

Utility Of Customized Protective Surgical Splint Concerning Soft Tissue Healing In Patients With Unilateral Cleft Alveolus Undergoing Secondary Alveolar Bone Grafting In Comparison To Those Without Splint

1] Dr. Apoorva Mishra 2] Dr. Rajiv Borle 3] Dr. Nitin Bhola 4] Dr. Prachet Dakshinkar

1) Dr. Apoorva Mishra, Assistant Professor, Fellow Cleft and Craniofacial Surgery
Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital,
Datta Meghe Institute of Medical Sciences (DMIMS), Sawangi (Meghe), Wardha
(Maharashtra), India; Email Address: drmishraapoorva@gmail.com
Mob No: 8389830802

2) Dr. Rajiv Borle, Vice Chancellor, Datta Meghe Institute of Medical Sciences (DMIMS),
Sawangi (Meghe), Wardha (Maharashtra), India; Email Address: ycdmimsdu@gmail.com;
Mob No: 9765404005

3) Dr. Nitin Bhola, Professor and Head of Department, Department of Oral and Maxillofacial
Surgery, Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Medical
Sciences (DMIMS), Sawangi (Meghe), Wardha (Maharashtra), India; Email Address:
drnitinbhola@gmail.com; Mob No: 9970070607

4) Dr. Prachet Dakshinkar
Designation: Assistant Professor, Fellow Cleft and Craniofacial Surgery
Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College and Hospital,
Datta Meghe Institute of Medical Sciences (DMIMS), Sawangi (Meghe), Wardha
(Maharashtra), India; Email Address: pracdak@gmail.com; Mob No: 9890124992

Corresponding Author's Name and Address:

Dr. Apoorva Mishra, Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College
and Hospital, Datta Meghe Institute of Medical Sciences (DMIMS), Sawangi (Meghe), Wardha
(Maharashtra), India

Abstract

Background: Alveolar cleft closure is vital in achieving stability of maxillary arch, providing a foundation for alar base, prevent the inferior turbinate from herniating into cleft area and giving impetus to teeth adjoining cleft. Intact Soft tissue cover over the grafted cleft site will provide a contained cavity which will help maintain the grafted bone in the compacted position till new bone formation occurs. Customized surgical splint over the operated site as a mechanical barrier can help improve the soft tissue healing in patients undergoing Alveolar bone grafting (ABG).

Aim: To compare the utility of customized surgical splint in terms of soft tissue healing overlying the grafted alveolar bone

Material and Methods: *Random allocation of unilateral cleft alveolus patients in two groups will be done. Group A, in which immediately after the surgery in a customized surgical splint will be placed. Group B, in which no splint will be given. Soft tissue healing will be assessed for both the groups on post-operative day 7th and 15th.*

Result: *Results will be analyzed using Student's paired t-test. It is expected that the soft tissue healing will be significantly better in the patients with surgical splints.*

Conclusion: *Expected results of better soft tissue healing with utilization of customized surgical splints in operated patients of cleft alveolus may be recommended as part of standard care protocol. It can play a pivotal role in subsequent successful uptake of graft by improving soft tissue healing*

Keywords: *Secondary ABG, ABG, Soft tissue healing*

INTRODUCTION

The utmost goal in alveolar bone grafting (ABG) procedures of cleft patients, aims at unifying the maxillary arch which will ultimately promote the eruption of the tooth in the arch. The concept of Secondary bone grafting which served as the biological and scientific basis was introduced by Boynes and Sands.¹ The surgical procedure of alveolar bone grafting should satisfy three main requisites which are intended for effective treatment: Hermetic seal of the fistula, Optimal reconstruction of the alveolar ridge dimension, and Water tight closure ensuring maximum take of the grafted bone.² The particular practice is typically undertaken during the period of mixed dentition wherein only two third of the permanent canine root is formed. Any intervention surgically generally may lead to poor metabolic response, and may reduce the wound healing.³ Soft tissue healing is one of the determinants of surgical outcome in Alveolar bone grafting. Gaping or dehiscence of the soft tissue may have an untoward effect on the outcome of graft.⁴ Poor soft tissue healing is the commonest reason for failures and compromised results. Area of Alveolar bone grafting is subjected to various insults in the oral environment like self-inflicted trauma from opposing tooth, repetitive tongue movement rubbing the site, hard food, food entrapment etc. Despite numerous advances in prophylactic measures, infections still remains a complication in ABG. The use of a customised splint providing a mechanical barrier to the surgical site may help improve the outcomes. Isolating the surgical area with the help of splints during its initial healing period may provide a better healing environment for satisfactory soft tissue healing. Utility of customized surgical splint in the surgical area of ABG is a novice, and has not been evaluated in the preceding literature.

Objectives:

- To evaluate soft tissue healing in patients with customized surgical splints (Group A)
- To evaluate soft tissue healing in patients without splints (Group B)
- To compare the soft tissue healing in both the groups.

Study Design:

 Randomized controlled parallel arm pilot study

The study population will be divided equally into two groups in a randomized manner alternatively. The subjects will be blinded to the allocation group.

- **Group A:** will comprise of the patients wearing customized surgical splint made up of acrylic.
- **Group B:** will comprise of the patients in whom splints will not be given

Methods:

The present randomized parallel arm pilot study is scheduled to be conducted in the "Unit of Maxillofacial Surgery, in coordination with Unit of Orthodontics, S.P Dental College, AVBR

Hospital Sawangi (M) Wardha”. This research would be conducted in accordance with the guidelines laid down by “Helsinki declaration and its later amendments” or comparable ethical standards and only after approval by the institutional ethical guidelines prescribed by “Central Ethics Committee on Human Research (C.E.C.H.R) of Datta Meghe Institute of Medical Sciences”.

This study will be conducted on systemically healthy subjects with unilateral cleft alveolus, scheduled for secondary- ABG reporting within stipulated duration of study.

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

CRITERION FOR INCLUSION:

- Patients having unilateral cleft alveolus
- Patients subjected to ABG in mixed dentition period.

CRITERION FOR EXCLUSION:

- Patients having bilateral cleft alveolus.
- Wide alveolar clefts (> 10mm) where ABG is contraindicated
- Patients allergic to acrylic material

METHODOLOGY:

Consent:

- Informed agreement will be obtained from all patients before inclusion in the study

Pre surgical protocol-

- Detail history as per case history proforma and clinical examination will be recorded
- Complete Blood investigations will be done and Physician and anesthetist fitness will be obtained for surgery.

Impression:

Prior to the surgical intervention, patients selected for placement of surgical splint will be undergoing for preliminary impression by suitable impression material

- ***Trial***

Trial of the prepared splint to ensure proper fit would be done prior to surgery



Surgical Intervention:

Recipient Site:

The preoperative considerations like, the type of cleft (unilateral or bilateral), availability of the mucosa for adequate soft tissue cover, the amount of communication present oronasally, and the bone support required for the anatomical areas like lateral pyriform rim and alar base, should be evaluated.

The treatment planning should be done to design the best suited flap which can maintain the adequate blood supply and help in achieving hermetic-tension-free tissue approximation.

Incisions are made along the cleft alveolar margins and continued anteriorly onto the alveolus and laterally joining with crevicular incisions which are given minimum two tooth lateral to the cleft in both the segments and mucoperiosteal flap is elevated. The pyriform aperture and the anterior nasal septum are exposed. The nasal lining is identified and separated with the cartilaginous portion of the septum using a periosteal elevator. The mobilized lining is traced up to the posterior part of the fistula, followed by closure of nasal lining.⁵

Though there are other sources of Autogenous bone grafts, but cancellous marrow from the iliac bone is considered as the gold standard, owing to number of reasons such as: it is easy to access, abundantly available and has better outcomes.^{6, 7, 8, 9} The bone graft material is placed and condensed manually, followed by the closure.

Donor site:

Incision is marked on the anterior iliac crest, on the superio- medial part to prevent scarring directly over the crest area. The skin incision of about 4 -6cm is given. To avoid damage to the nerve and prevent unsightly scarring it is given 2cm antero-inferiorly from the anterior superior iliac spine (ASIS). The dissection starts from the skin, continued through the subcutaneous tissue reaching up to the aponeurosis of the muscles to dissect the Scarpa's fascia followed by the periosteal reflection. Then iliacus muscle is retracted medially, and using the Trap door technique the bone graft is harvested. The cancellous bone marrow from the iliac crest is harvested from the medial most part using the bone gouge. The harvested graft is transferred to the saline solution, and prepared recipient site is condensed with material manually.¹⁰



Unilateral cleft alveolus of left side



Reconstruction of palatal layer with closure of oronasal communication forming recipient bed for the bone graft.



Packing of bone graft in the prepared site and Condensing with manual pressure

Donor site area (Anterior iliac crest)



Closure

- **ABG in unilateral cleft alveolus followed by placement of prepared surgical splint for 7 days in Group A, while for Group B no splint will be placed.**

Follow up

Postoperatively patient will be evaluated on 7th & 15th day.

Evaluation

Soft tissue healing will be evaluated using an index developed by Landry RG, Turnbull RS, Howley¹¹, by an independent observer who will be blinded to the study protocols

Evaluation of soft tissue healing

Healing index	Colour of the Tissue	Presence or Absence of Bleeding	Presence or Absence of Granulation	Healing at Incision Site	Presence or Absence of Suppuration
1 - Very Poor (When 2 or more signs are present)	≥ 50% of inflamed gingiva	Present	Present	Tissues unapproximated. Loss of epithelialization beyond the incision margin	Present

<u>2</u> – Poor	≥ 50% of inflamed gingiva	Present	Present	Tissues approximated, but not epithelized with connective tissue exposure	Absent
<u>3</u> – Good	25 - 50% of red gingiva	Absent	Absent	Completely epithelized, with no connective tissue exposure	Absent
<u>4</u> - Very Good	< 25% of red gingiva	Absent	Absent	Completely epithelized, with no connective tissue exposure.	Absent
<u>5</u> – Excellent	all pink tissues	Absent	Absent	Completely epithelized with no connective tissue exposure.	Absent

- Findings will then be recorded in the MS excel sheets and the results of the two groups will be compared and extrapolated to derive logical statistical analysis

Outcome:

The utility of customized Surgical splint in patients undergoing Alveolar bone grafting in Unilateral cleft alveolus immediately post-surgical intervention may improve the soft tissue healing as compared to the patients in which splints are not given. Thereby this unique intervention can substantially benefit the patients to prevent post-operative complications.

Expected Results:

- Significant soft tissue healing in Group A

Sample size determination:

As it is a pilot study, so all the patients reporting in S.P Dental College on outpatient basis or AVBR Hospital within the time duration of the study, for secondary ABG and fulfilling the criteria for the study will be recruited in the study and will be alternatively allocated in the group.

DISCUSSION:

Cleft alveolus is usually accompanied by Cleft of the Lip as well as Palate. The maxillary deficiency and retarded growth is the key feature of such patients and it warrants the balance between their functional and aesthetic components.¹² The surgical repair of the Cleft alveolus is considered as a constitutive part of the repair of cleft palate.¹³It is usually operated by the secondary alveolar grafting after the eruption of the two-third root of the permanent canine, approximately at an age of about 12-14 years. Soft tissue healing is usually compromised in the grafted area because of various reasons, such as trauma due to opposing tooth, hard food, food entrapment and continuous tongue movement which rubs the site. Thus a mechanical barrier can prevent trauma to the site and in turn also prevent the bacterial colonisation and thereby infection can be prevented.

Optimal soft tissue healing is detrimental towards the graft uptake and success of Alveolar Bone grafting. *Gunaseelan R et al 2010* in their published chapter on ABG advocated the utilization

of surgical splints as it immobilizes the grafted area and provides support to the palatal tissue, thereby aiding in graft uptake. Their findings are also suggestive of its role in minimizing the hematoma formation.¹⁴

Garg, et al 2011 conducted a study wherein they advocated the use of occlusal splint made of acrylic for prevention of any injury to the teeth.¹⁵

Therefore the use of customized surgical splints in Cleft alveolus patients immediately after performing Secondary Alveolar bone grafting will serve as a mechanical barrier and may help promote unhindered soft tissue healing. Thus it may be recommended as a component of standard care following ABG.

Conclusion:

The novelty of utilisation of customised surgical splints in the current study can become a standard treatment protocol in patients with ABG.

REFERENCES

1. Amanat N, Langdon D. J. Secondary alveolar bone grafting in clefts of the Lip and Palate. *Journal of Cranio-Maxillofacial Surgery*. 1991; 19(1):7-14
2. Kazem A, Stearns W. J, Fonseca J.R. Secondary grafting in the alveolar cleft patient. *Oral Maxillofacial Surg Clin N Am*. 2002; 14:477-490.
3. Kasatwar A, Borle R, Bholra N, Kambala R, Prasad GSV, Jadhav A. Prevalence of congenital cardiac anomalies in patients of Cleft lip and Palate- Its implications in surgical management. *Journal of Oral Biology and Craniofacial Research*. 2017; 8(3):241-244.
4. Chris A. Skouteris. Soft tissue closure techniques in alveolar cleft grafting. *J Oral Maxillofac Surg*. 2004; 62(1):104.
5. Mathes J. S. *Plastic Surgery, 2nd ed. Pediatric Plastic Surgery Vol IV*. California: W.B Saunders; 2006. p. 265-266.
6. Rudman RA. Prospective evaluation of morbidity associated with iliac crest harvest for alveolar cleft grafting. *J Oral Maxillofac Surg*. 1997; 55(3):219-23
7. Kortebein MJ, Nelson CL, Sadove AM. Retrospective analysis of 135 secondary alveolar cleft grafts using iliac or calvarial bone. *J Oral Maxillofac Surg*. 1991; 49(5):493-8.
8. Sadove MA, Nelson CL, Eppley BL, Nquyen B. Evaluation of calvarial and iliac donor sites in alveolar cleft grafting. *Cleft Palate J*. 1990; 27(3):225-8.
9. Kraut RA. The use of allogenic bone for alveolar cleft grafting. *Oral Surg Oral Med Oral Pathol*. 1987; 64(3):278-82.
10. Deshpande R, Yadav A, Borle R, Kala A, Jajoo SN, Thakkar D. Comparative efficacy of autologous alveolar bone grafting with autologous platelet-rich plasma and without platelet rich plasma in cleft alveolus patients. 2017. *Journal of Cleft lip and Palate and Craniofacial Anomalies*. 2017;1(4):22-25
11. Landry RG, Turbull RS, Howley T. Effectiveness of benzydamyne HCL in the treatment of periodontal post-surgical patients. *Res Clin Forums*. 1988; 10:105-118.
12. Cho-Lee G.Y, Garcia-Diez E.M, Nunes A.R, Pages C.M, Gil S.R, Baro R.A. Review of secondary alveolar cleft repair. *Ann Maxillofac Surg*. 2013; 3(1):46-50.
13. Pradel W, Lauer G. Tissue-engineered bone grafts for osteoplasty in patients with cleft alveolus. *Annals of Anatomy*. 2012; 194(6):545-548.
14. Gunaseelan R, Anantanarayanan. Alveolar Bone Grafting. *Surgical Correction of Facial Deformities*. 2010: 165-172.
15. Garg RM, Garg KA, Datarkar AN, Borle RM. Use of an Acrylic occlusal splint during operations on cleft palate to prevent iatrogenic injury to the teeth. *Br. J. Oral Maxillofac Surg*. 2011; 49(7):e63-64.