

Patient-Reported Quality-of-Life Outcome Measure After Parotidectomy

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IMPORTANCE There is a lack of reliable, patient-reported quality-of-life (QOL) instruments to address the multidimensional nature of patient-centered outcomes for patients undergoing parotidectomy. The Parotidectomy Quality of Life Index is a new 35-item validated patient-reported outcome instrument specific to recovery after parotidectomy.

OBJECTIVE To establish and validate a comprehensive English-language patient-reported QOL instrument specific to parotidectomy.

DESIGN, SETTING, AND PARTICIPANTS This survey study was conducted in 2 phases: first, in a single-institution cohort (October 12, 2021, to March 7, 2022), and second, as an anonymous web-based survey enrolled via printed promotional brochures and social media platforms (March 13 to July 31, 2023). Inclusion criteria were age at least 18 years and parotidectomy within the last year. For test-retest reliability, a subset of phase II participants volunteered to answer the survey a second time within 2 weeks. Data were analyzed from March 8, 2022, to November 3, 2023.

MAIN OUTCOMES AND MEASURES Item rankings from phase I participants were used to narrow the original 61-item survey down to 45 items in the phase II survey. To assess construct validity, an exploratory factor analysis was performed. Cronbach α and pairwise Pearson correlation coefficients were used to measure internal consistency, reliability, and redundancy. Test-retest reliability was evaluated using intraclass correlation coefficients.

RESULTS Phase I enrolled 38 individuals, of whom 30 completed the survey (15 women [60%]; 21 participants [84%] aged >40 years). Phase II enrolled 342 participants, of whom 317 completed the survey (305 women [89%]; 284 participants [83%] aged >40 years). A total of 42 items across 7 domains were selected based on exploratory factor analysis. After Cronbach α and pairwise correlation analysis, 33 items across 6 multi-item domains and 2 standalone items were incorporated into the final QOL instrument. Cronbach α s for each of the final 6 domains were at least 0.77, suggesting excellent internal validity. Pairwise correlations did not show strong correlations (ie, none ≥ 0.80), suggesting minimal redundancy between domains. Younger age was significantly associated with a lower global score. Participants with malignant tumors scored lower on 4 of the 6 multi-item domains. Test-retest reliability coefficients for the domains ranged from 0.82 to 0.93, indicating very good reproducibility over a 2-week interval.

CONCLUSIONS AND RELEVANCE These findings suggest the Parotidectomy Quality of Life Index demonstrated excellent internal validity and test-retest reliability. With further external validation, this instrument may provide opportunity for quality improvement in clinical practice and has potential as a key patient-reported outcome in future parotidectomy clinical trials.

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Parotidectomy is the treatment of choice for most benign and malignant tumors of the parotid gland.¹ Over the last 5 decades, multiple surgical approaches have emerged in the US and Europe, all with seemingly excellent outcomes when considering traditional metrics of surgical success, such as tumor recurrence and postoperative complications.²⁻⁶ More recently, assessments of parotidectomy outcomes have shifted toward functional outcomes.⁷⁻⁹ Few tools exist to evaluate the impact of parotidectomy on patient quality of life (QOL).

Existing tools commonly used include the postparotidectomy facial nerve grading system,¹⁰ but these capture outcomes as assessed by the clinician, not by patients. Measuring patient-reported outcomes (PROs) has improved our understanding of the outcomes of surgery and facilitated improved communication between patients and clinicians.¹¹ Patient concerns after parotidectomy, such as facial cosmesis, numbness, and pain, are not always considered when reporting surgical success, but all significantly affect patient QOL.¹²⁻¹⁶ These outcomes are subject to patient experience and therefore require dedicated PROs to fully capture.

The German Parotidectomy Outcome Inventory 8 (POI-8) is among the few validated instruments measuring QOL after parotidectomy,¹⁷ but it is limited to social, emotional, and aesthetic concerns^{14,18} and has limited utility in the US due to lack of validation in English. To our knowledge, no reliable patient-reported QOL instrument has been developed and validated in English for parotidectomy. Establishing and validating a comprehensive QOL questionnaire is critical to guide patient counseling and future interventional clinical trials. In this study, we aimed to establish and validate a comprehensive English-language patient-reported QOL instrument specific to parotidectomy.

Methods

Phases I and II of this survey study were approved by the institutional review board of Mayo Clinic. All participants provided electronic informed consent. This study is reported following the US Food and Drug Administration [Patient-Reported Outcome Measures: Use In Medical Product Development To Support Labeling Claims: Guidance For Industry](#).¹⁹

Expert Panel and Survey Construction

An expert panel consisting of a PRO specialist (K. J. Y.), parotidectomy surgeons (L.X.Y. and E.J. Moore), an experienced otolaryngologist (E.J. Martin), a patient advocate (H.S.), a statistician (C.M.L.), and a study coordinator (A.M.T.) was convened. The expert panel constructed a framework of domains and statements related to concerns after parotidectomy, selected based on clinical expertise and experience and previous PRO instruments in head and neck surgery. These domains included pain and sensations, facial aesthetics, facial nerve function, salivary function, emotional well-being, social and functional well-being, surgical recovery, shared decision-making, and surgical satisfaction. Previous validated PRO instruments considered

Key Points

Question Can a comprehensive English language, patient-reported quality-of-life (QOL) instrument specific to parotidectomy be developed and validated?

Findings In this survey study, 380 participants were enrolled to develop and validate a comprehensive QOL instrument after parotidectomy in 2 phases. The final QOL instrument included 33 items across 6 domains and 2 standalone items, and the instrument showed excellent internal validity and minimal redundancy between domains.

Meaning This survey study describes the Parotidectomy Quality of Life Index, a new 35-item validated patient reported outcome instrument for parotidectomy; with external validation, this instrument has potential as a key instrument in future surgical clinical trials.

included the Patient-Reported Outcomes Measurement Information System anxiety and depression²⁰ and social satisfaction forms,^{21,22} the FACE-Q Head & Neck Cancer module,²³ the postparotidectomy facial nerve grading system,¹⁰ and the POI-8.¹⁷ We mapped 61 items across 9 domains based on face validity and included in phase I of the study for content validation.

Phase I: Content Validation

A web-based survey on the Qualtrics platform and accompanying paper-based survey was constructed containing the phase I items. Phase I participants were recruited from Mayo Clinic. Inclusion criteria were age at least 18 years and parotidectomy within the last year. Exclusion criteria were concurrent surgical procedures with parotidectomy, prior parotid surgery, active adjuvant chemoradiotherapy after parotidectomy, history of facial nerve dysfunction prior to parotidectomy, prior facial cosmetic surgery (except rhinoplasty), and chronic salivary disease. Ultimately, 38 participants were enrolled, 30 of whom completed the survey from October 12, 2021, to March 7, 2022. Demographic and clinical histories were collected on 25 of 30 survey participants. Five participants did not offer identifying information in the web-based survey to determine histories.

Content validity is the extent to which the set of items reflects the content of the concept being measured.²⁴ For content validation, we adapted a process used to create National Comprehensive Cancer Network symptom indices.²⁵ Domains were presented to participants in random order. In step 1, participants selected up to 5 items in each domain that were important to them, and in step 2, participants were asked to select up to 3 items that were the most important. In addition to the selection exercise, participants were asked to list concerns or feelings that were not represented by the items in each domain.

Responses from the 30 participants were used by the expert panel to narrow the original 61-item survey down to the phase II survey for further validation. A threshold for chance selection was defined as the maximum number of items that could be selected for step 2, divided by the total number of items in the domain, multiplied by the number of

respondents.²⁶ Items that did not meet this threshold were reviewed by the expert panel for exclusion from the phase II survey. In addition, new items were developed based on free-text suggestions from participants.

Phase II: Construct Validity, Convergent Validity,

Test-Retest Reliability

In phase II, a Qualtrics web-based survey was constructed to include the preliminary content-validated survey at the end of phase I and other general and disease-specific measures to validate the resulting instrument, the Parotidectomy Quality of Life Index (PQOL), against, including question on the quality of overall parotidectomy care on a scale of 0 (worst care possible) to 10 (best care possible); Linear Analog Self-Assessments²⁷ of overall, mental, physical, emotional, and social QOL; and several other validated general and disease-specific instruments, including the Patient-Reported Outcomes Measurement Information System pain interference²⁸ and social roles and activities domains,²² Facial Disability Index,²⁹ the Facial Clinimetric Evaluation Scale,³⁰ the FACE-Q Head & Neck Cancer Appearance and Appearance Distress domains,²³ the Obstructive Salivary Problem Impact Test,³¹ the Shared Decision Making Questionnaire, the Surgical Satisfaction Questionnaire,³² and the POI-8.¹⁷ Participants were also asked a series of demographic and clinical history questions, including gender identity, age, timing of parotid surgery, and parotid tumor pathology.

Recruitment for phase II of this study occurred through a hybrid model from March 13 to July 31, 2023. Promotional brochures with a QR code were distributed at Mayo Clinic (check-out desk at the outpatient otolaryngology clinic and inside clinic rooms), and the study was promoted on multiple social media platforms and the online forums for the Parotid Patient Project. Participants provided electronic consent prior to proceeding to the Qualtrics survey. Questions at the beginning of the Qualtrics survey confirmed eligibility for participating in the study, including age 18 years or older and currently residing inside the US. Individuals outside the US at the time of the survey administration were excluded in accordance with the European Union General Data Protection Regulation laws. No other exclusion criteria were applied to the phase II participants. Participants who volunteered to repeat the survey provided an email address, and a subset of these volunteers was sent a link to the retest survey exactly 2 weeks after answering the first survey. Surveys were sent to volunteers until the target accrual of 50 to 100 patients for the retest validation was reached, after which no further invitations to complete the retest survey were sent. This subset of participants was also sent an electronic Health Insurance Portability and Accountability Act (HIPAA) form along with their retest survey, as it is necessary to retain identifiers to link the initial and retest survey data at the individual participant level. Only those who returned a signed HIPAA form were included in the test-retest analysis. Data for all other participants were anonymous.

Statistical Analysis

To assess construct validity, survey responses with non-missing data for all items in the preliminary QOL question-

Table 1. Summary of Demographic and Tumor Characteristics for Phase I and Phase II Participants

Characteristic	Participants, No. (%)	
	Phase I (n = 25) ^a	Phase II (n = 342)
Gender identity ^b		
Woman	15 (60)	305 (89)
Man	10 (40)	36 (11)
Age, y		
18-30	2 (8)	12 (4)
31-40	2 (8)	46 (13)
41-50	4 (16)	78 (23)
51-65	8 (32)	143 (41)
≥66	9 (36)	63 (18)
Timing of parotidectomy ^b		
<2 wk ago	8 (32)	27 (8)
2-4 wk ago	2 (8)	20 (6)
5 wk to 3 mo ago	7 (28)	40 (12)
4-6 mo ago	1 (4)	22 (6)
7-12 mo ago	4 (16)	55 (16)
>12 mo ago	3 (12)	177 (52)
Type of parotid tumor ^b		
Benign	14 (56)	235 (69)
Malignant	11 (44)	99 (29)
Unsure	0	7 (2)
Specific type of parotid tumor		
Pleomorphic adenoma	10 (40)	173 (51)
Mucoepidermoid carcinoma	2 (8)	28 (8)
Acinic cell carcinoma	2 (8)	20 (6)
Warthin tumor	1 (4)	14 (4)
Squamous cell carcinoma	2 (8)	12 (4)
Adenoid cystic carcinoma	0	9 (3)
Oncocytoma	0	9 (3)
Adenocarcinoma	0	8 (2)
Monomorphic adenoma	0	8 (2)
Carcinoma ex pleomorphic adenoma	1 (4)	5 (1)
Myoepithelial carcinoma	0	5 (1)
Other	7 (28)	20 (6)
Unsure	0	31 (9)

^a Thirty participants responded to the phase I survey, but only 25 participants offered identifying information to determine demographic and tumor history.

^b Missing data for 1 participant in phase II.

naire were subjected to exploratory factor analysis using principal components for initial factor extraction and then a promax rotation. The optimal number of factors to retain was determined using scree plots, eigenvalues, proportion of common variance explained, and interpretability criteria from O'Rourke and Hatcher.³³ These interpretability criteria stipulate that there should be at least 3 items with meaningful (≥ 0.40) loadings for each factor, that items within each factor should share a conceptual meaning, that different factors should measure different constructs, that most items have meaningful loadings on only 1 factor and near-zero loadings on the remaining factors, and that most fac-

Box. Final Parotidectomy Quality of Life Index

Pain and sensations: The statements below pertain to pain and sensations that you may have experienced in the past month in relation to your parotidectomy. Please select one response per line.

1. I am bothered by numbness in my face, neck, or ear on the surgical side.
2. I am bothered by pain in my face or neck on the surgical side.
3. I am bothered by strange sensations on my face (eg, tingling, zapping) after surgery.
4. I am bothered by a feeling of fullness or pressure in my ear after surgery.
5. I am bothered by pain with each first bite of food.
6. I am bothered by soreness or tightness in my jaw when I chew.
7. I am bothered by facial swelling on the surgical side when I eat.

Facial appearance: The statements below pertain to facial appearance in the past month in relation to your parotidectomy. Please select one response per line.

1. I am bothered by my facial appearance after surgery.
2. I am bothered by the appearance of my ear after surgery.
3. I am bothered by the dent in my face on the surgical side.
4. I am self-conscious that my scar is visible to others.
5. I am self-conscious that my face looks damaged or disfigured.

Facial nerve function: The statements below pertain to your facial nerve function in the past month in relation to your parotidectomy. Please select one response per line.

1. I am able to eat and drink normally.
2. I have equal movement on both sides of my face.
3. I can fully close my eye on the surgical side.
4. I have the same smile after surgery as I did before surgery.
5. I have more dryness and irritation of my eye on the surgical side compared to before surgery.
6. I feel discouraged about the recovery of my facial movements after surgery.

Tumor concerns: The statements below pertain to concerns that you may have experienced in the past month about the tumor removed during your parotidectomy. Please select one response per line.

1. I worry that my tumor will come back.
2. I worry about what causes parotid tumors to develop.
3. I worry that I will need additional treatment to address my condition.

Immediate surgical recovery: The statements below pertain to your surgical recovery in the first 2 weeks immediately after your parotidectomy. Please select one response per line.

1. I was bothered by fatigue.
2. I was bothered by saliva leaking from my incision when I ate.
3. I was bothered by the amount of bruising I had.
4. I was bothered by a hematoma (a pool of blood under the skin) at the surgical site.
5. I was discouraged by how my wound was healing.
6. I was bothered by facial swelling.
7. I was frustrated by how slowly I was recovering.

Decision-making and surgical satisfaction: The statements below pertain to decision-making before your parotidectomy and surgical

satisfaction after your parotidectomy. The "surgery team" includes the surgeon, other doctors, nurses, and any other therapists or medical staff who may have cared for you in relation to your parotidectomy. Please select one response per line.

1. I received enough unbiased information from the surgery team to make an informed decision about the treatment of my tumor.
2. The surgery team prepared me for the length of the recovery process.
3. The surgery team involved me in making a decision about the treatment of my tumor.
4. I would recommend the same surgery team to a family member or friend in my position.
5. Undergoing surgery was the right choice for me.

Other parotidectomy concerns: The statements below pertain to other concerns that you may have experienced in the past month in relation to your parotidectomy. Please select one response per line as it applies to your parotidectomy.

1. I am bothered by sweating on my face when I eat.
2. I am able to participate in social activities.

Scoring instructions: These instructions assume that responses of not at all or does not apply, a little bit, somewhat, quite a bit, and very much have been recorded as 1, 2, 3, 4, and 5, respectively. Reverse-score responses to items 1 through 12, items 17 through 28, and item 34 so that higher scores indicate more favorable health states or better quality of life. Recode responses to items 1 through 35 so that 1 = 0 points, 2 = 25 points, 3 = 50 points, 4 = 75 points, and 5 = 100 points. Determine the number of nonmissing items within each of the first 6 domains (pain and sensations, facial appearance, facial nerve function, tumor concerns, immediate surgical recovery, and decision-making and surgical satisfaction). If more than 50% of the items within a domain are not missing, calculate a domain-specific score as the mean of the recoded responses. For example, if a respondent completed more than 3 items within the pain and sensations domain, calculate a domain-specific score as the mean of the recoded responses to items 1 through 7. Domain-specific scores can range from 0 to 100, with higher scores indicating more favorable health states or better quality of life. If scores for the first 4 domains are not missing, calculate a global quality of life score as an equally weighted mean of the pain and sensations, facial appearance, facial nerve function, and tumor concerns domain scores. Domain scores for immediate surgical recovery and decision-making and surgical satisfaction are not included in the global quality of life score; these domain scores should be summarized separately. Lastly, a domain score is not calculated for the other parotidectomy concerns domain; recoded responses to these 2 items should be summarized separately.

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tors have meaningful loadings for some items and near-zero loadings for the remaining items.

Cronbach α (entire sample) and pairwise Pearson correlation coefficients (test-retest subset) were used to measure internal consistency and reliability and item relatedness within each domain suggested by the exploratory factor analysis. Items

with high pairwise correlations (≥ 0.7) were considered redundant. Cronbach α at least 0.7 was considered an indicator of good domain internal consistency supporting group-level interpretation of scores.³⁴ The expert panel then reconvened to review results of the exploratory factor analysis, as well as the internal consistency, reliability, and redundancy analyses. The items from

the phase II survey were refined to the final PQOL instrument. To determine whether domain scores could be combined into a single global score, a second-order exploratory factor analysis was conducted.

Test-retest reliability was evaluated using intraclass correlation coefficients. Convergent and discriminant validity of the PQOL was assessed using Pearson and Spearman rank correlations with respect to the other validated general and disease-specific instruments included in the phase II survey. Domain scores were estimated to correlate strongly with instruments measuring similar concepts and should not correlate with instruments measuring different concepts. Associations of the PQOL with demographics and tumor pathology were evaluated using Spearman rank correlation coefficients and 2-sample t , χ^2 , and Wilcoxon rank sum tests. All statistical analyses were conducted using SAS software version 9.4 (SAS Institute). Two-sided $P < .05$ was considered statistically significant. Data were analyzed from March 8, 2022, to November 3, 2023.

Results

In phase I, 30 of 38 participants (79%) completed the survey (Table 1). In phase II, a total of 342 participants were enrolled via social media platforms, and 317 participants (93%) completed the entire survey. Participants were asked to self-report their demographics and tumor histories (Table 1). Most participants in both phases were women (phase I: 15 women [60%]; phase II: 305 women [89%]) and older than 40 years (phase I: 21 participants [84%]; phase II: 284 participants [83%]) with benign tumors (phase I: 14 participants [56%]; phase II: 235 participants [69%]), which reflects the natural incidence and demographics of parotid tumors.¹

A total of 45 items across 9 domains were included in the phase II survey. All included items were assigned a common response scale of not at all, a little bit, somewhat, quite a bit, and very much. Responses from the phase II survey are displayed in eTable 1 in Supplement 1. We selected 42 items across 7 domains based on primary exploratory factor analysis. The salivary function domain was eliminated altogether due to poor factor loading of all items. The decision-making and surgical satisfaction domains were combined into a single domain due to high loading scores. Items from a previously constructed domain retained through exploratory factor analysis, social and functional well-being, showed poor Cronbach α , suggesting poor internal consistency. Furthermore, 2 of the remaining 3 items within the domain had an exceedingly high pairwise correlation coefficient of 0.91. As such, 1 of the redundant items was removed following review by the expert panel, and the remaining 2 items in the domain were retained as standalone questions as they loaded poorly onto all domains. Ultimately, 33 items across 6 domains and the 2 standalone items were incorporated into the final PQOL instrument (Box).

In the second-order exploratory factor analysis, the pain and sensations, facial appearance, facial nerve function, and tumor concerns domain scores loaded well onto a single factor and were thus combined into a single global score. The immediate surgi-

Table 2. PQOL Index Scores and Other General and Disease-Specific Instruments for Phase II Participants (N = 342)

Score ^a	Mean (SD)
PQOL Index	
Pain and sensations	73 (21)
Facial appearance	81 (22)
Facial nerve function	80 (24)
Tumor concerns	57 (28)
Global PQOL	73 (17)
Immediate surgical recovery	68 (22)
Decision-making and surgical satisfaction	82 (21)
Face sweating, No. (%)	
0	15 (4)
25	12 (4)
50	15 (4)
75	24 (7)
100	274 (81)
Social activities, No. (%)	
0	9 (3)
25	25 (7)
50	32 (9)
75	60 (18)
100	213 (63)
Other instruments	
Parotidectomy Outcome Inventory	10 (7)
Facial Disability Index, median (IQR)	90 (75-100)
Facial Clinimetric Evaluation Scale	79 (20)
FACE-Q appearance domain, median (IQR)	89 (59-100)
FACE-Q appearance distress domain, median (IQR)	90 (53-100)
Obstructive Salivary Problem Impact Test	9 (2-22)
PROMIS Pain Interference Domain, median (IQR)	41 (41-55)
Shared Decision Making Questionnaire	73 (24)
PROMIS Social Roles and Activities, median (IQR)	64 (52-64)
Surgical Satisfaction Questionnaire	33 (6)
Overall parotidectomy surgery care experience, median (IQR)	9 (8-10)
Linear Analog Self-Assessments, median (IQR)	
Overall quality of life	8 (7-10)
Overall mental (intellectual) well-being	8 (7-10)
Overall physical well-being	8 (6-9)
Overall emotional well-being	8 (6-9)
Level of social activity	8 (5-9)
Overall spiritual well-being	8 (7-10)

Abbreviations: PQOL, Parotidectomy Quality of Life Index; PROMIS, Patient-Reported Outcomes Measurement Information System.

^a Valid score ranges are 0-100 for the PQOL Index, 0-40 for the Parotidectomy Outcome Inventory, 0-100 for the Facial Disability Index, 0-100 for the Facial Clinimetric Evaluation Scale, 0-100 for the FACE-Q appearance domain and appearance distress domain, 0-100 for the Obstructive Salivary Problem Impact Test, 41.1-76.3 for the PROMIS pain interference domain, 0-100 for the Shared Decision Making Questionnaire, 27.5-64.2 for the PROMIS social roles and activities, 8-40 for the Surgical Satisfaction Questionnaire, and 0-10 for the linear analog self-assessments. Higher scores for the Parotidectomy Outcome Inventory, Obstructive Salivary Problem Impact Test, and PROMIS pain interference domain indicate greater perceived handicap, whereas higher scores for all other measures indicate more favorable health states or quality of life.

Table 3. Associations of PQOL Index Scores With Demographic and Tumor Characteristics for Phase II Participants (N = 342)

Characteristic	PQOL Index Scores							Patients, No. (%)	
	Mean (SD)								
	Pain and sensations	Facial appearance	Facial nerve	Tumor concerns	Global PQOL	Immediate recovery	Satis- faction	Face sweating = 100	Social activities = 100
Gender identity									
Woman	73 (21)	81 (22)	81 (23)	56 (28)	73 (17)	67 (22)	82 (21)	244 (81)	191 (63)
Man	71 (23)	78 (26)	73 (29)	65 (33)	72 (21)	73 (23)	81 (23)	29 (81)	21 (58)
P value	.70	.40	.08	.07	.80	.15	.80	.90	.60
Age, y ^a									
18-40	73 (19)	77 (24)	85 (21)	42 (25)	69 (15)	67 (20)	80 (19)	51 (88)	36 (63)
41-50	76 (19)	80 (20)	80 (23)	57 (24)	73 (15)	65 (21)	80 (20)	66 (85)	56 (72)
51-65	70 (23)	81 (21)	79 (25)	59 (29)	72 (19)	67 (23)	83 (21)	107 (75)	83 (58)
≥66	76 (21)	86 (23)	79 (24)	66 (29)	77 (18)	73 (20)	83 (23)	50 (81)	38 (61)
P value	.70	.001	.20	<.001	.004	.04	.04	.11	.30
Time since parotidectomy									
<2 wk	53 (24)	75 (19)	65 (24)	53 (28)	62 (16)	70 (19)	84 (19)	24 (89)	3 (11)
2-4 wk	59 (21)	69 (30)	64 (29)	58 (33)	62 (22)	66 (23)	76 (28)	17 (85)	7 (35)
5 wk to 3 mo	67 (21)	77 (23)	75 (24)	64 (26)	71 (19)	63 (24)	81 (18)	38 (95)	20 (50)
4-6 mo	66 (22)	71 (32)	77 (29)	42 (30)	64 (23)	67 (23)	83 (20)	20 (95)	14 (64)
7-12 mo	77 (18)	89 (15)	87 (19)	56 (27)	77 (14)	65 (22)	81 (23)	48 (87)	41 (77)
>12 mo	78 (19)	83 (21)	83 (22)	58 (28)	76 (16)	69 (21)	82 (21)	126 (72)	127 (72)
P value	<.001	.002	<.001	.80	<.001	.30	.70	<.001	<.001
Type of parotid tumor ^b									
Benign	75 (20)	85 (19)	85 (18)	62 (25)	77 (14)	68 (22)	82 (21)	188 (80)	166 (72)
Malignant	69 (23)	73 (25)	68 (30)	46 (31)	64 (20)	68 (22)	82 (20)	80 (82)	45 (45)
P value	.007	<.001	<.001	<.001	<.001	.90	.90	.80	<.001

Abbreviation: PQOL, Parotidectomy Quality of Life Index.

^a Age categories of 18-30 and 31-40 were combined for these analyses.^b Participants who were unsure whether their tumor was benign or malignant were excluded from these analyses.

cal recovery and the decision-making and surgical satisfaction domains were not included in the global score, as they were only meant to be assessed in the short-term (<3 months) recovery period after surgery. Responses of not at all (converted to not at all or does not apply), a little bit, somewhat, quite a bit, and very much were then assigned 0, 25, 50, 75, and 100 points, respectively. A global PQOL score was calculated as an equally weighted mean of the 4 domain scores. The SAS code for scoring the PQOL is presented in eTable 2 in Supplement 1.

All domains' Cronbach's alpha ranged from 0.77 to 0.85 (eTable 3 in Supplement 1), suggesting very good internal consistency within each of the domains. Similarly, pairwise correlations between all 6 domains and the 2 standalone questions showed only weak or moderate correlations (eTable 4 in Supplement 1), suggesting that the domains and standalone questions were unique constructs with minimal redundancy between them.

A summary of participant responses to the final PQOL index, as well as responses to the other anchoring disease-specific instruments included in the phase II survey, are displayed in Table 2. Discriminant and convergent validity of the 6 domains for the final domains was assessed. Correlations between PQOL domain scores and scores from other validated general and disease-specific instruments are displayed in eTable 5

in Supplement 1. In summary, the pain and sensations, facial appearance, and facial nerve domains, as well as the global PQOL score, correlated moderately well with existing disease-specific instruments, indicating good convergent validity. None of the domains nor the global PQOL score correlated well with overall mental, physical, emotional, social, or spiritual QOL measures, suggesting that these general QOL instruments may not capture disease-specific QOL information specific to parotidectomy.

Associations of PQOL scores with participant demographics and clinical characteristics are displayed in Table 3. Younger age of the participant and malignant tumors were significantly associated with a lower global PQOL score. Participants with more recent parotidectomy scored significantly lower across all domains except for tumor concerns, immediate recovery, and surgical satisfaction. There were no differences between genders across domain scores in the PQOL.

A total of 318 of 342 participants (93%) volunteered to complete the retest survey. Of 71 participants who provided retest survey responses, 60 participants completed the test-retest survey and the HIPAA consent form that allowed linkage between the original survey answers and the retest survey answers.

Table 4. Assessments of Test-Retest Reliability for PQOL Index Scores for a Subset of Phase II Participants (n = 60)

Score	Reliability ^a
Pain and sensations	0.84
Facial appearance	0.82
Facial nerve function	0.89
Tumor concerns	0.85
Global PQOL	0.89
Immediate surgical recovery	0.86
Decision-making and surgical satisfaction	0.89
Face sweating	0.93
Social activities	0.85

Abbreviation: PQOL, Parotidectomy Quality of Life Index.

^a Reliability summarized with intraclass correlation coefficients, with coefficients greater than 0.7 indicating acceptable reliability for score interpretation at the group level and coefficients greater than 0.9 indicating acceptable reliability for score interpretation at the individual level.

swers. A summary of the test-retest reliability of various domains and the standalone questions is displayed in **Table 4**. Reliability coefficients for the domains were strong and ranged from 0.82 to 0.93, indicating that the domains and standalone questions included in the PQOL had high reproducibility.

Discussion

In this survey study, we developed and validated a new 35-item PRO instrument specific to recovery after parotidectomy. This new instrument, the PQOL, assesses QOL across several domains after parotid surgery, including pain and sensations, facial appearance, facial nerve function, tumor concerns, immediate surgical recovery, decision-making, and surgical satisfaction. To our knowledge, this is the first English-language PRO instrument specific to parotidectomy recovery and aims to capture the complex impact of this surgery on a patient's everyday life, from the patient perspective. The PQOL demonstrates excellent content, construct, convergent, and test-retest validity. This validated PRO instrument provides a valuable tool both for clinical practice and research purposes, as it serves as a strong outcome measure specific to this surgical intervention.

While recent studies in parotidectomy outcomes have demonstrated a greater interest in PROs,^{7,13,35,36} QOL studies in parotidectomy are hindered by a lack of disease-specific instruments. The POI-8, a validated parotidectomy-specific QOL instrument in German,¹⁷ includes several outcomes that are highly specific to parotid surgery, including the impact of facial paralysis, Frey syndrome, and changes in salivary function. However, the instrument does not include specific questions on key features of acute and long-term parotidectomy recovery that have been shown to have a significant impact on patient QOL. These include first bite syndrome,³⁷ which has been shown to have a greater influence than either Frey syndrome or skin hypoesthesia on QOL³⁸; sialoceles,¹⁵ which can lower patient mood and ability to participate in social

activities³⁹; salivary fistula¹⁵; and hematoma.¹⁵ More importantly, the POI-8 has only been validated in German and Spanish.⁴⁰ Although it has been translated and used in English,¹³ it has never undergone cross-cultural and linguistic validation in English, an important process that the PRO Consortium deems necessary prior to PRO instrument adaptation in another language.⁴¹

The PQOL did use the pre-existing POI-8 as a starting point for instrument development. However, it also leveraged the expertise from an expert panel and engaged patients in content development. The result is an instrument that not only comprehensively evaluates patient-centered aspects of QOL after parotidectomy but also demonstrates construct, convergent, and discriminant validity. In other words, items within each domain of the PQOL measure the intended goal of that domain, and domains do not overlap in content. This is demonstrated in correlations between the PQOL domains and pre-existing validated PROs that are not specific to parotid surgery. For example, the facial nerve domain in the PQOL correlates well with the Facial Clinimetric Evaluation scale, a validated measure of impairment and disability associated with facial paralysis of all causes.

There is poor correlation between both specific PQOL domains and the global PQOL score with pre-existing overall QOL scales, such as the Linear Analog Self-Assessments.²⁷ In fact, previous studies on QOL after parotidectomy using generic QOL measures, such as the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire, showed no changes⁴² in QOL after benign parotidectomy, no differences in QOL based on surgical approach,⁴³ and minimal impact from complications, such as Frey syndrome.⁴⁴ The lack of differences seen in QOL in these studies¹⁴ likely speaks to the lack of specificity in the disease-agnostic PRO measure used as the primary outcome rather than a disease-specific measure that better captures patients' experiences. The lack of significant differences detected in QOL outcomes in the aforementioned studies emphasizes the importance of a comprehensive PRO instrument that measures QOL components specific to parotidectomy.

As parotidectomy, particularly for benign disease, moves into an era of surgical de-escalation marked by more conservative extent of parotidectomy,^{45,46} it will be imperative for surgeons to evaluate these minimally invasive techniques. The success of these newer techniques in partial parotidectomy should not be assessed only surgically, but also in PROs. For example, outcomes of incision design,^{47,48} use of compressive dressings⁴⁹ and drains,⁵⁰ outpatient surgical practice,⁵¹ and methods of reconstruction⁵²⁻⁵⁴ are reported only from the surgeon's point of view. The PQOL offers a unique opportunity for future research as a PRO instrument that can measure subtle differences in QOL specific to parotidectomy. In this study, we have already observed that the global PQOL performed differentially among patients with benign or malignant parotid tumors and improved with time after surgery. This suggests that the PQOL is effective at differentiating between different temporal experiences in patients after parotidectomy; however, future studies to demonstrate responsiveness to change are needed. On an individual-surgeon basis, in-

corporating the PQOL into clinical practice can hopefully facilitate better surgeon-patient communication.

Strengths and Limitations

Strengths of this study include a rigorous approach to survey development using an assembled expert panel, recruitment of patients from around the country using social media platforms, and use of simple language that offers translatability into other languages. Participants were diverse with respect to parotid pathologies and patient experiences.

Limitations include the potential selection bias of our validation cohort, which included mostly middle-aged women and which could reflect the predominant user of social media platforms discussing parotidectomy and mask differential performance of certain items among diverse gender and age groups. Despite the women-predominant participant cohort, the domain scores in the PQOL were not significantly different between genders. However, the homogeneity of the study cohort with respect to gender and social media use underscores the need to also assess the performance of the PQOL in a more demographically and socioeconomically diverse cohort, as these groups may prioritize different domains and items compared with the validation cohort in this study. On the other hand, the distribution of benign and malignant pathology of participants in this study did reflect the natural incidence of disease in the US population.⁵⁵ It is important to note that creation and validation of the PQOL in this study only demonstrates that the PQOL

appropriately captured the range of symptoms and experiences in a diverse population of patients after parotidectomy. It did not define the range of expected QOL changes after parotidectomy in patients with different salivary pathologies, treatments, or time periods after parotidectomy. Assessing responsiveness of the PQOL domain scores to various surgical techniques, adjuvant treatments, and changes over time in the constructs of interest could determine the minimal clinically important differences in domain scores. Understanding the responsiveness of the PQOL in different patient populations over time would facilitate interpretation of scores when used in clinical care and research but was beyond the scope of this study and will be addressed in future prospective research.

Conclusions

This survey study describes the development and validation of the PQOL, a new 35-item PRO instrument specific to recovery after parotidectomy. The PQOL demonstrated excellent content, construct, convergent, and discriminant validity and excellent test-retest and internal reliability. With further external validation and prospective longitudinal studies, the PQOL may provide opportunities for quality improvement in clinical practice and has potential as a key PRO instrument in future surgical clinical trials for benign and malignant salivary disease.

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