

# Comparison of Poliglecaprone 25 (monofilament) and Polyglactin 910 (multifilament) suture material in terms of soft tissue healing of surgical wound after cleft alveolar bone grafting.

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**Abstract: Background:** Grafting the maxilla having cleft in alveolus is a part of comprehensive sequential treatment of cleft patients so as to facilitate eruption of permanent canine, achieve continuity of maxilla for orthognathic corrections and supporting alar bases. Unhindered soft tissue healing is critical to preventing graft exposure and achieving graft uptake. Poliglecaprone 25(monofilament) suture is known to have low capillarity. Thus it can be of benefit in achieving the required healing of soft tissue over cleft maxilla after bone grafting. **Aim:** To Compare Poliglecaprone 25(monofilament) and Polyglactin 910(multifilament) suture material in terms of soft tissue healing of surgical wound after cleft alveolar bone grafting. **Material and Methods:** Patients of unilateral cleft alveolus will have to be randomly divided into two sections. Group A comprising of patients in whom closure will be done by Poliglecaprone 25 whereas Group B of patients in whom closure will be done by Polyglactin 910. Success of the choice of suture material will be evaluated in terms of soft tissue healing, suture slack and number of inflammatory cells on suture surface. **Result:** Results will be analyzed using Student's paired t test. It is expected that the healing will be significantly better in Group A than Group B. **Conclusion:** Efficacy of Poliglecaprone 25 in terms of soft tissue healing after alveolar bone grafting can be validated through this study.

**Keywords:** *Alveolar Bone Grafting (ABG), Soft tissue healing, Poliglecaprone 25(monofilament), Polyglactin 910(multifilament)*

## **INTRODUCTION**

Secondary bone grafting is introduced by many authors historically, in the 90's, but the concept for the scientific basis was introduced by Boyne and Sands.<sup>1</sup> Bone grafting prior to permanent cuspid eruption in maxillary cleft alveolus is necessary in comprehensive treatment. Rationale for undertaking a bone graft is to have a continuous maxilla, build bone for strengthening teeth lying adjacent to cleft alveolus, prevent drooping of alar base and facilitate canine eruption.<sup>2</sup> Peculiarly cleft maxilla is intervened at a stage of mixed dentition phase. Wound healing is generally impaired due to poor metabolic response, in any surgical intervention.<sup>3</sup> Optimum soft tissues healing at the cleft maxilla site is imperative to have a successful graft uptake. Poor soft tissue healing will lead to exposure of grafted bone and subsequent failure. 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, and food entrapment etc.<sup>4</sup> Despite numerous advances in prophylactic measures, infections still remains a complication in ABG (alveolar bone grafting). Sutures are most commonly used for wound closure. Every suture type has a role to approximate the tissues in their pre-existing site and form till the healing takes its own natural course. These wounds are more susceptible to food and bacterial colonisation. Intra oral tissues are continuously in function which places the wounds at high risk for getting gaped.<sup>5</sup> After bone grafting in cleft alveolus healing of soft tissues even becomes more critical as slightest of bone exposure can lead to failure of graft uptake. Multifilament sutures have been routinely used by cleft surgeons to close the surgical defect in alveolar bone grafting. Multifilament suture tends to harbour more food debris and microorganisms which can serve as a nidus for infection. The Monofilament sutures in comparison to multifilament sutures are known to harbour fewer bacteria and hence can reduce the chance of surgical site infection.

### **Objectives:**

- To evaluate soft tissue healing in monofilament group
- To evaluate soft tissue healing in multifilament group
- To evaluate suture slack in monofilament group.
- To evaluate suture slack in multifilament group.
- To evaluate inflammatory cells on monofilament suture sample.
- To evaluate inflammatory cells on multifilament suture sample.
- To compare soft tissue healing in both groups
- To compare suture slack in both groups.
- To compare inflammatory cells on both suture samples.

### **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:** Patients comprising in whom closure performed by poliglecaprone25.
- **Group B:** Patients comprising in whom closure performed by Polyglactin 910.

### **Methods:**

The present prospective randomized parallel arm pilot study is scheduled to be conducted in the Department of Oral & Maxillofacial Surgery, Sharad Pawar Dental College and Hospital in coordination with Department of Oral Pathology and Microbiology, Sharad

Pawar Dental College, Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha. The study would be conducted in accordance with the Helsinki declaration and its later amendments or comparable ethical standards and 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 undergoing surgical intervention scheduled to be conducted at AVBRH.

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

**CRITERION FOR INCLUSION:**

- Patients having unilateral cleft alveolus
- Patients subjected to alveolar bone grafting in mixed dentition period.
- Systemically healthy patients fit to undergo surgery

**CRITERION FOR EXCLUSION:**

- Patients having bilateral cleft alveolus.
- Patients having known allergy to suture materials used

**METHODOLOGY:**

**Assent:**

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

**Clinical examination:**

- A detailed case history will be recorded.
- The examination of patient will be initiated thorough history and clinical evaluation. Evaluation will be composed of residual cleft deformities and pliability of soft tissue adjacent to and overlying the cleft alveolus.

**Pre-operative investigations:**

Radiographic evaluation will include orthopantomograph, occlusal radiograph and periapical radiograph with grid of the cleft region. Complete Blood investigations will be done followed by Physician and anesthetist fitness for surgery.

**Surgical protocol:**

**Recipient Site:**

The preoperative considerations like, the type of cleft (unilateral or bilateral), availability of the mucosa for closure, the extent of the oronasal communication, the bony support needed for the lateral pyriform rim and the alar base, should be evaluated. Planning should be done for best suited design of the flap, to maintain the adequate blood supply and achieve tension-free closure.

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 is 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.<sup>6</sup>

Though there are other sources of Autogenous bone grafts, but cancellous marrow bone from the ilium is considered as the gold standard, owing to its ease of access, abundance in availability and better outcomes<sup>7-10</sup>. The bone graft material is placed and condensed manually, followed by closure of the final flap.

**Donor site:**

The marking of the incision is done on the superio-medial aspect of the anterior iliac crest to prevent scarring directly over the crest area. The skin incision of about 4 -6cm, 2cm antero-inferior to the anterior superior iliac spine (ASIS) to prevent the nerve damage and unsightly scarring is given. Dissection is carried through the skin, subcutaneous tissue and continued through the aponeurosis of the muscles to dissect the Scarpa's fascia. The periosteum is reflected and iliacus muscle is retracted medially, then using the Trap door technique the bone graft is harvested from the medial aspect of the crest using bone gouge. The harvested graft is transferred to the saline solution, and prepared recipient site is condensed with material manually.<sup>11</sup>



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

- **Alveolar grafting in unilateral cleft alveolus followed by closure using either of the two suture materials**

**Follow up**

Postoperatively patients will be evaluated on 3<sup>rd</sup> & 7<sup>th</sup> day.

**Evaluation**

**Soft tissue healing**

Soft tissue healing to be examined using an index developed by Landry RG, Turnbull RS, Howley<sup>12</sup>, by an independent individual who will be unaware to the study protocols .It will be evaluated on day 3 and day 7

Healing index	Tissue colour	Bleeding	Granulation	Incision	Suppuration
1 - Very Poor: 2 or more signs are present	≥ 50% of gingiva inflamed	Present	Present	Tissues unapproximated. Not epithelialized, with loss of epithelium beyond incision margin	Present
2 – Poor	≥ 50% of gingiva inflamed	Present	Present	Non epithelized with exposed connective tissue	Absent
3 – Good	25 - 50% of red gingiva	Absent	Absent	Completely epithelized. No exposed connective tissue	Absent
4 - Very Good	< 25% of red gingiva	Absent	Absent	Completely epithelized .No exposed connective tissue	Absent

5 – Excellent	all pink tissues	Absent	Absent	Completely epithelized .No exposed connective tissue	Absent
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- **To evaluate suture slack<sup>13</sup>**  
Postoperative amount of slack will be assessed for every suture material with the help of graduated probe UNC 15. The knot will be carefully lifted with cotton pliers, and the distance from the knot to the tissue will be measured to the nearest 0.5 mm. It will be evaluated on day 3 and day 7.
- **Evaluation of inflammatory cells on suture sample<sup>14</sup>**  
Each suture material from patient falling in respective group will be collected on suture removal day. Suture material embedded in tissue will be fixed. Three sections will be prepared after which they will be inspected. Quantification of inflammatory reaction will be objectively assessed as follows
  - Absence of inflammatory reaction (0 inflammatory cells)
  - Soft inflammatory reaction (< 30 inflammatory cells)
  - Average inflammatory reaction (30–60 inflammatory cells)
  - Severe inflammatory reaction (> 60 inflammatory cells)

It will be evaluated on day 7

Findings will then be recorded in the MS excel sheets and the results of the 2 group will be compared and extrapolated to derive logical statistical analysis

**Outcome:** Poliglecaprone 25 (Monocryl suture) may prevent the ingress of bacteria and infection at the bone grafted site owing to less capillarity thereby improving the graft uptake and improving the desired treatment goals

**Expected Results:**

- Improved soft tissue healing in Group A
- Less suture slack in patients of Group A
- Mild to moderate inflammatory cells in Group A

**Sample size determination:**

As it is a pilot study, so all the patients reporting in Sharad Pawar Dental College on outpatient basis or Acharya Vinoba Bhave Rural Hospital within the time duration of the study, for secondary Alveolar bone grafting and fulfilling the criteria for the study will be recruited in the study and will be alternatively allocated in the group

**DISCUSSION:**

The repair of the cleft is a multidisciplinary approach and it warrants a balance between the aesthetics and functional outcomes over the increased maxillary deficiency and restricted growth.<sup>15</sup> Cleft lip and palate often extends up to alveolus. To achieve results pertaining to form, function and aesthetics age based sequential treatment guidelines are in place wherein Cleft alveolus is usually operated by secondary alveolar grafting after the eruption of the permanent canine, approximately at an age of about 12-14 years. Optimal soft tissue healing can be compromised owing to bacterial colonisation, food accumulation and subsequent infection<sup>16,17</sup>. Multifilamentous suture has high risk of pushing the infective load to deeper

planes due to their conspicuous capillarity action. Miroslav Dragovic et al in 2019 compared four different suture materials in oral wound healing. They examined microbial ingress, tissue reactivity. They came to the conclusion that Non-resorbable polypropylene suture showed superiority among all sutures. Inflammation in its most mild form and best healing characters were found around this suture material. The poorest soft tissue healing was found around non-resorbable silk suture. This suture elicited strongest inflammatory reaction and showed the greatest microbial adherence compared to alternative sutures. Major factor for success of alveolar bone grafting is soft tissue healing. If monocryl sutures give encouraging results in alveolar bone grafting their use can be recommended as part of standard treatment for wound closure after alveolar bone grafting

**Conclusion:** Utility of Poliglecaprone 25 for wound closure after alveolar bone grafting can be validated through this study

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