

Comparative evaluation of healing after periodontal flap surgery using isoamyl 2-cyanoacrylate (bioadhesive material) and silk sutures: A Study Protocol

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Abstract: Background- *The main goal in periodontal surgery is the healing by primary intention because there is less scarring, more rapid healing and reduced discomfort. Cyanoacrylate is a tissue adhesive which provides benefits to the patient as a faster healing and less postoperative pain. Flap surgery for periodontal reattachment, demands close postoperative adaptation for the gingival tissue onto the prepared tooth surface. Objective-* *To evaluate the healing after periodontal flap surgery using isoamyl 2 - cyanoacrylate and silk sutures. Material and Methods-* *In this study, 40 patients of systemically healthy will be selected. Groups will be divided into test and control which consist of 20 defects in each. Informed written consent will be obtained from all the subjects before the surgery. Clinical measurements like Plaque index, Papillary bleeding index, Probing pocket depth, Healing index will be recorded. The test group will be treated by isoamyl 2 - cyanoacrylate, while the control group will be treated by Silk suture after periodontal flap surgery. Patients will be recalled at 1, 3, 6 months post surgically for periodontal re-evaluation. Expected Result-* *When all the parameters will be compared at 6 months post-operatively to baseline data, both the treatment group (test and control) will show significant CAL gain, PPD reduction. Test group will be found better healing as compared to control. Conclusion-* *Both the treatment group (test and control) will show significant CAL gain, PPD reduction. This study will be achieved effective healing response after periodontal flap surgery with sutures as compared to cyanoacrylate.*

Keywords- *Cyanoacrylate, Healing, Periodontal flap, Intrabony defects*

Introduction:

Periodontal plastic procedures are of utmost important for the regeneration of lost periodontal tissues. Healing of the oral mucosa through primary closure is appreciable after surgical procedure. Primary closure of wound shows less scare, fast healing & less pain.⁽¹⁾ Closure of surgical area through suturing has been found to be standard technique from ancient times.⁽²⁾ Various evolution come forward for the closure of wound which includes staples, adhesive tapes, adhesive glues, and fibrin sealants have to accelerate the healing.⁽³⁻⁵⁾ New innovation in tissue adhesives have been approved by the US Food and Drug Administration. They have found that tissue adhesives can replace the sutures in 25% to 33% in numerous cases of wound closure.⁽⁶⁾ From many years, application of surgical sutures has been carried out. Numerous biomaterials are used to suture the surgical area such as natural and synthetic. But several complications have been come across like fistula & granulation formation. Through suturing the piercing of parenchymal and inflammatory tissues takes place. Disruption in capillary action occurs through twisted or braided suture biomaterials which may cause inflammation & infection at surgical site as well as it impose removal of the suture thread at the 7 or 10 days postoperatively. These sutures may pose operator skills, high level of clinical judgement, exact control over the force application on the suture to avoid excess/inadequate tension in the suture. If force get exceeds it may leads to flap tear, necrosis and impaired the healing process.⁽⁷⁾

This limitations of sutures poses in creation of tissue adhesive for the closure of wound at surgical site. It reduces the efforts, avoids the pain of needle prick and tearing of flap. A novel innovation in tissue adhesive is Cynoacrylates. First proposed by Coover et al. in 1959 and marketed as Isoamyl 2- cyanoacrylate.^(8,9) Chemical formula of cyanoacrylate materials is $H_2C = C(CN)COOR$, where R-can be substituted for any alkyl group ranging from management of disease-induced changes in the periodontal methyl to decyl.

From Literature have been observed that the use of cyanoacrylates in the repair of organs, skin, vessels, nerves, mucosa grafts, closure of laceration wounds and incisions in many surgeries.⁽¹⁰⁻¹¹⁾ Application in cases of extraction sockets, fixation of mandibular fractures, healing of intra oral wounds, fixation of free gingival grafts, healing of periodontal flaps were observed predictable outcomes with this cyanoacrylate.⁽¹²⁻¹³⁾

It has advantage of easy application, biocompatible for tissues, bacteriostatic, non-toxic, rapid adhesive property & achieve immediate haemostasis. It get solidifies rapidly alkaline media and slowly in acidic media within 5- 10 seconds as well as shows no absorption into the blood streams. Thus, the aim of present randomized parallel clinical trial will be evaluated healing after periodontal flap surgery using isoamyl 2- cyanoacrylate and silk sutures.

OBJECTIVES

- 1) To evaluate healing after periodontal flap surgery using isoamyl 2- cyanoacrylate
- 2) To evaluate healing after periodontal flap surgery using silk sutures
- 3) To compare and evaluate healing after periodontal flap surgery using isoamyl 2- cyanoacrylate and silk sutures

STUDY POPULATION:

σ is population Standard Deviation(SD)

d is the difference to be detected

From the previous article it was proved that

1. Standard Deviation in first group $SD_1 = 0.49$
2. Standard Deviation in first group $SD_2 = 0.22$
3. Mean of first group = 0.94
4. Mean of second group = 0.6

After calculating in open Epi, version 3, open source calculator- SSMean

So by above formula sample size will be 40

Thus each group will have a sample size of 20.

24 patients having moderate to severe chronic periodontitis with clinical criteria (i.e., probing depth of ≥ 5 mm and bone loss on radiograph $\geq 50\%$) will be selected from the outpatient Department Of Periodontics, Sharad Pawar Dental College, Sawangi (Meghe), Wardha, using following criteria.

INCLUSION CRITERIA:

1. Patient should be free of systemic diseases.
2. Presence of ≥ 5 mm or deep periodontal pockets indicated for periodontal flap surgical procedures.
3. Presence of minimum ≥ 2 mm zone of keratinized gingiva surrounds the test teeth which allows full soft tissue coverage at defect site.

EXCLUSION CRITERIA:

1. Presence of localized aggressive periodontitis.
2. Patients with poor oral hygiene care (Plaque Index ≥ 1)
3. Patient who smokes (with recent history of smoking more than 10 cigarettes /day) or who consume any type of tobacco products.
4. Study tooth with improper endodontic / restorative therapy.
5. Study tooth with mobility exceeding grade II and exhibiting a class III or class IV furcation defect.
6. Previous History of periodontal surgery in selected quadrant selected for study purpose.
7. Pregnant females or lactating mothers.
8. Clinically determined and/or radiographic examined untreated acute infection present at selected area.
9. Presence of apical pathology, cemental pearls, root irregularities and fracture which causes difficulty in removal through odontoplasty process, untreated decayed tooth at cemento-enamel junction or at root surface.

Information related to dietary status, oral hygiene care, systemic background, gingival and periodontal condition details will be documented precisely in charts. Clinical evaluation of patients will be done through mouth mirror and William's graduated periodontal probe in good illumination.

INITIAL THERAPY:

In first visit, full mouth scaling will be undertaken followed by root planing under local anesthesia if required. Coronoplasty will be carried out and oral hygiene instructions will be given to patient. Plaque control measures will be repeated until plaque score will be ≤ 1 . After initial therapy, periodontal evaluation will be carried out once in 2 week.

The information about the need of study will be clarified and signed informed consent will be taken from patients. Study protocol is approved by Ethical committee of DMIMS (DU)/IEC/Aug-2019/8295), Sawangi (Meghe), Wardha.

For the Standardization of probe angulations and accurate position, custom made occlusal acrylic stent will be made. Alginate impression will be taken for cast model preparation on which occlusal stent will be fabricated through use of acrylic material. Stent should cover the occlusal surface of test tooth and extend to minimum one adjacent tooth and covers the coronal third of teeth. A reference point (slot) will be marked on the stent at the deepest site of involved tooth to facilitate reproducible periodontal probe positions. The apical margin will be linear and served as a fixed reference point.

STUDY DESIGN:

In this randomized clinical trial, split mouth study before undergoing surgical treatment, the chosen defects will be allocated randomly. In this study, 40 patients of systemically healthy will be selected. Groups will be divided into test and control which consist of 20 defects in each. The test group will be treated by isoamyl 2- cyanoacrylate, while the control group will be treated by Silk suture after periodontal flap surgery.

CLINICAL MEASUREMENTS:

Clinical measurements like Plaque index, Papillary bleeding index, Probing pocket depth, Healing index will be recorded. Papillary bleeding index and periodontal probing depth will be assessed again 6 weeks and 3 months after surgery, plaque index at 1 week, 6 weeks, and 3 months post-surgery and early healing index [Wachtel *et al.*] ⁽¹⁴⁾ will be assessed after 1 and 2 weeks post-surgery.

Oral health status of patient will be examined by using plaque index which will represent the accumulation of plaque present above the gingival margin of teeth. Gingival inflammation will be measured through Papillary bleeding index.

A. Indices

- 1. Plaque Index (PI)-** Turesky – Gillmore –Glickman Modification of Quigley-Hein 1970 ⁽¹⁵⁾
- 2. Sulcus Bleeding Index (SBI)-** Muhlemann & Son 1971 ⁽¹⁶⁾
- 3. Healing Index -** Wachtel et al 2003 ⁽¹⁴⁾

B. Probing Measurements

Both treatment groups will be recorded to evaluate the finding by probing measurement. Probing pocket depth will be measured from base of the pocket upto gingival margin. These measurements will be recorded with a UNC-15 calibrated (University of North

Carolina, Hu-Friedy) periodontal probe. These clinical parameters will be recorded after preparation of acrylic stent at baseline, at 3 months and at 6 months after surgery.

The width of keratinized gingiva will be recorded by measuring the sulcular depth and attached gingiva (from mucogingival junction upto free gingival groove) through UNC-15 calibrated Periodontal Probe. All the probing measurements will be recorded at baseline and 6 months of surgery.

SURGICAL PROCEDURE:

Before surgical treatment, patients will be advised to swish with 0.2 % chlorhexidine gluconate mouthwash for about 1-2 minute. Under all aseptic precaution and condition, nerve block will be given with local anesthetic solution of 2% xylocaine^(17,18) containing 1:1,00,000 epinephrine.

Flap Design (Incisions):

Bard-Parker number 12 or 15 surgical blades will be used to achieve predictable reflection of defect site. For reflection of flap intracrevicular incision will be given on buccal and lingual aspects. To achieve primary wound closure and to preserve complete interdental papillae, the incisions should be given as far interproximally as possible. To achieve added exposure, vertical releasing incisions will be placed on adjacent tooth.

Flap reflection:

To gain access to alveolar bone in area of bone defect, periosteal elevator (24G Hu-Friedy, USA) will be used to raise the full thickness flap. Thorough debridement of defect will be carried out by removing diseased tissue from undersurface of the flap and at the same time, proper measures should be taken to prevent the flap rupturing or papillae loss.

Debridement and root surface management:

Debridement of osseous defect will be initially done with hand scalers and curettes (Gracey curettes, Hu-Friedy, USA) followed by power driven scalers. The undersurface of the flap or papillae will be debrided judiciously to prevent over trimming of the flap. Thorough root planing will be done with hand instruments.

Depth of the vertical bone defects (BD) will be measured. The total osseous wall present will be recorded with UNC-15 probe. All osseous defects measuring ≥ 3 mm vertically will be included in the study. Intra marrow penetration of the base of the defect through use of half round bur will be done to ensure sufficient bleeding from the site.

Procedure for test group:

After debridement, the flap was trimmed and repositioned to accomplish as much complete interproximal closure as possible. Isoamyl 2- cyanoacrylate was placed in a dropwise manner on the flap margins, which were held in place. The application was done till a thin film of set cyanoacrylate formed. No periodontal pack was used.

Procedure for control group

The flap was then sutured with surgical silk material using interrupted sutures as necessary. No periodontal pack was used.

Post-operative care:

Post-operative medications will be prescribed which includes antibiotics & analgesics for 5 days. Patients will be advised to swish with 0.2% chlorhexidine mouthwash for about 6 weeks. Removal of Periodontal dressing and sutures will be done at 8-10 days after the surgery. Use of tooth brushing or chewing will be not allowed for 6 weeks in the treated area. Patients will be informed to cleanse the operated area in an apico-coronal direction with cotton pellet dip in 0.2 % chlorhexidine for additional 2-3 weeks. After that oral hygiene measures like brushing and interdental cleaning aids will be reinstructed to stop use of that and also resume the use of this chlorhexidine mouthwash.

Maintenance care:

Patients will be followed at 1, 3, 6 months post surgically for evaluation of PI and PBI. Oral hygiene care given to patient at every visit along with ultrasonic scaling. Care will be taken not to probe upto 6 month after surgery.

Re-examination:

A complete post operative evaluation will be performed at 6 months post-surgically. All clinical parameters and measurements will be re-assessed. In addition standardized radiographs and clinical photographs will be obtained at 6 month post surgery.

Statistical Analysis:

Indices like plaque index and papillary bleeding index and also all clinical parameters which includes healing index will be assessed by calculation of means and standard deviation (Mean \pm SD) values. Student's paired t-test will be applied to each treatment group to compare the data from baseline to 6 months. Student's unpaired t-test will be used for comparisons between the two treatment groups at baseline level and at 6 months follow up period. If the probability value (p) ≥ 0.05 then, difference found will be non-significant and if $p < 0.05$, it will be considered as significant.

Expected Result:

When all the parameters will be compared at 6 months post-operatively to baseline data, both the treatment group (test and control) will show significant CAL gain, PPD reduction. Test group will be found better healing as compared to control. Patient perception for pain will be evaluated through questionnaire and will be observed more significant results in iso-amyl cyanoacrylate group as compared to suture group. More plaque accumulation will be evaluated in suture group as compared to cyanoacrylate group because of the absence of the test materials, which will be removed at 7 days. Cyanoacrylate group will be observed the absence of pain, discomfort, burning sensation & esthetically acceptable for the patients.

Discussion

The current study will be carried out to compare and determine the healing response after periodontal flap surgery with sutures and cyanoacrylate. Tissue adhesive acts through valence bonding and van der waal's force (Miller et al.).⁽¹⁹⁾ Cyanoacrylate has better property to close the margins together.

In the present study, plaque accumulation more at the suture area due to difficulty in oral hygiene care. As the threads of suture material may act as a site of plaque and food accumulation. This findings will be similar to those reported by Binnie and Forrest.⁽²⁰⁾ Statistical significant difference will be observed when pain/discomfort, burning/itching, and esthetics will be evaluated in between test and control group. This study will be similar with findings reported by Giray et al.⁽²¹⁾. Padhye and Pol⁽²²⁾ stated that cyanoacrylate has been found to be an ideal alternative for suture with advantage with respect to time and technique to reduce the operators time. Related studies were also reported by Makhubele, H. D et al⁽²³⁾, Kathariya et al⁽²⁴⁾, Thakre et al⁽²⁵⁾ and Thombre at al⁽²⁶⁾.

Conclusion:

It will be concluded that cyanoacrylate provides better results with early healing. Both the treatment group (test and control) will show significant CAL gain, PPD reduction. This study will be achieved effective healing response after periodontal flap surgery with sutures as compared to cyanoacrylate.

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