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Patient-Reported Quality of Life After Hemiglossectomy: A Prospective Comparative Pilot Cohort Study of Radial Forearm Free Flap Versus Submental Island Pedicled Flap Reconstruction

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Patient-Reported Quality of Life After Hemiglossectomy: A Prospective Comparative Pilot Cohort Study of Radial Forearm Free Flap Versus Submental Island Pedicled Flap Reconstruction

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Abstract

Background: Reconstruction after major oral tongue resection for squamous cell carcinoma aims to preserve function and quality of life. The radial forearm free flap (RFFF) and submental island pedicled flap (SIPF) are both established reconstructive options, but prospective, baseline-adjusted comparisons of patient-reported quality of life between the two techniques are limited.

Methods: In this prospective observational comparative pilot cohort study (enrollment September 2024–April 2025; follow-up through April 2026), 28 patients undergoing hemiglossectomy with

immediate reconstruction (14 RFFF, 14 SIPF) were assessed using the university of washington quality of life questionnaire version 4 (UW-QOL v4) at baseline (~1 week preoperatively), 6 months, and 12 months postoperatively. Flap selection reflected clinical decision-making rather than randomization. The primary endpoint was 12-month composite UW-QOL adjusted for baseline score using ANCOVA.

Results: RFFF patients were significantly younger (46.3 ± 8.2 vs. 54.9 ± 3.6 years; p = 0.001) and had larger defects (~26.6 ± ~4.4 vs. ~21.4 ± ~4.7 cm²; p = 0.005); baseline UW-QOL did not differ significantly. RFFF was associated with significantly higher adjusted composite UW-QOL at 12 months (mean difference 7.88 points; 95% CI 1.56-14.20; p = 0.0165; unadjusted difference 6.4 points, p = 0.054), directionally consistent across the secondary 6-month analysis, longitudinal mixed-effects analysis, and sensitivity analyses; after age adjustment, the estimate remained similar but the confidence interval crossed zero (p = 0.061). RFFF showed higher patient-reported scores in activity, recreation, swallowing, and speech, but worse appearance outcomes, and longer operative time and hospital stay than SIPF.

Conclusions: In this small, non-randomized pilot cohort, RFFF was associated with a higher baseline-adjusted 12-month composite UW-QOL than SIPF, though attenuated after age adjustment. These findings are hypothesis-generating rather than evidence of causal superiority and require confirmation in a larger, adequately powered study.

Trial registration: ClinicalTrials.gov, NCT07819617. The study was prospectively conducted, but registered retrospectively.

Keywords

Oral tongue cancer; radial forearm free flap; submental island flap; quality of life; UW-QOL; reconstruction

Background

Achieving oncologic control in oral tongue squamous cell carcinoma often means a major resection, and the resulting defect can compromise speech, swallowing, and the everyday functions patients rely on [1,2]. Closing that defect is rarely just a technical step: how it is reconstructed shapes the patient's functional and psychosocial recovery long afterward.

Alongside oncologic and surgical endpoints, patient-reported quality of life has increasingly earned a place as an outcome in its own right in head and neck cancer care. The University of Washington Quality of Life Questionnaire (UW-QOL), first described by Hassan and Weymuller [3] and since revised into its current version 4 spanning twelve functional and psychosocial domains [4], remains one of the most widely used disease-specific instruments for this purpose, providing a structured patient-reported assessment of treatment-related function and quality of life.

Two reconstructive options are well established for oral tongue defects: the radial forearm free flap (RFFF) and the submental island pedicled flap (SIPF). RFFF, a fasciocutaneous free flap, provides a thin, pliable, reliably vascularized tissue paddle that can be tailored to a wide range of defect sizes, at the cost of microvascular surgical time and a separate forearm donor site [5]. SIPF, harvested locally within the existing neck dissection field, shortens the operation and spares the patient a distant donor site, but offers less flexibility in the size and mobility of tissue it can provide. Its use after oral cancer resection has also raised oncologic questions, because the flap pedicle lies close to the level I lymph nodes [6].

Most of what is known about RFFF versus SIPF comes from retrospective single- or multi-institutional reviews and, more recently, a propensity-matched retrospective comparison; these generally report shorter operative time and hospital stay with SIPF, alongside broadly comparable postoperative speech and swallowing function between the two techniques [7–9]. A prospective, baseline-adjusted comparison of overall patient-reported quality of life — rather than postoperative function assessed at a single timepoint with no reference to the patient's own preoperative status — remains limited for this specific comparison.

A baseline measurement matters here because it lets each patient's postoperative outcome be read against their own starting point, rather than assuming every patient begins from an equivalent functional baseline. Following patients out to 12 months, rather than stopping earlier, also allows assessment of longer-term postoperative recovery and possible effects of adjuvant treatment that may not yet be apparent at 6 months.

This study set out to compare 12-month patient-reported quality of life between RFFF and SIPF reconstruction after hemiglossectomy for oral tongue squamous cell carcinoma, adjusting for each patient's preoperative baseline. The primary comparison used a baseline-adjusted ANCOVA model, and change over time was assessed separately with a complementary mixed-effects analysis (see Methods). The 12-month composite UW-QOL, adjusted for baseline, therefore serves as this study's primary endpoint, chosen as a hypothesis-generating comparison relevant to reconstructive decision-making in this patient population.

Methods

Ethics and setting

This prospective comparative study was approved by the Ethics Committee of the Faculty of Dentistry, Al-Azhar University, Assiut Branch (approval reference AUAREC20240007-3). All patients provided informed consent prior to enrolment, and the study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was developed at Al-Azhar University, with clinical and surgical input from an external supervisor, a head and neck oncologic surgeon affiliated with the National Cancer Institute, Cairo University. Study registration: ClinicalTrials.gov, NCT07819617 (retrospectively registered, after completion of enrolment and follow-up).

Study design and participants

This was a prospective, observational, comparative pilot cohort study conducted from September 2024 to April 2026. Enrollment ran from September 2024 to April 2025, after which the study continued in a follow-up-only phase to complete the 12-month assessment for the last enrolled patients. Twenty-eight consecutive patients undergoing hemiglossectomy for oral tongue squamous cell carcinoma with immediate reconstruction were enrolled over this period: 14 reconstructed with a radial forearm free flap (RFFF) and 14 with a submental island pedicled flap (SIPF). This study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Eligibility criteria

Patients aged ≥18 years with histologically confirmed squamous cell carcinoma of the oral tongue, non-metastatic disease (M0), clinical stage T2 or T3, and nodal stage N0–N2c (AJCC 8th edition) were eligible, provided that adequate medical records were available for data extraction and they were able to complete the quality-of-life questionnaires. Patients were

excluded if they had incomplete medical records or missing follow-up data required for the study assessments; metastatic disease or a second primary tumour; previous surgical or radiotherapy treatment for tongue cancer; or cognitive impairment that could interfere with questionnaire completion.

Defect size and flap selection

The anticipated surgical defect area was estimated from preoperative imaging and used as a preoperative measure of defect size. Reconstructive technique was not randomized; flap selection was based on clinical and reconstructive decision-making by the treating surgical team, informed by defect characteristics and individual clinical considerations. The groups differed significantly at baseline in age and estimated defect area (Table 1); the non-randomized design does not allow the factors underlying this imbalance to be determined (see Limitations).

Quality-of-life questionnaire

The Arabic UW-QOL v4 was obtained from HaNC Support (Aintree University Hospital, Liverpool, UK) [10] and administered in Arabic to all participants. Psychometrically evaluated Arabic versions of the UW-QOL have been described, including a cross-cultural validation in a Moroccan cohort [11] and a Jordanian head-and-neck cancer cohort (Cronbach's $\alpha = 0.89$ for the total scale; excellent test–retest reliability) [12]; these are cited as supporting literature and are not the source of the questionnaire copy used here.

Reconstructive techniques

Both reconstructive techniques are established options for oral tongue defect closure. RFFF reconstruction was performed using a fasciocutaneous radial forearm free flap tailored to the

tongue defect, followed by transfer to the neck, microvascular anastomosis, and inset into the oral defect. The forearm donor site was managed with split-thickness skin grafting.

SIPF reconstruction was performed using a submental island pedicled flap harvested from the cervical/submental region and transferred to the oral defect through a pedicled route, without microvascular anastomosis [13]. The donor site was closed primarily within the cervical surgical field.

Outcome measurement

Quality of life was assessed prospectively using the University of Washington Quality of Life Questionnaire, Version 4 (UW-QOL v4), administered preoperatively at baseline (approximately one week before surgery) and at 6 and 12 months postoperatively. The UW-QOL v4 comprises 12 domains (pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder function, taste, saliva, mood, and anxiety), each scored from 0 (worst) to 100 (best); a composite score was calculated as the unweighted mean of the 12 domain scores. The primary endpoint was the composite UW-QOL score at 12 months postoperatively, adjusted for baseline composite score. The composite score at 6 months, similarly adjusted, was the secondary endpoint. Individual domain scores at 12 months, longitudinal trajectories across all three timepoints, operative time, and length of hospital stay were analyzed as supportive or exploratory outcomes. The 12-month timepoint was selected as the primary analytical endpoint because it represents the complete planned duration of prospective follow-up, rather than an arbitrary intermediate postoperative assessment. Quality-of-life data were collected prospectively at each of the three defined timepoints; demographic, clinical, surgical, and oncologic variables were extracted from medical

records for identified eligible patients, consistent with the study protocol's data-collection procedure.

Sample size

This study was designed as a prospective comparative pilot cohort intended to generate hypotheses and inform the design of a future, adequately powered confirmatory study; no formal a priori power calculation was performed, and the sample size (n = 28) reflected the number of consecutive eligible patients enrolled during the predefined recruitment period.

Missing data

Complete UW-QOL assessments were available for all 28 patients at all three timepoints (baseline, 6 months, and 12 months), with no missing observations for the primary or secondary outcomes; no imputation was therefore required.

Statistical analysis

Continuous variables are presented as mean ± SD and compared using the t-test (or Mann–Whitney U test where appropriate); categorical variables are compared using Fisher's exact test. The primary (12-month) and secondary (6-month) composite UW-QOL scores were analyzed using ANCOVA, with reconstructive group as the independent variable and baseline composite score as a covariate, and adjusted mean differences are reported with 95% CIs. ANCOVA was preferred to a change-score analysis for its efficiency and handling of baseline imbalance [14]; this guidance derives from randomized trials, and ANCOVA does not by itself remove confounding in this non-randomized cohort. Sensitivity models added age, estimated defect area, and postoperative radiotherapy (determined by pathological findings rather than flap type, and

therefore not included in the principal model) individually, and age with defect area together. Model assumptions and influential observations were checked for the primary model (Shapiro–Wilk, Breusch–Pagan, Cook's distance, leave-one-out). Trajectories were characterized using a random-intercept mixed-effects model with group, time (categorical, baseline as reference), and group × time interaction. The 12 UW-QOL domains at 12 months were analyzed exploratorily with the same model, applying Benjamini–Hochberg false discovery rate control. A two-sided $p < 0.05$ was considered significant for the primary and secondary endpoints. Analyses used Python 3 (SciPy, statsmodels).

Results

Participant characteristics

Twenty-eight patients undergoing hemiglossectomy for oral tongue squamous cell carcinoma, with immediate reconstruction, were enrolled: 14 reconstructed with a radial forearm free flap (RFFF) and 14 with a submental island pedicled flap (SIPF). Participant flow through enrollment, flap selection, and follow-up is shown in Figure 1. All 28 patients completed quality-of-life assessments prospectively at baseline, 6 months, and 12 months postoperatively, with no missing data at any timepoint.

Baseline demographic and clinical characteristics are summarized in Table 1. Patients in the RFFF group were significantly younger than those in the SIPF group (46.3 ± 8.2 vs. 54.9 ± 3.6 years; $p = 0.001$) and had a significantly larger estimated defect area (~26.6 ± ~4.4 vs. ~21.4 ± ~4.7 cm²; $p = 0.005$). Sex distribution did not differ significantly between groups (7F/7M vs. 11F/3M; $p = 0.236$). Baseline composite UW-QOL scores were similar between groups (RFFF 78.4 ± 12.3 vs.

SIPF 83.8 ± 11.0; p = 0.235); no statistically significant difference was detected, though this study's power to establish baseline balance is limited by its sample size (see Table 1). Age and estimated defect area showed notable baseline differences between groups in this non-randomized cohort. Perioperative, surgical, and complication data, including postoperative radiotherapy use, are presented separately.

Primary outcome: 12-month composite quality of life

The primary analysis compared composite UW-QOL scores at 12 months postoperatively between groups, adjusted for baseline composite score using analysis of covariance (ANCOVA). Unadjusted 12-month composite scores were 53.3 ± 8.5 for RFFF and 46.9 ± 8.2 for SIPF. After adjustment for baseline quality of life, patients reconstructed with RFFF showed a significantly higher composite UW-QOL at 12 months than those reconstructed with SIPF, with an adjusted mean difference of 7.88 points (95% CI 1.56–14.20; p = 0.0165; Table 2). Higher baseline composite UW-QOL was associated with higher 12-month composite UW-QOL after accounting for reconstruction group (β = 0.28, 95% CI 0.003–0.549, p = 0.048): each 1-point higher preoperative composite score was associated with a 0.28-point higher 12-month score.

Secondary outcome: 6-month composite quality of life

At 6 months, unadjusted composite scores were 66.7 ± 12.3 (RFFF) and 56.8 ± 14.1 (SIPF). The baseline-adjusted between-group difference at 6 months was 12.35 points (95% CI 2.51–22.18; p = 0.016), consistent in direction with the 12-month primary finding.

Sensitivity analyses

The adjusted difference was directionally consistent across all sensitivity models (Table 3):

+7.61 with age added (95% CI −0.39 to 15.62; p = 0.061), +11.56 with estimated defect area (95% CI 4.55 to 18.57; p = 0.002), +10.23 with both (95% CI 2.38 to 18.07; p = 0.013), and +7.02 with postoperative radiotherapy (95% CI 0.40 to 13.64; p = 0.039). Point estimates ranged from 7.0 to 11.6 points, but the confidence interval crossed zero after age adjustment. Because age differed significantly between groups at baseline (Table 1), residual confounding cannot be excluded.

Longitudinal analysis

In the random-intercept mixed-effects model, composite UW-QOL declined from baseline in both groups, but the decline was smaller in the RFFF group. Relative to SIPF, the RFFF group's decline from baseline was smaller by 15.2 points at 6 months (group × time interaction, p < 0.001) and by 11.8 points at 12 months (p = 0.005). Because this model uses the same patients' repeated measurements, it is a complementary analysis and not independent confirmation of the primary and secondary findings. Group-mean trajectories are shown in Figure 2.

Supportive perioperative outcomes

In addition to patient-reported quality of life, operative time and length of hospital stay were compared as supportive perioperative outcomes reflecting the relative procedural burden of the two reconstructive techniques. Operative time was significantly shorter with SIPF than with RFFF (4.2 ± 0.5 vs. 7.9 ± 0.7 hours; p < 0.001), consistent with the additional time required for microvascular anastomosis in free flap reconstruction. Length of hospital stay was similarly shorter following SIPF than RFFF (5.6 ± 1.2 vs. 10.6 ± 2.2 days; p < 0.001). In this cohort, the higher baseline-adjusted composite UW-QOL scores observed with RFFF were accompanied by longer operative time and hospital stay than with SIPF.

Exploratory domain-level analyses

Domain-level analyses at 12 months were exploratory, using the same baseline-adjusted model with Benjamini–Hochberg correction across the 12 domains (Table 4; Figure 3). After correction, RFFF was associated with higher scores than SIPF in Activity, Recreation, Swallowing, and Speech, whereas Appearance favored SIPF (adjusted difference −12.0 points; 95% CI −20.7 to −3.4; BH-adjusted p = 0.025). Chewing (BH-adjusted p = 0.050) and Anxiety (BH-adjusted p = 0.062) were not significant. Shoulder could not be analyzed with the adjusted model because all patients scored 100 at baseline; at 12 months, 12/14 patients in each group scored 100 and 2/14 scored 75 (identical distribution).

Early recurrence observations

Disease recurrence within the first 6 months after surgery was observed in 2 of 14 RFFF patients and 4 of 14 SIPF patients. The study was not designed or powered to compare recurrence, disease-free survival, or overall survival between groups, so these early recurrence figures are reported descriptively only; given the small subgroup sizes and short interval, they should not be read as evidence of a difference in oncologic outcome between techniques. Longer-term recurrence and survival data fell outside the scope of this study.

Neck dissection extent and donor-site morbidity

Bilateral neck dissection was more frequent in the RFFF group (7/14, 50% vs. 2/14, 14%; Table 5a), but the reasons cannot be determined from these data. A donor-site finding (predominantly scarring or pigmentation change) was recorded in 12 of 14 RFFF patients compared with 1 of 14 SIPF patients (Table 5c); this is expected, as the SIPF donor site lies within the neck dissection

incision and closes primarily, whereas RFFF requires a separate forearm donor site. These findings were clinical observations and were not assessed with a validated donor-site grading or patient-reported instrument.

Postoperative radiotherapy was decided after reconstruction, based on pathological findings, and not on flap type. Its more frequent use in the SIPF group (12/14 vs. 9/14), together with the higher rate of involved margins (3/14 vs. 1/14; Table 5a), may partly reflect differences in pathological characteristics, but the causal pathway cannot be established from this dataset (Figure 4), and the finding should be interpreted cautiously.

Discussion

In this prospective cohort of 28 patients undergoing hemiglossectomy for oral tongue squamous cell carcinoma, RFFF reconstruction was associated with a higher baseline-adjusted composite UW-QOL score at 12 months than SIPF (adjusted mean difference 7.88 points; 95% CI 1.56 – 14.20; $p = 0.0165$). The direction of association was consistent in the 6-month analysis, the mixed-effects model, and the sensitivity analyses, although the confidence interval included zero after adjustment for age. The wide interval reflects the small sample, and these findings are hypothesis-generating.

Binenbaum et al. [15] estimated the minimal clinically important difference (MCID) of the UW-QOL at 13.07 points for the Global QOL item, using a distribution-based method in a meta-analysis of 1,011 patients. This estimate does not necessarily apply to the 12-domain composite score used here, for which no MCID has been established. The adjusted difference (7.88 points) is numerically below this value, so its clinical importance is uncertain, although several domains

(Activity, Recreation, Swallowing, Speech) showed larger differences. Quality of life declined from baseline to 12 months in both groups, with a smaller decline in the RFFF group, whose baseline score was numerically lower (78.4 vs. 83.8; not significant); baseline-adjusted analyses were used to account for this.

Previous retrospective series and a propensity-matched cohort reported comparable speech and swallowing outcomes between the two flaps, with shorter operative time and hospital stay as the main advantage of SIPF [7 – 9]; Schönauer et al. [16] described SIPF as an alternative to microsurgical reconstruction in elderly patients. Our prospective, baseline-adjusted longitudinal design identified a difference in composite quality of life favoring RFFF. This may reflect differences in study design, patient population, or defect characteristics, and is best regarded as hypothesis-generating rather than as contradicting earlier work.

The perioperative findings (longer operative time and hospital stay with RFFF) agree with earlier reports [7,8] and, together with the quality-of-life results, are compatible with a trade-off between the two techniques. At the domain level, RFFF was associated with higher scores in functional domains, whereas Appearance favored SIPF. This may partly reflect the separate forearm donor site required for RFFF, in which scar-related findings were recorded more often, consistent with reported donor-site morbidity [5,17]. However, donor-site satisfaction and body image were not assessed with a validated instrument, so a causal link cannot be established. Flap selection should therefore consider individual patient priorities, defect characteristics, and perioperative factors.

Oncologic safety is a further consideration. The submental island flap lies close to the level I nodes, and the evidence is not uniform: a series of 101 patients with oral tongue carcinoma

reported higher flap-related locoregional recurrence when level I nodes were pathologically positive and did not support SIPF use in that setting [18], whereas a recent meta-analysis found the flap oncologically acceptable in carefully selected patients (pooled recurrence 16%) [6]. In our cohort, four SIPF patients had N2b disease, and early recurrence occurred in 4 of 14 SIPF and 2 of 14 RFFF patients. These numbers are too small to support conclusions on oncologic safety, but they underline the importance of nodal status in flap selection and of reporting recurrence-free and overall survival in larger studies.

Strengths and limitations

Strengths: prospective design with a prospectively collected preoperative baseline assessment; complete follow-up with no missing data at any timepoint; a consistently applied analytical framework across primary, secondary, and sensitivity analyses; multiple sensitivity analyses and a longitudinal model converging on a consistent direction of association; transparent reporting of a domain-level finding (Appearance) that runs counter to the study's overall direction, and of the attenuated significance seen after age adjustment.

Limitations: This pilot study has several limitations. The sample was small (n = 28), and flap allocation was not randomized: the groups differed significantly in age and estimated defect area, with only partly overlapping age distributions, so residual confounding cannot be excluded despite adjustment. Comorbidity, smoking, adjuvant treatment timing, and rehabilitation are not reported, and the effects of radiotherapy and early recurrence on 6- and 12-month scores could not be assessed separately. Patients with incomplete records or missing follow-up were excluded, and the numbers screened and excluded were not recorded, so selection bias cannot be excluded. Donor-site findings were not assessed with a validated instrument, and domain-level analyses were

exploratory. The study was registered after enrolment and follow-up were complete. These findings are hypothesis-generating and require confirmation in larger prospective studies.

Conclusions

In this small prospective observational cohort, RFFF was associated with a higher 12-month baseline-adjusted composite UW-QOL than SIPF, though the estimate was imprecise and sensitive to age adjustment. This suggests a possible patient-reported quality-of-life difference, particularly in specific functional domains, rather than providing evidence of causal superiority. At the domain level, the association came with higher scores in activity, recreation, swallowing, and speech, offset by worse self-reported appearance and by substantially longer operative time and hospital stay for RFFF. These results should be read as an adjusted association from a small, non-randomized cohort, not as evidence that either technique is causally superior; they are best treated as hypothesis-generating. Defect characteristics, perioperative factors, and patient priorities all deserve a place in how the reconstructive approach is chosen.

List of abbreviations

Abbreviation	Definition
AJCC	American Joint Committee on Cancer
ANCOVA	Analysis of covariance
BH	Benjamini–Hochberg (procedure for false discovery rate control)
CI	Confidence interval
DAG	Directed acyclic graph
ICMJE	International Committee of Medical Journal Editors
MCID	Minimal clinically important difference
NCI	National Cancer Institute
QOL	Quality of life
RFFF	Radial forearm free flap

Abbreviation	Definition
RT	Radiotherapy
SD	Standard deviation
SIPF	Submental island pedicled flap
UW-QOL	University of Washington Quality of Life Questionnaire

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Faculty of Dentistry, Al-Azhar University, Assiut Branch (approval reference AUAREC20240007-3), and conducted in accordance with the Declaration of Helsinki. All patients provided informed consent prior to enrolment.

Trial registration

ClinicalTrials.gov, NCT07819617. The study was prospectively conducted, but registered retrospectively.

Consent for publication

Not applicable (no identifiable individual patient data or images are presented).

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Competing interests

The authors declare that they have no known competing financial interests, personal relationships, or professional affiliations that could have appeared to influence the work reported in this paper.

All authors have reviewed and disclosed any potential conflicts of interest in accordance with the International Committee of Medical Journal Editors (ICMJE) recommendations, and none were identified.

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Author Contributions

Mohamed Serag: Conceptualization, Methodology, Investigation, Data curation, Project administration, Writing – original draft.

Ashraf Abd el Fatah: Conceptualization, Methodology, Investigation, Supervision, Writing – review & editing.

Mohamed Zedan: Conceptualization, Methodology, Investigation, Supervision, Writing – review & editing.

AbdelAziz Abdallah: Conceptualization, Methodology, Supervision, Writing – review & editing.

Mohamed Alaa Eldin Mohamed: Conceptualization, Methodology, Writing – review & editing.

Mohamed Ashraf Abd el Fatah: Conceptualization, Methodology, Writing – review & editing.

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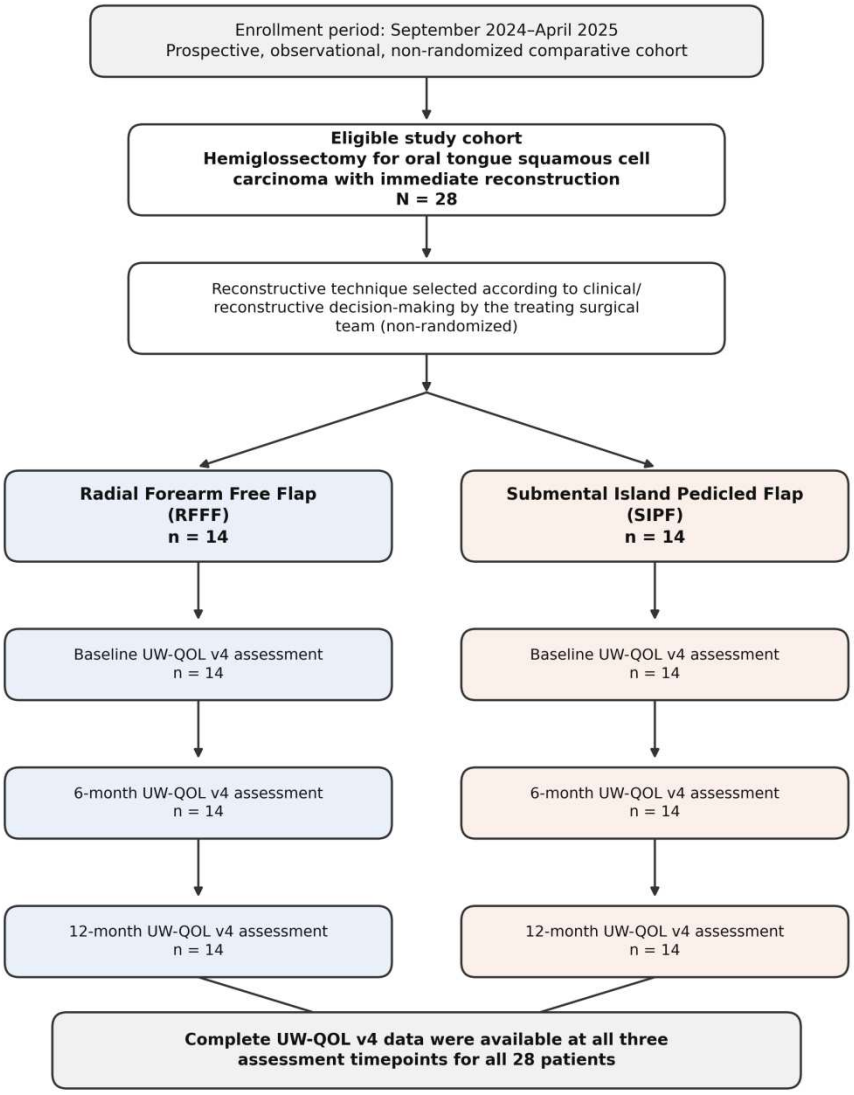
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Figures

Figure 1

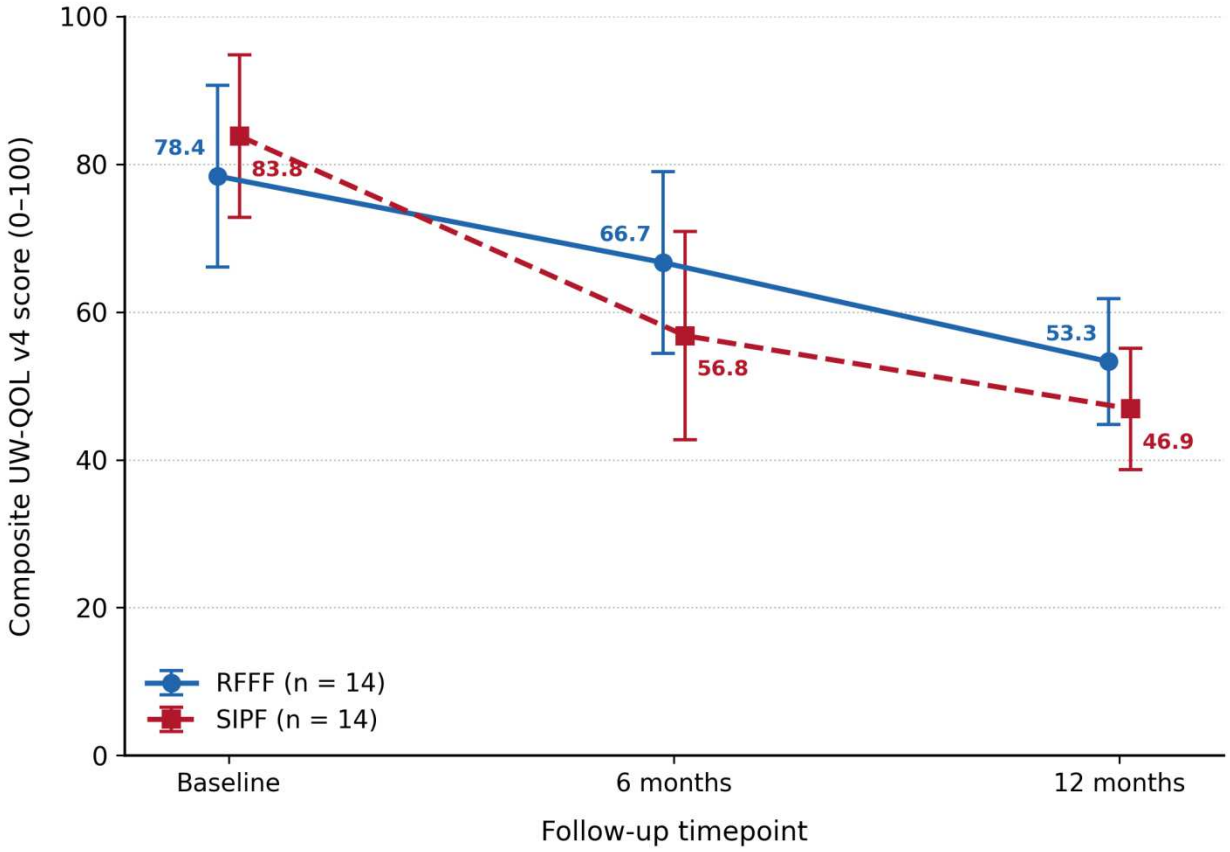
Participant flow diagram.



Screening, exclusions, follow-up losses, withdrawals, and missing questionnaires were not separately recorded. Reconstruction was non-randomized and based on clinical decision-making.

Figure 2

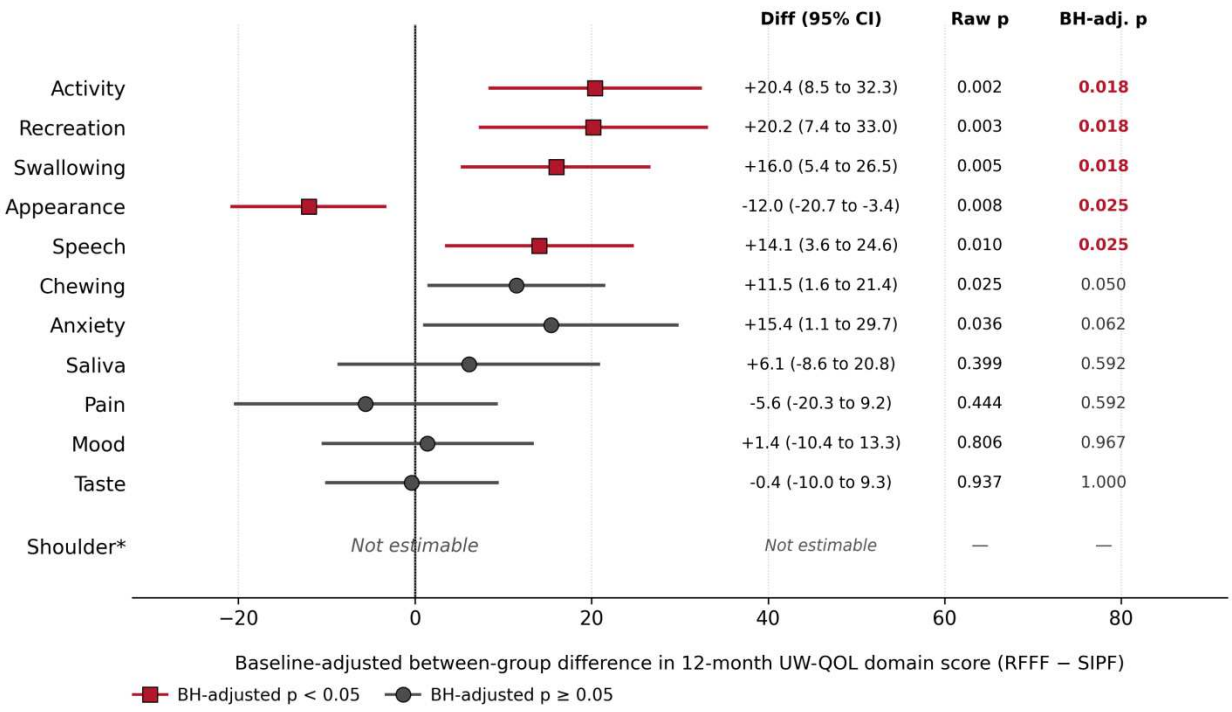
Longitudinal changes in composite UW-QOL v4 scores from baseline to 12 months by reconstruction group.



Points represent group means; error bars represent SD.

Figure 3

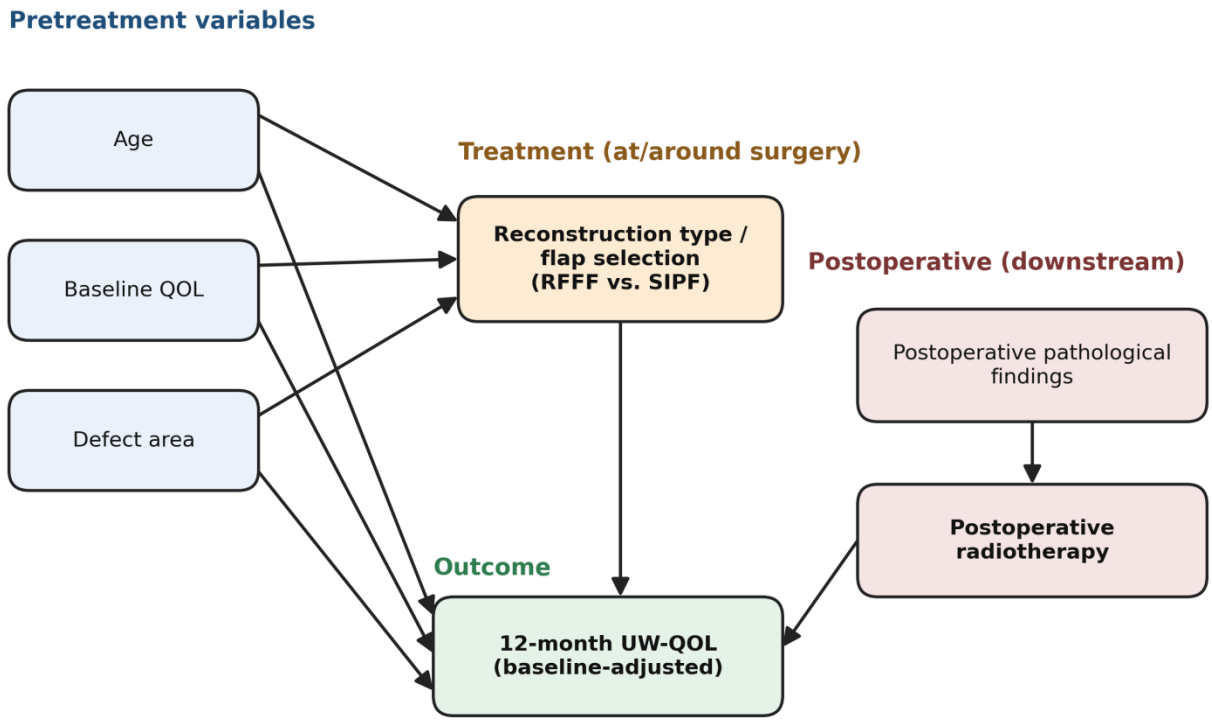
Forest plot of baseline-adjusted between-group differences in 12-month UW-QOL domain scores (RFFF minus SIPF).



Positive values favor RFFF; negative values favor SIPF. BH-adjusted p-values control FDR across 12 domains. Shoulder was not estimable because all baseline scores were 100.

Figure 4

Conceptual causal framework for the treatment-outcome relationship.



This DAG represents the authors' hypothesized causal relationships based on clinical knowledge and prior evidence; it is not a formally tested causal model.

Tables

Table 1

Baseline demographic, clinical, and tumour characteristics.

Characteristic	RFFF (n=14)	SIPF (n=14)	p-value
Age, years (mean ± SD)	46.3 ± 8.2	54.9 ± 3.6	0.001
Sex, F/M	7/7	11/3	0.236
T-stage, T2/T3	11/3	10/4	—
N-stage, N0/N1/N2b/N2c	5/4/3/2	3/7/4/0	—
Estimated defect area, cm² (mean ± SD)	26.6 ± 4.4	21.4 ± 4.7	0.005
Preoperative chemotherapy, yes	3/14	2/14	—
Baseline composite UW-QOL (mean ± SD)	78.4 ± 12.3	83.8 ± 11.0	0.235

No significant differences were observed in sex or baseline composite UW-QOL. Age and defect area differed significantly, indicating baseline imbalance in this non-randomized cohort.

460 **Table 2**

461 Composite UW-QOL across follow-up, with baseline-adjusted comparisons.

Timepoint	RFFF (mean ± SD)	SIPF (mean ± SD)	Unadjusted p	Baseline-adjusted difference (RFFF−SIPF)	95% CI	Adjusted p
Baseline	78.4 ± 12.3	83.8 ± 11.0	0.235	—	—	—
6 months (secondary)	66.7 ± 12.3	56.8 ± 14.1	0.061	+12.35	2.51 to 22.18	0.016
12 months (primary)	53.3 ± 8.5	46.9 ± 8.2	0.054	+7.88	1.56 to 14.20	0.0165

462 **Table 3**

463 Primary and sensitivity model estimates for the 12-month adjusted group difference.

Model	Adjustment set	RFFF−SIPF	95% CI	p
Model 1 (primary)	Group + Baseline QOL	+7.88	1.56 to 14.20	0.0165
Model 2a (sensitivity)	+ Age	+7.61	−0.39 to 15.62	0.061
Model 2b (sensitivity)	+ Estimated defect area	+11.56	4.55 to 18.57	0.002
Model 2c (sensitivity)	+ Age + Estimated defect area	+10.23	2.38 to 18.07	0.013
RT sensitivity model	+ Postoperative radiotherapy	+7.02	0.40 to 13.64	0.039

464 **Table 4**

465 Exploratory UW-QOL domain-level analyses at 12 months (baseline-adjusted).

Domain	RFFF−SIPF	95% CI	Raw p	BH-adjusted p
Activity	+20.4	8.5 to 32.3	0.002	0.018
Recreation	+20.2	7.4 to 33.0	0.003	0.018
Swallowing	+16.0	5.4 to 26.5	0.005	0.018
Appearance	−12.0	−20.7 to −3.4	0.008	0.025
Speech	+14.1	3.6 to 24.6	0.010	0.025
Chewing	+11.5	1.6 to 21.4	0.025	0.050
Anxiety	+15.4	1.1 to 29.7	0.036	0.062
Saliva	+6.1	−8.6 to 20.8	0.399	0.592
Pain	−5.6	−20.3 to 9.2	0.444	0.592
Mood	+1.4	−10.4 to 13.3	0.806	0.967
Taste	−0.4	−10.0 to 9.3	0.937	1.000
Shoulder*	Not estimable	Not estimable	Not estimable	Not estimable

Shoulder was not estimable because all baseline scores were 100. At 12 months, score distributions were identical (100: 12/14 in each group; 75: 2/14).

Table 5a

Perioperative outcomes and surgical extent.

Perioperative/surgical variable	RFFF (n=14)	SIPF (n=14)	p-value
Operative time, hours (mean ± SD)	7.9 ± 0.7	4.2 ± 0.5	<0.001
Hospital stay, days (mean ± SD)	10.6 ± 2.2	5.6 ± 1.2	<0.001
Bilateral neck dissection	7/14 (50%)	2/14 (14%)	—
Surgical margin, clear/close/involved	12/1/1	10/1/3	—
Postoperative radiotherapy, yes	9/14 (64%)	12/14 (86%)	0.385
Postoperative chemotherapy, yes	8/14	9/14	—
Early recurrence (within 6 months), yes	2/14	4/14	—

Table 5b

Recorded recipient-site findings.

Recipient-site finding	RFFF (n=14)	SIPF (n=14)
None	9	8
Hematoma	1	1
Orocutaneous fistula (conservative)	2	0
Partial flap necrosis (debrided)	1	1
Venous congestion (re-anastomosis)	1	0
Intraoral hair growth	0	3
Marginal epidermolysis	0	1

Table 5c

Recorded donor-site findings.

Donor-site finding	RFFF (n=14)	SIPF (n=14)
None (no donor-site complication)	2	13
Hypertrophic scar	7	0
Hyperpigmentation	3	0
Partial skin graft loss	1	0
Tight/contracted scar	1	0
Hematoma	0	1

Recipient-site complication counts were small and were not formally compared. Donor-site findings were more frequent with RFFF (12/14) than SIPF (1/14), reflecting the additional forearm donor site with RFFF. These were clinical observations, not validated donor-site-specific assessments.