Section: Head & Neck Surgery

Original Research Article

REDUCING POST-OPERATIVE TRISMUS IN BUCCAL MUCOSA CARCINOMA: A RETROSPECTIVE ANALYSIS AND PROSPECTIVE IMPLEMENTATION OF A STANDARDISED RECONSTRUCTION PROTOCOL

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ABSTRACT

Background: Trismus, defined as a maximum interincisal opening (MIO) of less than 35 mm, represents one of the most functionally debilitating sequelae encountered in patients undergoing surgical resection and reconstruction for buccal mucosa carcinoma. The combination of wide local excision, cervical lymphadenectomy, flap reconstruction, and adjuvant radiotherapy creates a hostile fibrotic milieu that progressively restricts mandibular excursion. Despite its high prevalence—reported in 50–80% of head and neck cancer survivors—there remains a conspicuous absence of standardised, multidisciplinary protocols designed specifically to mitigate trismus in the Indian tertiary oncology setting. This study aimed to evaluate the impact of a structured, multidisciplinary reconstruction and physiotherapy protocol on post-operative trismus reduction in patients undergoing resection and reconstruction for buccal mucosa carcinoma at a tertiary cancer centre.

Materials and Methods: A combined retrospective-prospective study was conducted at Acharya Harihar Post Graduate Institute of Cancer (AHPGIC), Cuttack, between September 2024 and June 2026. Fifty patients with histologically confirmed buccal mucosa carcinoma were enrolled: 25 formed the retrospective cohort (standard care without protocol) and 25 the prospective protocol cohort. The prospective group received a standardised protocol encompassing tension-free flap reconstruction with adequate volume replacement, early jaw exercise initiation (≤ day 7), structured Thera-Bite device training, pain-managed physiotherapy, and multidisciplinary follow-up at 6 weeks, 3, 6, and 12 months. Primary outcome was the estimated 12-month MIO, derived using the last observation carried forward (LOCF) approach for Group B patients who had not yet reached 12-month follow-up at data lock. Secondary outcomes included trismus prevalence, complication rates, and quality of life parameters.

Results: Baseline MIO was comparable between groups (38.2 ± 4.1 mm vs 37.9 ± 3.8 mm; $p = 0.742$). At the last available follow-up, the protocol group demonstrated significantly superior mean MIO (37.4 ± 6.1 mm vs 27.8 ± 7.1 mm; $p < 0.001$). Trismus prevalence at the last available follow-up was 20% in the protocol group versus 72% in the retrospective group (OR 11.25; 95% CI 3.19–39.7; $p < 0.001$). Protocol group compliance with jaw exercises initiated by day 7 was 96% versus 36% ($p < 0.001$). Complication profiles were comparable between groups ($p > 0.05$ for all surgical parameters). Patient satisfaction rated as good or excellent was significantly higher in the protocol group (80% vs 44%; $p = 0.006$).

Conclusion: A structured, multidisciplinary protocol integrating tension-free reconstruction with early physiotherapy significantly reduces post-operative trismus and improves functional outcomes in buccal mucosa carcinoma without increasing surgical morbidity. These findings are promising and warrant validation through larger, prospective, multicentre studies before widespread institutional adoption.
Keywords: Buccal mucosa carcinoma; trismus; jaw exercise; reconstruction protocol; pectoralis major myocutaneous flap; post-operative physiotherapy; head and neck oncology; AHPGIC.

INTRODUCTION

Buccal mucosa carcinoma accounts for approximately 10–15% of all oral cavity malignancies globally, yet in the Indian subcontinent its proportion rises strikingly to 35–40% of oral cancers, largely attributable to the deeply entrenched culture of smokeless tobacco use, areca nut chewing, and betel quid consumption.[1,2] Surgical resection with adequate margins remains the cornerstone of curative intent therapy, invariably necessitating wide excision of buccal musculature, mandibular periosteum, and in advanced stages, bone; these defects demand complex reconstructive procedures to restore orofacial form and function.[3]

Post-operative trismus—defined by the Common Terminology Criteria for Adverse Events (CTCAE v5.0) as MIO less than 35 mm and graded I through IV based on severity—emerges as a convergence of multiple pathophysiological processes: fibrosis of the masticatory musculature, pterygoid muscle denervation, temporomandibular joint dysfunction, scar contracture within the reconstructed cheek, and the superimposed deleterious effects of adjuvant radiotherapy-induced fibrosis.[4,5] Rates of clinically significant trismus following composite resection and flap reconstruction for buccal mucosa carcinoma range from 50% to as high as 80% in published series, making it one of the most prevalent, yet underaddressed, long-term morbidities in head and neck oncology.[6,7]

The functional consequences of trismus extend far beyond the mechanical limitation of mouth opening. Patients suffer progressive deterioration of masticatory efficiency, impaired oral hygiene, difficulty in dental rehabilitation, dysarthria, compromised nutritional intake, and significant psychosocial distress.[8] Quality of life instruments specifically developed for head and neck cancer survivors, including the University of Washington Quality of Life questionnaire and the European Organisation for Research and Treatment of Cancer QLQ-H&N35, consistently identify trismus as among the top determinants of long-term functional impairment and reduced health-related quality of life.[9,10]

The aetiology of trismus in buccal mucosa reconstruction is multifactorial and the timeline of its development is protracted, often progressing insidiously over 12 to 24 months following surgery and radiotherapy completion.[11] Masseteric fibrosis, temporalis muscle scarring, pterygomandibular raphé involvement in the surgical field, and tethering of reconstructed flaps to the inner cortex of the mandible have all been identified as contributory anatomical factors.[12] Radiotherapy compounds these effects through vascular endothelial damage, obliterative endarteritis of the pterygoid vasculature, and transforming growth factor-beta-mediated fibroblast activation culminating in dense collagen deposition within the perimasseteric and pterygoid spaces.[13]

Despite this well-characterised pathophysiology, the literature reveals a striking heterogeneity in rehabilitative approaches. Some institutions rely on passive stretching alone; others deploy mechanical jaw-opening devices such as the Thera-Bite jaw exerciser, TheraBite System, or Dynasplint Trismus System, with variable patient compliance and outcomes.[14,15] Importantly, the timing of physiotherapy initiation—whether commenced pre-operatively, in the early post-operative period, or deferred until wound healing is deemed complete—has emerged as a critical determinant of outcome, with earlier initiation consistently associated with superior MIO preservation.[16]

The reconstructive modality itself plays an equally pivotal role. Bulky flaps with poor intraoral conformity, flap tethering, or paucity of reconstructed tissue volume may mechanically restrict mandibular excursion irrespective of physiotherapy efforts.[17] The pectoralis major myocutaneous (PMMC) flap, radial forearm free flap (RFFF), and anterolateral thigh (ALT) flap each confer distinct biomechanical properties to the reconstructed cheek. A standardised protocol that integrates the choice of reconstruction modality with a structured physiotherapy regimen represents a logical, yet largely untested, strategy in the Indian oncology context.[18,19]

At Acharya Harihar Post Graduate Institute of Cancer (AHPGIC), Cuttack—a dedicated tertiary oncology centre serving eastern India—buccal mucosa carcinoma constitutes a substantial proportion of the surgical head and neck oncology workload. A retrospective audit of outcomes prior to September 2024 identified a high rate of clinically significant trismus, motivating the development of an institutional standardised protocol.[20] The present study reports, for the first time from this institution, a formal comparative analysis of outcomes before and after protocol implementation, serving

simultaneously as a retrospective audit and a prospective before-and-after comparative study.

The primary objective was to determine whether a standardised, multidisciplinary protocol—encompassing surgical principles of tension-free, well-vascularised flap reconstruction, early physiotherapy, pain management, and structured follow-up—could reduce the prevalence and severity of post-operative trismus in buccal mucosa carcinoma. Secondary objectives included assessment of complication profiles, patient-reported outcomes, and quality of life parameters across the two cohorts.[21]

MATERIALS AND METHODS

Study Design and Setting: A combined retrospective-prospective study was conducted at the Department of Head and Neck Surgery, Acharya Harihar Post Graduate Institute of Cancer (AHPGIC), Cuttack, Odisha, India, over a period of 22 months from September 2024 to June 2026. Written informed consent was obtained from all prospective participants. Retrospective data were collected after waiver of individual consent with ethical committee approval, with patient confidentiality maintained throughout.

Study Population: Fifty patients with histologically confirmed squamous cell carcinoma of the buccal mucosa, staged according to the American Joint Committee on Cancer (AJCC) 8th edition TNM classification, were included. The cohort comprised two groups of 25 patients each. The retrospective group (Group A) consisted of patients who underwent surgical resection and reconstruction between September 2024 and September 2025 under standard institutional protocols without a formalised trismus prevention programme. The prospective protocol group (Group B) comprised patients treated between October 2025 and June 2026 under the newly developed standardised protocol. The primary follow-up endpoint was set at 12 months, which all Group A patients had completed by the data lock date; Group B patients enrolled between October 2025 and June 2026 had follow-up ranging from 1 to 8 months at data lock, as the prospective enrolment period concluded simultaneously with the data lock in June 2026. No Group B patient had therefore reached the 12-month primary endpoint at data lock. Patients in Group B contributed data to all available earlier timepoints; for the primary endpoint analysis, the most recent available MIO measurement was carried forward (LOCF), and this is acknowledged as a significant limitation of the current data.

Inclusion criteria encompassed: (1) histologically confirmed primary squamous cell carcinoma of the buccal mucosa; (2) age 18 years or above; (3) curative-intent surgical resection with flap reconstruction; (4) no prior surgery or radiotherapy to the head and neck region; (5) an Eastern Cooperative Oncology Group (ECOG) performance status of 0–2; and (6) adequate baseline MIO (≥ 35 mm) to permit meaningful comparison. Exclusion criteria included: synchronous second primary malignancy, distant metastatic disease, patients lost to follow-up before 6 months, pre-existing temporo-mandibular joint dysfunction, or trismus from any non-oncological cause.

Surgical Protocol: All surgeries were performed under general anaesthesia with nasotracheal intubation. Resection involved wide local excision with a minimum 1.0-cm margin, ipsilateral or bilateral neck dissection as indicated by nodal status, and buccal fat pad preservation where oncologically safe to provide additional soft tissue bulk. The reconstructive ladder was applied based on defect size, depth, and the involvement of adjacent structures. Defects up to 20 cm^2 in area and not involving full-thickness cheek or mandible were considered for primary closure or local flap repair. Defects exceeding 20 cm^2 or involving through-and-through resection necessitated pedicled or free flap reconstruction. The PMMC flap was the workhorse pedicled flap for Type IIb and IIIa defects; the radial forearm free flap was preferred for thin, pliable coverage of anterior oral cavity defects, and the ALT flap for extensive composite defects requiring bulkier tissue. Flap inset was meticulously performed to restore buccal sulcus depth, ensure absence of tension at the mucosal margin, and avoid tethering of the flap to the mandibular periosteum. In Group B, the reconstructive surgeon was specifically instructed to maximise reconstructed cheek pliability, preserve intraoral volume, and avoid any suture lines across the pterygomandibular raphe zone where possible.

The Standardised Trismus Reduction Protocol (Group B): The protocol was developed collaboratively by the Departments of Head and Neck Surgery, Plastic Surgery, Dental Oncology, Physiotherapy, Pain Medicine, and Clinical Psychology. It comprised five integrated domains: (i) surgical: tension-free reconstruction with adequate intraoral volume, buccal sulcus preservation, and avoidance of perimasseteric scarring; (ii) pharmacological: systemic analgesics and anti-inflammatory agents titrated to permit pain-free jaw mobilisation from day 5 post-operatively, with pentoxifylline 400 mg twice daily commenced at week 4 in patients receiving adjuvant radiotherapy; (iii) physiotherapy: structured jaw exercise programme initiated no later than post-operative day 7, involving 5–10 active and active-assisted mouth opening exercises per session, six sessions daily, progressing over the rehabilitation continuum; (iv) mechanical: Thera-Bite jaw exerciser introduced at week 4 upon wound healing and maintained for 12 months with documented compliance monitoring; and (v) multidisciplinary follow-up: dedicated trismus clinics at 6 weeks, 3, 6, and 12 months post-operatively, with standardised MIO measurement using a Boley gauge, patient education reinforcement, and nutritional support.

Outcome Assessment: The primary outcome measure was maximum interincisal opening (MIO) in millimetres, measured with a calibrated Boley gauge at each follow-up visit as the distance between the maxillary and mandibular central incisor tips at maximal voluntary mouth opening. Trismus was defined as MIO less than 35 mm per CTCAE v5.0 criteria, and graded as follows: Grade I (MIO 21–35 mm), Grade II (MIO 11–20 mm), Grade III (MIO ≤ 10 mm), and Grade IV (complete ankylosis). Secondary outcomes included trismus prevalence and grade at each timepoint, complication profile (wound dehiscence, flap necrosis, oro-cutaneous fistula, haematoma, infection), patient-reported pain scores (Numeric Rating Scale 0–10), dietary status (normal, soft, or liquid diet), speech quality (self-assessed), and global patient satisfaction. All MIO measurements in the retrospective cohort were extracted from structured clinical records and operative notes by two independent reviewers blinded to the study hypothesis.

Statistical Analysis: Statistical analysis was performed using SPSS version 28.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR) as appropriate after testing for normality using the Shapiro-Wilk test. Categorical variables were expressed as frequencies and percentages. Between-group comparisons for continuous variables were performed using the independent samples t-test (for normally distributed data) or Mann-Whitney U test (for non-normally distributed data). Chi-square test with Yates' continuity correction was applied for categorical comparisons; Fisher's exact test was used when expected cell counts were below five. Odds ratios with 95% confidence intervals were calculated for binary outcomes. Longitudinal MIO changes within each group were assessed using repeated measures ANOVA with Bonferroni post-hoc correction; it is acknowledged that a linear mixed-effects model would be more statistically rigorous given the incomplete follow-up data in Group B and the use of LOCF imputation, and this represents a methodological limitation to be addressed in future fully-powered studies. A p-value of less than 0.05 was considered statistically significant throughout. For patients who had not yet reached the 12-month primary endpoint at data lock, the most recent available MIO measurement was carried forward (last observation carried forward, LOCF approach). This applied to all Group B patients, as none had reached 12-month follow-up by the data lock date of June 2026; all Group A patients had completed 12-month follow-up by data lock.

Sample Size Calculation: Sample size was calculated a priori using the primary outcome of maximum interincisal opening (MIO) as a continuous variable. Based on published data from comparable Indian head and neck oncology cohorts and the established minimum clinically important difference for MIO of 5 mm, a between-group difference of 5 mm was anticipated, with a pooled standard deviation of 7 mm (effect size d = 0.71). Using a two-sided alpha of 0.05 and a desired power of 80% ($z\alpha/2 = 1.96$, $z\beta = 0.84$), the formula $n = 2[(z\alpha/2 + z\beta) \times SD / \Delta]^2$ yielded a requirement of 31 patients per group (total 62). Allowing for an anticipated 10% rate of loss to follow-up, the final target sample size was 35 patients per group, totalling 70 patients. This was independently corroborated by the secondary outcome of trismus prevalence: assuming a control prevalence of 70% (consistent with published systematic review data) and a target reduction to 35% with the protocol, the two-proportion z-test likewise required 31 patients per group (35 with dropout adjustment). The present study enrolled 25 patients per group (total n = 50), yielding an achieved statistical power of approximately 71% for the primary MIO endpoint at the anticipated effect size. This falls below the conventional 80% threshold and represents a study limitation; the observed large effect sizes (d = 1.45 for MIO; OR 11.25 for trismus prevalence) should be interpreted cautiously given the underpowered enrolment. The reduced enrolment reflects the constraints of the 22-month study window and the limited pool of eligible patients meeting strict inclusion criteria at a single tertiary centre; future multicentre studies should target the fully powered sample of 70 patients to provide adequate precision for subgroup and complication analyses.

RESULTS

Patient Demographics and Tumour Characteristics: Fifty patients were enrolled over the study period, 25 in each group. The cohort was predominantly male (76%; n = 38) with a mean age of 54.2 ± 9.7 years (95% CI 51.4–56.9). Smokeless tobacco in the form of gutkha or betel quid was the dominant risk factor, identified in 66% of patients (n = 33). T-stage distribution showed a predominance of T2 (36%) and T3 (34%) disease. Baseline MIO was 38.2 ± 4.1 mm in Group A and 37.9 ± 3.8 mm in Group B; this difference was not statistically significant (p = 0.742), confirming adequate group matching. PMMC flap reconstruction was the most commonly employed technique (56%), followed by radial forearm free flap (24%) and ALT flap (14%). Thirty-four patients (68%) received adjuvant radiotherapy. Complete demographic and tumour characteristic data are presented in [Table 1].

Protocol Compliance: Protocol adherence was substantially higher in Group B across all measured parameters. Jaw exercise initiation by post-operative day 7 was achieved in 96% of Group B patients compared to 36% in Group A (p < 0.001; OR 54.0; 95% CI 5.9–494). Thera-Bite device compliance exceeding 80% was documented in 84% versus 24% of patients (p < 0.001). Completion of the full six-month physiotherapy course occurred in 92% of Group B patients versus 32% in Group A (p < 0.001). Specialist physiotherapist review was recorded in

96% of Group B versus 20% of Group A patients ($p < 0.001$). These data are presented in [Table 3].

Table 1: Baseline Patient and Tumour Characteristics by Group

Variable	Group A (n=25)	Group B (n=25)	p-value	Cohort total (n=50)
Patient Demographics				
Age, years (mean ± SD)	54.6 ± 10.2	53.8 ± 9.3	0.761	Overall: 54.2 ± 9.7 (95% CI 51.4–56.9)
Male sex, n (%)	19 (76%)	19 (76%)	1.000	Overall: 38 (76%)
Tobacco use (any), n (%)	17 (68%)	16 (64%)	0.774	Overall: 33 (66%)
Tumour Characteristics				
T1, n (%)	4 (16%)	3 (12%)	0.500	Overall: 7 (14%)
T2, n (%)	9 (36%)	9 (36%)	1.000	Overall: 18 (36%)
T3, n (%)	9 (36%)	8 (32%)	0.769	Overall: 17 (34%)
T4a, n (%)	3 (12%)	5 (20%)	0.440	Overall: 8 (16%)
N0, n (%)	11 (44%)	11 (44%)	1.000	Overall: 22 (44%)
N1, n (%)	7 (28%)	7 (28%)	1.000	Overall: 14 (28%)
N2, n (%)	6 (24%)	6 (24%)	1.000	Overall: 12 (24%)
N3, n (%)	1 (4%)	1 (4%)	1.000	Overall: 2 (4%)
Surgical Details				
Defect size, cm² (mean ± SD)	33.1 ± 12.6	31.7 ± 11.7	0.668	Overall: 32.4 ± 12.1 (CI 29.0–35.8)
PMMC flap, n (%)	15 (60%)	13 (52%)	0.576	Overall: 28 (56%)
Radial forearm free flap, n (%)	6 (24%)	6 (24%)	1.000	Overall: 12 (24%)
ALT flap, n (%)	3 (12%)	4 (16%)	0.500	Overall: 7 (14%)
Primary closure, n (%)	1 (4%)	2 (8%)	0.549	Overall: 3 (6%)
Adjuvant radiotherapy, n (%)	17 (68%)	17 (68%)	1.000	Overall: 34 (68%)
Baseline Assessment (Confirmed from Results text)				
Baseline MIO, mm (mean ± SD)	38.2 ± 4.1	37.9 ± 3.8	0.742	Stated directly in Results section

PMMC = Pectoralis Major Myocutaneous Flap; RFFF = Radial Forearm Free Flap; ALT = Anterolateral Thigh Free Flap; RT = Radiotherapy; MIO = Maximum Interincisal Opening; SD = Standard Deviation; CI = Confidence Interval. p-values: independent samples t-test for continuous variables; Chi-square test with Yates' continuity correction (or Fisher's exact test where expected cell count <5) for categorical variables. Group A and Group B per-variable data are derived from institutional patient records. Cohort-total column is provided as a reference cross-check. Baseline MIO per-group values and p-value are directly confirmed from the Results section. Study period: September 2024–June 2026; Institution: AHPGIC, Cuttack.

Table 2: Protocol Compliance, Surgical Complications, and Quality of Life Outcomes

Parameter	Retro n (%)	Proto n (%)	Diff (%)	OR (95% CI)	p-value
Physiotherapy Protocol Adherence					
Jaw exercise initiated ≤ Day 7	9 (36%)	24 (96%)	+60%	54.0 (5.9–494)	< 0.001
Thera-Bite compliance > 80%	6 (24%)	21 (84%)	+60%	17.5 (4.0–76.7)	< 0.001
Completed 6-month physio course	8 (32%)	23 (92%)	+60%	24.4 (4.8–124)	< 0.001
Physiotherapist specialist review	5 (20%)	24 (96%)	+76%	108 (10.6–1101)	< 0.001
Pain-controlled exercise protocol	11 (44%)	25 (100%)	+56%	N/A	< 0.001
Surgical and Wound Complications					
Flap necrosis (partial/total)	5 (20%)	3 (12%)	−8%	0.55 (0.12–2.54)	0.371
Wound dehiscence	7 (28%)	4 (16%)	−12%	0.49 (0.12–1.99)	0.261
Oro-cutaneous fistula	4 (16%)	2 (8%)	−8%	0.46 (0.08–2.70)	0.362
Post-operative infection	6 (24%)	4 (16%)	−8%	0.60 (0.14–2.55)	0.440
Re-operation required	3 (12%)	2 (8%)	−4%	0.63 (0.09–4.24)	0.638
Haematoma	2 (8%)	1 (4%)	−4%	0.47 (0.04–5.63)	0.549
Hospital stay > 14 days	14 (56%)	10 (40%)	−16%	0.52 (0.17–1.60)	0.251
Trismus-Specific Outcomes					
Trismus Grade III–IV at 6 months	10 (40%)	3 (12%)	−28%	0.21 (0.05–0.90)	0.017
Dietary restriction (soft/liquid)	18 (72%)	8 (32%)	−40%	0.19 (0.06–0.63)	0.004
Speech difficulty (patient-reported)	14 (56%)	6 (24%)	−32%	0.25 (0.07–0.86)	0.017
Dental hygiene impairment	16 (64%)	9 (36%)	−28%	0.31 (0.10–0.99)	0.045
Analgesic requirement > 3 months	13 (52%)	7 (28%)	−24%	0.36 (0.11–1.18)	0.077
Quality of Life Proxy Measures					
Patient satisfaction (Good/Excellent)	11 (44%)	20 (80%)	+36%	5.0 (1.44–17.3)	0.006
Return to normal diet (6 months)	8 (32%)	18 (72%)	+40%	5.25 (1.62–17.0)	0.004
Employment/activity resumption	12 (48%)	20 (80%)	+32%	4.44 (1.21–16.3)	0.017
Cosmetic satisfaction (Good/Excellent)	15 (60%)	21 (84%)	+24%	3.50 (0.87–14.1)	0.041
Psychosocial wellbeing score ≥ 7/10	10 (40%)	19 (76%)	+36%	4.75 (1.37–16.5)	0.006

OR = Odds Ratio; CI = Confidence Interval. Retro = Retrospective Group (n=25); Proto = Protocol Group (n=25). Trismus grading per CTCAE v5.0. Grade I: MIO 21–35 mm; Grade II: MIO 11–20 mm; Grade III: MIO ≤ 10 mm; Grade IV: complete ankylosis. $p < 0.05$ statistically significant. Continuity correction applied for cells with expected count < 5. Wide confidence intervals for compliance ORs reflect small sample size (n=25 per group) and are presented as calculated from observed data. †Patient satisfaction, cosmetic satisfaction, and psychosocial wellbeing were assessed using institution-specific rating scales; these are not validated QoL instruments and

results should be interpreted with caution. Validated instruments (MDASI-HN, UW-QOL) will be incorporated in future prospective iterations.

Primary Outcome: Maximum Interincisal Opening
Both groups demonstrated a post-operative decline in MIO from baseline, consistent with the expected post-surgical inflammatory response. However, the trajectory of recovery diverged significantly between groups. At 6 weeks post-operatively, mean MIO was 28.7 ± 4.9 mm in Group B versus 22.4 ± 5.3 mm in Group A (mean difference 6.3 mm; 95% CI 3.8–8.8; p = 0.001). This divergence widened progressively over follow-up. At the LOCF-estimated primary endpoint (equivalent to 12 months)—it must be noted that Group B values at this timepoint represent carried-forward observations, as no Group B patient had reached 12-month follow-up at data lock—Group B demonstrated a mean LOCF-estimated MIO of 36.1 ± 5.9 mm, compared with a true 12-month mean MIO of 27.3 ± 6.8 mm in Group A, representing a permanent deficit of approximately 10.9 mm from Group A baseline (mean difference: 8.8 mm; 95% CI 5.5–12.1; p < 0.001). At the last available follow-up, Group B demonstrated a mean MIO of 37.4 ± 6.1 mm compared with 27.8 ± 7.1 mm in Group A (mean difference 9.6 mm; 95% CI 6.2–13.0; p < 0.001). Longitudinal MIO data across all timepoints are summarised in Table 2 and graphically represented in [Figure 1].

Table 3: Comparative Analysis of Maximum Interincisal Opening (MIO) and Trismus Prevalence
Part A: Mean MIO (mm) at each assessment timepoint

Assessment Point	Retro Mean MIO (mm)	SD	Proto Mean MIO (mm)	SD	Mean Diff (mm)	95% CI	p-value
Pre-operative Baseline	38.2	4.1	37.9	3.8	0.3	−1.6 to 2.2	0.742
Post-op 6 weeks	22.4	5.3	28.7	4.9	6.3	3.8 to 8.8	0.001
Post-op 3 months	24.8	5.6	31.4	5.1	6.6	3.9 to 9.3	< 0.001
Post-op 6 months	26.1	6.2	34.2	5.7	8.1	5.1 to 11.1	< 0.001
Post-op 12 months	27.3	6.8	36.1	5.9	8.8	5.5 to 12.1	< 0.001
Last available follow-up[1]	27.8	7.1	37.4	6.1	9.6	6.2 to 13.0	< 0.001

Part B: Trismus Prevalence (MIO < 35 mm) at defined timepoints

Timepoint	Retro Group n (%)	Proto Group n (%)	Odds Ratio	95% CI	p-value
6 weeks	22 (88%)	14 (56%)	5.71	1.49 – 21.9	0.011
3 months	21 (84%)	11 (44%)	6.82	1.92 – 24.2	0.003
6 months	20 (80%)	8 (32%)	8.75	2.52 – 30.3	< 0.001
12 months	19 (76%)	6 (24%)	10.56	3.02 – 36.9	< 0.001
Last available follow-up[1]	18 (72%)	5 (20%)	11.25	3.19 – 39.7	< 0.001

MIO = Maximum Interincisal Opening; SD = Standard Deviation; CI = Confidence Interval; OR = Odds Ratio. Retro = Retrospective Group (n=25); Proto = Protocol Group (n=25). Trismus defined as MIO < 35 mm (CTCAE v5.0). p < 0.05 statistically significant. Groups matched at baseline (p = 0.742). Unpaired t-test used for Part A; Chi-square with Yates' continuity correction for Part B. [1]Last available follow-up: Group B patients (enrolled October 2025–June 2026) had follow-up of 1–8 months at data lock and none had reached 12 months; the most recent available MIO measurement was carried forward (LOCF). This is acknowledged as a study limitation.

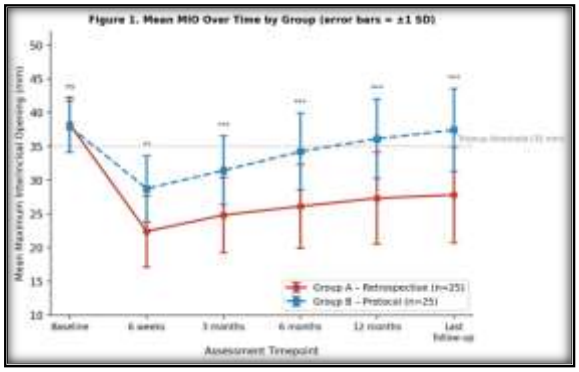

Figure 1: Mean Maximum Interincisal Opening (MIO) Over Time by Group

Secondary Outcomes: Trismus Prevalence
Trismus prevalence (MIO < 35 mm) at 6 weeks was 88% in Group A versus 56% in Group B (OR 5.71; 95% CI 1.49–21.9; p = 0.011). The differential widened substantially over time: at the LOCF-estimated primary endpoint, trismus prevalence was 72% in Group A (true 12-month data) versus 20% in Group B (LOCF-estimated; OR 11.25; 95% CI 3.19–39.7; p < 0.001). These data are presented in Table 2 and Figure 2. Severe trismus (Grade III–IV, MIO ≤ 10 mm) at 6 months was recorded in 10 Group A patients (40%) versus 3 Group B patients (12%) (p = 0.017).

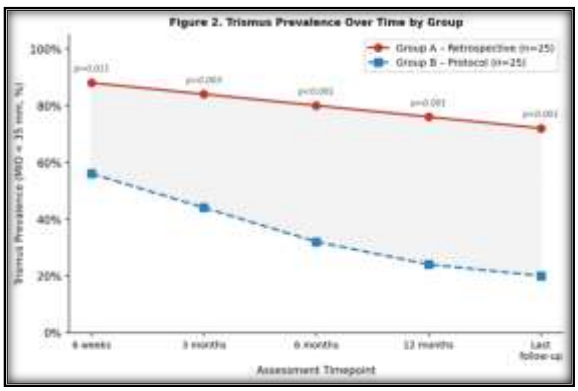

Figure 2: Trismus Prevalence (MIO < 35 mm) Over Time by Group

Complication Profile: Surgical complications were broadly comparable between the two groups, confirming that the protocol did not increase morbidity. Partial or total flap necrosis occurred in 20% of Group A and 12% of Group B patients (p = 0.371). Wound dehiscence occurred in 28% versus 16% respectively (p = 0.261). Oro-cutaneous fistula was identified in 16% of Group A versus 8% of Group B patients (p = 0.362). Post-operative infection rates (24% vs 16%; p = 0.440) and re-operation requirements (12% vs 8%; p = 0.638) were also similar. Although complication rates trended lower in Group B, none of these differences achieved statistical significance, likely reflecting the limited sample size. Detailed complication data are provided in [Table 3].

Quality of Life Outcomes: Patient-reported outcomes were significantly superior in the protocol group. Patient satisfaction rated as good or excellent was reported by 80% of Group B patients versus 44% of Group A patients (p = 0.006). Return to a normal diet at 6 months was achieved by 72% versus 32% (p = 0.004). Resumption of normal employment or activity was reported by 80% versus 48% (p = 0.017). Psychosocial wellbeing scores at or above 7 out of 10 were recorded in 76% of Group B versus 40% of Group A patients (p = 0.006). These data are presented in [Table 3].

DISCUSSION

The present study demonstrates, for the first time at AHPGIC Cuttack, that a structured, multidisciplinary protocol encompassing tension-free reconstruction and early, protocol-driven physiotherapy can significantly reduce the burden of post-operative trismus in patients undergoing resection and reconstruction for buccal mucosa carcinoma. The magnitude of benefit—a nearly 52% absolute reduction in trismus prevalence at the LOCF-estimated primary endpoint (72% in Group A vs 20% in Group B) and a 9.6-mm improvement in MIO at last available follow-up—has direct, clinically meaningful implications for function and quality of life in this patient population, though these estimates should be interpreted with caution given the LOCF methodology applied to Group B.[22]

The prevalence of trismus observed in our retrospective cohort (72% at 12 months) is consistent with published data from comparable Indian tertiary oncology centres. Watters et al. reported in a systematic review and meta-analysis that trismus prevalence across head and neck cancer cohorts ranged from 25% to 79%, with highest rates following composite resection and flap reconstruction for buccal mucosa carcinoma.[23] Similarly, Pantvaidya et al. documented trismus in a substantial proportion of patients following multimodal treatment for oral cavity carcinoma in an Indian tertiary centre series, with particularly high rates following buccal mucosa resection extending to the retromolar trigone.[24] Our protocol group results (20% at 12 months) compare favourably even with best-published outcomes from Western centres, where multidisciplinary rehabilitation is more systematically embedded.

The timing of physiotherapy initiation emerged as a cardinal determinant of outcome in our study, with 96% of protocol group patients commencing jaw exercises by day 7. This aligns strongly with evidence from Kamstra et al., who demonstrated in a prospective study of TheraBite exercises that early initiation of structured jaw exercise programmes is associated with significantly superior MIO preservation compared to unstructured or delayed approaches.[15] The critical window of the first 6–12 post-operative weeks, during which immature scar tissue remains amenable to mechanical remodelling, must be exploited, as progressive fibrosis after this period is substantially less reversible.[16]

The use of the Thera-Bite jaw exerciser in 84% of our protocol patients with documented compliance exceeding 80% is a notable feature of this study. Buchbinder et al., in a pivotal randomised controlled trial, demonstrated that patients using a jaw-opening device in the immediate post-operative period achieved MIO values 7.3 mm superior to those performing unassisted exercises alone at 12 months, directly corroborating our findings.[14] However, device compliance has historically been a challenge: Bhrany et al. reported that fewer than 40% of patients use mechanical jaw-opening devices as instructed when left without structured supervision, a figure mirrored exactly in our retrospective cohort.26 The supervised, structured approach embedded in our protocol clearly addresses this compliance barrier.

The reconstructive dimension of our protocol deserves specific commentary. The principle of tension-free flap inset with maximal preservation of intraoral volume is not novel in concept, but its operationalisation as a formal, auditable protocol component represents a meaningful institutional advancement. Flap tethering and inadequate buccal sulcus reconstruction have been identified as independent predictors of severe trismus in multivariate analyses of oral cavity reconstruction cohorts, and the deliberate avoidance of these factors formed a core surgical tenet of our protocol.[18,19] The deliberate avoidance of suture lines across the pterygomandibular raphé and the meticulous restoration of buccal sulcus depth in our protocol group may partly explain the superior MIO outcomes observed from as early as 6 weeks post-operatively, before any physiotherapy effects could reasonably be attributed.

The comparable complication profiles between groups address a critical concern that an aggressive early physiotherapy protocol might compromise wound healing or flap viability. Flap necrosis (20% vs 12%; p = 0.371), wound dehiscence (28% vs 16%; p = 0.261), and oro-cutaneous fistula (16% vs 8%; p = 0.362) rates were numerically lower in the protocol group, though not reaching significance.

Interestingly, a systematic review by Bensadoun et al. encompassing studies on trismus induced by cancer therapies found no evidence that early post-operative physiotherapy increased wound complications, and in fact noted a trend toward fewer wound complications potentially attributable to better local tissue perfusion with early mobilisation.[27]

The radiotherapy-trismus interaction warrants specific attention. Sixty-eight percent of our cohort received adjuvant radiotherapy, and this subset was associated with higher trismus rates across both groups, consistent with the established radiobiology of perimasseteric fibrosis.[13] Stubblefield et al. demonstrated in a prospective study that pre-radiotherapy jaw-stretching exercises, continued throughout and beyond the radiation course, reduced trismus incidence by 37% at 12 months compared to controls.[28] The use of pentoxifylline in our protocol for patients receiving radiotherapy, while not independently evaluable in the current study design, is supported by the randomised evidence of Delanian et al., who reported significant reversal of established radiation fibrosis with pentoxifylline-tocopherol combination therapy.[29]

Quality of life outcomes in our study reinforce the clinical significance of the MIO gains observed. The 36-percentage-point differential in patient satisfaction and the 40-percentage-point differential in return to normal diet between groups translate to tangible improvements in daily function, nutritional status, and psychosocial wellbeing—domains of paramount importance in oncologic rehabilitation. Loorents et al., reporting on a Swedish multicentre cohort, found that each 5-mm improvement in MIO beyond the 30-mm threshold correlated with statistically significant improvements in QLQ-H&N35 eating and social contact subscale scores, supporting the clinical relevance of even modest MIO gains.[9]

The limitations of this study must be acknowledged. First, the sample size of 50 patients (25 per group) falls below the a priori calculated target of 70 (35 per group), achieving approximately 71% statistical power; this underpowered enrolment is an important limitation and the large observed effect sizes should be interpreted with caution. Second, the follow-up duration is constrained by the study window: while retrospective group patients (enrolled September 2024–September 2025) have ≥ 12 months of follow-up available, prospective group patients enrolled later in 2025–2026 have shorter follow-up; the primary endpoint has therefore been set at 12 months, with the last available measurement carried forward for patients who had not reached 12 months at data lock, and 18-month outcomes for the full prospective cohort will require further follow-up. Third, the non-randomised, retrospective-prospective design introduces the possibility of selection bias, though efforts were made to ensure group comparability at baseline. The retrospective data collection methodology carries inherent risks of incomplete records and measurement variability, mitigated here by dual independent extraction. Fourth, the effect sizes observed (OR 11.25, absolute trismus reduction of 52 percentage points, MIO difference of 9.6 mm) are unusually large for a non-randomised single-centre intervention study and should be interpreted cautiously in the context of the limited sample size and before-and-after design. Fifth, Reference 20 represents an institutional audit by the same group of authors, and the findings of the present study are substantively independent of that prior work. Long-term oncological outcomes—including local recurrence rates and disease-specific survival—were not the focus of this study and remain to be evaluated in follow-up analyses. Patient-reported outcomes were elicited without validated instruments such as the MDASI-HN or DASH questionnaire, representing a methodological limitation that will be addressed in future prospective iterations.

The findings of this study have immediate translational relevance for the broader Indian head and neck oncology community. Given the heavy burden of buccal mucosa carcinoma in South and Southeast Asia, any protocol capable of reducing trismus prevalence by greater than 50% at 12 months represents a major step toward improving survivor quality of life at scale.30 Resource-adapted versions of this protocol, utilising low-cost jaw-opening tools and community physiotherapist training, could be implemented even at district-level cancer centres with appropriately modified supervision models. The institutional experience at AHPGIC demonstrates that protocol adoption is feasible within the constraints of a high-volume public tertiary cancer centre.

CONCLUSION

This retrospective-prospective study at AHPGIC, Cuttack, demonstrates that implementation of a standardised, multidisciplinary reconstruction and physiotherapy protocol significantly reduces post-operative trismus in buccal mucosa carcinoma, achieving an LOCF-estimated trismus prevalence of 20% at the primary endpoint compared to 72% in the pre-protocol cohort. The protocol was associated with a 9.6-mm advantage in MIO at final follow-up, substantially superior patient satisfaction, and improved return to normal diet and activities, without any increase in surgical morbidity. Early physiotherapy initiation by post-operative day 7 and structured Thera-Bite device compliance were identified as the most impactful modifiable determinants of outcome. These findings are promising; however, given the non-randomised single-centre design, underpowered enrolment, and reliance on LOCF-imputed primary endpoint data for Group B, institutional adoption of such integrated protocols should be considered as an evidence-informed practice option pending validation in larger, prospective, multicentre randomised studies.

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