# Validation of True Perio: 14 Items Questionnaire for Assessing Patient-based Outcomes Following Periodontal Flap Surgery

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## Abstract

**Aim:** This article aims to develop and validate a questionnaire to assess the patient-based outcomes following periodontal therapy (QPBOPT).

**Materials and methods:** Questionnaire (QPBOPT) was formulated with 14 items, considering patient-based outcomes after periodontal therapy. Content validation was undertaken by seven experts in the field of periodontology and the questionnaire was pilot tested. Reliability was assessed using Cronbach's alpha and test–retest methods. The questionnaire was administered among 140 subjects, aged between 30 and 55 years who underwent periodontal flap surgery for periodontitis. Construct validity was done through principal component factor analysis.

**Results:** Cronbach's alpha for the overall scale was 0.98 in this study, indicating a high correlation between the items, and the questionnaire was found to be reliable. Factor analysis explained a cumulative variance of 95.909%, which proved all the 14 items to be valid.

**Conclusion:** Analysis of the data presented here shows that the questionnaire is valid and reliable for assessing the patient-based outcomes following periodontal therapy.

**Clinical significance:** This questionnaire can be a very effective objective tool for the assessment of the treatment outcome following periodontal therapy.

**Keywords:** Outcome, Periodontal flap surgery, QPBOPT, Quality of life, Questionnaire, Reliability, Validity.

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## Introduction

The assessment of the quality of life (QOL) has become increasingly important in today's dental era. The dental researchers are interested not only in addressing the dental needs of the patients but also in investigating the impact of treatment on QOL.

Only if true endpoints are met, any intervention or therapy can be considered to be successful. True endpoints, as opposed to objective measurements like probing pocket depth (PPD) and clinical attachment level (CAL), evaluate the patient-based outcomes and are thus more directly proportional to the patient's QOL.[1–3] Evidence-based data is required whether improvement in surrogate metrics transfer to increased QOL in terms of oral comfort, function, aesthetics, and social performance. In the field of periodontics, surrogate estimations like PPD and CAL are frequently used in clinical trials.[4–9] Following periodontal therapy, patient-centered outcomes such as the comfort of teeth while chewing food, functionality, the appearance of teeth and gums, the sensitivity of teeth, the survival rate of teeth are never being considered.

Essentially, flap surgery, along with PPD and CAL (surrogate measures) measurements, should also assess the reduction in mobility of the teeth, sensitivity, bad breath, food entrapment, bleeding gums, and improvement in chewing food. There is a need to supplement the assessment of outcomes of periodontal flap surgery with a questionnaire that assesses the QOL of patients after the procedure.

A number of instruments have emerged with promising psychometric properties. Conventional methods of assessing oral health mostly rely on indices, which solely interpret the presence or absence of diseases. However, they do not reveal the people's well-being. As a result of this shortcoming, oral health-related quality of life (OHRQOL) measurements were developed. A number of metrics have been developed over time to assess OHRQOL, including social impacts of dental disease, Geriatric (General) Oral

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Health Assessment Index (GOHAI), Dental Impact Profile, Dental Impact on Daily Living (DIDL), Oral Health Impact Profile (OHIP), Oral Impacts on Daily Performances, Prosthetic Quality of Life, Child Perception Questionnaire.[10]

The existing questionnaires evaluating the QOL in patients undergoing dental treatment scarcely assessed periodontal parameters in detail. Also, the existing questionnaires did not pay complete attention to the various parameters pertaining to periodontal flap surgical outcomes and patients' perceptions and feedback on the success of periodontal therapy. Even though these existing questionnaires assess the influence of dental therapy on the daily activity of patients, they still may not be applicable to periodontal flap surgery. These instruments aren't designed specifically for determining true endpoints related to periodontal surgeries from patients' perspectives. As a result,

a custom-made questionnaire for determining periodontal true endpoints after periodontal flap surgery needs to be designed and validated. *In lieu* of the above, we intended to develop and validate a QPBOPT.

## MATERIALS AND METHODS

The protocol was evaluated and approved by the Institutional Ethical Committee and each participant signed a consent form affirming their voluntary involvement in the study. Subjects-to-ratio (Rule of thumb) was used to estimate the sample size and a ratio of 1:10 was assumed for the study. The study was carried out among 140 subjects fulfilling the inclusion criteria, who underwent periodontal flap surgery for periodontitis in a postgraduate clinic in Saveetha Dental College. The inclusion criteria for the study included patients of both genders, aged between 30 and 55 years, partial edentulism not exceeding two teeth per arch, and patients with Russell's periodontal index score ranging between 2 and 4.9. Patients with advanced cervical abrasions marked attrition and decayed, missing due to caries, and filled teeth (DMFT) scores of >4, history of prolonged antibiotic usage, immunosuppressive drug therapy, pregnancy, uncontrolled diabetes mellitus, and smoking were excluded from the study. The study was initiated in July 2021 and completed in January 2022.

A questionnaire for patient-based outcomes following periodontal therapy was formulated with 14 items exploring the possible observations and expectations of the patients after periodontal therapy (Table 1). The questionnaire assessed the patients' perspectives on the status of bleeding in the gingiva, reduction of food lodgement between the teeth, reduction in bad breath, perception of cleanliness in the teeth, confidence level during smiling, mobility of the teeth, comfort level in chewing food, improvement in chewing hard fibrous food, cessation of pain, gingival appearance, gingival positioning, sensitivity in the teeth and overall gain of self-confidence.

Content validity of QPBOPT was undertaken by seven experts in the field of Periodontology. The value of the content validity index (CVI) was 0.8. To obtain the sample size, a pilot study was conducted among 20 subjects. Internal consistency reliability and test-retest reliability were the two reliability estimates used to assess the questionnaire's reliability. The internal consistency was measured using Cronbach's alpha correlation coefficient, which was 0.98. The Wilcoxon paired signed-rank test was used to determine test-retest reliability, and a $p$-value of less than 0.05 indicated that there have been no significant variations between the responses at each time point.

The QPBOPT questionnaire administered to 140 patients who underwent periodontal flap therapy after a minimum period of 3 months after the procedure recorded the responses to the items using Likert scale with a maximum score of five and a minimum of one and the data were presented as mean and standard deviation (Table 2). Once the questionnaire was marked by the participating subjects, a single evaluator assessed the completeness of the responses. This evaluator ensured no incomplete or missed responses were present in the questionnaire. The data obtained from the questionnaire were organized, tabulated, and subjected to statistical analysis.

**Table 1:** Questionnaire to assess the patient-based outcomes following periodontal therapy

| S. No | Question | Strongly disagree 1 | Disagree 2 | Neutral 3 | Agree 4 | Strongly agree 5 |
|---|---|---|---|---|---|---|
| 1. | Is there a reduction in bleeding of gums? | | | | | |
| 2. | Is there a reduction in food lodgement between teeth? | | | | | |
| 3. | Is there a reduction in bad breath after the procedure? | | | | | |
| 4. | Did your teeth feel clean after the procedure? | | | | | |
| 5. | Have you gained confidence in showing your teeth while smiling? | | | | | |
| 6. | Is there a reduction in perceivable mobility? | | | | | |
| 7. | Are you able to chew food comfortably? | | | | | |
| 8. | Are you able to chew hard food more comfortably as compared to before procedure? | | | | | |
| 9. | Is there a reduction in pain in gums and teeth after the procedure? | | | | | |
| 10. | Are you satisfied with the appearance of gums after the procedure? | | | | | |
| 11. | Did the appearance of your gums after the procedure help you interact with people more confidently? | | | | | |
| 12. | Are you satisfied with the position of your gums? | | | | | |
| 13. | Is there a reduction in sensitivity of teeth as compared to before the procedure? | | | | | |
| 14. | Have you gained self-confidence after the treatment? | | | | | |

**Table 2:** Scoring pattern for the items in the QPBOPT questionnaire

|  | Mean (n = 140) | Std. deviation (n = 140) |
|---|---|---|
| Q1 | 4.59 | 0.494 |
| Q2 | 4.42 | 0.759 |
| Q3 | 4.59 | 0.494 |
| Q4 | 4.59 | 0.494 |
| Q5 | 4.59 | 0.494 |
| Q6 | 4.43 | 0.750 |
| Q7 | 4.80 | 0.401 |
| Q8 | 4.80 | 0.401 |
| Q9 | 4.59 | 0.494 |
| Q10 | 4.59 | 0.494 |
| Q11 | 4.59 | 0.494 |
| Q12 | 4.46 | 0.704 |
| Q13 | 4.44 | 0.732 |
| Q14 | 4.44 | 0.732 |

**Table 3:** Test for assessment of reliability and internal consistency

| Cronbach's alpha | Cronbach's alpha based on standardized items | No of items |
|---|---|---|
| 0.977 | 0.976 | 14 |

**Table 4a:** Principal component factor analysis with loadings

|  | Component | |
|---|---|---|
|  | 1 | 2 |
| Q1 | 0.984 | 0.072 |
| Q2 | 0.958 | 0.107 |
| Q3 | 0.984 | 0.072 |
| Q4 | 0.984 | 0.072 |
| Q5 | 0.984 | 0.072 |
| Q6 | 0.955 | 0.114 |
| Q7 | 0.086 | 0.996 |
| Q8 | 0.086 | 0.996 |
| Q9 | 0.984 | 0.072 |
| Q10 | 0.984 | 0.072 |
| Q11 | 0.984 | 0.072 |
| Q12 | 0.955 | 0.075 |
| Q13 | 0.952 | 0.129 |
| Q14 | 0.957 | 0.079 |

## RESULTS

The study subjects included 85 males and 55 female subjects with a mean age of 45 ± 2.1 years. All the patients enrolled in the investigation filled the QPBOPT questionnaire and completed the study and there were no dropouts. The data were extracted and organized. The organized data were consolidated and subjected to statistical analysis and interpretation. When the internal consistency of the items was evaluated, Cronbach's alpha for the overall scale was 0.98 in this study, indicating a high correlation between the items and the questionnaire was found to be reliable. Cronbach's alpha of the overall scale was 0.98, indicating a high correlation between the items and the questionnaire is consistently reliable (Table 3).

The theoretical construct of the QPBOPT questionnaire was assessed by factor analysis using Principal Component Analysis (PCA) method. In PCA, the total variance was analyzed. The factors were rotated using Varimax with Kaiser normalization, the most generally used orthogonal rotation, to maximize the loading on each variable while minimizing the loading on other factors. PCA confirmed the presence of two components. The first component consists of items 1–6, 9–14, and the second component consists of items 7 and 8. This analysis confirmed that all the 14 items could be retained in the present tool (Table 4a). Each component had a number of significant loadings, as revealed by the varimax rotation. Factors that had an eigenvalue ≥1 were retained. The two-component solution explained a cumulative % of the variance of 95.909%, which proved all the 14 items to be valid (Table 4b).

The factors that exist before the eigenvalues begin to decline and are retained were represented using a scree plot (Fig. 1). The scree plot identified two components with eigenvalues >1.

## DISCUSSION

Periodontal disease is one of the common oral diseases. Periodontal disease symptoms include swollen gums, bleeding gums, loose teeth, and unpleasant breath, all of which can be serious oral health issues from an individual's perspective. Literature search reveals a lack of a questionnaire for assessing the patient-based outcomes following periodontal flap surgery. Hence, the aim of the study was to develop and validate a questionnaire to measure the patient's satisfaction with routinely performed periodontal flap therapy in terms of the above-mentioned symptoms.

To our knowledge, our study is the first to develop and validate a tool to assess the patient-based outcomes following periodontal therapy (QPBOPT). The main objective of this study was to provide a platform that clearly explains the periodontal treatment outcome following flap surgery predominantly from a patient's perspective. The key aspects included observation of bleeding from the periodontal tissues post surgery, reduction in pain and mobility of tooth, improved ability to masticate properly, reduction in food impaction, and overall boosting of self-confidence. The responses to these factors were analyzed statistically for positive correlation with clinical therapeutic outcomes evaluating periodontal health. The DIDL scale has previously been used to assess the impact of implant therapy, complete dentures, and dental caries.[11–13] Omiri MK et al. used the DIDL and Neuroticism-Extraversion-Openness Five-Factor Inventory (NEO-FFI) scales to investigate the relationship between satisfaction with the dentition and dental prostheses and personality characteristics among patients treated with implant-supported prostheses.[11] Abu Hantash et al. utilized a similar method to look at the link between complete denture prosthesis satisfaction and its impact on everyday life and personality characteristics.[12] This measure was utilized by Ganesh et al. to find a link between the DMFT index and patient satisfaction.[13]

The precision of the measures utilized determines the research's integrity. Turton et al. validated a questionnaire to measure the oral health-related QOL for Cambodian children.[14] Jokovic et al. developed and validated child perceptions questionnaire for children aged 11–14 years with various dental, oral, and orofacial disorders.[15] Molek et al. investigated the validity and reliability of an oral health-related QOL measure in children with untreated dental caries.[16] In all these tools, content validity and construct validity were assessed similar to the present tool. But these tools were discussed under domains since it comprises a minimum of 25 items. In the present tool, the items were not categorized under domains, as the questionnaire consists of only 14 items

**Table 4b:** Principal component factor analysis with variances

| Component | Initial eigenvalues | | | Extraction sums of squared loadings | | | Rotation sums of squared loadings | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % | Total | % of variance | Cumulative % |
| 1 | 11.494 | 82.097 | 82.097 | 11.494 | 82.097 | 82.097 | 11.353 | 81.093 | 81.093 |
| 2 | 1.934 | 13.812 | 95.909 | 1.934 | 13.812 | 95.909 | 2.074 | 14.816 | 95.909 |
| 3 | 0.468 | 3.343 | 99.252 | | | | | | |
| 4 | 0.055 | 0.390 | 99.642 | | | | | | |
| 5 | 0.037 | 0.263 | 99.905 | | | | | | |
| 6 | 0.009 | 0.068 | 99.973 | | | | | | |
| 7 | 0.004 | 0.027 | 100.000 | | | | | | |
| 8 | 4.915E-18 | 3.511E-17 | 100.000 | | | | | | |
| 9 | 4.066E-19 | 2.904E-18 | 100.000 | | | | | | |
| 10 | 1.136E-34 | 8.113E-34 | 100.000 | | | | | | |
| 11 | 1.097E-35 | 7.834E-35 | 100.000 | | | | | | |
| 12 | -3.572E-19 | -2.552E-18 | 100.000 | | | | | | |
| 13 | -4.436E-19 | -3.169E-18 | 100.000 | | | | | | |
| 14 | -2.365E-16 | -1.689E-15 | 100.000 | | | | | | |
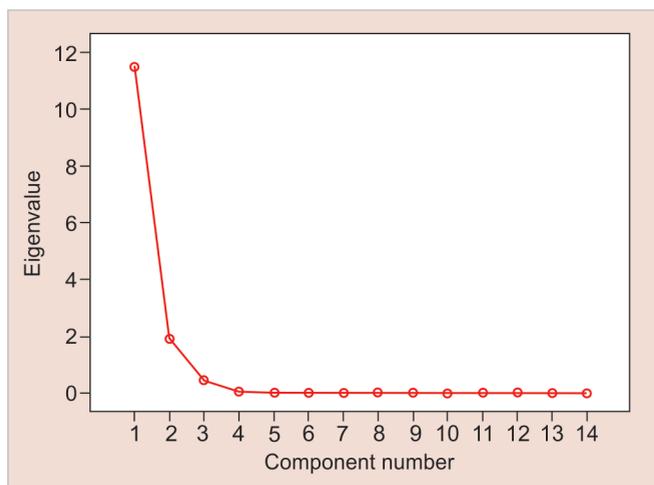


**Fig. 1:** Scree plot analysis for extraction of principal components

that are relevant to elicit the patient-based outcomes following periodontal therapy.

The current questionnaire's validity assessment revealed that it is an accurate tool for monitoring patient-based outcomes following-periodontal surgical therapy. The procedures for validating the questionnaire were thorough and effective. Content validity was used to determine whether the content was related to the study's concept. The internal consistency (alpha) attained the clinically acceptable threshold. For instruments used in clinical settings, several experts recommend that the alpha be at least 0.90.[17] Others argue that for a new instrument, an alpha of 0.70 is adequate.[18,19] Factor analysis assessed the theoretical construct of the questionnaire and proved construct validity.

The limitation of the study is that the present study is only about the validation process of the tool. The assessment of absolute correlation between surrogate measures and patient-based outcomes has to be tested in larger samples in various geographical locations.

## Conclusion

Analysis of the data presented here shows that the QPBOPT questionnaire is valid and reliable for assessing the patient-based outcomes following periodontal therapy. This questionnaire can be a very effective objective tool for the assessment of the treatment outcome following periodontal surgical therapy. However, this QPBOPT questionnaire needs to be more extensively tested in different populations for enhanced understanding and utility in diverse clinical situations.

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