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A Pilot Trial of Tongue Reconstruction Using the Chimeric Innervated Vastus Lateralis Muscle and Antero-Lateral Thigh Free Flap

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ABSTRACT

Background: Subtotal and total glossectomies for advanced tongue cancer result in significant speech- and swallow-related morbidity, impairing quality of life. This prospective pilot study compares the safety and functional outcomes associated with using a chimeric innervated muscle and fasciocutaneous flap for soft tissue reconstruction.

Materials and Methods: A prospective, non-randomized controlled pilot study evaluated a standardized technique for tongue reconstruction using a chimeric innervated vastus lateralis muscle and anterolateral thigh fasciocutaneous flap. Inclusion criteria were ≥ 50% resection of the oral tongue. Participants were followed longitudinally, with measures recorded at baseline, 6–8 weeks, 6 months, and 12 months after surgery. The primary endpoints were post-operative complications, time to radiotherapy, operative time, and locoregional failure, videofluoroscopy swallow studies (dynamic imaging grade of swallowing toxicity (DIGEST), penetration and aspiration score, performance status scale for head and neck). Secondary endpoints were patient-rated outcomes.

Results: Eighteen participants were recruited (10 intervention: 8 controls). Fourteen (78%) experienced complications, only one of which was related to the innervated flap. DIGEST scores deteriorated post-operatively across all participants but did not differ significantly between the intervention and control groups ($p = 0.4$) at any point post-surgery, despite more extensive resections in the intervention group. Those in the intervention group had better patient-rated intelligibility ($p = 0.04$). Multimodality treatment was associated with worse speech ($p = 0.03$) and normalcy of diet ($p = 0.02$). Less extensive resections were associated with better scores in eating in public ($p = 0.005$), tongue range of movement ($p = 0.0008$), intelligibility ($p = 0.006$), and diet ($p = 0.001$).

Conclusions: The innervated vastus lateralis and antero-lateral thigh free-flap technique is safe and improves speech intelligibility for patients with subtotal and total glossectomy defects. However, the technique requires refinement to optimize functional and quality-of-life outcomes.

1 | Introduction

Advanced tongue cancer that requires subtotal or total glossectomy is an unequivocally debilitating diagnosis. Quality of life is heavily compromised due to the severe impact of surgery on swallowing function and speech in those patients who survive the disease. Many patients rely on enteral feeding tubes to maintain nutrition [1], oral prosthetic rehabilitation [2, 3], and alternative or augmented communication options to supplement natural speech and maintain vocational and relationship roles [4, 5]. While survival, functional, and quality-of-life outcomes for early-stage tongue cancer are comparatively favorable [6, 7], all three outcomes are compromised for those who have more advanced disease [8]. This is of increasing concern, given that oral cancer is among the most common malignancies worldwide, associated with smoking, alcohol, and betel nut chewing, but also increasing in young people under the age of 45 who do not hold these risk factors [9]. Due to the significant morbidity associated with a subtotal or total glossectomy, both disease control and quality of life are considered synonymously in treatment planning.

Outside of improving screening for oral cancers to identify and treat cancers prior to their progression to late-stage disease, there are three main opportunities to optimize the functional outcomes for this challenging cohort of patients: optimizing (a) the surgical technique, (b) the radiation dose, and (c) the rehabilitation program. Ozkan et al. [10] used a chimeric vastus lateralis muscle and (fasciocutaneous) anterolateral thigh (VALT) free flap in a small study of six participants. They showed that the innervated tongue flap facilitated tongue elevation with satisfactory motor and sensory results. Others have studied the impact of radiation-sparing dysphagia and aspiration-related structures (Charters et al.) [11]. Post-operative adjuvant radiation is indicated for disease control in most cases of advanced tongue cancer; however, it is also associated with worse speech and swallowing outcomes [12, 13]. A targeted and individualized rehabilitation program is also indicated for this cohort, ideally starting prior to treatment. The two major opportunities for rehabilitation are exercise-based therapy and prosthodontic rehabilitation [3, 14].

At our center, the aim of reconstructive measures for glossectomy defects after cancer surgery is to provide sufficient passive tissue that may be moved by remaining functional tongue muscles. This concept works well in partial glossectomies, where the tongue's contralateral side retains its musculature, motor innervation, and sensation. However, in formal hemiglossectomies and subtotal and total glossectomies, the remaining muscle function is minimal, as most of the intrinsic and extrinsic tongue muscles are excised, and the hypoglossal neurovascular bundle is resected at least ipsilaterally. We have successfully used the VALT flap in facial reanimation surgery [15, 16]. In the subtotal/total glossectomy setting, it provides soft tissue bulk and contractile muscle elements that could provide a vector of movement able to facilitate the movement of the food bolus toward the pharynx and allow occlusion of the pharyngeal vestibulum during swallowing. The rationale of this study is to explore the potential of the innervated VALT flap with regard to swallowing and speech compared to standard non-innervated reconstruction. Our aim was to establish a standard protocol for VALT reconstruction, enabling a robust scientific evaluation of functional outcomes. We hypothesized that VALT reconstruction of subtotal and total glossectomy defects improves speech and swallowing function and quality of life.

2 | Materials and Methods

Ethical approval was granted by the Royal Prince Alfred Research and Ethics Committee, Protocol X19-0412 & 2019/ETH12967. All participants provided written informed consent.

This study is an open-label, non-randomized, controlled multisite pilot trial involving recruitment at one metropolitan and one regional cancer center. Patients were eligible if they were at least 18 years old and had been diagnosed with oral cancer that required a resection involving ≥ 50% of their oral tongue and/or tongue base, including the neurovascular pedicle on at least one side. Patients were excluded if the hypoglossal nerve was preserved bilaterally, if they had no residual hypoglossal nerve suitable for coaptation, if they had a congenital or acquired neuro-degenerative disorder, or if they had any other condition that may interfere with their ability to understand the requirements of the study or give informed consent. Participants were recruited consecutively between October 2020 and April 2022.

Suitability for VALT reconstruction was discussed in a head and neck cancer multidisciplinary team (MDT) meeting. This decision was based on the nature of the surgical defect, the burden of disease, comorbidities of the patient, and their willingness to participate. Demographic and clinicopathological data were recorded, including age, sex, tumor subsite, tumor laterality, and staging. Tumor categorization was performed according to the eighth edition of the American Joint Committee on Cancer (AJCC) staging manual. [17].

All participants were seen by a speech pathologist and dietitian prior to, during, and following their treatment, according to departmental standard of care. Swallow rehabilitation included compensatory and rehabilitation exercises specific to the participant's presenting condition, guided by an instrumental swallow assessment.

2.1 | Surgical Procedures

The formal hemiglossectomy, subtotal or total glossectomy, and neck dissection procedures were carried out for all 18 enrolled participants as curative procedures using standard techniques, guided by the extent of the tumor and lymph node metastasis. All resections involved lingual release of the tongue into the cervical wound without mandibulotomy [F 1a]. The extent of the lingual release was determined by the extent of the glossectomy, but was at least a hemilingual release in all cases.

Participants in the interventional group had their reconstruction innervated by raising a VALT free flap [Figures 1b–e and 2a–c] in a standardized fashion by, or under the supervision of, the senior author. The vastus lateralis is raised as a rectangular block of muscle perfused from the distal descending branch of

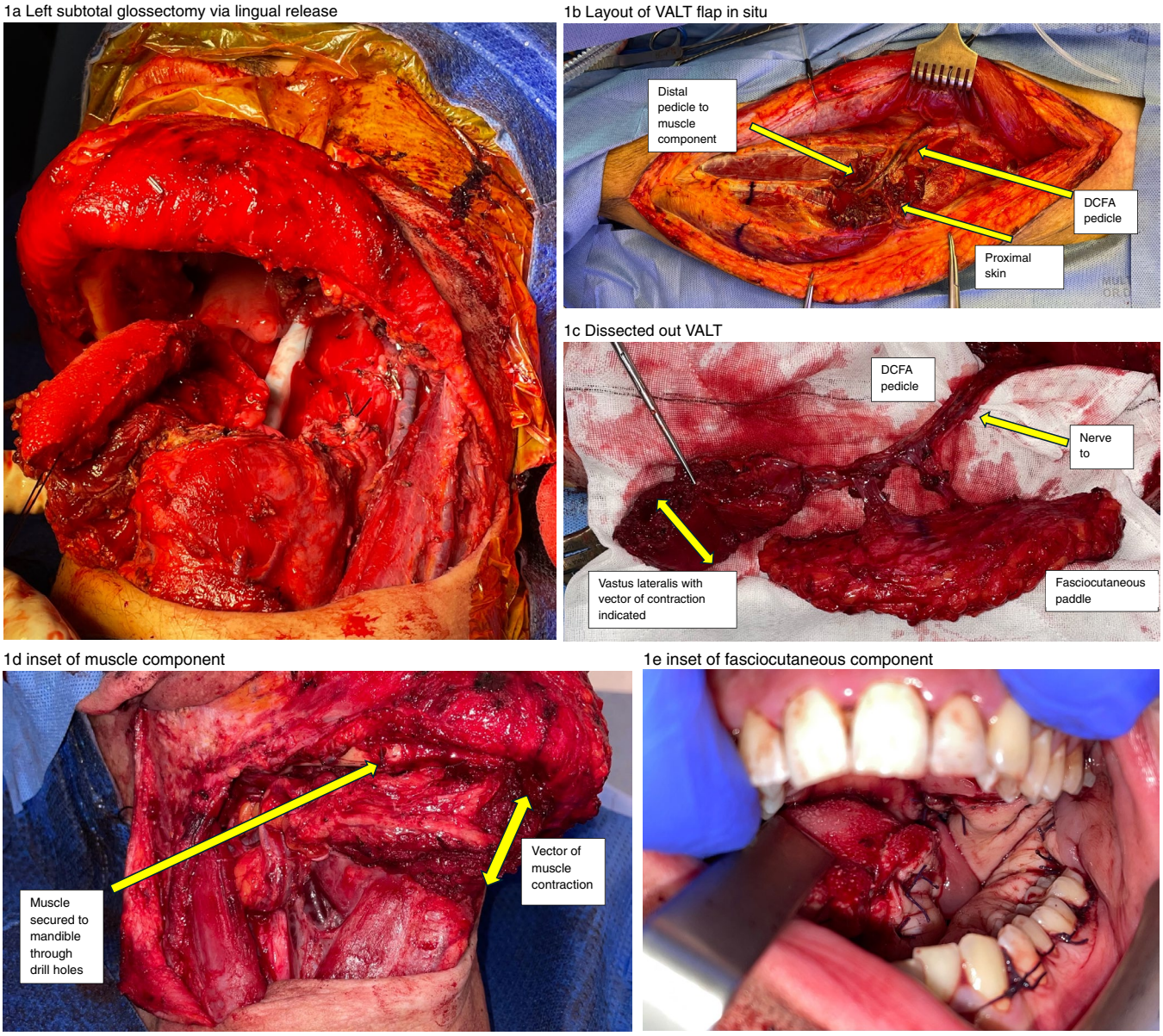

FIGURE 1 | (a) Left subtotal glossectomy via lingual release. (b) Layout of VALT flap in situ. (c) Dissected VALT flap. (d) inset of muscle component. (e) inset of fasciocutaneous component. [Color figure can be viewed at wileyonlinelibrary.com]

the lateral circumflex femoral artery pedicle, with a more proximal branch of the pedicle supplying the perforators to the fasciocutaneous component (1–2 perforators, close together to allow rotation of the skin paddle with respect to the muscle component) [Figure 1b]. The nerve to the muscle component is dissected, and intra-operative stimulation with a nerve stimulator is used to confirm the strength and vector of muscle contraction. The fasciocutaneous component includes the deep fascia, with the thickness varying between patients based on their body habitus. The perforator and pedicle are skeletonized to minimize bulk [Figure 1c]. The muscle paddle is sutured to the hyoid with 3-0 non-absorbable circumferential sutures along the exposed length of the hyoid (the degree of tongue resection determines the degree of hyoid exposure; the larger the resection, the more significant the hyoid exposure), and then to the lingual surface of the exposed mandible with non-absorbable braided sutures (3-0) via drill holes or Mitec (Mitek, Norwood, MA) anchors [Figure 1d]. The extent of the mandible inset again depends upon the extent of the tongue resected. Total and subtotal glossectomy defects included an inset of the vastus to the bilateral mandibular bodies. The vector of contraction is arranged to elevate the hyoid and larynx relative to the mandible upon stimulation, giving both isometric and isotonic contraction, such as to elevate the overlying fasciocutaneous component in a single vertical vector, aiming to obliterate the oral cavity and help propel the food bolus posteriorly. The vastus lateralis nerve branch is shortened as required and anastomosed to the stump of the resected hypoglossal nerve with 3 or 4 epineural sutures [8-0 nylon] and wrapped in a Surgicel sleeve using microsurgical techniques. The fascio-cutaneous flap is trimmed and sutured to the oral mucosa and vallecula defect with 3-0 braided absorbable sutures to form the neo-tongue, aiming for sufficient bulk to provide a convex contour in the oral cavity [Figure 1e].

Participants in the control group underwent reconstruction of the tongue defect with a standard fasciocutaneous

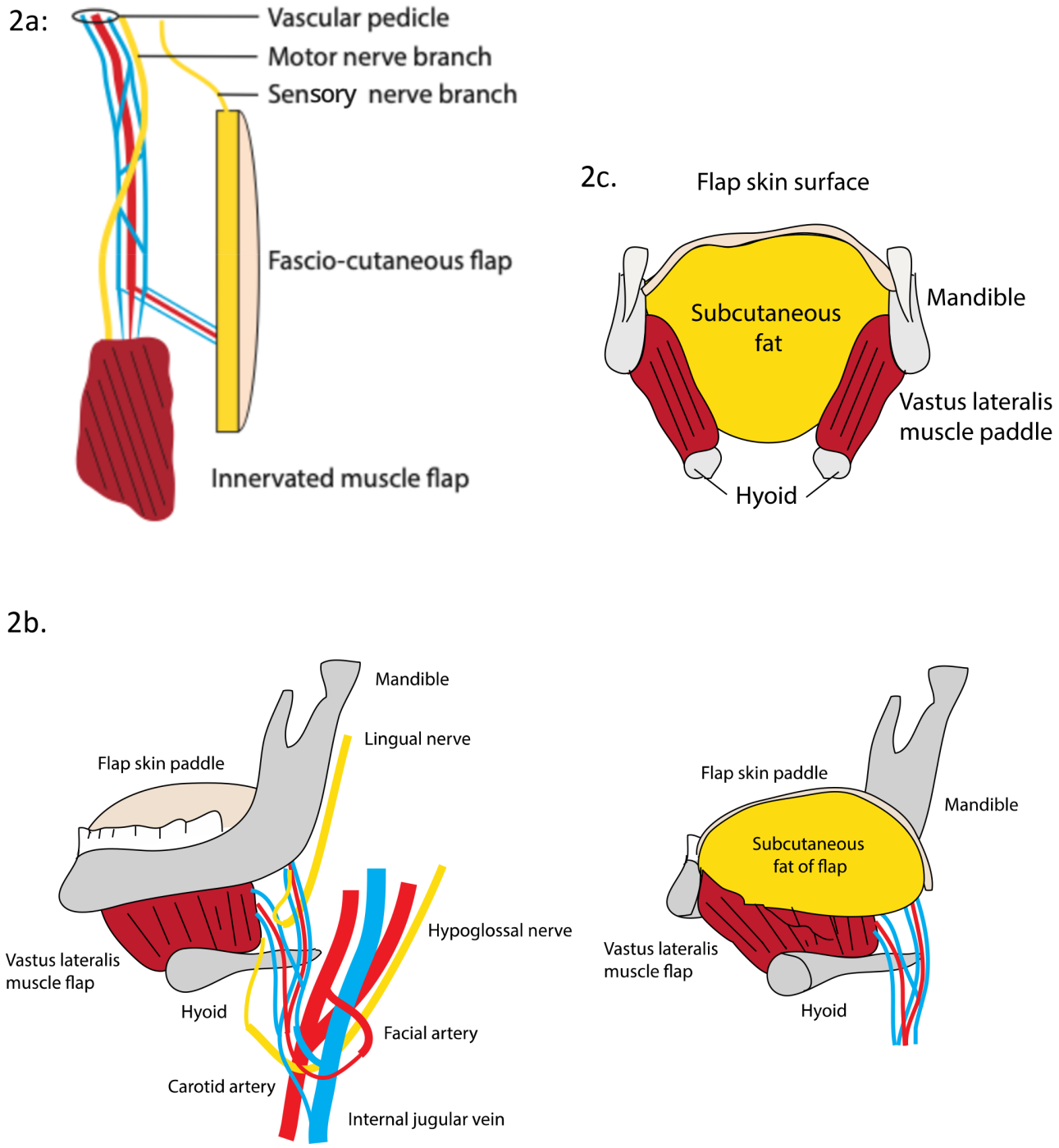

FIGURE 2 | (a) chimeric vastus lateralis and antero-lateral thigh (VALT) free flap. [Color figure can be viewed at wileyonlinelibrary.com]

anterolateral thigh (ALT) free flap pedicled on the descending branch of the lateral femoral circumflex artery and its concomitant veins.

The vascular pedicle is anastomosed to suitable vessels in the neck depending on individual anatomy and the extent of the neck dissection, using microsurgical techniques. The usual recipient artery is the facial, superior thyroid, or external carotid artery. Usually, two venous anastomoses are performed, with at least one vein sutured end to side to the internal jugular vein. Care is taken in each case to avoid kinking and twisting of the pedicle vessels and individual perforators to the muscle and fasciocutaneous components, as well as the neural coaptation. The neck is closed in layers, with drains placed in a routine fashion.

Post-operative surveillance involved monitoring the flap perfusion with Doppler ultrasound, performed hourly in the intensive care unit for the first 48 hours and then 4-hourly. Patients were nourished by nasogastric or percutaneous gastric feeding tubes for the first week, and thereafter, patients were allowed to swallow following speech pathology swallowing function assessment while an inpatient, if suitable. Discharge from the hospital was individually planned according to rehabilitation progress and individual social resources.

2.2 | Functional Evaluation

2.2.1 | Safety Outcomes

The complications of surgery for both the intervention and control groups were rated according to the Clavien–Dindo classification [18]. Complications were further described as medical or surgical [19].

2.2.2 | Functional Assessment

Functional evaluations were conducted using videofluoroscopic swallowing study, speech and intelligibility assessment, range of motion, and oromotor exam at 6–8 weeks, 6 months, and 12 months after surgery. This is composed of the motor and sensory capability of cranial nerves V, VII, IX–XI, and XII. Tongue range of motion was evaluated using the Lingual range-of-motion assessment scale, which categorizes protrusion, lateralization, and elevation from severely impaired to normal (0–100, respectively) [20].

A videofluroscopic swallowing study (VFSS) was conducted with two speech pathologists, a radiologist, and a radiographer. All participants followed the same protocol, involving lateral and anterior–posterior plane views of:

- 2×5 mL thin fluid (ultravist contrast) via cup.
- 2×10 mL thin fluid (ultravist contrast) via cup.
- 2× natural sips of thin fluid (ultravist contrast) via cup.
- 2×10 mL pudding mixed with barium powder via spoon.
- 1× biscuit coated with barium powder paste.

VFSSs were assessed applying the dynamic imaging grade of swallowing toxicity (DIGEST) method, a valid and reliable scoring system that reports the interaction of pharyngeal residue and laryngeal penetration/aspiration ratings on a five-point common terminology criteria for adverse events (CTCAE)–compatible grade [21]. Like the CTCAE, it rates zero as no toxicity (indicating both a safe and efficient swallow function) and four as life-threatening (indicating that swallow safety is severely or profoundly unsafe and inefficient).

To assess speech intelligibility, the percent consonants correct (PCC) score was calculated using the phonetic transcription of the Grandfather Passage Recording, then dividing the number of correct consonants by the total number of consonants in the sample [22–24]. This was then classified into the following: mild (> 85%), mild-moderate (65%–85%), moderate-severe (50%–65%), and severe (< 50%).

2.2.3 | Patient-Reported Outcome Assessments

All participants completed the MD Anderson Dysphagia Inventory (MDADI) [25], the Public Status Scale Head and Neck (PSSHN) [26]. Normalcy of Diet, Public Eating, and Understandability, the Speech Handicap Index (SHI) [27], and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck Module (EORTC QLQ H&N35) [28, 29] at baseline (pre-surgery), 6–8 weeks, 6 months, and 12 months after surgery. The MDADI involves 20 questions investigating how swallowing relates to an individual's global, physical, emotional, and functional swallowing function, where a composite score of 20 would indicate low, and 100 would indicate a high level of function. The PSSHN rates participants using 0 = low functioning and 100 = high functioning according to their (a) normalcy of diet, (b) ability to be understood, and (c) ability to eat in public. The SHI is rated between 0 and 120, where 0 indicates no problems and 120 indicates severe problems. The EORTC QLQ H&N35 consists of 35 questions about symptoms related to the participant's condition during the past week, where a high score denotes high levels of symptom burden [28, 29].

2.3 | Statistical Analysis

The statistical analysis was carried out using R version 3.6.0 (The R Foundation for Statistical Computing). Complications were examined using univariate repeated-measures *t*-tests. Generalized estimating equations (GEEs) were used to model changes in tongue range of movement, SHI, DIGEST, PCC, PSSHN, MDADI, and EORTC QLQ H&N35 scores, adjusting for time post-surgery, intervention versus control group, tumor category, and radiation (pre- or post-surgery) using the geepack and lme4 packages. P values less than or equal to 0.05 were considered statistically significant.

Intra- and inter-rater reliability was carried out following the methodology described in Tohara et al. [30]. Ten randomly selected studies were evaluated by two Speech Pathologists with an average of 8.2 ± 3.4 years of clinical experience working in head and neck oncology. All clinicians had undergone competency training for interpreting VFSS. Each clinician was blinded to the clinical and demographic details, studies were labeled 1–10 and distributed to the speech pathologists for evaluation using the DIGEST scoring form. Each assessor rated each VFSS study two times. Cohen's Kappa was used to assess reliability. Each participant had their VFSS evaluations scored by two assessors, with any discrepancies in scoring discussed and resolved through discussion. If unable to be resolved by discussion with the two assessors, a third assessor was consulted for a final judgment.

3 | Results

A total of 18 participants were recruited, with 8 allocated to the control group and 10 to the intervention group. Their demographic and clinical details are summarized in Table 1. The majority were males, with a mean age of 60 years. There was a statistically significant difference in age between the control group (mean: 66.0, standard deviation: 11.9) and the intervention group (mean: 55.4, standard deviation: 14.8) ($p = 0.002$). There was a difference in the extent of resection between the two groups, with a preponderance of formal hemiglossectomies in the control group. At baseline, the two groups did not differ according to any outcome measure with the exception of EORTC QLQ H&N35, with the control group reporting better health-related quality of life ($p = 0.02$) [Table 2].

TABLE 1 | Demographics and clinical details.

	VALT ($n=10$)	Control ($n=8$)	Total ($n=18$)
Tumor category (T)			
3	7 (70%)	8 (100%)	15 (83%)
4	3 (30%)	0 (0%)	3 (17%)
Nodal category (N)			
0	6 (60%)	5 (62.5%)	11 (61%)
1	1 (10%)	1 (12.5%)	2 (11%)
2	1 (10%)	2 (25%)	3 (17%)
3	2 (20%)	0	2 (11%)
Resection defect			
Hemiglossectomy	2 (20%)	6 (75%)	8 (44%)
Subtotal glossectomy	6 (60%)	2 (25%)	8 (44%)
Total glossectomy	2 (20%)	0	2 (12%)
Gender			
M	8 (80%)	4 (50%)	12 (67%)
F	2 (20%)	4 (50%)	6 (33%)
Age			
Mean (range)	55.4 (25–80)	66.0 (57–79)	60.1 (25–80)
Adjuvant radiation therapy			
66Gy/30#	5 (50%)	1 (12.5%)	6 (33%)
60Gy/30#	3 (30%)	4 (50%)	7 (39%)
Nil	0 (0%)	2 (25%)	2 (11%)
Prior radiation	2 (20%)	1 (12.5%)	3 (33%)
Adjuvant chemotherapy			
Yes	3 (30%)	1 (12.5%)	4 (22%)
No	7 (70%)	7 (87.5%)	14 (78%)

3.1 | Safety

According to the Clavien–Dindo classification, 16 complications occurred in 14 of 18 patients (77.8%). These were primarily surgical complications related to tumor ablation and oral reconstruction [Table 3]. While a higher percentage of patients in the control group experienced complications following surgery, this did not meet statistical significance ($p=0.4$), nor was there a statistically significant difference in Clavien–Dindo classifications ($p=0.7$).

3.2 | Length of Stay, Time to Radiation, and Operative Time

The length of stay (LOS) ranged from 10 to 23 days (median: 14, mean: 14.8). In the control group, the mean LOS was 14.1 days (11–17 days, standard deviation: 2.4) vs. 15.4 days (10–23 days; standard deviation: 4.9) in the intervention group ($p=0.5$).

Time to radiation for the 12 (66.7%) participants who underwent post-operative radiation therapy, ranged from 4 to 8 weeks. The control group's average time to adjuvant radiation was 6.7 weeks (median: 6.5, range: 5–8 weeks) vs. 6.0 weeks (median: 6 weeks, range: 5–8 weeks) in the intervention group ($p=0.4$). The operative time for the control group mean was 444.1 min (95% CI: 382.2–506.1). This was significantly ($p=0.05$) shorter than the intervention group, for which the mean operative time was 583.2 min (95% CI: 544.0–622.4).

3.3 | Clinician and Patient-Rated Outcome Measures

Intra- and inter-rater reliability was shown to be reliable among the speech pathologist raters (91% and 93% intra- and inter-rater agreement) for videofluroscopy PAS and DIGEST scoring. Univariate analysis on DIGEST scores found all patients deteriorated post-operatively (pre-operative mean: 1.5, 95% CI 0.9–2.0;

TABLE 2 | Multivariate analysis of the clinician and patient-reported outcome in the intervention compared with the control groups.

	Estimate	95% CI	*p*
TONGUE ROM (low score indicates greater dysfunction)			
Intervention: control	25.3	±7.8	0.1
Time point (weeks)	−0.3	±1.2	0.03
T category (4a vs. 3)	−29.9	±8.6	0.05
Radiation (yes)	−21.4	±4.5	0.4
Resection (hemiglossectomy)	28.5	±8.6	0.0008
SHI (high score indicates greater dysfunction)			
Intervention: control	6.1	±5.8	0.5
Time point (weeks)	1.7	±0.1	<0.03
T category (4a vs. 3)	−3.7	±6.8	0.7
Radiation (yes)	11.5	±4.1	0.03
Resection (hemiglossectomy)	−11.4	±9.1	0.3
PCC reading (low score indicates greater dysfunction)			
Intervention: control	−7.9	±4.1	0.2
Time point (weeks)	−0.2	±0.1	0.1
T category (4a vs. 3)	7.9	±5.5	0.05
Radiation (yes)	1.3	±3.3	0.7
Resection (hemiglossectomy)	13.4	±4.8	0.006
PCC conversation (low score indicates greater dysfunction)			
Intervention: control	−9.1	±4.0	0.2
Time point (weeks)	−0.2	±0.1	0.08
T category (4a vs. 3)	−24.8	±5.0	0.05
Radiation (yes)	−11.4	±3.2	0.2
Resection (hemiglossectomy)	13.5	±3.4	0.003
PSSHN INTEL (low score indicates greater dysfunction)			
Intervention: control	4.6	±4.5	0.4
Time point (weeks)	−0.1	±0.1	0.7
T category (4a vs. 3)	−20.4	±5.2	0.1
Radiation (Yes)	8.4	±2.9	0.1
Resection (hemiglossectomy)	10.6	±5.3	0.1
PSSHN PE (low score indicates greater dysfunction)			
Intervention: control	−18.5	±6.2	0.01
Time point (weeks)	−0.1	±0.1	0.7
T category (4a vs. 3)	−39.9	±7.0	0.009
Radiation (yes)	−13.7	±4.8	0.5
Resection (hemiglossectomy)	25.1	±6.1	0.005
PSSHN NOD (low score indicates greater dysfunction)			
Intervention: control	−5.8	±5.7	0.5
Time point (weeks)	−0.1	±0.1	0.6
T category (4a vs. 3)	−0.3	±5.3	0.9
Radiation (yes)	−15.4	±4.0	0.04
Resection (hemiglossectomy)	22.9	±4.6	0.001
MDADI (low score indicates greater dysfunction)			
Intervention: control	2.6	±3.4	0.6
Time point (weeks)	−0.1	±−0.1	0.4
T category (4a vs. 3)	−20.3	±3.9	0.001
Radiation (yes)	−8.5	±2.9	0.03
Resection (hemiglossectomy)	12.1	±3.6	0.4
DIGEST total (high score indicates greater dysfunction)			
Intervention: control	0.3	±2.5	0.4
Time point (weeks)	0.02	±0.1	0.0002
T category (4a vs. 3)	−0.7	±0.2	0.05
Radiation (Yes)	0.5	±0.1	0.5
Resection (hemiglossectomy)	−9.4	±	0.2
EORTC QLQ H&N35 (high score indicates greater dysfunction)			
Intervention: control	5.0	±6.5	0.5
Time point (weeks)	0.05	±0.1	0.8
T category (4a vs. 3)	3.8	±6.7	0.09
Radiation (yes)	16.4	±4.4	**0.02**
Resection (hemiglossectomy)	−4.0	±5.2	0.6

Abbreviations: CI, confidence intervals; DIGEST, dynamic imaging grade of swallowing toxicity; EORTC QLQ H&N35, European Organisation for research and treatment of cancer quality of life questionnaire head and neck module; GEE, generalized estimating equations; MDADI, MD Anderson Dysphagia Inventory; PCC, percentage of consonants correct; PSSHN INTEL, performance status scale head and neck intelligibility; PSSHN NOD, performance status scale head and neck normalcy of diet; PSSHN PE, performance status scale head and neck public eating; ROM, range of motion; SHI, speech handicap index; T, tumor.

post-operative mean: 2.8, 95% CI 2.5–3.0). There was no statistically significant difference ($p = 0.8$) between the control group (mean: 2.8, 95% CI 2.4–3.1) and the intervention group (mean: 2.6, 95% CI 2.5–3.0) at any time point.

TABLE 3 | Free-flap complications and classification according to the Clavien–Dindo system [18].

	Complication	Clavien–Dindo rating and frequency	Surgical or medical	Flap related
Intervention $n=10$	Venous congestion of native tongue	2	Surgical	No
	Orocutaneous fistula	4/8 (50%)	Surgical	Yes
	Deranged BSLs secondary to NG feeds		Medical	No
	Cellulitis on the proximal left neck dissection wound	3a	Surgical	No
	Ischemic tongue—Abx and debridement with leeches	1/8 (12.5%)	Surgical	No
	RTT for suspected hematoma. No hematoma, but chyle leak found.	3b	Surgical	No
	Left supraclavicular collection—evacuated	3/8 (37.5%)	Surgical	No
	Submental neck swelling—RTT		Surgical	No
Control $n=8$	Frontal ICH—conservatively managed	2	Medical	No
	Wound infection	4/8 (50%)	Surgical	No
	Recurrence of ascites		Surgical	No
	Dehiscence at the tip of the inset		Surgical	Yes
	Tongue ulceration requiring liposuction, flap reduction with lateral ellipse excision, and primary closure	3b	Surgical	Yes
	Wound dehiscence—RTT	4/8 (50%)	Surgical	No
	ALT skin paddle ischemic RTT for removal and primary closure		Surgical	Yes
	Neck hematoma evacuated		Surgical	No

Abbreviations: Abx, antibiotics; ALT, anterolateral thigh; BSLs, blood sugar levels; ICH, intracranial hemorrhage; RTT, return to theatre.

- Multivariate analysis found that multimodality treatment involving surgery followed by post-operative adjuvant chemo/radiation had a negative impact on speech-related quality of life (SHI estimate = 11.5, $p=0.03$), diet (PSSHN NOD estimate = −15.4, $p=0.04$) swallow-related quality of life (MDADI estimate = −8.5, $p=0.03$), and quality of life (EORTC estimate = 16.4, $p=0.02$) (Table 3). The intervention group had superior speech intelligibility (PSSHN Intelligibility estimate = 4.6, $p=0.04$) and public eating (PSSHN PE estimate 18.5, $p=0.01$); however, all other functional and quality of life outcomes did not differ between the intervention and control groups. Those with more advanced cancer (T4a) had worse swallow function (DIGEST estimate = −0.7, $p=0.05$, PSSHN estimate: −39.9, $p=0.009$) and swallow-related quality of life (MDADI estimate: −20.3, $p=0.001$) than those classified with T3 tumors. The control group had a shorter average length of feeding tube duration (184 [range 10–365] compared to 275 [range 46–365] days); however, this did not reach statistical significance ($p=0.2$). Those with more extensive resections (subtotal or total glossectomy) had worse tongue ROM (estimate: 28.5, $p=0.0008$), reading and conversational intelligibility (estimates: 13.4, $p=0.006$ and 13.5, $p=0.003$, respectively), and normalcy of diet ($p=22.9$, $p=0.001$).

4 | Discussion

The impact of subtotal/total glossectomy followed by (chemo-) radiation on function and quality of life cannot be overstated. This study pilots a new technique intended to improve patient outcomes by evaluating the functional and quality of life outcomes for 18 patients who underwent hemi, subtotal, or total glossectomy undergoing reconstruction with innervated VALT free flaps compared to standard fasciocutaneous reconstruction. It demonstrates that there are possible speech intelligibility advantages for the intervention group, and overall, the results between the groups are comparable despite significantly larger resections [and thus reconstructions] being undertaken in the intervention group. The impact on perceived speech intelligibility may have been related to either bulk from the VALT free flap, the presence of a functional muscular sling beneath the reconstructed tongue, or a combination of both these factors. It should be noted that the resective defects in the intervention group were more significant than

those in the control group, and those with larger resections (subtotal or total glossectomy) had worse outcomes for tongue mobility, speech, and swallowing.

It also identified the pervasive impact that multimodal (surgery with adjuvant radiation) treatment has on quality of life and functional outcomes. It is the first that looks at a reconstruction that involves an innervated vastus lateralis and ALT free flap with a control group who underwent standard reconstruction, concentrating not just on a range of motion or sensation but on the prospectively collated functional outcomes that follow. Previous studies exploring the use of motorized myocutaneous free flaps have indicated that this procedure may offer an advantage for swallowing function; [30–33] however, this was not found in this study. The differing findings can be explained by multiple covariates, low participant numbers, and differing measures of swallow function. It is imperative moving forward that outcomes are streamlined to make meaningful comparisons between groups. However, the demonstration of comparable swallowing outcomes, despite more extensive resections in the intervention group, does suggest benefits with this technique.

Early-stage diseases requiring less-extensive surgery, which maintains a greater volume of the native tongue, such as a hemi or partial glossectomy, have superior functional and quality-of-life outcomes than those with advanced disease requiring more extensive resection [34, 35]. Swallowing and speech impairment after subtotal or total glossectomy remain a challenging problem [34], particularly given the rising incidence of tongue cancer in young people who will live with the functional and quality-of-life challenges associated with a glossectomy throughout their lives [9]. Rehabilitation using exercises and prosthetic innovations has shown some positive results, but both require some degree of innervated movement to work with [36, 37]. Therefore, the concept of introducing an innervated free flap is of great interest.

The authors did not anastomose a sensory nerve from the ALT to the lingual nerve as originally proposed in the study design. As all resections were done via a lingual release, access to the lingual nerve stump was technically challenging in the already complex reconstructive surgical field and was therefore abandoned. The main potential benefit of this flap was thought to be from the motor reconstruction component.

A further technical challenge in this series related to the length of innervated muscle used in the reconstruction. The lower border of the mandible and the hyoid are only 1–2 cm apart in the normal physiological position, so the investigators only interposed a short length of muscle between these two bony fixation points in the hope of achieving an isotonic and isometric contraction that would elevate the soft tissue paddle of the flap. The complex nature of both the reconstruction and the surgical field in which it occurs, where post-operative scarring and the effects of radiotherapy are difficult to predict, made planning for the anticipated vector and amplitude of muscle movement difficult to estimate. Subjectively, elevation of the fasciocutaneous component of the flap in the intervention group was observed in some patients when they were asked to protrude their tongue. However, due to the highly subjective nature of this assessment, it was not included as a data point in this study.

It is apparent that an innervated vastus lateralis and antero-lateral thigh free flap may help improve some aspects of speech and swallowing. In the interim, patients will continue to rely heavily on either physiological or prosthetic rehabilitation to address the significant and lasting impact that a subtotal or total glossectomy, particularly those whose surgery is followed by radiation, has on a patient's life. This paper raises an intra-operative surgical innovation that could be advantageous for post-operative rehabilitation. It reports on both patient- and clinician-reported outcomes, including instrumental swallowing assessments. It uses blinded assessors to report on swallowing physiology, follows patient outcomes longitudinally, and draws from two major oncology centers comprising patients based in both metropolitan and regional centers. Future studies could utilize electromyography to understand when and what movement is achieved in each group, which could then guide clinicians how best to teach patients how to turn movement into function.

There are several limitations to this study. The study intended to establish a standardized protocol for VALT reconstruction with sufficient scientific rigor to evaluate the surgical approach and clinical outcomes first for safety and efficacy, and second as a basis for future refinement of the surgical technique. Therefore, the study was not powered to discover subtle improvements in functional and quality-of-life outcomes. As a result of a small participant number in this exploratory study, we also were unable to control for differences between tumor subgroups, and in particular, the preservation or sacrifice of the base of the tongue in the resection. The control group consisted primarily of formal hemiglossectomies, with the tongue base being resected in all but one case. The intervention group had only two formal hemiglossectomies, both of which involved tongue base resection, and the remaining eight defects were either subtotal glossectomies with only a small remnant of contralateral oral tongue/tongue base remaining or total glossectomy defects. Second, the non-randomized group designation introduces allocation bias between the groups. Allocation to the respective groups was done at the discretion of the surgeon and MDT, where those considered suitable were selected based on demographic and clinical factors, a finding reflected in the higher mean age of the control group. An adequately powered study for this patient population is challenging to achieve given the relative rarity of this stage of disease. Similarly, true randomization of these patients would be challenging given the complex nature of both their disease and reconstructive requirements. Finally, while the intervention was analyzed using both validated instrumental and patient-reported measures, the degree of hyoid elevation as a result of hypoglossal input was not measured. This will be an outcome of interest for future studies.

5 | Conclusions

Advanced tongue cancer requiring a subtotal or total glossectomy significantly impairs swallowing, speech function, and quality of life. The use of the innervated vastus lateralis and antero-lateral thigh free flap is a safe and reproducible technique that may offer an advantage of speech intelligibility in this patient group; however, future studies could modify the surgical technique to maximize its impact.

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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