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Research Protocol

Dentistry Section

Comparative Evaluation of Functional and Aesthetic Outcomes in Reconstruction of Commissure of Mouth with Radial Forearm Free Flap with and without Palmaris Longus Tendon in Patients being Operated for Squamous Cell Carcinoma of Buccal Mucosa and Lip: A Research Protocol

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ABSTRACT

Introduction: Previously conducted studies have demonstrated the effectiveness of the Radial Forearm Flap (RFF) in reconstructing lip and buccal mucosa deformities, both with and without the Palmaris Longus Tendon. The optimal therapy following large oncologic resections involves microvascular free flaps. The tissue produced by the Radial Forearm Free Flap (RFFF) is thin, malleable and well-vascularised, ensuring less morbidity at the donor site since it is harvested based on the radial artery. Successful vascularisation is facilitated by microvascular anastomosis. With a high success rate, RFFF provides good functional and cosmetic results for a range of intraoral reconstructions.

Need of the study: This study aims to evaluate the functional and aesthetic results of reconstructing the lip and buccal mucosa in cases of Squamous Cell Carcinoma (SCC). The long-term preservation of vertical lip height and lip support is achieved by the Palmaris Longus Tendon, which functions as a sling over which the flap is elevated.

Aim: To compare and evaluate functional and aesthetic outcomes in the reconstruction of the commissure of the mouth using RFFF, with and without the Palmaris Longus tendon, in patients undergoing surgery for SCC of the buccal mucosa and lip.

Materials and Methods: This parallel group randomised trial will be conducted at the Department of Oral and Maxillofacial Surgery, Siddharth Gupta Memorial Cancer Hospital, Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha, Maharashtra, India from August 2024 to September 2025. The procedure will be performed on patients who have histopathologically confirmed Oral Squamous Cell Carcinoma (OSCC). Detailed case histories, clinical examinations, past medical and dental histories, general personal information and biopsy procedures will be conducted. Patients with biopsy-proven SCC will then undergo radiographic examinations (CT scans) to determine the extent of the lesion and lymph node metastasis. Patients with biopsy confirmation who meet the inclusion criteria will be included in the study after obtaining detailed informed consent. The study will consist of two groups of eight patients each: one group will receive RFFF with the Palmaris Longus tendon and the other will receive RFFF without the Palmaris Longus tendon. Functional outcomes such as drooling, swallowing and speech, along with aesthetic outcomes including smile, lip competence and commissural ends, will be assessed.

Keywords: Drooling, Lip competence, Speech, Swallowing

INTRODUCTION

Oral cancer, a neoplastic condition of the oral cavity, ranks eighth globally, with over 300,000 cases per year. Its high mortality and aesthetic impacts underscore its significance as a public health concern [1]. The incidence and mortality rates of Oral Cancer (OC) vary globally, with developing countries, particularly India and other parts of South and Southeast Asia, experiencing higher rates, as well as France, Slovenia, Slovakia and Hungary [2]. These variations in incidence and mortality between high- and low-income nations, along with the higher death rate associated with OC in cultures with low development and significant societal inequities, suggest that societal factors, such as culture and lifestyle, play a role in its carcinogenesis [3].

The prevalence of OC is particularly high in Southeast Asia due to the traditional practice of chewing tobacco, especially betel quid [4]. OSCC, which is categorised into three grades ranging from well-differentiated (Grade I) to poorly-differentiated (Grade III), accounts for about 90-95% of OC cases [1]. The most common treatment modality for preserving the shape and functionality of the head and neck region remains curative resection and reconstruction. Despite recent advancements in treatment techniques, the prognosis for OSCC remains poor due to metastasis and local aggressiveness, with recurrence occurring in approximately 30% of patients [1]. OSCC is the most prevalent cancer among men and the third most common cancer overall in India, also ranking third among the various types of cancer that cause death in the nation [5].

One of the major health issues in India and the countries of the Indian subcontinent is oral cancer. The primary cause of oral cancer is tobacco use. In these countries, tobacco is consumed in various forms, such as betel quid, tobacco with lime, bidi and hookah. Oral cancer also has a few minor etiological factors, including the human papillomavirus, nutritional deficiencies and poor oral hygiene [6].

In North America and Western Europe, SCC of the buccal mucosa accounts for only 10% of all oral cavity carcinomas [7]. However,

due to the habit of chewing pan, a mixture of tobacco, nut and lime, buccal SCC is one of the most prevalent cancers in a geographic strip spanning from Central to Southeast Asia [8].

Advanced malignant oral cavity tumours are difficult to treat because they place significant demands on the treating physician's oncology and functional skills [9]. Compared to the upper lip (2% to 12%) or the commissure (1% to 15%), the lower lip is significantly more affected (80% to 95%). Most SCC of the lower lip originates at the vermilion border [10]. The higher prevalence of SCC of the lip in India compared to other countries is likely caused by the country's heavy tobacco use, as well as the chewing of pan, gutkha, or betel nut [11].

The optimal course of treatment for SCC of the lip is the surgical excision of the tumor, followed by reconstruction of the defect; in this series, all patients underwent this surgical intervention [12]. The main goal of the procedure is to remove the tumor completely, which entails excising the skin, muscle and underlying mucosa in their entirety to ensure a safe surgical margin [13]. While various treatment options, such as radiotherapy and chemotherapy, are available, the majority of SCC cases are typically treated surgically to completely remove the tumor and allow for subsequent reconstruction [14].

The RFFF was first introduced as a reconstructive option in 1978 and has since become extremely popular. This flap is considered a reconstructive workhorse due to its dependable anatomy, malleable tissue and relative simplicity of harvesting [15]. Good functional and aesthetic results have been observed in the reconstruction of whole lower lip and chin defects using the composite radial forearm-Palmaris Longus Tendon free flap [16].

The aim of this study is to compare and evaluate the functional and aesthetic results of reconstructing the commissure of the mouth using a RFFF in patients undergoing surgery for SCC of the lip and buccal mucosa, with and without the Palmaris Longus Tendon.

The primary objective is to evaluate functional outcomes in the reconstruction of the commissure of the mouth using RFFF, both with and without the Palmaris Longus Tendon, in patients undergoing surgery for SCC of the buccal mucosa and lip. The secondary objective is to compare and evaluate aesthetic outcomes in the reconstruction of the commissure of the mouth using RFFF, both with and without the Palmaris Longus Tendon, in these patients.

Null hypothesis: The RFFF with the Palmaris Longus Tendon will have similar functional and aesthetic outcomes compared to the RFFF without the Palmaris Longus Tendon.

Alternate hypothesis: The RFFF with the Palmaris Longus Tendon may have superior functional and aesthetic outcomes.

REVIEW OF LITERATURE

Carroll CMA et al., examined the use of a composite radial forearm-Palmaris Longus tendon-free flap for the functional and cosmetic repair of complete lip and chin deformities. Their goal was to present the method used and the experience gathered from restoring complete lip and chin deformities in ten consecutive patients who underwent surgery between 1992 and 1998. The technique utilised the Palmaris Longus tendon as a sling to help sustain lip support and vertical lip height over time. This was attributed to the transfer of facial muscular activity to the neolip and the maintenance of vertical lip height and support. According to the findings, every patient reported satisfaction with the outcome of their final reconstructive results. Additionally, the study indicated that oral competency was successfully achieved [16].

Ettl T et al., suggested that for intraoral mucosal restorations, the RFF has become the preferred option, providing thin skin with a safe blood supply. Perforator flaps, such as the Anterolateral Thigh (ALT) flap, have recently gained more attention for comparable uses. A folded RFF reconstruction was used to reconstruct the lip and/or nose of 12 patients with moderate to extensive abnormalities. The patients' histories, the specifics of their treatment and the results were examined from both an oncological and functional standpoint. All flaps survived without revision during the mean follow-up periods of 21.1 and 31.2 months, respectively, for the oncologic and functional aspects. The study included examples where the RFF and in some cases, the Palmaris Longus tendon, were used to restore significant lip deformities [17].

Moratin J et al., suggested that the best method for repairing the defects resulting from substantial oncologic resections involves using microvascular free flaps, which have proven to be both extremely effective and very safe [9]. The RFFF is an excellent option because it provides thin, malleable, well-vascularised soft tissue. A broad local excision was performed on a middle-aged male patient diagnosed with verrucous cancer of the left buccal mucosa. The RFFF was then used for reconstruction. Microvascular anastomosis was performed on the flap, which was pedicled on the radial artery and connected to the cephalic vein and the venae commitans. This procedure required careful execution under a surgical microscope to connect the radial artery with the facial artery and one branch of the venae commitans with the common facial vein [18,19].

MATERIALS AND METHODS

The study will be a parallel-group randomised trial. It will be conducted from August 2024 to September 2025. This clinical study will take place in the Department of Oral and Maxillofacial Surgery at Siddharth Gupta Memorial Cancer Hospital, Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha, Maharashtra, India. The research will be carried out under the auspices of the Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha.

Institutional Ethics Committee (IEC) approval from Datta Meghe Institute of Higher Education and Research (DMIHER) (DU) has been obtained, and the process will begin after explaining the detailed treatment protocol to the patients. (IEC Ref. No.: DMIHER(DU)/ ICE/2024/229) Clinical Trials Registry-India (CTRI) Trial Registration No.: CTRI/2024/07/070222.

A total of 30 patients will be assessed for biopsy-proven cases of SCC, with 12 patients meeting the criteria for the study.

Sample size calculation: A minimum sample size is required for piloting the study, as no other studies have been found for power analysis. We will consider 16 samples, eight per group, for the comparative evaluation of the results between the groups [20].

Formula for determining sample size:

$s=X^2NP(1-P)+d^2(N-1)+X^2P(1-P)$

s=required sample size

X^2=the table value of Chi-square for one degree of freedom at the desired confidence level (3.841)

N=the population size

P=the population proportion (assumed to be 0.50 since this would provide the maximum sample size)

d=the degree of accuracy expressed as a proportion (0.05)

N=Total patients in two and a half years=12 [21]

Sample Size n=3.84 * 12*0.50*0.50/(0.052* 15)+(3.84*0.5*0.5)

=11.66

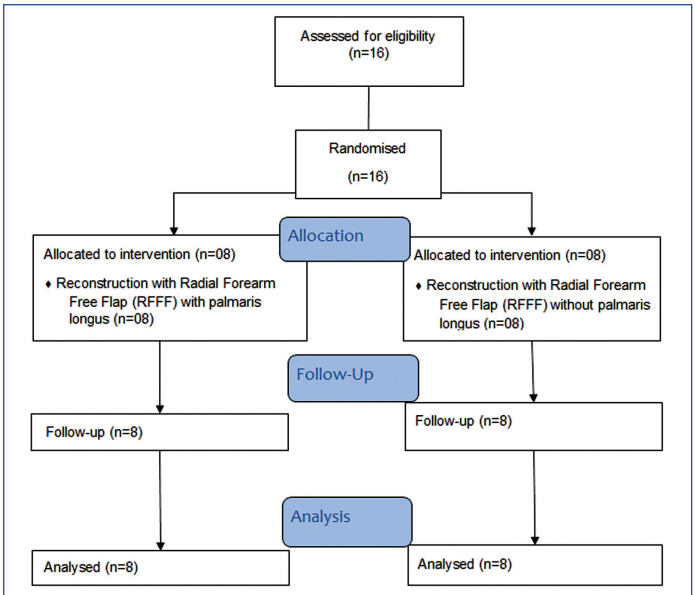
=12 patients needed in the study.

(6 in each group) [Table/Fig-1].

Study reference: Number of patients in the last two and a half years in the Oral Surgery Department.

Formula reference: Krejcie and Morgan (1970) [22].

After diagnosis, patients will be divided into two groups by computer-generated randomisation and then alternatively selected for reconstruction with RFFF with and without the Palmaris longus tendon, respectively.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flowchart.

Inclusion criteria:

- Biopsy-proven case of SCC of the buccal mucosa and lip;
- All patients with carcinoma of the commissure of the mouth;
- All patients with carcinoma of the buccal mucosa and lip;
- All patients who have shown a positive test on Doppler ultrasonography (Allen test), as a pre-requisite for RFFF with or without the Palmaris longus tendon [22].

Exclusion criteria:

- Any carcinoma (verrucous carcinoma, basal cell carcinoma, etc.,) other than SCC;
- Patients who have undergone surgery, or chemotherapy;
- Patients who have undergone radiotherapy;
- Patients who are lost to follow-up;
- Patients who are not fit for surgery;
- All patients not willing to undergo RFFF.

Study Procedure

The procedure will be conducted at Siddharth Gupta Memorial Cancer Hospital (SGMCH), DMIHER, Sawangi, Wardha, Maharashtra, India for patients presenting with non healing ulcers of the buccal mucosa and lip:

1. Patient evaluation: Patients reporting to the Department of Oral and Maxillofacial Surgery will undergo a thorough examination.
2. Case history: A detailed medical, dental and personal history will be documented.
3. Clinical examination: A comprehensive assessment of the oral cavity, focusing on the non healing ulcer sites, will be conducted.
4. Biopsy: A biopsy will be performed for histopathological examination to confirm the presence of SCC.
5. Radiographic examination: Patients with confirmed SCC will undergo a Computed Tomography (CT) scan to assess the extent of the lesion and to detect any lymph node metastasis.
6. All patients who have shown a positive test on the Allen test, as a prerequisite for RFFF with or without the Palmaris Longus tendon, will undergo the procedure for assessment and surgery [22].

This protocol ensures accurate diagnosis and appropriate management for patients presenting with suspected oral cancer at SGMCH. After diagnosis, patients will be divided into two groups by computer-generated randomisation and will undergo microvascular surgery under strict aseptic protocols. After surgery, the patients will be monitored and evaluations will take place one week, three months and six months postoperatively to assess functional and aesthetic outcomes, based on which the RFFF with or without the Palmaris longus tendon will be judged.

The two groups will be divided based on the type of reconstruction to be performed after wide local excision or composite resection of the lesion, along with suitable neck dissection:

Group I: Reconstruction with a RFFF with the Palmaris longus tendon.

Group II: Reconstruction with an RFFF without the Palmaris longus tendon.

Once the presurgical workup is completed, which includes pre-anesthetic fitness and signed, documented and fully informed consent, preoperative photos will be taken and the surgery will be performed.

The conical assessment of the outcomes of the two types of reconstruction will be based on functional and aesthetic results observed postoperatively at seven days, one month and three months of follow-up. This assessment will help to closely monitor the progress of the patients.

Primary outcomes: Functional outcomes, including swallowing, speech and mouth opening will be evaluated.

Secondary outcomes: Aesthetics outcomes will include smiles, lip competence and commissural end will be evaluation.

Outcomes will be assessed based on the following criteria [Table/Fig-2-7]:

Difficulty in swallowing	Score
Within normal limits	1
Minimal difficulty	2
Moderate difficulty	3
Severe dysphagia	4
Unable to swallow	5

[Table/Fig-2]: Swallowing scale.

Understandability of speech	Score
Always understandable	1
Near normal speech, occasional repetition necessary	2
Usually understandable, face to face contact necessary	3
Difficult to understand, use of actions necessary	4
Never understandable, might need to write for communication	5

[Table/Fig-3]: Speech scale.

Amount of mouth opening	Score
1. More than 30 mm	1
2. Between 25 to 30 mm	2
3. Between 20 to 25 mm	3
4. Below 20 mm	4

[Table/Fig-4]: Mouth opening scale.

Perception of the patient for his/her smile	Score
Perceived as an aesthetic smile	1
Satisfactory but could have been better	2
Need modifications in smile design	3
Not satisfied by the outcome of the smile	4
Purely disappointed by the way of patient's smile	5

[Table/Fig-5]: Smile.

Interincisal distance at rest	Score
Lips completely competent	1
Less than 2 mm	2
>2 mm but <4 mm	3

>4 mm but <6 mm	4
6 mm or above	5

[Table/Fig-6]: Lip competence.

Distance of the commissural ends from the center of columella	Score
Bilaterally symmetrical	1
Difference of less than 2 mm	2
Difference of more than 2 mm but less than 4 mm	3
Difference of more than 4 mm but less than 6 mm	4
Difference more than 6 mm	5

[Table/Fig-7]: Commissural end.

STATISTICAL ANALYSIS

Data will be input into Microsoft Excel and statistical analysis will be conducted using Stata version 10 software. The Chi-square test, Fisher's-exact test for categorical data and independent t-test for continuous data with normal distribution will be employed to assess functional and aesthetic outcomes in the reconstruction of the buccal mucosa involving the commissure of the mouth using the RFFF, both with and without the Palmaris longus tendon, in patients undergoing surgery for SCC of the buccal mucosa and lip. Functional outcomes, including drooling, swallowing and speech, as well as aesthetic outcomes such as smile, lip competence and commissural ends, will be evaluated. These parameters will be monitored at one week, three months and six months post-surgery.

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