COMPARATIVE ASSESSMENT OF WOUND HEALING AND PATIENT COMFORT AFTER PERIODONTAL FLAP SURGERY IN CHRONIC PERIODONTITIS CASES WITH OR WITHOUT PERIODONTAL DRESSING: A RANDOMIZED SPLIT MOUTH CLINICAL STUDY

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BABU BANARASI DAS UNIVERSITY,

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In the partial fulfillment of the requirements for the degreeof

MASTER OF DENTAL SURGERY

In

PERIODONTOLY

By

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF PHOTOGRAPHS

LIST OF ANNEXURES

LIST OF ABBREVIATIONS

VAS	Visual Analogue Scale
GI	Gingival Index
WHI	Wound Healing Index
PPD	Proding Pocket Depth

Abstract

Introduction: Periodontitis is a multi-factorial chronic inflammatory disease caused by host microbial interaction which results in the destruction of supporting structures of the teeth. Periodontal therapy includes both surgical and non surgical management of disease processes. Periodontal surgery is a common oral surgical method which is used to access the root surface for removing all local predisposing factors. Postoperatively the surgical site can be covered by periodontal dressing. Periodontal dressing plays the role of protecting the wound from mechanical trauma and stabilizing the surgical site during the healing process. However the use of periodontal dressing was questioned later by some researchers due to tissue inflammatory reaction, higher plaque accumulation, more irritation to soft tissue and patient pain and discomfort. Keeping both the aspects in consideration, this study has been taken up to assess whether there is a need of periodontal dressing post flap surgery or not.

Materials and Method: A randomized, split-mouth clinical study was conducted, with two groups- Periodontal flap surgery with dressing and Periodontal flap surgery without dressing. Thirty individualsin total were chosen, with thirty quadrants in one group and thirty in other group. In the Group I, the surgical area was protected and covered with the periodontal dressing and in the Group II, the surgical area was not protected and covered.

Result: Periodntal flap with dressings was superior in terms of the post operative pain, post-operative healing, and gingival health of the patient.

Conclusion:. The use of periodontal packs effectively improves the results of surgical treatments in patients due to improved blood coagulation stability, no bleeding in the wound area, and reduced riskof bacterial infection in the surgical area.

Keywords: periodontal dressing, periodontal flap surgery, gingival index, healing index, etc.

Periodontitis is a multi-factorial chronic inflammatory disease caused by host microbial interaction which results in the destruction of supporting structures of the teeth.[1] The etiology is complex with periodontopathogens forming a major crux for the initiation and progression of the disease.[2] Tissue destruction in periodontitis results in the breakdown of the collagen fibers of the periodontal ligament, resulting in the periodontal pocket between the gingiva and tooth.[3] Chronic Periodontitis is a slowly progressing disease, but the tissue destruction that occurs is irreversible.[4] Periodontal therapy includes both surgical and non surgical management of disease processes.[5] Periodontal surgery is a common oral surgical method which is used to access the root surface for removing all local predisposing factors.[6]

Like in any general surgery wound healing post surgery is of major concern, wound healing after periodontal surgery is of utmost importance. It is a complex process where the cellular structures and tissue layers are restored back to the original state and is broadly divided into 3 stages inflammatory, proliferative and remodelling.[7] A well coordinated series of events takes place within these three phases resulting in restoration of normal structure of the injured tissue. Wound healing following periodontal flap surgery is influenced by the factors like bacterial contamination, innate wound-healing potential, local site characteristics, surgical procedure/ technique and systemic and environmental factors (e.g diabetes and smoking). Postoperatively the surgical site can be covered by periodontal dressing. Periodontal dressing plays the role of protecting the wound from mechanical trauma and stabilizing the surgical site during the healing process.[8] The history of periodontal dressing dated back to 1923 when Ward introduced “Wondrpack” in order to protect surgical sites from mechanical trauma and splint soft tissue and mobile teeth.[9] From1923 until today many different periodontal dressings have been produced.

Periodontal dressings can be broadly classified into three groups:

(i) those containing zinc oxide and eugenol,

(ii) those containing zinc oxide without eugenol and

(iii) those containing neither zinc oxide nor eugenol.

Eugenol dressings

The Wondrpak was the first periodontal dressing introduced containing eugenol.[9] It was a 2-component system comprising a powder with zinc oxide, powdered pine resin, talc and asbestos and a liquid containing isopropyl alcohol, clove oil, pine resin, pine oil, peanut oil, camphor and coloring materials.[10] Zinc oxide and eugenol dressings are supplied as a liquid and powder or paste. These are mixed together on a waxed paper pad using a wooden tongue depressor or spatula. The powder or paste is gradually incorporated into the liquid until it reaches a dough-like consistency. The dressing may be used immediately or wrapped in aluminum foil and refrigerated for use for up to 1 week.[11]

Role of eugenol

Eugenol-based dressings were formerly popular, due to their property of obtunding pain and rendering sites less sensitive. Waerhaug and Loe in 1957[12] commented that zinc oxide eugenol dressings seemed to prevent or retard bacterial growth based on their antiseptic properties. However, eugenol was found to irritate oral mucosal tissues, induce allergic reactions and cause tissue necrosis, particularly of bone, which led to delay in healing.[13] Furthermore, it presents difficulties in manipulation and has a rough surface after setting. Histological evidence has also shown that eugenol-containing dressings produce greater tissue destruction, with more inflammatory cell infiltration and connective tissue response.[14,15] Eugenol has proven to be cytotoxic at higher concentrations and has an adverse effect on fibroblasts and osteoblast-like cells.[16] All of these reasons lead to the development of noneugenol dressings in the late 1950s.

Noneugenol dressings

Noneugenol dressings are currently the most widely used periodontal dressings. Commercially available noneugenol dressings include Coe-Pak, Cross Pack, Peripac, Septopack, PerioCare, Perio Putty and Periogenix.

Coe-Pak™

Coe-Pak is the most widely used noneugenol intraoral dressing in the United States, and is manufactured by Coe Laboratories (Alsip, IL, USA). It consists of 2 pastes: the base paste which contains zinc oxide with added oils and gums, and lorothidol which is a fungicide related to hexachlorophene. The catalyst paste contains coconut fatty acids thickened with colophony resin or rosin and chlorothymol as an antibacterial agent. Equal lengths of material are placed on a waxed paper pad and mixed using a wooden tongue depressor until a thick consistency and uniform color is reached. The setting time can be altered by adding a few drops of warm water during mixing or by immersing the pack into a bowl of warm water just after mixing. Once the paste loses its tackiness, it can be handled and molded using gloves lubricated with water or petroleum. The pack is then formed into pencil-sized rolls that are then mechanically interlocked in the facial and lingual interproximal areas.[17] The Coe-Pak is available in regular set and hard and fast set formulations, based on its setting time and consistency, and it is supplied commercially both in manual mix and automix varieties.

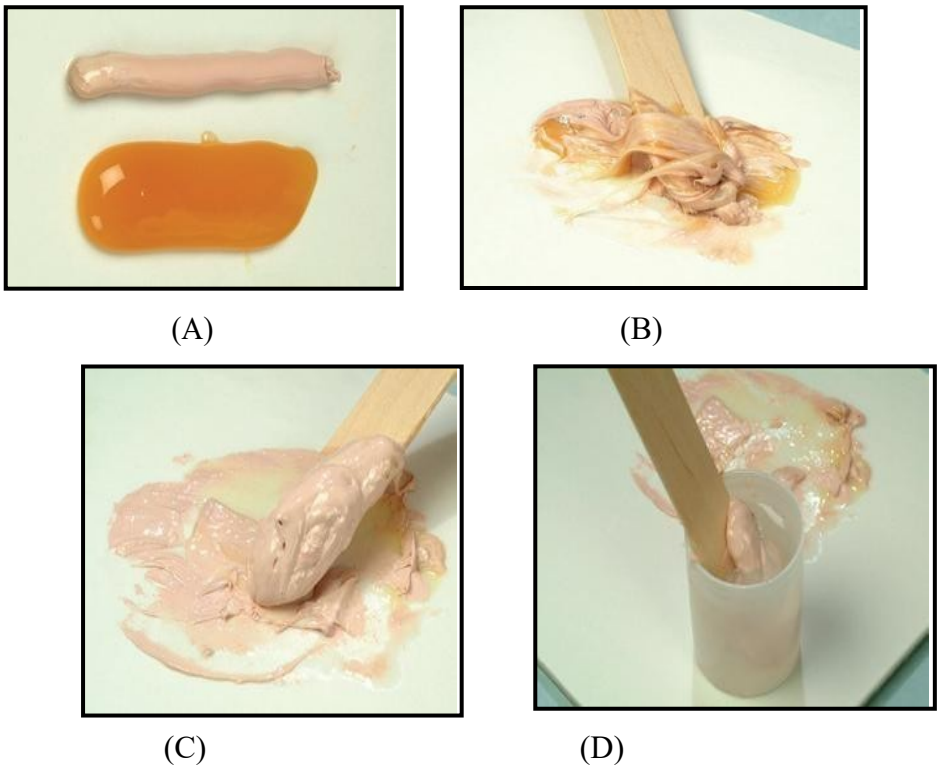


Figure- 1 Preparing the surgical pack (Coe-Pak). (A) Equal lengths of the two pastes are placed on a paper pad. (B) The pastes are mixed with a wooden tongue depressor for 2 or 3 minutes until (C) the paste loses its tackiness. (D) The mixed paste is placed in a paper cup of water at room temperature. With lubricated fingers, it is then rolled into cylinders and placed on the surgical wound.

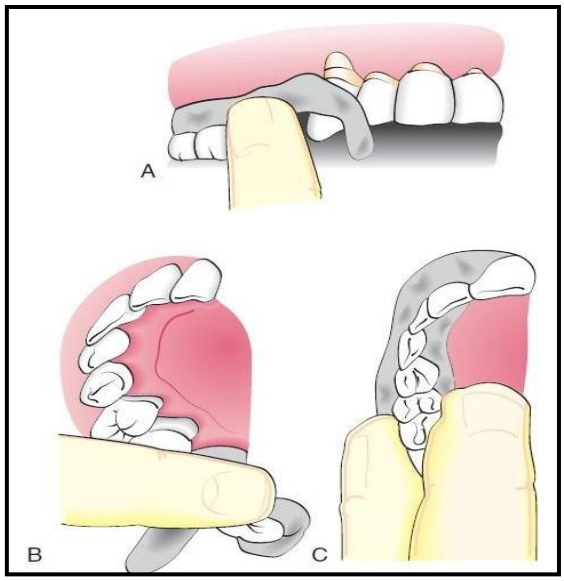


Figure- 2 Inserting the periodontal pack. (A) A strip of pack is hooked around the last molar and pressed into place anteriorly. (B) The lingual pack is joined to the facial strip at the distal surface of the last molar and fitted into place anteriorly. (C) Gentle pressure on the facial and lingual surfaces joins the pack interproximally.

The main advantages of noneugenol dressings are minimal irritation of the mucous membrane, pleasant odor, neutral taste, ease of manipulation, pliability which facilitates easy removal from undercut areas and elimination of the objectionable taste of eugenol. Although they possess neither the analgesic nor antibacterial properties of eugenol dressings, they are less irritating and form a closely adapted adhesive barrier to saliva and oral bacteria.[18]

Dressings containing neither zinc oxide nor eugenol

The third group of periodontal dressings consists of cyanoacrylate dressing, light cure dressing, collagen dressing and mucoadhesive/stomahesive dressing.

The use of a periodontal dressing is mainly to avoid physical injury to the wound, pain, infection, root sensitivity and to prevent formation of caseous deposits upon the root surfaces.[9] The most common and widely used non-soluble dressing is the Coe-Pak™ which is supplied as two pastes or as an auto-mixing system contained in a syringe.[19] It is based on a metallic oxide and fatty acid reaction. However the use of periodontal dressing was questioned later by some researchers due to tissue

inflammatory reaction,[20] higher plaque accumulation, more irritation to soft tissue[21] and patient pain and discomfort resulting that periodontal dressing did not have any advantage in terms of wound healing.

Keeping both the aspects in consideration, this study has been taken up to assess whether there is any need of periodontal dressing post flap surgery or not. Clinical parameters such as patient's postoperative comfort, degree of healing, gingival index, gingival embrasure opening, number of missing sutures will be observed to conclude.

AIM

The aim of the present study is to assess the wound healing and patient comfort post periodontal flap surgery in the cases of chronic periodontitis using periodontal dressing and to compare it without using periodontal dressing at seven days and one month.

OBJECTIVES

I. To assess patient postoperative comfort by VAS by Hayes and Patterson in 1921

II. To assess the degree of healing by Landry et al. in 1988.

III. To assess the gingival index by Loe and Sillness in 1963.

IV. To assess the gingival embrasure opening by Black Triangle Classification given by Nordland and Tarnow in 1998.

V. To assess number of missing sutures.

Ward AW (1923)[9] advocated the use of periodontal dressing for routine periodontal surgical procedures in order to reduce pain, infection, root sensitivity and minimise caseous deposits within the wound site.

Mann JB, Crane AB, Kaplan H (1934)[22] studied gingivectomy sites histologically and observed satisfactory healing when no periodontal dressings were used. After observation periods of six to sixteen days, the epithelium covering the tooth below the gingival margin. was very short (probably 0.2 to 0.5 mm.), but it increased in width as the observation period was extended, and after three months it may have been as wide as 2.5 mm. They assessed that all the soft tissue, including the epithelial cuff (epithelial attachment), had been removed when the Crane-Kaplan method had been used.

Orban B (1941)[23] observed using zinc oxide eugenol that better healing occurred if the dressing is changed every 2 to 4 days for 10 to 14 days. If the dressing was left in place in excess of 12 days, delayed healing occurred. He did not evaluate healing without the use of dressing though.

Bernier JL, Kaplan H (1947)[24] conducted a study of healing after gingivectomy and subsequent application of a surgical cement consisting of zinc oxide, resin, eugenol, and oil of bitter almond. They concluded that post gingivectomy packs facilitated the healing by serving as a surface contact. They were doubtful about the significance of the constituents of the various packs.

Linghorne WJ, O'connell DC (1949)[25] studied different periodontal dressings to determine their bacterioststic properties. The dressings were primarily zinc oxide and eugenol. They found the dressing to be an effective bacteriostatic agent in vitro, an effective agent in pocket therapy, a stimulant, and a local anesthetic.

Waerhaug J (1955)[26] studied the tissue reactions to a zinc oxide-eugenol surgical cement and concluded that this pack is slightly antiseptic and seems to prevent or retard bacterial growth. He pointed out that the application of a surgical dressing did not influence the final result of healing.

Waerhaug J, Loe H (1957)[27] evaluated histologically the effect of the surgical cement on the healing processes after gingivectomy. They reported that exposed tissues will heal irrespective of the application of a protector. They felt that the dressing provided an environment more favorable for optimum healing.

Blanquie RH (1962)[28] stated that the purposes of a periodontal dressing are to control postoperative discomfort, act as a splint for loose teeth, allow for tissue healing under aseptic conditions, prevent reestablishment of a periodontal pocket and desensitize denuded cementum.

Baer PN, Sumner CF, Miller G (1969)[29] using clinical and animal studies, indicated that postsurgical priodontal dressings do not exert any perceptible effect on the final healing following periodontal surgery. He stated that in a healthy person who is already healing at an optimal rate, there is probably very little that can be done to accelerate healing. The main purpose of a post surgical dressing is to provide patient comfort and to protect the wound from further injury while it is healing.

Stahl SS, Witkin GJ, Heller A, Brown Jr R (1969)[30] conducted a study in which he performed gingivectomies at 274 suprabony pockets in 100 female and 52 male patients ranging in age from 17 to 71 years using periodontal dressings on half the patients and no dressings on the other half. They concluded no significant differences in the repair sequence between dressed and non dressed sites. They therefore questioned the use of currently available dressings as a means of inducing more efficient tissue repair.

Greensmith AL, Wade AB (1974)[31] using a split mouth technique, studied the effect of applying a surgical dressing versus withholding a dressing after reverse bevel flap procedures in 24 patients. They concluded that the application of a dressing led to statistically slightly better results as indicated by a shallower pocket and lower gingival index in spite of a slight increase in inflammation. They felt that the application of a dressing after this type of surgical procedure should be a matter of preference.

O'neil TC (1975)[32] conducted a survey 430 flap and gingivectomy surgeries in which the wounds were dressed with coe-pak, either alone or with cross pack

and studied the antibacterial properties of periodontal dressings. They concluded that healing was more satisfactory when the dressing remain intact than if the dressing was lost after surgery. The degree of healing was judged subjectively.

Jones TM, Cassingham RJ (1979)[33] conducted a study in which seven patients with age range from 40 to 62 years were selected in which 20 quadrants were taken and clinical and histological results after access flap surgery with and without non-eugenol dressing were seen and evaluated fluid index, inflammatory index, pocket depth and patient comfort upto 16 weeks postoperatively. They concluded that results showed no difference in these parameters between quadrants where periodontal dressings were or were not used following surgery. The patients reported severe pain and discomfort postoperatively when the dressing was used. The results of this study suggest that a surgical dressing serves no useful purpose following a periodontal flap surgery.

Watts TL, Combe EC (1982)[34] assessed three dressing materials using two different methods of viscometry. The rheological characterizations are discussed with reference to clinical needs, and limitations of the experimental method are also considered. Suggestions are made for desirable rheological properties of future materials. They concluded that the ideal rheological requirements for a periodontal dressing in the stages of manipulation and application are particularly demanding. No material examined met all the suggested requirements, but both Coe-Pak and Peripac Improved showed some favourable characteristics. With Peripac, however, the setting system employed seems to create some disadvantages.

Eber RM, Shuler CF, Buchanan W, Beck FM, Horton JE (1989)[35] tested the effects of two eugenol containing and two non-eugenol periodontal dressings on cultured human gingival fibroblasts (HGF) (ATCC #1292). Replicate HGF cultures grown in microtiter plates were exposed to stock, 1:4 and 1:16 dilutions of extracts made from each of the four periodontal dressings. The HGF cultures were pulse labelled with tritiated thymidine (3HTdR) after 24, 48, and 72 hours. Incorporations of the labelled thymidine were measured using liquid scintillation counting and expressed as counts per minute. They concluded that the use of a human fibroblastic cell line for testing the effects of periodontal dressings may provide information about

the relative biological effects of these dressings. Using this cell line, they have found that eugenol dressings inhibit fibroblast proliferation to a greater extent than non-eugenol dressings.

Checchi L, Trombelli L (1993)[36] evaluated patient postoperative pain experience and discomfort with and without the use of a periodontal dressing in combination with a 0.2% chlorhexidine mouthwash after internal bevelled, full thickness, apically positioned flap procedure. Twenty-four patients requiring comparable bilateral flap procedures were selected. They concluded that no significant differences were found between treatment groups with respect to frequency distribution of patients who did or did not take analgesics or the daily and total consumption of analgesic drops. Although patients with dressing frequently experienced eating difficulty, most stated a psychological feeling of protection and well-being with its use.

Sigusch BW, Pfitzner A, Nietzsch T, Glockmann E (2005)[37] conducted a study on 36 patients with aggressive periodontitis. The periodontal parameters (pre-baseline) of 36 patients with aggressive periodontitis were obtained before the patients were treated initially (1st step) by a dental hygienist, who completely removed the supra- and subgingival concrements. Baseline parameters were raised 3 weeks after the 1st step, before the 2nd therapy step was conducted. It consisted of a non-surgical procedure, which comprised a closed full-mouth manual root curettage (root planing), immediate systemic application of metronidazole, and the placement of a periodontal dressing (Vocopac, Voco). The patients were randomized to two test groups having their periodontal packs removed after 3-4 days (group 1, n=12) and 7-8 days (group 2, n=12), respectively and a control group (n=12) without periodontal dressing. Clinical parameters were raised again after 6 and 24 months. They concluded that wound dressing has a positive effect on clinical long-term results using a two-step non-surgical procedure. Moreover, removing the dressing after 7-8 days leads to clearly better results than removing it earlier.

Abed AM, Yaghini J, Tavakoli M, Amjadi MR, Najafian E (2011)[38] evaluated and compared the clinical effects of Coe-pak after modified widman flap surgery. 23 patients needed modified widman flap in at least two quadrants. At first, the surgery site was dressed with Coe-pak and during the first week

post-operatively, the patients were recommended to use 0.2% chlorhexidine mouthwash. After 3 weeks to one month, the second surgery was performed on the contra-lateral side without any dressing and recommended to use 0.2% chlorhexidine mouthwash during the first week post-operatively. They concluded that the use of Coe-pak after modified widman flap influenced plaque formation, with no effect on pain and patient satisfaction.

Ghanbari H, Forouzanfar A, Fatemi K, Mokhtari M, Abrishami M, Ebrahiminik Z, Farazi F (2012)[39] evaluated the postoperative pain experience and gingival indexes with and without the use of periodontal dressing after Modified Widman flap procedure. Twenty patients requiring comparable bilateral flap procedures were selected. One quadrant of each jaw randomly received periodontal dressing after the surgery while the other one didn‟t. Plaque Index (PI), Sulcus Bleeding Index (SBI) and Probing Depth (PD) were measured prior to the surgery, one week and 2 weeks after the surgery. Postoperative pain experience also was assessed at the conclusion of study. They concluded that pain is reduced by periodontal dressing but no significant differences between dressed and undressed segments regarding changes in probing depth, plaque index or sulcus bleeding index were examined.

Freedman M, Stassen LF (2013)[40] conducted the study of the constituents, uses and effects of the common materials like oxidised regenerated cellulose, whitehead's varnish, carnoy's solution, bismuth iodoform paraffin paste, zinc oxide eugenol and alvogyl. They concluded that dressing materials can be used in the mouth to aid healing, prevent infection and reduce postoperative discomfort. All materials have the potential to cause local and systemic adverse reactions. It is important to be aware of the constituents and effects of these materials on the oral tissues.

Baghani Z, Kadkhodazadeh M (2013)[41] reviewed the commercially available periodontal dressings, their physical and chemical properties, biocompatibility and therapeutic effects. Electronic search of scientific papers from 1956 to 2012 was carried out using PubMed, Scopus and Wiley InterScience search engines using the searched terms periodontal dressing, periodontal pack. Numerous in vitro and in vivo studies have evaluated various

properties of periodontal dressings. Physical and chemical properties of dressings are directly related to their dimensional changes and adhesion properties. Their biocompatibility and therapeutic effect are among the other factors evaluated in the literature. Chlorhexidine is the most commonly used antibacterial agent in studies. In general, when comparing the advantages with the disadvantages, application of periodontal dressing seems to be beneficial. Numerous factors are involved in selection of an optimal dressing such as surgeon‟s intention, required time for the dressing to remain on the surgerysite and its dimensional changes.

Keestra JA, Coucke W, Quirynen M (2014)[42] evaluated a randomized, controlled split-mouth study including 24 patients. After one stage full mouth disinfection, a test and a control side were selected by means of a computer-generated randomization list. Test sides received a periodontal dressing (Coepak^{TM}) for 7 days and the control sides received no periodontal dressing. After 7 days the periodontal dressing was removed and the pain experience was recorded. After 3 months, the clinical periodontal parameters were recorded. They concluded that the use of a periodontal dressing for 7 days after a one stage full mouth disinfection offers an additional short-term clinical improvement and lowers the pain intensity.

Soheilifar S, Bidgoli M, Faradmal J, Soheilifar S (2015)[43] assessed the effect of periodontal dressing on wound healing and patient satisfaction following periodontal flap surgery. The clinical trial was conducted on 33 patients presenting to Hamadan University, School of Dentistry in 2012 whose treatment plan included two periodontal surgical procedures on both quadrants of the maxilla or mandible. The variables evaluated were severity of pain, bleeding, facial swelling and ease of nutrition experienced by patient during the first 3 days after surgery and inflammation, granulation tissue formation and gingival color at 7 and 14 days. They concluded that patients did not experience more bleeding, facial swelling or nutritional problems without periodontal dressing; however, the level of pain experienced was lower after surgeries with the use of periodontal dressing.

Monje A, Kramp AR, Criado E, Suárez-López del Amo F, Garaicoa-Pazmiño C, Gargallo-Albiol J, Wang HL (2016)[44] two examiners performed an electronic search in several databases for relevant articles published in English up to November 2013. Selected studies were randomized human clinical trials (prospective or retrospective trials) with the clear aim of investigating the effect of periodontal dressing placement

upon periodontal non-surgical mechanical therapy. They concluded that placement of periodontal dressing right after non-surgical mechanical therapy can be beneficial in improving overall short-term clinical outcomes, although more controlled studies are still needed to validate this finding.

Gholami L, Ansari-Moghadam S, Sadeghi F, Arbabi-Kalati F, Barati I (2019)[45] evaluated a study on 23 patients requiring modified Widman flap in at least two quadrants in the same arch were selected; one quadrant was dressed with Reso-pac, and the other was dressed with Coe-pak. The clinical efficacy of these two dressings was evaluated by comparing plaque, granulation tissue formation, pain, bleeding on probing, and color of gingiva. To compare their cytotoxicity, human gingival fibroblast were exposed to 1-and 3-day extracts of the dressings and MTT test was used to measure cell viability after 24 and 48 hours. They concluded that Reso-pac is as effective as Coe-pack. It also has further positive effects of less plaque accumulation and granulation tissue formation and is more biocompatible for HGF cells with less cytotoxic effects on cells in the first days after surgery.

Kumar MV, Narayanan V, Jalaluddin M, Almalki SA, Dey SM, Sathe S (2019)[46] conducted a study on a total of 45 patients between the age group of 30–45 years, with chronic generalized periodontitis with loss of attachment of 3–6 mm, who require periodontal flap surgery, were screened to include in the study. Out of 45 subjects, 24 were males and 21 were females. The subjects were randomized into 3 groups as 15 in each. Group I: a collagen dressing, group II: light-cure dressing, and group III: non-eugenol-based dressing. The clinical parameters such as plaque index, vertical probing depth, pain, gingival index, and patient satisfaction were documented for all the three groups on the 7th and the 14th day. Visual analog scale (VAS) was used to score the pain severity. They concluded that the periodontal wound covered with a collagen dressing material showed significant evidence to provide symptomatic relief and better healing to the patients compared to that of light-cure and non-eugenol periodontal dressing material.

Meghana MV, Deshmukh J, Devarathanamma MV, Asif K, Jyothi L, Sindhura H (2020)[47] assessed and compared the effect of Curcumin gel (Curenext) and noneugenol periodontal dressing (Coe pak) on tissue response, wound healing in the early stages, and pain post periodontal flap surgery in patients diagnosed with chronic

periodontitis. They evaluated a study on twenty patients requiring periodontal flap surgery were allotted to two groups at random, one receiving periodontal dressing and the other receiving curcumin for this cross over split-mouth study. Flap surgeries were performed on 2 quadrants with 3 weeks' interval. After suture removal, postoperative sites were assessed for tissue response (tissue color [TC] and tissue edema [TE]) and early wound healing as primary outcomes of the study. The secondary outcome was pain assessment and the number of analgesics taken by the individuals. They confirmed that periodontal dressing and curcumin are effective in reducing the TE, normalizing the TC, enhancing the wound healing and reducing the pain perception. Curcumin can thus be used as an alternative to periodontal dressing.

Sadighi M, Faramarzi M, Pourabbas R, Torab Z, Mohammadi H, Nazmi SH (2022)[48] evaluated a randomized clinical trial on 26 patients. Pain scores were assessed using visual analog scale (VAS) on the 3rd and 7th days postoperatively and compared between the two dressings. On the 7th and 14th days after both flap surgeries, surgical site healing was evaluated using the wound healing index (WHI). They concluded that The pain was less severe in both groups using periodontal dressing and also lower in the Diplen LX membrane group. In addition, based on WHI, wound healing score in patients was also higher and more favorable in the Diplex LX membrane group. Due to the above factors, the majority of patients preferred the use of the Diplen LX membrane.

Hameed M, Malik A, Shaukat MS, Khalid B, Umar M (2023)[49] conducted a study on Thirty three patients of both genders between ages 30-60 were included. Five clinical parameters were measured at baseline. These variables were recorded by University Of Michigan “O“‘‘Probe with William‘‘s Markings. The measurements were executed by a single, trained and calibrated examiner. Right and left quadrants of Maxilla and Mandible of the same patient were selected as the test and control sites respectively through random selection by lottery method. The maxillary and mandibular test sides were covered with periodontal dressing for 07 days, later the dressing was detached. After 12 weeks, all clinical parameters were recorded again by the same examiner. They concluded that periodontal dressing has significantly improved the clinical outcomes and the periodontal parameters after scaling and root planning procedures.

Clinical study was carried out in the Department of Periodontology, Babu Banarasi Das College of Dental Sciences (BBDCODS), Lucknow India. Ethical clearance was obtained from the ethical committee of BBDCODS (IEC 10); patients fulfilling the following inclusion and exclusion criteria were selected from the OPD of the Periodontology Department of BBDCODS.

Study Subjects

Systemically healthy individuals based on the inclusion and exclusion criteria to be selected.

Study Sample Size

A total of 30 patients.
Split mouth 60 quadrants.

Eligibility Criteria:

Inclusion criteria:

- Patients who give consent for inclusion in the study after thorough explanation of the study to the patient.
- Age range 30-65 years.
- Minimum 24 permanent teeth.
- Plaque score of 2.0-3.0 on plaque index.
- Systemically healthy individuals.
- Non-smokers and non-tobacco chewers.
- No history of antimicrobial therapy for the past 6 months.
- Diagnosed with chronic periodontitis having pocket depth of greater than or equal to 4mm.
- At least two separate quadrants involved.

Exclusion criteria:

- Pregnant and lactating females.
- Patients with a history of trauma in the past 6 months.
- Patients on phenytoin, calcium channel blockers, and cyclosporine medication.
- Immunocompromised patients.
- Patients suffering from any infectious or systemic disease.
- Oral prophylaxis within last 3 months.
- Five or more carious lesions requiring immediate restorative treatment.

ARMAMENTARIUM

- Mouth mirror
- UNC 15 Periodontal probe
- Tweezers
- Explorer
- Pezoelectronic ultrasonic scaler (Woodpecker)
- High vacuum suction
- Local anesthetic agent 2% lignocaine
- Syringe 3 ml and 5 ml
- Periosteal elevator
- Gracey's curettes
- Povidone iodine
- Saline
- Sutures
- BP blade handle
- 12 and 15 C surgical blade
- Adams tissue holding forceps
- Castroviejo scissors
- Needle holder
- Scissor
- Mixing spatula
- Kidney tray
- Glass slab
- Photographic mirrors
- Coe-pak™
- Medications

Study Design:

A randomized split mouth clinical study was conducted, with two groups namely, dressing and non-dressing using chit pick-up method.

Group I- Periodontal flap surgery with dressing.

Group II- Periodontal flap surgery without dressing.

A randomized split mouth clinical study will be conducted to assess patient's post-operative comfort, assessment of wound healing by swelling of soft tissue and the colour of gingiva. All subjects will answer a Visual Analog Scale (VAS) questionnaire that is Pain (0-10); which will be provided to them as a VAS chart by Hayes and Patterson in 1921, to evaluate post-operative symptoms. The healing index will be evaluated using Landry et al. Wound Healing Index in 1988. The gingival index will be evaluated by Loe and Silness Gingival Indexin 1963. The gingival embrasure opening will be evaluated by Black Triangle Classification given by Nordland and Tarnow in 1998. Sutures will be simply counted at the time of placement and after 7 days. Data will be statistically analyzed to assess the effectiveness with dressing and without dressing postoperatively.

INITIAL THERAPY

All 30 patients, following an initial examination, diagnosis and treatment planning were subjected to phase-I therapy which consisted of full mouth scaling and root debridement using hand and ultrasonic instruments. Detailed oral hygiene instructions were given to all the patients. Patients were kept on regular follow-up. Oral hygiene instructions were reinforced on every follow-up appointment until every patient maintained a good oral hygiene.

CLINICAL PARAMETERS AT BASELINE

Upon completion of the initial phase of therapy and confirming the suitability of the sites for the study, the randomization was done. In this study, the quadrants for periodontal flap surgery were randomly assigned to one of the two different study

groups by chit pick-up method (Periodontal flap surgery with dressing and periodontal flap surgery without dressing). After randomization PPD were evaluated at baseline using *Hu-friedy's* UNC-15 graduated periodontal probe and were recorded to the nearest millimeters. All the 4 sites (mesial, mid- buccal, distal, mid-lingual) per tooth were examined for PPD. The plaque scores were measured by Silness and Loe Plaque Index given in 1964 by assessing the thickness of plaque on the tooth and gingival margin from 0 to 3.

METHODOLOGY

A randomized split mouth clinical study will be conducted in the Department of Periodontology, Babu Banarasi Das College of Dental Sciences, Lucknow with a sample size of 30 subjects which will be shortlisted from the Outpatient Department (OPD) of the Periodontology. 30 patients will be selected on the basis of set inclusion and exclusion criteria. Since it is a split mouth study; 60 sides in these 30 subjects according to age and gender matched, will be randomly divided into two groups namely, dressing and non-dressing using chit pick-up method.

Group I- Periodontal flap surgery with dressing.

Group II- Periodontal flap surgery without dressing.

SURGICAL PROCEDURE

Pre-operative mouth rinsing with 5 ml of povidone iodine 2% gargle mint diluted with water was done to reduce the bacterial load. Throughout the surgical procedure, asepsis was maintained. Area subjected to surgery was anaesthetized by nerve block/local infiltration depending on the site using 2% lignocaine containing adrenaline at a concentration of 1:200,000, *Lignox 2% A, Indoco Remedies Ltd.* Using a #15 Bard Parker blade, intra-crevicular incisions were made on the facial and palatal/lingual aspects of the operative area, extending all the way to the crest of the alveolar bone. On both the palatal/lingual and facial sides, incisions were extended to one tooth mesial and one tooth distal to the area of interest. Full-thickness flaps on the facial and lingual aspects were raised using a periosteal elevator. A thorough debridement was carried out using the hand instruments after the flaps had been adequately reflected. After debridement the area was irrigated properly with the help of sterile saline. The flaps were repositioned and sutured to achieve a primary soft tissue closure with non-resorbable silk sutures *(Ethicon, Johnson and Johnson, Somerville, NJ, USA)*. Sutures will be simply counted at the time of placement and after seven days.

Group I- Periodontal flap surgery with dressing.

Post-surgery, the surgical area was protected and covered with the periodontal dressing *(COE PAK™ GC America Inc. Illinois, USA).*

Group II- Periodontal flap surgery without dressing.

Post-surgery, the surgical area was not protected and covered with the periodontal dressing *(COE PAK™ GC America Inc. Illinois, USA).*

Each patient was kept under an antibiotic, analgesic coverage for 5-days. Periodontal dressing and sutures (in group I) were removed 1-week post- surgery. Sutures (in group II) were removed 1-week post- surgery. Povidone-iodine solution was then used to carefully clean the surgical wound. Each patient was encouraged to begin mechanical oral hygiene, which entails using a soft toothbrush and the Charter's technique to brush their teeth gently, and to refrain from utilizing any kind of interdental cleaning tools in the surgically treated area for four weeks after the procedure.

The following clinical parameters were recorded after seven days at the time of suture removal and after one month.

Visual Analogue Scale by Hayes and Patterson in 1921

Pain assessment was done with Visual Analogue Scale (VAS) by Hayes and Patterson in 1921.

Patient was asked to indicate the intensity of pain over the past 7 days on a scale of 0 (no pain) to 10 (worst pain imaginable).

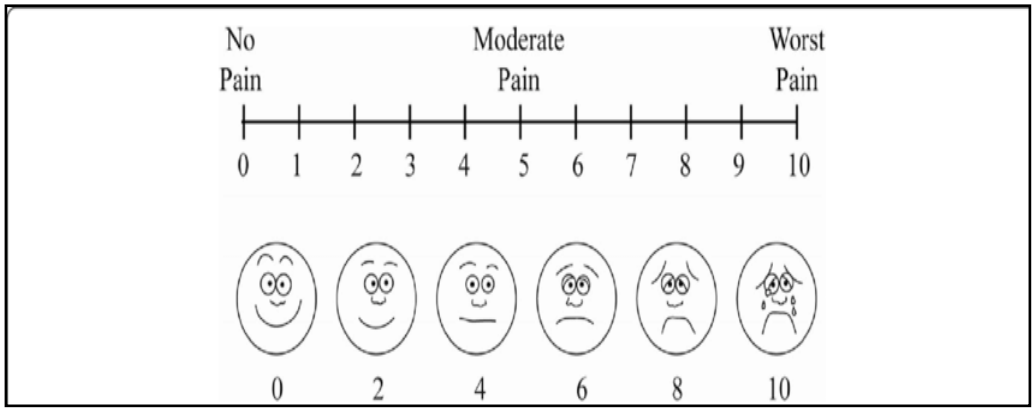


Figure- 3 Visual Analogue Scale by Hayes and Patterson in 1921

Wound Healing Index by Landry et al. in 1988

HEALING INDEX	TISSUE COLOR	BLEEDING ON PALPATION	GRANULATION TISSUE	INCISION MARGIN	SUPPURATION
1- VERY POOR Two or more signs are present	50% of red gingiva	Yes	Yes	Not epithelized, with loss of epithelium beyond incision margin	Yes
2- POOR	50% of red gingiva	Yes	Yes	Not epithelized, with exposed connective tissue	No
3- GOOD	25-50% of red gingiva	No	No	No exposed connective tissue	No
4- VERY GOOD	<25% of red gingiva	No	No	No exposed connective tissue	No
5- EXCELLENT	All pink tissues	No	No	No exposed connective tissue	No

Gingival Index by Loe and Sillness in 1963

It assesses the severity of gingivitis based on color, consistency, and bleeding on probing. It describes the clinical severity of gingival inflammation as well as its location. Instruments used- Mouth Mirror and Periodontal Probe.

TEETH EXAMINED- The scoring is done on the entire dentition or on selected teeth. The selected are known as INDEX TEETH.

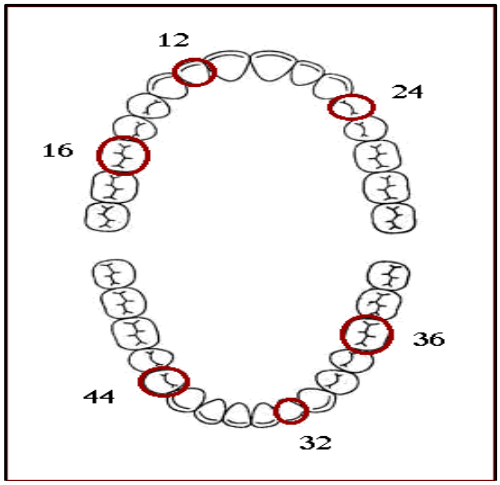


Figure- 4 Index Teeth

Surfaces examined on each Tooth: -Four gingival areas, i.e. distofacial, facial, mesiofacial and lingualsurfaces are examined.

Appearance	Bleeding	Inflammation	GI
normal	no bleeding	none	0
slight change in color and mild edema with slight change in texture	no bleeding	mild	1
redness, hypertrophy, edema and glazing	bleeding on probing/pressure	moderate	2
marked redness, hypertrophy, edema, ulceration	spontaneous bleeding	severe	3

CALCULATION AND INTERPRETATION

GI score for a tooth = Scores from 4 areas/4

GI score individual = Sum of indices of teeth/no.of teeth examinedGI score for group = Sum of all member/Total no of individuals Interpretation: gingivitis

0.1 - 1.0 : Mild gingivitis
1.1 – 2.0 : Moderate gingivitis
2.1 – 3.0 : Severe gingivitis

Gingival Embrasure Opening [Black Triangle Classification] ByNordland And Tarnow

A simple, descriptive system is included herein. The system utilizes 3 identifiable anatomical landmarks: the interdental contact point, the facial apical extent of the cemento-enamel junction (CEJ) and the

interproximal coronal extent of the CEJ.

Normal- Interdental papilla fills embrasure space to the apical extent of the interdental contact point/area.

Class I- The tip of the interdental papilla lies between the interdental contact point and the most coronal extent of the interproximal CEJ (space present but interproximal CEJ is not visible).

Class II- The tip of the interdental papilla lies at or apical to the interproximal CEJ but coronal to the apical extent of the facial CEJ (interproximal CEJ visible).

Class III- The tip of the interdental papilla lies level with or apical to the facial CEJ.

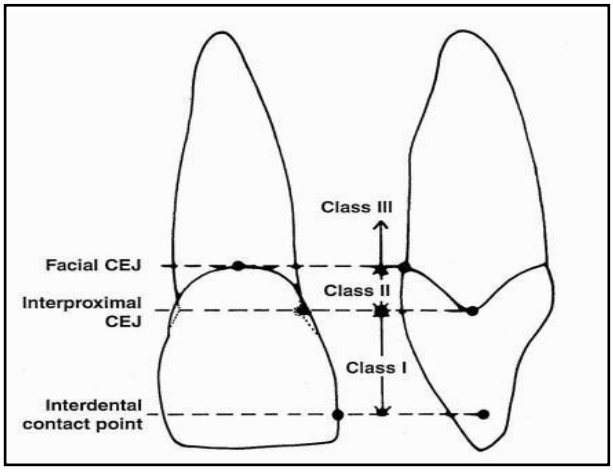
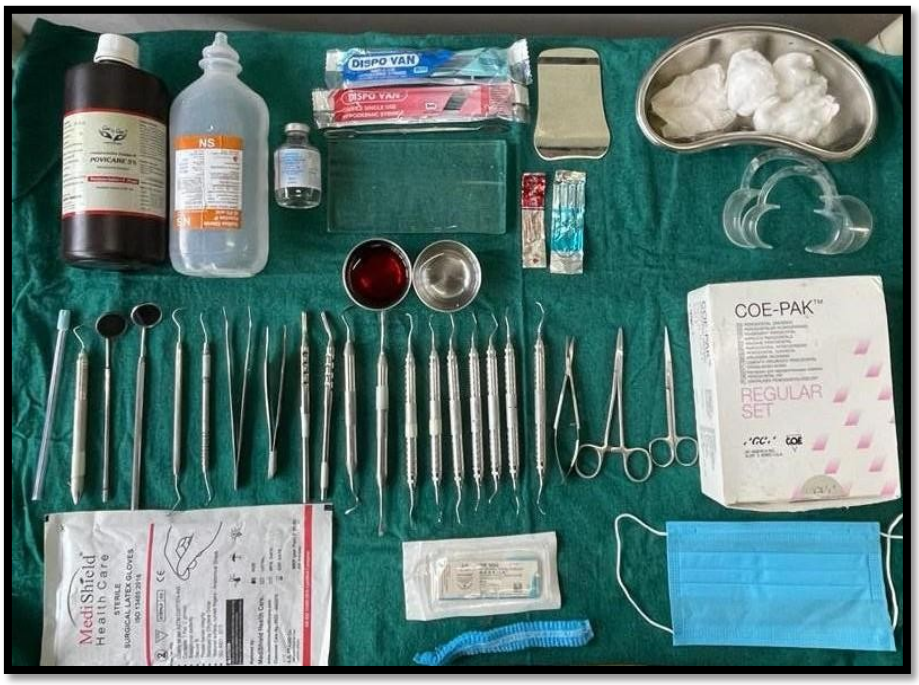
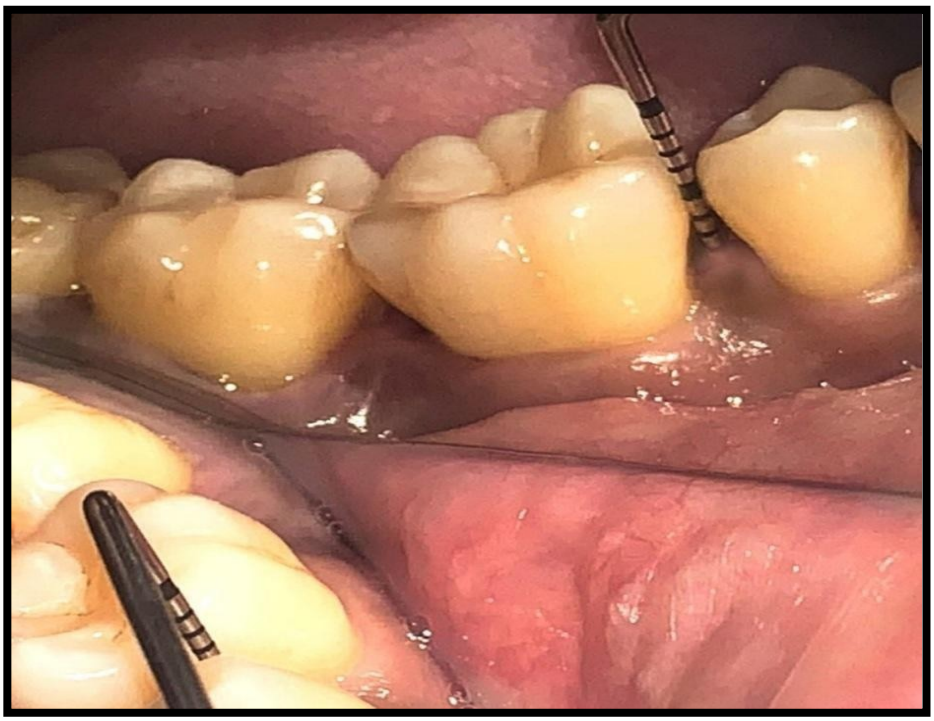


Figure- 5 Schematic illustration of the proposed classification system. The location of the tip of the interdental papilla in relation to the three indicated anatomical landmarks forms the basis for the classification.

GROUP I- PERIODONTAL FLAP SURGERY WITH DRESSING

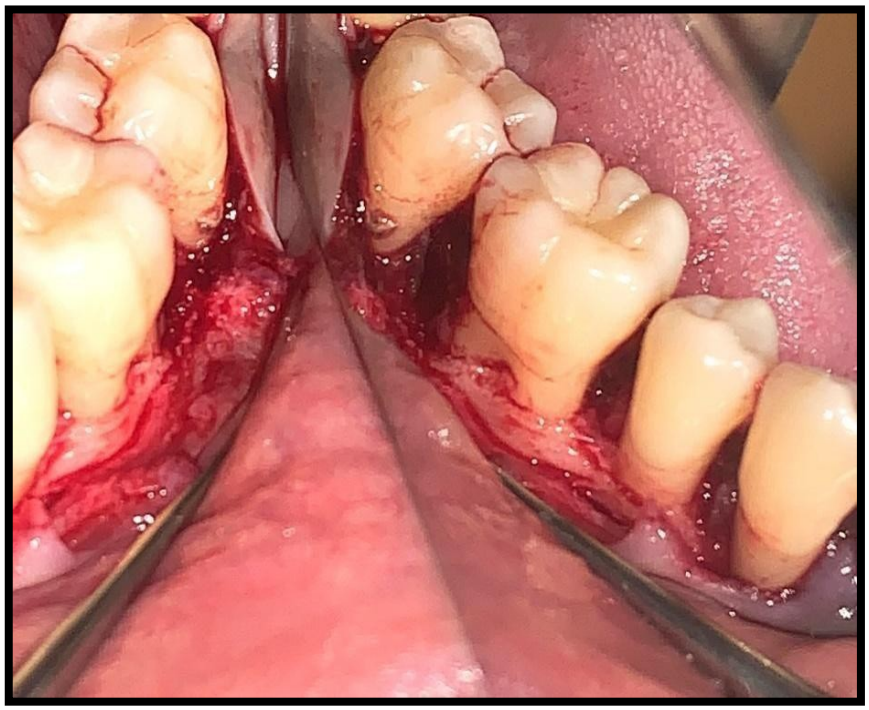


PHOTOGRAPH- i SURGICAL ARMAMENTARIUM FOR GROUP I- PERIODONTAL FLAP SURGERY WITH DRESSING

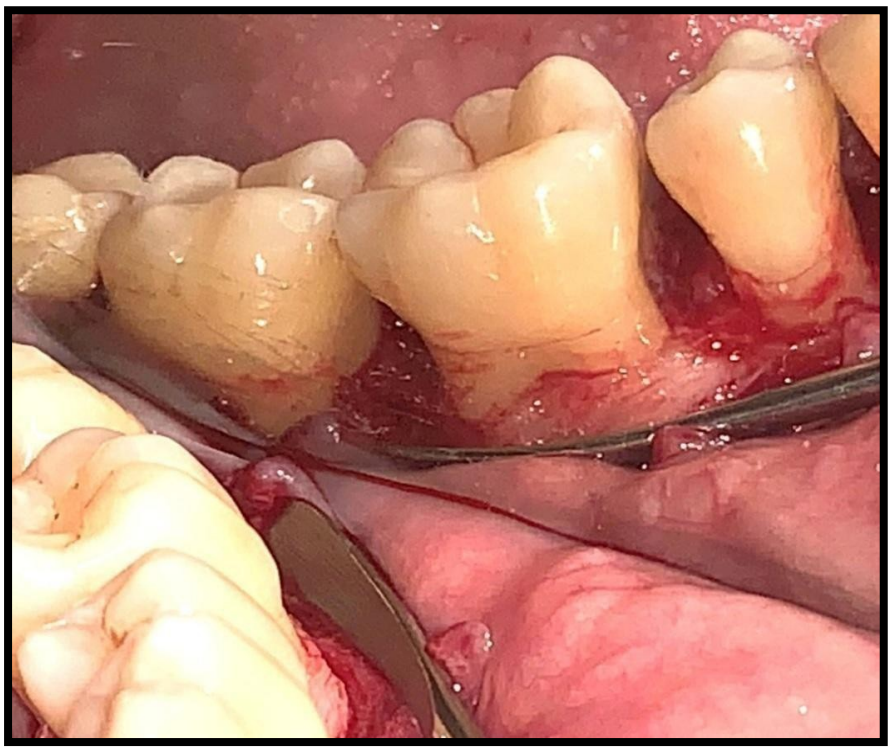


PHOTOGRAPH - ii PRE-OPERATIVE PROBING POCKET DEPTH

PLATE NO - 1

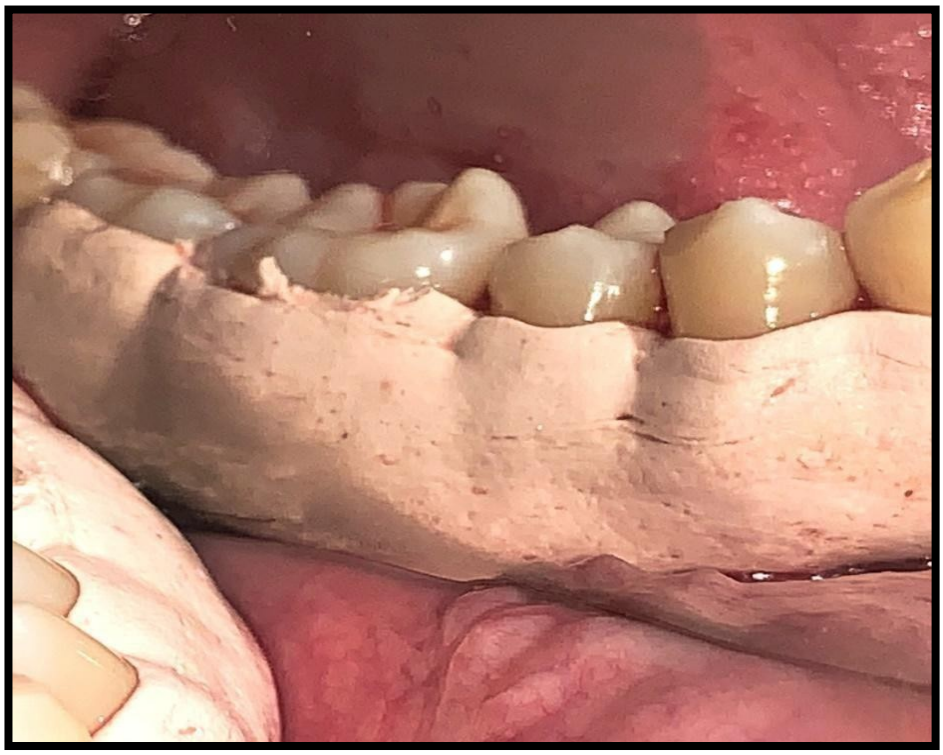


PHOTOGRAPH - iii REFLECTION OF THE MUCOPERIOSTEAL FLAP

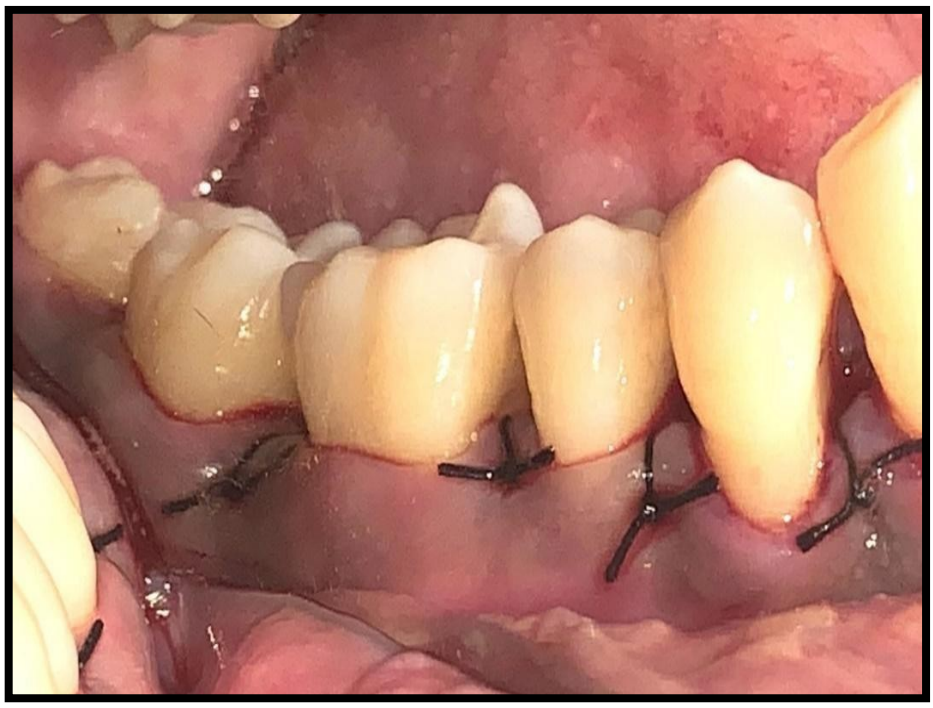


PHOTOGRAPH - iv AFTER FLAP DEBRIDEMENT

PLATE NO - 2

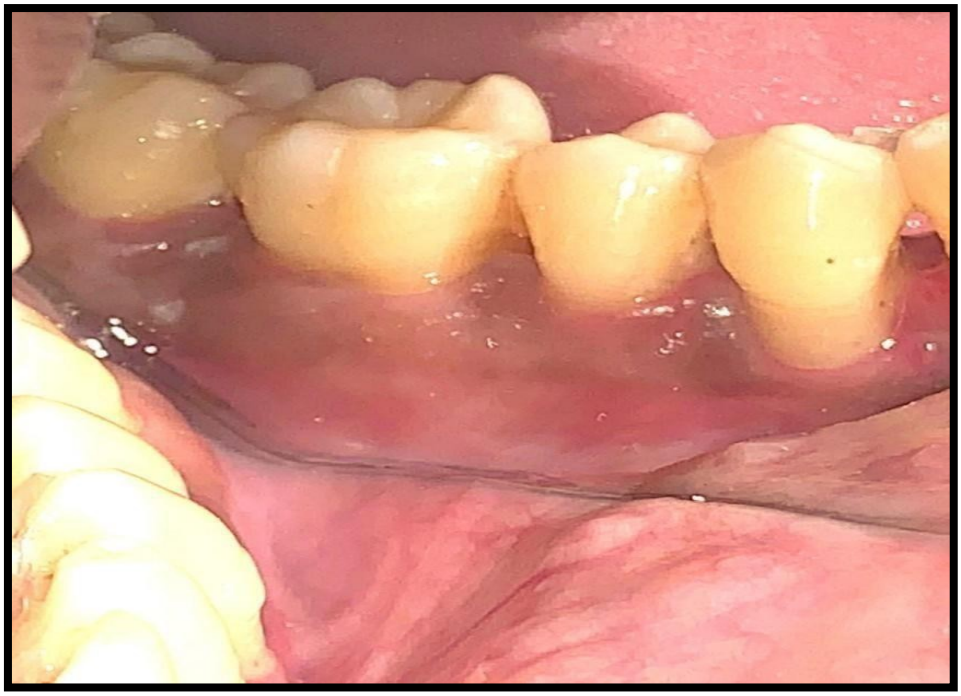


PHOTOGRAPH - v PERIODONTAL DRESSING

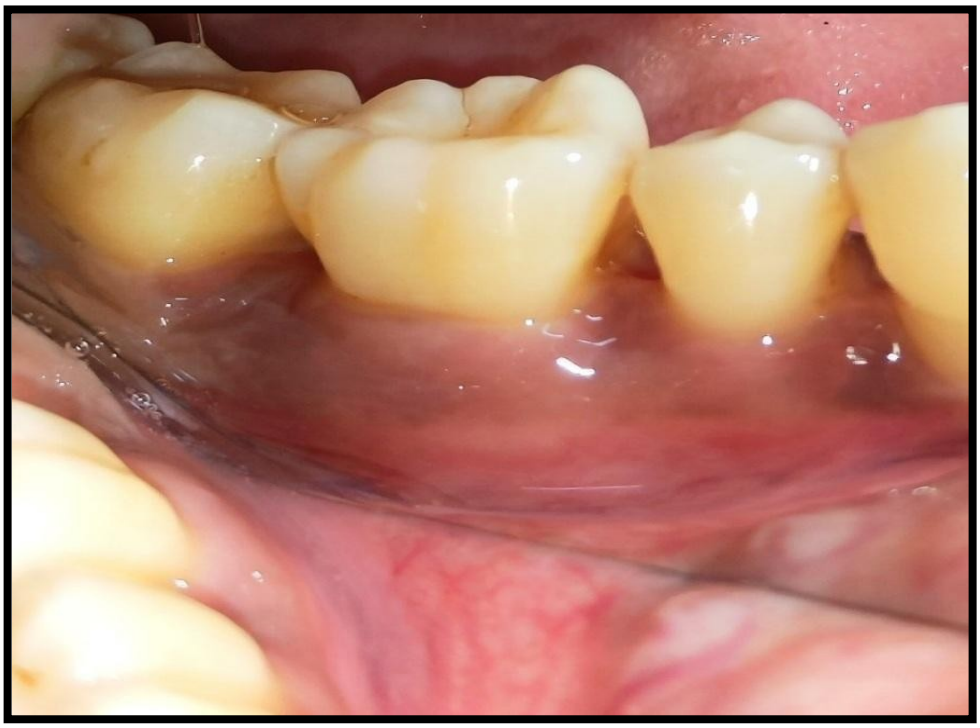


PHOTOGRAPH - vi FLAP APPROXIMATED WITH SUTURES

PLATE NO - 3



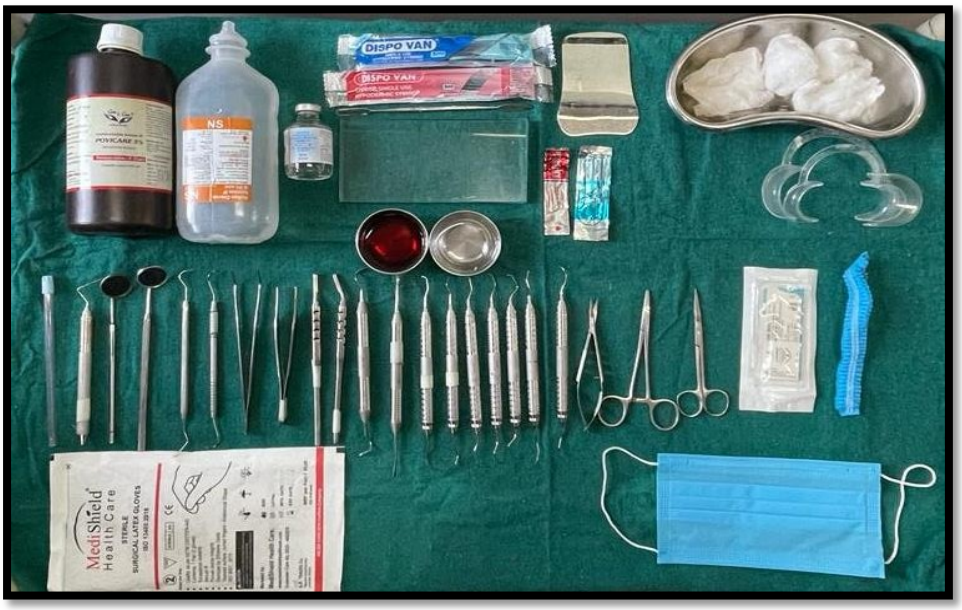
PHOTOGRAPH - vii SEVEN DAYS FOLLOW-UP



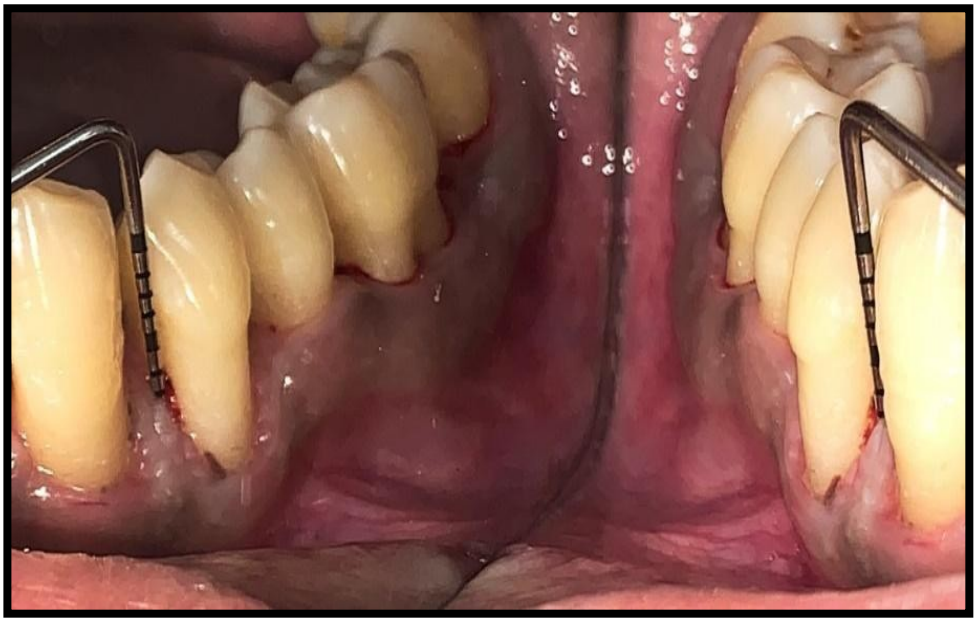
PHOTOGRAPH - viii ONE MONTH FOLLOW-UP

PLATE NO - 4

GROUP II- PERIODONTAL FLAP SURGERY WITHOUT DRESSING

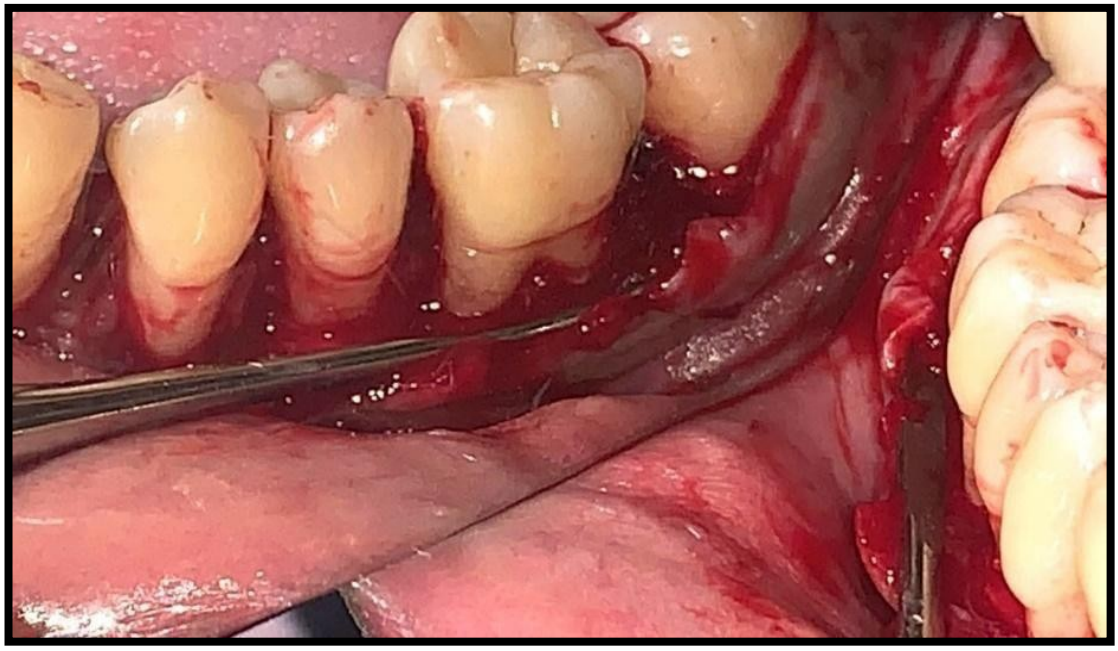


PHOTOGRAPH - i SURGICAL ARMAMENTARIUM FOR GROUP II- PERIODONTAL FLAP SURGERY WITHOUT DRESSING

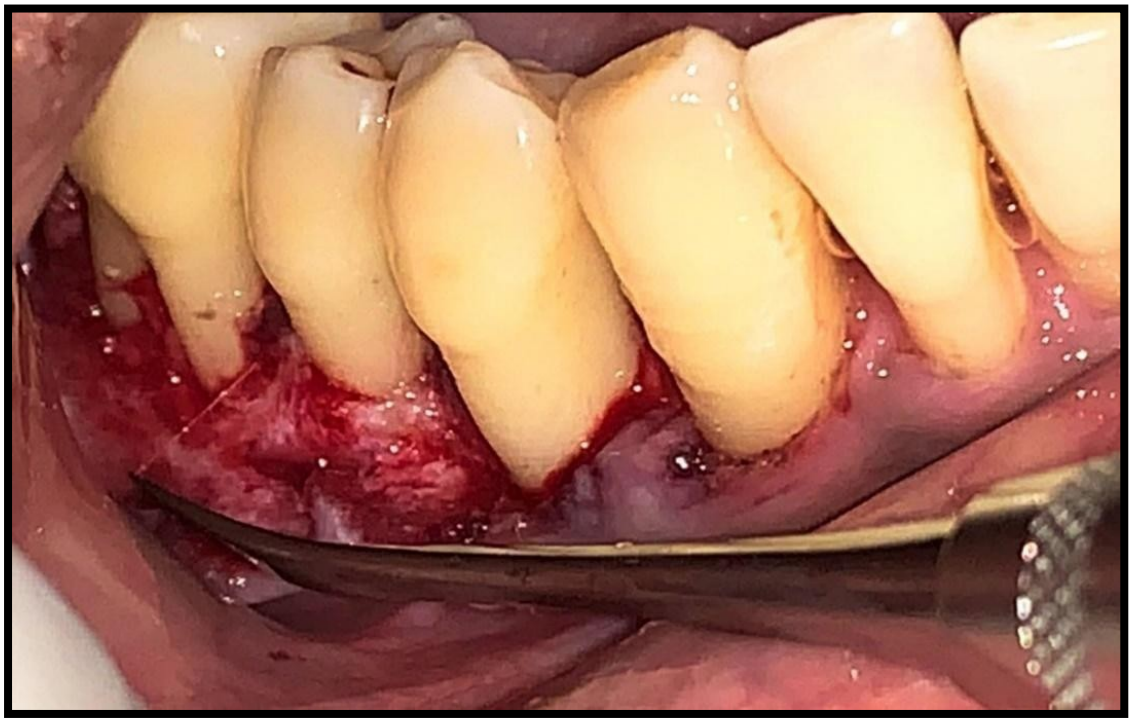


PHOTOGRAPH - ii PRE-OPERATIVE PROBING POCKET DEPTH

PLATE NO - 5

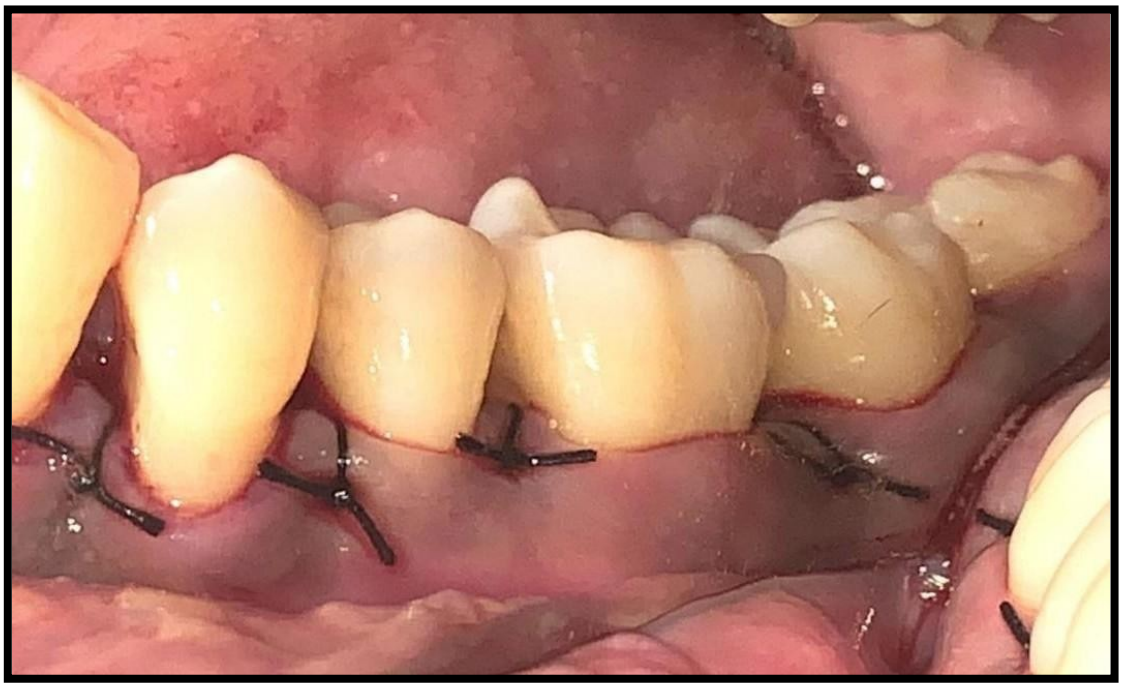


PHOTOGRAPH - iii REFLECTION OF THE MUCOPERIOSTEAL FLAP

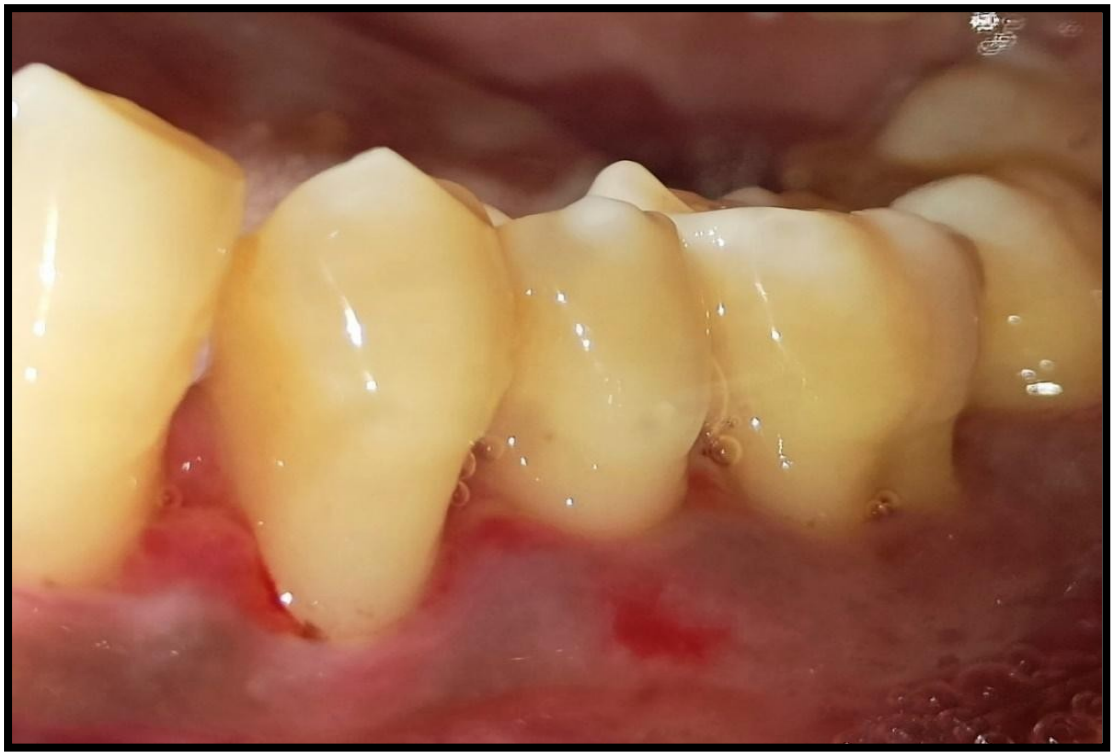


PHOTOGRAPH - iv AFTER FLAP DEBRIDEMENT

PLATE NO - 6

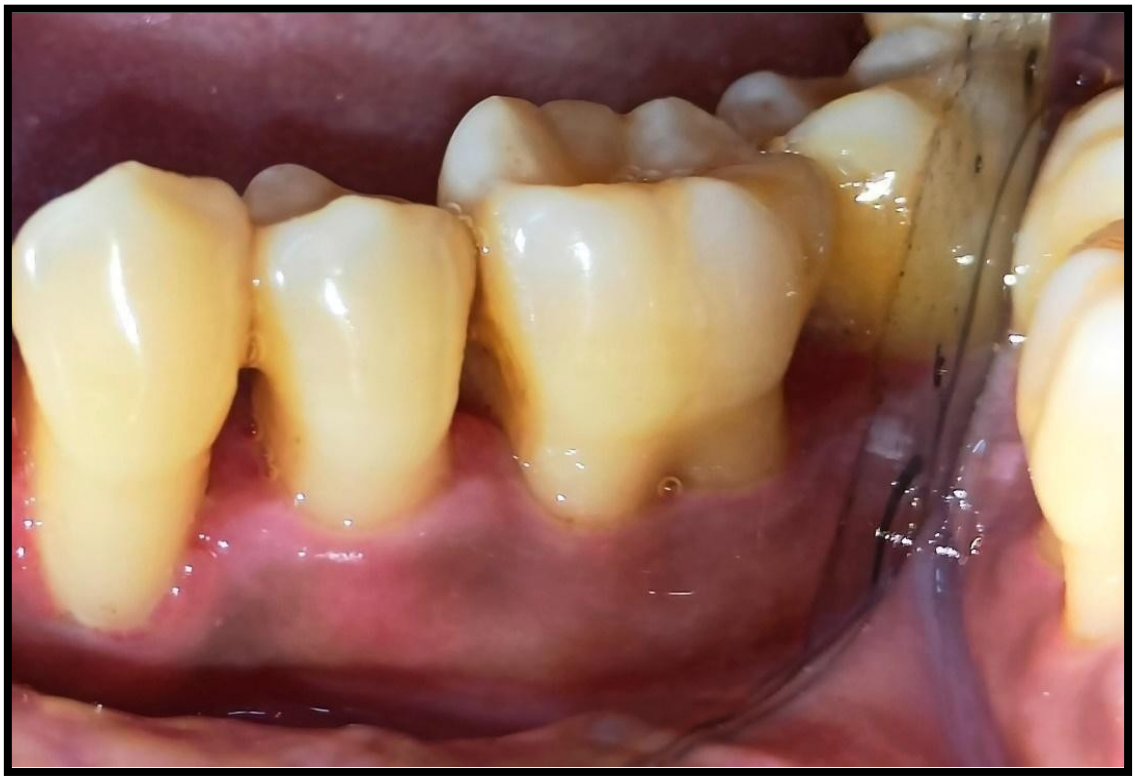


PHOTOGRAPH - v FLAP APPROXIMATED WITH SUTURES



PHOTOGRAPH - vi SEVEN DAYS FOLLOW-UP

PLATE NO - 7



PHOTOGRAPH - vii ONE MONTH FOLLOW-UP

PLATE NO - 8

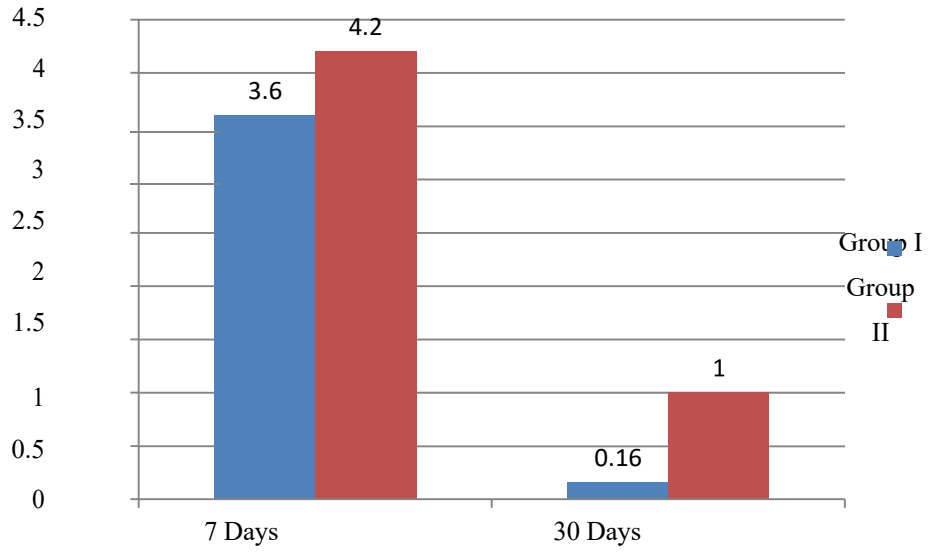
INTERGROUP COMPARISON OF VAS SCORE BETWEEN THE GROUPS AT DIFFERENT TIME INTERVALS

The mean VAS score at the 7th day in the Group I was 3.60 and in the Group II was 4.20. At the 30th day the mean VAS score was 0.16 in the Group I and 1.00 in the Group II. The intergroup comparison between Group I and Group II was statistically significant at 7th day and 30th day.

		Mean	Std Deviation	Std Error	P value	Significance
7 Days	Group I	3.60	1.248	0.227	0.020	Significant
	Group II	4.20	1.297	0.236		
30 Days	Group I	0.16	0.379	0.069	0.001	Significant
	Group II	1.00	0.694	0.126		

Independent t test with p value less than 0.05 is significant

TABLE-1 Depicts Intergroup Comparison Of VAS Score Between The Groups After Seven Days And One Month



GRAPH-1 Depicts Intergroup Comparison Of VAS Score Between The Groups After Seven Days And One Month

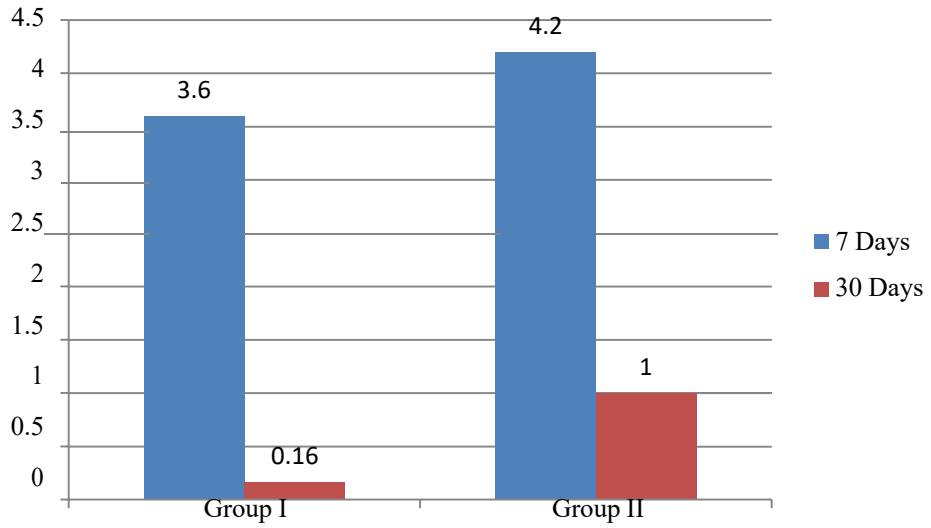
INTARGROUP COMPARISON OF VAS SCORE BETWEEN THE DIFFERENT TIME INTERVALS IN BOTH THE GROUPS

The mean VAS score at the 7th day in the Group I was 3.60 and in the Group II was 4.20. At the 30th day the mean VAS score was 0.16 in the Group I and 1.00 in the Group II. The intragroup change between 7th day and 30th day was statistically significant in both the groups.

		Mean	Std Deviation	Std Error	P value	Significance
Group I	7th day	3.60	1.248	0.227	0.001	Significant
	30th day	0.16	0.379	0.069		
Group II	7th day	4.20	1.297	0.236	0.001	Significant
	30th day	1.00	0.694	0.126		

Paired t test with p value less than 0.05 is significant

TABLE-2 Depicts Intargroup Comparison Of VAS Score After Seven Days And One Month In Both The Groups



GRAPH-2 Depicts Intargroup Comparison Of VAS Score After Seven Days And One Month In Both The Groups

INTERGROUP COMPARISON OF HEALING SCORES BETWEEN THE GROUPS AT DIFFERENT TIME INTERVALS

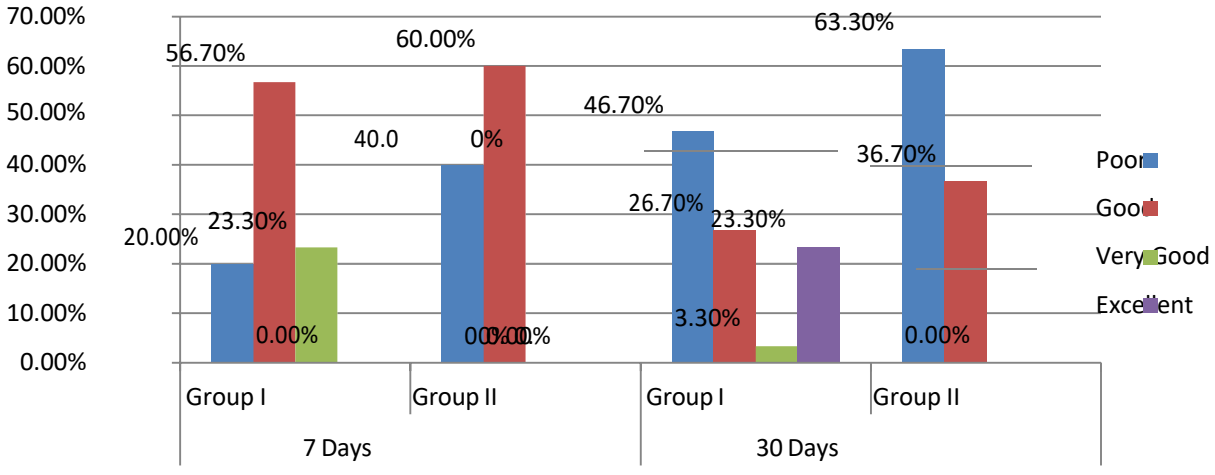
At the 7 th day, 20% were having poor healing, 56.7% were having good healing and 23.3% were having very good healing. In the Group II 40% were having poor healing ad 60% were having good healing in the Group II. The difference between the groups was statistically significant.

At the 30th day, 46.7% were having poor healing, 26.7% were having good healing and 23.3% were having excellent healing. In the Group II 63.3% were having poor healing ad 36.7% were having good healing The difference between the groups was statistically significant.

		Poor	Good	Very Good	Excellent	P value	Significance
7 Days	Group I	6 20.0%	17 56.7%	7 23.3%	0 .0%	0.001	Significant
	Group II	12 40.0%	18 60.0%	0 .0%	0 .0%		
30 Days	Group I	14 46.7%	8 26.7%	1 3.3%	7 23.3%	0.010	Significant
	Group II	19 63.3%	11 36.7%	0 .0%	0 .0%		

Chi Square test with p value less than 0.05 is significant

TABLE-3 Depicts Intergroup Comparison Of Healing Scores Between The Groups After Seven Days And One Month



GRAPH-3 Depicts Intergroup Comparison Of Healing Scores Between The Groups After Seven Days And One Month

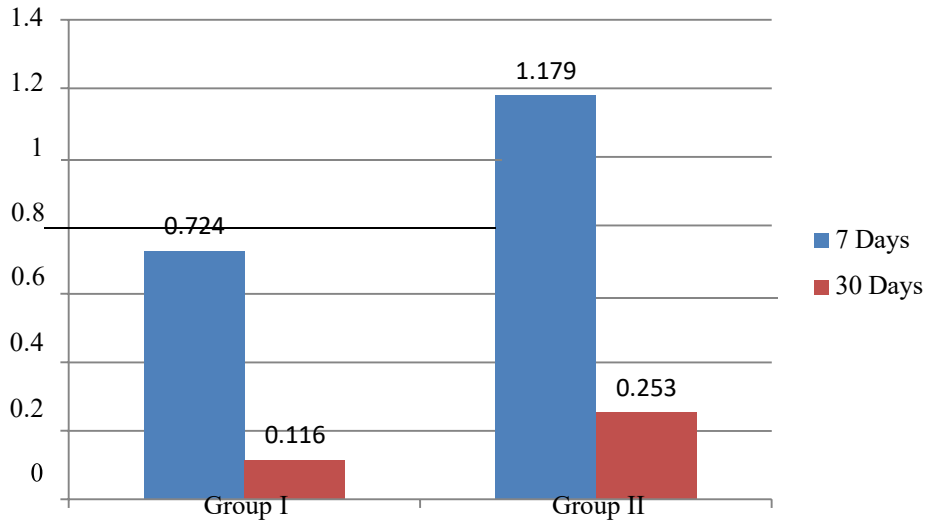
INTERGROUP COMPARISON OF GI SCORES BETWEEN THE GROUPS AT DIFFERENT TIME INTERVALS

The mean GI score at the 7th day in the Group I was 0.724 and in the Group II was 1.179. At the 30th day the mean GI score was 0.116 in the Group I and 0.253 in the Group II. The intergroup comparison between Group I and Group II was statistically significant at 7th day and 30th day.

		Mean	Std Deviation	Std Error	P value	Significance
7 Days	Group I	0.724	0.384	0.071	0.001	Significant
	Group II	1.179	0.411	0.076		
30 Days	Group I	0.116	0.155	0.028	0.010	Significant
	Group II	0.253	0.233	0.042		

Independent t test with p value less than 0.05 is significant

TABLE-4 Depicts Intergroup Comparison Of GI Scores Between The Groups After Seven Days And One Month



GRAPH-4 Depicts Intergroup Comparison Of GI Scores Between The Groups After Seven Days And One Month

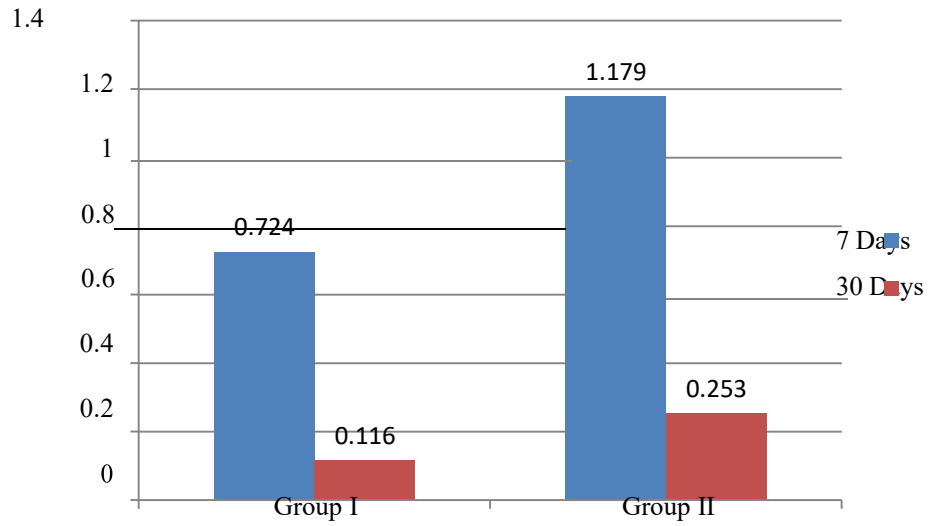
INTRAGROUP COMPARISON OF GI SCORES BETWEEN DIFFERENT TIME INTERVALS IN BOTH THE GROUPS

The mean GI score at the 7th day in the Group I was 0.724 and in the Group II was 1.179. At the 30th day the mean GI score was 0.116 in the Group I and 0.253 in the Group II. The intragroup change between 7th day and 30th day was statistically significant in both the groups.

		Mean	Std Deviation	Std Error	P value	Significance
Group I	7th day	0.724	0.384	0.071	0.001	Significant
	30th day	0.116	0.155	0.028		
Group II	7th day	1.179	0.411	0.076	0.010	Significant
	30th day	0.253	0.233	0.042		

Paired t t test with p value less than 0.05 is significant

TABLE-5 Depicts Intragroup Comparison Of GI Scores After Seven Days And One Month In Both The Groups



GRAPH-5 Depicts Intragroup Comparison Of GI Scores After Seven Days And One Month In Both The Groups

INTERGROUP COMPARISON OF GINGIVAL EMBRASURE OPENING BETWEEN THE GROUPS AT DIFFERENT TIME INTERVALS

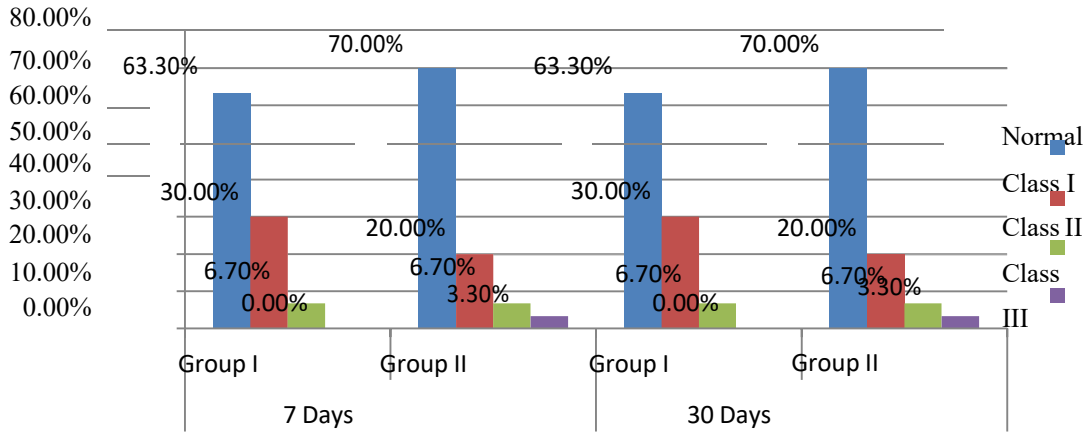
At the 7 th day, 63.3% were having normal embrasures, 30.0% were having Class I embrasures and 6.7% were having Class II embrasures. In the Group II, 70.0% were having normal embrasures, 20.0% were having Class I embrasures and 6.7% were having Class II embrasures The difference between the groups was statistically significant.

At the 30th day, 63.3% were having normal embrasures, 30.0% were having Class I embrasures and 6.7% were having Class II embrasures. In the Group II, 70.0% were having normal embrasures, 20.0% were having Class I embrasures and 6.7% were having Class II embrasures The difference between the groups was statistically significant.

		Normal	Class I	Class II	Class III	P value	Significance
7 Days	Group I	19	9	2	0	0.637	Non-Significant
		63.3%	30.0%	6.7%	.0%		
	Group II	21	6	2	1		
		70.0%	20.0%	6.7%	3.3%		
30 Days	Group I	19	9	2	0	0.637	Non-Significant
		63.3%	30.0%	6.7%	.0%		
	Group II	21	6	2	1		
		70.0%	20.0%	6.7%	3.3%		

Chi Square test with p value less than 0.05 is significant

Table-6 Depicts Intergroup Comparison Of Gingival Embrasure Opening Between The Groups At Different Time Intervals



GRAPH-6 Depicts Intergroup Comparison Of Gingival Embrasure Opening Between The Groups At Different Time Intervals

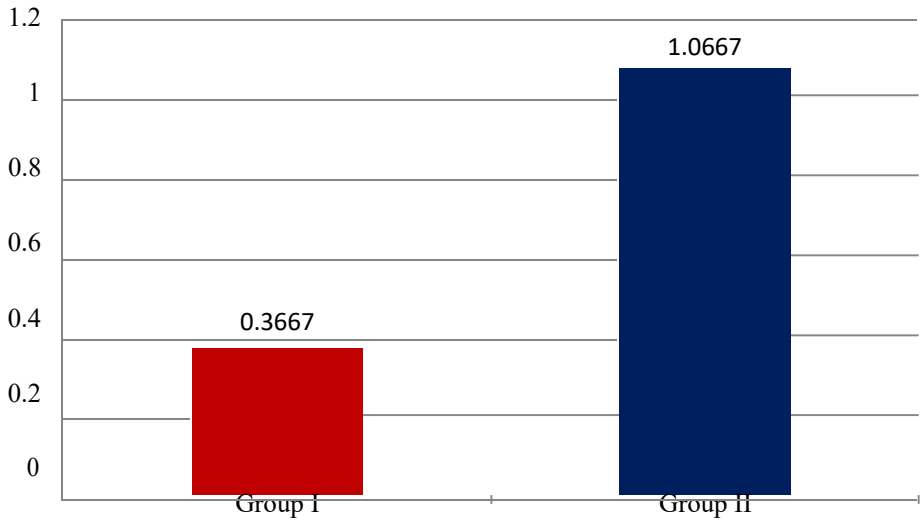
INTERGROUP COMPARISON OF MISSING SUTURES BETWEEN THE GROUPS AT DIFFERENT TIME INTERVALS

The mean number of missing sutures at the 7th day in the Group I was 0.366 and in the Group II was 1.066. The intergroup comparison between Group I and Group II was statistically significant.

	Mean	Std Deviation	Std Error	P value	Significance
Group I	0.366	0.808	0.147	0.001	Significant
Group II	1.066	1.172	0.214		

Independent t test with p value less than 0.05 is significant

TABLE-7 Depicts Intergroup Comparison Of Missing Sutures Between The Groups At The Time Of Placement And After Seven Days



GRAPH-7 Depicts Intergroup Comparison Of Missing Sutures Between The Groups At The Time Of Placement And After Seven Days

This randomized split mouth clinical study was designed to do a comparative assessment of wound healing and patient comfort after periodontal flap surgery in chronic periodontitis cases with or without periodontal dressing.

In periodontal surgery, the surgical site is usually covered with surgical dressing. The history of dressing dates back to 1923 when Ward introduced "Wondrpack" with the aim of protecting the surgical site, splinting of soft tissue and mobile teeth, immobilization of the surgical site, preventing tooth hypersensitivity and enhancing patient comfort.[9]

The oral cavity consists of bacteria which are opportunistic and also pathogenic which may cause chronic or acute infections with the persistence of any wound or cut in the epithelium. The proper precautionary measures are necessary to control the activity of the microorganisms, and its regeneration, to prevent the failure of respective surgery.[50] The main reason to close the surgical site post-periodontal surgery using periodontal dressing is to reduce the pain. It has been proved that the periodontal packs help in reducing discomfort and pain postoperatively by shielding the site of surgery and without any therapeutic effects.[43]

During the following years, periodontal packs were produced under different brand names with different compositions; their characteristics were extensively studied and underwent several changes. For instance, eugenol-containing compounds were discontinued due to allergic reactions and some other agents were incorporated into the composition of periodontal packs.[51] In 1984, a review article discussed the positive effects of periodontal dressings. Researchers in this article explained the benefits of dressing for minimizing the risk of postoperative complications such as wound infection and bleeding, enhancing tissue healing by preventing physical trauma duringmastication and speech and inhibiting granulation tissue formation.[40,51] It was long believed that covering the surgical site with periodontal dressing prevents microbial infections by decreasing plaque accumulation.[52,53] The possibility to reduce post surgical pain is among the main reasons for clinicians to cover the surgical site with dressing. It has been claimed that the periodontal packs may reduce post-operative pain and discomfort only by protecting the surgical site and they do not have therapeutic effects. **Ghanbari H et al[39]** confirmed pain reduction following the use of periodontal dressing.

However, absence of dressing is the preference of some clinicians There are studies that have questioned the positive effects of periodontal dressing on wound healing[54,55] while some others that have discussed its negative effects on surgical site healing.[19,33] **Checchi L et al[36], Abed AM et al[38], Bae SB et al[51], and Checchi et al[36]** reported the degree of post-surgical pain to be equal in patients with and without periodontal dressing.. The contrasting evidence about the efficacy of periodontal dressing mandated the present study to assess and compare the wound healing and patient comfort after periodontal flap surgery in chronic periodontitis cases with or without periodontal dressing.

A randomized split mouth clinical study was conducted to assess patient's post-operative comfort, assessment of wound healing by swelling of soft tissue and the color of gingiva. All subjects answered a Visual Analog Scale (VAS) questionnaire that is Pain (0-10); which was provided to them as a VAS chart by Hayes and Patterson in 1921, to evaluate post-operative symptoms. The healing index was evaluated using Landry et al. Wound Healing Index in 1988. The gingival index was evaluated by Loe and Silness Gingival Index in 1963. The gingival embrasure opening was evaluated by Black Triangle Classification given by Nordland and Tarnow in 1998. Sutures were simply counted at the time of placement and after 7 days. Data was statistically analyzed to assess the effectiveness with dressing and without dressing postoperatively.

In the present study the mean pain scores in the subjects with dressing was significantly lower than the subjects without dressing . The findings are in agreement with the findings of **Soheilifar S et al[43]** who conducted the clinical trial on 33 patients in split mouth study design to evaluate the pain swelling, inflammation and granulation tissue The mean (±SD) pain score was 1.73±1.153 and 2.79±1.933 in surgical sites with and without periodontal dressing, respectively and this difference was statistically significant (P=0.005). No significant difference was noted between sites with and without periodontal dressing in terms of swelling, bleeding, gingival consistency, granulation tissue formation, gingival color and ease of nutrition (P>0.05).

Our finding was in accordance with the results of **Ghanbari H et al[39]** who evaluated the postoperative pain experience and gingival indexes with and without the use of

periodontal dressing after Modified Widman flap procedure. Plaque Index (PI), Sulcus Bleeding Index (SBI) and Probing Depth (PD) were measured prior to the surgery, one week and 2 weeks after the surgery. Postoperative pain experience also was assessed at the conclusion of study The results showed no significant differences between dressed and undressed segments regarding changes in probing depth, plaque index or sulcus bleeding index. However patients reported significantly less pain postoperatively when the dressing was used.

Less pain with the use of periodontal dressing can be attributed to the coverage of denuded root surfaces and reduced dental hypersensitivity because in the majority of periodontal patients debridement traumatizes the cementum and causes denuded root dentin and subsequent tooth hypersensitivity. Periodontal pack covers the denuded root surfaces and reduces post-surgical pain.

The findings related to pain was in contrast to findings of **Checchi L et al[36], Abed AMet al[38] and Bae SB et al[51]** who reported similar pain scores in patients with and without periodontal dressing following periodontal surgery; while **Jones TM et al[33]** reported greater pain due to using dressing after surgery . This difference between their study results and ours may be due to the different severity of disease among understudy patients because by the progression of periodontal disease, bone loss and gingival recession increase and result in denuding of a larger root surface area. Therefore, root surface debridement increases tooth hypersensitivity. In contrast, in patients with mild periodontitis bone loss and gingival recession are minimal and a smaller cementum surface is invasively manipulated.

In the present study gingival score was higher in the subjects without dressing as compared to subjects with periodontal dressing The findings are in contrast to the findings of **Soheilifar S et al[43]** who reported that in terms of gingival bleeding and gingival inflammation the majority of patients in both groups had no or minimal bleeding during the first 3 days following surgery. In a study by **Jones TM et al[33]** seven patients with chronic moderate to severe generalized periodontitis, Internally beveled full thickness, apically positioned flaps with osseous recontouring were performed in 20 quadrants. Half the quadrants received a non-eugenol dressing, and the other half were left undressed. Fluid Index, Gingival Index, inflammatory index, pocket depth and patient comfort were studied up to 16 weeks postoperatively. The

results showed no difference in these parameters between quadrants where periodontal dressings were or were not used following surgery. Similar findings has been reported by **Allen DR et al**[56] who evaluated the clinical effects of a periodontal dressing after modified Widman flap surgery Gingival crevicular fluid flow and gingival inflammation were measured prior to surgery, 2 weeks, 1 month and 2 months after surgery. Clinical attachment level and pocket depth were measured prior to surgery, 1 month and 2 months after surgery. No significant differences were found between dressed and undressed segments regarding changes in clinical attachment levels, pocket depth, or gingival inflammation.

In the present study the healing was good and excellent in the subjects who had undergone dressing after the surgery as compared to subjects without dressing. The findings are in agreement with the study conducted by **Sadighi M et al**[48] In this randomized clinical trial, 26 patients were evaluated. Pain scores were assessed using visual analog scale (VAS) on the 3rd and 7th days postoperatively and compared between the two dressings. On the 7th and 14th days after both flap surgeries, surgical site healing was evaluated using the wound healing index (WHI).It was observed that the severity of pain in the studied patients on the 3rd and 7th days postoperatively was significantly lower in the intervention group than in the control group. It was also observed that the value of WHI in the studied patients on the 7th and 14th days postoperatively was significantly higher in the intervention group than in the control group.

In 2012, **Genovesi AM et al**[57] reported that the use of periodontal packs effectively improved the results of non-surgical treatments in patients due to improved blood coagulation stability, no bleeding in the wound area, and reduced risk of bacterial infection in the surgical area The probable reason for the present finding is that the primary periodontal dressings cover and protect the surgical site immobilized wound areas, controlled bleeding, created aseptic conditions for tissue repair, and physically protected the wound and its contents, leading to better repair.

Freedman M et al[40] explained other benefits of periodontal dressing for minimizing the risk of postoperative complication such as bleeding and wound infection, increased tissue healing by preventing physical trauma during speech and mastication, and reducing the formation of granulation tissue.

The findings are in contrast to findings of the many studies which stated that there was either no significant difference in dressing or no dressing or which stated that dressing delays the wound healing

The study by **Abed AM et al[38] and Bae SB et al[51]** indicated that postsurgical periodontal dressings do not exert any perceptible effect on the final healing following periodontal surgery. They stated that in a healthy person who is already healing at an optimal rate, there is probably very little that can be done to accelerate healing. **Soheilifar S et al[43]** noted no significant difference between sites with and without periodontal dressings in terms of swelling, bleeding, gingival consistency, granulation tissue formation, gingival colour and ease of nutrition with $p>0.005$. Similarly, no difference in three parameters were noticed by **Jones TM et al[33] and Ghanbari H et al.[39]** The reasoning for no difference in the healing scores between the groups was that most patients had no nutritional problem during the first 3 days following surgery and periodontal dressing did not decrease or increase post-surgical nutritional problems which could influence the wound healing.

The study conducted by **Bose S et al[19]** compared early wound healing events and patient comfort following periodontal flap surgery with and without a dressing . The higher trend for swelling of face was reported by the patients in the dressing group compared to non- dressing group. Clinical evaluation revealed more pronounced swelling and colour changes of the gingiva in patients with dressing. Also, the mean percentage increase of GCF flow was found to be higher with the same

In a study by **Mahtani AA et al[58]** the post operative healing index based on the usage of the periodontal dressing, majority of the cases that did not use a periodontal dressing had better healing as seen in Score, 5- Excellent healing and Score 4 - Very good healing, and very poor healing was seen by that used the periodontal dressing. A number of clinical trials have proposed that the use of periodontal dressing accumulates plaque, causing inflammation irritates the healing tissues and also produces transient bacteraemia during post-operative dressing change which causes more pain and swelling but less sensitivity and difficulty in eating. **Waerhaug Jet al[12]** reported that exposed tissue heals irrespective of application of a protective dressing. The fact that complete healing can take place even without a dressing, provided the surgical area is kept clean, and that signficant difference in healing was

found in non-dressed sites, supports the theory that not all surgical sites need to be packed.

The present study used a non-eugenol pack as the dressing similar to other studies **[Ganbhari H et al[39], Newmann PS et al[55]]**. Even though, eugenol-based dressing, were formerly popular especially following gingivectomy **[O' Neil TC[32]]**, due to their property of obtunding pain and retarding bacterial growth due to antiseptic properties **[Waerhaug J et al[12]]**, they were found to irritate oral mucosal tissues, induce allergic reactions and cause tissue necrosis particularly in bone leading to delayed wound healing **[Sarrami N et al[13]]**. Histological evidence also showed greater tissue destruction with more inflammatory cell infiltration and corrective tissue response on usage of eugenol **[Rivera-Hidalgo F et al[15]]**. They were also found to inhibit fibroblast proliferation to a greater extent than non-eugenol dressings **[Eber RM et al[35]]**. Due to these factors, non-eugenol dressings are currently more preferred than eugenol dressing., There is variability in the assessment of postoperative healing across the studies. Assessment of early wound healing was done by swelling of soft tissue, the colour of gingiva, volumetric GCF measurement and patient VAS score in one study **[Bose S et al[19]]**. The healing was evaluated during the first three days after the first postoperative week **[New Mann PS et al[55]]**, after two weeks **[Ghanbari H et al[39]]** and 16 weeks **[Jones TM et al[33]]** post-operatively in various studies. This couldbe a major reason why the results of the studies differ on the advocacy of usage of the periodontal dressing post-operatively, as the healing was evaluated at different intervals of time and using different criterion.

According to the results of this study, despite the limitations of the study concerning the reporting of patients‟ pain status subjectively, the severity of pain in group using periodontal dressings was low, as compared to subjects without dressing. In addition, the rate of wound healing was higher and excellent in the periodontal dressing group . The results of the present study must be viewed in the light of other important factors which can influence the outcome of the study such as – operator related factors in the terms of operating, manipulating, and handling of the material as well as the working time.

Within the limitations of this study, we found that the mean pain score was significantly lower in surgical sites with periodontal dressing. The significant differences were observed between the two groups in terms of gingival bleeding, gingival color, gingival consistency (measured by Gingival Index scores) and wound healing after surgery. Therefore, post-surgical healing is affected by the periodontal dressing Coe pak seems to serve the ideal role of protecting immediate post surgical wound healing with a periodontal dressing in patients who underwent periodontal flap surgeries. However there are Multiple factors which are involved in selection of the dressing of choice, such as: Surgeon's aim of using periodontal dressing, Required time for periodontal dressing to remain on the surgical area and Dimensional changes. The selection of ideal material for the surgical dressing should be based on these factors.

To pack or not to pack, the answer to this controversy, though still open to debate, is probably that the choice of use of a periodontal dressing is a matter of individual preference and the judgment of the operator. It is, however, prudent to use a dressing for stabilization of free gingival grafts and protection of donor site, retention of an apically positioned flap, protection of the denuded bone from further injury, protection of the graft site in periodontal regeneration and to facilitate retention of drugs delivered locally in the subgingival sites

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ANNEXURES

ANNEXURE-1

Institutional Ethical Committee Approval Certificate

BABU BANARASI DAS UNIVERSITY
BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

BBDCODS/IEC/09/2022 **Dated: 16th September, 2022**

Communication of the Decision of the Xth Institutional Ethics Sub-Committee Meeting

IEC Code: 31

Title of the Project: Comparative Assessment Of Wound Healing And Patient Comfort After Periodontal Flap Surgery In Chronic Periodontitis Cases With Or Without Periodontal Dressing: A Randomized Split Mouth Clinical Study.

Principal Investigator: Dr Bhibhuti Gupta **Department:** Periodontology

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Bhibhuti Gupta,

The Institutional Ethics Sub-Committee meeting comprising following members was held on 15th September, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry
2.	Dr. Praveen Singh Samant Member	Prof. & Head, Department of Conservative Dentistry & Endodontics
3.	Dr. Jiji George Member	Prof. & Head, Department of Oral Pathology & Microbiology
4.	Dr. Amrit Tandan Member	Professor, Department of Prosthodontics and Crown & Bridge
5.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopaedics

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI, thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Prof. Dr. Puneet Ahuja
Principal
BBD College of Dental Sciences
BBD University, Lucknow

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

Lakshmi Bala 16/09/22

Dr. Lakshmi Bala
Member-Secretary
Institutional Ethics Sub-Committee (IEC)
BBD College of Dental Sciences
BBD University, Lucknow

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

ANNEXURE-2

Institutional Research Committee Approval Certificate

BABU BANARASI DAS UNIVERSITY

BBD COLLEGE OF DENTAL SCIENCES, LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Assessment Of Wound Healing And Patient Comfort After Periodontal Flap Surgery In Chronic Periodontitis Cases With Or Without Periodontal Dressing: A Randomized Split Mouth Clinical Study"** submitted by **Dr Bhibhuti Gupta** Postgraduate student in the **Department of Periodontology** for the Thesis Dissertation as part of MDS Curriculum for the academic year 2021-2024 with the accompanying proforma was reviewed by the Institutional Research Committee in its meeting held on **14th September, 2022** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Dr. Puneet Ahuja
Chairperson

Dr. Mona Sharma
Co-Chairperson

ANNEXURE-3

Consent Form English

Babu Banarasi Das College Of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow –227105 (INDIA)

Consent Form (English)

Title of the Study : Comparative assessment of wound healing and patient comfort after periodontal flap surgery in chronic periodontitis patients with or without periodontal dressing : a randomized split mouth clinical study.

Study Number……..

Subject‟s Full Name…….

Date of Birth/Age……

Address of the Subject…….

Phone no. and e-mail address……

Qualification……

Occupation: Student / Self Employed/ Service/ Housewife/ Other (Please tick as appropriate)Annual income of the Subject……

Name and of the nominees(s) and his relation to the subject

.....(For thepurpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated……..for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without mymedical care or legal rights being affected.

3. I understand that the sponsor of the project, others working on the Sponsor„s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any

further research that may beconducted in relation to it, even if I withdraw from the trial. However, I understand that my identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample (tooth/tissue/blood) for future research.**Yes[] No[] NotApplicable[]**

6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer"sInformation document given to me.

Signature(orThumb impression)of the Subject/Legally Acceptable Representative:……..

Signatory,,s Name……. Date…….

Signature of the Investigator…… Date……..

Study Investigator,,s Name..... Date……..

Signature of the witness……. Date……..

Name of the witness……

Received a signed copy of the PID and duly filled consent form Signature/ thumb impression of the subject or legally Date.....

7. Acceptable Representative

ANNEXURE -4

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय)
बीबीडी वसटी, फै जाबाद रोड, लखनऊ -227105 (भारत) सहमवत प्रपत्र (अंग्रेजी)

अध्ययन का शीर्क: ल डे वसंग के साथ या उसके बना ाइवटस रोवगयों में पीररयडोट क्रोवनक पीररयडोट

पीररयडोटल फ्लैप सजरी के बाद घाि भरने और रोगी के आराम का तलनात्मक मूल्ांकन: एक यादृच्छिक च्छलिट माउथ च्छिनकल अध्ययन।

अध्ययन संख्या……..

विर्य का पूरा नाम…….

जन्मवतवथ/आयु……

विर्य का पता……..

फोन नंबर। और ई-मेल पता……

योग्यता……

व्यिसाय: छात्र / स्व-रोज़गार / सेिा / गृवहणी / अन्य (कृ पया उपयुक्त करूप में वटक करें) विर्य की िावर्क आय ……

नामांवकत व्यच्छक्त(यो) का नाम और विर्य से उसका सबंध .....(मुकदमे से संबंवधत मृत्यु के मामले में मुआिजे के उद्देश्य से)।

1. मैं पुवि करता हं वक मैंने उपरोक्त अध्ययन के वलए प्रवतभागी सूचना दस्तािेज़ वदनांक ..... को पढ़ और समझ वलया है और मुझे प्रश्न पूछने का अिसर वमला है। या मुझे अन्वेर्क द्वारा अध्ययन कीप्रकृ वत के बारे में समझाया गया है और प्रश्न पूछने का अिसर वदया गया है।

2. मैं समझता हं वक अध्ययन में मेरी भागीदारी स्वैच्छिक है और वबना वकसी दबाि के स्वतंत्र इिा से दी गई है और मैं वबना कोई कारण बताए और अपनी वचवकत्सा देखभाल या कानूनी अवधकारों को प्रभावित वकए वबना वकसी भी समय िापस लेने के वलए स्वतंत्र हं।

3. मैं समझता हं वक पररयोजना के प्रायोजक, प्रायोजक की ओर से काम करने िाले अन्य लोग, आचार सवमवत और वनयामक अवधकाररयों को ितमान अध्ययन और वकसी भी संबंध में मेरे स्वास्थ्य ररकॉडको दे खने के वलए मेरी अनुमवत की आिश्यकता नहीं होगी।

इसके संबंध में आगे का शोध वकया जा सकता है, भले ही मैं परीक्षण से हट जाऊं । हालांवक, मैं समझता ह वक तीसरे पक्ष को जारी या प्रकावशत वकसी भी जानकारी में मेरी पहचान उजागर नहीं की जाएगी।

4. मैं इस अध्ययन से उत्पन्न होने िाले वकसी भी डे टा या पररणाम के उपयोग को प्रवतबंवधत नहीं करने पर सहमत हं, बशते ऐसा उपयोग के िल िैज्ञावनक उद्देश्यों के वलए हो।

5. मैं भविष्य के अनुसंधान के वलए संग्रवहत नमूने (दांत/ऊतक/रक्त) के उपयोग की अनुमवत दे ता हं। हां[] नही[] लागू नही[]

6. मैं उपरोक्त अध्ययन में भाग लेने के वलए सहमत हं। मुझे जवटलताओं और दुष्प्रभाि, यवद कोई हो, के बारे में समझाया गया है और मैं उन्हें पूरी तरह से समझ चुका हं। मैंने मुझे वदए गए प्रवतभागी/स्वयंसेिक के सूचना दस्तािेज़ को भी पढ़ और समझ वलया है। विर्य/कानूनी रूप से स्वीकाय प्रवतवनवध के हस्ताक्षर (या अंगूठे का वनशान):……..

हस्ताक्षरकत◌ा क◌ा न◌ाम……. त◌ारीख ….।
अन्रेर्क के हस्ताक्षर…… वदनांक……..
अध्ययन अन्रेर्क का नाम..... वदनांक...
गिाह के हस्ताक्षर…… वदनांक……..
गिाह का नाम……

पीआईडी की एक हस्ताक्षररत प्रवत और विवधित भरा हुआ सहमवत पत्र प्राप्त हुआ, विर्य क हस्ताक्षर/अंगूठे का वनशान या कानूनी रूप से वदनांक.....

7. स्वीकाय प्रवतवनवध

ANNEXURE -5

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Participant Information Document (PID)

1. Study Title

Comparative assessment of wound healing and patient comfort after periodontal flap surgery in chronic periodontitis patients with or withoutperiodontal dressing : a randomized split mouth clinical study.

2. Invitation Paragraph

You are being invited to take part in a research/trial study. Before you decide it is important for you to understand why the research/study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

The aim of the present study is to assess the wound healing and patient comfort post periodontal flap surgery in the cases chronic periodontitis using periodontal dressing and to compare it without using periodontal dressing at seven days and one month.

4. Why have I been chosen?

You have been chosen for the study as you are fulfilling the required criteriafor the study.

5. Do I have to take part?

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a

6. What will happen to me if I take part?

You will be one of the participants in 30 patients enrolled in 2 groups in the study. All the participants diagnosed with Periodontal disease will be givendressing in one quadrant and without dressing in another quadrant and will be assessed after seven days and one month on the basis of wound healing and his/her comfort.

7. What do I have to do?

You do not have to change your regular lifestyles for the investigation of thestudy**.**

8. What is the procedure that is being tested?

The procedure will involve comparative assessment of wound healing and patient comfort after periodontal flap surgery in periodontal disease cases with or without periodontal dressing at seven daysand one month.

9. What are the interventions for the study?

All the participants diagnosed with Periodontal disease will be given dressing in one quadrant and without dressing in another quadrant and will be assessed after seven days and one month on the basis of wound healing and their comfort. They will be randomly divided into two groups namely, dressing and non- dressing using chit pick-up method.

Group I- Periodontal flap surgery with dressing.

Group II- Periodontal flap surgery without dressing.

10. What are the side effects of taking part?

11. What are the possible disadvantages and risks of taking part?

There are no risk or disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

This study will help us to know the comparative assessment of wound healing and patient comfort after periodontal flap surgery in periodontal disease cases with or without periodontal dressing at seven daysand one month.

13. What if new information becomes available?

Sometimes during a research project, new information becomes available about the research being studied. If this happens, your researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your researcher/investigator will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study finishes/stops before the stipulated time, this should be explained to the patient/volunteer.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study,the complaints will be handled by the doctors expertising in the field at BBDCODS opd.

16. Will my taking part in this study be kept confidential?

Yes, it will be kept confidential. Your name, address or any other personal information will not be shared outside the BBDCODS.

17. What will happen to the results of the research study?

The results of the study are the sole property of the institute. The results of the study will be used for comparative assessment of wound healing and patient comfort after periodontal flap surgery in periodontal disease cases with or without periodontal dressing at seven days and one month. Identity ofthe participants will not be disclosed in any result/ reports/ publications.

18. Who is organizing the research?

This research study is organized by the academic institute (BBDCODS)

Will the results of the study be made available after study is over?

Yes. If the patient wishes, the result of the study will be made available to him/her.

19. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Department, IEC/IRC of the institution.

20. Contact for further information

Dr. BHIBHUTI GUPTA

Department of Periodontology and ImplantologyBabu Banarasi Das College of Dental Sciences. Lucknow – 226028

Mob: 7017611436

Dr. Laxmi Bala,

Secretary And Member- Institutional Ethical Sub-Committee,Babu Banarasi Das College of Dental Sciences.

Lucknow – 226028 bbdcods.iec@gmail.com

Signature of PI……

Name……..

Date……..

ANNEXURE -6

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज
(बाबू बनारसी दास विश्वविद्यालय)
बीबीडी वसटी, फै जाबाद रोड, लखनऊ - 227105 (भारत)

प्रतभागी सूचना दस्तावेज़ (पीआईडी)

1. अध्ययन शीर्क

पीररय डोट ल डेवसंग के साथ या उसके वबना क्रोवनक पीररयडोट ाइवटस रोवगयों मेंं ल फ्लैप पीररयडोट

सजरी के बाद घाि भरने और रोगी के आराम का तुलनात्मक मूल्ांकन: एक यादृच्छिक च्छलिट माउथ च्छिवनकल अध्ययन।

2. वनमंत्रण अनुवेद

आपको एक शोध/परीक्षण अध्ययन मेंं भाग लेने के वलए आमंवत्रत वकया जा रहा है। वनणय लेने से पहले आपके वलए यह समझना महत्वपूण है वक शोध/अध्ययन क्ों वकया जा रहा है और इसमेंं क्ा शावमल होगा। कृ पया वनम्नवलखित जानकारी को ध्यान से पढ़ने के वलए समय वनकालेंं और यवद आप चाहेंं तो दोस्तो, ररश्तेदारोंं और अपने इलाज करने वाले वचवकत्सक/पाररिारक डॉक्टर के साथ इस पर चचा करेंं। हमसे पूछेंं वक क्ा ऐसा कु छ है जो स्पि नहीं है या यवद आप अवधक जानकारी चाहते हैंं। यह तय करने के वलए समय लें वक आप भाग लेना चाहते हैं या नही।ं

3. अध्ययन का उद्देश्य क्ा है?

वितमान अध्ययन का उद्देश्य पीररयडोट ल डेवसंग का उपयोग करके क्रोवनक ाइवटस के मामलोंं मेंं पीररयडोटल फ्लैप सजरी के बाद घाि भरने और रोगी के आराम का आकलन करना और सात वदनोंं और एक महीने मेंं ल डेवसंग का उपयोग वकए वबना इसकी तुलना करना है। पीररयडोट

4. मुझे क्ोंं चुना गया है?

आपको अध्ययन के वलए चुना गया है क्योंवक आप अध्ययन के वलए आिश्यक मानदंडोंं

कों पूरा कर रहे हैं।

5. क्या मुझे भाग लेना होगा?

शोध मेंं आपकी भागीदारी पूणत स्वैच्छिक है। यवद आप ऐसा करते हैं, तो आपको यह सूचना पत्रक रखने के वलए वदया जाएगा और एक सहमवत प्रपत्र पर हस्ताक्षर करने के वलए कहा जाएगा। अध्ययन के

दौरान आप अभी भी वकसी भी समय और वबना कोई सूचना वदए िापस लेने के वलए स्वतंत्र हैं

6. यवद मैं भाग लूंगा तो मेरा क्या होगा?

आप अध्ययन में 2 समूहों में नामांवकत 30 रोवगयों ल रोग से पीवित
में से एक प्रवतभागी होग े। पेररयोड
ोट

सभी प्रवतभावगयों को एक चतुथाश में डे वसंग दी जाएगी और दू सरे चतुथाश

में वबना डे वसंग के और घाि भरने और उसके आराम केआधार पर सात वदनों और एक

महीने केबाद मूल्ांकन वकया जाएगा।

7. मुझे क्या करना होगा?

अध्ययन की जांच के वलए आपको अपनी वनयवमत जीिनशैली में बदलाि करने की ज़रूरत नहीं है।

8. िह कौन सी प्रवक्रया है वजसका परीक्षण वकया जा रहा है?

इस प्रवक्रया में सात वदनों और एक महीने में पीररयडोटल डे वसगं के साथ या उसके वबना, पीररयडोटल

बीमारी के मामलों में ल फ्लैप सजरी के बाद घाि भरने और रोगी के आराम का तुलनात्मक
पीररयडोंटूल्ांकन

शावमल होगा।

9. अध्ययन के वलए क्या हस्तक्षेप हैं?

पेररयोडोटल रोग से पीवित सभी प्रवतभावगयों को एक चतुथ ाश में डे वसगं दी जाएगी
और दू सरे चतुथ ाश

में वबना डे वसंग के और घाि भरने और उनके आराम के आधार पर सात वदनों और

एक महीने के बाद मूल्ांकन वकया जाएगा। उन्हें वचट वपक-अप विवध का उपयोग करके

यादृच्छिक रूप से दो समूहों में विभावजत वकया जाएगा, डे वसंग और गैर-डे वसंग।

ग्रुप I- डे वसंग के साथ पेररयोडोटल फ्लैप सजरी।

ग्रुप II- वबना डे वसंग के
पेररयोडोटं 10. भाग लेने के दुष्प्रभाि क्या हैं?

ल फ्लैप सजरी।

11. भाग लेने के संभावित नुकसान और जोच्छखम क्या हैं?

इस अध्ययन मेंं भाग लेने का कोई जोच्छखम या नुकसान नहीं है।

12. भाग लेने के संभावित लाभ क्या हैं?

यह अध्ययन हमेंं सात वदनोंं और एक महीने मेंं पीररयडोटल डेवसगं के साथ या उसके वबना, पीररयडोटल

रोग के मामलों में पीरियडोटल फ्लैप सर्जरी के बाद घाव भरने और रोगी के आराम के तुलनात्मक

मूल्यांकन को जानने में मदद करेगा।

13. यदि नई जानकारी उपलब्ध हो जाए तो क्या होगा?

कभी-कभी क्लिनिकल शोध परियोजना के दौरान, अध्ययन किए जा रहे शोध के बारे में नई जानकारी उपलब्ध हो जाती है। यदि ऐसा होता है, तो आपका शोधकर्ता आपको इसके बारे में बताएगा और आपसे चर्चा करेगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप विड्रॉ लेने का निर्णय लेते हैं, तो आपका शोधकर्ता/अन्वेषक आपकी विड्रॉअल की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपसे एक अद्यतन सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

यदि अध्ययन निर्धारित समय से पहले समाप्त/बंद हो जाता है, तो रोगी/स्वयंसेविक को यह समझाया जाना चाहिए।

15. अगर कुछ गलत हो गया तो क्या होगा?

यदि कोई गंभीर प्रतिकूल घटना घटती है, या अध्ययन के दौरान कुछ गलत होता है, तो विशेषज्ञों द्वारा नियंत्रित किया जाएगा।

16. क्या इस अध्ययन में मेरी भागीदारी को गोपनीय रखा जाएगा?

हां, इसे गोपनीय रखा जायेगा। आपका नाम, पता या कोई अन्य व्यक्तिगत जानकारी बीबीडीसीओडीएस के बाहर साझा नहीं की जाएगी।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणाम संस्थान की एकमात्र संपत्ति हैं। अध्ययन के परिणामों का उपयोग सात दिनों और

एक महीने में पीरियडोट ल डिसंग के साथ या उसके बिना, ल बीमारी के मामलों में पीरियडोट

पीरियडोटल फ्लैप सर्जरी के बाद घाव भरने और रोगी के आराम के तुलनात्मक मूल्यांकन के लिए किया

जाएगा। वकसी भी पररणाम/ररपोट/प्रकाशन मेंं प्रवतभावगयोंं की पहचान का खुलासा नही ंवकया जाएगा।

18. अनुसंधान का आयोजन कौन कर रहा है?

यह शोध अध्ययन अकादवमक संलथान (बीबीडीसीओडीएस) द्वारा आयोवजत वकया जाता है।

क्ा अध्ययन के पररणाम अध्ययन समाप्त होने के बाद उपलब्ध कराए जाएं गे?

हा। यवद रोगी चाहे तो अध्ययन का पररणाम उसे उपलब्ध करया

जाएगा।

19. अध्ययन की समीक्षा वकसने की है?

अध्ययन की समीक्षा और अनुमोदन संलथान के वभागाध्यक्ष, आईईसी/आईआरसी द्वारा वकया

20. अवधक जानकारी के वलए संपक्ष

करेंं डॉ वभभूवत गुप्ता

पीररयडोटं ोलॉजी और इम्प्ि ो ा ंटोलॉजी विभाग बाबू बनारसी दास कॉलेज

ऑफ डेंं टल साइंं सेज। लखनऊ- 226028

मोबाइल: 7017611436

डॉ. लक्ष्मी बाला,

सवचि और सदस्य संलथागत नैवतक उप-समवत, बाबू बनारसी दास कॉलेज ऑफ

डेंं टल साइंं सेज। लखनऊ - 226028 bbdcods.iec@gmail.com

पीआई के हस्ताक्षर.....

नाम.....

तारीख.....

गया है।

ANNEXURE -7

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES

DEPARTMENT OF PERIODONTICS

PATIENT PROFORMA

NAME: **AGE/SEX:** **OPD NO:**

ADDRESS:

CONTACT NO:

OCCUPATION:

Chief complaint:

History of present illness: **Past medical history:**

Past dental history:

Personal history:

1. **Oral hygiene measures:**

2. **Habits:**

CLINICAL EVALUATION

GROUP I Periodontal flap surgery with dressing.

	MEASUREMENT AT	
	SEVEN DAYS	**ONE MONTH**
VAS SCORE		
HEALING INDEX		
GINGIVAL INEX		
GINGIVAL EMBRASURE OPENING		

NUMBER OF MISSING SUTURES	AT THE TIME OF PLACEMENT	AFTER SEVEN DAYS

GROUP II Periodontal flap surgery without dressing.

	MEASUREMENT AT	
	SEVEN DAYS	**ONE MONTH**
VAS SCORE		
HEALING INDEX		
GINGIVAL INEX		
GINGIVAL EMBRASURE OPENING		

NUMBER OF MISSING SUTURES	AT THE TIME OF PLACEMENT	AFTER SEVEN DAYS

SIGNATURE:

ANNEXURE -8
STATISTICAL ANALYSIS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included frequency and percentage. Some of the intra-operative and post operative parameters were measured in terms of mean and standard deviation. The level of the significance for the present study was fixed at 5%.

The intergroup comparison of the ordinal variable will be compared using Chi-Square test. The intragroup comparison of continuous variables was done using the independent t-test and intragroup comparison will be done using the paired t-test .depending upon the normality of the data.

Chi-Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test is commonly used to test association of variables in two-way tables, where the assumed model of independence is evaluated against the observed data. In general, the ***chi-square test statistic*** is of the form

$$X^2 = \sum \frac{(\text{observed - expected})^2}{\text{expected}}$$

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data.

Independent t-test

Independent t-test can be used to determine if two sets of data are significantly different from each other, and is most commonly applied when the test statistic would follow a normal distribution. The independent samples *t*-test is used when two separate sets of independent and identically distributed samples are obtained, one from each of the two populations being compared

$$t = \frac{\bar{X}_1 - \bar{X}_2}{\sqrt{\left(\frac{(N_1 - 1)s_1^2 + (N_2 - 1)s_2^2}{N_1 + N_2 - 2}\right)\left(\frac{1}{N_1} + \frac{1}{N_2}\right)}}$$

Where X1 = Mean of the first Group, X2 = Mean of the Second Group

Paired t-test

$$t = \frac{\bar{x} - 0}{SE_d} \quad \frac{\bar{x}}{SD_x / \sqrt{n}}$$

A paired t-test is used to compare two population means where you have two samples in which observations in one sample can be paired with observations in the other sample. Examples of where this might occur are: -

Before and after observations on the same subjects (e.g. students‟ diagnostic test results before and after a particular module or course).

OR

A comparison of two different methods of measurement or two different treatments where the measurements / treatments are applied to the same.

ANNEXURE - 9

PLAGIARISM REPORT

DrillBit

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Submission Information

Author Name	BHIBHUTI GUPTA
Title	COMPARATIVE ASSESSMENT OF WOUND HEALING AND PATIENT COMFORT AFTER PERIODONTAL FLAP SURGERY IN CHRONIC PERIODONTITIS CASES WITH OR WITHOUT PERIODONTAL DRESSING A RANDOMIZED SPLIT MOUTH CLINICAL STUDY
Paper Submission ID	1412758
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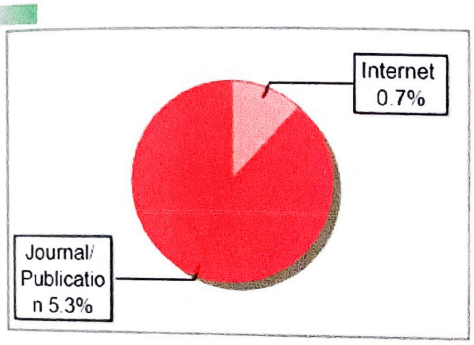

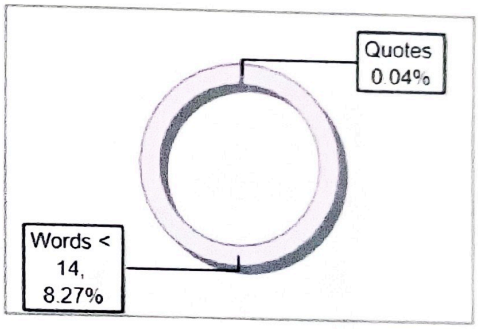

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