Evaluation and Comparison of Functional and Aesthetic Outcomes of McGregor and Stepped Lower Lip-Split Incisions for Exirpation of Primary Tumor in Cases of Squamous Cell Carcinoma of Oral Cavity (SCCOC)

Chetan Gupta a*, Nitin Bhola a, Anendd Jadhav a and Akhil Sharma a

a Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Datta Meghe Institute of Medical Sciences (D.U), Wardha, Maharashtra, India.

Authors’ contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i51B33509
Editor(s):
(1) Giuseppe Murdaca, University of Genoa, Italy.
Reviewers:
(1) Manjula GB, King Khalid University, Saudi Arabia.
(2) Cherry Bansal, Era Medical University, India.

Complete Peer review History, details of the editor(s), Reviewers and additional Reviewers are available here: https://www.sdiarticle5.com/review-history/74526

Study Protocol

Received 11 August 2021
Accepted 22 October 2021
Published 24 November 2021

ABSTRACT

Background: Clear surgical margins are of utmost importance in surgical oncological procedures. Secondary consideration includes the functional and aesthetic outcomes of the patients after the procedure. The recognised surgical approach to the posteriorly located oral cavity and oropharyngeal tumors involves the splitting of the lower lip with or without mandibulectomy. In order to perk up postoperative function and aesthetics, quite a lot of modifications of the unique midline lower lip splitting incision have been projected by various authors till date. A stepped ladder lower lip split incision (LLSI) helps in improved functional and aesthetic outcomes.

Objectives: The prime accent of the study is to compare the McGregor LLSI and the stepped LLSI with respect to functional and aesthetic outcomes in tumors ablation for SCCOC.

Methodology: The study population (n=22) is assigned randomly in two equal groups as a subject in the ratio of 1:1. Systemically healthy histologically diagnosed patients of SCCOC requiring LLSI...
for the tumours ablation will be included. In Group A- McGregor LLSI will be performed and in Group B- a Stepped LLSI would performed. Post-operative assessment of functional and aesthetic outcomes will be done.

**Expected Results:** A stepped ladder LLSI used for tumours ablation will be effective in preserving post-operative lip movement, lip competency and cosmesis.

**Conclusion:** Utility of a Stepped ladder LLSI for accessibility and ablation of posterior oral and oropharyngeal tumors would be undoubtedly beneficial for improving post-operative functional and aesthetic outcomes and could be executed in routine oncologic surgery.

Keywords: Lower lip split incision; aesthetic incision; mandibulectomy; oral squamous cell carcinoma.

### 1. INTRODUCTION

The basic tenet of any oncologic surgery is extirpation of tumors with the safe surgical margins while, maintaining the function and cosmesis after the ablative surgical procedure. Majority of intraoral tumors may be managed by an intraoral approach. However, in cases of trismus or posteriorly located tumours frequently pose difficult access for which a wide exposure is required. A splitting of the lower or upper lip can ease to reach the tumours [1]

The lower lip-split incision (LLSI) has been far rampanty implemented in head and neck (H&N) surgical oncology to offer enhanced access not only to intra-oral, pharyngeal and parapharyngeal tumours but also to the cervical part of spinal column. In mid-19th century Dieffenbach, Roux, Bernard, Trotter, Burow introduced midline straight incision. This incision not only combined along with a mandibulotomy/ mandibulectomy, but also be extended to the submandibular or the neck region, which allows a neck dissection [2].

Such transfacial approaches involving mid line straight lip splits incision are accompanied with bothersome aesthetic and functional post-operative sequelae. This may include unsightly scar, vermilion notching, chin-pad contour loss, dwindled lip sensation, lip mobility and oral commissure incontinence.

In an attempt to improve postoperative function and aesthetics, several modifications of the novel LLSI have been proposed by various authors till date. In 1839, Roux designed a midline lower lip incision which lies in a relaxed skin tension line (RSTL) and minimises damage to the underlying muscles, vessels and nerves of the lower lip [3,4].

McGregor and McDonald revised the original LLSI to trail the outline of the labio-mental groove. This improves the scar contracture as this incision hide in RSTL [5]. But such curvilinear incision design may cause scar puckering due to circumferential scar contracture [6]. Ramon et al. [7], introduced a stepped ladder incision technique which reduces vertical and circumferential scar contracture and preserve chin pad getting disfigured [7].

No attempt in the past has been made to compare McGregor incision with Stepped incision approach for oncologic tumours ablation. Hence, this study is pondered to compare the functional and aesthetic outcomes of McGregor LLSI versus stepped incision design with the hypothesis that stepped incision design would improve the functional and aesthetic outcomes.

1.1 Objectives

1. To evaluate the McGregor incision with respect to functional and esthetic outcomes in tumor ablation for SCCOC.
2. To evaluate the Stepped incision with respect to functional and esthetic outcomes in tumor ablation for SCCOC.
3. To compare the McGregor and Stepped incision with respect to functional and aesthetic outcomes in tumor ablation for SCCOC.

### 2. METHODS

**Study Design:** Prospective, comparative study design.

**Setting:** “The 22 histopathologically proven cases of SCCOC, reporting to department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital, and Acharya Vinoba Bhave Rural Hospital, Sawangi (M) Wardha (Maharashtra), who would undergo surgical resection of the primary tumour under general anesthesia between September 2020 to May 2021 were screened for the recruitment. This study will be performed in accordance with the
Helsinki declaration and its later amendments or comparable ethical standards and approval by institutional ethical guidelines prescribed by central ethics committee on human research (CECHR) of Datta Meghe Institute of Medical Sciences, Deemed to be University (Ref. No. DMIMS(DU)/IEC/2020-21/48)".

Patients fulfilling the criteria given below will be recruited for the study.

**Inclusion Criteria:**

1. Histologically proven cases of Oral squamous cell carcinoma where lip split incision is required for tumor ablation.
2. Medically fit patients under general anaesthesia.

**Exclusion Criteria:**

1. Immunocompromised and medically unfit patients for surgery.
2. Pre-operative treatment such as surgery/ radiotherapy or chemotherapy.
3. Patient with history of surgery in anterior chin region/ pre-existing scar and keloidal tendency.
4. Patients in whom ablative defect will extend to involve the lower lip and anterior mandible.

**2.1 Preoperative Screening and Evaluation**

All the patients who will satisfy the above mentioned criteria will be recruited for the study and detailed case history, TNM staging (acc to AJCC 7th edition, 2009 UICC guidelines) along with Histopathological grading (Broder’s grading) of the primary tumor were precisely documented in the record proforma (Annexure- I ). Patients would then be subjected to CECT/MRI in Department of Radio-Diagnosis, AVBRH, Sawangi (Meghe). Routine Blood investigations were done and the patient was posted for surgery under general anaesthesia with due fulfilment of the pre-anaesthetic checkup.

**3. METHODOLOGY**

The study population [n = 22 ] will be divided equally into two groups (group A (N=11) and group B) in a ratio of 1:1 by Lottery method of randomization. The subjects will be blinded to the allocation group.

**3.1 Surgical Protocol**

- All the cases will be operated by a single senior surgeon having considerable experience in oral oncology.

**3.2 Surgical Technique**

The patients will be randomly allocated by lottery method between two groups.

- **Group A:** McGregor incision will be used as the control incision to follow the outline of the lip-chin contour.
- **Group B:** a stepped incision technique starting with midline vermilion incision, continues down to 2mm above the mentolabial fold, where it extends 1 cm and then it is brought around the chin in small steps through the depressor labiinferioris muscle about 2 cm lateral to the mentalis muscle finally reaching the inferior mandibular edge lateral to the mentalis muscle.

**3.3 Data Sources/ Measurement**

The following parameters will be assessed and documented:-

- The average Intraoperative time required for surgery from incision to closure. It will be measured in seconds using a stopwatch.
- Post-operative lip movement and lip competency will be evaluated with asking patient to clench his teeth and retract the lip [8].
- Scar by Stony Brook Scar Evaluation Scale after 1 week and 1 month postoperatively [9].
- Post-operative complications like partial necrosis, hypertrophic scar and keloid will be assessed by

**Variables:** Time, function of lip, scar evaluation, postoperative complications.

**Bias:** There is no bias present.

**Study size:** The study size is arrived at.

Using the formula:

\[ n = \frac{Z_{a/2}^2 \times P \times (1-P)}{d^2} \]

\[ n = (1.96)^2 \times 0.01 \times (1-0.01)/(0.06)^2. \]
\[ = \frac{0.56}{10} \]

i.e. 11 patients needed in each group.

Where,

\[ Z_{\alpha/2} \] = is the level of significance at 5% at confidence interval = 1.96.
\[ P = \text{Prevalence of oral premalignant lesion} = 1\% \ i.e \ 0.01 \ [10] \]
\[ d = \text{desired error of margin} = 6\% \ i.e \ 0.06 \]

Statistical Methods: “Statistical analysis will be done by using descriptive and inferential statistics using chi-square test, Student’s paired and unpaired t test, software used in the analysis will be SPSS 24.0 version and Graph Pad Prism 7.0 version and \( p<0.05 \) will be considered as level of significance.”

3. RESULTS

3.1 Evaluation of Intra-Operative Time Required for Each Incision in Seconds

Incision time would be recorded from the beginning of incision till the time the final closure by an independent observer using digital clock in seconds.

3.2 Evaluation of Post-Operative Lip Movement and Lip Competency

The post-operative lip movement and lip competency will be assessed by Clinical functional assessment test [8]. This would be done by the same clinician by asking the patient to clench his mouth and ask to move/retract lip on 7th and 30th post-operative day. The results would be noted as, on rest, on effort and incompetent and respective scores would be 1,2,3. The lower score will indicate better function.

3.3 Evaluation of Post-Operative Scar

The post-operative scar evaluation will be done by Stony Brook Scar Evaluation scale (SBSES) [9]. The questionnaire will be explained to the clinician in detail requiring them to select one option which closely describes the status of the scar. The assessment and evaluation will be performed by the same clinician at the 7th and 30th post-operative day. The obtained scores will be tabulated and statistically evaluated to calculate the result. These scores would represent individual value which further summed and would rate ‘0’ as worst and ‘5’ as best scar.

3.4 Evaluation of Post-Operative Complication

Partial necrosis, hematoma and seroma will be assessed as present or absent.

3.5 Descriptive Data

Descriptive statistics will be done with the help of frequency, percentage, mean and standard deviation.

3.6 Discussion

The disease free survival in H&F cancer patients is very crucial it can be improved by various multimodality treatment option up to certain extent [11,12]. Emphasis should also be given to the quality of life [13]. In the modern epoch, the incisions are planned with immense value which should provide adequate enhanced wide exposure to the field of interest, facilitate reconstructive procedures and thereby maximize oncologic, functional and esthetic outcomes. The pattern of incision be governed by the site of the tumor and these are designed based upon certain anatomical landmarks [14,15].

The most perplexing surgical aspects include trouble in gaining adequate access to lesions of severe trismus patients, lesions present posterior to oral cavity and oro-pharyngeal lesions [16]. Pertaining to adequate access and ample exposure to the tumor, preservation of important neurovascular structures in the vicinity of the incision site becomes an edge. Failing to which may lead to functional impairment and aesthetic disfigurement [17,18].

The literature search reveals that, various access procedures to the head and neck tumour have been discussed and various lip splitting incisions were studied till date. The modest straight line vertical lower lip split incision advocated long ago in past is simple and reliable but has aesthetic and functional drawbacks. There is often scar contracture and vermilion notching because of loss of normal round and smooth architecture of lip-chin apparatus after closure post-operatively (Bernard in 1853, and Burowin 1855).

Langenbeck in 1877, advocated laterally access to the oral cavity by starting the incision from the
corner of mouth vertically along the lower edge of mandible. This incision results in unacceptable functional deformity as it cuts fibers of masseter, buccinators muscle and facial motor nerve supply to the lower lip [19].

Konig, in 1922 introduced median split method of the lower lip where vertical incision starts 1.5 cm medial to the corner of mouth over the inferior mandibular border. Again this technique leaves undesirable scar, lip eversion and small groove formation [19].

McGregor and MacDonald in 1983 modified midline LLSI rendering to the anatomy of the lip-chin apparatus. The prescribed design of the incision is as it starts in the midline, stops in the hollow just above the chin prominence. Then it curls around the base of the chin eminence to reach the submental area which further continues to aid in neck dissection [5].

Hyter et al. [20] in 1996 modified the McGregor incision but it was not practised routinely. Rapidis in [6], compared Hayter et al modification of McGregor incision gave the best post-operative results as compared to the Robson and Roux incision whereas, McGregor incision yielded good functional and aesthetic results. Shetty et al. [21] described functional and aesthetic outcomes in 30 patients undergoing surgery of the oral cavity tumor extirpation requiring lower lip split incision. The author compared Roux, Robson and McGregor incision and concluded that McGregor incision produced the best results over other two incisions.

However, in the McGregor incision the curved portion may result in circumferential skin contracture which further results in scar puckering. Moreover, the extension over the lower border may cut the mentalis muscle fibers [19].

| Table 1. Clinical functional assessment of lip competence [8] |
|-----------------------------------------------|--------|
| Assessment by clinician | Score |
| Lip competence | At rest | 1 |
| | On effort | 2 |
| | Incompetent | 3 |

Range 1–3, lower score indicating better function

| Table 2. The stony brooke scar evaluation test [9] |
|-----------------------------------------------|--------|
| Scar category | Points |
| Width | > 2mm | 0 |
| | ≤ 2mm | 1 |
| Height | Elevated/depressed in relation to surrounding skin | 0 |
| | Flat | 1 |
| color | Darker than surrounding skin | 0 |
| | Same color or lighter than surrounding skin | 1 |
| Hatch marks/suture marks | Present | 0 |
| | Absent | 1 |
| Overall appearance | Poor | 0 |
| | Good | 1 |

Total score – sum of individual score [Ranges from 0 (worst) -5 (best)]

Fig. 1. Stepped incision
Fig. 2. McGregor incision
Ramon et al. [7], popularised stepped incision technique for surgical access splitting the lower lip. The design of this incision starts from the midline of the lower lip. A 2cm vertical incision is started from midline upto the labiomental fold then crosses 1 cm laterally on either side at 90 degree to the vertical limb. Further the incision is continued in small ladder like fashion besides the chin prominence. As the incision is divided through the depressor labii inferior muscle about 2 mm laterally to the mentalis muscle and reaches the lower anterior edge of the mandible lateral to the mentalis muscle, which allows best anatomic and functional reconstruction. The innervation of the lip muscle also not compromised. According to the author, this technique would improve the functional and esthetic outcomes and also suffice the improved access for the surgery.

No attempt in the past has been carried out to compare the stepped LLSI with the McGregor LLSI for functional and esthetic outcomes.

The major limitation of the present study is that it is attempted to compare only two LLSI for assessment in low power. If a stepped incision will be proven to be better in terms of improved post-operative function and reduced scar formation as the incision which is in the natural skin folds will provide quick, firm healing and excellent aesthetics and will be validate to use in routine oncologic access surgery.

4. CONCLUSION

The utility of a Stepped ladder LLSI for accessibility and ablation of posterior oral cavity and oropharyngeal tumors would be undoubtedly beneficial for improving post-operative functional and aesthetic outcomes and could be executed in routine oncologic access surgery.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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ANNEXURES

PROFORMA

Name-                                                 IPD No:
Age/Sex-                                               Date of admission-
Address-                                               
Tel no-                                                 
Diagnosis-                                             

Date of surgery-

Treatment done-

Incision type-

1. Time taken from incision to exposure surgical site:

2. Lip competency:

| Assessment by clinician | Score | At 7th post-op day | At 30th post-op day |
|-------------------------|-------|---------------------|---------------------|
| Lip competence          |       |                     |                     |
| At rest                 | 1     |                     |                     |
| On effort               | 2     |                     |                     |
| Incompetent             | 3     |                     |                     |

Range 1–3, lower score indicating better function

3. Scar:

Stony Brook Scar Evaluation Scale [9]

| Scar category                  | Points | POD 7th | POD 30th |
|-------------------------------|--------|---------|----------|
| Width                         |        |         |          |
| > 2mm                         | 0      |         |          |
| \leq 2mm                      | 1      |         |          |
| Height                        |        |         |          |
| Elevated/depressed in relation to surrounding skin | 0 |         |          |
| Flat                          | 1      |         |          |
| color                         |        |         |          |
| Darker than surrounding skin  | 0      |         |          |
| Flat                          | 1      |         |          |
| Same color or lighter than surrounding skin | 1 |         |          |
| Hatch                         |        |         |          |
| Present                       | 0      |         |          |
| Absent                        | 1      |         |          |
| Hatch marks/suture marks      |        |         |          |
| Overall appearance            |        |         |          |
| Poor                          | 0      |         |          |
| Good                          | 1      |         |          |

Total score – sum of individual score [Ranges from 0 (worst) -5 (best)]

4. Post operative complication:

a. Partial necrosis: present/absent
b. Hematoma: present/absent
c. Seroma: present/absent

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Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/74526