observed with definitive obturator, possibly due to less than satisfactory restoration of oral functions. Besides lack of familiarity with use of prosthesis, compromised oral functions could have also been due to concurrent radiotherapy treatment in the early stages when intermediate obturator was used. Radiotherapy results in reduced salivation, development of trismus and hampers complete tissue healing [2, 8, 9]. It is imperative to point out that the observations pertaining to social domain did not increase appreciably after prosthodontic rehabilitation. The possible cause attributed to the same is that the patients did not perceive the obturator as a part of their body. As the obturator prosthesis was considered an artificial replacement of missing structures, the patients refrained from interacting with people, engaging in social activities, and establishing personal relations. It is also relevant to point out that an improvement in scores was observed after the use of definitive obturator prosthesis. The scores increased further with time of use of definitive obturator (T4). As the participants acquainted themselves with the obturator prosthesis, their ability to perform oral functions improved. Consequently, this enabled the participants to maintain a close to normal lifestyle after replacement of missing structures with artificial substitute. The value at T4 was however still lower than the T0 value (presurgical phase). This may be because the patients may perceive the replacement to be artificial and not “belonging to self”.

Observations of EORTC QLQ-H&N 35 questionnaire suggest that before the surgery, patients had difficulty in

conducting daily activities of life. The level of difficulty amplified after surgery, prior to any form of rehabilitation [4, 17, 20–22]. After rehabilitation with an obturator prosthesis there was a decrease in the scores suggesting that the improvement of oral function with the prosthesis improved the overall quality of life. The improvement was more with definitive obturator, probably due to improved quality of the obturator and enhanced comfort. Satisfactory oral functions were not established with intermediate obturator probably due to simultaneous radiotherapy treatment. It is important to point out that improvement was observed in response for all questions except for questions related to sexual wellness. An obturator is a removable prosthesis. Repeated removal and insertion of the prosthesis constantly reminded the participants about their disability. Participants also reported their lack of desire to engage in social events due to difficulty associated with speech, swallowing, mastication, leakage of liquids from the mouth or the nose, and adherence of food particles to the obturator prosthesis. The improvement in QOL was maximum after 12 weeks of use of obturator due to the time utilized by the patient to adapt and adjust to the prosthesis.

A high OFS score was observed at two weeks after insertion of intermediate obturator prosthesis (T2). This may be due to apprehension associated with use of prosthesis due to lack of familiarity, associated morbidity of tissues, and effects of radiotherapy on soft tissues. Just before insertion of definitive obturator prosthesis (at T3), there was a significant reduction of scores when compared to scores observed at 2 weeks of use of intermediate obturator prosthesis (at T2). This was probably due to adaptation of the patient to the prosthesis, resolution of the sequelae of effects of radiotherapy, and completion of healing of soft tissues. Comparative reduction in scores observed after 12 weeks of definitive obturator use (at T4) when compared to T3 and T2 may be attributed to improved design and quality of the prosthesis, as the transition from intermediate to definitive obturator was

**Table 7** Correlation coefficient of change in anxiety, Depression, QOL & obturator function after use of intermediate obturator at 2 weeks and definitive obturator at 12 weeks

	HADS-A	HADS-D	WHO-BREF Domain 1	WHO-BREF Domain 2	WHO-BREF Domain 3	WHO-BREF Domain 4	EORTC QLQ-H&N35	OFS
HADS-A	r 1							
	<i>P</i>							
HADS-D	r 0.2	1						
	<i>P</i> 0.3							
WHO-BREF Domain 1	r 0.6	0.1	1					
	<i>P</i> 0.01	0.5						
WHO-BREF Domain 2	r 0.3	0.3	0.5	1				
	<i>P</i> 0.1	0.1	0.02					
WHO-BREF Domain 3	r 0.9	0.2	0.4	0.3	1			
	<i>P</i> < .001	0.3	0.1	0.2				
WHO-BREF Domain 4	r 0.08	0.5	0.04	0.3	0.1	1		
	<i>P</i> 0.7	0.02	0.8	0.2	0.5			
EORTCQLQ-H&N35	r 0.3	0.5	0.1	0.3	0.3	0.6	1	
	<i>P</i> 0.2	0.02	0.5	0.2	0.2	0.02		
OFS	r 0.2	0.7	0.2	0.4	0.2	0.3	0.2	1
	<i>P</i> 0.4	< .001	0.3	0.1	0.3	0.1	0.4	

r: Regression Coefficient;

*P*: *P* value;

HADS-A: Hospital Anxiety and Depression Scale (Anxiety);

HADS-D: Hospital Anxiety and Depression Scale (Depression)

Domain 1: physical health;

Domain 2: psychological;

Domain 3: Social relationship;

Domain 4: Environment;

WHOQOL-BREF: World Health Organization Quality of Life QUESTIONNAIRE;

EORTCQLQ-H&N35 = European organization for research and treatment of cancer (EORTC) quality of life questionnaires – Head & Neck module;

OFS: Obturator Functioning Scale

made. The same could have contributed to improved fit and comfort to the patient. A well fitting prosthesis and completion of radiotherapy could have also permitted tissue recovery of the surgical site. Additionally, favourable results could have also been due to enhanced adaptation and improved compliance of the patients to the prosthesis over an observation period of 12 weeks. The cumulative effect yielded improvement in speech, mastication, appearance and reduced pain perception.

A positive and linear correlation between changes in scores of OFS, HADS-A, HADS-D, WHO-BREF, and EORTC QLQ-H&N 35 score suggests that as the obturator function improves, there is a simultaneous improvement in quality of life as expressed in the WHO-BREF and EORTC

QLQ-H&N 35 scores possibly due to satisfactorily restored oral function. There is also a re-establishment of sound psychological status as observed with reduction in anxiety (HADS-A) and depression (HADS-D) as obturator function improves. With improvement in quality of life, the participants have also witnessed a reduction in anxiety and depression, possibly because they feel they can independently meet the challenges of life. An overall state of well being was perceived by the participants after rehabilitation.

The limitations of the study are the small sample size. The study also does not consider other variables such as socioeconomic factors, consideration for the size of the defect, number of teeth remaining, and the periodontal status of the teeth.



## Conclusions

QOL and PS declines after maxillectomy. Rehabilitation with obturator leads to improvement in QOL and PS probably due to restored oral functions, and improved health of soft tissue. Both parameters improved with enhanced obturator quality and time. For patients with maxillectomy, all efforts should be made for early and prompt prosthodontic rehabilitation using obturator prosthesis. The transition from intermediate obturator to definitive obturator should be done soon as the functioning of obturator depends on the design of obturator and definitive obturator fulfils the purpose most favourably. The functioning is also enhanced when patients are given more time to adapt and as there is associated resolution of sequelae of radiotherapy and soft tissue healing. Sufficient information, education and counselling of patients about the surgery and consequences, prosthetic rehabilitation, and the outcome of the rehabilitation also play an important role along with well-functioning definitive obturator to improve the quality of life and psychological status of maxillectomy patients.

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